AUSTRALIS®
SPINAL SYSTEM

Surgical Technique & Guide

PRISM SURGICAL

PRISM SURGICAL

Surgical Technique & Guide

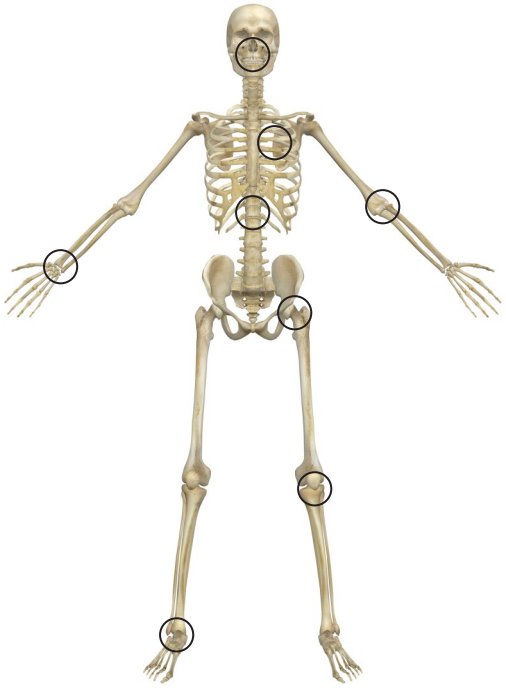
Material Characteristics and Cage Performance

Material Characteristics: PEEK-Optima®

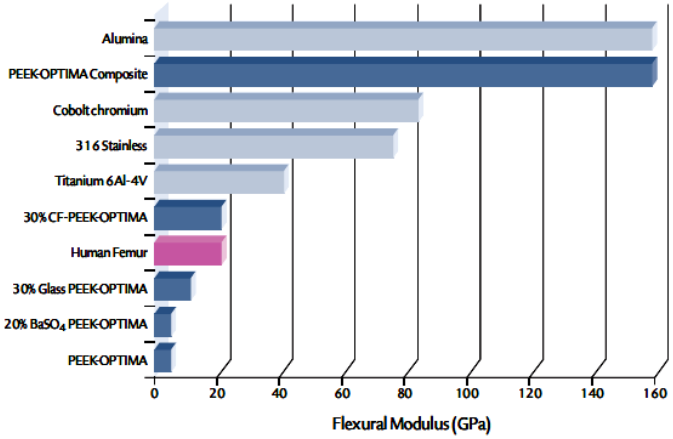
Biocompatibility

History of PEEK-OPTIMA® Material

Since its introduction to the market PEEK-Optima® has quickly gained the confidence and acceptance of the medical community as a highly reliable implantable material.



* More than 20 years of medical applications
* Has been successfully utilised in
  - Spinal implants
  - Orthopaedic fixation and trauma implants
  - Heart valves/stents
  - Artificial joints
  - Dental implants
  - Craniofacial devices
  - Cardiac/Neurological leads



The mechanical properties of an interbody cage are critical within the design to creating a load-sharing construct. A load sharing implant transfers axial compressive loads through the implant and selected graft material, stimulating bone healing.

The success of spinal interbody fusion depends on the mechanical and biological properties of the materials used. With a lengthy clinical history, PEEK-Optima® is universally recognised for its strength, stiffness and biocompatibility properties.

PEEK-Optima® features a lower modulus of elasticity compared to other materials and more closely mimics the material characteristics of cancellous or cortical bone. Thus PEEK-Optima® is an excellent material for promoting graft bone stimulus and fusion. This concept improves load sharing between device and graft by distributing axial load through the cage, stressing the graft area and creating an optimal environment for fusion in accordance with Wolff's Law.

Mechanical Characteristics: Australis® ALIF Cage

Fatigue Compression-Shear Testing of the Australis® ALIF Cage (Report no: 131-071-010 Rev A)

Extensive testing of the Australis® ALIF cage was conducted to characterise strength and fatigue performance. All testing was performed according to ASTM guidelines to determine the performance of the system under both static and dynamic loading conditions.

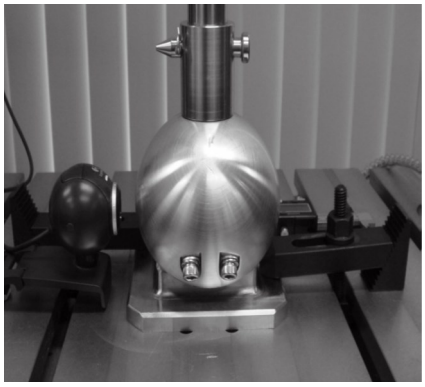
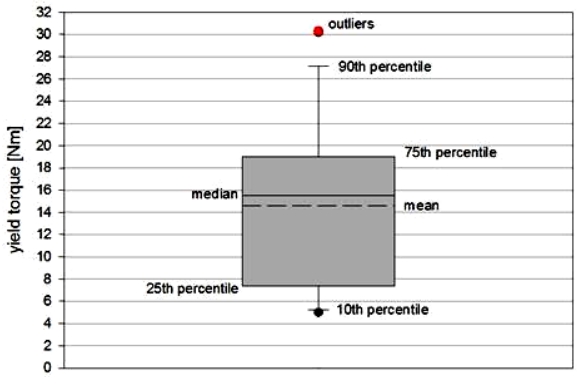


Image of test set-up used for compression-shear testing according to ASTMF2077

The Australis® ALIF cage was shown to achieve a 5 million cycle run out with a maximum load of 2.5kN under compression-shear loading. There were no signs of functional or mechanical failure in the cage throughout the remainder of the testing. The static compressive strength of the cage was found to be in excess of 45.5kN with no reported failure.

Static Torsion Testing of the Australis® ALIF Cage (Rep no: 263.131014.30.1053-rev0)

Torsional loading was conducted in accordance with ASTM F2077 standard. The cage was loaded until functional failure occurred. The Australis® cage revealed a yield torque of 29.6Nm as determined in this testing series and was well above the 90th percentile range reached by competitive cages of similar indication.



Statistical data for the yield torque established for the Australis® ALIF cage in comparison to equivalent competitive devices. The value is shown as a red dot.

Conclusions

The Australis® ALIF cage mechanical testing confirmed that the system met or exceeded all ASTM standards and guidelines.

*Mechanical testing is not indicative of clinical results.
**All testing was performed on the 'worst case' cage size as determined by FEA.

AUSTRALIS

Spine System

Design Rationale

Australis® Spine System Design Rationale

The Australis® Anterior Lumbar Interbody Fusion System features instrumentation that provides a simple one step precision placement of the Australis® cage. The innovative Insertion/Distraction system simultaneously provides the ability to perform controlled, repeatable distraction of the vertebral bodies during insertion whilst defining the placement of the implant within the disc space. No impaction is required.

The Australis® Spine System includes a range of trials and intuitive instruments to ensure optimal sizing and placement with a focus on restoration of sagittal balance.

Flexibility

The Australis® cage is available in a wide range of sizes to suit individual patient anatomy whilst reconstructing ideal individual sagittal and coronal alignment.

3 footprints, 7 heights and lordotic angles ranging from 12° to 25°.

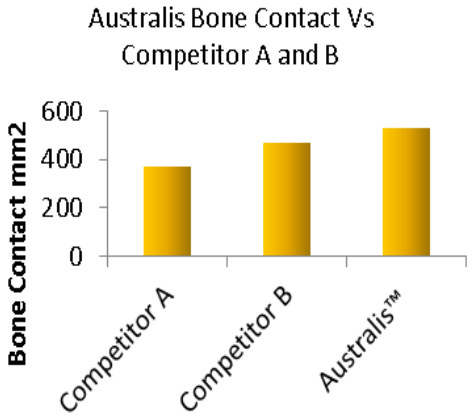
A unique footprint geometry that allows optimal endplate coverage and cortical rim engagement proven to assist in the prevention of postoperative subsidence. The Australis® cage has an anatomical 3D convex shape to ensure contact is complementary with the vertebral endplates.

Stability

Initial and secondary stabilising features prevent expulsion from the disc space. Initial stability is provided through 3 stabilising spikes situated on the postero and antero lateral corners to engage the hard cortical rim. Secondary stability is achieved through the pyramidal surface teeth that make contact with the vertebral body endplates.

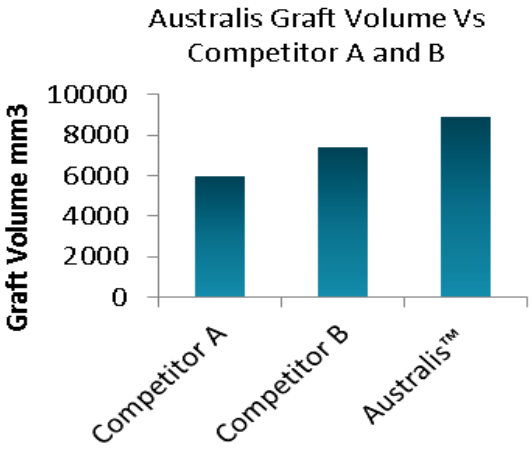
Restoration

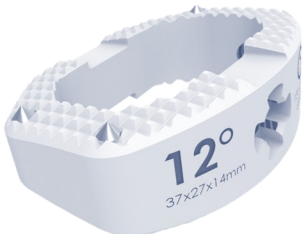
Traditional sagittal plane deformity correction techniques are often associated with significant morbidity, prolonged operative times, neurological complications and blood loss. With a unique offering of hyper-lordotic cages, the Australis® Spine System offers an alternative method of treating sagittal imbalance from the anterior column, and may provide the same correction capability with decreased complications and morbidity. Hyper-lordotic cages provide the ability to restore 30-40degrees through a two level ALIF representing a significant advancement in spinal deformity correction.



Fusion

The Australis® cage features one of the largest graft openings currently available. A considerably large and open architecture for selected graft material that permits enhanced fusion capability without compromising cage strength. There are no central struts of material. More endplate-graft contact ensures an optimal fusion environment is created.





Intended Use for Prism Surgical Interbody Fusion Cages

Intended Use

Prism Surgical Spinal Anterior Spinal Interbody Fusion Cages consist of single use, permanently implantable devices that are used to restore disc height and support loading during intervertebral body fusion. These devices are intended to be implanted by trained physicians who have appropriate training or experience in accordance with the device specific surgical technique. The devices are intended for skeletally mature patients who meet indications as determined by the treating physician. The cages are available in varying shape and size configurations to match patient anatomy. The cages are intended to be implanted via an anterior approach to the spine.

Prism Surgical Interbody Fusion Cages are manufactured from implant grade polyetheretherketone (PEEK) in accordance with ASTM F2026. The polymer cage structure is radiolucent with tantalum x-ray markers in accordance with ASTM F560 for radiographic visualization. The devices have ridges and/or pins made of Titanium Alloy per ASTM F136/ISO 5832 that resist rotation and migration and have a central cavity to accept packing of bone graft material. When used as interbody fusion devices these implants are intended for use with Prism Surgical supplemental internal fixation devices such as plates and screws. Prism Surgical Interbody Fusion Cages are implanted within a device specific range of spinal levels as specified by the device product labelling.

Indications and Contraindications

Indications

- Arthrodesis required at any paired vertebral bodies in the lumbosacral spine
- Degenerative Disc Disease
- Spondylolisthesis
- Pseudoarthrosis

Contraindications

- Severe segmental instability e.g., tumour, trauma
- High-grade spondylolisthesis
- Active systemic infection or localized infection of implantation site
- Severe osteoporosis
- Entities or conditions that totally preclude possibility of fusion e.g. cancer, severe obesity, pregnancy
- Other standard contraindications not described in the indications for use i.e. known allergy to materials, foreign body sensitivity

Important considerations for successful treatment of anterior pathology with the Australis® Spine System, but are not limited to;

- Proper patient selection
- Safe and adequate surgical approach and exposure to the appropriate degenerative disc level
- Complete discectomy and meticulous endplate preparation
- Proper implant selection and placement
- Adherence to physician recommended postoperative regimen

AUSTRALIS
Spine System

Surgical Steps

Patient Positioning

Place the patient in a supine position on a radiolucent table. Position the patients upper limbs so that there is space for circumferential C-arm movement over and around the operative level. The arms should either be outstretched or folded across the chest.

Surgical Approach

The skin incision may be longitudinal or transverse based on surgeon preference. The fascial incision may also be longitudinal or transverse, however a longitudinal fascial incision allows greater flexibility in extending the exposure if necessary.

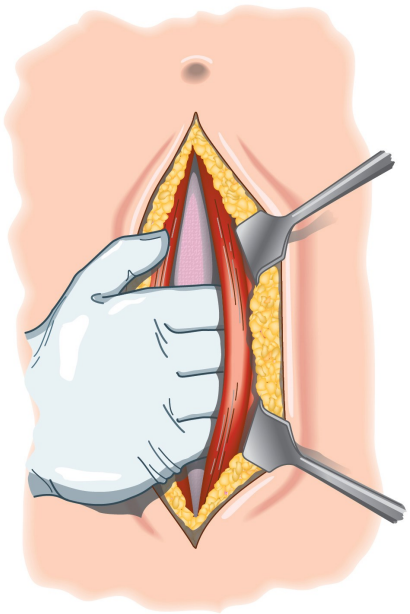
Retract the underlying subcutaneous tissue until the fascia is exposed. Divide longitudinally either in the midline or along the lateral rectus sheath using dissecting scissors.

Retract the left rectus muscle laterally with fingers or blunt retractors.

A left retroperitoneal approach is preferred.
A 4-6cm incision is recommended.

Elevate the posterior rectus sheath and divide longitudinally with dissection scissors. Blunt retroperitoneal dissection is used to expose the psoas muscle and overlying great vessels. Identify the psoas, iliac artery, and iliac vein.

Carefully apply an appropriate soft tissue retractor system.



Approach of L5/S1

The further dissection of the tissue anterior to the intervertebral disc is performed using blunt dissection.

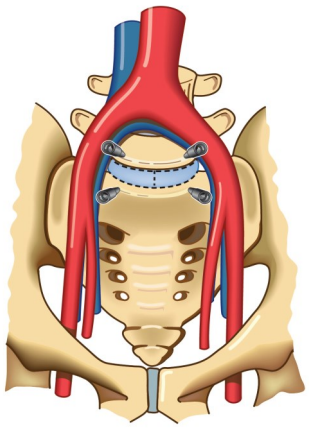
Do not use monopolar diathermy. Bipolar diathermy should be used sparingly. This will help lessen the risk of vessel and/or nerve injury.

Dissection is carried to the left and right to achieve the maximum possible lateral exposure of the disc. Extreme care should be taken to protect the left and right common iliac vessels. To safely dissect the anterior surface of the lumbar bodies, knowledge of their spatial relationship to these blood vessels is important.

Bluntly mobilise the left common iliac vein and artery with peanut swabs and then the right common iliac artery together with the right common iliac vein that lies posterior. These vessels are retracted laterally and slightly superiorly to maximally expose the disc in the midline.

Carefully apply an appropriate retraction system for the main vessels such as vessel pins. Verification of the vertebral level can now be achieved with lateral fluoroscopy.

Utilise a midline H shaped annular incision to create two midline opening annular flaps. These flaps may be used to retract and protect the laterally displaced vessels via an attached suture.



L5-S1 approach and retraction of the anterior vessels utilizing Australis® vessel pins.

Note: It should be emphasised that venous anomalies are not infrequent, and therefore it is important to exercise caution when anatomic variants are encountered.

Approach L4/5 and Above

For exposure of disc higher than L5/S1, it is necessary to a mobilize the overlying aorta and inferior vena cava medially. Carefully apply an appropriate external soft tissue retractor system. Moblise the iliac vein, iliac artery, vena cava and aorta to the right. Verify the vertebral level by lateral fluoroscopy. Utlise a left-justified H shaped incision in the annulus as described above.

Note: When the L4-5 disc is being exposed special attention should be paid to the iliolumbar or ascending vein, a large venous branch overlying the L5 body and draining into the lateral left common iliac vein.

Complete Discectomy and Endplate Preparation

Perform the initial central discectomy using standard discectomy instrumentation.

Care must be taken not to damage the bony endplate.

Perform an initial discectomy until enough disc material has been removed to allow the Australis® Central Spreader to be inserted partially into the disc space.

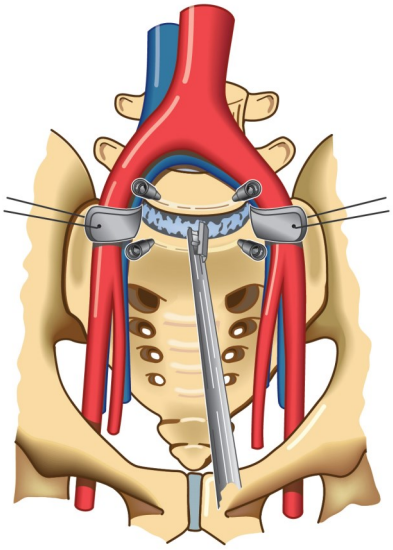
Apply controlled distraction using the Australis® Central Spreader and/or the Australis® Sequential Spreaders (7.5mm-14.5mm). Perform a complete discectomy leaving only lateral annulus.

TIP: It is imperative to remove as much disc material including the posterolateral aspect of the disc, the posterior annulus and to release the Posterior Longitudinal Ligament to facilitate:

- Parallel distraction which allows restoration of intervertebral height and sufficient opening of the neuroforamen
- Sufficient space for an appropriately sized Australis® cage. This will allow maximum capacity for fusion and minimize subsidence.

Remove the cartilaginous endplate utilising appropriate instrumentation. **Care must be taken not to breach the bony endplate.**

A preserved endplate will provide a firm base for stability and will help reduce the potential for implant subsidence.



A complete discectomy will allow parallel distraction of the endplates allowing restoration of intervertebral height and sufficient opening of the neuroforamen.

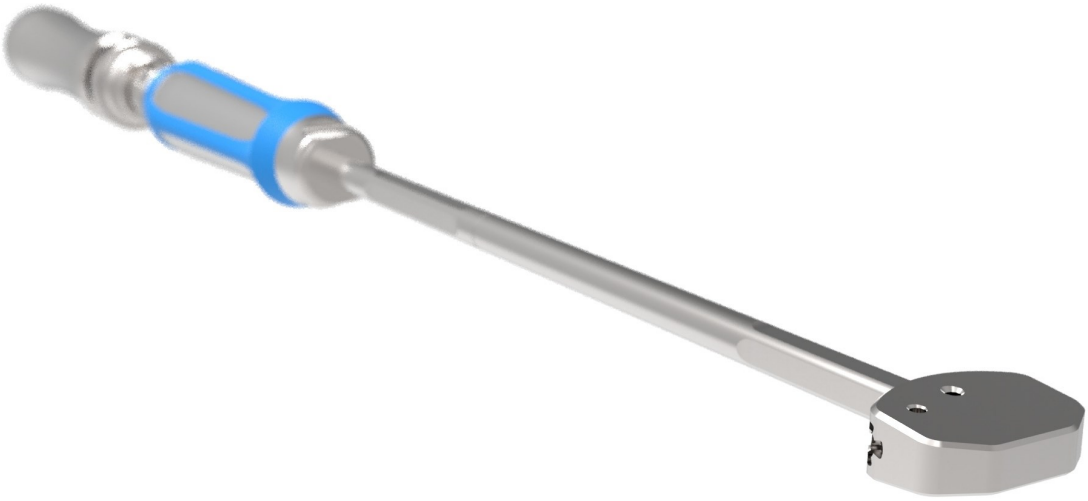
Sizing & Trialling

Determine the correct trial and load onto the trial inserter. Ensure the measuring sleeve is attached to the inserter shaft.

Insert the trial by impacting the impaction plate on the end of the insertion tool. If the trial cannot be placed in the desired position as confirmed by fluoroscopy, additional discectomy, posterior release or endplate preparation may be necessary.

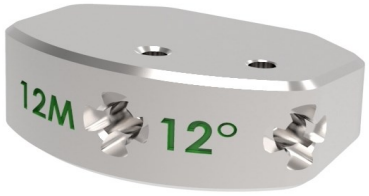
Verify correct size visually and by lateral fluoroscopy. Observation and tactile feedback while using the trials in the disc space can aid in verifying correct sizing.

Colour coding of the trials can be used to maintain consistency of sizing throughout the remainder of the procedure.



SMALL 27x35.5	BLUE
MEDIUM 29x38.5	GREEN
LARGE 31x42	GOLD

Colour Coding of Trials and Implants



A/P Depth Measurement (optional)

Keep the trial in the disc space on the inserter. Slide the A/P depth measurement sleeve forward as far as possible until it contacts the anterior aspect of the vertebral body.

Fluoroscopy may be utilized to check the position of the positive stops on the sleeve. This will ensure an accurate reading of the trials sagittal position within the disc space.

The number on the Depth Measuring Sleeve approximates the distance from the anterior aspect of the trial to the face of the vertebral body. Record this number. This reading will be used during insertion. The precision functioning of the Kraken (insertion/distraction instrument) is reliant on setting the A/P depth prior to implantation.

Remove the trial. If the trial is difficult to remove the slap-hammer may be connected to the top of the insertion instrument by pulling back on the collar and attaching to the impaction plate.

Implantation

There are two methods for insertion of the Australis® ALIF cage.

Option 1 – The Kraken (Distraction/Insertion Instrument)

Load the selected Australis® cage onto the standard insertion instrument by turning the knob clockwise until secure. Utilizing the Graft Packing Block, fill the cage with bone graft material of choice and assemble the Kraken (Distraction/Insertion Instrument).

Kraken Assembly

Slide the gold threaded rod into the main handle by pushing the release button. Attach the modular handle to the threaded rod. Wind the modular handle back until approximately 1 inch of rod is protruding from the main handle between the blades.

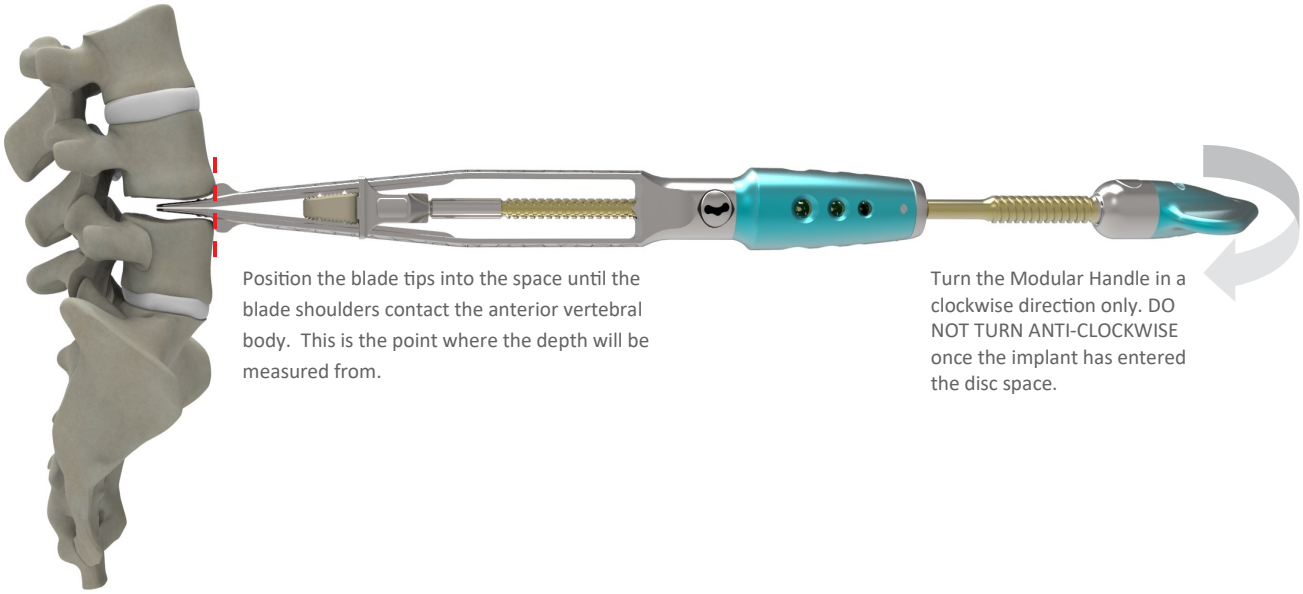
Set the A/P depth on the depth insertion piece previously recorded by the Depth Measuring Sleeve. If no depth was recorded at the trialling step, set the adjustable stop to “0” or utilize the fixed depth guide.

Slide the depth insertion piece between the blades of the Kraken by an inward and forward motion. Once the positive stops of the depth insertion piece are on either side of the blades, connect to the threaded rod by pulling back towards the threaded rod to engage the quick connection. A slight ‘click’ may be audible.

Lightly pull forward on the depth insertion piece to ensure a sound connection.

Load the Australis® cage containing selected graft material onto the depth insertion piece by simply pushing the insertion hole of the cage onto the corresponding connection point.

Implantation CONT...



Carefully position the Kraken paying attention in regard to the A/P midline and insert the blade tips into the space until the blade shoulders contact the anterior vertebral body.

Turn the modular handle to guide the implant toward the disc space. Ensure the shoulders of the blades lie flush against the vertebral bodies throughout the entire insertion. When the A/P depth stop contacts the vertebral body, the blades will automatically begin to retract from the disc space.

Continue turning the modular handle in a clockwise direction to complete retraction of the blades from the disc space leaving the implant at the desired posterior depth as determined by the depth measuring sleeve in prior steps.

Remove the Kraken from the disc space, leaving the implant in the desired position.

Implantation

The position of the implant can be altered using the cage impactor instrument. The cage impactor has a self aligning tip that will prevent slipping on impaction if seated within either insertion hole. The tip will self retract if impaction is required at an oblique angle other than where the insertion holes are positioned.

Note: Kraken Removal
Once the A/P stop of the depth insertion piece is flush with the anterior aspect of the vertebral body continue to turn the modular handle in a clockwise direction to remove the Kraken and leave the implant in place.

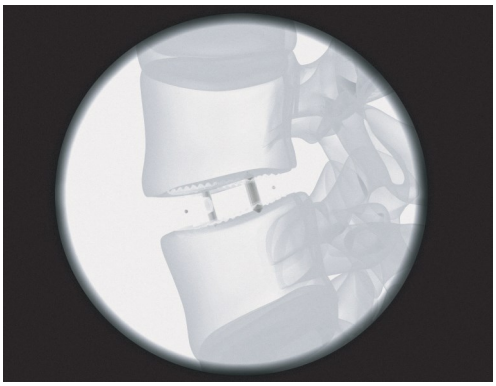
DO NOT reverse the modular handle. Turning the modular handle anti-clockwise will not remove the Kraken and blades if too far into the insertion process.

Option 2—Simple Impaction Technique

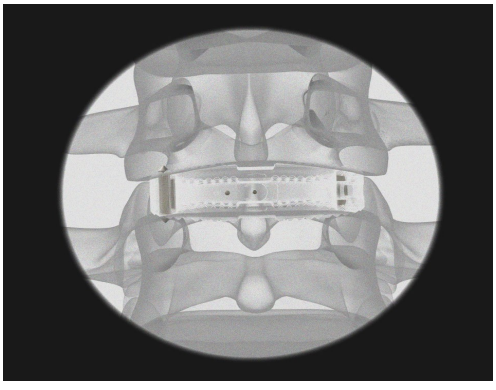
Follow the previous steps of cage selection and packing of selected graft material. Load the implant onto the cage inserter by turning the knob clockwise until secure.

Insert the cage into the prepared disc space by impacting on the impaction plate on the insertion instrument until the desired position is achieved. Monitor the insertion via fluoroscopy to aid in the control of posterior depth.

Check fluoroscopy in both the A/P and Lateral plane is recommended.



Lateral view
An anterior and posterior marker is visible demonstrating the most anterior and posterior margins of the cage.



A/P view
Lateral Spikes will be visible as lines demonstrating the most lateral margins of the cage.

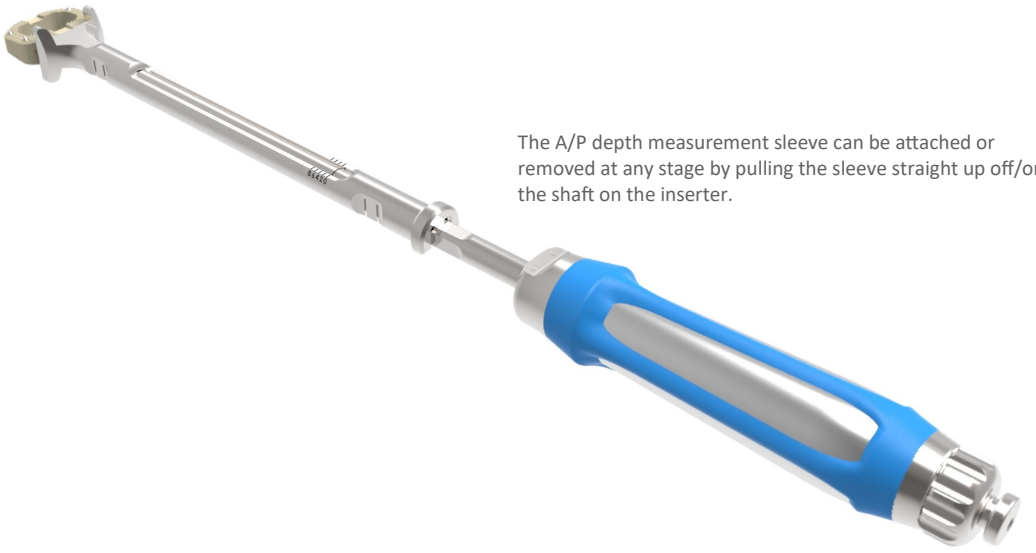
Implantation CONT….

If the insertion instrument has been released, the cage impaction instrument may be utilized to impact the implant further posteriorly if desired.

If the implant is not in the optimal position you should remove the implant as described on page p20.

Once removed the disc space should be inspected to ensure that sufficient discectomy and endplate preparation to allow correct positioning of the implant has taken place. The implantation steps may then be repeated.

Note: A/P Depth Measurement
The measuring sleeve may be utilised to confirm A/P depth of the implant in comparison to the depth measured at the trial stage as described on p17. The measuring sleeve may be connected or disconnected at any stage of the insertion procedure.



The A/P depth measurement sleeve can be attached or removed at any stage by pulling the sleeve straight up off/on the shaft on the inserter.

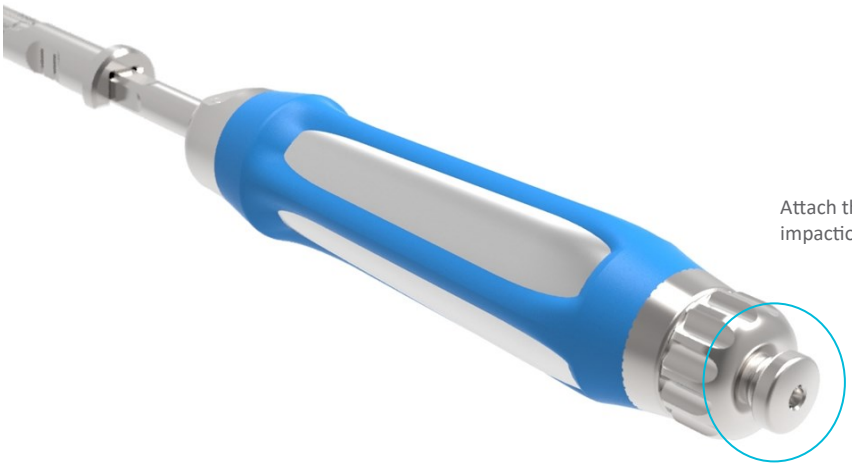
Final Positioning and Removal Technique

Verify the final position of the Australis® ALIF cage via fluoroscopy.

Should it be necessary to remove the Australis® ALIF cage, reconnect the insertion instrument and ensure the connection is secure. Wiggle the implant back and out if possible.

Extra extraction force may be applied by attaching the slap hammer to the impaction plate by pulling upward on the collar of the slap hammer.

Remove the implant. Inspect the implant for any damage. If any damage has occurred select a new implant and repeat implantation steps as outlined on p18.



Attach the Slap hammer to the impaction plate ring pictured.

Australis® Ordering Information

Reference Code & Description

Instruments

132-15-0025 Cage Inserter

132-15-0032 Cage Impactor

132-15-0117 Cage Inserter—Broad

132-15-0034 Graft Packing Jig

132-15-0064 Graft Trial Jig

132-072-044 Slap hammer

132-15-0059 Depth Measuring Sleeve

132-15-0001 Insertion/Distraction Tool (The Kraken)

132-15-0035 thru –0121 Trial Cages—all sizes

Implants

131-07-1201 12S 12°

131-07-1401 14S 12°

131-07-1601 16S 12°

131-07-1801 18S 12°

131-07-1202 12M 12°

131-07-1402 14M 12°

131-07-1602 16M 12°

131-07-1802 18M 12°

131-07-1203 12L 12°

131-07-1403 14L 12°

131-07-1603 16L 12°

131-07-1803 18L 12°

131-07-1621 16S 20°

131-07-1821 18S 20°

131-07-1622 16M 20°

131-07-1822 18M 20°

131-07-1822 18M 20°

131-07-2022 20M 20°

131-07-1623 16L 20°

131-07-1823 18L 20°

131-07-2023 20L 20°

131-07-1252 12M 5°-12°

131-07-1452 14M 5°-12°

131-07-1751 17S 25°

131-07-1951 19S 25°

131-07-2151 21S 25°

131-07-1852 18M 25°

131-07-2152 21M 25°

131-07-2352 23M 25°

131-07-2053 20L 25°

131-07-2253 22L 25°

131-07-2453 24L 25°

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