Parc ESTER - 1, rue Columbia - 87068 Limoges (France)
tél. +33 5 55 69 12 12 - fax. +33 5 55 35 06 50

CE 1014

INSTRUCTIONS FOR USE **ENGLISH**
NT/HA04/01/D (Last revision : April 2014)

This device must be used by qualified and trained staff, and who have read carefully these instructions and assimilated the surgical technique. This device is sterile and for single use.

Acetabular Implant

1. Description of the device

The **Acetabular Implant** is designed for hip reconstruction. This device exists in different models: cemented or cementless, with or without coating, with or without screw fixation or stud fixation, with dual mobility or not.
It is composed of one or several parts (including hoop and core) allowing variations.
Cemented acetabular monoblocks acetabular joint stops are in HDPE (ISO 5834-1 Standard). Additional studs for cemented acetabular components are in PMMA (ISO 7391-1 Standard).
Hoops are in titanium alloy (ISO 5832-3 Standard) or in chrome-cobalt alloy (ISO 5832-8 Standard) and can be coated, as the case may be, with hydroxyapatite (HAP - ISO 13779-2 Standard) and/or with alumina (Al2O3 – ISO 6474 Standard) and/or with sprayed titanium.
Inserts are in dense ceramic (ISO 6474 and ISO 13356 Standards) or in HDPE (ISO 5834-1 Standard).
Locking screws are in titanium alloy (ISO 5832-3 Standard) or in stainless steel (ISO 5832-9 Standard).

All of the I.Céram® components (hoop, insert, screw or stud) enable to realize variations providing to respect the dimensional compatibility of the parts and the materials. These variations must be realized with components manufactured or expressly approved by I.Céram®.

2. Packaging – Sterilization – Resterilization

Components of the **Acetabular Implant** are packed, as the case may be, in double or triple pack (example: peelable bag, tough blister).
The sterilization of each of these components is done by Gamma radiation at the minimum dose of 25 kGy. A sterilization mark, red if sterile, is on the box and another one is appended on the pack closest to the implant.
I.Céram® guarantees the implants' sterility providing that the pack is neither open nor damaged.
Each **I.Céram®** implant is for single use and cannot be sterilized again**. I.Céram®'**s responsibility is not involved in the case of the resterilization of one or several implants by the user. The reuse or resterilization of a single-use medical device is likely to induce undesirable clinical reactions from the patient (infection, embolism, poisoning). Desterilized implants are sent back to **I.Céram®.**
The sterilization of test implants and ancillaries is mandatory and under the responsibility of the health care facility, in conformity with the ISO 17665-2.

3. Storage

The I.Céram® implants must be stored in their original packaging, in a dry place and away from the light so as to preserve the integrity of their packaging.

4. Marking

Each implant has the batch number linked with its fabrication. This batch number is also on all the tags that allow the implant's designation, information on the different files, including the patient's.
The communication of this batch number enables to trace back each implant's fabrication in its entirety, from raw material to sterilization.

5. Instructions and precautions

For an optimal implantation of the **Acetabular Implant**, it is necessary to use the I.Céram® instrumentation dedicated to these devices.
For the implantation's recommendations and the appropriate use of the instrumentation, the surgeon will refer to the surgical technique written by I.Céram®.
Before any use, it is necessary to control dates and sterilization marks as well as the integrity of every pack in order to check the implant's sterility. Each component, sterile and for single use, will be taken out off its packaging, at the time of the installation, aseptically and handled with caution by qualified staff so it is not damaged and so that its sterility is protected.
The assembly surfaces must imperatively be kept clean to ensure the perfect adjustment of the components.

6. Indications

The implantation's indication for the **Acetabular Implant** is decided by the surgeon and under their responsibility. Likewise, the assembly of the components (hoop, insert, screw or stud) of the **Acetabular Implant** is to the surgeon's discretion.

The **Acetabular Implant** is especially indicated for total or intermediate hip reconstruction in cases of intense pain, post-traumatic or degenerative rheumatoid arthritis, femoral fracture, avascular necrosis, congenital hip aplasia, revision of the anterior material *(1).*

7. Contraindications and limiting factors

The implantation of the **Acetabular Implant** is especially contraindicated in cases of recent infection, pronounced atrophy, of bone, muscular, neurologic or vascular deficiency, allergic reaction, of any concomitant illness likely to affect the implant's function *(1).*

Severe osteoporosis, infectious illness, overweight, smoking, drug addiction, alcoholism, mental disorder, intense physical activity, exposure to excessive loads, risk of conflict with another implant: those are the most common factors among those likely to limit the implant's lifespan *(1).*

8. Complications or adverse reactions

Inequality of the member's length, dislocation, premature wear, stress fracture, migration or loosening of the implant;
Bruise, late healing, cardiovascular disease, pulmonary embolism, infarcts, negative bone reaction, infection;
Those are the most common complications or adverse reactions *(1).*

9. Advice for the patient

To guarantee the lifespan of the implanted prosthesis, it is extremely important that the surgeon informs their patient about the device's limits, the acceptable weight, the movements, the levels of activity allowed and the postoperative aftercare to which they have to agree to. I.Céram® can provide the patient with the booklet "To live with a total hip prosthesis".
Cases of senility, mental disorders or alcoholism can lead the patient to ignore these recommendations, and provoke postoperative complications.

(1) : These lists are not exhaustive

Best before YYYY-MM		STERILE R	*Sterilized by Irradiation*
For single use		*See the user instructions*	
LOT	*Lot code*	*REF*	*Catalogue's reference*
Do not use if damaged packaging		*Manufacturer*	