FlexiTrunk™ Infant Interface User Instructions

en

Intended Use

The F&P Infant Interface is designed to deliver noninvasive positive pressure ventilation to a spontaneously breathing patient weighing up to 10 kg in a hospital or clinical setting where the patient is adequately monitored by trained medical staff.

Product Specifications

BC190 **BC191** **BC192**	The F&P Infant Interface is designed to connect to the Fisher & Paykel Healthcare Bubble CPAP System. The adaptors allow connection to other manufacturers' CPAP circuits with 7.8 or 10 mm connectors.
Maximum input flow	15 L/min
Maximum allowable operating pressure	15 cmH_2O

Please refer to last page for dimensions and components.

Contraindications

- Non-spontaneous breathing
- Congenital abnormalities or malformations where bi-nasal prongs or nasal mask are contraindicated (e.g. choanal atresia).
- Congenital abnormalities or malformations where positive pressure therapies are contraindicated (e.g. diaghragmatic hernia and tracheo-osesphageal fistula).
- Nasal trauma/severe deformity that might be exacerbated by use of nasal prongs or nasal mask.

WARNINGS

- The components of the Infant Interface are designed for single patient use only. **Reuse may result in transmission of infectious substances, interruption to treatment, serious harm or death.**
- **Handle with care.** Use caution when positioning or disconnecting the Infant Interface. Avoid excessive pull forces, sharp objects and tubing holders. Damage to the tubing may cause loss of pressure and require immediate replacement.
- This product is intended to be used for a maximum of 7 days.
- DO NOT use if product or packaging is damaged.
- US Federal law restricts this device to sale by, or on the order of, a physician.
- DO NOT modify this product.
- Use patient oxygen monitoring.
- Connection to other manufacturers' humidification systems increases risk of condensate and/or high gas temperature delivery to the patient.
- Connect only pressure monitoring devices to the pressure monitoring port on the nasal tubing.
- Infant Interface components are supplied in a clean state. Employ suitable methods to prevent bio-contamination during use and upon disposal.
- DO NOT soak, wash, sterilize, or reuse this product.
- DO NOT over tighten the infant bonnet straps.
- DO NOT cover the infant's face with the Infant Bonnet as suffocation may occur.
- USE ONLY the recommended F&P Infant Interface components, impaired positioning of the nasal prongs and mask can occur from non-approved substitutes.
- Septal Necrosis can occur if correct sizing or placement of prongs and mask is not observed.
- **Always use pressure monitoring to verify that the patient is receiving the prescribed CPAP level.**
- DO NOT use medications containing Tyloxapol (such as Tacholiquin) as this may damage the tubing and lead to loss of CPAP pressure.
- California residents please be advised of the following, pursuant to Proposition 65:
  This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit: www.fphcare.com/prop65

Set-up

- **BC190, BC191, BC192**
- Refer to the F&P Bubble CPAP System instructions prior to set up of the Infant Interface.
- If using the adaptors, refer to the set-up instructions provided by the circuit manufacturer prior to set up of the Infant Interface.
- Refer to illustrations 1-15 for correct set up.
- For correct product sizing, refer to the tables on the last page.
- A maximum pressure relief device MUST be used. Pressure relief settings shall be suitable for infant CPAP.

Checks Before Operation

- When pressure monitor port on nasal tubing is not in use, the cap must be closed.
- Check that all circuit connections are tight before use and after any adjustment.

CE 0123

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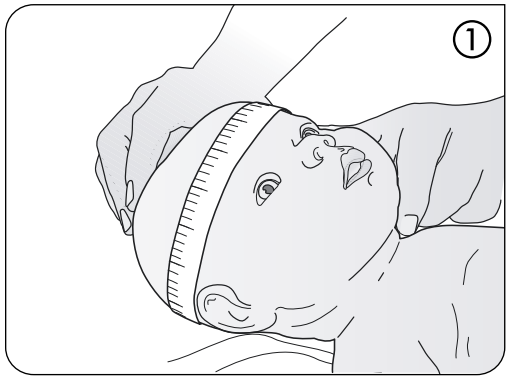
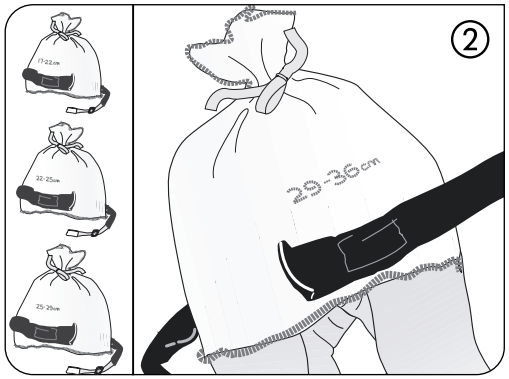
Fisher & Paykel HEALTHCARE

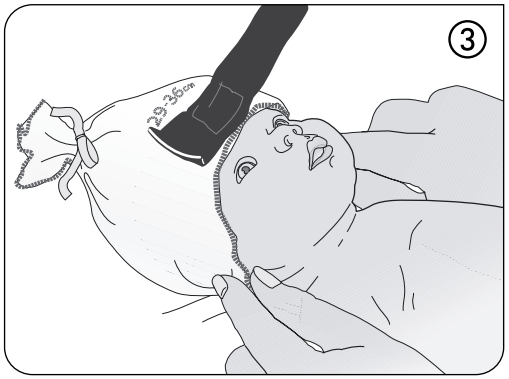
FlexiTrunk™ Infant Interface User Instructions



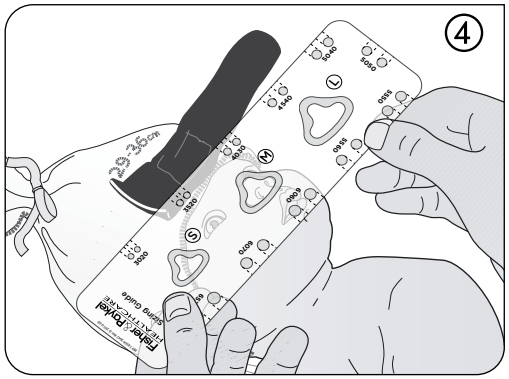
- Measure the baby's head circumference in centimeters.



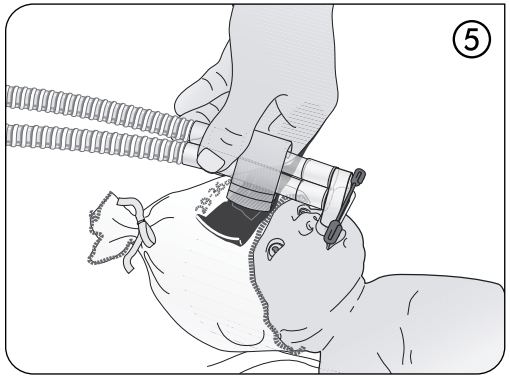
- Choose the correct sized bonnet. The bonnet should be snug fitting.
- Stretch the bonnet with your hands initially for ease of placement.



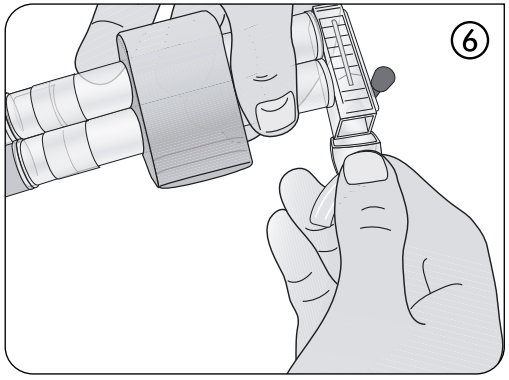
- Slip the bonnet onto the baby's head, completely covering the ears and with the back edge of the bonnet at the base of the neck. The front edge of the bonnet should be just above or on the eyebrows.



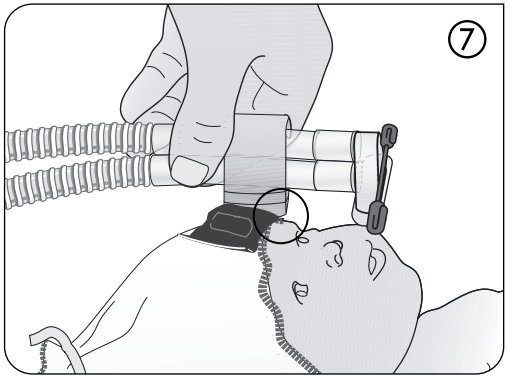
- Use the sizing guide to choose suitable prongs or mask.
- Prongs should fill the nares completely without stretching the skin. Use the biggest possible size.
- Mask should not touch the edge of the nose, septum or the eyes.



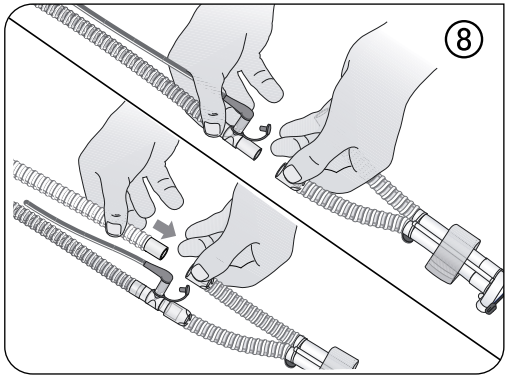
- Choose the correct length of the nasal tubing. Use the shortest length possible.
- The clear tubing should not extend over the infants forehead.
- The following may be used as a guide:
  50 mm ≤ 1.5 kg, 70 mm ≤ 2.5 kg,
  100 mm > 2.5 kg



- Connect prongs or mask to nasal tubing ensuring that it is inserted fully.
- If using prongs: squeeze sides of prongs firmly to expose grooves. Start from one end and insert prong grooves into nasal tubing. Push end in firmly.



- Remove tear-off strips as required to adjust the nasal tubing angle to optimise the seal.
- DO NOT discard tear-off strips as they may be needed when alternating between nasal prongs and masks.



- Attach the circuit to the nasal tubing in either orientation.
- Refer to instructions provided by circuit manufacturer for more detail.
- Note: Disconnect FlexiTrunk™ gently by twisting the connectors. DO NOT pull forcefully, as this may damage the tubing.

Handle with care.

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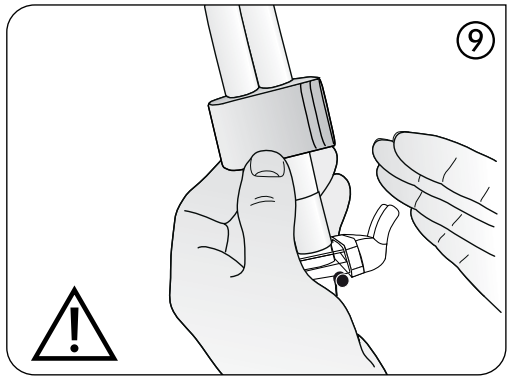
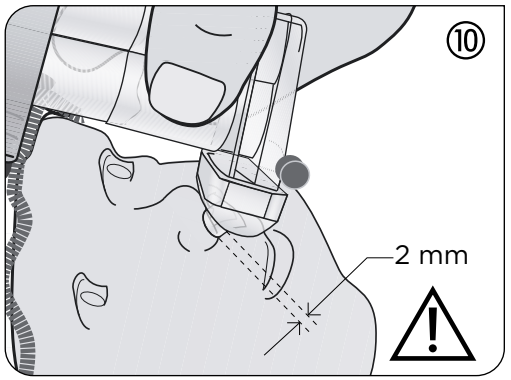
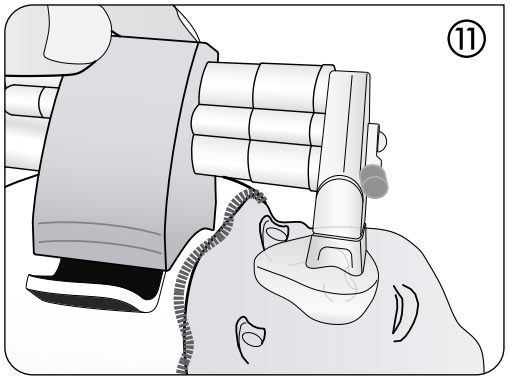


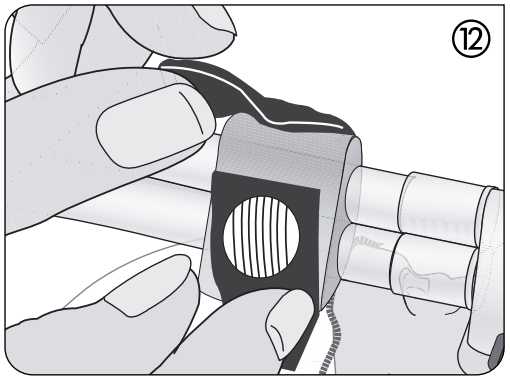
- Set gas flow to prescribed level.
- Turn the humidifier on. Refer to manufacturer's instructions.
- ⚠ Place hand close to nasal prongs or mask to ensure there is gas flow present.



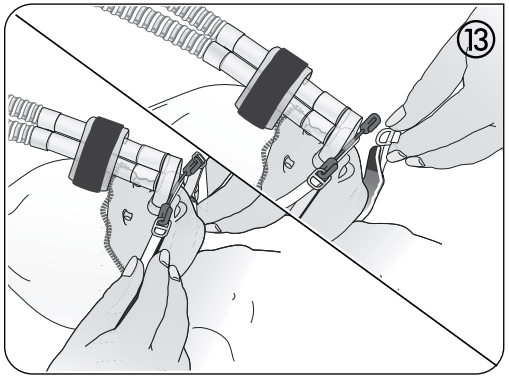
- **If using prongs:** Clear nasal secretions before inserting the nasal prongs.
- ⚠ Ensure the nasal prongs are positioned at least 2 mm (0.08 inches) from the septum to avoid pressure necrosis. Adjust as necessary.
- Hourly checks of the septum integrity are recommended.



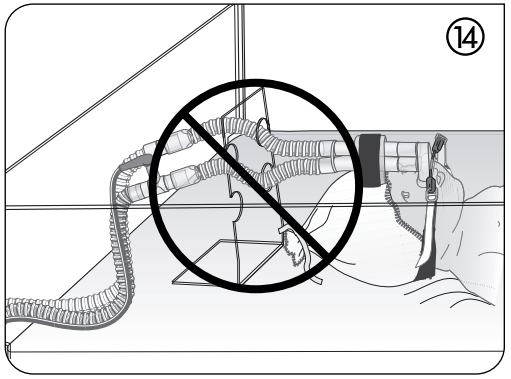
- **If using mask:** Connect to patient by placing mask around nose. The mask should sit comfortably around the patient's nose. It must not occlude the nostrils or touch the septum and should not be over the lip or over the eyes.



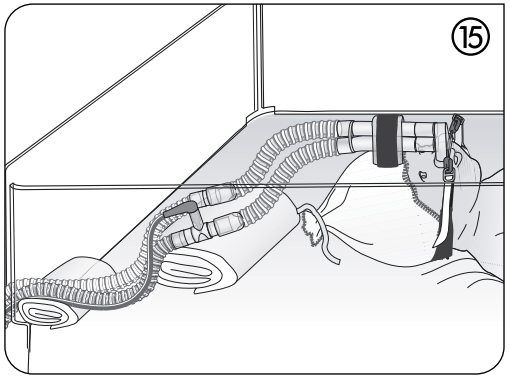
- Set height of the foam block by adding or removing tear-off strips. Setups with masks may require adding strips for proper positioning.
- Place the strap over the foam block and tighten to hold the tubing firmly in place.



- Hook the clips from the side straps of the bonnet to the glider.
- Pull both straps at the same time for central positioning.
- Affix the round velcro tabs to the blue strap of the bonnet.
- Use the least tension possible to maintain prescribed CPAP level and stability of the Infant Interface.



- DO NOT use angel frames, Christmas trees or similar devices as they can puncture the FlexiTrunk™ tubing and cause loss of pressure.



- Ensure the weight of the circuit is gently supported to reduce tension on the nasal tubing. A pillow or folded towel is recommended. The FlexiTrunk™ tubing must have free movement to allow the baby's head to move without restriction.
- The circuit should be kept below the level of the nasal tubing to minimize condensate at the baby.

- Check patient frequently for signs of redness, pressure sores or irritation which may result from extended prong or mask use. Hourly checks are recommended.
- Alternating between mask and prongs can reduce the risk of irritation. Alternating every 4 to 6 hours is recommended.
- Positioning of the mask should be adjusted for best fit and minimal leak. If excessive leak is still present, flow may be increased to compensate. Maximum allowable flow rate is 15 L/min.
- Check condensate regularly and drain as required.

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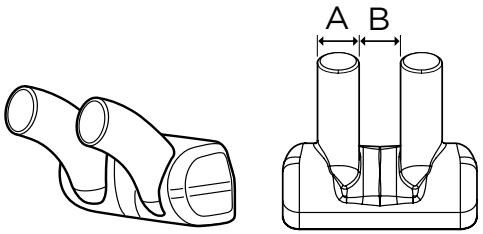
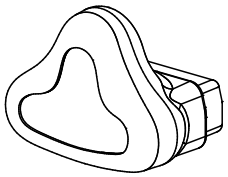
FlexiTrunk™ Infant Interface User Instructions

INFANT NASAL PRONGS



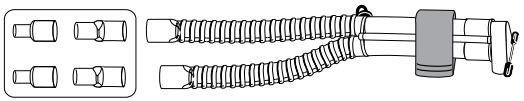
Product Code	A	B
BC3020	3.0 mm	2.0 mm
BC3520	3.5 mm	2.0 mm
BC4030	4.0 mm	3.0 mm
BC4540	4.5 mm	4.0 mm
BC5040	5.0 mm	4.0 mm
BC5050	5.0 mm	5.0 mm
BC5550	5.5 mm	5.0 mm
BC5560	5.5 mm	6.0 mm
BC6060	6.0 mm	6.0 mm
BC6070	6.0 mm	7.0 mm
BC6570	6.5 mm	7.0 mm

INFANT NASAL MASK



Product Code	Size
BC800	S
BC801	M
BC802	L
BC803	XL

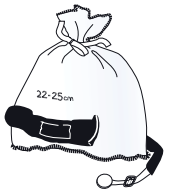
INFANT NASAL TUBING



BC19x series

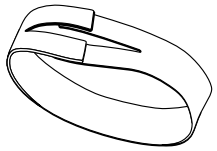
Product Code	Size
BC190	50 mm
BC191	70 mm
BC192	100 mm

INFANT BONNET



Product Code	Size
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

INFANT CHIN STRAP



Product Code	Size
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

INFANT HEADGEAR

Product Code	Size
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

CE 0123

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FlexiTrunk™ Interface für Säuglinge, Benutzerhandbuch

de

Verwendungszweck

Das F&P Interface für Säuglinge ist für die Abgabe nicht-invasiver Positivdruckbeatmung an einen spontan atmenden Patienten mit einem Gewicht von bis zu 10 kg vorgesehen. Zur Anwendung in einer Krankenhaus- oder Klinikumgebung, wobei der Patient von medizinisch geschultem Personal überwacht werden muss.

Produktspezifikationen

BC190 **BC191** **BC192**	Die F&P Interface für Säuglinge ist für den Anschluss an das Fisher & Paykel Healthcare Bubble CPAP-System vorgesehen. Die Adapter ermöglichen den Anschluss von CPAP-Beatmungsschläuchen anderer Hersteller mit Anschlüssen von 7,8 oder 10 mm.
Maximaler Eingangsflow	15 L/min
Maximal zulässiger Betriebsdruck	15 cmH_2O

Für Abmessungen und Komponenten, siehe letzte Seite.

Kontraindikationen

- Nicht-spontane Atmung.
- Angeborene Abnormitäten oder Fehlbildungen, wenn binasale Prongs oder Nasalmasken kontraindiziert sind (z.B. Choanalatresie).
- Angeborene Abnormitäten oder Fehlbildungen, wenn Positivdrucktherapien kontraindiziert sind (z.B. Zwerchfellhernie und Tracheoösophagealfistel).
- Nasaltrauma/schwere Deformität, die durch Verwendung von Nasal-Prongs oder einer Nasalmaske exazerbieren könnte.

WARNHINWEISE

Die Komponenten des Interface für Säuglinge sind ausschließlich für die Verwendung an einem Patienten vorgesehen. **Eine Wiederverwendung kann zur Übertragung infektiöser Agenzien, zum Abbruch der Behandlung, zu schweren Schädigungen oder zum Tod führen.**

Vorsichtig handhaben. Das Interface für Säuglinge vorsichtig positionieren bzw. abtrennen. Übermäßige Zugkräfte, scharfe Gegenstände und scharfkantige Schlauchhalter vermeiden. Eine Beschädigung des Schlauchs hätte evtl. Druckverlust zur Folge und er müsste unverzüglich ersetzt werden.

Dieses Produkt ist für eine Verwendung von maximal 7 Tagen bestimmt.

NICHT verwenden, wenn das Produkt oder die Verpackung beschädigt ist.

- Dieses Produkt NICHT modifizieren.
- Die Sauerstoffzufuhr des Patienten überwachen.
- Der Anschluss an Befeuchtungssysteme anderer Hersteller erhöht das Risiko von Kondensat und/ oder von Abgabe hoher Gastemperaturen an den Patienten.
- Schließen Sie an den Drucküberwachungsport an der Nasalen Schnittstelle nur Drucküberwachungsgeräte an.
- Die Komponenten des Interface für Säuglinge werden in sauberem Zustand geliefert. Wenden Sie geeignete Methoden an, um Biokontamination während des Gebrauchs und bei der Entsorgung zu verhindern.
- Dieses Produkt NICHT einweichen, waschen, sterilisieren oder wiederverwenden.
- Die Riemen der Säuglingshaube NICHT zu fest anziehen.
- Die Säuglingshaube NICHT auf das Gesicht des Säuglings legen, er könnte daran ersticken.
- Verwenden Sie NUR die empfohlenen Interfacekomponenten für Säuglinge von F&P, bei nicht zugelassenen Ersatzkomponenten könnte die Positionierung der Nasalprongs und der Maske nicht fest genug sein.
- Wenn die korrekte Größe oder Platzierung der Prongs und der Maske nicht eingehalten wird, kann dies zu einer Nekrose des Septums führen.
- **Es ist stets eine Drucküberwachung durchzuführen, damit dem Patienten das verschriebene CPAP-Niveau verabreicht wird.**
- KEINE Medikamente verwenden, die Tyloxapol enthalten (wie Tacholiquin), dies könnte den Schlauch beschädigen und zu einem Verlust von CPAP-Druck führen.

Set-up

- **BC190, BC191, BC192**

Vor dem Set-up des Interface für Säuglinge die Benutzerhinweise zum F&P Bubble CPAP-System beachten.

Bei der Verwendung von Adaptern sind vor dem Set-up des Interface für Säuglinge die Benutzerhinweise des Schlauchherstellers beachten.

- Für das korrekte Set-up die Abbildungen 1-15 beachten.
- Für eine Auswahl der korrekten Größe dieser Produkte verweisen wir auf die Tabelle auf der letzten Seite.
- Es MUSS ein Überdruckventil verwendet werden. Die Einstellungen für den Druckablass sollten für CPAP von Säuglingen geeignet sein.

Vor dem Betrieb zu prüfen

- Wenn der Drucküberwachungsport auf der Nasalen Schnittstelle nicht verwendet wird, muss die Kappe aufgesetzt sein.
- Vor und nach jeder Anpassung alle Schlauchverbindungen auf Dichtigkeit überprüfen.

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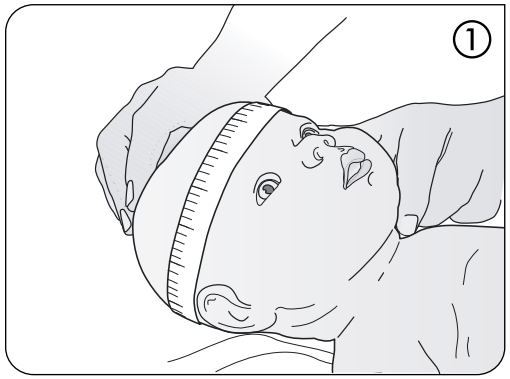
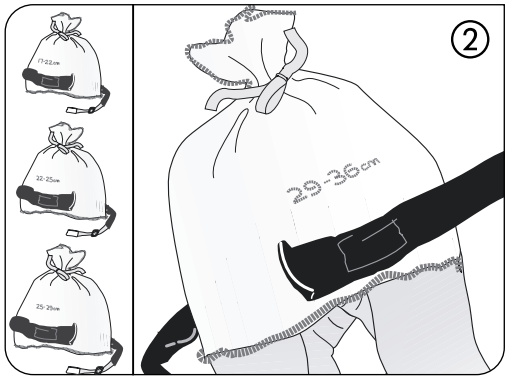
Fisher & Paykel HEALTHCARE

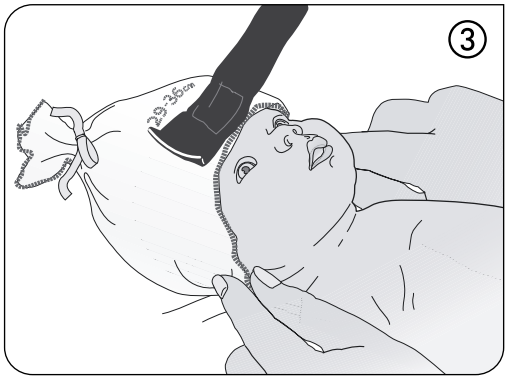
FlexiTrunk™ Interface für Säuglinge, Benutzerhandbuch



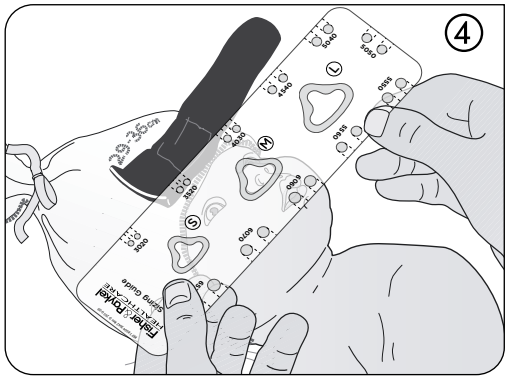
- Messen Sie den Kopfumfang des Babys in Zentimetern.



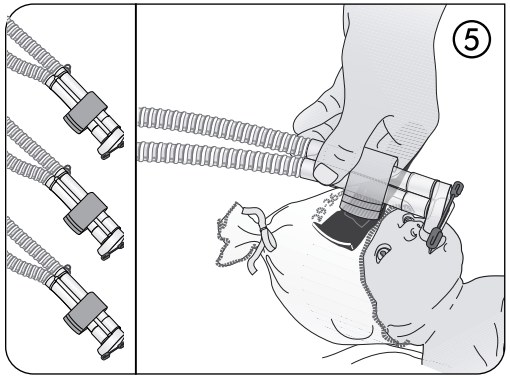
- Wählen Sie eine Haube passender Größe aus. Die Haube sollte bequem aufliegen.
- Zur leichteren Platzierung die Haube zuerst von Hand dehnen.



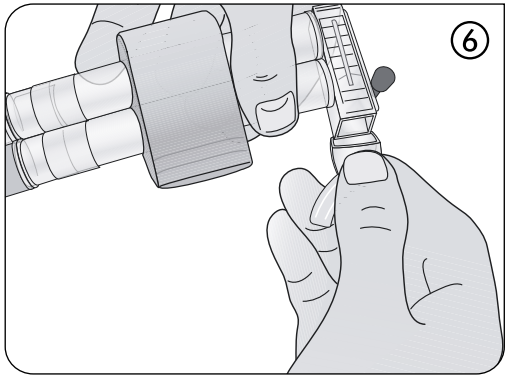
- Die Haube über den Kopf des Babys streifen, die Ohren sollten dabei vollständig bedeckt sein, der hintere Rand der Haube sollte am Nacken aufliegen. Der vordere Rand der Haube sollte auf Höhe der Augenbrauen oder knapp darüber liegen.



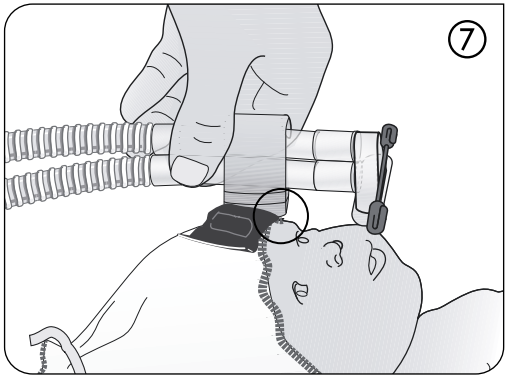
- Verwenden Sie zur Auswahl der geeigneten Prongs oder Maske die Größenlehre.
- Die Prongs sollten die Nasenlöcher vollständig ausfüllen, ohne die Haut zu straffen. Sie sollten so groß wie möglich sein.
- Die Maske sollte die Nasenseiten, das Septum und die Augen nicht berühren.



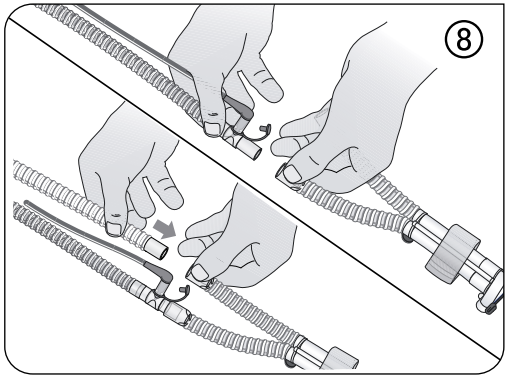
- Wählen Sie für die Nasale Schnittstelle die korrekte Länge aus. Diese sollte möglichst kurz sein.
- Der durchsichtige Schlauch sollte nicht über die Stirn des Säuglings hinausreichen.
- Die folgenden Angaben dienen als Richtwerte: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm › 2,5 kg



- Schließen Sie die Prongs oder Maske an der Nasalen Schnittstelle an und achten Sie darauf, dass diese vollständig verbunden sind.
- Bei Verwendung der Prongs: Die Prongs an den Seiten fest zusammendrücken, um die Nuten freizulegen. An einem Ende beginnen und die Prong-Nuten in den Nasalschlauch drücken. Das Ende fest eindrücken.



- Die Abreißstreifen nach Bedarf abnehmen, um den Winkel der Nasalen Schnittstelle zur Optimierung der Abdichtung anzupassen.
- Die Abreißstreifen NICHT entsorgen, da sie beim Wechsel zwischen Prongs und Masken evtl. gebraucht werden.



- Befestigen Sie die Schläuche in einer beliebigen Ausrichtung an der Nasalen Schnittstelle.
- Weitere Einzelheiten entnehmen Sie bitte den Anweisungen des Schlauchherstellers.
- Hinweis: Den FlexiTrunk™ vorsichtig durch Drehen der Anschlüsse lösen. NICHT gewaltsam ziehen, um den Schlauch nicht zu beschädigen.
- Vorsichtig handhaben.

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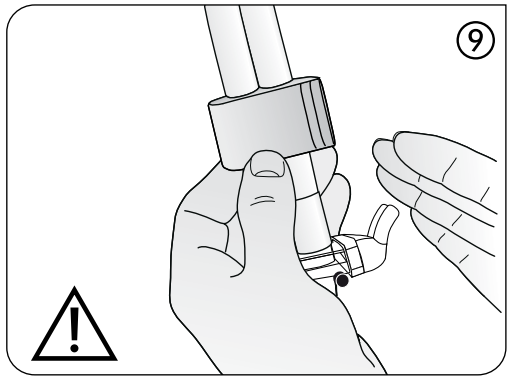
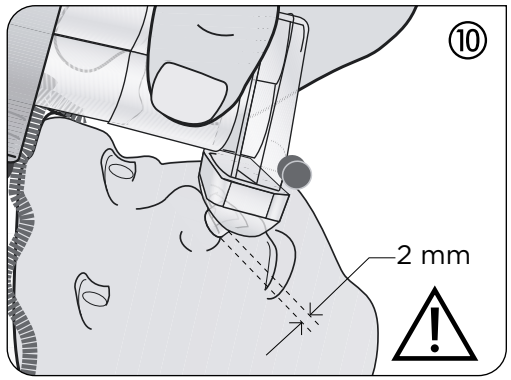
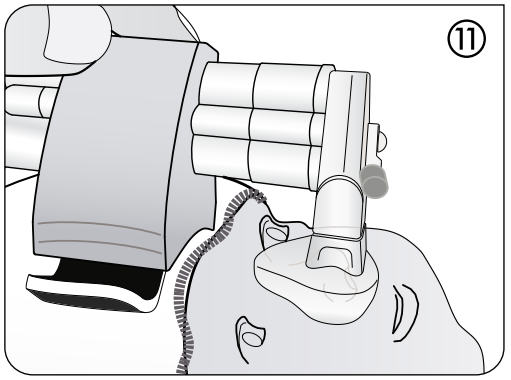
FlexiTrunk™ Interface für Säuglinge, Benutzerhandbuch



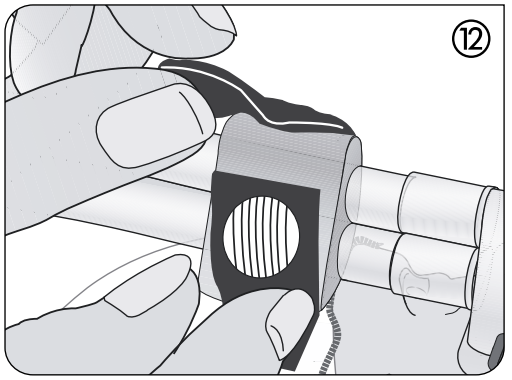
- Stellen Sie den Gasflow auf das vorgeschriebene Niveau ein.
- Schalten Sie den Befeuchter ein. Siehe die Anweisungen des Herstellers.
- ⚠ Legen Sie die Hand dicht an die Nasalprongs oder die Maske, um sicherzustellen, dass Gasflow vorliegt.



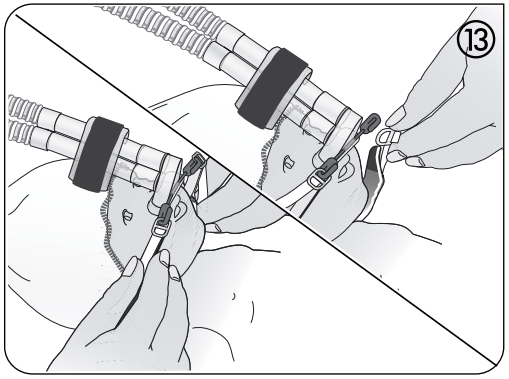
- **Bei Verwendung der Prongs:** Vor dem Einsetzen der Nasalprongs Nasensekret entfernen.
- ⚠ Achten Sie darauf, dass die Nasal-Prongs mindestens 2 mm (0,08 Zoll) vom Septum entfernt sind, um eine Drucknekrose zu vermeiden. Nach Bedarf anpassen.
- Eine stündliche Integritätsprüfung des Septums wird empfohlen.



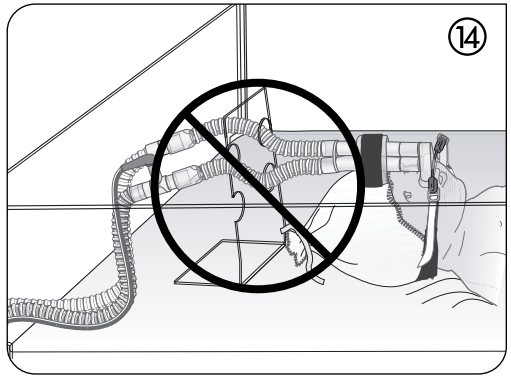
- **Bei Verwendung der Maske:** Maske auf die Nase des Patienten setzen. Sie sollte bequem um die Nase herum platziert werden. Die Nasenlöcher und das Septum nicht mit der Maske berühren und sie nicht auf der Lippe oder den Augen aufliegen lassen.



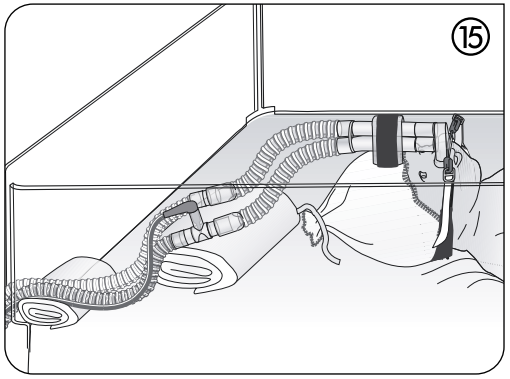
- Die Höhe des Schaumblocks durch Hinzufügen oder Entfernen von Abreißstreifen einstellen. Set-ups mit Masken erfordern für die korrekte Positionierung evtl. weitere Streifen.
- Den Klettriemen über den Schaumblock legen und festziehen, damit die Schläuche nicht verrutschen.



- Haken Sie die Clips an den Seitenriemen der Haube am Gleiter ein.
- Zur Zentrierung beide Bänder gleichzeitig ziehen.
- Befestigen Sie die runden Klettbänder am blauen Riemen der Haube.
- Die Spannung so gering wie möglich einstellen, um den vorgeschriebenen CPAP-Level und die Stabilität der Schnittstelle für Säuglinge aufrecht zu erhalten.



- KEINE Schlauchhalter oder Ähnliches verwenden, da sie den FlexiTrunk™ Schlauch punktieren und zu Druckverlust führen können.



- Das Gewicht der Schläuche muss abgestützt werden, um die Zugspannung an der Nasalen Schnittstelle zu verringern. Ein Kissen oder ein gefaltetes Handtuch wird empfohlen. Die FlexiTrunk™ Schläuche müssen frei beweglich sein, damit sich der Kopf des Babys ungehindert bewegen kann.
- Die Schläuche sollten sich unterhalb des Niveaus der Nasalen Schnittstelle befinden, um die Kondensatbildung am Säugling möglichst gering zu halten.

Kontrollen während des Betriebs

- Patienten regelmäßig auf Anzeichen einer Rötung, Druckstellen oder einer Reizung untersuchen, die bei längerer Verwendung der Prongs oder Maske auftreten können. Eine stündliche Überprüfung wird empfohlen.
- Eine abwechselnde Verwendung von Maske und Prongs kann das Risiko einer Reizung vermindern. Ein Wechsel alle 4 bis 6 Stunden wird empfohlen.
- Bei der Platzierung der Maske sollte auf optimale Passung und minimale Leckage geachtet werden. Wenn nach wie vor viel Gas entweicht, kann der Flow erhöht werden, um den Verlust auszugleichen. Die maximal zulässige Flowrate beträgt 15 L/min.

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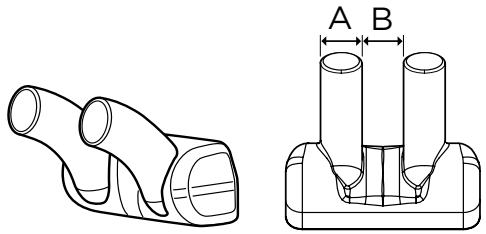
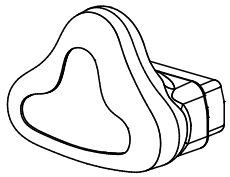
FlexiTrunk™ Interface für Säuglinge, Benutzerhandbuch

NASAL-PRONGS FÜR SÄUGLINGE



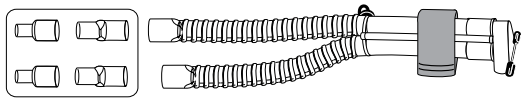
Produkt-Code	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

NASALMASKE FÜR SÄUGLINGE



Produkt-Code	Größe
BC800	Klein
BC801	Mittel
BC802	Groß
BC803	Extragroß

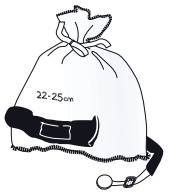
NASALE SCHNITTSTELLE FÜR SÄUGLINGE



BC19x Serie

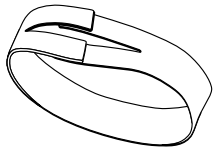
Produkt-Code	Größe
BC190	50 mm
BC191	70 mm
BC192	100 mm

HAUBE FÜR SÄUGLINGE



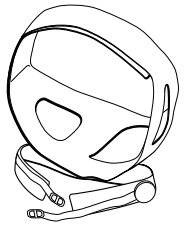
Produkt-Code	Größe
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

KINNBAND FÜR SÄUGLINGE



Produkt-Code	Größe
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

KOPFBÄNDER FÜR SÄUGLINGE



Produkt-Code	Größe
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ Instrucciones para el usuario de la interfaz para lactantes

es

La interfaz para lactantes de F&P está diseñada para el suministro de ventilación con presión positiva no invasiva a pacientes con respiración espontánea y un peso de hasta 10 kg en hospitales o clínicas donde personal médico con una formación adecuada puede monitorizar correctamente al paciente.

BC190 **BC191** **BC192**	La interfaz para lactantes F&P está diseñada para conectarse al sistema de CPAP de burbujas de Fisher & Paykel Healthcare. Los adaptadores permiten la conexión de otros circuitos de CPAP de otros fabricantes con conectores de 7,8 o 10 mm.
Caudal de entrada máximo	15 L/min
Máxima presión de funcionamiento permitida	15 cmH_2O

Consulte la última página para conocer las dimensiones y los componentes.

- Respiración no espontánea
- Anomalías congénitas o malformaciones en las que las cánulas binasales o las máscaras nasales estén contraindicadas (por ejemplo, atresia coanal).
- Anomalías congénitas o malformaciones en las que las terapias de presión positiva estén contraindicadas (por ejemplo, hernia diafragmática y fístula traqueoesofágica).• Trauma nasal/deformidad grave que pueda verse empeorada por el uso de las cánulas nasales o la máscara nasal.

Los componentes de la interfaz para lactantes están diseñados para utilizarlos con un único paciente. **Su reutilización puede causar la transmisión de sustancias infecciosas, la interrupción del tratamiento, daños graves o la muerte.**

Manipular con cuidado. Tenga cuidado al colocar o desconectar la interfaz neonatal. Evite tirar con demasiada fuerza, los objetos afilados y los soportes de tubos. Si los tubos resultan dañados, se puede producir una pérdida de presión y sería necesario sustituirlos.

Este producto se ha diseñado para su uso durante un máximo de 7 días.

NO utilizar si el producto o el embalaje están dañados.

- NO realizar ninguna modificación de este producto.
- Utilícese con un sistema de monitorización del oxígeno del paciente.
- La conexión de sistemas de humidificación de otros fabricantes aumenta el riesgo de condensación y de suministro de gas al paciente a elevadas temperaturas.
- Conecte los dispositivos de monitorización de la presión solo al puerto de monitorización de la presión del tubo nasal.
- Los componentes de la interfaz para lactantes se proporcionan limpios. Siga los procedimientos adecuados para evitar la contaminación biológica durante su uso y al desecharlos.
- NO sumerja, lave, esterilice ni reutilice este producto.
- NO apriete demasiado las correas del gorro para lactantes.
- NO cubra la cara del lactante con el gorro, ya que existe riesgo de asfixia.
- UTILICE SÓLO los componentes de la interfaz para lactantes de F&P recomendados. Si se utilizan cánulas nasales o máscaras no aprobadas, podrían quedar colocadas de forma inadecuada.
- Se puede producir una necrosis del tabique nasal si no se tiene en cuenta el tamaño adecuado y la colocación correcta de las cánulas y la máscara.
- **Monitorice siempre la presión para verificar que el paciente esté recibiendo el nivel de CPAP prescrito.**
- NO utilice medicamentos que contengan tiloxapol (como Tacholiquin), ya que esto podría dañar los tubos y causar la pérdida de presión CPAP.

- **BC190, BC191, BC192**

Consulte las instrucciones del sistema de CPAP de burbujas de F&P antes de instalar la interfaz para lactantes.

Si se utiliza un adaptador, consulte las instrucciones de instalación proporcionadas por el fabricante del circuito antes de instalar la interfaz para lactantes.

- Consulte las ilustraciones 1-15 para realizar correctamente la instalación.
- Consulte el tamaño correcto de los productos en las tablas de la última página.
- SE DEBE utilizar un dispositivo de liberación de presión máxima. La configuración de la liberación de presión debe ser adecuada para CPAP de lactantes.

- Cuando no se esté utilizando el puerto de monitorización de la presión del tubo nasal, se debe cerrar el tapón.
- Compruebe que todas las conexiones del circuito estén bien apretadas antes de usarlo y después de realizar cualquier ajuste.

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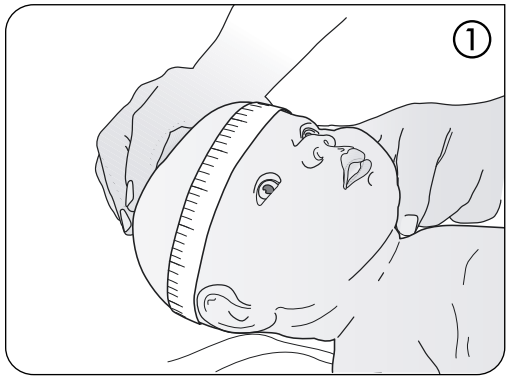
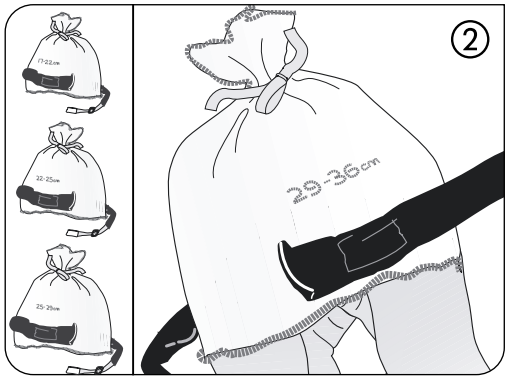
Fisher & Paykel HEALTHCARE

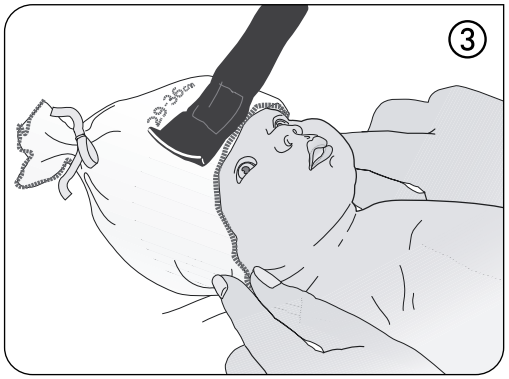
FlexiTrunk™ Instrucciones para el usuario de la interfaz para lactantes



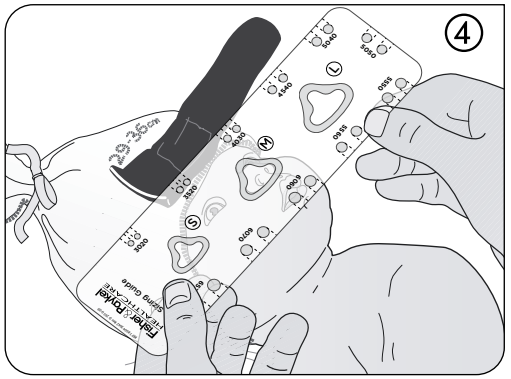
- Mida el perímetro de la cabeza del bebé en centímetros.



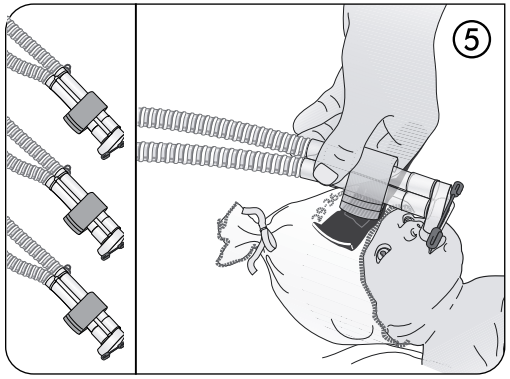
- Seleccione un gorro del tamaño correcto. El gorro debe quedarle ajustado.
- Estire primero el gorro con las manos para facilitar su colocación.



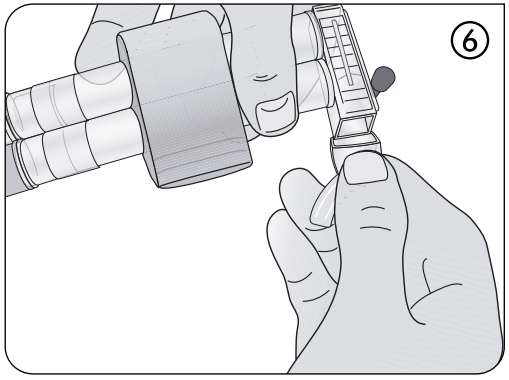
- Coloque el gorro en la cabeza del bebé de forma que cubra completamente las orejas y que el borde inferior quede en la base del cuello. El borde delantero del gorro debe quedar justo por encima de las cejas o sobre éstas.



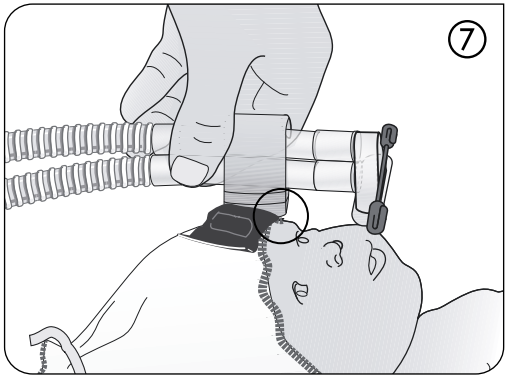
- Utilice la guía de tamaños de las cánulas y de la máscara para seleccionar las más adecuadas.
- Las cánulas deben ocupar por completo los orificios nasales sin estirar la piel. Utilice el mayor tamaño posible.
- La máscara no debe estar en contacto con la punta de la nariz, el tabique o los ojos.



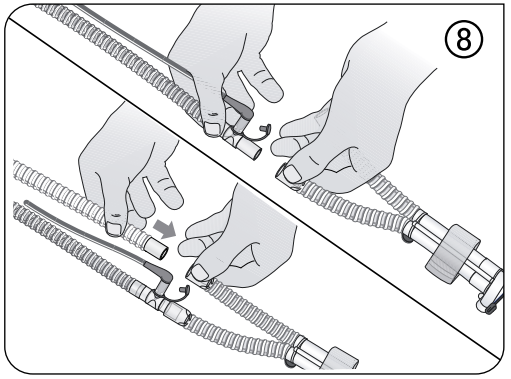
- Seleccione la longitud correcta para el tubo nasal. Utilice la menor longitud posible.
- El tubo transparente no debe sobrepasar la frente del lactante.
- Se pueden utilizar los siguientes datos como guía: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Conecte las cánulas o la máscara al tubo nasal, asegurándose de que quede insertado totalmente.
- Si utiliza cánulas nasales: apriete los lados de las cánulas con fuerza para exponer las ranuras. Comience por un extremo e introduzca las ranuras de las cánulas en los tubos nasales. Empuje el extremo con firmeza.



- Retire las cintas según sea necesario para ajustar el ángulo del tubo nasal de forma que consiga un cierre hermético óptimo.
- NO deseche las cintas, ya que pueden ser necesarias al cambiar entre cánulas nasales y máscaras.



- Conecte el circuito al tubo nasal con cualquier orientación.
- Consulte las instrucciones proporcionadas por el fabricante del circuito para obtener más detalles.
- Nota: desconecte el FlexiTrunk™ con cuidado, girando los conectores. NO tire en exceso, esto podría dañar los tubos.
- Manipular con cuidado.

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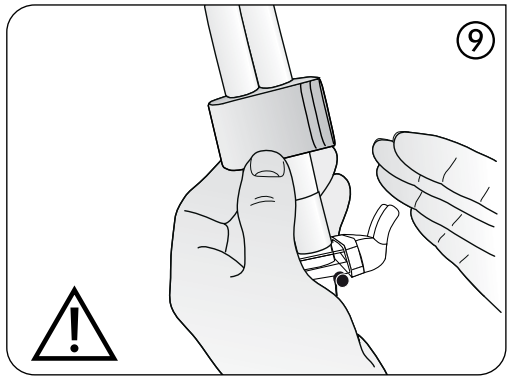
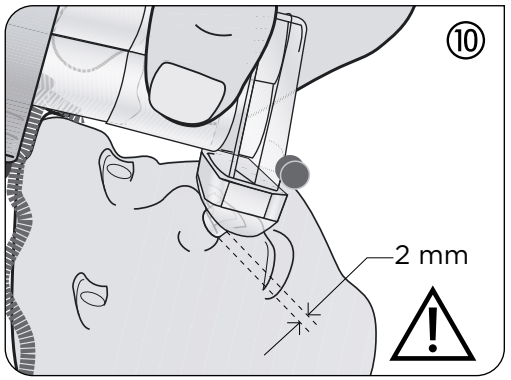
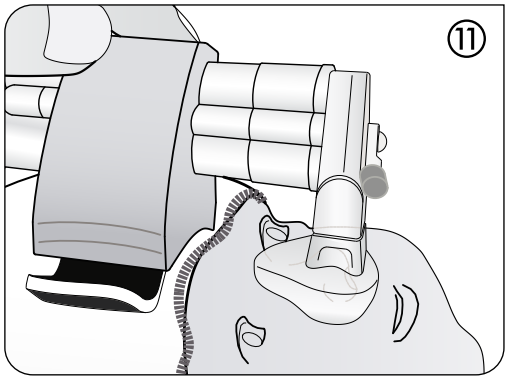
FlexiTrunk™ Instrucciones para el usuario de la interfaz para lactantes



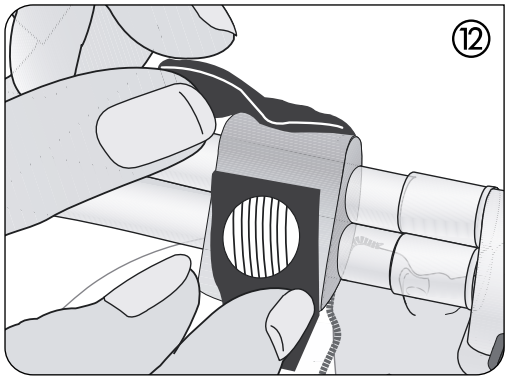
- Configure el flujo de gas hasta el nivel prescrito.
- Encienda el humidificador. Consulte las instrucciones del fabricante.
- ⚠ Coloque la mano cerca de las cánulas nasales o de la máscara para asegurarse de que existe flujo de gas.



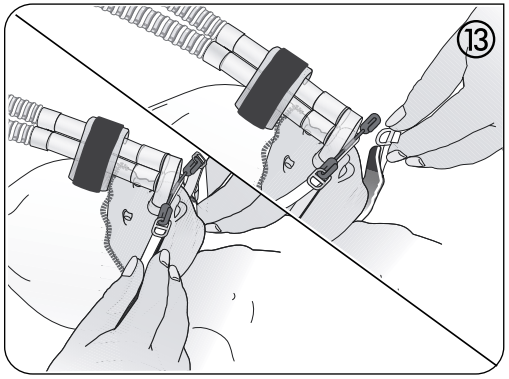
- **Si se utilizan cánulas:** Limpie las secreciones nasales antes de insertar las cánulas.
- ⚠ Asegúrese de que las cánulas nasales estén colocadas al menos a 2 mm (0,08 pulgadas) del tabique para evitar necrosis por presión. Ajústelas según sea necesario.
- Se recomienda comprobar la integridad del tabique nasal cada hora.



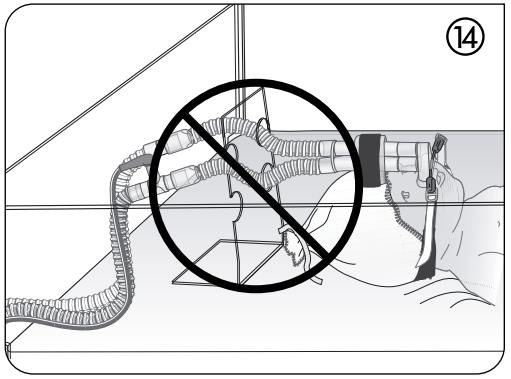
- **Si se utiliza máscara:** Conecte la máscara al paciente colocándosela alrededor de la nariz. La máscara debe quedar cómodamente asentada alrededor de la nariz del paciente. No debe ocluir las fosas nasales ni tocar el tabique, ni debe cubrir los labios o los ojos.



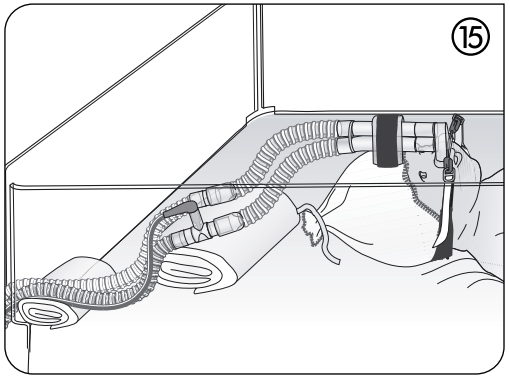
- Ajuste la altura de la almohadilla de espuma añadiendo o quitando cintas. Las configuraciones con máscara pueden necesitar el añadido de cintas para una correcta colocación.
- Coloque la correa sobre la almohadilla de espuma y apriete para sujetar el tubo firmemente en su posición.



- Enganche los pasadores de las correas laterales del gorro en la correa.
- Tire de las dos correas a la vez para que el dispositivo quede centrado.
- Pegue las lengüetas redondas de velcro a la correa azul del gorro.
- Aplique la mínima tensión posible para mantener el nivel de CPAP prescrito y la estabilidad de la interfaz para lactantes.



- NO utilice perchas o dispositivos de soporte similares, ya que pueden perforar los tubos FlexiTrunk™ y provocar una pérdida de presión.



- Asegúrese de que el circuito esté bien apoyado para reducir la tensión en los tubos nasales. Se recomienda usar una almohada o una toalla doblada. Los tubos FlexiTrunk™ deben poder moverse libremente para que el bebé pueda mover la cabeza sin restricciones.
- El circuito se debe mantener por debajo del nivel del tubo nasal para minimizar la condensación para el bebé.

Verificaciones durante el funcionamiento

- Compruebe con frecuencia si el paciente presenta signos de enrojecimiento, llagas por contacto o irritación, como resultado del uso prolongado de las cánulas o la máscara. Recomendamos realizar comprobaciones cada hora.
- Si se alterna el uso de cánulas y de máscara, se puede reducir el riesgo de irritación. Es recomendable alternar cada 4 o 6 horas.
- La posición de la máscara debe ajustarse para que encaje lo mejor posible y se produzca la menor pérdida posible. Si persiste una pérdida excesiva, se puede compensar aumentando el flujo. El caudal máximo permitido es de 15 L/min.
- Compruebe la condensación regularmente y drénelo cuando sea necesario.

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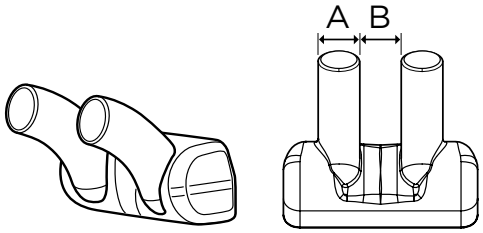
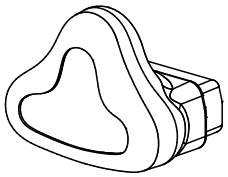
FlexiTrunk™ Instrucciones para el usuario de la interfaz para lactantes

CÁNULAS NASALES PARA LACTANTES



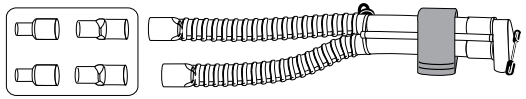
Código de producto	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MÁSCARA NASAL PARA LACTANTES



Código de producto	Tamaño
BC800	Pequeña
BC801	Mediana
BC802	Grande
BC803	Extra Grande

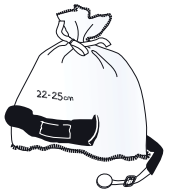
TUBO NASAL PARA LACTANTES



Serie BC19x

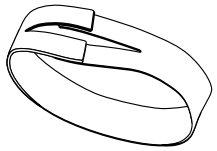
Código de producto	Tamaño
BC190	50 mm
BC191	70 mm
BC192	100 mm

GORRO PARA LACTANTES



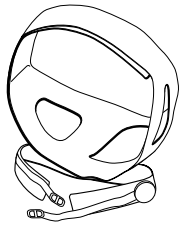
Código de producto	Tamaño
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

CORREA DE BARBILLA PARA LACTANTES



Código de producto	Tamaño
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

CUBIERTA PARA LACTANTES



Código de producto	Tamaño
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ Vastasyntyneiden potilasliitännän käyttöohje

fi

Käyttötarkoitus

Vastasyntyneiden F&P potilasliittymä on tarkoitettu antamaan ylipainehoitoa spontaanisti hengittäville enintään 10 kg painaville potilaille sairaalassa tai muussa kliinisessä ympäristössä, missä pätevä terveydenhuollon henkilöstö voi tarkkailla potilasta.

Tuotetiedot

BC190 **BC191** **BC192**	Vastasyntyneiden F&P-potilasliitäntä on tarkoitettu liitettäväksi Fisher & Paykel Healthcaren kuplia muodostavaan CPAP-järjestelmään. Sovittimet mahdollistavat yhdistämisen muiden valmistajien CPAP-letkustoihin 7,8 tai 10 mm:n liittimillä.
Maksimisisäänvirtaus	15 L/min
Suurin sallittu käyttöpaine	15 cmH_2O

Katso mitat ja osat edelliseltä sivulta.

Vasta-aiheet

- Ei spontaania hengitystä
- Synnynnäiset poikkeavuudet tai epämuodostumat, jotka muodostavat vasta-aiheen nenäkanyylin tai maskin käytölle (esim. koanaaliatresia).
- Synnynnäiset poikkeavuudet tai epämuodostumat, jotka muodostavat vasta-aiheen painehoidoille (esim. palleatyrä ja trakeoesofageaalinen fisteli).
- Nenävamma/vaikea epämuodostuma, jota nenäkanyylin tai maskin käyttö voi pahentaa.

VAROITUKSET

- Potilasliitännän osat on suunniteltu vain yhden potilaan käyttöä varten. **Uudelleenkäyttäminen voi johtaa tarttuvien aineiden kulkeutumiseen, hoidon keskeytymiseen, vakaviin haittoihin tai kuolemaan.**
- **Käsiteltävä varoen.** Ole varovainen, kun asetat tai poistat vastasyntyneen potilasliitäntää. Älä vedä potilasliitäntää liian voimakkaasti ja varo teräviä esineitä ja letkunpidikkeitä. Jos letku vaurioituu, paine voi laskea, jolloin letku on vaihdettava välittömästi.
- Tuote on tarkoitettu käytettäväksi enintään 7 päivän ajan.
- EI SAA käyttää, jos tuote tai sen pakkaus on vahingoittunut.
- Tuotetta EI SAA muunnella.
- Tarkkaile potilaan happitasoa.
- Yhdistäminen muiden valmistajien kostutusjärjestelmiin lisää kosteuden tiivistymisen ja/tai potilaalle annostellun ilman lämpötilan nousun riskiä.
- Yhdistä nenäletkun paineentarkkailuporttiin vain paineentarkkailulaitteita.
- Potilasliitännän osat toimitetaan puhtaina. Vältä biokontaminaatiota käytön ja hävittämisen aikana.
- Tuotetta EI SAA liottaa, pestä, steriloida tai käyttää uudelleen.
- Myssyn kiinnitysnauhoja EI SAA kiristää liian tiukalle.
- Lapsen kasvoja EI SAA peittää myssyllä, koska se voi aiheuttaa tukehtumisen.
- KÄYTÄ VAIN suositeltuja vastasyntyneiden F&P-potilasliitännän osia. Ei-hyväksyttyjen osien käyttö voi aiheuttaa nenäkanyylin ja maskin asettumisen virheelliseen asentoon.
- Jos nenäkanyyli ja maski ovat väärän kokoisia tai väärin asetettu, ne voivat aiheuttaa väliseinämän nekroosin.
- **Käytä aina paineentarkkailua, jotta potilas varmasti saa määrättyä CPAP-painetasoa.**
- ÄLÄ käytä tyloksapolia sisältäviä lääkkeitä (esimerkiksi Tacholiquinia), koska ne voivat vahingoittaa letkustoa ja alentaa CPAP-painetta.

Asetus

- **BC190, BC191, BC192**
- Tutustu kuplia muodostavan F&P CPAP-järjestelmän käyttöohjeisiin ennen potilasliitännän asettamista.
- Jos käytetään sovittimia, tutustu hengitysletkujen valmistajan ohjeisiin ennen potilasliitännän asettamista.
- Katso oikea asetustapa kuvista 1-15.
- Tarkista oikea tuotekoko viimeisellä sivulla olevista taulukoista.
- Maksimipaineen päästölaitetta TÄYTYY käyttää. Paineenpäästöasetusten tulee olla vastasyntyneen CPAP-hoitoon sopivat.

Tarkistukset ennen käyttöä

- Kun nenäletkun paineentarkkailuportti ei ole käytössä, suojus on suljettava.
- Tarkista liitosten tiiviys ennen käyttöä ja säätöjen jälkeen.

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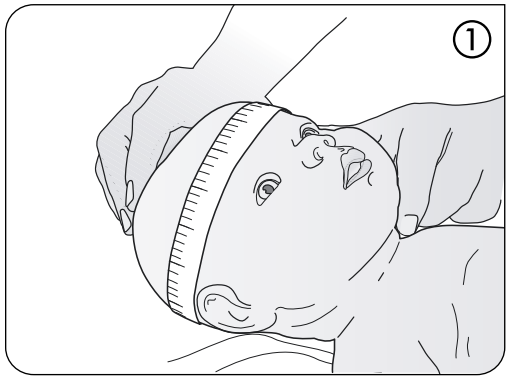
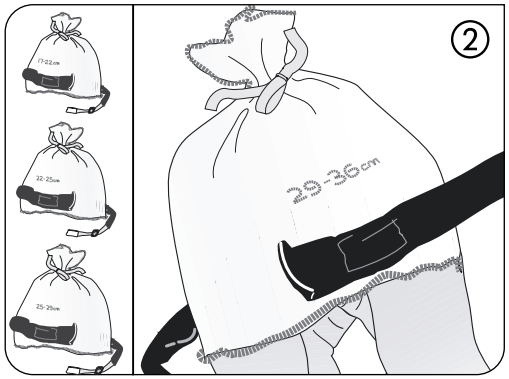
Fisher & Paykel HEALTHCARE

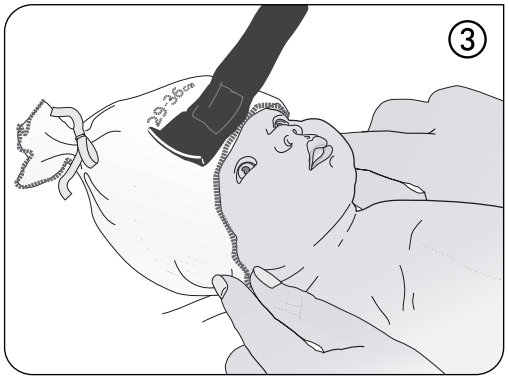
FlexiTrunk™ Vastasyntyneiden potilasliitännän käyttöohje



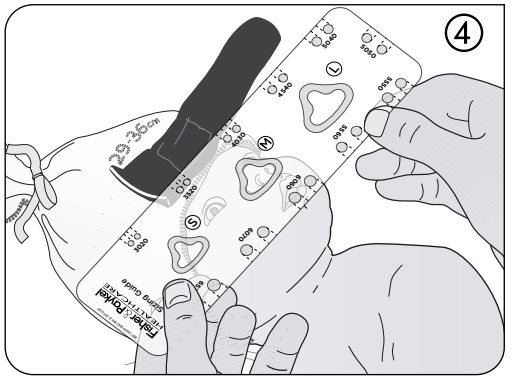
- Mittaa vastasyntyneen päänympärys senttimetreinä.



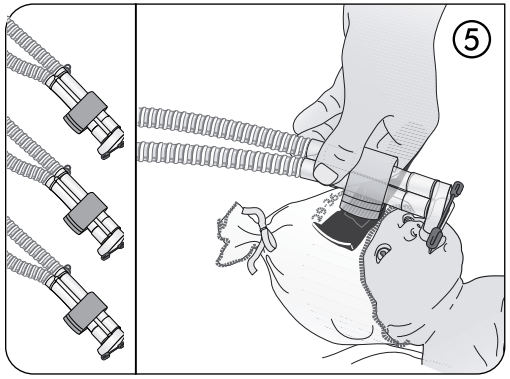
- Valitse oikean kokoinen myssy. Myssyn tulee istua tiukasti.
- Helpota myssyn asettamista paikalleen venyttämällä sitä käsin.



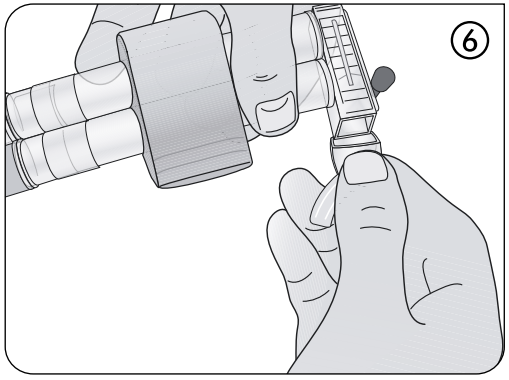
- Aseta myssy vastasyntyneen päähän niin, että se peittää kokonaan korvat ja takareuna on niskan tyvessä. Myssyn etureunan tulee olla juuri kulmakarvojen yläpuolella.



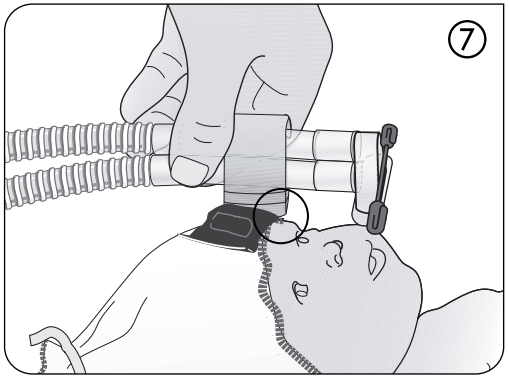
- Valitse oikeankokoinen nenäkanyyli tai maski kokotaulukon avulla.
- Kanyylin tulee täyttää sieraimet kokonaan venyttämättä niitä. Käytä suurinta mahdollista kokoa.
- Maski ei saa koskettaa nenän reunaa, väliseinämää eikä silmiä.



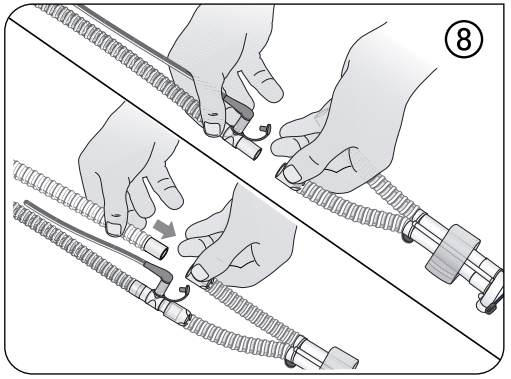
- Valitse oikeanpituinen nenäletku. Käytä lyhyintä mahdollista letkua.
- Letkujen ei pitäisi ulottua vastasyntyneen otsan yli.
- Suuntaa antava ohjeistus: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Yhdistä kanyyli tai maski nenäletkuihin ja varmista, että se on kunnolla paikallaan.
- Jos käytössä on kanyyli: purista kanyylin sivuja voimakkaasti niin, että uurteet tulevat näkyviin. Aloita toisesta päästä ja työnnä kanyylin uurteet nenäletkuun. Työnnä pää tukevasti sisään.



- Poista tarranauhat tarvittaessa ja säädä nenäletkujen kulmaa, jotta liitäntä olisi mahdollisimman tiivis.
- ÄLÄ hävitä tarranauhoja, sillä niitä voidaan tarvita, kun nenäkanyylit vaihdetaan maskiin tai maski nenäkanyyliin.



- Kiinnitä hengitysletkut nenäletkuihin kumman suuntaisesti tahansa.
- Katso lisäohjeita hengitysletkujen valmistajan käyttöohjeista.
- Huomautus: irrota FlexiTrunk™ varovasti kääntämällä liitintä. ÄLÄ vedä väkisin, koska letku voi vaurioitua.
- **Käsiteltävä varoen.**

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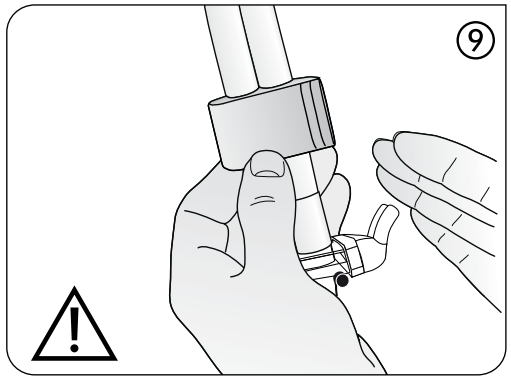
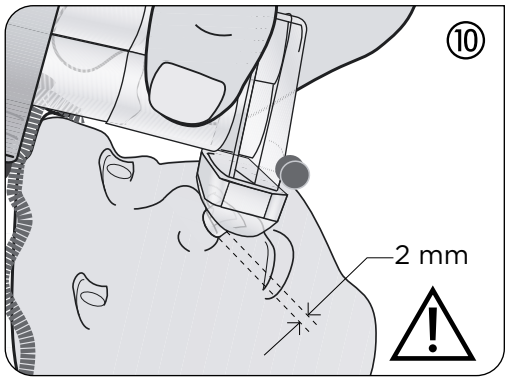
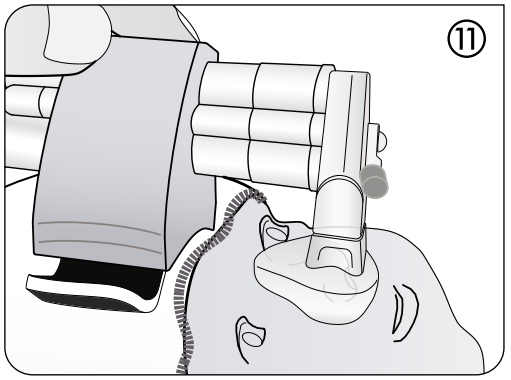
FlexiTrunk™ Vastasyntyneiden potilasliitännän käyttöohje



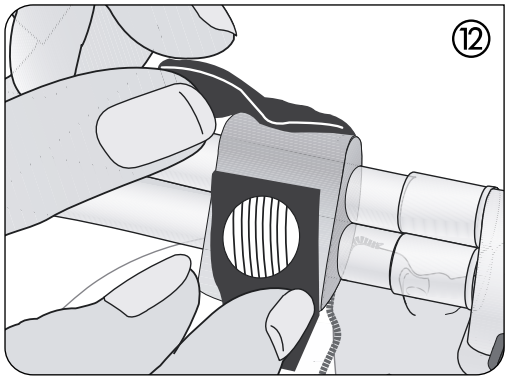
- Aseta ilman virtaus määrätylle tasolle.
- Kytke kostutin päälle. Tutustu valmistajan käyttöohjeisiin.
- ⚠ Pidä kättä nenäkanyylin tai maskin lähellä ja varmista, että ilmaa virtaa.



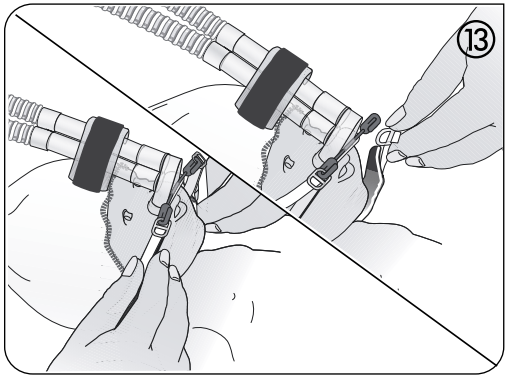
- **Kanyylia käytettäessä:** Puhdista nenästä eritteet ennen kanyylin asettamista.
- ⚠ Varmista, että nenäkanyyli on vähintään 2 mm:n (0.08 tuumaa) päässä väliseinämästä nekroosin välttämiseksi. Säädä tarvittaessa.
- On suositeltavaa tarkistaa väliseinämän kunto tunnin välein.



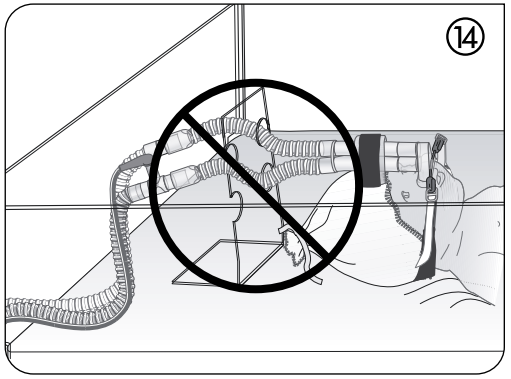
- **Maskia käytettäessä:** Yhdistä maski potilaaseen asettamalla se nenän ympärille. Maskin on asetuttava miellyttävästi potilaan nenän ympärille. Se ei saa tukkia sieraimia tai koskettaa väliseinämää, eikä se saa olla huulen tai silmien päällä.



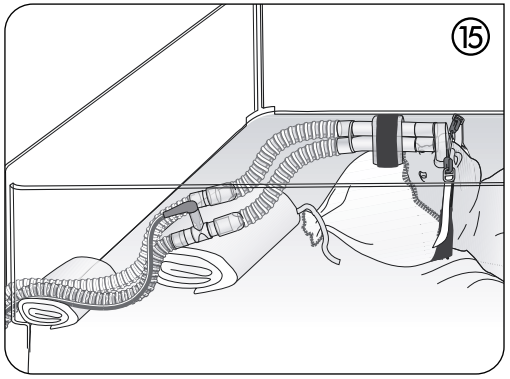
- Säädä vaahtomuovityynyn korkeus lisäämällä tai vähentämällä tarranauhoja. Kun vaahtomuovityynyn korkeutta säädetään maskin kanssa, voi olla tarpeen lisätä tarranauhoja, jotta maski saadaan oikeaan asentoon.
- Aseta hihna vaahtomuovityynyn päälle ja kiristä niin että letkut ovat tiukasti paikallaan.



- Kiinnitä myssyn sivuhihnojen pidikkeet liukusolkeen.
- Vedä molemmista hihnoista samaan aikaan.
- Kiinnitä pyöreät tarrat myssyn siniseen hihnaan.
- Kiristä niin vähän kuin mahdollista CPAP-painetason ja potilasliitännän vakauden ylläpitämiseksi.



- ÄLÄ käytä hengitysletkun pidikkeitä, koska ne voivat tehdä FlexiTrunk™ letkuun reiän ja aiheuttaa paineen alenemisen.



- Varmista, että hengitysletkujen paino on kannateltu, jotta nenäletkut eivät kiristy. Tyynyn tai taitetun pyyhkeen käyttöä suositellaan, FlexiTrunk™ letkujen on liikuttava vapaasti, jotta vastasyntynyt pystyy liikuttamaan päätään.
- Hengitysletkujen tulee olla nenäletkujen tason alapuolella kosteuden tiivistymisen minimoimiseksi.

Tarkistukset käytön aikana

- Tarkista potilas säännöllisesti pitkään jatkuneen kanyylin tai maskin käytön aiheuttaman punoituksen, painehaavojen tai ihoärsytyksen varalta. Tarkastusta tunnin välein suositellaan.
- Maskin ja kanyylin käytön vaihteleminen voi vähentää ihoärsytyksen riskiä. Suositeltu vaihteluväli on 4–6 tuntia.
- Maskin paikkaa tulee säätää siten, että maski istuu hyvin ja on mahdollisimman tiivis. Jos liikaa vuotoa esiintyy edelleen, vuotoa voi kompensoida virtausta lisäämällä. Suurin sallitu virtausnopeus on 15 L/min.
- Tarkista tiivistynyt vesi säännöllisesti ja poista se tarvittaessa.

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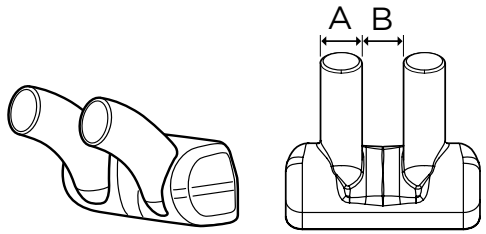
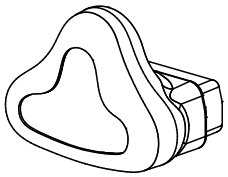
FlexiTrunk™ Vastasyntyneiden potilasliitännän käyttöohje

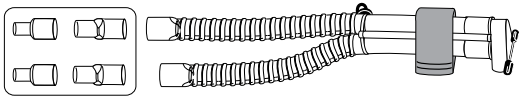


Tuotekoodi	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4.5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

VASTASYNTYNEEN NENÄMASKI



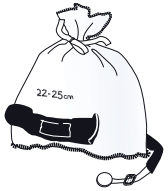
Tuotekoodi	Koko
BC800	Pieni
BC801	Keskikoko
BC802	Suuri
BC803	Erittäin suuri



BC19x sarja

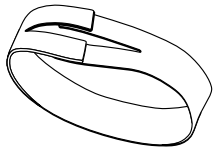
Tuotekoodi	Koko
BC190	50 mm
BC191	70 mm
BC192	100 mm

VASTASYNTYNEEN MYSSY



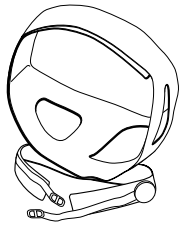
Tuotekoodi	Koko
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

VASTASYNTYNEEN LEUKAHIHNA



Tuotekoodi	Koko
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

VASTASYNTYNEEN PÄÄHINE



Tuotekoodi	Koko
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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F&P FlexiTrunk™ Instructions d'utilisation de l'interface pédiatrique

fr

Utilisation prévue

L'interface pédiatrique de F&P est conçue pour délivrer une ventilation non invasive en pression positive aux patients respirant spontanément et pesant jusqu'à 10 kg, en milieu hospitalier, où le patient est surveillé par un personnel médical qualifié.

Caractéristiques du produit

BC190 **BC191** **BC192**	L'interface pédiatrique de F&P est conçue pour être raccordée au système CPAP Fisher & Paykel Healthcare Bubble. Les adaptateurs permettent la connexion aux circuits de CPAP d'autres fabricants à l'aide de connecteurs de 7,8 ou 10 mm.
Débit d'alimentation maximum	15 L/min
Pression de fonctionnement maximale	15 cmH_2O

Se reporter à la dernière page pour les dimensions et les composants.

Contre-indications

- Absence de respiration spontanée.
- Anomalies ou malformations congénitales pour lesquelles l'utilisation d'une canule nasale ou d'un masque nasal est contre-indiquée (par ex. atrésie des choanes).
- Anomalies ou malformations congénitales pour lesquelles les traitements par pression positive sont contre-indiqués (par ex. hernie diaphragmatique et fistule trachéo-œsophagienne).
- Traumatisme nasal/difformité sévère qui peuvent être aggravés par l'utilisation de canules nasales ou d'un masque nasal.

AVERTISSEMENTS

Les composants de l'interface pédiatrique sont conçus pour un usage unique sur un seul patient. **Toute réutilisation peut avoir pour effet la transmission de substances infectieuses, l'interruption du traitement, des conséquences médicales graves ou la mort.**

Manipuler avec soin. Prendre des précautions lors de la mise en place ou de la déconnexion de l'interface pédiatrique. Éviter d'appliquer une force de traction excessive ou d'utiliser des objets tranchants et des support de tuyaux. Un tuyau endommagé peut entraîner une perte de pression et devoir être remplacé immédiatement.

Ce produit est destiné à être utilisé durant 7 jours au maximum.

NE PAS utiliser si le produit ou l'emballage sont endommagés.

- NE PAS modifier ce produit.
- Utiliser un monitorage de l'oxygène du patient.
- La connexion à des systèmes d'humidification d'autres fabricants augmente le risque de condensation et/ou d'une température élevée du gaz délivré au patient.
- Brancher uniquement des dispositifs de monitorage de pression au raccord de monitorage de pression du tuyau nasal.
- Les composants de l'interface pédiatrique sont fournis médicalement propres. Employer les méthodes appropriées pour prévenir toute contamination biologique durant l'utilisation et lors de l'élimination.
- NE PAS faire tremper, nettoyer, stériliser ni réutiliser ce produit.
- NE PAS trop serrer les sangles du bonnet du nourrisson.
- NE PAS couvrir le visage du nourrisson avec le bonnet, cela pourrait provoquer une suffocation.
- UTILISER UNIQUEMENT les composants recommandés de l'interface pédiatrique de F&P ; l'utilisation de dispositifs non agréés peut entraîner un mauvais positionnement de la canule nasale et du masque.
- Une nécrose septale peut se produire si la canule nasale et le masque sont d'une taille inappropriée ou mal positionnés.
- **Toujours utiliser un monitorage de la pression afin de vérifier que le patient reçoit le niveau de CPAP prescrit.**
- NE PAS utiliser de médicaments contenant du tyloxapol (tels que Tacholiquin), car cela risque d'endommager le tuyau et de provoquer une perte de pression CPAP.

Installation

- **BC190, BC191, BC192**

Se reporter aux instructions du système Bubble CPAP de F&P avant d'installer l'interface pédiatrique.

Si vous utilisez les adaptateurs, se reporter aux instructions d'installation fournies par le fabricant du circuit avant d'installer l'interface pédiatrique.

- Se reporter aux illustrations 1 à 15 pour une installation correcte.
- Pour choisir la bonne taille du produit, se reporter aux tableaux de la dernière page.
- Un dispositif de limitation de pression maximale DOIT être utilisé. Les réglages de limitation de pression maximale doivent être adaptés à une CPAP nasale pédiatrique.

Vérifications à effectuer avant utilisation

- Lorsque le raccord de monitorage de pression sur le support d'interface n'est pas utilisé, le bouchon doit être fermé.
- Vérifier que tous les raccords du circuit sont bien serrés avant utilisation et après tout réglage.

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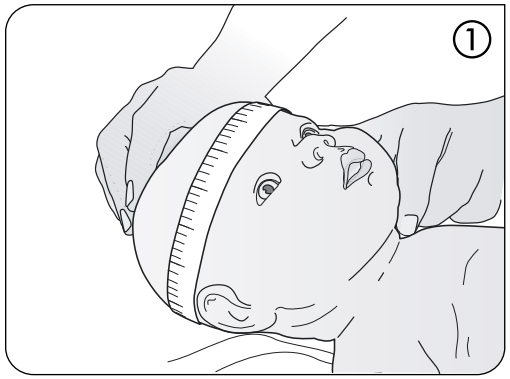
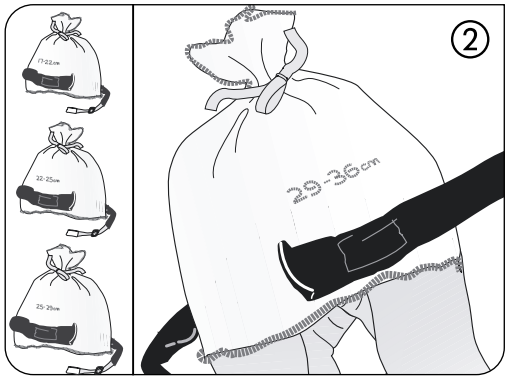
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

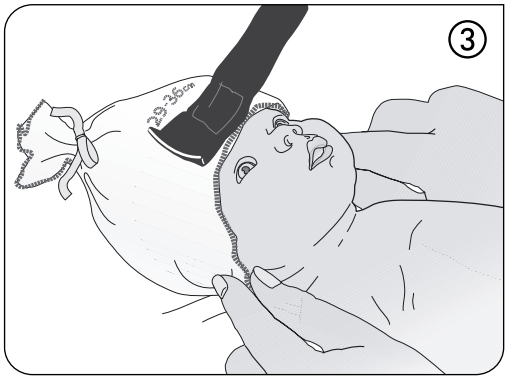
FlexiTrunk™ Instructions d'utilisation de l'interface pédiatrique



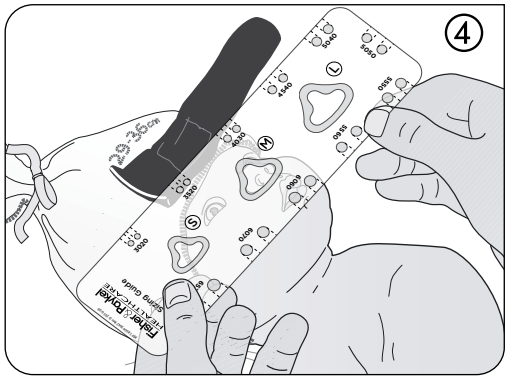
- Mesurer le périmètre crânien du bébé en centimètres.



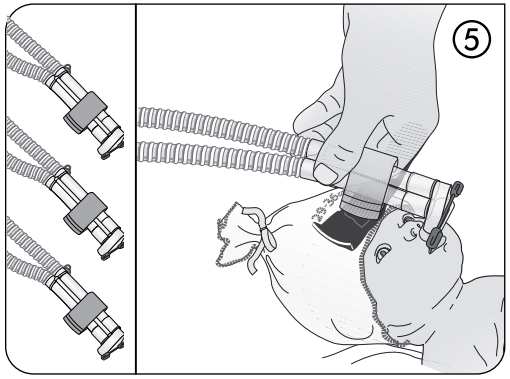
- Choisir la taille de bonnet appropriée. Le bonnet doit être bien serré.
- Au départ, étirer le bonnet avec les mains pour faciliter sa mise en place.



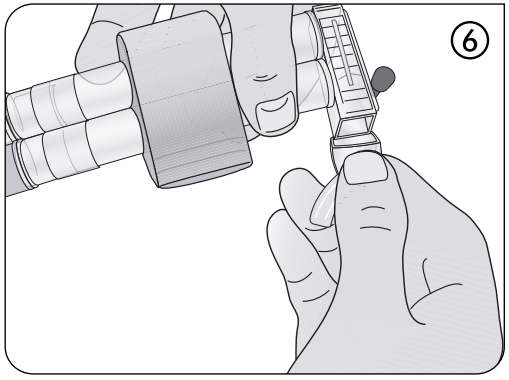
- Glisser le bonnet sur la tête du bébé, en couvrant complètement les oreilles, et en plaçant le bord de l'arrière du bonnet sur la base du cou. Le bord avant du bonnet doit se trouver juste au-dessus ou sur les sourcils.



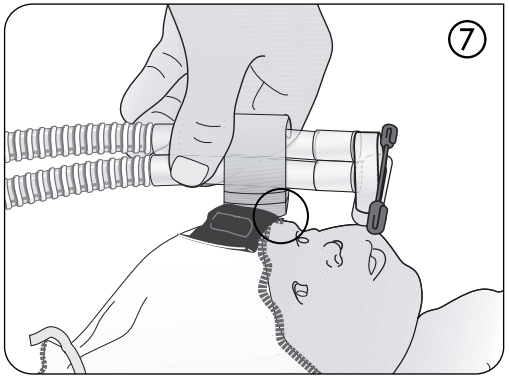
- Utiliser le gabarit de tailles des canules nasales ou du masque pour choisir la taille appropriée.
- La canule doit remplir entièrement les narines, sans étirer la peau. Utiliser la plus grande taille possible.
- Le masque ne doit pas toucher l'arrête du nez, le septum ni les yeux.



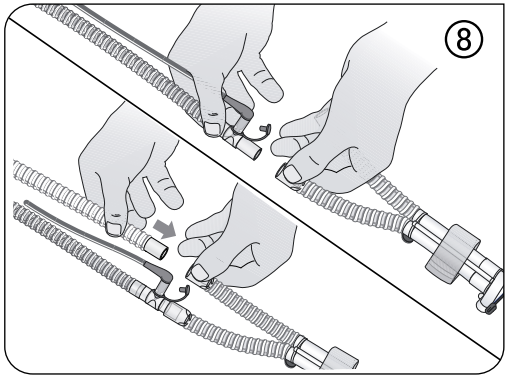
- Choisir la longueur adéquate du support d'interface. Utiliser la plus petite longueur possible.
- Le tuyau transparent ne doit pas reposer sur le front du nourrisson.
- Utiliser les indications suivantes comme guide :50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm › 2,5 kg



- Raccorder les canules ou le masque au support d'interface en prenant soin de les insérer entièrement.
- En cas d'utilisation de canules : presser fermement les côtés des canules de façon à exposer les rainures. Commencer par une extrémité et insérer les rainures de la canule dans le tuyau nasal. Pousser fermement sur l'extrémité pour l'insérer.



- Retirer les cales détachables le cas échéant pour ajuster l'angle du support d'interface afin d'optimiser l'étanchéité.
- NE PAS jeter les cales détachables, car elles peuvent être nécessaires lors de l'alternance entre les canules nasales et les masques nasaux.



- Connecter le circuit sur le support d'interface dans les deux sens.
- Se reporter aux instructions fournies par le fabricant du circuit pour plus de détails.
- Remarque : Déconnecter FlexiTrunk™ doucement en tournant les connecteurs. NE PAS tirer avec force, car cela risque d'endommager le tuyau.
- Manipuler avec soin.

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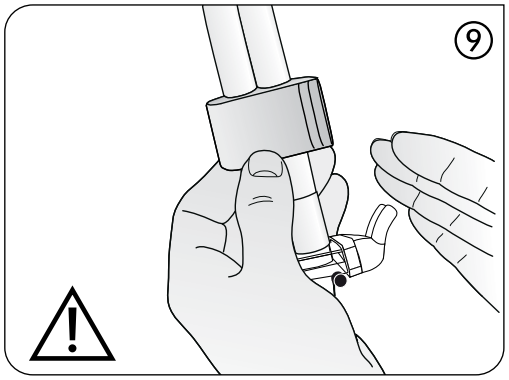
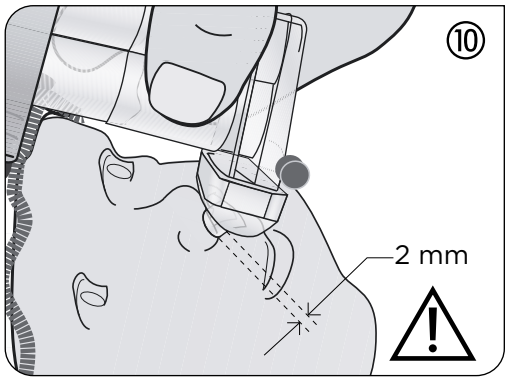
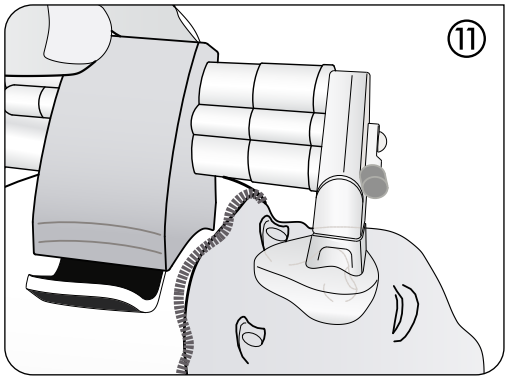
FlexiTrunk™ Instructions d'utilisation de l'interface pédiatrique



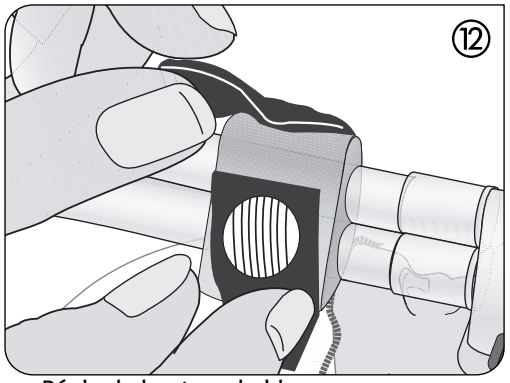
- Régler le débit de gaz au niveau prescrit.
- Allumer l'humidificateur. Se reporter aux instructions du fabricant.
- ⚠ Placer la main près de la canule nasale ou du masque pour vérifier la présence d'un débit de gaz.



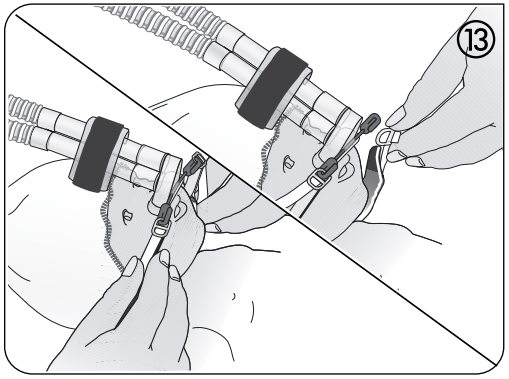
- **Utilisation des canules :** Enlever les sécrétions nasales avant d'introduire la canule nasale.
- ⚠ S'assurer que la canule nasale est à au moins 2 mm (0,08 pouces) du septum pour éviter toute nécrose due à la pression. Ajuster le cas échéant.
- Une vérification toutes les heures de l'intégrité du septum est recommandée.



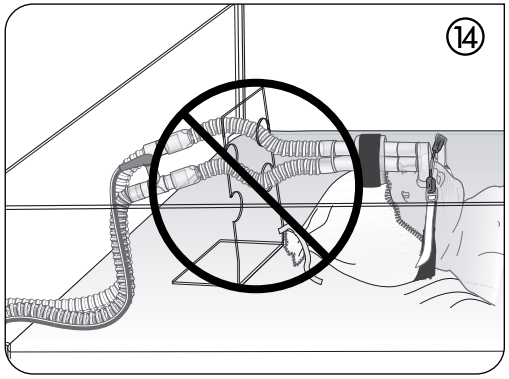
- **Utilisation du masque :** Raccorder au patient en plaçant le masque autour du nez. Le masque doit reposer confortablement autour du nez du patient. Il ne doit pas obturer les narines ni toucher le septum et ne doit pas être placé sur les lèvres ou les yeux.



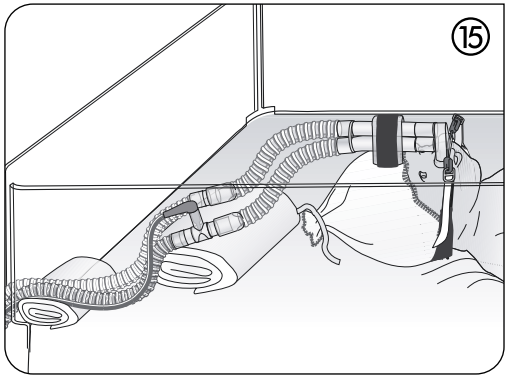
- Régler la hauteur du bloc en mousse en ajoutant ou en retirant des cales détachables. Les mises en place avec des masques peuvent nécessiter l'ajout de cales pour parvenir à un positionnement correct.
- Placer la sangle sur le bloc de mousse et serrer pour maintenir le tuyau fermement en place.



- Accrocher les clips des sangles latérales du bonnet à la glissière.
- Tirer sur les deux sangles en même temps pour la positionner au centre.
- Fixer les languettes velcro rondes sur la sangle bleue du bonnet.
- Utiliser la tension la moins forte possible pour maintenir le niveau de CPAP prescrit et la stabilité de l'interface.



- NE PAS utiliser de dispositifs de type bras support de tuyaux, car ils risquent de percer le tuyau FlexiTrunk™ et d'entraîner une perte de pression.



- S'assurer que le poids du circuit est légèrement soutenu pour réduire la tension sur le tuyau nasal. L'utilisation d'un oreiller ou d'une serviette pliée est recommandée. Le tuyau FlexiTrunk™ doit avoir une liberté de mouvement pour permettre au bébé de bouger la tête librement.
- Le circuit doit se trouver à un niveau plus bas que le support d'interface, et ceci afin de réduire la condensation au niveau du bébé.

Vérifications à effectuer pendant l'utilisation

- Vérifier fréquemment tout signe de rougeur, de douleurs dues à la pression ou d'irritation chez le patient, pouvant se produire lors d'une utilisation prolongée des canules ou du masque. Une vérification toutes les heures est recommandée.
- Alterner le masque et les canules peut réduire le risque d'irritation. Une alternance toutes les 4 à 6 heures est recommandée.
- Ajuster le positionnement du masque afin d'assurer une meilleure adaptation et de limiter les fuites. Le débit peut être augmenté afin de compenser une fuite excessive. Le débit maximum autorisé est de 15 L/min.
- Vérifier régulièrement la condensation, et vider si nécessaire.

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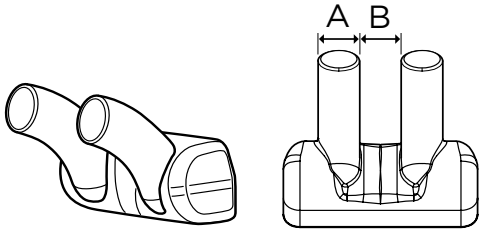
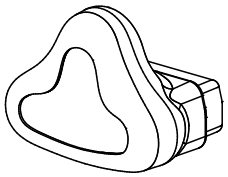
FlexiTrunk™ Instructions d'utilisation de l'interface pédiatrique

CANULE NASALE PÉDIATRIQUE



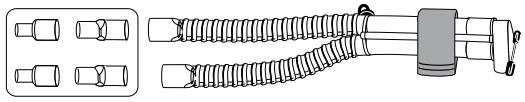
Référence produit	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MASQUE NASAL PÉDIATRIQUE



Référence produit	Taille
BC800	Small
BC801	Medium
BC802	Large
BC803	Extra large

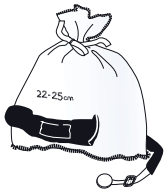
SUPPORT D'INTERFACE PÉDIATRIQUE



Série BC19x

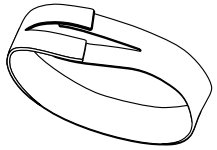
Référence produit	Taille
BC190	50 mm
BC191	70 mm
BC192	100 mm

BONNET PÉDIATRIQUE



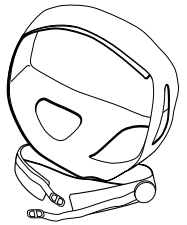
Référence produit	Taille
BC300	17 à 22 cm
BC303	22 à 25 cm
BC306	25 à 29 cm
BC309	29 à 36 cm

MENTONNIÈRE PÉDIATRIQUE



Référence produit	Taille
BC351	20 à 26 cm
BC353	26 à 32 cm
BC355	32 à 38 cm
BC357	38 à 44 cm

HARNAIS PÉDIATRIQUE



Référence produit	Taille
BC325	29 à 36 cm
BC328	35 à 40 cm
BC331	40 à 45 cm

LATEX

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Petunjuk Bagi Pengguna Alat Penghubung Bayi FlexiTrunk™

id

Tujuan Penggunaan

Alat Penghubung Bayi F&P dirancang untuk menyediakan ventilasi tekanan positif non-invasif kepada pasien bernapas spontan yang beratnya mencapai 10 kg di rumah sakit atau klinik tempat pasien dipantau secara memadai oleh staf medis yang terlatih.

Spesifikasi Produk

BC190 **BC191** **BC192**	Alat Penghubung Bayi F&P dirancang untuk disambungkan ke Sistem Bubble CPAP Fisher & Paykel Healthcare. Adaptor memungkinkan adanya koneksi ke sirkuit CPAP produsen lain dengan konektor 7,8 atau 10 mm.
Aliran masuk maksimum	15 L/mnt
Tekanan operasi maksimum yang diperbolehkan	15 cmH_2O

Harap lihat halaman terakhir untuk dimensi dan komponen.

Kontraindikasi

- Pernapasan tidak spontan
- Kelainan atau cacat bawaan yang sebaiknya tidak menggunakan nasal prong ganda atau masker hidung (misalnya atresia koanal).
- Kelainan atau cacat bawaan yang sebaiknya tidak menggunakan terapi tekanan positif (misalnya hernia diafragma dan fistula trakeoesofagus).
- Trauma/cacat parah pada hidung yang mungkin menjadi lebih buruk bila menggunakan nasal prong atau masker hidung.

PERINGATAN

Komponen Alat Penghubung Bayi ini dirancang hanya untuk digunakan pada satu pasien. **Pemakaian ulang dapat menyebabkan penyebaran bahan menular, gangguan pengobatan, bahaya serius, atau kematian.**

Tangani dengan hati-hati. Hati-hati saat memosisikan atau melepaskan Alat Penghubung Bayi. Hindari menarik dengan kekuatan berlebihan, benda tajam, dan pemegang selang. Kerusakan pada selang dapat menyebabkan hilangnya tekanan dan harus langsung diganti.

Produk ini dimaksudkan untuk digunakan selama maksimal 7 hari.

JANGAN digunakan jika produk atau kemasannya rusak.

- Undang-undang Federal A.S. membatasi penjualan perangkat ini oleh dokter atau atas perintah dokter.
- JANGAN memodifikasi produk ini.
- Gunakan pemantauan oksigen pasien.
- Sambungan ke sistem pelembapan produsen lain meningkatkan risiko kondensasi dan/atau pengantaran suhu gas yang tinggi ke pasien.
- Hubungkan hanya perangkat pemantau tekanan ke lubang pemantauan tekanan pada selang hidung.
- Komponen Alat Penghubung tersedia dalam keadaan bersih. Gunakan metode yang sesuai untuk mencegah kontaminasi bio selama penggunaan dan saat pembuangan
- JANGAN merendam, mencuci, mensterilkan atau memakai ulang produk ini.
- JANGAN terlalu erat mengencangkan tali topi bayi.
- JANGAN menutupi wajah bayi dengan Topi Bayi karena bisa menyebabkan mati lemas.
- HANYA GUNAKAN komponen Alat Penghubung Bayi F&P yang disarankan, karena kesalahan penempatan nasal prong dan masker hidung dapat terjadi bila menggunakan komponen pengganti yang tidak disetujui.
- Nekrosis Septum bisa terjadi jika ukuran atau penempatan nasal prong dan masker hidung yang benar tidak dipatuhi.
- **Selalu gunakan pemantauan tekanan untuk memastikan bahwa pasien mendapatkan level CPAP yang ditentukan.**
- JANGAN gunakan obat yang mengandung Tyloxapol (misalnya Tacholiquin) karena dapat merusak selang dan menyebabkan hilangnya tekanan CPAP.

Pemasangan

- **BC190, BC191, BC192**

Lihat petunjuk Sistem Bubble CPAP F&P sebelum memasang Alat Penghubung Bayi.

Jika menggunakan adaptor, lihat petunjuk pemasangan dari produsen sirkuit sebelum memasang Alat Penghubung Bayi.

- Lihat gambar 1-15 untuk pemasangan yang benar.
- Untuk ukuran produk yang benar, lihat tabel di halaman terakhir.
- Alat pelepas tekanan maksimum HARUS digunakan. Pengaturan pelepas tekanan harus sesuai untuk CPAP bayi.

Pemeriksaan Sebelum Pengoperasian

- Bila tidak menggunakan lubang pemantauan tekanan pada selang hidung, penutupnya harus ditutup.
- Periksa apakah semua sambungan sirkuit sudah erat atau belum sebelum digunakan dan setelah disesuaikan.

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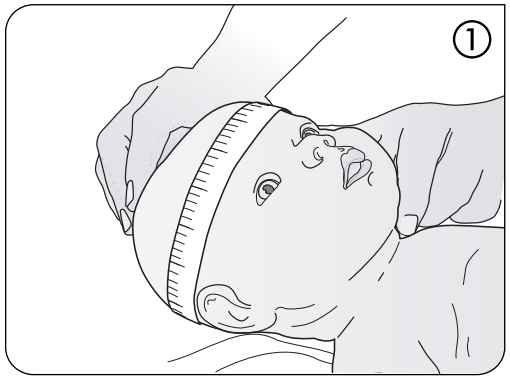
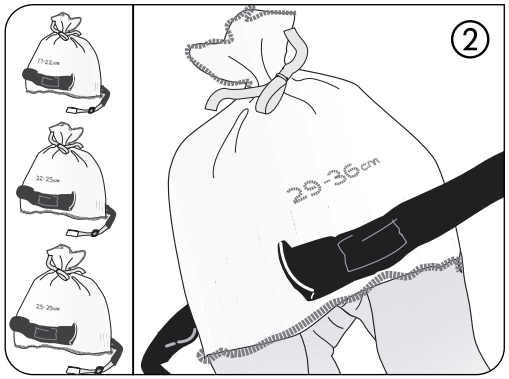
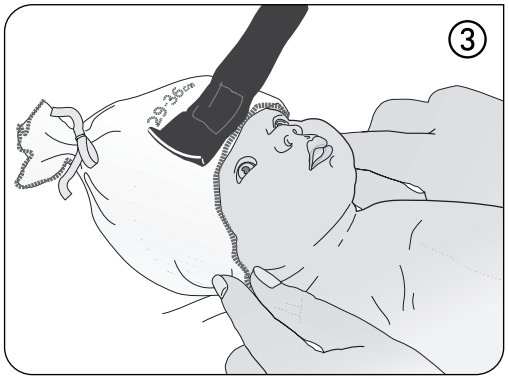
Petunjuk Bagi Pengguna Alat Penghubung Bayi FlexiTrunk™



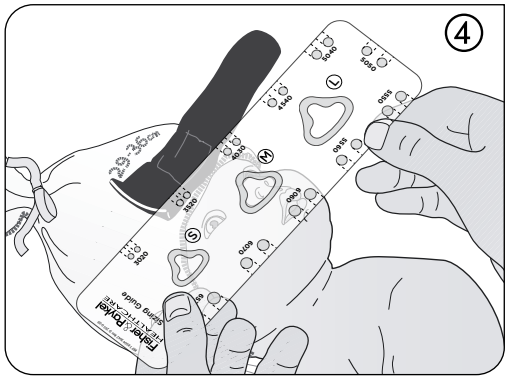
- Ukurlah lingkar kepala bayi dalam sentimeter.



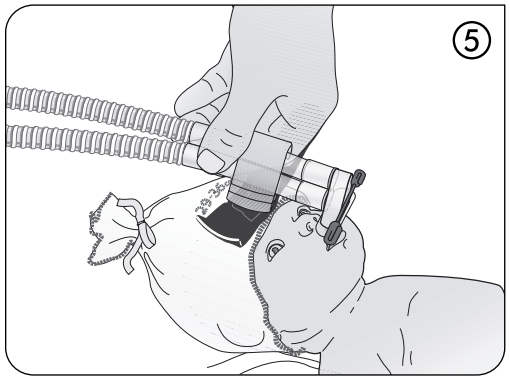
- Pilih ukuran topi yang tepat. Topinya harus pas dikenakan.
- Pertama-tama, regangkan topinya dengan tangan Anda agar mudah memakaikannya.



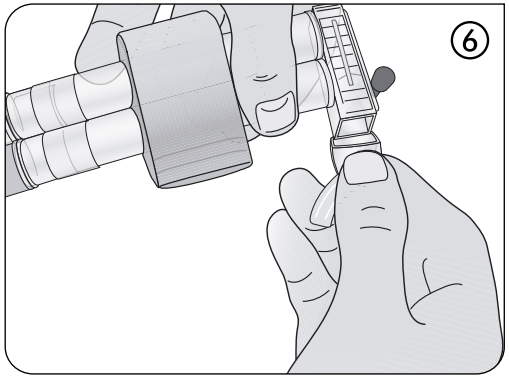
- Masukkan topi pada kepala bayi dalam posisi sepenuhnya menutupi telinga, dan ujung belakang topi berada di pangkal leher. Ujung depan topi harus tepat berada di atas alis atau pada alis.



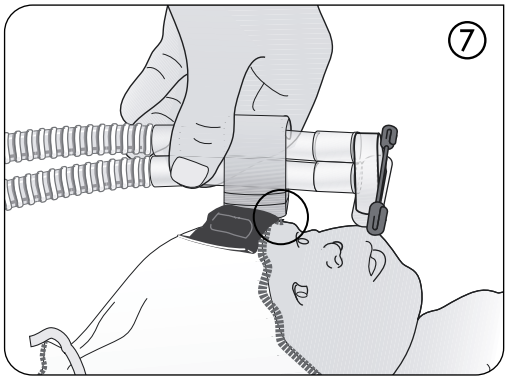
- Gunakan panduan ukuran untuk memilih prong atau masker yang sesuai.
- Prong harus mengisi kedua lubang hidung sepenuhnya tanpa meregangkan kulit. Gunakan ukuran yang sebesar mungkin.
- Maskernya tidak boleh menyentuh ujung hidung, septum, atau mata.



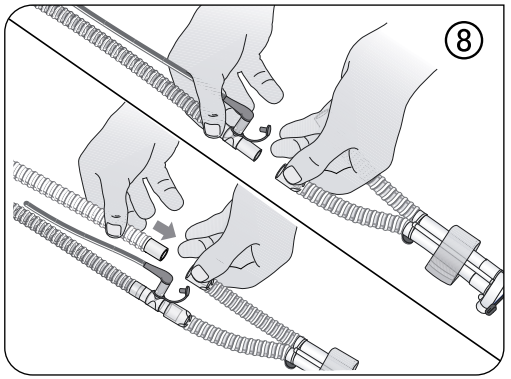
- Pilih panjang selang hidung yang tepat. Gunakan ukuran yang sependek mungkin.
- Selang bening tidak boleh melebihi dahi bayi.
- Panduan berikut ini dapat digunakan:
  50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg,
  100 mm > 2,5 kg



- Hubungkan prong atau masker ke selang hidung dengan memastikan sudah masuk sepenuhnya.
- Bila menggunakan prong: remas bagian samping prong dengan kuat untuk mengekspos alurnya. Mulai dari satu ujung, kemudian masukkan alur prong ke dalam selang hidung. Dorong ujungnya ke dalam dengan kuat.



- Lepaskan strip yang bisa dilepas sebagaimana diperlukan untuk menyesuaikan sudut selang hidung guna mengoptimalkan segelnya.
- JANGAN membuang strip yang bisa dilepas ini karena mungkin diperlukan saat menggunakan nasal prong dan masker hidung secara bergantian.



- Pasang sirkuitnya ke selang hidung dalam salah satu orientasi.
- Lihat petunjuk produsen sirkuit untuk rincian lebih lanjut.
- Catatan: Lepas FlexiTrunk™ secara lembut dengan memutar konektornya. JANGAN menarik dengan kuat, karena bisa merusak selang.
- **Tangani dengan hati-hati.**

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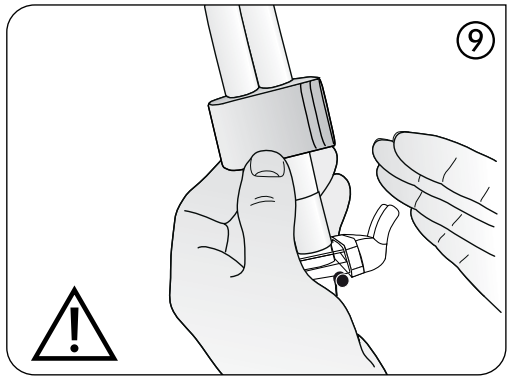
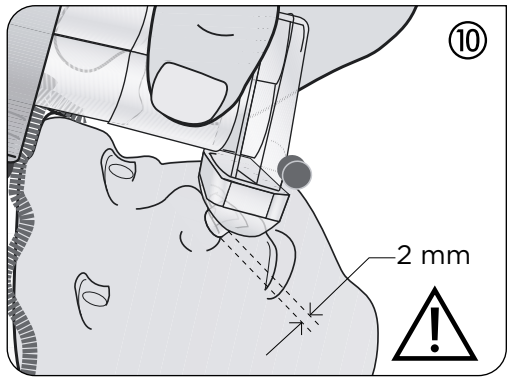
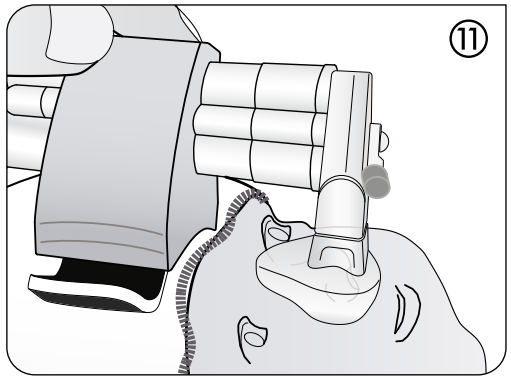
Petunjuk Bagi Pengguna Alat Penghubung Bayi FlexiTrunk™



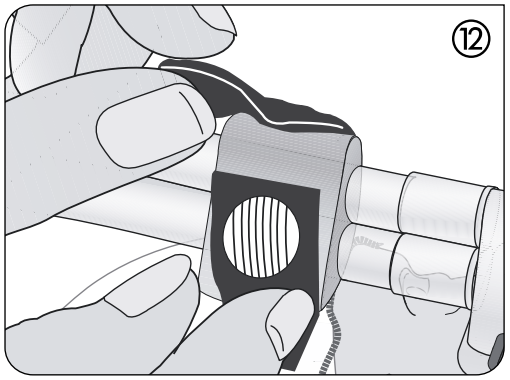
- Atur aliran gas pada level tingkat yang ditentukan.
- Nyalakan pelembap udara. Lihat petunjuk produsen.
- ⚠ Letakkan tangan di dekat nasal prong atau masker hidung untuk memastikan adanya aliran gas.



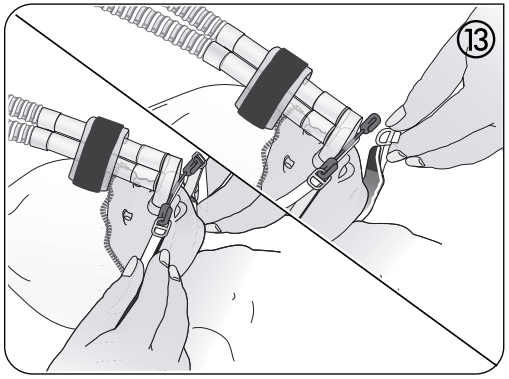
- **Bila menggunakan prong:** Bersihkan kotoran hidung sebelum memasukkan nasal prong.
- ⚠ Pastikan nasal prong ditempatkan setidaknya 2 mm (0,08 inci) dari septum untuk menghindari nekrosis tekanan. Sesuaikan bila perlu.
- Sebaiknya periksa integritas septum setiap jam.



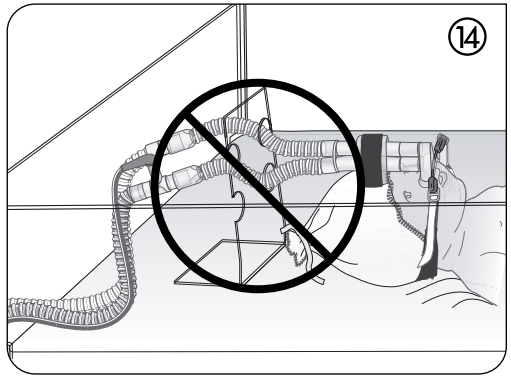
- **Bila menggunakan masker:** Hubungkan ke pasien dengan menempatkan masker di sekitar hidung. Masker harus terpasang dengan nyaman di sekitar hidung pasien. Masker tidak boleh menutup lubang hidung atau menyentuh septum dan tidak boleh menutupi bibir atau di atas mata.



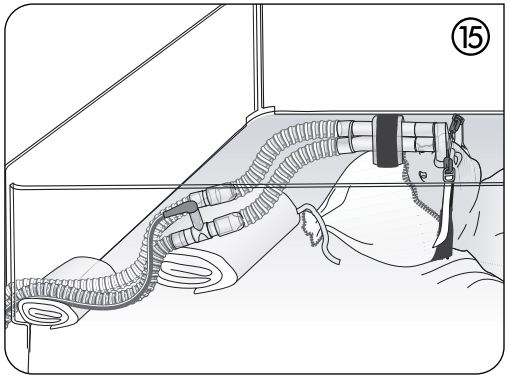
- Tentukan tinggi balok busa dengan membubuhkan atau melepas strip yang dapat dilepas. Pemasangan dengan masker mungkin perlu menambahkan strip agar dapat menentukan posisi dengan benar.
- Letakkan tali di atas balok busa dan kencangkan agar menahan selang di tempatnya dengan kuat.



- Kaitkan klip dari tali samping topi ke penggeser.
- Tarik kedua tali secara bersamaan untuk ditempatkan di tengah.
- Pasanglah tab velcro bundar pada tali biru topi.
- Gunakan sesedikit mungkin ketegangan untuk mempertahankan level CPAP yang ditentukan dan stabilitas Alat Penghubung Bayi.



- JANGAN menggunakan alat seperti penyangga (angel frame), pohon Natal atau alat serupa karena bisa menusuk selang FlexiTrunk™ dan menyebabkan hilangnya tekanan.



- Pastikan berat sirkuit ditopang dengan lembut untuk mengurangi ketegangan pada selang hidung. Sebaiknya gunakan bantal atau handuk yang dilipat. Selang FlexiTrunk™ harus dapat bergerak bebas agar kepala bayi dapat bergerak tanpa batasan.
- Sirkuitnya harus selalu lebih rendah dari selang hidung untuk meminimalkan kondensasi pada bayi.

- Sering periksa pasien untuk mengetahui tanda kemerahan, luka atau iritasi akibat tekanan yang mungkin terjadi akibat penggunaan nasal prong atau masker hidung dalam waktu lama. Sebaiknya lakukan pemeriksaan setiap jam.
- Bergantian menggunakan antara nasal prong dan masker hidung dapat mengurangi risiko iritasi. Sebaiknya gunakan bergantian setiap 4 sampai 6 jam.
- Posisi masker harus disesuaikan agar dapat benar-benar pas dan meminimalkan kebocoran. Jika masih terjadi kebocoran berlebihan, alirannya dapat ditambah untuk mengimbangi. Laju aliran maksimum yang diperbolehkan adalah 15 L/mnt.
- Periksa kondensasi secara rutin dan keringkan bila perlu.

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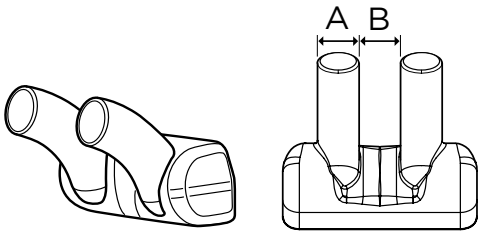
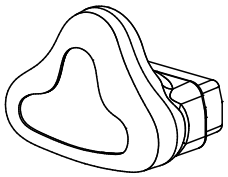
Petunjuk Bagi Pengguna Alat Penghubung Bayi FlexiTrunk™

NASAL PRONG BAYI



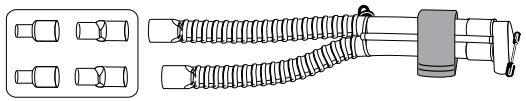
Kode Produk	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MASKER HIDUNG BAYI



Kode Produk	Ukuran
BC800	S
BC801	M
BC802	L
BC803	XL

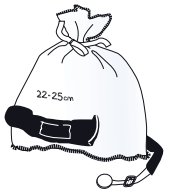
SELANG HIDUNG BAYI



Seri BC19x

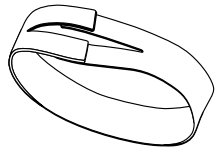
Kode Produk	Ukuran
BC190	50 mm
BC191	70 mm
BC192	100 mm

TOPI BAYI



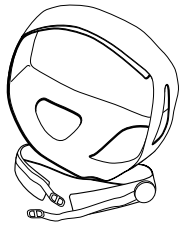
Kode Produk	Ukuran
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

TALI DAGU BAYI



Kode Produk	Ukuran
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

PELINDUNG KEPALA BAYI



Kode Produk	Ukuran
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ Istruzioni d'uso per interfaccia neonato

it

Uso previsto

L'interfaccia neonato F&P è progettata per erogare ventilazione a pressione positiva non invasiva a un paziente che respira spontaneamente con un peso massimo di 10 kg in un ospedale o struttura ospedaliera in cui il paziente sia adeguatamente monitorato da staff medico esperto.

Specifiche del prodotto

BC190 **BC191** **BC192**	L'interfaccia neonato F&P è stata progettata per il collegamento al sistema CPAP Fisher & Paykel Healthcare Bubble. Gli adattatori consentono il collegamento a circuiti CPAP di altri produttori con connettori da 7,8 o 10 mm.
Flusso di ingresso massimo	15 L/min
Pressione operativa massima consentita	15 cmH_2O

Per dettagli su dimensioni e componenti, fare riferimento all'ultima pagina.

Controindicazioni

- Respirazione non spontanea
- Anomalie congenite o malformazioni in cui le cannule binasali o le maschere nasali siano controindicate (ad es. atresia delle coane).
- Anomalie congenite o malformazioni in cui le terapie a pressione positiva siano controindicate (ad es. ernia diaframmatica e fistula tracheoesofagea).
- Trauma nasale/grave deformità che potrebbe aggravarsi a causa dell'uso di cannule nasali o maschere nasali.

AVVERTENZE

I componenti dell'interfaccia neonato sono monouso. **Il riutilizzo potrebbe provocare la trasmissione di sostanze infettive, l'interruzione del trattamento, gravi lesioni o il decesso.**

Maneggiare con cautela. Prestare attenzione nel posizionamento o scollegamento dell'interfaccia neonatale. Non strattonare, evitare gli oggetti taglienti e le clip fermatubi. Ogni danneggiamento del tubo può determinare diminuzioni della pressione e richiedere l'immediata sostituzione.

Questo prodotto può essere utilizzato per un tempo massimo di sette giorni.

NON utilizzare se il prodotto o l'imballo risultano danneggiati.

- NON modificare questo prodotto.
- Usare il monitoraggio dell'ossigeno del paziente.
- Il collegamento a sistemi di umidificazione di altri produttori aumenta il rischio di condensa e/o l'erogazione di temperature elevate al paziente.
- Collegare solo dispositivi di monitoraggio della pressione alla porta di monitoraggio della pressione sul tubo nasale.
- I componenti dell'interfaccia neonato vengono forniti clinicamente puliti. Utilizzare metodi idonei per evitare la biocontaminazione durante l'uso e al momento dello smaltimento.
- NON bagnare, lavare, sterilizzare o riutilizzare questo prodotto.
- NON stringere eccessivamente le cinghie.
- NON coprire il viso del neonato con la cuffia, poiché potrebbe verificarsi soffocamento.
- USARE SOLO componenti dell'interfaccia neonato F&P raccomandati; se si utilizzano componenti non approvati, potrebbe verificarsi un posizionamento non corretto della maschera e delle cannule nasali.
- Se non si utilizzano cannule e maschere delle giuste dimensioni o se non vengono posizionate correttamente, potrebbe verificarsi necrosi nasale.
- **Utilizzare sempre il monitoraggio della pressione per verificare che il paziente stia ricevendo il livello CPAP prescritto.**
- NON utilizzare medicinali contenenti Tyloxapol (ad es. Tacholiquin) onde evitare di danneggiare il tubo e indurre una riduzione della pressione CPAP.

Preparazione

- **BC190, BC191, BC192**

Fare riferimento alle istruzioni del sistema Bubble CPAP F&P prima di impostare l'interfaccia neonato.

Se si utilizzano gli adattatori, consultare le istruzioni di impostazione fornite dal produttore del circuito prima di impostare l'interfaccia neonatale.

- Fare riferimento alle illustrazioni 1-15 per l'impostazione corretta.
- Per informazioni sulle giuste dimensioni dei componenti, fare riferimento alle tabelle nell'ultima pagina.
- È NECESSARIO usare un dispositivo di diminuzione della pressione massima. Le impostazioni di diminuzione della pressione devono essere adeguate alla CPAP neonatale.

Controlli prima dell'utilizzo

- Quando la porta di monitoraggio della pressione sui tubi nasali non è in uso, il tappo deve essere chiuso.
- Controllare che tutte le connessioni siano ben strette prima dell'uso e dopo eventuali regolazioni.

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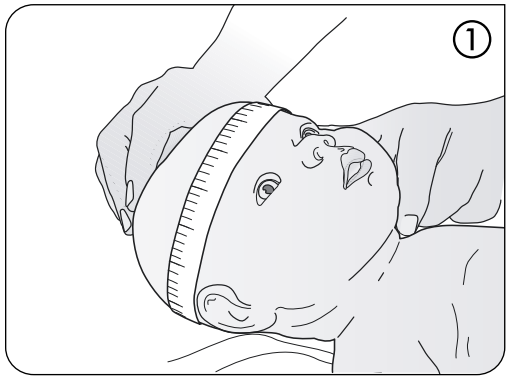
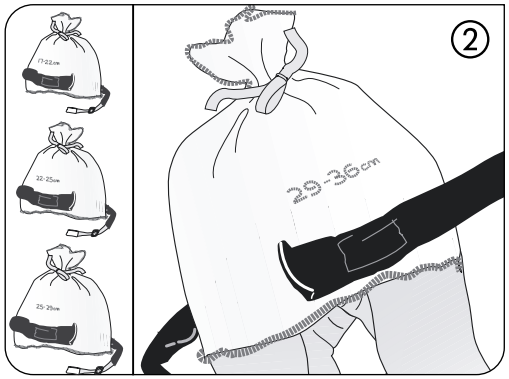
Fisher & Paykel HEALTHCARE

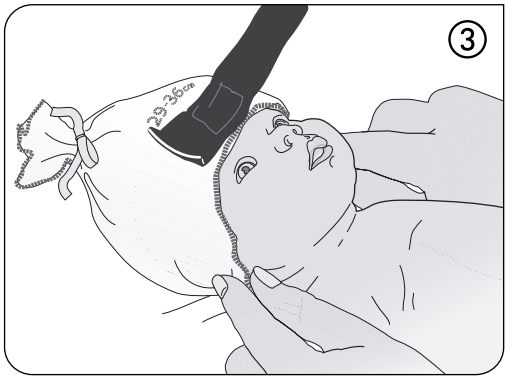
FlexiTrunk™ Istruzioni d'uso per interfaccia neonato



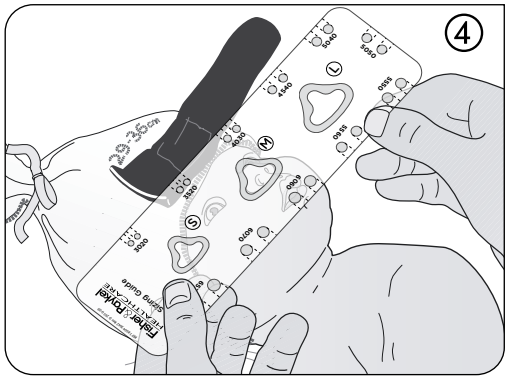
- Misurare la circonferenza cranica del bambino in centimetri.



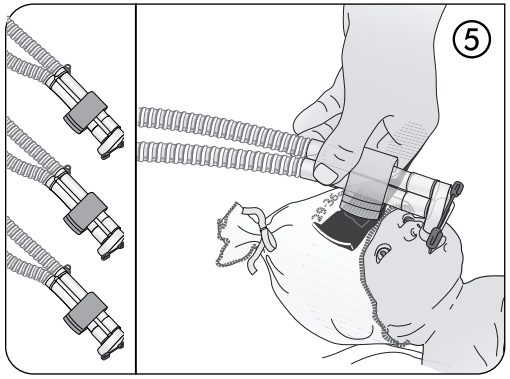
- Scegliere la cuffia di dimensioni corrette. La cuffia deve aderire alla testa.
- Inizialmente, allargare la cuffia con le mani per un facile posizionamento.



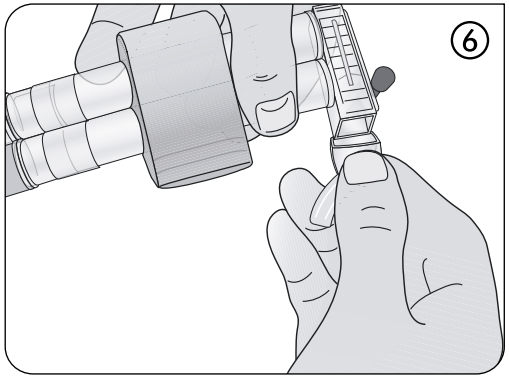
- Far scorrere la cuffia sulla testa del neonato coprendo completamente le orecchie e posizionare il lato posteriore della cuffia alla base del collo. Il lato anteriore della cuffia deve trovarsi direttamente sopra o sulle sopracciglia.



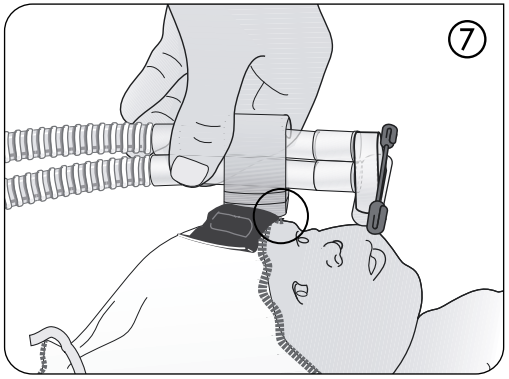
- Scegliere le cannule o la maschera di dimensioni adeguate utilizzando l'apposita guida.
- Le cannule devono poter essere inserite nelle narici completamente senza tirare la pelle. Usare le dimensioni maggiori possibili.
- La maschera non deve toccare il bordo del naso, il setto o gli occhi.



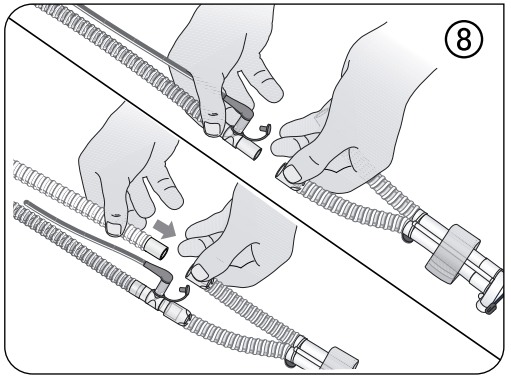
- Scegliere un tubo nasale di lunghezza adeguata. Usare il più corto possibile.
- Il tubo trasparente non deve estendersi sulla fronte del neonato.
- I seguenti valori possono essere usati come guida: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Collegare le cannule o la maschera al tubo nasale verificandone il completo inserimento.
- Se si utilizzano le cannule, schiacciare con fermezza i lati delle stesse per esporre le scanalature. Iniziare da un'estremità e inserire le scanalature della cannula nel tubo nasale. Inserire fermamente l'estremità.



- Rimuovere la gommapiuma a strati per regolare l'angolo del tubo nasale in modo da ottimizzare la tenuta.
- NON disfarsi della gommapiuma a strati perché potrebbe essere necessaria per alternare cannule nasali e maschere.



- Collegare il circuito al tubo nasale in entrambe le direzioni.
- Fare riferimento alle istruzioni fornite dal produttore del circuito per maggiori dettagli.
- Nota: scollegare delicatamente il tubo FlexiTrunk™ ruotando i connettori. NON strappare con forza per non danneggiare il tubo.
- Maneggiare con cautela.

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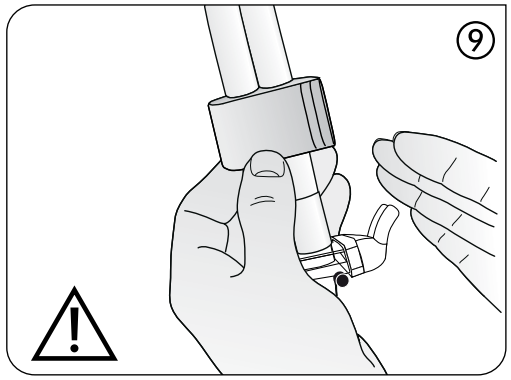
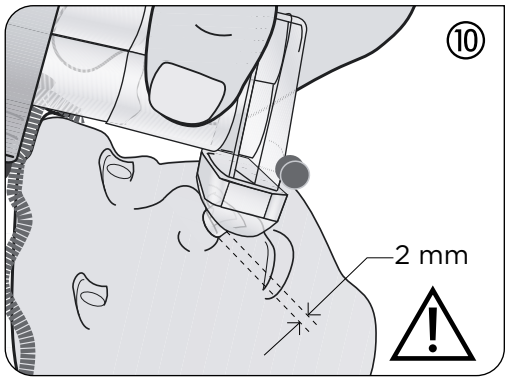
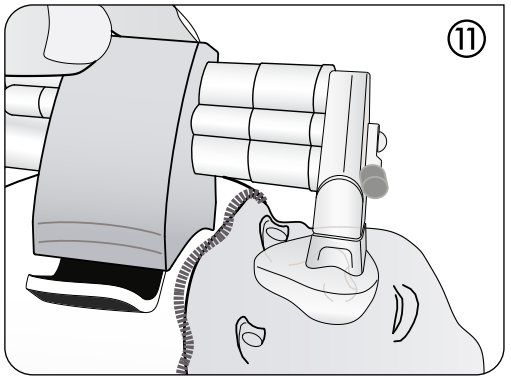
FlexiTrunk™ Istruzioni d’uso per interfaccia neonato



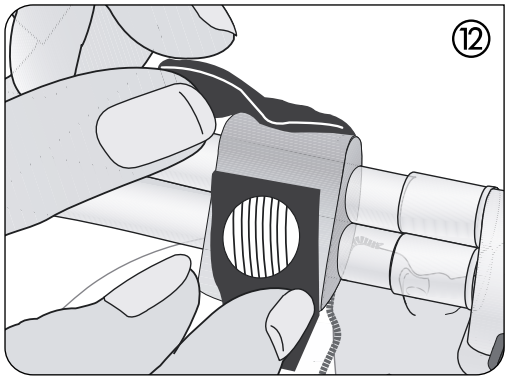
- Impostare il flusso di gas al livello prescritto.
- Accendere l’umidificatore. Fare riferimento alle specifiche del produttore.
- Avvicinare la mano alle cannule nasali o alla maschera per verificare la presenza del flusso di gas.



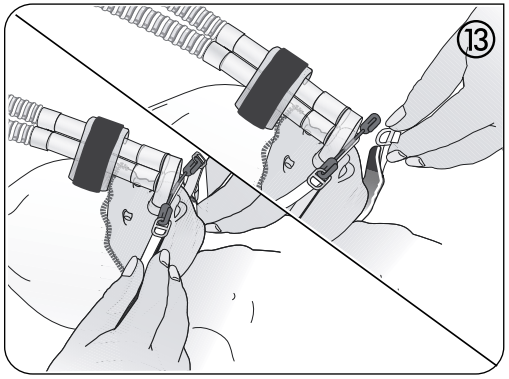
- **Se si utilizzano le cannule:** Pulire le secrezioni nasali prima di inserire le cannule.
- Assicurarsi che le cannule nasali siano posizionate ad almeno 2 mm (0,08 pollici) dal setto nasale per evitare necrosi da pressione. Riposizionarle se necessario.
- Si raccomanda di controllare l’integrità del setto ogni ora.



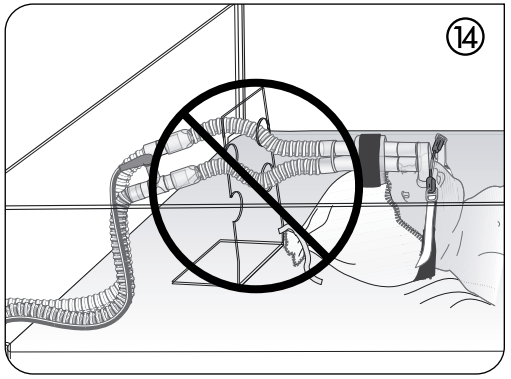
- **Se si utilizza la maschera:** Collegare la maschera al paziente posizionandola attorno al naso. La maschera deve adattarsi comodamente attorno al naso del paziente. Non deve occludere le narici né toccare il setto, inoltre non deve coprire le labbra o gli occhi.



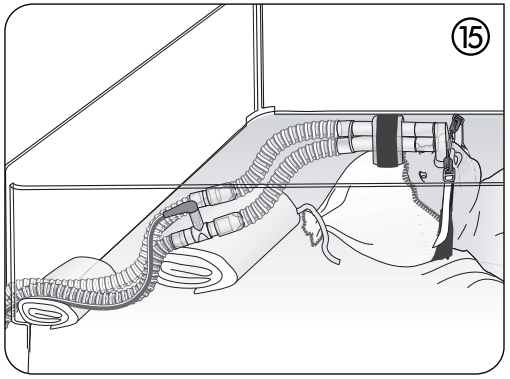
- Stabilire l’altezza del blocco in gommapiuma aggiungendo o rimuovendo gli strati di gommapiuma. Le configurazioni che prevedono l’utilizzo di maschere possono richiedere strati aggiuntivi per ottenere la posizione desiderata.
- Posizionare la cinghia sul blocco in gommapiuma e serrare per tenere il tubo saldamente in posizione.



- Agganciare le clip dalle fasce laterali della cuffia alla guida di scorrimento “glider”
- Tirare entrambe le cinghie contemporaneamente per ottenere un posizionamento centrale.
- Attaccare le fascette in velcro rotonde alla cinghia blu della cuffia.
- Applicare la tensione minore possibile per mantenere il livello di CPAP prescritto e la stabilità dell’interfaccia neonatale.



- NON utilizzare strutture ad angelo, alberi di natale o dispositivi simili, poiché potrebbero forare il tubo FlexiTrunk™ causando perdite di pressione.



- Verificare che il peso del circuito sia sostenuto agevolmente onde ridurre la tensione sul tubo nasale. Si raccomanda l’uso di un cuscino o un asciugamano ripiegato. Il tubo FlexiTrunk™ deve potersi muovere liberamente per consentire al bimbo di muovere il capo senza impedimenti.
- Il circuito deve essere tenuto al di sotto del livello del tubo nasale per ridurre al minimo la condensa che arriva al neonato.

Controlli durante il funzionamento

- Controllare frequentemente il paziente per verificare l’eventuale comparsa di arrossamento, fastidio o irritazione da pressione che potrebbero essere causati da un uso prolungato di cannule o maschera. Si raccomanda di effettuare dei controlli ogni ora.
- L’uso alternato di maschera e cannule può ridurre il rischio di irritazione. Si consiglia di alternare maschere e cannule ogni 4-6 ore.
- Regolare il posizionamento della maschera per adattarla al meglio e ridurre al minimo le perdite. In presenza di perdite eccessive, è possibile compensare aumentando il flusso. La portata di flusso massima consentita è 15 L/min.
- Controllare la condensa regolarmente e asciugare se necessario.

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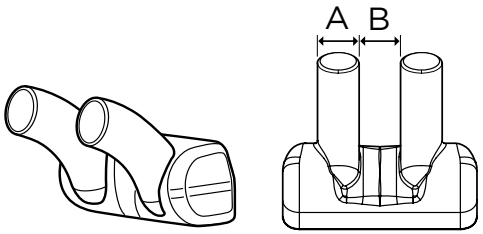
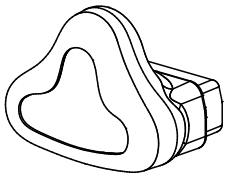
FlexiTrunk™ Istruzioni d'uso per interfaccia neonato

CANNULE NASALI NEONATALE

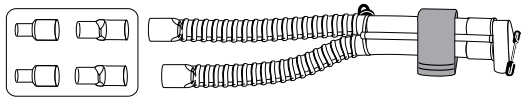


Codice prodotto	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MASCHERA NASALE NEONATALE



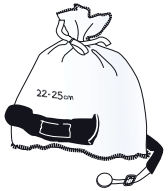
Codice prodotto	Dimensioni
BC800	Piccola
BC801	Media
BC802	Grande
BC803	Extra Grande



Serie BC19x

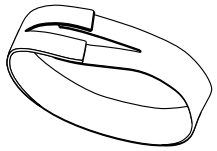
Codice prodotto	Dimensioni
BC190	50 mm
BC191	70 mm
BC192	100 mm

CUFFIA NEONATALE



Codice prodotto	Dimensioni
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

FASCIA SOTTOMENTO NEONATO



Codice prodotto	Dimensioni
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

FASCIA NUCALE NEONATO

Codice prodotto	Dimensioni
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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F&P FlexiTrunk™ 小児インタフェース取扱い説明書

ja

使用目的

F&P小児インタフェースは、病院またはクリニック環境下で、訓練を受けた医療従事者によって適切な監視下におかれた、自発呼吸をする体重10 kgまでの小児に、非侵襲的気道内陽圧換気を提供するために設計されています。

製品仕様

BC190 **BC191** **BC192**	F&P小児インタフェースは Fisher & Paykel Healthcare バブル CPAP システムに接続するよう設計されています。 アダプターを使用すると、他の製造メーカーの CPAP 回路に 7.8 または 10 mm コネクターで接続できます。
最大入力流量	15 L/min
最大許容動作圧力	15 cmH_2O

寸法と部品に関しては、最後のページを参照してください。

禁忌

- 非自発呼吸
- 両鼻腔プロングまたは鼻腔マスクが禁忌事項とする先天異常または奇形（例えば、後鼻腔閉鎖症）。
- 陽圧治療が禁忌事項とする先天異常または奇形（例えば、横隔膜ヘルニアおよび気管食道フィステル）。
- 鼻腔プロングまたは鼻腔マスクの使用が鼻のケガ・強度な変形を悪化させる可能性がある場合。

警告

② 小児インタフェースの部品は、個別患者のためのみに製造されています。**再利用は、感染性物質の伝播、治療の中断、深刻な傷害、または死亡につながることがあります。**

取扱いに注意してください。小児インターフェイスの配置と接続解除は慎重に行ってください。強い力で引っ張ったり、鋭い物体やチューブホルダーを使用したりすることは避けてください。チューブが破損すると圧力が減少するため、直ちに交換する必要があります。

7 当製品は、最大7日間の使用を目的としています。

製品または梱包に損傷がある場合は使用しないでください。

- 本製品を改造しないでください。
- 患者酸素モニタリングを使用してください。
- 他社製品の加湿システムに接続すると、結露および/または高温の気体が患者に供給されるリスクを増大します。
- 鼻腔チューブ上の圧力監視ポートには圧力監視器だけを接続してください。
- 小児インタフェース部品は洗浄された状態で納品されています。使用中と排気の際に、生物汚染を防ぐための適切な方法を用いてください。
- 当製品を浸けたり、洗浄したり、消毒または再利用したりしないでください。
- 小児ボンネットストラップをきつく締め過ぎないようにしてください。
- 窒息の危険があるため、小児の顔面を小児ボンネットで覆わないでください。
- 推奨された F&P 小児インターフェース 部品のみを使用してください。承認されていない代用品を使用すると、鼻腔プロングやマスクの位置設定が悪くなることがあります。
- 鼻腔プロングとマスクの正しいサイズまたは位置が遵守されていない場合、鼻中隔壊死が生じることがあります。
- **患者が処方されたCPAPレベルを受けていることを確認するために、必ず圧力モニタリングを行ってください。**
- チロキサポール (Tacholiquinなど) を含む薬剤はチューブを損傷し、CPAP圧力の減少につながる恐れがありますので使用しないでください。

セットアップ

- **BC190, BC191, BC192**

小児インタフェースのセットアップの前に、F&P バブルCPAPシステムの説明書を参照して下さい。

アダプターを使用する場合、小児インタフェースのセットアップの前に、回路製造メーカーのセットアップ指示を参照して下さい。

- 正しいセットアップのために図1-15を参照してください。
- 正しい製品の大きさについては、最後のページの表を参照してください。
- 最大圧力解放装置の使用は絶対必要です。圧力解放設定は小児CPAPに適したレベルとする必要がありあます。

動作前の点検事項

- 鼻腔チューブの圧力監視ポートが使用されていない場合は、キャップを閉める必要があります。
- 使用前と設定変更後は毎回、全ての接続部分に漏れがないか点検してください。

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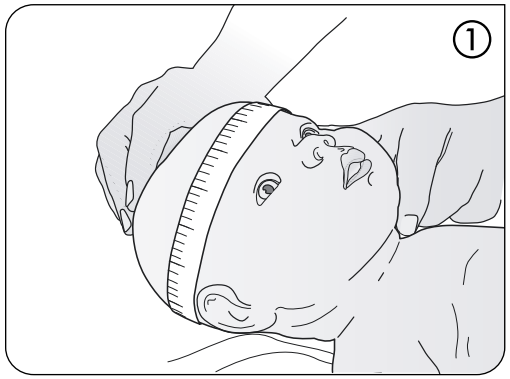
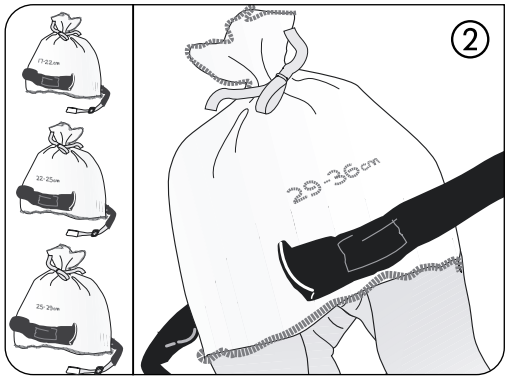
Fisher & Paykel HEALTHCARE

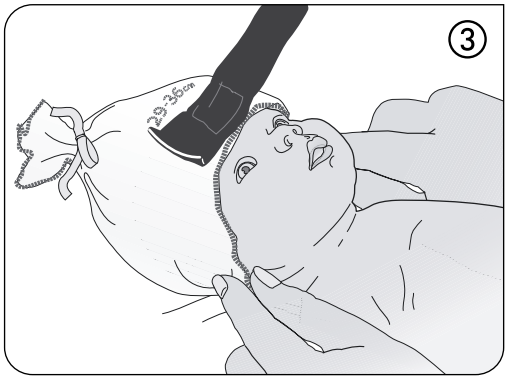
F&P FlexiTrunk™ 小児インタフェース取扱い説明書



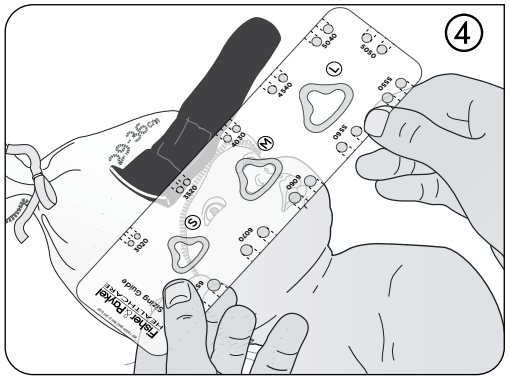
- 小児の頭回りのサイズをセンチメートル単位で測ってください。



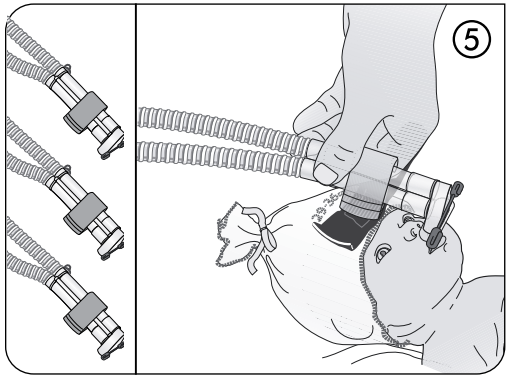
- 正しいサイズのボンネットを選択します。ボンネットは、ぴったり合う必要があります。
- 位置が合うように、最初にボンネットを両手で引張ってください。



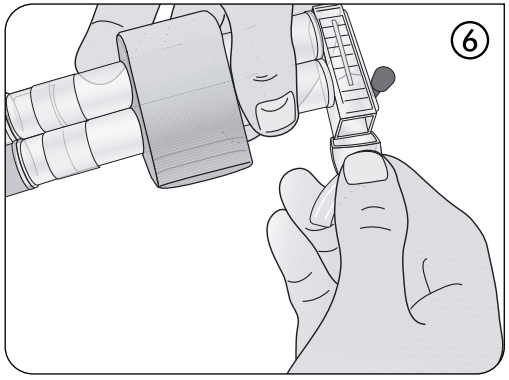
- ボンネットを小児の頭の上に両耳がかぶさるまで、およびボンネットの後ろの端が首の付け根に届くまで着装してください。ボンネットの前の端は、眉毛のわずか上か、あるいは眉毛の上に合わせてください。



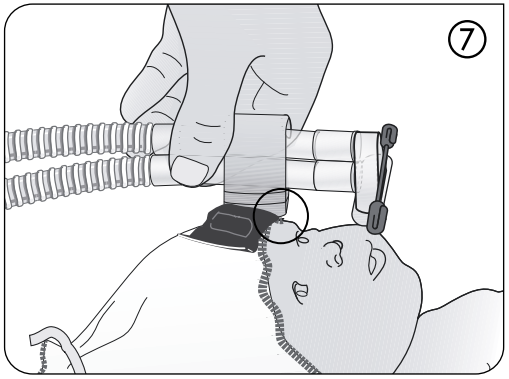
- サイズガイドを使用して適切な鼻腔プロングまたはマスクを選択してください。
- 鼻腔プロングは、皮膚を引張ることなく鼻道を完全に充たす必要があります。可能な限りおおきなサイズを使用してください。
- 鼻腔マスクが鼻の端、中隔膜、または目に触れないようにしてください。



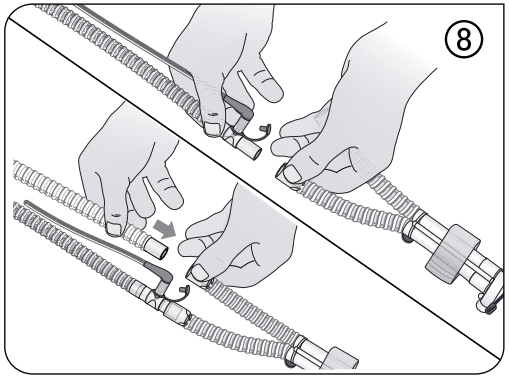
- 正しい長さの鼻腔チューブを選択してください。可能な限り長さが短いものを使用してください。
- 透明なチューブは、小児の額の上まで伸びてはなりません。
- 下記の値をガイドラインにしてください：
  50 mm ≤ 1.5 kg, 70 mm ≤ 2.5 kg,
  100 mm > 2.5 kg



- 鼻腔プロングまたはマスクを鼻腔チューブに完全に接続してください。
- プロングを使用する場合: プロングの両脇から強く押して溝を露出させます。片方の端からプロングの溝を鼻チューブに挿入します。端をしっかり中に押し入れます。



- 必要に応じて切り取り片を外して鼻腔チューブを調節し、適切に密閉してください。
- 鼻プロングをマスクに変更する際に必要となる場合があるため、切り取り片は破棄しないでください。



- 回路を鼻腔チューブにどちらかの向きで取り付けてください。

詳細は回路製造メーカーの説明書を参照してください。

- 備考: コネクタをねじりながらFlexiTrunk™ をゆっくりと外します。無理やり引っ張らないでください。チューブが破損する恐れがあります。

取扱いに注意してください。

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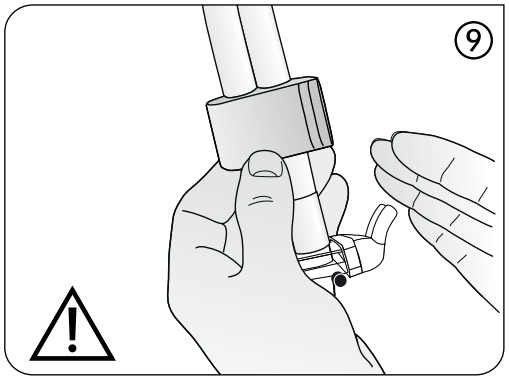
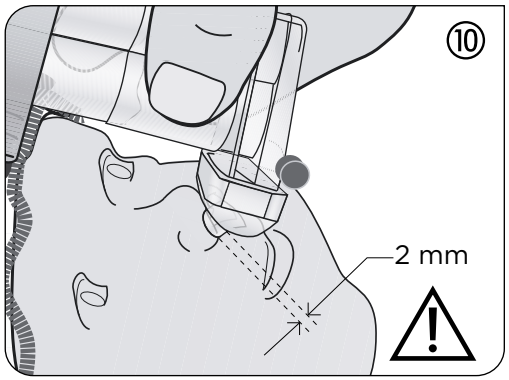
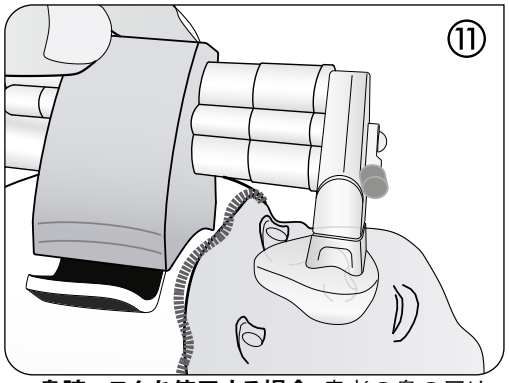
FlexiTrunk™ 小児インタフェース取扱い説明書



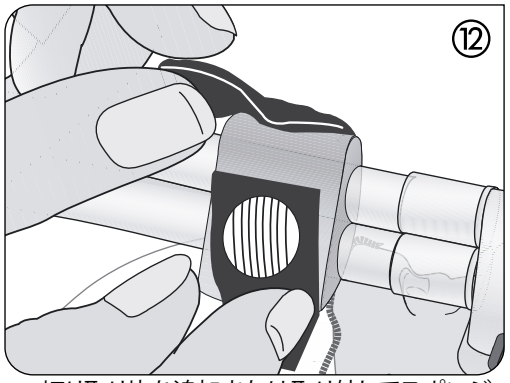
- ガス流量を処方されたレベルに設定します。
- 加湿器のスイッチを入れてください。製造メーカーの説明書を参照して下さい。
- ⚠ 鼻腔プロングまたはマスクの近くに手をやって、空気が流れていることを確認します。



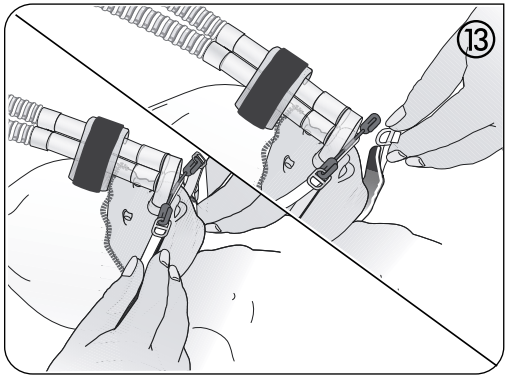
- **鼻腔プロングを使用する場合:** 鼻腔プロングを挿入する前に鼻の分泌物を除去してください。
- ⚠ 圧力による壊死を避けるために、鼻腔プロングが中隔膜から少なくとも2 mm (0.08 インチ) 離れていることを確認してください。必要に応じて調節します。
- 1時間ごとに中隔をチェックすることが推奨されます。



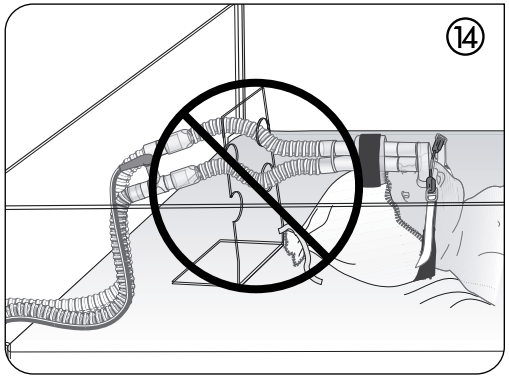
- **鼻腔マスクを使用する場合:** 患者の鼻の周りに鼻腔マスクを装着してください。マスクは患者の鼻の辺りにしっかり装着されるようにします。鼻孔を塞いだり、中隔膜に触れたりしないようにし、目や口にかからないようにします。



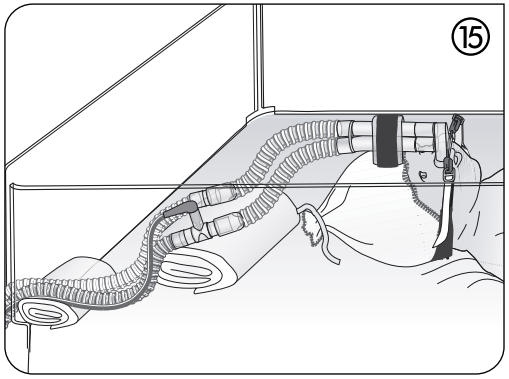
- 切り取り片を追加または取り外してスポンジブロックの高さを設定します。マスクのセットアップ時に、切り取り片を追加して正しい位置にする必要がある場合もあります。
- ベルトを発泡スチロールブロックの上に置き、チューブをその位置にしっかりと固定するためにベルトを締めます。



- ボンネットのサイドベルトのクリップをグライダーに引っ掛けます。
- 両方のベルトを同時に引張って中心に位置決めします。
- 円形のヴェルクロ・タブをボンネットの青色のベルトに固着します。
- 処方されたCPAPレベルと小児インタフェースの安定を維持するために、締め強度はなるべくゆるくしください。



- エンジェルフレーム、クリスマスツリー、それに類する器具は、FlexiTrunk™ チューブを損傷させて圧力を減少させるため使用しないでください。



- 鼻腔チューブにかかる応力を減少するために、呼吸回路の重さが確実に支えられるようにしてください 。枕または折りたたんだタオルの使用を推奨します。小児の頭が制限無く動けるように、FlexiTrunk™チューブ も自由に動かなければなりません。
- 小児のところでの結露を最少限にするために、呼吸回路は鼻腔チューブよりも低い位置に設置してください。

動作中の点検事項

- 鼻腔プロングやマスクを長時間使用することによって患者に充血、褥瘡、炎症の徴候がないか頻繁に確認してください。1時間ごとの点検を推奨します。
- 鼻腔マスクとプロングを交互に使用することで、炎症のリスクを低下させることができます。4〜6時間ごとの交換を推奨します。
- 鼻腔マスクは最もフィットし漏れが少なくなるように装着してください。漏れが多い場合は、フローを上げて補正することもできます。最大許容フロー速度は 15 L/分です。
- 結露を定期的に点検して、必要に応じて流して下さい。

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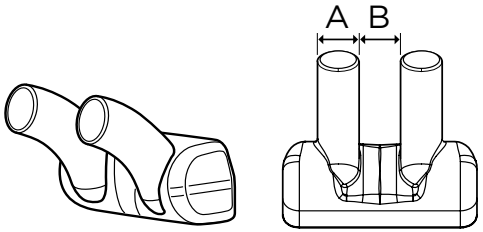
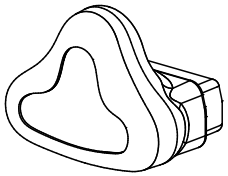
F&P FlexiTrunk™ 小児インタフェース取扱い説明書

小児鼻腔プロング



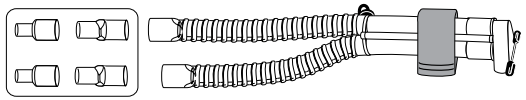
製品コード	A	B
BC3520	3.5 mm	2.0 mm
BC4030	4.0 mm	3.0 mm
BC4540	4.5 mm	4.0 mm
BC5040	5.0 mm	4.0 mm
BC5050	5.0 mm	5.0 mm
BC5550	5.5 mm	5.0 mm
BC5560	5.5 mm	6.0 mm
BC6060	6.0 mm	6.0 mm
BC6070	6.0 mm	7.0 mm

小児用鼻腔マスク



製品コード	サイズ
BC800	小
BC801	中
BC802	大
BC803	特大

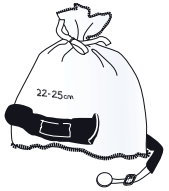
小児鼻腔チューブ



BC19x シリーズ

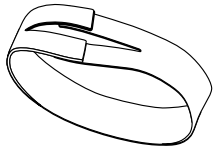
製品コード	サイズ
BC190	50 mm
BC191	70 mm
BC192	100 mm

小児ボンネット



製品コード	サイズ
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

小児顎ストラップ



製品コード	サイズ
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

小児ヘッドギア

製品コード	サイズ
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

CE 0123
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F&P FlexiTrunk™ 유아용 인터페이스 사용자 지침

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용도

F&P 유아용 인터페이스는 환자가 숙달된 의료진에게 적절하게 모니터링되는 병원 또는 임상 시설에서 체중이 최대 10kg인 자발 호흡 환자에게 비침습적 양압 환기요법을 제공하기 위해 고안되었습니다.

제품 사양

BC190 **BC191** **BC192**	F&P 유아용 인터페이스는 Fisher & Paykel Healthcare Bubble CPAP 시스템에 연결하여 사용하도록 고안되었습니다. 7.8 또는 10mm의 커넥터가 부착된 다른 제조업체의 CPAP 회로에 어댑터를 연결할 수 있습니다.
최대 입력 유량	15L/min
최대 허용 작동 압력	15cmH_2O

마지막 페이지에서 크기 및 구성품을 확인하십시오.

금기 사항

- 비자발적 호흡
- 양비강 기구 또는 비강 마스크의 사용이 금지된 선천적 장애 또는 기형(예: 후비공 폐쇄증).
- 양압 요법의 사용이 금지된 선천적 장애 또는 기형(예: 횡경막 탈장 및 기관지-식도 누공).
- 비강 기구 또는 비강 마스크의 사용으로 인해 악화될 수 있는 비강 외상/심각한 기형.

경고

유아용 인터페이스 구성품은 단일 환자에게만 사용되도록 고안되었습니다. **재사용할 경우 감염성 물질이 전달되어 치료가 중단되고 심각한 해를 입히거나 사망에 이르게 할 수 있습니다.**

취급 시 주의하십시오. 유아용 인터페이스의 위치를 조정하거나 분리할 때 주의하십시오. 무리하게 잡아 당기거나, 날카로운 물건을 사용하거나 튜브 홀더를 사용하지 마십시오. 튜브가 손상되면 압력이 손실될 수 있으므로 즉시 교체해야 합니다.

7 이 제품은 최대 7일 동안 사용할 수 있습니다.

제품 또는 포장이 손상된 경우에는 사용하지 마십시오.

- 미 연방법은 이 장치를 의사가 판매하거나 의사의 지시에 따라 판매하도록 제한합니다.
- 이 제품을 개조하지 마십시오.
- 환자 산소 모니터링을 사용하십시오.
- 다른 제조업체의 가습 시스템에 연결하면 고온 가스가 환자에게 전달되고/또는 응축될 위험이 높아집니다.
- 압력 모니터링 장치만 비강 튜브의 압력 모니터링 포트에 연결합니다.
- 유아용 인터페이스 구성품은 깨끗한 상태로 제공됩니다. 사용 중과 폐기 시 생물학적 오염을 예방하기에 적합한 방법을 이용합니다.
- 이 제품을 액체에 담그거나, 세척하거나, 살균하거나 재사용하지 마십시오.
- 유아용 보닛 스트랩을 지나치게 조이지 마십시오.
- 질식될 수 있으므로 유아용 보닛을 얼굴에 감싸지 마십시오.
- 권장 F&P 유아용 인터페이스 구성품만 사용하십시오. 승인되지 않은 대체품 사용으로 인해 비강 기구와 마스크 위치가 잘못될 수 있습니다.
- 프롱과 마스크의 크기나 배치가 올바르지 않을 경우 코중격 괴사가 발생할 수 있습니다.
- **항상 압력 모니터링을 이용하여 환자가 처방된 수준의 CPAP을 받고 있는지 확인하십시오.**
- Tyloxapol(예: Tacholiquin)이 함유된 약물을 사용하지 마십시오. 튜브를 손상시켜 CPAP 압력 손실이 발생할 수 있습니다.

장착

- **BC190, BC191, BC192**

유아용 인터페이스를 장착하기 전 F&P Bubble CPAP 시스템 지침을 참조하십시오.

어댑터를 사용 중인 경우, 유아용 인터페이스를 장착하기 전 회로 제조업체에서 제공한 장착 지침을 참조하십시오.

- 올바른 장착 방법은 그림 1-15를 참조하십시오.
- 올바른 제품 크기를 알아보려면 마지막 페이지의 표를 참조하십시오.
- 최대 압력 이완 장치가 사용되어야 합니다. 압력 이완 설정이 유아용 CPAP에 적합해야 합니다.

사용 전 점검사항

- 비강 튜브의 압력 모니터링 포트를 사용하고 있지 않은 경우 캡을 닫아 두어야 합니다.
- 사용 전과 조정 후에는 모든 회로가 단단하게 연결되어 있는지 확인하십시오.

CE 0123

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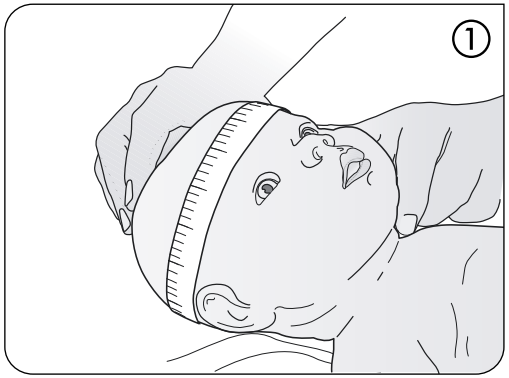
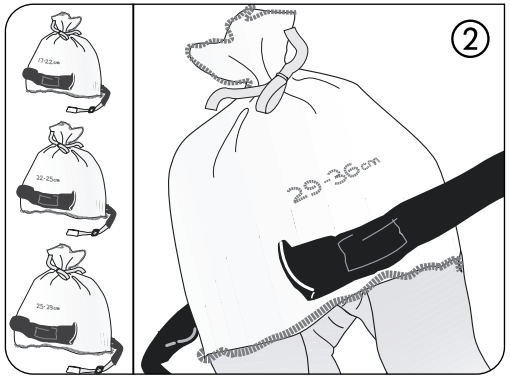
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

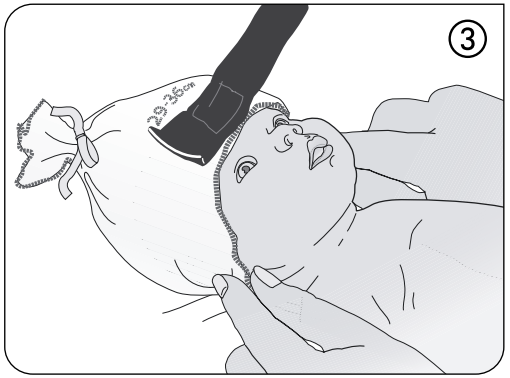
FlexiTrunk™ 유아용 인터페이스 사용자 지침



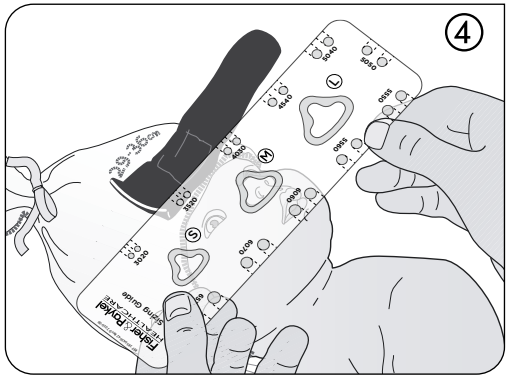
- 머리 둘레(cm)를 측정합니다.



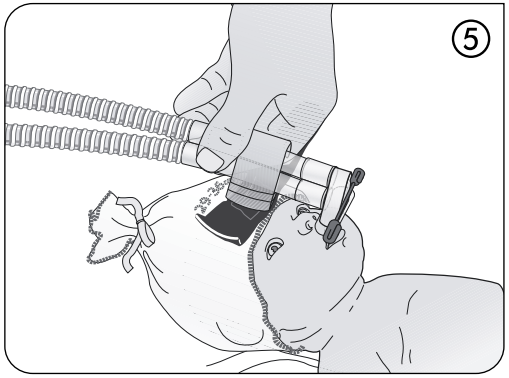
- 올바른 크기의 보닛을 선택합니다. 보닛은 딱 맞아야 합니다.
- 장착이 쉽도록 처음에 손으로 보닛을 늘려 줍니다.



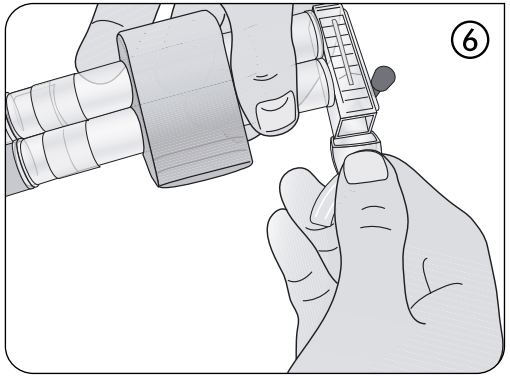
- 보닛을 머리에 씌우고, 귀를 완전히 가린 다음 보닛 뒤쪽 끝부분이 목 밑부분에 오도록 덮어 줍니다. 보닛 앞쪽 끝부분이 눈썹이나 눈썹 바로 위에 와야 합니다.



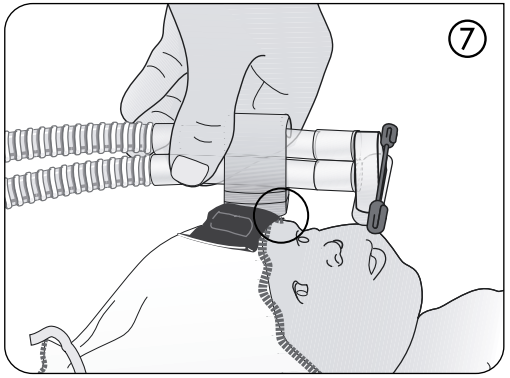
- 크기 가이드를 사용하여 적합한 프롱이나 마스크를 선택합니다.
- 프롱이 피부 당김 없이 콧구멍에 완전히 끼워져야 합니다. 최대한 큰 크기를 사용합니다.
- 마스크가 코, 코중격이나 눈 가장자리에 닿으면 안 됩니다.



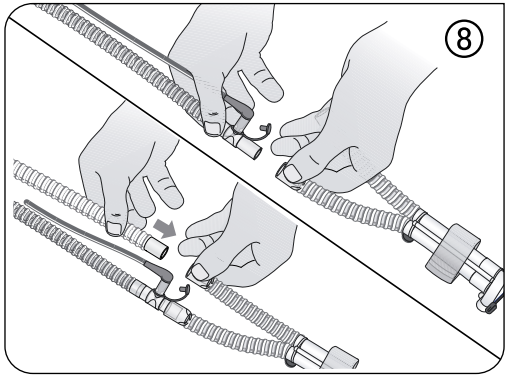
- 올바른 길이의 비강 튜브를 선택합니다. 최대한 길이가 짧은 튜브를 사용합니다.
- 투명한 튜브가 아기의 이마 위에 늘어져 있으면 안 됩니다.
- 다음을 가이드로 사용할 수 있습니다.
  50mm ≤ 1.5kg, 70mm ≤ 2.5kg,
  100mm > 2.5kg



- 프롱이나 마스크를 완전히 끼워진 비강 튜브에 연결합니다.
- 프롱을 사용 중인 경우: 프롱의 측면을 꽉 눌러 홈이 보이게 합니다. 한쪽 끝에서부터 프롱 홈을 비강 튜브에 끼웁니다. 끝을 꽉 누릅니다.



- 제대로 밀착되도록 필요한 만큼 접착식 스트립을 떼내 비강 튜브의 각도를 조절합니다.
- 비강 기구와 마스크를 갈아 끼울 때 필요할 수 있으므로 접착식 스트립을 버리지 마십시오.



- 양쪽 비강 튜브에 회로를 연결합니다.

자세한 정보는 회로 제조업체에서 제공한 지침을 참조하십시오.

- 참고: 커넥터를 가볍게 돌려 FlexiTrunk™를 분리합니다. 힘껏 당기지 마십시오. 튜브가 손상될 수 있습니다.

취급 시 주의하십시오.

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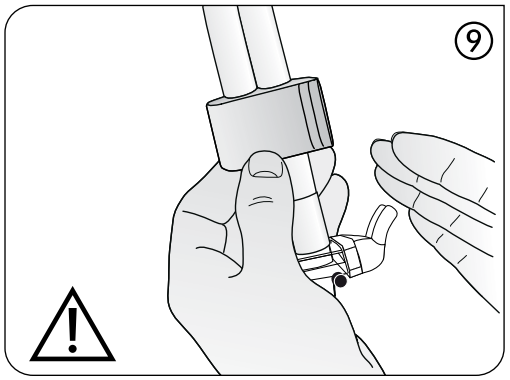
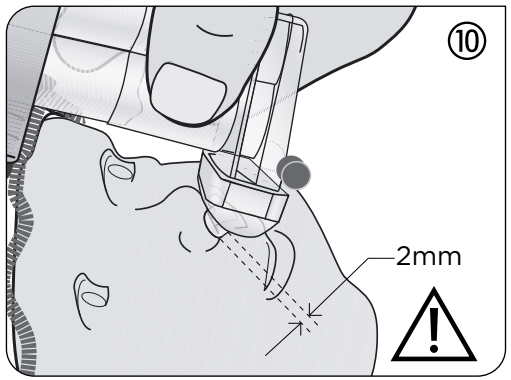
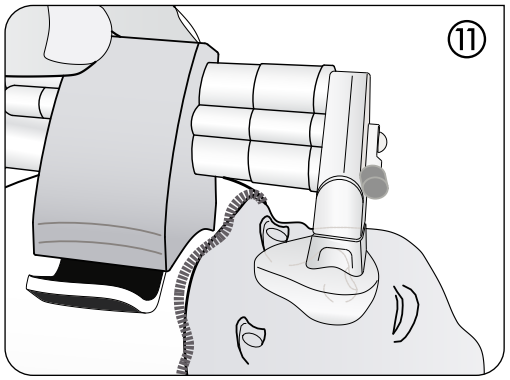
FlexiTrunk™ 유아용 인터페이스 사용자 지침



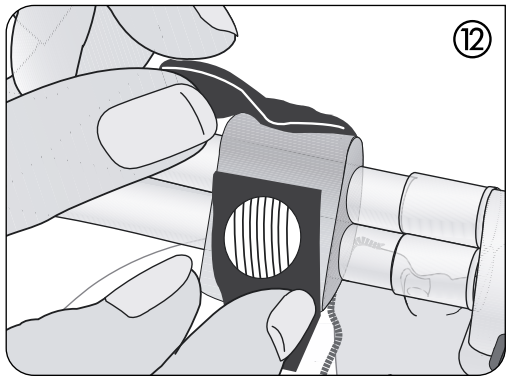
- 처방된 수준으로 가스 유량을 설정합니다. 가습기를 켜십시오. 제조업체의 지침을 참조합니다.
- 비강 기구 또는 마스크 근처에 손을 대고 가스가 흐르는지 확인합니다.



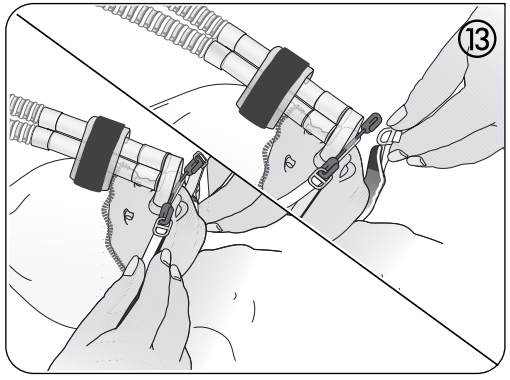
- 프롱을 사용하고 있는 경우: 코 분비물을 제거한 후 비강 기구를 삽입합니다.
- 비강 기구의 위치가 코중격으로부터 최소한 2mm (0.08인치) 인지 확인하여 압박괴사를 방지하십시오. 필요한 만큼 조정하십시오.
- 코중격에 상처가 생겼는지 1시간마다 확인해야 합니다.



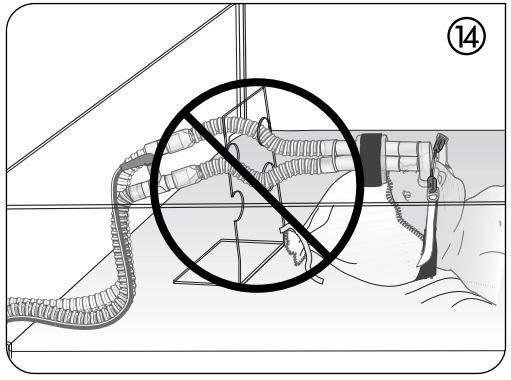
- 마스크를 사용하고 있는 경우: 코 주변에 마스크를 장착하여 환자와 연결합니다. 마스크는 환자의 코 주변에 편안하게 장착되어야 합니다. 콧구멍을 막거나 코중격에 닿으면 안 되고 입이나 눈 위에 위치하면 안 됩니다.



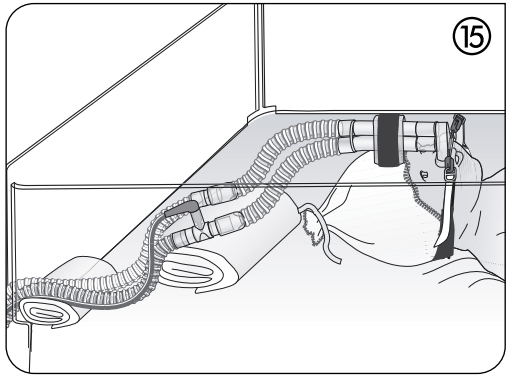
- 접착식 스트립을 추가하거나 제거하여 폼 블럭의 높이를 맞춥니다. 마스크를 씌울 때 올바른 위치에 오도록 스트립을 추가 할 수 있습니다
- 폼 블럭 위에 스트랩을 두고 꽉 조여 튜브가 제자리에 단단히 고정되게 합니다.



- 보닛의 측면 스트랩에서부터 글라이더까지 클립을 걸어 줍니다.
- 가운데에 위치하도록 동시에 두 스트랩을 당깁니다.
- 보닛의 파란색 스트랩에 원형 밸크로 탭을 부착합니다.
- 팽팽함을 최소화하여 처방된 CPAP 수준을 유지하고 유아용 인터페이스가 안정감 있게 장착되도록 합니다.



- 장식용 틀, 크리스마스 트리 또는 이와 유사한 장치를 사용하지 마십시오. FlexiTrunk™ 튜브에 구멍을 내 압력이 손실되게 할 수 있습니다.



- 회로를 완만하게 놓아 무게를 지탱하게 하여 비강 튜브가 팽팽해지지 않도록 합니다. 베개를 놓거나 수건을 접어 놓는 것이 좋습니다. 아기의 머리가 자유롭게 움직일 수 있도록 FlexiTrunk™ 튜브의 동선이 제한되지 않아야 합니다.
- 회로를 비강 튜브 아래쪽에 두어 아기에게 발생하는 응축액을 최소화합니다.

- 늘어난 프롱이나 마스크 사용으로 인해 발생할 수 있는 발적, 욕창 또는 자극 증상이 환자에게 있는지 자주 확인합니다. 1시간마다 확인해야 합니다.
- 마스크와 프롱을 번갈아 사용하면 자극을 줄일 수 있습니다. 4시간에서 6시간마다 교체하는 것이 좋습니다.
- 마스크가 잘 장착되고 누출이 최소화되도록 마스크의 위치를 조정해야 합니다. 과도한 누출이 계속되는 경우, 유량을 늘려 보충할 수 있습니다. 최대 허용 유량이 15L/min입니다.
- 응축액이 있는지 정기적으로 확인하고 필요한 경우 응축액을 빼냅니다.

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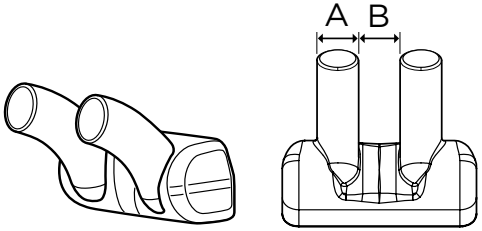
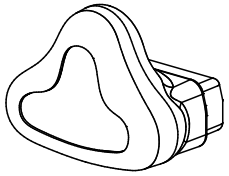
FlexiTrunk™ 유아용 인터페이스 사용자 지침

유아용 비강 기구



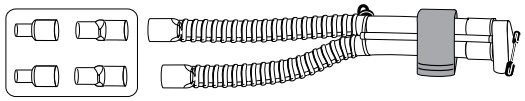
제품 코드	A	B
BC3020	3.0mm	2.0mm
BC3520	3.5mm	2.0mm
BC4030	4.0mm	3.0mm
BC4540	4.5mm	4.0mm
BC5040	5.0mm	4.0mm
BC5050	5.0mm	5.0mm
BC5550	5.5mm	5.0mm
BC5560	5.5mm	6.0mm
BC6060	6.0mm	6.0mm
BC6070	6.0mm	7.0mm
BC6570	6.5mm	7.0mm

유아용 비강 마스크



제품 코드	크기
BC800	S
BC801	M
BC802	L
BC803	XL

유아용 비강 튜브



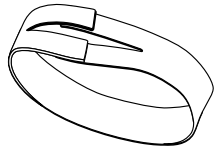
BC19x 시리즈

제품 코드	크기
BC190	50mm
BC191	70mm
BC192	100mm

유아용 보닛

제품 코드	크기
BC300	17–22cm
BC303	22–25cm
BC306	25–29cm
BC309	29–36cm

유아용 턱 스트랩



제품 코드	크기
BC351	20–26cm
BC353	26–32cm
BC355	32–38cm
BC357	38–44cm

유아용 헤드기어

제품 코드	크기
BC325	29–36cm
BC328	35–40cm
BC331	40–45cm

LATEX

CE 0123
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FlexiTrunk™ Gebruikersinstructies bij interface voor baby's

nl

Beoogd gebruik

De F&P interface voor baby's is bestemd voor niet-invasieve beademing met positieve druk bij een spontaan ademende patiënt die maximaal 10 kg weegt, in een ziekenhuis of klinische omgeving waar de patiënt adequaat wordt gecontroleerd door bekwame medische professionals.

Productspecificaties

BC190 **BC191** **BC192**	De F&P interface voor baby's is ontworpen om te worden aangesloten op het Fisher & Paykel Healthcare Bubble CPAP-systeem. De adapters kunnen worden aangesloten op CPAP-circuits van andere fabrikanten met behulp van 7,8 of 10 mm connectors.
Maximumtoevoer	15 L/min
Maximaal toegestane bedrijfsdruk	15 cmH_2O

Raadpleeg de laatste pagina voor afmetingen en onderdelen.

Contra-indicaties

- Niet spontane ademhaling
- Aangeboren afwijkingen of misvormingen waarvoor dubbelzijdige neuscanules of neusmaskers zijn gecontra-indiceerd (bijv. choanale atresie).
- Aangeboren afwijkingen of misvormingen waarvoor positieve druktherapieën zijn gecontra-indiceerd (bijv. hernia diafragmatica en tracheo-oesofageale fistel).
- Nasaal trauma/ernstige vervorming die kan worden verergerd door gebruik van neuscanules of neusmaskers.

WAARSCHUWINGEN

- De onderdelen van de interface voor baby's zijn uitsluitend bestemd voor gebruik bij één patiënt. **Hergebruik kan leiden tot overdracht van besmettelijke stoffen, onderbreking van de behandeling, ernstig letsel of overlijden.**
- **Voorzichtig hanteren.** Wees voorzichtig bij het positioneren of loskoppelen van de interface voor baby's. Trek er niet te hard aan en vermijd scherpe voorwerpen en slanghouders. Beschadiging van de slang kan een drukdaling veroorzaken, in welk geval de slang onmiddellijk moet worden vervangen.
- Dit product is bestemd voor een maximale gebruiksduur van 7 dagen.
- NIET gebruiken als product of verpakking beschadigd is.
- Breng GEEN wijzigingen in dit product aan.
- Sluit de patiënt aan op zuurstofcontroleapparatuur.
- Aansluiting op bevochtigingssystemen van andere fabrikanten verhoogt het risico van afgifte van condens en/of hoge gastemperaturen aan de patiënt.
- Sluit uitsluitend drukcontroleapparatuur aan op de drukcontrolepoort op de neusslang.
- Onderdelen van de interface voor baby's worden schoon aangeleverd. Gebruik geschikte methoden ter voorkoming van biologische besmetting tijdens gebruik en afvoer.
- Dit product NIET onderdompelen, wassen, steriliseren of opnieuw gebruiken.
- Trek de bandjes van de babymuts NIET te strak aan.
- Bedek het gezicht van de baby NIET met het babymutsje, aangezien dit tot verstikking kan leiden.
- GEBRUIK ALLEEN de aanbevolen F&P baby-interface-onderdelen. Bij het gebruik van niet-goedgekeurde alternatieven kan het zijn dat de neuscanules en het masker niet goed passen.
- Septumnecrose kan optreden als de juiste maat of positie van de canule en het masker niet wordt aangehouden.
- **Maak altijd gebruik van drukmonitor om te controleren of de CPAP-druk voor de patiënt is ingesteld op het voorgeschreven niveau.**
- GEEN geneesmiddelen met tyloxapol (zoals Tacholiquin) gebruiken: dat kan de slang beschadigen en resulteren in wegvallen van de CPAP-druk.

Installatie

- **BC190, BC191, BC192**
- Lees voordat u de interface voor baby's gebruiksklaar maakt eerst de handleiding van het F&P Bubble CPAP-systeem.
- Raadpleeg bij gebruik van de adapters de installatie-instructies die door de fabrikant van het circuit worden meegeleverd, alvorens de interface voor baby's te installeren.
- Raadpleeg afbeeldingen 1-15 voor de juiste installatie.
- Raadpleeg de tabellen op de laatste pagina voor de juiste maatvoering van het product.
- Er MOET een maximum drukbegrenzer worden gebruikt. De drukbegrenzingsinstellingen moeten geschikt zijn voor CPAP bij baby's.

Controles vóór behandeling

- Zorg ervoor dat de dop dicht is wanneer de drukpoort op de neusslang niet wordt gebruikt.
- Controleer vóór gebruik en na elke wijziging of alle circuitverbindingen goed vastzitten.

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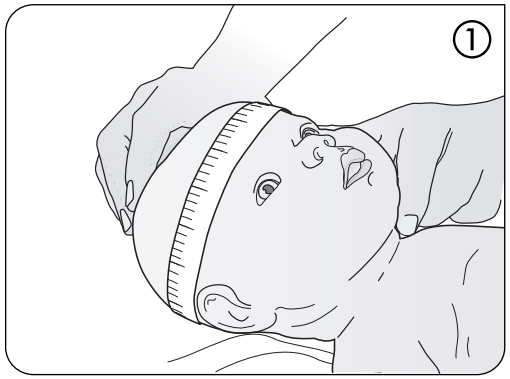
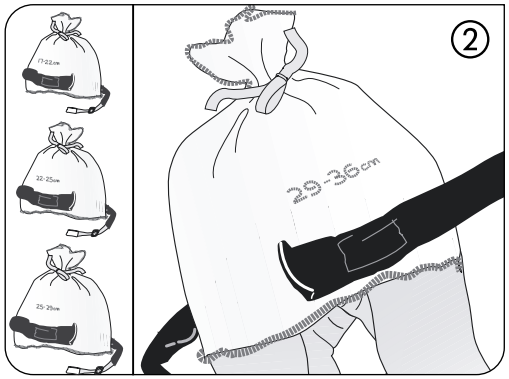
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

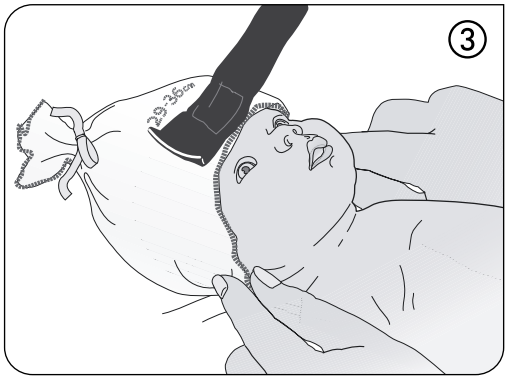
FlexiTrunk™ Gebruikersinstructies bij interface voor baby's



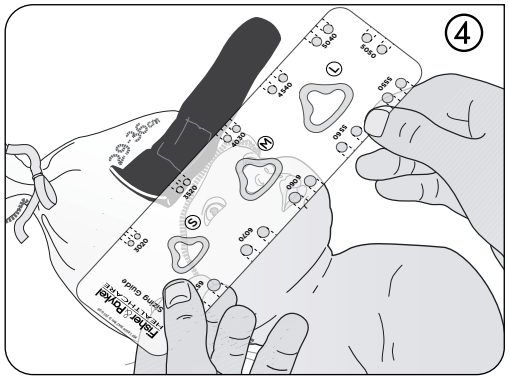
- Meet de omtrek van het hoofd van de baby in centimeters.



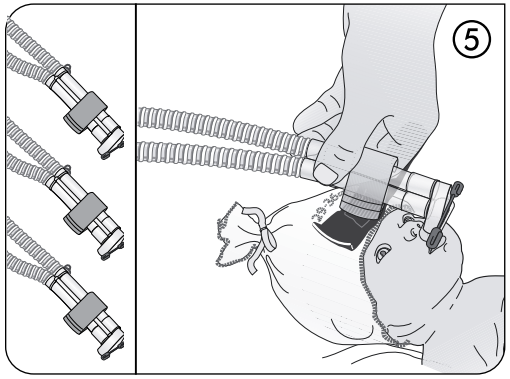
- Kies het mutsje van de juiste afmetingen. Het mutsje dient nauw om het hoofdje te passen.
- Rek het mutsje met uw handen op om het gemakkelijker te kunnen aanbrengen.



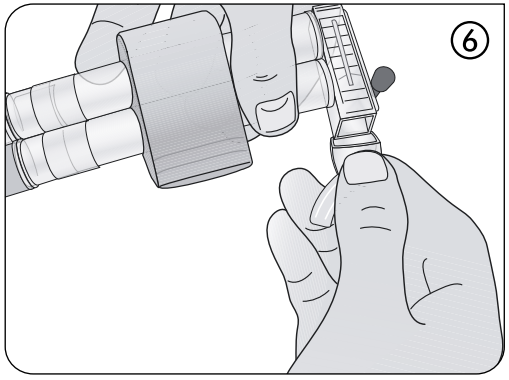
- Schuif het mutsje over het hoofdje van de baby, waarbij de oren volledig worden bedekt en de achterrand van het mutsje zich onder in de nek moet bevinden. De voorrand van het mutsje dient zich net boven, of op de wenkbrauwen te bevinden.



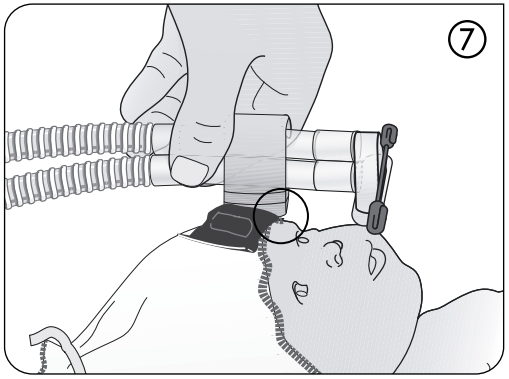
- Gebruik het meethulpmiddel om de juiste neuscanule of het juiste masker te kiezen.
- De canule dient de neusgaten volledig op te vullen zonder deze uit te rekken. Gebruik de grootst mogelijke maat.
- Het masker mag de rand van de neus, het septum of de ogen niet raken.



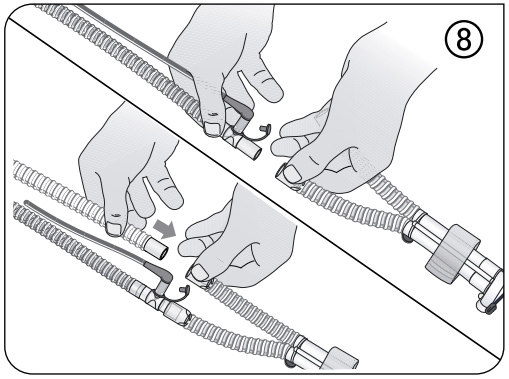
- Bepaal de juiste lengte van de neusslangen. Gebruik de kortst mogelijke neusslang.
- De doorzichtige slang mag niet langer zijn dan het voorhoofd van de baby.
- Als leidraad kan gelden: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Zorg bij het aansluiten van de canule of het masker op de neusslang dat deze goed is aangesloten.
- Bij gebruik van canules: knijp stevig in de zijkanten van de neuscanules om de groeven bloot te leggen. Begin aan de ene kant en steek de groeven van de neuscanules in de neusslang. Druk het uiteinde stevig aan.



- Verwijder zo nodig de strips om de hoek van de neusslang aan te passen voor optimalisering van de afdichting.
- Gooi de strips NIET weg: ze kunnen nodig zijn als wordt afgewisseld tussen gebruik van neuscanules en een neusmasker.



- Sluit het circuit op een van beide wijzen op de neusslang aan.
- Raadpleeg de instructies van de fabrikant van het circuit voor meer informatie.
- Opmerking: Haal de FlexiTrunk™ voorzichtig los door aan de connectors te draaien. Trek er NIET met geweld aan: dat kan de slang beschadigen.
- Voorzichtig hanteren.

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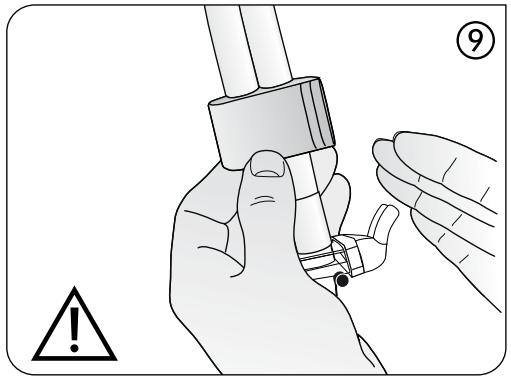
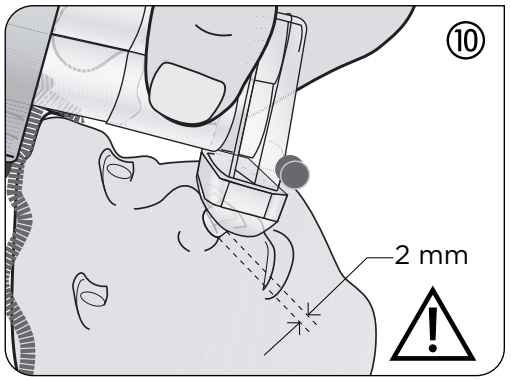
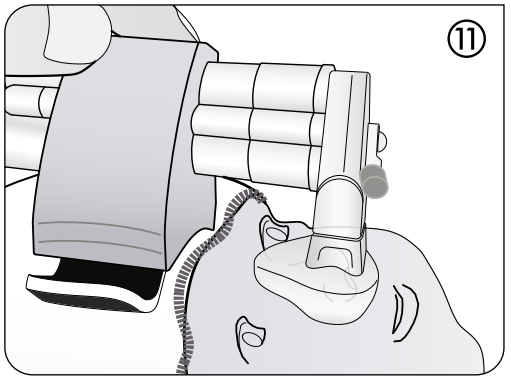
FlexiTrunk™ Gebruikersinstructies bij interface voor baby's



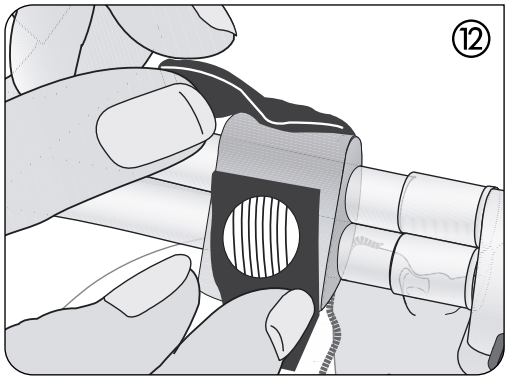
- Stel de gasstroom in op het voorgeschreven niveau.
- Zet de bevochtiger aan. Raadpleeg de instructies van de fabrikant.
- Plaats uw hand vlakbij de uitgangen van de neuscanules of het masker om er zeker van te zijn dat er lucht uit stroomt.



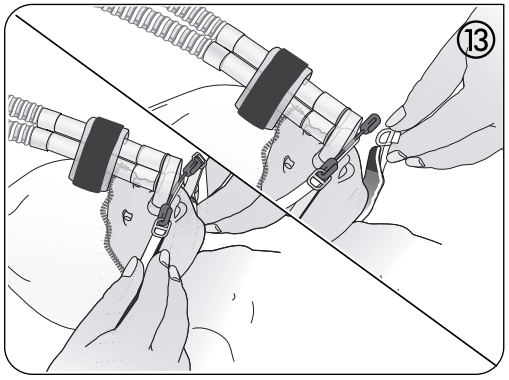
- **Bij gebruik van canules:** Verwijder eventuele afscheidingen uit de neus voordat de neuscanule wordt ingebracht.
- Zorg dat de neuscanules ten minste 2 mm (0,08 inch) van het neustussenschot af zitten om druknecrose te voorkomen. Stel dit zo nodig bij.
- Controle van de toestand van het septum om het uur wordt aanbevolen.



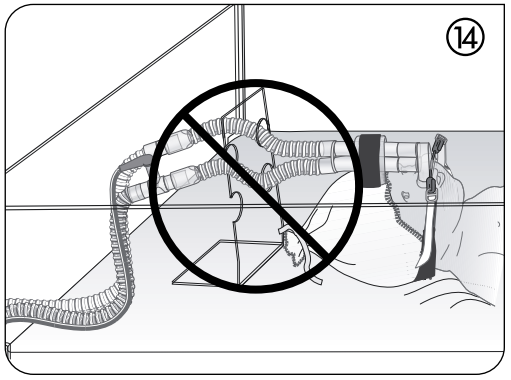
- **Bij gebruik van een masker:** Het masker op de patiënt aansluiten door het om de neus te plaatsen. Het masker dient comfortabel om de neus van de patiënt te zitten. Het mag de neusgaten niet afsluiten en het septum niet raken. Ook mag het niet over de lip of de ogen liggen.



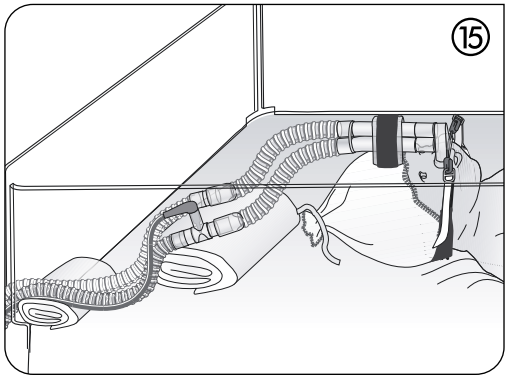
- Bepaal de hoogte van het schuimblokje door strips toe te voegen of te verwijderen. Bij installaties met een masker kunnen voor het verkrijgen van de juiste positie meer strips nodig zijn.
- Leid het bandje over het schuimblokje en maak het vast om de slangen goed op hun plaats te houden.



- Haak de beugeltjes aan de zijbandjes van het mutsje aan de glijder.
- Trek gelijktijdig aan beide riempjes voor een centrale positionering.
- Bevestig de ronde klittenband lipjes aan de blauwe band van het mutsje.
- Gebruik zo min mogelijk spanning om het voorgeschreven CPAP-niveau en de stabiliteit van de interface voor baby's te handhaven.



- GEEN verstelbare slangenhouders gebruiken: deze kunnen de FlexiTrunk™ slang doorboren en drukverlies veroorzaken.



- Zorg dat het gewicht van het circuit wordt ondersteund om spanning op de neusslang te verminderen. Gebruik van een kussen of opgevouwen handdoek wordt hiervoor aanbevolen. De FlexiTrunk™ slang moet vrij kunnen bewegen zodat het hoofdje van de baby ook vrij kan bewegen.
- Het circuit dient zich lager te bevinden dan de neusslangen zodat bij de baby zo min mogelijk condensaat ontstaat.

Controles tijdens behandeling

- Controleer de patiënt regelmatig op tekenen van roodheid, drukplekken of irritatie die het gevolg kunnen zijn van langdurig gebruik van de canule of het masker. Controle om het uur wordt aanbevolen.
- Het risico van irritatie kan worden verminderd door afwisselend gebruik van een masker en canule. Afwisseling om de 4 à 6 uur wordt aanbevolen.
- Het masker moet zo worden bijgesteld dat de beste pasvorm en een minimale lekkage worden verkregen. Als er nog steeds overmatige lekkage optreedt, kan de flow worden verhoogd om hiervoor te compenseren. De maximaal toegestane flowsnelheid is 15 L/min.
- Controleer regelmatig op condensaat en verwijder dit voor zover nodig.

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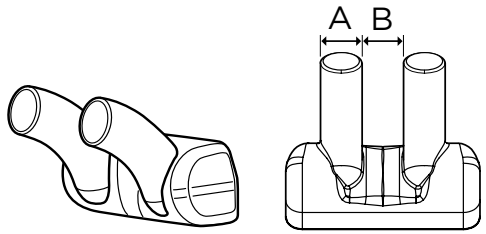
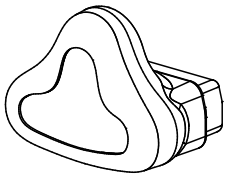
FlexiTrunk™ Gebruikersinstructies bij interface voor baby's

NEUSCANULE VOOR BABY'S



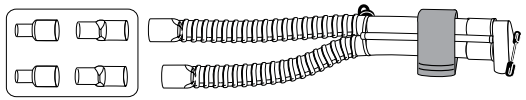
Productcode	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

NEUSMASKER VOOR BABY'S



Productcode	Maat
BC800	Small
BC801	Medium
BC802	Large
BC803	Extra Large

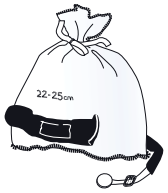
NEUSSLANG VOOR BABY'S



BC19x-serie

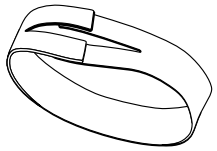
Productcode	Maat
BC190	50 mm
BC191	70 mm
BC192	100 mm

BABYMUTSJE



Productcode	Maat
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

KINBAND VOOR BABY'S



Productcode	Maat
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

HOOFDBAND VOOR BABY'S

Productcode	Maat
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ Instruções para o utilizador da interface para bebé

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Finalidade

A Interface para bebé da F&P foi concebida para administrar ventilação por pressão positiva não invasiva a um paciente com respiração espontânea que pese até 10 kgs num ambiente hospitalar ou clínico, no qual o paciente é monitorizado adequadamente por uma equipa médica com a devida formação.

Especificações do produto

BC190 **BC191** **BC192**	A Interface para bebé da F&P foi concebida para ser ligada ao Sistema CPAP de bolhas da Fisher & Paykel Healthcare. Os adaptadores permitem a ligação a circuitos de CPAP de outros fabricantes com conectores de 7,8 ou 10 mm.
Fluxo de entrada máximo	15 L/min
Pressão de funcionamento máxima permitida	15 cmH_2O

Por favor, consulte a última página para obter as dimensões e componentes.

Contra-indicações

- Respiração não espontânea
- Anomalias ou malformações congénitas nas quais está contra-indicada a utilização de tubos nasais ou de máscara nasal (por exemplo, atresia coanal).
- Anomalias ou malformações congénitas nas quais está contra-indicada a utilização de terapêutica por pressão positiva (por exemplo, hérnia diafragmática e fístula traqueo-esofágica).
- Traumatismo/deformação grave a nível nasal que possa ser exacerbada pela utilização de tubos nasais ou máscara nasal.

ADVERTÊNCIAS

- Os componentes da Interface para bebé foram concebidos para utilização exclusiva num único paciente. **A reutilização pode resultar na transmissão de substâncias infecciosas, interrupção do tratamento, lesões graves ou morte.**
- **Manusear com cuidado.** Use de precaução quando posicionar ou desligar a Interface para Recém-Nascido. Evite forças de puxar excessivas, objectos cortantes e suportes de tubulação. Danos na tubulação podem provocar perda de pressão e requerem uma substituição imediata.
- Este produto está destinado a ser utilizado por um período máximo de 7 dias.
- NÃO utilize se o produto ou a embalagem estiverem danificados.
- NÃO modifique este produto.
- Utilize uma monitorização do oxigénio do paciente.
- A ligação a sistemas de humidificação de outros fabricantes aumenta o risco de formação de condensação e/ou de administração de gás a temperaturas elevadas ao paciente.
- Ligue apenas dispositivos de monitorização da pressão à porta de monitorização da pressão da tubulação nasal.
- Os componentes da Interface para bebé são fornecidos limpos. Utilize métodos adequados para prevenir a biocontaminação durante a utilização e no momento da eliminação.
- NÃO coloque de molho, lave, esterilize ou volte a utilizar este produto.
- Não aperte demasiado as correias do gorro para bebé.
- NÃO tape a face do bebé com o Gorro infantil, dado que pode ocorrer sufocação.
- UTILIZE APENAS os componentes da Interface para bebé da F&P recomendados, dado que pode ocorrer um posicionamento incorrecto dos tubos nasais e da máscara caso se utilizem substitutos não aprovados.
- Pode ocorrer necrose septal caso não se respeite o dimensionamento ou colocação correctos dos tubos e da máscara.
- **Utilize sempre monitorização da pressão para confirmar se o paciente está a receber o nível de CPAP prescrito.**
- NÃO use fármacos contendo Tyloxapol (tal como Tacholiquin), dado que tal pode danificar a tubulação e originar uma perda da pressão CPAP.

Instalação

- **BC190, BC191, BC192**
- Consulte as instruções do Sistema CPAP de bolhas da F&P antes de instalar a Interface para bebé.
- Caso sejam utilizados os adaptadores, consulte as instruções de instalação fornecidas pelo fabricante do circuito antes de instalar a Interface para bebé.
- Consulte as ilustrações 1-15 para uma instalação correcta.
- Para o dimensionamento correcto do produto, consulte os quadros na última página.
- DEVE ser utilizado um dispositivo de alivio da pressão máxima. As configurações de alivio da pressão devem ser adequadas para CPAP em bebés.

Verificações a serem feitas antes do funcionamento

- Quando a porta de monitorização da pressão na tubulação nasal não estiver a ser utilizada, a tampa deve estar fechada.
- Verifique se todas as ligações do circuito estão bem apertadas antes do uso e depois de efectuar qualquer ajuste.

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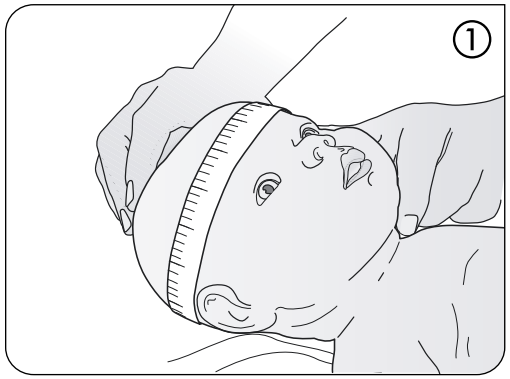
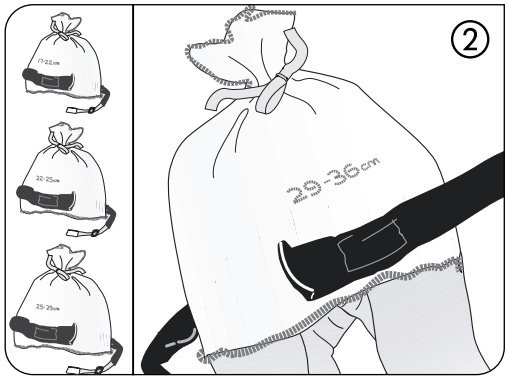
Fisher & Paykel HEALTHCARE

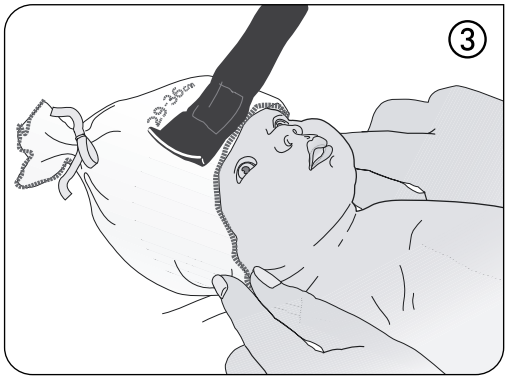
FlexiTrunk™ Instruções para o utilizador da interface para bebé



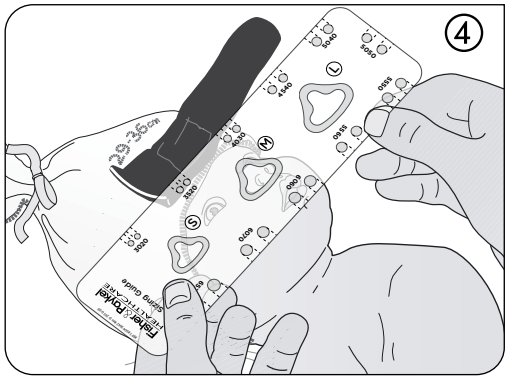
- Meça a circunferência cefálica do bebé em centímetros.



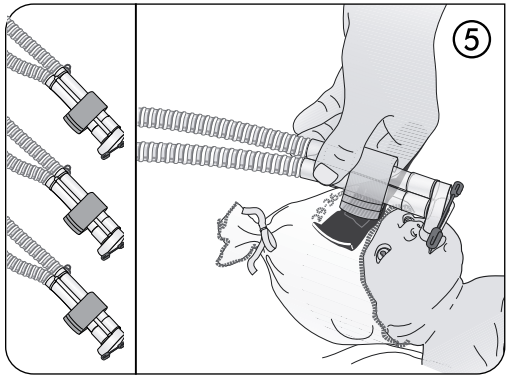
- Escolha o gorro do tamanho correcto. O gorro deve ficar justo.
- Estique inicialmente o gorro com as suas mãos para maior facilidade de colocação.



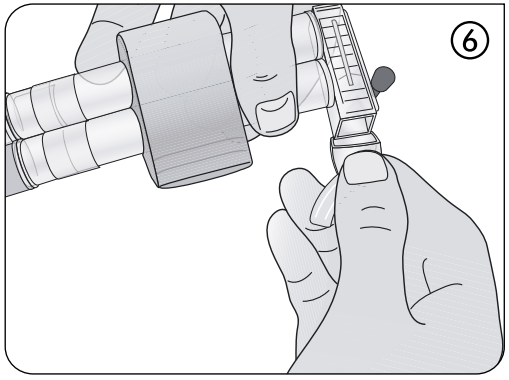
- Coloque o gorro na cabeça do bebé, cobrindo completamente as orelhas e com a extremidade traseira do gorro posicionada na base do pescoço. A extremidade dianteira do gorro deve ficar imediatamente acima das sobrancelhas ou a este nível.



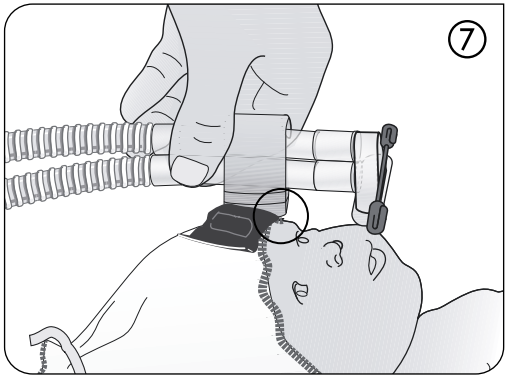
- Utilize o guia de dimensionamento para escolher os tubos nasais ou máscara adequados.
- Os tubos nasais devem encher completamente as narinas, sem esticar a pele. Utilize o maior tamanho possível.
- A máscara não deve tocar nas margens do nariz, septo ou olhos.



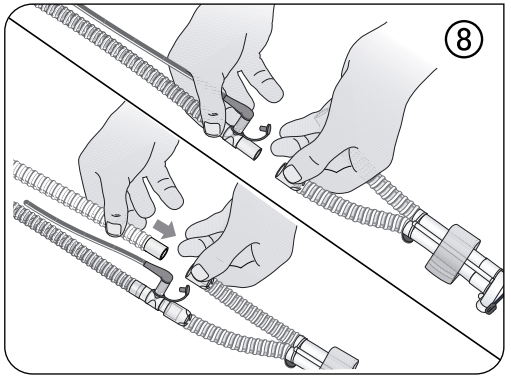
- Escolha o comprimento correcto da tubulação nasal. Utilize o comprimento mais curto possível.
- A tubulação transparente não se deve estender por cima da testa do bebé.
- Como orientação, pode utilizar-se o seguinte:
  50 mm para bebé ≤ 1,5 kg,
  70 mm para bebé ≤ 2,5 kg,
  100 mm para bebé > 2,5 kg



- Ligue os tubos nasais ou a máscara à tubulação nasal certificando-se que esta está inserida na totalidade.
- Se estiver a utilizar tubos nasais: aperte as faces laterais dos tubos nasais com firmeza para expor as ranhuras. Comece por uma extremidade e insira as ranhuras do prong na tubulação nasal. Empurre a extremidade com firmeza.



- Retire as tiras destacáveis conforme necessário para ajustar o ângulo da tubulação visando optimizar a vedação.
- NÃO descarte as tiras destacáveis dado que estas podem ser necessárias quando alternar entre os tubos nasais e as máscaras.



- Prenda o circuito à tubulação nasal em qualquer das orientações.
- Consulte as instruções fornecidas pelo fabricante do circuito para obter mais pormenores.
- Nota: Remova o FlexiTrunk™ suavemente rodando os conectores. NÃO puxe forçando, dado que tal pode danificar a tubulação.
- **Manusear com cuidado.**

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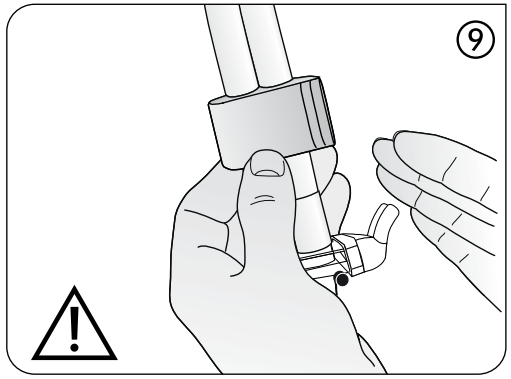
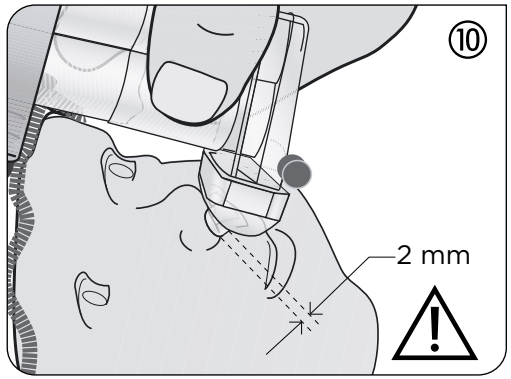
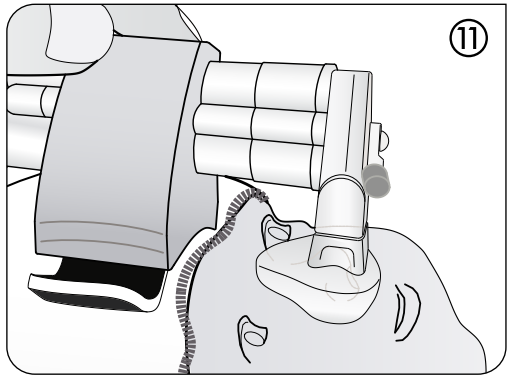
FlexiTrunk™ Instruções para o utilizador da interface para bebé



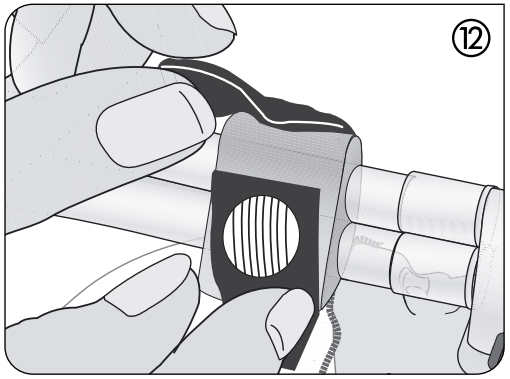
- Defina o fluxo de gás para o nível prescrito.
- Ligue o humidificador. Consulte as instruções do fabricante.
- ⚠ Coloque a mão próximo dos tubos nasais ou máscara para garantir que está presente fluxo de gás.



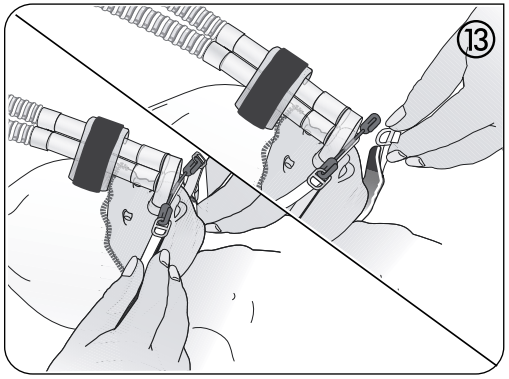
- **Se estiver a utilizar prongs:** Limpe as secreções nasais antes de introduzir os tubos nasais.
- ⚠ Assegure-se que os tubos nasais estão posicionados a, pelo menos, 2mm (0,08 polegadas) de distância do septo para evitar necrose por pressão. Ajuste conforme necessário.
- Recomendam-se verificações da integridade do septo de hora a hora.



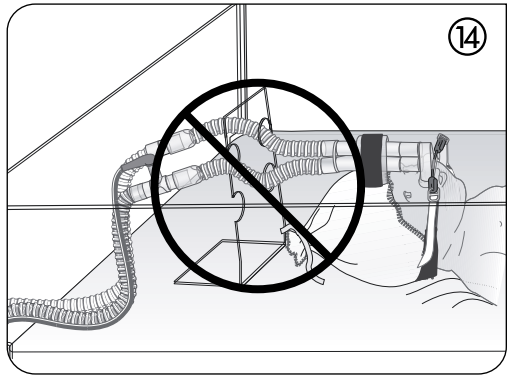
- **Se estiver a utilizar a máscara:** Coloque no doente ajustando a máscara em torno do nariz. A máscara deve assentar confortavelmente à volta do nariz do doente. Não deve ocluir as narinas nem tocar no septo e não deve estar por cima do lábio nem dos olhos.



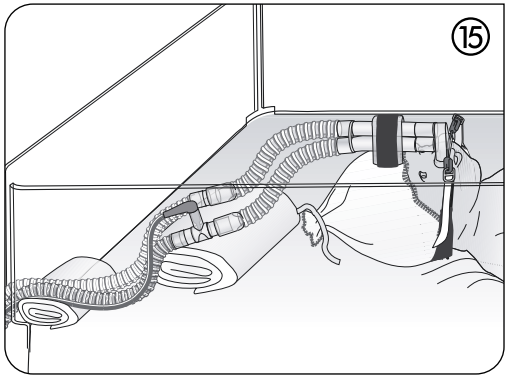
- Defina a altura da almofada de espuma adicionando ou removendo tiras destacáveis. As configurações com máscaras podem necessitar da adição de tiras para um posicionamento adequado.
- Coloque a correia por cima da almofada de espuma e aperte para segurar firmemente a tubulação no lugar.



- Engate os clipes das correias laterais do gorro ao deslizador.
- Puxe as duas correias simultaneamente para obter um posicionamento central.
- Fixe as abas redondas de velcro à correia azul do gorro.
- Utilize a menor tensão possível para manter o nível de CPAP prescrito e a estabilidade da Interface para bebé.



- NÃO utilize armações em forma de auréola, árvore de Natal ou dispositivos semelhantes, dado que estes podem furar a tubulação FlexiTrunk™ e provocar perda de pressão.



- Assegure-se que o peso do circuito fica apoiado suavemente, para reduzir a tensão na tubulação nasal. Recomenda-se uma almofada ou toalha dobrada. A tubulação FlexiTrunk™ deve ter um movimento livre para permitir que a cabeça do bebé se mova sem limitações.
- O circuito deve ser mantido abaixo do nível da tubulação nasal para minimizar a formação de condensação para o bebé.

Verificações a serem feitas durante o funcionamento

- Verifique o doente com frequência para detectar sinais de rubor, escaras de pressão ou irritação que possam ser originados por um uso prolongado da máscara ou dos tubos nasais. Recomendam-se verificações de hora a hora.
- Alternar entre a máscara e os tubos nasais pode reduzir o risco de irritação. Recomenda-se alternar a cada 4 a 6 horas.
- O posicionamento da máscara deve ser ajustado para o melhor ajuste e fugas mínimas. Caso esteja presente uma fuga excessiva, o fluxo pode ser aumentado para compensar. A taxa de fluxo máxima permitida é de 15 L/min.
- Verifique regularmente a existência de condensação e escoe conforme necessário.

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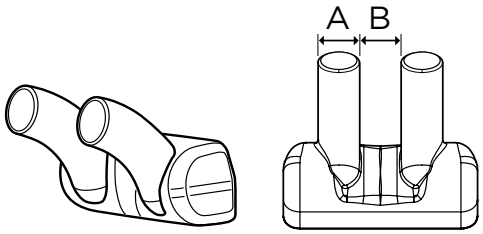
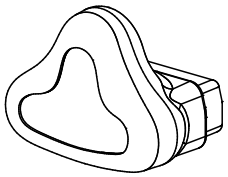
FlexiTrunk™ Instruções para o utilizador da interface para bebé

TUBOS NASAIS PARA BEBÉ



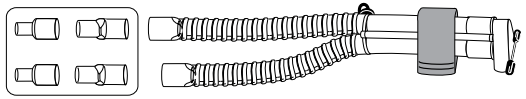
Código do produto	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MÁSCARA NASAL PARA BEBÉ



Código do produto	Dimensões
BC800	Pequeno
BC801	Médio
BC802	Grande
BC803	Extra Grande

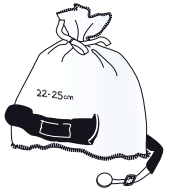
TUBULAÇÃO NASAL PARA BEBÉ



Série BC19x

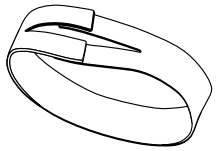
Código do produto	Dimensões
BC190	50 mm
BC191	70 mm
BC192	100 mm

GORRO PARA BEBÉ



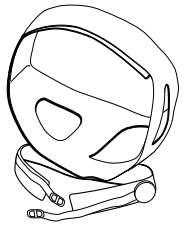
Código do produto	Dimensões
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

TIRA PARA O QUEIXO PARA BEBÉ



Código do produto	Dimensões
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

ARNÊS DE CABEÇA PARA BEBÉ



Código do produto	Dimensões
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

CE 0123

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FlexiTrunk™ Instrucţiuni de utilizare privind interfaţa pentru copii

ro

Utilizarea corespunzătoare

Interfaţa pentru copii F&P este concepută pentru a asigura ventilaţia neinvazivă cu presiune pozitivă pentru pacienţii cu respiraţie spontană care cântăresc până la 10 kg, într-un mediu de spital sau clinică, în care pacientul este monitorizat în mod adecvat de către personal cu pregătire medicală.

Specificaţii produs

BC190 **BC191** **BC192**	Interfaţa pentru copii F&P este concepută pentru a se conecta la sistemul CPAP cu bule Fisher & Paykel Healthcare. Adaptorii permit conectarea la circuitele CPAP ale altor producători folosind conectoare de 7,8 sau 10 mm.
Fluxul maxim de intrare	15 L/min
Presiunea de operare maximă permisă	15 cmH_2O

Consultaţi ultima pagină pentru a vedea dimensiunile şi componentele.

Contraindicaţii

- Respiraţie nespontană
- Dereglări sau malformaţii congenitale în cazul cărora sunt contraindicate canulele nazale sau masca nazală (de exemplu, atrezia coanală).
- Dereglări sau malformaţii congenitale în cazul cărora sunt contraindicate terapiile cu presiune pozitivă (de exemplu, hernia diafragmatică şi fistula traheo-esofagiană).
- Traumă nazală/deformare severă ce poate fi exacerbată de utilizarea canulelor nazale sau a măştii nazale.

AVERTIZĂRI

Componentele interfeţei pentru copii sunt concepute spre a fi utilizate la un singur pacient. **Refolosirea poate cauza transmiterea unor infecţii, întreruperea tratamentului, afecţiuni grave sau moartea.**

Manevraţi cu atenţie. Procedaţi cu grijă când poziţionaţi sau deconectaţi interfaţa pentru copii. Evitaţi folosirea unei forţe de tracţiune excesive, obiectele ascuţite şi suporturile de tubulatură. Deteriorarea tubulaturii poate provoca o pierdere de presiune şi poate impune înlocuirea imediată.

Acest produs a fost conceput pentru a fi folosit timp de maximum 7 zile.

A NU se utiliza dacă produsul sau ambalajul este deteriorat.

- NU modificaţi acest produs.
- Folosiţi un sistem de monitorizare a oxigenului la pacient.
- Conectarea la sisteme de umidificare produse de alţi producători sporeşte riscul de formare a condensului şi/sau furnizarea către pacient a gazului la temperatură ridicată.
- Conectaţi numai dispozitive de monitorizare a presiunii la portul de monitorizare a presiunii de la tubulatura nazală.
- Aplicaţi metode adecvate pentru a preveni contaminarea biologica în timpul utilizării şi la aruncarea produsului.
- NU imersaţi, nu spălaţi, nu sterilizaţi şi NU refolosiţi acest produs.
- NU strângeţi prea tare banderolele bonetei pentru copil.
- NU acoperiţi faţa copilului cu boneta, deoarece există riscul de sufocare.
- FOLOSIŢI NUMAI componentele recomandate pentru interfaţa pentru copii F&P, deoarece substitutele neaprobate pot duce la poziţionarea inadecvată a canulelor şi a măştii nazale.
- Există riscul de necroză de sept dacă nu se respectă dimensionarea sau poziţionarea corectă a canulelor şi a măştii nazale.
- **Monitorizaţi mereu presiunea pentru a verifica dacă pacientul primeşte nivelul de CPAP prescris.**
- NU utilizaţi medicaţie ce conţine Tyloxapol (precum Tacholiquin), întrucât acest lucru ar putea deteriora tubulatura şi conduce la pierderea de presiune CPAP.

Instalarea

- **BC190, BC191, BC192**

Consultaţi instrucţiunile sistemului CPAP cu bule F&P înainte de instalarea interfeţei pentru copii.

Dacă utilizaţi adaptori, consultaţi instrucţiunile de instalare furnizate de producătorul circuitului înainte de a instala interfaţa pentru copii.

- Consultaţi ilustraţiile 1-15 pentru instalarea corectă.
- Pentru dimensionarea corectă a produsului, consultaţi tabelele de pe ultima pagină.
- TREBUIE utilizată o supapă de supra-presiune. Reglajele supapei de supra-presiune trebuie să fie adecvate pentru utilizarea CPAP la copii.

Verificări Înaintea Punerii În Funcţiune

- Când nu se foloseşte portul de monitorizare a presiunii de la tubulatura nazală, trebuie închis capacul.
- Verificaţi ca toate conexiunile circuitului să fie strânse înainte de utilizare şi după efectuarea oricărui reglaj.

CE 0123

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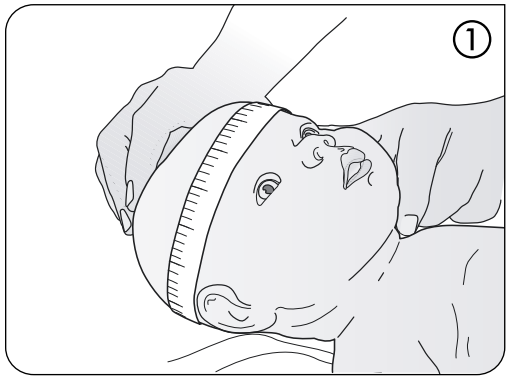
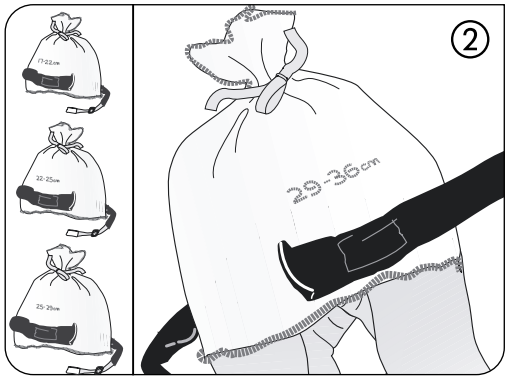
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

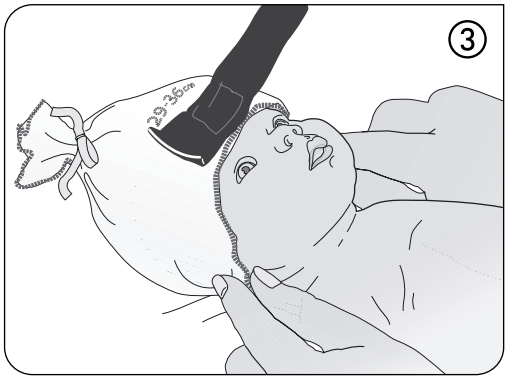
FlexiTrunk™ Instrucţiuni de utilizare privind interfaţa pentru copii



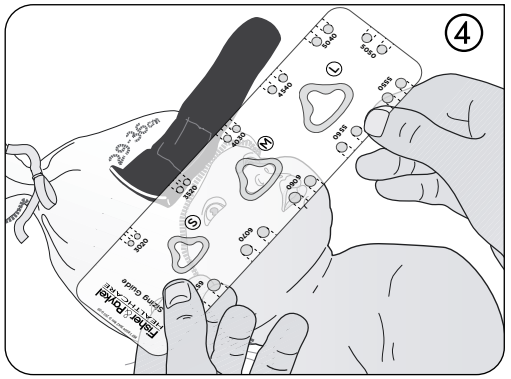
- Măsuraţi circumferinţa capului copilului în centimetri.



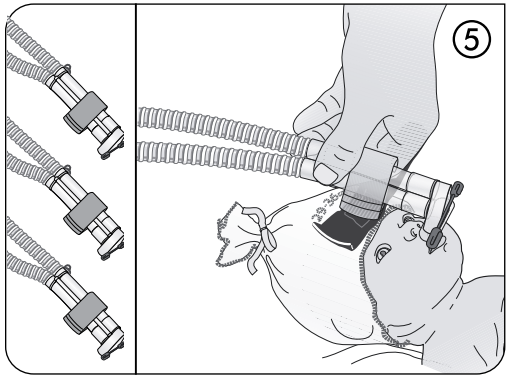
- Alegeţi boneta de dimensiunea corectă. Boneta trebuie să fie potrivită.
- Întindeţi iniţial boneta cu mâinile, pentru a o putea poziţiona uşor.



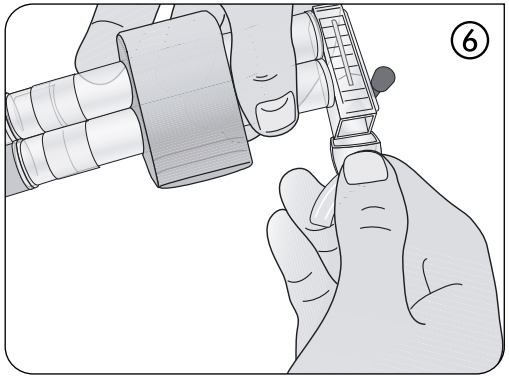
- Aşezaţi boneta pe capul copilului, acoperind complet urechile, cu marginea din spate a bonetei ajungând până la baza gâtului. Marginea din faţă a bonetei trebuie să fie pe sprâncene sau deasupra acestora.



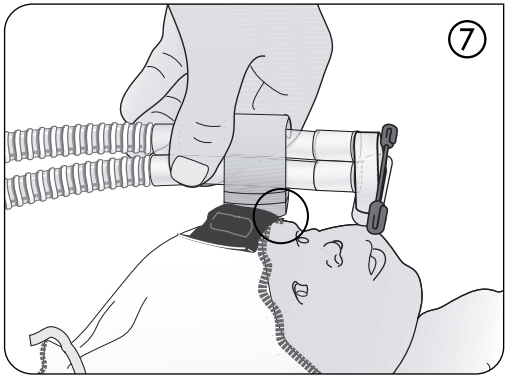
- Folosiţi ghidajul de dimensionare pentru a alege canula nazală sau masca adecvată.
- Canula trebuie să umple complet nările fără a întinde pielea. Folosiţi cea mai mare dimensiune posibilă.
- Masca nu trebuie să atingă marginea nasului, septul sau ochii.



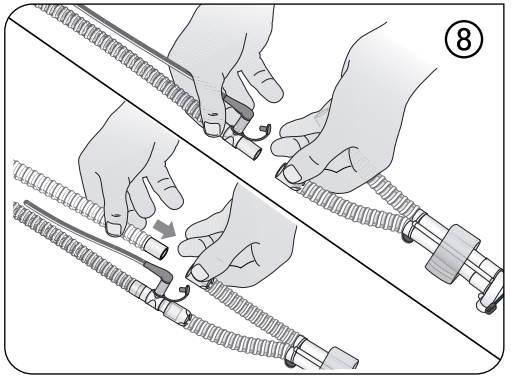
- Alegeţi lungimea corectă a tubulaturii nazale. Folosiţi cea mai mică lungime posibilă.
- Tubulatura transparentă nu trebuie să se întindă peste fruntea copilului.
- Următoarele măsurători pot fi folosite pentru ghidare: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Conectaţi canulele sau masca la tubulatura nazală, asigurându-vă că sunt bine îmbinate.
- Dacă folosiţi canule nazale: strângeţi bine lateralele canulei pentru a evidenţia canelurile. Începeţi de la un capăt şi introduceţi canelurile canulei în tubulatura nazală. Împingeţi bine capătul în interior.



- Îndepărtaţi fâşiile detaşabile după cum este necesar pentru a regla unghiul tubulaturii nazale în vederea optimizării etanşeităţii.
- NU aruncaţi fâşiile detaşabile deoarece acestea ar putea fi necesare la utilizarea alternativă a canulelor nazale şi a măştilor.



- Ataşaţi circuitul la tubulatura nazală în oricare direcţie.
- Pentru detalii suplimentare, consultaţi instrucţiunile furnizate de producătorul circuitului.
- Notă: Deconectaţi uşor FlexiTrunk™ răsucind conectoarele. NU trageţi excesiv, întrucât aceasta ar putea deteriora tubulatura.
- Manipulaţi cu atenţie.

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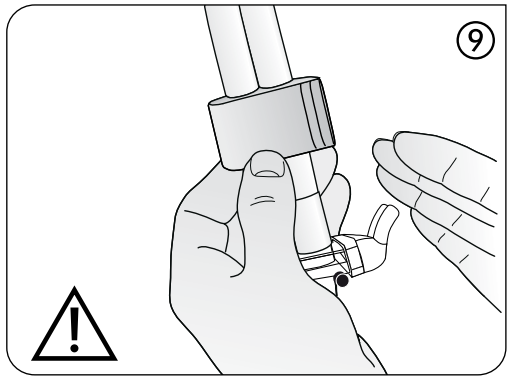
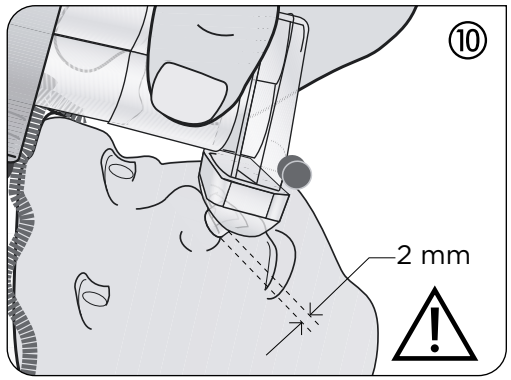
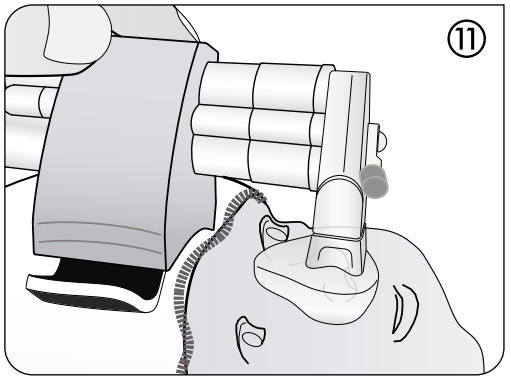
FlexiTrunk™ Instrucţiuni de utilizare privind interfaţa pentru copii



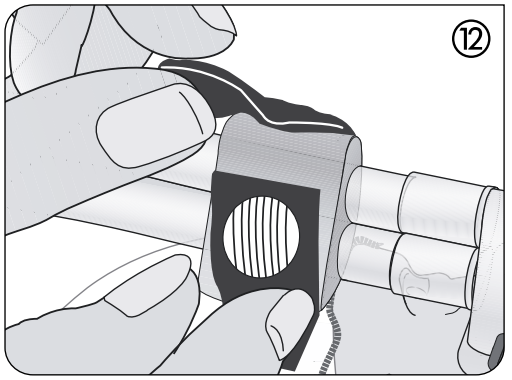
- Reglaţi debitul de gaz la nivelul prescris.
- Porniţi umidificatorul. Consultaţi instrucţiunile producătorului.
- Apropiaţi mâna de canulele nazale sau de mască pentru a vă asigura că există debit de gaz.



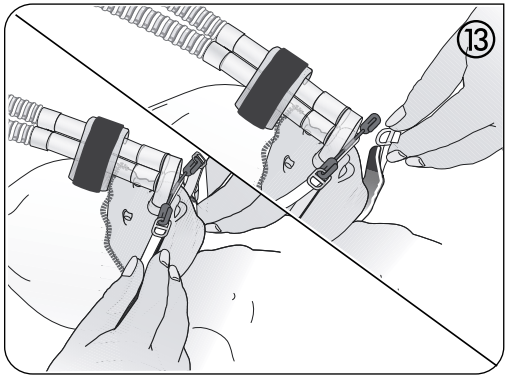
- **Dacă folosiţi canule:** Curăţaţi secreţiile nazale înainte de introducerea canulei nazale.
- Asiguraţi-vă astfel incât canula nazală să fie poziţionată la cel puţin 2 mm (0,08 inci) de sept, pentru a evita necroza de presiune. Reglaţi după cum este necesar.
- Se recomandă verificări ale integrităţii septului la intervale de o oră.



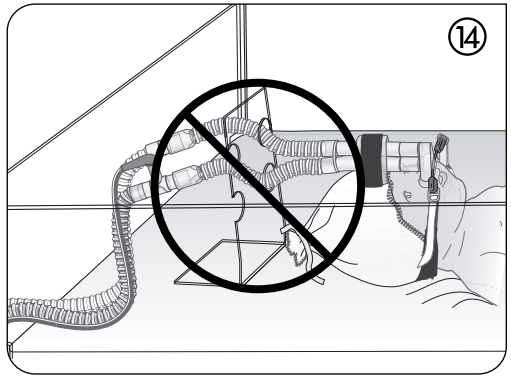
- **Dacă folosiţi mască:** Conectaţi masca la pacient aşezând-o în jurul nasului. Masca trebuie să stea confortabil în jurul nasului pacientului. Aceasta nu trebuie să obstrucţioneze nările şi nici să atingă septul; de asemenea, masca nu trebuie să ajungă peste buză sau peste ochi.



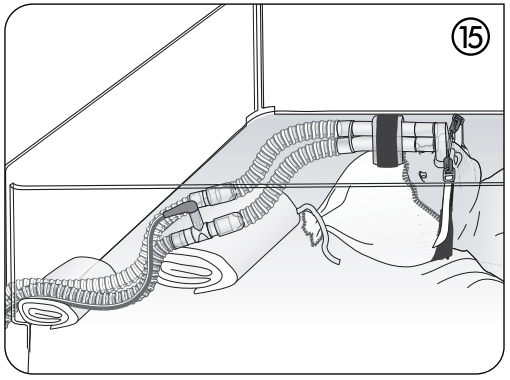
- Reglaţi înălţimea blocului de spumă adăugând sau îndepărtând fâşii detaşabile. Configuraţiile cu măşti ar putea necesita adăugarea de fâşii pentru o poziţionare adecvată.
- Poziţionaţi banderola peste blocul de spumă şi strângeţi-o pentru a fixa tubulatura.



- Prindeţi de glisor clemele de la banderolele laterale ale bonetei.
- Trageţi de ambele banderole în acelaşi timp pentru poziţionarea centrală.
- Fixaţi urechile rotunde cu Velcro de banderola albastră a bonetei.
- Aplicaţi cea mai redusă întindere cu putinţă pentru a menţine nivelul CPAP specificat şi stabilitatea interfeţei pentru copii.



- NU folosiţi cadrele tip „îngeraş”, brăduţi sau alte dispozitive, pentru că acestea pot perfora tubulatura FlexiTrunk™ şi pot provoca o pierdere de presiune.



- Asiguraţi-vă că greutatea circuitului este susţinută uşor, pentru a reduce întinderea la nivelul tubulaturii nazale. Se recomandă o pernă sau un prosop împăturit. Tubulatura FlexiTrunk™ trebuie să se mişte liber pentru a permite mişcarea fără restricţii a capului copilului.
- Circuitul trebuie păstrat sub nivelul tubulaturii nazale, pentru a reduce la minim formarea de condens către copil.

Verificări în timpul folosirii

- Verificaţi frecvent pacientul pentru a vedea dacă apar semne de roşeaţă, răni din cauza presiunii sau iritaţii ce pot rezulta în urma utilizării îndelungate a canulelor sau a măştii. Se recomandă verificări la intervale de o oră.
- Se poate reduce riscul de iritaţie folosind alternativ masca şi canulele. Se recomandă alternarea la intervale de 4-6 ore.
- Poziţia măştii trebuie reglată astfel încât să se potrivească optim şi să fie reduse la minim scurgerile. Dacă se produc încă scurgeri excesive, se poate mări debitul pentru compensare. Debitul maxim permis este de 15 L/min.
- Verificaţi în mod regulat dacă s-a format condens şi efectuaţi golirea după cum este necesar.

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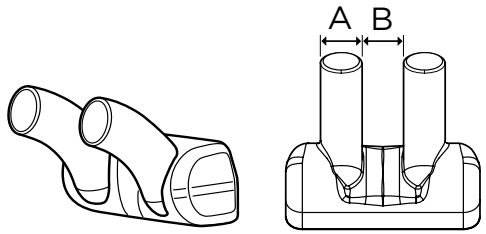
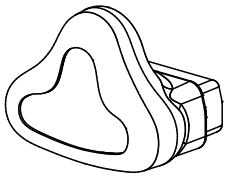
FlexiTrunk™ Instrucţiuni de utilizare privind interfaţa pentru copii

CANULĂ NAZALĂ PENTRU COPIL



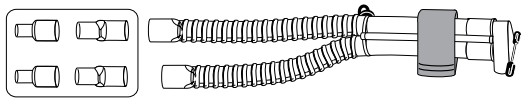
Codul produsului	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

MASCĂ NAZALĂ PENTRU COPIL



Codul produsului	Mărimea
BC800	Mică
BC801	Medie
BC802	Mare
BC803	Foarte Mare

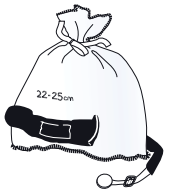
TUBULATURĂ NAZALĂ PENTRU COPIL



Seria BC19x

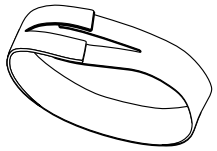
Codul produsului	Mărimea
BC190	50 mm
BC191	70 mm
BC192	100 mm

BONETĂ PENTRU COPIL



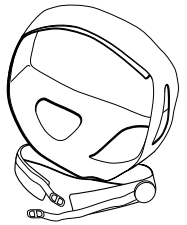
Codul produsului	Mărimea
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

BANDEROLĂ DE BĂRBIE PENTRU COPIL



Codul produsului	Mărimea
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

BANDEROLĂ DE CAP PENTRU COPIL



Codul produsului	Mărimea
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ Инструкции по эксплуатации Infant Interface

ru

Показания к применению

Устройство Infant Interface F&P предназначено для неинвазивной вентиляции легких с положительным давлением при самостоятельном дыхании детей весом до 10 кг в больнице или при возникновении какой-либо клинической ситуации, когда больной находится под надлежащим наблюдением квалифицированного медицинского персонала.

Технические характеристики устройства

BC190 **BC191** **BC192**	Устройство Infant Interface F&P предназначено для подключения к системе пузырькового CPAP компании Fisher & Paykel Healthcare. С помощью переходников можно подключить устройство к контурам CPAP с соединителями размером 7,8 или 10 мм других производителей.
Максимальный уровень интенсивности подачи	15 л/мин
Максимально допустимое рабочее давление	15 см H_2O

Размеры и перечень комплектующих приведены на последней странице.

Противопоказания

- Отсутствие самостоятельного дыхания
- Врожденные аномалии или пороки развития, при которых противопоказаны биназальные канюли или назальные маски (например, атрезия хоан).
- Врожденные аномалии или пороки развития, при которых противопоказано лечение под положительным давлением (например, диафрагмальная грыжа и трахеопищеводный свищ).
- Использование назальных канюль или назальных масок при травме/серьезной деформации носа может усугублять проблему.

ПРЕДУПРЕЖДЕНИЯ

Комплектующие устройства Infant Interface предназначены для использования только одним пациентом. **Повторное использование может стать причиной переноса инфекционных частиц, прерывания курса лечения, серьезного вреда для здоровья или смерти.**

Обращаться с осторожностью. Соблюдайте осторожность при установке и отключении Infant Interface. Не применяйте чрезмерных усилий при затягивании, избегайте использования острых предметов и держателей трубок. Повреждение трубок может привести к потере давления. Поврежденные части следует немедленно заменить.

7 Максимальная продолжительность применения данного устройства составляет 7 дней.

ЗАПРЕЩАЕТСЯ использовать в случае повреждения изделия или упаковки.

- ЗАПРЕЩАЕТСЯ модифицировать устройство.
- Используйте систему контроля подачи кислорода пациенту.
- Подключение к системам увлажнения других производителей повышает риск образования конденсата и/или поступления газа высокой температуры пациенту.
- Подключайте устройства контроля давления только к порту мониторинга давления на носовых трубках.
- Комплектующие Infant Interface поставляются в чистом виде. Во избежание биозагрязнения во время использования или при уничтожении следует применять надлежащие технологии.
- Данное устройство ЗАПРЕЩАЕТСЯ погружать в воду, мыть, стерилизовать или использовать повторно.
- НЕ затягивайте очень туго ремешки на детских шапочках.
- НЕ закрывайте лицо ребенка шапочкой, т.к. это может стать причиной удушья.
- ИСПОЛЬЗУЙТЕ ТОЛЬКО комплектующие Infant Interface, рекомендованные F&P. В случае замены на неутвержденные детали возможно нарушение положения назальных канюль и маски.
- При выборе неверного размера или неправильном размещении канюль и маски возможно развитие септального некроза.
- **Всегда используйте мониторинг давления с целью контроля соответствия уровня ППДДП рекомендованному для пациента уровню.**
- НЕ применяйте медицинские препараты, содержащие тилоксапол (такие как тахоликвин), так как применение таких препаратов может привести к повреждению трубок и к потере давления ППДДП.

Установка

- **BC190, BC191, BC192**

Перед установкой Infant Interface изучите инструкции по использованию системы пузырькового CPAP производства компании F&P.

В случае использования переходников перед установкой Infant Interface прочтите инструкции производителя контура по его установке.

- Для правильной установки см. рисунки 1–15.
- Для правильного определения размера устройства смотрите таблицы на последней странице.
- НЕОБХОДИМО использовать устройство сброса избыточного давления. Настройки устройства сброса давления должны соответствовать детской системе CPAP.

Проверка перед эксплуатацией

- Если порт датчика давления на носовых трубках не используется, колпачок должен быть закрыт.
- Перед использованием и после любой регулировки убедитесь, что все соединительные элементы надежно закреплены.

CE 0123
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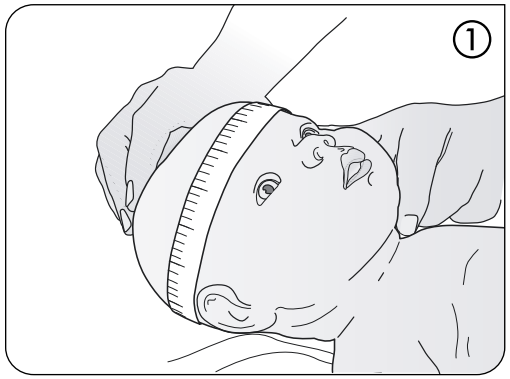
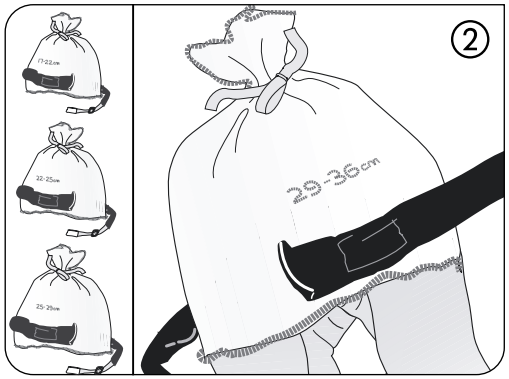
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

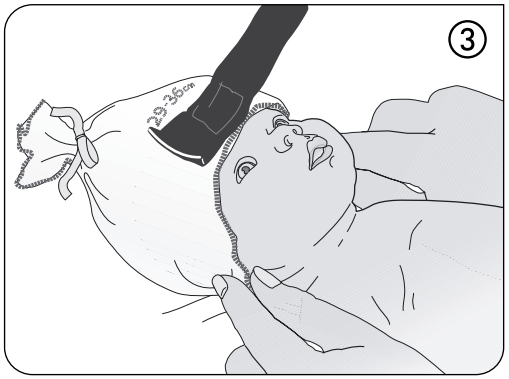
FlexiTrunk™ Инструкции по эксплуатации Infant Interface



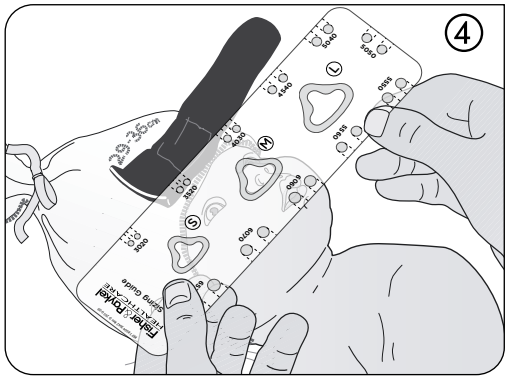
- Измерьте окружность головы ребенка в сантиметрах.



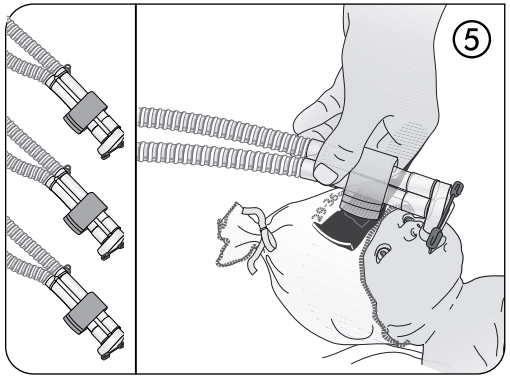
- Выберите шапочку соответствующего размера. Шапочка должна плотно облегать голову.
- Сначала немного потяните шапочку руками, чтобы легко ее надеть.



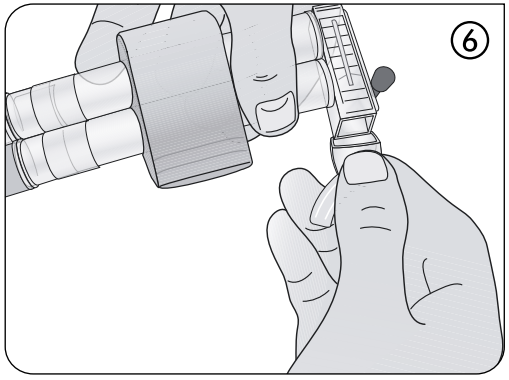
- Осторожно наденьте шапочку ребенку на голову так, чтобы она полностью закрывала уши, а задний край шапочки находился у основания шеи. Передний край шапочки должен располагаться немного выше бровей.



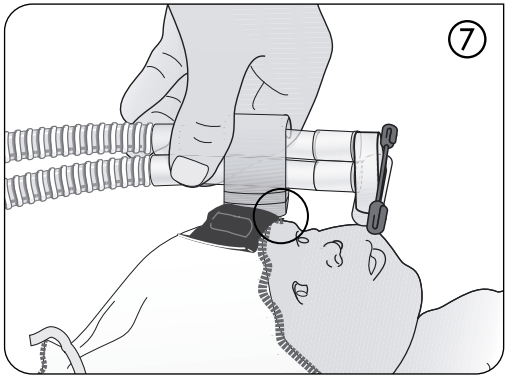
- Для выбора подходящих канюль или маски используйте специальное руководство по определению размера.
- Канюли должны полностью заполнять ноздри, не растягивая кожу. Выберите максимально возможный размер.
- Маска не должна касаться края носа, перегородки или глаз.



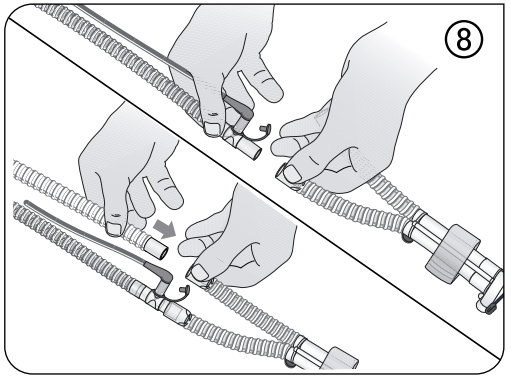
- Необходимо использовать носовые трубки правильной длины. Применяйте как можно более короткие трубки.
- Прозрачная трубка не должна размещаться перед лицом ребенка.
- В качестве рекомендаций можно использовать следующее: 50 мм ≤ 1,5 кг, 70 мм ≤ 2,5 кг, 100 мм > 2,5 кг



- Присоедините канюли или маску к носовым трубкам, обеспечив их полное введение.
- При использовании канюли: сильно надавите на боковые стороны канюли, чтобы показались пазы. Начиная с одного конца, вставьте пазы канюли в носовые трубки. С усилием протолкните конец.



- При необходимости удалите отрывные полоски для регулировки угла носовых трубок с целью оптимизации герметичности.
- НЕ выбрасывайте отрывные полоски, так как они могут пригодиться при поочередном применении маски и канюль.



- Подсоедините контур к носовым трубкам в любом из направлений.
- Более подробная информация приведена в инструкции производителя контура.
- Примечание. Осторожно отсоедините FlexiTrunk™, скрутив соединительные элементы. НЕ тяните сильно, так как это может привести к повреждению трубок.
- Обращаться с осторожностью.

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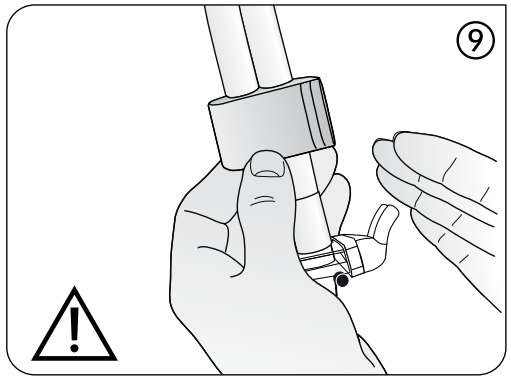
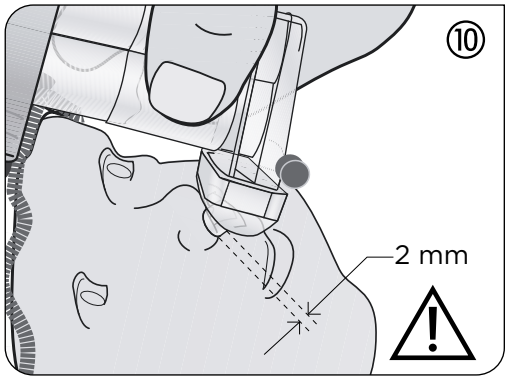
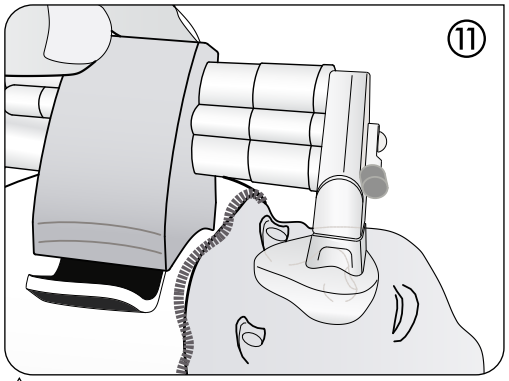
FlexiTrunk™ Инструкции по эксплуатации Infant Interface



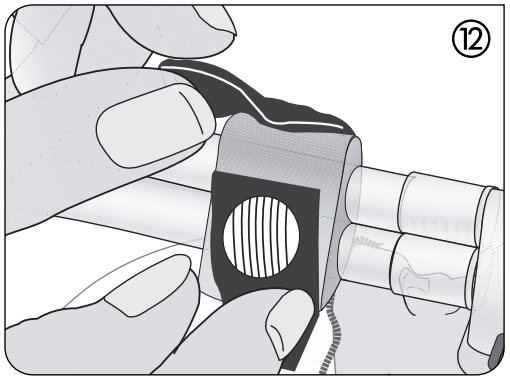
- Отрегулируйте газовый поток согласно рекомендованному уровню.
- Включите увлажнитель. Изучите инструкции производителя.
- ⚠ Приблизьте руку к назальным канюлям или маске, чтобы проверить наличие газового потока.



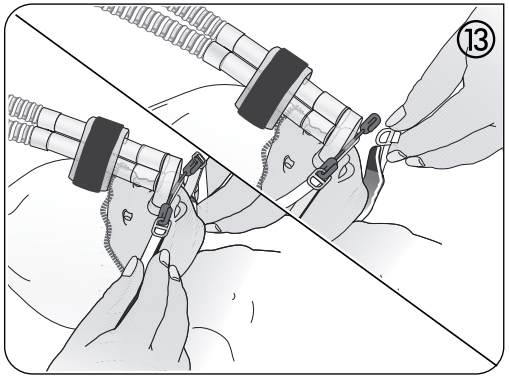
- **При использовании канюль:** Перед размещением назальных канюль необходимо удалить носовой секрет.
- ⚠ Во избежание некроза вследствие сдавливания убедитесь, что назальные канюли установлены на расстоянии не менее 2 мм (0,8 дюйма) от перегородки. Отрегулируйте при необходимости.
- Каждый час рекомендуется проводить осмотр перегородки.



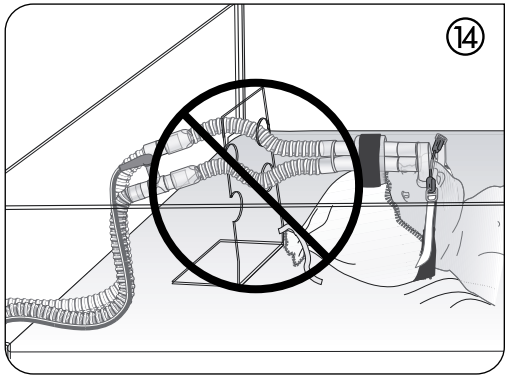
- ⚠ **При использовании маски:** Подключите к пациенту, разместив маску в области носа. Маска должна удобно располагаться вокруг носа пациента. Она не должна перекрывать ноздри или прикасаться к перегородке, а также размещаться поверх губ или глаз.



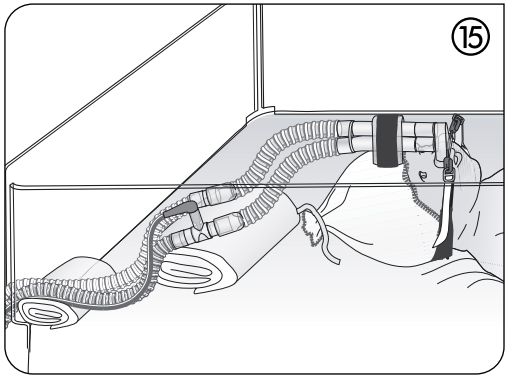
- Установите высоту паролонового блока, добавив или удалив отрывные полоски. При использовании установок с масками для достижения правильного положения могут потребоваться дополнительные отрывные полоски.
- Поместите ремень на поролоновый блок и прочно зафиксируйте трубки.



- Закрепите зажимы боковых ремешков шапочки в скользящей застежке.
- Следует тянуть к центру оба ремешка одновременно.
- Прикрепите круглые застежки-липучки к синему ремешку шапочки.
- Используйте минимально необходимое натяжение для поддержания рекомендуемого уровня ППДДП и устойчивого положения Infant Interface.



- НЕ используйте рамки для фотографий, новогодние елки и т.п., поскольку такие предметы могут проколоть трубки FlexiTrunk™ и привести к потере давления.



- Убедитесь, что вес контура слегка поддерживается, для того чтобы снизить натяжение носовых трубок. Для опоры рекомендуется использовать подушку или свернутое полотенце. Трубки FlexiTrunk™ должны свободно двигаться, чтобы не ограничивать движения головы ребенка.
- Контур должен быть размещен ниже уровня носовых трубок с целью минимизации конденсата, выделяемого на ребенка.

Контроль во время эксплуатации

- Регулярно проверяйте пациента на предмет наличия покраснений, пролежней или раздражений, которые могут быть обусловлены продолжительным использованием канюль или маски. Рекомендуется проводить осмотр каждый час.
- Поочередное применение маски и канюль способно снизить риск раздражения. Смены рекомендуется проводить через каждые 4 – 6 часов.
- Расположение маски следует отрегулировать таким образом, чтобы обеспечить ее наилучшее прилегание и минимальную утечку. Если чрезмерная утечка все же имеется, можно для компенсации увеличить поток. Максимально допустимая интенсивность подачи составляет 15 л/мин.
- Постоянно контролируйте объем образуемого конденсата и при необходимости просушивайте.

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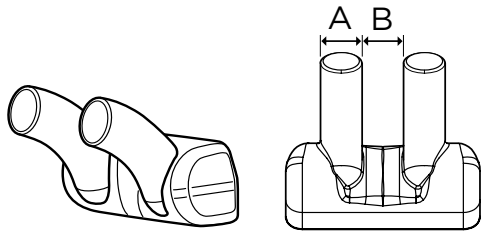
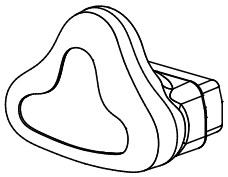
FlexiTrunk™ Инструкции по эксплуатации Infant Interface

ДЕТСКИЕ НАЗАЛЬНЫЕ КАНЮЛИ



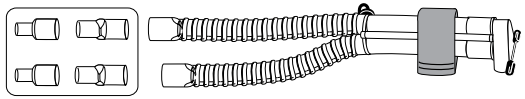
Код изделия	A	B
BC3020	3,0 мм	2,0 мм
BC3520	3,5 мм	2,0 мм
BC4030	4,0 мм	3,0 мм
BC4540	4,5 мм	4,0 мм
BC5040	5,0 мм	4,0 мм
BC5050	5,0 мм	5,0 мм
BC5550	5,5 мм	5,0 мм
BC5560	5,5 мм	6,0 мм
BC6060	6,0 мм	6,0 мм
BC6070	6,0 мм	7,0 мм
BC6570	6,5 мм	7,0 мм

ДЕТСКАЯ НАЗАЛЬНАЯ МАСКА



Код изделия	Размер
BC800	Малая
BC801	Средняя
BC802	Большая
BC803	Очень большая

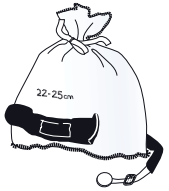
ДЕТСКИЕ НОСОВЫЕ ТРУБКИ



серия BC19x

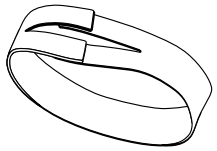
Код изделия	Размер
BC190	50 мм
BC191	70 мм
BC192	100 мм

ДЕТСКАЯ ШАПОЧКА



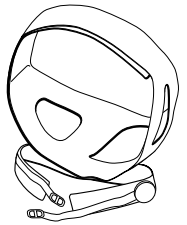
Код изделия	Размер
BC300	17-22 см
BC303	22-25 см
BC306	25-29 см
BC309	29-36 см

ДЕТСКИЙ ПОДБОРОДОЧНЫЙ РЕМЕШОК



Код изделия	Размер
BC351	20-26 см
BC353	26-32 см
BC355	32-38 см
BC357	38-44 см

ДЕТСКИЙ РЕМЕНЬ НА ГОЛОВУ



Код изделия	Размер
BC325	29-36 см
BC328	35-40 см
BC331	40-45 см

LATEX

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F&P คำแนะนำสำหรับผู้ใช้งาน FlexiTrunk™ Infant Interface

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วัตถุประสงค์ในการใช้งาน

Infant Interface ของ F&P ได้รับการออกแบบมาเพื่อส่งมอบการระบายอากาศแรงดันบวกที่ไม่เป็นอันตรายให้แก่ผู้ป่วยที่มีอาการหายใจลำบากซึ่งมีน้ำหนักไม่มากกว่า 10 กก. ในโรงพยาบาลหรือคลินิกที่ซึ่งผู้ป่วยได้รับการเฝ้าสังเกตอย่างเพียงพอโดยแพทย์ที่ผ่านการฝึกอบรมมา

ข้อกำหนดรายละเอียดของผลิตภัณฑ์

BC190 **BC191** **BC192**	Infant Interface ของ F&P ได้รับการออกแบบมาเพื่อเชื่อมต่อเข้ากับระบบอัดอากาศแรงดันบวกชนิดต่อเนื่องด้วยฟองอากาศของ Fisher & Paykel Healthcare หัวต่อแปลงช่วยให้สามารถเชื่อมต่อไปยังวงจรอัดอากาศแรงดันบวกชนิดต่อเนื่องของผู้ผลิตรายอื่นได้ด้วยตัวเชื่อมต่อขนาด 7.8 หรือ 10 มม.
การไหลเข้าสูงสุด	15 ลิตร/นาที
ค่าความดันสูงสุดที่อนุญาต	15 cmH_2O

โปรดอ้างอิงตามหน้าสุดท้ายในส่วนขอบเขตและส่วนประกอบ

ข้อห้ามใช้

- อาการที่ไม่สามารถหายใจได้ด้วยตนเองิ
- ความผิดปกติหรือความไม่สมประกอบแต่กำเนิดที่ห้ามใช้ท่อคู่ช่วยหายใจหรือหน้ากากช่วยหายใจ (เช่น ภาวะรูเปิดของโพรงจมูกด้านหลังตีบตัน)
- ความผิดปกติหรือความไม่สมประกอบแต่กำเนิดที่ห้ามใช้การบำบัดด้วยความดันบวก (เช่น ไส้เลื่อนกระบังลมและรอยเชื่อมระหว่างหลอดอาหารกับทางเดินหายใจ)
- ความผิดปกติร้ายแรง/บาดแผลในจมูกที่อาจเลวร้ายขึ้นได้เนื่องจากใช้งานท่อช่วยหายใจหรือหน้ากากช่วยหายใจ

คำเตือน

- ส่วนประกอบของ Infant Interface ได้รับการออกแบบมาให้ใช้ได้เพียงครั้งเดียวเท่านั้น **การนำกลับมาใช้ซ้ำอาจส่งผลให้มีการแพร่กระจายของสารติดเชื้อ การชัดจังหวะการบำบัด ผลอันตรายร้ายแรง หรืออาจเสียชีวิตได้**
- **ดำเนินการด้วยความระมัดระวัง** ใช้ความระมัดระวังในการวางตำแหน่งหรือถอดการเชื่อมต่อ Infant Interface หลีกเลี่ยงแรงดึงที่มากเกินไป วัตถุมีคม และที่วางท่อ ความเสียหายต่อท่ออาจก่อให้เกิดการสูญเสียความดันและจำเป็นต้องเปลี่ยนใหม่ทันที
- ผลิตภัณฑ์นี้มีไว้สำหรับใช้งานสูงสุด 7 วัน
- "ห้าม" ใช้งาน หากผลิตภัณฑ์หรือบรรจุภัณฑ์เสียหาย
- กฎหมายของรัฐบาลกลางสหรัฐฯ จำกัดให้แพทย์เป็นผู้สั่งหรือผู้ขายอุปกรณ์นี้
- "ห้าม" ดัดแปลงผลิตภัณฑ์นี้
- ใช้การตรวจสอบออกซิเจนในผู้ป่วย
- การเชื่อมต่อกับระบบทำความชื้นของผู้ผลิตรายอื่นเป็นการเพิ่มอัตราเสี่ยงของการควบแน่นและ/หรือการถ่ายอุณหภูมิก๊าซที่สูงให้แก่ผู้ป่วย
- เชื่อมต่ออุปกรณ์ตรวจสอบความดันเฉพาะกับพอร์ตตรวจสอบความดันบนท่อช่วยหายใจ
- ส่วนประกอบของ Infant Interface จะมาในสภาพสะอาด ใช้วิธีการที่เหมาะสมในการป้องกันการปนเปื้อนทางชีวภาพในระหว่างการใช้งานและการกำจัด
- "ห้าม" แช่ ล้าง ฆ่าเชื้อ หรือนำผลิตภัณฑ์นี้มาใช้ใหม่
- "ห้าม" รัดสายหมวกทารกแน่นจนเกินไป
- "ห้าม" ปิดหน้าทารกด้วยหมวกทารกซึ่งอาจทำให้ทารกหายใจไม่ออก
- "ใช้เฉพาะ" ส่วนประกอบของ Infant Interface ของ F&P ที่แนะนำเท่านั้น การจัดวางตำแหน่งท่อและหน้ากากช่วยหายใจที่ไม่ถูกต้องอาจเกิดจากสิ่งทดแทนที่ยังไม่ผ่านการอนุญาต
- อาจเกิดเนื้อร้ายของผนังกั้นหัวใจขึ้นได้ หากขนาดหรือการจัดวางท่อหรือหน้ากากไม่ถูกต้อง
- **ใช้การตรวจสอบความดันอยู่เสมอในการยืนยันว่าผู้ป่วยได้รับระดับแรงดันบวกชนิดต่อเนื่องตามที่กำหนดไว้**
- "ห้าม" ใช้ยาที่มี Tyloxapol (เช่น Tacholiquin) เนื่องจากอาจก่อให้เกิดความเสียหายต่อท่อและนำไปสู่การสูญเสียความดันของแรงดันบวกชนิดต่อเนื่องได้

การติดตั้ง

- **BC190, BC191, BC192**
- อ้างอิงตามคำแนะนำสำหรับระบบอัดอากาศแรงดันบวกชนิดต่อเนื่องด้วยฟองอากาศของ F&P ก่อนติดตั้ง Infant Interface
- หากใช้งานหัวต่อแปลง ให้ดูที่คำแนะนำการติดตั้งที่ให้มาโดยผู้ผลิตวงจรนั้น ก่อนติดตั้ง Infant Interface
- อ้างอิงตามภาพตัวอย่าง 1-15 สำหรับการติดตั้งที่ถูกต้อง
- อ้างอิงตามตารางในหน้าสุดท้ายสำหรับขนาดของผลิตภัณฑ์ที่ถูกต้อง
- "จำเป็น" ต้องใช้อุปกรณ์ระบายความดันสูงสุด การตั้งค่าการระบายความดันจะต้องเหมาะสมกับเครื่องอัดอากาศแรงดันบวกชนิดต่อเนื่องสำหรับทารก

ตรวจสอบก่อนการทำงาน

- หากไม่มีการใช้งานพอร์ตตรวจสอบความดันบนท่อช่วยหายใจ ต้องปิดฝาปิดเอาไว้
- ตรวจดูจุดเชื่อมต่อวงจรทุกจุดว่าแน่นหรือไม่ ทั้งก่อนใช้งานและหลังการปรับค่าใด ๆ

CE 0123
REF 185042952 REVV 2019-05 © 2019 Fisher & Paykel Healthcare Limited

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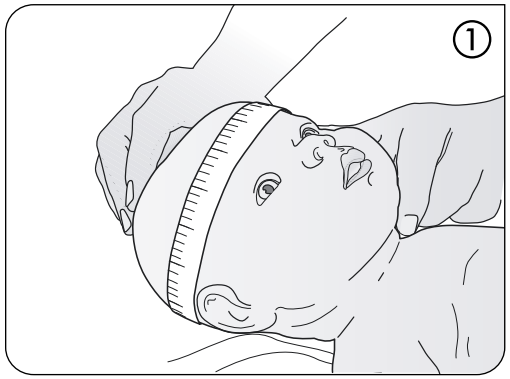
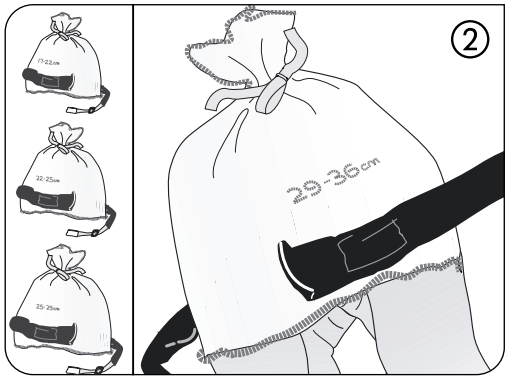
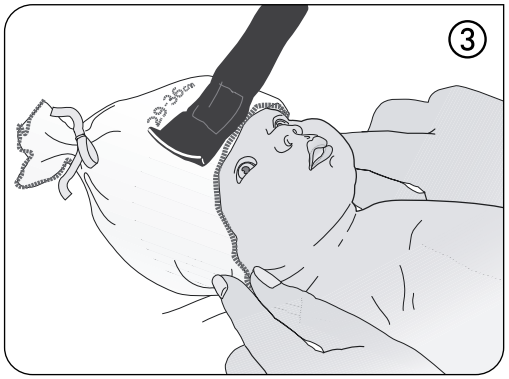
F&P คำแนะนำสำหรับผู้ใช้งาน FlexiTrunk™ Infant Interface



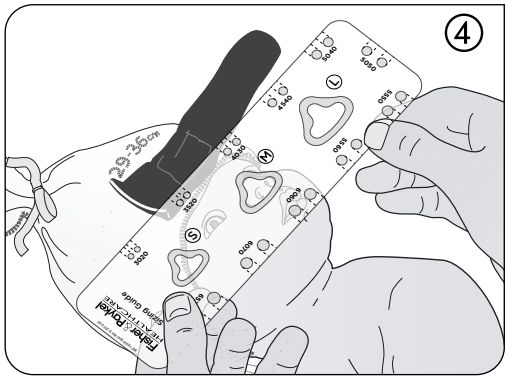
- วัดเส้นรอบวงศีรษะของทารกในหน่วยเซนติเมตร



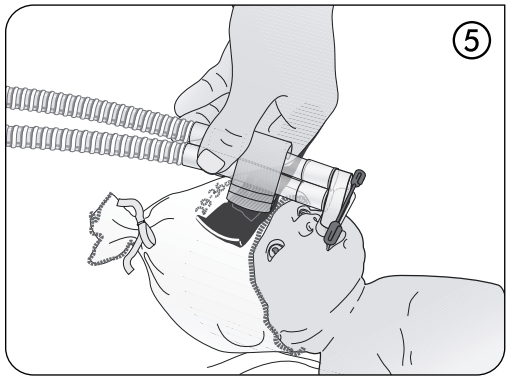
- เลือกขนาดหมวกที่ถูกต้อง หมวกทารกควรใส่ได้พอดี
- สวมหมวกบนมือของคุณในขั้นต้นสำหรับการจัดวางที่ง่ายดาย



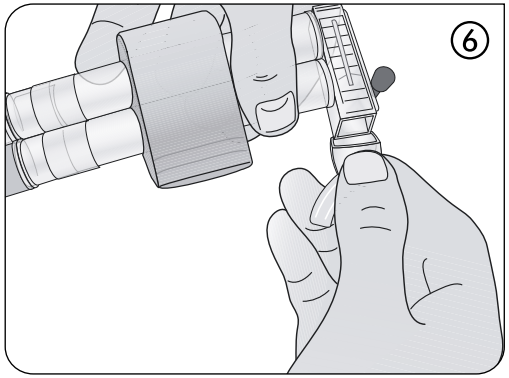
- ใส่หมวกลงบนศีรษะของทารกให้ครอบคลุมหูทั้งสองข้างและให้ขอบสีดำของหมวกคลุมคอของทารก ขอบด้านหน้าของหมวกควรอยู่เหนือคิ้วของทารกเล็กน้อยหรืออยู่บริเวณคิ้วของทารก



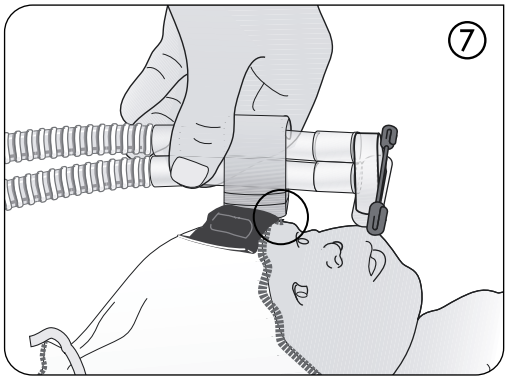
- ใช้คำแนะนำในการเลือกขนาดเพื่อเลือกท่อและหน้ากากที่เหมาะสม
- ท่อช่วยหายใจควรพอดีกับช่องจมูกโดยผิวหนังไม่ยืดตึง ใช้ขนาดท่อใหญ่ที่สุดเท่าที่เป็นได้
- หน้ากากช่วยหายใจไม่ควรสัมผัสกับขอบจมูก ผนังกั้นจมูก หรือดวงตา



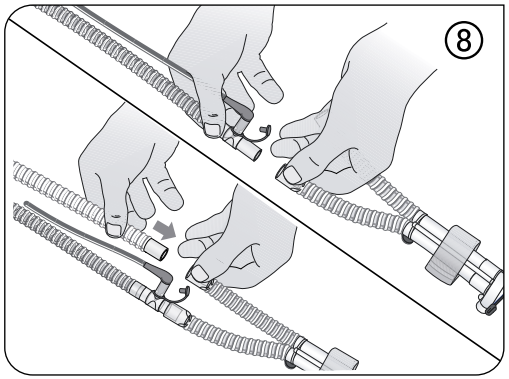
- เลือกความยาวของท่อช่วยหายใจให้ถูกต้อง ใช้ความยาวท่อสั้นที่สุดเท่าที่เป็นไปได้
- ท่อเปล่าไม่ควรยาวเกินกว่าหน้าผากของทารก
- ให้ใช้ตามแนวทางต่อไปนี้:
  50 มม. ≤ 1.5 กก., 70 มม. ≤ 2.5 กก.,
  100 มม. > 2.5 กก.



- เชื่อมต่อท่อหรือหน้ากากเข้ากับท่อช่วยหายใจเพื่อตรวจดูให้แน่ใจว่าได้ใส่พอดีเต็มแล้ว
- หากใช้ท่อ ให้บีบด้านข้างของท่อให้แน่นเพื่อแสดงให้เห็นร่อง เริ่มจากด้านปลายและใส่ร่องท่อเข้าในท่อช่วยหายใจ ดันสุดให้แน่น



- จำเป็นต้องถอดสายรัดแบบฉีกขาดออกในการปรับมุมท่อช่วยหายใจเพื่อเพิ่มประสิทธิภาพของซีล
- "ห้าม" ทิ้งสายรัดแบบฉีกขาด เนื่องจากอาจจำเป็นต้องใช้ตอนสลับเปลี่ยนระหว่างท่อและหน้ากากช่วยหายใจ



- ติดวงจรเข้ากับท่อช่วยหายใจทั้งสองทิศทาง
- อ้างอิงตามคำแนะนำที่ให้มาโดยผู้ผลิตวงจรสำหรับรายละเอียดเพิ่มเติม
- หมายเหตุ: ถอดการเชื่อมต่อ FlexiTrunk™ ออกเบา ๆ โดยการหมุนตัวเชื่อมต่อ "ห้าม" ดึงอย่างรุนแรง เนื่องจากอาจก่อให้เกิดความเสียหายต่อท่อ
- **ดำเนินการด้วยความระมัดระวัง**

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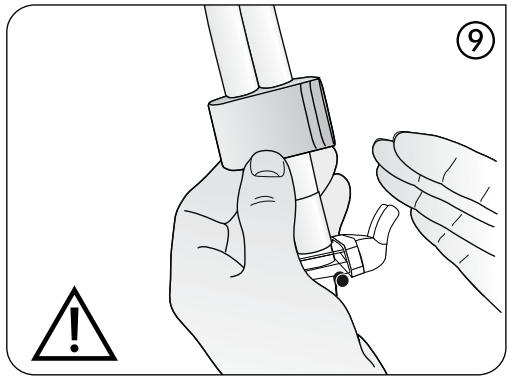
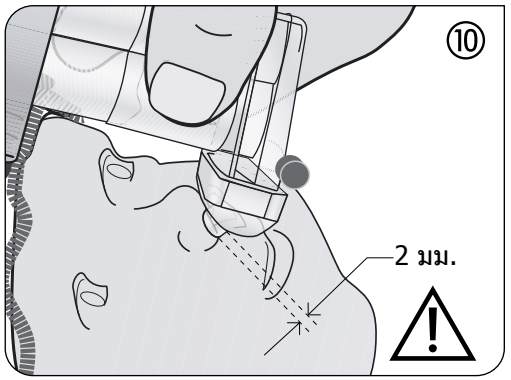
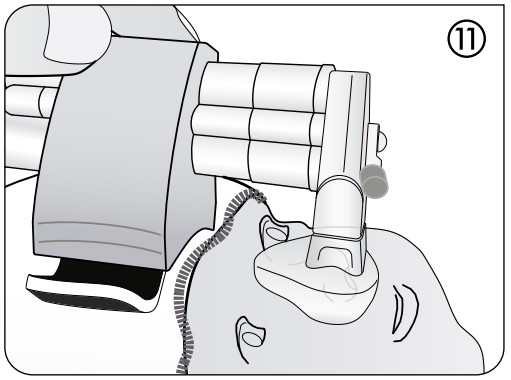
F&P คำแนะนำสำหรับผู้ใช้งาน FlexiTrunk™ Infant Interface



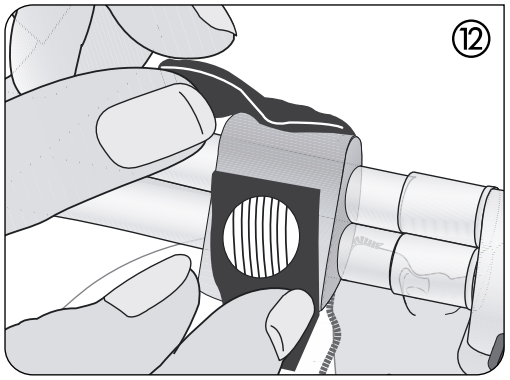
- ตั้งค่าการไหลของก๊าซตามระดับที่กำหนดไว้
- เปิดเครื่องทำความชื้น อ้างอิงตามคำแนะนำของผู้ผลิต
- ⚠ วางมือไว้ใกล้กับท่อหรือหน้ากากช่วยหายใจเพื่อตรวจให้แน่ใจว่ามีการไหลของก๊าซ



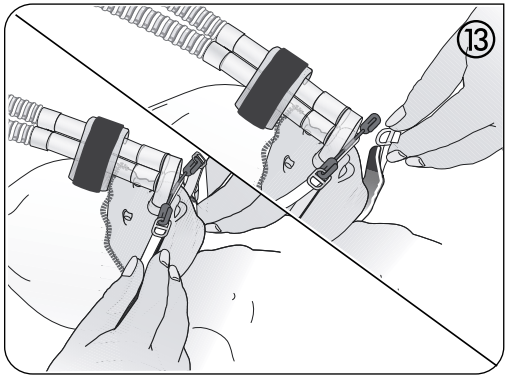
- **หากใช้ท่อ:** ทำความสะอาดน้ำมูกก่อนสอดใส่ท่อช่วยหายใจ
- ⚠ ตรวจดูให้แน่ใจว่าได้จัดวางตำแหน่งท่อช่วยหายใจห่างอย่างน้อย 2 มม. (0.08 นิ้ว) จากผนังกั้นจมูก เพื่อหลีกเลี่ยงแผลจากแรงกด ปรับค่าตามจะเป็น
- แนะนำให้ตรวจดูผนังกั้นจมูกทุก ๆ ชั่วโมง



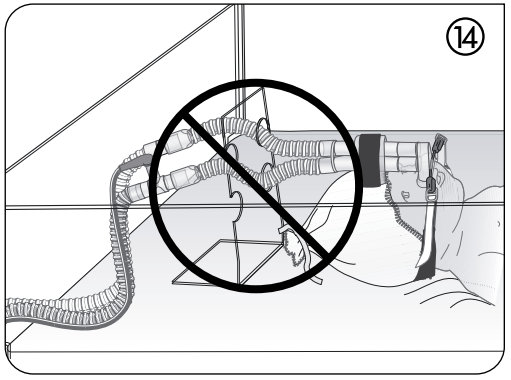
- **หากใช้หน้ากาก:** เชื่อมต่อเข้ากับผู้ป่วยโดยวางหน้ากากบริเวณรอบจมูก หน้ากากควรวางเบา ๆ บริเวณรอบจมูกของผู้ป่วย ซึ่งต้องไม่อุดจมูกหรือสัมผัสบริเวณผนังกั้นจมูกและไม่ควรปกคลุมเกินไปถึงบริเวณริมฝีปากหรือดวงตา



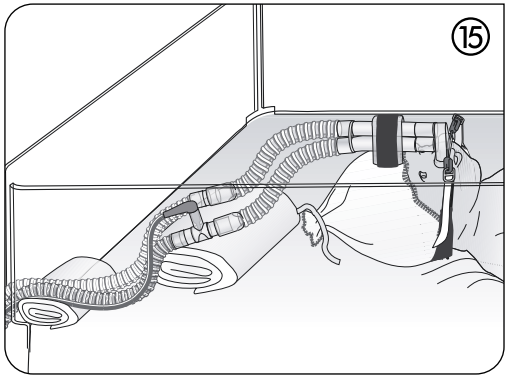
- จัดความสูงของบล็อกโฟมโดยเพิ่มหรือถอดสายรัดแบบฉีกขาด การติดตั้งหน้ากากอาจจำเป็นต้องมีการเพิ่มสายรัดสำหรับการจัดวางตำแหน่งที่ถูกต้อง
- วางสายรัดไว้เหนือบล็อกโฟมและรัดให้แน่นเพื่อยึดท่อเอาไว้ให้อยู่ในตำแหน่ง



- เกี่ยวคลิปจากสายรัดด้านข้างของหมวกเข้ากับเครื่องร่อน
- ดึงสายรัดทั้งสองพร้อมกันเพื่อให้ได้ตำแหน่งกลางพอดี
- ติดแถบเวลโครแบบวงกลมเข้ากับสายรัดสีน้ำเงินของหมวก
- ให้มีความตึงน้อยที่สุดเพื่อรักษาระดับแรงดันบวกชนิดต่อเนื่องที่กำหนดไว้และเสถียรภาพของ Infant Interface



- "ห้าม" ใช้ angel frames, Christmas trees หรืออุปกรณ์อื่นที่คล้ายกัน เนื่องจากสิ่งเหล่านี้อาจเจาะท่อ FlexiTrunk™ และก่อให้เกิดการสูญเสียความดัน



- ตรวจสอบให้แน่ใจว่าน้ำหนักของวงจรได้รับการสนับสนุนอย่างนุ่มนวล เพื่อช่วยลดความตึงของท่อช่วยหายใจ แนะนำให้ใช้ผ้าขนหนูพับหรือหมอน ท่อ FlexiTrunk™ ต้องมีการเคลื่อนไหวที่อิสระ เพื่อช่วยให้ศีรษะของเด็กสามารถเคลื่อนไหวได้โดยไม่ถูกจำกัดไว้
- ควรวางวงจรไว้ใต้ระดับท่อช่วยหายใจในการลดการควบแน่นในเด็กลง

- ตรวจดูผู้ป่วยบ่อย ๆ เพื่อหารอยแดง แผลจากแรงกด หรือการระคายเคือง ซึ่งอาจส่งผลมาจากการใช้งานท่อหรือหน้ากากเป็นเวลานาน แนะนำให้ตรวจดูทุก ๆ ชั่วโมง
- การสลับเปลี่ยนระหว่างการใช้หน้ากากและท่อสามารถช่วยลดความเสี่ยงของการระคายเคืองได้ แนะนำให้สลับเปลี่ยนทุก ๆ 4-6 ชั่วโมง
- ควรปรับตำแหน่งของหน้ากากให้พอดีที่สุดและมีรอยรั่วน้อยที่สุด หากมีรอยรั่วมากเกินไป อาจเพิ่มการไหลแทนได้ อัตราการไหลสูงสุดที่อนุญาตคือ 15 ลิตร/นาที
- ตรวจดูการควบแน่นอย่างสม่ำเสมอและระบายออกหากจำเป็น

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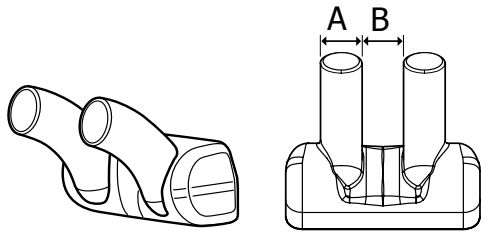
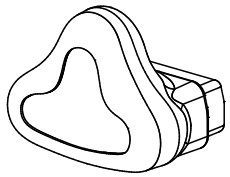
F&P คำแนะนำสำหรับผู้ใช้งาน FlexiTrunk™ Infant Interface

ท่อช่วยหายใจทางจมูกสำหรับทารก



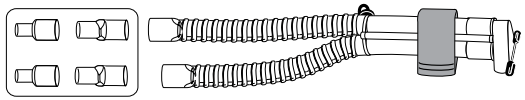
รหัสผลิตภัณฑ์	A	B
BC3020	3.0 มม.	2.0 มม.
BC3520	3.5 มม.	2.0 มม.
BC4030	4.0 มม.	3.0 มม.
BC4540	4.5 มม.	4.0 มม.
BC5040	5.0 มม.	4.0 มม.
BC5050	5.0 มม.	5.0 มม.
BC5550	5.5 มม.	5.0 มม.
BC5560	5.5 มม.	6.0 มม.
BC6060	6.0 มม.	6.0 มม.
BC6070	6.0 มม.	7.0 มม.
BC6570	6.5 มม.	7.0 มม.

หน้ากากช่วยหายใจสำหรับทารก



รหัสผลิตภัณฑ์	ขนาด
BC800	S
BC801	M
BC802	L
BC803	XL

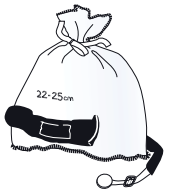
ท่อช่วยหายใจสำหรับทารก



ชุดผลิตภัณฑ์ **BC19x**

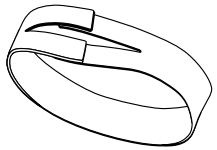
รหัสผลิตภัณฑ์	ขนาด
BC190	50 มม.
BC191	70 มม.
BC192	100 มม.

หมวกทารก



รหัสผลิตภัณฑ์	ขนาด
BC300	17-22 ซม.
BC303	22-25 ซม.
BC306	25-29 ซม.
BC309	29-36 ซม.

สายรัดคางสำหรับทารก



รหัสผลิตภัณฑ์	ขนาด
BC351	20-26 ซม.
BC353	26-32 ซม.
BC355	32-38 ซม.
BC357	38-44 ซม.

หมวกสำหรับทารก

รหัสผลิตภัณฑ์	ขนาด
BC325	29-36 ซม.
BC328	35-40 ซม.
BC331	40-45 ซม.

LATEX

CE 0123
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FlexiTrunk™ Bebekler İçin Arabağlantı Kullanıcı Talimatları

tr

Kullanım Amacı

F&P Bebekler İçin Arabağlantı, eğitimli tıbbi personel tarafından hastanın yeterli şekilde izlendiği hastanede veya klinik bir ortamda en fazla 10 kg ağırlığındaki spontan nefes alan bir hastaya noninvaziv pozitif basınçlı ventilasyon sağlamak üzere tasarlanmıştır.

Ürün Teknik Özellikleri

BC190 **BC191** **BC192**	F&P Bebekler İçin Arabağlantı, Fisher & Paykel Healthcare Bubble CPAP Sistemi'ne bağlanmak için tasarlanmıştır. Adaptörler, başka üreticinin CPAP devrelerinin 7,8 veya 10 mm'lik konektörler ile bağlantısını sağlar.
Maksimum giriş akışı	15 L/dk
İzin verilen maksimum çalışma basıncı	15 cmH_2O

Ebatlar ve bileşenler için lütfen son sayfaya bakın.

Kontrendikasyonlar

- Spontan olmayan solunum
- Binazal pronglar veya nazal maskenin kontrendike olduğu (örn. koanal atrezi) konjenital anomaliler veya malformasyonlar.
- Pozitif basınç tedavilerinin kontrendike olduğu (örn. diafragmatik herni ve trakeoözofageal fistül) konjenital anomaliler veya malformasyonlar.
- Nazal prongların veya nazal maskenin kullanımı ile şiddetlenebilen nazal travma/ciddi deformite.

UYARILAR

Bebek İçin Arabağlantının bileşenleri tek hastada kullanıma yöneliktir. **Tekrar kullanım, enfeksiyöz maddelerin bulaşmasına, tedavinin kesilmesine, ciddi zarara veya ölüme neden olabilir.**

Dikkatli tutun. Bebek İçin Arabağlantı'yı konumlandırıyor veya bağlantısını kesiyorken dikkatli olun. Aşırı çekme güçlerinden, keskin nesnelerden veya hortum sistemi tutucularından kaçının. Hortum sistemine zarar gelmesi basınç kaybına neden olabilir ve derhal değişim gerektirebilir.

Bu ürün maksimum 7 gün kullanılmaya yöneliktir.

Ürün veya paket zarar görmüşse KULLANMAYIN.

- ABD Federal Yasaları uyarınca, bu cihazın satışı yalnızca bir doktor tarafından veya bir doktorun talimatıyla yapılabilir.
- Bu ürünü DEĞİŞTİRMEYİN.
- Hasta oksijen izleme donanımı kullanın.
- Başka üreticilerin nemlendirme sistemlerine bağlama, hastaya yoğuşmalı ve/veya yüksek gaz sıcaklığı verilmesi riskini artırır.
- Basınç izleme cihazlarını sadece nazal tüp sistemi üzerindeki basınç izleme portuna bağlayın.
- Bebekler İçin Arabağlantı bileşenleri temiz durumda verilir. Kullanım sırasında ve imha ile biyokontaminasyonu önlemek için uygun yöntemleri uygulayın.
- Bu ürünü suya BATIRMAYIN, YIKAMAYIN, STERİLİZE ETMEYİN ya da YENİDEN KULLANMAYIN.
- Bebek bonesi askılarını fazla SIKMAYIN.
- Boğulma meydana gelebileceğinden bebeğin yüzünü Bebek Bonesi ile KAPATMAYIN.
- YALNIZCA tavsiye edilen F&P Bebek İçin Arabağlantı bileşenlerini KULLANIN, onaylanmayan yedek ürünlerle nazal prongların ve maskenin bozuk konumlandırılması ortaya çıkabilir.
- Prongların ve maskenin doğru ebatlandırmasına veya yerleşimine dikkat edilmezse Septal Nekroz meydana gelebilir.
- **Hastanın reçete edilen CPAP seviyesini aldığını doğrulamak için her zaman basınç izleme donanımı kullanın.**
- Tyloxapol (Tacholiquin gibi) içeren ilaçları KULLANMAYIN, bu hortum sistemine zarar verebilir ve CPAP basıncı kaybına yol açabilir.

Kurulum

- **BC190, BC191, BC192**

Bebek İçin Arabağlantı'nın kurulumundan önce F&P Bubble CPAP Sistem talimatlarına bakın.

Adaptörler kullanıyorsanız, Bebek İçin Arabağlantı'nın kurulumundan önce devre üreticisi tarafından sağlanan kurulum talimatlarına bakın.

- Doğru kurulum için 1-15. resimlere bakın.
- Doğru ürün boyutlandırması için, son sayfadaki tablolara bakın.
- Maksimum basınç tahliye cihazı KULLANILMALIDIR. Bebek CPAP sistemi için basınç tahliye ayarları olacaktır.

Çalışma Öncesindeki Kontroller

- Nazal tüp sistemindeki basınç izleme portu kullanılmadığında, kapak kapatılmalıdır.
- Kullanmadan önce ve herhangi bir ayardan sonra tüm devre bağlantılarının sıkı olduğunu kontrol edin.

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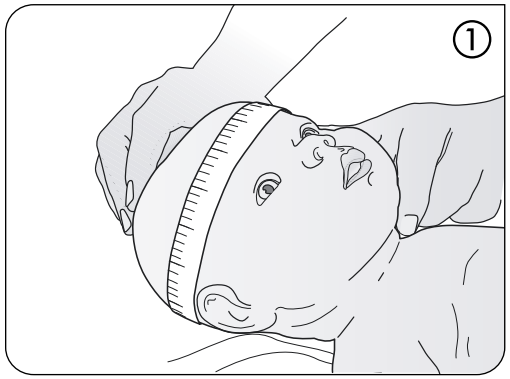
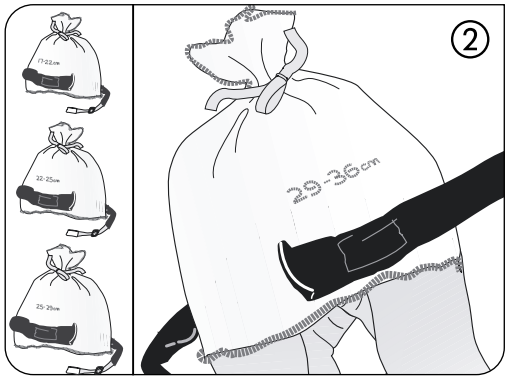
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

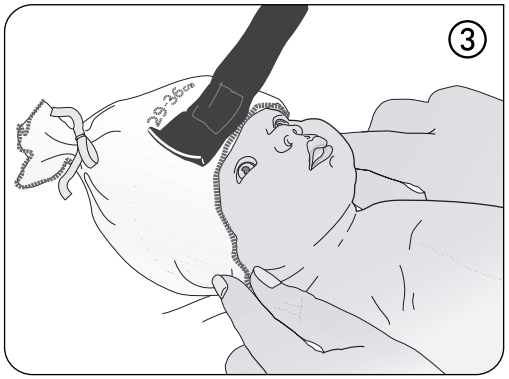
FlexiTrunk™ Bebekler İçin Arabağlantı Kullanıcı Talimatları



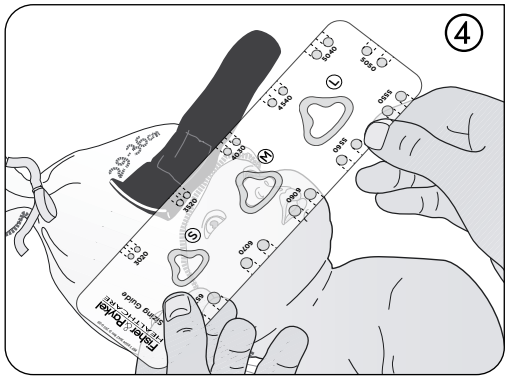
- Bebeğin başının çevresini santimetre olarak ölçün.



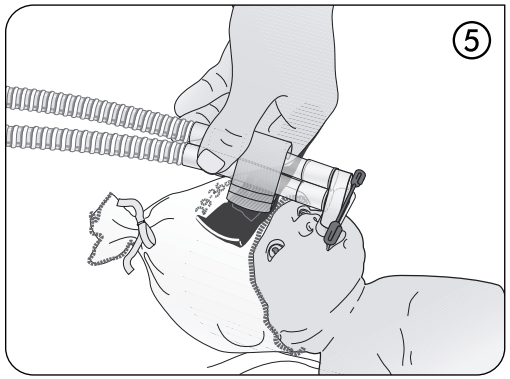
- Doğru ebattaki boneyi seçin. Bone tam oturmalıdır.
- Kolay yerleştirme için öncelikle boneyi ellerinizle gerdirin.



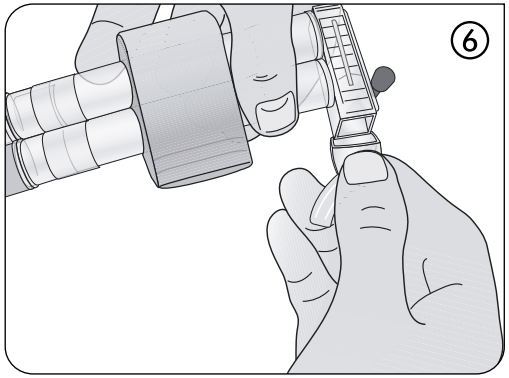
- Boneyi, kulakları tamamen kapatacak ve arka kenarı ense kökünde olacak şekilde bebeğin başı üzerinde kaydırın. Bonenin ön kenarı kaşların hemen yukarısında veya üzerinde olmalıdır.



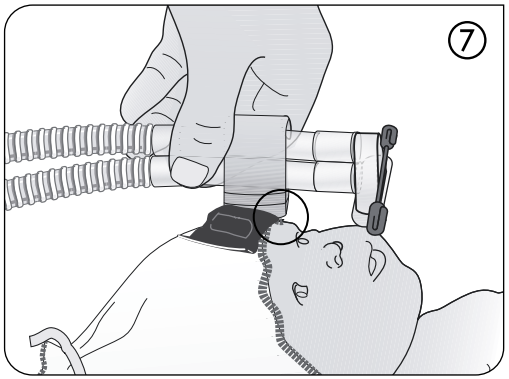
- Uygun pronglar veya maske seçimi için ebatlandırma kılavuzu kullanın.
- Pronglar cildi gerdirmeden burun deliklerini tamamen doldurmalıdır. Mümkün olan en büyük ebadı kullanın.
- Maske burun kenarı, septum veya gözlere temas etmemelidir.



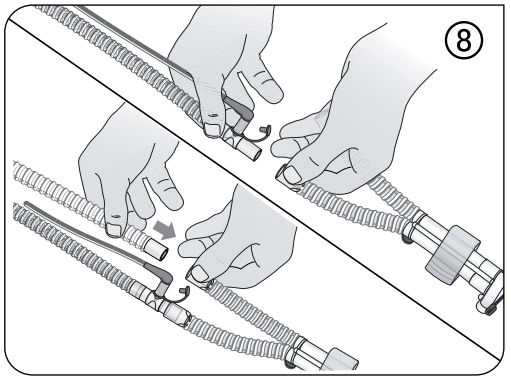
- Doğru nazal tüp sistemi boyunu seçin. Mümkün olan en kısa boyu kullanın.
- Temiz tüp sistemi, bebeklerin alnının ötesine geçmemelidir.
- Aşağıdaki boy bir kılavuz olarak kullanılabilir: 50 mm ≤ 1,5 kg, 70 mm ≤ 2,5 kg, 100 mm > 2,5 kg



- Tam olarak yerleştiğinden emin olmak için, prongları veya maskeyi nazal tüp sistemine bağlayın.
- Pronglar kullanıyorsanız: olukları açığa çıkarmak için prongların kenarlarını iyice sıkıştırın. Bir uçtan başlayın ve prong oluklarını nazal tüp sistemine yerleştirin. Ucu sıkıca itin.



- Çeperi en uyun hale getirmek üzere nazal tüp sistemi açısını ayarlamak için etiket şeritleri gerektiği şekilde çıkarın.
- Nazal pronglar ve maskeler arasında değişim yapıyorken gerekli olabileceklerinden etiket şeritlerini ATMAYIN.



- Devreyi nazal tüp sistemine her iki yönde bağlayın.
- Daha fazla ayrıntı için devre üreticisi tarafından verilen talimatlara bakın.
- Not: Konektörleri çevirerek FlexiTrunk™ sistemini yavaşça çıkarın. Tüp sistemine zarar verebileceğinden güç uygulayarak ÇEKMEYİN.
- **Dikkatli tutun.**

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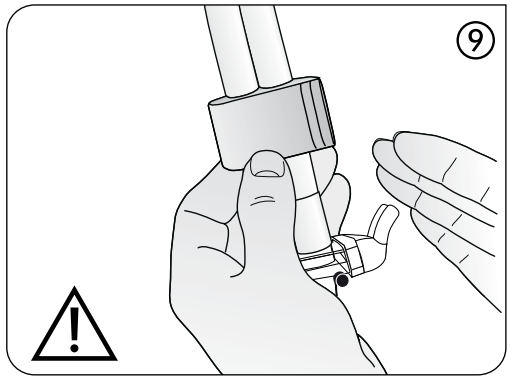
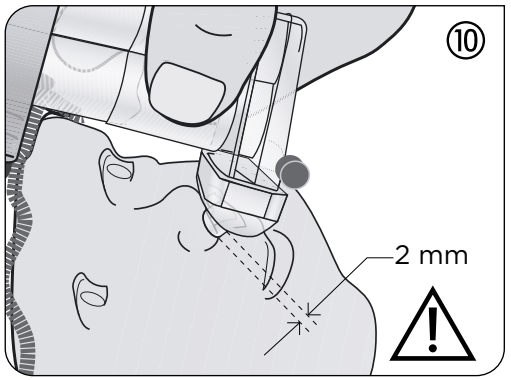
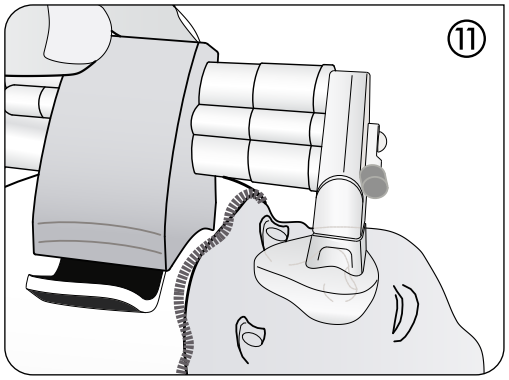
FlexiTrunk™ Bebekler İçin Arabağlantı Kullanıcı Talimatları



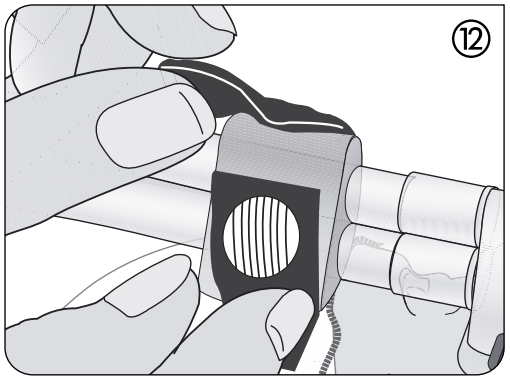
- Gaz akışını reçete edilen seviyeye ayarlayın.
- Nemlendiriciyi açın. Üreticinin talimatlarına bakın.
- ⚠ Gaz akışının olduğundan emin olmak için elinizi nazal pronglara veya maskeye yakın tutun.



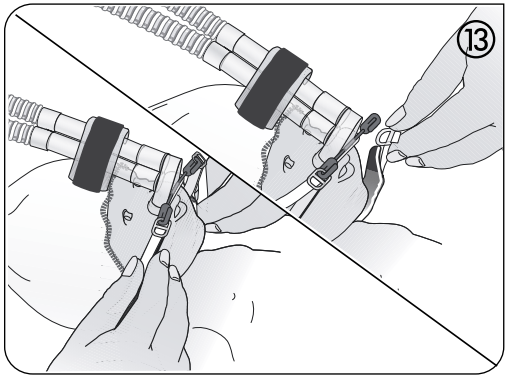
- **Pronglar kullanıyorsanız:** Nazal prongları yerleştirmeden önce nazal sekresyonları temizleyin.
- ⚠ Basınç nekrozunu önlemek için nazal prongların septumdan en az 2 mm (0,08 inç) uzağa yerleştirildiğinden emin olun. Gerektiği şekilde ayarlayın.
- Septum bütünlüğünün her saat başı kontrol edilmesi tavsiye edilir.



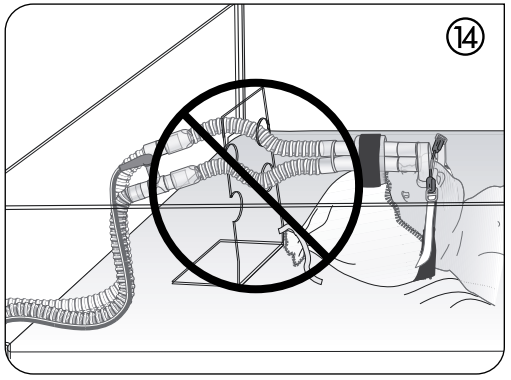
- **Maske kullanıyorsanız:** Maskeyi burun etrafına yerleştirerek hastaya bağlayın. Maske hastanın burnunun etrafına rahat bir şekilde oturmalıdır. Burun deliklerini tıkamamalı veya septuma temas etmemelidir ve dudak veya gözlerin üzerinde olmamalıdır.



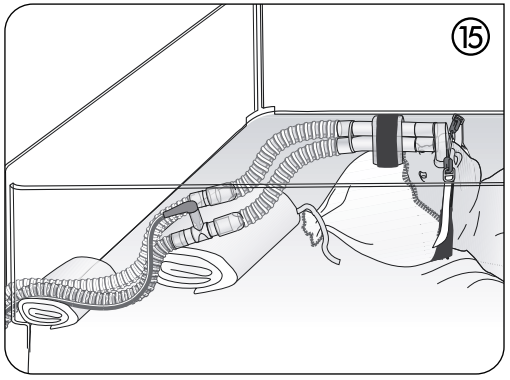
- Etiket şeritleri ekleyerek veya kaldırarak köpük bloğun yüksekliğini ayarlayın. Doğru konumlandırma için maske ile ilgili ayarlar şeritlerin eklenmesini gerektirebilir.
- Askıyı köpük blok üzerine yerleştirin ve tüp sistemini yerinde tutmak üzere sıkılaştırın.



- Bonenin yan askılarındaki klipsleri glider'a takın.
- Merkezi konumlandırma için her iki askıyı aynı anda çekin.
- Yuvarlak cırt cırt bantlarını bonenin mavi askısına yapıştırın.
- Reçete edilen CPAP seviyesini ve Bebek İçin Arabağlantı stabilitesini sürdürmek için mümkün olan en az gerilimi kullanın.



- FlexiTrunk™ tüp sistemini delebileceği ve basınç kaybına neden olabileceği için, açı çerçeveleri, Christmas tree veya benzeri cihazlar KULLANMAYIN.



- Nazal tüp sistemi üzerindeki gerilimi azaltmak için devre ağırlığının hafifçe desteklenmesini sağlayın. Bir yastık veya katlanmış havlu tavsiye edilir. FlexiTrunk™ tüp sistemi, bebeğin başının kısıtlama olmadan hareket etmesini sağlamak için serbest harekete sahip olmalıdır.
- Bebekteki yoğuşmayı en aza indirmek için devre, nazal tüp sistemi altında tutulmalıdır.

Çalışma Esnasındaki Kontroller

- Uzun süre prong veya maske kullanımından kaynaklanabilen kızarıklık, bası yaraları veya irritasyon için hastayı sık sık kontrol edin. Her saat başı kontrol tavsiye edilir.
- Maske ve pronglar arasında değişim yapılması irritasyon riskini azaltabilir. 4 ila 6 saatte bir değişim yapılması tavsiye edilir.
- Maskenin konumlandırılması en iyi uyum ve minimum sızıntı için ayarlanmalıdır. Hala fazla sızıntı varsa, telafi etmek için akış artırılabilir. İzin verilen maksimum akış hızı 15 L/dk'dir.
- Yoğuşmayı düzenli olarak kontrol edin ve gerekirse boşaltın.

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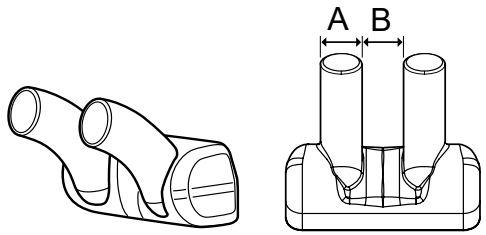
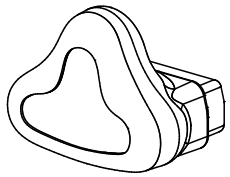
FlexiTrunk™ Bebekler İçin Arabağlantı Kullanıcı Talimatları

BEBEK NAZAL PRONGLARI



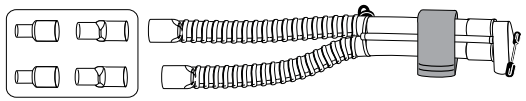
Ürün Kodu	A	B
BC3020	3,0 mm	2,0 mm
BC3520	3,5 mm	2,0 mm
BC4030	4,0 mm	3,0 mm
BC4540	4,5 mm	4,0 mm
BC5040	5,0 mm	4,0 mm
BC5050	5,0 mm	5,0 mm
BC5550	5,5 mm	5,0 mm
BC5560	5,5 mm	6,0 mm
BC6060	6,0 mm	6,0 mm
BC6070	6,0 mm	7,0 mm
BC6570	6,5 mm	7,0 mm

BEBEK NAZAL MASKESİ



Ürün Kodu	Ebat
BC800	S
BC801	M
BC802	L
BC803	XL

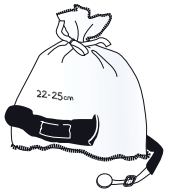
BEBEK NAZAL TÜP SİSTEMİ



BC19x serisi

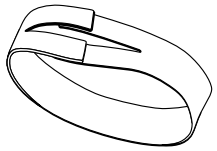
Ürün Kodu	Ebat
BC190	50 mm
BC191	70 mm
BC192	100 mm

BEBEK BONESİ



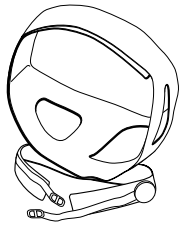
Ürün Kodu	Ebat
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

BEBEK ÇENE ASKISI



Ürün Kodu	Ebat
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

BEBEK BAŞLIĞI



Ürün Kodu	Ebat
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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FlexiTrunk™ 婴儿界面使用说明

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用途

费雪派克婴儿界面设计用于对医院或临床上体重不超过10公斤且能够自主呼吸的患儿提供无创正压通气，这些患儿须由经过熟练培训的的医务人员全面监护。

产品技术参数

BC190 **BC191** **BC192**	费雪派克（F&P）婴儿界面设计用于连接至费雪派克医疗保健公司婴儿正压呼吸治疗系统（Fisher & Paykel Healthcare Bubble CPAP）。 转接头可以通过 7.8 或 10 mm 接头连接其他制造商的 CPAP 管路。
最高输入流量	15 升/分钟
允许的最高工作压力	15厘米水柱

请参阅最后一页以了解尺寸和组件。

禁忌

- 非自主呼吸。
- 忌用双鼻塞或鼻罩的先天性异常或畸形（如：先天性后鼻孔闭锁）。
- 忌用正压治疗的先天性异常或畸形（如：膈疝和食管气管瘘）。
- 可能因使用鼻塞或鼻罩而加重的鼻外伤/严重畸形。

警告

婴儿界面的所有组件仅供患儿一次性使用。**重复使用会导致感染物质传播、干扰治疗、严重损伤乃至死亡。**

小心操作。固定或断开婴儿界面时请小心。避免用力拉扯，使用尖锐物品和管道架。管道损坏可导致压力丢失，必须立即更换。

此产品最多可使用7天。

如果产品或包装损坏，请勿使用。

- 请勿改动此产品。
- 固定婴儿界面时要小心。尖锐棱角和/或粗糙表面会损坏本产品。
- 对患儿进行氧气监测。
- 使用其他制造商的湿化系统有增加冷凝水和/或向患儿输送气体温度过高的危险。
- 压力监测设备只能连接在前置鼻管的压力监测口上。
- 婴儿界面的各组件均以清洁状态提供。在使用和弃置时，请采取适当的手段防止生物污染。
- 请勿浸泡、清洗、消毒或重复使用本产品。
- 不要过度地拉紧婴儿头套束带。
- 不要用婴儿头套覆盖在婴儿的脸部，可能会造成窒息。
- 建议只能使用推荐的费雪派克公司的婴儿界面组件，使用未批准的替代品会影响鼻塞和鼻罩的位置固定。
- 如果鼻塞和鼻罩的大小或固定不当，会引起鼻中隔坏死。
- **始终使用压力监控，以保证病人正接受处方的CPAP水平。**
- 不要使用含泰洛沙泊的药品(比如Tacholiquin), 因为这可导致管道损坏并使CPAP压力丧失。

安装

- **BC190, BC191, BC192**

安装婴儿界面前，请先参阅费雪派克婴儿正压呼吸治疗（Bubble CPAP）系统的说明。

如果使用转接头，安装婴儿界面前，请先参阅管路制造商提供的安装说明。

- 请参阅图1-15以了解正确的安装步骤。
- 有关正确的产品尺寸，请查阅最后一页上的表格。
- 必须使用具有压力释放功能的装置。压力释放设置应适合婴儿持续气道正压通气。

操作前的检查

- 如果不使用压力监测时，确保前置鼻管上压力监测口的盖子关闭。
- 使用前以及进行任何调整后，检查以确保所有回路连接均牢固。

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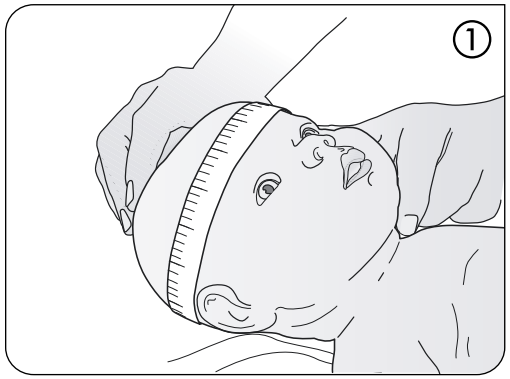
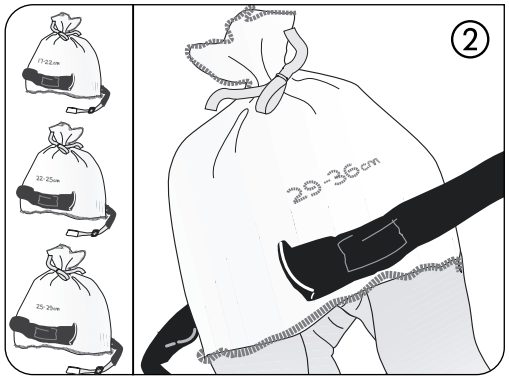
Fisher & Paykel HEALTHCARE

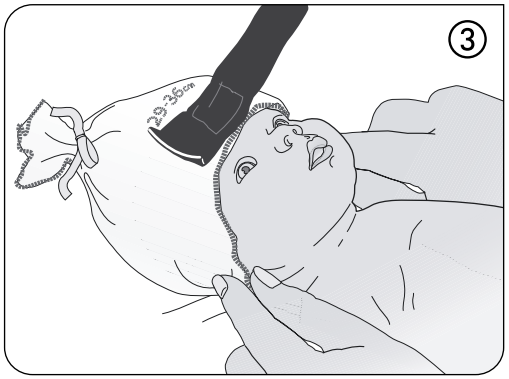
FlexiTrunk™ 婴儿界面使用说明



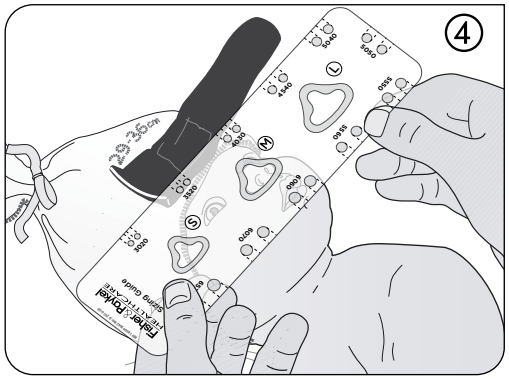
- 以厘米为单位测量婴儿头围的尺寸。



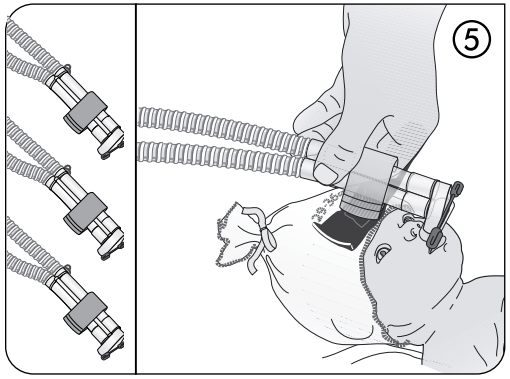
- 选择正确的头套尺寸，头套应帖服，大小合适。
- 用手撑开头套以便于佩戴。



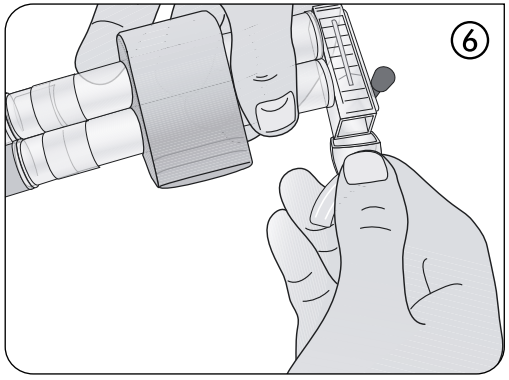
- 将头套戴到婴儿的头上，完全覆盖耳朵，头套后面的边缘应在颈背部。头套前边的帽檐应刚好在眉毛或稍上位置。



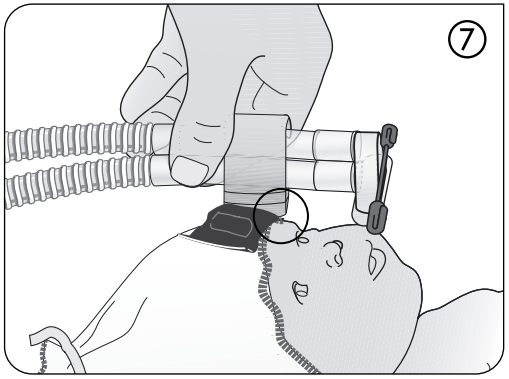
- 使用尺寸选择指南选择合适的鼻塞或鼻罩。
- 鼻塞应完全填满鼻孔，不要有挤压皮肤。尽可能使用最大尺寸的鼻塞。
- 鼻罩不应接触鼻周、鼻中隔或眼睛。



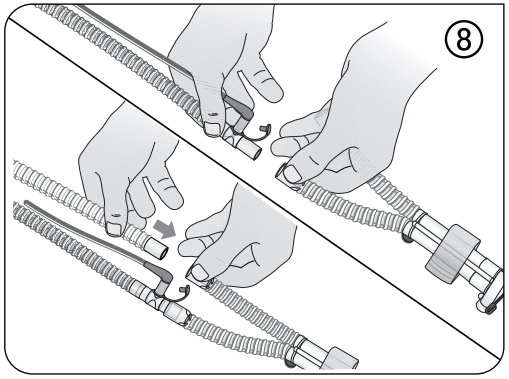
- 选择适当的前置鼻管长度。尽量采用长度最短的前置鼻管。
- 鼻管的透明部分不应超过婴儿的前额。
- 以下内容可作为指引：50毫米 ≤ 1.5公斤；70毫米 ≤ 2.5公斤；100毫米 > 2.5公斤



- 将鼻塞或鼻罩连接至鼻管，确保其完全插入。
- 如果使用鼻塞：挤压鼻塞侧面以显示沟槽。从一端开始，将鼻塞沟槽插入鼻管中。牢固推入至末端固定。



- 需要时撕下泡沫衬垫以调整鼻管角度，保证最佳密封状态。
- 不要丢弃可撕性泡沫衬垫片，因为在鼻塞和面罩替换使用时可能会需要到。



- 将回路连接至鼻管，不用区分进、出气管。
- 请参阅管路制造商提供的说明以了解更多信息。
- 注：通过轻轻扭转接头分离FlexiTrunk™。不要用力拉扯，因为这可使管损坏。
- 小心操作。

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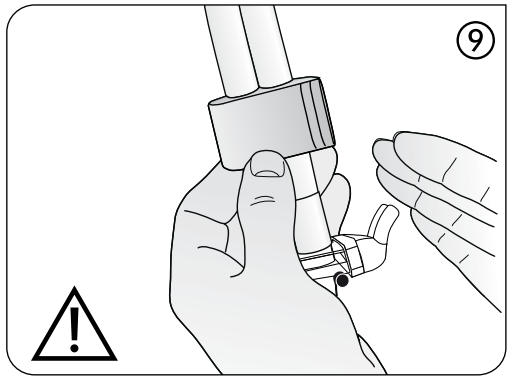
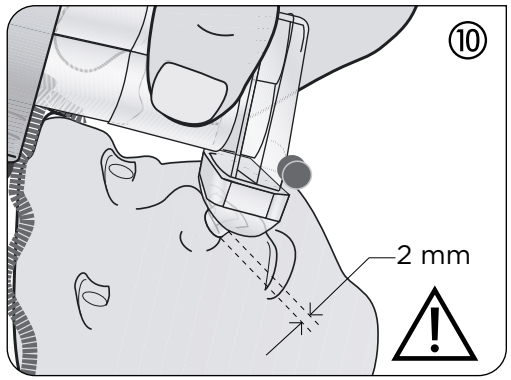
FlexiTrunk™ 婴儿界面使用说明



- 将气流设为指定的流量。

开启湿化器。请参阅制造商的说明。

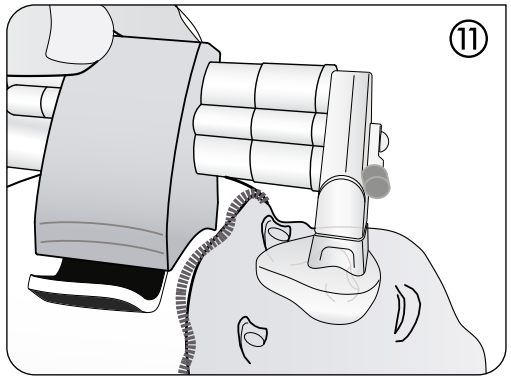
将手放近鼻塞或鼻罩确保存在气流。



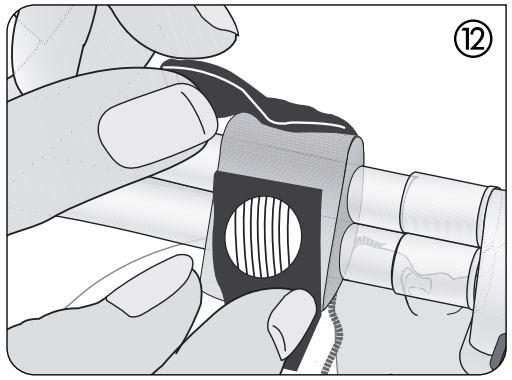
- **如果使用鼻塞**：插入鼻塞前应先清洁鼻中分泌物。

确保鼻塞在鼻中隔间至少留下2毫米（0.08英寸）间隔，以免鼻中隔受压坏死。根据需要进行调整。

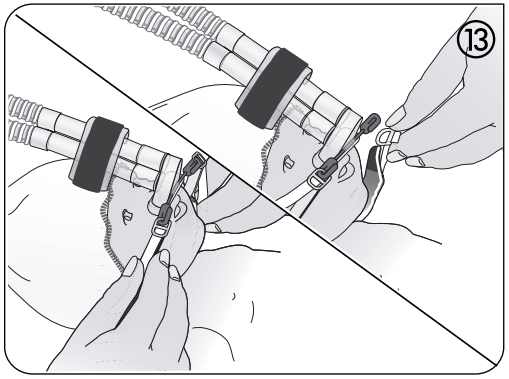
- 建议每小时检查一次鼻中隔的完整性。 建议每小时检查一次鼻中隔的完整性。



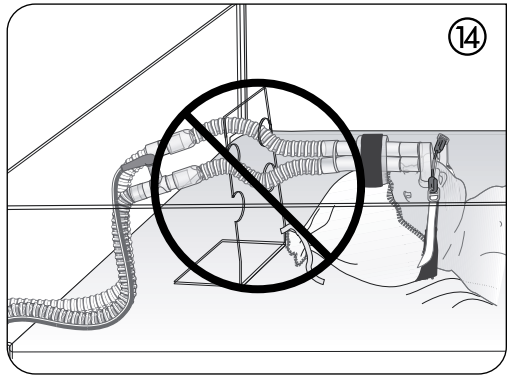
- **如果使用鼻罩**：将鼻罩罩住病人的鼻子。鼻罩应舒适地罩住鼻周。不能堵住鼻孔或触及鼻中隔，且不应在罩在嘴唇或眼睛之上。



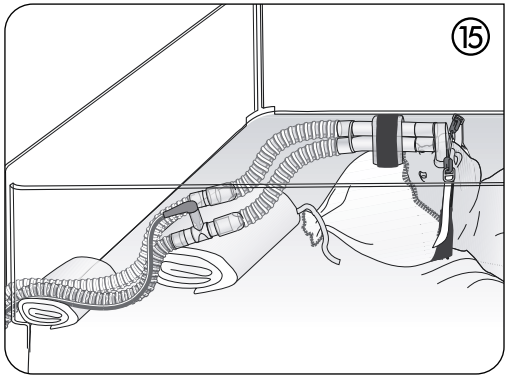
- 通过添加或除去可撕性泡沫衬垫片设置泡沫衬垫的高度。使用鼻罩时可能需要添加垫条以妥善固定。
- 将头套上尼龙搭扣带中间的带子包住鼻管泡沫部件并绷紧以固定鼻管的位置。



- 将头套侧面的带环挂到滑条上。
- 同时拉动两边的带子以中线定位。
- 头套上蓝色带子的末端粘贴到头套侧面的尼龙搭扣上。
- 尽量使用最小张力来保持指定的持续气道正压通气压力和婴儿界面的固定。



- 不要使用角度限位架、X-限位器或类似装置，因为它们可刺穿FlexiTrunk™管并导致压力丧失。



- 确保管路的重量有轻轻的支撑，以减少对前置鼻管的牵拉。推荐使用枕头或折叠毛巾。FlexiTrunk™管路必须有足够的长度以使婴儿头部活动不受限制。
- 管路应低于前置鼻管，以尽量减少婴儿端的冷凝水。

操作期间的检查

- 经常检查病人皮肤有无因鼻塞或鼻罩使用时间过长引起的发红、压疮或刺激的情况。建议每小时检查一次。
- 交替使用鼻罩和鼻塞可减少刺激风险。建议每4至6小时交替使用一次。
- 固定鼻罩时应调节至最舒适且漏气最小的位置。如果仍然漏气严重，则可通过提高流量来进行补偿。最大允许流量为15升/分钟。
- 定期检查有无冷凝水并根据需要排干。

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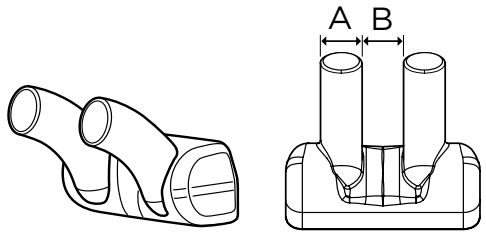
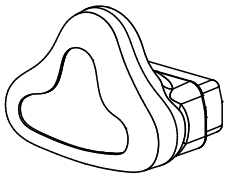
FlexiTrunk™ 婴儿界面使用说明

婴儿鼻塞



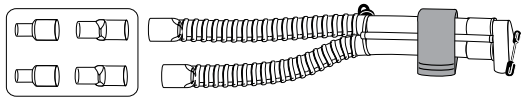
产品代码	A	B
BC3020	3.0 毫米	2.0 毫米
BC3520	3.5 毫米	2.0 毫米
BC4030	4.0 毫米	3.0 毫米
BC4540	4.5 毫米	4.0 毫米
BC5040	5.0 毫米	4.0 毫米
BC5050	5.0 毫米	5.0 毫米
BC5550	5.5 毫米	5.0 毫米
BC5560	5.5 毫米	6.0 毫米
BC6060	6.0 毫米	6.0 毫米
BC6070	6.0 毫米	7.0 毫米
BC6570	6.5 毫米	7.0 毫米

婴儿鼻罩



产品代码	尺码
BC800	小号
BC801	中号
BC802	大号
BC803	加大号

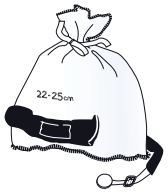
婴儿前置鼻管



系列

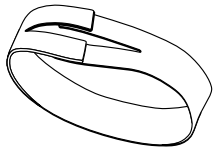
产品代码	尺码
BC190	50 毫米
BC191	70 毫米
BC192	100 毫米

婴儿头套



产品代码	尺码
BC300	17-22 厘米
BC303	22-25 厘米
BC306	25-29 厘米
BC309	29-36 厘米

婴儿下颌带



产品代码	尺码
BC351	20-26 厘米
BC353	26-32 厘米
BC355	32-38 厘米
BC357	38-44 厘米

婴儿头带

产品代码	尺码
BC325	29-36 厘米
BC328	35-40 厘米
BC331	40-45 厘米

LATEX

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产品名称	产品型号
婴儿正压呼吸治疗系统-前置鼻管	BC190-05，BC191-05，BC192-05
婴儿正压呼吸治疗系统-鼻塞	BC3020-10，BC3520-10，BC4030-10，BC4540-10， BC5040-10，BC5050-10，BC5550-10，BC5560-10， BC6060-10，BC6070-10，BC6570-10
婴儿正压呼吸治疗系统-鼻罩	BC800-10，BC801-10，BC802-10，BC803-10

注册人/生产企业名称：费雪派克医疗保健有限公司
注册人住所/生产企业住所/ 生产地址：15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand
联系方式 : +64 9 574 0100
医疗器械注册证编号/产品技术要求: 国械注进20193081702
参阅产品标签上的使用截止日期
生产日期: 参阅产品标签

符号定义

REF	目录编号
	请参考使用说明
	温度范围
PHT DEHP	含有 DEHP
Rx only	处方产品
	一次性使用
CE 0123	符合医疗器械指令 93/42/EEC
	制造商
EC REP	欧盟授权代表
LOT	批号
LATEX	不含天然乳胶
	制造日期
	在此日期前使用

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F&P FlexiTrunk™ 嬰兒介面使用說明

zht

設計用途

F&P 嬰兒介面是專為體重 10 公斤以下的自發呼吸病患，在醫院或臨床環境下接受非侵入式正壓通氣所設計的；使用本介面時，病患將受到經合格訓練的醫療人員的充份監控。

產品規格

BC190 **BC191** **BC192**	F&P 嬰兒介面是專為連接至 Fisher & Paykel Healthcare 公司之氣泡式連續氣道正壓系統所設計。 透過轉接頭，可與其他製造商所生產且含 7.8 或 10 mm 接頭的連續氣道正壓管路連接。
最大輸入流量	15 L/min
允許的最大工作壓力	15 cmH_2O

請參閱最後一頁，以取得尺寸和組件的相關資訊。

禁忌症

- 無自發性呼吸
- 先天異常或變形（例如後鼻孔閉鎖），禁忌使用雙鼻導管或鼻面罩。
- 先天異常或變形（例如橫膈膜疝氣及氣管食道廔管），禁忌使用正壓治療。
- 鼻創傷/嚴重變形，可能因使用鼻導管或鼻面罩而惡化。

警告

- 嬰兒介面的組件僅供單一病患使用。**重覆使用可能導致感染物質的傳播、治療中斷、嚴重傷害或死亡。**
- **請小心拿取。**在放置嬰兒介面或中斷其連接時，請小心謹慎。請避免過度用力拉扯、接觸到銳利的物體與管線支撐架。管路若有受損，可能會造成壓力降低，必須立即更換。
- 本產品最多可使用 7 天。
- 如果產品或包裝破損，切勿使用本產品。
- 美國聯邦法律規定本治療儀器為醫師處方產品。
- 切勿改裝本產品。
- 請監控病患的氧氣使用。
- 若是連接至其他製造商的濕化系統，將會增加冷凝的風險，且/或使供給病患的氣體溫度過高。
- 請只將壓力監控裝置連接至鼻管處的壓力監控埠。
- 嬰兒介面組件於供應時是處於清潔的狀態。請採用適合的做法，避免在使用與丟棄時造成生物污染。
- 切勿浸泡、洗滌、消毒或重複使用本產品。
- 切勿讓嬰兒軟帽帶過緊。
- 切勿讓嬰兒軟帽蓋住嬰兒的臉，因為這樣可能導致窒息。
- 僅使用建議的 F&P 嬰兒介面組件；使用未經核准的替代品，可能會導致鼻導管與面罩放置不當。
- 若未遵守鼻導管與面罩的正確尺寸與放置規定，可能會發生鼻中膈壞死。
- **務必進行壓力監控以確保病患獲得醫師處方的連續氣道正壓壓力。**
- 切勿使用含有四丁酚醛（例如 Tacholiquin）藥物，因為這會破壞管路及導致失去連續氣道正壓。

設定

- **BC190、BC191、BC192**
- 在設定嬰兒介面前，請先參閱「F&P 氣泡式連續氣道正壓系統」說明。
- 若使用轉接頭，在設定嬰兒介面前，請先參閱管路製造商所提供的設定說明。
- 請參閱插圖 1-15，以取得正確設定的相關資訊。
- 如需正確的產品尺寸，請參閱最後一頁的表格。
- 必須使用最大壓力釋放裝置。壓力釋放設定應適合嬰兒的連續氣道正壓。

操作前檢查事項

- 不使用鼻管上的壓力監控埠時，必須關上蓋子。
- 使用前及進行任何調整後，請先檢查所有管路連接都已緊固。

CE 0123
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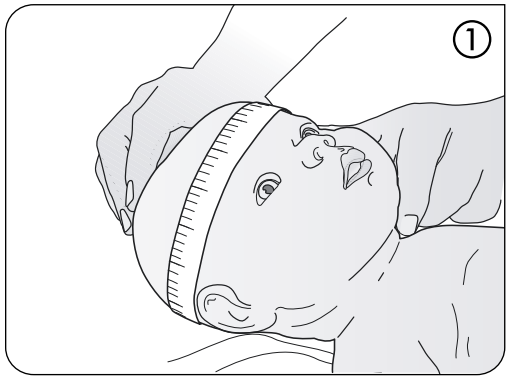
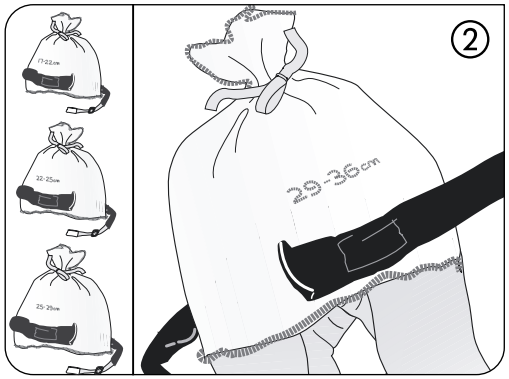
Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraiso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 94 1590 355 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH & Co. KG, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

Fisher & Paykel HEALTHCARE

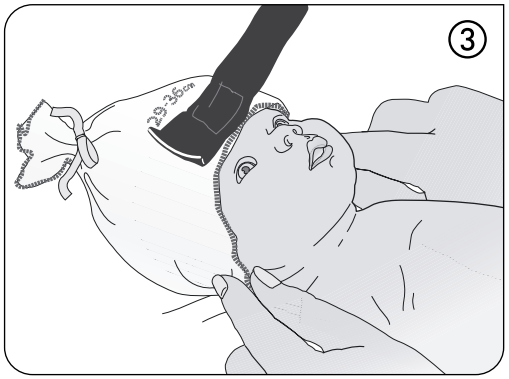
F&P FlexiTrunk™ 嬰兒介面使用說明



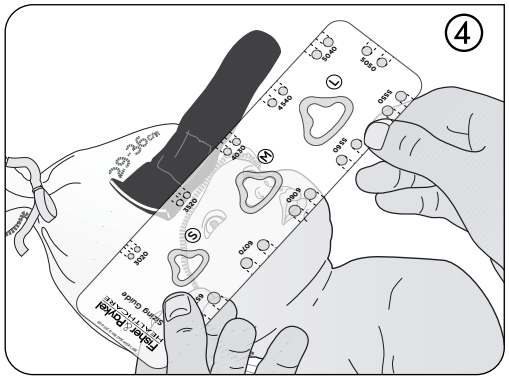
- 請以公分為單位測量嬰兒的頭圍。



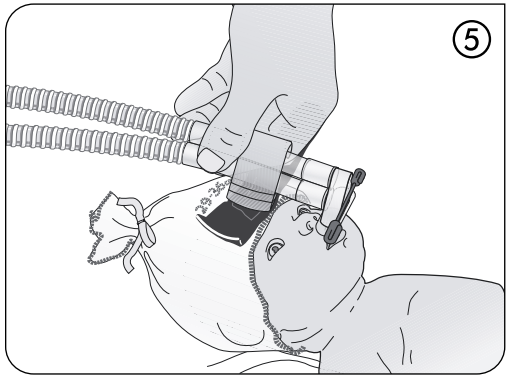
- 請選擇尺寸正確的軟帽。軟帽應緊密地貼合。
- 起初請先用手拉伸軟帽，使其容易戴上。



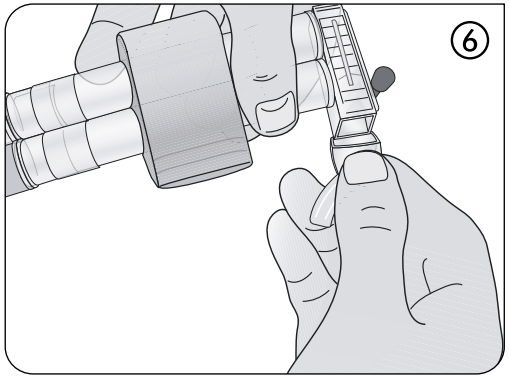
- 請將軟帽滑至嬰兒的頭上，完全蓋住雙耳，並且讓軟帽的後緣停在脖子的底部。軟帽的前緣應稍微高於眉毛或剛好在眉毛上。



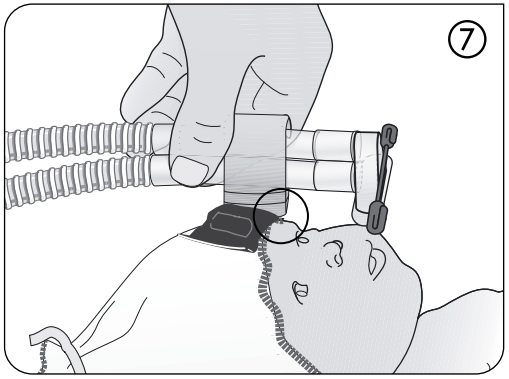
- 請使用尺寸說明指南來選擇適合的導管或面罩。
- 在不拉伸皮膚的情況下，導管應該完全填滿鼻孔。請儘可能使用最大的尺寸。
- 面罩不該碰觸鼻子的周圍、鼻中膈或眼睛。



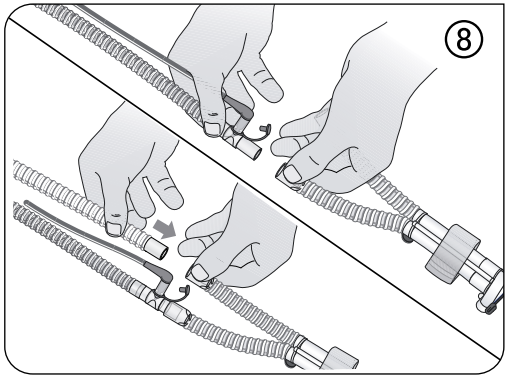
- 請選擇正確長度的鼻管。儘可能使用最短的長度。
- 不該讓透明管延伸至嬰兒的額頭上。
- 可按以下說明做選擇：
  50 mm ≤ 1.5 kg；70 mm ≤ 2.5 kg；
  100 mm > 2.5 kg



- 將導管或面罩接至鼻管時，請確保完全插入。
- 使用鼻導管時：請用力擠壓導管兩側，讓溝槽露出。請從一端開始，然後將鼻導管的溝槽插進鼻管。請用力將末端推入。



- 請依照要求移除可撕式泡綿墊，調整鼻管的角度，使密封獲得最佳效果。
- 切勿丟棄可撕式貼片，因為在鼻導管與面罩交替使用時，可能會需要用到泡綿墊。



- 請將管路以任一方向接至鼻管。

請參閱管路製造商所提供的說明，以取得更多詳細資訊。
注意：若要斷開 FlexiTrunk™ 連接，請輕輕扭轉接頭。切勿用力拉扯，因為這麼做可能會使管路受損。

請小心拿取。

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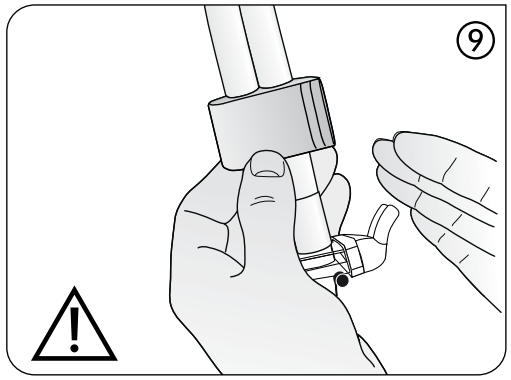
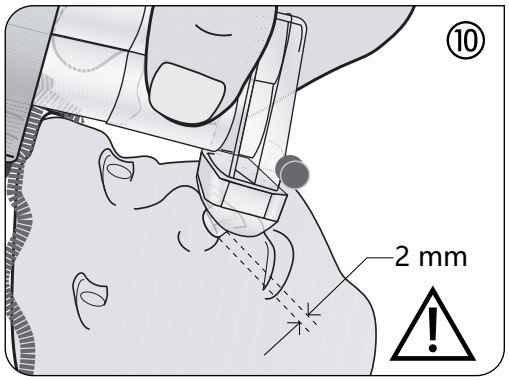
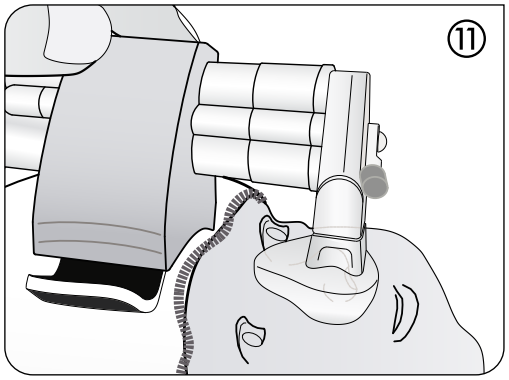
FlexiTrunk™ 嬰兒介面使用說明



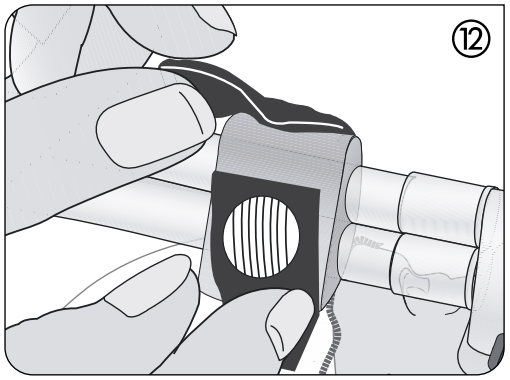
- 請將氣流設定至醫師處方的流量。
- 開啟濕化器。請參閱製造商的使用說明。
- ⚠ 請將手放在鼻導管或面罩附近，以確認有氣流存在。



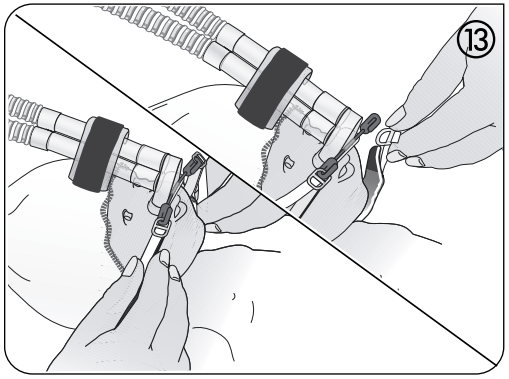
- **若使用導管時：**在插入鼻導管前，請先清除鼻子內的分泌物。
- ⚠ 請確保放置鼻導管的位置距離鼻中膈至少 2 mm（0.08 英吋），以避免壓迫性壞死。請視需要進行調整。
- 建議每小時檢查鼻中膈的完好性。



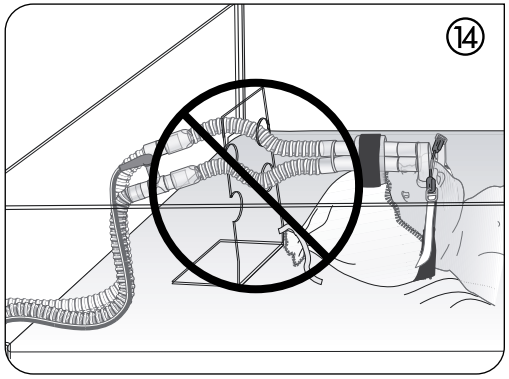
- **若使用面罩時：**請將面罩置於鼻子周圍，使病患戴上面罩。面罩應穩妥地落在病患鼻子周圍。面罩不得堵塞鼻孔或接觸鼻中膈，並且不應蓋住嘴唇或眼睛。



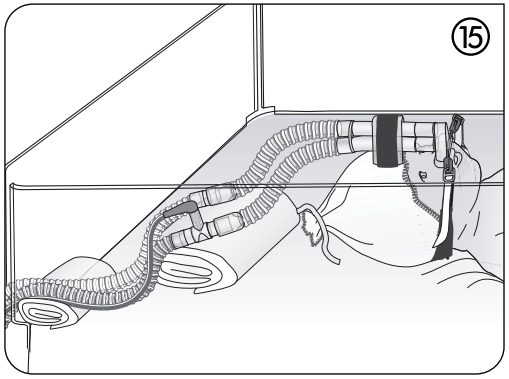
- 請藉著增加或移除可撕式泡綿墊來設定高度。設定面罩時可能需要增加可撕式泡綿墊，使其置於適當位置。
- 請將帶子置於泡綿墊上並拉緊，使管子牢牢固定到位。



- 請將軟帽側邊帶上的夾子勾住帶扣。
- 請同時拉動兩邊帶子，使其置中。
- 請將圓形的自黏貼片固定至軟帽的藍色帶子。
- 儘可能使用最小的拉力，來維持醫師處方下的連續氣道正壓壓力與嬰兒介面的穩定性。



- 切勿使用固定架、聖誕樹或類似的裝置，因為這類裝置可能會刺穿 FlexiTrunk™ 的管路，並且造成壓力喪失。



- 請小心確保管路的重量受到支撐，以降低鼻管的張力。建議使用枕頭或折疊的毛巾。FlexiTrunk™ 管路必須能夠自由移動，讓嬰兒的頭部移動時能夠不受限制。
- 管路應維持在鼻管的高度以下，將嬰兒端所產生的凝結減到最少。

- 請經常檢查患者是否因長時間使用導管或面罩，而出現皮膚發紅、壓力造成疼痛或刺激等問題。建議每小時進行檢查。
- 交替使用面罩與鼻導管，可以降低刺激的風險。建議每 4 到 6 小時交替使用。
- 應適當調整面罩的放置，以取得最佳密封效果及最少的洩漏。若仍存在過度的洩漏，可能需要增加氣流以補償損失。允許的最大流速為 15 L/min。
- 請定期檢查凝結，並視需要排水。

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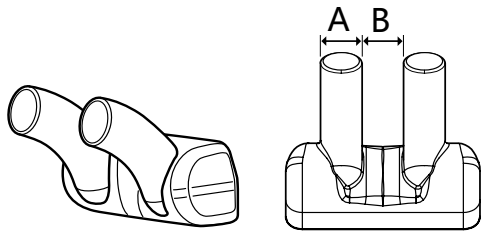
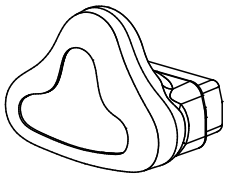
FlexiTrunk™ 嬰兒介面使用說明

嬰兒鼻導管



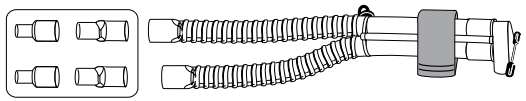
產品代號	A	B
BC3020	3.0 mm	2.0 mm
BC3520	3.5 mm	2.0 mm
BC4030	4.0 mm	3.0 mm
BC4540	4.5 mm	4.0 mm
BC5040	5.0 mm	4.0 mm
BC5050	5.0 mm	5.0 mm
BC5550	5.5 mm	5.0 mm
BC5560	5.5 mm	6.0 mm
BC6060	6.0 mm	6.0 mm
BC6070	6.0 mm	7.0 mm
BC6570	6.5 mm	7.0 mm

嬰兒鼻罩式面罩



產品代號	尺寸
BC800	S
BC801	M
BC802	L
BC803	XL

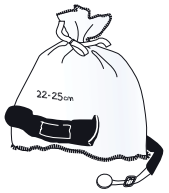
嬰兒鼻管



BC19x 系列

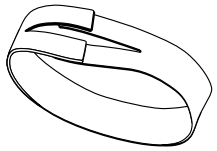
產品代號	尺寸
BC190	50 mm
BC191	70 mm
BC192	100 mm

嬰兒軟帽



產品代號	尺寸
BC300	17-22 cm
BC303	22-25 cm
BC306	25-29 cm
BC309	29-36 cm

嬰兒下巴帶



產品代號	尺寸
BC351	20-26 cm
BC353	26-32 cm
BC355	32-38 cm
BC357	38-44 cm

嬰兒頭套

產品代號	尺寸
BC325	29-36 cm
BC328	35-40 cm
BC331	40-45 cm

LATEX

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