Inion Freedom™

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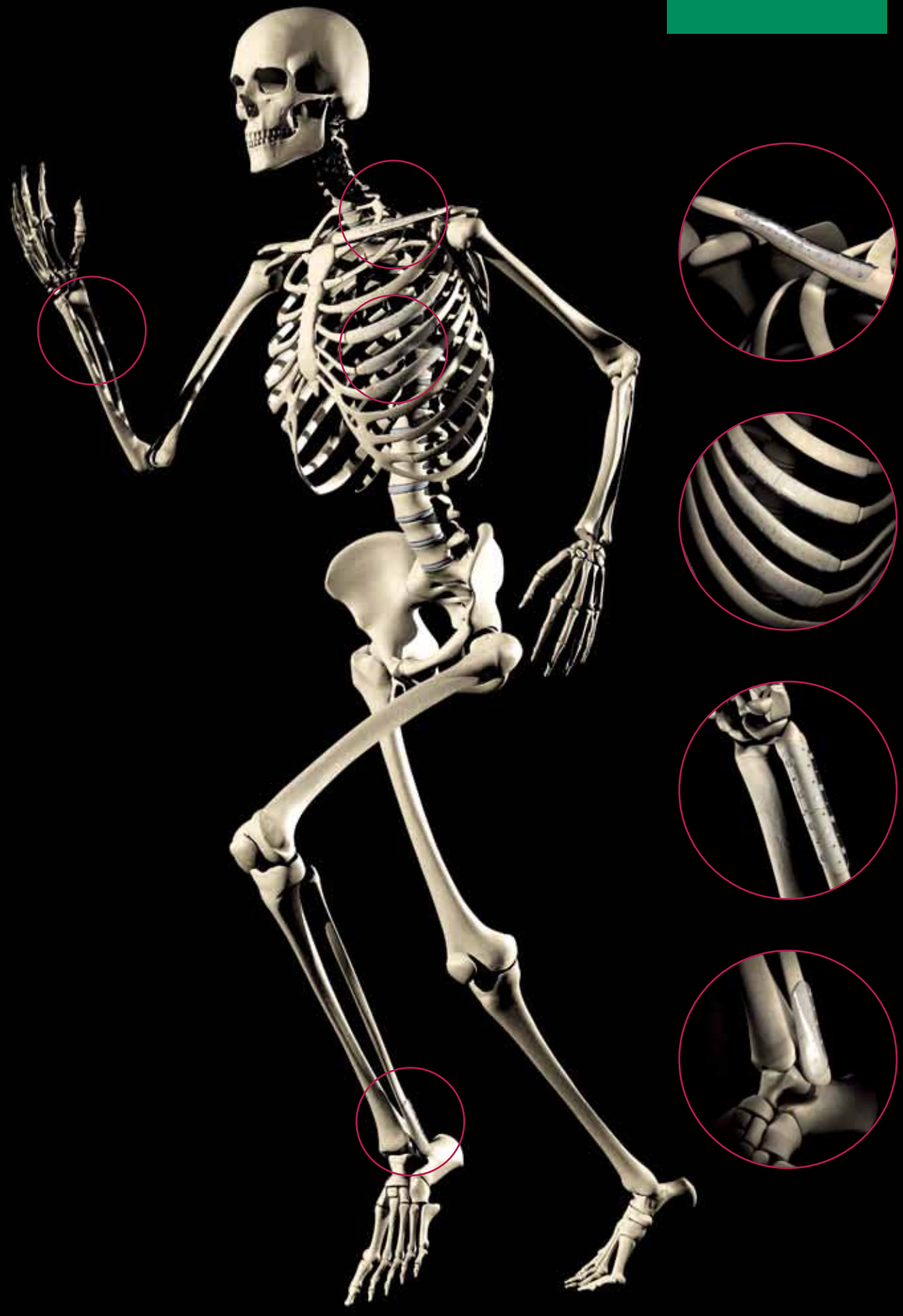

Inion Freedom™ – A Biodegradable Solution

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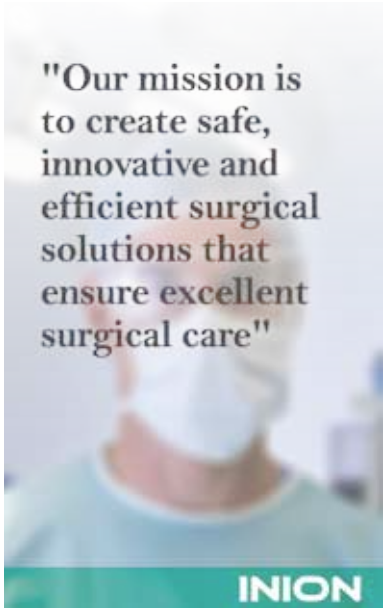
Company Introduction

Inion Oy is a medical device company focused on the development and manufacture of innovative biodegradable and bioactive medical implants based on proprietary biomaterials, which give rise to significant advantages from both a patient's and a clinician's perspective. The company's key market segments are Specialty Orthopaedics and Craniomaxillofacial.

Inion was founded in 1999 by an international group of experienced professionals, including surgeons and materials specialists, to create medical solutions that were not available to the surgical community. Initially their focus was perfecting biodegradable materials that could be used to manufacture a wide range of medical implants.



In 2001, only 14 months after its corporation, the company was able to develop its proprietary Inion® Family of Biodegradable Materials and launch its first FDA-cleared products onto the market. This was made possible by the help of Inion's scientists' over 25 years of expertise in processing of biodegradable polymers for medical use, as well as, know-how in clinical and regulatory requirements, and links with world-leading biomaterials manufacturers, universities and clinics. Since that initial launch, Inion has operated in five main clinical areas: craniomaxillofacial, dental, orthopaedic trauma, sports medicine and spinal surgery.

The company is based in Tampere, Finland, a city known as a center of excellence in health and biotechnology research. The modern 4500m^2 headquarters houses state-of-the-art manufacturing, laboratory and office facilities as well as ISO class 7 cleanrooms. The company's design and manufacturing processes conform to ISO 13485 and FDA 21 CFR 820.

Over 25 years of expertise in processing of biodegradable polymers for medical use.

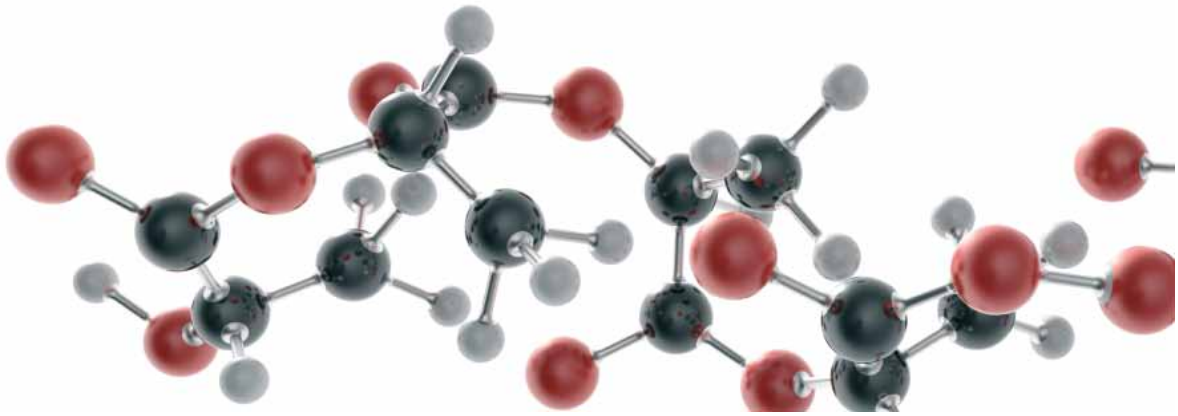
Inion's core biomaterials technology, Inion® Polymers, represents a range of proprietary biodegradable biomaterials with great potential for use in medical implants that enhance the healing of bone or soft tissue injuries to the skeleton. A key benefit of Inion® implants is that they provide support during the healing process, prior to safely and completely degrading into carbon dioxide and water at a predictable rate in the body.

Fundamental to Inion's approach is its thorough understanding of the requirements for bone and tissue healing. Inion recognizes that different types of injuries require fixation using implants with characteristics that provide the right combination of strength, rigidity, malleability and biodegradability to produce a successful clinical outcome.

By blending four safe and well-characterized rigid and elastic medical polymers in varying proportions, Inion has generated more than 40 Inion® blends. Typically, Inion® implants retain most of their initial strength for 9-12 weeks after implantation and degrade entirely in 2-4 years, but depending on the clinical requirements, these parameters can be optimized by varying the composition of the blend. Inion develops implants in consultation with leading surgeons, to ensure they meet specific clinical performance criteria.

Medical implants made from Inion® Polymers, such as plates, pins and screws, can be made for the fixation of a wide range of fractures or soft tissue injuries (torn tendons or ligaments) throughout the skeleton.

By blending four safe and well-characterized rigid and elastic biodegradable polymers in varying proportions, Inion has generated more than 40 Inion® Polymer blends.



Inion Freedom™

Inion Freedom™ is the only full biodegradable system with both plates and screws. Inion FreedomPlate™ and Inion FreedomScrew™ together form a resorbable locking plate system, which is unique of its kind.

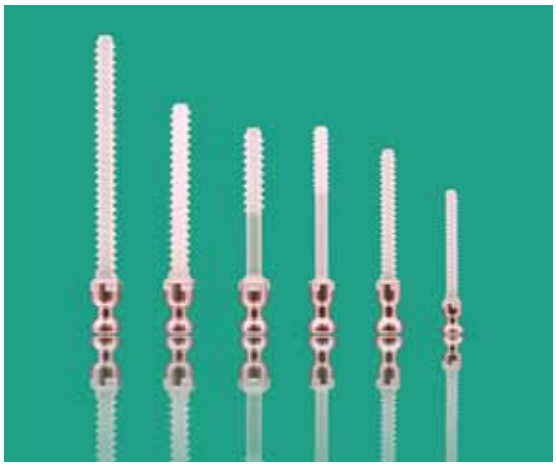
The initial principle behind the development of the Inion Freedom™ products has been to keep everything as simple and compatible with existing operation techniques as possible, and additionally, to offer clear benefits with full versatility and low inventories.

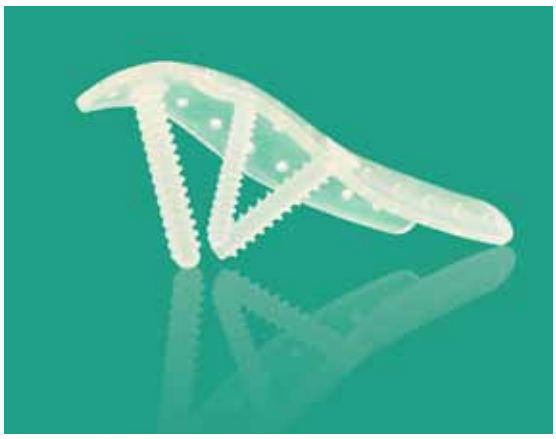
The Inion Freedom™ offers:

- Ease of use with versatile products, "one screw – one plate" ideology
- Contours perfectly to any anatomy
- Allows free screw placement to any desired position and angle
- Screws interlock to the plate
- Low-profile construct
- Transparent and radiolucent
- Low inventory of plates and screws
- ...and is biodegradable!

Over the decades, one of the known shortcomings of resorbable products has been the initial handling properties during screw insertion in the demanding orthopaedic fixations. With the Inion Freedom™, Inion has overcome this issue by developing new resorbable screws with significantly higher strength values and better handling properties compared to the old systems.

These exceptional new properties are based on Inion's patented raw material combinations, unique manufacturing methods and in-house material blending. Inion is the only manufacturer in the world tailoring the most optimal resorbable material compounds according to each indication.





Product description

Inion FreedomPlate™ is a versatile fracture fixation plate. The system includes a fully customizable plate which perfectly contours to all anatomies, and fixation screws which can be implanted polyaxially to provide the best possible fixation.

Benefits

- Customized plate for every patient by thermo forming and cutting to any desired size and shape
- Further plate contouring possible intraoperatively to meet challenging anatomies
- Low profile – low risk of tissue irritation
- Variable screw angulations
- Screws interlock to the plate – low risk of screw back-out
- Free placement of the screws
- Transparent and radiolucent
- Low inventory of plates and screws

Indications

Maintenance of alignment and fixation of

- bone fractures
- osteotomies
- arthrodesis

of long bones, flat bones, short bones, irregular bones, appendicular skeleton and thorax, in the presence of appropriate additional immobilization or fixation

Maintenance of relative position of weak bony tissue in trauma and reconstructive procedures, i.e.:

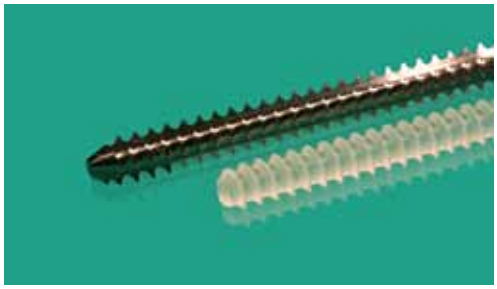
- bone grafts
- bone graft substitutes
- bone fragments in comminuted fractures

Inion FreedomScrew™

Product description

Inion FreedomScrew™ is a strong and fully versatile resorbable screw for orthopaedic fixations. Because of its unique manufacturing method and intelligent technical properties, Inion FreedomScrew™ offers many clear benefits for the operating surgeon who appreciates easiness, reliability and versatility from the implant.

Disposable insertion adapter and compatibility with generic (ISO, ASIF, AO) instrumentation



Good bite! - New screw profile with improved pull-out strength properties

Memory Effect – ability to create new screw heads along the shaft by temperature cautery

Benefits

- High strength properties to meet the challenges of demanding orthopaedic fixations
- Low screw head profile and ability to create "a new screw head" at a chosen point of the screw shaft by a temperature cautery
- Delivered with a disposable metallic adapter
- Compatible with most of the universal instrumentation used in hospitals around the world: **ISO, ASIF, AO**
- Can be cut to any desired length during the operation
- Screws interlock with the plate
- Transparent and radiolucent
- Low inventory quantities

Indications

The Inion FreedomScrew™ is intended for maintenance of alignment and fixation of bone fractures, comminuted fractures, osteotomies, arthrodesis or bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast or brace).

In addition, the Inion FreedomScrew™ 3.5/4.0/4.5 mm products are specifically intended for use in following indications:
A. General indications: maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodesis of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.
B. Specific indications: fractures and osteotomies of the malleoli, and ankle fractures.

Inion FreedomPlate™

Art. No.	Description	Qty
FRF-1065	20 x 65 mm concave plate	1
FRF-1066	20 x 100 mm concave plate	1

Inion FreedomScrew™ - Fully threaded

Art. No.	Description	Qty
OSA-2014	FreedomScrew 2.0 x 14 mm	1
OSA-2020	FreedomScrew 2.0 x 20 mm	1
OSA-2716	FreedomScrew 2.7 x 16 mm	1
OSA-2740	FreedomScrew 2.7 x 40 mm	1
OSA-3530	FreedomScrew 3.5 x 30 mm	1
OSA-3545	FreedomScrew 3.5 x 45 mm	1
OSA-4540	FreedomScrew 4.5 x 40 mm	1
OSA-4555	FreedomScrew 4.5 x 55 mm	1

Inion FreedomScrew™ - Partially threaded (LAG)

Art. No.	Description	Qty
OSB-3530	FreedomScrew 3.5 x 30 mm (LAG)	1
OSB-3535	FreedomScrew 3.5 x 35 mm (LAG)	1
OSB-3540	FreedomScrew 3.5 x 40 mm (LAG)	1
OSB-3545	FreedomScrew 3.5 x 45 mm (LAG)	1
OSB-4535	FreedomScrew 4.5 x 35 mm (LAG)	1
OSB-4540	FreedomScrew 4.5 x 40 mm (LAG)	1
OSB-4545	FreedomScrew 4.5 x 45 mm (LAG)	1
OSB-4550	FreedomScrew 4.5 x 50 mm (LAG)	1
OSB-4555	FreedomScrew 4.5 x 55 mm (LAG)	1

Inion FreedomScrew™ - Fully threaded, Cannulated

Art. No.	Description	Qty
OSC-3530	FreedomScrew 3.5 x 30 mm, Cannulated	1
OSC-3545	FreedomScrew 3.5 x 45 mm, Cannulated	1
OSC-4540	FreedomScrew 4.5 x 40 mm, Cannulated	1
OSC-4555	FreedomScrew 4.5 x 55 mm, Cannulated	1

Inion FreedomScrew™ - Fully threaded, Cannulated - Syndesmosis Screw

Art. No.	Description	Qty
OSC-4090	FreedomScrew 4.0 x 90 mm, Cannulated	1

Inion FreedomScrew™ - Partially threaded (LAG), Cannulated

Art. No.	Description	Qty
OSD-3530	FreedomScrew 3.5 x 30 mm (LAG) , Cannulated	1
OSD-3535	FreedomScrew 3.5 x 35 mm (LAG), Cannulated	1
OSD-3540	FreedomScrew 3.5 x 40 mm (LAG), Cannulated	1
OSD-3545	FreedomScrew 3.5 x 45 mm (LAG), Cannulated	1
OSD-4535	FreedomScrew 4.5 x 35 mm (LAG), Cannulated	1
OSD-4540	FreedomScrew 4.5 x 40 mm (LAG), Cannulated	1
OSD-4545	FreedomScrew 4.5 x 45 mm (LAG), Cannulated	1
OSD-4550	FreedomScrew 4.5 x 50 mm (LAG), Cannulated	1
OSD-4555	FreedomScrew 4.5 x 55 mm (LAG), Cannulated	1

Ordering Information - Instruments

IFS-9901 Complete instrument set and tray

IFS-2001	Drill bit	Ø 1.5 mm
IFS-2002	Tap	Ø 2.0 mm
IFS-2701	Drill bit	Ø 2.0 mm
IFS-2702	Tap	Ø 2.7 mm
IFS-3501	Drill bit	Ø 2.5 mm
IFS-3502	Tap	Ø 3.5 mm
IFS-3503	Drill bit	Ø 2.7 mm, cannulated
IFS-3504	Tap	Ø 3.5 mm, cannulated
IFS-4004	Tap	Ø 4.0 mm, cannulated
IFS-4501	Drill bit	Ø 3.2 mm
IFS-4502	Tap	Ø 4.5 mm
IFS-4503	Drill bit	Ø 3.2 mm, cannulated
IFS-4504	Tap	Ø 4.5 mm, cannulated
IFS-9001	Screwdriver shaft, hex 2.5 mm	
IFS-9002	Screwdriver shaft, hex 3.5 mm, cannulated	
IFS-9011	Holding sleeve for Ø 2.0/2.7 mm screws	
IFS-9012	Holding sleeve for Ø 3.5 - 4.5 mm screws	
IFS-9021	Drill sleeve	Ø 1.5/2.0 mm, for Ø 2.0 mm screws
IFS-9022	Drill sleeve	Ø 2.0/2.7 mm, for Ø 2.7 mm screws
IFS-9023	Drill sleeve	Ø 2.5 - 3.5 mm, for Ø 3.5 mm screws
IFS-9024	Drill sleeve	Ø 3.2 - 4.5 mm, for Ø 4.0/4.5 mm screws
IFS-9031	Countersink for Ø 2.0/2.7 mm screws	
IFS-9032	Countersink for Ø 3.5 - 4.5 mm screws, cannulated	
IFS-9041	Depth gauge for Ø 2.7/3.5 mm screws	
IFS-9042	Depth gauge for Ø 2.7 - 4.5 mm screws, with K-wire	
IFS-9043	K-wire Ø 1.6 mm for Ø 4.0/4.5 mm screws	
IFS-9051	Screw cutting pliers	
IFS-9052	Scale for Ø 2.0/2.7 mm screws	
IFS-9053	Scale for Ø 3.5 - 4.5 mm screws	
INS-9093	Small handle, cannulated (set contains two pieces of INS-9093)	
INS-9120	Large handle, cannulated	
IFS-9801	Instrument tray	

HTC-0000	Low Temperature Cautery
ACC-9810	Inion Thermo+™ water bath 230v
ACC-9840	Inion Thermo+™ water bath 110v
ACC-9802	Inion Thermo™ drape
IFS-4003	Drill bit Ø 3.2 mm, cannulated (same as IFS-4503)
IFS-9061	K-wire Ø 1.25 mm for Ø 3.5 mm screws
IFS-9062	K-wire Ø 1.6 mm for Ø 4.0/4.5 mm screws

Product description

The Inion OTPS™ Biodegradable Mesh Fixation System is designed for graft containment and to sustain the relative position of bone fragments. Inion Freedom™ screws can be used for fixation of the mesh.

Benefits

- Contours perfectly to patient anatomy
- Low profile – low risk of tissue irritation
- Variable screw angulations
- Flexible placement of the screws
- Transparent and radiolucent

Indications

Intended to sustain the relative position of weak bony tissue, e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures.

Indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, these implants are intended to sustain the relative position of weak bony tissue in trauma and reconstructive orthopaedic procedures involving the following:
- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), these implants are intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopaedic procedures involving:
- Tumor resections where bone strength has not been compromised
- Iliac crest harvest sites

Inion OTPS™ Mesh System

Art.No.	Description	Qty
MSH-1035	Mesh plate, 14 x 14 holes	1

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