



# HEDRONT

3D Printed TLIF Spacer



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



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

# **SURGICAL TECHNIQUE GUIDE**

# HEDRON T<sup>TM</sup>

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# **HEDRONT**

# **3D Printed TLIF 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.

# A New Dimension 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.\*

# Optimized Placement

Integrated articulation allows steerable placement within the anterior disc space.

# Ease of Insertion

Tapered leading edge self-distracts to reduce impaction and ease initial insertion.



\*Data on file

# **Footprint Options**

• Widths: 10mm and 11mm

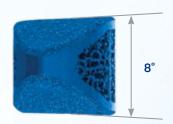
• Lengths: 28mm and 33mm

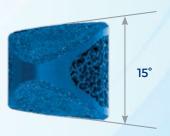
• Heights: 7-17mm





# **Lordotic Profiles**





# **INSTRUMENT** OVERVIEW

HEDRON T<sup>™</sup> uses SIGNATURE<sup>®</sup> instruments

# SIZERS/SHAVERS



	Height	Part Number	
70x	7mm	668.507	
8rm	8mm	668.508	
9mm	9mm	668.509	
10mm	10mm	668.510	
11mm B B B	11mm	668.511	

	Height	Part Number	
12mm  s  s  s  s	12mm	668.512	
13mm   5   5   5	13mm	668.513	
15mm   5   5   5	15mm	668.515	
17mm	17mm	668.517	

### PADDLE DISTRACTORS



	Height	Part Number	
7mm	7mm	668.407	
8mm	8mm	668.408	
9mm	9mm	668.409	
10mm	10mm	668.410	
11mm	11mm	668.411	

	Height	Part Number	
12mm	12mm	668.412	
13mm	13mm	668.413	
15mm	15mm	668.415	
17mm	17mm	668.417	

# TRIALS



Height	Small	Large
7mm	668.207	668.307
8mm	668.208	668.308
9mm	668.209	668.309
10mm	668.210	668.310
llmm	668.211	668.311
12mm	668.212	668.312
13mm	668.213	668.313
15mm	668.215	668.315
17mm	668.217	668.317

### **RASPS**



Rasp, Angled, Serrated 668.020



Rasp, Angled, Knurled 668.021

### **TAMPS**



Tamp, Straight 668.040



Tamp, Angled 668.041

# **HANDLES**



T-Handle 601.800

SIGNATURE® Quick Coupling Handle 668.160



L-Handle 679.010

### **IMPLANT HOLDER INSTRUMENTS**



SIGNATURE® Holder 668.150



SIGNATURE® Implant Holder, Long 668.100



SIGNATURE® Implant Holder, Short 668.101



SIGNATURE® Implant Holder, Short 668.101 SIGNATURE® Quick Coupling Handle 668.160 (Assembled)



### **OTHER INSTRUMENTS**



Slide Hammer, Small 622.410



SIGNATURE® Pin Driver 668.050

# **SURGICAL** TECHNIQUE HEDRON T

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 T<sup>™</sup> 3D Printed Spacers are to be used with supplemental fixation. Please refer to the technique guide for the corresponding supplemental fixation system.



# TRANSFORAMINAL APPROACH

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

# STEP

# **CREATING ACCESS**

Use the Osteotome to remove the inferior facet of the cephalad vertebrae and the superior facet of the caudal vertebrae at the appropriate level(s) to create a working transforaminal access window to the disc.



Transforaminal access

# **STEP**

# **ENDPLATE PREPARATION**

Remove disc material using Rongeurs, Currettes, and other suitable instruments. Insert the smallest Scraper into the disc space for further disc removal and endplate preparation, moving to larger Scrapers as needed. The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant. Remove the superficial layers of the cartilaginous endplates. Careful disc removal and endplate preparation helps to maximize the potential for successful fusion.



Discectomy using Shaver



# **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. Use caution to avoid damaging the endplate.



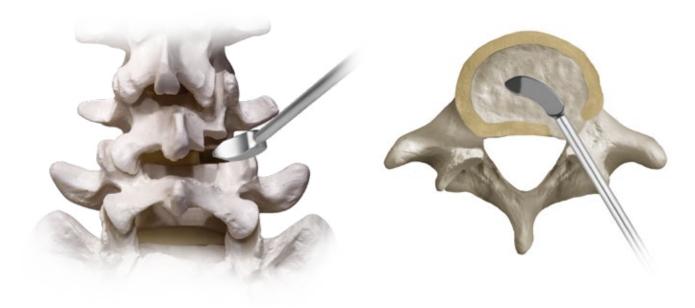
Distraction of disc space using **Paddle Distractor** 



Paddle Distractor in disc space

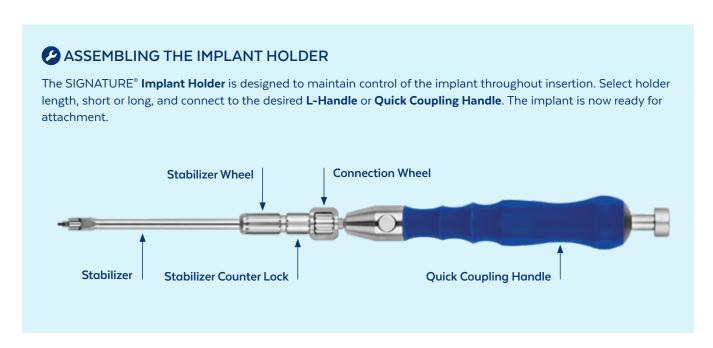
## **IMPLANT SIZING STEP**

Assemble the desired Trial onto the T-Handle. Insert the trial into the disc space, using gentle impaction if needed. Determine which trial 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.



Alternatively, the Paddle Distractor and Shavers may be used to size the disc space. Insert and rotate Paddles or Shavers to determine the appropriate implant height. Use caution to avoid damaging the endplate.





# LOADING IMPLANT (CONT'D)

Select the appropriate HEDRON  $\mathsf{T}^{\scriptscriptstyle{\mathsf{TM}}}$  implant and fill with autograft or allograft (cortical or corticocancellous) bone. Align the holder and insert into the pivot pin on the implant, as shown at right.

Rotate the thumb wheel clockwise to secure the implant.



Inserting pivot pin (top view)



Inserted pivot pin (side view)





Implant loaded

Rotate the Stabilizer Wheel clockwise to advance the Stabilizer for a rigid connection.





**Rigid connection** 

Rotate the Stabilizer Counter Lock clockwise until flush with the Stabilizer Lock.



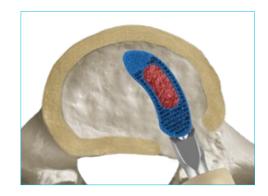


Implant fully locked

# STEP **IMPLANT INSERTION**

#### **Insert Implant**

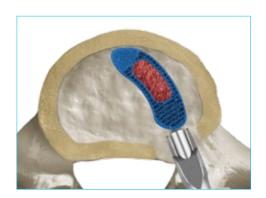
Insert the implant into the disc space with the holder Stabilizer engaged.



### **Disengage Stabilizers**

When the implant crosses the vertebral midline (identified by radiolucent markers in the implant), disengage the Stabilizer by rotating the Stabilizer Counter Lock counterclockwise. Rotate the stabilizer wheel counterclockwise.



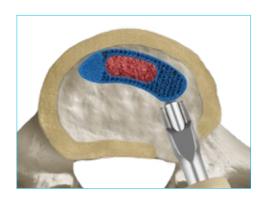


### **Articulate Implant**

Articulate the implant into the disc space, along the apophyseal ring.

Gently impact the implant into the disc space as needed. The implant should be recessed a few millimeters into the disc space.

Supplemental autograft or allograft bone should be packed around the implant if possible.

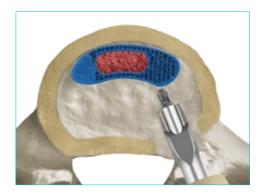


#### **Disengage Implant**

Using fluoroscopy, verify the final position before disengaging.

Release the implant from the holder by rotating the Connection Wheel counterclockwise.



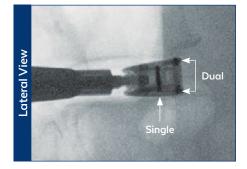


# RADIOGRAPHIC POSITIONING

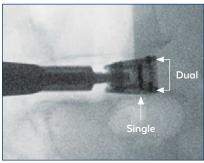
The ideal implant position is in the anterior portion of the disc space and centered across the midline of the vertebral body. The following features should be visible on the fluoroscopic images:

- · In a lateral view, the dual endplate markers in the tip should align with the single marker at the end, forming a single line
- In an AP view, implant should be centered over midline.

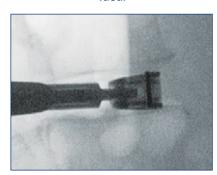
#### **Under-rotated**

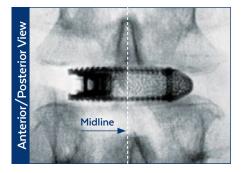


#### **Acceptable**



#### Ideal





# DISASSEMBLY

To disassemble the Implant Holder for cleaning, rotate the Stabilizer Lock clockwise until the Stabilizer and the Stabilizer Lock have both disengaged from the Main Shaft Assembly. Separate the Stabilizer from the Stabilizer Lock. Rotate the Counter Lock clockwise until it has disengaged from the Main Shaft Assembly.

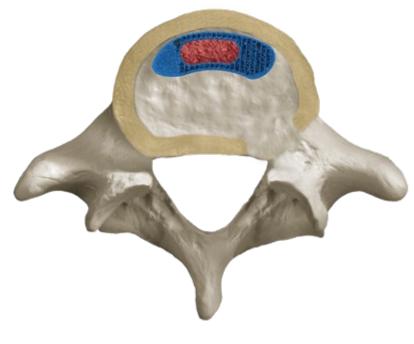


# DISASSEMBLY (CONT'D)

To reassemble the Implant Holder post cleaning, slide the Counter Lock down the main shaft assembly and thread until flush. Interlock the Stabilizer and the Stabilizer Lock together, slide down the Main Shaft Assembly, and thread until flush.



### FINAL POSITION



**Axial view** 

# SUPPLEMENTAL FIXATION

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

# **REMOVAL**

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

# HEDRON T<sup>™</sup> 10x28mm **IMPLANT SET 9225.9001**

### HEDRON T<sup>™</sup> Spacer, 10x28mm, 8°

Part No.	Length	QTY
1225.0007S	7mm	2
1225.0008S	8mm	2
1225.0009S	9mm	2
1225.0010S	10mm	2
1225.0011S	11mm	2
1225.0012S	12mm	2
1225.0013S	13mm	2
1225.0015S	15mm	2
1225.0017S	17mm	0

# HEDRON T<sup>™</sup> Spacer, 10x28mm, 15°

Part No.	Length	QTY
1225.0109S	9mm	2
1225.0110S	10mm	2
1225.0111S	llmm	2
1225.0112S	12mm	2
1225.0113S	13mm	2
1225.0115S	15mm	2
1225.0117S	17mm	0

9225.0001 HEDRON T<sup>™</sup> 10x28mm Implant Soft Case

# HEDRON T<sup>™</sup> 11x33mm **IMPLANT SET 9225.9002**

### HEDRON T<sup>™</sup> Spacer, 11x33mm, 8°

Part No.	Length	QTY
1225.1007S	7mm	2
1225.1008S	8mm	2
1225.1009S	9mm	2
1225.1010S	10mm	2
1225.1011S	11mm	2
1225.1012S	12mm	2
1225.1013S	13mm	2
1225.1015S	15mm	2
1225.1017S	17mm	0

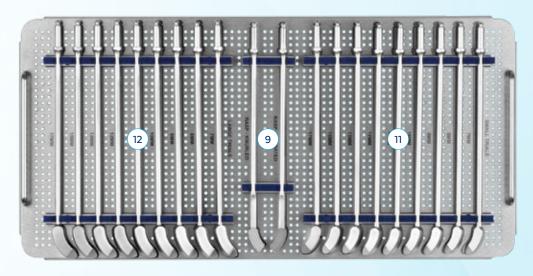
# HEDRON T<sup>™</sup> Spacer, 11x33mm, 15°

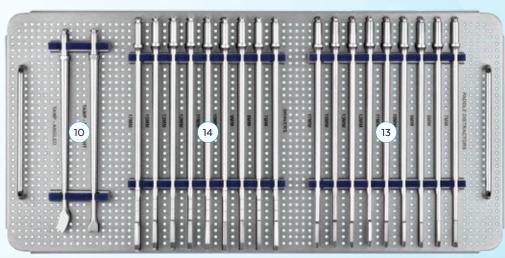
Part No.	Length	QTY
1225.1109S	9mm	2
1225.1110S	10mm	2
1225.1111S	11mm	2
1225.1112S	12mm	2
1225.1113S	13mm	2
1225.1115S	15mm	2
1225.1117S	17mm	0

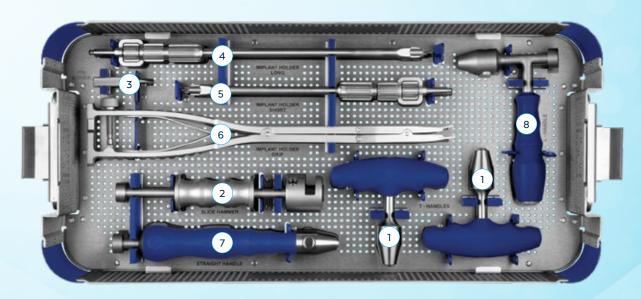
9225.0002 HEDRON T<sup>™</sup> 11x33mm Implant Soft Case

# **SIGNATURE**® **INSTRUMENT SET 968.901**

	Instrumer	nt	QTY		Instrume	nt	QTY
1	601.800	T-Handle	2	12	Large Trials	s (cont'd)	
2	622.410	Slide Hammer, Small	1		668.312	SIGNATURE®, Large, Trial, 12mm	1
3	668.050	SIGNATURE® Pin Driver	1		668.313	SIGNATURE®, Large, Trial, 13mm	1
4	668.100	SIGNATURE® Implant Holder, Long	1		668.315	SIGNATURE®, Large, Trial, 15mm	1
5	668.101	SIGNATURE® Implant Holder, Short	1		668.317	SIGNATURE®, Large, Trial, 17mm	1
6	668.150	SIGNATURE® Holder	1		B 111 B:		
7	668.160	SIGNATURE® Quick Coupling Handle	1	13	Paddle Dis		-
8	679.010	L-Handle	1		668.407	SIGNATURE® Paddle Distractor, 7mm	1
					668.408	SIGNATURE® Paddle Distractor, 8mm	1
9	Rasps		_		668.409	SIGNATURE® Paddle Distractor, 9mm	1
	668.020	SIGNATURE® Rasp, Angled, Serrated	1		668.410	SIGNATURE® Paddle Distractor, 10mm	
	668.021	SIGNATURE® Rasp, Angled, Knurled	1		668.411	SIGNATURE® Paddle Distractor, 11mm	1
10	Tamps				668.412	SIGNATURE® Paddle Distractor, 12mm	
	668.040	SIGNATURE® Tamp, Straight	1		668.413	SIGNATURE® Paddle Distractor, 13mm	
	668.041	SIGNATURE® Tamp, Angled	1		668.415	SIGNATURE® Paddle Distractor, 15mm	
					668.417	SIGNATURE® Paddle Distractor, 17mm	1
U	Small Trials			14	Sizers/Sha	evers	
	668.207	SIGNATURE®, Small, Trial, 7mm	1		668.507	SIGNATURE® Sizer/Shaver, 7mm	1
	668.208	SIGNATURE®, Small, Trial, 8mm	1		668.508	SIGNATURE® Sizer/Shaver, 8mm	1
	668.209	SIGNATURE®, Small, Trial, 9mm	1		668.509	SIGNATURE® Sizer/Shaver, 9mm	1
	668.210	SIGNATURE®, Small, Trial, 10mm	1		668.510	SIGNATURE® Sizer/Shaver, 10mm	1
	668.211	SIGNATURE®, Small, Trial, 11mm	1		668.511	SIGNATURE® Sizer/Shaver, 11mm	1
	668.212	SIGNATURE®, Small, Trial, 12mm	1		668.512	SIGNATURE® Sizer/Shaver, 12mm	1
	668.213	SIGNATURE®, Small, Trial, 13mm	1		668.513	SIGNATURE® Sizer/Shaver, 13mm	1
	668.215	SIGNATURE®, Small, Trial, 15mm	1		668.515	SIGNATURE® Sizer/Shaver, 15mm	1
	668.217	SIGNATURE®, Small, Trial, 17mm	1		668.517	SIGNATURE® Sizer/Shaver, 17mm	1
12	Large Trials				968.001	SIGNATURE® Instruments Graphic Cas	e
	668.307	SIGNATURE®, Large, Trial, 7mm	1				
	668.308	SIGNATURE®, Large, Trial, 8mm	1				
	668.309	SIGNATURE®, Large, Trial, 9mm	1				
	668.310	SIGNATURE®, Large, Trial, 10mm	1				
	668.311	SIGNATURE®, Large, Trial, 11mm	1				







#### 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.

 $HEDRON^{^{\text{\tiny{TM}}}}Lumbar\ Spacers\ (including\ HEDRON\ A^{^{\text{\tiny{TM}}}},\ HEDRON\ L^{^{\text{\tiny{TM}}}},\ HEDRON\ L^{^{\text{\tiny{TM}}}},\ HEDRON\ L^{^{\text{\tiny{TM}}}}$  $P^{\bowtie}$ , HEDRON  $RT^{\bowtie}$ , and HEDRON  $T^{\bowtie}$ ) are lumbar interbody fusion devices used to provide structural stability following discectomy. Each HEDRON $^{\bowtie}$ 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<sup>™</sup> anterior or anterolateral; HEDRON P<sup>™</sup> and HEDRON RT<sup>™</sup> posterior or transforaminal; and HEDRON T<sup>™</sup> 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<sup>™</sup> Spacers and HEDRON IC<sup>™</sup> 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<sup>™</sup> Spacers and HEDRON IC<sup>™</sup> 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, an  $\bar{d}/or$  cortico cancellous bone.

When the HEDRON IC<sup>™</sup> Spacer is used with the COALITION AGX<sup>®</sup> Plate, the plate-spacer assembly (HEDRON IC<sup>nst</sup> 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.

 $HEDRON^{^{TM}} Lumbar Spacers \ (HEDRON \ A^{^{TM}}, HEDRON \ L^{^{TM}}, HEDRON \ P^{^{TM}}, \\$ HEDRON T<sup>™</sup>, and HEDRON RT<sup>™</sup>) 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.

 $HEDRON\:IA^{\scriptscriptstyle{TM}}\:Integrated\:Lumbar\:Spacers\:are\:integrated\:lumbar\:interbody$ 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

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

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
- · 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
- 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.

These implants are available sterile and instruments are nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterile illipiants are sterilized by samma radiation, and the sterility Assurance Level (SAL) of 10<sup>-6</sup>. 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

- 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<sup>2</sup> 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 • 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
À	CAUTION	***	MANUFACTURER
2	SINGLE USE ONLY	Σ	USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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

Customer Service:

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

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