HEDRON IA®

3D Printed Integrated ALIF Spacer

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

HEDRON IA®

HEDRON IA®

3D Printed Integrated ALIF Spacer

HEDRON® Spacers feature a biomimetic porous scaffolding designed to promote bone formation onto and through the implant.

The Face of Fusion

An ovine interbody study demonstrated significantly more bone ingrowth within HEDRON® implants 6 weeks postoperatively compared to PEEK and solid titanium implants.*

In-Line Integrated Fixation

Innovative instruments facilitate simple implantation even with challenging patient anatomy.

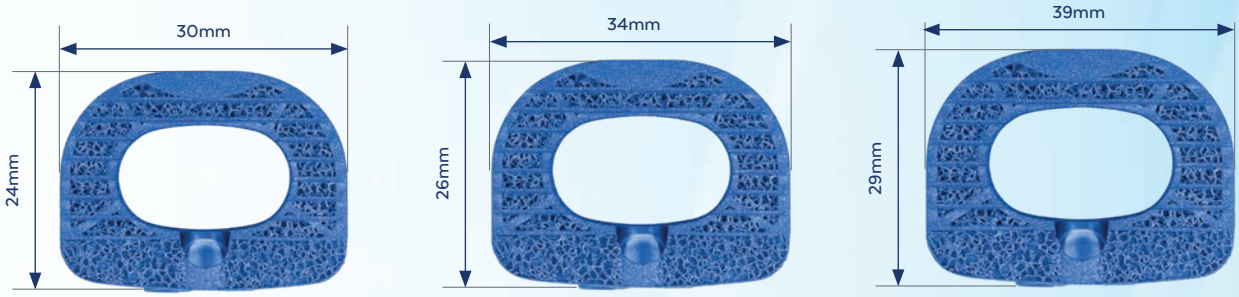
Intraoperative Versatility

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

*Data on file

Implant Options

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



Fixation Options

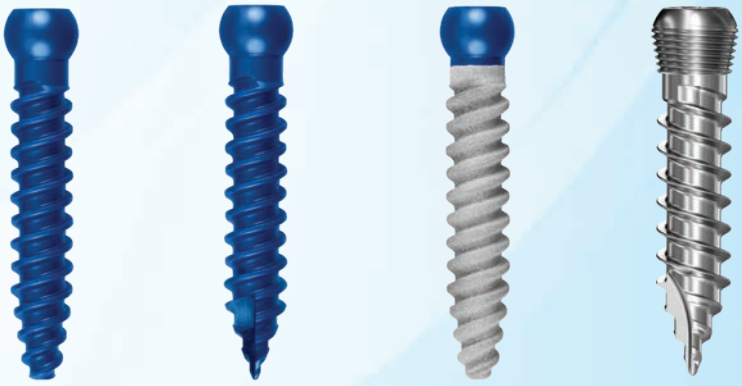
Lumbar Anchor Options

- Lengths: 20, 25, 27, 30mm
- 5.5mm diameter
- Titanium alloy

Lumbar Anchor

Screw Options

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



Variable Angle Self-Tapping Screw

Variable Angle Self-Drilling Screw

HA Coated Variable Angle Screw

Locking Screw (CoCr)

INSTRUMENT OVERVIEW

TRIALS

Small (24x30mm)						
Lordosis	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°	-	676.313	676.315	676.317	676.319	676.321
30°	-	676.353	676.355	676.357	676.359	676.361

Medium (26x34mm)						
Lordosis	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°	-	676.613	676.615	676.617	676.619	676.621
30°	-	676.663	676.665	676.667	676.669	676.671

Large (29x39mm)								
Lordosis	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°	-	676.833	676.835	676.837	676.839	676.841	-	-
25°	-	676.913	676.915	676.917	676.919	676.921	-	-
30°	-	-	676.985	676.987	676.989	676.991	676.993	676.995

TRIAL HOLDERS

Trial Holder 6108.0003

Trial Sleeve 6108.0001

Trial Holder Assembly

Items in gray are additionally available.

IMPLANT INSERTION INSTRUMENTS

Triple Barrel Anchor Guides

Size	Part No.
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

Freehand Holder 6135.0100

Hammer 603.977

STRAIGHT INSTRUMENTS

QC Handle, Small with Cap 650.105

3.5mm Hex Straight Driver 676.502

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

Self-Centering Straight Instrument with Retracting Front Sleeve

Self-Centering Straight Drill 676.704

Self-Centering Straight Awl 676.706

Self-Centering Straight Instrument Assembly

5.5mm Straight Tap 676.708

Set Screw Positioner, Torque Limiting (0.4Nm) 6108.1006

ANGLED INSTRUMENTS

Counter-Torque 676.699

Angled Sleeve 676.700

Angled Driver Shaft 676.701

Angled Driver 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 Assembly

REMOVAL INSTRUMENTS

Removal Tool 6135.0500

Slide Hammer 614.802

SURGICAL TECHNIQUE

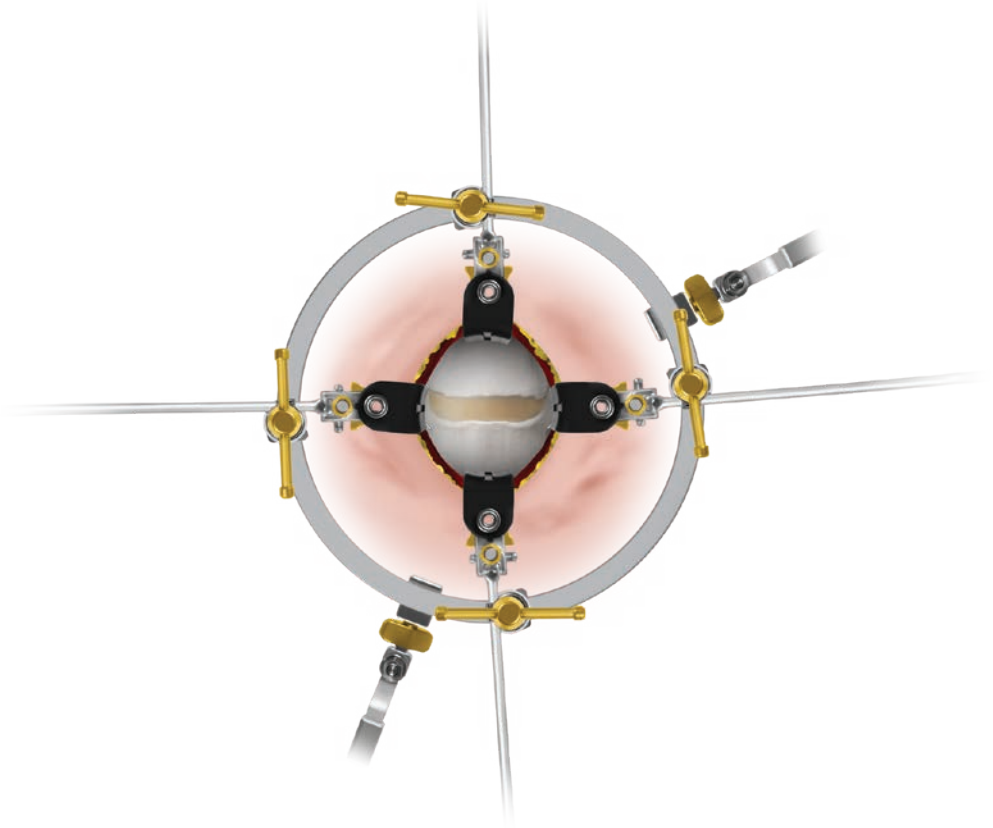
HEDRON IA®

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 and/or anchors 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 specific instructions on the corresponding supplemental fixation system.

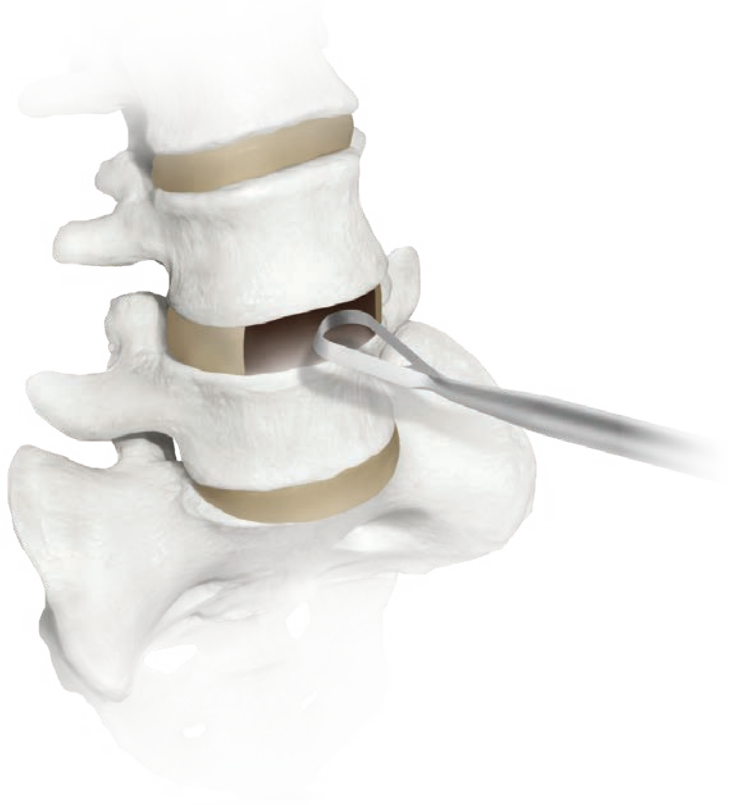
STEP 1 APPROACH

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



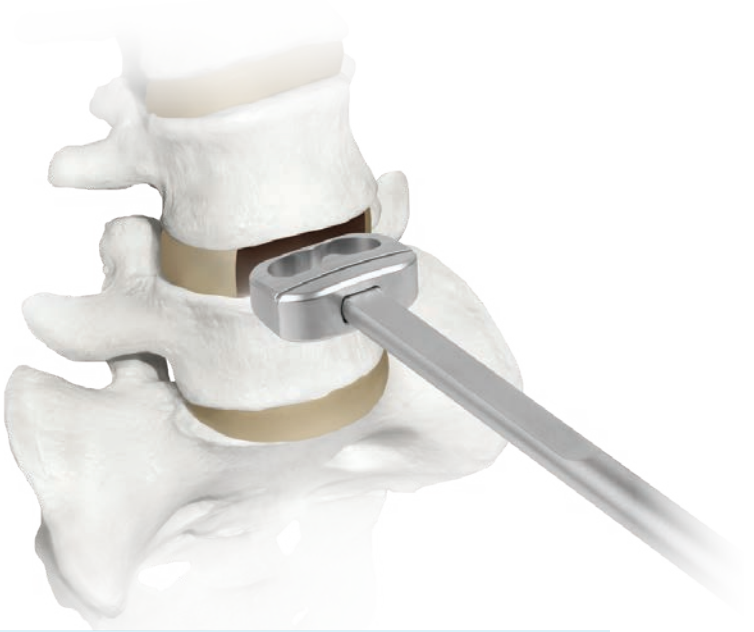
STEP 2 PREPARATION

Anterior disc preparation instruments may be used to expose the disc. Remove the disc materials using rongeurs and other suitable instruments. Scrapers may be used to remove superficial layers of the cartilaginous endplates. If desired, a **Parallel Distractor** may be used to distract the disc space. Preserve the posterior and lateral walls of the annulus to provide peripheral support. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



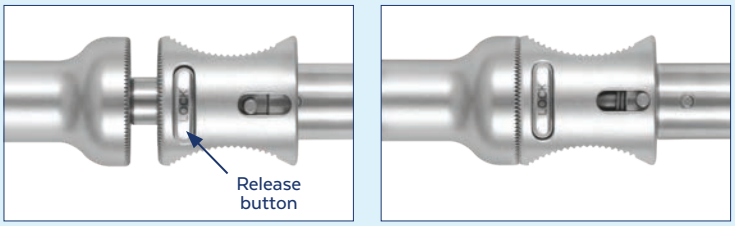
STEP 3 SIZING

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 to stabilize the segment. Confirm Trial placement using 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 sleeve back and rotate the handle counterclockwise.



Unlocked Locked

HEDRON IA® may be used with three anchors, three screws, or any combination of screws and anchors.

- **Using Anchors:** Follow steps 4a–7a on pages 13–16.
- **Using Screws:** Follow steps 4b–7b on pages 17–20.
- **Using Hybrid Anchors/Screws:** For anchor fixation follow steps 4a–7a on pages 13–16. For screw fixation follow steps 4b–7b on pages 17–20.

USING ANCHORS

STEP 4A ANCHOR LOADING

After determining spacer size, select the corresponding height **Triple Barrel Anchor Guide**.

Determine the desired anchor length using the Anchor Sizing Chart on page 24. Load the three selected anchors into the guide.

LOADING THE ANCHORS

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

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

STEP 5A SPACER INSERTION

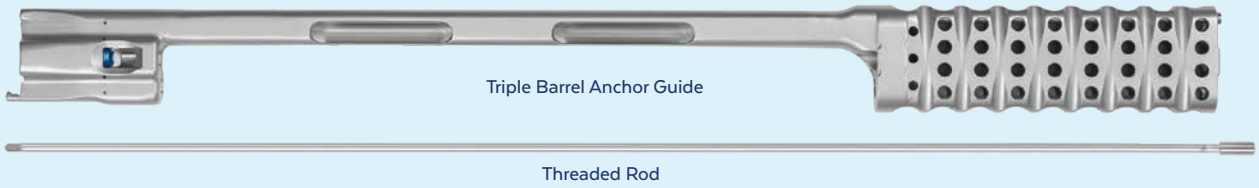
Select an appropriately sized HEDRON IA® spacer and pack with autogenous and/or allograft allogenic bone graft (cortical or corticocancellous). Attach the spacer to the Triple Barrel Anchor Guide, as shown below.

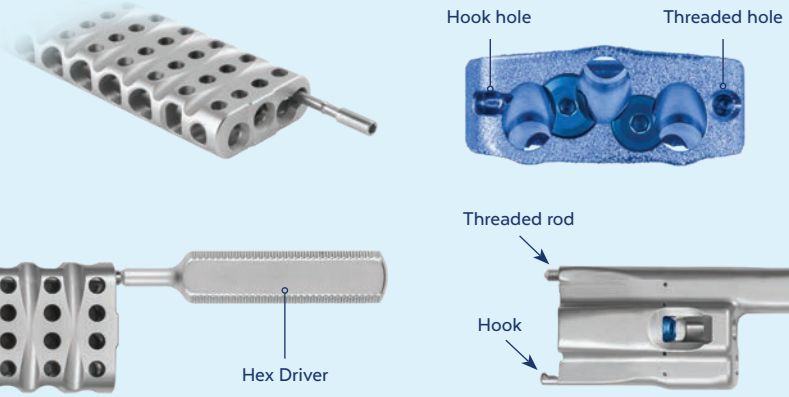
Insert the spacer into the prepared disc space. A **Hammer** may be used to gently position the spacer within the disc space. The spacer should sit flush with or recessed 1mm from the anterior portion of the vertebral bodies.

LOADING THE SPACER (TRIPLE BARREL ANCHOR GUIDE)

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

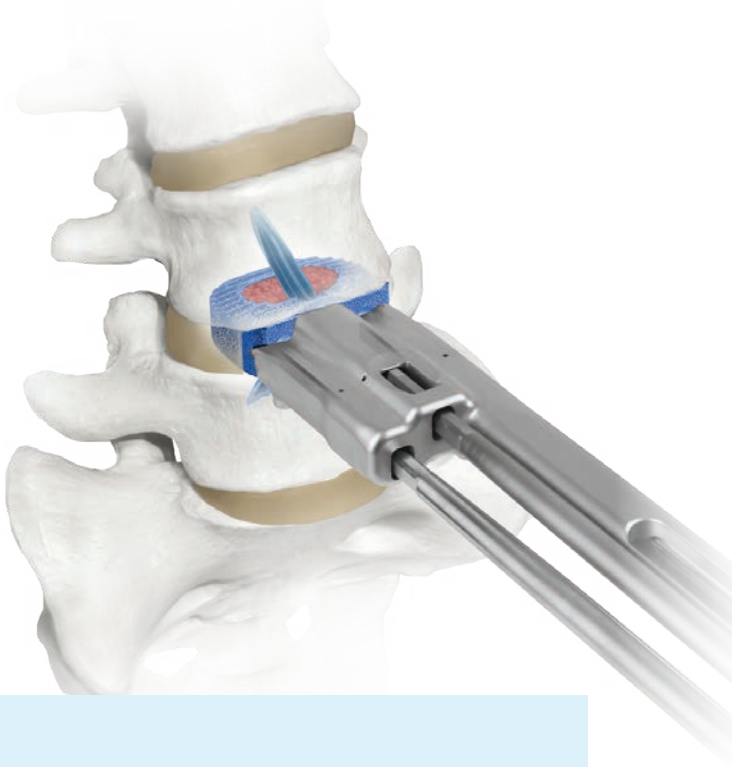
Insert the **Hex Driver** into the same hole. Engage the Threaded Rod and rotate the driver clockwise until the end emerges from the distal tip of the guide.





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

STEP 6A ANCHOR INSERTION



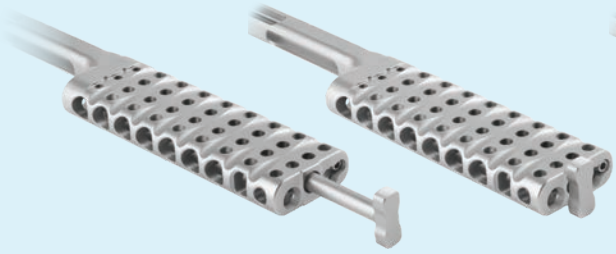
Confirm that the anterior face of the spacer is flush with or recessed 1mm from the anterior portion of the vertebral body. Insert the **Anchor Impactor** medially.

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.

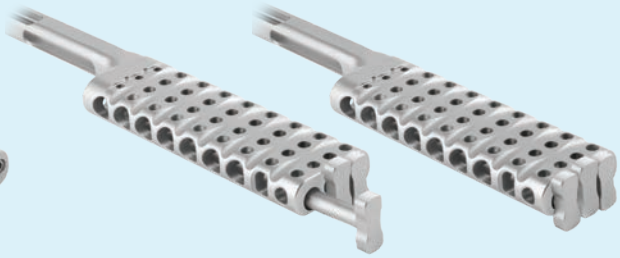
INSERTING ANCHOR IMPACTORS

Insert the Anchor Impactor into the proximal end of the Triple Barrel Anchor Guide until resistance is met. Advance the anchor to the vertebral endplate. Gently impact with the Hammer to insert the anchor into the vertebral body. Repeat for each anchor.

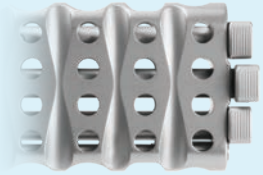
Note: The two lateral impactors sit slightly lower than the center impactor. The impactors are designed to only fit into the anchor guide in the orientation shown below.



Inserting first anchor



Inserting remaining anchors



Impactors flush against holder

Disengaging the Anchor Guide

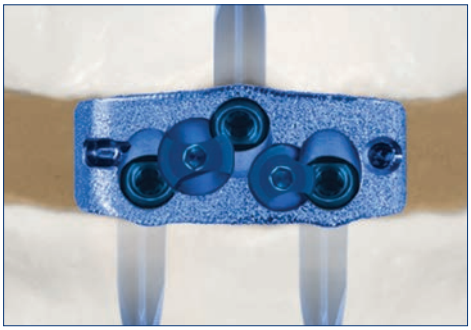
Following spacer and anchor insertion, remove the guide. To release the spacer, rotate the Threaded Rod counterclockwise using the Hex Driver. Gently rock the guide medial/lateral to release.

For disassembly, remove the Threaded Rod from the Triple Barrel Anchor Guide using the Hex Driver to rotate the Threaded Rod counterclockwise.

STEP 7A ANCHOR BLOCKING

Once the screws are fully seated, insert the **Set Screw Positioner, Torque Limiting** (0.4Nm) into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). Ensure that the set screws block the anchors.

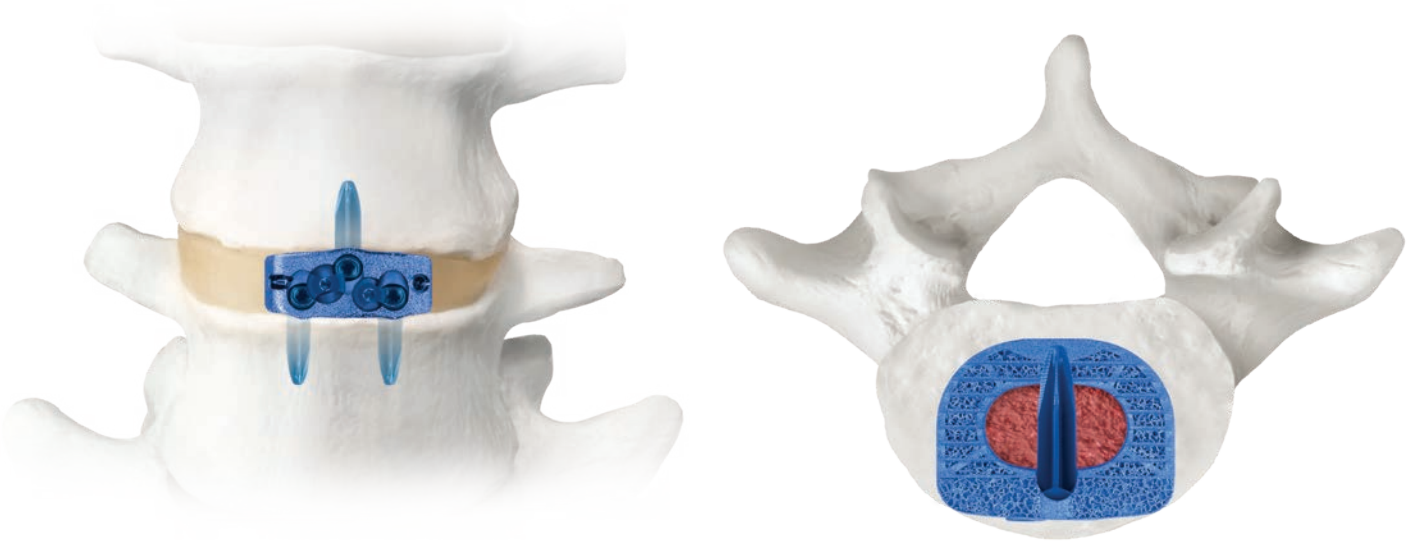
Initial position



Final position (blocked)

FINAL POSITION

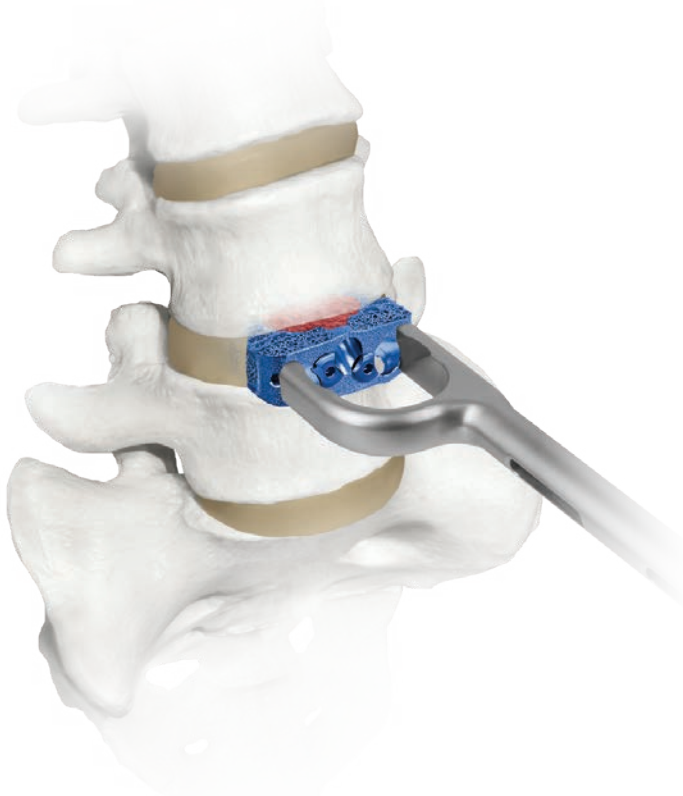
The final implant position is shown below. Additional autograft or allograft bone should be packed around the implant if possible. Supplemental fixation (e.g., facet screws or posterior fixation) is required when the HEDRON IA® spacer is used with one or more anchors (see page 21) or when hyperlordotic (≥25°) spacers are used.



HEDRON IA® with anchors

USING SCREWS

STEP 4B SPACER INSERTION



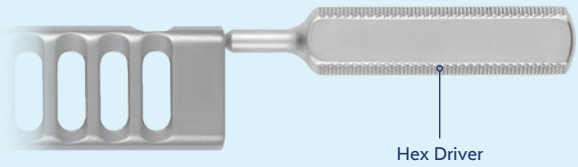
Select an appropriately sized HEDRON IA® spacer and pack with autogenous and/or allograft allogenic bone graft (cortical or corticocancellous). Attach the spacer to the Freehand Holder, as shown below.

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 with or recessed 1mm from the anterior portion of the vertebral bodies.

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

LOADING THE SPACER (FREEHAND HOLDER)

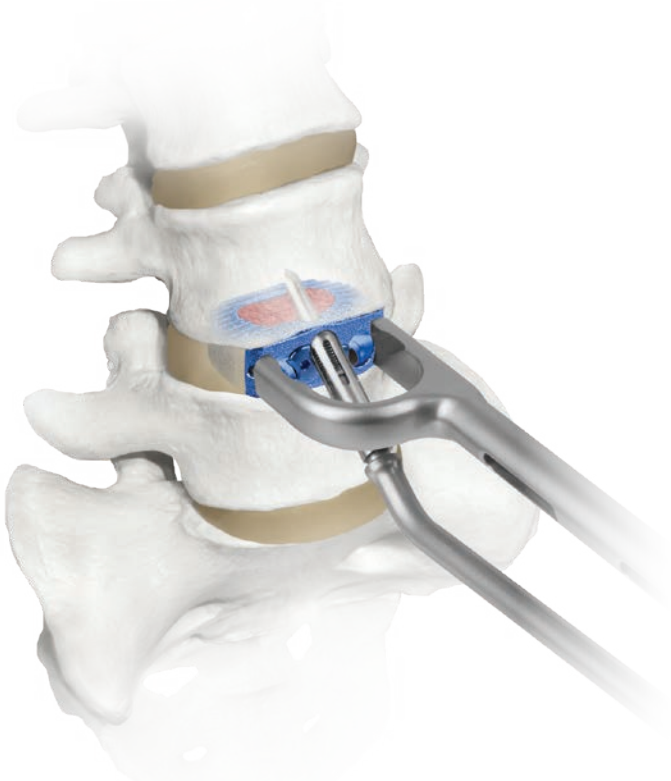
To assemble the Freehand Holder, insert the Threaded Rod into the proximal hole. Insert the Hex Driver into the proximal hole to engage the Threaded Rod. Rotate the driver clockwise until the end emerges from the distal tip of the holder.



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

STEP 5B SCREW HOLE PREPARATION

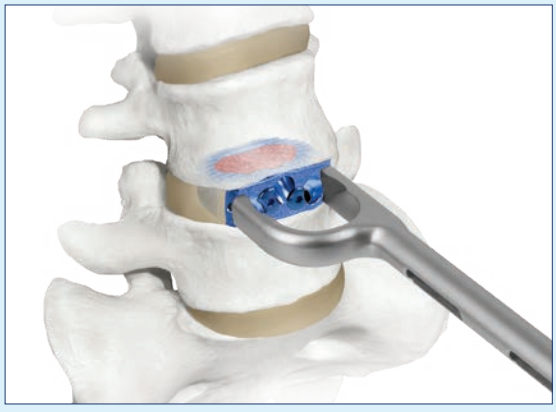
Insert a **Self-Centering Awl** to break the cortex. A **Self-Centering Drill** and **Tap** may be used to further prepare the screw hole.



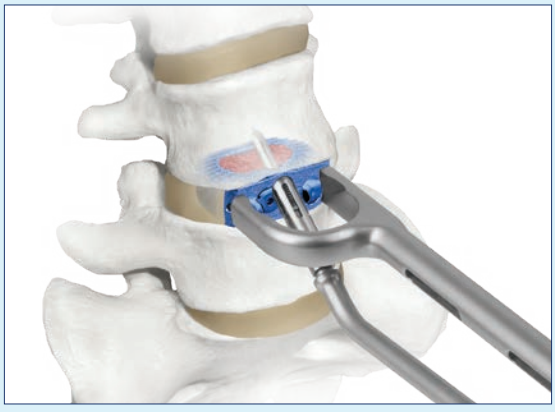
USING THE SELF-CENTERING INSTRUMENTS

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 may be used.



Freehand Holder



Self-Centering Angled Awl with retracted front sleeve

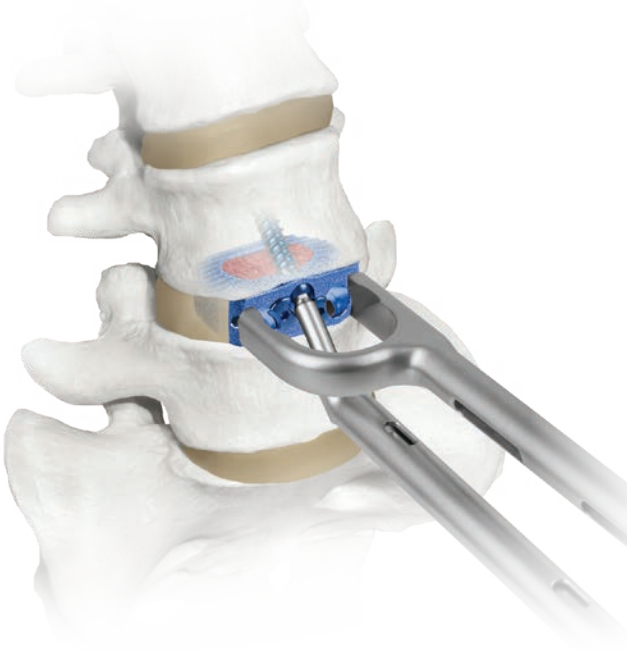
USING THE SELF-CENTERING SLEEVE

The Self-Centering Sleeve allows for proper screw trajectory without the use of a drill guide. The sleeve must be properly engaged (shown below) with the plate before advancing any screw hole preparation instrument. Proceed to screw insertion before preparing the remaining hole.

INCORRECT

CORRECT

STEP 6B SCREW INSERTION



Depending on the angle and position of the spacer, a Straight or Angled Driver may be used for screw insertion. 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.

Fixed or variable angle screws may be inserted freehand.

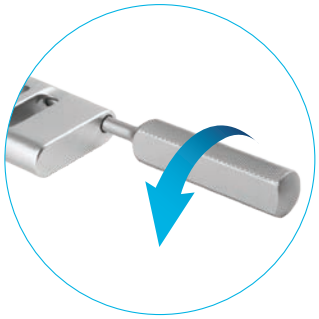
Select the desired screw size using the sizing chart on page 25. Load the screw onto the driver and insert the screw. The spacer lags to the bone during screw insertion. Repeat for the second and third screw.

Note: If inserting screws with the Freehand Holder attached, use the 3.5mm Angled Hex Driver, Long.

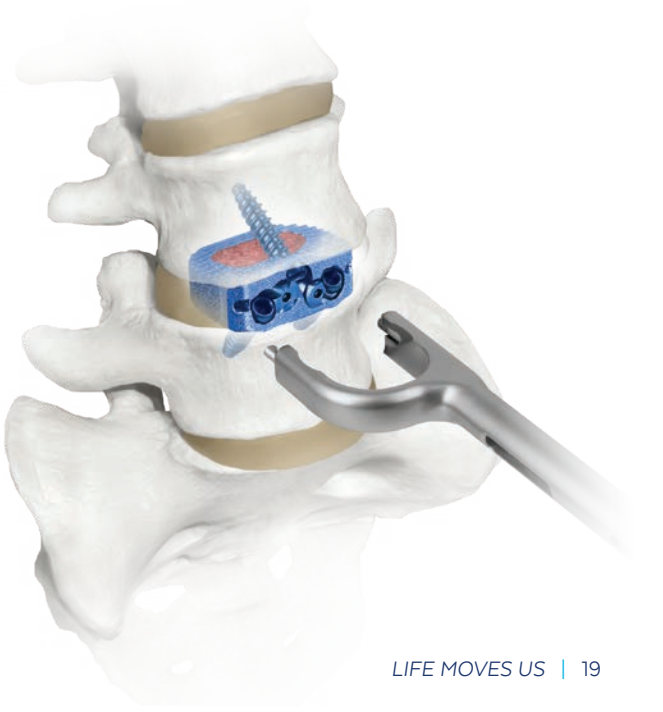
If using locking screws, the threaded screw head is designed to grip the screw hole and lock into the spacer.

Remove the Freehand 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.

For disassembly, remove the Threaded Rod from the Triple Barrel Anchor Guide using the Hex Driver to rotate the Threaded Rod counterclockwise.

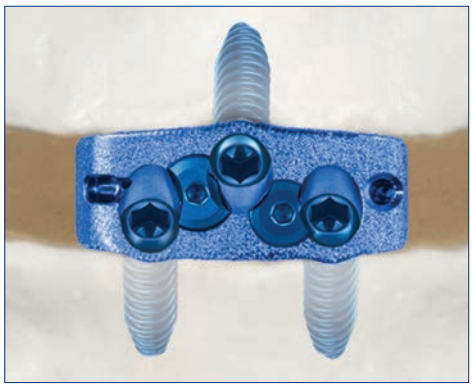


Rotating Threaded Rod counterclockwise

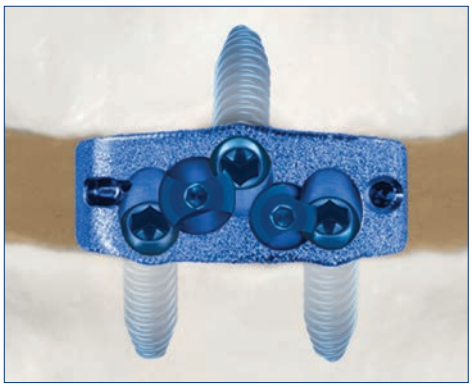


STEP 7B SCREW BLOCKING

Once the screws are fully seated, insert the Set Screw Positioner, Torque Limiting (0.4Nm) into the blocking set screw and rotate clockwise approximately 90° to the final position (blocked). Ensure that the set screws block the bone screws.



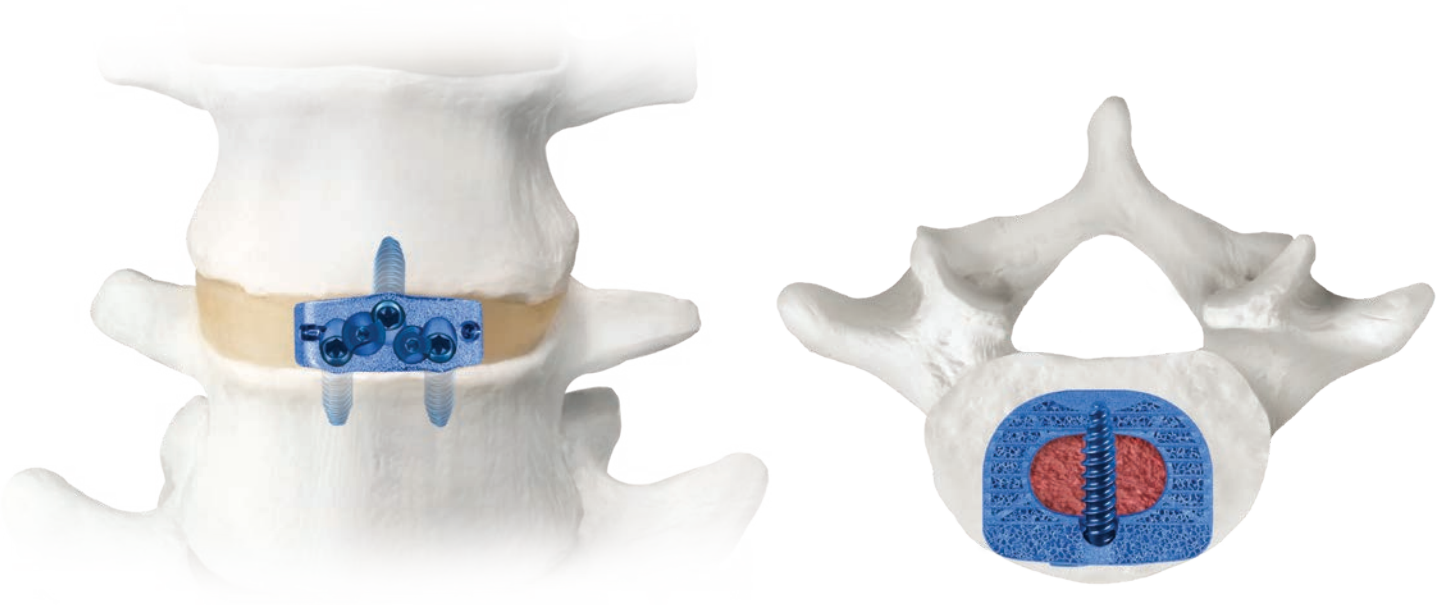
Initial position



Final position (blocked)

FINAL POSITION

The final implant position is shown below. Additional autograft or allograft bone should be packed around the implant if possible. Supplemental fixation (e.g., facet screws or posterior fixation) is required when hyperlordotic (≥25°) spacers are used.



HEDRON IA® with screws

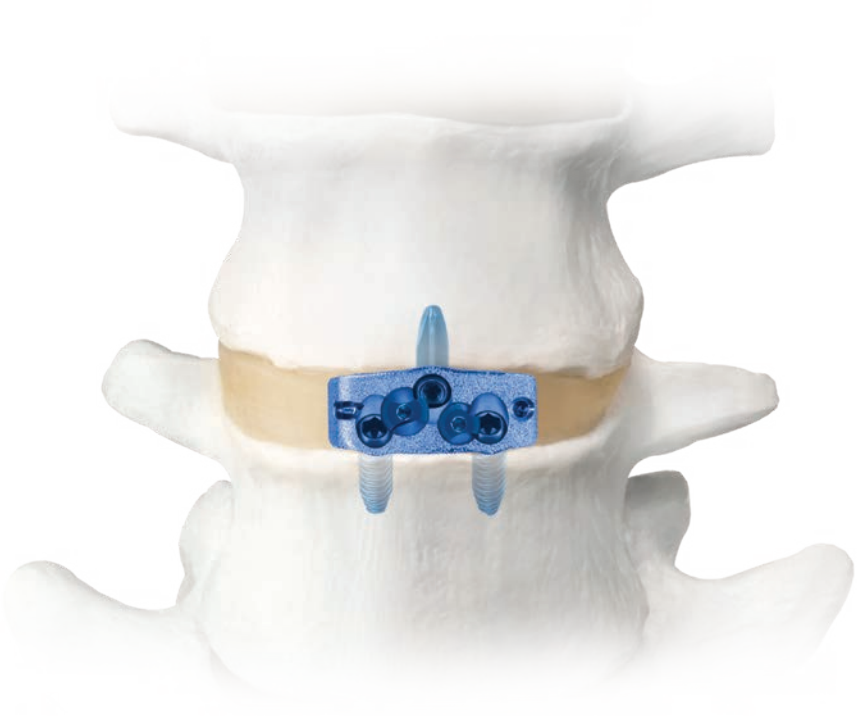
USING HYBRID SCREWS/ANCHORS

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

For anchor fixation, follow steps 4a–7a on pages 13-16.

For screw fixation, follow steps 4b–7b on pages 17-20.

FINAL POSITION



Hybrid final construct

SUPPLEMENTAL FIXATION

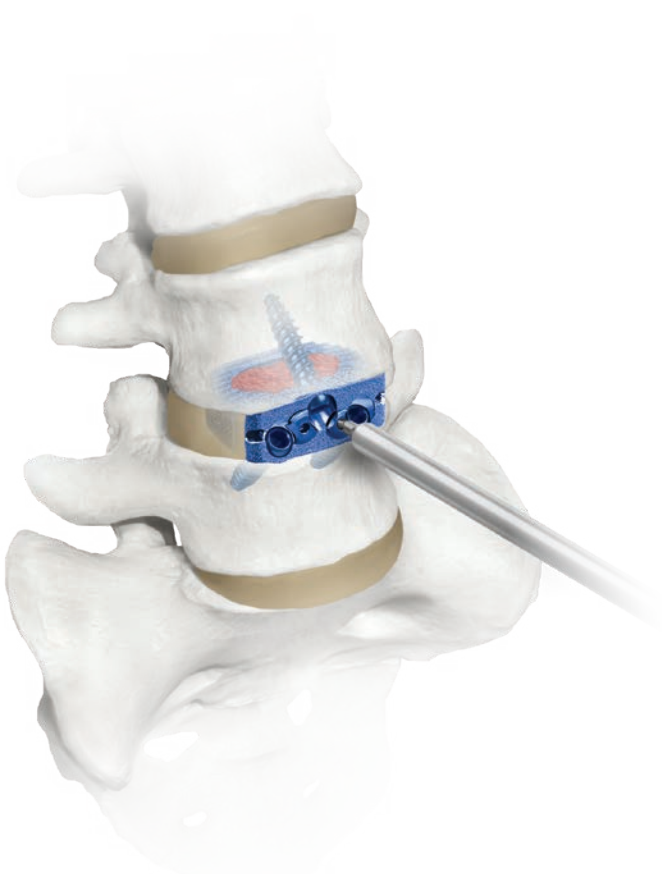
Supplemental fixation (e.g., facet screws or posterior fixation) is required when the HEDRON IA® Spacer is used with one or more anchors or when hyperlordotic (≥25°) spacers are used. Refer to the selected surgical technique guide for specific instructions on supplemental fixation.

OPTIONAL: REMOVAL

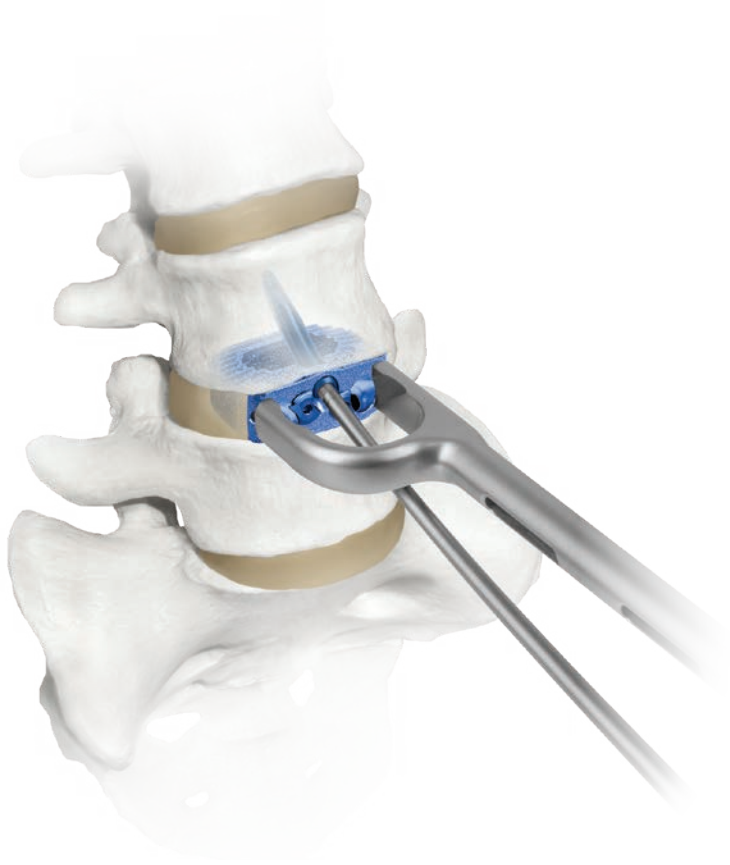
To remove the HEDRON IA® implant, unblock the blocking set screws using the Set Screw Positioner.

Remove any bone screws using the Straight or Angled Driver.

For anchor removal, the Freehand Holder may be used to help grip the spacer. Attach the holder to the spacer as described on page 17. Thread the **Anchor Removal Tool** into the head of the anchor until fully seated.

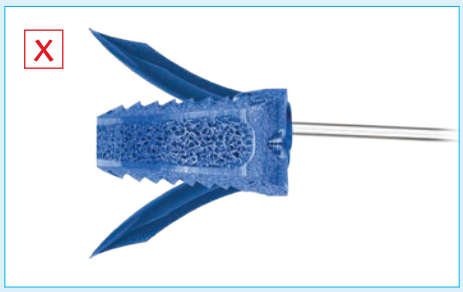


Unblocking blocking set screw using Set Screw Positioner

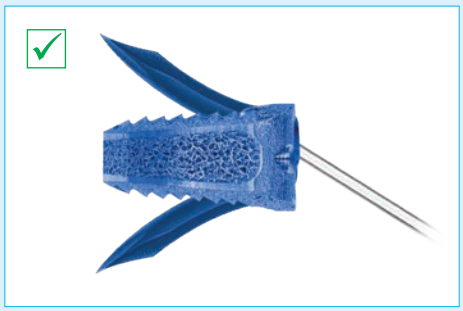


Anchor removal using Freehand Holder and Removal Tool

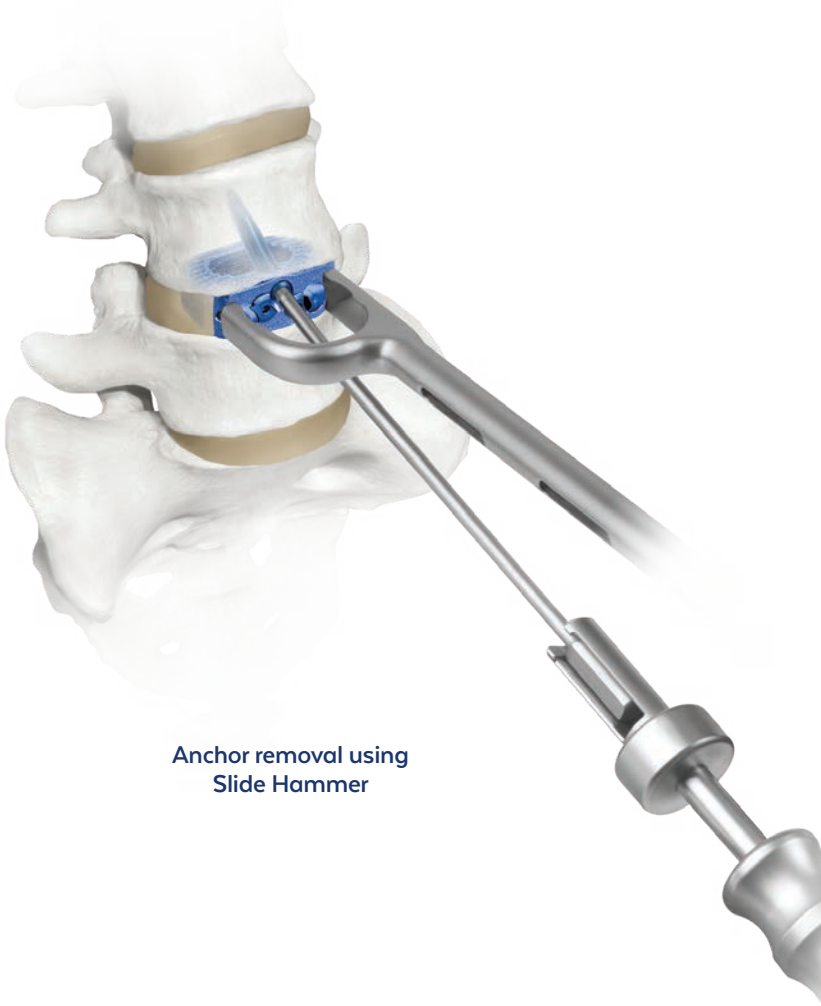
Use the **Slide Hammer** to gently remove the anchors.



INCORRECT



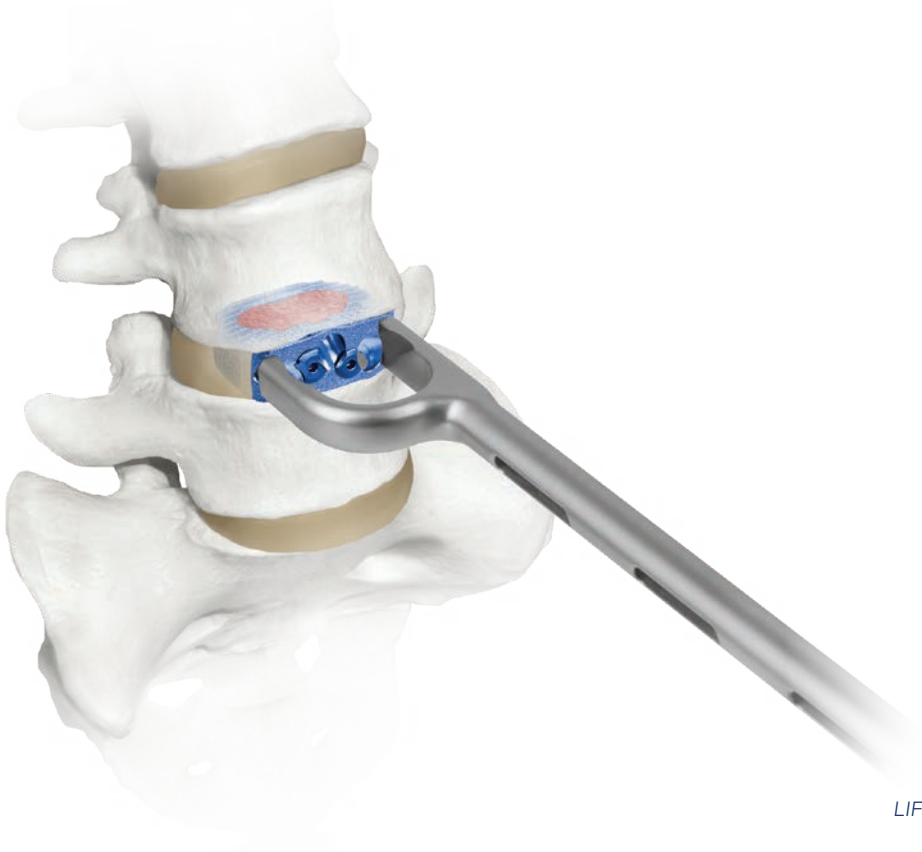
CORRECT



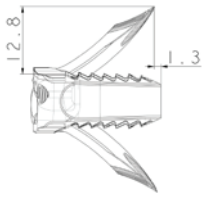
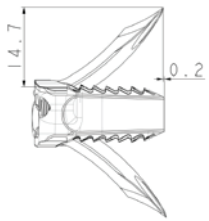
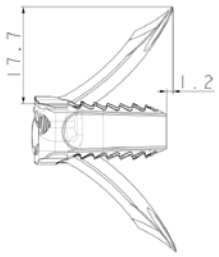
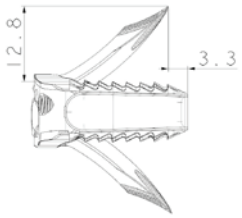
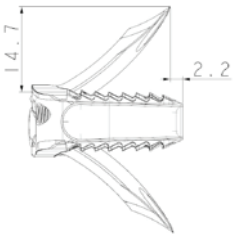
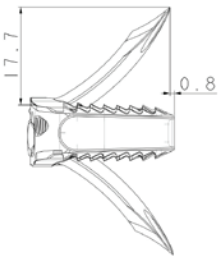
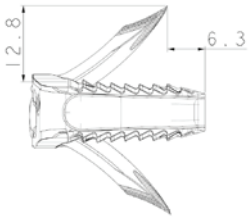
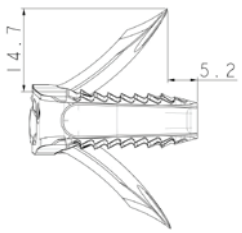
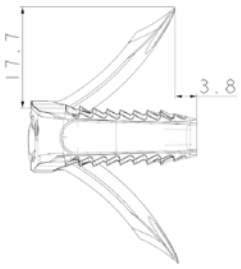
Anchor removal using
Slide Hammer

Anchors may be replaced by screws, if necessary, for revision surgery.

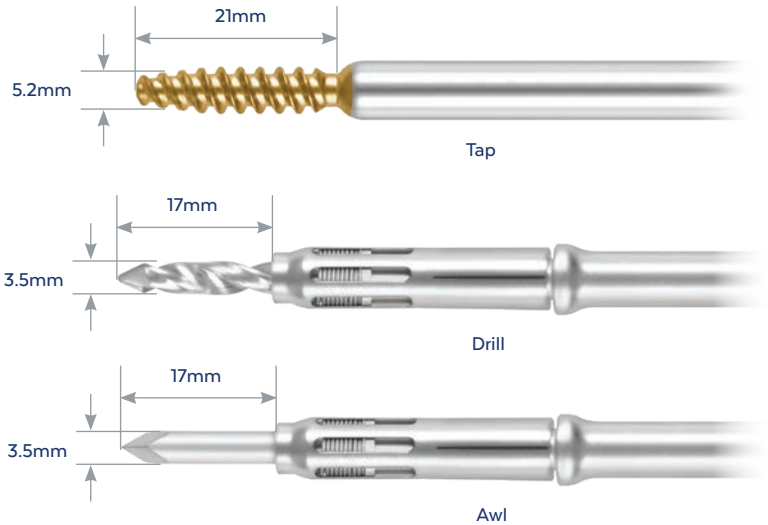
Remove the spacer using the Freehand Holder, forceps, or other manual surgical instruments.



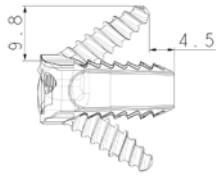
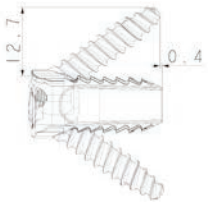
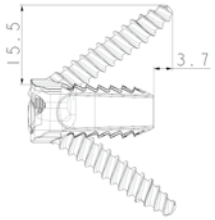
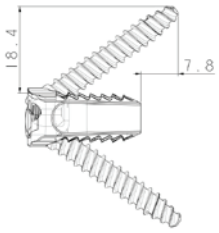
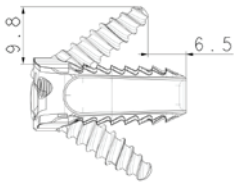
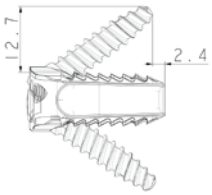
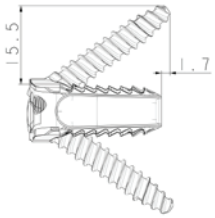
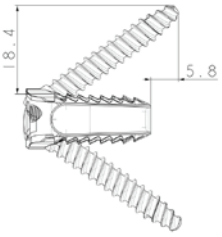
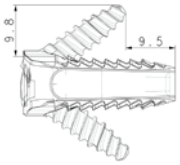
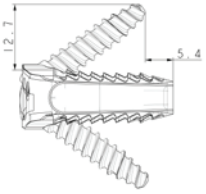
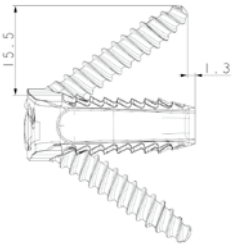
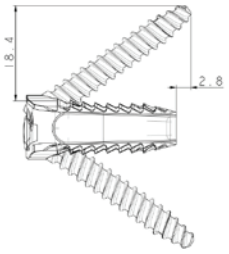
ADDITIONAL SPECIFICATIONS

Anchor Sizing Chart				
Anchor Lengths		25mm	27mm	30mm
Footprints	24x30mm			
	26x34mm			
	29x39mm			

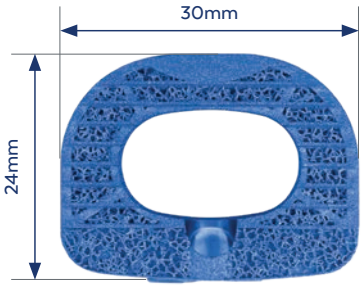
Drill, Awl, and Tap Dimensions



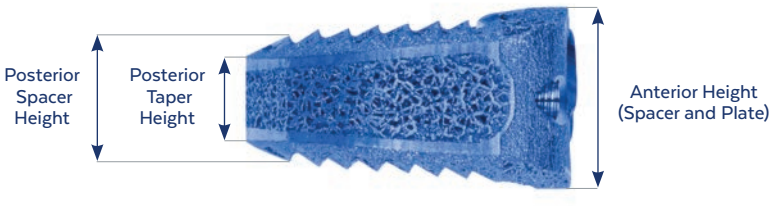
ADDITIONAL SPECIFICATIONS

Screw Sizing Chart					
Screw Lengths		20mm	25mm	30mm	35mm
Footprints	24x30mm				
	26x34mm				
	29x39mm				

ADDITIONAL SPECIFICATIONS

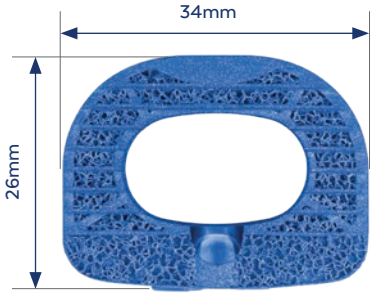


24x30mm

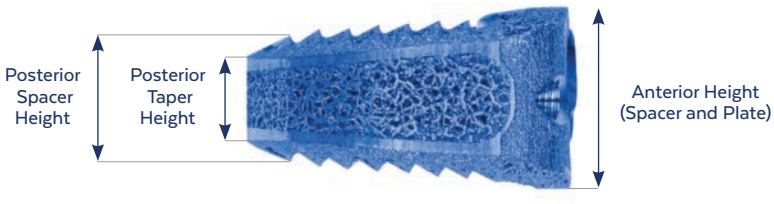


Implant Sizing Chart - 24x30mm					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	1212.0111S	12.4	9.8	6.3
	13mm	1212.0113S	14.4	11.8	8.3
	15mm	1212.0115S	16.4	13.8	10.3
	17mm	1212.0117S	18.4	15.8	12.3
15°	11mm	1212.0211S	12.4	8.7	5.1
	13mm	1212.0213S	14.4	10.7	7.1
	15mm	1212.0215S	16.4	12.7	9.1
	17mm	1212.0217S	18.4	14.7	11.1
20°	13mm	1212.0313S	14.4	10.0	6.1
	15mm	1212.0315S	16.4	12.0	8.1
	17mm	1212.0317S	18.4	14.0	10.1
25°	13mm	1212.0415S	16.4	11.2	5.4
	15mm	1212.0417S	18.4	13.2	7.4
	17mm	1212.0419S	20.4	15.2	9.4
	19mm	1212.0421S	22.4	17.2	11.4
30°	15mm	1212.0515S	16.4	10.5	4.0
	17mm	1212.0517S	18.4	12.5	6.0
	19mm	1212.0519S	20.4	14.5	8.0
	21mm	1212.0521S	22.4	16.5	10.0

ADDITIONAL SPECIFICATIONS

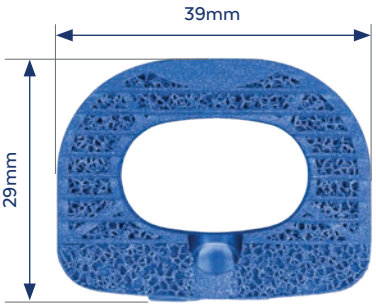


26x34mm

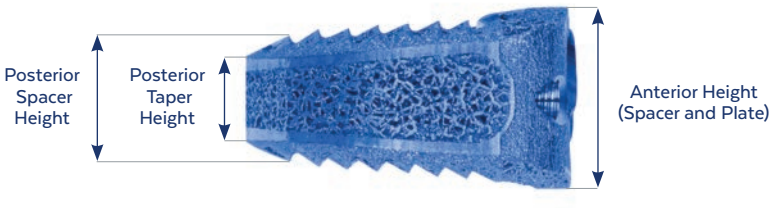


Implant Sizing Chart - 26x34mm					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	1212.0611S	12.4	9.3	6.1
	13mm	1212.0613S	14.4	11.3	8.1
	15mm	1212.0615S	16.4	13.3	10.1
	17mm	1212.0617S	18.4	15.3	12.1
	19mm	1212.0619S	20.4	17.3	14.1
	21mm	1212.0621S	22.4	19.3	16.1
15°	11mm	1212.0711S	12.4	8.0	4.6
	13mm	1212.0713S	14.4	10.0	6.6
	15mm	1212.0715S	16.4	12.0	8.6
	17mm	1212.0717S	18.4	14.0	10.6
	19mm	1212.0719S	20.4	16.0	12.6
	21mm	1212.0721S	22.4	18.0	14.6
20°	13mm	1212.0813S	14.4	9.1	5.5
	15mm	1212.0815S	16.4	11.1	7.5
	17mm	1212.0817S	18.4	13.1	9.5
	19mm	1212.0819S	20.4	15.1	11.5
	21mm	1212.0821S	22.4	17.1	13.5
25°	15mm	1212.0915S	16.4	10.2	4.5
	17mm	1212.0917S	18.4	12.2	6.5
	19mm	1212.0919S	20.4	14.2	8.5
	21mm	1212.0921S	22.4	16.2	10.5
30°	17mm	1212.1015S	16.4	9.3	3.0
	19mm	1212.1017S	18.4	11.3	5.0
	21mm	1212.1019S	20.4	13.3	7.0
	23mm	1212.1021S	22.4	15.3	9.0

ADDITIONAL SPECIFICATIONS



29x39mm



Implant Sizing Chart - 29x39mm					
Lordosis	**Height**	**Part No.**	**Anterior Height (mm)**	**Posterior Height (mm)**	**Posterior Taper Height (mm)**
8°	11mm	1212.1111S	12.4	8.4	6.2
	13mm	1212.1113S	14.4	10.4	8.2
	15mm	1212.1115S	16.4	12.4	10.2
	17mm	1212.1117S	18.4	14.4	12.2
	19mm	1212.1119S	20.4	16.4	14.2
	21mm	1212.1121S	22.4	18.4	16.2
15°	13mm	1212.1213S	14.4	8.8	5.6
	15mm	1212.1215S	16.4	10.8	7.6
	17mm	1212.1217S	18.4	12.8	9.6
	19mm	1212.1219S	20.4	14.8	11.6
	21mm	1212.1221S	22.4	16.8	13.6
20°	15mm	1212.1315S	16.4	9.6	5.2
	17mm	1212.1317S	18.4	11.6	7.2
	19mm	1212.1319S	20.4	13.6	9.2
	21mm	1212.1321S	22.4	15.6	11.2
25°	15mm	1212.1415S	16.4	8.5	2.8
	17mm	1212.1417S	18.4	10.5	4.8
	19mm	1212.1419S	20.4	12.5	6.8
	21mm	1212.1421S	22.4	14.5	8.8
30°	15mm	1212.1515S	16.4	8.1	2.4
	17mm	1212.1517S	18.4	9.7	3.0
	19mm	1212.1519S	20.4	11.7	5.0
	21mm	1212.1521S	22.4	13.7	7.0
	23mm	1212.1523S	24.4	15.7	9.0
	25mm	1212.1525S	26.4	17.7	11.0

HEDRON IA®
IMPLANT SET 9212.9001

HEDRON IA® Spacer, 24x30, 8°

Part No.	Height	Qty
1212.0111S	11mm	2
1212.0113S	13mm	2
1212.0115S	15mm	2
1212.0117S	17mm	2

HEDRON IA® Spacer, 24x30, 15°

Part No.	Height	Qty
1212.0211S	11mm	2
1212.0213S	13mm	2
1212.0215S	15mm	2
1212.0217S	17mm	2

HEDRON IA® Spacer, 26x34, 8°

Part No.	Height	Qty
1212.0611S	11mm	2
1212.0613S	13mm	2
1212.0615S	15mm	2
1212.0617S	17mm	2
1212.0619S	19mm	1
1212.0621S	21mm	1

HEDRON IA® Spacer, 26x34, 15°

Part No.	Height	Qty
1212.0711S	11mm	2
1212.0713S	13mm	2
1212.0715S	15mm	2
1212.0717S	17mm	2
1212.0719S	19mm	1
1212.0721S	21mm	1

HEDRON IA® Spacer, 29x39, 8°

Part No.	Height	Qty
1212.1111S	11mm	2
1212.1113S	13mm	2
1212.1115S	15mm	2
1212.1117S	17mm	2
1212.1119S	19mm	1
1212.1121S	21mm	1

HEDRON IA® Spacer, 29x39, 15°

Part No.	Height	Qty
1212.1213S	13mm	2
1212.1215S	15mm	2
1212.1217S	17mm	2
1212.1219S	19mm	1
1212.1221S	21mm	1

9212.0001	HEDRON IA® Implant Soft Case

HEDRON IA® HYPERLORDOTIC IMPLANT SET 9212.9002

HEDRON IA® Spacer, 24x30, 20°

Part No.	Height	Qty
11212.0313S	13mm	1
1212.0315S	15mm	1
1212.0317S	17mm	1

HEDRON IA® Spacer, 24x30, 25°

Part No.	Height	Qty
1212.0415S	15mm	1
1212.0417S	17mm	1
1212.0419S	19mm	1
1212.0421S	21mm	1

HEDRON IA® Spacer, 24x30, 30°

Part No.	Height	Qty
1212.0515S	15mm	1
1212.0517S	17mm	1
1212.0519S	19mm	1
1212.0521S	21mm	1

HEDRON IA® Spacer, 26x34, 20°

Part No.	Height	Qty
1212.0813S	13mm	1
1212.0815S	15mm	1
1212.0817S	17mm	1
1212.0819S	19mm	1
1212.0821S	21mm	1

HEDRON IA® Spacer, 26x34, 25°

Part No.	Height	Qty
1212.0915S	15mm	1
1212.0917S	17mm	1
1212.0919S	19mm	1
1212.0921S	21mm	1

HEDRON IA® Spacer, 26x34, 30°

Part No.	Height	Qty
1212.1015S	15mm	1
1212.1017S	17mm	1
1212.1019S	19mm	1
1212.1021S	21mm	1

HEDRON IA® Spacer, 29x39, 20°

Part No.	Height	Qty
1212.1315S	15mm	1
1212.1317S	17mm	1
1212.1319S	19mm	1
1212.1321S	21mm	1

HEDRON IA® Spacer, 29x39, 25°

Part No.	Height	Qty
1212.1415S	15mm	1
1212.1417S	17mm	1
1212.1419S	19mm	1
1212.1421S	21mm	1

HEDRON IA® Spacer, 29x39, 30°

Part No.	Height	Qty
1212.1515S	15mm	1
1212.1517S	17mm	1
1212.1519S	19mm	1
1212.1521S	21mm	1
1212.1523S	23mm	
1212.1525S	25mm	

9212.0002	HEDRON IA® Hyperlordotic Implant Soft Case

Items in gray are additionally available.

LUMBAR
ANCHOR SET 9135.9005

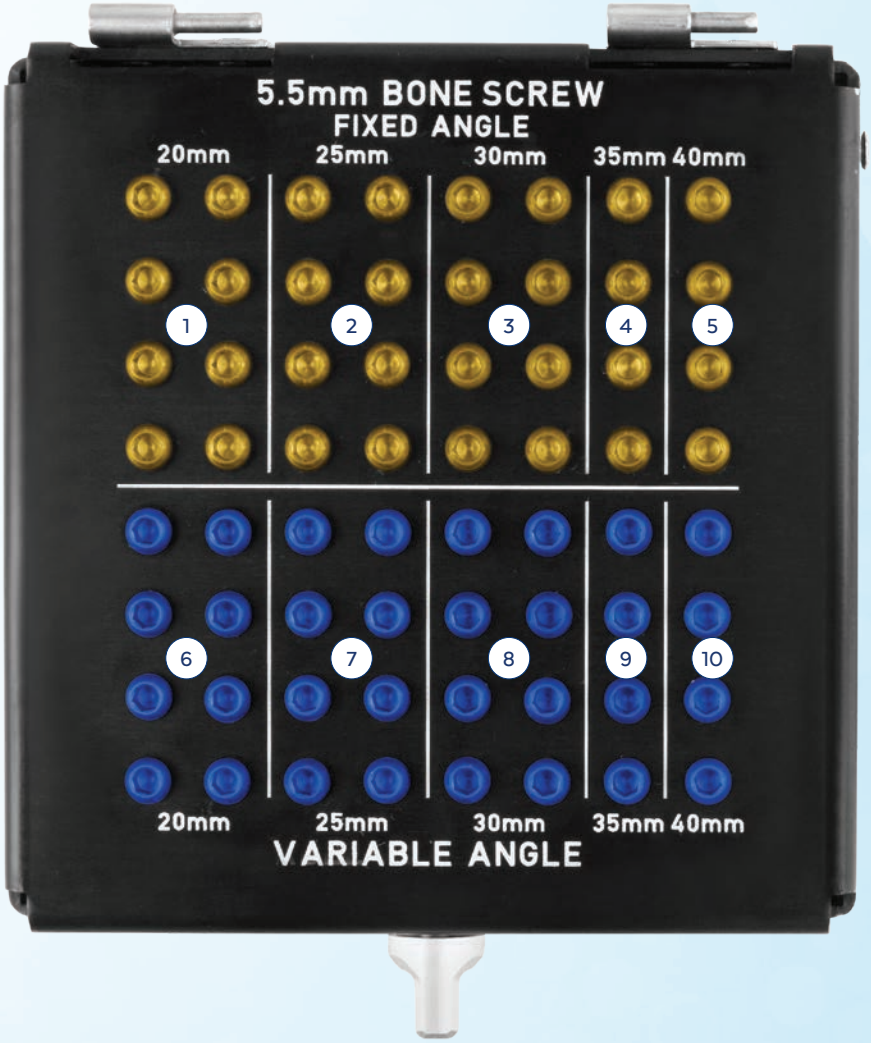
	Part No.	Description	Qty
	1135.0020	Lumbar Anchor, 20mm	
1	1135.0025	Lumbar Anchor, 25mm	9
2	1135.0027	Lumbar Anchor, 27mm	9
3	1135.0030	Lumbar Anchor, 30mm	9
	9135.0005	Anchor Module	

Items in gray are additionally available.

ALIF
BONE SCREW SET 925.907

	Part No.	Description	Qty
1	176.120	Bone Screw, Fixed Angle 5.5mm, 20mm	8
2	176.125	Bone Screw, Fixed Angle 5.5mm, 25mm	8
3	176.130	Bone Screw, Fixed Angle 5.5mm, 30mm	8
4	176.135	Bone Screw, Fixed Angle 5.5mm, 35mm	4
5	176.140	Bone Screw, Fixed Angle 5.5mm, 40mm	4
6	176.220	Bone Screw, Variable Angle 5.5mm, 20mm	8
7	176.225	Bone Screw, Variable Angle 5.5mm, 25mm	8
8	176.230	Bone Screw, Variable Angle 5.5mm, 30mm	8
9	176.235	Bone Screw, Variable Angle 5.5mm, 35mm	4
10	176.240	Bone Screw, Variable Angle 5.5mm, 40mm	4
	925.107	ALIF Bone Screw Set	

ALIF
BONE SCREW SET 925.907



INDEPENDENCE MIS®
TRIAL SET 9135.9006

INDEPENDENCE® Trial, Small, 8°

Part No.	Height	Qty
676.111	11mm	1
676.113	13mm	1
676.115	15mm	1
676.117	17mm	1

INDEPENDENCE® Trial, Small, 15°

Part No.	Height	Qty
676.211	11mm	1
676.213	13mm	1
676.215	15mm	1
676.217	17mm	1

INDEPENDENCE® Trial, Medium, 8°

Part No.	Height	Qty
676.411	11mm	1
676.413	13mm	1
676.415	15mm	1
676.417	17mm	1
676.419	19mm	1
676.421	21mm	1

INDEPENDENCE® Trial, Medium, 15°

Part No.	Height	Qty
676.511	11mm	1
676.513	13mm	1
676.515	15mm	1
676.517	17mm	1
676.519	19mm	1
676.521	21mm	1

INDEPENDENCE® Trial, Large, 8°

Part No.	Height	Qty
676.711	11mm	1
676.713	13mm	1
676.715	15mm	1
676.717	17mm	1
676.719	19mm	1
676.721	21mm	1

INDEPENDENCE® Trial, Large, 15°

Part No.	Height	Qty
676.813	13mm	1
676.815	15mm	1
676.817	17mm	1
676.819	19mm	1
676.821	21mm	1

9135.0006	INDEPENDENCE MIS® Trial Module

HEDRON IA® 20°
TRIAL SET 9212.9003

INDEPENDENCE® Trial, Small, 20°

Part No.	Height	Qty
676.233	13mm	1
676.235	15mm	1
676.237	17mm	1

INDEPENDENCE® Trial, Medium, 20°

Part No.	Height	Qty
676.533	13mm	1
676.535	15mm	1
676.537	17mm	1
676.539	19mm	1
676.541	21mm	1

INDEPENDENCE® Trial, Large, 20°

Part No.	Height	Qty
676.835	15mm	1
676.837	17mm	1
676.839	19mm	1
676.841	21mm	1

9212.0008	HEDRON IA® 20° Trial Module	

HEDRON IA® 25°
TRIAL SET 9212.9004

INDEPENDENCE® Trial, Small, 25°

Part No.	Height	Qty
676.315	15mm	1
676.317	17mm	1
676.319	19mm	1
676.321	21mm	1

INDEPENDENCE® Trial, Medium, 25°

Part No.	Height	Qty
676.615	15mm	1
676.617	17mm	1
676.619	19mm	1
676.621	21mm	1

INDEPENDENCE® Trial, Medium, 25°

Part No.	Height	Qty
676.915	15mm	1
676.917	17mm	1
676.919	19mm	1
676.921	21mm	1

9212.0009	HEDRON IA® 25° and 30° Trial Module

HEDRON IA® 30°
TRIAL SET 9212.9004

INDEPENDENCE® Trial, Small, 30°

Part No.	Height	Qty
676.355	15mm	1
676.357	17mm	1
676.359	19mm	1
676.361	21mm	1

INDEPENDENCE® Trial, Medium, 30°

Part No.	Height	Qty
676.665	15mm	1
676.667	17mm	1
676.669	19mm	1
676.671	21mm	1

INDEPENDENCE® Trial, Large, 30°

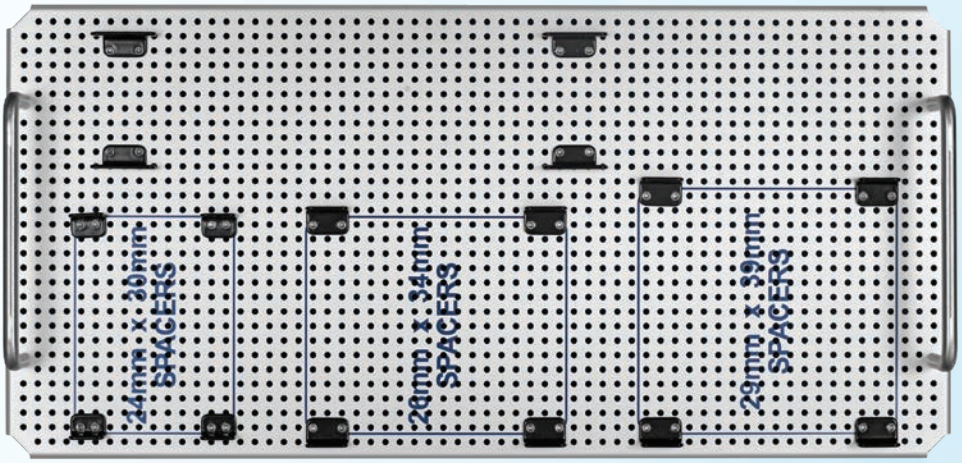
Part No.	Height	Qty
676.985	15mm	1
676.987	17mm	1
676.989	19mm	1
676.991	21mm	1
676.993	23mm	
676.995	25mm	

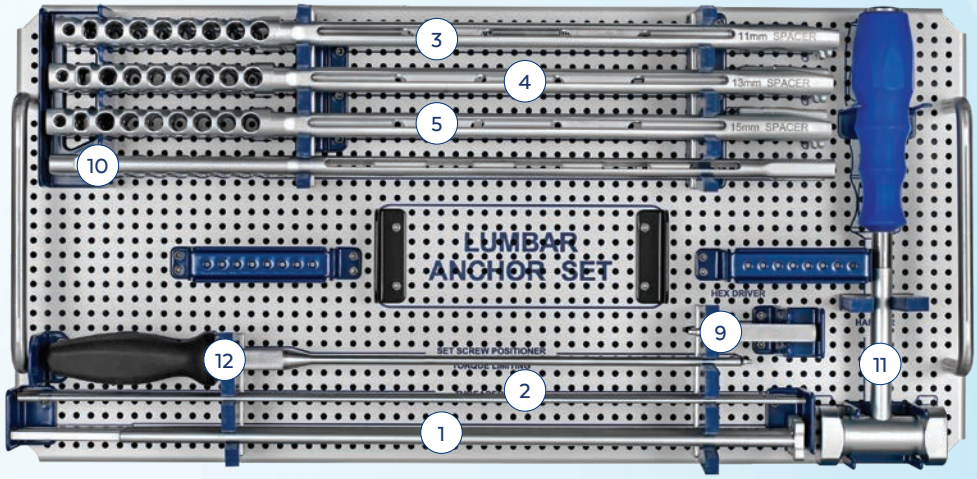
9212.0009	HEDRON IA® 25° and 30° Trial Module

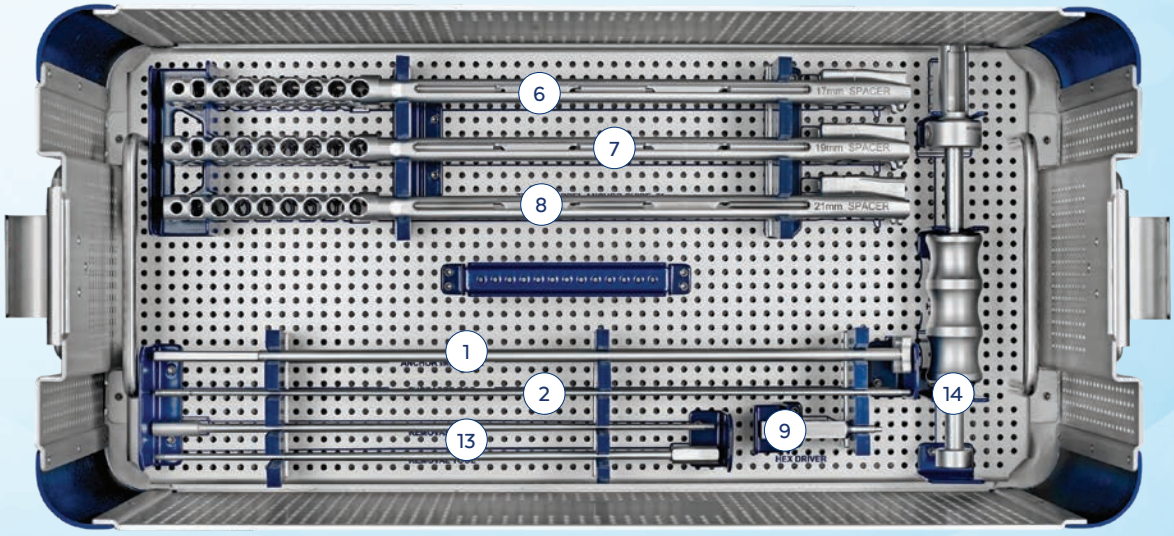
INDEPENDENCE MIS®
INSTRUMENT SET 9135.9001

	Part No.	Description	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	

INDEPENDENCE MIS®
INSTRUMENT SET 9135.9001



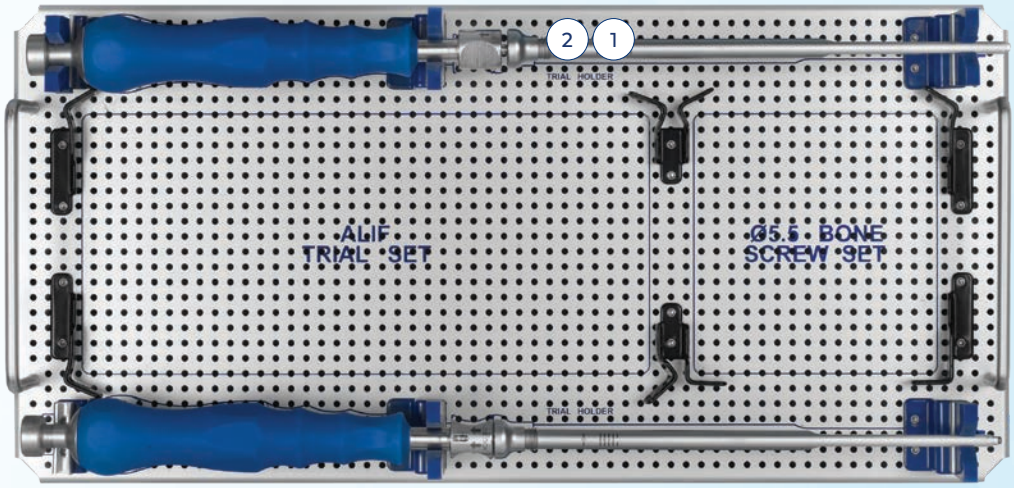


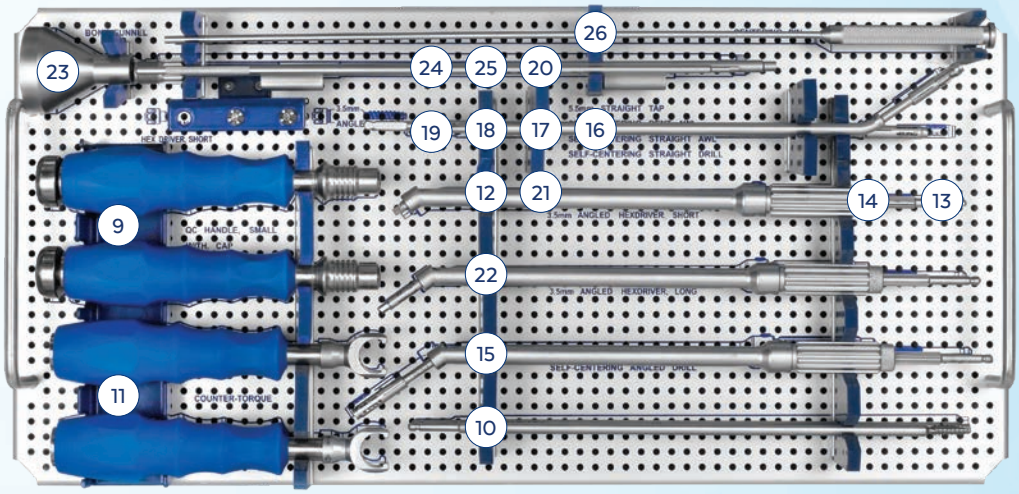


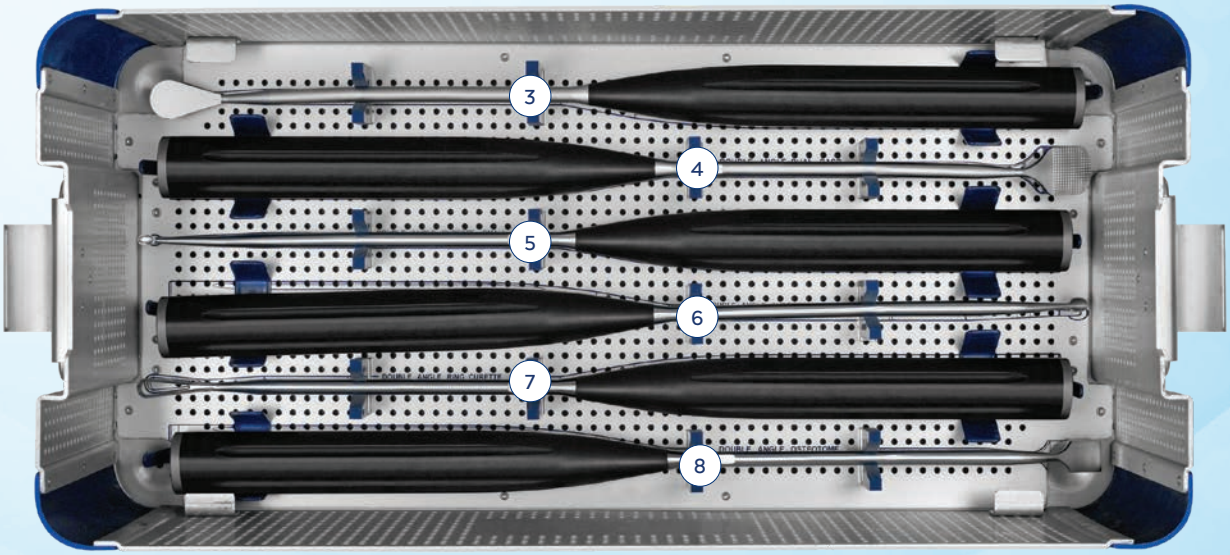
ALIF
INSTRUMENT SET 925.905

	Part No.	Description	Qty
1	6108.0001	Trial Holder Sleeve	2
2	6108.0003	Trial Holder	2
3	6108.2004	Double-Angled Cobb, 20mm, Up	1
4	6108.2005	Double-Angled Dual Rasp	1
5	6108.2007	Double-Angled Curette, Small, Up	1
6	6108.2009	Double-Angled Curette, Large, Up	1
7	6108.2011	Double-Angled Ring Curette, Up	1
8	6108.2012	Double-Angled Osteotome	1
9	650.105	QC Handle, Small, with Cap	2
10	676.502	3.5mm Hex Straight Driver	2
11	676.699	Counter-Torque	2
12	676.700	Angled Sleeve	3
13	676.701	Shaft	3
14	676.702	Nut	3
15	676.703	Self-Centering Angled Drill	1
16	676.704	Self-Centering Straight Drill	1
17	676.705	Self-Centering Bent Awl	1
18	676.706	Self-Centering Straight Awl	1
19	676.707	5.5mm Angled Tap	1
20	676.708	5.5mm Straight Tap	1
21	676.710	3.5mm Angled Hex Driver, Short	2
22	676.809	3.5mm Angled Hex Driver, Long	2
23	6126.6000	Bone Funnel	1
24	6126.6001	Bone Funnel Tube	1
25	6126.6002	Bone Funnel Guide	1
26	6126.6003	Bone Pusher	1
	925.105	ALIF Instrument Graphic Case	

ALIF
INSTRUMENT SET 925.905



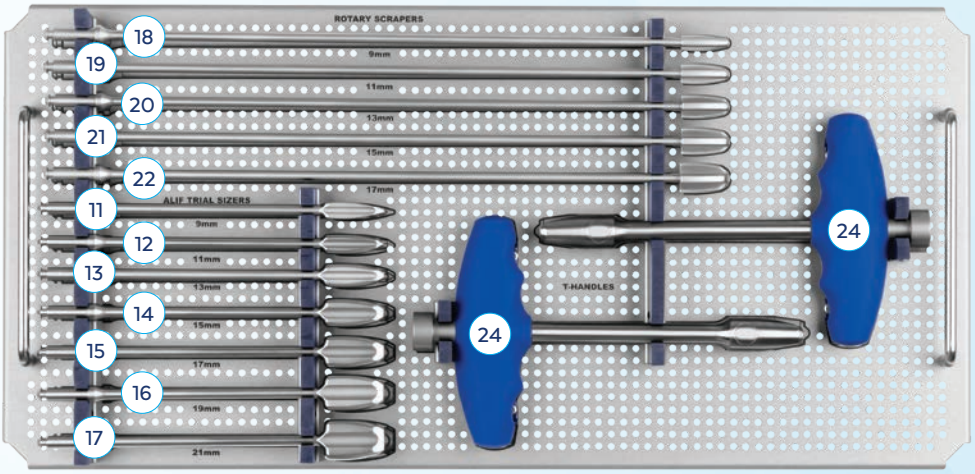


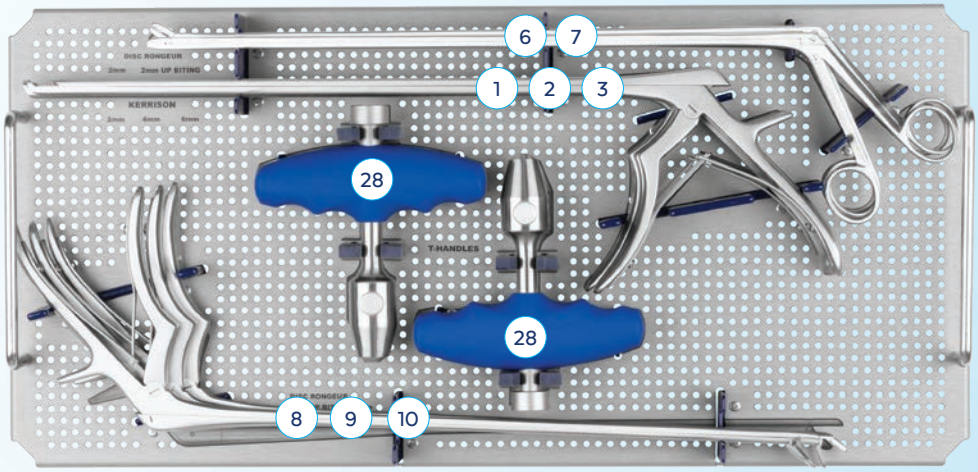


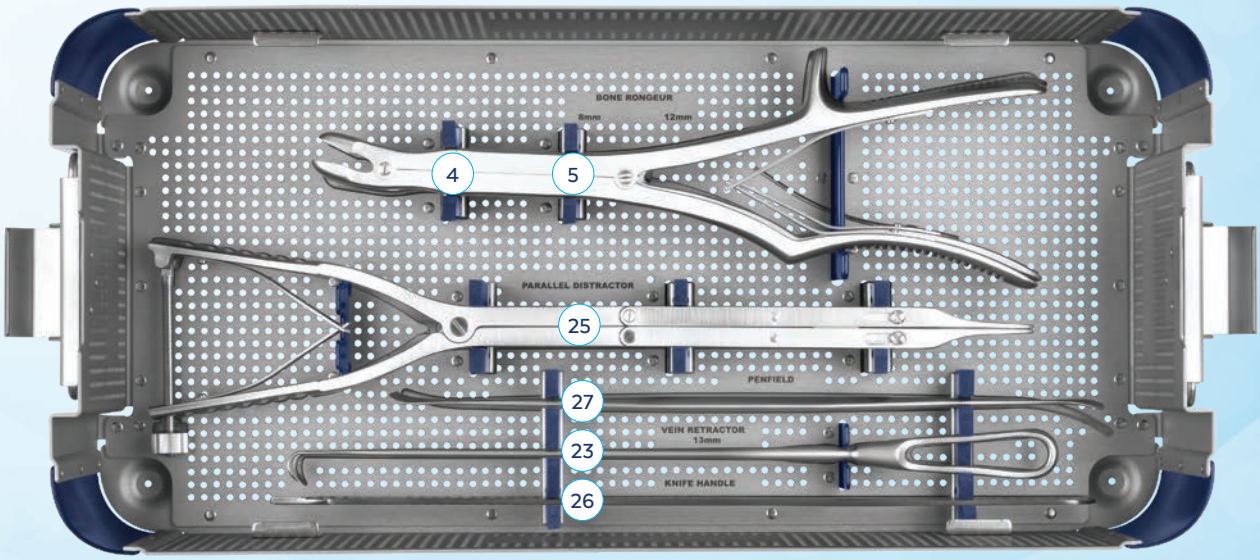
ANTERIOR DISC PREP I
INSTRUMENT SET 925.901

	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	

ANTERIOR DISC PREP I
INSTRUMENT SET 925.901





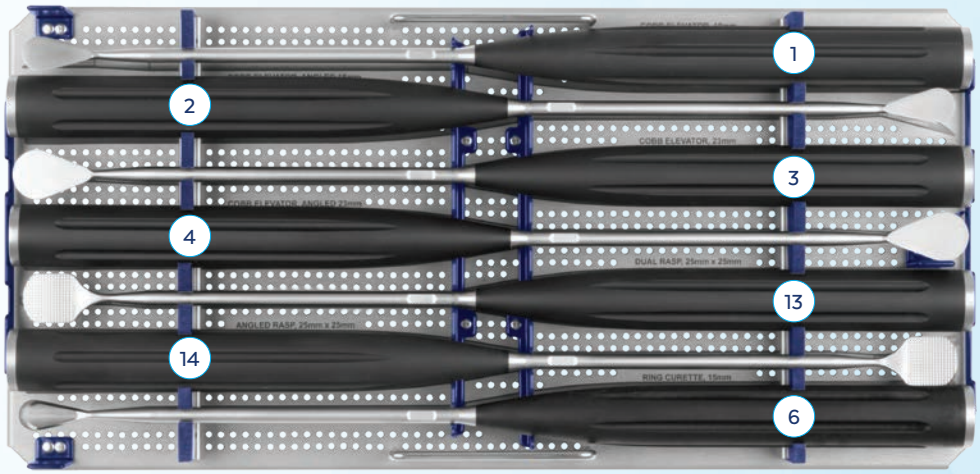


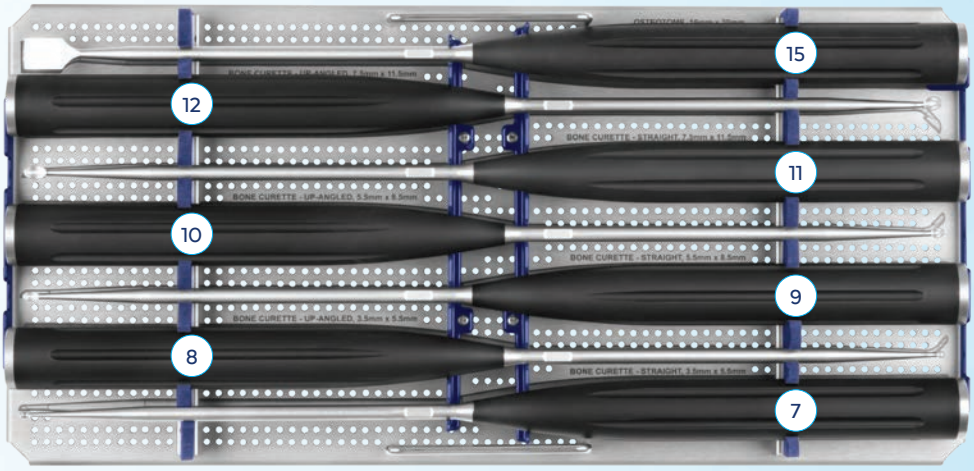
ANTERIOR DISC PREP II
INSTRUMENT SET 925.902

	Part No.	Description	Qty
1	625.101	Cobb Elevator, 18mm	1
2	625.102	Cobb Elevator, Angled, 18mm	1
3	625.103	Cobb Elevator, 23mm	1
4	625.104	Cobb Elevator, Angled, 23mm	1
5	625.401	Ring Curette, 10mm	1
6	625.402	Ring Curette, 15mm	1
7	625.403	Bone Curette, 3.5x5.5mm, Straight	1
8	625.404	Bone Curette, 3.5x5.5mm, Up-Angled	1
9	625.405	Bone Curette, 5.5x8.5mm, Straight	1
10	625.406	Bone Curette, 5.5x8.5mm, Up-Angled	1
11	625.407	Bone Curette, 7.5x11.5mm, Straight	1
12	625.408	Bone Curette, 7.5x11.5mm, Up-Angled	1
	625.409	Bone Curette, 9.5x14.5mm, Straight	
	625.410	Bone Curette, 9.5x14.5mm, Up-Angled	
	625.411	Bone Curette, 11.5x17.5mm, Straight	
	625.412	Bone Curette, 11.5x17.5mm, Up-Angled	
	625.413	Bone Curette, 13.5x20.5mm, Straight	
	625.414	Bone Curette, 13.5x20.5mm, Up-Angled	
13	625.501	Dual Rasp	1
14	625.502	Angled Rasp	1
15	625.803	Osteotome, 16x20mm	1
	925.102	Graphic Case 2	

Items in gray are additionally available.

ANTERIOR DISC PREP II
INSTRUMENT SET 925.902





MARS™ ANTERIOR I
INSTRUMENT SET 9101.9001

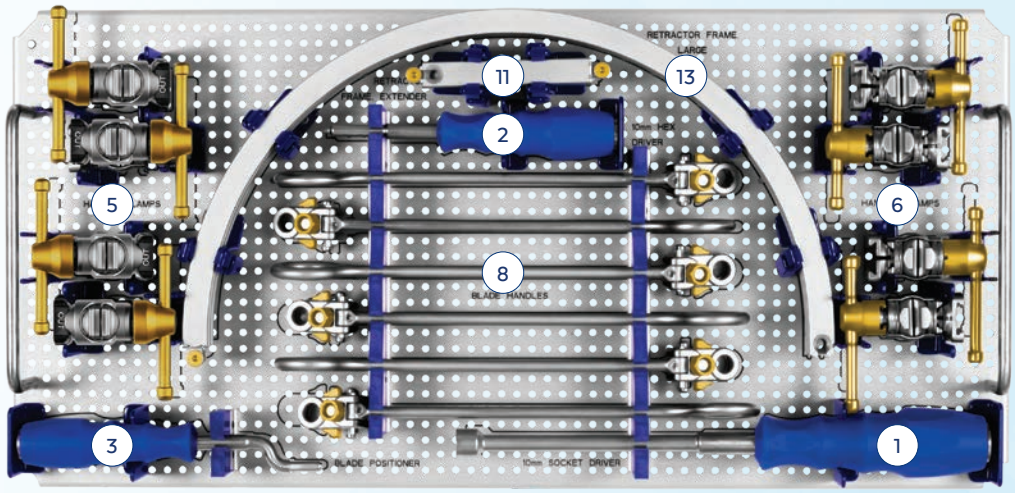
	Part No.	Description	Qty
1	6101.0002	10mm Socket Driver	1
2	6101.0004	2.5mm Hex Driver	1
3	6101.0006	Blade Positioner	1
4	6101.0008	Hand Held Retractor, 25x175mm	2
5	6101.0012	Handle Clamp	4
6	6101.0022	Handle Clamp, Low Profile	4
	6101.0023	Low Profile T-Handle	4
7	6101.0014	Blade Handle, Fixed	6
8	6101.0016	Blade Handle	6
9	6101.0018	Docking Pin Sleeve	4
10	6101.0020	Docking Pin Sleeve, Offset	4
11	6101.0082	Retractor Frame, Extender	2
12	6101.0200	200mm Retractor Frame, Small	1
13	6101.0300	300mm Retractor Frame, Large	2
14	636.451	Quick-Connect Handle	3
15	675.513	8” Suction	1
16	698.240	Shim Tool, CC	1
17	698.260	2.5mm Hex Screw Driver (Docking Pin Tool)	1
	698.310S	Docking Pin, 10mm	4

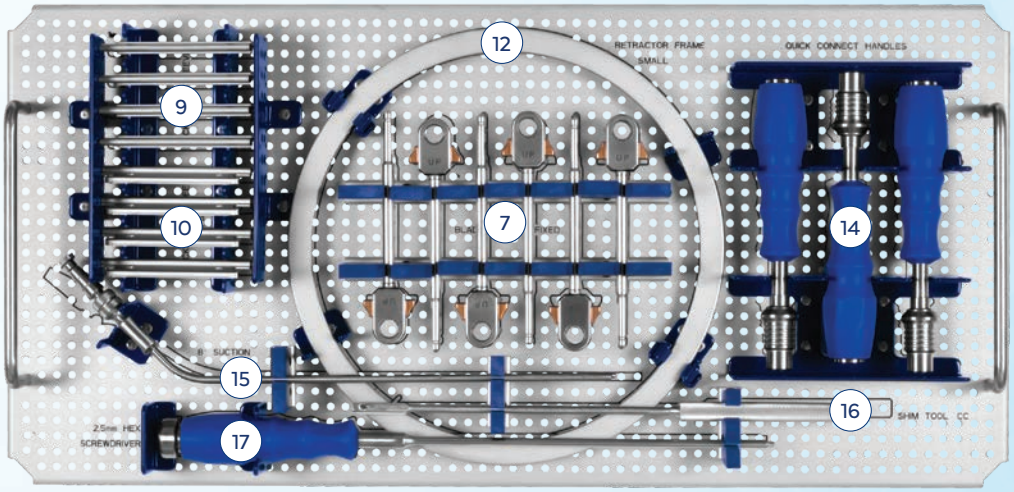
Additionally Available

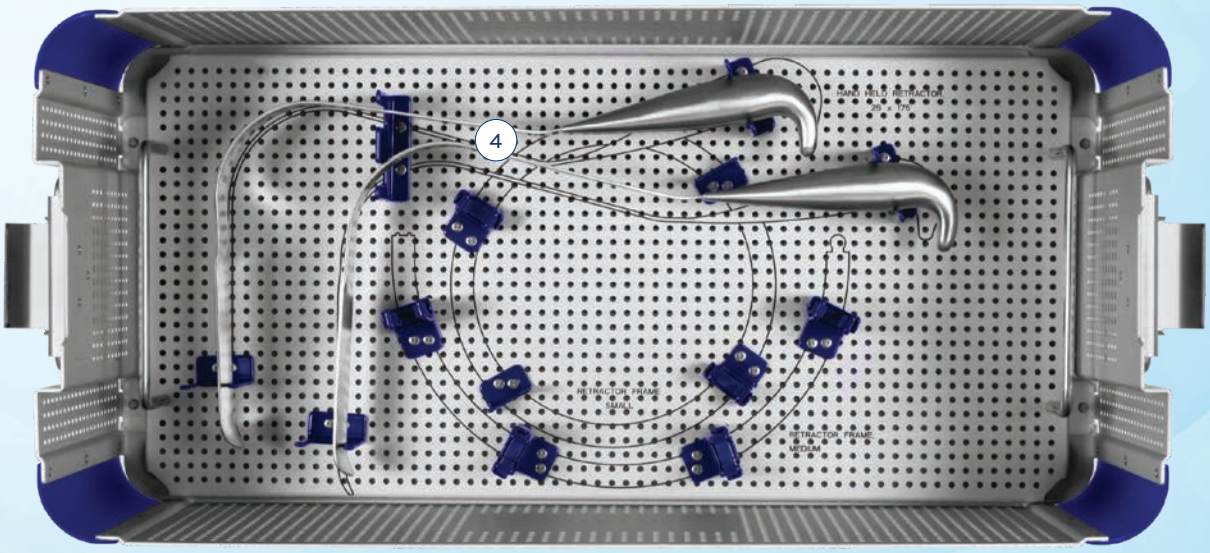
6101.0230 230mm Retractor Frame, Medium

Items in gray are additionally available.

MARS™ ANTERIOR I
INSTRUMENT SET 9101.9001



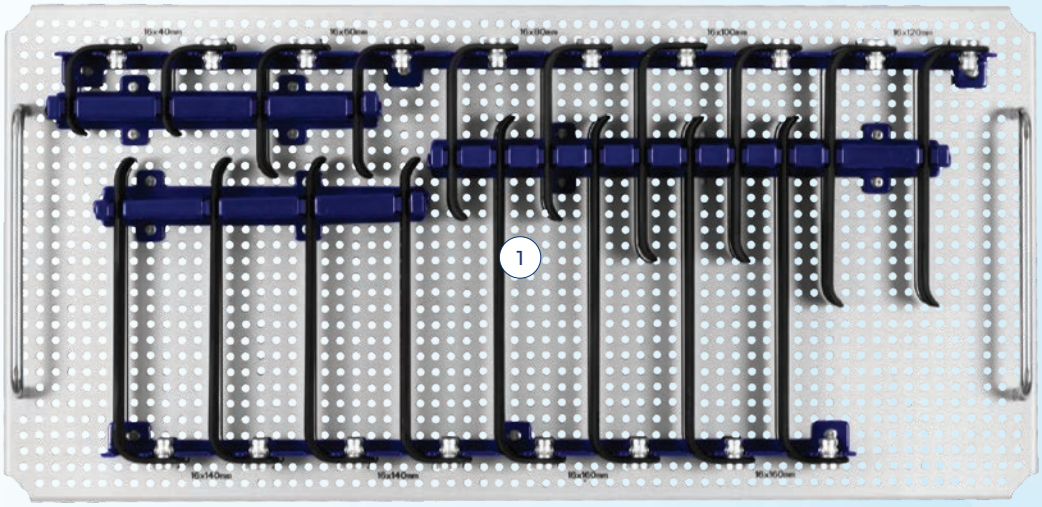


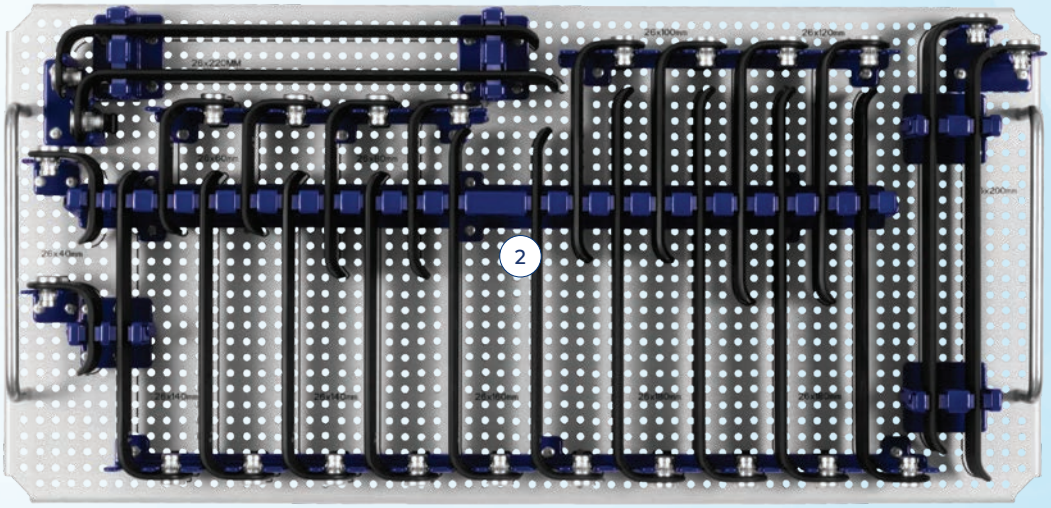


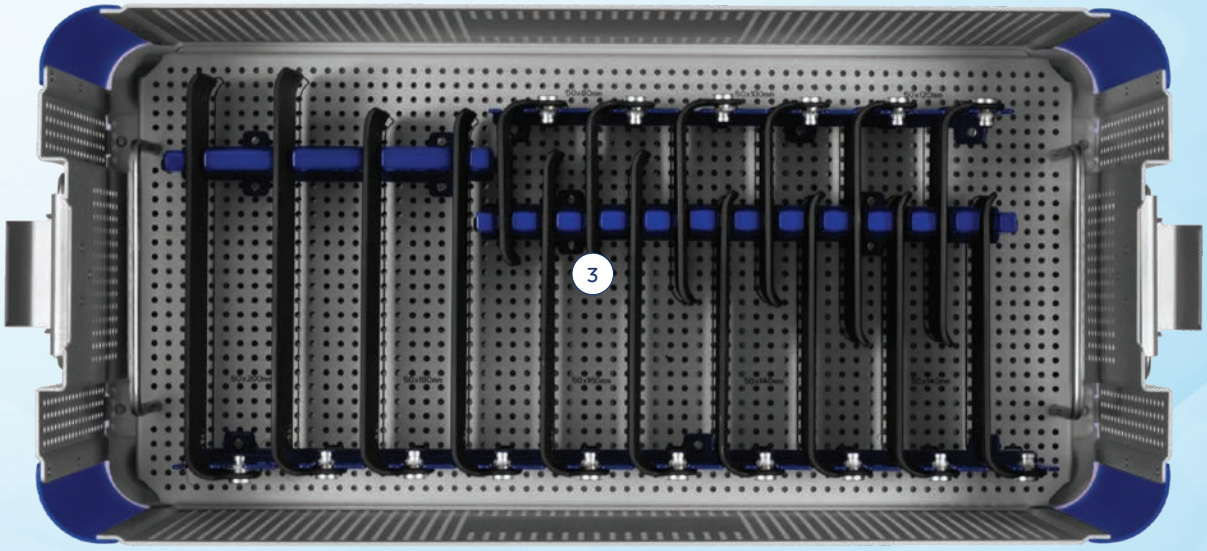
MARS™ ANTERIOR II
INSTRUMENT SET 9101.9002

	Part No.	Description	Qty
1	6101.3040	Radiolucent Retractor Blade, 16x40mm	2
	6101.3060	Radiolucent Retractor Blade, 16x60mm	2
	6101.3080	Radiolucent Retractor Blade, 16x80mm	2
	6101.3100	Radiolucent Retractor Blade, 16x100mm	2
	6101.3120	Radiolucent Retractor Blade, 16x120mm	2
	6101.3140	Radiolucent Retractor Blade, 16x140mm	4
	6101.3160	Radiolucent Retractor Blade, 16x160mm	4
2	6101.4040	Radiolucent Retractor Blade, 26x40mm	2
	6101.4060	Radiolucent Retractor Blade, 26x60mm	2
	6101.4080	Radiolucent Retractor Blade, 26x80mm	2
	6101.4100	Radiolucent Retractor Blade, 26x100mm	2
	6101.4120	Radiolucent Retractor Blade, 26x120mm	2
	6101.4140	Radiolucent Retractor Blade, 26x140mm	4
	6101.4160	Radiolucent Retractor Blade, 26x160mm	2
	6101.4180	Radiolucent Retractor Blade, 26x180mm	4
	6101.4200	Radiolucent Retractor Blade, 26x200mm	2
	6101.4220	Radiolucent Retractor Blade, 26x220mm	2
3	6101.6080	Radiolucent Retractor Blade, 50x80mm	2
	6101.6100	Radiolucent Retractor Blade, 50x100mm	2
	6101.6120	Radiolucent Retractor Blade, 50x120mm	2
	6101.6140	Radiolucent Retractor Blade, 50x140mm	4
	6101.6160	Radiolucent Retractor Blade, 50x160mm	2
	6101.6180	Radiolucent Retractor Blade, 50x180mm	2
	6101.6200	Radiolucent Retractor Blade, 50x200mm	2

MARS™ ANTERIOR II
INSTRUMENT SET 9101.9002



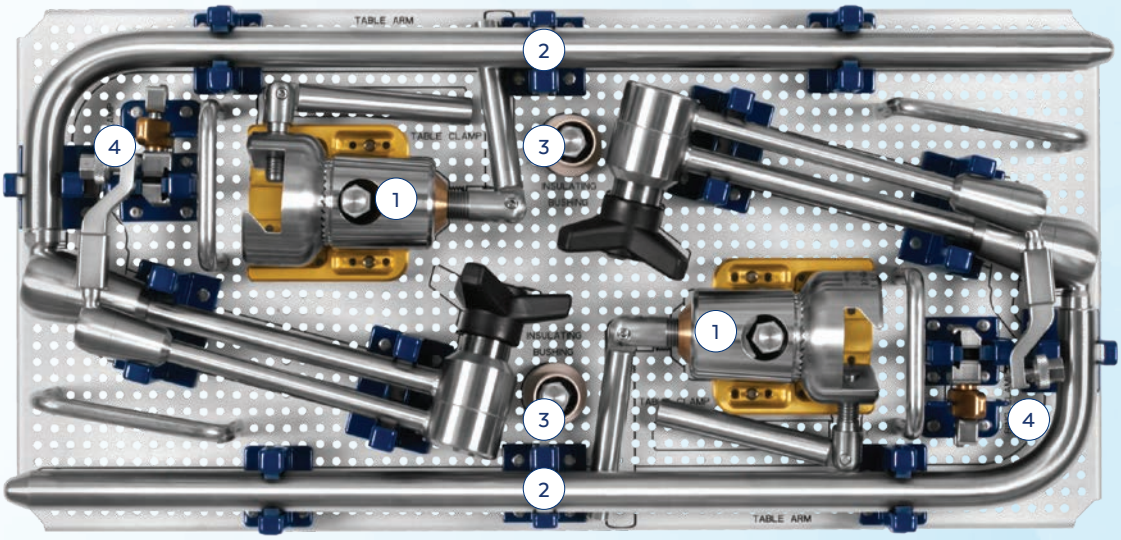


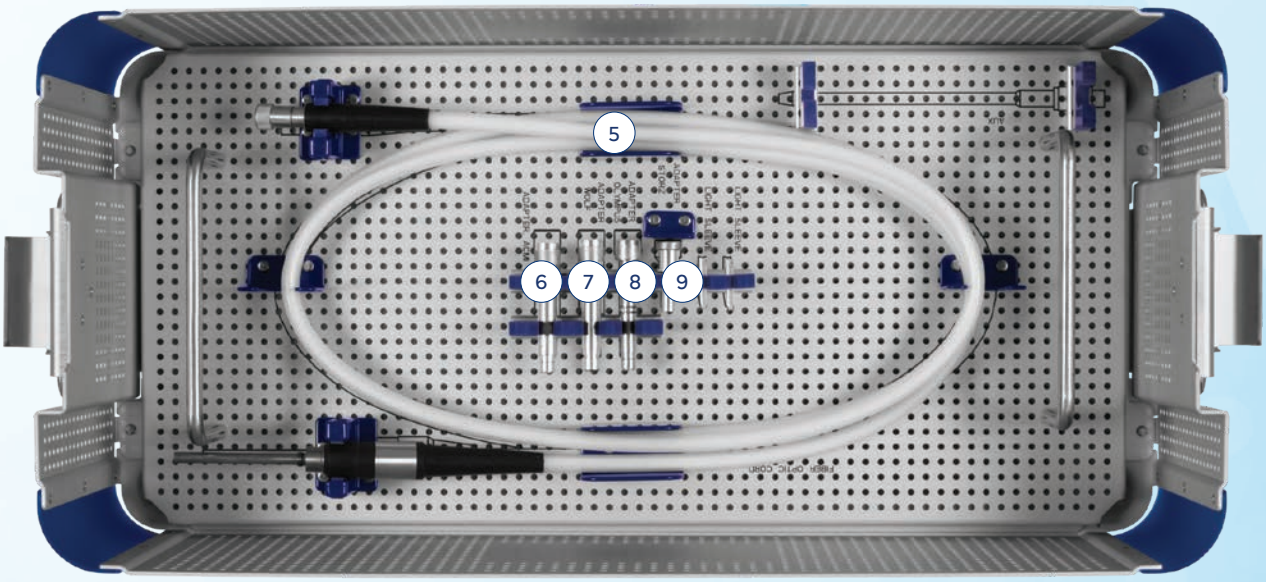


MARS™ ANTERIOR III
INSTRUMENT SET 9101.9003

	Part No.	Description	Qty
1	632.505	Table Clamp	2
2	632.780	Table Arm	2
3	632.785	Insulating Bushing	2
4	6101.0010	Ring Clamp	2
5	632.300	Fiber-Optic Cord	1
6	632.305	Adapter, ACMI	1
7	632.306	Adapter, Wolf	1
8	632.307	Adapter, Olympus	1
9	632.308	Adapter, Storz	1
	698.605S	Illumination System	1

MARS™ ANTERIOR III
INSTRUMENT SET 9101.9003





INDEPENDENCE® HA COATED BONE SCREW SET 976.908

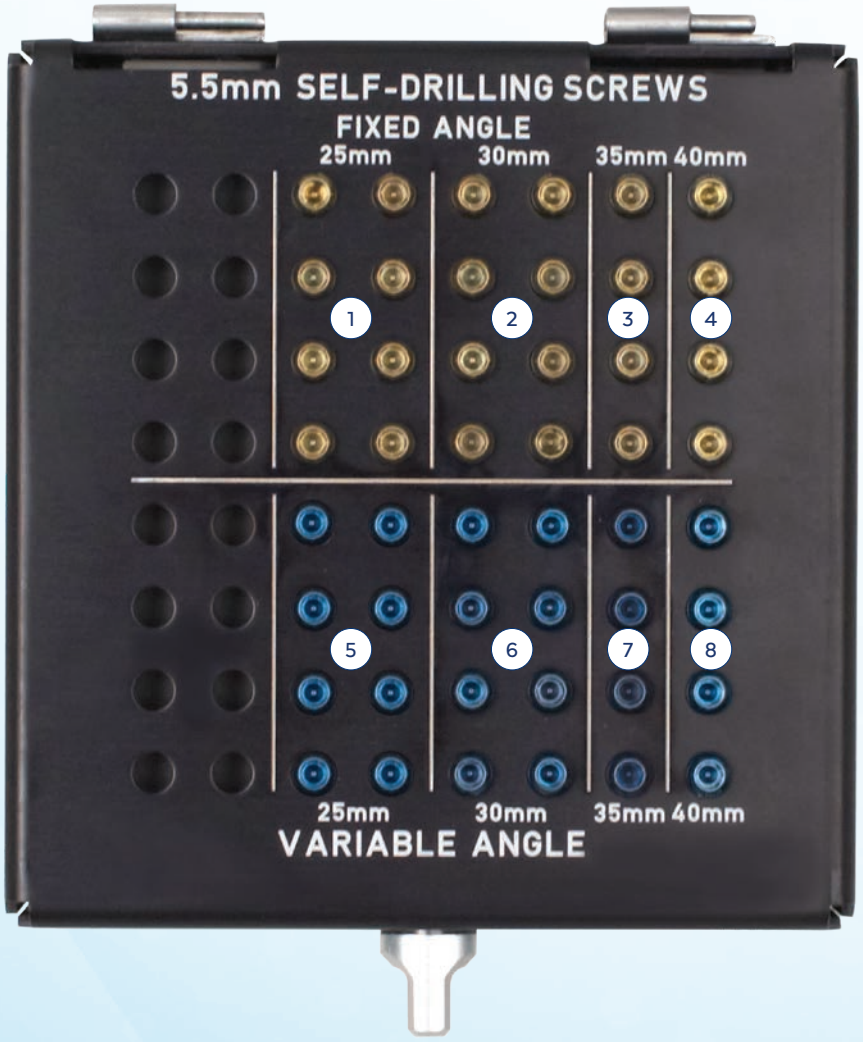
	Part No.	Description	Qty
1	176.420S	HA Coated Bone Screw, Variable Angle 5.5mm, 20mm	9
2	176.425S	HA Coated Bone Screw, Variable Angle 5.5mm, 25mm	9
3	176.430S	HA Coated Bone Screw, Variable Angle 5.5mm, 30mm	9
4	176.435S	HA Coated Bone Screw, Variable Angle 5.5mm, 35mm	9
	176.440S	HA Coated Bone Screw, Variable Angle 5.5mm, 40mm	
	176.925S	HA Coated Self-Drilling Screw, Variable Angle 5.5mm, 25mm	
	176.930S	HA Coated Self-Drilling Screw, Variable Angle 5.5mm, 30mm	
	976.008	Soft Case	

Items in gray are additionally available.

INDEPENDENCE® HA COATED
BONE SCREW SET 976.908

ALIF
SELF-DRILLING SCREW SET 925.908

	Part No.	Description	Qty
1	176.625	Self-Drilling Screw, Fixed Angle 5.5mm, 25mm	8
2	176.630	Self-Drilling Screw, Fixed Angle 5.5mm, 30mm	8
3	176.635	Self-Drilling Screw, Fixed Angle 5.5mm, 35mm	4
4	176.640	Self-Drilling Screw, Fixed Angle 5.5mm, 40mm	4
5	176.725	Self-Drilling Screw, Variable Angle 5.5mm, 25mm	8
6	176.730	Self-Drilling Screw, Variable Angle 5.5mm, 30mm	8
7	176.735	Self-Drilling Screw, Variable Angle 5.5mm, 35mm	4
8	176.740	Self-Drilling Screw, Variable Angle 5.5mm, 40mm	4
	925.108	ALIF Self-Drilling Screw Set	



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	

IMPORTANT INFORMATION ABOUT HEDRON® SPACERS

DESCRIPTION

HEDRON® Cervical Spacers (HEDRON C® and HEDRON IC®) are anterior cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. HEDRON® Cervical Spacers are additively manufactured from titanium powder, as specified in ASTM F3001.

HEDRON IC® Spacers may be assembled with COALITION AGX® Plates to create the HEDRON IC® Plate-Spacer which is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. COALITION AGX® Plates and bone screws are described in the COALITION® device insert.

HEDRON® Lumbar Spacers (including HEDRON A™, HEDRON L®, HEDRON P®, HEDRON RT™, and HEDRON T™) are lumbar interbody fusion devices used to provide structural stability following discectomy. Each HEDRON® spacer has a different shape to accommodate various surgical approaches to the spine. HEDRON L® Spacers are inserted using an anterior, anterolateral, or lateral approach; HEDRON A™ anterior or anterolateral; HEDRON P® and HEDRON RT™ posterior or transforaminal; and HEDRON T™ transforaminal. All approaches may be used in the lumbar spine; only anterior, anterolateral, or lateral approaches may be used in the thoracic spine.

HEDRON IA® Integrated Lumbar Spacers are integrated anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. HEDRON IA® Spacers may be used with screws and/or anchors.

HEDRON® Lumbar Spacers are additively manufactured from titanium powder, as specified in ASTM F3001. Screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and 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

HEDRON C® Spacers and HEDRON IC® Spacers are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

HEDRON C® Spacers and HEDRON IC® Spacers are intended to be used with supplemental fixation, such as an anterior cervical plate or posterior cervical fixation. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

When the HEDRON IC® Spacer is used with the COALITION AGX® Plate, the plate-spacer assembly (HEDRON IC® Plate-Spacer) is a stand-alone device intended for use at one or two levels of the cervical spine (C2-T1) in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. These devices are to be used with two titanium alloy screws which accompany the implant. Hyperlordotic implants (≥20°) must be used with supplemental fixation in addition to the two screws.

HEDRON® Lumbar Spacers (HEDRON A™, HEDRON L®, HEDRON P®, HEDRON T™, and HEDRON RT™) are lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. HEDRON® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

HEDRON IA® Integrated Lumbar Spacers are integrated 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. These devices 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. HEDRON IA® 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 titanium alloy and cobalt chromium alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical, and functional reasons.

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

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 may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

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

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

MRI SAFETY INFORMATION

MR

The HEDRON® 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 HEDRON® 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

IMPORTANT INFORMATION ABOUT HEDRON® SPACERS

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

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
- Signs of local inflammation.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- 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 risk versus the benefits to the patient.
- 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.
- Any patient not willing to cooperate with postoperative instructions.
- Any condition not described in the indications for use.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for used would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
- 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 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 locking screws and 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 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.

IMPORTANT INFORMATION ABOUT HEDRON® SPACERS

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 are available sterile and instruments are nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10-6. Sterile products are packaged in a thermoplastic polyurethane pouch inside a PETG tray with a heat-sealed Tyvek lid or a poly/Tyvek pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile 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 in2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) 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		

DI211A Rev D

NOTES

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

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

GMTGD219
06.23 Rev E