REPROCESSING, CLEANING AND STERILIZATION PROCEDURES

Lapro-Clip™ reusable single clip applier

Always refer to the instructions for use (IFU) supplied with the Lapro-Clip™ reusable single clip applier handles for complete indications, contraindications, warnings, precautions and instructions prior to use.
Reprocessing, cleaning and sterilization procedures

These instructions were taken directly from the IFU. Do not disassemble the Lapro-Clip™ reusable single clip applier handles any further than described here.

Manual reprocessing should be conducted at point of use. Remove excess soil with disposable wipes, or wrap instrument in moist towel if reprocessing is not conducted immediately.

The clip applier has a limited life and may be used up to 350 times. A tracking card is provided in the package of the clip applier for the purpose of tracking the number of uses.

Cleaning and disinfection

Instrument should be cleaned thoroughly immediately after use to remove all traces of blood and debris. To accomplish cleaning effectively, the end cap must be removed and the inner shaft assembly separated from the handle (Figures 1A and 1B). No further disassembly required.

All three pieces can be cleaned/sterilized as described. Particular attention should be paid to crevices and hard-to-reach areas. Scrub with a soft bristle brush under warm water (20–25º C) using a mild detergent/enzymatic cleaner. Manual brush time should be greater than five minutes and until visibly clean. Final rinse should be with purified water for at least 1 minute.

Caution: Enzymatic cleaners should have a pH between 7.5 and 9.5 and alkaline cleaners should have a pH between 12.7 and 14.0.

Figure 1A: Disassembly required for sterilization

Figure 1B: Disassembly required for sterilization
Automatic cleaning

Reusable instruments should be cleaned thoroughly immediately after each use to remove all traces of blood and debris. Pay particular attention to crevices and hard-to-reach areas while scrubbing instruments with a soft bristle brush in warm water (20–25° C) with a mild detergent/enzymatic cleaner. Manual brush time should be greater than five minutes and until visibly clean. Medtronic reusable devices may be placed in an automatic dishwasher at 194° F (90° C).

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Time (MM:SS) minimum</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>00:45</td>
<td>Cold Tap Water</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>04:00</td>
<td>Hot Tap Water</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot Tap Water</td>
</tr>
<tr>
<td>Wash</td>
<td>03:00</td>
<td>Hot Tap Water</td>
</tr>
<tr>
<td>Rinse</td>
<td>00:15</td>
<td>Hot Tap Water</td>
</tr>
<tr>
<td>Thermal Rinse</td>
<td>01:00</td>
<td>Hot Tap Water (heated to 180º F or 82º C)</td>
</tr>
<tr>
<td>Dry</td>
<td>05:00</td>
<td>High Setting (203º F or 95º C)</td>
</tr>
</tbody>
</table>

Lubrication

Prior to sterilization, devices should be lubricated with a water soluble lubricant such as Tomac™ solution to help insure proper operation.

Sterilization

The Lapro-Clip™ device is provided nonsterile and is designed for reuse. It may be sterilized in accordance with the following process parameters:

- **Steam sterilization**
  - 4 minutes 132° C prevacuum, wrapped
  - 3 minutes 134° C prevacuum, wrapped
  - 15 minutes 121° C gravity cycle, wrapped

- **Dry time**
  - Prevacuum for 15 minutes
  - Gravity cycles for 20 minutes

Maintenance

Visually inspect the instrument for damage or wear and check for proper function prior to each use.