

805-15mm-XX Instructions for Use

Description and Specifications

The accessory Air Supply Tubing consist of flexible ribbed medical grade biocompatible plastic tubing with internal diameter of 15mm and variable specified lengths. Tubes are supplied with a cuff designed to fit the ISO 22mm tapered conical connector with an interference fit with the length configurable (XX) in 1" increments from 6" – 120".

REF	Cuff Material	Tube Material	Temperature limits	Cleaning	Disinfection	Sterilization	Use type	Shelf Life
805-15mm-XX	TPE	TPE and Low-Density Polyethylene	from -20 °C to 70°C	Yes, see below	Yes, see below	Not autoclavable	Single Patient Use	2 Years

Intended Use: Smooth-Bor Plastics air supply tubing is intended to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). The tubing is used as a component in Continuous Positive Airway Pressure devices used 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. Design features may make cleaning difficult. 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. Do not use for more than 30 days continuous use. Do not use with ozone and/or ultraviolet (UV) light-based CPAP cleaners.

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.

Compatibility

Tubes are supplied with an 15mm ID according to ISO 5367 and are compatible with equipment and masks with 22mm outlets. Please see the instruction for use of your equipment and mask for dimensional specification of the connectors. Incorrect connection to the equipment and/or mask might compromise the efficiency of the treatment. Can be used with heated and non-heated air. Compatibility tested with Fisher and Paykel Sleep Style CPAP system; Model: USA.

Disposal/Recycle WARNINGS:

ALWAYS follow procedures for safe disposal of biohazardous materials before sending a used medical device to a waste treatment facility. Contains no hazardous substances. ALWAYS collect this product separately for recycling. DO NOT dispose of this product as unsorted municipal waste. Contact your local distributor for disposal information.

Symbols - Please see www.smoothborplastics.com/symbols/ for explanation of symbols used.

Cleaning and Disinfection

Detergents - Dawn-soap / Dishwashing liquid

Cleaning – 90 Cycles

Step	Parameters
Clean	Rinse the tubing under running utility (tap) water to remove excess soil. Prepare a sink full of diluted mild detergent, such as dawn soap, in lukewarm tap water. Use approximately 2 ml of Dawn-soap per 1 l water. Immerse the articles into the prepared detergent bath and allow to soak for a minimum of 1 minute. Rinse the tubing under running utility (tap) water to remove any visible detergent.

Disinfection

Steps	Parameters
Prep	Conduct Cleaning as outlined above. Prepare a sink full of water (tap water) with a temperature of at least 70°C.
Disinfect	Submerge the tubing into the water for at least 30 minutes. Be sure to get all bubbles out from inside of the tube.
Rinse	Remove and rinse thoroughly with distilled water
Dry	Hang and allow to fully air dry
Inspect	Visually inspect the tubing for any damage or discoloration – use a new tubing if you notice any damages or discoloration.

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



Smooth-Bor Plastics
23322 Del Lago Drive,
Laguna Hills, CA 92653, USA
+1 949 581-9530 (USA)
www.smoothborplastics.com



MEDUTEK
Handelsgesellschaft
für Medizintechnik mbH & Co. KG
Stresemannstraße 54
28207 Bremen, Germany



OBELIS S.A
Bd. Général Wahis, 53
1030 Brussels,
Belgium
Tel: +32.0.732.59.54
mail@obelis.net

