⚠	Rx only	81-18000-000-00

ICONACY™ I-HIP™ INSTRUMENT SYSTEM

ICONACY Orthopedic Implants, LLC
PO Box 1033
Warsaw, Indiana 46581-1033
U.S.A.
Tel.: +1 (574) 269-4266

Revision 1
Issued: July 2012
Printed in U.S.A.
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ICONACY™ I-Hip™ Instrument System: Instrument Use, Care, Cleaning, Disinfection, Inspection, Maintenance, and Sterilization

Instrument Use

Carefully read all instructions and be familiar with the surgical technique prior to use and use universal precautions when handling contaminated or biohazardous components/materials.

Before using a product placed on the market by ICONACY, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature). ICONACY is not liable for complications that may arise from the use of the device in circumstances outside of ICONACY's control including, but not limited to, product selection and deviations from the device's indicated uses or surgical techniques.

Instrument Care

- Failure to follow these instructions could result in instrument breakage and potential adverse effects on user(s) or patient.
- Use only instruments specifically designed for use with their associated devices.
- Misuse reduces useful life and/or increases injury risk. Repeated processing according to these instructions has minimal effect on ICONACY reusable manual instruments. End of life is normally determined by wear and damage due to use.
- Refer to AORN Standards, Recommended Practices, and Guidelines for guidelines related to proper care, maintenance, reprocessing, and handling of surgical instruments.

Warnings

- Instruments must be thoroughly cleaned prior to sterilization. Instruments that are not clean may not be effectively sterilized.
- Reuse of a single-use device that has come in contact with blood, bone, tissue, or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single-use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
- Do not use instruments/provisional trials that are deformed, corroded, damaged, or worn. They may not perform as intended.
- Do not subject stainless steel to chlorine or chloride-based agents. Corrosion or discoloration may occur.
- Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.
- Use only compatible components with the I-Hip instrument system (see product literature for the list of compatible components).

Precautions

- Inspect all instruments carefully prior to each use.

Instrument Cleaning and Disinfection

- Where applicable, disassemble instruments prior to cleaning. Refer to www.iconacy.com for the applicable instrument disassembly instructions.
- Thoroughly clean and dry reusable instruments immediately after use to minimize corrosion and potential cross-contamination.
- Neutral 6.0-8.0 pH enzymatic and cleaning agents with low-foaming/low-sudsing surfactants are preferred and recommended by ICONACY. Alkaline agents with pH of 12 or less may be used where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and thorough rinsing. All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).
- Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush).
- Remove the device from the enzyme solution and rinse in warm (38°C-48°C) water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to reach areas.
- Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
- Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
- Repeat the sonication and rinse steps above.
- If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.
- Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Instrument Inspection and Functional Testing

- Carefully inspect each device to ensure that all visible blood and soil have been removed. If contamination is noted, repeat the cleaning and disinfection.
- Check the action of moving parts (e.g., hinges) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features for distortion.
- Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.
- If damage or wear is noted that may compromise the function of the instrument, do not use the device and contact your ICONACY representative for a replacement.

Instrument Maintenance

- After cleaning, lubricate moving parts with a water soluble lubricant, reassemble, and tighten screws where appropriate.

Instrument Sterilization Instructions

- The provided sterilization instructions are consistent with ANSI/AAMI/ISO standards and guidelines. They should be used for items supplied non-sterile, for reprocessing reusable devices, and sterile items that were opened but unused.
- In the event of inadvertent loss of sterility while preparing for surgery, sterile instruments may be sterilized only once for immediate use, following the recommended sterilization specifications for reusable instruments.
- Do not reuse instruments or devices labeled for single use only. Reuse of a single-use device that has come in contact with blood, bone, tissue, or other body fluids may lead to patient or user injury. DO NOT RESTERILIZE single-use only components that have been contaminated with body fluids or debris or previously implanted. Possible risks associated with reuse of a single-use device include, but are not limited to, mechanical failure, and transmission of infectious agents.
- Where possible, reusable instruments should be disassembled for sterilization.
- The CODMAN® QUAD-LOCK™ Sterilization Container System (K120117) should be used to organize and protect the surgical instruments for sterilization by pre-vacuum steam following the recommended sterilization specifications for reusable instruments. For additional information on this sterilization container system, refer the manufacturer's instructions for use.
- Do not use the original plastic cavities or lids for resterilization.
- Do not stack heavy items on top of any sterilization cases made from plastic. The resulting deformation can cause cracking of the plastic material.
- Polysulfone instruments may show crazing and/or cracking due to steam boiler chemicals and lubricants.
- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated, and provides protection from dust, moisture, insects, vermin, and temperature and humidity extremes.
- Sterile, packaged instruments should be examined carefully prior to opening to ensure that there has been no loss of package integrity.

Recommended Sterilization/Resterilization Specifications

Instruments are supplied non-sterile and must be cleaned and sterilized prior to use in surgery. Follow the sterilizer manufacturer's instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads. The following parameters are recommended as they have been validated for a Sterility Assurance Level of 10^{-6}.

Method	Cycle Type	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each facility's sterilization equipment and product load configuration by trained personnel in sterilization processes to substantiate the reliability and reproducibility of the process.

Please contact ICONACY at +1 (574) 269-4266, if you have additional questions.

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