

bone & tissue
regeneration

botiss
biomaterials

NOVAMag[®]

RESORBABLE MAGNESIUM
MATERIAL SELECTION



biomaterials

Origins of NOVAMag[®] product line

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[®] product line was developed.

Material Selection

Magnesium is a biodegradable metal with a long history of use as a medical material, yet the NOVAMag[®] product line 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[®] product line 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

as a Medical Material

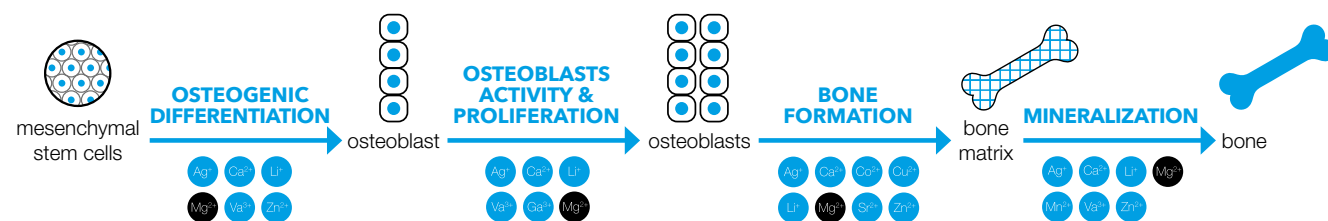
History

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

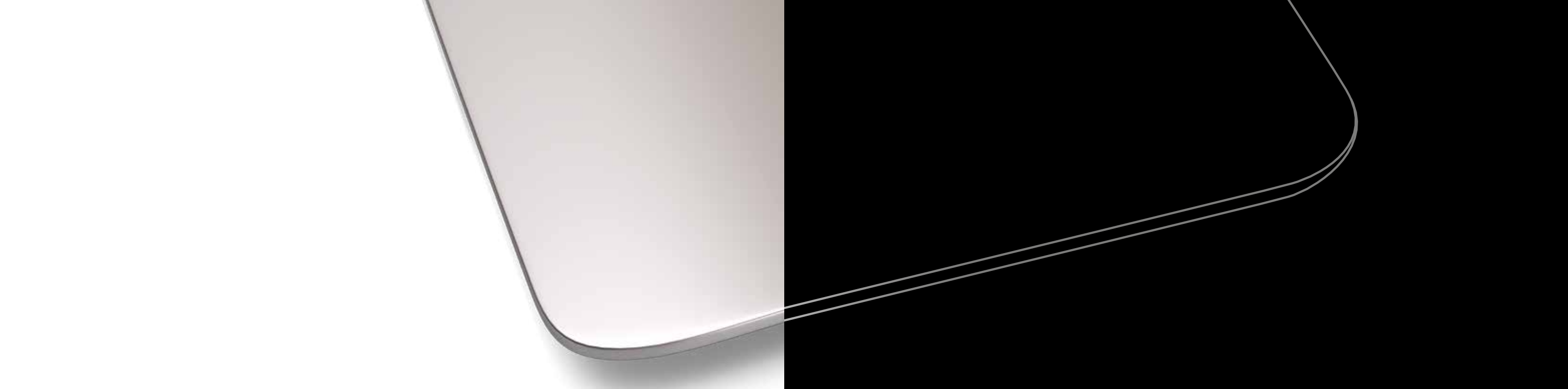
Magnesium has many beneficial properties for use as an implant material. A long history of use in medical applications has produced a proven track record for its biocompatibility. Its strong but degradable properties mean that it provides initial stability during the critical healing period, but degrades, 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.

NOVAMag[®]

product line

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.



NOVAMag[®] membrane

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.

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

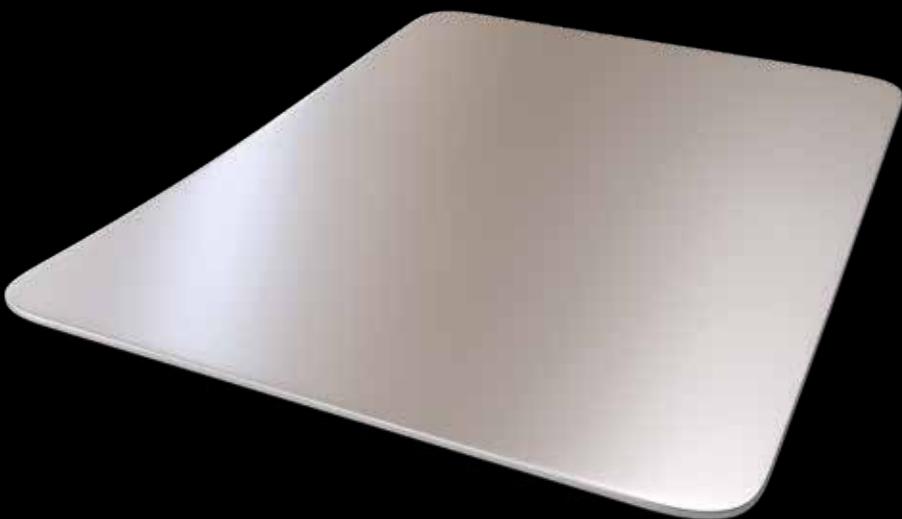
CONTRAINDICATIONS

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

NOVAMag[®] membrane

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[®].



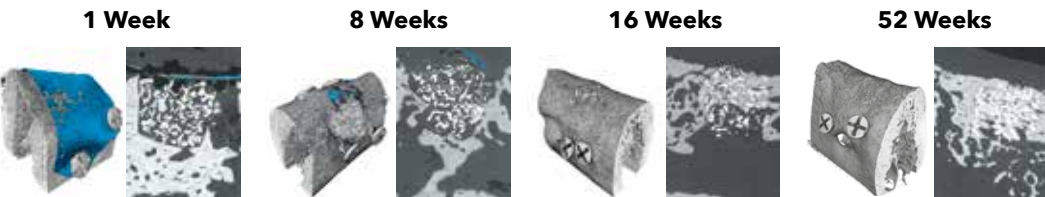
Product	Size	Amount	Art. No.
NOVAMag [®] membrane	S – 15 x 20 mm	1/ box	721520
	M – 20 x 30 mm	1/ box	722030
	L – 30 x 40 mm	1/ box	723040

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)

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, μ CT 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.

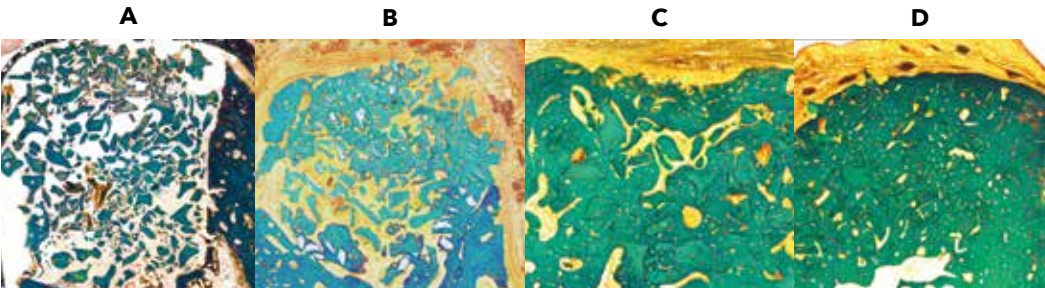


Degradation of the NOVAMag® membrane in-vivo. The metal structure of the NOVAMag® membrane is shown in a blue color. The metallic and salt phases of the NOVAMag® membrane maintained an effective barrier during the critical healing period and retained the positioning of the augmentation material.

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.



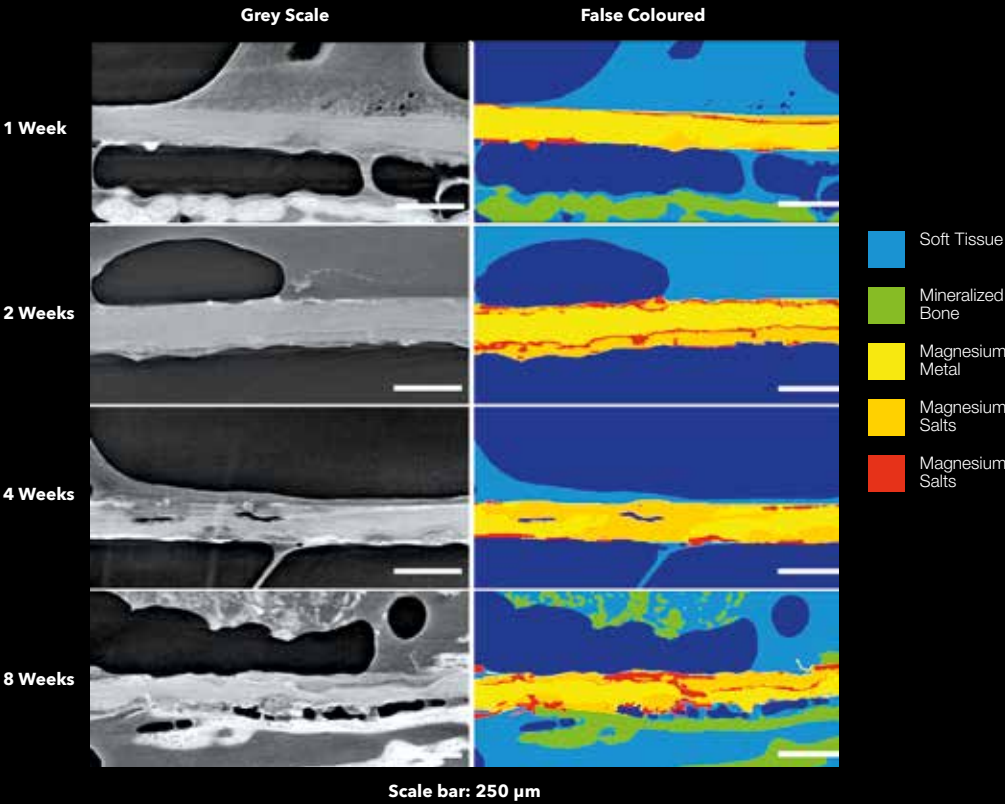
The NOVAMag® membrane maintains an occlusive cellular barrier enabling new bone to fill the defect void. A) 1 week, B) 8 weeks, C) 16 weeks, D) 52 weeks

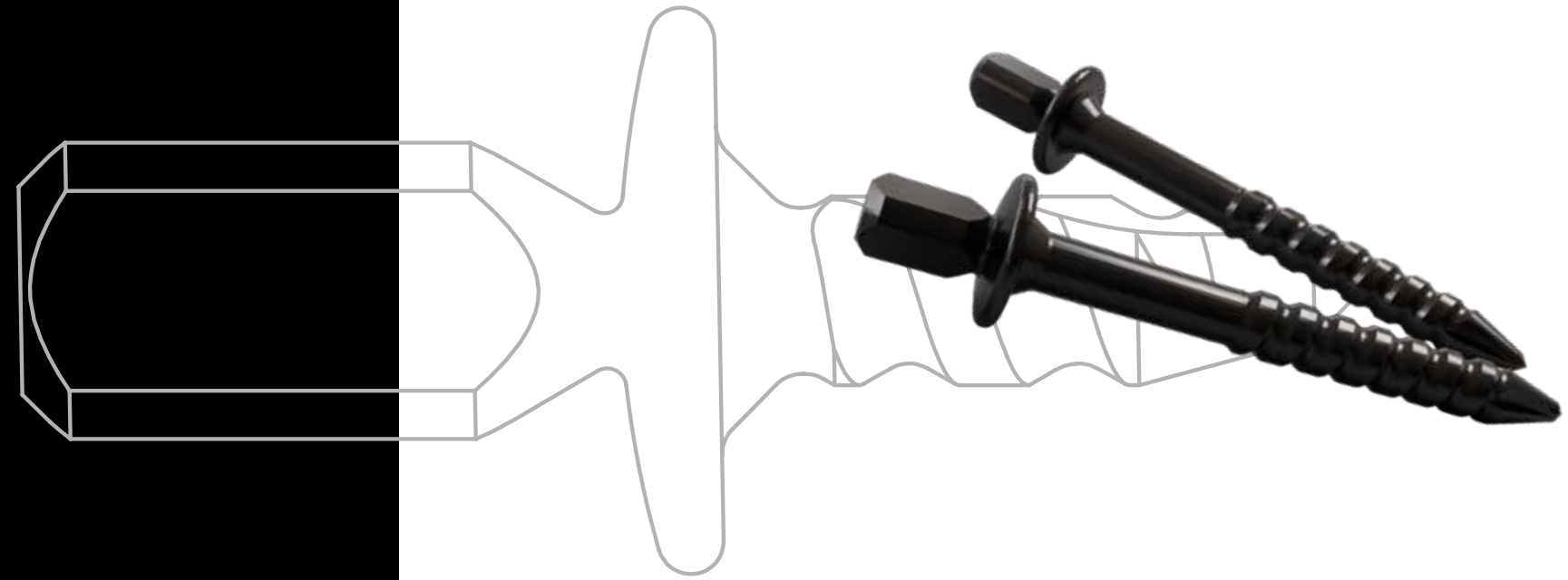
IDEAL FOR TISSUE REGENERATION

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 8 WEEKS





NOVAMag[®] 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.

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

NOVAMag[®] fixation screw

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)

Please note that the NOVAMag[®] connector (see page 17) is also required to insert the NOVAMag[®] fastening screws correctly.

Product	Size	Amount	Art. No.
NOVAMag [®] fixation screw	XS – 1.0 mm x 3.5 mm	2/ box	74100402
	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

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 continues 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 degrades 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.

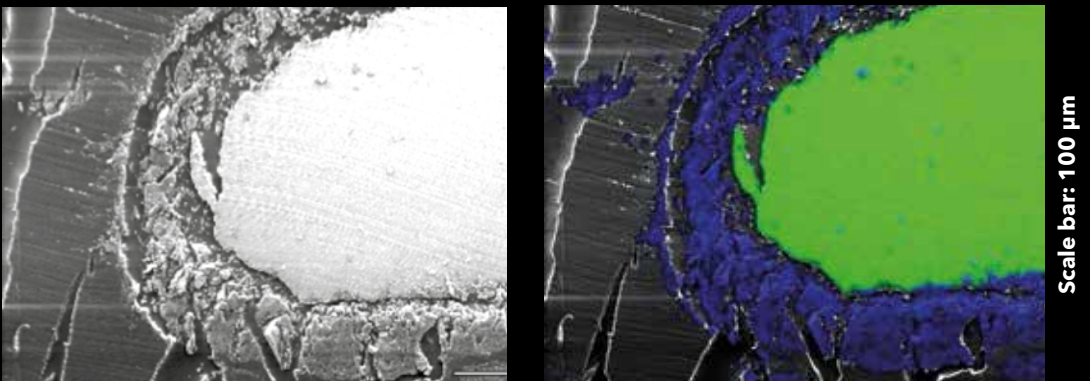


Figure 1: SEM image of a cross-section from a corroding NOVAMag® fixation screw XS screwhead, 6 weeks after implantation in vivo. In the false colored image, the magnesium metal (green) can be seen transitioning into magnesium salts (blue) that reside as a thick layer around the screw.

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.

NOVAMag® Instrumentation

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

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



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



NOVAMag® 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	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	BT2010
	drill 1.2, 1/ box	BT2012
	drill 1.35, 1/ box	BT2013



NOVAMag® 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	Amount	Art. No.
NOVAMag® connector	1/ box	74000





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

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



NOVAMag® 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.

Product	Content	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

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Innovation.
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