# Patient Information Leaflet

## Bone substitute MyBone® Custom

Product information :

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|---|---|
| Devicel model | Bone substitute - custom-made device<br>CND code : P.90.04.03<br>Non-biodegradable devices, filler and reconstructive |
| Brand | MyBone® Custom |
| Component | Synthetic hydroxyapatite |
| Legal manufacturer | **Cerhum s.a**<br>PIMW – Bât.56<br>Rue des Pôles, 1<br>4000 Liège<br>Belgium<br>www.cerhum.com |

## What is MyBone® Custom used for ?

MyBone® Custom is a patient-specific bone graft, it is designed according to a surgeon description and to medical imaging data (CAT-scan, X rays, RMI).

MyBone® Custom is intended for bone reconstruction of cranial, jaw and facial regions. Bone defects can be caused by traumatic lesions (as an accident or a fall), bone diseases, congenital malformations or tumor removal. This medical device can also be used for aesthetic purposes, for example to increase bone volume.

MyBone® Custom is designed to remain in your body for life. It is not intended for the reconstruction of growing bones.



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## Security information regarding the use of MyBone® Custom :

For safe use of the bone graft, you should carefully follow the instructions provided by your healthcare professional, as the level of care required differs from case to case.

It is important to follow these recommendations and inform your healthcare professional as soon as possible if you experience pain, redness, exposure of the implant, inflammation or infection in the implanted area.

Shocks to the implanted area should be avoided. A strong blow can lead to significant complications such as implant fracture and/or the need for additional surgery.

Avoid heavy loading of the implant during the bone healing phase (3 to 4 months), otherwise the implant may fail.

MyBone® Custom is made of hydroxyapatite, a compound that is fully compatible with medical imaging. Similarly, you are not at risk for magnetic resonance imaging. However, be sure to inform the medical staff that you are wearing your implant.

## What are the potential adverse effects ?

Any surgery has risks and can cause side effects such as pain, swelling, bleeding, infection and bruising.

In the case of MyBone® Custom, the following side effects may occur :

- non-union, delayed union or malunion between the natural bone and the implant
- superficial or deep wound infection
- opening of the wound
- exposure of the implant
- re-fracture
- osteomyelitis (bone infection)
- hematoma
- cellulitis
- cyst recurrence

These side effects are likely to cause deformation and/or failure of the implant. It is also possible to experience discomfort or changes in sensitivity in the implanted area.



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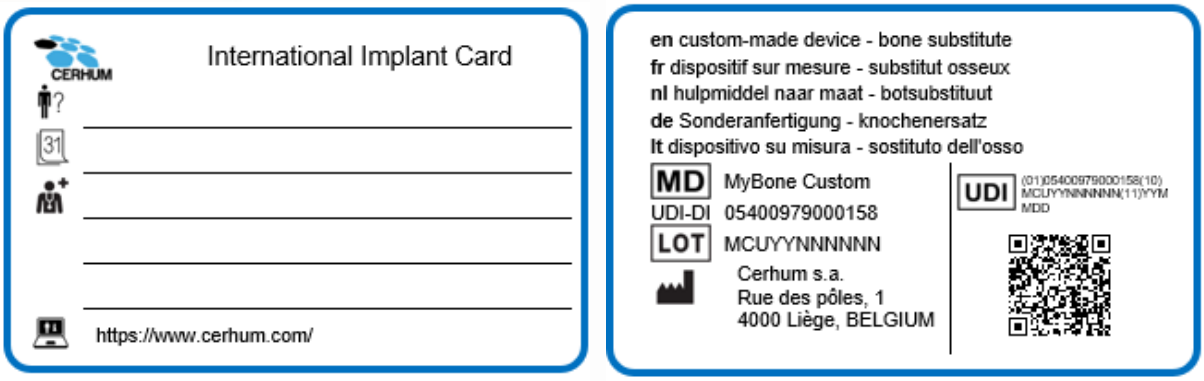
How can you identify your implant ?

You will receive an "International Implant Card" which will contain all the information necessary to identify your implant. The surgeon will also write information specific to your procedure.

Present this card to any healthcare professional who may ask for it.




* This card is representative and information may differ depending on the country in which the implant was purchased.

| | |
|---|---|
| | Patient name |
| | Date of implantation |
| | Name and address of the healthcare institution |
| | Patient information website |
| MD | Device name |
| UDI-DI | Device identifier |
| LOT | Batch number |
| | Manufacturer |
| UDI | Unique Device Identifier |

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