

INDICATIONS

The MC Bio “Supertack” INSTRUMENTS are used for the handling and the fixation of the “Supertack” tacks.

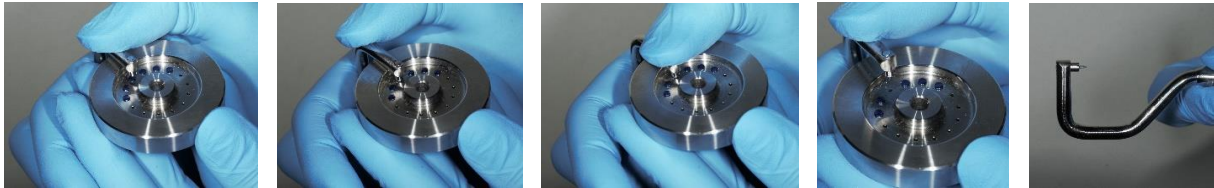
The MC Bio “SUPERTACK” system is designed to stabilize barrier membranes onto cortical plate bone, this may be used in maxillofacial or mandibular bone. General patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.

DESCRIPTION

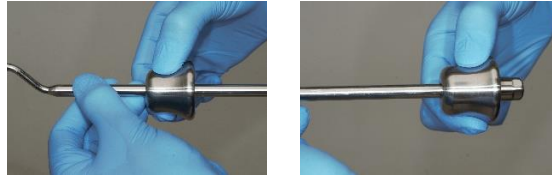
The MC Bio “SUPERTACK” system is comprised of a surgical box, a tack organizer, a placement instrument, a back applicator, a mallet, 3 mm, 4 mm and 5 mm tacks, and other instruments. All these devices are supplied NON-STERILE, and can be sterilized by steam autoclave.

SURGICAL PROCEDURE

1. The tacks and the instrumentation are provided NON-STERILE and must be sterilized prior to use.
2. Remove the tacks from their NON-STERILE packaging and place them into an FDA approved pouch for the sterilization.
3. Firmly press the back applicator onto the head of the desired tack in the organizer. This will grip the tack to be carried to the placement site.



4. Seat the tack through the barrier material only with the back applicator perpendicular to the bone surface or the tack may be damaged. Placement should be accomplished with firm taps on the base of the applicator with the mallet. To disengage the tack, angle the applicator to one side.



5. Repeat this process until the barrier is firmly anchored.

CONTRAINDICATIONS

General patient evaluation is critical prior to any 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's 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 back applicator must be held perpendicular to the bone during placement to avoid bending the tack. Complete seating should be attempted with a single strike of the mallet.

The tacks are not designed to endure excessive or abnormal functional forces.

While stainless steel and aluminum have superior corrosion resistance, it will discolor and corrode when exposed to higher than recommended chemical concentrations or certain chemicals. Stainless steel should not be exposed to the following chemicals: Sodium Hypochlorite (household bleach), Tartaric Acid (stain and tartar remover), Aluminum Chloride, Barium Chloride, Bichloride of Mercury, Calcium Chloride, Carboic Acid, Chlorinated Lime, Citric Acid, Dakin's Solution, Ferrous Chloride, Lysol, Mercuric Chloride, Mercury Salts, Phenol, Potassium Permanganate, Potassium Thiocyanate or Stannous Chloride.

The following chemicals should NEVER be used with stainless steel and aluminum: Aqua Regia, Ferric Chloride, Sulfuric Acid, Hydrochloric Acid or Iodine.

HOW SUPPLIED

All components are provided NON-STERILE.

STERILIZING

MC Bio recommends sterilization of the instruments wrapped separately in a FDA approved pouch and in a steam sterilizer with Dynamic Air Removal at, and not over, 275° F (135° C).

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

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