• 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.

Magnetic Resonance Imaging (MRI)
The Neooss 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.

Membrane Screws, Membrane Tacks, Tack Positioning Instruments 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 are delivered sterile. Instruments are delivered non-sterile and must be sterilized prior to use. During surgery, membrane fastening means are mounted in the Membrane Tack and Screw Cassette from which they are easily picked up and accurately placed using corresponding instruments.

Procedures
This Instructions For Use (IFU) covers specific points relevant to the Membrane Screws, Membrane Tacks, Tack Positioning Instruments 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 Membrane Screw/Tack package and utilizing the Membrane Tack and Screw Cassette
Screws and Tacks are provided sterile. Prior to surgery, place the Screws/Tacks into the cleaned and sterilized Cassette and make sure the sterility is maintained.

Note: Screws/Tacks are distributed in three separate compartments in the blister for easy selection of appropriate amount for the surgery. Unopened compartments remain sterile. After the surgery, any unused Screws/Tacks from an opened compartment shall be disposed.

Membrane Tack – fastening
• Related 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.

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.
Membrane fastening means 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 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.

**Note:** The Tack Positioning Instruments shall be demounted during cleaning.

**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**

Instruments and accessories 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.

**Sterilization**

Instruments and related accessories such as the 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. The following heat sterilization method and process parameters are validated in accordance with EN ISO 17664 and recommended by Neoss Ltd. The components are packaged in a sterilization bag and autoclaved in a prevacuum cycle at 134°C /273°F, exposure time 15 min, drying cycle 60 min at pressure 30 PSI (206 kPa). According to EN ISO 17664, it is the user’s and processor’s responsibility to ensure that the recommended process parameters above are validated and controlled. Neoss products can withstand temperatures up to 150°C unless otherwise stated.

**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.