

	R_x _{only}	81-10001-000-00
ICONACY™ I-HIP™ PROSTHESIS		
	 ICONACY Orthopedic Implants, LLC PO Box 1033 Warsaw, Indiana 46581-1033 U.S.A. Tel.: +1 (574) 269-4266	Revision 3 Issued: September 2012 Printed in U.S.A. © 2012 ICONACY

ICONACY™ I-Hip™ Prosthesis

Description

The ICONACY I-Hip prosthesis consists of a collarless, tapered, forged titanium alloy femoral stem, mated to a cobalt chrome alloy modular femoral head. This femoral construct articulates with an acetabular device assembly. The acetabular device assembly consists of a hemispherical titanium alloy cup (i.e., shell) coupled with a highly cross linked ultra-high molecular weight polyethylene (HXL-UHMWPE) liner. Forty percent of the femoral stem is circumferentially coated with a titanium coating designed to attain a cementless, press-fit fixation. The acetabular cup is machined from forged Ti-6Al-4V ELI alloy. The cup has a threaded polar hole for insertion and two screw holes to permit the use of screws for adjunct fixation. The outer hemispheric surface of the cup has a titanium plasma spray coating for cementless, press-fit fixation. A titanium locking ring is fixed into a groove on the cup to engage the groove on the HXL-UHMWPE liner.

Indications for Use

The ICONACY I-Hip system is indicated for the following conditions:

- A severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
- Certain cases of ankylosis
- Nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip system consists of femoral stem and acetabular cup (i.e., shell) porous coated components intended for cementless, press-fit fixation.

Contraindications

Use of this device is contraindicated in the following conditions:

- Active local or systemic infection.
- Bone stock that is inadequate for support or fixation of the prosthesis. Poor bone quality, i.e., osteoporosis, may result in considerable migration of the prosthesis or possible fracture of the femoral shaft and/or lack of adequate supporting bone.
- Loss of musculature, neurovascular compromise or vascular deficiency in the affected limb which renders the procedure unjustifiable.
- Charcot's or Paget's disease.
- Skeletal immaturity.
- Any mental or neuromuscular disorder that would create an unacceptable risk of prosthesis instability, prosthetic fixation failure, or complications in postoperative care.
- Obesity, as an extremely overweight patient can produce loads on the device that can lead to failure of the device or to its fixation.

Warnings

- Implant selection is critical. The proper sizes must be used to obtain optimal stability and longevity of the components for total hip arthroplasty. Proper implant selection includes design, fixation and environmental variables including patient weight, age, bone quality and size, activity level and preoperative level of health, as well as the surgeon's experience and familiarity with the implants, instruments and surgical technique. Longevity and stability may be affected by these factors.
- The following patient conditions tend to impose severe loading on the affected extremity and place the patient at higher risk of device failure: excessive weight, manual labor, active participation in sports, high levels of activity, falls, alcohol or drug addiction, or other disabilities. Other conditions can adversely affect the performance of the device and ultimate clinical results; they include osteoporosis and poor bone stock, metabolic disorders (diabetes), steroid therapy, tumors of supporting bone, and a history of general or local infections.
- Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the hip replacement by causing a change in position of the device, device fracture, and/or excessive wear. The patient should be informed that factors such as weight and activity levels may significantly affect device performance (see Patient Information section).
- Do not substitute another manufacturer's device for any component of the I-Hip prosthesis system. Any such use could compromise the intended performance of the ICONACY device. The taper size of the femoral stem must be matched to the taper size of the femoral head.
- The smaller sized femoral components are intended for patients with smaller intramedullary canals. The geometry results in a decrease in fatigue strength and load bearing. Patients with a high physical activity, poor bone quality, or who are overweight may not be suitable candidates for the smaller size stem.
- The surgical and postoperative management of the patient must consider all existing conditions. Mental attitudes or disorders resulting in a patient's failure to comply with the surgeon's orders may delay postoperative recovery and increase the risk of adverse effects including implant or implant fixation failure.

Precautions

- Hip prosthesis components should never be reimplanted. Even though the device appears undamaged it may have developed microscopic imperfections that may result in device failure.
- The ICONACY I-Hip prosthesis has not been evaluated for safety and compatibility in the MR environment. The ICONACY I-Hip prosthesis has not been tested for heating or migration in the MR environment.
- Seat modular femoral heads firmly on the femoral component to prevent disassociation. Machined taper surfaces must be clean and dry to ensure proper seating and assembly.
- It is recommended that components at least one size larger and smaller than preoperatively determined be available during surgery to accommodate intraoperative selection of the optimal size.
- Specialized instruments are available and should be used to help ensure accurate implantation of the components.

Adverse Effects

- Dislocation or change of position of the components can occur due to excessive patient activity, trauma, or other biomechanical considerations (i.e., sitting on a low chair or stool).
- Peripheral neuropathies, nerve damage, pain, circulatory compromise and heterotopic bone formation may occur.
- Acetabular pain or perforation may occur due to device loosening.
- Early or late loosening of the prosthetic components may occur.
- Fatigue fracture of the femoral stem has been reported following total hip arthroplasty.
- Early or late infection can occur.
- Tissue reactions, osteolysis, and/or implant loosening have been reported. The causes may be related to metallic corrosion, metal sensitivity reactions, or the accumulation of polyethylene debris.
- Delayed wound healing.
- Damage to blood vessels or hematoma.
- Cardiovascular disorders, including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Periarticular calcification or heterotopic ossification with or without impediment to joint mobility.
- Trochanteric nonunion due to inadequate reattachment or early weight bearing.
- Trochanteric avulsion, the result of excessive muscular tension, or early weight bearing.
- Inadequate range of motion due to improper selection or positioning of components, femoral impingement, or periarticular calcification.
- Femoral fracture while seating the device, by trauma, or excessive loading.
- Leg length discrepancies.

Patient Information

- Surgeons may wish to advise patients about the limitations of the total hip replacement and the need to protect the device from full weight bearing until adequate healing has occurred.
- Dental procedures, endoscopic examinations, and other minor surgical procedures have been associated with transient bacteremia. Instruct patients to inform their doctors or dentists that they have a total hip replacement. The practitioners may wish to provide antibiotic cover for such procedures.
- Surgeons should warn the patient about surgical risks and possible adverse effects.

Sterilization

If sterilization of metal components is necessary, 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.

Ultra High Molecular Weight Polyethylene components should not be resterilized.

Instruments are supplied non-sterile and must be cleaned and sterilized prior to use in surgery, per the parameters above.

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

Storage

All implants must be stored in a clean, dry environment and protected from sunlight and temperature extremes.

Caution

Federal law (U.S.) restricts this device to sale by the order of a physician.

ICONACY Orthopedic Implants, LLC
PO Box 1033
Warsaw, Indiana 46581-1033
U.S.A