

Cleaning and Sterilization Instructions

Treace Medical Concepts (TMC): General Instruments

Manual Cleaning

The TMC general instruments must be cleaned to achieve sterilization. The recommended manual cleaning instructions are described below:

- Instruments should be cleaned as soon as possible. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Do not allow blood and debris to dry on the instrument.
- Disassemble instrumentation, if applicable.
- Rinse the device thoroughly under running warm (35-40°C) tap water for a minimum of 1 minute. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from device.
- Soak the device in a neutral enzymatic cleaner (e.g. Enzol or equivalent) for a minimum of fifteen (15) minutes. Components must be fully immersed in the cleaner. Ensure that there are no air pockets in the hard to reach areas such as lumens or mated surfaces. Follow the cleaner manufacturer's instructions for cleaner preparation and maximum exposure time.
- Thoroughly rinse the components with warm (35-40°C) water for a minimum of 1 minute. While rinsing, use soft bristle brushes, a syringe to clean out lumens, holes, and other challenging features.
- Manually scrub the device thoroughly in freshly prepared, clean, neutral pH enzymatic cleaner using soft bristle brushes or syringes. All lumens, holes, hinged components, mating surfaces, and crevices, and challenging features should be thoroughly scrubbed. Actuate all moveable features 3X and expose all areas to the cleaner.
- Rinse the device thoroughly with deionized water; using a syringe the flush lumens, holes, and other hard to reach or challenging features for a minimum of 1 minute. Actuate all movable features to fully irrigate all areas.
- Visually inspect device for soil. Repeat the cleaning procedure until no visible soil remains on the components.
- Perform a final rinse on the components using deionized water for a minimum of 1 minute.
- Dry the components using clean compressed air or a soft, lint free, clean cloth.
- Use Weiman® Instrument Lubricant (or equivalent lubricant, CAS Number 8042-47-5) on any moving parts to ensure that they move freely and do not bind during use. Always follow the lubricant manufacturer's instructions.
- Orthopaedic instrumentation does not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning and sterilization processes. Instruments should be carefully inspected prior to use to ensure that they are fully functional. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor functionality. Damaged instruments should be replaced to prevent potential patient injury such as deposition of metal fragments into the surgical site.

Sterilization

When sterilizing the TMC Instrument Trays or TMC general instruments, please use the following guidelines:

Method	Pre-vacuum steam sterilization
Wrapping	Wrap tray and/or instruments in two layers of FDA-cleared sterilization wrap
Temperature	270°F (132°C)
Exposure Time	4 minutes
Drying Time	30 minutes (minimum, in chamber)

Method	Gravity steam sterilization
Wrapping	Wrap tray and/or instruments in two layers of FDA-cleared sterilization wrap
Temperature	270°F (132°C)
Exposure Time	15 minutes
Drying Time	15 minutes (minimum, in chamber)

An autoclave cycle has been validated by Treace Medical Concepts, Inc. as being capable of achieving sterile medical devices; however, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should verify the process that they use, employing the actual equipment and operators that routinely process the devices.

