



Information for patients carrying an implant

HYPE[®] SC cementless Stems



You have been implanted with a Hype[®] SC cementless hip stem.

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. However, this lifespan will depend on how you will use it and, in particular, on your physical activity and your weight load.

Certain precautions must be followed daily:

- Sleeping preferably on your back or on your side with a cushion between your 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 your back to the seat and pivoting with legs together in a flexed position.

Materials constituting your implant :

The HYPE[®] cementless stems is made from titanium alloy according to ISO 5832-3 standard with a coating of titanium according to ISO 13179-1 standard and hydroxyapatite according to ISO 13779-2 standard.

MRI Safety Information:

If the patient undergoes an examination involving magnetic and electro-magnetic fields, he must say that he has an artificial joint.

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

- static magnetic field of 1.5 or 3 Tesla with a maximum force product B0*[dB0/dr] value of 44.65 T2/m (Tesla2/meter),
- maximum spatial gradient magnetic field of 28.37 T/m (Tesla/meter) at 1.5 T and 14.18 T/m at 3 T,
- maximum MR system reported whole-body-averaged specific absorption rate (SAR) 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.

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



MRI Safety Information:

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 and the table below.

Standardized non-clinical testing have shown that a patient with a Hype[®] cementless hip stem may be safely scanned under the following conditions:

| Name / Identification of the device | Hype [®] SC cementless hip stem |
|---|--|
| Nominal value(s) of Static Magnetic Field [T] | 1.5T and 3.0T |
| Maximum Spatial Field Gradient [T/m and gauss/cm] | 30 T/m (3,000 gauss/cm) |
| RF Excitation | Circularly Polarized (CP) |
| RF Transmit Coil Type | Whole body transmit coil. Head RF transmit-receive coil |
| Operating Mode | Normal Operating Mode (subject to RF Conditions below) |
| RF Conditions | For 1.5 T Scanners: maximum Whole-body SAR of 1 W/kg for 60 min of continuous RF (a sequence or back to back series/scans without breaks) for any landmark, or maximum Whole-body SAR of 2 W/kg for 60 min of continuous RF (a sequence or back to back series/scans without breaks) if implanted device is at least 40 cm from isocenter. |
| | For 3.0 T Scanners: maximum Whole-body SAR of 0.5 W/kg for 60 min of continuous RF (a sequence or back to back series/scans without breaks) for any landmark, or maximum Whole-body SAR of 2 W/kg for 60 min of continuous RF (a sequence or back to back series/scans without breaks) if implanted device is at least 40 cm from isocenter |
| MR Image Artifact | The presence of this implant may produce an image artifact |

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

Failure to follow these conditions may result in injury.

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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.

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

Meaning of the symbols on your implant card:

