# SHALBY ADVANCED TECHNOLOGIES

## TAHOE UNI KNEE SYSTEM

## Instructions for Use (IFU)

**IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.**

**DESCRIPTION**

The TAHOE UNI KNEE SYSTEM (TUKS) is an unconstrained, round-on-flat, fixed-bearing unicompartmental knee system designed to replace the medial or lateral compartments of the knee. The TUKS includes a metal femoral component, plastic tibial insert, and metal tibial baseplate.

The TUKS femoral component is manufactured from cast CoCrMo (ASTM F75). The femoral component is symmetric and comes in eight sizes (1-8). Its primary articular surface is spherical and highly polished to maximize wear performance. The femoral component employs a curved distal backside surface with posterior facet to conserve bone. The backside features duel pegs and is grit blasted to enhance cement fixation.

The TUKS metal-backed tibial component includes two parts to be assembled at the time of surgery: a tibial baseplate and tibial insert. The baseplate (i.e. tray) is manufactured from wrought CoCrMo (ASTM F1537, warm worked) or cast CoCrMo (ASTM F75). The baseplate is asymmetric and comes in nine sizes (0-8). Its superior geometry includes a fully enclosed peripheral rim to allow encapsulation of the tibial insert, which forms the tibiofemoral bearing surface. Its backside surface features a keel and angled peg, and is grit blasted to enhance cement fixation. The tibial insert is manufactured from UHMWPE (ASTM F648) or VitalitE (ASTM F648, ASTM F2695), and is offered in nine sizes (0-8) and seven poly thicknesses (6-12mm). When combined with the baseplate, the tibial thickness ranges from 8mm to 14mm. The insert's articular surface is flat to allow unconstrained motion of the femur and up to 15 deg varus/valgus femoral tilt. The insert is designed to lock into the baseplate at its anterior and posterior ends.

**HOW PRODUCT IS SUPPLIED**

Each component is supplied in individually sterilized boxes or packages, in a wide range of sizes. Please refer to the current price list, surgical technique, or catalog for the catalog numbers and sizes available.

The recommended instruments and trial components are used for size determination, preparation, trial reduction, and range of motion evaluation. The use of trials preserves the integrity of implants and sterile packaging. Trials are not intended for implantation.

**INFORMATION FOR USE**

Indications for the use of the TUKS must be carefully considered with respect to the patient's entire evaluation and alternative procedures. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated further surgery. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Unicompartmental knee joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding activity and joint loading are assured. This includes all patients who may or may not have multiple joint involvements, for which restoration of joint mobility leads to an expectation or greater mobility and an improvement in the quality of life.

In using the TUKS, the surgeon should be aware that the prostheses should not be re-implanted; therefore, initial size selection is extremely important.

**ASSEMBLY OF COMPONENTS**

The TUKS tibial component consists of two parts to be assembled at the time of surgery, a metal tibial baseplate and polyethylene tibial insert of the same size. Due to the round-on-flat tibiofemoral articulation, the baseplate/insert construct is designed to allow all femoral sizes to be used interchangeably for maximum intraoperative flexibility (Table 1). At the time of surgery, the tibial insert will be snapped onto the baseplate by first sliding the posterior aspect of the insert under the posterior lip of the baseplate, and then engaging the anterior snap mechanism either by hand or impaction. The snap mechanism must be fully engaged.

THE SNAP MECHANISM MUST BE ENGAGED ONLY ONCE. DO NOT ATTEMPT TO INSTALL THE TIBIAL INSERT A SECOND TIME.

| | | Femoral Component | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Baseplate/Insert Construct | 0 | x | x | x | x | x | x | x | x |
| | 1 | x | x | x | x | x | x | x | x |
| | 2 | x | x | x | x | x | x | x | x |
| | 3 | x | x | x | x | x | x | x | x |
| | 4 | x | x | x | x | x | x | x | x |
| | 5 | x | x | x | x | x | x | x | x |
| | 6 | x | x | x | x | x | x | x | x |
| | 7 | x | x | x | x | x | x | x | x |
| | 8 | x | x | x | x | x | x | x | x |

**Table 1:** Size compatibility between TUKS femoral and tibial components. Shalby Advanced Technologies (SAT) recommends following the size compatibility table for optimal surgical outcome.

**INDICATIONS FOR USE**

The TAHOE Unicompartmental Knee System (TUKS) is designed as a system and is not intended for substitution of components from other systems. The indications for use are as follows:

Primary medial or lateral compartmental intervention of (1) primary non-inflammatory degenerative disease, including osteoarthritis, traumatic arthritis, or osteonecrosis; (2) post-traumatic degenerative disease; (3) varus or valgus deformities; and (4) damage due to previous surgical intervention when the opposite compartment is preserved and when the anterior cruciate, posterior cruciate, medial collateral, and lateral collateral ligaments are present and functional.

All TUKS implants are single use only, and are intended for implantation only with bone cement.

**INTENDED PERFORMANCE**

All TUKS components are intended to perform in a safe and effective manner in restoring knee function within the intended use of the product.

A. The intended range of flexion/extension of the TUKS femoral component relative to the tibial component is from 10° hyperextension to at least 120° flexion.
B. The TUKS components are designed to transmit load to the tibia during daily activities including, but not limited to walking, stair climbing, and chair ascent.
C. The profile of the TUKS femoral component is intended to fully cover the resected medial or lateral femoral condyles with anterior-posterior and medial-lateral articular widths ranging from 34.6mm to 50.4mm and from 16.3mm to 26mm respectively.
D. The profile of the TUKS tibial baseplate is intended to fully cover the resected medial or lateral tibial plateau with anterior-posterior and medial-lateral widths ranging from 38.0mm to 56.1mm and 22.6 to 33.4mm respectively.
E. The CoCr femoral component and tibial baseplate are designed to minimize stress shielding at the bone-implant interface.
F. The round-on-flat articulation are designed to minimize wear and loosening.
G. The mirror finish of the femoral articular surface are designed to minimize wear.
H. The grit blasted backside surfaces including cement pockets are designed to enhance cement adhesion.

**CONTRAINDICATIONS**

A. Any active or suspected latent infection in or about the knee joint.
B. Mental or neuromuscular disorders which would create unacceptable risk of prosthesis instability or complications in post-operative care.
C. Bone stock compromised by disease, infection, or prior implantation that cannot provide adequate support and fixation of the device.
D. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper mechanics to be re-established.
E. Conditions which tend to place increased loads on implants, such as age, weight, and activity level which are incompatible with a satisfactory clinical long-term result.
F. Severe deterioration of the opposite compartment or the patellofemoral joint.

**PRECAUTIONS**

A. Before any implant is used the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
B. Instruct patients on the limitations of the prosthesis and how to modify their activities accordingly.
C. Proper selection of type and placement of the knee components are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the implant service life.
D. The surgeon and O.R. staff must be extremely careful to protect the components from being marred, nicked or notched as a result of contact with metal or any abrasive objects.
E. Use only instruments and trial components specifically designed for use with these devices to help ensure accurate surgical implantation, soft tissue balancing, and evaluation of knee function.
F. Selection of polyethylene components is a matter of physician discretion. Thicker polyethylene components may be needed if the patient is young, heavy, and/or physically active.
G. Ensure tibial baseplate surface is cleaned prior to snapping on tibial insert.
H. Ensure tibial insert is properly snapped, in place, and fully seated against the tibial baseplate.
I. Ensure adequate balancing of soft tissues to prevent postoperative instability and dislocation of the tibial insert from the baseplate.
J. All TUKS implants are intended FOR CEMENTED USE ONLY.

**WARNINGS**

A. All TUKS components are supplied sterile. The physician's insert and double Tyvek packages are subject to ethylene oxide sterilization. Do not use any component if the package has been breached. If packages appear damaged or tampered with, they should be returned to the supplier.
B. This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability.
C. Take care to protect polished bearing and machined surfaces from coming in contact with hard or abrasive surfaces.
D. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
E. Never tamper with implants. Tampering may have a detrimental effect on the performance of the implant.
F. Shalby Advanced Technologies strongly advises against the use of another manufacturer's component with any TUKS component.
G. Removal of implant may require the use of special instruments to disrupt the bone interface. These techniques may require practice in the laboratory before being attempted clinically.
H. Trials are instruments and must not be implanted.

**ADVERSE EFFECTS**

A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture breakage, bending of the components, component disassembly, or positional changes of the components.
B. Sensitivity reactions to component materials could occur, and should be ruled out preoperatively.

C. Knee joint arthroplasty is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, and third party wear associated with UHMWPE.
D. Pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
E. Reoperation may be necessary to correct adverse effects.
F. On rare occasions, complications may require arthrodesis or amputation of the limb.
G. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.
H. Postoperative femoral or tibial fracture can occur due to trauma, the presence of defects, or poor bone stock.

**PATIENT COUNSELING INFORMATION**

Complications and/or failure of unicompartmental knee prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients that fail to follow through with the required rehabilitation program. Excessive physical activity and injury can result in loosening, wear, and/or fracture of the knee implant. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. The implant may not, and is not guaranteed to, last the rest of the patient's life. Because prosthetic joints are not as strong, reliable, or durable as natural healthy joints; all prosthetic knees may need to be replaced at some point.

**IMPORTANT INFORMATION FOR THE HOSPITAL/CLINIC STAFF**

**WARNING:** THE TAHOE UNI KNEE SYSTEM FEMORAL AND TIBIAL COMPONENTS HAVE NOT BEEN APPROVED FOR NON-CEMENTED APPLICATION.

**CAUTION:** DISPOSAL OF SINGLE USE IMPLANT DEVICE: THE DEVICE SHOULD BE REGARDED AS BIO-CONTAMINATED AND HANDLED ACCORDINGLY. PLASTIC OR METAL IMPLANTS SHOULD BE TERMINALLY STERILIZED AND DISPOSED OF FOLLOWING EXISTING HOSPITAL POLICIES AND PROCEDURES.

**CAUTION:** THE TAHOE UNI 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 TAHOE UNI KNEE SYSTEM IN THE MR ENVIRONMENT IS UNKNOWN. SCANNING A PATIENT WHO HAS THIS DEVICE MAY RESULT IN PATIENT INJURY. PATIENTS SHOULD REGISTER THEIR IMPLANT INFORMATION WITH THE MEDICALERT FOUNDATION (WWW.MEDICALERT.ORG), OR EQUIVALENT ORGANIZATION.

**CAUTION:** FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Shalby Advanced Technologies
1115 Windfield Way
El Dorado Hills, CA 95762-9623
800-240-0500
916-355-7100
info@consensusortho.com