INTENDED USE:
Key Surgical® Toothbrush-Style Cleaning Brushes and general cleaning brushes (BR-04-003, N-3000, N-4000 & S-4000, Acetabular bone reamer brush, N-2000) are designed to clean a variety of medical and non-medical products, devices, and surfaces in the cleaning and decontamination process.

PRECAUTION:
Stainless steel and brass bristles are not intended for use on insulated, plated, or coated instruments. For cleaning these, nylon bristles are recommended. Consult device manufacturer IFU for specific bristle recommendations.

CONTRAINDICATIONS:
There are no known contraindications and/or adverse effects.

PREPARATION:
Brushes must be cleaned and disinfected prior to reuse.

CLEANING & DISINFECTION:
Clean and disinfect brushes daily, at a minimum, prior to reuse. Brushes can be cleaned manually or using an automatic washer/disinfector.

MANUAL CLEANING:
1. Pre-rinse soiled brushes under cold tap water for one (1) minute to remove gross debris.
2. Prepare an enzymatic cleaning solution with suitable enzymes for cleaning the types of soil the brush may have come in contact with during use- follow the cleaning solution manufacturer’s written IFU for minimum effective concentration.
3. Soak brushes in prepared enzymatic solution for two (2) minutes (*Agitating bristles during this step may improve results).
4. Rinse brushes under cold tap water for one (1) minute.
5. Visually inspect brushes to ensure complete removal of soil from surfaces. No visible soil should be observed.
6. If soil is still visible, repeat above steps until brush is free from visible soil.
7. Protein assay tests may be used to ensure complete removal of protein residual.

DISINFECTION:
1. The thermal disinfection stage of an automated washer is sufficient for disinfection of the cleaning brushes.
2. Brushes may be disinfected with liquid chemical disinfectants in accordance with the disinfectant manufacturer’s written IFU. Confirm material compatibility (nylon and stainless steel) information with the disinfectant manufacturer.

INSPECTION:
Brushes should be inspected between uses and replaced when worn, frayed, bent or otherwise damaged. Worn or damaged bristles and handles are ineffective in cleaning and may damage the device.

STERILIZATION:
This sterilization is intended for one time use of brushes in a sterile setting and is not for brushes that have already been used.

New, unused brushes are provided non-sterile and have been validated for sterilization efficacy using gravity and pre-vacuum steam sterilization methods according to applicable international process standards and guidance at the following cycle parameters:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Minimum Time – Full Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>121° C (250° F)</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>132° C (270° F)</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>134° C (273° F)</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>134° C (273° F)</td>
<td>18 minutes</td>
</tr>
</tbody>
</table>

It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

STORAGE:
Store brushes in a manner that will reduce cross contamination.

DISPOSAL:
There are no special disposal instructions.