SHALBY ADVANCED TECHNOLOGIES

TAPERSET™ HIP SYSTEM
Femoral Stem Components

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 TAPERSET™ HIP SYSTEM is comprised of the TAPERSET™ line of femoral stem components, and compatible components of the CONSENSUS® HIP SYSTEM (CHS). The present IFU applies to all TAPERSET™ femoral stem components. Refer to IFU 40737 for instructions on using compatible CHS acetabular cup and femoral head components, including the CHS sub-family of CS2™ HIP SYSTEM acetabular cup components.

The TAPERSET™ femoral stem employs a clinically proven dual-taper-wedge stem design. The TAPERSET™ femoral stem is manufactured from wrought Titanium alloy (Ti-6Al-4V ELI, ASTM F136) or forged Titanium alloy (Ti 6Al-4V ELI, ASTM F620). Small TAPERSET™ stems (sizes 5mm and 6mm) are manufactured from forged Titanium alloy only. The proximal portion of the femoral stem is coated with a commercially pure Titanium plasma spray (ASTM F1580). The femoral stem is available in both standard and 7mm lateralized neck options. Both standard and lateralized neck options are available in Reduced Distal Profile (RDP) or non-RDP options. The RDP stem is proximally identical to the non-RDP stem; however, the RDP stem has been reduced in the medial/lateral plane distal to the plasma coating to accommodate femurs with proximal/distal size mismatch.

HOW PRODUCT IS SUPPLIED

All TAPERSET™ HIP SYTEM implant components are supplied STERILE, are contained in individual boxes or packages designed to maintain sterility; and are available in a wide range of sizes. Refer to the current price list, surgical technique, or the implant catalog for size availability.

INDICATIONS FOR USE

The TAPERSET™ HIP SYSTEM is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the CONSENSUS® HIP SYSTEM.

The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-union of proximal femoral neck fractures.

F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TAPERSET™ hip stem is indicated for cementless use.

INTENDED PERFORMANCE

All components of the TAPERSET™ 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 TAPERSET™ range of motion complies with ISO 21535, except that the 28/+10mm CoCr femoral head used with the 20 deg hooded acetabular insert limits flexion/extension to 98 deg.
B. The TAPERSET™ femoral stem components, when used with compatible CHS acetabular cup and femoral head components, are designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
C. The Titanium alloy TAPERSET™ stems are designed to minimize stress shielding at the bone-implant interface when compared with CoCr alloy stems.
D. The proximal fixation surfaces of the TAPERSET™ stem are Ti plasma 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 TAPERSET™ HIP SYSTEM implant 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 effect on the performance of the implant.
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. TAPERSET™ femoral stems may ONLY be used in conjunction with CHS metal femoral heads, Biolox *delta* Ceramic femoral heads, or Zirconia Ceramic femoral heads.
I. TAPERSET™ femoral stems should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert combination.
J. Do not use another manufacturer's component with any TAPERSET™ HIP SYSTEM components, other than those specified as compatible.

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. 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 SHALBY ADVANCED TECHNOLOGIES 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 COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

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 TAPERSET™ hip system has not been evaluated for safety and compatibility in the MR environment. The TAPERSET™ hip system has not been tested for heating or migration in the MR environment.

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

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