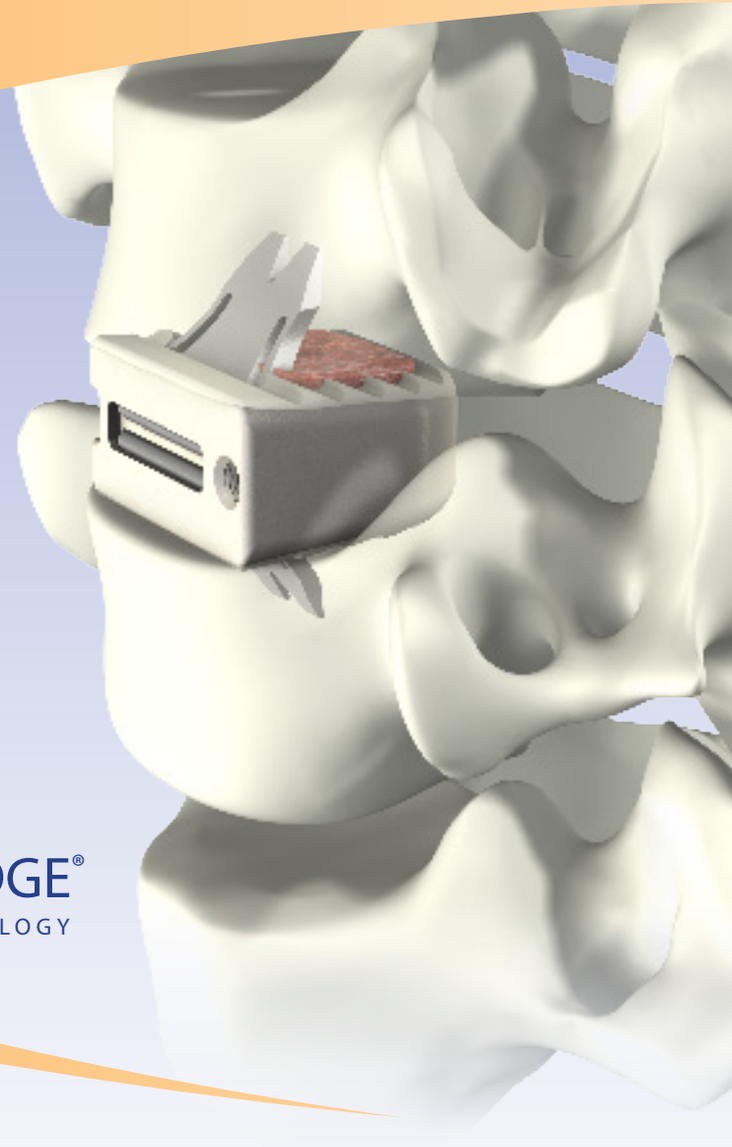
ROI-C®
CERVICAL CAGE

Surgical Technique



VerteBRIDGE®
PLATING TECHNOLOGY

LDR
a passion for innovation®

TABLE OF CONTENTS

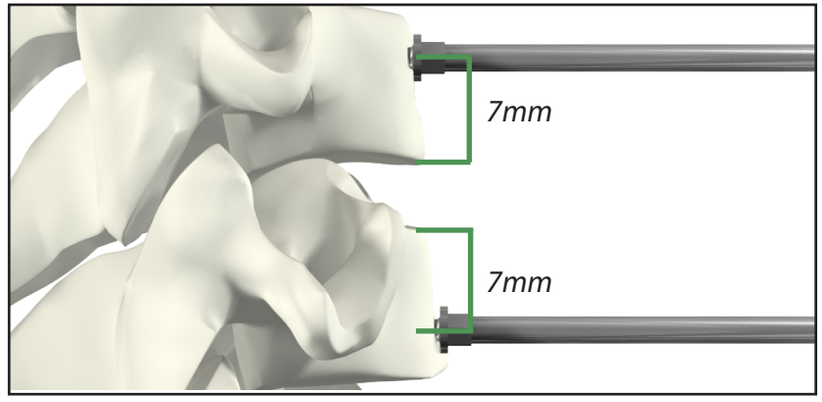
Anatomic

Lordotic

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.

DISTRACTION AND 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.



After the discectomy, distract as necessary to achieve adequate access to the disc space.

If using a Caspar Distractor, the pins should be placed approximately 7mm from both endplates to avoid contact between the Caspar Pins and ROI-C anchoring plates during insertion.

If patient anatomy doesn't allow 7mm of space, then remove the Caspar Pins prior to plate advancement to eliminate any risk of plate obstruction.

During the discectomy, consider the two available implant profiles:

- **ROI-C Anatomic**: Designed with a curved superior surface that compliments healthy endplate contours. The anatomic implant has a 6° of built-in lordosis.

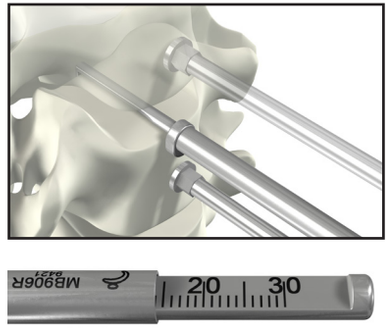
- **ROI-C Lordotic**: Features a tapered profile for patients with flattened endplates. The lordotic implant has 7° of built-in lordosis.

TRIAL SELECTION AND POSITIONING

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

Using fluoroscopy, estimate the footprint and height to best choose a Trial. A Trial can be placed in front of the space to visually determine width. (Reference the tables on page 18 depth, width, and height combinations.)

Trialing should begin with:

- The selection of implant profile: anatomic or lordotic.
- A conservative height not to exceed the height of healthy adjacent discs.
- A width that should extend to the uncinate processes, but should not ride up onto either uncus.
- A depth that leaves 1mm of space from the anterior and posterior vertebral borders.

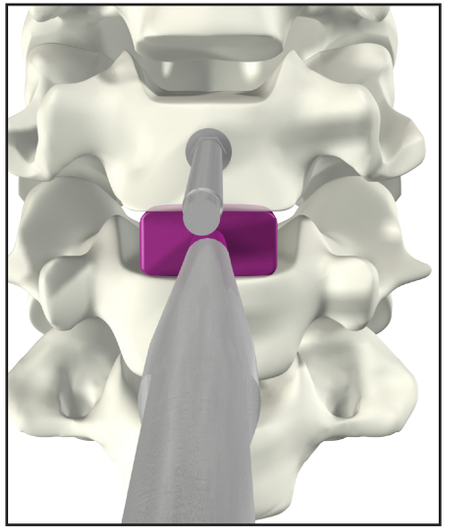
14x15.5mm

The ROI-C Trials:

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

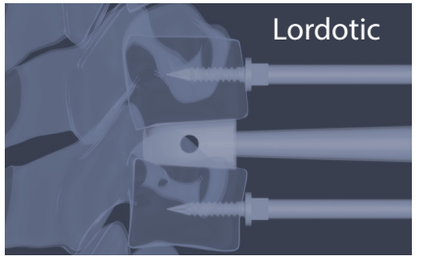
Insert the selected Trial into the space. Use lateral radiographic imaging to confirm Trial sizing.

Release the distraction in order to best assess the disc space height and restore the best 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.*

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



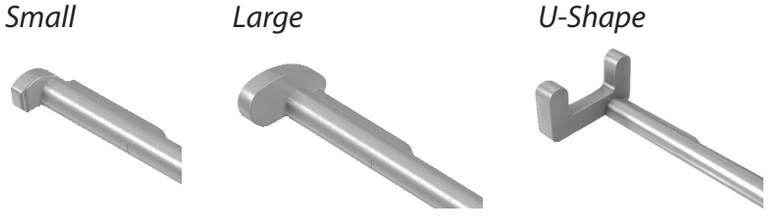
Note: ROI-C Trials are available with depth stops upon surgeon request.

IMPLANT INSERTION

DEPTH STOP SELECTION

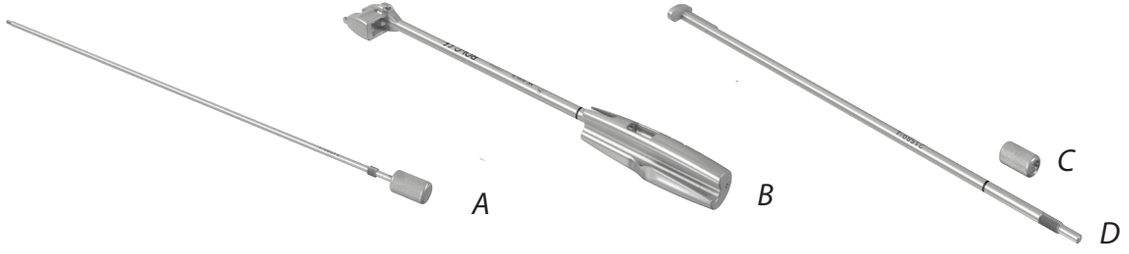
The ROI-C system offers three depth stops:

- Small Depth Stop (Part of MC9091R-3): width 5mm x height 3.72mm
- Large Depth Stop (MC9004R): width 8.2mm x height 4mm
- U-Shape Depth Stop (SI-ROIC-0063): width 14.41mm x height 6.35mm



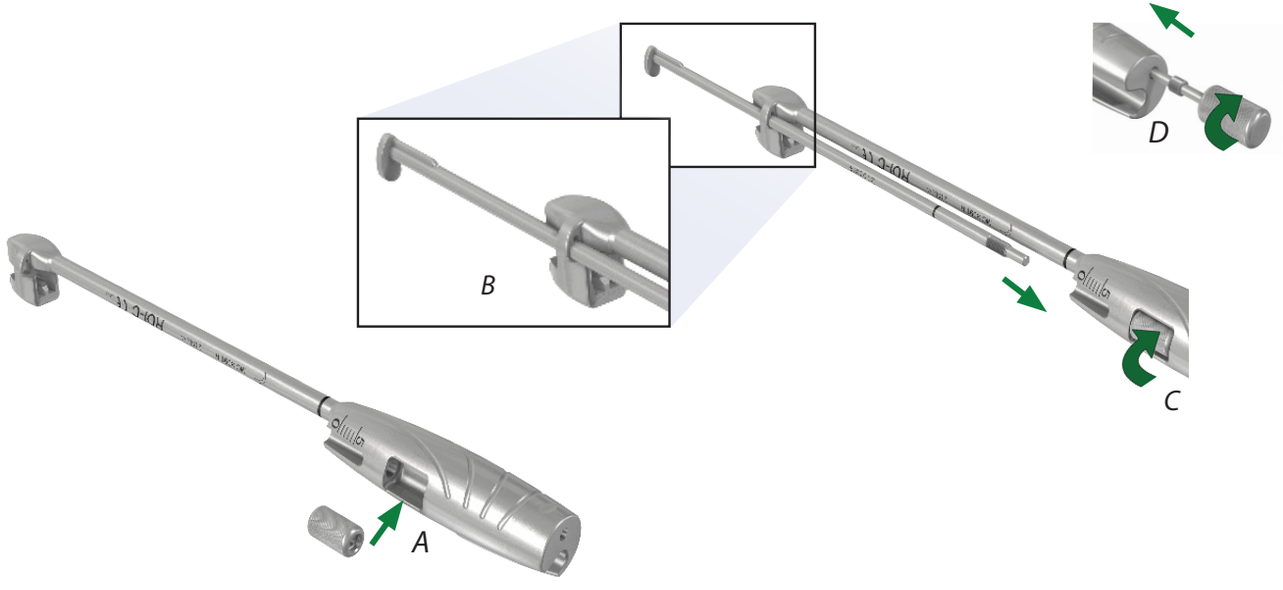
IMPLANT HOLDER COMPONENTS

A. Inner Threaded Rod (MC9091R-2)
B. Implant Holder (MC9091R)
C. Thumb Wheel (MC9091R-4)
D. Depth Stop (Large shown here)



IMPLANT HOLDER ASSEMBLY

1. Load the thumb wheel (A) into the pocket on the inserter body. Hold thumb over wheel to mantain position.
2. Slide the depth stop through the arch at the distal tip of the inserter (B) and into the thumb wheel. Capture the depth stop by rotating the thumb wheel clockwise (C), and adjust to 0.
3. Load the threaded rod into the cannula of the inserter through the handle (D) and rotate clockwise to securely capture.



IMPLANT CONNECTION TO IMPLANT HOLDER

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

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

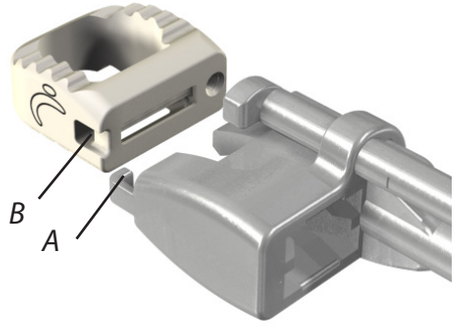
It is critical to firmly secure the implant to the holder, without over tightening.

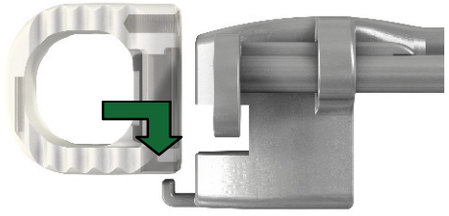
The connection is fully secure when there is:

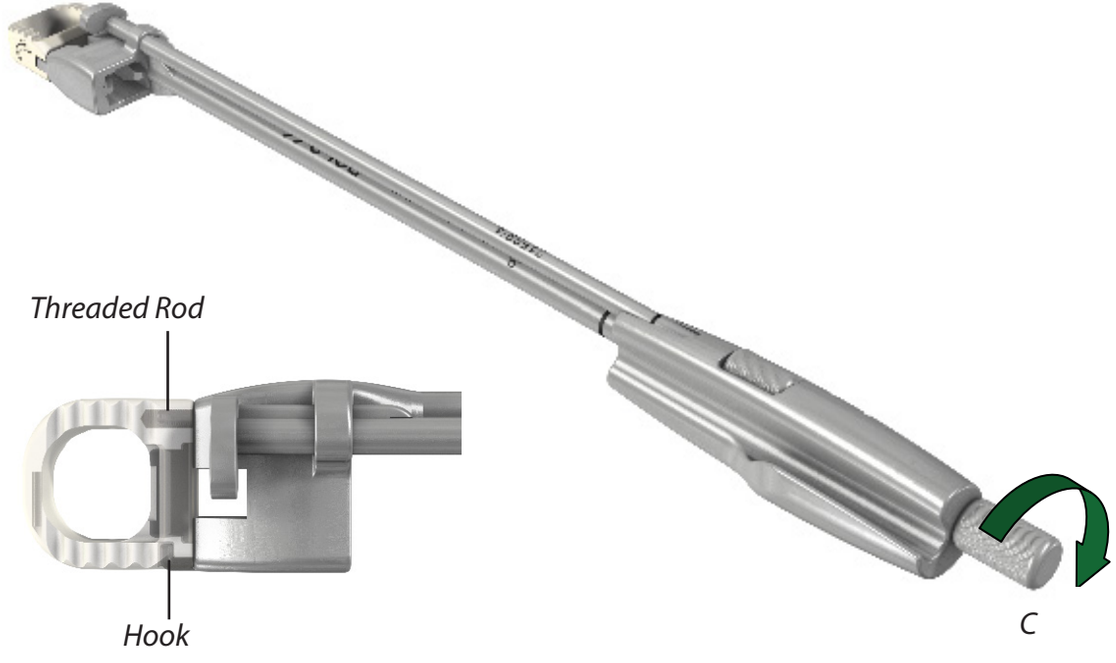
- No toggle in the connection.
- No gap visible between the knob and the handle.

Load the central space of the implant with graft.

Note: Overtightening of the threaded rod on the implant could strip the PEEK threads and weaken the implant to Holder connection.

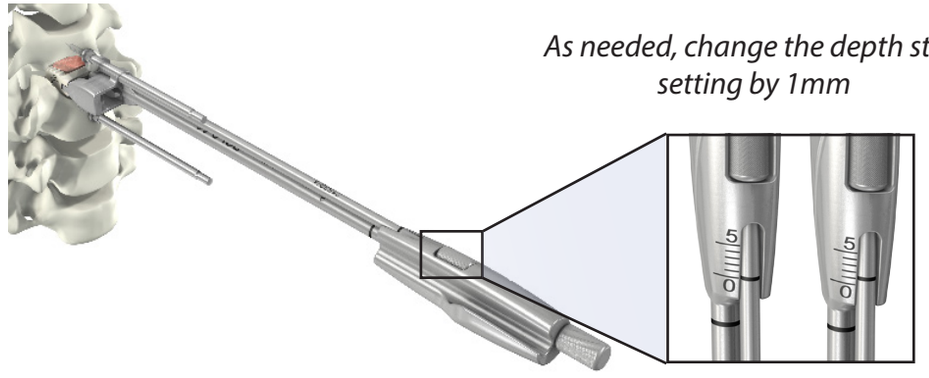






IMPLANT INSERTION

Start by setting the depth stop on the Implant Holder to 0mm. When the stop is set to 0mm, the implant will be recessed from the anterior aspect of the vertebral body by **1mm** into the disc space.

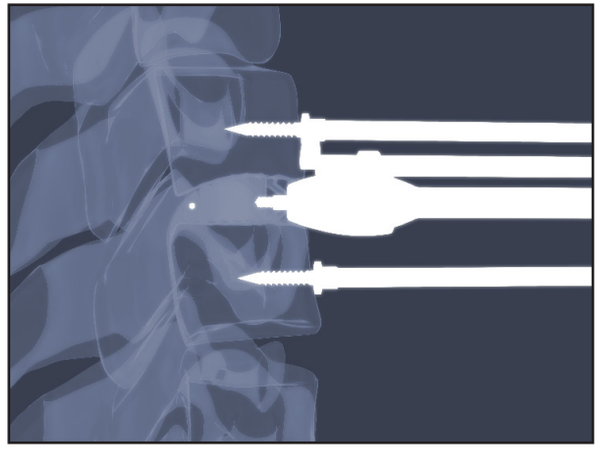


As needed, change the depth stop setting by 1mm

Insert the implant into the disc space by gently tapping on the end of the Implant Holder. Try to keep the Implant Holder at a 90° angle to the disc space during insertion.

As needed, change the depth stop setting by 1mm for posterior adjustment, by turning the knurled wheel clockwise.

*Use radiographic imaging to make a final assessment of the implant depth and endplate coverage, prior to plate insertion. A tantalum marker is located 1mm from the posterior implant edge for positioning reference.



**Note: Radiographic imaging is mandatory prior to plate insertion.*

OPTIONAL

STARTER AWL PLATE SELECTION

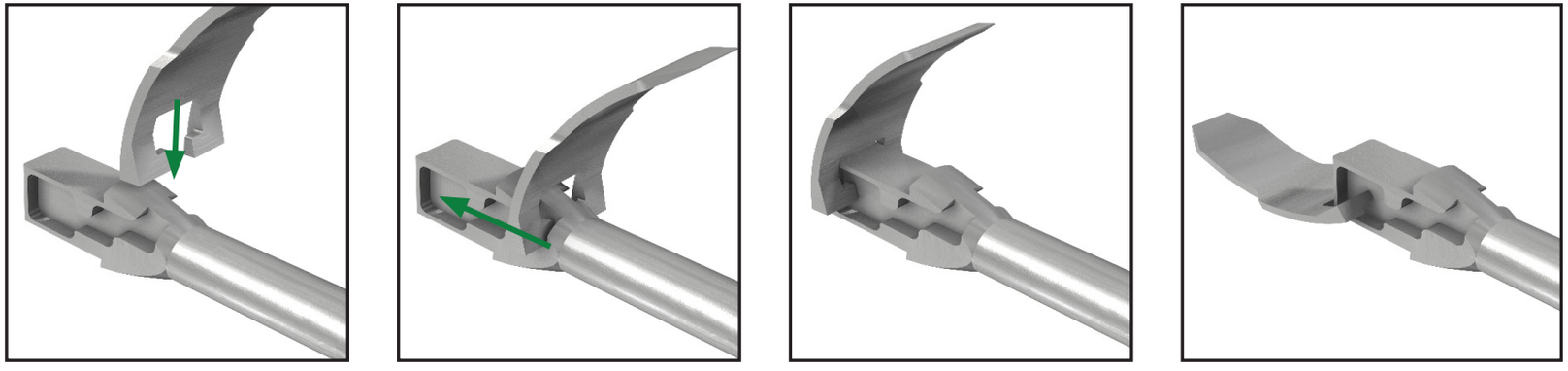
The Starter Awl (SI-ROIC-0065) may be used especially when sclerotic bone is detected. With the cage in the final position, the Awl may be used to initiate the path for the VerteBRIDGE® plates.

The Starter Awl works with two different sizes of Starter Plates, selected based on the height of the implant.

- Short (SI-ROIC-0067) for implants with 5-7mm heights
- Long (SI-ROIC-0066) for implants with 8-10mm heights

STARTER AWL ASSEMBLY

Choose the proper size Starter Plate and slide the plate into the grooves at the distal end of the Starter Awl as shown below.



STARTER AWL INSERTION

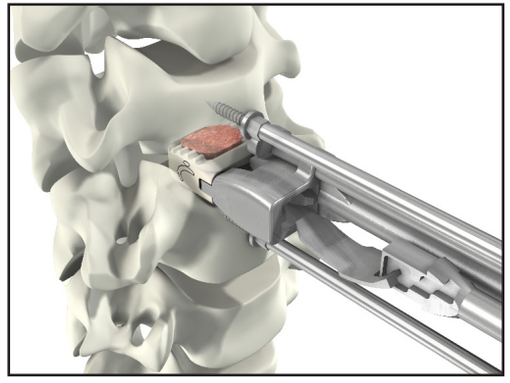
Place the Starter Awl into the chosen slot in the Implant Holder,* the same channel used for a VerteBRIDGE plate. The plate paths cross in the Implant Holder, so a Starter Awl inserted into the cranial slot will advance into the caudal vertebral body; a Starter Awl inserted into the caudal slot will advance into the cranial vertebral body.

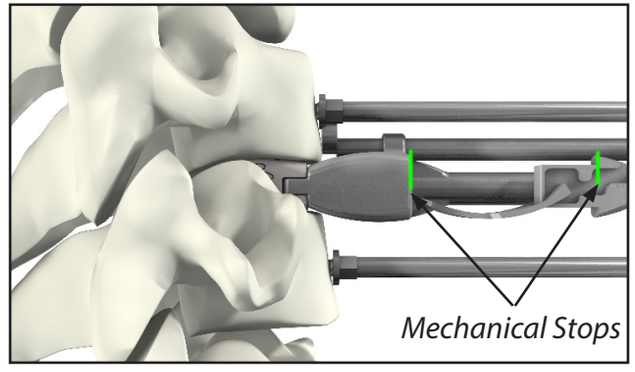
**Note: Use the same method as the VerteBRIDGE plates.*

Impact the Starter Awl with a mallet until the mechanical stop on the Starter Awl Impactor meets the mechanical stop on the Implant Holder. Remove the Starter Awl with the attached Starter Awl Plate.

Repeat the Starter Awl insertion on the opposite vertebral body.

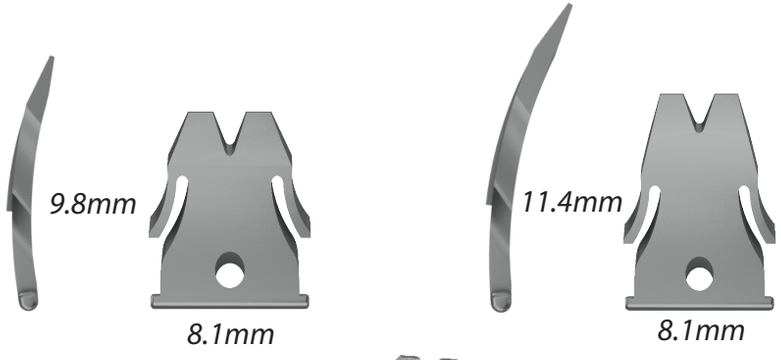
Note: A pair of pick-ups may assist in feeding the Starter Awl Plate into the slot of the Implant Holder.

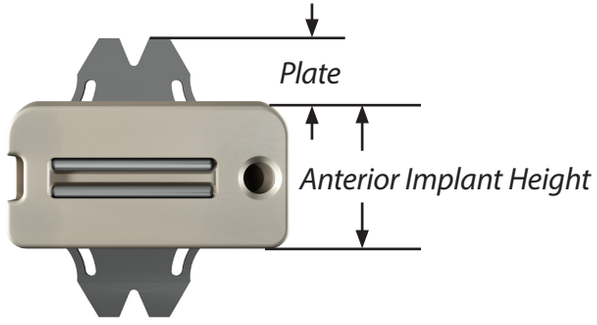




VERTEBRIDGE PLATE SELECTION

Select the plate length according to the height of the implant besing used. Use the ROI-C Standard Plate (MC1005T) with heights 5-7mm and the ROI-C Long Plate (MC1006T) with 8-10mm heights.





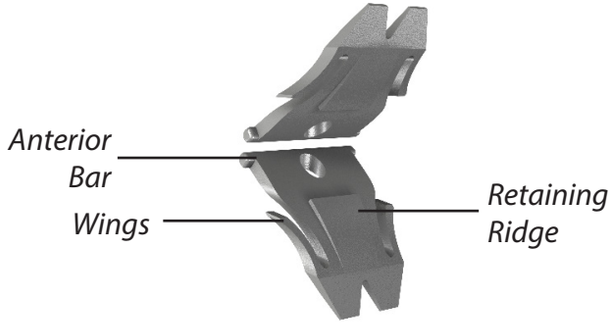


PLATE REFERENCE TABLE

Implant Height (mm)	H5	H6	H7	H8
Plate Size (Reference Number)	Standard MC 1005T			Long MC 1006T
Plate Height (mm)	5.5	5.0	4.5	5.6

Anatomic

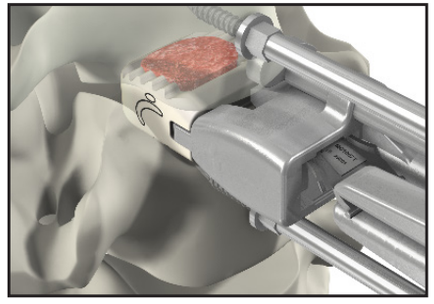
Implant Height (mm)	H5	H6	H7	H8	H9	H10
Plate Size (Reference Number)	Standard MC 1005T			Long MC 1006T		
Plate Height (mm)	5.7	5.3	4.8	5.9	5.4	4.9

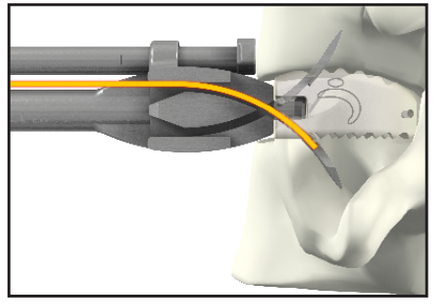
Lordotic

LOAD FIRST PLATE

Prior to inserting the first plate, release the distractor and Caspar Pins (if used), to allow compression of the construct.

With the implant in the final position, load the first plate into the cranial slot of the Implant Holder using the Plate Holder (MC901R). The plate paths cross within the Implant Holder so the plate inserted into the cranial slot will be advanced into the caudal vertebral body.



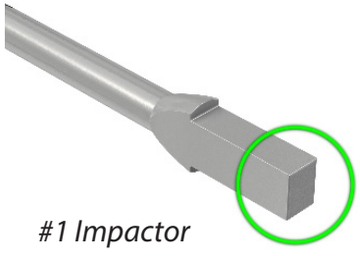


Note: The plates may be inserted into the cranial or caudal slot for the first plate.

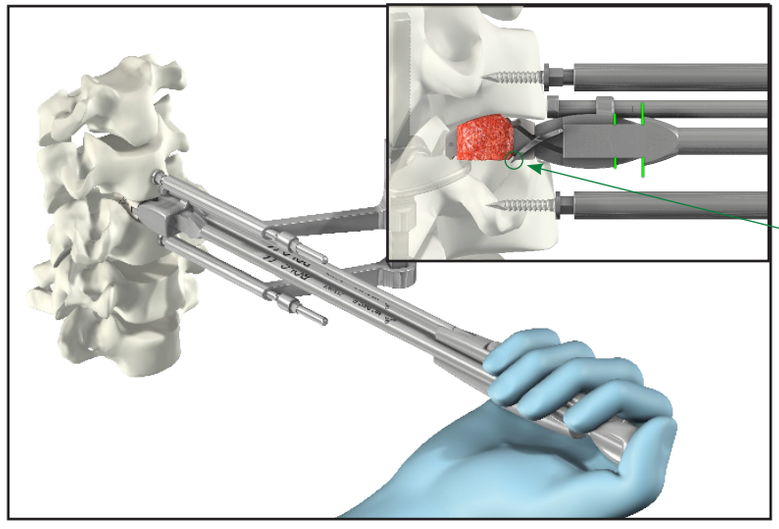
ADVANCE FIRST PLATE

Using thumb pressure, insert the #1 Impactor (MC9092R) to advance the first plate until it touches bone.* Take a lateral radiographic image to verify the plate is touching the bone.

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



#1 Impactor



bone/plate contact

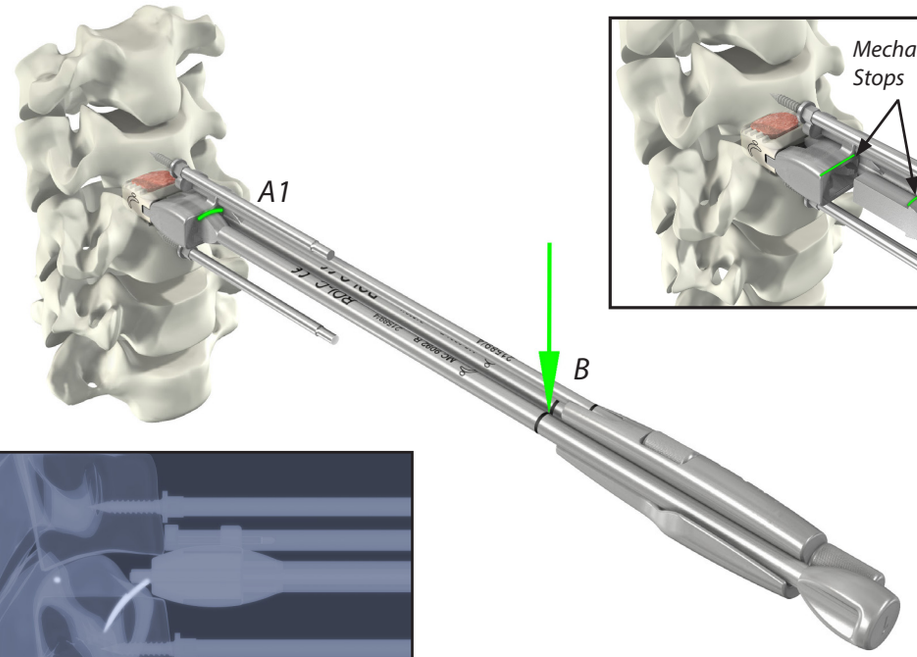
ADVANCE FIRST PLATE CONTINUED

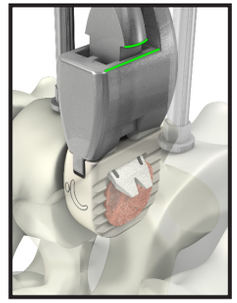
Use a mallet to impact the first plate into the bone. The plate is fully advanced when the:

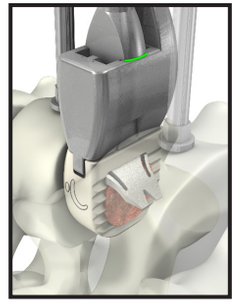
- Mechanical stop on the Impactor meets the mechanical stop of the Implant Holder (A1/A2).

Do not proceed to the #2 Impactor until proper placement of the implant and first plate are confirmed via fluoroscopy or x-ray (C).

**Note: The impaction lines (B) will allow visualization of the plates' advancement and the mechanical stops should make contact when the lines appear aligned.*

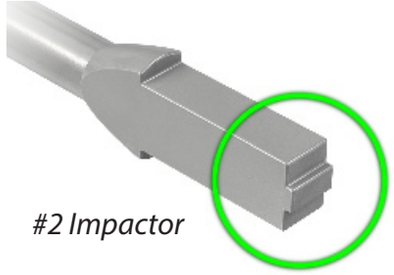






FINALIZE FIRST PLATE POSITION

Once position is confirmed, use the #2 Impactor (MC9093R) to finalize the advancement of the first plate. Again, the plate will have advanced completely when the mechanical stop on the #2 Impactor meets the mechanical stop on the Implant Holder.



#2 Impactor

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

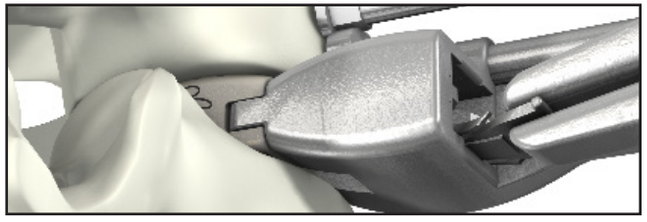
**Note: The plates must be advanced and finalized using this sequence:*

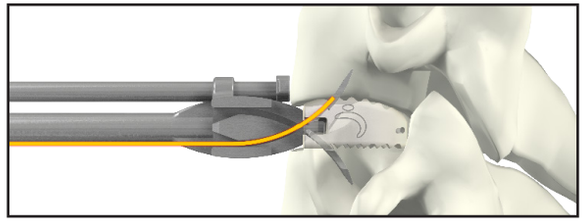
1st Plate	*• Advance with thumb pressure* *• #1 Impactor* *• #2 Impactor*
2nd Plate	*• Advance with thumb pressure* *• #1 Impactor* *• #2 Impactor*

LOAD SECOND PLATE

Confirm that the knob on end of Implant Holder is fully tightened. Insert the second plate into the caudal slot of the Implant Holder (or the cranial slot if the first plate was inserted into the caudal slot).

The second plate can only be inserted after the first plate is fully advanced.

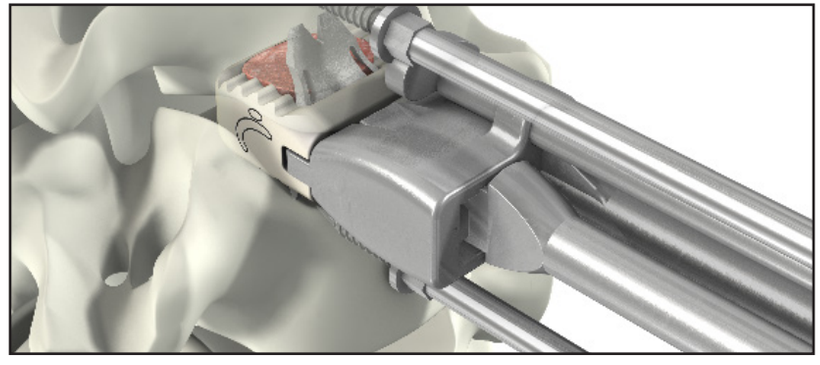




ADVANCE AND FINALIZE SECOND PLATE

Using the same plate advancement and confirmation technique, apply thumb pressure on the #1 Impactor to advance the second plate until it touches bone. Then mallet the #1 Impactor to insert the second plate into the bone.

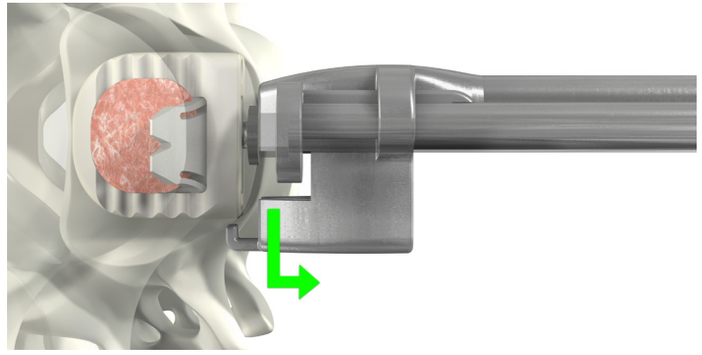
Confirm position under radiographic imaging, then use the #2 Impactor to finish advancing the plate. The plate is fully advanced when the mechanical stop on the Impactor meets the mechanical stop of the Implant Holder.



IMPLANT HOLDER REMOVAL AND FINAL ASSESSMENT

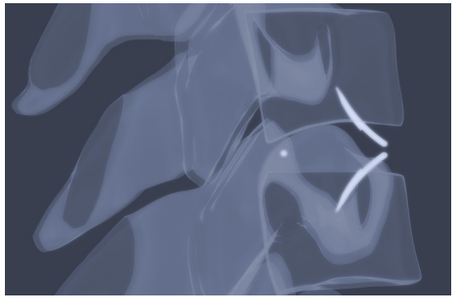
IMPLANT HOLDER REMOVAL

Remove the Implant Holder by turning the knob on the end of the Holder counter-clockwise until the threads disengage and the inner threaded rod can be removed from the inserter. Slide the Holder to the left releasing the hook from the slot in the implant before removing the Holder from the wound.

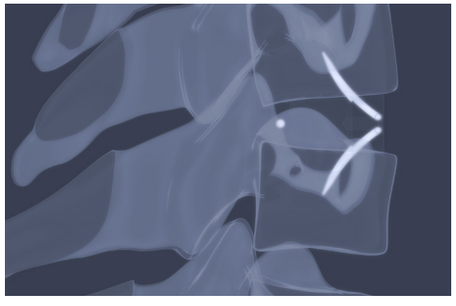


FINAL FLUOROSCOPY OR X-RAY OF PROPER PLACEMENT*

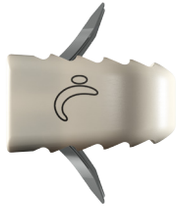
Confirm proper placement with radiographic imaging.



Anatomic



Lordotic

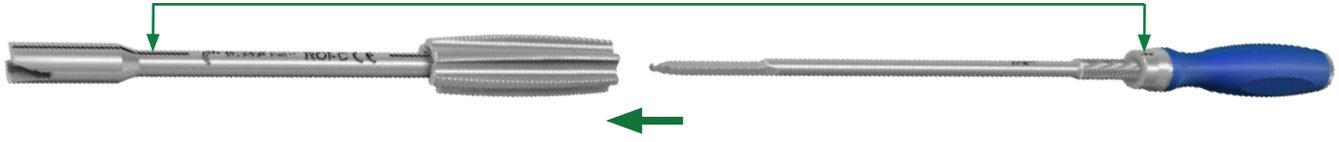


**Note: In cases of vertebral instability or significant bone removal the ROI-C implant with VerteBRIDGE plating should be augmented with additional supplemental fixation.*

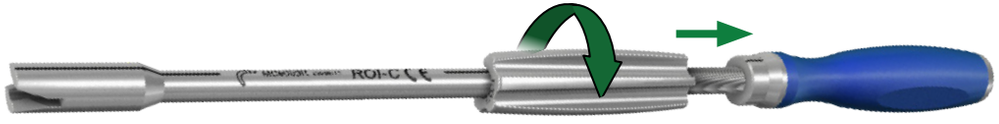
REVISION INSTRUMENT ASSEMBLY

Insert the knob onto the sleeve of the Revision Instrument (MC9089R).

Orient the black line on the distal end of the sleeve with the black line on the handle. With this orientation, the top or opening of the hook is visible. Then, insert the hook into the sleeve of the removal instrument.



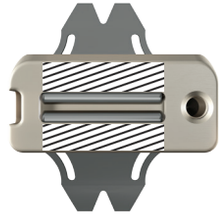
Rotate the knob counter-clockwise until it stops against the handle.



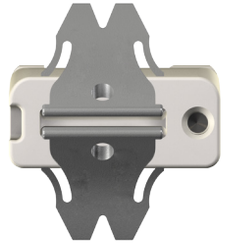
The assembled Plate Removal Instrument is shown here.

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 removed. The diagonal stripes show the PEEK that must be removed to expose the plates.

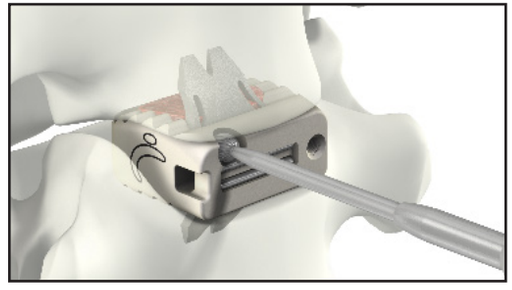


Removal areas



After removal

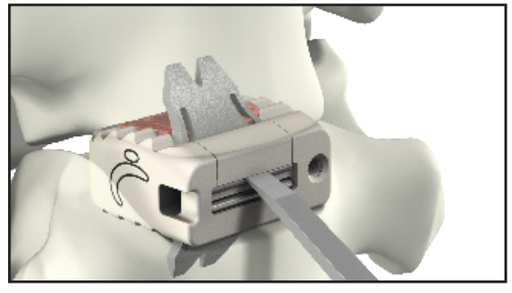
Under irrigation, use a burr to create a notch on each side of the plate, weakening the PEEK for removal.



Use a pick-up to remove loose pieces of PEEK. The Osteotome (MC9088R) can also be used to break and release any remnant PEEK pieces.

Note: An Osteotome may be used instead of the burr for PEEK removal.

Repeat these steps to remove the PEEK in front of the second plate.

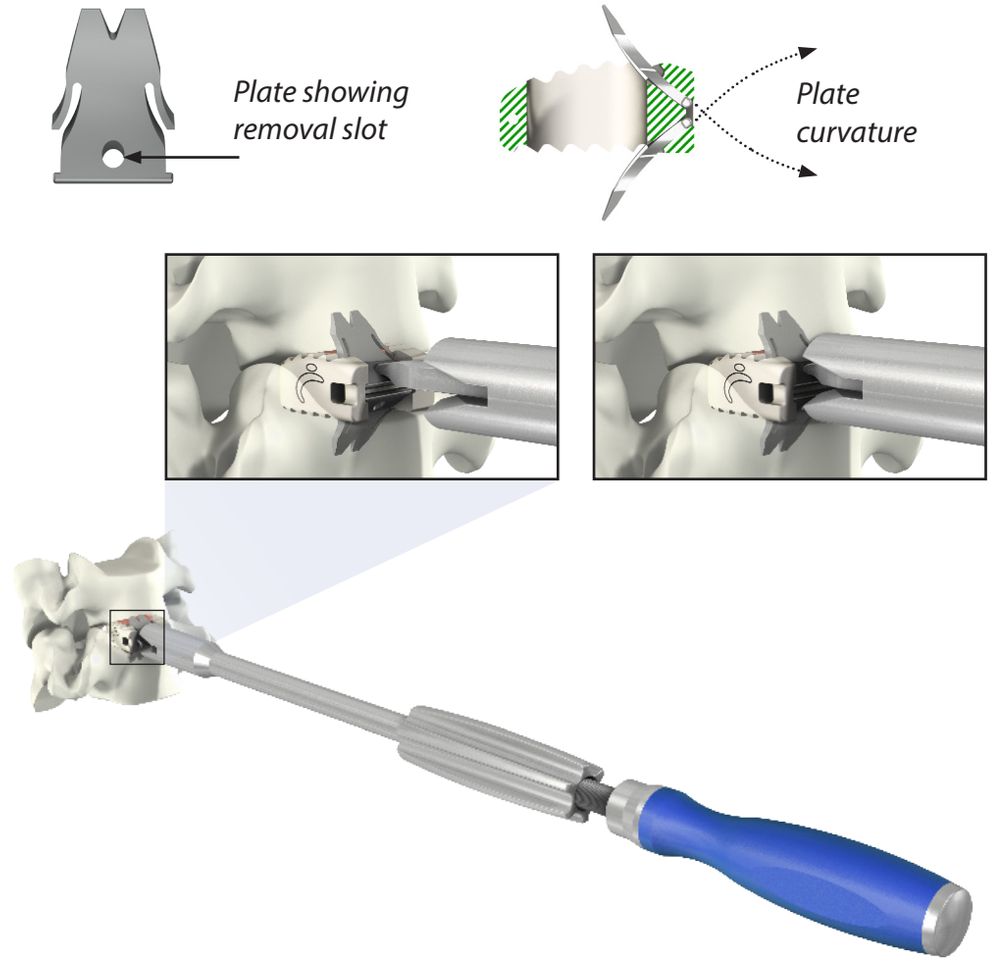


Insert the hook of the Plate Removal Instrument in the plate hole.

Advance the sleeve of the removal instrument to the anterior face of the vertebrae by turning the knob of the removal instrument clockwise.

Lock the hook on the plate and continue turning the knob clockwise to remove the plate from the cage.

Turn the instrument 180° such that the hook is positioned to grasp the second plate, and repeat these steps to extract the second plate.



IMPLANT REMOVAL

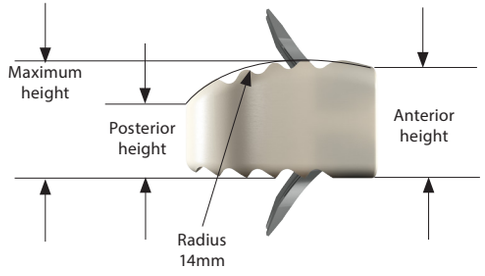
A Kocher may be used or the Implant Holder attached to remove the implant anteriorly. If the implant cannot be easily removed, a Cobb Elevator or Osteotome may be used to loosen the bone to implant interface.

Note: The Plate Removal Instrument should be disassembled before being placed in the tray for sterilization.

IMPLANT REFERENCE TABLES

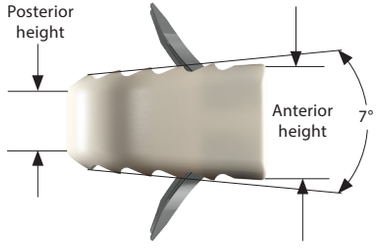
Anatomic

Depth x Width (mm)	Reference Number	Anterior Height	Maximum Height	Posterior Height	Graft Volume (cc)
12x14 , H5	MC 1341 P	5	5.5	3	0.31
12x14 , H6	MC 1342 P	6	6.5	4	0.36
12x14 , H7	MC 1343 P	7	7.5	5	0.41
12x14 , H8	MC 1344 P	8	8.5	6	0.45
12 x 15.5, H5	MC 1351 P	5	5.5	3	0.31
12 x 15.5 , H6	MC 1352 P	6	6.5	4	0.36
12 x 15.5 , H7	MC 1353 P	7	7.5	5	0.41
12 x 15.5 , H8	MC 1354 P	8	8.5	6	0.45
14 x 15.5 , H5	MC 1321 P	5	5.9	3	0.42
14 x 15.5 , H6	MC 1322 P	6	6.9	4	0.48
14 x 15.5 , H7	MC 1323 P	7	7.9	5	0.54
14 x 15.5 , H8	MC 1324 P	8	8.9	6	0.60
14 x 17 , H5	MC 1331 P	5	5.9	3	0.51
14 x 17 , H6	MC 1332 P	6	6.9	4	0.60
14 x 17 , H7	MC 1333 P	7	7.9	5	0.67
14 x 17 , H8	MC 1334 P	8	8.9	6	0.75



Lordotic

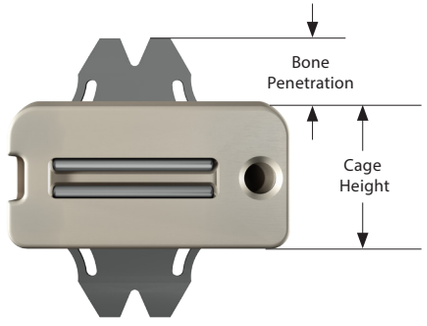
Depth x Width (mm)	Reference Number	Anterior Height	Posterior Height	Graft Volume (cc)
12 x 14 , H5	MC 1441 P	5	2.3	0.30
12 x 14 , H6	MC 1442 P	6	3.1	0.35
12 x 14 , H7	MC 1443 P	7	4.1	0.41
12 x 14 , H8	MC 1444 P	8	5.1	0.47
12 x 14 , H9	MC 1445 P	9	6.1	0.53
12 x14, H10	MC 1446 P	10	7.1	0.59
12 x 15.5, H5	MC 1451 P	5	2.3	0.30
12 x 15.5 , H6	MC 1452 P	6	3.1	0.35
12 x 15.5 , H7	MC 1453 P	7	4.1	0.41
12 x 15.5 , H8	MC 1454 P	8	5.1	0.47
12 x 15.5 , H9	MC 1455 P	9	6.1	0.53
12 x 15.5 , H10	MC 1456 P	10	7.1	0.59
14 x 15.5 , H5	MC 1421 P	5	2.4	0.36
14 x 15.5 , H6	MC 1422 P	6	3.2	0.42
14 x 15.5 , H7	MC 1423 P	7	4.2	0.49
14 x 15.5 , H8	MC 1424 P	8	5.2	0.57
14 x 15.5 , H9	MC 1425 P	9	6.2	0.64
14 x 15.5 , H10	MC 1426 P	10	7.2	0.72
14 x 17 , H5	MC 1431 P	5	2.4	0.44
14 x 17 , H6	MC 1432 P	6	3.2	0.52
14 x 17 , H7	MC 1433 P	7	4.2	0.61
14 x 17 , H8	MC 1434 P	8	5.2	0.71
14 x 17 , H9	MC 1435 P	9	6.2	0.80
14 x 17 , H10	MC 1436 P	10	7.2	0.89



STARTER AWL PLATE AND VERTEBRIDGE PLATE REFERENCE TABLES

Anatomic

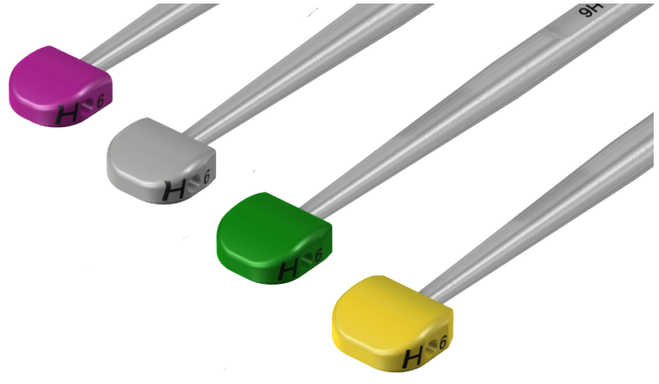
	Starter Plate		ROI-C VerteBRIDGE® Plate		
Cage Height	Size	Bone Penetration (mm)	Part Number	Bone Penetration (mm)	Penetration Difference (mm)
H5	Short (SI-ROIC-0067)	5.2	Short (MC 1005T)	5.5	0.3
H6		4.7		5.0	0.3
H7		4.2		4.5	0.3
H8	Long (SI-ROIC-0066)	5.3	Long (MC 1006T)	5.6	0.3



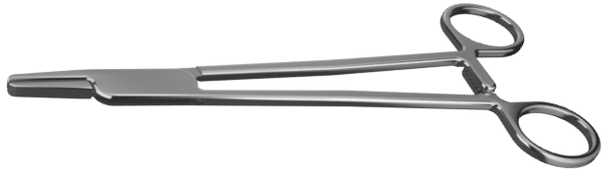
Lordotic

	Starter Plate		ROI-C VerteBRIDGE® Plate		
Cage Height	Size	Bone Penetration (mm)	Part Number	Bone Penetration (mm)	Penetration Difference (mm)
H5	Short (SI-ROIC-0067)	5.4	Short (MC 1005T)	5.7	0.3
H6		5.0		5.3	0.3
H7		4.5		4.8	0.3
H8	Long (SI-ROIC-0066)	5.6	Long (MC 1006T)	5.9	0.3
H9		5.1		5.4	0.3
H10		4.6		4.9	0.3

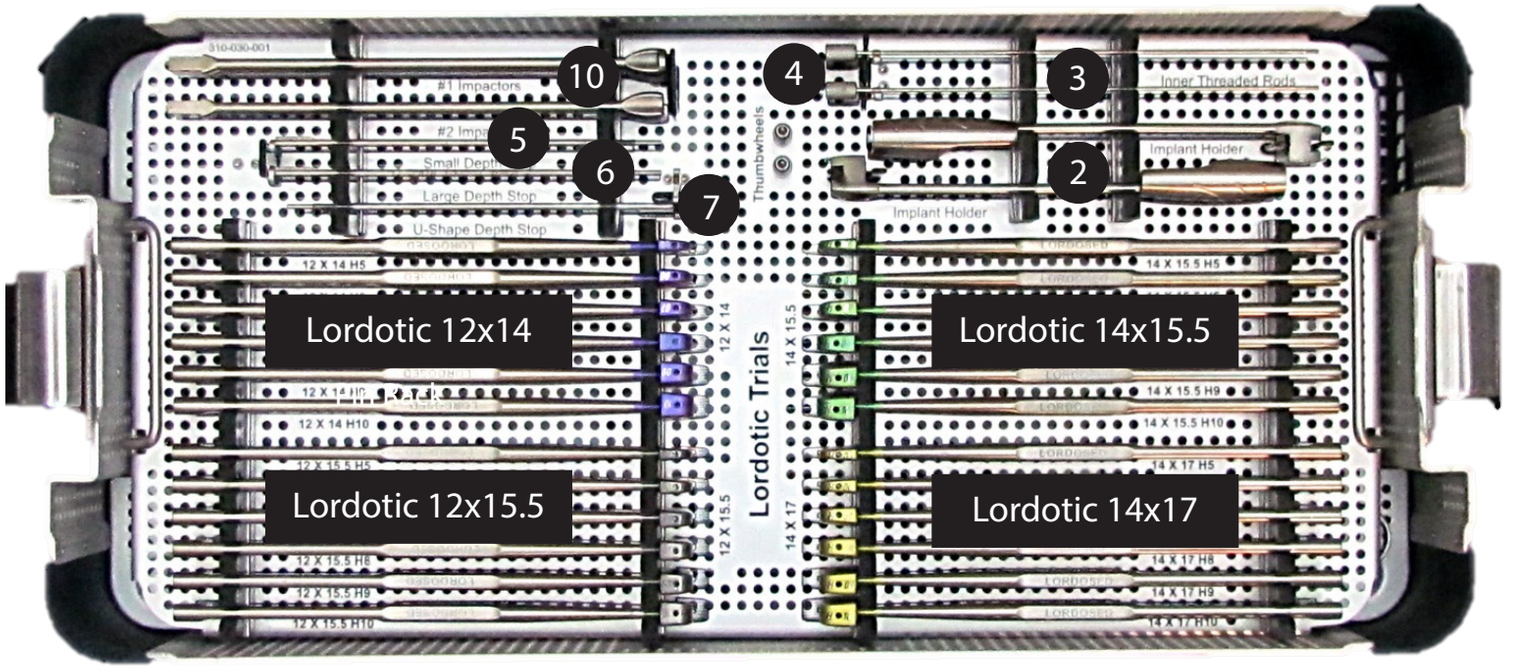
Lordotic Trials (Top Tray)		Anatomic Trials (Bottom Tray)	
MC9100R	Trial 12x14 H5	MC9011R	Trial 12x14 H5
MC9101R	Trial 12x14 H6	MC9012R	Trial 12x14 H6
MC9102R	Trial 12x14 H7	MC9013R	Trial 12x14 H7
MC9103R	Trial 12x14 H8	MC9014R	Trial 12x14 H8
MC9104R	Trial 12x14 H9		
MC9105R	Trial 12x14 H10	MC9018R	Trial 12x15.5 H5
		MC9019R	Trial 12x15.5 H6
MC9106R	Trial 12x15.5 H5	MC9020R	Trial 12x15.5 H7
MC9107R	Trial 12x15.5 H6	MC9021R	Trial 12x15.5 H8
MC9108R	Trial 12x15.5 H7		
MC9109R	Trial 12x15.5 H8	MC9032R	Trial 14x15.5 H5
MC9110R	Trial 12x15.5 H9	MC9033R	Trial 14x15.5 H6
MC9111R	Trial 12x15.5 H10	MC9034R	Trial 14x15.5 H7
		MC9035R	Trial 14x15.5 H8
MC9118R	Trial 14x15.5 H5		
MC9119R	Trial 14x15.5 H6	MC9039R	Trial 14x17 H5
MC9120R	Trial 14x15.5 H7	MC9040R	Trial 14x17 H6
MC9121R	Trial 14x15.5 H8	MC9041R	Trial 14x17 H7
MC9122R	Trial 14x15.5 H9	MC9042R	Trial 14x17 H8
MC9123R	Trial 14x15.5 H10		
MC9124R	Trial 14x17 H5		
MC9125R	Trial 14x17 H6		
MC9126R	Trial 14x17 H7		
MC9127R	Trial 14x17 H8		
MC9128R	Trial 14x17 H9		
MC9129R	Trial 14x17 H10		



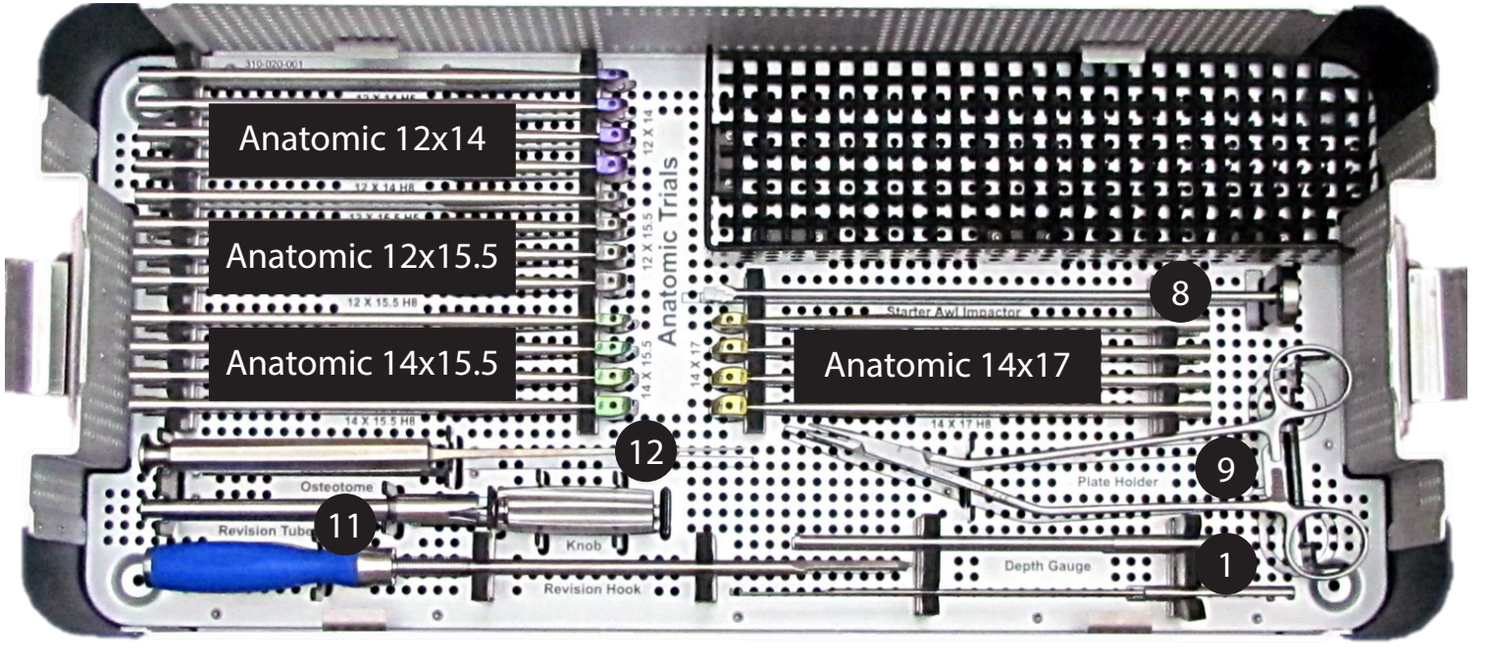
1	MB906R	Depth Gauge	
2	MC9091R	Implant Holder	
3	MC9091R-2	Inner Threaded Rod	
4	MC9091R-4	Thumb Wheel	
5	MC9091R-3	Small Depth Stop	
6	MC9004R	Large Depth Stop	
7	SI-ROIC-0063	U-Shape Depth Stop	

8	SI-ROIC-0065	Starter Awl Impactor	
9	MC901R	Plate Holder	
10	MC9092R	ROI-C Impactor #1	
	MC9093R	ROI-C Impactor #2	
11	MC9089R	ROI-C Plate Removal Instrument	
12	MC9088R	Osteotome	

Top Tray



Bottom Tray



DEVICE DESCRIPTION AND USE GUIDELINES

DEVICE DESCRIPTION

The ROI-C Implant System consists of 'D' shaped blocks in a variety of footprints and heights. The lordotic shape of the ROI-C Lordotic Implants allows for optimum surface area contact with vertebrae that embody a flat surface morphology. The curved shape of the ROI-C Anatomic Implants allows for optimum surface area contact with vertebrae that embody a curved surface morphology. The ROI-C Implant System 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 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-C Implant System has been designed to be compatible with optional supplemental fixation specific for the system. The two piece VerteBRIDGE Anchor Plate is available and may be used to affix the ROI-C Implant System implants to the underlying vertebral bone, and to specifically allow for the option of a standalone construct. Additional or other supplemental fixation may be used, as patient needs dictate.

INDICATIONS

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 non-operative treatment. The ROI-C Implant System implants are to be used with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous 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 cervical interbody fusion construct is appropriate. Additional supplemental fixation options that can be used with the ROI-C cage (with or without VerteBRIDGE Plating) include anterior vertebral plating and other fixation devices cleared by the FDA in the cervical spine.

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.

WARNINGS

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

- The device can break if it is subjected to increased loading associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Discard all damaged or mishandled implants.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily 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.

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.)
- Supplemental internal fixation is required when using the *ROI -C Implant System*. The two piece *VerteBRIDGE* Anchor Plate system is available for use with the *ROI-C Implant System*, 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.

MRI SAFETY INFORMATION

LDR Inc.'s ROI-C Implant System is comprised of non-ferromagnetic titanium alloy (Ti6Al4V), polyetheretherketone (PEEK) and tantalum.
Non-clinical testing has demonstrated that the Interbody Cage Systems are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 3100 G/cm (31 T/m) for 1.5T systems and 1500 G/cm (15 T/m) for 3.0T systems.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning at 3.0T.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

3.0T RF heating
In non-clinical testing with body coil excitation, the ROI-C Implant System produced a differential temperature rise of less than or equal to 1.0ºC when exposed to a whole-body averaged specific absorption rate (SAR) of 3.2 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that a maximum whole-body SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0ºC.

1.5T RF heating
In non-clinical testing with body coil excitation, the ROI-C Implant System produced a differential temperature rise of less than or equal to 1.0ºC when exposed to a whole-body averaged specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that a maximum whole-body SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than or equal to 1.0ºC.

MR Artifacts
In testing using 1.5T and 3.0T systems with gradient-echo sequencing, the shape of the image artifact produced follows the approximate contour of the device and extends radially up to 1.0 cm from the implant.

PRODUCT COMPLAINTS

Any healthcare professional (e.g. a surgeon using a product) who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the system should notify LDR Spine USA. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, telephone, fax or letter should notify LDR Spine USA as soon as possible. All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s). The person formulating the complaint should give as many details as possible and state the response required. For further information, kindly contact LDR Spine USA.

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