ENG50837 Rev6

Full XPE Cup

Safety statements

EC REP

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

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

DESCRIPTION

The Full XPE Cup is manufactured from highly-cross linked UHMWPE (ASTM F648-14/ISO 5834-1:2005 and ISO 5834-2:2011) and assembled with PMMA Spacers (USP Class VI) and has a Co alloy (ASTM F90-09) wire marker ring for identification on X-Ray. All Full XPE Cups are available in a range of sizes to fit varying anatomical requirements.

INDICATIONS

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, 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 and femoral neck fractures of the proximal femur with head involvement that is unmanageable using other techniques.

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. Obesity. An overweight or obese 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. 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. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
5. 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.
6. 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.
7. Intraoperative fissure, fracture, or perforation of the acetabulum can occur due to impaction of the component into the prepared acetabulum. Postoperative acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock. Metal sensitivity reactions have been reported following joint replacement.
8. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
9. 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. 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. This device is designed for single use only. Never use prosthetic components which have been used before.
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. 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.
6. Only unused implants taken from the original packaging may be used. Never reuse an implant again, even though it may appear undamaged. Reuse of this product will cause the risk of cross infection and unpredictable health threat.
7. The position of the prosthesis components has a direct influence on the range of movement and thus represents a potential risk of impingement, luxation or subluxation. For cups which are too steep, surface pressure on the acetabular edge increases. This can lead to increased wear. The cup position is oriented in accordance with the safety zone described by Lewinnek.
8. The joint may luxate with strenuous exercise, or subluxate through the impingement of implant components or soft tissues.
9. The inclination of the cups should not significantly exceed or fall below a value of 40-45°. The anteversion of the cups should not significantly exceed or fall below a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the head from the cup.
10. Bearing areas must always be clean and free of debris prior to assembly.
11. Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**
12. 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.

PRECAUTIONS

PREOPERATIVE

1. Surgeon must inform the patient that an artificial joint cannot be subjected to the same demands as a natural joint, and the patient should not have unrealistic functional expectations. Surgeons should instruct patients about the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient's weight or activity, and be taught to govern their activities accordingly. Any kind of competitive sport, i.e. sport types with jolting or jerking movements, involving the artificial joint is contraindicated and leads to excessive strains. 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.
2. The implant must be carefully preserved and transported properly. Cut or scratch the surface of the implant will significantly reduce its static, fatigue strength or influence its friction characteristics. These may have small defects and internal stress patterns invisible to the naked eye which may lead to early failure of the device. Implants and instruments are not stored in the salt air.
3. Enough sizes of the implants should prepare for surgery, including larger and smaller size. Special size is also recommended to prepare.
4. Pay attention to special conditions of patient as the description of contraindication.
5. Preoperative screening should be considered if the materials of the device cause allergy or other reaction of patients although this condition occurs seldom.
6. Radiographic templates are available to assist in the preoperative prediction of component size and style.
7. Surgeon must read the surgical protocol carefully before operation.
8. Check the colored sterilization indicator of the packaging.
9. The labels must be checked to see that they match the labels on the devices.

INTRAOPERATIVE

1. The United Surgical Protocols provide additional procedural information.
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 should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
4. 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.

5. The joint is tested for free movement and stability using sample heads of the intended diameter. Please take care that the plastic femoral head will be removed after checking.
6. The joint may not luxate with movement, or subluxate through the impingement of implant components or soft tissues.

POSTOPERATIVE

1. Postoperative care and instructions for patients are very important. Postoperative weight bearing must increase gradually and individually.
2. After postoperative, patients must be reminded, do not make large movement of hip joint individually with no help or without auxiliaries, especially when going to the toilet or performing the higher degree of activities.
3. Moving the patient carefully and paying attention to support the affected area and avoid exerting pressure on it.
4. The postoperative treatment should take care of the strength of muscles around the hip and increase activity gradually.
5. Regular X-rays shall be taken to evaluate if the implant move, loose, bend, fracture or the cement or bone loss. If these conditions occur, please pay attention to the progress of condition and consider the advantage of revision.
6. Should consider the use of antibiotics in patients to prevent bacterial infection.

PACKAGING AND LABELING

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. The packaging of all products should be inspected for their integrity and should only be accepted with proper packaging and labeling intactness.
3. All implants should be stored in their original packaging in a clean and dry environment.
4. If the sterile blister pack became wet or damaged, the implants should not be used and be returned to the supplier.

STERILIZATION

1. All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label.
2. This device is ethylene oxide sterilized. All components can be verified from the colored sterilization indicator on the packaging.
3. The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of any flaws, 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.
4. This device delivered in sterilized form and must be kept unopened in the original packaging until it is ready to be used. Check the sterilization expiry date on the sterile packing and check the protective packing for damage prior to use. If the sterilization expiry date has

passed or in case of any damage to the protective packaging, the implants must not be used or re-sterilized and must be discarded or returned to the supplier.

5. Aseptic methods must be followed when removing the component from its original packaging and during the entire implantation. In the event of contamination, this product must be discarded.

RE-STERILIZATION

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

STORAGE AND HANDLING

1. All implants must be stored unopened in the original packaging.
2. The protective packaging must be inspected for signs of damage before the devices are removed, since this could affect the sterility. The sterility expiry date must be observed. If the protective packaging is damaged or the sterility date has passed, the implants must be returned to United.
3. Protection may only be removed directly before use.
4. The implants which can no longer be used may be returned to the manufacturer for correct disposal.
5. The expiry time of sterilization is 5 years.

INTERACTION WITH DRUGS

There have been no reported interactions with drugs to date.

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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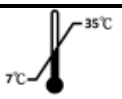
SYMBOLS GLOSSARY

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