

SHALBY ADVANCED TECHNOLOGIES, INC.

UNISYN™ HIP 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 SHALBY ADVANCED TECHNOLOGIES, INC. UNISYN™ HIP SYSTEM - PRIMARY/REVISION Hip is comprised of four modular components – a neck segment, a body segment, a stem, and a locking nut. The modular neck segment is manufactured from titanium alloy (Ti-6Al-4V, ASTM F620). It attaches to the body segment by means of a locking taper and flexible collet junction. Multiple neck options are provided to allow horizontal and vertical offset adjustment. The neck segment utilizes a Morse taper as a means for attaching a modular femoral head. The body segment is manufactured from forged titanium alloy (Ti 6Al 4V, ASTM F136 or ASTM F1472). Plasma sprayed necks and bodies are coated with commercially pure titanium (C. P. Ti, ASTM F1580). Body segments are also available with hydroxylapatite (HA) coating (empirical formula $\text{Ca}_5(\text{PO}_4)_3\text{OH}$, ASTM F1185). The stem components are manufactured from (Ti 6Al-4V, ASTM F1472). The stem is attached to the neck segment by means of a locking taper. The stem is then secured to the neck via a locking nut (Ti 6Al-4V, ASTM F136). The locking nut has a Spirallock® thread to resist loosening. The nut is applied to the stem after the stem has been preloaded and assembled. The UniSyn Hip System was designed for uncemented use, however, if it is necessary to cement a Unisyn hip we recommend the addition of cement to appropriately stabilize the chosen implant. The design details of all taper connections are proprietary to SHALBY ADVANCED TECHNOLOGIES, INC.

The UNISYN™ HIP SYSTEM may only be used in conjunction with CONSENSUS® ceramic and metal femoral heads, the CONSENSUS® ACETABULAR CUP, the CS2™ ACETABULAR CUP, CONSENSUS® low profile cancellous bone screws, CONSENSUS® BIPOLAR heads, CONSENSUS® UNIPOLAR heads, and the CONSENSUS® ALL-POLY ACETABULAR CUP. The UNISYN™ HIP SYSTEM is designed to allow full interchangeability between all UNISYN™ components of any size configuration for maximum intraoperative flexibility. CONSENSUS ORTHOPEDICS advises to use the 30 and 45mm locking nut with the 30 to 36mm and 45 to 55mm vertical offset neck sizes respectively. All UNISYN™ component configurations may be used with all CONSENSUS® femoral head and acetabular component configurations.

For a complete description of the CONSENSUS® HIP SYSTEM components for use with the UNISYN™ HIP SYSTEM, refer to the IFU included with the appropriate product package.

UNISYN™ stems used with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN™ stems used with plasma/HA or HA coated bodies are intended for uncemented use only.

HOW PRODUCT IS SUPPLIED

Each component of the UNISYN™ HIP SYSTEM is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to the current price list, surgical technique or catalog for the catalog numbers and sizes available.

INDICATIONS AND USAGE

Indications for the use of the UNISYN™ HIP SYSTEM must be carefully considered with respect to the patient's entire evaluation and alternative procedures. The selection of the UNISYN™ HIP SYSTEM is based on the judgment of the

Surgeon as to the needs of the patient and the expected post-operative conditions. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery.

Indications for use of the UNISYN™ HIP SYSTEM

Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.

Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.

- A. Proximal femoral fractures.
- B. Avascular necrosis of the femoral head.
- C. Non-union of proximal femoral neck fractures.
- D. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

INTENDED PERFORMANCE

All components of the UNISYN™ HIP SYSTEM are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

- A. The UniSyn® HIP SYSTEM range of motion complies with ISO 21535, except that the Consensus® Hip System 28mm/+10 CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees.
- B. The UNISYN™ HIP SYSTEM is designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
- C. The taper and collet connections between modular components of the UNISYN™ HIP SYSTEM are designed to reduce micromotion and fretting, and maximize total contact area for torsional strength and fatigue resistance.
- D. The UNISYN™ HIP SYSTEM is designed to minimize stress shielding at the implant-bone interface when compared with CoCr.
- E. The fixation surfaces of nonporous (roughened) UNISYN™ body segments are grit blasted at the implant-bone interface.
- F. The fixation surfaces of plasma coated UNISYN™ body segments provide biological fixation at the implant-bone interface.
- G. The fixation surfaces of plasma/HA UNISYN™ body segments are HA coated to provide biological fixation at the implant-bone interface.

CONTRAINDICATIONS

- A. Any joint with active or suspected latent infection.
- B. Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
- C. Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
- D. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
- E. Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.

- F. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.

WARNINGS

- A. All UNISYN™ HIP SYSTEM components are sold sterile. 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. Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.
- D. Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- E. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- F. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant. Handling of the HA treated regions must be avoided as it potentially could result in the compromise of the treatment effectiveness.
- G. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- H. UNISYN™ products may ONLY be used in conjunction with Consensus Orthopedics CONSENSUS® ceramic and metal femoral heads.
- I. Do not use bone cement with HA coated implants.
- J. UNISYN™ products should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert.

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. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
- C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
- E. 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 the activity and joint loading are assured.
- F. Instruct patients on the limitations of the prosthesis and how to modify their activities accordingly.

- G. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the life expectancy of the implant.

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, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.
- D. Acetabular 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.

INFORMATION

Surgical techniques may be obtained from a CONSENSUS ORTHOPEDICS representative or the company directly.

STERILIZATION AND HANDLING

All components have been sterilized through an ethylene oxide sterilization process. Do not use any component if the package has been breached.

USE CAUTION IN HANDLING PLASMA SPRAYED or HA COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

COMPONENTS THAT ARE MANUFACTURED FROM ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE), POLYMETHYL-METHACRYLATE (PMMA) OR CERAMIC SHOULD NOT BE AUTOCLAVED.

CERAMIC FEMORAL HEAD INSTRUCTIONS FOR USE

PREPARATORY PHASE

- A. Use ceramic heads only on stems with tapers approved for ceramic heads.
- B. A ceramic head impacted once, and then removed, must not be mounted onto another stem.
- C. Never place a ceramic femoral head onto a stem taper that has previously been in use with a head of any type. A metal head must be used as a replacement for any type of head that has been removed from a stem taper.
- D. Never use a ceramic head which has fallen to the floor.
- E. Avoid thermal shocks to ceramic heads. Do not quench the ceramic components in cold liquids.

DURING OPERATION

- A. Keep metal instruments clear of taper. Taper surface of UNISYN™ stem, body, and neck must not be scratched or damaged.
- B. Clean and dry taper of UNISYN™ neck and ceramic head before attaching the ceramic head.
- C. Use only plastic impactor to fasten ceramic heads. Never use a metal impaction instrument.

REPLACEMENT OF FRACTURED CERAMIC HEAD

In the case of a fractured ceramic head, remove all ceramic particles from the wound. If you wish to replace the fractured ceramic head with another ceramic head, the polyethylene insert and UNISYN™ neck component must be changed. If the neck taper is undamaged, a metal head may be used with the existing stem in lieu of a ceramic head.

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 UNISYN™ hip system has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicalAlert Foundation (www.medicalert.org), or equivalent organization.

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

FOR ADDITIONAL INFORMATION CONTACT:

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