

Information for patients carrying an implant

Cementless femoral stem LIBRA®

Standard
cementless stem
LIBRA® HA



Collared standard
cementless stem
LIBRA® HA A



Lateralized
cementless stem
LIBRA® HA OF



You have been implanted with a cementless femoral stem LIBRA®.

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

Recommendations :

Your prosthesis has a lifespan of approximately 15 years. However, this lifespan 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:

The implant is a femoral stem made in 100% of titanium alloy according to ISO 5832-3 standard and coated with hydroxyapatite according to ISO 13779-6 et ISO 13779-2 standards.

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:

- Static magnetic field of 1.5 or 3 T (Tesla) with a maximum force product values of 43.35 T²/m,
- Maximum spatial gradient magnetic field of 7.4T/m (Tesla/mètre) at 1.5T and 12T/m at 3T,
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of limited to Normal operating mode (2-W/kg) during 8 continuous minutes of scanning with a 1,5 T MRI or during 15 continuous minutes of scanning with a 3T MRI,
- Maximal gradient slew rate of 120 T/m/s (Tesla/mètre/seconde) at 1.5T and 200 T/m/s at 3T.

The quality of the MRI image may be degraded if the region of interest is in the same area as the implant or is close to it.

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 LIBRA® HA, LIBRA® HA A, LIBRA® HA OF femoral stems 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.

**If you have any questions
please do not hesitate to contact your surgeon.**

Meaning of the symbols on your implant card:

 Patient name.

 Date of implantation.

 Name and address of the implanting healthcare institution and provider.

 Information website for patients.

REF Catalogue number.

LOT Batch number.

UDI Unique device identification.

STERILE R Sterilized using irradiation

 Use by *(if the device is not implanted)*

 Manufacturer.

Mat. Symbol preceding the constituent materials of the implant.

 Conditional magnetic resonance.

Cementless Cementless device.

 Maximum patient weight recommended by SERF.

 Mean taper angle.