



Information for patients carrying an implant

# HYPE® cup



- **HYPE® cup** – Cementless acetabular cup
- **Insert HIC** – BioloX® delta ceramic liner
- **Insert HIPER** – Lipped polyethylene liner



You have been implanted with an HYPE® acetabular cup.

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 how you will use it and in particular your physical activity and your weight load.

Certain precautions must be followed daily for the period determined by your surgeon:

- 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:

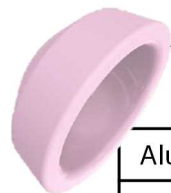
The implant is a cup made of titanium alloy, coated with titanium and hydroxyapatite, to which a ceramic or polyethylene insert is attached.

Here is the chemical element composition of metallic materials for the HYPE® cup:



| HYPE      | Cup              | Coating  |
|-----------|------------------|--|
|           | % titanium alloy | % Porous titanium  |
| Titanium  | Main item        | Main item  |
| Aluminium | [5,5 ; 6,5]      | -  |
| Vanadium  | [3,5 ; 4,5]      | -  |
| Iron      | ≤ 0,3            | ≤ 0,6  |
| Oxygen    | ≤ 0,2            | ≤ 10   |
| Carbon    | ≤ 0,08           | ≤ 0,1  |
| Nitrogen  | ≤ 0,05           | ≤ 5  |
| Hydrogen  | ≤ 0,015          | ≤ 0,2  |
|           |                  | Hydroxyapatite   |
|           |                  | Calcium phosphate ceramic with the formula: $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ . |

Here is the chemical element composition of the materials for the liner:



| HIC                                     | % ceramic (liner) |
|---|-------------------|
| Alumina                                 | [60 ; 90]         |
| Zirconium $\text{ZrO}_2 + \text{HfO}_2$ | [10 ; 30]         |
| HfO2 content in $\text{ZrO}_2$          | ≤ 5               |
| Additives                               | ≤ 10              |
| Total amount of impurities              | ≤ 0,2             |

**OR**



| HIPER   |
|---|
| Ultra High Molecular Weight Polyethylene (UHMWPE) Type 2 $(\text{C}_2\text{H}_4)_n$ |

**Note:** Depending on your preoperative bone condition, optional screws (VS screws) could be implanted. If this is the case, these screws are made of a titanium alloy (same composition as the HYPE cup).

### 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  $B_0 \cdot [dB_0/dr]$  value of  $44.65 \text{ T}^2/\text{m}$  ( $\text{Tesla}^2/\text{meter}$ ),
- Maximum spatial gradient magnetic field of  $28.37 \text{ T/m}$  ( $\text{Tesla}/\text{mètre}$ ) at 1.5 T and  $14.18 \text{ T/m}$  at 3 T,
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of  $2 \text{ W/kg}$  ( $\text{Watt/kg}$ ) for 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 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.   |
|  | Serial number.  |

|  |  |
|--|--|
|   | Unique device identification.                              |
|  | Sterilized using irradiation.                              |
|   | Use by (if the device is not implanted)                    |
|  | Cementless implant.  |
|   | Symbol preceding the constituent materials of the implant. |
|   | Conditional magnetic resonance.                            |
|   | Manufacturer.  |