Patient Information Leaflet for
TREKKING TOTAL KNEE ARTHROPLASTY

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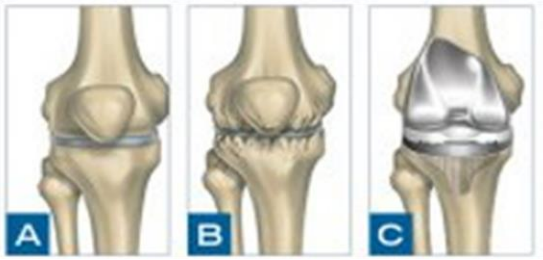
What is in this leaflet?

This leaflet answers some common questions about the SAMO Trekking Total Knee Replacement System. 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.



A. Normal Knee B. Arthritic Knee C. Knee Replacement

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

What is a Total Knee Replacement?

Total Knee Replacement is a surgical procedure to restore a damaged knee. Metal and plastic parts are used to cap the ends of the bones forming the knee joint.

Who is a candidate?

The SAMO Trekking Total Knee Replacement can be used in skeletally mature patients presenting one or more of the indicated conditions:

- Gonarthrosis
- Extensive primary or secondary joint destruction
- Severe joint diseases deriving from degenerative and rheumatoid arthritis
- Articular fractures or bone necrosis
- Postoperative conditions following surgery with or without implant use.

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 bi/tricompartmental knee 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;
- Displacement 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 periprosthetic metallosis
- Deformation of one or more implant components due to incorrect fixation or positioning,
- Fibrosis and peri-articular adhesions.
- Periarticular ossification
- Displacement of implant components.

What is the Trekking Total Knee Replacement System made of?

- Femoral components are made of a CoCrMo alloy, or of a CoCrMo coated with TiNbN.
- Metal tibial components are made of CoCrMo alloy, or of a CoCrMo alloy coated with TiNbN, or of titanium alloy.
- Patellar components and tibial inserts are made in UHMWPE or in UHMWPE with Vitamin E

Reporting adverse effects:

You should report any adverse effects you believe are a result of the SAMO Trekking Total Knee Replacement System. 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.