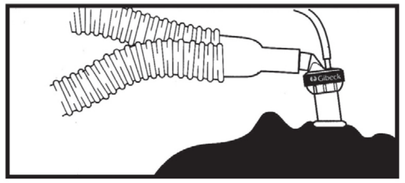

Gibeck Humid-Vent® Filter Pedi

Instructions for use

Teleflex Medical Sdn. Bhd.
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Made in Malaysia

EC REP
Teleflex Medical
IDA Business & Technology Park,
Dublin Road, Athlone,
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CE 0124

en

Description:
Humid-Vent Filter Pedi is a combined heat and moisture exchanger (HME) and bacterial/viral filer for humidification and bacterial/viral filtration during anaesthesia and intensive care. With luer lock port for $ETCO_2$, anesthetic agent or pressure monitoring V_T 50-250 ml. It reduces hypothermia and post-operative shivering as well as the risk of bacterial/viral contamination.

Instructions for use:
- This device shall be placed between the proximal end of the artificial airway and the wye piece of the breathing circuit. See picture.
- If luer-lock monitoring port is not used make sure the cap is securely fastened to the port.
- Take total system dead space into consideration before use.
- Expert clinical judgement must be used in assessing the patients humidification requirements.
- Do not use if package is broken or product is damaged.

Specifications:

• Dead space	13 ml, ISO 9360
• Weight	12 g
• Connectors	15F/22M-15F, ISO 5356-1
• Medium: HME part	Hygroscopic Microwell paper
• Medium: Filter part	Electrostatic Polymer fiber
• Moisture output	V_T 70, 31 mg H_2O/l air, ISO 9360
• Resistance to flow	0.7 cm H_2O at 10 l/min
• Maximum use	24 hours
• Bacterial/viral filtration Efficiency	99.9+% (records on file)
• Clean	Manufactured under GMP

Warnings
- Replace unit immediately if soiled with secretions, hemoptysis or otherwise obstructed.
- Do not use this device together with active humidification systems.
- Do not use with explosive anesthetic gases.
- Humid-Vent® Filter Pedi is designed for single use only and should not be cleaned or re-used.
- ②
  Re-processing of medical devices intended for single use only may result in degraded performance or a loss of functionality. Re-use of single use only medical devices may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these medical devices. This product is not designed to be cleaned, disinfected, or sterilized.
- The Humid-Vent Filter® Pedi must be removed while nebulized medication is delivered to the patient. The medication may block the device.
- If an uncuffed endotracheal tube is used, leakage around the tube normally occurs, this redices the humidification efficiency.

Caution:
- US federal law restricts this device to sale by or on the order of a physician.
- **This product does not contain natural rubber latex.**

Storage Instruction
Keep away from sunlight and keep dry. Do not use if the product sterilisation barrier or its packaging is compromised.

Explanation of important symbols and markings on the product label.

Qty	Quantity, Number of items
	Do not use if package is damaged
	This product does not contain natural rubber latex

STERILE EO Rx Only

M.S.D.N: 0106619054 - C.T.T.N.H.H
CÔNG TY TNHH THƯƠNG MẠI SIXMURS HTH VIỆT NAM
Q. NAM TỪ LIÊM - TP. HÀ NỘI
GIÁM ĐỐC
Phạm Thị Thu Hằng

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