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 7.

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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amplitude

IMPLANTS

For Total Hip Replacement

IMPORTANT PATIENT LEAFLET

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

WHAT IS IN THIS LEAFLET

Intended Use

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

Patients with a mature skeleton may be implanted with a total/partial hip 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/partial hip prosthesis is left to the surgeon after evaluation of the risk/benefit balance and after discussion with you.

Devices expected lifetime

The expected survivorships for the following hip implant systems are at least at 10 years:
- 95% for primary total hip replacement with a standard stem,
- 88% for primary total hip replacement with a lateralized stem,
- 84% for revision total hip replacement with a standard stem,
- 94% for hemiarthroplasty.

It can be reduced or extended depending on your activity level or events that could compromise implants integrity (falls. accidents…).

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;
- Allergy to the implants materials;
- Infections;
- Severe mental, muscular, neurological or vascular deficiencies affecting the limb in question;
- Destruction of bone or poor bone quality which may affect the stability of the implant.

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 rare (inferior to 1 for 1,000 cases). The following devices: EVOK recorded occasional side effects (between 1 for 1,000 cases and 1 for 100* cases).

Please consult your surgeon if any doubt.

- Difficult recovery after major surgery;
- Infection;
- Pain;
- Allergy to implanted materials;
- Bone degeneration*;
- Premature wear on joint surfaces ;
- Bone fracture;
- Prosthesis dislocation, displacement or loosening;
- Premature wear on joint surfaces;
- Prosthesis breakage;
- Conflict between the components of the prosthesis;
- Friction/conflict between the prosthesis and the surrounding tissue
- Noise from the prosthesis;
- Tissue reactions to prosthetic debris and wear particles;
- Uneven legs length*;
- Neurovascular disorders;

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

- Phlebitis, fat or pulmonary embolism;
- Bruises;
- Bone ossification abnormalities ;
- Poor bone healing.
- Serious/ fatal complication of orthopaedic surgery, involving bone cement

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.

Warnings and precautions

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

- Overweight; weight gain after surgery (especially for stems with weight restrictions);
- 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;
- Addictive behaviour;
- Playing sports intensively;
- Playing risky sports or engaging in risky activities.

SPECIFIC WARNINGS & MRI INFORMATION

The materials used in your implant may trigger security gates/scanners.

PLEASE INFORM PERSONNEL ABOUT YOUR IMPLANTED DEVICE.

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 3T for a 15min-procedure.
- Maximum spatial gradient field of 1.500Gauss/cm.
- Normal operation mode only;
- The image artefact caused by the implants extends approximately 118.5mm from these implants. MR images may be blurred next to the implants.

MAXIMUM MEASURED TEMPERATURE RISE
with 3T MRI, for a 15min procedure

EVOK stems - cementless	9.2°C (calorimetry WB-SAR of 4.71 W/kg)
F.A.I.R. stems—cementless	8.1°C (calorimetry WB-SAR of 4.08 W/kg)
All other implants	5.7°C (calorimetry WB-SAR of 2.06 W/kg)

Specific weight restrictions for the
Modular necks in association with OPTIMAL modular stems

High L/M Neck	Lateralized Neck Version Maximum patient weight: **90 kg**
L/M+10.5 Neck	Lateralized and Medialized Neck Versions Maximum patient weight: **90 kg**

Specific weight restrictions:

INITIALE stem Dysplastic	Size 121D Maximum patient weight: **72 kg**	
ACOR monobloc stem Lateralized	Size 1 Maximum patient weight: **60 kg**	
EVOK stem Standard	Size 7 Maximum patient weight: **68 kg**	Size 8 Maximum patient weight: **85 kg**
EVOK stem Lateralized	Size 8 Maximum patient weight: **64 kg**	Size 9 Maximum patient weight: **89 kg**

MATERIALS COMPOSITIONS AND DISTRIBUTIONS FOR HIP IMPLANTS

Mass-to-mass ratio %

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 **Hydroxyapatite coating & titanium undercoating** Ca5(PO4)3OH: 100% & C: ≤ 0.1% / H: ≤ 0.3% / Fe: ≤ 0.6% / N: ≤ 5,0% / O: ≤10.0% / Ti: Balance	**SATURNE** tripolar cup - Cementless **SATURNE II** dual mobility cup - Cementless
Stainless steel C: ≤ 0.08% / Si: ≤0.75% / Mn: 2.00% - 4.25% / Ni: 9.00% - 11.00% / Cr: 19.50% - 22.0% / 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	**SATURNE** tripolar cup - Cemented **E²** stem - Cemented **ACOR** monobloc stem - Cemented **EVOK** stem - Cemented **INITIALE and INITIALE revision** stem - Cemented **GENERIC and GENERIC revision** stems - Cemented **SPHERIC** bipolar cup Stainless Steel femoral head
BIOLOX® Delta ceramic Al_2O_3: 60.00 - 90.00% / ZrO_2 + HfO_2: 10.00 - 30.00% / HfO_2 in ZrO_2: ≤5.00% Intended additives: ≤10.0% Total amount of impurities ≤0.2%	Ceramic femoral head Ceramic revision femoral head **HORIZON II** liner
Cobalt-Chromium alloy Cr: 26.00% - 30.00% / Mo: 5.00% - 7.00% / Fe: ≤0.75% / Mn: ≤1.00% / C: ≤0.14% / Ni: ≤1.00% / N: ≤ 0.25% / Co: Balance	Cobalt-Chromium femoral head
Highly cross-linked Polyethylene PE: 100% Possible traces of Ti, Ca, Cl, Al.	**AUSTRAL** liner
Titanium alloy Al: 5.50% - 6.75% / Va: 3.50% - 4.50% / Fe: ≤0.30% / O: ≤0.20% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance **Hydroxyapatite coating & titanium undercoating** Ca5(PO4)3OH: 100% & C: ≤ 0.1% / H: ≤ 0.3% / Fe: ≤ 0.6% / N: ≤ 5,0% / O: ≤10.0% / Ti: Balance	**HORIZON II** cup with holes - Cementless **HORIZON II** cup without holes - Cementless
Titanium alloy Al: 5.50% - 6.75% / Va: 3.50% - 4.50% / Fe: ≤0.3% / O: ≤0.20% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance **Unalloyed titanium porous coating** O: ≤0.40% / Fe: ≤ 0.50% / C: ≤ 0.08% / H: ≤ 0.05% / N: ≤ 0.05% / Ti: Balance	**AUSTRAL** cup - Cementless
Titanium alloy Al: 5.50% - 6.75% / Va: 3.50% - 4.50% / Fe: ≤0.30% / O: ≤0.20% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance **Hydroxyapatite coating** $Ca_5(PO_4)_3OH$: 100%	**EVOK** stem - Cementless **F.A.I.R.** stem - Cementless **ACOR** monobloc stem - Cementless **INTEGRALE and** stem - Cementless **INTEGRALE revision** stem - Cementless **OPTIMAL** stem - Cementless
Titanium alloy Al: 5.50% - 6.75% / Va: 3.50% - 4.50% / Fe: ≤0.30% / O: ≤0.20% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance	Sleeve *(used with Ceramic revision femoral head)* Modular neck
Polyethylene PE: 100% Possible traces of Ti, Ca, Cl, Al.	**SATURNE** liner for tripolar cup

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.

ACETABULAR COMPONENTS

HORIZON II CUPS & LINERS RANGE

- ☐ **HORIZON II** cup (with holes) - Cementless
- ☐ **HORIZON II** liner to be inserted
- ☐ **HORIZON II** cup (without holes) with preassembled ceramic insert - Cementless

SATURNE CUPS & LINERS RANGE

- ☐ **SATURNE** tripolar cup - Cementless
- ☐ **SATURNE II** dual mobility cup - Cementless
- ☐ **SATURNE** tripolar cup - Cemented
- ☐ **SATURNE** liner for tripolar cup to be inserted

AUSTRAL CUPS & LINERS RANGE

- ☐ **AUSTRAL** or **C2** cup - Cementless
- ☐ **AUSTRAL** or **C2** liner to be inserted

SPHERIC RANGE

- ☐ **SPHERIC** bipolar cup

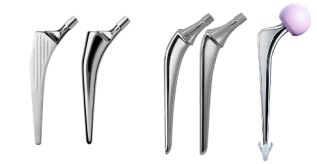
FEMORAL COMPONENTS

FEMORAL HEADS RANGE

- ☐ BIOLOX® *Delta* **Femoral head**
- ☐ Metal (Stainless steel) **Femoral head**
- ☐ Metal (Cobalt-Chromium) **Femoral head**
- ☐ BIOLOX® *Delta* **Revision Femoral head** with sleeve

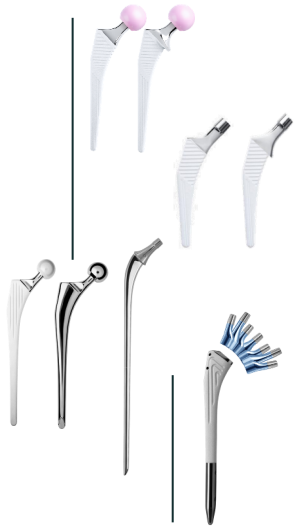
FEMORAL STEMS RANGES

- ☐ **INTEGRALE** femoral stem - Cementless
- ☐ **GENERIC** femoral stem - Cemented
- ☐ **INITIALE** femoral stem - Cemented
- ☐ **INITIALE** dysplastic femoral stem - Cemented
- ☐ **E²** femoral stem - Cemented



- ☐ **ACOR** anatomic monobloc stem **standard** - Cementless
- ☐ **ACOR** anatomic monobloc stem **lateralized** - Cementless
- ☐ **ACOR** anatomic monobloc stem **standard** - Cemented

- ☐ **EVOK** femoral stem **standard collarless** - Cementless or Cemented
- ☐ **EVOK** femoral stem **standard collared** - Cementless
- ☐ **EVOK** femoral stem **lateralized collarless** - Cementless
- ☐ **EVOK** femoral stem **lateralized collared** - Cementless
- ☐ **EVOK** femoral stem **high offset collarless** - Cementless
- ☐ **F.A.I.R.** femoral stem **standard collarless** - Cementless
- ☐ **F.A.I.R.** femoral stem **standard collared** - Cementless
- ☐ **F.A.I.R.** femoral stem **lateralized collarless** - Cementless
- ☐ **F.A.I.R.** femoral stem **lateralized collared** - Cementless



- ☐ **INTEGRALE** femoral revision stem - Cementless
- ☐ **GENERIC** femoral revision stem - Cemented
- ☐ **INITIALE** femoral revision stem - Cemented

- ☐ **OPTIMAL** revision modular stem - Cementless *(with modular necks)*
- ☐ **OPTIMAL** reconstruction modular stem - Cementless *(with modular necks)*