F&P RT-series single-use products: Guidance on reprocessing and use beyond the stated duration of use

The COVID-19 pandemic has led to an increase in demand for medical products such as respiratory circuits and NIV masks, and it has also highlighted the potential for product shortages. Customers and healthcare professionals have asked for guidance on reprocessing single-use products and using products beyond the stated duration of use.

Off-label use

These devices are required to be prescribed by a clinician as per their intended use. If a device is used off-label, the user recognizes that it is not the approved use of the device and that the responsibility for doing so is their own.

Reprocessing of Fisher & Paykel Healthcare RT-series single-use products

F&P Healthcare DO NOT recommend reprocessing of, or reuse on multiple patients, of RT-series single-use products.

Background information on reprocessing

The information provided below may help explain why reprocessing of F&P Healthcare single-use products is not possible.

Effective reprocessing of any medical device involves three key steps to achieve sterilization: Cleaning, disinfection and sterilization. The success of each step is very dependent on the preceding steps achieving their expected level of sporicidal action.

Cleaning: The removal of gross contaminants or visible dirt from the device.

Disinfection: Destruction of the bulk of 'invisible' contaminants. For respiratory equipment that contacts mucous membranes, the minimum inactivation level is high-level disinfection (HLD). High-level disinfection destroys all microorganisms except large numbers of bacterial spores.

Sterilization: Destruction of all microbial life. Whenever sterilization is possible it is considered the default best practice.

Product-specific issues with reprocessing

Product*	Cleaning	Washer-Disinfectors	Chemical Disinfection	Sterilization
RT-series single-use respiratory circuits (RTXXX)	For RT-series circuits, the tube length, narrow bore, opaque circuit walls and corrugations make it very difficult to access all internal and external surfaces to remove any contaminants and virtually impossible to detect whether any dirt remains. This inability to immediately remove contaminants compromises the next step in the disinfection or sterilization process.	Many hospitals use washer-disinfectors for disinfection of respiratory circuits. Washer-disinfectors have specialized attachments that jet water, detergent and hot air through the tubes. This process will typically reach temperatures of at least 90 °C during the disinfection stage and possibly even higher during the drying stage. This temperature is very close to the softening temperature of the materials used in RT-series circuits and may lead to tube deformation and connector leaks.	Chemical disinfectant solutions are an alternative to washer-disinfectors. However, these rely on full wetting of all surfaces to achieve high-level disinfection. Complete wetting is challenging to accomplish in the tubes of single-use circuits, which will readily trap tiny air bubbles in each corrugation. Plastic respiratory circuits will also float near the surface of the solution making full wetting challenging to achieve. Respiratory circuits are untested with typical disinfection chemicals. These chemicals may degrade the polymers and compromise the circuit's integrity.	Sterilization processes rely on the successful completion of the preceding reprocessing steps. F&P Healthcare believes achieving this will be unlikely for single-use corrugated respiratory circuits and single-use masks. Irrespective of the proposed sterilization method, it will NOT result in a sterile respiratory circuit or mask suitable for use on another patient if the preceding cleaning and disinfection steps are not successfully completed.
FreeMotion™ mask range (RT040, RT041, and RT043)	Full disassembly of the mask components is required to allow the removal of gross contaminates. Disassembly of single-use masks is not possible, compromising the next step in the disinfection or sterilsation process.	This process will typically reach temperatures of at least 90 °C during the disinfection stage and possibly even higher during the drying stage. This temperature is very close to the softening temperature of our FreeMotion mask materials.	Single-use NIV masks are untested with typical disinfection chemicals. These chemicals may degrade the polymers and compromise the mask's integrity.	
Nivairo™ mask range (RT045, RT046, and RT047)	Full disassembly of the mask components is required to allow the removal of gross contaminates. Disassembly of single-use masks is not possible, compromising the next step in the disinfection or sterilization process.	The materials used in this mask are more able to withstand the temperatures of the disinfection process. However, because complete disassembly is unachievable, any gross contaminates left on the mask will compromise this process.		

Risks of reprocessing

The risk of not achieving the desired level of disinfection or sterilization, and thus potentially infecting multiple patients, is significant.

Reprocessing also introduces a risk of material degradation in products that may impact the delivery of the desired therapy to the patient. These material-related risks vary depending on the product.

The main risks based on any damage through reprocessing are listed below:

Product*	Main Risks
RT-series single-use Respiratory circuits (RTXXX)	• Increased circuit leaks due to material degradation in connectors or tubes • Poor fitting or loose connections due to material degradation in connectors or tubes • Heater wire safety and performance may be compromised due to material degradation in heater wire and electrical connections
FreeMotion mask range (RT040, RT041, and RT043)	• Damage to connections resulting in poor fitting or loose connections • An increased leak from the mask • Damage to moving parts resulting in reduced functional movement
Nivairo mask range (RT045, RT046, and RT047)	• Damage to connections resulting in poor fitting or loose connections • An increased leak from the mask • Damage to moving parts resulting in reduced functional movement

Using F&P RT-series single-use products beyond their stated Duration of Use

F&P Healthcare DO NOT recommend using any product past its maximum duration of use.

Single-use products have a maximum duration of use which has been determined through extensive testing of the individual components and as a whole. Using these products past the stated duration of use can increase the risk of the product (or a single part) failing or not working as expected. Failures may result in harm to a patient.

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* Not all products are available in all markets