SUBCONDYLER MANDIBLE PLATING SYSTEM – 2mm

- SURGICAL TECHNIQUE

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FEATURES:

- The Ortho Max Subcondylar Plates are designed to adapt on the curved topography and limited lateral bone surface in the condylar neck region of the mandible.
- Ergonomically designed and developed in consultation with surgeons,
- The Subcondylar Plates provide stable fixation for the mandibular subcondylar region:
- Multiple designs allow surgeon to select various shapes addressing various types of fractures
- Plate shape and screw hole positioning help prevent inadvertent placement of screws over mandibular foramen and into the nerve
- Compatible with Basic Plating Set of Ortho Max.
- 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

INDICATIONS:

The Ortho Max Mandible Subcondylar Plates are intended for the trauma of the mandible, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.

CONTRAINDICATIONS:

- Acute or Chronic, local or systemic infections
- Allergy to implants materials
- Insufficient bone quality to secure plates and screws

INTENDED USE:

- The Subcondyler Plates 2mm are intended for Mandible subcondyle region surgery comprises of:

- High subcondylar fracture

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- Low subcondylar fracture
- Fracture at condylar basis

PLATES OPTIONS:

There are several options of plates that can be used with condyler fractures:

1. Delta Plate for high condyler fractures
2. Trapezoid Condyler Plate (TCP) for low condyler fractures
3. Grid Plate for condyler base fractures

Note: At the time of surgery, the decision to use any of above options is based on fracture morphology, the amount of bone available to hold plates and screws and on surgeon preference.

Ideally, plates should be used in a triangular fashion with each side of the fracture line, a minimum of two screws have to be inserted

Approach:

For this procedure the following approaches may be used:

- Facelift (rhytidectomy) approach)
- Submandibular approach
- Preauricular approach
- Retromandibular approaches

In general, a minimum of three points of fixation should be used to provide stable internal fixation of Subcondyler region fractures because the subcondyler region undergoes twisting during function, three point plates can prevent such motion from occurring.

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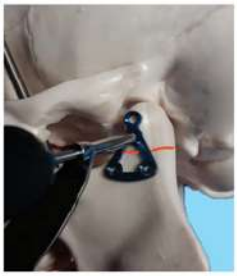
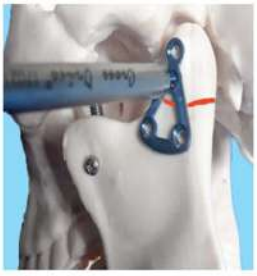
SURGICAL TECHNIQUE:

Step 1: Plate contouring - Apply the **Delta or TCP** plate of 2mm dia to the centered over the long axis of the condylar process.
If required, contour the plate using Modelling Lever and Bending pliers.

Note: In the condylar neck and subcondylar region, the plate does not require much bending.
Warning: **Repeated bending can damage the plate and holes**





Step 2 : Drill a hole in the mid axis of the condylar fragment through the plate hole closest to the fracture line using the 1.5 mm diameter drill. Apply the plate and insert the first screw but do not completely tighten it. The aim of not tightening the screw completely is to be able to apply traction to the fragments later in the procedure.
Note: The use of the drill sleeve is recommended to avoid injuries in the soft tissues.

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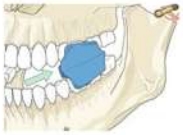
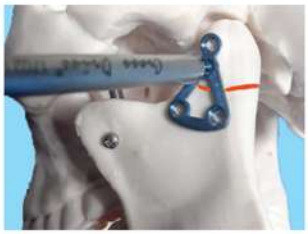
Step 3: Reduction of the fracture is done under direct vision by aligning the posterior border of the ramus. Pull the mandible inferior and anterior in order to restore the posterior height of the ramus and achieve reduction. The lower end of the plate prevents the medial displacement of the condylar fragment during reduction. The plate acts as stop during the reduction and prevents medial displacement of the condylar fragment.
In order to align the posterior border, pull traction on most distal hole of the plate with a clamp.



Note : To keep the jaw open and aid fracture reduction, a bite block is placed in the molar region after placement of the first screw in the anterior hole. This results in posterior vertical distraction and rotation of the mandible.



Step 4: Place the lower inferior screw of the plate while the patient is in occlusion.
Completely tighten both screws at this time.Insert other superior screw and then lower inferior screw holes and fully tighten them.

End of Surgical Technique.

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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 intraoperatively 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.

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 bloodborne 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, dam-age to soft tissues incl. swelling, abnormal 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 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 refracture.**

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.

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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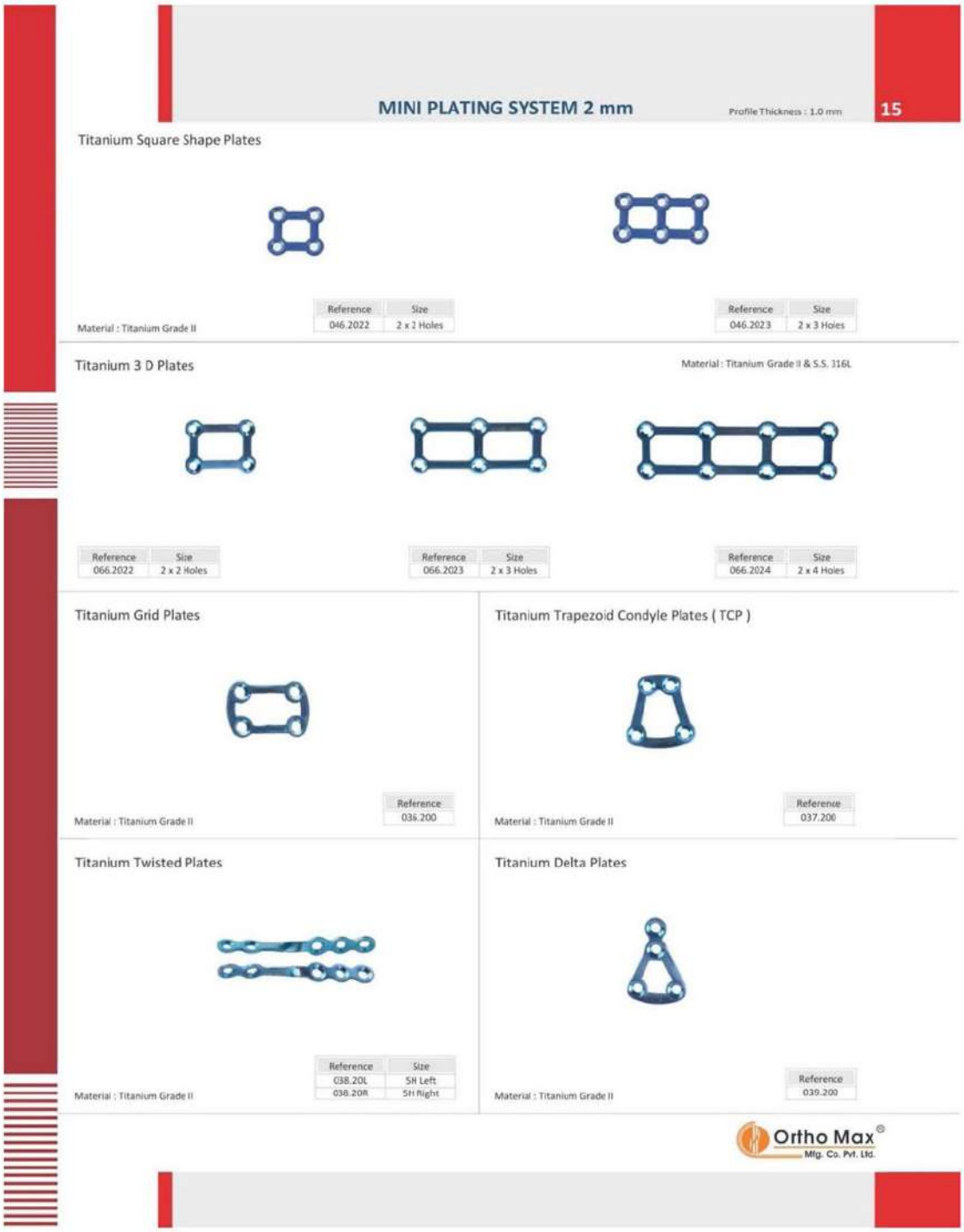
Product Details:



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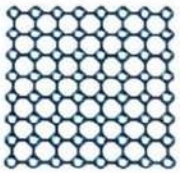
MINI PLATING SYSTEM 2 mm

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

Ortho Max®
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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

Ortho Max® Mfg. Co. Pvt. Ltd.

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Instruments Certified : CE

Ortho Max
Mfg. Co. Pvt. Ltd.

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