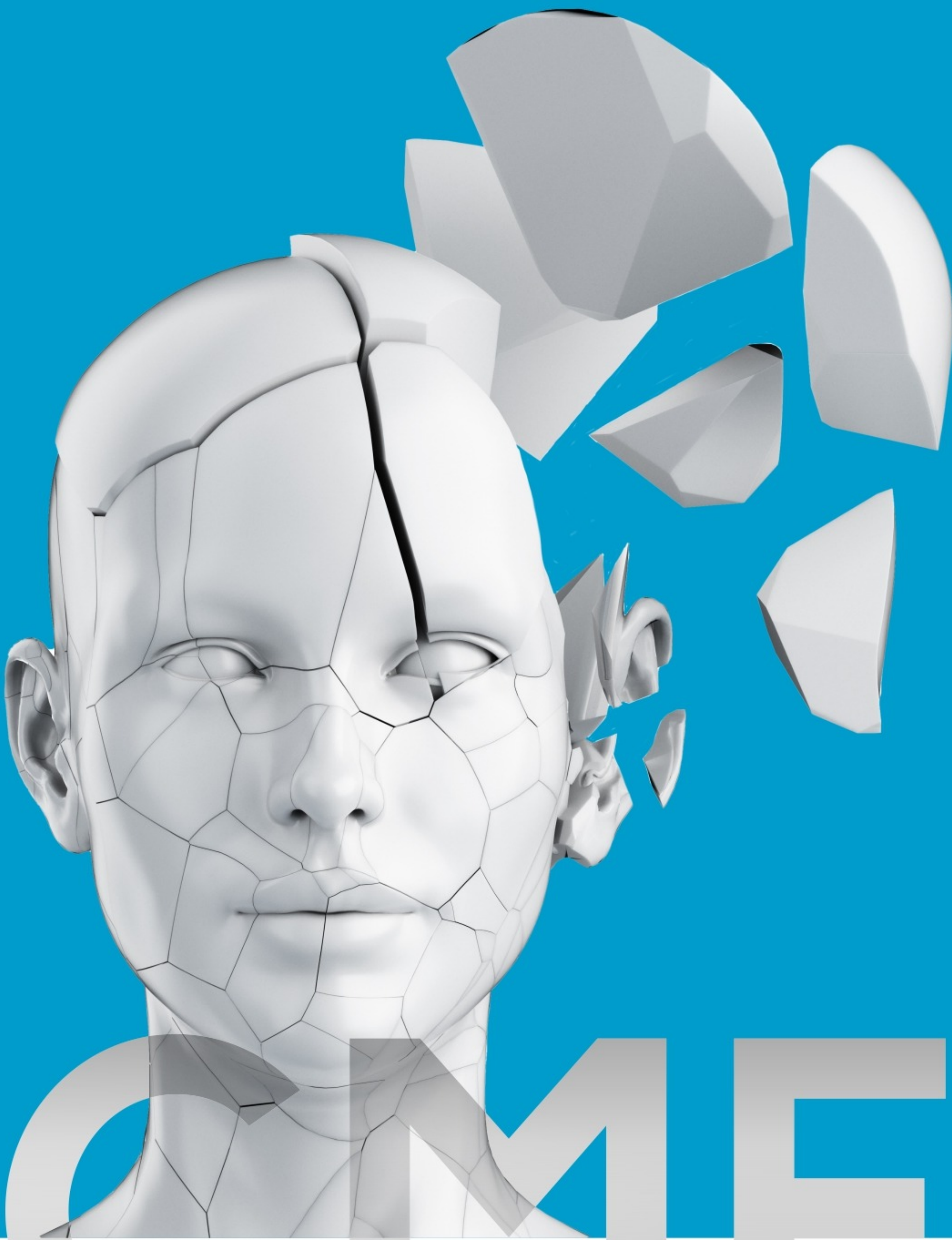


ENDURING
30+
YEARS' LEGACY



CRANIOFACIAL

PRODUCT CATALOGUE

**SURGERY
IMPLANTS**



QMAX[®]
Enduring Care

PREFACE

QMAX is new only by name not by legacy which is fostered with deep passion and commitment backed by 30+ years' experience of its promoters.

We take great pleasure to present the first edition of our products catalogue for Cranio-Maxillofacial (CMF) & Plastic surgery Implants. This edition brings and demonstrates most comprehensive range of Implants required in CMF & Plastic surgery. The promoters have been striving hard since 1993 to achieve excellence in manufacturing quality products at affordable prices for Orthopaedics, Cranio-Maxillofacial, Neuro & Plastic Surgery fostering the spirit of "Make In India" to serve globally.

All our Implants are approved by Indian FDA (CDSCO) under MD-9 License and manufactured under strict compliance of ISO 13485 standards which reflects our commitment and dedication towards the word "QUALITY & SAFETY".

The internationally acclaimed use of raw materials, high tech machining- special polish treatment- cleaning & packaging in most hygienic condition enriches our products to utmost "PERFECTION". We keep proper check and measure every little detail count in making every product fit for all critical surgical procedure. We aim at making our products most vital part of surgery because we believe that the quality of the products helps to elevate all surgical procedures to a whole new standard. We thank all our users and channel partners for their valuable feedback and suggestions for the continual improvement to achieve the highest parameters of product quality & safety.

All our products can be easily bought by contacting our nearest dealers or by simply sending your purchase enquiry to: **contact@qmaxindia.in** or Whatsapp: **+91 9429408861**

Please do visit our website to know more about us and products: **www.qmaxindia.in**



First Edition : **November 2025**

2025



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COLOR CODING

Plate Profile Thickness	Color
0.8 mm	Pink
1.0 mm	Blue
1.2 mm	Green
1.8 mm	Golden

Ezy Mesh Profile Thickness	Color
0.4 mm	Turquoise Blue
0.6 mm	Golden

Screw Dia.	Color
1.5 mm	Pink
2.0 mm	Blue
2.5 mm	Green
Emergency	Golden

N.B. : All the images shown in this catalogue are for illustration only. Not to scale.



CDSCO Approved



ISO Certified

Titanium Plates

Without Bar



Ref.	Size	Ref.	Size
101.T1502	2 Holes	101.T1510	10 Holes
101.T1503	3 Holes	101.T1512	12 Holes
101.T1504	4 Holes	101.T1516	16 Holes
101.T1505	5 Holes	101.T1520	20 Holes
101.T1506	6 Holes	101.T1530	30 Holes
101.T1508	8 Holes	101.T1550	50 Holes

Titanium Plates

With Bar



Ref.	Size
102.T1502	2 Holes
102.T1503	3 Holes
102.T1504	4 Holes
102.T1505	5 Holes
102.T1506	6 Holes
102.T1508	8 Holes

Titanium Plates

With Long Bar



Ref.	Size
117.T152L	2 Holes
117.T154L	4 Holes

Titanium "L" Shape Plates 90°



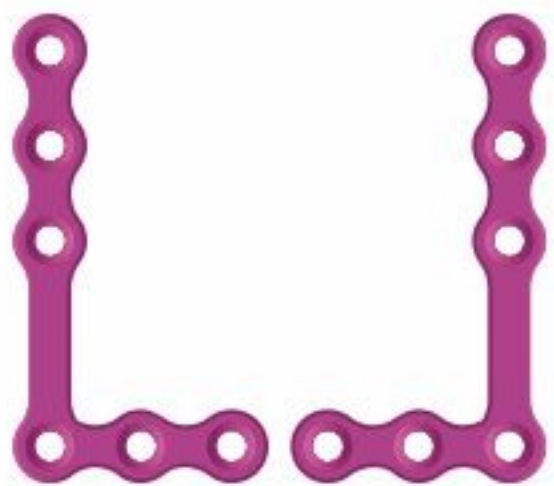
Ref.	Size
103.T155L	Small Left
103.T155R	Small Right

Ref.	Size
103.T15BL	Big Left
103.T15BR	Big Right

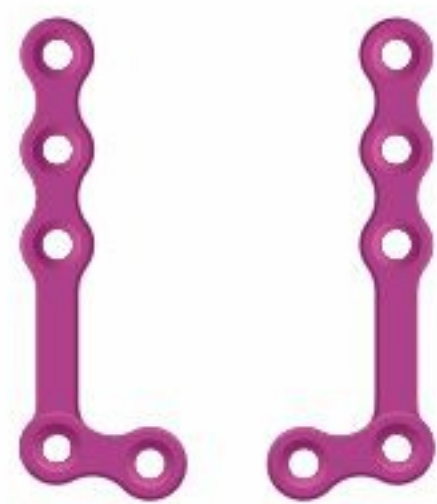


Ref.	Size
103.T15ER	XB Right 3+2
103.T15EL	XB Left 3+2

Ref.	Size
103.T15XL	XB 3+3 H Left
103.T15XR	XB 3+3 H Right



Titanium "L" Shape Plates 100°



Ref.	Size
118.T15EL	XB 3+2 - Left
118.T15ER	XB 3+2 - Right

Titanium "L" Shape Plates 120°



Ref.	Size
104.T15SL	Small - Left
104.T15SR	Small - Right

Titanium "T" Shape Plates

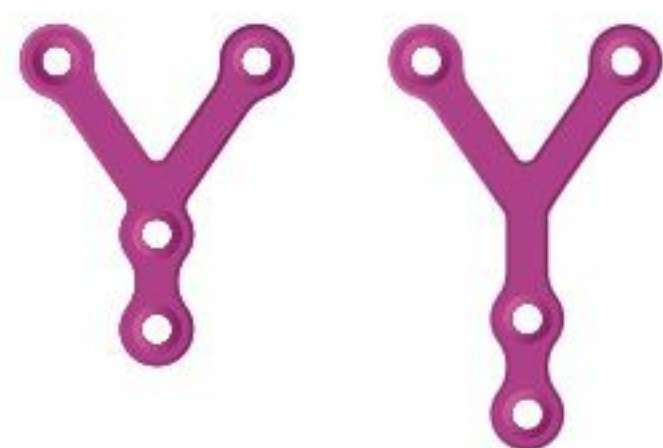


Ref.	Size
105.T20S	Small
105.T20B	Big
105.T20X	Extra Big



Ref.	Size
104.T15BL	Big - Left
104.T15BR	Big - Right

Titanium "Y" Shape Plates



Ref.	Size
106.T15S	Small
106.T15B	Big

Titanium Double "Y" Shape Plates



Ref.
119.T15

Titanium "I" Shape Plates



Ref.
120.T15

Titanium "H" Shape Plates



Ref.
163.T15

Titanium "X" Shape Plates



Ref.
121.T15

Titanium "Z" Shape Plates



Ref.
122.T15

Titanium Orbita Plates
With Bar



Ref.	Size
107.T1504	4 Holes



Ref.	Size
107.T1506	6 Holes



Ref.	Size
107.T1508	8 Holes

Titanium Orbita Plates
Without Bar



Ref.	Size
108.T1504	4 Holes



Ref.	Size
108.T1506	6 Holes



Ref.	Size
108.T1508	8 Holes

UPPER FACE PLATING SYSTEM 1.5mm

Titanium Orbital Floor Plates

Profile Thickness : 0.3mm



Ref.	Size
162.T01	Small



Ref.	Size
162.T02	Medium



Ref.	Size
162.T03	Big

Titanium Square Shape Plates



Ref.	Size
123.T1522	2+2 Holes
123.T1523	2+3 Holes
123.T1524	2+4 Holes

Profile Thickness : 0.8 mm

Titanium 3D Plates



Ref.	Size
109.T1522	2+2 Holes
109.T1523	2+3 Holes
109.T1524	2+4 Holes

Profile Thickness : 0.8 mm

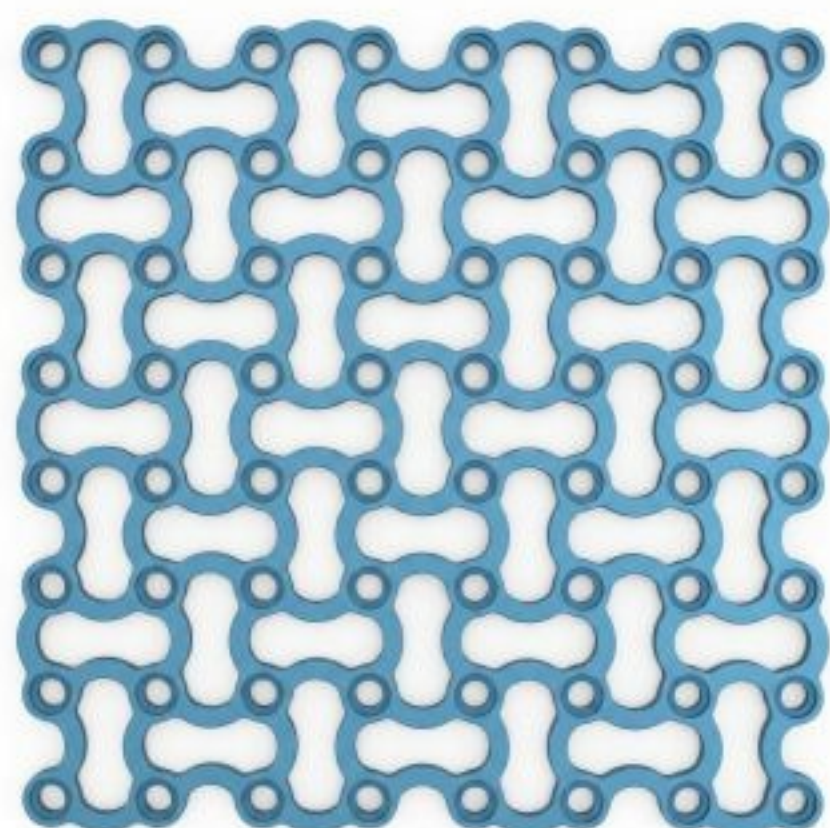
Titanium Micro Burr Holes Cover Plates

Profile Thickness : 0.6mm



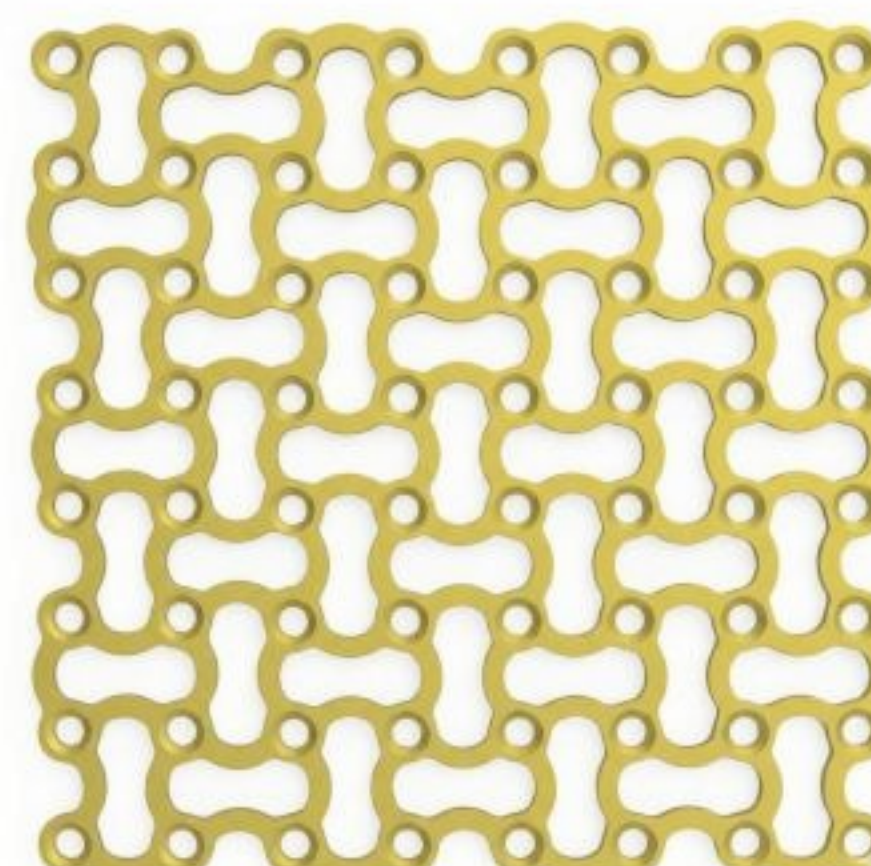
Ref.
108.T1508

Titanium Ezy Mesh Plates



Ref.	Size
126.T411	25 x 25mm
126.T422	50 x 50mm
126.T424	50 x 100mm
126.T426	50 x 150mm
126.T444	100 x 100mm
126.T446	100 x 150mm
126.T466	150 x 150mm

Profile Thickness : 0.4mm



Ref.	Size
126.T611	25 x 25mm
126.T622	50 x 50mm
126.T624	50 x 100mm
126.T626	50 x 150mm
126.T644	100 x 100mm
126.T646	100 x 150mm
126.T666	150 x 150mm

Profile Thickness : 0.6mm

Titanium Ezy Mesh Plates - Pre Contoured



Profile Thickness : 0.6mm

Ref.	Size
127.T622	50 x 50mm
127.T644	100 x 100mm
127.T666	150 x 150mm

Titanium Screw QuikDrive®

Thd. Dia.: 1.5mm
Drill Size : 1.0mm

Ref.	Size
137.T1503	3mm
137.T1504	4mm
137.T1505	5mm
137.T1506	6mm
137.T1507	7mm
137.T1508	8mm
137.T1509	9mm
137.T1510	10mm
137.T1512	12mm

Titanium Screw - Single Slotted

Thd. Dia.: 1.5mm
Drill Size : 1.0mm

Ref.	Size
110.T1504	4mm
110.T1505	5mm
110.T1506	6mm
110.T1507	7mm
110.T1508	8mm
110.T1509	9mm
110.T1510	10mm
110.T1512	12mm

Titanium Emergency Screw QuikDrive®



Thd. Dia.: 1.8mm

Ref.	Size
139.T1806	6mm
139.T1807	7mm
139.T1808	8mm
139.T1809	9mm
139.T1810	10mm

Titanium Emergency Screw - Single Slotted

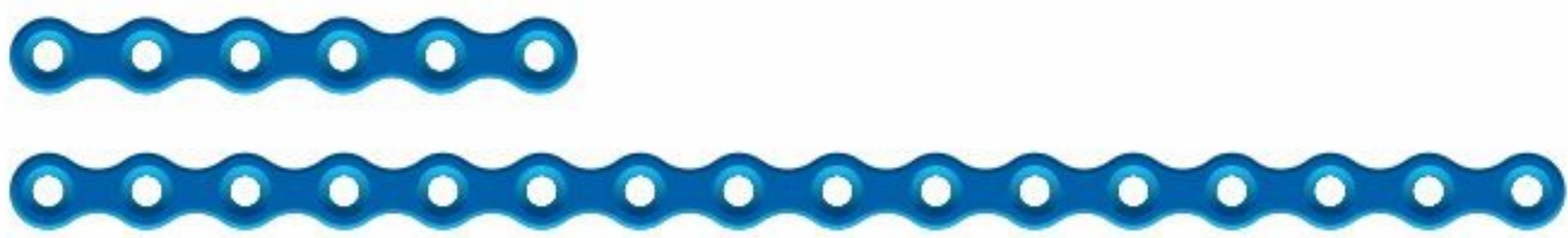


Thd. Dia.: 1.8mm

Ref.	Size
113.T1806	6mm
113.T1807	7mm
113.T1808	8mm
113.T1809	9mm
113.T1810	10mm

Titanium Plates

Without Bar



Ref.	Size	Ref.	Size
101.T2002	2 Holes	101.T2010	10 Holes
101.T2003	3 Holes	101.T2012	12 Holes
101.T2004	4 Holes	101.T2016	16 Holes
101.T2005	5 Holes	101.T2020	20 Holes
101.T2006	6 Holes	101.T2030	30 Holes
101.T2008	8 Holes	101.T2050	50 Holes

Titanium Plates

With Bar



Ref.	Size
102.T2002	2 Holes
102.T2003	3 Holes
102.T2004	4 Holes
102.T2005	5 Holes
102.T2006	6 Holes
102.T2008	8 Holes

Titanium "L" Shape Plates 90°



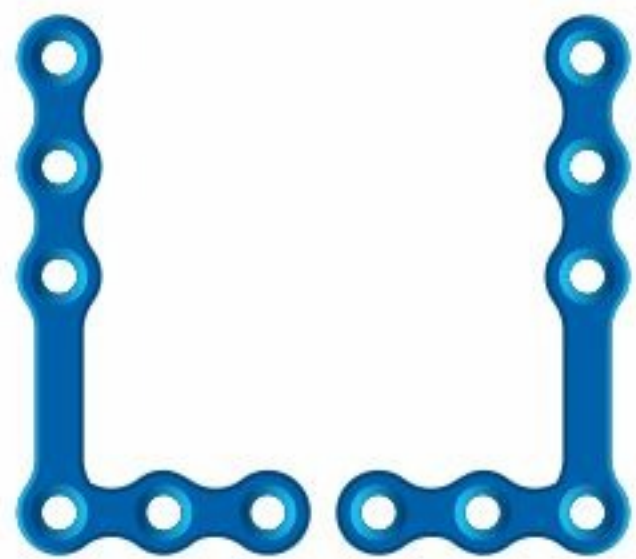
Ref.	Size
103.T20SL	Small Left
103.T20SR	Small Right

Ref.	Size
103.T20BL	Big Left
103.T20BR	Big Right

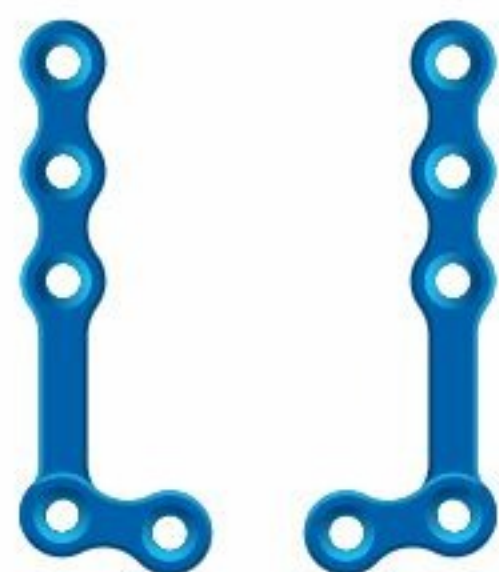


Ref.	Size
103.T20EL	XB 3+2H Left
103.T20ER	XB 3+2H Right

Ref.	Size
103.T20XL	XB 3+3H Left
103.T20XR	XB 3+3H Right



Titanium "L" Shape Plates 100°



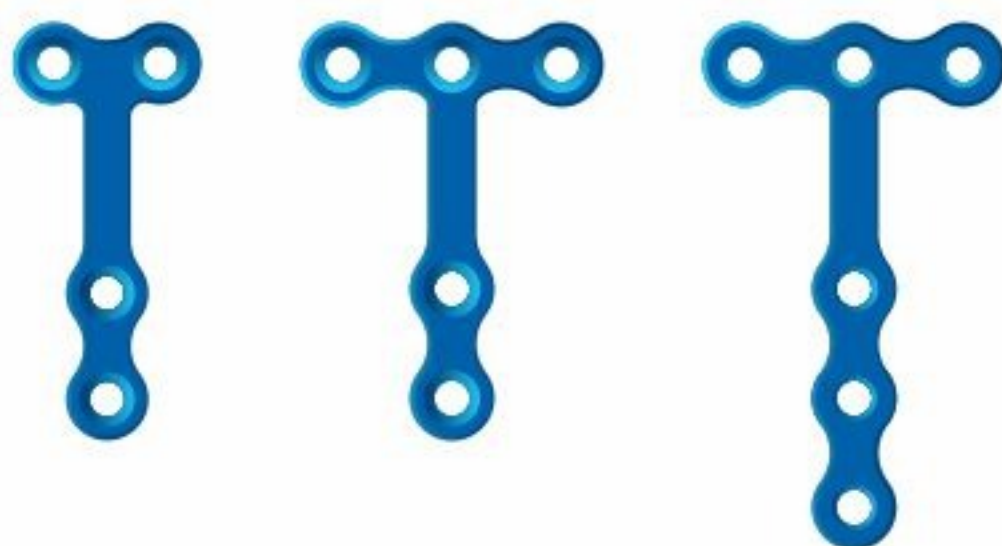
Ref.	Size
118.T20EL	XB 3+2 - Left
118.T20ER	XB 3+2 - Right

Titanium "L" Shape Plates 120°



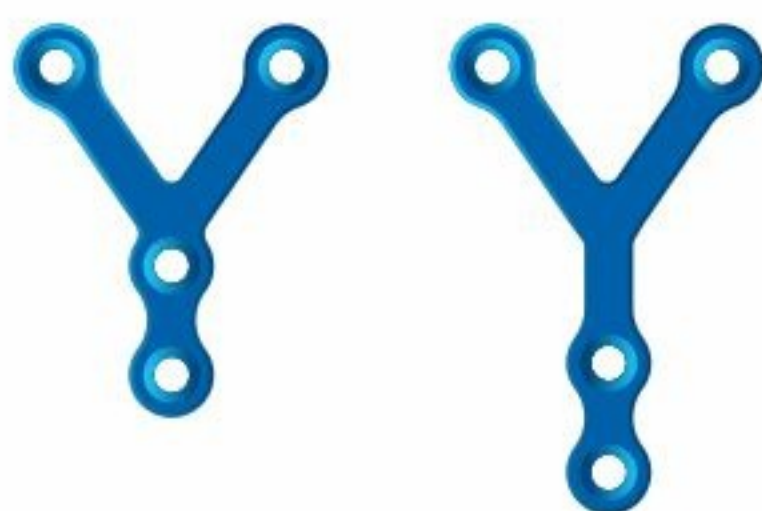
Ref.	Size
104.T20SL	Small Left
104.T20SR	Small Right
104.T20BL	Big Left
104.T20BR	Big Right

Titanium "T" Shape Plate



Ref.	Size
105.T20S	Small
105.T20B	Big
105.T20X	Extra Big

Titanium "Y" Shape Plate



Ref.	Size
106.T20S	Small
106.T20B	Big

Titanium Double "Y" Shape Plate



Ref.
119.T20

Titanium "I" Shape Plate



Ref.
120.T20

Titanium "H" Shape Plate



Ref.
163.T20

Titanium "X" Shape Plate



Ref.
121.T20

Titanium "Z" Shape Plate



Ref.
122.T20

Titanium Orbita Plates

With Bar



Ref.	Size
107.T2004	4 Holes
107.T2006	6 Holes

Titanium Orbita Plates

Without Bar



Ref.	Size
108.T2006	6 Holes
108.T2008	8 Holes

Titanium Grid Plate



Ref.
128.T20

Titanium Trapezoid Condyle Plate (TCP)



Ref.
129.T20

Titanium Delta Plate



Ref.
131.T20

Titanium Sub "Y" Plate



Right



Left

Ref.	Size
133.T20L	Left
133.T20R	Right

Titanium TriFix Plate



Right



Left

Ref.	Size
134.T20L	Left
134.T20R	Right

Titanium Chin Plates



Ref.	Size
132.T2006	6mm Bar
132.T2008	8mm Bar
132.T2010	10mm Bar
132.T2012	12mm Bar

Titanium Twisted Plates



Ref.	Size
130.T20L	5H Left
130.T20R	5H Right

Titanium Square Shape Plates



Ref.	Size
123.T2022	2x2 Holes
123.T2023	2x3 Holes
123.T2024	2x4 Holes

Titanium 3D Plates



Ref.	Size
109.T2022	2x2 Holes
109.T2023	2x3 Holes
109.T2024	2x4 Holes

Titanium Screw - QuikDrive®



Ref.	Size
137.T2003	3mm
137.T2004	4mm
137.T2005	5mm
137.T2006	6mm
137.T2007	7mm
137.T2008	8mm
137.T2009	9mm
137.T2010	10mm
137.T2011	11mm
137.T2012	12mm
137.T2014	14mm
137.T2016	16mm

Thd. Dia.: 2mm
Drill Size : 1.5mm

Titanium Screw - Single Slotted



Ref.	Size
110.T2004	4mm
110.T2005	5mm
110.T2006	6mm
110.T2007	7mm
110.T2008	8mm
110.T2009	9mm
110.T2010	10mm
110.T2011	11mm
110.T2012	12mm
110.T2014	14mm
110.T2016	16mm

Thd. Dia.: 2mm
Drill Size : 1.5mm

Titanium Emergency Screw - QuikDrive®



Ref.	Size
139.T2306	6mm
139.T2307	7mm
139.T2308	8mm
139.T2309	9mm
139.T2310	10mm
139.T2312	12mm

Thd. Dia.: 2.3mm

Titanium Emergency Screw - Single Slotted



Ref.	Size
113.T2306	6mm
113.T2307	7mm
113.T2308	8mm
113.T2309	9mm
113.T2310	10mm
113.T2312	12mm

Thd. Dia.: 2.3mm

MANDIBLE PLATING SYSTEM 2.5mm

Profile Thickness : 1.2 mm

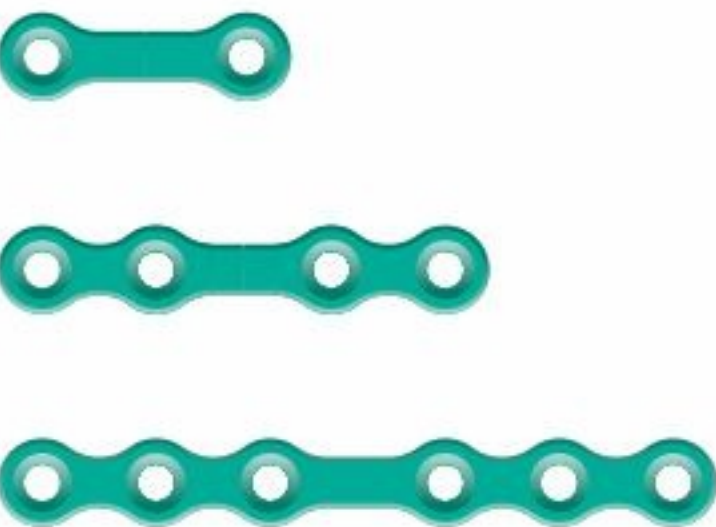
Titanium Bone Plates
Without Bar



Ref.	Size
101.T2502	2 Holes
101.T2503	3 Holes
101.T2504	4 Holes
101.T2505	5 Holes
101.T2506	6 Holes
101.T2508	8 Holes
101.T2510	10 Holes
101.T2512	12 Holes
101.T2516	16 Holes
101.T2520	20 Holes
101.T2530	30 Holes
101.T2550	50 Holes

Titanium Bone Plates

With Bar



Profile Thickness : 1.2mm

Ref.	Size
102.T2502	2 Holes
102.T2503	3 Holes
102.T2504	4 Holes
102.T2505	5 Holes
102.T2506	6 Holes
102.T2508	8 Holes

Titanium MaxLock® Mandible Angle Plates

Profile : 1.8mm x 6mm
* Can be used with Locking or Non Locking Screws



Ref.	Size
148.TA06	3+3 Holes
148.TA08	4+4 Holes

Titanium Screw - QuikDrive®



Thd. Dia.: 2.5mm
Drill Size : 2.0mm

Ref.	Size
137.T2504	4mm
137.T2505	5mm
137.T2506	6mm
137.T2507	7mm
137.T2508	8mm
137.T2509	9mm
137.T2510	10mm
137.T2511	11mm
137.T2512	12mm
137.T2513	13mm
137.T2514	14mm
137.T2515	15mm
137.T2516	16mm

Titanium Screw - Single Slotted



Thd. Dia.: 2.5mm
Drill Size : 2.0mm

Ref.	Size
110.T2504	4mm
110.T2505	5mm
110.T2506	6mm
110.T2507	7mm
110.T2508	8mm
110.T2509	9mm
110.T2510	10mm
110.T2511	11mm
110.T2512	12mm
110.T2513	13mm
110.T2514	14mm
110.T2515	15mm
110.T2516	16mm

Titanium Emergency Screw - QuikDrive®



Thd. Dia.: 2.7mm

Ref.	Size
139.T2706	6mm
139.T2707	7mm
139.T2708	8mm
139.T2709	9mm
139.T2710	10mm
139.T2712	12mm

Titanium Emergency Screw - Single Slotted



Thd. Dia.: 2.7mm

Ref.	Size
113.T2706	6mm
113.T2707	7mm
113.T2708	8mm
113.T2709	9mm
113.T2710	10mm
113.T2712	12mm

EzyDrill Intermaxillary Fixation (IMF) Screw



Thd. Dia.: 2.0mm
Material : S.S. 316L

Ref.	Size
114.S2006	6mm
114.S2007	7mm
114.S2008	8mm
114.S2009	9mm
114.S2010	10mm
114.S2012	12mm

Titanium Lag Screw - QuikDrive®



Thd. Dia.: 2.0mm
Drill Size : 1.5mm
Gliding Hole Drill Size : 1.7mm

Ref.	Size
142.T2008	8 mm
142.T2010	10 mm
142.T2012	12 mm
142.T2014	14 mm
142.T2016	16 mm
142.T2018	18 mm
142.T2020	20 mm
142.T2022	22 mm
142.T2024	24 mm
142.T2026	26 mm

MaxLock QuikDrive® Screw



Thd. Dia.: 2.0mm
Drill Size : 1.5mm
Material : S.S. 316L
To be used with EzyBar

Ref.	Size
116.S2006	6mm
116.S2008	8mm
116.S2010	10mm

Ezy Bar



Ref.	Size
115.S02	150mm

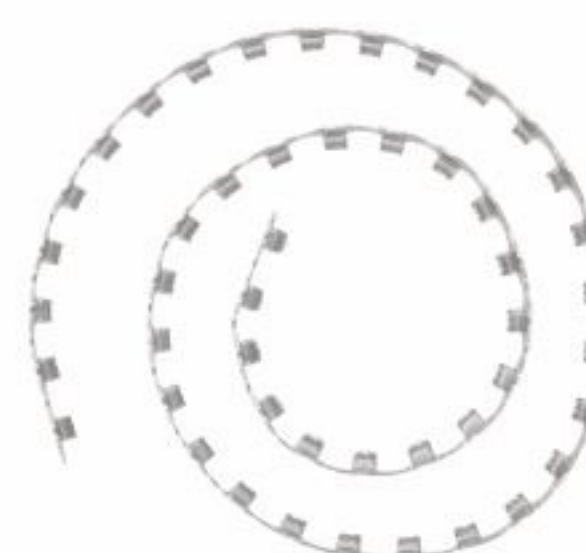
S.S. Wire Reels



Length : 10 mtrs.

Ref.	Size
633.S24	24 Gauge
633.S26	26 Gauge
633.S28	28 Gauge
633.S30	30 Gauge

Arch Bar



Ref.	Size
115.S01	1 Feet



Ref.
101.001

Implant Contents	Qty	Qty
Tita. Mini Bone Plates 1.5mm		
With Bar - 2H/2, 4H/3, 6H/2		7
Wirthout Bar - 20H		2
L-90*- Big - Left & Right - 1 each		2
L-90*- Extra Big - 3+2H - Left & Right - 1 each		2
Orbita with Bar - 4H, 6H - 2 each		4
Orbita without Bar - 6H, 8H - 1 each		2
"T" Shape Small 2+2H, Big 3+2H - 1 each		2
"Y" Shape Big		1
Double "Y" Shape		1
Tita. Mini Bone Plates 2.0mm		
With Bar - 2H/2, 4H/3, 6H/2		7
Without Bar - 16H, 20H - 2 each		4
L-90*- Big 2+2H Left & Right - 1 each		2
L-90*- Extra Big 3+3H Left & Right - 1 each		2
"T" Shape Small 2+2H, Big 3+2H - 1 each		2
"Y" Shape Big		1
Double "Y" Shape		1
Delta Plate		2
3D Shape 2x3H		1
Tita. Mini Bone Plates 2.5mm		
With Bar - 4H/4, 6H/2		6
Without Bar - 4H/1, 6H/1, 20H/2		4
Tita. MaxLock®Mandible Recon. Plates -		
Angled - 3+3Holes		1
Tita. Orbital Floor Plate -		
Medium, Big - 1 each		2

Implant Contents	Qty
Tita. Mini Bone Screws - QuikDrive®	
1.5mm x 4mm/10, 5mm/10, 6mm/30, 8mm/10	60
2.0mm x 6mm/20, 8mm/30, 10mm/10	60
2.5mm x 6mm/10, 8mm/20, 10mm/20, 12mm/10	60
Tita. Emergency Screws QuikDrive®	
1.8mm x 6mm/6, 8mm/6	12
2.3mm x 6mm/6, 8mm/6	12
2.7mm x 8mm/6, 10mm/6	12
EzyDrill IMF Screws QuikDrive® SS	
2mm x 8mm/8, 10mm/8	16
Wire Reel - S.S. 26G	1
Arch Bar	2

Instruments Contents	Qty
QuikDrive Screw Driver Handle Quick Coupling	1
QuikDrive Screw Driver Shaft 1.2/1.5mm	1
QuikDrive Screw Driver Shaft 2/2.5mm	1
Universal QuikDrive Screw Driver	1
Mini Plate Cutter (Vertical)	1
Modelling Lever	1
Plier	1
Wire Cutter - Premium	1
Wire Twisting Forceps (Thick)	1
Screws & Plate Holding Forceps	1
S.S. Drill Bits For Micromotor	
Short Flute - 1x8x65mm, 1.5x12x65mm - 2 each	4
Regular - 2x20x65mm	2
Container For All In One QuikDrive CMF Kit	1

CMF IMPLANTS INSTRUCTION FOR USE (IFU)

Instructions concerning for below mentioned CMF IMPLANTS made by QMAX MEDTECH PVT LTD

CONTENTS: The Device package contains single use CMF Implants (CMF Plate & CMF Screw) of the QMAX MedTech Pvt Ltd

DESCRIPTION : The CMF IMPLANTS are single use device supplied Non-sterile. The devices are available in Titanium and SS 316L for CMF Plate & CMF Screw with different sizes.

INTENDED USE :

CMF Plates :

These implants are used in human body to unite fractured bones of different parts of the skull. Plates are of different types e.g. Mini Bone plates with bar and without bar, L shape, T, Orbita Plates are generally used in upper, mid and lower ends of face.

CMF Screws :

These implants are used in human body to unite fractured bones of different parts of skull. Screws are of different types e.g. Mini Bone screws, Intermaxillary Fixation Screws, Lag Screws, Emergency Screws which are used with Mini Bone Plates to unite fractures of upper, mid and lower ends of face.

SELECTION OF THE IMPLANTS :

- Responsibility of the proper selection of patients, adequate training, experience in the choice, placement of the implant & the decision to leave or remove implant postoperatively, rests with the surgeon.
- The CMF Plate & CMF Screw are available in variety of configurations, these shall be used in combination with related corresponding implants & instruments made by QMAX MedTech Pvt Ltd only.
- The product should be used in combination with the devices made up similar material only. (Titanium with Titanium implants, SS implants with SS implants)
- The Surgeon should discuss the expectation of the surgery inherent the use of the product with the patient. Particular attention should be given to a discussion postoperatively & the necessity should be focused for periodic medical follow-up.
- The Correct selection of the product is extremely important. The product should be used in the correct anatomical location, consistent with the accepted standard for the internal fixation. Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to ensure adequate blood supply & provide rigid fixation may result in loosening, bending or cracking of the product and/ or bone fracture.

CONTRAINDICATIONS :

Do not use the CMF Plate & CMF Screw in cases of:

- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Early or Late Infection, both deep and / or superficial
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance

ADVERSE REACTIONS :

Adverse reactions may include but are not limited to:

- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

SAFETY PRECAUTIONS :

- The Product should only be used by the medical personnel who hold relevant qualification.
- Never use the product that has been damaged by Improper handling in the hospital or in any other way.
- Never reuse an implant. Although the implant appears to be undamaged, previous stresses may have created non-visible damage that could result in implant failure.
- Safety Precaution for Special Cases

Pregnant Women

- Ensure that there should be less blood loss during the surgery.
- Anaesthesia should not be used in such case.
- Operational environment must be free from radiation.

Infant / Children

- Ensure that there should be less blood loss during the surgery.
- Operational environment must be free from radiation.
- Epiphysis should not be damaged

Polymorbid & Breastfeeding Women

- On Polymorbid patients and breastfeeding women, the implant shall be used at the discretion of surgeon.

WARNING:

The use of implants for surgery other than those for which they are intended may result in damage/ breakage of implants or patient injury.

- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete

information on these subjects must be readily available at the workplace.

- The operating surgeon must be especially trained in Cranio-Maxillofacial, Orthopedic surgery, biomechanical principles of the skeleton, and the relevant operating techniques.
- The patient is aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant & implantation procedure and about possible alternative treatments.
- The implant can be failed due to excessive load, wear and tear or infection.
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload too early through extreme strain, work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have his/her physician to carry out follow-up examinations of the implants at regular intervals.
- If device used in joints, kindly inform to patient do not move excessively, it may cause pain or damage surrounding tissue where implant were placed.

HOW SUPPLIED/STORAGE:

The implants are individually packed in protective packaging that is labelled to its contents properly. All Single use Non-sterile implants are supplied.

- Implants should be stored in the original protective packaging.
- Store the implants in a dry and dust-free place (standard hospital environment).

INSPECTION:

Before use, inspect the box carefully. Do not use when

- Implants has scratches or damaged
- Improper threads with damages
- Prior to surgery check suitability of fixation of this implant with its corresponding implant, and also ensure strength of whole assembly.

OPERATING INSTRUCTIONS :

- The QMAX MedTech Pvt Ltd implants should be implanted only with the related corresponding instruments made by QMAX MedTech Pvt Ltd
- Also ensure the availability of same implant as standby.
- Surgeon should document the implant details (name, item, number, lot number) in surgery record.

PRE-OPERATIVE :

- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough understanding of both, the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon. The operating surgeon draws up an operation plan specifying and documenting the following:
 - Implant component(s) and their dimensions.
 - Determination of intra-operative orientation points.

The following conditions must be fulfilled prior to application:

- All required implant components are sterilized and readily available.
- All requisite sterile implantation instruments must be available and in working order.
- Highly aseptic operating conditions are present.

Sterilization: All Single use NON-STERILE implants and instrument used in the surgery must be cleaned & Sterile prior to use.

Do not forget to remove plastic packing of implant before cleaning.

Cleaning Procedure:

All the new products must be carefully cleaned before initial sterilization. Only trained personnel must perform cleaning

Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH 7.

- Rinse Implants under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to clean the Implants.
- Soak Implants in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes.

Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.

- Rinse Implants with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels, and other hard to reach areas.
- Manually clean Implants for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution using a soft-bristled brush. Clean Implants under water to prevent aerosolization of contaminants.

Note: Freshly prepared solution is a newly-made, clean solution.

- Rinse Implants thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens and channels.
- Visually inspect Implants.

- Perform a final rinse on Implants using DI or PURW water.
- Dry Implants using a clean, soft, lint-free cloth or clean compressed air.

Note: Cleaning Agent Information: We used the following cleaning agents during internal processes of these cleaning recommendations. These cleaning agents are not listed in preference to other available cleaning agents which may perform satisfactorily- neutral pH enzymatic detergents (e.g. Prolystica 2X Concentrate Enzymatic Cleaner, Enzol, Endozime, and Neodisher Medizym) and neutral pH detergents (e.g. Prolystica 2X Neutral Detergent).

We suggest following parameter for the sterilization;

Method	Temperature	Exposure time	Pressure
Steam (autoclave)	121 Deg C.	15 Minutes	103421 Pa / 0.1 MPa / 15 psi

Note: Recommended Steam Sterilizer (Autoclave) is Class B.

INTRA-OPERATIVE :

- Prior to use, verify the integrity of the implant.
- Modification of the Implant Set is not allowed.
- Small bending of the CMF Plate & CMF Screw is possible. When contouring this CMF Plate & CMF Screw, do not over bend and / or bend back in original shape
- Use the appropriate Drill Guide, Drill and Tap set to make the holes and threading for the bone screws to avoid damage to the CMF Plate & CMF Screw or bone.
- Ensure sufficient rinsing in-situ for cooling and removing of potential wear material.
- Before locking the screw to the CMF Plate, the bone has to be correctly repositioned.

POST-OPERATIVE :

- Reiterate preoperative instructions to the patient.
 - During the post-operative phase, in addition to mobility it is of vital importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
 - Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.
 - Doctor shall ensure that proper follow-up timelines are given to patients as in when required.
- During the follow-ups, doctor need to verify whether the product is meeting its specified intended purpose.
- Doctor shall also communicate to patient regarding the cases when the follow-up has to be done like having abnormal reactions e.g., swelling, severe pain etc.
 - Information regarding weight bearing and other physical activities timelines shall be communicated to patient.

REVISION SURGERY/IMPLANT REMOVAL :

Metallic implants can be loosen, fracture, migrate, cause pain, or stress shield bone even after a fracture is healed, particularly in young active patients. The surgeon must make the final decision on implant removal if either of these occurs. If there are not any of these complications, we recommend the permanent implantation of this implants because of the risk of re-fracture and the possible complications of an additional operation.

- The surgeon must make the final decision on implant removal if either of these occurs;
 - Patient's choice
 - Doctor's Advice based on the clinical condition of the patient
 - Deep Wound Infection/Bone Atrophy
 - Growing Skeleton
 - Tenosynovitis
 - Intra-Articular Material
 - Post - traumatic Arthritis
 - Avascular Necrosis
 - Intractable Pain
 - Perforating Material
 - Infection
 - Paresthesia
- Time of removal of implant shall be suggested by the doctor depending upon the clinical condition of the patient either after the surgery or during the follow ups.
- Removal of Implant may cause the risk of re-fracture, neurovascular injury & infection.
- Bone in-growth and wear of the implant can make the removal difficult.

MRI SAFETY INFORMATION :

- QMAX MedTech Pvt Ltd implants are manufactured from Titanium & SS316L material for CMF Plate & CMF Screw which are non-magnetic material, hence it do not pose any safety risk.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The QMAX MedTech Pvt Ltd implants has not been evaluated for safety and compatibility in the MR environment but based on literature study below mentioned points can be taken care during MRI
 - The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.
 - The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

CLINICAL EVALUATION OF CMF PLATE & CMF SCREW :

- The QMAX MedTech Pvt Ltd CMF Plate & CMF Screw is clinically safe, and effective in use as discussed and proved up to the mark in the clinical evaluation of the device.

DISPOSAL OF CMF PLATE & CMF SCREW :

- Please note that using a single use device (SUD) which comes into contact with human blood or tissue constitutes, these device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

FOR FURTHER INFORMATION :

- Please contact QMAX MedTech Pvt Ltd in case of any Query, Complain or Adverse Effect
Mobile No: +91 94294 08861, E-mail: contact@qmaxindia.in

Non-Sterile Indicating that the device has not been sterilized.



Medical device Indicates the item is a medical device



Consult Instructions For Use - Note: This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.



Do not re-use - Indicates a medical device that is intended for one single use only



Date Of Manufacture - Note: This symbol is accompanied by the date that the device was manufactured. The date could be year, year and month, or year, month and day, as appropriate.



Catalogue Number - Note: This symbol be accompanied by the catalogue number relevant to the device bearing the symbol.



Batch Code - Note: This symbol should be accompanied by the batch code relevant to the device bearing the symbol.



Do Not Use If Package Is Damaged
Do not use, if the packaging is compromised.



Caution - This symbol is to denote that there some warning or precautions associated with device, which are not otherwise found on labels



In Single Pack Number Of Quantity Packed

QTY

Raw Material used for manufacturing

MAT

Manufacturers Company Logo



Country of Manufacture - To identify the country of manufacture of products



Manufacturer - QMAX MedTech Pvt Ltd
Plot no. A2-424/B, GIDC Estate, Makarpura, Vadodara-390010. Gujara, India



Keep Dry - Indicates a medical device that needs to be protected from moisture



Keep away from Sunlight -
Indicates a medical device that needs protection from light sources





FUELING THE FUTURE OF SURGERY WITH PASSION



Reg. Office & Mfg. Unit

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