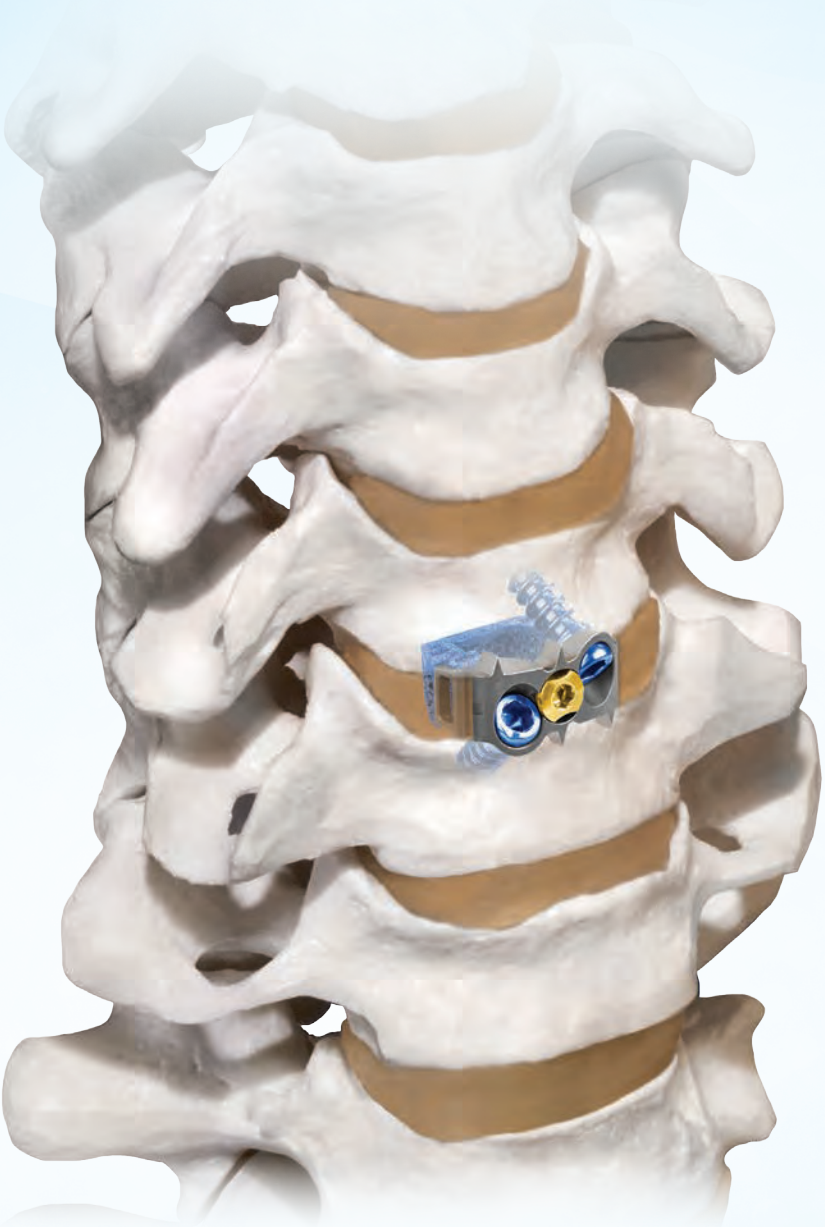

HEDRON IC™

3D Printed Integrated ACDF Plate-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.

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SURGICAL TECHNIQUE GUIDE

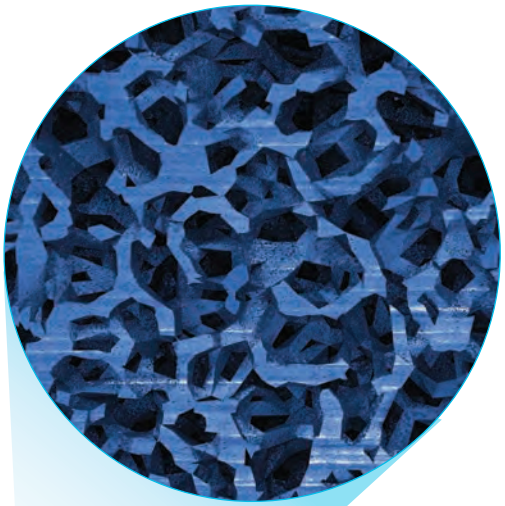
HEDRON IC™

HEDRON IC™

3D Printed Integrated ACDF Plate-Spacer

HEDRON IC™ spacers are anterior cervical interbody fusion devices. When a HEDRON IC™ spacer is assembled with a COALITION AGX® plate, the final assembly is the stand-alone HEDRON IC™ Plate-Spacer, which is used with two titanium alloy screws.

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



The Face of Fusion

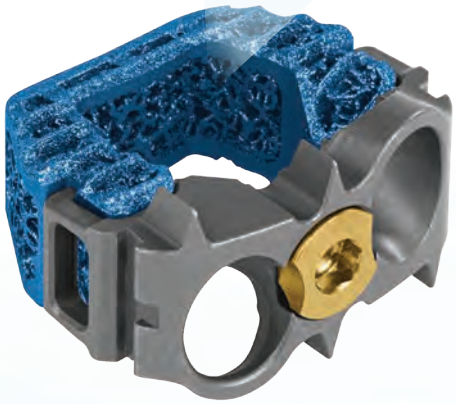
An ovine interbody study demonstrated significantly more bone ingrowth within HEDRON™ implants at 6 weeks post-op compared to PEEK and solid titanium implants.*

Intraoperative Integration

The HEDRON IC™ spacer and COALITION AGX® RP plate are intraoperatively assembled as an integrated plate-spacer for a low-profile approach requiring minimal retraction.

Natural Anatomical Profile

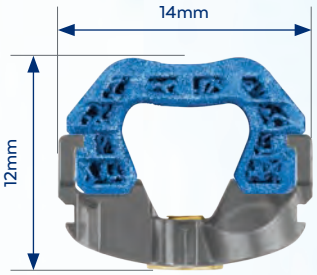
The HEDRON IC™ Plate-Spacer is designed to preserve the natural anatomical profile of the cervical vertebral body.

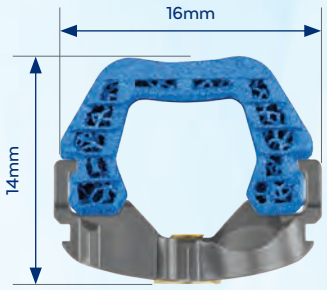


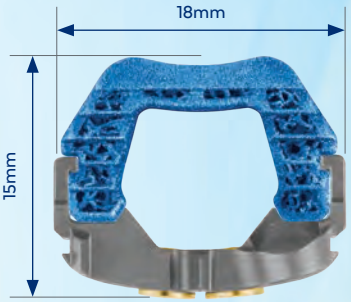
*Data on File

HEDRON IC™ Plate-Spacer

- **Footprints:** 12x14, 14x16, and 15x18mm
- **Heights:** 5–12mm (1mm increments)
- **Sagittal profiles:** 0°, 7°, and 12° lordotic
- **Intraoperatively assembled** using the HEDRON IC™ spacer, COALITION AGX® plate or COALITION AGX® RP plate

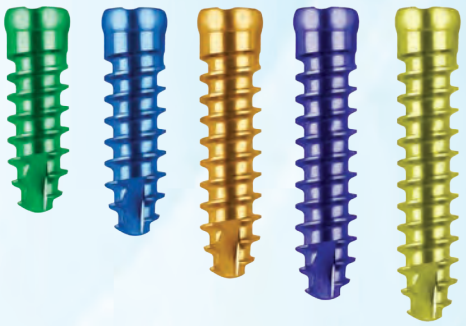






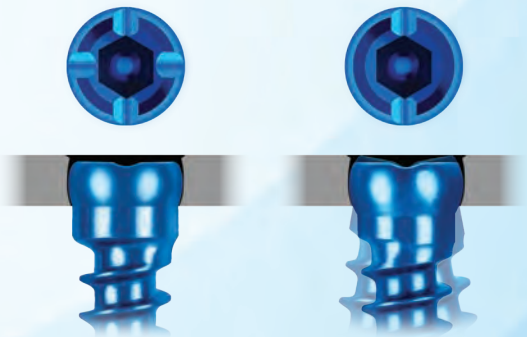
Screw Options

- **Diameter:** 3.6mm and 4.2mm
- **Length:** 12–20mm (2mm increments)
- **Type:** Self-drilling or self-tapping
- **Variable and fixed angle**



Screw Angulation

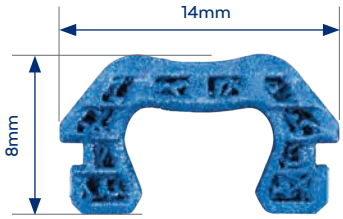
- **Screw orientation:** 35° cephalad/caudal
- **Variable angle acrews:** ±4°
- **Medial angulation:**
  - 16° for 12x14mm
  - 12° for 14x16mm
  - 14° for 15x18mm

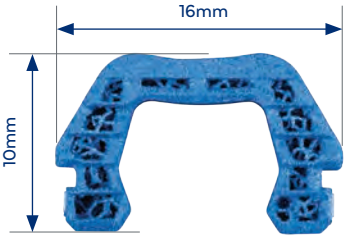


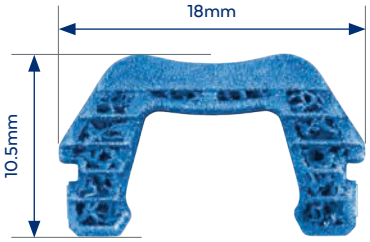
IMPLANT OVERVIEW

HEDRON IC™ Spacer

- **Footprints:** 8x14, 10x16, and 10.5x18mm
- **Heights:** 5–12mm (1mm increments)
- **Sagittal profiles:** 0°, 7°, and 12° lordotic







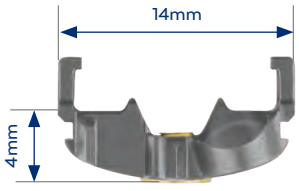
0°

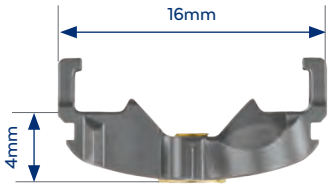
7°

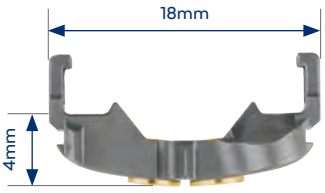
12°

COALITION AGX® RP Plate

- **Widths:** 14, 16, and 18mm widths
- **Heights:** 5–12mm (1mm increments)
- **Screw Blocking:** Audible, tactile, and visual confirmation







INSTRUMENT OVERVIEW

DISTRACTION INSTRUMENTS

Distractor, Left 601.020

Distractor, Right 601.021

Distractor Locking Nuts 665.606

Distractor Pins

	Height	Part Number
	12mm	665.612
	14mm	665.614
	16mm	665.616
	18mm	665.618

Distractor Pin Driver 665.608

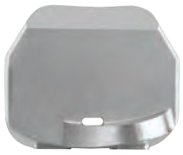
AGX MODULAR TRIALS - *FOR USE WITH STANDARD PLATE*

Trial Holder, Modular Trial/Rasp Heads - Inner Shaft Assembly

Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve 6147.9001

12x14mm		
Size	**0°**	**7°**
5mm	6128.1205	6128.1275
6mm	6128.1206	6128.1276
7mm	6128.1207	6128.1277
8mm	6128.1208	6128.1278
9mm	6128.1209	6128.1279
10mm	6128.1210	6128.1280
11mm	6128.1211	6128.1281
12mm	6128.1212	6128.1282

14x16mm		
Size	**0°**	**7°**
5mm	6128.1405	6128.1475
6mm	6128.1406	6128.1476
7mm	6128.1407	6128.1477
8mm	6128.1408	6128.1478
9mm	6128.1409	6128.1479
10mm	6128.1410	6128.1480
11mm	6128.1411	6128.1481
12mm	6128.1412	6128.1482

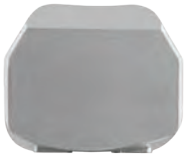


15x18mm		
Size	**0°**	**7°**
5mm	6128.1505	6128.1575
6mm	6128.1506	6128.1576
7mm	6128.1507	6128.1577
8mm	6128.1508	6128.1578
9mm	6128.1509	6128.1579
10mm	6128.1510	6128.1580
11mm	6128.1511	6128.1581
12mm	6128.1512	6128.1582

AGX MODULAR TRIALS - *FOR USE WITH RP PLATE*

12x14mm			
Size	**0°**	**7°**	**12°**
5mm	6128.2205	6128.2275	6128.2285
6mm	6128.2206	6128.2276	6128.2286
7mm	6128.2207	6128.2277	6128.2287
8mm	6128.2208	6128.2278	6128.2288
9mm	6128.2209	6128.2279	6128.2289
10mm	6128.2210	6128.2280	6128.2290
11mm	6128.2211	6128.2281	6128.2291
12mm	6128.2212	6128.2282	6128.2292

14x16mm			
Size	**0°**	**7°**	**12°**
5mm	6128.2405	6128.2475	6128.2485
6mm	6128.2406	6128.2476	6128.2486
7mm	6128.2407	6128.2477	6128.2487
8mm	6128.2408	6128.2478	6128.2488
9mm	6128.2409	6128.2479	6128.2489
10mm	6128.2410	6128.2480	6128.2490
11mm	6128.2411	6128.2481	6128.2491
12mm	6128.2412	6128.2482	6128.2492



15x18mm			
Size	**0°**	**7°**	**12°**
5mm	6128.2505	6128.2575	6128.2585
6mm	6128.2506	6128.2576	6128.2586
7mm	6128.2507	6128.2577	6128.2587
8mm	6128.2508	6128.2578	6128.2588
9mm	6128.2509	6128.2579	6128.2589
10mm	6128.2510	6128.2580	6128.2590
11mm	6128.2511	6128.2581	6128.2591
12mm	6128.2512	6128.2582	6128.2592

UNIVERSAL ACDF RASPS

12x14mm		
Size	**0°**	**7°**
5mm	6147.1025	-
6mm	6147.1026	6147.1126
7mm	6147.1027	6147.1127
8mm	6147.1028	6147.1128
9mm	6147.1029	6147.1129
10mm	6147.1030	6147.1130
11mm	6147.1031	6147.1131
12mm	6147.1032	6147.1132

14x16mm		
Size	**0°**	**7°**
5mm	6147.2025	-
6mm	6147.2026	6147.2126
7mm	6147.2027	6147.2127
8mm	6147.2028	6147.2128
9mm	6147.2029	6147.2129
10mm	6147.2030	6147.2130
11mm	6147.2031	6147.2131
12mm	6147.2032	6147.2132

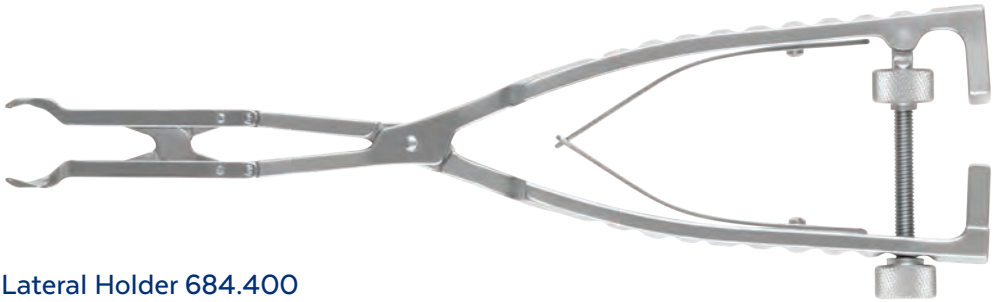
15x18mm		
Size	**0°**	**7°**
5mm	6147.3025	6147.3125
6mm	6147.3026	6147.3126
7mm	6147.3027	6147.3127
8mm	6147.3028	6147.3128
9mm	6147.3029	6147.3129
10mm	6147.3030	6147.3130
11mm	6147.3031	6147.3131
12mm	6147.3032	6147.3132

IMPLANT INSERTION INSTRUMENTS

Inner Shaft

Outer Shaft

Implant/Drill Guide Holder 684.001
(Assembled)



Lateral Holder 684.400

Impactor 665.607

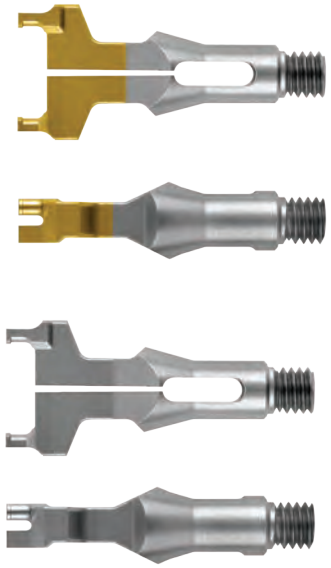
IMPLANT HOLDER TIPS - *FOR USE WITH STANDARD PLATES*

DTS Guide, Pre-Set Angle

Height	12x14mm	14x16mm	15x18mm
5mm	6128.4205	6128.4405	6128.4505
6mm	6128.4206	6128.4406	6128.4506
7mm	6128.4207	6128.4407	6128.4507
8mm	6128.4208	6128.4408	6128.4508
9mm	6128.4209	6128.4409	6128.4509
10mm	6128.4210	6128.4410	6128.4510
11mm	6128.4211	6128.4411	6128.4511
12mm	6128.4212	6128.4412	6128.4512

Midline Holder Tips

Gold (Small) 12x14mm and 14x16mm		Silver (Large) 15x18mm	
Height	Part No.	Height	Part No.
5mm	6128.4005	5mm	6128.4105
6mm	6128.4006	6mm	6128.4106
7mm	6128.4007	7mm	6128.4107
8mm	6128.4008	8mm	6128.4108
9mm	6128.4009	9mm	6128.4109
10mm	6128.4010	10mm	6128.4110
11mm	6128.4011	11mm	6128.4111
12mm	6128.4012	12mm	6128.4112



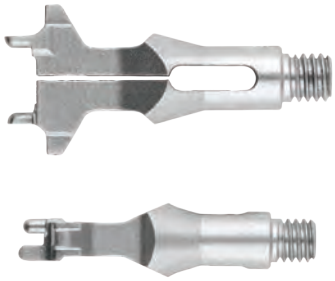
IMPLANT HOLDER TIPS - *FOR USE WITH RP PLATES*

DTS Guide, Pre-Set Angle

Height	12x14mm	14x16mm	15x18mm
5mm	684.155	684.165	684.175
6mm	684.156	684.166	684.176
7mm	684.157	684.167	684.177
8mm	684.158	684.168	684.178
9mm	684.159	684.169	684.179
10mm	684.160	684.170	684.180
11mm	684.161	684.171	684.181
12mm	684.162	684.172	684.182

Midline Holder Tips

Height	Part No.
5mm	-
6mm	684.406
7mm	684.407
8mm	684.408
9mm	684.409
10mm	684.410
11mm	684.411
12mm	684.412



Freehand Gripping Tips

12x14mm
684.113

14x16mm
684.123

15x18mm
684.133

STRAIGHT INSTRUMENTS

Quick Connect Handle, Swivel 636.450

Awl, Straight with Self-Centering Sleeve 684.403

Tap, Straight 684.004

Awl with Retractable Sleeve 684.006

Drills, Straight with Self-Centering Sleeve

Lengths	Part No.
12mm	684.422
14mm	684.424
16mm	684.426
18mm	684.428
20mm	684.430

Screwdriver, 2.5mm Hex, Self-Retaining, with Cap 684.305

ANGLED INSTRUMENTS

Awl, Bent with Self-Centering Sleeve 684.404

Angled Driver (Sleeve) Body 684.415

Drill Guide 6128.3000

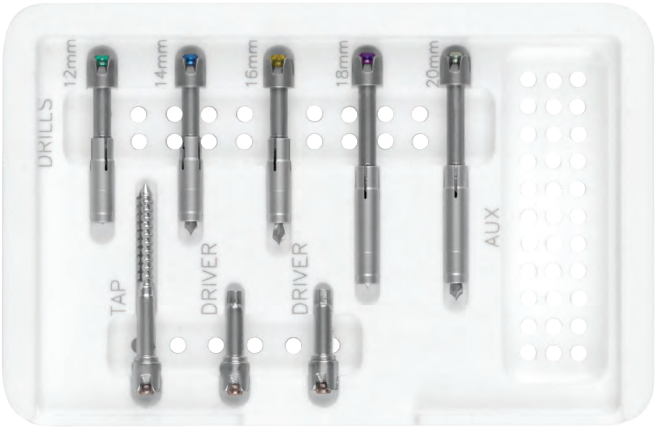
Angled Driver Nut 684.416

Counter Torque 684.421

Angled Driver Shaft 684.417

Angled Tap, Driver and Drills

Instrument	Part No.
Angled Tap	684.416
Angled Driver	684.418
Angled Drill, 12mm	684.432
Angled Drill, 14mm	684.434
Angled Drill, 16mm	684.436
Angled Drill, 18mm	684.438
Angled Drill, 20mm	684.440



SET SCREW INSTRUMENTS

Set Screw Positioner, 2.0mm Hex, Torque Limiting 650.312

Screwdriver, 2.1mm Hex, QC 671.313

PLATE AND SPACER ASSEMBLY

Assembly Tool 6128.3102 Upper

Assembly Tool 6128.3101 Lower

ADDITIONAL INSTRUMENTS

Self-Centering Sleeve, Short 684.401

Self-Centering Sleeve, Long 684.402

Drill Sleeve Adjuster 684.309

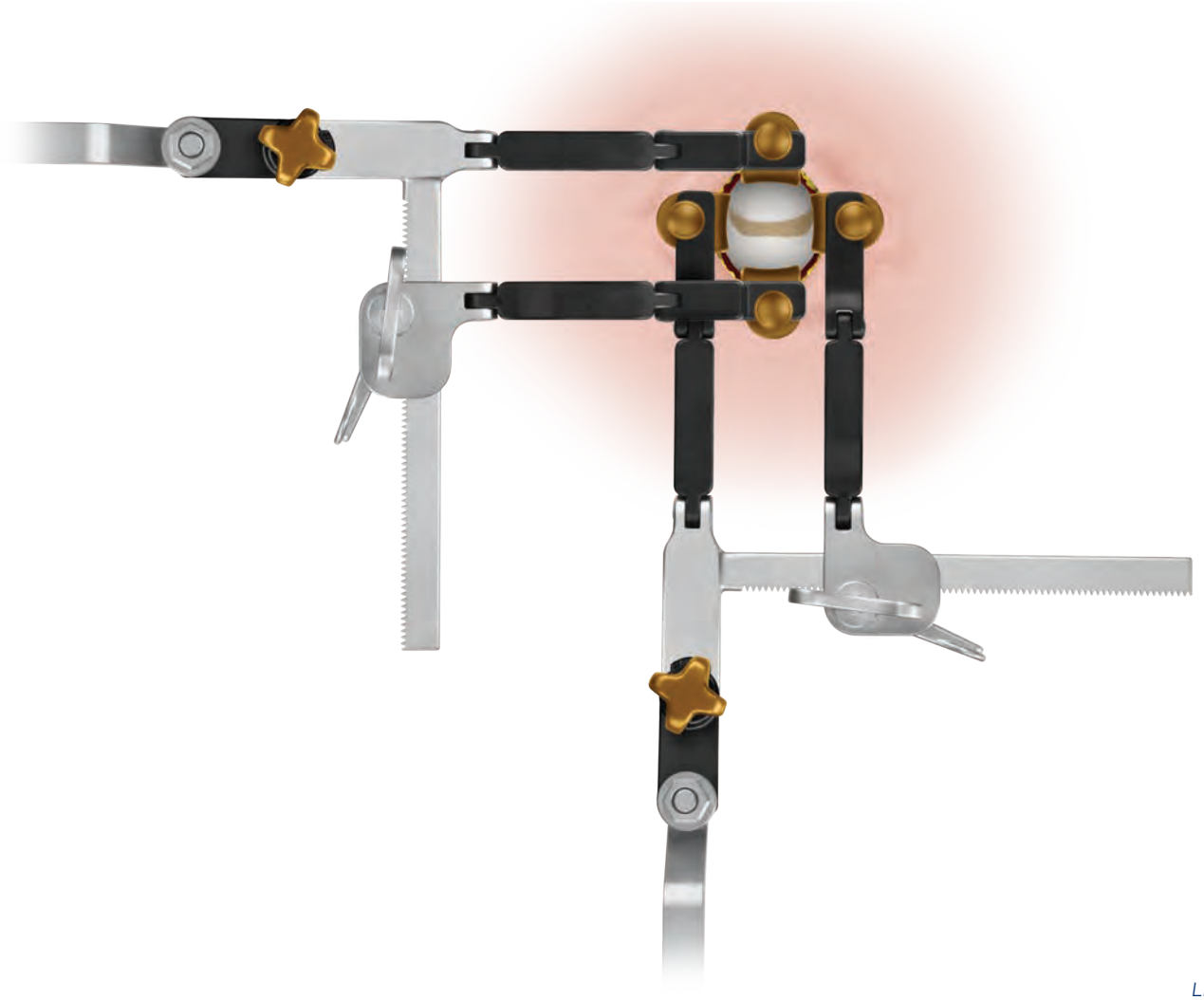
SURGICAL TECHNIQUE

HEDRON IC™

Please refer to the device 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.

STEP 1 APPROACH AND DISC PREPARATION

An anterior approach to the cervical spine is used. The patient is placed under anesthesia and positioned supine with support of the posterior cervical spine to maintain cervical lordosis. Traditional cervical retractors may be used. The operative area is carefully cleaned and an incision is made at the appropriate level.

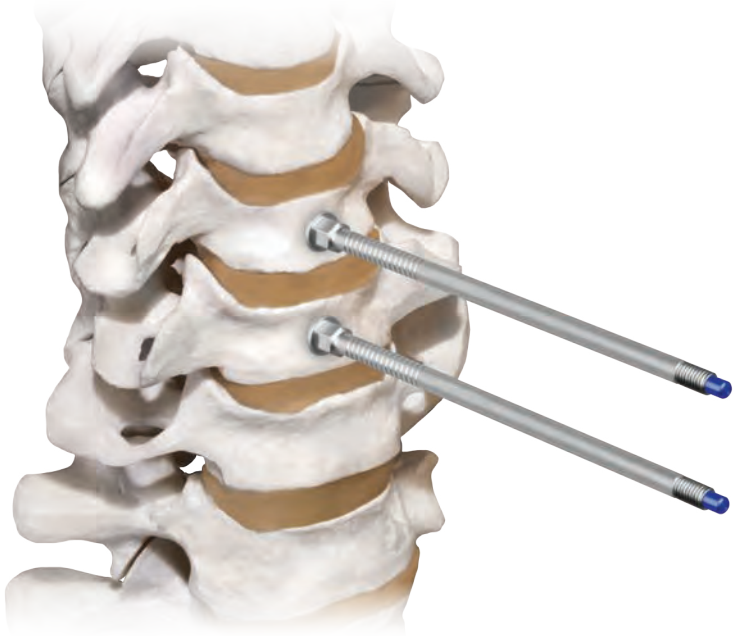


STEP 2 DISTRACTION

Distraction may be accomplished using the **Distractor**, or other distraction methods.

To use the Distractor, determine pin placement within the vertebral bodies. Select the appropriate pin length and place the **Distractor Pins** into adjacent vertebral bodies using the **Distractor Pin Driver**. Care should be taken when placing pins to avoid interference with any supplemental fixation.

Inserting Distractor Pins



Distractor Pins inserted

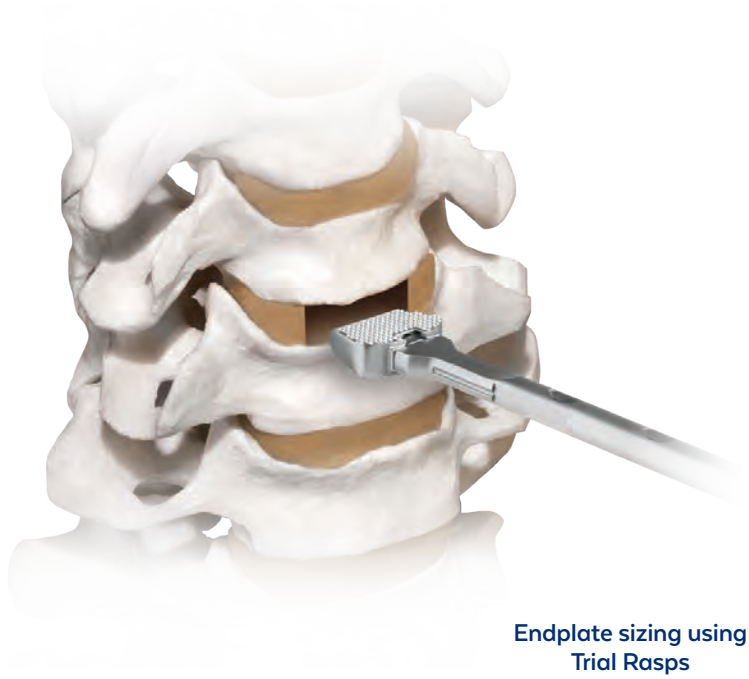
Place the Distractor, right or left as desired, over pins until seated. Once seated, secure the Distractor by attaching the **Distractor Locking Nuts** and rotating clockwise. Rotate the ratchet handle clockwise to distract to the desired amount, white being careful not to overdistract the segment. Distraction may be used throughout the technique to provide visualization and access to the disc and osseous structures.

Distracting the disc space using the Distractor

STEP 3 DISCECTOMY/ENDPLATE PREPARATION

Expose the disc space. Leaving the lateral annulus intact, remove the intervertebral disc and any osteophytes using ronguers, curettes, rasps and other instruments as needed. Remove the superficial layers of the cartilaginous endplates to expose bleeding bone. The lateral walls of the annulus should be preserved to provide peripheral support. Alternatively, **Trial Rasps** match the size and shape of corresponding trials with rasp surfaces and may be used to expose bleeding bone. Removal of Distractor Pins is advised before spacer insertion, but optional if needed to maintain distraction of the disc space.

Note: Excessive endplate preparation may weaken the vertebral endplates and may result in subsidence.



Endplate sizing using Trial Rasps

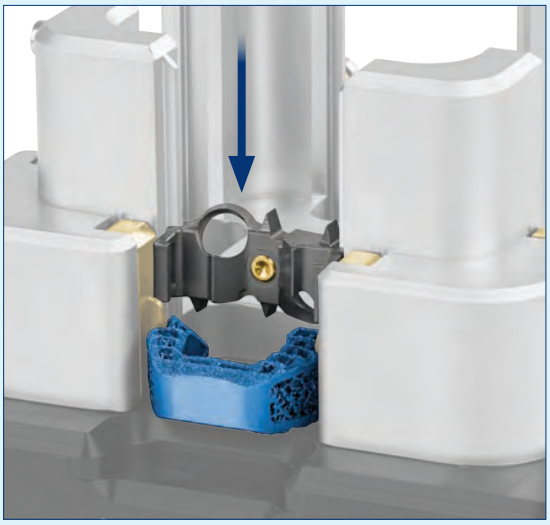
STEP 4 SPACER AND PLATE ASSEMBLY

Determine the appropriate spacer profile for the desired segment. Insert the smallest **Trial** into the disc space first, moving to larger trials as 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 feedback.

Plate and Spacer Sizing Matrix		
COALITION AGX® Plate	**HEDRON IC™ Spacer**	**Assembly**
14mm width	8x14mm	12x14mm footprint
16mm width	10x16mm	14x16mm footprint
18mm width	10.5x18mm	15x18mm footprint

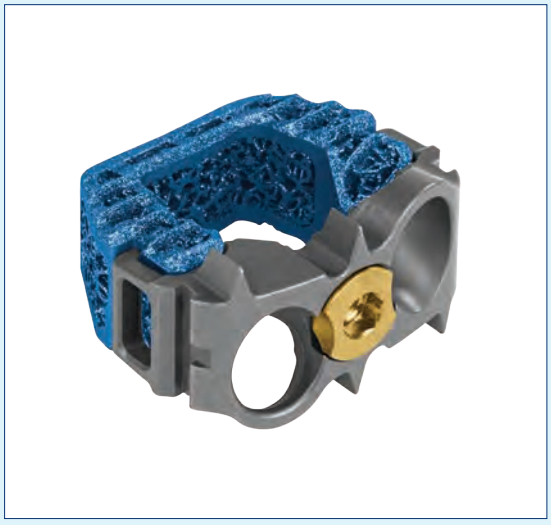
ASSEMBLING THE PLATE AND SPACER

Select the desired footprint and slide the spacer onto the gold track with the opening facing inward.



Insert a matching plate onto the silver track with the open side facing outward. Press down gently on the plate until it is engaged with the spacer.

Correctly align and place the lid onto the base. Press down to assemble plate and spacer. Visually confirm that the plate and spacer are fully assembled by ensuring the plate's lateral extensions are within the grooves of the spacer.



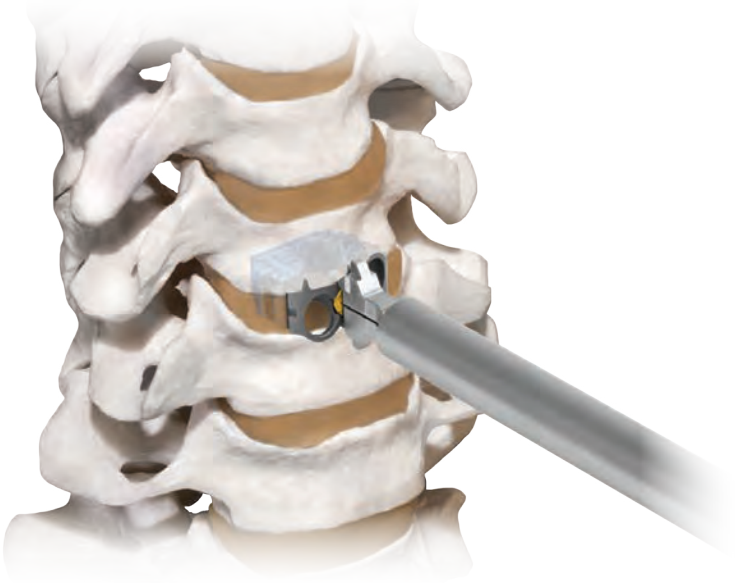
Implant fully assembled

STEP 5 IMPLANT INSERTION

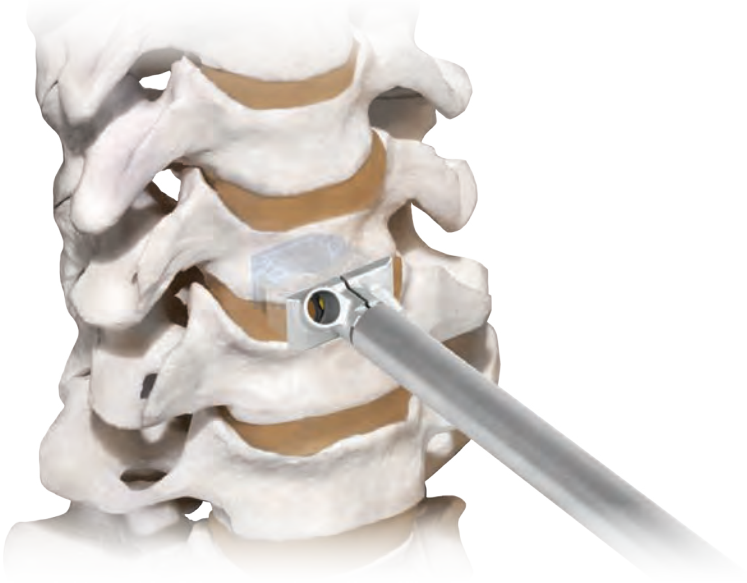
Fill the assembled HEDRON IC™ Plate-Spacer with autogeneous or allogenic bone graft material composed of cancellous, cortical or cortico-cancellous bone. The **Lateral Implant Holder**, the **Implant/Drill Guide Holder with the Midline Implant Holding Tip, DTS Guide, Pre-Set Angle** or the **Freehand Gripping Tip** may be used for insertion.

Assemble the holder and attach the appropriate sized tip.

Load the implant on the selected holder and insert into the disc space. Lateral portions of the plate should be slightly within the anterior margin of the disc space. Light impaction may be applied using the holder or an impactor.



Insertion with Midline Implant Holding Tip

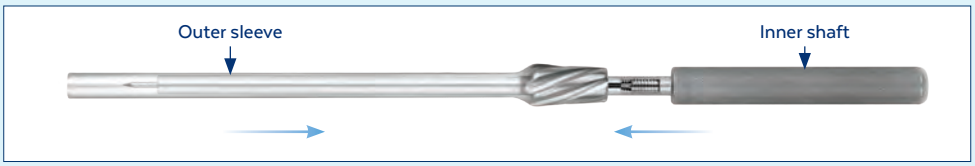


Insertion with DTS Guide, Pre-Set Angle

ASSEMBLING THE IMPLANT/DRILL GUIDE HOLDER

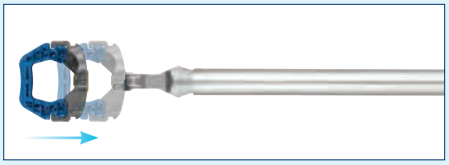
The Implant/Drill Guide Holder has two components. To assemble, slide the outer sleeve over the inner shaft and thread by rotating the inner shaft clockwise, as shown below. Continue to rotate until contact is made between the inner shaft and outer sleeve.

Note: Do not continue to rotate the inner shaft after initial contact.

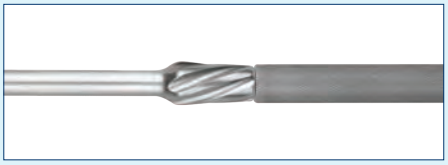


Connect the Midline Implant Holder by rotating the handle of the inner shaft clockwise until secure.

Prior to loading the implant, confirm that the outer and inner shafts are touching. Rotate the outer shaft counterclockwise to spread the tips. Attach the implant onto the holder. The implant is held lightly but is not yet secured.

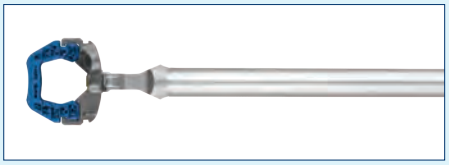


Attach implant onto Midline Holding Tip

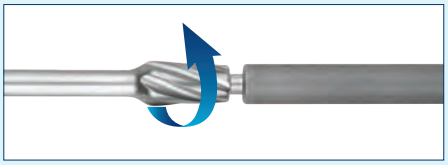


Implant loading position

To secure the implant to the holder, rotate the outer sleeve clockwise until it stops. The implant is now secured to the holder.

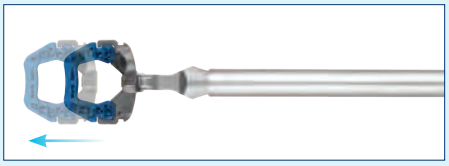


Implant secured into Midline Holding Tip

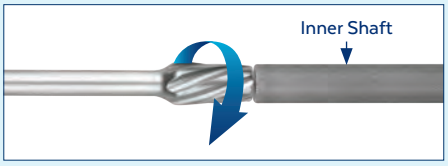


Secured position

To release the implant, hold the inner shaft and rotate the outer sleeve counterclockwise until the inner shaft and outer sleeve touch. Continue to rotate the outer sleeve counterclockwise until the Midline Holding Tip releases the implant.



Implant releases from Midline Holding Tip



Disengaged position

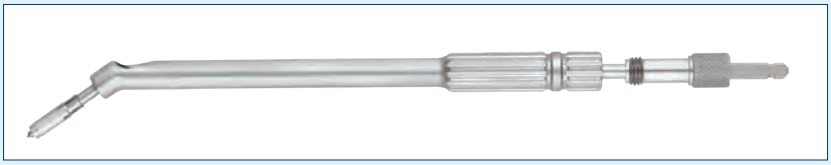
ASSEMBLING THE ANGLED INSTRUMENTS

Select the appropriate Angled Driver, Angled Drill or Angled Tap for assembly with the body and shaft.

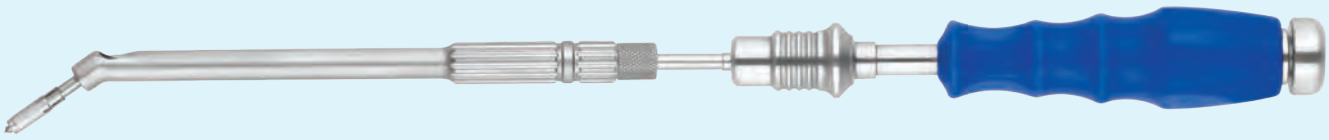
Hold the **Angled Driver Body** pointed downward with the distal cutout facing upward. Insert the selected tip into the cutout.

Insert the **Angled Driver Shaft** into the driver body until the gears on the shaft and the selected tip mate.

Place the **Backing Nut** over the shaft. Rotate the threads clockwise until the nut sits flush with the driver body.



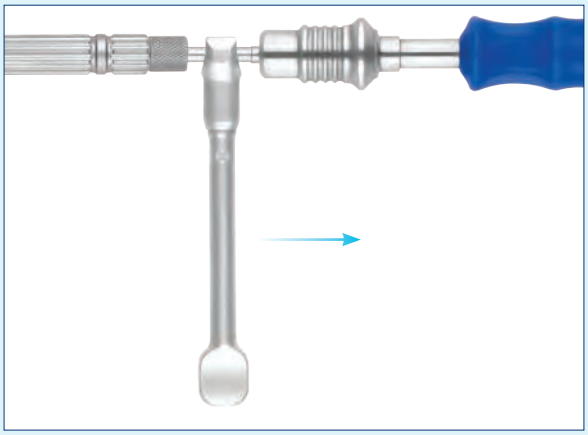
Attach a **Quick Connect Handle, Swivel**. The driver is now ready for use.



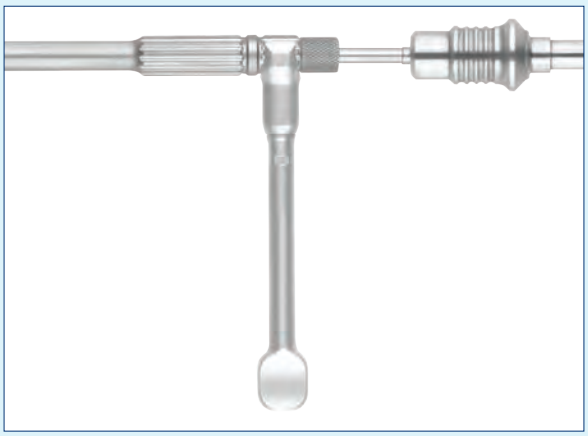
ASSEMBLING THE ANGLED INSTRUMENTS (CONT'D)

For additional control, a **Counter Torque** handle may be attached to the angled instruments.

Starting from the top, slide the Counter Torque from the smooth portion of the Angled Driver Body to the knurled portion until fully seated.

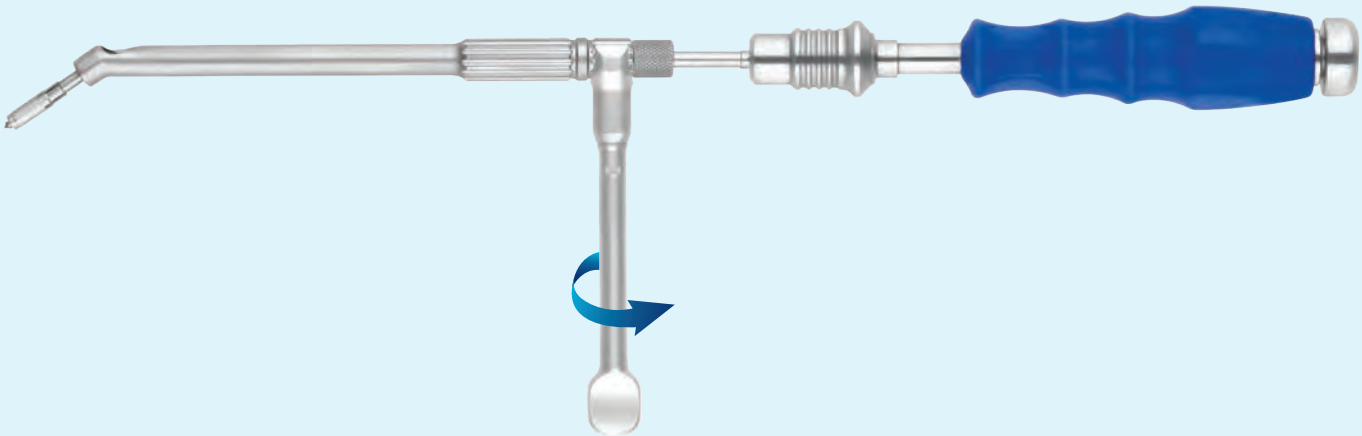


Attaching the Counter Torque



Counter Torque in final position

Rotate the Counter Torque clockwise to final tighten.



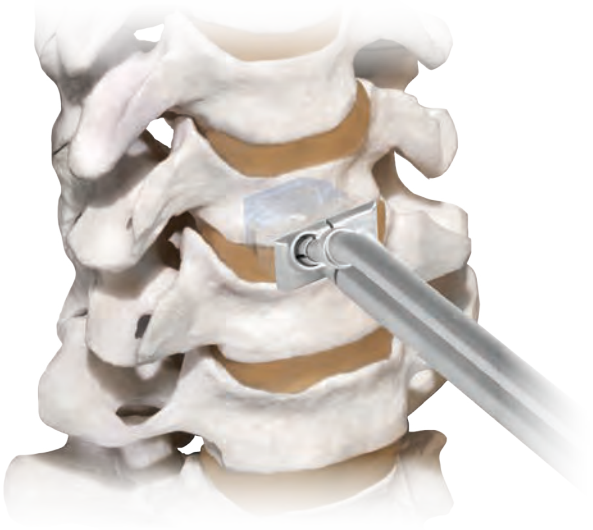
STEP 6 SCREW HOLE PREPARATION

Using the Pre-Set Angled Drill Guide

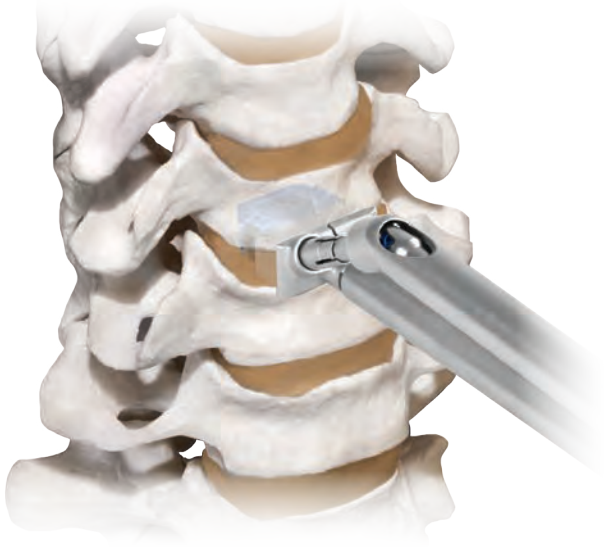
Insert the **Awl with Self-Centering Sleeve, Bent** through the screw hole within the plate and break the cortex.

Determine the desired depth and select the appropriate fixed length drill. If desired, a depth gauge may be used to determine the appropriate depth. Drills are color-coded by screw length. Insert the drill into the drill guide and drill to the stop.

Screw holes may be tapped using the Straight or Angled Tap.



Using Awl with Self-Centering Sleeve, Bent



Using Angled Drill with Self-Centering Sleeve

Note: The same screw hole preparation instruments are used for the Implant/Drill Guide Holder, Lateral Holder, and Midline Implant Holder.

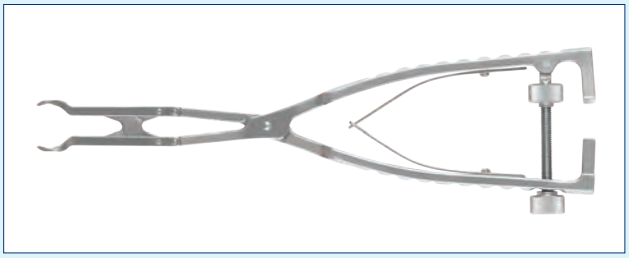
USING THE DRILL SLEEVE ADJUSTER

Ensure that the drill sleeve is in the proper position by first gripping the drill sleeve with the **Drill Sleeve Adjuster**, then pulling the sleeve distally.

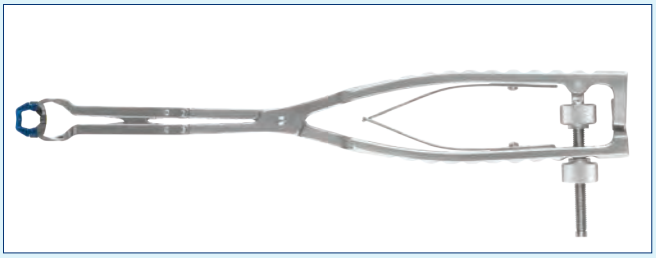
Gripping the drill sleeve

Pulling sleeve distally

USING THE LATERAL HOLDER

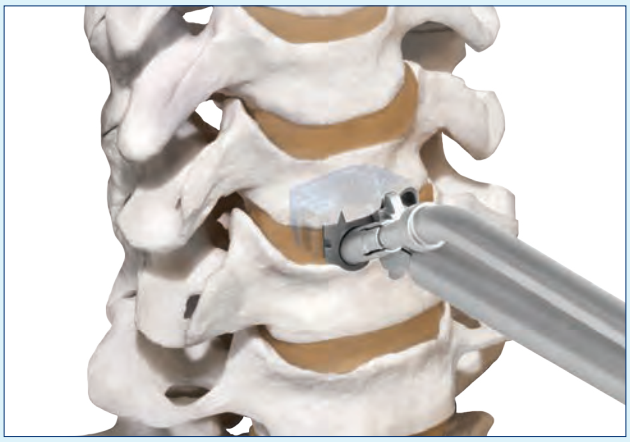


Fully open the Lateral Holder by rotating the locking nut counterclockwise.

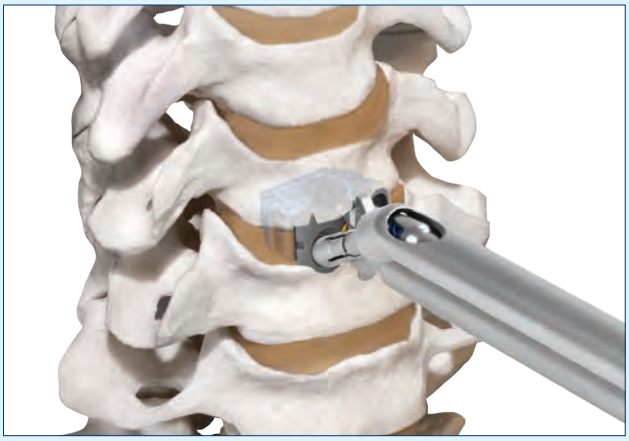


Place the appropriately sized implant on the Lateral Holder, compress the handles and rotate the locking nut clockwise until finger tight.

USING THE MIDLINE IMPLANT HOLDER



Insert the Awl with Self-Centering Sleeve, Bent to break the cortex.



A **Self-Centering Drill** and **Tap** may be used to further prepare the screw hole. Depending on the angle and position, a straight or angled instrument may be used.

ALIGNING THE SELF-CENTERING SLEEVE

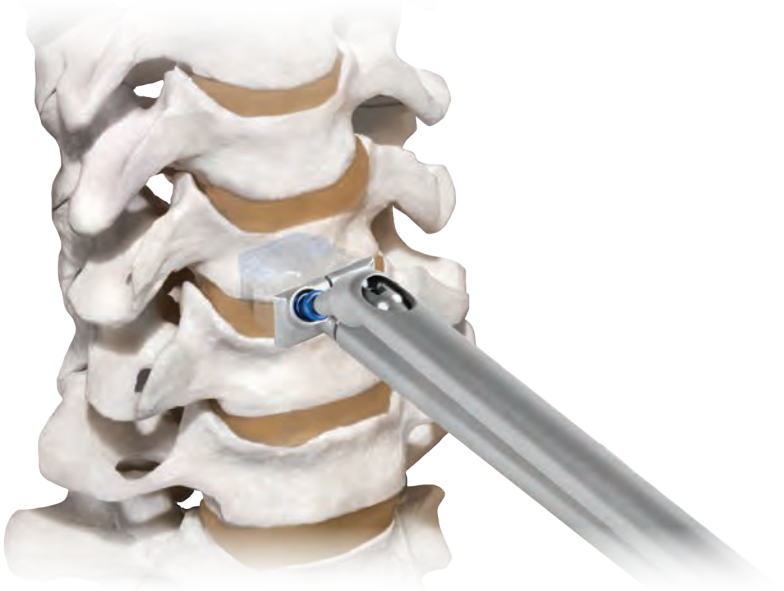
The Self-Centering Sleeves ensure proper screw trajectory without the use of a drill guide. The sleeve must be properly engaged with the plate before advancing any screw hole preparation instrument. Proceed to screw insertion prior to preparing the remaining screw hole.

INCORRECT

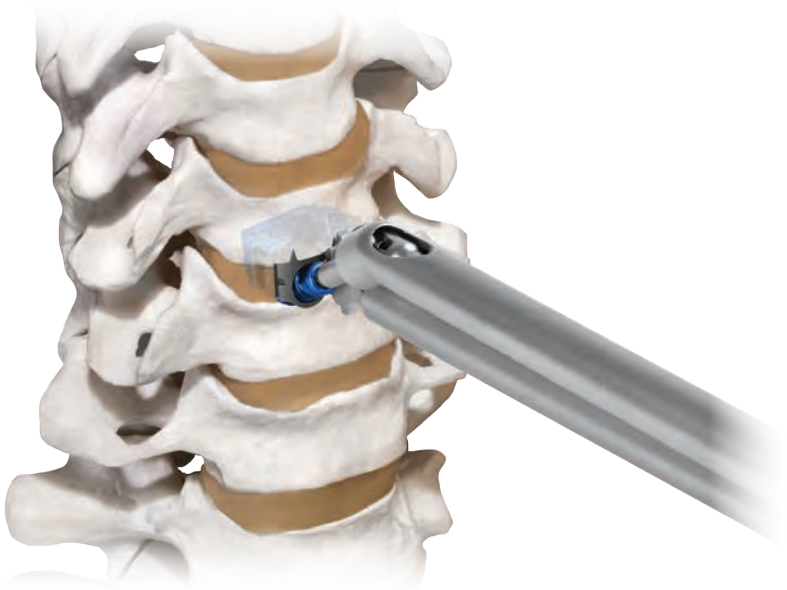
CORRECT

STEP 7 SCREW INSERTION

Load the desired screw onto the **Screwdriver, 2.5mm Hex, Self-Retaining, with Cap** or **Angled Driver**. Confirm screw length and diameter using the gauges within the screw module. Insert the screw though the screw hole. As the screw is inserted, the vertebral bodies lag to the spacer. Repeat for the second screw.



Screw insertion with DTS Guide, Pre-Set Angle

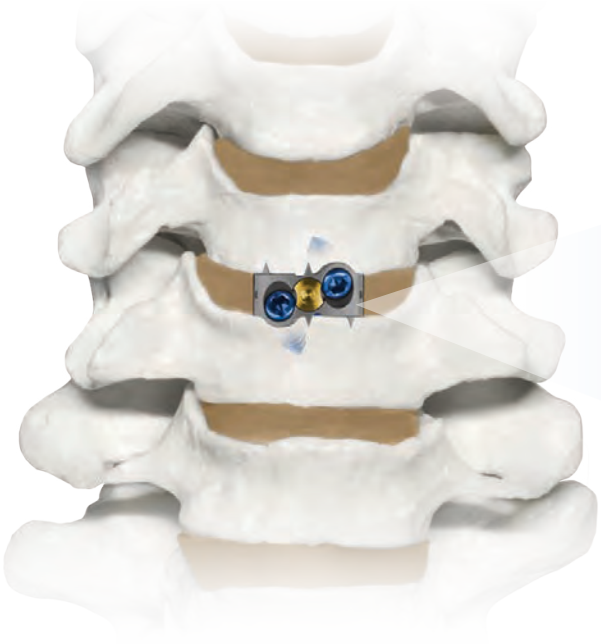


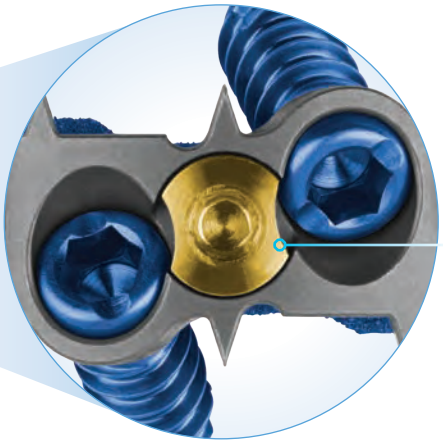
Screw insertion with Midline Implant Holder

STEP 8 SCREW BLOCKING

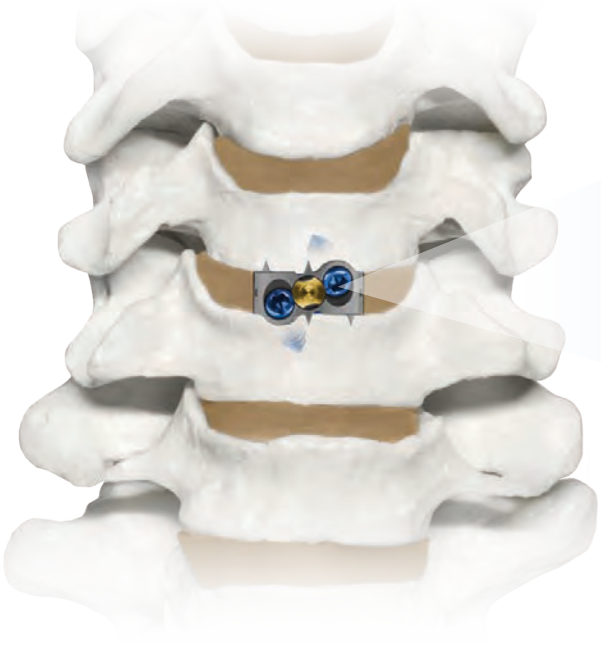
Once the screws are fully seated within the plate, insert the **Set Screw Positioner, 2.0mm Hex, 0.3Nm Torque Limiting** into the blocking set screw and rotate clockwise approximately 90°. The positioner provides audible and tactile confirmation that the screw is blocked from backing out.

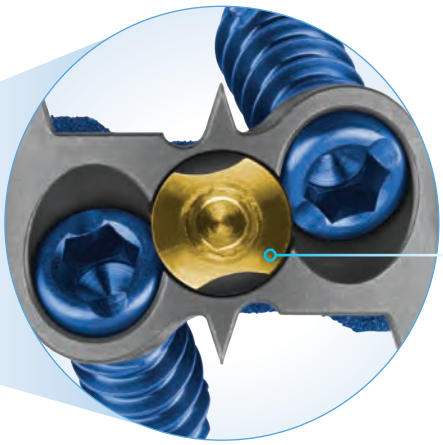
If the blocking set screw does not rotate, check screw angulation and ensure that screws are fully seated.





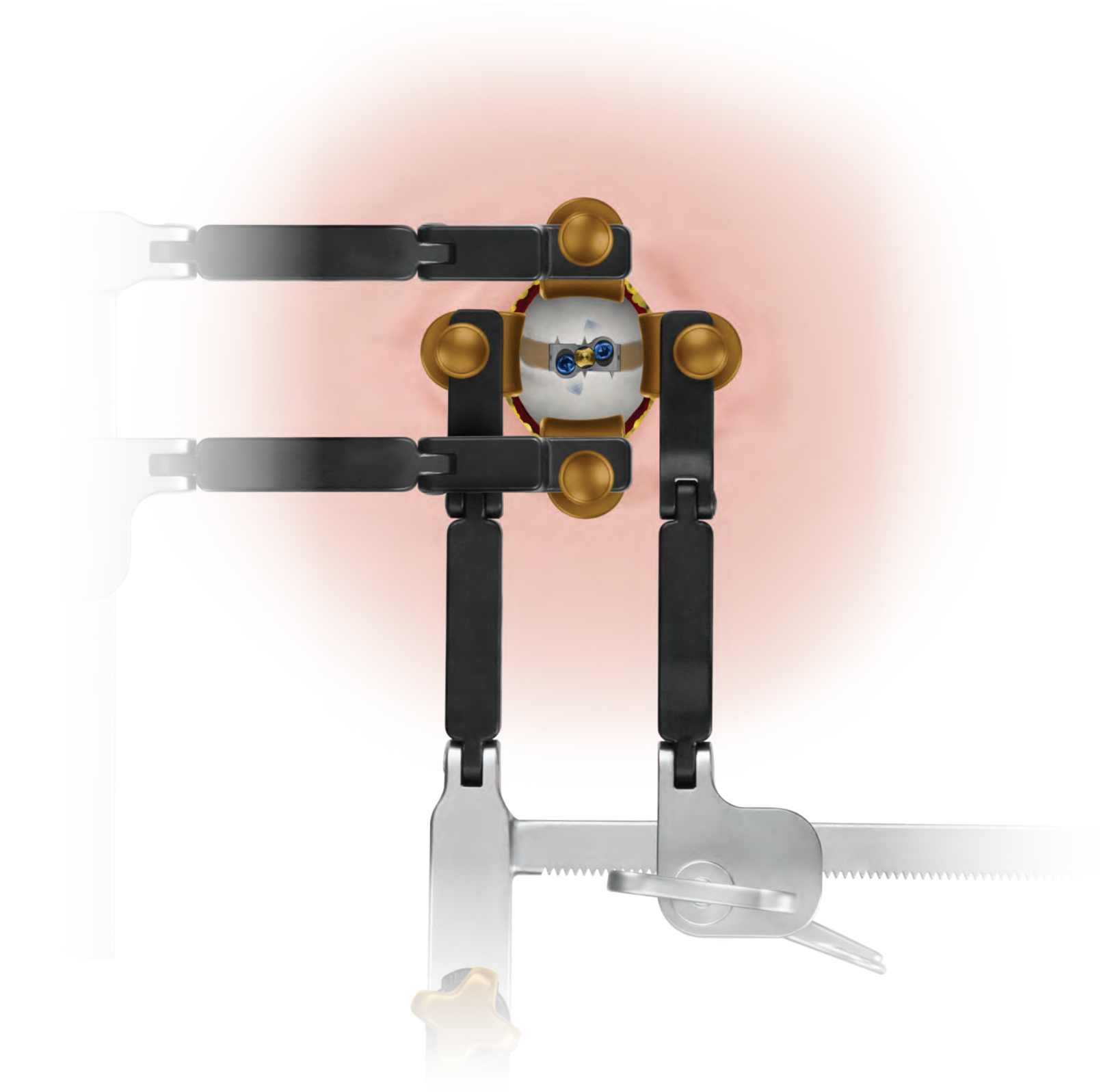
Initial Unlocked Position:
Blocking set screw ***facing*** bone screw



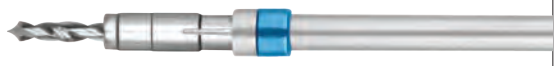


Final Locked Position:
Blocking set screw ***facing away*** from bone screw

FINAL CONSTRUCT



ADDITIONAL SPECIFICATIONS

Instrument	Diameter (mm)	Depth (mm)	Design
Straight/Bent Awl	2.4	8.6	
Retractable Awl	2.4	8.6	
Straight/Angled Taps	3.5	10.4	
12mm Drill	2.4	8.6	
14mm Drill	2.4	10.6	
16mm Drill	2.4	12.6	
18mm Drill	2.4	14.6	
20mm Drill	2.4	16.6	

HEDRON IC™ 12x14 and 14x16mm IMPLANT SET 9213.9001

HEDRON IC™ Spacer, 8x14mm, 0°

Part No.	Length	QTY
1213.4005S	5mm	2
1213.4006S	6mm	3
1213.4007S	7mm	3
1213.4008S	8mm	3
1213.4009S	9mm	2
1213.4010S	10mm	2
1213.4011S	11mm	1
1213.4012S	12mm	1

HEDRON IC™ Spacer, 10x16mm, 0°

Part No.	Length	QTY
1213.6005S	5mm	2
1213.6006S	6mm	3
1213.6007S	7mm	3
1213.6008S	8mm	3
1213.6009S	9mm	2
1213.6010S	10mm	2
1213.6011S	11mm	1
1213.6012S	12mm	1

HEDRON IC™ Spacer, 8x14mm, 7°

Part No.	Length	QTY
1213.4075S	5mm	2
1213.4076S	6mm	3
1213.4077S	7mm	3
1213.4078S	8mm	3
1213.4079S	9mm	2
1213.4080S	10mm	2
1213.4081S	11mm	1
1213.4082S	12mm	1

HEDRON IC™ Spacer, 10x16mm, 7°

Part No.	Length	QTY
1213.6075S	5mm	2
1213.6076S	6mm	3
1213.6077S	7mm	3
1213.6078S	8mm	3
1213.6079S	9mm	2
1213.6080S	10mm	2
1213.6081S	11mm	1
1213.6082S	12mm	1

9213.0001 HEDRON IC™ 12x14 and 14x16 Spacer Soft Case

HEDRON IC™ 15x18mm
IMPLANT SET 9213.9002

HEDRON IC™ Spacer, 10.5x18mm, 0°

Part No.	Length	QTY
1213.8005S	5mm	2
1213.8006S	6mm	3
1213.8007S	7mm	3
1213.8008S	8mm	3
1213.8009S	9mm	2
1213.8010S	10mm	2
1213.8011S	11mm	1
1213.8012S	12mm	1

HEDRON IC™ Spacer, 10.5x18mm, 7°

Part No.	Length	QTY
1213.8075S	5mm	2
1213.8076S	6mm	3
1213.8077S	7mm	3
1213.8078S	8mm	3
1213.8079S	9mm	2
1213.8080S	10mm	2
1213.8081S	11mm	1
1213.8082S	12mm	1

9213.0002 HEDRON IC™ 15x18 Spacer Soft Case

HEDRON IC™ 12°
IMPLANT SET 9213.9003

HEDRON IC™ Spacer, 8x14mm, 12°

Part No.	Length	QTY
1213.4085S	5mm	2
1213.4086S	6mm	3
1213.4087S	7mm	3
1213.4088S	8mm	3
1213.4089S	9mm	2
1213.4090S	10mm	2
1213.4091S	11mm	1
1213.4092S	12mm	1

HEDRON IC™ Spacer, 10x16mm, 12°

Part No.	Length	QTY
1213.6085S	5mm	2
1213.6086S	6mm	3
1213.6087S	7mm	3
1213.6088S	8mm	3
1213.6089S	9mm	2
1213.6090S	10mm	2
1213.6091S	11mm	1
1213.6092S	12mm	1

HEDRON IC™ Spacer, 10.5x18mm, 12°

Part No.	Length	QTY
1213.8085S	5mm	2
1213.8086S	6mm	3
1213.8087S	7mm	3
1213.8088S	8mm	3
1213.8089S	9mm	2
1213.8090S	10mm	2
1213.8091S	11mm	1
1213.8092S	12mm	1

9213.0003 HEDRON IC™ 12° Spacer Soft Case

COALITION AGX®
INSTRUMENT SET 9128.9001

AGX DTS Guides, Pre-Set Angle

Part No.	Description	QTY
6128.4205	14mm W, 5mm H	1
6128.4206	14mm W, 6mm H	1
6128.4207	14mm W, 7mm H	1
6128.4208	14mm W, 8mm H	1
6128.4209	14mm W, 9mm H	1
6128.4210	14mm W, 10mm H	1
6128.4211	14mm W, 11mm H	1
6128.4212	14mm W, 12mm H	1
6128.4405	16mm W, 5mm H	1
6128.4406	16mm W, 6mm H	1
6128.4407	16mm W, 7mm H	1
6128.4408	16mm W, 8mm H	1
6128.4409	16mm W, 9mm H	1
6128.4410	16mm W, 10mm H	1
6128.4411	16mm W, 11mm H	1
6128.4412	16mm W, 12mm H	1
6128.4505	18mm W, 5mm H	1
6128.4506	18mm W, 6mm H	1
6128.4507	18mm W, 7mm H	1
6128.4508	18mm W, 8mm H	1
6128.4509	18mm W, 9mm H	1
6128.4510	18mm W, 10mm H	1
6128.4511	18mm W, 11mm H	1
6128.4512	18mm W, 12mm H	1

Midline Holding Tip

Part No.	Length	QTY
6128.4005	5mm	1
6128.4006	6mm	1
6128.4007	7mm	1
6128.4008	8mm	1
6128.4009	9mm	1
6128.4010	10mm	1
6128.4011	11mm	1
6128.4012	12mm	1

Midline Holding Tip, Large

Part No.	Length	QTY
6128.4105	5mm	1
6128.4106	6mm	1
6128.4107	7mm	1
6128.4108	8mm	1
6128.4109	9mm	1
6128.4110	10mm	1
6128.4111	11mm	1
6128.4112	12mm	1

Other Instruments

Part No.	Description	QTY
650.312	Set Screw Positioner, 2.0mm Hex, Torque Limiting	1
684.001	Implant/Drill Guide Holder	1
684.113	Free Hand Gripping Tip, 12x14mm	1
684.123	Free Hand Gripping Tip, 14x16mm	1
684.133	Free Hand Gripping Tip, 15x18mm	1
684.400	Lateral Holder	1
6128.3000	Handheld Drill Guide	1
6128.3101	Assembly Press, Lower	1
6128.3102	Assembly Press, Upper	1
9128.0001	COALITION AGX® Graphic Case	

COALITION AGX®
PLATE SETS

COALITION AGX® 12x14 and 14x16mm Plate Set 9128.9002

Part No.	Description	QTY
1128.1205	14mm W, 5mm H	2
1128.1206	14mm W, 6mm H	3
1128.1207	14mm W, 7mm H	3
1128.1208	14mm W, 8mm H	3
1128.1209	14mm W, 9mm H	2
1128.1210	14mm W, 10mm H	2
1128.1211	14mm W, 11mm H	1
1128.1212	14mm W, 12mm H	1
1128.1405	16mm W, 5mm H	2
1128.1406	16mm W, 6mm H	3
1128.1407	16mm W, 7mm H	3
1128.1408	16mm W, 8mm H	3
1128.1409	16mm W, 9mm H	2
1128.1410	16mm W, 10mm H	2
1128.1411	16mm W, 11mm H	1
1128.1412	16mm W, 12mm H	1

9128.0002 COALITION AGX® Plate Module, 12x14 and 14x16

COALITION AGX® 15x18 and 15x20mm Plate Set 9128.9003

Part No.	Description	QTY
1128.1505	18mm W, 5mm H	2
1128.1506	18mm W, 6mm H	3
1128.1507	18mm W, 7mm H	3
1128.1508	18mm W, 8mm H	3
1128.1509	18mm W, 9mm H	2
1128.1510	18mm W, 10mm H	2
1128.1511	18mm W, 11mm H	1
1128.1512	18mm W, 12mm H	1
1128.1525	20mm W, 5mm H	1
1128.1526	20mm W, 6mm H	1
1128.1527	20mm W, 7mm H	1
1128.1528	20mm W, 8mm H	1
1128.1529	20mm W, 9mm H	1
1128.1530	20mm W, 10mm H	1
1128.1531	20mm W, 11mm H	1
1128.1532	20mm W, 12mm H	1

9128.0003 COALITION AGX® Plate Module, 15x18 and 15x20mm

COALITION AGX® 12x14 and 14x16mm MODULAR TRIAL SET 9128.9006

COALITION AGX® 12x14mm, 0° Trials

Part No.	Length	QTY
6128.1205	5mm	1
6128.1206	6mm	1
6128.1207	7mm	1
6128.1208	8mm	1
6128.1209	9mm	1
6128.1210	10mm	1
6128.1211	11mm	1
6128.1212	12mm	1

COALITION AGX® 14x16mm, 0° Trials

Part No.	Length	QTY
6128.1405	5mm	1
6128.1406	6mm	1
6128.1407	7mm	1
6128.1408	8mm	1
6128.1409	9mm	1
6128.1410	10mm	1
6128.1411	11mm	1
6128.1412	12mm	1

COALITION AGX® 12x14mm, 7° Trials

Part No.	Length	QTY
6128.1275	5mm	1
6128.1276	6mm	1
6128.1277	7mm	1
6128.1278	8mm	1
6128.1279	9mm	1
6128.1280	10mm	1
6128.1281	11mm	1
6128.1282	12mm	1

COALITION AGX® 14x16mm, 7° Trials

Part No.	Length	QTY
6128.1475	5mm	1
6128.1476	6mm	1
6128.1477	7mm	1
6128.1478	8mm	1
6128.1479	9mm	1
6128.1480	10mm	1
6128.1481	11mm	1
6128.1482	12mm	1

9128.0006 AGX Modular Trial Module, 12x14 and 14x16

COALITION AGX® 15x18 and 15x20mm MODULAR TRIAL SET 9128.9007

COALITION AGX® 15x18, 0° Modular Trials

Part No.	Length	QTY
6128.1505	5mm	1
6128.1506	6mm	1
6128.1507	7mm	1
6128.1508	8mm	1
6128.1509	9mm	1
6128.1510	10mm	1
6128.1511	11mm	1
6128.1512	12mm	1

COALITION AGX® 15x20, 0° Modular Trials

Part No.	Length	QTY
6128.1525	5mm	1
6128.1526	6mm	1
6128.1527	7mm	1
6128.1528	8mm	1
6128.1529	9mm	1
6128.1530	10mm	1
6128.1531	11mm	1
6128.1532	12mm	1

COALITION AGX® 15x18, 7° Modular Trials

Part No.	Length	QTY
6128.1575	5mm	1
6128.1576	6mm	1
6128.1577	7mm	1
6128.1578	8mm	1
6128.1579	9mm	1
6128.1580	10mm	1
6128.1581	11mm	1
6128.1582	12mm	1

COALITION AGX® 15x20, 7° Modular Trials

Part No.	Length	QTY
6128.1535	5mm	1
6128.1536	6mm	1
6128.1537	7mm	1
6128.1538	8mm	1
6128.1539	9mm	1
6128.1540	10mm	1
6128.1541	11mm	1
6128.1542	12mm	1

9128.0007 AGX Modular Trial Module, 12x14 and 14x16

UNIVERSAL ACDF
INSTRUMENT SET 9147.9001

Part No.	Description	QTY
601.020	Distractor, Left	1
601.021	Distractor, Right	1
6147.9001	Trial Holder, Modular Trial / Rasp Heads - Outer Sleeve	3
6147.9002	Trial Holder, Modular Trial / Rasp Heads - Inner Shaft Assembly	3
6147.9003	Packing Block	1
636.450	Quick Connect Handle, Swivel	2
665.504	Bone Packer	1
665.606	Distractor Locking Nuts	4
665.607	Impactor	1
665.608	Distractor Pin Driver	1
665.610	Distractor Pin, 10mm	0
665.612	Distractor Pin, 12mm	2
665.614	Distractor Pin, 14mm	2
665.616	Distractor Pin, 16mm	2
665.618	Distractor Pin, 18mm	2
671.313	VIP® Screwdriver, 2.1mm Hex, QC	1
684.004	Tap, Straight	1
684.006	Awl with Retractable Sleeve	1
684.305	Screwdriver, 2.5mm Hex, Self-Retaining, with Cap	2
684.309	Drill Sleeve Adjuster	1
684.401	Self-Centering Sleeve-Short	2
684.402	Self-Centering Sleeve-Long	2
684.403	Awl with Self-Centering Sleeve, Straight	1
684.404	Awl with Self-Centering Sleeve, Bent	1
684.405	Sleeved Driver	0
684.415	Angled Sleeve	2
684.416	Angled Sleeve with Backing Nut	2
684.417	Angled Driving Shaft	2
684.418	Hex Driver Assembly	2
684.419	Angled Tap Tip	1

Part No.	Description	QTY
684.421	Counter Torque, Angled Instrument	2
684.422	Straight Drill with Self-Centering Sleeve, 12mm	1
684.424	Straight Drill with Self-Centering Sleeve, 14mm	1
684.425	Angled Driver Tip, Short	0
684.426	Straight Drill with Self-Centering Sleeve, 16mm	1
684.428	Straight Drill with Self-Centering Sleeve, 18mm	1
684.430	Straight Drill with Self-Centering Sleeve, 20mm	1
684.432	Angled Drill Tip with Self-Centering Sleeve, 12mm	1
684.434	Angled Drill Tip with Self-Centering Sleeve, 14mm	1
684.436	Angled Drill Tip with Self-Centering Sleeve, 16mm	1
684.438	Angled Drill Tip with Self-Centering Sleeve, 18mm	1
684.440	Angled Drill Tip with Self-Centering Sleeve, 20mm	1
9147.0001	Universal ACDF Instrument Graphic Case	
984.004	COALITION® Module, Angled Instruments	

**Items in gray are additionally available*

UNIVERSAL ACDF 12x14mm
RASP SET 9147.9003

Universal ACDF 12x14mm, 0° Modular Rasps

Part No.	Length	QTY
6147.1025	5mm	1
6147.1026	6mm	1
6147.1027	7mm	1
6147.1028	8mm	1
6147.1029	9mm	1
6147.1030	10mm	1
6147.1031	11mm	1
6147.1032	12mm	1

Universal ACDF 12x14mm, 7° Modular Rasps

Part No.	Length	QTY
6147.1126	6mm	1
6147.1127	7mm	1
6147.1128	8mm	1
6147.1129	9mm	1
6147.1130	10mm	1
6147.1131	11mm	1
6147.1132	12mm	1

9147.0003 12x14mm Universal Rasps

UNIVERSAL ACDF 14x16mm
RASP SET 9147.9004

Universal ACDF 14x16mm, 0° Modular Rasps

Part No.	Length	QTY
6147.2025	5mm	1
6147.2026	6mm	1
6147.2027	7mm	1
6147.2028	8mm	1
6147.2029	9mm	1
6147.2030	10mm	1
6147.2031	11mm	1
6147.2032	12mm	1

Universal ACDF 14x16mm, 7° Modular Rasps

Part No.	Length	QTY
6147.2126	6mm	1
6147.2127	7mm	1
6147.2128	8mm	1
6147.2129	9mm	1
6147.2130	10mm	1
6147.2131	11mm	1
6147.2132	12mm	1

9147.0004 14x16mm Universal Rasps

UNIVERSAL ACDF 15x18mm
RASP SET 9147.9005

Universal ACDF 12x14mm, 0° Modular Rasps

Part No.	Length	QTY
6147.3025	5mm	1
6147.3026	6mm	1
6147.3027	7mm	1
6147.3028	8mm	1
6147.3029	9mm	1
6147.3030	10mm	1
6147.3031	11mm	1
6147.3032	12mm	1

Universal ACDF 12x14mm, 7° Modular Rasps

Part No.	Length	QTY
6147.3126	6mm	1
6147.3127	7mm	1
6147.3128	8mm	1
6147.3129	9mm	1
6147.3130	10mm	1
6147.3131	11mm	1
6147.3132	12mm	1

9147.0005 15x18mm Universal Rasps

UNIVERSAL ACDF
SCREW SET 9147.9008

4.2mm Bone Screw Variable, Self-Tapping

Part No.	Length	QTY
184.012	12mm	6
184.014	14mm	6
184.016	16mm	6
184.018	18mm	4
184.020	20mm	4

3.6mm Bone Screw Variable, Self-Tapping

Part No.	Length	QTY
184.112	12mm	6
184.114	14mm	6
184.116	16mm	6
184.118	18mm	4
184.120	20mm	4

4.2mm Bone Screw Fixed, Self-Tapping

Part No.	Length	QTY
184.032	12mm	6
184.034	14mm	6
184.036	16mm	6
184.038	18mm	4
184.040	20mm	4

3.6mm Bone Screw Fixed, Self-Tapping

Part No.	Length	QTY
184.132	12mm	6
184.134	14mm	6
184.136	16mm	6
184.138	18mm	4
184.140	20mm	4

4.2mm Bone Screw Variable, Self-Drilling

Part No.	Length	QTY
184.052	12mm	6
184.054	14mm	6
184.056	16mm	6
184.058	18mm	4
184.060	20mm	4

3.6mm Bone Screw Variable, Self-Drilling

Part No.	Length	QTY
184.152	12mm	6
184.154	14mm	6
184.156	16mm	6
184.158	18mm	4
184.160	20mm	4

4.2mm Bone Screw Fixed, Self-Drilling

Part No.	Length	QTY
184.072	12mm	6
184.074	14mm	6
184.076	16mm	6
184.078	18mm	4
184.080	20mm	4

3.6mm Bone Screw Fixed, Self-Drilling

Part No.	Length	QTY
184.172	12mm	6
184.174	14mm	6
184.176	16mm	6
184.178	18mm	4
184.180	20mm	4

9147.0008	Screw Module, Universal ACDF

COALITION AGX® RP
INSTRUMENT SET 9128.9021

DTS Guides, 12mm x 14mm

Part No.	Length	QTY
684.155	5mm	1
684.156	6mm	1
684.157	7mm	1
684.158	8mm	1
684.159	9mm	1
684.160	10mm	1
684.161	11mm	1
684.162	12mm	1
684.165	5mm	1
684.166	6mm	1
684.167	7mm	1
684.166	6mm	1
684.167	7mm	1
684.168	8mm	1
684.169	9mm	1
684.170	10mm	1
684.171	11mm	1
684.172	12mm	1
684.175	5mm	1
684.176	6mm	1
684.177	7mm	1
684.178	8mm	1
684.179	9mm	1
684.180	10mm	1
684.181	11mm	1
684.182	12mm	1

Midline Holding Tip

Part No.	Length	QTY
684.406	6mm	1
684.407	7mm	1
684.408	8mm	1
684.409	9mm	1
684.410	10mm	1
684.411	11mm	1
684.412	12mm	1

Free Hand Gripping Tip

Part No.	Description	QTY
684.113	12mm x 14mm	1
684.123	14mm x 16mm	1
684.133	15mm x 18mm	1

Other Instruments

Part No.	Description	QTY
6128.3000	Hand Held Drill Guide	1
6128.3101	COALITION AGX® Assembly Press, Lower	1
6128.3102	COALITION AGX® Assembly Press, Upper	1
650.312	Set Screw Positioner, 2.0mm Hex, Torque-Limiting	1
684.001	Implant/Drill Guide Insertion Holder	1
684.400	Lateral Holder	1

9128.0021 COALITION AGX® RP Graphic Case

COALITION AGX® RP PLATE SETS

COALITION AGX® 12x14 and 14x16mm RP Plate Sets 9128.9022

Part No.	Description	QTY
1128.2205	14mm W, 5mm H	2
1128.2206	14mm W, 6mm H	3
1128.2207	14mm W, 7mm H	3
1128.2208	14mm W, 8mm H	3
1128.2209	14mm W, 9mm H	2
1128.2210	14mm W, 10mm H	2
1128.2211	14mm W, 11mm H	1
1128.2212	14mm W, 12mm H	1
1128.2405	16mm W, 5mm H	2
1128.2406	16mm W, 6mm H	3
1128.2407	16mm W, 7mm H	3
1128.2408	16mm W, 8mm H	3
1128.2409	16mm W, 9mm H	2
1128.2410	16mm W, 10mm H	2
1128.2411	16mm W, 11mm H	1
1128.2412	16mm W, 12mm H	1

9128.0022 COALITION AGX® RP Plate Module, 12x14 and 14x16

COALITION AGX® 15x18 and 15x20mm RP Plate Sets 9128.9023

Part No.	Description	QTY
1128.2505	18mm W, 5mm H	2
1128.2506	18mm W, 6mm H	3
1128.2507	18mm W, 7mm H	3
1128.2508	18mm W, 8mm H	3
1128.2509	18mm W, 9mm H	2
1128.2510	18mm W, 10mm H	2
1128.2511	18mm W, 11mm H	1
1128.2512	18mm W, 12mm H	1
1128.2525	20mm W, 5mm H	1
1128.2526	20mm W, 6mm H	1
1128.2527	20mm W, 7mm H	1
1128.2528	20mm W, 8mm H	1
1128.2529	20mm W, 9mm H	1
1128.2530	20mm W, 10mm H	1
1128.2531	20mm W, 11mm H	1
1128.2532	20mm W, 12mm H	1

9128.0023 COALITION AGX® RP Plate Module, 15x18 and 15x20

COALITION AGX® RP 12x14 and 14x16mm MODULAR TRIAL SET 9128.9026

COALITION AGX® RP 12x14, 0° Modular Trials

Part No.	Length	QTY
6128.2205	5mm H	1
6128.2206	6mm H	1
6128.2207	7mm H	1
6128.2208	8mm H	1
6128.2209	9mm H	1
6128.2210	10mm H	1
6128.2211	11mm H	1
6128.2212	12mm H	1

COALITION AGX® RP 14x16, 0° Modular Trials

Part No.	Length	QTY
6128.2405	5mm H	1
6128.2406	6mm H	1
6128.2407	7mm H	1
6128.2408	8mm H	1
6128.2409	9mm H	1
6128.2410	10mm H	1
6128.2411	11mm H	1
6128.2412	12mm H	1

COALITION AGX® RP 12x14, 7° Modular Trials

Part No.	Length	QTY
6128.2275	5mm H	1
6128.2276	6mm H	1
6128.2277	7mm H	1
6128.2278	8mm H	1
6128.2279	9mm H	1
6128.2280	10mm H	1
6128.2281	11mm H	1
6128.2282	12mm H	1

COALITION AGX® RP 14x16, 7° Modular Trials

Part No.	Length	QTY
6128.2475	5mm H	1
6128.2476	6mm H	1
6128.2477	7mm H	1
6128.2478	8mm H	1
6128.2479	9mm H	1
6128.2480	10mm H	1
6128.2481	11mm H	1
6128.2482	12mm H	1

9128.0026 AGX Modular RP Trial Module, 12x14 and 14x16

COALITION AGX® RP 15x18 and 15x20mm MODULAR TRIAL SET 9128.9027

COALITION AGX® RP 15x18, 0° Modular Trials

Part No.	Length	QTY
6128.2505	5mm H	1
6128.2506	6mm H	1
6128.2507	7mm H	1
6128.2508	8mm H	1
6128.2509	9mm H	1
6128.2510	10mm H	1
6128.2511	11mm H	1
6128.2512	12mm H	1

COALITION AGX® RP 15x20, 0° Modular Trials

Part No.	Length	QTY
6128.2525	5mm H	1
6128.2526	6mm H	1
6128.2527	7mm H	1
6128.2528	8mm H	1
6128.2529	9mm H	1
6128.2530	10mm H	1
6128.2531	11mm H	1
6128.2532	12mm H	1

COALITION AGX® RP 15x18, 7° Modular Trials

Part No.	Length	QTY
6128.2575	5mm H	1
6128.2576	6mm H	1
6128.2577	7mm H	1
6128.2578	8mm H	1
6128.2579	9mm H	1
6128.2580	10mm H	1
6128.2581	11mm H	1
6128.2582	12mm H	1

COALITION AGX® RP 15x20, 7° Modular Trials

Part No.	Length	QTY
6128.2535	5mm H	1
6128.2536	6mm H	1
6128.2537	7mm H	1
6128.2538	8mm H	1
6128.2539	9mm H	1
6128.2540	10mm H	1
6128.2541	11mm H	1
6128.2542	12mm H	1

9128.0027 AGX Modular RP Trial Module, 12x14 and 14x16

COALITION AGX® RP 12°
MODULAR TRIAL SET 9128.9028

COALITION AGX® 12x14mm, 12° Modular Trials

Part No.	Length	QTY
6128.2285	5mm H	1
6128.2286	6mm H	1
6128.2287	7mm H	1
6128.2288	8mm H	1
6128.2289	9mm H	1
6128.2290	10mm H	1
6128.2291	11mm H	1
6128.2292	12mm H	1

COALITION AGX® 14x16mm, 12° Modular Trials

Part No.	Length	QTY
6128.2485	5mm H	1
6128.2486	6mm H	1
6128.2487	7mm H	1
6128.2488	8mm H	1
6128.2489	9mm H	1
6128.2490	10mm H	1
6128.2491	11mm H	1
6128.2492	12mm H	1

COALITION AGX® 15x18mm, 12° Modular Trials

Part No.	Length	QTY
6128.2585	5mm H	1
6128.2586	6mm H	1
6128.2587	7mm H	1
6128.2588	8mm H	1
6128.2589	9mm H	1
6128.2590	10mm H	1
6128.2591	11mm H	1
6128.2592	12mm H	1

COALITION AGX® RP 15x20, 12° Modular Trials

Part No.	Length	QTY
6128.2545	5mm H	1
6128.2546	6mm H	1
6128.2547	7mm H	1
6128.2548	8mm H	1
6128.2549	9mm H	1
6128.2550	10mm H	1
6128.2551	11mm H	1
6128.2552	12mm H	1

9128.0028 AGX RP Modular Trial Module, 12°

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.

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

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:

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.

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

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).

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		

DI211A REV A

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

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

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