WARNINGs:
Follow the instructions and warnings issued by the manufacturers of any cleaning and disinfection agents and equipment used.

CARE AT THE POINT OF USE:
Clean Key Surgical® instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in an enzymatic solution or water to prevent drying and encrustation of surgical soil. Avoid prolonged exposure to saline to minimize the chance of corrosion. Remove excessive soil with a disposable wipe.

PREPARATION FOR CLEANING:
For instruments that require disassembly for cleaning, perform disassembly for that instrument.

MANUAL CLEANING (ALL INSTRUMENTS):
1. Clean delicate instruments separately from other instruments.
2. Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions.
3. Soak soiled instruments according to the instructions for use for the enzymatic solution.
4. Use a soft bristle brush to remove all visible traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
5. Rinse the instrument thoroughly with warm water.
6. Dry the instrument immediately after final rinse.
7. Follow the additional steps based on the instrument categories described below.

MANUAL CLEANING (INSTRUMENTS WITH CANNULATIONS, LUMENS, TUBES OR HOLES):
1. Follow the steps in Manual Cleaning for All Instruments.
2. When cleaning, fully immerse the instrument in the cleaning solution to avoid aerosol generation. Always brush with instrument submerged to prevent sprays/splashes and to remove all traces of blood and debris. Pay close attention to threads, crevices, seams and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks or spring-loaded features, to free trapped blood and debris.
3. When cleaning, use a form-fitting, soft, cleaning brush to scrub the cannula, lumen or hole. Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic cleaning solution to flush hard-to-reach internal areas.
4. Ultrasonically clean the instrument in a fully opened position for at least 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions.
5. When rinsing, pay particular attention to flush the cannulations, lumens, or holes with warm water.
6. Dry internal areas with filtered compressed air.

MANUAL CLEANING (INSTRUMENTS WITH MOVEABLE PARTS):
1. Follow the steps in Manual Cleaning for All Instruments.
2. When cleaning, fully immerse the instrument in the cleaning solution to avoid aerosol generation. Use a brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks or spring-loaded features, to free trapped blood and debris.
3. Ultrasonically clean the instrument in a fully opened position for at least 10 minutes in a neutral pH detergent, prepared in accordance with the manufacturer’s instructions.
4. When rinsing, pay particular attention to internal areas and movable parts. Actuate moveable parts while rinsing.
5. Dry internal areas with filtered compressed air.

AUTOMATED CLEANING (Continued):
1. Brush the instrument, actuate mechanisms, agitate and/or irrigate while submerged in the cleaning solution to prevent the creation of aerosols.
2. Load instruments so that hinges are open and cannulations and holes can drain.
3. Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.
4. For instruments with concave surfaces, such as curettes, place instrument with concave surface facing downward to facilitate draining.
5. Run the automatic wash cycle – minimum cycle parameters:
   • 5-minute cold prewash
   • 5-minute enzyme wash at 43° C minimum temperature
   • 5-minute detergent wash at 55° C minimum temperature
   • 1-minute rinse at 45° C minimum temperature

CLEANING INSPECTION:
Visually inspect all instruments before sterilization or storage to ensure the complete removal of soil from surfaces, holes and tubes and moveable parts. If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse the instruments thoroughly after using hydrogen peroxide solution. If soil is still present, re-clean the instrument.

DISINFECTION:
Instruments must be terminally sterilized prior to surgical use. See sterilization instructions below.

MAINTENANCE:
Between uses, lubricate moving parts with a water-soluble lubricant in accordance with the lubricant manufacturer’s instructions.

INJECTION AND FUNCTIONALITY TESTING:
Visually inspect the instrument and check for water damage. Jaws and teeth should properly align. Moveable parts should have smooth movement without excessive play. Locking mechanisms should fasten securely and close easily. Long, thin instruments should be free of bending and distortion. It is up to the individual user to determine when an instrument will no longer function properly.

PACKAGING:
Instruments may be packaged in facility approved containers, pouches or trays and sterilized according to the packaging manufacturer’s instructions.

STERILIZATION:
The Surgical Instruments have been validated for sterilization efficacy according to applicable international process standards and guidance for the following methods and parameters:

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temp.</th>
<th>Minimum Time – Full Cycle</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>121° C (250° F)</td>
<td>30 minutes</td>
<td>Unwrapped Instruments: 15 Minutes Wrapped Containment Devices: 30 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum</td>
<td>132° C (270° F)</td>
<td>4 minutes</td>
<td>Unwrapped Instruments: 15 Minutes Wrapped Containment Devices: 30 minutes</td>
</tr>
<tr>
<td>Pre-Vacuum Immediate Use</td>
<td>135° C (275° F)</td>
<td>3 minutes</td>
<td>Not Applicable</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.

Instruments have a life span and will require replacing if there any signs of deterioration.

STORAGE:
Store sterile package instruments in a manner that provides protection from dust, moisture and extremes of temperature and humidity.

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