INSTRUCTIONS FOR USE
AFFINITI SHOULDER PROSTHESIS

IMPORTANT: The implantation of a joint prosthesis requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculoskeletal system and may be performed only by a qualified surgeon. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery. Patients should be aware of the possible complications that can occur by disregarding the precautions listed below.

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

1. Description: Tornier's Affiniti Shoulder System is a non-constrained glenohumeral prosthesis intended for use as a total or hemi-shoulder replacement system. The total shoulder consists of a metal humeral stem, a metal humeral head and an ultrahigh molecular weight polyethylene glenoid. The hemi-shoulder consists of a metal humeral stem and a metal humeral head. For a more detailed description of the implants and their utilization, please refer to technical documentation, or contact your Tornier representative. It is essential to implant the Affiniti Shoulder System with the Affiniti instrumentation specifically designed for this purpose. Affiniti implants are not compatible with components from other manufactures. Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement. Humeral stems are indicated for press-fit un-cemented use or for use with bone cement.

2. Materials: The material used in the manufacture of the Affiniti implants is titanium alloy (Ti-6AL-4V) in accordance with ASTM standard F136 or chromium-cobalt alloy (CrCo) according to ASTM standard F1537. The glenoid component is made of ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM standard F648.

3. Indications:
The Affiniti Total and Hemi-Shoulder System are indicated for:

-A 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).

The Affiniti Hemi-Shoulder System is also indicated for:

-Ununited humeral head fractures;
-Avascular necrosis of the humeral head.
-Rotator cuff tear arthropathy.

4. Known contra-indications to date:
Total or Hemi-shoulder
-Lack of quality bone to seat and support the implant, including that resulting from skeletal immaturity or osteoporosis.
-Metal allergies or sensitivity
-Infection at or near the site of implantation
-Distant or systemic infection
Total Shoulder
-Lack of sufficient sound muscle or rotator cuff to seat and support the implant

5. Side-effects and possible complications: As is common with all implantable devices, risks can include component loosening, dislocation, subluxation, bone resorption, poor bone formation, tissue or nerve damage as a result of surgical trauma, infection and/or those events common to any surgery (pulmonary embolism, stroke, heart attack, hematoma, pneumonia, slow wound healing). Additionally, iatrogenic fracture and traumatic fracture below the humeral component have been reported following use of similar devices. Metal sensitivity in patients following total joint replacement have been rarely reported. In the case of revision, all events are more likely and more severe, including difficulty in removing the prior implant and bone cement, challenges in placing the incision and hematoma, as well as wound healing.

6. Warnings and Precautions:
The functional life expectancy has not been determined for this device.

Using a glenoid prosthesis in patients with cuff tear arthropathy could increase the risk of glenoid loosening due to the proximal migration and non anatomic loading.

Although studies indicate that the MRI procedure has minimal effects on material in the Affiniti System implants; Patients should be informed that there are several different manufacturers and generations of MRI equipment available, and Tornier Inc. cannot make claims regarding the compatibility of Affiniti System implants with any specific MRI unit. It is recommended that patients contact the surgeon or the manufacturer of the MRI equipment to discuss the compatibility of the Affiniti System implants with the MRI equipment before undergoing any test.

If the surgeon determines this implant is appropriate for a patient with any of the following conditions, the surgeon must advise the patient of the strength limitations of the implant, the possibility of implant dislocation, migration, loosening or failure and the precautions the patient must take to minimize the possibility of an adverse clinical result.

The following conditions may impose excessive loading on the device:
-Patient age and activity level
-Certain sports activities
-Manual labor
-Obesity
-Impaired balance, excessive prescription drug or alcohol use or other medical conditions that can lead to falls
-Mental disorders or attitudes potentially resulting in failure to follow post-operative orders

The following conditions may adversely affect implant fixation if they create poor bone stock or a poor environment:
-Metabolic or systemic disorders
-Existing poor bone stock, marked osteoporosis, or tumors
-History of general or local infections
-Disabilities of other joints
-Severe deformity
-Sensitivity to implant materials
-Pharmacological treatments
-Tissue reactions to implant corrosion or wear debris

Never re-use an implant, even if it is in perfect condition.
Do not use with a device from other manufacturers
Do not implant trials
Do not modify the implant

7. Surgical process

- Pre-operatively:

The surgeon must be fully conversant with all the aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific operative technique of the product which is available from the manufacturer. As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors are present that will affect the correct conduct of the operation and the postoperative period. An appropriate range of sizes must be available at the time of the operation. Check that the implant package has not suffered from any deterioration.

- Per-operatively:

The correct selection of the type and size of the implant appropriate to the patient and the position of the implant are extremely important. Handle the implant using proper aseptic technique including the use of sterile surgical gloves. Leave the protective cover on until the device is needed. The functional surfaces of the implant must not suffer any damage, abrasion or other deterioration. Do not increase the anteversion of the glenoid component as it may result in instability and dislocation. Before closing the incision, clean out all ectopic bone, extraneous cement and bone chips as debris left in the site may cause dislocation, pain, restricted movement or pre-mature wear.

- Post-operatively:

Patients should be informed about the precautions they must take in everyday life to help maximize the service life of the implant. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider the action to be taken. Normal wear of the implant according to the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented.

8. Storage and handling: The prosthetic components must be handled and stored with care in accordance with the provisions of the ISO standard 8828. The implant must be stored in their sealed packaging of origin.

9. Packaging and sterilization: The implants are individually packaged and supplied sterile. All metal implants have been sterilized by gamma irradiation. All polyethylene implants have been sterilized using gamma with nitrogen flush packaging. The expiration date for sterilization must be checked. Only those products implanted before the end of the expiration date may be considered sterile. The packaging and labelling must be checked for integrity. Reject any implant if the packaging is damaged. Every precaution must be taken to ensure sterility when opening the packaging of the implant and when inserting it. Never re-sterilize and implant.

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IFU Number : 2007-01
DWG Number : 0020178 R1 9/23/08