IMPLANTS

For Total Knee Replacement

IMPORTANT PATIENT LEAFLET

score revision

READ CAREFULLY THIS LEAFLET BEFORE SURGERY.

IT CONTAINS IMPORTANT INFORMATION FOR YOU.

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Intended Use

The Total Knee system is intended to replace the natural knee joint through an artificial system in order 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 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 data, the expected 10-years survival rate are:

- 93% of SCORE Revision prosthesis used in primary surgery and
- 80% of SCORE Revision 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 knee.
- Destruction of bone or poor bone quality.
- Arthrosis requiring only a local treatment.
- Anatomic disorder.
- Allergy to implanted materials.

The use of the SCORE tibial baseplate cementless is contraindicated with the SCORE revision system in case of revision surgery.
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 Revision femoral component - cemented** **SCORE Tibial baseplate - cemented**
Polyethylene PE: 100%. *Represents 97.7% to 98.95% (Score Revision mobile bearing insert).* Possible traces of Ti, Al, Ca, Cl	**SCORE Revision mobile bearing insert** **Patellar components**
Stainless steel M30NW 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	**Femoral augments for Total Knee Prosthesis - cemented** **Standard keel (provided with tibial baseplate - cemented and femoral component - cemented** **Tibial augment for Total Knee Prosthesis - cemented** **Offset adapter for Total Knee Prosthesis** **Extension stem for Total Knee Prosthesis**
Stainless steel M25W Fe: balance / Cr: 17.00% - 19.00% / Ni: 13.00% - 15.00% / Mn: ≤ 2.00% / Mo: 2.25% - 3.00% / N: ≤ 0.10% / Cu: ≤ 0.50% / Si: ≤ 1.00% / C: ≤ 0.030% / S: ≤ 0.010% / P: ≤ 0.025% *Represents 2.3% to 1.05%*	**Metallic reinforcement** **(in the SCORE Revision mobile bearing insert)**
Titanium alloy Ti: >88.10% / Al: 5.50% - 6.75% / Va: 3.50% - 4.50% / Fe: < 0.30% / O: <0.20% / C: <0.08% / N: <0.05% / H: <0.02%	**Screw for femoral augments (provided with distal and posterior femoral augments)**

IMPLANTS YOU HAVE BEEN IMPLANTED WITH:

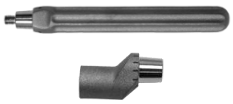
The surgeon needs to tick the boxes corresponding to the devices you have been implanted with.

Associations with other devices have to be validated by Amplitude.

FEMORAL COMPONENTS

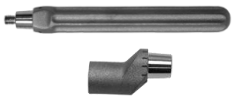
- ☐ **SCORE Revision femoral component** - cemented
- ☐ **Distal femoral augment for Total Knee Prosthesis** - cemented

- ☐ **Posterior femoral augment for Total Knee Prosthesis** - cemented
- ☐ **Extension stem for Total Knee Prosthesis**
- ☐ **Offset adapter for Total Knee Prosthesis**



TIBIAL COMPONENTS

- ☐ **SCORE Tibial baseplate** - cemented
- ☐ **SCORE Revision mobile bearing insert**
- ☐ **Tibial augment for Total Knee Prosthesis** - cemented
- ☐ **Extension stem for Total Knee Prosthesis**
- ☐ **Offset adapter for Total Knee Prosthesis**



PATELLAR COMPONENTS

- ☐ **Resurfacing patellar implant** - cemented
- ☐ **Resurfacing patellar implant NM** - cemented

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 a 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 operating mode only.
- 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)

Amplitude recommends the following 45-minutes scanning sequence:

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

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. Please consult your surgeon if any doubt.

Lower than 1 per 1000 cases:

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

Between 1 per 1,000 and 1 per 100 cases:

- Prosthesis loosening.
- Infection.
- Patellar problems.
- Pain.

Other events linked to the general risks of surgeries or known in the state of the art:

- 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

Pre-operative precautions:

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

- Overweight.
- History of infection or falls.
- Metabolic disorders.
- Local bone tumours.
- Severe bone deformities.
- Severe osteoporosis.
- Playing sports intensively.
- Playing risky sports or engaging in risky activities.
- Addictive behaviour.

Post-operative precautions:
Please inform your surgeon if anything strange happens that could harm the implant. It is also recommended to perform a medical check with you surgeon on a regular base after the operation to make sure the implant is working well. If you hear any noise coming from the replaced joint, you should tell the surgeon, even if you consider that this has no impact on the device performance.

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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