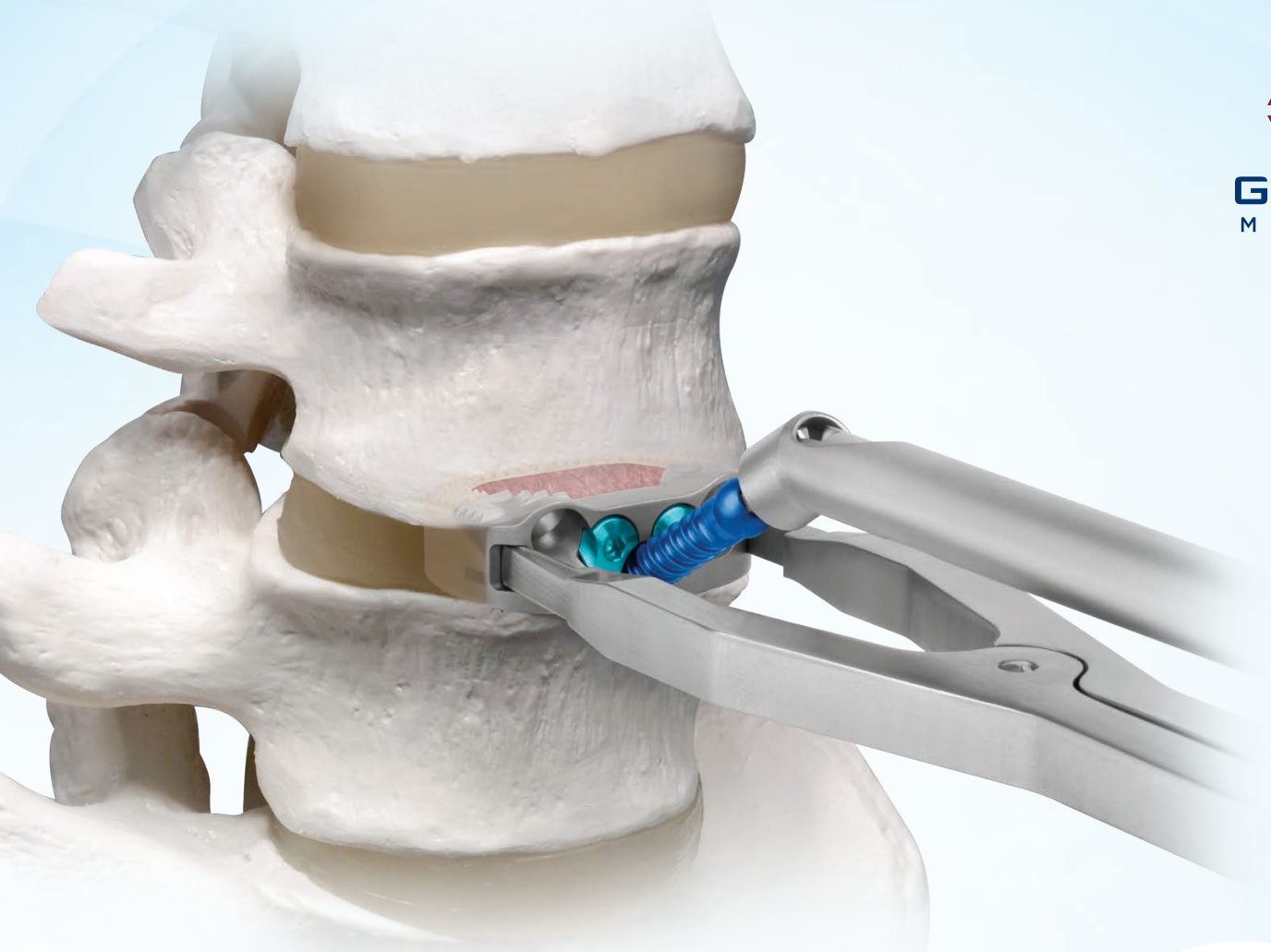

INDEPENDENCE®

Stand-Alone ALIF System

SURGICAL TECHNIQUE GUIDE

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

Life moves us

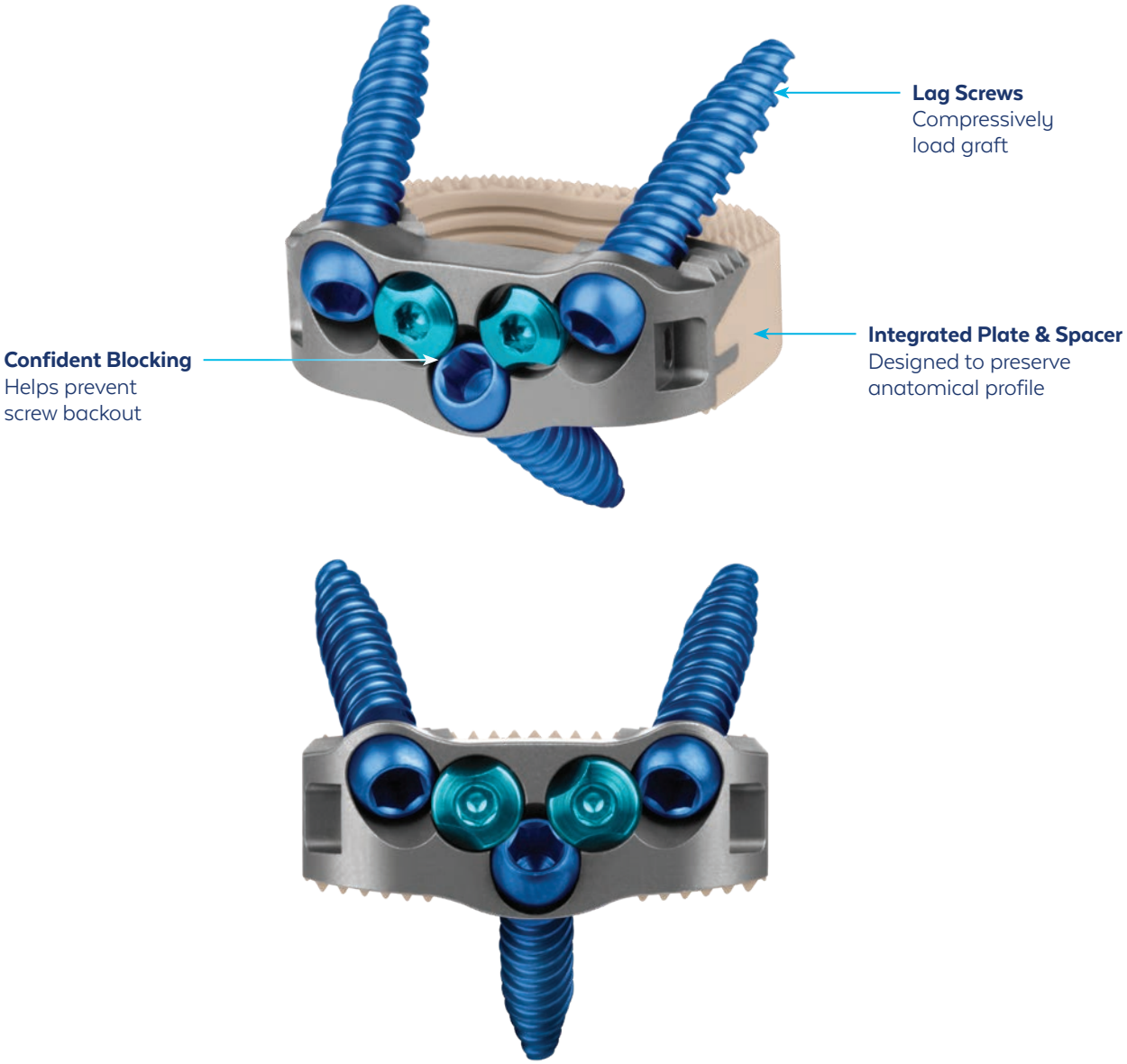
SURGICAL TECHNIQUE GUIDE

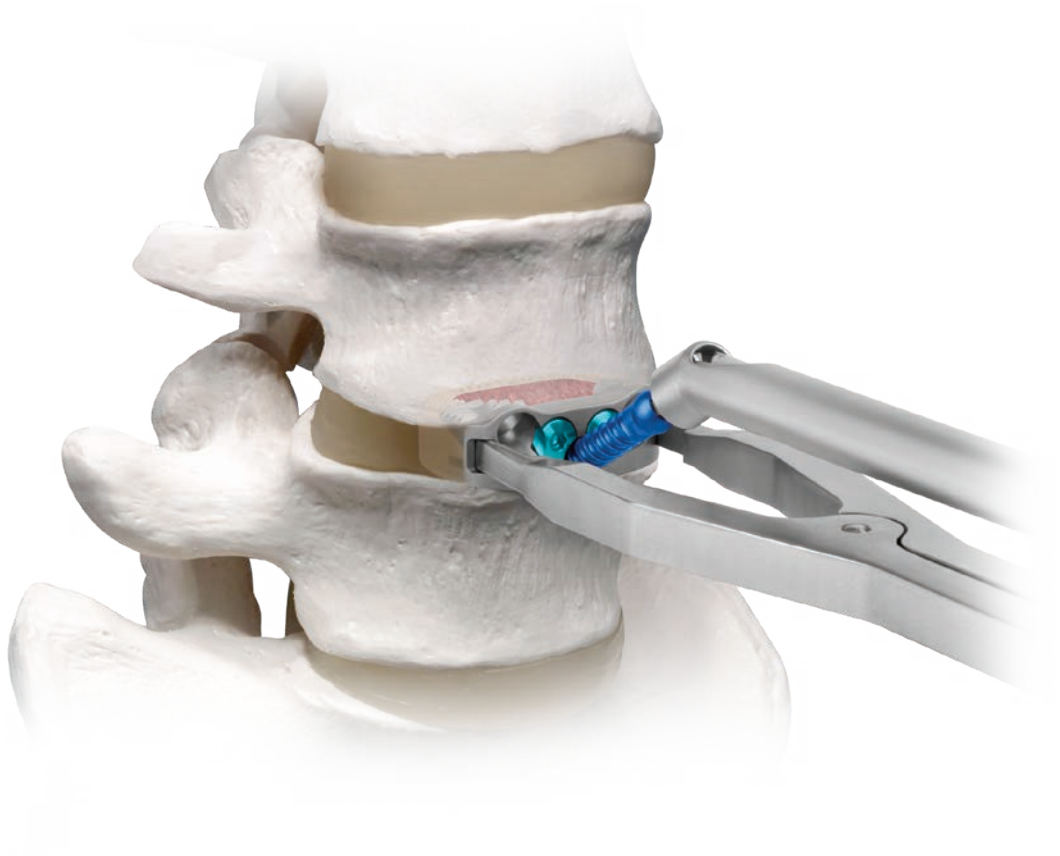
INDEPENDENCE®

INDEPENDENCE®

Stand-Alone ALIF System

INDEPENDENCE® is an integrated plate and spacer system designed to provide the biomechanical strength of a traditional ALIF while minimizing disruption to patient anatomy and preserving the natural anatomical profile of the lumbar spine.





Natural Anatomical Profile

Integrated plate and spacer designed to restore sagittal balance and preserve the natural anatomical profile of the lumbar vertebral body

Less Disruptive

Three-screw design combined with low-profile instruments allows for streamlined delivery of implants with minimal retraction and access

Proven Strength and Stability

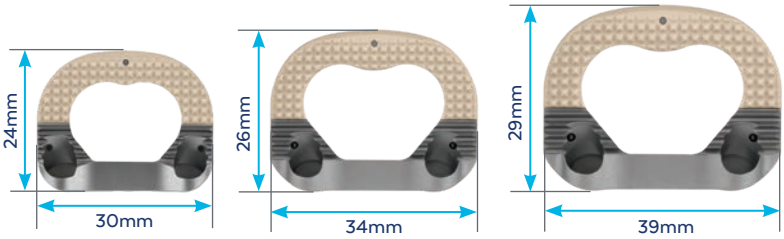
Biomechanically comparable to a traditional anterior spacer with plate and to a competitive four-screw integrated spacer*

*Testing on file

IMPLANT OVERVIEW

INDEPENDENCE® Spacer

- Bi-convex radiolucent PEEK spacer
- Three axial footprints (24x30mm, 26x34mm, 29x39mm)
- Six heights (11, 13, 15, 17, 19, 21mm)
- Three sagittal profiles (8°, 15°, 20°*)
- Tapered leading edge for ease of insertion
- Large single axial graft chamber with graft containment ridges



INDEPENDENCE® Plate

- Titanium plate preassembled with a PEEK spacer
- Audible, tactile, and visual confirmation of screw blocking

Screw Options

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

Variable Angle Self-Tapping Screw

Variable Angle Self-Drilling Screw*

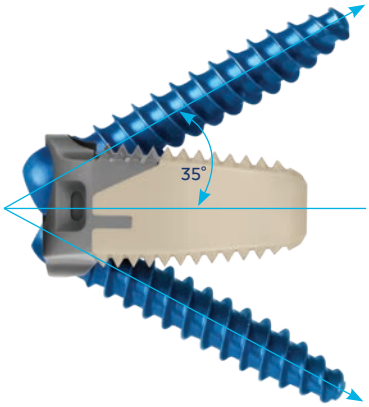
HA Coated Variable Angle Screw*

Locking Screw (CoCr) *

*Additionally available

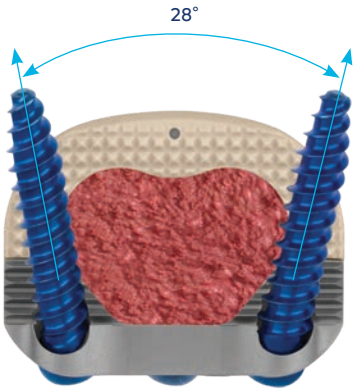
Screw Angulation

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



Instruments

- Straight and angled awls, drills, and taps
- Slim angled drill, tap, and drivers designed to improve visibility and reduce incision size
- Self-centering sleeves on awls and drills
- Inserter/Distractor for insertion without impaction

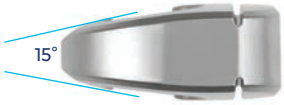


Implant Holder with Angled Driver

ALIF Inserter/Distractor

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	–	–

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

Large (29x39mm)						
Angle	**11mm**	**13mm**	**15mm**	**17mm**	**19mm**	**21mm**
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

DRILL GUIDES

Small		**Medium**		**Large**	
					
Height	**Part No.**	**Height**	**Part No.**	**Height**	**Part No.**
11mm	676.931	11mm	676.951	11mm	676.971
13mm	676.933	13mm	676.953	13mm	676.973
15mm	676.935	15mm	676.955	15mm	676.975
17mm	676.937	17mm	676.957	17mm	676.977
-	-	19mm	676.959	19mm	676.979
-	-	21mm	676.961	21mm	676.981

Items in gray are additionally available.

TRIAL AND DRILL GUIDE HOLDERS

Implant/Trial Holder Tool 664.500

Implant/Trial Holder Sleeve 664.501

Implant/Trial Holder Tool 664.500
Implant/Trial Holder Sleeve 664.501
(Assembled)

Drill Guide Holder 676.008

TRIAL AND DRILL GUIDE HOLDERS

Implant Holder 676.500

ALIF Inserter/Distractor 676.650

TRIAL AND DRILL GUIDE HOLDERS (CONT'D)

INDEPENDENCE® Attachment
Tip 676.660

ALIF Inserter/Distractor
Tip Driver 676.655

Screw Driver, 1.0mm Hex 676.604

STRAIGHT INSTRUMENTS

Quick-Connect Handle, Swivel 650.105

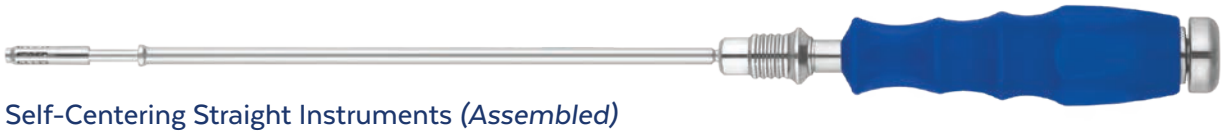
3.5mm Hex Straight Shaft 676.502

Quick-Connect Handle, Swivel 650.105
3.5mm Hex Straight Shaft 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 Driver, 2.5mm Hex (1.0Nm Torque) 676.600

ANGLED INSTRUMENTS

Counter-Torque 676.699

Angled Sleeve 676.700

**Drill, awl, and tap dimensions can be found on page 26.*

ANGLED INSTRUMENTS (CONT'D)

Shaft 676.701

Nut 676.702

Self-Centering Angled Drill 676.703*

5.5mm Angled Tap 676.707*

3.5mm Angled Hex Driver 676.709

3.5mm Angled Hex Driver, Short 676.710

Angled Driver System with 3.5mm Angled Hex Driver, Short *(Assembled)*

Self-Centering Bent Awl 676.705*

**Drill, awl, and tap dimensions can be found on page 26.*

SURGICAL TECHNIQUE

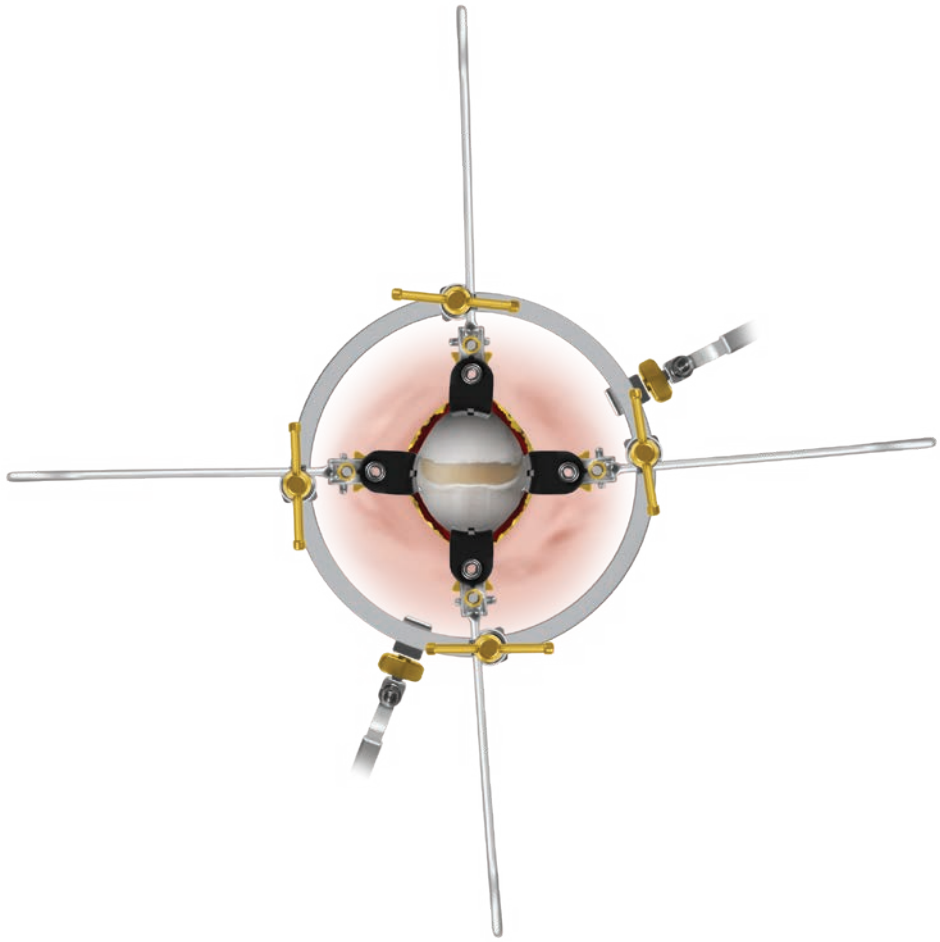
INDEPENDENCE®

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

These devices are intended for use with supplemental fixation (e.g., facet screws or posterior fixation), and may be used with or without three screws that accompany the implant. In addition, these devices are intended for stand-alone use in patients with degenerative disc disease at one or two levels only when <25° lordotic implants are used with three screws per implant. Please refer to the selected technique guide for the corresponding supplemental fixation system for specific instructions.

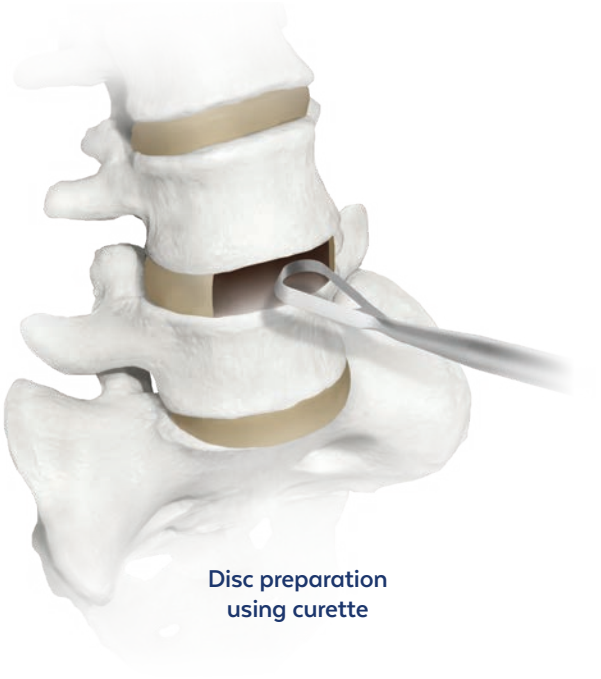
STEP 1 APPROACH

For the purposes of this technique guide, a standard mini-open anterior approach is used. The patient is placed supine, and access to the disc space may be created using the MARS™ Anterior Retractor.



STEP 2 PREPARATION

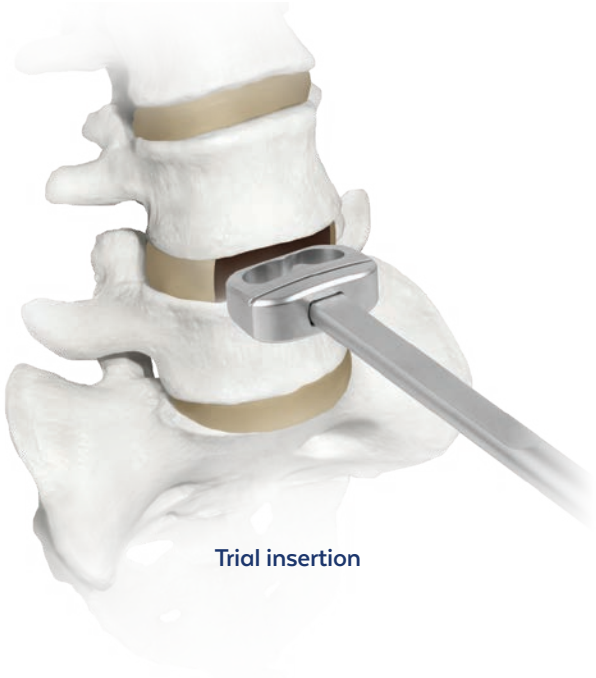
Anterior Disc Preparation instruments may be used to expose the disc. Remove the disc material using rongeurs and other suitable instruments. Scrapers may be used to remove superficial layers of the cartilaginous endplates. The posterior and lateral walls of the annulus should be preserved to provide peripheral support. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



Disc preparation using curette

STEP 3 IMPLANT SIZING

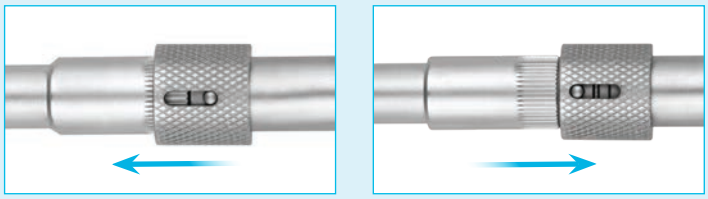
Select an appropriately sized **Trial** and attach it to the **Trial Holder Assembly**. Insert the trial into the disc space. Gently impact as necessary. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and stabilize the segment. Confirm trial placement using fluoroscopy and tactile feel.



Trial insertion

USING THE TRIAL HOLDER

Ensure the Implant/Trial Holder is in the unlocked position. Thread the trial into the holder by rotating the handle clockwise. Lock the holder by sliding the lock forward. To disengage, unlock and rotate the handle counterclockwise.



Locked Unlocked

STEP 4 IMPLANT INSERTION

Option A: Using the Implant Holder

Select the appropriate size implant and attach it to the **Implant Holder** and optional **Drill Guide**, as shown below. Tighten the locking nut on the holder to ensure a secure connection. Pack the center of the implant with autogenous bone graft material.*

Insert the implant into the disc space. The implant should be flush or recessed 1mm, with the drill guide remaining flush with the anterior portion of the vertebral body, if used.

Note: Two screws are inserted into the superior vertebrae and one screw is inserted into the inferior vertebrae. The implant can be flipped 180° as needed.

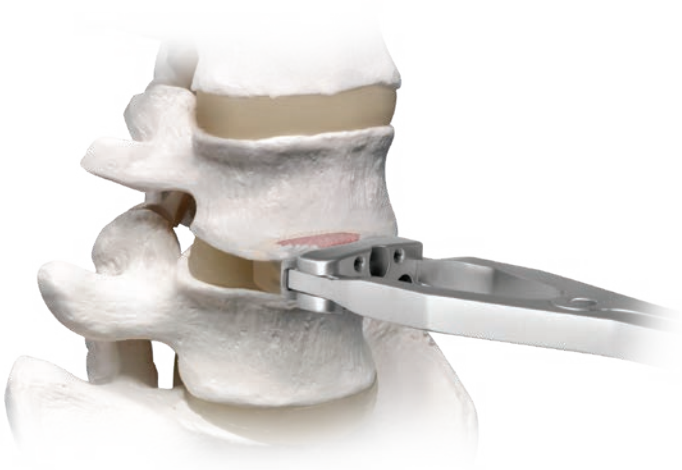
Instructions for loading the implant onto the Implant Holder can be found on page 16.

Without Drill Guide

Inserting implant

Direction of screw insertion

With Drill Guide



Inserting implant

Direction of screw insertion

*Graft volumes can be found on page 26.

LOADING THE IMPLANT HOLDER WITHOUT THE DRILL GUIDE

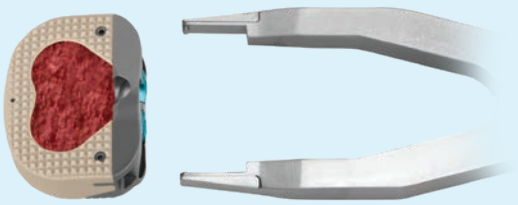
The **Self-Centering Sleeves** on the Straight and Angled Instruments facilitate insertion of the screws without the use of a Drill Guide.

Fully open the Implant Holder by rotating the locking nut counterclockwise.

Choose the appropriate size implant.

Place the implant on the holder by matching the mating features of the implant to the holder. Compress the handles and tighten the locking nut. Insert the implant.

After inserting the implant, rotate the locking nut counterclockwise to its open position to release the implant.



Implant and Implant Holder

Implant and Implant Holder connected

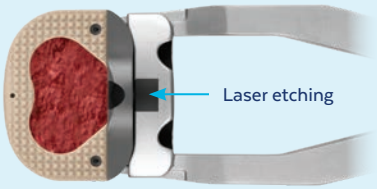
LOADING THE IMPLANT HOLDER WITH THE DRILL GUIDE

Fully open the Implant Holder by rotating the locking nut counterclockwise.

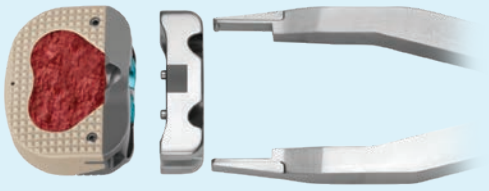
Choose the appropriate size Drill Guide and implant.

Slightly compress the handles of the holder in order to load the guide. This does not require significant force as it will slide on freely.

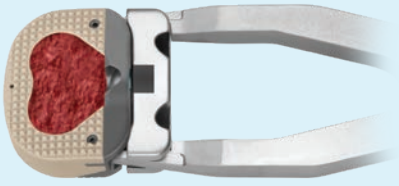
Release the handles to return the holder to its original position. This engages the guide and locks it into place.



Place the implant on the holder by aligning the medial hole with the laser etching on the top of the guide. Compress the handles of the holder and tighten the locking nut in order to insert the implant.



Implant, Drill Guide, and Implant Holder



Implant, Drill Guide, and Implant Holder connected

After inserting the implant, rotate the locking nut counterclockwise to its open position to release the implant into the disc space.

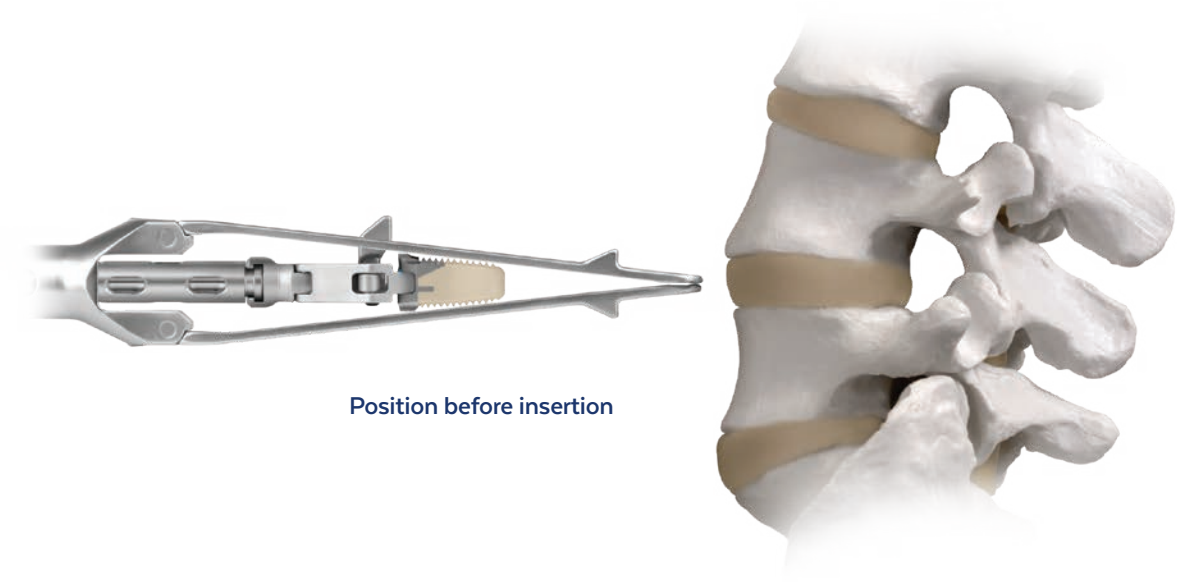
The Implant Holder retains the Drill Guide for removal.

IMPLANT INSERTION (CONT'D)

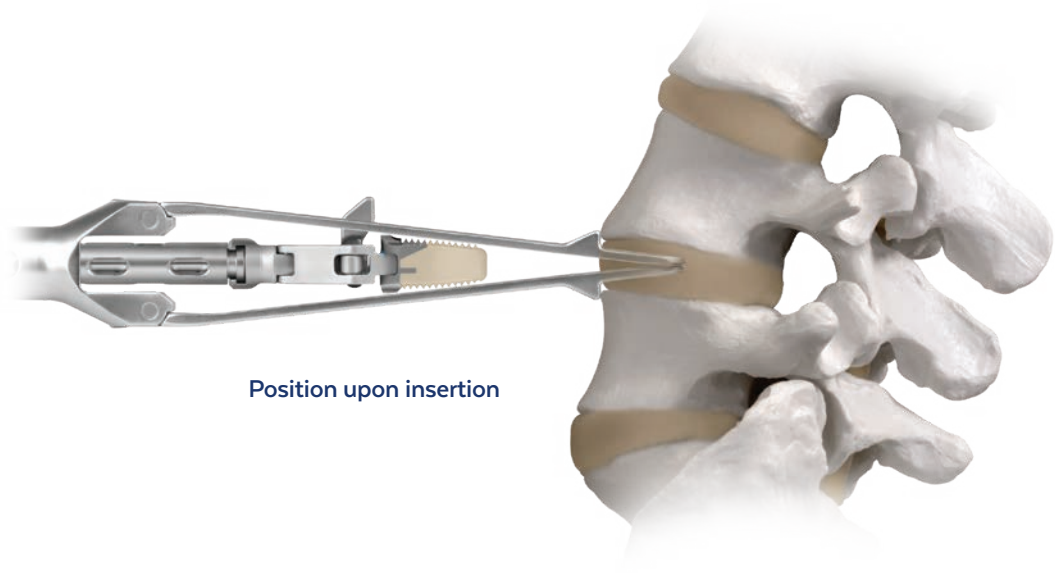
Option B: Using the ALIF Inserter/Distractor

Insert the distraction arms of the **ALIF Inserter/Distractor** into the disc space until the vertebral body depth stops are flush against the anterior rim of the vertebral bodies. Rotate the T-handle clockwise while applying light pressure to advance the implant into the disc space.

Note: Instructions for loading the implant onto the ALIF Inserter/Distractor can be found on page 19.



Position before insertion

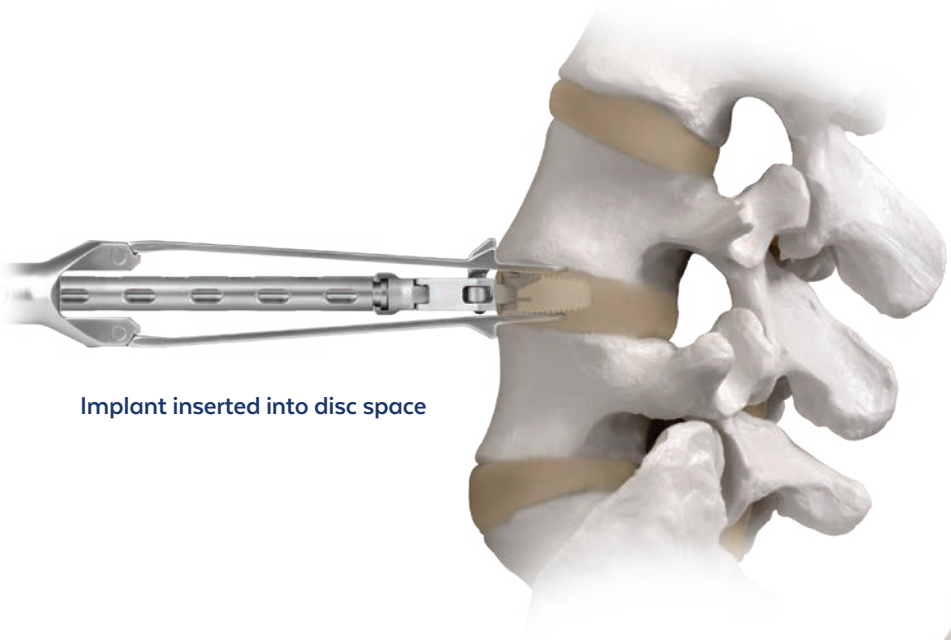


Position upon insertion

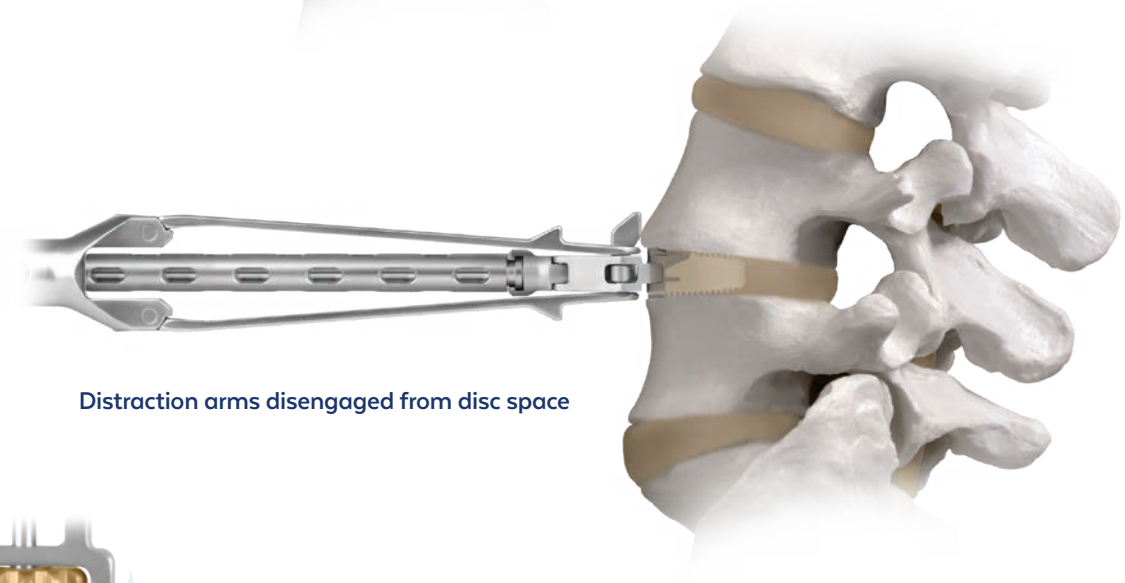
IMPLANT INSERTION (CONT'D)

Option B: Using the ALIF Inserter/Distractor (Cont'd)

Once the ejection prong on the **Attachment Tip** contacts the vertebral body, the implant is fully inserted. Continue to rotate the T-handle clockwise; this pulls the distraction arms out of the disc space, leaving the implant in the disc space. Rotate the gold knob counterclockwise to disengage the implant. The ALIF Inserter/Distractor can now be removed.



Implant inserted into disc space



Distraction arms disengaged from disc space

Rotate gold knob counterclockwise to disengage implant

ASSEMBLING THE ALIF INSERTER/DISTRACTOR: PREPARING THE ATTACHMENT TIP

The attachment tip accompanies the ALIF Inserter/Distractor, pictured below.

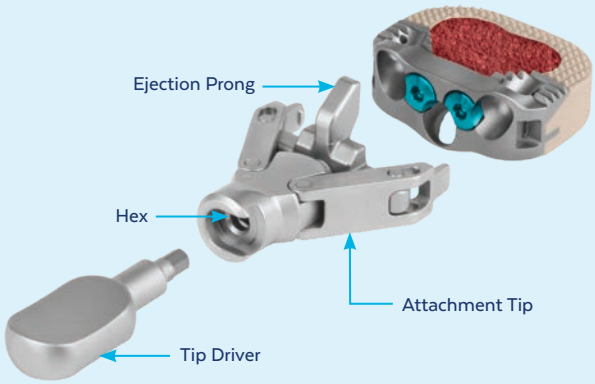
INDEPENDENCE® Attachment Tip

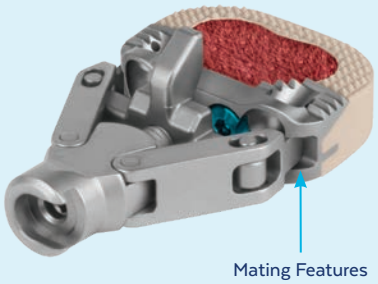
Note: The INDEPENDENCE® Attachment Tip connects to all INDEPENDENCE® implants.

Engage the connections of the tip to the mating features of the implant with the ejection prong aligned with the top or bottom of the implant, as shown below.

To secure the implant, use the **Tip Driver** to rotate the hex of the tip until it is finger tight.

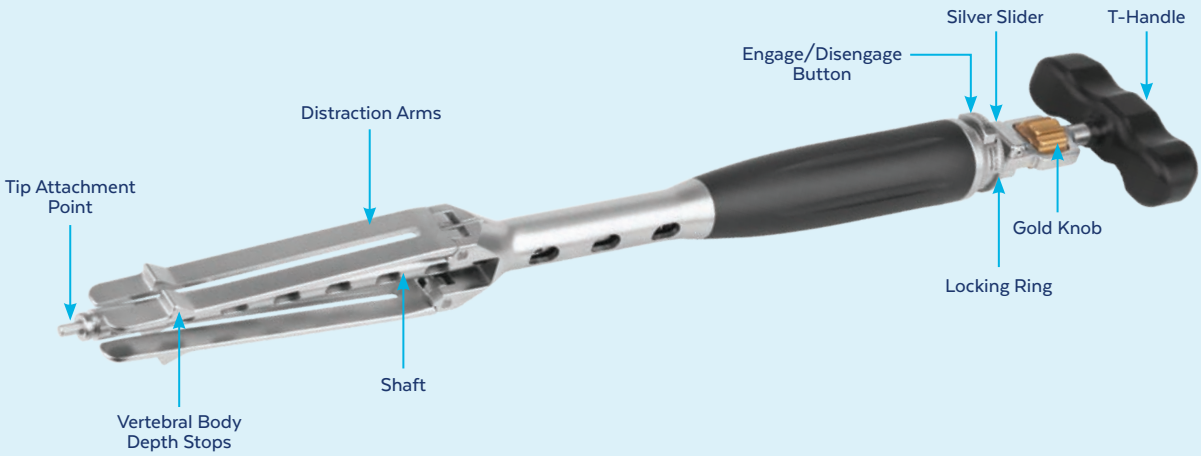
Pack autogenous bone graft into the graft chamber of the selected implant.* The Attachment Tip is ready to be loaded onto the ALIF Inserter/Distractor.



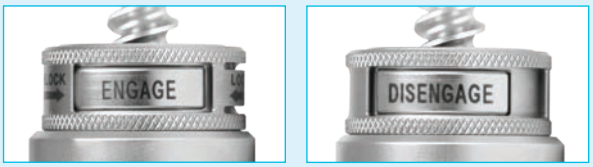


*Graft volumes can be found on page 27.

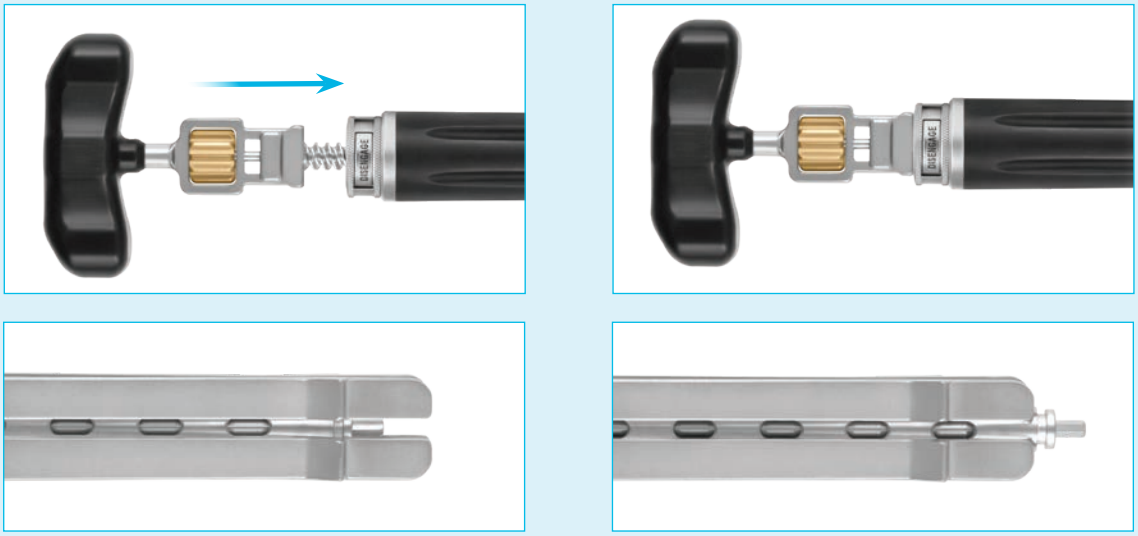
ASSEMBLING THE ALIF INSERTER/DISTRACTOR: CONNECTING THE ATTACHMENT TIP



Locate the engage/disengage button on the inserter/distractor. This button engages and disengages the thread.



Ensure the disengage button is depressed and slide the main shaft down by pushing the T-handle until it bottoms out. The tip attachment point will be exposed past the ends of the distraction arms.



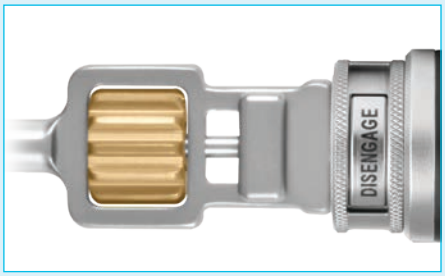
Tip attachment point retracted

Tip attachment point exposed

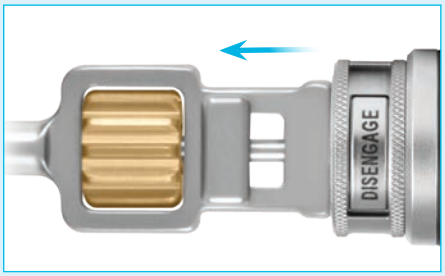
ASSEMBLING THE ALIF INSERTER/DISTRACTOR: CONNECTING THE ATTACHMENT TIP

Pull the silver slider back to retract the exposed hex on the tip attachment point, slide the tip on from the side, and release the slider.

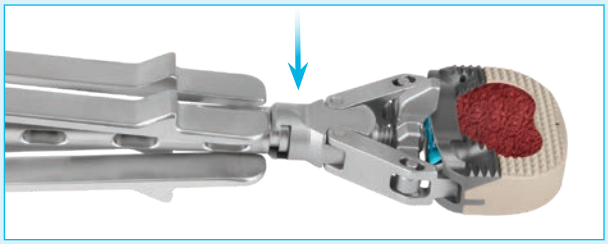
If the slider does not fully return to its initial position, rotate the gold knob until the slider returns and is flush against the front of the slot. At this point, the tip is locked onto the main shaft.



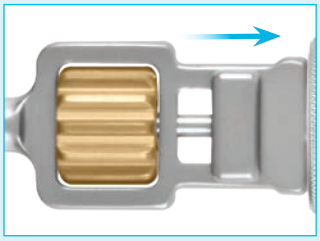
Starting position, hex exposed



Pull the silver slider back to retract exposed hex

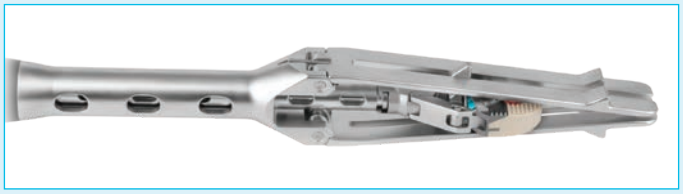


Slide attachment tip on from the side



Release slider to lock attachment tip to main shaft

Pull the shaft back until the distal ends of the distraction arms touch. Press the engage button and rotate the locking ring 90°. The implant is ready to be inserted.



Distraction arms touching

Press engage button

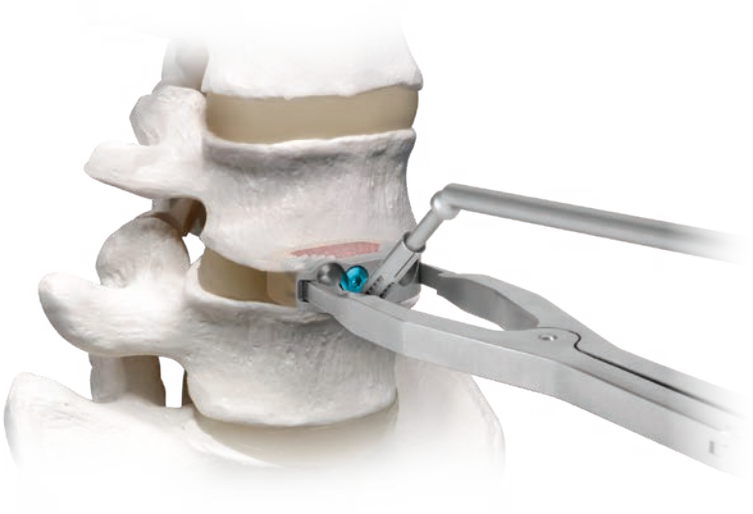
Rotate locking ring 90°

STEP 5 SCREW HOLE PREPARATION

Without Drill Guide

Insert the awl with the self-centering sleeve to break the cortex.* A Self-Centering Drill and Tap may be used to further prepare the screw hole.

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



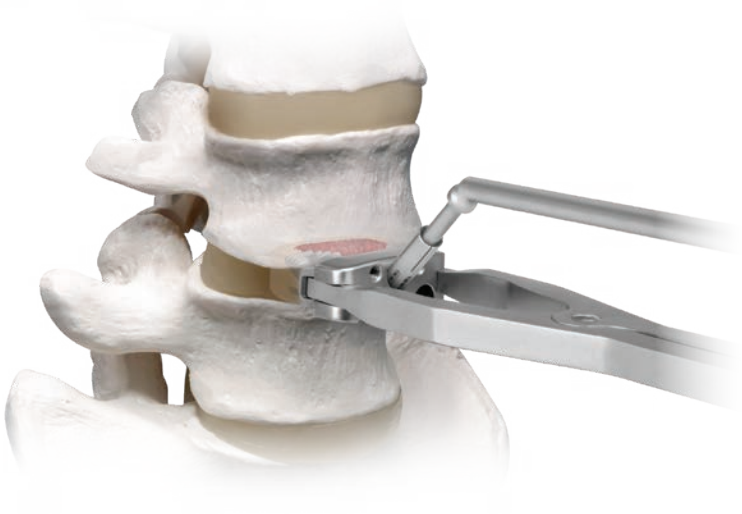
Inserting Self-Centering Bent Awl

With Drill Guide

If using the Drill Guide, insert the awl with the self-centering sleeve through the Drill Guide to break the cortex.* A Self-Centering Drill and Tap may be used to further prepare the screw hole.

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

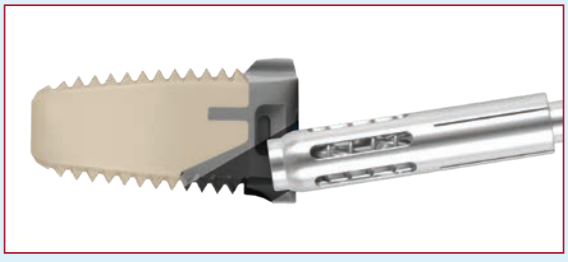
Note: See the Appendix for Angled Instrument Assembly Instructions.



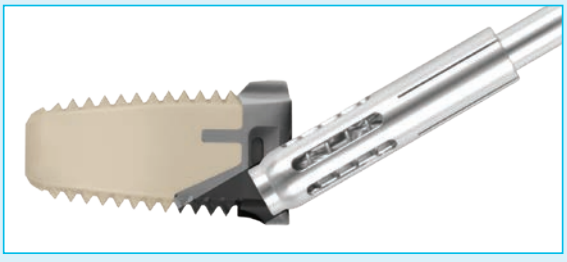
Inserting Self-Centering Bent Awl through Drill Guide

ALIGNING THE SELF-CENTERING SLEEVE

The self-centering sleeves ensure proper screw trajectory without the 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 prior to preparing the remaining hole.



Incorrect



Correct

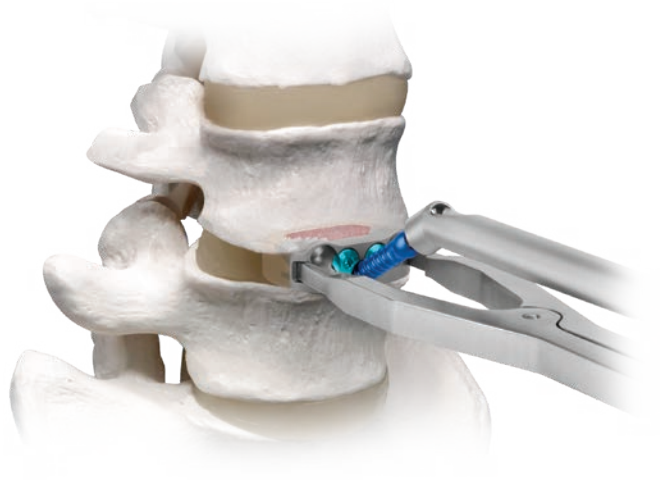
*Drill, awl, and tap dimensions can be found on page 27.

STEP 6 SCREW INSERTION

Select the appropriate length screw.* Insert the screw using a straight or angled self-retaining screwdriver. Repeat this step completely for each screw hole before moving to the next, as shown below. Use caution when inserting self-drilling screws to ensure that the tip does not cause damage.

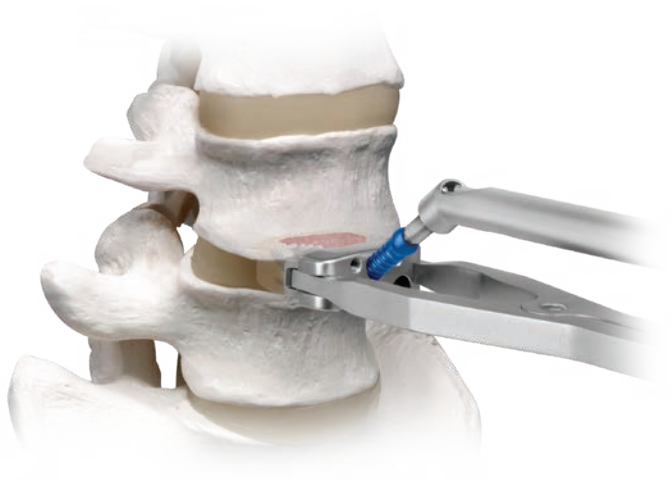
Note: If using the Drill Guide, do not overtighten; screws may be final tightened after the Drill Guide is removed.

Without Drill Guide



Inserting screw using
Angled Screwdriver, Short

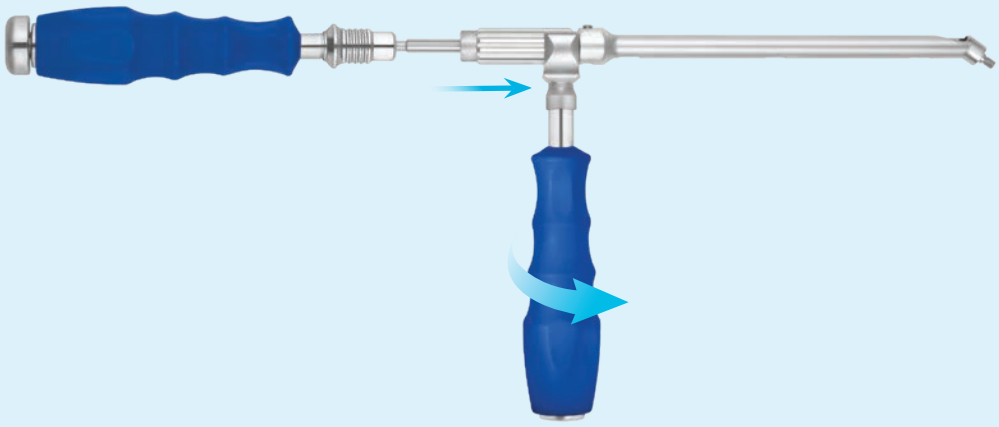
With Drill Guide



Inserting screw using Angled
Screwdriver and Drill Guide

CONNECTING THE COUNTER-TORQUE TO THE ANGLED INSTRUMENTS

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



*Screw dimensions can be found on page 28.

STEP 7 IMPLANT HOLDER REMOVAL

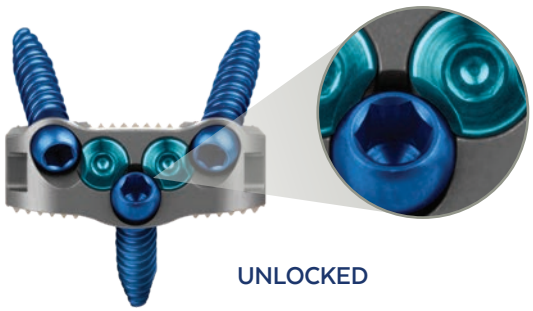
Once the screws are inserted, remove the Drill Guide and Implant Holder by fully releasing the locking nut on the holder to disengage the implant. The guide is retained by the holder, as shown at right. After the holder is removed, ensure the screws are fully seated. The screws lag the bone to the implant.

Drill Guide released from implant

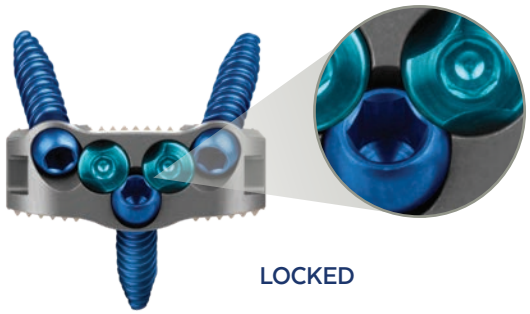
STEP 8 POSITIONING SET SCREW

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

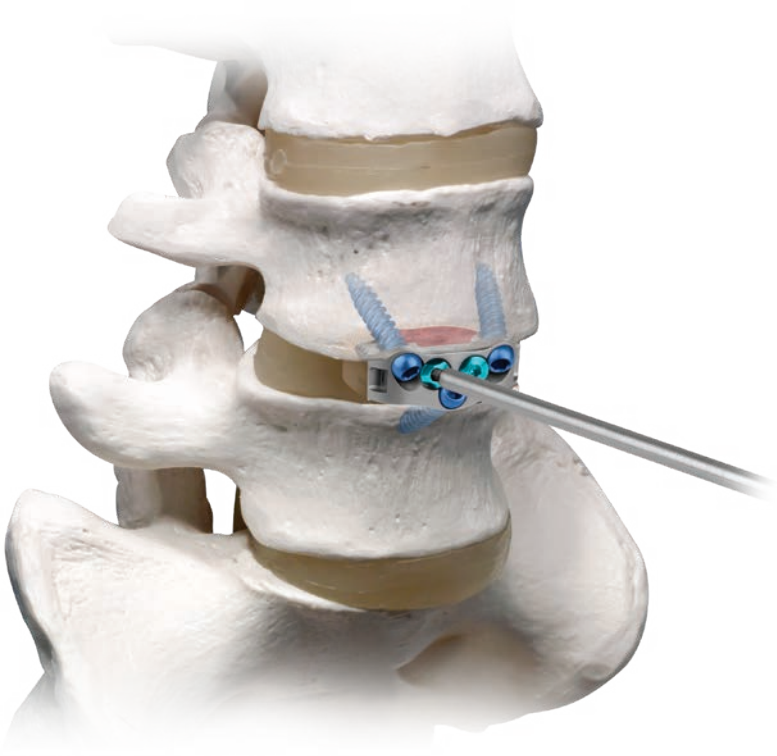
Note: The Set Screw Driver has a 1.0Nm torque limit.



UNLOCKED

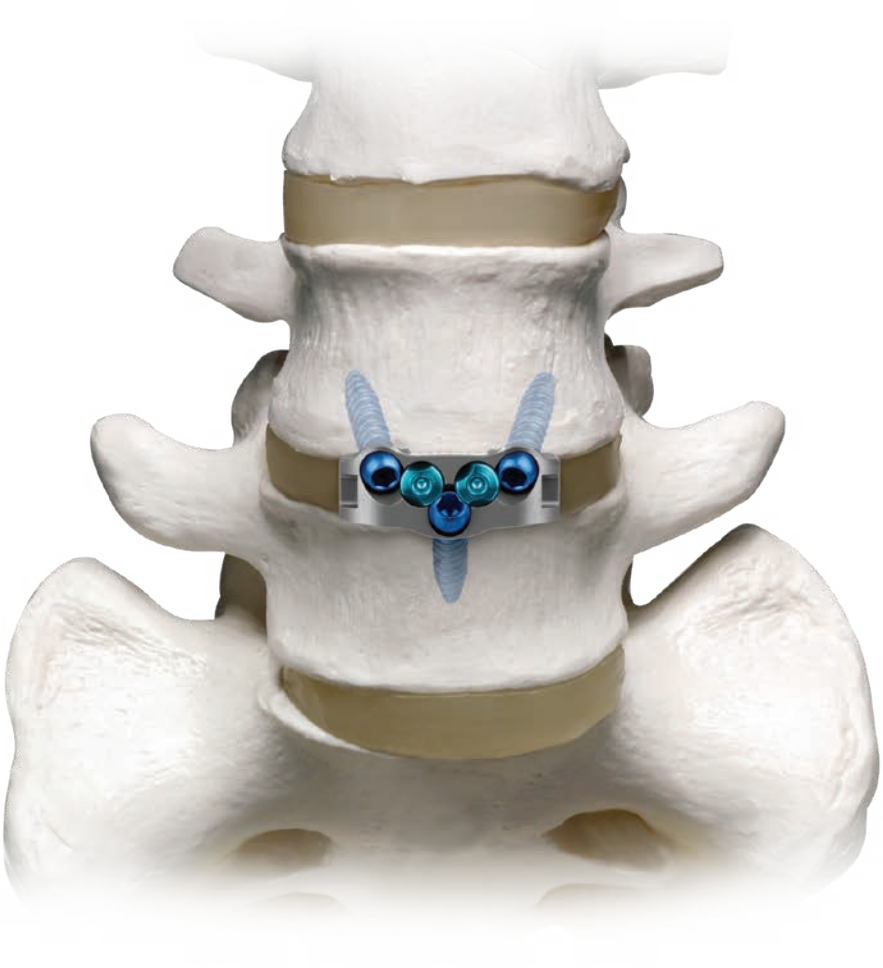


LOCKED

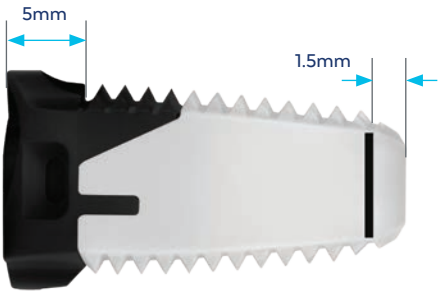


Locking set screw

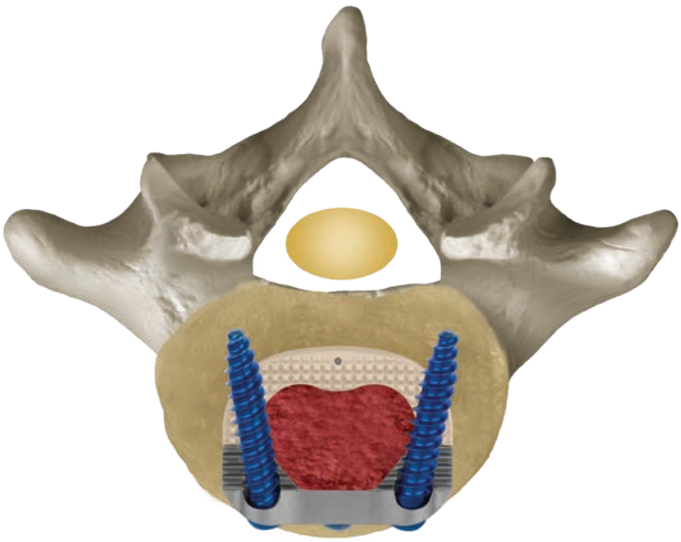
FINAL POSITION



Anterior view



Radiographic markers



Axial view

ADDITIONAL SPECIFICATIONS

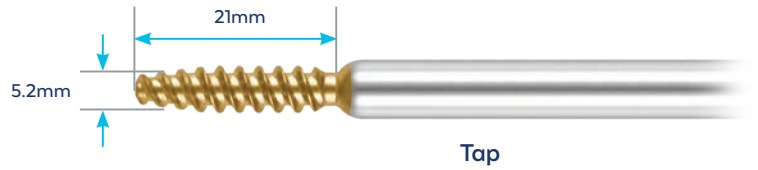
INDEPENDENCE® Graft Volumes

Small 8° (24x30mm)	
Part No.	Graft Volume (cc)
376.111	2.4
376.113	2.9
376.115	3.3
376.117	3.7
Medium 8° (26x34mm)	
Part No.	Graft Volume (cc)
376.411	3.1
376.413	3.7
376.415	4.3
376.417	4.9
376.419	5.5
376.421	6.1
Large 8° (29x39mm)	
Part No.	Graft Volume (cc)
376.711	3.8
376.713	4.6
376.715	5.3
376.717	6.0
376.719	6.7
376.721	7.4

Small 15° (24x30mm)	
Part No.	Graft Volume (cc)
376.211	2.3
376.213	2.7
376.215	3.2
376.217	3.6
Medium 15° (26x34mm)	
Part No.	Graft Volume (cc)
376.511	2.8
376.513	3.4
376.515	4.0
376.517	4.5
376.519	5.1
376.521	5.6
Large 15° (29x39mm)	
Part No.	Graft Volume (cc)
-	-
376.813	4.2
376.815	4.9
376.817	5.6
376.819	6.3
376.821	7.0

Small 20° (24x30mm)	
Part No.	Graft Volume (cc)
-	-
376.233	2.5
376.235	3.0
376.237	3.4
Medium 20° (26x34mm)	
Part No.	Graft Volume (cc)
-	-
376.533	3.2
376.535	3.7
376.537	4.3
376.539	4.8
376.541	5.4
Large 20° (29x39mm)	
Part No.	Graft Volume (cc)
-	-
-	-
376.835	4.6
376.837	5.3
376.839	6.1
376.841	6.8

INDEPENDENCE® Drill, Awl, and Tap: Dimensions



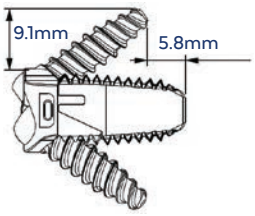
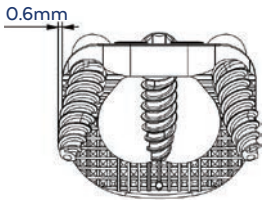
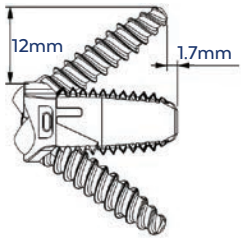
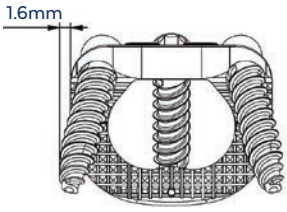
Tap

Drill

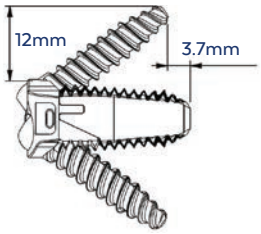
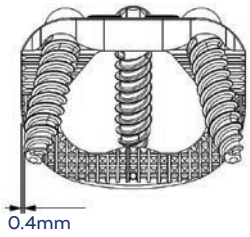
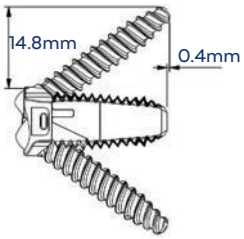
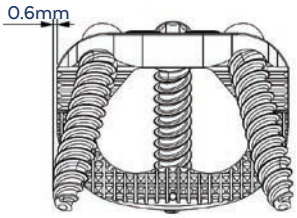
Awl

ADDITIONAL SPECIFICATIONS

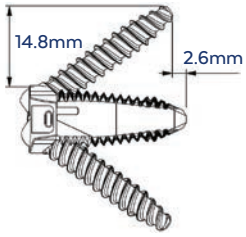
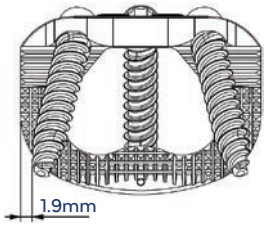
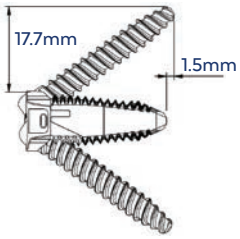
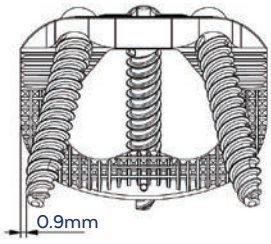
Small Spacer (24x30mm)

20mm Screws		25mm Screws	
			
Lateral View	Axial View	Lateral View	Axial View

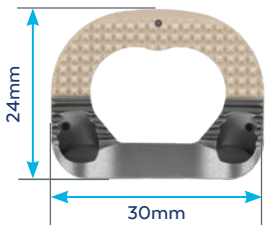
Medium Spacer (26x34mm)

25mm Screws		30mm Screws	
			
Lateral View	Axial View	Lateral View	Axial View

Large Spacer (29x39mm)

30mm Screws		35mm Screws	
			
Lateral View	Axial View	Lateral View	Axial View

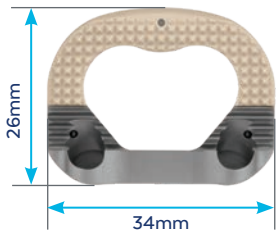
ADDITIONAL SPECIFICATIONS



24x30mm

Implant Sizing Chart - Small (24x30mm)					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	376.111	11.0	7.6	3.0
	13mm	376.113	13.0	9.6	5.0
	15mm	376.115	15.0	11.6	7.0
	17mm	376.117	17.0	13.6	9.0
15°	11mm	376.211	11.0	5.7	1.3
	13mm	376.213	13.0	7.7	3.3
	15mm	376.215	15.0	9.7	5.3
	17mm	376.217	17.0	11.7	7.3
20°	13mm	376.233	13.0	4.1	2.4
	15mm	376.235	15.0	6.1	4.4
	17mm	376.237	17.0	8.1	6.4

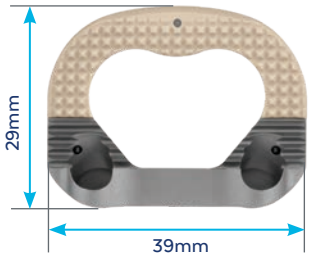
ADDITIONAL SPECIFICATIONS



26x34mm

Implant Sizing Chart - Medium (26x34mm)					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	376.411	11.0	6.9	2.6
	13mm	376.413	13.0	8.9	4.6
	15mm	376.415	15.0	10.9	6.6
	17mm	376.417	17.0	12.9	8.6
	19mm	376.419	19.0	14.9	10.6
	21mm	376.421	21.0	16.9	12.6
15°	11mm	376.511	11.0	4.8	0.8
	13mm	376.513	13.0	6.8	2.8
	15mm	376.515	15.0	8.8	4.8
	17mm	376.517	17.0	10.8	6.8
	19mm	376.519	19.0	12.8	8.8
	21mm	376.521	21.0	14.8	10.8
20°	13mm	376.533	13.0	3.2	1.6
	15mm	376.535	15.0	5.2	3.6
	17mm	376.537	17.0	7.2	5.6
	19mm	376.539	19.0	9.2	7.6
	21mm	376.541	21.0	11.2	9.6

ADDITIONAL SPECIFICATIONS



29x39mm

Implant Sizing Chart - Large (29x39mm)					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	376.711	11.0	5.3	0.6
	13mm	376.713	13.0	7.3	2.6
	15mm	376.715	15.0	9.3	4.6
	17mm	376.717	17.0	11.3	6.6
	19mm	376.719	19.0	13.3	8.6
	21mm	376.721	21.0	15.3	10.6
15°	13mm	376.813	13.0	4.8	0.7
	15mm	376.815	15.0	6.8	2.7
	17mm	376.817	17.0	8.8	4.7
	19mm	376.819	19.0	10.8	6.7
	21mm	376.821	21.0	12.8	8.7
20°	15mm	376.835	15.0	3.0	1.8
	17mm	376.837	17.0	5.0	3.8
	19mm	376.839	19.0	7.0	5.8
	21mm	376.841	21.0	9.0	7.8

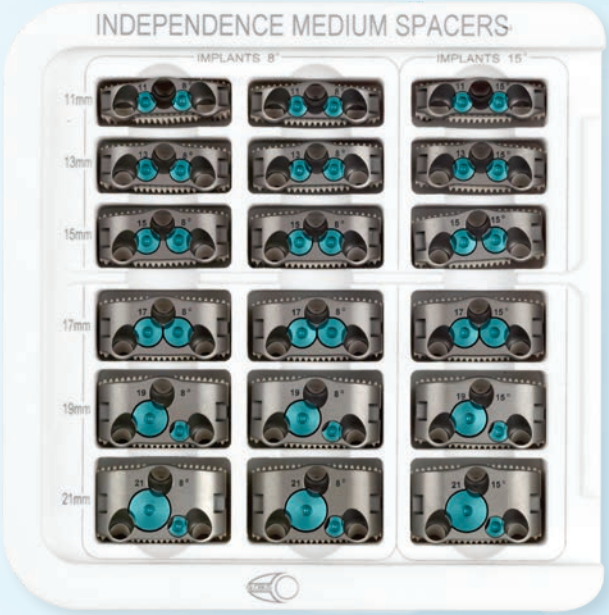
INDEPENDENCE®
IMPLANT SETS

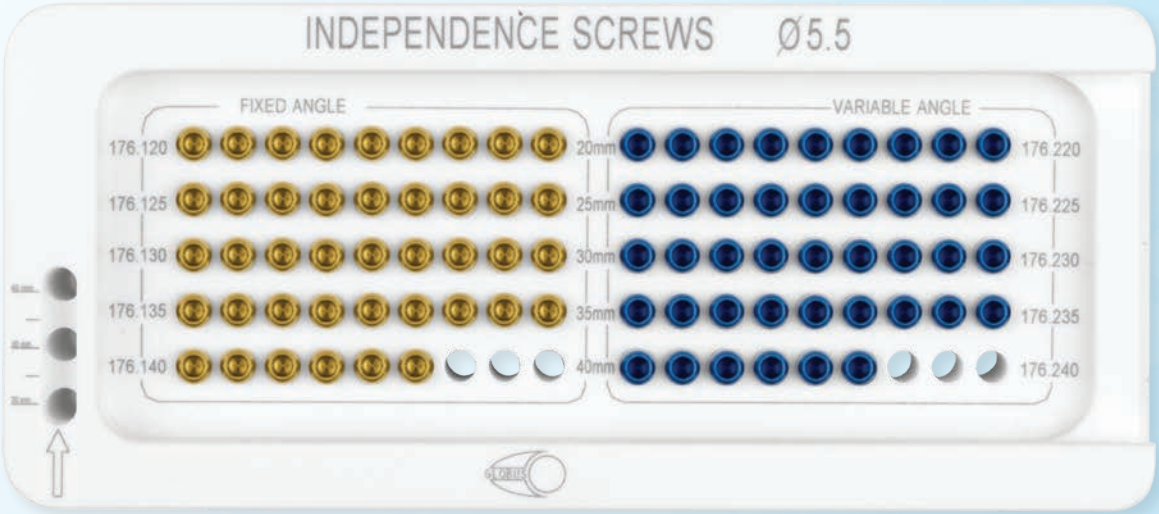
INDEPENDENCE® Implants – Small Set 976.902		Qty
376.111	Small, 8°, 11mm	2
376.113	Small, 8°, 13mm	2
376.115	Small, 8°, 15mm	2
376.117	Small, 8°, 17mm	2
376.211	Small, 15°, 11mm	1
376.213	Small, 15°, 13mm	1
376.215	Small, 15°, 15mm	1
376.217	Small, 15°, 17mm	1
976.002	INDEPENDENCE® Small Module	

INDEPENDENCE® Implants – Medium Set 976.901		Qty
376.411	Medium, 8°, 11mm	2
376.413	Medium, 8°, 13mm	2
376.415	Medium, 8°, 15mm	2
376.417	Medium, 8°, 17mm	2
376.419	Medium, 8°, 19mm	2
376.421	Medium, 8°, 21mm	2
376.511	Medium, 15°, 11mm	1
376.513	Medium, 15°, 13mm	1
376.515	Medium, 15°, 15mm	1
376.517	Medium, 15°, 17mm	1
376.519	Medium, 15°, 19mm	1
376.521	Medium, 15°, 21mm	1
976.001	INDEPENDENCE® Medium Module	

INDEPENDENCE® Bone Screw Set 976.904		Qty
176.120	Fixed Angle 5.5mm, 20mm	9
176.125	Fixed Angle 5.5mm, 25mm	9
176.130	Fixed Angle 5.5mm, 30mm	9
176.135	Fixed Angle 5.5mm, 35mm	9
176.140	Fixed Angle 5.5mm, 40mm	6
176.220	Variable Angle 5.5mm, 20mm	9
176.225	Variable Angle 5.5mm, 25mm	9
176.230	Variable Angle 5.5mm, 30mm	9
176.235	Variable Angle 5.5mm, 35mm	9
176.240	Variable Angle 5.5mm, 40mm	6
976.004	INDEPENDENCE® Screw Module	

INDEPENDENCE®
IMPLANT SETS





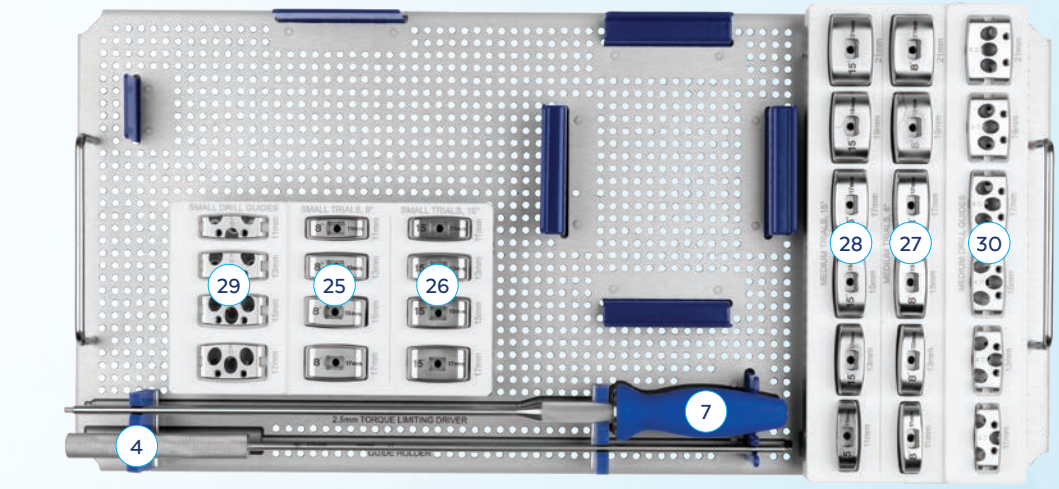
INDEPENDENCE®
INSTRUMENT SET 976.909

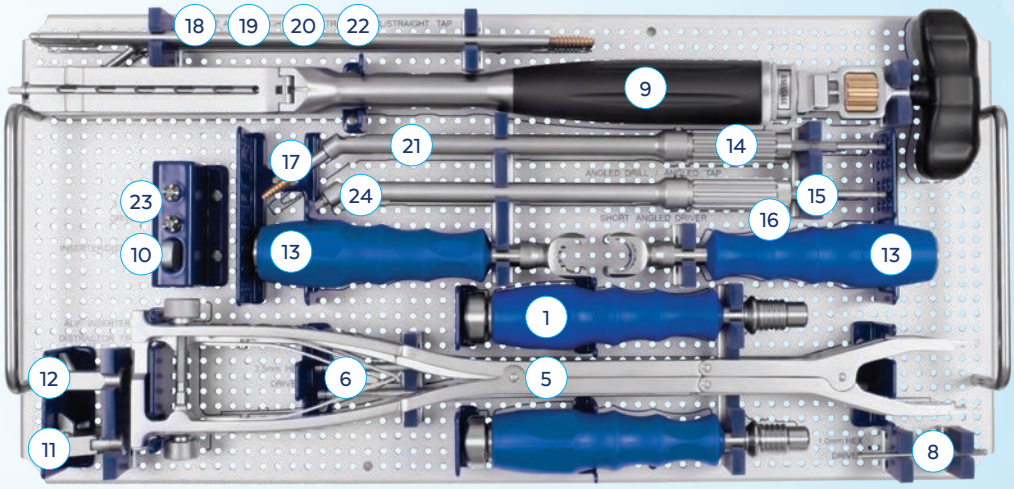
	Part No.	Description	Qty
1	650.105	QC Handle, Small, with Cap	2
2	664.500	PATRIOT® CONTINENTAL® Holder/Inserter	2
3	664.501	PATRIOT® CONTINENTAL® Holder/Inserter Sleeve	2
4	676.008	INDEPENDENCE® Drill Guide Holder	1
5	676.500	INDEPENDENCE® Implant Holder	1
6	676.502	INDEPENDENCE® 3.5mm Hex Straight Shaft	1
7	676.600	INDEPENDENCE® Set Screw Driver, 2.5mm Hex	1
8	676.604	INDEPENDENCE® Screw Driver, 1.0mm Hex	1
9	676.650	ALIF Inserter/Distractor	1
10	676.655	Tip Driver	1
11	676.660	INDEPENDENCE® Tip	1
12	676.670	CONTINENTAL® Tip	1
13	676.699	Counter-Torque	2
14	676.700	Angled Sleeve	4
15	676.701	Shaft	4
16	676.702	Nut	4
17	676.703	Self-Centering Angled Drill	1
18	676.704	Self-Centering Straight Drill	1
19	676.705	Self-Centering Bent Awl	1
20	676.706	Self-Centering Straight Awl	1
21	676.707	5.5mm Angled Tap	1
22	676.708	5.5mm Straight Tap	1
23	676.709	3.5mm Angled Hex Driver	2
24	676.710	3.5mm Angled Hex Driver, Short	2
	976.005	INDEPENDENCE® Graphic Case	

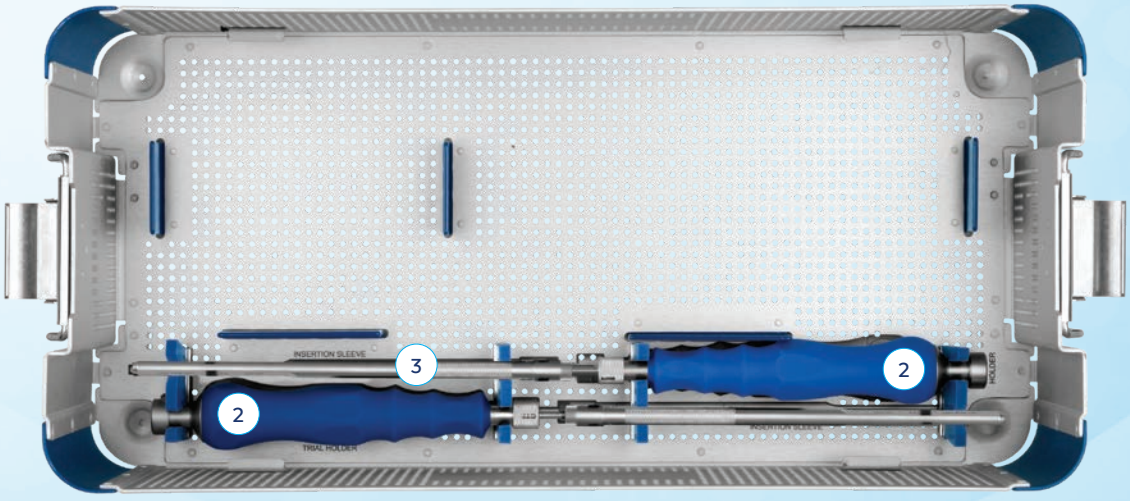
	INDEPENDENCE® Trials		Qty
25	676.111	Small, 8°, 11mm	1
	676.113	Small, 8°, 13mm	1
	676.115	Small, 8°, 15mm	1
	676.117	Small, 8°, 17mm	1
26	676.211	Small, 15°, 11mm	1
	676.213	Small, 15°, 13mm	1
	676.215	Small, 15°, 15mm	1
	676.217	Small, 15°, 17mm	1
27	676.411	Medium, 8°, 11mm	1
	676.413	Medium, 8°, 13mm	1
	676.415	Medium, 8°, 15mm	1
	676.417	Medium, 8°, 17mm	1
	676.419	Medium, 8°, 19mm	1
	676.421	Medium, 8°, 21mm	1
28	676.511	Medium, 15°, 11mm	1
	676.513	Medium, 15°, 13mm	1
	676.515	Medium, 15°, 15mm	1
	676.517	Medium, 15°, 17mm	1
	676.519	Medium, 15°, 19mm	1
	676.521	Medium, 15°, 21mm	1

	INDEPENDENCE® Drill Guides		Qty
29	676.931	Small Drill Guide, 11mm	1
	676.933	Small Drill Guide, 13mm	1
	676.935	Small Drill Guide, 15mm	1
	676.937	Small Drill Guide, 17mm	1
30	676.951	Medium Drill Guide, 11mm	1
	676.953	Medium Drill Guide, 13mm	1
	676.955	Medium Drill Guide, 15mm	1
	676.957	Medium Drill Guide, 17mm	1
	676.959	Medium Drill Guide, 19mm	1
	676.961	Medium Drill Guide, 21mm	1

INDEPENDENCE®
INSTRUMENT SET 976.909







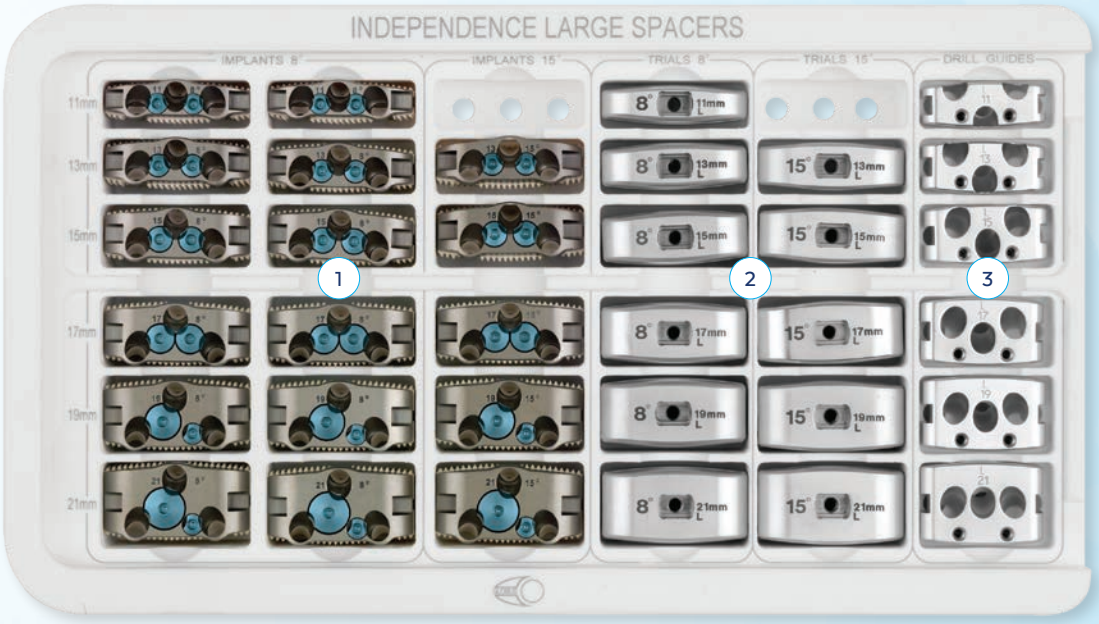
INDEPENDENCE® IMPLANTS, TRIALS, AND DRILL GUIDES – LARGE SET 976.903

1	**INDEPENDENCE® Implants**		**Qty**
	376.711	Large, 8°, 11mm	2
	376.713	Large, 8°, 13mm	2
	376.715	Large, 8°, 15mm	2
	376.717	Large, 8°, 17mm	2
	376.719	Large, 8°, 19mm	2
	376.721	Large, 8°, 21mm	2
	376.813	Large, 15°, 13mm	1
	376.815	Large, 15°, 15mm	1
	376.817	Large, 15°, 17mm	1
	376.819	Large, 15°, 19mm	1
	376.821	Large, 15°, 21mm	1

2	**INDEPENDENCE® Trials**		**Qty**
	676.711	Large, 8°, 11mm	1
	676.713	Large, 8°, 13mm	1
	676.715	Large, 8°, 15mm	1
	676.717	Large, 8°, 17mm	1
	676.719	Large, 8°, 19mm	1
	676.721	Large, 8°, 21mm	1
	676.813	Large, 15°, 13mm	1
	676.815	Large, 15°, 15mm	1
	676.817	Large, 15°, 17mm	1
	676.819	Large, 15°, 19mm	1
	676.821	Large, 15°, 21mm	1

3	**INDEPENDENCE® Drill Guides**		**Qty**
	676.971	Large Drill Guide, 11mm	1
	676.973	Large Drill Guide, 13mm	1
	676.975	Large Drill Guide, 15mm	1
	676.977	Large Drill Guide, 17mm	1
	676.979	Large Drill Guide, 19mm	1
	676.981	Large Drill Guide, 21mm	1
	976.003	INDEPENDENCE® Large Module	

INDEPENDENCE® IMPLANTS, TRIALS, AND DRILL GUIDES – LARGE SET 976.903

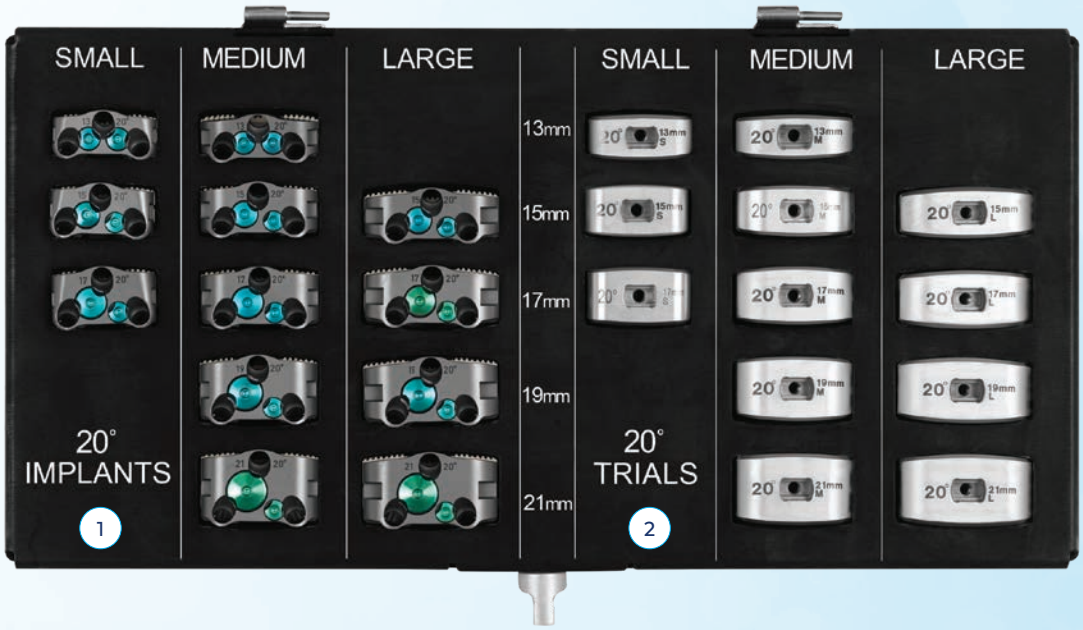


INDEPENDENCE®
20° IMPLANT SET 976.111 *(Additionally Available)*

1	INDEPENDENCE® Implants		Qty
	376.233	Small, 20°, 13mm	1
	376.235	Small, 20°, 15mm	1
	376.237	Small, 20°, 17mm	1
	376.533	Medium, 20°, 13mm	1
	376.535	Medium, 20°, 15mm	1
	376.537	Medium, 20°, 17mm	1
	376.539	Medium, 20°, 19mm	1
	376.541	Medium, 20°, 21mm	1
	376.835	Large, 20°, 15mm	1
	376.837	Large, 20°, 17mm	1
	376.839	Large, 20°, 19mm	1
	376.841	Large, 20°, 21mm	1

2	INDEPENDENCE® Trials		Qty
	676.233	Small, 20°, 13mm	1
	676.235	Small, 20°, 15mm	1
	676.237	Small, 20°, 17mm	1
	676.533	Medium, 20°, 13mm	1
	676.535	Medium, 20°, 15mm	1
	676.537	Medium, 20°, 17mm	1
	676.539	Medium, 20°, 19mm	1
	676.541	Medium, 20°, 21mm	1
	376.835	Large, 20°, 15mm	1
	676.837	Large, 20°, 17mm	1
	676.839	Large, 20°, 19mm	1
	676.841	Large, 20°, 21mm	1
	976.011	INDEPENDENCE® 20° Module	

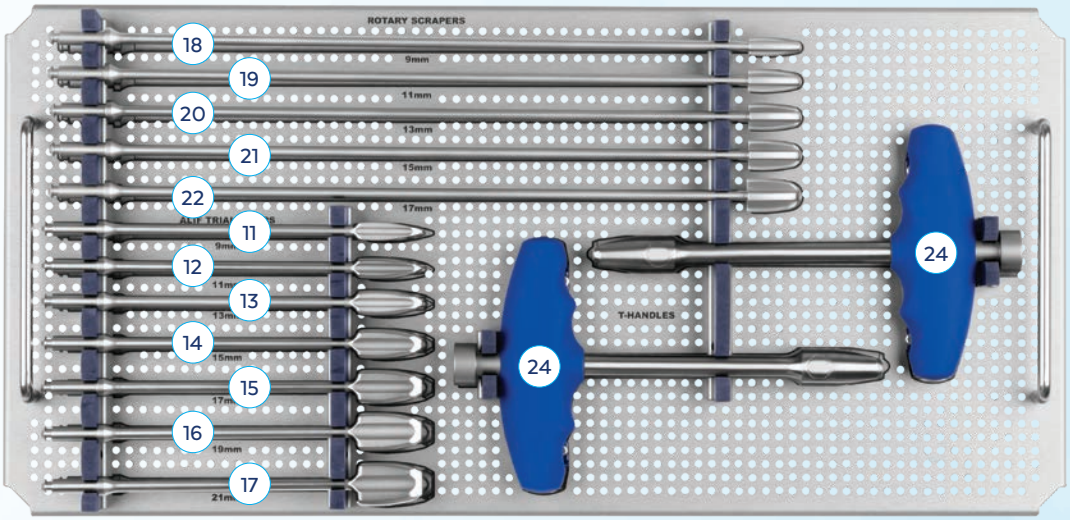
INDEPENDENCE®
20° IMPLANT SET 976.111 *(Additionally Available)*

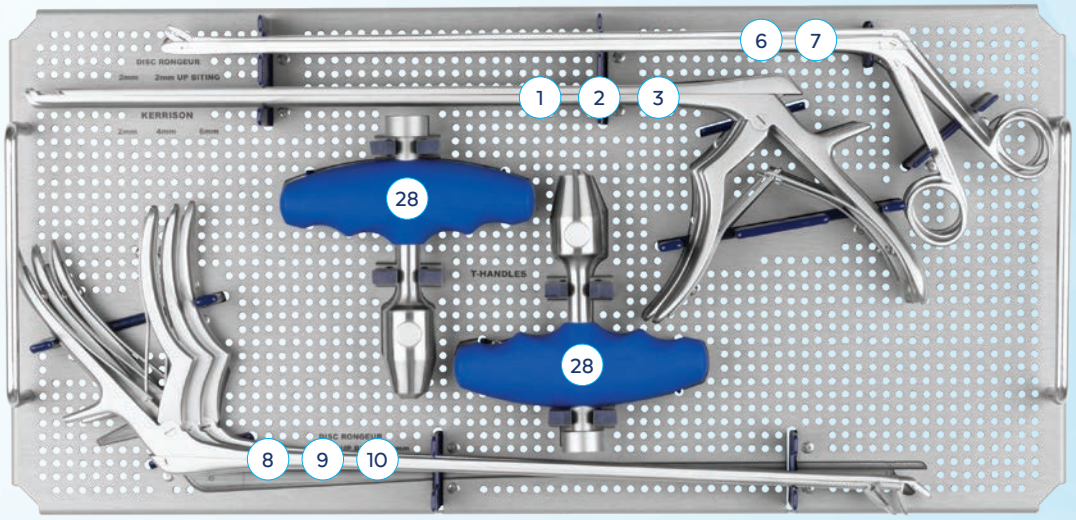


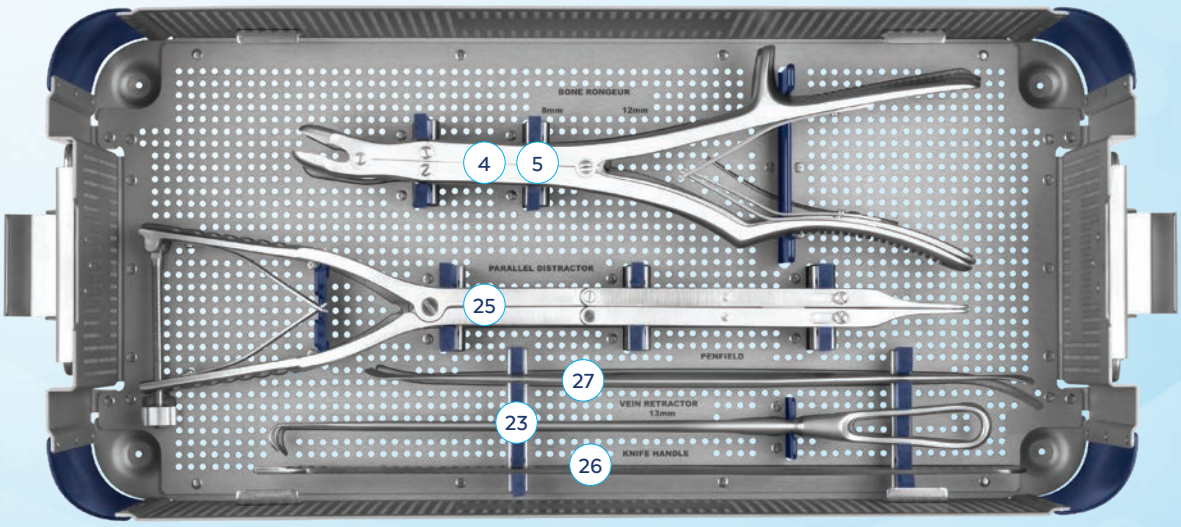
ANTERIOR DISC PREP I
INSTRUMENT SET 925.901

	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

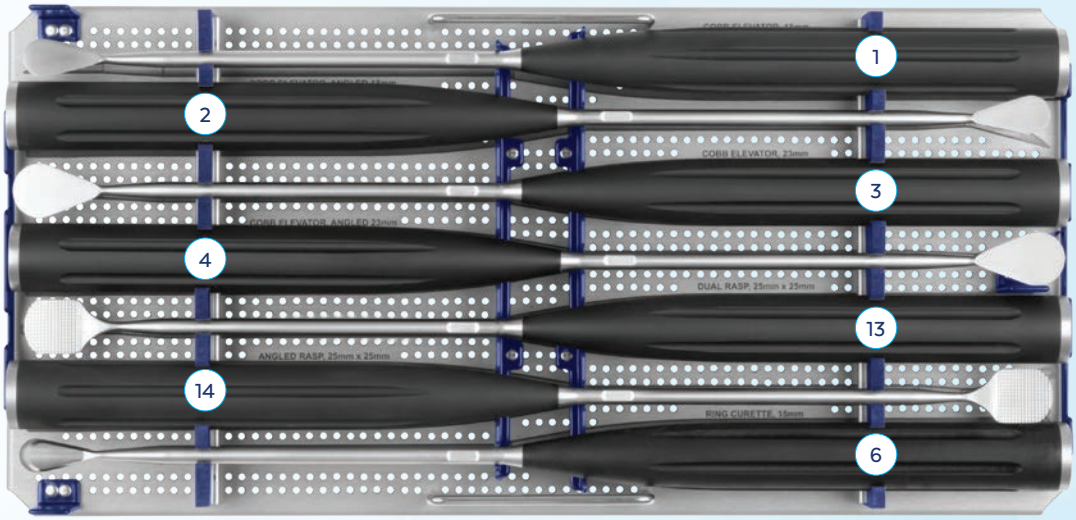
	Part No.	Description	Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette,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

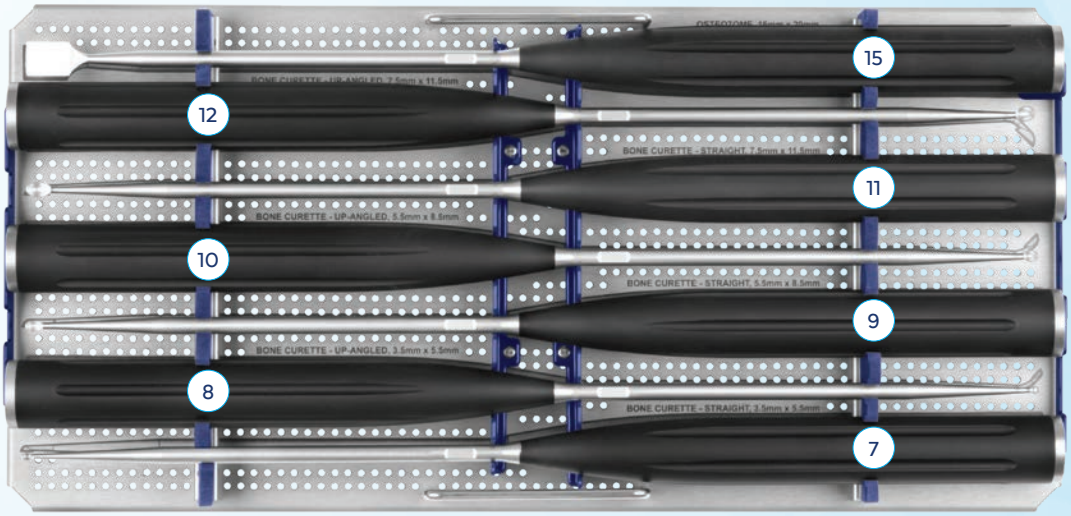
Additionally Available Instruments

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 in gray are additionally available.

ANTERIOR DISC PREP II
INSTRUMENT SET 925.902





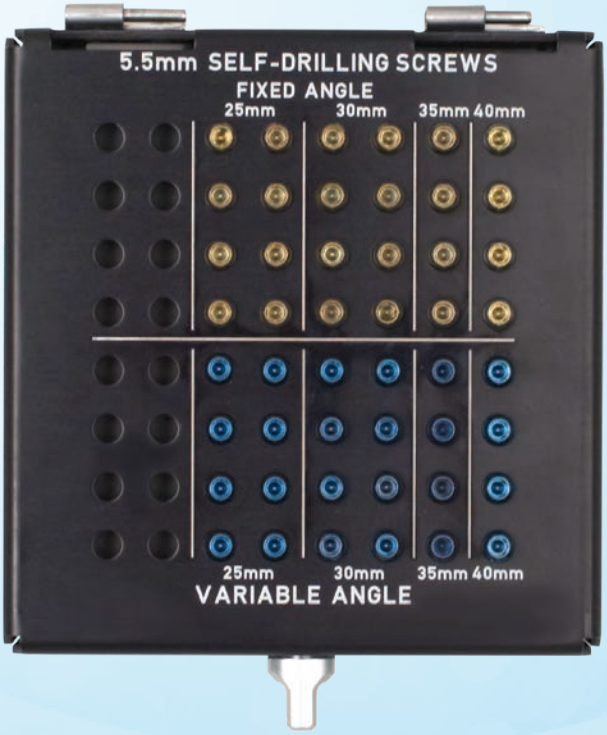
INDEPENDENCE®
ANTERIOR BONE SCREW SETS

INDEPENDENCE® HA Coated Bone Screw Set 976.908		Qty
176.420S	Variable Angle, 20mm	9
176.425S	Variable Angle, 25mm	9
176.430S	Variable Angle, 30mm	9
176.435S	Variable Angle, 35mm	9
176.440S	Variable Angle, 40mm	
176.925S	Self-Drilling, Variable Angle, 25mm	
176.930S	Self-Drilling, Variable Angle, 30mm	
976.008	INDEPENDENCE® HA Coated Screw Soft Case	

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

Items in gray are additionally available.

INDEPENDENCE®
ANTERIOR BONE SCREW SETS



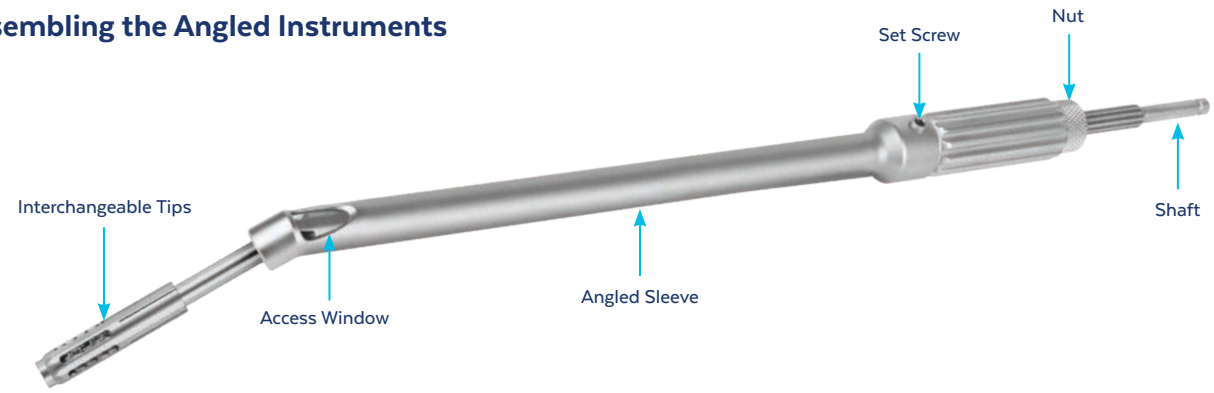
ALIF
LOCKING SCREW SET 9212.9005

	Part No.	Description	Qty
1	7212.0020	Locking Bone Screw, 5.5mm, 20mm	8
2	7212.0025	Locking Bone Screw, 5.5mm, 25mm	8
3	7212.0030	Locking Bone Screw, 5.5mm, 30mm	8
4	7212.0035	Locking Bone Screw, 5.5mm, 35mm	4
5	7212.0040	Locking Bone Screw, 5.5mm, 40mm	4
6	7212.1025	Locking Bone Screw, Self-Drilling 5.5mm, 25mm	8
7	7212.1030	Locking Bone Screw, Self-Drilling 5.5mm, 30mm	8
8	7212.1035	Locking Bone Screw, Self-Drilling 5.5mm, 35mm	4
9	7212.1040	Locking Bone Screw, Self-Drilling 5.5mm, 40mm	4
	9212.0003	ALIF Locking Screw Module	

ALIF
LOCKING SCREW SET 9212.9005

APPENDIX

Assembling the Angled Instruments



Note: The angled instruments for INDEPENDENCE® are provided preassembled in the middle instrument tray. Two additional DTS Driver Tips are included that can be assembled if the Drill Guide is used. The Counter-Torque should be attached to provide greater control of the distal tip.

1. Select the appropriate tip:

Self-Centering Angled Drill 676.703

3.5mm Angled Hex Driver, Short 676.710

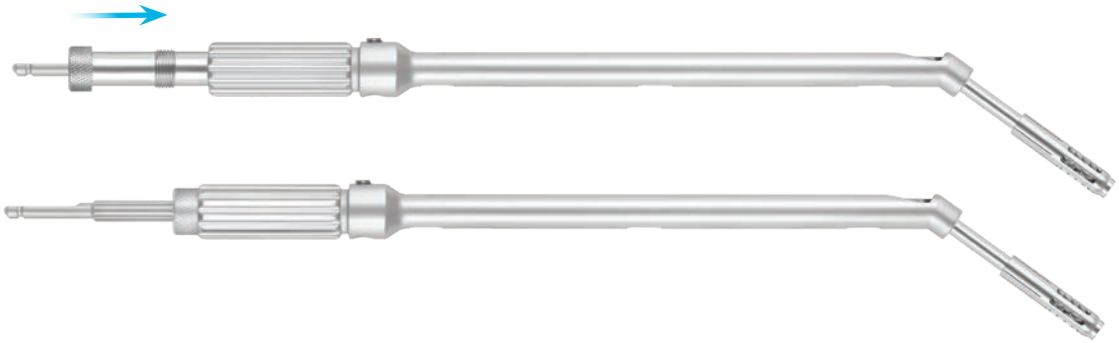
5.5mm Angled Tap 676.707

3.5mm Angled Hex Driver 676.709

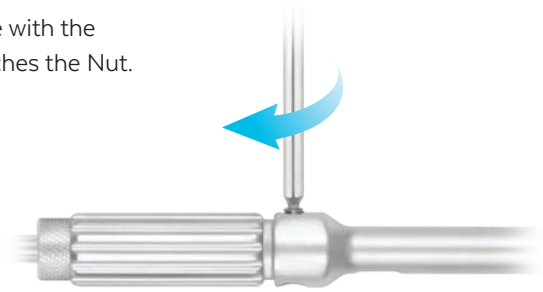
2. Hold the Angled Sleeve downward with the access window facing upward.
   Insert the selected tip into the window on the distal end of the Angled Sleeve.

3. Insert the shaft into the Angled Sleeve until the gears on the shaft join with the gears on the selected Tip.

4. Place the Nut over the shaft. Rotate the threads clockwise until the Nut sits flush with the Angled Sleeve.



5. Tighten the set screw by rotating it clockwise with the **Set Screw Driver** until it clicks twice and reaches the Nut.



6. Attach a **Quick-Connect Handle**.

IMPORTANT INFORMATION ON INDEPENDENCE® SPACERS

DESCRIPTION

INDEPENDENCE® (including INDEPENDENCE MIS®, and INDEPENDENCE MIS AGX™) 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. The spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

INDEPENDENCE® Spacers are stand-alone devices used with screws that are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. INDEPENDENCE MIS®, INDEPENDENCE MIS AGX™, Spacers may be used with screws and/or anchors. When used with screws, these devices are stand-alone constructs. When used with anchors, these devices are intended to be used with supplemental fixation such as the INDEPENDENCE MIS AGX™ Integrated Ti Spacer or CITADEL Anterior Lumbar Plate System.

INDEPENDENCE® and INDEPENDENCE MIS® Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The anterior portion of the implants are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

The INDEPENDENCE MIS AGX™ Integrated Ti Spacer is made from titanium alloy as specified in ASTM F136, F1295, and F1472. INDEPENDENCE MIS AGX™ Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560.

INDEPENDENCE® TPS, INDEPENDENCE MIS® TPS, and INDEPENDENCE MIS AGX™ TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

The mating 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. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537.

INDICATIONS

INDEPENDENCE® Spacers (including INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™) are integrated anterior lumbar interbody fusion devices 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. All INDEPENDENCE® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

INDEPENDENCE® Spacers are intended to be used with or without three screws which accompany the implants. INDEPENDENCE MIS® and INDEPENDENCE MIS AGX™ Integrated Spacers are intended to be used with or without three screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). In addition, these devices are intended for stand-alone use in patients with DDD at one or two levels only when <25° lordotic implants are used with three screws per implant.

INDEPENDENCE MIS AGX™ Spacers are C-shaped, non-integrated PEEK spacers that are intended to be used with supplemental fixation (e.g. facet screws or posterior fixation). When used in conjunction with the INDEPENDENCE MIS AGX™ Integrated Ti Spacer, these devices become the INDEPENDENCE MIS AGX™ Integrated Spacer.

All INDEPENDENCE® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

WARNINGS

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

- device component fracture;
- 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, commercially pure titanium, 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.

MRI SAFETY INFORMATION

The INDEPENDENCE® 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 INDEPENDENCE® 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 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 INDEPENDENCE® SPACERS

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 EFFECTS

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile 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 pouch or container/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. Sterile implants meet pyrogen limit specifications.

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

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

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

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

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

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.

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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