Instrument Care, Cleaning and Sterilization instructions

.

CONFORMIS® iTotal® REUSABLE INSTRUMENT SET
(iTotal® Identity™ and Identity™ Imprint™)

Non Sterile. Sterilize Before Use

Important Information: Please read before use.

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

The iTotal® Reusable Instrument Tray is intended to house the reusable instrumentation associated with Conformis® knee implant systems and define their organization and configuration during sterilization, transportation, and storage within the hospital environment. The iTotal® Reusable Instrument Tray can hold up to 17lbs of instruments. The iTotal® Reusable Instrument Tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration.

The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:

Cycle Type	Temperature	Exposure Time	Dry Time
Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

The reusable instruments are intended for use with Conformis® knee replacement systems in the osteoarthritic knee, to facilitate implantation of devices intended for replacement of damaged areas of the articular surface in patients with evidence of adequate healthy bone to support the components.

Surgeons are offered training on the Conformis® iTotal® Knee Replacement System design concepts and surgical implantation techniques. The training may include a review of the surgical indications, design approach, surgical implantation methods via surgical technique, live surgery videos, and surgical observations. On request, Conformis® also provides hands on training via bioskills labs.

These cleaning and sterilization instructions have been validated as being capable of preparing Conformis® reusable instruments for reuse. It is the responsibility of the healthcare facility 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 healthcare facility 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® REUSABLE INSTRUMENTS ARE INTENDED FOR USE ONLY BY FULLY TRAINED PHYSICIANS.

REFER TO THE CONFORMIS® SURGICAL TECHNIQUE GUIDES FOR INFORMATION ON SPECIFIC INSTRUMENTS AND THEIR USE DURING THE SURGICAL PROCEDURE.

IF THERE ARE ANY QUESTIONS, CONTACT CONFORMIS®, INC. AT +1.781.345.9001 OR YOUR LOCAL SALES REPRESENTATIVE OR DISTRIBUTOR.

Manufacturer	Conformis®, Inc.
Device Description	The iTotal® Reusable Instrument Tray is intended to house the Conformis® reusable instrumentation associated with Conformis® knee implant systems during sterilization, transportation and storage within the hospital environment. The reusable instruments are composed of non-sterile manual orthopedic instruments placed in an arrangement described by the laser etchings on the trays. Replacement reusable instruments may be provided separately and need to be reintegrated into the sterilization tray.
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. • Alkaline agents with a pH ≥ 10 may be used. Alkaline agents should be followed with a neutralizer and/or thorough rinsing. • 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 normally determined by 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 the 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:	• Trays are intended for transport and storage of re-usable instruments. They are not designed for cleaning in the fully assembled state. The lid must be removed from the tray and the inner trays separated out from the base for adequate cleaning results. • Disconnect all quick-connect components. All adjustable sliding and/or articulating features should be moved to the open position. • Care must be exercised to avoid losing small parts such as pins or tips. • Prepare enzyme and cleaning agents at the use-dilution and temperature as recommended by manufacturer(s). • 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 an 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 running (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 two inner trays will be removed from the main tray but set to the side of it, 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.

Automated Cleaning with an Alkaline Solution (pH ≥ 10)

Note: Fully automated cleaning is not recommended without manual pre-cleaning.

1. Prepare a cleaning solution with an alkaline (pH ≥ 10) cleaning agent at the concentration and temperature specified by the cleaning agent manufacturer
2. Completely submerge the instruments in a cleaning 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 the automated washer, place instruments into their tray. Washer cycles will be performed with trays open. The two inner trays will be removed from the main tray but set to the side of it, 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/Disinfector Cycle Alkaline Cleaning Agent (pH ≥ 10)

Step	Description	Minimum Temperature	Minimum Cycle Time
1	Pre-Wash	Cold Tap Water (Facility)	5 Minutes
2	Detergent Wash (0.4% cleaning agent)	60°C (140°F)	10 Minutes
3	Neutralization	Hot Tap Water (Facility)	5 Minutes
4	Rinse	Demineralized Warm Water	1 Minute
5	Thermal Disinfection (A_0 = 3000)	90°C (194°F)	5 Minutes
6	Hot Air Drying	110°C (230°F)	30 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 keel punch 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: • 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. 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 silicone lubricants should not be used.
Packaging:	**Instruments must be visibly dry prior to packaging for sterilization.** 1. Place instruments in pre-configured tray lay-outs within the Conformis® trays. Do not overload the sterilization 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 only. Use Manufacturer's instructions.*

<table>
<tr><td>Sterilization:</td><td>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 sterilization methods for Conformis® reusable instruments.
The recommended parameters demonstrate the minimum validated steam sterilization time and temperature required to achieve a $1.0x10^{-6}$ 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<table><tr><th>Cycle Type</th><th>Temperature</th><th>Exposure Time</th><th>Dry Time</th></tr><tr><td>Pre-vacuum</td><td>132°C (270°F)</td><td>4 minutes</td><td>30 minutes</td></tr><tr><td colspan="2">EtO: Not Validated</td><td colspan="2">VHP (Sterrad): Not Validated</td></tr></table>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.

Do not stack trays in the autoclave chamber. Stacking of trays will adversely affect sterilization and drying effectiveness. If there is moisture present after sterilization, re-sterilize the load and increase the drying time.</td></tr>
<tr><td>Storage:</td><td>Store sterile packaged instruments in an area that provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.</td></tr>
<tr><td>Additional Information:</td><td>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.</td></tr>
<tr><td>Manufacturer Contact:</td><td> 
Conformis®, Inc.
600 Technology Park Drive, 4th Floor
Billerica, MA 01821
USA
Tel.: +1.781.345.9001
Fax: +1.781.345.0104</td></tr>
</table>

LABELING SYMBOL DEFINITIONS	
	Caution: USA Federal Law restricts this device to sale by or on the order of a physician
	Model Number
	Caution. Consult Accompanying Documents
	Consult Electronic Instructions For Use (eIFU)
	Lot Number
	Manufacturer
	Non-Sterile. Sterilize Before Use.