TORNIER

INSTRUCTIONS FOR USE

US AEQUALIS™ PERFORM+ GLENOID

IFU-2066 Rev. B

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:

The Tornier shoulder prostheses are non-constrained prostheses used in the total replacement of the glenohumeral articulation.

The Aequalis™ PerFORM™+ glenoids are made up of two models:

- CortiLoc™ pegged glenoid
- Keeled glenoid

The Aequalis™ PerFORM+ glenoids are intended to replace the glenoid part of the scapulohumeral joint as part of a total anatomical shoulder prosthesis.

The Aequalis™ PerFORM+ glenoids must be associated with a Tornier humeral component.

Combinations of glenoid / humeral components:

Recommendations about how to size the humeral head / glenoid sizes are specified in the table below:

Aequalis* or Simpliciti*

Humeral Head Size	37 x 13.5 39 x 14 41 x 15	43 x 16 36 x 17	48 x 18 50 x 16 50 x 19	52 x 19 52 x 23 54 x 23 54 x 27
PerFORM+ glenoid size	Small	Medium	Large	Extra-Large

Affiniti*

Humeral Head Size	40	44 48	52	56
PerFORM+ glenoid size	Small	Medium	Large	Extra-Large

Ascend*

Humeral Head Size	38 40 42	44 46	48 50	52 54
PerFORM+ glenoid size	Small	Medium	Large	Extra-Large

*Not all models are available in all geographies.

Ancillary instruments are also provided for the implantation of the prosthesis:

- 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 Tornier 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.

Symbols can be used to identify some implants (labelling or marking). They are defined as follows:

L = Left R = Right
S = Small M = Medium
L = Large XL = Extra Large

2. Materials:

The glenoid implant is made of ultra-high molecular weight polyethylene (UHMWPE) in accordance with ISO 5834-2 and contains a radiolucent wire made of cobalt chromium (CoCr) in accordance with ISO 5832-7.

3. Intended Use:

The Tornier shoulder prostheses are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

4. Indications for Use

Prosthetic replacement with this device (Aequalis PerFORM+ glenoid component + humeral component) may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthrosis, post traumatic arthrosis
- Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed

The Aequalis PerFORM+ glenoids are intended for cemented use only.
The Aequalis monobloc stem is for cemented use
The Aequalis Press-Fit is for uncemented use

5. Known-contraindications to date:

- Systemic Infection
- Fever and / or local inflammation
- Rapid joint destruction or bone resorption apparent on roentgenograms
- Evaluation of sedimentation rate unexplained by other disease, elevation of WBC count
- Distant foci of infection from genitourinary, pulmonary, skin and other sites, dental focus infection that may cause haematogenous spread to the implant site.
- Use of this implant is contraindicated in the presence of significant injury to the upper brachial plexus
- Poor quality and / or insufficient quantity of glenoid bone stock (pre- or intraoperative glenoid fracture)
- Non-functional deltoid or external rotator muscles
- Important and non-repairable rupture of the rotator cuff
- Neuromuscular disease (e.g. joint neuropathy)
- Known allergy to one of the materials
- Patient pregnancy

6. Side-effects and possible complications:

- Dislocation
- Component loosening
- Component breakage
- Component wear
- Component migration
- Bone resorption
- Poor bone regrowth
- Overtension of the soft tissues
- Impingement
- Postoperative pain
- Nerve or tissue lesion
- Infection or any other event that could follow surgery (pulmonary embolism, heart attack, etc)
- Iatrogenic fracture and traumatic fracture below the humeral component
- Possible metal sensitivity
- In case of arthroplasty after fracture: malunion, non-union
- After a revision: all events cited above are at a greater risk of occurring
- Some complications and side effects could result from lack of awareness of the precautions for use mentioned in this instruction for use.

7. Warnings and Cautions:

This product is provided sterile in an undamaged package and is for ONE TIME USE ONLY. If either the implant or the package appears damaged, expiration date has been exceeded or if the sterility is questioned for any reason, the implant should not be used. DO NOT clean, re-sterilize or reuse as this may damage or compromise performance of the devices and may expose patient to risk of transmitting infectious diseases.

MRI WARNING:

This product has not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or

image artifact in the MR environment. The safety of the Tornier products in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.
- Patient has not reached full skeletal maturity

Preoperatively:

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. It is recommended to assess glenoid wear and orientation as well as the presence of osteophutes on x-rays and / or CT scan views. The surgeon 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:

During the preparation of the glenoid, it is not recommended to ream to the trabecular (spongy) bone because of the limited osseous stock. Aggressive milling must be avoided to prevent glenoid fracture.
At the time of implantation, the prosthetic lower surface of the glenoid implant must be in contact with the bone glenoid surface to ensure fixation of the implant.
It is recommended to use fluid cement as well as a syringe to introduce the cement into the holes intended to receive the pegs of CortiLoc™ glenoids.
The correct selection of the type and size of the implant and positioning of the implant is extremely important for the patient.
The use of trial pieces allows the surgeon to check the proper contact between the bone glenoid surface and the future implant.
The prostheses must not be used if their functional surfaces have been damaged or have undergone shock, abrasion or other deterioration.
The geometry of the implant must not be modified. In case of revision, special care must be taken not to damage the components that are not removed.

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
- It is not recommended to use physiotherapy devices transmitting electrical or acoustic energy (ultrasounds) near the implant
- 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 x-ray 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.

10. Implant Retrieval and Handling:

In case of retrieval of the implant from the patient, the retrieved implant should be handled according to appropriate and validated hospital procedures.

LIMITED WARRANTY

Tornier, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Tornier, Inc. does not warrant the outcome of the surgical procedure.

SYMBOLS

Symbol	Meaning
REF	Catalog Number
SN	Serial Number
	Caution, Consult Accompanying Documents
STERILE R	Sterilized Using Irradiation
	Consult Instructions for Use
	Do Not Reuse
	Use By Date
	Not Made with Natural Rubber Latex
	Do Not Use if package is damaged
	Manufacturer
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Do Not Resterilize

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