

INION OTPS™
Biodegradable Pins
Operation Technique



Inion OTPS™ Biodegradable Pins

DESCRIPTION

The Inion OTPS™ Biodegradable Pins are intended to maintain accurate alignment of fragments of fractured bone in the presence of appropriate immobilization.

The Inion OTPS™ implants 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 coloured pins are dyed green for better visualisation during the surgical procedure. The colour is achieved by using a minimal amount of Drug and Cosmetic (D&C) Green No. 6, which is used in several biodegradable sutures. The Pins gradually lose most of their strength within 18-36 weeks. Bioresorption takes place within two to four years.

The Pins are offered in different sizes and they are designed to be used with customized instrumentation. The Pins are sterile, non-collagenous, and non-pyrogenic.

INDICATIONS

The Pins are indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (for example, rigid fixation implants, cast, brace).

CONTRAINDICATIONS

The Pins should not be used in fractures and osteotomies of diaphyseal bone or in cases with insufficient quality or quantity of bone. Other contraindications are active or potential infections, patient conditions including limited blood supply, and where patient cooperation cannot be guaranteed (for example, alcoholism, drug abuse). There are currently no known additional contraindications to the use of the Inion OTPS™ Biodegradable Pins.

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 followed by fixation with clamp(s).
- Radiographs can be taken before wound closure to check the alignment/reduction after fixation.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.

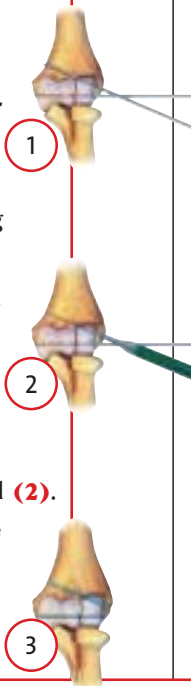
BENEFITS

- Improved visibility.
- No need for removal upon remobilisation reducing patient trauma and costs.
- Degradation profile tailored to progressively load the bone to improve bone regeneration.
- Implants are supplied sterile.
- Can be easily cut.

SURGICAL TECHNIQUE*

- 1) **Reduce and stabilize the fracture.**
- 2) **Insert two diverging 1.5 mm or 2.0 mm Inion K-wires (Trocax Tip Drill) through the fragment and both cortices to secure the fragment (1).**
- 3) **Check the correct anatomical reduction** by using AP and lateral radiographic views.
- 4) **Remove one K-wire.** Flush and measure the depth of the channel.
- 5) **Select an appropriate length OTPS Pin** of the same diameter as the K-wire used (1.5 or 2.0 mm).
- 6) Using Inion Pin Applicator (1.5 or 2.0 mm), **insert the OTPS Pin by tapping** it gently in to the channel (2).
- 7) **Replace the other K-wire** with an appropriate size OTPS Pin in the same manner (3).

* Biodegradable fixation in traumatology and orthopaedics. 2nd edition. University of Helsinki, 2002: 47-51.



PRECAUTIONS:

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

ARTHROSCOPIC TECHNIQUE

Insert the Inion Arthroscopic Tip into the joint. (1)

Select the instrument size corresponding to the OTPS™ Pin required (1.5 or 2.0mm).

Drill hole for the OTPS™ Pin with corresponding size (1.5mm or 2.0mm) Inion K-Wire (Trocár Tip Drill) through the Arthroscopic Tip . (2)

Check the channel depth from the drill bit. Depth marks on the Trocar Tip Drill bit (1.5/2.0mm) are every 10 mm. Channel should be 1-2mm deeper than the Pin length.

ALTERNATIVELY: Place one Inion K-wire and then slide Arthroscopic Tip over it.

IF REQUIRED: The bone fragments can be secured before preparing the first pin channel. Drill in one 1.5mm Inion K-wire to hold the bones and insert this wire through the hole in the instrument handle. This will maintain the alignment while drilling and placing the first pin through the Arthroscopic Tip.

Select the correct Pin length. (3) If required, the Pin can be cut by using sterile surgical scissors. Remove the K-wire, keeping the Arthroscopic Tip in place and insert the selected OTPS™ Pin (1.5/2.0mm) into the cannula.

Gently tap Inion Arthroscopic Piston (1.5/2.0mm) to insert the Pin into the bone. (4)

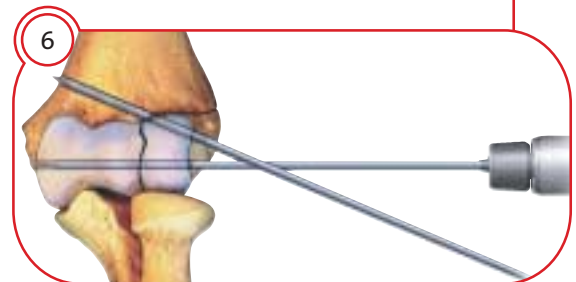
Pin insertion may be observed from the window on the side of Arthroscopic Tip. (5)

Insert at least two pins at diverging angles. (6)

Note! The Pins must be inserted completely inside the bone especially if they are in the articular surface. Otherwise they may cause damage to the cartilage and other tissue.

TIP: If the end result is not satisfactory, the Pins and fixation can be removed by overdrilling them.

It is essential to select the correct Pin length before inserting the Pin when operating arthroscopically in the articular surface.



1.5 mm pins



PIN-1520	1.5 x 20 mm
PIN-1530	1.5 x 30 mm
PIN-1540	1.5 x 40 mm
PIN-1550	1.5 x 50 mm

2.0 mm pins



PIN-2020	2.0 x 20 mm
PIN-2025	2.0 x 25 mm
PIN-2030	2.0 x 30 mm
PIN-2035	2.0 x 35 mm
PIN-2040	2.0 x 40 mm
PIN-2050	2.0 x 50 mm

Inion OTPS Pin instruments:

INS-9230 (T)	Pin applicator 1.5 mm
INS-9231 (T)	Pin applicator 2.0 mm

INS-9232 (T)	Arthroscopic handle
INS-9233 (T)	Arthroscopic tip 1.5 mm
INS-9234 (T)	Arthroscopic tip 2.0 mm
INS-9235 (T)	Arthroscopic piston 1.5 mm
INS-9236 (T)	Arthroscopic piston 2.0 mm
INS-9237 (T)	K-wire (Trocara tip drill) 1.5 mm
INS-9238 (T)	K-wire (Trocara tip drill) 2.0 mm
INS-9240 (T)	Wrench

ACC-9820 (T)	Sterilisation tray
ACC-9821 (T)	Sterilisation tray complete



Pin applicator



Arthroscopic
Pin applicator

Colour coded instruments for easier identification

1.5 mm green

2.0 mm blue



Sterilisation tray



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