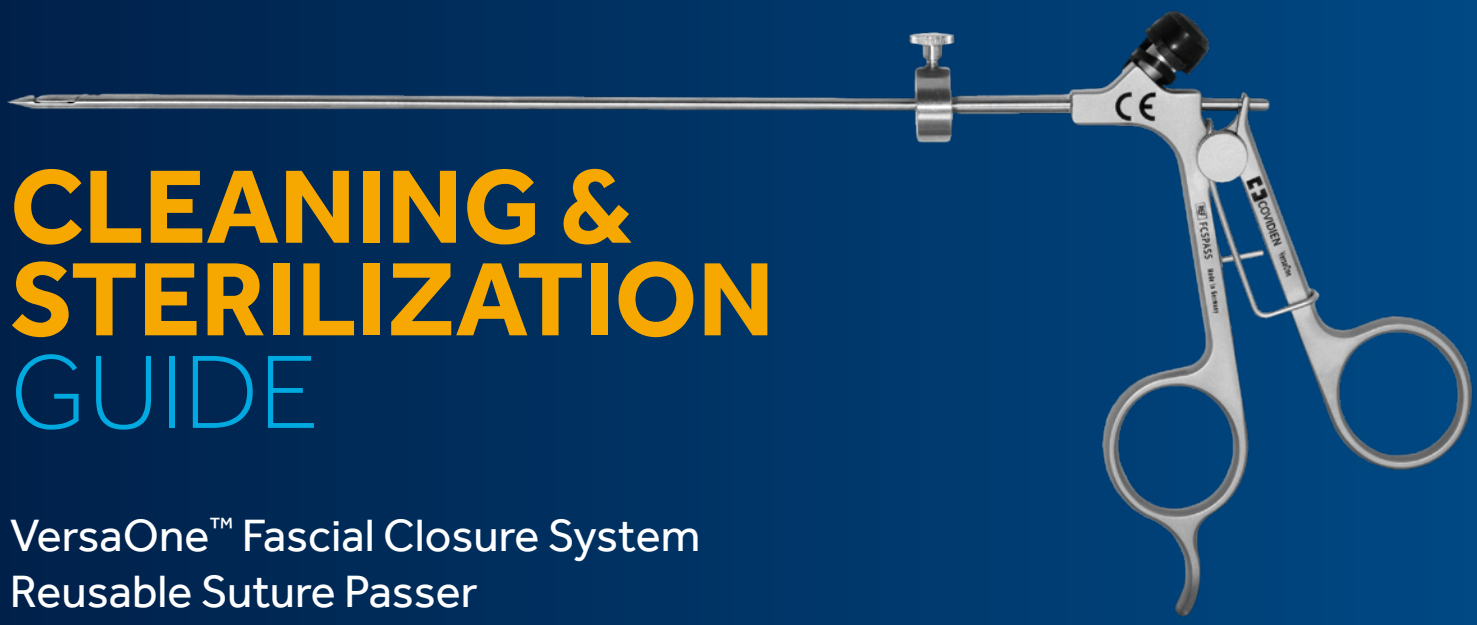
CLEANING & STERILIZATION GUIDE



VersaOne™ Fascial Closure System
Reusable Suture Passer

REPROCESSING INSTRUCTIONS

Always ensure that the devices are handled and processed by qualified personnel who are specially trained & adequately experienced in regard of hospital hygiene and sterilization technology. In order to ensure safe and effective reprocessing of the devices, the following instructions have been validated for efficacy and compatibility with the devices by the manufacturer. It is the responsibility of the end user to ensure that the cleaning and sterilization is performed using appropriate equipment, materials, and personnel to achieve the desired result. Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

WARNING

Before initial use and any subsequent use, all reusable products have to be subjected to reprocessing as described in the following sections. Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants, and cleaning agents used.

PREPARATION PRIOR TO FIRST USE

The reusable products are delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.

PREPARATION AT THE POINT OF USE PRIOR TO REPROCESSING

Remove all traces of contamination immediately after use to avoid incrustation. Do not use fixative agents or hot water (>40°C). Avoid using a metal brush, steel wool, or other cleaning devices containing metal in order to avoid risk of insulation damage or corrosion. Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container.

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CLEANING INSTRUCTIONS

WARNING
Failure to properly clean, rinse and dry a device may result in retention of potentially hazardous residues or in inadequate sterilization.

MANUAL PRE-CLEANING
The instruments shall be brushed under cold water until all visible contamination is removed. After manual brushing, rinse the lumen of the sheath via its flushing port with a water jet pistol (static pressure above 4 bar) for at least 10 seconds.

AUTOMATED CLEANING
Associated parts are to be stored together in order to facilitate a subsequent identification. Make sure that instruments do not contact each other. Devices from different materials such as titanium, brass, aluminum, stainless steel, etc. need to be cleaned separately in order to avoid formation of a rust film. Composite instruments particularly stainless steel combined with ceramics need to be placed with sufficient distance to other products, so they do not break due to the pressure of different thermal expansions.

RECOMMENDED PROCESS-EQUIPMENT
- Washer: Miele™* Type G7836 CD
- Cleaners: TWIN PH10™* and TWINZYME™* (Borer Switzerland)

AUTOMATED CLEANING CYCLE
Two-component alkaline-enzymatic cleaning program:

1. 3 minutes pre-washing with cold tap water
2. Drain
3. 10 minutes washing at 45°C with tap water and:
   - 0.3% dosing TWIN PH10™* at 35°C
   - 0.2% dosing TWIN ZYME™* at 40°C
4. Drain
5. 2 minutes intermediate rinsing with warm deionized water (>30°C)
6. Drain
7. 1 minute intermediate rinsing with cold deionized water
8. Drain
9. 5 minutes thermal disinfection at >90°C
10. 30 minutes drying

MAINTENANCE

Apply a small amount of high-grade surgical lubricant on all joints or other moveable parts which are supposed to move smoothly. Sort out all blunt or damaged instruments. Clearly damaged instruments (cracks on the insulation, breakage, strongly bleached polymer handles or coatings) are NOT to be reused but repaired or disposed of.

TESTING AND INSPECTION

Jointed instruments are to be tested for ease of movement (avoid too much backlash). The functionality of ratchet mechanisms needs to be checked. All instruments: visually check for damage and wear. Blades should be even and without notches. Long and narrow instruments (especially jointed instruments) should be particularly checked for damages. If instruments are part of a larger set, they are to be checked together with all associated components.

WARNING
In case of present or suspected damage to the devices, do not try to repair the instrument. Avoid any further use of damaged instruments.

PACKAGING

Packaging suitable for steam sterilization must comply with the requirements according to DIN EN ISO 11607 / ANSI/ AAMI ST79 / AAMI TIR12:2010, for example, disposable sterilization packs (single or double packs) temperature resistant up to at least 137°C (279°F) and sufficient steam permeability, which provide sufficient protection against mechanical damage, or sterilization containers which need to be maintained according to the manufacturer's instructions.

STERILIZATION

WARNING

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Sterilization is preferably performed by steam sterilization. The following cycles has been validated in accordance with internationally harmonized standards regarding its suitability and efficacy for the devices fractionated pre-vacuum cycle.

- 132°C / 270°F, 4 minutes (wrapped), minimum 20 minutes drying.

Or

- 134°C/ 273°F, 4 minutes (wrapped), minimum 20 minutes drying.

STORAGE

Store instruments secured against mechanical damage. Use additional wrapping to protect against dust. Do not stack instruments which are packed sterile; especially do not place heavy items on top in order to avoid damage to the sterile packaging of other instruments.

ADDITIONAL INFORMATION

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

For more information or to order the VersaOne™ fascial closure device, call 800-772-8772.
Visit us at medtronic.com/versaone-closure

Important: Always refer to the instructions for use (IFU) supplied with the product for complete instructions, indications, contraindications, warnings, and precautions.

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