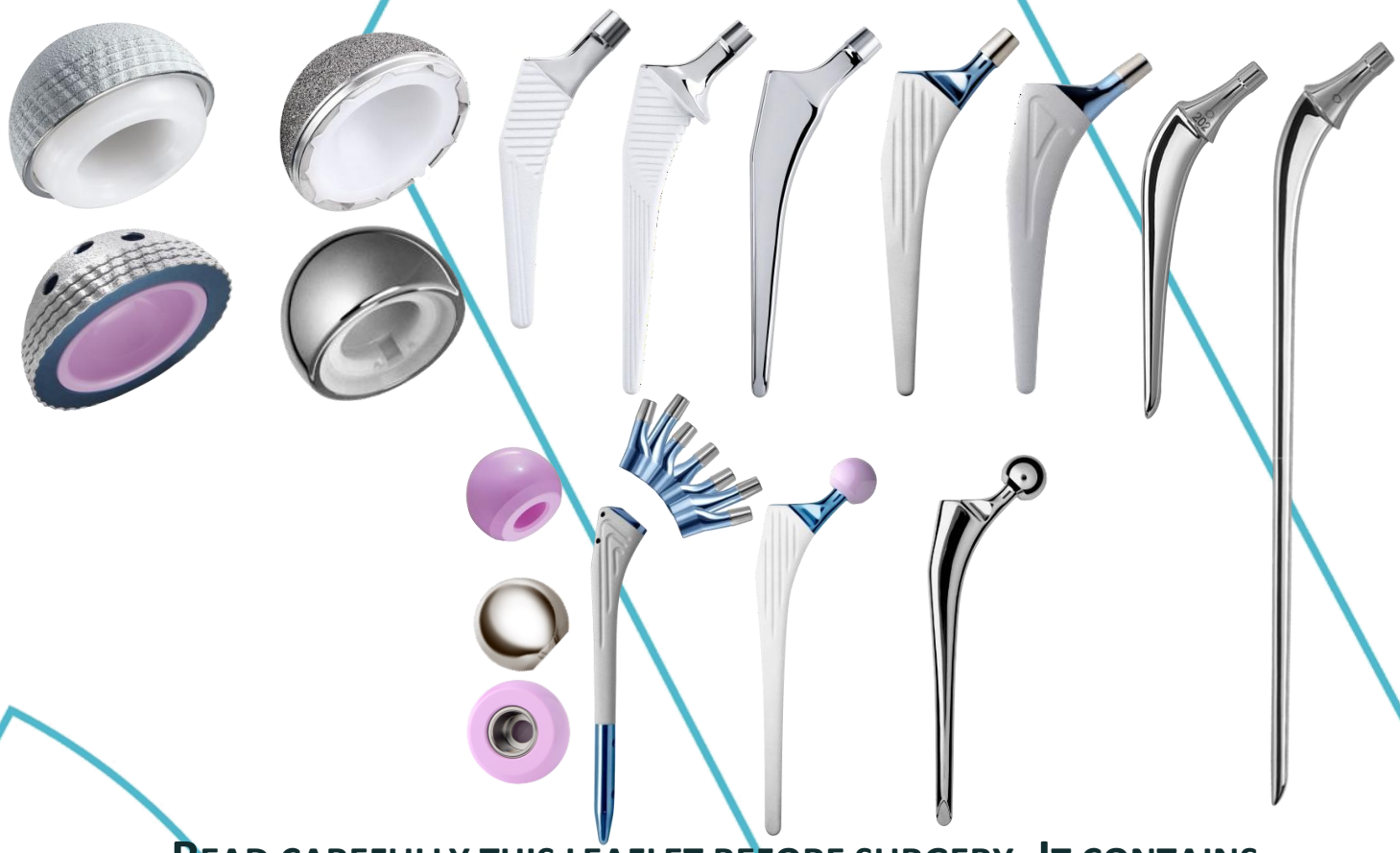
IMPLANTS

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 (only for components made of CoCr alloy);
- 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.

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** dual mobility 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% - 22.00% / 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	**SATURNE** Tripolar cup - **Cemented** **E2** stem - **Cemented** **ACOR** monobloc stem - **Cemented** **EVOK** stem - **Cemented** **INITIALE and INITIALE revision** stems - **Cemented** **GENERIC and GENERIC revision** stems - **Cemented** **SPHERIC** bipolar cup Stainless Steel femoral head
BIOLOX® Delta Ceramic Al2O3: 60.0 - 90.0% / ZrO2 + HfO2: 10.0 - 30.0% / HfO2 in ZrO2: ≤5.0% 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**
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 **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** Ca5(PO4)3OH: 100%	**EVOK** stem - **Cementless** **F.A.I.R.** stem - **Cementless** **ACOR** monobloc stem - **Cementless** **INTEGRALE** 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 Threaded pin – Ø4,7 mm
Polyethylene PE: 100% Traces possibles de Ti, Ca, Cl, Al.	**SATURNE** liner for dual mobility cup

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.

ACETABULAR COMPONENTS

HORIZON II CUPS & LINERS RANGE

- ☐ **HORIZON II** Cup (with holes) – Cementless
- ☐ **HORIZON II** liner to be inserted

SATURNE CUPS & LINERS RANGE

- ☐ **SATURNE** dual mobility cup – Cementless
- ☐ **SATURNE II** dual mobility cup – Cementless
- ☐ **SATURNE** dual mobility cup – Cemented

- ☐ **SATURNE** liner for dual mobility cup to be inserted

AUSTRAL CUPS & LINERS RANGE

- ☐ **AUSTRAL** cup – Cementless

- ☐ **AUSTRAL** liner to be inserted

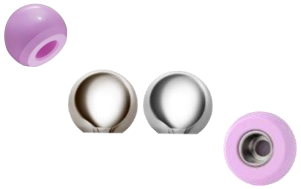
SPHERIC RANGE

- ☐ **SPHERIC** bipolar cup

FEMORAL COMPONENTS

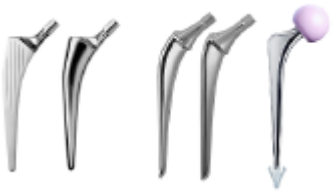
FEMORAL HEADS RANGE

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



FEMORAL STEMS RANGE

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

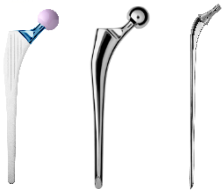


- ☐ **ACOR** anatomic monobloc stem **standard** - Cementless
- ☐ **ACOR** anatomic monobloc stem **lateralized** - Cementless
- ☐ **ACOR** anatomic monobloc stem **standard** - Cemented

- ☐ **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 **collared -** Cementless

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



- ☐ **OPTIMAL** revision modular stem - Cementless *(with modular neck)*
- ☐ **OPTIMAL** reconstruction modular stem - Cementless *(with modular neck)*
- ☐ Threaded pin – Ø4,7 mm

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 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 15 min 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 version Maximum patient weight: 90 kg

Specific weight restrictions:		
INITIALE stem Dysplasia	Size 121D Maximum patient weight: 72 kg	
ACOR 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

POSSIBLE SIDE EFFECTS

You must be informed about the side effects in relation to the device that might occur. Those recorded by Amplitude are rare (inferior to 1 out of 1,000 cases). The following devices recorded occasional side effects (between 1 out of 1,000 cases and 1 out of 100 cases): EVOK stem[1], BIOLOX® *Delta* femoral heads[2], INTEGRALE/GENERIC stems[3], INTEGRALE revision stem[4], GENERIC revision stem[5], INITIALE revision stem[6], OPTIMAL[8], ACOR monobloc cementless lateralized[9], AUSTRAL[10], M30NW and CoCr femoral heads[11]. The effects in red are recorded as 'frequent' for concerned devices (between 1 out of 100 cases and 1 out of 10 cases).

Please consult your surgeon if any doubt.

- Allergy to implanted materials,
- Bone degeneration,
- Bone fracture[1, 3, 4, 5, 6, 8, 10],
- Conflict between the components of the prosthesis,
- Difficult recovery after major surgery,
- Friction/conflict between the prosthesis and the surrounding tissue,
- Infection[1, 2, 4, 5, 6, 8, 10],
- Neurovascular disorders,
- Noise from the prosthesis,
- Pain,
- Premature wear on joint surfaces,
- Prosthesis breakage,
- Prosthesis dislocation[1, 4, 5, 10],
- Prosthesis displacement[8],
- Prosthesis loosening[4, 5, 9, 10],
- Tissue reactions to prosthetic debris and wear particles,
- Uneven legs length.

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

- Bone ossification abnormalities.
- Bruises.
- Phlebitis, fat or pulmonary embolism.
- Poor bone healing.
- Serious/ fatal complication of orthopaedic surgery, involving bone cement (only for cemented stems).

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; 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.

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.

AMPLITUDE
11 cours Jacques Offenbach – ZA Mozart 2 – 26000 VALENCE – France
https://implantcard.amplitude-ortho.com

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