

Instrument Cleaning and Sterilization Instructions

General

The hospital and hospital staff are responsible for processing and/or reprocessing appropriately using the materials, equipment, and processes outlined in this document. In addition, the hospital is responsible for ensuring that the staff and personnel within the reprocessing facility have been adequately trained to perform the procedure correctly and as outlined in this document. All equipment and processes used should be validated and monitored regularly. Any deviation from the processes outlined in these instructions should be appropriately documented and evaluated for effectiveness in order to avoid in adverse outcomes or issues related to cleanliness or sterilization.

Warnings and Precautions

- Instruments are critical devices and must be terminally sterilized by steam sterilization prior to surgical use.
- Prior to sterilization and promptly following each procedure, thoroughly clean all instruments according to the procedures outlined below. The parameters for sterilization and sterilization processes listed below are only valid for devices that have been properly cleaned.
- All instruments should not be allowed to dry before reprocessing to effectively clean and remove contaminants including blood, body fluids, bone and tissue debris, and other contaminants.
- Contaminated instruments should not be rinsed with hot water [temperatures greater than 110°F (45°C)], concentrated alcohol, certain liquid chemical sterilants, or certain disinfectants such as glutaraldehyde or ortho-phthalaldehyde as these may cause protein-based contaminants to denature rendering them difficult to remove.
- Do not use silicon or oil-based lubricants as these may inhibit sterilization.
- Do not use metal cleaning tools such as metal or wire brushes, scouring pads, etc. to clean the instruments as these may damage the surface of the instruments.
- To properly clean the instruments manually, the user facility may use tools such as (non-metallic) soft-bristled brushes, pipe cleaners (multiple diameters and lengths), low-linting cloths, and flushing tools for cannulated instruments such as syringes, water guns, etc. All brushes and cleaners should be appropriately sized to pass down or through cannulations while maintaining contact with all internal surfaces.

Instrument Disassembly

Refer to Appendix A for the instruments that must be disassembled prior to cleaning and the disassembly instructions.

Cleaning and Decontamination

Instruments and cases may be processed using manual or automated cleaning methods using the steps listed below.

Prior to Cleaning

All Engage™ Partial Knee System instruments must be disassembled prior to cleaning (if applicable). To prevent injury, separate pointed and sharp instruments and place them in a separate tray.

Cleaning Agents and Water

- Select enzymatic cleaning solutions that are intended to breakdown blood, body fluids, fat, and tissue. Enzymatic solutions designed specifically for the breakdown of fecal matter or other organic contaminants are not suitable choices for orthopedic instruments.
- Ensure that the appropriate cleaning agents are selected for the cleaning equipment in which they are used and follow the cleaning agent manufacturer's recommendations for water quality, temperature, exposure times, and concentration.
- Natural pH enzymatic cleaning agents should be used as alkaline or acidic agents may cause corrosion or discoloration of the stainless steel and aluminum instruments.
- All cleaning agents should be easily and completely rinsed from devices to prevent residue buildup.

Manual Cleaning Method

1. Rinse soiled instruments under running cold tap water. Actuate all instruments through their full range of motion. While rinsing, remove all gross visible soil with a damp gauze pad, wipe, or soft-bristled brush. Flush hard-to-reach areas with a syringe.
2. Prepare an enzymatic cleaning solution per the manufacturer's instructions. Immerse all instruments in the cleaning solution for a minimum of 10 minutes. Thoroughly scrub all instruments with a soft-bristled brush while immersed in the solution to prevent aerosolization of contaminants. Scrubbing must also include any lumens with an appropriately sized round brush or flushing with a syringe and cold water. Actuate joints, handles, and other movable instrument features to expose areas to the cleaning solution several times.
3. Thoroughly rinse all instruments under running water for one minute.
4. Prepare a fresh enzymatic cleaning solution per the manufacturer's instructions in a sonicator. Transfer all instruments to the fresh enzymatic cleaning solution in the sonicator. Actuate all instruments through their full range of motion. Flush hard-to-reach areas using a syringe. Ultrasonically clean all instruments while immersed in the cleaning solution for at least 10 minutes.
5. Remove all instruments from the cleaning solution and rinse all instruments thoroughly with purified, reverse osmosis/deionized (RO/DI), or sterile water for three minutes. Actuate all movable parts through their full range of motion. Flush all hard-to-reach areas with a syringe.
6. Verify that all instruments are visually clean; if not, repeat the cleaning process from the beginning until all instruments are clean.
7. Dry instruments with a clean and soft cloth, with clean compressed air, and/or allow to air dry.

Automated Cleaning Method

1. Prepare an enzymatic cleaning solution per the manufacturer's instructions. Immerse all instruments in the cleaning solution for a minimum of 2 minutes.
2. Thoroughly scrub all instruments with a soft-bristled brush while immersed in the solution to prevent aerosolization of contaminants. Scrubbing must also include any lumens with an appropriately sized round brush or flushing with a syringe. Actuate joints, handles, and other movable instrument features to expose areas to the cleaning solution several times.
3. Thoroughly rinse all instruments under running water for one minute.
4. Transfer all instruments into the washer for processing.
5. Pre-wash with cold water for 2 minutes.
6. Wash with an enzymatic cleaning solution of per the manufacturer's instructions for 10 minutes.
7. Rinse with warm water 140°F (60°C) for 2 minutes.
8. Rinse with warm RO/DI or purified water for 2 minutes.
9. Dry at ≥ 230°F (110°C) for 7 minutes.
10. Verify that all instruments are visually clean; if not, repeat the cleaning process from the beginning until all instruments are clean.

Steam Sterilization Instructions (Reusable Instruments)

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time. If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried, and sterilization repeated.

1. All instruments should be inspected prior to use or sterilization for corrosion, pitting, discoloration, cracking, or anything that might indicate excessive wear or improper function. If any part shows excessive wear or improper function, return to Engage Surgical for a replacement.
2. Visually inspect the instrument tray and content for dry blood or other contaminants.
3. Return the instruments to their designated location in the sterilization tray.
4. Any instruments not stored in the tray should be sterilized individually per validated hospital procedure.

Sterilize the instruments prior to use according to the following parameters:

Option 1 - Pre-vacuum Steam Cycle

- 3 Pre-conditioning pulses
- Minimum temperature of 132° C (270° F)
- Cycle time 4 minutes
- Minimum Dry Time of 30 minutes
- Single wrapped configuration using an FDA cleared wrap

Option 2 – Gravity Displacement Steam Cycle

- Minimum temperature of 132° C (270° F)
- Cycle time 10 minutes
- Minimum Dry Time of 30 minutes
- Single wrapped configuration using an FDA cleared wrap

Caution: It is recommended that an FDA-cleared sterilization wrap is used when wrapping the containers for Option 1 and 2.

The reusable instruments can be steam sterilized using the ONE TRAY® Sealed Sterilization Container System (K052567) which is a rigid reusable case from Innovative Sterilization Technologies, LLC. After completing steps 1-3 above place the Engage sterilization container **without** the lid installed, into the ONE TRAY® Sealed Sterilization Container System. Follow the Innovative Sterilization Technologies, LLC instructions for the ONE TRAY® Container System. Sterilize the instruments using the following parameters:

Option 3 - ONE TRAY® - Pre-vacuum Steam Cycle

- 3 Pre-conditioning pulses
- Minimum temperature of 132° C (270° F)
- Cycle time 4 minutes
- Minimum Dry Time of 0 minutes

The Engage sterilization containers are compatible for use with ONE TRAY® Models M2104, M2106, M2108, M2404, M2406, and M2408.

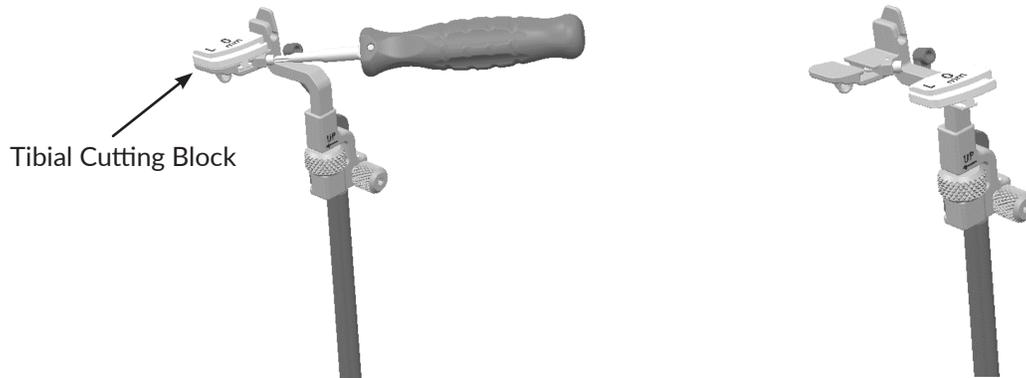
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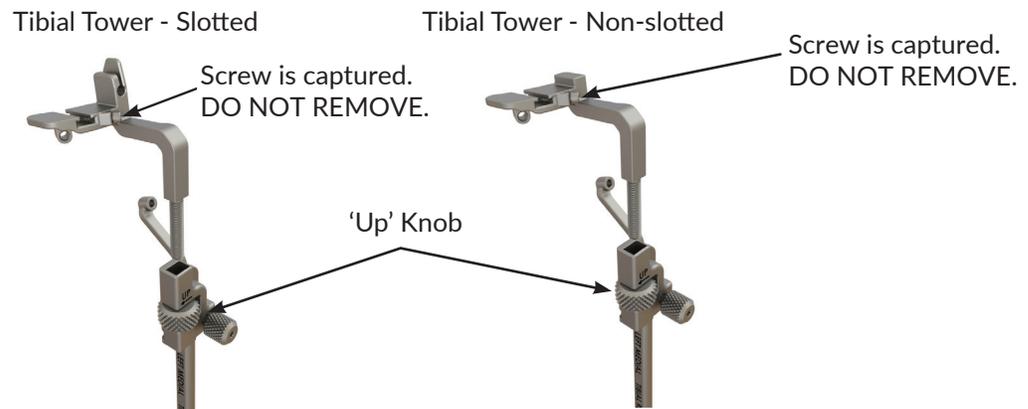
Appendix A

Instrument Disassembly Instructions

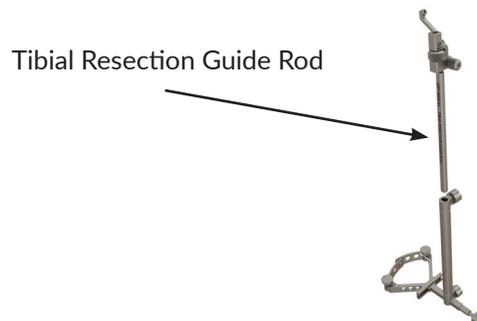
Remove the Tibial Cutting Block by loosening the screw and sliding the Block off the Tower.



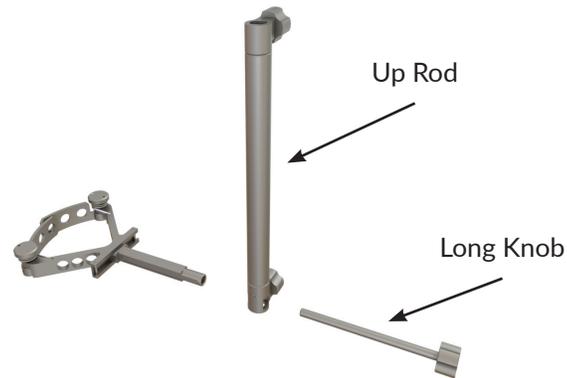
Remove the Tibial Tower by turning the knob in the indicated 'up' direction until it is completely removed.



Remove the Tibial Resection Guide Rod by loosening the knob and sliding the Rod out.



Disassemble the Ankle Clamp by first unscrewing the long knob fully out and then loosening the side knob and sliding the Up-rod off.



When applicable, disassemble the Shim from the Tensor Block by pinching the sides and sliding the Shim up.

