Aesculap MILI Obturator

CARE AND HANDLING OF: MILI OBTURATOR (ME777R)

Assembled Obturator

PRODUCT DESCRIPTION
The Obturator consists of the following instruments:

- Outer Shaft
- Inner Shaft

The instrumentation is intended for use during posterior fusion of the lumbar spine with the MILI implant system. The Obturator is designed to be inserted into the Downtube and this assembly is inserted over a guide wire. Detailed instructions for using this device are provided in the MILI Surgical Technique.

PRECAUTION
The use of these instruments for tasks other than those indicated in the MILI Surgical Technique Guide may cause injury to the patient or damage or potentially break the instrument.

WARNING
If this device is/was used in a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to eliminate the risk of cross-contamination through reprocessing or sterilization.

Proper cleaning, handling, sterilization, and standard routine maintenance will ensure that all instruments perform as intended and will extend their useful lives.

HOW SUPPLIED
All MILI instruments are supplied non-sterile and must be cleaned and sterilized prior to each use according to the procedures outlined in this document.

INSPECTION
Before use, inspect the instrument components for possible damage, wear or non-functioning parts. Carefully inspect the critical components (e.g. locking pins protrude in the locked position and retract in the unlock position.).

Damaged or defective instruments should not be used or processed. Contact your local sales representative or Aesculap Implant Systems, Inc. for repair or replacement.

Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris.

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.

CARE AND HANDLING
The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

1. PRE-CLEANING
Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Disassemble components to expose all surfaces and clean separately.

2. CLEANING
Cleaning Precautions
- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

a. Manual Cleaning
Hand wash using a low-sediment protein dissolving detergent. Follow manufacturers’ directions regarding concentration, temperature, contact time and reuse.

Totally immerse instruments during cleaning to prevent aerosolization.

Use a large syringe or pulsating water jet to thoroughly flush all channels and cavities with cleaning solution to remove debris.

Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

Use a brush to clean the cannulation.

3. DRYING
Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

4. RINSE
Rinse all instruments thoroughly with tap water, deionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal cavities and ratchets are thoroughly rinsed.

5. DECONTAMINATION
Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent’s recommended directions regarding concentration, temperature, contact time and solution re-use.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury.

Completely immerse instruments in the disinfecting solution. Force solution into all areas and cavities.

Thoroughly rinse with distilled water to remove all traces of disinfecting solution. USE STERILE WATER ON THE FINAL RINSE.

6. LUBRICATION / ASSEMBLY
Lubrication is recommended every time instruments are processed. Special attention should be given to lubrication of joints and movable parts. Only lubricate dry instruments.

Do not use mineral oil, petroleum, or silicone-based products. To lubricate joints, use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Instrument Oil, JG598.

Reassemble instruments, as necessary, before assembly into baskets or trays. Inspect instrument components for mechanical damage, pits, cracks, misalignment and corrosion. Remove damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly.

STERILIZATION
NOTE: Disassembly of instrument is recommended prior to sterilization.

Sterilization of instruments is to be accomplished by steam. The recommended sterilization parameters are as follows:

Preconditioning Pulses: 3

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Full Cycle Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>270-275°F</td>
<td>10 minutes</td>
<td>20 minutes</td>
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<tr>
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<td>132-135°C</td>
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The cycle times for wrapped product are based on the recommendations of the AAMI Guidelines ST46 for steam sterilization. Instruments have also been validated for sterility in a STERILCONTAINER™ System at the above recommended cycle parameters.

Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle, design, and packaging/containerization. The manufacturer’s instructions must be followed for each sterilization chamber.

STORAGE
Once the product is sterilized, it can be stored in the sterilcontainer.

MAINTENANCE AND REPAIR
If any Aesculap MILI System instrument or its components require repair or maintenance, return the entire instrument set in a sturdy box with adequate foam, bubble wrap or other packaging material to protect it. Send the packaged instrument to:

Aesculap Technical Services
615 Lambert Point
Hazelwood, MO 63042

Instruments returned to Aesculap Implant Systems for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.