Inion S-1™

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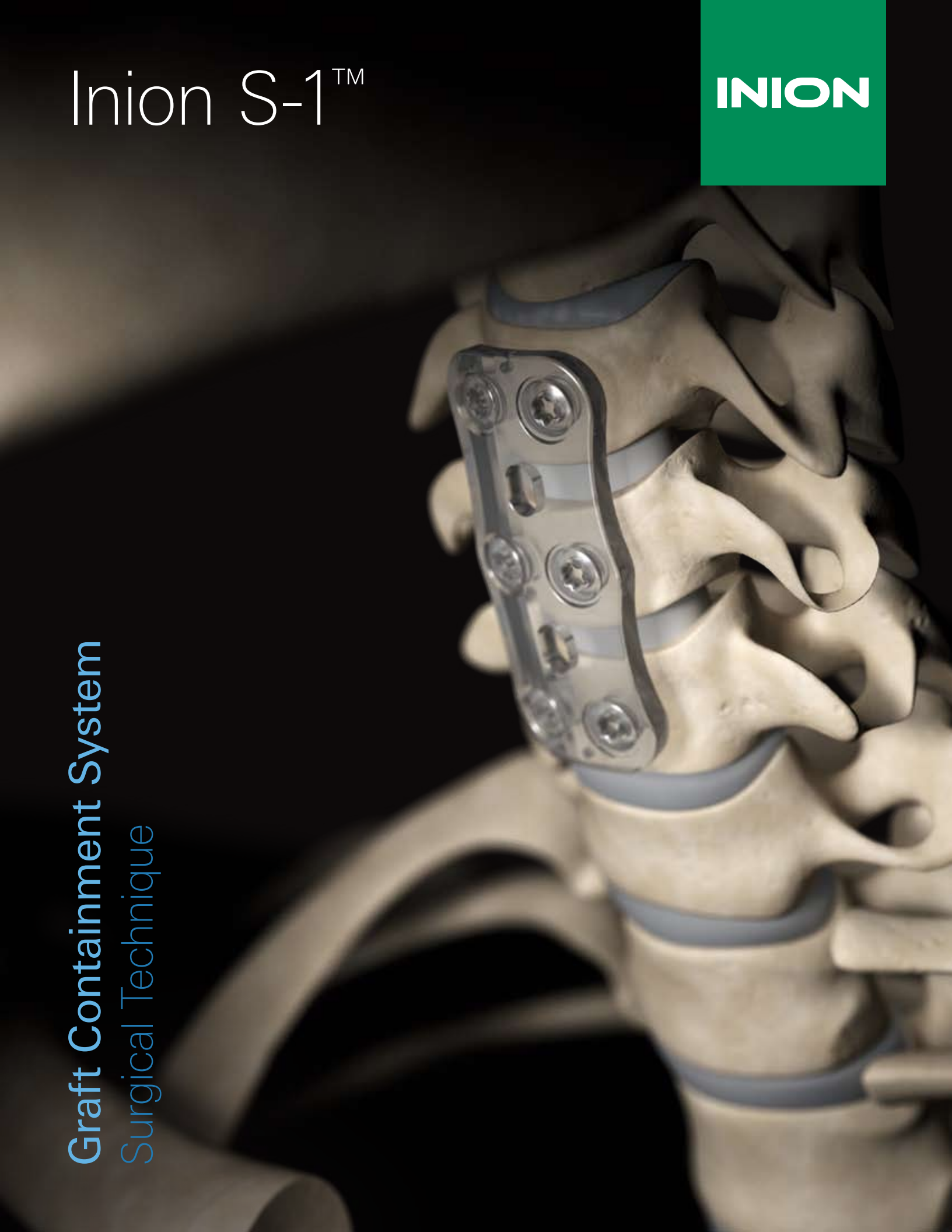


Graft Containment System

Surgical Technique

Product Overview

The **Inion S-1™ Biodegradable Anterior Cervical Fusion System for graft containment** consists of plates and screws made of degradable co-polymers composed of L-lactic and D-lactic acid. These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alpha-hydroxy acids that are metabolised by the body. Based on in vitro testing, the implants retain most of their initial strength up to 16 weeks and gradually lose their strength thereafter; bioresorption takes place within two to four years. The plates and screws contain radiopaque tantalum markers for postoperative radiographic imaging.

The Inion S-1™ Biodegradable Anterior Cervical Fusion System plates are available in different sizes for use in single and double level fusions.

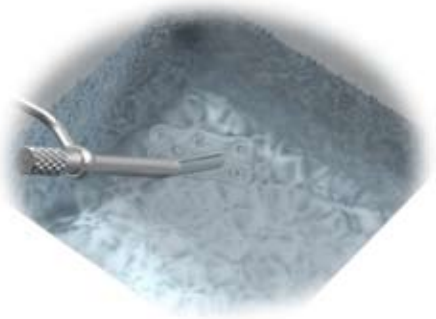
Indications

The **Inion S-1™ graft containment system**, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintan the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Inion implants are contraindicated for:

- Active or potential infection
- Cancer
- Pseudoarthrosis
- Patient conditions including limited blood supply, insufficient quantity or quality of bone and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse)

Surgical technique



1. Determine the correct plate size

Once the graft is in place, the plate templates can be used to determine the right size of the Inion S-1™ plate. The plate holder can be used for positioning the template and is attached by positioning the distal end of the plate holder into the middle hole of the template and then tightening the screw on the plate holder.

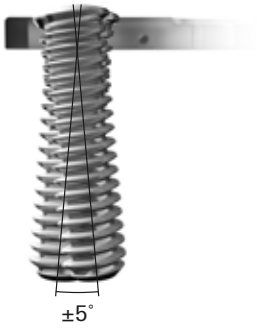
Once a desired position is achieved use the awl, through the drill guide, to mark screw hole locations. Use the depth markers on the shaft of the awl to monitor the progress of the awl and ensure the desired depth is achieved.

2. Contour the Inion S-1™ plate

Using the plate holder, precondition the chosen Inion S-1™ plate in the Inion Thermo+™ water bath for approximately 1 minute.

Soon after heating position the plate on the cervical spine and contour the plate to the patient's anatomy using fingers.

The plate is malleable for approximately 10 seconds. Preconditioning can be repeated up to 3 times. A reimmersion of only 30 seconds in the Inion Thermo+ water bath is required for further contouring.



3. Insert the temporary fixation screws

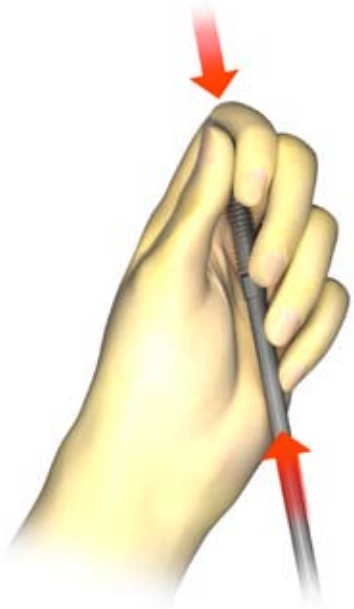
Using the plate holder, place the contoured Inion S-1™ plate at the desired level and insert at least one temporary fixation screw in each end of the plate, ideally in opposing screw holes.

Once the plate is fixed into position, with temporary screws, the plate holder can be removed.

4. Drill the screw hole

It is advised that you always use the drill guide whenever preparing screw holes in the Inion S-1™ plate. This allows the correct screw trajectory and depth to be achieved as well as ensuring the plate is sufficiently seated to the bone. The drill bits are colour coded. Each colour corresponds to a screw depth and the number of bands corresponds to the screw diameter.

Select the desired screw length and using the corresponding drill, drill a screw hole into the bone through the plate whilst applying downward pressure to the drill guide to ensure the plate is adequately seated and the correct screw trajectory and depth is achieved.



5. Tap the screw hole

As with step 4, it is advised that you always use the drill guide when ever tapping the screw holes in the Inion S-1™ plate. This allows the correct screw trajectory and depth to be maintained as well as ensuring the plate is sufficiently seated to the bone. The taps, like the drill bits, are colour coded. Each colour corresponds to a screw depth.

With the drill guide in place and the correct tap selected tap the first hole through the Inion S-1™ plate using a 2 turns forwards and one turn back motion. This motion ensures optimum screw thread preparation which will encourage safe seating of the Inion S-1™ screw. Be sure to thread all the way to the pre-set stop of the tap.

Flush the drilled hole with sterile water or saline.

6. Insert the first Inion S-1™ screw

Load the desired Inion S-1™ screw on to the screwdriver supplied. Ensure the screw is seated by applying a firm downward pressure when engaging the screwdriver shaft into the Inion S-1™ screw head.

It is advised that you always use the drill guide when inserting screws into the Inion S-1™ plate.This allows the correct screw trajectory and depth to be achieved as well as ensuring the plate is sufficiently seated to the bone. Pass the screw through the drill guide until you feel it locates the plate.

Start advancing the screw into the plate whilst applying gentle, but positive pressure. You will feel resistance as the screw passes through the plate.

Ensure you maintain downward pressure on the plate using the drill guide and on the screw using the screwdriver.

The markers on the screwdriver shaft will allow you to monitor the progress of the screw advancement. As the resistance increases and screw advancement reaches its optimum, reduce the speed of screw advancement.

You can check your progress by lifting the drill guide, whilst maintaining screwdriver/screw head engagement, and checking to see if the screw is fully engaged into the plate. Continue until the Inion S-1™ screw head is fully engaged into the Inion S-1™ plate. Do not overtighten the screw as this may lead to head or thread stripping.

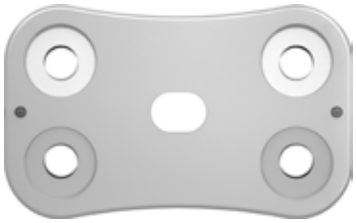
7. Finalise fixation of the plate

Repeat steps 4–6 for the second Inion S-1™ screw ideally in a position at the other end of the Inion S-1™ plate.

Once you have positioned an Inion S-1™ screw in each end of the plate, ideally in opposing screw holes, remove the temporary fixation screws and repeat steps 4–6 for the remaining screw holes to ensure complete fixation. To ensure there has been no plate movement during this step revisit the initial Inion S-1™ screws and ensure they are tight and flush to the Inion S-1™ plate.

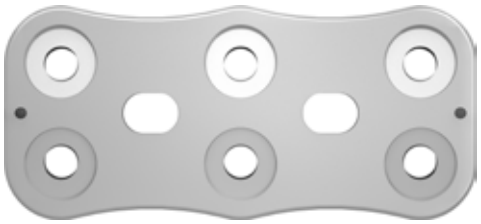
Complete the procedure by applying posterior interspinous wiring. For more detailed instructions, please see the Instructions for Use.

Ordering information

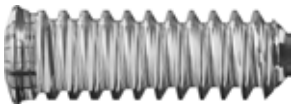


Inion S-1™ Plates

Art. No.	Description	Qty
SPN-5010	Single level plate, 21 x 19 x 2.0 mm	1
SPN-5011	Single level plate, 23 x 19 x 2.0 mm	1
SPN-5012	Single level plate, 25 x 19 x 2.0 mm	1
SPN-5013	Single level plate, 27 x 19 x 2.0 mm	1
SPN-5014	Single level plate, 29 x 19 x 2.0 mm	1
SPN-5015	Single level plate, 31 x 19 x 2.0 mm	1



SPN-5016	Double level plate, 33 x 19 x 2.0 mm	1
SPN-5017	Double level plate, 36 x 19 x 2.0 mm	1
SPN-5018	Double level plate, 39 x 19 x 2.0 mm	1
SPN-5019	Double level plate, 42 x 19 x 2.0 mm	1
SPN-5020	Double level plate, 45 x 19 x 2.0 mm	1
SPN-5021	Double level plate, 48 x 19 x 2.0 mm	1



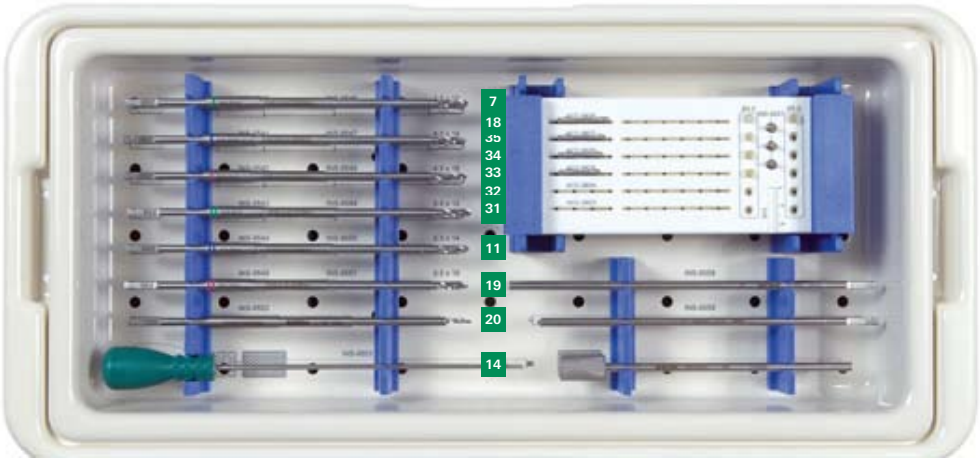
Inion® Screws

Art. No.	Description	Qty
SPN-5220	Screw 4.5 x 12 mm	2
SPN-5221	Screw 4.5 x 14 mm	2
SPN-5222	Screw 4.5 x 16 mm	2
SPN-5223	Screw 5.0 x 12 mm	1
SPN-5224	Screw 5.0 x 14 mm	1
SPN-5225	Screw 5.0 x 16 mm	1

Instruments

Art. No.	Description	Ref
INS-9540	Drill bit 3.7 mm, stop for 12 mm screw	1
INS-9541	Drill bit 3.7 mm, stop for 14 mm screw	2
INS-9542	Drill bit 3.7 mm, stop for 16 mm screw	3
INS-9543	Drill bit 4.2 mm, stop for 12 mm screw	4
INS-9544	Drill bit 4.2 mm, stop for 14 mm screw	5
INS-9545	Drill bit 4.2 mm, stop for 16 mm screw	6
INS-9546	Bone tap 4.5 mm, stop for 12 mm screw	7
INS-9547	Bone tap 4.5 mm, stop for 14 mm screw	8
INS-9548	Bone tap 4.5 mm, stop for 16 mm screw	9
INS-9549	Bone tap 5.0 mm, stop for 12 mm screw	10
INS-9550	Bone tap 5.0 mm, stop for 14 mm screw	11
INS-9551	Bone tap 5.0 mm, stop for 16 mm screw	12
INS-9552	Drill bit 2.0 mm	13
INS-9553	Screw removal instrument	14
INS-9554	Drill guide, single	15
INS-9555	Drill guide, twin	16
INS-9556	Plate holder	17
INS-9527	Temporary fixation screw	18
INS-9558	Screwdriver shaft for temporary screw	19
INS-9559	Screwdriver shaft	20
INS-9560	Awl	21
INS-9024	Plate bending pliers	22
INS-9120	Screwdriver handle, cannulated	23
INS-9121	Screwdriver handle, ratchet	24
ACC-9823	Plate template, 21 x 19 mm	25
ACC-9824	Plate template, 23 x 19 mm	26
ACC-9825	Plate template, 25 x 19 mm	27
ACC-9826	Plate template, 27 x 19 mm	28
ACC-9827	Plate template, 29 x 19 mm	29
ACC-9828	Plate template, 31 x 19 mm	30
ACC-9829	Plate template, 33 x 19 mm	31
ACC-9830	Plate template, 36 x 19 mm	32
ACC-9831	Plate template, 39 x 19 mm	33
ACC-9832	Plate template, 42 x 19 mm	34
ACC-9833	Plate template, 45 x 19 mm	35
ACC-9834	Plate template, 48 x 19 mm	36
ACC-9802	Inion Thermo™ drape	
ACC-9840	Inion Thermo+™ (water bath 110V)	
ACC-9841	Sterilization tray for instruments	

Instrument trays



Surgical technique quick reference

1. Determine the correct plate size

2. Contour the Inion S-1™ plate

3. Insert temporary fixation screws

4. Drill the screw hole

5. Tap the screw hole

6. Insert the first Inion S-1™ screw

7. Finalise fixation of the plate. Complete the procedure by applying appropriate traditional rigid fixation, i.e. posterior interspinous wiring.

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