

bone & tissue
regeneration

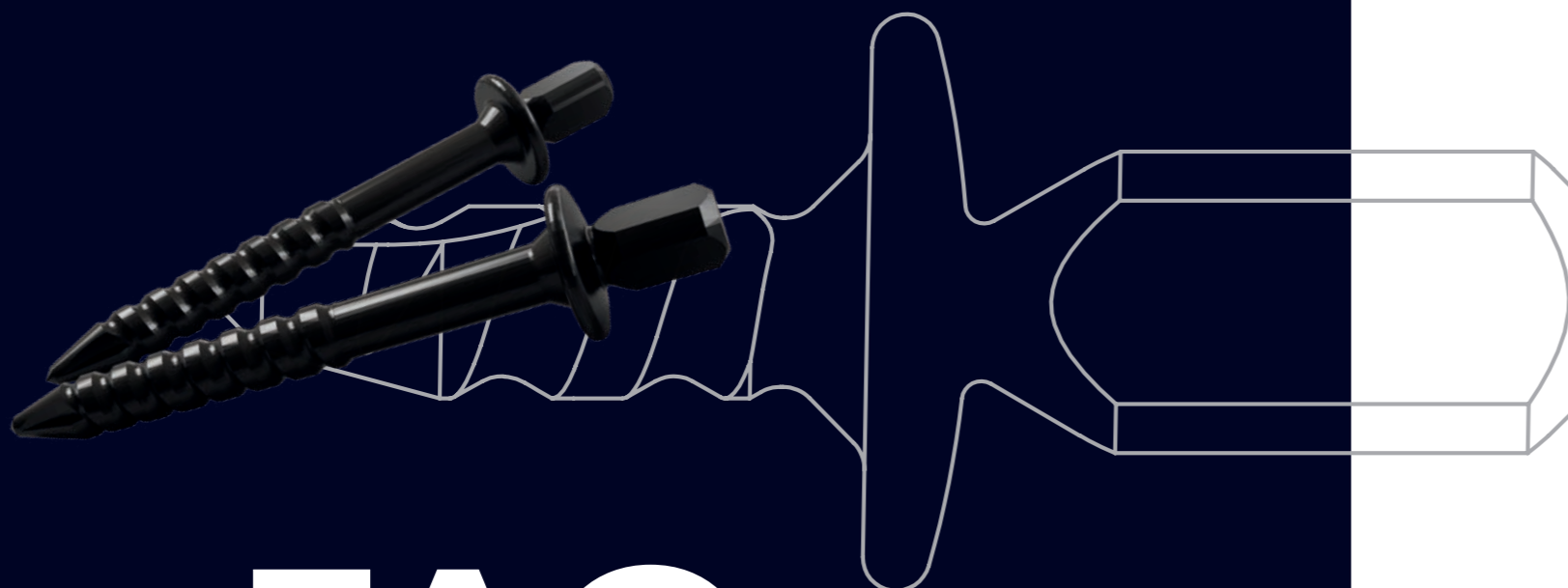
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NOVAMag[®] fixation screws

FAQ

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FAQ

NOVAMag® fixation screws

Frequently Asked Questions

Here you will find answers to the most frequently asked questions about the material, application and special features of NOVAMag® fixation screws.

What are biodegradable metals?

Biodegradable metals are a class of metals that when implanted will gradually corrode and be completely resorbed. The corrosion products are then metabolized by the human body.¹ Among these metals are magnesium, zinc, and calcium.

What is the advantage of using NOVAMag® fixation screw?

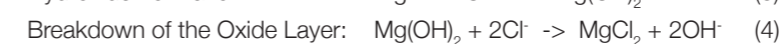
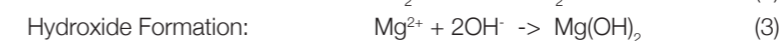
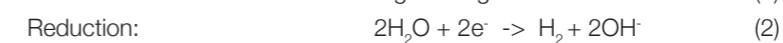
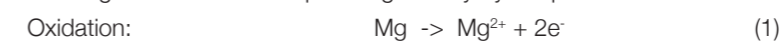
NOVAMag® fixation screw provides a secure fixation of barrier membranes and bone augmentation material.^{2,3} Unlike conventional fixation screws composed of steel or titanium, NOVAMag® fixation screw is completely degradable. Despite its degradative properties, NOVAMag® fixation screw provides stable fixation during the necessary healing period. Compared to other degradable fixation screw devices, NOVAMag® fixation screws have superior mechanical properties. Moreover, as NOVAMag® fixation screw degrades, it releases magnesium ions (Mg^{2+}). Mg^{2+} are involved in the different cellular processes of bone formation and mineralization.⁴ NOVAMag® fixation screws degrade gradually and are eventually replaced by native bone.⁶

Which material is NOVAMag® fixation screw made of?

NOVAMag® fixation screw is made of a resorbable magnesium metal alloy that meets the mechanical requirements of a fixation system. NOVAMag® fixation screw has a specially developed surface that gives the screws a dark outer layer. This layer delays the onset of degradation of the magnesium metal so that the stability of the screws is maintained during the critical healing phase.

How do magnesium-based biomaterials resorb in the human body?

Under physiological conditions, magnesium-based biomaterials, such as NOVAMag® membrane, undergo an electrochemical corrosion process whereby the metallic magnesium base material is oxidized to magnesium ions (Mg^{2+}) (Eq. 1), while water (H_2O) from the environment is reduced to hydrogen gas (H_2) and hydroxide ions (OH^-) (Eq. 2). This forms an oxide passivation layer of magnesium salts (i.a. $Mg(OH)_2$) on the surface of the membrane (Eq. 3). This passivation layer is then dissolved by ions from the surrounding biological fluids, in particular by chloride ions (Cl^-), allowing the degradation process to continue (Eq. 4).¹ A simplified representation of the degradation and resorption processes are demonstrated in equations (1)-(4). All corrosion products are then resorbed by the human body and the magnesium salts are replaced gradually by the patient's own bone.



Are the corrosion products of NOVAMag® fixation screw harmful?

Magnesium degrades in the human body without the production of toxic byproducts.¹ In tests performed by botiss biomaterials GmbH, it was shown that as NOVAMag® fixation screw degrades, the release of magnesium ions (Mg²⁺) as well as the trace and alloying elements remained within safe levels for the human body.

Can an overdose of magnesium occur if several NOVAMag® screws are inserted? Are there any general systemic effects?

No, since magnesium is an essential mineral for human nutrition with a recommended daily intake of about 300-400 mg/day for adults.⁵ The largest NOVAMag® fixation screw (1.4 x 13 mm) contains about 36 mg of magnesium that is released gradually in the human body in the form of magnesium ions (Mg²⁺) over a period of about 1 year; hence an abrupt release of Mg²⁺ into the body is not expected.⁶ Furthermore, the human body has an established pathway for the excretion of excess Mg²⁺ in urine.⁷ Therefore, it is safe to apply several screws at the same time. It is still recommended not to exceed a maximum number of 20 NOVAMag® fixation screw XS and 8 NOVAMag® fixation screw XL per adult patient (see instructions for use).

Are there any known allergies related to NOVAMag® fixation screw?

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

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

The nature of magnesium degradation is associated with hydrogen gas evolution. Hydrogen gas is highly diffusive and is absorbed by the body. However, it is expected that during the degradation of the membrane, a small accumulation of gas may collect around each device that is visible in X-rays and results in a slight elevation of the soft tissues, which typically resolves on its own within about 2 weeks. Gas development at the implantation site has no reported negative effects on the process of bone regeneration.

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.

Are there specific precautions that clinicians and patients need to be aware of?

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 NOVAMag® fixation screw or NOVAMag® membrane 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 long does it take for NOVAMag® fixation screw to be completely resorbed?

In an in-vivo animal model, it was shown that NOVAMag® fixation screw XS maintains its mechanical properties for 4 weeks after implantation and degrades completely after about 1 year.⁶

Do remnants of NOVAMag® fixation screw cause any problems for re-entry?

In an in-vivo animal model, it was shown that NOVAMag® fixation screw XS maintains its mechanical properties for 4 weeks and degrades completely after about 1 year after implantation. Therefore, it is possible that remnants of the screws will still be present during the re-entry surgery.

Implant placement can be performed as usual following the same drilling protocol of the chosen implant system. NOVAMag® fixation screw is made of a light magnesium alloy and clinicians can easily drill through the small remaining fragments of the screw without any negative effects on the drill itself or the dental implant. There is no need to remove any remaining fragments of the screw at the time of re-entry as they will continue to be resorbed by the body.

How easy is the NOVAMag® fixation screw to handle? Does it require the use of specialized instruments?

NOVAMag® fixation screw provides a secure fixation to the bone in a simple procedure (please see NOVAMag® brochure). However, despite it being made from metal, the insertion torque required for 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. The pilot drills (Ø 1.0-1.35) are necessary to make insertion holes for NOVAMag® fixation screws S-XL (please see NOVAMag® brochure). The precision drill is only used for the insertion of the NOVAMag® fixation screw XS. The specially developed connector (NOVAMag® connector) is used to hold NOVAMag® fixation screw, whereby the head of the connector grips the drive of the screw. NOVAMag® safety cutter is used to remove the screw drive of NOVAMag® fixation screws XS-XL effectively and safely. Usually, the drive of NOVAMag® fixation screws XS can be snapped off easily with a gentle rocking motion once the screw has been seated; however, NOVAMag® safety cutter can be also used.

Which sterilization method is suitable for NOVAMag® instruments?

As with most surgical instruments, steam moist heat sterilization is suitable for NOVAMag® Instruments.

Can NOVAMag® fixation screw be re-sterilized?

No, as this would severely impair the properties of the screw. In case of a damaged package, the contents should be disposed.

How does NOVAMag® fixation screw appear on an X-ray?

In the initial stage, NOVAMag® fixation screw will appear radiolucent due to the formation of degradation products at the vicinity of the screw. The degradation products will eventually be resorbed and replaced by the patient's own bone and the area where the screw was placed will return to a normal radiopacity in x-rays overtime.

What is the intended use of NOVAMag® fixation screw XS-XL?

The smallest screw (NOVAMag® fixation screw XS) is specially designed for the fixation of NOVAMag® membrane and collagen membranes (e.g., Jason® membrane or collprotect® membrane) as well as non-resorbable PTFE membranes (e.g., permamem®). NOVAMag® fixation screw S-XL is intended for the fixation of bone blocks. NOVAMag® fixation screw S can be also used for fixing thicker collagen membranes and collagen matrices (e.g., mucoderm®).

Is pre-drilling necessary when NOVAMag® fixation screw is used to fix collagen membranes?

Pre-drilling according to the botiss drilling protocol is always necessary for inserting NOVAMag® fixation screw (see NOVAMag® brochure).

References

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- ³ **Blašковић M, Blašković D, Hangyasi DB, et al.** Evaluation between Biodegradable Magnesium Metal GBR Membrane and Bovine Graft with or without Hyaluronate. *Membranes.* 2023;13(8):691. <https://www.mdpi.com/2077-0375/13/8/691>.
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- ⁵ **Institute of Medicine (US)** Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Magnesium. In: *Intakes, Institute of Medicine Standing Committee on the Scientific Evaluation of Dietary Reference, ed. Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride: National Academies Press (US); 1997.*
- ⁶ **Kačarević ŽP, Rider P, Elad A, et al.** Biodegradable magnesium fixation screw for barrier membranes used in guided bone regeneration. *Bioactive Materials.* 2022;14:15–30. <https://www.sciencedirect.com/science/article/pii/S2452199X21005028>.
- ⁷ **Jahnen-Dechent W, Ketteler M.** Magnesium basics. *Clinical Kidney Journal.* 2012;5(Suppl 1):i3-i14. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455825/>.

Do you still have questions about our products and their application? Our experts will be happy to answer them. Please feel free to contact our product management: product-management@botiss.com

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