ENG50822 Rev8

UNITED Hip System
UCP Stem
Safety Statements

EC REP

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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 UCP Stem is intended to use in primary or revision hip arthroplasty. It is available in an array of styles and sizes to accommodate various hip surgical requirements. The UCP Stem is intended to be fixed only with the use of PMMA bone cement and should be used with centralizer and cement restrictor. UCP Stem may be used with UNITED metal or ceramic femoral heads except for Forte ceramic femoral heads. For total hip arthroplasty, UCP Stem may be used with UNITED acetabular liner and cup. For bipolar hip replacement, UCP Stem may be used with UNITED bipolar prosthesis.

MATERIALS

Forged Co-Cr-Mo Alloy ASTM F799-11 (Raw material:ASTM F1537-11/ ISO 5832-12:2007)	Stem
PMMA USP Class VI	Centralizer
UHMWPE ASTM F648-14/ISO 5834-1:2005 and ISO 5834-2:2011	Cement restrictor

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. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.
4. Revision procedures where other treatments or devices have failed.
5. Patients with acute femoral neck fractures.

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

CONTRAINDICAITONS

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. 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.
5. Patients who allergic to any material of the device.
6. Skeletal immaturity.

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. 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.
8. 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 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.
9. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
10. Metal sensitivity reactions have been reported following joint replacement.
11. Infections that include acute post-operative wound infection and later on deep wound sepsis.
12. Trochanteric nonunion, it usually associates with early weight bearing or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
13. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection.

WARNINGS

1. This device should only be applied by qualified and specially trained surgeons who have the corresponding knowledge and experience in the field of hip joint replacement. The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
2. Factors outside the control of United are not United's responsibility, including any modification after delivering to the hospitals and any mishandled pre-operation, intra-operation or post-operation. The operating surgeon shall be responsible for any negative effects and complications resulting from non-compliance with the user instructions, improper treatment of the material or an incorrect assessment of indications.
3. If the product does not meet the specifications, please immediately notify the supplier, and dilate the problems that occur. If possible, please return the product to the supplier.
4. Surgeon must inform the patient about the relative information of this device, including its effects and the possible risks during operation, possible post-surgical complications, as well as inspect the materials biocompatibility of the products used with this device.
5. Discard all damaged or mishandled implants.

6. 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.
7. Bearing areas must always be clean and free of debris prior to assembly.
8. At time of assembly, machined taper surfaces must be clean and dry to ensure proper seating and assembly security.
9. Improper seating of the head may result in a discrepancy in neck length, component disassociation and/or dislocation.
10. UCP stem must be used with centralizer to ensure the designated function.
11. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
12. 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.
13. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
14. United strongly advises against the use of another manufacturer's tapered head, centralizer or acetabular component with any United femoral stem component. Any such use will negate the responsibility of United for the performance of the resulting mixed component implant.
15. 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.
16. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

PRECAUTIONS

– PREOPERATIVE

1. Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.
2. Multiple sizes of implants should be prepared for surgery, including larger and smaller size. Preparation of special size implants also recommended.
3. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
4. Screening should be considered for patients who are allergic to the material of implants.
5. Radiographic templates are available to assist in the preoperative prediction of component size and style.
6. 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.

7. To inspect the red dot on package to make sure the product has been properly sterilized.
8. To check the label information, especially the size designation, is consistent with the device.

– INTRAOPERATIVE

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. 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 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 prevent paralytic sciatica for developmental dysplasia of the hip. Extra small femoral implants are usually required to fit its small and straight femur bone.
4. Demand of surgical skill is higher for the revision surgery. Long operation time will increase blood loss, chance of pulmonary embolism and wound hematoma. Common mistakes include improper exposure of femur bone, improper fixation of implant and inadequate removal of osteophyte.
5. For the revision surgery, the fixation of the original implant and cement should be carefully checked. When necessary replacement of the original implant should be considered.
6. Prevent surface of metal implant being marred. The implant cannot be reused in any condition because invisible change of stress inside implant may lead to deformation or fracture of the implant.
7. Before wound closure, any bone fragment or bone cement should be removed from surgical site. Heterotopic bone, bone spurs or bone fragment may cause pain or limitation of activity for patients.
8. For patients who have rheumatoid arthritis and rely on steroid, prevention of penetration of femur bone or greater trochanter duo to osteoporosis is important.
9. The United Surgical Protocols provide additional procedural information.

– POSTOPERATIVE

1. It is very important for patients to receive care and instruction from surgeon postoperatively. Postoperative weight bearing should be gradually and should provide individual plan for each individual patient.
2. Reminding patient to prevent activities of large range of motion in hip joint (such as go to the toilet) independently.
3. When move the patient, it is important to provide support with the surgical site and prevent adding pressure on it.
4. Restoring muscle strength around hip joint and increase level of activity gradually.

5. Periodically X-ray examination to ensure the fixation of the implant and bone cement, and bone quality.
6. Usage of antibiotic should be considered to prevent infection.

PACKAGING, 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.

IMPORTANT FOR OPENED COMPONENTS

If the package is opened, but the product is not used, the component must be discarded or returned to the supplier.

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.

Catalogue number for the compatible ceramic femoral heads

Catalog No.	Description
1203-5028	Ceramic Femoral Head, Delta, O.D.Ø28mm, 12/14- S
1203-5228	Ceramic Femoral Head, Delta, O.D.Ø28mm, 12/14- M
1203-5428	Ceramic Femoral Head, Delta, O.D.Ø28mm, 12/14- L
1203-5032	Ceramic Femoral Head, Delta, O.D.Ø32mm, 12/14- S
1203-5232	Ceramic Femoral Head, Delta, O.D.Ø32mm, 12/14- M
1203-5432	Ceramic Femoral Head, Delta, O.D.Ø32mm, 12/14- L
1203-5632	Ceramic Femoral Head, Delta, O.D.Ø32mm, 12/14- XL
1203-5036	Ceramic Femoral Head, Delta, O.D.Ø36mm, 12/14- S
1203-5236	Ceramic Femoral Head, Delta, O.D.Ø36mm, 12/14- M
1203-5436	Ceramic Femoral Head, Delta, O.D.Ø36mm, 12/14- L
1203-5636	Ceramic Femoral Head, Delta, O.D.Ø36mm, 12/14- XL
1203-5040	Ceramic Femoral Head, Delta, O.D.Ø40mm, 12/14- S
1203-5240	Ceramic Femoral Head, Delta, O.D.Ø40mm, 12/14- M
1203-5440	Ceramic Femoral Head, Delta, O.D.Ø40mm, 12/14- L
1203-5640	Ceramic Femoral Head, Delta, O.D.Ø40mm, 12/14- XL

INFORMATION

For further information, please contact

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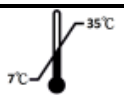
SYMBOLS GLOSSARY

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