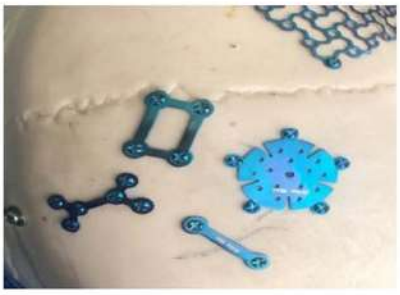
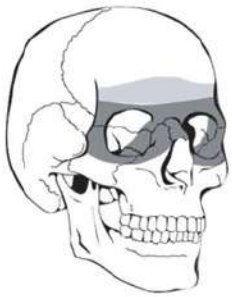
NEUROFIX Bone Plating for Cranial- 1.2mm System
Surgical Technique





Intended Use:

Ortho Max NeuroFix plate and screw system is intended for use in trauma repair and reconstruction of the cranial and/or bone fixation.

Indications:

Craniotomies, cranial trauma repair and reconstruction.

Contraindications:

Use in areas with active or latent infection or insufficient quantity or quality of bone.

Anatomical Region: Cranial and frontal region

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

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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

- **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.

Surgical Technique:

Step 1:

Expose and reduce fracture

After completing the preoperative plan, expose the fracture or osteotomy site. In trauma reduce the fracture as required

Step 2:

Select and prepare the implant

Select the appropriate plate from variety of plate and mesh options available in NeuroFix System for the nature of the fracture. Ensure that the plates counter sink on topside is facing out. Cut to length, if necessary.

Precautions:*In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.

*Take care to protect soft tissue from trimmed plate edges.

Step 3:

Contour the plate

Contour the plate to fit to the patient anatomy using the bending pliers. Ensure the plate is passively adapted to the bone.

Precautions: If contouring is necessary, the surgeon should avoid bending the device at a screw hole. Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage.

Step 4:

Position the plate over the fracture or osteotomy site

Step 5:

Drill the hole

Drill the first hole close to the fracture or osteotomy site with 0.8mm Drill with short flute of screw length.

Precautions:

- Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.
- Drill speed rate should never exceed 1,800rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
  - thermal necrosis of the bone,
  - soft tissue burns,
  - An oversized hole, which can lead to reduced pull-out force, increased ease of the screws stripping in bone, suboptimal fixation, and/or the need for emergency screws.
- Always irrigate during drilling to avoid thermal damage to the bone and ensure drill bit is concentric to plate hole.
- Avoid damaging the plate threads with the drill.
- Avoid drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.

Step 6:

Screw insertion

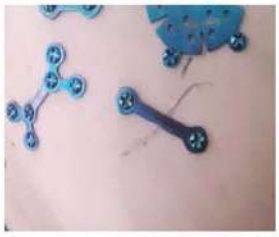
To engage the screw on the Driver's shaft, align the shaft over the cross head by fully pulling back the shaft sleeve and then pushing forward until fully seat it into the screw. Check the grip and rotation of the screw after lifting from tray.

Insert the first screw close to the fracture or osteotomy site, and tighten until secure firmly. Shaft sleeve has to be pulled back for final tightening the remaining last threads of the screw.
Insert the second screw on the opposite side of the fracture or osteotomy site, and then all remaining screws following the outlined procedure.
If the screw is inserted with angulation, verify that the screw is safely retained in the plate hole and that the construct profile is not significantly increased.

Precautions:

- Confirm screw length prior to implantation.
- In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.
- Tighten screws in a controlled manner.
- Applying too much torque to the screws may cause screw/ plate deformation or bone stripping.
  If bone becomes stripped, remove the screw from the bone and replace with an emergency screw

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



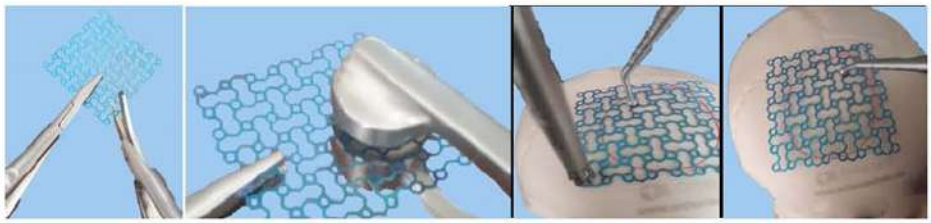
- End of surgical technique

SURGICAL TECHNIQUE FOR MESH PLATES:

1. **Selection of Implants**:

Select the appropriate shape, design, size and thickness of Mesh (Ezy or Regular Mesh – 0.4mm and 0.6mm profile – Flat or pre-contoured) that best suits the bony anatomy and treatment objective.

2. **Cut/Contour and Adapt Mesh plate to the bone:**

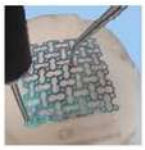


If required, cut and contour the plate to fit to the patient anatomy using the Mesh Cutter and the bending pliers or mesh bender respectively. Ensure that the plate is passively adapted to the bone.

Precautions:

- Confirm that plate positioning allows for adequate clearance of nerves and any other critical structures.
- If contouring is necessary, the surgeon should avoid bending the device at a screw hole.
- Avoid sharp bends, repetitive and reverse bending as it increases the risk of implant breakage.
- Avoid contouring of the implant in situ that may lead to implant malposition and/or posterior canti-lever effect.
- Take care to protect soft tissue from trimmed edges.

3. Drill the hole



Drill the hole with the appropriate diameter drill bit.

Precautions:

- Confirm that drill bit length and diameter correspond to selected screw length prior to drilling.
- Drill speed rate should never exceed 1,800rpm, particularly in dense, hard bone. Higher drill speed rates can result in:
- thermal necrosis of the bone,
- soft tissue burns,
- Always irrigate during drilling to avoid thermal damage to the bone and ensure drill bit is concentric to plate hole
- Avoid drilling over nerve or tooth roots.
- Take care while drilling as to not damage, entrap, or tear a patient's soft tissue or damage critical structures. Be sure to keep drill clear of loose surgical materials.

4. **Fix the Mesh plate to the bone**

Stabilize the implant with screws inserted through selected screw holes in the plate. Insert 1.2 mm screws of appropriate length to secure the plate to the bone. If the screw is inserted with angulation, verify that the screw is safely retained in the plate hole and that the construct profile is not significantly increased.

Precautions:

- Confirm screw length prior to implantation.
- Tighten screws in a controlled manner. Applying too much torque to the screws may cause screw/ plate deformation or bone stripping. If bone becomes stripped, remove the screw from the bone and replace with an emergency screw of 1.5mm dia.
- In order to determine the appropriate amount of screws needed to achieve stable construct fixation, the surgeon should consider the fracture size and shape.

End of Surgical Technique

- **Warnings, Precautions, General Adverse Events:**

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 physician'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 physician'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 physician'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.
- While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate post-operative management to avoid re-fracture.

Precautions:

- Confirm functionality of instruments and check for wear during reprocessing. Replace worn or damaged instruments prior to use.
- It is recommended to only use the instruments identified for use within the NeuroFix or Upper Face system of Ortho Max based on the surgical techniques recommended for implants.
- Handle devices with care and dispose worn bone cutting instruments in a sharps container.
- Always irrigate and apply suction for removal of debris potentially generated during implantation or removal.

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, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage 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 hypersensitivity 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, resulting in reoperation.

Device-specific Adverse Events

Device-specific adverse events include but are not limited to:

- Malunion / non-union that may be associated with:
  - Implant inappropriately dimensioned for the intended use
  - Hole deformation due to plate bending
  - Construct failure due to inadequate strength design
  - Construct strength too weak for post-operative loading forces

- Plate/mesh hole diameter too large or screw head too small
- Wrong implant material/design
- Misleading/incorrect label
- Information provided to the end-user (i.e. IFU)is insufficient, incorrect or imprecise
- Insufficient screw holes left after plate has been cut
- Reverse and repeated bending applied

• Adverse Tissue Reaction that may be associated with:

- Instruments debris/particle created during cutting
- Instruments debris/particle created during implantation and/or removal
- Incorrect label i.e. wrong data provided on the LMD i.e. wrong text, missing symbols, wrong expiry date

• Damage to vital organs / surrounding structures that may be associated with:

- Premature plate/mesh failure
- Plate/mesh does not offer enough options for screw placement
- Plate/mesh too thick for anatomical area
- Fixation holes do not allow for appropriate fixation
- Insufficient mesh structure
- Screw placement into nerve, tooth buds/roots and or any other critical structures
- Screw core diameter is too small leading to screw breakage post-operatively
- Screw deforms or breaks during insertion with generation of fragments that the surgeon is unaware of or unable to retrieve, potentially resulting in fragment migration
- Screw recess strips due to blade cam-out
- Burrs/sharped geson edge of plate
- Plate/mesh inadequately contoured resulting in adequate reduction
- Screw breaks during insertion and fragments are not retrieved
- Screw breakage post-operatively
- Blade cams-out of screw recess
- Screw passes completely through plate
- Generation of particle debris during surgical procedure
- Screw strips bone post-operatively
- Screw not safely retained resulting in loss of screw intra-operatively
- Screw or plate migrates or deforms post-operatively
- Plate hole does not hold screw head
- Implant loses functionality post-operatively
- Improper use of implant resulting in treatment failure
- Wrong plate selection
- Incorrect plate/screw position resulting in irreversible damage
- Inappropriate use of screws or drill bits

- Overheating of drill bit causing thermal necrosis of bone
• Injury to user that may be associated with:
- Sharp edges caused during cutting of plates punctures surgical glove/hand
• Loosening that may be associated with:
- Insufficient implant fixation
- Screw breakage post-operatively
- Inappropriate screw used
• Peripheral Nerve that may be associated with:
- Screws inserted into nerve, tooth buds/roots and or any other critical structures
• Soft Tissue Damage that may be associated with:
- Premature plate/mesh failure
- Screw breakage post-operatively
- Burrs/sharp edges one age of plate
- Implant loses its function post-operatively
• Systemic Infection that may be associated with:
- Incomplete/incorrect processing leading to implantation of a non-sterile product
- Sterile barrier compromised leading to implantation of a non-sterile product
- Implantation of non-sterile product
- Implantation of non-sterile unclean product due to incorrect label
- Reuse of single use implant

IMPLANTS REMOVAL:

The NeuroFix Plates or Mesh 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 1.2mm 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 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.

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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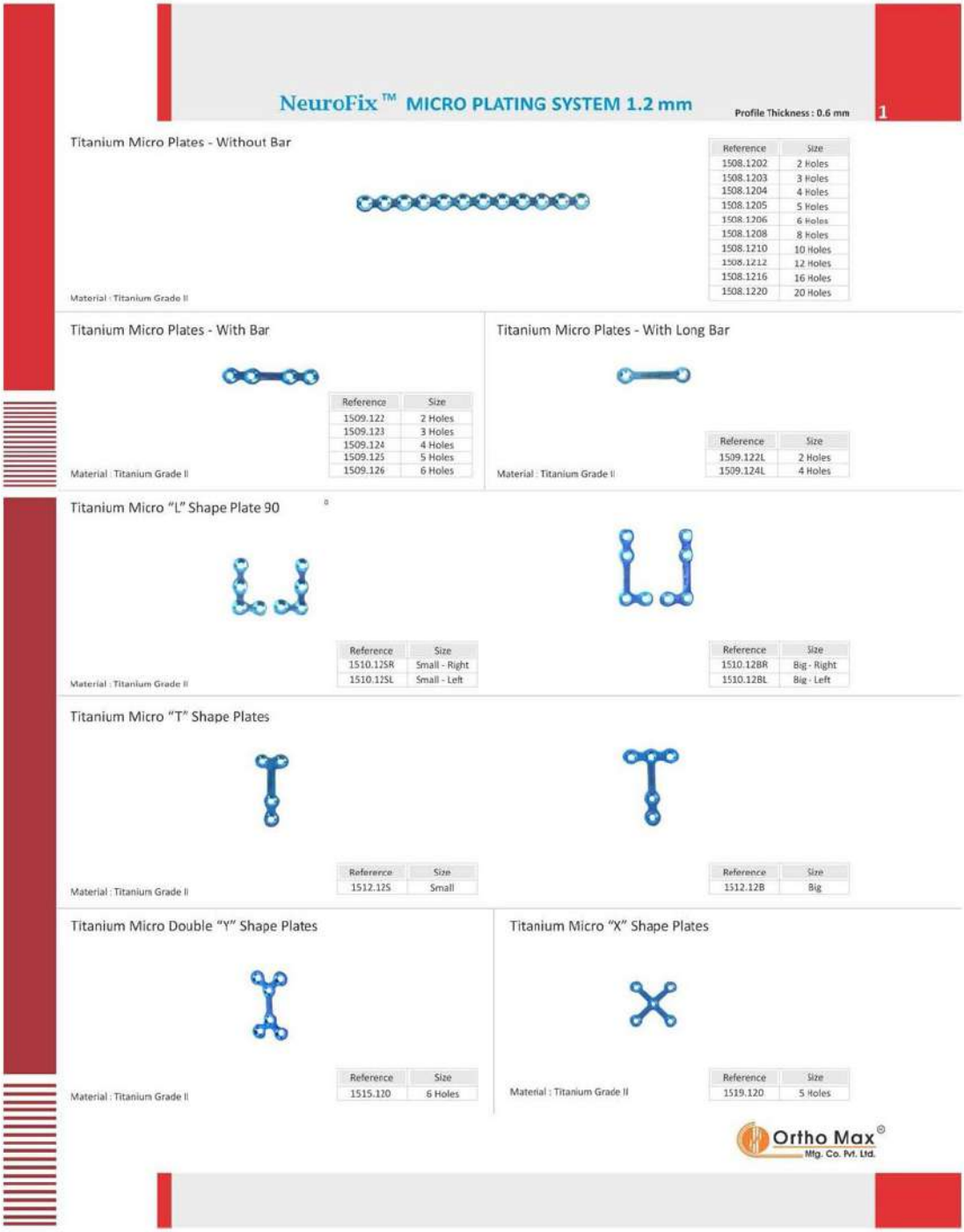
Product Details:

1.2mm system all Implants and instruments set



2 Profile Thickness : 0.6 mm

NeuroFix™ MICRO PLATING SYSTEM 1.2 mm

Titanium Micro "Y" Shape Plates

Reference	Size
1514.12S	Small

Reference	Size
1514.12B	Big

Material : Titanium Grade II

Titanium Micro Orbita Plates - With Bar

Reference	Size
1521.124	4 Holes
1521.126	6 Holes
1521.128	8 Holes

Material : Titanium Grade II

Titanium Micro Orbita Plates - Without Bar

Reference	Size
1522.124	4 Holes
1522.126	6 Holes
1522.128	8 Holes

Material : Titanium Grade II

Titanium Micro Square Shape Plates

Reference	Size
1525.1222	2 x 2 Holes

Reference	Size
1525.1223	2 x 3 Holes

Material : Titanium Grade II

Titanium Micro 3 D Plates

Reference	Size
1527.1222	2 x 2 Holes

Reference	Size
1527.1223	2 x 3 Holes

Material : Titanium Grade II

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Mfg. Co. Pvt. Ltd.

NEUROFIX Bone Plating for Cranial- 1.2mm System
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Titanium Micro Mastoid Plates


Reference	Size
1528.1SR	Small - Right
1528.1SL	Small - Left


Reference	Size
1528.1BR	Big - Right
1528.1BL	Big - Left

Material : Titanium Grade II

Titanium Micro Burr Holes Cover Plates

Reference	Size
1526.120	12 mm

Material : Titanium Grade II

Titanium Ezy Mesh Plates

Reference	Size
44.411	25 x 25 mm
44.422	50 x 50 mm
44.424	50 x 100 mm
44.426	50 x 150 mm
44.444	100 x 100 mm
44.446	100 x 150 mm
44.466	150 x 150 mm

Profile Thickness : 0.4 mm
Material : Titanium Grade II

NEUROFIX Bone Plating for Cranial- 1.2mm System
Surgical Technique

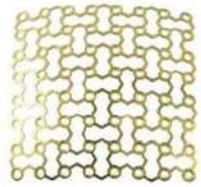
NeuroFix ™ MICRO PLATING SYSTEM 1.2 mm

Titanium Ezy Mesh Plates

Profile Thickness : 0.6 mm
Material : Titanium Grade II

Reference	Size
44.611	25 x 25 mm
44.622	50 x 50 mm
44.624	50 x 100 mm
44.626	50 x 150 mm
44.644	100 x 100 mm
44.646	100 x 150 mm
44.666	150 x 150 mm

Titanium Ezy Mesh Plates - Pre Contoured



Profile Thickness : 0.6 mm
Material : Titanium Grade II

Reference	Size
45.622	50 x 50 mm
45.644	100 x 100 mm

Titanium Screws - *Cross Drive*®

Thd. Dia. : 1.2 mm
Drill Size : 0.8 mm
Material : Titanium Grade V

Reference	Size
088.124	4 mm
088.125	5 mm
088.126	6 mm

Titanium Screws - *Cross Drive*® (For Emergency)

Thd. Dia. : 1.5 mm
Drill Size : 1.0 mm
Material : Titanium Grade V

Reference	Size
088.154	4 mm
088.155	5 mm
088.156	6 mm

S. S. Drill Bits for Micromotor - Short Flute

Reference	Dia. x Flute x Length
411.083	0.8 mm x 3 mm x 65 mm
411.084	0.8 mm x 4 mm x 65 mm
411.085	0.8 mm x 5 mm x 65 mm
411.086	0.8 mm x 6 mm x 65 mm

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All In One NeuroFix™ KIT

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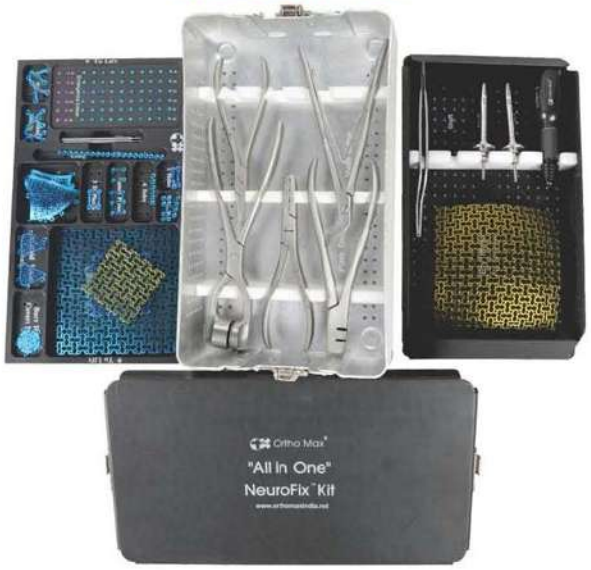

Implants Contents:	Qty.
Titanium Micro Plates 1.2 mm	
4H, 6H, 20H Without Bar - 1 each	03 Nos
2H with Long Bar	02 Nos
2H with Bar	01 No
4H with Bar	02 Nos
Y Shape Small, Big - 1 each	02 Nos
X Shape, Double Y Shape - 1 each	02 Nos
Square Shape 2x2H, 2x3H - 1 each	02 Nos
3D Plate 2x2H	01No
Burr Hole Cover Plate	01 Nos
Mastoid Plates Small Left & Right - 1 each	02 Nos
Mastoid Plates Big Left & Right - 1 each	02 Nos
Total	**20 Nos**
Titanium Ezy Mesh Plates	
0.4 mm - 50 x 50 mm	01 No
0.4 mm - 100 x 100 mm	01 No
0.6 mm - 50 x 50 mm	01 No
0.6 mm Pre Contoured - 100 x 100 mm	01 No
Titanium Screws *Cross Drive*® - 1.2mm x 4mm, 5mm, 6mm - 20 each	**60 Nos**
Titanium Screws *Cross Drive*® - 1.5mm (For Emergency) x 4mm, 5mm, 6mm - 4 each	**12 Nos**

Instruments Contents:	Qty
Cross Drive® Screw Driver Quick Coupling Handle	01 No
Cross Drive® Screw Driver Shaft 1.2 mm	02 Nos
S.S. Drill Bits For Micromotor - Short Flute 0.8 mm x 4 mm, 5 mm, 6 mm - 1 each	03 Nos
Plier	01 No
Modelling Lever	01 No
Screw/Plate Holding Forceps	01 No
Mini Plate Cutter - Vertical	01 No
Mesh Cutter	01 No
Mesh Bender	01 No
All In One NeuroFix™ Container	01 No

Reference
043.002

Ortho Max®
Mfg. Co. Pvt. Ltd.

Instruments Certified by Self Declaration CE :

MFG. UNIT & REGD. OFFICE
C-1-B/886/4, G.I.D.C. ESTATE
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