

INION OTPS™
Biodegradable Mesh
Operation Technique



Inion OTPS™ Biodegradable Mesh System

DESCRIPTION

The Inion OTPS™ Mesh Fixation System is designed for graft containment and to reinforce and stabilise bony fragments. 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 OTPS™ products gradually lose most of their strength within 18-36 weeks. Bioresorption takes place within two to four years.

INDICATIONS

The implants are intended to sustain the relative position of weak bony tissue, for example bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The implants are also indicated for cement restriction in total joint arthroplasty procedures.

Inion OTPS™ Mesh Fixation System needs to be used in conjunction with traditional rigid fixation for load bearing indications, i.e. for the applications with:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the implants are intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopaedic procedures involving:

- Tumour resections where bone strength has not been compromised.
- Iliac crest harvest sites.

CONTRAINDICATIONS

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

- Spine indications.
- Load bearing indications unless used in conjunction with traditional rigid fixation.
- Situations where active or potential infection has to be respected.
- Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (for example, alcoholism, drug abuse).

PRECAUTIONS:

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



INION THERMO+ WATER BATH SET-UP

Place the water bath on a sterile draped cart so that it can be located close to the surgeon. The sterile Thermodrape (ACC-9802T) will completely cover the bath. However the bath cannot be sterilised.

CAUTION: Do not switch on the water bath until there is water in the bath or the drape will melt !

TIP: By switching the unit on, but leaving it unplugged, you are saved from having to find the switch through the drape. (1)

Place the water bath inside sterile Inion Thermo drape (ACC-9802T). Make a depression in the drape into which the sterile water can be poured. **(2)**

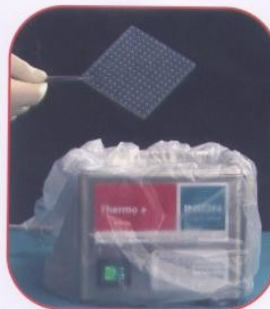
TIP: Flatten the bottom of the drape inside the bath to prevent airpockets under the drape.

Fill the bath to just over half-full (about 0.4 litres) with sterile water or saline. Once the water is in the bath it can be switched on. It takes about 30 minutes for the water to reach the required temperature of 70⁰ C or 157 F, so make sure to set it up at the beginning of the procedure. **(3)**

The 70⁰ C water bath is used instead of the 55⁰ C water bath (green label) which is used for the OTPS™ Mini Plating System.

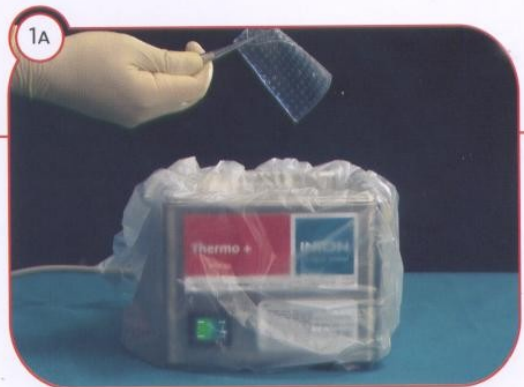
The Mesh plates need to be in the water bath 1 minute before use. **CAUTION: Do not warm screws in the water bath.** **CAUTION:** Take care not to perforate the drape with the surgical instruments.

TIP: It is recommended to have the Thermo+ water bath as close as possible to the operation table, since the Meshes cool off rapidly.



OPERATION TECHNIQUE

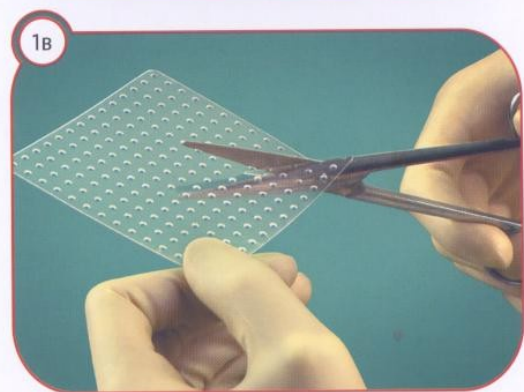
Immerse the Mesh in the Thermo+ water bath for approximately one minute. After water bath treatment the Mesh is easily malleable for 10-15 seconds. **(1A)**



The Mesh is easy to cut to the desired shape with sterile scissors. **(1B)**

TIP: Before cutting the Mesh, activate it in the water bath and then let it cool.

Place the Mesh back into the water bath for 5-10 seconds after cutting.

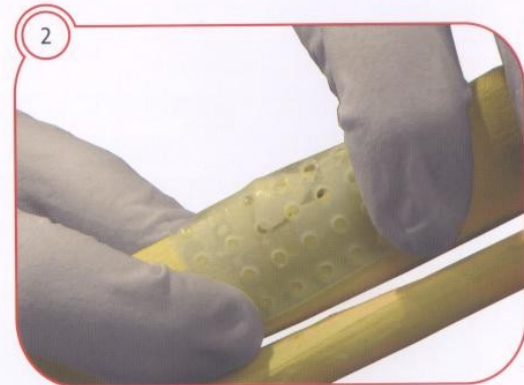


• **Place the Mesh against the bone. (2)**

Mold the Mesh to the desired shape using finger pressure and/or the Inion plate bending pliers.

- If molding is not satisfactory, the water bath treatment can be repeated. If only part of the Mesh needs adaptation, dip only that portion of the Mesh back in the water bath.

Repeated bending can weaken the Mesh, especially once cooled. Bending when warm can be carried out up to three times.

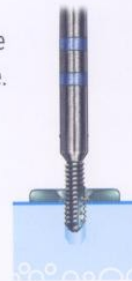


MANUAL TAP METHOD

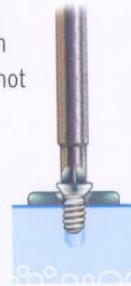
Create a screw hole to the required depth using the appropriate drill bit attached to a slow speed drill (maximum 2,000 rpm) and irrigation.



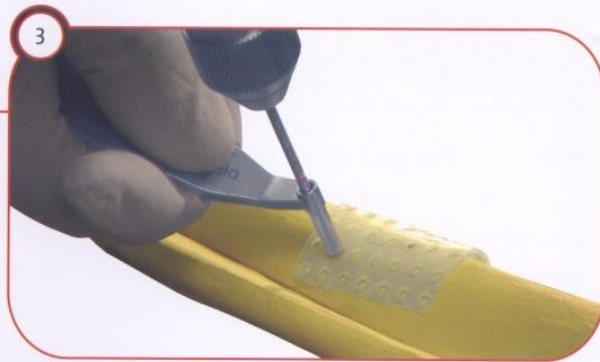
Manually tap the hole in the bone.



Insert screw with screwdriver. Do not overtighten.

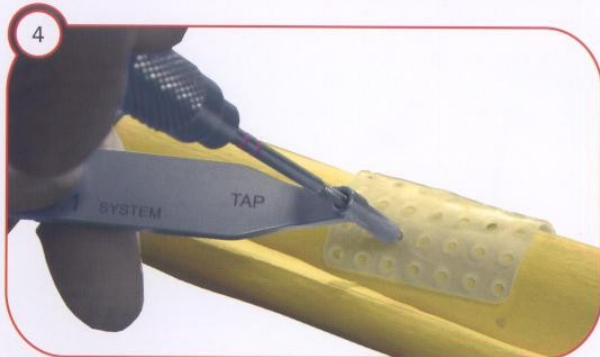


Drill through one of the Mesh hole using the Inion drill corresponding to the screw diameter. Use the drill guide to limit lateral movement. **(3)**

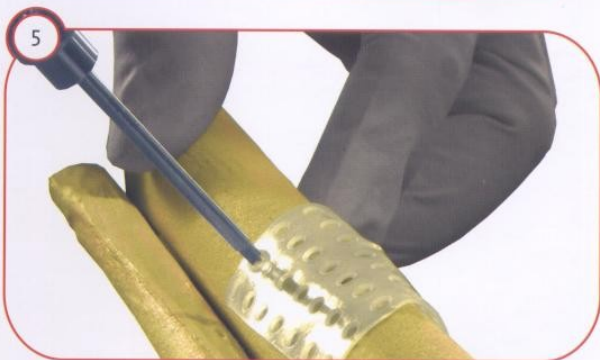


Tap through the Mesh using an appropriate size Inion tap. **(4)**

Flush with sterile water or saline.



Insert the screw using an Inion screwdriver. Place as many screws as is needed for proper Mesh fixation. **(5)**



If the screwhead shears off during insertion, do one of the below steps:

1. Leave it and use another hole in the Mesh.
2. Drill through the screw remnants with the same size drill as previously used, tap with the same size tap and place another screw of the same size.

If the hole becomes wider, use a larger size tap and screw.



SCREW PICK-UP GUIDE

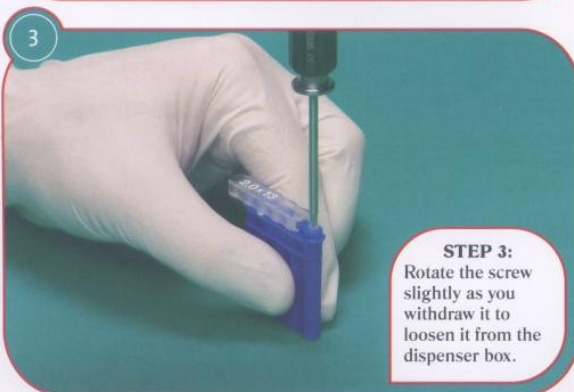
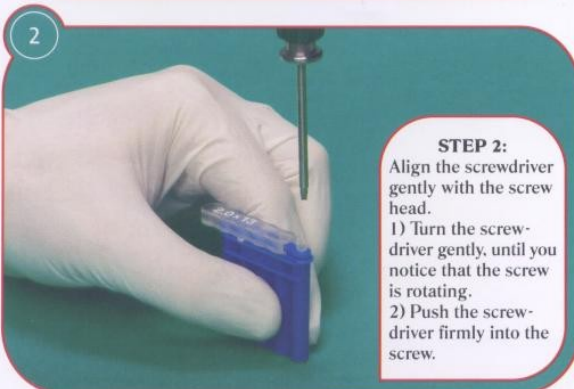
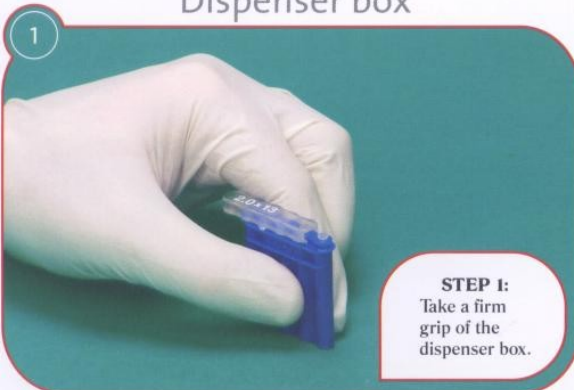
PLEASE NOTE:

It is important that the screwdriver is aligned properly before pushing it into the screw head.

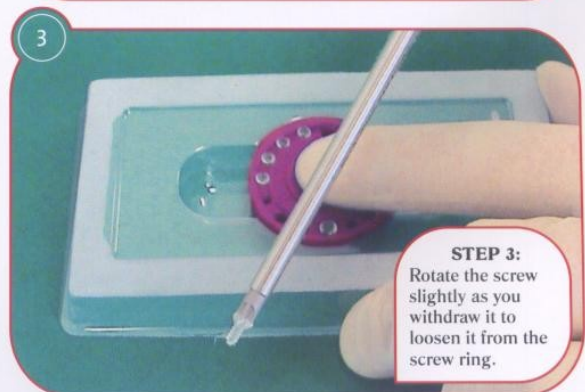
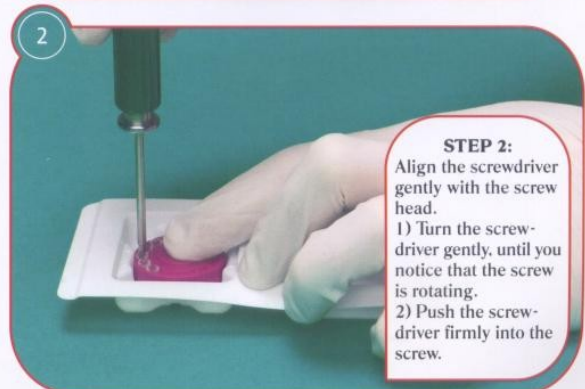
Insufficient pressure will not mount the screw securely.

OTPS™ screws all have an X slot push-fit, which allows for secure pick-up.

Dispenser box



Screw ring





2.0 mm Inion short screws are packed in a screw ring containing 5 screws and one emergency screw. **(A)**

2.5 mm Inion short screws are packed to screw ring containing 5 screws. If an emergency screw is needed the next diameter can be used.

2.8 mm Inion screws are supplied in dispenser boxes containing two screws. 3.1-4.5 mm screws are individually packed. **(B)**

TIP: If required, the screws can be cut to the desired length with standard surgical scissors or wire cutters.

UNIVERSAL INSTRUMENTS

INS-9024 (T)	Plate bending pliers
INS-9029 (T)	Universal screwdriver blade
INS-9099 (T)	Drill guide 1.5/2.0 mm
INS-9088 (T)	Drill guide 2.5/2.8/3.1 mm
INS-9089 (T)	Drill guide 4.5 mm
INS-9091 (T)	Depth gauge 2.0 mm- 3.1 mm
INS-9093 (T)	Screwdriver handle, cannulated
INS-9094 (T)	Screwdriver shaft, crosshead
INS-9095 (T)	Screwdriver shaft, hexalobular, cannulated
ACC-9802 (T)	Inion Thermo drape (5 drapes)
ACC-9810 (T)	Inion Thermo+ water bath (230 V + EU plug)
ACC-9812 (T)	Inion Thermo+ water bath (230 V + UK plug)
ACC-9840 (T)	Inion Thermo+ water bath (110 V + US plug)
ACC-9813 (T)	Sterilisation tray for instruments
ACC-9818 (T)	Inion Compact Instrument Tray



2.0 mm INSTRUMENTS

INS-9096 (T)	1.75 mm drill bit with 6 mm stop (AO-bayonet)
INS-9098 (T)	2.0 mm bone tap (manual, AO-bayonet)
INS-9104 (T)	1.7 mm drill bit with 22 mm stop (AO-bayonet)
INS-9105 (T)	2.0 mm bone tap with 22 mm stop (AO-bayonet)

2.5 mm INSTRUMENTS

INS-9069 (T)	2.2 mm drill bit with 8 mm stop (AO-bayonet)
INS-9070 (T)	2.2 mm drill bit with 32 mm stop (AO-bayonet)
INS-9080 (T)	2.5 mm bone tap with 32 mm stop (manual, AO-bayonet)

2.8 mm INSTRUMENTS

INS-9073 (T)	2.5 mm drill bit with 42 mm stop (AO-bayonet)
INS-9081 (T)	2.8 mm bone tap with 42 mm stop (manual, AO-bayonet)

3.1 mm INSTRUMENTS

INS-9076 (T)	2.8 mm drill bit with 42 mm stop (AO-bayonet)
INS-9082 (T)	3.1 mm bone tap with 42 mm stop (manual, AO-bayonet)

4.5 mm INSTRUMENTS

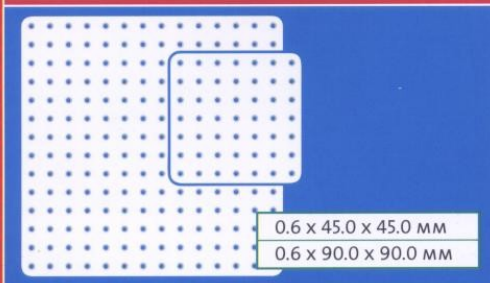
INS-9078 (T)	3.5 mm drill bit (AO-bayonet)
INS-9083 (T)	4.5 mm bone tap (manual, AO-bayonet)

⧗ Instruments are colour coded

2.0 mm MESH PLATES



REF. NO.	DESCRIPTION
MSH-1032	Mesh plate, 7 x 7 holes
MSH-1033	Mesh plate, 14 x 14 holes



2.0 mm SCREWS

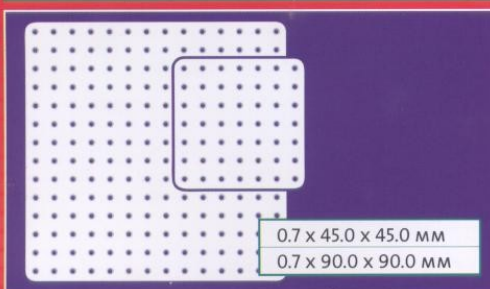


FRF-1224	2.0 x 5 mm (5 pcs. + E)
FRF-1225	2.0 x 7 mm (5 pcs. + E)
FRF-1289	2.0 x 20 mm screw (2 pcs.)

2.5 mm MESH PLATES



MSH-1034	Mesh plate, 7 x 7 holes
MSH-1035	Mesh plate, 14 x 14 holes



2.5 mm SCREWS



REF. NO.	DESCRIPTION
FRF-1206	2.5 x 6 mm screw (5 pcs.)
FRF-1207	2.5 x 8 mm screw (5 pcs.)
FRF-1248	2.5 x 10 mm screw (2 pcs.)
FRF-1249	2.5 x 12 mm screw (2 pcs.)
FRF-1250	2.5 x 14 mm screw (2 pcs.)
FRF-1251	2.5 x 16 mm screw (2 pcs.)
FRF-1252	2.5 x 18 mm screw (2 pcs.)
FRF-1253	2.5 x 23 mm screw (2 pcs.)
FRF-1254	2.5 x 30 mm screw (2 pcs.)

2.8 mm SCREWS



FRF-1257	2.8 x 10 mm screws (2 pcs.)
FRF-1258	2.8 x 12 mm screws (2 pcs.)
FRF-1259	2.8 x 14 mm screws (2 pcs.)
FRF-1260	2.8 x 16 mm screws (2 pcs.)
FRF-1261	2.8 x 18 mm screws (2 pcs.)
FRF-1262	2.8 x 23 mm screws (2 pcs.)
FRF-1263	2.8 x 40 mm screws (2 pcs.)

3.1 mm SCREWS



FRF-1266	3.1 x 10 mm screw (1 pcs.)
FRF-1267	3.1 x 12 mm screw (1 pcs.)
FRF-1268	3.1 x 14 mm screw (1 pcs.)
FRF-1269	3.1 x 16 mm screw (1 pcs.)
FRF-1270	3.1 x 18 mm screw (1 pcs.)
FRF-1271	3.1 x 40 mm screw (1 pcs.)

4.5 mm SCREWS



FRF-1235	4.5 x 20 mm screw (1 pcs.)
FRF-1236	4.5 x 25 mm screw (1 pcs.)
FRF-1237	4.5 x 30 mm screw (1 pcs.)
FRF-1238	4.5 x 35 mm screw (1 pcs.)
FRF-1244	4.5 x 40 mm screw (1 pcs.)
FRF-1245	4.5 x 45 mm screw (1 pcs.)



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