ENG50871 Rev5

USTAR II Knee System

Safety Statement

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

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

※Carefully read all instructions and be familiar with the surgical techniques prior to use.

※CAUTION: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

DESCRIPTION

The USTAR II Knee System is designed for patients who need a special prosthesis for their particular indication, which may present large quantity of bone loss and deformity associated with previous failed arthroplasty, bone tumors resection, or trauma, and may require a further operation or reconstruction. USTAR II Knee System is based on modular combinations. It offers a variety of component options for treatment of patients that require femoral component, tibial baseplate and insert. The tibial augment, segment part and stem are provided for patient with more bone resection. USTAR II Knee System is able to be used with “UNITED” patella components for total knee replacement.

MATERIALS

Co-Cr-Mo Alloy / Highly cross-linked UHMWPE	ASTM F75 (raw materials ASTM F1537/ISO 5832-12)	Femoral Component, Hinged

	ASTM F648/ISO 5834-1 and ISO 5834-2	
Co-Cr-Mo Alloy / Ti-6Al-4V Alloy / Highly cross-linked UHMWPE	ASTM F75 (raw materials ASTM F1537/ISO 5832-12) ASTM F136/ISO 5832-3 ASTM F648/ISO 5834-1 and ISO 5834-2	Distal Femoral Component, RHS
Co-Cr-Mo Alloy / Ti-6Al-4V Alloy / Highly cross-linked UHMWPE	ASTM F75 (raw materials ASTM F1537/ISO 5832-12) ASTM F136/ISO 5832-3 ASTM F648/ISO 5834-1 and ISO 5834-2	Tibial Baseplate, hinged
Co-Cr-Mo Alloy / Ti-6Al-4V Alloy / Highly cross-linked UHMWPE / Metallic powder for Ti plasma spray	ASTM F75 (raw materials ASTM F1537/ISO 5832-12) ASTM F136/ISO 5832-3 ASTM F648/ISO 5834-1 and ISO 5834-2 ASTM F1580	Proximal Tibial Component, RHS
Co-Cr-Mo Alloy / Ti-6Al-4V Alloy / UHMWPE	ASTM F1537/ISO 5832-12 ASTM F136/ISO 5832-3 ASTM F648/ISO 5834-1 and ISO 5834-2	Tibial Insert
Co-Cr-Mo Alloy / Ti-6Al-4V Alloy / Highly cross-linked UHMWPE	ASTM F1537/ISO 5832-12 ASTM F136 /ISO 5832-3 ASTM F648/ISO 5834-1 and ISO 5834-2	XPE Tibial Insert
Co-Cr-Mo Alloy	ASTM F1537/ISO 5832-12	Cemented Tibial Stem
Ti-6Al-4V Alloy	ASTM F136 /ISO 5832-3	Tibial stem
Co-Cr-Mo Alloy	ASTM F1537/ISO 5832-12	Cemented Curved Stem, RHS, non coated Cemented Straight Stem, RHS, non coated
Co-Cr-Mo Alloy /	ASTM F1537/ISO 5832-12 ASTM F1580	Cemented Curved Stem, RHS

Metallic powder for Ti plasma spray		Cemented Straight Stem, RHS
Ti-6Al-4V Alloy	ASTM F136/ISO 5832-3	Tibial Augment
Ti-6Al-4V Alloy	ASTM F136/ISO 5832-3	Segment Part, RHS Segment Part, RHS, Bridge

INDICATIONS

1. Metastatic tumor (i.e. osteosarcoma, chondrosarcoma, giant cell tumor or osteoma) where massive resection and transplantation are needed.
2. Severe knee joint damage resulting from trauma where massive resection and transplantation are needed.
3. Non-inflammatory degenerative joint disease such as avascular necrosis, osteoarthritis, or traumatic arthritis.
4. Revision of previously failed total joint arthroplasty, osteotomy, or arthrodesis.
5. Joint instability resulting from excessive bone resection.

For Femoral component, Hinged/ Tibial baseplate, Hinged/ Cemented tibial stem/ Cemented Straight stem, RHS, non coated/ Cemented Curved stem, RHS, non coated/ Cemented Straight stem, RHS/ Cemented Curved stem, RHS/ Tibial Augment: These devices are single use implant and intended for cemented use only.

For Distal Femoral Component, RHS/ Proximal Tibial Component, RHS/ Tibial stem/ Segment Part, RHS/ Segment Part, RHS, Bridge: These devices are single use implant and intended for cementless use only.

CONTRAINDICATIONS

1. Infection: infection could be an absolute contraindications or relative contraindications. However, indications that could compromise the surgery result such as infection history, date of infection, local inflammation, fever, erythrocyte sedimentation rate increasing, rapid bone destruction or osteolysis will need to be overcome.
2. Sepsis or osteomyelitis.
3. Factors that could induce joint overuse: 1) Charcot's Joint, 2) muscle defects 3) various joint diseases 4) refusing to limit activity levels proceeding the operation 5) overweight.
4. Factors that could induce overloading on prosthesis: 1) overweight. 2) labor intensive occupation 3) highly active lifestyle 4) falling 5) psychosis or mental illness (e.g. mental insufficiency, senescence, drug treatment or alcoholism).
5. Vascular insufficiency resulting from previous surgery or alcoholism.
6. Other factors include: 1) disruption of bone growth due to metabolic disorders, 2) osteomalacia, 3) other sources of infection may spread to the implants 4) apparent bone loss or bone resorption observed under roentgenogram 5) vascular insufficiency, muscular atrophy, or neuromuscular disease.
7. Patients who is sensitive to any material of the device.

POSSIBLE ADVERSE EFFECT

1. Malunion, fissured, acetabular fractures, or avulsion fracture of femur, trochanter or intertrochanter.
2. Dislocation, subluxation, rotation, decreased post-operation range of motion or shorted or elongated femur length due to malimplantation, loosening of implants, bone or ligaments, inappropriate patient activity, trauma or other biomechanical considerations.
3. Fatigue fracture of implants due to heavy, physically active individual or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
4. Femoral fracture due to excessive correction or severe osteoporosis.
5. Heterotopic ossification.
6. Infections including post-operation infection, deep wound infection and sepsis.
7. Cardiovascular Diseases: wound hematoma or thromboembolism (including vein thrombosis and pulmonary embolism).
8. Temporary or Permanent Neurological Diseases: cases of neurological diseases of femoral, sciatic, peroneal nerve and the lateral compact bone of femur have been reported.
9. Pulmonary Disorders such as pneumonia or atelectasis.
10. Tissue reaction: foreign body reaction, especially for male patients with mast arthritis. People with low pre-operation range of motion, history of myositis, having previously received operation or infections will increase the chance of myositis ossificans.
11. Scaring or delayed healing of wounds for patients suffering from rheumatoid arthritis or patients who received steroid therapy within one year post operation.
12. Trauma or leg length discrepancy caused by operation; malposition of implantation; deterioration or pain of other joints or back caused by muscle defects.
13. Osteolysis caused by particles from excessive wear of the articular surface.
14. Allergic reactions in soft tissue due to corrosion, implant wear or bone cement debris.
15. Urologic complications, especially dysuria and infections.
16. Aseptic loosening.
17. Excessive metal wear debris from the loss of protective metal coating.

WARNINGS

1. Discard all damaged or mishandled implants.
2. 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.
3. Bearing areas must always be clean and free of debris prior to assembly. At time of assembly, machined snap-in surfaces or machined taper surfaces must be clean and dry to ensure proper seating.
4. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
5. Care should be taken when handling any sharp-edged orthopedic devices to avoid piercing surgical gloves.

6. 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.
7. Check the label information, especially the size designation, is consistent with the device.
8. Return all implants with damaged packaging to the supplier. **Do not resterilize**.
9. The shelf-life of UHMWPE made components is five years.
10. Based on the current scientific literature, it has been shown that oxidation in gamma sterilized UHMWPE should be expected and has a detrimental effect on the mechanical properties of UHMWPE, which can lead to premature failure arising from: accelerated wear, fatigue fracture, disassociation of the acetabular components, and periprosthetic loosening.

PRECAUTIONS

1. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have such functional expectations. Patients should be instructed for the limitations of the prosthesis, including, but not limited to, the consequences of excessive loading through patient weight or activity. They should be taught to manage their activity levels accordingly. If the patient is involved in an occupation or activity, which involves substantial walking, running, lifting, or muscle strain, the resulting forces can cause failure of the device or its fixation.
2. Appropriate selection, placement and fixation of the curved or straight stems, etc. are critical factors that affect implant longevity. Being similar to all other prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit its longevity. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximizing its longevity.
3. Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Note: As for segment connection, combination with other segments is prohibited except for bridge type segment.

UTILIZATION AND IMPLANTATION

1. The original trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
2. Radiographic templates are available to assist in the preoperative prediction of component size and style.
3. The United Surgical Protocols provides additional procedural information.

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. All components have been sterilized by gamma radiation.
2. 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.
3. Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
4. 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.

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

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.

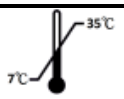
INFORMATION

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

For further information, please contact

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