CUSTOMBONE SERVICE (EN)
CUSTOM-MADE IMPLANT FOR THE RECONSTRUCTION OF CRANIAL DEFECTS
INSTRUCTIONS FOR USE

DESCRIPTION

Hydroxyapatite is found in human bones in proportions ranging from 65% to 80% and it is one of the most important elements of human bone structure. One of hydroxyapatite's recognised properties is its resistance to the formation of bacterial biofilms, resulting in greater resistance to infections.

CustomBone Service, a custom-made device for the reconstruction of cranial and craniofacial defects, is composed of biomimetic porous hydroxyapatite, with a chemical composition and structure that mimic the mineral component of human bone.

This biomaterial is highly porous, with a trabecular structure, and contains pores with the following characteristics:

- macro-pores, which promote the migration and housing of the cells responsible for bone regeneration;
- interconnecting pores, which are essential to ensure an adequate supply of nutrients and body fluids to the cells that colonise the prosthesis;
- micro-pores, which facilitate rapid hydration of the medical device.

This material has a high degree of biocompatibility and promotes the colonisation of the cells with consequent bone neoformation, allowing the achievement of an excellent aesthetic and functional result.
Thanks to its biochemical characteristics, the device shows good resistance to infections (bacteriostatic properties).

The implants are designed and produced by Fin-ceramica Faenza in accordance with a medical prescription and based on the patient's CT scan data, acquired in compliance with a specific protocol. The specialist prescribing the customised device is responsible for its approval and design specifications.

A specific declaration of conformity and an implant card are provided with each device.
The patient implant card shall be filled in by the hospital staff, and it should bear patient information and the label, supplied by the manufacturer together with the device, which contains all the information about the device implanted.
The patient implant card, completely filled, shall be given to the patient by the hospital.

INTENDED USE

CustomBone Service is indicated to replace bony voids in the cranial and/or craniofacial skeleton.
The device is indicated both in adult and paediatric patients (for children above 2 years of age).
CustomBone Service is suitable for the reconstruction of cranial defects resulting from:

- trauma and vascular pathologies, whether or not associated with cranial decompression;
- tumour removals;
- autologous bone resorption;
- failure of other prosthetic materials;
- congenital malformations.

CustomBone Service is specifically intended to repair bone defects and to be in direct contact with bone tissue, and has no therapeutic purpose as concerning the central nervous system.

The following factors should be considered when choosing a cranioplasty implant and the surgical treatment, such as : the patient's age and general clinical conditions, the possibility of direct contact between the prosthesis and the vascularised bone tissue, in order to ensure the complete filling of the bone cavity and to obtain a correct and sufficient primary stabilisation of the prosthesis.

CustomBone Service can be used in association with autologous bone and combined with growth factors, haemostatic agents, fibrin glues and antibiotics.

AVAILABLE FORMATS

CustomBone Service implants are custom-made devices designed for a specific patient: the devices are designed on the basis of a medical prescription written by a qualified surgeon and related patient's CT scan data. Each prosthesis is supplied with a back-up device.

OPERATING INSTRUCTIONS

The device is intended exclusively for surgical use under sterile conditions.
Check that the device packaging (both secondary and primary) is intact and that the device has not expired or damaged.
Carefully open the package to prevent the device damage.
Prior to the surgical intervention, make sure that the implant identification data exactly match with those of patient's, as detailed in the patient's documents and medical records.
In addition, before surgery, check all the project documentation in order to verify the exact conformity of the device with the bone lacuna to be treated.
Nonetheless, clinical results on the use of implant prostheses for cranial reconstruction can vary according to multiple factors, such as age, location and complexity of the defect, the surgical procedure, as well as the patient's compliance to the post-operative indications provided by the qualified specialist during the rehabilitation process.

Preoperative treatment

As per standard surgical practice, we recommend you to consider administering an appropriate preoperative antibiotic therapy.
Please, carefully verify that no infections nor local inflammations are present prior to surgery.
Intraoperative aspects:

Before implanting CustomBone Service, it is recommended to soak the device in an antibiotic solution to prevent possible infection during surgery. Antibiotic immersion is a precautionary measure to limit bacterial contamination. This method allows reduction of early infections by decreasing bacterial adhesion and implant colonisation.

- Preparing the cavity
  Once the cranial defect is exposed, it is recommended to remove any fibrotic or dural tissues from the bone edges to ensure bone/prosthesis contact as much as possible. The integration of the prosthesis is facilitated by contact with as much of the vascularised bone as possible.
  If necessary, the edges of the bone can be lightly milled to obtain slight bleeding (avoid the use of diamond cutters and excessive milling of the bone, either of which could cause tissue necrosis or an undesired enlargement of the defect perimeter).

- Procedure for implanting and fixing the device
  Avoid exerting excessive pressure on the implant while positioning; incorrect handling may cause damage to the prosthesis. To fix the prosthesis, align the holes on the edge of the bone lacuna to mirror those plotted on the edge of the customised device. Then fix the prosthesis with suture thread of less than 2mm in diameter (non-absorbable).
  The effects of using alternative fixation systems to those indicated by the manufacturer (non-absorbable suture thread) are not known. However, if the surgeon decides, due to necessity and under his/her own responsibility, to use fixation systems other than non-absorbable suture thread, utmost care must be taken to avoid traumatic manipulation that could damage the prosthesis, such as the use of metal screws and/or other fixation devices whose indications for use state their incompatibility with ceramic materials (e.g., hydroxyapatite).
  The central part of the prosthesis also has holes for dural suspension. The decision to carry out this procedure is at the surgeon's own discretion, and it depends on the overall clinical state of the patient.

Once the implant has been fixed, the surgical site shoud be closed acording the standard surgical procedures.

Postoperative treatment:
According to the surgical procedures, we recommend you to consider administering an appropriate postoperative antibiotic therapy.
The surgeon must provide the patient with all the indications to ensure proper post-operative recovery, in relation to the localization and entitiy of the defect as well as to the overall patient's clinical condition.
Particular care should be taken to avoid direct trauma to the implant area during the first few months after the surgery. In case of no post-operative complications, and whether post-operative instructions given by the surgeon are correctly followed, the primary stabilisation of the implant is clinically proven.

CONTRAINDICATIONS

Do not use CustomBone Service in presence of inflammatory conditions and active infections of the surgical site. CustomBone Service prostheses should not be implanted in case of dura tear, in patients affected by proven hyer-sensibility to calcium phosphate salts or severe forms of demineralising diseases, as well as in case of chronic hypertension, coagulation disorders, in the presence of infections resulting from previous surgeries, or in patients undergoing steroid or anticoagulant therapy.
The device should not be implanted in areas with insufficient skin tissue to fully cover the implant, except in case of use of rotation flaps, whether previously agreed by the plastic surgeon specialist.

RESTRICTIONS ON USE

The efficacy of CustomBone Service is not known in the case of:

- pregnancy;
- breastfeeding;
- ongoing radiotherapy;
- major cardiovascular or renal disease.

Moreover, CustomBone Service should not be used in paediatric patients who do not meet the feasibility requirements, which include:

- A significant difference between the device and the receiving-bone thickness;
- Wide bifrontal defects;
- Presence of fronto-parieto-temporal defects together with pathological conditions (i.e. cerebral herniation) that might prevent the ideal implant lodging.

All the above-mentioned points are evaluated by the qualified surgeon prescribing the device during the feasibility process.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

The following minor post-operative complications can be reported: abdominal pain, anosmia, anxiety, arthralgia, asthenia, benign positional vertigo, cerebrospinal fluid otorrhea, cicatricial haematoma, cutaneous hypoaesthesia on scalp, decreased prothrombin, dry cough, epistaxis, facial pain, facial dysaesthesia, fistula, tumor relapse, headache, headache with sensation of vertigo when changing position, hypertension, hyperthermia, hypernatremia, increase of anxio-depressive syndrome, inhalation pneumopathy, intermittent hypotension, lower limb clonism, low back pain, mental depression, mood alteration, necrotic hemorrhagic gingivitis, haematoma of the eyelid, bleeding of the scalp, scar retraction, convulsions, occipital heaviness, sero-haematic effusion, scar tissue pain at the implantation site, subcutaneous haematoma, thalamic pain, trunk burn, partial VP shunt obstruction, vomiting, complication in wound healing on the head scar, hydrocephalus and epidural haematoma.

These types of complications, mainly related to the surgical procedure, are reported infrequently in patients who have undergone implantation with CustomBone Service and can be conservatively managed. In case of severe complications, surgical revision might be required.

Complications which can occur and that are considered as NOT related to the device are:

- implant infection, resulting from infection of the surgical site or from intra-operative and/or post-operative contamination;
- implant mobilization: if the fixation system employed does not provide full stabilisation of the prosthesis;
- implant fracture due to post-operative trauma.

Complications related to the device:

- Mobilisation;
- Fracture;
- Foreign body reaction due to hypersensitivity to calcium phosphates.

Some adverse events can be treated conservatively, while serious conditions may require reoperation or implant removal.

WARNINGS

Carefully read the instructions for sue before proceeding with surgery.

The use of the CustomBone Service is reserved exclusively to qualified medical personnel.

It is therefore recommended not to modify the device in any way. Any change made to the device shall be solely and exclusively under the responsibility of the physician who prescribed the implant. If necessary, and only if the physician decides to make minimal modifications, it is advisable to proceed with extreme caution, under irrigation and using diamond cutters at low speed.

In order to avoid any risk of bacterial infection, it is recommended to place the prosthesis in areas where full and complete coverage with skin tissues is possible.

In order to promote correct device stabilization, it is recommend to carefully evaluate - both during project approval and during surgery - any hypertension conditions or brain herniations which may hinder proper prosthesis positioning.

In paediatric patients, a significant discrepancy between the thickness of the device and the thickness of the bone edges of the cranial defect could lead to microinstability of the device and therefore affect its mechanical properties. In cases where the reconstruction of the frontal bone might involve direct exposure with the frontal sinuses open to the nasal tracts, surgery is intended to keep the complete separation between the prosthesis and the airways.

The effects of using alternative fixation systems to those indicated by the manufacturer (non-absorbable suture thread) are not known. Whether, in case of need and under his/her own responsibility, the surgeon might decide to use fixation systems other than non-absorbable suture thread, , utmost care is recommended to avoid traumatic manipulations that could damage the prosthesis, such as the use of metal screws and/or other fixation devices whose indications for use state incompatibility with ceramic materials (e.g., hydroxyapatite).

Skin expanders or other similar techniques cannot be applied to the implanted device but can be used in the pre-operative period.

CustomBone Service prostheses are single-use devices. Unused devices must not be used in other surgical operations.

Any residues must be disposed of as contaminated hospital waste, according to the provisions in force at the hospital facility.

The device cannot be re-sterilised.

Do not use the product if the packaging is damaged. Do not use the product if expired.
Prior to surgery, it is mandatory to check: the Surgical Notes included in the project report and approved by the surgeon, the labelling on the device and the presence of all patient labels. Please, carefully assess the conformity between the traceability data displayed on the device and on all the packaging.

The package contains additional labels with product traceability data.
Should another surgery be required, the back-up device may be used, after assessment of the consistency between the bone void and the device. However, it is recommended to have two equivalent devices available at the time of surgery.

The user must report any serious incident that occurs in relation to the device to the manufacturer and to the competent authority of the country in which the user and/or patient resides.

PRECAUTIONS

In pre-operative and intra-operative phases, the device must be handled with extreme care, avoiding any manoeuvre that could damage it.
In the event of accidental damage or contamination of the device, complete the surgery using the back-up device.
Direct trauma to the implant area should be avoided during the post-operative stage.

STERILIZATION

All CustomBone Service products are supplied sterile (i.e. steam sterilization). The products are single-use and must not be re-sterilised.
Their total or partial reuse may involve the risk of cross-contamination and the danger of infection of the implant site.

STORAGE

The product must be stored in a cool and dry place, protected from direct light and from heating sources (+ 10 °C / + 40 °C)

SHELF LIFE and DISPOSAL

Do not use the product after its expiry date.
CustomBone Service is a single-use product. Opened and unused devices must not be made available for other operations or other patients but need to be disposed of as contaminated hospital waste, according to the provisions in force at the hospital facility. The product may not be re-sterilised.

SYMBOLS

	Do not re-sterilise
	Do not re-use
	Do not use if the package is damaged
	Sterilized using steam or dry heat
	Use-by Date
	Manufacturer
	Medical Device
	Patient Number
	Date of Manufacture

	Catalogue number
	Batch number
	Number of pieces
	Caution: see the instructions for use
	Consult Instructions for Use in electronic format
	Electronic operating instructions
	Patient's name
	Implantation date
	Healthcare facility

Fin-ceramica faenza spa
Via ravegnana 186
48018 faenza (RA), Italy

www.finceramica.it
info@finceramica.it