Mesh Bag

INTENDED USE:
Key Surgical® Mesh Bags are intended to group together and/or contain small, accessory parts (from a medical device) during decontamination, disinfection and/or sterilization.

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

INSTRUCTIONS FOR USE:
1. Place the small items for cleaning in open bag.
2. Holding the cord, gather the top of the bag to close the top.
3. Press the button on the barrel lock and pull down to gathered top to close.

POINT OF USE CARE:
Clean Mesh Bag as soon as possible after use. If cleaning must be delayed, immerse in an enzymatic solution or water to prevent drying and encrustation of surgical soil. Remove excessive soil with a disposable wipe.

MANUAL CLEANING:
1. Pre-rinse under cold tap water for one (1) minute to remove gross debris
2. Soak for a minimum of two (2) minutes in a pH neutral detergent, prepared in accordance with the manufacturer’s instructions for use.
3. Rinse under cold tap water for one (1) minute.
4. Ultrasonically clean for a minimum of five (5) minutes in a neutral pH detergent, prepared in accordance with the manufacturer’s instructions for use.
5. Rinse under cold tap water for one (1) minute.

AUTOMATED CLEANING:
It may be necessary to manually clean prior to automated processing to improve the removal of adherent soil. Follow the previous instructions for manual cleaning.
1. Run the automatic wash cycle – minimum cycle parameters:
   • 1 minute cold pre-rinse
   • 5 minute enzyme wash at 43°C minimum temperature
   • 1 minute cold rinse
   • 7 minute dry at 90°C minimum temperature

CLEANING INSPECTION:
Visually inspect before sterilization or storage to ensure the complete removal of soil from surfaces. If soil is still present, re-clean the Mesh Bag.

HIGH LEVEL DISINFECTION:
The mesh bags have been tested for material compatibility in:
• 3% Glutaraldehyde solution for minimum 8-hour contact time
• OPA for minimum 8-hour contact time

STERILIZATION:
The mesh bags are provided non-sterile and have been validated for sterilization according to applicable international process standards and guidance for the following methods and parameters:

<table>
<thead>
<tr>
<th>100% Ethylene Oxide (EtO)</th>
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<tbody>
<tr>
<td>Concentration</td>
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<tr>
<td>Temperature</td>
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<tr>
<td>Exposure Time</td>
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<td>Humidity</td>
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<table>
<thead>
<tr>
<th>STERRAD® System and Cycle within the United States</th>
<th>STERRAD® System and Cycle outside the United States</th>
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<tr>
<td>STERRAD® 50</td>
<td>STERRAD® 50</td>
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<tr>
<td>STERRAD® 200</td>
<td>STERRAD® 200 Short cycle</td>
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<td>STERRAD® 100S</td>
<td>STERRAD® 100S Short cycle</td>
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<tr>
<td>STERRAD® NX Advanced cycle</td>
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<td>STERRAD® 100NX Standard cycle</td>
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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.

DISPOSAL:
Mesh Bags have a life span and will require replacing if there are any signs of deterioration or loss of functionality. Dispose of product following facility policy for disposal.

MANUFACTURER: KEY SURGICAL LLC
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