

Inion S-2™ Graft Containment System

INION

Surgical Technique

**Bioabsorbable Implant System
for Thoraco-Lumbar Fusion**

My Fellow Colleagues,



It is my privilege to introduce to you the Inion S-2™ bioabsorbable anterior lumbar spinal implant system. The concept of bioabsorbable technology has interested me for many years and I always believed there was a use for it in our field of spinal reconstructive surgery. When I initially became aware of the first generation Inion® lumbar product, I was intrigued by its bioabsorbable properties and after investigating further, I came to the conclusion that this technology would be quite useful in my practice. So in collaboration with Inion we developed implants and instruments that better fit today's anterior lumbar plating needs. This unique system allows for the creation of an anterior "tension band" after interbody reconstruction (ALIF) for lordosis creation, prior to posterior compression and instrumentation of your choice.

Compared to traditional methods, the inherent nature of these new, stronger, bioabsorbable polymer materials in the Inion S-2™ implant system provide the following benefits in my practice:

1. They are fully absorbable without seroma formation and do not need to be removed for fear of loosening or interference with the (vascular) anatomy in the retroperitoneal space.
2. These implants allow for excellent imaging of the patient's anatomy of both bone- and soft-tissues, and do not interfere with your ability to assess the patient's (fusion) progress during follow-up visits.
3. Registration steps necessary prior to Robotic guidance or Navigation can be performed without anterior metallic hardware interference.
4. If a revision procedure becomes necessary prior to full resorption, all that is required is to drill through the implants as if you were performing the primary procedure.
5. Compared to single vertebral body buttress fixation, plating across the grafted intervertebral body space prevents opening of that anterior space (gap formation) with possible loss of interference fit with the anterior graft or graft dislodgement (spit-out).

Over the first months while using the new Inion S-2™ bioabsorbable anterior lumbar graft containment system we developed a technique which has simplified the insertion of these implants for me. I have detailed this in the pages that follow and it is my sincere hope that you find this technique and these implants useful in your practice as we all strive to provide the very best care for our patients.

Respectfully,

Kornelis Poelstra, MD, PhD

Orthopaedic and Neurological Spine Surgeon

President

The Spine Institute on the Emerald Coast

Chairman

Department of Surgery

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Product Overview

Introduction

The Inion S-2™ Bioabsorbable 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 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 and are designed for use with dedicated Inion® instrumentation.

Indication

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)



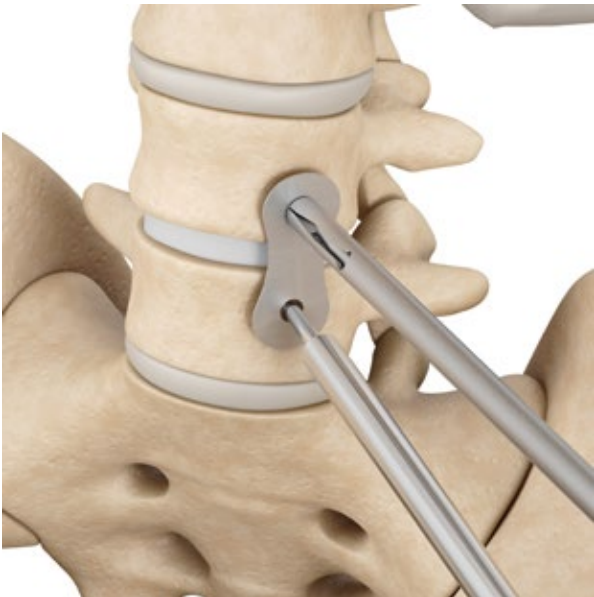
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1. Determine the plate length

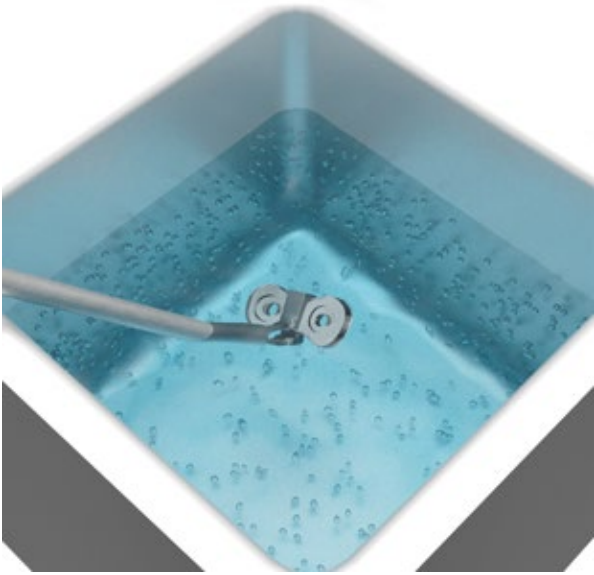
After insertion of the interbody spacer or graft, the Plate templates provided in the set can be used to determine the correct size of the Inion S-2™ plate to be implanted. The intent is to respect the sometimes close proximity of tenuous (vascular) immediately anterior to the bony anatomy. The Plate holder can be used for the positioning of the template.

Contour the Plate template to fit the anatomy of the spine. This can be done by hand or with pliers supplied in the set. The contoured Template can then be used when contouring the Inion S-2™ plate.



2. Mark the screw holes

After contouring the Plate template, the Awl can be used to mark-and-pinch the intended screw hole locations. This can be useful when hard osteophytic bone is encountered at the endplate rim.

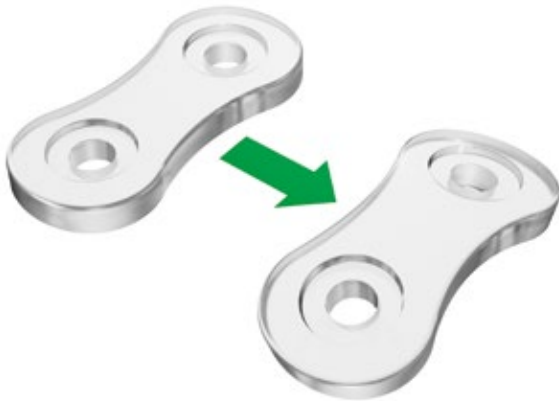


3. Contour the plate

Based on observed anatomy or the templating, select the corresponding plate length and place the implant in the supplied Inion Thermo™ + Water bath, preheated to 158 °F (70 °C). Soak the plate for approximately 1 minute until malleable.

Remove the plate from the water bath and use the previously contoured Plate template or gently finger pressure to form the plate to the desired shape.

*The plate is malleable for 10-15 seconds so it is recommended that the anterior surface of the plate is identified prior to placement in water bath using the recessed screw holes as reference and that the surgeon removes the plate from the water bath. Both of these actions will allow for the best use of the malleability time. If reshaping of the plate is necessary, place the plate back into the water bath for only 30 seconds. This process can be repeated up to three times.



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4. Place the plate and insert the Temporary fixation screws

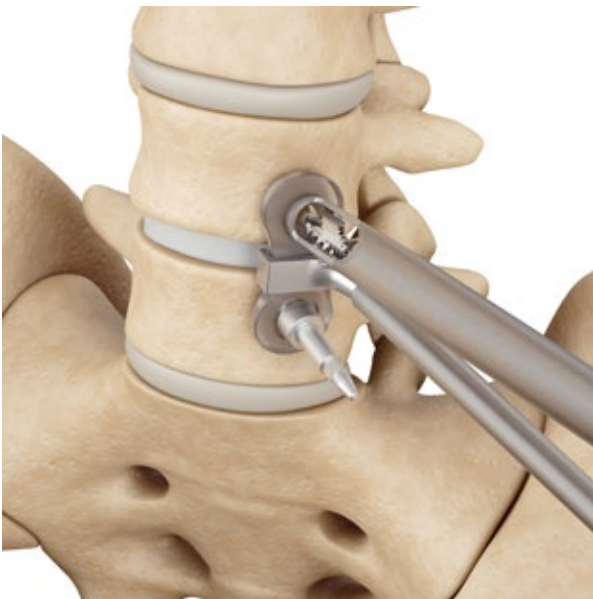
Use the Plate holder or long DeBakey forceps to place the Inion S-2™ plate in the desired position and insert one Temporary fixation screw through the screw hole at either end of the plate. The Temporary fixation screws are self-tapping but a light mallet tap may be needed to start, especially when placing in hard bone at the edge of the endplate. Then remove the Plate holder.



Temporary fixation screw.

5. Drill and tap the first screw hole

Use the supplied Self-drilling tap and Drill guide to create a screw hole through the plate. It is advised to always use the Drill guide with downward pressure onto the plate and spine whenever drilling screw holes in the Inion S-2™ plate. This allows the correct trajectory to be maintained and for the proper depth to be achieved. Apply firm downward pressure on the plate through the Drill guide to ensure the plate remains properly seated throughout the drilling process.



Use a low RPM power drill at a steady rotational speed from the beginning and advance slowly under controlled pressure until the stop on the Drill guide has been reached. This will ensure that the proper depth has been drilled. Power drilling is advised to achieve the best control, however hand drilling is also possible, depending on the bone quality. It is important to drill until the stop on the Drill guide has been reached, as this ensures that the proper depth has been reached with the Self-drilling tap. It is also important to note that

you will be tapping threads into both the plate and bone so care must always be taken during this step to ensure a solid screw purchase and fixation with plate is achieved. Avoid continuing to turn the Self-drilling tap once the stop limit has been reached on the back of the guide. Insert ONE screw first prior to preparing the opposite side.

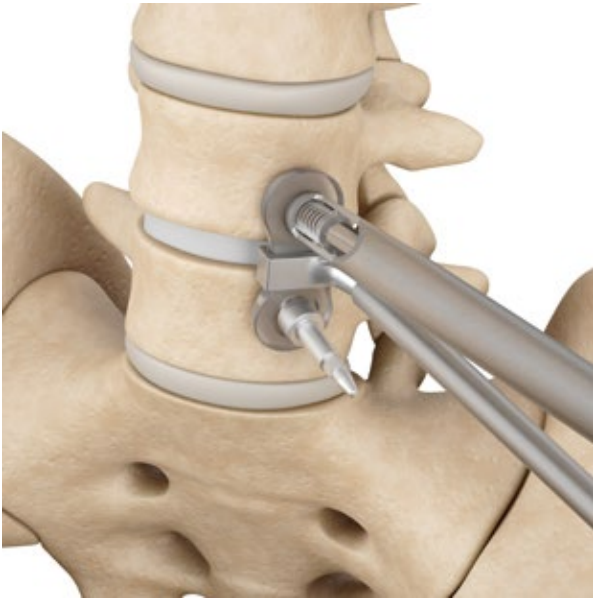
6. Insert screw ONE

Load the Inion S-2™ screw on the Screwdriver. Ensure that the screw is fully seated on the Screwdriver. It is advised to place the screw onto the driver in the supplied Screw holding block, so that both hands can be used to hold the Screwdriver and apply firm downward pressure to the screw head to fully seat it onto the driver.



It is advised to insert the screws through the Drill guide to better maintain the correct trajectory and ensure the plate is sufficiently seated onto the bone. After removing the tap, simply keep downward pressure onto the guide and insert the screw with the ratcheting driver. Keeping steady downward pressure onto the guide prevents the plate from accidentally riding up the screw during the screw insertion process.

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Start advancing the screw into the plate while applying gentle but positive pressure. You will feel resistance as the screw passes deeper through the plate with more resistance as the screw is nearing full seating. As the resistance increases and the screw advancement is reaching its endpoint, reduce the speed of screw advancement. The threads underneath the head will firmly lock the screw into the plate hole. Depending on the amount of fluid in the area a squeaking sound may be heard when this final locking occurs, which is entirely normal. Continue until the screw head is fully engaged into the plate. Do not overtighten the screw as this may lead to head or thread stripping.

Screws may be inserted in any direction through the plate. Please note that increased angulation will cause part of the screw head to sit slightly proud. If desired you may elect to use a cutting burr to remove the proud portion of the screw head. It is important that care is taken not to damage the screw-plate interface when doing this step.

Note: It is important to drill tap and then place the screw before moving to the next screw hole.



7. Insert screw TWO

Load the next Inion S-2™ screw onto the Screwdriver. Remove the Temporary fixation screw and repeat steps 5 to 7 to place the second and final screw through the guide. This will ensure that the plate does not move out of its position and optimizes the fixation. Ensure that all screws are firmly locked.

Proceed to the next interbody reconstruction level if needed or close the approach and complete the procedure by applying posterior spinal fixation. The Inion S-2™ system is not intended for 'stand-alone' anterior fixation. For more detailed instructions please see the Instructions for Use.

8. Salvage fixation

If fixation with either one of the two screws should become compromised during insertion (e.g. screw fracture during insertion into extremely hard bone, or compromised screw-driver interface due to stripping of the head of the screw) or if the decision is made to change the angulation/direction of the screw through the plate, larger diameter salvage screws are available.

A new trajectory needs to be prepared with the larger diameter drill and tap, similar to the outlined steps 5 to 7, and the larger diameter salvage screw can then be inserted using the same technique.

A very appealing feature of this bioabsorbable system is that the old screw does not have to be removed. The material composition allows for drilling 'away' any part of a prior inserted Inion S-2™ screw with ease and optimal fixation can be achieved with the salvage screw despite (parts of) the old screw still being in place.

Warnings

- The Inion S-2™ Biodegradable Anterior Thoraco-Lumbar Fusion System devices provide fixation and are not intended to replace healthy tissues or withstand the stress of full load bearing.
- Incorrect selection, placement, positioning, or fixation of the implant can cause subsequent undesirable results or breakage of implants or instruments. The surgeon should be familiar with the devices, the method of application and the surgical procedure prior to performing the surgery.
- The safety and efficacy of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and efficacy of pedicle screw spinal systems for any other conditions are unknown.

Precautions

- Instruments are available to aid accurate implantation of the Inion S-2™ Biodegradable Anterior Thoraco-Lumbar Fusion 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 S-2™ instruments.
- Use only the Inion S-2™ screws to secure the Inion S-2™ plates. DO NOT use the Inion S-2™ screws to secure plates other than those of Inion S-2™ (e.g., metal plates).
- DO NOT use for unintended applications! The proper function (i.e., efficacy and safety) of these implants cannot be guaranteed in the event of off-label use.
- The safety and effectiveness of this device, as an adjunct to fusion, when used without rigid supplemental internal fixation has not been established. This device is not designed to withstand physiologic loads when used by itself.
- 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 immobilisation may cause non-union or mal-union.
- The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of the specific pedicle screw spinal system because the procedure is technically demanding and presents a risk of serious injury to the patient.

Ordering Information

Inion S-2™ Plates



Inion S-2™ Screws



Art. No.	Description	Qty
SPN-5421	Plate, 31 mm (16 mm hole span)	1
SPN-5422	Plate, 34 mm (19 mm hole span)	1
SPN-5423	Plate, 37 mm (22 mm hole span)	1
SPN-5424	Plate, 40 mm (25 mm hole span)	1

(Plates are 3.2 mm thick and 15 mm wide)

Art. No.	Description	Qty
SPN-5501	6.0 x 25 mm screw	2
SPN-5504	6.7 x 22 mm screw	1

Inion® Instruments

Art. No.	Description	Qty
C60	Plate holder	1
C61	Drill guide	1
C62	Self-drilling bone tap for 6.0 x 25 mm screw	1
C63	Screw – screwdriver attachment block	1
INS-9562	Drill bit 5.0 mm for 6.0 x 25 mm screw	1
INS-9565	Drill bit 5.7 mm for 6.7 x 22 mm screw	1
INS-9570	Bone tap 6.0 mm for 6.0 x 25 mm screw	1
INS-9573	Bone tap 6.7 mm for 6.7 x 22 mm screw	1
INS-9580	Awl	1
INS-9581	Temporary fixation screw	1
INS-9582	Screwdriver shaft for temporary screw	1
INS-9583	Screwdriver shaft	1
INS-9120	Screwdriver handle	1
INS-9121	Screwdriver handle, ratchet	1
ACC-9855	Template 31 mm (16 mm hole span)	1
ACC-9856	Template 34 mm (19 mm hole span)	1
ACC-9857	Template 37 mm (22 mm hole span)	1
ACC-9858	Template 40 mm (25 mm hole span)	1



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