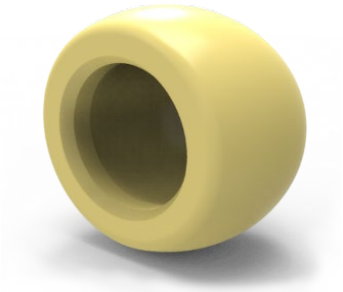
serf PATIENTINFOS

Information for patients carrying an implant

NOVAE® Dual mobility acetabular cups

SUNFIT TH cup	NOVAE E TH cup	COPTOS TH cup
		

NOVAE STICK cup	CI E liner	XPEO-E liner
		

VCI Screw


You have been implanted with a NOVAE® Dual mobility acetabular cup.

A NOVAE® Dual mobility acetabular cup consists of one of four cups (SUNFIT TH, NOVAE E TH with its pegs, COPTOS TH with its pegs, NOVAE STICK) combined with a mobile liner (CI E liner or XPEO-E liner).
VCI screws may also have been used with NOVAE E TH or COPTOS TH cup.

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, 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 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:

- SUNFIT TH, NOVAE E TH and COPTOS TH cups are made from 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 associated with NOVAE E TH and COPTOS TH cups are made from stainless steel according to ISO 5832-1 standard.
- The NOVAE STICK cup is made from stainless steel according to ISO 5832-1 standard.
- The CI E liner is made from ultra-high-molecular-weight polyethylene according to ISO 5834-2 standard.
- The XPEO-E liner is made of highly crosslinked ultra-high-molecular-weight polyethylene stabilized with an antioxidant (Vitamin E)
- VCI screws are made from stainless steel according to the ISO 5832-1 standard.

Note: the plastic piece shown on NOVAE STICK labels is only an accessory for implantation of the cup. ***It is not implanted*** *and was discarded after your surgery.*

MRI Safety Information:

Joint replacement implants may contain metal that may interact with the magnetic or electronic fields used for Magnetic Resonance Imaging (MRI).
If you undergo an MRI exam, you must warn the operator that you have an artificial joint and show them your implant card and the scan conditions in the tables.

Scan conditions depend on the implants composing the prosthesis; check the name of implant and company on each implant card.

SERF cup/head/stem association

If the NOVAE® Dual mobility acetabular cup is associated with only SERF implants, the patient may be safely scanned under the following condition:

Name / Identification of the device	NOVAE® Dual mobility acetabular cup
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.

SERF cup + Stryker Orthopaedics head/stem association

If the NOVAE® Dual mobility acetabular cup is associated with implants from Howmedica Osteonics Corp (herein referred to as Stryker Orthopaedics), the patient may be safely scanned under the following condition:

Name / Identification of the device	NOVAE® Dual mobility acetabular cup
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly 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 1W/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

Failure to follow these conditions may result in injury.

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:


Patient identification


Date of implantation


Name and address of the implanting healthcare institution and provider


Patient information website

Catalogue number

Batch code

Unique device identifier


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


Manufacturer

Symbol preceding the constituent materials of the implant.

MR Conditional

Sterilized using irradiation

Uncemented implant

Cemented implant

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