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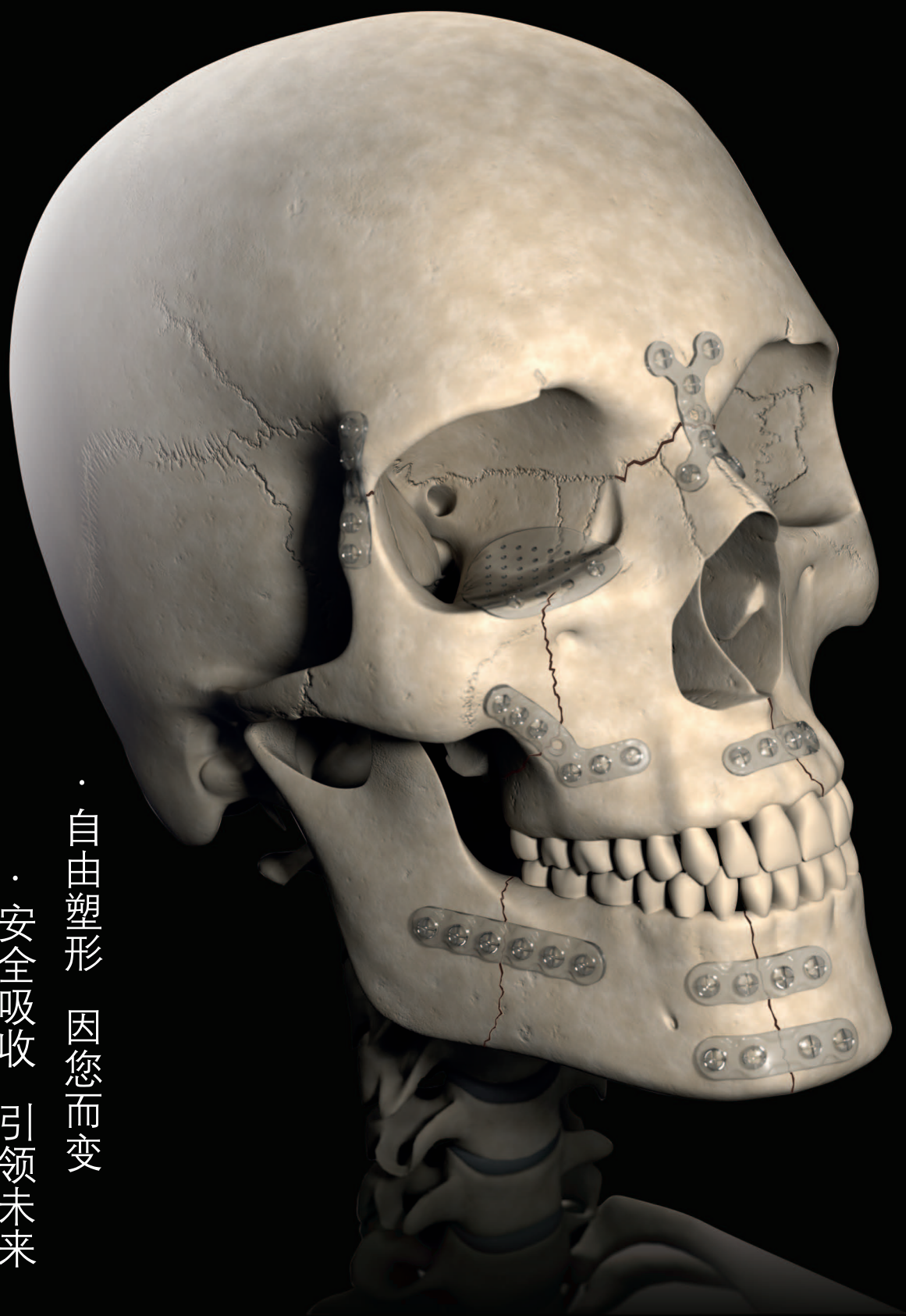
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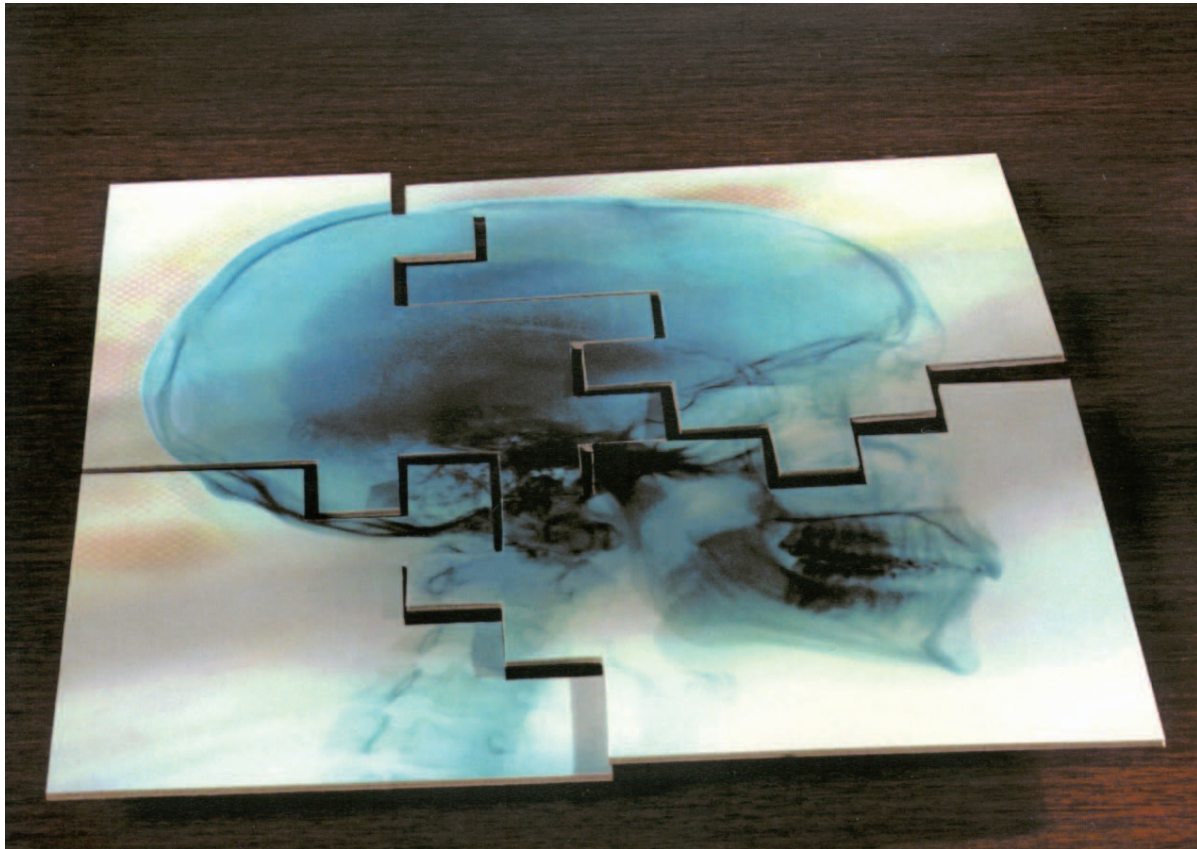
Inion CPS®

生物型可吸收颅颌面内固定系统

INION



· 自由塑形 因您而变
· 安全吸收 引领未来



A fully biodegradable solution for CMF surgery provided by Inion

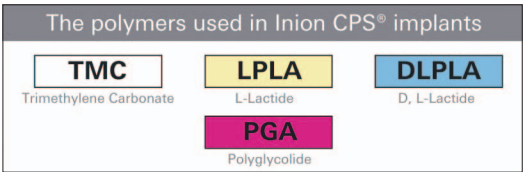
What are the Inion® biodegradable implants made from?
Inion®可降解植入材料的组成是什么？

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.

所有的 Inion CPS®内植入物都是以Inion®的可降解性聚合物为基础，并具有杰出的可操作性，其强度和可降解的特性都以更自然的愈合过程为支撑。

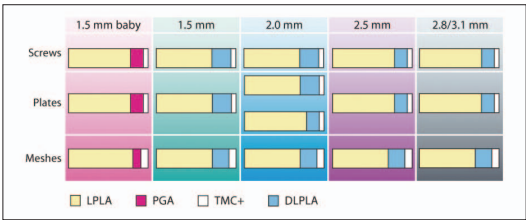
The Inion® biodegradable co-polymers used for the Inion CPS® Fixation Systems are composed of L-Lactide, D,L-Lactide, Polyglycolide and TMC (Trimethylene Carbonate). These polymers have long histories of safe clinical use.

Inion CPS®内固定系统应用的是Inion®生物性可降解聚合物，组成成分为：L-丙交酯，D,L-丙交酯，聚乙二醇，和TMC（三亚甲基碳酸盐）。这些聚合物具有悠久的临床安全应用的历史。



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.

根据具体每款产品的应用预期不同，每种聚合物的比例是各不相同的，所以其强度、延展性、可降解性都更完美的符合临床需求。



Inion® biodegradable polymer advantage
Inion®生物型可降解聚合物的优点

- Inion CPS® implants are biodegradable. No permanent metal implant left in the body reducing risk of implant migration and stress shielding
Inion CPS® 内植入物具有生物可降解性。没有了永久的金属内植入物留在体内，从而降低了植入物游走和应力遮挡的风险。
- Inion CPS® implants reduce risk of growth restriction in children
Inion CPS® 内植入物降低了儿童骨生长限制的风险。
- Predictable degradation progressively loads the bone to aid bone regeneration
可控的降解过程，逐渐的加载在骨上来帮助骨再生。
- No interference with postoperative imaging (X-ray, CT, MRI) which might be required for future diagnosis, as the implants are non-metallic
对于影像学检查（X-ray, CT, MRI）没有任何影响，所以不会影响后期诊断。
- Implants are supplied sterile and single packed, solving concerns about possible decontamination of implants which may cause cross-infection
所有内植入物都是无菌独立包装，解决了目前备受关注的内植入物交叉感染的可能。
- Easy and precise anatomical contouring of plates after simply heating in the Inion Thermo™ water bath
Inion 电热水浴箱加热便可以实现简单精确的解剖塑形。

Inion CPS® - a complete system for CMF fixation

颅颌面内固定的全面解决方案

The degradation profile

关于可降解材料

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®可降解高分子聚合物是非结晶体，在体内通过水解作用和新陈代谢生成二氧化碳和水排出体外。材料的可降解性可以精确地提供初期稳定性，并可以逐步的转移骨负载来协助骨重建，减少应力遮挡。在此之后才出现质量损失。

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

Inion CPS®系统，植入后9周至少保持70%的初始强度。两到四年可以完全降解。

Key elements

关键要素

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

基于向颅颌面外科手术提供一整体解决方案，Inion CPS®系统包括三个关键要素：

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

每一款产品都有其特别的设计，可以包绕面部骨表面来满足特定的生物力学需求。

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.

高分子材料的选择和比例的不同，制造工艺和产品的设计都保证每块产品实现最佳强度，延展性和可吸收性，来满足特定的临床需求。

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.

Inion CPS®是唯一一套可应用于全面部所有区域的生物可降解性CMF系统，包含一整套可吸收板、螺钉和可吸收网，能应用于儿童和成人。

Inion CPS® - a complete system for CMF fixation 颅颌面内固定的全面解决方案



1.5 mm CPS SYSTEM

For cranial and midface fixation, strength retention is minimum 9 weeks
颅骨和面中部内固定产品, 强度至少保持9周。

Inion CPS® systems



2.0 mm CPS SYSTEM

For midface and orthognathic fixation, strength retention is minimum 9 weeks
面中和正颌内固定产品, 强度至少保持9周。



2.5 mm CPS SYSTEM

For mandibular fixation, strength retention is minimum 9 weeks
下颌内固定产品, 强度至少保持9周。

Clinical advantages 临床优势

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.

自从2001年推出此套系统以来, INION内固定系统已经成功应用于5.5万例手术中, 而且这一数量还在快速增加。

- Most comprehensive biodegradable plating system available - the only one comparable to titanium in its scope of use
最全面可靠的可降解性内固定系统: 唯一一套应用范围可与钛相媲美的内固定系统
- Quick and easy to use
使用简单、便捷
- Avoidance of removal surgery reducing patient trauma and cost
避免患者二次手术, 降低手术风险和费用

- Unlike other biodegradables it has implants suited for all CMF areas
不同于其它的可降解内固定系统, 它适用于全面部的手术。包括:
 - paediatric craniofacial trauma and reconstruction
儿童颅颌面的创伤和重建
 - fractures and reconstructive procedures of the cranium
颅骨的骨折和重建
 - orthognathic surgery and trauma of the mid-face and maxilla
面中部和上颌骨的正颌与骨折手术
 - fractures and osteotomies of the mandible
下颌骨的骨折和正颌截骨术

Innovative plate design 可吸收板的创新设计

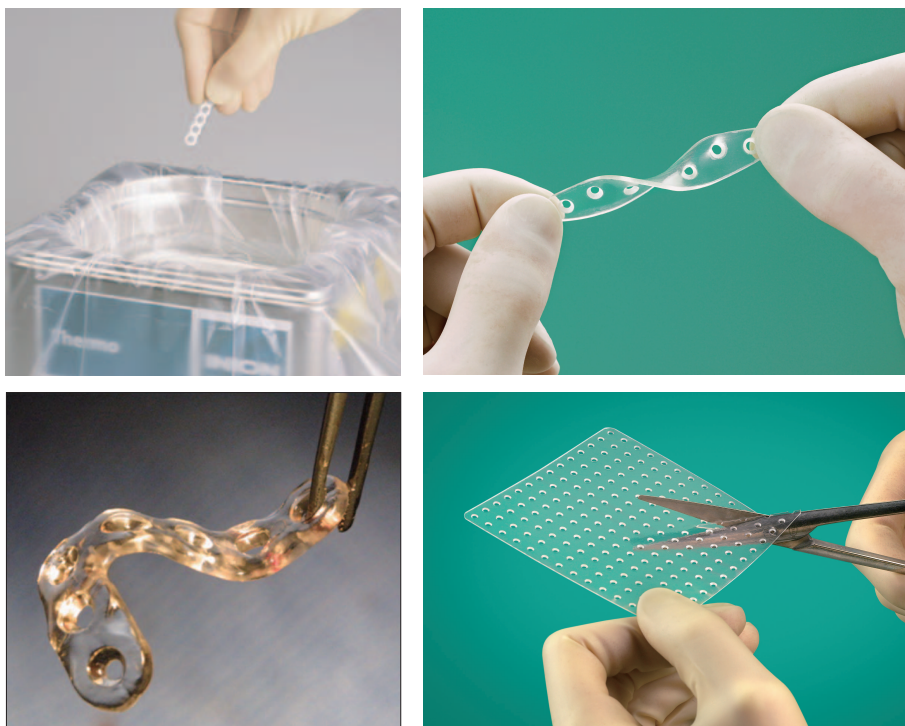


Plate characteristics 可吸收板的特征

- Optimised strength / material ratio
强度/材料比更加优化
- Minimised screw hole deformation during bending
在弯曲时钉孔形变最小
- Low plate / screw profile for reduced palpability
更低的切迹降低了钉对软组织的刺激

Handling advantage 操作的优势

Plates are malleable after activation in the Inion Thermo™ water bath (55°C).
可吸收板经过INION的恒温水浴箱(55°C)激活后变得柔软, 可以塑形。

After water bath treatment, plates are most malleable for 10-15 seconds for easy adaptation to the bone.
经过水浴处理后, 可吸收板在10-15秒内可以很容易的实现与骨的解剖外形的贴合。

They can also be re-heated up to three times for further contouring.
更精确塑形, 板可以反复加热三次以上。

Plates can be easily cut with scissors.
板很容易被剪刀裁剪。

Innovative versatile screw design 多功能螺钉的创新设计



5

Innovative screw solutions 创新的螺钉方案

- Fine screw threads provide maximum engagement in cortical bone
细小螺纹可以提供和皮质骨最好的衔接
- Monocortical screws are packaged in a convenient screw ring (5 + 1 emergency screw included in 1.5 / 2.0 mm screw ring)
单皮质螺钉都被包装在一个便利的螺钉盒里 (5+1应急螺钉, 包括1.5 / 2.0毫米的螺钉盒)
- Bicortical screws (2.0 / 2.5 / 2.8) are packaged in an easy to use dispenser
双皮质螺钉 (2.0 / 2.5 / 2.8) 都被包装在一个便于使用的装置里
- Universal screwdriver blade used for all Inion CPS® screw sizes
通用螺丝刀适用于所有的INION螺钉
- Simple and secure push-fit screw pick-up
更简单安全的实现螺钉取出和攻入

手术操作要点

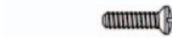
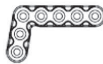
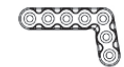
- 可吸收板放入INION的恒温水浴箱(55°C)1分钟将其激活, 变得柔软, 10-15秒内任意塑形, 可以很容易的实现与骨的解剖外形的贴合。(其最大加热时间不得超过30分钟)
- 一旦待可吸收板冷却后, 将恢复原来的硬度, 此时若想塑形可以使用塑形钳。但冷却下塑形会降低产品的强度。
- 板可以反复加热塑形三次以上, 第一次水浴加热激活后, 以后塑形只需水浴加热5-10秒即可。
- 可吸收板塑形后, 对于塑形不佳的部位, 可将其放入水浴中进行微调。
- 板很容易被剪刀裁剪, 如果必要的话长钉也可裁剪。
- 打钻后需要攻丝才可以进钉。

Inion CPS® information

产品信息

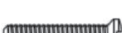
Inion CPS® I.5 mm System , For cranial and midface fixation			
编号	规格	描述	
PLT-1005	1.0 × 5.8 × 20.8	4孔板	
PLT-1006	1.0 × 5.8 × 30.8	6孔板	
PLT-1007	1.0 × 5.8 × 100.8	20孔板	
PLT-1008	1.0 × 5.8 × 33.1	C-形板, 7孔板	
PLT-1009	1.0 × 5.8 × 27.5	L 形右弯 7 孔固定板	
PLT-1010	1.0 × 5.8 × 27.5	L 形左弯 7 孔固定板	
PLT-1011	1.0mm thick, covers 14 mm hole	三角形板	
PLT-1012	1.0 × 5.8 × 27.5	X-形板, 7孔板	
PLT-1030	0.5 × 45.0 × 45.0	网板7X7孔	
PLT-1031	0.5 × 90.0 × 90.0	网板14X14孔	
PLT-1081	0.5 × 25 × 24	眶底板	
PLT-1082	0.5 × 25 × 24	眶底板	
PLT-1083	0.5 × 30 × 28	眶底板	
PLT-1084	0.5 × 30 × 28	眶底板	
PLT-1085	0.5 × 30 × 28	眶底板	
PLT-1086	0.5 × 30 × 28	眶底板	
PLT-1087	0.5 × 40 × 40	眶底板	
SCR-1222	1.5 mm × 4 mm	5 颗 1.5 × 4 mm 环形钉盒(备 1 颗 2.0 × 5 mm 螺钉)	
SCR-1223	1.5 mm × 6 mm	5 颗 1.5 × 6 mm 环形钉盒(备 1 颗 2.0 × 7 mm 螺钉)	
SCR-2223	1.5 mm × 6 mm	2 颗 1.5 × 6 mm/盒	

Inion CPS® 2.0 mm System , For midface and orthognathic fixation		
编号	规格	描述
PLT-1013	1.3 x 7.0 x 25	4 孔固定板
PLT-1014	1.3 x 7.0 x 28	4 孔长固定板
PLT-1038	1.3 x 7 x 37	6孔固定板
PLT-1016	1.3 x 7.0 x 61	10孔板
PLT-1017	1.3 x 7.0 x 40.9	C-形板, 7孔板
PLT-1039	1.3 x 7 x 33	L 形右弯 7 孔固定板
PLT-1040	1.3 x 7 x 33	L 形左弯 7 孔固定板
PLT-1037	1.3 x 18.3 x 30.3	X-形板, 7孔板
PLT-1032	0.6 x 45 x 45	可吸收骨网 7X7孔
PLT-1033	0.6 x 90 x 90	可吸收骨网 14X14孔



Inion CPS® information
产品信息

Inion CPS® 2.5 mm System , For mandibular fixation			
编号	规格	描述	
PLT-1023	1.3/1.7 (min/max) x 8.5 x29.5	4 孔固定板	
PLT-1024	1.3/1.7 (min/max) x 8.5 x32.5	4 孔加长固定板	
PLT-1041	1.3/1.7 (min/max) x 8.5 x36.5	4孔特加长固定板	
PLT-1025	1.3/1.7 (min/max) x 8.5 x43.5	6孔板	
PLT-1026	1.3/1.7 (min/max) x 8.5 x46.5	6 孔加长固定板	
PLT-1027	1.3/1.7 (min/max) x 8.5 x57.5	8孔板	
PLT-1036	1.3/1.7 (min/max) x 8.5 x71.5	10孔板	
PLT-1034	0.7 x 45.0 x 45.0	可吸收骨网 7X7孔	
PLT-1035	0.7 x 90.0 x 90.0	可吸收骨网 14X14孔	

SCR-1206	2.5 mm x 6 mm	5 颗 2.5 x 6 mm 环形钉盒	
SCR-1207	2.5 mm x 8 mm	5 颗 2.5 x 8 mm/环形钉盒	
SCR-2207	2.5 mm x 8 mm	2颗 2.5 x 8mm/盒	
SCR-1290	2.5 mm x 10 mm	2 颗 2.5 x 10 mm/盒	
SCR-1291	2.5 mm x 12 mm	2 颗 2.5 x 12 mm/盒	
SCR-1292	2.5 mm x 14 mm	螺钉-2.5 x 14 mm 螺钉 - 2 螺钉/盒	
SCR-1293	2.5 mm x 16 mm	螺钉-2.5 x 16 mm 螺钉 - 2 螺钉/盒	
SCR-1294	2.5 mm x 18 mm	2 颗 2.5 x 18 mm/盒	
SCR-1208	2.5 mm x 23 mm	1 颗 2.5 x 23 mm/盒	
SCR-1297	2.8 mm x 10 mm	2 颗 2.8 x 10mm/盒	
SCR-1298	2.8 mm x 12 mm	2 颗 2.8 x 12 mm/盒	
SCR-1299	2.8 mm x 14 mm	2 颗 2.8 x 14 mm/盒	
SCR-1300	2.8 mm x 16 mm	2 颗 2.8 x 16mm/盒	
SCR-1301	2.8 mm x 18 mm	2 颗 2.8 x 18 mm/盒	

References 参考文献

Cheung LK, Yip ISI, Chow LKR. Stability and morbidities of Le Fort I osteotomies with bioresorbable fixation: a randomized controlled trial. *Int J Oral Maxillofac Surg* 37:232-241, 2008.

- Comparable horizontal and angular relapses treated with the Inion OTPS® and titanium plating systems. No differences in complications between the two groups. The long-term stability of Le Fort I osteotomy in horizontal and vertical planes was similar for bioresorbable and titanium mini-plate fixation.

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.

- Post-surgical period was uneventful in all cases. Fractured bone stability and healing were achieved without any major local reactions or impairments of skeletal growing.

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.

- Clinical and radiographic evaluation indicated clinical union of all fractures at the 8-week follow-up.

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.

- All the fractures in both groups healed both clinically and radiologically. Comparable inpatient treatment time of the patients. After 6 months all patients had perfect occlusions in both groups.

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* 19(3):748-756, 2008.

- Study shows effective biodegradation of the Inion OTPS® Baby plates and screws by 12 months and normal inflammatory sequelae in an adult rabbit model.

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* 19:1155-1163, 2008.

- The Inion OTPS® plates and screws maintained adequate strength for the healing period (6 to 12 weeks) of the bone fracture or osteotomy. Degradation in two years without producing harmful foreign body reactions.

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.

- The primary recovery was uneventful in all cases. There was no case with delayed union.

Turvey TA. Biodegradable bone plates and screws. Their use in more than 500 maxillofacial surgery patients. The 7th Asian Congress on Oral and Maxillofacial Surgery (ACOMS), Hong Kong, November 5-9, 2006.

- Stability in orthognathic surgery is similar to that observed with titanium fixation. Radiographic studies indicate complete degradation and bone fill in to the screw holes by 3 to 5 years post surgery.