Encore® Medical, L.P.
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Austin, TX 78758-5445 USA

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A printable copy of the IFU for this device can be located at: https://www.djoglobal.com/surgical/ifus. A paper copy can be requested via phone at +1-800-520-8976.

EN

1. Product Handling
Devices not returned to the Surgical division of Enovis™ should be treated as biohazardous material and disposed of in accordance with local laws and regulations.

Recommendation for the Care and Handling for the Surgical division of Enovis™ Instruments and Instrument Cases

REUSABLE INSTRUMENT DESCRIPTION	Enovis™ instrumentation consists of devices and their accessories used in surgical procedures. Implantation of Enovis™ products should only be performed with Enovis™ instrumentation or instrumentation distributed by Enovis™. Enovis™ instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and detailed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with FDA cleared sterilization wrap to maintain sterility. Instruments are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.
WARNINGS	Automated cleaning may not be thorough enough. Carefully inspect each instrument to ensure that all visible blood residue and other contaminants have been removed.
CAUTION	Federal Law (USA) restricts this device to sale by or on the order of a physician.
REPROCESSING LIMITATIONS	Enovis™ instruments can be steam sterilized and repeat sterilization will not adversely affect them. If problems related to instrument sets are identified when using our instruments or instrument cases, please bring it to the attention of Enovis™ for investigation. The lifetime of an instrument is typically limited by normal wear and damage due to use.
DISCLAIMER	Enovis™ instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. Enovis™ has verified through laboratory testing that our instrument cases are suitable for the sterilization cycles listed in the sterilization section of the IFU. It is the user's responsibility to verify that equipment is performing as intended, and conditions are achieved.

INSTRUCTIONS FOR USE

POINT OF USE PREPARATION	Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after the completion of the surgical procedure. If cleaning must be delayed, place instruments in a covered container with pH Neutral enzymatic detergent to delay drying. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning. Wash all instruments whether they were used or were inadvertently contacted with blood. Disassemble instruments with removable parts; loosen instruments with movable parts, as applicable.
DECONTAMINATION	Decontamination is for the purpose of microbial inactivation. Saturate the surface completely with full strength intermediate disinfectant/cleaner* (e.g. CaviCide) and allow to remain in contact with devices for 5 minutes.

A. MANUAL CLEANING: ALL INSTRUMENTS	1. **Pre-Cleaning:** Remove all visible soil by immersing the devices in room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and disassemble/loosen instruments, that allow for disassembly/loosening and where doing so would improve the ability to clean. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. Scrub with the appropriate soft bristle brush until visibly clean; actuate through the full range of motion. 2. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. MetriZyme) and sonicate for 10 minutes. Ultrasonic cleaners can be used at the temperatures recommended by the detergent and ultrasonic cleaner manufacturers; however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment. 3. **Rinsing:** Thoroughly rinse the devices with Critical water (per AAMI TIR34). For example, a minimum of 2 minutes three (3) times. * Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Enovis™ has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.
B. MANUAL CLEANING: INSTRUMENTS WITH CANNULAS, LUMENS, OR HOLES	1. **Pre-Cleaning:** Follow the "Pre-Cleaning" and "Washing" steps in Section A. Manual Cleaning – ALL INSTRUMENTS. 2. **Washing:** After ultrasonic cleaning, in a fresh enzymatic cleaning bath use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub any cannula, lumen, or hole(s). Push in and out, using a twisting motion to remove debris. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas. 3. **Rinsing:** Flush the instrument paying special attention to the cannulations, lumens, and/or holes with Critical water (per AAMI TIR34). For example, a minimum of 2 minutes three (3) times.

C. MANUAL CLEANING: ARTICULATING INSTRUMENTS

1. **Pre-Cleaning:** Follow the "Pre-Cleaning" and "Washing" steps in Section A. Manual Cleaning – ALL INSTRUMENTS.
2. **Washing:** After ultrasonic cleaning, immerse the instrument in fresh neutral pH enzymatic cleaning solution to avoid aerosol generation. Actuate moveable mechanisms through full range of motion, such as knobs, hinges, box locks, or spring-loaded/retractable features. For instruments with flexible shafts, bend or flex the instrument under the neutral pH cleaning solution while brushing the flexible areas. For instruments with internal cavities, after actuating components in the neutral PH cleaning solution, fully open components and use a tight-fitting, soft, non-metallic cleaning brush or pipe cleaner to scrub the internal cavities. Use a syringe filled with enzymatic neutral pH cleaning solution to flush hard to reach internal areas.
3. **Rinsing:** Actuate and/or retract moveable parts while rinsing with deionized or distilled water. For example, a minimum of 2 minutes three (3) times. For instruments with flexible shafts, flex the instrument while rinsing.

AUTOMATED CLEANING

ALL INSTRUMENTS Manual Cleaning steps in Section A, and Section B for instruments with cannulas, lumens or holes and Section C for articulating instruments required before automated cleaning. The following minimum parameters required for automated cleaning of Enovis™ instruments. These parameters have been validated by Enovis™ under laboratory conditions.

Treatment / Phase	Minimum Time	Minimum Temperature	Cleaning Detergent Type
Pre-Wash	1 Minute	Cold Tap Water	N/A
Enzyme Wash	3 Minute	Warm Tap Water 38°C	Neutral pH Enzymatic Detergent
Wash	5 Minute	Warm Tap Water 38°C	Neutral pH Detergent
Rinse	2 Minute	Warm Tap Water 38°C	N/A
Final Rinse	1 Minute	Hot Deionized Water 82°C	N/A
Thermal Pure Water Rinse	5 Minute	Deionized Water 93°C	N/A

DRYING

Ensure device is dry prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored. Filtered compressed air may be used prior to air drying if available.

MAINTENANCE INSPECTION AND TESTING

After cleaning, the instruments (disassembled, if applicable) should be visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts (e.g. hinges) to verify that each instrument functions throughout its intended range of motion. Place instruments into appropriate configuration within instrument case and wrap with protective FDA cleared sterilization wrap according to AAMI / AORN guidelines.

Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:

1. Visually inspect instrument cases and instruments for damage when received and after each use and cleaning. All steps of the cleaning process should be repeated for incompletely cleaned instruments; those that need repair should be returned for servicing.
2. Only use an instrument for its intended purpose.
3. When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
4. If instruments appear to be damaged in such a way that may compromise the performance of the instrument, contact your Enovis™ representative for a replacement.
5. Visually inspect the instrument and check for damage and wear, moveable parts should have smooth movement, locking mechanisms should fasten securely.

TRANSPORT

Compliance with the general precautionary measures for handling contaminated/biologically hazardous materials is required.

STERILIZATION

Instruments supplied by Enovis™ have been thoroughly cleaned, inspected and tested for proper function prior to shipment. Unless otherwise indicated, these instruments are NOT STERILE and must be sterilized prior to use. Instruments provided outside of instrument sets should be fully loosened/disassembled and wrapped in FDA cleared sterilization wrap per AAMI ST:79/AORN Guidelines.

The following are minimum cycles required for steam sterilization that have been validated by Enovis™ under laboratory conditions to achieve a SAL of 10^{-6} with components loosened or disassembled. Enovis™ has data on file.

Sterilization with a Pre-Vacuum Sterilizer (HI-VAC):

270° F (132° C), 4-minute exposure time

Sterilization with a Gravity Displacement Sterilizer:

270° F (132° C), 15-minute exposure time

DRY TIME

The following are minimum dry time requirements for the indicated steam sterilization cycles.

FA Name	Dry Time Requirements (minutes)	
	Pre-Vacuum Sterilizer **270° F (132°C), 4-minute**	Gravity Displacement Sterilizer **270° F (132°C), 15-minute**
FA AKA POP S1 FEMORAL PREP	50	60
FA AKA POP S1 GEN INST	50	60
FA AKA POP S2 GEN INST	50	60

DRY TIME – RIGID CONTAINER, STEAM STERILIZATION

Aesculap Container Jk442

FA Name	Dry Time Requirements (minutes)	
	Pre-Vacuum Sterilizer **270° F (132°C), 4-minute**	Gravity Displacement Sterilizer **270° F (132°C), 15-minute**

DRY TIME – RIGID CONTAINER, STEAM STERILIZATION

Aesculap Container Jk 444

FA Name	Dry Time Requirements (minutes)	
	Pre-Vacuum Sterilizer **270° F (132°C), 4-minute**	Gravity Displacement Sterilizer **270° F (132°C), 15-minute**

DRY TIME – RIGID CONTAINER, STEAM STERILIZATION

Aesculap Container Jk 446

FA Name	Dry Time Requirements (minutes)	
	Pre-Vacuum Sterilizer **270° F (132°C), 4-minute**	Gravity Displacement Sterilizer **270° F (132°C), 15-minute**

DRY TIME – HALF RIGID CONTAINER, STEAM STERILIZATION Aesculap Container Jk 342	FA Name	Dry Time Requirements (minutes) Pre-Vacuum Sterilizer 270° F (132°C), 4-minute	 Gravity Displacement Sterilizer 270° F (132°C), 15-minute

STORAGE/INSTRUMENT CARE	Instruments must be thoroughly dried to remove residual moisture before they are stored. Instruments or instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped instruments or instrument cases to prevent damage to the barrier. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling. If necessary, hinged, rotating, or articulating instruments can be lubricated with a neutral pH instrument lubricant specifically designed for compatibility with steam sterilization that has been listed with the FDA. Instrument lubricants containing mineral oil, silicone oil, or other oil bases should NOT be used.
CONTACT INFORMATION	**Enovis™** **ATTN: Customer Service** **9800 Metric Boulevard** **Austin TX, 78758 USA** **+ 1-800-456-8696**

The instructions provided above have been validated by Enovis™ as being capable of preparing a medical device for re-use. It remains the responsibility of the user to ensure that the reprocessing is performed using appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained to achieve the desired result. This normally requires validation and routine monitoring of the process.

An electronic version of this IFU can be located at:
https://www.djoglobal.com/surgical/ifus

Some Enovis™ products use SurgiBit® technology. The SurgiBit® technology is protected by the following patents: Drill Point protected under U.S. Design Patents D523313 & D523398.
U.S. Utility Patents Pending.

2. Product Description
The devices covered by this IFU are the instruments used to implant Enovis™ implantable devices, as well as the instrument cases used to store said instruments for cleaning and transportation.

3. Indications
Reference the applicable implant IFU for Indications.

4. Intended Use
Reference the applicable implant IFU for device Intended Use.

5. Contraindications
Reference the applicable implant IFU for Contraindications.

6. Precautions and Warnings
Reference the applicable implant IFU for Precautions and Warnings.

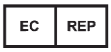
7. Preoperative Planning and Postoperative Care
Reference the applicable implant IFU for Preoperative Planning and Postoperative Care.

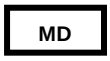
8. Adverse Effects
Reference the applicable implant IFU for Adverse Effects.
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the relevant Competent Authority as defined in EU 2017/745.

9. Lifetime of Device
Enovis™ does not define the maximum number of uses appropriate for re-usable instruments. While the expected lifetime of surgical instruments may be subject to a multitude of factors such as patient characteristics, surgeon experience, amount of use, and surgical technique, evaluating the time between the release of an instrument from production and the return of that instrument to the manufacturer from the user can give an indication of its expected lifetime.
Based on this information, Powered Instruments have shown to last as short as 5 days in the field or as long as 9.5 years in the field, with an average lifetime of 2.3 years. Non-Powered Impaction or Extraction Instruments have shown to last as short as 3.5 months in the field or as long as 18 years in the field, with an average lifetime of 2.8 years. Non-Powered Guide Instruments have shown to last as short as 35 days in the field or as long as 9.1 years in the field, with an average lifetime of 2.9 years. Non-Powered, Non-Impaction/Extraction, & Non-Guide Instruments have shown to last as short as 56 days in the field or as long as 9.3 years in the field, with an average lifetime of 3.5 years.
As product data continues to be collected, these lifetime estimates may be re-evaluated and adjusted if required. Users should note that careful inspection of the instrument before use is the best method of determining the end of serviceable life.

10. Trademarks and Patents
Reference the applicable

Symbol Glossary:

 ISO 15223-1 5.4.2	***Single use – do not reuse***
 ISO 15223-1 5.1.4	***Expiration Date***
 ISO 15223-1 5.3.4	***Keep Dry***
 ISO 15223-1 5.1.5	***Lot number/Batch Code***
 ISO 15223-1 5.2.1	***Sterile***
 ISO 15223-1 5.2.4	***Sterility symbol: R: Sterile Using Irradiation***
	***Sterile symbol: H_2O_2: Sterilized Using Hydrogen Peroxide Gas Plasma***
 ISO 15223-1 5.2.7	***Non-sterile***
 ISO 15223-1 5.4.3	***See "Instructions for Use"***
 ISO 15223-1 5.1.1	***Manufacturer***
	***Quantity of items in package***
 ISO 15223-1 5.1.2	***Authorized Representative in European Community***

 ISO 15223-1 5.1.6	***Catalog Number***
 ISO 15223-1 5.2.6	***Do not resterilize***
 ISO 15223-1 5.2.8	***Do not use if package is damaged***
 ASTM F2503:2013	***MR Safe***
 ASTM F2503:2013	***MR Conditional***
 ASTM F2503:2013	***MRI Unsafe***
Rx 21 CFR 801.109	***Federal Law (USA) restricts this device to sale by or on the order of a physician.***
 Article 13.3	***Importer***
 ISO 15223-1 5.2.8	***Medical Device***
 ISO 3166-1	***Country Code of Manufacturer – US***
 ISO 7000-3704	***Double sterile barrier system***