

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.

Céramil® Bioceramics

1. Description of the device

CERAMIL bioceramics are designed to be used as addition wedges or bone filling on the entire skeleton.

These devices include tibial osteotomy addition wedges, calcaneum wedges, anterior tibial tuberosity derotation wedges, cervical cages, corporectomy blocks, lumbar cages, trepan caps, bone filling blocks.

2. Packaging – Sterilization – Resterilization

Céramil® bioceramics are packed, as the case may be, in double or triple pack (example: peelable bag, rigid 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.CERAM® guarantees the implants' sterility providing that the pack is neither open nor damaged.

Each I.CERAM® implant is for single use and cannot be sterilized again. I.CERAM®'s responsibility is not involved in the case of the resterilization of one or several implants by the user. The re-use 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.CERAM®.

The sterilization of test implants and instrumentation sets is mandatory and under the responsibility of the health care facility, in conformity with the ISO 17665-2.

3. Storage

The I.CERAM® 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

The use of additional osteosynthesis is compatible with Céramil® bioceramics

Screws, washers, plates and pins are in stainless steel (ISO 5832-1 or 5832-9 Standard).

Staples are in chrome-cobalt alloy and molybdenum (ISO 5832-4 Standard).

All the I.CERAM® components previously listed enables the realization of variations provided that the dimensional compatibility of the parts and the materials is respected. These variations must be realized with components manufactured or expressly approved by I.CERAM®.

For an optimal implantation of the Céramil® bioceramics, it is necessary to use the I.CERAM® instrumentation dedicated to this system.

For the implantation recommendations and the appropriate use of the instrumentation, the surgeon will refer to the surgical technique written by I.CERAM®. 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 staff so it is not damaged and so that its sterility is protected.

6. Indications

The implantation's indication for Céramil® bioceramics is decided by the surgeon and under their responsibility. Likewise, the use of additional osteosynthesis is for the surgeon's discretion.

Céramil® bioceramics are especially indicated for bone reconstruction at the level of the spine (cervical and lumbar), of the tibia, of the foot, of the skull. (1).

7. Contraindications and limiting factors

The implantation of céramil® bioceramics is especially contraindicated in cases of recent infection, pronounced atrophy, allergic reaction, of any concomitant illness likely to affect the implant's function (1).

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

Bruising, late healing, cardiovascular disease, pulmonary embolism, infarcts, negative bone reaction, infection;

Those are the most common complications or adverse effects (1).

9. Advice for the patient

To guarantee the implant's lifespan, it is extremely important that the surgeon informs their patient about the device's limits, the acceptable weight, the movements, the allowed activity levels and about the postoperative aftercare to which they have to agree to. 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



Sterilized by Irradiation



For single use



See the user instructions



Lot code



Catalogue's reference



Do not use if damaged packaging



Manufacturer