TORNIER

INSTRUCTIONS FOR USE

AEQUALIS™ ADJUSTABLE REVERSED SHOULDER PROSTHESIS

IFU-6703 Rev. A

IMPORTANT: The manufacturer recommends that all personnel responsible for handling and implanting the devices read and understand this information before use. The implantation of a joint prosthesis and its associated implants requires knowledge of anatomy, biomechanics and reconstructive surgery of the musculo-skeletal 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. The patient must be properly informed about the device and the information contained in the present instructions for use.

Caution: The Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician.

1. Description:

Aequalis Adjustable Reversed

The Aequalis Adjustable Reversed Shoulder humeral implant is a component of the semi-constrained Aequalis Reversed Shoulder System and must be used in association with Aequalis Reversed or Aequalis Reversed II glenoid implants, which are equivalent.

The glenoid implant is composed of a base with anchoring screws and a sphere.

The humeral implant consists of a humeral stem, a humeral metaphysis which is fit with an articular insert congruent with the Glenoid sphere. The humeral stem has the option of a stem spacer which extends the overall length. The humeral components are secured with a locking screw and securitization screw

Ancillary instruments are also provided:

- trial pieces for testing implantation during the surgery,
- instruments for the assembly and proper implanting of the prosthesis.

For a more detailed description of the implants and their utilization, please refer to the technical documentation, or contact your Tornier representative. It is essential to implant the Aequalis Adjustable Reversed shoulder prostheses with the Tornier instrumentation specifically designed for this purpose. Tornier implants must be assembled using Tornier components defined as being compatible with one another. The selection of the appropriate implants can be made by using the recommendations of the surgical technique and the trial pieces and templates supplied with the instrumentation.

2. Materials:

The constituent material of the Aequalis Adjustable Reversed Shoulder implants is marked on the packaging.

Cemented Aequalis Adjustable Reversed humeral implants: Humeral stems are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and are available in 2 options : 1) Uncoated and 2) Titanium plasma spray coated according to ASTM F-1580. Metaphysis components are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3. Inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) according to ISO 5834-2. Spacers are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3. Locking screws are manufactured from chromium cobalt alloy (CoCr) according to ISO 5832-7. The Securitization System Screw and Locking Cap are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and chromium cobalt alloy (CoCr) according to ISO 5832-7 respectively.

Uncemented Aequalis Reversed humeral implants: Humeral stems are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and are available in 4 options: 1) Uncoated, 2) Hydroxylapatite (HAP) coated according to ASTM F-1185, 3) HAP coated over titanium plasma spray according to ASTM F-1185 and ASTM F-1580 and 4) Titanium plasma spray coated according to ASTM F-1580. Metaphysis components are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3. Inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) according to ISO 5834-2. Spacers are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3. Locking screws are manufactured from chromium cobalt alloy (CoCr) according to ISO 5832-7. The Securitization System Screw and Locking Cap are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and chromium cobalt alloy (CoCr) according to ISO 5832-7 respectively.

3. Intended and Indications for use:

The Aequalis Adjustable Reversed Shoulder System is indicated for patients with a functional deltoid muscle and a massive and non repairable rotator cuff tear as a replacement of Shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains

Notes:

All components are single use

The humeral stems:

- The uncoated humeral stems are for cemented or cementless use;
- The titanium plasma spray coated stems are for cemented or cementless use;
- The hydroxylapatite coated stems are for cementless use only
- The hydroxylapatite over titanium plasma spray coated stems are for cementless use only
- The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

4. Additional Notes

The Aequalis Adjustable Reversed Shoulder humeral stem is used in association with the glenoid components of the Aequalis Reversed Shoulder Prosthesis.

5. Known-contraindications to date:

Common contraindications for the Aequalis Adjustable Reversed Shoulder:

- Poor quality and insufficient quantity of glenoid bone stock.
- Pre or per-operative glenoid fracture.
- Acromion fracture.
- Non functional deltoid or external rotator muscles.
- Systemic infection, fever and/or local inflammation.
- Rapid joint destruction or bone resorption apparent on roentgenograms.
- Elevation of sedimentation rate unexplained by other disease, elevation of WBC count, or marked shift in WBC differential count.
- Distant foci of infection from genitourinary, pulmonary, skin and other sites, dental focus infection which may cause hematogenous spread to the implant site. The foci of infection should be treated prior to, during and after implantation.
- Use of this implant is contraindicated in the presence of significant injury to the upper brachial plexus.
- Paralysis of the axillary nerve.
- Neuromuscular disease (e.g. joint neuropathy).
- Known allergy to one of the materials.
- Patient pregnancy.
- Insufficient metaphyseal bone stock making the stable securing of humeral components impossible.

6. Side-effects and possible complications:

- Dissociation of glenoid or humeral components.
- Component loosening.
- Dislocation.
- Break.
- Loss of shoulder motion.
- Axillary column erosion.
- Metal sensitivity in patients following total joint replacement has been rarely reported.
- Sepsis.
- Acromial fracture caused by fatigue.

- 7. **Warnings and Cautions**:
- This product is intended for single patient use only. Re-sterilization or reuse of this device has not been tested and may result in compromised device performance.

- Never re-sterilize an implant delivered sterile.

THE FOLLOWING SITUATIONS THREATEN THE SUCCESS OF THE SHOULDER REPLACEMENT IMPLANT:

- sport activity or high activity level
- people likely to fall
- alcoholism or drug abuse
- inability of the patient to follow the surgeon's recommendations and the physical therapy program.

• **<u>Preoperatively</u>:**

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. He must also check that the quality of the bone is satisfactory enough to support the implantation. An appropriate range of sizes must be available at the time of the operation.

• **Intraoperatively:**

The correct selection of the type and size of the implant appropriate to the patient and the positioning of the implant are extremely important.
The use of trial pieces allows for the proper size selection of the implants.
The prostheses must not be used if their functional surfaces have been damaged or have undergone shock, abrasion, or other deterioration.
The implants coated with hydroxylapatite (HA) must be handled with care and be used according to the recommendations of the surgical technique to avoid deterioration of the coating. The implants coated with hydroxylapatite must not be cemented.

• **Postoperatively:**

The surgeon must inform patients about:
- precautions to take in daily life to guarantee maximum implant survival,
- the fact that their weight and level of activity can affect the life span of the prosthesis,

The Aequalis Adjustable Reversed Shoulder prostheses have not been evaluated for safety and compatibility in the MR environment. The Aequalis Adjustable Reversed shoulder prostheses have not been tested for heating or migration in the MR environment.
It is recommended that a regular postoperative follow-up is 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 in respect of 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 specific to the patient.

8. Storage and handling:

IMPLANTS MUST BE STORED IN THEIR ORIGINAL SEALED PACKAGING. THE STORAGE PLACE MUST BE AWAY FROM HUMIDITY. IMPLANTS MUST NOT BE EXPOSED TO DIRECT SUNLIGHT, IONIZING RADIATION, EXTREME TEMPERATURES NOR PARTICULAR CONTAMINATION. IMPLANTS MUST BE HANDLED WITH CARE TO PRESERVE THE INTEGRITY OF THE PACKAGING.

9. Packaging and sterilization:

The implants are supplied sterile (gamma radiation). The expiration date for sterilization and integrity of the packaging must be checked.
An implant whose packaging is open or damaged or whose expiration date has passed must not be used.
Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.
Ancillary instruments may be supplied sterile.
For handling and sterilization of non-sterile ancillary instruments, refer to the ancillary instruments instructions. The templates are supplied non-sterile and should not be sterilized.

For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.

SYMBOLS


Do not reuse


Use by date

Sterilized using irradiation

Batch code

Serial number

Catalog number


Caution, consult accompanying documents


Consult Instructions for use


Non-sterile


Do not use if package is damaged


Do not resterilize


Not Made with Natural Rubber Latex

CAUTION: FEDERAL LAW RESTRICTS THE SALE OF THIS DEVICE TO OR ON THE ORDER OF A PHYSICIAN

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