## 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.

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## Devices expected lifetime

The expected survivorships for the following hip implant systems are at least at 10 years:
- 95% for primary total hip replacement,
- 80% for revision total hip replacement,
- 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.**

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## 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.**

- Heavy surgery, difficult recovery;
- Infection;
- Pain*;
- Allergy to implant materials;
- Osteolysis*;
- Wear of the prosthesis with the presence of debris. sometimes poorly tolerated by the surrounding muscles and tendons;
- Fracture of the bones*;
- Dislocation, displacement or loosening* of the prosthesis;
- Premature wear of joint surfaces;
- Breakage of the prosthesis material;
- Conflict between the components of the prosthesis during movement;
- Noise in the prosthetic joint during movement;
- Poor tolerance of muscles and tendons in contact with the prosthesis (conflicts. friction)*;
- Uneven legs length;

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

- Phlebitis, fat or pulmonary embolism;
- Hematoma;
- Abnormal ossification;
- Poor healing of the bones.

**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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## 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)** |
| **All other implants** | **5.7°C (calorimetry WB-SAR of 2.06 W/kg)** |

**Specific weight restrictions for the Modular necks in association with ACOR modular stems and 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** |
| **All other neck versions** | **Lateralized and Medialized Neck Versions** Maximum patient weight: **100 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** (ISO 5832-9 standard) C: ≤ 0.08% / Si: ≤0.75% / Mn: 2.00% - 4.25% / Ni: 9.0% - 11.0% / Cr: 19.5% - 22.0% / Mo: 2.0% - 3.0% / Nb: 0.25% - 0.80% / S ≤0.01% / P: ≤0.025% / Cu: ≤0.25% / N: 0.25% - 0.50% / Fe: Balance | **SATURNE** tripolar cup - Cementless **SATURNE II** dual mobility cup - Cementless | **Titanium alloy** (ISO 5832-3 standard) Al: 5.5% - 6.75% / Va: 3.5% - 4.5% / Fe: ≤0.3% / O: ≤0.2% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance | | | | |
| **Hydroxyapatite coating & titanium undercoating** (ISO 13779-2, ISO 13779-6, ASTM F1185 and ASTM F1580 standards) $Ca_5(PO_4)_3OH$: 100% **&** O: ≤0.40% / Fe: ≤ 0.50% / C: ≤ 0.08% / H: ≤ 0.05% / N: ≤ 0.05% / Ti: Balance | | **Hydroxyapatite coating & titanium undercoating** (ISO 13779-2, ISO 13779-6, ASTM F1185 and ASTM F1580 standards) $Ca_5(PO_4)_3OH$: 100% **&** O: ≤0.40% / Fe: ≤ 0.50% / C: ≤ 0.08% / H: ≤ 0.05% / N: ≤ 0.05% / Ti: Balance | | | | |
| **Stainless steel** (ISO 5832-9 standard) C: ≤ 0.08% / Si: ≤0.75% / Mn: 2.00% - 4.25% / Ni: 9.0% - 11.0% / Cr: 19.5% - 22.0% / Mo: 2.0% - 3.0% / 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** stem - **Cemented** **INITIALE revision** stem - **Cemented** **GENERIC** stem - **Cemented** **GENERIC revision** stem - **Cemented** **SPHERIC** bipolar cup Stainless Steel femoral head | **Titanium alloy** (ISO 5832-3 standard) Al: 5.5% - 6.75% / Va: 3.5% - 4.5% / Fe: ≤0.3% / O: ≤0.2% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance **Unalloyed titanium porous coating** (ASTM 1580 standard) O: ≤0.40% / Fe: ≤ 0.50% / C: ≤ 0.08% / H: ≤ 0.05% / N: ≤ 0.05% / Ti: Balance | **EVOK** stem - **Cementless** **F.A.I.R.** stem - **Cementless** **ACOR** monobloc stem - **Cementless** **INTEGRALE** stem - **Cementless** **INTEGRALE revision** stem - **Cementless** **OPTIMAL** stem - **Cementless** **ACOR** modular stem - **Cemented** Sleeve *(used with Ceramic revision femoral head)* Modular neck Assembly screw and Locknut *(provided with EXTREME® stems)* | **AUSTRAL** cup - **Cementless** **C2** cup - **Cementless** | **HORIZON II** cup with holes - **Cementless** **HORIZON II** cup without holes - **Cementless** |
| **Stainless steel** (ISO 5832-1 standard) C: ≤ 0.030% / Si: ≤ 1.0% / Mn: ≤ 2.0% / P: ≤ 0.025% / S: ≤ 0.010% / N: ≤0.10% / Cr: 17.0% - 19.0% / Mo: 2.25% - 3.00% / Ni: 13.0% - 15.0% / Cu: ≤ 0.50% / Fe: Balance | Metal wires (x-ray markers) in **INITIALE** cup | **Titanium alloy** (ISO 5832-3 standard) Al: 5.5% - 6.75% / Va: 3.5% - 4.5% / Fe: ≤0.3% / O: ≤0.2% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance **Hydroxyapatite coating** (ISO 13779-2, ISO13779-6 and ASTM F1185 standards) $Ca_5(PO_4)_3OH$: 100% | | | | |
| **BIOLOX® Delta ceramic** (ISO 6474-2 standard) $Al_2O_3$: 60.0 - 90.0% / $ZrO_2$ + $HfO_2$: 10.0 - 30.0% / $HfO_2$ in $ZrO_2$: ≤5.0% Intended additives: ≤10.0% Total amount of impurities ≤0.2% | Ceramic femoral head Ceramic revision femoral head **HORIZON II** liner | **Titanium alloy** (ISO 5832-3 standard) Al: 5.5% - 6.75% / Va: 3.5% - 4.5% / Fe: ≤0.3% / O: ≤0.2% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance | | | | |
| **Cobalt-Chromium alloy** (ISO 5832-12 standard) Cr: 26.0% - 30.0% / Mo: 5.0% - 7.0% / Fe: ≤0.75% / Mn: ≤1.0% / C: ≤0.14% / Ni: ≤1.0% / N: ≤ 0.25% / Co: Balance | Cobalt-Chromium femoral head | **Titanium alloy** (ISO 5832-3 standard) Al: 5.5% - 6.75% / Va: 3.5% - 4.5% / Fe: ≤0.3% / O: ≤0.2% / C: ≤0.08% / N: ≤0.05% / H: ≤0.015% / Ti: Balance | **Polyethylene** (ISO 5834-1 and 5834-2 standards) PE: 100% Possible traces of Ti, Ca, Cl, Al. | | | |
| **Highly cross-linked Polyethylene** (ISO 5834-1 and ISO 5834-2 standards) PE: 100% Possible traces of Ti, Ca, Cl, Al. | **AUSTRAL** or **C2** liner | | | | | |

# 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 OR C2 CUPS & LINERS RANGE

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

### INITIALE CUP RANGE

- ☐ **INITIAL** cup - Cemented

### SPHERIC RANGE

- ☐ **SPHERIC** bipolar cup

## FEMORAL COMPONENTS

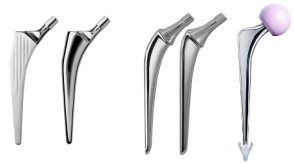
### FEMORAL HEADS RANGE

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

- ☐ BIOLOX® *Delta* **Revision Femoral head** with sleeve

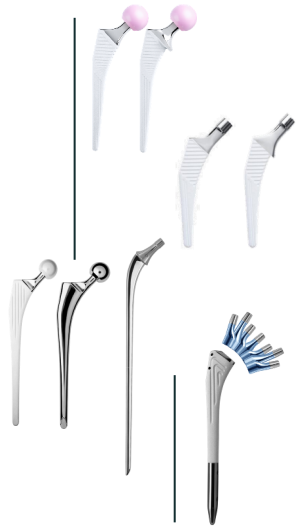
### FEMORAL STEMS RANGES

- ☐ **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
- ☐ **ACOR** anatomic modular stem - Cementless *(with modular necks)*
- ☐ **ACOR** anatomic modular stem - Cemented *(with modular necks)*

- ☐ **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)*