

Salvin Titanium Membrane Tack System

Technique Guide

INDICATIONS:

Bone Tacks are indicated for stabilization during guided tissue regeneration (GTR) and bone repair in the maxillofacial region.

USAGE:

The Salvin Titanium Membrane Tack System is designed to stabilize Barrier Membranes onto cortical plate bone. This may be used in craniofacial, maxillofacial or mandibular bone.

General patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.

DESCRIPTION:

The Titanium Membrane Tack system is comprised of a tack placement instrument, an autoclavable tack holder, a mallet, 3 and 5 mm length tacks and other ancillary instrumentation. The system and components are supplied non-sterile.

SURGICAL PROCEDURE:

1. Remove the tacks from their non sterile packaging and place in the autoclavable tack holder. The tacks and instrumentation are provided NON-STERILE and must be sterilized prior to use. An aseptic technique is required for predictable success.



2. Remove the cap from the placement instrument.

3. Firmly press the placement instrument onto the head of the desired length tack in the tack holder. This will grip the tack to be carried to the placement site.

4. Seat the tack through the barrier material only with the tip of the placement instrument perpendicular to the bone surface or the tack may be damaged. Placement should be accomplished with a single firm tap on the base of the placement instrument with the mallet. To disengage the tack, roll the placement instrument to one side. If the tack is not completely seated after the first mallet strike, place the protective cap on the placement instrument and complete the process by tapping on the placement instrument with the cap positioned against the tack head. The placement instrument may be damaged if it is repeatedly struck with the tack in the "held" position.

5. Repeat this process until the barrier is firmly anchored. Always store the placement instrument with the cap in place. Otherwise, it may become distorted and not able to grip and pick up the tacks.

6. A pilot drill hole may be required in areas of dense cortical bone. The twist drill required for this process is delicate and must be used with a cautious and light pressures to prevent fracture. A pilot hole should be placed through laminar bone when it is being used as the barrier.

7. Every effort should be made to assure primary closure of all areas. Suture the soft tissue in the usual manner when the surgical procedure is complete.

8. The Patient's Record should include Radiographs and written documentation indicating number and position of tacks.

9. In instances where tack removal is required, after normal surgical exposure the tacks may be dislodged by using a periosteal elevator, scalpel, or other thin flat instrument. The tacks should be removed, inventoried and discarded. The surgical site is now re sutured. Reuse of the tacks is NOT recommended.

CONTRAINDICATIONS:

General patient evaluation is critical prior to any surgical procedure. Contraindications include, but are not limited to, local or systemic infection, clotting disorders, vascular impairment, radiation, steroid, or anticoagulant therapy, diabetes or other systemic or metabolic limitations which would compromise healing.

COMPLICATIONS:

Complications include those associated with any osseous surgical procedure and an esthetic usage. Severity and type of complications may indicate tack removal at the discretion of the clinician.

WARNING:

It is the clinician's responsibility to become familiar with proper technique for use of this device. The clinician should have training and experience with bone fixation techniques.

The placement instrument must be held perpendicular to the bone during placement to avoid bending the tack. Complete placement should be attempted with a single strike of the mallet. An inadequately seated tack will not disengage from the placement instrument. The tacks are not designed to endure excessive or abnormal functional forces.

HOW SUPPLIED:

All components are supplied NON-STERILE. The tacks cannot be sterilized in the original packaging.

STERILIZATION METHOD:

Tacks should be removed from their vials and placed in the tack holder to be autoclaved. The recommended process is as follows:

Autoclave Profile: Gravity

Chamber Purge Time: 1 minute

Sterilization Temperature Set Point: 121°C (250°F)

Full Cycle Sterilization: Time 15 minutes

Dry Time: 30 minutes

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed dentist or physician. Use by any other person is prohibited.