SURGICAL TECHNIQUE
ROI-T®
TLIF CAGE
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Indications (United States)

The ROI-T® 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.
**Approach and facet/pedicle preparation**

**Step 1 Surgical approach**
Identify the affected disc with fluoroscopy. Expose the intervertebral space using the surgeon’s customary posterior approach: median posterior, Wiltse, or minimally invasive.

**Step 2 Facet resection**
In order to gain access to the disc, resect the facet joints on the desired side for implant insertion.*

*Note: The facet joint can be preserved if sufficient access exists for discectomy and implant insertion or if the approach is extraforaminal.

**Step 3 Pedicle screw installation**
Install SpineTune™ TL or Easyspine® Pedicle Screws in the levels above and below the affected disc. Screws can be used for distraction, which may be necessary for the discectomy, as well as the trial and implantation steps.
**Controlled distraction options**

The restoration of the desired height of the intervertebral body space is obtained by distraction. The distraction can be carried out by leveraging against:

A. The pedicle screws on the insertion side:
   Distraction occurs between the pedicle screws. Use the LDR Distractor with the ROI-T Rod Blades (ES965R / IR9039R). The Rod Blade mates with the pedicle screw and is secured by the set screw.

B. The spinous processes:
   The Wide Spinous Process Distractor (IR9093R) separates the spinous processes.
C. The pedicle screws on the insertion side:
   Distraction occurs between the pedicle screws. Use the Easyspine® Distraction Forceps (ES9002R).

**For any distraction method:**
In the case of an extremely collapsed disc, a rod can be installed on the side opposite implant insertion. Once preliminarily locked, the rod will help maintain distraction.
**Discectomy and endplate preparation**

**Step 5: Discectomy**

While the restored height of the disc is maintained with the chosen distraction method, incise the disc anterior to the foramen.*

Use the Shavers, available in graduating sizes in 1mm increments from 8-15mm, to continue the discectomy. Freshen the space as widely as possible by alternating the method of distraction as necessary.

*Note: The minimum width necessary for insertion of the implant is about 12mm.

**Endplate preparation**

Complete the discectomy with the Straight and/or the Angled Curettes (IR 9083/9096/9097 R). Prepare the endplates just enough so as not to weaken the cortical bone, but still creating a surface that will encourage vascularity between the graft and endplates.

The discectomy area should take into consideration cage placement and preferred graft position (anterior and/or posterior to the cage).
Optional **Box Chisels**

If necessary, use the Box Chisels (available in sizes 8, 10, 12, 14, and 16mm) to remove posterior osteophytes, establishing an opening in the cortical bone* to facilitate implant insertion.

*Note: Use the Box Chisels to cut into the intervertebral space to a depth of about 5mm.
**Step 6**

**Trial selection**

Choose the appropriate sized implant using the ROI-T trials. The Trials have the same dimensions as the implants and make it possible to determine the appropriate height and lordosis.

**Assemble Trial to Holder**

Slide the selected Trial onto the edge of the ROI-T Implant Holder. The teeth and the threaded rod of the Implant Holder fit into the corresponding notches and threaded hole of the Trial implant.

Two Holders are available with angulations of 0° and 15° between the implant and the instrument, IR9138R and IR9139R respectively. Choose the Holder angulation according to the selected approach.

**Lock Trial to Holder**

Lock the Trial by fully tightening the screw knob at the end of the Holder, prior to impacting the Trial into place. The implant is locked when contact is made between the knob and handle.*

*Note: Take care not to over tighten the Holder knob, making the Trial difficult to disconnect.
**Trial positioning**

Once the Trial is locked on the Holder, insert into the disc space as close to final implant position as possible. Release the distraction temporarily and test the stability of the Trial by moving the handle.

Check the height of the Trial by fluoroscopy. Confirm desired disc distraction and detect any anatomic obstacles preventing the correct positioning of the implant.

*CAUTION: Do not release the Trial from the Holder.*

**Final size selection**

Re-establish distraction and withdraw the Trial. Release the Trial by unscrewing the Holder knob. Repeat the trialing process until satisfied with the size, lordosis, and stability of the Trial.

**Assemble implant to Holder**

**Assemble and lock the implant to the Holder**

Use the same Holder and assembly technique for the implant as used with the Trial. Confirm the Holder knob is fully tightened prior to impacting the implant into place.*

*Note: Take care not to over tighten Holder knob, making the implant difficult to disconnect.*
**Surgical Technique**

**Load graft material and place anterior graft**

**Optional**

**Load and secure implant to Graft Support**

The centering pin on the Graft Support base (IR9140R) fits into the implant’s internal cavity on the side next to the Holder.

Push the platform down, inserting the teeth on the underside of the platform into the implant’s internal cavity. Then, secure the implant by turning the knurled screw knob.

**Compact bone graft**

Place bone graft into the funnel of the holding plate and compact into the implant with the Graft Compactor (IR9141R).

**Optional**

**Anterior graft**

Bone graft can be inserted anteriorly into the disc space before placement of the implant using the Anterior Graft Spatula (IR9009R). The surgeon will need to pre-plan for anterior graft placement during the discectomy (Step 5).
**Implant insertion**

**Step 8**

**Implant insertion**

Insert implant loaded with bone graft into the intervertebral space along the same insertion path as the Trial. Implant should be placed as close to final position as possible.

**Remove ROI-T Holder**

After fluoroscopic assessment of implant position, withdraw the Holder by loosening the locking screw, detaching the Holder from the implant and withdrawing in a motion reverse of that used to insert the implant.

**Step 9**

**Final implant placement**

Use the Secondary Impactor (IR9098R) to push the implant into final position; centered medial lateral and to the anterior edge of the vertebral body.

Use fluoroscopy throughout final implant positioning to ensure proper final placement.
Final implant verification and install posterior graft

**Verify implant placement**

Check the implant’s final position (lateral and anterior/posterior), verifying location by fluoroscopy (the implant has integrated tantalum markers).

Markers will be vertical and aligned with one another to form a line from a lateral view.*

From an anterior/posterior view, the middle marker should be centered on the vertebral body and appear as a circle.**

* Lateral View  **Anterior/Posterior View

**Install posterior graft**

Install supplementary cancellous bone graft into the intervertebral fusion space, as desired. Like anterior graft placement, the surgeon will need to pre-plan for posterior graft placement during the discectomy (Step 5).
Stabilization/compression and removal or revision

**Stabilization and compression**

Once the ROI-T implant is in situ, compress the segment via the posterior screws and rod to stabilize the ROI-T.

Make sure the lordosing compression has not caused any foraminal stenosis and assure total radicular freedom.

**Removal or revision**

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 any scar tissue, which can make exposure more challenging than in the un-operated spine.
- The position of supplemental fixation.

**Distraction**

For a posterior or transforaminal approach, distraction can be used to separate the vertebrae easing implant removal. Distract between the:
- Pedicle screws on the insertion side using either the LDR Distractor with the ROI-T Rod Blades (ES965R/IR9039R) or the Easyspine® Distraction Forceps (ES9002R) (both options on request).
- Spinous processes (if still intact) with the Easyspine Distraction Forceps or the ROI-T Wide Spinous Process Distractor (IR9093R).
Removal or revision continued

Removal– Implant NOT advanced to final position

If the Secondary Impactor (IR9098R) has not been used to push the implant into final position:
- Reattach a 0° or 15° Implant Holder (IR9138R/IR9139R) to the implant. Slide the prongs of the Implant Holder along the body of the implant to mate with the implant holes. Lock the implant to the Holder by fully tightening the Holder’s screw knob. The Threaded Removal Rod (IR9018R) can also be attached to the threaded implant holes.
- Alternately, a standard operating instrument like a Kocher can be used to grab the implant.
- Remove implant along the same path as its entry.

Removal– Implant ADVANCED to final position

If the implant is in the final position (the Secondary Impactor has been used), consider three approach options, presented in the order of the most common occurrence:
- TLIF- First use a TLIF approach from either the original insertion point or opposite virgin side. A revision from the original approach side provides the minor advantage of access to the implant’s threaded hole with the disadvantage of having to go through scar tissue created from the original surgery. If adjustments need to be made to existing pedicle screws, additional screws are required at adjacent levels, or the implant is loose, the posterior approach may be the best choice.
- Direct lateral- This approach provides a direct path to the threaded holes used for ROI-T insertion/removal, making for potentially easier implant reach and removal and also avoids the nerve roots and any scar tissue created by the initial surgery. However, a direct lateral approach does not allow for posterior anatomy or pedicle screw work and is not an option for an L5-S1 revision.
- ALIF- Rarely used for the TLIF revision case, the ALIF approach may be a good option when the disc space is infected and needs a thorough debridement with a lowered risk of introducing the infection into the epidural space.
**TLIF approach**

- Utilize a standard operating instrument like a Kocher to grab or turn the implant.
- Attach the Removal Rod (if the threaded insertion hole is accessible) or use a Kocher to remove the implant along the same path as its entry.
- If the implant cannot easily be removed, a Cobb Elevator or Osteotome should be used to loosen the bone to implant interface.

1. Initial medial trajectory - grasp implant and rotate.
2. Secondary lateral trajectory - remove implant over pedicle.

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**Direct lateral approach**

- Depending on the implant angle and approach side, the Removal Rod can be attached to the ROI-T for extraction.
- Alternately, a standard operating instrument like a Kocher can be used to grip the implant for removal.
- If the implant cannot easily be removed, a Cobb Elevator or Osteotome should be used to loosen the bone to implant interface.

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**ALIF approach**

- Use a standard operating instrument like a Kocher to grip the implant for removal.
- If the implant cannot be easily removed, a Cobb Elevator or Osteotome should be used to loosen the bone to implant interface.

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Device description and use guidelines

**Device description**

The ROI-T Implant System consists of crescent shaped blocks in a variety of heights and lordosis angles. The ROI-T implant has an enclosed 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-T implant is intended to be implanted singularly or in pairs via a transforaminal approach and is intended to be used with autologous bone graft. The devices must be used with supplemental internal fixation.

The materials used in the manufacturing of the ROI-T implants are (radiolucent) PEEK Optima® LT1 and tantalum alloy radiological position markers. Instruments used to implant the ROI-T implants 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.

**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 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 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.)

• 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.

**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, 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.
**Warnings continued**

- 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-T Implant 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 postoperative management to avoid fracture.
- The ROI-T Implant System has not been evaluated for safety and compatibility in the MR environment.
- The ROI-T Implant System has not been tested for heating or migration in the MR environment.