Instructions For Use

Titan™ Modular Shoulder System

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Description

The Titan™ Total Shoulder System consists of a line of metaphyseal bodies, humeral stems, humeral heads and all polyethylene glenoid components. The body, stem and humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The metaphyseal bodies and humeral stems are shaped to provide proximal fixation and optimal fixation area. Their variable length and proximally-filling shape are designed to accommodate the natural humeral geometry and provide stable fixation, proximal bone loading and proper head placement. The humeral heads are offered with both concentric and eccentric articulating surfaces. The humeral head may articulate against the natural glenoid bone, if it is of sufficient quality, or against the all polyethylene cemented glenoid. There are three glenoid options: keel, peg or anchor peg (Fin-Lock®). Glenoid options are designed to function with both the concentric and eccentric heads.

The Titan Reverse Shoulder System is a semi-constrained total shoulder construct. The humeral components consist of Humeral Stems, varying heights of Reverse Bodies, and Humeral Poly Liners. The Humeral Poly Liners are available in varying thicknesses and constraints to achieve stability of the glenohumeral joint. The variable length and proximally-filling shape of the Humeral Bodies are designed to accommodate the natural humeral geometry and provide stable fixation as well as proximal bone loading. The glenoid components are composed of a Baseplate secured by 4 peripheral screws, two of which can be locked as well as a central compression screw. Both the Reverse Humeral Bodies and the Baseplate are porous coated for secondary fixation. A Glenosphere is attached to the Baseplate via a taper lock. Glenospheres are available in varying offsets and lateralizations.

Indications for Use

Total Shoulder Arthroplasty or Hemiarthroplasty is indicated for:

- Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon’s experience indicates that alternative methods of treatment are unsatisfactory.
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Shoulder Hemiarthroplasty is also indicated for:

- Ununited humeral head fractures.
- Avascular necrosis of the humeral head.
- Rotator cuff arthropathy.
- Deformity and/or limited motion.

The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

Reverse Total Shoulder System is indicated for:

- Use in a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient’s joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The Titan Reverse Shoulder System is indicated for primary fractures, including proximal humeral or revision total shoulder replacement, for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use.

Contraindications

The following conditions are contraindications for total shoulder arthroplasty and hemiarthroplasty:

- Active local or systemic infection
- Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components
- Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid
- Pregnancy
- Muscular, neurologic or vascular deficiencies that compromise the affected extremity
- Known metal allergies

The following condition is a contraindication for total shoulder arthroplasty:

- Absent, irreparable or nonfunctional rotator cuff or other essential muscles

The following conditions are contraindications for reverse total shoulder arthroplasty:

- Patients without a functional deltoid muscle
- Active local or systemic infection
- Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components
- Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/or a chance of fracture of the humerus or glenoid
- Pregnancy
- Muscular, neurologic or vascular deficiencies that compromise the affected extremity
- Known metal allergies

**Warnings**

The use of a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid component loosening due to non-anatomic loading conditions. The following conditions tend to adversely affect shoulder replacement implants, jeopardizing the efficacy of the implant:

- Excessive patient weight
- High levels of patient activity
- Likelihood of falls
- Poor bone stock
- Metabolic disorders
- Disabilities of other joints

**Precautions**

- Do not reuse this device. Reuse of this product may result in infection or other systemic complication that may affect the patient’s overall health. Additionally, the reuse of this product could adversely affect function of the device. Any implant that has been damaged, mishandled or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate and should be discarded.
- The Titan Total Shoulder System and Reverse Shoulder System have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Titan Total Shoulder System and the Titan Reverse Shoulder System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Sterility**

The Fin-Lock Glenoid implants have been sterilized by Ethylene Oxide (EO) and are sterile in the unopened, undamaged package. If either the implant or the package appears to be damaged or has been opened, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize this product.

All other Titan System Implants have been sterilized by gamma radiation and are sterile in the unopened, undamaged package. If either the implant or the package appears damaged or has been opened, or if sterility is questioned for any reason, the implant should not be used. Do not resterilize this product.

**Adverse Events**

- Potential adverse events include early or late postoperative infection, allergic reaction, intraoperative or postoperative bone fracture and/or postoperative pain.
- Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
- Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and/or excessive activity.
- Surgical intervention may be required to treat adverse effects.
- MDR Reporting Reminder: Medical device manufacturers and users are required by law and regulation to report serious injuries and death.

**Surgical Procedure**

A surgical technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.
### Training

Surgeons may obtain training from a qualified instructor prior to implanting the Titan Total Shoulder System or the Titan Reverse Shoulder System to ensure thorough understanding of the implantation techniques and the instrumentation.

### Product Information Disclosure

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### Symbols Used on Labeling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tr>
<td><strong>STERILE</strong></td>
<td>Sterilized using Ethylene Oxide</td>
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<tr>
<td><strong>STERILE</strong></td>
<td>Sterilized using irradiation</td>
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<tr>
<td><strong>LOT</strong></td>
<td>Lot number</td>
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<td><strong>REF</strong></td>
<td>Catalog number</td>
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<td><strong>EC REF</strong></td>
<td>Authorized Representative in the European Community</td>
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<tr>
<td><strong>Cementless</strong></td>
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<tr>
<td><strong>MATL: UHMWPE</strong></td>
<td>Ultra high molecular weight polyethylene</td>
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<td><strong>MATL: Ti6Al4V</strong></td>
<td>Titanium alloy</td>
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<tr>
<td><strong>MATL: CoCrMo</strong></td>
<td>Cobalt chromium molybdenum alloy</td>
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<td><strong>Consult Instructions for Use</strong></td>
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<td><strong>Do not re-use</strong></td>
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<td><strong>Cemented</strong></td>
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