

Rigid Stylet

Technical Bulletin IntuBrite® VLS1060 Rigid Reusable Stylet

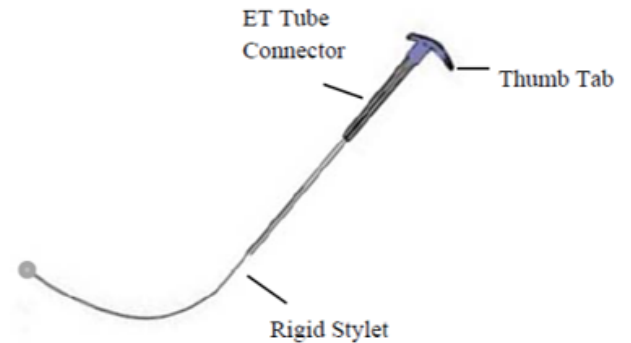
Please read and follow the instruction for use prior to using the Rigid Stylet.

DESCRIPTION

The IntuBrite® VLS Rigid Stylet is a reusable device intended to aide in the placement of the endotracheal (ET) tube. The Stylet helps to shape the endotracheal tube and facilitate intubation when using video laryngoscopes. The Rigid Stylet is designed for use with a 6.0mm and larger endotracheal tubes.

INSTRUCTIONS FOR USE

1. Prior to first use and between patients, ensure the Rigid Stylet has been high-level disinfected or sterilized.
2. Place the ET tube onto the Rigid Stylet assuring the distal end of the Rigid Stylet does not extend beyond the distal end of the ET tube.
3. Insert the ET tube into the oral cavity adjacent to the laryngoscope blade.
4. Position the tip of the ET tube above the vocal cords. Do not insert the Rigid Stylet through the vocal cords.
5. When the ET tube is properly positioned in the glottic opening, use your thumb to apply pressure on the Thumb Tab and pull the Rigid Stylet back 5cm . This allows the ET tube tip advancement past the vocal cords.
6. Position the ET tube as per standard protocol and remove the Rigid Stylet.



CAUTIONS

- The Rigid Stylet is packaged nonsterile. Clean the device and either sterilize or high-level disinfect prior to first use.
- Inspect the packaging prior to use. Do not use if damaged or tampering are evident.
- Inspect device before each use. Do not use and discard if damaged.
- Do not advance the Rigid Stylet into or pass the glottis under any circumstance.
- Do not advance the Rigid Stylet pass the distal end of the endotracheal tube.
- This is a semi-critical device and may become contaminated with human blood or body fluids. Clean and either high-level disinfect or sterilize after each use.

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Rigid Reusable Stylet Cleaning Instructions

CLEANING INSTRUCTIONS

IntuBrite™ VLS Rigid Stylet is a reusable, semi-critical device and may be used on multiple patients. The Rigid Stylet requires cleaning followed by either high-level disinfection or sterilization prior to first use and between patients.

Step 1. Clean Rigid Stylet

1. Clean the Rigid Stylet with a low- or intermediate-level disinfectant solution to remove visible debris or contamination. To clean the device use either a mild liquid detergent or an intermediate-level disinfectant listed in the table below. Follow the manufacturer's instructions for proper use of disinfectant wipes or spray.
2. Rinse the Rigid Stylet with water to reduce the risk of cytotoxic residual from cleaning solutions.
3. Visually inspect for contaminants. Repeat cleaning process if necessary.
4. Dry the Rigid Stylet with a lint-free cloth, clean air or low-temperature dryer.

Step 2. High-Level Disinfection or Sterilization

1. After the Rigid Stylet is cleaned, high-level disinfect or sterilize the device.
 - a. For high-level disinfection use a 0.55% to 0.60% ortho-phthalaldehyde (OPA) solution or 2% accelerated hydrogen peroxide (AHP) solution. Rinse thoroughly with water and dry the device before packaging.
 - b. For sterilization use a low-temperature hydrogen peroxide gas plasma systems, or autoclave (steam cycle) for a minimum of 4 minutes at 132°C (270°F).
2. Visually inspect device. Discard if signs of damage or cracking are noted.
3. Package and store to maintain sterility or high-level disinfection.

Recommended processes for intermediate- and high-level disinfection and sterilization.

Disinfectant Level	Sterile	High	Inter
STERIS V-PRO® System	X		
ASP STERRAD® NX System	X		
ASP STERRAD® 100S System	X		
ASP STERRAD® 100NX System	X		
Autoclave (Steam Cycle)	X		
Metrex Metricide™ OPA Plus		X	
ASP Cidex® OPA		X	
Steris Revital-Ox RESERT HLD		X	
Metrex CaviWipes™ Towelettes			X
Metrex CaviCide™ Spray			X
Super Sani-Cloth Disinfecting Wipes			X
Sani-Cloth Prime Disinfecting Wipes			X

CAUTIONS

- Do not use caustic cleaning solutions. Do not use solutions with high chlorine (>5000 ppm) content.
- Follow the manufacturers' Instructions for Use for disinfectant solutions and sterilization processes.