Part No.030-1552
Rev. N

OSTEOMED
CFx™ Rigid Fixation System
M3/M4 / Craniomaxillofacial Trauma Fixation
Craniofacial Modular Fixation Systems

Product Information and Instructions for Use

Description

The *OSTEOMED CFx™ Rigid Fixation Systems* are comprised of plates, screws and instrumentation used for fixation of craniofacial, maxillofacial and mandibular fractures and reconstructions. The system features 1.2mm, 1.6mm, 2.0mm and 2.4mm plates ranging from 0.25mm to 2.5mm thick, Locking plates ranging from 1.0mm to 2.5mm thick, 1.6mm Low Profile Midface Plates(LPM) 0.5mm thick, 1.6mm LPM Mesh ranging 0.5mm to 0.7mm thick, 1.2 mm to 2.7mm diameter standard screws in lengths from 2.0mm to 22.0mm, 1.6mm Auto-Drive® screws in lengths from 3.5mm to 8.0mm, MMF(Maxillo-Mandibular-Fixation) screws are offered in 2.4mm diameter standard screws in lengths from 10mm to 20mm and 2.0mm diameter Auto-Drive® screws 8mm in length and 2.0mm diameter Auto-Drive® Lag in lengths of 11mm and 14mm, and Locking Screws in diameters of 2.0mm in lengths of 6.0mm to 18.0mm and diameter of 2.4mm in lengths of 6.0mm to 22.0mm. Low Profile 1.6mm Auto-Drive® screws in lengths of 3.5mm and 6.0mm. Angled Locking Plates and screws allow up to 20 degrees of angulations within screw placement. The Mandible 2.0mm Angled Locking System features 2.0mm Angled Locking Standard Screws with lengths 4mm to 18mm, 2.0mm Angled Locking Auto-Drive® Screws with lengths of 5mm to 8mm, and 2.0mm Angled Locking Safety Screws with lengths ranging from 4mm to 18mm. The mandible plates are 1.5mm in thickness. The Mandible 2.4mm Angled Locking System features 2.4mm Angled Locking Standard Screws with lengths of 6mm to 22mm, 2.4mm Angled Locking Auto-Drive® Screws with lengths of 6mm to 8mm, and 2.7mm Angled Locking Safety Screws with lengths ranging from 6mm to 22mm. The fracture plates range in thicknesses of 1.5mm to 2.0mm and the reconstruction plates are 2.5mm.

The instruments include drill bits, plate bending forceps, plate holding forceps, plate cutters, cannulae, taps, countersinks, plate bending pliers, mesh benders, 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 CFx™ Rigid Fixation Systems* are indicated for fracture fixation during cranial and facial trauma reconstructions, orthognathic reconstruction, mandibular reconstruction and surgery involving osteotomies and trauma.

The *OSTEOMED 2.0 Locking Plate System* is indicated for oral, maxillofacial surgery; trauma; reconstructive surgery; and orthognathic surgery (surgical correction of dentofacial deformities). Screws and Plates are intended for single patient use only.

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 Angulated Locking Fixation System* is indicated for mandibular fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The *OSTEOMED CFx™ Rigid Fixation Systems* implants and drills are intended for single use only. System instruments are reusable. OsteoMed single use devices/instruments 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 CFx™ Rigid Fixation Systems* are contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium or stainless steel; 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 Angled 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 when drilling.
10. When placing additional screws, ensure that subsequent screw placement does not interfere with the other screws.
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 transbuccal approach, ensure cheek retractor is used to protect soft tissue.
13. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.
14. The *OSTEOMED CFx™ Rigid Fixation Systems* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.

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 CFx™ Rigid Fixation Systems* 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 to driver.
5. The *OSTEOMED CFx™ Rigid Fixation Systems* are 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.
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: 1.2mm drills are Yellow, 1.6mm drills are White, 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. Depth gauge marking tolerance:±0.76mm

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 for Mandible Applications.

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 screw 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.

Attention: Instructions for Use are in the Surgical Technique Guide (030-1559) or OsteoMed MFxTM Surgical Technique Guide 030-1623 (for Angulated Locking) or PI 030-1567.

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	*CFx™* Rigid Fixation Systems - Plastic Tray	*CFx™* 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 (Kimguard KC600 – 510(k) K082554)	Wrapped tray in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554)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.		

Note: Biological indicator of *G. stearothermophilus* was used in sterilization validation.

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 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use by (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG Date)	EC REP	Authorized Representative in the European Community
	Manufacturer (MFR)		Attention, See Instructions for Use Caution, Consult Accompanying Documents
STERILE R	Sterile, Method of Sterilization Using Irradiation	Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.

Printed in U.S.A.
OSTEOMED August 2014