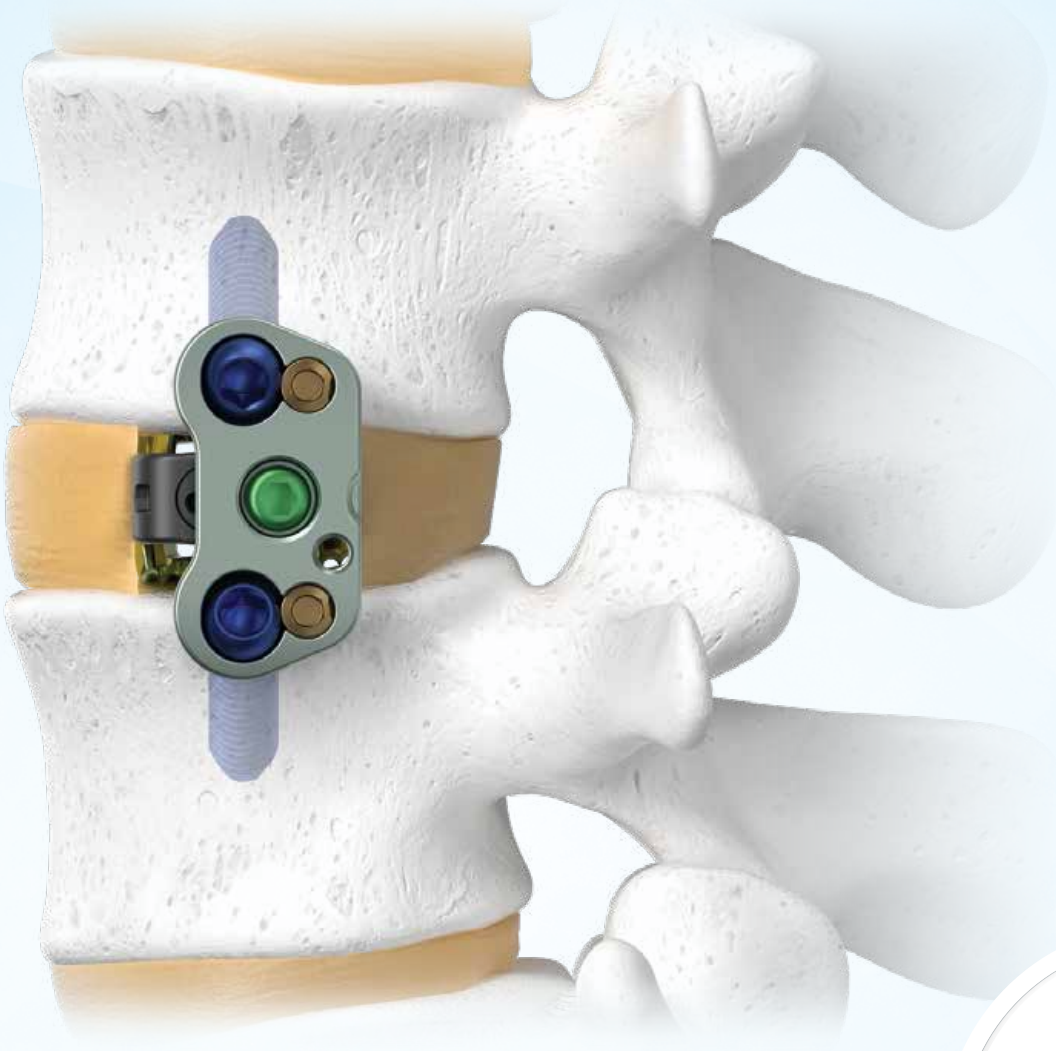

# ADIRA™

## XLIF™ Plate System

SURGICAL TECHNIQUE GUIDE

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# SURGICAL TECHNIQUE GUIDE

# ADIRA™


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# ADIRA™

## XLIF™ Plate System

The ADIRA™ XLIF™ Plate System is designed to refine lateral plating by offering simplified insertion workflows and a rigid coupling mechanism to confidently align plates over interbody spacers to enhance construct stability.

### Spacer Migration Protection

ADIRA™ plates are designed to rigidly thread into compatible interbody spacers to help reduce the risk of spacer migration, creating a stand-alone construct when used with two bone screws.*

### Construct Versatility

ADIRA™ plates offer compatibility with a suite of fixation bone screws, as well as lateral MIS anchors.

### Fewer Procedural Steps

Static compatible plates can be inserted as a single construct, thereby reducing the number of instrument passes required for insertion.

**ADIRA™ 2-Hole Plate-Spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two screws.*

# IMPLANT OVERVIEW

## Plate Lengths Measured Hole to Hole

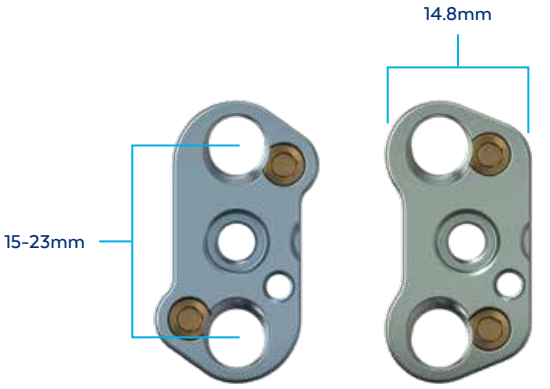



Plate Length (Two-Hole)

Plate Width (Two-Hole)

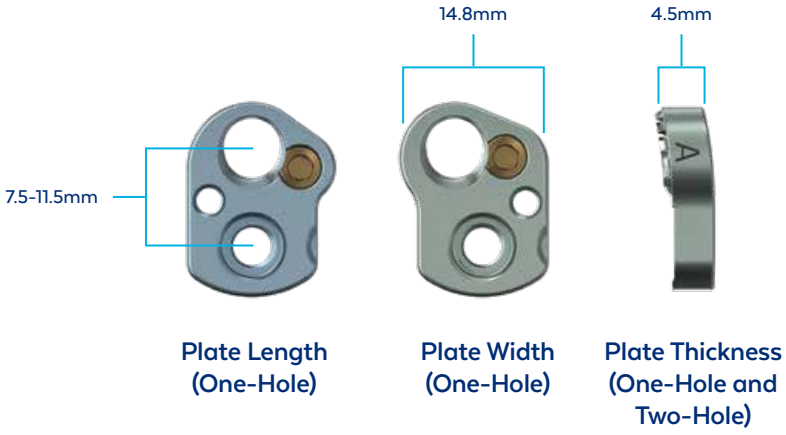



Plate Length (One-Hole)

Plate Width (One-Hole)

Plate Thickness (One-Hole and Two-Hole)

## Two-Hole Plates

- Lengths: 15-23mm in 2mm increments

## One-Hole Plates

- Designed to rigidly attach to lateral interbody spacers to help improve construct stability and lower the risk of implant migration while maintaining a low profile
- Lengths: 7.5-11.5mm in 1mm increments

ADIRA™-RLX:
RISE™-L

ADIRA™ Static Compatible:
HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™, TransContinental™ TPS, and CoRoent™

## Multiple Fixation Options

- A comprehensive range of fixation options is offered to accommodate varying patient anatomy

## Screw Options

- Titanium bone screws
- Variable angled screws (0°-20°)
- Lengths: 30-60mm, in 5mm increments
- 5.5mm diameter
- Self-tapping and self-drilling
- Hydroxyapatite (HA) coated option
- Cobalt chrome (CoCr) alloy locking screws

## Anchor Options

- Titanium bone anchors
- 22, 25, and 27mm lengths
- 5.4mm diameter

Variable Angle Self-Tapping Screw

Variable Angle Self-Drilling Screw

Lateral MIS Anchor

HA Coated Variable Angle Screw

CoCr Variable Angle Screw

## Confident Screw Blocking Design

- Blocking screw mechanism is integrated into the plate
- Provides audible, tactile, and visual confirmation of blocked bone screws or lateral MIS anchors

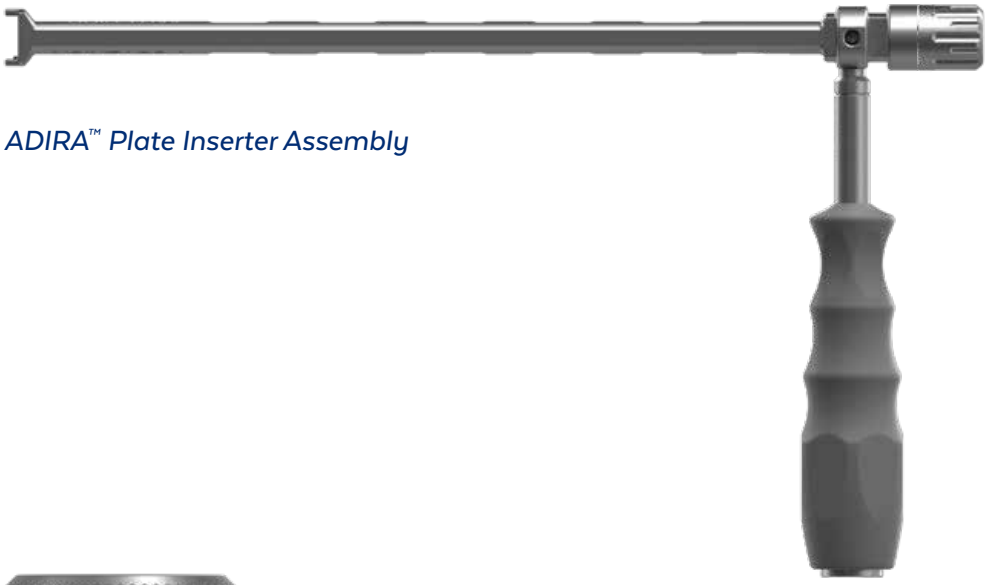
Unblocked

Blocked

# **INSTRUMENT** OVERVIEW

ADIRA™ Plate Inserter, Threaded Shaft 6264.0100

ADIRA™ Plate Inserter, Sleeve 6264.0200



*ADIRA™ Plate Inserter Assembly*

Inserter Wrench 693.614

ADIRA™ Threaded Plate Holder 6264.0500

Ratchet Handle 687.105

Quick-Connect Swivel Handle 687.005

Torque-Limiting Quick-Connect Handle, 1.0Nm 6264.0600

Blocking Screw Driver, 2.5mm 6264.0300

2.5mm Hex Driver (HD2060984), 650.906

InterContinental™ Straight Shaft Awl 687.524

Angled Awl, 10° 6122.0511

InterContinental™ Straight Shaft 3.5mm Hex Driver 687.527

Expandable 3.5mm Hex Driver 687.603

Single Anchor Inserter 6219.1000

# SURGICAL TECHNIQUE

# ADIRA™

Refer to the package insert (also printed in the back of this manual) for important information on the intended use, indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

If the XLIF™ technique utilizing the Maxcess Retractor™ and NVM5™ is preferred for the surgical approach, please refer to the XLIF™ Surgical Technique Guide (reference number 9500138).

## STEP 1 SURGICAL APPROACH AND PREPARATION

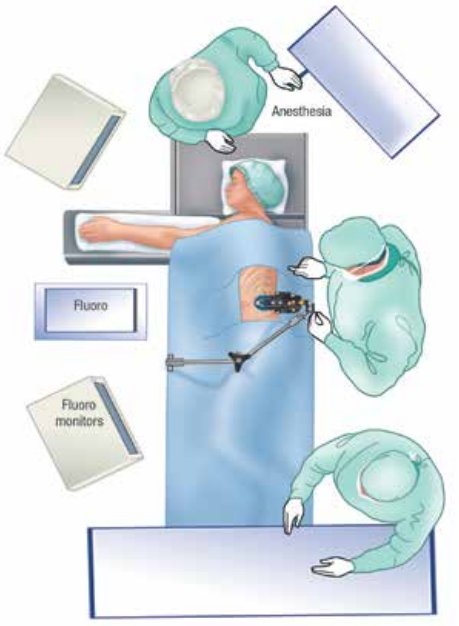
### Patient Positioning

The ADIRA™ plate may be inserted into the thoracolumbar spine through a lateral or anterolateral approach, from either the patient's left or right side. Each plate may be used independently or attached to specific interbody fusion devices to create a plate-spacer. Interbody fusion techniques should be performed prior to plating. Refer to the applicable surgical technique guide for the selected, corresponding interbody spacer system for specific instructions on interbody spacer insertion.

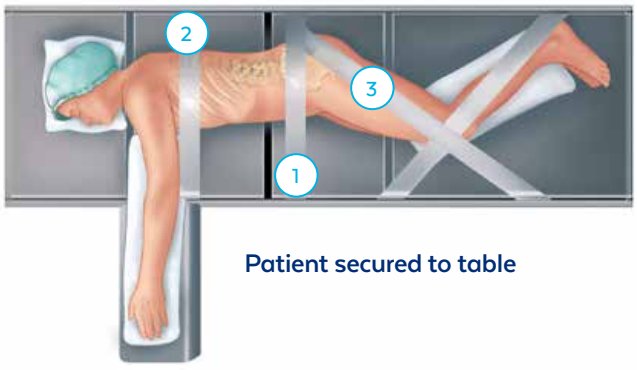
The patient is placed under anesthesia and positioned in the lateral decubitus or prone position. The instructions below are specific to the lateral decubitus position. The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

The patient is secured to the table at the following locations: (1) just beneath the iliac crest; (2) over the thoracic region, just under the shoulder; (3) from the back of the table, over the ankle, and past the knee to the front of the table.

The table should be flexed to open the interval between the 12th rib and iliac crest, and provide direct access to the disc space, as shown below.




**Patient positioning**




**Patient secured to table**

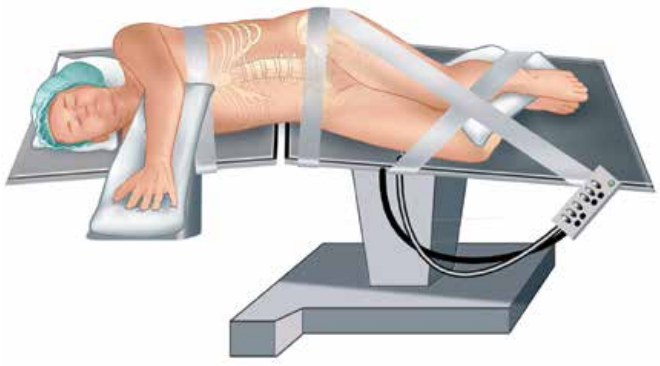
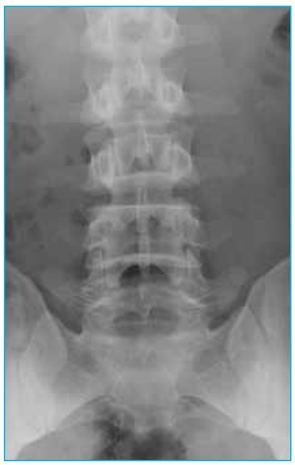


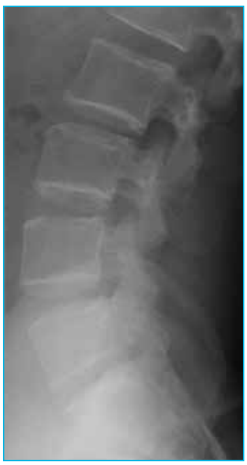
**Table flexed**

## X-Ray Confirmation

Fluoroscopy is used to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images at 0° and straight lateral images at 90°.



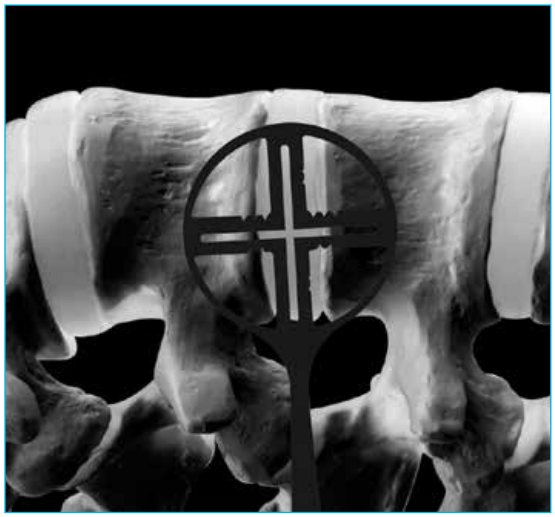
AP image



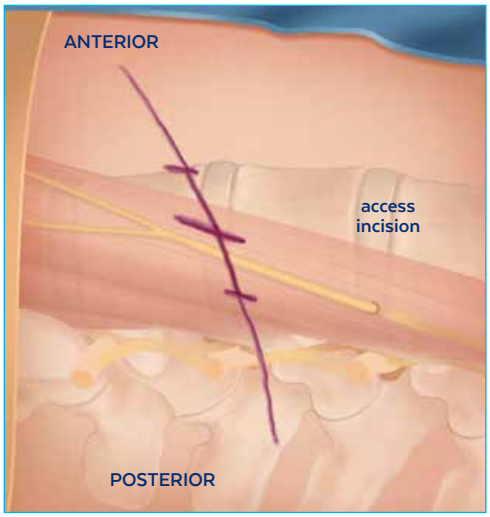
Lateral image

## Incision Location

The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s). The **Incision Locator** is used under fluoroscopy to identify the middle of the disc space to be fused. An access incision mark is traced on the patient's skin to indicate the position and insertion site for the retractor. Position the desired retractor.



Using Incision Locator




Marking incision locations

# SURGICAL APPROACH AND PREPARATION (CONT'D)

ADIRA™ plates may be used independently or attached to specific interbody fusion devices to create a plate-spacer. ADIRA™ plates may be used with static and expandable interbody spacers, including RISE™-L, HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™, TransContinental™ TPS, and CoRoent™.

RISE™-L/ADIRA™ plate constructs using ADIRA™-RLX plates must be assembled by following the *In Situ* Assembly Insertion Technique. Static interbody ADIRA™ plate constructs may be assembled by following either the *In Situ* Assembly Insertion Technique or the Plate-Spacer Assembly Insertion Technique.

Follow steps 3a-4a for option A, the *In Situ* Assembly Insertion Technique. *In situ* assembly insertion is applicable for ADIRA™ constructs utilizing the following interbody spacers: RISE™-L, HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™, TransContinental™ TPS, and CoRoent™.


***In situ* assembly insertion**

Follow steps 3b-4b for option B, the Plate-Spacer Assembly Insertion Technique. Plate-spacer assembly insertion is applicable for ADIRA™ constructs utilizing the following interbody spacers: RISE™-L, HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™, TransContinental™ TPS, and CoRoent™.

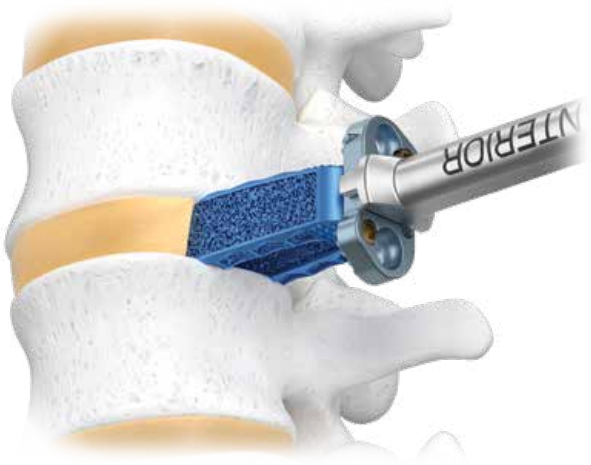



**Plate-spacer assembly insertion**

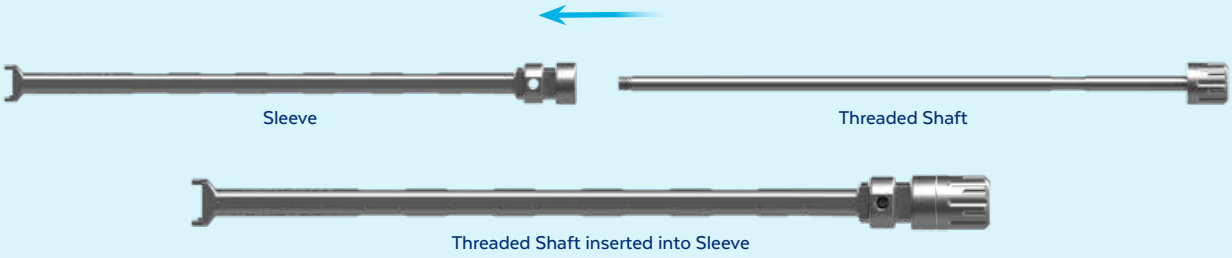
Follow instructions in the Optional Technique: Plate Only (No Spacer) Insertion section for using ADIRA™ plates without coupling directly to an interbody spacer.

**Plate only insertion**

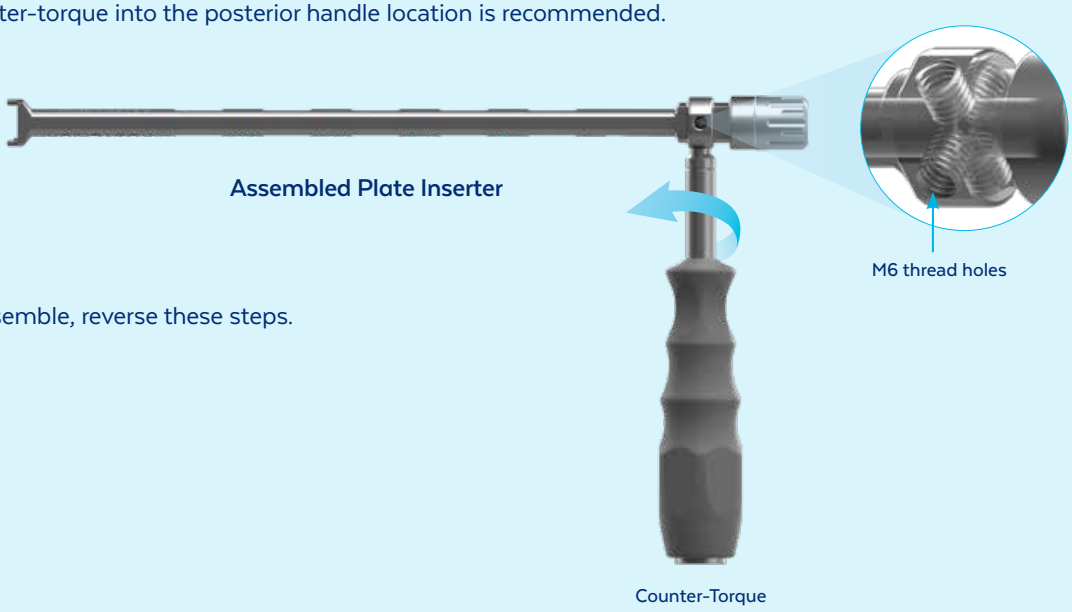
The same inserter is required for the insertion of the ADIRA™ plate regardless of which interbody spacer is used. Instructions on how to assemble the **ADIRA™ Plate Inserter** are listed below.

## ADIRA™ PLATE INSERTER ASSEMBLY

Insert the **ADIRA™ Plate Inserter, Threaded Shaft** into the **ADIRA™ Plate Inserter, Sleeve**.




Thread the **Counter-Torque M6x1** into one of the four designated M6 thread holes on the proximal end of the inserter sleeve. Handle location and placement are determined by surgeon preference. For direct lateral procedures, threading the counter-torque into the posterior handle location is recommended.

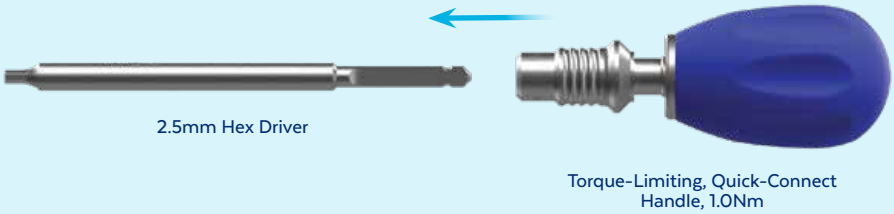



To disassemble, reverse these steps.

Assemble the **2.5mm Hex Driver**.

## ASSEMBLING THE 2.5mm HEX DRIVER

Attach the 2.5mm Hex Driver to the **Torque-Limiting Quick-Connect Handle, 1.0Nm**. Pull the metal collar on the handle towards the blue handle grip to engage the quick-connect feature. Release the collar once the hex driver is in place.



# STEP 2 PLATE AND SCREW IDENTIFICATION

The table below references the appropriate alignment screw and ADIRA™ plate style based on interbody spacer selection.

| Interbody Spacer | Alignment Screw Part No. | Alignment Screw Thread, Color | ADIRA™ Plate Style |
|---|---|---|---|
| RISE™-L  | 1264.0101 | M4.5, Green  | RLX  |
| HEDRON L™  | 1264.0001 | M4, Blue  | Static  |
| TransContinental™ (including TransContinental™ TPS)  | | | |
| Modulus™ XLIF™  | 1264.0002 | 10-24S, Purple  | |
| CoRoent™  | | | |
| Cohere™ XLIF™  | 1264.0004 | 10-24L, Pink  | |

# *In Situ* Assembly Insertion Technique

ADIRA™ static plates may be assembled to a static interbody spacer prior to insertion, or assembled *in situ*.

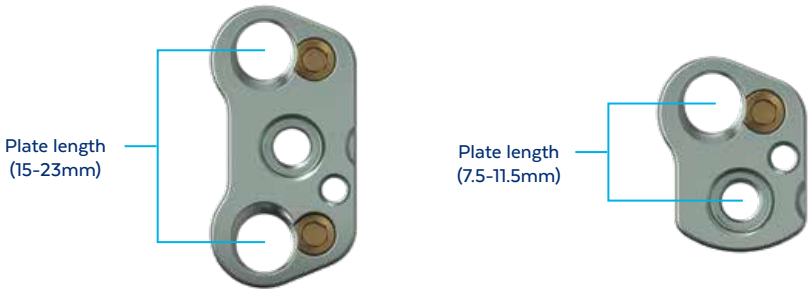
*Note: ADIRA™ RLX plates must be assembled to the expandable interbody spacer in situ to allow for device expansion.*

Select the corresponding alignment screw for RISE™-L and insert the RISE™-L interbody spacer per the recommended surgical technique; expand the implant to the desired height.

## STEP 3A PLATE SELECTION AND ASSEMBLY

The ADIRA™ system offers one-hole and two-hole plates that have the option to connect to RISE™-L, HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™ (including TransContinental™ TPS), and CoRoent™ spacers *in situ*. The height of the inserted interbody spacer is used to determine the necessary plate length. See the table below for recommended plate length based on the selected interbody spacer height or patient anatomy.

*Note: For two-hole plates, ADIRA™ plate length is the distance between the cephalad and caudal holes (center to center). For one-hole plates, ADIRA™ plate length is the distance between the bone screw hole and central insertion hole (center to center). Plate length is etched on each plate.*



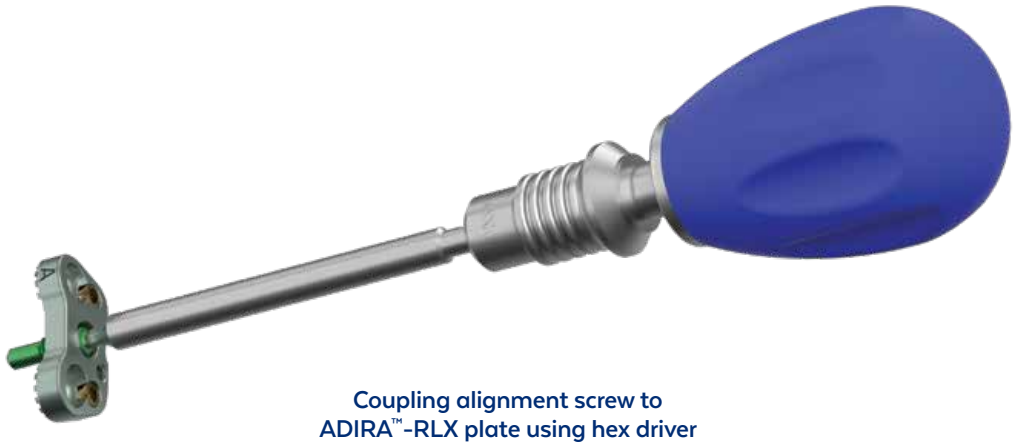

### Minimum Compatible Plate Length (mm)

| | | | Interbody Spacer Height | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| Lordosis | 0° | Two Hole | 15 | 15 | 15 | 17 | 17 | 19 | 19 | 21 | 21 | 23 | 23 |
| | | One Hole | 7.5 | 7.5 | 7.5 | 8.5 | 8.5 | 9.5 | 9.5 | 10.5 | 10.5 | 11.5 | 11.5 |
| | 5° and 6° | Two Hole | 15 | 15 | 15 | 15 | 15 | 17 | 17 | 19 | 19 | 21 | 21 |
| | | One Hole | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 8.5 | 8.5 | 9.5 | 9.5 | 10.5 | 10.5 |
| | 10° | Two Hole | 15 | 15 | 15 | 15 | 15 | 17 | 17 | 19 | 19 | 21 | 21 |
| | | One Hole | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 8.5 | 8.5 | 9.5 | 9.5 | 10.5 | 10.5 |
| | 15° | Two Hole | 15 | 15 | 15 | 15 | 15 | 17 | 17 | 19 | 19 | 21 | 21 |
| | | One Hole | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 8.5 | 8.5 | 9.5 | 9.5 | 10.5 | 10.5 |
| | Adjustable Lordosis: 3°-15° | Two Hole | 15 | 15 | 15 | 15 | 15 | 17 | 17 | 19 | | | |
| | | One Hole | 7.5 | 7.5 | 7.5 | 7.5 | 7.5 | 8.5 | 8.5 | 9.5 | | | |

# PLATE SELECTION AND ASSEMBLY (CONT'D)

For example, a 7-14mm 0° RISE™-L implant expanded to 11mm in height is compatible with a minimum ADIRA™-RLX two-hole plate length of 17mm. This same RISE™-L interbody at 11mm tall is compatible with an 8.5mm tall one-hole plate.

Using the assembled 2.5 hex driver, insert the appropriate alignment screw though the plate until it is captured. The ADIRA™ Lateral Plates feature a capture thread that helps to retain the alignment screw within the plate. The screw head should sit flush relative to the face of the plate. Remove the hex driver.



**Coupling alignment screw to ADIRA™-RLX plate using hex driver**

Assemble the **Blocking Screw Driver, 2.5mm**.

## ASSEMBLING THE 2.5mm BLOCKING SCREW DRIVER

Attach the Blocking Screw Driver, 2.5mm to the Torque-Limiting Quick-Connect Handle, 1.0Nm.

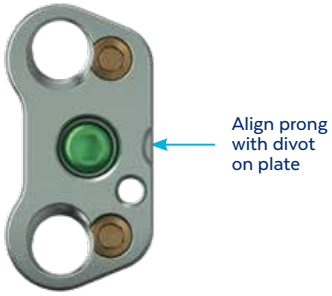
Blocking Screw Driver, 2.5mm

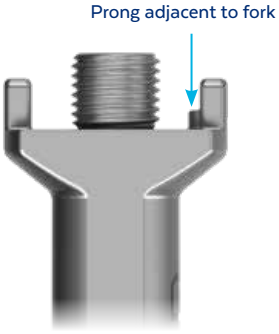
Torque-Limiting Quick-Connect Handle, 1.0Nm

# STEP 4A PLATE PLACEMENT AND COUPLING WITH THE ADIRA™ INSERTER

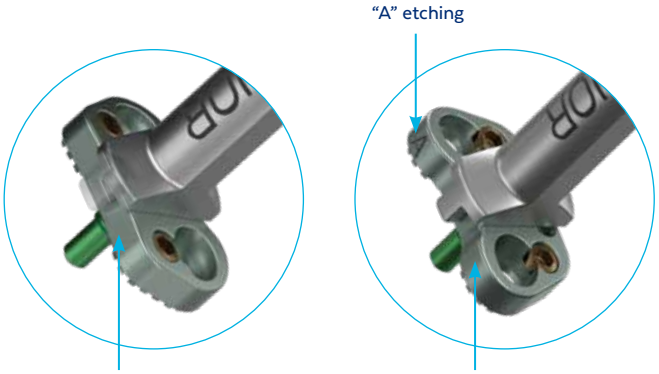
Once the appropriate alignment screw has been threaded into the ADIRA™ plate, thread the plate and screw construct onto the ADIRA™ Plate Inserter.

Align the prong adjacent to the fork at the distal end of the inserter sleeve with the divot on the chosen plate, ensuring the anterior side of the plate (indicated by an "A" etching) is aligned with the anterior side of the inserter ("Anterior" etching). Rotate the knob of the inserter threaded shaft clockwise to engage the plate and secure it to the inserter.



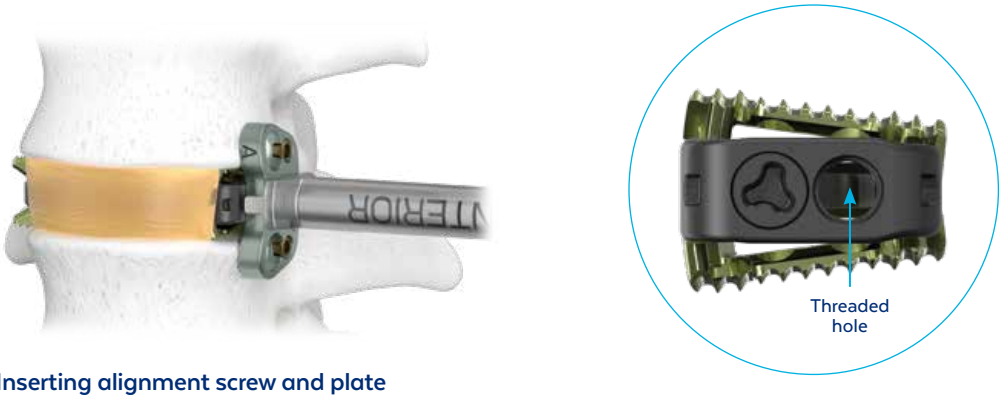

Aligning ADIRA™ plate divot with inserter prong




Securing ADIRA™ plate to ADIRA™ inserter

# PLATE PLACEMENT AND COUPLING WITH THE ADIRA™ INSERTER (CONT'D)

Use the plate inserter to position the alignment screw and plate onto the interbody spacer. Center the alignment screw and plate over the threaded hole on the proximal end of the interbody spacer. Use the tip of the alignment screw to locate the threaded hole. The threaded hole on RISE™-L is shown as an example below.



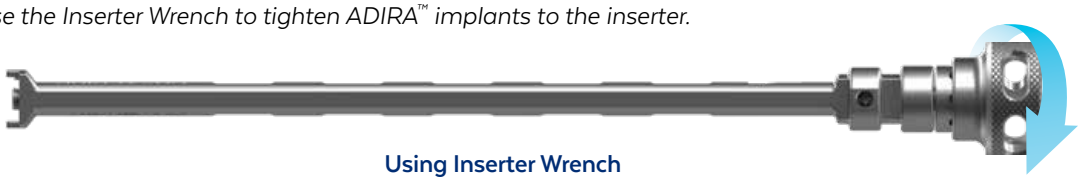

**Inserting alignment screw and plate assembly into threaded hole in RISE™-L**

Slide the blocking screw driver through the ADIRA™ Plate Inserter and engage the alignment screw. Rotate the driver clockwise until it reaches the 1.0Nm torque limit to rigidly couple the ADIRA™ plate to the interbody spacer.

**Coupling ADIRA™ plate to RISE™-L**

Once the ADIRA™ plate is in the desired location, remove the blocking screw driver. Rotate the knob on the proximal end of the inserter counterclockwise to gently release the inserter from the implant. If necessary, the **Inserter Wrench** may be used to loosen the thumbwheel.

*Note: Do not use the Inserter Wrench to tighten ADIRA™ implants to the inserter.*



**Using Inserter Wrench**

Proceed to Step 5 (Fixation).

Alternatively, the **Threaded Plate Holder** can be used to position the alignment screw and plate to the interbody spacer.

## USING THE THREADED PLATE HOLDER

After using the 2.5mm Hex Driver to fully seat the alignment screw in the desired ADIRA™ plate, thread the Threaded Plate Holder into the universal threaded port on the anterior face of the plate by rotating clockwise.

Use the Threaded Plate Holder to align the plate and screw construct over the threaded hole on the selected interbody spacer.

Engage the alignment screw with the blocking screw driver and rotate the driver clockwise until it reaches the 1.0Nm torque limit to rigidly couple the ADIRA™ plate to the selected interbody spacer.

**Engaging alignment screw**

To disengage the Threaded Plate Holder, unthread the plate holder from the universal threaded port by rotating the instrument counterclockwise.

Proceed to Step 5 (Fixation).

# Plate-Spacer Assembly Insertion Technique

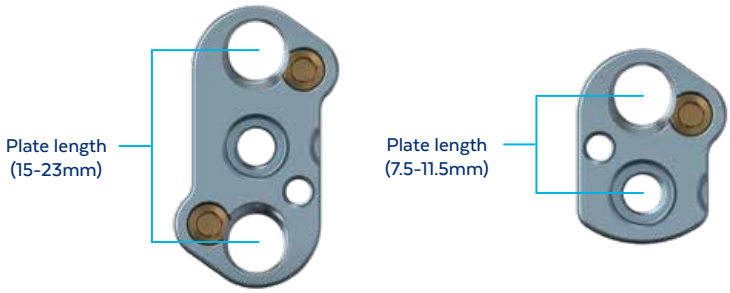
ADIRA™ static plates may be assembled to a static interbody spacer prior to insertion, or assembled *in situ*.

*Note: ADIRA™ RLX plates must be assembled to the expandable interbody spacer in situ to allow for device expansion.*

## STEP 3B PLATE SELECTION AND PLATE-SPACER ASSEMBLY

Determine the plate style for intraoperative assembly to the selected interbody fusion device using the corresponding alignment screws, as shown in Step 2. The ADIRA™ XLIF™ Plate System offers one-screw and two-screw plates that have the option to connect to HEDRON L™, Modulus™ XLIF™, Cohere™ XLIF™, TransContinental™ (including TransContinental™ TPS), and CoRoent™ spacers. The height of the inserted interbody spacer is used to determine the necessary plate length.

*Note: For two-hole plates, ADIRA™ plate length is the distance between the cephalad and caudal holes (center to center). For one-hole plates, ADIRA™ plate length is the distance between the bone screw hole and central insertion hole (center to center). Plate length is etched on each plate.*

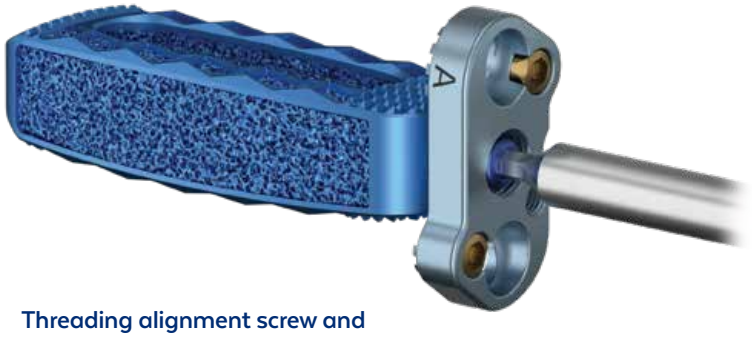



Use the table in Step 3A (under the *In Situ* Assembly Insertion Technique) to identify the minimum compatible plate length based on interbody height.

After selecting the desired ADIRA™ plate length, and the correct alignment screw based on the chosen interbody spacer, use the assembled 2.5mm Hex Driver to insert the alignment screw through the plate until it is captured.

**Coupling alignment screw to ADIRA™ static plate using 2.5 hex driver**

Align the plate-screw construct with the selected interbody spacer. Ensure that the anterior side of the plate (indicated by an "A" etching) faces anteriorly. Use the 2.5mm Hex Driver assembly to thread the alignment screw into the interbody spacer until it reaches the torque limit.

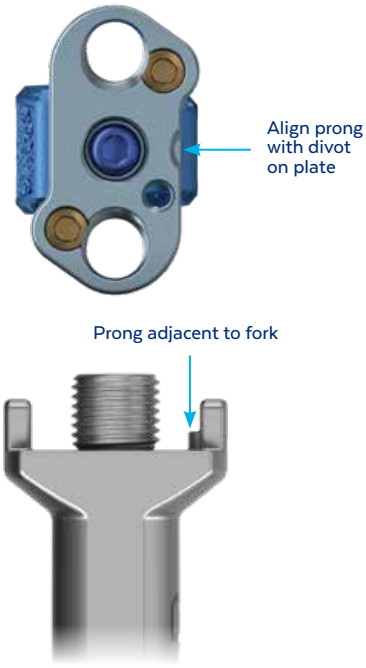



**Threading alignment screw and plate to HEDRON L™ Spacer**

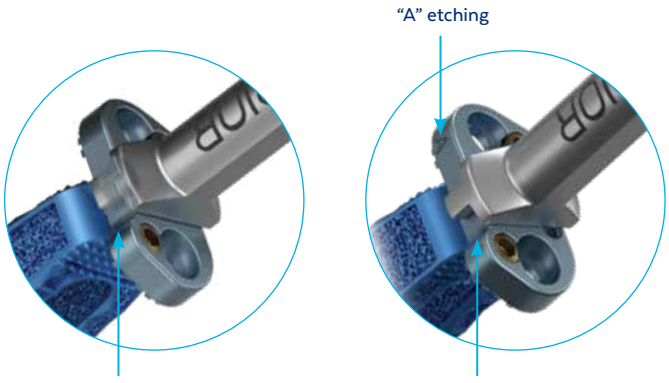
# STEP 4B PLATE PLACEMENT AND COUPLING WITH THE ADIRA™ PLATE INSERTER

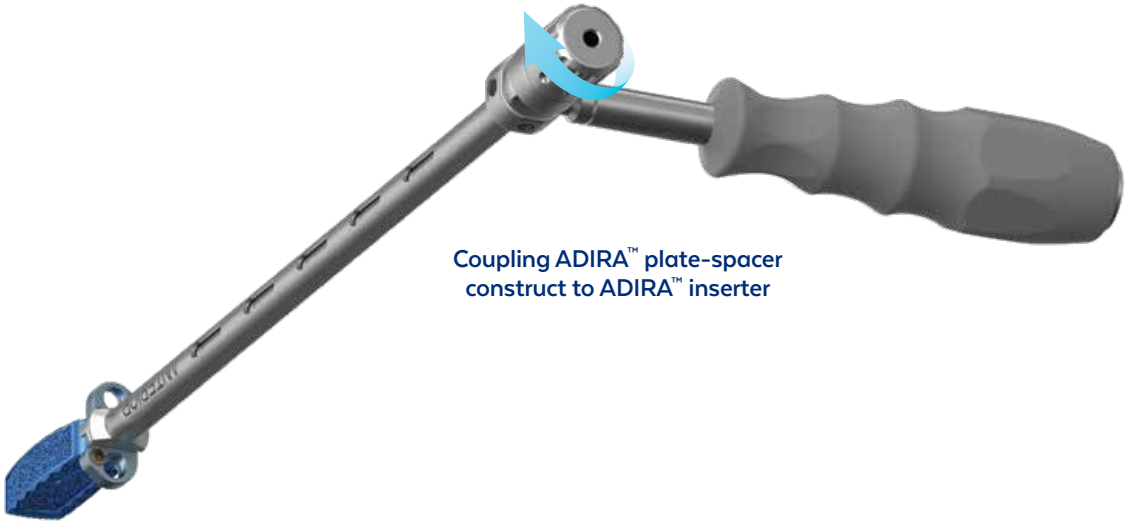
Once the appropriate alignment screw and ADIRA™ plate are rigidly coupled to the interbody spacer, thread the plate and spacer construct to the ADIRA™ Plate Inserter.

Align the prong adjacent to the fork at the distal end of the inserter sleeve with the divot on the chosen plate, ensuring the anterior side of the plate (indicated by an "A" etching) is aligned with the anterior side of the inserter ("Anterior" etching). Rotate the knob of the inserter threaded shaft clockwise to engage the plate and secure it to the inserter.



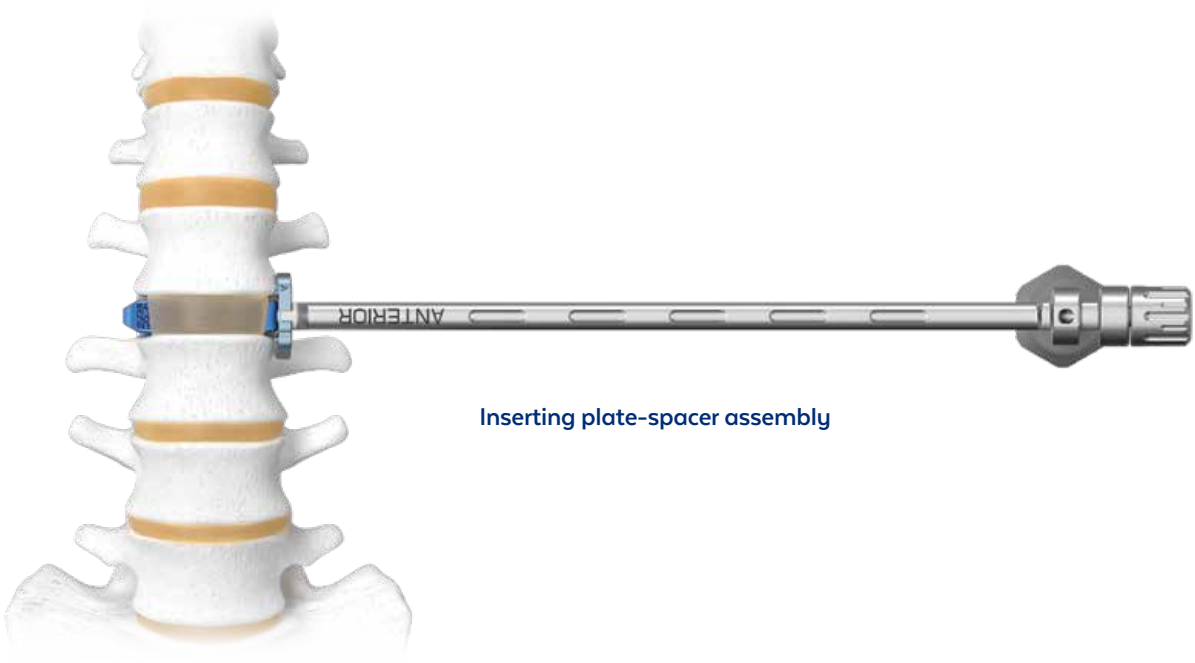

Aligning ADIRA™ plate divot with inserter prong



Coupling ADIRA™ plate-spacer construct to ADIRA™ inserter

Using gentle impaction, insert the plate-spacer into the desired position within the disc space. Ensure that interbody sizing, selection, and insertion technique are consistent with that of the specific interbody system.




**Inserting plate-spacer assembly**

Once the ADIRA™ plate is in the desired location, rotate the knob on the proximal end of the inserter counterclockwise to gently release the inserter from the implant. If necessary, the Inserter Wrench may be used to loosen the inserter knob (see page 18).

*Note: Do not use the Inserter Wrench to tighten ADIRA™ implants to the inserter.*

Proceed to Step 5 (Fixation).

# OPTIONAL TECHNIQUE: PLATE ONLY (NO SPACER) INSERTION

After selecting the appropriate plate size, thread the Threaded Plate Holder into the small threaded hole on the plate as shown. Position the plate on the vertebral bodies in the desired location and proceed to Step 5 (Fixation).

Alternately, the ADIRA™ Plate Inserter can be used to position the plate on the vertebral bodies as desired.

**Positioning plate using Threaded Plate Holder**


**Positioning plate using ADIRA™ Plate Inserter**

# STEP 5 FIXATION

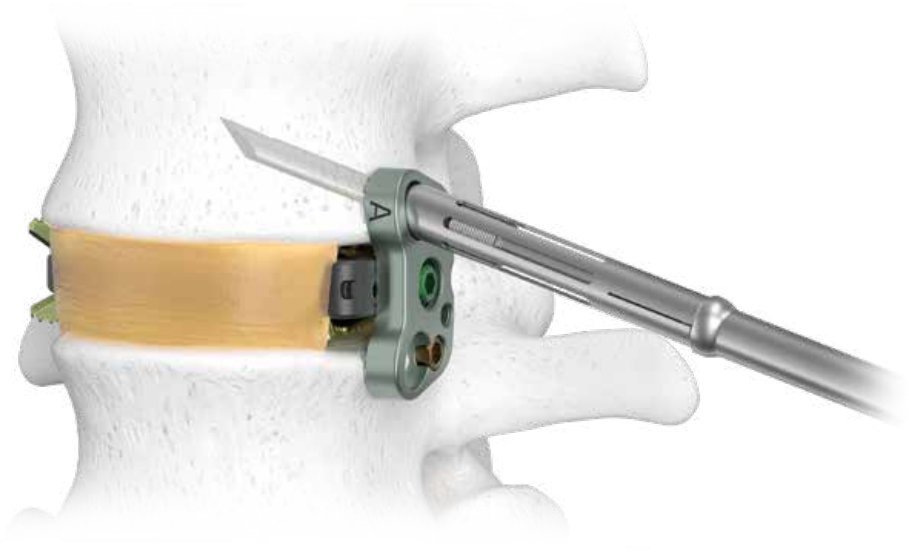
The following steps regarding screw hole preparation and screw or anchor insertion are the same regardless of interbody style or ADIRA™ implant insertion technique. It should also be noted that the fixation steps are the same if no interbody spacer is used and only the ADIRA™ plate is implanted.

ADIRA™ plates may be used with screws, anchors, or a combination of both screws and anchors (hybrid).

## *Screw Fixation*

### Screw Hole Preparation

Insert an awl through the screw hole at the desired angle in the ADIRA™ plate to perforate the cortex. A drill and tap may be used to further prepare the screw hole. While inserting the awl, ensure that the flat on the upper shaft faces the endplate being prepared. Remove the awl and clear any tissue in the bone screw hole. If using a two-hole plate, prepare one screw hole and move to screw insertion before preparing the second screw hole. Repeat for all screw holes.

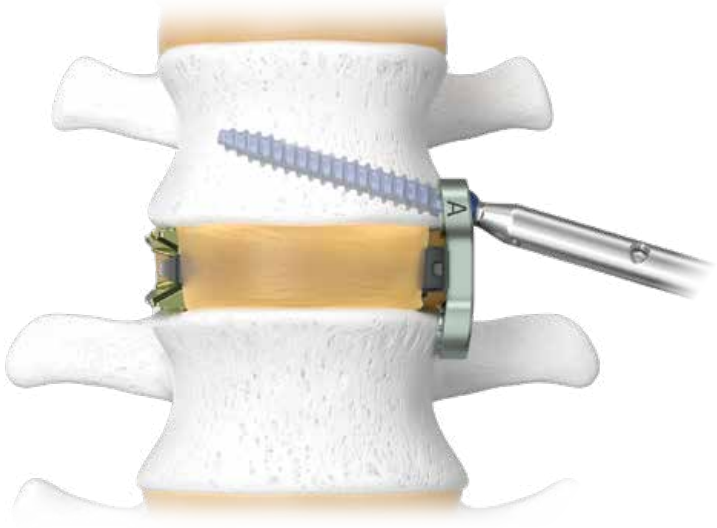


**Preparing screw hole using awl**

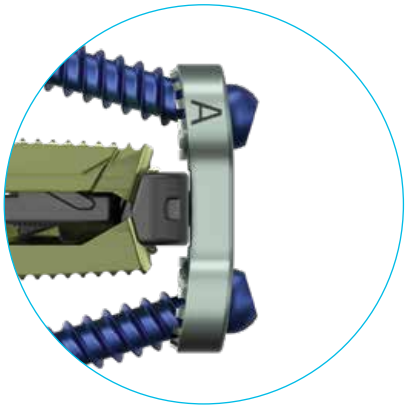
## Screw Insertion

Select and insert the desired bone screw or locking screw with the **InterContinental™ Straight Shaft 3.5mm Hex Driver** or **Expandable 3.5mm Hex Driver** until the screw head contacts the plate. Confirm that the bone screw is at the same angle as the awl. Ensure that the screws do not disrupt any adjacent structures outside the vertebrae. Repeat for all screw holes. If using locking screws, thread the screw into the plate until fully seated.

*Note: If using a two-hole plate, do not final tighten at this time. Repeat screw hole preparation and screw insertion for the second screw hole.*



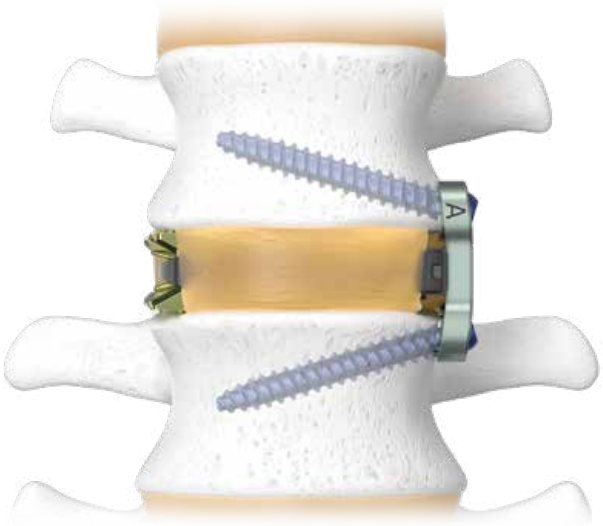
Inserting screws using
Expandable 3.5mm Hex Driver



Screws not fully inserted

## Final Screw Positioning

Once both screws are inserted and positioned, final tighten each screw using the 3.5mm Hex Driver Assembly until fully seated within the plate.



Final screw positioning

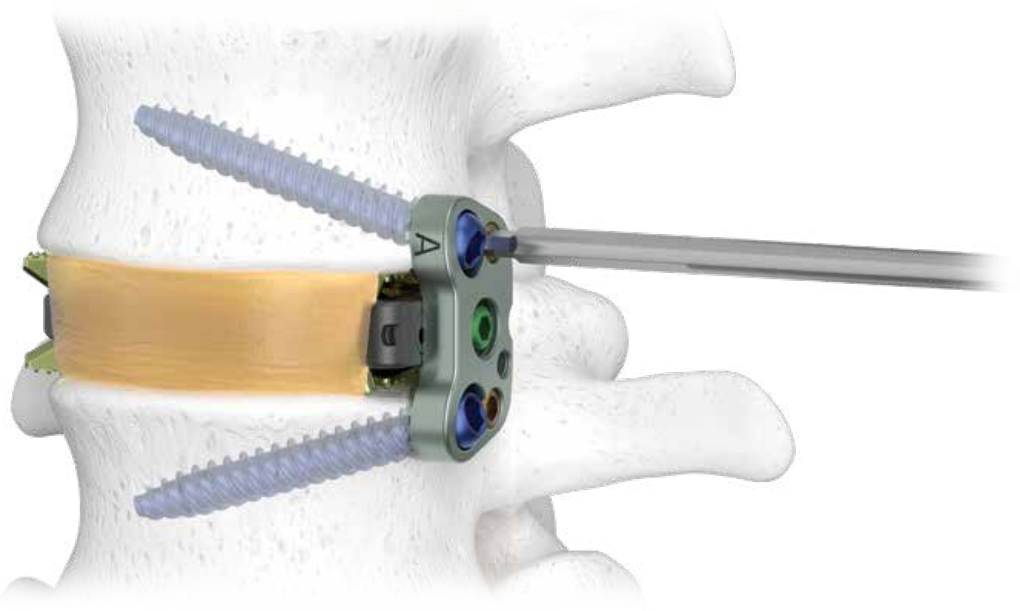
# *Screw Fixation (Cont'd)*

## Screw Blocking

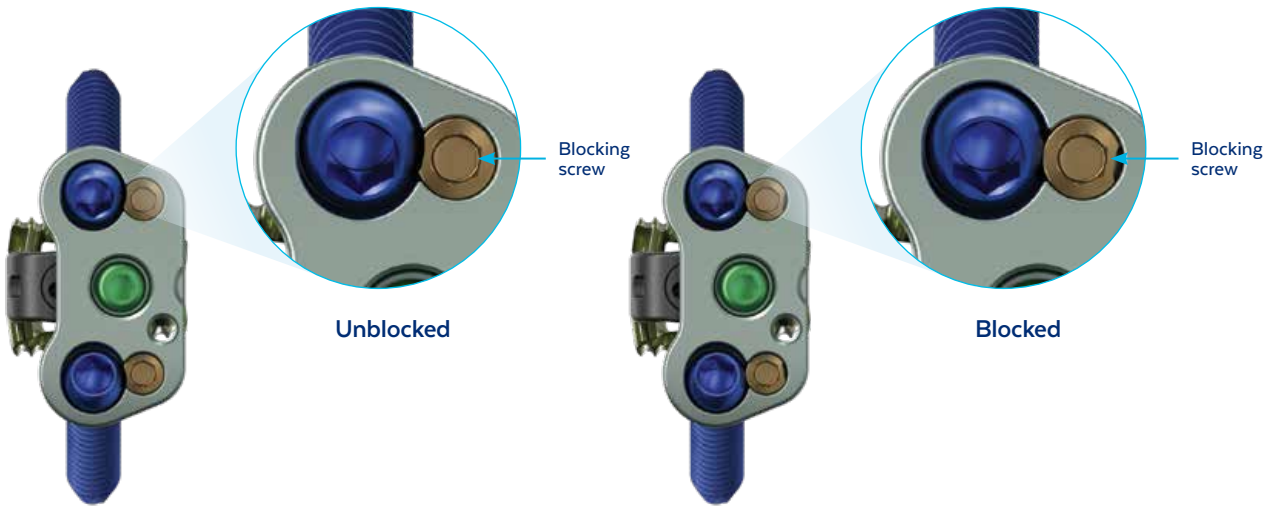
Once all screws are fully seated, all blocking screws must be rotated into position to secure them to the plate.

Assemble the 2.5mm blocking set screwdriver by attaching the torque-limiting quick-connect handle to the driver shaft.

Insert the blocking set screwdriver into the blocking screw and rotate clockwise until the blocking screw is in the blocked position. An audible and tactile click occurs when the blocking screw reaches its final position. The screws are locked to the plate when the blocking screw covers the bone screw head. Repeat for all blocking screws.



**Rotating blocking screw using 2.5mm driver**

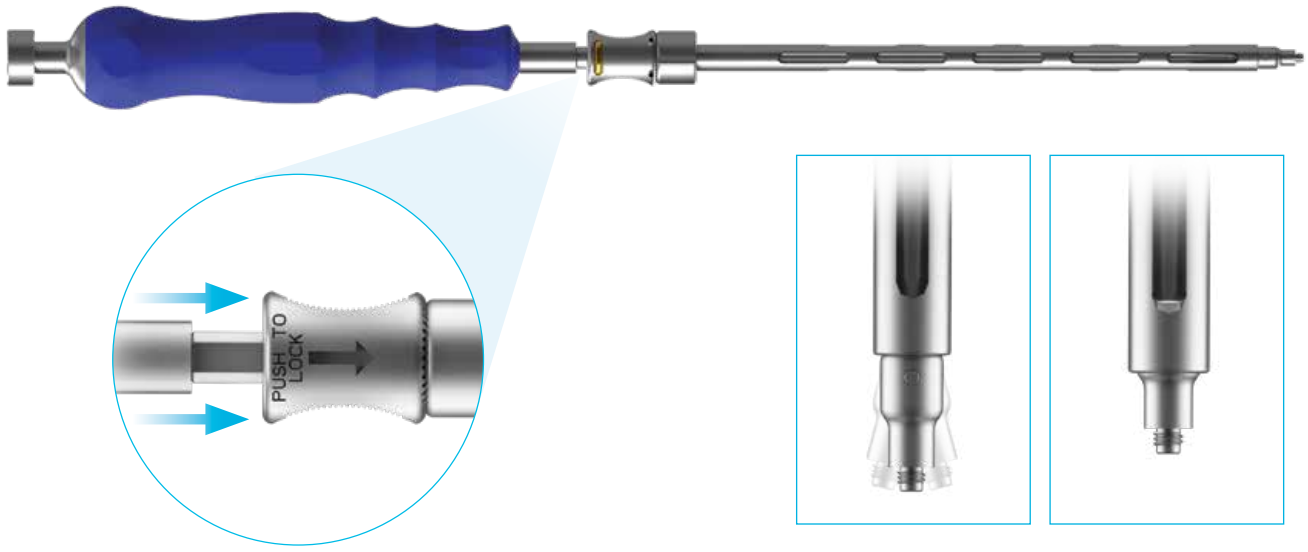



**Screw blocking**

# *Anchor Fixation*

## Anchor Insertion

Place the **Single Anchor Inserter, Lateral** in the locked position by sliding the lock assembly towards the distal end. To confirm that the inserter is locked, ensure that the outer sleeve is pushed forward and the tip does not angulate.



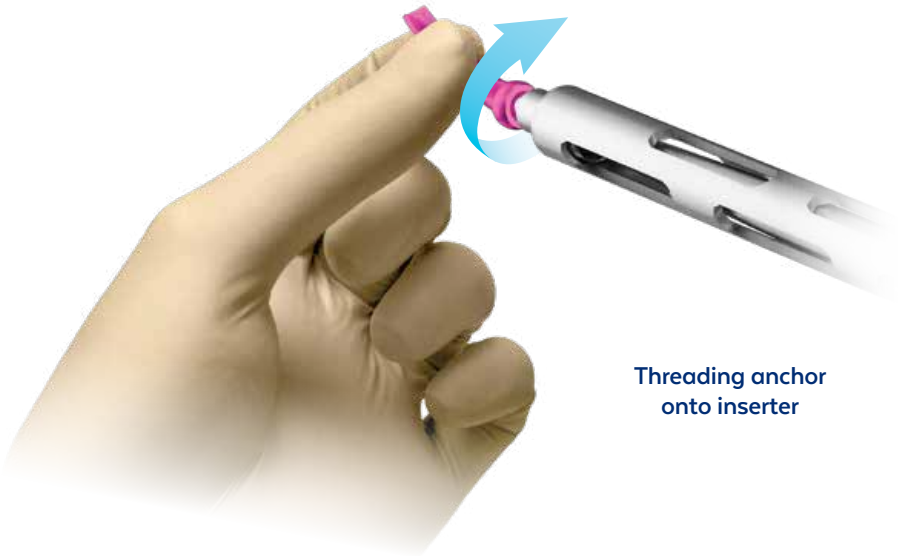

Placing instrument in locked position

Unlocked

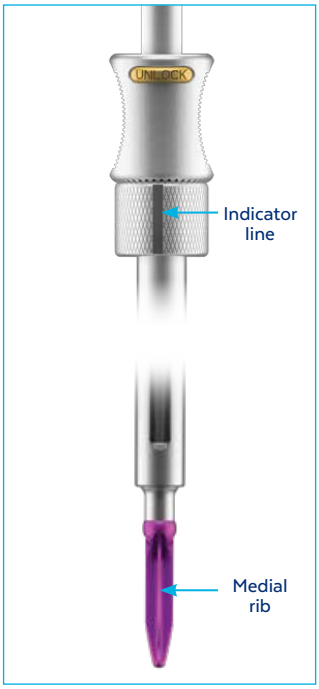
Locked

Confirm the plate is flush with the vertebral body, then select the appropriate anchor length. Thread the selected anchor onto the inserter by rotating the handle clockwise. Ensure the anchor is flush against the inserter. Do not over-tighten the anchor, as this may damage the threads or make removal challenging. Use care when handling the anchor as the tip is sharp.

The directional indicator can be used to track the direction of the anchor after being introduced into the surgical corridor. To adjust the indicator, pull down distally and rotate to align the indicator line with the medial rib of the anchor.



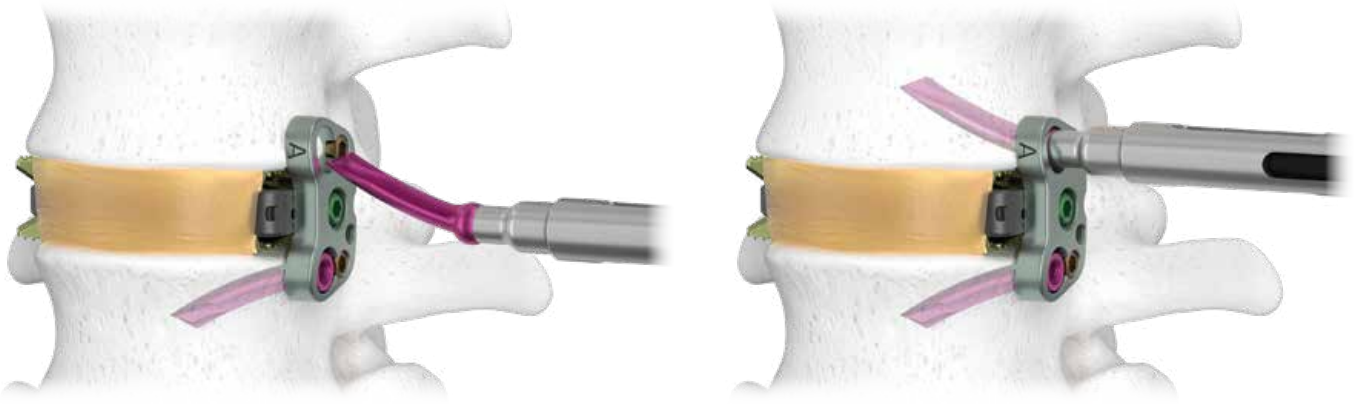
Threading anchor onto inserter




Directional indicator

# *Anchor Fixation (Cont'd)*

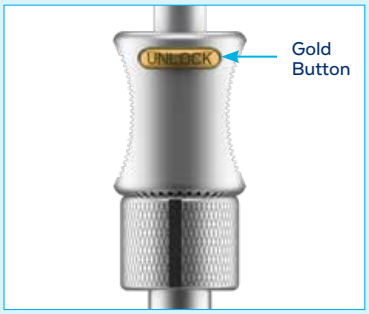
Carefully insert the anchor into the surgical corridor to seat the anchor tip into a fixation hole in the plate. Check the desired trajectory. Using a mallet, gently tamp the inserter to advance the anchor under AP fluoroscopy. Repeat for the second anchor.

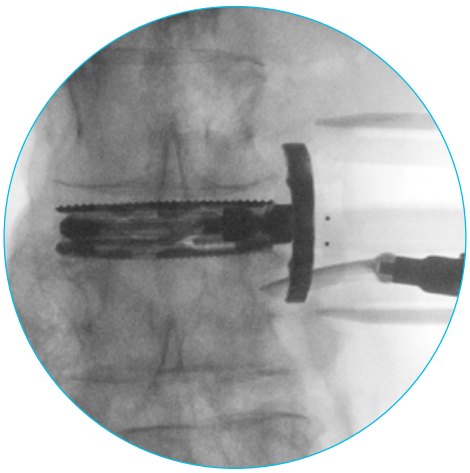


**Inserting anchors using Anchor Inserter**

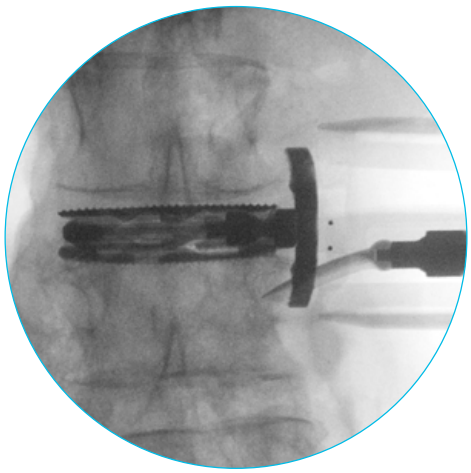
## ANCHOR ANGULATION

The tip on the Anchor Inserter is designed to angulate for difficult trajectories. After placing the anchor into the fixation hole, begin impacting the inserter. If needed, press the gold button to release the slider to allow angulation. The anchor may be impacted while in the unlocked position.



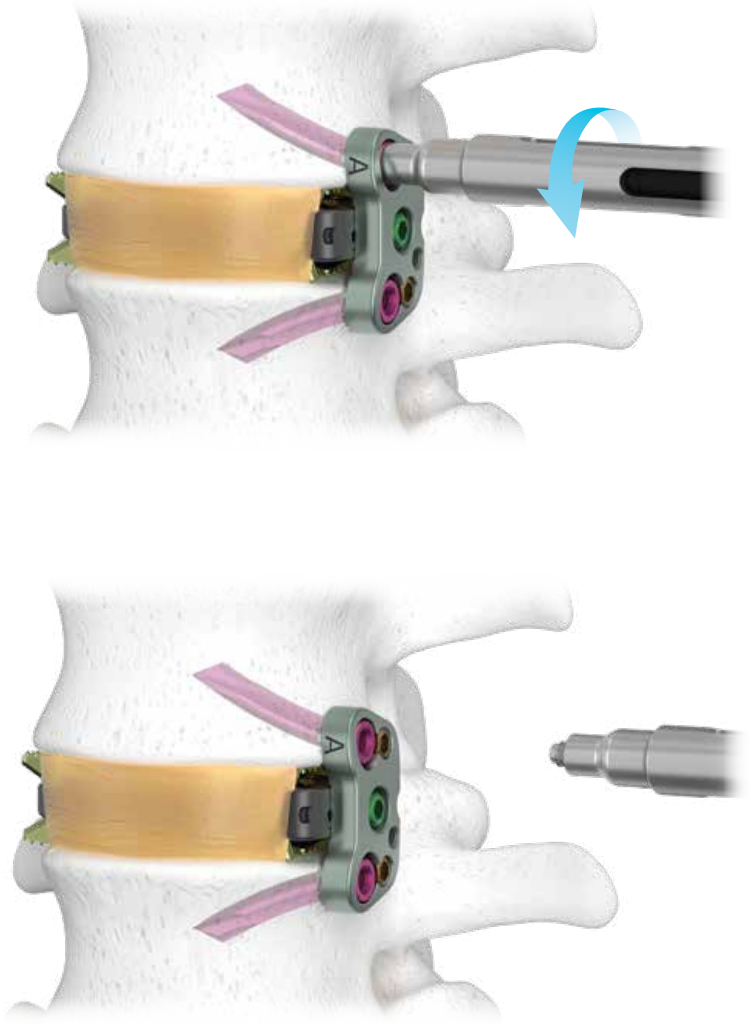
**Unlocked**



**Locked**

## Inserter Removal

Once the anchor is fully seated in the fixation hole, rotate the inserter counterclockwise to disengage the anchor. When the inserter is disconnected, it may be removed.



**Disconnecting and removing inserter**

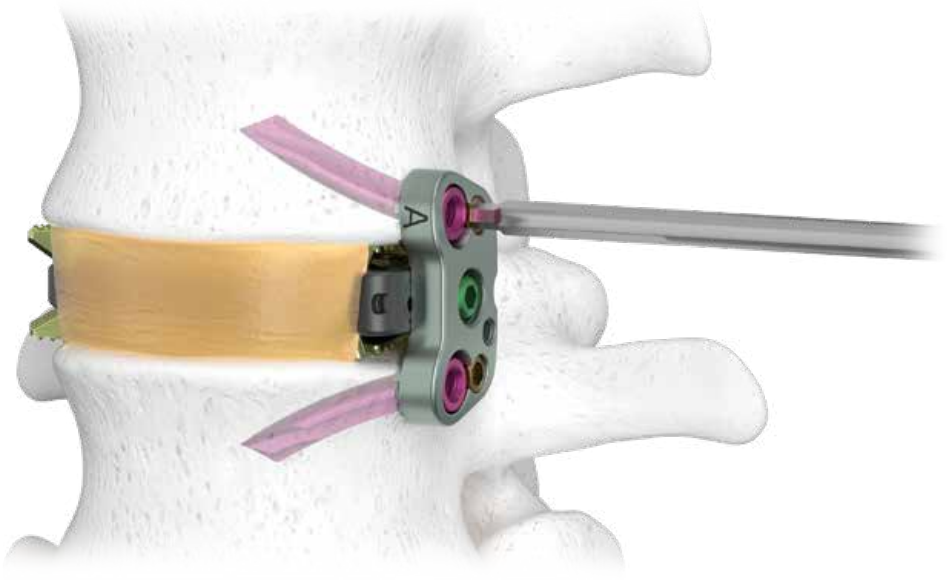
# *Anchor Fixation (Cont'd)*

## Anchor Blocking

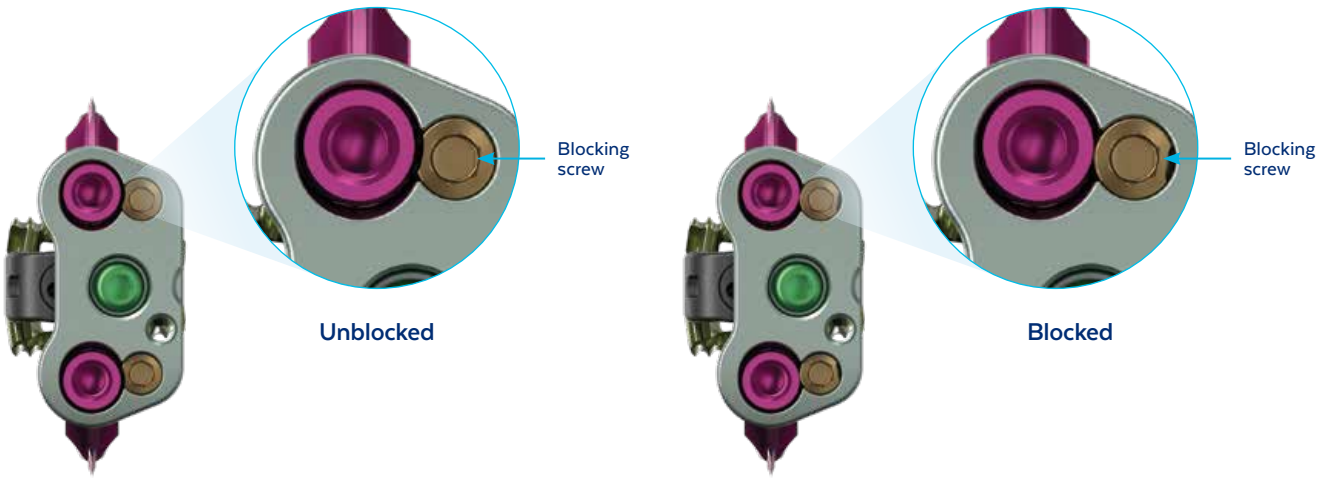
Once all anchors are fully seated, all blocking screws must be rotated into position to secure them to the plate.

Assemble the 2.5mm blocking set screwdriver by attaching the torque-limiting quick-connect handle to the driver shaft.

Insert the blocking set screwdriver into the blocking screw and rotate clockwise until the blocking screw is in the blocked position. An audible and tactile click occurs when the blocking screw reaches its final position. The anchors are locked to the plate when the blocking screw covers the anchor head. Repeat for all blocking screws. When using anchors, supplemental fixation is required. See the Supplemental Fixation section for details.



**Rotating blocking screw using 2.5mm driver**

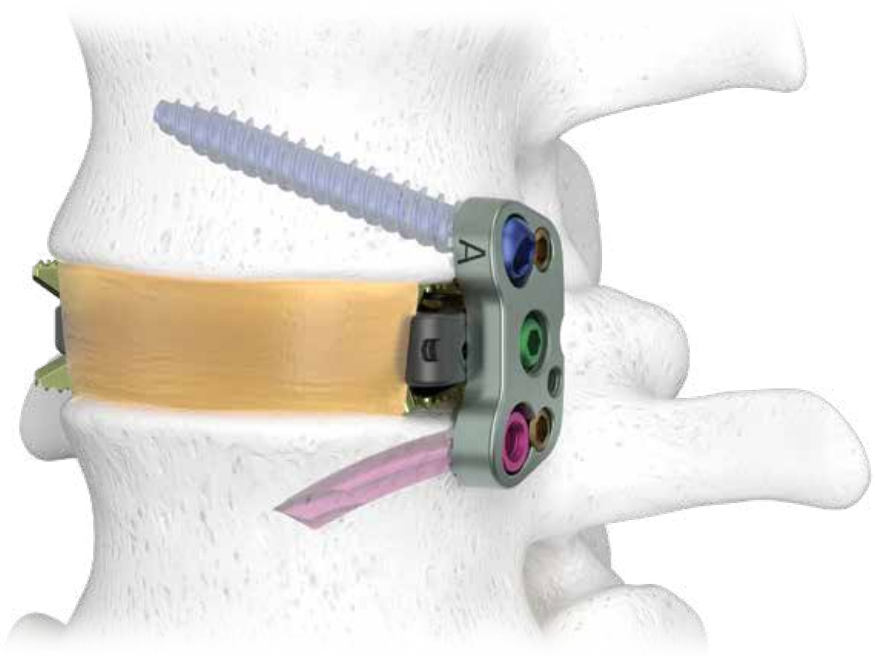



**Anchor blocking**

## *Hybrid Screw/Anchor Fixation*

If a hybrid screw/anchor construct is desired, follow instructions for screw fixation and anchor fixation.

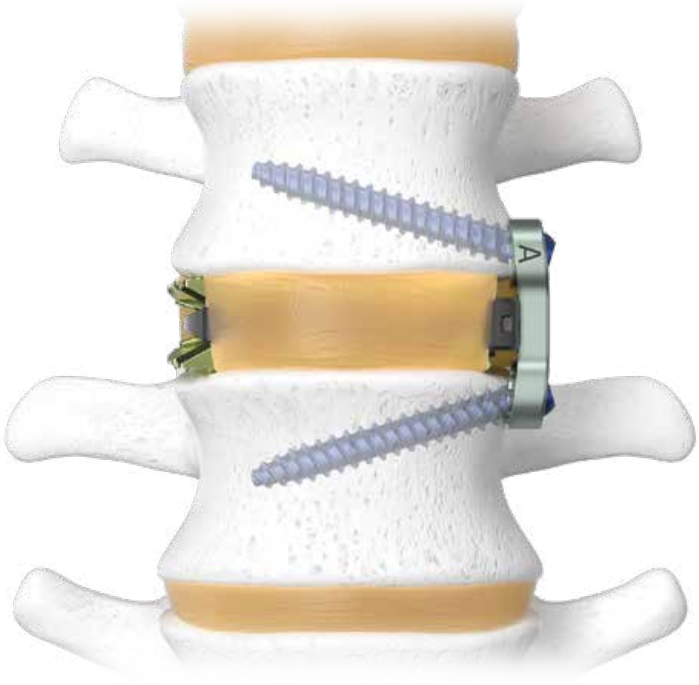
When using anchors, supplemental fixation is required. See the Supplemental Fixation section for details.



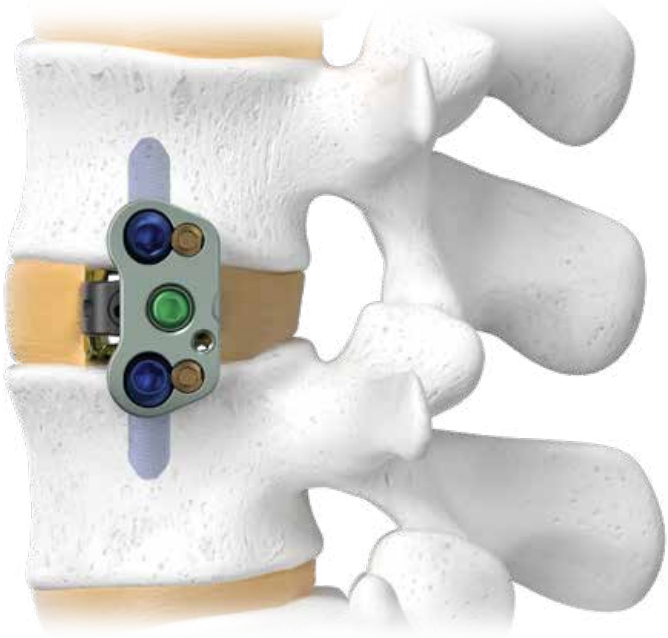

**Hybrid final implant position**

# SCREW FIXATION FINAL POSITION

When using one-hole plates, supplemental fixation is required. See the Supplemental Fixation section for details.



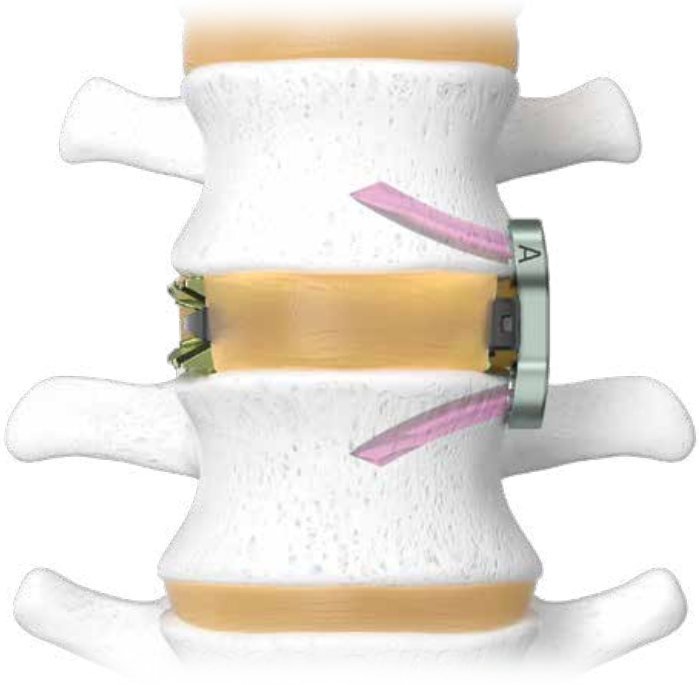

**AP view**



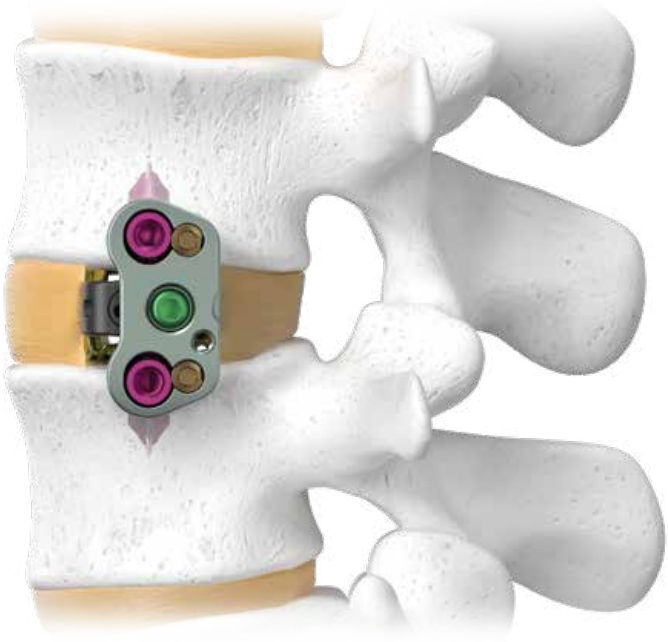
**Lateral view**

# ANCHOR FIXATION FINAL POSITION

When using anchors, supplemental fixation is required. See the Supplemental Fixation section for details.



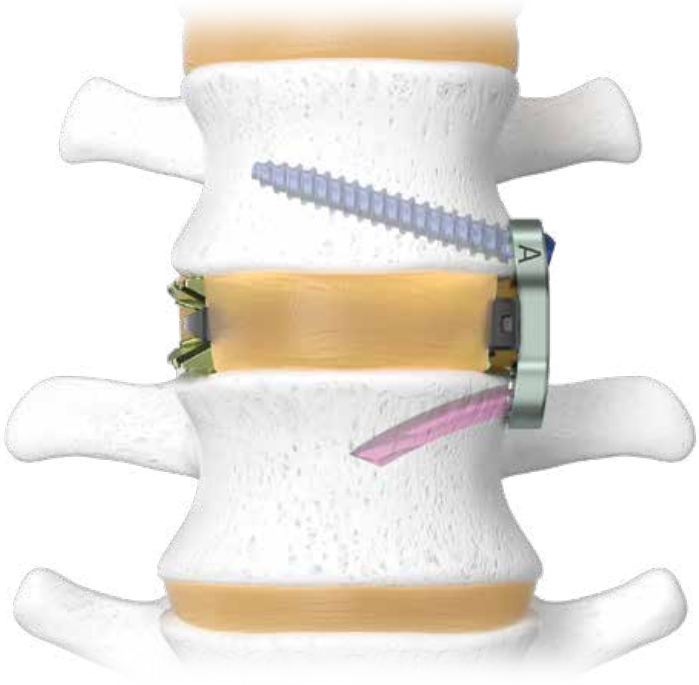

**AP view**



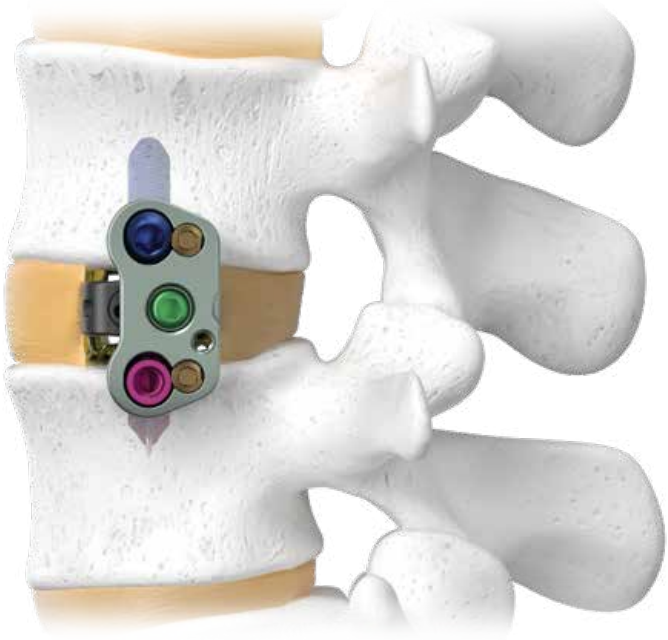
**Lateral view**

# HYBRID FIXATION FINAL POSITION

When using anchors, supplemental fixation is required. See the Supplemental Fixation section for details.




**AP view**



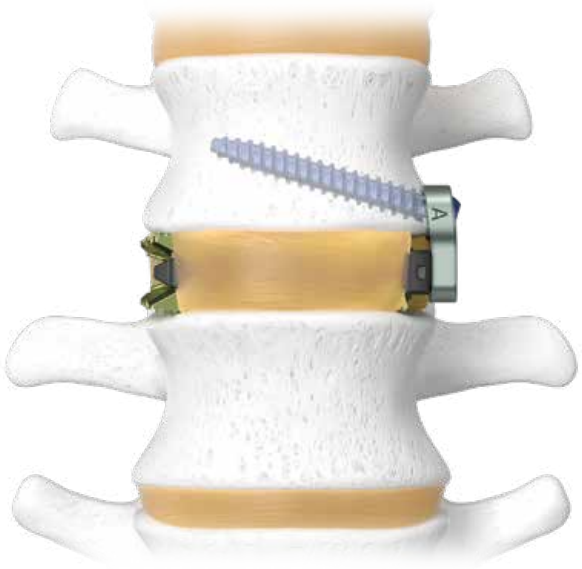
**Lateral view**

# FINAL CONSTRUCTS: ADIRA™-RLX

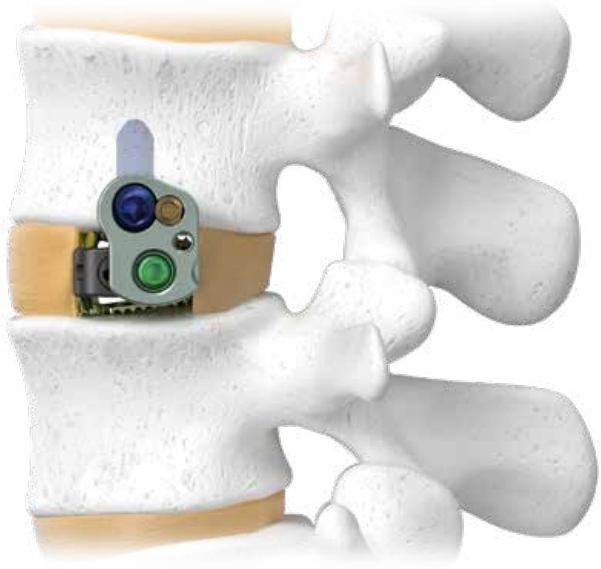
ADIRA™ plate-spacers are intended to be used with screws and/or anchors that accompany the implants. These devices are intended for use with supplemental fixation (e.g., facet screws or posterior fixation). In addition, the two-hole plate-spacers are intended for stand-alone use in patients with degenerative disc disease (DDD) at one or two levels only when <20° lordotic implants are used with two screws.

## One-Hole ADIRA™-RLX RISE™-L Plate-Spacer Constructs

*Supplemental fixation required*

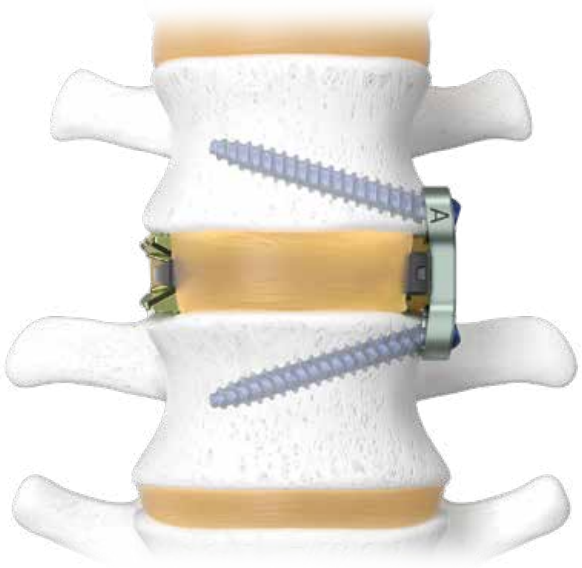


AP view

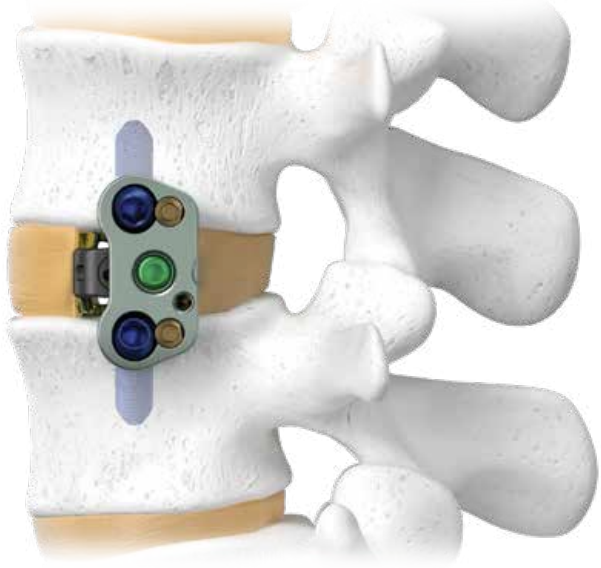


Lateral view

## Two-Hole ADIRA™-RLX RISE™-L Plate-Spacer Constructs



AP view



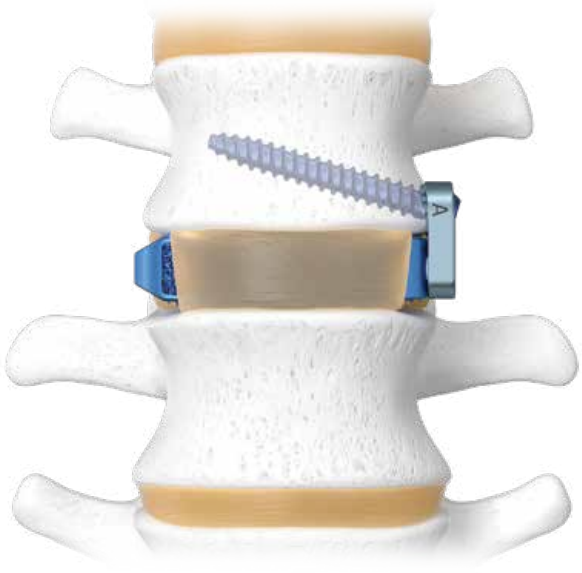
Lateral view

# FINAL CONSTRUCTS: ADIRA™ STATIC COMPATIBLE

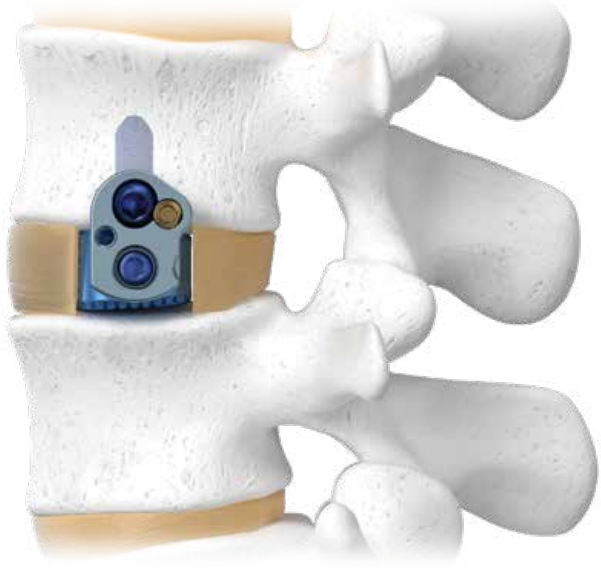
ADIRA™ plate-spacers are intended to be used with screws and/or anchors that accompany the implants. These devices are intended for use with supplemental fixation (e.g., facet screws or posterior fixation). In addition, the two-hole plate-spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two screws.

## One-Hole ADIRA™ HEDRON L™ Plate-Spacer Constructs

*Supplemental fixation required*

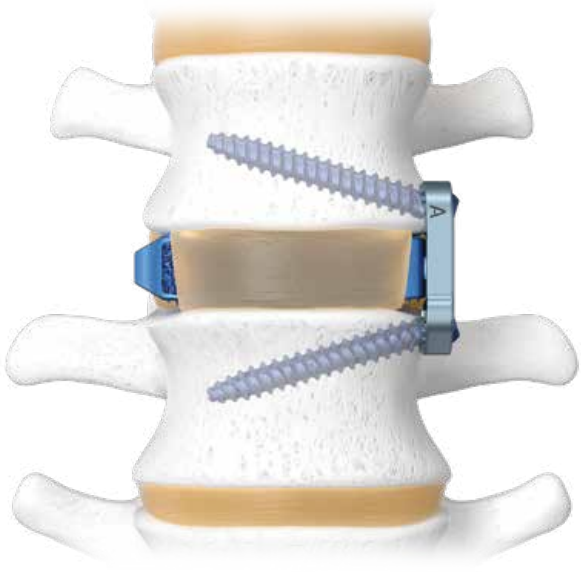


AP view

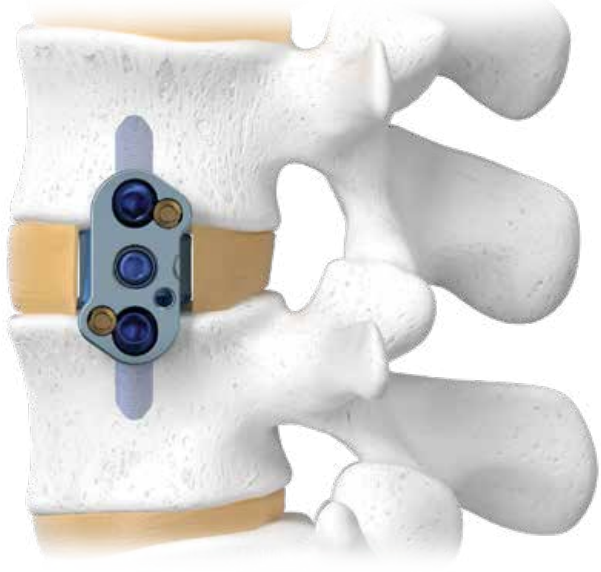


Lateral view

## Two-Hole ADIRA™ HEDRON L™ Plate-Spacer Constructs



AP view



Lateral view

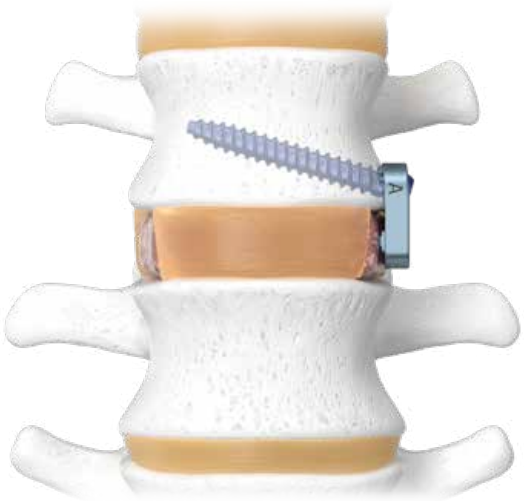
# FINAL CONSTRUCTS: ADIRA™ LATERAL PLATE SYSTEM (PLATE ONLY)

The ADIRA™ Two-Hole Plate, when used with screws only, is intended for use in the treatment of thoracolumbar (T1-L5) spinal instability as a result of fracture (including dislocation and subluxation), tumor, DDD, scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spinal surgery.

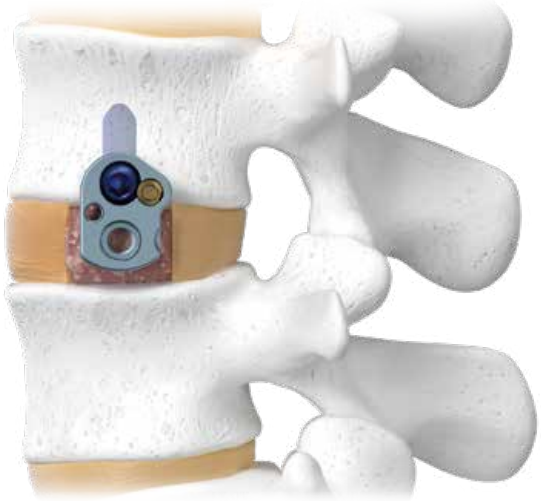
The ADIRA™ One-Hole Plate is intended to stabilize allograft or autograft at one level (T1-L5), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. It may be used alone or with other anterior, lateral, anterolateral, or posterior spinal systems. The device is not intended for load bearing applications.

## One-Hole ADIRA™ Plate Stabilizing Allograft

*Supplemental fixation required*

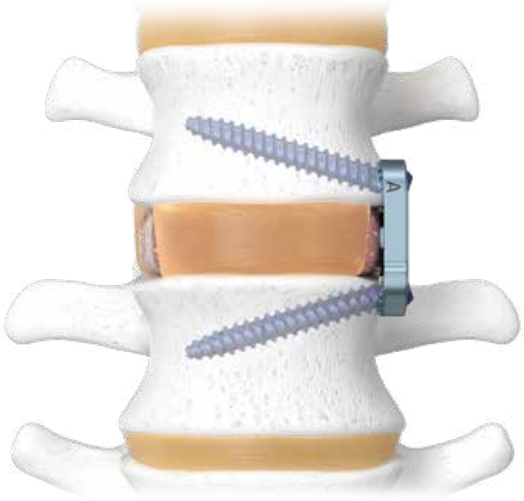


AP view

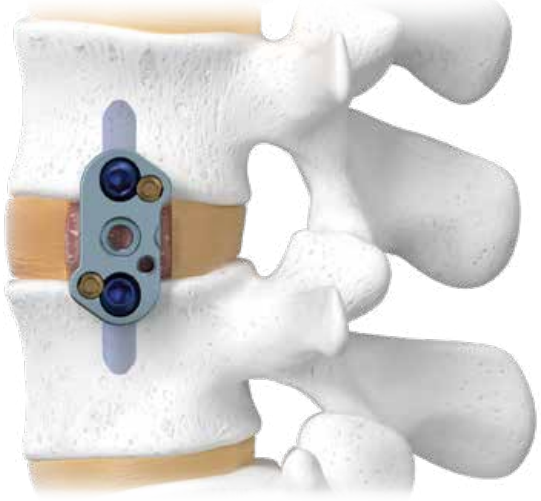


Lateral view

## Two-Hole ADIRA™ Plate Stabilizing Allograft



AP view



Lateral view

# SUPPLEMENTAL FIXATION

Assembled ADIRA™ plate-spacers are intended to be used with supplemental fixation. In addition, these devices are intended for stand-alone use in patients with DDD at one or two levels only when ADIRA™ plates are used with screws and attached to a <20° lordotic interbody fusion device. Refer to the surgical technique manual for the desired supplemental fixation system for specific instructions.

# OPTIONAL: PLATE REVISION OR REMOVAL

To remove the ADIRA™ plate, unlock the blocking screw using the Blocking Screw Driver, 2.5mm. Loosen and remove the bone screws using the 3.5mm screw driver. Remove anchors by reattaching the inserter and using a **Slide Hammer**.

Use the same blocking screw driver to unthread the alignment screw that mates the plate to the spacer.

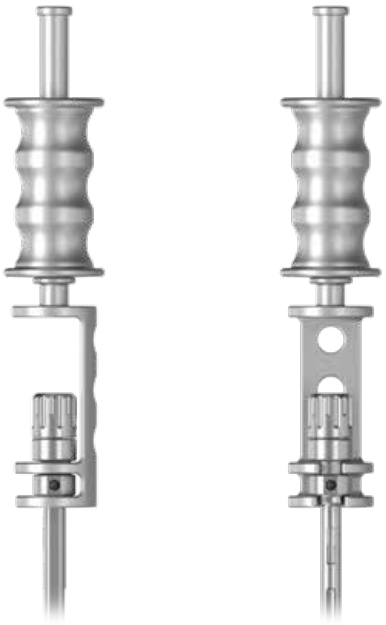
Once all screws are removed, the plate may be removed using the Threaded Plate Holder, inserter, or standard forceps.

**Attaching Slide Hammer to anchor inserter**

# OPTIONAL: PLATE-SPACER CONSTRUCT REMOVAL

To remove an ADIRA™ plate and interbody spacer as a construct, unlock the blocking screw using the Blocking Screw Driver, 2.5mm. Loosen and remove the bone screws. Reattach the plate inserter to the ADIRA™ plate-spacer construct. Remove anchors by reattaching the inserter and using a Slide Hammer.

Use the Slide Hammer to remove the ADIRA™ plate-spacer construct.



# ADIRA™
# INSTRUMENT SET 9264.9001

| Part No. | Description | Qty |
|---|---|---|
| 176.730 | Self-Drilling Screw, Variable Angle, 5.5mm, 30mm | 2 |
| 176.735 | Self-Drilling Screw, Variable Angle, 5.5mm, 35mm | 4 |
| 176.740 | Self-Drilling Screw, Variable Angle, 5.5mm, 40mm | 4 |
| 176.745 | Self-Drilling Screw, Variable Angle, 5.5mm, 45mm | 4 |
| 176.750 | Self-Drilling Screw, Variable Angle, 5.5mm, 50mm | 2 |
| 687.524 | InterContinental™ Straight Shaft Awl | 1 |
| 6122.0511 | Angled Awl, 10° | 1 |
| 687.527 | InterContinental™ Straight Shaft 3.5mm Hex Driver | 1 |
| 687.005 | Quick-Connect Swivel Handle | 1 |
| 687.105 | Ratchet Handle | 1 |
| 687.603 | Expandable 3.5mm Hex Driver | 1 |
| 693.614 | Inserter Wrench | 1 |
| 6264.0500 | Threaded Plate Holder | 1 |
| 6264.0100 | ADIRA™ Inserter, Threaded Shaft | 2 |
| 6264.0200 | ADIRA™ Inserter, Outer Sleeve | 2 |
| 6154.3003 | Counter-Torque M6x1 | 2 |
| 694.018 | Slide Hammer | 1 |
| 6264.0300 | Blocking Screw Driver, 2.5mm | 2 |
| 6264.0600 | Torque-Limiting Quick-Connect Handle, 1.0Nm | 2 |
| 650.906 | 2.5mm Hex Driver (HD2060984) | 1 |
| | | |
| 9264.0001 | ADIRA™ Instrument Graphic Case | |

# ADIRA™
# IMPLANT SET, RLX 9264.9002

| Part No. | Description | Qty |
|---|---|---|
| 1264.1107 | ADIRA™ Plate, 1 Hole, 7.5mm, Up, RLX | 2 |
| 1264.1108 | ADIRA™ Plate, 1 Hole, 8.5mm, Up, RLX | 2 |
| 1264.1109 | ADIRA™ Plate, 1 Hole, 9.5mm, Up, RLX | 2 |
| 1264.1110 | ADIRA™ Plate, 1 Hole, 10.5mm, Up, RLX | 2 |
| 1264.1111 | ADIRA™ Plate, 1 Hole, 11.5mm, Up, RLX | 1 |
| 1264.2115 | ADIRA™ Plate, 2 Hole, 15mm, RLX | 2 |
| 1264.2117 | ADIRA™ Plate, 2 Hole, 17mm, RLX | 2 |
| 1264.2119 | ADIRA™ Plate, 2 Hole, 19mm, RLX | 2 |
| 1264.2121 | ADIRA™ Plate, 2 Hole, 21mm, RLX | 2 |
| 1264.2123 | ADIRA™ Plate, 2 Hole, 23mm, RLX | 1 |
| 1264.0101 | ADIRA™ Alignment Screw, M4.5, Green | 4 |
| | | |
| 9264.0002 | ADIRA™ Implant Set, RLX | |

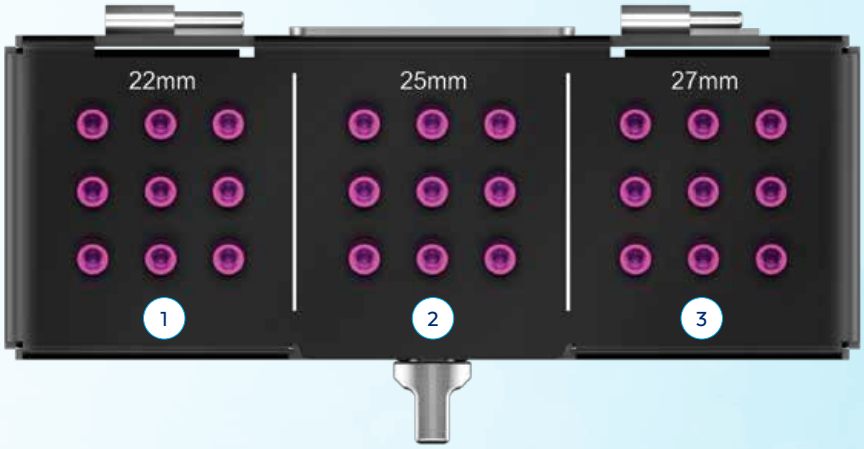
# ADIRA™
# IMPLANT SET, STATIC 9264.9003

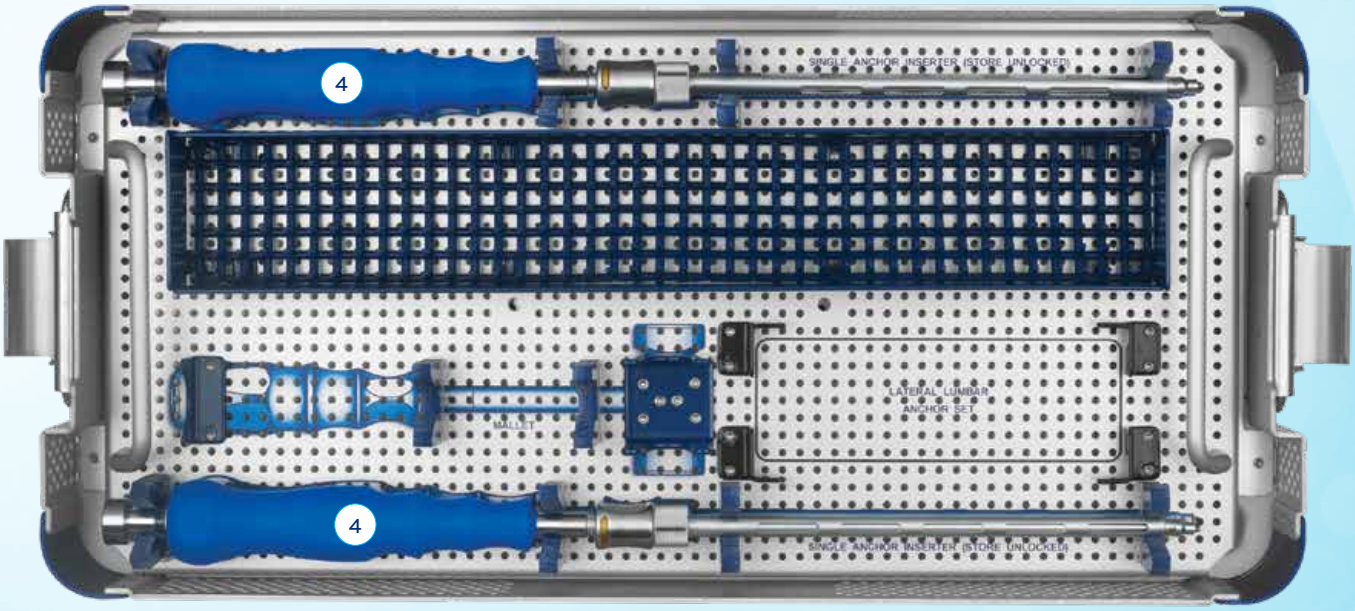
| Part No. | Description | Qty |
|---|---|---|
| 1264.1007 | ADIRA™ Plate, 1 Hole, 7.5mm, Static | 2 |
| 1264.1008 | ADIRA™ Plate, 1 Hole, 8.5mm, Static | 2 |
| 1264.1009 | ADIRA™ Plate, 1 Hole, 9.5mm, Static | 2 |
| 1264.1010 | ADIRA™ Plate, 1 Hole, 10.5mm, Static | 2 |
| 1264.1011 | ADIRA™ Plate, 1 Hole, 11.5mm, Static | 1 |
| 1264.2015 | ADIRA™ Plate, 2 Hole, 15mm, Static | 2 |
| 1264.2017 | ADIRA™ Plate, 2 Hole, 17mm, Static | 2 |
| 1264.2019 | ADIRA™ Plate, 2 Hole, 19mm, Static | 2 |
| 1264.2021 | ADIRA™ Plate, 2 Hole, 21mm, Static | 2 |
| 1264.2023 | ADIRA™ Plate, 2 Hole, 23mm, Static | 1 |
| 1264.0001 | ADIRA™ Alignment Screw, M4, Blue | 4 |
| 1264.0002 | ADIRA™ Alignment Screw, 10-24S, Purple | 4 |
| 1264.0004 | ADIRA™ Alignment Screw, 10-24L, Pink | 4 |
| | | |
| 9264.0003 | ADIRA™ Implant Set, Static | |

# LATERAL MIS
## IMPLANTS AND INSTRUMENTS SET 9219.9001

| | Part No. | Description | Qty |
|---|---|---|---|
| 1 | 1219.0022 | Lateral Anchor, 22mm | 6 |
| 2 | 1219.0025 | Lateral Anchor, 25mm | 6 |
| 3 | 1219.0027 | Lateral Anchor, 27mm | 6 |
| 4 | 6219.1000 | Single Anchor Inserter, Lateral | 2 |
| | 9219.0001 | Lateral MIS Anchor Module | |
| | 9219.0002 | Lateral MIS Graphic Case | |

# LATERAL MIS
## IMPLANTS AND INSTRUMENTS SET 9219.9001



# IMPORTANT INFORMATION ON THE ADIRA™ LATERAL PLATE SYSTEM

**DESCRIPTION**

The ADIRA™ Lateral Plate System consists of one-level thoracolumbar plates and buttress plates that are used with variable, fixed angle, or locking bone screws for attachment to the lateral or anterolateral portion of the vertebral body of the thoracolumbar spine. (T1-L5).

ADIRA™ plates may be assembled to lateral lumbar interbody fusion devices (HEDRON L™, TransContinental™, RISE™-L, Modulus™ XLIF, Cohere™ XLIF, or CoRoent™) with an alignment screw to create an ADIRA™ Plate-Spacer assembly, to provide structural stability in skeletally mature individuals following discectomy. The plate-spacer assembly is used with bone screws and/or lateral anchors.

ADIRA™ plates, alignment screws, bone screws, and anchors are manufactured from titanium alloy, as specified in ASTM F136 or F1295. Bone screws and anchors are available with hydroxyapatite (HA) coating, as specified in ASTM F1185. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537.

**INDICATIONS**

***ADIRA™ Lateral Plate System***

The ADIRA™ 2-Hole and 4-Hole Plates, when used with screws only, are intended for use in the treatment of thoracolumbar (T1-L5) spinal instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spinal surgery.

The ADIRA™ 1-Hole Plate is intended to stabilize allograft or autograft at one level (T1-L5), aiding in spinal fusion and to provide temporary stabilization and augment development of a spinal fusion. It may be used alone or with other anterior, lateral, anterolateral, or posterior spinal systems. The device is not intended for load bearing applications.

***ADIRA™ Plate-Spacer Assemblies***

ADIRA™ Plates may be assembled to a lateral lumbar interbody fusion device (HEDRON L™, TransContinental™, RISE™-L, Modulus™ XLIF, CoRoent™, or Cohere™ XLIF Spacers) to create a plate-spacer assembly. When assembled to HEDRON L™, TransContinental™, or RISE™-L Spacers, the plate-spacer assembly is indicated for use at one or more levels of the lumbosacral spine (L1-L5), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. When ADIRA™ Plates are assembled to Modulus™ XLIF, CoRoent™, or Cohere™ XLIF Spacers, the plate-spacer assembly takes on the indications of the interbody device.

ADIRA™ Plate-Spacers are intended to be used with screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, the 2-Hole or 4-Hole Plate-Spacers are intended for stand-alone use in patients with DDD at one or two levels only when <20° lordotic implants are used with two or four screws, respectively.

ADIRA™ Plate-Spacers are to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

**WARNINGS**

One of the following potential risks identified with this system is death. Other potential risks, which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

Patients with previous spinal surgery at the involved level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Possible adverse effects that may occur include: failed fusion or pseudarthrosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy and cobalt chromium alloy. Mixing of stainless steel implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

**PRECAUTIONS**

The implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size and screw diameter and length.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

**CONTRAINDICATIONS**

Use of this system is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Signs of local inflammation.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any patient not willing to cooperate with postoperative instructions.
- Any condition not described in the indications for use.

**MRI SAFETY INFORMATION**

MR

MRI Safety Information

A person implanted with the ADIRA™ Lateral Plate System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

| | |
|---|---|
| Device Name | ADIRA™ Lateral Plate System |
| Static Magnetic Field Strength ($B_0$) | 1.5T or 3.0T |
| Maximum Spatial Field Gradient | 30 T/m (3,000 gauss/cm) |
| RF Excitation | Circularly Polarized (CP) |
| RF Transmit Coil Type | There are no Transmit Coil restrictions |
| Operating Mode | Normal Operating Mode |
| Maximum Whole-Body SAR | 2 W/kg (Normal Operating Mode) |
| Maximum Head SAR | 3.2 W/kg (Normal Operating Mode) |
| Scan Duration | 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) |
| MR Image Artifact | The presence of this implant may produce an image artifact. |

**PACKAGING**

The implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility

# IMPORTANT INFORMATION ON THE ADIRA™ LATERAL PLATE SYSTEM

of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The implants and instruments may be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

**HANDLING**

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

**CLEANING**

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol™ (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol™ (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

**CONTACT INFORMATION**

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

**STERILIZATION**

These implants may be provided sterile or nonsterile. Instruments are provided nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of $10^{-6}$. Sterile devices are packaged in a heat-sealed double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants that become nonsterile or have expired packaging are considered nonsterile and should be discarded. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of $10^{-6}$. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $in^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 Minutes | 30 Minutes |
| Steam | Pre-vacuum | 134°C (273°F) | 3 Minutes | 30 Minutes |

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

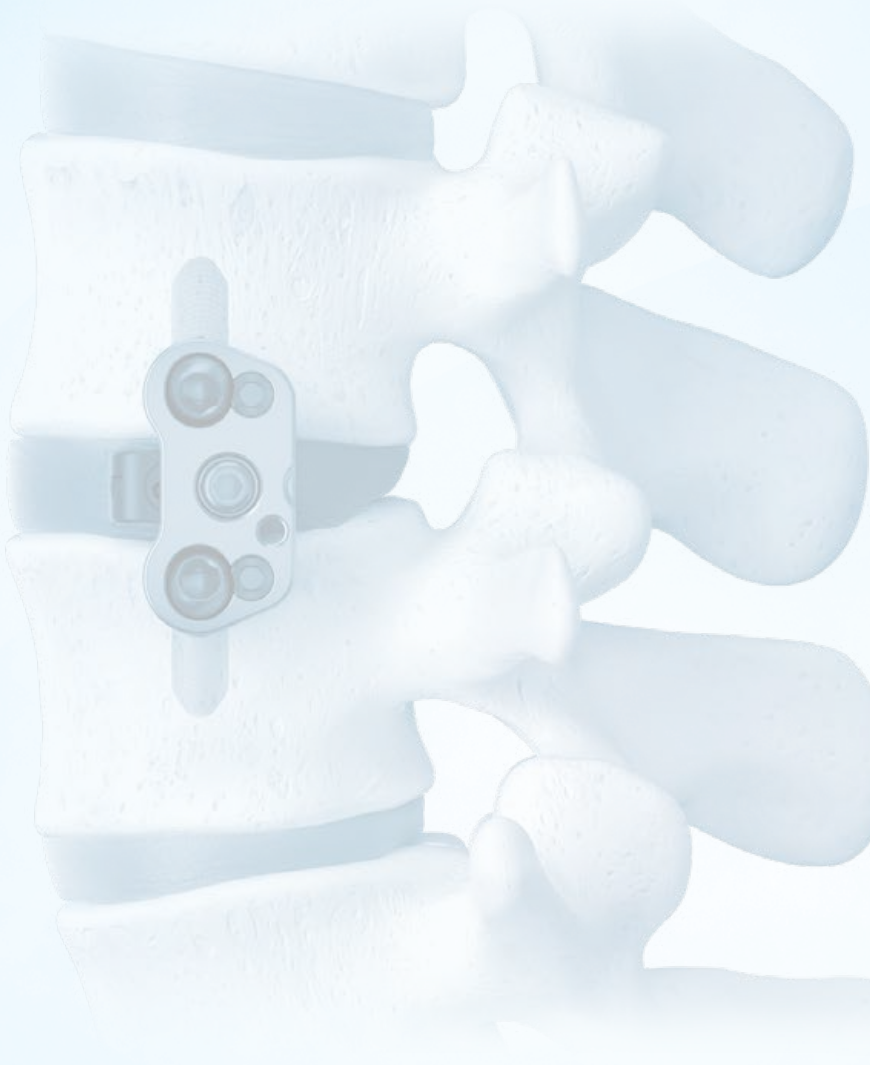
**CAUTION:** Federal (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

| SYMBOL TRANSLATION | | | |
|---|---|---|---|
| REF | CATALOGUE NUMBER | NON STERILE | NON-STERILE |
| LOT | LOT NUMBER | | MANUFACTURER |
| | CAUTION | | USE BY (YYYY-MM-DD) |
| | SINGLE USE ONLY | | DO NOT USE IF PACKAGE IS DAMAGED |
| STERILIZE | DO NOT RESTERILIZE | Rx ONLY | PRESCRIPTION USE ONLY |
| MD | MEDICAL DEVICE | MR | MR CONDITIONAL |

**DI230A Rev A**

# NOTES

# NOTES



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GMTGD287
07.24 Rev B