



Customised Solutions

Patient Information
Yxoss CBR®

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Patient Information
Yxoss CBR®

Patient Information for Yxoss CBR®

(Manufacturer's Information)

Dear Patient,

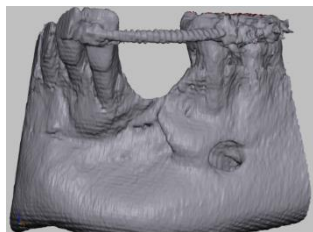
The medical examination has shown that with the reconstruction of new bone in the maxillary crest, missing bone could be regenerated and thus also the chewing ability could be restored or improved. This may also be done in connection with the implantation of one or several dental implants (artificial tooth roots) into the jaw bone.

The implantation of dental implants can also be considered for aesthetic and/or masticatory reasons. The dental implants will be used to fix denture (crowns, bridges or dentures) after the complete healing.

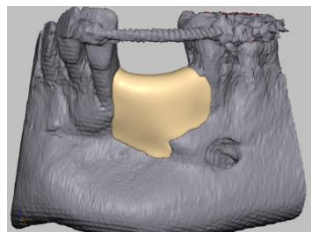
Bone Augmentation / Reconstruction of the Bone

In the reconstruction of new bone in maxillary defects, the final bone structure is an important factor to meet the highest aesthetic expectations. Sufficient bone supply is the prerequisite for a safe and long-term anchoring of dental implants in the maxillary crest.

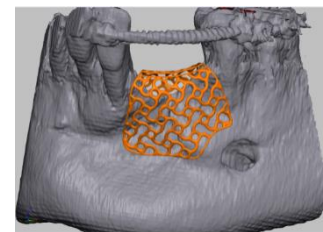
The high-quality pure titanium scaffolds (Yxoss CBR®), produced by ReOss GmbH, can be implanted precisely into the bone defect. This allows an accurate shaping of the newly formed bone.



Horizontal and vertical bone defect



Model and virtual bone replacement



Yxoss CBR®

Alternatives

As an alternative, a block of your own bone can be harvested at a suitable location (e.g. from the lower jaw or pelvic ridge). This can be modeled to fit the area where bone is missing in your jaw.

Other medical products may be used, such as membranes of various materials (e.g. collagen) or hand-shaped titanium scaffolds. Your physician will inform you about the advantages and disadvantages of the individual solution.

Surgical procedure

Under local anesthesia, or more rarely in anesthesia or narcosis, the soft tissue of the gum is opened in the area of the defect, where the implantation of Yxoss CBR® is planned and the bone is exposed. The Yxoss CBR® titanium scaffold is then inserted exactly into the bone defect and the missing bone volume is filled by own bone or a mixture of own harvested bone and artificial bone.

According to the decision of the surgeon, one or more implants can be placed in the maxillary bone at the same surgery. The gingiva is then sutured and adapted to the new volume. After the procedure, temporary swelling of the cheek or the lip can occur.

Pain after surgery is rather rare!

Occasionally, it is shown during the surgery, that simultaneous implantation of dental implants is not possible. Then, first the missing bone is rebuilt, and the implantation of the dental implant is carried out later on, after a healing time of usually 4-6 months.

Healing period

After approximately 4-6 months the replaced bone is re-vascularized and stable. During this healing period you must not strain the operated area and avoid chewing on this side in order not to endanger the healing. Yxoss will be removed after the healing period.

Possible complications

The success of a treatment and the absolute risk-free healing cannot be guaranteed by any surgeon. The general hazards of surgical procedures, e.g. infections, are comparatively rare in this procedure. Thanks to progress in medicine, it can be done more than before.

It is rarely possible to open the nasal cavity or the maxillary sinus in the upper jaw in the direct proximity to them. In most cases, the healing of the Yxoss CBR® treatment is not influenced. In the posterior jaw area of the lower jaw, the lower jaw nerve can be injured in rare cases. This implicates a temporary, in very rare cases a permanent numbness of the lower lip. The mobility of the lip is not impaired thereby.

In rare cases, a wound opening (dehiscence) may occur during the wound healing phase. There is also a small risk that the bone implant material, which has been introduced, is not sufficiently regenerated and thus the desired volume is not reached. Wound healing problems in the area of the titanium scaffold can lead to wound healing deficits, which could lead to a total loss of the bone substitute material.

Clinical experience shows in most cases, a satisfactory healing is still achieved.

If the infection cannot be treated with systemic and/or local antimicrobial treatment, early removal of Yxoss CBR® may be necessary.

Potential impact to the therapy success

Your oral hygiene has a decisive influence on the success of the treatment. Only if you are willing to carefully clean your teeth and the area of the Yxoss CBR® implant after every meal, a long lasting success is possible.

Questionnaire for the patient

In order to minimize the risk as much as possible, please answer the following questions:

1. Do you suffer from a disease or illness?
 - Yes; Please explain: _____

 - No

2. Do you have an allergy (e.g. hay fever), hypersensitivity to food (e.g. fruit), drugs, medical strips / patches, local anesthetics, metals?
 - Yes; Please explain: _____

 - No

3. In the past, did you respond well and have good tolerance to local anesthetic injections, e.g. during hoot extraction or other dental procedures?
 - Yes; Please explain: _____

 - No

4. Do you have an increased tendency to bleed, even in the case of minor injuries or after "tooth extraction"?
 - Yes; Please explain: _____

 - No

5. Do you take medicine on a regularly base?
 - Yes; Please explain: _____

 - No

Please feel free to ask us, if you want to know more details about the treatment or about possible complications.

Declaration of the patient after the informed consent discussion

Name of patient: _____

Dr.: _____

has conducted today the informed consent, on the basis of the information leaflet and I had the opportunity to ask all questions that concerned me.

With my consent to the Yxoss CBR® implant, I am aware of the following:

- The Yxoss CBR® implant is patient-specific and accurately shaped
- There are no long-term results available
- I understand that the potential risks mentioned above may be associated with the procedure
- I hereby agree to the proposed intervention
- I agree that the implantation may be recorded on video and may be used for training, research or product registration purposes.

Date: _____

Signature of the patient or legal custody:

Signature of the dental surgeon:
