

Talos® Interbody Fusion Devices Instruments
Method: Reprocessing for Instruments and Tray

Manufacturer: Meditech Spine, LLC

CAUTIONS

1. The TALOS® Interbody Fusion Devices instruments are provided non-sterile and must be thoroughly cleaned and sterilized before use.
2. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
3. Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.
4. Saline solution has a corrosive effect on stainless steel and should not be used.
5. Use only neutral pH cleaning agents and detergents.
6. These guidelines are not intended for TALOS® spinal implants.

LIMITATIONS ON REPROCESSING:

1. Repeated processing has limited effect on REUSABLE instruments.
2. End of life is determined by wear and damage due to use.

PROCEDURE

1. Preparation for Decontamination:

NOTE: if applicable, the instruments must be disassembled.

- Immediately after use, remove visible body fluid, tissue and/or bone (soil) from instruments/parts using clean flowing tap water and disposable wipes. This prevents any soil from drying on the instruments prior to reprocessing.
- Reprocess instruments as soon as possible after use.

2. Cleaning—Manual:

- Automated washer/disinfector systems may not be used as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.
- Prepare a neutral pH cleaning solution (0.8% ENZOL®) at room temperature.
- Completely submerge the instruments/parts in the cleaning solution.
- Thoroughly clean for at least 1.5 minutes with a soft non-sterile cloth or soft bristle brush. .
- Clean the lumens of the Implant Inserter or Trials with a long, narrow, soft-bristled brush.
- Thoroughly flush lumens with the cleaning solution.
- Remove the instrument/parts from the cleaning solution and rinse in de-ionized water for a minimum of 1 minute. Repeat rinse 2 times for a total of 3 rinses.
- After manual cleaning, when all visible soil has been removed, ultra-sonic cleaning may be used.
- Use de-ionized water for a final rinse of all components.
- After rinsing, dry the instruments with lint free clean gauze or operating room towels and place in tray.

3. Disinfection:

- Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

4. Inspection:

- Visually inspect each instrument/part and the Inserter lumen to ensure that all visible soil has been removed. If soil is visible, repeat Step 2.

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- If soil cannot be removed by cleaning, dispose of the instrument per facility procedures.
- Visually inspect for damage and/or wear, such as corrosion, pitting, or discoloration, which could affect the function of the instrument. Do not use - contact your Meditech Spine, LLC representative for a replacement.

5. Packaging:

- The Tray containing the instruments/ parts must be wrapped in a double layer of non-woven CSR wrap and placed in the sterilizer.

6. Sterilization:

- The instruments are provided non-sterile and must be autoclave sterilized and dried before use, according to these validated procedures.
- Sterilize utilizing a pre-vacuum steam autoclave for a minimum of 4 minutes at 270°F (132°C) with 4 pulses (3 pull pulses and one sterilization charge).

7. Drying:

- A minimum drying time of 20 minutes is required.
- After the end of the cycle, remove the tray from sterilizer and allow it to cool to room temperature for 60 minutes.
- Reassemble the Implant Insertor before use.

8. Storage:

- Store sterilized instruments in the tray in a controlled/sterile reprocessing area until use. Follow your facility procedure for storage shelf life of sterilized medical devices.
- Store unsterilized instruments in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.

The instructions provided above have been validated by Meditech Spine, LLC as being capable of preparing medical device instruments and trays for reuse. **It remains the responsibility of the processor to ensure that the reprocessing is actually performed, using equipment, materials, and personnel in the reprocessing facility to achieve the desired result.** Effective sterilization normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

MANUFACTURER CONTACT AND SHIPPING INFORMATION:

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