



Screw & Tack Kit

User Manual & Sterilization

DESCRIPTION

The content of the **Screw & Tack Kit** can consist of a storage block, bone screws, tacks, mesh and instruments. The storage block is made of anodized aluminum. The J-TACs and the bone screws are made of titanium alloy and the mesh of pure titanium.

Applying titanium mesh over a cavity provides stable mechanical support while maintaining sufficient flexibility for placement. Applying titanium screws for the on-lay bone above the alveolar bone provides stable mechanical rigidity and stability.

Materials

- **Storage Block**
Anodized aluminum
- **Screw**
Titanium Alloy (ASTMF 136)
- **J-TAC**
Titanium Alloy (ASTMF 136)
- **Mesh**
Pure Titanium (ASTMF 67 Grade 1)



J-TAC



SCREW



MESH

INDICATIONS FOR USE

All instruments and materials must be sterilized before use. Steam autoclave at 121°C for at least 15 minutes.

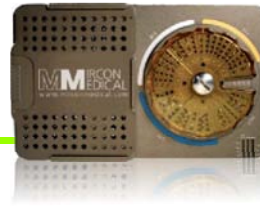
The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. **Single patient use only.**

Guided Bone Regeneration Case

- 1 Measure the cavity size.
 - 2 Use suitable cutters to cut the mesh to desirable size for the cavity site. Must consider the hole for screws.
 - 3 The shape of the mesh must be similar to recipient graft out of selected mesh.
 - 4 Attach the pre-shaped mesh over the cavity site.
 - 5 As the decision of dentist, drill holes for micro auto screws. In the use of Auto Screw (Self-Drilling Screw, insert it in the surgical site without pre-drilling).
- Note: In the use of auto screw, refer to Caution & Warning Section.*
- 6 Insert screws into each drilled hole using micro driver through mesh and cortical wall to secure the mesh. Less than 4 screws fixation is not recommended, unless there is absolutely not enough wall to place 4 screws.

On-lay Graft Case

- 1 Choose a mini screw of proper size to fix the block bone on the recipient site.
 - 2 Firmly fix the bone block prior to drill. Use proper instrument to fix bone block over the intended bone defect site.
 - 3 Drill pilot holes through the graft and recipient cortical wall. Unless there is absolutely not enough wall to place two screws, single screw fixation is not recommended. In the use of Auto screw (Self-drilling screw: AT series), insert it in the surgical site without pre-drilling.
- Note: In the use of auto screw, refer to Caution & Warning Section.*
- 4 Overdrill the holes in the graft; carefully overdrill with drill bit or burr, the hole size must be smaller than the head of screw.
 - 5 Estimate the length of screw required.
Confirm that the selected screws are suitable for the holes.
 - 6 Insert selected screws. Dentists should insert more than 2 screws to prevent rotating of bone block.



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WARNINGS & CAUTIONS

- For safe and effective use of the system, the dentist should have specific training, experience and thorough familiarity with oral surgery.
- Mesh and Screw to be applied must be carefully decided by the dentist and should take into consideration the bone quality and type, non-directional mastication load and post-operative patient compliance.
- With the cut edge of titanium mesh, there are some possibilities to sustain cuts from the sharp end. The dentist must carefully suture the implanted region.
- Use of an undersized screw in areas of functional stress may lead to device fracture and failure.
- The dentist should inform the patient of risks associated with surgery.
- Once applied, never reuse this device.
- During the insertion, do not press excessive load. It could cause the fracture of the device.
- In case that the patient's bone density is too dense or thick, the dentist should perform predrilling before inserting auto screws.

HANDLING & STERILIZATION

- All components must be sterilized before use.
- Sterilization method: Steam Sterilization
Note: The ETO sterilization method is available.
- Sterilization temperature: 121°C
- Sterilization Time: 15 min.
- Packaging: individual sale or packaged sale (including the storage block and instruments)

POSSIBLE ADVERSE EFFECTS

- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to non-integration.
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity, or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

- This device must not be used in infected sites.
- This device must not to be used in a patient who has sensitivity to titanium.

