OSTEOMED
MFx™ Rigid Fixation System
Mandibular Fracture/Reconstruction System
Product Information and Instructions for Use

Description
The ***OSTEOMED MFx™*** *Rigid Fixation System* is comprised of plates, screws and instrumentation used for fixation of maxillofacial and mandibular fractures and reconstructions. The system features 2.0mm and 2.4mm mandibular standard plates, locking plates, standard/locking plates, Angulated Locking plates, and reduction plates. The plates range in thicknesses of 0.8mm to 2.5mm. The system also includes 2.0mm and 2.4mm diameter standard screws in lengths from 4mm to 22mm, 2.3mm and 2.7mm diameter standard safety screws in lengths from 4mm to 22mm, 2.0mm diameter Auto-Drive® screws in lengths from 4.0mm to 8.0mm, 2.0mm and 2.4mm diameter locking screws in lengths from 6.0mm to 18.0mm, 2.0mm and 2.4mm diameter Angulated Locking screws in lengths from 4mm to 22mm, 2.3mm and 2.7mm Angulated Locking safety screws in lengths from 4mm to 22mm, 2.0mm and 2.4mm diameter Angulated Locking Auto-Drive® screws in lengths from 5mm to 8mm, 2.0mm Auto-Drive® MMF screws in lengths of 8mm, 11mm, and 14mm, and 2.4mm diameter MMF screws in lengths from 10m to 20mm. The system instruments include drill bits, plate bending forceps, plate holding forceps, reduction forceps, plate cutters, cannulae, taps, countersinks, plate bending pliers, plate cutters, drill guides and screwdrivers to facilitate the placement of screws and modification of plates.

Material
The screws are made from Titanium Alloy (ASTM F-136). The plates are made from Titanium Alloy (ASTM F-136) or commercially pure Titanium (ASTM F-67). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications
The ***OSTEOMED MFx™ Mandibular Fracture/ Reconstruction System*** is indicated for fracture fixation, mandibular reconstruction and surgery involving osteotomies and trauma.
The ***OSTEOMED Angulated Locking Fixation System*** is indicated for mandibular trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.
The ***OSTEOMED 2.0 Locking Plate System*** is indicated for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities).
The ***OSTEOMED MMF Screws*** are indicated for temporary ligature and wire lock fixation for temporary constriction and stabilization of fractured bone segments in the oral cavity in conjunction with primary fixation devices.
The ***OSTEOMED Reduction Plates and Forceps*** are intended for mandibular body fractures, symphysis fractures and parasymphysis for tension, compression or both.
The ***OSTEOMED MFx™ Rigid Fixation System*** implants, templates and drills are intended for **single use only**. System instruments are reusable. OsteoMed single use devices cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications
- Use of the ***OSTEOMED MFx™*** *Rigid Fixation System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases.
- It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation plate and screw implants and/or in patients where there is insufficient bone or poor bone quality.
- The ***OSTEOMED*** *MMF Screws* are also contraindicated in patients with disorders which could prevent the patient from following the limitations of temporary ligature and wire fixation.
- The use of 2.4mm Angulated Locking Auto-Drive® screws are contraindicated in bi-cortical bone placement on the mandible.

Warnings
1. Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Multiple bending may weaken the plate and could result in implant fracture and failure.
4. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
5. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient.
6. Use of excessive torque during insertion of screws may lead to implant failure.
7. ***OSTEOMED*** MMF Screws: Use of an undersized wire or screw in areas of high abnormal functional stresses may lead to wire or screw fracture and failure.
8. ***OSTEOMED*** MMF Screws: Screws and wire are intended for temporary fixation and are to be implanted for a maximum of four weeks.
9. Cannula is never to be used as a cheek retractor.
10. When placing additional screws, ensure that subsequent screw placement does not interfere with the other screws.
11. When using the reduction forceps (220-0231) with the reduction plates, do not use excessive force when lodging the tip into the slot.
12. 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.
13. When using the transbuccal approach, ensure cheek retractor is used to protect soft tissue.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
3. The ***OSTEOMED MFx™*** *Rigid Fixation System* plates and screws are not intended to endure excessive abnormal functional stresses.
4. When loading a screw onto driver, apply a perpendicular force to engage screw cruciform with driver. The surgeon should avoid multiple insertions of driver into the same screw to maintain self retention feature of screw and driver.
5. The ***OSTEOMED MFx™*** *Rigid Fixation System* is intended for temporary fixation only until osteogenesis occurs.
6. All ***OSTEOMED*** plates, screws, and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal. All implants are held in the organizer block. Remove lid from block by holding down the button, pull and lift lid to open.
7. Carefully inspect the ***OSTEOMED*** implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to ***OSTEOMED*** for disposition and repair.
8. When placing more than one screw, ensure that subsequent screw placement does not interfere with other screws. Insert the second screw on the opposite side of the fracture or osteotomy site, and then all remaining screws, following the outlined procedures.
9. ***OSTEOMED*** recommends the use of ***OSTEOMED*** products in a sterile environment.
10. Drill using the appropriate **pilot drill**. Note: Speed and torque parameters must be in accordance to the Power System Instruction for Use. Use irrigation when pilot drilling.
    NOTE: Drill Color Bands Denotes Size: 2.0mm drills are Blue and 2.4mm drills are Green.
11. After cutting plate, utilize diamond file on the plate cutter handle (220-0584) to remove sharp edges on the plate.
12. When using Plate Benders 220-0548 and 220-0529, note they can only be used with Reconstruction plates.
13. The legend for the Rainbow Drills is located on the back of the lid of the organizer blocks which contain Rainbow Drills. The six proximal color bands on the Rainbow Drills denote the depth of the drilled hole: Red(0mm), Orange(4mm), Magenta(8mm), Black(12mm), Aqua(16mm) and Yellow(20mm).
14. The distal banding on the transbuccal instrumentation, including drills, denotes with which cannula the instrumentation is to be used.

Instructions for Use, Auto-Drive® Screws
The Auto-Drive® screws are self drilling and can be inserted in one step. Insert the screw in a TaperLock™ screwdriver and drive into the bone at a 90° angle using moderate pressure until the head is flush with the surface of the bone/plate. Higher torque may be required to fully engage the threads than when using a normal screw with a pilot drill.
NOTE: In high density bone pilot drilling may be necessary.

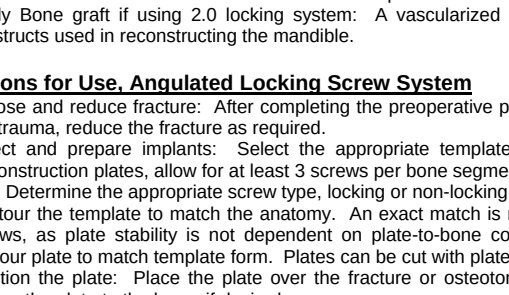
Instructions for Use, Locking Screw System
1. Expose and reduce fracture: After completing the preoperative plan, expose the fracture or osteotomy site. For trauma, reduce the fracture as required.
2. Select and prepare implants: Select the appropriate template/plate depending on the indication. For Reconstruction plates, allow for at least 3 screws per bone segment. Orient the plate so the topside is facing out. Determine the appropriate screw type, locking or non-locking.
3. Place bending inserts into holes selected to receive screws. Contour the template to match the anatomy. An exact match is not required when using locking screws, as plate stability is not dependent on plate-to-bone contact when screws are locked. Cut and contour plate to match template form. Plates can be cut with plate cutters.
4. Position the plate: Place the plate over the fracture or osteotomy site. Use the plate holding forceps to secure the plate to the bone, if desired.
5. Drill the first hole: Select the threaded drill guide and insert it into the first plate hole nearest the fracture or osteotomy site. Rotate the drill guide clockwise to engage the threads in the plate. Drill using the appropriate drill bit.
6. Measure screw length: Remove guide and use depth gauge to measure hole depth to determine appropriate screw length.
7. Insert the screw: Insert the proper length locking or non-locking screw through the plate and tighten until secure.
8. Drill and place the remaining screws: Insert the second screw on the opposite side of the fracture or osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten all screws unless resection is to follow.

9. For ablative procedures:
   - Resect the desired area
   - Once the plate is in place, remove the plate and screws, taking note of each screw placement. Resect the desired area
10. Replace the implants:
    - Place the plate back onto the osteotomy in its original position.
    - Reinsert each predetermined screw.
    - Check all screws to ensure a secure fit in the plate.
11. Apply Bone graft if using 2.0 locking system: A vascularized bone graft must be applied to all 2.0mm constructs used in reconstructing the mandible.

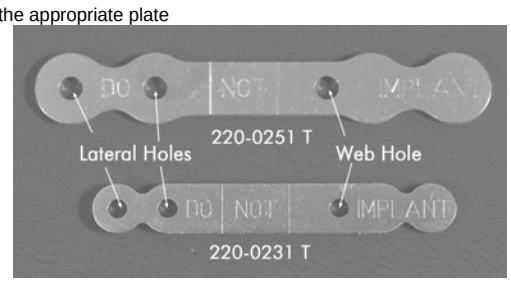
Instructions for Use, Angulated Locking Screw System
1. Expose and reduce fracture: After completing the preoperative plan, expose the fracture or osteotomy site. For trauma, reduce the fracture as required.
2. Select and prepare implants: Select the appropriate template/plate depending on the indication. For Reconstruction plates, allow for at least 3 screws per bone segment. Orient the plate so the topside is facing out. Determine the appropriate screw type, locking or non-locking.
3. Contour the template to match the anatomy. An exact match is not required when using angulated locking screws, as plate stability is not dependent on plate-to-bone contact when screws are locked. Cut and contour plate to match template form. Plates can be cut with plate cutters.
4. Position the plate: Place the plate over the fracture or osteotomy site. Use the plate holding forceps to secure the plate to the bone, if desired.
5. Drill the first hole: Select the Angulated Locking Drill Guide and insert it into the first plate hole nearest the fracture or osteotomy site. Ensure Angulated Locking Drill Guide is flush and perpendicular to the plate. Drill guide will provide up to 10 degrees of angulation in any direction. Drill using the appropriate drill bit.
   NOTE: If transbuccal approach is needed, ensure that only the Neutral Drill Guide is used and drill the pilot hole utilizing the proper technique.
6. Measure screw length: Remove drill guide and use depth gauge to measure hole depth to determine appropriate screw length.
7. Insert the screw: Insert the proper length Angulated Locking or standard(non-locking) screw through the plate and tighten until secure.
8. Drill and place the remaining screws: Insert the second screw on the opposite side of the fracture or osteotomy site, and then all remaining screws, following the previously outlined procedure. Securely tighten all screws unless resection is to follow.
   NOTE: When placing additional screws, ensure that subsequent screw placement does not interfere with the other screws.
9. For ablative procedures:
   - Resect the desired area
   - Once the plate is in place, remove the plate and screws, taking note of each screw placement. Resect the desired area
10. Replace the implants:
    - Place the plate back onto the osteotomy in its original position.
    - Reinsert each predetermined screw.
    - Check all screws to ensure a secure fit in the plate.

Instructions for Use, Mandible Lag Screw System
1. Select proper fracture access and reduce fracture with reduction clamp.
2. Place sliding length gauge over lag screw depth gauge cannula.
3. Determine drill placement area and angulations. Final drill path/angle is shown by tip of sliding length gauge.
4. Align open irrigation tip of cannula ventral to fracture sight to allow irrigation. Drill using drill bit.
5. Screw hole length can be determined by reading measurement on gauge or cannula. Cannula gauge is measured by reading mark on cannula where back of sliding length gauge rests on cannula. Measurement can also be read by determining point of sliding length gauge that aligns with tip of cannula.
6. Countersink and/or tap if desired then place screw.
7. Retrieve the chosen screw with the appropriate driver stem and insert lag screw.
8. Drive the screw to compress the fracture.

Instructions for Use, Reduction Plates & Forceps:
1. Expose the fracture

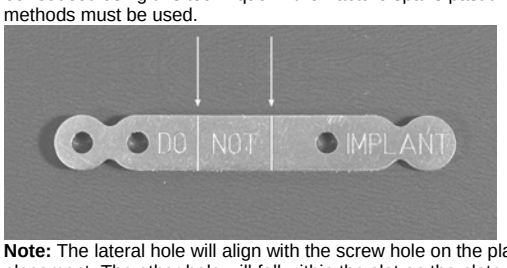


2. Select the appropriate plate

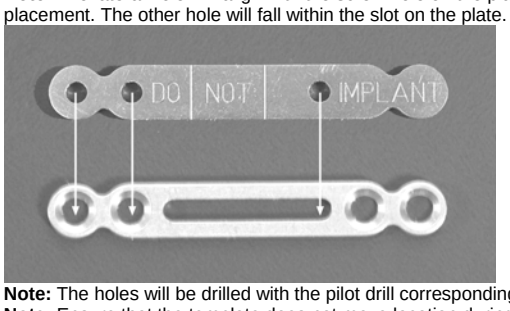


3. Select the corresponding template

4. Drill forceps insertion holes
   • Place the template across the fracture; ensure that the fracture lines fall entirely within the limit lines on the template.
   • Drill the first insertion hole through the template's web hole and the second hole through one of the lateral holes.
   Note: The etched lines present on the template indicate the maximum fracture displacement that can be reduced using this technique. If the fracture spans past the limit lines, conventional reduction methods must be used.



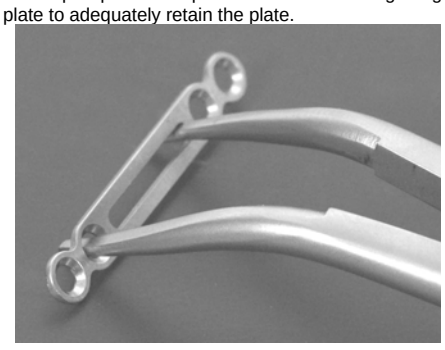
Note: The lateral hole will align with the screw hole on the plate and serve as a pilot hole during screw placement. The other hole will fall within the slot on the plate.



Note: The holes will be drilled with the pilot drill corresponding to the screws used with the plate.
Note: Ensure that the template does not move location during the drilling of the holes and that the holes are drilled as close to parallel as possible.

5. Remove the template
   Technique Tip: If little or no contouring of the plate is required go to Step 6, if significant contouring is required continue to Step 5.1
   5.1. Reduce the fracture
   Insert the forceps into the pre-drilled holes on the fragments and reduce the fracture.
   5.2. Contour the template by placing above or below the forceps
   Note: Plate must be flush with the bone to provide adequate contouring
   5.3. Contour the plate to match the template.
   Technique Tip: Utilize one of the OsteoMed plate contouring options.
   Note: Multiple bending of the plate may weaken the plate and could result in implant fracture and failure.
   5.4. Remove the forceps from the bone

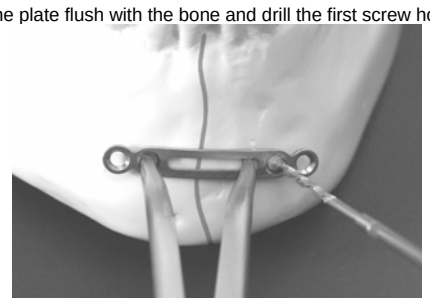
6. Insert the forceps' tips into the plate until there is enough engagement between the tip of the forceps and the slot of the plate to adequately retain the plate.



6.1 One tip of the forceps must be placed in the slot and the second tip must be placed in one of the screw holes on the opposing side of the fracture.
Note: Do not use excessive force when lodging the tip into the slot

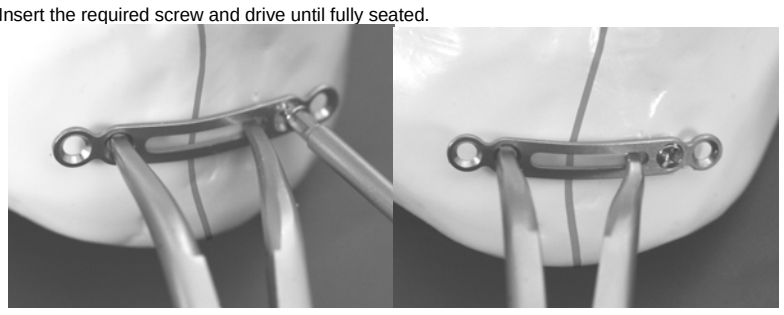
7. Engage the reduction forceps into the mandible fracture fragments, reduce the fracture.
   Note: Forceps will continue to provide reduction/compression during screw placement.

8. Push the plate flush with the bone and drill the first screw hole using the appropriate drill.



9. Use Depth Gauge to measure the screw length required.

10. Insert the required screw and drive until fully seated.



11. Place opposite side lateral screw to maintain reduction.

12. Remove forceps and place remaining screws.

13. Close per standard practice.

For Further information on instruments or techniques, refer to ***OSTEOMED MFx™*** Surgical Technique Guide 030-1623 or OsteoMed Rigid Fixation Instrumentation 030-1559

Instructions for Use, MMF Screws

1. Screws are placed through the mucosa without making an incision, taking care to avoid the roots of the teeth. Choose screw sites away from the root apices usually medial or distal to the cuspid tooth.
2. Prepare bone with a pilot drill that is longer than the intended screw when using 2.4mm MMF screws, taking care to avoid critical structures.
   NOTE: 2.0mm MMF Screws are self drilling, Auto-Drive®.
3. Select appropriate MMF screw length.
4. Engage driver tip lightly into screw cruciform and apply moderate pressure. Vertically retract driver and screw from organizer and verify length with length gauge. Insert the screw into the pilot hole and drive the screw to the appropriate depth, leaving the wire-passing hole exposed. Do not over torque or bottom out the screw.
5. For secondary screw ensure placement in the mandible is 5mm inferior and medial or lateral to the canine tooth roots.
6. A minimum of three pairs of MMF screws are recommended to ensure adequate stability. A pair consists of one screw in the mandible and an opposing screw in the maxilla.
7. Wire screws using 24 gauge stainless steel wire (207-0120) through exposed wire passing holes into maxillary and opposing mandibular MMF screw heads in a vertical and "X" pattern. Tighten only enough to provide provisional fixation.
8. Establish occlusion and tighten wire fully.

Cleaning

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- ***OSTEOMED*** recommends the following cleaning and sterilization instructions for Instrumentation:
  1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
  2. Thoroughly rinse all instruments and the sterilization tray with water.
  3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
  4. Steam Autoclave per the following Sterilization Instructions.

Sterility

- Product is supplied **NON-STERILE unless expressly labeled as STERILE.**
- Select plates and screws are available sterile packaged (Gamma Sterilized) in 5-packs. **DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.**
- OsteoForm Mesh is also available sterile packaged (Gamma Sterilized). **DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.**
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of ***OSTEOMED*** implant systems, the following parameters should be used.

Pre-Vacuum Steam Sterilization	**MFx™ Rigid Fixation Systems - Plastic Tray**	**MFx™ Rigid Fixation Systems - Aluminum Tray**
Temperature:	273°F (134°C)	270°F (132°C)
Time:	30 minutes	10 minutes
Dry Time:	55 minutes	55 minutes
Configuration:	Wrapped tray	Wrapped tray
Wrapping Technique:	Wrapped tray in two layers of 1-ply polypropylene wrap.	Wrapped tray in two layers of 1-ply polypropylene wrap with towel placed between the wraps and bottom of the tray.
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.		

Storage

Sterile packaged implants should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering.

Caution

- **Federal (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 procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.**

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CE 0197

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture	EC REP	Authorized Representative in the European Community
	Attention, See Instructions for Use Caution, Consult Accompanying Documents		Manufacturer

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