Instructions for Use
Yxoss CBR®

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Instructions for Use
Important Information on the ReOss Yxoss CBR® scaffold

Purpose – Intended Use

Yxoss CBR® is a metal device intended for the use with or without a dental implant to stabilize and support bone graft in dento-alveolar bony defect sites. The patients should be skeletally mature. The intended users are specifically trained personnel (dentists or medical specialist with the appropriate qualifications and experience which correspond to the state of the art in the medical science in this field).

Description

Yxoss CBR® is a titanium scaffold, which will be surgically inserted over bone defects as a volume support for contouring newly formed bone over a bone defect. The titanium scaffold is held in place with standard titanium screw(s) to the existing bone. Yxoss CBR® thus stabilize the bone graft in the defect area and specifies the shape of the bone to be augmented.

Yxoss CBR® consists of commercial pure titanium and is individually made by special manufacturing process. Yxoss CBR® is produced as a patient-specific customized product, it is for single use only even at the same patient. The patient-specific scaffold structure allows shaping the area to be augmented in the sense of backward planning for the ideal implant position. Furthermore, it ensures a stable positioning of the augmented autologous bone and/or bone substitute material on native local bone.

This individual titanium scaffold is designed using CAD/CAM technology by generating a 3D-model of the bony defect after the acquisition of Cone-Beam CT or (DVT) data. In dental implant cases to plan the perfect location of the implant following the backward planning principle patients wear a waxed-up radiopaque prosthesis to evaluate the missing bone volume.

By using a specific reconstruction software a 3D-projection of the atrophied segment can be obtained and a customized scaffold can be designed. The 3D model assists in accurate contouring of plates and/or planning of bone graft harvest geometry before surgery.

These Data, providing 3D information about the shape of Yxoss CBR® will be approved by the responsible surgeon based upon a 3D-model. The approved 3D-model will be sent to production. Directly from the 3D-model, the Yxoss CBR® will be built using selective laser sintering (SLS). After the SLS process, the component undergoes a surface treatment process (blasting), will be ultra-sonic cleaned and packaged in a sealed double bag for the subsequent autoclaving at the surgeons' site.

The human skeleton is constantly changing. Therefore, the scan data used to design creation and production should not be older than three months to avoid potential inaccuracies and errors. The bone remodeling process after tooth extraction must be finished.

The Yxoss CBR may be used in a one-stage approach with simultaneous placement of a bone level dental implant with cover screw.
In a two stage approach, the dental implant will be placed after revascularization of the augmented bone. In a two stage approach there are two options available:

- Standard Yxoss scaffold (without integrated implant positioning)
- Backward Yxoss scaffold (with integrated implant positioning)

The Backward Yxoss scaffold has already the predetermined implant positioning integrated in the scaffold on top of the implant. The hole for the dental root implant will be pre-drilled with a smaller drill than to be used for the final dental root implant. Then the Yxoss CBR ® scaffold will be explanted. Afterwards the standard implantation procedure of the dental root implant can be followed.
The titanium scaffold will always be explanted. Explantation of the scaffold is recommended after a bone healing time of 4-6 months. At the latest Yxoss CBR® should be explanted 9 month after surgery.

The system has to be used only by specially trained dentists, specialized dental practitioners and medical specialists with appropriate qualifications and experience.
Yxoss CBR® as a titanium, customized scaffold offers all advantages of a titanium scaffold compared with an individualized situation. Titanium shows a high grade of biocompatibility, corrosion resistance and positive thermal effects. The inherent rigidity of stiff titanium scaffolds maintains the space needed to allow bone growth in a sense of modern GBR (Guided Bone Regeneration) technique.
The pre-formed titanium scaffold with round and blunt edges can prevent mucosal irritation as well as they eliminate operation errors; it offers a precise fit and a high stability after screw fixation. Working with a pre-formed scaffold, duration of surgery can be reduced because adaption and cutting of an alternative general scaffold can be avoided.

Single Use

The implants of ReOss® are for single use. It is forbidden to reuse or try to re-sterilize any part of the Yxoss CBR®. The reuse of any part of the system may lead to a risk for the patient. An attempt to reprocess, clean, sterilize and/or disinfect the implant might lead to infection or toxic reaction. Furthermore it may negatively impact the performance and characteristics of sub-sequent dental implant(s).

Indications

Yxoss CBR® is used for reconstruction of alveolar bone deficits prior to placing a dental implant, shaping alveolar bone and as a support to the augmented bone volume in the regeneration of bone defects that may include:

- extraction sites provided there are no acute clinically inflammatory symptoms (pus, local pain, robur, calor, swelling)
- horizontal and/or vertical augmentation of the alveolar ridge
- reconstruction of bone defects in the maxillofacial area

Contraindications

Any complications that occur are usually not directly related to the product itself, but is caused by a non-appropriate definition of the indication, by insufficient training and/or incompetence of the surgical treatment team, therefore caused by medical malpractice.

Yxoss CBR® should only be used by specifically trained personnel and should not be used in the following cases, but are not limited to:

- Patients with an infection in the jaw area to be augmented or signs of local inflammation
- Suspected or documented titanium allergy or intolerance
- Patients in or have had bisphosphonate therapy or treatment with RANKL antagonists
- Patients with chemo and radiation therapy in surgical area
- Pregnancy
- Any patient having inadequate tissue coverage over the operative area
- Pediatric patients or where the patient still has general skeletal growth (age under 18 years*)
- Osteoporosis or lacking revascularization ability (progressive bone resorption could lead to an insufficient fixation of the Yxoss CBR® and might end up in a loosening of the scaffold)
- Osteomalacia
- Uncontrolled metabolic diseases (e.g. diabetic patients)
- Patients with blood clotting issues or issues with wound healing
- Patients who smoke or drink excessively
- Patients without adequate compliance, who are unwilling or unable to follow the follow-up instructions due to mental or neurological conditions
- Any case not described in the indications

These contraindications may be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive, Surgeons must discuss the relative contraindications with the patient.
*) In cases where skeletal growth may not be completed, take an X-ray of the wrist in order to confirm the closed epiphyseal.

Complications – Adverse Events

In general, after every surgical procedure, possible side effects in the sense of post-bleeding, suture episodes or postoperative infections are to be expected. Temporary pain, swelling and gum inflammation may occur after surgery. Persistent neurological problems as well as chronic pain symptoms may occur as prolonged symptoms. 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 operating area can lead to earlier explanation of the titanium scaffold, which can lead to a total loss of the construction material.
Adequate information of the patient, also regarding treatment alter-natives pre-operatively is subject to the dental/medical obligation. In addition, accurate planning at the beginning of the therapy makes it possible to exclude risk factors and thus reduce side effects and/or possible complications.
In general, special attention should be paid to the postoperative review and the need for regular medical checks to be able to take appropriate treatment measures at an early stage.

All of the following adverse events associated with the Yxoss CBR® to support defect bridging are possible. A listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any implanted component
- Breakage of any implanted component
- Pressure on the skin from Yxoss CBR® in the patient with inadequate tissue coverage over the implant possibly causing skin and/or mucosal penetration, irritation, fibrosis, necrosis, and/or pain.
- Lesion of the nasal cavity or the maxillary sinus in the upper jaw could occur
- Lower jaw nerve could be injured (numbness of the lower lip)
- Wound opening (dehiscence)

The use of Yxoss CBR® requires special knowledge and skills for bone augmentation. Therefore, Yxoss CBR® is only distributed to physicians/dentists.

If the wound is insufficiently or not tension-free, the wound can be damaged by the overlying soft tissue. Clinical experience shows that, in most cases, where a complete closure of the wound was not possible, a satisfactory healing still takes place. If the infection does not ease after treatment with systemic and/or local antimicrobial treatment, early removal of Yxoss CBR® may be necessary.
In the case of excessive bone growth, the newly formed bone can grow through the porous titanium scaffold. The explantation of the titanium scaffold could then be more difficult.

Despite all the technical possibilities, the construction of the titanium scaffold and precise pre-operative planning, there is the possibility that Yxoss CBR® cannot optimally fitted to the defect. In these rare cases it is allowed to flex Yxoss CBR® with a sterile forceps on the edges. Care must be taken to ensure that the predetermined breaking point is not damaged.

Local risk factors

- Locally present, unprovided fractures
- Absolute nerve proximity, for example, in the sense of occlusal mental foramen in highly atrophied mandible jaw
- Infected Wounds
- Residual Root in the operating area
- Persistent local problems in terms of residual cysts, osteomyelitis, odontogenic tumors, acute sinusitis in planned therapy in the maxilla

In general, the same guidelines apply as during general implantation and/or augmentation. The scaffold provides the volume which needs to be augmented (bone defect), therefore it needs to be relined with the space-filling materials such as autologous bone and/or bone replacement.

These issues can be due to the lack of bone or poor bone quality, an infection, patient's poor oral hygiene, non-compliance with post-op procedures, movement of the implant, degradation of surrounding tissue, or improper placement of the implant.

Managing Complications

Best practices to avoid complications and situations potentially leading to adverse events are described in the surgical technique.

Warning

The safety and effectiveness of Yxoss CBR® have been established only for maxillar or mandibular jaw conditions with significant bone loss requiring bone augmentation. The safety and effectiveness of this device for any other conditions are unknown. This product must not be used for any other than GBR procedures.
For the one-stage procedure (Yxoss CBR® scaffold and dental implant inserted in one surgical intervention) only a titanium or titanium alloy implant bone level implants with cover screw is allowed.
The Yxoss CBR® device is a thin walled titanium device to hold bone graft material in place. It cannot be placed in loaded areas and must not be loaded e.g. by above placed temporarily prosthesis.

Preoperative

Only patients that meet the criteria described in the indications section should be selected.
Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants should be protected during storage, especially from corrosive environments. And adequate inventory of titanium osteosynthesis screws should be available at the time of surgery, normally a quantity in excess of what is expected to be used. The surgeon should be familiar with the various components before using the equipment and should personally verify that the necessary items are available before the surgery.

Yxoss CBR® implants should only be implanted with titanium or titanium alloy osteosynthesis screws for fixation with a diameter between 1.3 mm - 1.5 mm and with a length between 5 mm and 13 mm, recommended:

- Synthes 1.3 mm self-drilling screws (510K No. K983485)
- Salvin Dental 1.5 mm Tenting Screws (510K No. K161857)

The screws should provide a stable fixation of Yxoss CBR ® in the determined final position.

Packaging and Sterilization

The following general principles of sterile working have to be considered in the application of Yxoss CBR®.

The sterility of the implants falls under your responsibility. Please ensure that only sufficiently device and product specifically validated procedures will be used for sterilization, that the used devices (sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the hospital.

Caution: FDA-cleared sterilization accessories are to be used for the recommended sterilization parameters when performing the following steps in the United States.

Packaging

The device Yxoss CBR® is delivered to the clients as a non-sterile, single use device. In the card box, the product is packed in a double bag of sterilizable paper pouches. The product will be placed in unpacked condition with its inner and outer pouch into the sterilizer.

FOR U.S. ONLY!
Please remove the Yxoss CBR® from the original packaging and place it in a standard sterilization tray and pack them in sterilization containers, which fulfill the following requirements (material/ process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the implants as well as of the sterilization packaging to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

Caution: Packages for each of the component(s) should be intact upon receipt. All boxes should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to the local distributor or to ReOss GmbH.

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- dynamic air removal procedure[1,2] (with sufficient product drying[3])
- steam sterilizer according to EN 13060 / EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	dynamic air removal	gravity displacement
USA / EU / Other countries	4 min at 132 °C (270 °F), drying time at least 20 min[3]	not recommended
EU / Other countries	3 min at 135 °C (275 °F), drying time at least 20 min[3]	not recommended

[1] at least three vacuum steps
[2] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific process development and validation under sole responsibility of the user.
[3] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

After sterilization Yxoss CBR® should be removed in the operation room from the sterilized peel pouches according to standard surgical procedure and is ready to use.

Caution: Sterility of the product packed in a double bag of sterilizable paper pouches is validated with a shelf life of 5 days. Products have to be used within 5 days after sterilization.

Caution: when using different packaging material or FDA-cleared sterilization accessories for sterilization (e.g. standard sterilization trays) refer to their instructions for use provided by the supplier and follow the instructions for the validated shelf-life.

Intraoperative

Extreme caution should be used around the nerves in the implantation area. Damage to the nerves will cause loss of neurological functions.
Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
Use great care to ensure that the implant surfaces are not scratched or notched, since such action may reduce the functional strength of the construct.
Utilize an imaging system to facilitate surgery.

Bone graft must be placed in the area between Yxoss CBR® and the remaining bone. The compensation of the bone deficit is performed with autologous bone representing the golden standard in combination with bone grafting material due to its osteoconductive properties and also avoiding resorption.

Autologous bone can be obtained at the common intraoral donor sites. Placing a dental implant can be performed at the same session or delayed after the recommended healing time. Before closing all the screws must be tightened according to the ReOss surgical technique.

Postoperative

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance are extremely important. Detailed instructions on the use and limitations of the device should be given to the patient.

The Yxoss CBR® implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the bone substitutes are successfully integrated (vascularized) these devices serve no functional purpose and should be removed for further treatment of the denture replacement.

Any retrieved device should be treated in such a manner that reuse in another surgical procedure is not possible. As with all implants, the ReOss Yxoss CBR® must not be reused under any circumstances.

In the case of suture removal and in the further course of wound healing, the soft tissue conditions must be clinically regularly checked for the absence of dehisced areas and for general inflammation signs. After a corresponding bone healing phase of the bone substitutes (approx. 4-6 months) Yxoss CBR® should be removed.

The Yxoss CBR® has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Yxoss CBR® in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Explantation of Yxoss CBR®

The procedure for removal of the Yxoss CBR® is described in the surgical technique.

Storage conditions

Store all products in a dry place at normal room temperature (15 - 30°C). Avoid direct sunlight.

Product Complaints

Any health care professional (e.g., customer or user of this product) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributer of ReOss GmbH. Further, if any of the implanted component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately, If any ReOss GmbH product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence.

When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

Product liability

Any product liability is extinguished:

- In case of damage due to improper storage, handling, cleaning and/or sterilization
- Incorrect cleaning and sterilization
- Failure due to not following the instructions for use or the surgical technique

Clinical Data

Yxoss CBR is on the market in EU since 2015 as custom made implant. Several publications and case reports were published. Please find this information on www.Reoss.eu or get in contact with your local distributor.

Further Information

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact ReOss GmbH.

Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Do not use if package is damaged		Not tested for MRI safety
Rxonly	Caution: Federal law (USA) restricts these devices to sale by or on the order of a licensed healthcare practitioner		Non Sterile
	Consult instructions for use		Used by date
	Do not re-use		Catalogue number
	Batch code		Do not re-sterilize
	Manufacturer		Caution / Warning