UNITED U2 Hip Stem-Cemented

Safety Statements

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

DESCRIPTION

UNITED U2 Hip Stem is intended to use in primary or revision hip arthroplasty. It is available in an array of styles and matrixed sizes to accommodate various hip surgical requirements. UNITED U2 Hip Stem consists of Cemented Stem, Press-fit Stem, Revision Stem. The UNITED U2 Cemented Stem is intended to be fixed only with the use of PMMA bone cement and should be used with cement restrictor. The UNITED restrictors are made of UHMWPE, which is designed to be used with U2 Cemented Stem. The shuttlecock-like shape makes them ideal for medullary cavity obturation.

Note: The Cemented Stem is designed for cemented use only and can not be used with Ceramic Femoral Head.

MATERIALS

ASTM F620-11 (raw materials ASTM F136-13/ISO 5832-3:1996) Revision Cemented Femoral Stem	Ti alloy
ASTM F75-12(raw materials ASTM F1537-11/ISO 5832-12:2007) Cemented Femoral stem (casting)	Co-Cr-Mo alloy

ASTM F799-11 Cemented Femoral stem (casting)	Co-Cr-Mo alloy
USP Class VI Spacer & Centralizer	PMMA
ASTM F648-14/ISO5834-1:2005 and ISO 5834-2:2011 Restrictors	UHMWPE

INDICATIONS

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 is unmanageable using other techniques.
6. The cement restrictors are intended for obturation of the medullary cavity prior to the introduction of acrylic cement. They have been designed to inhibit the infiltration of cement into the diaphysis and to help generate pressure.

This device is a single use implant and intended for cemented use only.

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. Overweight. An overweight patient will increase loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.
6. This device must only be used in a sterile operating room. Rigorous aseptic techniques must be practiced to prevent any risk of surface contamination.
7. This device is meant for single-use and must not be re-sterilized. Reuse of this product will cause the risk of cross infection and unpredictable health threat.
8. The product should not be modified in any way (it should never be cut or shaped).
9. Do not use if the packaging is damaged.
10. Do not use after the expiration date printed on the label.
11. Do not allow product come into contact with any pollutant, even if it is still in its packaging.
12. Patients who is sensitive to any materials of the device.

POSSIBLE ADVERSE EFFECT

1. While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials 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. Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
4. Fatigue fracture of femoral stems and/or fracture of ceramic heads occurred in a small percentage of cases. Stem/head fracture is more likely to occur in the heavy, physically active individual or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
5. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
6. 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.
7. Acetabular pain may occur after acetabular replacement due to loosening of the implant, or after bipolar hip arthroplasty due to localized pressure associated with incongruities of fit or tissue inflammation.
8. Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock. 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, 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. Secondarily, particulate can also 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. Polished bearing areas and machined taper surfaces must not come in contact with hard or abrasive surfaces.
3. Bearing areas must always-be clean and free of debris prior to assembly.
4. At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
5. Improper seating of the head or Endo neck extension may result in a discrepancy in neck length, component disassociation and/or dislocation.
6. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
7. Infra-operative preparation and implantation of a femoral stem component can result in cracks of the proximal femur. The application of prophylactic cerclage wiring to the proximal femur may aid in the prevention of femoral cracks, crack propagation or their displacement.
8. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
9. United strongly advises against the use of another manufacturer's PMMA spacer with any United femoral stem component. Any such use will negate the responsibility of United for the performance of the resulting mixed component implant.
10. 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.
11. Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize**.
12. The shelf-life of UHMWPE made components is five years.
13. In compliance with the regulations, this product should only be handled and implanted by fully qualified and trained healthcare professionals who are thoroughly familiar with these instructions.

14. The manufacturer must be notified immediately of any product which does not conform to the specifications. Observed deviation(s) should be recorded and reported in detail and, if possible, the product itself should be returned.
15. It is the prescribing surgeon's sole responsibility to provide patient any relevant information (on the efficacy of the device and any risks associated with the implanting operation) both before and after the procedure as well as confirming the compatibility of materials produced by other parties which are used in conjunction with this device.

PRECAUTIONS

1. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in 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. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanical 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 from being marred, nicked or notched as a result of contact with metal or abrasive objects.

UTILIZATION AND IMPLANTATION

1. The recommended trial components should be used for size determination, canal preparation evaluation, 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.
3. The United Surgical Protocols provide additional procedural information.

PACKAGING AND LABELING

All implants should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION

1. All components have been sterilized by gamma radiation.

2. The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
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.

IMPORTANT FOR OPENED COMPONENTS

The plastic components, if opened, are not permitted be re-sterilization by any method. The metal components, if opened, please return to United Orthopedic Corporation. A suitable handing in cleaning (if necessary), packaging and gamma radiation will be done.

STORAGE CONDITIONS

All implants should be stored at ambient warehouse conditions, within this recommended range: 7°C to 35°C 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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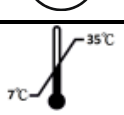
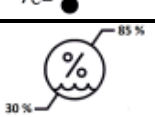
SYMBOLS GLOSSARY

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