bone & tissue regeneration

botiss biomaterials

NOVA**Mag**®

RESORBABLE MAGNESIUM SURGICAL PROCEDURE

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SURGICAL PROCEDURE

Guided bone regeneration using products from the NOVAMag® product line

The following sections will explain a guided bone regeneration (GBR) procedure using the NOVAMag® membrane secured using the NOVAMag® fixation screw XS.

screw XS.

XS & membrane

General Guidelines

When inserting and securing the NOVAMag® membrane, a standard GBR protocol must be followed. The membrane should be trimmed to the correct size using the NOVAMag® scissors, ensuring that there will be a 3-4 mm overlap of the defect walls. To prevent perforations of the soft tissue, the edges of the membrane must be flattened using the back end of the NOVAMag® sculptor.

Before placement, use the sculptor to shape the membrane into a rounded form according to the defect requirements. It is strongly recommended that the membrane is secured on both the buccal and oral sides to restrict the restoring forces of the membrane, an important step in controlling the soft tissue management.

The membrane should be secured to the bone using NOVAMag® fixation screws or other commercially available fixation systems comprising of titanium screws or sutures. To provide volume stability, the defect space should be filled with autologous bone or bone substitute material such as cerabone®.

The NOVAMag® fixation screw XS is specifically designed for membrane fixation, however all NOVAMag® fixation screws can be used for this purpose. Via the “drive”, the fixation screw can be attached to a contra angle or hand wrench using a NOVAMag® connector.

The drive of the NOVAMag® fixation screw XS sheers off once the screw is seated, however, when using any of the other NOVAMag® fixation screw sizes, the NOVAMag® safety cutter should be used for safely removing the drive.

NOTE: The sheering function of the drive is only possible with the NOVAMag® fixation screw XS.

Please consult the relevant IFUs before performing a surgery.

GENERAL **PREPARATION**

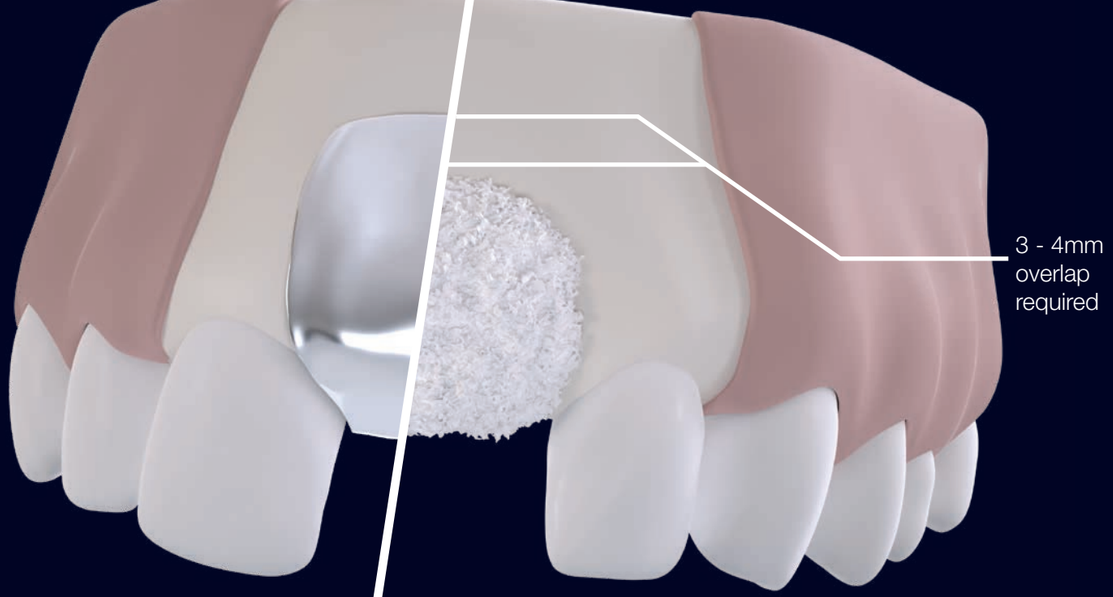
IMPLANT BED PREPARATION

For the mucoperiosteal flap preparation, it should be taken into consideration that after the GBR surgery, the flap needs to be closed without tension. After exposing the defect, the necessary surgery should be performed.
The full flap is elevated, bone is cleaned, and a suitable augmentation material, such as intraoral autologous bone or cerabone® is applied.

OPENING THE PACKAGING

The NOVAMag® membrane is provided sterile within two gas-tight clear plastic pouches. The outer pouch, which is sterile on the inside, can be removed by an assistant in the unsterile operational area. The inner pouch, which is sterile on the inside and on the outside, is then handed to a member of the surgery team in the sterile area.

The peel pouches should be opened slowly by applying a steady and even force to both sides of the pouch opening. Only after the bone defect has been prepared, should the NOVAMag® membrane be removed from the inner packaging, maintaining sterility.



MEMBRANE **PREPARATION**

TRIMMING OF THE MEMBRANE

The NOVAMag® membrane can be cut to size using a pair of NOVAMag® scissors and an appropriate template. The membrane should be trimmed to overlap the edge of the defect walls by at least 3-4 mm, thereby ensuring the secure placement of the membrane. Any sharp edges to the membrane must be blunted using the back end of the NOVAMag® sculptor to prevent flap perforation(s).

SHAPING OF THE MEMBRANE

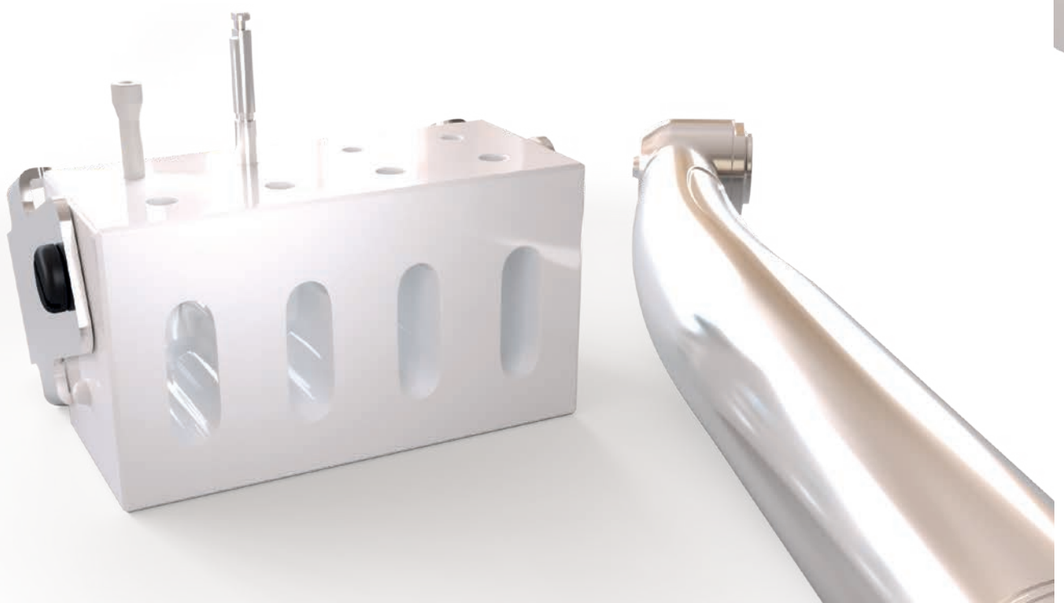
Using the NOVAMag® sculptor, the NOVAMag® membrane can be molded according to the shape of the defect site. The long, rounded stem of the sculptor can be used to bend the membrane, reducing the effect of material restoring forces. For precise shaping, the pointed tip can be used to create more detailed impressions. Once the membrane is in the correct shape, it can be positioned over the defect and slightly pressed down to hold it in place.

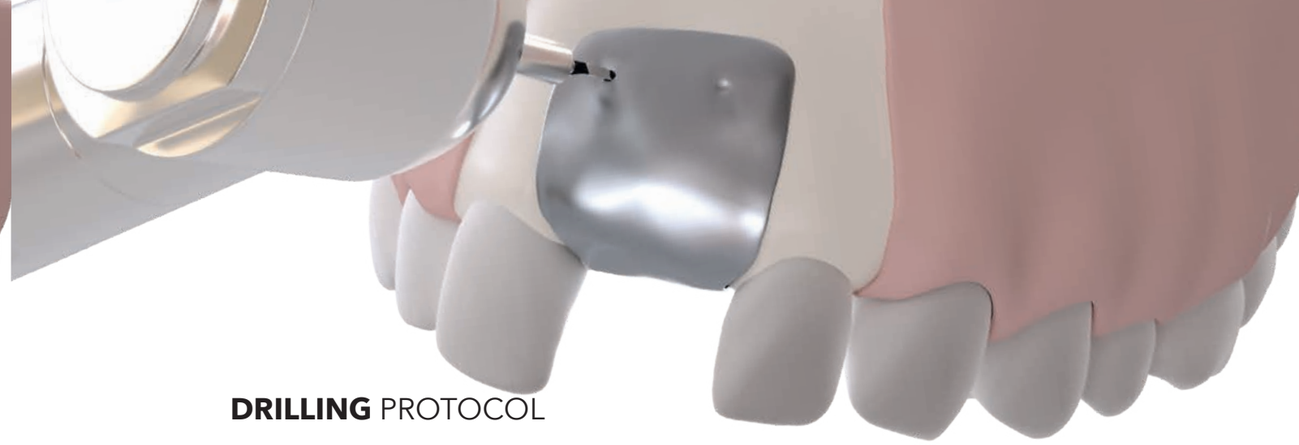
SECURING
THE MEMBRANE

Due to its biomechanical strength, the NOVAMag® membrane must be secured to the bone using the NOVAMag® fixation screw XS or other commercially available fixation systems comprising of titanium screws or sutures.

Fixation of the NOVAMag® membrane on both sides of the defect (orally and buccally) is strongly recommended to avoid displacement due to its elastic restoring force. This is important for soft tissue management.

Using the tip of the NOVAMag® sculptor, positions of the screws can be marked as a guide for drilling. The membrane can be perforated using either a drill or a rubber dam punch.





DRILLING PROTOCOL

The NOVAMag® drill rack can be used to aid with the attachment procedure when using the NOVAMag® fixation screw XS. The NOVAMag® drill rack will hold and support pilot drills 1.0, 1.2, 1.35, the precision drill and NOVAMag® fixation screws XS-XL.
During surgery, the drill rack displays the drills in a clear and easily accessible manner, enabling quicker selection and changing of drill bits.

For fixation of the membrane using the NOVAMag® fixation screw XS, insertion holes should be prepared using the precision drill, which has a 0.9 mm diameter. The precision drill has a depth mark indicating the necessary hole depth for the correct insertion of the NOVAMag® fixation screw XS. For very hard bone, it may be necessary to widen the cortical bone section of the prepared hole using the pilot drill 1.0. For very soft bone do not drill to the full depth but only prepare a starter hole for the screw to engage. Drilling should be perpendicular to the bone surface.
CAUTION: The precision drill is very sharp.

GET **CONNECT**ED

In preparation for screw insertion, NOVAMag® fixation screws can be placed drive side up in the NOVAMag® drill rack. By holding and supporting the downwards position of the fixation screws, the drill rack assists with the attachment of the NOVAMag® connector to the drive.

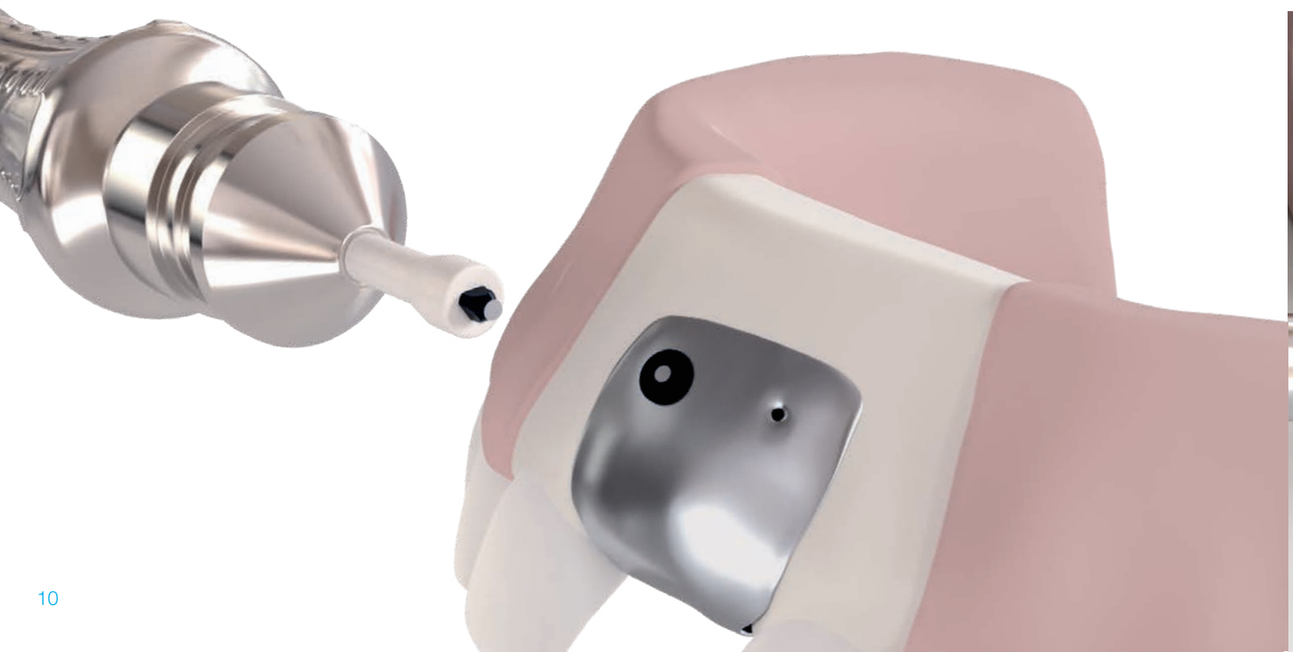
To pick up the screw, the connector is first attached to a contra angle or hand wrench. The head of the connector is then placed on to the screw drive and slowly twisted, applying mild pressure until the connector engages with the drive.

FIXATION SCREW
INSERTION

Position the screw over the prepared hole and apply a slight downward pressure to aid threading the screw.
During insertion, the axis of the NOVAMag® fixation screw XS must align to the angulation of the prepared fixation hole – perpendicular to the bone surface.
When the fixation screw XS is properly seated, the drive should automatically shear off from the screw and remain within the NOVAMag® connector. It is also possible to remove the drive with a gentle rocking motion or by using the NOVAMag® safety cutter. If the safety cutter is used, it must remain closed to retain the drive upon detachment and should only be reopened outside of the patient's mouth.

COLLAGEN MEMBRANES

For the fixation of collagen membranes (such as the Jason® membrane or collprotect® membrane) using the NOVAMag® fixation screw XS, it is recommended to predrill several pilot holes using the precision drill prior to the placement of the collagen membrane. The membrane is then stretched over the bone and held in position, possibly by using a pair of dental forceps. Using a dental probe or the NOVAMag® sculptor, the insertion holes can be located through the collagen membrane before the fixation screw is inserted.



FLAP MANAGEMENT

NOVAMag® membrane is designed for closed wound healing. For wound closure, the mucoperiosteal flap is repositioned over the membrane tightly, yet without a high tension, and then sutured. NOVAMag® membrane should be completely covered by the mucoperiosteal flap as exposure can lead to accelerated resorption.

CHECK-LIST:
GBR using NOVAMag® membrane

- ☐ Consideration of soft tissue management
- ☐ No sharp edges on the membrane
- ☐ 3 - 4 mm overlap of the membrane over the defect walls
- ☐ Edge of the membrane flattened using the NOVAMag® sculptor
- ☐ Bending membrane to shape using the NOVAMag® sculptor, removing restoring forces
- ☐ Membrane is shaped prior to placement
- ☐ Membrane secured using the NOVAMag® fixation screw XS, titanium screws or sutures
- ☐ Fixation of the membrane on both the buccal and oral sides
- ☐ Drive removed from the NOVAMag® fixation screw head
- ☐ Membrane completely covered by the mucoperiosteal flap for closed wound healing

SURGICAL PROCEDURE

Bone block fixation using products from the NOVAMag® product line

The following sections will explain a block augmentation procedure using NOVAMag® fixation screw S - XL.

S - XL

General Guidelines

NOVAMag® fixation screws are used for securing barrier membranes, bone grafts and bone filling material within the oral cavity.

Available in five sizes, the fixation screws can be used for the attachment of materials with a wide range of depths/ thicknesses. Material dimensions should be taken into consideration before selecting the appropriate NOVAMag® fixation screw. The NOVAMag® fixation screw XS is used specifically for membrane fixation.

Fixation screw size	Maximum thickness of graft material for fixation*
NOVAMag® fixation screw S	2 mm
NOVAMag® fixation screw M	4 mm
NOVAMag® fixation screw L	6 mm
NOVAMag® fixation screw XL	8 mm

*Subject to native bone quality to achieve adequate stability of the fixation screw

To prepare NOVAMag® fixation screws S, M, L and XL (not the NOVAMag® fixation screw XS) for insertion, begin by drilling a pilot hole using the pilot drill 1.0 to assess the bone density. For soft bone, the 1.0 mm diameter hole should be sufficient in size, however for harder bone types, increase the hole diameter using either the pilot drill 1.2 or 1.35.

CAUTION: Once the fixation screw is seated, the screw drive must be removed using the NOVAMag® safety cutter. The NOVAMag® fixation screw XS is specifically designed for securing barrier membranes and should not be used for the attachment of bone blocks.

Please consult the relevant IFUs before performing a surgery.

DRILLING Protocol

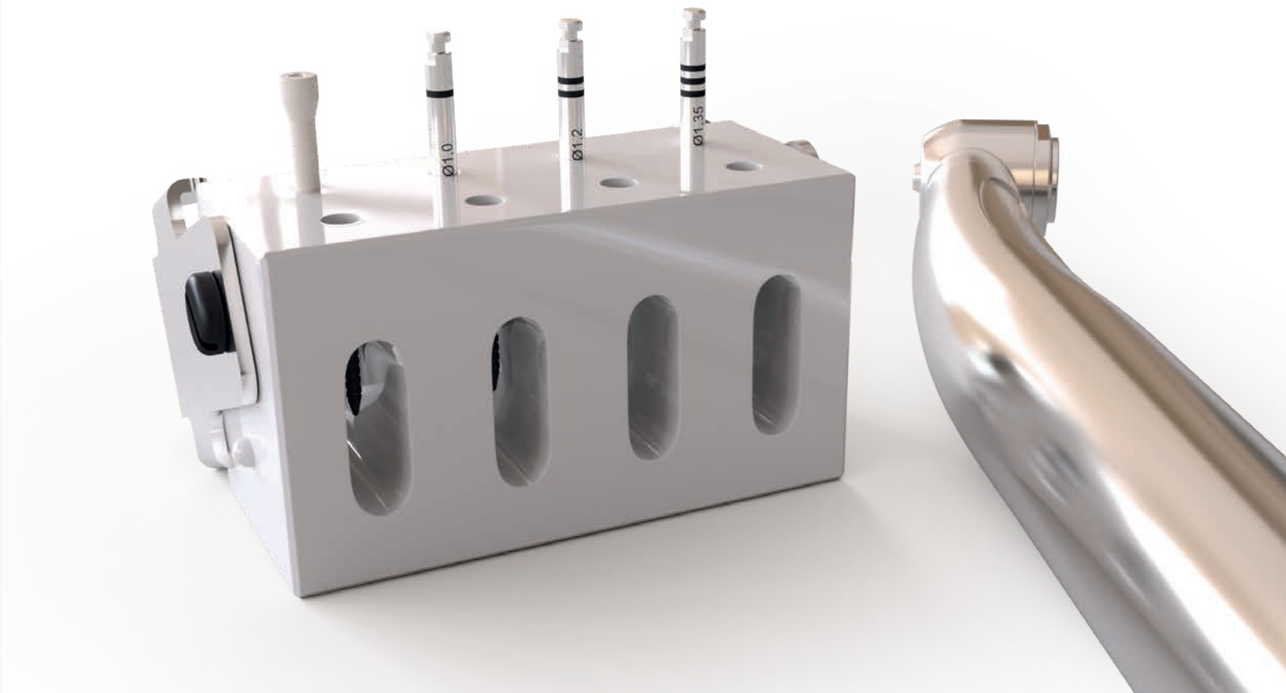
Determine the positions of NOVAMag® fixation screws within the oral cavity. To prepare the insertion of NOVAMag® fixation screw S - XL, use the pilot drills.

The pilot drills are laser engraved with rings at the ends of their shanks for easily identifying their size (1 ring for the 1.0 mm Ø drill, 2 rings for the 1.2 mm Ø, and 3 rings for the 1.35 mm Ø drill). Along the body of the drills are depth marks corresponding to the length of the different NOVAMag® fixation screw sizes.

The NOVAMag® drill rack provides two functions: it is used to organize and display the drills for ease of selection during surgery, additionally it holds and supports the NOVAMag® fixation screws to aid with their attachment to the NOVAMag® connector.

A pilot hole should be drilled using the pilot drill 1.0 to assess bone hardness. For soft bone, a 1.0 mm diameter hole should be sufficient; for harder bone, increase the hole diameter using either the pilot drill 1.2 or 1.35. The hole diameter should facilitate screw insertion without sacrificing screw stability.

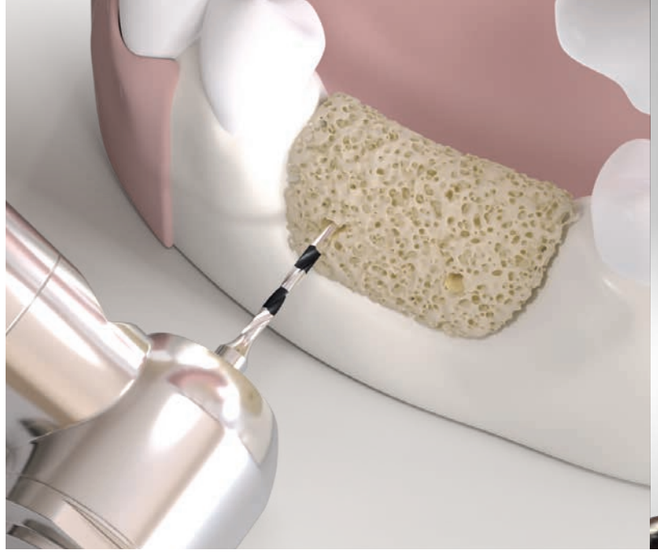
NOTE: For bone block fixation, it is recommended to open the hole through the bone block using the 1.35 mm drill, the size of which is independent of the size of drill used for the hole in the patient's native bone.

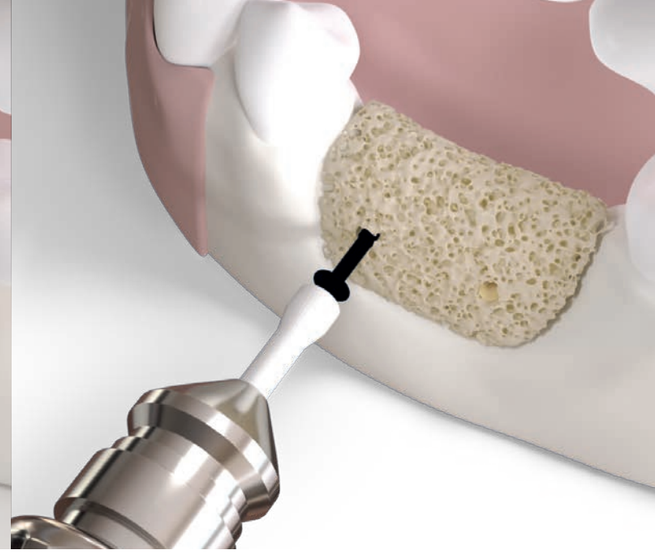


FIXATION SCREW **INSERTION**

In preparation for screw insertion, the NOVAMag® fixation screws can be placed drive side up in the NOVAMag® drill rack. By holding and supporting the downwards position of the fixation screws, the drill rack assists with the attachment of the NOVAMag® connector to the screw drive.

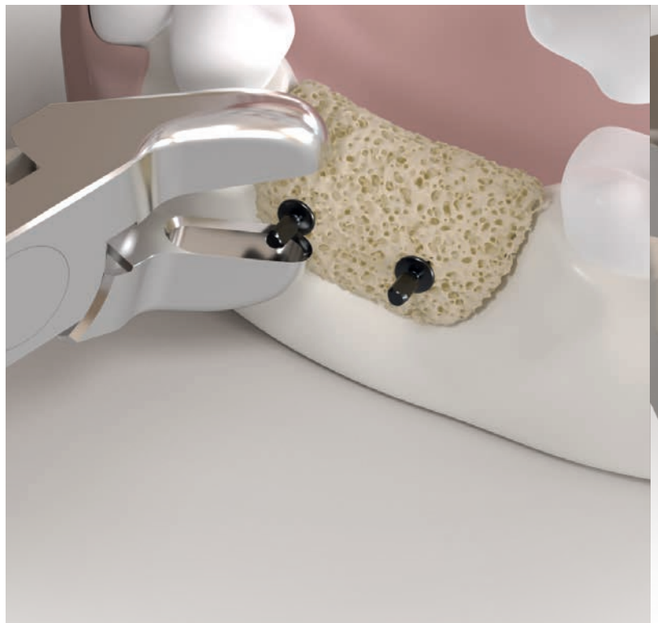
To pick up the screw, the connector is first attached to a contra angle or hand wrench. The head of the connector is then placed on to the screw drive and slowly twisted, applying a mild pressure until the connector engages with the drive.

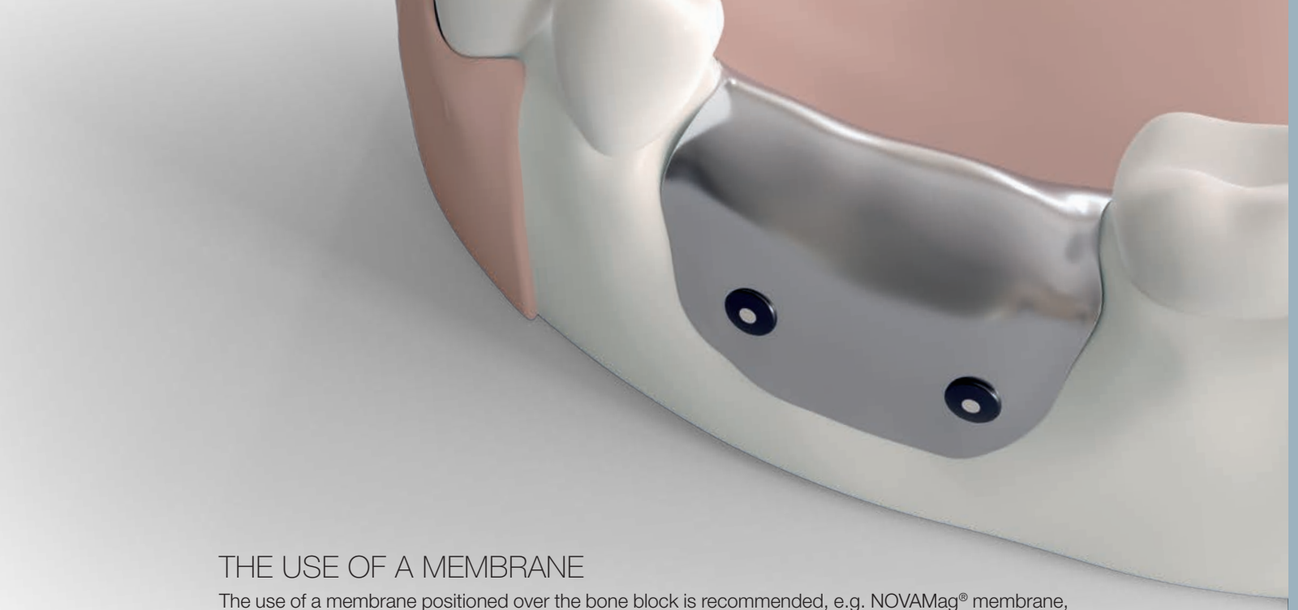




Position the screw over the prepared hole and apply a slight downward pressure to aid threading the screw. During insertion, the axis of the NOVAMag® fixation screw must align to the angulation of the prepared fixation hole.

CAUTION: Only insert the fixation screws S - XL until the screw head visibly contacts the bone block, gently pressing the bone block against the native bone. Once seated, it is mandatory to use the NOVAMag® safety cutter to remove the screw drive. Upon detachment, the drive will be retained within the NOVAMag® safety cutter, which must remain closed until out of the oral cavity and in a position to dispose of the detached drive.





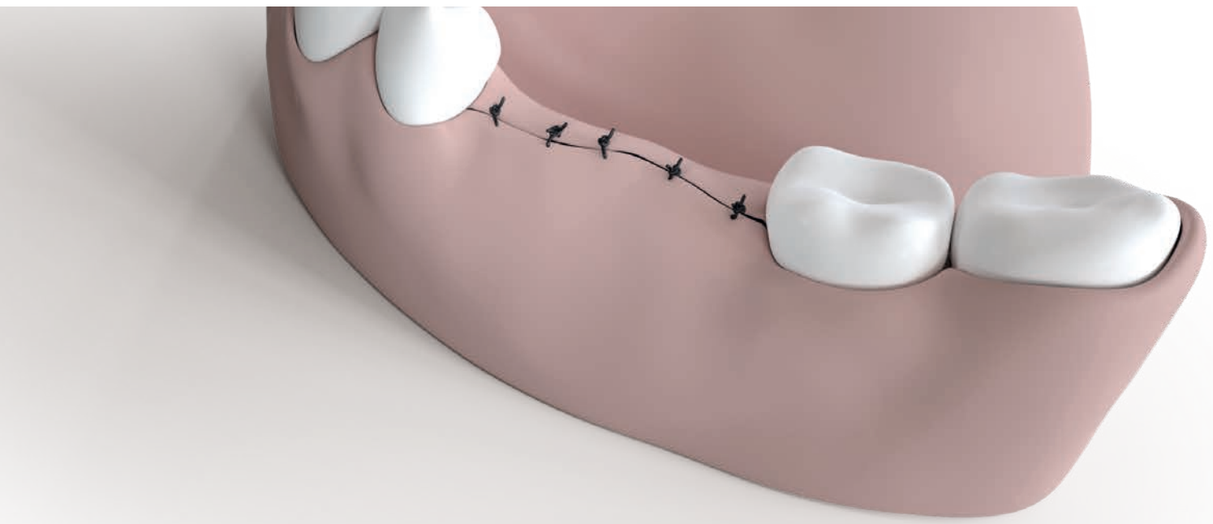
THE USE OF A MEMBRANE

The use of a membrane positioned over the bone block is recommended, e.g. NOVAMag® membrane, Jason® membrane or collprotect® membrane. The membrane should be secured using a suitable fixation system, such as the NOVAMag® fixation screw XS.

FLAP MANAGEMENT

For wound closure, the mucoperiosteal flap is repositioned over the membrane tightly, yet without high tension, and then sutured.

All NOVAMag® fixation screws should be completely covered by the mucoperiosteal flap – any exposure could lead to accelerated resorption.



CHECK-LIST:
Bone block fixation using NOVAMag® fixation screws

- ☐ Consideration of soft tissue management
- ☐ Appropriate screw size selected for augmentation
- ☐ Bone block predrilled using the pilot drill 1.35
- ☐ Pilot hole drilled using the pilot drill 1.0
- ☐ The insertion hole widened using the pilot drill 1.2 or 1.35 for medium to hard bone types
- ☐ Screw drive removed using the NOVAMag® safety cutter
- ☐ Membrane secured over the bone block
- ☐ Fixation screws are completely covered by the mucoperiosteal flap for closed wound healing

POST-OPERATIVE **CARE**

Care should be taken to avoid a heavy loading (mechanical trauma) to the treated site. Patients need to be instructed that a certain level of pain is expected after surgery. An appropriate treatment plan for pain management should be provided for the patient.

A postoperative antibiotic treatment should be considered that lasts between 5-10 days, as is the case following any other GBR surgery. This can include measures such as plaque control with chlorhexidine or triclosan.

After a period of 1 week, the patient should be recalled for monitoring of the healing process.

POST-OPERATIVE X-RAYS

As the magnesium implant degrades, it will produce an alkaline environment. The alkaline environment will delay the onset of bone mineralization in the immediate vicinity of the implant. Once the magnesium has fully degraded, the surrounding bone will mineralize as normal.
During the degradative period, X-rays taken of the defect will appear to show the NOVAMag® membrane and the NOVAMag® fixation screw surrounded by regions with a high radiolucency. This is an expected phenomenon, and is not related to an inflammatory response that would otherwise cause a radiolucency of the bone.

COMPLICATION MANAGEMENT / TROUBLESHOOTING

It is recommended that the surgical site be closed for healing. Cases of small dehiscence should disappear after 2-5 weeks. For instances of exposure, it is recommended that special care is taken for controlling oral hygiene, rinsing the area with e.g. CHX solutions until the infection clears and avoiding acidic food and/or drink products. There is no need for membrane removal in the case of localized exposure. In case of dehiscences, changes in color of the membrane is expected. An exposure of the NOVAMag® membrane during the healing phase might shorten the resorption time.

A temporary formation of gas cavities cannot be excluded. However, the gas cavities will not interfere with the regeneration process and will be resorbed by the body. During the degradation process, patients might feel a slight tingly sensation at the wound site. In severe cases, prescribing pain killers may alleviate the symptoms.

Possible general complications might be caused by the surgical intervention itself, such as a recession of the gingiva, heavy gum bleeding, swelling of the soft tissue, temperature sensitivity, desquamation of the gingival epithelium in the area of the flap, a resorption or ankylosis of the treated dental root, a minor loss of crestal bone height, infections, pain or complications due to the use of anesthetics.

Documented clinical studies

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