ENG50923 Rev2

UTS Stem
Safety Statements

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

DESCRIPTION

UTS Stem is a wedge-shaped stem with 12/14 neck taper, which is indicated for use in primary or revision hip arthroplasty. The stem substrate is made of Ti-6Al-4V and is proximally coated with titanium plasma spray which provides biological fixation.

For total hip replacement, UTS Stem can be used in conjunction with UNITED Femoral Head, U2 Acetabular Components, U-Motion II Acetabular Components. As using with the U2 Acetabular Components, UTS Stem can be used with 26mm-36mm metal Femoral Head and 28mm-36mm Ceramic Femoral Head. As using with the U-Motion II Acetabular Components, UTS Stem can be used with 28mm-36mm metal Femoral Head and 28mm-40mm Ceramic Femoral Head. For bipolar hip replacement, UTS Stem also can be used in conjunction with 22mm-36mm Femoral Head, 28mm-36mm Ceramic Femoral Head and Bipolar implants.

MATERIALS

Ti- 6Al-4V Alloy	ASTM F136	UTS stem
Ti powder for Ti plasma spray	ASTM F1580	Ti plasma spray

INDICATIONS

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.

3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatments or devices have failed.

This device is designed for cementless use.

CONTRAINDICAITONS

1. Any active or suspected latent infection in or about the operative site.
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 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. For use as a Hip Replacement, 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.
7. Patients who is sensitive to any materials of the device.

POSSIBLE ADVERSE EFFECTS

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 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.
9. Acetabular pain may occur after bipolar/hemi-hip arthroplasty due to localized pressure associated with incongruities of fit or tissue inflammation.
10. Metal sensitivity reactions have been reported following joint replacement.
11. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
12. 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.
3. Polished neck areas and machined taper surfaces 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. At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
6. Improper seating of the head may result in a discrepancy in neck length, component disassociation and/or dislocation.
7. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
8. Intra-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.
9. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.

10. Except general instruments, this device may only be implanted combined with UOC implants by using the instruments released by UOC. Any improperly use will negate the responsibility of UOC.
11. Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize**.

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, 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. Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, mal-alignment, trauma, non-union, or excessive weight.
4. 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 UOC 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. This device is sterile and double packaged to ensure the product is suitable for surgery at any time. The sealed package can protect the implants and keep the sterilized condition under normal storage and transport.
2. All components have been sterilized by gamma radiation at least 25 kGy, which can be verified from the colored sterilization indicator on the packaging. The method of sterilization is noted on the package label.

3. This device is provided sterile and should be stored in the original packaging until it is ready to be used.
4. Prior to used, check the sterilization expiry date and verify the integrity of the sterile packaging. If the sterilization expiry date has expired or in case of any damage to the protective packaging, 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.
5. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
6. If the package is opened, but the product is not used, the component **must not** be resterilized and must be returned to the supplier.
7. The implant should not be used if the outer sterile barrier is damaged or intentionally opened during surgical use but the implant was not used during surgery and was taken out of the sterile field.

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) ENVIONMENT

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

The Surgical Technique is provided on the web site: http://www.uoc.com.tw

For further information, please contact

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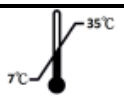
SYMBOLS GLOSSARY

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