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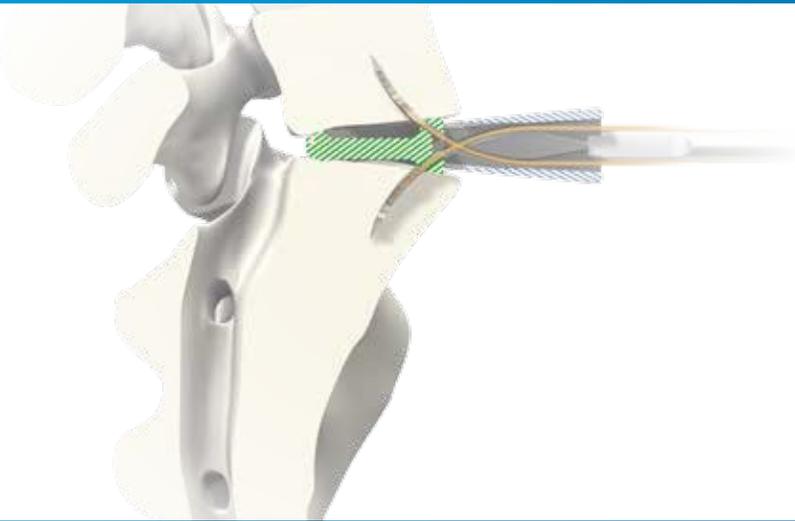


Thoracolumbar Solutions

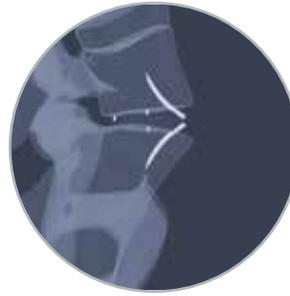
ROI-A®
ALIF Cage



The ROI-A system utilizes innovative VerteBRIDGE plating technology in an ALIF application, to deliver integrated fixation in the same plane as the disc space.



ROI-A



LATERAL VIEW



AP VIEW

Deliver

WITH ACCURACY

The ROI-A cage with VerteBRIDGE fixation offers a unique system in which integrated fixation is delivered in a self-guided fashion with the implant holder. This allows for accurate impaction of self-locking VerteBRIDGE plating, giving surgeons confidence in the plating trajectory.



Customization

- Multiple footprints, lordosis, and heights as well as three plate lengths for optimized fit and stability in various patient anatomies



Visualization

- PEEK-OPTIMA® material for biocompatibility and radiolucency, and Tantalum markers for verification of cage positioning



Security

- Self-guided, self-locking plating system within the implant holder protects soft tissue anatomy from contact during integrated fixation delivery

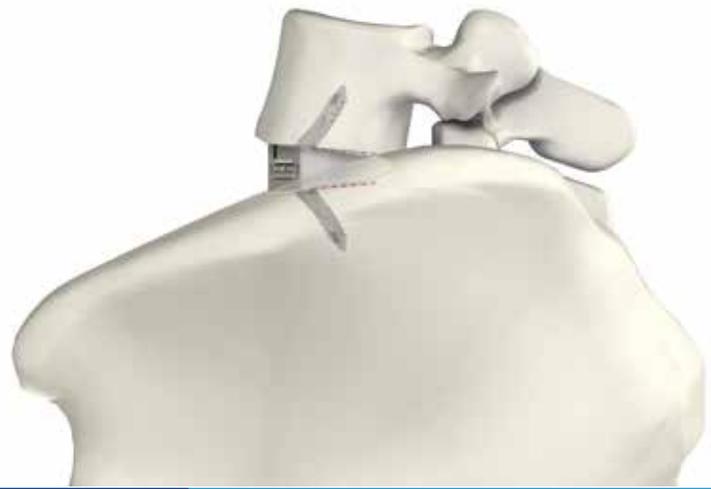
ROI-A Oblique



LATERAL VIEW



AP VIEW



ROI-A ALIF Cage



ROI-A Oblique ALIF Cage

ROI-A DIMENSIONS

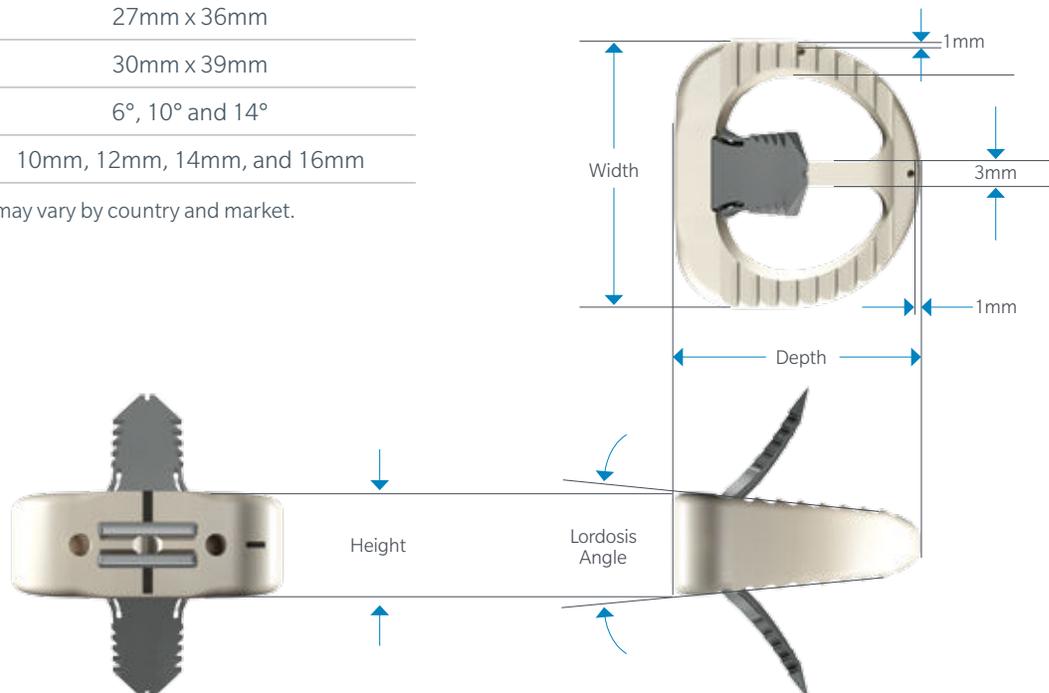
The ROI-A system offers a wide range of implant options, as well as an oblique option, in each implant kit to address a variety of patient anatomies and surgical situations.



ROI-A PRODUCT RANGE AND SIZING †

	23mm x 26mm
Footprints (Depth X Width)	27mm x 30mm
	27mm x 36mm
	30mm x 39mm
Lordosis	6°, 10° and 14°
Heights	10mm, 12mm, 14mm, and 16mm

†Product availability may vary by country and market.

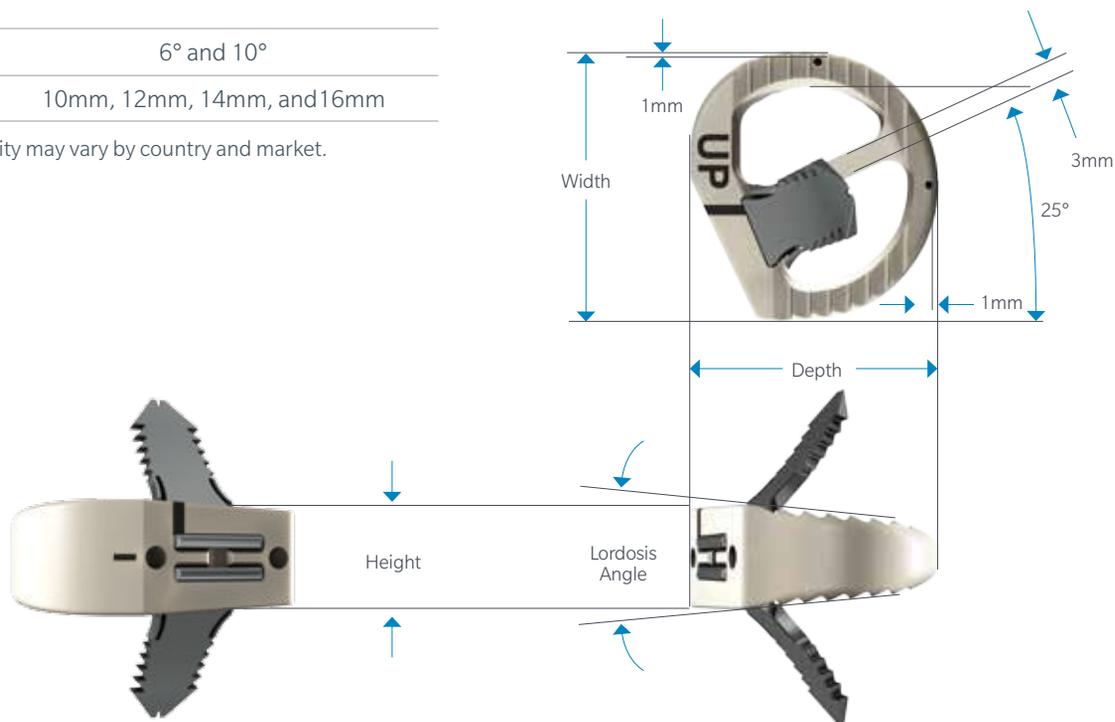


ROI-A OBLIQUE DIMENSIONS

ROI-A OBLIQUE PRODUCT RANGE AND SIZING †

Footprints (Depth X Width)	27mm x 30mm
Lordosis	6° and 10°
Heights	10mm, 12mm, 14mm, and 16mm

†Product availability may vary by country and market.



The ROI-A Oblique ALIF cage system is a novel system designed for zero-profile, stand-alone lumbar interbody fusion. While it shares the features and benefits of the original ROI-A ALIF cage, which was designed for direct anterior insertion, the ROI-A Oblique cage and VerteBRIDGE plating can be inserted from a 25° anterolateral angle that may reduce retraction of the great vessels and minimize the associated management of segmental vessels. It also avoids the neurologic challenges of lateral trans-psoas techniques. These can be key advantages when treating degenerative disease of the lumbar spine, particularly at the L4-L5 level.*



*In cases of spondylolisthesis or vertebral instability, the ROI-A implant should be augmented with additional supplemental fixation



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Please see the package insert for a complete listing of the indications, contraindications, precautions, warnings, adverse effects, and patient counseling information. Rx Only. Results may vary. Not all patients are candidates for this product and/or procedure.

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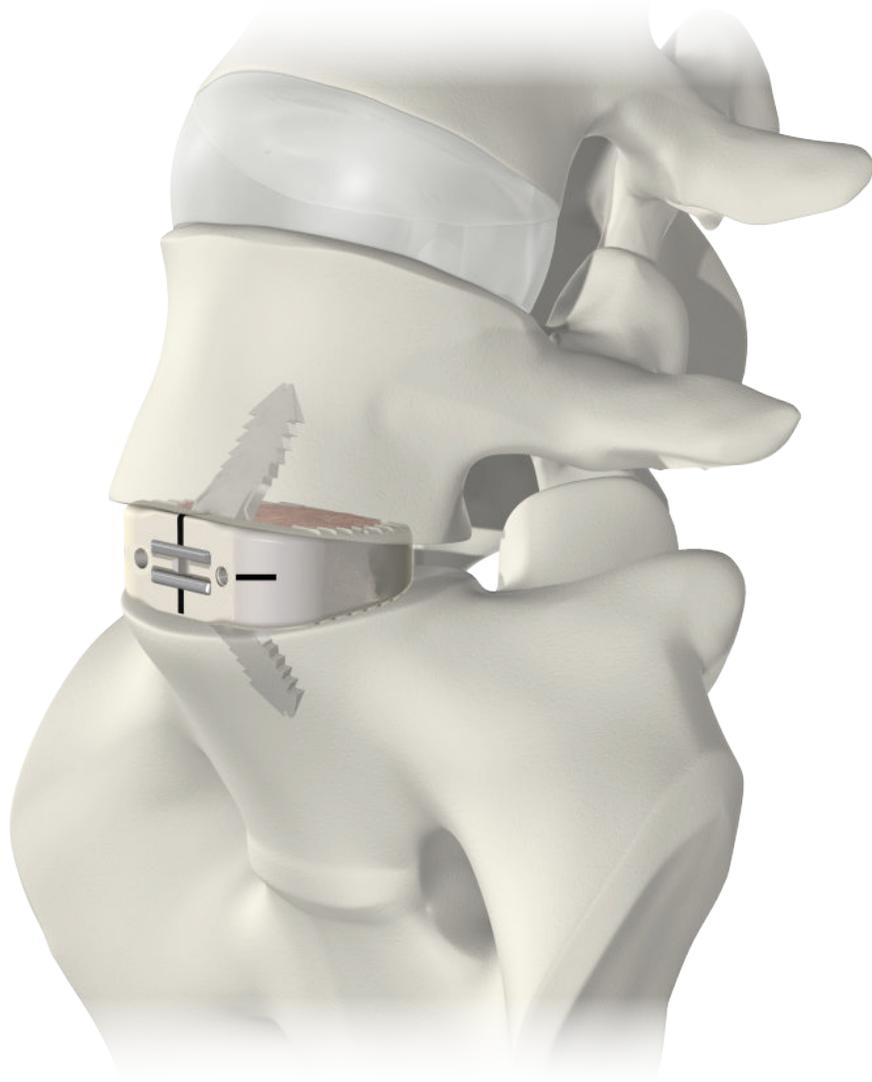


Thoracolumbar Solutions

ROI-A®
ALIF Cage



Surgical Technique Guide



*Featuring VerteBRIDGE®
Plating Technology*

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Note: VerteBRIDGE® Plating is the supplemental fixation designed specifically for ROI-A cage and can be used in application where a stand-alone anterior construct is appropriate. Additional supplemental fixation options that be used with ROI-A cage (with or without VerteBRIDGE Plating) include posterior screw/rod systems or additional vertebral plating.

PATIENT POSITIONING AND OBLIQUE SURGICAL APPROACH

Approach to the Surgery

Perform the customary approach for an ALIF as chosen by the surgeon.

Oblique Surgical Approach

The disc space can be reached through a left sided retroperitoneal approach. Generally, access may be gained by a:

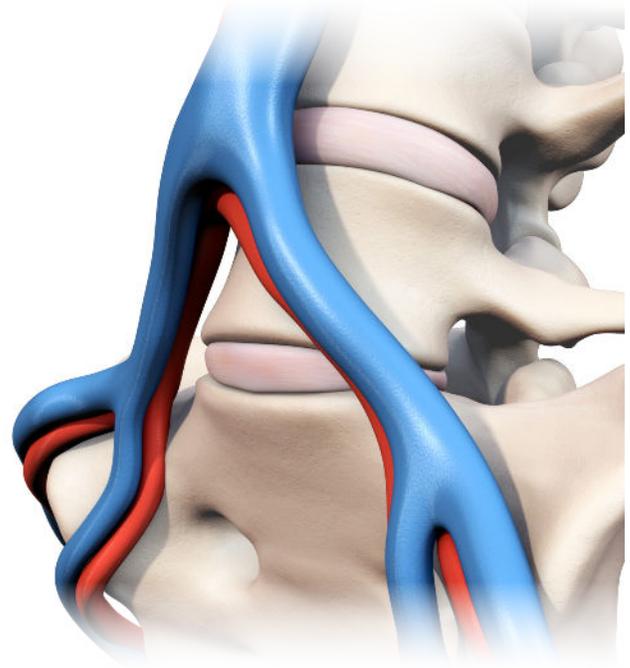
- Flank incision - Make a horizontal incision, 2-3 inches long, lateral to the midline at the appropriate level; OR
- Paramedian incision - Start two finger breadths to the left of the umbilicus to 2-3 inches cephalad.

Note: While cleared for use at L5-S1, the anatomic position of the iliac crest or left femoral artery can make an oblique approach challenging at the L5-S1 level.

The vena lumbalis ascendens and/or the intersegmental vessels may be sutured, as necessary, to mobilize the major vessels medially. The exposure may be secured using appropriate retractors.

Confirm Disc Location with Fluoroscopy

A disc marker may be inserted into the affected disc and a radiographic image taken to confirm the appropriate level.



DISCECTOMY

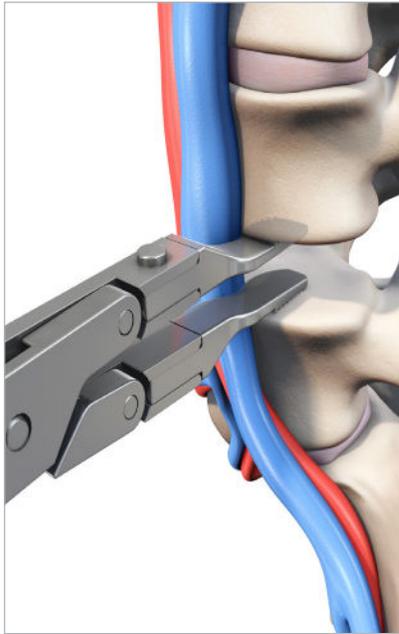


Figure 1a

Unilateral distractor – Place on one side, distract, and maintain the position by dialing down the locking knob. Complete the discectomy on the exposed side. Move the unilateral distractor as needed and complete the discectomy on the contralateral side.

Note: Make sure the distractor head is flush with the anterior aspect of the vertebra.

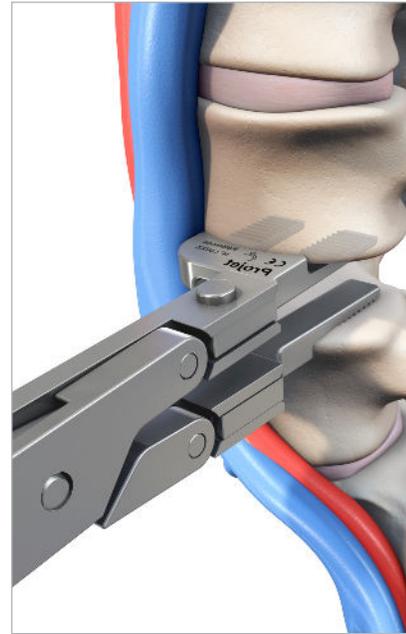


Figure 1b

Bilateral distractor – Place the distractor, distract, and maintain position by dialing down the locking knob. The distraction allows a more thorough posterior discectomy or, if necessary, a posterior release. The bilateral distractor can also be used to preliminary open the disc space for the implant.

Note: Make sure the distractor head is flush with the anterior aspect of the vertebra.

STEP 1: DISCECTOMY

Use the surgeon's preferred anterior discectomy instruments and procedure to remove the disc down to the osseous endplate. A Cobb elevator (7571-91) is available to aid the discectomy.

Note: Remove disc just enough for the implant footprint; preserving lateral annulus improves post-operative stability.

Use the surgeon's preferred distraction method. As needed to complete the discectomy, assemble the unilateral distractor tips (IG022/023R) or the bilateral distractor tips (IG024/025R) to the distraction forceps (IG021R).

Take care to remove any anterior or posterior osteophytes and scrape the endplates both inferior and superior with the rasp (756-1712-0C) to expose bleeding bone.

Note: Prepare the endplates just enough to create a surface that will encourage vascularization between the endplates and the graft, without weakening the cortical bone.

ASSESS THE DEPTH



Figure 2a
Assess the depth



Figure 2b
Depth gauge

STEP 2: ASSESS THE DEPTH

Keeping the unilateral distractor in position, place the hook of the ROI-A depth gauge (IR9430R) just over the posterior edge of the inferior vertebra.

To get the most accurate reading:

- Completely remove all anterior and posterior osteophytes

View the depth reading at the end of the depth gauge.

TRIALING

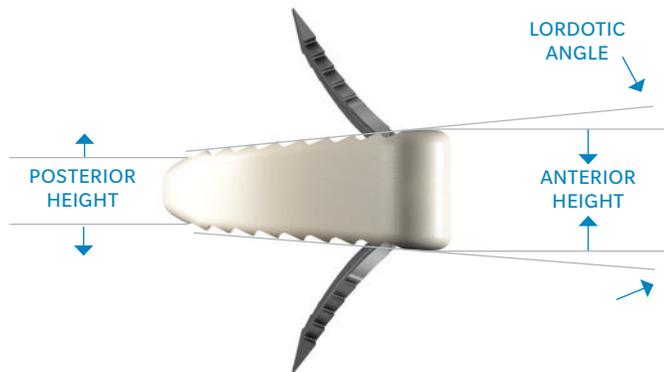


Figure 3a
Trial sizing parameters

STEP 3: SELECT THE TRIAL

When selecting the trial, consider the three sizing parameters: footprint, lordosis, and height. An ideal trial fit provides full endplate coverage and takes into account the disc height and lordosis of healthy adjacent levels to ensure primary stability. The trials have the same dimensions as the implants.

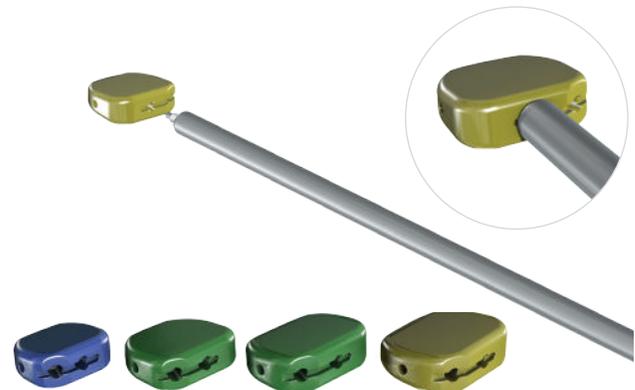


Figure 3b
Assemble and lock trial to holder



Figure 3c
Oblique trial

ASSEMBLE AND LOCK TRIAL TO THE HOLDER SELECT THE TRIAL

Line up the tabs on the end of the holder with the corresponding grooves on the trial; then insert the threaded rod. Lock the trial by fully screwing the knob at the end of the holder clockwise, prior to impacting the trial into place. With the footprint identified, select the desired height and lordosis. For a given footprint, there are multiple configurations of anterior height and lordosis that will give the same posterior height.

Note: If anatomy necessitates an oblique implant, the 27x30mm trial can be used to trial the proper height and lordosis. **(Figure 3c)**

TRIALING (continued)



Figure 3d
Median trial inserting



Figure 3e
Oblique trial inserting

POSITION THE TRIAL

After the trial is locked on the holder, it may be inserted into the disc space.

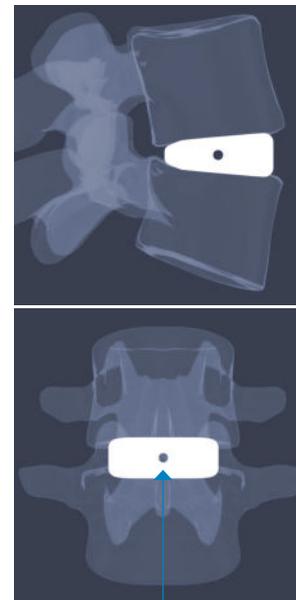
Under lateral fluoroscopy confirm the:

- Trial depth, height, and lordosis.
- Endplate coverage (anterior-posterior).
- Trial rotation.

Under anterior-posterior fluoroscopy confirm the:

- Midline placement.
- Endplate coverage (medial-lateral).
- Trial rotation.

Note: (Oblique) Even though the trial is being implanted at 25° oblique to the midline, under direct fluoroscopy, the hole through the trial should appear circular.



An oval shape indicates possible trial rotation.

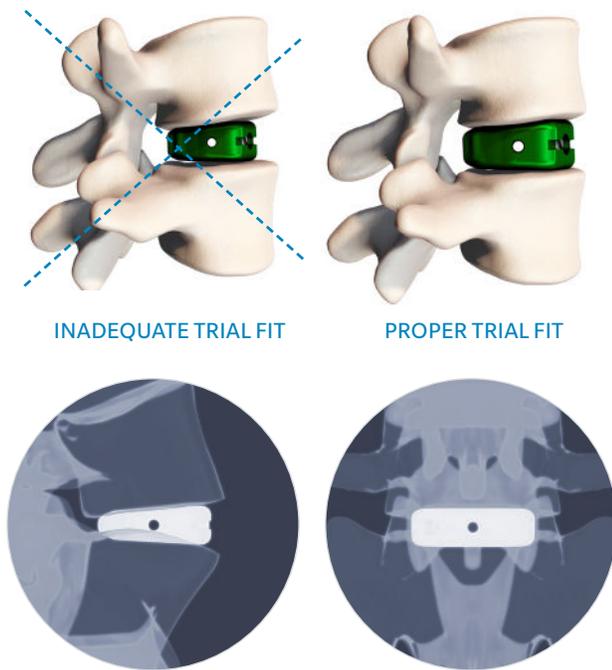


Figure 3f
Trial fit

CONFIRM TRIAL'S FIT AND FILL

Repeat the trialing process until satisfied with the footprint, height, and lordosis. It is very important that the trial has:

Intimate contact with the inferior and superior endplates via proper anterior height and lordosis selection.

A height that matches adjacent disc heights and corrects the patient's sagittal balance.

Proper A/P coverage of the endplates to facilitate cage stability.



Figure 3g
Trial removal with trial holder

Once the proper size has been determined, remove the trial using the trial holder. (**Figure 3g**) If needed, a slap hammer (IR9405R) is available to facilitate trial removal.

ADJUSTABLE STOP ASSEMBLY – OPTIONAL

STEP 1

Assemble the foot and attached threaded shaft into the screw-secured ROI-A adjustable stop bulkhead, as shown.

Note: The orientation shown is the default setting for the adjustable stop to contact the superior vertebral body. If it is desired to attach the adjustable stop on the inferior surface of the implant holder, insert the threaded shaft into the opposite face of the adjustable stop bulkhead and proceed with the assembly steps.

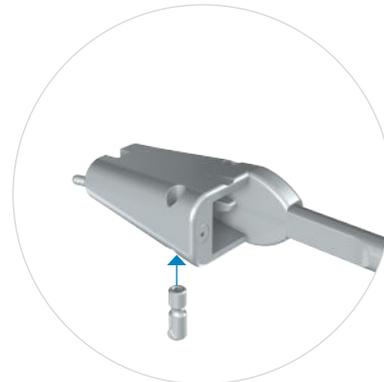


Step 1

STEP 2

Insert the threaded insert into the through-hole of the implant holder, from the inferior side, with the triangular flange oriented toward the lateral cut-out of the through-hole, as shown.

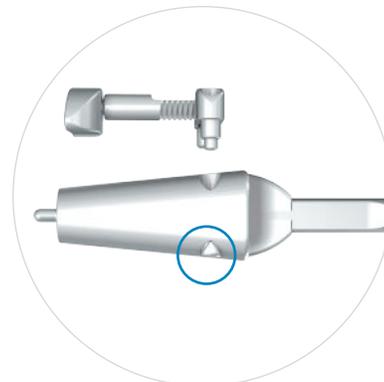
Note: If attaching the adjustable stop on the inferior surface of the implant holder, insert the threaded insert into the through-hole from the opposite (superior) face of the implant holder and proceed with the assembly steps.



Step 2

STEP 3

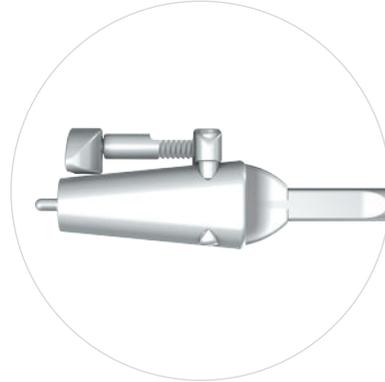
Press the threaded insert flush with the face of the implant holder. An internal ball detent feature will engage the groove in the threaded insert to keep it in place for the subsequent assembly steps.



Step 3

STEP 4

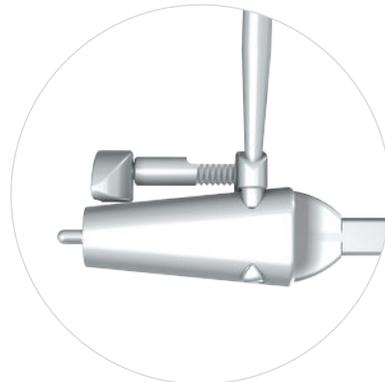
Orient the adjustable stop with the captured retaining screw aligned with the threaded insert.



Step 4

STEP 5

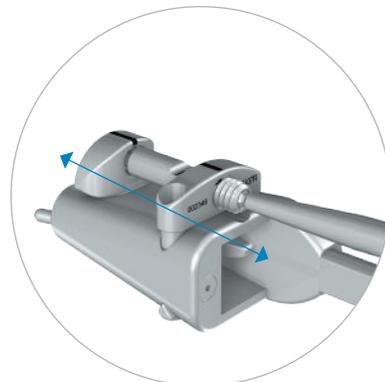
Use the adjustable stop screwdriver to advance the captured retaining screw through the implant holder into the threaded insert, until the adjustable stop is securely attached to the implant holder.



Step 5

STEP 6

Use the adjustable stop screwdriver to adjust the anterior/posterior position of the depth stop foot, confirming the depth with the gauge on the threaded rod.



Step 6

ASSEMBLE CAGE TO IMPLANT HOLDER

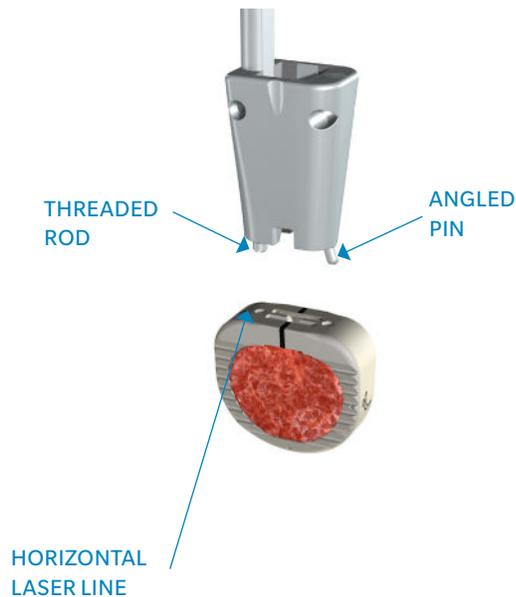


Figure 4a
Attach implant to holder



Figure 4b
Screw threaded rod and secure implant

STEP 4: ASSEMBLE CAGE TO IMPLANT HOLDER

When encountering a collapsed disc space, the ROI-A anterior delivery device may assist with implantation. Please refer to page 15 for technique.

After loading the bone graft into the graft window per normal technique, place the ROI-A implant holder (IR9280R) onto the anterior face of the implant. For oblique, attach the implant holder to the anterolateral face of the implant.

Note: The implant holder must be flipped to accommodate attachment to oblique implant.

- First insert the angled pin into the smooth hole.
- Then insert the threaded rod into the threaded hole. The laser line indicates the threaded hole (**Figure 4a**).

Screw the threaded rod by tightening the knob at the end of the implant holder by hand. As the distance closes between the knob and the implant holder, audible clicks can be heard as the ball detent engages the grooves on the knob. (**Figure 4b**)

It is important to firmly secure the implant to the holder.

The connection is secure when:

- Without over-tightening, there is no toggle in the connection.
- There is no visible gap between the knob and the handle.

Note: Overtightening could strip the PEEK threads and weaken the implant to holder connection.



Figure 4c
Attached median implant



Figure 4d
Attached oblique implant

IMPLANT CAGE



Figure 5a

Insertion

STEP 5: IMPLANT CAGE

Prior to implant insertion, assess bone quality. Sclerotic bone may make advancing the VerteBRIDGE plates difficult. In these cases, the ROI-A starter awl (page 19) may be useful.

Median Implant Insertion: Insert implant directly in the plane of the disc without moving or tilting the holder side-to-side or up-and-down. Gently mallet the end of the implant holder as necessary.

Oblique Implant Insertion: The ROI-A Oblique requires a specific superior-inferior implant orientation for insertion. The following describes cage orientation for insertion on the patient's left, the more common approach.

- The 'UP' and laser line marked on the superior and anterior implant face indicate the superior side of the implant for insertion.
- When inserted properly, the teeth of the cage run parallel to the frontal plane.

Implantation with the cage in this position ensure the lordosis slopes correctly anterior to posterior.

Insert the implant at a 25° angle to midline without moving or tilting the holder side-to-side or up-and-down. The 25° angle can be identified using the ROI-A level (IR9407R). Slip the horizontal level into the hole in the handle of the holder until the clip is flush. The holder is at 25° when the level is parallel to the frontal plane of the patient.

Note: Assess implant depth and rotation under fluoroscopy. Tantalum markers are located 1mm from the implant edges for positioning reference. When the implant is in the proper alignment, the two rotational markers will be aligned in the lateral view.

Once implant is positioned between vertebrae, do not try to reposition the implant by rotating the holder. Instead, remove the implant completely, confirm the implant holder connection is sound, and reinsert the implant into the desired position.

IMPLANT CAGE (continued)

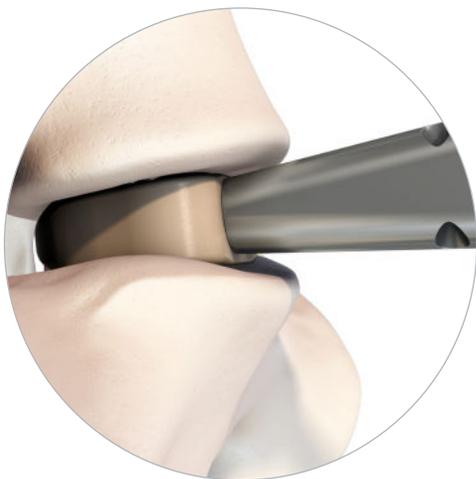
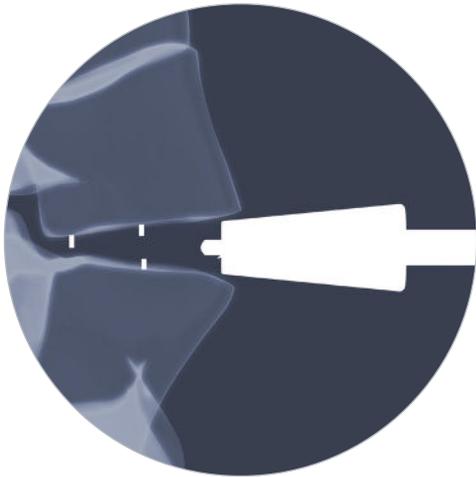
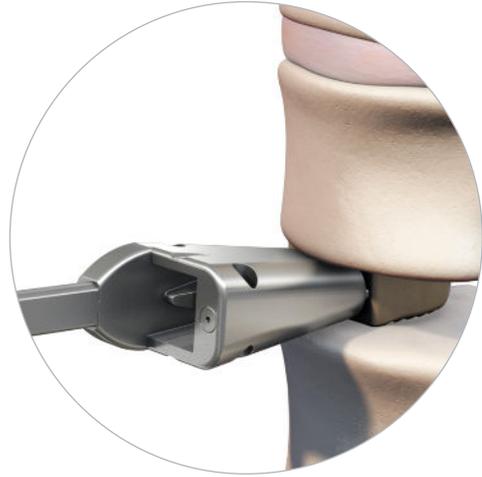
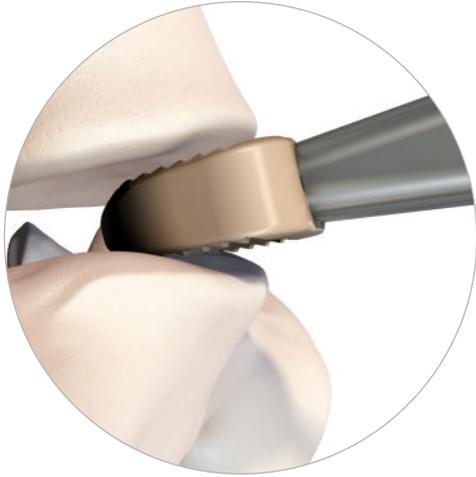


Figure 5b
Median

Figure 5c
Oblique

ROI-A ANTERIOR DELIVERY DEVICE (RADD) – OPTIONAL

This instrument is an optional insertion tool to assist a surgeon when encountering a collapsed disc space where distraction of the endplates may be beneficial during implant insertion.

The device consists of the following components:



RADD Body	PART NUMBER
	SI-ROA-0023



Retention Rod	PART NUMBER
	SI-ROIA-0027



RADD Body Solid Distraction Blade	PART NUMBER
	SI-ROIA-0024



Impaction Handle	PART NUMBER
	SI-ROIA-0028



RADD Split Distraction Blade	PART NUMBER
	SI-ROIA-0025



RADD Impactor (Long)	PART NUMBER
	SI-ROIA-0029

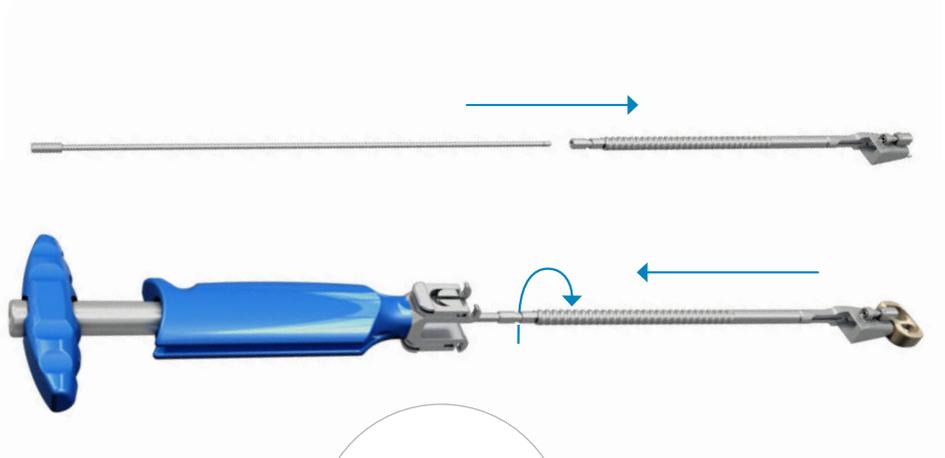


Implant Holder Shaft	PART NUMBER
	SI-ROIA-0026



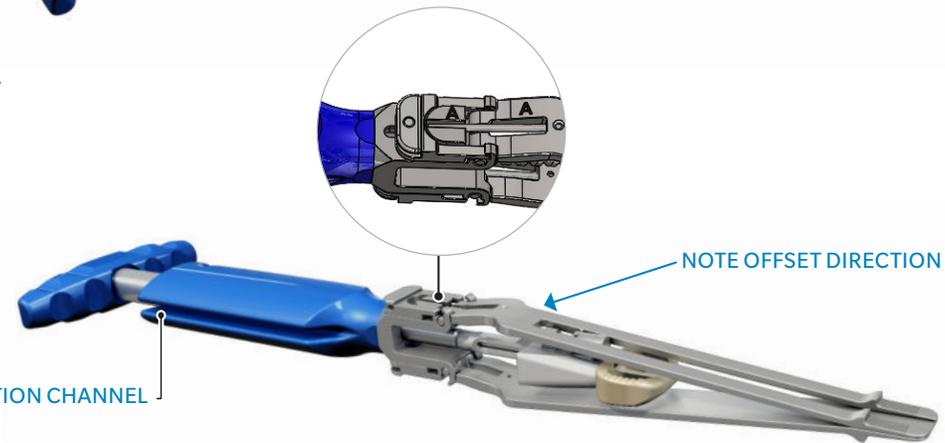
RADD Impactor (Short)	PART NUMBER
	SI-ROIA-0030

ROI-A ANTERIOR DELIVERY DEVICE (RADD) – OPTIONAL (*continued*)



Step 1a

Assemble RADD body



Step 1b

Be sure to match:

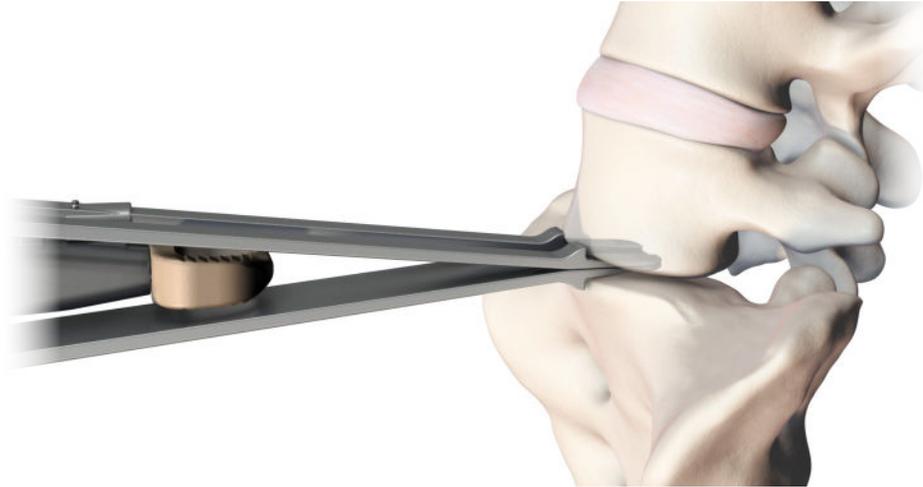
- A to A for superior blade
- B to B for inferior blade

STEP 1: ASSEMBLE RADD BODY AND LOAD IMPLANT

- Insert the threaded end of the retention rod (SI-ROIA-0027) into the proximal end of the implant holder shaft (SI-ROIA-0026).
- After placing the angled pin of the implant holder into the smooth hole on the implant, insert the threaded portion of the retention rod into the laser marked hole on the implant. Rotate clockwise, until finger tight, to fully secure the implant. Before continuing on, ensure the depth stop is set to "0." It can be adjusted using the ROI-A screwdriver (IG017R or IR9433R).
- Insert the implant holder shaft into the RADD body (SI-ROIA-0023) and rotate the shaft counter-clockwise until fully seated.
- Attach the distractor blades to the RADD body by depressing and pulling back on the quick release buttons. Keep in mind that the split distraction blade (SI-ROIA-0025) is superior and should allow space for the superior depth stop on the implant holder. The solid distraction blade (SI-ROIA-0024) should be on the inferior side of the implant holder.

Note: The distraction blades should be assembled using the "A" and "B" laser markings on the RADD body and distraction blades.

- Once assembled, turn the t-handle on the RADD body counter-clockwise to fully recess the implant holder.

**Step 2**

Advance implant

STEP 2: ADVANCE IMPLANT

- At this point, the distraction blades can be inserted into the disc space until the mechanical stops on the superior and inferior distraction blades come in contact with the anterior face of the vertebral bodies.
- To advance the cage, rotate the t-handle clockwise. As the cage advances, the RADD will simultaneously distract the disc space and advance the implant. The cage will advance until the adjustable depth stop is lined up with the mechanical stop on the distraction blade. Should the surgeon wish to advance the cage more posteriorly, the depth stop can be adjusted using the ROI-A screwdriver (IG017R or IR9433R). Rotating the screwdriver counter-clockwise will allow for the depth stop to be pulled back, allowing the surgeon to recess the implant.

- Once the cage is in the proper position in the disc space, further clockwise rotation of the t-handle will retract the distraction blades out of the disc space using counter pressure from the depth stop.

STEP 3: INSERT VERTEBRIDGE PLATING

- When the distraction blades are fully retracted out of the disc space, the surgeon implants the VerteBRIDGE plates (refer to pages 22-26). However, there are specialized, offset RADD impactors that must be used in lieu of the typical ROI-A impactors. The short RADD impactor (SI-ROIA-0030) must be used first, with thumb pressure before impaction. The long RADD impactor (SI-ROIA-0029) can then be used to fully seat the VerteBRIDGE plates.

ROI-A ANTERIOR DELIVERY DEVICE (RADD) – OPTIONAL (*continued*)



Step 3

Insert VerteBRIDGE plating

STEP 3: INSERT VERTEBRIDGE PLATING (*continued*)

- To remove the implant from the implant holder, insert the ROI-A screwdriver into the hole at the proximal end of the t-handle to engage the inner retention rod. Rotate the screwdriver counter-clockwise to disengage the implant.

STEP 4 – OPTIONAL

- Should the surgeon wish to fully remove the RADD body and distraction blades from the implant holder shaft before VerteBRIDGE plate insertion, continue to rotate the t-handle clockwise until the RADD body and distraction blades are released. The implant and implant holder shaft will remain in place in the disc space. At this point, the surgeon can attach the impaction handle (SI-ROIA-0028) to the proximal end



Step 4 – Optional

Fully remove the RADD body and distraction blade

of the implant holder shaft using the quick release button on the handle. Now, the VerteBRIDGE plates can be inserted and impacted using the regular short and long impactors that are used with the original ROI-A implant holder. The ROI-A unlocking key can then be used, in a counter-clockwise fashion, to disengage the implant.

CLEANING AND DISASSEMBLY

- The instrument must be disassembled after use and prior to cleaning and sterilization. To disassemble the instrument for cleaning, please use the reverse steps of this technique guide to break down the instrument into the components listed on page fifteen.

STARTER AWL FOR ANCHORING PLATE – OPTIONAL



Description	PART NUMBER
ROI-A Sterile Starter Awl for Anchoring Plate	IR92000R-S



Description	PART NUMBER
ROI-A Starter Awl Impactor	IR92001R



Description	PART NUMBER
ROI-A Starter Awl Support for S Anchoring Plate	IR92002R
ROI-A Starter Awl Support for M Anchoring Plate	IR92003R
ROI-A Starter Awl Support for L Anchoring Plate	IR92004R

This instrument is being introduced as an optional insertion tool to assist surgeons when encountering sclerotic bone during an ROI-A procedure. If it is detected that the patient has sclerotic bone through CT scan or bone preparation, it may be beneficial to use the awl.

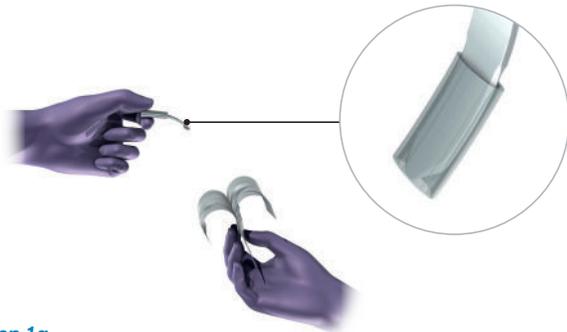
Once the ROI-A cage has been recessed into the disc space at the optimal depth, the awl may be used to initiate the VerteBRIDGE plate pathway.

The awl support(s) are designed to provide the proper depth of the awl based on the VerteBRIDGE plate selection (i.e. short ROI-A plate = short support (IR92002R)). The sterile starter awls are made of stainless steel and are available in one size.

Precautions

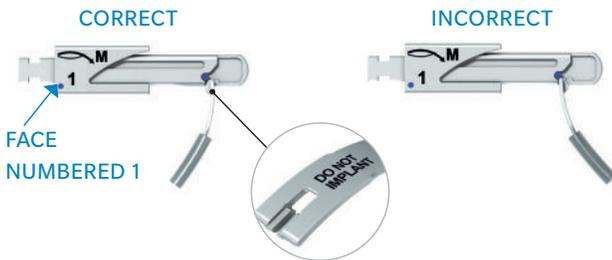
The ROI-A starter awl is only indicated to prepare ROI-A anchoring plate paths. Its use is recommended in cases of hard, sclerotic bone and can be used for a unique surgical intervention. In cases of repeated use, the integrity of the starter awl must be maintained. In cases of doubt, it is necessary to use a new starter awl to prepare second plate path. Furthermore, ROI-A sterile awls are **not intended for patient implantation** under any circumstance and should be properly disposed of following surgery. The awls are to be used only with approved sterile awl impactors and strictly for endplate preparation. ROI-A awls should never be used with the ROI-A plate impactor.

STARTER AWL FOR ANCHORING PLATE – OPTIONAL *(continued)*



Step 1a

Silicone protection cap



Step 1b

Correct insertion

Step 1c

Incorrect insertion



Step 1d

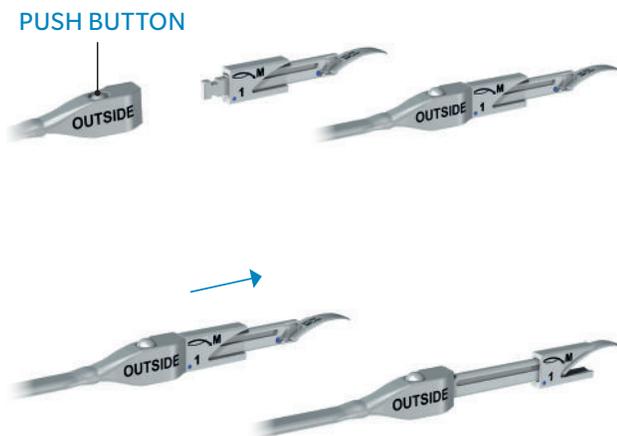
Removing silicone sleeve

STEP 1: CHOOSE SUPPORT AND LOAD STARTER AWL FOR ANCHORING PLATE

- Choose the proper length awl support (S, M, or L), corresponding to the desired VerteBRIDGE plate length. Grasp the awl by the silicone protector to remove it from sterile packaging.
- Grasp the starter awl support with the **side numbered "1" facing up**.

Instructions to attach the starter awl for anchoring plate to the awl support:

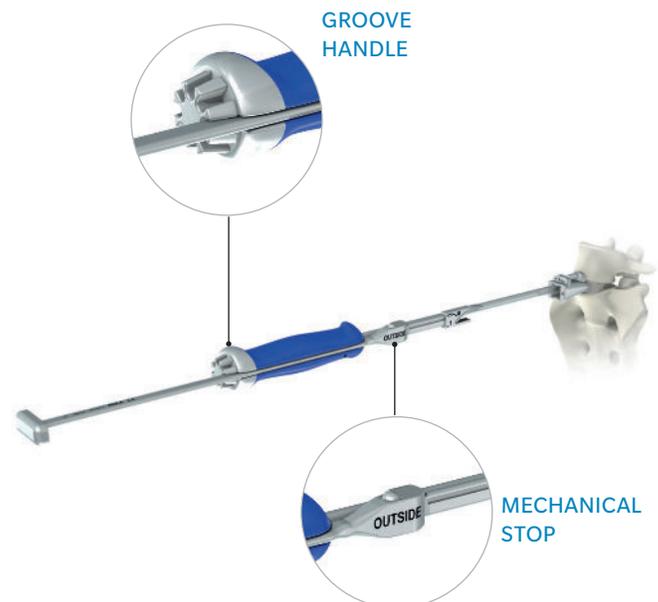
1. Orient the concavity of the awl opposite the awl support, **with the Do Not Implant marking face up**, and insert the awl slot onto the awl support.
2. Slide the groove of the awl along the blue silicone stud on the awl support (**do not slide on top of blue silicone studs**).
3. Remove and discard the silicone sleeve.



Step 2a
Assembly

STEP 2: ASSEMBLE AWL SUPPORT WITH STARTER AWL FOR ANCHORING PLATE ONTO AWL IMPACTOR

- To assemble the awl support and starter awl for anchoring plate onto impactor, press the button on the impactor and connect at the distal end of the impactor as shown.
- Manually slide the metal sleeve over the awl to maintain proper position.

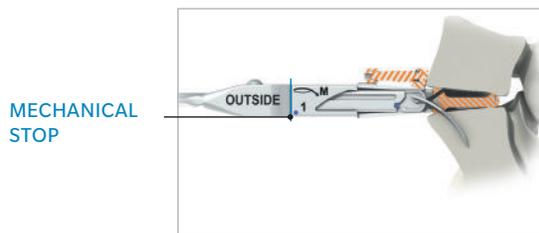
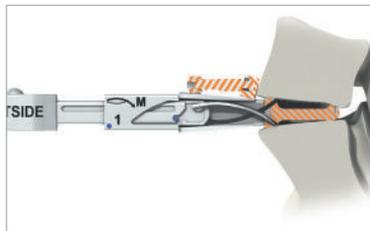
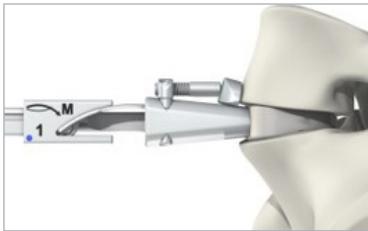


Step 2b
Impact the awl anchoring plate

IMPACT THE AWL FOR ANCHORING PLATE

- Place the awl plate (while still attached to the impactor) into the chosen slot in the inserter, as would normally be done with a typical VerteBRIDGE plate (top slot for the inferior vertebral body; bottom slot for penetration into the superior vertebral body)
- Confirm a notch on the implant holder knob is aligned with the notch in the implant holder handle. Then, proceed to load the impactor in the same fashion as the normal ROI-A impactor. The mechanical stop will guide the awl impactor along the length of the implant holder.

STARTER AWL FOR ANCHORING PLATE – OPTIONAL (*continued*)



Step 2c

Mechanical stop



Step 2d

Repeat with awl marked 2

IMPACT THE AWL FOR ANCHORING PLATE (*continued*)

- After using thumb pressure and with awl in contact with bone, impact with a mallet until the mechanical stop on the impactor is fully seated on the metal sleeve of the awl support. After completely seating the awl impactor, remove the impactor along with the attached starter awl plate.

Note: When using the starter awl instrumentation it is recommended to use the adjustable stop to provide stability of the cage and ensure the VerteBRIDGE plate follows the prepared pathway during impaction. See page 10 for assembly instructions.

- Very sclerotic bone may necessitate the impaction of the awl to be done in stages with complete removal of the awl from the vertebral body between each step.
- The cage must be maintained in place to ensure the awl will be inserted in the channel being prepared every time.
- After removing the starter awl, it is time to impact the first VerteBRIDGE plate as usual keeping in mind in which vertebrae the awl pathway was prepared. Refer to page 23 for VerteBRIDGE plate insertion.
- Once the first VerteBRIDGE plate is impacted, the second pathway may be prepared by repeating steps 1-3 (page 20) using the awl with side number "2" on the awl support showing. To do this, press the quick-release button on the awl impactor and flip the awl support to expose the 2 marking face.
- At this point you are ready to impact the awl in the same fashion as above.
- After the pathway has been prepared, impact and lock the second VerteBRIDGE plate as described on page 26.

INSERT FIRST PLATE AND ADVANCE

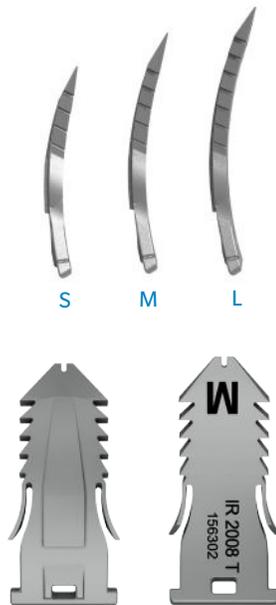


Figure 6a
Plate sizes

STEP 6: SELECT PLATE

Select the VerteBRIDGE plate length: short (IR2009T), medium (IR2008T), or long (IR2007T).

Plate sizing recommendations:

- The short plate cannot be used with 16mm implants.
- Consider using a short or medium plate on patients with small anatomy.
- At S1 consider the sacrum and the plate's anterior curves when seated in the cage; a shorter plate may be required to avoid penetration of the anterior wall of the sacrum.
- For multi-level procedures:
 - Confirm the central vertebra can accommodate the plate lengths selected. (Refer to table on page 28 for plate vertebrae penetration).
 - It is possible to use a long plate on the most superior and inferior vertebral bodies, while using a short or medium plate on the shared, central vertebra.
 - The superior implant may be placed slightly posterior in reference to the inferior cage to avoid plate paths crossing.

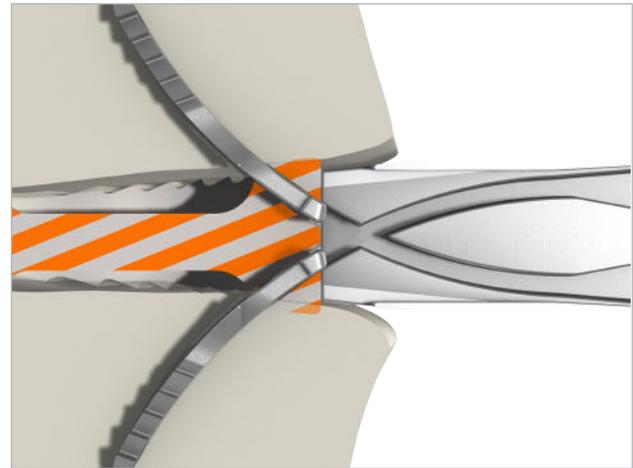


Figure 6b
Plate loading

When in doubt, refer to the x-ray transparency templates (IR-A ST 8) to anticipate plate curvature and bony purchase.

Plate Loading Notes:

- The plate paths cross inside the implant holder; load the inferior plate into the superior slot and vice versa.
- The concave surface of the plate will always face the mid-plane of the holder.
- The plate is loaded correctly when it drops completely into the holder

INSERT FIRST PLATE AND ADVANCE (*continued*)

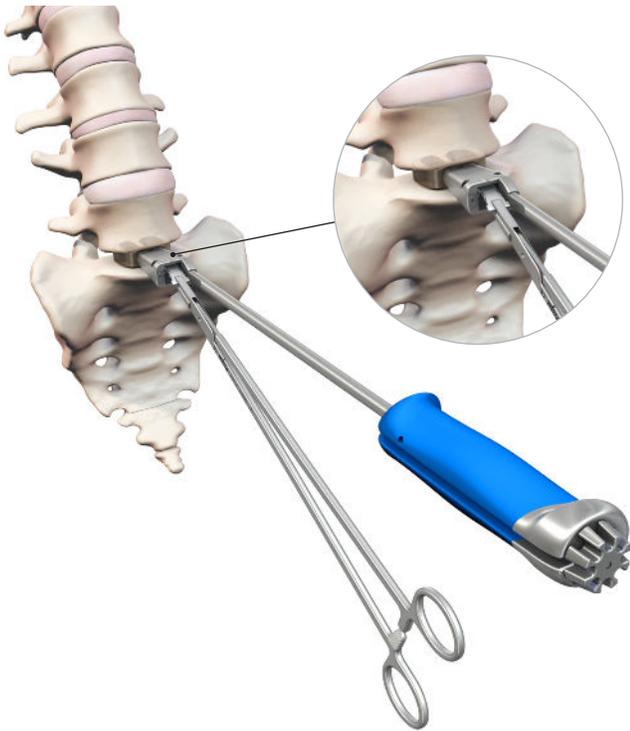


Figure 6c
Plate loading with anchoring plate holder

LOAD FIRST PLATE

Insert first plate using the anchoring plate holder (IR9203R) into a slot on the implant holder. By default, load the plate into the superior slot for the inferior vertebral body first, unless anatomy dictates otherwise.

Caution: Only load one plate at a time.

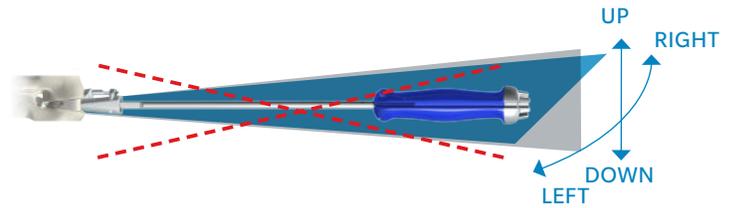


Figure 6d
Caution: Do not toggle the holder during plate insertion



Figure 6e
Plate loading (medium)

During impaction of the plates, keep the holder directly in the plane of the disc; avoid tilting the holder left-to-right or up-and-down. Do not use the holder as leverage to move the vertebral bodies during cage or plate insertion.

Caution: Toggling the holder during plate insertion can stress the implant to holder connection.

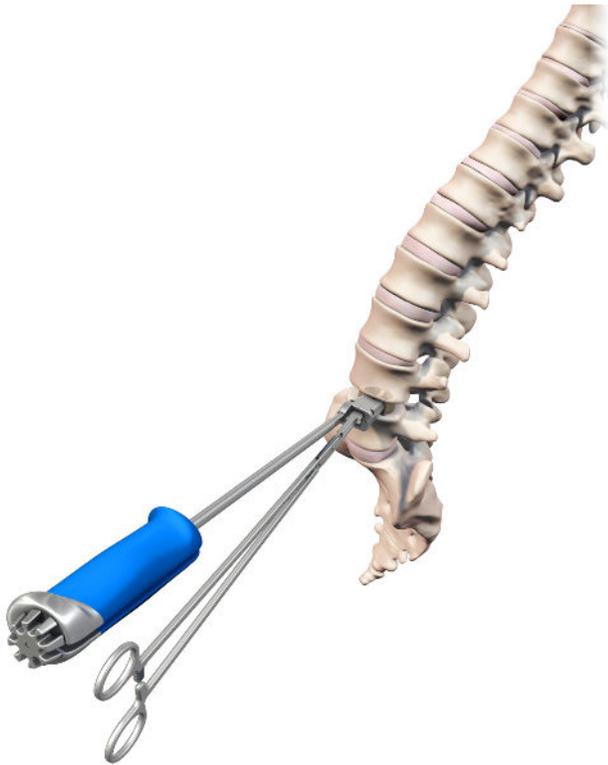


Figure 6f

Advance first plate (oblique)

ADVANCE FIRST PLATE

Once the position of the implant is optimal, use the short plate impactor (IR9432R) to impact the plate:

- Confirm the notch in the implant holder knob is aligned with the notch in the implant holder handle. If not, the plate impactor cannot be loaded.
- Prior to malleting, insert the impactor using thumb pressure to advance the plate into the implant until it makes contact with bone.
- After impaction, confirm the underside of the plate impactor collar makes contact with the body of the implant holder. This assures the plate has advanced completely. If not flush, the first plate may not lock properly and the second plate may not advance.

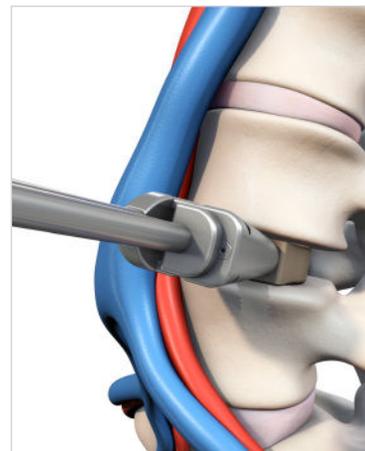
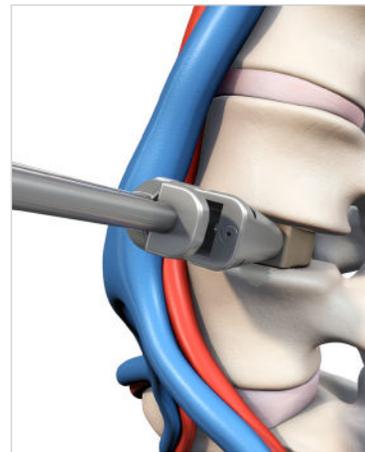


Figure 6g
Oblique

LOCK PLATE



Figure 7

Lock first plate

STEP 7: VERIFY FIRST PLATE POSITION

Take a lateral fluoroscopy image to ensure proper implant and plate position. If poorly positioned, the plate may be removed using the anchoring plate hook (IR9288R) through the implant holder. See page 31 for further explanation.

LOCK FIRST PLATE

Once position is confirmed, use the plate impactor (IR9431R) to lock the first plate in place. Plate has advanced completely when the underside of the plate impactor collar is flush with the body of the implant holder. **Do not proceed to the second plate insertion until proper placement of the device and first plate is confirmed via fluoroscopy.**

INSERT SECOND PLATE AND REPEAT

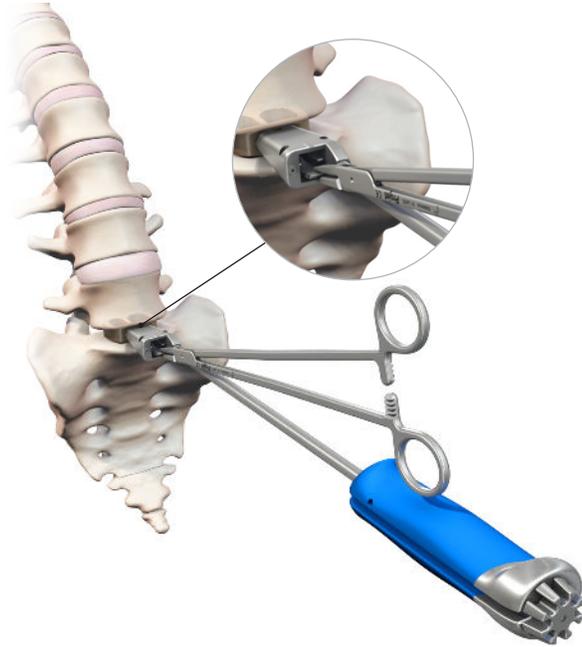


Figure 8a
Inserting second plate (median)

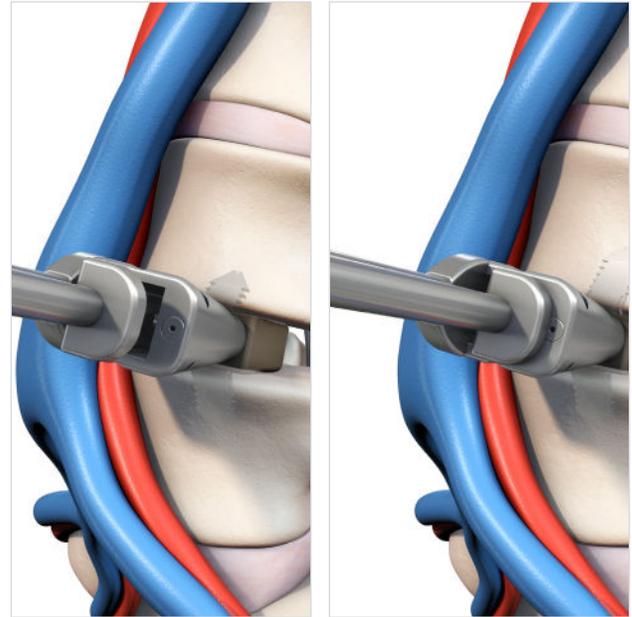


Figure 8b
Inserting second plate (oblique)

STEP 8: LOAD, ADVANCE, AND LOCK SECOND PLATE

Insert the second plate into the opposite slot of the implant holder using the plate holder. Confirm proper plate alignment by first advancing the plate by hand into the implant using the impactor. Fully advance the second plate with the short plate impactor.

Confirm position under fluoroscopy and then final lock the plate using the plate impactor, as described previously.

The placement of both locks the implant in place and secures the implant between the vertebrae.

REMOVE INSERTER



Figure 9a
Unlock key

STEP 9: UNLOCKING KEY

After both plates are locked and the plate impactor is removed, the ROI-A unlocking key (IR9434R) can be used to help disconnect the implant from the implant holder.

Note: Do not use the unlocking key to screw the cage to the holder.

Aligning the two tabs with the notches on the implant holder, slip the unlocking key over the knob at the end of the handle and turn counter-clockwise.

Figure 9b
Plate penetration into vertebrae

PLATE PENETRATION INTO VERTEBRAE

SIZE	HEIGHT (W/H10)	HEIGHT (W/H12)	HEIGHT (W/H14)	HEIGHT (W/H16)	PART NUMBER
S	13	12	11	N/A	IR2009T
M	16	15	14	13	IR2008T
H	19	18	17	16	IR2007T

CONFIRM WITH FLUOROSCOPY – OPTIONAL

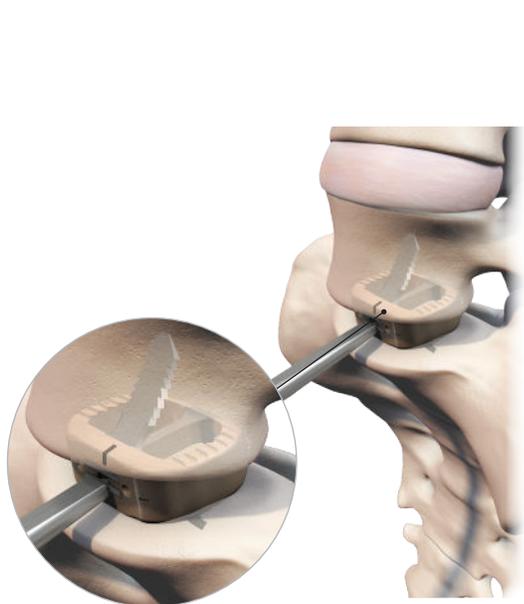


Figure 10a
Confirm final lock (median)

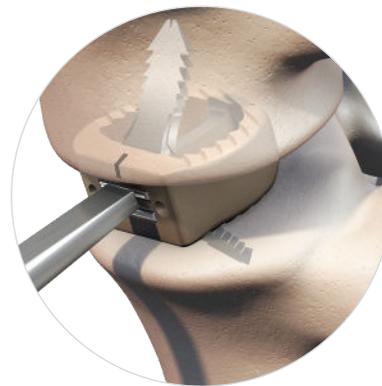
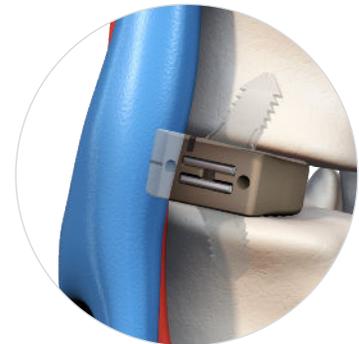


Figure 10a
Confirm final lock (oblique)



STEP 10: CONFIRM FINAL LOCK OF EACH PLATE

Use the final plate impactor (IR9202R) to confirm the final lock of the plates. The radius of the plate end will remain slightly proud of the implant face even after use of the final plate impactor

- For each plate, match the groove in the impactor to the anterior edge of the plate, then mallet the impactor.
- The final plate impactor should be used only after advancing the plate with the plate impactor as shown on page 16.

Caution: It is VERY IMPORTANT to confirm final locking of both plates to ensure full impaction.

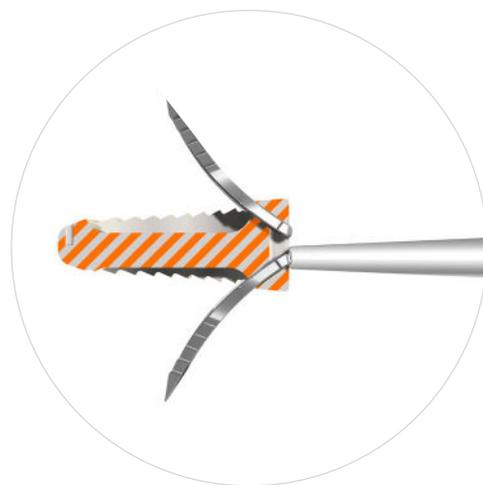
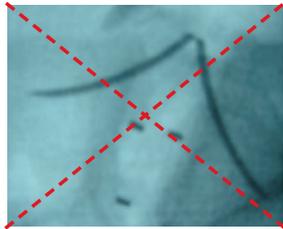
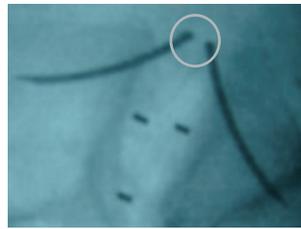


Figure 10c
Confirm final lock

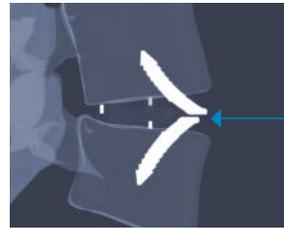
CONFIRM WITH FLUOROSCOPY – OPTIONAL (*continued*)



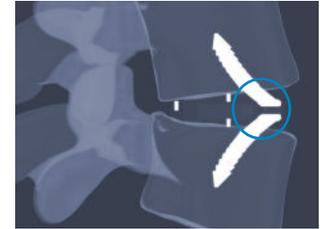
Plates need advancing.



Approximately 2.5mm of space indicates proper position.



Plates need advancing.



Approximately 2.5mm of space indicates proper position.

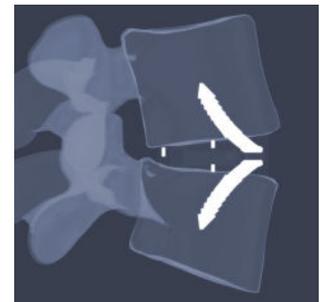
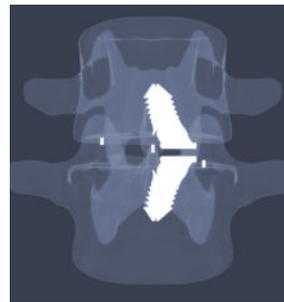
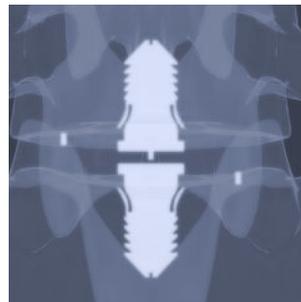


Figure 10d
Median

Figure 10e
Oblique

ASSESS FINAL POSITION

Take final lateral and anterior-posterior fluoroscopy images to:

- Confirm position of the plates.
- Use the final impactor to advance the plates if needed.
- Assess implant position

Caution: In cases of spondylolisthesis or vertebral instability, the ROI-A implant with VertBRIDGE plating should be augmented with adequate posterior pedicle screw fixation and/or anterior plating.

CAGE REMOVAL

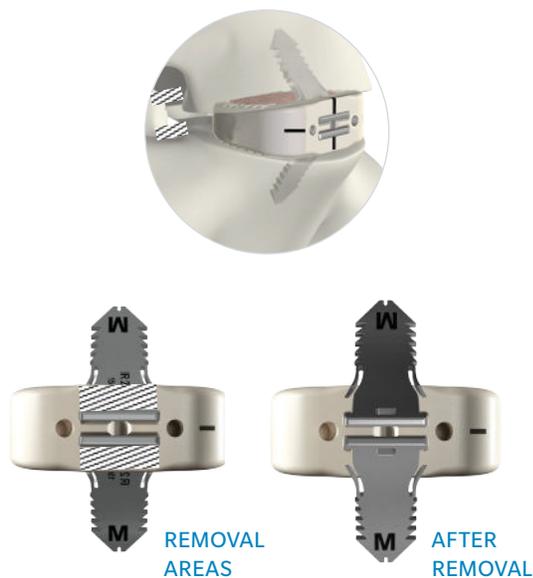


Figure 11a
Median

STEP 11: REMOVE PLATES

When removal or revision is indicated, care should be taken to study radiographic images. Make note of:

- Implant position, which can affect optimum surgical approach.
- The presence of the scar tissue, which can make exposure more challenging than in the un-operated spine.
- The position of supplemental fixation.

Start the explant process with the removal of the plates. To remove the plates, portions of the anterior face of the PEEK implant must be taken out with an osteotome or burr. On the above illustrations, the diagonal stripes show the PEEK that must be removed until the plates are visible (**Figure 11a**).

Once visible, remove each plate with the anchoring plate hook (IR9288R) by engaging the removal hole on the plate. Pull each plate out along the same path as its curvature (**Figure 11c**).

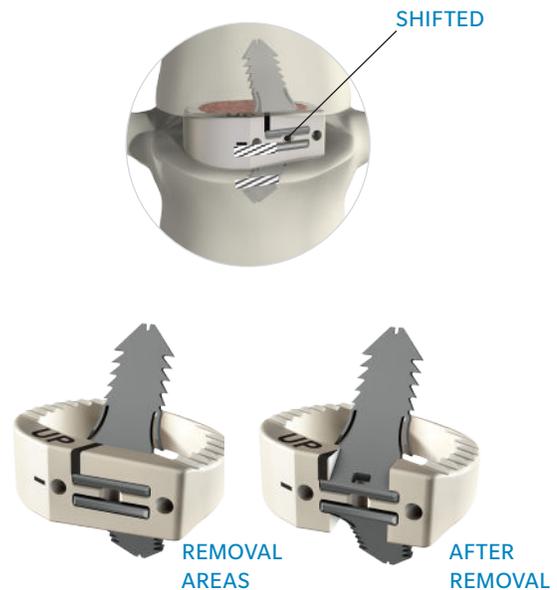


Figure 11b
Oblique

STEP 11: REMOVE IMPLANT

Use a kocher to remove the implant anteriorly.

If the implant cannot be easily removed, a Cobb elevator or osteotome should be used to loosen the bone to implant interface.

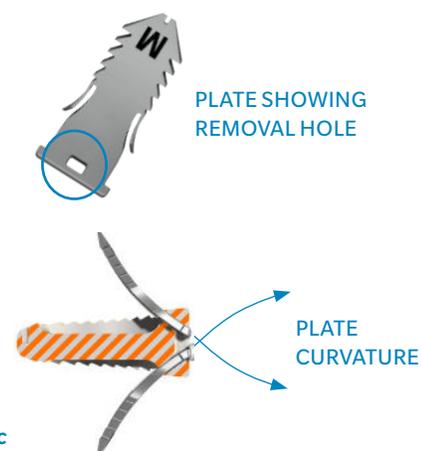


Figure 11c
Oblique

ROI-A IMPLANTS

Median Implant Sizes

23mm depth x 26mm width

LORDOSIS ANGLE	ANTERIOR HEIGHT	MAXIMUM HEIGHT	cc	PART NUMBER
6°	10mm	8mm	1.83	IR 2422 P
	12mm	10mm	2.25	IR 2424 P
	14mm	12mm	2.67	IR 2426 P
10°	10mm	6mm	1.62	IR 2431 P
	12mm	8mm	2.00	IR 2433 P
	14mm	10mm	2.42	IR 2435 P

27mm depth x 30mm width

LORDOSIS ANGLE	ANTERIOR HEIGHT	MAXIMUM HEIGHT	cc	PART NUMBER
6°	10mm	7.5mm	2.84	IR 2522 P
	12mm	9.5mm	3.47	IR 2524 P
	14mm	11.5mm	4.13	IR 2526 P
10°	12mm	7.5mm	3.15	IR 2532 P
	14mm	9.5mm	3.78	IR 2534 P
	16mm	11.5mm	4.44	IR 2536 P
14°	12mm	5.9mm	2.92	IR 2541 P
	14mm	7.5mm	3.44	IR 2543 P
	16mm	9.5mm	4.10	IR 2545 P

27mm depth x 36mm width

LORDOSIS ANGLE	ANTERIOR HEIGHT	MAXIMUM HEIGHT	cc	PART NUMBER
6°	10mm	7.5mm	3.63	IR 5221 P
	12mm	9.5mm	4.44	IR 5223 P
	14mm	11.5mm	5.29	IR 5225 P
10°	12mm	7.5mm	4.02	IR 5232 P
	14mm	9.5mm	4.84	IR 5234 P
	16mm	11.5mm	5.69	IR 5236 P
14°	12mm	5.9mm	3.72	IR 5241 P
	14mm	7.5mm	4.39	IR 5243 P
	16mm	9.5mm	5.24	IR 5245 P

30mm depth x 39mm width

LORDOSIS ANGLE	ANTERIOR HEIGHT	MAXIMUM HEIGHT	cc	PART NUMBER
6°	12mm	9mm	5.21	IR 5323 P
	14mm	11mm	6.23	IR 5325 P
10°	12mm	7mm	4.76	IR 5332 P
	14mm	9mm	5.75	IR 5334 P
	16mm	11mm	6.77	IR 5336 P
14°	14mm	6.7mm	5.09	IR 5341 P
	16mm	8.7mm	6.11	IR 5343 P

Oblique Implant Sizes

27mm depth x 30mm width

LORDOSIS ANGLE	ANTERIOR HEIGHT	MAXIMUM HEIGHT	cc	PART NUMBER
6°	10mm	7.5mm	2.59	IR 4222 P
	12mm	9.5mm	3.17	IR 4224 P
	14mm	13.5mm	4.38	IR 4226 P
10°	12mm	7.5mm	2.86	IR 4232 P
	14mm	9.5mm	3.45	IR 4234 P
	16mm	11.5mm	4.05	IR 4236 P

Note: Trials are color coded by implant depth.

IMPORTANT INFORMATION ON THE ROI-A ALIF CAGE

Device Description

The ROI-A implants are cylinder shaped blocks in a variety of footprints, heights, and lordosis angles. The shape of the ROI-A allows for a large implant (length and width) to be used allowing for more surface area contact. The ROI-A ALIF Cage is offered in a closed graft space design. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and to prevent movement of the implants. The ROI-A ALIF Cage is intended to be implanted singularly via an anterior approach and is intended to be used with autologous bone graft. The devices must be used with supplemental internal fixation. The ROI-A ALIF Cage has been designed to be compatible with optional supplemental fixation specific for the system. The VerteBRIDGE Plates are available to be used to affix the ROI-A implant to the underlying vertebral bone and to specifically allow for the option of a stand-alone construct. Additional or other supplemental fixation may be used, as patient needs dictate.

The materials used in the manufacturing of the ROI-A implants are (radiolucent) PEEK-Optima® LT1 and tantalum alloy radiological position markers. The ROI-A ALIF Cage VerteBRIDGE Plates are manufactured from surgical titanium (Ti6Al4V ELI), which complies with ASTM F136. Instruments used to implant the ROI-A ALIF Cage are made of medical grade stainless steel.

Indications for Use (United States)

The ROI-A ALIF Cage is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Contraindications

Contraindications include, but are not limited to:

- Presence of fever or acute, chronic, systemic, or localized infection.
- Metal sensitivity or allergies to the implant materials, documented or suspected.
- Severe osteopenia.
- Pregnancy.
- Prior fusion at the level(s) to be treated.
- Patients unwilling or unable to follow post-operative care instructions.
- Other medical risks, anesthetic risks, or surgical conditions which would preclude the potential benefit of spinal implant surgery.
- Any condition not described in the indication of use.

Warnings

- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- Potential risks associated with the use of this system, which may require additional surgery, include device component failure (bending, loosening or fracture), loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss (impaction of implant into vertebral end plates), allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, expulsion.

IMPORTANT INFORMATION ON THE ROI-A ALIF CAGE (*continued*)

- The device can break if it is subjected to increased loading associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Discard all damaged or mishandled implants.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily fluids should never be reused at risk of contamination of the patient.
- **Mixing Metal:** Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals (e.g.) stainless steel and titanium), however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase. Internal fixation devices such as rods, connectors, screws, hooks, etc, which come into contact with other metal objects must be made from like or compatible metals. This is an important consideration when using supplemental fixation, as required by the indications for use of the System. Because different manufacturers employ different materials, varying tolerances, manufacturing specifications, and differing parameters, components of the ROI-A ALIF Cage should not be used in conjunction with components from any other manufacturer's implant systems. Any such use will negate the responsibility of LDR Spine USA for the performance of the resulting mixed component implant.

- Any decision by a surgeon to remove the implanted device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal should be followed by adequate postoperative management to avoid fracture

Precautions

- Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of intervertebral body fusion devices or partial vertebral body replacement devices should be performed only by experienced spine surgeons with specific training in the use of this system and who have knowledge of the present instruction for use.
- The surgeon should consider the location of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system.
- Patients who smoke have been shown to have an increased of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting of significant loads, or muscle strain. resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of the implantation that they may substantially decrease the expected useful life to the device. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants.)
- Supplemental internal fixation is required when using the ROI-A ALIF Cage. The VerteBRIDGE Plate system is available for use with the ROI-A ALIF Cage and is the supplemental fixation available for use in situations where a stand-alone construct is appropriate. The system may be augmented with additional supplemental fixation, as needed and determined by the user. The instructions for use for any additional supplemental fixation system(s) should be followed according to the manufacturer's guidelines.
- Care must be taken to protect the components from being marred, nicked or notched as a result of a contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

- Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
- Sale of this product is restricted to physicians.

MR Safety Information



- Non-clinical testing has demonstrated that the Interbody Cage Systems are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions: MRI system.
- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T) only.
- Maximum spatial gradient field of 3100 G/cm (31 T/m) for 1.5T Systems and 1500 G/cm (15T/m) for 3.0T systems
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of
 - 2.0 W/kg for 15 minutes of scanning at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning at 3.0T.
- When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.
- Under the scan conditions defined above, the ROI-A Implant System is expected to produce a maximum temperature rise of less than 1°C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 1.0cm from the ROI-A ALIF Cage when imaged with a gradient echo pulse sequence in either a 1.5T or a 3.0T MRI system.

References

1. Tsung-Hsi Tu, MD, et al., Heterotopic ossification after cervical total disc replacement: determination by CT and effects on clinical outcomes, J Neurosurg Spine 14:457–465, 2011 457

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.



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