DI216A-EN (Rev E)	HIP JOINT REPLACEMENT IMPLANTS
06/2025	**IMPORTANT INFORMATION ON HIP JOINT REPLACEMENT IMPLANTS**

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON HIP JOINT REPLACEMENT IMPLANTS

GENERAL PRODUCT INFORMATION

Through the advancement of partial and total hip joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, ceramic, and plastic materials and that any joint replacement, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

Hip implant components are indicated for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints. If cemented fixation is required for the component being used, then the respective component label will include the statement; **"This device is intended for cemented use only."**

DESCRIPTION

Globus hip implants include the Provident®, Provident® II, ProForm™, ProClass™, Protract™, and Progeny™ systems. Hip stems are designed for reconstruction of the proximal femur. Each stem design shares common acetabular components and femoral heads. The trunnion of each stem features identical geometry, and each are designed to mate with a wide array of cobalt chrome alloy and ceramic heads. Hip stems are available in numerous sizes with either a standard or lateralized version.

The Dual Taper Wedge (DTW) stem is manufactured from forged alloy titanium (Ti-6Al-4V) and is available in a range of sizes. The design of the stem and instrumentation will provide a line fit in the medial and lateral directions. The anterior and posterior surfaces form a wedge with rib like projections to secure the stem and to compress cancellous bone. The trunnion is a 12/14 modified Morse taper. Heads from other vendors should be avoided.

The Uni-Polar Head is produced from CoCr with a highly polished surface which must be protected from marring at all times. The head diameter varies and is supplied with three neck lengths, extra short (-5), short (0), and long (+7). The tapered hole is a modified Morse taper and will fit on any Globus hip stem.

The Bipolar Head is CoCr alloy with a highly polished surface, which must be protected from marring at all times. The insert and snap ring are machined from UHMWPE (polyethylene). A 28mm diameter or a 22mm diameter femoral head must be used on the femoral stem. The bipolar head is available in a range of sizes. Assemble the snap ring over the trunnion on the stem. Place femoral head on trunnion, and then place the femoral head into the bipolar head. Secure snap ring into the bipolar.

ONVOY™ implants consist of acetabular shells, fixed bearing liners, dual mobility liners and bearings, and bone screws. Shells are available in multiple sizes and are for cementless fixation. The shells are made from either forged alloy Titanium 6Al-4V (Ti-6Al-4V) ELI or additively manufactured from Ti6-Al-4V ELI. The fixed bearing liners and dual mobility bearings are made from UHMWPE blended with Vitamin E. The dual mobility liners are made from CoCr alloy. ONVOY™ implants may be used with other Globus/Stelkast femoral implants.

CAUTION

Before using, the physician must understand the implant procedure. The physician has to be completely aware of the implant procedure before starting.

INDICATIONS FOR USE

All hip implants except Dual Taper Wedge Stem, Polar Heads, and ONVOY™:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Cemented and uncemented applications.

Dual Taper Wedge Stem:

- Joint impairment from arthritis (rheumatoid, osteo and post traumatic).
- Revision of failed femoral head replacements.
- When alternative reconstructive techniques are not viable.
- When arthrodesis is contraindicated.
- Avascular necrosis or fracture of the femoral head.
- Congenital defects that will allow adequate function of the system.

Bipolar Head:

- Fractures of the proximal femur.
- Non-unions of proximal femoral neck fractures.
- Aseptic necrosis of the femoral head.
- Osteo-rheumatoid and post-traumatic arthritis of the hip with minimal distortion of the acetabulum.
- Salvage of failed total hip arthroplasty.

Uni-Polar Head:

- The head is an integral component of hip replacement systems and, therefore, is indicated under the same conditions as their respective systems.
- Three neck lengths are indicated based upon medical observation of leg length and abductor muscle tightness.

ONVOY™ Acetabular System:

The ONVOY™ Acetabular System is intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Dislocation risks.

The ONVOY™ Acetabular System is used in conjunction with Globus/StelKast hip systems. The acetabular components of this system are intended for cementless fixation.

Hip implant components are indicated for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints. If cemented fixation is required for the component being used, then the respective component label will include the statement; **"This device is intended for cemented use only."**

Hip System components are indicated for either cemented or cementless use for reconstruction of the articulating surface of the femoral and/or acetabular portions of the hip that are severely disabled and/or very painful resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, or fracture of the femoral head provided there is sufficient sound bone to seat the prosthesis. The components can be used for primary hip implant or for hip revision of a failed implant, and can be used for congenital defects that allow adequate function of the system.

CONTRAINDICATIONS

All hip implants except Dual Taper Wedge Stem and Polar Heads:

Hip implant components are contraindicated in:

- Patients with active infection
- Patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis
- Patients without sufficient soft tissue integrity to provide adequate stability, muscle laxity or inadequate soft tissue for proper function and healing
- Any pathological conditions that would interfere with the performance of the system
- Patients with either mental or neuromuscular disorders that do not allow control of the affected joint
- Patients whose weight, age or activity level might cause extreme loads and early failure of the system

The Biolox Delta ceramic heads are contraindicated for use with any cup other than an UHMWPE cup or metal backed UHMWPE cup. The Zirconia ceramic head is contraindicated for use with any cup other than an UHMWPE cup or metal backed UHMWPE cup.

Dual Taper Wedge Stem:

- Any joint with active or suspected infection.
- Any neuromuscular or mental disorders which could result in system failure from abuse.
- Minimal bone stock to provide adequate support.
- Overweight patients who may over stress the components.
- Any pathological conditions that would interfere with the performance of the system.
- Muscle laxity or inadequate soft tissue for proper function and healing.

Uni-Polar Head:

- Any joint with active or suspected of infection.

Bipolar Head:

- Any joint with active or suspected infection.
- Any neuromuscular or mental disorders that could result in system failure from abuse.
- Overweight patients who may over stress the components.
- Any pathological conditions that would interfere with the performance of the system.

WARNINGS & PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for hip joint arthroplasty and the implant system is essential for success of the procedure. Improper position of the components could result in dislocation.

Only surgeons who have reviewed the literature regarding hip surgery and have had training in the technique should utilize the device. Patient selection is based on age, bone stock, and size. The surgeon or his designee should instruct patients in the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly. Patient lifestyles must be evaluated by the physician, and patient properly advised of any required modifications.

Hip implant components must not be reused. The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may reduce fatigue strength and could result in failure under load. Any prostheses so damaged must not be used. In the case of hip cup revisions in which the hip stem is not revised, ceramic femoral heads could break because of trunnion damage or mismatch. Care must be taken when ceramic heads are implanted to avoid overuse of force during seating the head on the trunnion. The stem trunnion and head bore should be dry and free of contamination prior to assembly of a ceramic head to the trunnion.

Components of hip implants should not be used with those of another manufacturer since articular and dimensional compatibility cannot be assured, including possible femoral head taper mismatch. **Only Globus femoral heads should be used with Globus hip stems.**

Dual Taper Wedge Stem:

- The surgeon must be familiar with the procedure prior to surgery.
- The patient must be informed of any life style modifications.
- Proper selection and insertion of implants are mandatory.
- The components must be protected during the procedure from mishandling and marring of the surfaces.
- Do not implant any damaged components.
- Do not reuse implants.
- Protect polished surfaces and the trunnion from scratching and marring.
- Patient selection is based on age, bone stock and size.
- Components are designed for mature skeletal systems.
- Patient lifestyles must be evaluated by the physician, and patient properly advised of any required modifications.
- Improper position of the stem could result in dislocation.

Uni-Polar Head:

- Leg lengths and abductor muscle tightness can be affected by the selection of the neck lengths.
- The surface of the head must be reasonably protected throughout the implant procedure.
- The head requires impact to properly seat on the stem trunnion.
- Do not implant any component that is damaged or scratched.
- Do not implant a used head.
- If the head is not seated, then it can disengage from the stem.

Bipolar Head:

- The patient must be informed of any life style modifications.
- Proper selection and insertion of implants are mandatory.
- The components must be protected during the procedure from mishandling and marring of the surfaces.
- Do not implant any damaged components.
- Do not reuse implants.

ONVOY™ Acetabular System:

- Component malposition or the use of a total hip with a modular skirted head and a hooded liner can decrease joint range of motion and can increase the potential for component wear, impingement, premature dislocation or revision. In these cases, the surgeon should inform the patient that high range of motion activities should be avoided.

MRI SAFETY INFORMATION

Globus hip implants have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of Globus hip implants in the MR environment is unknown. Performing an MR exam on a person who has these devices may result in injury or device malfunction.

ADVERSE EFFECTS

As with all hip joint implant systems, potential adverse effects include infection, loosening of the components, breakage, bending or disassembly of the components, or change in position of the components. There have been reports of sensitivity reactions to the implant components. Other potential adverse effects of hip implant joint surgery include neurovascular damage, dislocation, thromboembolic disease, acetabular pain, component failure and wear debris, and other less common adverse effects. On rare occasions, amputations have been necessary due to complications.

Dual Taper Wedge Stem:

- All components have the potential for failure including infection, loosening, fracture, disassembly and positional changes.
- Wear debris can result from loose titanium particles.
- Certain patients may experience reactions to various materials.
- Joint replacement surgery is associated with, but not limited to, nerve injury, arterial injury, deep vein thrombosis, acetabular pain, component failure and wear debris.
- Reoperation may be necessary to correct adverse effects.
- On rare occasions, amputations have been necessary.

Uni-Polar Head:

- Heads have the potential for adverse effects including infection, loosening, fracture and disengagement of the stem.
- Certain patients may be sensitive to CoCr.
- On rare occasions, amputation may be required due to complications.

Bipolar Head:

- Heads have the potential for adverse effects including infection, loosening, fracture, disassembly and positional changes.
- Certain patients may experience reactions to polyethylene or bone cement.
- On rare occasions, amputation may be required due to complications.
- Wear debris can occur at the articulating surface.

PACKAGING

The Dual Taper Wedge stem is supplied in a double Tyvek package. If the seal or package is breached, then the component should not be used.

The surface of the uni-polar heads is protected with a cover and placed in a double Tyvek package.

The assembled bipolar head is sterile barrier packaged in an inner foil pouch and placed in an outer Tyvek package. If the seal or package is breached, then the component should not be used.

STERILITY AND HANDLING

Each hip implant component is supplied sterile in double sealed containers maintaining double sterile barriers. If the seals or containers are breached, then the component should not be used. The components are not represented to be “pyrogen-free.”

Metal and ceramic parts as well as polyethylene (UHMWPE) parts and/or components containing polyethylene or polymethylmethacrylate (PMMA) are supplied exposed to a minimum of 2.5 Mrad of gamma irradiation or Ethylene Oxide sterilization and must be kept unopened in the double protective packaging until implantation. The sterilization method used is listed on the respective component label. The sterile container is to be checked for possible damage. Do not use any component if the packages have been breached.

The Dual Taper Wedge stem and the double Tyvek package are subjected to 2.5 Mrad radiation. Do not use any component if the package has been breached.

The assembled bipolar head and the sterile barrier packaging are subjected to gamma sterilization. Do not use any component if the package has been breached.

Resterilization by any method is ruled out.

Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

UTILIZATION AND IMPLANTATION

Selection of hip implant components depends on the judgment of the surgeon with regard to the relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: (1) appropriate reading of the literature, and (2) training in the operative skills and techniques required for hip joint arthroplasty surgery.

MATERIALS USED

The materials used are listed on the respective product label.

INFORMATION

For any further information, please contact the supplier. Please be sure to refer to the Catalog Number designated with REF.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.