Art.-Nr. 301284/2108

ENGLISH

Geistlich
Nexo-Gide®

Caution: Federal law restricts this device to sale by or on the order of a physician

Geistlich Nexo-Gide® Collagen Membrane

Resorbable membrane for the management and protection of tendon injuries

Important Product Information. Please read before use.

PRODUCT DESCRIPTION

Geistlich Nexo-Gide® is resorbable, highly purified, naturally dual surface bi-layer therefore a structurally optimal collagen membrane for the management and protection of tendon injuries. Geistlich Nexo-Gide® provides a biocompatible protective encasement to support the body's healing process and is manufactured according to a standardized and controlled process. The Geistlich Nexo-Gide® features two distinct surfaces (an upper compact, smooth surface and a lower porous surface) and serves as an interface between the tendon and the surrounding tissues. The membrane consists of porcine collagen and is processed without cross-linking or chemical additives. The aluminum template provided can be used to estimate the size required to wrap the tendon repair site. Geistlich Nexo-Gide® and the aluminum template are sterilized in double-blister packaging by means of irradiation.

INTENDED USE/INDICATIONS

Geistlich Nexo-Gide® is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

PROPERTIES/ACTION

Geistlich Nexo-Gide® is a biocompatible collagen membrane that provides a non-constricting, protective encasement for an injured tendon.
The 'top' layer of the native collagen structure (placed facing surrounding tissues marked with the word "UP") is occlusive and provides a protective environment while the tendon is healing. The porous structure of the Geistlich Nexo-Gide® (placed facing tendon) consists of collagen fibers in a loose, porous arrangement.
Since the membrane is a purified native structure, the structural integrity of Geistlich Nexo-Gide® is assured even when fully hydrated.
Geistlich Nexo-Gide® is easy to handle, conformable and can be placed under, around or over an injured tendon. If needed, the collagen membrane can be firmly fixed into place (i.e., by suturing).

CONTRAINDICATIONS

Geistlich Nexo-Gide® is **not indicated** to replace or repair damaged tendon.

Geistlich Nexo-Gide® is **not indicated** to reinforce the strength of any tendon repair.

Geistlich Nexo-Gide® must not be used in patients with a known allergy to porcine collagen.
Geistlich Nexo-Gide® must not be placed where active infection exists in surgical site.

PRECAUTIONS

- Geistlich Nexo-Gide® should be used only by surgeons who are familiar with tendon repair techniques.
- DO NOT RESTERILIZE. Any opened, unused material must be discarded.
- The aluminum template must not be implanted.
- If the sterile packaging is damaged or opened, the product must not be used.
- The content of the double-blister packaging is designed for single use only, on a single patient. Discard any unused material.
- Do not use after the expiration date.
- Geistlich Nexo-Gide® has not been studied in pregnant women and breastfeeding mothers.
- Geistlich Nexo-Gide® should be used with special caution in patients who take medications or have diseases impairing tissue regeneration.
- Abstinence from smoking during or after treatment is advised.
- On the discretion of the surgeon, Geistlich Nexo-Gide® can be fixed to the implantation site using resorbable suture, as lack of or insufficient fixation of the Nexo-Gide® can lead to its displacement.
- Direct mixing of Geistlich Nexo-Gide® with medicinal products, alcohol, disinfectants or antibiotics is not advisable and has not been studied.
- Geistlich Nexo-Gide® should not be applied until bleeding and infection are controlled.

INSTRUCTIONS FOR USE

1. Always handle Geistlich Nexo-Gide® using aseptic technique.
2. Remove the device and if needed, use a sterile pen to lightly mark the compact layer marked "UP" that will face the surrounding tissues. The "UP" sign might not be visible once the membrane has been trimmed and hydrated.
3. 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.
4. 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.
5. 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.
6. In adults, up to 4 membranes may be used side-by-side to cover the entire repair site as determined necessary by the surgeon.
7. Apply the Geistlich Nexo-Gide® with the compact layer marked with the word UP facing surrounding tissues ensuring that the porous layer is facing the site of the tendon repair.
8. 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.
9. Geistlich Nexo-Gide® may be rotated such that suture line is away from the injured soft tissue (i.e. the skin suture line).
10. Thoroughly irrigate the surgical site and close the incision in the standard fashion.

POST-OPERATIVE CARE AND REHABILITATION

Standard postoperative treatment protocol must be followed. The surgeon must determine motion and strength requirements according to standard practice based on the extent of the tendon repair.

SAFETY

Geistlich Nexo-Gide® is manufactured from porcine collagen sourced from veterinary certified pigs. Required testing in accordance with International Standards has been performed to confirm biocompatibility of the device.

ADVERSE REACTIONS

Geistlich Nexo-Gide® is made of collagen, therefore, allergic reactions to collagen may not be totally excluded. Possible observations which may occur with any surgery include swelling at the surgical site, bleeding, hematoma, increased pain, and local inflammation.
No risks, complications or adverse events are known for the transient use of the aluminum template.

STORAGE AND HANDLING

- Store at controlled room temperature 59°–77 °F (15°–25 °C) and in a dry place.
- Keep away from sunlight.
- The device should be handled using sterile gloves and sterile instruments.

HOW SUPPLIED

One Geistlich Nexo-Gide® collagen membrane and one Aluminum Template are separately packed in inner blisters and packaged in a single outer blister. The Geistlich Nexo-Gide® and Aluminum Template size 38 x 38 mm are presented sterile.

Re-order #	Sizes
500662	Geistlich Nexo-Gide®, 20 x 30 mm
500663	Geistlich Nexo-Gide®, 30 x 40 mm
500664	Geistlich Nexo-Gide®, 40 x 50 mm

Distributed by:
Geistlich Pharma North America, Inc.
Princeton, New Jersey 08540
877-485-2968
www.nexogide.com

Manufacturer:
Geistlich Pharma AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland

Status of Information: 2021-08