

**Instructions for Use: LTA Internal Channel G-Flex Brushes**

<b>Brand Name of Product</b>	LTA Internal Channel G-Flex Brushes
<b>Generic Name of Product</b>	Channel Brushes
<b>Product Code Number(s)</b>	6xx-25SP, 6xx-50SP, 610, 620, 635, 655, 680, 685, 690, 610-00, 620-00, 635-00, 655-00, 680-00, 685-00, 690-00
<b>Intended Use</b>	Intended for internal cleaning of laparoscopic or rigid endoscopy devices with medium to large channels.
<b>Range of Applications for Product</b>	Medium to large channels.
<b>Key specifications of product</b>	<ul style="list-style-type: none"> <li>• Bristle diameters correspond to standard inner channels</li> <li>• Available in a variety of sizes</li> <li>• Wands are re-usable</li> <li>• Flexible wire made of Peek</li> <li>• Connection and spring 300 series stainless steel</li> <li>• Code laser engraved</li> <li>• Ergonomic rubber handle</li> </ul>

**Shipping & Storage**

<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	Store in a pouch that is the correct length.
<b>Packaging Conditions</b>	
<b>Shelf Life</b>	

**Instructions for Using Product**

<b>Description of Use (s)</b>	Designed for internal Cleaning
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>• Cleaning any cannulated medical device such as, a suction tube, requires the use of the proper size cleaning brush in accordance with the medical device manufacturers IFUs.</li> <li>• It is important to match the diameter size of the brush you are using with the channel you are cleaning.</li> <li>• The Healthmark brush-sizing chart or similar type of tool may be used to select the proper diameter brush.</li> <li>• It is also critical to select a brush which is longer than the channel to insure that the entire channel receives cleaning action.</li> <li>• It is also important to be sure the material composition of the brush bristles is suitable for the device to be cleaned. This should be in compliance with the device manufacturer's IFU for the device.</li> <li>• Brushes should be inspected prior to each use to be certain they are not worn, frayed or damaged if discrepancies are noted the brush should be discarded and not used.</li> <li>• Brushes should also be inspected between uses for any residual organic soil that may cross contaminate the next device cleaned. If there is visual soil, the brush should be cleaned in accordance with the method(s) described below.</li> </ul>

**Diagrams (drawings, pictures):**

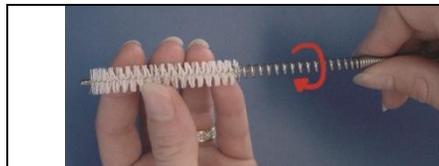
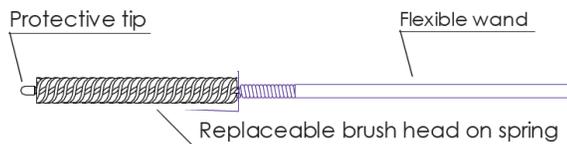


Figure 1

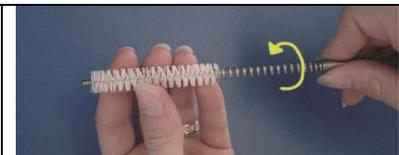


Figure 2

<b>Steps for Use of Product</b>	<ul style="list-style-type: none"> <li>Consult the manufacturer's IFU for the device you are cleaning and follow those instructions closely.</li> <li>Insert the cleaning brush by the non-brush end in the proximal aperture, pushing the shaft into the instrument channel, until it reappears at the end. Pull the cleaning brush regularly until the brush is completely withdrawn.</li> </ul> <p><b>Replacement of refills (2 months for 610 and 620 and 3 months for 630 to 690 under normal use):</b></p> <ul style="list-style-type: none"> <li><b>Unscrewing:</b> Keep the brush between the fingers of one hand, while rotating the rod anticlockwise on the other hand. (figure 1)</li> <li><b>Screwing:</b> Insert the brush into the spring by turning the rod in the direction of clockwise. Stop the screwing when the spring end is between 2 and 3 mm from the outer protection. (figure 2)</li> </ul>
<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>Tube style brushes are intended for use as cleaning tools only. They are not for use in patient care or aseptic techniques.</li> <li>When inserting in channel do not hold brush at compromising angle that would cause it to bend.</li> <li>Not to be used for cleaning plastic and/or fragile materials such as silicone.</li> <li>Avoid brush compression during sterilization and storage.</li> <li>Always protect yourself from brush splatter and contamination.</li> <li>Clean between each use and disinfect at least daily, preferably between each use in order to limit the chance for cross contamination. See instructions for reprocessing below.</li> </ul>
<b>Disposal</b>	Because tube brushes are used to clean patient used medical devices, it is recommended to dispose of them in the biohazard container with other contaminated devices.

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	<ol style="list-style-type: none"> <li>Use external brush sweep out debris that can be brushed out of internal G-Flex brush.</li> <li>Rinse gross contaminates from the brush in a deep sink and a spray apparatus, such as a shower gun.</li> <li>Use the facilities cold water supply for this rinsing.</li> </ol>
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	<ul style="list-style-type: none"> <li>Brushes may be cleaned manually utilizing a high alkaline instrument detergent or an enzymatic detergent with the suitable enzymes for cleaning the types of soil the brush may come in contact with during cleaning (i.e., protease, lipase, etc.).</li> <li>The IFU for the cleaning agent should be followed closely to insure sufficient exposure time is allowed for the cleaning solution to work.</li> <li>It is recommended that agitation accompany the cleaning process to improve results.</li> </ul>
<b>Cleaning – Automated:</b>	<ul style="list-style-type: none"> <li>Machine cleaning is recommended in a washer disinfector cleared by the FDA.</li> <li>Products should be positioned in the washer to allow maximum water penetration and drainage.</li> <li>No overlapping - partially covered devices will not be washed properly</li> <li>Brushes should be secured in some way, such as the use of a wire or perforated tray that has a wire or perforated lid to prevent brushes from blowing around the wash chamber during cleaning. A container such as the brush cleaning tube from Healthmark is a suitable solution.</li> <li>Products can be cleaned with alkaline, acidic and neutral detergents.</li> <li>For final rinse, DI or RO water is recommended.</li> <li>The standard program to include: <ol style="list-style-type: none"> <li>Pre-wash with cold water (&lt;100°F) rinse for a minimum of 2 minutes.</li> <li>Washing cycle with alkaline or enzymatic detergent at temperature recommended by the detergent manufacturer for 5 minutes.</li> <li>Washing cycle with neutral pH or neutralizing detergent at temperature recommended by the detergent manufacturer for 5 minutes.</li> <li>Rinse cycle for 2 minutes (preferably with DI or RO water).</li> <li>Thermal disinfection of up to 195°F in compliance with the washer manufacturer recommendations for time and temperature.</li> </ol> </li> </ul>

	6. Drying cycle at temperature not to exceed 240°F. 7. Caution when unloading machine as products will be hot. 8. Visual inspection is required to ensure complete removal of soil. 9. If product still shows soil repeat program.
<b>Disinfection:</b>	<ul style="list-style-type: none"> <li>• The thermal disinfection stage of an automated washer is sufficient for disinfection of the cleaning brushes. Minimum temperature should be 180°F and not exceed 200°F.</li> <li>• Brushes may be disinfected with liquid chemical sterilants in accordance with the disinfection manufactures' IFUs. Be sure to check material compatibility information from the disinfectant manufacturer. Should be compatible with nylon and with stainless steel.</li> </ul>
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	<ol style="list-style-type: none"> <li>1. Inspect for wear, fraying or damaged bristles or the twisted wire shaft. If observed, the brush should be discarded in compliance with the disposal instructions described above.</li> <li>2. Brushes should also be inspected between uses for any residual organic soil that may cross contaminate the next device cleaned. If there is visual soil, the brush should be cleaned in accordance with the method(s) described below.</li> <li>3. Recommended maximum use life:           <ul style="list-style-type: none"> <li>○ 2 months for 610 and 620</li> <li>○ 3 months for 630 to 690</li> </ul> </li> </ol>
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	<ul style="list-style-type: none"> <li>• Terminal sterilization of brushes is not normally necessary. However, these brushes are compatible with steam sterilization.</li> <li>• For the brush part: maximum number of recommended sterilization cycles is 100 cycles.</li> <li>• For the wand part: maximum number of recommended sterilization cycles is 600 cycles.</li> <li>• If steam sterilizing, use standard FDA cleared cycles: 270F/4 minutes or 275F/3 minutes.</li> </ul>
<b>Storage:</b>	Avoid brush compression during sterilization and storage.
<b>Additional Information:</b>	Follow all manufacturers' directions for proper usage and disposal of all cleaning agents and chemical disinfectants agents.

<b>Related Healthmark Products</b>	Brush Cleaning Tools
<b>Other Product Support Documents</b>	Prosys Brochure, Prosys Pricelist
<b>Reference Documents</b>	
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> <a href="http://hmark.com">hmark.com</a>

2016-02-29 Ralph J Basile