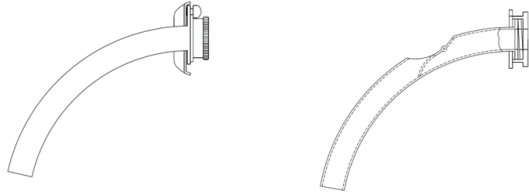


INSTRUMENT DESCRIPTION

THE FOLLOWING INSTRUCTIONS ARE FOR METAL, REUSABLE TRACHEOSTOMY AND LARYNGECTOMY TUBES:



For additional information or guidance on Cleaning and Sterilization instructions, contact your Teleflex Sales Representative or Teleflex Customer Service.

Indications for Use

Teleflex instruments are designed to perform a specific function, such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, or suturing. Instruments are for use by, or as directed by, a surgeon. Instruments should be used only for the purpose for which they are designed. The proper surgical technique for the use of the instrument is the responsibility of the medical professional.

Instructions

- Before use, inspect the instrument to ensure it functions correctly.
- During cleaning of lumina, drill holes and blind holes, special attention is required.
- When lubricating the instrument, do not use mineral oil, petroleum or silicon-based products.
- Flash sterilization is not recommended.

Due to the product design and the materials used, no limit for the maximum number of cleaning and sterilization cycles is specified. The service life of an instrument is determined by the intended function, actual use and handling. All instruments must be inspected prior to use. In case of damage the instrument should be cleaned and sterilized before sending back to Teleflex Medical.

Preparation at Point of Use

Directly after use, remove coarse contamination from the instrument and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water (>104°F (40°C)) since this may lead to the fixation of residue and can have a negative influence on the cleaning process.

Transportation

Store contaminated instrument securely in a closed container to avoid damage to the instrument and contamination of the environment. Transport the instrument to the processing site.

Preparation for Reprocessing

Where applicable, the instrument must be disassembled for cleaning and sterilization. Clean and sterilize as per the instructions below. Failure to clean the instrument could lead to inadequate sterilization.

CLEANING, DISINFECTION AND DRYING INSTRUCTIONS

Home Use Cleaning Instructions

- Disassemble the instrument prior to cleaning.
- Rinse the disassembled instrument pieces under running, lukewarm water until all visible debris is removed.
- Prepare a sink for use in cleaning the instruments: add at least one (1) small drop of a neutral dishwashing liquid (such as Ivory®) to a sink containing at least one (1) gallon of lukewarm water.
- Place the rinsed instrument pieces in the sink and soak for a minimum of ten (10) minutes.
- After soaking, use a soft-bristled brush to thoroughly scrub the inside and outside portions of the instrument pieces while still immersed in the sink. Ensure that all instrument surfaces (inner and outer lumens) have been scrubbed.
- Once the instrument pieces have been sufficiently scrubbed, remove the pieces from the sink and rinse with running lukewarm water for at least one (1) minute. Ensure that all soap residue and visible debris has been removed.
- If necessary, the instrument pieces can be dried with a clean, lint-free cloth or towel.
- Reassemble the instrument.

Automatic Processing instructions	Manual Processing Instructions
<p>Alkaline Cleaning</p> <ul style="list-style-type: none"> • Place the opened instruments in a perforated basket on the slide-in tray and start the cleaning process. • Pre-rinse for 2 minutes with cold water. • Empty. • Pre-rinse for 3 minutes with cold water. • Empty. • Wash for 5 minutes at 131°F (55°C) with a 0.5% alkaline detergent. • Empty. • Neutralize for 3 minutes with cold water. • Empty. • Rinse for 2 minutes with cold water. • Empty. <p>Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use of the manufacturer. Examples of detergents used in validations: Alkaline Detergent: Neodisher Mediclean.</p>	<p>Enzymatic Pre-Cleaning</p> <ul style="list-style-type: none"> • Soak the instrument in lukewarm tap water for a minimum time of 5 minutes. • Flush the inside of the instrument with lukewarm tap water. • Brush the instrument under lukewarm tap water for approximately 15 seconds until no residues are visible. • Flush the inside of the instrument with lukewarm tap water. <p>Cleaning</p> <ul style="list-style-type: none"> • Soak the instrument in an ultrasonic bath for 10 minutes at 104°F (40°C) with 0.8% solution of enzymatic cleaner (See Note below). • Rinse the instrument with tap water for approximately 15 seconds. • Remove the instrument and flush with lukewarm tap water for approximately 15 seconds while simultaneously brushing with a soft-bristled brush. • Dry with a clean, lint-free cloth. <p>Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use of the manufacturer. Examples of detergents used in validations: Enzymatic Detergent: Cidezyme/Enzol.</p>
<p>Enzymatic Pre-Cleaning</p> <ul style="list-style-type: none"> • Soak the instrument in lukewarm tap water for a minimum time of 5 minutes. • Flush the inside of the instrument with lukewarm tap water. • Brush the instrument under lukewarm tap water for approximately 15 seconds until no residues are visible. <p>Cleaning</p> <ul style="list-style-type: none"> • Place the opened instruments in a perforated basket on the slide-in tray and start the cleaning process. • Pre-rinse for 2 minutes with cold water. • Empty. • Wash for 5 minutes at 131°F (55°C) with a 0.8% enzymatic detergent. • Empty. • Neutralize for 3 minutes with cold water. • Empty. • Rinse for 2 minutes with cold water. • Empty. <p>Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use of the manufacturer. Examples of detergents used in validations: Enzymatic Detergent: Cidezyme/Enzol.</p>	<p>Disinfection</p> <p>Perform disinfection as per disinfectant manufacturer's guidelines.</p> <p>Drying</p> <p>Dry the outside of the instruments using the drying cycle of the cleaning/disinfection device. If necessary, the instruments can additionally be dried by hand with a clean, lint-free cloth. Compressed air can be used for instruments with lumen.</p>
<p>Disinfection</p> <p>Perform disinfection as per disinfectant manufacturer's guidelines.</p>	<p>Disinfection</p> <p>Perform disinfection as per disinfectant manufacturer's guidelines.</p> <p>Drying</p> <p>Dry the instruments with a clean, lint-free cloth. Compressed air can be used for instruments with lumen.</p>

Inspection and Functional Check

- Inspect readability of device markings as applicable.
- It is mandatory to inspect the instrument prior to use as it may be damaged during transit to the customer, at the customer's site during receiving, during use in a previous procedure or during the cleaning or sterilization process.
- Repair or replace any instrument found not to be acceptable.
- All moving parts, tips, must be inspected for wear and confirmed to be functional.

Packaging

After cleaning and inspection, place the instrument in terminally sterilizable packaging (as per ISO 11607) or a sterilization container which will protect the instrument from the environment as well as permit sterilization. After sterilization the instrument should remain in the packaging or sterilization container for protection from the environment and to maintain sterility.

Sterilization

The following parameters may be used to steam sterilize (autoclave) the Pilling Trachea Tubes:

Sterilization Method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying Time (minimum)
Pre-vacuum	Wrapped	270°F (132°C)	4 minutes	10 minutes
Pre-vacuum	Wrapped	273°F (134°C) to 279°F (137°C)	3 minutes	10 minutes
Pre-vacuum	Wrapped	275°F (135°C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	270°F (132°C) to 275°F (135°C)	10 minutes	10 minutes

NOTE: Flash sterilization is not recommended for use with these instruments.

Storage

Instrument must be stored in a dry, clean, chemical-free and dust-free environment. Instrument must remain wrapped or within the sterilization container to maintain sterility.

Additional Instructions

Use of cleaning and sterilization methods other than those provided by Teleflex must be validated by the healthcare facility using appropriate validated laboratory methods.

WARNING

Instruments which are used consciously on patients with a prion based disease (transmissible spongiform encephalopathy disease, CJD, BSE, etc.) or on patients suspected of having one of these diseases are not safe to be reused and must be disposed of as per approved hospital procedures.

Do not clean and/or sterilize instruments suspected of prion-contamination prior to disposal, as introducing these instruments to the reprocessing facility may lead to contamination of other instruments and/or the reprocessing facility equipment.

Product Information Disclosure

Teleflex excludes all warranties, except Teleflex's applicable Standard Warranty whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Teleflex shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product except for the intended use specified. Teleflex does not assume nor authorize any person to assume for them any other or additional liability or responsibility in connection with these products.

PILLING TRACHEA TUBE BRUSHES FEATURE:

- Locked in, white DuPont Nylon bristles to guarantee long life.
- Silver soldered ball end to prevent scratching.
- Stainless steel shank that will not rust or corrode.
- Autoclavable construction that will survive abuse.
- Loop ends for hanging to facilitate storage.

Catalog No.	Description	Max. Brush Diam. At Center	Brush Length	Overall Length	For Tube Sizes
508546	Trachea Tube Brush: SMALL	3/8"	1-3/4"	6"	00-3
508547	Trachea Tube Brush: MEDIUM	5/8"	2-3/4"	7"	4-7
508548	Trachea Tube Brush: LARGE	3/4"	3-1/4"	8"	8-12
508545 (Set of 3)	SMALL MEDIUM LARGE	3/8" 5/8" 3/4"	1-3/4" 2-3/4" 3-1/4"	6" 7" 8"	00-3 4-7 8-12

Trachea tube brushes must be bent and formed to the curve and contour of the tube.

For additional information, go to: www.teleflex.com/ifu

Manufactured for:



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