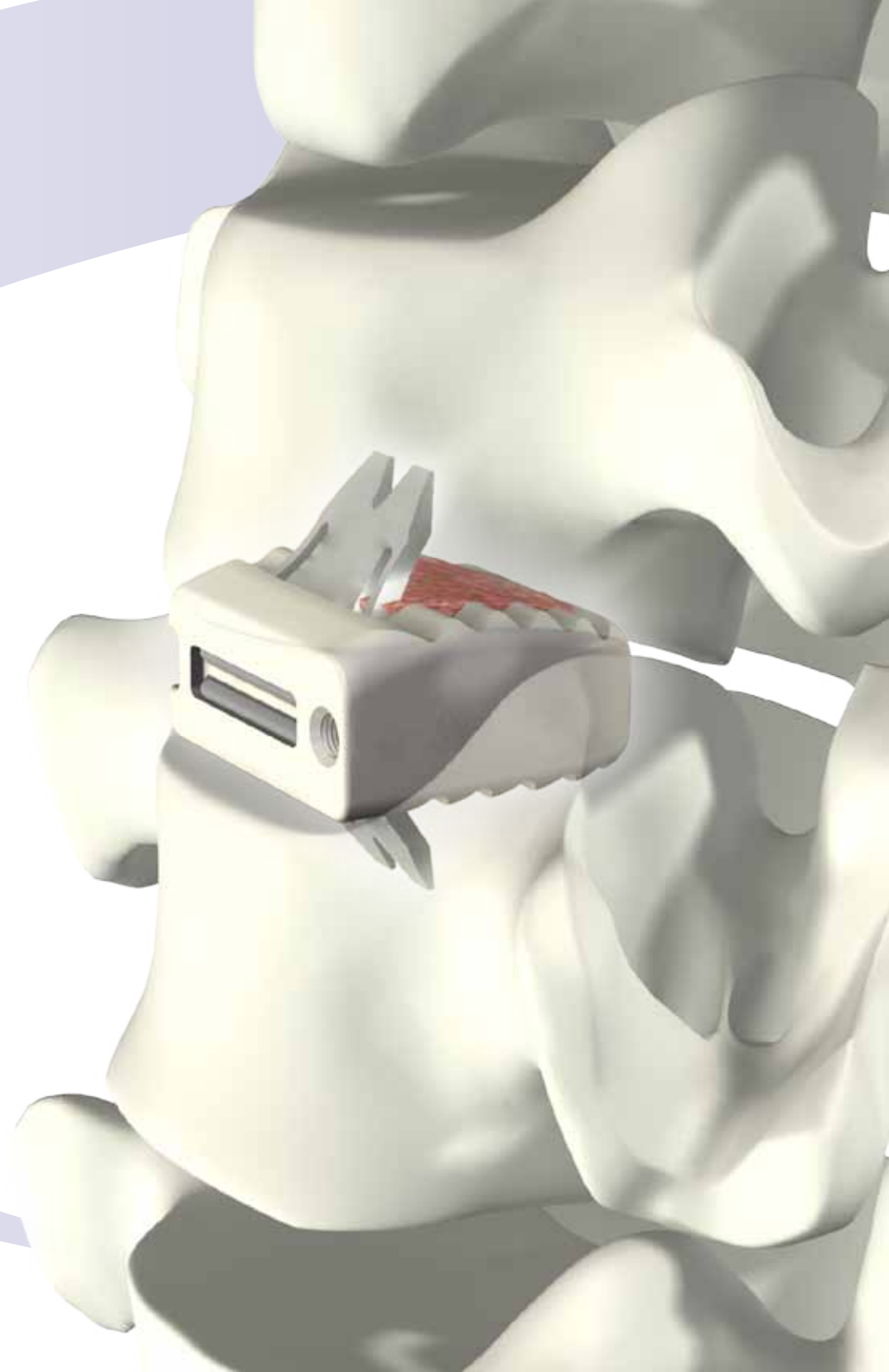




SURGICAL TECHNIQUE

ROI-C[®]

CERVICAL CAGE with



ROI-C[®]

CERVICAL CAGE

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Indications (United States)

When used as an intervertebral body fusion device, the ROI-C Implant System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment. The ROI-C implants are to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

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

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.

Surgical approach and discectomy

Surgical approach

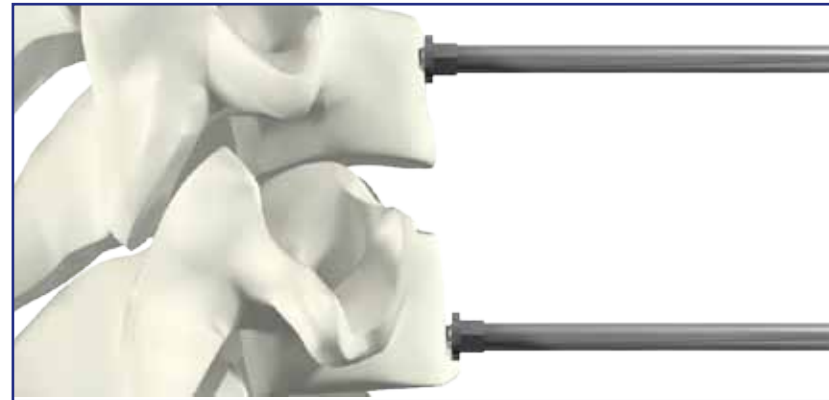
Identify the affected level radiographically and perform a customary ACDF approach.

Distraction

Distract as necessary to achieve adequate access to the disc space.

If using a Caspar Distractor, the pins must be placed midline and at least 7mm from both endplates surrounding the disc being replaced to avoid contact between the Caspar Pins, the Implant Holder (MC9001R), and ROI-C plates.

Remove Caspar Pins prior to plate advancement to eliminate any risk of plate obstruction.



Discectomy

Perform a thorough discectomy to remove the disc down to the osseous endplates. Prepare the endplates just enough to create a surface that will encourage vascularization between the endplates and the graft without weakening cortical bone.

CAUTION: *The anatomic shape of the ROI-C implant requires preservation of the endplates, including the superior endplate dome. Endplate removal may increase the risk of subsidence and necessitate supplemental fixation in addition to the ROI-C plate.*

Step 2 Trialing

Depth assessment

Place the hook of the Depth Gauge (MB906R) just over the posterior edge of the inferior vertebra.

To achieve the most accurate reading, position the Depth Gauge as medial as possible and completely remove all anterior and posterior osteophytes.

View the depth reading at the end of the Depth Gauge and determine if the 12 or 14mm depth implant will provide a more optimal fit.



Depth Gauge measurement: 14mm

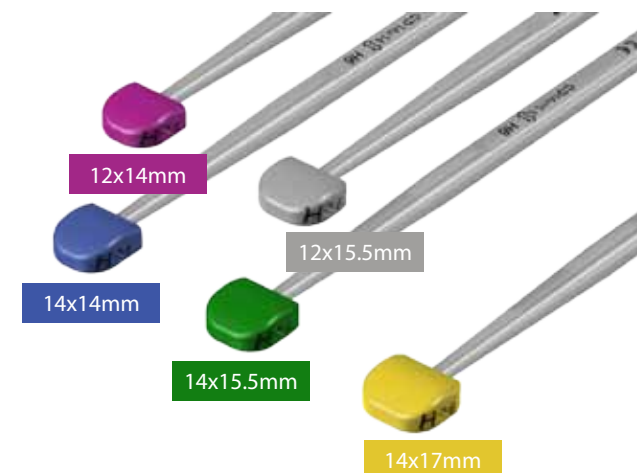
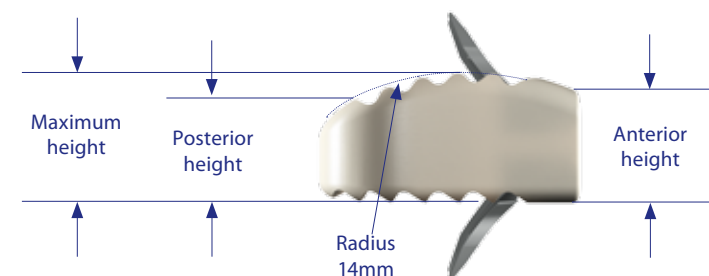
Trial selection

Using the depth measurement determined by the gauge, select an available width and height to choose a Trial. Reference the table on the next page for depth, width, and height combinations. Trialing should begin with:

- A conservative height not to exceed the height of healthy adjacent discs.*
- A width that should extend to the uncinete processes, but should not ride up onto either uncus.
- A depth that leaves 1mm of space from the anterior and posterior vertebral borders. The Trial should not protrude past the edge of the vertebrae.

The ROI-C Trials:

- Should provide optimal endplate coverage, height restoration, and good stability.
- Have the same dimensions as the implants.
- Are color coded by footprint size to match the implant packaging's color dot on the side of the box.



Implant reference table

Size	Reference Number	Depth (mm)	Width (mm)	Height (mm)			Graft Volume (cc)
				Anterior	Maximum	Posterior	
12 x 14 , H4.5	MC 1340 P	12	14	4.5	5.1	3	0.29
12 x 14 , H5	MC 1341 P	12	14	5	5.5	3	0.31
12 x 14 , H6	MC 1342 P	12	14	6	6.5	4	0.36
12 x 14 , H7	MC 1343 P	12	14	7	7.5	5	0.41
12 x 14 , H8	MC 1344 P	12	14	8	8.5	6	0.45
12 x 15.5 , H4.5	MC 1350 P	12	15.5	4.5	5.1	3	0.29
12 x 15.5 , H5	MC 1351 P	12	15.5	5	5.5	3	0.31
12 x 15.5 , H6	MC 1352 P	12	15.5	6	6.5	4	0.36
12 x 15.5 , H7	MC 1353 P	12	15.5	7	7.5	5	0.41
12 x 15.5 , H8	MC 1354 P	12	15.5	8	8.5	6	0.45
14 x 14 , H4.5	MC 1310 P	14	14	4.5	5.6	3	0.39
14 x 14 , H5	MC 1311 P	14	14	5	5.9	3	0.42
14 x 14 , H6	MC 1312 P	14	14	6	6.9	4	0.48
14 x 14 , H7	MC 1313 P	14	14	7	7.9	5	0.54
14 x 14 , H8	MC 1314 P	14	14	8	8.9	6	0.60
14 x 15.5 , H4.5	MC 1320 P	14	15.5	4.5	5.6	3	0.39
14 x 15.5 , H5	MC 1321 P	14	15.5	5	5.9	3	0.42
14 x 15.5 , H6	MC 1322 P	14	15.5	6	6.9	4	0.48
14 x 15.5 , H7	MC 1323 P	14	15.5	7	7.9	5	0.54
14 x 15.5 , H8	MC 1324 P	14	15.5	8	8.9	6	0.60
14 x 17 , H5	MC 1331 P	14	17	5	5.9	3	0.51
14 x 17 , H6	MC 1332 P	14	17	6	6.9	4	0.60
14 x 17 , H7	MC 1333 P	14	17	7	7.9	5	0.67
14 x 17 , H8	MC 1334 P	14	17	8	8.9	6	0.75

Trialing

Trial positioning

Place the Trial in front of the space to visually determine width.

Insert the selected Trial into the space.

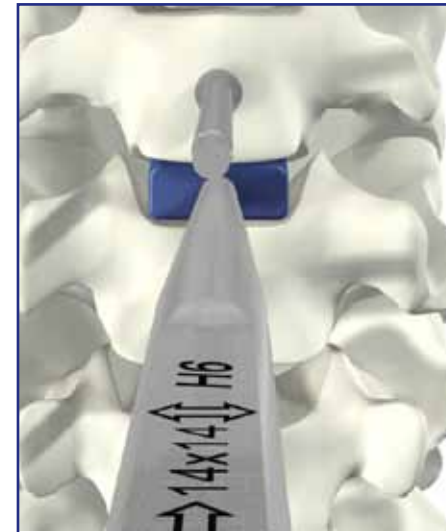
Under lateral radiographic imaging confirm the:

- Implant depth and height
- Endplate coverage (anterior-posterior)
- Conformity with the superior dome.

Release the distraction in order to assess the height that will best restore anatomic shape of the operated space, as well as the best stability to the implant.*



- **Note: Without distraction, the Trial should be snug in the disc space even as the Trial's integrated handle is gently pulled away directly anterior from the vertebrae to assess fit.*



Final size selection

Repeat the trialing process until satisfied with the footprint and height.*

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

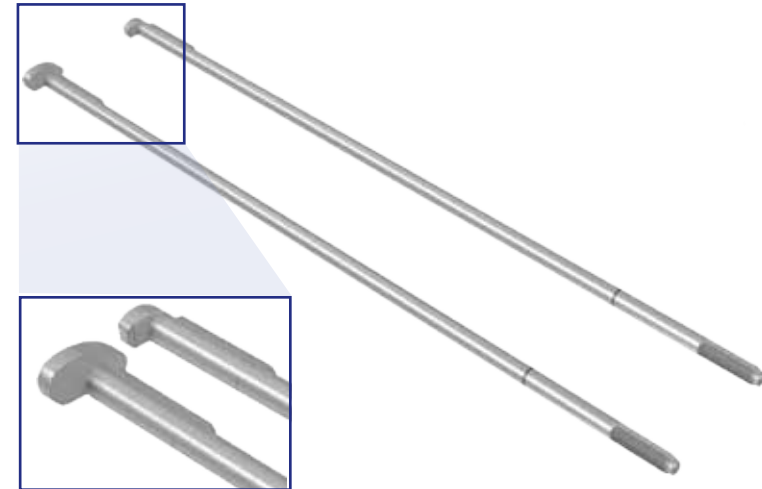


- **Note: Radiographic imaging is mandatory to confirm sizing. The hole through the Trial should appear circular. An oval shape indicates possible rotation.*

Depth stop selection

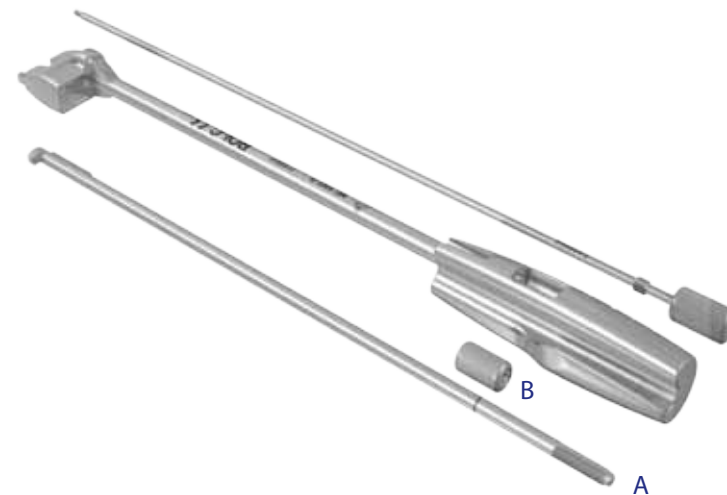
The ROI-C system offers two depth stops: the standard adjustable depth stop and the ROI-C Adjustable Stop (MC9004R) with a larger footprint.

The larger footprint depth stop can be used with sclerotic bone where the force required to seat the plates may be greater. The larger depth stop can also serve as a gauge for assessing Caspar Pin placement. If the Caspar Pin sits above the larger depth stop, there will be adequate clearance for the plate to completely seat in the PEEK without risk of hitting the pin.



Holder components

Detach the knurled thumb wheel (B) from the end of the selected depth stop (A), which for shipping purposes comes assembled in the tray.

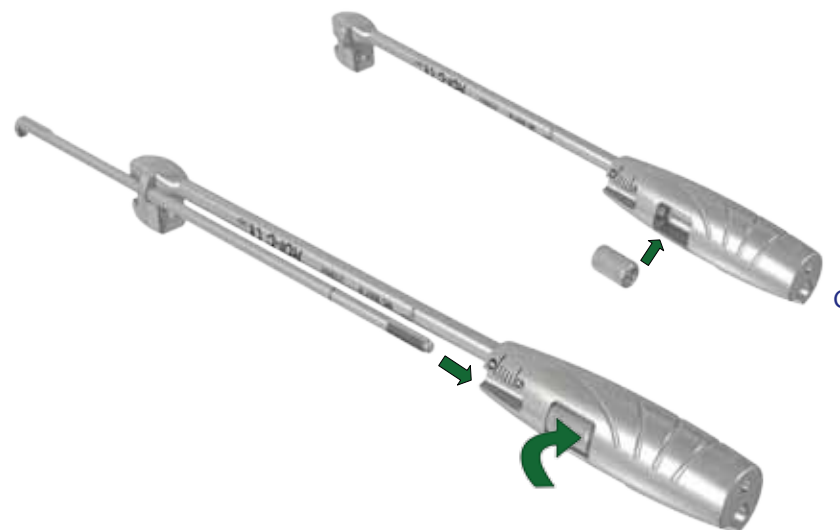


Implant insertion

Depth stop assembly

Load the knurled thumb wheel into the pocket on the body of the Implant Holder (C).

Slide the selected depth stop through the distal tip of the Implant Holder and into the knurled wheel. Secure the depth stop by rotating the thumb wheel in a clockwise direction. Setting the length of the depth stop or Adjustable Stop is discussed further on page 10.



Threaded rod assembly

Load the threaded rod (D) in the handle and down the shaft of the Implant Holder; rotate the knurled knob clockwise to secure.



Implant connection to Holder

Connect the selected implant to the Implant Holder by engaging the hook on the Holder with the slot on the side of the implant.

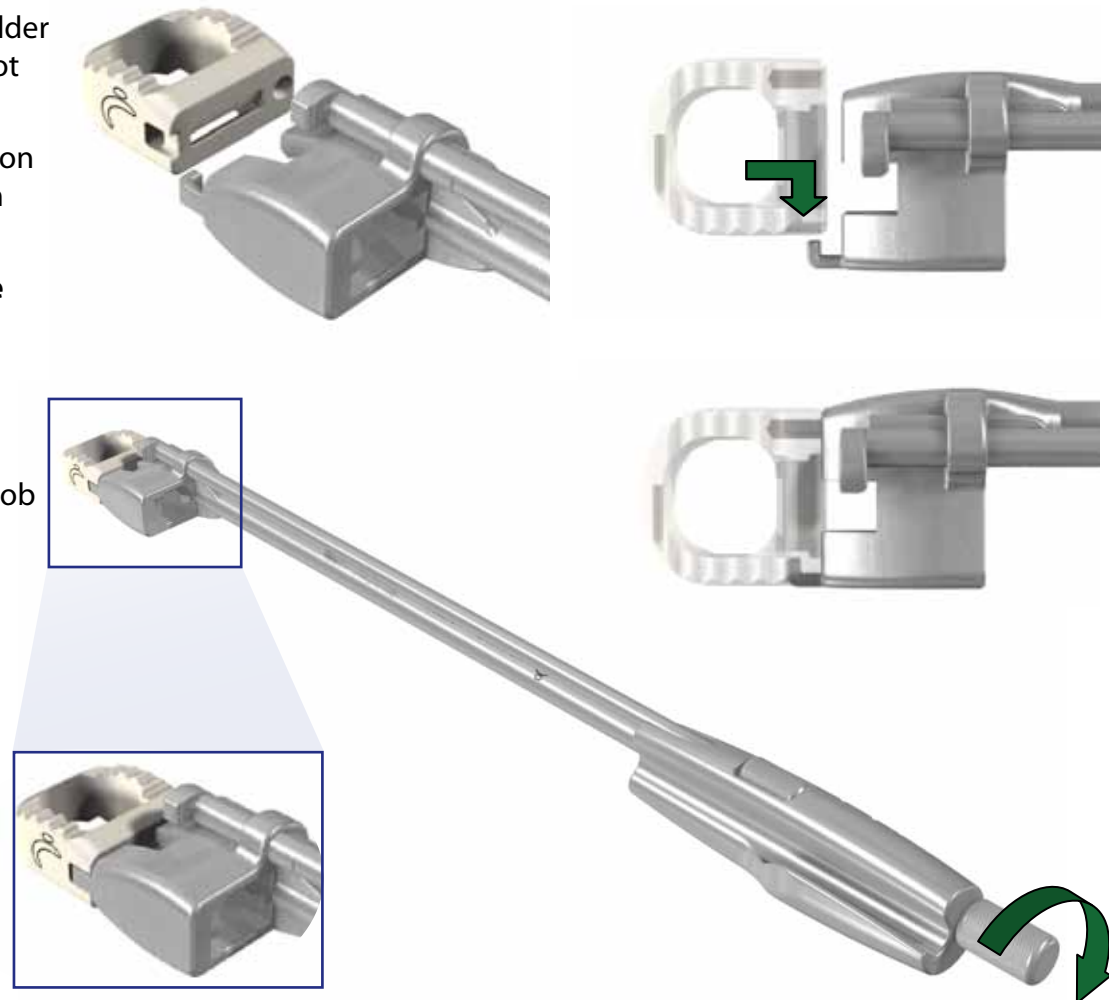
Once the hook is engaged, fully screw the knob on the end of the Holder with the threaded rod to secure the implant with the threaded rod.

It is critical to firmly secure the implant to the Holder.

The connection is secure when after finger tightening:*

- There should be no toggle in the connection.
- There should be no gap visible between the knob and the handle.

**Note: Over tightening could strip the PEEK threads and weaken the implant to Holder connection.*



Implant insertion

Bone graft loading

Load the central space of the implant with autologous bone.



Implant insertion

The Adjustable Stop is designed to ensure proper location and fixation of the plates into the vertebrae. Set the Adjustable Stop on the Implant Holder to 0mm. When the depth stop is set to 0mm, the implant will be recessed by 1mm into the disc space.

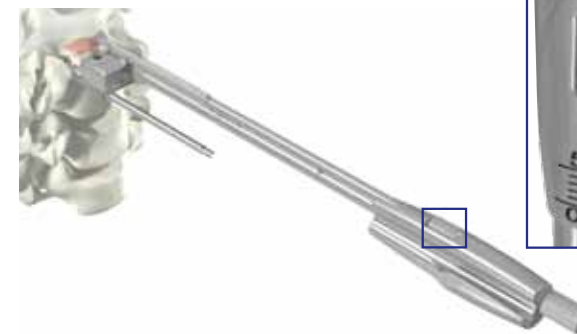
Insert implant by gently tapping the end of the Implant Holder as necessary to insert the implant. Try to keep the Implant Holder at a 90° angle to the disc space.

If the implant position is too anterior, the AP positioning can be adjusted by dialing the Adjustable Stop from 0-5mm. For each millimeter the depth stop advances, the implant moves 1mm posterior.

Under radiographic imaging, complete the insertion of the implant and do a final assessment of implant depth and endplate coverage, prior to plate insertion.

A tantalum marker is located 1mm from the posterior implant edge for positioning reference. Verify the marker is at least 1 or 2mm anterior to the canal to avoid dura mater compression.

CAUTION: Radiographic imaging is mandatory prior to plate insertion.



As needed, change adjustable stop setting by 1mm



Plate insertion

Plate selection

Select the plate length according to implant height. Use the ROI-C Standard Plate (MC1005T) with heights 4.5-7mm and the ROI-C Long Plate (MC1006 T) with 8mm high implants.

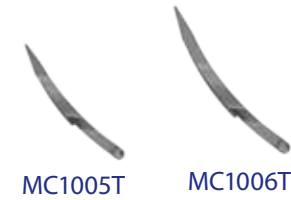
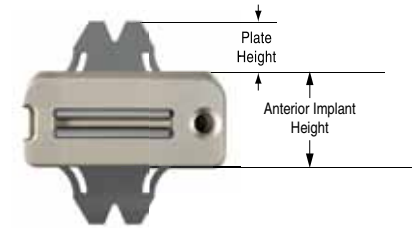


Plate reference table

Anterior Implant Height (mm)	H4.5	H5	H6	H7	H8
Plate Size (Reference Number)	Standard MC1005T				Long MC1006T
Plate Height (mm)	5.9	5.5	5.0	4.5	5.6



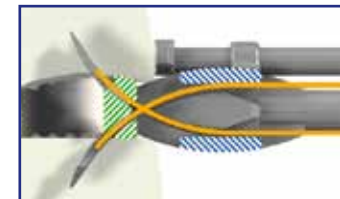
Remove distractor

Remove the distractor and Caspar Pins if used, to allow compression of the construct.*

Load first plate

With the implant in the optimal position, load the first plate into the cranial slot of the Implant Holder using the Plate Holder (MC901R).

As the plate paths cross within the Implant Holder, the plate inserted into the cranial slot will be advanced into the caudal vertebral body.



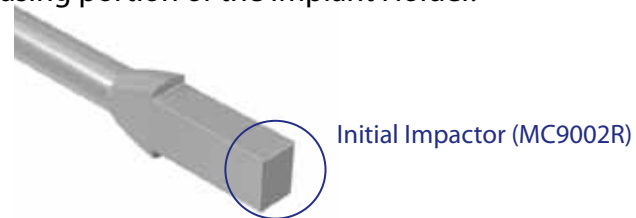
**Note: The Implant Holder must be left attached to the implant during placement of the plates.*

Plate insertion

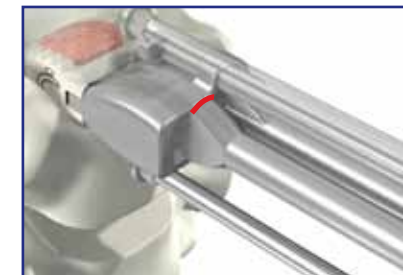
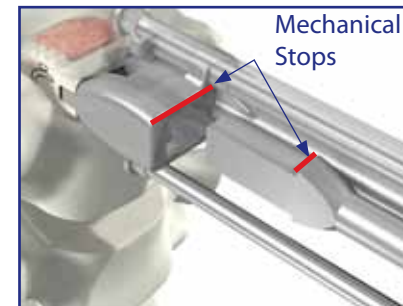
Advance first plate

Confirm implant is still securely attached to the holder.

Using thumb pressure, insert the ROI-C Initial Impactor (MC9002R) to advance the first plate until it touches bone.* Take a lateral radiographic image to verify the plate is touching the bone. Then use a mallet to finish the first plate's insertion into the bone. Confirm the mechanical stop on the impactor meets the mechanical stop on the plate housing portion of the Implant Holder.



**Note: If the plate does not advance with thumb pressure, confirm the plate is properly loaded in the Holder and the Holder is aligned with the PEEK.*



Verify first plate position

Take a lateral radiographic image to ensure proper implant and plate position and stability.

Do not proceed to lock the first plate until proper placement of the device and first plate is confirmed via fluoroscopy or x-ray.

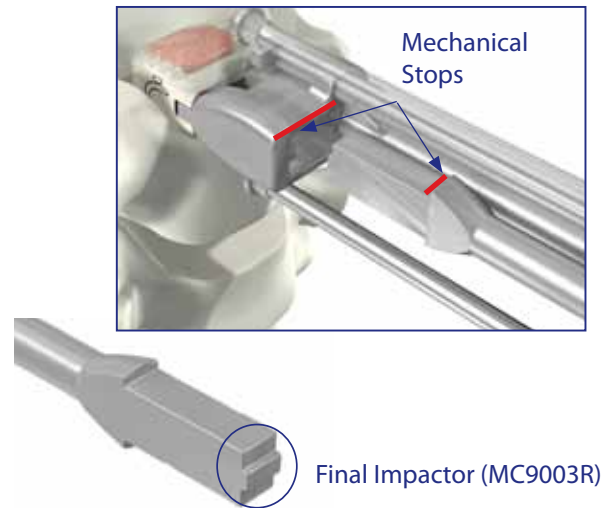


Lock first plate

Once position is confirmed, use the ROI-C Final Impactor (MC9003R) to lock the first plate in place. Again, the plate will have advanced completely when the mechanical stop on the Final Impactor meets the mechanical stop on the Implant Holder.*

Verify first plate final position

After final lock, take a lateral radiographic image to ensure proper implant and plate position, and overall stability.



**Note: To ensure proper lock, the plates must be advanced and locked using this impactor sequence:*

1st Plate:

- Advance with thumb pressure
- Initial Impactor
- Final Impactor

2nd Plate:

- Advance with thumb pressure
- Initial Impactor
- Final Impactor

Load second plate

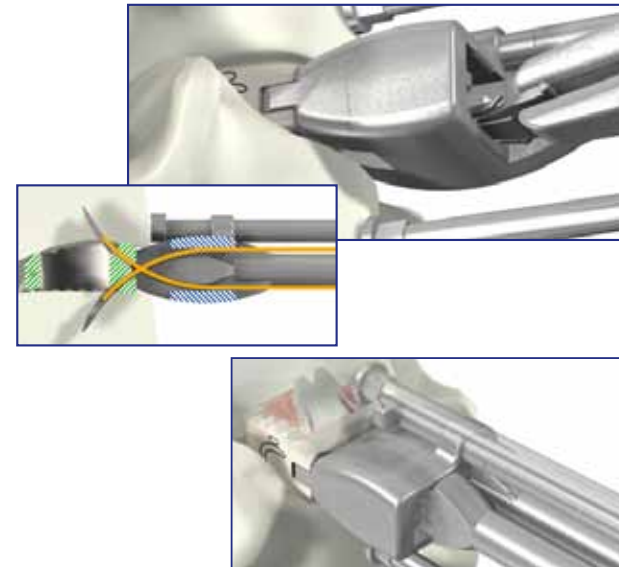
Confirm knob on end of Implant Holder is fully tightened. Insert the second plate into the caudal slot of the Implant Holder.

The plates must be inserted one after the other, as the plate paths cross in the plate housing portion of the Implant Holder. The second plate can only be inserted after the first plate is locked.

Advance and lock second plate

Using the same technique as the first plate, with thumb pressure insert the ROI-C Initial Impactor to advance the second plate until it touches bone. Then use a mallet to finish the second plate's insertion into the bone and to the mechanical stops.

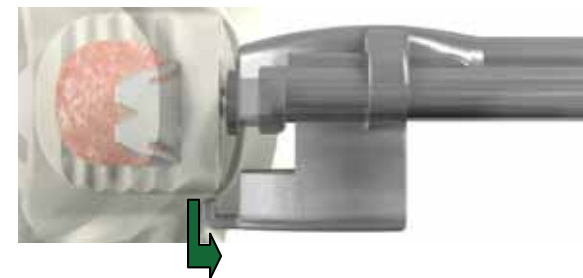
Confirm position under radiographic imaging and then final lock the plate using the ROI-C Final Impactor. The placement of both plates locks and secures the implant in place.



Step 5 Implant Holder removal and final assessment

Implant Holder removal

Remove the Implant Holder by turning the knob on the end of the Holder counter-clockwise until the threads disengage. Then slide the Holder to the left releasing the hook from the slot in the implant before removing the Holder.



Final fluoroscopy or x-ray of proper placement*

Confirm proper placement with radiographic imaging.

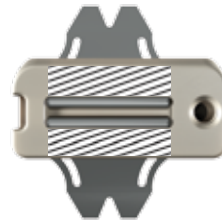


**Note: In cases of vertebral instability or significant bone removal the ROI-C implant with VerteBRIDGE plating should be augmented with anterior plating and/or posterior pedicle screws.*

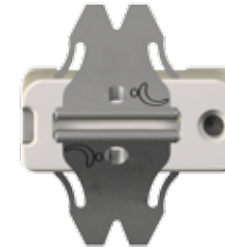
Removal or revision

Plate removal

Start the explant process with the removal of the two 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 exposed as shown.



Removal areas



After removal

Once visible, remove each plate with an Adson by engaging the removal slot on the plate. Pull each plate out along the same path as its curvature.



Plate showing removal slot

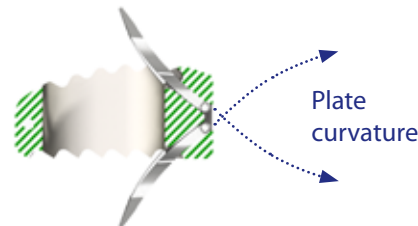


Plate curvature

Implant removal

A Kocher may be used 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 and use guidelines

Device description

The ROI-C Implant System consists of roughly rectangular shaped blocks in a variety of footprints and heights. The shape of the ROI-C allows for a large implant (length and width) to be used allowing for more surface area contact. The ROI-C is offered in a closed graft space design. The implants feature an enclosed chamber intended to be filled with autologous bone graft. The superior and inferior surfaces of the implants have a pattern of teeth to provide increased stability and to help prevent movement of the device. The ROI-C is intended to be implanted singularly via an anterior approach. The devices must be used with supplemental internal fixation.

NOTE: The ROI-C has been designed to be compatible with optional supplemental fixation specific for the system. The VerteBRIDGE® Plates are available and may be used to affix the ROI-C implants 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-C implants are (radiolucent) PEEK Optima® LT1 and tantalum alloy radiological position markers. The ROI-C VerteBRIDGE Plates are manufactured from surgical titanium (Ti6A14V), which complies with ASTM F136. Instruments used to implant ROI-C 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, anesthetic 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 instructions 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.)
- Supplemental internal fixation is required when using the ROI-C System. The VerteBRIDGE Plate system is available for use with ROI-C, 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-distracted, 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-C 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.





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