bone & tissue regeneration

botiss biomaterials

NOVA**Mag**®

RESORBABLE MAGNESIUM

biomaterials

Origins of NOVAMag® regeneration system

Every bone augmentation procedure is unique, necessitating the use of materials with diverse properties. Until now, the choice has been between mechanically strong, non-resorbable materials that either remain permanently in-situ or are extracted with a second surgery, or resorbable materials that are either soft and durable or hard and brittle. To fulfill the need for a resorbable augmentation material that is both strong and durable, the NOVAMag® regeneration system was developed.

Material Selection

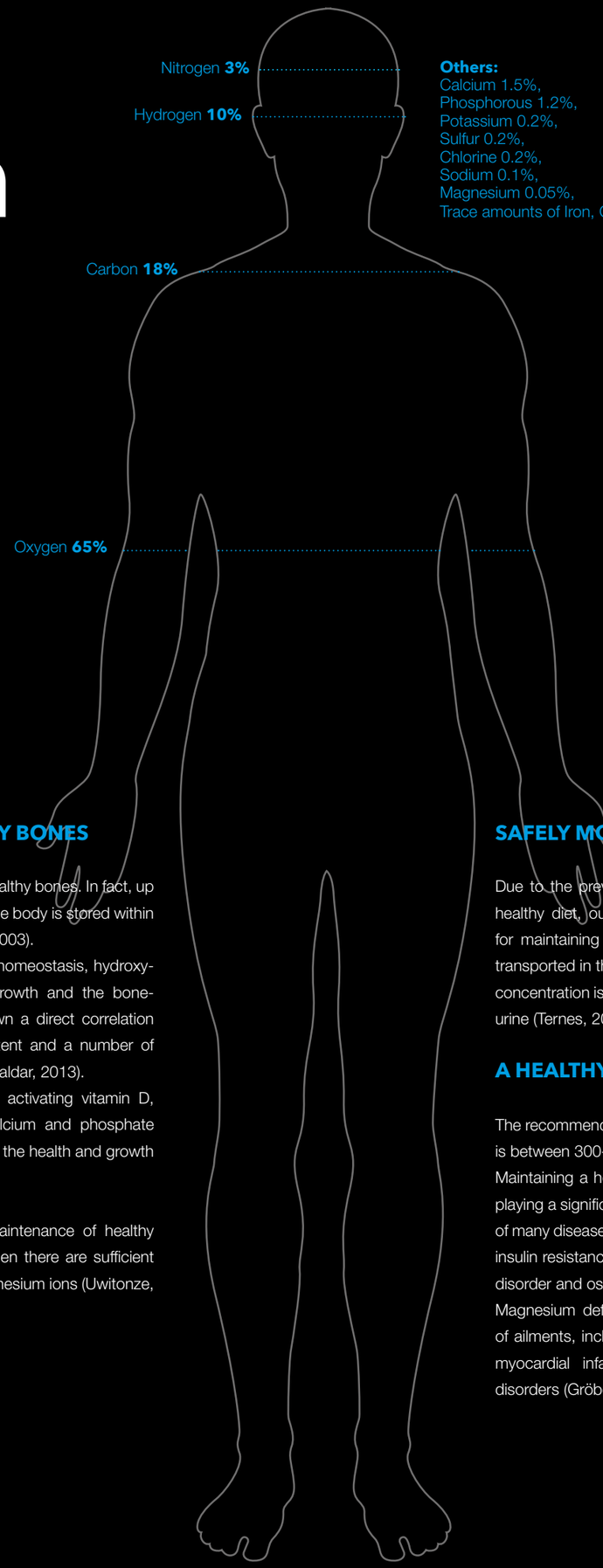
Magnesium is a biodegradable metal with a long history of use as a medical material, yet the NOVAMag® regeneration system is the first to utilise the material for regenerative dentistry.

Early use was restricted by a lack of metallurgic knowledge that prevented the magnesium properties from being tailored to the ideal characteristics required for tissue engineering. This is why there are no other dental magnesium products on the market.

Thanks to advances in metallurgic knowledge and technology, the NOVAMag® regeneration system has been developed by experts. Each NOVAMag® magnesium product is finely tuned to provide the ideal properties for bone augmentation and tissue regeneration in the oral cavity.

Magnesium
at a Glance

Magnesium is released by the stars in supernova explosions and is the ninth most abundant element in the universe. It is an essential element of life that is present throughout nature and supports vital mechanisms within the human body.



Others:
Calcium 1.5%,
Phosphorous 1.2%,
Potassium 0.2%,
Sulfur 0.2%,
Chlorine 0.2%,
Sodium 0.1%,
Magnesium 0.05%,
Trace amounts of Iron, Cobalt, Copper, Zinc, Iodine

THE IMPORTANCE OF MAGNESIUM

The following is a short list of biochemical processes requiring the presence of magnesium ions (Gröber, 2015):

- ATP production – yielding energy to our cells
- The formation of nucleotides – building blocks of DNA and RNA
- Active transportation of calcium and potassium ions across cell membranes; a process which produces nerve impulses, muscle contraction and a healthy heart rhythm
- Maintainance of healthy bones via magnesium dependent vitamin D activation

An Important Element in the Human Body

Magnesium is found in many foods associated with a healthy lifestyle, such as nuts, whole grains and grain products, seafood, some vegetables, legumes, berries and bananas (EFSA NDA Panel, 2015; Arena, 1997).
In the human body, magnesium is the eleventh most abundant element, the fourth most abundant cation, and is found in almost every cell (EFSA NDA Panel, 2015).

Magnesium is an important co-factor in more than 300 enzyme systems regulating vital biochemical reactions in the human body. These reactions include protein synthesis, muscle and nerve function, blood glucose control and blood pressure regulation (Gröber, 2015; Wolf, 2003; Saris, 2000).

CRUCIAL FOR HEALTHY BONES

Magnesium is associated with healthy bones. In fact, up to 60% of all the magnesium in the body is stored within our bones (Gröber, 2015; Wolf, 2003).
It is pivotal in mineral and bone homeostasis, hydroxy-apatite crystal formation and growth and the bone-cell function. Studies have shown a direct correlation between bone magnesium content and a number of bone mechanical properties (Havaldar, 2013).
Magnesium is also required for activating vitamin D, which is known to regulate calcium and phosphate homeostasis, as well as maintain the health and growth of bones (Uwitonze, 2017).

It has been shown that the maintenance of healthy bones can only be achieved when there are sufficient levels of both vitamin D and magnesium ions (Uwitonze, 2017).

SAFELY MODULATED BY THE BODY

Due to the prevalence of magnesium within a normal healthy diet, our bodies have an established method for maintaining healthy concentrations. Magnesium is transported in the blood serum to the kidneys where its concentration is regulated and any excess is excreted in urine (Ternes, 2013; Jahnen-Dechent, 2012).

A HEALTHY CHOICE

The recommended daily intake of magnesium for adults is between 300-350 mg/day (EFSA NDA Panel, 2015).
Maintaining a healthy level of magnesium is important, playing a significant role in the prevention and treatment of many diseases, such as Alzheimer's disease, asthma, insulin resistance, migraine headaches, attention deficit disorder and osteoporosis (Gröber, 2015).
Magnesium deficiencies have been linked to a range of ailments, including atherosclerosis, type 2 diabetes, myocardial infarction, hypertension and psychiatric disorders (Gröber, 2015).

AN ENERGY REJUVENATOR

Due to its many positive functions associated with muscle contraction and creating energy for the cells, athletes sometimes take magnesium supplements to increase their energy and endurance.
During a heavy workout, lactic acid can build up in the muscles and cause pain. By taking magnesium supplements, pain can be alleviated by improving the removal of lactic acid from the muscles and promoting faster recovery from a heavy workout.

THE RIGHT CHOICE

Given the broad range of benefits, it is understandable that people choose to supplement their daily lives with magnesium.
Equally understandable is the use of magnesium for bone regeneration in the oral cavity. Magnesium implants protect and stabilize the wound, and once absorbed, provide an additional source of magnesium ions, sustaining other important functions within the body.

Magnesium
as a Medical Material

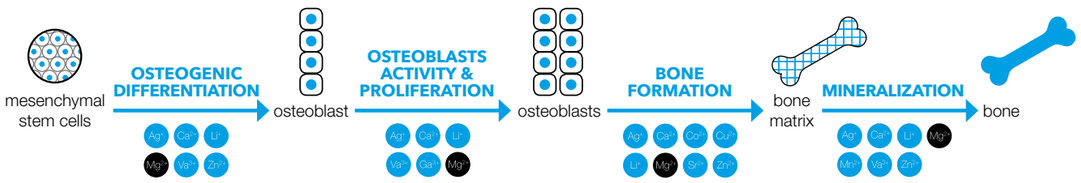
History

Magnesium metal has been used as a medical implant material since the late 19th century (Witte, 2010). In 1878, the physician Edward C. Huse used magnesium wires as ligature to stop bleeding radial arteries. His research reported excellent biocompatible properties and the in situ degradation of the magnesium wires. However, it wasn't until 1900 that magnesium was applied to musculoskeletal applications by Erwin Payr, who introduced the idea of using magnesium plates and sheets in joint arthroplasties.

Early clinical research was hindered by a limited metallurgical knowledge and technology. This prevented magnesium from becoming a significant implant material.

INFLUENCE OF METAL IONS ON BIOLOGICAL PROCESSES

Bone Regeneration



Properties

Mechanical

One of the major benefits of using magnesium metal for bone regeneration and repair is its mechanical properties. Unlike other metallic implants that have a high stiffness, magnesium has a stiffness that is more similar to that of human bone (Chen, 2018; Riaz, 2018; Wang, 2012). As the magnesium metal is degradable, it initially provides a secure structure during the critical healing period, after which, it is replaced by the patient's native bone.

Compared to other resorbable materials such as collagen or synthetic polymers, magnesium is inherently stronger. The increased mechanical strength of magnesium translates into enhanced fixation capabilities of the NOVAMag® fixation screw, and a better stability and space maintenance under the NOVAMag® membrane.

Degradation

Implanted in the body, magnesium metal will naturally degrade. As the magnesium degrades it forms magnesium salts that are then resorbed by the body (Agha et al., 2016). Many of the magnesium salts that are produced are used medically as antacids or as powder in toothpaste.

During the degradation process, magnesium metal releases magnesium ions (Mg^{2+}) that have many positive effects within the body, playing an active role in ATP production, nerve impulses, muscle contraction and the growth and the health of bones (Gröber, 2015; Wolf, 2003). Some of the positive influences of Mg^{2+} on bones include stimulating its growth and maintenance (Glenske, 2018).

As the human body has a regular natural intake of magnesium ions, it has an established pathway for its excretion in urine (Ternes, 2013). Therefore, the body can utilize this pathway for the removal of excess magnesium ions released during degradation.

Tissue Regeneration

Implanted magnesium scaffolds demonstrate an excellent tissue response, including bone tissue ingrowth and vascularization (Yazdimamaghani, 2017). As the magnesium metal degrades it releases magnesium ions (Mg^{2+}), which are known to have positive effects on the growth of bone cells and accelerate bone healing (Liu, 2018; Hieu, 2013). It has been shown that Mg^{2+} increased the metabolic rate of osteoblasts and protein levels in bone-derived cells (Zreiqat, 1999).

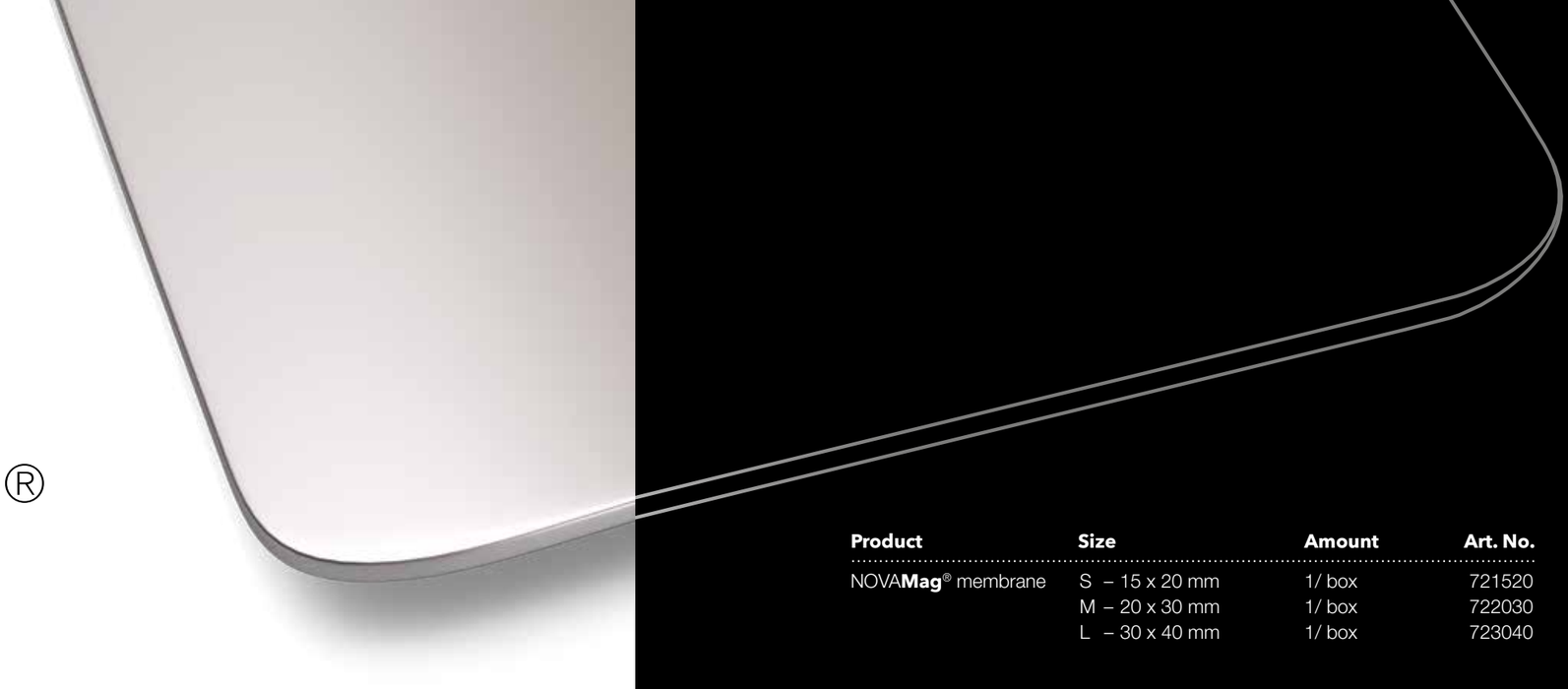
An Ideal Implant Material

Magnesium has many beneficial properties for use as an implant material. A long history of use in medical applications has produced a proven track record for its biocompatibility. Its strong but degradable properties mean that it provides initial stability during the critical healing period, but degrades, removing the requirement for its extraction in an additional surgery, reducing invasiveness and patient morbidity. As it degrades it releases magnesium ions, an essential element in the human body and well known to provide many positive effects on bone.

All of these properties combined make magnesium an ideal implant material and perfect for application in dental regenerative surgeries.

NOVA**Mag**®
regeneration system

Magnesium metal is ideal for regenerative surgeries. It provides the mechanical stability of a metallic structure, whilst offering reliable degradation and resorption. Products produced from magnesium metal do not need to be extracted, resulting in fewer surgeries, reduced invasiveness and less chair time. These factors make the NOVAMag® membrane and the NOVAMag® fixation screw ideally suited for regenerative surgeries.



NOVA**Mag**® membrane

Product	Size	Amount	Art. No.
NOVA**Mag**® membrane	S – 15 x 20 mm	1/ box	721520
	M – 20 x 30 mm	1/ box	722030
	L – 30 x 40 mm	1/ box	723040

The magnesium membrane is strong but ductile. It can be trimmed to size and shaped for treating individual bone defects. Because the NOVAMag® membrane is completely resorbed within a few months after implantation, a second surgical intervention to remove the membrane is not necessary.

The NOVAMag® membrane is produced from pure magnesium metal. Due to the inherent properties of magnesium metal, the membrane is mechanically strong yet degradable. It is ideal for protecting the bone defect voids during bone regeneration and maintaining the positioning of autologous bone and bone augmentation materials such as cerabone®.

INDICATIONS

- bone defects and bone wall defects
- sinus floor augmentation
- ridge augmentation or reconstruction for prosthetic treatment
- treatment of fenestration defects
- periodontal bone defects (one to three-wall defects, furcation defects)
- after apicectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- extraction sockets after tooth extractions
- GBR in conjunction with immediate or delayed implant placement

CONTRAINDICATIONS

The NOVAMag® membrane must not be used in patients suffering from:

- acute infections in the oral cavity or acute or chronic inflammation at the implantation site
- general diseases, where measures of stomatology, maxillofacial surgery, implantology, periodontology or other measures of oral surgery must not be performed
- known hypersensitivity to any of the trace elements
- inadequate coverage of the defect site with healthy tissue

PRODUCT PROPERTIES

Origin	Synthetic
Composition	Magnesium (Mg)
Thickness	140 ± 20 µm
Fixation	The membrane should be completely immobilized on both sides of the defect (orally and buccally) with the NOVAMag® fixation screw XS or other commercially available fixation systems comprising of titanium screws or sutures.
Degradation time	Resorbable (within 2-4 months)
Removal	Not necessary (resorbable)

NOVA**Mag**® fixation screw

Made from a completely resorbable, biodegradable, magnesium metal alloy, NOVAMag® fixation screws are ideal for securing barrier membranes, bone grafts and bone augmenting material. The fixation screws come in five sizes to suit all fixation requirements.

The smallest screw (the NOVAMag® fixation screw XS) is specifically designed for securing membranes, such as the NOVAMag® membrane, the collagen membranes Jason® membrane or collprotect® membrane, as well as non-resorbable PTFE membranes, such as permamem®.

PRODUCT PROPERTIES

Origin	Synthetic
Composition	Magnesium Alloy
Diameter	1.0 mm (XS) or 1.4 mm (S, M, L, XL)
Length	3.5 mm (XS), 7 mm (S), 9 mm (M), 11 mm (L), 13 mm (XL)
Application	Follow the appropriate drilling protocol as directed in the NOVAMag® fixation screw IFU
Degradation time	Resorbable (within approximately 1 year)
Removal	Not necessary (resorbable)

Product	Size	Amount	Art. No.
NOVA**Mag**® fixation screw	XS – 1.0 mm x 3.5 mm	2/ box	74100402
	XS – 1.0 mm x 3.5 mm	4/ box	74100404
	S – 1.4 mm x 7 mm	1/ box	74140701
	M – 1.4 mm x 9 mm	1/ box	74140901
	L – 1.4 mm x 11 mm	1/ box	74141101
	XL – 1.4 mm x 13 mm	1/ box	74141301

NOVAMag® fixation screws can be used in combination with augmentation materials such as autogenous bone or cerabone®. Because the fixation screws are completely resorbed approximately one year after implantation, a second surgical intervention is not needed to remove them.

INDICATIONS

- bone defects and bone wall defects
- sinus floor augmentation
- ridge augmentation or reconstruction for prosthetic treatment
- treatment of fenestration defects
- maxillofacial surgeries (not to be used in conjunction with a plate system)
- periodontal bone defects (one to three-wall defects, furcation defects)
- apicectomy, cystectomy, resection of retained teeth and resection of other bone lesions
- GBR in conjunction with immediate or delayed implant placement

CONTRAINDICATIONS

NOVAMag® fixation screws must not be used in patients suffering from:

- acute infections in the oral cavity, or acute or chronic inflammation at the implantation site
- general diseases, where measures of stomatology, maxillofacial surgery, implantology, periodontology or other measures of oral surgery must not be performed
- known hypersensitivity to Magnesium or any of the alloying elements including Copper, Fluoride, Iron, Manganese, Nickel, Yttrium, Zinc, Zirconium
- insufficient quantity and quality of bone to securely anchor NOVAMag® fixation screws
- inadequate coverage of the defect site with healthy tissue

NOVA**Mag**® Instrumentation

To facilitate surgeries using the NOVAMag® membrane and / or the NOVAMag® fixation screw, botiss has developed a range of NOVAMag® instruments.

NOVA**Mag**® scissors

The NOVAMag® scissors have a rounded blade to create a smooth, curved edge when cutting the NOVAMag® membrane. The high-quality blades of the scissors deliver long-lasting sharpness and consistent cutting results.

Product	Size/Amount	Art. No.
NOVAMag® scissors	1/ box	BT1003

NOVA**Mag**® sculptor

The NOVAMag® sculptor is a specially designed multi-purpose tool developed to prepare the NOVAMag® membrane for its use in GBR procedures. Its shape and size enable the user to mold the NOVAMag® membrane in a simple yet effective manner.

Once the NOVAMag® membrane has been cut to shape, the back end of the handle can be used to smoothen out the rim. The shaft can be used to bend the membrane into a rounded shape mimicking the ridge to be augmented, whilst the tip can be used for finessing contours of the membrane to match the profile of the augmentation site. The point of the tip can also be used to mark the planned fixation points when the membrane is positioned over the defect.

Product	Size/Amount	Art. No
NOVAMag® sculptor	1/ box	BT1002

NOVA**Mag**® drill rack

The NOVAMag® drill rack holds and supports the pilot drills 1.0, 1.2, 1.35, the precision drill as well as NOVAMag® fixation screws XS-XL.

Between surgeries, the NOVAMag® drill rack provides a secure means of storing and transporting drills.

During surgery, the drills are displayed in a clear and easily accessible manner, improving selection and changing of drill bits. The NOVAMag® drill rack also assists with the attachment process of NOVAMag® fixation screws XS-XL to the NOVAMag® connector.

Product	Size/Amount	Art. No.
NOVAMag® drill rack	1/ box	BT1004

precision drill

The precision drill is a sharp and precise drill for preparing bone and the NOVAMag® membrane for insertion of the NOVAMag® fixation screw XS. A laser engraved depth mark indicates the optimal drilling depth required for proper positioning of the fixation screw.

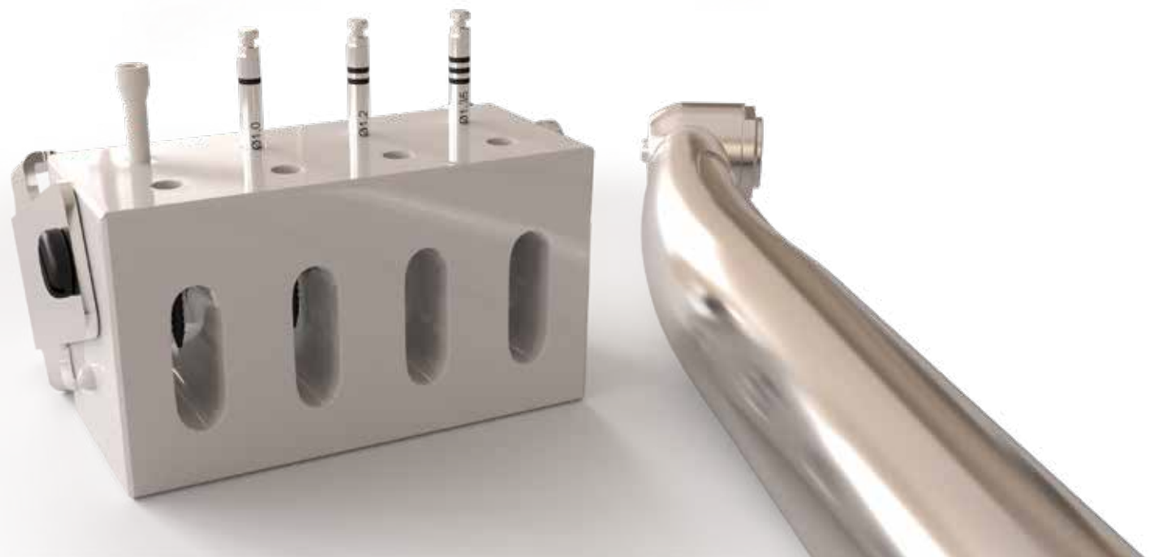
Product	Size/Amount	Art. No.
precision drill	drill 0.9, 1/ box	BT2009

pilot drills 1.0, 1.2 and 1.35

The pilot drills 1.0, 1.2 and 1.35 are used to create insertion holes for NOVAMag® fixation screw S-XL. The drills are designed to produce precisely sized holes, facilitating screw insertion without sacrificing screw stability.

For convenience, the body of each drill bit is laser engraved with depth marks that correspond to the lengths of the respective NOVAMag® fixation screw sizes. Each drill is also engraved with rings at either end of their shank for easy identification of their size (1 ring for the 1.0 mm Ø drill, 2 rings for the 1.2 mm Ø drill, and 3 rings for the 1.35 mm Ø drill). An initial hole should be drilled using the pilot drill 1.0 to ascertain bone hardness. For soft bone, the 1.0 mm diameter hole should be sufficient, however for harder bone types, the use of the pilot drill 1.2 or 1.35 may be necessary.

Product	Size/Amount	Art. No.
pilot drills	drill 1.0, 1/ box drill 1.2, 1/ box drill 1.35, 1/ box	BT2010 BT2012 BT2013



NOVA**Mag**® connector

The NOVAMag® connector is a single-patient-use device designed to enable the correct insertion of NOVAMag® fixation screws XS – XL.

Made from high-quality medical-grade PEEK, the connector is a strong and durable device that can transfer the necessary insertion torque to safely seat NOVAMag® fixation screws.

Product	Size/Amount	Art. No.
NOVAMag® connector	1/ box	74000
	4/ box	74004
	8/ box	74008

NOVA**Mag**® safety cutter

After NOVAMag® fixation screw S-XL have been seated, the NOVAMag® connector is disengaged from the screw, exposing the screw drive. In order to create a smooth and flat profile to the screw head, the drive should be removed using the NOVAMag® safety cutter. The NOVAMag® safety cutter is a plier with a built-in cavity for retaining the drive upon detachment.

Using the cutter is the most effective and safest method for removing the drive of the NOVAMag® fixation screw S-XL in situ. By holding the plier closed, the drive is retained within the plier cavity, allowing it to be safely extracted from the oral environment and disposed of.

Product	Size/Amount	Art. No.
NOVAMag® safety cutter	1/ box	BT1001

NOVA**Mag**® steri WashTray

The NOVAMag® steri WashTray perfectly holds all of the NOVAMag® instruments in a condensed and easily accessible manner for storage, transport and sterilization.

Product	Size/Amount	Art. No.
NOVAMag® steri WashTray	1/ box	BT1005

NOVA**Mag**® bundle

For your convenience, all of the individual NOVAMag® instruments can be ordered together using the NOVAMag® bundle. The NOVAMag® bundle contains the NOVAMag® steri WashTray, which holds the NOVAMag® sculptor, NOVAMag® scissors, NOVAMag® safety cutter and the NOVAMag® drill rack.

Produt	Size/Amount	Art. No.
NOVAMag® bundle	1 x NOVAMag® steri Wash Tray 1 x NOVAMag® scissor 1 x NOVAMag® sculptor, 1 x NOVAMag® safety cutter 1 x NOVAMag® drill rack	BT1006

SURGICAL PROCEDURE

Guided Bone Regeneration using Products from the NOVAMag® regeneration system

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

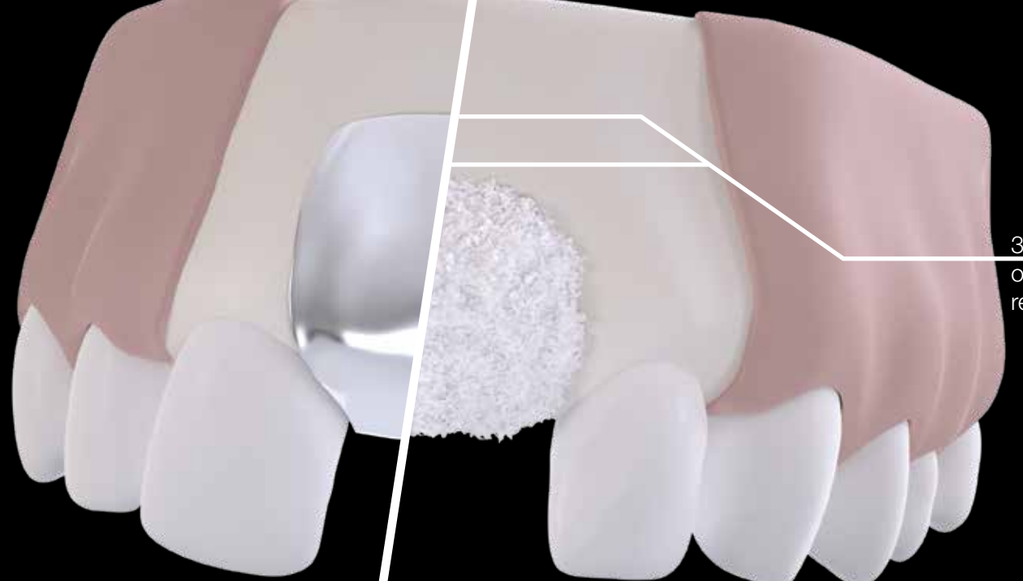
IMPLANT BED PREPARATION

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.



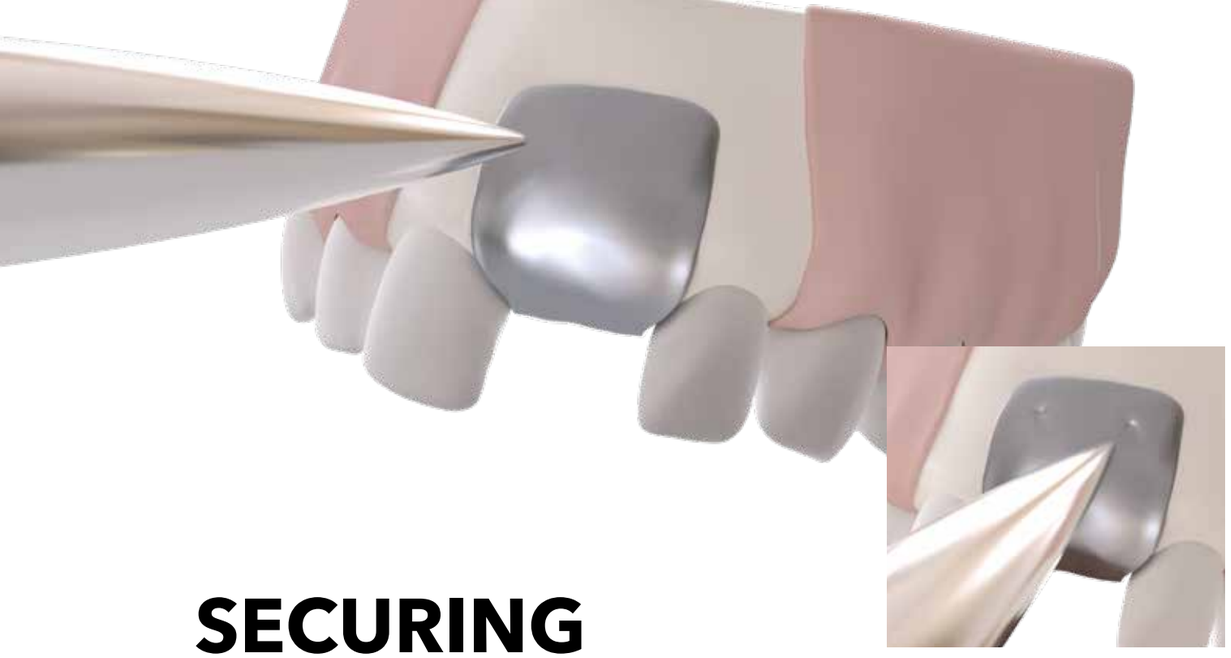
MEMBRANE **PREPARATION**

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.

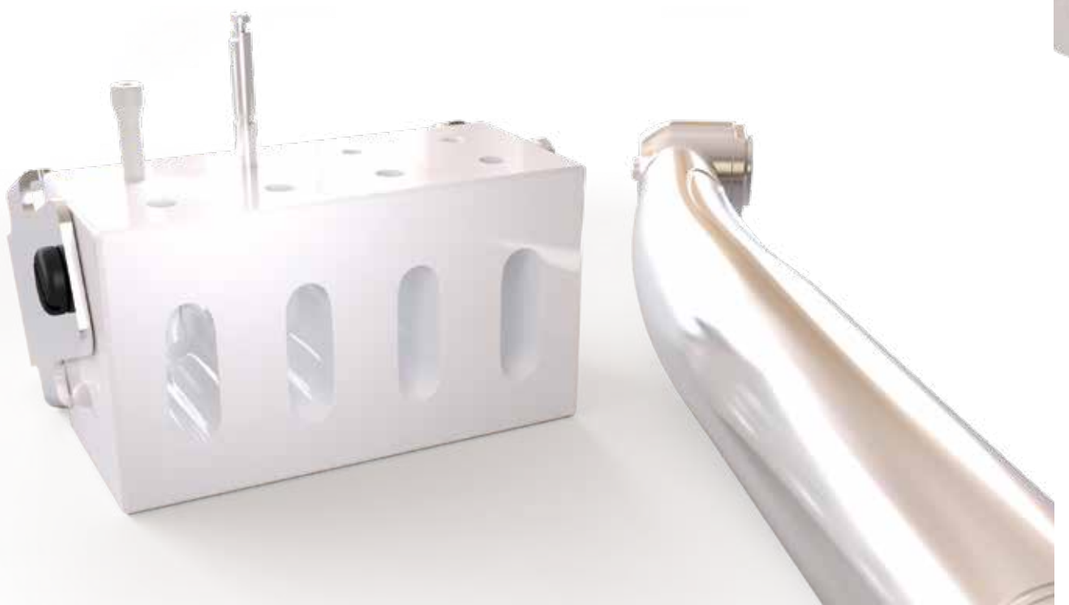


SECURING
THE MEMBRANE

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 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® regeneration system

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

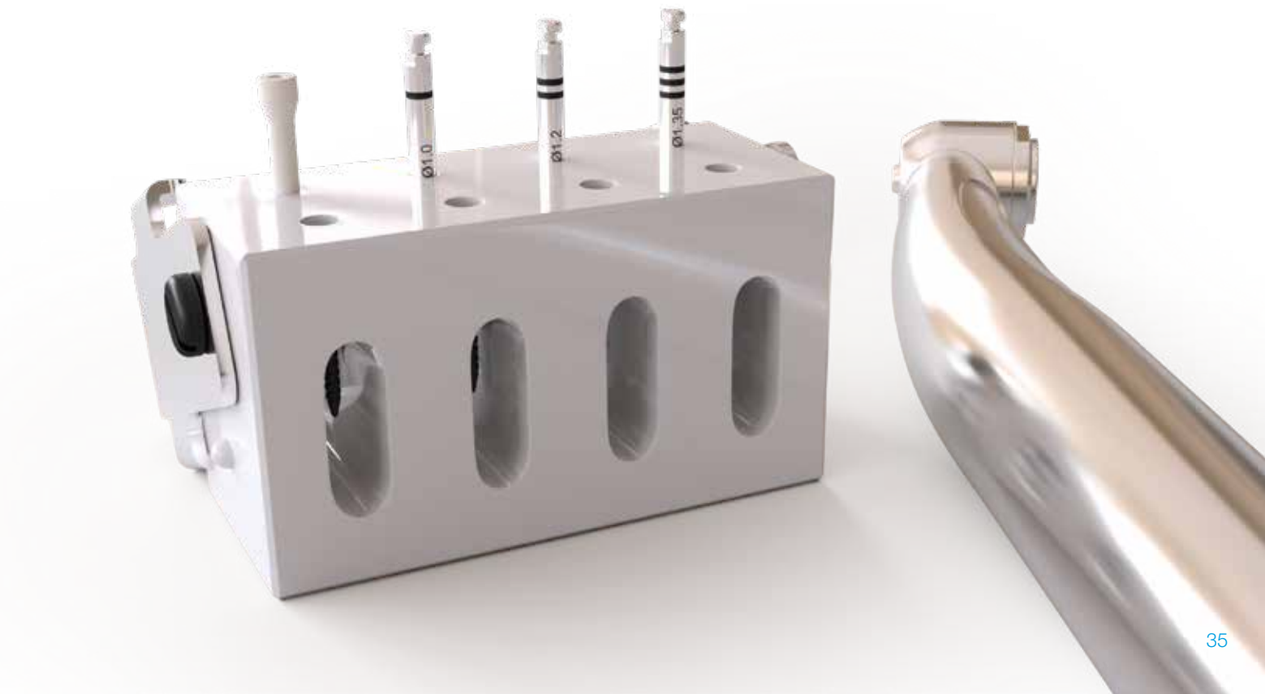
Determine the positions of NOVAMag® fixation screws within the oral cavity. To prepare the insertion of NOVAMag® fixation screw S – XL, use the pilot drills.

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.

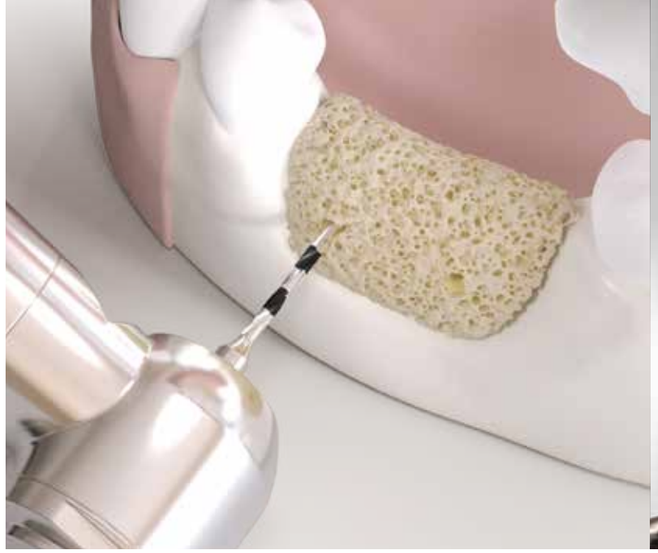
NOTE: For bone block fixation, it is recommended to open the hole through the bone block using the 1.35 mm drill, the size of which is independent of the size of drill used for the hole in the patient's native bone.



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 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.

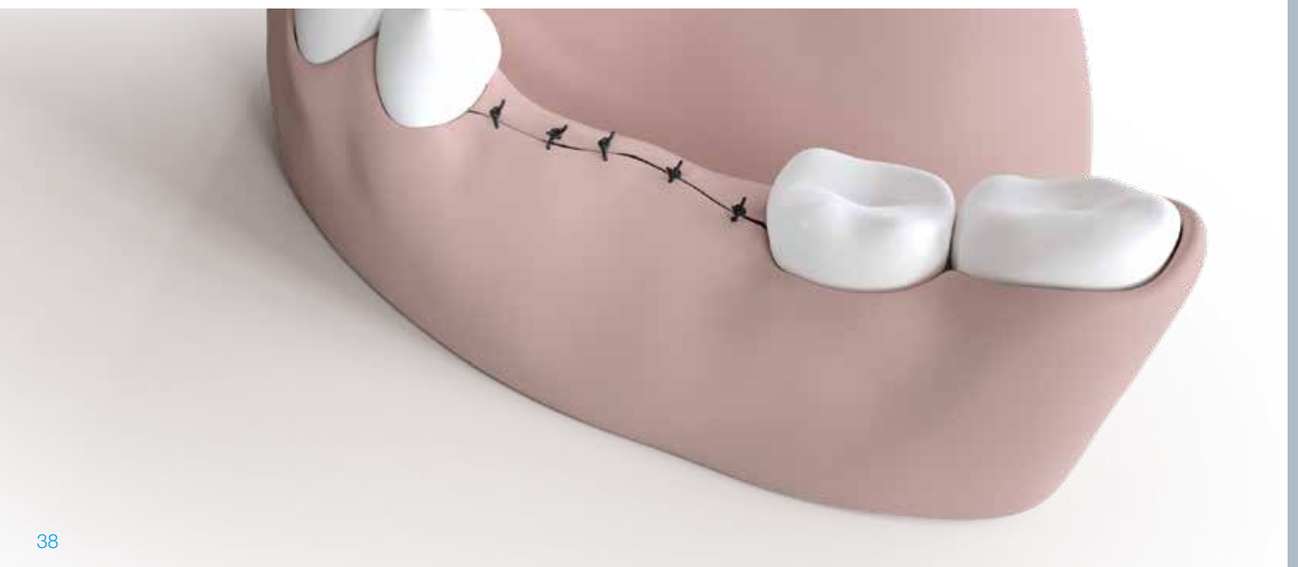
CAUTION: Only insert the fixation screws S – XL until the screw head visibly contacts the bone block, gently pressing the bone block against the native bone. Once seated, it is mandatory to use the NOVAMag® safety cutter to remove the screw drive. Upon detachment, the drive will be retained within the 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

POSTOPERATIVE **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.

POSTOPERATIVE 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.

The Science Behind NOVA**Mag®**

Magnesium
AN ESSENTIAL ELEMENT

Produced by the stars and released into space during supernova explosions (Sarangi, 2018), magnesium is the ninth most abundant element in the universe. Naturally occurring on earth too, the Earth's crust contains about 1.9% of Magnesium (Mg) (in the form of Dolomite, Magnesite etc.) and accounts for around 17% of all the salts in sea water (Ternes, 2013). Due to its prevalence in our environment it has become an integral part of life. In the human body, magnesium is the eleventh most abundant element and fourth most abundant cation (Wolf, 2003).

Magnesium is defined as an essential element for humans. The human body contains about 25 g elemental magnesium, of this, 50% is bound to hydroxyapatite-crystals (about 1.1 g Mg/kg bone), 25-30% is stored in the muscle, with the remaining amount stored mostly intracellularly (Ternes, 2013; Jahnen-Dechent, 2012). Magnesium ions (Mg^{2+}) are involved in many vital biological functions and are one of the most important co-factors in more than 300 biochemical reactions in the human body (Ternes, 2013; Jahnen-Dechent, 2012; Wolf, 2003).

One of these biochemical reactions is the activation of vitamin D, which regulates calcium and phosphate homeostasis, maintaining the health and growth of bones (Uwitonze, 2017). Therefore, without the presence of Mg^{2+}, the maintenance and health of bones is negatively affected (Uwitonze, 2017).

Magnesium ions are naturally occurring in many foods associated with a healthy lifestyle (Arena,1997). The recommended daily intake of magnesium is about 300-350 mg/day for adults and between 80-170 mg/day for kids depending on their age. As the presence of magnesium is well established as part of a healthy human diet, mechanisms already exist for controlling Mg^{2+} levels within the body. Approximately 4.8 mg of Mg^{2+} is transported to the kidneys daily, the majority of which is reabsorbed back into the body via the Henle-Schleife. Excess Mg^{2+} is not resorbed and is excreted as a component of urine (Ternes, 2013; Jahnen-Dechent, 2012).

A BIOCOMPATIBLE MATERIAL

The first application of magnesium as a biodegradable implant material in humans dates back to over a century ago. Although performed without the knowledge of its unique biodegradable properties, Edward C. Huse reported the first successful usage of pure magnesium wire ligature to stop bleeding radial arteries in 1878 (Witte, 2010). Since then, magnesium implants have continued to be investigated for many different applications due to their superb biocompatibility (Chen, 2018).
Magnesium implants have demonstrated an excellent interaction with both hard and soft tissues. Studies have shown an abundance in bone formation around magnesium implants accompanied by a Mg^{2+} instigated substantial increase in the presence of an osteoanabolic peptide (Zhang, 2016).
Studies have shown additional positive effects of Mg^{2+} on bone regeneration, such as on vascularisation (Yazdimamaghani, 2017), the growth of bone cells and accelerating bone healing (Liu, 2018; Hieu, 2013). In relation to the soft tissue response, the release of Mg^{2+} (as the magnesium implants degrade) has been demonstrated to promote the adhesion of human gingival fibroblasts (Amberg, 2018; Amberg, 2019), which is beneficial for barrier membrane applications.

A STRONG BIOMATERIAL

Magnesium metal and its alloys are lightweight yet structurally strong materials that are used in many applications, such as in aerospace engineering, automotive engines, laptops, cameras and power tools (Hirsch, 2013). Combined with the known biocompatibility of magnesium and the many uses of magnesium ions within the body, magnesium metal is considered ideal for hard tissue regeneration.
The many benefits of magnesium metal have so far been harnessed for medical devi es such as stents, screws, fracture plates and osteosynthesis systems (Chen, 2018). Commercially available magnesium implants are used as cardiovascular stents and orthopedic screws.

A RESORBABLE METAL

A major benefit of magnesium is its biodegradability. This means that once it is implanted into the body, over time it will completely degrade and be fully resorbed.

During the corrosion process, the metallic magnesium is oxidized and magnesium ions are released as corrosion products (Eq.1). At the same time, the hydrogen in water molecules is reduced (Eq.2), releasing molecular hydrogen as an additional corrosion product.

A magnesium hydroxide layer is formed from the interaction of the magnesium metal and water molecules (Eq.3), which is deposited on the surface of the magnesium implant (Seitz et al., 2014). These layers are susceptible to corrosion, especially in the presence of anions (Eq.4). The magnesium hydroxide present in the corrosion layer is attacked by soluble chloride ions (Atrens, 2015; Zheng, 2014; Xin, 2008). As a result, the protective $Mg(OH)_2$ layer is dissolved, at least locally, enabling the corrosion process to continue. This principle leads to the complete corrosion of the magnesium implant (Atrens, 2015; Zheng, 2014).

Oxidation:	$Mg \rightarrow Mg^{2+} + 2e^-$	**(1)**
Reduction:	$2H_2O + 2e^- \rightarrow H_2 + 2OH^-$	**(2)**
Hydroxide Formation:	$Mg^{2+} + 2OH^- \rightarrow Mg(OH)_2$	**(3)**
Breakdown of Hydroxide Layer:	$Mg(OH)_2 + 2Cl^- \rightarrow MgCl_2 + 2OH^-$	**(4)**

Based on these equations, the direct degradation products are hydrogen gas and magnesium hydroxide salt (Mg(OH)2).

In a physiological environment, the composition of the liquid surrounding the magnesium implant is very complex. This can lead to the formation of other magnesium salts, such as (Agha et al., 2016):

Magnesium oxide
Magnesium phosphates
Magnesium carbonate
Epsom salt

Many of these magnesium salts are used medically as antacids to treat heartburn or as laxatives for constipation. Magnesium carbonate is commonly used as a powder in toothpaste.

Hydrogen gas is another byproduct of the magnesium degradation process (Eq. 2). Hydrogen is a non-toxic gas that is highly diffusible (Hong, 2010). The diffusion and solubility of hydrogen in biological tissues has been widely reviewed (Piiper, 1962). As magnesium degrades, hydrogen gas pockets can temporarily form, however due to the solubility and diffusive properties of hydrogen gas, these gas pockets will be resorbed by the body.

GUIDED BONE REGENERATION

Successful GBR surgical outcomes depend on multiple factors. In addition to the bone augmentation material used, the applied barrier membrane and fixation system used to protect the material are key to the overall success of the regenerative outcome. Magnesium is a material that has degradable and mechanical properties that make it ideally suited for use as a barrier membrane or fixation screw.

BARRIER MEMBRANES

The optimal barrier membrane design is one that is strong to protect the defect void, as well as degradable, whilst maintaining cell occlusivity during the critical healing period. The NOVAMag® membrane, made from pure magnesium, has been designed to be strong but easy to handle. It fulfills the need for a mechanically stable membrane that can protect the defect void from collapse while being completely degradable, reducing the need for additional surgical interventions for its removal.

FIXATION SYSTEMS

The optimal fixation system is one that provides a secure fixation, but also degrades quickly after fixation of the augmentation material is no longer required. Made from a resorbable magnesium metal alloy, the NOVAMag® fixation screw provides a secure fixation with an optimal resorption rate.

THE PERFECT CHOICE FOR HARD TISSUE REGENERATION

Magnesium is a highly attractive material choice for hard tissue regeneration, being biocompatible, strong and degradable. This is why it has been chosen by botiss biomaterials GmbH and diligently developed into the NOVAMag® regeneration system, offering two unique solutions: the NOVAMag® membrane and the NOVAMag® fixation screw.

NOVA**Mag**® membrane
IMPLANT REQUIREMENTS

The NOVAMag® membrane has been developed to fill the need of a mechanically stable barrier membrane that is also degradable.

In order to attain the best results, a degradable barrier membrane should provide the following properties:

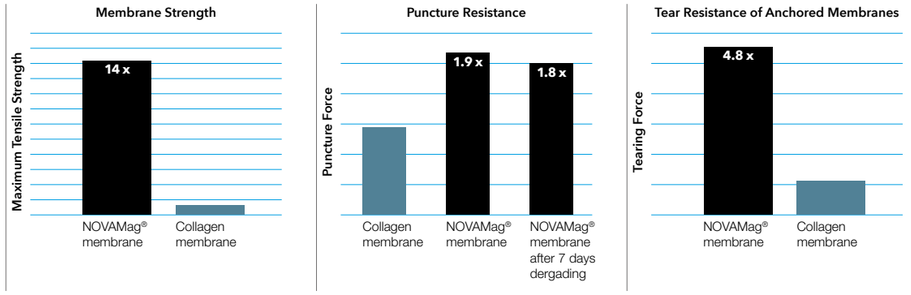
- Easy handling
- Protect the defect void from collapse
- Maintain the positioning of augmentation material
- Cell occlusivity during the critical healing period
- Fully degradable for fewer surgeries and less invasiveness
- Biocompatible and degrades into non-toxic byproducts that do not accumulate

During the development process of the NOVAMag® membrane, botiss ensured that these requirements were successfully achieved.

EASY HANDLING

For the best surgical results, the surgeon needs to be able to shape and position the membrane with ease and without damaging the material. To make certain that the best handling experience is provided, purposely designed instruments are provided to cut and shape the membrane.
The handling of the NOVAMag® membrane and its instruments has been evaluated in multiple usability tests performed by clinicians. These tests confirmed a high level of satisfaction in the cutting, shaping and insertion of the NOVAMag® membrane (data on file at botiss biomaterials GmbH).

Part of the implantation procedure for the NOVAMag® membrane requires that the membrane is pre-shaped prior to its insertion. Bending tests performed according to ISO 7438:2005, established that during bending there was no damage to the surface of the membrane, which remained structurally stable. This stability has been confirmed during in vivo GBR studies where efficacy and safety was demonstrated.



PROTECTS THE DEFECT VOID

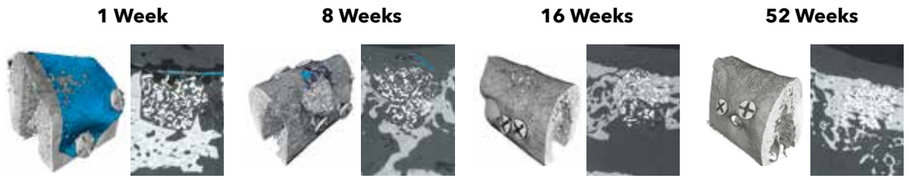
An important aspect of a barrier membrane is its ability to protect the defect void from collapse. This is most easy achieved by using a strong material that can resist the external pressures of soft tissue accumulation and the forces experienced during mastication.
In tests performed according to ISO 6892-1:2017-02, the NOVAMag® membrane had a tensile strength that was 14.0x larger than that of a collagen membrane (data on file at botiss biomaterials GmbH, collagen data taken from publication by Ortolani, 2015). Having a high tensile strength can help protect against the membrane collapsing into the defect space.

Not only does the high mechanical strength of the magnesium membrane help prevent the collapse of soft tissue into the defect void, it also has a high resistance to being punctured. Puncturing of a membrane could occur during mastication, impeding the cell occlusive barrier.
During puncture tests performed according to ASTM F2183-02 (data on file at botiss biomaterials GmbH), the resistance of the NOVAMag® membrane to penetration was 1.9x higher than that of a collagen membrane. Even after 7 days under degradative conditions, the magnesium membrane remained 1.8x more resistant to puncture than that of the undegraded collagen membrane.

Restricting the movement of a barrier membrane using a fixation system will prevent the loss of bone augmentation material, as well as maintain the barrier between the defect void and the overlying soft tissue. Tearing of the membrane will result in a loss of stability and a high risk of dislodgement. As long as a barrier membrane does not tear or loosen at its points of fixation, it will remain securely positioned over the defect.
During tear tests performed according to ASTM F564, membranes were secured with titanium screws and pulled until they tore. In the test, the resistance of the NOVAMag® membrane to tearing was so great that the anchorage of the titanium fixation screw failed before the membrane tore (data on file at botiss biomaterials GmbH). In contrast, all collagen membranes tore at about 20% of the fixation strength of the titanium fixation screw.

MEMBRANE RESORPTION FOR REDUCED INVASIVENESS

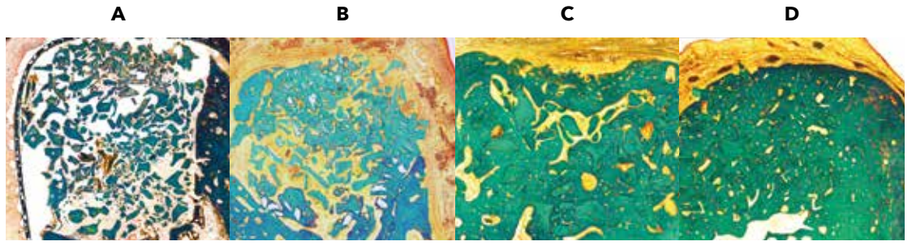
Magnesium metal will begin to degrade once implanted, forming magnesium salts which are then resorbed by the body. The formation of the magnesium salts acts as another barrier to soft tissue ingrowth and provides a second phase to the functional lifespan of the NOVAMag® membrane (data on file at botiss biomaterials GmbH.) In-vivo experiments demonstrated that the NOVAMag® membrane provides a barrier to the soft tissue during the critical healing period, and that the magnesium metal and its byproducts are completely resorbed over an 8–16 week period.
One week after implantation, µCT images show dark patches around the metallic NOVAMag® membrane (metallic phase of membrane colorized in a magenta shade) in the cross sectional images shown in Figure 2. The dark patches represent the formation of hydrogen gas pockets that maintain a separation of the soft and the hard tissues. By week 8, the majority of hydrogen gas has been absorbed by the body, and by week 16 and 52, no gas pockets are visible.



Degradation of the NOVAMag® membrane in-vivo. The metal structure of the NOVAMag® membrane is shown in a blue color. The metallic and salt phases of the NOVAMag® membrane maintained an effective barrier during the critical healing period and retained the positioning of the augmentation material.

CELL OCCLUSIVE

During the critical healing period, it is important that a barrier membrane isolates the defect void from fast growing connective and epithelial tissues that would otherwise quickly occupy the space and restrict bone ingrowth.
In vivo testing has demonstrated the excellent performance of the NOVAMag® membrane during GBR surgeries. Most of the metallic magnesium has degraded over the initial 8 weeks after implantation, however its transformation into magnesium salts and thin hydrogen gas pockets maintained a separation of the soft and hard tissues. A separation of the soft and hard tissues was evident at every follow-up over the 52 week follow-up period, enabling new bone to fill the defect space.



The NOVAMag® membrane maintains an occlusive cellular barrier enabling new bone to fill the defect void. A) 1 week, B) 8 weeks, C) 16 weeks, D) 52 weeks

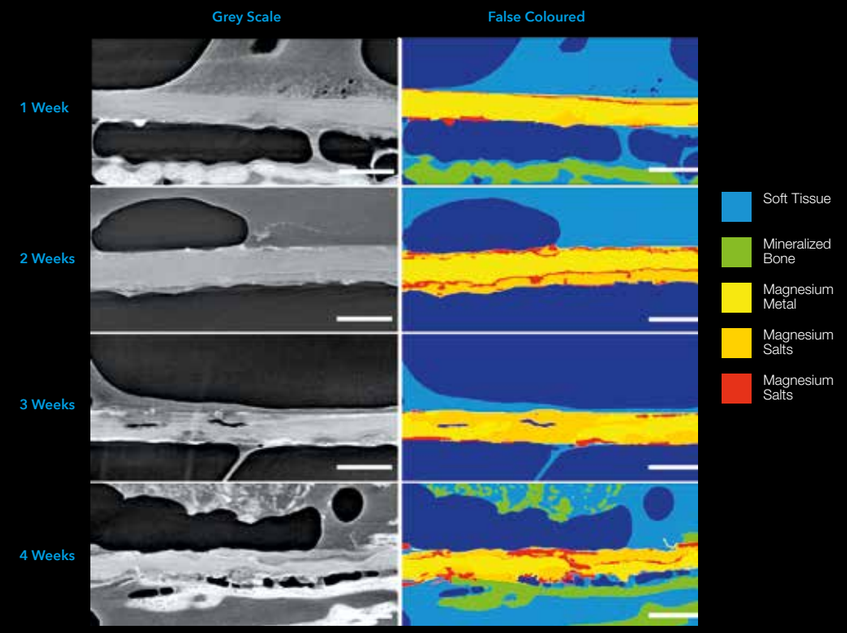
IDEAL FOR TISSUE REGENERATION

The best surgical outcome (involving a barrier membrane) is achieved by the seclusion of the defect void from the overlying soft tissues, enabling new bone growth; the complete resorption of the barrier membrane; and the replacement of the membrane with healthy tissue.

Over a 4-8 week period after implantation in vivo, the NOVAMag® membrane maintained a barrier, enabling new bone to grow and fill the defect void. It degraded so that none of its byproducts were detectable at the defect site 52 weeks after its implantation. The magnesium membrane was also completely replaced by healthy new bone. During the resorption of the magnesium metal and magnesium salts, it was observed that the membrane became surrounded and then replaced by new bone.

NOVAMag® **MEMBRANE** DEGRADATION:
IN THE FIRST 4 WEEKS

STUDY: Degradation kinetics of membranes pinned in-vivo



Scale bar: 250 µm

NOVA**Mag**® fixation screw
IMPLANT REQUIREMENTS

The NOVAMag® fixation screw has been created to fulfill the requirement of a fixation system that provides a secure fixation of a membrane or bone augmentation material, which quickly and completely degrades after fixation is no longer required.

A resorbable fixation system should have the following properties:

- Safe insertion / easy handling
- Secure anchorage within the bone
- Reliable fixation of a membrane or bone block
- Fully degradable for fewer surgeries and less invasiveness
- Biocompatible and degrades into non-toxic byproducts that do not accumulate
- Replaced with healthy tissue

During the development process of the NOVAMag® fixation screw, botiss ensured that these requirements were successfully achieved.

SAFE INSERTION

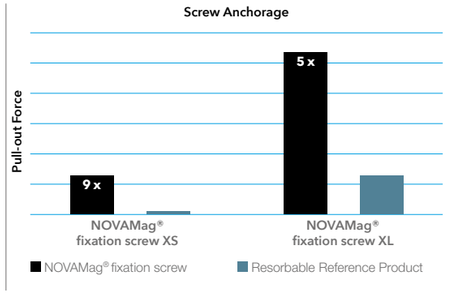
The safe insertion of the fixation screw is vital to protect the wellbeing of both the patient and the surgeon. As part of the development process, an appropriate drilling protocol was developed that enabled the screws to be inserted with ease, while enabling secure fixation of the screws inserted into bone.
By following the appropriate drilling protocol, insertion of the fixation screws requires an approximate maximum force of 3.5 N.cm, which is significantly lower than that required for the insertion of titanium fixation screws (data on file at botiss biomaterials GmbH).

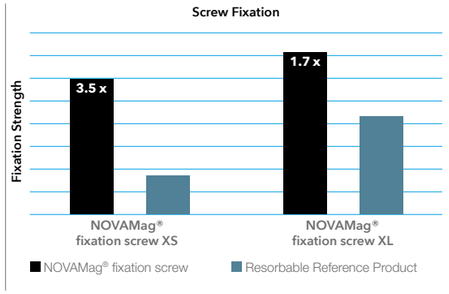
BONE ANCHORAGE

For the fixation screw to function properly, it must be securely anchored within the patient's bone. This has been evaluated by testing the force required to pull out the screw after insertion.
The results of a pull-out test based on ASTM F543-17, showed that the NOVAMag® fixation screw XS and the NOVAMag® fixation screw XL provided an anchorage that was superior to the equivalent polymeric resorbable pin or screw (data on file at botiss biomaterials GmbH).
The NOVAMag® fixation screw XS required a force that was 9x greater than the polymeric resorbable pin, whilst the NOVAMag® fixation screw XL required a force that was 5x greater than its comparator.

FIXATION CAPABILITY

After being securely anchored in position, the fixation screw must prevent sideways movement of the secured material. Barrier membranes require a secure fixation to prevent the loss of the augmentation material and maintain an effective barrier. For bone blocks, a bony union can only form between the augmented and native bone when the bone block is held steady.
In tests based on ASTM F564-17, the NOVAMag® fixation screw XS was 3.5x more resistant to sideways forces than a polymeric equivalent resorbable screw. The NOVAMag® fixation screw XL was 1.7x more resistant than its equivalent polymeric screw (data on file at botiss biomaterials GmbH).



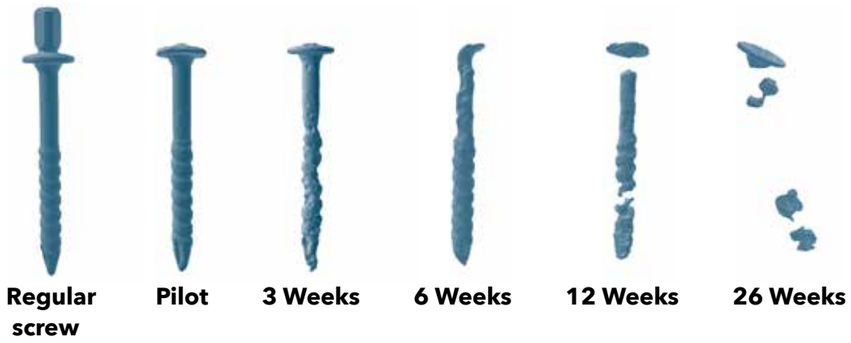


FIXATION SCREW RESORPTION
FOR REDUCED INVASIVENESS

The fixation capability of the NOVAMag® fixation screw is maintained by a controlled and gradual degradation during the critical healing period. In an in-vivo model, the NOVAMag® fixation screw XS gradually degrades over the first 8 weeks. During this time, the screw maintains a fixation of the barrier membrane. Over a period of approximately one year, the screw contiunes to degrade until it has been completely resorbed.

The NOVAMag® fixation screw XS gradually degrades over a 16-week period to provide a secure membrane fixation

Due to its larger size, the NOVAMag® fixation screw XL maintains fixation capabilities for longer than the NOVAMag® fixation screw XS. Between 6-12 weeks after being implanted in-vivo, the fixation screw XL remains largely intact. After approximately 1 year, there are no detectable remnants of the screw.



The NOVAMag® fixation screw S-XL gradually degrade to provide a secure fixation of the bone augmentation material during the critical healing period

DEGRADATION PRODUCTS

As the magnesium metal degrades it is transformed into magnesium salts and hydrogen gas. The composition of the magnesium salts includes many important elements that lay the foundation for the newly developing bone to replace the NOVAMag® fixation screw.

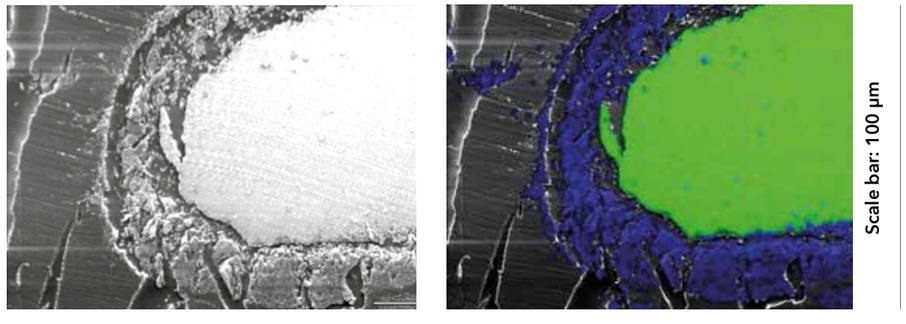
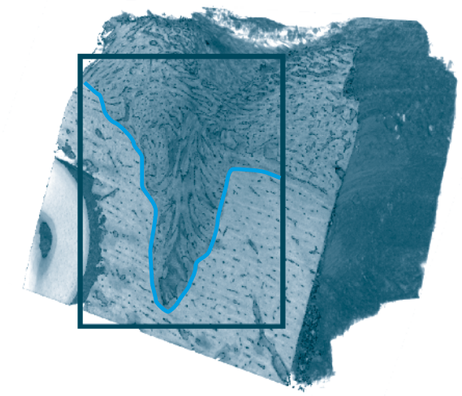


Figure 1: SEM image of a cross-section from a corroding NOVAMag® fixation screw XS screwhead, 6 weeks after implantation in vivo. In the false colored image, the magnesium metal (green) can be seen transitioning into magnesium salts (blue) that reside as a thick layer around the screw.

Element	Element Wt.%	Wt.% Error	Atom %	Atom % Error
P	14.96	± 0.21	9.52	0.14
Ca	12.92	± 0.35	6.35	0.17
Mg	7.57	± 0.14	6.14	0.12
F	1.95	± 0.10	2.19	0.12

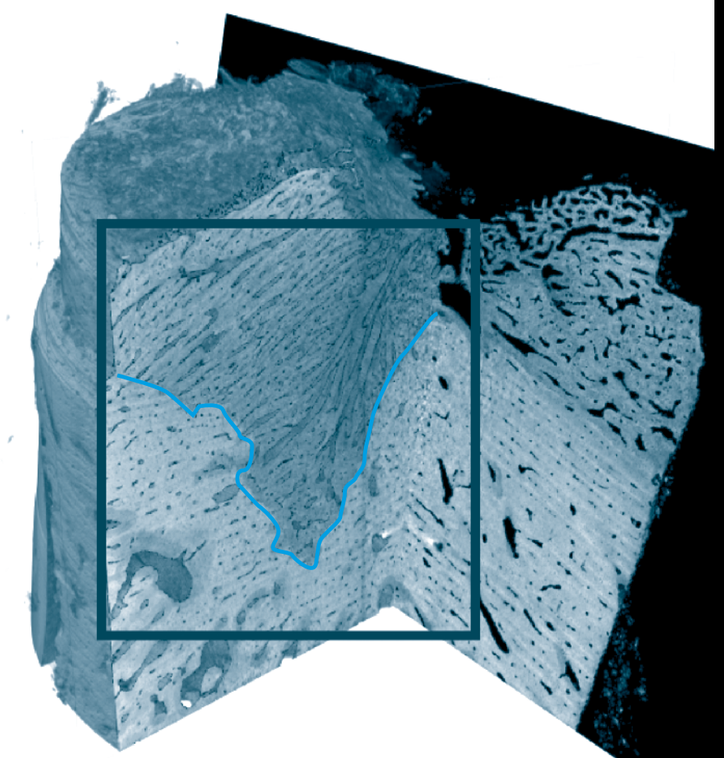
Figure 2: EDX measurements of corrosion products around the NOVAMag® fixation screw.



IDEAL FOR TISSUE REGENERATION

For ideal tissue regeneration, a resorbable fixation system must provide firm anchorage in the bone, a secure fixation of the membrane or augmentation material, degradation without negatively affecting the fixation requirements during the critical healing period, and replacement with healthy tissue after degradation.

As the NOVAMag® fixation screw degrades, new bone replaces its structure. Once the entire NOVAMag® fixation screw has degraded, only healthy new bone remains.



After the complete degradation of the NOVAMag® fixation screw XS, only new bone remains

THE ULTIMATE REGENERATION SYSTEM

The NOVAMag® regeneration system offers the latest technological advancement in regenerative dental care. Used together, the NOVAMag® membrane and the NOVAMag® fixation screw complement each other for optimal bone regeneration within the oral cavity.

Each product has undergone extensive testing to ensure their safety and reliability, and to confirm that they provide the ultimate regenerative result. Combined with autologous bone or other applicable bone augmentation materials, the NOVAMag® regeneration system represents the future of regenerative dental care.

FAQs

What are biodegradable metals?

Biodegradable metals are a class of metal that when implanted will gradually corrode and be completely resorbed. The corrosion products are then metabolized by the human body (Zheng et al., 2014).

How do the magnesium NOVAMag® implants resorb?

Under physiological conditions, as magnesium degrades, it forms an oxide passivation layer on its surface. This passivation layer is then dissolved by chloride ions present within the surrounding biological fluids, enabling the degradation process to continue (Zheng, 2014). All corrosion products are subsequently metabolized by the human body.

A simplified representation of the degradation and resorption processes are demonstrated in equations 1-4.

Oxidation:	$Mg \rightarrow Mg^{2+} + 2e^-$	(1)
Reduction:	$2H_2O + 2e^- \rightarrow H_2 + 2OH^-$	(2)
Hydroxide Formation:	$Mg^{2+} + 2OH^- \rightarrow Mg(OH)_2$	(3)
Breakdown of the Oxide Layer:	$Mg(OH)_2 + 2Cl^- \rightarrow MgCl_2 + 2OH^-$	(4)

What is the expected host response? Do the corrosion products cause any harm?

Magnesium is resorbed by the human body without the production of toxic byproducts (Zheng, 2014). In tests performed by botiss biomaterials GmbH, it was shown that as the NOVAMag® membrane and the NOVAMag® fixation screw degrade, the release of Mg^{2+}, as well as the trace and alloying elements, remained within safe levels for the human body.

Is it normal for gas to develop at the implantation site?

As magnesium corrodes it produces hydrogen gas. Hydrogen gas is highly diffusive and is absorbed by the body. The rate of hydrogen production from the implanted NOVAMag® membrane and NOVAMag® fixation screw (XS–XL) is below the limit of tissue absorption. However, it is expected that during the degradation of the NOVAMag® products, a small accumulation of gas may collect around each device that is visible in X-rays and results in a slight swelling of the soft tissues.

Are there any general systemic effects? Can an overdose occur if several membranes are inserted?

Within the oral cavity, the recommended limit of NOVAMag® products that can be implanted is a combination of 4 membranes, 20 XS fixation screws with 8 XL fixation screws.

How long does the membrane provide a barrier function?

The NOVAMag® membrane provides a barrier function for between 4-8 weeks and is completely degraded and resorbed after 16 weeks.

How easy are the NOVAMag® implants to handle?

Due to the unique handling properties of the NOVAMag® regenerative system implants, mandatory training is provided.

The NOVAMag® membrane can be implanted using a simple to follow procedure (please see surgical procedure outlined on pages 21-30 and 40-41). Even though the NOVAMag® membrane provides a level of strength that enables it to independently maintain its shape and help protect defect voids from collapse, it can also be easily cut and shaped according to surgical requirements. For the best handling experience, it is recommended that the specially developed NOVAMag® sculptor and NOVAMag® scissors are used.

The NOVAMag® fixation screw provides a secure fixation to the bone in a simple procedure (please see surgical procedure outlined on pages 33-41). However, despite it being made from metal, the insertion torque required for the NOVAMag® fixation screw is much lower than that of other titanium or stainless steel fixations screws. This is an important aspect that must be taken into consideration during screw insertion.

What kind of fixation system is required for the NOVAMag® membrane?

It is recommended that the NOVAMag® membrane is secured using the NOVAMag® fixation screw XS. However, it is also possible to use the Membrane Fixation Screw, USTOMED Instrumente Ulrich Storz GmbH & Co. KG or the Pro-fix™ Precision Fixation System, Osteogenics Biomedical Inc.

Are there any known allergies related to the product?

Magnesium is considered as non-allergenic and there are no known allergies associated with the NOVAMag® membrane or the NOVAMag® fixation screw. However rare cases of hypersensitivity to any of the trace or alloying elements cannot be ruled out.

What is the advantage of using the NOVAMag® membrane?

The NOVAMag® membrane is designed to work as a degradable barrier membrane comparable to other degradable membranes. However, due to its metallic structure, the NOVAMag® membrane provides improved mechanical properties to protect defect voids and support the regenerative process.

FAQs of NOVA**Mag**®

What are the advantages of using the NOVAMag® fixation screw?

The NOVAMag® fixation screw provides a secure fixation of barrier membranes and bone augmentation material. Unlike conventional fixation screws composed of steel or titanium, the NOVAMag® fixation screw is completely degradable. Despite their degradative properties, the NOVAMag® fixation screw is stable during the necessary healing period. Compared to other degradable fixation screw devices, the NOVAMag® fixation screws have superior mechanical properties.

Why use a completely synthetic material?

As the material is completely synthetic, it provides an alternative for patients with different lifestyles in a global setting.

If the membrane was to become exposed, what is the recommended course of action? Should it be left exposed? Is there an increased risk of infection?

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. Cases of small dehiscence should disappear after 2-5 weeks. There is no need for membrane removal in the case of localized exposure.

Are there specific recommendations regarding soft tissue management?

As in all augmentation procedures, special attention must be paid to soft tissue management. It is important to ensure that the flap remains tension free and consideration is given to mucosal, muscular and/or frenula interaction.

When cutting the NOVAMag® membrane to the desired shape, avoid the creation of sharp edges that could potentially penetrate the soft tissue.

After inserting the NOVAMag® fixation screws, ensure the drive is removed, using either the NOVAMag® safety cutter, or the sheering function of the NOVAMag® fixation screw XS. This will create a flat and level contour of the screw head.

How to handle in a thin biotype?

Like all augmentation procedures, special consideration must be paid to handling thin biotypes. The precautions mentioned in the answer to the previous question, “Are there specific recommendations regarding soft tissue management?“, are even more applicable for thin biotypes. Special care should be used to prevent creating sharp edges on membrane as well as ensuring that there is a tension free flap. Thickening of the biotype should be considered before performing a GBR surgery, leading to improved soft tissue healing.

Is it mandatory to use special scissors?

Although not mandatory, using the NOVAMag® scissors, which have been specifically designed for cutting the NOVAMag® membrane, is highly recommended.

Can the NOVAMag® membrane be used in combination with other membranes/ materials?

The NOVAMag® membrane is designed to work independently of other membranes, however the use of autologous bone or bovine bone substitute material like cerabone® in a granulated form is recommended depending upon the indication and size of the defect.

Can the NOVAMag® fixation screw XS be used for the fixation of membranes other than the NOVAMag® membrane?

The NOVAMag® fixation screw XS can be used for the fixation of collagen and PTFE membranes as well as the NOVAMag® membrane.

Is special training required before using the NOVAMag® regeneration system?

As the NOVAMag® membrane and the NOVAMag® fixation screw deliver an entirely new material to the dental surgical field, we not only recommend attending a training course, we provide mandatory training materials and courses.

What should be done if the patient complains about a tingly feeling?

Due to the magnesium degradation process, it can occur that the patient will feel a slight tingly feeling at the wound site. In severe cases, prescribing pain killers may alleviate the symptoms.

Does the membrane change color when dehiscence occurs?

Due to the degradation process, the NOVAMag® membrane will lose its shiny appearance independently of dehiscence. Should the membrane become exposed, it is expected that it will have a matte grey surface.

Can the NOVAMag® membrane be used as any other membrane?

Similarly to other bioresorbable membranes, the NOVAMag® membrane can be used in stomatology and maxillofacial surgery, implantology, periodontology and oral surgery to support guided tissue and bone regeneration, for covering implants and for periodontal tissue regeneration. As it is a new material there are special consideration for the handling of the membrane (p. 21-31).

Can the NOVAMag® fixation screw be used as any other fixation screw?

The NOVAMag® fixation screw is composed of completely resorbable, biodegradable, magnesium metal alloy and is available in various sizes suitable for use in stomatology and maxillofacial surgery, implantology, periodontology and oral surgery, to be used for the fixation of barrier membranes and/or bone grafts or bone filling material, in the support of guided tissue and bone regeneration.
Due to its inherent metallic properties, the fixation screws provide a more secure fixation result in comparison to alternative polymeric resorbable fixation systems. However, in comparison to conventional, non-resorbable steel or titanium metal fixation screws, the insertion torque required to insert the screws is much lower, which must be considered during insertion.

How does the NOVAMag® membrane degrade?

The NOVAMag® membrane has a smooth and shiny surface. Immediately upon implantation, the membrane begins to degrade. Degradation occurs uniformly over the surface, creating a roughness that improves the adhesion of the soft tissues.

As the magnesium metal degrades, magnesium salts and hydrogen gas are formed at the surface. The combination of the magnesium metal and the magnesium salts provide an effective barrier during the critical healing period.

In some instances, hydrogen gas develops as an additional layer between the soft tissue and the NOVAMag® membrane, thereby acting as an additional barrier without affecting the regenerating bone. The NOVAMag® membrane will be completely degraded and replaced with native bone within a few months after its implantation.

How does the NOVAMag® fixation screw degrade?

The NOVAMag® fixation screw has a specially developed surface to delay the onset of the magnesium metal degradation. This enables the screw to provide a secure fixation during the critical healing period.

As it degrades the magnesium metal is transformed into magnesium salts, which are then resorbed by the body. As the magnesium salts are resorbed, they are replaced by the patients' native bone.

What influence does pH have on the performance of the NOVAMag® membrane or fixation screw?

Acidic conditions will increase the degradation rate as it prevents the formation of a passivation layer. Therefore, at the time of surgery or upon dehiscence, it is not recommended to combine the use of the NOVAMag® membrane or fixation screw with additional healing materials that produce an acidic pH. Additionally, it is recommended to avoid acidic food and drinks over the first 2-3 weeks after implantation.

How does the NOVAMag® membrane and the NOVAMag® fixation screw appear on an X-ray

As the NOVAMag® membrane and the NOVAMag® fixation screw degrade, they will produce an alkaline environment. The alkaline environment will delay the onset of bone mineralization in the immediate vicinity of the implant, which will appear radiolucent in x-rays. Once the magnesium has fully degraded, the surrounding bone will mineralize as normal and return to a normal radiopacity in x-rays.

Is there any danger of the NOVAMag® membrane igniting during the drilling of the fixation holes?

Magnesium will ignite at a temperature around 473°C. When following standard drilling practices that prevent damaging the patient's tissue, this temperature should not be reached.

What happens to the magnesium particles that are produced during drilling?

The magnesium particles that are produced during the drilling process have a large surface area to volume ratio. This means that they will be quickly degraded and resorbed by the body, and do not pose a risk to the patient.

PRODUCT REFERENCE **LIST**

	Product	Size/Amount	Art. No.
	NOVAMag® membrane	15 x 20 mm, 1/ box	721520
		20 x 30 mm, 1/ box	722030
		30 x 40 mm, 1/ box	723040
	NOVAMag® fixation screw	XS – 1.0 mm x 3.5 mm, 2/ box	74100402
		XS – 1.0 mm x 3.5 mm, 4/ box	74100404
		S – 1.4 mm x 7 mm, 1/ box	74140701
		M – 1.4 mm x 9 mm, 1/ box	74140901
		L – 1.4 mm x 11 mm, 1/ box	74141101
		XL – 1.4 mm x 13 mm, 1/ box	74141301
	NOVAMag® scissors	1/ box	BT1003
	NOVAMag® sculptor	1/ box	BT1002
	precision drill	Drill 0.9, 1/ box	BT2009
	pilot drills 1.0, 1.2 and 1.35	Drill 1.0, 1/ box	BT2010
		Drill 1.2, 1/ box	BT2012
		Drill 1.35, 1/ box	BT2013
	NOVAMag® drill rack	1/ box	BT1004
	NOVAMag® connector	1/ box	74000
		4/ box	74004
		8/ box	74008
	NOVAMag® safety cutter	1/ box	BT1001
	NOVAMag® steri WashTray	1/ box	BT1005
	NOVAMag® bundle	1 x NOVAMag® steri Wash Tray 1 x NOVAMag® scissor 1 x NOVAMag® sculptor, 1 x NOVAMag® safety cutter 1 x NOVAMag® drill rack	BT1006

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