serf PATIENTINFOS

Information for patients carrying an implant

NOVAE® cups and CI E liner

SUNFIT TH	NOVAE E TH	COPTOS TH
		

NOVAE STICK	CI E
	

You have been implanted with a NOVAE cup and CI E liner.

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 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:

NOVAE STICK cup is made in 100% of stainless steel according to ISO 5832-1 standard.

SUNFIT TH, NOVAE E TH and COPTOS TH cups are made in 100% of stainless steel according to ISO 5832-1 standard and are coated with titanium according to ISO 13179-1 standard and with hydroxyapatite according to ISO 13779-2 standard.

Pegs, used with NOVAE E TH and COPTOS TH cups, are made in 100% of stainless steel according to ISO 5832-1 standard and is coated with alumina Al_2O_3.

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.

<u>In case of SERF stem + SERF head/insert/cup association:</u>
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 B0*[dB0/dr] value of 44,65 T^2/m ($Tesla^2/meter$),
- Maximum spatial gradient magnetic field of 28,37T/m (Tesla/meter) at 1.5T and 14,18T/m at 3T,
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Watt/kg)

during 15 continuous minutes of scanning with a 3T MRI or during 8 continuous minutes of scanning with a 1,5T MRI.

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.

In case of STRYKER stem/head + SERF insert/cup association:

A patient with the subject Serf hip devices combined with Stryker hip devices may be safely scanned under the following conditions. Failure to follow these conditions may result in injury:

Device name	Subject Stryker Hip Devices
Static Magnetic Field Strength (Bo)	1.5T or 3.0T
Maximum Spatial Field Gradient	3000 Gauss/cm (30T/m)
RF Excitation	Circularity Polarized (CP)
RF Transmit Coil Type	Whole Body
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	1.0 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan duration	Patients can be scanned at 1 W/kg whole-body average SAR for 15 minutes, followed by 15 minutes of wait time. This sequence can be repeated twice in 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.

- Scan duration: Under the scanning conditions and sequence defined above, these devices are expected to produce a temperature rise of less than 5.0 °C.
- MR Image Artifact: In nonclinical testing, the image artifact caused by the device extends approximately 84 mm from the device when imaged with a gradient echo pulse sequence using a 3.0 T/128 MHz MR system.

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 SUNFIT TH cup, NOVAE E TH cup, COPTOS TH cup, NOVAE STICK cup and CI E 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:

	Patient name.		Use by (if the device is not implanted).
	Date of implantation.		Manufacturer.
	Name and address of the implanting healthcare institution and provider.		Symbol preceding the constituent materials of the implant.
	Information website for patients.		Conditional magnetic resonance.
	Catalogue number.		Cementless device.
	Batch number.		Unique device identification.
	Sterilized using irradiation.		Cemented device.

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