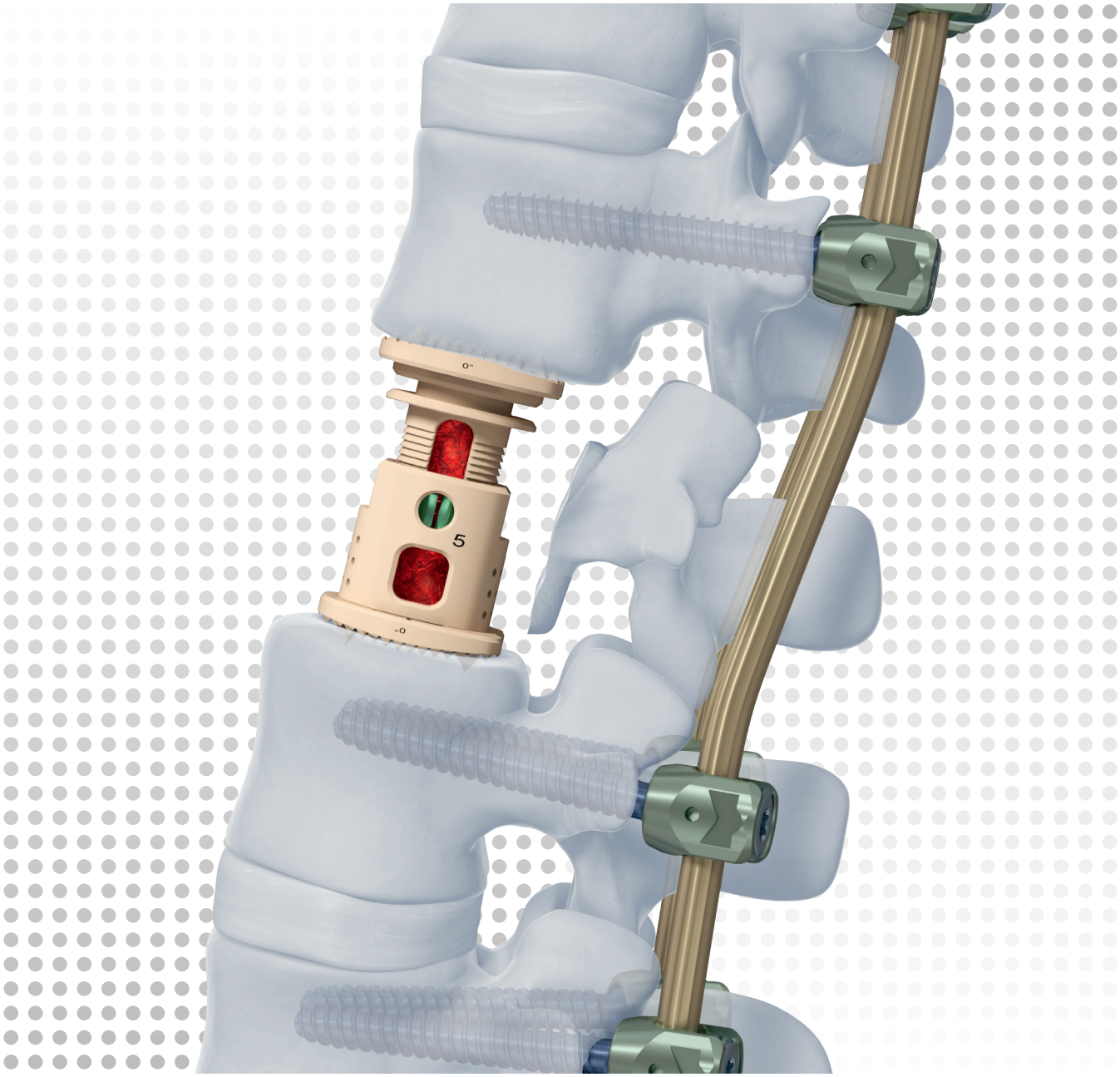
XRL®

Vertebral Body Replacement Device

Surgical Technique Guide



DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Table of Contents

▲ Warnings

* For Product Catalog contact your local Depuy Synthes representative

Introduction

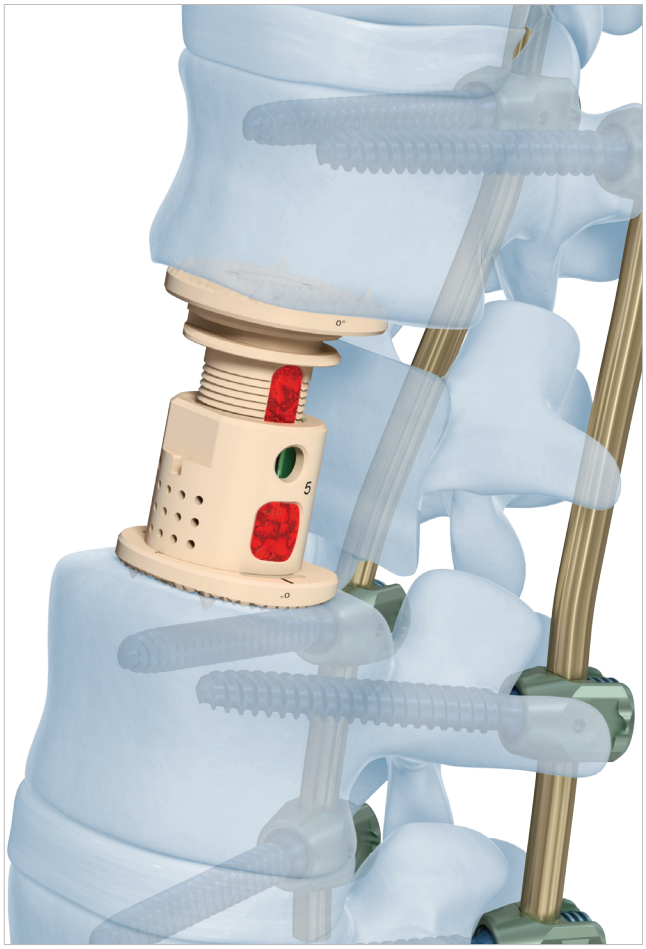
XRL®. A modular expandable radiolucent vertebral body replacement system.

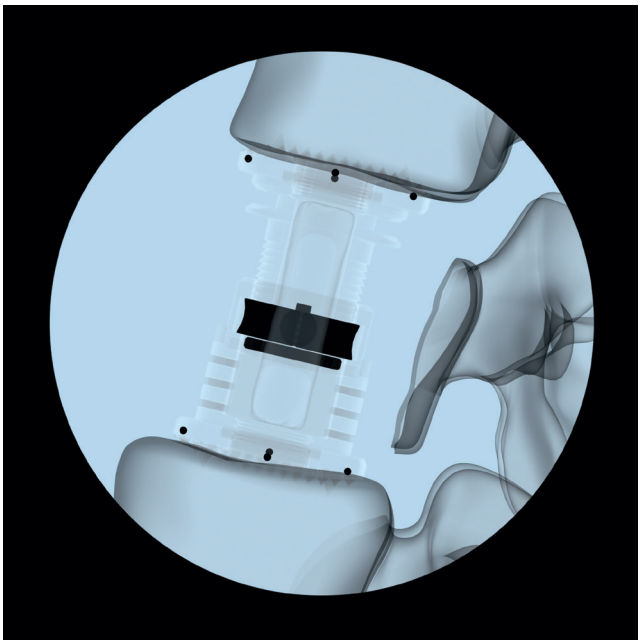
XRL is designed to provide surgeons the ability to expand the device in situ.

- Integrated and modular implants.
- Multiple surgical approach options.
- Various implant options to accommodate a range of anatomies.

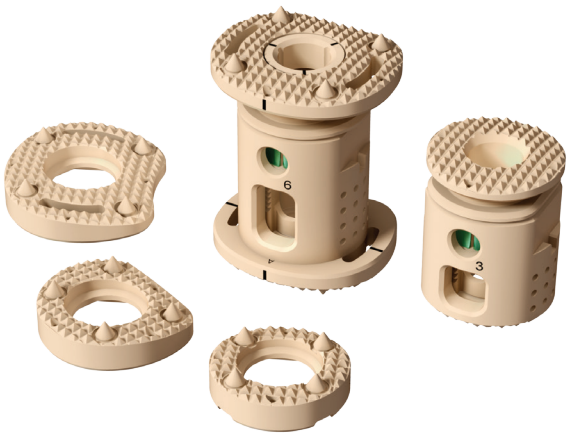
PEEK Material

- Provides radiolucent imaging.
- Offers a modulus of elasticity similar to that of bone.





Implant Options



Modular Implants

The modular implant consists of a central body on which two endplates are attached.

Central body
- The octagonal shape permits various surgical approach options

Endplates
- Numerous footprint sizes and angles

Endplate screw
- Secures the endplate to the central body

Integrated Implants

- No assembly required.
- Can be used where low-profile constructs might be needed.

Self-locking expansion mechanism

- Distracts and locks in 1 mm increments.

Open architecture

- The open central body and endplate design allows placement of bone graft material.
  (Implant cannulation : 8.4mm diameter)

Instrumentation

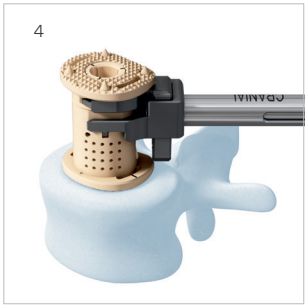
One instrument, designed to provide:
- Holding and insertion of the implant
- Distraction and locking
- Contraction and repositioning of implant if needed

Ratchet mechanism and continuous expansion options
- Implant can be expanded incrementally or continually
- Scale indicates the amount of distraction performed

Repositionable handle (prior to insertion) to facilitate intraoperative visualization”

Approach Options

- Anterior (1)
- Anterolateral (2)
- Lateral (3)
- Posterolateral (4)



AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.[1,2]

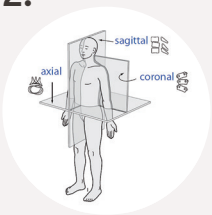
AO Principles[1,2]

1.

Stability

Stabilization to achieve a specific therapeutic outcome.

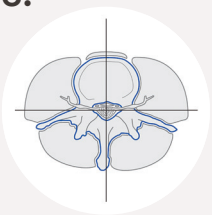
2.



Alignment

Balancing the spine in three dimensions.

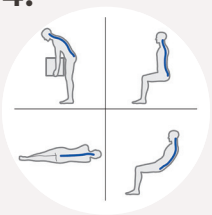
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

Preservations and restoration of function to prevent disability.

Preparation

1. Access

Various approaches are suitable depending on the affected spinal level involved.

The following surgical technique is described using a lateral approach from the left at L1. As with all vertebral body replacement systems, preoperative planning is always required to ascertain that the implant matches the patient specific anatomy.

- **The desired approach respecting the patient specific situation has to be established by the surgeon.**

2. Perform corpectomy

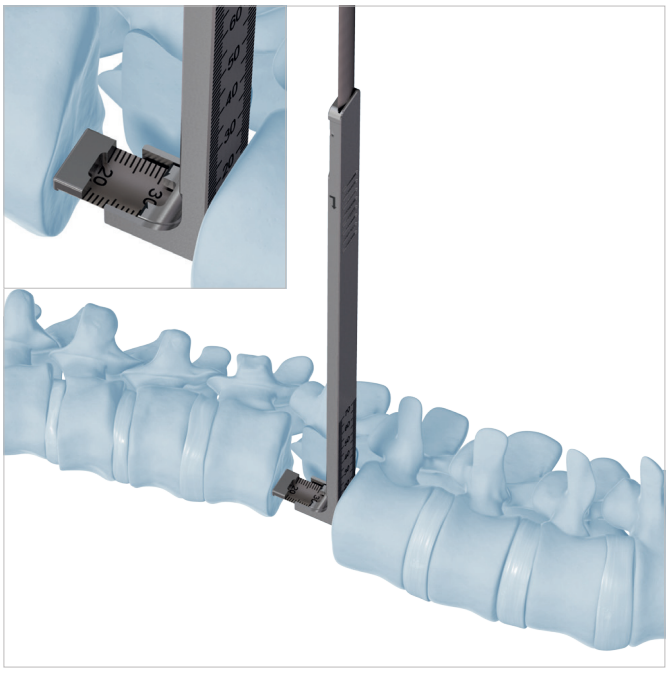
Perform a partial or complete corpectomy as required. Remove the superficial layers of the entire cartilaginous endplates and expose bleeding bone.

▲ Warning:

Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the XRL implant, potentially resulting in subsidence.

Insert Trial Implant

The XRL Vertebral Body Replacement contains a range of central body and endplate trial implants that correspond to each central body and endplate implant. Trials are placed into the corpectomy site intraoperatively to determine the appropriate endplate footprint, angle, and central body height.

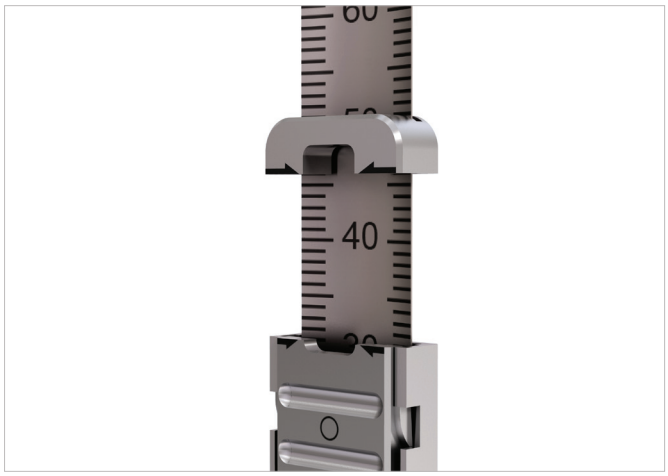


1. Determine defect size

Instrument	
03.661.010	Metal Tape Gauge, measuring range 20 to 150 mm

The metal tape gauge can be used to determine the overall defect size.

If the corpectomy height is less than 34 mm, then proceed to step 4 of this section and use the integrated trials.



2. Select endplate footprint size and angle

Instruments	
XRL Medium, Endplate Trials Instrument for Footprint	
03.807.364	21 mm, round
03.807.365	21 × 24 mm
03.807.366	26 × 30 mm

The endplate footprint trial can be adjusted to represent the desired approach. Pull the sleeve ① and turn the endplate trial to the desired position ②. Release the sleeve to lock the position of the trial.

- Determine the footprint using the endplate footprint trial. Determine the angle using lateral x-ray imaging.

▲ Precaution:

Make sure that the endplate trial contacts the maximum area of the neighboring vertebral bodies but do not project over the edge.

3. Determine central body size

The optimal central body height is calculated using endplate trial height which is found on the back of the module lid for reference. The trials do not account for the implant spikes (1); therefore, 1 mm clearance on each end of the trial is required.

Optimal Central Body Height (CBH) = Overall defect – Cranial trial endplate height – Caudal trial endplate height – Clearance for spikes

Example for 46 mm defect with a 5° cranial endplate and 10° caudal endplate:

CBH = 46 mm–6.5 mm–8.5 mm–2 mm
CBH = 29 mm

Insert the selected trial endplates onto the trial central body. Align the etch lines before pressing the components together. Ensure there is no gap between the endplate and central body trial.

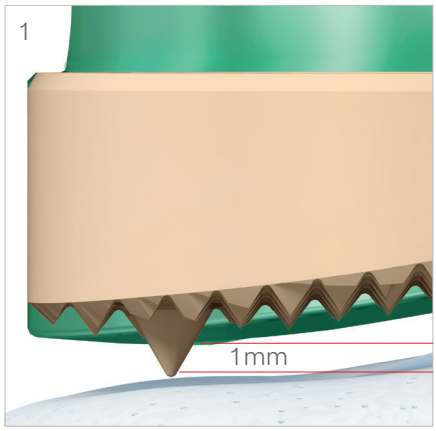
- **The endplate height is independent of the footprint.**

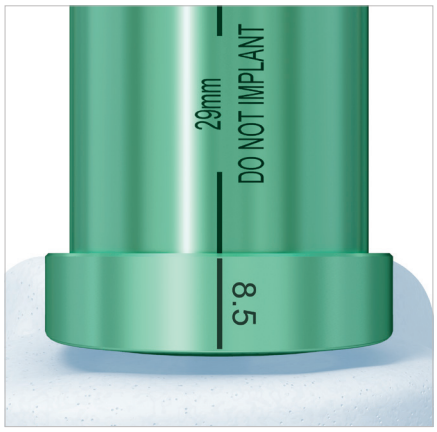
▲ Warning:

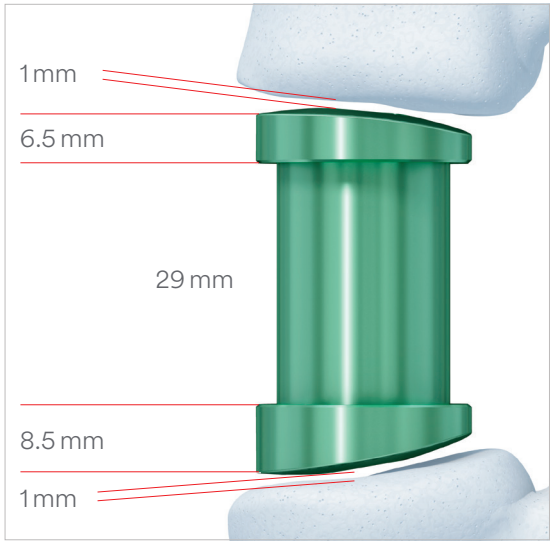
The trials are not for implantation and must be removed before insertion of the XRL implant. Total construct angle must not exceed 30° lordosis/ kyphosis.

Medium Endplate Trial	
Angle	Height (mm)
0°	5
5°	6.5
10°	8.5
15°	10.5
–5°	6.5
–10°	8.5

See page 28 for endplate and central body cross reference list.

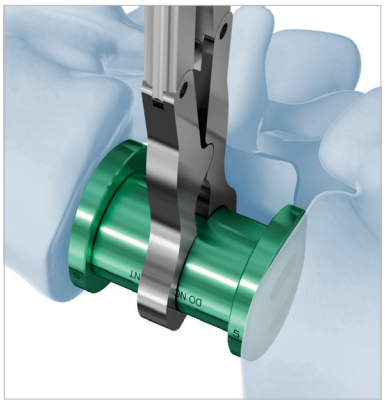






4. Insert trial

Instrument	
03.807.382	XRL Medium Implant Holder



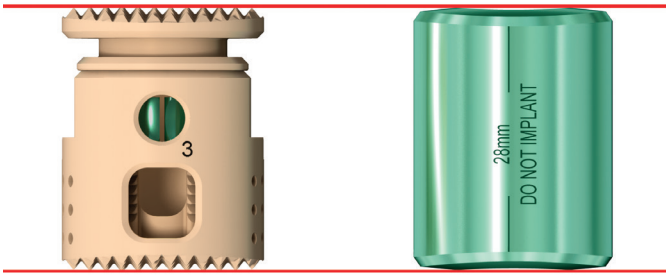
Using the implant holder, insert the trial into the corpectomy site. Be sure the appropriate endplate is oriented in the cranial/caudal position and the etch lines on the trial are facing anterior. The optimal position for the trial is centered on the vertebral bodies with clearance to account for the implant spikes. Trials must always be securely held while in the wound.

- **Integrated implants do not have tall spikes and therefore the integrated trials are the same height as the corresponding collapsed implant.**

Change trial central body and endplates as necessary to achieve the desired height, angle, and footprint.

▲ Warning:

Do not excessively impact on trial implants and or implant holder. Use light impaction only.



Implantation

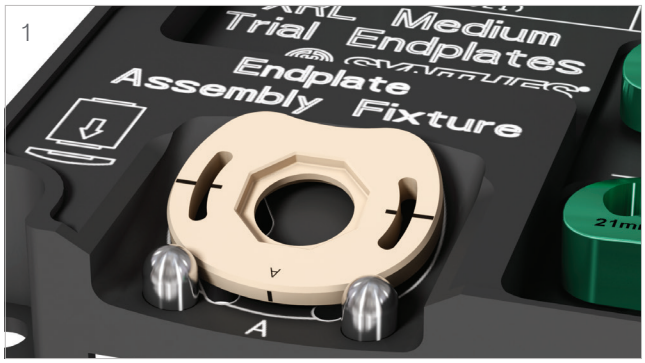
1. Assemble implant

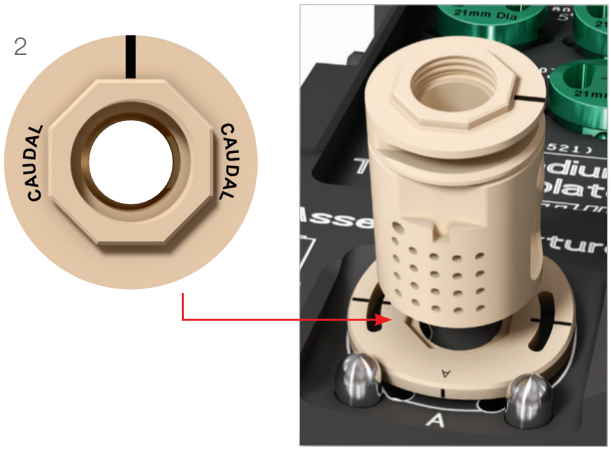
Select implant based on corresponding trial (see pages 27–28 for trial/implant list).

If an integrated assembly is selected, skip to step 4, Prepare implant.

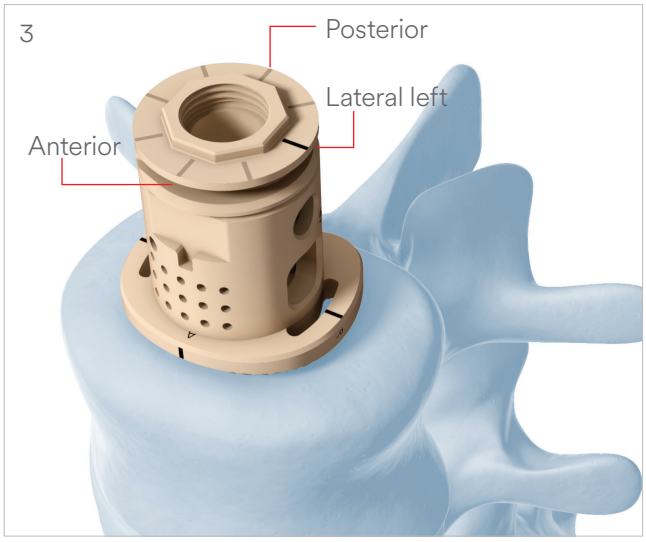
The Endplate Assembly Fixture is found in the Trial Endplate Module. When assembling the implant, orient the caudal endplate into the endplate assembly fixture spike side down, aligning the “A” (Anterior) on the endplate with the “A” on the endplate assembly fixture (1). Position the central body with the locking ring facing the direction of the desired approach (2). Attach the caudal endplate first by pressing the endplate onto the octagon until fully seated. Repeat with the cranial endplate.

- **The etch lines on the ends of the central body, the graft window, and the locking ring may all be used to indicate the direction of approach. Figure 3 shows the orientation of the etch line with respect to the caudal endplate for each approach option.**





Shown: Lateral left approach

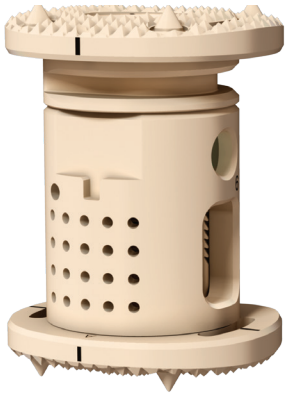


The etch line on the anterior aspect of the endplate ensures that both endplates are in the same direction (lateral left shown in Figure 4).

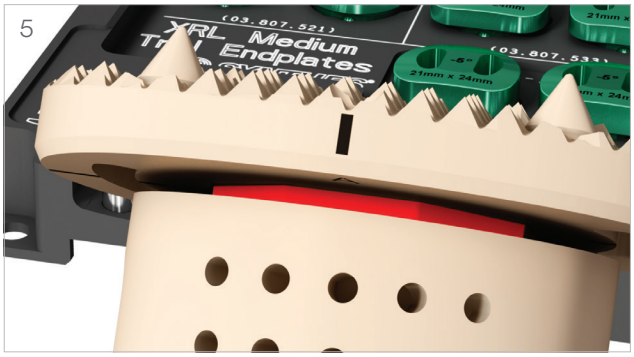
▲ Warnings:

- When pressing on the endplates, ensure the endplate properly seats on the central body. This can be checked visually (5). If the endplate is not properly seated, there is a risk that it could detach from the central body.
- The XRL central body must never be implanted without cranial and caudal endplates properly secured with endplate screws (See step 3, Attach endplate screws).

4



5



2. Reposition endplates (optional) Instrument

03.807.354	XRL Endplate Removal Tool

If necessary, the endplates can be repositioned by manually removing them from the central body, except for the round endplates which are removed using the XRL endplate removal tool. Be sure to perform endplate removal over a sterile table.

▲ Warning:

Endplates release from central body abruptly. Make sure to have a firm grip on both the central body and the endplate during removal.

To remove round endplates, align the tip of the XRL endplate removal tool with the slot in the endplate. Apply a slight, constant pressure and rotate the tool to release the endplate.

3. Attach endplate screws

Instruments	
03.807.351	XRL Medium Endplate Screwdriver Tip
03.807.357	XRL Medium Torque Limiting Handle

Align the endplate screwdriver tip into the open end of the torque limiting handle (1).

Press until an audible “click” is heard.

Align the tri-lobal feature of the tip and the etchings on the endplate screw. Lightly press the screw onto the screwdriver tip. The screwdriver tip will retain the screw (2).

Align the torque limiting handle with the central body to prevent cross threading. While gripping the large end of the torque limiting handle, rotate the torque limiting handle clockwise to advance the screw through the caudal endplate and into the central body. Tighten until an audible “click” in the torque limiting handle is heard. Repeat this step to fi xate the cranial endplate (3).

- **Please follow torque limiting handle calibration instructions to ensure proper functionality.**

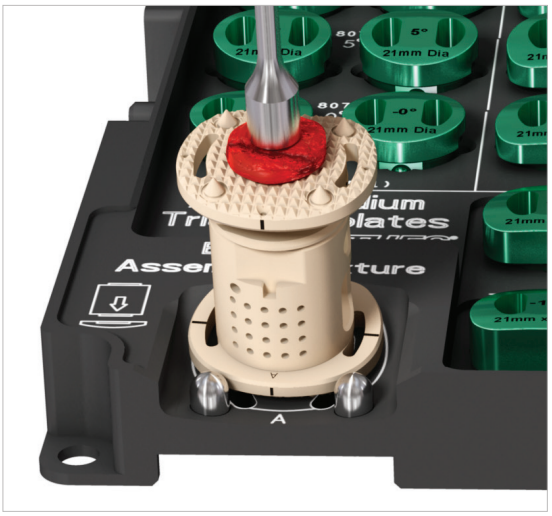
4. Prepare implant

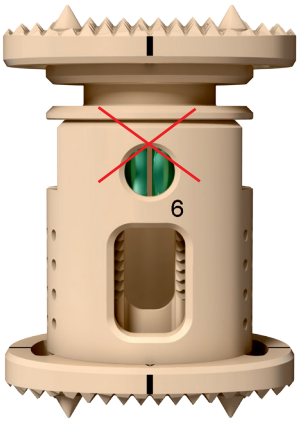
Instruments	
03.807.374	XRL Medium, Cancellous Bone Graft Packing Preparation Tamp

Prior to implanting, use the graft packing preparation tamp to facilitate packing of bone graft into the XRL implant. Graft can be packed through the cannulation in the endplate and graft windows.

▲ Warning:

DO NOT pack graft into the locking ring. DO NOT use excessive force while packing graft. DO NOT pack graft while implant is loaded onto the spreader.





5. Assemble spreader instrument

Instruments	
03.807.300	XRL Spreader
03.807.310	XRL Medium Shaft, straight, for No. 03.807.300
03.807.311– 03.807.315	XRL Medium Spreader Tops, straight, distraction width 3–15 mm
03.807.355	XRL Medium, Spreader Top, straight, distraction width 5 mm
03.807.348	XRL Release Tool for No. 03.807.300

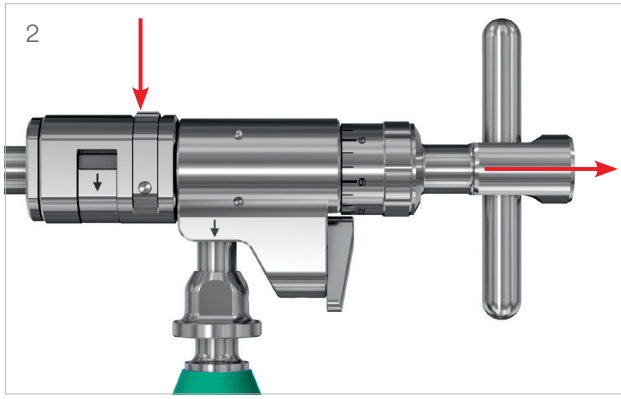
Assemble the appropriate size spreader top to the XRL spreader according to the implant central body size selected (See page 28 cross reference list). The spreader tops are designed to prevent over-distracting the implant.

While holding the spreader with the shaft in the horizontal position, set ratchet lever to the “OFF” position (1).

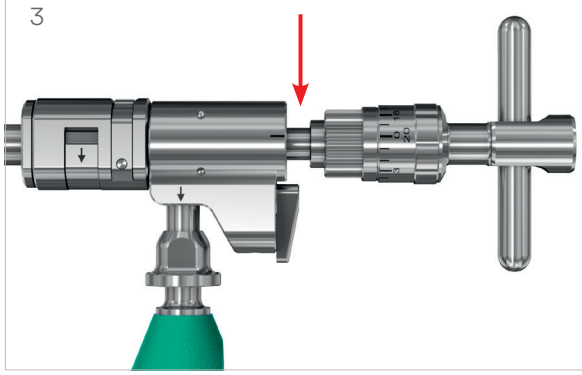
Press T-driver release button and pull back on the T-driver (2). Release the button to set T-driver in the open position (3). T-driver should not be fully removed during this operation.

1

2

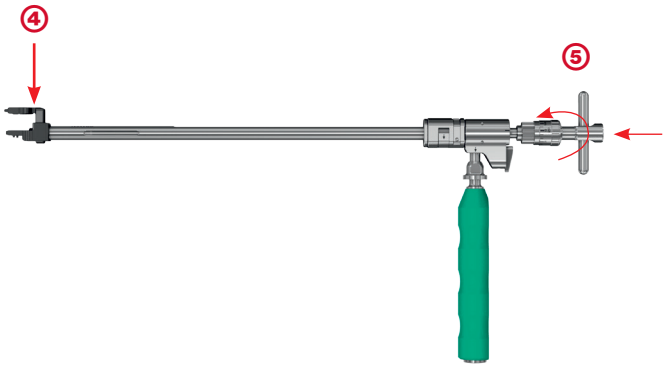


3



Insert the selected spreader top into the spreader shaft ④ and insert the T-driver ⑤ by gently pushing and turning the T-driver into the spreader assembly.

Check functionality of the spreader top by rotating the T-driver. If properly assembled, the spreader top should translate during T-driver rotation, and the T-driver will remain retained by the spreader assembly.



6. Secure implant to spreader

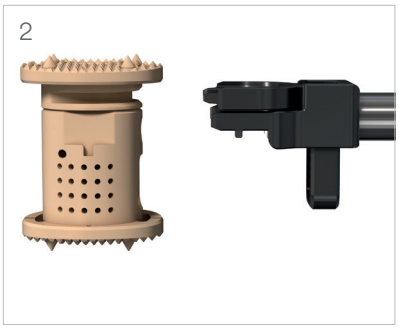
Instruments	
03.807.300	XRL Spreader
03.807.310	XRL Medium Shaft, straight, for No.03.807.300
03.807.311– 03.807.315	XRL Medium Spreader Tops, straight, distraction width 3–15 mm
03.807.348	XRL Release Tool for No. 03.807.300
03.807.355	XRL Medium Spreader Top, straight, distraction width 5 mm

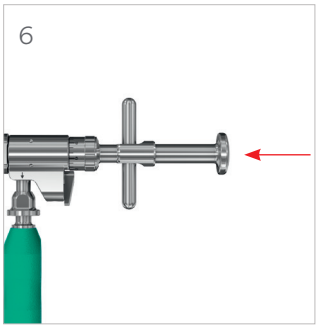
To load the implant, fully collapse the spreader top and set the ratchet lever to the “OFF” position (1).

With the opening of the locking ring facing the instrument, slide the spreader top into the slots below the cranial endplate (2). Do not force the spreader top onto the implant. Set the ratchet lever “ON” (3) and slightly turn the T-driver clockwise until the spreader shaft engages the notch on the implant for a secure hold (4). Verify the implant is secured over the sterile field.

Set the scale to zero (5).

Completely insert the release tool through the XRL spreader and into the locking ring (6).





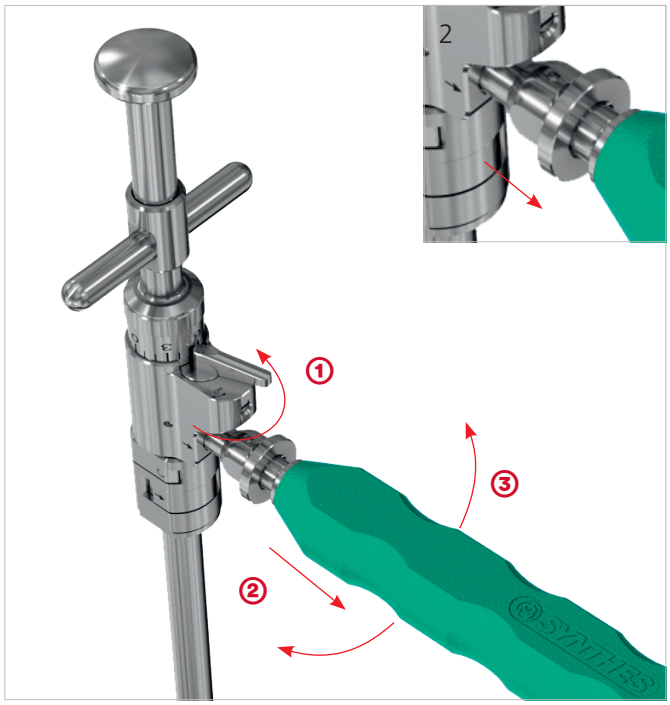
7. Insert implant

Instrument	
03.807.300	XRL Spreader

Prior to inserting the implant the spreader handle can be rotated at 90° increments to aid in visualization. Set ratchet lever to “OFF” position ①. With one hand gripping the spreader shaft, pull back on retaining collar and rotate the spreader handle to the desired position (②,③). Release retaining collar. Verify that the spreader handle is locked into position. Reset scale to zero.

▲ Warning:

Do not adjust spreader handle when ratchet lever is set to “ON”. This will result in premature distraction of the implant. Do not insert the implant into corpectomy until spreader handle is locked into desired position.



Guide and position the implant with the spreader. Slight distraction of the vertebral bodies may be necessary to ease insertion.

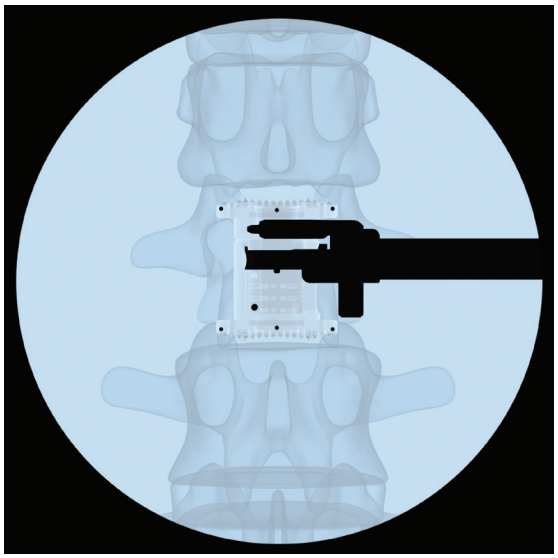
The optimal position for the implant is in the center of the vertebral body endplate. Maintain space around the endplate of the implant to allow peripheral bony fusion.

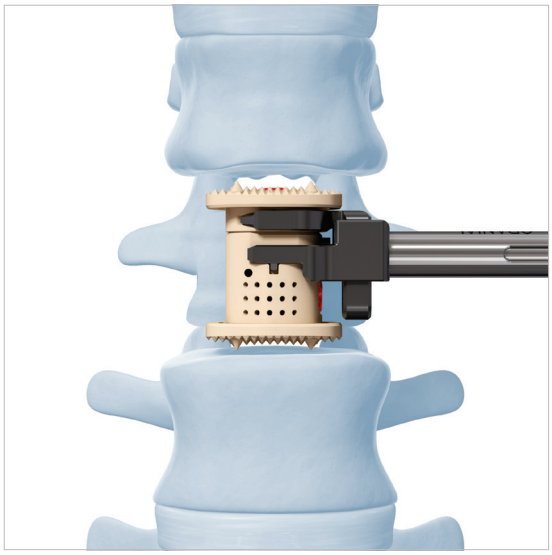
▲ Warning:

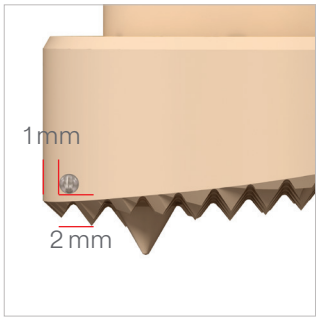
Do not impact on spreader or implant. Do not manipulate implant unless both the slot and notch are engaged (see step 6, Secure Implant to Spreader).

Verify the position of the implant using the image intensifier.

- Tantalum markers and a titanium locking ring is used to determine orientation of the implant
- The 1 mm diameter tantalum markers are embedded into the PEEK endplates to provide radiographic markers for intraoperative or postoperative imaging
- The anterior and medial/lateral markers are located approximately 1 mm from the edges of the implant. The posterior marker is located 1 mm from the edge of the round implant, and 2 mm from the edge of the anatomically shaped endplates. The cranial/caudal locations of the markers are 2 mm from the end of the pyramidal teeth.







8. Distract and check position

Instrument	
03.807.300	XRL Spreader

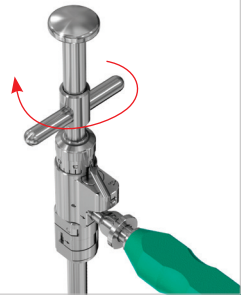
Ensure the release tool is engaged and the ratchet lever is set to the ”ON” position (1), then turn the spreader T-driver clockwise (2) and expand the implant until the desired amount of distraction is achieved.

Once the implant has been distracted, fully remove the release tool, (3) and with constant clockwise torque on the T-driver, place the ratchet lever in the “OFF” position (4).

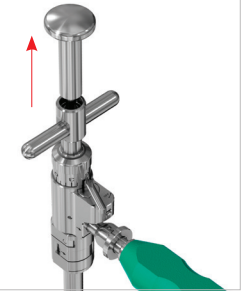
- **The release tool may also be set in the resting position instead of being fully removed from the spreader. Pull up on the release tool until it travels ~15 mm and it will be retained by the spreader in the resting position.**

1

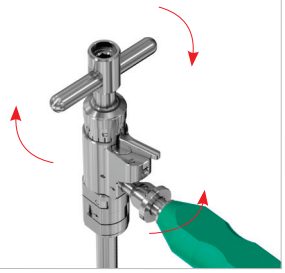
2



3



4



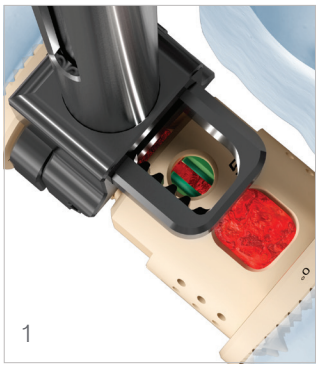
Before removing the spreader, verify the locking ring is properly closed by collapsing the spreader top and visually inspecting the slot through the spreader top (1). When the slot is approximately 1 mm (2), the implant is locked and secured. If the slot is larger (3), re-expand the spreader top and distract the implant slightly to close the locking ring. If implant remains unlocked, follow step 9, Reposition implant (optional). If the locking ring is not visible, inspect lock after spreader is removed (see step 10). Remove the spreader from the implant by setting the ratchet lever to “OFF” and turning the T-driver counterclockwise. When spreader top is fully collapsed, the spreader can now be removed.

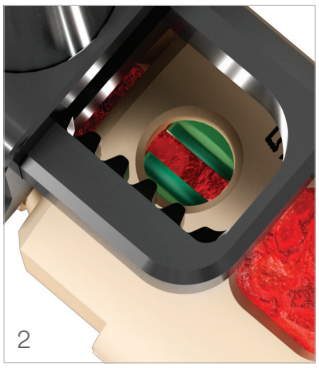
Visually inspect implant/vertebral body interface for gaps to prevent point loading. If a gap is found, repositioning (see step 9, Reposition implant (optional)) is necessary to ensure full endplate surface contact (4).

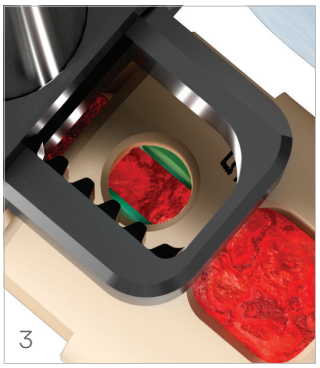
Verify the position of the implant using the image intensifier. The stop pin can be used to approximate the amount of distraction available. When stop pin (a) is within 1 mm of the locking ring (b), the implant is fully expanded (5).

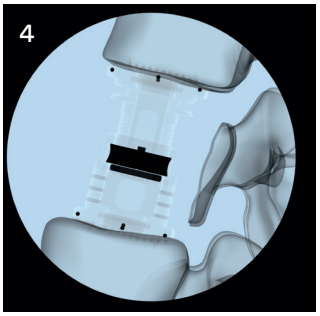
▲ Warnings:

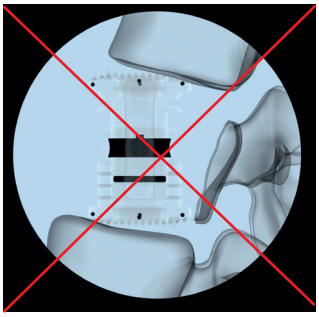
- Do not reuse XRL implants.
- Do not reposition spreader handle during or after distraction. Do not impact on the XRL spreader or implant when repositioning the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to “OFF”. Else, the T-driver may release abruptly.
- Distraction of the implant is only permitted with the XRL instrument set.

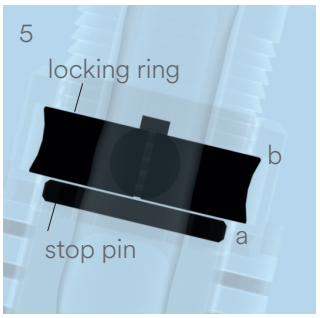












9. Reposition implant (optional)

Instrument	
03.807.300	XRL Spreader

To reposition the implant, fully collapse the spreader top and set the ratchet lever to the “OFF” position (1).

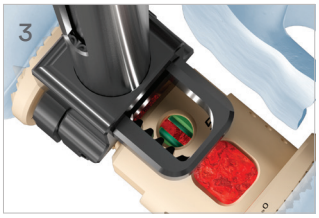
Be sure the release tool is removed or disengaged and set to the resting position (2).

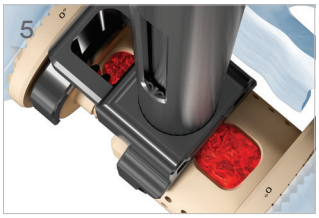
Slide the spreader top into the slots below the cranial endplate (3). Set ratchet lever to “ON” (4) and turn the T-driver clockwise until spreader engages the notch on the implant for a secure hold (5). Fully insert the release tool (6).

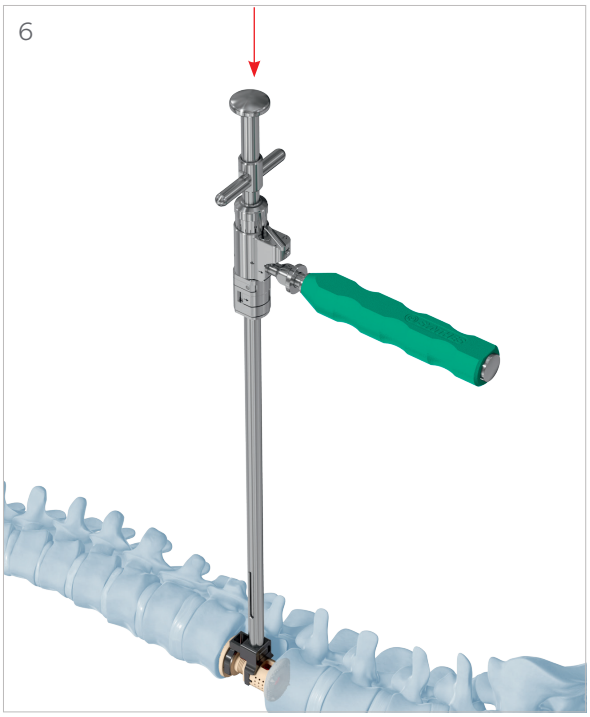
With constant clockwise torque on the T-driver, set the ratchet lever to “OFF” position and compress the implant by turning the T-driver counterclockwise. Reposition the implant to the desired location and follow step 8 to re-distract implant.

▲ Warnings:

- **Do not impact on the XRL spreader or implant when repositioning the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to “OFF”. Else, the T-driver may release abruptly.**
- **Repositioning of the implant is only permitted with the XRL Instrument Set.**







10. Verify lock

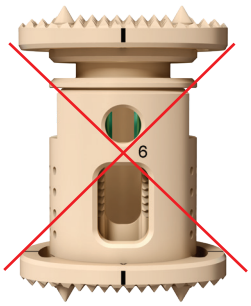
When the implant is in its final position, verify the locking ring on the central body is closed. When the slot is approximately 1 mm (1), the implant is locked and secured. If the slot is larger (2), re-engage the implant with the spreader, with the ratchet lever in the “OFF” position, and with the release tool fully removed, distract the implant slightly to close the locking ring. If implant remains unlocked, repeat step 9 and verify locking ring is closed.

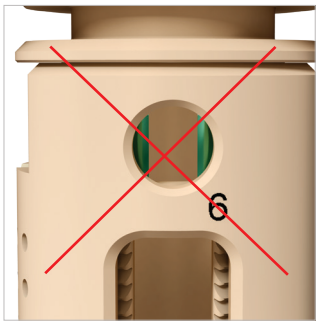
▲ Warning:

Locking ring must be properly closed to ensure final implant height is maintained.

1

2





Supplemental Fixation

1. Apply bone graft material

Instruments	
03.807.371	XRL Medium, Cancellous Bone Graft Packing Tamp
03.807.374	XRL Medium, Cancellous Bone Graft Packing Preparation Tamp

In situ graft packing must not occur until final implant position is achieved, as additional bone graft may obstruct repositioning of the implant.

Before packing additional bone graft in or around the cage, use AP and lateral radiographs to verify the position of the implant in relation to the vertebral bodies using the tantalum markers and locking ring for references.

The graft packing tamp has 2 different ends to fit the corresponding window of the expanded central body. The preparation tamp has an angled end that can be used to gain compression on graft that is not accessible with the graft packing tamp.

Graft packing tamp will not fit inside the window of integrated implant, however can still be used to tamp graft material.

▲ Warning:

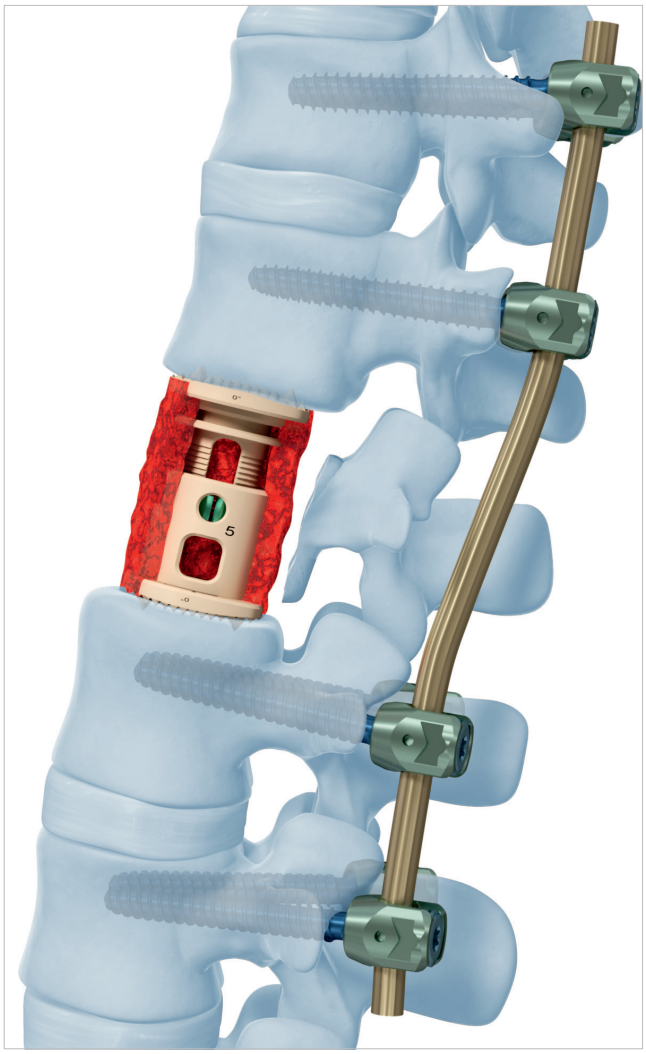
Do not use excessive force while packing graft.

2. Apply internal fixation system

For spinal stability and to maintain adequate compression on the construct, XRL must be used with an internal fixation system.

▲ Warning:

Take care when applying supplemental fixation that the superior and inferior vertebral body endplates remain fixed. Manipulation of vertebral bodies may cause the XRL implant to shift in the wound possibly resulting in a need to reposition the implant.



Implant Removal

If a XRL Implant has to be removed the following technique is recommended:

Assemble spreader instrument see section 5. for detailed description

XRL Implant Removal

Instrument	
03.807.300	XRL Spreader

To remove the implant, fully collapse the spreader top and set the ratchet lever to the “OFF” position (1).

Be sure the release tool is removed or disengaged and set to the resting position (2).

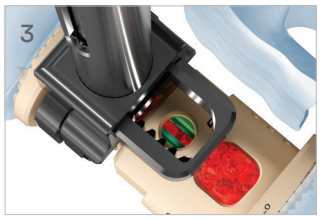
Slide the spreader top into the slots below the cranial endplate (3). Set ratchet lever to “ON” (4) and turn the T-driver clockwise until spreader engages the notch on the implant for a secure hold (5). Fully insert the release tool (6).

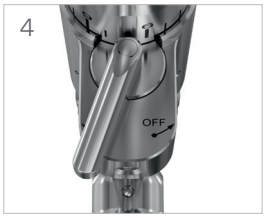
With constant clockwise torque on the T-driver, set the ratchet lever to “OFF” position and compress the implant by turning the T-driver counterclockwise.

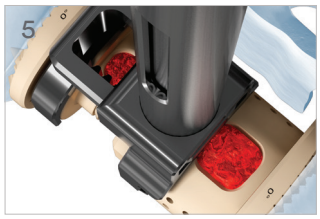
Remove the implant.

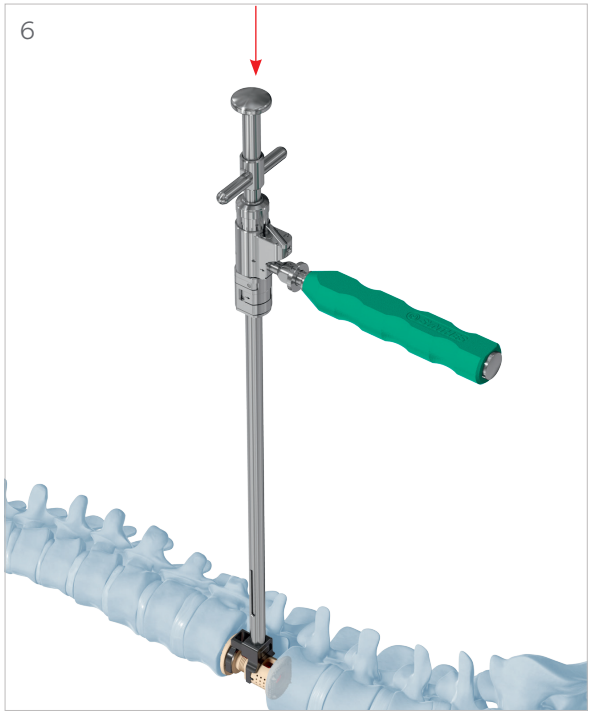
▲ Warnings

- **Do not impact on the XRL spreader or implant when removing the implant. Be sure to apply constant clockwise torque when switching the ratchet lever to “OFF”. Else, the T-driver may release abruptly.**
- **Removing of the implant is only permitted with the XRL Instrument Set**



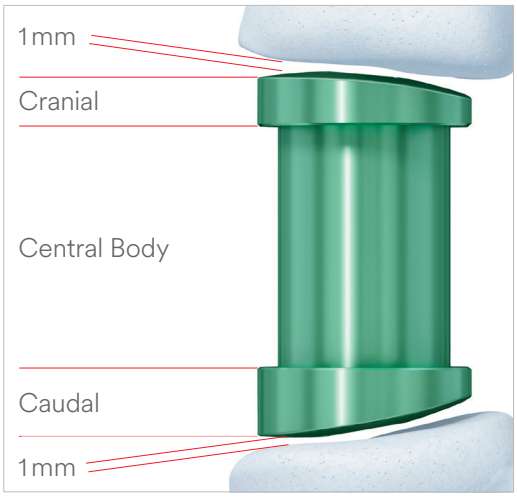






Cross Reference List

XRL Medium



Cranial	Endplate Angle					
Endplate Footprint	–10°	–5°	0°	5°	10°	15°
21 mm	8.5	6.5	5	6.5	8.5	10.5 Endplate
21 mm × 24 mm	8.5	6.5	5	6.5	8.5	10.5 Height
26 mm × 30 mm	8.5	6.5	5	6.5	8.5	10.5 (mm)

Central Body Number	Central Body Height (mm)	Distraction Range (mm)	Spreader Top
1*	22*	3	1
2*	24*	5	2
3*	28*	8	3
4	22	5	6
5	25	8	3
6	29	10	4
7	33	10	4
8	37	15	5
9	44	15	5
10	51	15	5
11	62	15	5
12	73	15	5
13	84	15	5
14	95	15	5
15	106	15	5

Caudal	Endplate Angle					
Endplate Footprint	–10°	–5°	0°	5°	10°	15°
21 mm	8.5	6.5	5	6.5	8.5	10.5 Endplate
21 mm × 24 mm	8.5	6.5	5	6.5	8.5	10.5 Height
26 mm × 30 mm	8.5	6.5	5	6.5	8.5	10.5 (mm)

* Integrated Assembly, no endplates needed

Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

2. Aebi M, JS Thalgott, JK Webb. (1998). AO ASIF Principles in Spine Surgery. Berlin: Springer-Verlag.

Not all products may currently be available in all markets.
This publication is not intended for distribution in the USA.
Surgical techniques are available as PDF files at www.depuysynthes.com/ifu

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11

www.jnjmedicaldevices.com

SE_862967_AA (036.001.566; DSEM/SPN/1215/0390) EOS 183635-210720 EMEA 09/21