

INDICATIONS

The MC Bio “Supertack” tacks are used for the stabilization of absorbable and non-absorbable membranes during the bone tissue regeneration and bone repair in the maxillofacial or mandibular area.

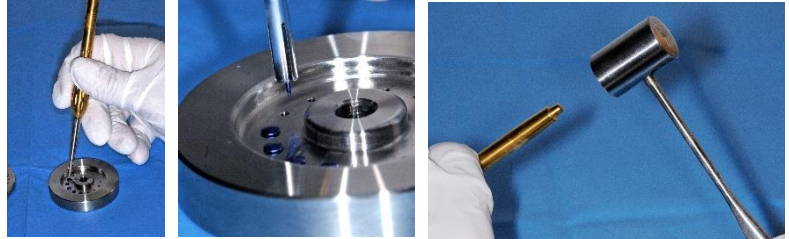
The MC Bio “SUPERTACK” system is designed to stabilize barrier membranes onto cortical plate bone, this may be used in maxillofacial or mandibular bone. General patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.

DESCRIPTION

The MC Bio “SUPERTACK” system is comprised of a tack organizer, an placement instrument, 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. Remove the tacks from their NON-STERILE packaging and place them into a FDA approved pouch. The tacks and the instrumentation are provided NON-STERILE and must be sterilized prior to use.
2. Firmly press the placement instrument onto the head of the desired tack in the organizer. This will grip the tack to be carried to the placement site.
3. Seat the tack through the barrier material only with the placement instrument perpendicular to the bone surface or the tack may be damaged. Placement should be accomplished with firm taps on the base of the placement instrument with the mallet. To disengage the tack, roll the placement instrument to one side.
4. Repeat this process until the barrier is firmly anchored. Always store the placement instrument in the surgical box; otherwise, it may become distorted and not able to grip and pick up the tacks.
5. A pilot drill hole may be required in areas of dense cortical bone.
6. Every effort should be made to assume primary closure of all areas. Suture the soft tissue when the surgical procedure is complete.
7. The Patient’s Record should include radiographs and all pertaining written documentation including number and position of the tacks.
8. The “Supertack” tacks are not intended for long-term implantation but should be removed upon completion of the healing process. In instances where the tack removal is required, after normal surgical exposure, the tacks may be dislodged by using a periosteal elevator, scalpel or other suitable thin flat instrument. The tacks should be removed, inventoried, and discarded. The surgical site is now re-sutured. MC Bio “Supertack” tacks are for single use only therefore reuse of the tacks is NOT recommended.



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 MC Bio “Supertack” has not been evaluated for safety and compatibility in the MRI environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the MC Bio “Supertack” in the MRI environment is unknown. Scanning a patient who has this device may result in patient injury.

The placement instrument 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.

HOW SUPPLIED

All components are provided NON-STERILE. Tacks are inside a glass vial, enclosed in a transparent blister sealed by a Tyvek cover. The tacks can’t be sterilized in the original packaging.

STERILIZING

MC Bio recommends sterilization of the tack wrapped in a FDA approved pouch and in a steam sterilizer with Dynamic Air Removal.

STEAM AUTOCLAVE METHOD

- Insertion of the Tacks into a FDA approved pouch
- Pre-vacuum cycle
- Sterilization time: 4 min. at 275° F (135° C).
- Drying time: 30 minutes

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.

Distributed by **Geistlich Biomaterials**
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