

## Information for patients carrying an implant

### NOVAE® cementless cups CI E liner

SUNFIT TH cup



NOVAE E TH cup



COPTOS TH cup



CI E liner



You have been implanted with a NOVAE cementless cup and 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:**

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 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<sub>2</sub>O<sub>3</sub>.

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:

- static magnetic field of 1.5 or 3 T (tesla) with a maximum force product B0\*[dB0/dr] value of 44.65 T<sup>2</sup>/m (tesla<sup>2</sup>/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) of 2 W/kg (Watt/kg) during 15 continuous minutes of scanning with a 3 T MRI and during 8 continuous minutes of scanning with a 1.5 T 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.

**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, NOVAE E TH, COPTOS TH cups 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](mailto: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.



Catalogue number.



Batch number.



Sterilized using irradiation



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



Manufacturer.



Symbol preceding the constituent materials of the implant.



Conditional magnetic resonance.



Cementless device.



Unique device identification