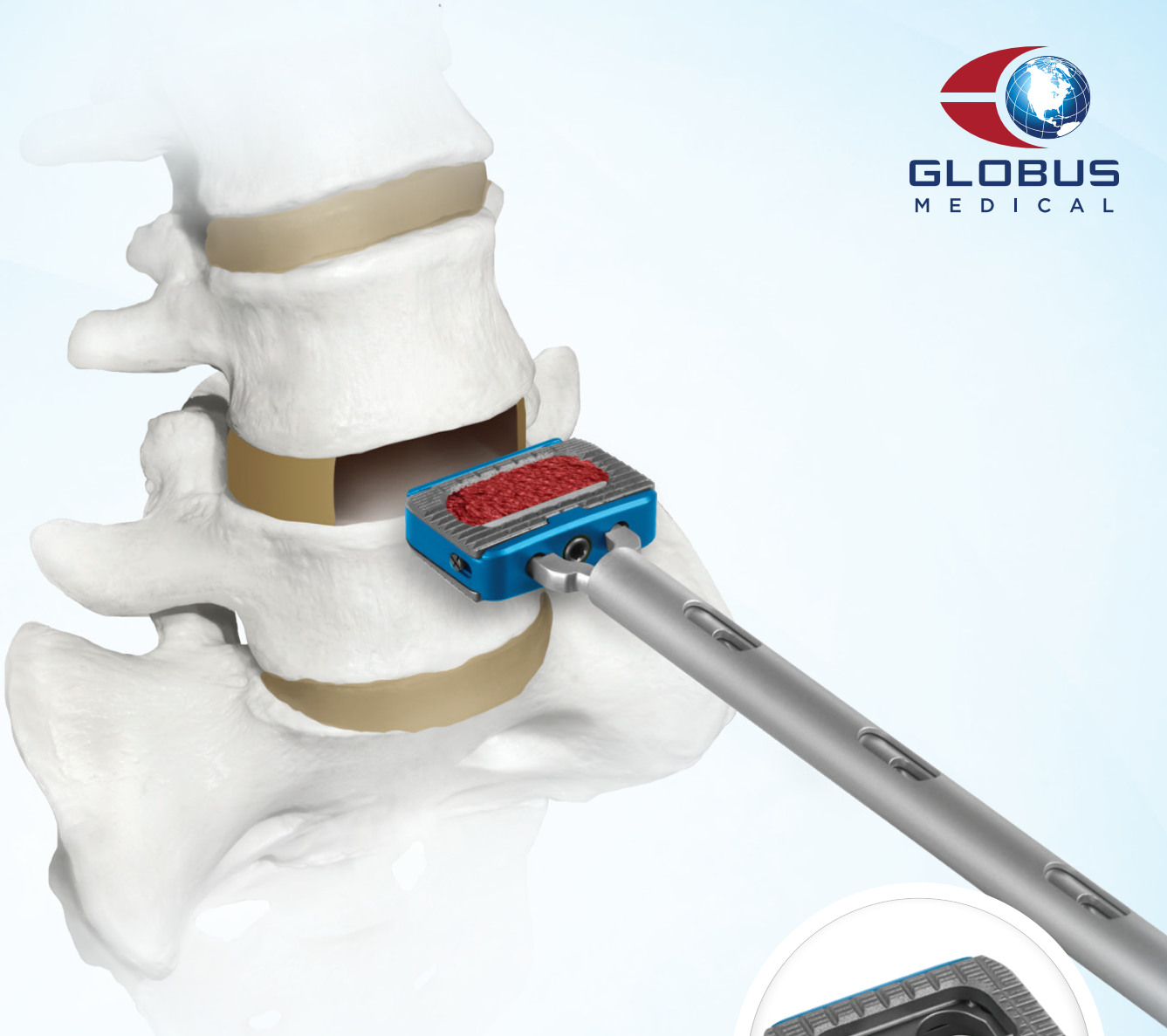
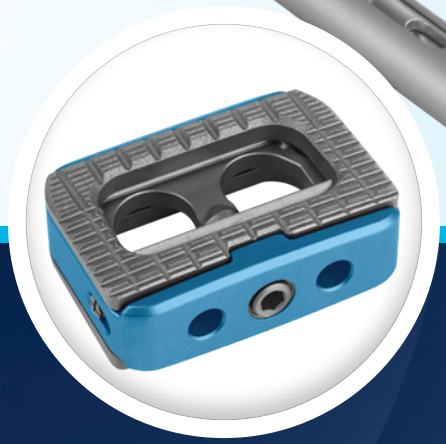




MAGNIFY®

Expandable ALIF Spacer 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

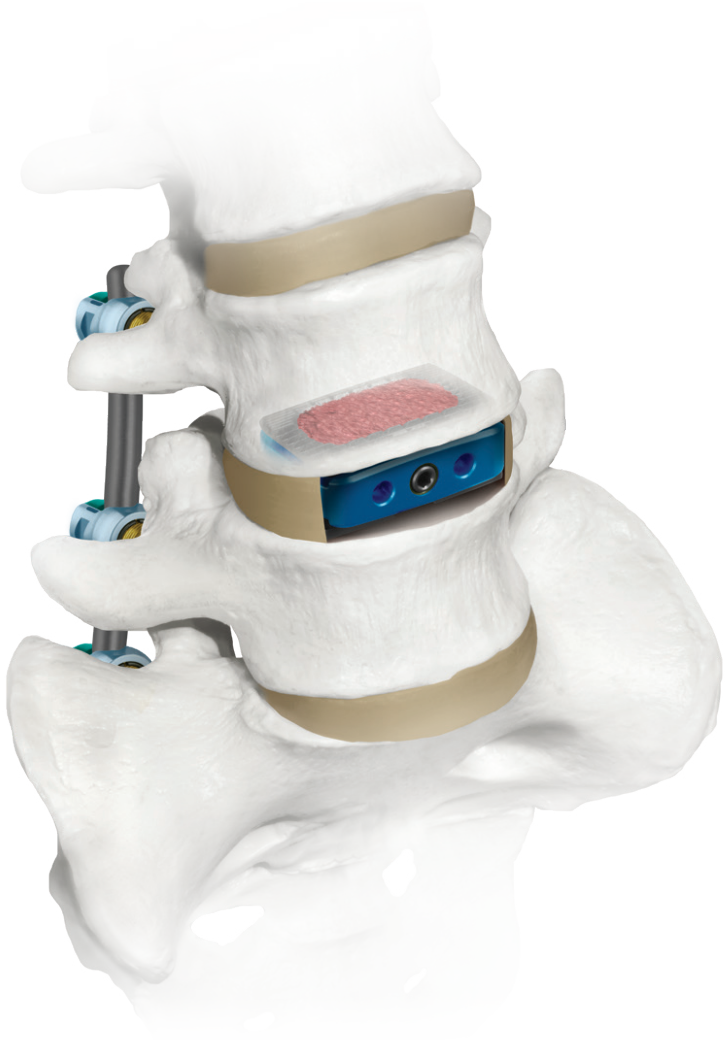
SURGICAL TECHNIQUE GUIDE

MAGNIFY®

MAGNIFY®

Expandable ALIF Spacer System

The MAGNIFY® Expandable ALIF Spacer System is designed to minimize impaction, maximize indirect decompression, and optimize fusion. Minimized insertion height, continuous expansion, and the ability to backfill additional bone graft sets MAGNIFY® apart from traditional ALIF spacers. In addition, directional teeth and roughened implant surfaces help secure vertebral endplates while the low-profile inserter helps minimize tissue disruption.



Minimize Impaction

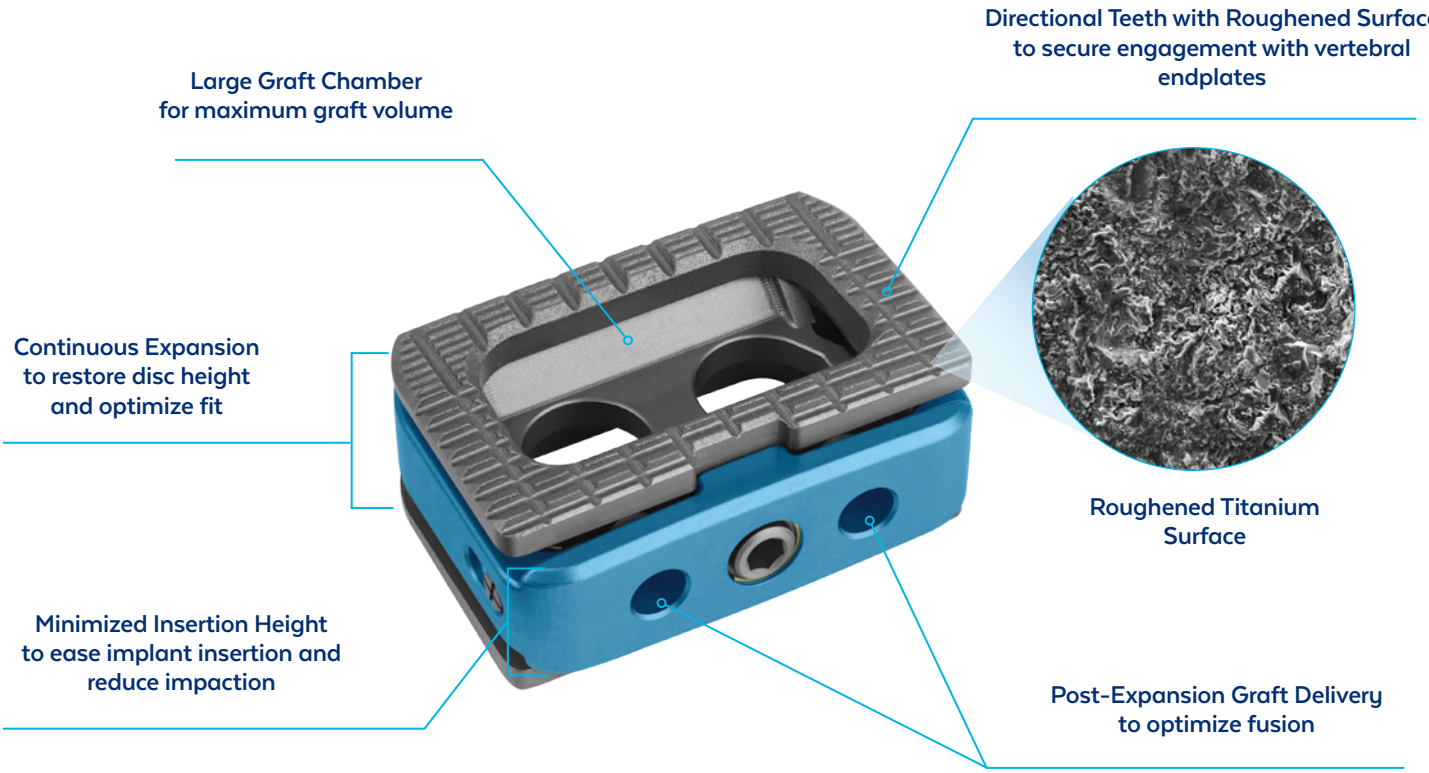
Minimized insertion height eases implant placement without the need for traumatic impaction.

Maximize Indirect Decompression

Continuous, controlled distraction maximizes indirect decompression to help restore disc height.

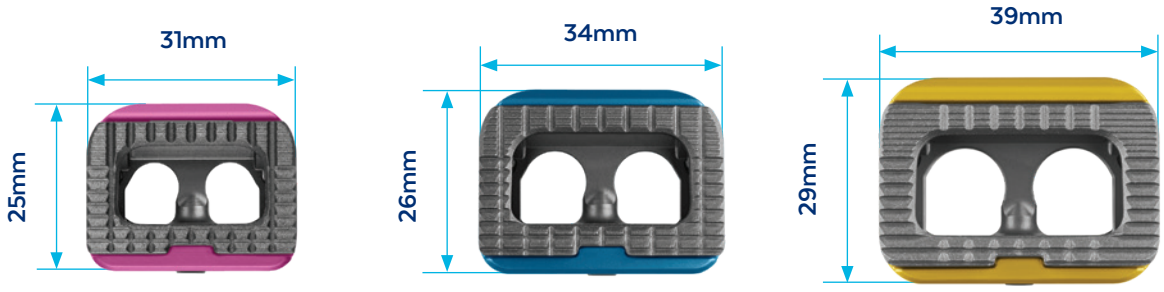
Optimize Fusion

Post-expansion delivery of autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone optimizes fusion potential by maximizing the volume of the graft within the spacer.



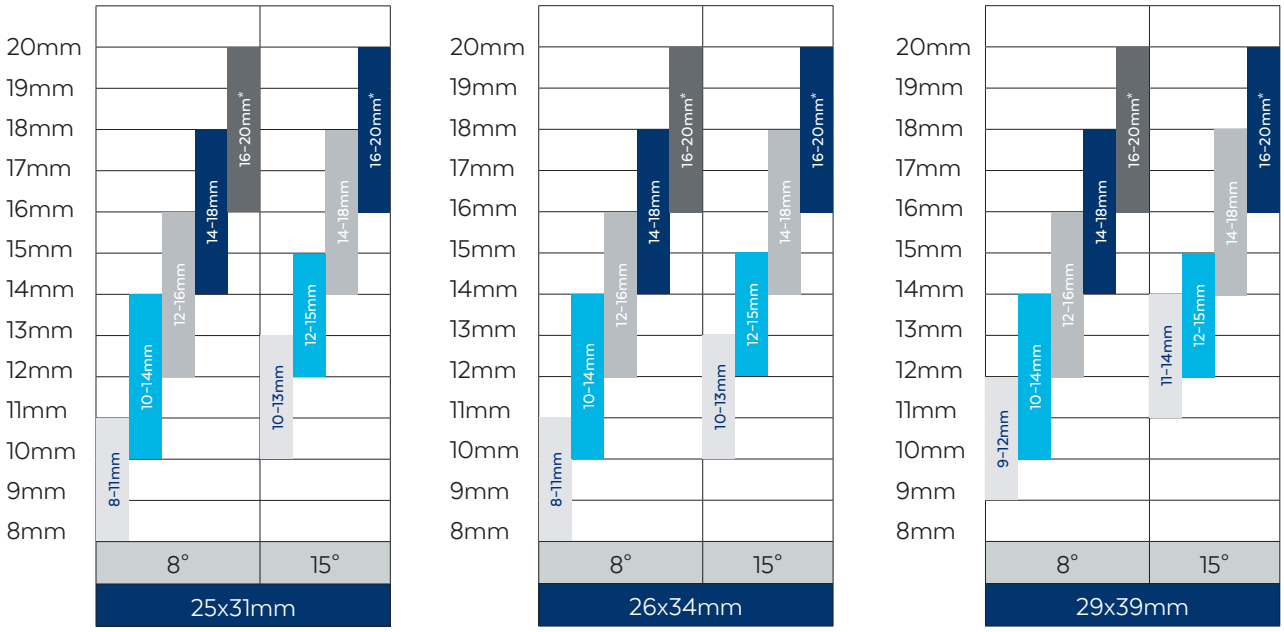
IMPLANT OVERVIEW

Three Axial Footprints: 25x31, 26x34 and 29x39mm



Two Sagittal Profiles: 8° and 15°

Multiple Implant Options:



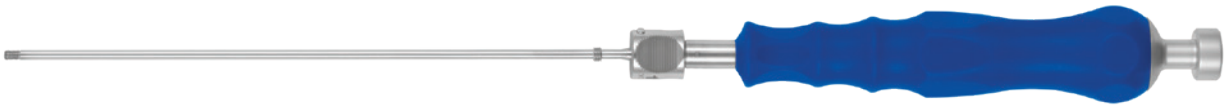
*Additionally available

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

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*

Inline Holder 6126.6500

Inline Holder Tip 6126.6501

Inline Holder Assembly

Torque-Limiting Hex Driver 6126.6004

Counter-Torque 676.699*

*Available in ALIF Instrument Set (925.905)

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)

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®

The MAGNIFY® Spacer is an expandable anterior interbody fusion device used to provide structural stability in skeletally mature individuals following 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.

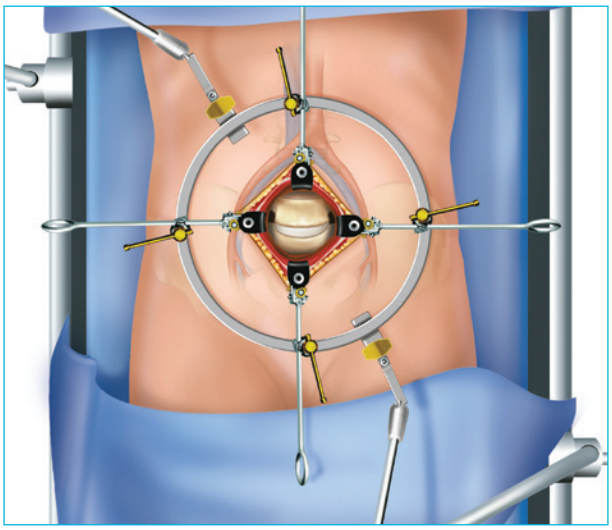
The MAGNIFY® Spacer is to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Refer to the corresponding technique guide.

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® 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.

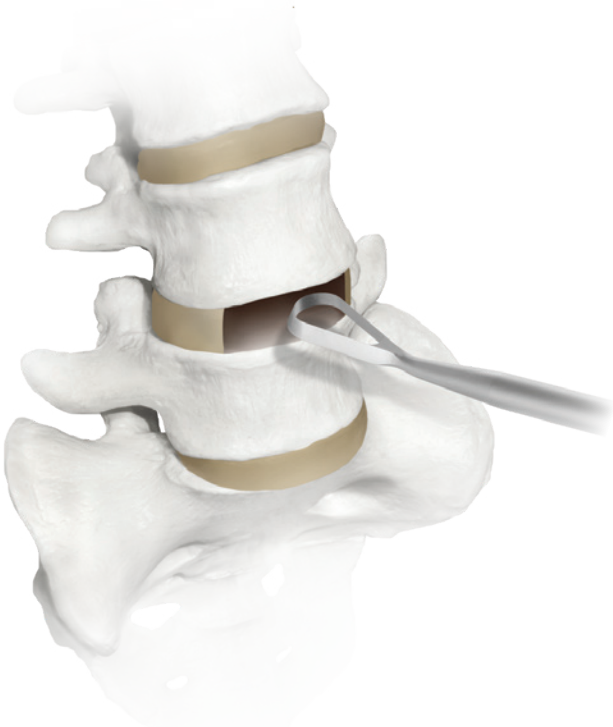
2. Kim KT, Lee SH, Suk KS, Bae SC. The quantitative analysis of tissue injury markers after mini-open lumbar fusion, *Spine B* (2006): 712-16.

STEP 2 DISC PREPARATION

Anterior disc preparation instruments* such as rongeurs and other suitable instruments may be used to expose the disc and remove disc material.** 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.

**Disc preparation instruments are available in the Anterior Disc Prep Instrument Set I (925.901) and II (925.902).*

***Distractors and Retractors are available in the Anterior Lumbar Distractor/ Retractor Set (906.902).*

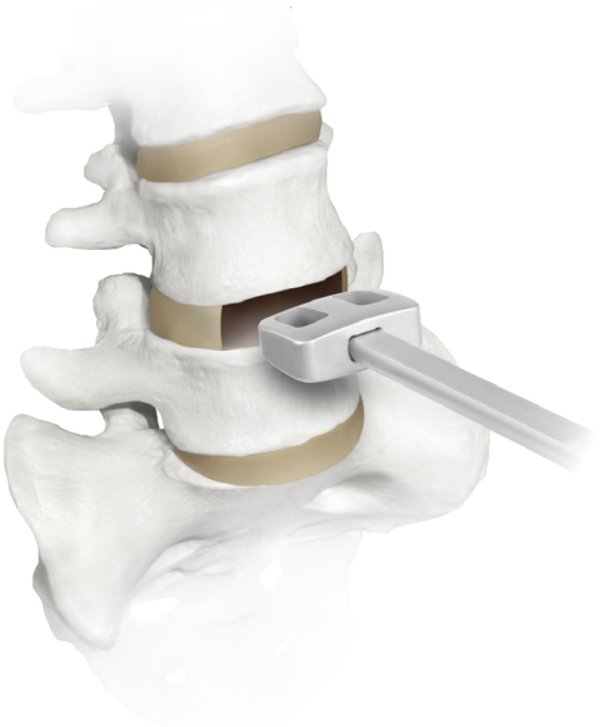


Using Ring Curette

STEP 3 IMPLANT SIZING

Select an appropriate sized Trial† and attach 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 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.



Inserting Trial

†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

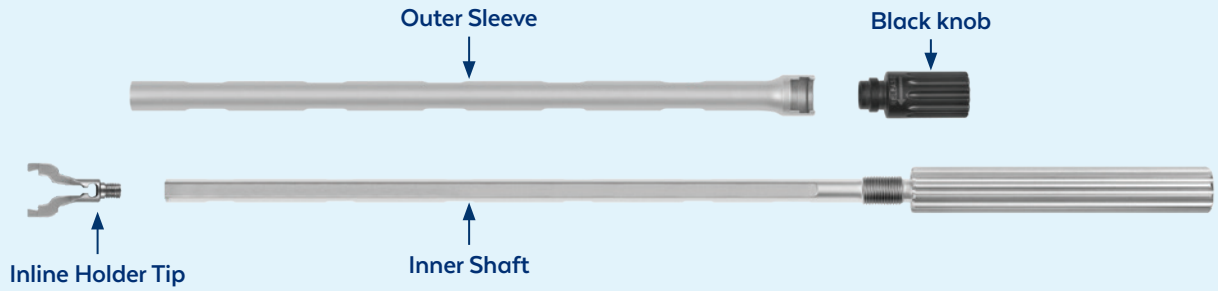
Unlocked

STEP 4 IMPLANT INSERTION

Implant insertion is achieved using the **Inline Holder Assembly**. To assemble, follow the instructions on page 16.

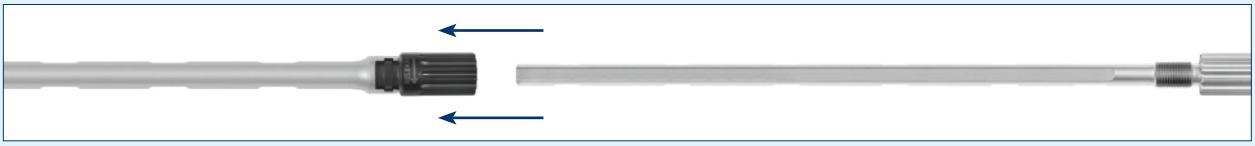
Inline Holder Assembly

MIDLINE INSERTER ASSEMBLY

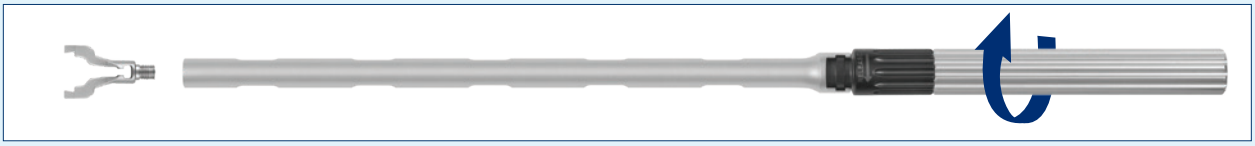


Place the Black Knob into the groove on the Outer Sleeve.

Slide the Inner Shaft into the assembled sleeve and knob. Rotate the Black Knob counterclockwise to attach the Inner Shaft to the Outer Sleeve.



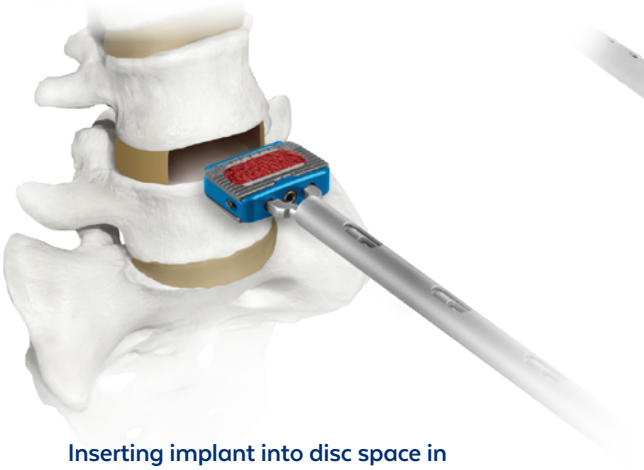
Thread the **Inline Holder** sleeve assembly onto the **Inline Holder Tip**.



Rotate the Black Knob clockwise to attach the implant or counterclockwise to release the implant.

IMPLANT INSERTION (CONT'D)

Select the appropriately sized implant and attach to the Inline Holder Assembly. 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 **holder**. If needed, impact gently on the distal end of the holder handle. The implant should be placed flush with the anterior vertebral body or recessed up to 1mm.

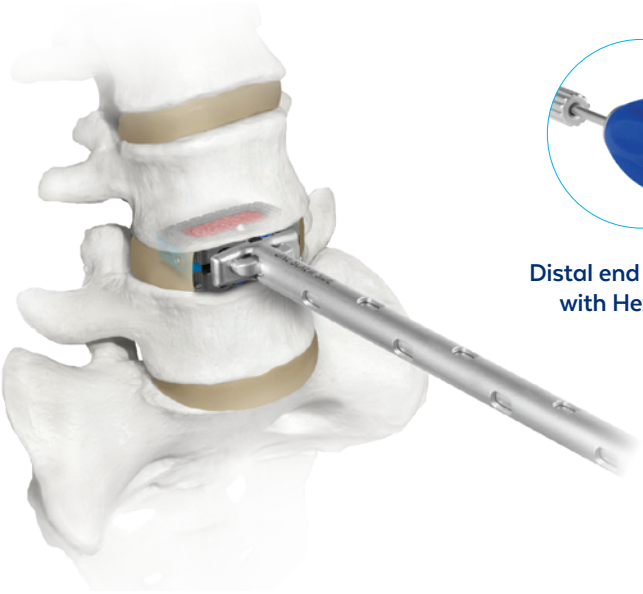


Inserting implant into disc space in contracted state

Distal end of holder

STEP 5 IMPLANT EXPANSION

Insert the **Torque-Limiting Hex Driver** into the Inline Holder and rotate clockwise to expand the implant to the desired height. Once the desired height is achieved, remove the holder. Alternatively, the holder can be removed before expansion. After expansion, additional bone graft material may be inserted (see Step 7).



Distal end of inserter with Hex Driver

IMPLANT EXPANSION (CONT'D)

CONNECTING THE COUNTER-TORQUE TO THE INLINE HOLDER

For additional control of the Torque-Limiting Hex Driver, a **Counter-Torque*** can be attached. Starting from the top, slide the Counter-Torque down the knurled portion of the handle until fully seated. Rotate the Counter-Torque clockwise to final tighten.

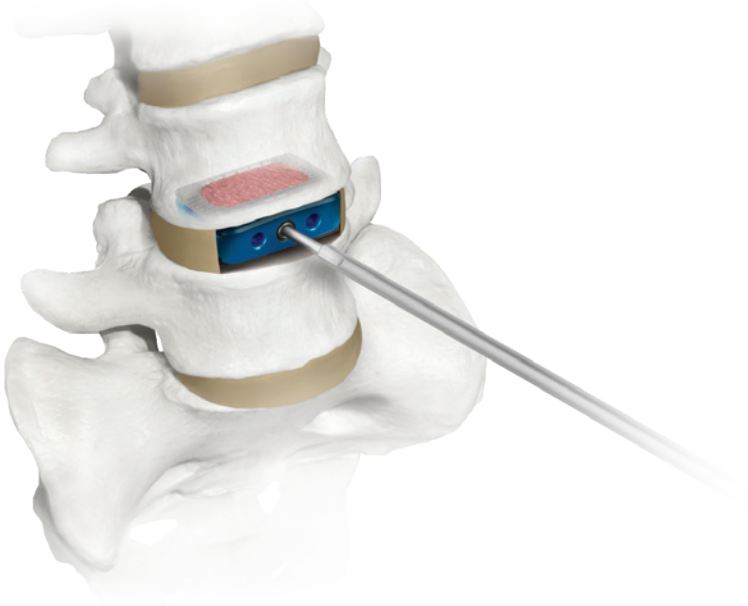
**Counter-Torque (676.699) is available in ALIF Instrument Set (925.905)*

Determining Implant Height

Implant expansion is determined through tactile feel of the implant in the disc space as it is expanded. Gently toggle the implant to determine if the desired fit is achieved. Confirm visually or under fluoroscopy.

The holder may be removed for height adjustments. Rotate the Black Knob on the Inline Holder counterclockwise to remove the holder (Refer to page 16).

Height adjustments may be made after the implant is detached from the holder by rotating the Torque-Limiting Hex Driver clockwise.



The overall height can be determined by counting the number of revolutions of the driver. MAGNIFY® implants expand 1mm for every 1.2 revolutions. The arrow at the end of the driver may be used to count revolutions.

The driver is designed to allow the user to identify when either the implant has reached its maximum expansion height or the maximum allowable torque has been reached.

Note: The torque limit (3Nm) 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.

Caution: Do not overcontract or overdistract the implant, as this could compromise implant integrity.

Arrow on back end of driver used to count revolutions

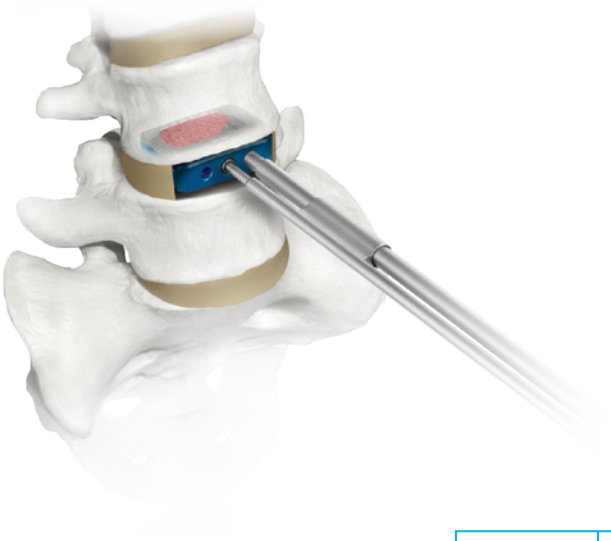
STEP 6 DISENGAGING THE IMPLANT

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.

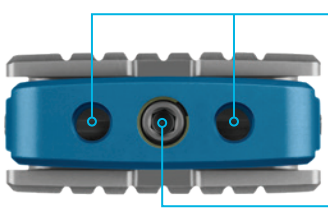
Rotate Black Knob counterclockwise to detach implant

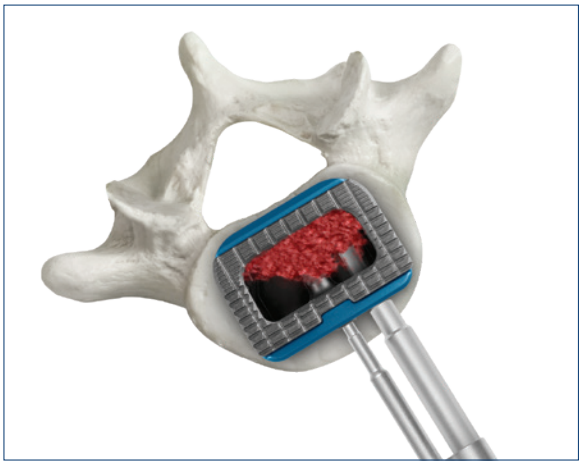
STEP 7 BONE GRAFT PACKING

After the implant is expanded within the disc space, a **Bone Funnel Guide, Bone Funnel Tube, Bone Funnel,** and **Bone Pusher** may be used 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 surrounding disc space. Dock the Bone Funnel Guide with the center set screw hole of the implant. Insert the Bone Funnel Tube through the guide to dock with the graft hole. Place morselized autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the Bone Funnel and pack into the implant with the Bone Pusher. Rotate the Bone Funnel Tube to the contralateral graft hole on the implant and pack additional autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone into the implant. See page 23 for bone graft volumes.

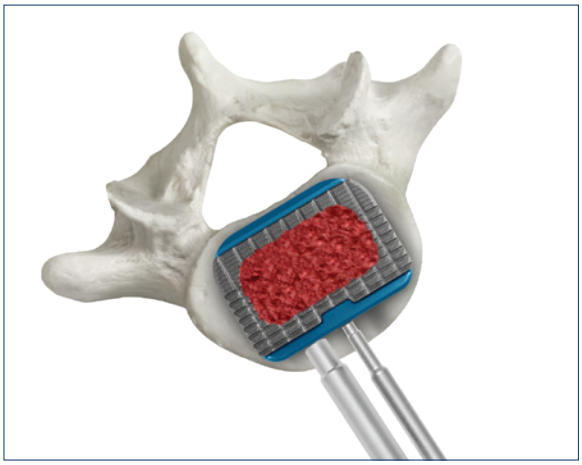


Distal end of the Bone Funnel Assembly





Packing bone graft into implant

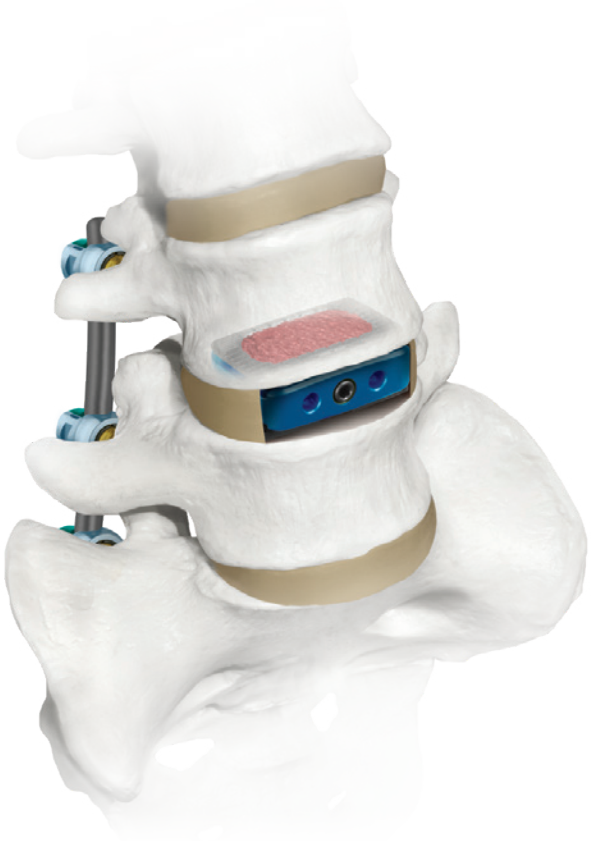


Packing additional bone graft into implant through contralateral graft hole

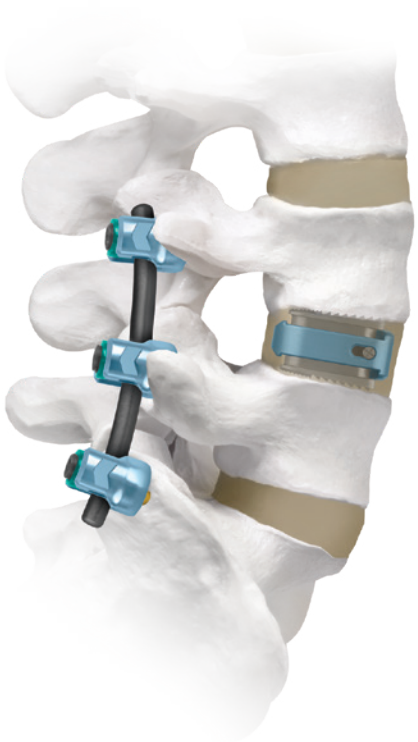
STEP 8 SUPPLEMENTAL FIXATION

In addition to the described interbody fusion technique, supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedical screw and rod systems, anterior plate system, and anterior screw and rod systems) must be used at the appropriate level(s). Refer to the corresponding surgical technique guides.

FINAL CONSTRUCT



Oblique View



Lateral View

OPTIONAL: IMPLANT REMOVAL

For implant removal, attach the Inline Holder Assembly. Insert the Torque-Limiting Hex Driver to contract and remove the implant. Alternatively, use the Torque-Limiting Hex Driver to contract the implant. Forceps or other manual surgical instruments may then be used to grasp and remove the implant.

SETS TO ORDER

Required Sets

Set No.	Set Description	Category
9126.9501	MAGNIFY® Instrument Set	MAGNIFY® Instruments
9126.9503	MAGNIFY® 25x31mm Implant Set	MAGNIFY® Implants
9126.9504	MAGNIFY® 26x34mm Implant Set	
9126.9505	MAGNIFY® 29x39mm Implant Set	
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	
925.902	Anterior Disc Prep II	

Supplemental Fixation

MAGNIFY® is to be used with supplemental fixation. Be sure to order the required supplemental fixation system for the case.

Additionally Available

MAGNIFY® Implants

Part No.	Description
5126.0116	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 16-20mm
5126.0216	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 16-20mm
5126.1116	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 16-20mm
5126.1216	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 16-20mm
5126.2116	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 16-20mm
5126.2216	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 16-20mm

Distractor-Retractor Instruments 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

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

PRODUCT SPECIFICATIONS

MAGNIFY® Implant Sets – Dimensions and Graft Volume

9126.9503 MAGNIFY® 25x31mm Implant Set			
Part No.	Description	Height Range (mm)	Graft Volume Range (cc)
5126.0108	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 8-11mm	8-11	1.3-2.1
5126.0110	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 10-14mm	10-14	1.7-2.8
5126.0112	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 12-16mm	12-16	2.1-3.2
5126.0114	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 14-18mm	14-18	2.3-3.4
5126.0116	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 16-20mm	16-20	2.6-3.7
5126.0210	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 10-13mm	10-13	1.5-2.3
5126.0212	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 12-15mm	12-15	1.9-2.8
5126.0214	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 14-18mm	14-18	2.3-3.4
5126.0216	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 16-20mm	16-20	2.7-3.8

9126.9504 MAGNIFY® 26x34mm Implant Set			
Part No.	Description	Height Range (mm)	Graft Volume Range (cc)
5126.1108	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 8-11mm	8-11	1.7-2.7
5126.1110	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 10-14mm	10-14	2.2-3.5
5126.1112	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 12-16mm	12-16	2.7-4.1
5126.1114	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 14-18mm	14-18	3.0-4.3
5126.1116	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 16-20mm	16-20	3.4-4.7
5126.1210	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 10-13mm	10-13	1.9-3.0
5126.1212	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 12-15mm	12-15	2.5-3.6
5126.1214	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 14-18mm	14-18	3.0-4.4
5126.1216	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 16-20mm	16-20	3.5-4.8

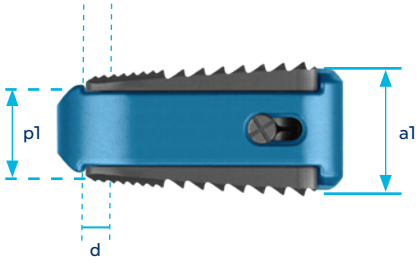
9126.9505 MAGNIFY® 29x39mm Implant Set			
Part No.	Description	Height Range (mm)	Graft Volume Range (cc)
5126.2109	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 9-12mm	9-12	2.7-4.0
5126.2110	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 10-14mm	10-14	2.9-4.8
5126.2112	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 12-16mm	12-16	3.6-5.4
5126.2114	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 14-18mm	14-18	4.1-5.8
5126.2116	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 16-20mm	16-20	4.6-6.4
5126.2211	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 11-14mm	11-14	2.9-4.3
5126.2212	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 12-15mm	12-15	3.3-4.7
5126.2214	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 14-18mm	14-18	4.1-5.8
5126.2216	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 16-20mm	16-20	4.9-6.4

All implants expand 1mm for every 1.2 revolutions.
Note: Graft material may compress in situ, allowing delivery of graft volumes in excess of the ranges listed.

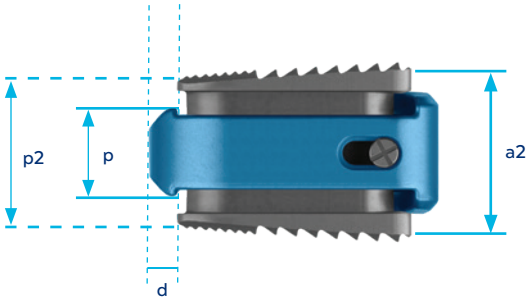
PRODUCT SPECIFICATIONS

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)
5126.0108	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 8-11mm	8	11	6	6	9	4
5126.0110	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 10-14mm	10	14	7	8	12	4
5126.0112	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 12-16mm	12	16	8	10	14	3
5126.0114	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 14-18mm	14	18	10	11	15	3
5126.0116	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 8°, 16-20mm	16	20	12	13	17	3
5126.0210	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 10-13mm	10	13	6	6	9	4
5126.0212	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 12-15mm	12	15	6	7	10	3
5126.0214	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 14-18mm	14	18	7	9	13	3
5126.0216	MAGNIFY® Expandable ALIF Spacer, 25x31mm, 15°, 16-20mm	16	20	9	11	15	3

PRODUCT SPECIFICATIONS

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)
5126.1108	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 8-11mm	8	11	6	6	9	4
5126.1110	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 10-14mm	10	14	7	8	12	4
5126.1112	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 12-16mm	12	16	8	10	14	3
5126.1114	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 14-18mm	14	18	10	11	15	3
5126.1116	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 8°, 16-20mm	16	20	12	13	17	3
5126.1210	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 10-13mm	10	13	6	6	9	4
5126.1212	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 12-15mm	12	15	6	7	10	3
5126.1214	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 14-18mm	14	18	7	9	13	3
5126.1216	MAGNIFY® Expandable ALIF Spacer, 26x34mm, 15°, 16-20mm	16	20	9	11	15	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)
5126.2109	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 9-12mm	9	12	6	7	10	5
5126.2110	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 10-14mm	10	14	7	8	12	5
5126.2112	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 12-16mm	12	16	8	10	14	4
5126.2114	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 14-18mm	14	18	10	11	15	4
5126.2116	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 8°, 16-20mm	16	20	12	13	17	4
5126.2211	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 11-14mm	11	14	6	7	10	5
5126.2212	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 12-15mm	12	15	6	7	10	5
5126.2214	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 14-18mm	14	18	7	9	13	5
5126.2216	MAGNIFY® Expandable ALIF Spacer, 29x39mm, 15°, 16-20mm	16	20	9	11	15	4

MAGNIFY®
IMPLANT SETS

MAGNIFY® 25x31mm Implant Set 9126.9503

Part No.	Description	Qty
5126.0108	25x31mm, 8°, 8-11mm	2
5126.0110	25x31mm, 8°, 10-14mm	2
5126.0112	25x31mm, 8°, 12-16mm	2
5126.0114	25x31mm, 8°, 14-18mm	2
5126.0210	25x31mm, 15°, 10-13mm	2
5126.0212	25x31mm, 15°, 12-15mm	2
5126.0214	25x31mm, 15°, 14-18mm	2
9126.0503	25x31mm MAGNIFY® Implant Module	

MAGNIFY® 26x34mm Implant Set 9126.9504

Part No.	Description	Qty
5126.1108	26x34mm, 8°, 8-11mm	2
5126.1110	26x34mm, 8°, 10-14mm	2
5126.1112	26x34mm, 8°, 12-16mm	2
5126.1114	26x34mm, 8°, 14-18mm	2
5126.1210	26x34mm, 15°, 10-13mm	2
5126.1212	26x34mm, 15°, 12-15mm	2
5126.1214	26x34mm, 15°, 14-18mm	2
9126.0504	26x34mm MAGNIFY® Implant Module	

MAGNIFY® 29x39mm Implant Set 9126.9505

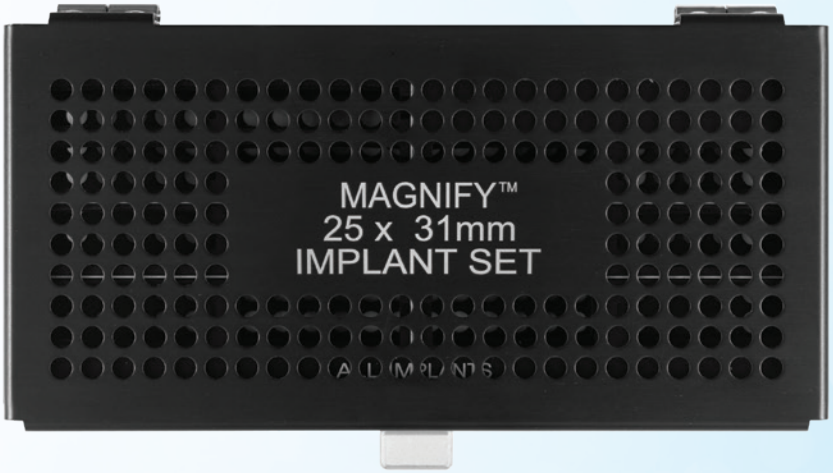
Part No.	Description	Qty
5126.2109	29x39mm, 8°, 9-12mm	2
5126.2110	29x39mm, 8°, 10-14mm	2
5126.2112	29x39mm, 8°, 12-16mm	2
5126.2114	29x39mm, 8°, 14-18mm	2
5126.2211	29x39mm, 15°, 11-14mm	2
5126.2212	29x39mm, 15°, 12-15mm	2
5126.2214	29x39mm, 15°, 14-18mm	2
9126.0505	29x39mm MAGNIFY® Implant Module	

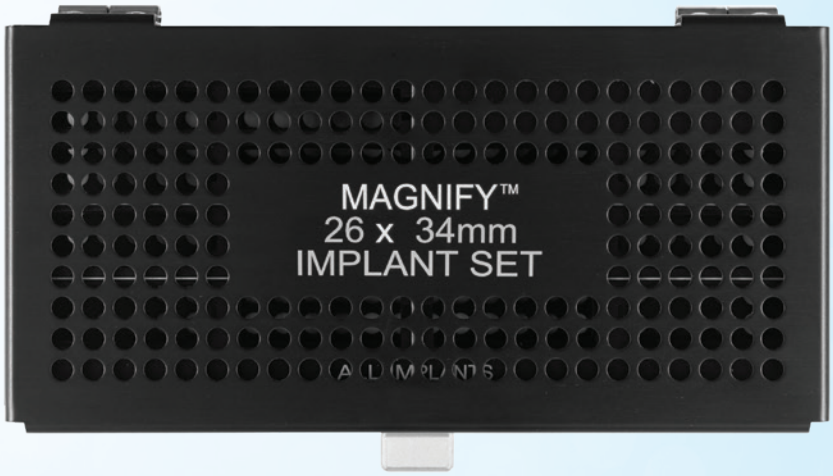
Additionally Available

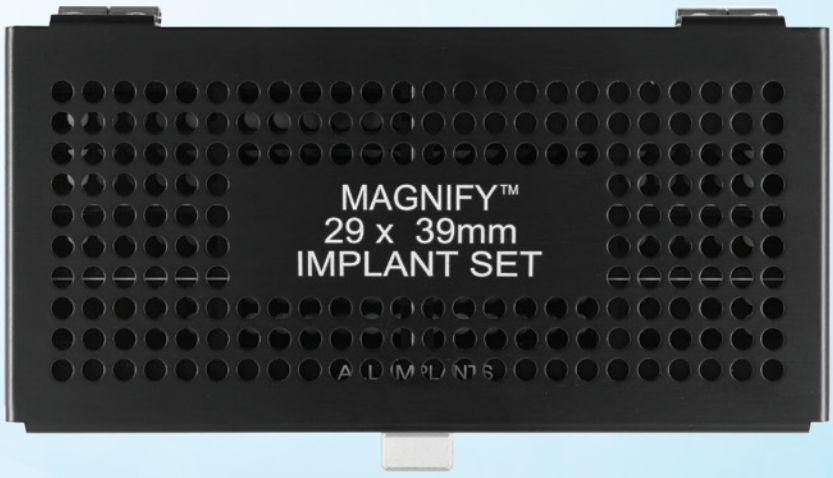
Part No.	Description
5126.0116	25x31mm, 8°, 16-20mm
5126.0216	25x31mm, 15°, 16-20mm
5126.1116	26x34mm, 8°, 16-20mm
5126.1216	26x34mm, 15°, 16-20mm
5126.2116	29x39mm, 8°, 16-20mm
5126.2216	29x39mm, 15°, 16-20mm

Items in gray are additionally available.

MAGNIFY®
IMPLANT SETS



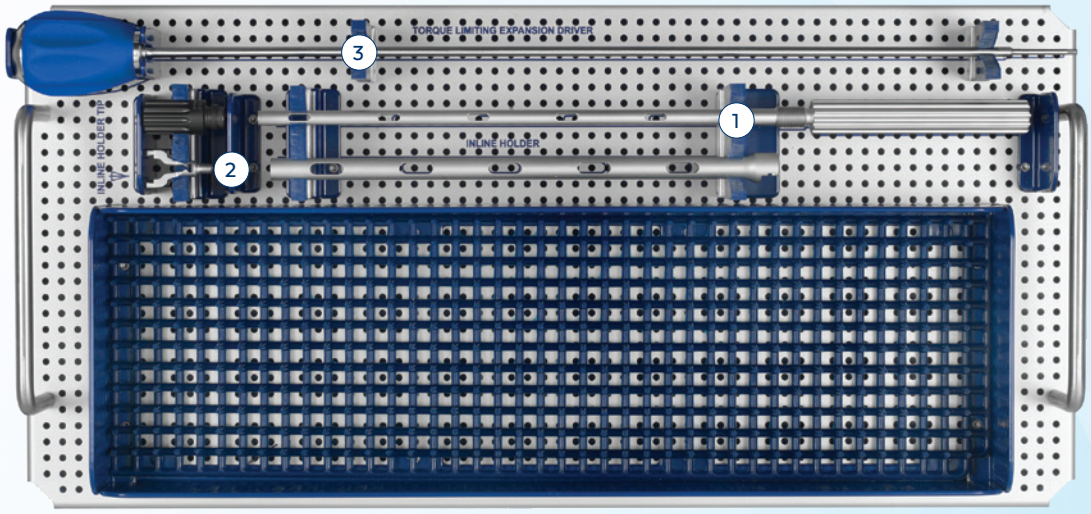


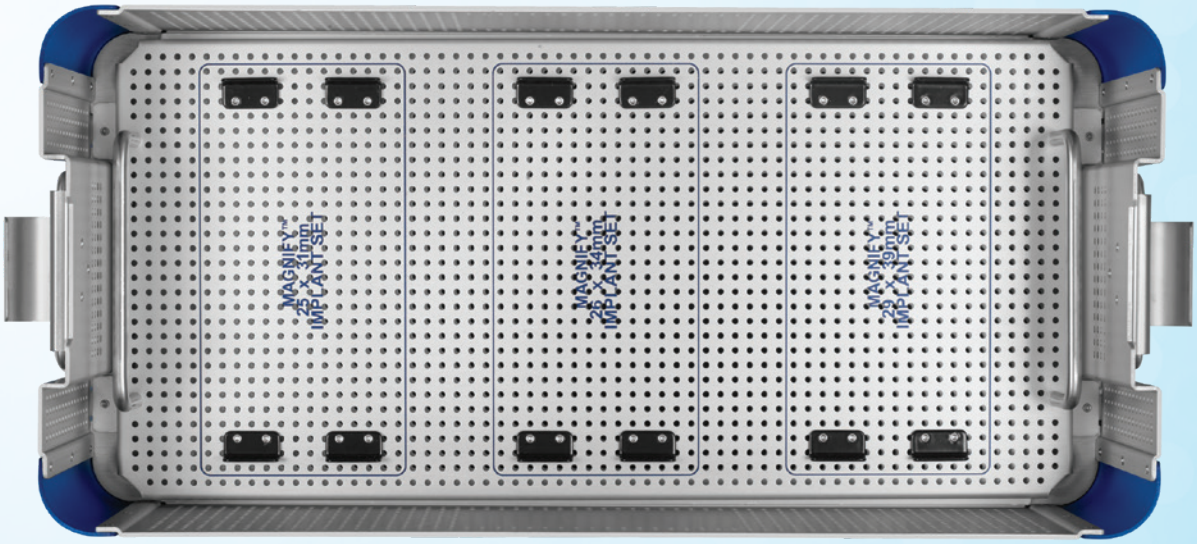


MAGNIFY®
INSTRUMENT SET 9126.9501

	Part No.	Description	Qty
1	6126.6500	Inline Holder	1
2	6126.6501	Inline Holder Tip	1
3	6126.6004	Torque-Limiting Hex Driver	1
	9126.0501	MAGNIFY® Graphic Case	

MAGNIFY®
INSTRUMENT SET 9126.9501

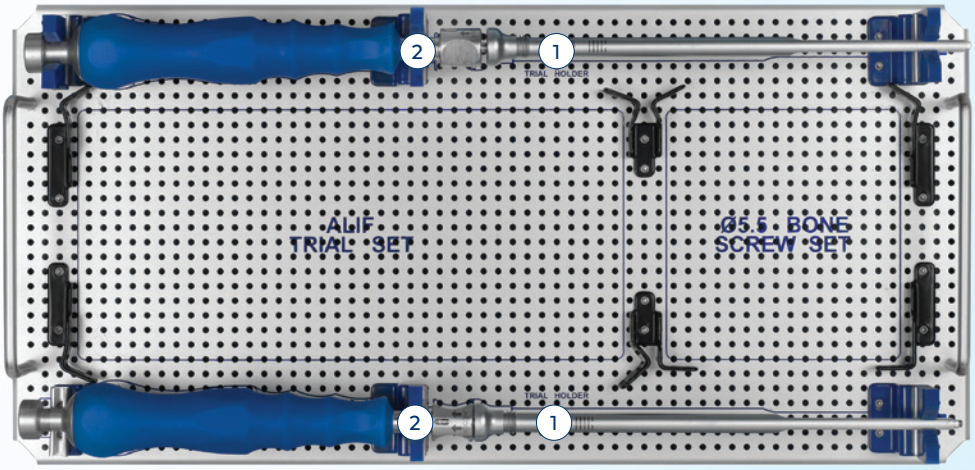


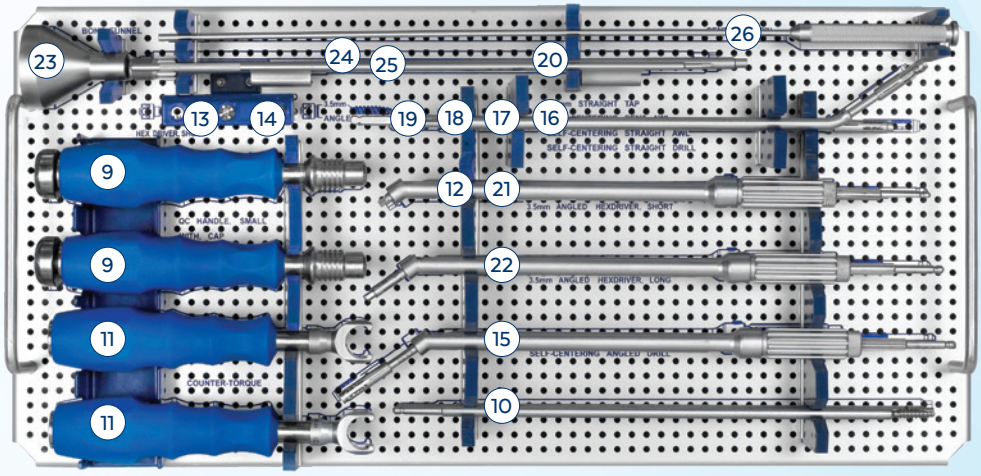


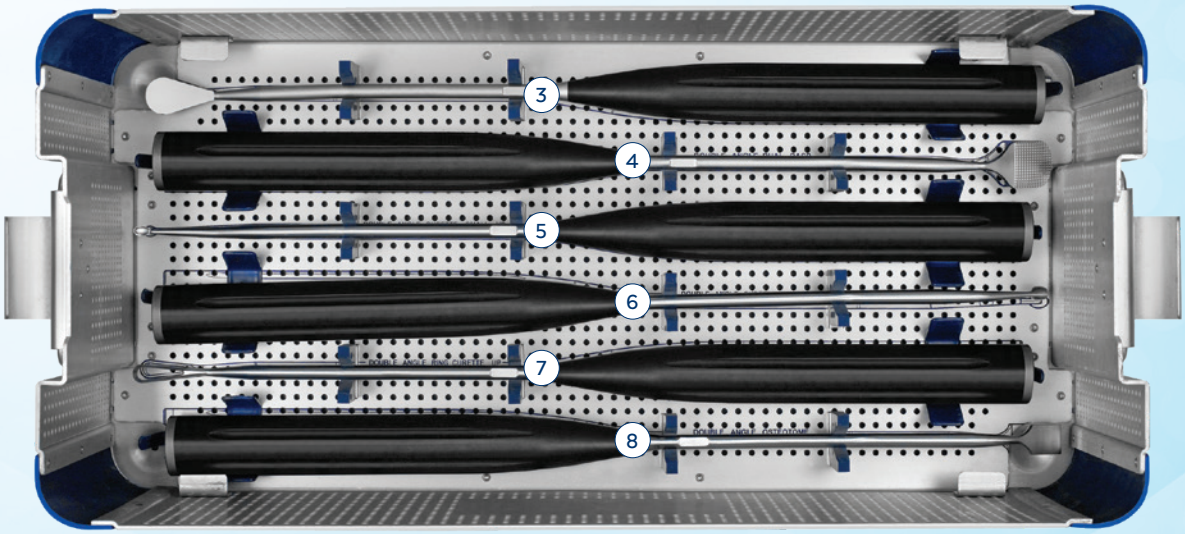
ALIF
INSTRUMENT SET 925.905

	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





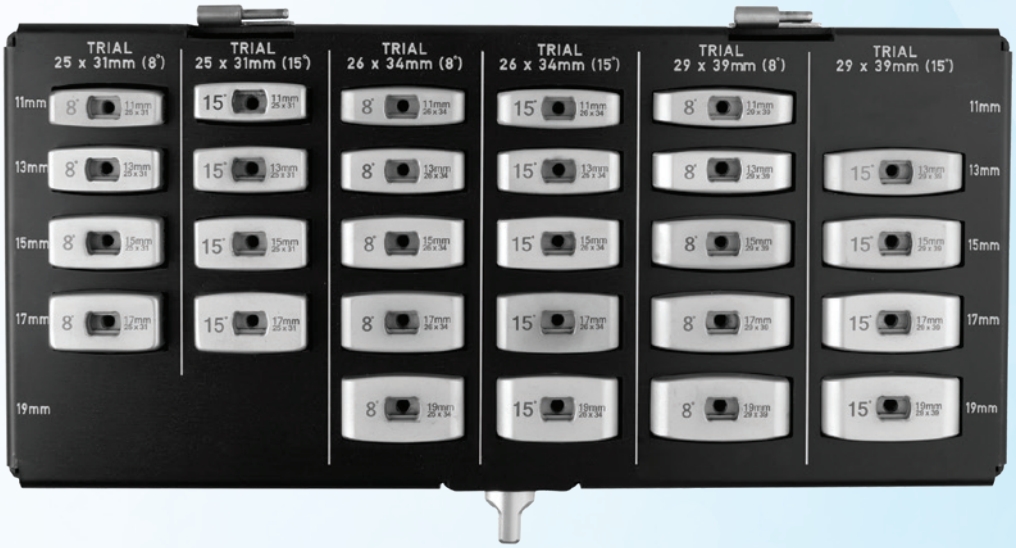


ALIF
TRIAL SET 925.906

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.

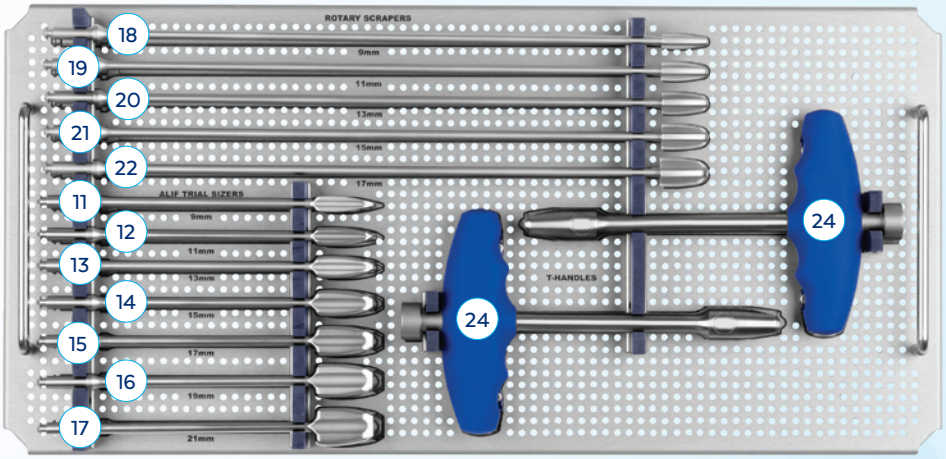
ALIF
TRIAL SET 925.906

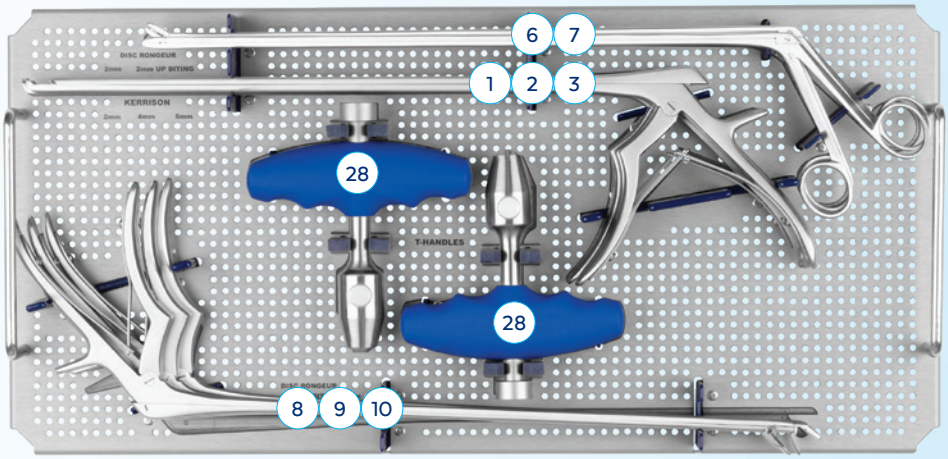


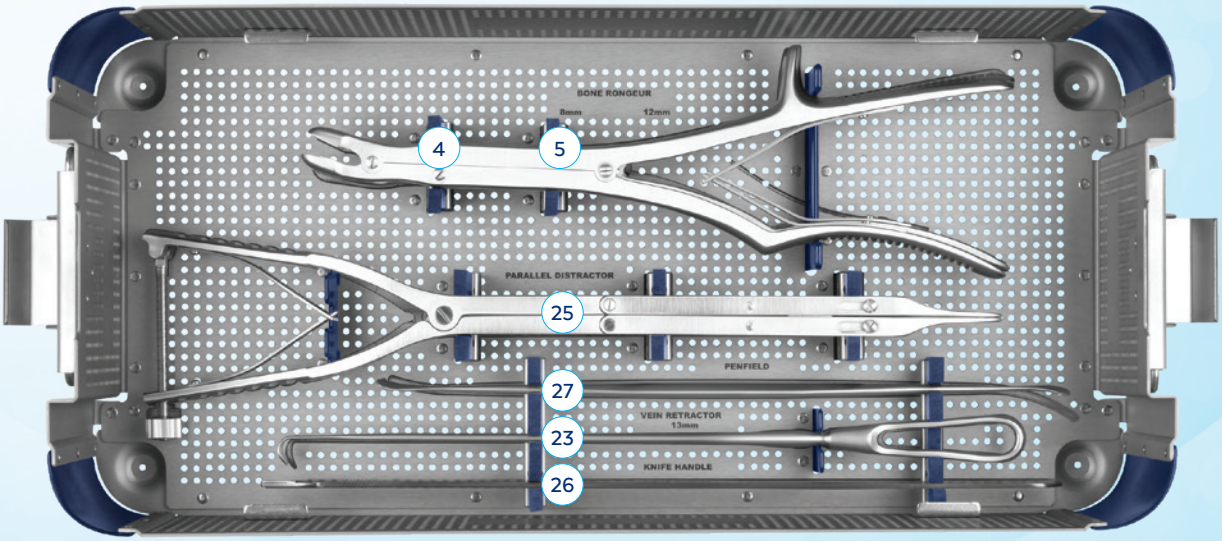
ANTERIOR DISC PREP I
INSTRUMENT SET 925.901

	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





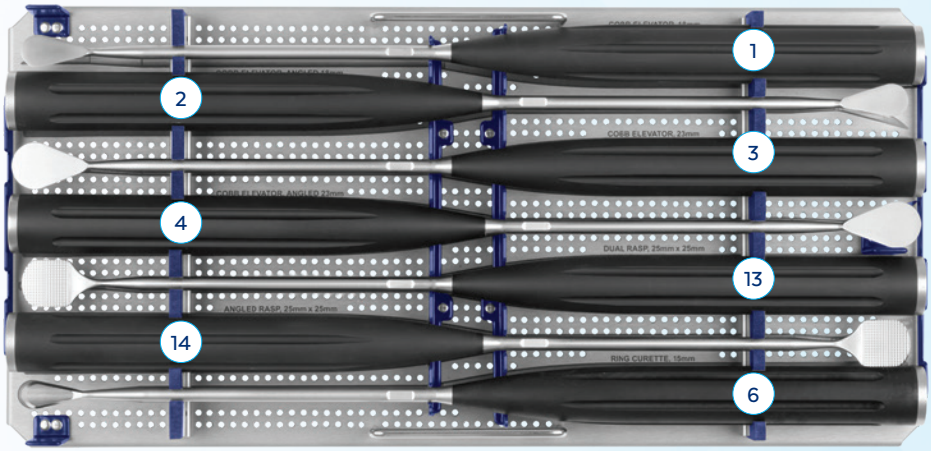


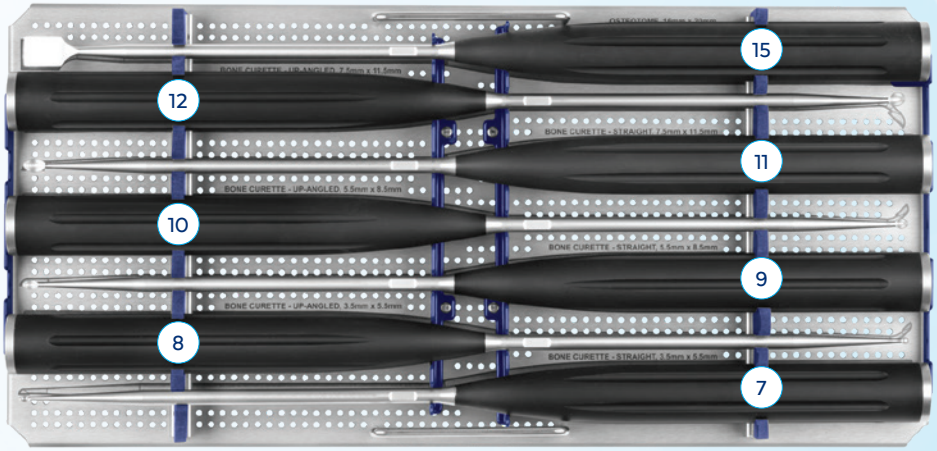
ANTERIOR DISC PREP II
INSTRUMENT SET 925.902

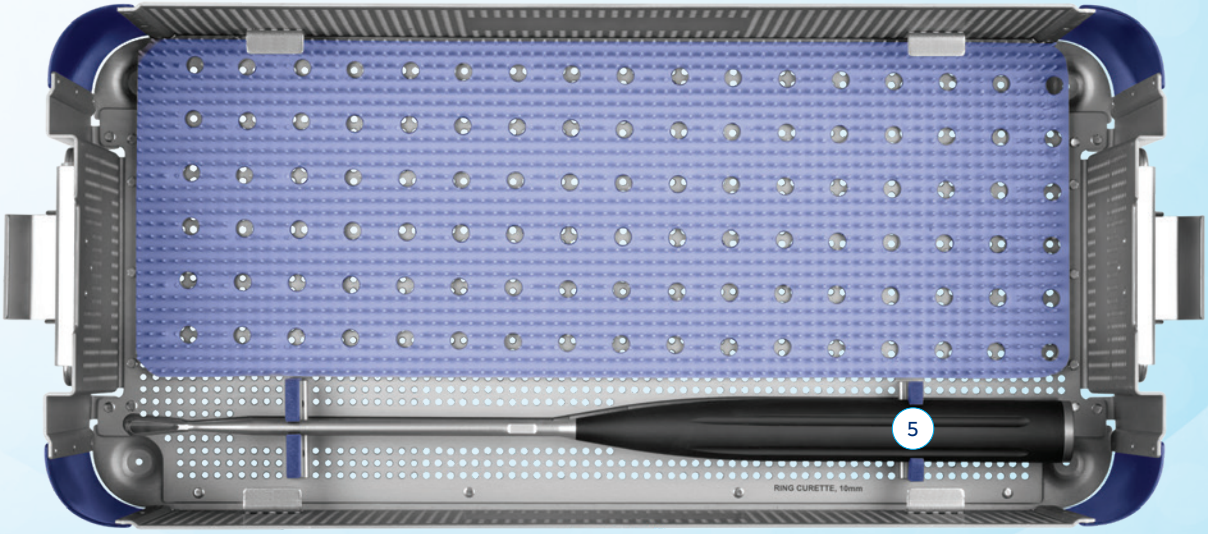
	Part No.	Description	Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette, 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 (CONT'D)





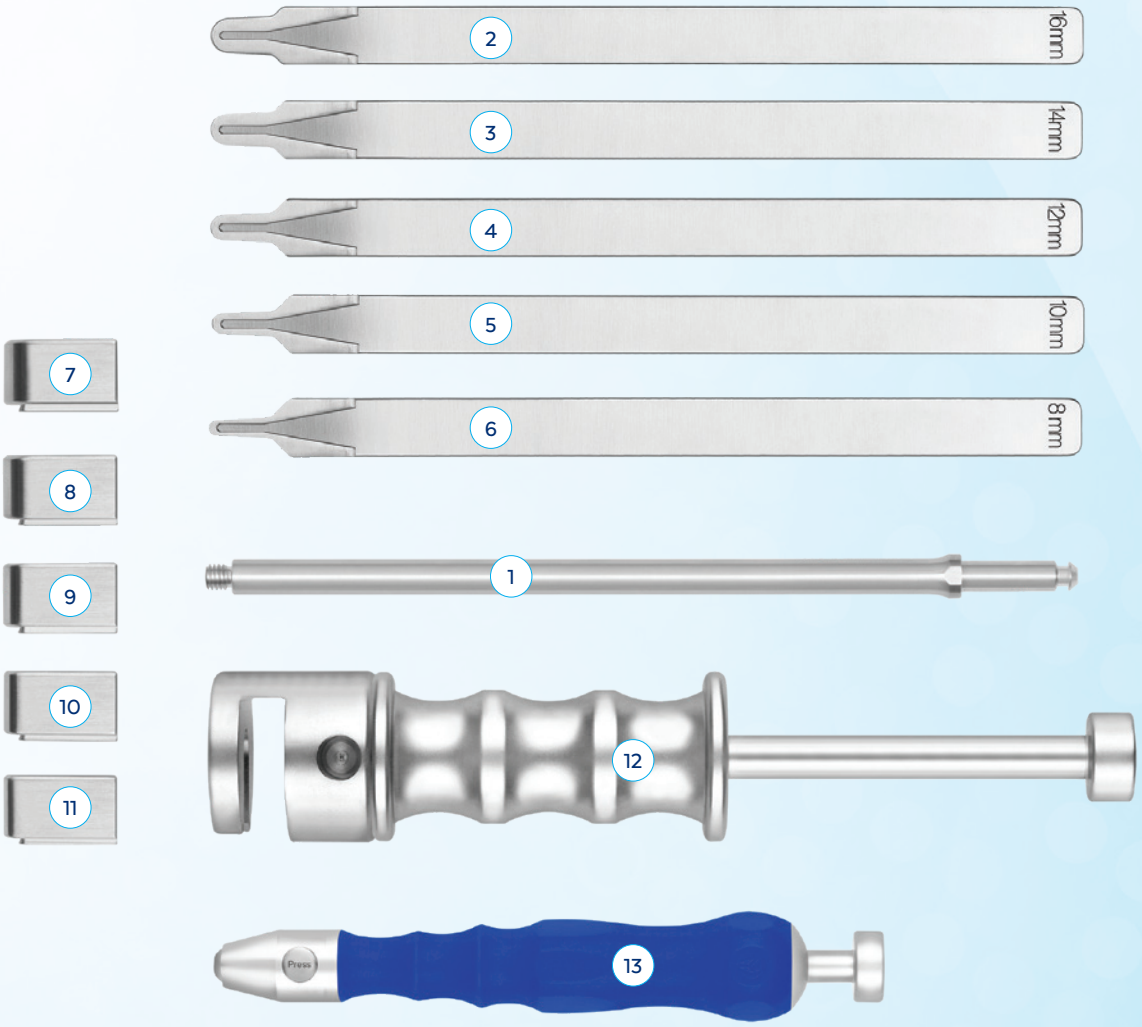


ANTERIOR LUMBAR DISTRACTOR/RETRACTOR ADDITIONALLY AVAILABLE

	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



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.

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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.
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.

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		

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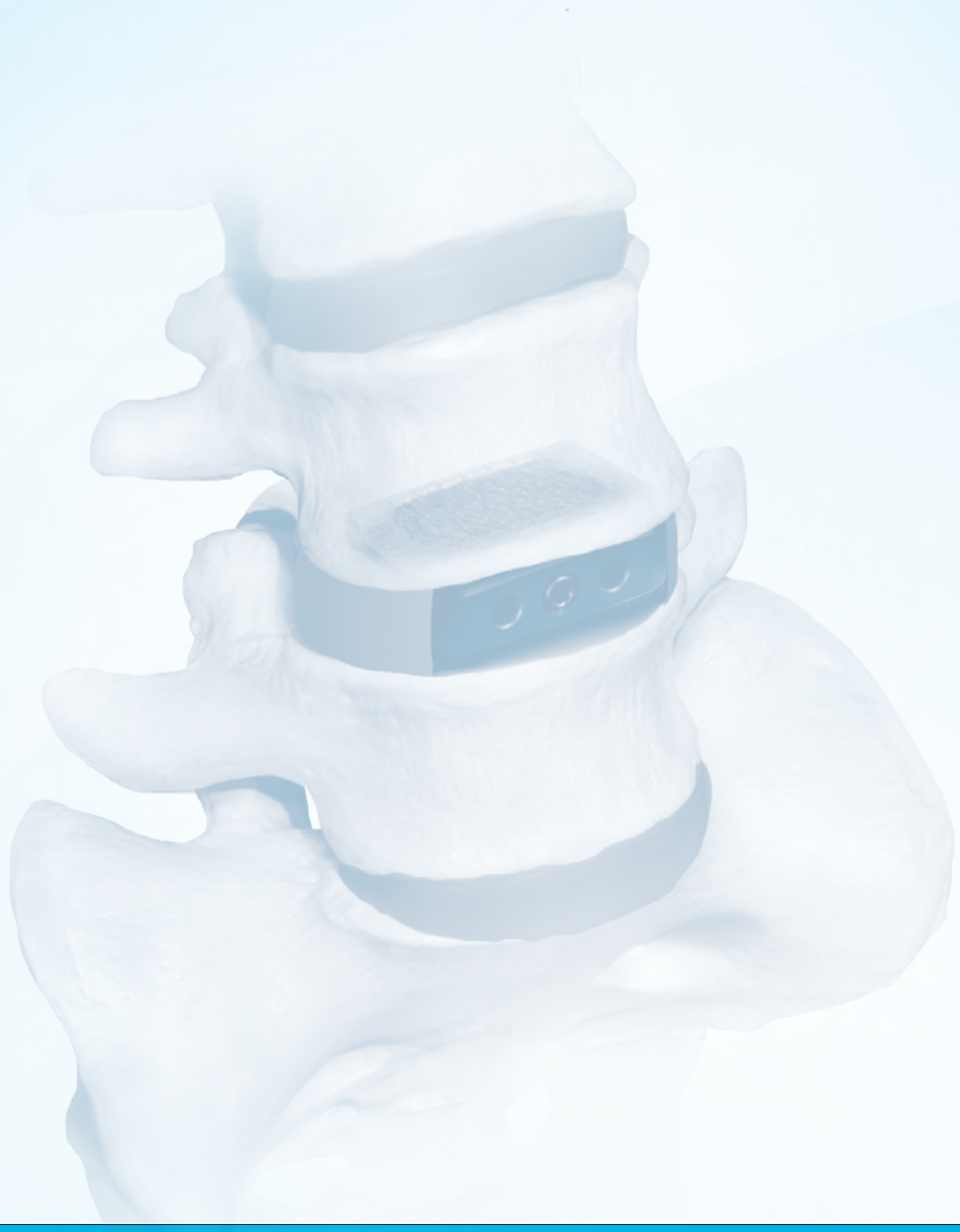

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GMTGD152
02.24 Rev D