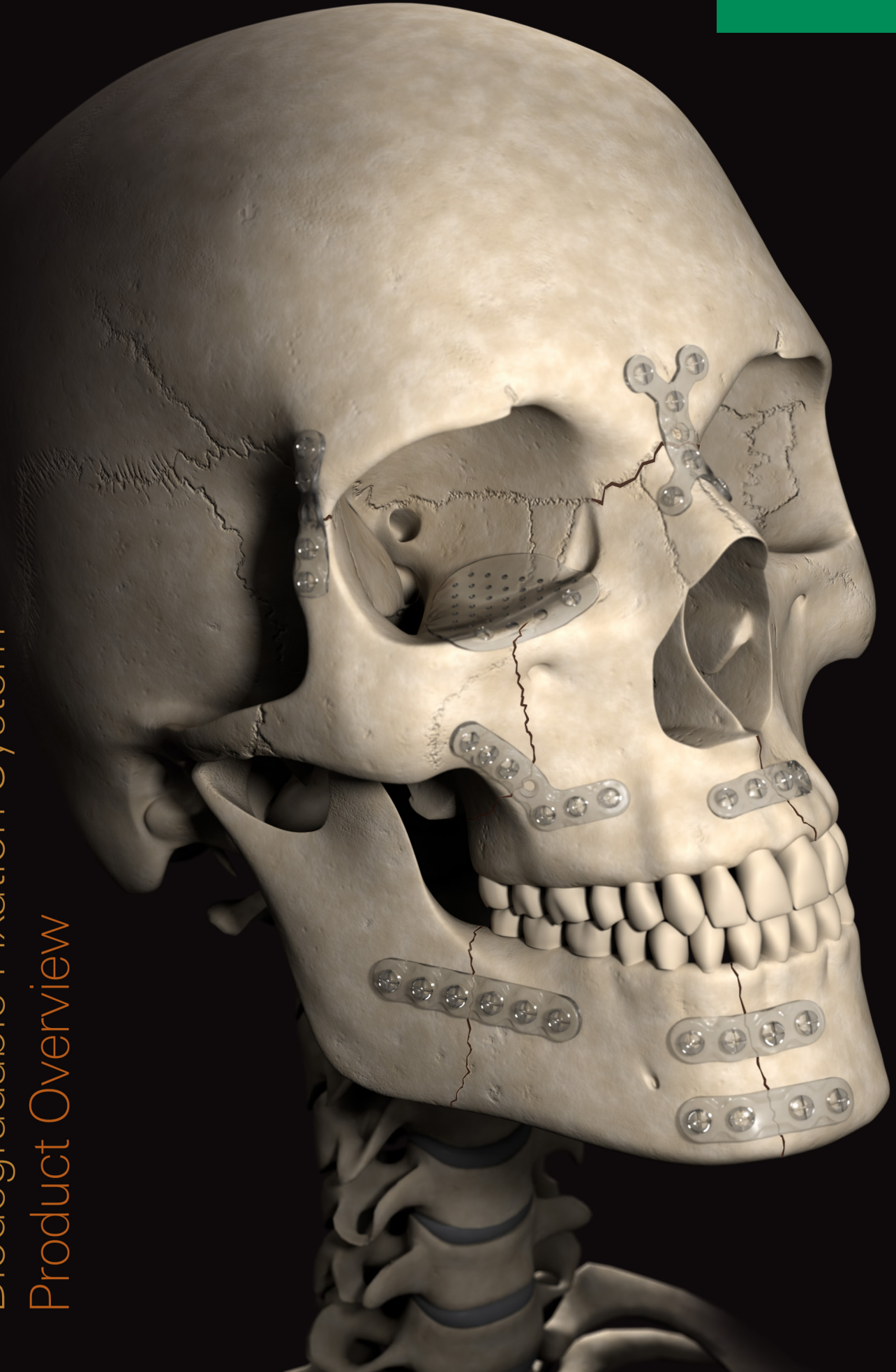


Inion CPS[®]

INION

Biodegradable Fixation System
Product Overview

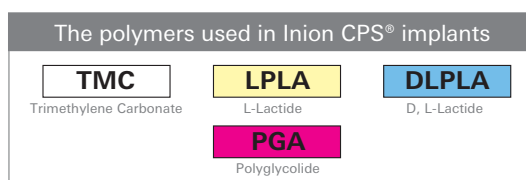


Material advantage

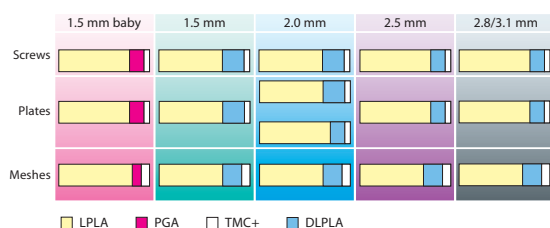
What are the Inion® biodegradable implants made from?

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

The Inion® biodegradable 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® biodegradable polymers are amorphous, degrade in vivo by hydrolysis and are metabolised by the body into CO₂ 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.

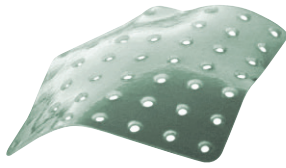
Inion CPS® Baby implants, specifically designed for pediatric patients, retain minimum of 70 % of their initial strength 6 weeks after implantation. Bioresorption takes place within two to three years.

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

Inion® biodegradable polymer advantage

- Inion CPS® implants are biodegradable. 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

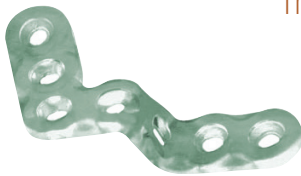


1.5 mm CPS BABY SYSTEM
For paediatric craniofacial procedures
(similar use to titanium 1.0 - 1.2 mm)
Strength retention is minimum 6 weeks



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 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 biodegradable CMF system with applications for all areas of the facial skeleton, and comprises a range of biodegradable plates, screws and mesh for use in children and adults.

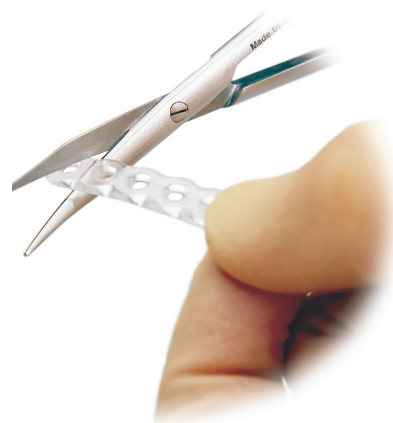
Clinical advantages

Since their introduction in 2001, the Inion CPS® implants have been used successfully in more than 60,000 operations by an increasing number of physicians.

- Most comprehensive biodegradable plating system available - the only one comparable to titanium in its scope of use
- Quick and easy to use
- Avoidance of removal surgery reducing patient trauma and cost
- Unlike other biodegradables 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



3

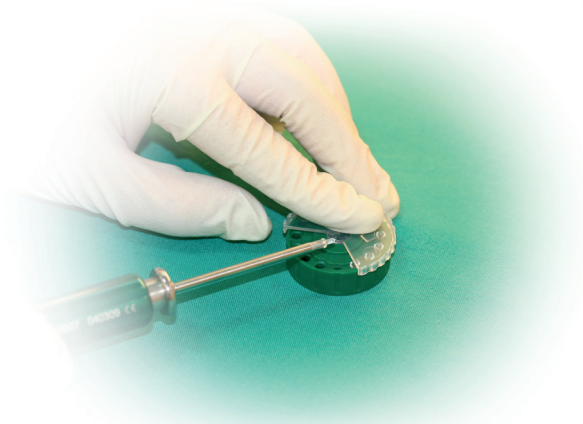
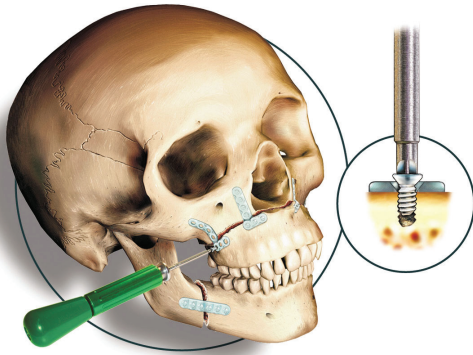
Plate characteristics

- Patented 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

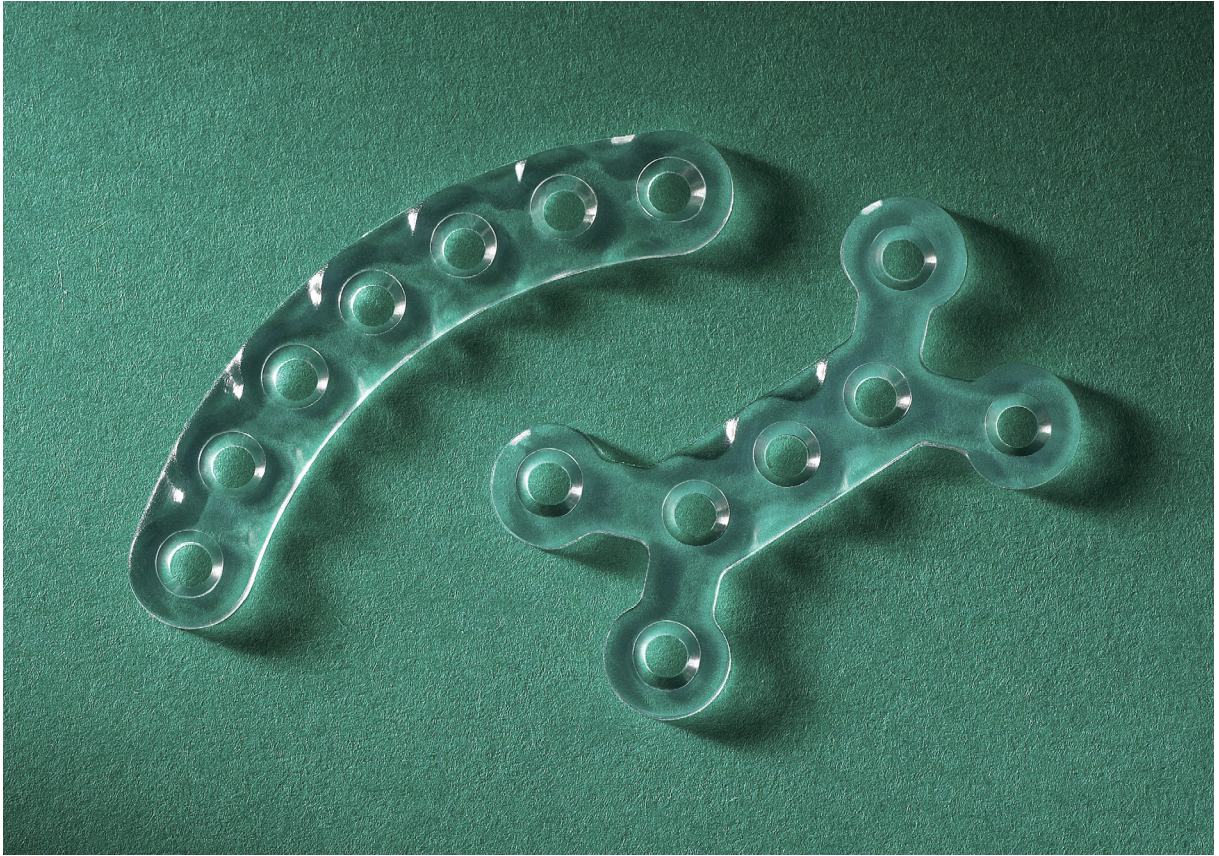


Fast and easy to use techniques

- 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



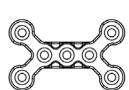

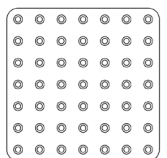
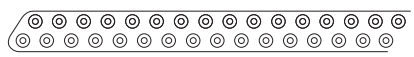
- Fine screw threads provide maximum engagement in cortical bone
- Monocortical screws are packaged in a convenient screw ring (5 + 1 emergency screw included in 1.5 / 2.0 mm screw ring)
- Bicortical screws (2.0 / 2.5 / 2.8 mm) are packaged in an easy to use dispenser
- Universal screwdriver blade used 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







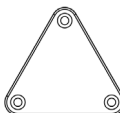
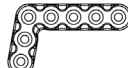

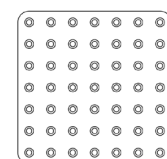
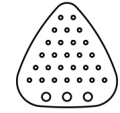
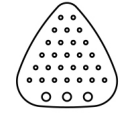
Art. No.	Description	
PLT-1000	4 hole plate	
PLT-1001	20 hole plate (reinforced centre hole)	
PLT-1002	C-plate, 7 holes	
PLT-1003	X-plate, 7 holes	
PLT-1028	Mesh plate, 7 x 7 holes	
PLT-1029	Mesh plate, 14 x 14 holes	
PLT-1059	64 hole plate	

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.)	
SCR-1210	2.0 x 5 mm Screw Ring 5pcs	
SCR-1211	2.0 x 7 mm Screw Ring 5pcs	

Inion CPS® 1.5 mm System

For cranial and mid face 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

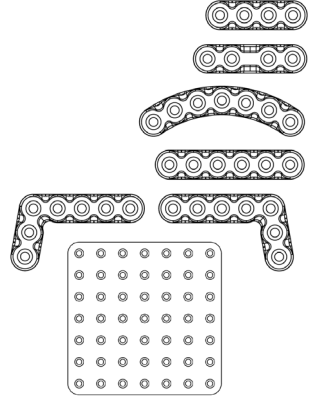
Art. No.	Description	
SCR-1222	1.5 x 4 mm Screw Ring 5pcs (+ one 2.0 x 5 mm emerg.)	
SCR-1223	1.5 x 6 mm Screw Ring 5pcs (+ one 2.0 x 7 mm emerg.)	

Inion CPS® implants

Inion CPS® 2.0 mm System

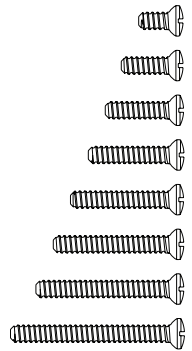
For midface and orthognathic fixation, similar us e to titanium 1.5-1.7 mm

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














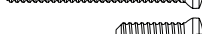







Inion CPS® 2.5 mm System

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	



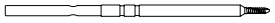


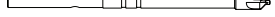
Screws

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


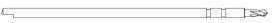
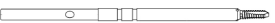

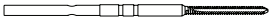
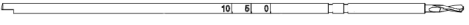
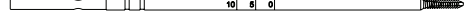


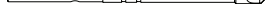
1.5 mm Instruments

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-9261	1.5 mm self-drilling bone tap	70	Pentagonal	
INS-9263	1.5 mm self-drilling bone tap	70	Manual	
INS-9047	Counter sink 1.5/2.0 mm	70	Manual	



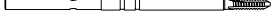
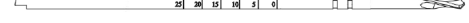

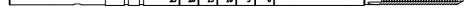

2.0 mm Instruments

Colour Code 

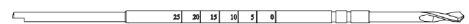
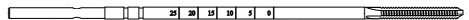
Art. No.	Description	Length (mm)	Coupling	
INS-9001	1.6 mm drill bit short with 7 mm stop	50	J-latch	
INS-9003	1.6 mm drill bit with 7 mm stop	70	J-latch	
INS-9030	2.0 mm bone tap with 7 mm stop	70	Manual	
INS-9004	1.6 mm drill bit with 22 mm stop	70	J-latch	
INS-9060	2.0 mm bone tap with 22 mm stop	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-9262	2.0 mm self-drilling bone tap	70	Pentagonal	
INS-9264	2.0 mm self-drilling bone tap	70	Manual	
INS-9047	Counter sink 1.5/2.0 mm	70	Manual	

Mandibular System Instruments

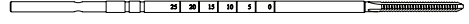
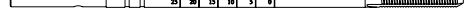
Colour Code 

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	

Colour Code 

INS-9014	2.35 mm drill bit long	120	J-latch	
INS-9034	2.8 mm bone tap long	120	Manual	

Colour Code 

INS-9016	2.65 mm drill bit long	120	J-latch	
INS-9032	3.1 mm bone tap long	120	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		
PDS-5000-1	Pro-Driver, Pro-Dex surgical driver (Pentagonal Coupling)		
PDBP-001-2	Pro-Dex, Single Pouch Battery pack X 1		



Key evidence

Baek RM, Min KH, Heo CY, Eun SC. The perilobule approach to subcondylar fractures. *Ann Plast Surg*. 2011 Mar;66(3):253-6.

Ballon A, Laudemann K, Sader R, Landes CA. Patients' preoperative expectations and postoperative satisfaction of dysgnathic patients operated on with resorbable osteosyntheses. *J Craniofac Surg*. 2011 Mar;22(2):730-4.

Ballon A, Laudemann K, Sader R, Landes CA. Segmental stability of resorbable P(L/DL)LA-TMC osteosynthesis versus titanium miniplates in orthognathic surgery. *J Craniomaxillofac Surg*. 2012 Apr 12.

Bayat M, Garajei A, Ghorbani K, Motamedi MH. Treatment of mandibular angle fractures using a single bioresorbable miniplate. *J Oral Maxillofac Surg*. 2010 Jul;68(7):1573-7.

Blakey GH, Rossouw E, Turvey TA, Phillips C, Proffit WR, White PR: Are bioresorbable polylactate devices comparable to titanium devices for stabilizing Le Fort I advancement?. *Int J Oral Maxillofac Surg*. 2014 APR;43(4):437-44.

Cheung LK, Yip IH, Chow RL. Stability and morbidity of Le Fort I osteotomy with bioresorbable fixation: a randomized controlled trial. *Int J Oral Maxillofac Surg*. 2008 Mar;37(3):232-41.

Hormozi AK, Shahverdiani R, Mohammadi HR, Zali A, Mofrad HR. Surgical treatment of metopic synostosis. *J Craniofac Surg*. 2011 Jan;22(1):261-5.

Hwang K, You SH, Sohn IA. Analysis of orbital bone fractures: a 12-year study of 391 patients. *J Craniofac Surg*. 2009 Jul;20(4):1218-23.

Hwang K. Medial orbital wall reconstruction through subciliary approach: revisited. *J Craniofac Surg*. 2009 Jul;20(4):1280-2.

Hwang K, Kim DH, Park IS. A use of poly-L-lactide, D-lactide sheet on posterior orbital floor fracture. *J Craniofac Surg*. 2010 Jul;21(4):1221-3.

Hwang K, Kim DH. Comparison of the supporting strength of a poly-L-lactic acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures. *J Craniofac Surg*. 2010 May;21(3):847-53.

Iatrou I, Theologie-Lygidakis N, Tzerbos F, Alexandridis K. The use of biodegradable plates in oral and maxillofacial surgery in children. The XVIIIth Congress of the European Association for Cranio-Maxillofacial Surgery, Barcelona, Spain, September 12-15, 2006. / *Journal of Cranio-Maxillofacial Surgery* 34 (Suppl. 1): 67, 2006.

Kim CY, Kim KW. Fractured facial bone reduction and resorbable plate fixation using tapper. *J Craniofac Surg*. 2011 Jul;22(4):1215-8.

Laughlin RM, Block MS, Wilk R, Malloy RB, Kent JN. Resorbable plates for the fixation of mandibular fractures: A prospective study. *J Oral Maxillofac Surg* 65: 89-96, 2007.

Lee JH, Kim SM, Lee BK, Jeon JH, Kim MJ. 3D vector analysis of mandibular condyle stability in mandibular setback surgery with bicortical bioabsorbable screw fixation. *J Craniomaxillofac Surg*. 2014 Jul;42(5):e105-10.

Leonhardt H, Demmrich A, Mueller A, Mai R, Loukota R, Eckelt U. INION compared with titanium osteosynthesis: a prospective investigation of the treatment of mandibular fractures. *Br J Oral Maxillofac Surg*. 2008 Dec;46(8):631-4.

Lim HY, Jung CH, Kim SY, Cho JY, Ryu JY, Kim HM. Comparison of resorbable plates and titanium plates for fixation stability of combined mandibular symphysis and angle fractures. *J Korean Assoc Oral Maxillofac Surg*. 2014 Dec;40(6):285-90.

Losken HW, van Aalst JA, Mooney MP, Godfrey VL, Burt T, Teotia S, Dean SB, Moss JR, Rahbar R. Biodegradation of Inion fast-absorbing biodegradable plates and screws. *J Craniofac Surg*. 2008 May;19(3):748-56.

Nieminen T, Rantala I, Hiidenheimo I, Keränen J, Kainulainen H, Wuolijoki E, Kallela I. Degradative and mechanical properties of a novel resorbable plating system during a 3-year follow-up in vivo and in vitro. *J Mater Sci Mater Med*. 2008 Mar;19(3):1155-63.

Paeng JY, Hong J, Kim CS, Kim MJ. Comparative study of skeletal stability between bicortical resorbable and titanium screw fixation after sagittal split ramus osteotomy for mandibular prognathism. *J Craniomaxillofac Surg*. 2011 Dec 28.

Sadigh PL, Chang LR, Feng KM, Jeng SF. The "In Situ Molding Technique:" An Accurate and Simple Way to Fix Resorbable Plates to the Facial Skeleton. *J Craniofac Surg* 2014 Sep;25(5):1766-8.

Salokorpi N, Sinikumpu JJ, Iber T, Zibo HN, Areda T, Ylikontiola L, Sandor GK, Serlo W. Frontal cranial modeling using endocranial resorbable plate fixation in 27 consecutive plagiocephaly and trigonocephaly patients. *Childs Nerv Syst*. 2015 Jul;31(7):1121-8.

Serlo WS, Ylikontiola LP, Vesala A-L, Kaarela OI, Iber T, Sándor GKB, Ashammakhi N. Effective correction of frontal cranial deformities using biodegradable fixation on the inner surface of the cranial bones during infancy. *Childs Nerv Syst* (2007) 23:1439-1445.

Singh V, Sharma B, Bhagol A. Evaluating the applicability of a biodegradable osteosynthesis plating system in the management of zygomatico-maxillary complex fractures. *Otolaryngol Head Neck Surg*. 2011 Dec;145(6):924-9.

Turvey TA, Proffit WP, Phillips C. Biodegradable fixation for craniomaxillofacial surgery: a 10-year experience involving 761 operations and 745 patients. *Int J Oral Maxillofac Surg*. 2011 Mar;40(3):244-9.

van Bakelen NB, Boermans BD, Buijs GJ, Jansma J, Pruim GJ, Hoppenreijts TJ, Bergsma JE, Stegenga B, Bos RR. Comparison of the long-term skeletal stability between a biodegradable and a titanium fixation system following BSSO advancement – A cohort study based on a multicentre randomised controlled trial. *Br J Oral Maxillofac Surg*. 2014 Oct;52(8):721-8.

Vázquez-Morales DE, Dyalram-Silverberg D, Lazow SK, Berger JR. Treatment of mandible fractures using resorbable plates with a mean of 3 weeks maxillomandibular fixation: a prospective study. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2012 Aug 23.

You JP, Kim DW, Jeon BJ, Jeong SH, Han SK, Dhong ES, Kim WK. Two-Year Follow-up on the Use of Absorbable Mesh Plates in the Treatment of Medial Orbital Wall Fractures. *Arch Plast Surg*. 2013 Nov;40(6):728-34.

Yu S, Bloomquist D. Can resorbable screws effectively be used in fixing bilateral sagittal split osteotomies for mandibular advancement? A randomized controlled trial. *J Oral Maxillofac Surg*. 2014 Nov; 72(11):2273-7.



INION OY
Lääkärintätkä 2
FI-33520 Tampere, FINLAND
tel: +358-10-830 6600
fax: +358-10-830 6601
email: info@inion.com
internet: www.inion.com

INION INC
2800 Glades Circle
Suite 138, Weston
FL 33327
USA
Toll-free tel: 866-INION-US
tel: 954-659-9224 fax: 954-659-7997