

Information for patients carrying an implant

BI-MENTUM™ cementless cup and PE liner

BI-MENTUM™ PressFit cup



BI-MENTUM™ Plus cup



BI-MENTUM™ Revision cup



BI-MENTUM™ PE Liner



You have been implanted with a BI-MENTUM™ cementless cup and a BI-MENTUM™ PE Liner.

Before your surgery, your surgeon informed you of the contraindications, complications and possible side effects related to hip surgery.

Recommandations :

Your prosthesis has a lifespan of approximately 15 years for a primary surgery and 10 years for a revision surgery. However, these lifespans will depend on several factors such as your physical activity and your weight.

Certain precautions must be followed daily:

- Sleeping preferably on his back or on his side with a cushion between his legs,
- Taking a shower instead of a bath,
- Using a bar or a stable support to get out of the bath,
- Raising the height of the toilets and installing a support bar,
- Avoiding excessively deep armchairs,
- Getting dressed and putting on shoes in a seated position and using a shoehorn,
- Placing the knee of the operated leg on the floor or putting the operated leg behind in order to bend down,
- Getting into or out of the car by sitting with his back to the seat and pivoting with legs together in a flexed position.

Materials constituting your implant:

BI-MENTUM™ cementless cup is made in 100% of stainless steel according to ISO 5832-1 standard and is coated with titanium according to ISO 13179-1 standard and with hydroxyapatite according to ISO 13779-2 standard.

Pegs, used with BI-MENTUM™ Plus and Revision cups, are made in 100% of stainless steel according to ISO 5832-1 standard and is coated with alumina Al₂O₃.

BI-MENTUM™ PE Liner is made in 100% of polyethylene according to ISO 5834-2 standard.

Magnetic resonance medical imaging :

If you undergo an examination involving magnetic and electro-magnetic fields, you must warn the operator that you have an artificial joint and show him your implant card.

Standardized non-clinical testing have shown that a patient with SERF hip implant can be scanned safely immediately after implantation, under the following conditions:

- Nominal value(s) of static magnetic field : 1,5 or 3,0 T (Tesla)
- Maximum spatial field gradient : 27.3T/m (Tesla/meter) at 1.5T and 13.6T/m at 3T,
- RF excitation : circularly polarized (CP)
- RF transmit coil type : whole body transmit coil, Head RF transmit-receive coil
- Maximum whole body SAR at 1,5 and 3,0 T (tesla) : 2,0 W/kg (watt / kg)
- Limits on scan duration : 2,0 W/kg (watt/kg) whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
- MR image artefact : the presence of this implant is not expected to produce an image artefact extending further than 132 mm

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Follow-up after implantation:

It is important to inform your surgeon of any discomfort and / or any event concerning your operated hip (ex: fall, persistent pain, etc.).

You should also follow the advice of your surgeon and, upon request, submit to periodic checks to detect the appearance of possible complications.

Summary of safety and clinical performances:

Summary of safety and clinical performances of BI-MENTUM™ PressFit cup, BI-MENTUM™ Plus cup, BI-MENTUM™ Revision cup and BI-MENTUM™ PE liner is available from the manufacturer on request (in the absence of EUDAMED database) to the following e-mail address serf@serf.fr and by phone on +33(0)4 72 05 60 10.

Meaning of the symbols on your implant card:

<p> Patient name.</p> <p> Date of implantation.</p> <p> Name and address of the implanting healthcare institution and provider.</p> <p> Information website for patients.</p> <p> Catalogue number.</p> <p> Batch number.</p> <p> Sterilized using irradiation</p>	<p> Use by <i>(if the device is not implanted)</i></p> <p> Manufacturer.</p> <p> Symbol preceding the constituent materials of the implant.</p> <p> Conditional magnetic resonance.</p> <p> Cementless device.</p> <p> Unique device identification</p>
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If you have any questions please do not hesitate to contact your surgeon.