EN

Vital Signs™ Hytrel Tube, Reusable

Instructions for Use

REF

587040200	Vital Signs™ Patient Hytrel Tube, Adult, 600 mm/ 24 in, connectors 22/22 mm, Reusable
587040500	Vital Signs™ Patient Hytrel Tube, Adult, 450 mm/ 18 in, connectors 22/22 mm, Reusable
587040600	Vital Signs™ Patient Hytrel Tube, Adult, 750 mm/ 30 in, connectors 22/22 mm, Reusable
587040700	Vital Signs™ Patient Hytrel Tube, Adult, 1500 mm/ 59 in, connectors 22/22 mm, Reusable
587040800	Vital Signs™ Patient Hytrel Tube, Adult, 1000 mm/ 39 in, connectors 22/22 mm, Reusable
587040900	Vital Signs™ Patient Hytrel Tube, Adult, 1200 mm/ 47 in, connectors 22/22 mm, Reusable
8004515	Vital Signs™ Patient Hytrel Tube, Adult, 900 mm/ 35 in, connectors 22/22 mm, Reusable
427010700	Vital Signs™ Patient Hytrel Tube, Pediatric, 1500 mm/ 59 in, connectors 22/15 mm, Reusable

REF	Catalogue number	NON STERILE	Non-sterile
LOT	Lot number		Consult instructions for use
QTY	Quantity		Date of manufacture
	Manufacturer	Rx ONLY	U.S. Federal law restricts this device to sale by or on the order of a physician.
UDI	Unique device identifier		

Intended use
Hytrel tubes are intended to deliver gas mixtures to, and removal of waste gas from adult and pediatric patients in anesthesia and intensive care.

Material
Si (Silicone plastic)
TPE (Polyester thermoplastic elastomer)
Not made with natural rubber latex.

How Supplied
Products are supplied non-sterile. Cleaning and sterilization of device shall occur prior to first use and after each use. AirLife has successfully tested the enclosed reprocessing instructions for 20 cycles.

Warnings
- Device shall be used in accordance with these Instructions for Use. Read all sections of this IFU prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and may cause serious injury to the health care provider or the patient.
- This product should not be used if the integrity of the packaging has been compromised.
- Before use, verify that the device is not occluded and that air will flow through it.
- During the use of this product, the patient and the breathing system shall be closely monitored and proper airway care administered if complications arise.

1. All connections should be securely attached, by using a twisting action, to ensure a leak free fit.
2. Device must be leak tested prior to patient connection.
3. Device is to be used only by professional healthcare personnel.
4. If the product contains elbow, water trap or other components, see separate instructions included in each package.
5. Monitor the tubing and in case water accumulates, empty the tube or water
trap if used.

Cautions
- If there are any variations between these Instructions for Use and either your facility's policies and/or your cleaning/sterilizing equipment manufacturer's instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.
- Use of a device for a task other than what it is intended for will usually result in a damaged or broken device.
- Prior to use, inspect devices to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or if they have physical damage.
- Avoid mechanical shock or overstressing the devices.
- Only the cleaning and sterilization processes which are defined within these Instructions for Use have been validated. Use only neutral pH (6-8) detergent solutions.

United States and International

Pre-processing Instructions
1. Ensure all pre-processing instructions are followed prior to cleaning and sterilization.
2. Initiate cleaning of device as soon as possible after use (recommended within 2 hours).
3. Transport device via the institutions established transport procedure.
4. Remove excess gross soil as soon as possible after use by rinsing or wiping the device.
5. Device shall be cleaned and sterilized utilizing a minimum of one (1) cleaning method and one (1) sterilization method outlined below.

Cleaning Instructions
1. Prepare the enzymatic / neutral pH detergent, utilizing tap water entailing a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
2. Completely immerse the device in the detergent solution and allow device to soak for a minimum of 5 minutes.
3. Using an appropriately sized brush (equivalent lumen length and inner diameter), brush the device to remove all visible soil from the device paying particular attention to crevices and other hard to clean areas. **Note**: It is recommended that enzymatic or neutral pH detergent solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
4. With the distal tip pointed down and using an appropriately sized syringe, flush the internal lumen of the device with a minimum of 50mL of pH-neutral/enzymatic detergent solution utilizing a temperature range of 27°C to 44°C (81°F to 111°F). Repeat the flush process a minimum of 2 times (i.e. total of 3 times) ensuring all fluid exiting the lumen is clear of soil.
5. If visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen.
6. Rinse the device by completely immersing the device in 4 gallons of lukewarm tap water with a temperature range of 27°C to 44 (81°F to 111°F) for a minimum of 30 seconds to remove any residual detergent or debris.
7. Following the rinsing step above, point the distal tip down and flush the device with a minimum of 50mL of tap water utilizing a temperature range of 27°C to 44°C (81°F to 111°F). Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
8. Drying: Dry the device with a clean, lint-free towel. Place the device on a drying rack to allow rinse water to drain from the lumen.
9. Visually examine each device for cleanliness.
10. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

Inspection
After manual cleaning **and** prior to each use the products have to be checked for damages (cracks, ruptures etc.) and leaks. Damaged products **must not** be re-used.

Sterilization

Sterilization for United States Market
STANDARD PREVACUUM STEAM STERILIZATION CYCLES
Prevacuum Steam Sterilization Cycle (U.S. "FDA Compliant – Wrapped")
- Conditioning Pulses: 3
- Exposure Temperature: 132°C
- Exposure Time: 4 minutes
- Dry Time: 30 minutes
- Sterilization Configuration: FDA Cleared Sterilization Wrap (2 layer -1 ply, or 1 layer - 2 ply – examples: cellulose, polypropylene, muslin)

Sterilization for International Market
Prevacuum Steam Sterilization Cycle (Wrapped)
- Conditioning Pulses: 3
- Exposure Temperature: 132°C - 135°C
- Exposure Time: 3 - 18 minutes
- Dry Time: 30 minutes
- Sterilization Configuration: Sterilization Wrap
(2 layer -1 ply, or 1 layer - 2 ply – examples: cellulose, polypropylene, muslin)

Service
Prior to the return of medical products for complaint/repair must have run through the complete reprocessing process to exclude any risk for the AirLife staff. For safety reasons AirLife preserves the right to refuse dirty or contaminated products.

Disposal
Used or damaged products must be disposed according to applicable national and international legal directives.

Ordering information
For further information, please contact your local sales representative or visit myAirLife.com.

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1000009345 Rev. A 2025/03

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