CONSENSUS ORTHOPEDICS INC.

CONSENSUS HIP SYSTEMS

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 CONSENSUS ORTHOPEDICS, INC. TAPERSET™ HIP SYSTEM – PRIMARY HIP, the CS2™ HIP SYSTEM – PRIMARY HIP, and the CONSENSUS® HIP SYSTEM – PRIMARY HIP (Consensus Hip Systems) are comprised of a femoral stem component, femoral head component, acetabular component and cancellous bone screws, and for cemented applications include distal centralizers and proximal spacers.

The femoral stem component of the CONSENSUS® HIP SYSTEM is manufactured from forged cobalt chrome alloy (CoCrMo, ASTM F799) for cemented applications, or forged titanium alloy (Ti 6Al-4V ELI, ASTM F620) for uncemented applications. They hydroxyapatite components are surface treated with hydroxyapatite (ASTM F1185).

The femoral stem component of the CS2 ™ HIP SYSTEM is manufactured from forged titanium alloy (Ti 6Al-4V ELI, ASTM F620) for uncemented applications. The proximal portion of the femoral stem component is plasma sprayed with commercially pure Titanium (C.P. Ti, ASTM F1580). The CS2™ HIP SYSTEM is available in both collared and collarless options.

The femoral stem component of the TAPERSET™ HIP SYSTEM is manufactured from wrought titanium alloy (Ti-6Al-4V ELI, ASTM F136) or forged titanium alloy (Ti 6Al-4V ELI, ASTM F620). The proximal portion of the femoral stem component is plasma sprayed with commercially pure Titanium (C. P. Ti, ASTM F1580). The femoral stem is available in both standard and 7mm lateralized options. Both standard and lateralized TAPERSET™ femoral stems are available in a Reduced Distal Profile (RDP). The TAPERSET™ RDP is proximally identical to the TAPERSET™, but distal to the plasma coating it has been reduced in the medial/lateral plane to accommodate femurs with proximal/distal size mismatch.

The CONSENSUS® femoral head components are manufactured from either Cobalt Chrome alloy (CoCrMo, ASTM F799 or ASTM F1537), Biolox® *delta* Ceramic (Al_2O_3, ZrO_2, ISO 6474)(not CE marked, see CeramTec Biolox *delta* IFU), or Zirconia Ceramic (ZrO_2+Y_2O_3, ISO 13356). All femoral heads are highly polished and available in multiple neck lengths and head diameters. Cobalt Chrome femoral heads are designed for use with all CONSENSUS®, TAPERSET™, and CS2 femoral stems, and Biolox *delta* Ceramic femoral heads are designed for use only with titanium alloy CONSENSUS®, TAPERSET™, and CS2 femoral stems.

The CONSENSUS® acetabular component consists of a shell and a mating insert. The acetabular component is designed for cemented or uncemented use. The acetabular shell is manufactured from Titanium

alloy (Ti-6Al-4V ELI, ASTM F620 or ASTM F136), with a porous coating of commercially pure Titanium beads (C.P. Ti ASTM F-67). The acetabular shells are available in five different configurations. These are (1) Hemispherical with three screw holes, (2) Hemispherical without screw holes, (3) Hemispherical with multiple screw holes, (4) Flared rim with three screw holes, (5) Flared rim without screw holes, and (6) Flared Rim with multiple screw holes. The component has matching circumferential scallops on the shell and insert that rotationally secure the insert in the shell and allow for dialing the insert in a desired orientation. The shells with screw holes have three anatomically placed holes, which accommodate optional cancellous bone screws to augment initial fixation. An optional CONSENSUS® apical dome hole plug and cement pod spacer are available. The acetabular insert is manufactured from either ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648),highly cross linked Polyethylene (UHMWPE, ASTM F648), or highly cross linked Polyethylene that has been doped with Vitamin E (UHMWPE, ASTM F648, ASTM F2695), and features a Titanium alloy X-ray marker (Ti-6Al-4V ELI, ASTM F136) in hooded inserts.

The cancellous bone screws and apical dome hole plug are manufactured from wrought Titanium alloy (Ti 6Al-4V ELI, ASTM F136 or F1472). The cancellous bone screws are 6.5mm diameter and have a low profile head with a hex drive recess. The apical dome hole plug threads into the apical dome hole with a hex drive recess.

The CONSENSUS BIPOLAR and UNIPOLAR are intended for cementless use and are designed for use with all Consensus Hip Systems femoral stem components. The CONSENSUS BIPOLAR consists of a bipolar femoral head component with preassembled locking ring and a bipolar insert component. The CONSENSUS UNIPOLAR consists of only a unipolar femoral head component. The bipolar femoral head component is manufactured from Cobalt Chrome alloy (CoCrMo, ASTM F75, ASTM F799, or ASTM F1537). The bipolar head has a highly polished spherical outer surface with a cylindrical bored internal diameter which accepts the polyethylene bipolar insert. The bipolar head comes with a polyethylene locking ring preassembled in a circumferential groove on the internal diameter. The bipolar insert component and locking ring are manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648). The bipolar insert and locking ring are designed for use with the appropriate size bipolar head component. The unipolar femoral heads are manufactured from cobalt chrome alloy (CoCrMo, ASTM F75 or ASTM F1537).

The CONSENSUS ALL-POLY ACETABULAR CUP is designed for use with all Consensus Hip Systems femoral stem components. The CONSENSUS ALL-POLY ACETABULAR CUP is a one piece acetabular component designed for cemented use only, manufactured from ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648), and features a titanium alloy X-ray marker (Ti 6Al-4V ELI, ASTM F136).

The proximal spacer, distal centralizer, and cement pod spacer are manufactured from polymethylmethacrylate (PMMA, ASTM D5436). The proximal spacer and distal centralizer are designed for use with the CoCr femoral stem component for cemented applications.

HOW PRODUCT IS SUPPLIED

All components of Consensus Hip Systems are supplied STERILE, are contained in individual boxes or packages designed to maintain sterility, and are 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 FOR USE OF THE CONSENSUS® HIP SYSTEM-PRIMARY HIP, CS2™ HIP SYSTEM-PRIMARY HIP, AND THE TAPERSET™ HIP SYSTEM-PRIMARY HIP:

The CONSENSUS® HIP SYSTEM, CS2™ HIP SYSTEM, and the TAPERSET™ HIP SYSTEM are 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 CONSENSUS® hip stem is indicated for cemented or cementless use.The CS2™ and TAPERSET™ hip stems are indicated for cementless use.

INDICATIONS FOR USE OF THE CONSENSUS® BIPOLAR OR UNIPOLAR:

A. Primary replacement of the femoral head and neck with very little if any acetabular degradation noted.
B. Rheumatoid, osteo, and post traumatic arthritis.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-unions of proximal femoral neck fractures.
F. Revision of failed total hip arthroplasty.
G. Treatment of malunion or nonunion acetabular fractures.

The CONSENSUS® BIPOLAR or UNIPOLAR are intended for cementless use.

INTENDED PERFORMANCE

All components of the Consensus Hip Systems are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

A. The Consensus Hip Systems' range of motion complies with ISO 21535, except that the 28/+10mm CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees in all Consensus Hip Systems.
B. The Consensus Hip Systems are designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
C. The Ti alloy femoral and acetabular components are designed to minimize stress shielding at the bone-implant interface when compared with CoCr.
D. The matching articulating surfaces at the acetabular-femoral articulation are intended to reduce wear over time when compared with point loading.
E. The high polish finish of the articulating surface of the CoCr, Biolox *delta* Ceramic, and Zirconia Ceramic femoral heads is intended to reduce wear of the acetabular insert.
F. The high polish finish of the unipolar and bipolar heads is intended to reduce wear of the natural acetabular cartilage.
G. The proximal fixation surfaces of nonporous femoral stems are grit blasted to enhance adhesion at the implant-cement interface.
H. The proximal fixation surfaces of porous Consensus Hip Stems and the external fixation surfaces of acetabular components are porous 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. Components of all Consensus hip systems 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.
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. The Biolox *delta* Ceramic Femoral Head is to be used ONLY with CONSENSUS ORTHOPEDICS, INC. titanium hip stems with a 12/14 taper trunnion.
I. Consensus femoral stems may ONLY be used in conjunction with CONSENSUS® metal femoral heads, Biolox *delta* Ceramic femoral heads, or Zirconia Ceramic femoral heads.
J. CONSENSUS® femoral heads may ONLY be used in conjunction with CONSENSUS® acetabular components.
K. Consensus Hip 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. 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, POROUS COATED, or HYDROXYAPATITE 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 the femoral stem must not be scratched or damaged.
B. Clean and dry taper of femoral stem 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 femoral stem must be changed. If the stem 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: This CONSENSUS®, CS2™ and the TAPERSET™ hip systems have not been evaluated for safety and compatibility in the MR environment. This CONSENSUS®, CS2™ and the TAPERSET™ hip systems have not been tested for heating or migration in the MR environment.

CAUTION: Biolox Delta products and Zirconia Ceramic products not offered in countries under CE mark regulatory governance approval process.

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

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