403-XX Instructions for use

Description and Specifications: The Smooth-Bor Air Supply Tubing consist of flexible ribbed medical grade biocompatible plastic tubing with internal diameter of 19mm and variable specified lengths. The 403-XX tubes are length configurable (XX) in 1" increments from 6" – 120". They are supplied with a 22mm silicon cuff on both ends. This product is CE-marked according to the EC directive 93/42/EEC for medical devices.

REF	Cuff Material	Tube Material	Temperature limits	Cleaning	Disinfection	Sterilization	Use type	# of Autoclave Cycles	Shelf Life
403-XX	Silicon Rubber	Thermoplastic Elastomer Hytrel	-20 °C to 140°C	Yes, see instructions below	Yes, see instructions below	Autoclavable, see instructions below	Multi-Patient Multiuse	25	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 (CPAP) 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.

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. Do not use with ozone and/or ultraviolet (UV) light-based CPAP cleaners.

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: The 403-XX tubes are supplied with an 22mm cuff. 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 200 CPAP system; Model: HC231.

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 – 52 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 – 52 cycles

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 - Steam Cycle Parameters – 25 cycles

Wrapping method	Cycle	Minimum Temperature	Maximum Temperature	Minimum Exposure Time	Minimum Dry Time
Wrapped	Gravity	132°C (270°F)	140°C (284°F)	15 minutes	30 minutes
Tubing should be packaged individually in single pouches such as Cardinal Health T900009, FDA cleared 510(k) number K153540 or equivalent.					

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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