Instructions for Use, MMF Screws

1. Choose screw lengths appropriate to the surgical site.

2. Place bone screws through the foramen without making an incision, taking care to avoid the roots of the tooth and the foramen itself. Begin with the smallest screw diameter available and increase to the appropriate size.

3. Prepare bone with a pilot drill that is longer than the inserted screw when using 2.0mm, 2.4mm or 2.6mm screws.

4. Note: Use a drill with drill bit diameter of 0.8mm for 2.0mm, 0.9mm for 2.4mm, and 1.0mm for 2.6mm screws.

5. Select appropriate MMF screw length.

6. Insert the drill tip lightly into screw cruciform and apply moderate pressure. Vertically retract driver and remove from screw head to verify length. Insert the screw into the pilot hole and drive the screw to the appropriate depth, leaving the wire/pilot hole exposed. Do not over-torque or over-engage.

7. For secondary screw ensure placement in the mandible is 3mm inferior and medial or lateral to the canine tooth.

8. A minimum of three pairs of MMF screws are recommended to ensure adequate stability. A pair consists of two screws in the mandible and one opposing screw in the maxilla.

9. Wire screws using 24 gauge stainless steel wire (207-0120) through exposed wire passing holes into the bone and opposing mandible MMF screws head in a vertical and “X” pattern. Tighten only enough to provide provisional fixation.

10. Establish occlusion and tighten wire fully.

Cleaning

• Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and chemical inspection prior to sterilization.
• Compliance is required with the equipment manufacturer’s user instructions (manual and or machine operation guide).
• OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation: Clean all instruments thoroughly using methyl alcohol, stainless steel and warm water. Ensure all metal alloys are rinsed clean. Do not use steam sterilization. Bone, stone and other devices are washed with the instruments and sterilization tray.

11. When using the drill guide, do not apply a side load on the drill. This may result in friction, which may generate a thermal burn. Axial loading should always be used.

12. When using the trial procedure, ensure chuck retractors are used to protect soft tissue.


to avoid compromising functions of polymeric implantation.

Storage

Sterile packaged implants should be stored at controlled room temperature out of direct sunlight. Non-sterile packaged implants may be stored in a cool, dark location in a dry environment. Leave the sterile package on or inside the sterile disposal bag until the package is opened and the implant is placed in the mouth or muzzle. The implant should only be handled by the operator.

Caution

“General (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so. Do not attempt a surgical approach with faulty, damaged, or suspected OsteoMed instruments or implants. Inspect all components preoperatively to assure usability. Alternate fixation methods should be available intraproactively.

13. When placing additional screws, ensure that the subsequent screw placement does not interfere with the other screws.

14. When using the drill guide, do not apply a side load on the drill. This may result in friction, which may generate a thermal burn. Axial loading should always be used.

15. When using the trial procedure, ensure chuck retractors are used to protect soft tissue.

Maintaining Device Effectiveness

In surgeons of specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.

In surgeons must have the following knowledge of the indications for MMF screws used to assure adequate bone fixation postoperatively.

1. The OsteoMed Angulated Locking Fixation System is indicated for fracture fixation during cranial and facial reconstructions (osteoconductive, orthognathic repositioning, mandibular reconstruction and surgery involving osteotomies and trauma).

2. The OsteoMed 2.0 Angled Locking Plate System is indicated for fracture fixation in oral cavity, trauma, resection, and oncologic surgery.

3. The OsteoMed Unusual Screw System is intended for temporary ligature and wire lock fixation for temporary postoperative stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

4. The OsteoMed Angulated Locking Fixation System is indicated for fracture fixation during cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic repositioning.

5. The OsteoMed Rigid Fixation Systems are comprised of plates, screws and instrumentation used for osteotomies and trauma.

6. The OsteoMed MMF Screws are indicated for temporary ligature and wire lock fixation for temporary postoperative stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

7. The OsteoMed Angulated Locking Fixation System is indicated for fracture fixation during cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic repositioning.

8. The OsteoMed MMF Screws are indicated for temporary ligature and wire lock fixation for temporary postoperative stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

9. The OsteoMed Unusual Screw System is intended for temporary ligature and wire lock fixation for temporary postoperative stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

10. The OsteoMed Angulated Locking Fixation System is indicated for fracture fixation during cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic repositioning.

11. The OsteoMed Unusual Screw System is intended for temporary ligature and wire lock fixation for temporary postoperative stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.

12. The OsteoMed Angulated Locking Fixation System is indicated for fracture fixation during cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic repositioning.

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