SURGICAL TECHNIQUE

ROI-A®

ALIF CAGE with

VerteBRIDGE® PLATING TECHNOLOGY
The surgical technique is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Indications (United States)

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 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.

The ROI-A implants are intended to be implanted singularly.

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 fixaton options that can be used with ROI-A cage (with or without VerteBRIDGE Plating) include posterior screw/rod systems or additional vertebral plating.
**Approach to the surgery**

Perform the customary approach for an ALIF as chosen by the surgeon for the patient’s condition.

**Confirm disc location with fluoroscopy**

A pin can be inserted into the affected disc to both confirm the appropriate level and the disc’s midline.

**Discectomy**

Use the surgeon’s preferred anterior discectomy instruments and procedure to remove the disc down to the osseous endplate. A Cobb Elevator (MD 9105 R or MD 900 R/ Endplate Rugine) is available to aid the discectomy.

Use the surgeon’s preferred distraction method. As needed, assemble the Unilateral Distractor Tips (MD 953/954 R) to the Distraction Forceps (MD 907 R).

Place the distractor to one side, distract, and maintain the position by dialing down the locking knob. Complete the discectomy on the exposed side. 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.

**Move the Unilateral Distractor and repeat discectomy on the opposite side.**

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*Note: Remove disc just sufficient for the implant footprint; preserving lateral annulus improves 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.
Surgical Technique

ROI-A®

Approach and discectomy

Assess the depth

Keeping the Unilateral Distractor in position, place the hook of the ROI-A Depth Gauge (IR 9430 R) just over the posterior edge of the inferior vertebra.

To get the most accurate reading:
- Angle the Depth Gauge as medial as possible.
- Completely remove all anterior and posterior osteophytes.

View the depth reading at the end of the Depth Gauge.

Optional Distract in parallel

Load the Bilateral Distractor tips (MD 955/956 R) onto the Distraction Forceps. Place the Distractor* and distract.

The Bilateral Distractor works to disperse distraction forces over the vertebral surface and can be used to stretch tight posterior elements, opening the space for implant insertion.

*Note: Make sure the Distractor head is flush with the anterior aspect of the vertebrae.
**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.

Use the depth reading from Page 4 to select the closest implant footprint; available depths include 23, 27, and 30mm.

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. Refer to the table on page 6 for sizing options.

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

**Assemble and lock Trial to the Holder**

Assemble the selected Trial to the Trial Holder (IR 9433 R).

Lock the Trial by fully screwing the knob at the end of the Holder, prior to impacting the Trial into place.
## Implant Sizing Table

<table>
<thead>
<tr>
<th>Implant Reference</th>
<th>Footprint (Depth x Width) (mm)</th>
<th>Lordosis Angle</th>
<th>Anterior Height (mm)</th>
<th>Posterior Height (mm)</th>
<th>Approximate Graft Volume (cc)</th>
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Note: 2° sizes are available upon request.
**Position the trial**

Once the Trial is locked on the Holder, insert into the disc space.

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

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

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

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

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

Select the final size

Repeat the trialing process until satisfied with the footprint, height, and lordosis.

It is very important that the Trial has good contact with inferior and superior endplates via proper anterior height and lordosis selection.

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

If needed, a Slap Hammer (IR 9405 R) is available to help with Trial removal.

*CAUTION: Fluoroscopy is mandatory to confirm sizing.*
**Step 3**

**ROI-A ALIF Cage insertion**

**Load bone graft**
Place implant on the Graft Support (IR 9204 R) with the anterior flat surface showing the plate slots facing out. Load the inner space of the implant with autograft.
Refer to the table on page 6 for approximate graft volume.
Compartment graft using the Graft Compactor (IR 9205 R) as needed.

**Adjustable Stop**
The ROI-A Adjustable Stop (IR 9283 R) can be used for better control of the implant’s AP position throughout insertion.
Use the Adjustable Stop Screwdriver (IR 9408 R) to set the stop; fully screwing the stop to 0 will leave the implant recessed by approximately 2mm. Unscrew the stop 1 turn to recess the implant by 1mm more.
To assemble, insert the two pegs on the Adjustable Stop into the holes on the Implant Holder head.*
See page 11 for implant insertion with the Adjustable Stop.

*Note: Adjustable Stop can be assembled either inferior or superior depending on anatomic conditions.*
**Assemble 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 anterior face of the 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.

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.

*Note: Overtightening could strip the PEEK threads and weaken the implant to Holder connection.*
CAUTION: Fluoroscopy is mandatory prior to plate insertion. 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.

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CAUTION: Fluoroscopy is mandatory prior to plate insertion.

*Note: Prior to implant insertion, assess bone quality. Sclerotic bone can make advancing the plates difficult. A curette or burr can be used to create a small hole where the plates will enter the vertebral.

CAUTION: Toggling the Holder during cage insertion can stress the implant to Holder connection.

CAUTION: At L5-S1, make sure the implant is not positioned too anteriorly. The plate can curve out of the anterior wall of the sacrum.

*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 in the plane of the disc.
Step 4  VerteBRIDGE® Plate loading and locking

Select plate

Select the plate length: S (short) (IR 2009T), M (medium) (IR 2008T), or L (long) (IR 2007 T).

Plate sizing recommendations:
• S sized plate should not be used with the 16 and 18mm implants.
• Consider using an S or M plate on patients with small anatomy.
• At S1 consider the posterior tilt of the sacrum and the plate’s anterior curve when seated in the cage; a shorter plate may be required to avoid plate 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 15 for plate vertebrae penetration.)
  - It is possible to use an L sized plate on the most superior and inferior vertebral bodies, while using an S or M sized plate on the shared, central vertebra.
  - The superior implant can be placed slightly posterior in reference to the inferior cage to avoid plate paths from crossing.

CAUTION: Check to make sure that plate trajectory is clear of any additional hardware.

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.

CAUTION: Only load one plate at a time.

Plate loading pearls:
• 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.
**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, advance the Impactor by hand to introduce 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 second plate may not advance.

**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.
**VerteBRIDGE® Plate loading and locking**

**Verify first plate position**
Take a lateral fluoroscopic image to ensure proper implant and plate position and stability. 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. 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 plates locks the implant in place and secures the implant between the vertebrae.

Remove the Implant Holder by unscrewing the knob.

*Note: If there is a need to remove the first plate (or reposition the implant), use the hole in the center of the plate.
Unlocking Key

After removal of the locking Plate Impactor, the ROI-A Unlocking Key (IR 9434 R) can be used to help disconnect the implant from the Implant 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.

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

<table>
<thead>
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<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>
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</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 as shown on page 14.

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

Take final lateral and anterior-posterior fluoroscopic images to:
• Confirm position of the plates.
• Use the Final Plate Impactor to advance the plates if needed.
• Assess implant 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

Plates need advancing.

Approximately 2.5mm of space indicates proper position.
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 scar tissue, which can make exposure more challenging than in the un-operated spine.
- The position of supplemental fixation.

**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 Anchoring 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 should be used to loosen the bone to implant interface.
Device description and use guidelines

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 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 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 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 implants are (radiolucent) PEEK-Optima® LT1 and tantalum alloy radiological position markers. The ROI-A Implant System VerteBRIDGE Plates are manufactured from surgical titanium (Ti6A14V), 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 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 the 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 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.