Tetrous EnFix® Instruments
INSTRUCTIONS FOR USE

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

GENERAL INFORMATION

This document is intended to provide detailed instructions for processing reusable surgical instruments manufactured by Tetrous. Tetrous instruments are manufactured from various materials commonly used in reusable medical and surgical instruments, including stainless steel, aluminum and polymers. Tetrous has validated the processes provided in these instructions. Alternative methods of processing outside the scope of this document may be suitable for reprocessing. However, these processes must be validated by the user.

WARNINGS

- Instruments are provided non-sterile and must be cleaned and sterilized before use. The validated cleaning process is provided in the CLEANING INSTRUCTIONS sections of this document; and validated sterilization parameters are described in the STERILIZATION INSTRUCTIONS section of this document.
- Some instruments may have sharp edges or points. Care should be taken in handling such instruments to avoid injury to the user or patient.
- Staff should wear suitable protective clothing and equipment at all times. Special note should be taken of the instructions provided by the manufacturers of the cleaning agents used in the cleaning process.
- The surgeon should have a complete understanding of the surgical technique and of the function and limitations of each instrument.

CLEANING AND MAINTENANCE

All instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures for contaminant removal. Only cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration and use of those agents.

Cleaning instructions are provided in accordance with recognized standards and regulations, and are intended to supplement a hospital's existing device cleaning and disinfecting protocols. Contaminated devices should be rinsed and wiped clean of visible soil at the point of use prior to being transferred to a central processing unit for cleaning and sterilization. Used instruments should be transported to the sterile processing facility in closed or covered containers to prevent unnecessary contamination or risk. Contaminated devices must be cleaned promptly after use per these provided instructions in order to ensure effective cleaning.

Instruments and trays should be visually inspected for any damage between surgeries. Functionality of mating fits and of moving parts should also be checked between surgeries. The sterilization tray must be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent. In the US, an FDA-cleared steam sterilization wrap must be used.

CLEANING INSTRUCTIONS FOR INSTRUMENTS

Follow the manual cleaning instructions listed below prior to sterilization to clean the individual instruments.

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Tetrous recommends 8mL/L Neodisher Mediclean Forte Detergent, or equivalent. Scrub using a soft-bristled, nylon brush (crevices, lumens, mated surfaces and other hard to clean areas should be attended) until all visible soil has been removed. Clean cannulations and holes using an appropriate brush ensuring that the full depth of the feature is reached. Hold the items low in the sink to limit the generation of aerosols during scrubbing.
2. Remove the device from solution and rinse in purified water (from one or any combination of the following: ultra-filter (UF), reverse osmosis (ROI), deionized (DI) or distilled) for a minimum of 3 minutes. Thoroughly flush holes and other difficult to reach areas. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied.
3. Pour the prepared cleaning solution into a sonication unit, completely submerge the device in the solution and sonicate for 10 minutes at 40-50Hz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
7. If stainless steel instruments are stained or corroded, an acidic anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

CLEANING INSTRUCTIONS FOR TRAY

Follow the automated cleaning instructions listed below prior to sterilization to clean the empty tray (no instruments should be in the tray during automated cleaning).

1. The Tetrous instrument tray was validated using a Steris Single-Chamber Washer using neutral pH Steris Prolystica Ultra Concentrate under the parameters shown below.

Phase		Time	Temperature
Pre-wash		2 minutes	Cold tap water (nominal temperature < 21°C or < 70°F)
Wash	Stage 1	1 minute	122°F (50°C)
	Stage 2	2 minutes	150°F (65.6°C)
Rinse		15 seconds	Hot tap water (nominal temperature 43-66°C or 110-150°F)
Thermal Rinse		1 minute	194°F (90°C)
Dry		5 minutes 30 seconds	NA

STERILIZATION INSTRUCTIONS

All instruments and instrument tray must be sterilized prior to use. The following steam sterilization parameters have been validated for the individual Tetrous instruments and for the Tetrous instruments loaded into the instrument tray:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

Note: Sterilization parameters were validated using standard blue sterile wraps.

These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. It is the user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared or approved by the regulatory authority of their country for the selected sterilization cycle specifications (time and temperature).

STORAGE

Store the instruments and instrument tray in standard hospital environmental conditions. Instrument trays are not intended to maintain product sterility. Sterilization wraps may be used post sterilization. In the US, these sterilization wraps must be FDA-cleared.

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