INSTRUCTIONS FOR USE
Ensemble Orthopedics Surgical Instruments

Caution: Federal Law restricts this device to sale by or on the order of a Physician.

General Instrument Description:

Ensemble Orthopedics ("Ensemble") surgical instruments are an array of generic and unique instruments designed specifically for orthopedic surgery. Such tools facilitate orthopedic surgeons achieve, enable or expedite specific tasks related to surgical techniques and implant systems. All Ensemble surgical instruments are reusable devices manufactured from medical-grade stainless steel and/or common medical device polymers. Instruments are hand-held and manually operated. Instruments should only be used with the appropriate Ensemble devices (i.e. interacting instruments and implants) per the associated surgical technique.

Indications for Use:

Ensemble surgical instruments are manual surgical instruments intended to be used in surgical procedures to assist in the implantation of Ensemble implants.

Contraindications:

Ensemble surgical instruments shall only be used for their intended purpose. Ensemble surgical techniques provide instructions on the use of the instrumentation. The decision to use an instrument must be based on sound medical judgement that takes into consideration factors such as surgical application, physical and mechanical properties. Medical personnel are encouraged to contact their Ensemble representative(s) if a more comprehensive understanding of the instrument mechanics or its method of use is required.

Warnings and Precautions:

1. Ensemble surgical instruments have been designed for use with Ensemble implantable devices. Use of these instruments to implant other devices may result in non-optimal patient outcomes.
2. Failure to thoroughly clean the instruments in accordance with the validated cleaning method may prevent adequate disinfection or sterilization, posing a risk of infection to the patient.
3. Instruments should be rinsed of cleaning agents to prevent residue.
4. Do not use mineral oil or silicone lubricants on instruments.
5. Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
6. Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, lumens, proper function, wear and tear.
7. Instruments are subject to wear with repeated use. Inspect instruments for damage or malfunction prior to use to verify condition and do not use if damaged or worn.
8. A full inventory of instruments and implants should be available prior to initiating a surgical procedure. Components should be tested in trial assembly prior to the actual operation.
9. Use caution in the handling and storage of instruments. After sterilization, instruments should be stored in the sterilization wrapped rigid container in a dry and dust-free environment. Instruments should be stored away from environments and agents that may cause contamination and deterioration.

Cleaning:

The recommended manual cleaning instructions are described below. Ensemble surgical instruments supplied to the user non-sterile must be cleaned and steam sterilized prior to surgical use. Other cleaning methods that differ from the instructions below are not recommended must be validated by the user.

Point of Use Processing:

Cleaning should begin at the point of use, prior to processing. Throughout the surgical procedure, blood and/or debris should be wiped from the instruments using a disposable gauge pad or cloth to prevent it from drying on the surface. Additionally, a towel moistened with sterile or distilled water should be draped over the used instruments. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on the instruments.

Cleaning Instructions:

For non-sterile, reusable instruments, Ensemble recommends cleaning devices within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning. Ensemble recommends using the following validated cleaning procedure. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve cleanliness.

Recommended Manual Cleaning Instructions

Process	Water Quality/Temp	Time	Cleaning Instructions
Pre-Wash	Tap Water 15-25 °C	Minimum 1 minute	Rinse with clean, cool, running tap water. Use soft-bristled brush to clean instrument thoroughly.
Soaking	Tap Water 27-44 °C	20-25 minutes	Submerge instruments in proteolytic enzymatic cleaning solution diluted per manufacturer recommendations. Remove visible soil with soft-bristled brush.
Rinse	Tap Water 27-44 °C	Minimum 1 minute	Remove instruments from enzyme solution and thoroughly rinse with running tap water.
Inspect	N/A	N/A	After rinsing, visually inspect instruments to ensure debris removal. If debris remains, thoroughly and aggressively flush the device or repeat rinsing until debris is removed.
Ultrasonic Clean	Tap Water 25-30 °C	10-15 minutes	Prepare proteolytic cleaning solution diluted according to manufacturer's recommendations in ultrasonic cleaner. Completely submerge instruments and sonicate.
Rinse	Purified Water 22-43 °C	Minimum 1 minute	Fully immerse and gently agitate the instruments in a basin of purified water.
Dry	N/A	N/A	Dry with a clean, lint-free or low lint cloth.
Inspect	N/A	N/A	Visually inspect each instrument for remaining soil and moisture. If soil remains, repeat the cleaning process.

Additional Inspection:

Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Ensemble representative for a replacement.

- When inspecting devices look for the following:
  - Cutting edges should be free of nicks and have a continuous edge.
  - Long thin instruments should be free of bending or distortion.

Sterilization Instructions:

Ensemble recommends the following sterilization procedures for non-sterile instruments. These instruments are intended for steam sterilization at the healthcare facility. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve sterility.

1. Place properly cleaned and dried instruments into the designated slots or arranged to ensure instruments do not touch inside the sterilization tray. Disassemble instruments and place components inside the sterilization tray.
2. Wrap the instrument tray with commercially available CSR wrap.
3. Place wrapped instrument tray in steam sterilizer, sterilize for 4 minutes in 132°C pre-vacuum cycle with 20-minute dry time.
4. Upon cycle completion, remove the wrapped instrument tray from sterilizer and place tray on a padded surface to prevent condensation during cooling.
5. Store the sterilized instrument tray in a clean and dry area.

Steam Sterilization Cycle Parameters

Parameters	Cycle Parameters
Cycle type	Pre-vacuum with 4 pulses
Temperature	132°C
Exposure Time	4 minutes
Dry Time	20 minutes

Additional Ensemble recommendations are as follows:

- Follow ANSI/AAMI ST79:2006 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- Usage of an FDA cleared wrap is recommended to ensure the instruments are sterile prior to use.

Symbols Glossary:

For product shipped, the following symbols may be indicated on the labels placed on the packaging:

Symbol	Symbol Description	Explanatory Text
Standard Development Organization: ISO 15223-1: 2021 – Symbols to be used with medical device labels, labelling and information to be supplied		
	Manufacturer (Ref # 5.1.1)	Indicates the medical device manufacturer
	Date of Manufacture (Ref # 5.1.3)	Indicates the date when the medical device was manufactured
	Use-by-date (Ref # 5.1.4)	Indicates the date after which the medical device is not to be used.
	Lot Number (Ref # 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalog Number (Ref # 5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified
	Non-sterile (Ref # 5.2.7)	Indicates a medical device that has not been subjected to a sterilization process.
	Consult Instructions for Use (Ref # 5.4.3)	Indicates the need for the user to consult the instructions for use.
Symbols not from Standards		
℞ Only	Prescription Only (21 CFR 801.15 (c)(1)(i); 21 CFR 801.109)	Caution: Federal law restricts this device to sale by or on the order of a physician

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