ENG50928 Rev2

UNITED U2 Acetabular Components

Safety Statements

EC REP

mdi Europa GmbH
Langenhagener Straße 71
30855 Langenhagen, Germany
TEL: +49-511-3908 9530
FAX: +49-511-3908 9539

United Orthopedic Corporation
No. 57, Park Ave 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-5773351
FAX: +886-3-5777156

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

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

DESCRIPTION

UNITED U2 Acetabular Components is a modular type of product system with hemispherical design consists of U2 Ti porous Cup, U2 Ti Plasma Cup, U2 HA/Ti Plasma Cup, Ti Cancellous Bone Screw and Screw Hole Plugs, U2 Cup Liner and XPE Cup Liner. The acetabular cups are available in three surface structure types such as titanium (Ti) porous-coated for U2 Ti porous Cup, Ti plasma spray for U2 Ti Plasma Cup and Ti plasma spray with Hydroxylapatite surface treatment for U2 HA/Ti Plasma Cup. The type of surface structure for this component and the crossinking condition are indicated on the package label. There are three types of screw hole for surgeon's choice: clustered, no-hole, and multi-hole. The cancellous bone screw can be screwed into screw hole to fix the acetabular component. The screw hole plugs can be used while the screw holes are needless.

UNITED U2 Acetabular Components, includes cup shell and cup liner, are intended to be used with compatible size of UNITED Femoral Heads, UNITED Ceramic Femoral Heads and UNITED Femoral Stems of total hip replacement. All implantable devices are designed for single use only.

Note: U2 Acetabular Cup Liners with ID 22mm and 26mm are only compatible with UNITED Femoral Heads in following specification.

U2 Acetabular Cup Liner	UNITED Femoral Head (Catalog No.)	
Liner Size (ID)	**U1 Femoral Head**	**U2 Femoral Head**
22 mm	1201-1122	1206-1122
26 mm	1201-1126 1201-1326	1206-1026 1206-1126 1206-1326

MATERIALS

ASTM F620-11 Titanium 6Al-4V ELI (raw materials ASTM F136-13/ISO 5832-3:1996)	Acetabular cup, Ti porous coated, HA plasma spray coating
ASTM F136-13/ISO 5832-3:1996 Ti alloy	Ti Cancellous bone screw
ASTM F1580-12 Ti alloy	Metallic powder for Ti porous coating
ASTM F1580-12 Titanium	Metallic powder for Ti plasma spray
ASTM F1185-03(2014) Hydroxylapatite	Hydroxylapatite powder for HA plasma spray coating
ASTM F648-14/ISO 5834-2:2011 UHMWPE	U2 Acetabular cup liner, XPE
	Acetabular cup liner, screw hole plug

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.

This device is a single use implant and intended for cementless use only except cemented stem which is designed 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 that cannot provide adequate support and/or fixation to the prosthesis.
4. Skeletal immaturity.
5. 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.
6. 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 acetabular cup occurred in a small percentage of cases. Acetabular cup 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 re-operation, 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. The patient should be warned of surgical risks, and made aware of possible adverse effects.
2. Discard all damaged or mishandled implants.
3. 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.
4. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.
5. Bearing areas must always be clean and free of debris prior to assembly.
6. At time of assembly, machined snap-in surfaces must be clean and dry to ensure proper seating and assembly security.
7. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
8. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
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. The shelf-life of UHMWPE made components is five years.
11. Bone cement is not allowed to be used with U2 Acetabular Cup for implant fixation or for acetabular bone grafting. There is a possibility of implant loosening while applying cement with U2 Acetabular Cup.

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 that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics 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. To check the label information, especially the size designation, is consistent with the device.

2. The recommended 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.
3. Radiographic templates are available to assist in the preoperative prediction of component size and style.
4. 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. If the sterile barrier has been broken, return the component to United Orthopedic Corporation.

STERILIZATION

All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. Inspect packages for punctures or other damage prior to surgery. Metal components, coated metal components, and HA coated metal components are radiation sterilized. Plastic components are radiation sterilized or ethylene oxide sterilized. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded. 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.

Radiation sterilized: metal components, coated metal components, and HA coated metal components and plastic components (except highly crosslinked UHMWPE products).

Ethylene oxide sterilized: highly crosslinked UHMWPE products.

IMPORTANT FOR OPENED COMPONENTS

If the package is opened, but the product is not used, the component must be returned to the United Orthopedic Corporation. If necessary, a suitable sterilization and/or special cleaning procedures 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

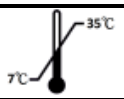
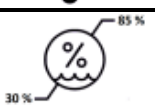
This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INFORMATION

For further information, please contact

United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-577-3351
FAX: +886-3-577-7156
Contact Information: unitedorthopedic.com/contact

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