GLOBUS MEDICAL

MAGNIFY®-S

Expandable Stand-Alone ALIF System

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

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

MAGNIFY®-S

MAGNIFY®-S

Expandable Stand-Alone ALIF System

MAGNIFY®-S is an all titanium expandable stand-alone ALIF device designed to maximize indirect decompression, restore disc height, and optimize fusion.

The minimized insertion height allows for ideal implant placement with minimal impaction while controlled distraction allows for indirect decompression.

A continuous expansion mechanism in lordotic sagittal profile facilitates optimal disc height restoration and segmental lordosis to aid in sagittal balance.

Maximized Indirect Decompression

The implant's robust distraction capability maximizes indirect decompression without the need for traumatic impaction forces.

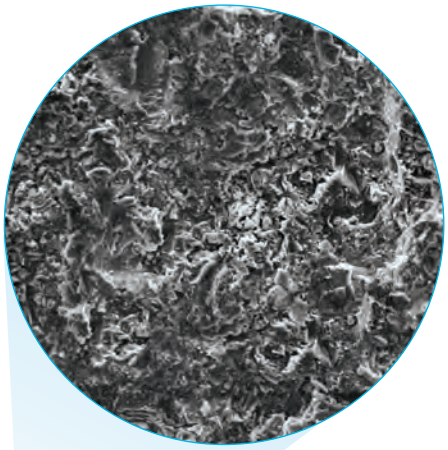
Controlled Height Restoration

Continuous implant expansion optimizes disc height to aid in sagittal balance.

Optimized Fusion

Post-expansion delivery of autogenous bone graft optimizes fusion potential by maximizing graft volume within the spacer.

Scanning Electron Micrograph
showing roughened surface
[1000x magnification]



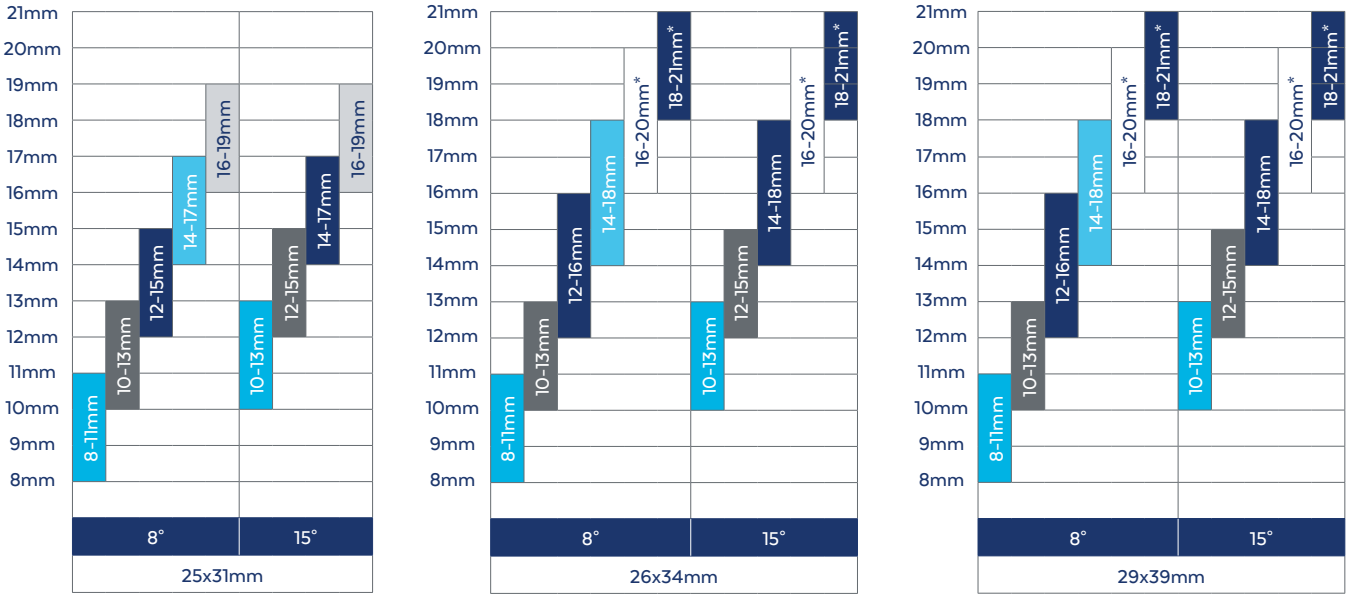
Robust titanium body with
roughened surface technology

IMPLANT OVERVIEW

Three axial footprints: 25x31, 26x34, and 29x39mm

Two sagittal profiles: 8° and 15°

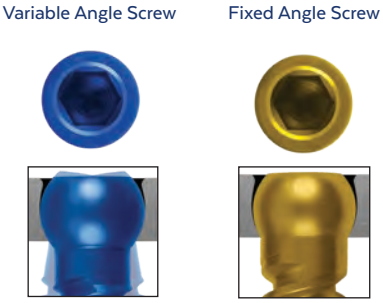
MAGNIFY®-S implant options



*Additionally available

Screw Options

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




Variable Angle Self-Tapping Screw

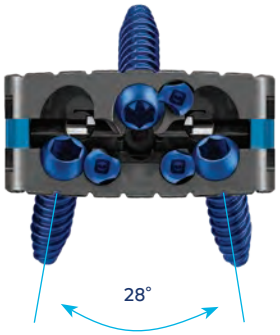

Variable Angle Self-Drilling Screw*

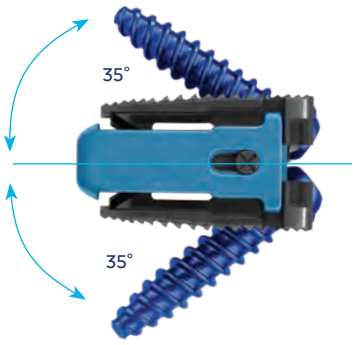

HA-Coated Variable Angle Screw*


Locking Screw (CoCr)*

Screw Angulation

- 35° cephalad/caudal orientation
- 28° medial divergence
- Variable angle offers 5° conical angulation





Additionally available

INSTRUMENT OVERVIEW

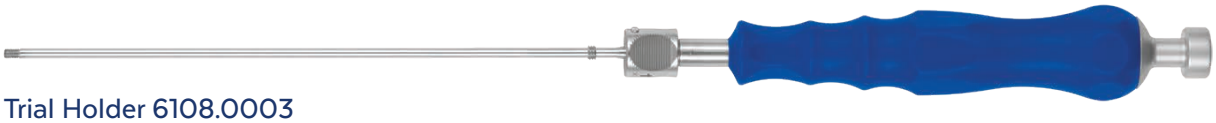
TRIALS*

25x31mm			26x34mm			29x39mm		
								
Height	**8°**	**15°**	**Height**	**8°**	**15°**	**Height**	**8°**	**15°**
9mm	6108.0109	-	9mm	6108.0409	-	9mm	6108.0709	-
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

Expandable Trial, 25x31mm, 8°, 7-15mm 6126.0001

Adjustable Trial Handle 694.418

TRIAL HOLDERS**



Trial Holder 6108.0003

Trial Holder Sleeve 6108.0001

Trial Holder Assembly

**Available in ALIF Trial Set (925.906)*
***Available in ALIF Instrument Set (925.905)*
Items in gray are additionally available.

INSERTION INSTRUMENTS

Midline Inserter 6126.6100

Offset Inserter 6126.6101

Lateral Inserter 6126.6102

Set Screw Positioner 6126.6103

Torque-Limiting Hex Driver, 1.75Nm 6126.6005

BONE PACKING INSTRUMENTS*

Bone Funnel 6126.6000

Bone Funnel Tube 6126.6001

Bone Funnel Guide 6126.6002

Bone Pusher 6126.6003

Bone Packing Assembly

Available in ALIF Instrument Set (925.905)

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

*Available in ALIF Instrument Set (925.905)

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)

**Available in ALIF Instrument Set (925.905)*

ADDITIONALLY AVAILABLE INSTRUMENTS**

Trial Holder 606.800

Distractor/Retractor, 8mm 606.808

	Height	Part No.
	10mm	606.810
	12mm	606.812
	14mm	606.814
	16mm	606.816

Distractor Trial Head, 8mm 606.858

	Height	Part No.
	10mm	606.860
	12mm	606.862
	14mm	606.864
	16mm	606.866

***Available in Anterior Lumbar Distractor/Retractor Set (906.902)*

ADDITIONALLY AVAILABLE INSTRUMENTS** (CONT'D)

Quick-Coupling Handle 668.160

Distractor/Retractor Assembled

Slide Hammer, Small 622.410

***Available in Anterior Lumbar Distractor/Retractor Set (906.902)*

SURGICAL TECHNIQUE

MAGNIFY®-S

The MAGNIFY®-S Spacer is an expandable stand-alone anterior lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following a discectomy. The spacers are available in various footprint, height, and lordotic options to fit the anatomical needs of a wide variety of patients. Refer to the package insert (printed at the back of this manual) for information on the intended usage/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

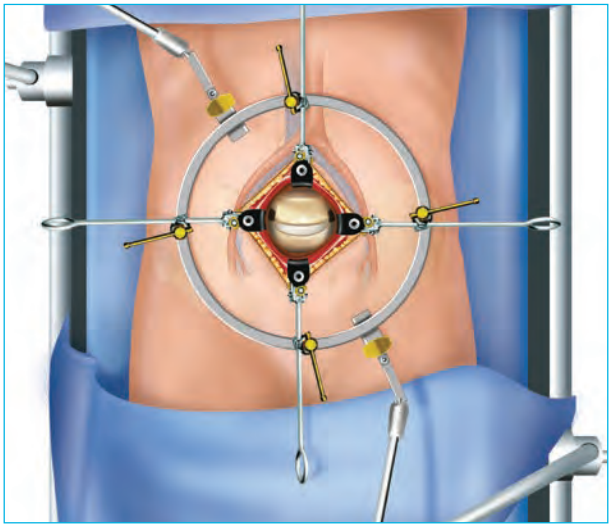
These devices are intended for use with supplemental fixation (e.g., facet screws or posterior fixation), and may be used with or without three screws that accompany the implant. In addition, these devices are intended for stand-alone use in patients with degenerative disc disease at one or two levels only when used with three screws per implant.

STEP 1 APPROACH

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

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

An anterior approach is used to implant the MAGNIFY®-S Spacer. Insertion can be accomplished using a minimally invasive surgical approach. A standard mini-open anterior approach is shown. The patient is positioned supine and access to the disc space is created.



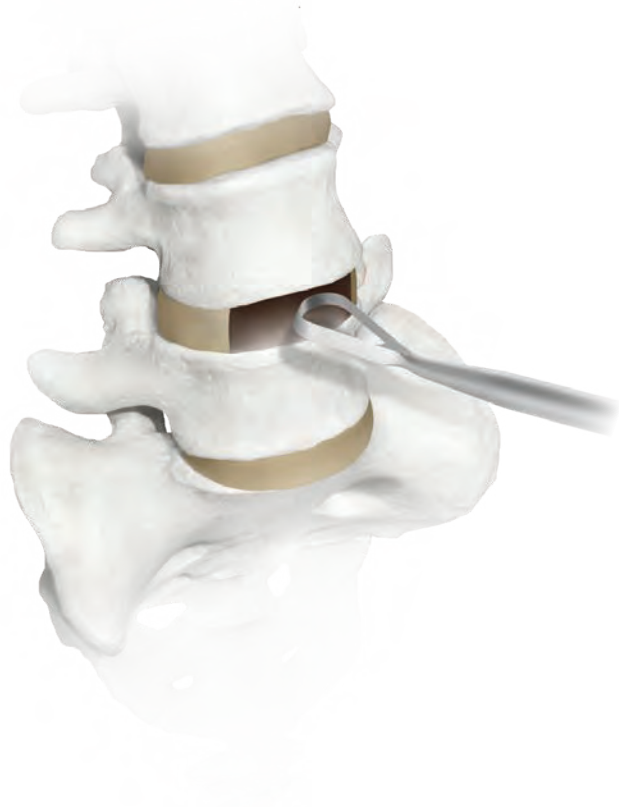
1. Lee SH, Choi WG, Lim SR, Kand HY. Minimally invasive anterior lumbar fusion followed by percutaneous pedicle screw fixation for isthmic spondylolistheseis, *The Spine Journal 4* (2004): 644-49.

2. Kim KT, Lee SH, Suk KS, Bae SC. The quantitative analysis of tissue injury markers after mini-open lumbar fusion, *Spine B* (2006): 712-16.

STEP 2 DISC PREPARATION

Anterior Disc Preparation Instruments may be used to expose the disc. Remove disc material using rongeurs and other suitable instruments. Scrapers are used to remove superficial layers of the cartilaginous endplates. The posterior and lateral walls of the annulus can be preserved to provide peripheral support, if desired.

Note: Disc Preparation Instruments are available in the Anterior Disc Prep Instrument Set I (925.901) and II (925.902). Distractor/Retractors are available in the Anterior Lumbar Distractor/Retractor Set (906.902).



STEP 3 IMPLANT SIZING

Either a static or the Expandable Trial may be used to determine implant size.

Using the Static Trial

Select an appropriate size **Trial*** and attach it to the **Trial Holder Assembly**. 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 can be confirmed using fluoroscopy and tactile feel. For height trialing, start with the smallest height Trial, moving to larger Trials as needed.

Note: The shortest Trial height is 9mm. Some of the implant starting heights are lower than Trial heights and may not require trialing. For example, if the desired height is 11mm, use the 8-11mm implant.

*Trials and Trial Holders are available in the ALIF Trial Set (925.906) and ALIF Instrument Set (925.905)

USING THE TRIAL HOLDER

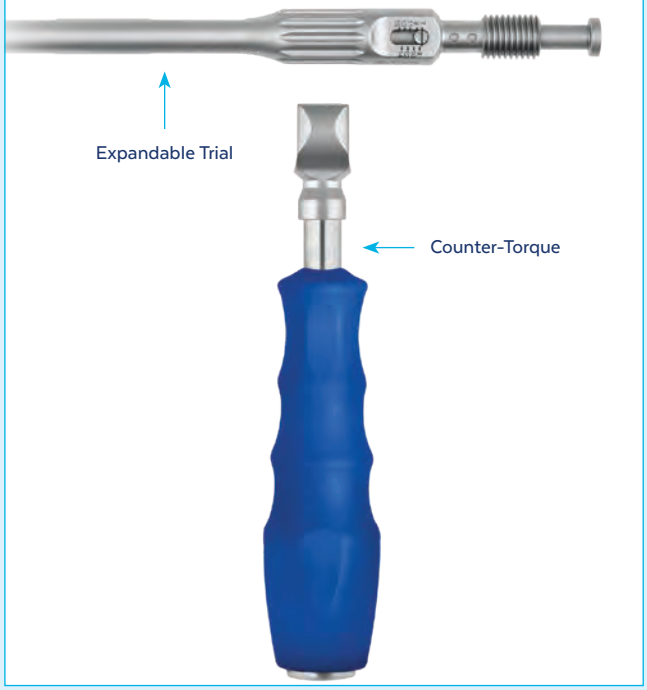
Ensure the Trial Holder Assembly is in the unlocked position. Thread the Trial onto the holder by rotating the handle clockwise. Lock the holder by pressing the release button and pushing the lock forward. To disengage, pull the locking sleeve back and rotate the handle counterclockwise.

Trial attached to the Trial Holder*

Locked Unlocked

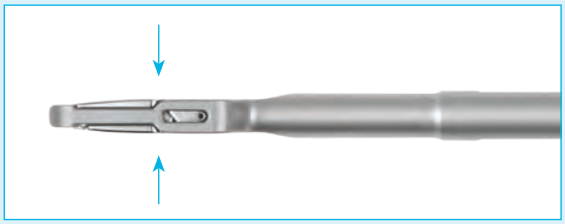
ASSEMBLING THE EXPANDABLE TRIAL

1. Slide the **Counter-Torque** from the smooth portion of the **Expandable Trial** to the knurled portion until fully seated. Rotate the Counter-Torque clockwise to final tighten.



2. Thread the **Adjustable Trial Handle** onto the proximal end of the Expandable Trial until it snaps in place.

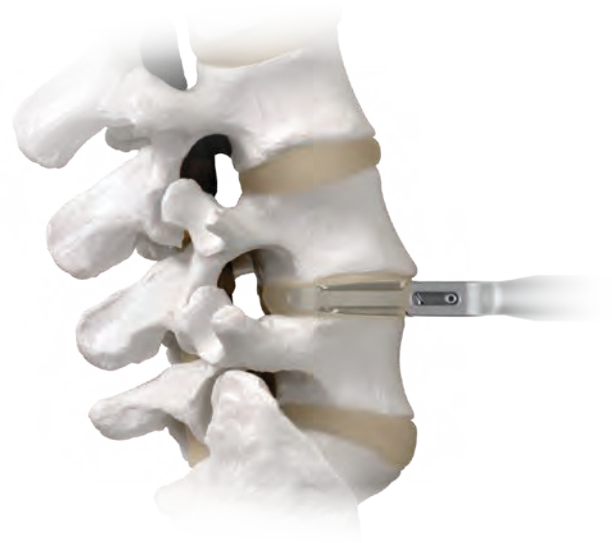
3. Contract the Expandable Trial back to its starting height by rotating the trial handle counterclockwise until it stops.



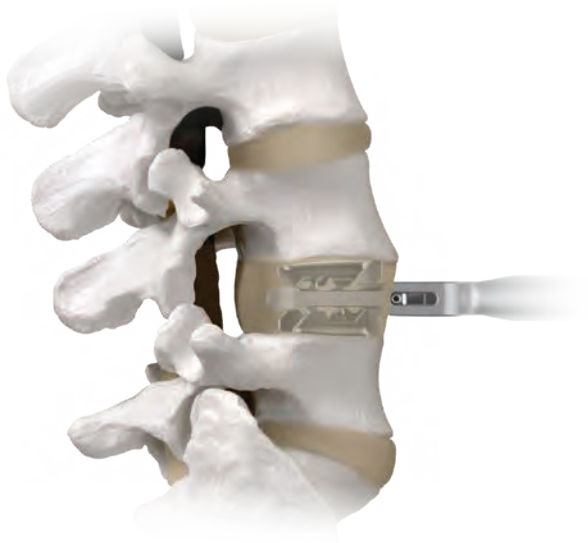
Trials and Trial Holders are available in the ALIF Trial Set (925.906) and ALIF Instrument Set (925.905)

Using the Expandable Trial (Cont'd)

Insert the Expandable Trial Assembly into the disc space at a contracted height. Expand the trial gradually to the desired height by rotating the handle clockwise. Use care while expanding the trial to avoid excessive distraction or damage to the endplates.



Trial inserted at contracted height



Trial expanded to final height

Determine which height best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. The final implant height may be confirmed using fluoroscopy.

Indicator on Adjustable Trial Assembly shows disc height between 9mm and 10mm

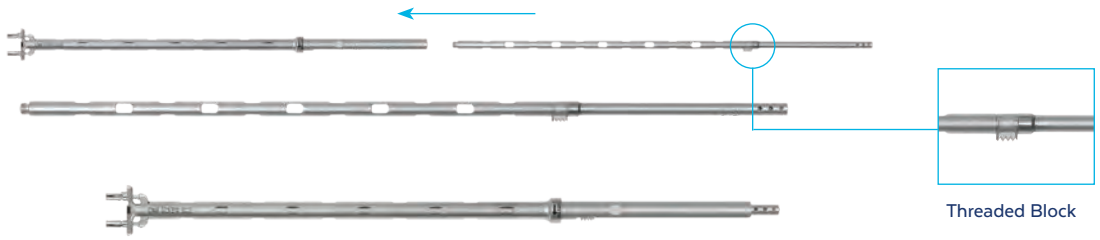
STEP 4 IMPLANT INSERTION

The selected implant can be inserted into the disc space using any of the following inserter options:
Midline Inserter, Offset Inserter, and Lateral Inserter. Steps 4 through 6 use the Midline Inserter. For the Offset Inserter and Lateral Inserter, refer to pages 30 and 32.

MIDLINE INSERTER ASSEMBLY

The **Midline Inserter** is provided disassembled. For assembly, follow the steps shown below.

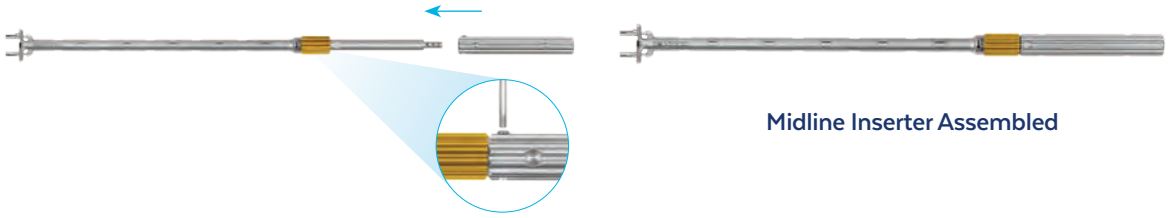
Ensure that the Threaded Block on the **Retractor Sleeve** is aligned with the opening slot on the Inserter Body. Slide the **Retractor Sleeve** onto the Inserter Body and gently rotate clockwise until the sleeve is fully threaded into the body.



Retractor Sleeve fully threaded into Inserter Body

Slide the **Gold Knob** over the Inserter Body and thread it onto the Threaded Block. Gently rotate the Gold Knob counterclockwise until finger tight. Do not overtighten.

Slide the **Grip Handle** onto the Retractor Sleeve. Tighten the handle set screw on the Grip Handle using the **Torque-Limiting Hex Driver, 1.75Nm. Do not overtighten the set screw.**



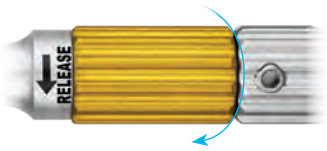
Midline Inserter Assembled

IMPLANT INSERTION (CONT'D)

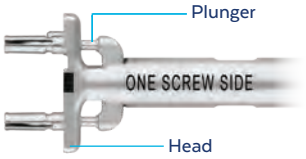
LOADING THE IMPLANT

Before loading the implant, ensure the **Plunger** is in a retracted position. Rotate the Gold Knob to the "RELEASE" position. The three set screws on the implant must be in the unlocked position. Use the **Set Screw Positioner** for adjustments.

Do not overtighten the Gold Knob when adjusting.



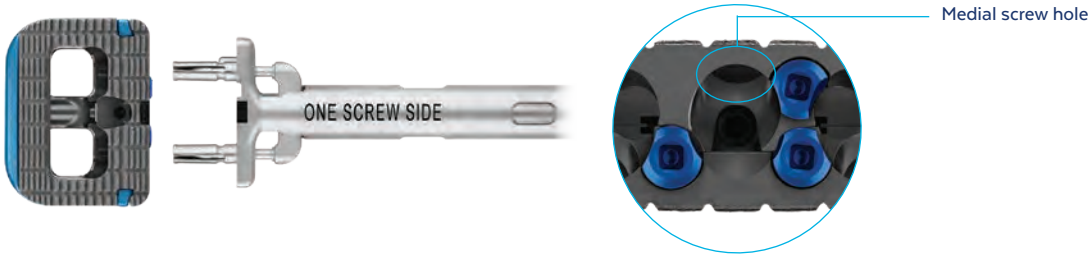
Rotate counterclockwise to "RELEASE" position



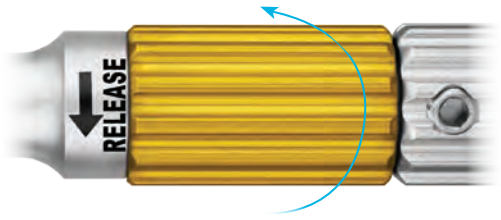
Plunger position prior to implant attachment

Set screws in unlocked position

To load the implant onto the Midline Inserter, align the etched line on the "ONE SCREW SIDE" of the inserter with the medial screw hole on the implant.



Rotate the Gold Knob clockwise until the Plunger is fully engaged in the implant. Pack autogenous bone graft into the graft chamber.



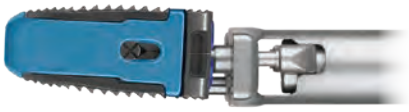
CORRECT ASSEMBLY

Axial View

Lateral View

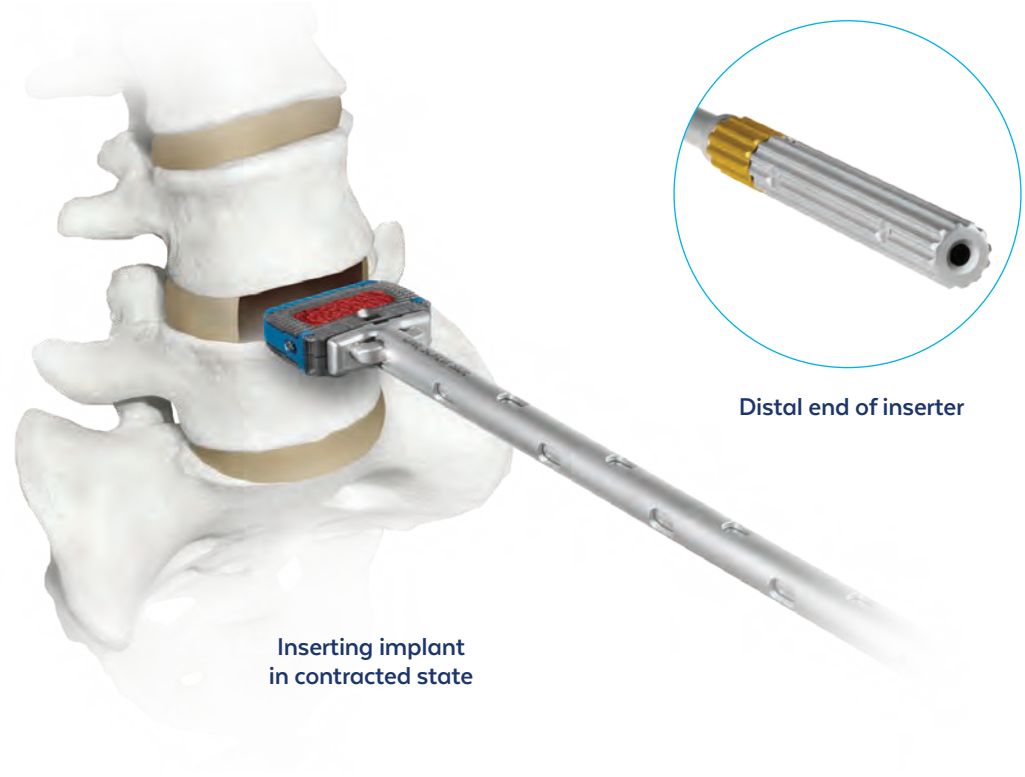
INCORRECT ASSEMBLY

Axial View



Lateral View

Select the appropriate implant and pack autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the implant. Insert the implant into the disc space using the Midline Inserter. If needed, gently impact on the back of the inserter handle. Place the implant flush anteriorly or recessed up to 1mm.



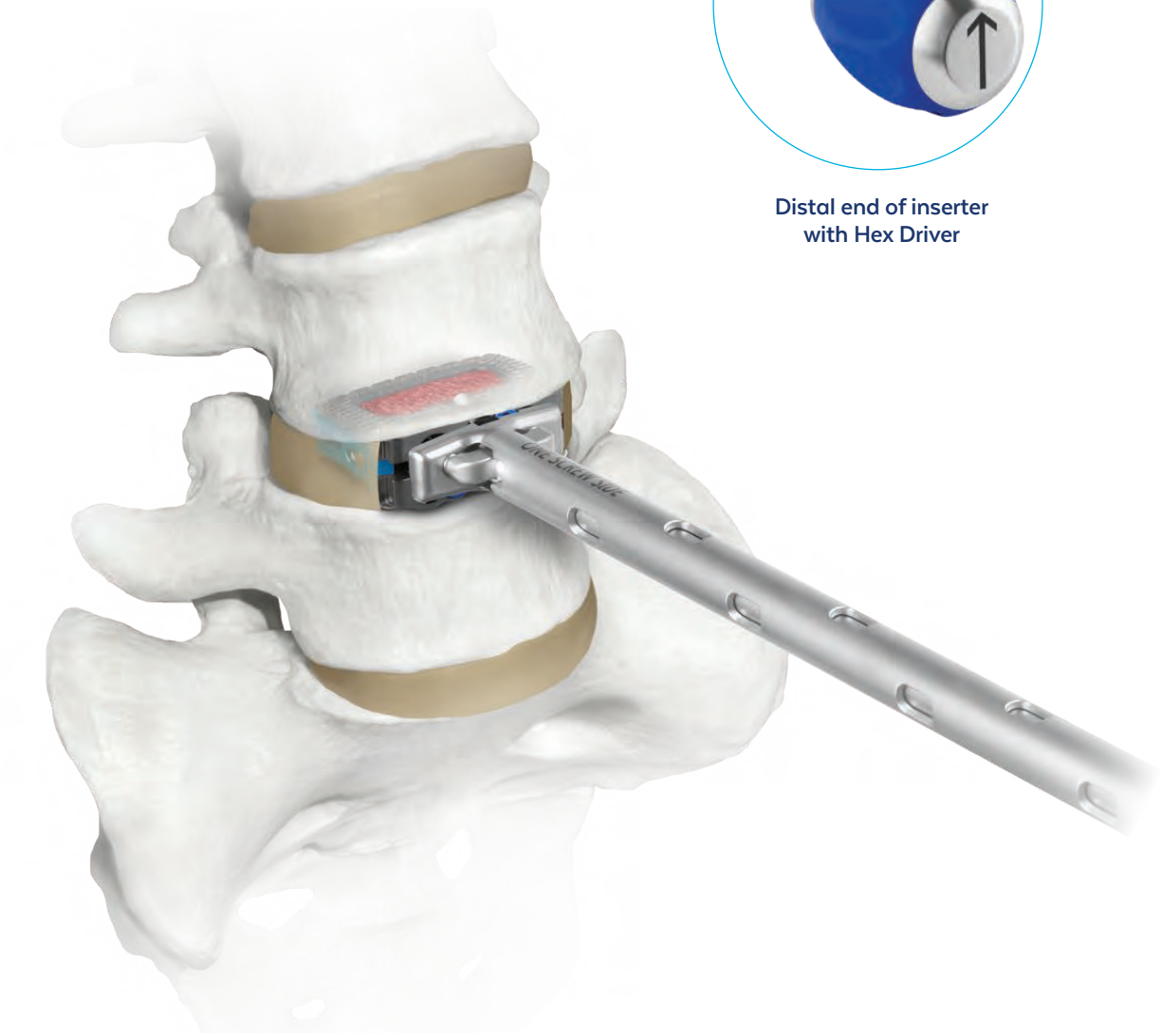
Inserting implant
in contracted state

Distal end of inserter

STEP 5 IMPLANT EXPANSION

Insert the Torque-Limiting Hex Driver, 1.75Nm into the Midline Inserter and rotate clockwise to expand the implant to the desired height. Attach the Counter-Torque if desired.

Distal end of inserter with Hex Driver



CONNECTING THE COUNTER-TORQUE TO THE MIDLINE INSERTER

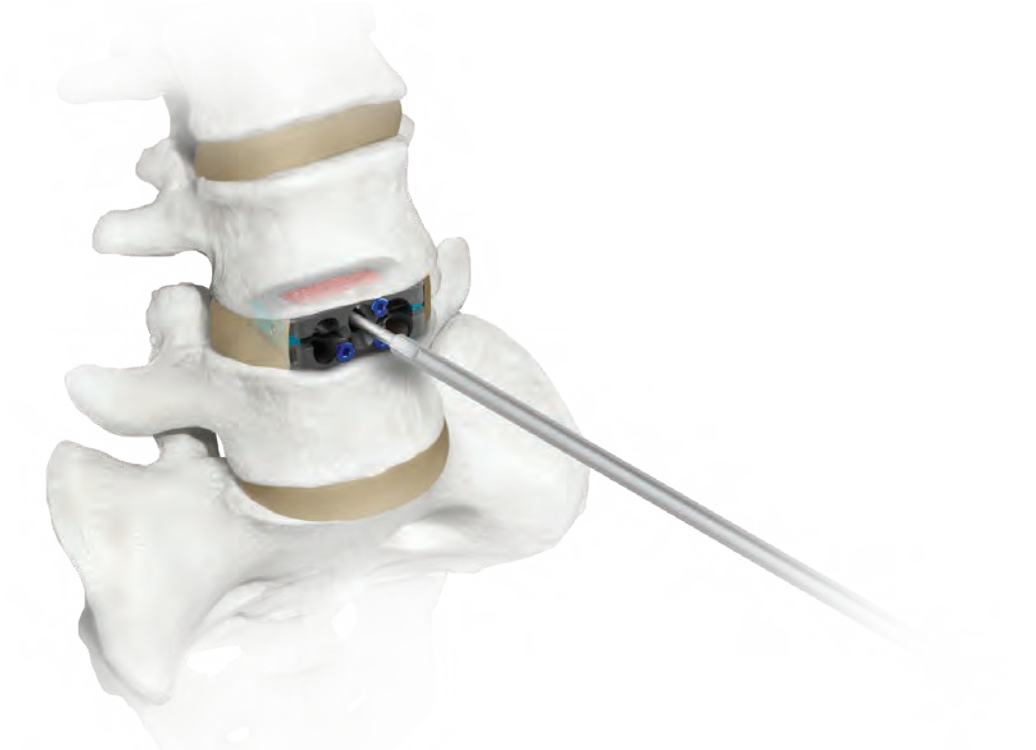
To allow for additional control of the Torque-Limiting Hex Driver, 1.75Nm, attach the Counter-Torque.* Slide the Counter-Torque down the knurled portion of the handle until fully seated. Rotate the Counter-Torque clockwise to final tighten.

**Counter-Torque (676.699) is available in ALIF Instrument Set (925.905)*

Determining Implant Height

Implant expansion is determined by the tactile feel of the implant in the disc space as it is expanded. Gently toggle the implant until the desired fit is achieved. Confirm visually or using fluoroscopy.

Remove the inserter for height adjustments. Rotate the Gold Knob on the Midline Inserter counterclockwise to remove the inserter (see Step 6).



Make minor height adjustments after the implant is detached from the inserter by rotating the Torque-Limiting Hex Driver, 1.75Nm, clockwise. Determine the overall height by counting the number of revolutions of the driver. All implants expand 1mm for every 1.5 revolutions. Use the arrow at the end of the driver to count revolutions.

Use the Hex Driver to identify when the implant has reached its maximum height expansion or the maximum allowable torque has been reached.

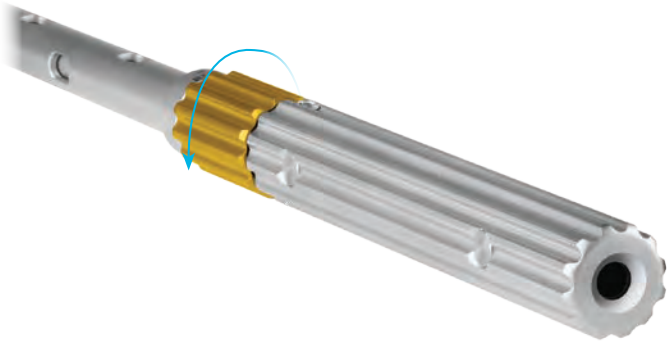
Note: The torque limit is designed to protect the function of the implant. Use care while expanding the implant to avoid excessive distraction and damage to the vertebral body endplates. It is not necessary to torque out the Hex Driver.

Do not over-contract or over-distract the implant to avoid compromising implant integrity.

Arrow on back end of driver used to count revolutions

STEP 6 DISENGAGING THE IMPLANT

Using fluoroscopy, verify final implant position before disengaging the implant. Once the desired height is achieved, rotate the Gold Knob on the Midline Inserter counterclockwise to disengage the implant.



Rotate the Gold Knob counterclockwise to detach the implant

STEP 7 AUTOGRAFT PACKING

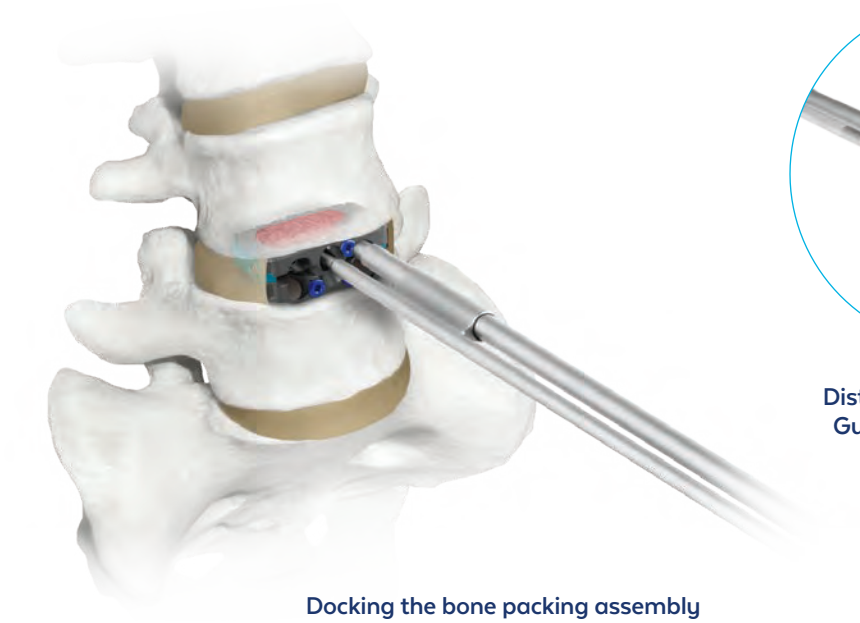
After implant expansion, use the **Bone Funnel Guide**, **Bone Funnel Tube**, **Bone Funnel**, and **Bone Pusher** to deliver additional autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the graft access holes on the implant and surounding disc space.

Dock the Bone Funnel Guide with the center screw hole of the implant. Insert the Bone Funnel Tube through the Bone Funnel Guide to dock within the bone screw hole.

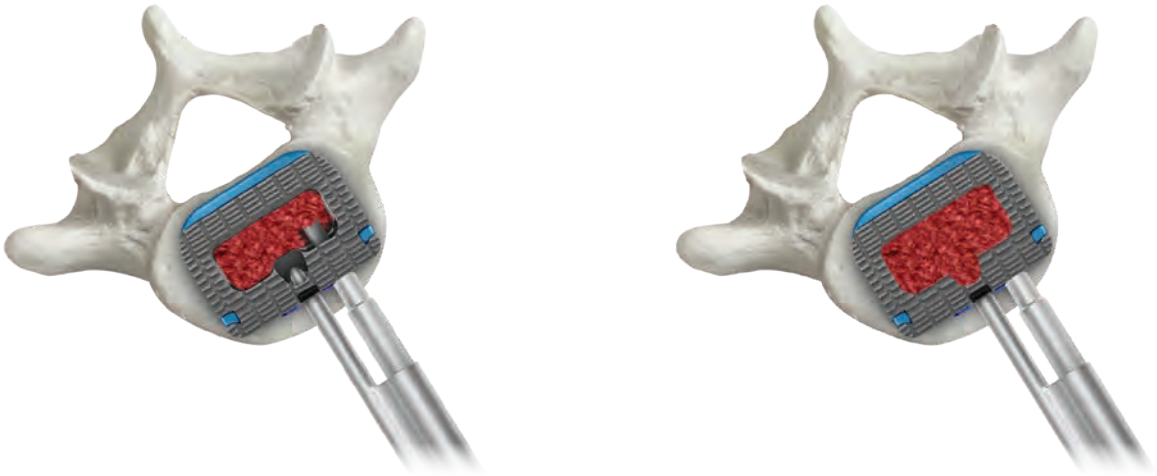
Place morselized autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the Bone Funnel Guide and pack into the implant with the Bone Pusher. Rotate the Bone Funnel Tube to the contralateral graft hole in the implant and pack additional autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the implant.

Do not pack bone graft inside the screw holes.

Distal end of Bone Funnel Guide with Bone Pusher



Docking the bone packing assembly



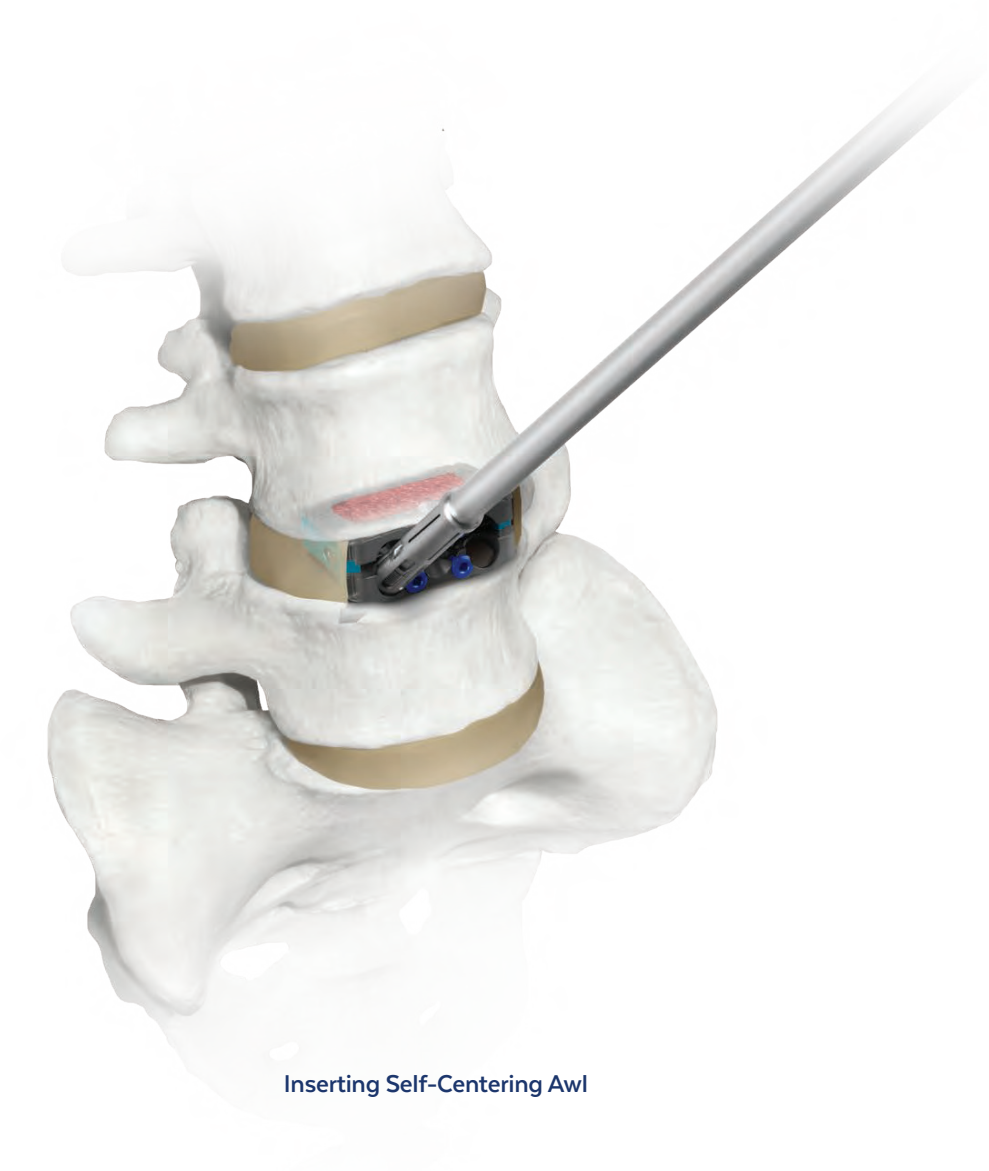
Packing bone graft

STEP 8 SCREW HOLE PREPARATION

Insert the **Self-Centering Awl** into each screw hole to break the cortex. Use the **Self-Centering Drill** and **Tap** 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 remaining screw holes.

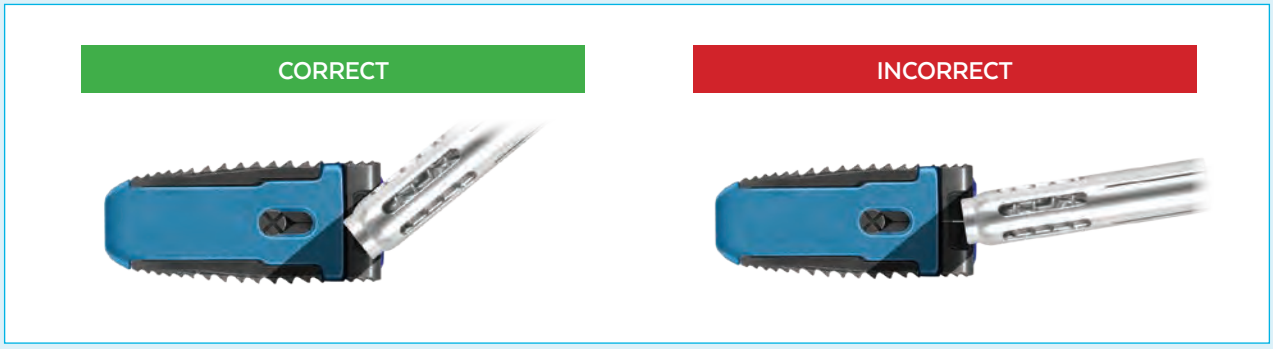
Note: For angled instrument assembly, see page 36.



Inserting Self-Centering Awl

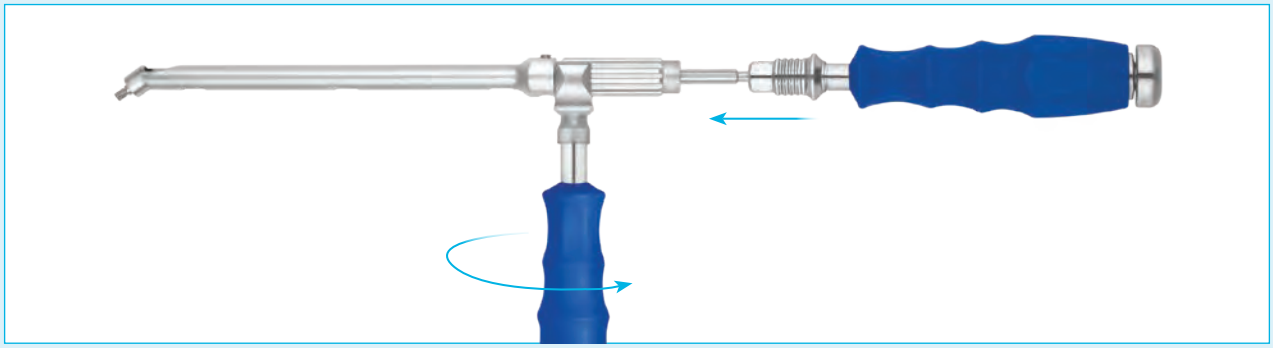
ALIGNING THE SELF-CENTERING SLEEVE

The self-centering sleeve ensures proper screw trajectory. Engage the sleeve properly with the plate before advancing screw hole preparation instruments. Proceed to screw insertion prior to preparing the remaining holes.



CONNECTING THE COUNTER-TORQUE TO THE ANGLED INSTRUMENTS

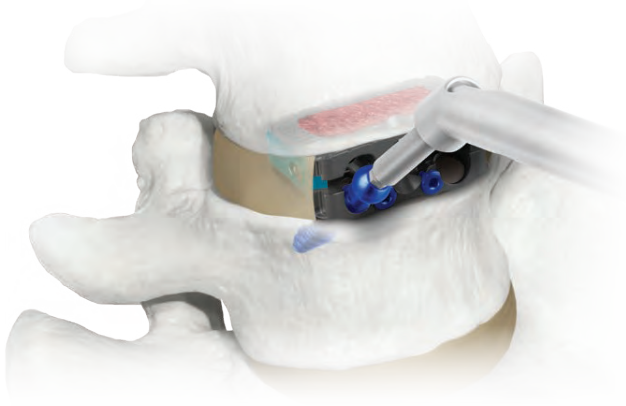
For additional control of angled Instruments, attach a Counter-Torque.* Starting from the top, slide the Counter-Torque from the smooth portion of the **Angled Driver Body** to the knurled portion until fully seated. Rotate the Counter-Torque clockwise to final tighten.



Counter-Torque (676.699) is available in ALIF Instrument Set (925.905)

STEP 9 SCREW INSERTION

Select the appropriate screw length. Insert the screw using a **Straight** or **Angled Screwdriver**. Repeat Steps 8 and 9 for each hole before moving to the next step.

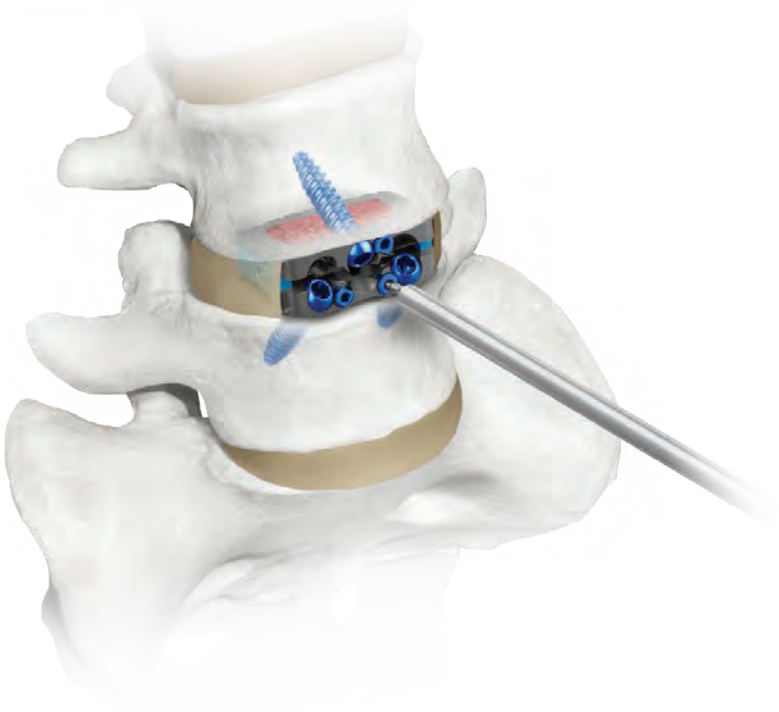


Inserting screw using Angled Screwdriver

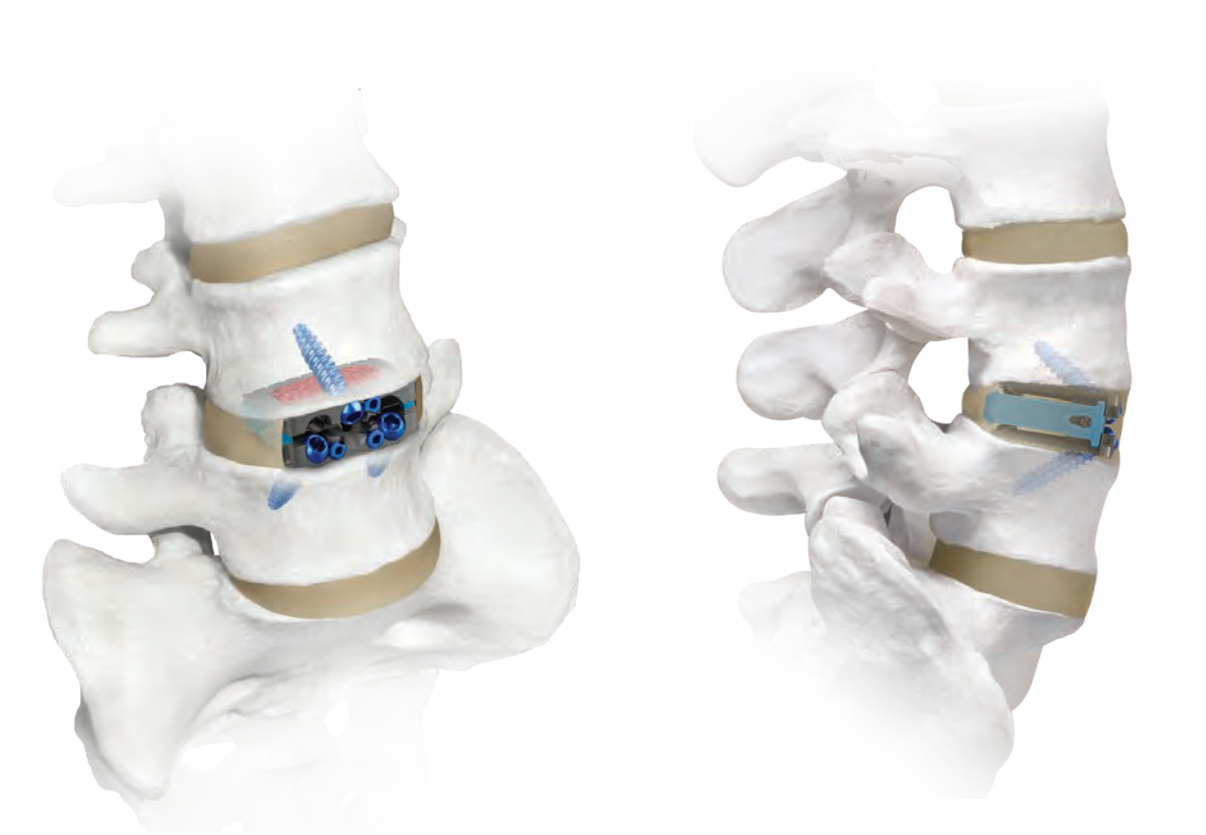
STEP 10 POSITIONING SET SCREWS

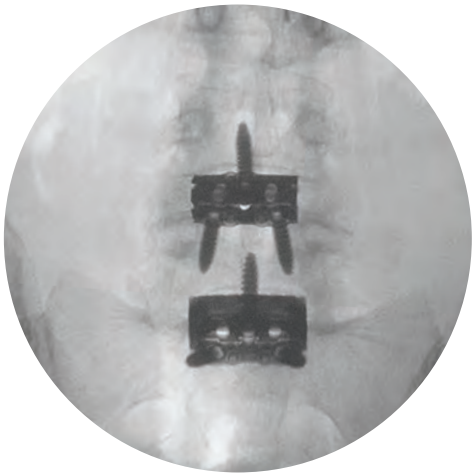
Use the Set Screw Positioner to engage the blocking set screws. Rotate the set screws clockwise 90° until the driver clicks twice. Ensure that the set screws block the bone screws.

Note: The Set Screw Positioner has a 0.4Nm torque limit.

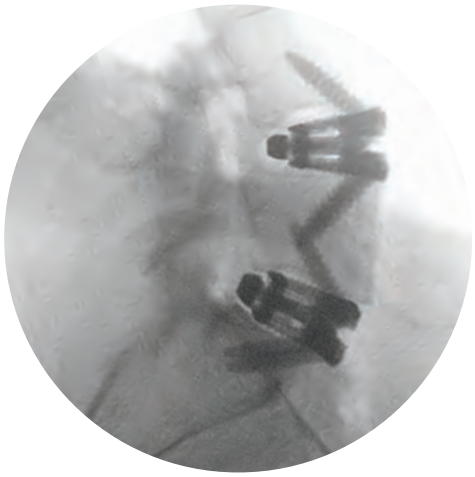


FINAL POSITION





AP View



Lateral View

OPTIONAL: SCREW REMOVAL

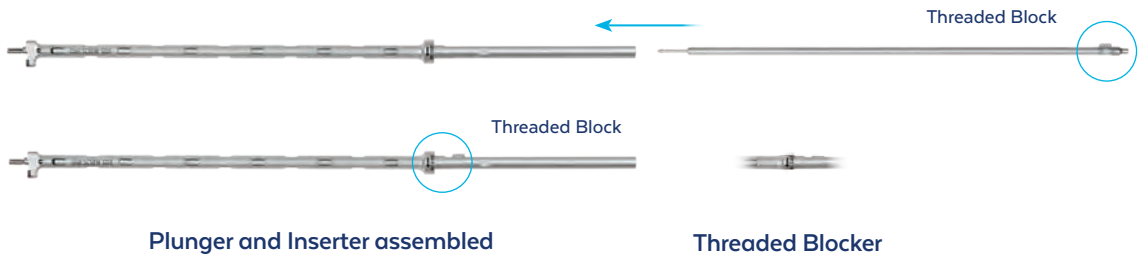
For implant removal, unlock the blocking set screws and remove all bone screws. Attach the Lateral Inserter. Insert the Torque-Limiting Hex Driver, 1.75Nm to contract and remove the implant. Forceps or other manual surgical instruments may then be used to grasp and remove the implant.

OPTIONAL TECHNIQUES: USING THE OFFSET INSERTER

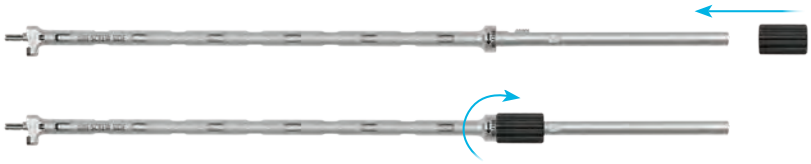
OFFSET INSERTER ASSEMBLY

The **Offset Inserter** is provided disassembled. For assembly, follow steps shown below. See page 39 for instructions on disassembly.

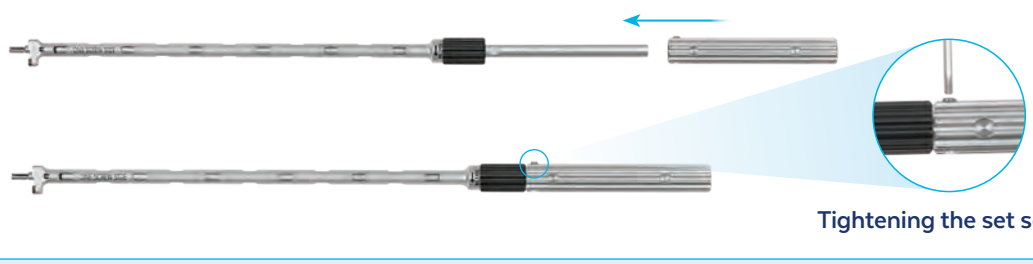
Ensure that the Threaded Block on the Plunger is aligned with the opening slot on the Inserter. Slide the Plunger into the Inserter.



Slide the Black Knob onto the Inserter. Gently rotate counterclockwise to thread it onto the Threaded Block until finger tight. **Do not overtighten.**



Slide the Grip Handle onto the Inserter. Tighten the set screw on the Grip Handle using the Torque-Limiting Hex Driver, 1.75Nm. **Do not overtighten the set screw on the Grip Handle.**



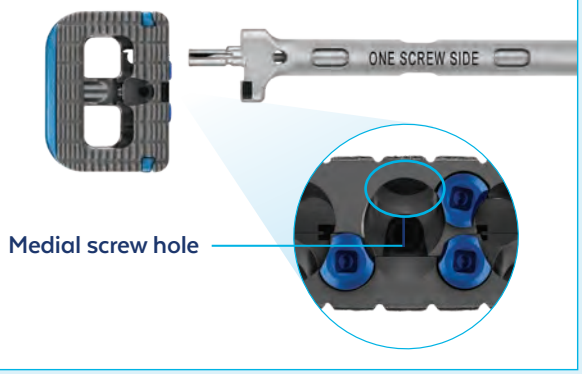
LOADING THE IMPLANT

Before loading the implant, ensure the Plunger is in a retracted position. Rotate the Black Knob on the Inserter counterclockwise to the “RELEASE” position. Ensure the three set screws are in the unlocked position. Adjust if needed using the Set Screw Positioner. **Do not overtighten the Black Knob when adjusting**.

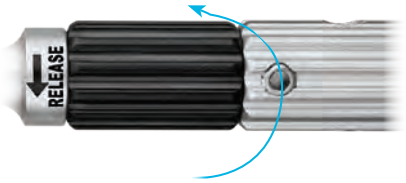
Rotate counterclockwise to “RELEASE” position

Set screws in unlocked position

To load the implant, align the etched line on the “ONE SCREW SIDE” of the Inserter with the medial screw hole on the implant.



Rotate the Black Knob clockwise until the Plunger is fully engaged into the implant. Pack autogenous bone graft into the graft chamber.



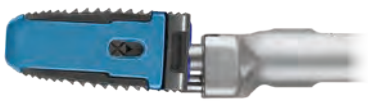
CORRECT ASSEMBLY

Axial View

Lateral View

INCORRECT ASSEMBLY

Axial View



Lateral View

OPTIONAL TECHNIQUES: USING THE LATERAL INSERTER

LOADING THE IMPLANT

Fully open the **Lateral Inserter** by rotating the locking nut counterclockwise. Choose the appropriate implant.

Place the implant on the inserter by matching the mating features on the side of the implant to the inserter.

Compress the handles and tighten the locking nut. Pack autogenous bone graft into the implant.

OPTIONAL TECHNIQUES: USING THE OFFSET INSERTER OR LATERAL INSERTER

Implant Insertion

Insert the implant using the Offset Inserter or Lateral Inserter. Attach the implant to the inserter (refer to pages 30-32).

If impaction is required, gently impact the back of the inserter. Ensure the implant is flush anterior or recessed up to 1mm.

Offset Inserter

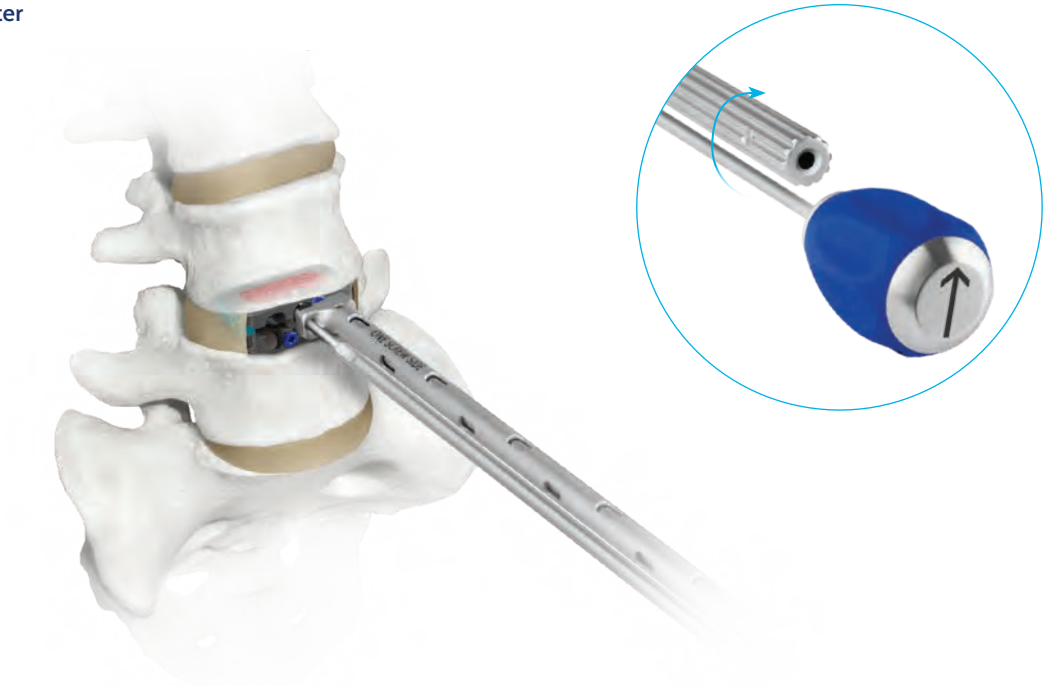
Lateral Inserter

Inserting implant

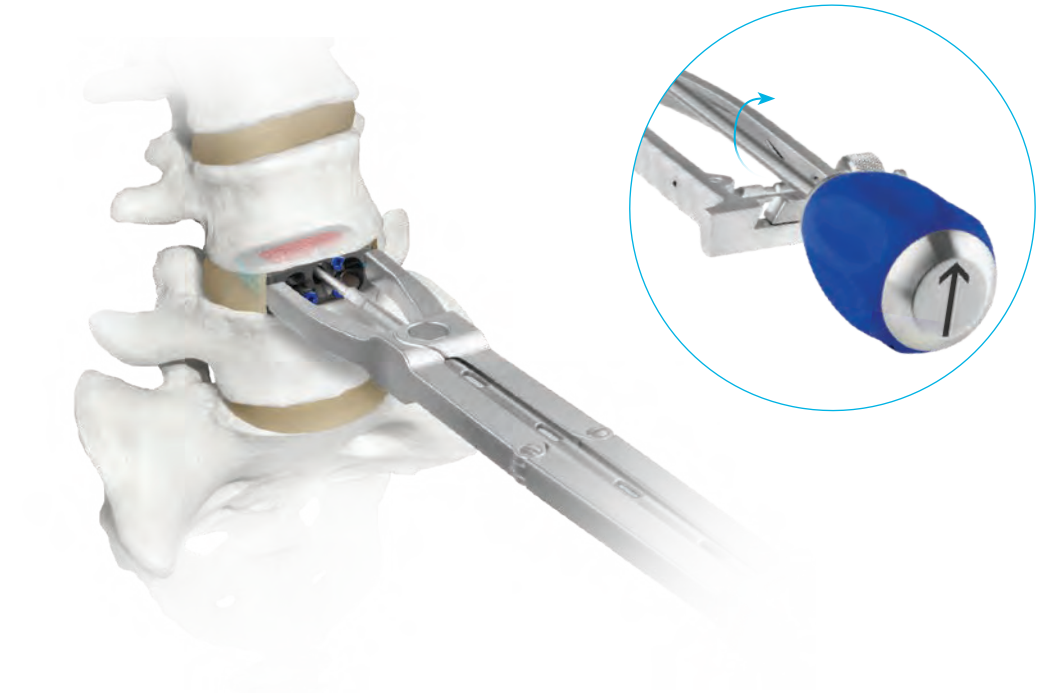
Implant Expansion

Insert the Torque-Limiting Hex Driver, 1.75Nm into the inserter and rotate clockwise to expand the implant to the appropriate height.

Offset Inserter



Lateral Inserter

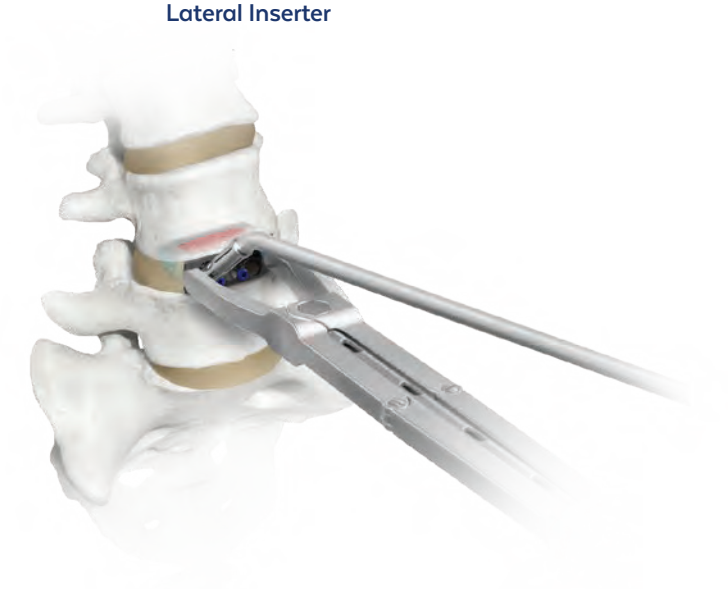


Screw Hole Preparation

Insert the Self-Centering Awl to break the cortex. Use the Self-Centering Drill and Tap 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 remaining screw holes.

Offset Inserter

Lateral Inserter

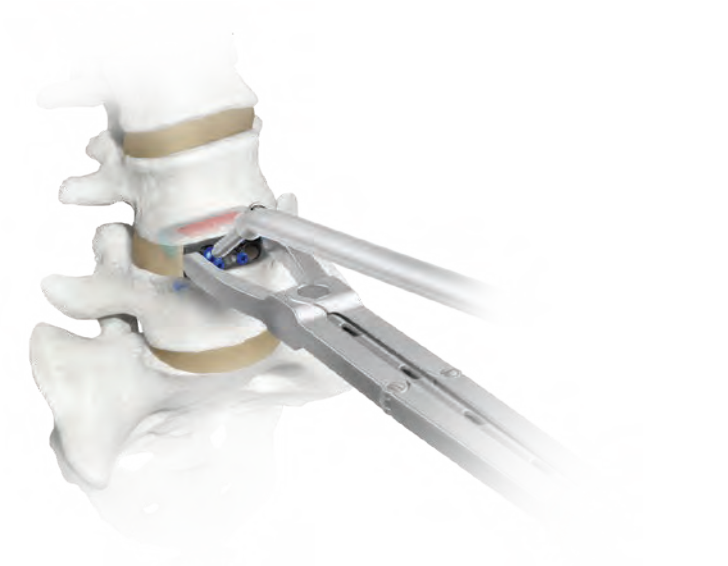


Screw Insertion

Select the appropriate screw length. Insert the screw using a straight or angled Self-Retaining Screwdriver. Repeat screw hole preparation and screw insertion for each screw hole before moving to the next step.

Offset Inserter

Lateral Inserter



INSTRUMENT ASSEMBLY

Angled Instruments

Angled instruments are preassembled. Attach the Counter-Torque to the driver for greater control of the distal tip.

Angled Driver Body

Select the appropriate tip:

Self-Centering Angled Drill 676.703

5.5mm Angled Tap 676.707

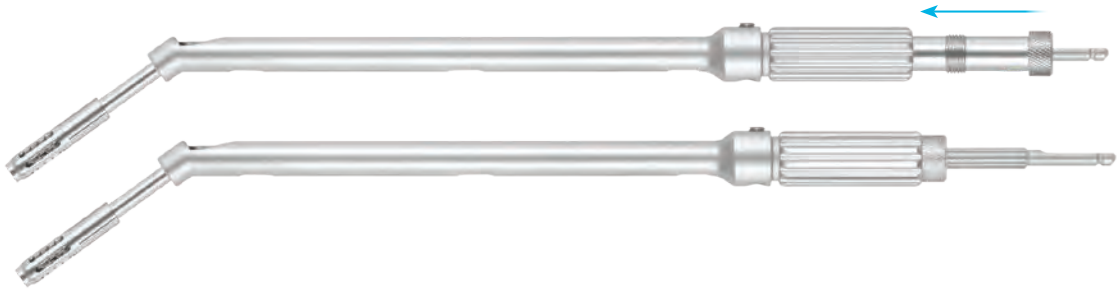
3.5mm Angled Hex Driver, Long 676.809

3.5mm Angled Hex Driver, Short 676.710

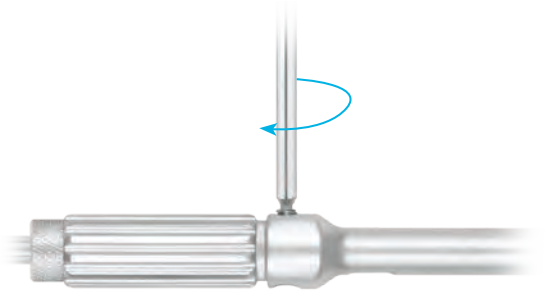
Hold the **Angled Driver Body** downward with the access window facing upward. Insert the selected tip into the window on the distal end of the driver.

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

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



Tighten the set screw by rotating it clockwise with the Torque-Limiting Hex Driver, 1.75Nm until finger tight.



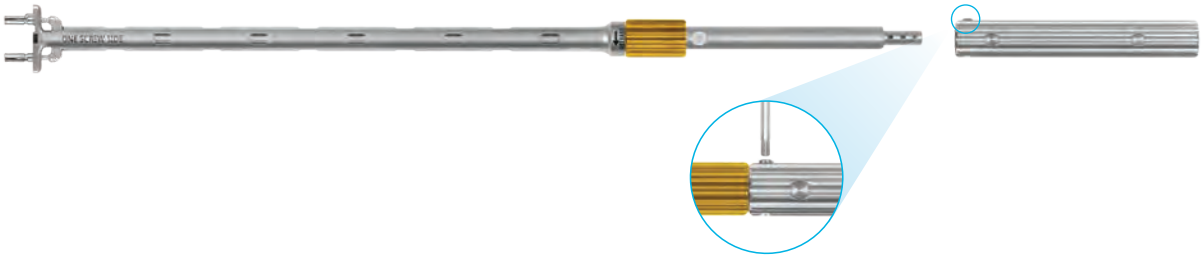
Attach the **Quick-Connect Handle**.

INSERTER DISASSEMBLY

Midline Inserter

Disassemble the Midline Inserter for cleaning. For disassembly, follow the steps below. Refer to page 19 for assembly instructions.

Using the Torque-Limiting Hex Driver, 1.75Nm gently rotate the set screw on the Grip Handle counterclockwise until it stops. Slide the Grip Handle off the Inserter Body. **Do not use excessive torque as it can strip the set screw.**



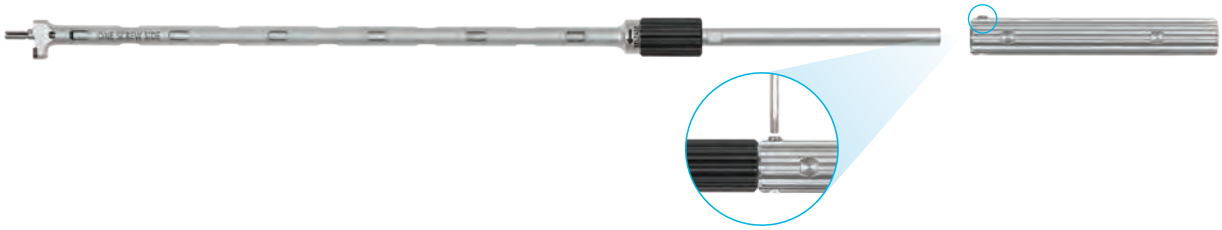
Unthread the Gold Knob from the inserter by rotating clockwise and sliding it off the Inserter Body.

Unthread the Retractor Sleeve by rotating counterclockwise and sliding it out of the Inserter Body. The instrument is ready for cleaning.

Offset Inserter

Disassemble the Offset Inserter for cleaning. For disassembly, follow the steps below. Refer to page 30 for assembly instructions.

Rotate the set screw on the Grip Handle counterclockwise until it stops. Slide the Grip Handle off the Inserter.



Unthread the Black Knob from the Inserter by rotating it clockwise and sliding it off the Inserter.

Slide the Plunger out of the Inserter. The Offset Inserter is ready for cleaning.

ADDITIONAL SPECIFICATIONS

ALIF Drill, Awl, and Tap Dimensions

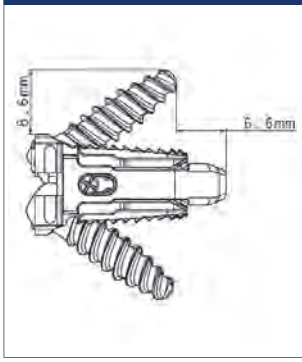
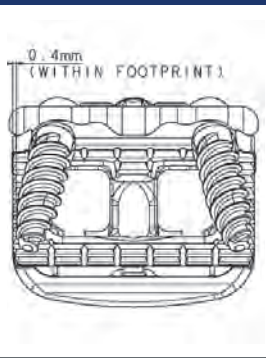
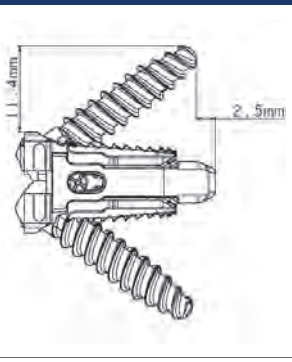
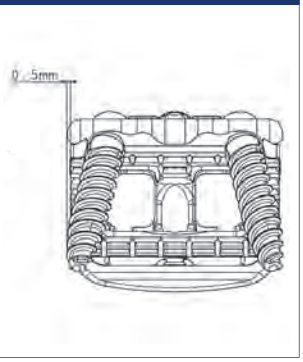
Tap

Drill

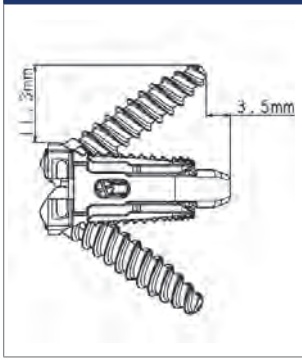
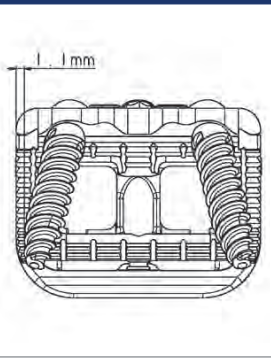
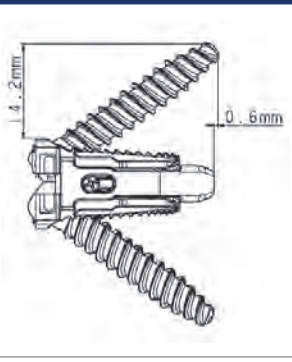
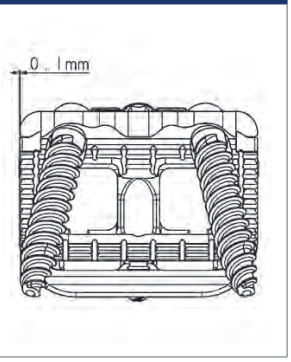
Awl

MAGNIFY®-S Screw Diagrams

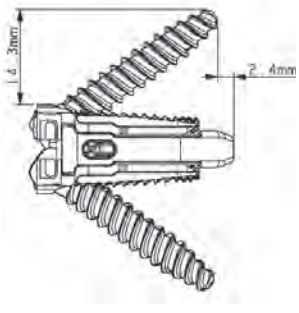
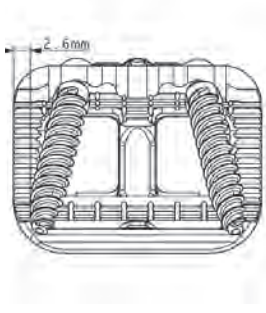
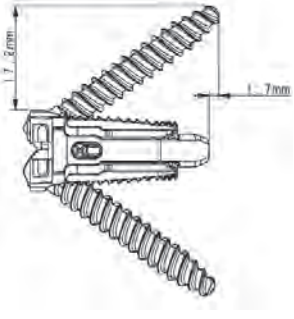
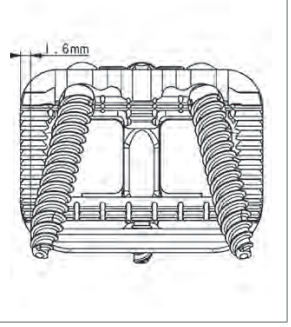
Small Spacer (25x31mm)

20mm Screws		25mm Screws	
			

Medium Spacer (26x34mm)

25mm Screws		30mm Screws	
			

Large Spacer (29x39mm)

30mm Screws		35mm Screws	
			

PRODUCT SPECIFICATIONS

MAGNIFY®-S Expansion Ranges and Graft Volumes

Small 8° (25x31mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.0108	8 - 11	1.1 - 1.7
1126.0110	10 - 13	1.4 - 2.1
1126.0112	12 - 15	2.2 - 2.9
1126.0114	14 - 17	2.6 - 3.3
1126.0116	16 - 19	2.8 - 3.5

Small 15° (25x31mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.0210	10 -13	1.3 - 2.0
1126.0212	12 - 15	1.6 - 2.3
1126.0214	14 - 17	2.5 - 3.2
1126.0216	16 - 19	2.8 - 3.5

Medium 8° (26x34mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.1108	8 - 11	1.3 - 2.1
1126.1110	10 - 13	1.8 - 2.6
1126.1112	12 - 16	2.5 - 3.4
1126.1114	14 - 18	2.8 - 3.8
1126.1116	16 - 20	3.0 - 4.0
1126.1118	18 - 21	3.7 - 4.5

Medium 15° (26x34mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.1210	10 - 13	1.7 - 2.5
1126.1212	12 - 15	2.0 - 2.8
1126.1214	14 - 18	2.7 - 3.7
1126.1216	16 - 20	3.0 - 4.0
1126.1218	18 - 21	3.7 - 4.6

Large 8° (29x39mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.2108	8 - 11	2.5 - 4.2
1126.2110	10 - 13	2.9 - 4.7
1126.2112	12 - 16	3.6 - 5.3
1126.2114	14 - 18	3.4 - 5.2
1126.2116	16 - 20	4.7 - 6.4
1126.2118	18 - 21	5.4 - 6.7

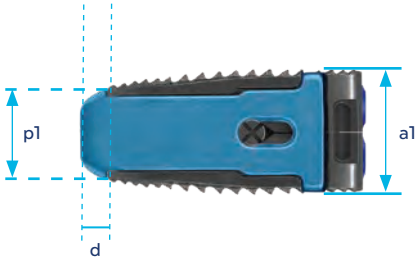
Large 8° (29x39mm)		
Part No.	Height Expansion Range (mm)	Graft Volume Range (cc)
1126.2210	10 - 13	3.0 - 4.3
1126.2212	12 - 15	3.3 - 4.7
1126.2214	14 - 18	3.8 - 5.6
1126.2216	16 - 20	4.6 - 6.3
1126.2218	18 - 21	5.3 - 6.6

All implants expand 1mm for every 1.5 revolutions.

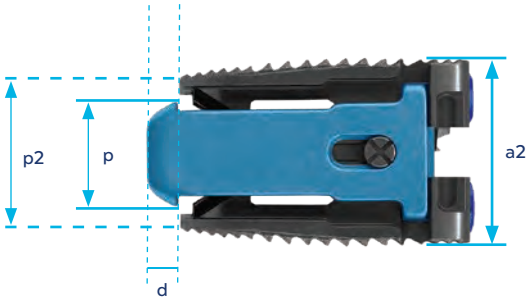
Note: Graft material may compress in situ, allowing delivery of graft volumes in excess of the ranges listed.

Anterior and Posterior Height

Implant Fully Contracted



Implant Fully Expanded



KEY

a1 = Fully contracted anterior height

a2 = Fully expanded anterior height

p1 = Posterior height before expansion

p2 = Posterior height after expansion

p = Posterior taper height

d = Distance from frame to edge of endplate

Part No.	Description	Fully Contracted Anterior Height, a1 (mm) Contracted Anterior Height, a1 (mm)	Fully Expanded Anterior Height, a2 (mm)	Posterior Taper Height, p (mm)	Posterior Height Before Expansion, p1 (mm)	Posterior Height After Expansion, p2 (mm)	Distance From Frame To Edge of Endplate, d (mm)
1126.0108	MAGNIFY®-S Spacer, 25x31mm, 8°, 8-11mm	8	11	6	6	9	5
1126.0110	MAGNIFY®-S Spacer, 25x31mm, 8°, 10-13mm	10	13	7	8	11	5
1126.0112	MAGNIFY®-S Spacer, 25x31mm, 8°, 12-15mm	12	15	9	10	13	3
1126.0114	MAGNIFY®-S Spacer, 25x31mm, 8°, 14-17mm	14	17	11	12	15	3
1126.0116	MAGNIFY®-S Spacer, 25x31mm, 8°, 16-19mm	16	19	13	14	17	3
1126.0210	MAGNIFY®-S Spacer, 25x31mm, 15°, 10-13mm	10	13	6	6	9	5
1126.0212	MAGNIFY®-S Spacer, 25x31mm, 15°, 12-15mm	12	15	7	8	11	5
1126.0214	MAGNIFY®-S Spacer, 25x31mm, 15°, 14-17mm	14	17	9	9	12	3
1126.0216	MAGNIFY®-S Spacer, 25x31mm, 15°, 16-19mm	16	19	11	11	14	3

Anterior and Posterior Height (Cont'd)

Part No.	Description	Fully Contracted Anterior Height, a1 (mm)	Fully Expanded Anterior Height, a2 (mm)	Posterior Taper Height, p (mm)	Posterior Height Before Expansion, p1 (mm)	Posterior Height After Expansion, p2 (mm)	Distance From Frame To Edge of Endplate, d (mm)
1126.1108	MAGNIFY®-S Spacer, 26x34mm, 8°, 8-11mm	8	11	6	6	9	5
1126.1110	MAGNIFY®-S Spacer, 26x34mm, 8°, 10-13mm	10	13	7	8	11	5
1126.1112	MAGNIFY®-S Spacer, 26x34mm, 8°, 12-16mm	12	16	9	10	14	3
1126.1114	MAGNIFY®-S Spacer, 26x34mm, 8°, 14-18mm	14	18	11	12	16	3
1126.1116	MAGNIFY®-S Spacer, 26x34mm, 8°, 16-20mm	16	20	13	14	18	3
1126.1118	MAGNIFY®-S Spacer, 26x34mm, 8°, 18-21mm	18	21	15	16	19	3
1126.1210	MAGNIFY®-S Spacer, 26x34mm, 15°, 10-13mm	10	13	6	6	9	5
1126.1212	MAGNIFY®-S Spacer, 26x34mm, 15°, 12-15mm	12	15	7	8	11	5
1126.1214	MAGNIFY®-S Spacer, 26x34mm, 15°, 14-18mm	14	18	9	9	13	3
1126.1216	MAGNIFY®-S Spacer, 26x34mm, 15°, 16-20mm	16	20	11	11	15	3
1126.1218	MAGNIFY®-S Spacer, 26x34mm, 15°, 18-21mm	18	21	13	13	16	3

Part No.	Description	Fully Contracted Anterior Height, a1 (mm)	Fully Expanded Anterior Height, a2 (mm)	Posterior Taper Height, p (mm)	Posterior Height Before Expansion, p1 (mm)	Posterior Height After Expansion, p2 (mm)	Distance From Frame To Edge of Endplate, d (mm)
1126.2108	MAGNIFY®-S Spacer, 29x39mm, 8°, 8-11mm	8	11	6	6	9	5
1126.2110	MAGNIFY®-S Spacer, 29x39mm, 8°, 10-13mm	10	13	7	8	11	5
1126.2112	MAGNIFY®-S Spacer, 29x39mm, 8°, 12-16mm	12	16	9	10	14	3
1126.2114	MAGNIFY®-S Spacer, 29x39mm, 8°, 14-18mm	14	18	11	12	16	3
1126.2116	MAGNIFY®-S Spacer, 29x39mm, 8°, 16-20mm	16	20	13	14	18	3
1128.2118	MAGNIFY®-S Spacer, 29x39mm, 8°, 18-21mm	18	21	15	16	19	3
1126.2210	MAGNIFY®-S Spacer, 29x39mm, 15°, 10-13mm	10	13	6	6	9	5
1126.2212	MAGNIFY®-S Spacer, 29x39mm, 15°, 12-15mm	12	15	7	8	11	5
1126.2214	MAGNIFY®-S Spacer, 29x39mm, 15°, 14-18mm	14	18	9	9	13	3
1126.2216	MAGNIFY®-S Spacer, 29x39mm, 15°, 16-20mm	16	20	11	11	15	3
1126.2218	MAGNIFY®-S Spacer, 29x39mm, 15°, 18-21mm	18	21	13	13	16	3

SETS TO ORDER

Required Sets

Part No.	Set Description	Category
9126.9102	MAGNIFY®-S 25x31mm Implant Set	MAGNIFY®-S Implants
9126.9103	MAGNIFY®-S 26x34mm Implant Set	
9126.9104	MAGNIFY®-S 29x39mm Implant Set	
9126.9101	MAGNIFY®-S Instrument Set	MAGNIFY®-S Instruments
925.907	ALIF Bone Screws	Bone Screws
925.905	ALIF Instrument Set	Disc Prep and Trials
925.906	ALIF Trials	
925.901	Anterior Disc Prep I	
925.902	Anterior Disc Prep II	

Additionally Available

MAGNIFY®-S Implants

Part No.	Description
1126.1116	MAGNIFY®-S Spacer, 26x34mm, 8°, 16-20mm
1126.1118	MAGNIFY®-S Spacer, 26x34mm, 8°, 18-21mm
1126.1216	MAGNIFY®-S Spacer, 26x34mm, 15°, 16-20mm
1126.1218	MAGNIFY®-S Spacer, 26x34mm, 15°, 18-21mm
1126.2116	MAGNIFY®-S Spacer, 29x39mm, 8°, 16-20mm
1126.2118	MAGNIFY®-S Spacer, 29x39mm, 8°, 18-21mm
1126.2216	MAGNIFY®-S Spacer, 29x39mm, 15°, 16-20mm
1126.2216	MAGNIFY®-S Spacer, 29x39mm, 15°, 18-21mm

Disc Prep Instruments

Part No.	Description
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

Distractor/Retractor Set 906.902

Part No.	Description
606.800	Trial Holder
606.808	Distractor/Retractor, 8mm
606.810	Distractor/Retractor, 10mm
606.812	Distractor/Retractor, 12mm
606.814	Distractor/Retractor, 14mm
606.816	Distractor/Retractor, 16mm
606.858	Distractor Trial Head, 8mm
606.860	Distractor Trial Head, 10mm
606.862	Distractor Trial Head, 12mm
606.864	Distractor Trial Head, 14mm
606.866	Distractor Trial Head, 16mm
622.410	Slide Hammer, Small
668.160	SIGNATURE® Quick-Coupling Handle

Bone Screws

Part No.	Description
925.908	ALIF Self-Drilling Screws
976.908	INDEPENDENCE® HA-Coated Bone
9212.9005	ALIF Locking Screw Set

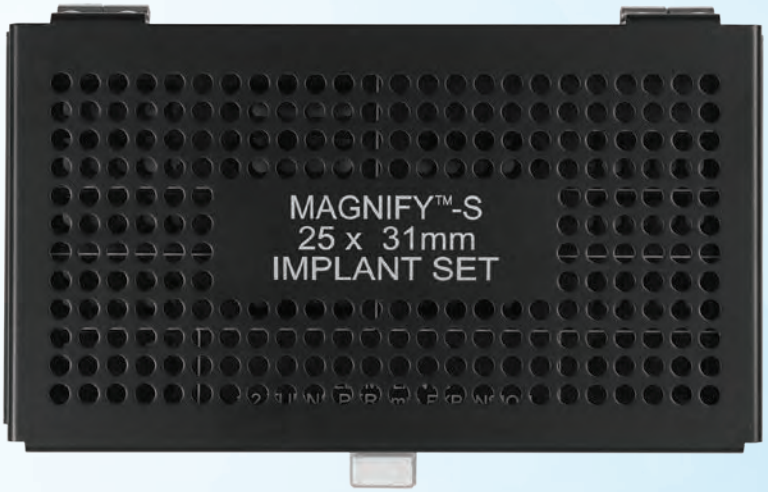
Items in gray are additionally available.

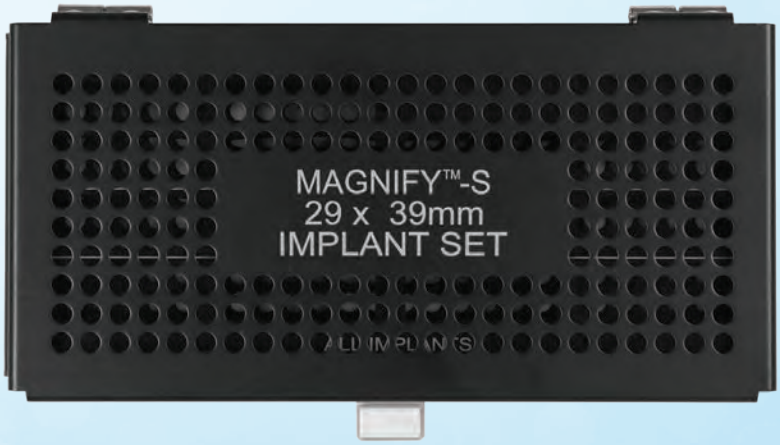
MAGNIFY®-S
IMPLANT SETS

Part No.	Description	Qty
25x31mm Implant Set 9126.9102		
1126.0108	MAGNIFY®-S Spacer, 25x31mm, 8°, 8-11mm	2
1126.0110	MAGNIFY®-S Spacer, 25x31mm, 8°, 10-13mm	2
1126.0112	MAGNIFY®-S Spacer, 25x31mm, 8°, 12-15mm	2
1126.0114	MAGNIFY®-S Spacer, 25x31mm, 8°, 14-17mm	2
1126.0116	MAGNIFY®-S Spacer, 25x31mm, 15°, 16-19mm	1
1126.0210	MAGNIFY®-S Spacer, 25x31mm, 15°, 10-13mm	2
1126.0212	MAGNIFY®-S Spacer, 25x31mm, 15°, 12-15mm	2
1126.0214	MAGNIFY®-S Spacer, 25x31mm, 15°, 14-17mm	2
1126.0216	MAGNIFY®-S Spacer, 25x31mm, 15°, 16-19mm	1
9126.0102	25x31mm MAGNIFY®-S Implant Module	
26x34mm Implant Set 9126.9103		
1126.1108	MAGNIFY®-S Spacer, 26x34mm, 8°, 8-11mm	2
1126.1110	MAGNIFY®-S Spacer, 26x34mm, 8°, 10-13mm	2
1126.1112	MAGNIFY®-S Spacer, 26x34mm, 8°, 12-16mm	2
1126.1114	MAGNIFY®-S Spacer, 26x34mm, 8°, 14-18mm	2
1126.1210	MAGNIFY®-S Spacer, 26x34mm, 15°, 10-13mm	2
1126.1212	MAGNIFY®-S Spacer, 26x34mm, 15°, 12-15mm	2
1126.1214	MAGNIFY®-S Spacer, 26x34mm, 15°, 14-18mm	2
9126.0103	26x34mm MAGNIFY®-S Implant Module	
29x39mm Implant Set 9126.9104		
1126.2108	MAGNIFY®-S Spacer, 29x39mm, 8°, 8-11mm	2
1126.2110	MAGNIFY®-S Spacer, 29x39mm, 8°, 10-13mm	2
1126.2112	MAGNIFY®-S Spacer, 29x39mm, 8°, 12-16mm	2
1126.2114	MAGNIFY®-S Spacer, 29x39mm, 8°, 14-18mm	2
1126.2210	MAGNIFY®-S Spacer, 29x39mm, 15°, 10-13mm	2
1126.2212	MAGNIFY®-S Spacer, 29x39mm, 15°, 12-15mm	2
1126.2214	MAGNIFY®-S Spacer, 29x39mm, 15°, 14-18mm	2
9126.0104	29x39mm MAGNIFY®-S Implant Module	
Additionally Available		
1126.1116	MAGNIFY®-S Spacer, 26x34mm, 8°, 16-20mm	
1126.1118	MAGNIFY®-S Spacer, 26x34mm, 8°, 18-21mm	
1126.1216	MAGNIFY®-S Spacer, 26x34mm, 15°, 16-20mm	
1126.1218	MAGNIFY®-S Spacer, 26x34mm, 15°, 18-21mm	
1126.2116	MAGNIFY®-S Spacer, 29x39mm, 8°, 16-20mm	
1126.2118	MAGNIFY®-S Spacer, 29x39mm, 8°, 18-21mm	
1126.2216	MAGNIFY®-S Spacer, 29x39mm, 15°, 16-20mm	
1126.2218	MAGNIFY®-S Spacer, 29x39mm, 15°, 18-21mm	

Items in gray are additionally available.

MAGNIFY®-S
IMPLANT SETS



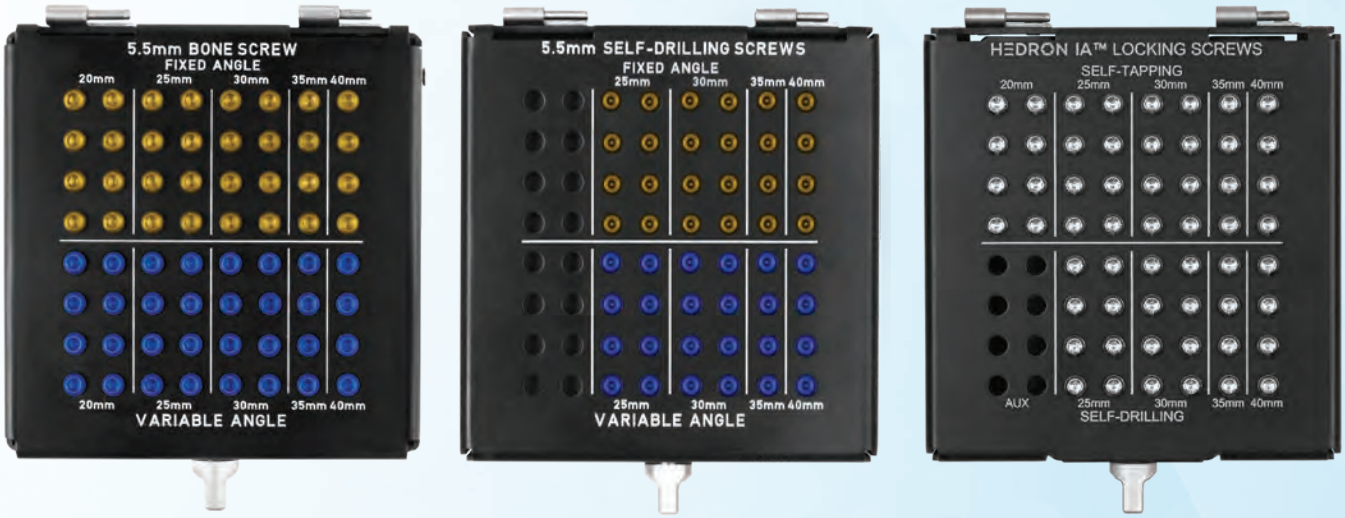


ANTERIOR BONE SCREW SETS

Part No.	Description	Qty
ALIF Bone Screws 925.907		
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	
INDEPENDENCE® HA-Coated Bone Screw Set 976.908		
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	9
976.008	INDEPENDENCE® HA-Coated Screw Soft Case	
ALIF Self-Drilling Screw Set 925.908		
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	
ALIF Locking Screw Set 9212.9005		
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	

Items in gray are additionally available.

ANTERIOR BONE SCREW SETS

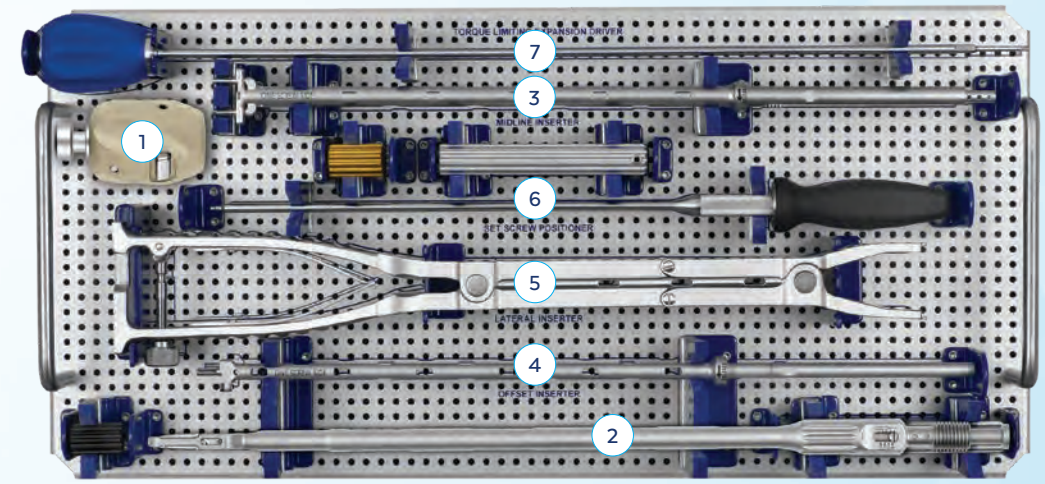


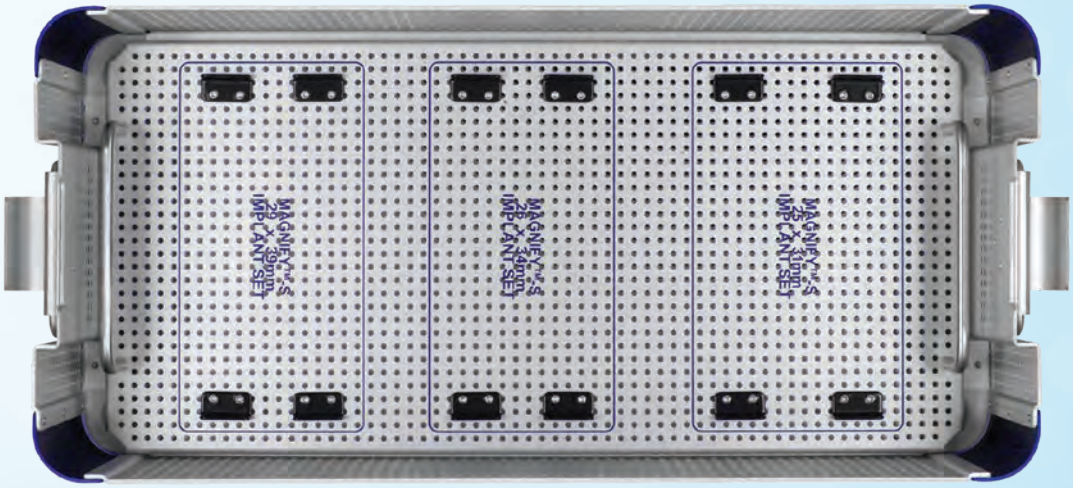
MAGNIFY®-S
INSTRUMENT SET 9126.9101

	Part No.	Description	Qty
1	694.418	Adjustable Trial Handle*	1
2	6126.0001	Expandable Trial, 25x31mm, 8°, 7-15mm*	1
3	6126.6100	Midline Inserter	1
4	6126.6101	Offset Inserter	1
5	6126.6102	Lateral Inserter	1
6	6126.6103	Set Screw Positioner	1
7	9126.6005	Torque-Limiting Hex Driver, 1.75Nm	1
	9126.0101	MAGNIFY®-S Graphic Case	

*Available in loaner sets only

MAGNIFY®-S
INSTRUMENT SET 9126.9101

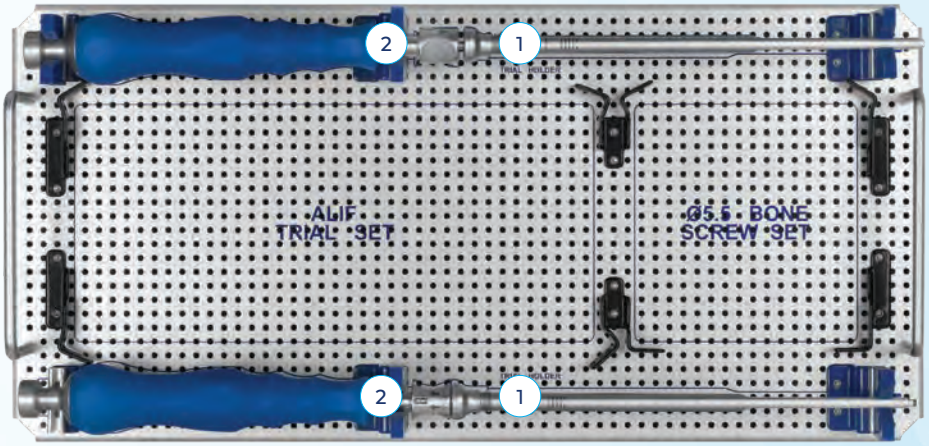


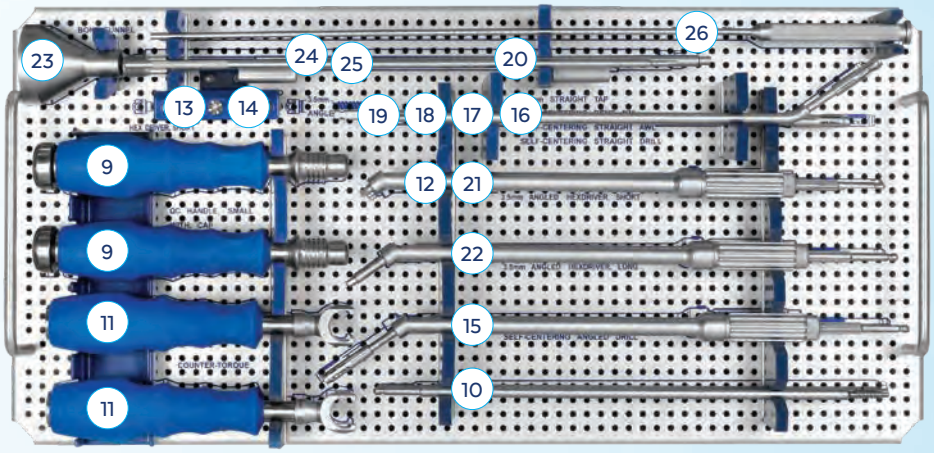


ALIF
INSTRUMENT SET 925.905

	Part No.	Description	Qty
1	6108.0001	MONUMENT® Trial Holder Sleeve	2
2	6108.0003	MONUMENT® Trial Holder	2
3	6108.2004	MONUMENT® Double-Angled Cobb, 20mm, Up	1
4	6108.2005	MONUMENT® Double-Angled Dual Rasp	1
5	6108.2007	MONUMENT® Double Angle Curette, Small, Up	1
6	6108.2009	MONUMENT® Double Angle Curette, Large, Up	1
7	6108.2011	MONUMENT® Double-Angled Ring Curette, Up	1
8	6108.2012	MONUMENT® Double-Angled Osteotome	1
9	650.105	QC Handle, Small, with Cap	2
10	676.502	INDEPENDENCE® 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
23	6126.6000	Bone Funnel	1
24	6126.6001	Bone Funnel Tube	1
25	6126.6002	Bone Funnel Guide	1
26	6126.6003	Bone Pusher	1
	925.105	ALIF Instrument Graphic Case	

ALIF
INSTRUMENT SET 925.905





ALIF
TRIAL SET 925.906

Part No.	Description	Qty
6108.0109	ALIF Trial, Small, 8°, 9mm	
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
6108.0409	ALIF Trial, Medium, 8°, 9mm	
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
6108.0709	ALIF Trial, Large, 8°, 9mm	
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	

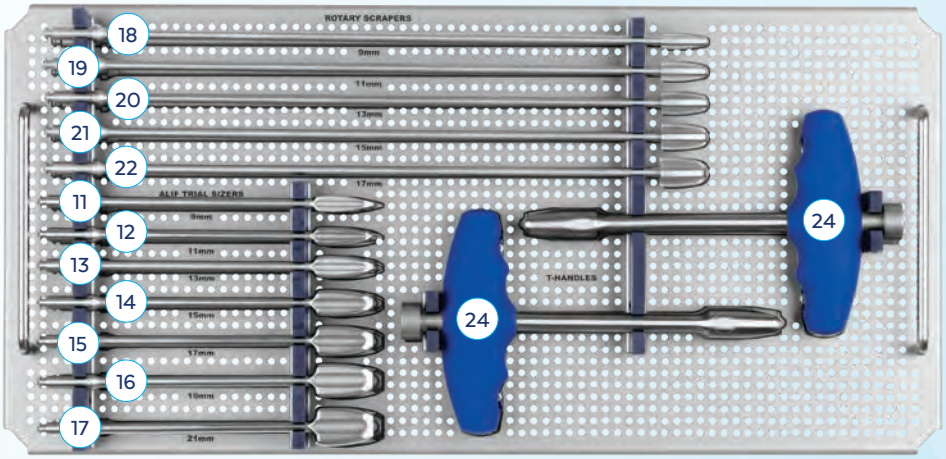
Items in gray are additionally available.

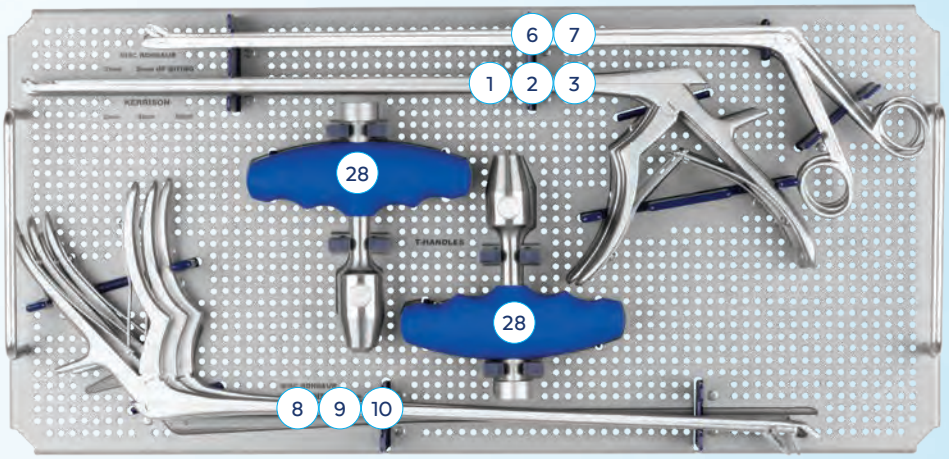
ALIF
TRIAL SET 925.906

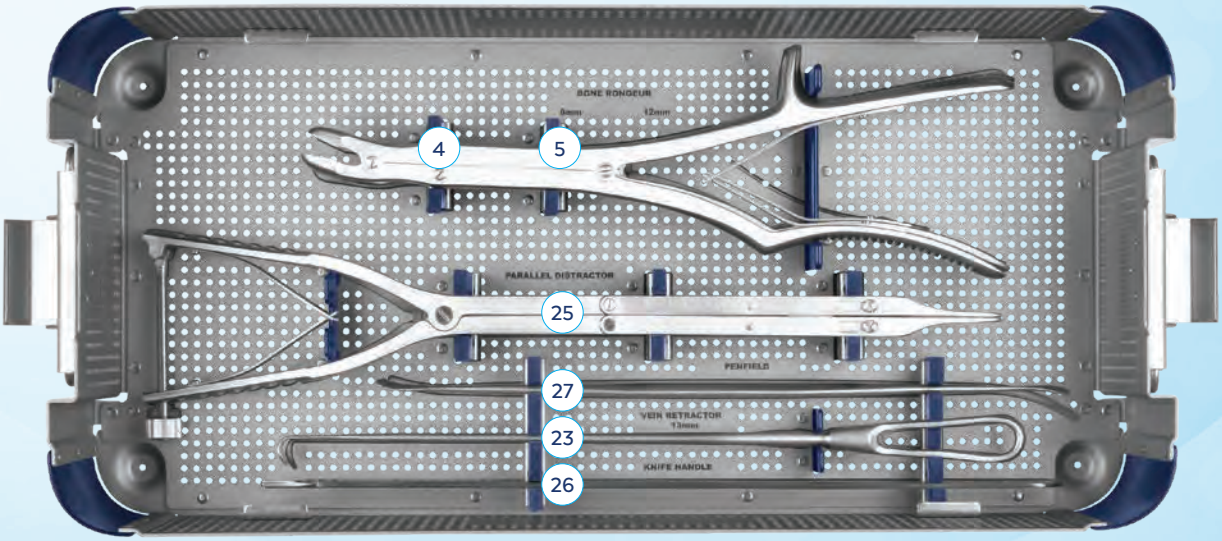
ANTERIOR DISC PREP I
INSTRUMENT SET 925.901

	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





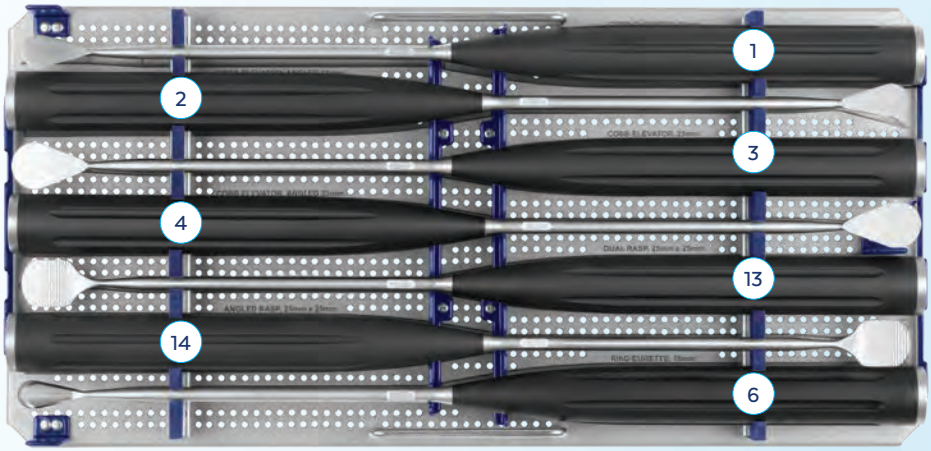


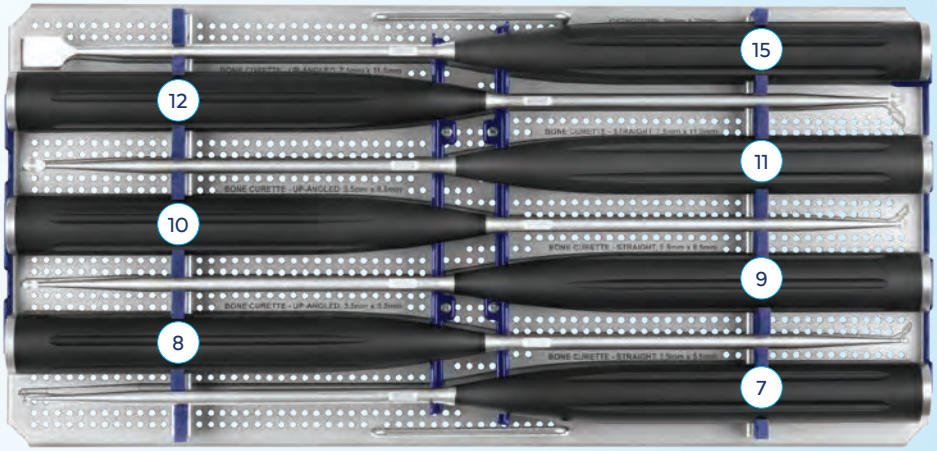
ANTERIOR DISC PREP II
INSTRUMENT SET 925.902

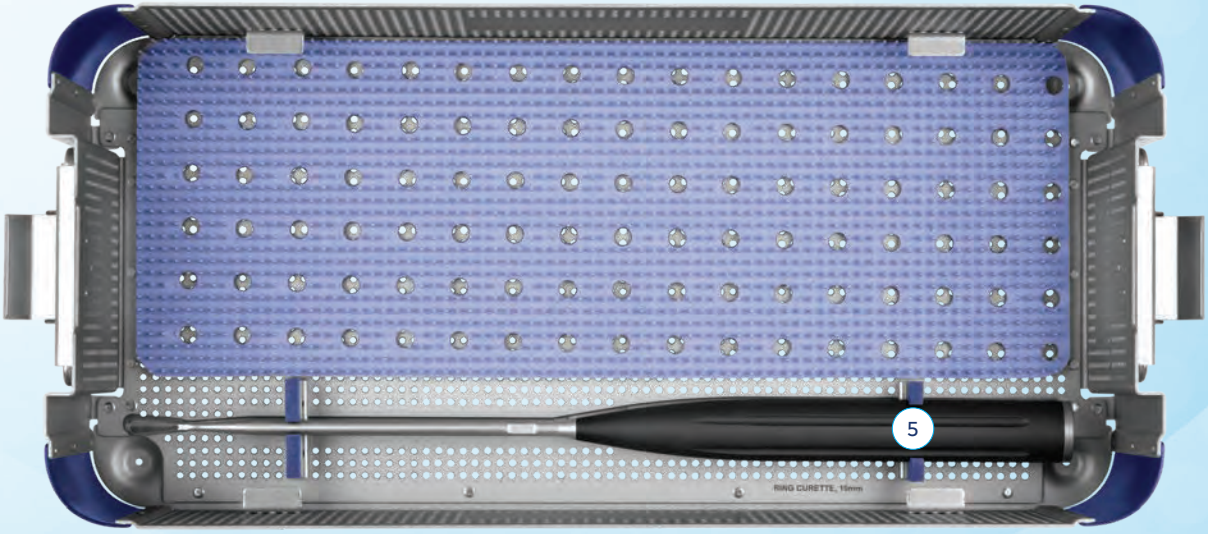
	Part No.	Description	Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette, 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
	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	
13	625.501	Dual Rasp	1
14	625.502	Angled Rasp	1
15	625.803	Osteotome, 16x20mm	1
	925.102	Graphic Case II	

Items in gray are additionally available.

ANTERIOR DISC PREP II
INSTRUMENT SET 925.902





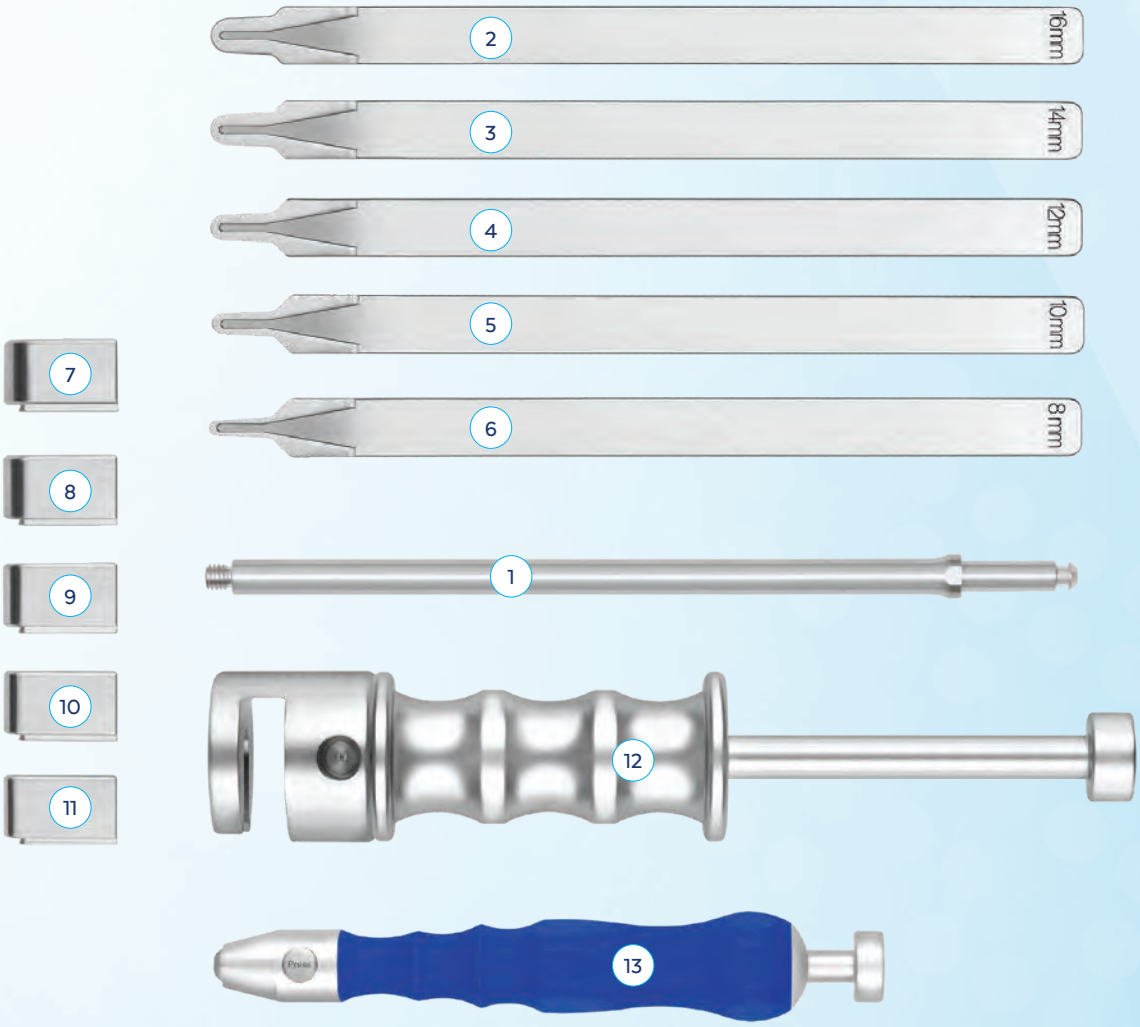


ANTERIOR LUMBAR DISTRACTOR/RETRACTOR
ADDITIONALLY AVAILABLE ITEMS

	Part No.	Description
1	606.800	Trial Holder
2	606.808	Distractor/Retractor, 8mm
3	606.810	Disctractor/Retractor, 10mm
4	606.812	Disctractor/Retractor, 12mm
5	606.814	Disctractor/Retractor, 14mm
6	606.816	Disctractor/Retractor, 16mm
7	606.858	Distractor Trial Head, 8mm
8	606.860	Distractor Trial Head, 10mm
9	606.862	Distractor Trial Head, 12mm
10	606.864	Distractor Trial Head, 14mm
11	606.866	Distractor Trial Head, 16mm
12	622.410	Slide Hammer, Small
13	668.160	Quick-Coupling Handle

Items in gray are additionally available.

ANTERIOR LUMBAR DISTRACTOR/RETRACTOR
ADDITIONALLY AVAILABLE ITEMS



IMPORTANT INFORMATION ON THE MAGNIFY® LUMBAR SPACERS

DESCRIPTION

MAGNIFY® Spacers are expandable anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various height expansion ranges 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. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The MAGNIFY® Spacer is to be used with supplemental fixation. The MAGNIFY®-S Spacer is to be used with three screws that accompany the implant.

MAGNIFY® Spacers are manufactured from titanium alloy, as specified in ASTM F136, and include an internal component manufactured from radiolucent PEEK polymer, as specified in ASTM F2026. The screws used with MAGNIFY®-S 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 MAGNIFY® Spacer is an interbody fusion device intended for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or 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), 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.

The MAGNIFY® Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone, and is to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

The MAGNIFY®-S 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), 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.

The MAGNIFY®-S Spacer is to be used with or without three screws which accompany the implant. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, these devices are intended for stand-alone use in patients with DDD at one or two levels only when used with three screws per implant. The MAGNIFY®-S 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 that 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 from any other manufacturer.

The components of this system are manufactured from radiolucent PEEK polymer and titanium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended for metallurgical, mechanical, and functional reasons.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.These warnings do not include all adverse effects that 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. .

These warnings do not include all adverse effects that 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 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 may appear undamaged, it may have small defects and internal stress patterns that could lead to breakage.

Adequately instruct the patient. Mental or physical impairment that 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. that may impact the performance of the system.

MRI SAFETY INFORMATION

MR

The MAGNIFY® Spacers are 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 MAGNIFY® Spacers are 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 these implants 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 instructions.
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 that 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, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.

IMPORTANT INFORMATION ON THE MAGNIFY® LUMBAR SPACERS

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 Grade I.
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 EVENTS

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
- 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

These implants and instruments may be supplied 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 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 AND USE

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, 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 screws are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat-sealed, double foil 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 and instruments that become nonsterile or have expired packaging are considered nonsterile and may be cleaned then sterilized according to instructions for nonsterile implants and instruments below, with the exception of HA-coated implants, which cannot be resterilized and should be disposed of according to hospital protocol.

IMPORTANT INFORMATION ON THE MAGNIFY® LUMBAR SPACERS

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). Sterile implants meet pyrogen limit specifications.

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		

DI194A REV G

NOTES

NOTES

NOTES

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

CE 0297

GMTGD155
08.23 Rev H