ENG50885 Rev4

“UNITED” U2 Total Knee System
E-XPE Tibial insert and Patella
Safety Statements

EC REP

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

DESCRIPTION

“UNITED” U2 Total Knee System – E-XPE Tibial insert and Patella is an extension design of “UNITED” U2 Total Knee system, which is indicated for use in primary or revision knee arthroplasty. The component composed of polyethylene insert and patellar which are designed to be use with femoral components and tibial baseplate components to achieve total replacement of the knee joint. For cemented femoral components, patellar components, tibial baseplate components and tibial inserts components: this device is a single use implant and intended for cemented use only. For porous coated femoral component: this device is a single use implant and intended for cementless use only.

E-XPE Tibial insert

E-XPE Tibial inserts are available in various thicknesses and in five design configurations: Cruciate Retained (CR) type, Posterior Stabilized (PS) type, Ultracongruent (UC) and Posterior Stabilized Augmentable (PSA) type. There are a variety of collocation components of femoral component and baseplate of U2 total knee system that provides a variety options for surgeon to treat their patients.

E-XPE Patella

E-XPE patella components are available in all plastic in-set and on-set designs with dome shape configurations.

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

MATERIALS

Vitamin E-blended highly cross-linked UHMWPE	ASTM F2695-12, ASTM F648/ISO 5834	Tibial insert Patella
Ti-6Al-4V alloy	ASTM F136	Tibial screw

INDICATIONS

For E-XPE Insert (CR, PS and UC type) and Patella

The device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device is a single use implant and intended for cemented use only.

For E-XPE Insert (PSA type)

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. 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 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 allergic to any material of the device.
7. Fever or leukocytosis.
8. Any other medical or surgical process which would preclude the potential benefit of knee implant surgery, such as the presence of tumors or congenital abnormalities, fracture local

to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Pregnancy.
10. 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.
11. Severe instability, maltracking, malalignment of the patella, patellofemoral and/or tibiofemoral joints.
12. The presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus.

POSSIBLE ADVERSE EFFECTS

1. While the expected life of total knee 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. Serious complications may be associated with any total knee 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.
5. Dislocation can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
6. 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.
7. Change in mental status.
8. Breakage or bending may result due to inadequate support of the component by the underlying bone or poor component fixation.
9. 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.

10. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb.
11. Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone absorption, loosening and infection.
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. 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.
13. Very small particles from metal and polyethylene components can be shed from the components during normal use and over time. Although most of this debris says in the relevant joint (i.e. contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can be disseminated (migrate) throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. Given the insufficient time period during which patients with these devices have been followed and the fact that these devices are currently being used in younger patients and remain in the body for increasingly longer periods of time, it should be said that the long-term effects, if any, from these particles, is unknown. The long-term effects have been theorized to included:
    - Cancer: There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
    - Lymphadenopathy and accumulation in other tissues/organs: There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
    - Systemic disease: There has been some speculation that there could be an association between migration of debris and as yet unidentified systemic effects. It is possible that some long-term effect may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.
14. Decreasing range of motion caused by improper positioning.

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 knee 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.
12. Bearing areas must always be clean and free of debris prior to assembly.
13. At time of assembly, machined snap-in surfaces must be clean and dry to ensure proper seating and assembly security.
14. The joint may luxate with strenuous exercise, or subluxate through the impingement of implant components or soft tissues.

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.
10. 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 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. An additional risk is posed by patients with high body weight, with a weak osseous system or by those who are physically very active. Brief, extreme overloading such as a trauma, an accident or excessive strain can lead to fracturing, sometimes long after the event. The patient also must be informed of possible post-surgical complications.
11. Radiographic templates are available to assist in the preoperative prediction of component size and style.

– 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 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. 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.
9. Cemented application: Care should be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations which may lead to failure of the procedure. Prevent bone cement and all parts of the device from blood and grease. Complete cleaning (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surface of the implant. Before implantation, replacement of surgical gloves is recommended.
10. 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.
11. 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.

– 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 knee joint individually with no help or without auxiliaries, especially when 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 knee 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.

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 ethylene oxide gas, 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 implants must not be used or resterilized and must be discarded or returned to the supplier. 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.
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

E-XPE Insert (PSA type) 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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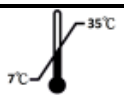
SYMBOLS GLOSSARY

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