5.1. Limitation of Reprocessing
Repetitive processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on device’s life span and function. The life span is mainly affected by wear or damage during surgical use as well as proper care and handling techniques.

5.2. Point of Use
Remove the excess soils with a disposable cloth or paper wipe promptly after any use. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

4.2 Preparation for Cleaning
Disassembly is not required.

5.3. Manual Cleaning

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymatic Cleaner (e.g. Miltex EZ-Zyme)</td>
<td>Neutral Enzymatic Detergent Solution (e.g. Miltex EZ-Zyme)</td>
</tr>
<tr>
<td>Cleaning Brush (e.g. Soft Bristle Brush)</td>
<td>Ultrasonic Cleaning Bath</td>
</tr>
</tbody>
</table>

**Steps:**
1) Soak the device in an Enzymatic Cleaner for 10 minutes in accordance to manufacturer’s specifications
2) Rinse the devices under running tap water to remove debris
3) Immerse the devices in an Ultrasonic Cleaning Bath filled with Neutral Enzymatic Detergent Solution in accordance to manufacturer’s specifications for 10 minutes
4) Remaining debris are to be removed using a Cleaning Brush
5) Rinse the devices under running tap water to remove debris

5.4. Automatic Cleaning

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic Bath</td>
<td>Alkaline Cleaner (e.g. Dr. Weigert Neodisher FA)</td>
</tr>
<tr>
<td>Cleaning and Disinfectant Device (Miele G 7736 CD)</td>
<td></td>
</tr>
</tbody>
</table>

**Steps:**
1) Immerse the devices into an Ultrasonic Bath with 0.5% Alkaline Cleaner for 15 minutes at 40 °C.
2) Automatic Cleaning in the Cleaning and Disinfectant Device following the steps below:
   2a) 1 min pre-cleaning with cold water
   2b) Discharging
   2c) 3 min pre-cleaning with cold water
   2d) Discharging
   2e) 5 minutes with 0.5 % Alkaline Cleaner at 55°
   2f) Discharging
   2g) 3 minutes Neutralization with warm Water (>40°C)
   2h) Discharging
   2i) 2 minutes brushing with warm Water (>40°C)
   2j) Discharging

5.5. Manual and Automated Disinfection

**Manual:** Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified soaking time. Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

**Automatic:** Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to the A0 value (see ISO 15883).

5.5.1. Inspection and Functional Testing
Black & Black’s devices must be inspected after processing and prior to sterilization for:
- Cleanliness
- Damages
- Included but not limited to: corrosion, discoloration, excessive scratches, cracks and wear

5.6. Packaging

**Equipment:** - Sterilization Wraps

**Steps:** Wrap instrument in accordance with local procedures and using standard techniques such as those described in ANSI/AAMI ST77 ANSI/AAMI ST79 and ISO 11607

5.7. Sterilization

**Equipment:** - Steam Pre-Vacuum or Gravity Sterilizer

**Steps:**
- Cycle Type T (°C - °F)
- Time (min)
- Pre-Vacuum 132 - 270
- 4
- Gravity 132 - 270
- 15

5.8. Storage
Store the packaged devices in a normal environmental condition free from dust, insects, vermin as well as temperature and humidity fluctuations.

6. Used Symbols for IFU and Label

- **Symbol for “Manufacturer”**
- **Symbol for “Catalog Number”**
- **Symbol for “Batch Code”**
- **Symbol for “Serial Number”**
- **Symbol for “Consult the Instruction for Use”**
- **Symbol for “Non-Sterile”**
- **Symbol for “Caution, consult accompanying documents”**
- **Symbol for “Do not Reuse”**
- **Symbol for “Conformity to the Essential Requirements”**