ENG50991 Rev4

United Hip System
Conformity Stem
Safety Statements

EC REP

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CE 2195 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

The conformity stem is intended to use in hip arthroplasty. There are two types of conformity stem, including Conformity stem and Conformity stem, cemented. Conformity stem is intended for cementless use and made by Ti-6Al-4V alloy with HA plasma spray. Conformity stem, cemented is made by CoCrMo alloy and is intended to be fixed only with the use of PMMA bone cement and should be used with UNITED cement restrictor. Both types of stem are available in a variety of sizes to accommodate various hip surgical requirements.

Conformity Stem can be used with UNITED metal or ceramic femoral heads. For total hip arthroplasty, Conformity Stem can be used with UNITED acetabular liner and cup. For bipolar hip replacement, Conformity Stem can be used with UNITED bipolar prosthesis.

MATERIALS

Ti-6Al-4V Alloy	ASTM F136	Conformity Stem
	ISO 5832-3	Conformity stem, high offset, collared
		Conformity stem, collared
		Conformity stem, high offset
		Conformity stem, coxa vara, collared
		Conformity stem, short neck, collared
CoCrMo Alloy	ASTM F1537	Conformity Stem, cemented
	ASTM F799	Conformity Stem, cemented, high offset
	ISO 5832-12	
Hydroxylapatite	ASTM F1185	HA plasma spray

INDICATIONS

The device is indicated for use in hip arthroplasty in skeletally mature patients with the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dyplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacment or total hip replacement.
5. Certain cases of ankylosis.

Conformity stem is for cementless use only.

Conformity stem, cemented is for cemented use only.

CONTRAINDICAITONS

The following conditions are contraindications for total or hemi-hip replacement:

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. Obesity. An 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 are allergic to any material of the device.
7. Fever or leukocytosis.
8. Pregnancy.

9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.

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. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
3. Infections that include acute post-operative wound infection and later on deep wound sepsis.
4. Metal sensitivity reactions have been reported following joint replacement.
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 embolism; myocardial infarction or death.
6. Dislocation can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
7. Loosening of the 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.
8. Change in mental status.
9. Breakage or bending may result due to inadequate support of the component by the underlying bone or poor component fixation.
10. Fatigue fracture of the implants occurred in a small percentage of cases. Implants 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.
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 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. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.
3. 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.
4. 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.
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. Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.
7. 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.
8. Discard all damaged or mishandled implants.
9. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
10. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
11. 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. Only patients that meet the criteria described in the indications should be selected.
2. Pay attention to special conditions of patient as the description of contraindication.
3. Enough sizes of the implants should prepare for surgery, including larger and smaller size. Special size is also recommended to prepare.
4. Preoperative screening should be considered if the materials of the device cause allergy or other reaction of patients although this condition occurs seldom.
5. Surgeon must read the surgical protocol carefully before operation.
6. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Surgeons should instruct patients about the limitations of the prosthesis.
7. 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.
8. Check the colored sterilization indicator of the packaging.
9. To check the label information, especially the size designation, is consistent with the device.

– INTRAOPERATIVE

1. The United Surgical Protocols provide additional procedural information.
2. The suggested surgical procedure should be strictly adhered to.
3. Appropriate selection, placement and fixation of the 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 biological, 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.
4. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
5. Care must be taken to protect the components from being marred, nicked or notched as a result of contacting with metal or abrasive objects.
6. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
7. Before wound closure, any bone fragment should be removed from surgical site. Heterotopic bone, bone spurs or bone fragment may cause pain or limitation of activity for patients.
8. At time of assembly, machined snap-in surfaces must be clean and dry to ensure proper seating and assembly security.

– POSTOPERATIVE

1. Postoperative care and instructions for patients are very important. Detailed instructions on the use and limitations of the device should be given to the patient. 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. Usage of antibiotic should be considered to prevent infection.

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°C to 35°C 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

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

For further information, please contact

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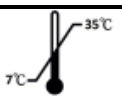
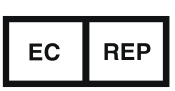
SYMBOLS GLOSSARY

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