8 Other Information / Symbol Description

Production date and manufacturer:

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Content is not sterile

Do not reuse, single use only

See instructions for safety information

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Customized Bone Regeneration

Yxoss CBR® (Customized Bone Regeneration)

02/2015

Customized Bone Regeneration

1. Product Description
Yxoss CBR® is manufactured as a custom-made, patient-specific titanium scaffold, that provides a defined shape for new bone to grow into.

It is surgically placed over a bone defect to create volume for new bone to grow into. It is fixed with a titanium screw to existing bone. Yxoss CBR® thus stabilizes the defect area and defines the shape of the augmentation area.

For the custom-made form of Yxoss CBR®, data transmitted by the treating physician were used. The final design of the Yxoss CBR® implant was checked by the physician and approved for production.

Yxoss CBR® consists of pure titanium according to ISO 5832-2, ASTM F 67 and is individually made by a special manufacturing process utilizing CAD / CAM to fit patient-specific needs. The patient-specific grid structure allows the shape of the area to be augmented to be ideally planned in terms of implant-prosthetic position, according backward planning.

Furthermore, it ensures a stable position, of autologous bone and / or bone substitute material added above the bone bed at the augmentation site. It serves as a barrier to protect undisturbed bone healing and thus eliminates competitive wound healing.

In accordance with to the principle of osteopromotion, slow-growing bone cells are favored over faster-growing soft-tissue fibroblasts that are prevented from growing into the defect.

Yxoss CBR® may be inserted in a one-step procedure with simultaneous implantation, or used in a 2-step procedure that first allows vascularization of the augmented bone. It is to be explanted after bone healing of approximately 4-6 months.

Yxoss CBR® may be used only by specially trained dentists, specialized dental practitioners and medical specialists with appropriate qualifications and experience who are up-to-date with the most actual state of knowledge in the relevant medical field.

2. Indications
Yxoss CBR® has a supportive function in the regeneration of bone defects, for example, in:

- immediate or delayed augmentation in extraction alveoli
- horizontal and / or vertical alveolar ridge augmentation
- 3-dimensional augmentation of the alveolar crest area
- reconstruction of bone defects in the maxillofacial area

The compensation of a bone deficit is achieved mainly through the use of autologous bone, the present-day gold standard. Bone substitute material may also be used as resorption protection and because of its osteoconductive properties.

Autologous bone can be harvested from the usual intraoral donor sites. Dental implant placement can be performed in one-step together with the bone augmentation, or delayed.

3. Contraindications / Precautions

3.1 Contraindications
Potential complications are usually not directly related to the product itself, but rather occur with off-label use, through inadequate training and / or expertise of the treatment team, meaning, ultimately an application error.

Yxoss CBR® should be used only by trained dentists and surgeons and cannot be used in the following situations:

- patients with an infection in the jaw area to be augmented
- known titanium allergy
- patients without adequate compliance, who because of their mental or neurological condition are unwilling or unable to comply with the post-operative care instructions

3.2 Precautions
a) General / Systemic Risk Factors:
- patients with impaired circulation
- patients with unstable physical and / or mental health
- patients with general risk factors such as known immunodeficiency, radio / chemotherapy, at / after bisphosphonate therapy or treatment with RANKL-antagonists or those taking high dose cortisone therapy

- uncontrolled metabolic diseases
- excessive smoking habits
- osteoporosis, limited or lacking revascularization, advanced bone resorption and inadequate fixation of Yxoss CBR® can lead to loosening of the mesh and no mechanical rest in the course of bone healing

b) Local Risk Factors:
- locally present, untreated fractures
- absolute nerve proximity, for example, in the case of eventual mental foramen occlusal impingement in a highly atrophied mandible
- infected wounds
- root remains in the operating area
- persistent local complications in terms of residual cysts, osteomyelitis, odontogenic tumors, acute sinusitis in planned therapy of the maxilla

Generally, the same guidelines which should be adhered to in the course of implantation and / or augmentation, also apply here.

For the Yxoss CBR® volume to become filled with augmented bone, the mesh must first be filled with material such as autologous bone and / or bone substitute. The human skeleton is constantly changing. Therefore, the scan data used for design creation and device production should not be older than 2 months to avoid potential inaccuracies and errors.

4. Possible side effects and complications

4.1 Side Effects
Generally, after any surgical procedure possible side effects may occur, such as bleeding, suture dehiscence, or postoperative infections. Temporary non-severe pain, swelling and inflammation of the gums can be expected after surgery. Longer lasting ailments of persisting neurological problems or chronic pain may also occur. Additionally, there is a small risk that the bone augmentation material used is not sufficiently regenerated and thus the desired volume is not reached.

Wound healing disturbance in the area of the operation can lead to the need to prematurely explant the mesh. This can result in total augmentation failure. Providing adequate patient information, also about alternate treatment choices in advance is the duty of the physician. Further, with initial accurate planning one can exclude risk factors, and reduce side effects and / or complications.

In general, special attention should be paid to postoperative instructions and the need for regular follow-up checkups to facilitate early detection should additional therapy measures be required.

4.2 Complications
Improper surgical procedure can lead to a lack of, or inadequate bone formation. The use of Yxoss CBR® requires special knowledge and skills related to bone augmentation. The custom-made titanium scaffold is based on data provided by the treating physician. The specifications of the new bone volume are entirely the judgment of the treating physician. Yxoss CBR® is thus manufactured only for doctors / dentists.

In case of insufficient or non-tension-free wound closure of the overlying soft tissue, dehiscence may occur. Clinical experience shows that in most cases in which a complete wound closure was not possible, satisfactory healing still occurred. In case of infection, should it not subside when treated with systemic and / or local antimicrobial therapy, then a premature removal of Yxoss CBR® may be necessary.

In cases of excessive bone growth, the newly formed bone can grow through the openings of the titanium mesh and osseointegrate, complicating device removal.

• Yxoss CBR® does not fit exactly to the defect game
Despite all the technical possibilities and the construction of the meshs based on the established DVT data, the Yxoss CBR® could partly not be optimally adapted to the defect. In these rare cases, it is allowed that Yxoss CBR® is slightly bended with sterile forceps at the edge games. It must be ensured that the predetermined breaking point is not damaged.

- The breaking point of Yxoss CBR® breaks when implanted. Due to vigorous handling during insertion or excessive bending Yxoss CBR® could break prematurely at the predesigned breaking point. In most cases, surgery can be performed and the Yxoss CBR® must be secured by additional screws. Sharp edges must be removed with sterile forceps.

- The bone grafting material is not integrated. If the bone graft material is partially not integrated, the healing period should be extended. This can be scheduled after the radiological control before removal of the mesh, as well as after opening the area to be augmented.

In general the biological limits for a bony structure must be considered in the planning process . In very rare cases, the bone graft material may not become integrated and there is a total loss of the augmentation. This may be due to a lack of vascularization or due to a local inflammatory process. In such case a complete cleaning of the augmented area, removal of the augmentation material and the removal of possible granulation tissue is recommended. After a common healing period of the site without inflammation it is possible to plan a new grafting procedure using Yxoss CBR®.

5. Preparation

5.1 Pre-requirements
Yxoss CBR® should be used only by trained dentists and surgeons. The general principles of sterile handling and patient medication must be taken into account when using Yxoss CBR®. Each Yxoss CBR® product is manufactured for a specific patient with data supplied by the physician and may only be used for the intended patient.

6. Use

6.1.1 Sterilization
Yxoss CBR® is delivered non-sterile. Damaged packages of Yxoss CBR® should not be sterilized or used.

The main steps to prepare Yxoss CBR® for use after opening the packaging are:

- open the outer peel-bag
- place the inner peel-bag directly in the autoclave
- steam sterilize at 134 degrees Celsius for 20 minutes
- remove the Yxoss CBR® from the sterilized peel-bag

The general principles of sterile handling and patient medication must be taken into account when using Yxoss CBR®.

Re-sterilization is not possible. In the event of reuse, even in the same patient, the intended cannot be guaranteed.

6.1.2 Surgery
In general, the surgical sequence can be divided into the careful preparation of the defect, the process of bone harvesting for augmentation, and the combination of the two processes followed by wound closure:

- Under local anesthesia, a marginal incision along the linea alba (if possible without vestibular release) is performed.
- Subsequent steps involve the preparation of a mucoperiosteal flap, debridement of scar tissue and the exposure of the defect.
- Debridement of the bone under the implant site may be performed.
- Then, in a one-step procedure, implants may be aligned at the same time using the positioning rail and inserted in the selected region.
- During the try-in of the prefabricated, custom-fit titanium scaffold Yxoss CBR® a passive tension-free fit should be realized and the biological provisions respected (1.5 mm to the adjacent teeth or nerve structures).
- From the typical intraoral donor sites, the bone harvesting is carried out and the graft is prepared in particulate form.
- Then, the mesh is filled with bone augmentation material (autologous bone and bone substitute material).
- The stable fixation of Yxoss CBR® takes place on the existing residual bone with an osteosynthesis screw. It can be generally introduced, depending on the intended position, through any opening of the titanium grid.
- During wound closure, the mucoperiosteal flap is positioned tightly over Yxoss CBR® and is sutured tension-free with single-interrupted and deep mattress sutures.

6.1.3 Initial healing period

After suture removal and throughout the course of wound healing the soft-tissue situation should be clinically checked regularly for the absence of dehiscence and controlled for signs of general inflammation. After an appropriate bone healing phase of the augmented area (ca. 4-6 months) Yxoss CBR® can be removed.

6.1.4 Removal of Yxoss CBR®
- Preparation of a mucoperiosteal flap
- Loosen the fixation screw to remove the mesh
- Loosen Yxoss CBR® by slight lateral extrusion movements made possible through the easy removal function
- If dental implants were inserted they should be checked for complete osseointegration with good vascularization of the surrounding tissue and stable adherence to the substrate bone. A perio-test can be carried out as an indicator for a stable osseointegration.
- Tension-free wound closure can be combined with a mucosal graft to increase the amount of keratinized gingiva. Sutures are to be removed one week thereafter.

Before use, please carefully read the enclosed „Surgical Technique" documentation.

7. Additional Documentation

Disclaimers: all product liability seizes
- In case of damage due to improper storage, handling, cleaning and / or sterilization
- Incorrect cleaning and sterilization
- Failure to follow these instructions for use