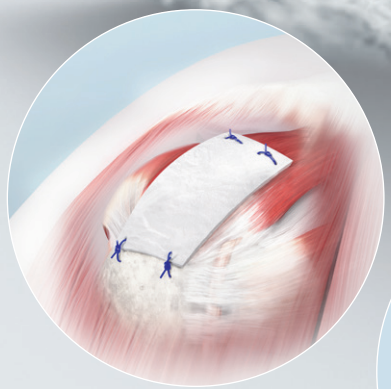
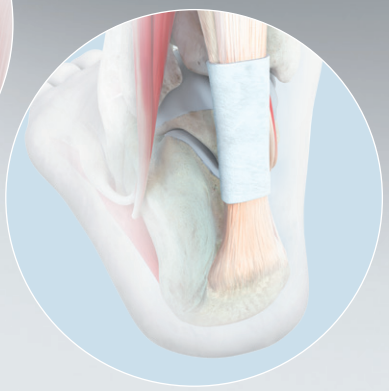
leading regeneration

Geistlich

A naturally optimized design to support tendon healing





Geistlich Nexo-Gide®

Dual-Surface Membrane from the Regeneration Experts

From the Regeneration Experts

A family-owned company with a long-standing tradition

Who is Geistlich?

Geistlich has been family owned since 1851 when it started to produce collagen based raw materials. Geistlich uses a substantial part of its budget for its own research and development. The entire value-added chain is under Geistlich's control at its site in Central Switzerland.

For over 30 years Geistlich has been a leader in the field of regenerative technologies that leverage the body's own ability to repair bone and soft tissue.

Across all of the global corporate businesses, a Geistlich implant is used to support healing in a patient every 15 seconds. With decades of clinical use of Geistlich technologies, the company has an extensive track record in providing safe, biocompatible solutions for orthopedics.

A naturally optimized design to support tendon healing

Geistlich Nexo-Gide® combines purpose-driven design with performance-guided processing in an effort to optimize the structure, handling characteristics, and healing potential of your surgical repairs.

Dual surfaces support regenerative healing

What makes Geistlich Nexo-Gide® Unique?

- Porcine dual surface collagen type membrane
- Biocompatible and naturally resorbed
- Optimized handling characteristics, easy to trim/shape and suture in both dry and hydrated states
- Porous lower surface features an open porous structure for cell migration, proliferation and differentiation[1,2]
- Smooth upper surface for cell retention[1]

Purpose Driven Design

Geistlich Nexo-Gide® is an FDA-cleared membrane for the management and protection of tendon injuries.

Proven Soft Tissue Source

Geistlich Nexo-Gide® is a native porcine collagen membrane

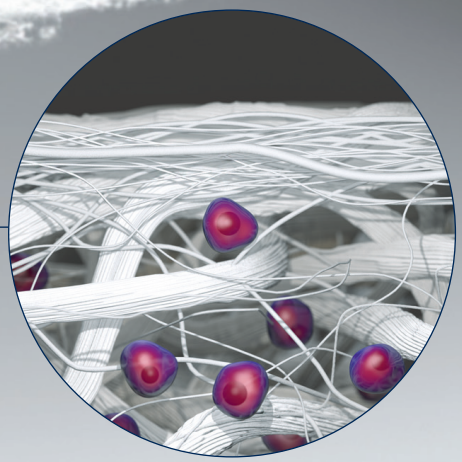
- Porcine collagen has been shown to have high homology to humans as compared to other animals used to source raw materials for medical device materials[1]
- Native collagen molecules and fiber structures are maintained[1] and **no additional materials** (such as PLLA), are added

Natural Dual Surface Material

Geistlich utilizes a source material that features a smooth upper and a porous lower surface

Porous lower surface[1–3]
features an open porous structure that has shown to support cell migration, proliferation, differentiation, and the formation of new tissue

Smooth upper surface[1,2]
- creates an environment that supports cell retention and containment at the site of injury or repair
- demonstrated in pre-clinical testing that the incidence and severity of surrounding tissue attachment was reduced as compared to the surgical control, which may result in decreased post-operative complications for surrounding tissue



Performance Guided Processing

Geistlich's expertise in processing ensures biocompatibility* of the implant while maintaining key natural properties

The Geistlich Process

Extraction and Purification steps remove antigens, lipids and non-collagenous proteins, rendering the source material accelular[1]

Geistlich processes all of it's own tissue at our state of the art facility in central Switzerland

Processing & purification expertise

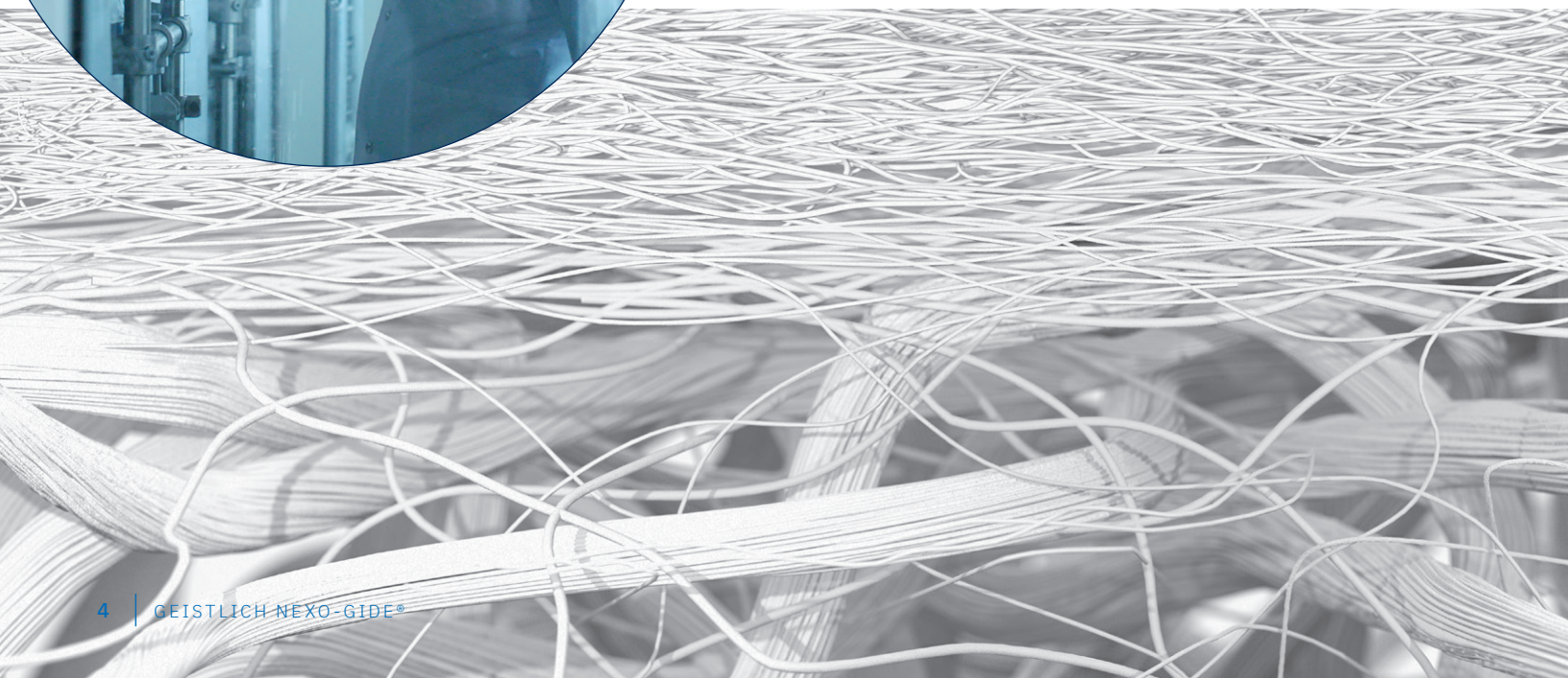
For decades, Geistlich has proven to be a world leader in processing xenograft tissue for a variety of clinical and surgical applications

- Through our proprietary purification process, antigens, lipids and non-collagenous proteins are **safely** and **effectively** removed, reducing the likelihood of acute and chronic biological reactions[1]
- For more than 30 years, Geistlich has processed and distributed porcine derived products with extensive published evidence of clinical effectiveness[1]

Maintaining key material properties

- **Native collagen molecules and fiber structures are maintained** in the smooth upper surface, which is shown to support cell retention[1]
- Native material characteristics result in a thin, pliable membrane that is easy to handle and suture even in a hydrated state[1]

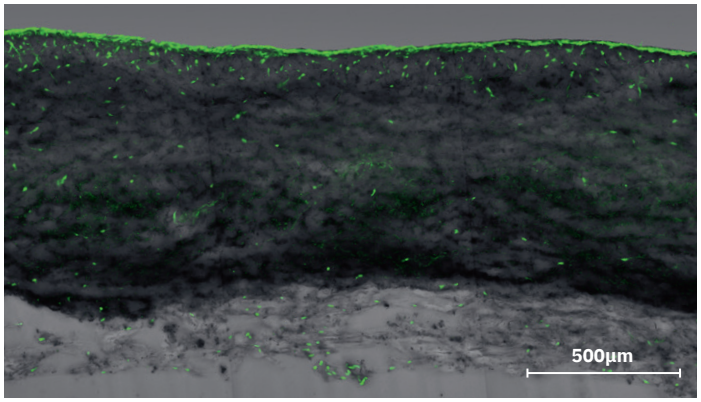
* biocompatible when used as intended



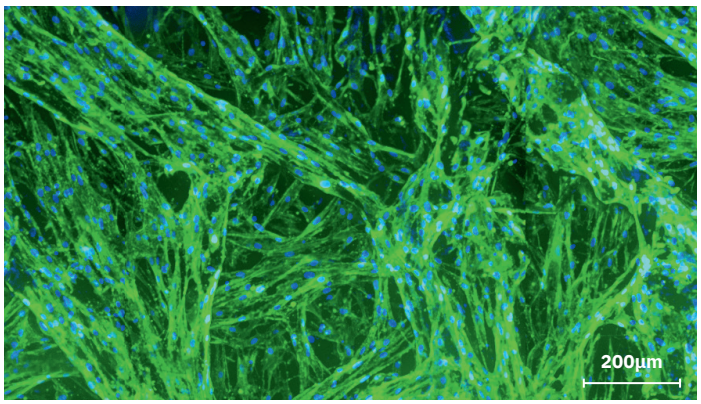
Proven Scientific Evidence

The **Dual Surfaces** found in Geistlich Nexo-Gide® have been shown in pre-clinical and *in vitro* testing to provide an environment where cells migrate, proliferate, and differentiate, which supports the formation of new tissue[1–3].

- *In vitro* testing with cells demostrated retention characteristics that support the maintenance of cells in the location desired[1].
- It was demonstrated in pre-clinical testing that the incidence and severity of surrounding tissue attachment was reduced as compared to the surgical control. This may result in decreased post-operative complications.[1]
- *In vitro* testing with cells demonstrated that the Geistlich Nexo-Gide® provides an environment where cells migrate, proliferate and differentiate[1,2].



Cells (green) on Geistlich Nexo-Gide® (grey, fibrous structure) demonstrating cell retention.



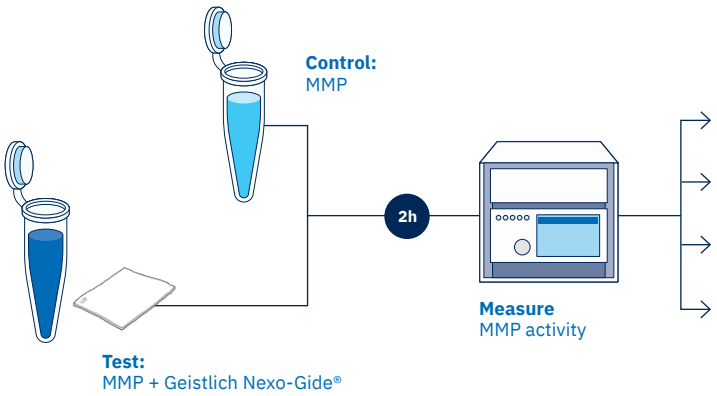
Cells (nuclei in blue, cytoskeleton in green) on Geistlich Nexo-Gide® demonstrating migration and proliferation throughout the porous lower surface with cells dispersed evenly on the native collagen fiber structure.

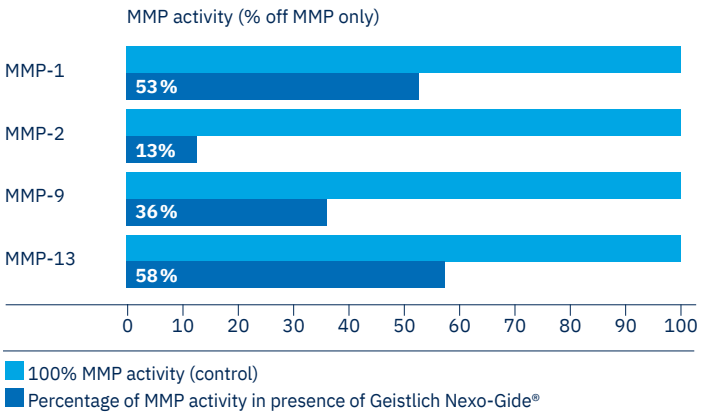
MMP Activity and Tendon Healing

Elevated MMP activity after tendon injury has been associated with deterioration of the collagen network[4]. Significant increases of MMP-13 were found in patients undergoing rotator cuff repair for full thickness tears[4] while MMP-1 and -9 were seen to be elevated in tendons of patients which had failed healing of the rotator cuff[5]. Finally, Alfredson *et al* showed an upregulation of MMP-2 expression in achilles tendinopathy[6].

Reduction of MMP activity close to the repair site may improve tendon healing[7]. Geistlich Nexo-Gide® is shown to modulate the activity of MMPs related to tendon repair *in vitro*. Incubation of MMPs 1, 2, 9 and 13 with Geistlich Nexo-Gide® led to a reduction of MMP activity[1].

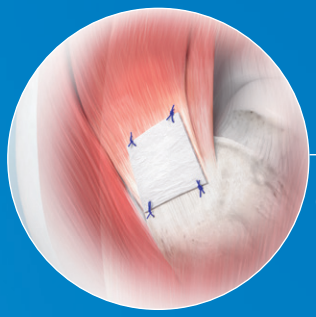
Conclusion: Geistlich Nexo-Gide® has demonstrated the ability to modulate MMP activity *in vitro*[1]. Modulation of MMP activity after rotator cuff repair may reduce pathologic tissue degradation and favorably influence healing after rotator cuff repair[6].





Patient Centered Versatility

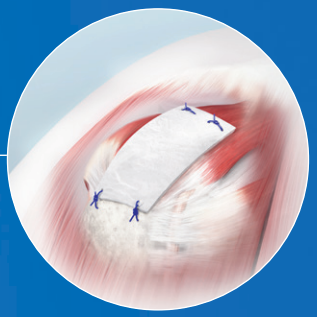
Geistlich Nexo-Gide® can be used in a wide variety of applications, providing significant versatility for physicians and their patients.



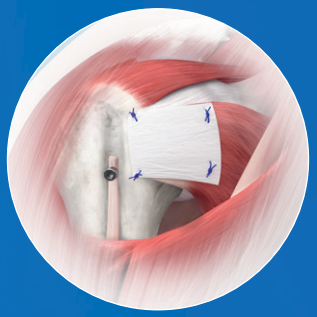
Gluteus Medius

Patella Tendon

Achilles



Rotator Cuff



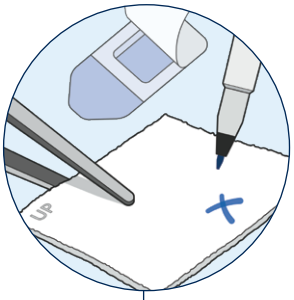
Quad Tendon

Peroneus

Physician Focused Handling and Ease of Use

Geistlich Nexo-Gide® is an off the shelf product that can be easily sutured, trimmed using standard surgical instruments, and naturally conforms to the soft tissue once hydrated.

Surgical technique for achilles wrapping

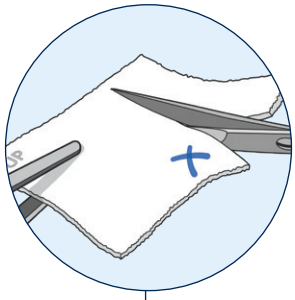


1
Removal & Orientation

Remove Geistlich Nexo-Gide® and if needed, use a sterile pen to lightly mark the smooth, upper surface marked “UP” that will face the surrounding tissues. The “UP” sign might not be visible once the membrane has been trimmed and hydrated.

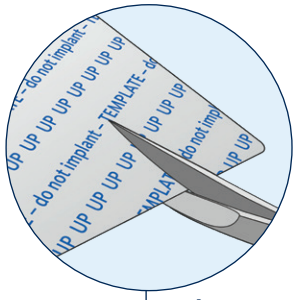
2
Hydration

Hydrate the Geistlich Nexo-Gide® using sterile saline solution for at least 1–2 minutes. An increase in membrane size of around 10–15% is to be expected when hydrated. If hydrated in advance, the product should be covered with sterile gauze until it is implanted.



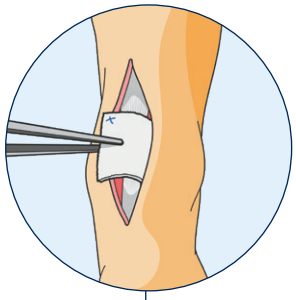
3a
Size & Trim

Following tenolysis or primary repair of the tendon, determine the appropriate size, wrap the membrane in a single layer around the affected region and trim away excessive material to minimize membrane overlap. Geistlich Nexo-Gide® should be cut to a size that extends the entire length of the incision or damaged area in the tendon sheath.



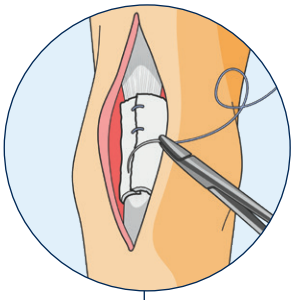
3b
Size & Trim (optional)

In order to properly cover a small repair site, where it may be required to trim the membrane to size, the Aluminum Template can be used to determine the length of the suture line on the tendon. The Geistlich Nexo-Gide® or tendon tissue should not contact the printed side of the aluminum template.



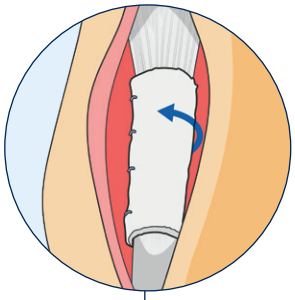
4
Apply

Apply the Geistlich Nexo-Gide® with the smooth, upper surface marked with the word “UP” facing surrounding tissues ensuring that the porous layer is facing the site of the tendon repair.



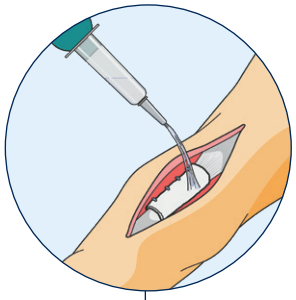
5
Secure

The membrane may be secured to the tendon with absorbable suture using a non-cutting needle and a low-tension suture technique. The membrane can also be sutured to itself if suturing to the tendon tissue is not applicable. Use the minimum number of sutures/stitches required to avoid irritation of the adjacent tissues.



6
Rotate (if needed)

Geistlich Nexo-Gide® may be rotated such that suture line is away from the injured soft tissue (i.e. the skin suture line).



7
Irrigate

Thoroughly irrigate the surgical site and closure of surgical wound can be completed as usual (no specific additional steps are required).

Geistlich

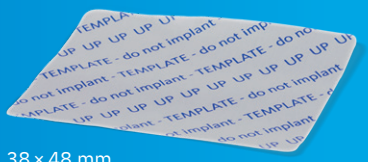
Provider Dedicated Support

Geistlich Nexo-Gide® is available in three sizes

For more information, or to order Geistlich Nexo-Gide®, call **877-485-2968** or email **info@geistlich-na.com.**

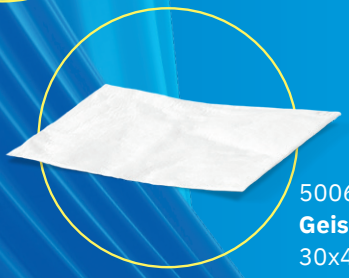
A sterile aluminum template is included

Where it may be required to trim the membrane to size, the Aluminum Template can be used to determine the length of the suture line on the tendon.



38 × 48 mm

500662
Geistlich Nexo-Gide®
20x30mm



500663
Geistlich Nexo-Gide®
30x40mm

500664
Geistlich Nexo-Gide®
40x50mm

1 Data on file
2 Gantenbein B, et al. World J Stem Cells. 2015; 7(2): 521–534.
3 Fulco I, et al. Lancet 2014; 384: 337–46.
4 Lo IKY, et al. Am J Sports Medicine. 2004;32(5):1223–1229.
5 Robertson CM, et al. Am J Sports Medicine. 2012;40(9):1993–2001.
6 Alfredson H, et al. J Orthopaed Res. 2003;21(6):970–975.
7 Bedi A, et al. J Shoulder Elb Surg. 2010;19(3):384–391.
8 Del Buono, et al. J Shoulder Elb Surg. 2012 Feb;21(2):200–8.

www.nexogide.com

Manufacturer
Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen, Switzerland
Phone +41 41 492 55 55
Fax +41 41 492 56 39

Distributed by
Geistlich Pharma North America, Inc.
902 Carnegie Center Boulevard,
Suite 360
Princeton, NJ 08540 USA
Phone toll-free 877-485-2968
info@geistlich-na.com

Caution: Federal law restricts this device to sell by or on the order of a licensed health care provider.

Product availability may vary from country to country.