

FAQs of NOVAMag[®]

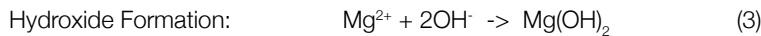
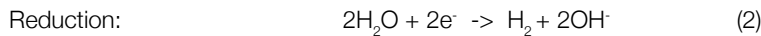
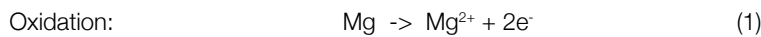
What are biodegradable metals?

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[®] products 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.



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 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 easy are the NOVAMag® products 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 NOVAMag® brochure). 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 NOVAMag® brochure). 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.

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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.

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.

FAQs of NOVAMag®

Is special training required before using the NOVAMag® products?

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 (please see NOVAMag® brochure).

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® 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.