Non Sterile. Sterilize Before Use.

CONFORMIS HIP INSTRUMENTS

Prior to use of Conformis' hip implants, the surgeon shall receive training describing the surgical technique for implantation. The training will include a review of the surgical indications, design concept, and surgical implantation methods.

These cleaning and sterilization instructions have been validated to sufficiently prepare the instruments for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing is performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

Caution: USA federal law restricts this device to sale by or on the order of a physician.

The Conformis hip instruments are intended for use only by fully trained physicians.

Refer to the associated Conformis hip product's Surgical Technique Guide for information on specific instruments and their use during the surgical procedure.

Refer to the associated hip implant instruction for use for information on use of the implant system.

If there are any questions, contact Conformis, Inc. at +1.781.345.9001 or your local distributor.

Refer to www.conformis.com/eifu for an electronic version of this IFU. For a printed copy or to have an electronic copy e-mailed to you call +1.781.345.9001

Manufacturer	Conformis, Inc.
Device Description	The reusable instruments are composed of non-sterile manual orthopedic instruments packaged in a sterilization tray or provided individually.
Warnings	• The reusable instruments are provided NON-STERILE and must be cleaned and sterilized before first use and any reuse. • Metal brushes or scouring pads will damage surface and finish of devices and must not be used during manual cleaning. • Corrosive cleaning/disinfecting agents containing aldehyde, bromide, bromine, chloride, active chlorine, iodide, iodine or mercury should not be used. • Enzymatic & cleaning agents with a neutral pH are recommended. • These instruments should never be used to prepare bone for implant components from different manufacturers. They should only be used with Conformis implants. • Exercise caution when handling devices with sharp points or cutting edges. Personal Protective Equipment should be worn when handling contaminated or potentially contaminated devices or material.
Limitations	• Repeated processing has a minimal effect on instrument life and function. • End of useful life is determined based on wear and damage due to use. • Before using an instrument (and between re-uses), inspect it for damage or defects. See the **Inspection** section for details. • Damaged instruments should be replaced to prevent potential patient injury.

REPROCESSING INSTRUCTIONS

Point of use:	1. Remove excess fluids or tissue from instruments with a sterile disposable, non-shedding wipe. 2. Place devices in a tray of distilled water or cover with damp towels.
Containment and Transportation	• Instruments should be cleaned within 30 minutes of use to prevent drying prior to cleaning. Do not allow contaminated devices to dry prior to reprocessing. • Universal Precautions should be observed by all hospital personnel exposed to contaminated or potentially contaminated devices.
Preparation for Decontamination:	1. Instruments must be removed from trays for manual cleaning. Lids and Trays should be cleaned individually. 2. Disconnect all quick-connect components and loosen and/or disassemble all instruments with removable parts, if applicable. 3. Care must be exercised to avoid losing small parts such as pins or tips. 4. Prepare enzyme and cleaning agents at the use-dilution and temperature as recommended by manufacturer(s). 5. Grossly contaminated solutions should be replaced with clean solution.
Manual Cleaning	1. Prepare a cleaning bath with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer 2. Completely submerge instruments in the enzyme solution for 20 minutes. 3. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams and any other hard to access areas. Actuate any moving mechanisms to free trapped blood and debris. 4. Remove instruments from the cleaning solution. Rinse in tap water for 3 minutes or until all traces of cleaning solution are removed, whichever is longer. Thoroughly and aggressively flush lumens, holes or other hard to access areas. 5. Prepare an ultrasonic bath with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer. 6. Completely submerge instruments in ultrasonic cleaner with prepared enzymatic solution. Clean for 10 minutes. 7. Rinse instruments in purified water for 3 minutes or until rinse stream is clean of blood or soil, whichever is longer. Thoroughly and aggressively flush lumens, holes, or other hard to access areas. 8. Visually inspect each device for remaining soil. If soil remains repeat the ultrasonic cleaning process (Steps 5-7). 9. Dry instruments immediately after final rinse. **Instruments must be terminally sterilized prior to surgical use. See Sterilization instructions.**

Automated Cleaning with an Enzymatic Solution

Note: Fully automated cleaning is not recommended without manual pre-cleaning (Steps 1 to 4).

1. Prepare a cleaning solution with an enzymatic detergent at the concentration and temperature specified by the detergent manufacturer
2. Completely submerge the instruments in an enzyme solution and allow to soak for 10 minutes.
3. Scrub with soft bristle brush to remove all visible soil. Pay close attention to threads, crevices, seams and any other hard to access areas. Actuate any moving mechanisms to free trapped blood and debris.
4. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
5. Prior to loading into the automated washer, place instruments into their tray. Washer cycles will be performed with trays open. The femoral tray insert and acetabular tray insert will be removed from the main trays and set to the side of the main trays, and will be included in the washer during the cycle.
6. Operate the washer-disinfector cycle following the minimum parameters described below:

Typical Automated Washer Cycle with an Enzymatic Detergent

Step	Description	Minimum Temperature	Minimum Cycle Time
1	Pre-Wash	Cold Tap Water (Facility)	2 Minutes
2	Enzyme Wash, (0.8% cleaning agent) Includes spray, soak, and 2 rinses	Hot Tap Water (Facility)	4 Minutes
3	Detergent Wash	66°C (150°F)	6 Minutes
4	Hot Water Rinse	Hot Tap Water (Facility)	15 Seconds
5	Thermal Rinse	88°C (190°F)	6 Minutes
6	Hot Air Dry	115°C (239°F)	15 Minutes

7. Upon completion, unload the washer-disinfector.
8. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process.

Note: The washer/disinfector manufacturer's recommendations should always be followed. Use only cleaning agents recommended for the specific type of automated washer / disinfector. A washer / disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

Instruments must be terminally sterilized prior to surgical use. See Sterilization instructions.

Inspection:

Before preparing for sterilization, all re-usable instruments should be inspected.

- Un-magnified visual inspection under good lighting conditions is sufficient.
- All parts of the devices should be checked for visible soil, discoloration and/or corrosion.

Particular attention should be paid to:

- Soil "traps" such as mating surfaces, hinges and threaded features.
- Recessed features (holes, cannulations).
- Features where soil may be impacted into the device, such as drill flutes adjacent to the cutting tip and broach surfaces.
- Cutting edges should be checked for sharpness and damage.
- For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Functional checks should be performed at all times:

- Check that all components are re-tightened and re-assembled if required.
- Mating devices should be checked for proper assembly.
- Instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).
- Rotating instruments, such as multiple use drill bits, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface.

1. Note: Conformis does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

Maintenance:

Hinged, sliding or articulating surfaces can be lubricated with a water-soluble product intended for use with surgical instruments (such as Instrument Milk). Mineral oil or silicon lubricants should not be used.

Packaging:

Instruments must be visibly dry prior to packaging for sterilization.

1. Place instruments in the Conformis tray.
2. Commercially available, medical grade steam sterilization wraps may be used to package trays. Package should be prepared using the ANSI/AAMI ST79:2010 double wrap or equivalent method.

Wraps used during steam sterilization process are to be FDA cleared wraps. Use per the manufacturer's instructions.

Sterilization:

Moist heat sterilization with a Pre-vacuum cycle is the recommended method of sterilization. Gravity displacement cycle is not recommended.

- Vaporized Hydrogen Peroxide (VHP), Ethylene oxide (EO), gas plasma and dry heat are **not recommended** as sterilization methods for Conformis reusable instruments.
- The recommended parameters demonstrate the minimum validated steam sterilization time and temperature required to achieve a 10^{-6} sterility assurance level (SAL).
- The validated reprocessing instructions are not applicable to Conformis trays that include devices not manufactured or distributed by Conformis.

Recommended Steam Sterilization Parameters

Cycle Type	Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	30 minutes, or until visibly dry
EtO: Not Validated		VHP (Sterrad): Not Validated	

Note for non-US countries: Where there is risk of TSE/CJD contamination, the World Health Organization (WHO) recommends a pre-

	vacuum cycle of 18 minutes at 134°C (273°F). Consult WHO for further information.
Storage:	Store sterile packaged instruments in an area that provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
Additional Information:	Sterilizer manufacturer's recommendations should always be followed. When sterilizing multiple instruments, ensure that the maximum load is not exceeded. Local or national specifications should be followed if they are stricter and more conservative.
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Symbol Glossary:		Caution: USA Federal Law restricts this device to sale by or on the order of a physician
		Consult electronic Instructions For Use (eIFU)
		Nonsterile
		Catalogue Number and Description
		Item Lot Control Reference Number
		Manufacturer
		Caution, Consult Accompanying Documents