

MANDIBLE PLATING SYSTEM – 2/2.5mm - SURGICAL TECHNIQUE

INDICATIONS:

Indications for Mini Bone plating would include any fracture that has excellent bony buttressing, for example most simple fractures.

CONTRAINDICATIONS:

Mini Bone plating is contraindicated when there is not good bony buttressing at the fracture site, as is seen in atrophic edentulous mandible fractures, defect fractures, comminuted fractures, and other complex mandibular fractures.

It is also contraindicated in simple fractures with an extreme oblique pattern (sagittal fractures) that are often suitable for compression osteosynthesis using lag screw fixation.

INTENDED USE:

- Mini Bone Plating System 2mm/2.5mm is intended for Oral and Maxillofacial Surgery comprises of:
- Maxillofacial Trauma
- Reconstructive
- Orthognathic surgery for Dentofacial deformity corrections

PLATES FEATURES:

- Made of Pure Titanium Grade II materials
- Color coded for easy identification of profile
- Smoother edges for less soft tissue irritations
- Optimum counter hole sink for ideal screw head projections
- CAD design profile for uniform shape

SCREW FEATURES:

- Made of Titanium Alloy Grade V (Ti6Al4V)
- Concave screw slot in Cross Drive screws for better purchase and driving comfort
- No slippage in final tightening due to ideal slot depth in single slotted
- Specially designed trocar tip screw point for easy insertion without tapping

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SURGICAL TECHNIQUE:

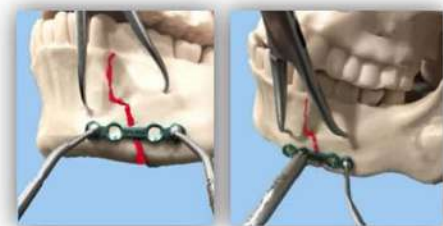


Step 1: Expose fracture site. Prepare plate fixing area and reduce the fracture with Bone Holding Forceps pointed 6". In general, a minimum of two points of fixation should be used to provide stable internal fixation of mandibular symphysis fractures because the mandibular symphysis undergoes twisting during function, two miniplates can prevent such motion from occurring.



Step 2: Plate contouring - Apply the first plate of 2.5mm dia x 4 Holes with bar to the inferior border of the mandible. Contour the plate using Modelling Lever and Bending pliers as per requirement.

Warning: **Repeated bending can damage the plates.**



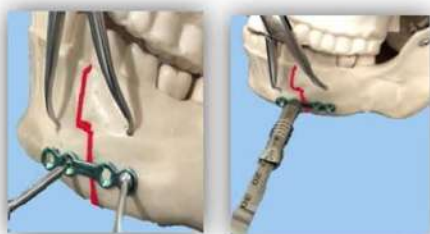
Step 3: Plate positioning - Position the selected plate a few millimeters superior to the inferior border because mini plate fixation is adaptation osteosynthesis and does not compress the fracture, the plate can be placed in a direction other than perpendicular to the fracture line. Hold the reduced fracture with Bone Holding forceps

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Step 4: Hold the plate with the help of Plate Holding Fork and start drilling first screw hole. Use Trocar/Drill Sleeve to mark a point on bone and take 2mm drill bit to drill the first hole through the plate hole next to the fracture. Surgeon shall decide whether to do mono cortical or bi cortical screw fixation.



Step 5: Take a Depth Gauge to verify the drill depth and to make screw length selection. Insert a 2.5 mm x 7mm/8mm length screw for mono cortical fixation or 9mm/10mm length screw for Bi cortical fixation. Do not fully tighten it until the final reduction and plate position are confirmed.



Step 6: Insert second screw- Insert a second screw on the other side of the fracture. Follow same procedures.

Tighten both screws.

Step 7: Additional screw placement- Fill the remaining plate holes with same screws and procedures.

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Step 8 :Application of second plate- Remove the reduction forceps. Now place a second mini plate of 2mmdia. X 4 holes with bar below the apices of the tooth roots. Occasionally, the plate must be positioned higher on the mandible. Great care must be taken when drilling in this area as tooth roots can be just below the cortex and can be damaged even using a 1.5mm x 8mm drill bit with short flute. Fixation procedures shall be followed same as above.

Step 9: Confirmation of reduction-

Confirm adequate reduction is achieved. There must be no gap at the lingual aspect. Such a gap would lead to occlusal disturbance and mandibular widening. MMF is released and the occlusion checked. Because two points of fixation have been applied (two mini plates), it is not essential that the arch bars remain in position.

Fracture fixation of Mandibular is completed.

End of Surgical Technique.

Technique Warning:

This surgical technique is not sufficient for immediate use of the plating system of implants & instrumentation. Training, Instructions and supervision by a surgeon well experienced in handling

This plating system is highly recommended. We do not take responsibility of wrong or mishandling of any implants or instruments and its consequences.

Device Warning:

These devices can break intra-operatively when subjected to excessive forces or outside the recommended surgical technique. While the surgeon must make the final decision on removal of the broken part based on the associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part be removed.

Instruments, screws, and cut plates may have sharp edges or moving joints that may pinch or tear the user's glove or skin.

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Select the correct implant size, shape, and design.

Do not use excessive force during screw insertion. Do not over tighten screws.

Precautions:

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Check instruments for wear or damage before starting surgery.

Combination of medical devices:

Ortho Max has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Device Specific Adverse Events:

Device specific adverse events include but are not limited to:

- Loosening, bending, or breakage of the device
- Non-union, mal-union or delayed union which may lead to breakage of the implant
- Pain, discomfort or abnormal sensation due to the presence of the device
- Infection, nerve and/or tooth root damage and pain
- Soft tissue irritation, laceration or migration of the device through the skin
- Allergic reactions from material incompatibility
- Glove tear or user puncture
- Graft failure
- Restricted or impaired bone growth
- Possible transmission of blood borne pathogens to the user
- Injury of patient
- Soft tissue thermal damage
- Bone necrosis
- Parasthesia
- Loss of tooth

General Adverse Events:

As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:

Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal

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scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hyper reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation

Warnings:

Using an internal fixation system on patients with active or latent infection may cause potential risks which may include construct failure and deterioration of infection. It is at the Surgeon's discretion to evaluate the patient's medical conditions and select a fixation device most appropriate for the individual patient. It is also at the Surgeon's discretion to consider all other necessary treatment methods to effectively manage the infection.

- Confirm the quality of bone at the selected plate position. Using an internal fixation system on patients with insufficient quantity or quality of bone may cause potential risks which may include device loosening and construct failure. It is at the Surgeon's discretion to evaluate the patient's medical conditions and select a fixation device most appropriate for the individual patient.
- These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed. Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.
 - Instruments, screws and cut plates may have sharp edges or moving joints that may pinch or tear user's glove or skin.
 - Take care to remove all fragments that are not fixated during the surgery.

IMPLANTS REMOVAL:

The Mandible Plates should first be removed by following screw removal technique of cortical screws. Take care while removing the screws, first unlock all screws from the plate with respective Screw Driver of single slotted or Cross Drive recess of 2 or 2.5mm then remove the screws completely from the bone. This prevents rotation of the plate when removing the last screw. Ensure that the tip of the screw driver sits fully into the head of the screws. Partial engagement may lead to wear out of screw head or screw driver tip. Don't use high torque while removing the screws.

- **Note: The final decision of removing the implants shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed**

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once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients. **Implant removal should be followed by adequate post-operative management to avoid re-fracture.**

MRI Information:

It is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body

CAUTION:

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuse of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed off properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose off the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

PACKAGING MATERIAL DISPOSAL: The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such a way that keeps out of reach of children and stray animals.

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SINGLE BRAND USAGE: Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

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Product Details:

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Profile Thickness : 1.0 mm

MINI PLATING SYSTEM 2 mm


Titanium Plates - Without Bar



Reference	Size
051.202	2 Holes
051.203	3 Holes
051.204	4 Holes
051.205	5 Holes
051.206	6 Holes
051.208	8 Holes
051.2010	10 Holes
051.2012	12 Holes
051.2016	16 Holes
051.2020	20 Holes
051.2030	30 Holes
051.2050	50 Holes

Material : Titanium Grade II & S.S. 316L


Titanium Plates - With Bar



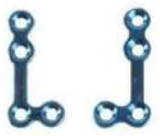
Reference	Size
052.202	2 Holes
052.203	3 Holes
052.204	4 Holes
052.205	5 Holes
052.206	6 Holes
052.208	8 Holes

Material : Titanium Grade II & S.S. 316L


Titanium " L " Shape Plate 90°




Reference	Size
053.205R	Small - Right
053.205L	Small - Left



Reference	Size
053.208R	Big - Right
053.208L	Big - Left




Reference	Size
053.20ER	XB 3+2H - Right
053.20EL	XB 3+2H - Left



Reference	Size
053.20XR	XB 3+2H - Right
053.20XL	XB 3+2H - Left

Material : Titanium Grade II & S.S. 316L


Ortho Max[®]
Mfg. Co. Pvt. Ltd.

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MINI PLATING SYSTEM 2 mm

Profile Thickness : 1.0 mm

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Titanium "L" Shape Plate 120



Reference	Size
054.20SR	Small - Right
054.20SL	Small - Left

Reference	Size
054.20BR	Big - Right
054.20BL	Big - Left

Material : Titanium Grade II & S.S. 316L

Titanium "T" Shape Plates

Material : Titanium Grade II & S.S. 316L



Reference	Size
055.20S	Small

Reference	Size
055.20B	Big

Reference	Size
055.20X	Extra Big

Titanium "Y" Shape Plates

Material : Titanium Grade II & S.S. 316L



Reference	Size
057.20S	Small

Reference	Size
057.20B	Big

Titanium Double "Y" Shape Plates



Material : Titanium Grade II & S.S. 316L

Reference	Size
058.200	6 Holes

Titanium "I" Shape Plates



Material : Titanium Grade II & S.S. 316L

Reference
056.200

Titanium "H" Shape Plates



Material : Titanium Grade II & S.S. 316L

Reference
059.200


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Profile Thickness : 1.0 mm

MINI PLATING SYSTEM 2 mm


Titanium "X" Shape Plates



Material : Titanium Grade II & S.S. 316L

Reference
062.200


Titanium "Z" Shape Plates



Material : Titanium Grade II & S.S. 316L


Reference
063.200

Titanium Orbita Plates - With Bar




Reference	Size
064.204	4 Holes

Material : Titanium Grade II & S.S. 316L




Reference	Size
064.206	6 Holes




Reference	Size
064.208	8 Holes

Titanium Orbita Plates - Without Bar




Reference	Size
065.204	4 Holes


Material : Titanium Grade II & S.S. 316L



Reference	Size
065.206	6 Holes



Reference	Size
065.208	8 Holes



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MINI PLATING SYSTEM 2 mm

Profile Thickness : 1.0 mm

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Titanium Square Shape Plates



Material : Titanium Grade II

Reference	Size
046.2022	2 x 2 Holes

Reference	Size
046.2023	2 x 3 Holes

Titanium 3 D Plates

Material : Titanium Grade II & S.S. 316L



Reference	Size
066.2022	2 x 2 Holes

Reference	Size
066.2023	2 x 3 Holes

Reference	Size
066.2024	2 x 4 Holes

Titanium Grid Plates



Material : Titanium Grade II

Reference
036.200

Titanium Trapezoid Condyle Plates (TCP)



Material : Titanium Grade II

Reference
037.200

Titanium Twisted Plates



Material : Titanium Grade II

Reference	Size
038.20L	5H Left
038.20R	5H Right

Titanium Delta Plates



Material : Titanium Grade II

Reference
039.200

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MINI PLATING SYSTEM 2 mm

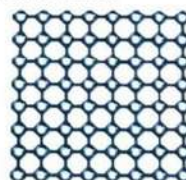
Titanium Chin Plates



Profile Thickness : 1.0 mm
Material : Titanium Grade II

Reference	Size
068.206	6 mm Bar
068.208	8 mm Bar
068.2010	10 mm Bar
068.2012	12 mm Bar

Titanium Wire Mesh



Profile Thickness : 0.6 mm
Material : Titanium Grade II & S.S. 316L

Reference	Size
078.2011	25 x 25 mm
078.2022	50 x 50 mm
078.2024	50 x 100 mm
078.2026	50 x 150 mm
078.2028	50 x 200 mm
078.2044	100 x 100 mm
078.2046	100 x 150 mm

Titanium Screws - *Cross Drive*®



Thd. Dia. : 2 mm
Drill Size : 1.5 mm
Material : Titanium Grade V

Reference	Size
088.205	5 mm
088.206	6 mm
088.207	7 mm
088.208	8 mm
088.209	9 mm
088.2010	10 mm
088.2011	11 mm
088.2012	12 mm
088.2014	14 mm

Titanium Screws - Single Slotted



Thd. Dia. : 2 mm
Drill Size : 1.5 mm
Material : Titanium Grade V & S.S. 316L

Reference	Size
079.205	5 mm
079.206	6 mm
079.207	7 mm
079.208	8 mm
079.209	9 mm
079.2010	10 mm
079.2011	11 mm
079.2012	12 mm
079.2014	14 mm

Titanium Emergency Screws - *Cross Drive*®



Thd. Dia. : 2.3 mm
Core Dia. : 1.8 mm
Material : Titanium Grade V

Reference	Size
089.236	6 mm
089.237	7 mm
089.238	8 mm
089.239	9 mm
089.2310	10 mm
089.2312	12 mm

Titanium Emergency Screws - Single Slotted



Thd. Dia. : 2.3 mm
Core Dia. : 1.8 mm
Material : Titanium Grade V & S.S. 316L

Reference	Size
082.236	6 mm
082.237	7 mm
082.238	8 mm
082.239	9 mm
082.2310	10 mm
082.2312	12 mm

S. S. Drill Bits for Micromotor



Reference	Dia. x Flute x Length
411.150	1.5 mm x 20 mm x 65 mm
411.154L	1.5 mm x 20 mm x 100 mm

S. S. Drill Bits for Micromotor - Short Flute



Reference	Dia. x Flute x Length
411.154	1.5 mm x 4 mm x 65 mm
411.156	1.5 mm x 6 mm x 65 mm
411.158	1.5 mm x 8 mm x 65 mm
411.1510	1.5 mm x 10 mm x 65 mm
411.1512	1.5 mm x 12 mm x 65 mm

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MANDIBLE PLATING SYSTEM 2.5 mm

Profile Thickness : 1.2 mm

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Titanium Bone Plates - Without Bar



Reference	Size
051.252	2 Holes
051.253	3 Holes
051.254	4 Holes
051.255	5 Holes
051.256	6 Holes
051.258	8 Holes
051.2510	10 Holes
051.2512	12 Holes
051.2516	16 Holes
051.2520	20 Holes
051.2530	30 Holes
051.2550	50 Holes

Material : Titanium Grade II & S.S. 316L

Titanium Bone Plates - With Bar



Reference	Size
052.252	2 Holes
052.253	3 Holes
052.254	4 Holes
052.255	5 Holes
052.256	6 Holes
052.258	8 Holes

Material : Titanium Grade II & S.S. 316L

Titanium *Ultra Lock*® Mandible Angle Plates



Profile : 1.8mm x 6mm

Material : Titanium Grade II

* Can be used with Locking or Non Locking Screws

Reference	Size
040.A06	3+3 Holes

Titanium *Ultra Lock*® Mandibular Reconstruction Plates - Primary Straight



Profile : 1.8mm x 6mm

Material : Titanium Grade II

* Can be used with Locking or Non Locking Screws

Reference	Size
040.S04	4 Holes
040.S06	6 Holes
040.S08	8 Holes
040.S10	10 Holes
040.S12	12 Holes
040.S16	16 Holes
040.S20	20 Holes
040.S24	24 Holes

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MANDIBLE PLATING SYSTEM 2.5 mm

Titanium Screws - *Cross Drive*®



Reference	Size
088.256	6 mm
088.257	7 mm
088.258	8 mm
088.259	9 mm
088.2510	10 mm
088.2512	12 mm
088.2514	14 mm
088.2516	16 mm

Thd. Dia. : 2.5 mm
Drill Size : 2.0 mm
Material : Titanium Grade V

Titanium Screws - Single Slotted



Reference	Size
079.256	6 mm
079.257	7 mm
079.258	8 mm
079.259	9 mm
079.2510	10 mm
079.2512	12 mm
079.2514	14 mm
079.2516	16 mm

Thd. Dia. : 2.5 mm
Drill Size : 2.0 mm
Material : Titanium Grade V & S.S. 316 L

Titanium Emergency Screws - *Cross Drive*®



Reference	Size
089.276	6 mm
089.277	7 mm
089.278	8 mm
089.279	9 mm
089.2710	10 mm
089.2712	12 mm

Thd. Dia. : 2.7 mm
Core Dia. : 2.2 mm
Material : Titanium Grade V

Titanium Emergency Screws - Single Slotted



Reference	Size
082.276	6 mm
082.277	7 mm
082.278	8 mm
082.279	9 mm
082.2710	10 mm
082.2712	12 mm

Thd. Dia. : 2.7 mm
Core Dia. : 2.2 mm
Material : Titanium Grade V & S.S. 316L

S. S. Drill Bits for Micromotor



Reference	Dia. x Flute x Length
411.200	2.0 mm x 20 mm x 65 mm
411.204L	2.0 mm x 20 mm x 100 mm

S. S. Drill Bits for Micromotor - Short Flute



Reference	Dia. x Flute x Length
411.206	2.0 mm x 6 mm x 65 mm
411.208	2.0 mm x 8 mm x 65 mm
411.2010	2.0 mm x 10 mm x 65 mm
411.2012	2.0 mm x 12 mm x 65 mm

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All In One Cross Drive® Max Kit®



Implants Contents:	Qty
Titanium Plates 1.5 mm	
With Bar 2H/02, 4H/03	05 Nos
"L"-90° Big Left & Right - 1 each	02 Nos
"T" Shape Small & Big - 1 each	02 Nos
Orbita 4H, 6H with Bar - 2 each	04 Nos
Without Bar 16H	02 Nos
Titanium Plates 2.0 mm	
With Bar 4H/05, 6H/02	07 Nos
"L"-90° Big Left & Right - 1 each	02 Nos
"T" Shape Small & Big - 1 each	02 Nos
Without Bar 16H & 20H - 2 each	04 Nos
Titanium Plates 2.5 mm	
With Bar 4H/04, 6H/02	06 Nos
Without Bar 4H/01, 6H/01, 20H/02	04 Nos
Total	40 Nos
Titanium Screws Cross Drive®	
1.5 mm x 4mm/10, 5mm/10, 6mm/20 x 8mm/10	50 Nos
2.0 mm x 6mm/20, 8mm/30, 10mm/10	60 Nos
2.5 mm x 6mm, 8mm, 10mm, 12mm - 10 each	40 Nos
Total	150 Nos
Titanium Emergency Screws Cross Drive®	
1.8mm/10, 2.3mm/10, 2.7mm/10	30 Nos

Instruments Contents:	Qty
Cross Drive® Screw Driver	
Quick Coupling Handle	01 No
Cross Drive® Screw Driver Shaft	
1.5 mm, 2 mm, 2.5 mm - 1 each	03 Nos
S.S. Drill Bits For Micromotar	
1mm, 1.5mm, 2mm-2 each	06 Nos
Plier	01 No
Modelling Lever	01 No
Screw/Plate Holding Forceps	01 No
Mini Plate Cutter - Vertical	01 No
All In One Container with 3 Trays	01 No

Reference
043.001

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Instruments Certified : 



MFG. UNIT & REGD. OFFICE

C-1-B/886/4, G.I.D.C. ESTATE

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