Inion CPS™

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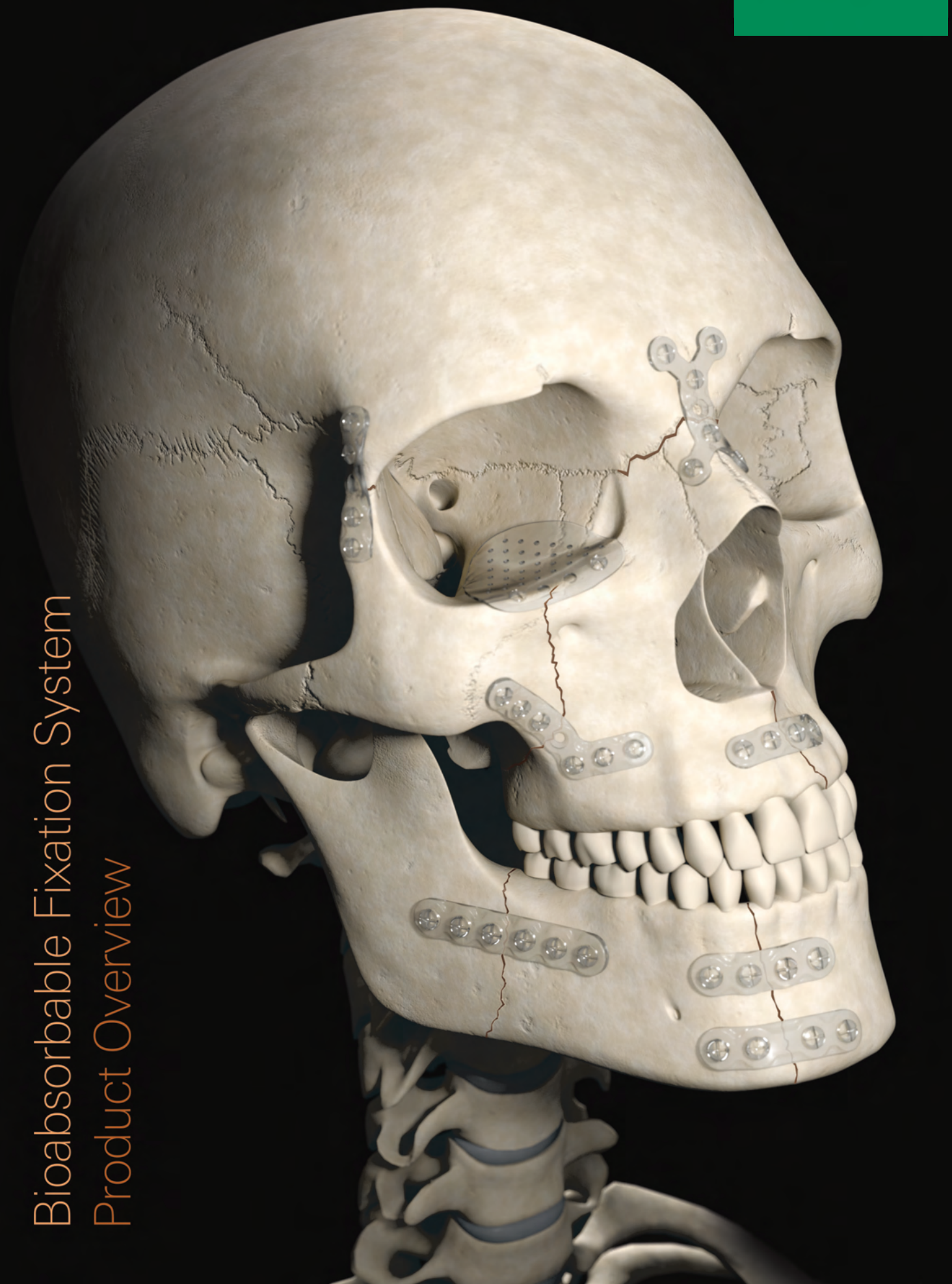


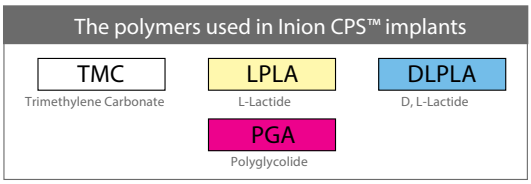
Bioabsorbable Fixation System
Product Overview

Material advantage

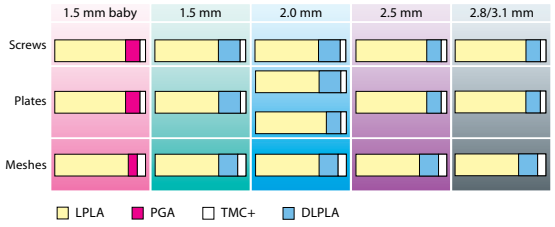
What are the Inion® bioabsorbable implants made from?

All Inion CPS™ implants are based on Inion® bioabsorbable polymer blends and have excellent handling properties, and strength and degradation characteristics that support a more natural healing process.

The Inion® bioabsorbable co-polymers used for the Inion CPS™ Fixation Systems are composed of L-Lactide, D,L-Lactide, Polyglycolide and TMC (Trimethylene Carbonate). These polymers have long histories of safe clinical use.



The proportion of each polymer is varied according to the intended application of the specific implant, so that the strength, malleability and degradation profile best suits the clinical requirements.



The degradation profile

Inion® bioabsorbable polymers are amorphous, degrade in vivo by hydrolysis and are metabolised by the body into CO_2 and water. The degradation profiles have been tailored to provide initial stability and then progressively transfer the load to bone to aid bone regeneration. Mass loss occurs thereafter.

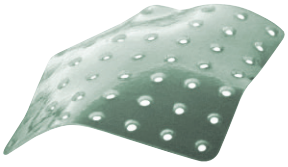
Inion CPS™ Baby implants, specifically designed for pediatric patients, retain minimum of 70 % of their initial strength 6 weeks after implantation. Bioresorption takes place within two to three years.

Inion CPS™ implants retain minimum of 70 % of their initial strength 9 weeks after implantation. Bioresorption takes place within two to four years.

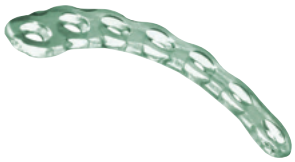
Inion® bioabsorbable polymer advantage

- Inion CPS™ implants are bioabsorbable. No permanent metal implant left in the body reducing risk of implant migration and stress shielding
- Inion CPS™ Baby implants reduce risk of growth restriction in children
- Predictable degradation progressively loads the bone to aid bone regeneration
- Addresses patient concerns about implant permanence, palpability and temperature sensitivity
- No interference with postoperative imaging (X-ray, CT, MRI) which might be required for future diagnosis, as the implants are non-metallic
- Implants are supplied sterile and single packed, solving concerns about possible decontamination of implants which may cause cross-infection
- Easy and precise anatomical contouring of plates after simply heating in the Inion Thermo™ water bath

Inion CPS™ - a complete system for CMF fixation



1.5 mm CPS BABY SYSTEM
For paediatric craniofacial procedures
(similar use to titanium 1.0 - 1.2 mm)
Strength retention is minimum 6 weeks



1.5 mm CPS SYSTEM
For cranial and midface fixation
(similar use to titanium 1.0 - 1.2 mm)
Strength retention is minimum 9 weeks

Inion CPS™ systems

2.0 mm CPS SYSTEM
For midface, mandibular and orthognathic fixation
(similar use to titanium 1.5 - 1.7 mm)
Strength retention is minimum 9 weeks

2.5 mm CPS SYSTEM
For mandibular fixation
(similar use to titanium 2.0 - 2.4 mm)
Strength retention is minimum 9 weeks**

Key elements

The Inion CPS™ system comprises of three key elements developed to provide a total solution for craniomaxillofacial surgery:

Each product has been specifically designed to encompass the particular biomechanical requirements of each facial skeleton area.

Tailoring the polymer selections, manufacturing processes and product designs provides each product with optimal strength, malleability and resorption profiles to meet their specific clinical requirements.

Inion CPS™ is the only bioabsorbable CMF system with applications for all areas of the facial skeleton, and comprises a range of bioabsorbable plates, screws and mesh for use in children and adults.

Clinical advantages

Since their introduction in 2001, the Inion CPS™ and Inion CPS™ Baby implants have been used successfully in more than 120,000 operations by an increasing number of physicians.

- Most comprehensive bioabsorbable plating system available - the only one comparable to titanium in its scope of use
- Quick and easy to use
- Avoidance of routine removal surgery reducing patient trauma and cost
- Unlike other bioabsorbable it has implants suited for all CMF areas, including:
  - paediatric craniofacial trauma and reconstruction
  - fractures and reconstructive procedures of the cranium
  - orthognathic surgery and trauma of the mid-face and maxilla
  - fractures and osteotomies of the mandible**

** in conjunction with appropriate maxillomandibular fixation

Innovative plate design

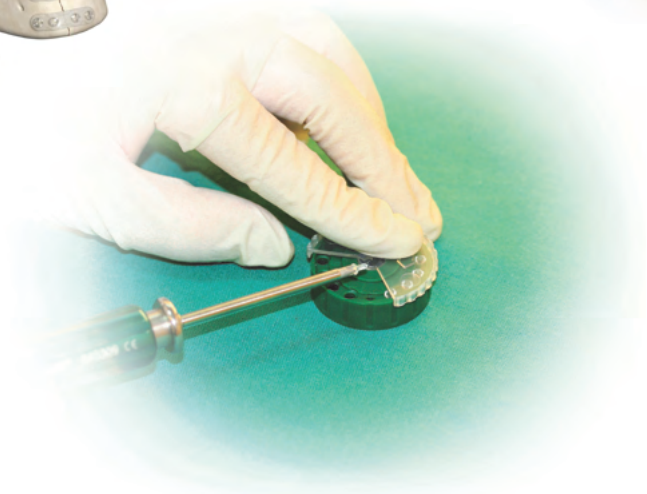
Plate characteristics

- Scalloped plate design
- Optimised strength / material ratio
- Minimised screw hole deformation during bending
- Low plate / screw profile for reduced palpability

Handling advantage

- Plates are malleable after activation in the Inion Thermo™ water bath (55°C).
- After water bath treatment, plates are most malleable for 10-15 seconds for easy adaptation to the bone.
- They can also be re-heated up to three times for further contouring. Maximum heating time is 30 minutes.
- Plates can be easily cut with scissors.

Versatile screw insertion methods

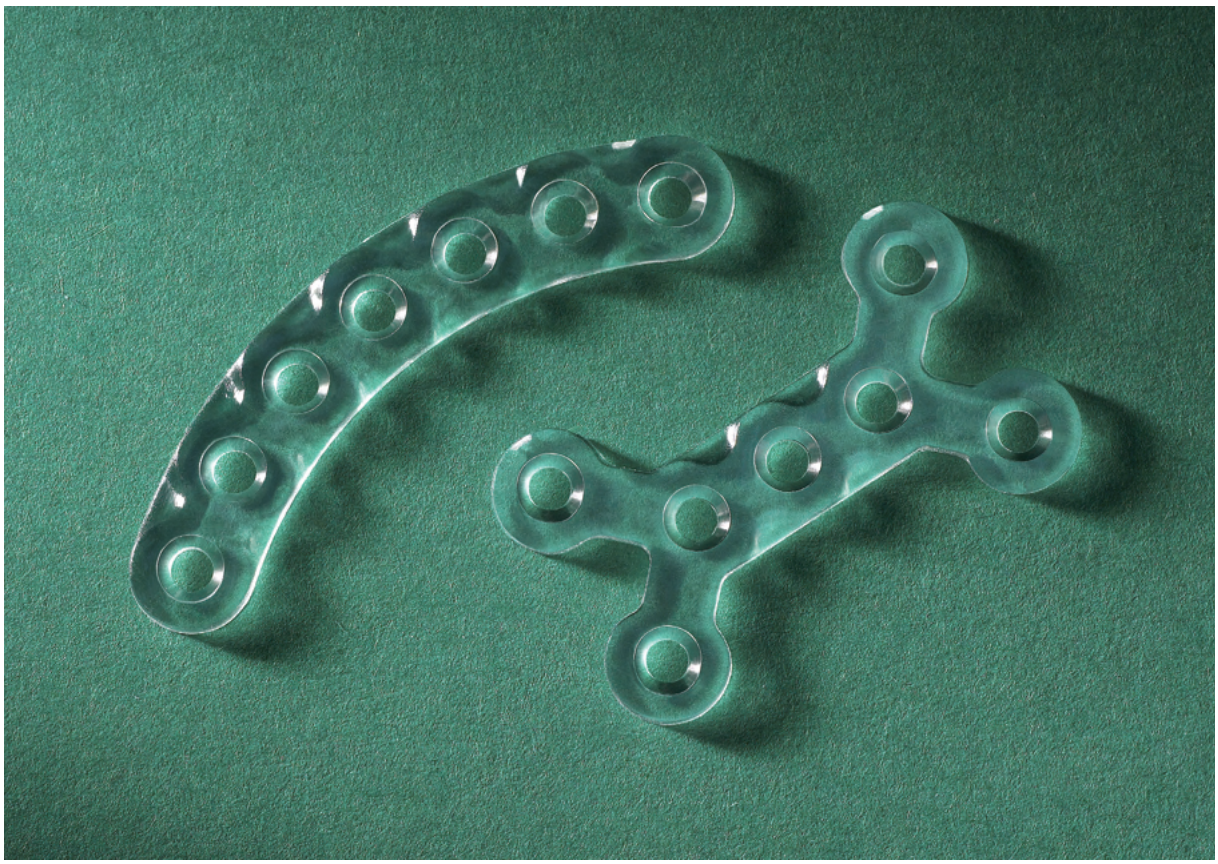


Fast and easy to use techniques

- Manual tap method
- Self-drilling bone tap method (self-drilling tap for 1.5 mm and 2.0 mm screws)
- Self-tapping screws (1.5 / 2.0mm screws thin monocortical applications)

Innovative screw solutions

- Fine screw threads provide maximum engagement in cortical bone
- Monocortical screws are packaged in a convenient screw ring (5 + 1 emergency screw included in 1.5 / 2.0 mm screw ring)
- Bicortical screws (2.0 / 2.5 / 2.8 mm) are packaged in an easy to use dispenser
- Universal screwdriver blade used for all Inion CPS™ screw sizes
- Simple and secure push-fit screw pick-up

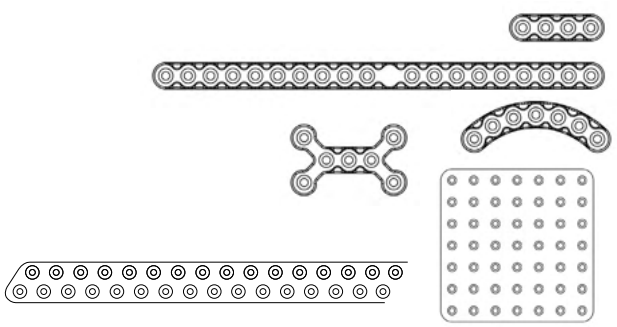


Inion CPS™ implants

Inion CPS™ Baby 1.5 mm System

For paediatric procedures, similar use to titanium 1.0-1.2 mm

Art. No.	Description
PLT-1000	4 hole plate
PLT-1001	20 hole plate (reinforced centre hole)
PLT-1002	C-plate, 7 holes
PLT-1003	X-plate, 7 holes
PLT-1028	Mesh plate, 7 x 7 holes
PLT-1029	Mesh plate, 14 x 14 holes
PLT-1059	64 hole plate



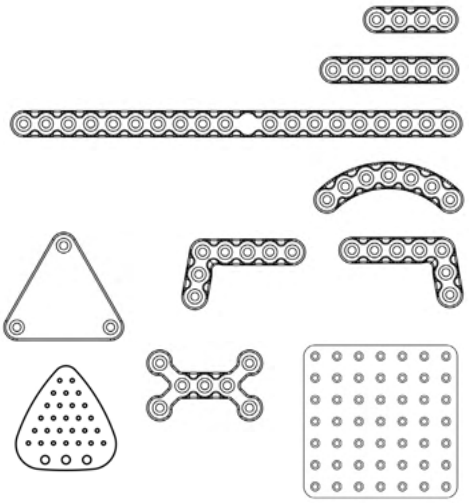
Screws

Art. No.	Description
SCR-1220	1.5 x 4 mm Screw Ring 5pcs (+ one 2.0 x 5 mm emerg.)
SCR-1221	1.5 x 6 mm Screw Ring 5pcs (+ one 2.0 x 7 mm emerg.)

Inion CPS™ 1.5 mm System

For cranial and midface fixation, similar use to titanium 1.0-1.2 mm

Art. No.	Description
PLT-1005	4 hole plate
PLT-1006	6 hole plate
PLT-1007	20 hole plate (reinforced centre hole)
PLT-1008	C-plate, 7 holes
PLT-1009	L-plate, right, 7 holes (on the left)
PLT-1010	L-plate, left, 7 holes (on the right)
PLT-1011	Burrhole plate
PLT-1012	X-plate, 7 holes
PLT-1030	Mesh plate, 7 x 7 holes
PLT-1031	Mesh plate, 14 x 14 holes
PLT-1081	Orbital plate, 25 x 24mm
PLT-1083	Orbital plate, 30 x 28mm



Screws

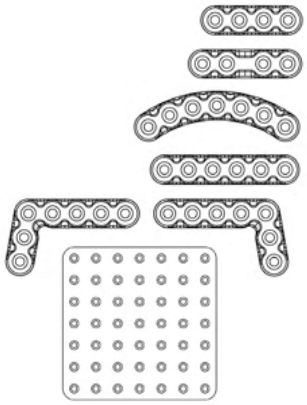
Art. No.	Description
SCR-1222	1.5 x 4 mm Screw Ring 5pcs (+ one 2.0 x 5 mm emerg.)
SCR-1223	1.5 x 6 mm Screw Ring 5pcs (+ one 2.0 x 7 mm emerg.)

Inion CPS™ implants

Inion CPS™ 2.0 mm System

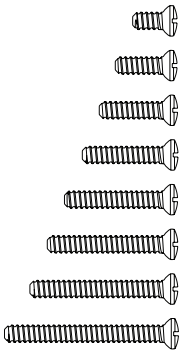
For midface, mandibular and orthognathic fixation, similar us e to titanium 1.5-1.7 mm

Art. No.	Description
PLT-1013	4 hole plate
PLT-1014	4 hole plate, extended
PLT-1017	C-plate, 7 holes
PLT-1038	Orthognathic 6 hole plate
PLT-1039	Orthognathic L-plate, right, 7 holes (on the left)
PLT-1040	Orthognathic L-plate, left, 7 holes (on the right)
PLT-1032	Mesh plate, 7 x 7 holes



Screws

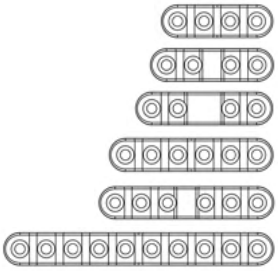
Art. No.	Description
SCR-1224	2.0 x 5 mm Screw Ring 5pcs (+ one 2.5 x 6 mm emerg.)
SCR-1225	2.0 x 7 mm Screw Ring 5pcs (+ one 2.5 x 8 mm emerg.)
SCR-1284	2.0 x 9 mm 2 Screws / box
SCR-1285	2.0 x 11 mm 2 Screws / box
SCR-1286	2.0 x 13 mm 2 Screws / box
SCR-1287	2.0 x 15 mm 2 Screws / box
SCR-1288	2.0 x 17 mm 2 Screws / box
SCR-1289	2.0 x 20 mm 2 Screws / box



Inion CPS™2.5 mm System

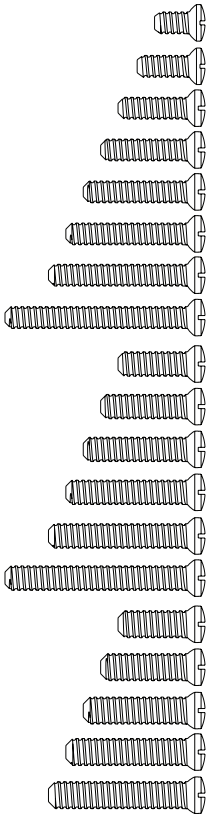
For mandibular fixation, similar use to titanium 2.0-2.4 mm

Art. No.	Description
PLT-1023	4 hole plate
PLT-1024	4 hole plate, extended
PLT-1041	4 hole plate, extended long
PLT-1025	6 hole plate
PLT-1026	6 hole plate, extended
PLT-1036	10 hole plate



Screws

Art. No.	Description
SCR-1206	2.5 x 6 mm Screw Ring 5pcs
SCR-1207	2.5 x 8 mm Screw Ring 5pcs
SCR-1290	2.5 x 10 mm 2 Screws / box
SCR-1291	2.5 x 12 mm 2 Screws / box
SCR-1292	2.5 x 14 mm 2 Screws / box
SCR-1293	2.5 x 16 mm 2 Screws / box
SCR-1294	2.5 x 18 mm 2 Screws / box
SCR-1208	2.5 x 23 mm 1 Screw / box
SCR-1297	2.8 x 10 mm 2 Screws / box
SCR-1298	2.8 x 12 mm 2 Screws / box
SCR-1299	2.8 x 14 mm 2 Screws / box
SCR-1300	2.8 x 16 mm 2 Screws / box
SCR-1301	2.8 x 18 mm 2 Screws / box
SCR-1209	2.8 x 23 mm 1 Screw / box
SCR-1226	3.1 x 10 mm 1 Screw / box
SCR-1227	3.1 x 12 mm 1 Screw / box
SCR-1228	3.1 x 14 mm 1 Screw / box
SCR-1229	3.1 x 16 mm 1 Screw / box
SCR-1230	3.1 x 18 mm 1 Screw / box



Inion CPS™ instruments

1.5 mm Instruments **Colour Code**

Art. No.	Description	Length (mm)	Coupling
INS-9116	1.2 mm drill bit short with 5 mm stop	50	J-latch
INS-9002	1.2 mm drill bit with 5 mm stop	70	J-latch
INS-9027	1.5 mm bone tap with 6 mm stop	70	Manual
INS-9263	1.5 mm self-drilling bone tap	70	Manual
INS-9047	Counter sink 1.5/2.0 mm	70	Manual

2.0 mm Instruments **Colour Code**

Art. No.	Description	Length (mm)	Coupling
INS-9001	1.6 mm drill bit short with 7 mm stop	50	J-latch
INS-9003	1.6 mm drill bit with 7 mm stop	70	J-latch
INS-9030	2.0 mm bone tap with 7 mm stop	70	Manual
INS-9004	1.6 mm drill bit with 22 mm stop	70	J-latch
INS-9060	2.0 mm bone tap with 22 mm stop	70	Manual
INS-9006	1.6 mm drill bit long with 10 mm stop	120	J-latch
INS-9107	2.0 mm bone tap long with 10 mm stop	120	Manual
INS-9264	2.0 mm self-drilling bone tap	70	Manual
INS-9047	Counter sink 1.5/2.0 mm	70	Manual

2.5 mm Instruments **Colour Code**

Art. No.	Description	Length (mm)	Coupling
INS-9009	2.10 mm drill bit short with 8 mm stop	50	J-latch
INS-9011	2.10 mm drill bit with 11 mm stop	70	J-latch
INS-9103	2.5 mm bone tap with 10 mm stop	70	Manual
INS-9012	2.10 mm drill bit long	120	J-latch
INS-9031	2.5 mm bone tap	70	Manual
INS-9033	2.5 mm bone tap long	120	Manual
INS-9048	Counter sink 2.5/2.8/3.1 mm	105	Manual

2.8 mm Instruments **Colour Code**

Art. No.	Description	Length (mm)	Coupling
INS-9014	2.35 mm drill bit long	120	J-latch
INS-9034	2.8 mm bone tap long	120	Manual
INS-9048	Counter sink 2.5/2.8/3.1 mm	105	Manual

3.1 mm Instruments **Colour Code**

Art. No.	Description	Length (mm)	Coupling
INS-9016	2.65 mm drill bit long	120	J-latch
INS-9032	3.1 mm bone tap long	120	Manual
INS-9048	Counter sink 2.5/2.8/3.1 mm	105	Manual

Universal Instruments

Art. No.	Description	Length (mm)	Coupling
INS-9029	Universal screwdriver blade	70	Manual
INS-9040	Universal screwdriver blade long	120	Manual
INS-9007	Universal screwdriver handle (Manual Coupling)		
INS-9024	Plate bending pliers		
INS-9046	Transbuccal trocar set complete (containing INS-9042, INS-9043, INS-9044, INS-9045, INS-9068)		
INS-9109	Screw cutting pliers		
INS-9110	Scale 1.5 mm-3.1 mm		
INS-9091	Depth Gauge 2.0 mm - 3.1 mm		
ACC-9801	Inion Thermo™ (water bath 230v)		
ACC-9804	Inion Thermo™ (water bath 110v)		
ACC-9802	Inion Thermo™ drape		
ACC-9813	Inion universal instrument tray		
ACC-9818	Inion compact instrument tray		

Key evidence

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