Membrane Tacks, Tack Positioning Instruments, Membrane Screws and accessories

Description
Membrane fastening means (i.e. Tacks and Screws) are universally applicable for easy and secure attachment of regenerative membranes to the bone structure. Regenerative membranes are designed to prevent ingrowth of gingival soft tissue into bony defects, in order to facilitate the bone formation during the repair process of the defect. Membrane fastening means are made of titanium while related instruments and accessories are made in stainless steel. The Membrane fastening means are single-use only while the instruments are for multiple use. Membrane fastening means and instruments are delivered NON-STERILE and must be sterilized prior to use. Membrane fastening means are easily stored in the Membrane Tack and Screw Cassette from which they are picked up and accurately placed using corresponding instruments.

Procedures
This Instructions For Use (IFU) covers specific points relevant to the Membrane Tacks, Tack Positioning Instruments, Membrane Screws and related accessories only. Please consult applicable membrane instructions for use as well as appropriate surgical and restorative manuals and textbooks for information on treatment planning and medical evaluation.

Opening the package and utilizing the Membrane Tack and Screw Cassette
The NON-STERILE vial is opened and the Tacks or Screws are carefully poured onto the Membrane Tack and Screw Cassette where they are placed in the dedicated compartments before closing the lid of the Membrane Tack and Screw Cassette prior to storage/sterilization.

Membrane Tack application
• Tacks shall be sterilized prior to use, preferably when placed in the Membrane Tack and Screw Cassette. 
• Tack Positioning Instruments shall be cleaned and sterilized prior to use. 
• Sterile field should be maintained throughout the procedure. 
• Discard the Tack if dropped in the oral cavity. 
• Prepare the surgical site and the membrane according to the membrane instructions for use.
• Make sure that the condition of the bone allows for proper tack application. 
• 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. 
• Buccal placement of Tacks is preferred in order to facilitate the retrieval of the tacks. However, lingual placement is sometimes required, especially when large defects are treated. 
• Insert the Tack through the membrane into the bone. To achieve satisfactory contact between the Tack and the membrane, make sure that the head of the Tack is parallel with the membrane and the bone. 
• Do not place the Tack too close to the edge of the membrane. Allow at least 1 mm of membrane material surrounding the Tack. 
• Gently tap with the mallet until the head of the Tack is completely flush to the bone and the membrane. 

Magnetic Resonance Imaging (MRI)
The Neoss products are MRI safe. Based on evaluating MR data it can be concluded that NeoGen® PTFE membranes and fastening means will unlikely interfere with patient safety under the MRI conditions up to 7T. Image artefacts still needs to be considered at image analysis.
Infection has been properly treated. Where active infection exists. Prior to placement, the surgeon should assure that any active or recent contraindications apply. Membrane fastening means should not be placed which membrane and bone grafting materials are being used.

Membrane Tack removal
Removal of the Tacks is made in conjunction with the removal of the membrane.
• Expose the surgical site and pry the head of the Tack from the underlying membrane using a thin and flat tool, such as a scalpel blade.
• Make sure that all Tacks are removed and properly disposed. Do not reuse the Tacks.

Membrane Screw application
• Screws shall be sterilized prior to use, preferably when placed in the Membrane Tack and Screw Cassette.
• Related instruments shall be cleaned and sterilized prior to use.
• Sterile field should be maintained throughout the procedure.
• Discard the Screw if dropped in the oral cavity.
• Prepare the surgical site and the membrane according to the membrane Instructions For Use.
• Make sure that the condition of the bone allows for proper Screw application.
• 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 Screws is preferred in order to facilitate the retrieval of the Screws. However, lingual placement is sometimes required, especially when large defects are treated.
• Insert the Screw through the membrane into the bone applying a torque of less than 10 Ncm. Note: In soft bone care needs to be taken to avoid the screw spinning. To achieve satisfactory contact between the Screw and the membrane, make sure that the head of the Screw is parallel with the membrane and the bone.
• Do not place the Screw too close to the edge of the membrane. Allow at least 1 mm of membrane material surrounding the Screw. Note: Hard bone can require pre-puncture of the cortical bone with the Neoss Lance Drill.
• When the Screw is fully seated, i.e. completely flush to the bone and the membrane, carefully tilt the Neoss Implant Inserter to disengage the instrument from the Screw.

Membrane Screw removal
Removal of the Screws is made in conjunction with the removal of the membrane.
• Expose the surgical site and unscrew the Membrane Screws using the tip of a Neoss Implant Inserter.
• Make sure that all Screws are removed and properly disposed. Do not reuse the Screws.

Indications
Membrane Tacks and Membrane Screws are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.

Contraindications
Contraindications for membrane treatment apply. Membrane fastening means should not be placed where active infection exists. Prior to placement, the surgeon should assure that any active or recent infection has been properly treated.

Precautions
Because of the small size of the Membrane fastening means, care must be taken that they are not swallowed or aspirated by the patient. Implantable temporary non-resorbable membranes including Membrane fastening means, used to achieve tissue regeneration or augmentation should be used by persons trained in this method. Such training is offered at a number of centers.

Adverse effects
Membrane fastening means do not have any known specific product related adverse effects. Non-resorbable membranes techniques including the application of Membrane fastening means have normal contraindications and risks including gingival recession, pain, swelling, inflammation, infection, loss of crestal bone height, perforation or abscess formation where osteoporosis, inhibited revascularization and poor bone regeneration can lead to loss of fixation. Depending on the type and severity of the complication, as judged by the clinician, membrane removal or antibiotic therapy may be indicated. The placement of tacks through the tapping procedure might in very rare cases lead to Benign paroxysmal positional vertigo (BPPV). This risk can be avoided by using screws instead.

Cleaning
Membrane fastening means are delivered cleaned. Instruments, including the Tack and Screw Cassette, must be carefully cleaned before sterilization. This also applies for new instruments. Cleaning must be performed by trained person (manual and/or machine cleaning, ultrasonic treatment, etc.). Complete adherence to equipment manufacturer’s user instructions and recommendations for chemical detergents is required. Note: The Tack Positioning Instruments shall be demounted during cleaning.

Sterilization
Membrane Tacks, Tack positioning instruments, Membrane Screws and related accessories such as the Membrane Tack and Screw Cassette are supplied NON-sterile and as such must be sterilized prior to insertion. Locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed. Use only the sterilization procedures specified below to sterilize Tacks and related instrument. For autoclaving, the components should be packaged in a sterilization bag and autoclaved in a prevacuum cycle at 132°C/270°F (for Instruments 134°C/273°F), exposure time 15 min, drying cycle 60 min at pressure 30 PSI (206 kPa). Sterilization methods must be validated in compliance with EN ISO 17665. The responsibility for the sterility of the devices lies with the user. The equipment and devices must be properly maintained and serviced at regular intervals as stipulated by the equipment and device provider.

Disposal
Explanted Membrane Tacks or Membrane Screws should be handled as hazardous materials according to established procedures at the hospital/clinic.

Cautions:
• Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist.
• Membrane Tacks and Membrane Screws must be used solely on one patient. Single use devices should not be reused due to risks of product contamination, patient/user infection and/or failure of the device to perform as intended.
• Care must be taken that Membrane Tacks and Membrane Screws are not swallowed or aspirated by the patient.
• Membrane Tacks and Membrane Screws are NOT intended as permanent implants. They are designed to facilitate the regeneration of specific oral tissue and should be removed after function.