IMPLANTS

For Total Knee Replacement

IMPORTANT PATIENT LEAFLET

score II

READ CAREFULLY THIS LEAFLET BEFORE SURGERY.

IT CONTAINS IMPORTANT INFORMATION FOR YOU.

WHAT IS IN THIS LEAFLET

Intended Use

The knee implant system is intended to replace the natural knee joint (total knee arthroplasty) through an artificial system.

Patients with a mature skeleton may be implanted with a total knee prosthesis in cases of severe joint pathology (cartilage wear, inflammation like arthritis or after an injury such as a bone fracture after a fall) and where other devices or treatments have failed.

Please ask your surgeon for details. The decision to implant a total knee prosthesis is left to the surgeon after evaluation of the risk/benefit balance and after discussion with you.

Devices Expected Lifetime

Based on literature and national registry, the expected 10-years survival rates are:

- 95% of SCORE II total knee prosthesis used in primary surgery
- 80% of SCORE II total knee prosthesis used in revision 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;
- Infections;
- Severe mental, muscular, neurological or vascular deficiencies affecting the limb in question.
- Destruction of bone or poor bone quality which may affect stability of the implant.
- Highly localized arthrosis requiring osteotomy or unicompartmental arthroplasty.
- Anatomic disorder requiring a constrained or hinge prosthesis.
- Allergy to the implant materials.

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

MATERIALS COMPOSITIONS AND DISTRIBUTIONS FOR KNEE IMPLANTS

Mass-to-mass ratio %

Cobalt-Chromium alloy Cr: 26.50% - 30.00% / Mo: 4.50% - 7.00% / Ni ≤ 1.00% / Fe ≤ 1.00% / C ≤ 0.35% / Mn ≤ 1.00% / Si ≤ 1.00% / Co: Balance	**SCORE II Femoral component - cemented** **SCORE Tibial baseplate - cemented**
Cobalt-Chromium alloy Cr: 26.50% - 30.00% / Mo: 4.50% - 7.00% / Ni ≤ 1.00% / Fe ≤ 1.00% / C ≤ 0.35% / Mn ≤ 1.00% / Si ≤ 1.00% / Co: Balance **Hydroxyapatite coating** (pentacalcium hydroxide tris(orthophosphate) Ca5(PO4)3OH: 100%) **& titanium undercoating** (C ≤ 0.10% / H ≤ 0.30% / Fe ≤ 0.60% / N ≤ 5.00% / O ≤ 10.00% / Ti: Balance)	**SCORE II Femoral component - cementless** **SCORE Tibial baseplate - cementless**
Polyethylene PE: 100%. Possible traces of Ti, Al, Ca, Cl	**SCORE II mobile bearing insert** **Patellar components**
Stainless steel C ≤ 0.08% / Si ≤ 0.75% / Mn: 2.00% - 4.25% / Ni: 9.00% - 11.00% / Cr: 19.50% - 22.00% / Mo: 2.00% - 3.00% / Nb: 0.25% - 0.80% / S ≤ 0.01% / P ≤ 0.025% / Cu ≤ 0.25% / N: 0.25% - 0.50% / Fe: Balance	**Standard keel (provided with tibial baseplates - cemented or cementless)** **Tibial augment for Total Knee Prosthesis - cemented** **Offset adapter for Total Knee Prosthesis** **Extension stem for Total Knee Prosthesis**

IMPLANTS YOU HAVE BEEN IMPLANTED WITH:

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

Associations with other devices have to be validated by Amplitude.

COMPONENTS

FEMORAL COMPONENTS

□ **SCORE II Femoral component - cementless**

□ **SCORE II Femoral component - cemented**

TIBIAL COMPONENTS

□ **SCORE Tibial baseplate – cementless**

□ **SCORE Tibial baseplate – cemented**

□ **SCORE II mobile bearing insert**

□ **Tibial augment for Total Knee Prosthesis - cemented**

□ **Offset adapter for Total Knee Prosthesis**

□ **Extension stem for Total Knee Prosthesis**

PATELLAR COMPONENTS

□ **Resurfacing patellar implant - cemented**

□ **Resurfacing patellar implant NM - cemented**

□ **Inset patellar implant – cemented**

□ **Inset patellar implant – cementless**

SPECIFIC WARNINGS & MRI INFORMATION

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 demonstrated that the implants are MR Conditional. A patient with one of these devices can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5T or 3T for a 15min-procedure.
- 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 operation mode only.
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.
- The image artefact caused by the device extends at maximum 99 mm when imaged with a gradient echo pulse sequence and a 1.5T or 3T MRI system. 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)

Amplitude recommends the following 45-minutes scanning sequence:

- 5 imaging sessions.
- Imaging session duration: 3 minutes.
- Time between imaging session: 6 minutes.

POSSIBLE SIDE EFFECTS

You must be informed about the side effects in relation to the device that might occur. Those recorded by Amplitude are all rare (lower than 1 per 1000 cases) or occasional* side effects (between 1 for 1000 cases and 1 for 100 cases).

Please consult your surgeon if any doubt.

- Difficult recovery after major surgery
- 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*
- Instability
- Pain
- Patellar problems
- Allergy to implanted materials
- Bone degeneration
- Tissue reactions to prosthetic debris and wear particles
- Bone fracture
- Prosthesis dislocation
- Prosthesis loosening
- Premature wear on joint surfaces
- Prosthesis breakage
- Prosthesis displacement
- Friction/conflict between the prosthesis and the surrounding tissue

Other events linked to the surgery or current knowledge can also occur:

- 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 **jeopardize your recovery or your implant lifetime**. Please ask your surgeon for further information.

WARNINGS AND PRECAUTIONS

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

- Overweight;
- Case history detailing infections and/or falls;
- Metabolic disorders that reduce your resistance or induce progressive bone deterioration;
- Local bone tumours;
- Severe bone deformities;
- Severe osteoporosis;
- Playing sports intensively;
- Playing risky sports or engaging in risky activities;
- Addictive behaviour.

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 **side effects not listed** in this leaflet, talk to your doctor or pharmacist. See page 6.

This leaflet has been written assuming the person receiving the implants will read it.

REPORTING ADVERSE EVENTS

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

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