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510(k) SUMMARY

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SUBMITTED BY

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CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Smooth or threaded metallic bone fixation fastener (ref: 21 CFR 888.3040)
Common/Usual Name: Bone Tack, Bone Screw or Bone Fixation Device
Proprietary Names: IMZ Membrane Tack System

PREDICATE DEVICES

Straumann, USA MemFix™ Mini-Screw Kits

DEVICE DESCRIPTION

The IMZ Membrane Tack System consists of components and instruments designed to stabilize guided tissue regeneration membranes during the healing process by providing an attachment mechanism for the membrane to resident and adjacent bone at the surgical site. The Membrane Tack is fabricated of titanium alloy and has a thin low profile head and a barb at the tip for stabilization.

INDICATIONS FOR USE

The Membrane Tack is a titanium alloy, machined, miniature nail designed to stabilize guided tissue regeneration membranes during the healing process by providing an attachment mechanism for the membrane to resident and adjacent bone at the surgical site. The guided tissue regeneration membranes are intended for use in wrapping bone or cartilage, or in soft tissue defects when bony or soft tissue ingrowth and attachment is required. Guided tissue regeneration membranes are also appropriate for augmentation of slight tissue deficiencies. These are medical devices currently cleared by FDA and commercially available for sale in the United States. While not yet classified by FDA, the FDA Dental Advisory Panel has recommended a Class II Classification for guided tissue regeneration devices, both resorbable and non-resorbable.

The Membrane Tack is designed for implantation during the healing period during which tissue regeneration takes place. It is not intended for long-term implantation, but should be removed upon completion of the healing process.

PRINCIPLES OF OPERATION

The Membrane Tack System is used in conjunction with commercially available guided tissue regeneration membranes. Surgically, the implantation site for the membrane is prepared following the membrane manufacturer's Directions-for-Use. At the point in surgery where the membrane is properly located at the surgical site and sufficient space is left under the material for tissue regeneration, the Membrane Tack vial is opened and the sterile contents of one or more vials are delivered to the sterile operative field. The Membrane Tacks are then aseptically transferred to a pre-sterilized Tack Holder where they may be picked up by either a straight or curved Tack Seating Instrument. The Tack is engaged by the Tack Seating Instrument by firmly pressing the tip of the instrument onto the head of the Tack. The Tack is then delivered to the desired position over the membrane.

The Tack may be seated by one of two methods:

1. In cancellous or "soft" bone, the Tack may be seated by gently tapping the end of the Tack Seating Instrument with a Surgical Mallet; or alternatively,
2. In cortico-cancellous, cortical or "hard" bone, the Tack may be placed by pre-drilling a small guide hole in the desired bone location which is designed to facilitate Tack placement. This is accomplished by placing the Tack Drill Guide immediately over the membrane at the desired Tack attachment site and using a pre-sterilized 0.4 mm Twist Drill connected to a dental hand-piece to drill through the Drill Guide opening and bone to create a guide hole in the dense bone approximately perpendicular to the plane of the membrane. There are "teeth" on the Tack Drill Guide designed to hold the membrane to the underlying bone during the drilling process. Care must be exercised in use of the Twist Drill since it is delicate. Abnormal forces may cause the drill to fracture at the hub. Following preparation of the guide hole, the knob on the Tack Drill Guide is pulled back to the open position and, using the pre-sterilized Tack Seating Instrument to deliver the Tack into the guide hole, the Tack is seated by gently tapping the Seating Instrument with a Surgical Mallet.

Please note that the Tack Seating Instrument is designed to disengage from the Tack after it is securely seated into the bone by rolling the Instrument tip to one side (away from perpendicular to the bone). Because the design of the Tack Seating Instrument is such that it requires a spring action on the tip of the device to retain the Tack, there is a special tip protector which must remain in place over the tip when the Seating Instrument is not in use.

It is recommended that both written and radiographic documentation of the number and location of the Tacks be obtained for later removal.

When the tissue regeneration procedure is complete, the Tacks may be removed by exposing the surgical site and using a scalpel blade, periosteal elevator or other similar thin,

flat surface, to pry the head of the Tack away from the underlying bone. The removed Tacks should be accounted for and discarded. If the membrane is non-resorbable, it should be removed in accordance with the manufacturer's Directions-for-Use. The surgical site would then be resutured.

CONTRAINDICATIONS

Contraindications customary to the use of bone grafts and membrane techniques should be observed. These include, but are not limited to, current local infection, vascular impairment at the implant site, uncontrolled diabetes, chronic high dose steroid therapy, clotting disorders, current anticoagulant therapy, metabolic bone disease, and other metabolic or systemic disorders which affect bone or wound healing.

COMPLICATIONS

Possible complications with any oral reconstructive surgery include infection, flap sloughing, perforation, abscess formation, bone loss, pain, soft tissue irregularities, and additional complications associated with the use of dental implants or anesthesia.

In addition to these complications, augmentation material perforation or exfoliation may occur. Depending on the type and severity of the complication(s), augmentation material and Tack removal may be indicated.

MATERIALS OF CONSTRUCTION

Membrane Tack -	Titanium Alloy
Tack Dispenser (holds Tacks inside dispensing vial) -	Polysulfone Resin
Tack Dispenser Cover -	Polycarbonate
Silicone Stopper -	Medical Grade Silicone Tubing
Tack Holder -	Stainless Steel
Tack Seating Instrument (straight) ¹ -	Stainless Steel
Tack Seating Instrument (curved) ¹ -	Stainless Steel
Tack Seating Instrument, straight, tip only -	Stainless Steel
Tack Seating Instrument, curved, tip only -	Stainless Steel
Tack Seating Instrument Protective Cap -	Stainless Steel

¹ Includes protective cap.

Handle, Tack Seating Instrument or Drill Guide -	Stainless Steel
Surgical Mallet - Handle and Head -	Stainless Steel
Twist Drill, 0.4 mm diameter	Tool Steel with an aluminum alloy shank
Twist Drill Inserts -	Polymer
Twist Drill Case -	Vendor material number 90191
Tack Drill Guide, Handle - Drill Guide, Tip -	Stainless Steel Stainless Steel
Sliding Drill Guide, Tack Positioner - Anchor Pins - Screw - Nut -	Stainless Steel Stainless Steel Stainless Steel Stainless Steel
Tack Drill Guide, Tip only -	Stainless Steel
Bone Tack System Sterilization Tray Lid - Base - Shelf - Stud - Pick-up Posts (2) - Legs - Inserts -	Aluminum Alloy Aluminum Aluminum Alloy Stainless Steel Stainless Steel Stainless Steel Virgin Teflon

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The design, material, configuration, method of sterilization and other technological characteristics are similar to the currently marketed predicate device.

NONCLINICAL TEST CONCLUSIONS

Pull Force testing of the IMZ Membrane Tack was performed using membrane material tacked into cortical and cancellous bone. Results showed that the membrane material does not possess the strength to pull the implanted Tack out of the bone without compromising itself in the process.