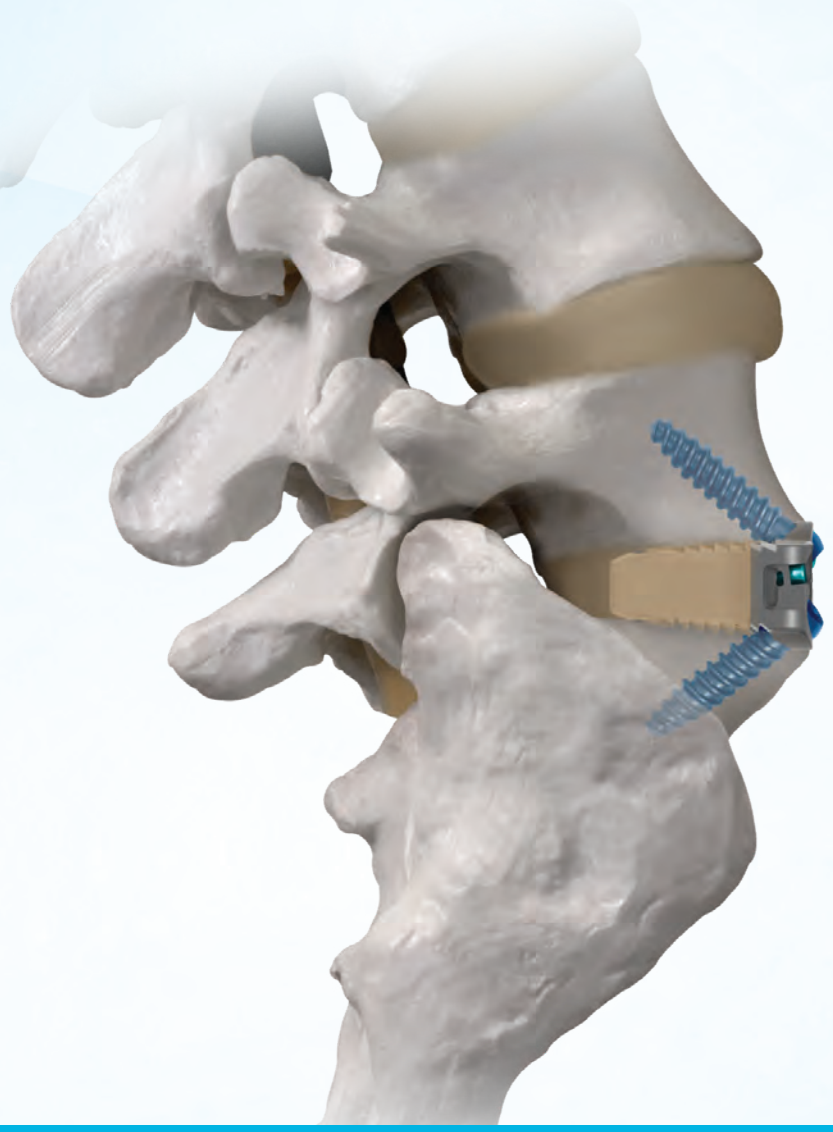
GLOBUS MEDICAL



MONUMENT®

Anterior Spondylolisthesis Reduction System

SURGICAL TECHNIQUE GUIDE

GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

SURGICAL TECHNIQUE GUIDE

MONUMENT®

MONUMENT®

Anterior Spondylolisthesis Reduction System

MONUMENT® is a unique ALIF system with a built-in mechanical reduction feature that is designed to aid in spondylolithesis reduction (Grade 1 or Grade 2).

The self-locking reduction feature simplifies the procedure with no additional step to lock the implant after the desired amount of reduction has been achieved.

Up to 8mm of Translation

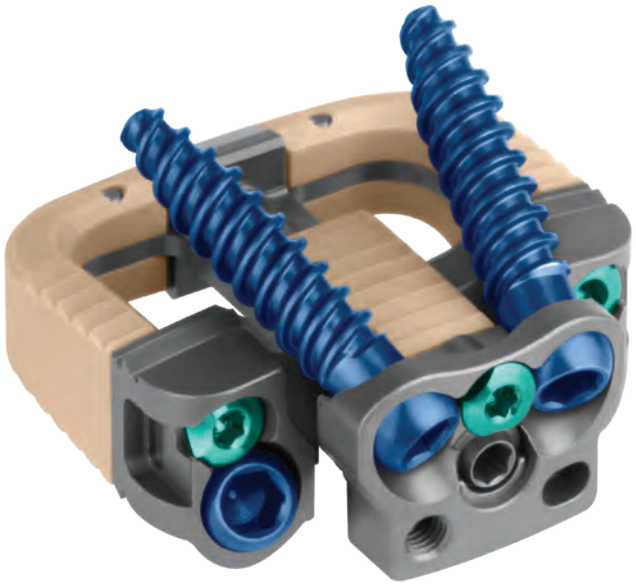
Built-in mechanical reduction feature allows for continuous translation up to 8mm and optimal cortical bone screw purchase

Self-Locking Reduction Feature

Simplifies procedure with no additional step to lock after translation

Enhanced Endplate Fixation

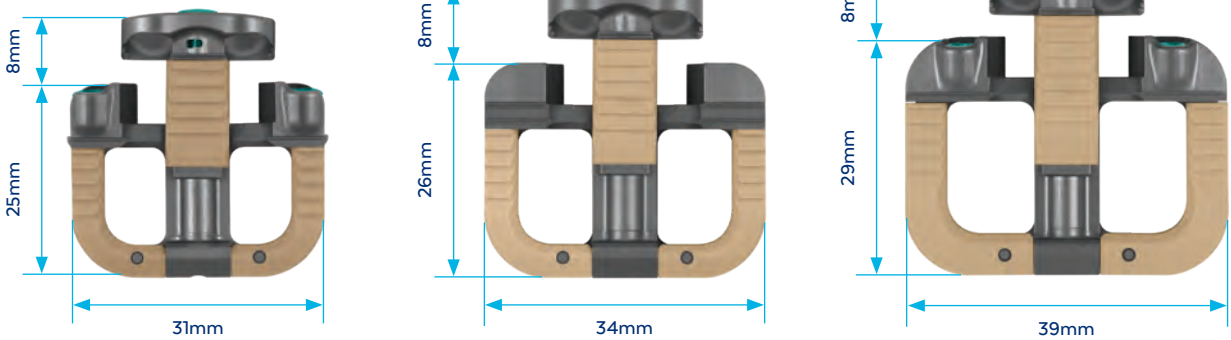
Directional teeth contact vertebral endplates to increase engagement during reduction

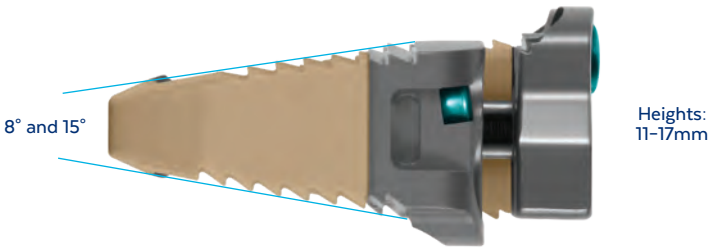


IMPLANT OVERVIEW

MONUMENT® Spacer

- Integrated titanium and radiolucent PEEK spacer
- Three axial footprints: 25x31, 26x34, and 29x39mm
- Four heights: 11, 13, 15, 17mm
- Two sagittal profiles: 8° and 15°
- Tapered leading edge for ease of insertion
- Large axial graft chambers
- Up to 8mm of reduction





Screw Options

- 5.5mm screw diameter
- Fixed and variable angle screws (±5°)
- Self-tapping screws (20, 25, 30, 35, 40mm)
- Self-drilling screws (25, 30, 35, 40mm)*
- Hydroxyapatite (HA) coated screws*
- Locking screws (cobalt chrome alloy only)*

Variable Angle Self-Drilling Screw

Fixed Angle Self-Drilling Screw

Variable Angle Self-Tapping Screw

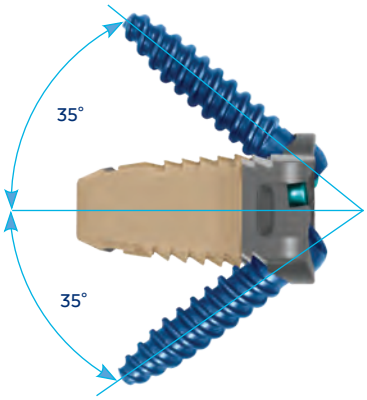
Variable Angle Self-Drilling Screw*

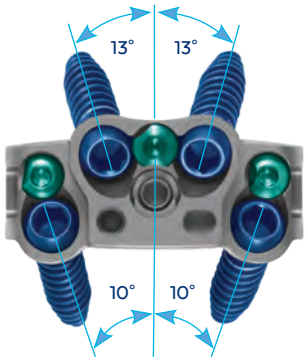
HA-Coated Variable Angle Screw*

Locking Screw (CoCr)*

Screw Angulation

- 35° cephalad/caudal angulation
- 20° convergence - inferior screw angle
- 26° divergence - superior screw angle
- Variable angle offers 5° conical variability





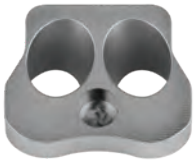
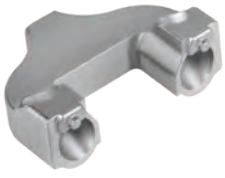
*Additionally available upon request

INSTRUMENT OVERVIEW

TRIALS

25x31mm			26x34mm			29x39mm		
								
Height	**8°**	**15°**	**Height**	**8°**	**15°**	**Height**	**8°**	**15°**
11mm	6108.0111	6108.0211	11mm	6108.0411	6108.0511	11mm	6108.0711	-
13mm	6108.0113	6108.0213	13mm	6108.0413	6108.0513	13mm	6108.0713	6108.0813
15mm	6108.0115	6108.0215	15mm	6108.0415	6108.0515	15mm	6108.0715	6108.0815
17mm	6108.0117	6108.0217	17mm	6108.0417	6108.0517	17mm	6108.0717	6108.0817

DTS GUIDES

Medial DTS Guides		Lateral DTS Guide
		
Height	**Part No.**	
11mm	6108.3011*	6108.3001*
13mm	6108.3013*	
15mm	6108.3015*	
17mm	6108.3017*	

**DTS guides are additionally available.*

TRIAL AND DTS GUIDE HOLDERS

Trial Holder 6108.0003

Trial Holder Sleeve 6108.0001

Locking Ring 6108.0004

Trial Measuring Sleeve 6108.0002

Trial Holder Assembly
Trial Holder 6108.0003
Trial Holder Sleeve 6108.0001
Locking Ring 6108.0004
Trial Measuring Sleeve 6108.0002
(Assembled)

Angled Holder 675.980

INDEPENDENCE® Drill Guide Holder 676.008

IMPLANT INSERTION INSTRUMENTS

Implant Holder 6108.1001

Holder Reducer 6108.1002

Holder Reducer, Angled 6108.1003

Reducer Driver, 3.0mm 6108.1005

Holder Reducer Assembly
Implant Holder 6108.1001
Holder Reducer 6108.1002
Reducer Driver 6108.1005
(Assembled)

Midline Implant Holder 6108.1008

Midline Holder Sleeve 6108.1009

Midline Implant Holder Assembly
Midline Implant Holder 6108.1008
Midline Holder Sleeve 6108.1009
(Assembled)

Implant Reduction Driver, Torque-Limiting 6108.1004

Implant Reduction Driver, Short 6108.1007

STRAIGHT INSTRUMENTS

QC Handle, Small with Cap 650.105

3.5mm Hex Straight Driver 676.502

QC Handle, Small with Cap 650.105
3.5mm Hex Straight Driver 676.502
(Assembled)

Self-Centering Straight Instruments with Retracting Front Sleeve

Self-Centering Straight Drill 676.704*

Self-Centering Straight Awl 676.706*

Self-Centering Straight Instruments (Assembled)

5.5mm Straight Tap 676.708*

Set Screw Positioner, Torque-Limiting (0.4Nm) 6108.1006

**Drill, awl, and tap dimensions are shown on page 35.*

ANGLED INSTRUMENTS

Counter-Torque 676.699

Angled Sleeve 676.700

Shaft 676.701

Nut 676.702

Self-Centering Bent Awl 676.705

Self-Centering Angled Drill 676.703*

5.5mm Angled Tap 676.707*

3.5mm Angled Hex Driver, Long 676.809

3.5mm Angled Hex Driver, Short 676.710

Angled Driver Body 676.700
Angled Driver Shaft 676.701
Angled Driver Nut 676.702
3.5mm Angled Hex Driver, Short 676.710
(Assembled)

**Drill, Awl, and Tap dimensions are shown on page 35.*

ANGLED DISC PREP INSTRUMENTS

Double-Angled Cobb, 20mm, Up 6108.2004

Double-Angled Rasp, 7mm 6108.2005

Double-Angled Curette, 5.5x8.5mm, Up 6108.2007

Double-Angled Curette, 7.5x11.5mm, Up 6108.2009

Double-Angled Ring Curette, 10mm, Up 6108.2011

Double-Angled Osteotome 6108.2012

SURGICAL TECHNIQUE

MONUMENT®

STEP 1 PATIENT POSITIONING

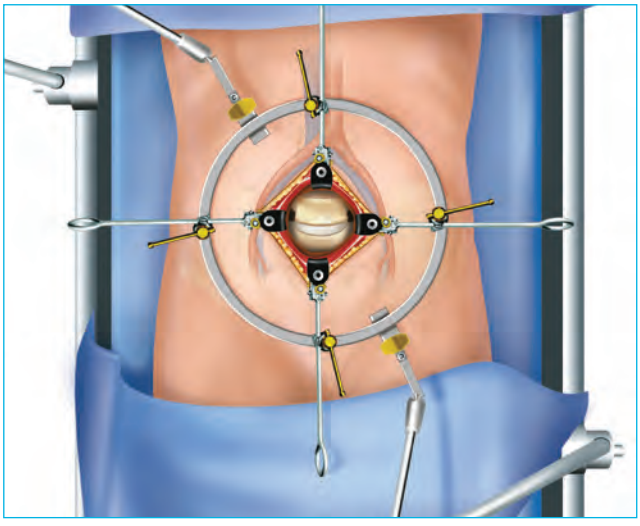
Patient positioning is key for an anterior spondylolisthesis reduction procedure. The following are helpful suggestions:

- Place the patient supine with their arms crossed over their chest to keep them out of the way of the C-arm and operating area
- Place foam pads underneath the knees so they are slightly bent at a 30° angle
- Reposition patient to ensure that the C-arm is able to clear the patient and that the disc space is open with the lumbar spine placed into lordosis
- Mark each disc space anteriorly and laterally from L3-S1 as well as the midline
- Wrap bolster in a pillow case and position under operative level

STEP 2 APPROACH

Advances in minimally invasive surgery, with respect to instrumentation and retractor systems such as MARS™ Anterior, have allowed surgeons to utilize mini-open anterior retroperitoneal approaches. Without compromising surgical goals, minimally invasive surgery has been shown[1,2] to:

- Reduce trauma and soft tissue disruption
- Reduce blood loss
- Reduce scarring
- Reduce postoperative pain
- Shorten hospital stay
- Shorten recovery time



1. Lee SH, Choi WG, Lim SR, Kand HY. "Minimally invasive anterior lumbar fusion followed by percutaneous pedicle screw fixation for isthmic spondylolistheseis," *The Spine Journal* 4 (2004): 664-649.

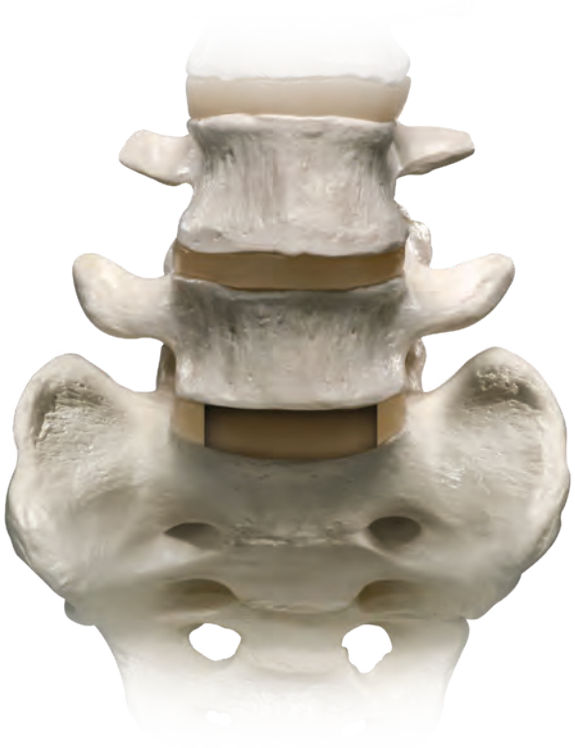
2. Kim KT, Lee SH, Suk KS, Bae SC. "The quantitative analysis of tissue injury markers after mini-open lumbar fusion," *Spine* B (2006): 712-716.

STEP 3 PREPARATION

Anterior disc preparation instruments and spondylolisthesis-specific disc preparation instruments may be used to expose the disc and remove disc material. Scrapers may be used to remove superficial layers of the cartilaginous endplates. A complete discectomy is recommended. The posterior annulus and posterior longitudinal ligament should be released, especially for Grade 2 spondylolisthesis. The lateral walls of the annulus should be preserved to provide peripheral support for the implant and any laterally placed autogenous bone graft materials. A complete discectomy and soft tissue resection allows for ease of spondylolisthesis reduction.

Spondylolisthesis-specific disc preparation instruments have additional bends near the tip to allow for the instrument to reach the desired disc space.

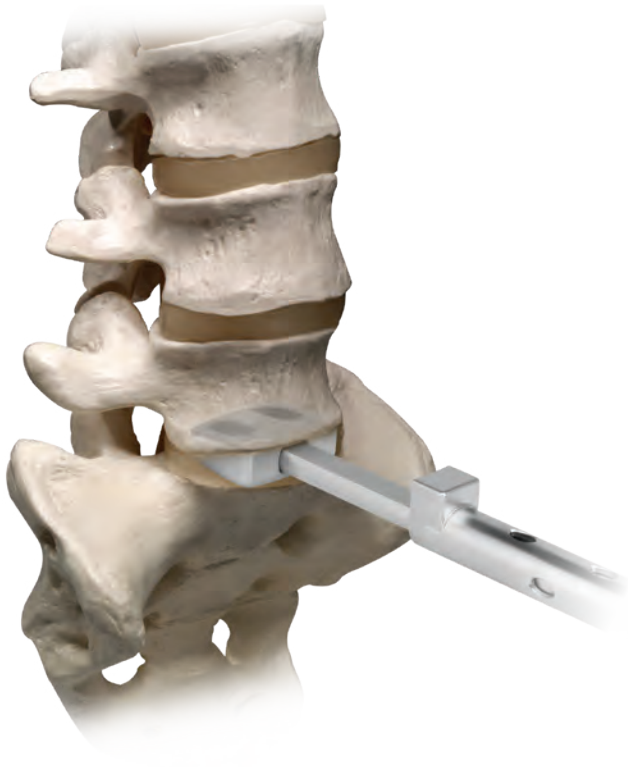
Note: Spondylolisthesis reduction may be partially achieved by disc preparation, annulus release, and patient positioning.



STEP 4 IMPLANT SIZING

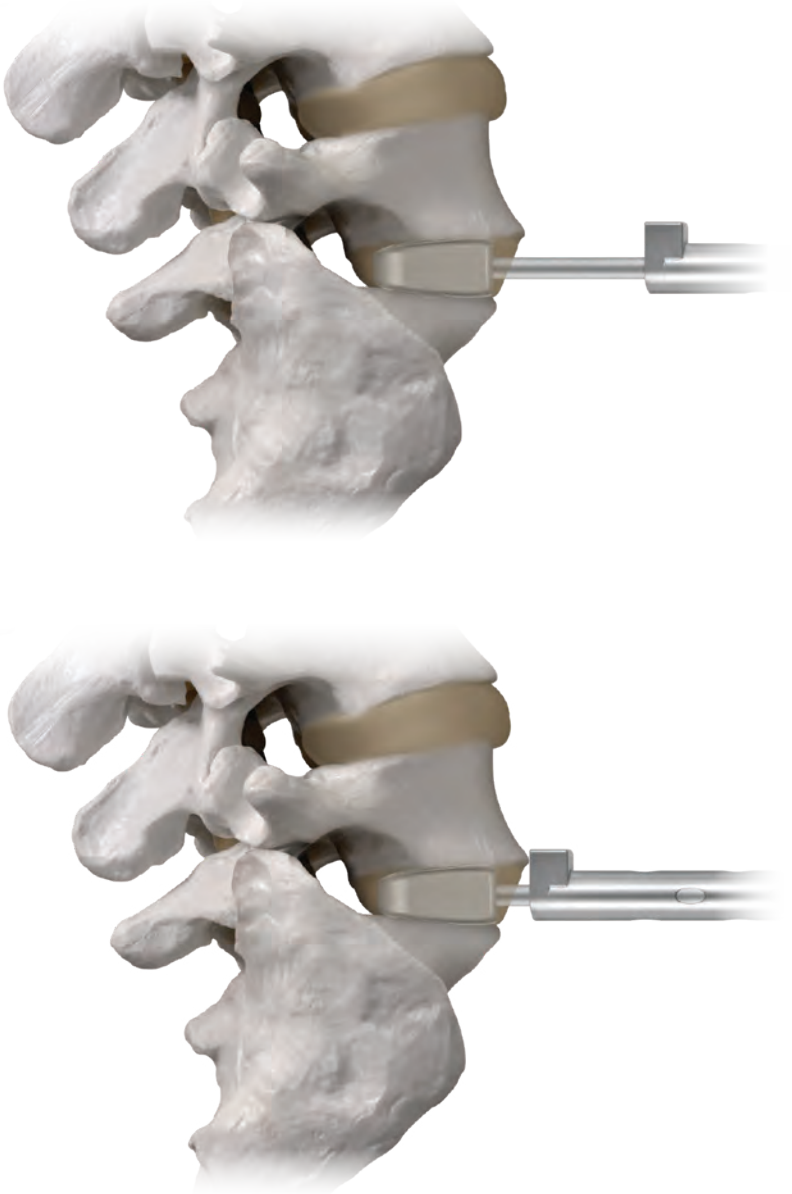
Select an appropriate sized **Trial** and attach it to the **Trial Holder Assembly**. Depending on the level and patient anatomy, a straight or **Angled Trial Holder** may be used. Insert the trial into the disc space as shown at right. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment, and may be confirmed using fluoroscopy and tactile feel.

If desired, the spondylolisthesis can be measured using the **Trial Measuring Sleeve**, as shown in Step 5. Otherwise, please proceed to Step 6.



STEP 5 SPONDYLOLISTHESIS MEASURING

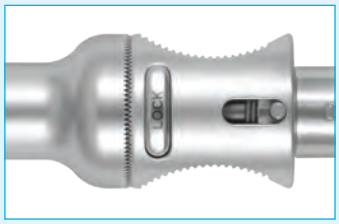
Ensure the trial is fully engaged within the disc space and aligned with the anterior side of the inferior vertebral body. The spondylolisthesis overlap is measured from the marks on the Trial Holder Sleeve. The measurement is taken from the edge of the measuring sleeve.



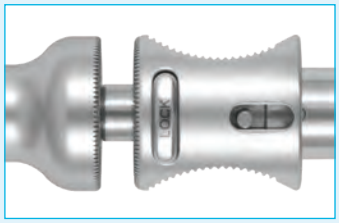
Adjust measuring sleeve distally until tip touches superior vertebral body.

USING THE TRIAL HOLDER

Ensure the Trial Holder Assembly is in the unlocked position. Thread the Trial into the holder by rotating the handle clockwise. Lock the holder by pressing the release button and pushing the lock forward. To disengage, pull the locking sleeve back and rotate the handle counterclockwise.



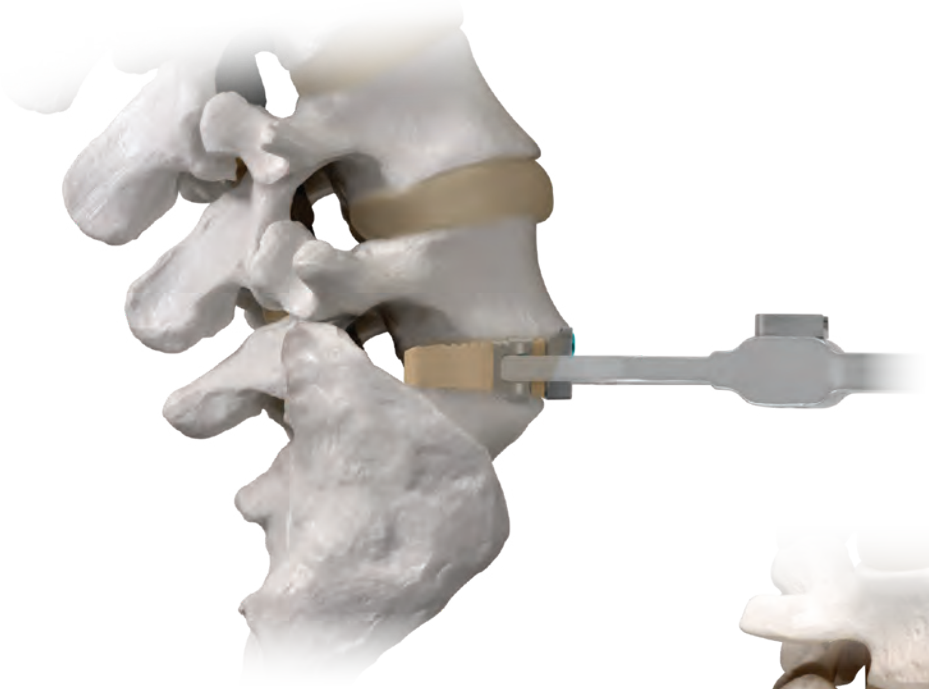
Locked



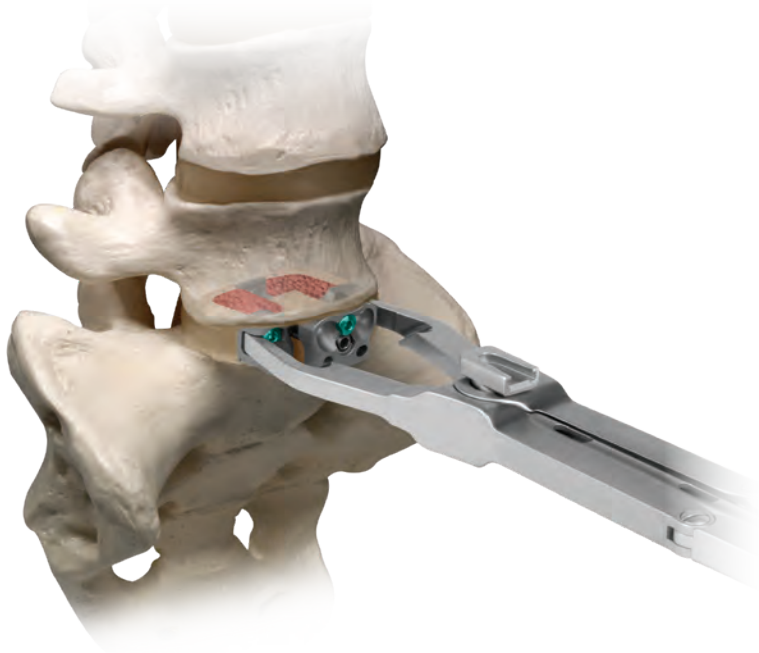
Unlocked

STEP 6 IMPLANT INSERTION

Select the appropriate size implant and attach it to the **Implant Holder**. Fill the implant with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. Insert the implant into the disc space. The lateral portions of the implant should be flush with the inferior vertebral body.



Inserting implant into disc space, lateral view



Inserting implant into disc space, oblique view

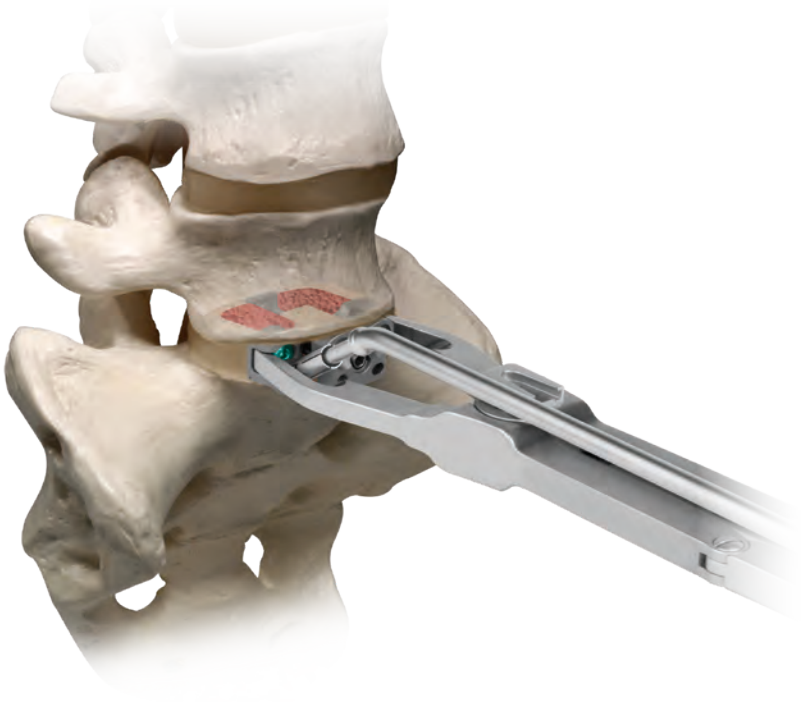
If the medial portion of the implant is not aligned with the superior vertebral body, use the **Implant Reduction Driver, Torque-Limiting** to reduce the medial portion of the implant to align with the superior vertebral body.

Note: This must be completed before preparing and inserting the medial screws.

STEP 7 LATERAL SCREW HOLE PREPARATION

Insert the **Self-Centering Awl*** to break the cortex. A **Self-Centering Drill*** and **Tap*** may be used to further prepare the screw hole.

Depending on the angle and position, a straight or angled instrument may be used. Proceed to screw insertion prior to preparing the second lateral screw hole.



Inserting Self-Centering Bent Awl

ALIGNING THE SELF-CENTERING SLEEVE

The Self-Centering Sleeves ensure proper screw trajectory without the use of a DTS guide. The sleeve must be properly engaged with the plate before advancing any screw hole preparation instruments. Proceed to screw insertion prior to preparing the remaining hole.

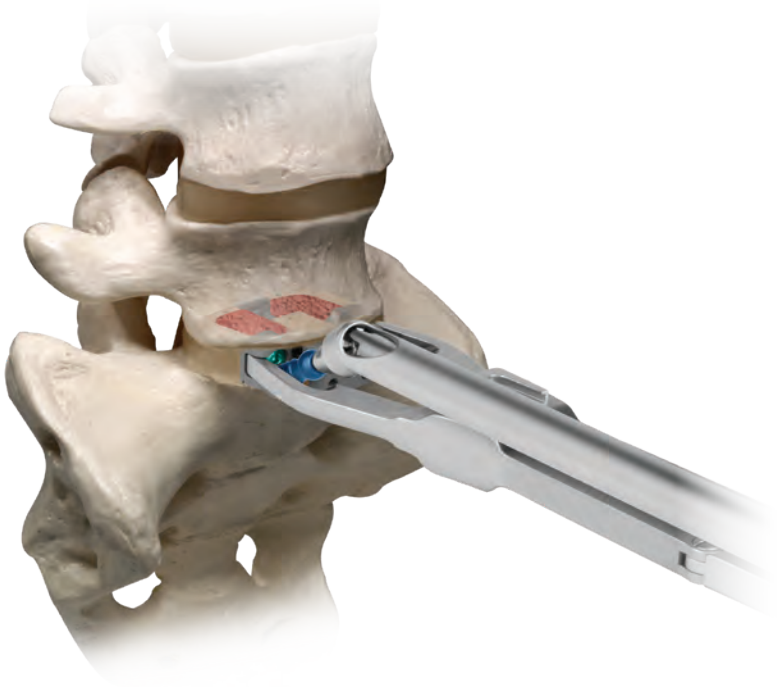
INCORRECT

CORRECT

*Drill, awl, and tap dimensions are shown on page 35.

STEP 8 LATERAL SCREW INSERTION

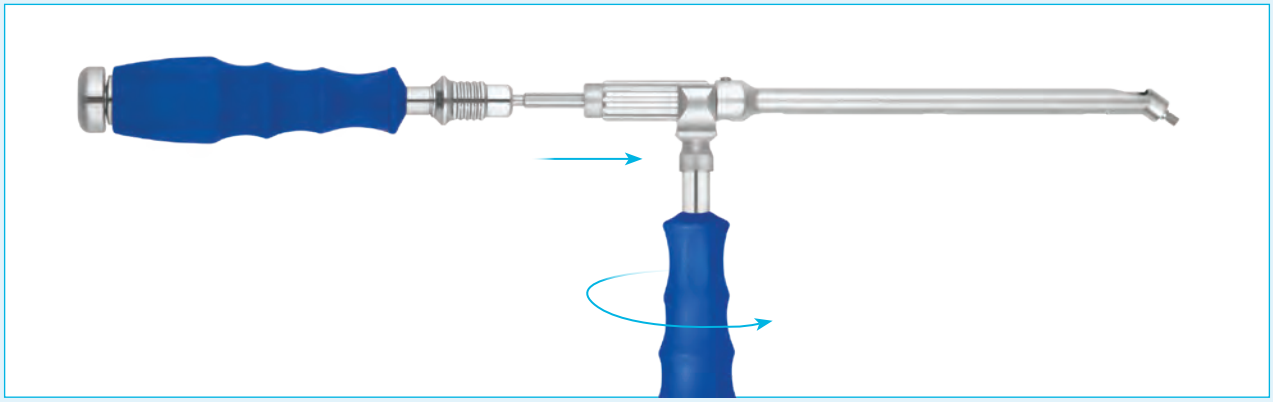
Select the appropriate length screw.* Insert the screw using a straight or angled **3.5mm Hex Screwdriver**. Repeat steps 7 and 8 for the second lateral screw hole before moving to the next step.



Inserting screw using Angled Screwdriver

CONNECTING THE COUNTER-TORQUE TO THE ANGLED INSTRUMENTS

To allow for additional control of the distal tip of the Angled Instruments, a **Counter-Torque** handle should be attached. Starting from the top, slide the Counter-Torque from the smooth portion of the **Angled Driver Body** to the knurled portion until fully seated. Once fully seated, rotate the Counter-Torque clockwise to final tighten.

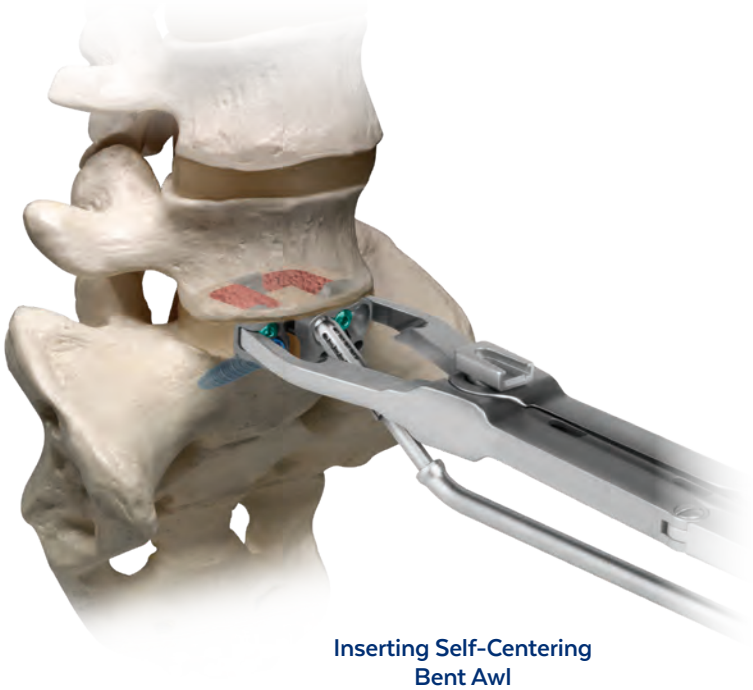


*Screw length dimensions are shown on page 33.

STEP 9 MEDIAL SCREW HOLE PREPARATION

Insert the straight or bent awl to break the cortex. A self-centering drill and tap may be used to further prepare the screw hole.

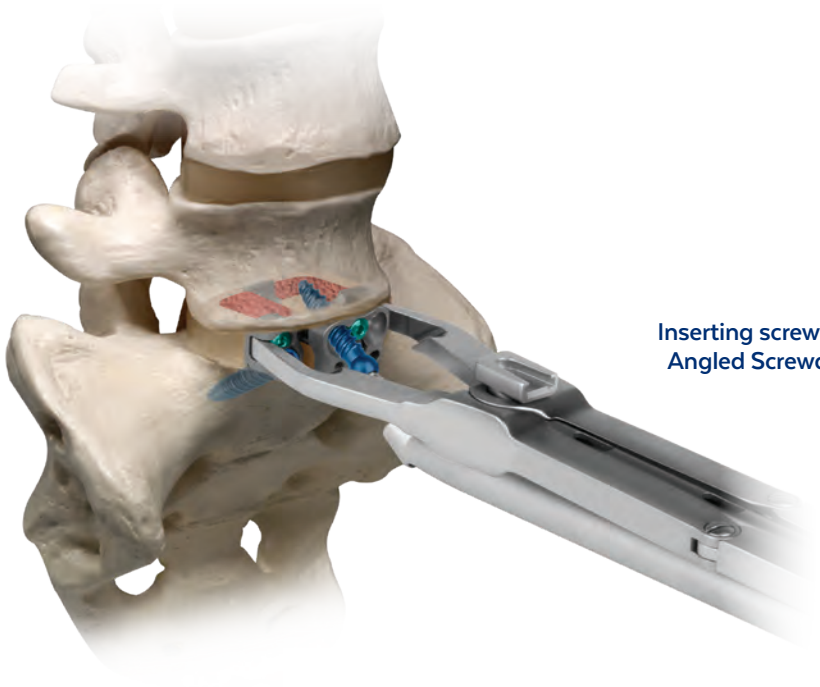
Depending on the angle and position, a straight or angled instrument may be used. Proceed to screw insertion prior to preparing the second medial screw hole.



Inserting Self-Centering Bent Awl

STEP 10 MEDIAL SCREW INSERTION

Select the appropriate length screw. Insert the screw using a straight or angled 3.5mm Hex Screwdriver. Repeat steps 9 and 10 for the second medial screw hole before continuing.

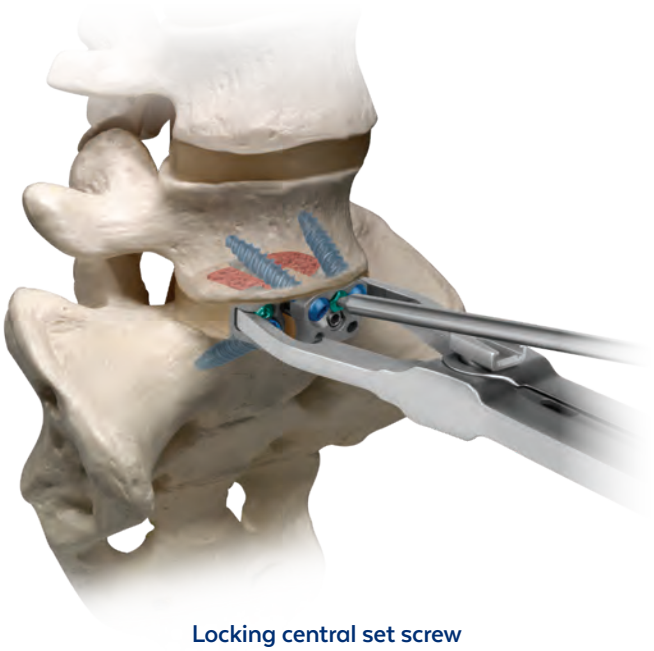


Inserting screw using Angled Screwdriver

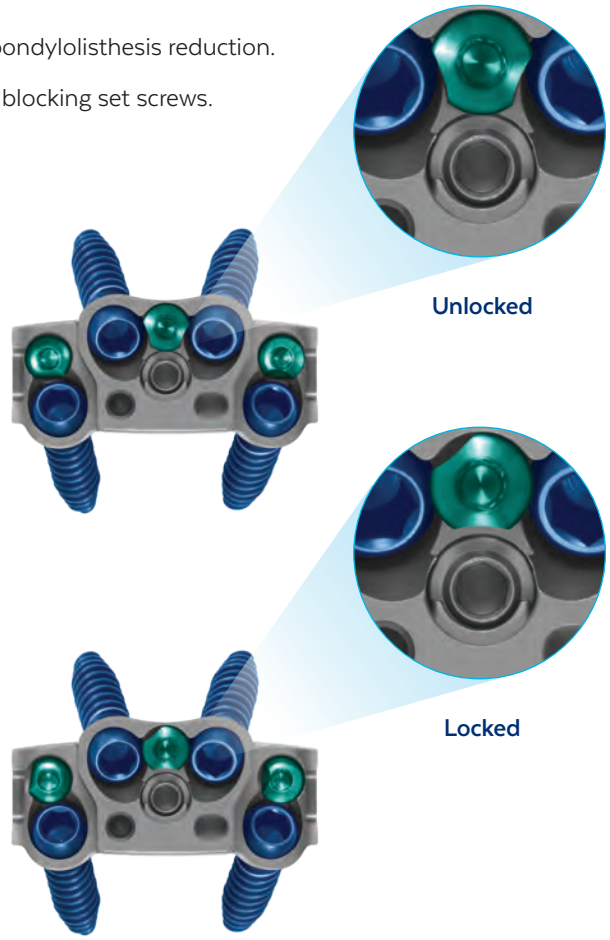
STEP 11 POSITIONING CENTRAL SET SCREW

The central set screw must be rotated to secure the screws prior to spondylolisthesis reduction.

Use the **Set Screw Positioner, Torque-Limiting** to engage the medial blocking set screws. Rotate the set screws clockwise 90° until the driver clicks.



Locking central set screw

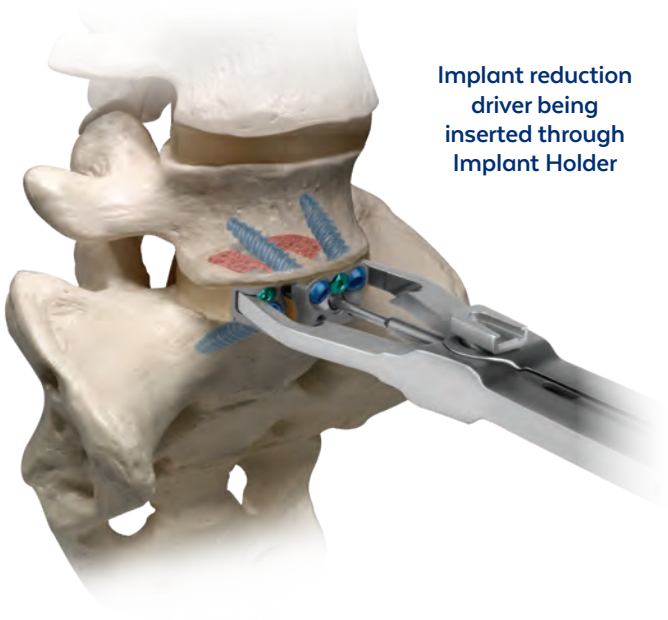


Unlocked

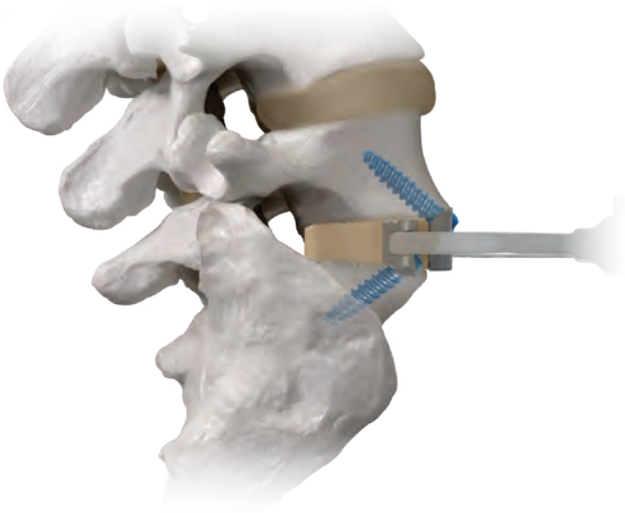
Locked

STEP 12 SPONDYLOLISTHESIS REDUCTION

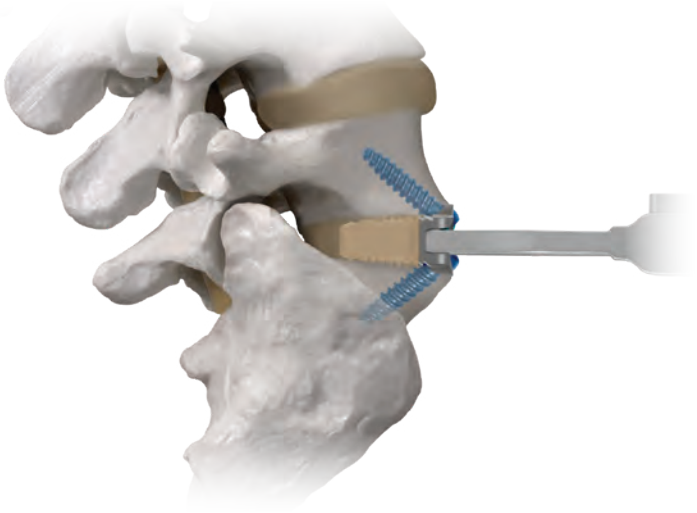
After insertion of the screws into the vertebral bodies, insert the **Implant Reduction Driver, Torque Limiting** through the Implant Holder. Ensure that the hex on the driver is fully seated in the reduction screw of the implant. Rotate the driver clockwise to begin reduction. Use care during reduction and apply deliberate pressure on the driver. Ensure that fixation is maintained while reducing. Slowly advance until the desired amount of reduction is achieved. Complete or partial reduction may be achieved. Each 360° rotation of the driver reduces the vertebral body by approximately 0.5mm.



Implant reduction driver being inserted through Implant Holder



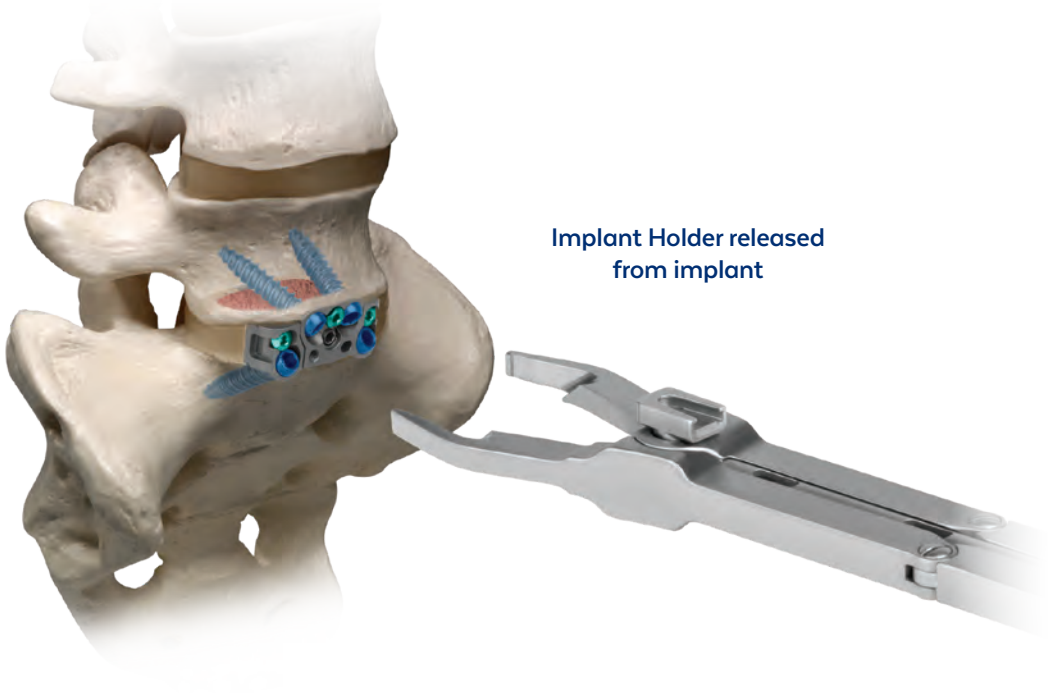
Before reduction



After reduction

STEP 13 IMPLANT HOLDER REMOVAL

Once the screws are inserted, remove the Implant Holder by fully releasing the locking nut on the holder to disengage the implant. After the holder is removed, ensure the screws are fully seated. The screws lag the bone to the implant.

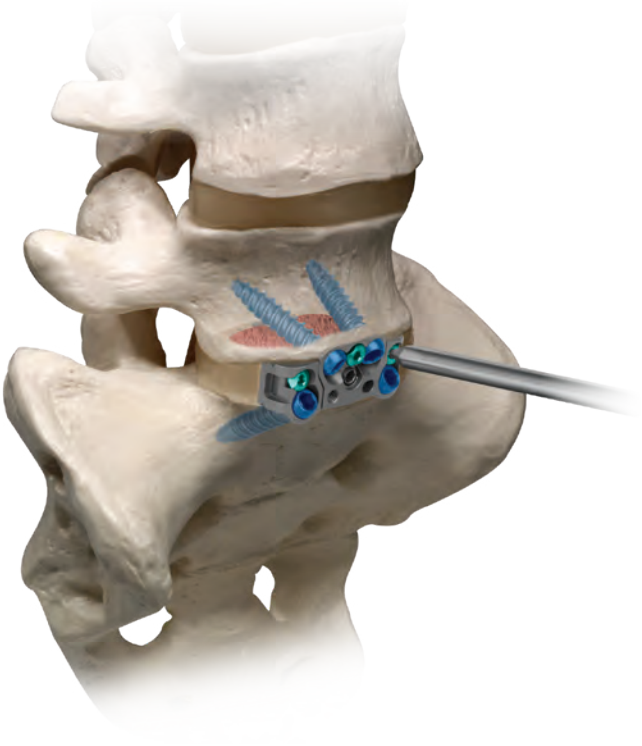


Implant Holder released from implant

STEP 14 POSITIONING LATERAL SET SCREWS

Use the Set Screw Positioner, Torque-Limiting to engage the lateral blocking set screws. Rotate the set screws clockwise until the positioner clicks, indicating that the torque limit has been reached.

Confirm that all three blocking set screws are rotated 90° and are in the locked position.



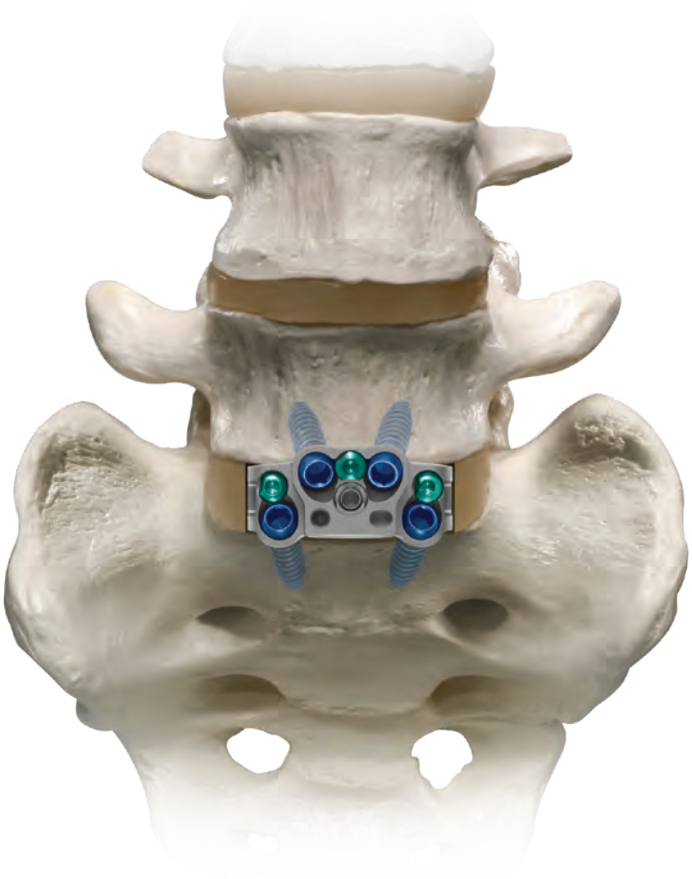
Locking lateral set screw

Note: Additional techniques for the midline holder and DTS guides are found under Optional Techniques, starting on page 26.

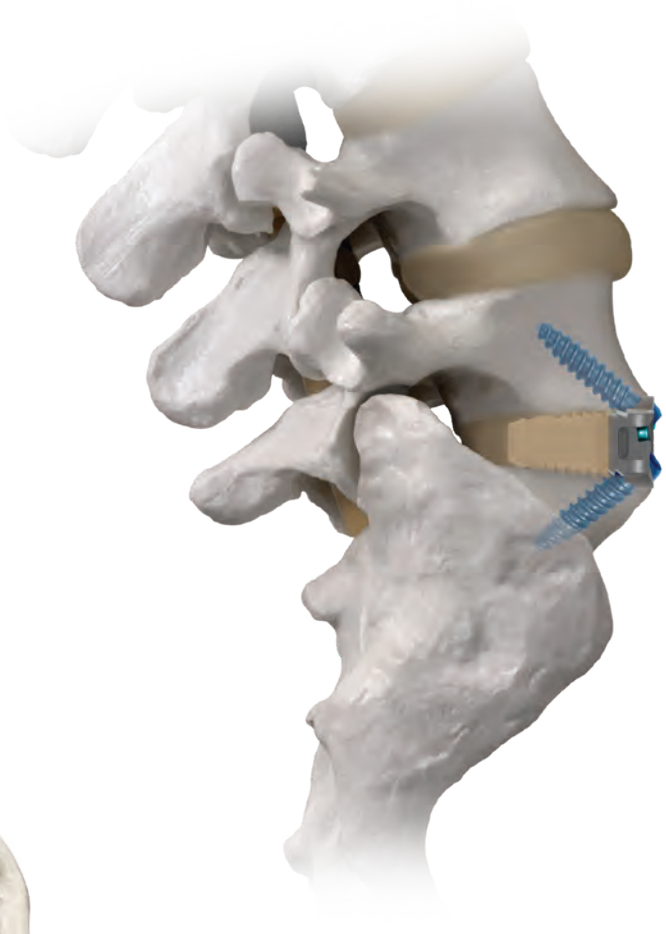
STEP 15 SUPPLEMENTAL FIXATION

Supplemental fixation (i.e., pedicle screws or facet fixation) is required, in addition to the integrated screws of the implant. When performing a two-stage procedure, weight bearing is not recommended until after supplemental fixation has been implanted.

FINAL CONSTRUCT



Anterior view



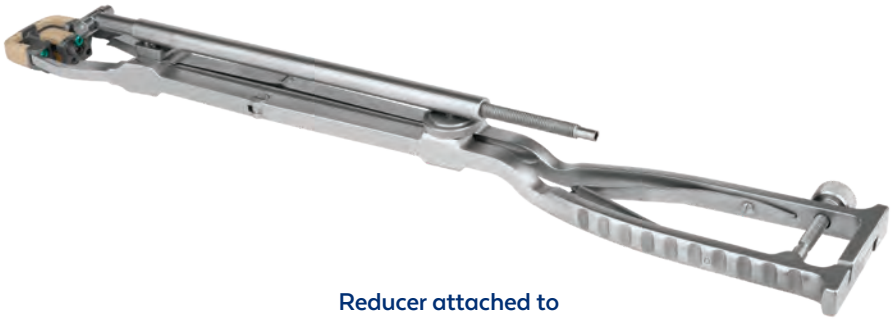
Lateral view

Note: construct is shown without supplemental fixation for clarity.

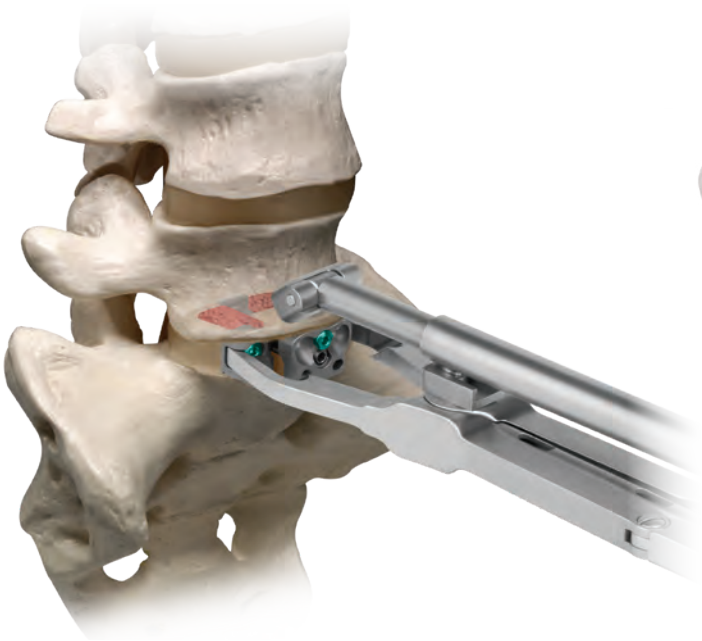
OPTIONAL TECHNIQUE: IMPLANT INSERTION WITH OPTIONAL REDUCER

Attach the **MONUMENT® Holder Reducer** to the Implant Holder.

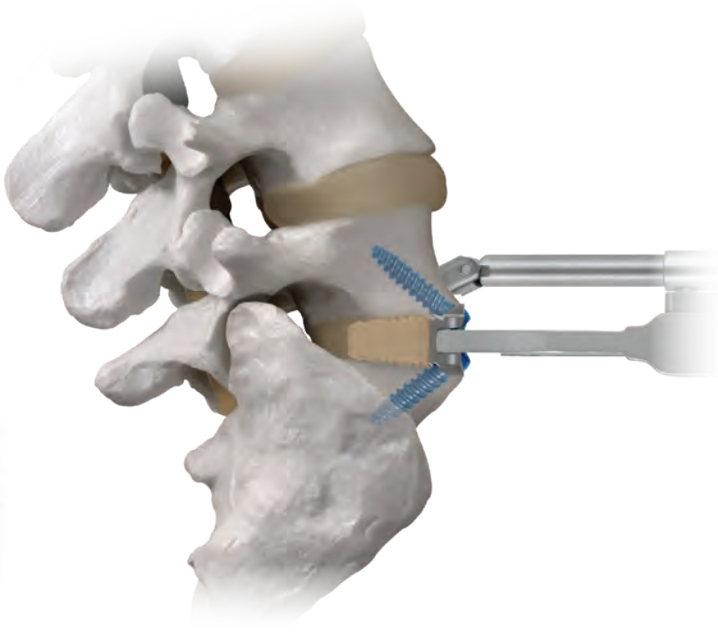
Insert the implant into the disc space. The lateral portion of the implant should be flush with the inferior vertebral body.



Reducer attached to Implant Holder



Implant insertion using reducer (oblique view)



Implant insertion using reducer (lateral view)

OPTIONAL TECHNIQUE: SPONDYLOLISTHESIS REDUCTION WITH OPTIONAL REDUCER

After insertion of the lateral screws into the inferior vertebral body, reduce the superior vertebral body using the Holder Reducer Assembly with the reducer attachment.

Rotate the Reducer Driver, 3.0mm clockwise to advance the reducer until reaching the desired amount of reduction. Each 360° rotation of the driver reduces the spondylolisthesis by approximately 1mm. Upon reaching the desired reduction, leave the reducer in place and proceed to preparing the medial screw holes.

Before reduction **After reduction**

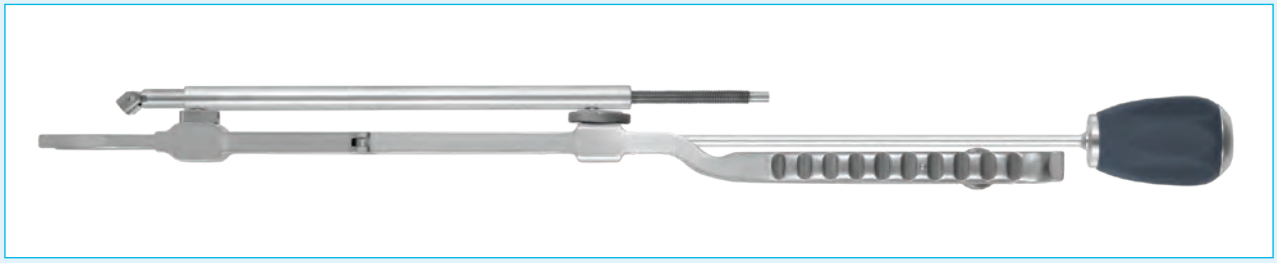
If the medial portion of the implant is not aligned with the superior vertebral body, use the Implant Reduction Driver, Torque-Limiting to reduce the medial portion of the implant such that it aligns with the superior vertebral body (see Step 14 for instructions).

Note: This must be completed before preparing and inserting the medial screws.

ATTACHING THE HOLDER REDUCER ASSEMBLY

Ensure the proximal coupling ring on the Implant Holder is rotated to the “Open” position. Slide the Holder Reducer into the slots on both coupling rings. Rotate the proximal coupling ring clockwise 180° to the “Closed” position to lock it into place.

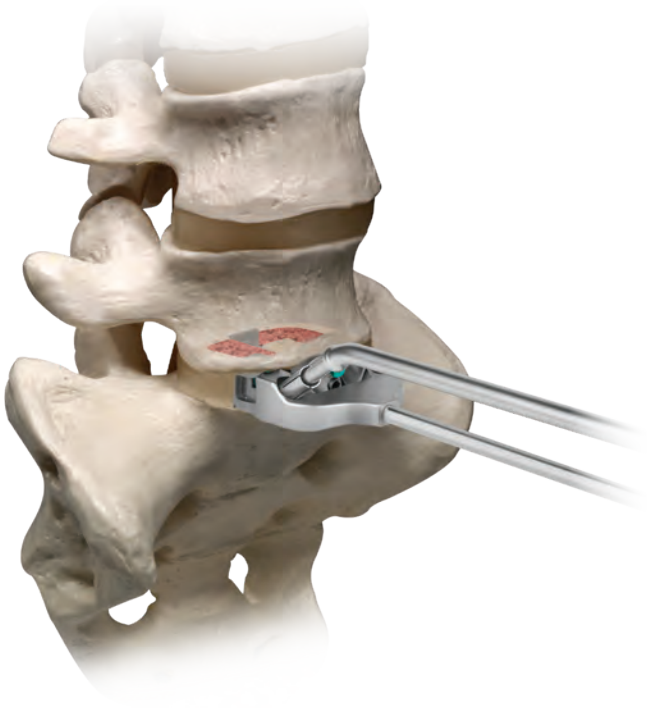
Open **Closed**



OPTIONAL TECHNIQUE: LATERAL SCREW HOLE PREPARATION WITH DTS GUIDE

If using a DTS guide, remove the Holder Reducer Assembly and align the **Lateral DTS Guide** with the lateral screw holes. Insert the awl through the DTS guide to break the cortex. The Self-Centering Drill and Tap may be used to further prepare the screw hole.

Depending on the angle and position, a straight or angled instrument may be used. Proceed to screw insertion prior to preparing the second lateral screw hole.



Inserting Self-Centering Bent Awl through DTS guide

ALIGNING THE SELF-CENTERING SLEEVE

The Self-Centering Sleeves ensure proper screw trajectory without the use of a DTS guide. The sleeve must be properly engaged with the plate before advancing any screw hole preparation instruments. Proceed to screw insertion prior to preparing the remaining hole.

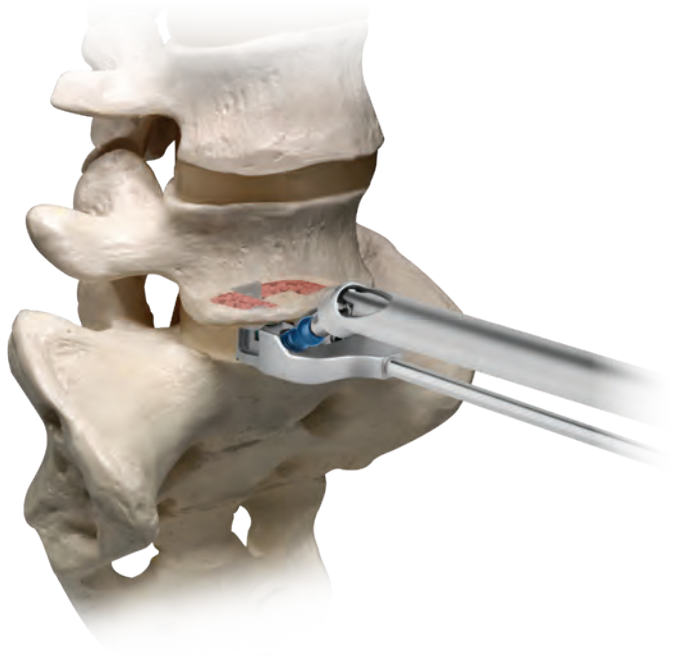
INCORRECT

CORRECT

OPTIONAL TECHNIQUE: LATERAL SCREW INSERTION WITH DTS GUIDE

Select the appropriate length screw. Insert the screw using a straight or angled 3.5mm Hex Screwdriver. Repeat screw preparation and screw insertion steps for the second lateral screw hole.

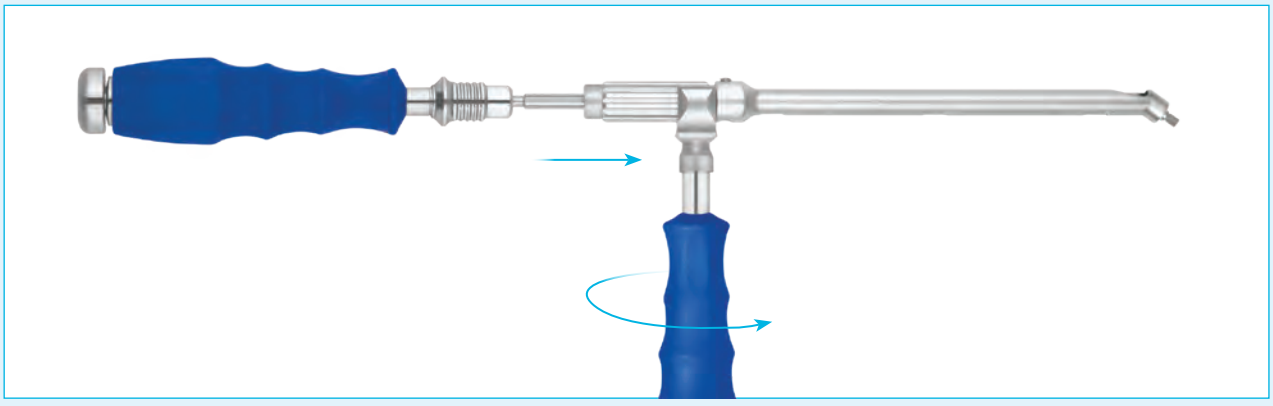
Do not over-tighten the screws; they are final tightened using a torque-limiting driver after the DTS guide is removed.



Inserting screw using Angled Screwdriver and Drill Guide

CONNECTING THE COUNTER-TORQUE TO THE ANGLED INSTRUMENTS

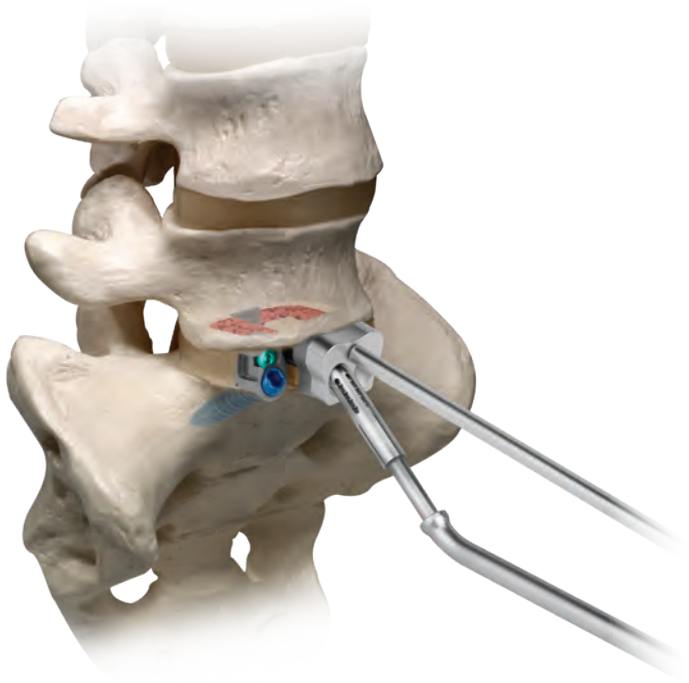
For additional control of the distal tip of the Angled Instrument, a Counter-Torque handle may be attached. Starting from the top, slide the Counter-Torque from the smooth portion of the Angled Driver Body to the knurled portion until fully seated. Once fully seated, rotate the handle clockwise to final tighten.



OPTIONAL TECHNIQUE: MEDIAL SCREW HOLE PREPARATION WITH DTS GUIDE

Insert the straight or bent awl with self-centering sleeve through the Medial DTS Guide to break the cortex. A self-centering drill and tap may be used to further prepare the screw hole.

Depending on the angle and position, a straight or angled instrument may be used. Proceed to screw insertion prior to preparing the second medial screw hole.

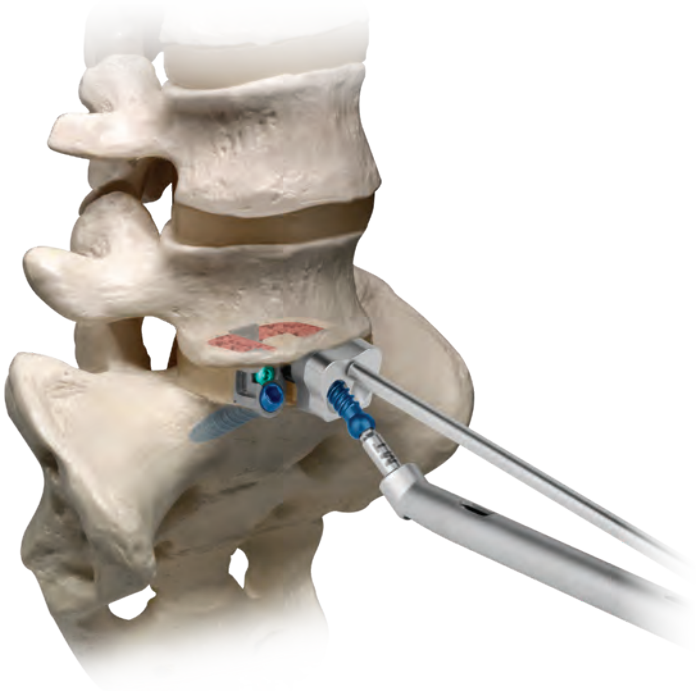


Inserting Self-Centering Bent Awl using DTS guide

OPTIONAL TECHNIQUE: MEDIAL SCREW INSERTION WITH DTS GUIDE

Select the appropriate length screw. Insert the screw using a straight or angled 3.5mm Hex Screwdriver. Repeat screw preparation and screw insertion steps for the second medial screw hole.

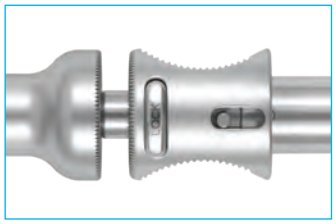
Do not over-tighten the screws; they are final tightened using a torque-limiting driver after the DTS guide is removed.



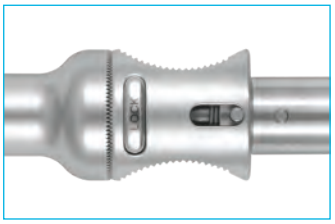
Inserting screw through Medial DTS Guide using Angled 3.5mm Hex Screwdriver and Drill

OPTIONAL TECHNIQUE: MIDLINE IMPLANT HOLDER

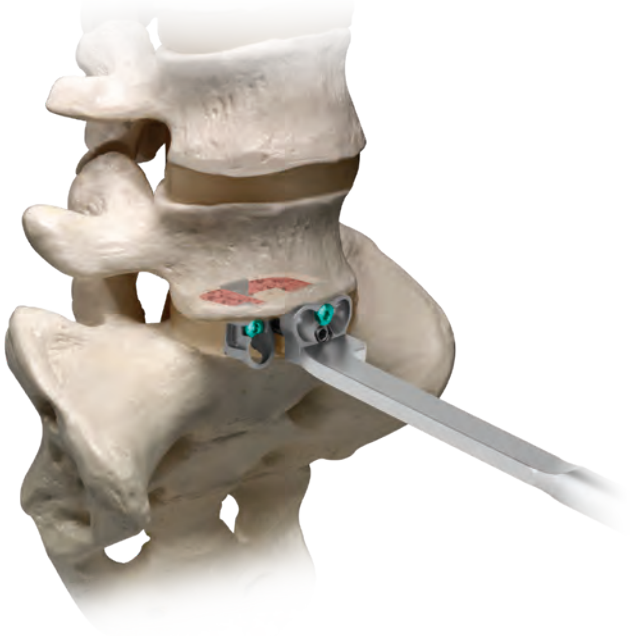
Ensure the Midline Implant Holder is in the unlocked position. Thread the implant onto the holder by rotating the handle clockwise. Prior to implant insertion, lock the holder by pressing the release button, sliding the locking sleeve forward.



Holder unlocked

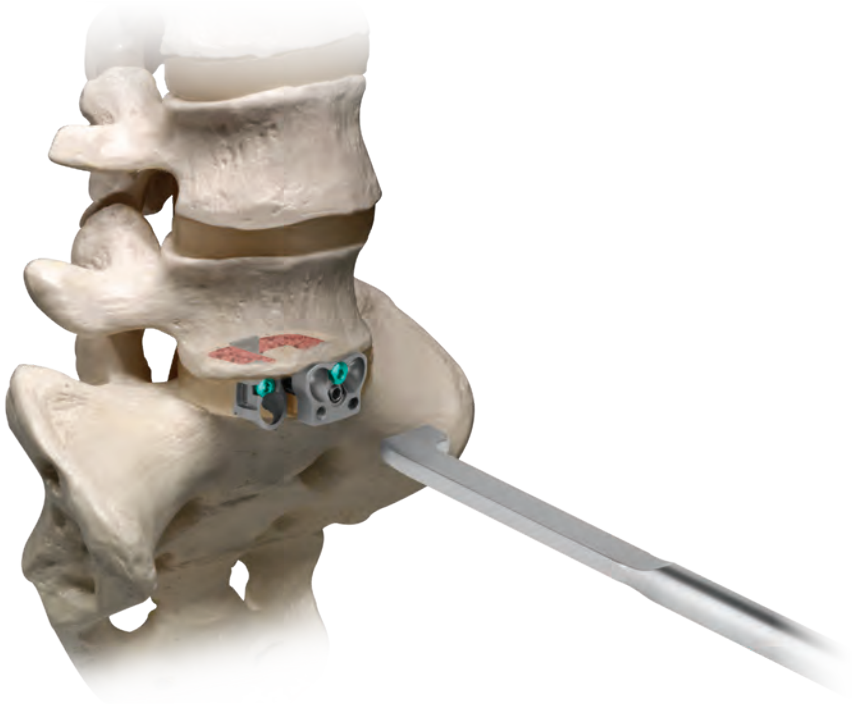


Holder locked



Implant attached to Midline Implant Holder

To disengage the Midline Implant Holder, pull the locking sleeve back and rotate the handle counterclockwise.

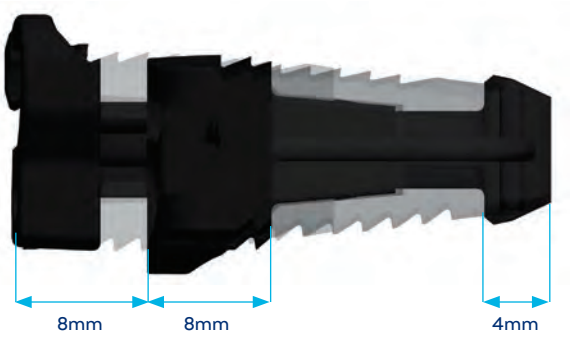


Implant disengagement

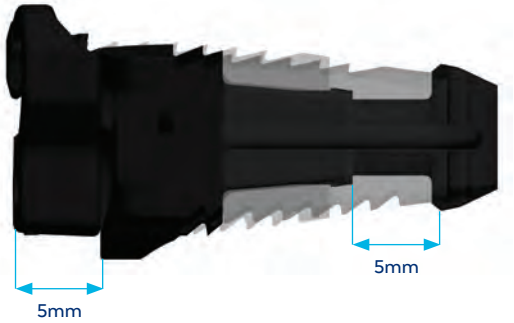
ADDITIONAL SPECIFICATIONS

MONUMENT® Radiographic Images

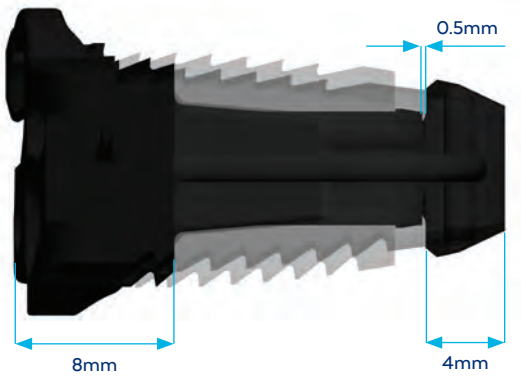
Initial Position



3mm Reduced

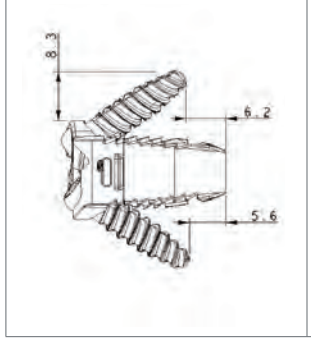
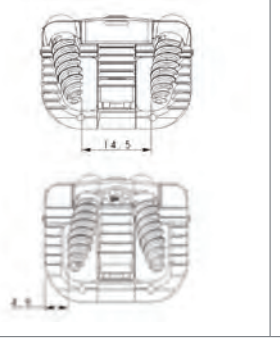
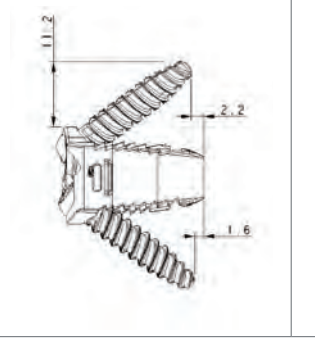
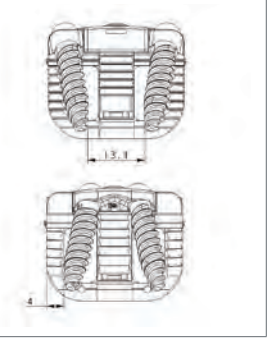


Fully Reduced

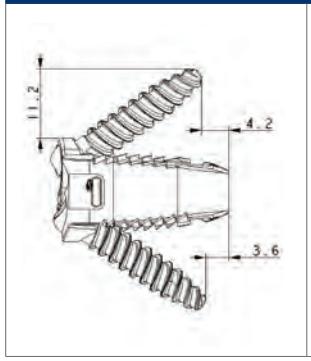
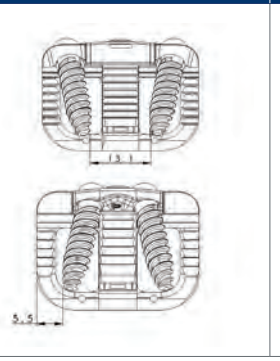
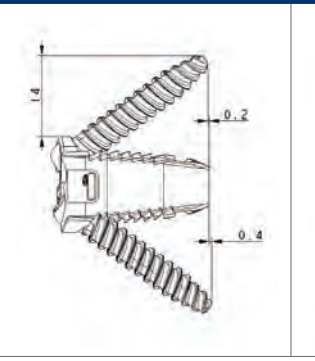
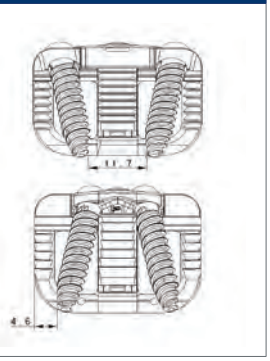


MONUMENT® Screw Diagrams

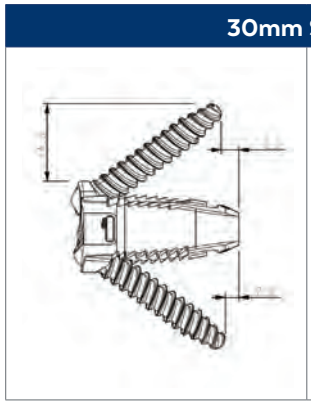
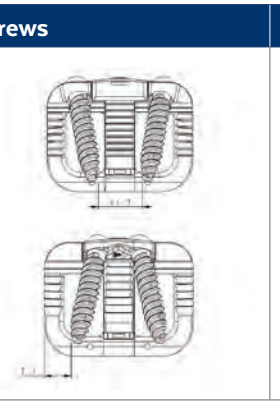
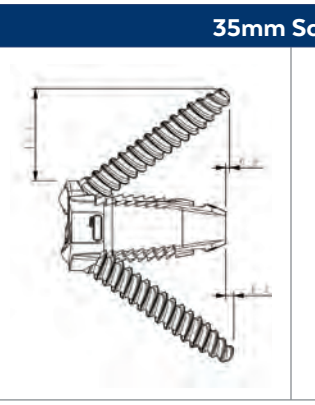
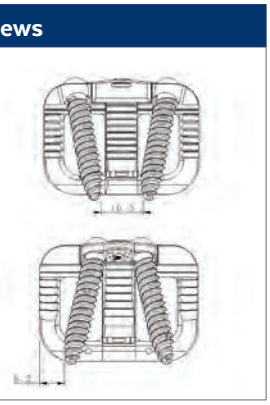
Small Spacer (25x31mm)

20mm Screws		25mm Screws	
			

Medium Spacer (26x34mm)

25mm Screws		30mm Screws	
			

Large Spacer (29x39mm)

30mm Screws		35mm Screws	
			

ADDITIONAL SPECIFICATIONS (CONT'D)

MONUMENT® Graft Volumes

Small 8° (25x31mm)	
Part No.	Graft Volume (cc)
3108.0111	1.6
3108.0113	2.0
3108.0115	2.3
3108.0117	2.6

Small 15° (25x31mm)	
Part No.	Graft Volume (cc)
3108.0211	1.4
3108.0213	1.7
3108.0215	2.1
3108.0217	2.4

Medium 8° (26x34mm)	
Part No.	Graft Volume (cc)
3108.0411	2.2
3108.0413	2.7
3108.0415	3.2
3108.0417	3.7

Medium 15° (26x34mm)	
Part No.	Graft Volume (cc)
3108.0511	1.9
3108.0513	2.4
3108.0515	2.9
3108.0517	3.4

Large 8° (29x39mm)	
Part No.	Graft Volume (cc)
3108.0711	3.0
3108.0713	3.6
3108.0715	4.3
3108.0717	5.0

Large 15° (29x39mm)	
Part No.	Graft Volume (cc)
-	-
3108.0813	3.2
3108.0815	3.8
3108.0817	4.5

MONUMENT® Drill, Awl, and Tap Dimensions

Tap

Drill

Awl

INSTRUMENT ASSEMBLY

Angled Driver Body

The angled instruments for MONUMENT® are provided preassembled. Two additional DTS Driver Tips are provided for uses when a DTS guide is used. The Counter-Torque may be attached to provide greater control of the distal tip.

Select the appropriate tip:

Self-Centering Angled Drill 676.703

5.5mm Angled Tap 676.707

3.5mm Angled Hex Driver, Long 676.809

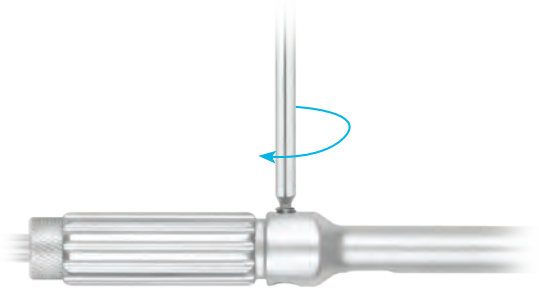
3.5mm Angled Hex Driver, Short 676.710

Hold the **Angled Driver Body** downward with the access window facing upward. Insert the selected tip into the window on the distal end of the driver.

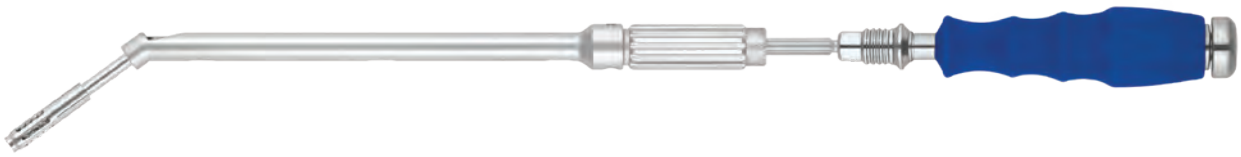
Insert the **Angled Driver Shaft** until the gears on the shaft join with the gears on the selected tip.

Place the **Angled Driver Nut** over the shaft. Rotate the threads clockwise until the nut sits flush with the angled body.

Tighten the set screw by rotating it clockwise with the Implant Reducer Driver, Torque Limiting, until it clicks twice.



Attach a **Quick-Connect Handle**.



MONUMENT®
IMPLANT SETS

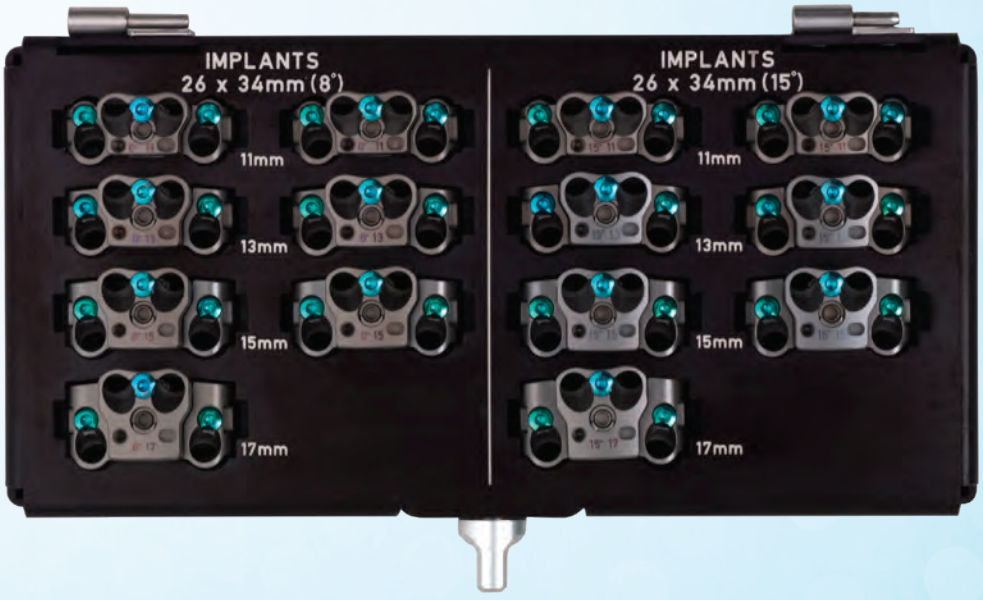
MONUMENT® 25x31mm Implant Set 9108.9001

Part No.	Description	Qty
3108.0111	MONUMENT® Spacer, 25x31mm, 8°, 11mm	2
3108.0113	MONUMENT® Spacer, 25x31mm, 8°, 13mm	2
3108.0115	MONUMENT® Spacer, 25x31mm, 8°, 15mm	2
3108.0117	MONUMENT® Spacer, 25x31mm, 8°, 17mm	1
3108.0211	MONUMENT® Spacer, 25x31mm, 15°, 11mm	2
3108.0213	MONUMENT® Spacer, 25x31mm, 15°, 13mm	2
3108.0215	MONUMENT® Spacer, 25x31mm, 15°, 15mm	2
3108.0217	MONUMENT® Spacer, 25x31mm, 15°, 17mm	1
9108.0001	MONUMENT® 25x31mm Implant Module	

MONUMENT® 26x34mm Implant Set 9108.9002

Part No.	Description	Qty
3108.0411	MONUMENT® Spacer, 26x34mm, 8°, 11mm	2
3108.0413	MONUMENT® Spacer, 26x34mm, 8°, 13mm	2
3108.0415	MONUMENT® Spacer, 26x34mm, 8°, 15mm	2
3108.0417	MONUMENT® Spacer, 26x34mm, 8°, 17mm	1
3108.0511	MONUMENT® Spacer, 26x34mm, 15°, 11mm	2
3108.0513	MONUMENT® Spacer, 26x34mm, 15°, 13mm	2
3108.0515	MONUMENT® Spacer, 26x34mm, 15°, 15mm	2
3108.0517	MONUMENT® Spacer, 26x34mm, 15°, 17mm	1
9108.0002	MONUMENT® 26x34mm Implant Module	

MONUMENT®
IMPLANT SETS (CONT'D)



MONUMENT®
IMPLANT SETS (CONT'D)

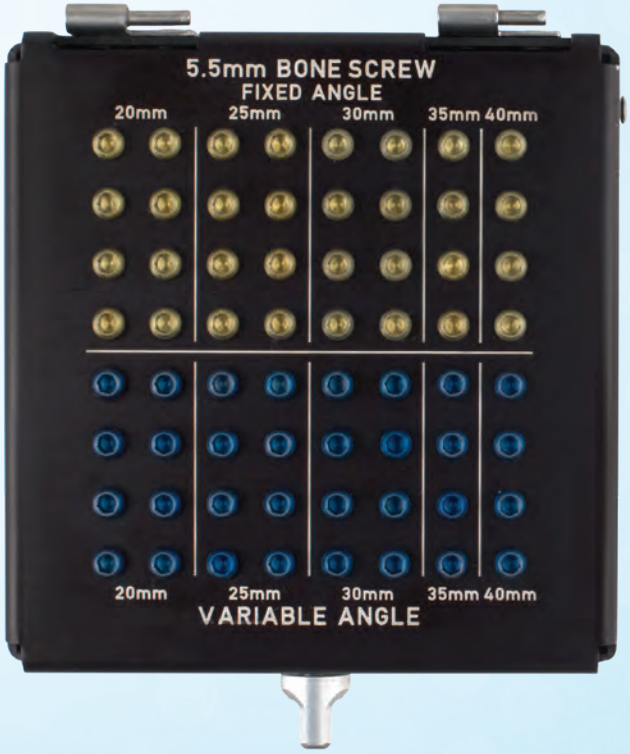
MONUMENT® 29x39mm Implant Set 9108.9003

Part No.	Description	Qty
3108.0711	MONUMENT® Spacer, 29x39mm, 8°, 11mm	2
3108.0713	MONUMENT® Spacer, 29x39mm, 8°, 13mm	2
3108.0715	MONUMENT® Spacer, 29x39mm, 8°, 15mm	2
3108.0717	MONUMENT® Spacer, 29x39mm, 8°, 17mm	1
3108.0813	MONUMENT® Spacer, 29x39mm, 15°, 13mm	2
3108.0815	MONUMENT® Spacer, 29x39mm, 15°, 15mm	2
3108.0817	MONUMENT® Spacer, 29x39mm, 15°, 17mm	1
9108.0003	MONUMENT® 29x39mm Implant Module	

ALIF Bone Screws 925.907

Part No.	Description	Qty
176.120	Bone Screw, Fixed Angle 5.5mm, 20mm	8
176.125	Bone Screw, Fixed Angle 5.5mm, 25mm	8
176.130	Bone Screw, Fixed Angle 5.5mm, 30mm	8
176.135	Bone Screw, Fixed Angle 5.5mm, 35mm	4
176.140	Bone Screw, Fixed Angle 5.5mm, 40mm	4
176.220	Bone Screw, Variable Angle 5.5mm, 20mm	8
176.225	Bone Screw, Variable Angle 5.5mm, 25mm	8
176.230	Bone Screw, Variable Angle 5.5mm, 30mm	8
176.235	Bone Screw, Variable Angle 5.5mm, 35mm	4
176.240	Bone Screw, Variable Angle 5.5mm, 40mm	4
925.107	Bone Screw Module	

MONUMENT®
IMPLANT SETS (CONT'D)



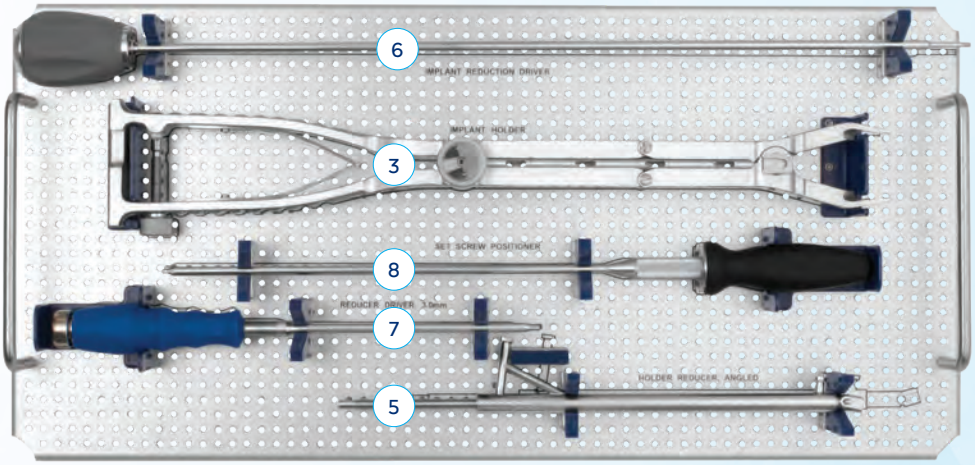
MONUMENT®
INSTRUMENT SET I 9108.9005

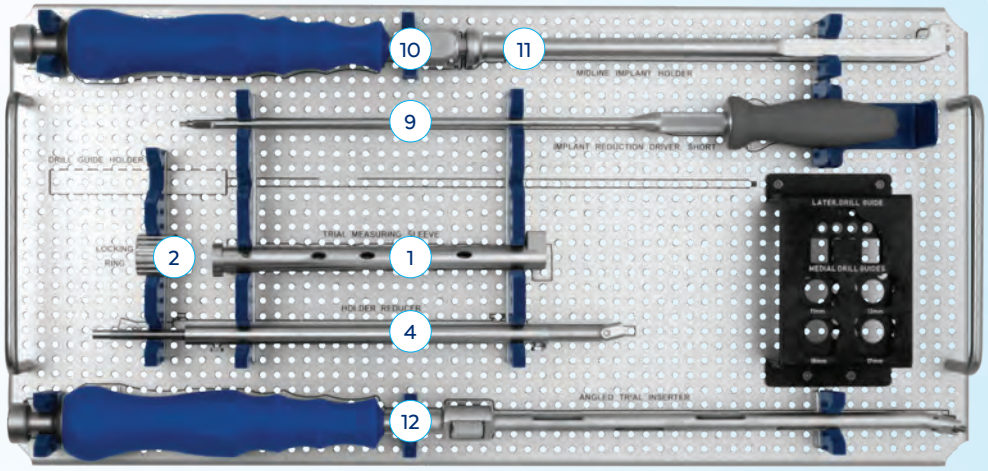
	Part No.	Description	Qty
1	6108.0002	MONUMENT® Trial Measuring Sleeve	1
2	6108.0004	MONUMENT® Locking Ring	1
3	6108.1001	MONUMENT® Implant Holder	1
4	6108.1002	MONUMENT® Holder Reducer	1
5	6108.1003	MONUMENT® Holder Reducer, Angled	1
6	6108.1004	MONUMENT® Implant Reduction Driver, Torque Limiting	1
7	6108.1005	MONUMENT® Reducer Driver, 3.0mm	1
8	6108.1006	MONUMENT® Set Screw Positioner, Torque Limiting	1
9	6108.1007	MONUMENT® Implant Reduction Driver, Short	1
10	6108.1008	MONUMENT® Midline Implant Holder	1
11	6108.1009	MONUMENT® Midline Holder Sleeve	1
12	675.980	Angled Trial Inserter	1
	9108.0005	MONUMENT® Instrument Graphic Case I	

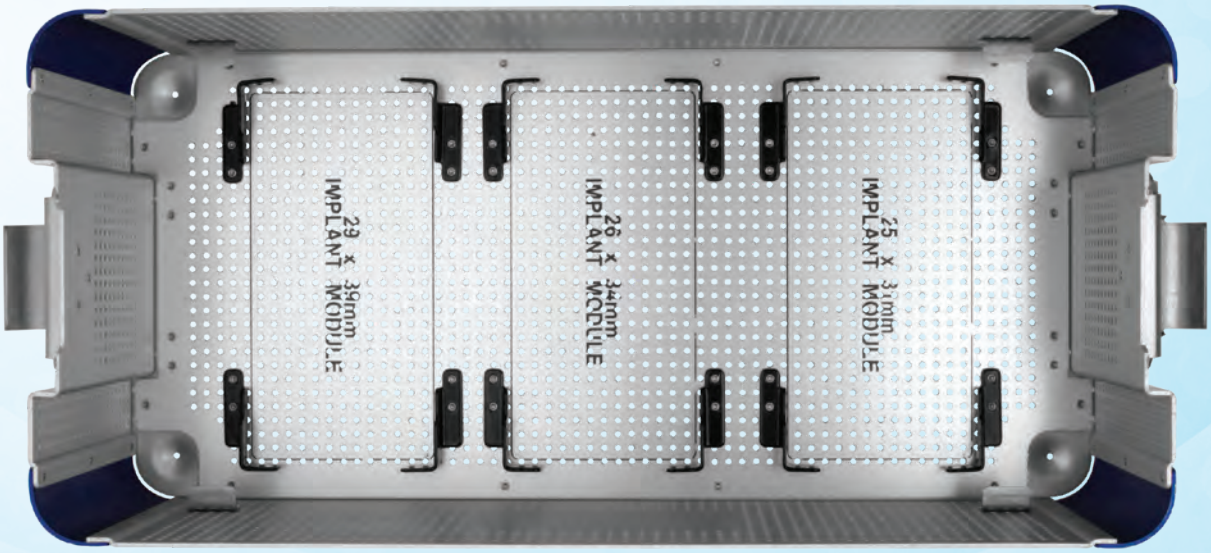
Additionally Available

6108.3001	MONUMENT® DTS Guide, Lateral
6108.3011	MONUMENT® Medial Drill Guide, 11mm
6108.3013	MONUMENT® Medial Drill Guide, 13mm
6108.3015	MONUMENT® Medial Drill Guide, 15mm
6108.3017	MONUMENT® Medial Drill Guide, 17mm
676.008	INDEPENDENCE® Drill Guide Holder

MONUMENT®
INSTRUMENT SET I 9108.9005



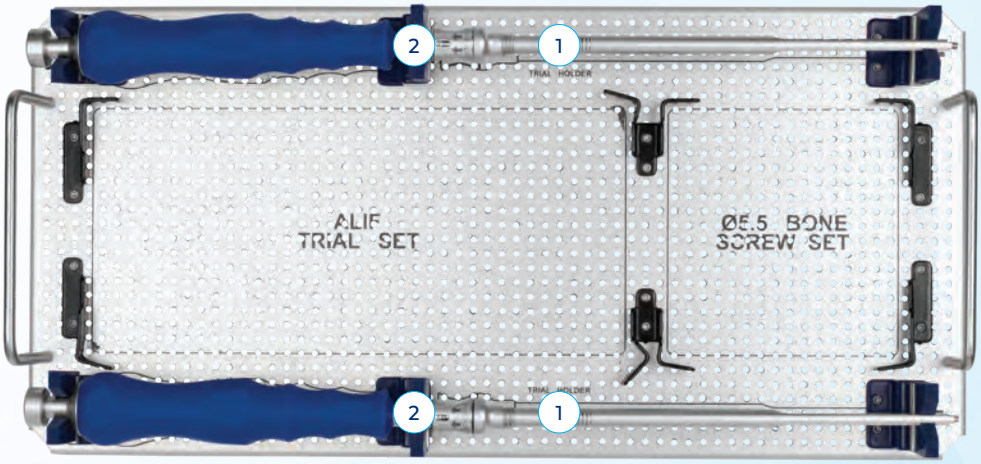


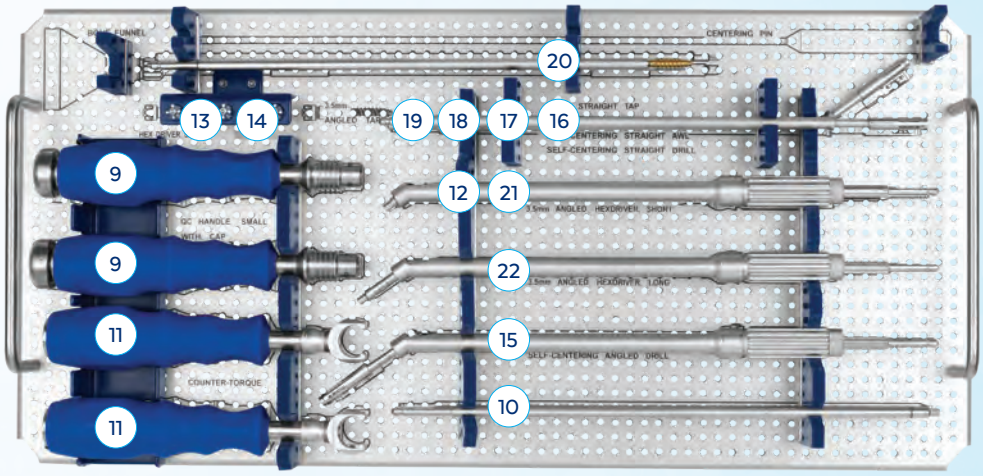


ALIF
INSTRUMENT SET I 925.905

	Part No.	Description	Qty
1	6108.0001	Trial Holder Sleeve	2
2	6108.0003	Trial Holder	2
3	6108.2004	Double-Angled Cobb, 20mm, Up	1
4	6108.2005	Double-Angled Dual Rasp	1
5	6108.2007	Double Angle Curette, Small, Up	1
6	6108.2009	Double Angle Curette, Large, Up	1
7	6108.2011	Double-Angled Ring Curette, Up	1
8	6108.2012	Double-Angled Osteotome	1
9	650.105	QC Handle, Small, with Cap	2
10	676.502	3.5mm Hex Straight Driver	2
11	676.699	Counter-Torque	2
12	676.700	Angled Sleeve	3
13	676.701	Shaft	3
14	676.702	Nut	3
15	676.703	Self-Centering Angled Drill	1
16	676.704	Self-Centering Straight Drill	1
17	676.705	Self-Centering Bent Awl	1
18	676.706	Self-Centering Straight Awl	1
19	676.707	5.5mm Angled Tap	1
20	676.708	5.5mm Straight Tap	1
21	676.710	3.5mm Angled Hex Driver, Short	2
22	676.809	3.5mm Angled Hex Driver, Long	2
	925.105	ALIF Instrument Graphic Case	

ALIF
INSTRUMENT SET I 925.905 (CONT'D)





ALIF
TRIAL SET 925.906

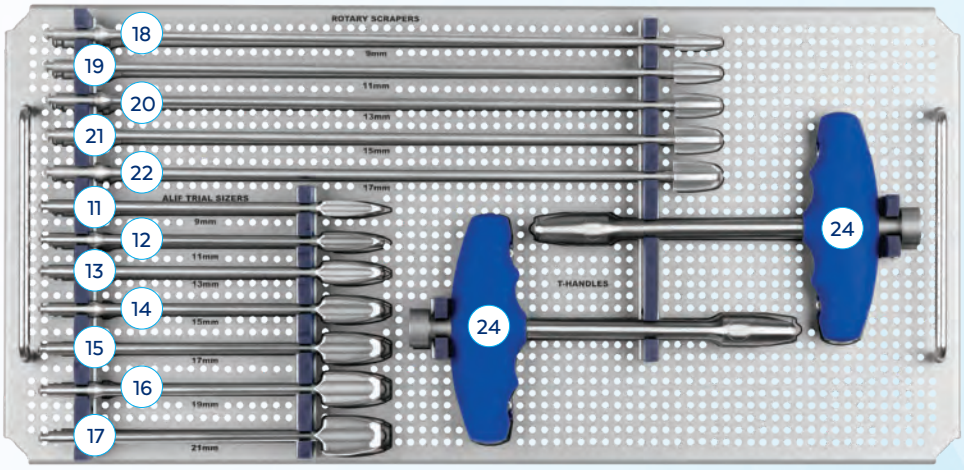
Part No.	Description	Qty
6108.0111	ALIF Trial, Small, 8°, 11mm	1
6108.0113	ALIF Trial, Small, 8°, 13mm	1
6108.0115	ALIF Trial, Small, 8°, 15mm	1
6108.0117	ALIF Trial, Small, 8°, 17mm	1
6108.0211	ALIF Trial, Small, 15°, 11mm	1
6108.0213	ALIF Trial, Small, 15°, 13mm	1
6108.0215	ALIF Trial, Small, 15°, 15mm	1
6108.0217	ALIF Trial, Small, 15°, 17mm	1
6108.0411	ALIF Trial, Medium, 8°, 11mm	1
6108.0413	ALIF Trial, Medium, 8°, 13mm	1
6108.0415	ALIF Trial, Medium, 8°, 15mm	1
6108.0417	ALIF Trial, Medium, 8°, 17mm	1
6108.0419	ALIF Trial, Medium, 8°, 19mm	1
6108.0511	ALIF Trial, Medium, 15°, 11mm	1
6108.0513	ALIF Trial, Medium, 15°, 13mm	1
6108.0515	ALIF Trial, Medium, 15°, 15mm	1
6108.0517	ALIF Trial, Medium, 15°, 17mm	1
6108.0519	ALIF Trial, Medium, 15°, 19mm	1
6108.0711	ALIF Trial, Large, 8°, 11mm	1
6108.0713	ALIF Trial, Large, 8°, 13mm	1
6108.0715	ALIF Trial, Large, 8°, 15mm	1
6108.0717	ALIF Trial, Large, 8°, 17mm	1
6108.0719	ALIF Trial, Large, 8°, 19mm	1
6108.0813	ALIF Trial, Large, 15°, 13mm	1
6108.0815	ALIF Trial, Large, 15°, 15mm	1
6108.0817	ALIF Trial, Large, 15°, 17mm	1
6108.0819	ALIF Trial, Large, 15°, 19mm	1
925.106	Universal ALIF Trial Module	

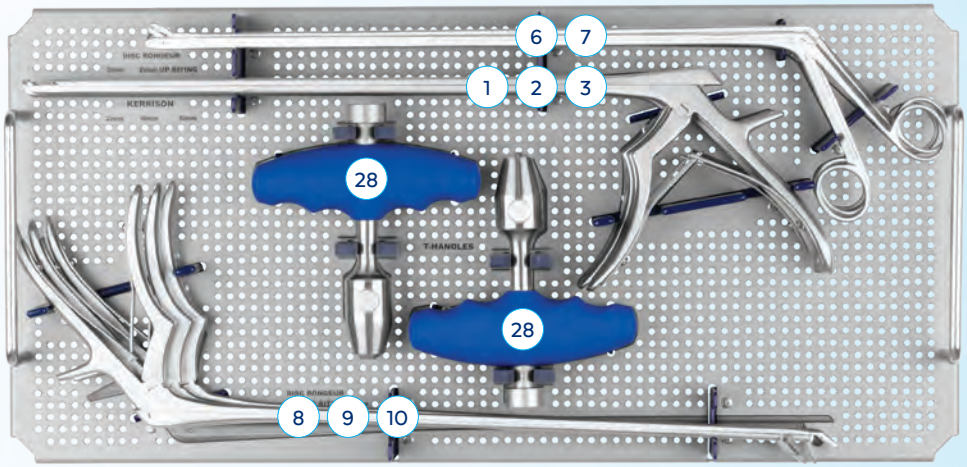
ALIF
TRIAL SET 925.906 (CONT'D)

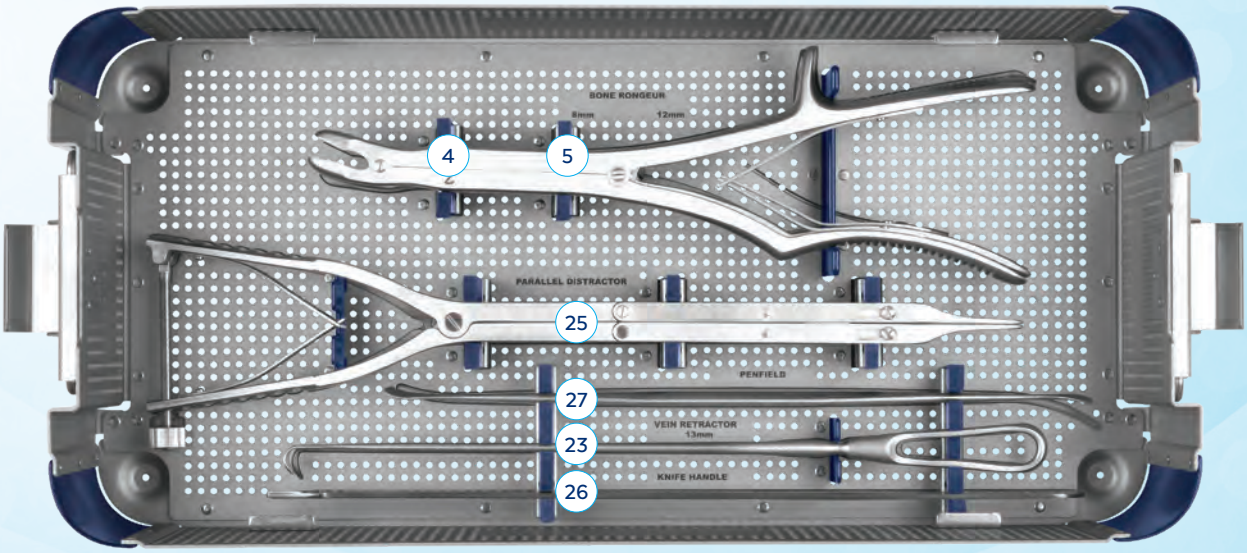
ANTERIOR DISC PREP I
INSTRUMENT SET 925.901

	Part No.	Description	Qty
1	625.201	Kerrison, 2mm	1
2	625.202	Kerrison, 4mm	1
3	625.203	Kerrison, 6mm	1
4	625.301	Bone Rongeur, Double Acting, 8mm	1
5	625.302	Bone Rongeur, Double Acting, 12mm	1
6	625.303	Disc Rongeur, 2mm	1
7	625.304	Disc Rongeur, 2mm, Up Biting	1
8	625.305	Disc Rongeur, 4mm	1
9	625.306	Disc Rongeur, 4mm, Up Biting	1
10	625.307	Disc Rongeur, 6mm	1
11	625.609	ALIF Trial Sizer, 9mm	1
12	625.611	ALIF Trial Sizer, 11mm	1
13	625.613	ALIF Trial Sizer, 13mm	1
14	625.615	ALIF Trial Sizer, 15mm	1
15	625.617	ALIF Trial Sizer, 17mm	1
16	625.619	ALIF Trial Sizer, 19mm	1
17	625.621	ALIF Trial Sizer, 21mm	1
18	625.709	Rotary Scraper, 9mm	1
19	625.711	Rotary Scraper, 11mm	1
20	625.713	Rotary Scraper, 13mm	1
21	625.715	Rotary Scraper, 15mm	1
22	625.717	Rotary Scraper, 17mm	1
23	625.801	Vein Retractor	1
24	625.804	T-Handle with Impaction Cap, Long	2
25	625.805	Parallel Distractor	1
26	625.806	Knife Handle	1
27	625.811	Long Penfield	1
28	675.005	T-Handle with Impaction Cap	2
	925.101	Graphic Case I	

ANTERIOR DISC PREP I
INSTRUMENT SET 925.901 (CONT'D)







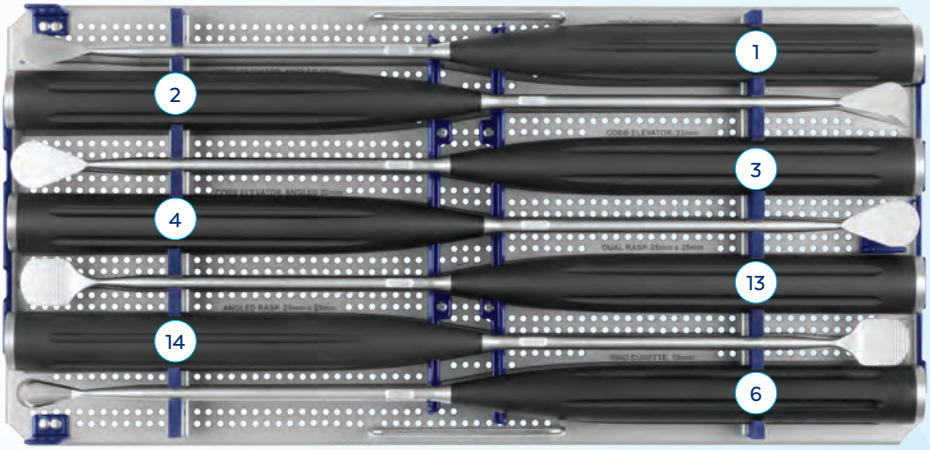
ANTERIOR DISC PREP II
INSTRUMENT SET 925.902

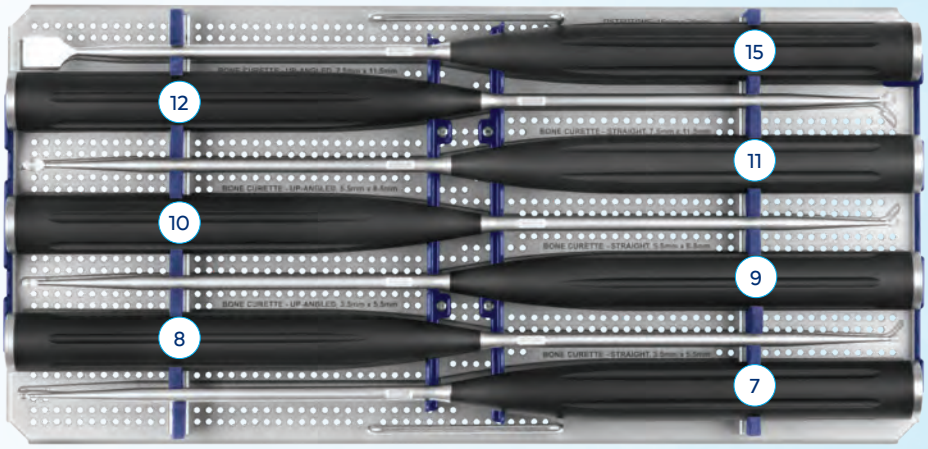
	Part No.	Description	Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette, 3.5x5.5mm, Up-Angled	1
9	625.405	Bone Curette, 5.5x8.5mm, Straight	1
10	625.406	Bone Curette, 5.5x8.5mm, Up-Angled	1
11	625.407	Bone Curette, 7.5x11.5mm, Straight	1
12	625.408	Bone Curette, 7.5x11.5mm, Up-Angled	1
13	625.501	Dual Rasp	1
14	625.502	Angled Rasp	1
15	625.803	Osteotome, 16x20mm	1
	925.102	Graphic Case II	

Additionally Available

625.409	Bone Curette, 9.5x14.5mm, Straight
625.410	Bone Curette, 9.5x14.5mm, Up-Angled
625.411	Bone Curette, 11.5x17.5mm, Straight
625.412	Bone Curette, 11.5x17.5mm, Up-Angled
625.413	Bone Curette, 13.5x20.5mm, Straight
625.414	Bone Curette, 13.5x20.5mm, Up-Angled

ANTERIOR DISC PREP II
INSTRUMENT SET 925.902 (CONT'D)





ALIF
ANTERIOR BONE SCREW SETS

INDEPENDENCE® HA-Coated Bone Screw Set 976.908

Part No.	Description	Qty
176.420S	INDEPENDENCE® HA-Coated Bone Screw, Variable Angle, 20mm	9
176.425S	INDEPENDENCE® HA-Coated Bone Screw, Variable Angle, 25mm	9
176.430S	INDEPENDENCE® HA-Coated Bone Screw, Variable Angle, 30mm	9
176.435S	INDEPENDENCE® HA-Coated Bone Screw, Variable Angle, 35mm	9
176.440S	INDEPENDENCE® HA-Coated Bone Screw, Variable Angle, 40mm	0
976.008	INDEPENDENCE® HA-Coated Screw Soft Case	

ALIF Locking Screw Set 9212.9005

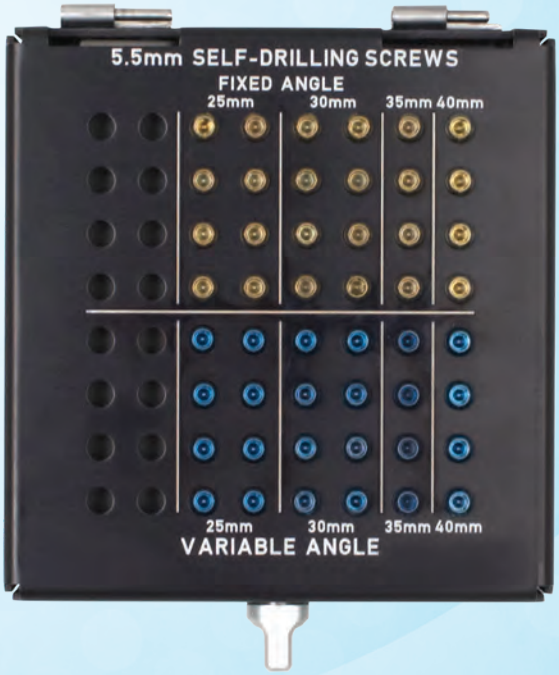
Part No.	Description	Qty
7212.0020	Locking Bone Screw, 5.5mm, 20mm	8
7212.0025	Locking Bone Screw, 5.5mm, 25mm	8
7212.0030	Locking Bone Screw, 5.5mm, 30mm	8
7212.0035	Locking Bone Screw, 5.5mm, 35mm	4
7212.0040	Locking Bone Screw, 5.5mm, 40mm	4
7212.1025	Locking Bone Screw, Self-Drilling 5.5mm, 25mm	8
7212.1030	Locking Bone Screw, Self-Drilling 5.5mm, 30mm	8
7212.1035	Locking Bone Screw, Self-Drilling 5.5mm, 35mm	4
7212.1040	Locking Bone Screw, Self-Drilling 5.5mm, 40mm	4
9212.0003	ALIF Locking Screw Module	

ALIF Self-Drilling Screw Set 925.908

Part No.	Description	Qty
176.625	Self-Drilling Screw, Fixed Angle 5.5mm, 25mm	8
176.630	Self-Drilling Screw, Fixed Angle 5.5mm, 30mm	8
176.635	Self-Drilling Screw, Fixed Angle 5.5mm, 35mm	4
176.640	Self-Drilling Screw, Fixed Angle 5.5mm, 40mm	4
176.725	Self-Drilling Screw, Variable Angle 5.5mm, 25mm	8
176.730	Self-Drilling Screw, Variable Angle 5.5mm, 30mm	8
176.735	Self-Drilling Screw, Variable Angle 5.5mm, 35mm	4
176.740	Self-Drilling Screw, Variable Angle 5.5mm, 40mm	4
925.108	ALIF Self-Drilling Screw Set Module	

Items in gray are additionally available.

ALIF
ANTERIOR BONE SCREW SETS (CONT'D)



IMPORTANT INFORMATION ON MONUMENT® SPACERS

DESCRIPTION

The MONUMENT® Spacer is an anterior lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The MONUMENT® Spacer is intended to aid in reduction of a Grade 1 or Grade 2 spondylolisthesis. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The MONUMENT® spacer is made from PEEK radiolucent polymer and titanium alloy, as specified in ASTM F136, F1295, and F2026. The MONUMENT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580. The mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and 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

The MONUMENT® Spacer is an interbody fusion device indicated for use at one or more levels of the lumbosacral spine (L1-S1), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). In addition, these patients may have up to Grade 2 spondylolisthesis or retrolisthesis at the involved level(s). 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. All MONUMENT® TPS coated spacers are indicated for the same use as non-coated spacers.

The MONUMENT® Spacer is to be used with four screws that accompany the implant. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The MONUMENT® Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

WARNINGS

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

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

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.

Components of this system should not be used with components of any other manufacturer.

Components of this system are manufactured from PEEK radiolucent polymer and titanium 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.

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

PRECAUTIONS

The implantation of intervertebral fusion 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.

Surgical implants 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.

MRI SAFETY INFORMATION

The MONUMENT® Spacer is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the MONUMENT® Spacer is expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of the MONUMENT® Spacer is contraindicated in patients with the following conditions:

1. Active systemic infection, infection or inflammation 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.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. 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.
5. 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.
6. Any patient not willing to cooperate with postoperative instruction.
7. Any condition not described in the indications for use.
8. Signs of local inflammation.
9. Fever or leukocytosis.
10. Morbid obesity.
11. Pregnancy.
12. Mental illness.
13. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
14. Suspected or documented allergy or intolerance to composite materials.
15. Any case not needing a fusion.
16. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
17. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
18. Spondylolisthesis unable to be reduced to approximately Grade 1.
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
20. Any case that requires the mixing of metals from two different components or systems.
21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system

IMPORTANT INFORMATION ON MONUMENT® SPACERS

- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

PACKAGING

MONUMENT® Spacer implants are supplied non-sterile or pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility 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 implants from the packaging using aseptic technique.

The instrument sets are also provided non-sterile 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 AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments 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 of instruments 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 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 and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

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

Nonsterile MONUMENT® 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	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

DI189A Rev J

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