

Inion S-2™

INION

Graft Containment System
Surgical Technique





Product Overview

The **Inion S-2™ Biodegradable Anterior Thoraco-Lumbar 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; and bioresorption takes place within two to four years. The plates and screws contain radiopaque tantalum markers for postoperative radiographic imaging.

The Inion S-2™ Biodegradable Anterior Thoraco-Lumbar Fusion System plates and screws are available in different sizes for use in single level fusions and are designed for use with dedicated Inion instrumentation.

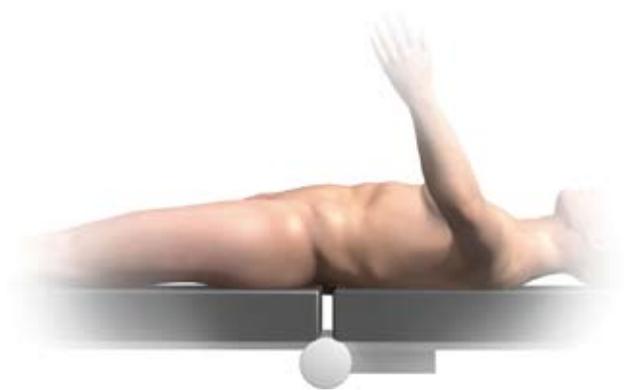
Indications

The **Inion S-2™ graft containment system**, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This 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)

Anterior approach to the lumbar spine



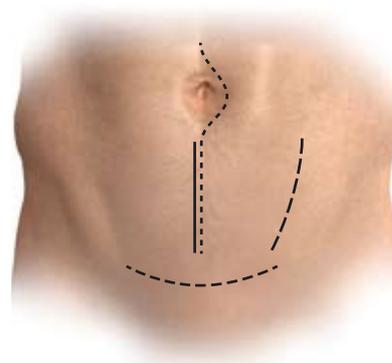
Introduction

Reaching the anterior aspect of the lumbar spine poses certain challenges for the surgeon and should only be performed by those with experience of these approaches and the pitfalls that may be encountered. An access surgeon should be considered for the less experienced and a vascular surgeon should be aware of the schedule, to be available if necessary.

There are three routes of access, employing a retroperitoneal approach, which is favoured because of the reduced risk of retrograde ejaculation in men and bowel injury in all patients. These are the true anterior, antero-lateral and lateral.

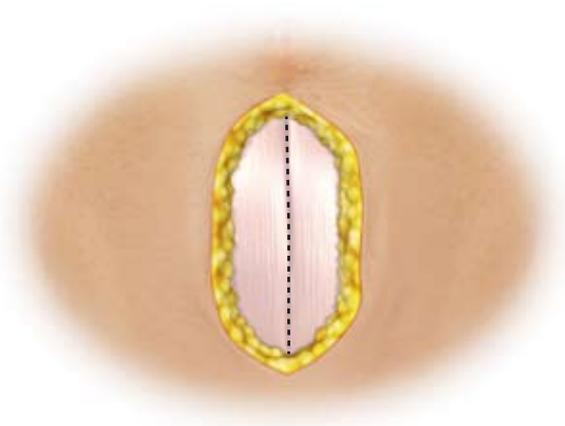
True anterior

The patient is positioned supine on a radio-lucent operating table, allowing both AP and lateral C-arm fluoroscopy. A break in the table behind the lumbar spine may be useful to increase extension, or, alternatively, a padded gel roll may be used. This increases the lordotic curve and opens up the disc spaces.

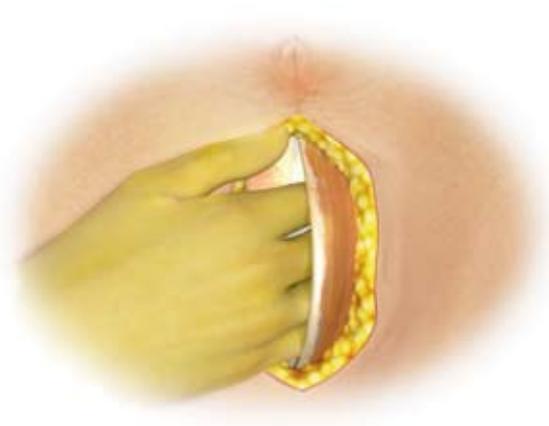


- Incision Options:
- L3 - L4
 - L4 - L5
 - L4 - L5
 - L5 - S1

An incision is made in the skin overlying the disc to be approached, or between the two discs. A transverse incision is better from a cosmetic perspective and heals well, possibly with less wound pain. It should be centred on the midline.



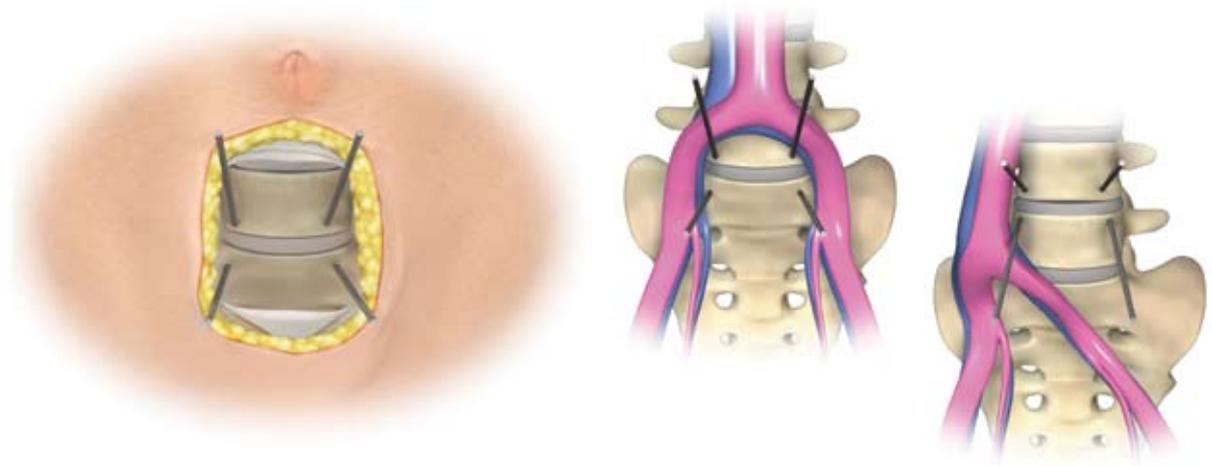
Subcutaneous tissues are parted to expose the anterior rectus sheath, which is in turn opened bilaterally in the line of the skin incision. The underlying muscle must not be traumatised, as bleeding vessels may retract and prove difficult to control. The two incisions in the sheath are joined across the midline, elevating them whilst cutting across with scissors. The lateral extent of the rectus sheath opening may stop short of its lateral edge (linea semilunaris) for a single level procedure. The rectus sheath is then elevated as a “flap”, separating it from the underlying muscle above and below. Some fibres are adherent and may bleed; this must be controlled to prevent subsequent rectus sheath haematoma (which may mimic an acute abdomen). Sharp scissor dissection is required in the midline, taking care to prevent peritoneal injury.



The rectus muscles are now parted in the midline, typically with finger dissection only. Bleeding points are coagulated en route, care being taken to avoid the inferior epigastric vascular bundle. The left rectus muscle is then elevated, a large Langenbeck type retractor may be used. Below the arcuate line, as for an L5/S1 exposure, there is no posterior sheath.

The aponeurosis of the transversus abdominis must now be separated from the underlying peritoneum. This is easiest laterally, where in a healthy individual there will be muscle fibres, which run transversely and can be parted with finger dissection or scissors, taking care not to enter the peritoneum. Once this space is identified, it is developed with blunt dissection and the transversalis fascia is further parted. The fingers can then be passed laterally, to mobilise the peritoneum towards the midline, first stripping it off the lateral abdominal wall and then the psoas muscle. Care is taken here to avoid trauma to the ilio-inguinal nerve on the surface of psoas.

Anterior approach to the lumbar spine



As the spine is approached medial to the psoas muscle, the common iliac vessels will be identified, together with the ureter and sympathetic trunk. The sympathetic trunk must be preserved and gently mobilised laterally. The ureter is usually mobilised medially with the peritoneum and the pre-sacral nerve, often not directly seen, should also move across with the peritoneum. At L5/S1 the exposure of the disc space is between the vessels, the median sacral vessels being divided. At higher levels the approach is lateral to the vessels which need to be adequately mobilised to the right side. This often involves ligating and dividing the ilio-lumbar vein, which would otherwise be over-stretched by the retraction and bleed profusely. Occasionally, particularly at L4/5, the best approach is to part the left common iliac artery and vein and reach the spine between these.

A straight, hand-held, Kelly retractor is useful for aiding visualisation. Steinman pins, preferably covered in silastic, may be tapped into the vertebral bodies above and below the disc being operated upon, to hold back the tissues and maintain retraction. Constant retraction over a prolonged period, by this method, may lead to thrombosis in the iliac veins, or even arterial injury.

Antero-lateral

The same positioning is employed as for the true anterior approach.

Here the incision is centred on the linea semilunaris, the lateral edge of the rectus muscle, or even slightly lateral to this point. The anterior rectus sheath is opened laterally and the incision extended into the external oblique aponeurosis. The underlying transversus abdominis muscle, or more likely in this location its fascia, is parted and the extra-peritoneal space is developed with blunt dissection.

The retroperitoneal approach to the spine then proceeds as above. It is difficult, but not impossible, to achieve a direct anterior approach

into the disc space using this approach. It does require a lot of retraction, pulling not only the intra-peritoneal structures, but also the rectus muscle and its sheath across the midline. This approach should, therefore, be reserved for cases where direct anterior placement of a device into the disc space is not necessary.

Lateral

This approach is not an option at L5/S1, due to the vascular anatomy.

The patient is positioned on their side. A decision is made, depending upon symptoms and pathology, as to which side should be uppermost, i.e. the side to approach the spine from. If the symptoms are unilateral, the approach should be on the symptomatic side. If there is a gross collapse of a disc space laterally, e.g. degenerative scoliosis, it may be that approaching the spine from the concave side will give the best chance of restoring the alignment.

A transverse incision is made over the disc being operated upon, slightly angled to follow the lines of the cutaneous nerve supply, and therefore hopefully limiting post-operative pain. The length of the incision is determined by the

instrumentation to be used, the experience of the surgeon and any prosthetics/implants planned. The external and internal oblique muscles are opened in a "grid-iron" manner and the transversus abdominis fibres are parted to enter the extra-peritoneal space. This is developed by finger dissection, towards the lateral margin of the psoas muscle.

Great care must be taken to avoid traumatising the nerve roots as they exit behind psoas, or occasionally through the muscle. Neurophysiological monitoring is useful at this stage, reducing this risk of nerve root damage. Retracting the psoas muscle posteriorly, to gain better exposure of the lateral aspect of the disc can also damage the exiting roots. This may compress the root against the transverse process of the vertebra below. If this degree of retraction is going to be necessary, it may be safer to amputate the relevant transverse processes initially. Splitting psoas gives good access and a suitable self-retaining retractor, or pins into the vertebral bodies, will maintain access. The segmental vessels cross roughly at the midpoint of the vertebral body, so care should be taken to prevent bleeding here, or they may be divided in anticipation.

Complications of the approaches

There are complications and risks common to all of the above. Infection, haemorrhage and a paralytic ileus are similar risks for all three approaches. A haematoma within the rectus sheath can be very painful and present as an acute abdomen. It is easy to diagnose on ultrasound. A retro-peritoneal haematoma may prolong the ileus and potentially lead to cardio-vascular instability if major. Muscle trauma from over-zealous retraction may be painful, but the muscles will usually recover, as their nerve supply should not be affected.

Peritoneal tears, if small should always be closed, to prevent bowel hernia and strangulation. Large defects, or multiple holes, should be left widely open. Bowel injury must be dealt with by an expert abdominal surgeon, but would, of course, prevent the use of any implants or further surgery on the disc. Similarly injury to the ureter (or kidney or bladder) must be attended to by a urological surgeon.

Vascular injury is not uncommon. If the disc is grossly inflamed, the vessels may be stuck to it and bleeding may occur, usually from a branch, when mobilising these. A suture on a round bodied needle, liga-clips or, if all else fails, a pin to compress the bleeding portion against the bone (rather like a drawing pin / thumb tack) may be used.

Sympathectomy will probably occur in around 5% of patients, the risk being higher if a wide exposure is required. This is usually self-limiting over a few months. Retro-grade ejaculation is common at L5/S1 in men, with a trans-peritoneal approach, but much less frequent with the above. Nevertheless, male patients should be advised about this risk and, if they may wish to have children in the future, should be advised to visit the sperm bank, in advance of the surgery. This complication may also improve in time, perhaps in around two thirds of cases.

John Sutcliffe
February 2008

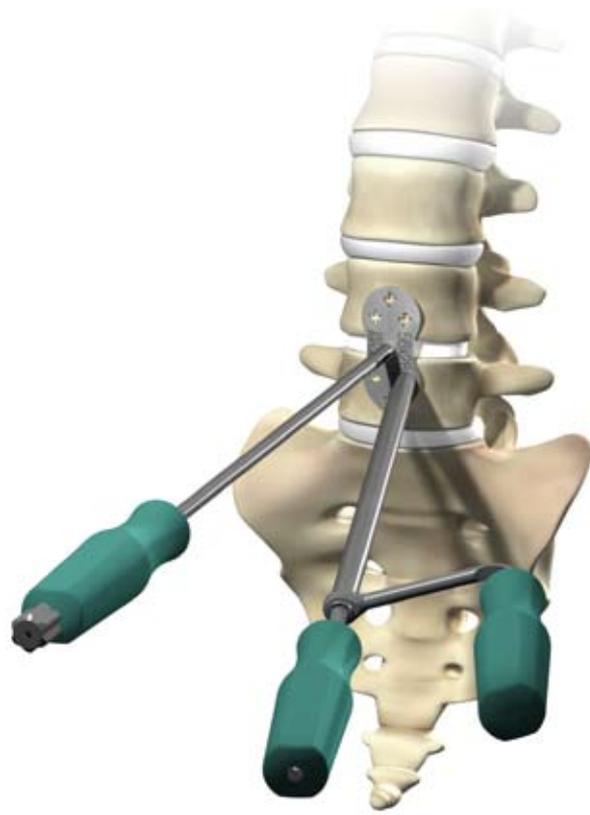


1. Determine the correct plate size

Once the graft is in place, the plate templates can be used to determine the right size of Inion S-2™ plate. The plate holder can be used for positioning the template.

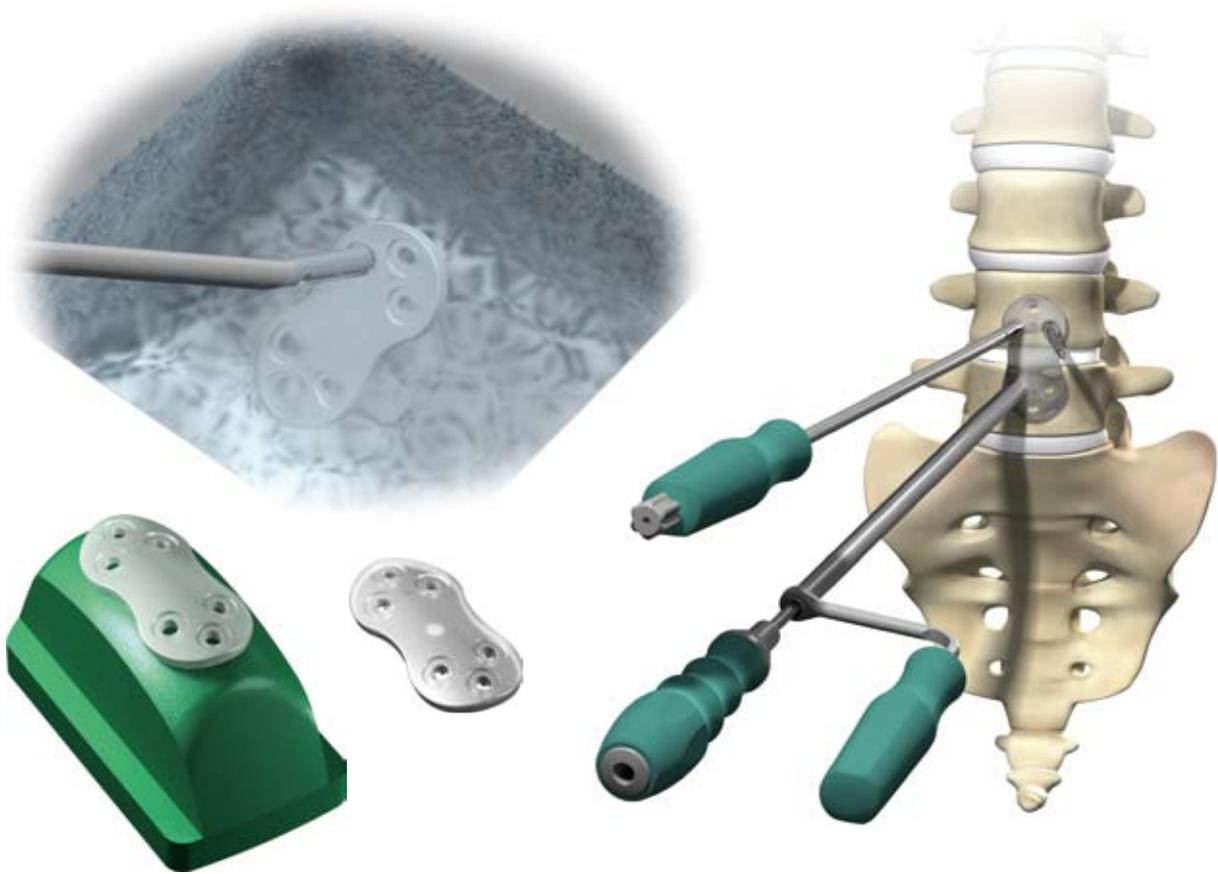
After the plate size is determined, pliers can be used to shape the plate template to fit the anatomical contours of spine.

The contoured plate template can also be used when contouring the Inion S-2™ plate as described in step 3.



2. Mark screw holes with the Awl

After contouring the plate template use the awl 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.



3. Contour the Inion S-2™ plate

Precondition the chosen Inion S-2™ plate in the Inion Thermo+™ water bath for a minimum of 1 minute.

Use the contoured plate template (from Step 1) or plate contouring block to shape the preconditioned plate to the desired shape.

The preconditioning can be repeated up to 3 times, however a reimmersion of 30 seconds in the Inion Thermo+™ water bath is required, if further contouring is needed.

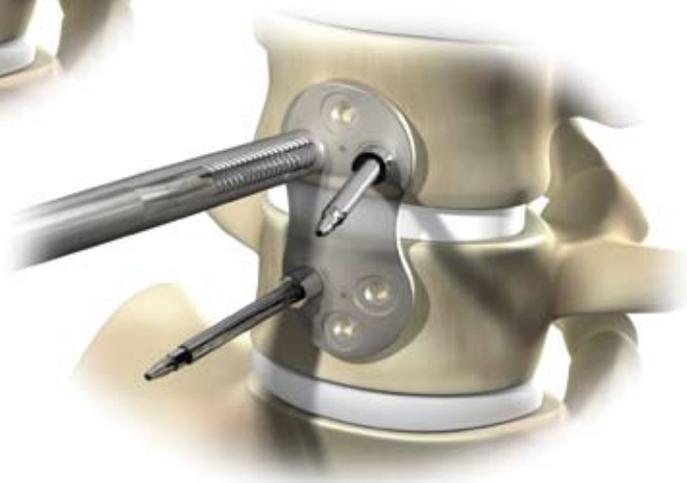
4. Place the plate on the bone with the Temporary Fixation Screws

Using the plate holder, place the contoured Inion S-2™ plate at the desired level and insert at least one temporary fixation screw to 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.



5. Drill the screw hole



6. Tap the screw hole

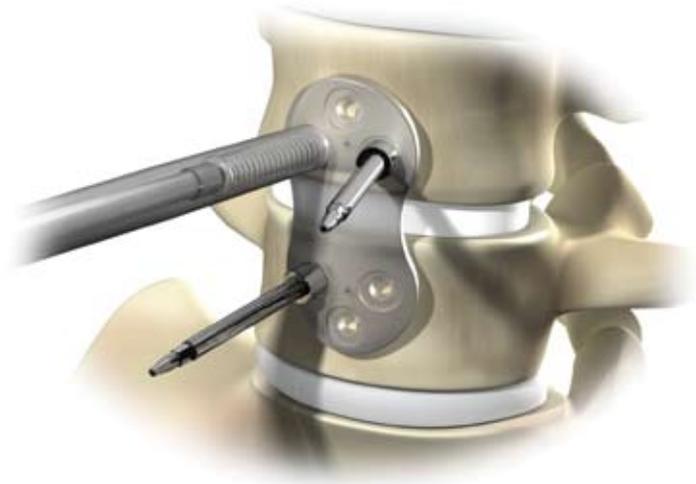
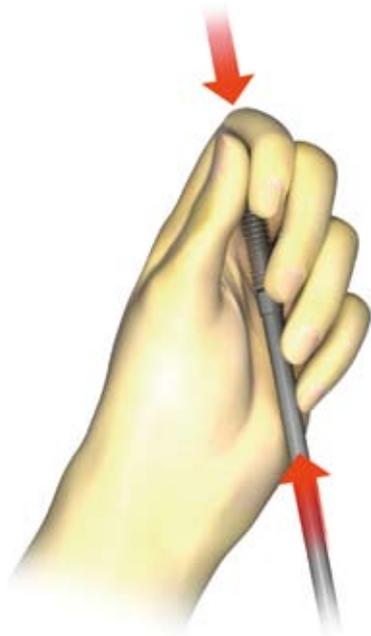
It is advised that you always use the drill guide whenever preparing screw holes in the Inion S-2™ plate. This allows the correct screw trajectory and depth to be achieved as well as ensuring the plate is sufficiently seated to the bone. The drill bits are colour coded. Each colour corresponds to a screw depth and the number of bands corresponds to the screw diameter.

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



As with in step 5 it is advised that you always use the drill guide when ever tapping the screw holes in the Inion S-2™ 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, as with 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-2™ 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-2™ screw.

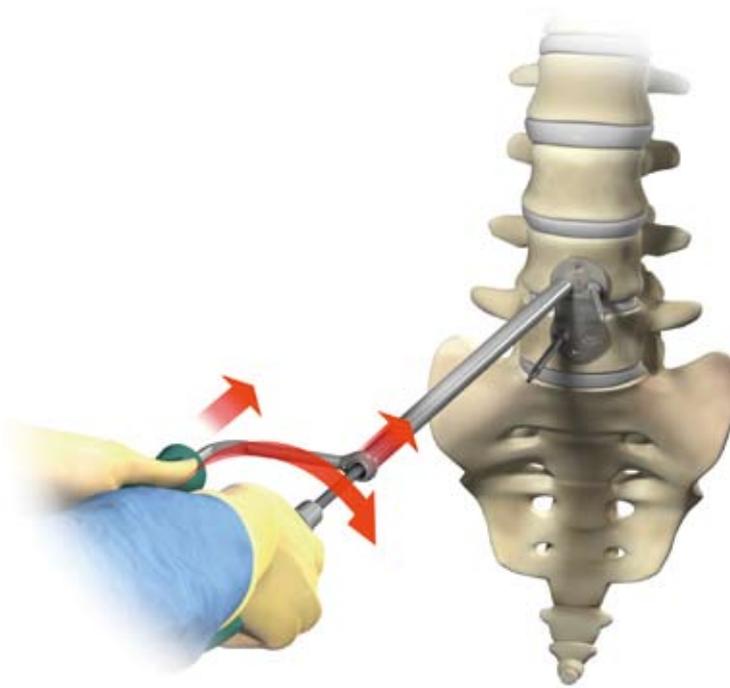


7. Insert the first Inion S-2™ screw

Load the desired Inion S-2™ 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-2™ screw head.

It is advised that you always use the drill guide when inserting screws into the Inion S-2™ 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 locate the plate.



Start advancing the screw into the plate whilst applying gentle, but positive downward 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-2™ screw head is fully engaged into the Inion S-2™ plate. Do not overtighten the screw as this may lead to head or thread stripping.



8. Insert the second Inion S-2™ screw

Repeat steps 5–7 for the second Inion S-2™ screw ideally in a position at the other end of the Inion S-2™ plate.

9. Replace temporary fixation screws with Inion S-2™ screws

Once you have positioned an Inion S-2™ screw in each end of the plate, ideally in opposing screw holes, remove the temporary fixation screws and repeat steps 5, 6 and 7 to the remaining screw holes to ensure complete fixation. To ensure there has been no plate movement during this step revisit the initial Inion S-2™ screws and ensure they are tight and flush to the Inion S-2™ plate.

Complete the procedure by applying appropriate traditional rigid fixation, e.g., pedicle screws.

Ordering information

Inion S-2™ Plates



Art. No.	Description	Qty
SPN-5401	Plate 37 x 28 x 3.2 mm	1
SPN-5402	Plate 40 x 28 x 3.2 mm	1
SPN-5403	Plate 43 x 28 x 3.2 mm	1
SPN-5404	Plate 46 x 28 x 3.2 mm	1
SPN-5405	Plate 49 x 28 x 3.2 mm	1



SPN-5406	Plate 50 x 28 x 3.2 mm	1
SPN-5407	Plate 53 x 28 x 3.2 mm	1
SPN-5408	Plate 56 x 28 x 3.2 mm	1
SPN-5409	Plate 59 x 28 x 3.2 mm	1
SPN-5410	Plate 62 x 28 x 3.2 mm	1



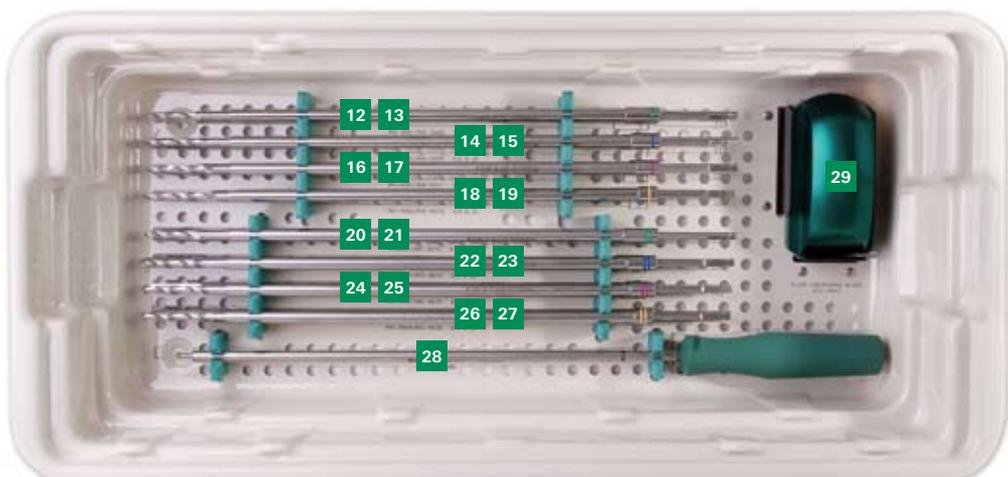
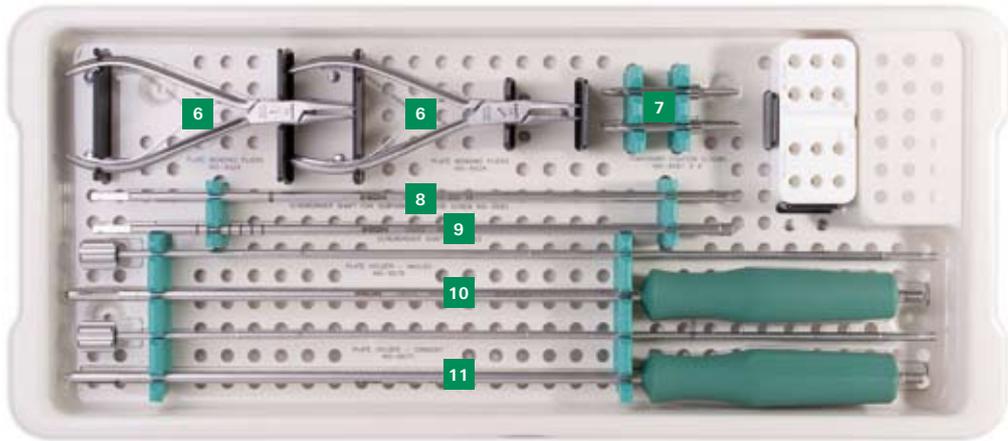
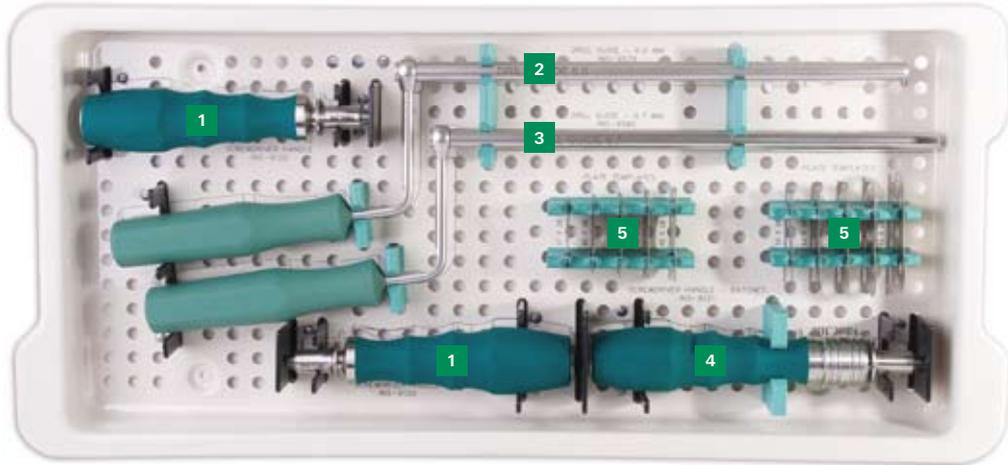
Inion® Screws

Art. No.	Description	Qty
SPN-5500	Screw 6.0 x 22 mm	2
SPN-5501	Screw 6.0 x 25 mm	2
SPN-5502	Screw 6.0 x 28 mm	2
SPN-5503	Screw 6.0 x 31 mm	2
SPN-5504	Screw 6.7 x 22 mm	1
SPN-5505	Screw 6.7 x 25 mm	1
SPN-5506	Screw 6.7 x 28 mm	1
SPN-5507	Screw 6.7 x 31 mm	1

Instruments

Art. No.	Description	Ref
INS-9120	Screwdriver handle, cannulated	1
INS-9579	Drill guide 6.0 mm	2
INS-9585	Drill guide 6.7 mm	3
INS-9121	Screwdriver handle, ratchet	4
ACC-9845	S-2 Plate template 37 x 28 mm	5
ACC-9846	S-2 Plate template 40 x 28 mm	
ACC-9847	S-2 Plate template 43 x 28 mm	
ACC-9848	S-2 Plate template 46 x 28 mm	
ACC-9849	S-2 Plate template 49 x 28 mm	
ACC-9850	S-2 Plate template 50 x 28 mm	
ACC-9851	S-2 Plate template 53 x 28 mm	
ACC-9852	S-2 Plate template 56 x 28 mm	
ACC-9853	S-2 Plate template 59 x 28 mm	
ACC-9854	S-2 Plate template 62 x 28 mm	
INS-9024	Plate bending pliers	6
INS-9581	Temporary fixation screws	7
INS-9582	Temporary fixation screw screwdriver shaft	8
INS-9583	Inion screw screwdriver shaft	9
INS-9578	Plate holder, angled	10
INS-9577	Plate holder, straight	11
INS-9561	Drill bit 5.0 mm stop for 22 mm screw	12
INS-9569	Bone tap 6.0 mm stop for 22 mm screw	13
INS-9562	Drill bit 5.0 mm stop for 25 mm screw	14
INS-9570	Bone tap 6.0 mm stop for 25 mm screw	15
INS-9563	Drill bit 5.0 mm stop for 28 mm screw	16
INS-9571	Bone tap 6.0 mm stop for 28 mm screw	17
INS-9564	Drill bit 5.0 mm stop for 31 mm screw	18
INS-9572	Bone tap 6.0 mm stop for 31 mm screw	19
INS-9565	Drill bit 5.7 mm stop for 22 mm screw	20
INS-9573	Bone tap 6.7 mm stop for 22 mm screw	21
INS-9566	Drill bit 5.7 mm stop for 25 mm screw	22
INS-9574	Bone tap 6.7 mm stop for 25 mm screw	23
INS-9567	Drill bit 5.7 mm stop for 28 mm screw	24
INS-9575	Bone tap 6.7 mm stop for 28 mm screw	25
INS-9568	Drill bit 5.7 mm stop for 31 mm screw	26
INS-9576	Bone tap 6.7 mm stop for 31 mm screw	27
INS-9580	Awl	28
ACC-9843	Plate contouring block	29
ACC-9842	S-2 Sterilisation tray for Instruments	
ACC-9802	Inion Thermo drape	
ACC-9840	Inion Thermo+ (water bath 110 V)	

Instrument trays



Surgical technique quick reference



1. Determine the correct plate size



2. Mark screw holes with the awl



3. Contour the Inion S-2™ plate



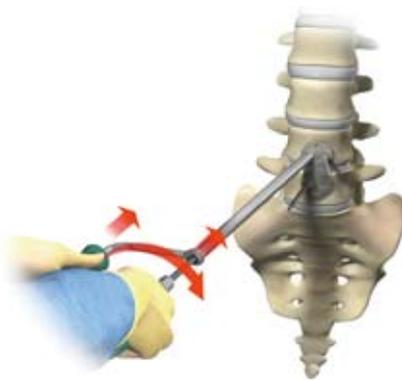
4. Place the plate on the bone with the temporary fixation screws



5. Drill the screw holes



6. Tap the screw holes



7. Insert the first Inion S-2™ screw



8. Insert the second Inion S-2™ screw



9. Replace temporary fixation screws with Inion S-2™ screws. Complete the procedure by applying appropriate traditional rigid fixation e.g. pedicle screws.



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