MC-Bone Tac

Caution | Do not re-use | Non-Sterile | CE 2195

Description

The MC-Bone Tac is fabricated of titanium of alloy(ASTM F 136, Titanium 64L-4V ELI) and has a low profile head, round, lens shaped head and a barb at the trip. It is designed to guide tissue membranes during the healing process by providing an attachment mechanism to the adjacent bone at the surgical site. The device are provided non-sterile and are to be sterilized by the user using accepted steam sterilization techniques.

Intended Use

The MC-Bone Tac is designed to Membrane onto a region of cortical plate. This may be used in craniofacial, maxillofacial or mandibular bone.

Storage Conditions Room temperature

Shelf Life N/A

Package 1EA/PACKAGE, 3EA/PACKAGE, 5EA/PACKAGE, 10EA/PACKAGE

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Pictogram

	Do not re-use
	Caution
	Date of manufactured
	Manufacturer
EC REP	Authorized representative in the European Community
LOT	Batch Code
NON STERILE	Non-sterile

Instructions

Preparations before use

1. Be fully aware of the anatomical structure around and at the implant site in order to minimize unnecessary surgical damage
2. Check the product for defects before use, and if a defect is found, do not use the products.
3. Instruments used for a surgical operation should be sterilized before their first use.
4. Since the product is a non-sterile product, it should be subject to steam sterilization under pressure at a temperature of 134℃ for 15 minutes.

Using Methods

1. Decide on the size and proper implant site depending on treatment purposes.
2. Check for Membrane and Mesh Plate at the implant site and place the screw.
3. Make the location where the screw is implanted.
4. Insert the screw.

Keeping and storing of used products.

This is desposable product, Do not reuse.

Cautions

1. A specialist, who is fully aware of the instructions for use, should perform an operation.
2. The operator should examine the patient's surgical site, and then decide whether or not this product should be used and what kind of operation method should be used.
3. The product may be damaged in some cases and abnormalities may occur during the fixation process. In such cases the operation should be performed again with the new product.
4. The product is intended for single use only.

Contraindications

1. Patients with insufficient quantity quality of bone.
2. Patients with active infection.
3. Patient conditions including : blood supply limitations, latent infections.
4. Patients with mental or neurological conditions who are unwilling or incapable of following post-operative care instructions.
5. Immunodeficiency, irradiated patients, severe diabetes, severe osteoporosis.

Side Effect
1.Inflammation of the gums
2.Damage due ti device
3.Recurrence after treatment

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