

Axis-ALIF

Anterior Lumbar Interbody Fusion System

SURGICAL TECHNIQUE

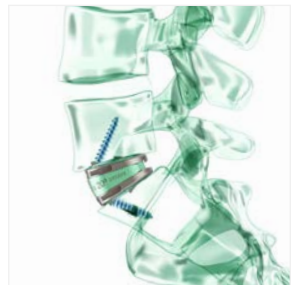
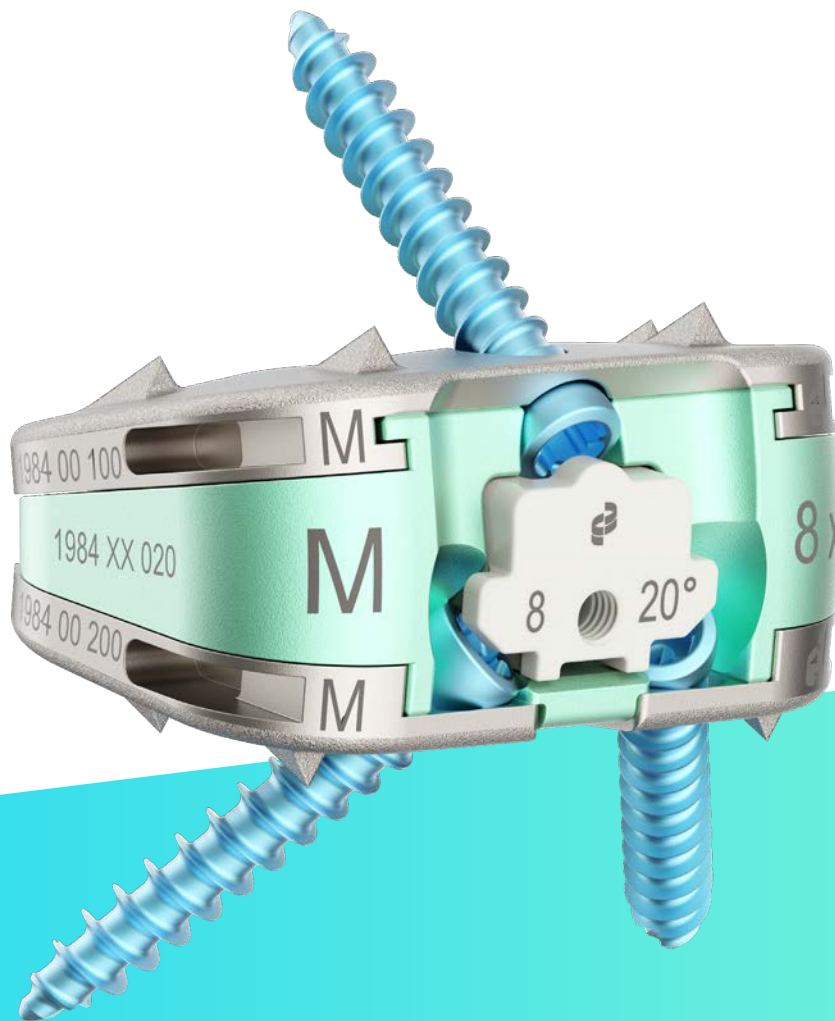


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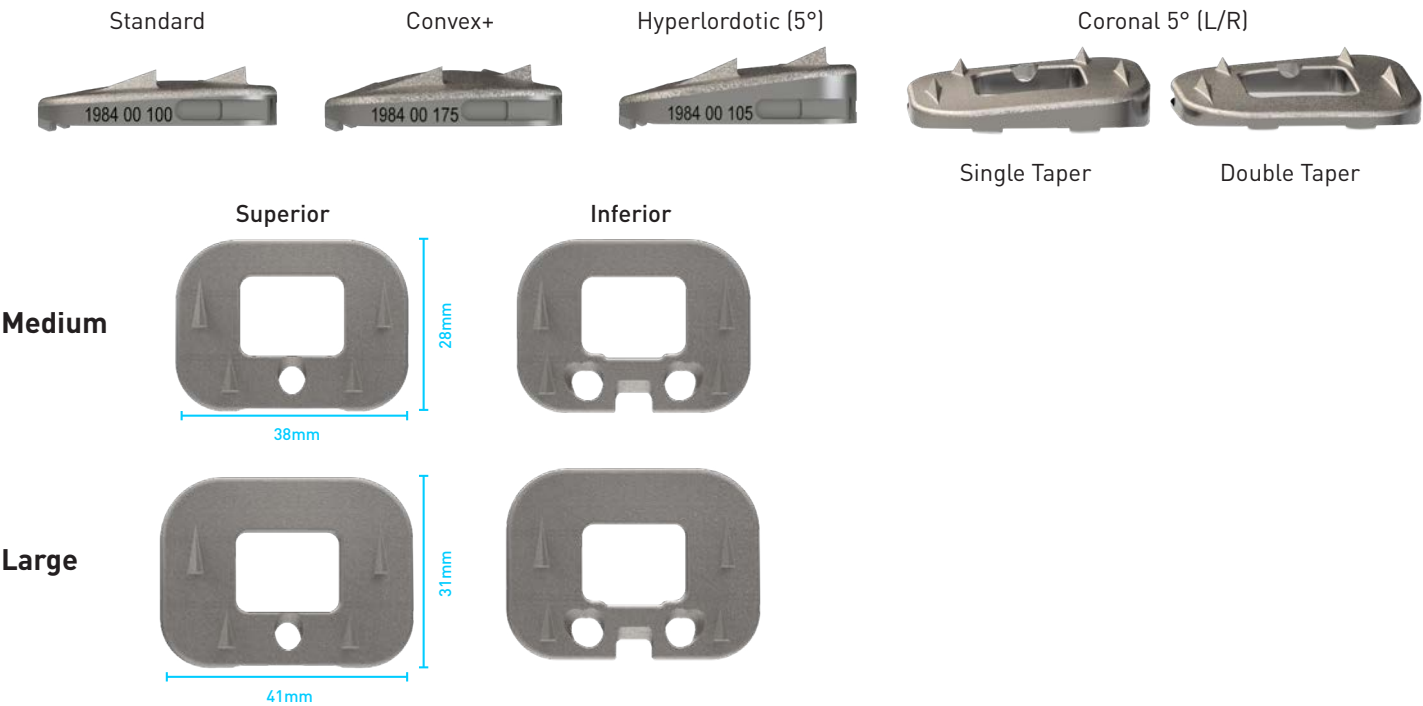
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Implant Overview

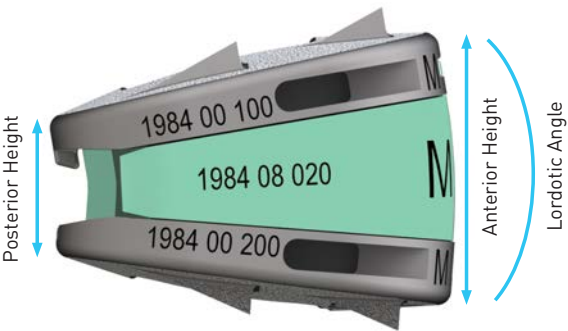
Endplates



Cores

M/L Standard Cores

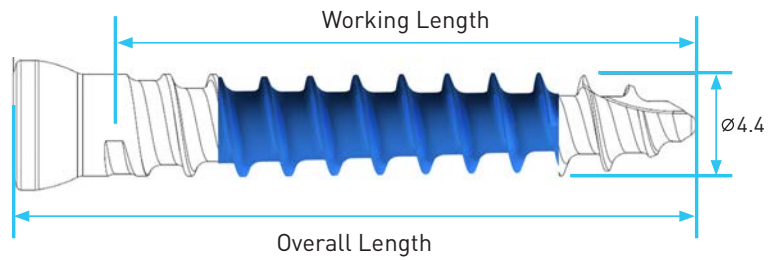
Description	Posterior Height (mm)	Anterior Height (mm)	Angle(°)	Implant Graft Volume (cc)
6x10°	6	12	10	2.6
6x15°	6	14	15	2.8
6x20°	6	16	20	3.0
6x25°	6	18	25	3.2
6x30°	6	21	30	3.4
8x10°	8	14	10	3.0
8x15°	8	16	15	3.2
8x20°	8	18	20	3.4
8x25°	8	20	25	3.6
8x30°	8	23	30	3.8
10x10°	10	16	10	3.4
10x15°	10	18	15	3.6
10x20°	10	20	20	3.8



Screws

Screw Dimensions

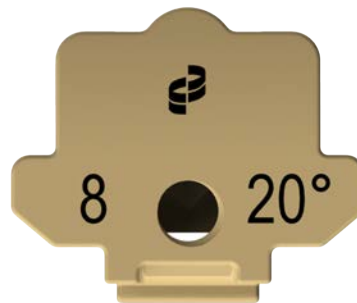
Diameter	Length
4.4mm	20mm
	25mm
	30mm
	35mm



Locking Caps

Locking Cap Measures

Core Angle	Core posterior heights
10°	
15°	6mm
20°	8mm
25°	10mm
30°	



Instrument Overview



ALIF Endplate Sizer	Product Nr
Medium (Slim)	AI-2015
Large (Slim)	AI-2027
Medium - Standard/Convex +	AI-2022
Medium - Standard/DT Coronal	AI-2034
Medium - Standard/ST Coronal	AI-2042



ALIF Distractor – Parallel	Product Nr
6mm	A6200106
8mm	A6200108
10mm	A6200110
12mm	A6200112



Dual Hinge Inserter	Product Nr
Superior Arm	AI-4000.1
Inferior Arm	AI-4000.2
Connector	AI-4000.3



Dual Hinge Inserter - Alignment Tool	Product Nr
	AI-4011/AI-4010



Dual Hinge Inserter - Trial Core Loader	Product Nr
	AI-4020



Dual Hinge Inserter - Implant Core Loader	Product Nr
	AI-4030



ALIF Tamp	Product Nr
Standard	A6202400
Slim	A6202450



Dual Hinge Inserter - Core Trial	Product Nr
6x10°	AI-4610
6x15°	AI-4615
6x20°	AI-4620
6x25°	AI-4625
6x30°	AI-4630
8x10°	AI-4810
8x15°	AI-4815
8x20°	AI-4820
8x25°	AI-4825
8x30°	AI-4830
10x10°	AI-4110
10x15°	AI-4115
10x20°	AI-4120



T-Handles	Product Nr
Fixed ¼ "	GI-9010
Ratcheted ¼ "	GI-9015



ALIF Core Graft Filler Tools	Product Nr
Block	A6202650
Tamp	A6202655



ALIF Angled Screw Inserter Counter Torque	Product Nr
	A6200550



ALIF Graft Syringes	Product Nr
Small - Body	AI-6010.1
Small - Plunger	AI-6010.2
Medium - Body	AI-6012.1
Medium - Plunger	AI-6012.2
Plunger Knob	AI-6011



Straight Handles	Product Nr
Fixed 1/4"	GI-9020
Ratcheted 1/4"	GI-9025



ALIF Locking Cap Inserter	Product Nr
Shaft	AI-6030.1
Sleeve	AI-6030.2



ALIF Retractable Awls	Product Nr
Straight	AI-5027.1
Straight - Inner	AI-5027.2
Angled	AI-5025.1
Angled - Inner	AI-5025.2



ALIF Slotted Mallet	Product Nr
	A6201950



ALIF Screwdrivers	Product Nr
Straight 1/4" H20	A6200325
Straight 1/4" H20 XL	A6200375
Angled 1/4" H20	AI-5040



ALIF Locking Cap Inserter Removal Tool	Product Nr
	AI-6030.3



ALIF Slaphammer	Product Nr
	A6130000



ALIF Implant Extractor	Product Nr
Body	A6120100
Shaft	A6120200
Sleeve	A6120300



Body	AI-7000.1
Sleeve	AI-7000.2



ALIF Divergent Screw Guide*	Product Nr
	A6160100



ALIF Awls*	Product Nr
Angled XL	A6201550
Straight XL	A6201475



ALIF Single Awl Guides*	Product Nr
Inline	A6201260
Angled	A6201270

Indications For Use

The ALIF system is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The ALIF system 10°-20° lordotic cages may be used as a standalone system. The ALIF system 25°-40° lordotic cages must be used with supplemental internal spinal fixation systems (i.e., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

The ALIF system implants can also be used as an adjunct to fusion in patients diagnosed with multi-level degenerative scoliosis; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the ALIF system must be used with a supplemental internal spinal fixation system (e.g. pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

Surgical Approach

Axis Spine Technologies ALIF is designed for use with any of the standard approaches for anterior lumbar interbody fusion (ALIF).

The surgical approach depends on the patient indication, level to be treated and surgeon training.

Locate the correct operative level and incision site by taking a lateral fluoroscopic view while holding a straight metal instrument on the side of the patient. This helps position the incision and exposure to allow direct access to the targeted level and enable easier screw insertion.

Expose the intervertebral space such that there is sufficient space either side of the vertebral midline.

Discectomy

After exposure has been completed, the disc will be partially removed.

Step 1 – Prepare Disc Space

- Create an annulotomy that is centered on the midline.
- The annulotomy should be wide enough to accommodate the Implant (M & L).
- An Endplate Sizer is recommended be used as a template to indicate if the width of the annulotomy is sufficient to receive the implant (M and L) (Fig. 1).
- A box incision of the annulus may be preferred, allowing some space for the gripper arms of the instrumentation.
- Excise disc material out to the posterior longitudinal ligament (PLL) and carefully remove the cartilaginous endplates to expose the bony vertebral endplates while taking care to limit damage to the bony endplates as much as possible.

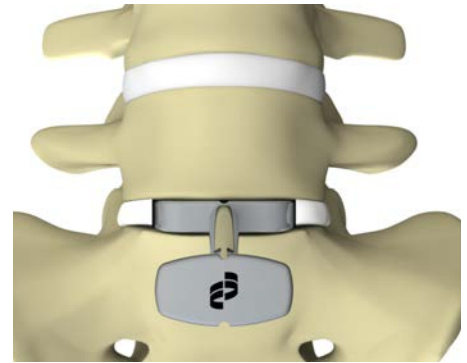


Fig. 1



The Endplate Sizer can also be used to confirm depth of discectomy to ensure the cage will fit in the AP direction. A gap of 1-2mm on each side of the Sizer will aid the insertion and release of the ALIF Inserter.



CAUTION

Adequate preparation of the endplates without compromising the structural integrity is important to enable an appropriate vascular supply to the bone graft and fusion mass while offering weight-bearing strength of the endplates.

Note: Too aggressive preparation may cause removal of bone beneath the cartilaginous layers, potentially resulting in weakened endplates.

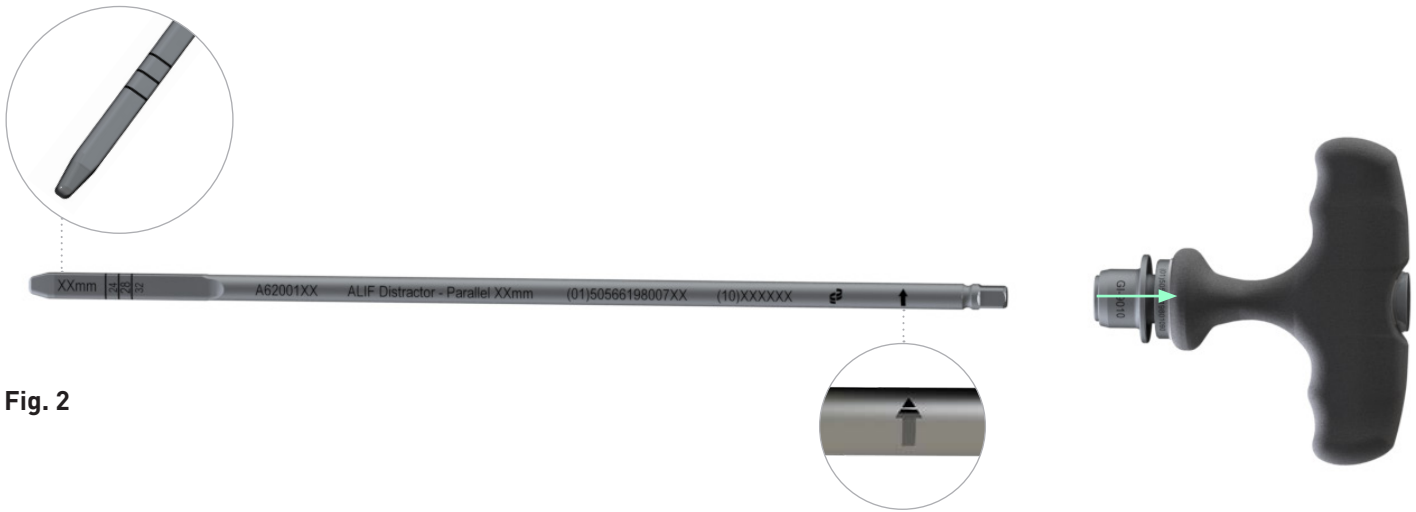


Fig. 2

Step 2 – Distract Intervertebral Disc Space

- Select an appropriately sized Distractor (Parallel; 6, 8, 10, 12mm) and attach it to the T-handle (Fig. 2).
- The Distractors are radiused on one side (Fig. 2 magnification) to prevent endplate disruption and therefore must be rotated clockwise. The shaft is laser marked with an arrow to confirm the direction of rotation.
- Insert the distractor into the disc space (Figs. 3-4) and rotate in a clockwise direction to provide localized distraction (Fig. 5).

Note: An intervertebral disc spreader may be used to aid distraction of disc space mobilisation (see AA-02-0003).

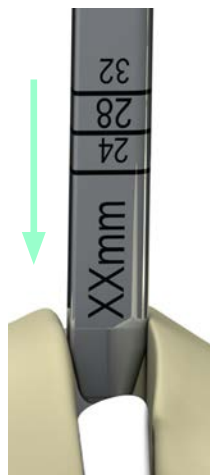


Fig. 3

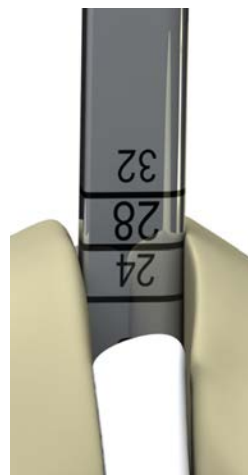


Fig. 4

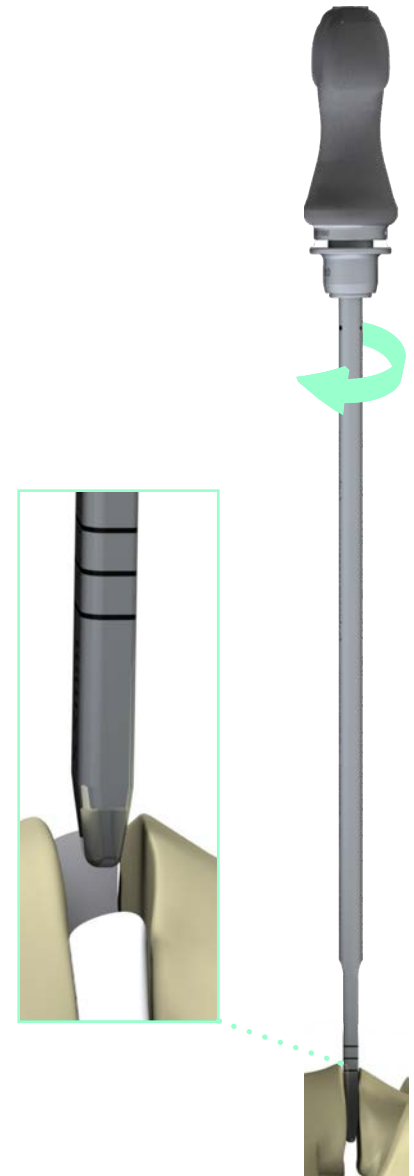


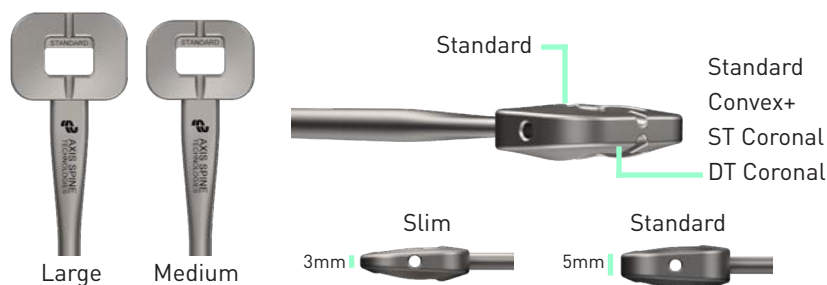
Fig. 5



Two Distractors can be prepared simultaneously using the two T-handles provided in the instrument set, enabling contralateral disc clearance.

Endplate Sizing

Use of the endplate sizer both confirms the optimal footprint required while indicating adequate disc clearance such that the endplates can be inserted.



Note: The insertion height of the slim sizers is approximately 3mm.

Fig. 6

Step 3 – Trial For Footprint Size

- Use the Endplate Sizers (Fig. 6) to determine the implant footprint and endplate topography required. The Standard Endplate Sizers represent the height, width and depth dimensions of the actual implant endplates, when inserted in collapsed position (prior to insertion of implant Core). The Standard Endplate Sizer range includes options to aid assessment of fit to bone. Options include a Standard paired with either a Convex +, Single Taper Coronal or Double Taper Coronal.

Note: A Slim Endplate Sizer may first be introduced to help facilitate distraction of a severely collapsed intervertebral space.

- AP and lateral fluoroscopy can be used to confirm the trial is in its correct position, indicating the footprint required.
- The Endplate Sizer includes a lateral, circular through hole that allow visualization on an image intensifier to confirm that the Sizer is in straight AP position (Fig. 7). The Endplate Sizer also features a central groove (as seen in Fig. 6) to aid positioning the device on the midline.

PRECAUTION:

- Carefully assess the position of the anterior edges of the Endplate Sizer to ensure they are within the confines of the vertebral bodies (Fig. 8).

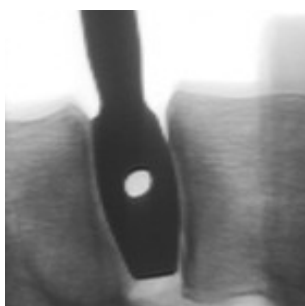


Fig. 7



Fig. 8

Endplate Insertion

Step 4 – Assemble the Alignment Tool

The Alignment Tool instrument is designed to keep the implant endplates aligned during insertion.

- Align the two arms of the Inserter using the lug features near the lever (Fig. 9) for guidance.
- Whilst holding the arms together in the correct position, slide the Alignment Tool from the top in between the arms (Fig. 10), ensuring it is engaged in the rail on both sides.
- Advance the Alignment Tool down the Inserter until both triggers audibly click into place and return to their neutral position (Fig. 11).
- Check the Alignment Tool is correctly assembled by inspecting the lug features for alignment as in Fig. 9. There should be no space between the Inserter arms (Fig. 12) and the Alignment Tool should feel securely attached to both superior and inferior arms.

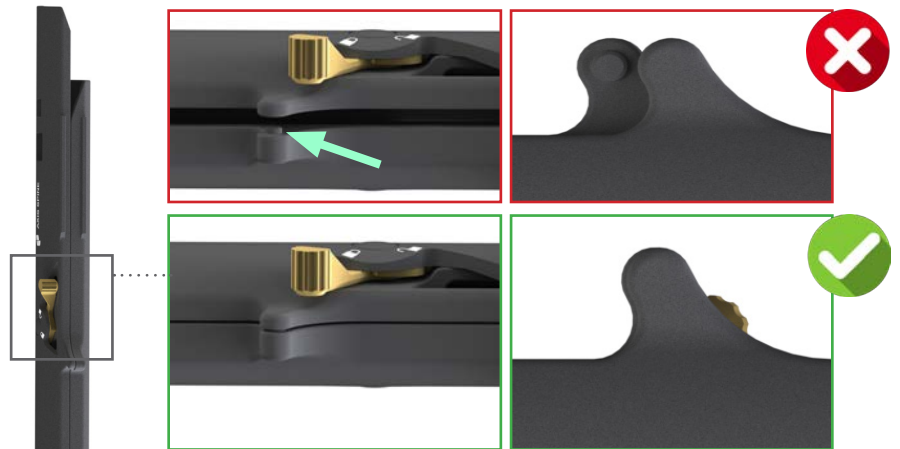


Fig. 9

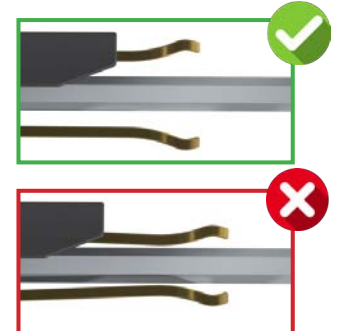


Fig. 11

Fig. 10

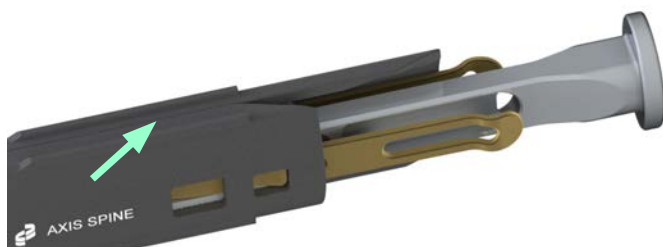


Fig. 12

Step 5– Attach Endplates to Inserter arms

To attach the Endplates (Fig. 13) to the Inserter arms:

- Rotate the lever to its fully unlocked position in order to open the grippers (gold) (Fig. 14).
- Place the Endplate between the grippers (Fig. 15), guiding it onto the rail of the alignment tool
- Whilst holding the Endplate on the end of the grippers, rotate the lever to the fully locked position to lock the grippers into the Endplate (Fig. 14)
- Ensure the Endplate is securely attached between the grippers and locked by trying to remove it from the inserter arm (Fig. 16).
- Repeat for both Superior and Inferior endplates.
- Check that the endplates are now seated together and that the inferior endplate is not loose (Fig. 17)

Fig. 13

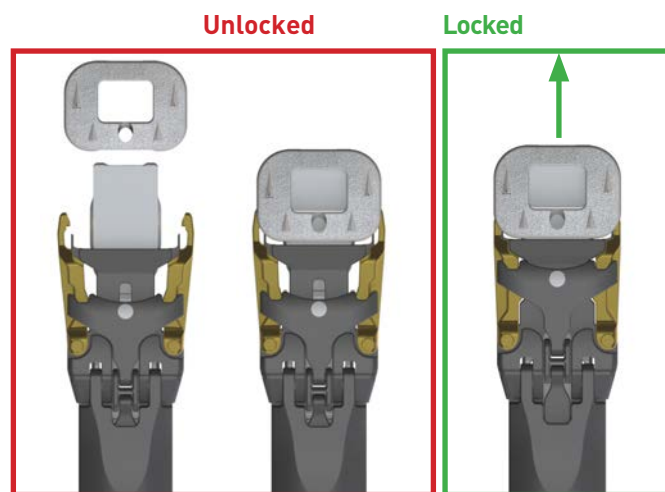
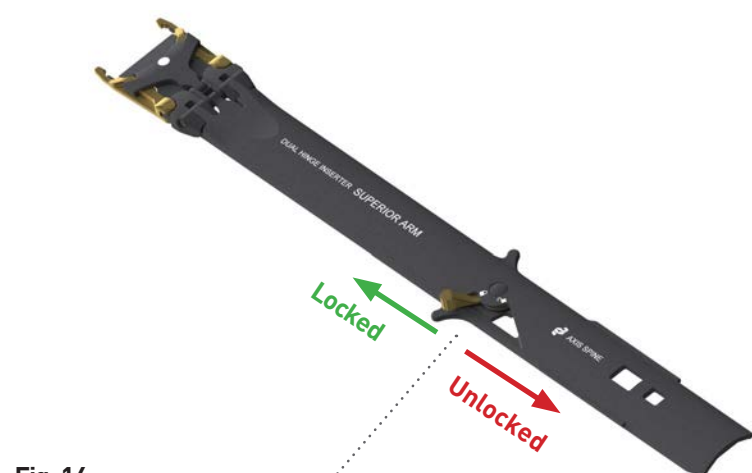


Fig. 14

Locked

Not fully unlocked

Unlocked

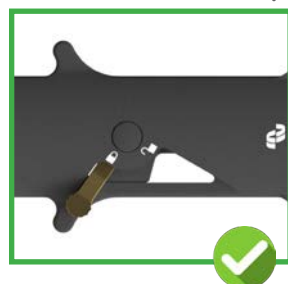


Fig. 15

Fig. 16

Fig. 17



To help prevent incorrect assembly of the endplates, match the dot markings on the Inserter arms with the number of holes of the corresponding endplates: a single dot corresponds with a superior endplate (single screw hole) and two dots corresponds with an inferior endplate (two screw holes).

- The Inserter allows the anterior of the implant endplates to be placed flush to the anterior portion of the vertebral endplate. A small amount of recessing is also allowed by the design (Fig. 18).



CAUTION

As the Endplate Sizer, that was used previously, has the same shape and size of the endplates on the Inserter **minimal impaction** should be required during insertion. Assuming sufficient disc material has been removed, only light impaction should be applied to the Endplate Alignment Tool for insertion.



CAUTION

Care should be taken to avoid harm to soft tissues when inserting endplates with fixation teeth

Impaction surface



Fig. 18

Step 6 – Assemble the Connector



AP images should be taken prior to the assembly of the Connector to aid visibility of the implant.

Note: It is important that the Inserter connector is assembled before proceeding with implant sizing. This makes sure that the endplates maintain their alignment during subsequent steps.

To assemble the Connector:

- Slide the Connector over the Inserter arms down towards the spine whilst in situ (Fig. 19). The arrows on the Connector indicate the direction of assembly. Hold the Connector in its closed position during assembly.
- The Connector is designed to audibly click into place when engaged correctly (Figs. 20-21) and each side of the connector body should feel securely attached to both Superior and Inferior arms.
- The Alignment Tool can now be removed leaving the Inserter assembly and endplates in position. Squeeze both triggers on the Alignment Tool and pull up and out of the Inserter to remove (Fig. 21).



Once the endplates are positioned into the disc space, care should be taken to not disturb the position of the Inserter, particularly during the deployment of the implant core.

Note: If it is necessary to remove and reinsert the Endplates from the disc space, then ensure the Inserter construct and Endplates remain correctly assembled with the use of the Alignment Tool. Do not reinsert the Alignment tool whilst the Inserter is still in the disc space.



Fig. 19



Fig. 20

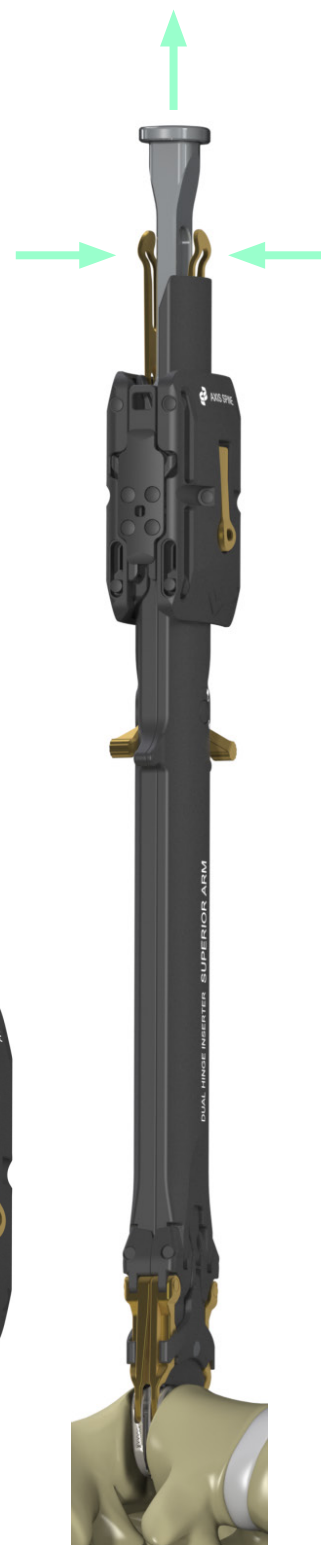


Fig. 21

Core Sizing

Core Trials allow trial sizing of posterior height and/or desired angle of lordosis, depending on surgical goals.

Step 7 – Loading of Core Trial

- The individual Core Trials connect onto the Trial Core Loader (Fig. 22). Slide the button back, attach the trial over its gripper ends and then release to secure the trial onto the loader.
- Load the Trial Core Loader into the Inserter assembly (Fig. 23).
- Ensure the loader carriage is engaged with the receiving features of the Connector body (Fig. 24).

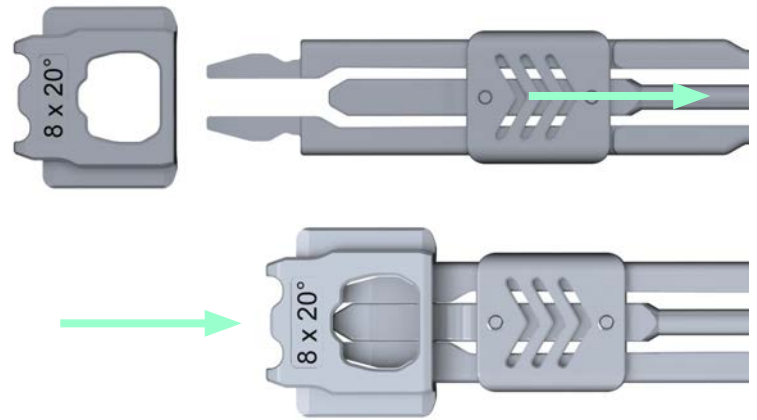


Fig. 22

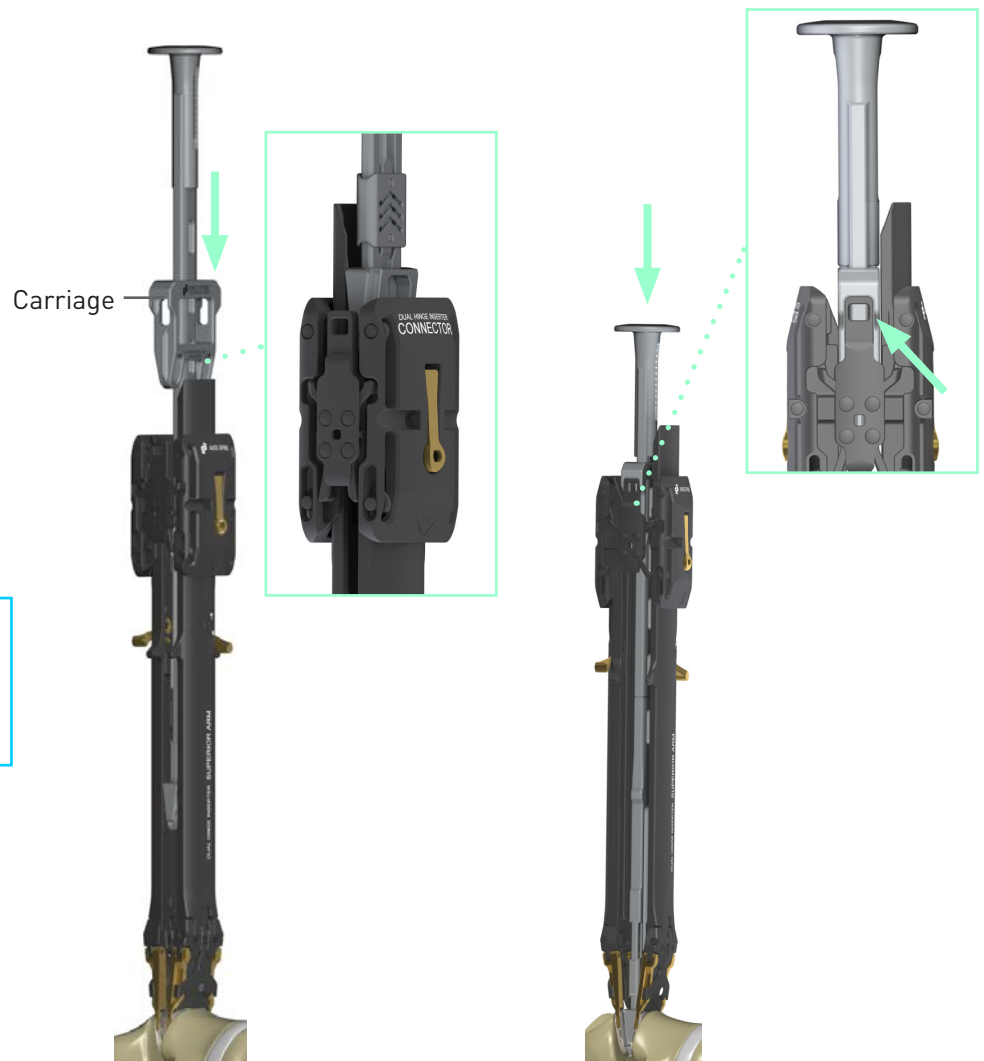


Fig. 23

Fig. 24



CAUTION

Ensure carriage is correctly located prior to commencing trialling

- Advance the Core Trial until it is received between the endplates. Imaging should be used to help to check if the correct depth is achieved. In this way, the trial assembly is representative of the position of the final implant.
- When the core trial is seated in between the endplates, it will be aligned flush with the anterior face of each vertebral endplate (Fig. 25). Imaging should be used to confirm core trial position. In a lateral x-ray, a small gap should be visible at the posterior of the configuration, as indicated in Fig. 25.
- Once the correct size has been determined select the correspondingly sized implant core.
- Pull the loader up and out from the Inserter. To aid removal, a slap hammer or slotted mallet may be used. The slap hammer connects to the feature on the strike plate.

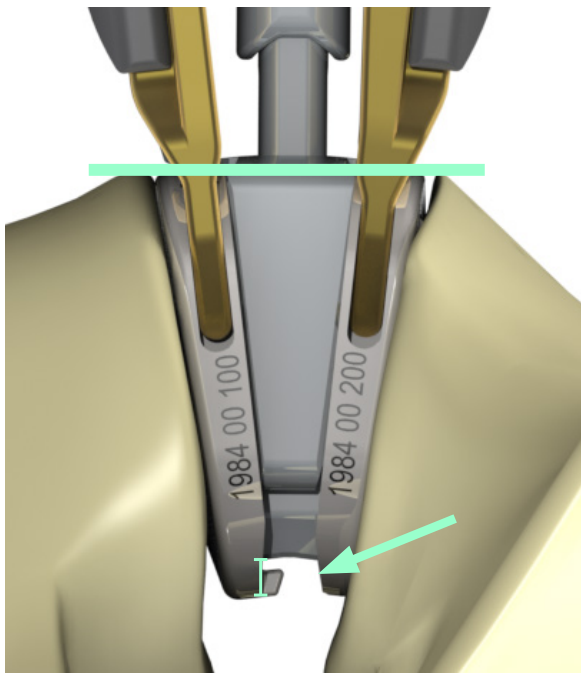


Fig. 25

- Anterior core heights for each size of core are shown in Table 1 for reference.



Table 1: Anterior Core Heights					
Posterior Height (mm)	Lordotic Angle (°)				
	10	15	20	25	30
6	12mm	14mm	16mm	18mm	21mm
8	14mm	16mm	18mm	20mm	23mm
10	16mm	18mm	20mm	-	-

Core Insertion

Once the correct Core size required has been selected it can now be prepared for insertion.

Step 8 – Grafting the Core

- Pack the core with graft, using the Graft Filler Tamp & Block (Fig. 26). Ensure that no debris falls outside of the implant graft cavity.
- Graft volumes for each size of core within standard endplates are shown in Table 2. For all other endplates, an additional 1.2-2.0 cc should be used for Medium and Large implants.

Fig. 26



Fig. 27



Fig. 27b

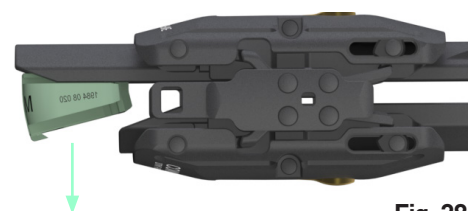


Fig. 28

Step 9 – Insertion of Core

- Position the superior face of the core against the internal face of the superior arm (Fig. 27), retaining control of the core until it is engaged into the superior Inserter arm rails.
- Check the core is orientated correctly and slide into the Inserter, retaining control of the core until it is engaged in the rails (Fig. 27b). Ensure core is engaged to the rail on both sides by gently pulling it away from the Inserter arm (Fig. 28)



Expand the connector body to aid visualisation of the engagement of the core to the rails.

Table 2: Max Graft Volumes (cc)

Posterior Height (mm)	Lordotic Angle (°)				
	10	15	20	25	30
6	2.6	2.8	3.0	3.2	3.4
8	3.0	3.2	3.4	3.6	3.8
10	3.4	3.6	3.8	-	-

- Insert the implant core loader behind the core (Fig. 29), such that the carriage engages into the connector.
- Push the Core Loader down into the Inserter ensuring the nose of the loader locates within the Locking Cap slot (Fig. 30).
- The Core Loader can now advance the Core through light impaction. The Core will advance until it locks into the endplates.
- When the Implant core locks into the endplates, it will be aligned flush with the anterior face of each vertebral endplate (Fig. 31). Imaging should be used to confirm core position. In a lateral x-ray, a small gap should be visible at the posterior of the configuration, as indicated in Fig 31.
- Once the core has been deployed, pull the loader up and out of the inserter. To aid removal, the slotted mallet may be used.

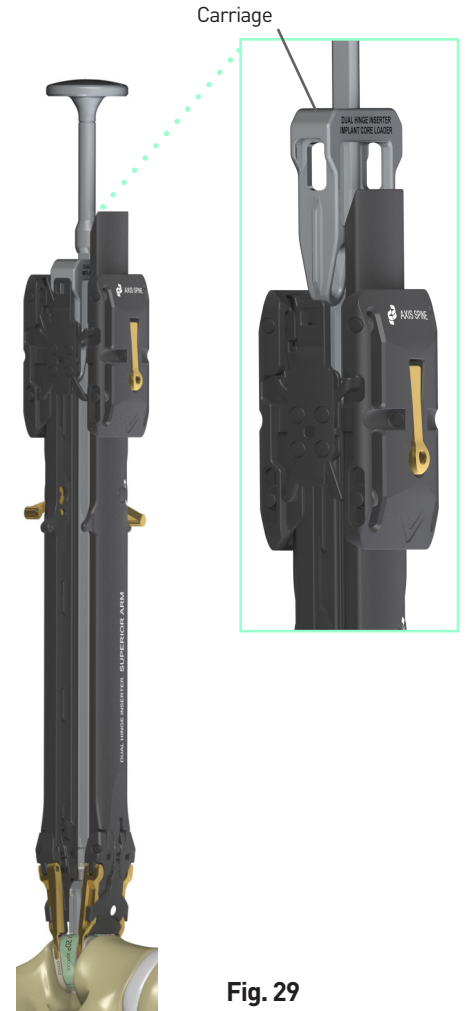


Fig. 29



During deployment of the core, allow the superior arm and hinge to straighten to aid passage into the endplates.

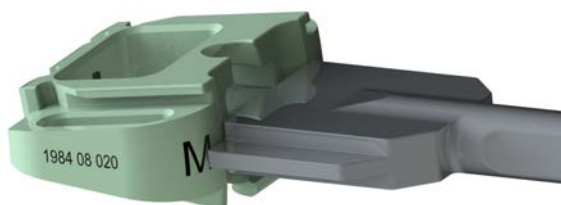


Fig. 30

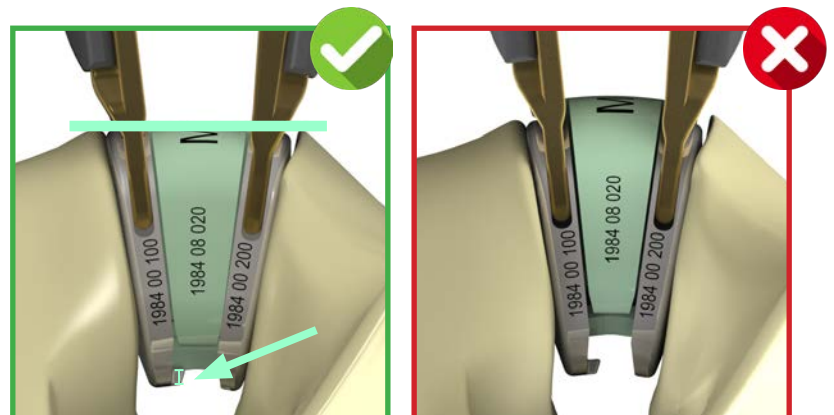


Fig. 31

Inserter Removal & Disassembly

Step 10– Removal of Inserter

Once the core is fully inserted, and its correct position confirmed, the Inserter is removed.

- First remove the connector body by pressing the superior and inferior buttons (Fig. 32) while sliding the connector off the Inserter arms (Fig. 33). Care should be taken to allow free movement of the Inserter mechanism during withdrawal.



CAUTION

The connector needs to be removed prior to detaching the inserter arms from the implant. This aids removal by maintaining each arm on plane relative to the endplates.

- Rotate the levers to the **fully** unlocked position on both the inferior and superior arms to allow the Inserter grippers to open and detach from the endplates (Fig. 34).
- Each individual arm can now be detached from the implant (Fig. 35).



Once the Inserter has been removed, the implant position can be adjusted using the Tamps.

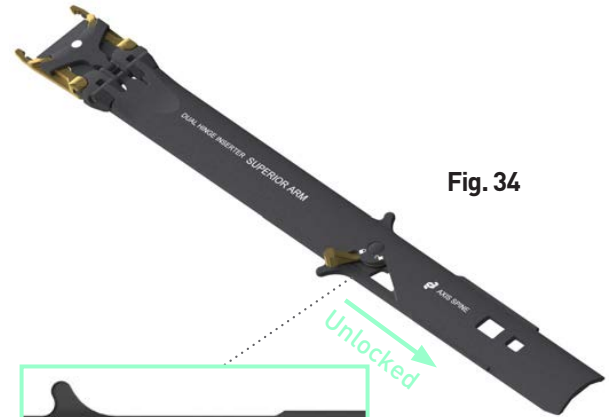


Fig. 34

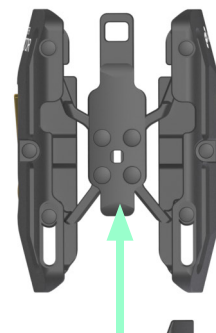


Fig. 33



Fig. 35

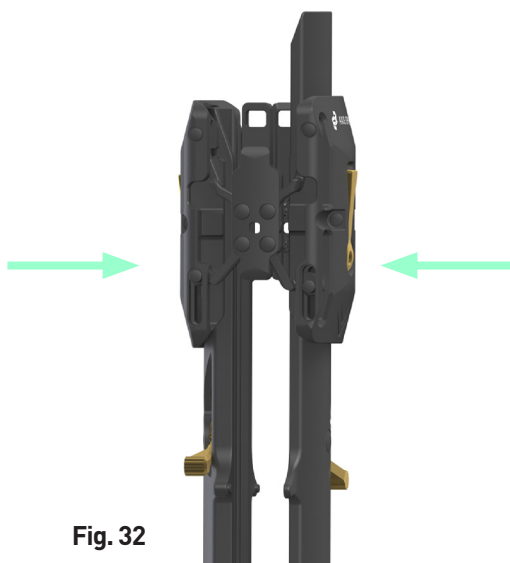


Fig. 32

Bone Screw Fixation

Pilot holes for bone screws are created using the various awls and guides, or retractable awls provided.

Step 11 – Preparation of Screw Holes using Retractable Awls

- Assemble the retractable awl (straight or angled) by selecting the appropriate inner part and loading it into its respective body (Fig. 36): i.e. the straight inner part into the straight body and the flexible inner part into the curved body.



The marker on the strike plate of the retractable awl (Fig. 37) can be used as an orientation guide during the operation and to aid assembly of the part.

- Secure the two parts together by first rotating the retraction nut followed by the assembly nut until hand tight (Fig. 38). A marked band on the inner part should be visible if the retraction nut has been fully secured.



CAUTION

CAUTION: It is important that both nuts are fully secured prior to use.

- To create the pilot hole, engage the barrel of the awl into the screw hole of the implant at the desired trajectory (Fig. 39). The awl is then deployed through gentle impaction of the strike plate.
- If the awl does not easily remove from the bone, the retraction nut can be turned counterclockwise, which will help awl retraction.

- To disassemble the awl, rotate the assembly nut counterclockwise. Once an audible click is heard, the retraction nut can be turned counterclockwise until fully disassembled.

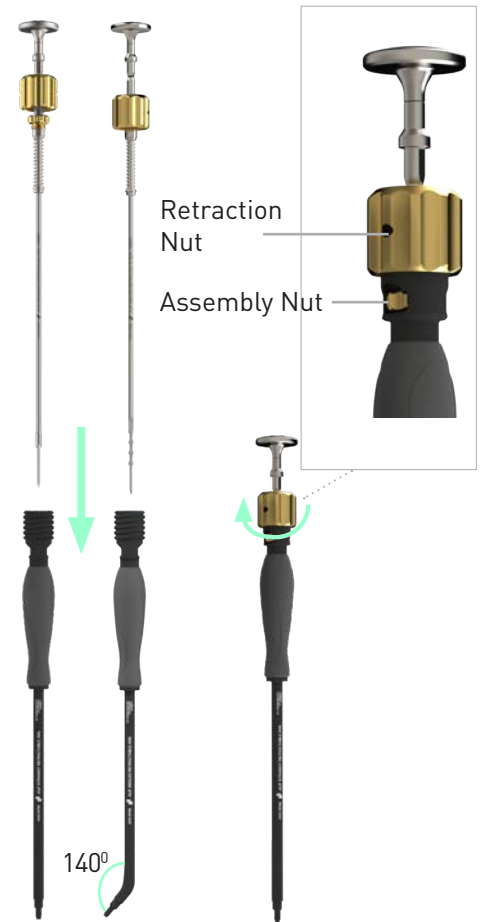


Fig. 36

Fig. 38



Freehand awls and guides (inline and angled) are available if desirable.



Fig. 37



Fig. 39

Step 12 – Insertion of Bone Screws using the Angled Screwdriver

- The Counter Torque handle can be attached to the Angled Screwdriver by first loosening the nut (Fig 40). Locate the hook around the neck of the screwdriver and engage the ball plunger. Retighten the nut to secure (Fig. 40).
- The screw does not lock into features on the endplate. As a result care should be taken to avoid over-tightening. The screw should be fully seated into the recess of the endplates (Figs. 41-42).

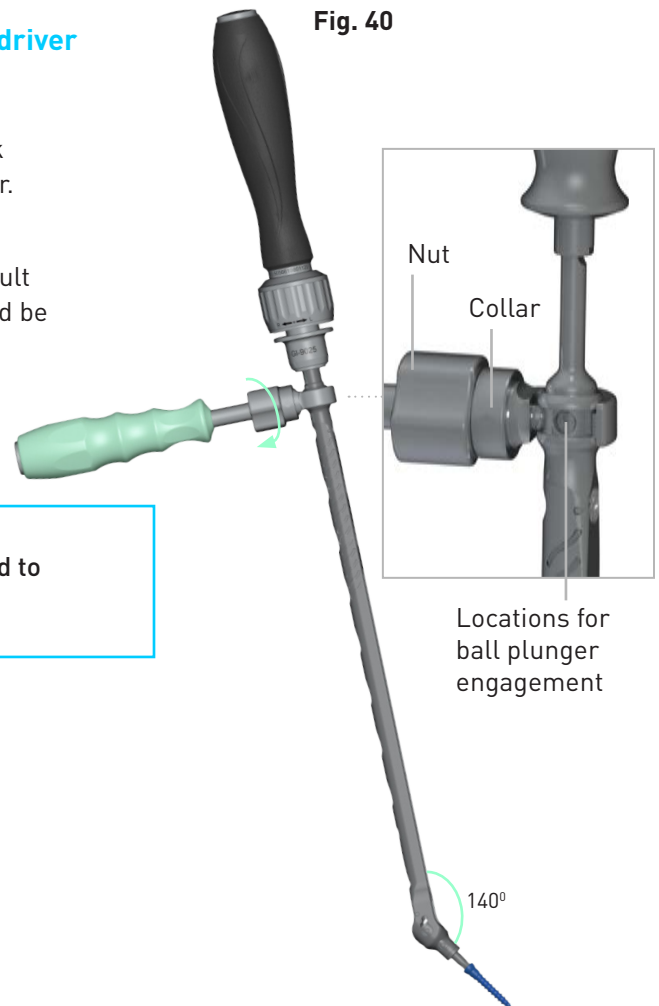


Fig. 40



CAUTION

Care must be taken not to overtighten as this can lead to stripping the screw threads in the bone.

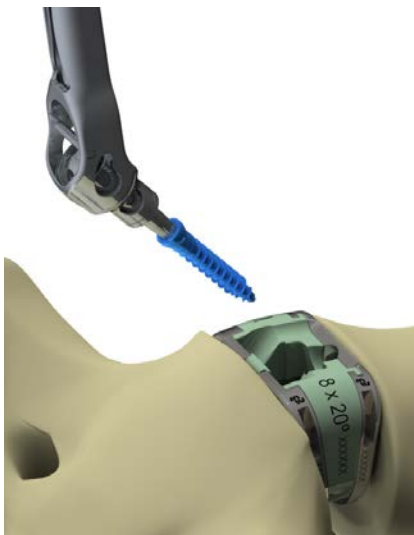


Fig. 41



Fig. 42

Step 13 – Insertion of Bone Screws using the Divergent Screw Guide

- The Divergent Screw Guide may be used to guide the first inferior screw (Fig. 43).
- Set the Divergent Screw Guide into the opposing inferior screw hole (Fig. 43), ensuring that the cylindrical feature locates into the opposing screw hole. Press the screw onto the Screwdriver tip and insert screw through the Screw Guide and into the implant (Fig. 44).



The implant contains features to allow both parallel and divergent (30 degree) screw trajectories into the Inferior endplate.

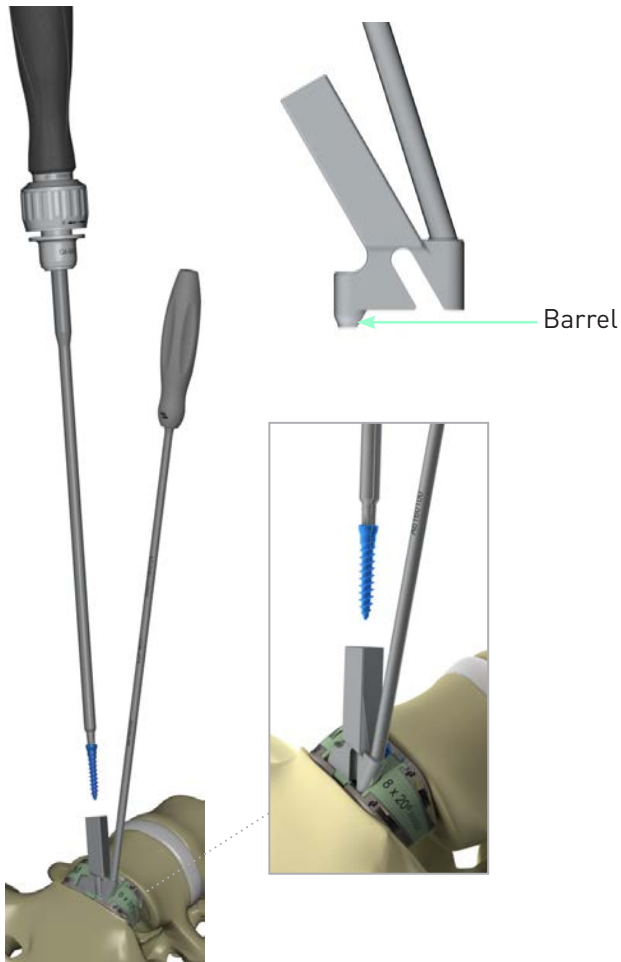


Fig. 43

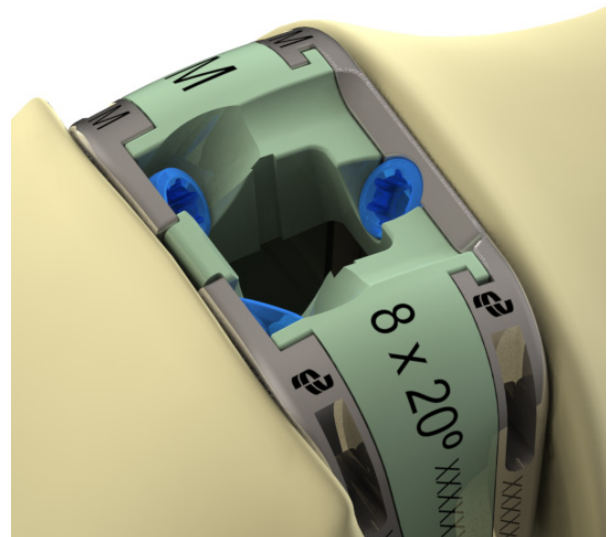


Fig. 44

Bone Grafting

Once the Cage and Screws are inserted, the Core can be post-packed using supplementary bone graft via the Graft Syringe.

Step 14 – Filling of Core with Additional Bone Graft

To assemble the Graft Syringes:

- Insert the selected Syringe Plunger into its corresponding Syringe Body (Fig. 45). Ensure the Plunger is correctly orientated before inserting, using the shape-matched features and laser marking for guidance.
- Secure the assembly using the Plunger Knob (Fig. 46). Ensure it is fully engaged by rotating until hand tight.
- Introduce graft material into end of Graft Syringe. The syringes locate into the graft chamber window (Fig 47). Once positioned, press the plunger knob to deploy the graft material into the cage. The Medium Syringe can be loaded up to 2cc for all core sizes, except 6x10°, 6x15° and 8x10°. The Small Syringe up to 0.9cc for all core sizes.

Fig. 46





The shaft of the syringe can be removed to use as tamp.

Note that this should be light manual tamping and should not be impacted with a mallet or any other instrument.

Fig. 45

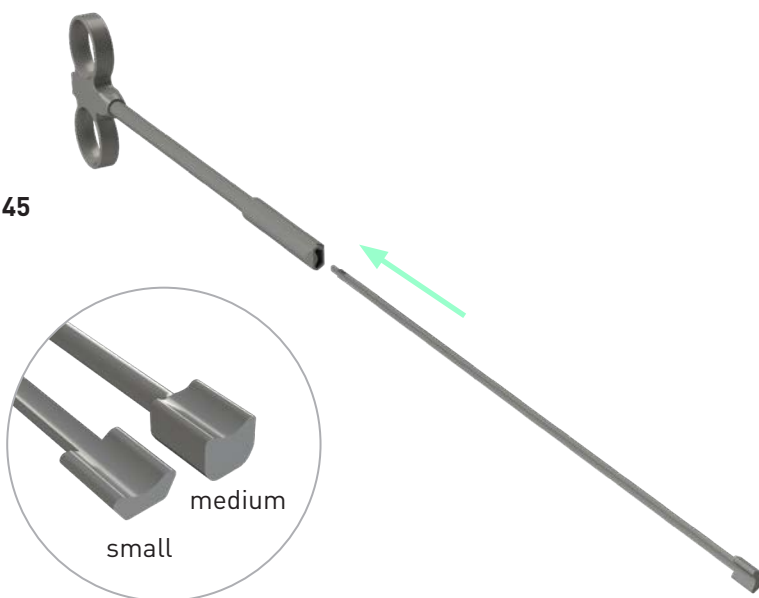


Fig. 47

Locking Cap Insertion

The Locking Cap helps to prevent back-out of the screws as well as keeping the graft material within the cage.

Step 15 – Insert Locking Cap

- Assemble the Locking Cap Inserter by sliding the shaft onto the sleeve and winding until secure.
- Locate the Locking Cap to the Locking Cap Inserter using the shape-matched surface to aid orientation (Fig. 48-49). The axis logo points towards the superior endplate.
- Rotate the Inserter handle whilst maintaining the position of the Locking Cap, until the Locking Cap is securely attached to the inserter.

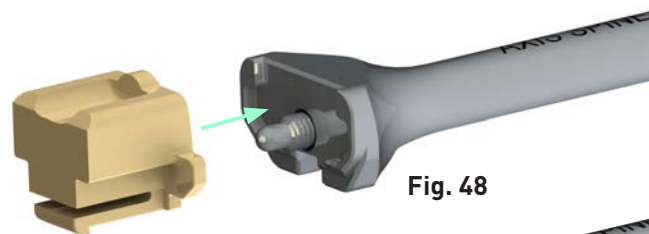


Fig. 48



Fig. 49



Bone graft needs to be compacted into the cavity prior to inserting the locking cap

- Manually push the Locking Cap into the implant recess. It should snap securely into place (Fig. 50) and be resistant to light forces to pull it out.
- Test the Locking Cap is secure with gentle pulling (Fig. 51), once secure the Locking Cap Inserter can be detached by unscrewing.



Fig. 50



Fig. 51



CAUTION

The Locking Cap should not be impacted and is secured using a press fit. Use of the Locking Cap is important, as it seals the graft chamber and prevents the Bone Screws from backing out.

Final Assessment

Check the final position of the implant using the image intensifier in both A/P and Lateral views (Fig. 52).

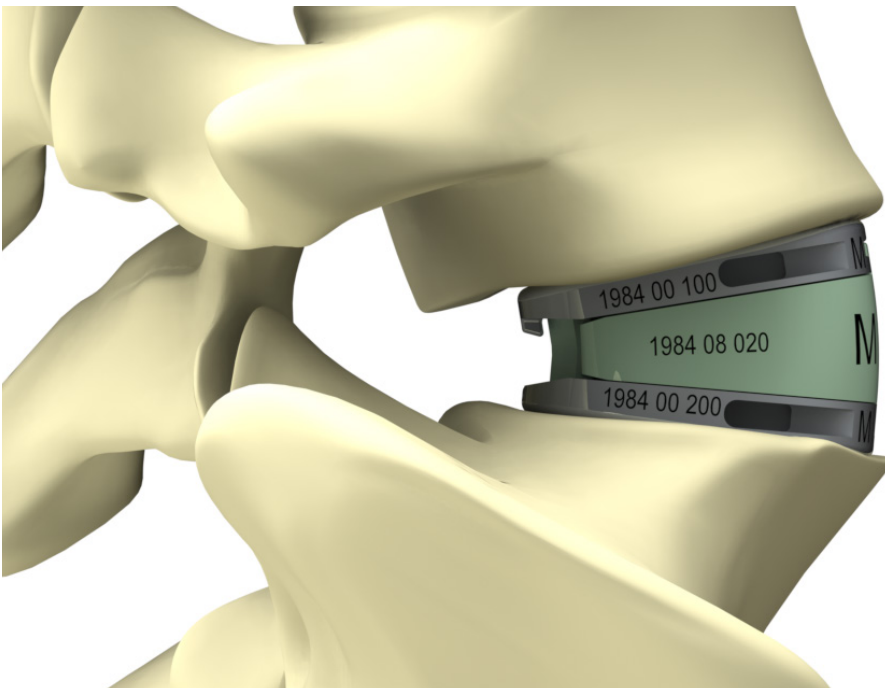
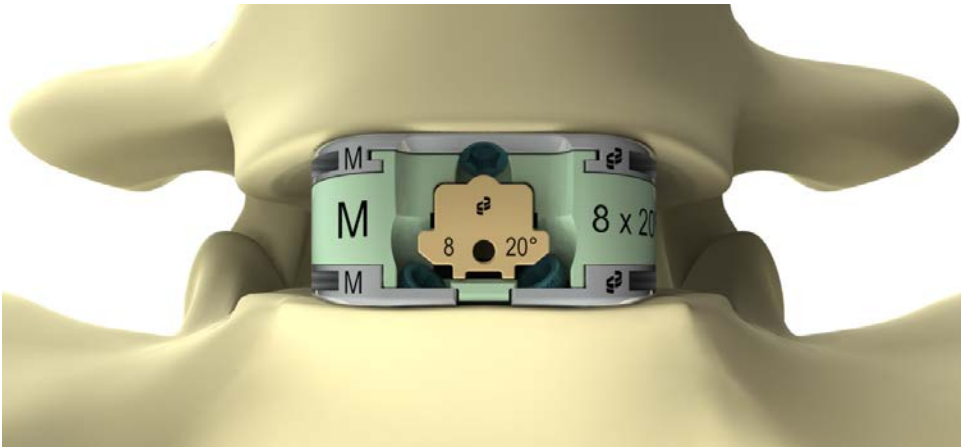


Fig. 52

Implant Removal

Locking Cap and Screw Removal

In the rare case that the implant needs to be removed, the Locking Cap must first be removed.

- The Locking Cap Inserter Removal Tool should be assembled onto the Locking Cap Inserter sleeve (Fig. 53).
- Insert the Locking Cap Inserter Shaft into the assembly and rotate the handle until secure (Fig. 54).
- Locate the Locking Cap Inserter sleeve onto the Locking Cap in situ (Fig. 55), using the shape-matched features as guidance.
- Turn the handle to attach the tool into the Locking Cap
- Deploy the Removal Tool by pushing down the assembly (Fig. 56).
- The Locking Cap is now unlocked and can be removed by pulling on the Locking Cap Inserter assembly in one linear motion (Fig. 57).
- Following removal of the locking cap the screws can be removed using the insertion screwdrivers, rotating counterclockwise.

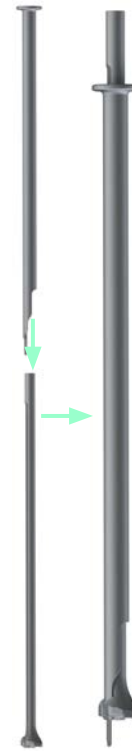


Fig. 53

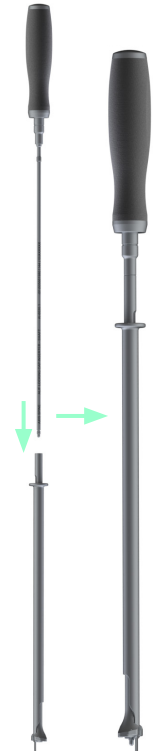


Fig. 54

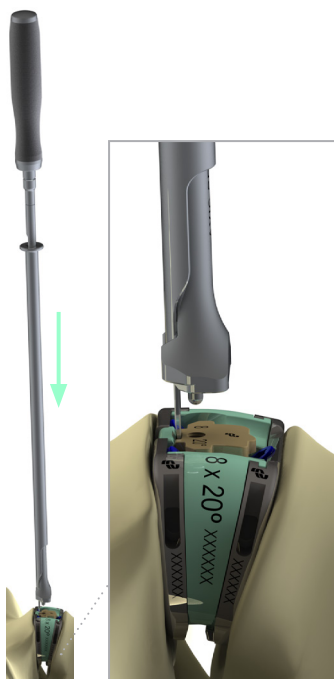


Fig. 55

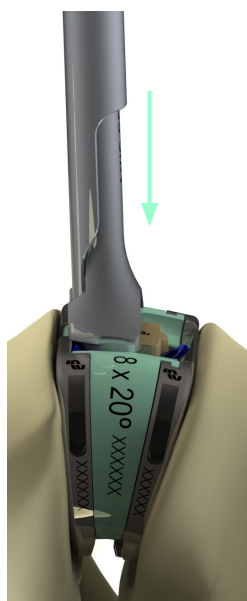


Fig. 56

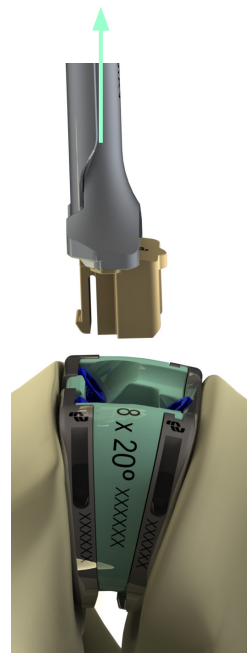


Fig. 57

Core and Endplate Assembly Removal

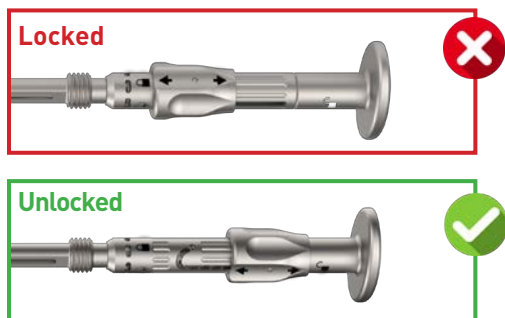


Fig. 58

- Ensure the Implant Extractor Body is in its fully unlocked position. To unlock, push the nut down, twist and release (Fig. 58). The arrow should align with the unlock symbol.
- Assemble the Implant Extractor by inserting the Extractor Body into the Extractor Sleeve and threading together until it stops (Fig. 59).
- Insert the distal end of the Implant Extractor assembly into the implant (Fig. 60), ensuring the tangs are aligned in the implant graft window in M-L direction.
- Lock the Extractor Body to deploy the tangs. To lock, push the nut down, twist and release (Fig. 60). The arrow on the nut will align with the lock symbol when correctly locked.
- Rotate the Extractor Sleeve nut until the Sleeve meets the anterior face of the implant to secure the instrument to the implant (Fig. 61). The connection to the implant must feel firm, with no perceptible play or movement between the instrument and implant.
- The implant is now fully secured to the Implant Extractor and can be removed by pulling on the implant Extractor.
- The Slap-hammer can be attached to the back of the Implant Extractor to aid removal of the implant if required (Fig. 62).

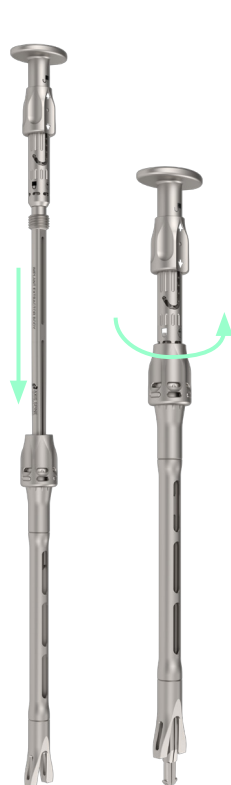


Fig. 59

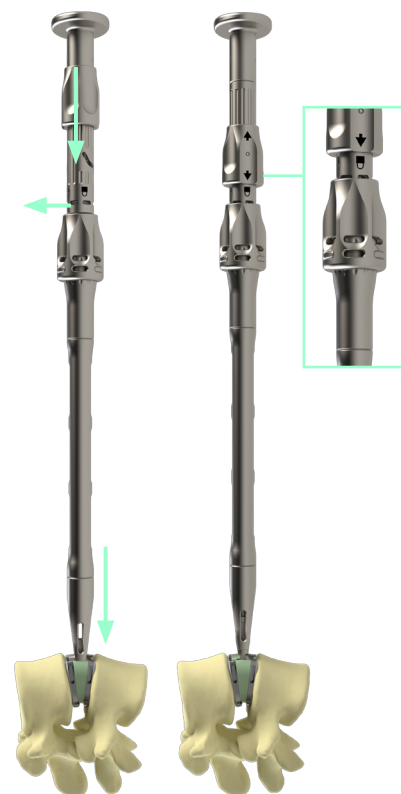


Fig. 60



Fig. 61

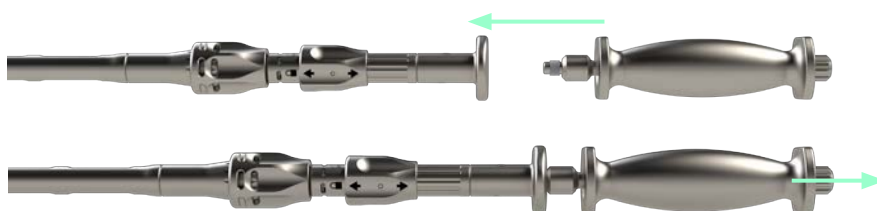
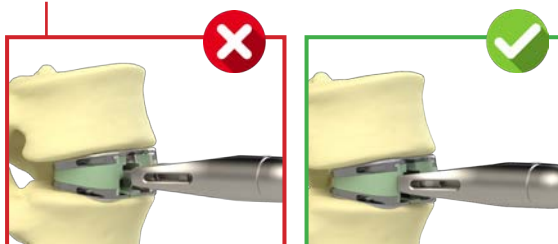


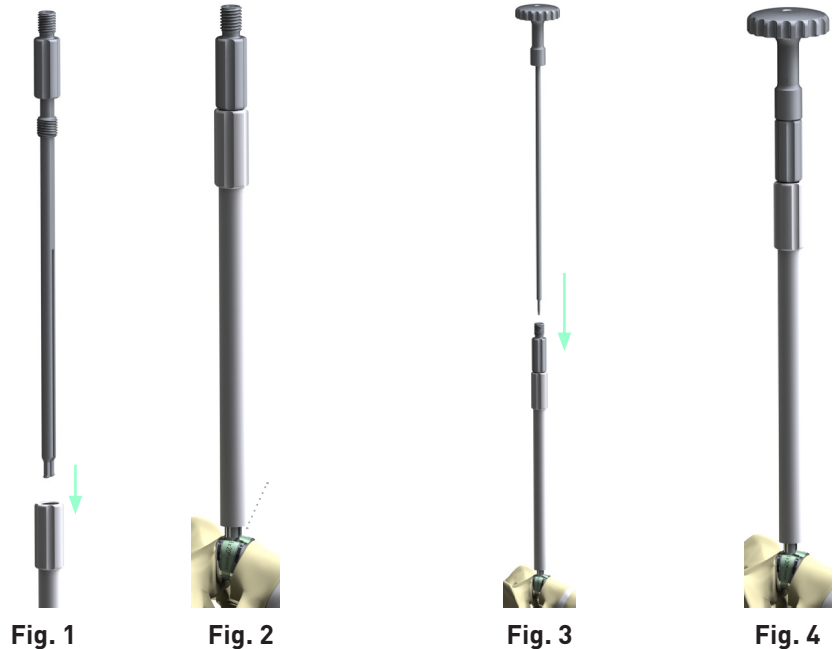
Fig. 62

APPENDIX 1

Core and Endplate Assembly Removal - Secondary Instrument

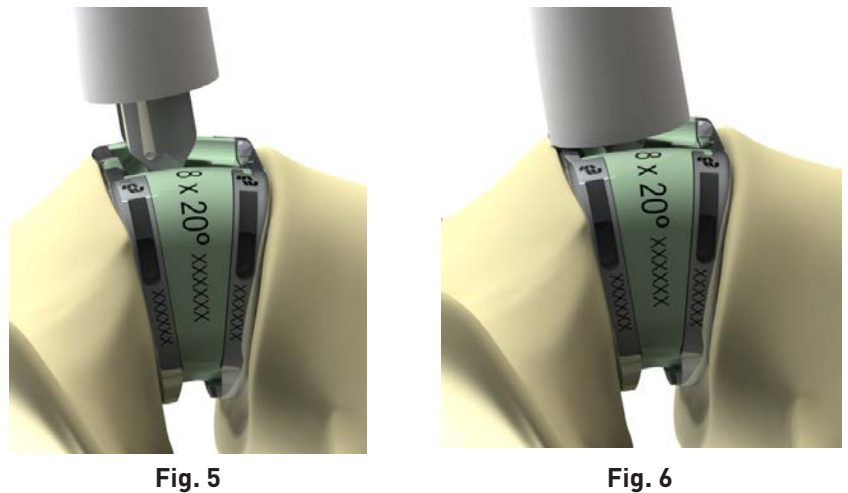
To remove the implant, use the Implant Extractor tools:

- The outer sleeve should be wound counterclockwise onto the extractor body, up to the shoulder (Fig. 1).
- The tool can now be inserted into the graft window of the implant (Fig. 2).
- The inner shaft can now be inserted (Fig. 3) and rotated until it reaches a stop (Fig. 4).

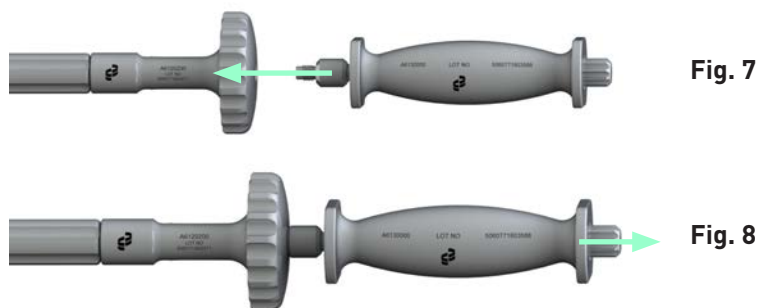


Now the Implant Extractor is secured to the implant.

- The sleeve can now be rotated to advance it to the anterior face of the implant (Fig. 5).
- The implant is now fully secured to the Implant Extractor and can be removed by pulling on the Implant Extractor (Fig. 6).



 The Slap-hammer can be attached to the back of the extractor to aid removal of the implant if required (Figs. 7-8)



ALIF: Instructions for Use



Manufacturer:
Axis Spine Technologies Ltd
Century Offices, 2175 Century Way,
Thorpe Park, Leeds, LS15 8ZB.
United Kingdom
Phone: 888 921 1017 (USA)

Rx ONLY Caution: Federal Law restricts this device to sale by or on the order of physician.



LOT NUMBER



CATALOGUE
NUMBER



NON-STERILE



MATERIAL

DESCRIPTION

The Axis Spine Technologies ALIF System is a device designed to be inserted within the intervertebral disc space in order to provide structural stability in skeletally mature individuals.

The ALIF System is a modular system that can be assembled in a variety of geometries to suit individual pathology and anatomical conditions.

The interior of the implant has openings that can be intra-operatively packed with autograft and includes a cover plate to retain the autograft and prevent screw loosening.

The ALIF System must be used with supplemental internal spinal fixation systems (i.e. posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

INDICATIONS FOR USE

The ALIF System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

The ALIF System 10° - 20° lordotic cages may be used as a standalone system. The ALIF System 25° - 40° lordotic cages must be used with supplemental internal spinal fixation systems (i.e., posterior pedicle screw and rod system) that are cleared by the FDA for use in the lumbar spine.

The ALIF System implants can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis; however, when used in these patients at multiple levels and for patients with degenerative spondylolisthesis, the ALIF System must be used with a supplemental internal spinal fixation system (e.g., pedicle screw system) cleared by the FDA for use in the lumbar spine in addition to the integrated screws.

For use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection localized to the site of the proposed implantation.
2. Signs of local inflammation.
3. Patients with known allergy or foreign body sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Device component fracture
- Loss of fixation
- Pseudarthrosis (Nonunion or delayed union)
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The implantation of intervertebral body fusion devices should be performed only by experienced spinal surgeons.

The ALIF device is intended for use only as indicated.

The ALIF Device is for single use only. No implant should be reused if it has come in contact with blood or other bodily fluids. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

All sizers and instrumentation are provided non-sterile and must be steam sterilized prior to use.

All implants, sizers and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to Axis Spine Technologies.

Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

When implanted at two contiguous levels, the ALIF System must be implanted in the same orientation to prevent screw impingement or potential bone fracture.

Preoperative planning and patient anatomy should be considered when selecting implant size. Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

It is important to select the appropriate length ALIF screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials. If fewer than the maximum number of screws accommodated by the device are used, then the system is intended to be used with additional supplemental fixation (cleared by the FDA) for use in the lumbar spine.

These devices can break when subjected to the increased load associated with delayed union or nonunion.

Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes

compared to those without a previous surgery.

Care should be taken to insure that all components are ideally fixated prior to closure.

PATIENT EDUCATION:

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

MATERIALS

The ALIF System is manufactured from Ti6Al-4V ELI conforming to ASTM F136/ISO 5832-3 and PEEK-Optima LT-1 (Polyether-etherketone) conforming to ASTM F2026.

MRI SAFETY INFORMATION:

The ALIF System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment.

The safety of the ALIF System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use ALIF System with components of other systems. Unless stated otherwise, Axis Spine Technologies devices are not to be combined with the components of another system.

PRE-OPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the ALIF implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device must be

given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weightbearing, muscular activity or sudden jolts or shock to the spine.

- The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

METHOD OF USE

Please refer to the Surgical Technique for this device.

PACKAGING

Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Axis Spine Technologies.

All implants are provided non-sterile are single use and should be sterilized per instructions provided below.

Instruments provided non-sterile are reusable and should be reprocessed using instructions provided below.

CLEANING AND DECONTAMINATION

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the Axis Spine Technologies Cleaning and Sterilization Instructions before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to Axis Spine Technologies. Contact your local representative or Axis Spine Technologies directly for any additional information related to cleaning of Axis Spine Technologies surgical instruments.

STERILIZATION

All non-sterile instruments and implants are sterilizable by steam autoclave using standard hospital practices, in addition to Axis Spine Technologies's validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the Axis Spine Technologies Cleaning and Sterilization Instructions.

INFORMATION

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local Axis Spine Technologies representative.



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AA-02-0004.1 Rev. F

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