



neoss PTFE Membranes and Related Instruments And Accessories Instruction Manual

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neoss PTFE Membranes and Related Instruments And Accessories



Product Information

The NeoGen PTFE membranes and related instruments and accessories are used for bone regenerative treatment of the jaw bone.



Membranes



Membrane fixation devices



Tack instruments and storage

The product includes:

- Membranes
- Membrane fixation devices
- Tack instruments and storage

Membrane Fixation Devices

The Membrane fixation devices are designed with a head and a stem (straight for Tacks and threaded for Screws) that allows for secure attachment of regenerative membranes to the bone structure. The Membrane Screws and the Cape Spacer are designed to be held and inserted with Neo screwdrivers or the tip of Neoss Implant Inserter SP instruments. The Membrane Tack has a flat head for surgical placement by the Tack Positioning Instrument and the Tack Mallet.

Tack Instruments and Storage

The Tack instruments and storage include the Tack Positioning Instrument and the Tack Mallet which are used for surgical placement of the Membrane Tack. The product also includes storage options for the instruments.

Product Usage Instructions

Intended Use

The Membrane fixation devices are intended to stabilize regenerative membranes during the healing process by providing an attachment mechanism for the membrane. Membrane Tacks and Membrane Screws are used to fixate the regenerative membranes to the bone structure whereas the Cape Spacer utilizes the implant for membrane stabilization/fixation at the surgical site.

Indication for Use

The NeoGen PTFE membranes and related instruments and accessories are indicated for use in resorbed maxillary or mandibular bone in need of regeneration to increase bone volume, for example, to place dental implants.

Patient Target Group

The product can be used for any patient in need of bone regenerative treatment of the jaw bone, not excluded by virtue of medical history.

Intended User and Clinical Setting

A licensed dental practitioner or physician will perform the clinical treatment using standardized, well-established surgical or prosthetic procedures in a hospital/clinic setting.

Expected Clinical Benefits

The product is expected to fulfill its intended use in the specified indications during its expected lifetime.

Products (Product Categories)

1. Membranes
2. Membrane fixation devices
3. Tack instruments

DESCRIPTION

Membranes: NeoGen® PTFE membranes are non-resorbable membranes available in non-reinforced or Ti-reinforced configurations. The membrane is a textured and expanded polytetrafluoroethylene (PTFE) membrane with different properties for the soft and hard tissue sides. The Ti-reinforced membrane has a shapable titanium mesh enveloped by the two PTFE sides. NeoGen® PTFE membranes come in different anatomical shapes and sizes. One type, NeoGen® Cape, is designed with a through hole compatible with the Cape spacer for attachment to a Neoss ProActive implant.

Membrane fixation devices: The Membrane fixation devices are designed with a head and a stem (straight for Tacks and threaded for Screws) to secure attachment of regenerative membranes to the bone structure, or in the case of the Cape Spacer the Neoss ProActive implants.

The Membrane Screws and the Cape Spacer are designed to be held and inserted with Neo screwdrivers or the tip of Neoss Implant Inserter SP instruments.

The Membrane Tack has a flat head for surgical placement by the Tack Positioning Instrument and the Tack Mallet.

Tack instruments and storage

- The Tack Positioning Instrument is designed with a spring function to pick up the head of the Membrane Tack placed in the Tack and Screw Cassette and hold the Tack during attachment to the bone using the Tack Mallet. A protection cap is mounted on the instrument when not in use.
- The Tack Mallet with its handle and heavy head is designed to manually hit the end of the Tack positioning Instrument holding a Membrane Tack.
- The Tack and Screw Cassette is designed to store and organize the Membrane Tacks and Screws during surgery and allow easy pick-up.

Membrane removal

- Ideally, membrane that is placed in a submerged application should remain in place three to nine months or until bone regeneration is complete.
- If the membrane is exposed, it is recommended that shorter-term removal (at approximately four to twelve weeks) be accomplished to avoid compromising the regenerative result.
- Expose the membrane using appropriate flap technique.
- Remove any fixation devices (Tacks or Screws or Cape cover screw) before removing the membrane. See procedures below.
- Remove the membrane. A well tissue integrated membrane might require careful dissection and removal from the tissue to avoid layers of material being separated during removal.
- Close the flap.
- Make sure that all removed products are properly disposed. Do not reuse any removed products.



















Post augmentation care

- Perform careful post-operative management as described above.
- Final maturation of the augmented bone will not occur for up to one year. Plan further treatment accordingly.
- Debridement should be avoided within at least one year following guided tissue regeneration.

Membrane Tacks and Screws – fastening

- Make sure that the condition of the bone allows for proper Tack/Screw application.
- Pick up Tack/Screw:
- Tack: Remove the protection cap from the Tack Positioning Instrument. Pick up the Tack by firmly pushing the Tack Positioning Instrument over the head of the Tack. Ensure vertical position of the instrument before pushing it onto the Tack. An audible click is heard, indicating that the Tack is attached to the instrument and ready to be inserted.
- Screw: Pick up the Screw by firmly pushing the tip of a Neoss Implant Inserter into the head of the Screw. Ensure vertical position of the instrument before pushing it into the Screw.
Note: The Neoss Screwdriver cannot be used.
- Buccal placement of Tacks/Screws is preferred to facilitate their retrieval. However, lingual placement is sometimes required, especially when large defects are treated.
- Insert the Tack/Screw through the membrane into the bone. To achieve satisfactory contact between the Tack/Screw and the membrane, make sure that the head of the Tack/Screw is parallel with the membrane and the bone.
- Do not place the Tack/Screw too close to the edge of the membrane
Allow at least 1 mm of membrane material surrounding the Tack/Screw.
- **Note:** Hard bone can require pre-puncture of the cortical bone with a narrow-pointed drill, such as the Neoss Lance Drill.
- Insert the Tack/Screw into the bone:

SYMBOLS USED ON PACKAGING

	Non-sterile
	temperature limit
	Keep dry
	Use by/Expiry date
	Do not re-use (single use only)
	Sterilized using ethylene oxide
	Unique device identifier
	Lot/Batch number
	Sterilized using irradiation
	Date of manufacture
	Manufacturer
	Medical device
	Catalogue number
	Consult Instructions For Use
	Do not use if package is damaged
	Keep away from sunlight
	Narrow Platform
	Standard Platform

Documents / Resources



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PTFE Membranes and Related Instruments And Accessories, PTFE, Membranes and Related Instruments And Accessories, Instruments And Accessories

References

- [Neoss - Intelligent Simplicity](#)
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