HEDRON P™

3D Printed Posterior Lumbar Interbody Spacer

SURGICAL TECHNIQUE GUIDE

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

Life moves us

SURGICAL TECHNIQUE GUIDE

HEDRON P™

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3D Printed Posterior Lumbar Interbody Spacer

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

The implants are available in a wide range of footprints and two lordotic profiles to fit individual patient anatomies and aid in sagittal balance.

The Face of Fusion

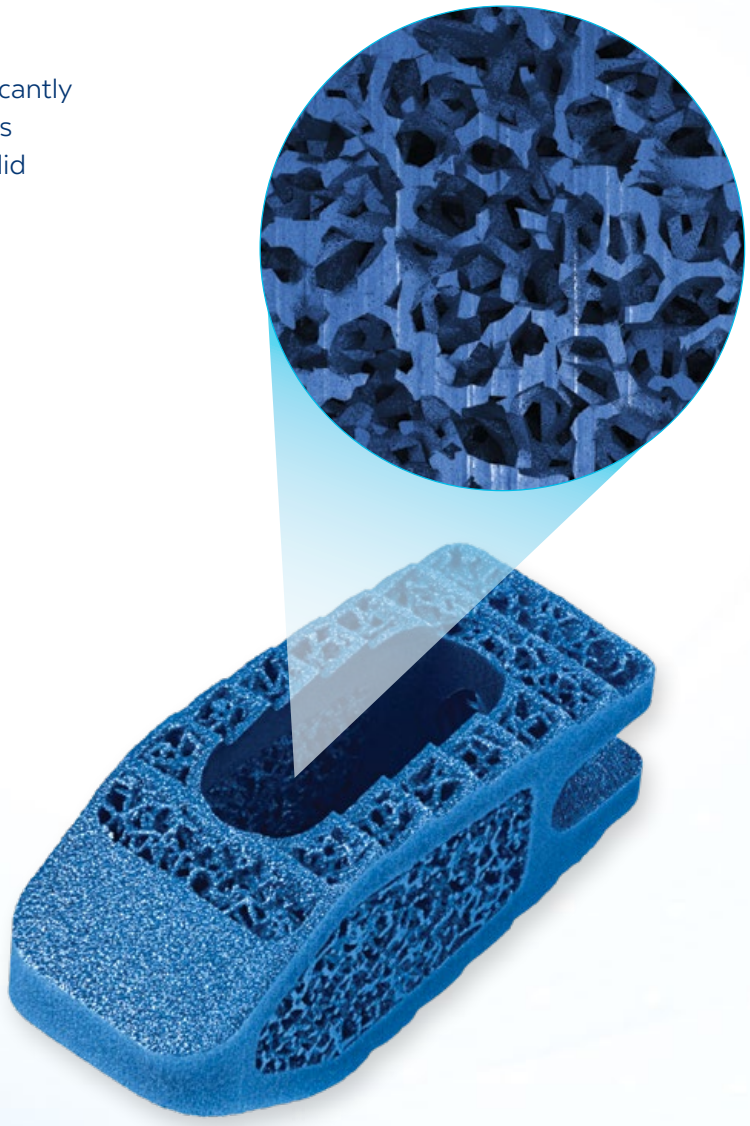
An ovine interbody study demonstrated significantly more bone ingrowth within HEDRON™ implants at 6 weeks post-op compared to PEEK and solid titanium implants.*

Threaded Connection

Robust threaded design provides a secure connection during impaction.

Radiographic Imaging

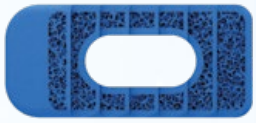
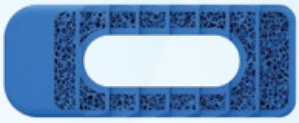
Clear imaging facilitates ideal assessment of placement and fusion.



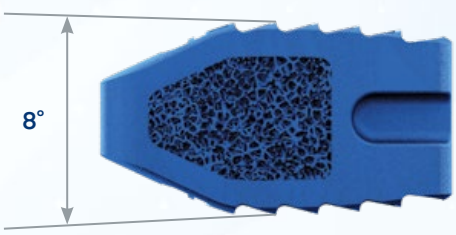
Data on file

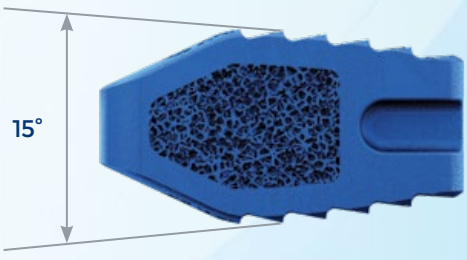
Footprint Options

- **Widths:** 8mm, 10mm and 12mm
- **Lengths:** 22mm, 26mm and 30mm
- **Heights:** 7-17mm, 1mm increments

	22mm	26mm	30mm
8mm		–	–
10mm			
12mm	–		

Lordotic Profiles





INSTRUMENT OVERVIEW

SIZERS/SHAVERS

Height	Part Number
7mm	626.507
8mm	626.508
9mm	626.509
10mm	626.510
11mm	626.511
12mm	626.512
13mm	626.513
14mm	626.514
15mm	626.515
16mm	626.516
17mm	626.517

PADDLE DISTRACTORS

Height	Part Number
7mm	626.407
8mm	626.408
9mm	626.409
10mm	626.410
11mm	626.411
12mm	626.412
13mm	626.413
14mm	626.414
15mm	626.415
16mm	626.416
17mm	626.417

TRIALS

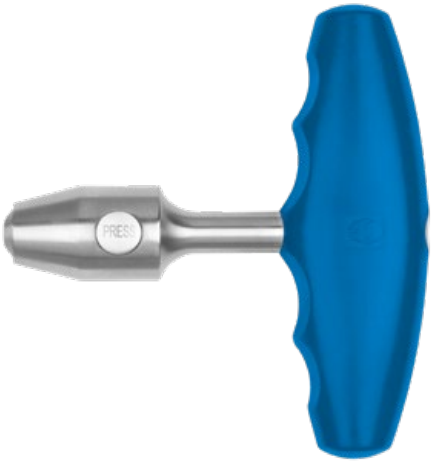
Trial Shaft 6145.4500

Trial L-Handle 6210.4101

Trial Head

Size	Part Number
10x22mm, 6mm, 0°	6210.0046
10x22mm, 7mm, 4°	6210.0147
10x22mm, 8mm, 8°	6210.0148
10x22mm, 9mm, 8°	6210.0149
10x22mm, 10mm, 8°	6210.0150
10x22mm, 11mm, 8°	6210.0151
10x22mm, 12mm, 8°	6210.0152
10x22mm, 13mm, 8°	6210.0153
10x22mm, 14mm, 8°	6210.0154
10x22mm, 15mm, 8°	6210.0155
10x22mm, 10mm, 15°	6210.0250
10x22mm, 11mm, 15°	6210.0251
10x22mm, 12mm, 15°	6210.0252
10x22mm, 13mm, 15°	6210.0253
10x22mm, 14mm, 15°	6210.0254
10x22mm, 15mm, 15°	6210.0255

HANDLES



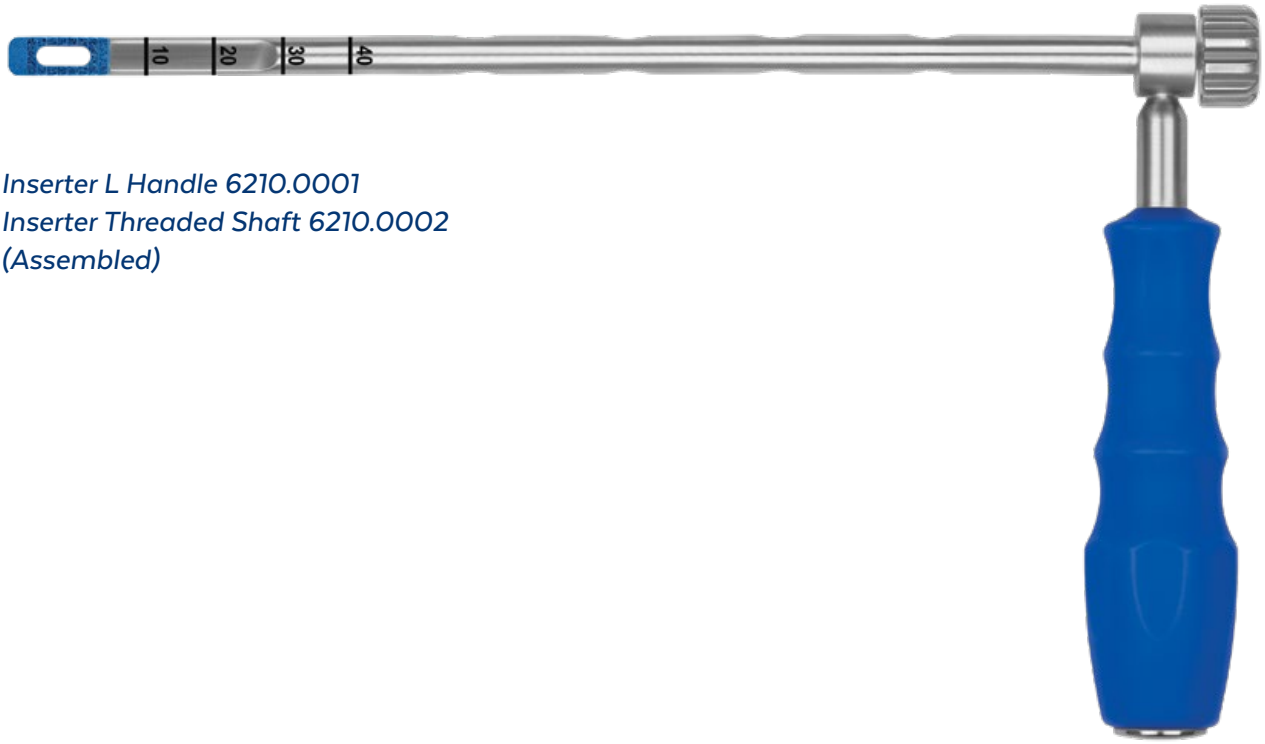
T-Handle 601.800

IMPLANT HOLDER INSTRUMENTS

Inserter L Handle 6210.0001

Inserter Threaded Shaft 6210.0002

IMPLANT HOLDER INSTRUMENTS (CONT'D)



Inserter L Handle 6210.0001
Inserter Threaded Shaft 6210.0002
(Assembled)

OTHER INSTRUMENTS

6145.8010 Slide Hammer

6145.8800 Endplate Spreader

SURGICAL TECHNIQUE

HEDRON P™

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.

HEDRON P™ 3D Printed Spacers are to be used with supplemental fixation. Please refer to the technique guide for the corresponding supplemental fixation system.

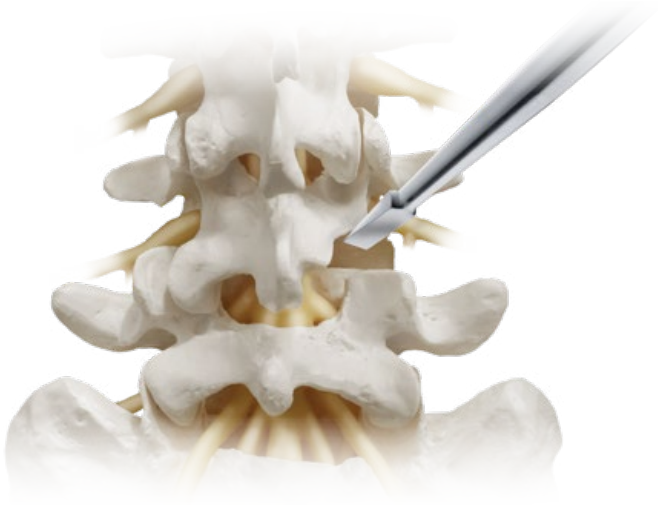
STEP 1 APPROACH

A posterior or transforaminal approach may be used. A transforaminal approach is shown.

The patient is placed under anesthesia and positioned prone. Lateral C-arm fluoroscopy or other radiographic methods can be used throughout the surgery to ensure correct implant placement. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s).

STEP 2 CREATING UNILATERAL ACCESS

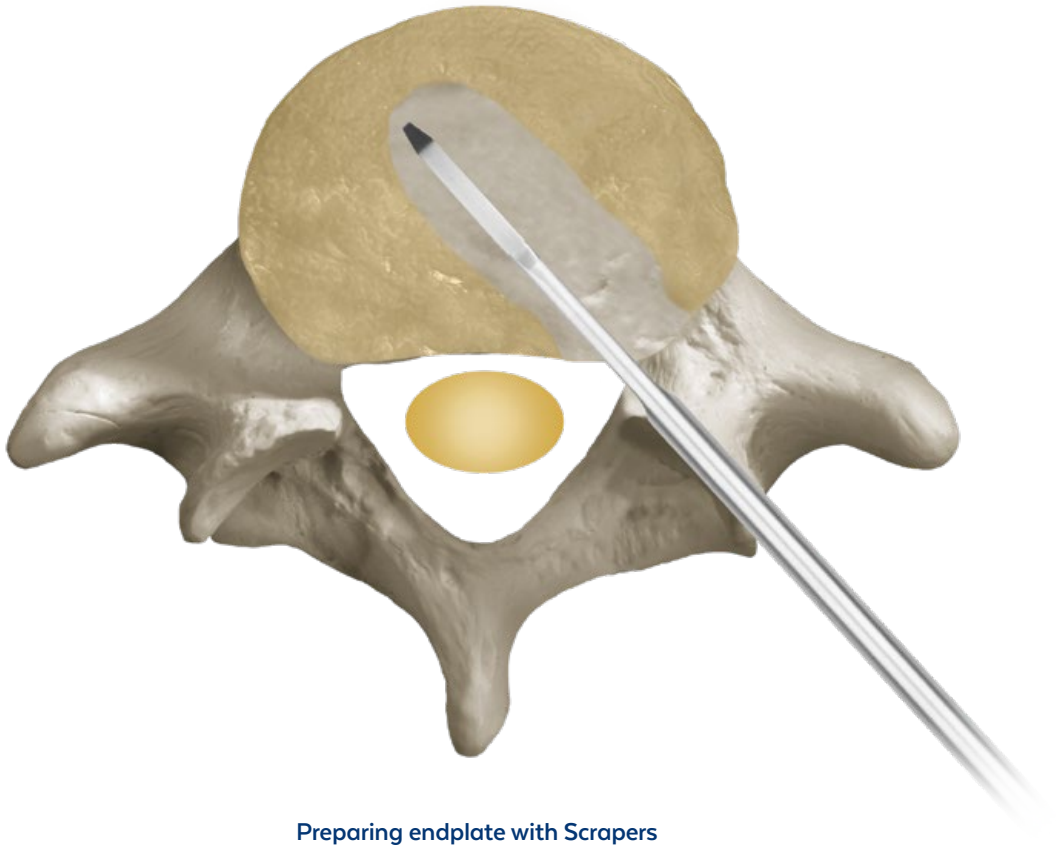
Use an Osteotome and Laminectomy Punch to remove the inferior facet of the cranial vertebrae and the superior facet of the caudal vertebra at the appropriate level(s) to create a working unilateral access window to the disc.



Using an Osteotome to create unilateral access

STEP 3 ENDPLATE PREPARATION

Remove disc material with Rongeurs or other suitable instruments. Insert the smallest **Scraper** into the disc space for further disc removal and endplate preparation, moving to larger Scrapers as needed. Careful disc removal and endplate preparation maximizes the potential for successful fusion. The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant. For a collapsed disc space, a **Paddle Distractor** may be inserted to open the disc space.



Preparing endplate with Scrapers

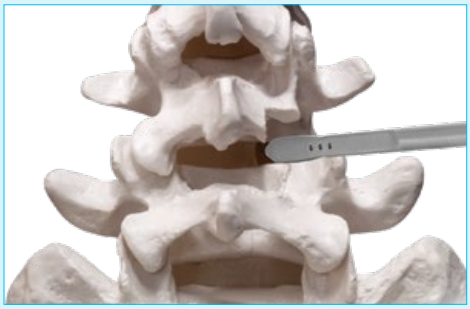
STEP 4 DISTRACTION

Distraction of the disc space aids in visualization as well as decompression and restoration of disc height. Assemble the desired Paddle Distractor onto the **T-Handle** and insert into the disc space. To achieve adequate distraction, rotate the distractor until the desired height is reached. Alternatively, **Shavers** may be used for distraction. Avoid damaging the endplate.

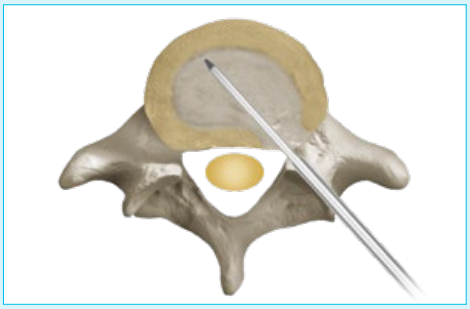
DISTRACTION (CONT'D)

DISTRACTION USING PADDLE DISTRACTORS, TRIALS OR SCRAPERS

To use the Paddle Distractors for distraction, begin with the smallest distractor and insert, using larger sizes until the desired distraction is achieved.

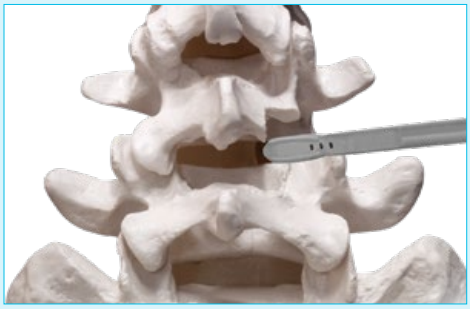


Distraction of disc space using Paddle Distractor

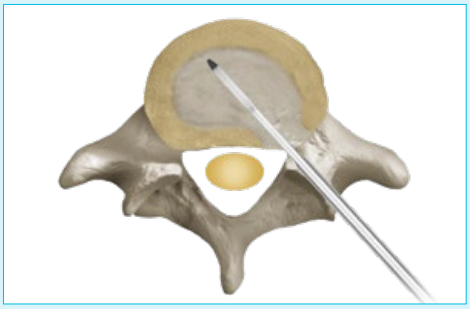


Paddle Distractor in disc space

To use the Scraper for distraction, begin with the smallest Scraper and insert, using larger sizes until the desired distraction is achieved.

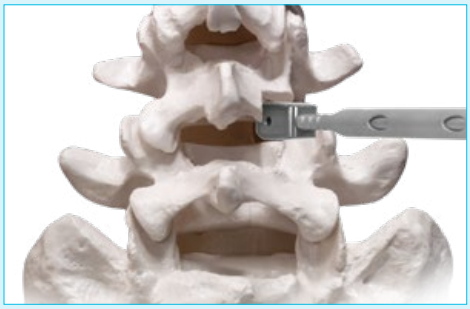


Distraction of disc space using Scraper

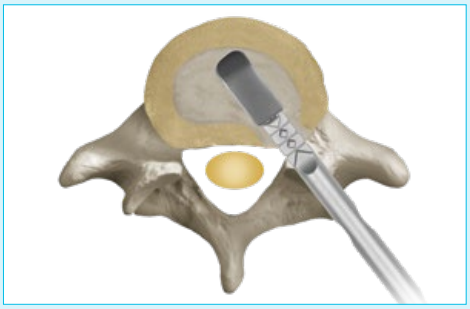


Scraper in disc space

To use the **Trial** for distraction, begin with the smallest Trial and insert, using larger sizes until the desired distraction is achieved.



Distraction of disc space using Trial

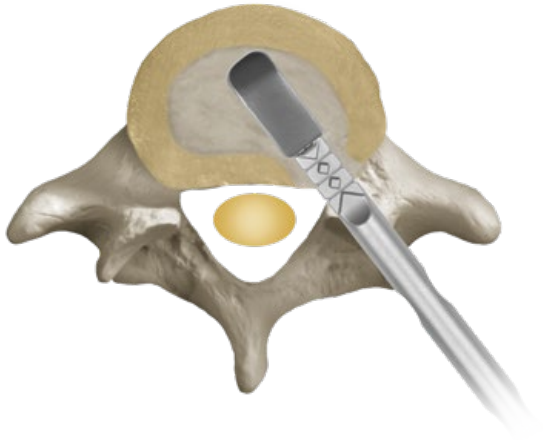


Trial in disc space

Avoid damaging the endplate while using Scrapers or Paddle Distractors for distraction.

STEP 5 IMPLANT SIZING

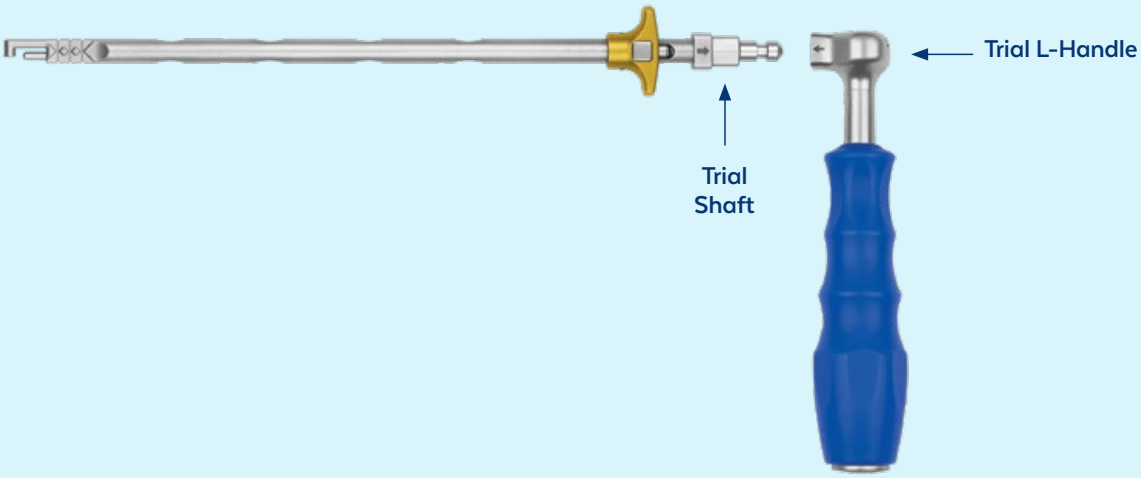
Assemble the desired Trial onto the **Trial Shaft**. Insert the smallest Trial into disc space, gently impacting if needed. Determine which Trial and corresponding implant best fits the prepared disc space. A secure fit is desirable to maintain disc height and to stabilize the segment. Confirm placement using fluoroscopy and tactile feel.



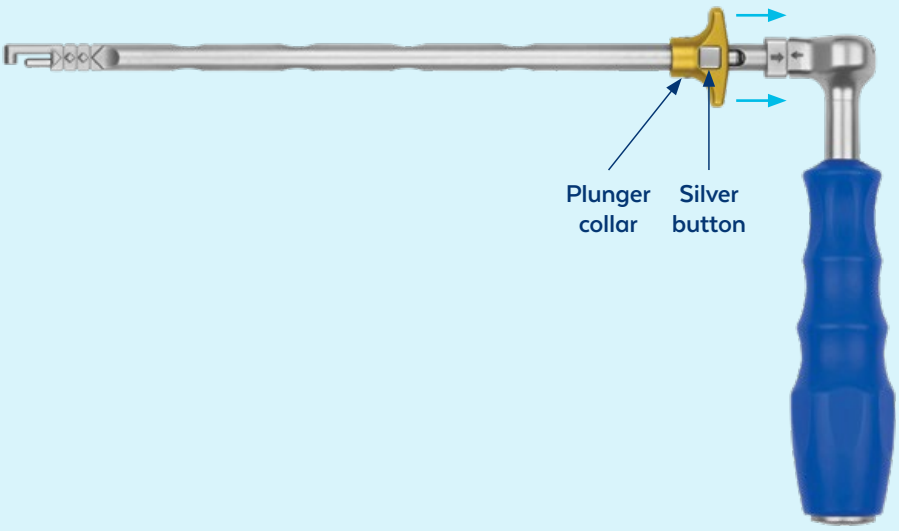
Sizing disc space using Trial

ASSEMBLING THE TRIAL SHAFT

Assemble the **Trial L-Handle** to the Trial Shaft.



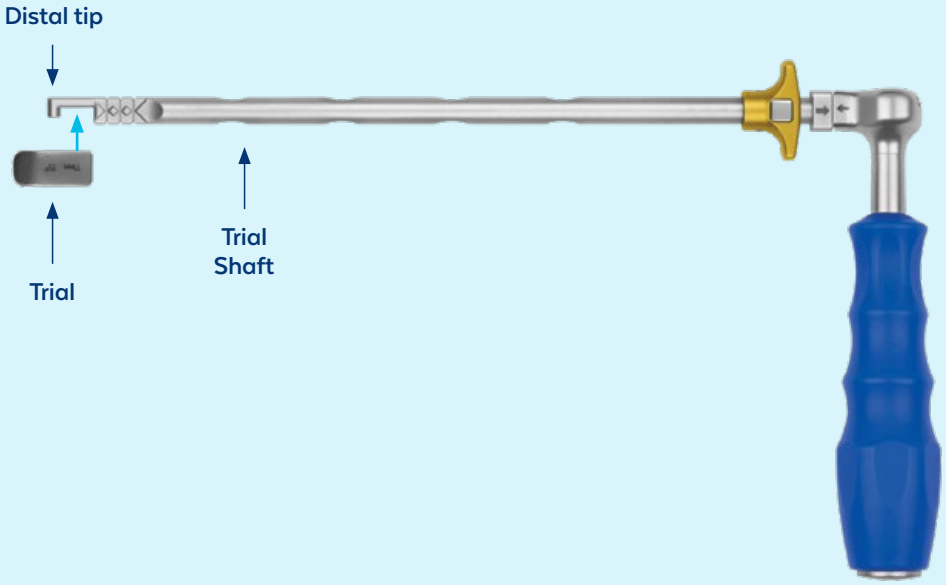
Depress the silver button and pull back on the plunger collar on the Trial Shaft.



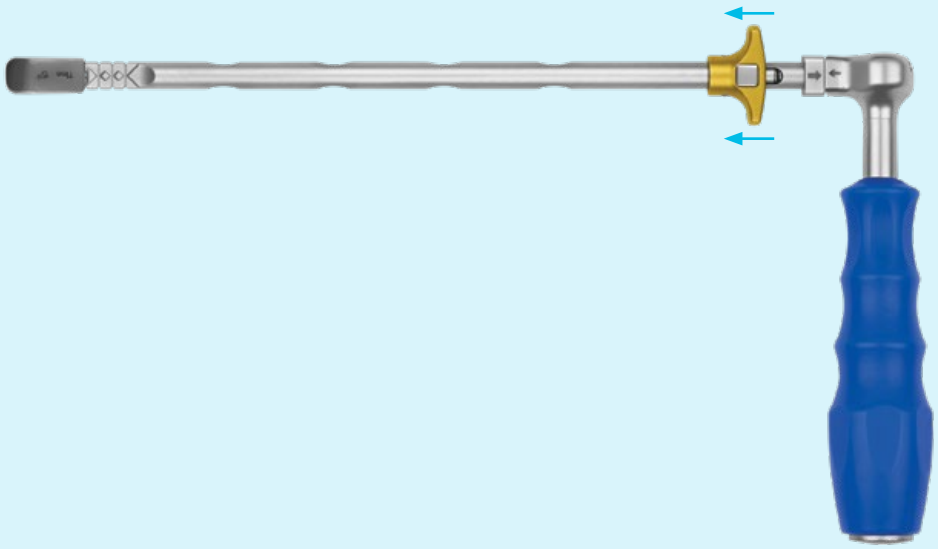
IMPLANT SIZING (CONT'D)

ASSEMBLING THE TRIAL SHAFT (CONT'D)

Place the distal tip of the Trial Shaft into the desired Trial from a side approach.



Release the plunger collar. The retaining plunger inserts into the Trial to complete the Trial assembly.

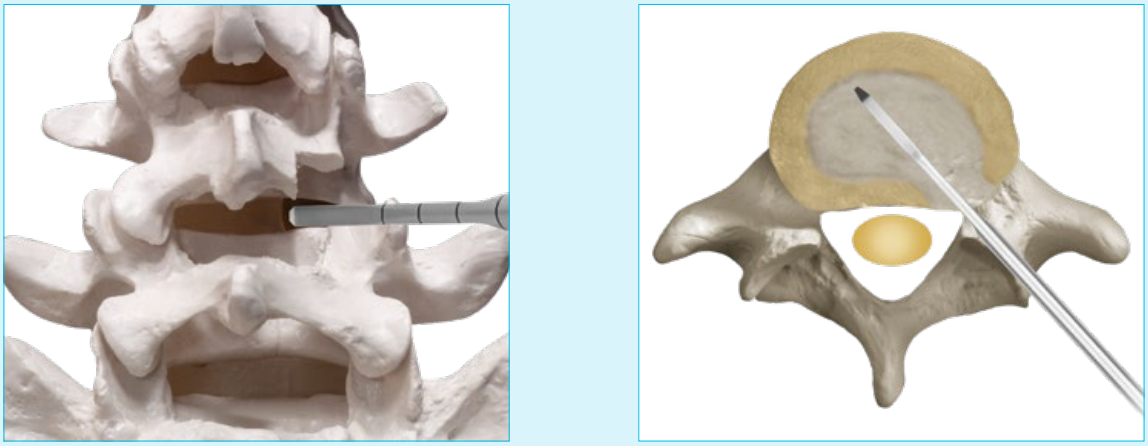


Confirm the Trial is secured to the Trial Shaft.

SIZING USING PADDLE DISTRACTORS, TRIALS OR SCRAPERS

Paddle Distractors and Scrapers may be used to size the disc space. Insert horizontally and rotate 90° to determine the appropriate height. Avoid damaging the endplates while using Scrapers or Paddle Distractors for sizing.

Sizing disc space using Paddle Distractor



Sizing disc space using Scraper

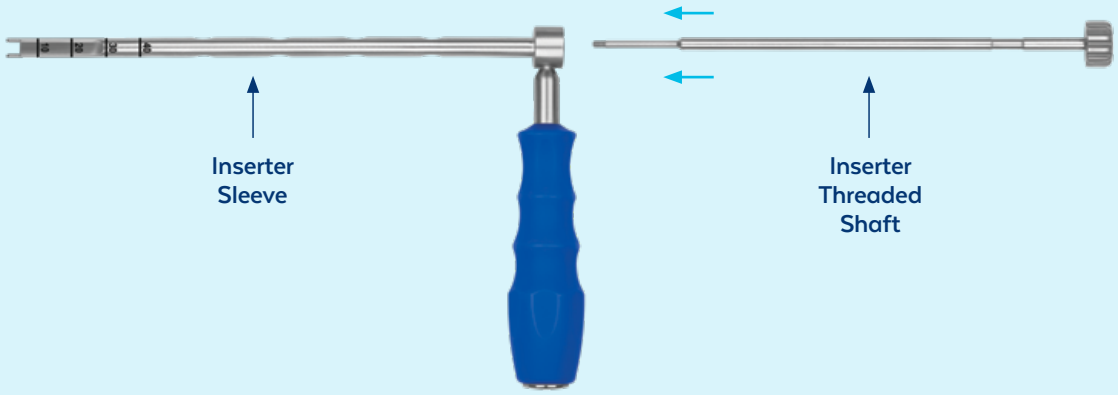
STEP 6 IMPLANT INSERTION

Select an appropriately sized spacer and fill the chamber with autograft or allograft (cortical or corticocancellous) bone. Attach the spacer to the **Implant Holder** and insert into the intervertebral space. Gently impact the holder until the spacer is in the desired position.

The implant should be recessed into the disc space. Supplemental autograft or allograft bone should be placed around the spacer if possible. Compression may be necessary to help restore sagittal alignment and resist posterior migration.

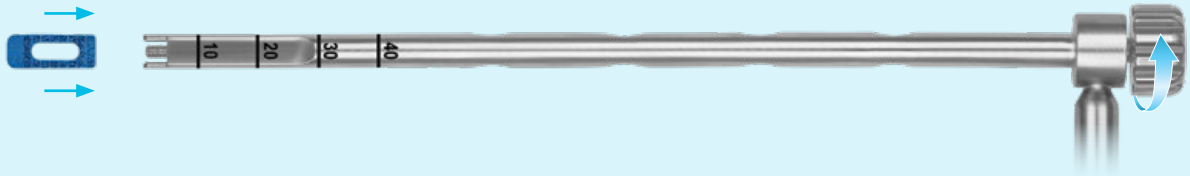
ASSEMBLING THE IMPLANT INSERTER

Place the **Inserter Threaded Shaft** into the **Inserter Sleeve**.



Align the posterior implant grooves with the Inserter Sleeve forks.

With the implant in place, thread the Inserter Threaded Shaft to the implant until finger tight.

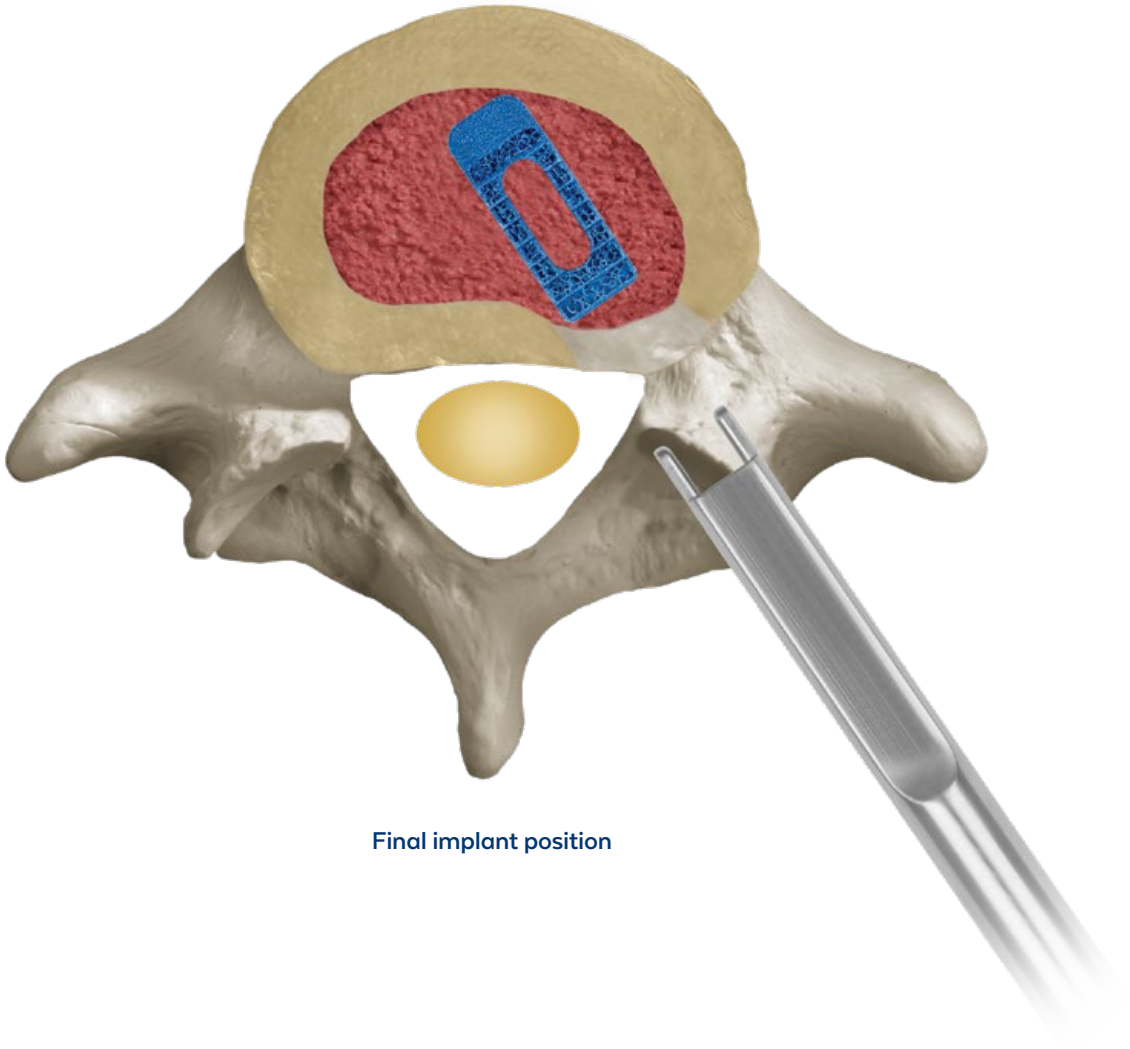


Disassemble by reversing assembly steps.

Using fluoroscopy, verify implant position before disengaging the implant.

To disengage the implant, rotate the Inserter Threaded Shaft counterclockwise and gently pull the assembly away from the implant. If necessary, the **Spanner Wrench** may be used to aid in loosening the Inserter Threaded Shaft.

FINAL POSITION



Final implant position

SUPPLEMENTAL FIXATION

HEDRON P™ is intended for use with supplemental fixation, such as CREO®, REVERE® or REVOLVE®. Refer to the corresponding supplemental fixation system's surgical technique guide for specific instructions.

OPTIONAL: REMOVAL

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

HEDRON P™ 8x22 and 10x22
IMPLANT SET 9210.9010

HEDRON P™ Spacer, 8x22mm, 4°

Part No.	Length	QTY
1210.0107S	7mm	2

HEDRON P™ Spacer, 8x22mm, 8°

Part No.	Length	QTY
1210.0108S	8mm	2
1210.0109S	9mm	2
1210.0110S	10mm	2
1210.0111S	11mm	2
1210.0112S	12mm	2
1210.0113S	13mm	2
1210.0114S	14mm	2
1210.0115S	15mm	2
1210.0116S	16mm	0
1210.0117S	17mm	0

HEDRON P™ Spacer, 8x22mm, 15°

Part No.	Length	QTY
1210.0210S	10mm	2
1210.0211S	11mm	2
1210.0212S	12mm	2
1210.0213S	13mm	2
1210.0214S	14mm	2
1210.0215S	15mm	2
1210.0216S	16mm	0
1210.0217S	17mm	0

HEDRON P™ Spacer, 10x22mm, 4°

Part No.	Length	QTY
1210.0147S	7mm	2

HEDRON P™ Spacer, 10x22mm, 8°

Part No.	Length	QTY
1210.0148S	8mm	2
1210.0149S	9mm	2
1210.0150S	10mm	2
1210.0151S	11mm	2
1210.0152S	12mm	2
1210.0153S	13mm	2
1210.0154S	14mm	2
1210.0155S	15mm	2
1210.0156S	16mm	0
1210.0157S	17mm	0

HEDRON P™ Spacer, 10x22mm, 15°

Part No.	Length	QTY
1210.0250S	10mm	2
1210.0251S	11mm	2
1210.0252S	12mm	2
1210.0253S	13mm	2
1210.0254S	14mm	2
1210.0255S	15mm	2
1210.0256S	16mm	0
1210.0257S	17mm	0

9210.0010	HEDRON P™ 8x22 and 10x22 Implant Soft Case

**Items in gray are additionally available*

HEDRON P™ 10x26 and 10x30
IMPLANT SET 9210.9020

HEDRON P™ Spacer, 10x26mm, 4°

Part No.	Length	QTY
1210.1147S	7mm	2

HEDRON P™ Spacer, 10x26mm, 8°

Part No.	Length	QTY
1210.1148S	8mm	2
1210.1149S	9mm	2
1210.1150S	10mm	2
1210.1151S	11mm	2
1210.1152S	12mm	2
1210.1153S	13mm	2
1210.1154S	14mm	2
1210.1155S	15mm	2
1210.1156S	16mm	0
1210.1157S	17mm	0

HEDRON P™ Spacer, 10x26mm, 15°

Part No.	Length	QTY
1210.1250S	10mm	2
1210.1251S	11mm	2
1210.1252S	12mm	2
1210.1253S	13mm	2
1210.1254S	14mm	2
1210.1255S	15mm	2
1210.1256S	16mm	0
1210.1257S	17mm	0

HEDRON P™ Spacer, 10x30mm, 0°

Part No.	Length	QTY
1210.2147S	7mm	2

HEDRON P™ Spacer, 10x30mm, 4°

Part No.	Length	QTY
1210.2148S	8mm	2

HEDRON P™ Spacer, 10x30mm, 8°

Part No.	Length	QTY
1210.2149S	9mm	2
1210.2150S	10mm	2
1210.2151S	11mm	2
1210.2152S	12mm	2
1210.2153S	13mm	2
1210.2154S	14mm	2
1210.2155S	15mm	2
1210.2156S	16mm	0
1210.2157S	17mm	0

HEDRON P™ Spacer, 10x30mm, 12°

Part No.	Length	QTY
1210.2250S	10mm	2
1210.2251S	11mm	2

HEDRON P™ Spacer, 10x30mm, 15°

Part No.	Length	QTY
1210.2252S	12mm	2
1210.2253S	13mm	2
1210.2254S	14mm	2
1210.2255S	15mm	2
1210.2256S	16mm	0
1210.2257S	17mm	0

9210.0020	HEDRON P™ 10x26 and 10x30 Implant Soft Case

**Items in gray are additionally available*

HEDRON P™ 12mm
IMPLANT SET 9210.9030

HEDRON P™ Spacer, 12x26mm, 4°

Part No.	Length	QTY
1210.1187S	7mm	2

HEDRON P™ Spacer, 12x26mm, 8°

Part No.	Length	QTY
1210.1188S	8mm	2
1210.1189S	9mm	2
1210.1190S	10mm	2
1210.1191S	11mm	2
1210.1192S	12mm	2
1210.1193S	13mm	2
1210.1194S	14mm	2
1210.1195S	15mm	2
1210.1196S	16mm	0
1210.1197S	17mm	0

HEDRON P™ Spacer, 12x26mm, 15°

Part No.	Length	QTY
1210.1290S	10mm	2
1210.1291S	11mm	2
1210.1292S	12mm	2
1210.1293S	13mm	2
1210.1294S	14mm	2
1210.1295S	15mm	2
1210.1296S	16mm	0
1210.1297S	17mm	0

HEDRON P™ Spacer, 12x30mm, 0°

Part No.	Length	QTY
1210.2187S	7mm	2

HEDRON P™ Spacer, 12x30mm, 4°

Part No.	Length	QTY
1210.2188S	8mm	2

HEDRON P™ Spacer, 12x30mm, 8°

Part No.	Length	QTY
1210.2189S	9mm	2
1210.2190S	10mm	2
1210.2191S	11mm	2
1210.2192S	12mm	2
1210.2193S	13mm	2
1210.2194S	14mm	2
1210.2195S	15mm	2
1210.2196S	16mm	0
1210.2197S	17mm	0

HEDRON P™ Spacer, 12x30mm, 12°

Part No.	Length	QTY
1210.2290S	10mm	2
1210.2291S	11mm	2

HEDRON P™ Spacer, 12x30mm, 15°

Part No.	Length	QTY
1210.2292S	12mm	2
1210.2293S	13mm	2
1210.2294S	14mm	2
1210.2295S	15mm	2
1210.2296S	16mm	0
1210.2297S	17mm	0

9210.0030	HEDRON P™ 12mm Implant Soft Case

**Items in gray are additionally available*

HEDRON P™
INSTRUMENT SET 9210.9001

	Instrument		QTY
1	601.800	T-Handle	2
2	626.406	Paddle Distractor, 6mm	1
3	626.407	Paddle Distractor, 7mm	1
4	626.408	Paddle Distractor, 8mm	1
5	626.409	Paddle Distractor, 9mm	1
6	626.410	Paddle Distractor, 10mm	1
7	626.411	Paddle Distractor, 11mm	1
8	626.412	Paddle Distractor, 12mm	1
9	626.413	Paddle Distractor, 13mm	1
10	626.414	Paddle Distractor, 14mm	1
11	626.415	Paddle Distractor, 15mm	1
12	626.506	Sizer/Shaver, 6mm	1
13	626.507	Sizer/Shaver, 7mm	1
14	626.508	Sizer/Shaver, 8mm	1
15	626.509	Sizer/Shaver, 9mm	1
16	626.510	Sizer/Shaver, 10mm	1
17	626.511	Sizer/Shaver, 11mm	1
18	626.512	Sizer/Shaver, 12mm	1
19	626.513	Sizer/Shaver, 13mm	1
20	626.514	Sizer/Shaver, 14mm	1
21	626.515	Sizer/Shaver, 15mm	1
22	6210.1306	Trial Head, 10x22mm, 6mm, 0°	1
23	6210.1307	Trial Head, 10x22mm, 7mm, 4°	1
24	6210.1308	Trial Head, 10x22mm, 8mm, 8°	1
25	6210.1309	Trial Head, 10x22mm, 9mm, 8°	1
26	6210.1310	Trial Head, 10x22mm, 10mm, 8°	1
27	6210.1311	Trial Head, 10x22mm, 11mm, 8°	1
28	6210.1312	Trial Head, 10x22mm, 12mm, 8°	1
29	6210.1313	Trial Head, 10x22mm, 13mm, 8°	1
30	6210.1314	Trial Head, 10x22mm, 14mm, 8°	1
31	6210.1315	Trial Head, 10x22mm, 15mm, 8°	1

	Instrument		QTY
32	6210.2310	Trial Head, 10x22mm, 10mm, 15°	1
33	6210.2311	Trial Head, 10x22mm, 11mm, 15°	1
34	6210.2312	Trial Head, 10x22mm, 12mm, 15°	1
35	6210.2313	Trial Head, 10x22mm, 13mm, 15°	1
36	6210.2314	Trial Head, 10x22mm, 14mm, 15°	1
37	6210.2315	Trial Head, 10x22mm, 15mm, 15°	1
38	6145.4100	Trial Shaft	2
39	6210.4101	Trial L Handle	2
40	6210.0001	Inserter L Handle	2
41	6210.0002	Inserter Threaded shaft	2
42	6145.8010	Slide Hammer	1
43	6145.8800	Endplate Spreader	1
44	6210.2007	Spanner Wrench	1
	9210.0001	HEDRON P™ Instrument Graphic Case	

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
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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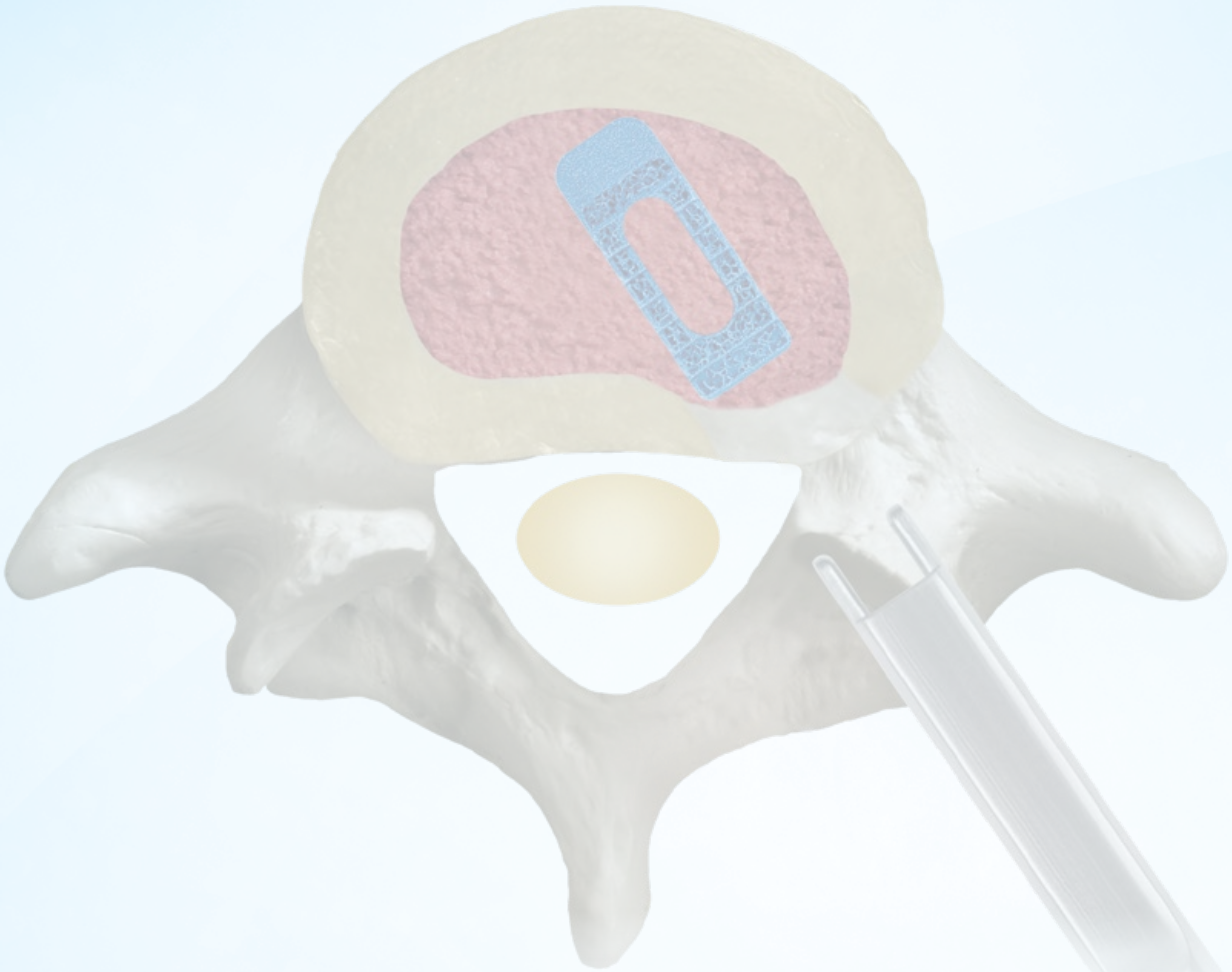

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