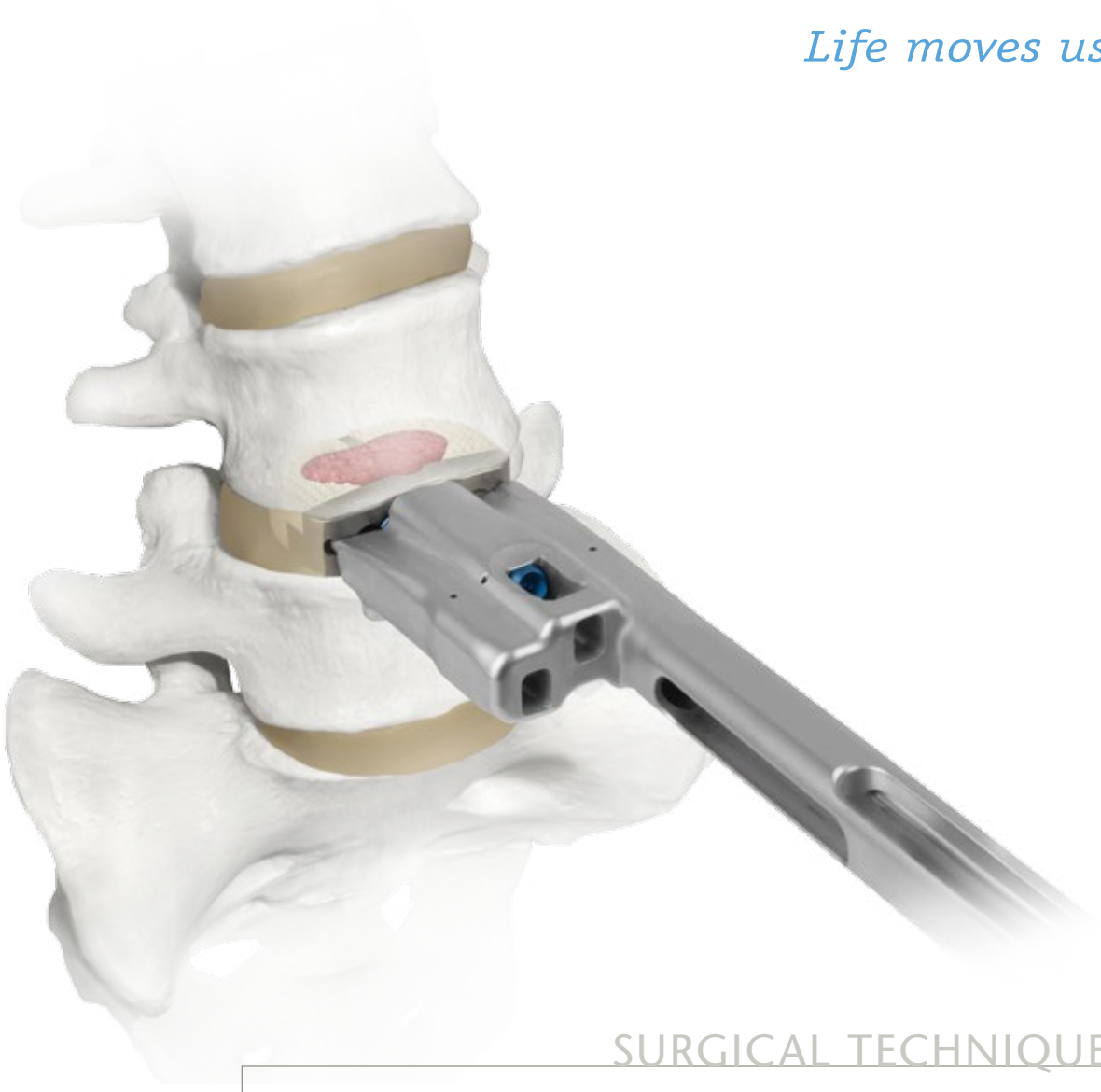
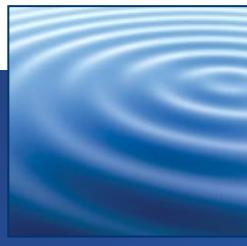
Life moves us



SURGICAL TECHNIQUE



INDEPENDENCE MIS®

Anterior Lumbar Interbody Fusion System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

INDEPENDENCE MIS®

Anterior Lumbar Interbody Fusion System

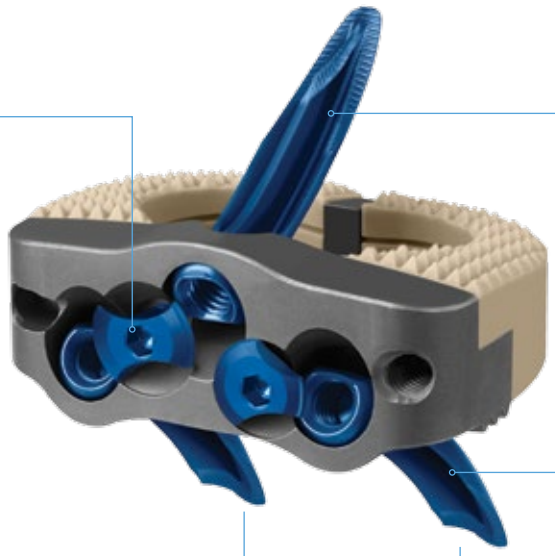
INDEPENDENCE MIS® is an integrated lumbar plate-spacer designed to deliver anchor fixation in fewer procedural steps through a less invasive surgical corridor than traditional integrated spacers.

INDEPENDENCE MIS®

ANTERIOR LUMBAR INTERBODY FUSION SYSTEM

Confident Blocking
Helps prevent screw and anchor backout

Anchor Design
Provides purchase and strength



Staggered Fixation Position
Eliminates interference with adjacent level implant

Intraoperative Versatility
Allows for screws or anchors

In-line Integrated Fixation

Innovative instruments facilitate simple implantation even with challenging patient anatomy.

Biomechanical Stability

Biomechanically comparable with a traditional stand-alone ALIF system when used with screws.

Intraoperative Versatility

Compatible with anchors and screws, providing multiple options for securing the spacer to the vertebral bodies.

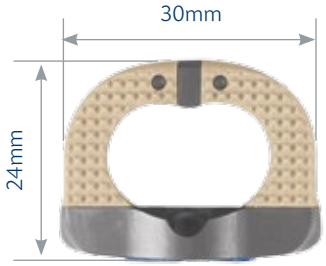
CONTENTS

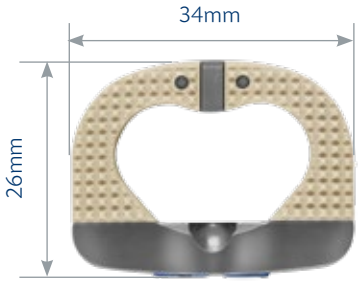
The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

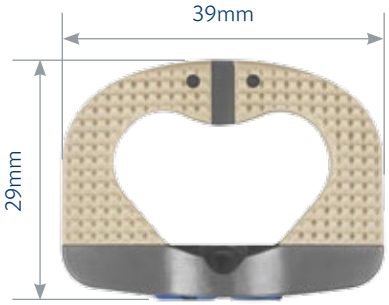
IMPLANT OVERVIEW

Spacer Options

- Three axial footprints: 24x30, 26x34, 29x39mm
- Six heights: 11, 13, 15, 17, 19, 21mm
- Three sagittal profiles: 8°, 15°, 20°*, 25°*, 30°*







Fixation Options

Lumbar Anchor Options

- Four anchor lengths: 20*, 25, 27, and 30mm
- 5.5mm diameter

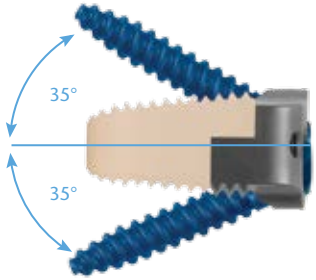
Lumbar Anchor

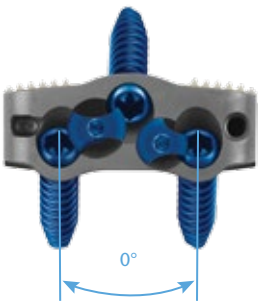
Screw Options

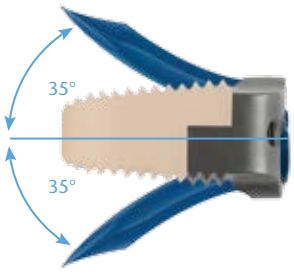
- Fixed and variable angle screws (±5)
- Five screw lengths: 20, 25, 30, 35, 40mm
- 5.5mm diameter
- Self-tapping, self-drilling*
- Hydroxyapatite (HA) coated*

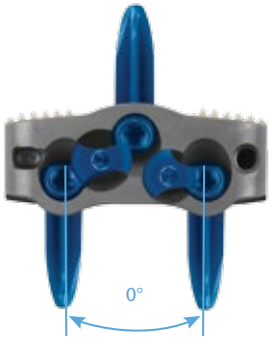
Fixation Angulation

- 35° cephalad/caudal orientation
- 0° medial divergence
- Variable angle offers 5° conical angulation









**Additionally Available*

INSTRUMENT OVERVIEW

Trials

Small (24x30mm)						
Angle	**11mm**	**13mm**	**15mm**	**17mm**	**19mm**	**21mm**
8°	676.111	676.113	676.115	676.117	–	–
15°	676.211	676.213	676.215	676.217	–	–
20°*	–	676.233	676.235	676.237	–	–
25°*	–	–	676.315	676.317	676.319	676.321
30°*	–	–	676.355	676.357	676.359	676.361

Medium (26x34mm)						
Angle	**11mm**	**13mm**	**15mm**	**17mm**	**19mm**	**21mm**
8°	676.411	676.413	676.415	676.417	676.419	676.421
15°	676.511	676.513	676.515	676.517	676.519	676.521
20°*	–	676.533	676.535	676.537	676.539	676.541
25°*	–	–	676.615	676.617	676.619	676.621
30°*	–	–	–	676.667	676.669	676.671

Large (29x39mm)*								
Angle	**11mm**	**13mm**	**15mm**	**17mm**	**19mm**	**21mm**	**23mm**	**25mm**
8°	676.711	676.713	676.715	676.717	676.719	676.721	–	–
15°	–	676.813	676.815	676.817	676.819	676.821	–	–
20°*	–	–	676.835	676.837	676.839	676.841	–	–
25°*	–	–	–	676.917	676.919	676.921	–	–
30°*	–	–	–	–	–	676.991	676.993	676.995

Trial Holders*

Trial Holder 6108.0003

Trial Sleeve 6108.0001

Trial Holder Assembly

**Available in the ALIF Instrument Set (925.905)*

Implant Insertion Instruments

Triple Barrel Anchor Guides

Size	Part Number
11mm	6135.0011
13mm	6135.0013
15mm	6135.0015
17mm	6135.0017
19mm	6135.0019
21mm	6135.0021

Threaded Rod 6135.0010

Anchor Impactor 6135.0001

Hex Driver 6135.0050

Freehold Holder 6135.0100

Hammer 603.977

Straight Instruments*

QC Handle, Small with Cap 650.105

3.5mm Hex Straight Driver 676.502

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

*Self-Centering Straight Instruments with Retracting Front Sleeve***

Self-Centering Straight Drill 676.704**

Self-Centering Straight Awl 676.706**

Self-Centering Straight Instruments (Assembled)

5.5mm Straight Tap 676.708*

Set Screw Positioner, Torque Limiting (0.4Nm) 6108.1006

*Available in ALIF Instrument Set
**Drill, awl and tap dimensions can be found on page 28

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

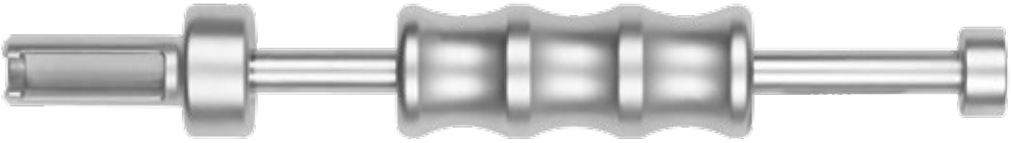
3.5mm Angled Hex Driver, Short 676.710

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*
***Drill, awl and tap dimensions can be found on page 28*

Removal Instruments

Removal Tool (Disposable) 6135.0500



Slide Hammer 614.802

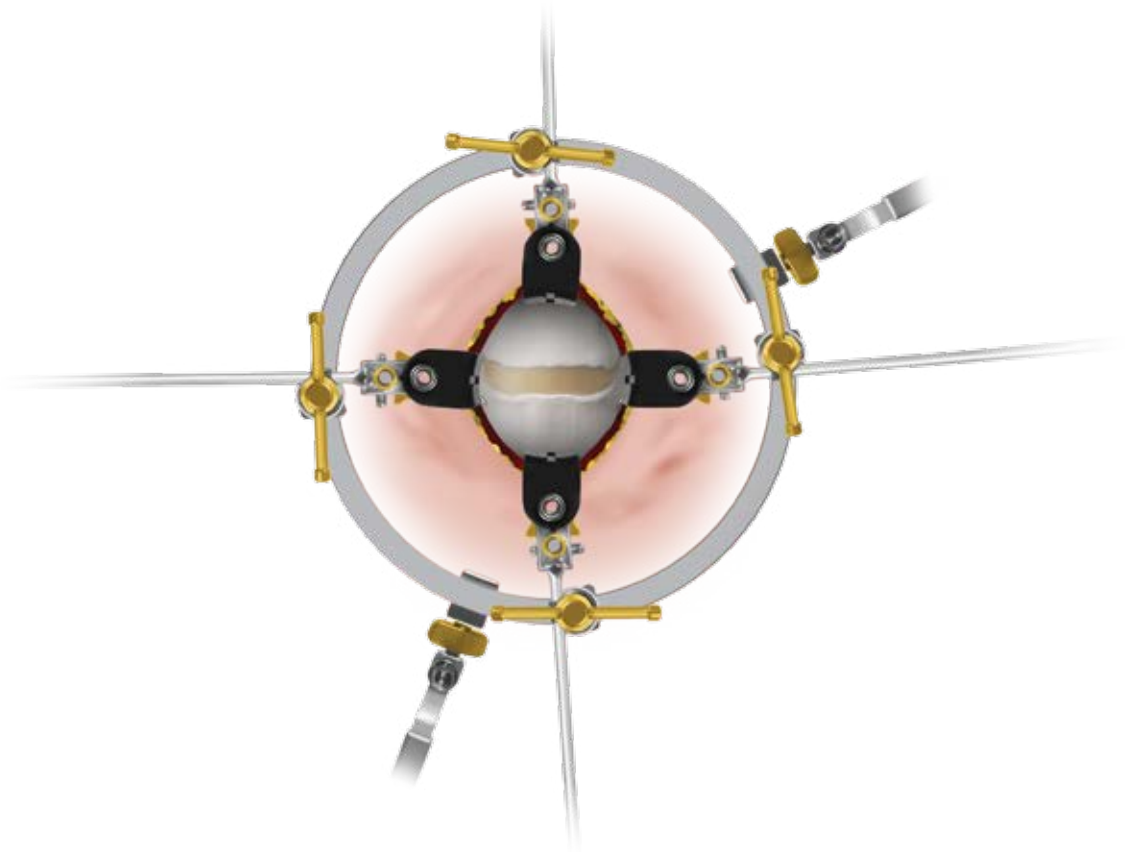
INDEPENDENCE MIS®
SURGICAL TECHNIQUE

Step 1 Approach

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

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

An anterior approach is used to implant the INDEPENDENCE MIS® Spacer. Insertion can be accomplished through a minimally invasive surgical approach. A standard mini-open anterior approach is shown. The patient is placed in the supine position, and access to the disc space is created.

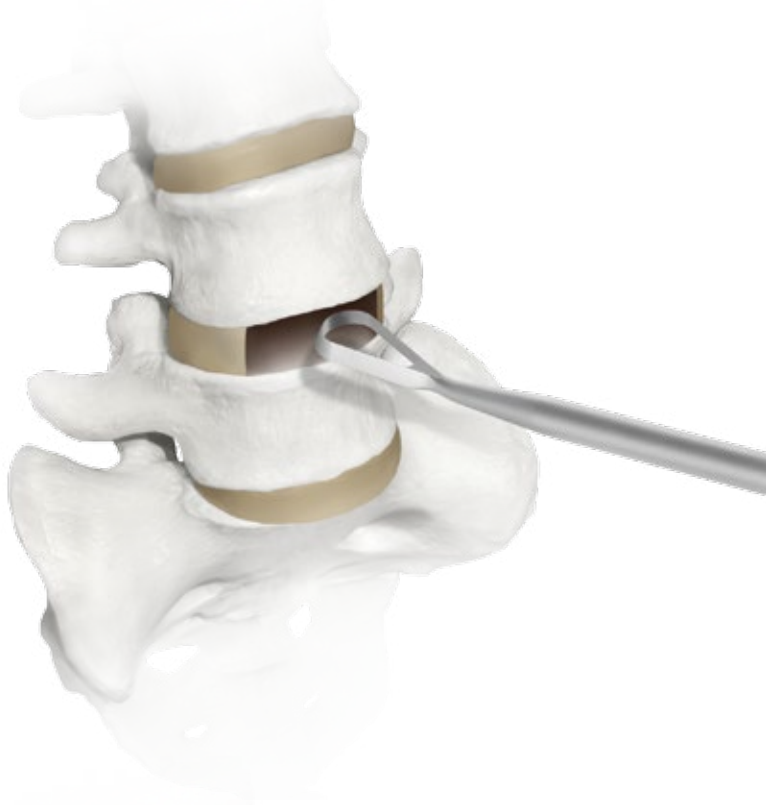


1. Lee SH, Choi WG, Lim SR, Kand HY. Minimally invasive anterior lumbar fusion followed by percutaneous pedicle screw fixation for isthmic spondylolisthesis. Spine J. 2004;4(6):664-669.

2. Kim KT, Lee SH, Suk KS, Bae SC. The quantitative analysis of tissue injury markers after mini-open lumbar fusion. Spine (Phila Pa 1976). 2006;31(6):712-716.

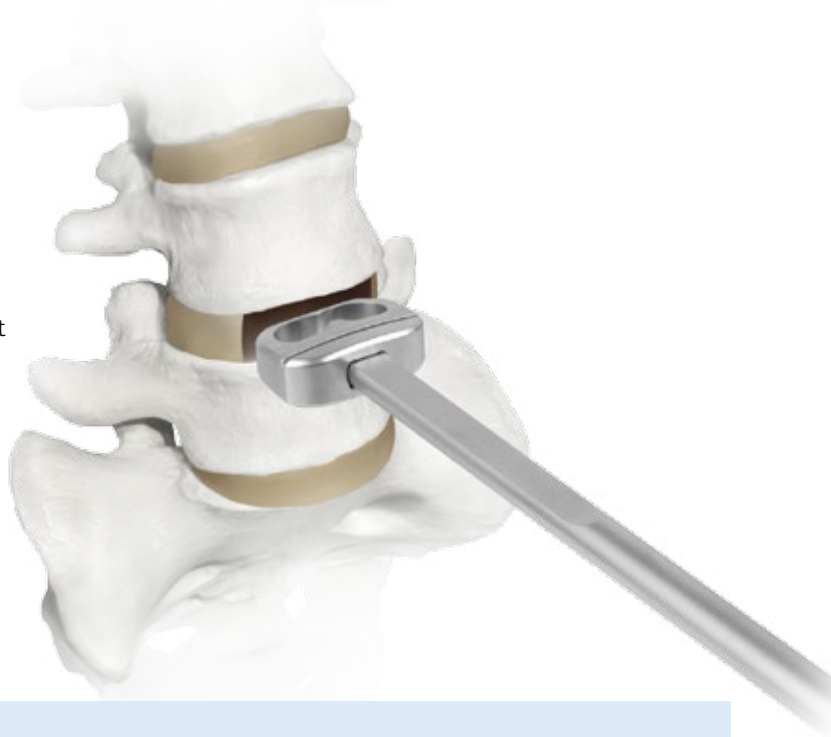
Step 2 Preparation

Anterior Disc Preparation instruments may be used to expose the disc and remove the disc materials with rongeurs and other suitable instruments. Scrapers may be used to remove superficial layers of the cartilaginous endplates. The posterior and lateral walls of the annulus should be preserved to provide peripheral support.



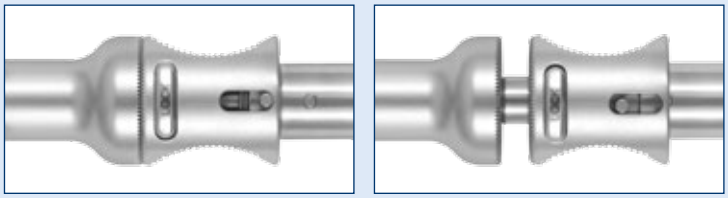
Step 3 Implant Sizing

Select an appropriately sized **Trial** and attach it to the **Trial Holder Assembly**. Insert the Trial into the disc space, as shown on the right. Determine which Trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and stabilize the segment, and can be confirmed by fluoroscopy and tactile feel.



Using the Trial Holder

Ensure that 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 compressing the lock forward. To disengage, pull the locking sleeves back and rotate the handle counterclockwise.



Locked Unlocked

INDEPENDENCE MIS® may be used with three anchors, three screws, or any combination of screws and anchors.

- **Use with Anchors:** Follow steps 4-8 on pages 12-15.
- **Use with Screws:** Follow steps 4-8 on pages 16-19.
- **Hybrid use with Anchors and Screws:** For anchor fixation follow steps 4-8 on pages 12-15. For screw fixation follow steps 4-8 on pages 16-19.

Use with Anchors

Step 4 Anchor Loading

After determining the appropriately sized spacer, choose the corresponding **Triple Barrel Anchor Guide**.

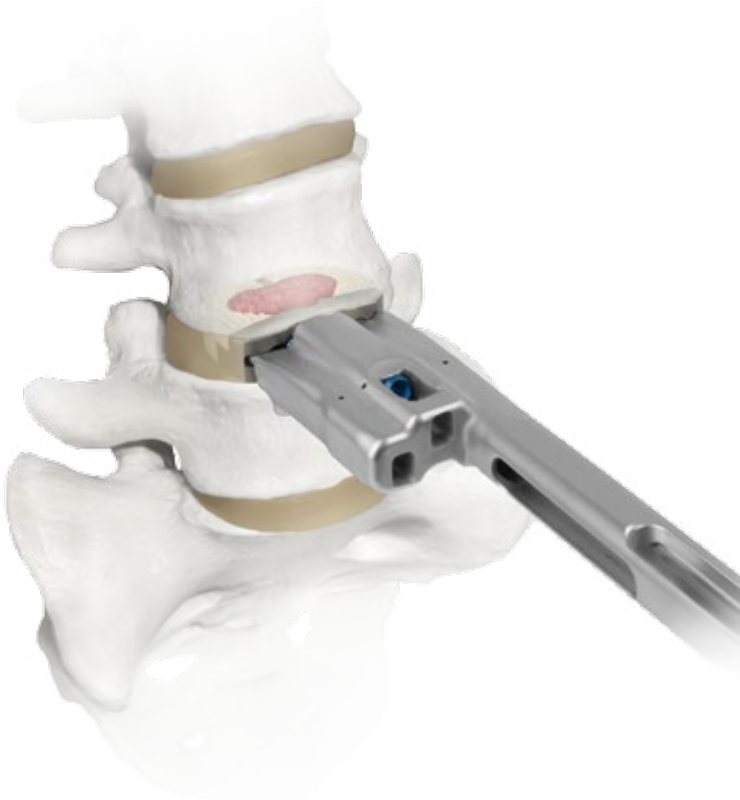
Select the desired anchor using the sizing chart on page 26. Load the selected anchors into the guide.

Loading the Anchors

Align the anchor with the slot at the distal end of the Triple Barrel Anchor Guide.

Push the anchor into the slot using a finger until a tactile and audible click is achieved. Repeat for the two remaining anchors. Confirm that anchors are fully seated before loading the spacer.

Step 5 Spacer Insertion



Select an appropriately sized INDEPENDENCE MIS® Spacer and pack with bone graft material (autogenous and/or allogenic bone graft composed of cancellous and/or cortical cancellous bone graft material). Attach the spacer to the Triple Barrel Anchor Guide.

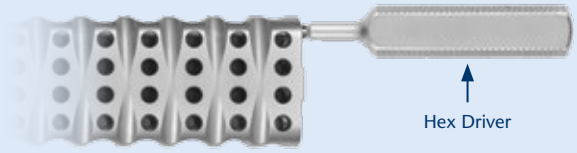
Insert the spacer into the prepared disc space. The **Hammer** may be used to gently position the spacer within the disc space. The spacer should sit flush or recessed 1mm within the anterior portion of the vertebral bodies.

*Note: If using a spacer height of 23mm or greater, the **Freehand Holder** must be used for implant insertion.*

Loading the Spacer

To assemble the Triple Barrel Anchor Guide, insert the **Threaded Rod** into the small round hole at the proximal end.

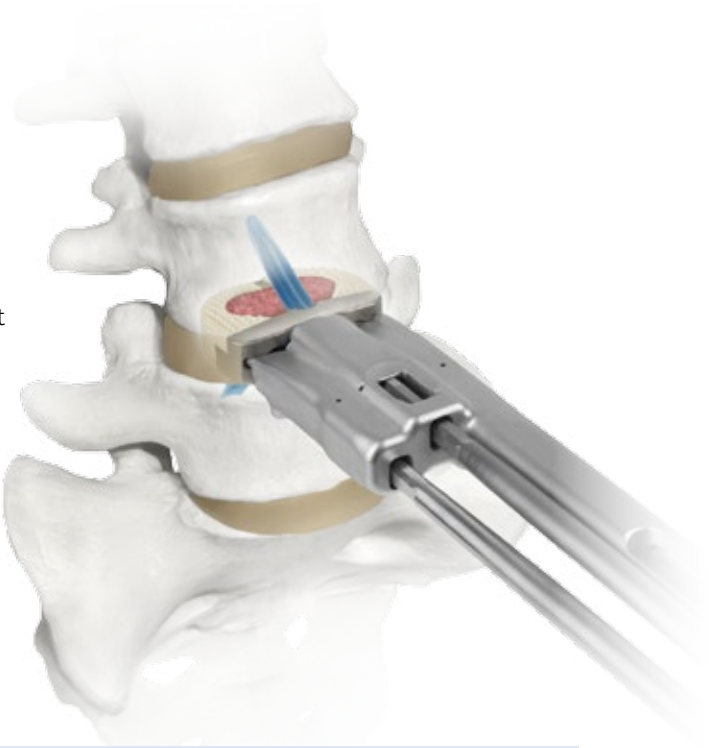
Insert the **Hex Driver** into the same hole to engage the Threaded Rod. Rotate the driver clockwise until the end of the Threaded Rod emerges from the distal end of the guide.



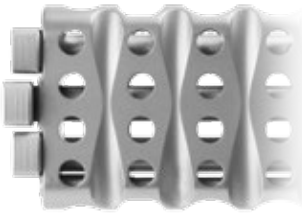
To attach the spacer, connect the hook to the spacer's hook hole. Align the Threaded Rod tip into the spacer's threaded hole. Using the Hex Driver, rotate the Threaded Rod clockwise to secure the spacer.

Step 6 Anchor Insertion

Confirm that the anterior face of the spacer is flush or recessed 1mm within the anterior portion of the vertebral body. Insert the medial **Anchor Impactor**. Gently tamp the impactor with the Hammer until the rectangular portion of the impactor is flat against the holder. Repeat for the two lateral anchors.



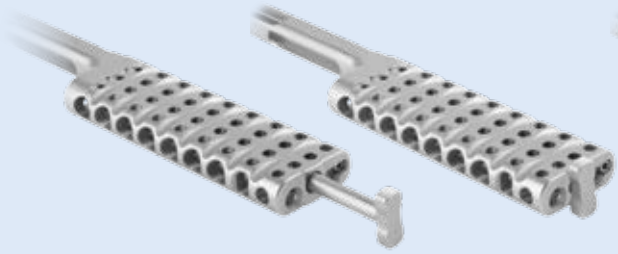
Ensure all impactors are flush with the holder



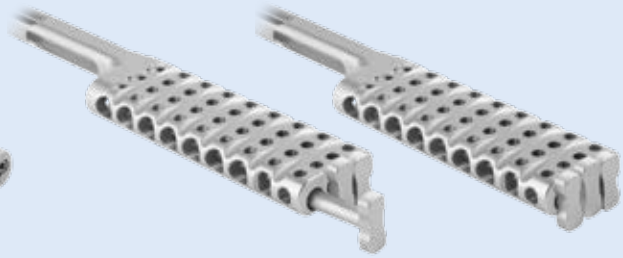
Inserting the Anchor Impactor

Insert an Anchor Impactor into the hole at the proximal end of the Triple Barrel Anchor Guide. Press down to advance the anchor to the vertebral endplate. Gently impact with the Hammer to advance each anchor into the vertebral body.

Please note that the two lateral impactors sit 0.5mm lower than the center impactor.



Inserting the first anchor



Inserting the remaining anchors

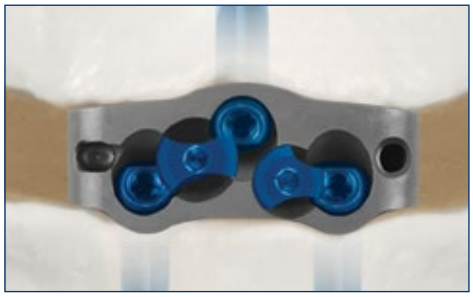
Disengaging the Anchor Guide

Following spacer and anchor insertion, remove the guide. To release the spacer, rotate the Threaded Rod counterclockwise using the Hex Driver. Gently rock the guide medial/lateral to release.

Step 7 Anchor Blocking

Once the anchors are fully seated, insert the **Set Screw Positioner, Torque Limiting** into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). The positioner provides audible, visual, and tactile confirmation that the screw is blocked.

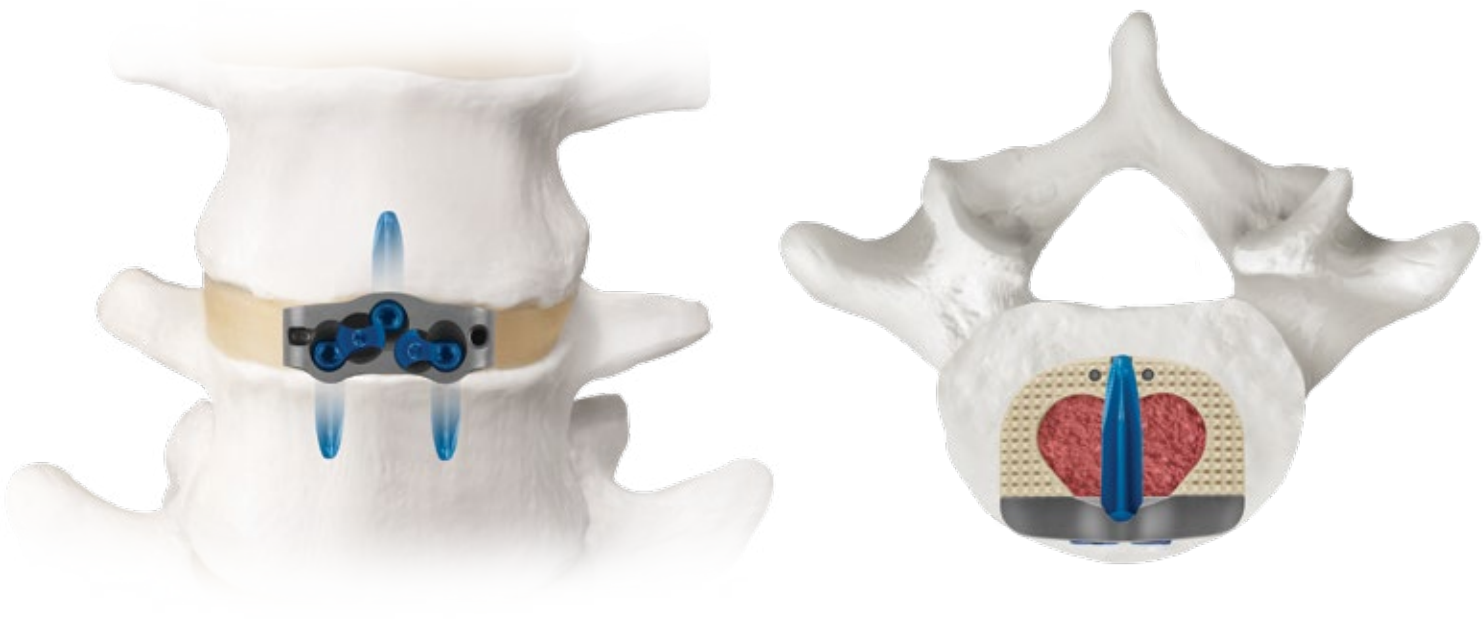
Initial Position



Final Position (Blocked)

Step 8 Final Position

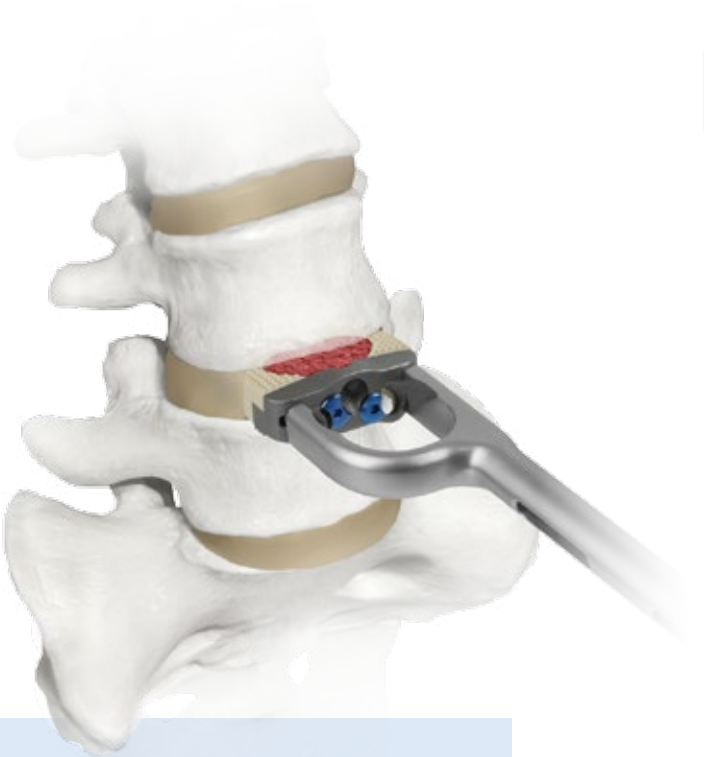
The final implant position is shown below. Supplemental fixation (e.g. facet screws or posterior fixation) is required when the INDEPENDENCE MIS® Spacer is used with anchors (see Step 9, page 20).



INDEPENDENCE MIS® with Anchors

Use with Screws

Step 4 Spacer Insertion



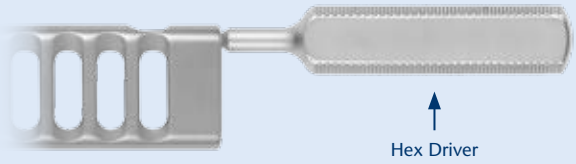
Select an appropriately sized INDEPENDENCE MIS® spacer and pack with autogenous bone graft material. Attach the spacer to the **Freehand Holder**.

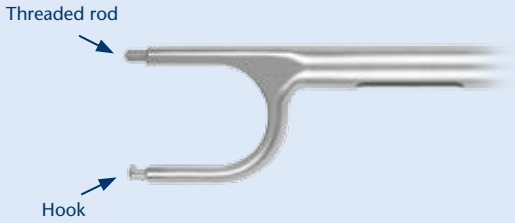
Insert the spacer into the prepared disc space. A Hammer may be used to gently position the spacer within the disc space. The spacer should sit flush or recessed 1mm within the anterior portion of the vertebral bodies.

Loading the Freehand Holder

To assemble the Freehand Holder, insert the Threaded Rod into the hole at the proximal end of the holder.

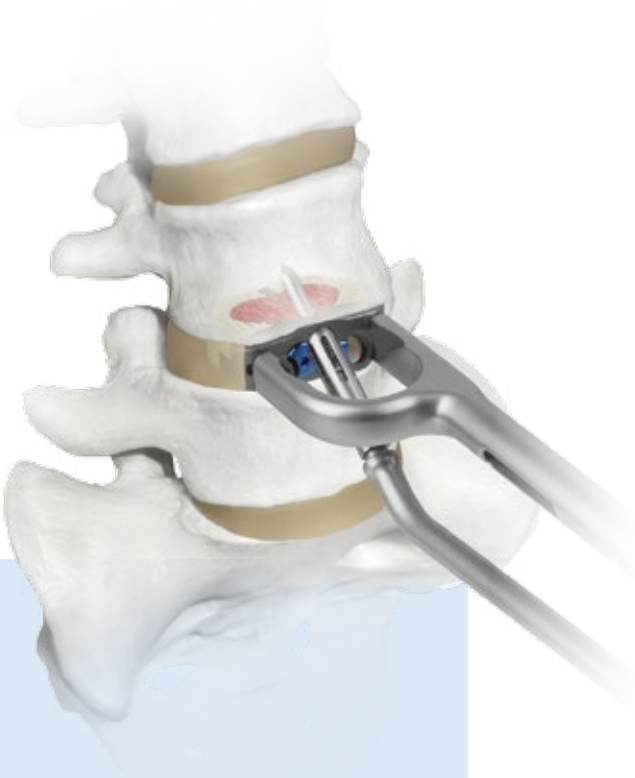
Insert the Hex Driver into the hole at the proximal end of the holder. Engage the Threaded Rod and rotate the driver clockwise until the end of the rod emerges from the distal end of the holder.





To attach the spacer, connect the hook on the holder into the spacer's hook hole. Align the Threaded Rod tip into the spacer's threaded hole. Using the Hex Driver, rotate the Threaded Rod clockwise to secure the spacer.

Step 5 Screw Hole Preparation



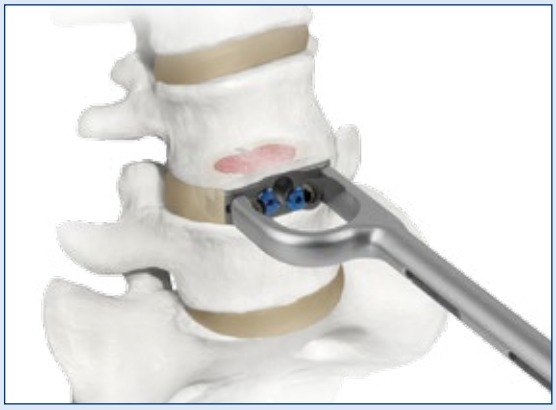
Insert a **Self-Centering Awl** to break the cortex. A **Self-Centering Drill** and **Tap** may be used to further prepare the screw hole. Fixed angle screws are used with self-centering instruments, while variable angle screws can be inserted freehand.

Angled instrument assembly instructions are available on pages 23–24.

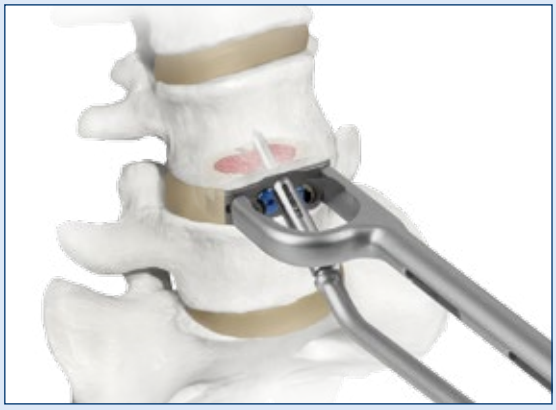
Using the Self-Centering Instruments

Self-centering awls (bent and straight) and drills are available for screw trajectories of 35° cephalad/caudal.

Insert a self-centering awl to break the cortex. A self-centering drill and tap may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument can be used.



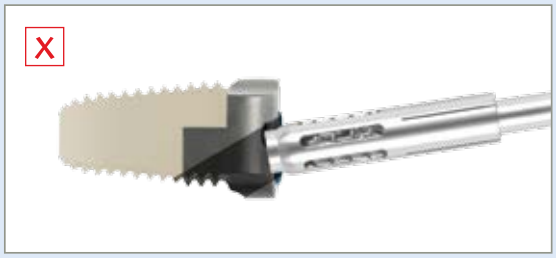
Freehand inserter



Self-Centering Bent Awl
with Retracting Front Sleeve

Aligning the Self-Centering Sleeve

The self-centering sleeve ensures proper screw trajectory without use of a drill guide. The sleeve must be properly engaged with the plate before advancing any screw hole preparation instruments. Proceed to screw insertion before preparing the remaining hole.

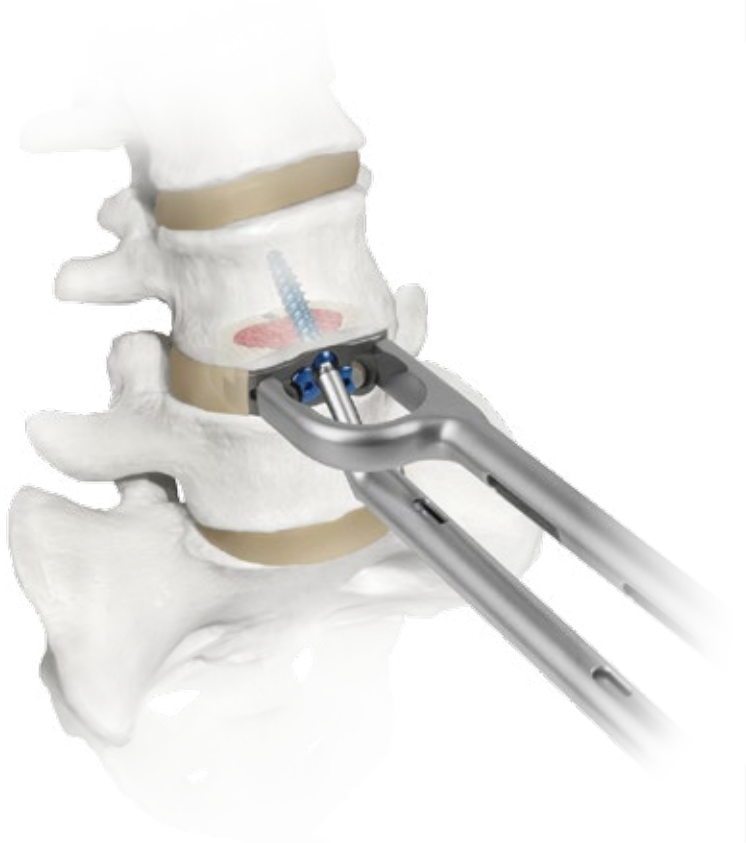


Step 6 Screw Insertion

Depending on the angle and position of the spacer, a Straight or Angled Driver may be used. If drilling is preferred, determine the desired drill depth and select the appropriate fixed length drill. Insert the drill into the screw hole and drill to the stop.

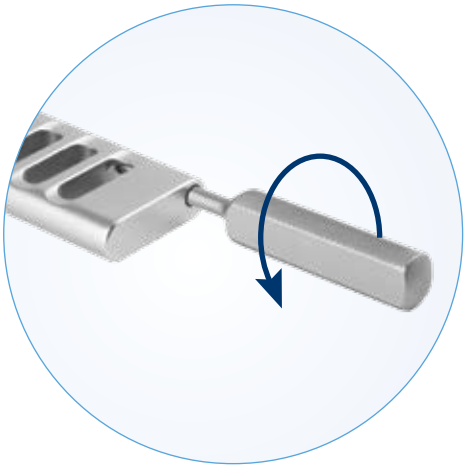
Select the desired screw size using the sizing chart on page 27. Load the screw onto the driver and insert the screw. The spacer lags to the bone during screw insertion. Repeat for the second screw.

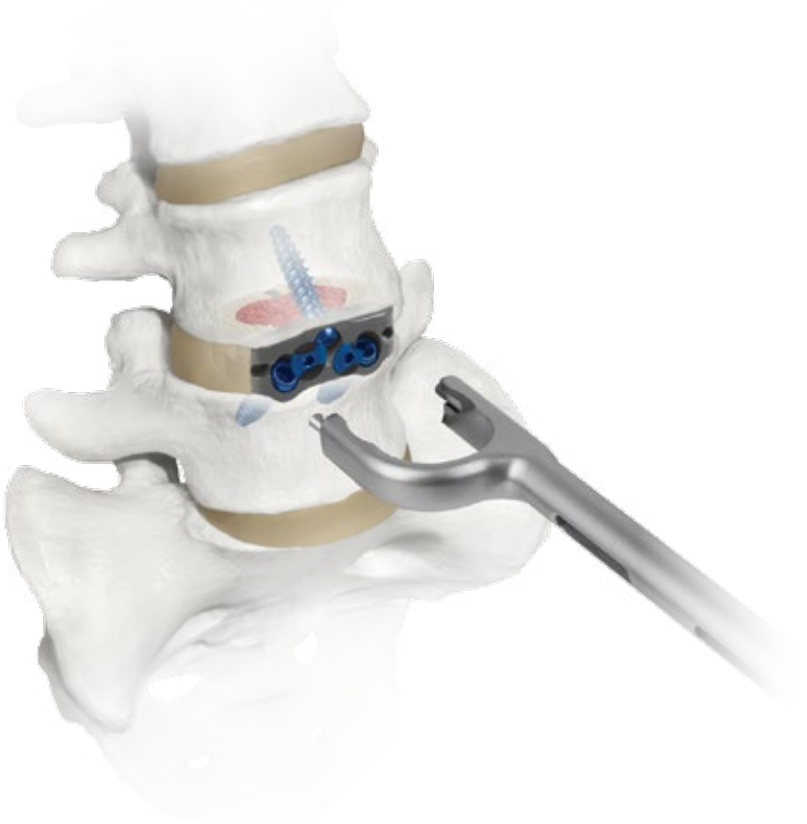
Note: If inserting screws with the Freehand Holder attached, the 3.5mm Angled Hex Driver, Long will need to be used.



Disengaging the Freehand Holder

Remove the Freehold Holder after spacer and screw insertion. To release the spacer, rotate the Threaded Rod counterclockwise using the Hex Driver. Gently rock the inserter medial/lateral to release.





Step 7 Screw Blocking

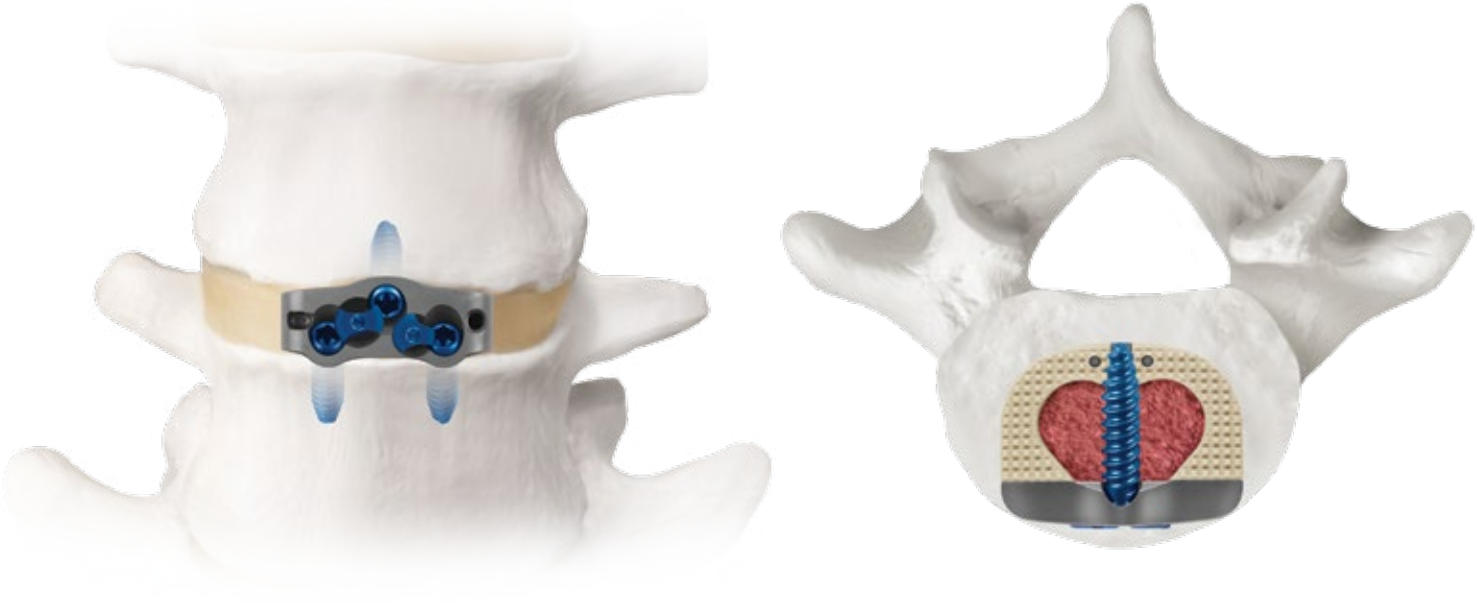
Once the screws are fully seated, insert the **Set Screw Positioner, Torque Limiting** into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). The positioner provides audible, visual, and tactile confirmation that the screw is blocked.

Initial Position

Final Position (Blocked)

Step 8 Final Position

The final implant position is shown below (see Step 9, page 20).



INDEPENDENCE MIS® with Screws

Use with Hybrid Screw/Anchor Fixation

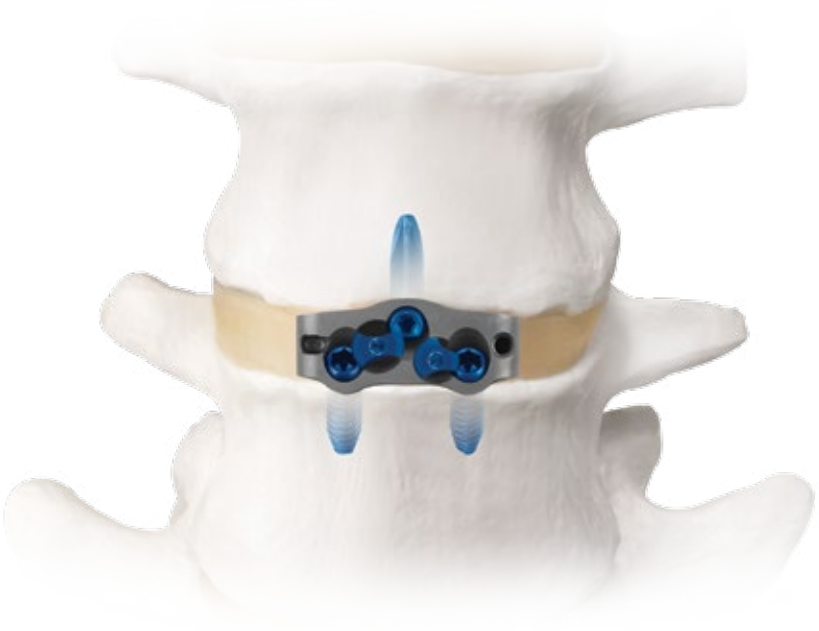
If a hybrid screw/anchor construct is desired, follow steps 1-3 for disc prep and implant sizing.

For anchor fixation, follow steps 4-7 on pages 12-15.

For screw fixation, follow steps 4-7 on pages 16-19.

Step 8 Final Position

The final implant position is shown below. Supplemental fixation (e.g. facet screws or posterior fixation) is required when the INDEPENDENCE MIS® Spacer is used with anchors (see below, Step 9).



Hybrid Final Construct

Step 9 Supplemental Fixation

Supplemental fixation (e.g. facet screws or posterior fixation) is required when the INDEPENDENCE MIS® Spacer is used with one or more anchors or when hyperlordotic spacers (≥25°) are used. Refer to the surgical technique guide for the selected supplemental fixation for specific instructions.

Optional: Removal

To remove the INDEPENDENCE MIS® implant, begin by unblocking the locking set screw using the Set Screw Positioner.

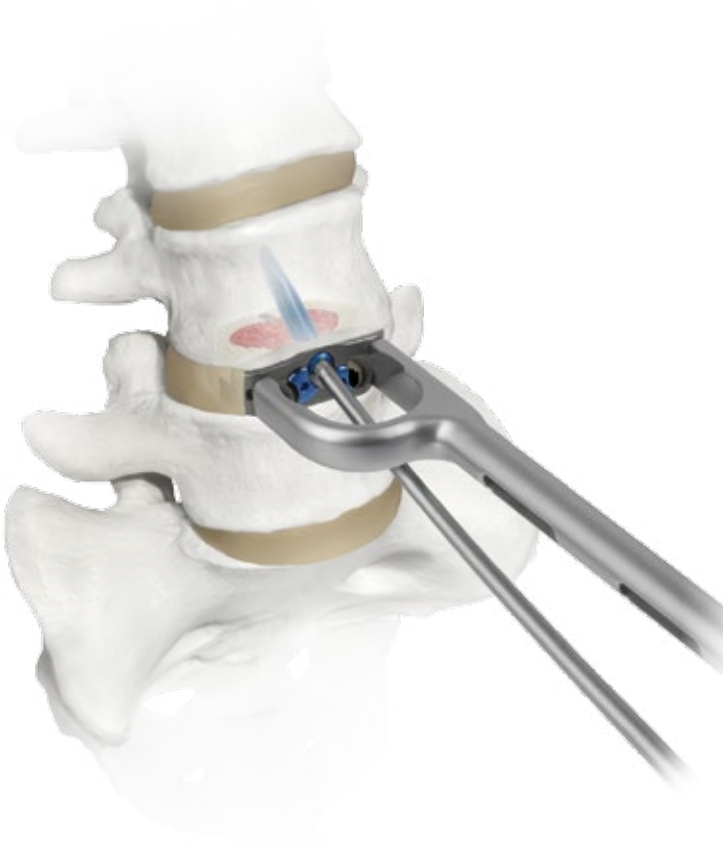
Screws

Remove bone screws using the Driver.

Anchors

The Freehand Holder may be used to help grip the spacer during anchor removal. Attach the holder to the spacer as described in step 4 on page 16. Thread the **Anchor Removal Tool (Disposable)** into the head of the anchor until fully seated.

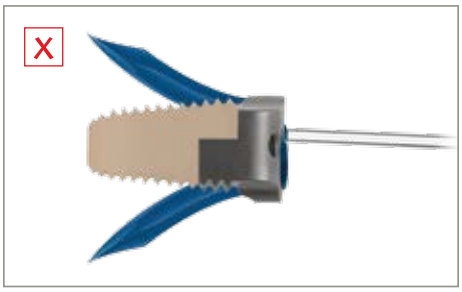
Unblocking the locking set screw using the Set Screw Positioner

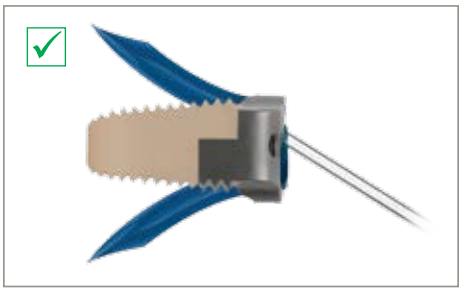


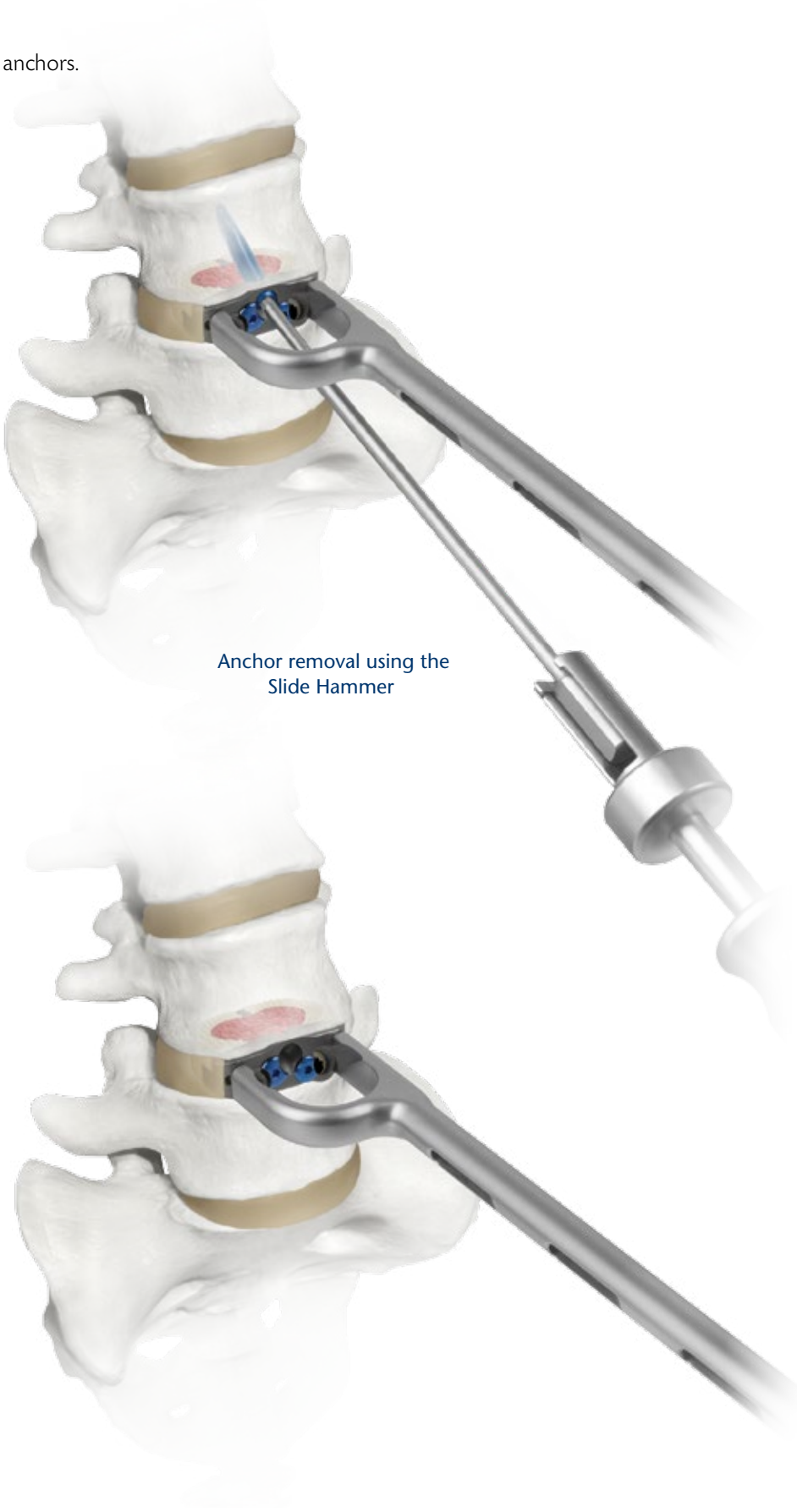
Anchor removal using the Freehand Holder and Removal Tool

Optional: Removal (cont'd)

Use the **Slide Hammer** to gently remove the anchors.







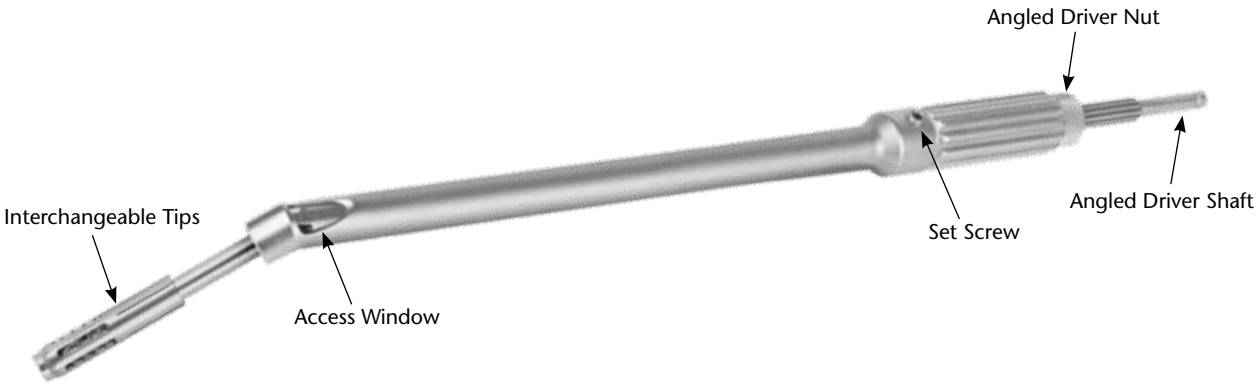
Anchor removal using the Slide Hammer

Remove the spacer using the Freehand Holder, forceps, or other manual surgical instruments.

Anchors may be replaced by screws for revision surgery.

ANGLED INSTRUMENT ASSEMBLY

Angled instruments are provided preassembled. Two additional driver tips are available for use and must be assembled. The counter torque may be attached to the driver to provide greater control of the distal tip. To disassemble, follow assembly steps in reverse order.



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

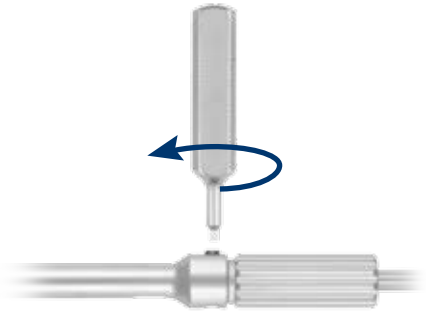
Hold the **Angled Driver Body** downward with the access window facing upward. Insert the selected tip into the window on the distal end of the driver.

ANGLED INSTRUMENT ASSEMBLY (CONT'D)

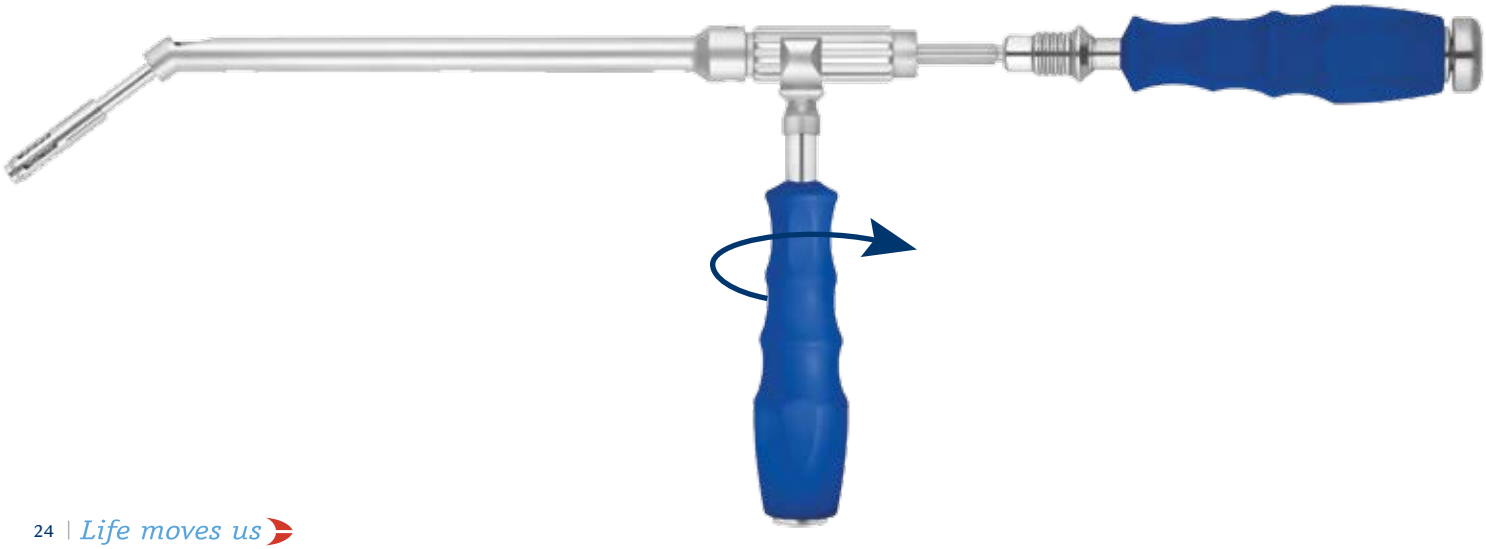
Insert the **Angled Driver Shaft** until the gears on the shaft mate with the gears on the selected tip.

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 the Hex Driver clockwise until finger tight.



Attach a quick connect handle. Optionally attach the counter torque.



ADDITIONAL SPECIFICATIONS

INDEPENDENCE MIS® Graft Volumes

Small 8° (24x30mm)	
Part Number	**Graft Volume (cc)**
3135.0111	2.3
3135.0113	2.7
3135.0115	3.1
3135.0117	3.6
Medium 8° (26x34mm)	
Part Number	**Graft Volume (cc)**
3135.0611	3.0
3135.0613	3.6
3135.0615	4.2
3135.0617	4.7
3135.0619	5.3
3135.0621	5.9
Large 8° (29x39mm)	
Part Number	**Graft Volume (cc)**
3135.1111	3.7
3135.1113	4.4
3135.1115	5.1
3135.1117	5.8
3135.1119	6.5
3135.1121	7.2

Small 15° (24x30mm)	
Part Number	**Graft Volume (cc)**
3135.0211	2.2
3135.0213	2.7
3135.0215	3.1
3135.0217	3.5
Medium 15° (26x34mm)	
Part Number	**Graft Volume (cc)**
3135.0711	2.9
3135.0713	3.7
3135.0715	4.0
3135.0717	4.6
3135.0719	5.2
3135.0721	5.7
Large 15° (29x39mm)	
Part Number	**Graft Volume (cc)**
-	-
3135.1213	4.2
3135.1215	4.9
3135.1217	5.6
3135.1219	6.3
3135.1221	7.0

Small 20° (24x30mm)*	
Part Number	**Graft Volume (cc)**
-	-
3135.0313	2.6
3135.0315	3.0
3135.0317	3.5
Medium 20° (26x34mm)*	
Part Number	**Graft Volume (cc)**
-	-
3135.0813	3.4
3135.0815	4.0
3135.0817	4.5
3135.0819	5.1
3135.0821	5.7
Large 20° (29x39mm)*	
Part Number	**Graft Volume (cc)**
-	-
-	-
3135.1315	4.8
3135.1317	5.5
3135.1319	6.2
3135.1321	6.9

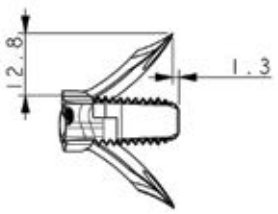
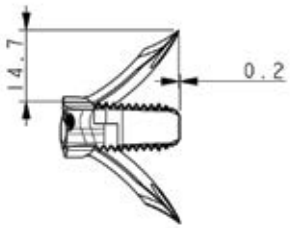
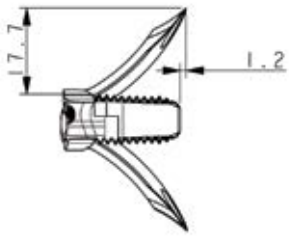
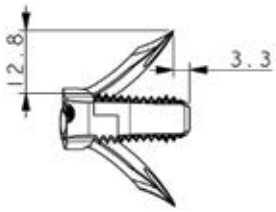
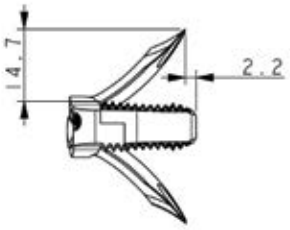
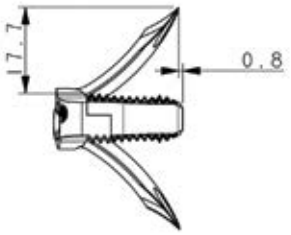
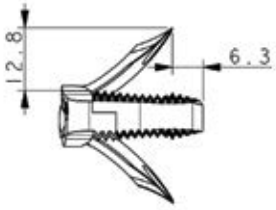
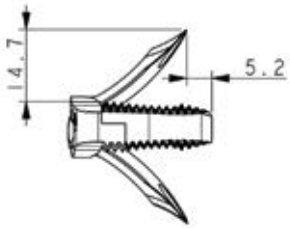
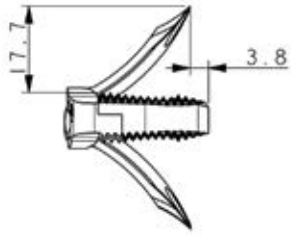
Small 25° (24x30mm)*	
Part Number	**Graft Volume (cc)**
3135.0415	2.5
3135.0417	2.9
3135.0419	3.4
3135.0421	3.8
Medium 25° (26x34mm)*	
Part Number	**Graft Volume (cc)**
3135.0915	3.2
3135.0917	3.8
3135.0919	4.4
3135.0921	4.9
Large 25° (29x39mm)*	
Part Number	**Graft Volume (cc)**
3135.1417	4.6
3135.1419	5.3
3135.1421	6.0

Small 30° (24x30mm)*	
Part Number	**Graft Volume (cc)**
3135.0515	2.5
3135.0517	2.9
3135.0519	3.3
3135.0521	3.7
Medium 30° (26x34mm)*	
Part Number	**Graft Volume (cc)**
–	–
3135.1017	3.7
3135.1019	4.3
3135.1021	4.9
Large 30° (29x39mm)*	
Part Number	**Graft Volume (cc)**
3135.1521	5.9
3135.1523	6.6
3135.1525	7.3

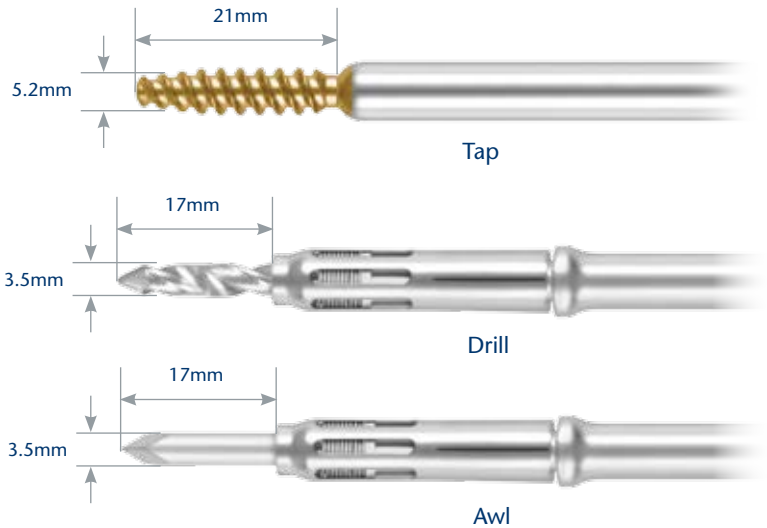
**Additionally Available*

ADDITIONAL SPECIFICATIONS

Anchor Sizing Chart

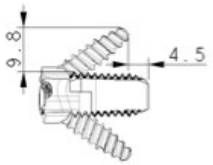
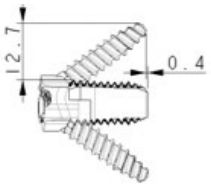
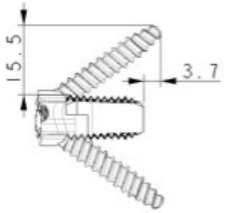
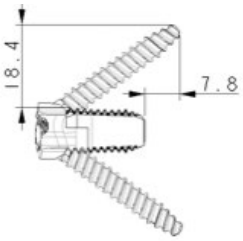
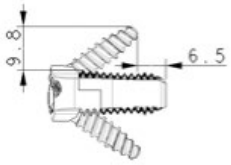
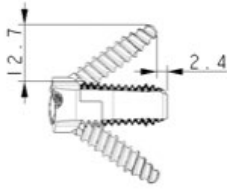
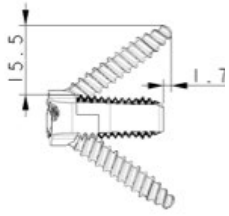
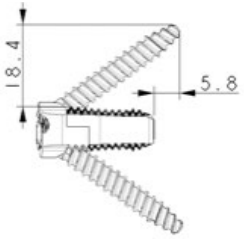
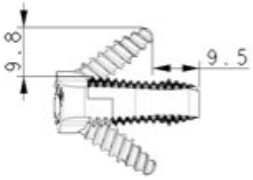
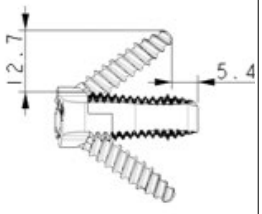
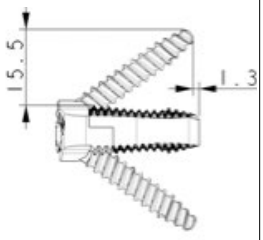
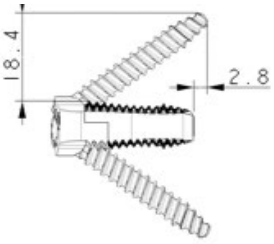
Anchors	25mm	27mm	30mm
24x30mm			
26x34mm			
29x39mm			

INDEPENDENCE MIS® Drill, Awl and Tap: Dimensions



ADDITIONAL SPECIFICATIONS

Screw Sizing Chart

Screws	20mm	25mm	30mm	35mm
24x30mm				
26x34mm				
29x39mm				

INDEPENDENCE MIS® Spacer, 24x30mm Set

INDEPENDENCE MIS® Spacer, 26x34mm Set

INDEPENDENCE MIS® Spacer, 24x30mm Set 9135.9002

Part No.	Description	Qty
3135.0111	INDEPENDENCE MIS® 24x30mm, 8°, 11mm	2
3135.0113	INDEPENDENCE MIS® 24x30mm, 8°, 13mm	2
3135.0115	INDEPENDENCE MIS® 24x30mm, 8°, 15mm	2
3135.0117	INDEPENDENCE MIS® 24x30mm, 8°, 17mm	2
3135.0211	INDEPENDENCE MIS® 24x30mm, 15°, 11mm	1
3135.0213	INDEPENDENCE MIS® 24x30mm, 15°, 13mm	1
3135.0215	INDEPENDENCE MIS® 24x30mm, 15°, 15mm	1
3135.0217	INDEPENDENCE MIS® 24x30mm, 15°, 17mm	1
9135.0002	INDEPENDENCE MIS® Implant Module, 24x30mm	

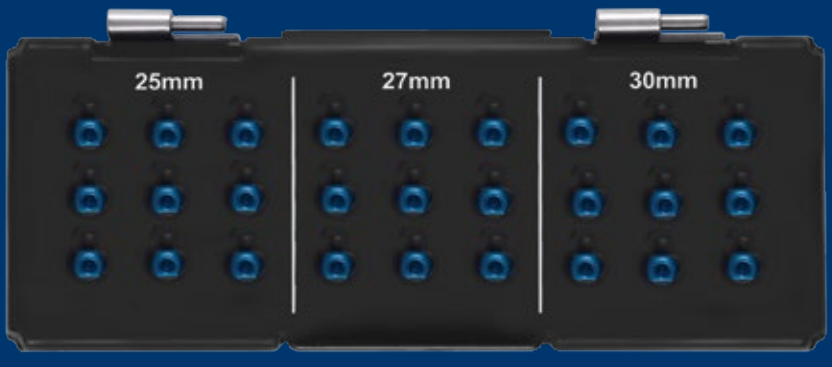
INDEPENDENCE MIS® Spacer, 26x34mm Set 9135.9003

Part No.	Description	Qty
3135.0611	INDEPENDENCE MIS® 26x34mm, 8°, 11mm	2
3135.0613	INDEPENDENCE MIS® 26x34mm, 8°, 13mm	2
3135.0615	INDEPENDENCE MIS® 26x34mm, 8°, 15mm	2
3135.0617	INDEPENDENCE MIS® 26x34mm, 8°, 17mm	2
3135.0619	INDEPENDENCE MIS® 26x34mm, 8°, 19mm	2
3135.0621	INDEPENDENCE MIS® 26x34mm, 8°, 21mm	2
3135.0711	INDEPENDENCE MIS® 26x34mm, 15°, 11mm	1
3135.0713	INDEPENDENCE MIS® 26x34mm, 15°, 13mm	1
3135.0715	INDEPENDENCE MIS® 26x34mm, 15°, 15mm	1
3135.0717	INDEPENDENCE MIS® 26x34mm, 15°, 17mm	1
3135.0719	INDEPENDENCE MIS® 26x34mm, 15°, 19mm	1
3135.0721	INDEPENDENCE MIS® 26x34mm, 15°, 21mm	1
9135.0003	INDEPENDENCE MIS® Implant Module, 26x34mm	

Items listed in gray are additionally available.

INDEPENDENCE MIS® Spacer, 29x39mm Set

Lumbar Anchor Set



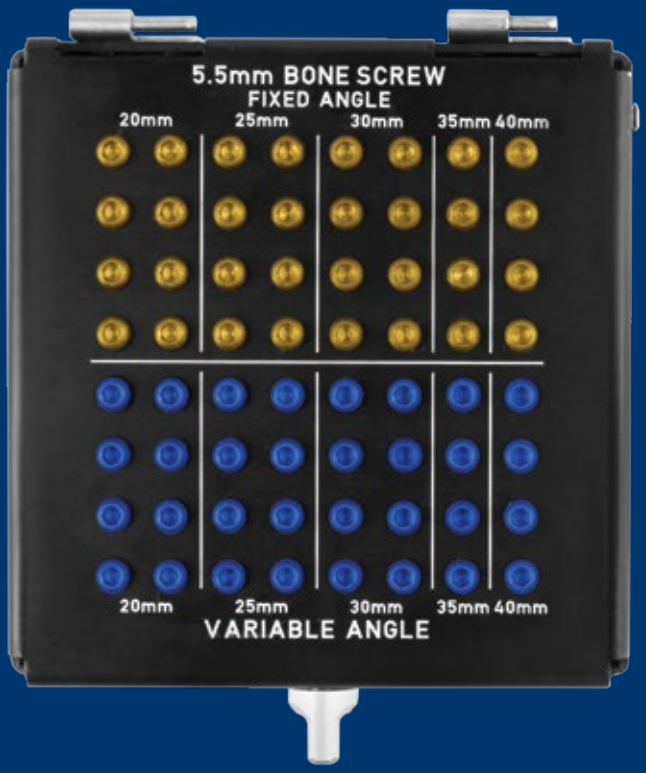
INDEPENDENCE MIS® Spacer, 29x39mm Set 9135.9004

Part No.	Description	Qty
3135.1111	INDEPENDENCE MIS® 29x39mm, 8°, 11mm	2
3135.1113	INDEPENDENCE MIS® 29x39mm, 8°, 13mm	2
3135.1115	INDEPENDENCE MIS® 29x39mm, 8°, 15mm	2
3135.1117	INDEPENDENCE MIS® 29x39mm, 8°, 17mm	2
3135.1119	INDEPENDENCE MIS® 29x39mm, 8°, 19mm	2
3135.1121	INDEPENDENCE MIS® 29x39mm, 8°, 21mm	2
3135.1213	INDEPENDENCE MIS® 29x39mm, 15°, 13mm	1
3135.1215	INDEPENDENCE MIS® 29x39mm, 15°, 15mm	1
3135.1217	INDEPENDENCE MIS® 29x39mm, 15°, 17mm	1
3135.1219	INDEPENDENCE MIS® 29x39mm, 15°, 19mm	1
3135.1221	INDEPENDENCE MIS® 29x39mm, 15°, 21mm	1
9135.0004	INDEPENDENCE MIS® Implant Module, 29x39mm	

Lumbar Anchor Set 9135.9005

Part No.	Description	Qty
1135.0020	Lumbar Anchor, 20mm	0
1135.0025	Lumbar Anchor, 25mm	9
1135.0027	Lumbar Anchor, 27mm	9
1135.0030	Lumbar Anchor, 30mm	9
9135.0005	Lumbar Module	

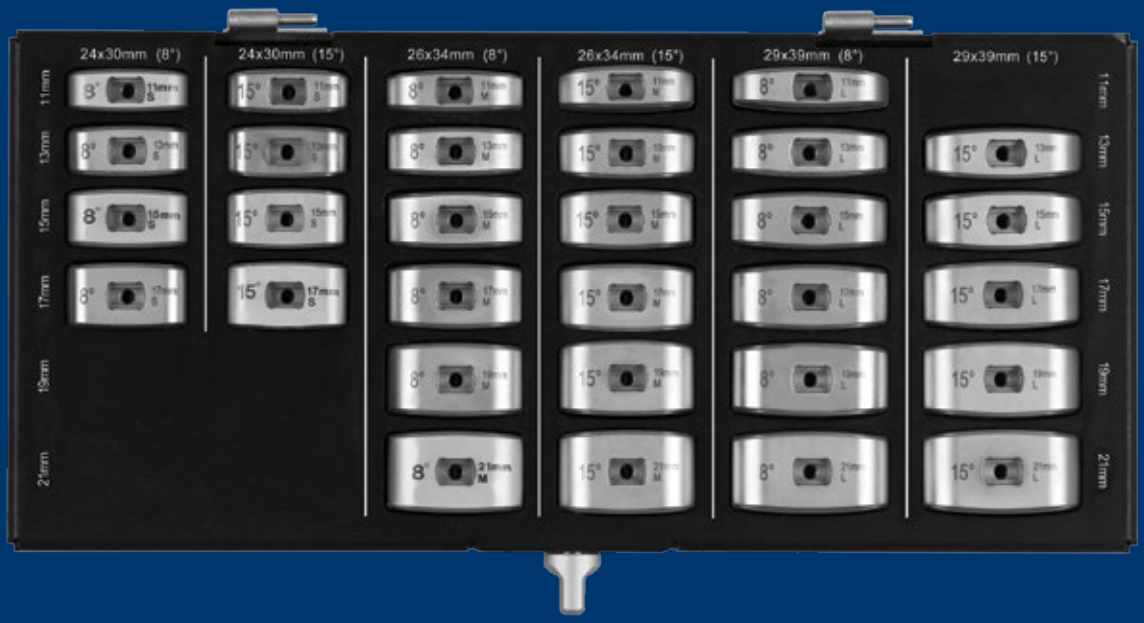
ALIF Bone Screw Set



ALIF Bone Screw Set 925.907

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

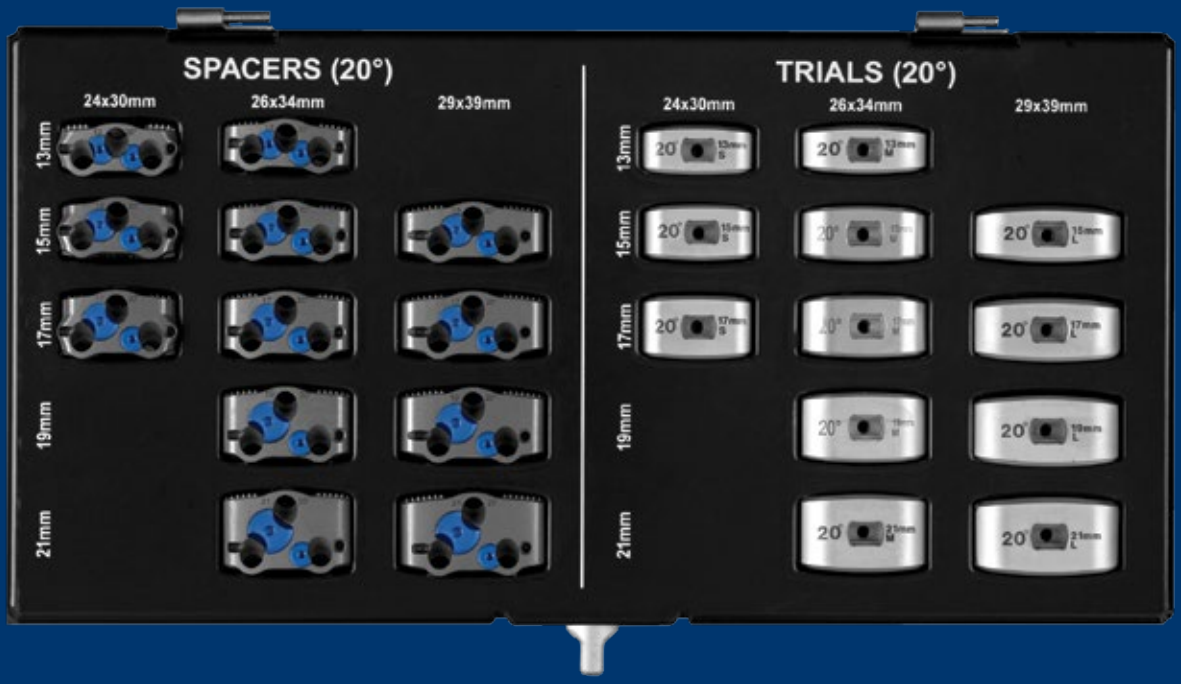
INDEPENDENCE MIS® Trial Set



INDEPENDENCE MIS® Trial Set 9135.9006

Part No.	Description	Qty
676.111	INDEPENDENCE® Trial, Small, 8°, 11mm	1
676.113	INDEPENDENCE® Trial, Small, 8°, 13mm	1
676.115	INDEPENDENCE® Trial, Small, 8°, 15mm	1
676.117	INDEPENDENCE® Trial, Small, 8°, 17mm	1
676.211	INDEPENDENCE® Trial, Small, 15°, 11mm	1
676.213	INDEPENDENCE® Trial, Small, 15°, 13mm	1
676.215	INDEPENDENCE® Trial, Small, 15°, 15mm	1
676.217	INDEPENDENCE® Trial, Small, 15°, 17mm	1
676.411	INDEPENDENCE® Trial, Medium, 8°, 11mm	1
676.413	INDEPENDENCE® Trial, Medium, 8°, 13mm	1
676.415	INDEPENDENCE® Trial, Medium, 8°, 15mm	1
676.417	INDEPENDENCE® Trial, Medium, 8°, 17mm	1
676.419	INDEPENDENCE® Trial, Medium, 8°, 19mm	1
676.421	INDEPENDENCE® Trial, Medium, 8°, 21mm	1
676.511	INDEPENDENCE® Trial, Medium, 15°, 11mm	1
676.513	INDEPENDENCE® Trial, Medium, 15°, 13mm	1
676.515	INDEPENDENCE® Trial, Medium, 15°, 15mm	1
676.517	INDEPENDENCE® Trial, Medium, 15°, 17mm	1
676.519	INDEPENDENCE® Trial, Medium, 15°, 19mm	1
676.521	INDEPENDENCE® Trial, Medium, 15°, 21mm	1
676.711	INDEPENDENCE® Trial, Large, 8°, 11mm	1
676.713	INDEPENDENCE® Trial, Large, 8°, 13mm	1
676.715	INDEPENDENCE® Trial, Large, 8°, 15mm	1
676.717	INDEPENDENCE® Trial, Large, 8°, 17mm	1
676.719	INDEPENDENCE® Trial, Large, 8°, 19mm	1
676.721	INDEPENDENCE® Trial, Large, 8°, 21mm	1
676.813	INDEPENDENCE® Trial, Large, 15°, 13mm	1
676.815	INDEPENDENCE® Trial, Large, 15°, 15mm	1
676.817	INDEPENDENCE® Trial, Large, 15°, 17mm	1
676.819	INDEPENDENCE® Trial, Large, 15°, 19mm	1
676.821	INDEPENDENCE® Trial, Large, 15°, 21mm	1
9135.0006	INDEPENDENCE MIS® Trial Module	

INDEPENDENCE MIS® 20° Set



INDEPENDENCE MIS® 20° Set 9135.9007

Part No.	Description	Qty
3135.0313	INDEPENDENCE MIS® 24x30mm, 20°, 13mm	1
3135.0315	INDEPENDENCE MIS® 24x30mm, 20°, 15mm	1
3135.0317	INDEPENDENCE MIS® 24x30mm, 20°, 17mm	1
3135.0813	INDEPENDENCE MIS® 26x34mm, 20°, 13mm	1
3135.0815	INDEPENDENCE MIS® 26x34mm, 20°, 20mm	1
3135.0817	INDEPENDENCE MIS® 26x34mm, 20°, 17mm	1
3135.0819	INDEPENDENCE MIS® 26x34mm, 20°, 19mm	1
3135.0821	INDEPENDENCE MIS® 26x34mm, 20°, 21mm	1
3135.1315	INDEPENDENCE MIS® 29x39mm, 20°, 15mm	1
3135.1317	INDEPENDENCE MIS® 29x39mm, 20°, 17mm	1
3135.1319	INDEPENDENCE MIS® 29x39mm, 20°, 19mm	1
3135.1321	INDEPENDENCE MIS® 29x39mm, 20°, 21mm	1
676.233	INDEPENDENCE® Trial, Small, 20°, 13mm	1
676.235	INDEPENDENCE® Trial, Small, 20°, 15mm	1
676.237	INDEPENDENCE® Trial, Small, 20°, 17mm	1
676.533	INDEPENDENCE® Trial, Medium, 20°, 13mm	1
676.535	INDEPENDENCE® Trial, Medium, 20°, 15mm	1
676.537	INDEPENDENCE® Trial, Medium, 20°, 17mm	1
676.539	INDEPENDENCE® Trial, Medium, 20°, 19mm	1
676.541	INDEPENDENCE® Trial, Medium, 20°, 21mm	1
676.835	INDEPENDENCE® Trial, Large, 20°, 15mm	1
676.837	INDEPENDENCE® Trial, Large, 20°, 17mm	1
676.839	INDEPENDENCE® Trial, Large, 20°, 19mm	1
676.841	INDEPENDENCE® Trial, Large, 20°, 21mm	1
9135.0007	INDEPENDENCE MIS® 20° Implant/Trial Module	

INDEPENDENCE MIS® 25° Set 9135.9009

Part No.	Description
3135.0415	INDEPENDENCE MIS® 24x30mm, 25°, 15mm
3135.0417	INDEPENDENCE MIS® 24x30mm, 25°, 17mm
3135.0419	INDEPENDENCE MIS® 24x30mm, 25°, 19mm
3135.0421	INDEPENDENCE MIS® 24x30mm, 25°, 21mm
3135.0915	INDEPENDENCE MIS® 26x34mm, 25°, 15mm
3135.0917	INDEPENDENCE MIS® 26x34mm, 25°, 17mm
3135.0919	INDEPENDENCE MIS® 26x34mm, 25°, 19mm
3135.0921	INDEPENDENCE MIS® 26x34mm, 25°, 21mm
3135.1417	INDEPENDENCE MIS® 29x39mm, 25°, 17mm
3135.1419	INDEPENDENCE MIS® 29x39mm, 25°, 19mm
3135.1421	INDEPENDENCE MIS® 29x39mm, 25°, 21mm
676.315	INDEPENDENCE® Trial, Small, 25°, 15mm
676.317	INDEPENDENCE® Trial, Small, 25°, 17mm
676.319	INDEPENDENCE® Trial, Small, 25°, 19mm
676.321	INDEPENDENCE® Trial, Small, 25°, 21mm
676.615	INDEPENDENCE® Trial, Medium, 25°, 15mm
676.617	INDEPENDENCE® Trial, Medium, 25°, 17mm
676.619	INDEPENDENCE® Trial, Medium, 25°, 19mm
676.621	INDEPENDENCE® Trial, Medium, 25°, 21mm
676.917	INDEPENDENCE® Trial, Large, 25°, 17mm
676.919	INDEPENDENCE® Trial, Large, 25°, 19mm
676.921	INDEPENDENCE® Trial, Large, 25°, 21mm
9135.0009	INDEPENDENCE MIS® 25° Module

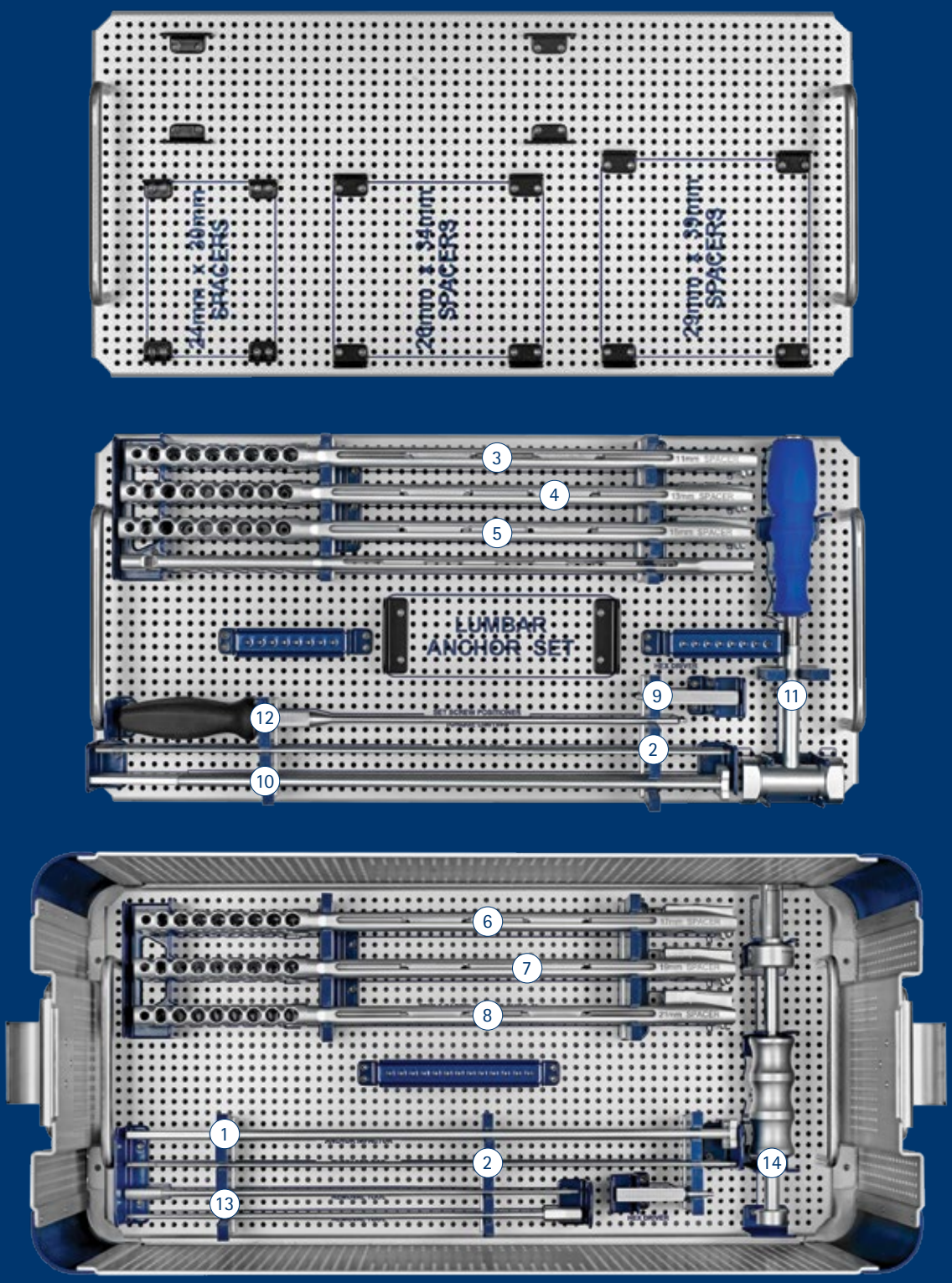
Items listed in gray are additionally available.

INDEPENDENCE MIS® 30° Set 9135.9010

Part No.	Description
3135.0515	INDEPENDENCE MIS® 24x30mm, 30°, 15mm
3135.0517	INDEPENDENCE MIS® 24x30mm, 30°, 17mm
3135.0519	INDEPENDENCE MIS® 24x30mm, 30°, 19mm
3135.0521	INDEPENDENCE MIS® 24x30mm, 30°, 21mm
3135.1017	INDEPENDENCE MIS® 26x34mm, 30°, 17mm
3135.1019	INDEPENDENCE MIS® 26x34mm, 30°, 19mm
3135.1021	INDEPENDENCE MIS® 26x34mm, 30°, 21mm
3135.1521	INDEPENDENCE MIS® 29x39mm, 30°, 21mm
3135.1523	INDEPENDENCE MIS® 29x39mm, 30°, 23mm
3135.1525	INDEPENDENCE MIS® 29x39mm, 30°, 25mm
676.355	INDEPENDENCE® Trial, Small, 30°, 15mm
676.357	INDEPENDENCE® Trial, Small, 30°, 17mm
676.359	INDEPENDENCE® Trial, Small, 30°, 19mm
676.361	INDEPENDENCE® Trial, Small, 30°, 21mm
676.667	INDEPENDENCE® Trial, Medium, 30°, 17mm
676.669	INDEPENDENCE® Trial, Medium, 30°, 19mm
676.671	INDEPENDENCE® Trial, Medium, 30°, 21mm
676.991	INDEPENDENCE® Trial, Large, 30°, 21mm
676.993	INDEPENDENCE® Trial, Large, 30°, 23mm
676.995	INDEPENDENCE® Trial, Large, 30°, 25mm
9135.0010	INDEPENDENCE MIS® 30° Module

Items listed in gray are additionally available.

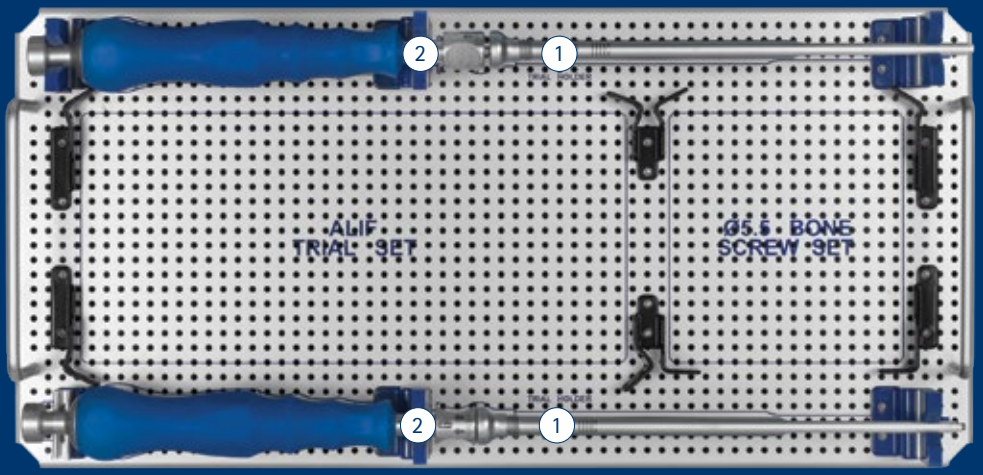
INDEPENDENCE MIS® INSTRUMENT SET

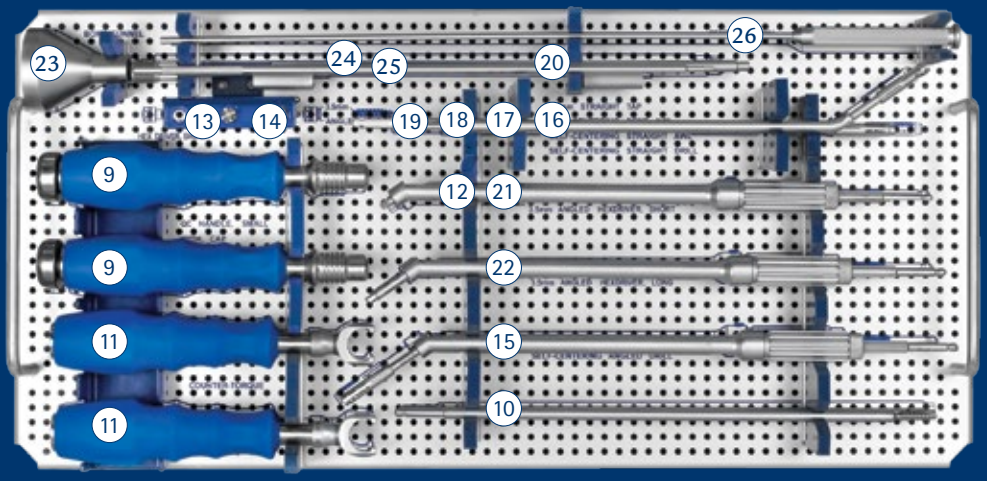


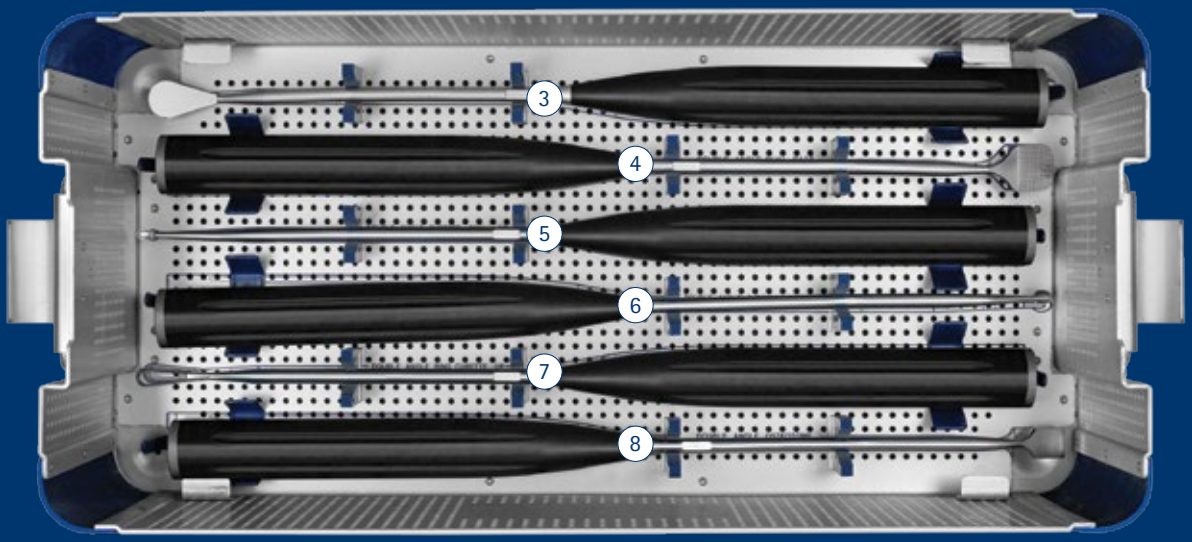
INDEPENDENCE MIS® Instrument Set 9135.9001

	Instrument		Qty
1	6135.0001	Anchor Impactor	6
2	6135.0010	Threaded Rod	6
3	6135.0011	Triple Barrel Anchor Guide 11mm	1
4	6135.0013	Triple Barrel Anchor Guide 13mm	1
5	6135.0015	Triple Barrel Anchor Guide 15mm	1
6	6135.0017	Triple Barrel Anchor Guide 17mm	1
7	6135.0019	Triple Barrel Anchor Guide 19mm	1
8	6135.0021	Triple Barrel Anchor Guide 21mm	1
9	6135.0050	Hex Driver	2
10	6135.0100	Freehand Holder	1
11	603.977	Hammer	1
12	6108.1006	MONUMENT® Set Screw Positioner, Torque Limiting	1
13	6135.0500	Removal Tool (Disposable)	4
14	614.802	Slide Hammer	1
	9135.0001	INDEPENDENCE MIS® Graphic Case	

ALIF INSTRUMENT SET



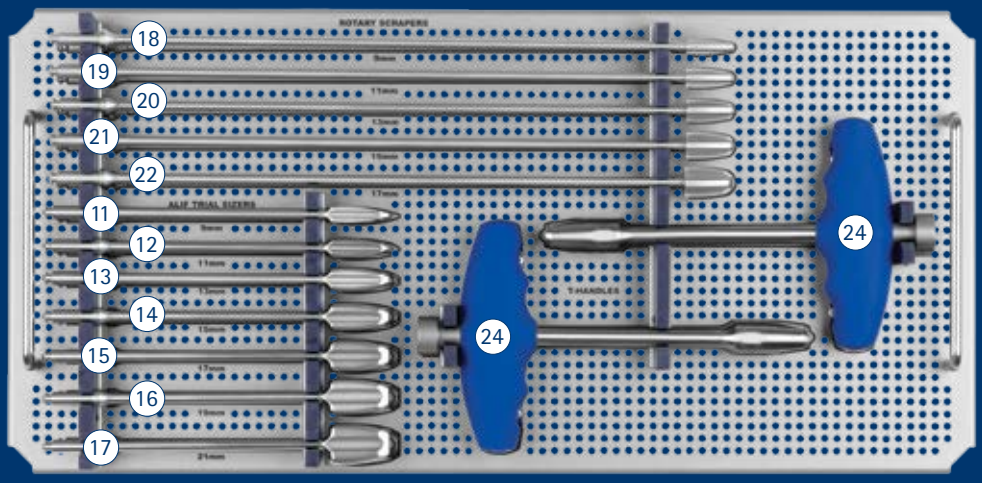


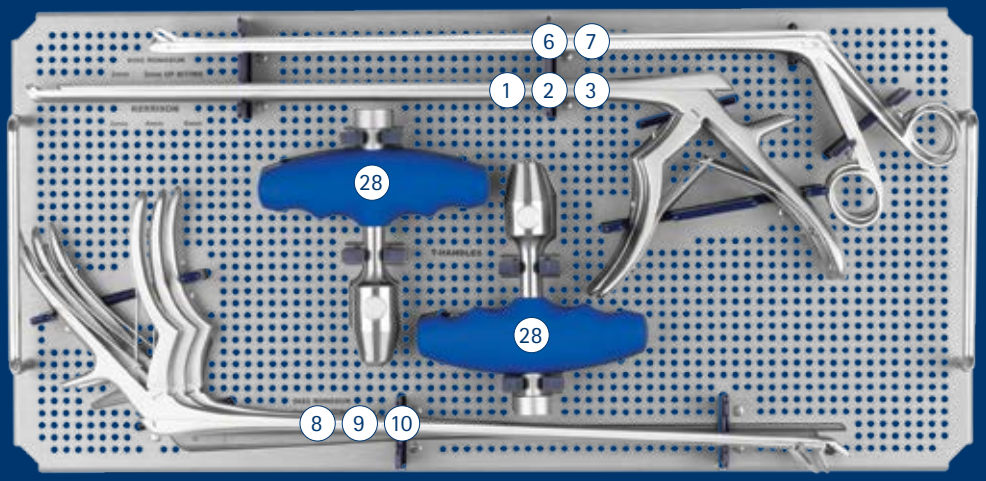


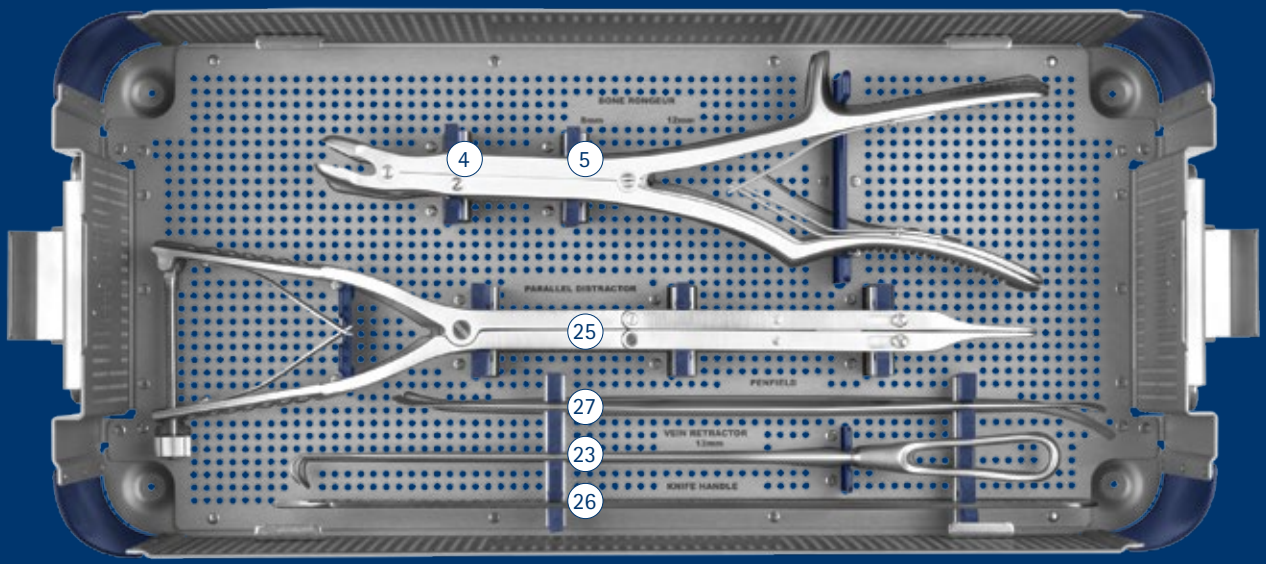
ALIF Instrument Set 925.905

	Instruments		Qty
1	6108.0001	Trial Holder Sleeve	2
2	6108.0003	Trial Holder	2
3	6108.2004	Double-Angled Cobb, 20mm, Up	1
4	6108.2005	Double-Angled Dual Rasp	1
5	6108.2007	Double Angle Curette, Small, Up	1
6	6108.2009	Double Angle Curette, Large, Up	1
7	6108.2011	Double-Angled Ring Curette, Up	1
8	6108.2012	Double-Angled Osteotome	1
9	650.105	QC Handle, Small, with Cap	2
10	676.502	3.5mm Hex Straight Driver	2
11	676.699	Counter-Torque	2
12	676.700	Angled Sleeve	3
13	676.701	Shaft	3
14	676.702	Nut	3
15	676.703	Self-Centering Angled Drill	1
16	676.704	Self-Centering Straight Drill	1
17	676.705	Self-Centering Bent Awl	1
18	676.706	Self-Centering Straight Awl	1
19	676.707	5.5mm Angled Tap	1
20	676.708	5.5mm Straight Tap	1
21	676.710	3.5mm Angled HexDriver, 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	

ANTERIOR DISC PREP I INSTRUMENT SET



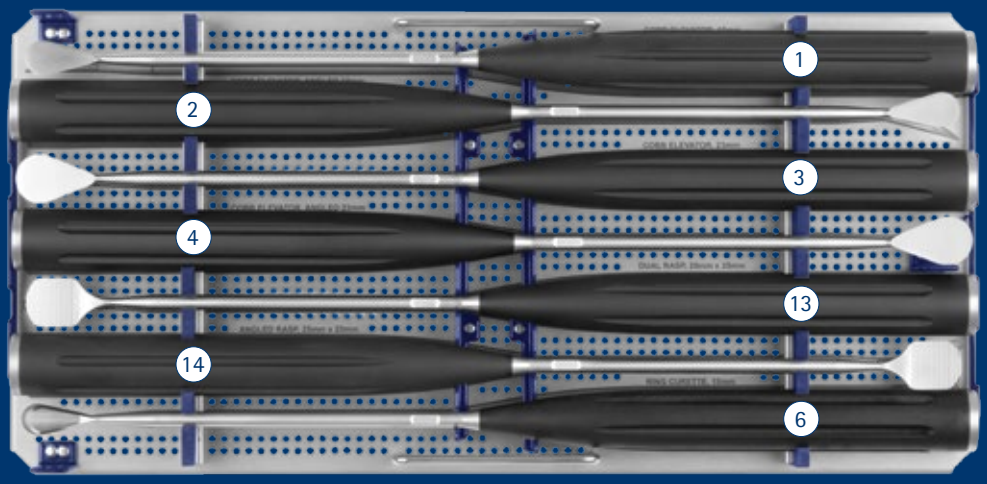


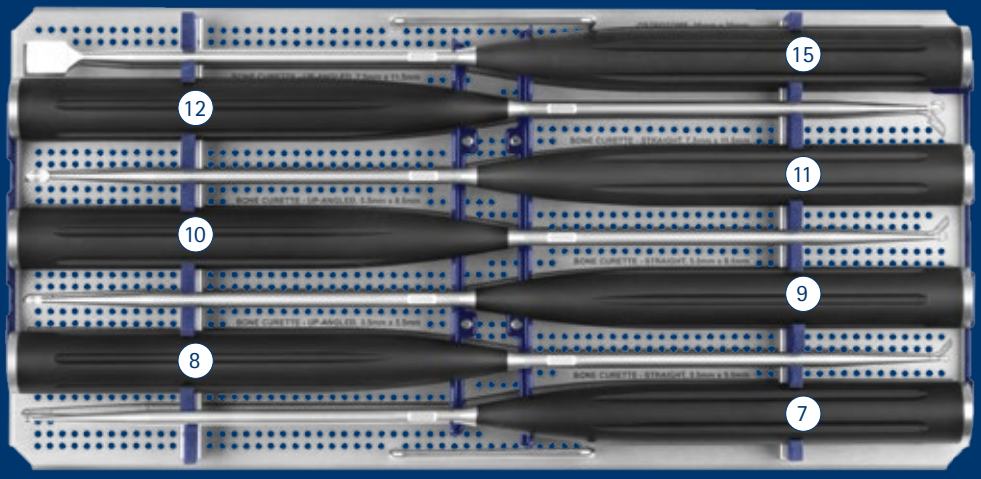


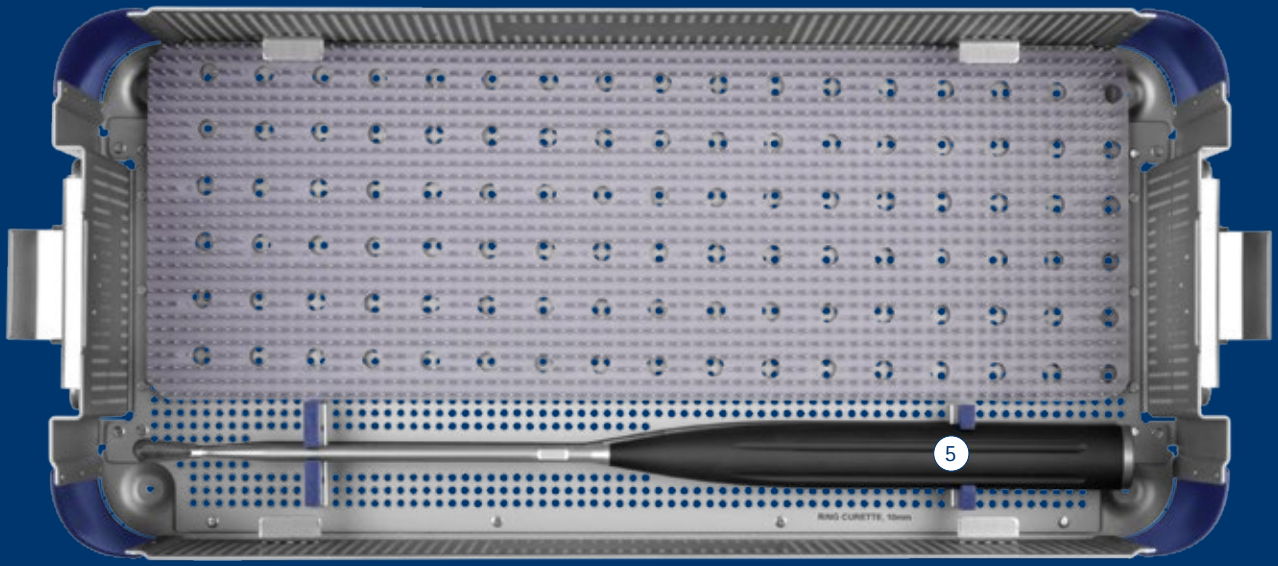
Anterior Disc Prep I Instrument Set 925.901

	Instruments		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 II INSTRUMENT SET







Anterior Disc Prep II Instrument Set 925.902

	Instruments		Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette, 3.5x5.5mm, Up-Angled	1
9	625.405	Bone Curette, 5.5x8.5mm, Straight	1
10	625.406	Bone Curette, 5.5x8.5mm, Up-Angled	1
11	625.407	Bone Curette, 7.5x11.5mm, Straight	1
12	625.408	Bone Curette, 7.5x11.5mm, Up-Angled	1
13	625.501	Dual Rasp	1
14	625.502	Angled Rasp	1
15	625.803	Osteotome, 16x20mm	1
	925.102	Graphic Case II	

Additionally Available

625.409 Bone Curette, 9.5x14.5mm, Straight

625.410 Bone Curette, 9.5x14.5mm, Up-Angled

625.411 Bone Curette, 11.5x17.5mm, Straight

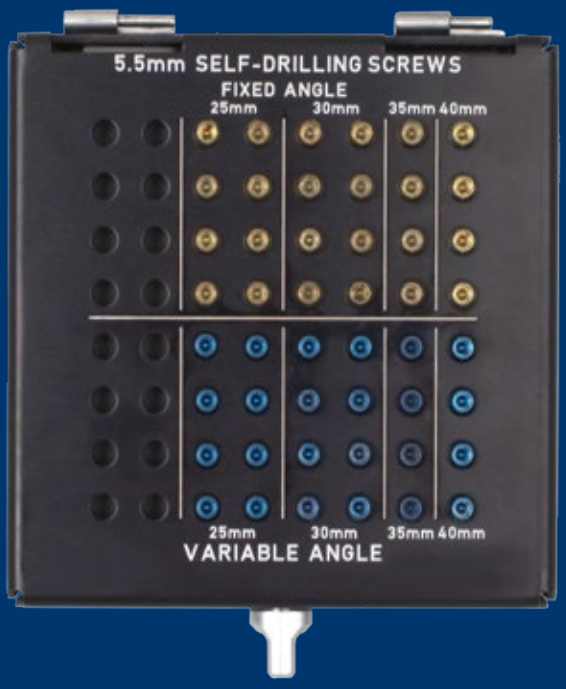
625.412 Bone Curette, 11.5x17.5mm, Up-Angled

625.413 Bone Curette, 13.5x20.5mm, Straight

625.414 Bone Curette, 13.5x20.5mm, Up-Angled

Items listed in gray are additionally available.

INDEPENDENCE® ANTERIOR BONE SCREW SET



INDEPENDENCE® Anterior Bone Screw Set

INDEPENDENCE® HA Coated Bone Screw Set 976.908		Qty
176.420S	INDEPENDENCE® HA Coated Bone Screw, Variable Angle, 20mm	9
176.425S	INDEPENDENCE® HA Coated Bone Screw, Variable Angle, 25mm	9
176.430S	INDEPENDENCE® HA Coated Bone Screw, Variable Angle, 30mm	9
176.435S	INDEPENDENCE® HA Coated Bone Screw, Variable Angle, 35mm	9
176.440S	INDEPENDENCE® HA Coated Bone Screw, Variable Angle, 40mm	
976.008	INDEPENDENCE® HA Coated Screw Soft Case	

ALIF Self-Drilling Screw Set 925.908		Qty
176.625	Self-Drilling Screw, Fixed Angle 5.5mm, 25mm	8
176.630	Self-Drilling Screw, Fixed Angle 5.5mm, 30mm	8
176.635	Self-Drilling Screw, Fixed Angle 5.5mm, 35mm	4
176.640	Self-Drilling Screw, Fixed Angle 5.5mm, 40mm	4
176.725	Self-Drilling Screw, Variable Angle 5.5mm, 25mm	8
176.730	Self-Drilling Screw, Variable Angle 5.5mm, 30mm	8
176.735	Self-Drilling Screw, Variable Angle 5.5mm, 35mm	4
176.740	Self-Drilling Screw, Variable Angle 5.5mm, 40mm	4
925.108	ALIF Self-Drilling Screw Set Module	

**Items highlighted in gray are additionally available*

IMPORTANT INFORMATION ON THE INDEPENDENCE® SPACER

DESCRIPTION

INDEPENDENCE® (including INDEPENDENCE® MIS, INDEPENDENCE® TPS, and INDEPENDENCE® MIS TPS) Spacers are anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The INDEPENDENCE® MIS Spacer may also be used with anchors inserted through the anterior titanium portion of the implants into adjacent vertebral bodies for bony fixation.

INDEPENDENCE® and INDEPENDENCE® MIS Spacers are made from titanium alloy and radiolucent polymer with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. INDEPENDENCE® MIS Spacers are additionally available in an all titanium alloy version. All PEEK implants are additionally available with a commercially pure titanium plasma spray coating (TPS), as specified in ASTM F1580 and F67. The screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and the screws and anchors are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

INDICATIONS

INDEPENDENCE® (including INDEPENDENCE® MIS, INDEPENDENCE® TPS, and INDEPENDENCE® MIS TPS) Spacers are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INDEPENDENCE® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

The INDEPENDENCE® Spacer is a stand-alone interbody fusion device intended to be used with three titanium alloy screws which accompany the implant. The INDEPENDENCE® MIS Spacer is an interbody fusion device to be used with three titanium alloy screws or anchors which accompany the implants. When used with screws, the INDEPENDENCE® MIS Spacer is a stand-alone interbody fusion device. When used with anchors, the INDEPENDENCE® MIS Spacer is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

WARNINGS

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

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

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

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

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

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

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

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

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

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

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

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

INDEPENDENCE® Spacers have not been evaluated for safety and compatibility in the MR environment. These devices have not been tested for heating, migration, or image artifact in the MR environment. The safety of INDEPENDENCE® Spacers in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
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 condition not described in the indications for use.
7. Signs of local inflammation.
8. Fever or leukocytosis.
9. Morbid obesity.
10. Pregnancy.
11. Mental illness.

IMPORTANT INFORMATION ON THE INDEPENDENCE® SPACER

12. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
13. Suspected or documented allergy or intolerance to composite materials.
14. Any case not needing a fusion.
15. Any patient not willing to cooperate with postoperative instruction.
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, nor where the patient still has general skeletal growth.
18. Spondylolisthesis unable to be reduced to Grade 1.
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
20. Any case that requires the mixing of metals from two different components or systems.
21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE 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 products from the packaging using aseptic technique.

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

HANDLING 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 (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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.

IMPORTANT INFORMATION ON THE INDEPENDENCE® SPACER (CONT'D)

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

TThese implants and instruments may be available sterile or nonsterile. HA-coated implants 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 on 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 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).

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

Do not stack trays during sterilization. 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.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
QTY	QUANTITY		MANUFACTURER
	USE BY (YYYY-MM-DD)		

DI134A
REV J

Notes

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CE 0297

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