



Patient Information Leaflet for HIP JOINT IMPLANTS

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What is in this leaflet?

This leaflet answers some common questions about the SAMO Hip Joint Implants. Please read this leaflet carefully and keep it in a safe place, so you may refer to it in future if needed.

WARNING: all statements in this Information Leaflet are generic, they do not represent the complete picture and they may not apply to your specific case. Please always refer to your medical doctor for your specific information.



Normal Hip

Damage Hip

Hip Replacement

The actual implant product code will be the one shown on the sticker on your Patient Implant Card.

What is the Hip Replacement?

The Hip Replacement is a surgical procedure to restore the worn or damaged hip with a prosthetic mechanism, ensuring greater mobility than the pre-operative state

Who is a candidate?

The SAMO Hip Joint Implants can be used in skeletally mature patients presenting with one or more of the indicated conditions:

- Extensive primary and secondary destruction of the joint to the extent that the functional efficiency of the locomotive apparatus is reduced
- Severe pathological condition affecting the articulation caused by degenerative rheumatoid arthritis
- Joint fracture or bone necrosis
- Post-surgical conditions after previous operations with or without consequent use of a prosthesis

What are the contraindications?

- On-going acute inflammatory process in the periarticular region
- Severe loss of bone tissue such as to inhibit a primary stabilization of the prosthesis
- Degenerative changes in the patient's neurological condition
- Severe instability in the ligament area that cannot be remedied
- Foreseeable causes of fatigue of the implanted joint due to obesity or excessive physical activity
- Severe osteoporosis
- Bone cancer in the implant anchoring area
- Alcohol and drug abuse
- Allergy to the materials employed
- Lack of collaboration by the patient

Warning:

Possible implant interference with any following complementary investigations (MRI and similar imaging techniques)

Postoperative monitoring

A postoperative monitoring must be carried out in consultation with the responsible surgeon.

Expected Device Lifetime

As reported in the arthroplasty registries, the survivorship of a primary total hip prosthesis is approximately 92% at 15 years.

What are the risks?

- Hematomas in the region of the operation;
- Late onset of acute infections in the region of the operation;
- Momentary or persistent functional alterations in the nerves of the anatomical area
- Venous thrombosis, pulmonary embolism, heart failure;
- Change in position and/or loosening of the prosthesis;
- Joint dislocation;
- Shortening or lengthening of the limb concerned;
- Pathological bone fracture caused by changes in load;
- Allergic reactions or metallosis in the peripheral region of the implant
- Periarticular ossification

What is the SAMO Hip Joint Implants made of?

- Stem components are made of Titanium alloy, or of High Nitrogen Stainless Steel, or of Cobalt Chromium Molybdenum alloy. The coating is made of pure Titanium or Titanium and hydroxiapatite
- Articular heads are made of AlZir Bioceramic, or of Cobalt Chromium Molybdenum alloy, or of High Nitrogen Stainless Steel
- Acetabular Cups are made of Titanium alloy Ti6Al4V, or of UHMW polyethylene. The coating is made of Pure Titanium and hydroxiapatite, or of only pure Titanium
- Liners are made of AlZir Bioceramic, or of UHMW Polyethylene, or of Cross-linked polyethylene with vitamin E, or of only Cross-linked polyethylene, or of UHMW Polyethylene and Ti6Al4V
- Acetabular reinforcements and screws for acetabular cups are made of Titanium

Reporting adverse effects:

You should report any adverse effects you believe are a result of the SAMO Hip Joint Implants. Please contact Samo S.p.A. Address: Via Giacomo Matteotti, 37 Cadriano - Granarolo Emilia BO 40057 Italy Email: info@samobiomedica.com Internet: www.samobiomedica.com Reports should also be made directly to the Therapeutic Goods Administration via the website: <http://www.tga.gov.au/reporting-problems>.