

| Brand Name of Product                    | Instrument Tube Brushes (ITB)  |
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| Generic Name of Product                  | Instrument Tube Brushes (ITB)  |
| Product Code Number(s)                   | ITB2-30-4, ITB2-30-6, ITB2-30-15, ITB2-60-6, ITB2-60-4, ITB-30-9, ITB-30-12, ITB-60- |
|  | 9, ITB-60-12, ITB2-60-15   |
| Intended Use                             | A tool for cleaning internal lumens/channels.  |
| <b>Range of Applications for Product</b> | Cleaning internal lumens/channels.   |
| Key Specifications of Product            | (Single use) ITB are available in a variety of sizes.                                |

| Shipping & Storage                 |     |
|------------------------------------|-----|
| Shipping Conditions & Requirements | N/A |
| Storage Conditions                 | N/A |
| Packaging Conditions               | N/A |
| Shelf Life                         | N/A |

| Instructions for Using Product |   |
|--------------------------------|---|
| Description of Use(s)          | Intended as a tool for the cleaning of internal lumens/channels.  |
| Preparation for Use            | <ul> <li>Intended as a tool for the cleaning of internal fulfield vectors.</li> <li>Cleaning a cannulated item requires the use of the proper size cleaning ITB in accordance with the manufacturer's (Mfr.'s) IFU.</li> <li>The Healthmark Brush Sizing Chart, or similar type of tool, may be used to select the proper diameter of the brush. It is important that the: <ul> <li>Diameter of the brush should be greater than the channel to be cleaned to ensure effective contact with surfaces.</li> <li>Length of the brush is longer than the channel to ensure the entire channel receives cleaning action.</li> </ul> </li> <li>Prior to each use, inspect brushes to be certain they are not (a) damaged, (b) have loose, missing, or frayed bristles, or (c) other signs of damage. If discrepancies are noted, the brush should not be used and discarded.</li> <li>Ensure the material composition of the brush's bristles is suitable for the item to be cleaned and in compliance with the Mfr.'s IFU.</li> </ul> |
|                                | <ul> <li>All brush bristles must exit the distal tip of the item being cleaned.</li> <li>Brushes should be inspected and cleaned in between each passthrough of an item if passed through more than once.         <ul> <li>Check for and clean any remaining bioburden or debris on or in the bristles (even if there is none, clean the brush anyway)</li> <li>Inspect the brush and shaft to ensure no damage (i.e., broken or matted bristles or kinked or damaged shafts) has occurred during the</li> </ul> </li> </ul>  |
| Diagrams (drawings, pictures)  | previous pass through. If so, dispose of the brush and use a new one<br>to complete the cleaning process.   |

|                                   | Bristles<br>Shaft<br>Shaft<br>Normal Brush   |
|-----------------------------------|--|
|                                   | Bristles<br>Shaft<br>Damage to the Shaft   |
|                                   | Bristles<br>Shaft<br>Fallen Bristles   |
|                                   | Bristles<br>Shaft<br>Shaft   |
|                                   | Loose or Missing Bristles  |
| Steps for Use of Product          | <ol> <li>Push Method: Insert the cleaning brush into lumen using short strokes. Feed the brush through the lumen until it emerges from the distal end.</li> <li>Pull Method: Insert the non-bristle end of the brush into the lumen, then follow with the bristles. (NOTE: This insertion technique optimizes cleaning action and prevents/reduces kinking or bending at the point where the brush is inserted.)</li> <li>(Important!) Ensure the brush is long enough to exit the lumen/channel completely when brushing so that the bristles can be examined and cleaned before next use.</li> <li>Twist the brush (helical spinning of the brush) while inserting it through the entire length of the lumen to help remove debris.</li> <li>While brushing, the brush should pass freely through the lumen.         <ul> <li>a. If significant resistance is encountered, stop and pull back.</li> <li>b. (Caution) Continuing to brush/force through the resistance might cause</li> </ul> </li> </ol>   |
|                                   | damage to the lumen.   |
|                                   | Consult the Mfr.'s IFU of the item being cleaned.  |
| Interpretation of Results         | Click Here         Click Here <thclick here<="" th="">         Click Here         Click He</thclick> |
| Contraindications of Test Results | N/A  |
| Documentation                     | N/A  |
|                                   |  |

| Special Warnings and Cautions | <ul> <li>Brushes are intended only as cleaning tools (<i>they are not for use in patient care</i>).</li> <li>Wear proper PPE when cleaning contaminated items.</li> <li>The brushes are intended for single-use. <ul> <li>A "use" should be defined by the healthcare facility upon a multi-disciplinary risk assessment.</li> <li>A "use" might be each: <ul> <li>Item.</li> <li>Set or case cart of instruments.</li> <li>Shift or day the brush is used.</li> </ul> </li> </ul></li></ul> |
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| Disposal                      | It is recommended to dispose of ITBs in the biohazard container because tube brushes are utilized to clean patient-used items (contaminated).  |

| Reprocessing Instructions            |     |
|--------------------------------------|-----|
| Point of Use                         | N/A |
| Preparation for Decontamination      | N/A |
| Disassembly Instructions             | N/A |
| Cleaning – Manual                    | N/A |
| Cleaning – Automated                 | N/A |
| Disinfection                         | N/A |
| Drying                               | N/A |
| Maintenance, Inspection, and Testing | N/A |
| Reassembly Instructions              | N/A |
| Packaging                            | N/A |
| Sterilization                        | N/A |
| Storage                              | N/A |
| Additional Information               | N/A |

| <b>Related Healthmark Products</b> | Brush Cleaning Tools   |
|------------------------------------|--|
| Other Product Support Documents    | ProSys <sup>™</sup> Brochure, ProSys <sup>™</sup> Price List |
| Reference Documents                | N/A  |
| Customer Service Contact           | Healthmark Industries Company, Inc.                          |
|                                    | 18600 Malyn Blvd.  |
|                                    | Fraser, MI 48026   |
|                                    | 1-586-774-7600   |
|                                    | healthmark@hmark.com   |
|                                    | hmark.com  |