

105-XX-YY Instructions for use

Description and Specifications

The EVA Tubing consist of flexible ribbed medical grade biocompatible plastic tubing with internal diameter and variable specified lengths that are single use items. The 105-XX-YY tubes are supplied with an ID (XX) that is designed by the customer with the length configurable (YY) in 1" increments from 6" – 120". They are not supplied with a cuff

REF	Cuff Material	Tube Material	Temperature limits	Cleaning	Disinfection	Sterilization	Use type	Shelf Life
105-XX-YY	No cuff	EVA 15%	from -20 °C to 60°C	No	No	No	Single Patient Use, Single Use	1 Year

Intended Use: Smooth Bor Plastics air supply tubing is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). The CPAP device is for use on adult patients at home or in the sleep lab. The product is supplied in non-sterile condition and intended to be used as a replacement device. Follow your doctors and original equipment requirements for suitability of use.

Precautions: Grasp tubing by cuff or fitting and not by tube when disengaging from equipment. Follow original equipment manufacturers directions for connection instructions. Modification of this product without the authorization of the manufacturer is not recommended. Reuse may create a contamination risk and compromise structural integrity resulting in operational failure. Inspect tubing prior to and after installation for connection, leaks or degradation of performance. Kinking or collapse of tubing may result in restricted airflow or leakage. Replace tubing if discovered. Humidity, condensation, sharing with others and failure to comply with equipment manufacturers instructions for cleaning may lead to infection or cross infection and result in patient and/or healthcare staff injury. Critical product information may be lost during repackaging.

Warnings: Do not use chlorinated solutions, subject to prolonged exposure to ultraviolet (UV) light or exposure to conditions outside the limits. Damaged tubing or/and connectors need to be replaced immediately to prevent leaks/inadvertent detachments. Upon receiving of the product please verify the completeness and correctness of the content. Skin irritation may occur if allergic to tube and/or cuff materials. Do not use if allergic. Do not use near sources of heat, like ovens, heaters, etc. as tubing could be a conduit of fire. Aerosol generation and risk of contamination of respiratory droplets with virus may be present if infection exists. Do not wrap around neck as this could lead to asphyxiation or strangulation.

Contraindications: This tubing is not for use on patients with the following conditions: excessive reflux, impaired cough reflex, and impaired cardiac sphincter function. This tubing is not for use on patient who are taking a prescription drug that induces vomiting, or on patients who are uncooperative, unresponsive or unable to remove the tubing by themselves. This tubing should not be placed over open wound or skin under risk of decubitus ulcers that are prone to infection. The tubing should not be used on neonatal patients or for off-label uses.

Adverse Events/ Side Effects: The following may occur: trouble getting used to wearing device, tolerating forced air, dry stuffy nose, feeling claustrophobic, difficulty falling asleep, dry mouth, irritation of the face/mask interface.

Symbols

Please see www.smoothborplastics.com for explanation of symbols used.

For any question related to this product, please contact your local distributor or Smooth-Bor Plastics directly:



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