MyBone

Instructions for use

MyBone® Custom

Custom-made medical device

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INTRODUCTION

The **MyBone**® Custom device is a single use custom-made device that replaces bone defects. Based on 3D design the device perfectly fits the defect of the individual patient.

The **MyBone**® Custom device is composed of hydroxyapatite a non-resorbable calcium phosphate based bioceramic. The hydroxyapatite ratio is greater than 95%.

The device is designed with interconnected pores that help free circulation of blood, tissue fluids and cells. The **MyBone**® Custom device is made from biocompatible material that allows for host tissue integration.

MyBone® Custom device is patient specific. The device is designed based on the description of a qualified surgeon and based on patient imaging data (CAT-scan, X-ray, MRI). During the preoperative step, the surgeon must approve the design of the final device. Each patient specific device is supplied with an equivalent secondary back-up device.

INTENDED USE

The **MyBone**® Custom device is intended to fill, augment or reconstruct periodontal or bony defects in the craniomaxillofacial (CMF) area including the midface, orbital, mandibular periodontal and cranial (without contact with dura mater) regions. The device is intended only for voids or gaps that are not intrinsic to the stability of the bony structure and for non-weight bearing applications.

Periodontal or bony defects in the abovementioned regions typically result from:

- Traumatic injury to the bone (e.g. accident, falls);
- Surgical creations of cavities, gaps or voids following a bone affecting disease (e.g. cyst or tumor);
- Resorption of autologous bone;
- Rejection of other prosthetic materials;
- Congenital malformations;
- Need of bone augmentation (e.g. chin augmentation);
- Need of aesthetic reshaping;
- Need of dental implant preparation;
- Need of dental preprosthetic surgery

AVAILABLE CONDITIONING

The **MyBone**® Custom devices are patient specific: the device is designed based upon the prescription of a qualified surgeon and related to patient medical imaging data.

CERHUM

PRECAUTIONS

- The use of the **MyBone**® Custom device is reserved exclusively to qualified specialists.
- In pre- and intra-operative phases, the device must be handled with great care, avoiding any maneuvers that might damage or contaminate the device.
- The device is patient specific and manufactured exclusively for the patient indicated in the physician's prescription. Thus, do not modify the patient specific device in any way. Any modification to the supplied device will be the sole and exclusive responsibility of the surgeon. In this case, surgical team should be particularly cautious with freed particles that could cause harm to the patient if released in the operation site.
- In order to help to achieve adequate **MyBone**® Custom device fixation, surgeons are recommended to carefully evaluate the device, both during design validation and during surgery including any condition leading to elevated pressure that may hinder proper device positioning.
- The implant should be fixed to the host bone by non-resorbable suture (diameter smaller than 2 mm). The utilization of screws is under the sole responsibility of the surgeon and pre-implanted test on prototype must be carried out.
- Since the device has a very rough surface, it could pick up material from its surrounding and thus get contaminated. Contamination from EPIs fibers, surgical field fibers, surgical tools coating is possible.
- Due to its unique design – shape and material – the device might present sharp edges. Care should be taken to avoid cuttings or wounds due to the edges.
- It is expressly asked to make sure the implant orientation is determined beforehand and that no doubt is possible about its orientation during the surgery.
- Be aware that the device is brittle and may break if pushed under too much force. Device should be handled with care. This is especially true when securing it in its final position.
- Given the very high specific design of the device, it should not be in contact with any disinfectant or antiseptic liquids. If this occurs, the liquid will be absorbed by the device and could compromise its functioning.
- The **MyBone**® Custom device is prepared to be implanted as is. Do not put it in contact with any chemicals before implantation.
- The device should not be implanted next to another implant at the same time to avoid degradation (mechanical or chemical) between implants.
- If the **MyBone**® Custom device is foreseen to be used together with a resection guide, particular care should be taken about the guide. The guide material must be biocompatible and the gap between the guide and the implant should be large enough to avoid the device scraping surgical guide material by friction.
- The indications and warnings given to the patient by the surgeon for the postoperative period are extremely important. Patients should be warned to avoid direct traumas in the implanted area. Violent blows to the implant area might lead to complications such as device mobilization and/or fracture. Any stress to the implanted area should be avoided.
- The patient should be informed about the potential side effects of the implants on future treatments planning – radiosurgery or cancer treatment by radiation could be impacted by the device because of a different behaviour of the radiations through the implant (absorption, scattering…).
- The **MyBone**® Custom device is a single use product. Any mishandled, damaged or explanted or post-operative devices or devices residue must be disposed of properly as recommended per local regulations. In case of re-use the integrity of the device could be compromised.
- When the device is implanted into the oral cavity, the risk of infection is higher.

WARNINGS

The following warnings are applicable to the **MyBone**® Custom device:

- In case of use in patients treated with bisphosphonates;
- In specific clinical situations, such as is presence of tumor, ongoing chemotherapy, immunodeficiency, uncontrolled diabetes and allergies.

STERILITY

The **MyBone**® Custom device is supplied clean but non-sterile.

It is strictly forbidden to clean the device as this may cause irreversible damage.

Sterilization method is a steam sterilization at 134°C for minimum 3 minutes and maximum 18 minutes.

The manufacturer cannot guarantee the device cleanliness if the inner package seal is broken, if the package is improperly opened or if the product is mishandled. In case of such event please contact Cerhum immediately.

Further instructions are available in **MyBone**® Custom sterilization protocol attached.

The sterilization protocol has to be transmitted to the sterilization center.

STORAGE INFORMATIONS

The device must be stored in a cool and dry area, and should be protected from direct light and heat sources (+10°C/+40°C°).

The device is unique and fragile. It should be handled with caution in order to prevent any impact.

MR CONSIDERATION

The **MyBone**® Custom device is made of hydroxyapatite which is magnetic resonance safe and fully compatible with medical imaging.

CONTRAINDICATIONS

The **MyBone**® Custom device is contraindicated in the following cases:

- For voids or gaps that are intrinsic to the stability of the bony structure;
- For weight-bearing applications;
- For fractures of the growth plate;
- For segmental defects;
- For indications where the device may be subjected to excessive impact or stresses;
- When there are metabolic or systemic disorders that affect bone or wound healing;
- In presence of infections (local or systemic);
- In presence of osteonecrosis, for example on irradiated bone for tumor treatment;
- In case of allergy to the device material (hydroxyapatite – calcium phosphates);
- In presence of meningeal breach for cranial applications;
- Nicotine abuse
- Based on advice of the surgeon.

POTENTIAL SIDE EFFECTS

The **MyBone**® Custom device presents the same potential complications as those encountered in alloplastic prosthesis implantation, which include the following:

- Superficial or deep wound infection;
- Osteomyelitis;
- Nonunion, delayed union or malunion;
- Wound dehiscence;
- Exposure
- Re-fracture;
- Cyst recurrence;
- Hematoma;
- Cellulitis.

Any serious accident or complication occurred in relation to the device should be reported to Cerhum and the competent authority as required by the Regulation (EU) 2017/745.

PROCEDURE

These instructions are intended as guidelines for the use of **MyBone**® Custom device; they are not designed to replace or change the standard procedures for the treatment of bony defects or augmentation. Clinical results of implants used for the reconstruction of bony defects or augmentation depend on several factors. When choosing an implant and the surgical techniques to be used, the following factors need to be considered : the patient's age and general clinical conditions, the bone quality, the possibility to achieve tight contact between the implant and the vascularized bone tissue, certainty of the complete filling of the defect as well as the possibility to obtain a correct and sufficient primary stabilization of the device.

Prior to the surgical intervention, make sure that the identification data on the device match exactly with the patient's documents and medical records.

In addition, before surgery, please check all documents related to the **MyBone**® Custom device to be sure that device matches exactly with the bone gap to be treated.

Preoperative treatment

As for any standard surgical practice, prior to the surgery the patient should be subjected to common antibiotic treatment. For patients that are allergic to specific antibiotics, an alternative treatment should be considered. It is necessary to carefully verify that there is no infection or inflammation at the time of the operation.

Intraoperative treatment

Once the bone has been exposed, it is necessary to remove any fibrotic tissues from the bone edges to

ensure maximum surface contact between the bone and the **MyBone**® Custom device.

The integration of the implant is highly favored when it is in contact with the greatest amount of vascularized bone tissue. Avoid exerting excessive pressure on the implant while positioning it; incorrect handling could lead to device damage. In order to stabilize the implant, prepare the suture holes on the edges of the bone specular to the ones on the edges of the implant. Then, secure the device using suture thread with a diameter less than 2 mm (non-resorbable). Any other technique such as screws is under the sole surgeon's responsibility.
Once completed the implant fixation, the surgical site should be closed tightly according to standard surgical procedures.

Postoperative treatment

In accordance with standard postsurgical procedures, an appropriate antibiotic therapy should be administered. The surgeon must provide the patient with all the indications for a correct postoperative recovery, in relation to the localization and nature of the defect as well as to the overall clinical status of the patient. The patient should be advised to pay particular attention to avoid direct traumas in the area of the implant during the first months after the surgery.

If there are no postoperative complications and the postoperative recommendations given by the surgeon are correctly followed, the primary stabilization of the implant should occur after 6 to 8 weeks. Otherwise it is recommended to proceed to a check of the implanted device.

CE LABELLING

The CE marking is not required for custom-made medical devices as mentioned in Article 20 of Regulation (EU) 2017/745.

STAFF QUALIFICATION

According Regulation (EU) 2017/745, the **MyBone**® Custom device should be handled by qualified people and which have read carefully this instructions for use.

OTHER ISSUES

If any issue is met during the reception, the sterilization, the storage or the implantation, please contact Cerhum as soon as possible. Unless otherwise informed by Cerhum, please do not use the device if it is deteriorated or broken.

PACKAGING SYMBOLS

	Manufacturer
	Date of manufacture
	Lot number
	Do not re-use
	Caution
	Do not use if package is damaged
	Consult instructions for use
	Fragile
	Keep dry
	Non sterile (*)

(*) optional symbol placed on the packaging but may be found elsewhere than on the packaging label

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