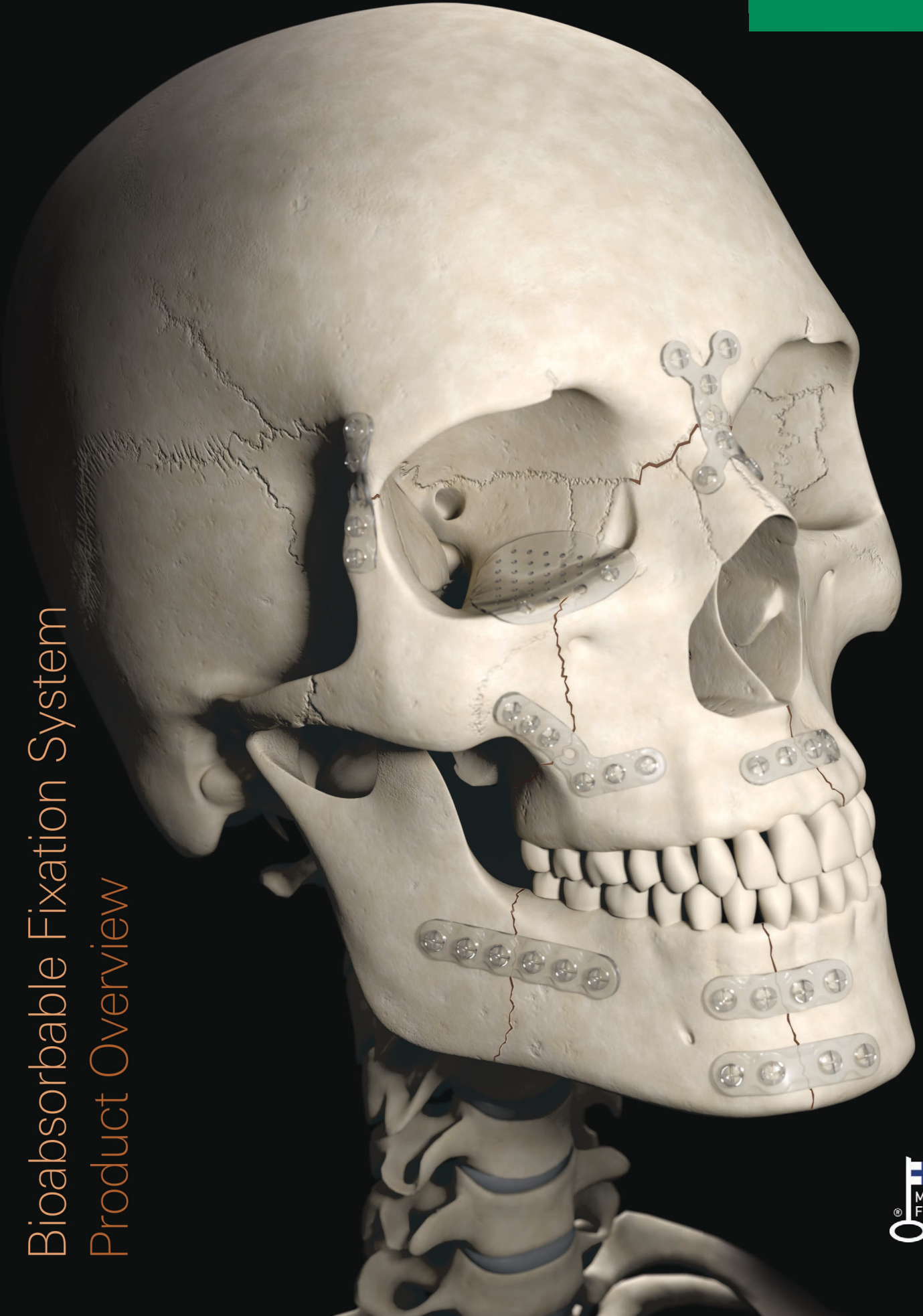


Inion CPS™

INION

Bioabsorbable Fixation System
Product Overview

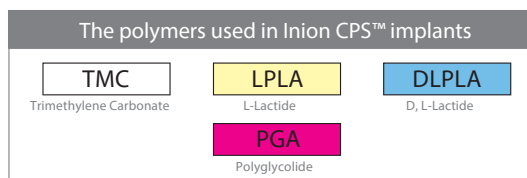


Material advantage

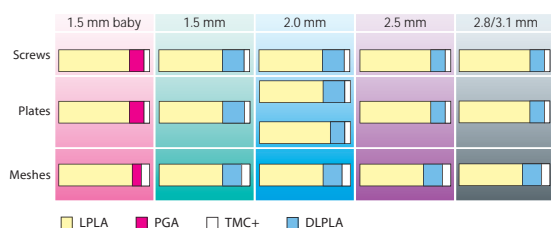
What are the Inion® bioabsorbable implants made from?

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.



FDA cleared and CE-marked

Inion CPS™ and Inion CPS™ Baby implants are FDA cleared and CE-marked medical devices, manufactured by Inion Oy. The conformity assessment was conducted by BSI The Netherlands (CE 2797).

The degradation profile

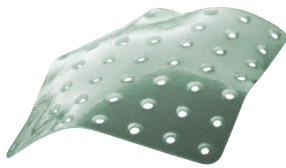
Inion® bioabsorbable polymers are amorphous, degrade in vivo by hydrolysis and are metabolised by the body into CO₂ and water. The degradation profiles have been tailored to provide initial stability and then progressively transfer the load to bone to aid bone regeneration. Mass loss occurs thereafter.

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.

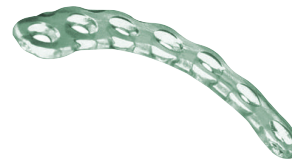
Inion CPS™ implants retain minimum of 70 % of their initial strength 9 weeks after implantation. Bioresorption takes place within two to four years.

Inion® 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

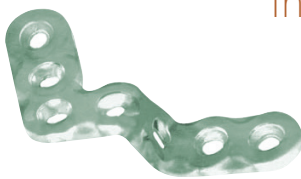


1.5 mm CPS BABY SYSTEM
For paediatric craniofacial procedures
(similar use to titanium 1.0 - 1.2 mm)
Strength retention is minimum 6 weeks



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 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 of 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 150,000 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 systems, 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

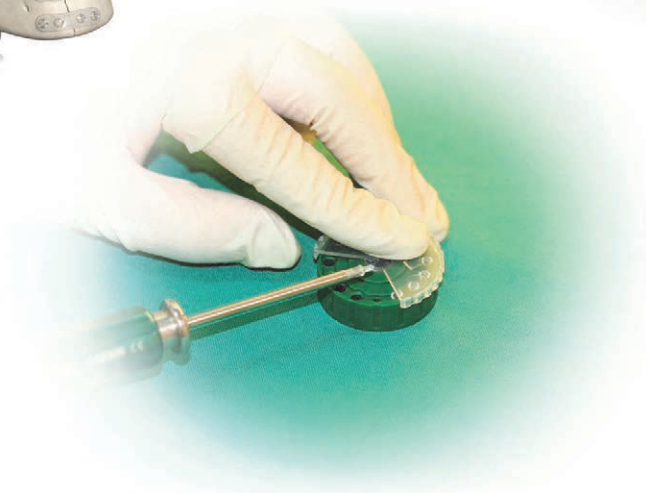
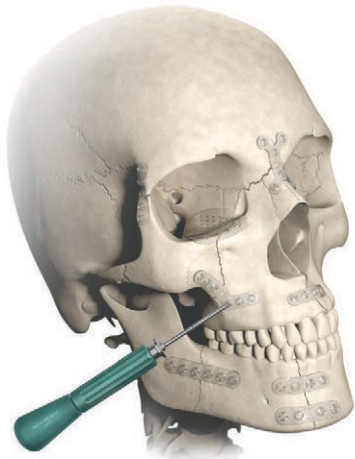
Plate characteristics

- 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

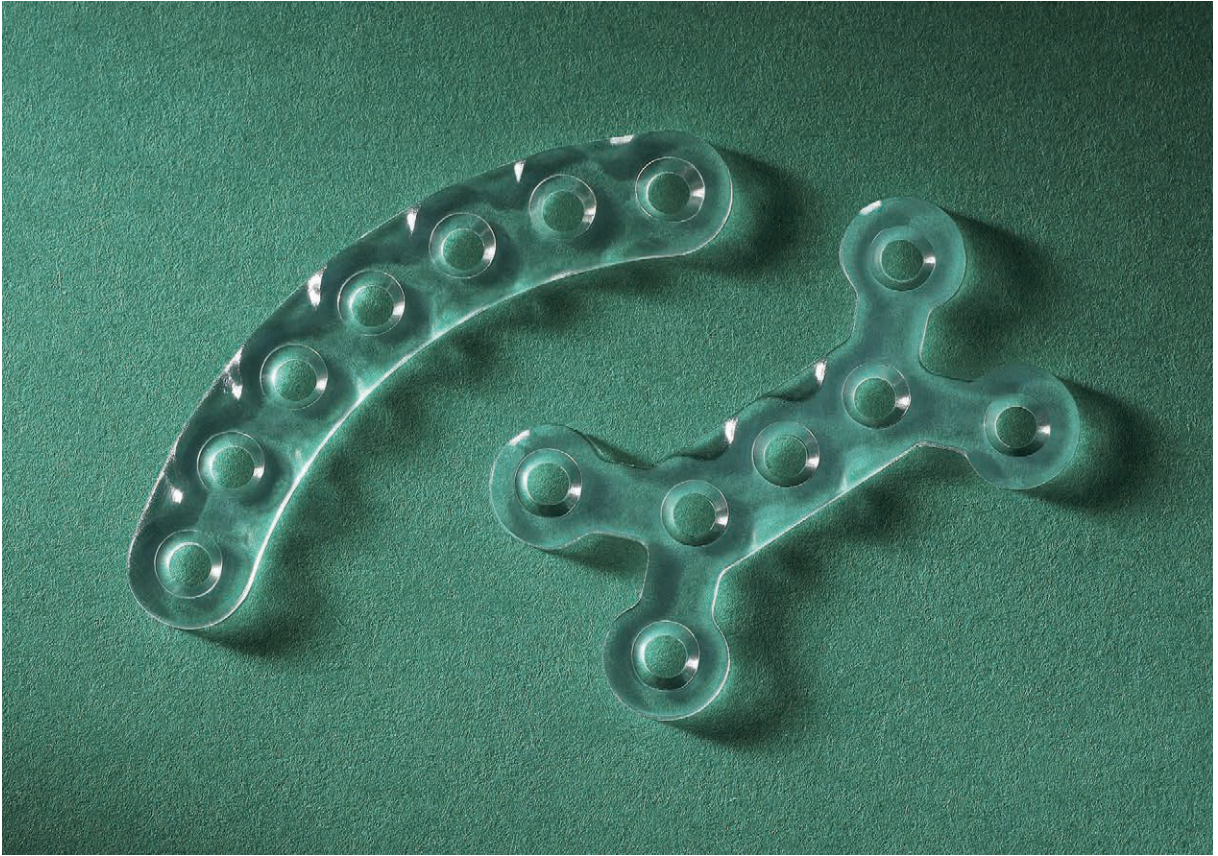


Fast and easy to use techniques

- Manual tap method
- 1.5 / 2.0 mm screws for thin monocortical applications in soft bone without tapping

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

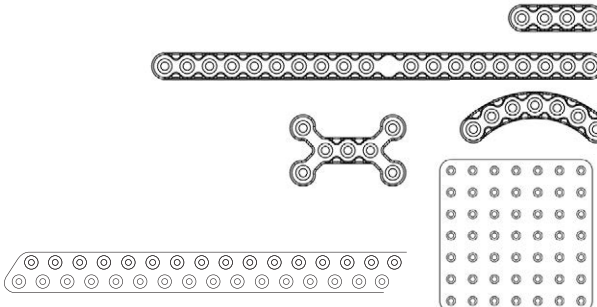


Inion CPS™ Implant Overview

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

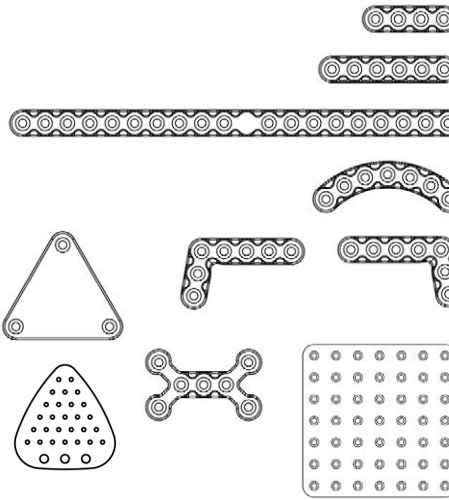
Art. No.	Description
SCR-1220	1.5 x 4 mm Screw Ring 5 pcs (+ one 2.0 x 5 mm emerg.)
SCR-1221	1.5 x 6 mm Screw Ring 5 pcs (+ one 2.0 x 7 mm emerg.)



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
PLT-1087	Orbital sheet 40x40 mm, anatomic



Screws

Art. No.	Description
SCR-1222	1.5 x 4 mm Screw Ring 5 pcs (+ one 2.0 x 5 mm emerg.)
SCR-1223	1.5 x 6 mm Screw Ring 5 pcs (+ one 2.0 x 7 mm emerg.)
SCR-2222	1.5 x 4 mm Screw Ring 2 pcs
SCR-2223	1.5 x 6 mm Screw Ring 2 pcs



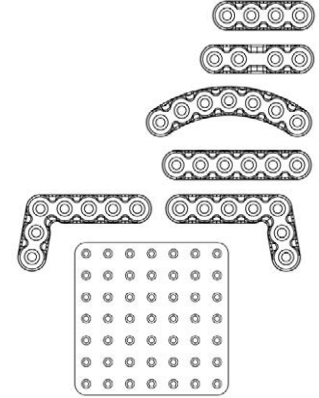
Please confirm up-to-date product availability with Inion Sales.

Inion CPS™ Implant Overview

Inion CPS™ 2.0 mm System

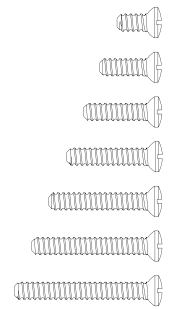
For midface, mandibular and orthognathic fixation, similar use to titanium 1.5-1.7 mm

Art. No.	Description
PLT-1013	4 hole plate
PLT-1014	4 hole plate, extended
PLT-1016	10 hole plate
PLT-1017	C-plate, 7 holes
PLT-1032	Mesh plate, 7 x 7 holes
PLT-1033	Mesh plate 14 x14 holes
PLT-1037	X-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)



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-2224	2.0 x 5 mm Screw Ring 2pcs
SCR-2225	2.0 x 7 mm Screw Ring 2pcs
SCR-1284	2.0 x 9 mm 2 Screws / pack
SCR-1285	2.0 x 11 mm 2 Screws / pack
SCR-1286	2.0 x 13 mm 2 Screws / pack
SCR-1287	2.0 x 15 mm 2 Screws / pack
SCR-1289	2.0 x 20 mm 2 Screws / pack



Inion CPS™ Implant Overview

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-1025	6 hole plate	
PLT-1026	6 hole plate, extended	
PLT-1036	10 hole plate	


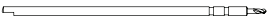
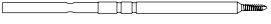


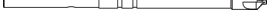
Screws

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 / pack	
SCR-1291	2.5 x 12 mm 2 Screws / pack	
SCR-1294	2.5 x 18 mm 2 Screws / pack	
SCR-1301	2.8 x 18 mm 2 Screws / pack	
SCR-1230	3.1 x 18 mm Single screw	

Inion CPS™ Instrument Overview

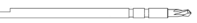




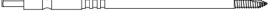

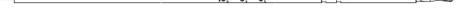
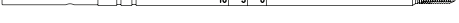
1.5 mm Instruments

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	



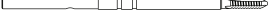
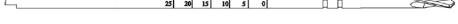

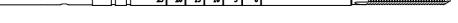

2.0 mm Instruments

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-9004	1.6 mm drill bit with 22 mm stop	70	J-latch	
INS-9030	2.0 mm bone tap with 7 mm stop	70	Manual	
INS-9060	2.0 mm bone tap with 22 mm stop	70	Manual	
INS-9262	2.0 mm self-drilling bone tap	70	Pentagonal	
INS-9264	2.0 mm self-drilling bone tap	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	

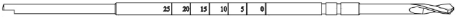
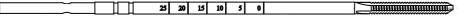

2.5 mm Instruments

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	

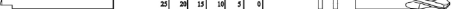
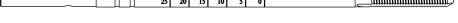

2.8 mm Instruments

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

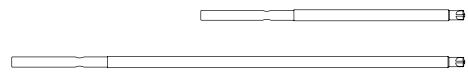
Colour Code 

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	

Inion CPS™ Instrument Overview

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)		
IFS-9051	Screw cutting pliers		
IFS-9052	Scale for \varnothing 3.2 mm screws (used together with IFS-9051)		
INS-9091	Depth gauge 2.0 mm - 3.1 mm		
INS-9119	Depth gauge 1.5 mm		
ACC-9801	Inion Thermo™ (water bath 230v)		
ACC-9804	Inion Thermo™ (water bath 110v)		
ACC-9802	Inion Thermo™ drape 5pcs		
ACC-9813	Inion universal instrument tray		
ACC-9818	Inion compact instrument tray		



Key evidence

Ali AA, Kabbash MM, Said S, Shoeib MA, Osman MH. Use of biodegradable plates and screws in the treatment of pediatric facial bone fractures. *Egyptian J Oral & Maxillofacial Surg.* 2016 Oct 1;7(3):86-93.

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 Craniocfac 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 Craniocfac 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 Craniocfac Surg.* 2009 Jul;20(4):1218-23.

Hwang K. Medial orbital wall reconstruction through subciliary approach: revisited. *J Craniocfac 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 Craniocfac 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 Craniocfac 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 Craniocfac 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 Craniocfac 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.

Reilly FO, Clinton S, Dillon P, Carr S, Bracken S, Caird J, Murray DJ. Examining the relationship between wound complications and the use of resorbable plates in cranial vault reconstruction. *J Craniocfac Surg.* 2021 Oct 1;32(7):2310-3.

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 Craniocfac 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 M, Singh RK, Passi D, Aggarwal M, Kaur G. Management of pediatric mandibular fractures using bioresorbable plating system—Efficacy, stability, and clinical outcomes: Our experiences and literature review. *J Oral Biology and Craniocfacial Research.* 2016 May 1;6(2):101-6.

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
Lääkärintäti 2
FI-33520 Tampere
FINLAND
tel: +358-10-830 6600
email: info@inion.com
internet: www.inion.com

INION INC
37 North Orange Avenue, Suite 900C
Orlando, FL 32801
USA
Toll-free tel: 866-INION-US
tel: +1 954-659-9224
email: inion.us@inion.com