IMPLANTS

For Unicompartmental Knee System

IMPORTANT PATIENT LEAFLET

uni score



READ CAREFULLY THIS LEAFLET BEFORE SURGERY.
IT CONTAINS IMPORTANT INFORMATION FOR YOU.

WHAT IS IN THIS LEAFLET

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Keep this leaflet

You may need to read it again. If you have any further questions, ask your surgeon.
If you experience any side effect, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See page 4.
This leaflet has been written assuming the person receiving the implants is reading it .

Intended Use

The implant is a half knee prothesis intended to reduce pain and restore knee function. The implant must be inserted without damaging the ligaments.
Patients with a mature skeleton may be implanted with a half knee system in cases of severe joint pathology and where other devices or treatments have failed.
Please ask your surgeon for details. The decision to implant a half knee system is left to the surgeon after evaluation of the risk/benefit balance and after discussion with you.

Warning and Precautions

You must be informed the factors that could compromise the success of the surgery and post operative results :

- Age < 60 years*.
- Overweight: Body Mass Index (BMI) ≥ 25 kg/m² *.
- History of infection or falls.
- Metabolic disorders.
- Local bone tumours.
- Severe bone deformitie.
- Severe osteoporosis.
- Serious and untreatable instabilities of ligaments or muscular contractures.
- Hypercorrection.
- Extensive damage to the femoro-patellar compartment.
- Extensive flexion.
- Addictive behaviour.
- Playing sports intensively*.
- Playing risky sports or engaging in risky activities.

* Only for prosthesis with insert and cementless calf bone (tibia) part.

Furthermore, the UNI SCORE all-polyethylene tibial component must not be combined with a cementless femoral component. It is essential not to modify the components.

The materials used in your implant may trigger security gates/scanners.
PLEASE INFORM PERSONNEL ABOUT YOUR IMPLANTED DEVICE.

The following technical information is intended for medical staff, to ensure that MRI equipment is used in the best possible conditions.

Non-clinical testing desmonstrated that the implants are **MR Conditional.** A patient with one of these devices can be scanned safely in a MR system under the following conditions:

- Static magnetic field of 1.5T or 3T.
- Maximum spatial gradient field of 38 T/m (=3,800 G/cm) for a 1.5T MRI system and 19 T/m (= 1900 G/cm) for a 3.0T MRI system.
- Normal operating mode only.
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning may be blurred next to the implants.
- The image artefact caused by the implants extends approximately 99mm from these implants. MR images may be blurred next to the implants.

Maximum measured temperature rise with 1.5T MRI, for a 15min procedure	8.6°C (calorimetry WB-SAR of 3.27W/kg)
Maximum measured temperature rise with 3T MRI, for a 15min procedure	9.9°C (calorimetry WB-SAR of 2.39W/kg)

REPORTING ADVERSE EVENTS

Any incident in relation to the device shall be reported to your surgeon, healthcare facilities or family doctor.

YOU HAVE BEEN IMPLANTED WITH :

The surgeon needs to tick boxes corresponding to the devices you have been implanted with.

Associations with other devices have to be validated by Amplitude.

FEMORAL COMPONENTS



☐ **uni score femoral component - cementless**

☐ **uni score femoral component - cemented**

TIBIAL COMPONENTS



☐ **uni score tibial tray for fixed bearing insert - cementless (with peg)**



☐ **uni score fixed bearing insert**

☐ **uni score all-poly tibial component - cemented**

MATERIALS

Cobalt-Chromium alloy without coating : Cr: 27.00% - 30.00% / Mo: 5.00% - 7.00% / Ni ≤ 0.50% / Fe ≤ 0.75% / C ≤ 0.35% / Mn ≤ 1.00% / Si ≤ 1.00% / W ≤ 0.20% / P ≤ 0.020% / S ≤ 0.010% / N ≤ 0.25% / Al ≤ 0.10% / Ti ≤ 0.10% / B ≤ 0.010% / Co: Balance	**uni score femoral component - cemented**
Cobalt-Chromium alloy : Cr: 27.00% - 30.00% / Mo: 5.00% - 7.00% / Ni ≤ 0.50% / Fe ≤ 0.75% / C ≤ 0.35% / Mn ≤ 1.00% / Si ≤ 1.00% / W ≤ 0.20% / P ≤ 0.020% / S ≤ 0.010% / N ≤ 0.25% / Al ≤ 0.10% / Ti ≤ 0.10% / B ≤ 0.010% / Co: Balance **Hydroxyapatite coating** (Ca5(PO4)3OH): 100%) **& titanium undercoating** (C: ≤0.10% / H: ≤0.30 % / Fe: ≤0.60 % / N: ≤5.00 % / O: ≤10.00 % / Ti: Balance)	**uni score femoral component - cementless**
Cobalt-Chromium alloy Cr : 26.00% - 30.00% / Mo : 5.00% - 7.00% / Fe ≤ 0.75% / Mn ≤ 1.00% / Si ≤ 1.00% / C : 0.15% - 0.35% / Ni ≤ 1.00% / N ≤ 0.25% / Co : Balance **Hydroxyapatite coating** (Ca5(PO4)3OH): 100%) **& titanium undercoating** (C: ≤0.10% / H: ≤0.30 % / Fe: ≤0.60 % / N: ≤5.00 % / O: ≤10.00 % / Ti: Balance) **Polyetheretherketone (PEEK)** Homopolymer of PEEK: 100%. Possible traces of Mo, Cu, Pb, Hg, Cd, As, Bi, Sb, Sn.	**uni score tibial trays for fixed bearing insert - cementless (with peg)**

DEVICES EXPECTED LIFETIME

Based on literature and national registry data, about 89% of unicompartmental knee implants with all-polyethylene tibial component and about 90% of unicompartimental knee implant with tibial fixed bearing insert continue to function at 10 years after surgery. However, patients' factors such as weight, bone quality, activity level and other medical condition and comorbidities may increase or decrease the expected lifetime of any implantable orthopaedic device. **Please attend regular check-ups according to your surgeon's advice.**

Contraindications

At the time of the surgery, these conditions are not recommended :

- Pregnancy and breastfeeding.
- Destruction of other knee compartments.
- Destruction of bone or poor bone quality.
- Ligament instability.
- Knee deviation too great.
- Arthrosis requiring only a local treatment.
- Anatomic disorder.
- Infections.
- Severe mental, muscular, neurological, or vascular deficiencies affecting the knee.
- Allergy to the implanted materials.
- Age < 60 years *.
- Overweight: Body Mass Index (BMI) ≥ 25 kg/m² *.
- Playing sports intensively *

* Only for prosthesis with insert and cementless calf bone (tibia) part.

The use of fixation elements is contraindicated in cases of bone destructions or poor bone quality which may affect stability of the screw.

These conditions should be discussed with your surgeon. Any pathology (even if not listed above) must be mentioned to your surgeon beforehand as well.

Possible side effects

You must be informed about the side effects in relation with the device that might occur. Those recorded by Amplitude are all rare (lower than 1 per 100 cases). **Please consult your surgeon if any doubt.**

- Injury to a major artery or nerve in the lower limb.
- Disruption or rupture of the thigh tendons.
- Tear of a thigh muscle.
- Infection.
- Stiffness.
- Allergy to the implanted materials.
- Bone degeneration.
- Tissue reactions to prothetic debris and wear particles
- Bone fracture.
- Prosthesis loosening.
- Premature wear on joint surfaces.
- Prosthesis breakage.
- Friction/conflict between the prosthesis and the surrounding tissue.
- Pain.
- Instability.
- Prosthesis displacement.
- Prosthesis dislocation.
- Difficult recovery after major surgery.

Other events linked to the general risks of surgeries:

- Phlebitis, fat or pulmonary embolism.
- Bruises.
- Complex regional pain syndrome (Algoneurodystrophy)
- Bone ossification abnormalities.
- Poor bone healing.

You must also be aware of the risks and possible side effects of surgery - please ask your surgeon for further information.

After a joint replacement, you should pay attention during your daily life: any blow, fall or accident may **jeopardise your recovery or your implant lifetime .** Please ask your surgeon for further information.

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