



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:

Note 1: 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.

Note 2: Instruments must be removed from the trays or cases throughout the cleaning.

Note 3: Disassemble instrumentation, if applicable. Positioner Caps do not need to be disassembled.

Note 4: Use 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.

Note 5: 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.

1) Cleaning Instructions:

Step Number	Process Instruction
1	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. <i>Note: Pay special attention to all holes, mated surfaces, and crevices.</i>
2	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.
3	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.
4	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.
5	Rinse the device thoroughly with deionized water; using a syringe to 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.
6	Visually inspect device for soil. Repeat the cleaning procedure until no visible soil remains on the components.
7	Perform a final rinse on the components using deionized water for a minimum of 1 minute.
8	Dry the components using clean compressed air or a soft, lint free, clean cloth.

Automated Wash

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

Note 1: 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.

Note 2: Instruments must be removed from the trays or cases throughout the cleaning.

Note 3: Disassemble instrumentation, if applicable. Positioner Caps do not need to be disassembled.

Instrumentation precleaning shall be performed prior to cleaning through the automated washer.

1) Pre-Cleaning Instructions:

Step Number	Process Instruction
1	Soak the instrument in tap water for a minimum time of 10 minutes. While soaking, brush the instrument using a soft bristle brush to loosen and remove as much visible soil as possible from instrument. Note: Pay special attention to all holes, mated surfaces, and crevices.
2	Using a syringe, flush all lumens (if present) for 30 seconds with tap water.
3	Brush under tap water with a soft bristled brush for a minimum of 40 seconds or until all residues are removed. Actuate all moveable parts to expose all areas to the tap water.
4	Rinse the instrument under tap water for a minimum of one (1) minute.
5	Visually inspect device for soil. Repeat steps 1 through 4 if visible soil remains.
6	Dry the instruments using clean compressed air or a soft, lint free, clean cloth.

2) Automated Washer Instructions

- a. Washer should be compliant to requirements established by ISO 15883.

Automated Wash Cleaning Cycle:

Cleaning Procedure			
Automated Cleaning Criteria			
Cycle	Time	Temperature	Detergent & Concentration
Pre-rinse	3 min	Cold Water	N/A
Enzymatic Wash	5 min	131 °F (55°C)	Enzymatic Detergent (e.g. Enzo [®] or equivalent)
Wash 2	3 min	150 °F (65.5°C)	Neutral Detergent (e.g. Prolystica [®] 2X concentrate or equivalent)
Rinse	3 min	Warm water (> 110 °F (> 43°C))	N/A
Drying	Dry the outside of the instruments using the drying cycle of the cleaning equipment. If necessary, instruments can be dried by hand with a sterile lint-free cloth. Compressed, filtered air can be used for instruments with lumens.		

Note 4: Use 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.

Note 5: 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.

Note 6: An automated wash cleaning cycle has been validated by Treace Medical Concepts, Inc. as being capable of achieving clean medical devices; however, automated wash 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.

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)

Note 1: 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.

