ENG50397 Rev18

# U2 Total Knee System

## Safety statements

EC REP

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

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

**DESCRIPTION**

The U2 Total Knee System include femoral components, patellar components, tibial baseplate components and tibial inserts components which are designed to be used together to achieve total replacement of the knee joint.

The femoral components are available in Cruciate Retained (CR) and Posterior Stabilized (PS) designs. The CR femoral components include cemented and porous coated types.

The tibial baseplate components include fixed and mobile types with groove for cement fixation. Tibial inserts for the fixed type tibial baseplate are available in a range of thicknesses and in three design configurations: Cruciate Retained (CR) inserts have increased anterior and posterior bearing geometry surfaces for additional stability against subluxation. Posterior Stabilized (PS) inserts have raised tibial eminence for increased anterior and posterior constraint, prevention of posterior subluxation and varus/valgus stability. Ultracongruent (UC) insert has raised prominent anterior lip to prevent femur paradoxical anterior sliding during knee flexion, increase contact area for enhancing wear resistance and eliminate the need to cut out a bone box such as PS knee. Tibial inserts for the mobile type tibial baseplate include MB and MBC types. They are available in a range of thicknesses and freely rotated with metallic tibial baseplate. CR, UC and MBC insert types were designed to collocate with CR femoral

component, while PS and MB insert types were designed to collocate with PS femoral component. CR knee design (CR femoral component collocate with CR insert) used for posterior cruciate ligament was excised, while PS knee design (PS femkoral component collocate with PS, UC and MB inserts) used for both cruciate ligaments were excised. The patellar components are available in all plastic in-set and on-set designs with dome shape configurations. The tibial insert and patellar components are manufactured from UHMWPE with or without cross-linking. The cross-linking condition is indicated on the package label. Product compatibility is shown in the table below.

| | Femoral Component | Tibial Insert | Baseplate | Patella |
|---|---|---|---|---|
| CR Knee | Femoral Component, CR | Tibial Insert, CR<br>XPE Tibial Insert, CR | Tibial Baseplate, Cemented | Patella, onset<br>XPE Patella, onset<br>XPE Patella |
| | | Tibial insert, UC | Tibial Baseplate, Cemented | Patella, onset<br>XPE Patella, onset<br>XPE Patella |
| PS Knee | Femoral Component, PS | Tibial insert, PS<br>XPE Tibial insert, PS | Tibial Baseplate, Cemented | Patella, onset<br>XPE Patella, onset<br>XPE Patella |

**Note:** The mobile type tibial baseplate, tibial insert-MB and tibial insert-MBC are not for sale in the U.S.A.

**MATERIALS**

| | |
|---|---|
| ASTM F75 Co-Cr-Mo alloy | Femoral component, Sintered bead, Tibial baseplate-mobile |
| ASTM F136 Titanium 6Al-4V ELI alloy | Tibial baseplate |
| ISO 5834/2 UHMWPE | Tibial insert, Patella |

**INDICATIONS**

The U2 Total Knee system 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 cannot be satisfactorily balanced and stabilized at the time of surgery.

**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.

## CONTRAINDICAITONS

The U2 Total Knee System is contraindicated in patients with any active or suspected latent infection in or about the knee joint. Patients without sufficient bone stock to provide adequate support and/or fixation to the prosthesis. Patients without sufficient soft tissue integrity to provide adequate stability. Patients with either mental or neuromuscular disorders which would create an unacceptable risk of prosthesis instability or complications in postoperative care, and in patients who are overweight or obese, age or activity level might cause extreme loads on the prosthesis and early failure of the system. Patient who is sensitive to any materials of the device.

## ADVERSE EFFECTS

Potential adverse effects include infection, decreasing range of motion, loosening of the components, breakage or bending of the components, or malalignment of the components. Dislocation can occur due to inappropriate patient activity, trauma or other biomechanical considerations. Loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment, osteolysis or trauma. Breakage or bending may result due to inadequate support of the component by the underlying bone or poor component fixation. Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone absorption, loosening and infection. Other potential adverse effects of total knee surgery include genitourinary disorders; gastrointestinal disorders; neurovascular damage, embolism, myocardial infarction and other less common adverse effects. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb. Due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

## WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical Technique for total knee arthroplasty and the U2 Total Knee System is essential for success of the total knee procedure. Only surgeons who have reviewed the literature regarding total knee surgery and have had training in the technique should utilize the device. Patients should be instructed 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.

Accordingly, strict adherence to the indications, contraindications, precaution and warnings for this product is essential to potentially maximize service life. Appropriate selection, placement and fixation of the total knee 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 biological, biomechanical and other extrinsic factors, which limit their service life.

The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the components. Discard all damaged or mishandled implants. Never reuse an implant. Reuse of this product will cause the risk of cross infection and unpredictable health threat. Keep bearing areas clean and free of debris prior to assembly. Components of the U2 Total Knee System should not be used with those of another manufacturer's total knee component since articular and dimensional compatibility cannot be assured. 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. Intentional removal of the plastic tibial insert after its assembly into the tibial tray results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial tray during insert removal. Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**

**UTILIZATION AND IMPLANTATION**

Selection of the U2 Total Knee System depends on the requirement of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: (1) appropriate reading of the literature and (2) training in the operative skills and techniques required for total knee arthroplasty surgery. The trial components should be used for size determination, trial reduction and range of motion evaluation. Radiographic templates are available to assist in the preoperative prediction component size and style. The UHMWPE plugs may be removed from the screw holes, and bone screw may be used for additional fixation. The U2 Surgical Protocols provide procedural information.

**PACKAGING, LABELING AND STERILIZATION**

All U2 Total Knee implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. Inspect packages for punctures or other damage prior to surgery. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded. 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.

**Radiation sterilized**: Metal components and plastic components (except highly crosslinked UHMWPE products).

**Ethylene oxide sterilized**: Highly crosslinked UHMWPE products.

**IMPORTANT FOR OPENED COMPONENTS**

If the package is opened, but the product is not used, the component must be returned to the United Orthopedic Corporation. If necessary, a suitable sterilization and/or special cleaning procedures will be done.

**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**

The U2 Total Knee System 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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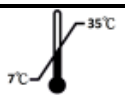
## SYMBOLS GLOSSARY

| 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 |