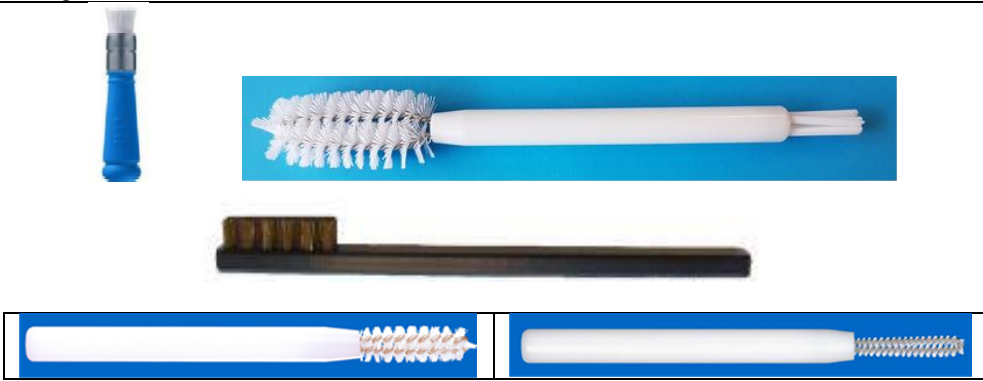


## Instructions for Use: LTA Precision External Cleaning Brushes

|                                          |                                                                                                                                                                                                             |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Brand Name of Product</b>             | LTA Precision External Cleaning Brushes                                                                                                                                                                     |
| <b>Generic Name of Product</b>           | Brushes                                                                                                                                                                                                     |
| <b>Product Code Number(s)</b>            | 410, 430, 560, 565, 570                                                                                                                                                                                     |
| <b>Intended Use</b>                      | For cleaning of burs, cutters, blades, drills, rasps, shavers and electrodes (bipolar or tripolar cutting / coagulation forceps / DeBakey forceps)                                                          |
| <b>Range of Applications for Product</b> | For the cleaning of external surfaces of items.                                                                                                                                                             |
| <b>Key Specifications of Product</b>     | <ul style="list-style-type: none"> <li>● Handle - Thermoplastic composite (autoclavable)</li> <li>● Brush catch - Stainless steel</li> <li>● Fibers - Thermoplastic compound with low absorbency</li> </ul> |

| <b>Shipping &amp; Storage</b>                 |  |
|-----------------------------------------------|--|
| <b>Shipping Conditions &amp; Requirements</b> |  |
| <b>Storage Conditions</b>                     |  |
| <b>Shelf Life</b>                             |  |

| <b>Instructions for Using Product</b>    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Description of Use(s)</b>             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Preparation for Use</b>               | Before each use, check the integrity and the condition of the brush. Replace any worn or damaged brush.                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Diagrams (drawings, pictures)</b>     |                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Steps for Use of Product</b>          | <ol style="list-style-type: none"> <li>1. Consult the manufacturer's IFU for the item you are cleaning and follow those instructions closely. Pay close attention to recommendations on the material composition of the brush trim.</li> <li>2. Visually inspect box lock area and serration for any debris / residual / bioburden / blood / protein.</li> <li>3. Use the brush first on all serrations.</li> </ol>                                                                |
| <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>● External brushes are intended for use as cleaning tools only. They are not for use in patient care or aseptic techniques.</li> <li>● Wear proper PPE in compliance with facility policy.</li> <li>● Clean and inspect each brush between each use and disinfect at least daily, preferably between each use in order to limit the opportunity for cross contamination. See instructions for reprocessing and inspection below.</li> </ul> |
| <b>Disposal</b>                          | <ul style="list-style-type: none"> <li>● Because these brushes are used to clean patient used items, it is recommended to dispose of them in a biohazard container when no longer useful for their purpose.</li> </ul>                                                                                                                                                                                                                                                             |

### Reprocessing Instructions

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|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Point of Use</b>                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Preparation for Decontamination</b>      | <ol style="list-style-type: none"> <li>1. Rinse gross contaminants from the brush in a deep sink and use a spray apparatus, such as a shower gun.</li> <li>2. Use the facilities cold water supply for this rinsing (to avoid corrosion do not immerse brushes in chlorine, bleach or acid solutions.)</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Disassembly Instructions</b>             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Cleaning – Manual</b>                    | <ol style="list-style-type: none"> <li>1. 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 use (i.e., protease, lipase, etc.). Only use facility approved cleaning agents / solutions.</li> <li>2. The IFU for the cleaning agent should be followed closely.</li> <li>3. It is recommended that agitation accompany the cleaning process to improve results.</li> <li>4. Thoroughly rinse cleaning solution from all surfaces of the brush.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Cleaning – Automated</b>                 | <ol style="list-style-type: none"> <li>1. Machine cleaning is recommended in a washer disinfector meeting the requirements of AAMI/ISO 15883-1.</li> <li>2. Products should be positioned in the washer to allow maximum water penetration and drainage.</li> <li>3. No overlapping - partially covered devices will not be washed properly.</li> <li>4. 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>5. Products can be cleaned with alkaline, acidic and neutral detergents.</li> <li>6. For final rinse, AAMI TIR34 Critical Water is recommended.</li> <li>7. The standard program includes: <ol style="list-style-type: none"> <li>1. Pre-wash with cold water (&lt;100°F) rinse for a minimum of 2 minutes.</li> <li>2. Washing cycle with alkaline or enzymatic detergent at temperature recommended by the detergent manufacturer for a minimum of 4 minutes.</li> <li>3. Washing cycle with neutral pH or neutralizing detergent at temperature recommended by the detergent manufacturer for a minimum of 2 minutes.</li> <li>4. Rinse cycle for a minimum of 1 minute.</li> <li>5. Thermal disinfection rinse at a minimum temperature of 180°F for a minimum of 1 minute. For final rinse, AAMI TIR34 Critical Water is recommended.</li> <li>6. Drying cycle at temperature not to exceed 240°F.</li> <li>7. Use caution when unloading machine as products will be hot.</li> <li>8. Visual inspection is required to ensure complete removal of soil.</li> <li>9. If visual soil remain, reclean.</li> </ol> </li> </ol> |
| <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 to exceed 200°F.</li> <li>• Brushes may be disinfected with liquid disinfectants in accordance with the disinfectant manufacturer's IFUs. Be sure to check material compatibility information from the disinfectant manufacturer. Use only facility approved disinfectant.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Drying</b>                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Maintenance, Inspection, and Testing</b> | <ul style="list-style-type: none"> <li>• Inspect for wear, fraying or damaged bristles. If observed, the brush should be discarded in compliance with the disposal instructions described above.</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 above.</li> <li>• Recommended maximum use life: 1 month</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <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>• Maximum number of recommended sterilization cycles is 30 cycles.</li> <li>• If steam sterilizing, recommended cycles are: 270F/4 minutes or 275F/3 minutes.</li> <li>• Maximum sterilization cycle time is 30 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 disinfectant agents.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Related Healthmark Products</b>          | Brush Cleaning Tools                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Other Product Support Documents</b>      | ProSys™ Brochure, ProSys™ Pricelist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

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|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reference Documents</b>      | AAMI TIR34;AAMI/ISO 15883-1: AAMI ST 79                                                                                                                                                                |
| <b>Customer Service Contact</b> | Healthmark Industries Company, Inc<br>33671 Doreka<br>Fraser, MI 48026<br>1-586-774-7600<br><a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a><br><a href="http://hmark.com">hmark.com</a> |

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