ENG50729 Rev9

U2 Bipolar Implant
Safety Statements

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CE 2797 STERILE R 85 % 30 % 35℃ 7℃ Rx only

Note: The CE mark is valid only if it is also printed on the product label.

DESCRIPTION

United Orthopedic Corporation's U2 Bipolar Implant is intraoperatively assembled to any appropriately sized UNITED Hip System femoral stem with compatible head size. The bipolar component is comprised of an outer shell (ASTM F75-12/ISO 5832-4:2014 casting Co-Cr-Mo alloy, raw materials ASTM F1537-11/ISO 5832-12:2007) into which a bearing insert (ASTM F648-14/ISO 5834-1:2005 and ISO 5834-2:2011) has been permanently assembled. The bearing insert has a factory assembled stopper ring (ASTM F648-14/ISO 5834-1:2005 and ISO 5834-2:2011). The assembled prosthesis provides for primary articulation at the femoral head/inner polyethylene bearing interface and secondary articulation at the outer shell/acetabulum interface.

The internal aspect of the shell is designed to lock the polyethylene liner. The outer metal surface of the bipolar hip prosthesis is highly polished for articulation with the patient's acetabulum. Components are available in a range of sizes to fit varying anatomical requirements.

A complete instrumentation and trial system is available to assist in accurate implantation of all United Hip System Prostheses.

MATERIALS

1. Bipolar outer shell:
   ASTM F75-12 / ISO 5832-4:2014 (raw materials ASTM F1537-11 / ISO 5832-12:2007) Cobalt Chromium Alloy

2. Assembled bearing insert:
   ASTM F648-14 / ISO 5834-1:2005 and ISO 5834-2:2011 Ultra-High Molecular Weight Polyethylene (UHMWPE)

INDICATIONS

U2 Bipolar Implant is intended for use in combination with UNITED Femoral System for cemented or cementless hemi-arthroplasty. This device may be used for the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of function deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

OTHER CONSIDERATIONS:

1. Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
2. Salvage of failed total hip arthroplasty.

CONTRAINDICATIONS

1. Any active or suspected latent infection in or about the hip joint.
2. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
3. Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
4. Skeletal immaturity.
5. Pathological conditions of the acetabulum which would prevent achieving adequate range of motion, appropriate head stability, and/or a well-seated and supported smooth acetabular articulation of the head.
6. Patients who is sensitive to any materials of the device.

ADVERSE EFFECTS

1. While the expected life of hemi-arthroplasty components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
2. Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
3. Peripheral neuropathies, nerve damage, circulatory compromised and heterotopic bone formation may occur.

4. Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders, gastrointestinal disorders, vascular disorders, including thrombus, bronchopulmonary disorders, including emboli, myocardial infarction or death.
5. Acetabular pain may occur due to localized pressure associated with incongruities of fit or tissue inflammation.
6. Sizing mismatch of the bipolar component within the acetabulum can result in pain and acetabular erosion.
7. Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
8. Metal sensitivity reactions have been reported following joint replacement.
9. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
10. With all implant devices, asymptomatic and localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Also, particulate can be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

WARNINGS

1. Discard all damaged or mishandled implants.
2. Never reuse an implant, even though it may appear undamaged. Reuse of this product will cause the risk of cross infection and unpredictable health threat.
3. Polished bearing areas must not come in contact with hard or abrasive surfaces.
4. Bearing areas must always be clean and free of debris prior to assembly.
5. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
6. This unit was assembled and functionally tested at the factory. Tampering with that assembly (e.g., disassembly and reassembly of the retaining ring) can result in improper function of the retaining mechanism.
7. Care should be taken not to puncture surgical gloves when handling any sharp-edged orthopaedic device.
8. Improper seating of the head or Endo neck extension may result in a discrepancy in neck length, component disassociation and/or dislocation.
9. Except general instruments, this device may only be implanted combined with United implants by using the instruments released by United. Any improperly use will negate the responsibility of United.
10. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

11. The shelf-life of UHMWPE components is five years.
12. Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.
13. This product is not intended to use with THA.

PRECAUTIONS

1. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Surgeons should instruct patients about the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
2. Appropriate selection, placement and fixation of the femoral stem and/or acetabular components are critical factors which affect implant service life. Being similar to all other prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
3. Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

UTILIZATION AND IMPLANTATION

1. The recommended gauge and trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
2. Radiographic templates are available to assist in the preoperative prediction of component size and style.

STERILIZATION

1. This device has been sterilized by gamma radiation.
2. The packaging of all sterile products should be inspected for their integrity and should be accepted only with proper packaging and labeling intact.
3. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
4. If the package is opened, but the product is not used, the component must not be resterilized and must be discarded or returned to the supplier. A suitable handling will be done.

STORAGE CONDITIONS

All implants should be stored at ambient warehouse conditions, within this recommended range: 7℃ to 35℃ at 30%-85% relative humidity.

SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INFORMATION

For further information, please contact

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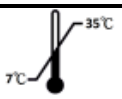
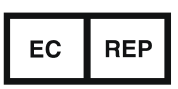
SYMBOLS GLOSSARY

Symbol	Title of symbol	Description of symbol	EN ISO 15223-1
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can beidentified.	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Do not resterilize	Indicates a medical device that is not to be resterilized.	5.2.6
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2