SURGICAL TECHNIQUE

ROI-A® Oblique

ALIF CAGE with

VerteBRIDGE® PLATING TECHNOLOGY
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Indications (United States)

When used as an intervertebral body fusion device, the ROI-A Implant System 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 I 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.

Note: VerteBRIDGE® Plating is the supplemental fixation designed specifically for the ROI-A cage and can be used in applications where a stand-alone anterior construct is appropriate. Additional supplemental fixation options can be used with the ROI-A cage (with or without VerteBRIDGE Plating) including posterior pedicle systems or additional vertebral plating.
Step 1  Patient positioning and oblique surgical approach

**Patient positioning**

For the more common left-sided approach, the patient may be positioned:
- Supine – the patient’s left leg can be elevated with a calf bolster as bending the knee relaxes the psoas muscle and reduces the stretch on the genitofemoral nerve. Position the arms at the patient’s side, extended or elevated; OR
- Partial right lateral decubitus – A bolster can be placed on the patient’s left side, allowing the patient to be rolled from a true right-sided lateral position to a 45° angle. This position can be helpful with heavier patients, allowing gravity to provide some retraction of the viscera and abdominal structures.

The patient position should allow the use of a C-arm in the anteroposterior and mediolateral planes.

**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; the incision extends from the level of the umbilicus to 2-3 inches cephalad.

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.

*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.
**Surgical Technique**

**ROI-A® Oblique**

**Step 2**

**Discectomy and trialing**

### 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

Perform a discectomy down to the osseous endplate.* A Cobb Elevator (MD 9105 R) or Endplate Rugine (MD 900 R) is available to aid with disc separation from the endplates.

Take care to remove any anterior or posterior osteophytes and scrape the endplates both inferior and superior with the Rasp (MD 901 R) to expose bleeding bone.**

*Note: Remove disc sufficient for the expected implant footprint and fusion; however note that preserving lateral annulus may improve post-operative stability.**

**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.
Distraction

As needed to complete the discectomy, assemble the Unilateral Distractor Tips (MD 953/954 R) or the Bilateral Distractor Tips (MD 955/956 R) to the Distraction Forceps (MD 907 R).

• **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 opposite size.

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

*Note: Again, take care to remove any anterior or posterior osteophytes and scrape the endplates both inferior and superior with a rasp to expose bleeding bone.

**Note: Make sure the Distractor head is flush with the anterior aspect of the vertebra.
Discectomy and trialing

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.

With the footprint identified (27x30 or 30x33), select the desired height and lordosis angle.*

The Trials and implant packaging are color coded by footprint size.

Implant sizing tables

<table>
<thead>
<tr>
<th>Implant Reference</th>
<th>Footprint (Depth x Width)</th>
<th>Lordosis Angle</th>
<th>Anterior Height</th>
<th>Posterior Height</th>
<th>Approx. Graft Volume (cc)</th>
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<tr>
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*Note: For a given footprint there may be multiple configurations of anterior height and lordosis that will give the same posterior height.
Assemble and lock Trial to the Holder

Assemble the selected Trial to the Trial Holder (IR 9433 R) using the oblique hole.*

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.

*Note: Do not use the Trial’s median screw hole, if available, when trialing the oblique implant.

Position the Trial

After locking the Trial on the Holder, insert Trial into the disc space.

Under lateral fluoroscopy confirm the:
- Implant depth*, height, and lordosis.
- Endplate coverage (anterior-posterior).
- Trial alignment. **

Under anterior-posterior fluoroscopy confirm the:
- Midline placement.
- Endplate coverage (medial-lateral).
- Trial rotation. **

The Trial Holder may be removed to assess the Trial fit.

*Note: Ideally the implant will sit approximately 2mm from the anterior and posterior edges.

**Note: Under direct fluoroscopy, each hole through the Trial should appear circular. An oval shape indicates possible implant rotation.
Discectomy and trialing

**Confirm the Trial’s fit and fill**

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 AP coverage of the endplates to facilitate cage stability.

**Select the final implant size**

If necessary, repeat the trialing process using fluoroscopy confirmation until satisfied with the footprint, height, and lordosis.

Once the proper size is determined, remove the Trial using the Trial Holder.

If needed, a Slap Hammer (IR 9405 R) is available to facilitate Trial removal.
### Cage insertion

#### Load bone graft

Place implant on the Graft Support (IR 9204 R) so that the anterolateral flat surface with the plate slots faces out and the “UP” marking faces superior. Load the inner space of the implant with autograft.

Refer to the table on page 6 for approximate graft volume.

Compact graft using the Graft Compactor (IR 9205 R) as needed.

#### Adjustable Stop

The ROI-A Adjustable Stop (IR 9283 R) may be used for better control of the implant’s position during insertion.

To assemble, insert the two pegs on the Adjustable Stop into the holes on the Implant Holder head.*

Use the Adjustable Stop Screwdriver (IR 9408 R) to set the stop. While the stop may be used to provide stability and prevent movement of the cage during insertion, the depth markings should be disregarded as they are designed to reflect position of the implant when inserted anteriorly rather than obliquely.

See page 12 for implant insertion with the Adjustable Stop.

*Note: Adjustable Stop can be assembled either inferior or superior depending on anatomic conditions.
Assemble implant to the Implant Holder

Rotate the Graft Support 90° to aid assembly of the Holder to the implant.

Place the ROI-A Implant Holder (IR 9280 R) onto the anterolateral face of the implant.
- First insert the angled pin into the smooth hole.
- Then insert the threaded rod into the threaded hole. The laser marked line indicates the threaded hole.

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 spring ball engages the grooves on the knob.

**It’s important to firmly secure the implant to the Holder.**

The connection is secure when:
- Without over tightening*, there should be no toggle in the connection.
- There should be no gap visible between the knob and the handle.

Make sure one of the slots in the knob aligns with the slot in the handle to allow insertion of the Impactor.

*Note: Overtightening could strip the PEEK threads and weaken the implant to Holder connection.
**Implant orientation for 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.
- The Holder shaft and handle will be median; plate insertion and impaction will occur laterally.
- The threaded hole can be used as a reference of the implant’s midplane.
- When inserted properly, the teeth on the cage run parallel to the frontal plane.

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

*Note: Where anatomy requires an approach from the patient’s right, the cage is inserted with the ‘UP’ laser marking facing inferiorly.

**Implant insertion angle**

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 (IR 9407 R). 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.
Cage insertion

**Implant insertion***

Gently mallet the end of the Implant Holder as necessary.

*CAUTION: Toggling the Holder (side-to-side or up-and-down) during cage insertion can stress the implant to Holder connection.*

Assess implant depth and rotation under fluoroscopy.* Tantalum markers are located 1 mm 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.

*CAUTION: Fluoroscopy is mandatory prior to plate insertion.*

*Note: Prior to implant insertion, assess bone quality. Sclerotic bone may make advancing the VerteBRIDGE plates difficult. A curette or burr can be used to prepare the endplates where the plates will enter the vertebrae.

*Note: Once positioned between the vertebrae, do not try to reposition the implant by rotating the Holder. Instead, remove the implant completely, confirm the implant to Holder connection is sound, and reinsert the implant into the desired position.*
Plate loading and locking

**Select plate**

Select the VerteBRIDGE® plate length: Short (IR 2009 T), Medium (IR 2008 T), or Long (IR 2007 T).

Plate sizing recommendations:
- The Short plate cannot be used with the 16 and 18mm implants.
- Consider using a Short or Medium plate on patients with small anatomy.
- For multi-level procedures:
  - Confirm the central vertebra can accommodate the plate lengths selected. (Refer to table on page 16 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.

**Load first plate**

Insert first plate* using the Plate Holder (IR 9203 R) 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.

*Note:
- 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.

**CAUTION:** Only load one plate at a time.
**Plate loading and locking**

**Keep Implant Holder in the plane of the disc**
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.*

**Advance first plate**
Once the position of the implant is optimal, use the Short Plate Impactor (IR 9432 R) to impact the plate:

A. Confirm a notch in the Implant Holder knob is aligned with the notch in the Implant Holder handle. If not, the Plate Impactor cannot be loaded.
B. Prior to malleting, insert the Impactor using thumb pressure to advance the plate into the implant until it makes contact with bone.
C. 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.

**Short Plate Impactor** = Advancing Impactor (IR 9432 R)
**Plate Impactor** = Locking Impactor (IR 9431 R)
Verify first plate position

Take a lateral fluoroscopic image to ensure proper implant and plate position. Do not proceed to the second plate insertion until proper placement of the device and first plate is confirmed via fluoroscopy.*

Lock first plate

Once position is confirmed, use the Plate Impactor (IR 9431 R) 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.

Load, advance, and lock second plate

Insert the second plate into the opposite slot of the Implant Holder using the Plate Holder. To confirm proper plate alignment use thumb pressure to insert the Short Plate Impactor, advancing the second plate until it touches bone. 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 plates locks the implant in place and secures the implant between the vertebrae.

Remove the Implant Holder by unscrewing the knob counter-clockwise.

*Note: If there is a need to remove the first plate (or reposition the implant) the hole in the center of the plate may be used as a grasping point.
Plate loading and locking

Unlocking Key

After both plates are locked and the Plate Impactor is removed, the ROI-A Unlocking Key (IR 9434 R) can be used to help disconnect the implant from the Implant Holder.*

Slip the Unlocking Key over the knob at the end of the handle by aligning the two tabs with the notches on the Implant Holder and turn counterclockwise.

*Note: Do not use the Unlocking Key to screw the cage to the Holder.

Plate reference table

<table>
<thead>
<tr>
<th>Plate Reference</th>
<th>Size</th>
<th>Plate Height (w/ H10)</th>
<th>Plate Height (w/ H12)</th>
<th>Plate Height (w/ H14)</th>
<th>Plate Height (w/ H16)</th>
<th>Plate Height (w/ H18)</th>
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<tr>
<td>IR 2009 T</td>
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</tbody>
</table>
Confirm final lock of each plate

Use the Final Plate Impactor (IR 9202 R) 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 plates with the Plate Impactor.

CAUTION: It is VERY IMPORTANT to confirm final locking of both plates to ensure full impaction.
Plate loading and locking

Assess final position

Take final lateral and anterior-posterior fluoroscopic images to assess implant position and confirm position of the plates. Determine need for any further final plate impaction.

Plate needs advancing.

Approximately 2.5mm of space indicates proper position.

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

Final fluoroscopy of proper placement
Cage removal

Remove plates
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 below illustrations, the diagonal stripes show the PEEK that must be removed until the plates are visible.

Once visible, remove each plate with the Plate Hook (IR 9288 R) by engaging the removal hole on the plate. Pull each plate out along the same path as its curvature.

Remove implant
Use a Kocher to remove the implant anteriorly.
If the implant cannot be easily removed, a cobb elevator or osteotome may be used to loosen the bone to implant interface.
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 larger implant (length and width) to be used allowing for more surface area contact. The ROI-A Implant System 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 Implant System is intended to be implanted singularly via a direct anterior approach as well as an oblique anterior approach. The ROI-A Implant System is intended to be used with autologous bone graft. The devices must be used with supplemental internal fixation. The ROI-A Implant System 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 Implant System implants are (radiolucent) PEEK OPTIMA® LT1 and tantalum alloy radiological position markers. The ROI-A Implant System VerteBRIDGE Plates are manufactured from surgical titanium (Ti6Al4V), which complies with ASTM F136. Instruments used to implant the ROI-A Implant System are made of medical grade stainless steel.

Contraindications

- 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, anesthetics risks, or surgical conditions which would preclude the potential benefit of spinal implant surgery.
- Any condition not described in the indications for use.
Precautions

• Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of intervertebral body fusion 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.
• Based on fatigue testing results, when using the ROI-A Implant System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
• Patients who smoke have been shown to have an increased risk 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 implantation that they may substantially decrease the expected useful life of 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 pre-operative and surgical techniques, cautions and potential risks associated with 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 system. The VerteBRIDGE Plate system is available for use with ROI-A 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.
**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 endplates), allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, or expulsion.
- 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 effect 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 tissues or 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 steels 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 design parameters, components of the ROI-A System 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 post-operative management to avoid fracture.
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