PATIENT INFORMATION LEAFLET

Shoulder Replacement

1. Device identification

Component	Model
Humeral Stem	Mirai cemented Ti6Al4V; Mirai cementless Ti6Al4V; Mirai revision cemented Ti6Al4V; Mirai revision cementless Ti6Al4V; Mirai trauma cemented Ti6Al4V; Mirai trauma cementless Ti6Al4V; Mirai humeral metaphiseal component cementless Ti6Al4V
Humeral Core	Mirai cage Traser cementless Ti6Al4V; Mirai trauma Traser cementless Ti6Al4V; Mirai trauma cage Traser cementless Ti6Al4V; Mirai trauma cemented Ti6Al4V
Humeral head	Mirai anatomical UHMWPE; Mirai anatomical Vital-E; Mirai anatomical CoCrMo; Mirai anatomical PM734; Mirai anatomical CTA CoCrMo; Mirai anatomical CTA PM734
Glenoid Base Plate	Mirai cementless Ti6Al4V; Mirai trauma cemetless Ti6Al4V; Mirai glenoid component cemented UHWPE
Glenoid Insert	Mirai anatomical Ti6Al4V
Humeral Insert	Mirai for reverse prosthesis Ti6Al4V
Glenosphere	Mirai all poly for reverse prosthesis UHMWPE; Mirai all poly for reverse prosthesis Vital-E
Other components	Mirai Anatomical humeral head adapter Ti6Al4V; Mirai central peg for glenoid base plate Ti6Al4V; Mirai peg screw for glenoid base plate Ti6Al4V; Mirai fixation screw for glenoid base plate Ti6Al4V; Mirai humeral insert spacer for reverse prosthesis Ti6Al4V; Mirai glenosphere safety screw Ti6Al4V; Mirai all poly glenosphere adapter Ti6Al4V
--	Custom made devices

2. Intended purpose & kind of patients for whom device is intended

Shoulder joint prostheses are indicated in primary and revision total or partial shoulder arthroplasties, in all cases of primary non-inflammatory degenerative joint diseases, secondary osteoarthritis due to post-traumatic degenerative factors or degenerative diseases of the rotator cuff, avascular necrosis of the humeral head, joint degeneration secondary to rheumatoid arthritis, psoriatic arthritis or similar diseases, Acute fractures of the humeral head or glenoid, Failure of previous prosthetic replacements or osteosynthesis of the gleno-humeral joint.

A joint prosthesis is intended to reduce joint pain and to properly restore a healthy joint function and bearing capacity allowing patient to return to normal daily living activities.

Shoulder joint prostheses are intended for adult patients with a mature skeleton. If, according to the surgeon's opinion, an unequivocal indication for total or partial shoulder replacement outweighs the risks associated with the age of the patient, shoulder replacement may be considered also for young patients.

For further information about shoulder replacement, please visit Permedica website: https://www.permedica.it/en/patients/shoulder/ .

3. Special operating instructions

The patient is not required to follow any operating instructions for the use of the device. The patient should always refer to the instructions of his/her orthopaedic surgeon.

The operating instructions for the use of the implanted device are competence of the orthopaedic surgeon. It could be advisable that the patient follows some of the mentioned precautions by mutual agreement with his/her orthopaedic surgeon.

4. Intended performance & undesirable side effects

A joint prosthesis is meant to reproduce the natural joint that it replaces. However, even if successfully implanted, a replaced joint will be inferior to a natural, healthy joint.

An excessive physical activity may reduce the expected implant life or lead to early reintervention. On the other side for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Patient conditions that may reduce the effectiveness of a joint replacement include:

- Systemic infections and any septic condition in the region surrounding the joint;
- Persistent, local or systemic osteomyelitis;
- Allergy to implant component materials;

- Acute or chronic neurologic and/or muscular insufficiency which compromises the shoulder joint functionality, as axillary nerve injury with subsequent insufficiency of the deltoid muscle.
- Chronic or acute local infections, even far from the implant site (risk of hematogenous spread of the infection towards the implant site);
- History of infections, recurrent falls to the ground;
- Insufficient bone structures at the proximal or distal level of the joint, which do not guarantee stability to the anchoring of the prosthetic components;
- Severe deformities that can lead to insufficient anchoring or implant malpositioning;
- Severe vascular, neurological or muscular diseases compromising the involved extremities;
- Multiple joint diseases or disabilities that can lead to unnatural joint mobility;
- Muscolar insufficiency;
- Obesity;
- Severe osteoporosis, osteomalacia;
- Hypotrophy of the periarticular soft parts;
- Dysmetabolic diseases (eg. Kidney failure);
- Skeletal immaturity.

The possible side effects listed below are among the known consequences of a joint replacement implant:

- Pain;
- Fever;
- Bone fractures as a result of unilateral overloads or weakening of the bone substance;
- Allergies and hypersensitivity reactions to implantable materials;
- Fatigue breakage, wear or loosening of the prosthetic components due to: scapular notching; excessive overloads; non-physiological stresses (local trauma); components damage; partial or total detachment; improper handling or execution of the implant (wrong choice of component type or size, incorrect alignment, improper fixing of components, inadequate anchoring);
- Mobilization of the joint prosthesis following a change in load transmission conditions (wear and tear of the bone cement and / or reaction of the tissues to the implant) or early and late infections;
- Mobilization of the joint prosthesis following inflammatory phenomena due to the production and migration of wear debris;
- Dislocation, subluxation, limited execution of movements, medialization of the humerus;
- Detachment of the coating and wear (only related to the joint surfaces);
- Joint instability due to inadequate soft tissues balancing;
- Intra-operative or post-operative complications such as: perforation or fracture of the bone segments; vascular injuries; temporary or permanent nerve lesions that can cause pain and numbness throughout the limb or causing dysfunction; cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction; local haematomas; late wound healing; local or systemic, acute or late infections.

5. Residual risks due to shortcoming of protection measures

The following risk factors can lead to unsatisfactory results for the implantation of a joint prosthesis:

- patient's inability to understand and follow the surgeon's recommendations and the physical therapy program;
- carrying out physical, work or sports activities associated with strong stresses that can subject the system to shocks and / or excessive loads;
- abuse of medicines, nicotine, alcohol and use of drugs.

6. Warnings & Precautions

Implantable prosthetic devices have not been tested for safety and compatibility in an MRI (Magnetic Resonance) environment, nor to determine their specifications for conditional status. They have not been tested for heating, migration, or image artefacts in the MR environment.

Therefore, the safety of implants in the MR environment is unknown, and the scan could result in injury to patients with the implant. The surgeon should make the patients aware about the risks connected to the exposure to magnetic fields. The patient must also be informed that implants can affect the results of magnetic resonance imaging (MRI) scans.

The implant does not require any maintenance by the patient. During postoperative cares, rehabilitation and in the following years the patient should follow the indications of his/her orthopaedic surgeon and undergo periodically follow-up visits to detect early signs of wear, loosening of the prosthesis, etc., and to consider the actions to be taken. Patient should avoid high impact sports or highly demanding repetitive physical activities, pay attention to prevent accidental trauma, avoid alcoholism or drug addiction. The level of activity should be reasonably controlled and excessive loads on the replaced joint should be avoided.

Patient should refer immediately to his/her orthopaedic surgeon if complaining any kind of pain or shoulder deficiency or dysfunction. Common symptoms of device dysfunction may include, but are not limited to, shoulder pain, reduction of shoulder mobility, function limitations, fever, swelling, skin rashes or any other anomalous symptom.

The expected lifetime of a joint prosthesis is limited as it is subject to inevitable wear and aging. Mechanical endurance tests have performed and each component was required to sustain many million cycles with no significant reduction of performance, as recommended by applicable international standards.
The expected lifetime can be reduced or increased depending on the activity level or events that could compromise implants integrity. Furthermore, a joint prosthesis initially implanted in a stable way can over time undergo to mobilization and be compromised in functionality. Wear, aging, loosening can imply a reoperation.

7. Materials and substances included in device

The following tables refer to the reference standards for raw materials:

ISO5832/3: Titanium 6-Aluminium4-Vanadium alloy (Ti6Al4V)	
ELEMENT	*PERCENT MASS FRACTION*
Aluminium	From 5,5 to 6,75 %
Vanadium	From 3,5 % to 4,5 %
Iron	Max. 0,3%
Oxygen	Max. 0,2%
Carbon	Max. 0,08%
Nitrogen	Max. 0,05%
Hydrogen	Max. 0,015%
Titanium	Balance

ISO5832/9: High nitrogen stainless steel (PM734)	
ELEMENT	*PERCENT MASS FRACTION*
Carbon	Max. 0,08 %
Chromium	From 19,5 % to 22,0 %
Copper	Max. 0,25 %
Manganese	From 2,00 % to 4,25 %
Molybdenum	From 2,0 % to 3,0 %
Nitrogen	From 0,25 % to 0,50 %
Niobium	From 0,25 % to 0,80 %
Nickel	From 9,0 % to 11,0 %
Phosphorus	Max. 0,025 %
Sulfur	Max. 0,01 %

Silicon	Max. 0,75 %
Iron	Balance
Residuals: Each	Max. 0.1 %
Total	Max. 0,4 %

ISO5832/12: Cobalt-chromium molybdenum alloy (CoCrMo)	
ELEMENT	*PERCENT MASS FRACTION*
Chromium	From 26,05 to 30,0 %
Molybdenum	From 5,0 % to 7,0 %
Nickel	Max. 1,0%
Iron	Max. 0,75%
Carbon	Max. 0,14% for low carbon alloy; from 0,15% to 0,35% for high carbon alloy
Manganese	Max. 1,0%
Silicon	Max. 1,0%
Nitrogen	Max. 0,25%
Cobalt	Balance

ASTM F2924: Titanium-6 Aluminum-4 Vanadium Powder (Ti6Al4V) for Additive Manufacturing	
ELEMENT	*PERCENT MASS FRACTION*
Aluminum	From 5,50 to 6,75
Vanadium	From 3,50 to 4,50
Oxygen	Max. 0,20
Nitrogen	Max. 0,05
Hydrogen	Max. 0,015
Iron	Max. 0,30
Carbon	Max. 0,08
Yttrium	Max. 0,005
Residuals: Each	Max. 0,10 %
Total	Max. 0,40 %
Titanium	Remainder

ISO5834/1-ISO5834/2 – ASTM F648: Ultra-high molecular-weight polyethylene (UHMWPE) **ASTM F2695: Ultra-high molecular-weight polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications (Vital-E)**	
ELEMENT	*MAXIMUM QUANTITY PERMITTED [mg/kg]*
Titanium	40
Calcium	5
Chlorine	30
Aluminum	20

The following tables refer to the reference standards for coating materials:

ASTM F1580: Pure Titanium (Ti) for coatings (X-Pore)	
ELEMENT	*PERCENT MASS FRACTION*
Oxygen	0.40%
Nitrogen	0.05%
Hydrogen	0.05%
Carbon	0.08%
Iron	0.50%
Silicon	0.04%
Chlorine	0.20%
Sodium	0.50%
Titanium	Remainder

ISO 13779/2 – ASTM F1185: Thermally sprayed coatings of hydroxyapatite (HA)	
TRACE ELEMENT	*MAXIMUM LIMIT [mg/kg]*
Arsenic	3
Cadmium	5
Mercury	5
Lead	30
Heavy Metals	50

Physical vapour deposited coating of titanium niobium nitride (TiNbN - Bioloy) – *No reference standard available*	
TRACE ELEMENT	*PERCENT MASS FRACTION*
Titanium	74.5% ± 1%
Niobium	25.5% ± 1%
Oxygen	Max. 0.1%
Nitrogen	Max. 0.01%
Carbon	Max. 0.03%
Hydrogen	Max. 0.01%
Iron	Max. 0.1%

The reference to the raw material and to the coating material (if any) is reported on the device label placed on the implant card.

8. Serious Incident Reporting

Please report all serious incidents to the manufacturer (contact details reported below) and, for Australia only, to the TGA **https://www.tga.gov.au/reporting-adverse-events**

Manufacturer

Permedica S.p.A. - via Como 38, 23807 Merate (LC) - ITALY
tel: +39.039.9514811 - fax: +39.039.9903078
info@permedica.it - www.permedica.it