



INDIAN FDA APPROVED



Austeofix Surgical Pvt. Ltd.

A Perfect Fixation

AN ISO 9001:2015, ISO 13485:2016, CE & GMP CERTIFIED COMPANY





Cranio Maxillofacial System

1.5 MM SYSTEM



Straight Plate with Gap
2 hole to 6 hole
Mat:- Titanium Cat No.: T.502.02-06



Burr Hole Cover Plate
Mat:- Titanium
Cat No.: T.523



Straight Plate Continuous
4 hole to 15 hole
Mat:- Titanium Cat No.: T.501.02-50



L Plate with Gap Left / Right
4 hole to 6 hole
Mat:- Titanium Cat No.: T.504.04-06



L Plate without Gap Left / Right
4 hole to 6 hole
Mat:- Titanium Cat No.: T503.04



Orbita Plate Continuous
4 hole to 20 hole
Mat:-Titanium Cat No.: T507.04-20



Y Plate
4 hole to 6 hole
Mat:- Titanium
Cat No.: T510.04-06



Double Y Plate
4 hole to 6 hole
Mat:- Titanium
Cat No.: T511.06



X Plate
4 hole to 6 hole
Mat:- Titanium
Cat No.:T509.05-06



Orbita Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No.: T506.04-06



Screw Single Slot
4 mm to 10 mm
Mat:- Titanium Cat No.: T519.4-12



T Plate
4 hole to 6 hole
Mat:- Titanium Cat No.: T508.04-06



Screw Cross Slot
4 mm to 10 mm
Mat:- Titanium Cat No.: T520.4-12



Cranio Maxillofacial System

2.0 MM SYSTEM



3D Medial Plate
4 hole, 8 hole, 16 hole
Mat:- Titanium Cat No. : T544.04-08



Straight Plate Continuous
4 hole to 50 hole
Mat:- Titanium Cat No. : T525.04-50



Trapezoidal Plate
4 hole
Mat:- Titanium Cat No. : T541.04



Grid Plate
4 hole
Mat:- Titanium Cat No. : T540.4



Delta Plate
4 hole
Mat:- Titanium Cat No. : T539.04



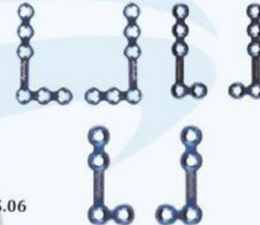
Straight Plate with Gap
2 hole to 6 hole
Mat:- Titanium Cat No. : T526.04-06



Y Plate
4 hole to 6 hole
Mat:- Titanium Cat No. : T534.04-06



Double Y Plate
4 hole to 6 hole
Mat:- Titanium Cat No. : T535.06



L Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No. : T528.04-06



Z Plate
4 hole
Mat:- Titanium Cat No. : T536.04



X Plate
5 hole
Mat:- Titanium Cat No. : T533.05-06



Orbita Plate Continuous
4 hole to 20 hole
Mat:- Titanium Cat No. : T531.04-20



L Plate without Gap
4 hole
Mat:- Titanium Cat No. : T527.04



T Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No. : T532.04-06



I.M.F. Screw
8 mm to 12 mm
Mat:- Titanium Cat No. : T550.6-14



Screw Cross Slot
4 mm to 12 mm
Mat:- Titanium Cat No. : T547.4-12



Screw Single Slot
4 mm to 12 mm
Mat:- Titanium Cat No. : T546.4-12

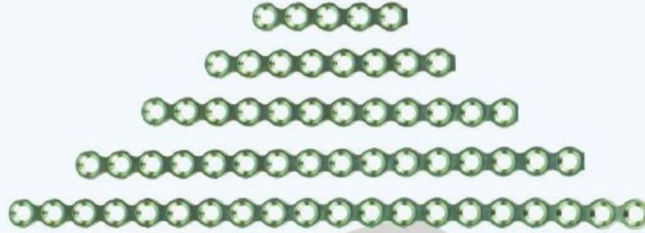


Orbita Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No. : T530.04-06



Cranio Maxillofacial System

2.5 MM SYSTEM



Straight Plate Continuous
4 hole to 50 hole
Mat:- Titanium Cat No. : T551.02-50



Straight Plate with Gap
2 hole to 6 hole
Mat:- Titanium Cat No. : T552.02-06



Z Plate
4 hole
Mat:- Titanium Cat No. : T562.04



Y Plate
4 hole to 6 hole
Mat:- Titanium Cat No. : T560.04-06



L Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No. : T554.04-06



T Plate with Gap
4 hole to 6 hole
Mat:- Titanium Cat No. : T558.04-06



Orbita Plate with Gap
4 hole to 6 hole
Mat:- Titanium
Cat No. : T556.04-06



Screw Cross Slot
4 mm to 12 mm
Mat:- Titanium
Cat No. : T564.04-12



Screw Single Slot
4 mm to 12 mm
Mat:- Titanium
Cat No. : T563.04-12



I.M.F. Screw
8 mm to 12 mm
Mat:- Titanium
Cat No. : T566.6-14



Orbita Plate Continuous
4 hole to 20 hole
Mat:- Titanium
Cat No. : T557.04-20



Cranio Maxillofacial System

SPECIAL PLATES



T.M.J. Angle Reconstruction Plate
Size : 2.7 mm
Mat.: Titanium Cat.No. : T568.204



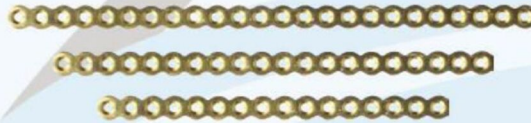
Full Mandibular Reconstruction Plate
Size : 2.7 mm
Mat.: Titanium Cat.No. : T571.12412



Angle Reconstruction Plate
Size : 2.7 mm
Mat.: Titanium Cat.No. : T569.204



Double Angle Reconstruction Plate
Size : 2.7 mm 24 Hole
Mat.: Titanium Cat.No. : T570.4204



Straight Reconstruction Plate
Size : 2.7 mm 8,10,12,16,20,24 Hole
Mat.: Titanium Cat.No. : T572.24



T.M.J. Condyle
Size : 2.7mm 3 Hole
Mat.: Titanium Cat.No. : T567.03



Orbital Floor Mesh
Size : 1.5mm
Mat.: Titanium Cat.No. : T516.S



Pre Contured Wire Mesh Plate
Size : 1.5 mm (0.7 mm Thick)
Mat.: Titanium Cat.No. : T517



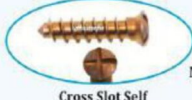
Orbital Floor Mesh
Size : 1.5mm
Mat.: Titanium Cat.No. : T516.L



Cross Slot Self Picking Screw (Premium)
Size : 1.5mm
Mat.: Titanium Cat.No. : T521.4-12



Cross Slot Self Picking Screw (Premium)
Size : 2.0 mm
Mat.: Titanium Cat.No. : T548.4-12



Cross Slot Self Picking Screw (Premium)
Size : 2.5 mm
Mat.: Titanium Cat.No. : T565.4-14



Orbital Floor Mesh
Size : 1.5mm
Mat.: Titanium Cat.No. : T516.M



Cross Slot Self Drilling Screw (Premium)
Size : 1.5mm
Mat.: Titanium Cat.No. : T522.04-08



Cross Slot Self Drilling Screw (Premium)
Size : 2.0 mm
Mat.: Titanium Cat.No. : T549.04-08



Cranio Maxillofacial System

BASIC INSTRUMENTS



Drill Bit Titanium Coated
Size :- 1, 1.5, 2 mm
Mat.: S.S. Cat. No.: INS.DB1-2



Drill Bit Stainless Steel
Size :- 1, 1.5, 2 mm
Mat.: S.S. Cat. No.: INS DB S.1-2



Cutting Burr
Size :- 2, 2.5, 3, 3.5, 4, 5, 6 mm
Mat.: S.S. Cat. No.: INS-CB-2-6



Wire Cutter (Stainless Steel)
Size :- 5 Inch
Mat.: S.S. Cat. No.: INS-SSWC



Wire Cutter (Disposable)
Size :- 4 Inch
Mat.: Iron Cat. No.: INS-WCD



Plate Bender
Size :- 5 Inch
Mat.: S.S. Cat. No.:INS-PBF



Arch Bar
Size :- 1 Mtr.
Mat.: S.S. Cat. No.: S.AB



Modeling Lever
Size :- 5 Inch
Mat.: S.S. Cat. No.: INS-ML-3P



Plier
Size :- 5 Inch
Mat.: S.S. Cat. No.: INS-P



S.S. Wire Reel
Size :- 3 Mtr., Gauge : 22,24,26,28
Mat.: S.S. Cat. No.: S.169.22-28



Screw Driver Self Holding/Ordinary
Size :- 1.5 mm
Mat.: S.S. Cat. No.: INS.MSD.CS/SH 1.5



Screw Driver Self Holding/Ordinary
Size :- 2.0 mm
Mat.: S.S. Cat. No.: INS.MSD.CS/SH 2.0



Screw Driver Self Holding/Ordinary
Size :- 2.5 mm
Mat.: S.S. Cat. No.: INS.MSD.CS/SH 2.5



Screw Driver Self Picking (Premium)
Size :- Fit to All
Mat.: S.S. Cat. No.: INS-SDH/SP1
INS-SDSS PSI



Transbuccal Trocar
Mat.: S.S. Cat. No.: INS-TBT



Screw Driver Self Picking Collate Type
Size :- 1.5, 2.0, 2.5 mm
Mat.: S.S. Cat. No.: INS-SD-SH 3C



Cranio Maxillofacial System

DISTRACTORS



Alveolar Distractor
Mat.: S.S.
Cat.No. : D-AD



Mandibular Intraoral Distractor
Mat.: Titanium/S.S.
Cat.No. : D-MID



Maxillary Intraoral Mini Distractor
Mat.: S.S.
Cat.No. : D-MIMD



Vertical Distractor
Mat.: S.S.
Cat.No.: D-VD

BOXES & CONTAINERS



Maxillofacial Implant Kit
Cat. No.: INS-MIKA2T




Maxillofacial Implant Kit (Premium)
Cat. No.: INS-MIKIST






QUALITY MANAGEMENT SYSTEM

Certificate of Registration


 This is to Certify That The Quality Management System of
AUSTEOFIX SURGICAL PVT. LTD.
 PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1,
 DEHMI KALAN, JAIPUR AJMER EXPRESS HIGHWAY,
 BAGRU, JAIPUR- 303007, RAJASTHAN, INDIA
 has been assessed and found to conform to the requirements of
ISO 9001:2015
 for the following scope :
 DESIGN, MANUFACTURE AND SUPPLY OF VARIOUS TYPES
 OF TRAUMA (VARIOUS LOCKING AND NON LOCKING), SPINE,
 ARTHROPLASTY, ARTHROSCOPIC, MAXILLOFACIAL (DENTAL),
 CRANIO MAXILLOFACIAL, EXTERNAL FIXATORS AND
 VARIOUS TYPES OF ORTHOPEDIC SURGICAL INSTRUMENTS

Certificate No : **20DQGUS8**
 Initial Registration Date : 02/06/2020 Issuance Date : 02/06/2020
 Date of Expiry* : 01/06/2021
 Date of Re certification : 02/06/2023


DIRECTOR
ROHS Certification Pvt. Ltd.
408, Medication Building, 53, Tirota Place, New Delhi - 110 018, India
 Phone : +91 011 42552522 | Email : info@rohs-certification.co.uk | Website : www.rohs-certification.co.uk
 The Registration is not a Product Quality Certificate. It is for successful completion of surveillance audits. Visit for verifications on www.rohs-certification.co.uk
 Certificate is the property of ROHS and return when demanded.

CERTIFICATE


CERTIFICATE
 This is to Certify that the
 Medical Device Quality Management System of
AUSTEOFIX SURGICAL PRIVATE LIMITED
 PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1, DEHMI KALAN,
 JAIPUR AJMER EXPRESS HIGHWAY, BAGRU, JAIPUR - 303007,
 RAJASTHAN, INDIA
 has been independently assessed and is compliant with the requirements of:
ISO 13485:2016
 (Medical devices - Quality management systems - Requirements for regulatory purposes)
 This certificate is applicable to the following scope of operations:
 DESIGN, MANUFACTURE, EXPORT AND SUPPLY OF ALL TYPES OF
 TRAUMA (ALL LOCKING AND NON LOCKING), SPINE, ARTHROPLASTY,
 ARTHROSCOPIC, MAXILLOFACIAL (DENTAL), CRANIO MAXILLOFACIAL,
 EXTERNAL FIXATORS AND ALL TYPES OF ORTHOPEDIC AND
 GENERAL SURGICAL INSTRUMENTS

Certificate No.: **SPC17M1226** Date of Initial Registration: 29-04-2017
 Date of This Certificate: 01-06-2020
 Surveillance audit on or before: 28-04-2021
 Date of Re-Certification: 29-04-2023


 Authorised Signatory
SP Certification Limited
 130, Old Street, London,
 EC1V9BD, U.K.
 Email: info@spcertification.co.uk
 www.spcertification.co.uk





Accredited by Accreditation Forum of International Standards [AFIST (UK) LTD.]
 9, Park View Road, Leeds, LS4 2LG, United Kingdom (UK), Email : info@afist.org, Website : www.afist.org
 The approval is subject to the company maintaining its system to the required standards, which will be monitored by SPC.
 The Certificate remains the property of SPC and must be returned on request.
 To check validity of this certificate please visit www.spcertification.co.uk and www.afist.org

CERTIFICATE


CERTIFICATE
 Of Compliance
 This is to certify that the technical documentation has been independently assessed and
 compliant with the requirements of MDD directive 93/42/EEC

Manufacturer
 Name : **AUSTEOFIX SURGICAL PRIVATE LIMITED**
 Address : **PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK,
 PHASE 1, DEHMI KALAN, JAIPUR AJMER EXPRESS
 HIGHWAY, BAGRU, JAIPUR - 303007, RAJASTHAN, INDIA**
 Product Details : **TRAUMA (ALL LOCKING AND NON LOCKING), SPINE,
 ARTHROPLASTY, ARTHROSCOPIC, MAXILLOFACIAL
 (DENTAL), CRANIO MAXILLOFACIAL, EXTERNAL
 FIXATORS AND ALL TYPES OF ORTHOPEDIC AND
 GENERAL SURGICAL INSTRUMENTS (AS PER
 ANNEXURE ATTACHED)**
 Applicable Standard : **Directive 93/42/EEC as amended 2007/47/EC**

This certificate refers to the information examined and read with manufacturer's declaration of conformity.
 Further, the product liability rests with the manufacturer or his representative in accordance with the council
 directive 93/42/EEC as amended 2007/47/EC. The CE Mark as shown below can be used, under the
 responsibility of manufacturer, after completion of a CE Declaration of conformity and compliance with the
 relevant CE Directives.

Certificate No.: **SPC17C1228** Date of Initial Registration: 29-04-2017
 Date of This Certificate: 01-06-2020
 Surveillance audit on or before: 28-04-2021
 Date of Re-Certification: 29-04-2023


 Authorised Signatory
SP Certification Limited
 130, Old Street, London,
 EC1V9BD, U.K.
 Email: info@spcertification.co.uk
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Central Drugs Standard Control Organisation
 Directorate General of Health Services
 Ministry of Health & Family Welfare
 (Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
 New Delhi-110002
 Phone No-011-23236965
 Fax: 23236973
 Dated : 22-APR-2020

File No. : NZ/MD/2019/000033

M/s Austeofix Surgical Pvt. Ltd.,
 10-11-12, PLOT NO. 6, Vivekanand Marg,
 C-Scheme, Jaipur, Rajasthan, India, 302001
 Jaipur , Jaipur, Rajasthan (India) - 302001
 Telephone No.: 9314522429 FAX:
 9782002006 Email: info@austeofix.com

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in
 Sir, Form MD-9 under Medical Device Rules, 2017- regarding.

Manufacturing licence No. MFG/MD/2020/000091 in Form MD-9 is hereby forwarded to you.
 This licence is subject to following conditions:

- Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
- The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
- The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
- The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
- The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;



Factory Address :-

Plot No.81, Solitaire Industrial Park Phase 1, Dahmi Kalan. Jaipur Ajmer Exp. Highway

RIICO Ind.Area, Bagru, jaipur

Ph. : +91-9511348306

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