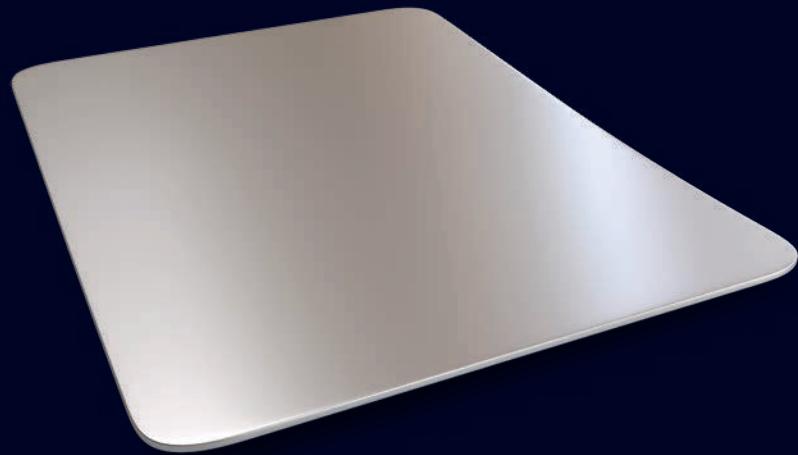




# NOVAMag<sup>®</sup> membrane

## FAQ



biomaterials



# FAQ

## Frequently Asked Questions

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

NOVAMag®  
membrane

### 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.<sup>1</sup> Among these metals are magnesium, zinc, and calcium.

### Why use a completely synthetic material?

NOVAMag® membrane is a synthetic metallic membrane made of pure magnesium that degrades completely in the human body by releasing magnesium ions ( $Mg^{2+}$ ) which is an essential element for humans.<sup>2</sup> Synthetic materials also provide an alternative for patients with different lifestyles in a global setting.

### What is the advantage of using NOVAMag® membrane?

NOVAMag® membrane is designed to work as an initially mechanically stable degradable barrier membrane to protect defect voids and support regenerative processes. Compared to other degradable membranes, NOVAMag® membrane provides superior mechanical properties, making it an ideal alternative to non-degradable titanium-reinforced PTFE membranes and titanium meshes in many clinical situations.<sup>3-6</sup> Moreover, as NOVAMag® membrane degrades, it releases magnesium ions ( $Mg^{2+}$ ).  $Mg^{2+}$  are involved in the different cellular processes of bone formation and mineralization, thereby stimulating bone growth and maintenance.<sup>7</sup>

### 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 (Eq. 1), while water from the environment is reduced to hydrogen gas and hydroxide ions (Eq. 2). This forms an oxide passivation layer of magnesium salts 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, allowing the degradation process to continue (Eq. 4).<sup>1</sup> 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.

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)

### Do the corrosion products of NOVAMag® membrane cause any harm?

Magnesium degrades in the human body without the production of toxic byproducts.<sup>1</sup> In tests performed by botiss biomaterials GmbH, it was shown that as NOVAMag® membrane degrades, the release of magnesium ions ( $Mg^{2+}$ ) as well as trace elements remains within safe levels for the human body.

### Can an overdose of magnesium occur if several NOVAMag® membranes 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.<sup>8</sup> The largest NOVAMag® membrane (30 x 40 mm) contains 288 mg of magnesium on average that is released gradually in the human body in the form of magnesium ions ( $Mg^{2+}$ ) over a period of 16 weeks; hence an abrupt release of  $Mg^{2+}$  into the body is not expected. Furthermore, the human body has an established pathway for the excretion of excess  $Mg^{2+}$  in urine.<sup>2</sup> Therefore, it is safe to apply several membranes at the same time.

### Are there any known allergies related to NOVAMag® membrane?

NOVAMag® membrane is produced from pure magnesium metal. Magnesium is considered as non-allergenic and there are no known allergies associated with NOVAMag® membrane. However rare cases of hypersensitivity to any of the trace elements cannot be ruled out.<sup>9</sup>

### 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 informed about?**

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® membrane or NOVAMag® 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.

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### **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, drinks or drinking products. Cases of small dehiscence should disappear after 2-5 weeks. There is no need for membrane removal in the case of localized exposure.

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### **Are there specific handling tips to be considered?**

NOVAMag® membrane can be implanted using a simple to follow procedure (please see NOVAMag® brochure). Even though 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.

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### **Is it mandatory to use the NOVAMag® instruments (scissors & sculptor) to cut and shape the NOVAMag® membrane?**

Using NOVAMag® instruments for shaping NOVAMag® membrane is not mandatory but is highly recommended. NOVAMag® scissors are designed with high-quality blades that deliver long-lasting sharpness and consistent cutting results. NOVAMag® membrane can be molded according to the shape of the defect site using NOVAMag® sculptor. 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. Using NOVAMag® instruments is highly recommended, but not mandatory. Moreover, NOVAMag® instruments are made of a high-quality metal that does not transfer elements (e.g., iron) on the surface of the membrane during the handling process that interact with magnesium metal and may influence its degradation behavior.

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### **Which sterilization method is suitable for NOVAMag® instruments?**

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

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### **Can NOVAMag® membrane be re-sterilized?**

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

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### **How does NOVAMag® membrane appear on an X-ray?**

In the initial stage, NOVAMag® membrane will appear radiolucent due to the formation of degradation products at the vicinity of the membrane. The membrane and the degradation products will be resorbed gradually, and the grafted area will mineralize as normal and return to a normal radiopacity in x-rays overtime.

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### **Is it important on which side up the NOVAMag® membrane is applied?**

NOVAMag® membrane has a smooth surface on both sides, and it can be applied with either side facing the defect.

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### **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 NOVAMag® membrane to the desired shape, avoid the creation of sharp edges that could potentially penetrate the soft tissue. It is recommended to use the back end of NOVAMag® sculptor to flatten the edges of the membrane.

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**How long does NOVAMag® membrane provide a barrier function?**

In an in-vivo animal model, it was shown that the initial metallic phase of NOVAMag® membrane maintains the barrier function for up to 8 weeks, which is an adequate time for the bone to regenerate.<sup>9</sup> The functional lifespan of the magnesium membrane is extended further up to 16 weeks due to the formation of a corrosion layer of magnesium salts and small local gas cavities that maintain a separation of the soft and hard tissues.<sup>9</sup> The salt layer is eventually replaced with native bone.

**Is there a limitation regarding the type of bone substitute material to be used in combination with NOVAMag® membrane?**

NOVAMag® membrane can be used in combination with a wide range of bone substitute materials. The choice of the grafting material depends on the condition and the treatment plan as well as the patient-clinician shared decision. Previous studies reported the use of NOVAMag® membrane together with allografts (e.g., maxgraft® granules),<sup>10</sup> xenografts (e.g., cerabone® and cerabone® plus),<sup>3,4,11</sup> and bone graft combinations.<sup>5,6,12</sup>

**What are common applications for NOVAMag® membrane?**

NOVAMag® membrane is used in combination with NOVAMag® fixation screws (alternatively with titanium screws) for guided bone regeneration (GBR), especially when space maintenance is required.<sup>3-5</sup> Building missing buccal and/or lingual walls after tooth extraction with or without immediate implant placement is another common application for NOVAMag® membrane (NOVAMag® shield technique), whereby the membrane is inserted in the socket without the need for fixation screws.<sup>10</sup> Due to its mechanical properties and its ability to be cut with scissors and easily bent to shape, NOVAMag® membrane is also used for treating small intrabony defects.<sup>11</sup> NOVAMag® membrane can be used in sinus lift procedures, especially in the cases where there has been a large rupture of the Schneiderian membrane that cannot be closed with a collagen membrane.<sup>12</sup>

**Is it necessary for NOVAMag® membrane to be fixed with screws?**

In some instances, mechanically stable NOVAMag® membrane can be used alone without fixation screws, such as for treating compromised walls in extraction sockets following the NOVAMag® shield technique.<sup>10</sup> In this new approach, tooth extraction is performed and NOVAMag® membrane is tucked in under the periosteum on the buccal or palatal side without the need for fixation screws, and the defect is filled with the chosen bone substitute material. Due to its mechanical properties, NOVAMag® membrane is able to resist external forces effectively and maintains the space for bone regeneration. In horizontal or combined horizontal and vertical defects NOVAMag® membrane should be fixed with a fixation system to stabilize the membrane around the augmentation material.<sup>3-5</sup>

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

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

**Does NOVAMag® membrane need to be perforated before application to enhance the blood supply to the augmentation site?**

NOVAMag® membrane is designed with a smooth metallic surface with no perforations in order to isolate the soft tissue effectively. There is no need to make extra perforations in the membrane before application since these may interfere with the barrier function of the membrane and accelerate its degradation. Augmentation sites covered with NOVAMag® membrane receive sufficient blood supply from the host bone side and the surrounding. Bone augmentation using NOVAMag® membrane has shown excellent results in multiple studies regarding the quality and quantity of the regenerated bone.<sup>3-5</sup>

**Does the membrane change color when dehiscence occurs?**

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

**Is there any danger of 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.

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