HEDRON L™

3D Printed Lateral Spacer

SURGICAL TECHNIQUE GUIDE

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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 L™

HEDRON L™

3D Printed Lateral Spacer

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

The Face of Fusion

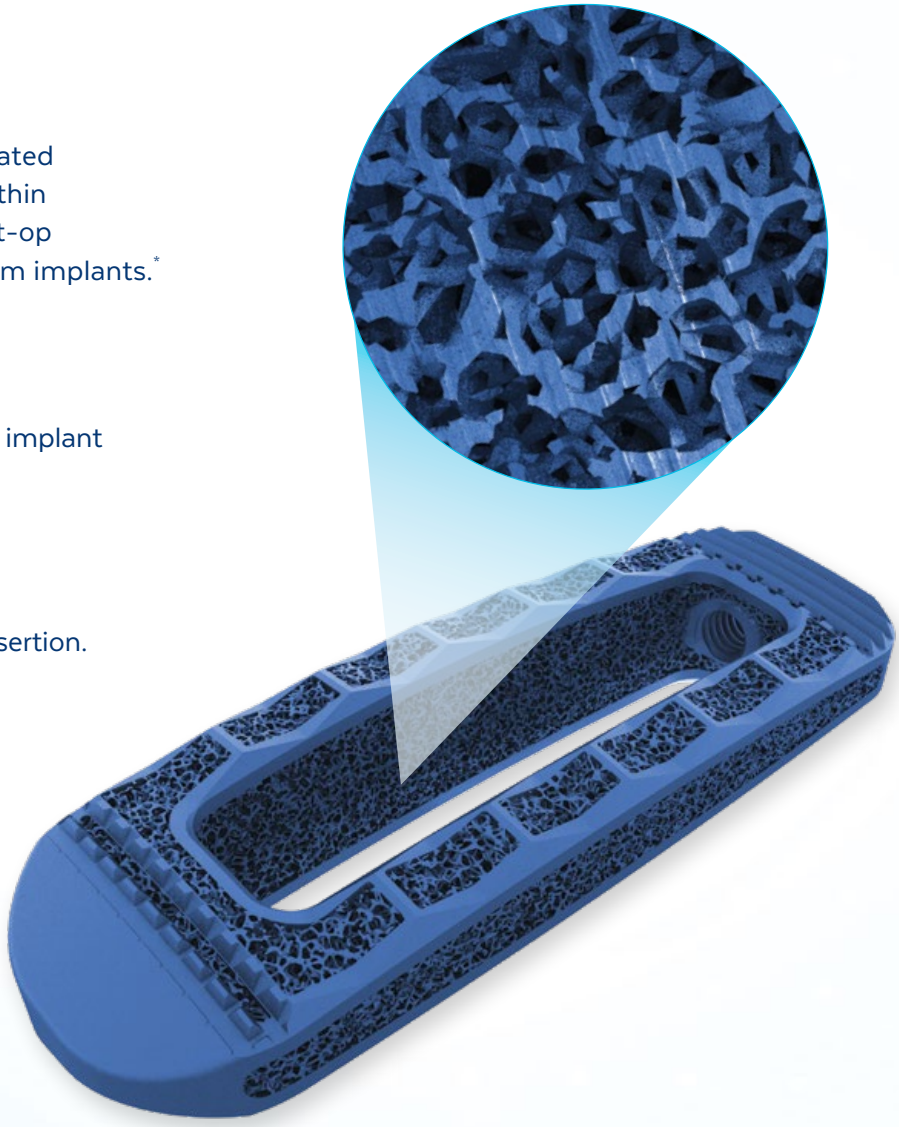
An ovine interbody study demonstrated significantly more bone ingrowth within HEDRON™ implants at 6 weeks post-op compared to PEEK and solid titanium implants.*

Initial Fixation

Bidirectional teeth designed to resist implant expulsion and migration.

Ease of Insertion

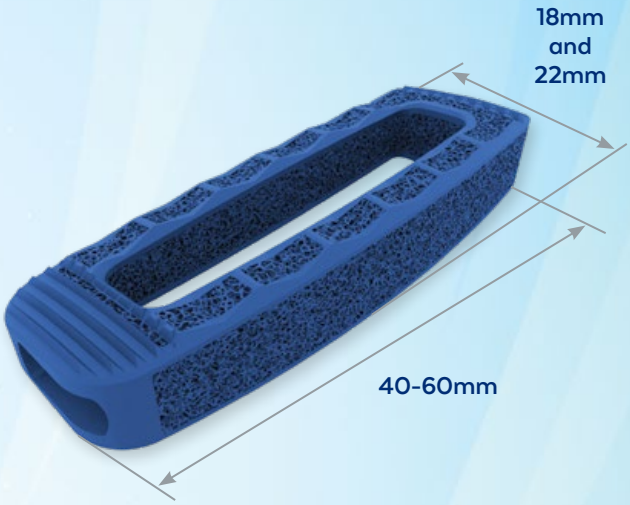
Smooth implant edges for ease of insertion.



*Data on File

Footprint Options

- **Widths:** 18mm and 22mm
- **Lengths:** 40-60mm, in 5mm increments
- **Heights:** 7-15mm, in 2mm increments



Sagittal Profiles

10° Lordotic

15° Lordotic

INSTRUMENT OVERVIEW

DISC PREP INSTRUMENTS

Bayonetted Annulotomy Knife 675.405S

Penfield, Bayonetted, Pull 675.173

Penfield, Bayonetted, Pull, 190mm 675.174

Cobb Elevator, Straight, 20mm 675.503

Cobb Elevator, Straight, 10mm 675.504

Thin Rasp, 12x20mm 675.510

DISC PREP INSTRUMENTS (CONT'D)

Cobb, 10mm, 7° Up-Angle 675.515

Cobb, 20mm, 7° Up-Angle 675.516

Ring Curette, 10mm Straight 675.518

Ring Curette, 10mm 7°, Up-Angle 675.519

Double Rasp 675.520

Cup Curette, 6.5x9.5mm, Straight 675.525

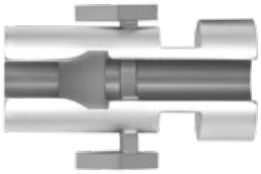
Cup Curette, 6.5x9.5mm, 15°, Up-angle 675.526

Cup Curette, 6.5x9.5mm, 90°, Down-angle 675.527

DISC PREP INSTRUMENTS (CONT'D)

Kerrison, 4mm 625.202
Kerrison, 6mm 625.203

Disc Rongeur, 4mm 625.305
Disc Rongeur, 6mm 625.307



Slap Hammer Adaptor 675.002

Quick-Connect Guide 675.201

HANDLES

T-Handle 675.005

L-Handle 679.010

**Items in gray are additionally available*

SCRAPERS

	Height	Part Number
	5mm	675.605
	7mm	675.607
	9mm	675.609
	11mm	675.611
	13mm	675.613
	15mm	675.615
	17mm	675.617

PADDLE DISTRACTORS

	Height	Part Number
	5mm	675.855
	7mm	675.857
	9mm	675.859
	11mm	675.861
	13mm	675.863

DISC BOX CUTTERS

	Height	Part Number
	5mm	675.533
	7mm	675.534
	9mm	675.535

TRIALS

Trial, Lordotic

TransContinental® Trials		
Width	**Part Number**	**Description**
18mm	675.065	TransContinental® 18mm Trial, 10° Lordotic, 5mm
	675.067	TransContinental® 18mm Trial, 10° Lordotic, 7mm
	675.067	TransContinental® 18mm Trial, 10° Lordotic, 9mm
	675.071	TransContinental® 18mm Trial, 10° Lordotic, 11mm
	675.073	TransContinental® 18mm Trial, 10° Lordotic, 13mm
	675.075	TransContinental® 18mm Trial, 10° Lordotic, 15mm
	675.077	TransContinental® 18mm Trial, 10° Lordotic, 17mm
	675.631	TransContinental® 18mm Trial, 15°, 7mm
	675.632	TransContinental® 18mm Trial, 15°, 9mm
	675.633	TransContinental® 18mm Trial, 15°, 11mm
	675.634	TransContinental® 18mm Trial, 15°, 13mm
22mm	675.365	TransContinental® 22mm Trial, 10° Lordotic, 5mm
	675.637	TransContinental® 22mm Trial, 10° Lordotic, 7mm
	675.639	TransContinental® 22mm Trial, 10° Lordotic, 9mm
	675.371	TransContinental® 22mm Trial, 10° Lordotic, 11mm
	675.373	TransContinental® 22mm Trial, 10° Lordotic, 13mm
	675.375	TransContinental® 22mm Trial, 10° Lordotic, 15mm
	675.377	TransContinental® 22mm Trial, 10° Lordotic, 17mm
	675.641	TransContinental® 22mm Trial, 15°, 7mm
	675.642	TransContinental® 22mm Trial, 15°, 9mm
	675.643	TransContinental® 22mm Trial, 15°, 11mm
	675.644	TransContinental® 22mm Trial, 15°, 13mm

INSERTION INSTRUMENTS

Slide Hammer, Long 675.004

PATRIOT® Continental® Holder/Inserter 664.500

Insertion Sleeve 675.501

Part Number	Description
675.501	Insertion Sleeve
675.522	Insertion Sleeve, 22mm
675.599	Insertion Sleeve 18mm, 15°
675.699	Insertion Sleeve 22mm, 15°

PATRIOT® Continental® Holder/Inserter 664.500,
Insertion Sleeve 675.501 (Assembled)

Tamp 675.502

MIS Handle 673.003

SURGICAL TECHNIQUE

HEDRON L™

Refer to the package insert printed at the back of this guide for important information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

HEDRON L™ spacers are intended to be used with supplemental fixation. Refer to the corresponding supplemental fixation system's surgical technique guide for specific instructions.

STEP 1 APPROACH

An anterior, anterolateral, or lateral approach may be used to implant the HEDRON L™ spacer. A lateral approach is shown.

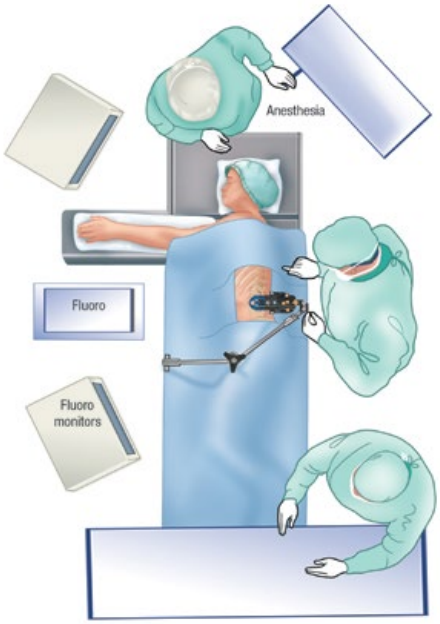
STEP 2 PREPARATION

Patient Positioning

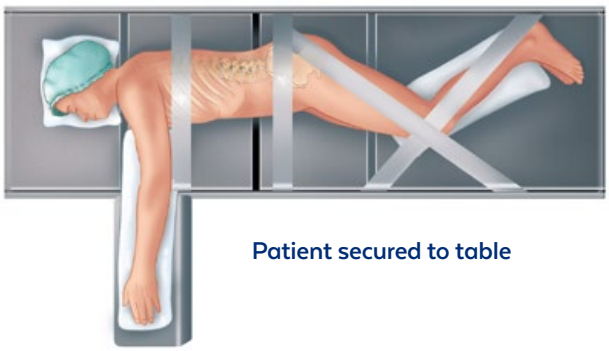
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break.

The patient is then secured to the table at the following locations: beneath the iliac crest, over the thoracic region, just under the shoulder; from the back of the table, over the ankle, and past the knee to the front of the table.

The table should be flexed to open the interval between the 12th rib and iliac crest, and provide access to the disc space.



Patient positioning



Patient secured to table

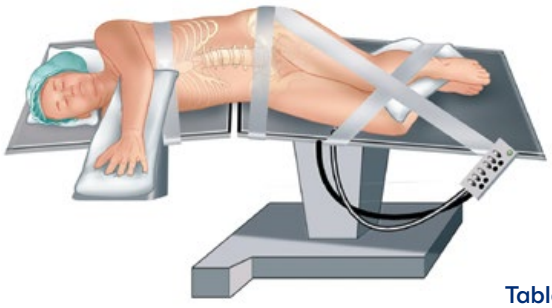


Table flexed

X-ray Confirmation

Use fluoroscopy to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images when at 0° and straight lateral images at 90°.

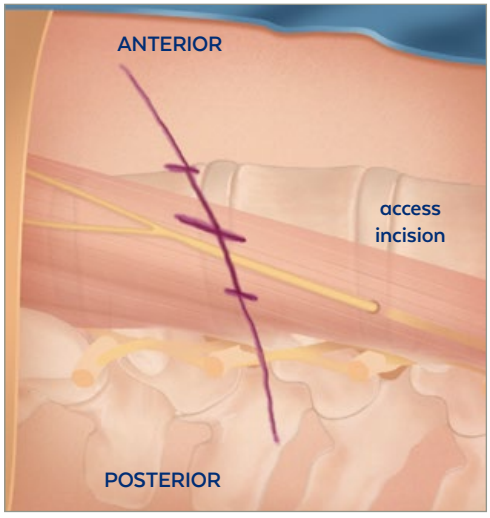
Lateral view

AP view

Incision Location

The operative area is carefully cleaned and the **Incision Locator** is used under fluoroscopy to identify the middle of the disc space to be fused. An access incision mark is then traced on the patient's skin to indicate the position and insertion site for the retractor. Position the desired retractor.

Using Incision Locator



Marking the incision locations

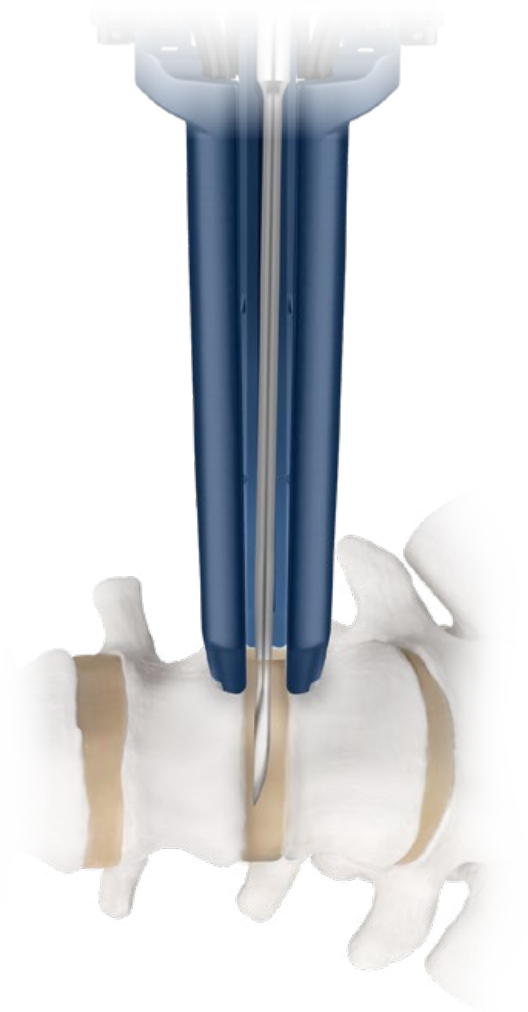
STEP 3 DISC PREPARATION

Annulotomy

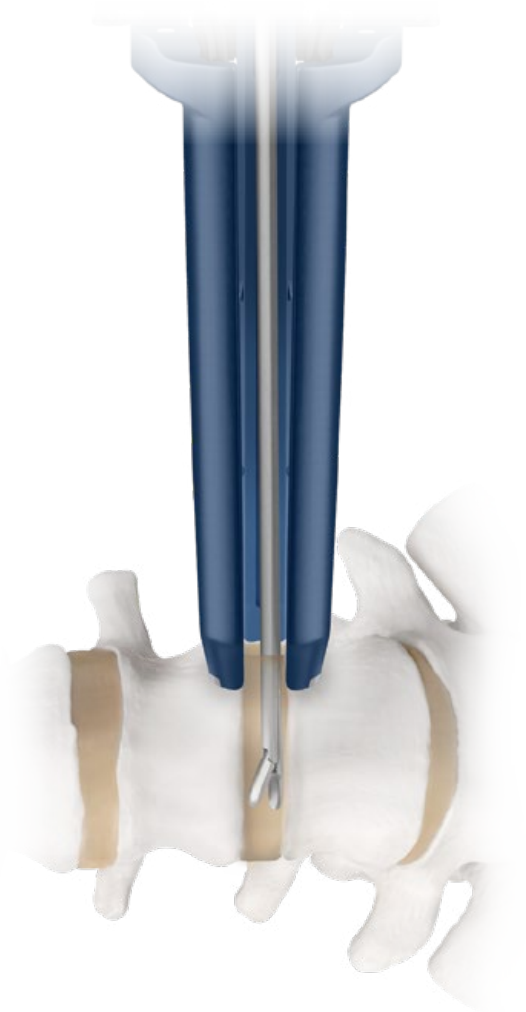
Expose the disc. The **Bayonneted Annulotomy Knife** may be used to create a window centered in the anterior half of the annulus, large enough for implant insertion.

Contralateral Annulus Release

The **Cobb Elavator** may be passed along both endplates through the disc space to remove the superficial layers of the cartilaginous endplates, and far enough to provide the release of the contralateral annulus. This allows for height restoration upon implant insertion.



Using the Cobb Elevator



Using the Disc Rongeur

Disc Space Preparation

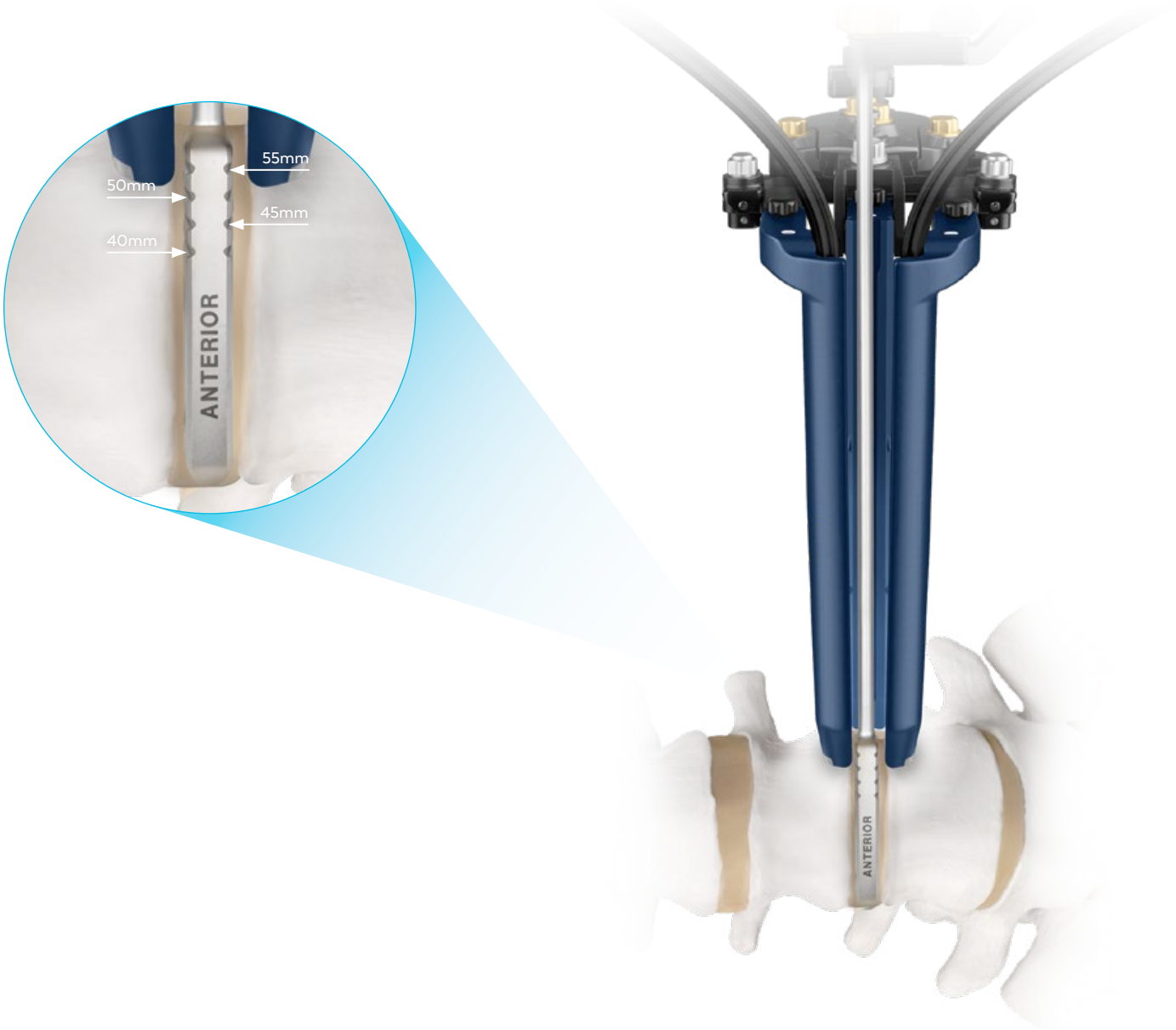
Leaving the anterior and posterior annulus intact, remove the intervertebral disc and osteophytes as needed. The **Disc Box Cutter**, **Disc Rongeurs**, **Kerrisons**, **Curettes**, **Scrapers**, and **Rasps** may be used for careful disc removal and endplate preparation to maximize the potential for a successful fusion.

STEP 4 SIZING

Trials are used to distract the disc space and determine implant length. To determine the appropriate implant size, insert the smallest static trial into the disc space, moving to larger trials as needed.

For correct orientation, insert the trial into the disc space with the side etched ‘ANTERIOR’ facing the patient’s anterior side. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and to stabilize the segment, and can be confirmed using fluoroscopy and tactile feel.

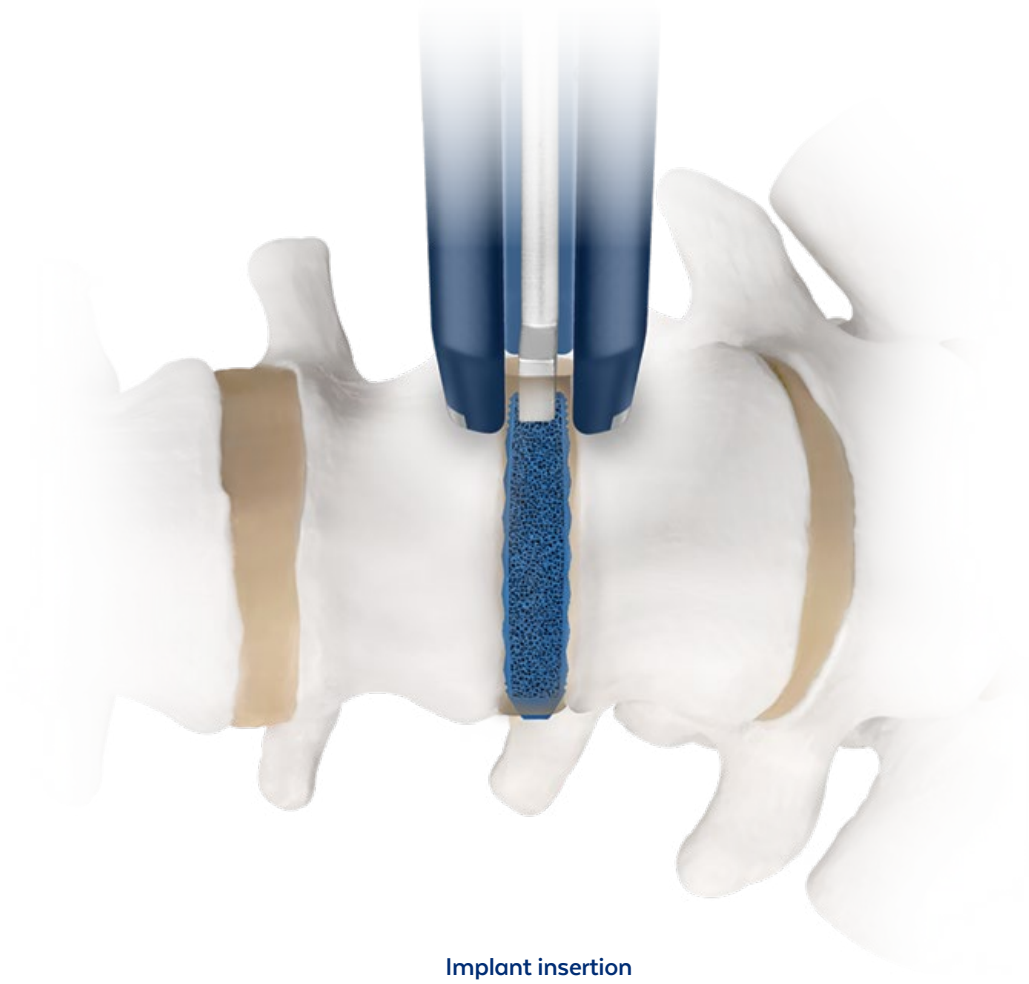
Ensure that the tapered end of the trial overhangs the contralateral edge to account for implant-endplate contact.



Implant sizing

STEP 5 INSERTION

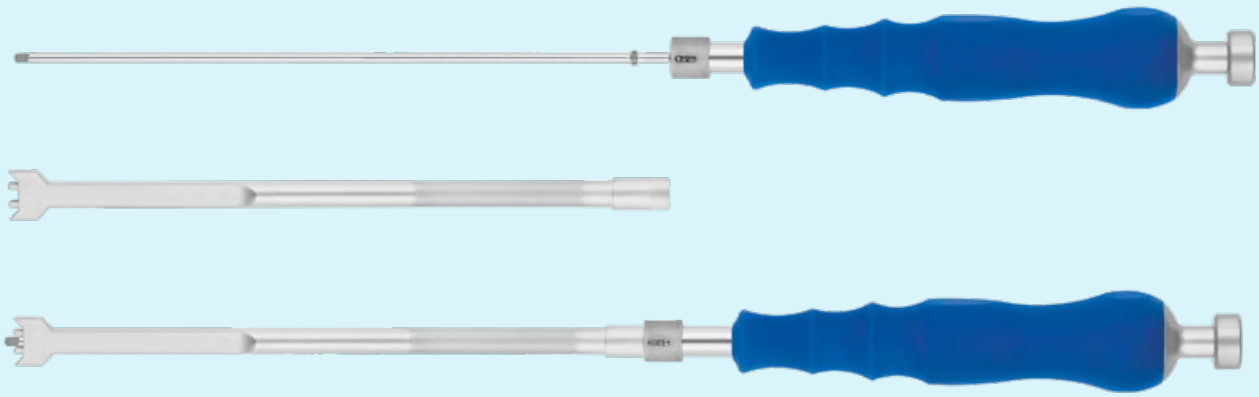
Based on the trial, select the appropriately sized HEDRON L™ spacer to be inserted. Pack the central chamber with autograft or allograft (cortical or corticocancellous) bone. Gently insert the spacer into the intervertebral space using the assembled **PATRIOT® CONTINENTAL® Holder/Inserter** and **Insertion Sleeve**. Use AP fluoroscopy to facilitate implant placement. Once the position is confirmed, release the implant from the inserter.



Implant insertion

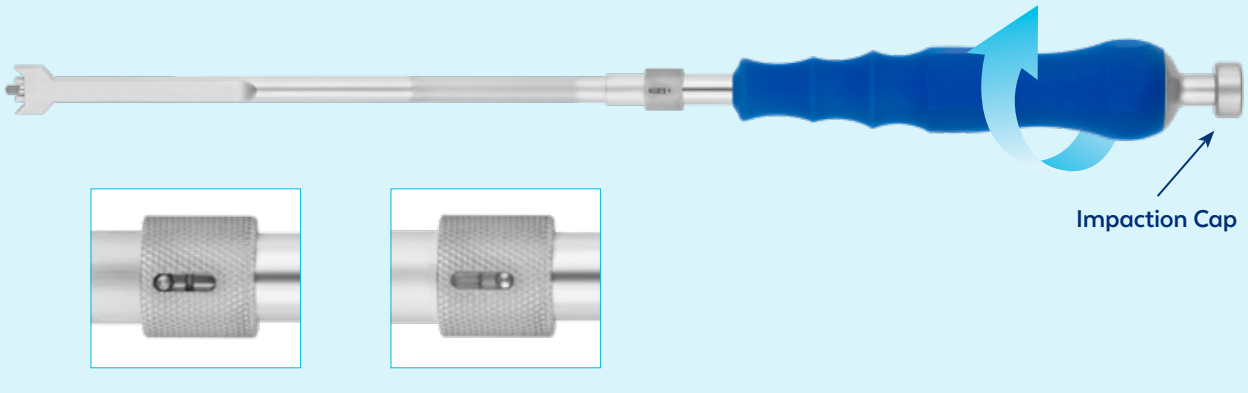
ASSEMBLING IMPLANT INSERTER

Thread the PATRIOT® CONTINENTAL® Holder/Inserter clockwise into the Insertion Sleeve. Disassemble by rotating the handle counterclockwise.



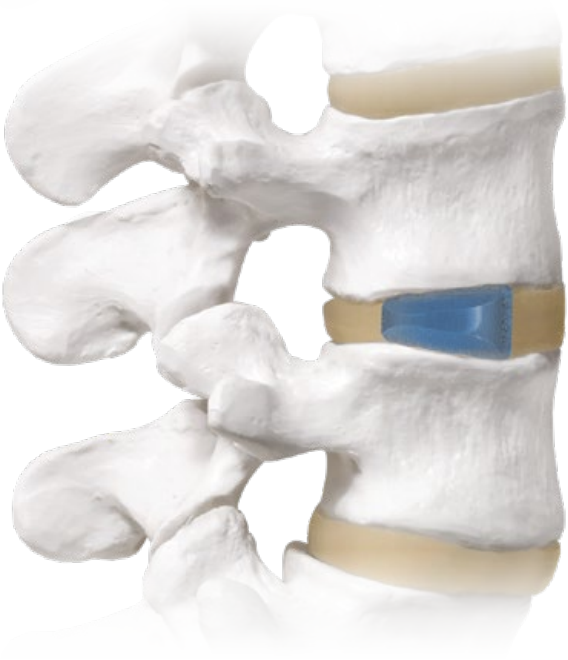
USING IMPLANT INSERTER

Ensure the **Implant Inserter** is in the unlocked position. Thread the implant onto the inserter by rotating the handle clockwise, stopping when the implant sits flush with the sleeve. Slide the locking nut forward to secure the implant to the inserter. Insert the implant. To disengage, unlock and rotate the handle counterclockwise.



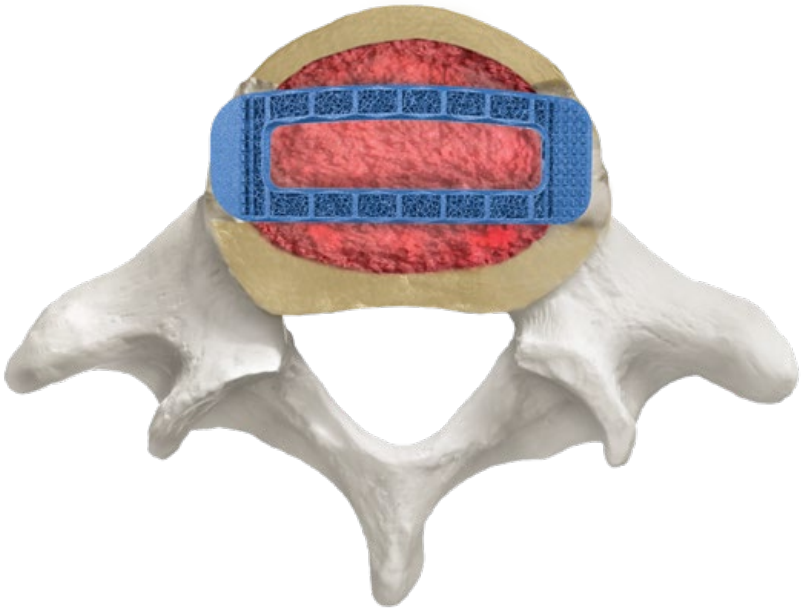
STEP 6 VERIFY PLACEMENT

Verify implant placement. The implant should fill the lateral width of the disc space. Supplemental autograft or allograft should be packed around the implant if possible. Final implant position is shown below.



Lateral view

AP view



Axial view

STEP 7 SUPPLEMENTAL FIXATION

This device is to be used with supplemental fixation such as CREO MIS® or REVOLVE®. Refer to the surgical technique manual for the supplemental fixation system.

CREO MIS® STABILIZATION SYSTEM

Minimized Muscle Disruption

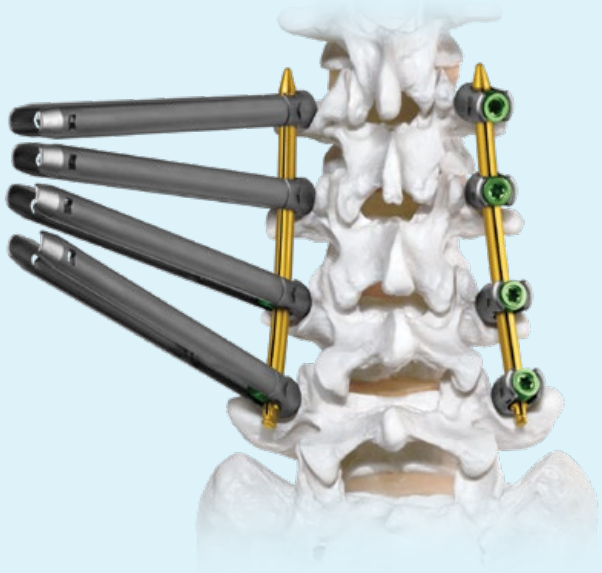
Extended screw heads provide a minimized outer diameter to help reduce muscle disruption and screw sleeve interference.

Powerful MIS Correction

Deformity adapters rigidly attach to the extended screw head and allow for screw manipulation and deformity correction.

Integrated Rod Reduction

Ensures proper thread alignment while capturing, reducing, and locking the rod in one simplified step.



REMOVAL

Implant removal may be performed using forceps or other manual surgical instruments.

HEDRON L™
10° IMPLANT SET 9209.9010

HEDRON L™ Spacer, 18x40mm, 10°

Part No.	Height	QTY
1209.0277S	7mm	2
1209.0279S	9mm	2
1209.0281S	11mm	2
1209.0283S	13mm	2
1209.0285S	15mm	1

HEDRON L™ Spacer, 18x45mm, 10°

Part No.	Height	QTY
1209.0297S	7mm	2
1209.0299S	9mm	2
1209.0301S	11mm	2
1209.0303S	13mm	2
1209.0305S	15mm	1

HEDRON L™ Spacer, 18x50mm, 10°

Part No.	Height	QTY
1209.0317S	7mm	2
1209.0319S	9mm	2
1209.0321S	11mm	2
1209.0323S	13mm	2
1209.0325S	15mm	1

HEDRON L™ Spacer, 18x55mm, 10°

Part No.	Height	QTY
1209.0337S	7mm	2
1209.0339S	9mm	2
1209.0341S	11mm	2
1209.0343S	13mm	2
1209.0345S	15mm	1

HEDRON L™ Spacer, 18x60mm, 10°

Part No.	Height	QTY
1209.0357S	7mm	2
1209.0359S	9mm	2
1209.0361S	11mm	2
1209.0363S	13mm	2
1209.0365S	15mm	1

HEDRON L™ Spacer, 22x40mm, 10°

Part No.	Height	QTY
1209.0977S	7mm	2
1209.0979S	9mm	2
1209.0981S	11mm	2
1209.0983S	13mm	2
1209.0985S	15mm	1

HEDRON L™ Spacer, 22x45mm, 10°

Part No.	Height	QTY
1209.0997S	7mm	2
1209.0999S	9mm	2
1209.1001S	11mm	2
1209.1003S	13mm	2
1209.1005S	15mm	1

HEDRON L™ Spacer, 22x50mm, 10°

Part No.	Height	QTY
1209.2267S	7mm	2
1209.1009S	9mm	2
1209.1011S	11mm	2
1209.1013S	13mm	2
1209.1015S	15mm	1

HEDRON L™ Spacer, 22x55mm, 10°

Part No.	Height	QTY
1209.1027S	7mm	2
1209.1029S	9mm	2
1209.1031S	11mm	2
1209.1033S	13mm	2
1209.1035S	15mm	1

HEDRON L™ Spacer, 22x60mm, 10°

Part No.	Height	QTY
1209.1047S	7mm	2
1209.1049S	9mm	2
1209.1051S	11mm	2
1209.1053S	13mm	2
1209.1055S	15mm	1

9209.0018	18mm Implants Soft Case

HEDRON L™
15° IMPLANT SET 9209.9015

HEDRON L™ Spacer, 18x40mm, 15°

Part No.	Height	QTY
1209.1969S	9mm	2
1209.1971S	11mm	2
1209.1973S	13mm	2
1209.1975S	15mm	1

HEDRON L™ Spacer, 18x45mm, 15°

Part No.	Height	QTY
1209.1989S	9mm	2
1209.1991S	11mm	2
1209.1993S	13mm	2
1209.1995S	15mm	1

HEDRON L™ Spacer, 18x50mm, 15°

Part No.	Height	QTY
1209.2009S	9mm	2
1209.2011S	11mm	2
1209.2013S	13mm	2
1209.2015S	15mm	1

HEDRON L™ Spacer, 18x55mm, 15°

Part No.	Height	QTY
1209.2029S	9mm	2
1209.2031S	11mm	2
1209.2033S	13mm	2
1209.2035S	15mm	1

HEDRON L™ Spacer, 18x60mm, 15°

Part No.	Height	QTY
1209.2049S	9mm	2
1209.2051S	11mm	2
1209.2053S	13mm	2
1209.2055S	15mm	1

HEDRON L™ Spacer, 22x40mm, 15°

Part No.	Height	QTY
1209.2069S	9mm	2
1209.2071S	11mm	2
1209.2073S	13mm	2
1209.2075S	15mm	1

HEDRON L™ Spacer, 22x45mm, 15°

Part No.	Height	QTY
1209.2089S	9mm	2
1209.2091S	11mm	2
1209.2093S	13mm	2
1209.2095S	15mm	1

HEDRON L™ Spacer, 22x50mm, 15°

Part No.	Height	QTY
1209.2109S	9mm	2
1209.2111S	11mm	2
1209.2113S	13mm	2
1209.2115S	15mm	1

HEDRON L™ Spacer, 22x55mm, 15°

Part No.	Height	QTY
1209.2129S	9mm	2
1209.2131S	11mm	2
1209.2133S	13mm	2
1209.2135S	15mm	1

HEDRON L™ Spacer, 22x60mm, 15°

Part No.	Height	QTY
1209.2149S	9mm	2
1209.2151S	11mm	2
1209.2153S	13mm	2
1209.2155S	15mm	1

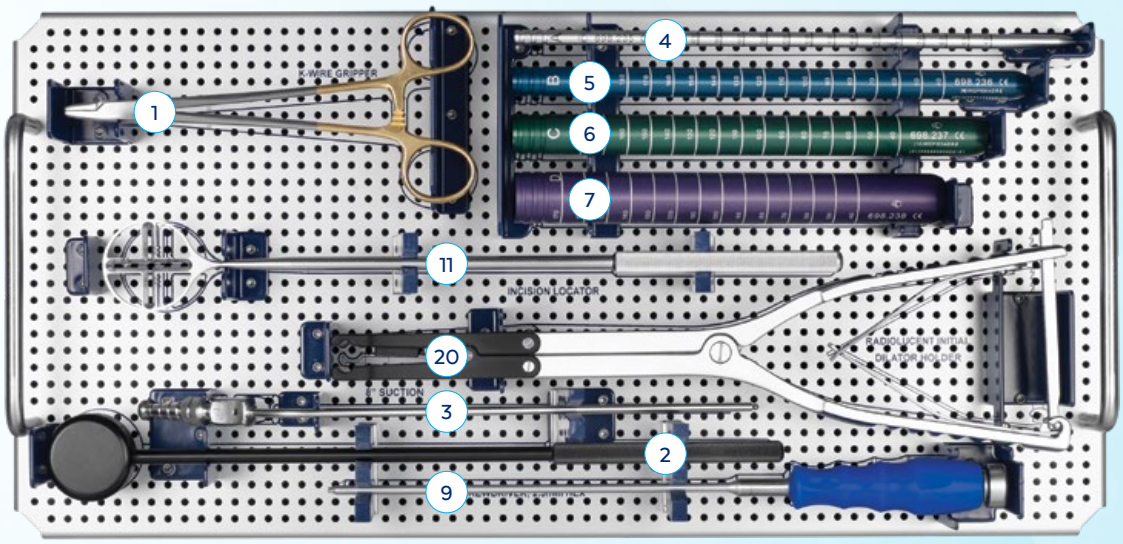
9209.0015	15° Implants Soft Case

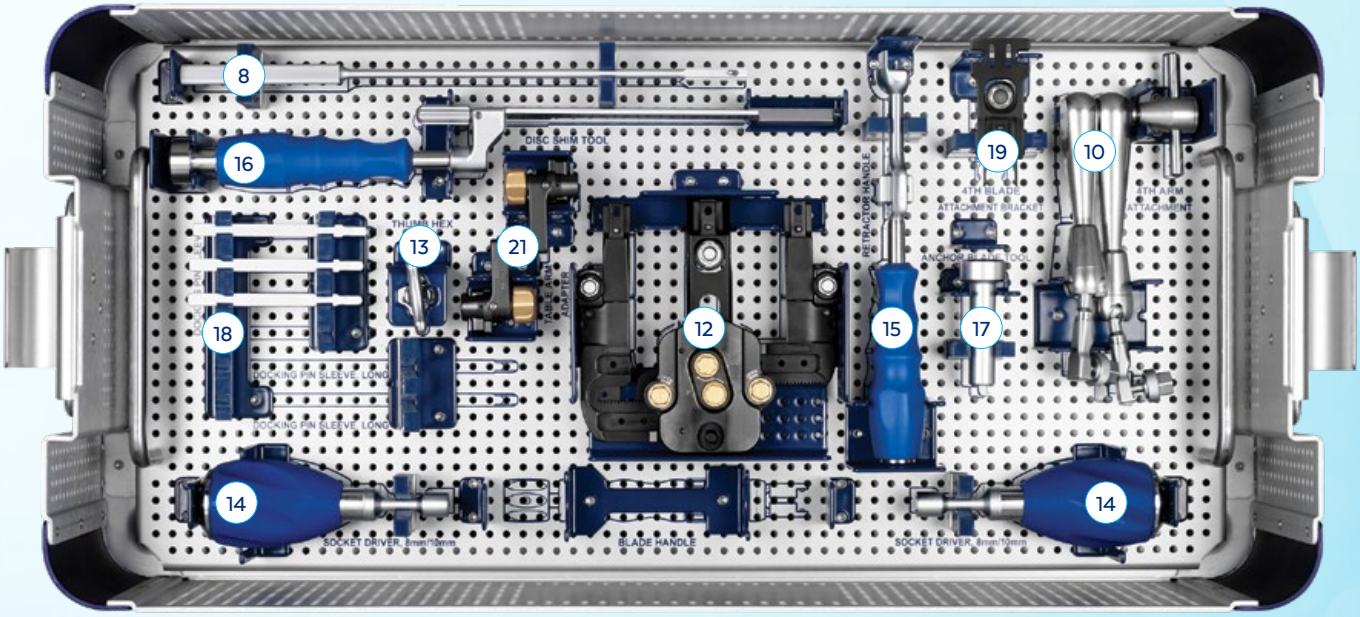
MARS™ 3VL RETRACTOR
INSTRUMENT I SET 9133.9001

	Instruments		QTY
1	623.003	K-Wire Gripper	1
2	675.403	Fluoro Modulator	1
3	675.513	8” Suction	1
4	698.235	Stainless Steel Cannula A	1
5	698.236	Aluminum Cannula B	1
6	698.237	Aluminum Cannula C	1
7	698.238	Aluminum Cannula D	1
8	698.240	Shim Tool, CC	1
9	698.260	Screwdriver, 2.5mm Hex	1
10	698.355	MARS™ 3V 4th Arm Attachment	1
11	6133.0001	Incision Locator	1
12	6133.0100	MARS™ 3VL Retractor	1
13	6133.0148	Thumb Hex	1
14	6133.0150	Socket Driver, 8mm/10mm	2
15	6133.0230	Retractor Handle	1
16	6133.0330	Disc Shim Tool	1
17	6133.0332	Anchor Blade Tool	1
18	6133.0340	Docking Pin Sleeve	4
	6133.0341	Docking Pin, Sleeve, Long	0
19	6133.0357	4th Blade Attachment Bracket	1
20	6133.0360	Radiolucent Initial Dilator Holder	1
21	6133.0790	Table Arm Adapter	2
	9133.0001	MARS™ 3VL Retractor Instruments I Graphic Case	

Disposables		QTY
6133.0300S	Lengthening Shim	2
6133.0305S	Widening Shim	2
6133.0310S	Docking Pin, 3.3mm, 10mm	2
6133.0311S	Docking Pin, 3.75mm, Long, 10mm	0
6133.0320S	Docking Pin, 3.3mm, 20mm	2
6133.0322S	Docking Pin, 3.75mm, Long, 20mm	0
6133.0325S	Disc Shim, Aluminum	1
6133.0326S	Disc Shim, Stainless Steel	1
6133.0399S	K-Wires, Threaded, Blunt	1
675.405S	Bayonetted Annulotomy Knife	1

**Items in gray are additionally available*

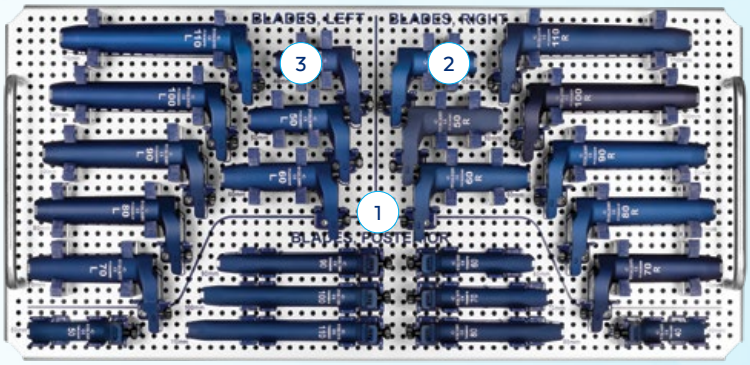

1
4
5
6
7
11
INCISION LOCATOR
20
3
2
9

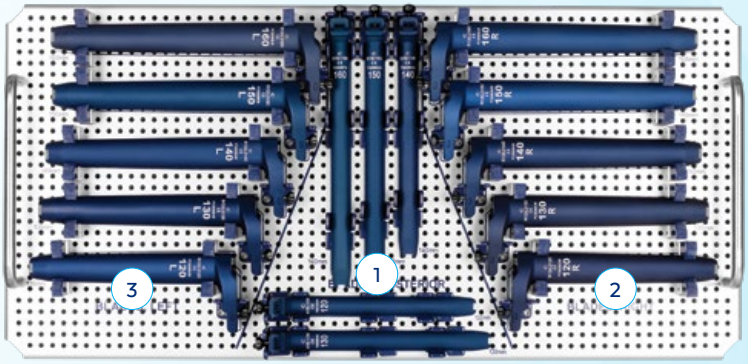

8
16
DISC SHIM TOOL
19
10
4TH BLADE ATTACHMENT BRACKET
4TH ARM ATTACHMENT
RETRACTOR HANDLE
ANCHOR BLADE TOOL
THUMB HEX
13
21
18
12
15
17
LOCKING PIN SLEEVE, LONG
LOCKING PIN SLEEVE, LONG
14
SOCKET DRIVER, 8mm/10mm
BLADE HANDLE
SOCKET DRIVER, 8mm/10mm
14

MARS™ 3VL RETRACTOR
INSTRUMENT II, BLADES SET 9133.9002

	Instruments		QTY
1	6133.1040	Blade, Posterior, 40mm	1
	6133.1050	Blade, Posterior, 50mm	1
	6133.1060	Blade, Posterior, 60mm	1
	6133.1070	Blade, Posterior, 70mm	1
	6133.1080	Blade, Posterior, 80mm	1
	6133.1090	Blade, Posterior, 90mm	1
	6133.1100	Blade, Posterior, 100mm	1
	6133.1110	Blade, Posterior, 110mm	1
	6133.1120	Blade, Posterior, 120mm	1
	6133.1130	Blade, Posterior, 130mm	1
	6133.1140	Blade, Posterior, 140mm	1
	6133.1150	Blade, Posterior, 150mm	1
	6133.1160	Blade, Posterior, 160mm	1
	6133.1170	Blade, Posterior, 170mm	1
	6133.1180	Blade, Posterior, 180mm	1
	6133.1190	Blade, Posterior, 190mm	1
	6133.1200	Blade, Posterior, 200mm	1
2	6133.2040	Blade, Right, 40mm	1
	6133.2050	Blade, Right, 50mm	1
	6133.2060	Blade, Right, 60mm	1
	6133.2070	Blade, Right, 70mm	1
	6133.2080	Blade, Right, 80mm	1
	6133.2090	Blade, Right, 90mm	1
	6133.2100	Blade, Right, 100mm	1
	6133.2110	Blade, Right, 110mm	1
	6133.2120	Blade, Right, 120mm	1
	6133.2130	Blade, Right, 130mm	1
	6133.2140	Blade, Right, 140mm	1
	6133.2150	Blade, Right, 150mm	1
	6133.2160	Blade, Right, 160mm	1
	6133.2170	Blade, Right, 170mm	1
	6133.2180	Blade, Right, 180mm	1
	6133.2190	Blade, Right, 190mm	1
	6133.2200	Blade, Right, 200mm	1

	Instruments		QTY
3	6133.3040	Blade, Left, 40mm	1
	6133.3050	Blade, Left, 50mm	1
	6133.3060	Blade, Left, 60mm	1
	6133.3070	Blade, Left, 70mm	1
	6133.3080	Blade, Left, 80mm	1
	6133.3090	Blade, Left, 90mm	1
	6133.3100	Blade, Left, 100mm	1
	6133.3110	Blade, Left, 110mm	1
	6133.3120	Blade, Left, 120mm	1
	6133.3130	Blade, Left, 130mm	1
	6133.3140	Blade, Left, 140mm	1
	6133.3150	Blade, Left, 150mm	1
	6133.3160	Blade, Left, 160mm	1
	6133.3170	Blade, Left, 170mm	1
	6133.3180	Blade, Left, 180mm	1
	6133.3190	Blade, Left, 190mm	1
	6133.3200	Blade, Left, 200mm	1
4	6133.4060	Anchor Blade, 60mm	1
	6133.4070	Anchor Blade, 70mm	1
	6133.4080	Anchor Blade, 80mm	1
	6133.4090	Anchor Blade, 90mm	1
	6133.4100	Anchor Blade, 100mm	1
	6133.4110	Anchor Blade, 110mm	1
	6133.4120	Anchor Blade, 120mm	1
	6133.4130	Anchor Blade, 130mm	1
	6133.4140	Anchor Blade, 140mm	1
	6133.4150	Anchor Blade, 150mm	1
	6133.4160	Anchor Blade, 160mm	1
	6133.4170	Anchor Blade, 170mm	1
	6133.4180	Anchor Blade, 180mm	1
	6133.4190	Anchor Blade, 190mm	1
	6133.4200	Anchor Blade, 200mm	1
	9133.0002	MARS™ 3VL Retractor Instruments II Graphic Case	


BLADES LEFT
BLADES RIGHT
3
2
1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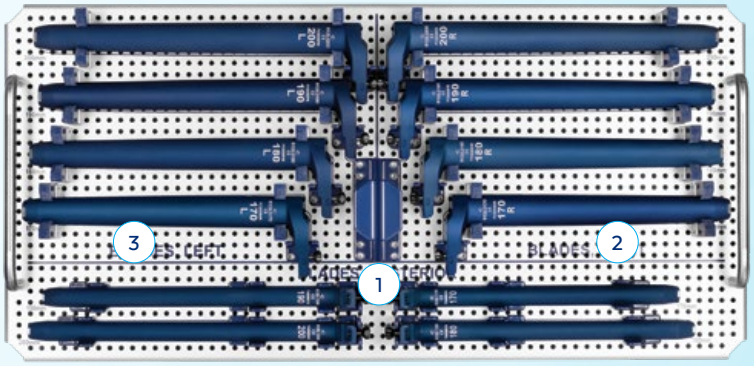
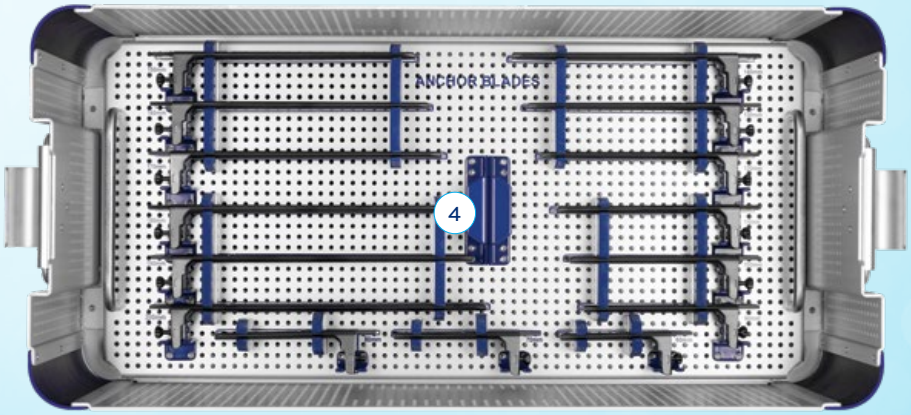
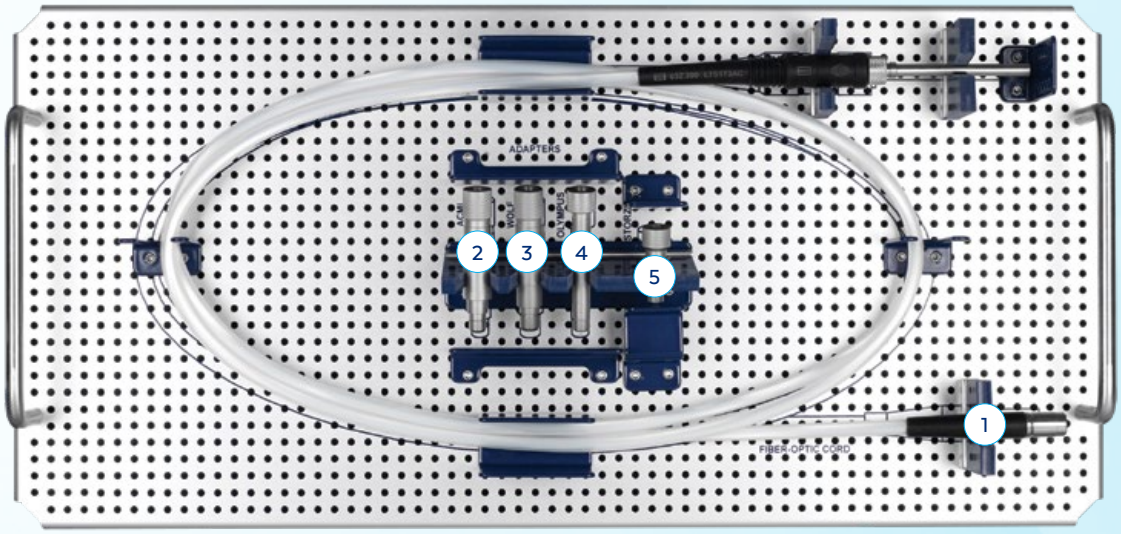
1
2

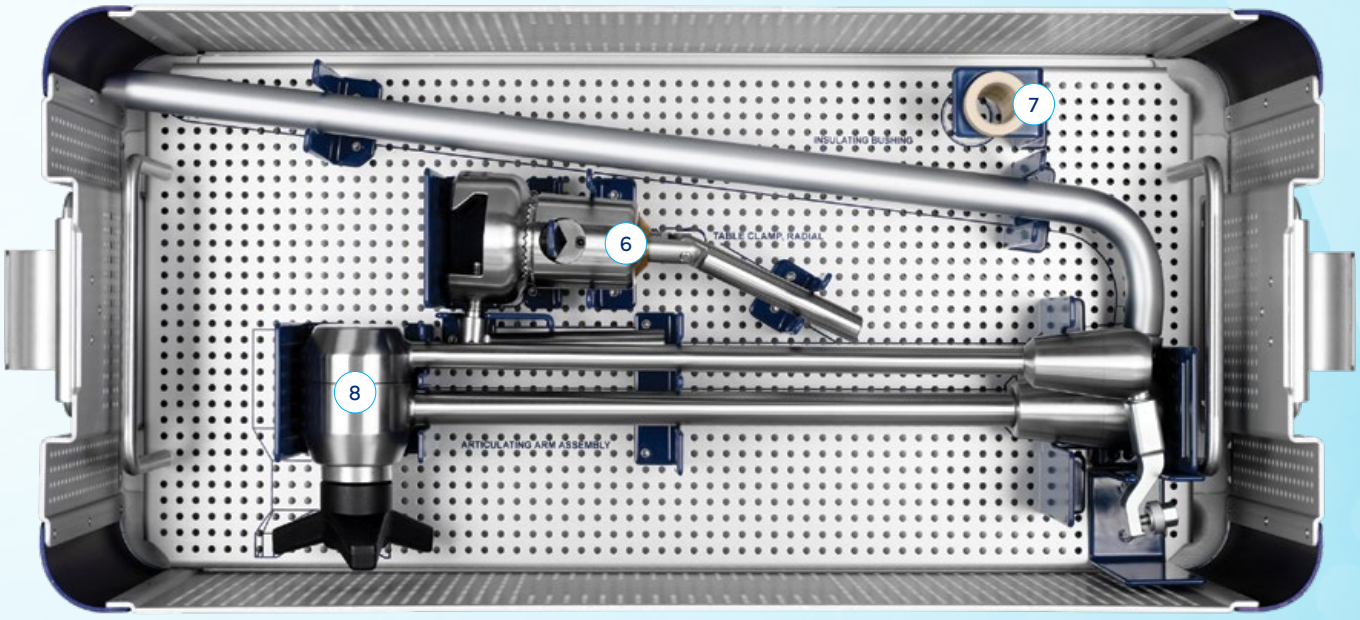

3
2
1


ANCHOR BLADES
4

MARS™3VL
INSTRUMENT III, MOUNT SET 9133.9003

	Instruments		QTY
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
6	632.505	Table Clamp, Radial	1
7	632.785	Insulating Bushing	1
8	6133.0780	Articulating Arm Assembly	1
	698.605S	Illumination System	1
	9133.0003	MARS™3VL Retractor Instruments III Graphic Case	


ADAPTERS
2
3
4
5
1
FIBER-OPTIC CORD

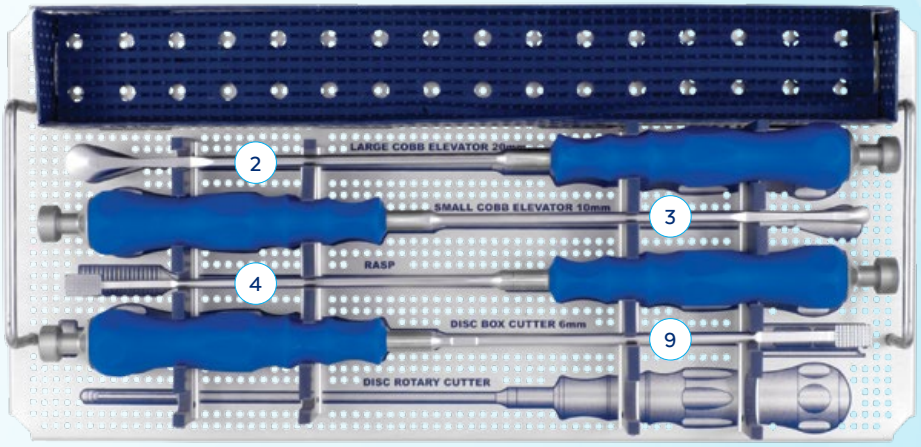

7
INSULATING BUSHING
6
TABLE CLAMP, RADIAL
8
ARTICULATING ARM ASSEMBLY

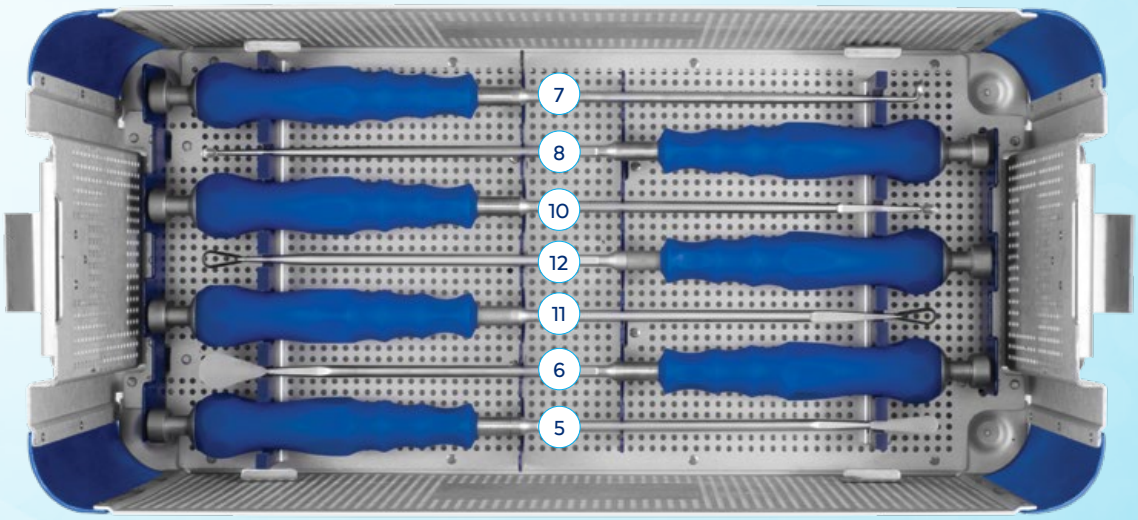
LATERAL DISC PREP
INSTRUMENT SET 975.914

	Instrument		QTY
1	675.005	T-Handle with Impaction Cap	2
2	675.503	Large Cobb Elevator	1
3	675.504	Small Cobb Elevator	1
4	675.510	Thin Rasp, 12x20mm	1
5	675.515	Cobb, 10mm, 7° Up-Angled	1
6	675.516	Cobb, 20mm, 7° Up-Angled	1
7	675.518	Ring Curette, 10mm, Straight	1
8	675.519	Ring Curette, 10mm, 7° Up-Angle Tip	1
9	675.520	Double Rasp	1
10	675.525	Cup Curette, 6.5x9.5mm, Straight	1
11	675.526	Cup Curette, 6.5x9.5mm, 15° Up-Angle	1
12	675.527	Cup Curette, 6.5x9.5mm, 90° Down-Angle	1
13	675.605	Scraper, 5mm	1
	675.607	Scraper, 7mm	1
	675.609	Scraper, 9mm	1
	675.611	Scraper, 11mm	1
	675.613	Scraper, 13mm	1
	675.615	Scraper, 15mm	1
	675.617	Scraper, 17mm	1
	675.855	Paddle Distractor, 5mm	1
	675.857	Paddle Distractor, 7mm	1
	675.859	Paddle Distractor, 9mm	1
	675.861	Paddle Distractor, 11mm	1
	675.863	Paddle Distractor, 13mm	1
	675.170S	Bipolar Forceps Bayonetted, Straight	0
	675.171S	Bipolar Forceps Bayonetted, Angled	0
	975.008	TransContinental® Graphic Case - Disc Prep	

**Items in gray are additionally available*


1
T-HANDLE WITH
IMPACTION CAP (X2)
1
13
SCRAPER 11mm
SCRAPER 13mm
SCRAPER 15mm
SCRAPER 17mm


2
LARGE COBB ELEVATOR 20mm
SMALL COBB ELEVATOR 10mm
3
4
RASP
DISC BOX CUTTER 6mm
9
DISC ROTARY CUTTER


7
8
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12
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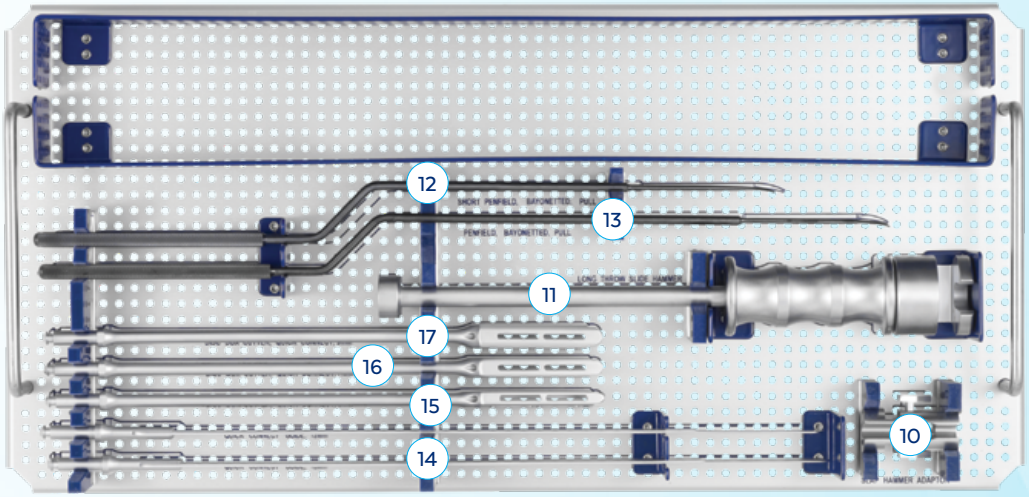
LATERAL DISC PREP II
INSTRUMENT SET 975.917

	Instrument		QTY
1	6105.2016	Osteophyte Removal Tool	1
2	625.202	Kerrison, 4mm	1
3	625.203	Kerrison, 6mm	1
4	625.305	Disc Rongeur, 4mm	1
5	625.307	Disc Rongeur, 6mm	1
6	626.240	Disc Rongeur, 250x4mm, Straight	1
7	626.241	Disc Rongeur, 250x6mm, Straight	1
8	626.250	Kerrison, 250x3mm, Straight	1
9	626.252	Kerrison, 250x5mm, Straight	1
10	675.002	Slap Hammer Adaptor	1
11	675.004	Long Throw Slide Hammer	1
12	675.173	Penfield, Bayonetted, Pull	1
13	675.174	Penfield #4, Pull, 190mm	1
14	675.201	Quick-Connect Guide, 12mm	2
15	675.533	Disc Box Cutter, 5mm	1
16	675.534	Disc Box Cutter, 7mm	1
17	675.535	Disc Box Cutter, 9mm	1
	975.017	LLIF Disc Prep II Graphic Case	


12
13
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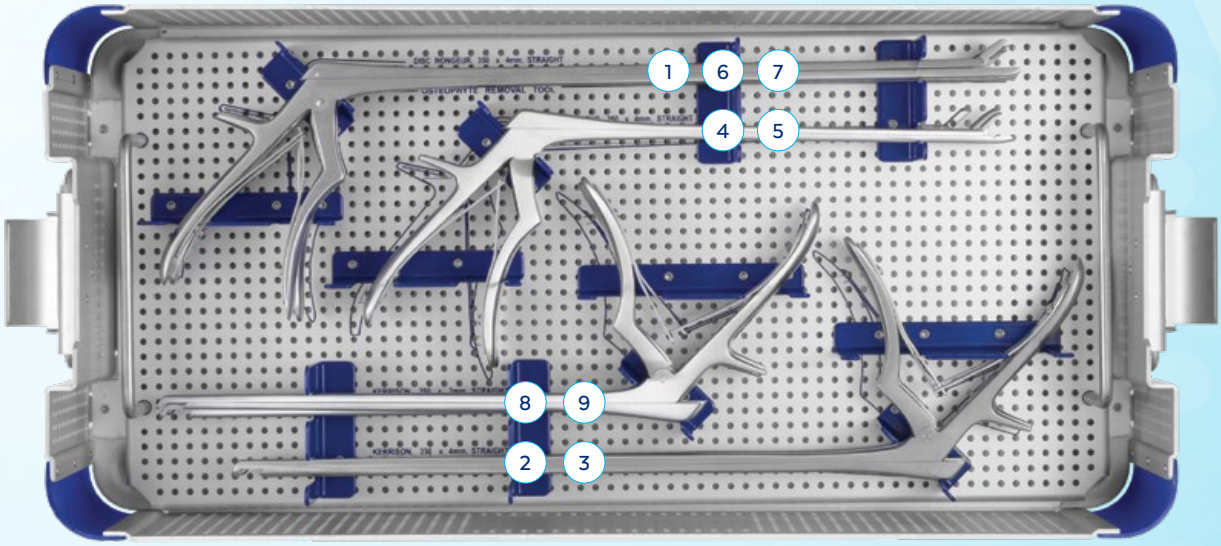
15
14
10


1
6
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9
2
3

TransContinental®
15° IMPLANT SET 975.927

Part No.	Description	QTY
375.030	TransContinental® LLIF Spacer, 18x40mm, 15°, 9mm	0
375.032	TransContinental® LLIF Spacer, 18x40mm, 15°, 11mm	0
375.034	TransContinental® LLIF Spacer, 18x40mm, 15°, 13mm	0
375.048	TransContinental® LLIF Spacer, 18x45mm, 15°, 9mm	2
375.050	TransContinental® LLIF Spacer, 18x45mm, 15°, 11mm	2
375.052	TransContinental® LLIF Spacer, 18x45mm, 15°, 13mm	2
375.065	TransContinental® LLIF Spacer, 18x50mm, 15°, 9mm	2
375.066	TransContinental® LLIF Spacer, 18x50mm, 15°, 11mm	2
375.080	TransContinental® LLIF Spacer, 18x50mm, 15°, 13mm	2
375.088	TransContinental® LLIF Spacer, 18x55mm, 15°, 9mm	2
375.098	TransContinental® LLIF Spacer, 18x55mm, 15°, 11mm	2
375.099	TransContinental® LLIF Spacer, 18x55mm, 15°, 13mm	2
375.136	TransContinental® LLIF Spacer, 18x60mm, 15°, 9mm	0
375.138	TransContinental® LLIF Spacer, 18x60mm, 15°, 11mm	0
375.150	TransContinental® LLIF Spacer, 18x60mm, 15°, 13mm	0
375.158	TransContinental® LLIF Spacer, 22x40mm, 15°, 9mm	0
375.165	TransContinental® LLIF Spacer, 22x40mm, 15°, 11mm	0
375.166	TransContinental® LLIF Spacer, 22x40mm, 15°, 13mm	0
375.186	TransContinental® LLIF Spacer, 22x45mm, 15°, 9mm	2
375.188	TransContinental® LLIF Spacer, 22x45mm, 15°, 11mm	2
375.198	TransContinental® LLIF Spacer, 22x45mm, 15°, 13mm	2
375.234	TransContinental® LLIF Spacer, 22x50mm, 15°, 9mm	2
375.236	TransContinental® LLIF Spacer, 22x50mm, 15°, 11mm	2
375.238	TransContinental® LLIF Spacer, 22x50mm, 15°, 13mm	2
375.252	TransContinental® LLIF Spacer, 22x55mm, 15°, 9mm	2
375.254	TransContinental® LLIF Spacer, 22x55mm, 15°, 11mm	2
375.256	TransContinental® LLIF Spacer, 22x55mm, 15°, 13mm	2
375.280	TransContinental® LLIF Spacer, 22x60mm, 15°, 9mm	0
375.282	TransContinental® LLIF Spacer, 22x60mm, 15°, 11mm	0
375.284	TransContinental® LLIF Spacer, 22x60mm, 15°, 13mm	0
375.299	TransContinental® LLIF Spacer, 26x40mm, 15°, 11mm	0
375.330	TransContinental® LLIF Spacer, 26x40mm, 15°, 13mm	0
375.332	TransContinental® LLIF Spacer, 26x40mm, 15°, 15mm	0
375.338	TransContinental® LLIF Spacer, 26x45mm, 15°, 11mm	2
375.350	TransContinental® LLIF Spacer, 26x45mm, 15°, 13mm	2

**Items in gray are additionally available*


18mm WIDE
22mm WIDE
26mm WIDE
18mm 15° INSERTION SLEEVE
22mm 15° INSERTION SLEEVE
26mm 15° INSERTION SLEEVE


18mm WIDE
22mm WIDE
26mm WIDE
AUX
45mm
50mm
55mm
65mm
TRANSCONTINENTAL 15° IMPLANTS
LENGTH
WIDTH
AUXILIARY
HOLDER INSERTER

TransContinental®
15° IMPLANT SET 975.927 (CONT'D)

Part No.	Description	QTY
375.352	TransContinental® LLIF Spacer, 26x45mm, 15°, 15mm	2
375.358	TransContinental® LLIF Spacer, 26x50mm, 15°, 11mm	2
375.380	TransContinental® LLIF Spacer, 26x50mm, 15°, 13mm	2
375.382	TransContinental® LLIF Spacer, 26x50mm, 15°, 15mm	2
375.388	TransContinental® LLIF Spacer, 26x55mm, 15°, 11mm	2
375.398	TransContinental® LLIF Spacer, 26x55mm, 15°, 13mm	2
375.399	TransContinental® LLIF Spacer, 26x55mm, 15°, 15mm	2
375.534	TransContinental® LLIF Spacer, 26x60mm, 15°, 11mm	0
375.536	TransContinental® LLIF Spacer, 26x60mm, 15°, 13mm	0
375.538	TransContinental® LLIF Spacer, 26x60mm, 15°, 15mm	0
664.500	PATRIOT® CONTINENTAL® Holder/Inserter	2
675.500	Insertion Sleeve, 26mm	1
675.599	Insertion Sleeve, 18mm, 15°	1
675.631	TransContinental® 18mm Trial, 15°, 7mm	1
675.632	TransContinental® 18mm Trial, 15°, 9mm	1
675.633	TransContinental® 18mm Trial, 15°, 11mm	1
675.634	TransContinental® 18mm Trial, 15°, 13mm	1
675.641	TransContinental® 22mm Trial, 15°, 7mm	1
675.642	TransContinental® 22mm Trial, 15°, 9mm	1
675.643	TransContinental® 22mm Trial, 15°, 11mm	1
675.644	TransContinental® 22mm Trial, 15°, 13mm	1
675.652	TransContinental® 26mm Trial, 15°, 9mm	1
675.653	TransContinental® 26mm Trial, 15°, 11mm	1
675.654	TransContinental® 26mm Trial, 15°, 13mm	1
675.655	TransContinental® 26mm Trial, 15°, 15mm	1
675.699	Insertion Sleeve 22mm, 15°	1
975.027	Transcontinental® 15° Graphic Case	

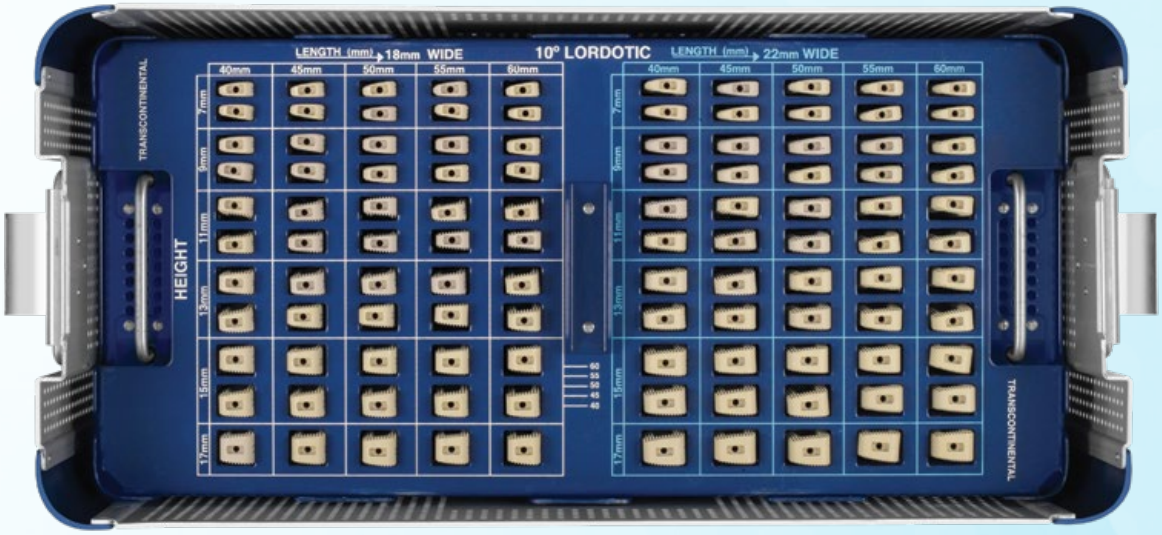
**Items in gray are additionally available*


18mm WIDE
22mm WIDE
26mm WIDE
18mm 15° INSERTION SLEEVE
22mm 15° INSERTION SLEEVE
26mm 15° INSERTION SLEEVE


18mm WIDE
22mm WIDE
26mm WIDE
AUX
TRANSCONTINENTAL 15° IMPLANTS
LENGTH
WIDTH
AUXILIARY
HOLDER INSERTER

TransContinental®
10° LORDOTIC IMPLANT SET 975.924

Part No.	Description	QTY
375.067	TransContinental® Spacer, 18mm Wide, Small, 10°, 7mm	2
375.069	TransContinental® Spacer, 18mm Wide, Small, 10°, 9mm	2
375.071	TransContinental® Spacer, 18mm Wide, Small, 10°, 11mm	2
375.073	TransContinental® Spacer, 18mm Wide, Small, 10°, 13mm	2
375.075	TransContinental® Spacer, 18mm Wide, Small, 10°, 15mm	2
375.077	TransContinental® Spacer, 18mm Wide, Small, 10°, 17mm	1
375.167	TransContinental® Spacer, 22mm Wide, Small, 10°, 7mm	2
375.169	TransContinental® Spacer, 22mm Wide, Small, 10°, 9mm	2
375.171	TransContinental® Spacer, 22mm Wide, Small, 10°, 11mm	2
375.173	TransContinental® Spacer, 22mm Wide, Small, 10°, 13mm	2
375.175	TransContinental® Spacer, 22mm Wide, Small, 10°, 15mm	2
375.177	TransContinental® Spacer, 22mm Wide, Small, 10°, 17mm	1
375.267	TransContinental® Spacer, 18mm Wide, Medium, 10°, 7mm	2
375.269	TransContinental® Spacer, 18mm Wide, Medium, 10°, 9mm	2
375.271	TransContinental® Spacer, 18mm Wide, Medium, 10°, 11mm	2
375.273	TransContinental® Spacer, 18mm Wide, Medium, 10°, 13mm	2
375.275	TransContinental® Spacer, 18mm Wide, Medium, 10°, 15mm	2
375.277	TransContinental® Spacer, 18mm Wide, Medium, 10°, 17mm	1
375.367	TransContinental® Spacer, 22mm Wide, Medium, 10, 7mm	2
375.369	TransContinental® Spacer, 22mm Wide, Medium, 10°, 9mm	2
375.371	TransContinental® Spacer, 22mm Wide, Medium, 10°, 11mm	2
375.373	TransContinental® Spacer, 22mm Wide, Medium, 10°, 13mm	2
375.375	TransContinental® Spacer, 22mm Wide, Medium, 10°, 15mm	2
375.377	TransContinental® Spacer, 22mm Wide, Medium, 10°, 17mm	1
375.467	TransContinental® Spacer, 18mm Wide, Large, 10°, 7mm	2
375.469	TransContinental® Spacer, 18mm Wide, Large, 10°, 9mm	2
375.471	TransContinental® Spacer, 18mm Wide, Large, 10°, 11mm	2
375.473	TransContinental® Spacer, 18mm Wide, Large, 10°, 13mm	2
375.475	TransContinental® Spacer, 18mm Wide, Large, 10°, 15mm	2
375.477	TransContinental® Spacer, 18mm Wide, Large, 10°, 17mm	1
375.567	TransContinental® Spacer, 22mm Wide, Large, 10°, 7mm	2
375.569	TransContinental® Spacer, 22mm Wide, Large, 10°, 9mm	2
375.571	TransContinental® Spacer, 22mm Wide, Large, 10°, 11mm	2
375.573	TransContinental® Spacer, 22mm Wide, Large, 10°, 13mm	2
375.575	TransContinental® Spacer, 22mm Wide, Large, 10°, 15mm	2
375.577	TransContinental® Spacer, 22mm Wide, Large, 10°, 17mm	1
375.667	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 7mm	2
375.669	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 9mm	2
375.671	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 11mm	2
375.673	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 13mm	2
375.675	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 15mm	2
375.677	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 17mm	1

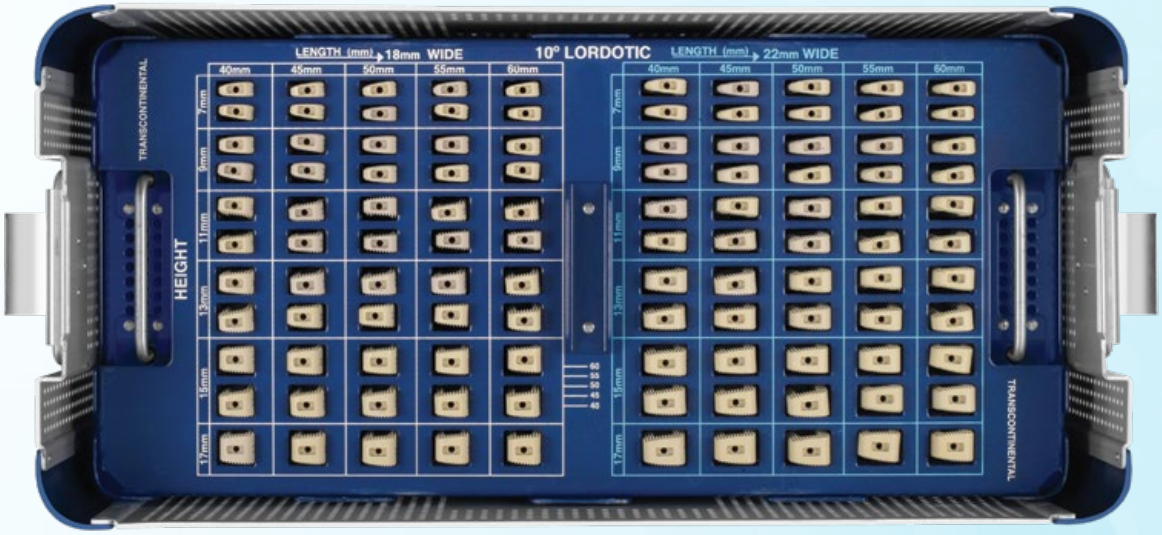

LENGTH (mm)
18mm WIDE
10° LORDOTIC
LENGTH (mm)
22mm WIDE
40mm
45mm
50mm
55mm
60mm
HEIGHT
7mm
9mm
11mm
13mm
15mm
17mm
TRANSCONTINENTAL


TRANSCONTINENTAL

TransContinental®
10° LORDOTIC IMPLANT SET 975.924 (CONT'D)

Part No.	Description	QTY
375.767	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 7mm	2
375.769	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 9mm	2
375.771	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 11mm	2
375.773	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 13mm	2
375.775	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 15mm	2
375.777	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 17mm	1
375.867	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 7mm	2
375.869	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 9mm	2
375.871	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 11mm	2
375.873	TransContinental® Spacer, 18mm Wide, X-Small, 10° 13mm	2
375.875	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 15mm	2
375.877	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 17mm	1
375.967	TransContinenta® Spacer, 22mm Wide, X-Small, 10°, 7mm	2
375.969	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 9mm	2
375.971	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 11mm	2
375.973	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 13mm	2
375.975	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 15mm	2
375.977	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 17mm	1

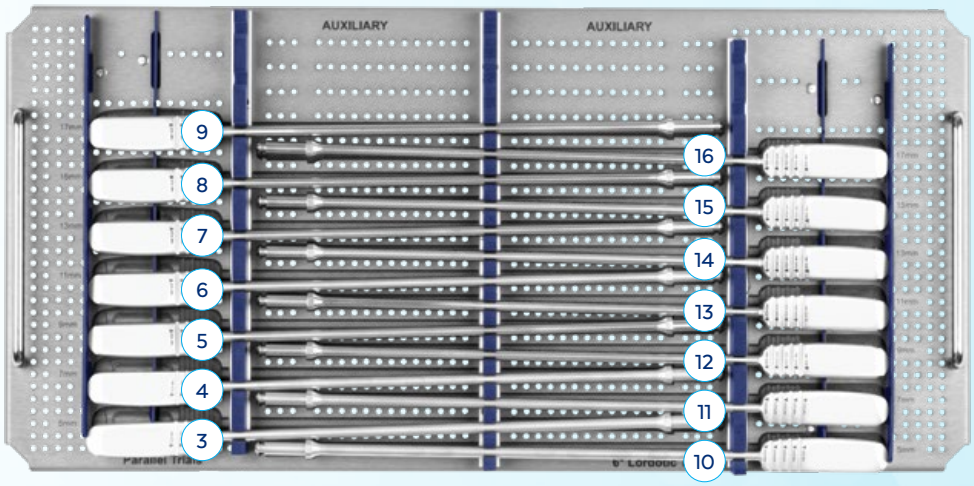
Part No.	Description	QTY
675.065	TransContinental® 18mm Trial, 10° Lordotic, 5mm	1
675.067	TransContinental® 18mm Trial, 10° Lordotic, 7mm	1
675.069	TransContinental® 18mm Trial, 10° Lordotic, 9mm	1
675.071	TransContinental® 18mm Trial, 10° Lordotic, 11mm	1
675.073	TransContinental® 18mm Trial, 10° Lordotic, 13mm	1
675.075	TransContinental® 18mm Trial, 10° Lordotic, 15mm	1
675.077	TransContinental® 18mm Trial, 10° Lordotic, 17mm	1
675.365	TransContinental® 22mm Trial, 10° Lordotic, 5mm	1
675.367	TransContinental® 22mm Trial, 10° Lordotic, 7mm	1
675.369	TransContinental® 22mm Trial, 10° Lordotic, 9mm	1
675.371	TransContinental® 22mm Trial, 10° Lordotic, 11mm	1
675.373	TransContinental® 22mm Trial, 10° Lordotic, 13mm	1
675.375	TransContinental® 22mm Trial, 10° Lordotic, 15mm	1
675.377	TransContinental® 22mm Trial, 10° Lordotic, 17mm	1
675.501	Insertion Sleeve	1
675.522	Insertion Sleeve, 22mm	1
975.024	TransContinental® 10° Lordotic Implant Graphic Case	


LENGTH (mm)
18mm WIDE
10° LORDOTIC
LENGTH (mm)
22mm WIDE
40mm
45mm
50mm
55mm
60mm
HEIGHT
7mm
9mm
11mm
13mm
15mm
17mm
TRANSCONTINENTAL


TRANSCONTINENTAL

TransContinental®
INSERTION INSTRUMENT SET 975.915

	Instrument		QTY
1	664.500	PATRIOT® Continental® Holder/Inserter	2
2	675.005	T-Handle with Impaction Cap	2
3	675.006	TransContinental® Trial, Parallel, 5mm	1
4	675.007	TransContinental® Trial, Parallel, 7mm	1
5	675.009	TransContinental® Trial, Parallel, 9mm	1
6	675.011	TransContinental® Trial, Parallel, 11mm	1
7	675.013	TransContinental® Trial, Parallel, 13mm	1
8	675.015	TransContinental® Trial, Parallel, 15mm	1
9	675.017	TransContinental® Trial, Parallel, 17mm	1
10	675.106	TransContinental® Trial, Lordotic, 5mm	1
11	675.107	TransContinental® Trial, Lordotic, 7mm	1
12	675.109	TransContinental® Trial, Lordotic, 9mm	1
13	675.111	TransContinental® Trial, Lordotic, 11mm	1
14	675.113	TransContinental® Trial, Lordotic, 13mm	1
15	675.115	TransContinental® Trial, Lordotic, 15mm	1
16	675.117	TransContinental® Trial, Lordotic, 17mm	1
17	675.501	Insertion Sleeve	2
18	675.502	Tamp	1
19	679.010	L-Handle	1
	975.007	TransContinental® Graphic Case – Insertion	


AUXILIARY
AUXILIARY
9
8
7
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16
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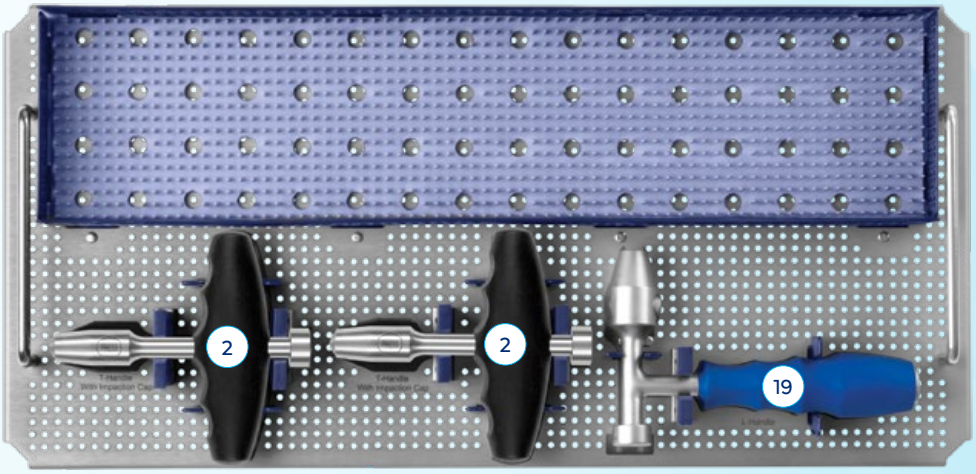
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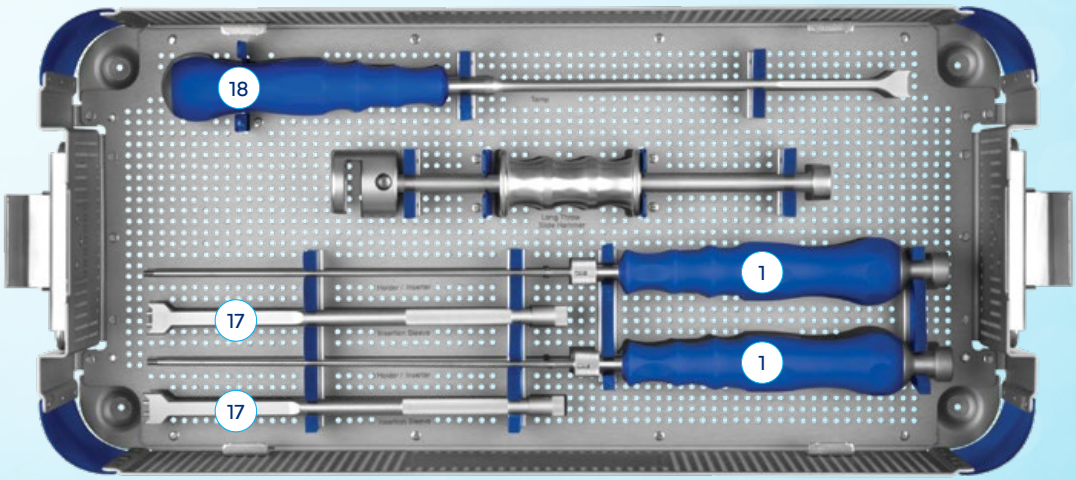
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IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

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 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 intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). HEDRON IA™ 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 three titanium alloy screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). When used without screws or anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:
- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

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

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

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

The components of this system are manufactured from titanium 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

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

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

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

1. 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.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. 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.
6. 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.
7. Any patient not willing to cooperate with postoperative instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. 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.
12. Any case not needing a fusion.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. 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 are 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 accidently contaminated.

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants 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. 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).

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

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 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

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.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
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⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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