

405-15mm-XX-.530-.438H Instructions for Use

Description and Specifications

The Smooth Nor Air Supply Tubing consist of flexible ribbed medical grade biocompatible plastic tubing with internal diameter of 19mm and variable specified lengths that are used for up to 30 days total use for non-life supporting ventilation system, including Continuous Positive Airway Pressure (CPAP) systems for adult and pediatric patients with a minimum weight of 30kg. The 405-15mm-XX-.530-.438H tubes are supplied with and 15mm ID with the length configurable (XX) in 1" increments from 6" – 120". They are supplied with .530" cuffs on one end and .438H" cuff on the other end.

REF	Cuff Material	Tube Material	Temperature limits	Cleaning	Disinfection	Sterilization	Use type	Shelf Life
405-15mm-XX-.530-.438H	Silicon	Thermoplastic Elastomer Hytrel	from -20 °C to 150°C	Yes, see below	Yes, see below	Yes, see below	Re-usable	1 Year

This product is CE-marked according to the EC directive 93/42/EEC for medical devices

Intended Use

The 405-15mm-XX-.530-.438H Smooth Bor Plastics breathing tubing is intended for use with non-life supporting ventilation systems, including Continuous Positive Airway Pressure (CPAP) systems for adult and pediatric patients with a minimum weight of 30kg. The product is for single patient use for up to 30 days total, unless cleaned and disinfected or sterilized for re-use. The product is supplied in non-sterile condition.

Precautions: Grasp tubing by cuff or fitting and not by tube when disengaging from equipment. DO NOT modify this product without the authorization of the manufacturer. 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. Replace tubing if discovered. 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 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.

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 patients who are dependent on mechanical ventilation for their life support. 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 patient. The tubing should not be exposed to prolonged ultraviolet (UV) light; or to incompatible chemicals like chlorinated solutions.

Compatibility

The 405-15mm-XX-.530-.438H tubes are supplied with an 15mm ID and are compatible with all ventilation/CPAP units and masks requiring .530" cuffs. Please see the instruction for use of your ventilation/CPAP equipment and mask for dimensional specification of the connectors. Incorrect connection to the ventilation/CPAP equipment and/or mask might compromise the efficiency of the ventilation/CPAP treatment.

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.

Symbols

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

Cleaning, Disinfection and Sterilization

Detergents - Dawn-soap / Dishwashing liquid

Cleaning

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 and Inspect	Hang and allow to fully air dry. Visually inspect the tubing for any damage or discoloration – use a new tubing if you notice any damages or discoloration.

Sterilization - Validated Steam Cycle Parameters

Wrapping method	Cycle	Minimum Temperature	Maximum Temperature	Minimum Exposure Time	Minimum Dry Time
Wrapped	Gravity	132°C (270°F)	135°C (275°F)	15 minutes	30 minutes

Tubing should be packaged individually in single pouches (Cardinal Health T900009, FDA cleared 510(k) number K153540)

Validation is based upon AAMI TIR12:2010, ISO 17664:2017, ISO 14937:2009 and ISO 17665-1:2006.

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



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