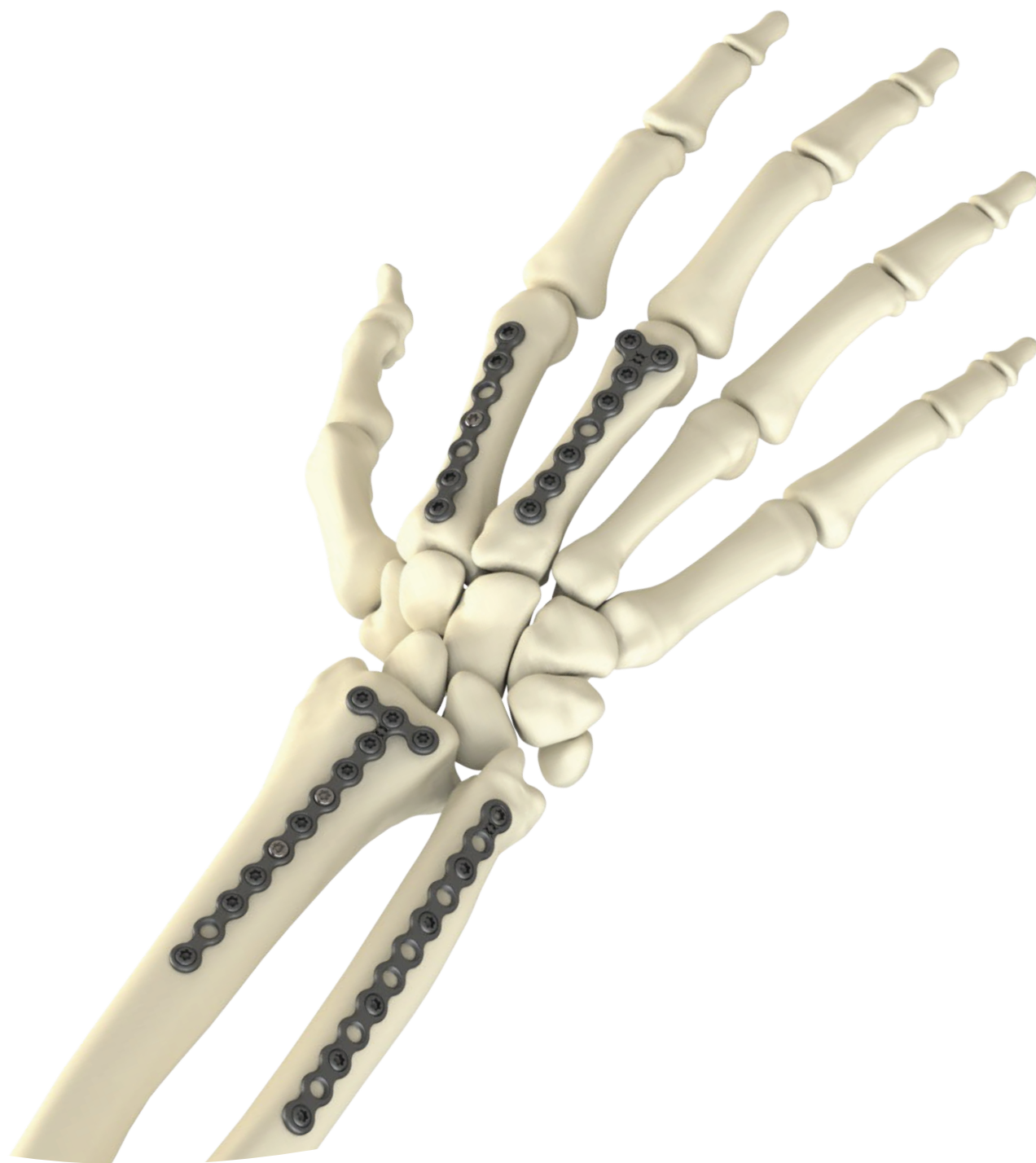




OIC Mini Fragment Plates Surgical Technique Guide

Table of Contents

SYSTEM OVERVIEW	3
Introduction	3
Plate Features	3
Screw Features	3
Instruments	4
INDICATIONS AND WARNINGS	5
Indications for Use	5
Contraindications	5
Warnings and Precautions	5
Adverse Effects	6
Materials	6
SURGICAL TECHNIQUE	7
Plate and Screw Insertion	7
Fracture Reduction	8
Plate Selection and Alterations	8
Plate Bending (Optional)	8
Plate Cutting (Optional)	9
Drilling	9
Measuring	10
Screw Insertion	10
Implant Removal (Optional)	10
CATALOG INFORMATION	11
Implants	11
Disposables	12
Instruments	12

The technique description herein is made available to the healthcare professional to illustrate the author’s suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the specific needs of the patient.

INTRODUCTION

OIC's Mini Fragment Plates has been developed to optimize inventory and efficiency, reducing complexity while providing a wide berth of treatment solutions for common fractures. The OIC Mini Fragment Plates were built upon the foundations of OIC's Small Fragment Plating System, using the same screws, instrumentation, and methods surgeons have become familiar with.

PLATE FEATURES

- Plates offered in 4 base shapes, with instruments allowing for variation in final plate shape
- Variable angle (15°) and fixed angle locking options in every hole
- Plates offered in a standard (1.3mm thick) and broad (1.5mm thick) profile
- All plates use the same screws and instrumentation, minimizing complexity
- Options for locking and non-locking fixation in each hole

SCREW FEATURES

- 2.5mm locking and non-locking screws
- Hexalobe socket for improved torque insertion and socket strength
- Self-tapping threads remove need for tapping instrument
- Buttressed threads improve pull out strength in cancellous bone
- Rounded head minimizes sharp edges and soft tissue irritation
- Head shape allows variability in screw trajectory up to 15°
- Self-retaining screwdriver/socket interface
- All 2.5mm specific instruments feature a **GOLD BAND**



2.5mm
08-50mm



INSTRUMENTS

Drill Guides

Drill guides are offered in locking and in hand-held formats. Drill bits feature calibration marks indicating drill depth. Hand-held drill guides feature a fixed angle end and a variable angle end with 15° of angulation. Locking drill guides feature internal threads allowing for stacking of guides when extra length is needed.



Plate Cutting

OIC plates may be cut to size using the provided cutting pliers. Cutting/Bending Combo Pliers allow for both controlled cutting and in-plane bending of plates with one instrument.



Plate Bending

OIC plates may be bent when variation is needed. Bending pliers, in-plane bending pliers, and bending bars are provided with the system. Bending bars feature slots to accommodate bending of all mini fragment plates.



Lag (Interfragmentary) Screw Fixation

Lag screw drill guides allow for effective over-drilling and controlled centered drilling for interfragmentary screw fixation. Drill guides are color coded for easy drill identification. Countersinks are available to improve concentric loading and surface area of lag screws.



INDICATIONS FOR USE

The OIC Small / Mini Fragment Plate System is indicated for the fixation of fractures, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

CONTRAINDICATIONS

- Sensitivity to implant material
- Active or latent infection
- Osteoporosis
- Insufficient quantity or quality of bone/soft tissue
- Conditions which tend to retard healing such as, blood supply limitations, previous infections, etc.
- Insufficient quantity or quality of bone to permit stabilization of the fracture complex and/or fusion of the joints
- Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations unless supplemental fixation or stabilization methods are utilized.

WARNINGS AND PRECAUTIONS

For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitation, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation, stress, excessive activity, or weight bearing or loading bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. Osteoporotic patients are also at risk for loss of fixation and construct failure due to the poor quality of their bone.

Once applied, the implant should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.

Even with anatomic reduction, lack of fracture gap and appropriate construct creation, initial weight bearing restrictions are indicated. In order to prevent loss of correction and premature plate failure, it is recommended that partial weight bearing be instituted for 6-12 weeks followed by advancement to full weight bearing only when radiographs confirm significant callus and bony healing.

WARNINGS AND PRECAUTIONS (CONTINUED)

Instruments shall be inspected for wear or damage prior to usage.

Protect implant appliances against scratching and nicking, which may cause stress concentrations leading to failure. Plate shape should only be altered using the provided bending and cutting instruments. When bending plates, care should be taken to avoid repeated bending at a single site along the plate.

In no case should an implant be sharply bent, notched, gouged, reamed, or scratched.

The OIC Small / Mini Fragment Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of OIC Small / Mini Fragment Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

The system is to be used only in skeletally mature adult patients

ADVERSE EFFECTS

Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion.

Implant migration and/or loosening.

Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material.

Pain, discomfort, or abnormal sensations due to the presence of an implant.

Nerve damage resulting from surgical trauma.

Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing.

MATERIALS

All implant materials for the OIC Small / Mini Fragment Plate System are implant grade Ti6Al4V or Commercially Pure Titanium. These materials are not ferromagnetic, susceptible to aging, nor will steam sterilization have an effect on the materials properties. The instruments are made from stainless steel, aluminum, PEEK, medical grade silicone and phenolic plastic.



SURGICAL TECHNIQUE

Plate and Screw Insertion

1

FRACTURE REDUCTION

Fractures should be reduced using standard reduction techniques. Care should be taken to avoid additional stripping of the periosteum during reduction. Ø1.25mm and Ø1.60mm K-Wires can be utilized for temporary fixation of comminuted fragments.

2

PLATE SELECTION AND ALTERATIONS

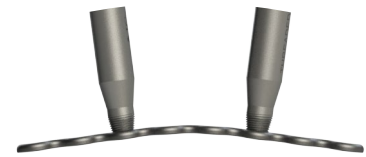
Select the plate shape and length that best fits the fracture pattern. All mini fragment plates are neutral and may be used on either side of the body. The plate should be inserted on reduced bone when able. In some cases, the plate will need to be used as a reduction tool if fracture instability or comminution does not allow for prior reduction. Further alterations to plate length and shape may be completed using the provided plate benders and cutters.

PLATE BENDING (OPTIONAL)

When plate shape needs to be bent to better fit anatomy, use the provided bending instruments (01-MF01, 01-MF03, 01-MF05) to create alterations as needed.

For out-of-plane convex or concave bending, bending bars (01-MF03) and bending pliers (01-MF05) should be utilized. Bending bars feature a threaded end for out-of-plane bending. Ensure bending bars are fully threaded into screw holes in the plate to minimize damage to the screw hole during bending.

Bending pliers may be inserted into any hole within a plate. Ensure bending pliers are fully clamped and centered in screw holes during use to minimize damage to screw holes during bending. Bending pliers should only be inserted through the top of the plate, as indicated by the "TOP OF PLATE" markings.



Note: The bending bars may be threaded into the top of the plate for convex bends or threaded into the bottom of the plate for concave bends.



Caution: To ensure the integrity of threads in screw holes, avoid centering the bend directly over screw holes that are receiving screws.

Surgical Technique

Plate and Screw Insertion

For in-plane bending, the cutting/bending combo pliers (01-MF01) and the bending bars (01-MF03) should be utilized.

The cutting/bending combo pliers feature a recessed slot that works with all mini fragment plates. Plates may be placed with the top surface facing upwards or downwards within slot.

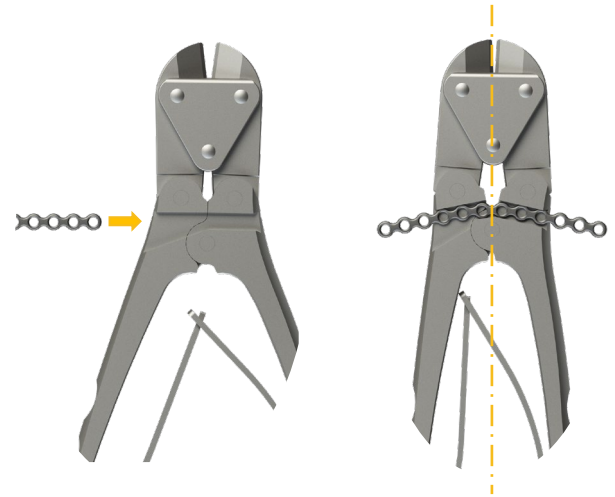
Care should be taken to avoid bending the plate excessively.

Bending bars feature bending slots that fit all mini fragment plates and can be additionally used for in-plane bends.

PLATE CUTTING (OPTIONAL)

When plate shape needs to be cut to length to better fit anatomy, use the provided cutting/bending combo pliers (01-MF01). With one hand holding onto to the desired end of the plate, center the two cutting blades at the intended cut location on the plate and apply pressure until the plate has been trimmed to size. Inspect site of cutting on the plate prior to implantation. Small burrs and edges may be present post-cutting.

Deburring of edges using a deburring tool or knurled instrument under power is recommended prior to implantation.



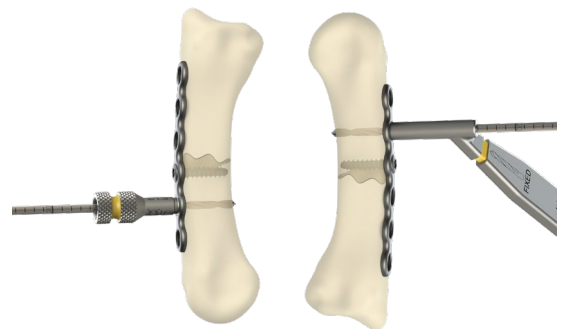
Note: Insert plates through the side of the slot to ensure plates remain within the slot during bending. Position the plate with the intended location for the bend aligned with the center of the pliers.



3

DRILLING

With the plate positioned, screws may be inserted in any order. When inserting a screw into a plate, pre-drilling is required. For fixed angle drilling, securely attach either the thread-in drill guide (LG-0018) or the hand-held drill guide (DG-1818) into the receiving screw hole. The conical shape of the “fixed” end of the hand-held drill guide lines up axially with screw trajectory. The thread-in drill guide may be threaded in by hand or with the respective screwdriver (01-T08085). The screwdriver self retains with each drill guide to improve handling when removing from tray. With the preferred drill guide in place, drill through plate and bone to the far cortex with the respective drill bit (DR18-110). Drill depth can be measured by reading the drill calibration marks off the top of the drill guide.



Surgical Technique

Plate and Screw Insertion

4

MEASURING

Following drilling, the drill and subsequent screw depth may be measured using the drill bit calibration marks, or by using the appropriate depth gauge (01-MF04). Drill bit calibration marks are calibrated to the end of drill guides. Depth gauge nozzles fit snug in screw holes up to bone.

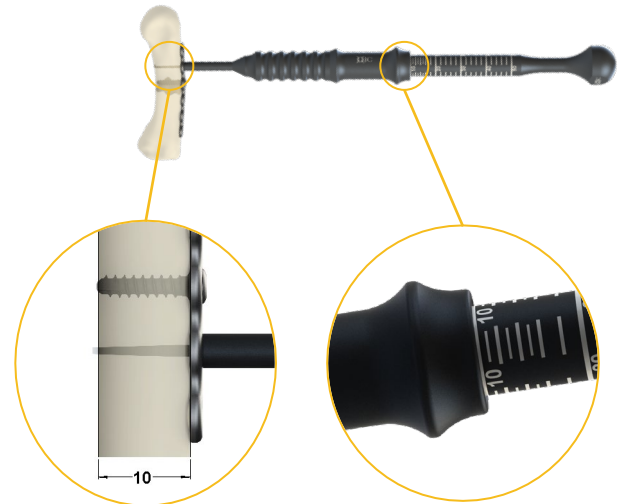
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SCREW INSERTION

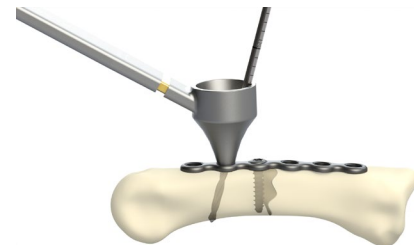
With screw length determined, insert the screw using the respective screwdriver (01-T08085).

SCREW INSERTION (VARIABLE ANGLE)

The same locking screws (LS-25XX,) used for fixed angle fixation can be placed up to 15 degrees in any direction. This is achieved through cross-threading the screws into the plate. Screws can be re-inserted at different angles up to 3 times without compromising the mechanical stability of the locking feature. To place locking screws at a variable angle, place the “variable” side of the hand-held drill guide through the screw hole at the desired angle. Drill using the appropriate drill bit. Color-coded instrumentation allows for easy drill and guide identification. Drill depth and screw size can be measured using the calibration marks on the drill bit or depth gauge. Insert the appropriate length screw using the respective screwdriver.



Note: Depth Gauge is calibrated from the bottom of the plate to the leading tip of the screws. For full bicortical purchase, it may be appropriate to round up or add 1mm to the depth gauge reading.



6

IMPLANT REMOVAL (OPTIONAL)

If the plate requires removal, use the appropriate included drivers (01-T08085) or a standard T8 hexalobular driver to remove all screws from the plate. The plate may be freely removed after all screws have been removed.

Implants

STRAIGHT PLATES

MFS-12083	Neutral 12H x 83mm
MFS-20139	Neutral 20H x 139mm

BROAD PLATES

MFB-12083	Neutral 12H x 83mm
MFB-20139	Neutral 20H x 139mm

T PLATE

MFT-10069	Neutral 10H x 69mm
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Y PLATE

MFY-10076	Neutral 10H x 76mm
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2.5MM LOCKING SCREWS

LS-2508	2.5mm x 8mm
LS-2509	2.5mm x 9mm
LS-2510	2.5mm x 10mm
LS-2511	2.5mm x 11mm
LS-2512	2.5mm x 12mm
LS-2513	2.5mm x 13mm
LS-2514	2.5mm x 14mm
LS-2515	2.5mm x 15mm
LS-2516	2.5mm x 16mm
LS-2518	2.5mm x 18mm
LS-2520	2.5mm x 20mm
LS-2522	2.5mm x 22mm
LS-2524	2.5mm x 24mm
LS-2526	2.5mm x 26mm
LS-2528	2.5mm x 28mm
LS-2530	2.5mm x 30mm
LS-2532	2.5mm x 32mm
LS-2534	2.5mm x 34mm
LS-2536	2.5mm x 36mm
LS-2538	2.5mm x 38mm
LS-2540	2.5mm x 40mm
LS-2545	2.5mm x 45mm
LS-2550	2.5mm x 50mm



2.5MM CORTEX SCREWS

ST-2508	2.5mm x 8mm
ST-2509	2.5mm x 9mm
ST-2510	2.5mm x 10mm
ST-2511	2.5mm x 11mm
ST-2512	2.5mm x 12mm
ST-2513	2.5mm x 13mm
ST-2514	2.5mm x 14mm
ST-2515	2.5mm x 15mm
ST-2516	2.5mm x 16mm
ST-2518	2.5mm x 18mm
ST-2520	2.5mm x 20mm
ST-2522	2.5mm x 22mm
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ST-2526	2.5mm x 26mm
ST-2528	2.5mm x 28mm
ST-2530	2.5mm x 30mm
ST-2532	2.5mm x 32mm
ST-2534	2.5mm x 34mm
ST-2536	2.5mm x 36mm
ST-2538	2.5mm x 38mm
ST-2540	2.5mm x 40mm
ST-2545	2.5mm x 45mm
ST-2550	2.5mm x 50mm



MF-WSHR	2.7mm x 5.0mm Washer
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Disposables

KW125-150 1.25mm K-Wires



KW160-150 1.60mm K-Wires



DR18-110 Ø1.80mm X 110mm Drill Bit



Instruments

01-SF02 Sharp Hook



01-SF03 Lobster Claw Reduction Forceps



01-SF04 Small Pointed Reduction Forceps



01-SF05 Periosteal Elevator



01-SF06 Mini Bennet Retractors



01-SF07 Mini Hohmann Retractors



01-SF08 Screw Countersink



01-MF01 Mini Fragment Cutting/Bending Combo Plier



Instruments

Catalog Information

01-MF02	Mini Fragment Ball Spike Pusher	
01-MF03	Mini Fragment Threaded Bending Bar	
01-MF04	Mini Fragment Depth Gauge	
01-MF05	Mini Fragment Plate Bending Pliers	
01-4006	Small Screwdriver Handle	
DG-1818	Ø1.8mm Hand-Held Drill Guide	
LG-0018	Ø1.8mm Thread-In Drill Guide	
01-T08085	T8 x 85mm Screwdriver	
DG-1825	Ø1.8mm/Ø2.5mm Hand-Held Drill Guide	
01-SF20	Ø1.8mm ID/Ø2.5mm OD Tophat	
DR25-110	Ø2.5mm x 110mm Drill Bit	

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN



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