

INION OTPS™
Biodegradable Ankle Screws
Operation Technique

This device is not
cleared by the FDA
for distribution
in the United States



Inion OTPS™

Biodegradable Ankle screw

DESCRIPTION

The Inion OTPS™ Biodegradable Fixation System consists of fixation screws made of biodegradable polylactide/trimethylene carbonate copolymer. The Inion OTPS™ screws are made of biodegradable copolymers composed from L-Lactide, D-Lactide and TMC monomers. These have long histories of safe medical use and degrade in-vivo by hydrolysis and are metabolised by the body into CO₂ and water. The OTPS™ products gradually lose most of their strength within 18-36 weeks. Bioresorption takes place within two to four years. Inion OTPS™ Fixation System implants are sterile, non-collagenous and non-pyrogenic.

INDICATIONS

A. General indications: These implants are generally intended for maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilisation.

B. Specific indications:

- Fractures and osteotomies of the malleoli Ankle fractures
- Ankle fractures

CONTRAINDICATIONS

These implants are not intended for use in and are contraindicated for:

- Active or potential infection.
- Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (for example, alcoholism, drug abuse).
- High-load bearing applications

INFORMATION FOR USE

Surgical considerations and reminders

- Prophylactic perioperative antibiotic treatment is recommended.
- Use proper local, regional or general anaesthesia.
- Maintain sterile field throughout the procedure.
- Proper exposure using standard surgical procedure.
- Thoroughly prepare the surgical site preserving the neurovascular structures by careful dissection.
- Good alignment/reduction of the fracture/osteotomy.
- Radiographs should be taken to check the alignment/reduction after fixation.
- Meticulous hemostasis and complete primary soft tissue closure over the implant are essential.

Evaluation of results

Radiographs should be taken to evaluate healing.

PRECAUTIONS:

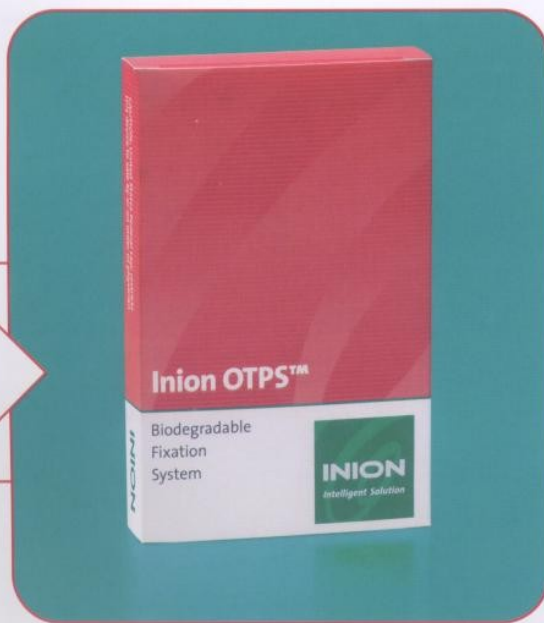
Before using Inion implants, study carefully the Instructions For Use booklet that is included in the Inion implant box.

WARNINGS

- The **Inion OTPS™ Biodegradable fixation System** implants provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.
- Incorrect selection, placement, positioning, and fixation of the implant can cause subsequent undesirable results. The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.

PRECAUTIONS

- Instruments are available to aid accurate implantation of the **Inion OTPS™ Biodegradable fixation System**. Surgical instruments are subject to wear with normal usage and may break. Surgical instruments are only to be used for their intended purpose.



All instruments are to be regularly inspected for wear and damage. Use only the Inion instruments.

- **DO NOT** use for unintended applications! Proper function (i.e. efficacy and safety) of these implants can not be guaranteed in the event of off-label use.
- The patient should be warned that the implants can break or loosen as a result of early stress, activity or load bearing. Premature discontinuation of the cast or other immobilisation technique may cause non-union or mal-union of the fracture or osteotomy.

ADVERSE EFFECTS

Complications are similar to those encountered with any other method of internal fixation:

- Premature bending, loosening, fracture or migration of the devices may result from early stress, activity or load bearing.
- Infection can lead to failure of the procedure.
- Neurovascular injuries can occur due to surgical trauma.
- Implantation of foreign materials can result in an inflammatory response or allergic reaction. Transient local fluid accumulation may occur in sterile circumstances.

OPERATION TECHNIQUE

– Syndesmosis screw

Precautions: Before using cannulated Inion instruments (INS-9079T, INS-9084T, INS-9086T, INS-9092T, INS-9093T and INS-9095T), check that Inion K-wire slides smoothly through them.

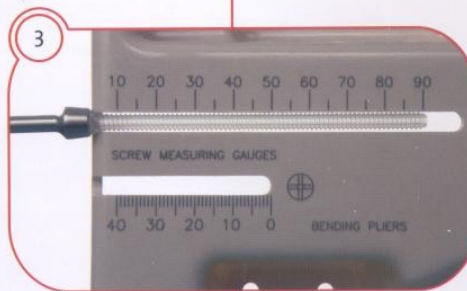
Drill the Inion K-wire (INS-9087T) through the fibula and tibia (four cortices). (1)



Remove the driver and leave Inion K-wire (INS-9087T) in place. Slide the cannulated 4.5mm depth gauge (INS-9092T) over the K-wire. Read the required length using the black mark on K-wire. (2)



Cut the 90 mm syndesmosis screw to the desired length. If the screwhead is to be cut off after insertion of the screw, allow an extra 5 mm length so that the head stands proud off the plate for easy trimming. (3)

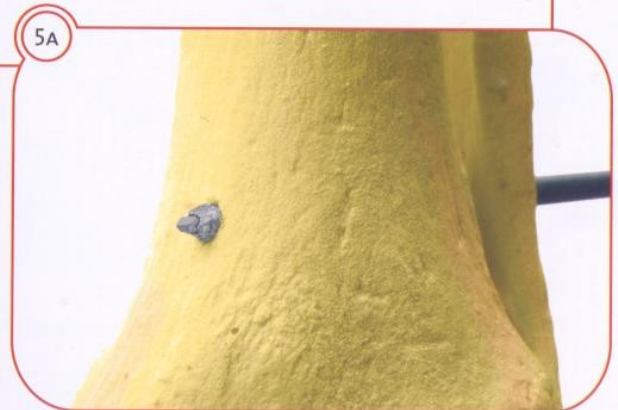


When measuring the screw use the gauge in Universal Instrument Tray.

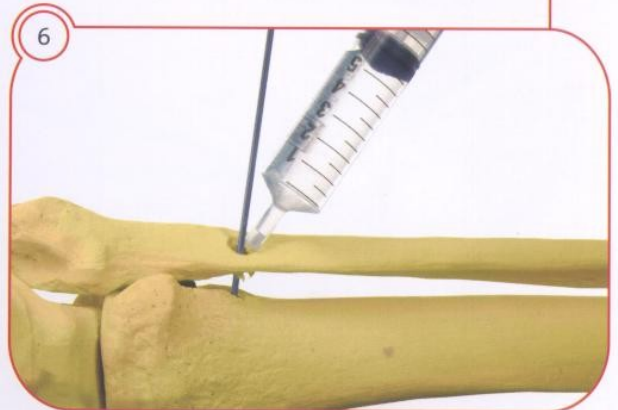
Drill through all four cortices over the Inion K-wire using the cannulated drill bit (INS-9079T). **(4)**



Tap through all four cortices over the Inion K-wire using cannulated tap (INS-9084T) and handle. **(5a)**

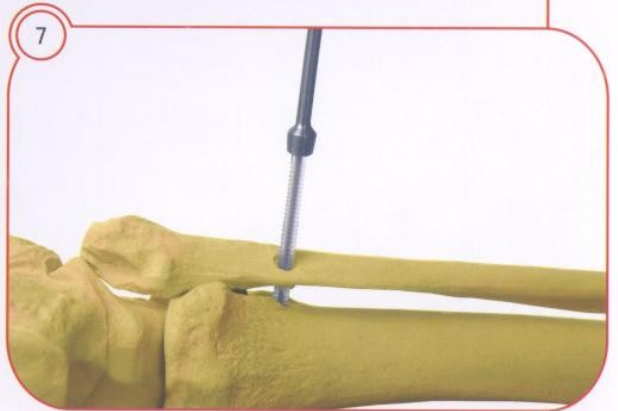


OPTIONAL! Countersink (INS-9086T) if desired, if the screw is not applied through the ankle plate. **(5b)**



Remove the tap.
Flush with sterile water or saline. **(6)**

Insert the cannulated screw over the Inion K-wire and tighten using Inion screwdriver (INS-9095T) and handle. **DO NOT COMPRESS FIBULA AGAINST TIBIA.** **(7)**



Remove the Inion K-wire.
The screw head may be cut level with the bone or plate surface to avoid soft tissue irritation caused by the protruding screw head. **(8)**



OPERATION TECHNIQUE

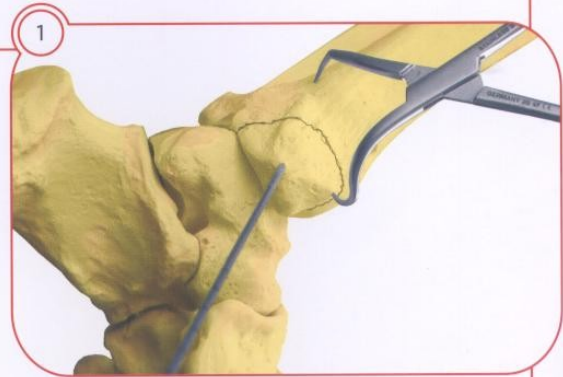
– Malleoli screw

After the reduction of the fracture/osteotomy, **drill 2.0 mm K-wire through to the fracture line to hold the bone fragments during screw insertion. (1)**

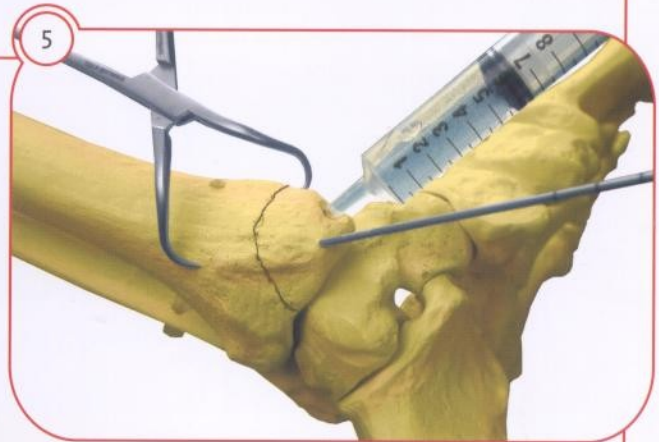
Use the drill guide when drilling the screw channel. Measure the depth of the drill hole. (2)

Tap the drill hole through the drill/tap guide using Inion tap (INS-9083T) and handle. If required take an X-ray with the instrument inserted. (3A)

OPTIONAL! The Inion countersink (INS-9086T) can be used to prepare the site for the screw. (3B)



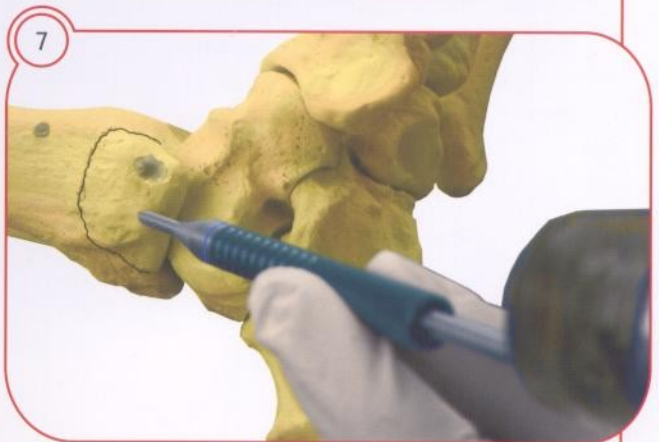
Flush the drill hole with sterile water or saline. (5)



Insert the 4.5mm screw using Inion screwdriver (INS-9095T) and handle. (6)
The screw head may be cut level with the bone or plate surface to avoid soft tissue irritation caused by the protruding screw head. However, **DO NOT CUT THE HEAD OFF THE LAG SCREW** (= partially threaded screw).

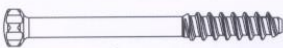
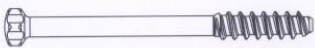
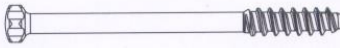






Remove the 2.0 mm K-wire and replace it with 2.0mm Inion OTPS Pin using Inion Pin applicator (INS-9231T). Cut the pin to length. (7)



Please refer the Inion OTPS Pin Operating Technique brochure for detailed Pin insertion technique. (8)



4.5 mm Malleoli screws			Single packed
			
FRF-1272, 4.5 x 45 mm	FRF-1273, 4.5 x 50 mm	FRF-1274, 4.5 x 55 mm	
			
FRF-1245, 4.5 x 45 mm	FRF-1277, 4.5 x 50 mm	FRF-1278, 4.5 x 55 mm	

4.5 mm Syndesmosis screw	Single packed
	
FRF-1275, 4.5 x 90 mm, cannulated	

Instruments



4.5 mm	
REF. NO.	DESCRIPTION
INS-9078	3.5 mm drill bit
INS-9079	3.8 mm drill bit, cannulated
INS-9083	4.5 mm bone tap
INS-9084	4.5 mm cortex screw bone tap, cannulated

UNIVERSAL INSTRUMENTS	
REF. NO.	DESCRIPTION
INS-9086(τ)	Countersink 4.5 mm, cannulated (AO-bayonet)
INS-9087(τ)	K-wire 1.6 mm (2 pcs)
INS-9089(τ)	Drill guide 4.5 mm
INS-9092(τ)	Depth gauge 4.5 mm, cannulated
INS-9093(τ)	Screwdriver handle, cannulated 1.5 mm - 3.1 mm
INS-9095(τ)	Screwdriver shaft, hexalobular, cannulated 4.5 mm



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