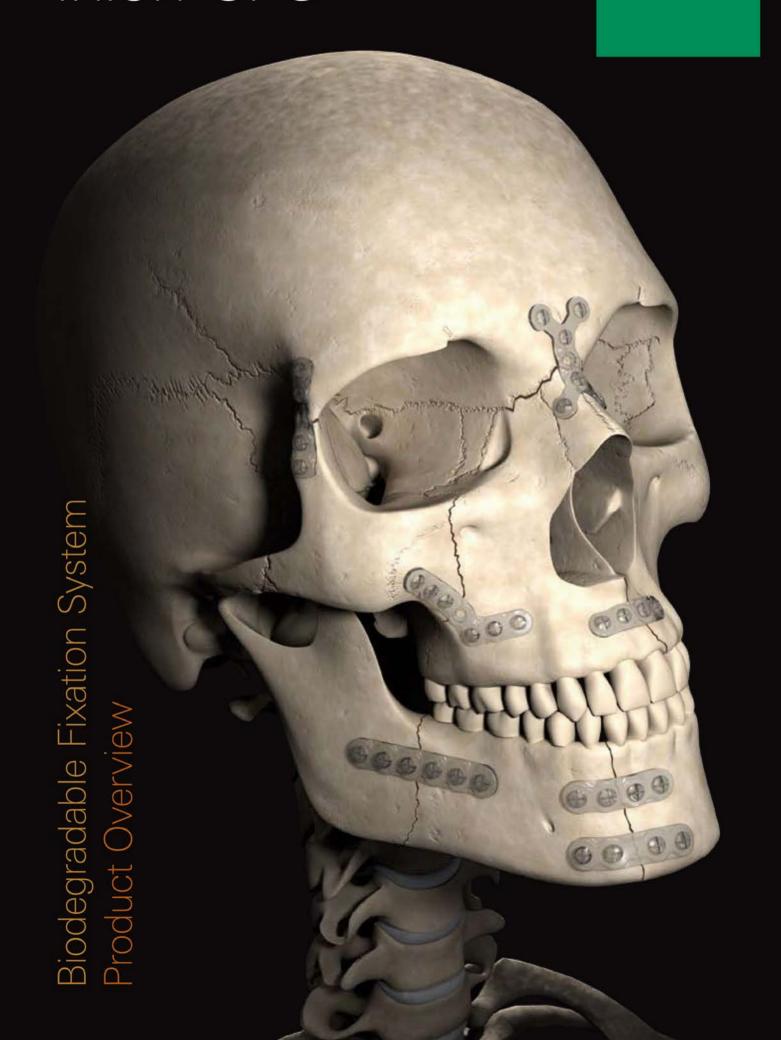
# Inion CPS®

## INION

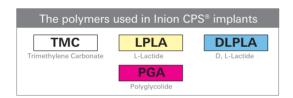


### Material advantage

## What are the Inion<sup>®</sup> 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 CO<sub>2</sub> 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<sup>™</sup> water bath

1

## 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 55 000 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 midface and maxilla
  - fractures and osteotomies of the mandible\*\*

 $<sup>\</sup>ensuremath{^{**}}$  in conjunction with appropriate maxilloman dibular fixation



#### Plate characteristics

- 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.



#### 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 (1.5/2.0 mm screws for 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



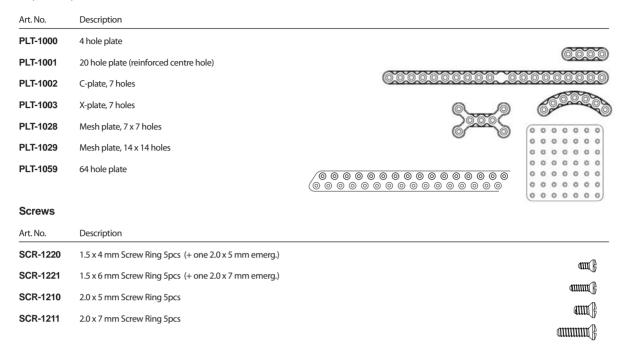




## Inion CPS® implants

#### Inion CPS® Baby 1.5 mm System

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



#### 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	00000
PLT-1083	Orbital plate, 30 x 28mm	0 0 0 0 0 0 0
Screws		
Art. No.	Description	
SCR-1222	$1.5 \times 4$ mm Screw Ring 5pcs (+ one $2.0 \times 5$ mm emerg.)	am (f
SCR-1223	$1.5 \times 6$ mm Screw Ring 5pcs (+ one $2.0 \times 7$ mm emerg.)	Ammin Ammin

## Inion CPS® implants

#### Inion CPS® 2.0 mm System

For midface 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-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	$2.0 \times 5$ mm Screw Ring 5pcs (+ one $2.5 \times 6$ mm emerg.)	A.
SCR-1225	$2.0 \times 7$ mm Screw Ring 5pcs (+ one $2.5 \times 8$ 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

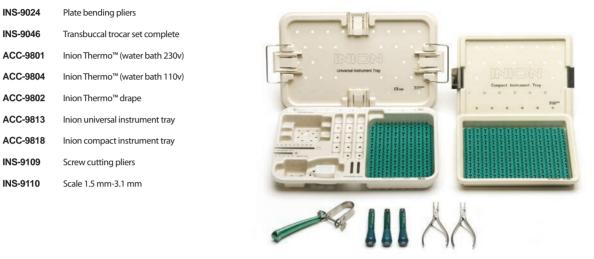
00.0		
Art. No.	Description	
SCR-1206	2.5 x 6 mm Screw Ring 5pcs	
SCR-1207	2.5 x 8 mm Screw Ring 5pcs	
SCR-1290	2.5 x 10 mm 2 Screws / box	
SCR-1291	2.5 x 12 mm 2 Screws / box	
SCR-1292	2.5 x 14 mm 2 Screws / box	
SCR-1293	2.5 x 16 mm 2 Screws / box	
SCR-1294	2.5 x 18 mm 2 Screws / box	
SCR-1208	2.5 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 Inst	ruments			Colour Code
Art. No.	Description	Length (mm)	Coupling	
INS-9116	1.2 mm drill bit short	50	J-latch	~
INS-9002	1.2 mm drill bit with 5 mm stop	70	J-latch	<u> </u>
INS-9027	1.5 mm bone tap	70	Manual	
INS-9047	Countersink 1.5/2.0 mm	70	Manual	
INS-9261	1.5 mm self-drilling bone tap	70	Pentagonal	
INS-9263	1.5 mm self-drilling bone tap	70	Manual	
2.0 mm Inst	ruments			Colour Code
Art. No.	Description	Length (mm)	Coupling	
INS-9117	1.75 mm drill bit short	50	J-latch	
INS-9010	1.75 mm drill bit with 6 mm stop	70	J-latch	<u> </u>
INS-9030	2.0 mm bone tap	70	Manual	Ţ, justini jus
INS-9055	1.75 mm drill bit with 22 mm stop	70	J-latch	
INS-9060	2.0 mm bone tap with 22 mm stop	70	Manual	
INS-9106	1.7 mm drill bit long with 10 mm stop	120	J-latch	10 5 0
INS-9107	2.0 mm bone tap long with 10 mm stop	120	Manual	10 5 0
INS-9047	Countersink 1.5/2.0 mm	70	Manual	
INS-9262	2.0 mm self-drilling bone tap	70	Pentagonal	
INS-9264	2.0 mm self-drilling bone tap	70	Manual	
2.5/2.8/3.1m	nm Instruments			Colour Code
Art. No.	Description	Length (mm)	Coupling	
INS-9118	2.25 mm drill bit short	50	J-latch	
INS-9015	2.25 mm drill bit with 7 mm stop	70	J-latch	
INS-9103	2.5 mm bone tap with 10 mm stop	70	Manual	
INS-9017	2.25 mm drill bit long	120	J-latch	
INS-9033	2.5 mm bone tap long	120	Manual	2 20 15 16 5 0
INS-9048	Countersink 2.5/2.8/3.1 mm	105	Manual	
INS-9022	2.5 mm drill bit long	120	J-latch	Colour Code
INS-9034	2.8 mm bone tap long	120	Manual	5 30 10 10 10
- 2				
				Colour Code
INS-9050	2.8 mm drill bit long	120	J-latch	25/ 20/ 15/ 10/ 10/ 10/ 10/ 10/ 10/ 10/ 10/ 10/ 10
INS-9032	3.1 mm bone tap long	120	Manual	22 20 15 10 5 0

#### **Universal Instruments**

Art. No.	Description	Length (mm)	Coupling	
INS-9029	Universal screwdriver blade	70	Manual	9
INS-9040	Universal screwdriver blade long	120	Manual	[ ]
INS-9007	Universal screwdriver handle			



## 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 orthognatic 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.

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-Llactic acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures. J Craniofac Surg. 2010 May;21(3):847-53.

latrou 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.

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.

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.

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.

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.



INION OY Lääkärinkatu 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