ENG50819 Rev6

“UNITED” U2 Total Knee System
CMA Type Safety Statements

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

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

This Product May Only Be Used By An Accredited Orthopaedic Surgeon Or Physician

DESCRIPTION

“UNITED” U2 Total Knee System – Tibial Baseplate, CMA type is an extension and a modular design of “UNITED” U2 Total Knee system, which is indicated for use in primary or revision knee arthroplasty. The tibial component composed of a polyethylene inserts machined from compressed molded UHMWPE and a Ti-6Al-4V metallic tibial baseplates. The crosslinking condition is indicated on the package label. The CMA type is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock.

The tibial baseplate component has recess for cement fixation. Tibial inserts are available in various thicknesses and in three four 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 including femoral component of U2 total knee system, femoral augment set, tibial augment, stem extension and offset stem adapter that provides a variety options for surgeon to treat their patients. The device is designed to have a maximum active flexion over 155 degree.

INDICATIONS

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 joint surface erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device may also be indicated in the salvage or previously failed surgical attempts or for knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. This device system is designed for cemented use only.

CONTRAINDICATIONS

The U2 Tibial Baseplate, CMA type 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 can 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 Tibial Baseplate, CMA 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. Components of the U2 Tibial Baseplate, CMA 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 Tibial Baseplate, CMA 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 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

The plastic components, if opened, are not permitted be re-sterilization by any method. The metal components, if opened, please return to United Orthopedic Corporation. A suitable handing in cleaning (if necessary), packaging and gamma radiation 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) ENVIRONMENT

The U2 Tibial Baseplate, CMA 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

For further information, contact

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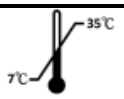
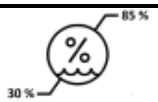
SYMBOLS GLOSSARY

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