SHALBY ADVANCED TECHNOLOGIES, INC.

CONSENSUS® KNEE SYSTEM

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 Shalby Advanced Technologies, Inc. CONSENSUS® KNEE SYSTEM consists of a left and a right configuration of the femoral component and the tibial component. The patellar component is designed to fit both right and left patella. It is an unconstrained design and both medial and lateral collateral ligaments must be intact.

The femoral component is manufactured from cast CoCrMo (ASTM F75). The two styles offered are the primary and the reduced lateral profile (RLP). When porous coated, interior fixation surfaces are partially coated with CoCrMo beads covered with a Ti layer (ASTM B348). Uncoated and coated (CoCrMo beads without a Ti layer) versions are also available. An uncoated, RLP, Titanium Niobium Nitride (TiNbN) overcoat style is available.

The tibial component consists of two parts to be assembled at the time of surgery: a baseplate and a plastic insert. The metal tray or baseplate is made of Ti-6Al-4V and coated with commercially pure titanium beads (C.P.Ti, ASTM F67) or is made of CoCrMo (ASTM F75, F799, or F1537). When porous coated, inferior fixation surfaces are partially coated with CoCrMo beads covered with a Ti layer. An uncoated, CoCrMo, TiNbN overcoat style is also available. The baseplate is recessed to allow encapsulation of plastic inserts which form the bearing surface for femoral-tibial articulations. These inserts are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE, ASTM F648) or VitalitE, an Ultra-High Molecular Weight Polyethylene blended with Vitamin E. VitalitE inserts are available for use as a congruent and PCL substituting insert only. The two tibial insert variations available for the primary (STD) and RLP CKS are the congruent and PCL substituting. The congruent insert is an anatomic, asymmetric, cruciate retaining design while the PCL substituting is an anatomic, asymmetric, cruciate sacrificing design.

The all-polyethylene tibia component is manufactured from UHMWPE. It is a symmetric cruciate-retaining tibial component and is designed to articulate with the CONSENSUS® KNEE primary femoral component.

The patellar component is a round and oval configuration designed to provide more coverage of the resected patella bone. The articular surface of the patella is an offset spherical dome. The patella is provided in two variations – all-poly and metal backed. The all-poly version is a one-piece design and is manufactured from UHMWPE or VitalitE, an Ultra-High Molecular Weight Polyethylene blended with Vitamin E. VitalitE patellas are only available in the all-poly variation. The metal backed version is a two-piece design. The UHMWPE dome is attached preassembled to a CoCrMo or titanium backing and partially coated with CoCrMo beads covered with a Ti layer.

The CONSENSUS® KNEE SYSTEM primary posterior stabilized (P.S.) and reduced lateral profile posterior stabilized (P.S. RLP) femoral components are manufactured from cast CoCrMo. When porous coated, interior fixation surfaces are partially coated with CoCrMo beads covered with a Ti layer. Uncoated and coated (CoCrMo beads without a Ti layer) versions are also available. An uncoated, P.S. RLP, TiNbN overcoat style is available. It is an anatomic, asymmetric, cruciate-sacrificing femoral component similar to the CONSENSUS® KNEE primary femoral component and is designed to articulate with the

CONSENSUS® KNEE P.S. tibial insert thus providing resistance to posterior subluxation of the proximal tibia in the absence of the posterior cruciate ligament. It is also designed to articulate with the CONSENSUS® patella components. The CONSENSUS® KNEE posterior stabilized (P.S.) tibial insert is manufactured from UHMWPE. It is an anatomic, asymmetric, cruciate-sacrificing tibial insert and is designed to articulate with the CONSENSUS® primary P.S. femoral component.

HOW PRODUCT IS SUPPLIED

Each component of the CONSENSUS® KNEE SYSTEM 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 trial components are used for size determination, preparation, evaluation, trial reduction, and range of motion evaluation. The use of trials preserves the integrity of implants and sterile packaging.

INFORMATION FOR USE

Indications for the use of the CONSENSUS® KNEE SYSTEM 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. Total 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 involvement, for whom restoration of joint mobility leads to an expectation or greater mobility and an improvement in the quality of life.

In using the CONSENSUS® KNEE SYSTEM, the surgeon should be aware of the following:
The porous-coated metal should not be allowed to contact cloth or other lint-shedding materials prior to implantation. Prostheses should not be re-implanted; therefore, initial size selection is extremely important. Conventional cleaning techniques cannot be relied upon to remove lint, dirt, or body tissue from the porous coating.

ASSEMBLY OF COMPONENTS

The CONSENSUS® KNEE All-Polyethylene tibia requires no assembly.

The CONSENSUS® KNEE SYSTEM tibial component consists of two parts to be assembled at the time of surgery, the baseplate and the tibial insert, and optional recessed holes to accept bone screws to augment initial fixation. The baseplate is recessed to allow encapsulation of the plastic insert. The tibial insert forms the congruent articular surface, with radii to match the femoral component. The tibial insert is designed to allow up to one femur size larger or smaller to be used interchangeably for maximum intraoperative flexibility. At the time of surgery, the appropriate tibial insert will be snapped onto the baseplate. THE SNAP MECHANISM MAY BE ENGAGED ONLY ONCE. DO NOT ATTEMPT TO REINSERT A TIBIAL INSERT A SECOND TIME.

Size Compatibility

Tibia Size	Femur Size					
	1	2	3	4	5	6
0	Yes	Yes	Yes	Yes	-	-
1/2	Yes	Yes	Yes	Yes	-	-
3/4	Yes	Yes	Yes	Yes	Yes	Yes
5/6	-	-	Yes	Yes	Yes	Yes

Round Patella/Femur Compatibility Chart

		Femur Sizes					
		1	2	3	4	5	6
Patella Components Sizes	**Size 0** (7.5mm)	Yes	-	-	-	-	-
	Size 1 (7.5mm & 10mm)	Yes	Yes	Yes	-	-	-
	Size 2 (7.5mm & 10mm)	Yes	Yes	Yes	Yes	Yes	-
	Size 3 (10mm)	Yes	Yes	Yes	Yes	Yes	Yes

**All oval patellas may be used with all femoral components*

Inter-Component Compatibility

		Femoral Components			
		RLP	STD	PS	PS RLP
Tibial Inserts (Inserts can be assembled with all baseplates)	All-Poly	Yes	Yes	-	-
	Congruent	Yes	Yes	-	-
	PCL Substituting	Yes	Yes	-	-
	PS	-	-	Yes	Yes
Patella Components	All-Poly	Yes	Yes	Yes	Yes
	Metal backed	Yes	Yes	Yes	Yes

INDICATIONS AND USAGE

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

The indications for use are:

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.

B. Failed osteotomy or unicompartmental replacements.

C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

D. The non-porous (uncoated, coated with CoCr beads without Titanium, and uncoated with a TiNbN overcoat) components may only be used with cement.

E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.

INTENDED PERFORMANCE

All components of the CONSENSUS® KNEE SYSTEM 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 femur relative to the tibia is from 10° hyperextension to at least 120° flexion.

B. The CONSENSUS® KNEE SYSTEM is 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 CONSENSUS® KNEE femoral component is intended to fully cover the resected femoral condyles with anterior-posterior and medial-lateral widths ranging from 37 to 58 mm and 59 to 80 mm respectively.

D. The profile of the CONSENSUS® KNEE tibial baseplate is intended to fully cover the resected tibial plateau with anterior-posterior and medial-lateral widths ranging from 40 to 56 mm and 62 to 86 mm respectively.

E. The CONSENSUS® KNEE femoral component and tibial baseplate are designed to reduce stress shielding at the bone-implant interface.

F. The matching articulating surfaces at the tibiofemoral articulation are intended to reduce wear over time.

G. The mirror finish of the articulating surface of the CONSENSUS® KNEE femoral component is intended to reduce wear of the tibial insert.

H. The interior fixation surfaces of the nonporous, uncoated femoral component and nonporous, uncoated tibial baseplate are grit blasted at the implant-cement-bone interface.

I. The interior fixation surfaces of the porous femoral component and porous tibial baseplate are partially coated with CoCrMo beads covered with a Ti layer.

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.

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. For non-cemented use of porous coated products, the surgeon may need to consider appropriate changes to post-operative patient management.

F. When considering non-cemented use of semi-constrained knee components, the surgeon should carefully evaluate the patient for adequate bone quality and other risk factors affecting fixation.

WARNINGS

A. All CONSENSUS® KNEE SYSTEM components are sold sterile. The insert and the 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. Do not implant any device that has been used, even if it appears undamaged.

C. Take care to protect polished bearing areas 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 affect on the performance of the implant. Handling of porous coated regions must be avoided as it potentially could result in the compromise of the device effectiveness.

F. Shalby Advanced Technologies, Inc. strongly advises against the use of another manufacturer's component with any CONSENSUS® KNEE 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. Shalby Advanced Technologies, Inc. strongly advises not to use any CONSENSUS® KNEE components off-label.

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. Total joint replacement surgery 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, Girdlestone procedure 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 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.

WARNING: Single Use Only: 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.

CAUTION: DISPOSAL OF SINGLE-USE IMPLANT DEVICE - THIS 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 CONSENSUS® KNEE SYSTEM HAS NOT BEEN EVALUATED FOR SAFETY IN THE MR ENVIRONMENT. IT HAS NOT BEEN TESTED FOR HEATING OR UNWANTED MOVEMENT IN THE MR

ENVIRONMENT. THE SAFETY OF THE CONSENSUS® KNEE SYSTEM IN THE MR ENVIRONMENT IS UNKNOWN. PERFORMING AN MR EXAM ON A PERSON WHO HAS THE MEDICAL DEVICE MAY RESULT IN INJURY OR DEVICE MALFUNCTION.

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.

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