ENG50634 Rev13

U2 Total Knee System – PSA Type

Safety Statements

EC REP
mdi Europa GmbH
Langenhagener Straße 71
30855 Langenhagen, Germany
TEL: +49-511-3908 9530
FAX: +49-511-3908 9539

United Orthopedic Corporation
No. 57, Park Ave 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-5773351
FAX: +886-3-5777156

DESCRIPTION

"UNITED" U2 Total Knee System – Posterior Stabilized Augmentable (PSA) type is an extended design of "UNITED" U2 Total Knee system. It is a patellofemorotibial polymer / metal / polymer, semi-constrained, cemented knee prosthesis, which has a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral component and a tibial component composed of a polyethylene insert machined from compressed molded UHMWPE and a Ti-6Al-4V metallic tibial baseplate. Tibial inserts are available in a range of thicknesses and in two design configurations: for the PSA type insert, it is intended for use in patients who require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. While PSA low constrained type (PSA, LC) insert provide less constrained stabilization than PSA type insert. This system is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock. There are a variety of components including femoral augment set, tibial augment, stem extension and offset stem adapter that provide more choices for surgeon to treat their patients. In addition, this system provides more stability for patients with inadequate medial-lateral, anterior-posterior or varus-valgus soft tissue imbalance. For total knee replacement, "UNITED" patella components are intended to be used with U2 Total Knee System – PSA Type. The components of U2 Total Knee system – PSA Type are listed as below.

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

MATERIALS

Co-Cr-Mo alloy	ASTM F75 (raw materials ASTM F1537/ISO 5832-12)	Femoral component

Co-Cr-Mo alloy	ASTM F1537/ ISO 5832-12	Femoral augment set
Co-Cr-Mo alloy	ASTM F75 (raw materials ASTM F1537/ISO 5832-12)	Femoral augment set
Ti-6Al-4V ELI alloy	ASTM F136-13/ISO 5832-3	Tibial baseplate, Tibial screw, Femoral augment set, Tibial augment, Offset stem adapter, Femoral screw, Stem
UHMWPE	ASTM F648/ISO 5834 -1 and ISO 5834-2	Tibial insert
Titanium	ASTM F1580	Metallic powder for Ti plasma spray

INDICATIONS

This device is indicated in knee arthroplasty 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 joint surface 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 increased stabilization for tibiofemoral joint due to soft tissue imbalance. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

Note: In the US, this device is for cemented use only.

CONTRAINDICAITONS

The U2 Total Knee System is contraindicated in patients who with:

- any active or suspected latent of infection in the affected joint.
- skeletal immaturity.
- either mental or neuromuscular disorders which would create an unacceptable risk of prosthesis instability or complications in postoperative care.
- an ulcer of the skin or a history of recurrent.
- breakdown of the skin.
- sensitive to any materials of the device.
- Overweight. An overweight patient will increase loads on the prosthesis which could lead to failure of the fixation of the device or to failure of the device itself.

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 – PSA Type is essential for success of the total knee procedure. Only surgeons who have reviewed the literature regarding total knee surgery and have been 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. Keep bearing areas clean and free of debris prior to assembly. The tibial augment is only to be used with bone cement. Components of the U2 Total Knee System – PSA Type 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. Femoral component and tibial insert should belong to the one single system; therefore, femoral component of U2 Total Knee System – PSA Type cannot be coupled with tibial insert of U2 Total Knee System, vice versa. 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. This device is for single use only. Do not reuse and Do not resterilize. Reuse of this product will cause the risk of cross infection and unpredictable health threat.

UTILIZATION AND IMPLANTATION

Selection of the U2 Total Knee System – PSA Type 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.

PACKAGING, LABELING AND STERILIZATION

All U2 Total Knee System – PSA type 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. Metal components are radiation sterilized. Plastic components are radiation sterilized or ethylene oxide sterilized. The packaging of all sterile products should be inspected for their integrity and should be accepted only with proper packaging and labeling intact. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded. If the package is opened, but the product is not used, the component must not be resterilized and must be discarded or returned to the supplier.

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℃ to 35℃ at 30%-85% relative humidity.

SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIONMENT

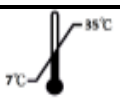
This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INFORMATION

For further information, please contact

United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-577-3351
FAX: +886-3-577-7156
Contact Information: unitedorthopedic.com/contact

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