HEDRON C™

3D Printed ACDF Spacer

SURGICAL TECHNIQUE GUIDE

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

HEDRON C™

HEDRON C™

3D Printed ACDF Spacer

HEDRON C™ spacers are anterior cervical interbody fusion devices. HEDRON C™ spacers feature a biomimetic porous scaffolding designed to promote bone formation onto and through the implant.

Implants are available in numerous footprints, heights, and sagittal profiles to accommodate various patient anatomies. The system includes innovative instruments designed to streamline the anterior cervical fusion procedure.

Face of Fusion

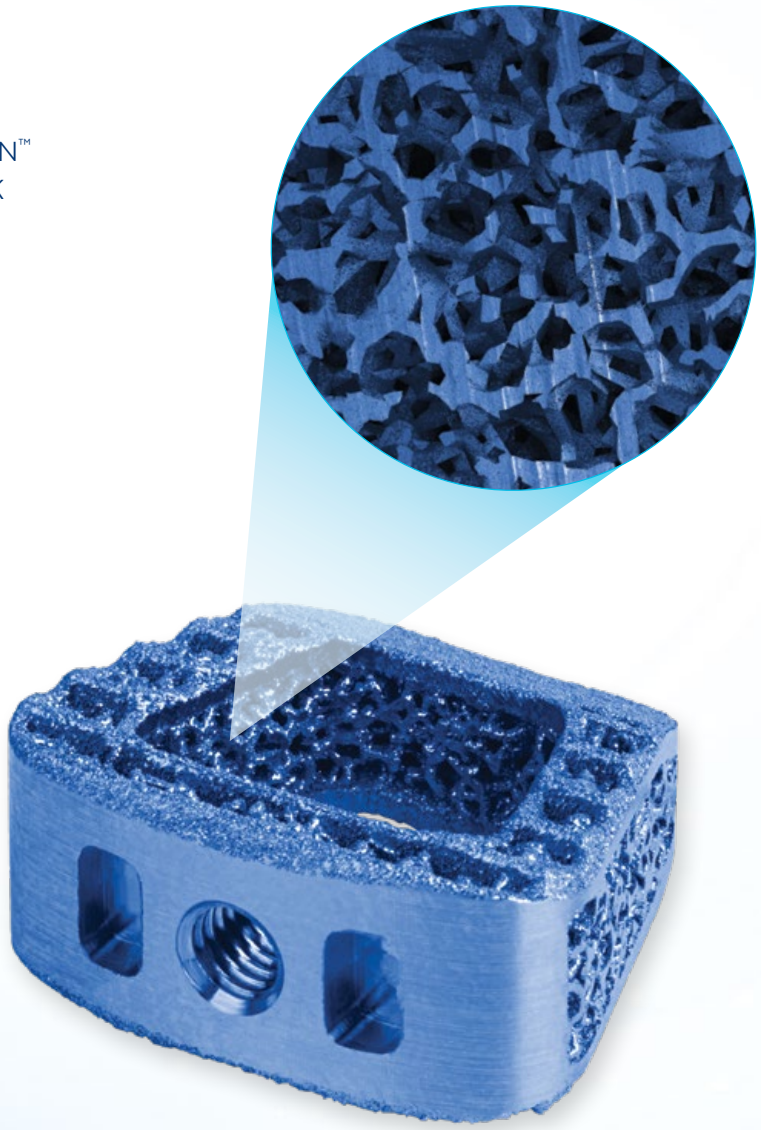
An ovine interbody study demonstrated significantly more bone ingrowth within HEDRON™ implants at 6 weeks post-op compared to PEEK and solid titanium implants.*

Resistance to Expulsion and Migration

Directional ridged teeth are designed to resist implant expulsion and migration.

Ease of Insertion

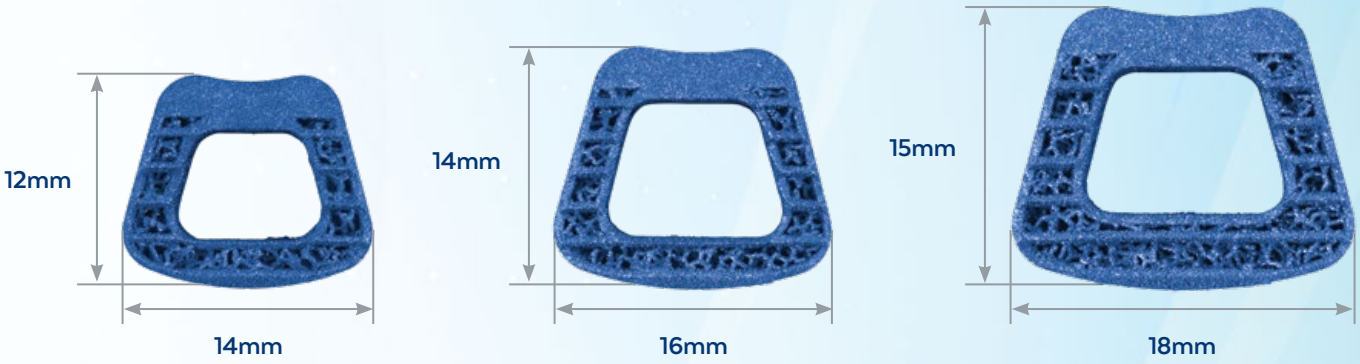
Self-distracting leading edge and smooth edges help to ease insertion.



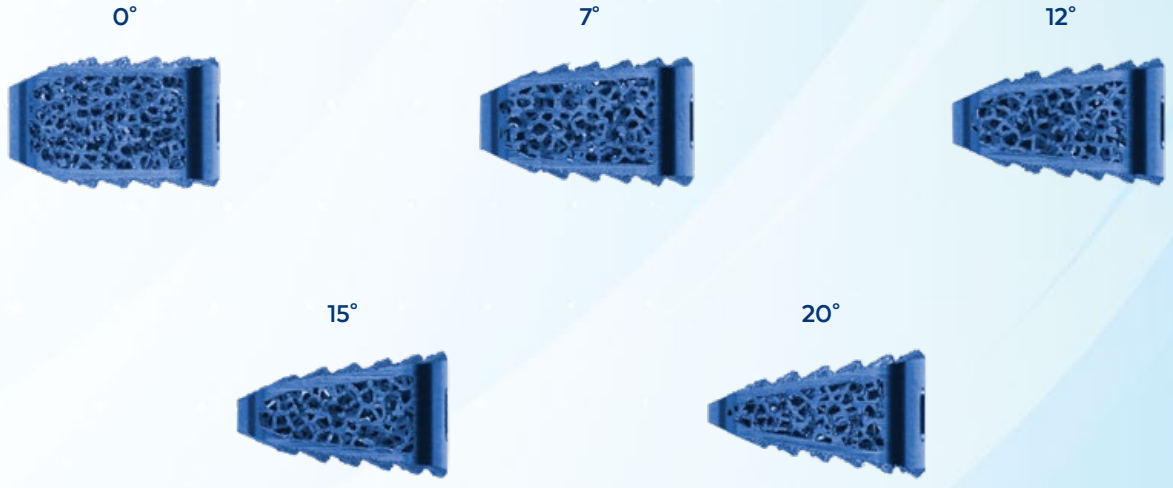
*Data on file

HEDRON C™ 3D Printed ACDF Spacer

- **Footprints:** 12x14, 14x16, and 15x18mm
- **Heights:** 5-12mm (in 1mm increments)
- **Sagittal profiles:** 0°, 7°, 12°, 15°, and 20°

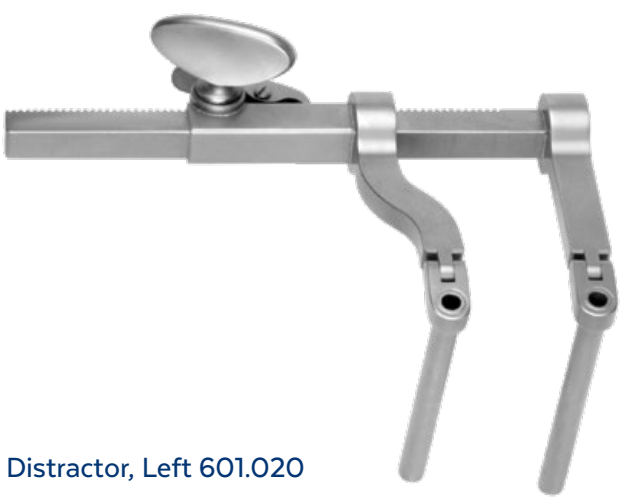


Sagittal Profiles

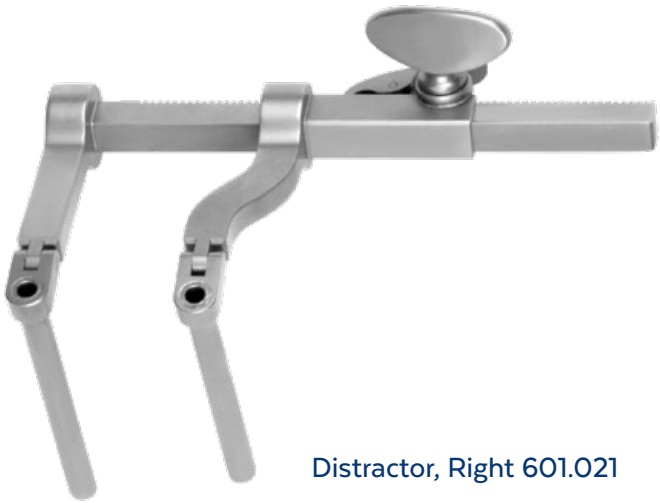


INSTRUMENT OVERVIEW

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

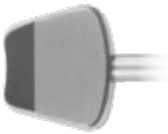
Distractor Pin Driver 665.608

TRIALS

COLONIAL® Trial Rasps

12x14mm		
Height	**0°**	**7°**
5mm	665.325	-
6mm	665.326	665.426
7mm	665.327	665.427
8mm	665.328	665.428
9mm	665.329	665.429
10mm	665.330	665.430
11mm	665.331	665.431
12mm	665.332	665.432

COLONIAL® Trials

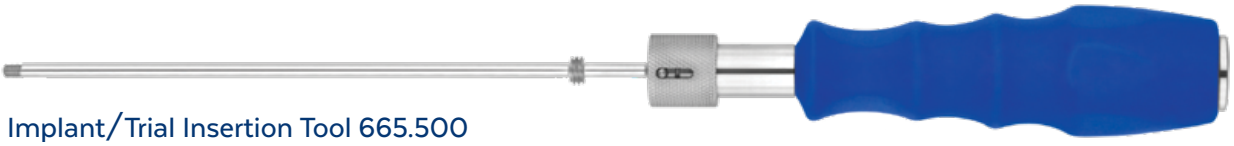


14x16mm		
Height	**0°**	**7°**
5mm	665.805	665.705
6mm	665.806	665.706
7mm	665.807	665.707
8mm	665.808	665.708
9mm	665.809	665.709
10mm	665.810	665.710
11mm	665.811	665.711
12mm	665.812	665.712

12x14mm		
Height	**0°**	**7°**
5mm	665.305	665.405
6mm	665.306	665.406
7mm	665.307	665.407
8mm	665.308	665.408
9mm	665.309	665.409
10mm	665.310	665.410
11mm	665.311	665.411
12mm	665.312	665.412

15x18mm		
Height	**0°**	**7°**
5mm	665.045	665.065
6mm	665.046	665.066
7mm	665.047	665.067
8mm	665.048	665.068
9mm	665.049	665.069
10mm	665.050	665.070
11mm	665.051	665.071
12mm	665.052	665.072

IMPLANT/TRIAL HOLDER



Implant/Trial Insertion Tool 665.500

Implant/Trial Insertion Sleeve 665.501

Implant/Trial Insertion Tool 665.500
Implant/Trial Insertion Sleeve 665.501
(Assembled)

ADDITIONAL INSTRUMENTS

MAINTAIN® Holder 601.135

Box Curette 665.502

Bone Packing Block 665.503

Bone Packer 665.504

Impactor 665.607

UNIVERSAL ACDF MODULAR TRIALS

Trial Holder, Modular Trial/Rasp Heads - Inner Shaft Assembly 6147.9002

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

Trial Holder, Modular Trial/Rasp Heads - Inner Shaft Assembly 6147.9002
Trial Holder, Modular Trial/Rasp Heads - Outer Sleeve 6147.9001
(Assembled)

12x14mm			
Height	**12°**	**15°**	**20°**
5mm	-	-	-
6mm	6147.1206	6147.1306	-
7mm	6147.1207	6147.1307	6147.1407
8mm	6147.1208	6147.1308	6147.1408
9mm	6147.1209	6147.1309	6147.1409
10mm	6147.1210	6147.1310	6147.1410
11mm	6147.1211	6147.1311	6147.1411
12mm	6147.1212	6147.1312	6147.1412

14x16mm			
Height	**12°**	**15°**	**20°**
5mm	-	-	-
6mm	6147.2206	-	-
7mm	6147.2207	6147.2307	-
8mm	6147.2208	6147.2308	6147.2408
9mm	6147.2209	6147.2309	6147.2409
10mm	6147.2210	6147.2310	6147.2410
11mm	6147.2211	6147.2311	6147.2411
12mm	6147.2212	6147.2312	6147.2412

15x18mm			
Height	**12°**	**15°**	**20°**
5mm	-	-	-
6mm	6147.3206	-	-
7mm	6147.3207	6147.3307	-
8mm	6147.3208	6147.3308	6147.3408
9mm	6147.3209	6147.3309	6147.3409
10mm	6147.3210	6147.3310	6147.3410
11mm	6147.3211	6147.3311	6147.3411
12mm	6147.3212	6147.3312	6147.3412

SURGICAL TECHNIQUE

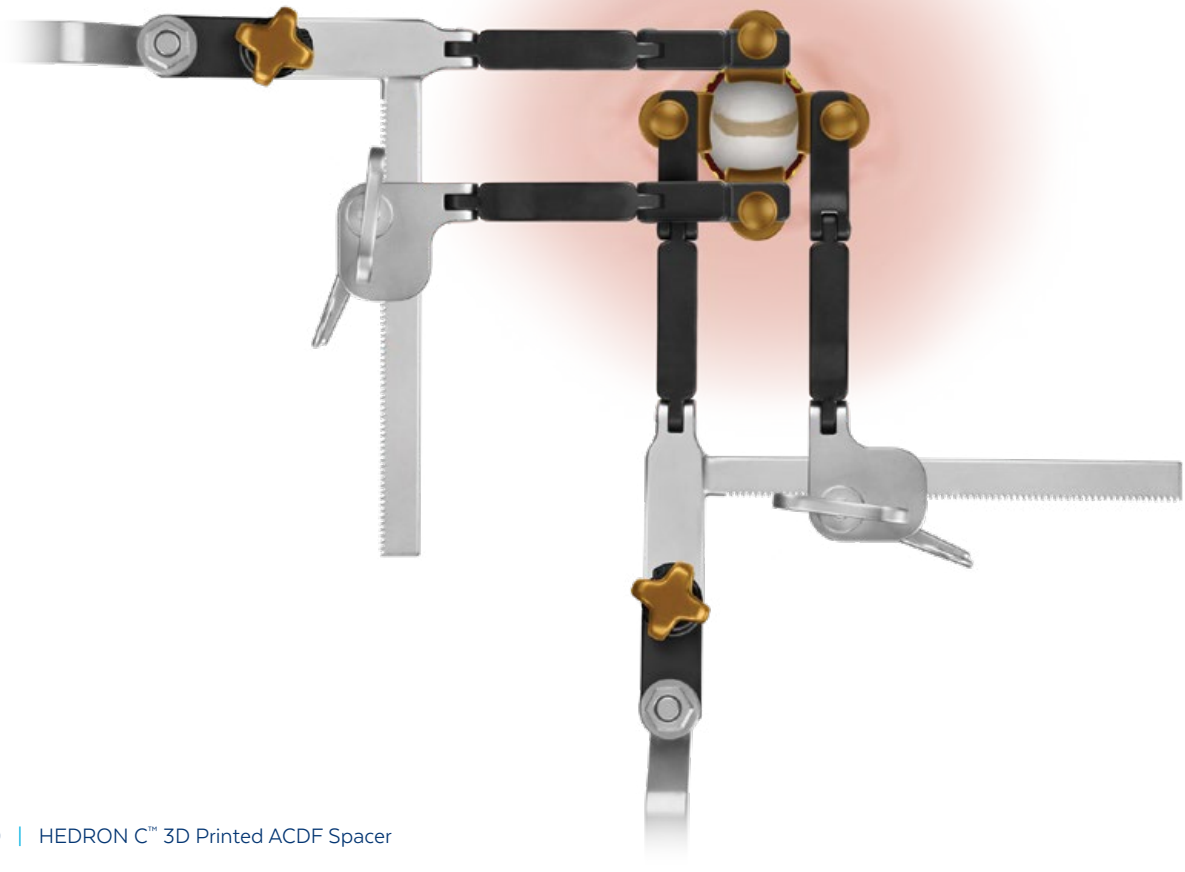
HEDRON C™

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 C™ spacers are to be used with supplemental fixation. Please refer to the technique guide for the corresponding supplemental fixation system for specific instructions.

STEP 1 APPROACH AND DISC PREPARATION

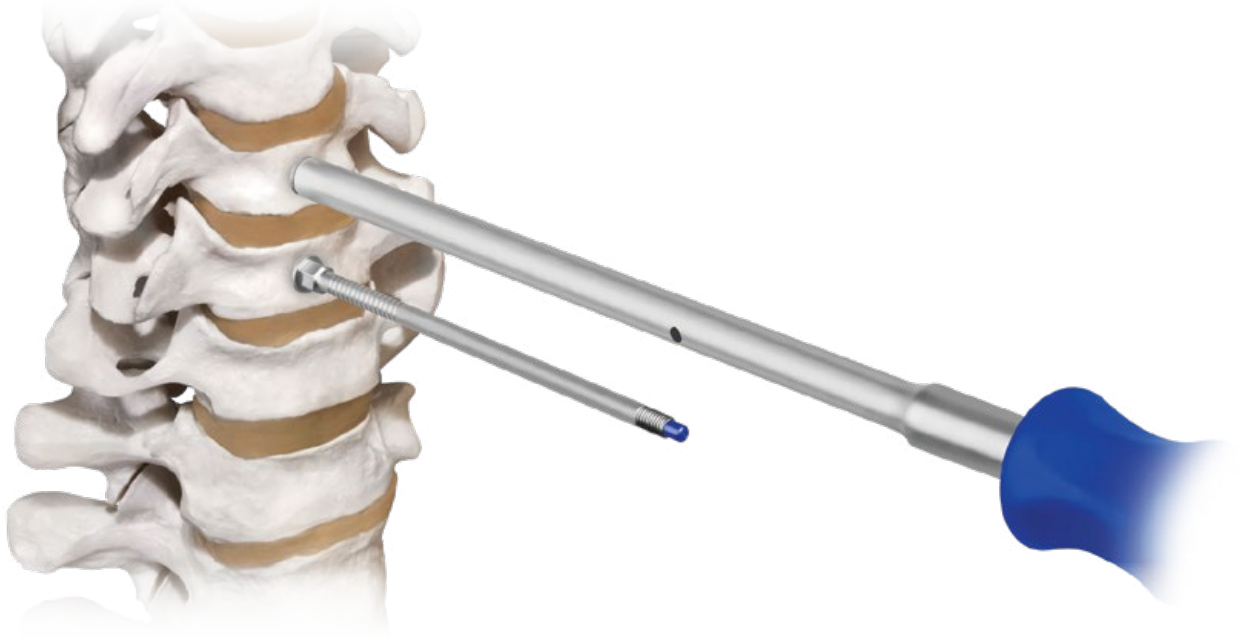
An anterior cervical approach is used to implant the HEDRON C™ Spacer. The patient is placed under anesthesia and positioned supine with support of the posterior cervical spine to maintain cervical lordosis. Traditional cervical retractors may be used. The operative area is carefully cleaned and an incision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



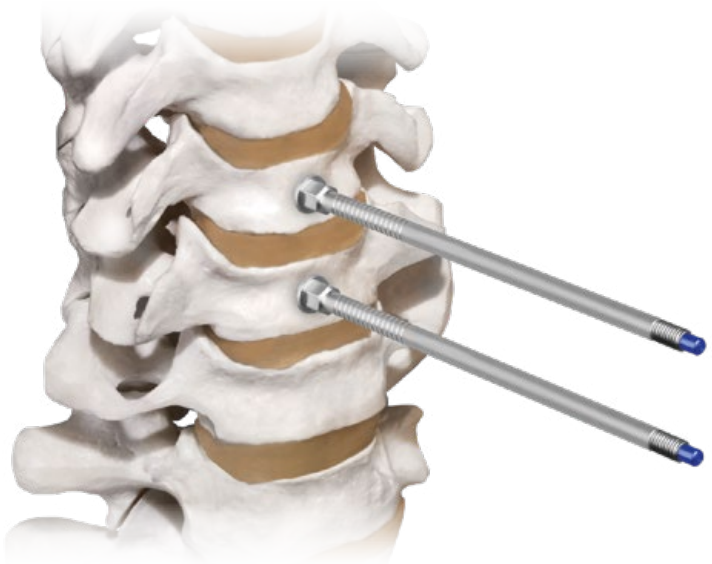
STEP 2 DISTRACTION

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 supplemental fixation.



Inserting Distractor Pins



Distractor Pins inserted

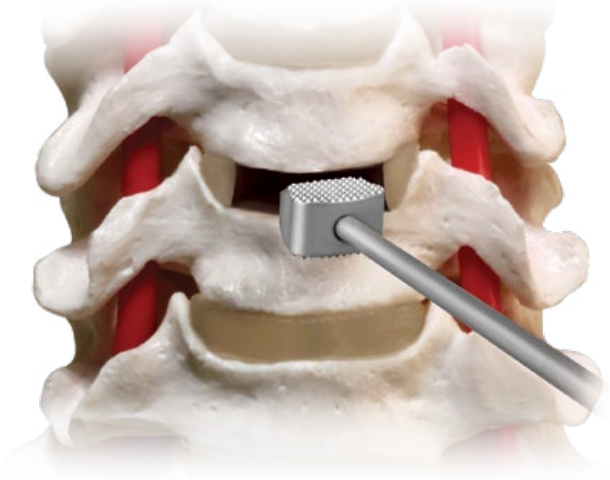
Place the Distractor, right or left as desired, over pins until seated. Once seated, secure the Distractor by attaching the **Distractor Locking Nuts** and rotating clockwise. Rotate the ratchet handle clockwise to distract to the desired amount, carefully avoiding over-distraction. Distraction may be used throughout the technique to provide visualization and access to the disc and osseous structures.

Distracting disc space using Distractor

STEP 3 DISCECTOMY/ENDPLATE PREPARATION

Expose the disc space. Leaving the lateral annulus intact, remove the intervertebral disc and any osteophytes, using rongeurs, 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 trial design and may be used to expose bleeding bone. Removal of Distractor Pins is recommended before spacer insertion, but optional if needed to maintain distraction of the disc space.

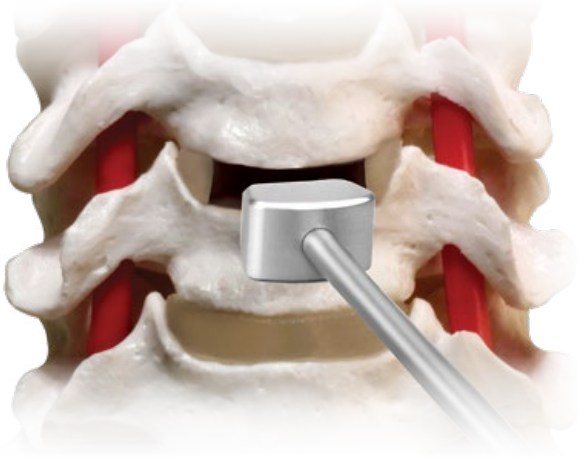
Note: Excessive endplate preparation may weaken the vertebral endplates and may result in subsidence.



Endplate preparation using Trial Rasp

STEP 4 IMPLANT SIZING

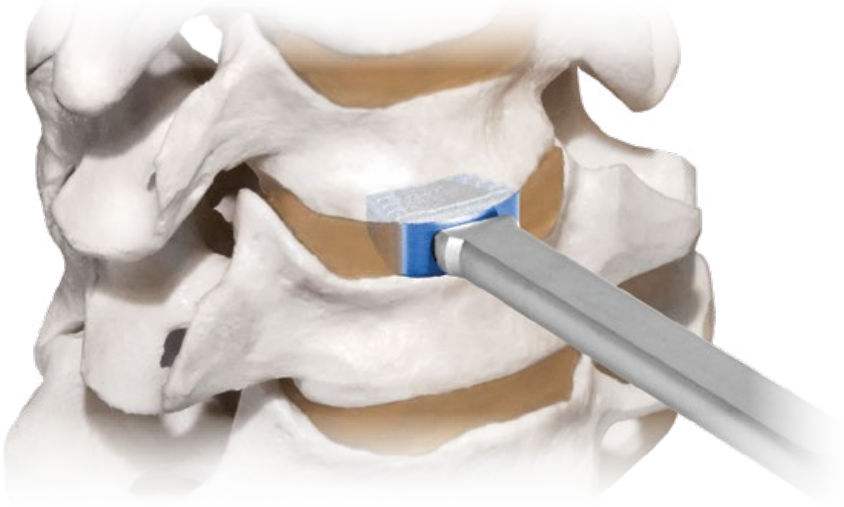
Determine the appropriate spacer profile for the desired segment. Insert the smallest Trial into the disc space first, moving to larger trials as needed. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and to stabilize the segment. Confirm size using fluoroscopy and tactile feedback.



Trialing for spacer size

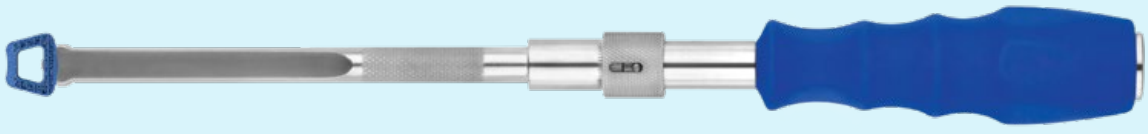
STEP 5 IMPLANT INSERTION

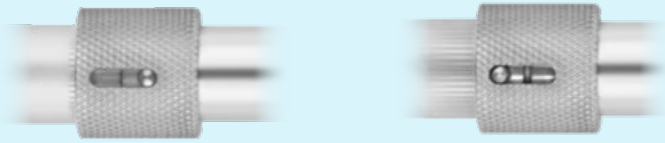
Select an appropriately sized implant and fill with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. Thread the implant onto the **Implant/Trial Holder** and insert into the intervertebral space. The spacer should be slightly recessed into the disc space. If needed, the **Impactor** may be used for light impaction. Where possible, supplemental bone graft material should be packed in and around the implant.



USING THE IMPLANT/TRIAL HOLDER

Ensure that the Implant/Trial Holder is in the unlocked position. Thread the implant onto the holder by rotating the handle clockwise. Lock the holder by pushing the locking nut forward. The implant is now ready to insert. To disengage the implant from the holder, unlock the holder by pulling the locking nut back and rotate the handle counterclockwise.

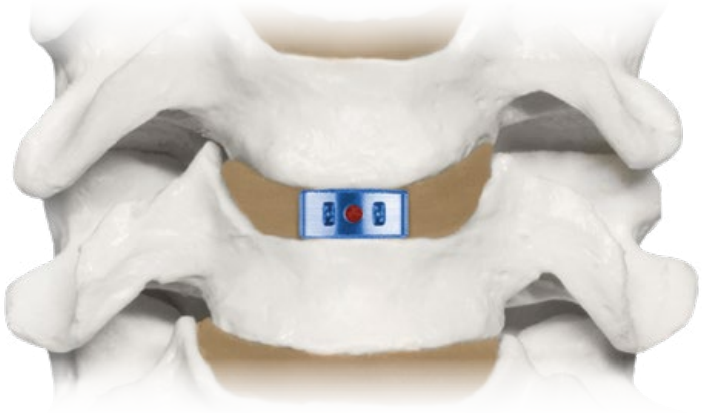




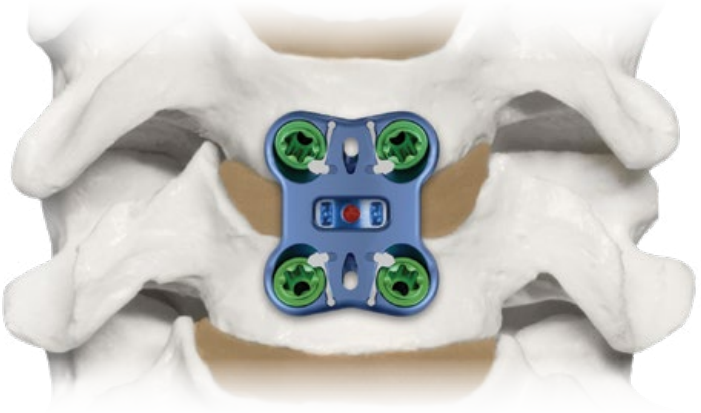
Locked Unlocked

FINAL POSITION

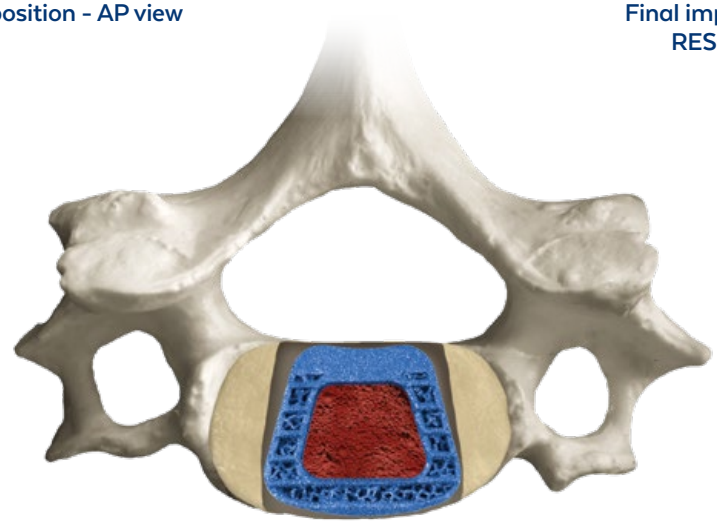
HEDRON C™ is required for use with supplemental fixation (e.g. RESONATE™, PROVIDENCE®, or other anterior cervical plating systems). Refer to the corresponding supplemental fixation system's surgical technique guide for specific instructions.



Final implant position - AP view



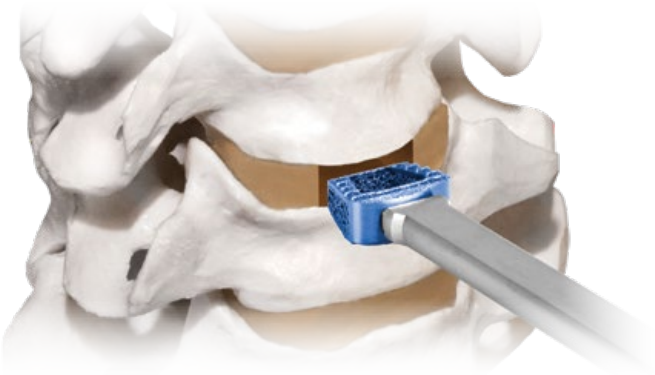
Final implant position with RESONATE™ plate



Final implant position - axial view

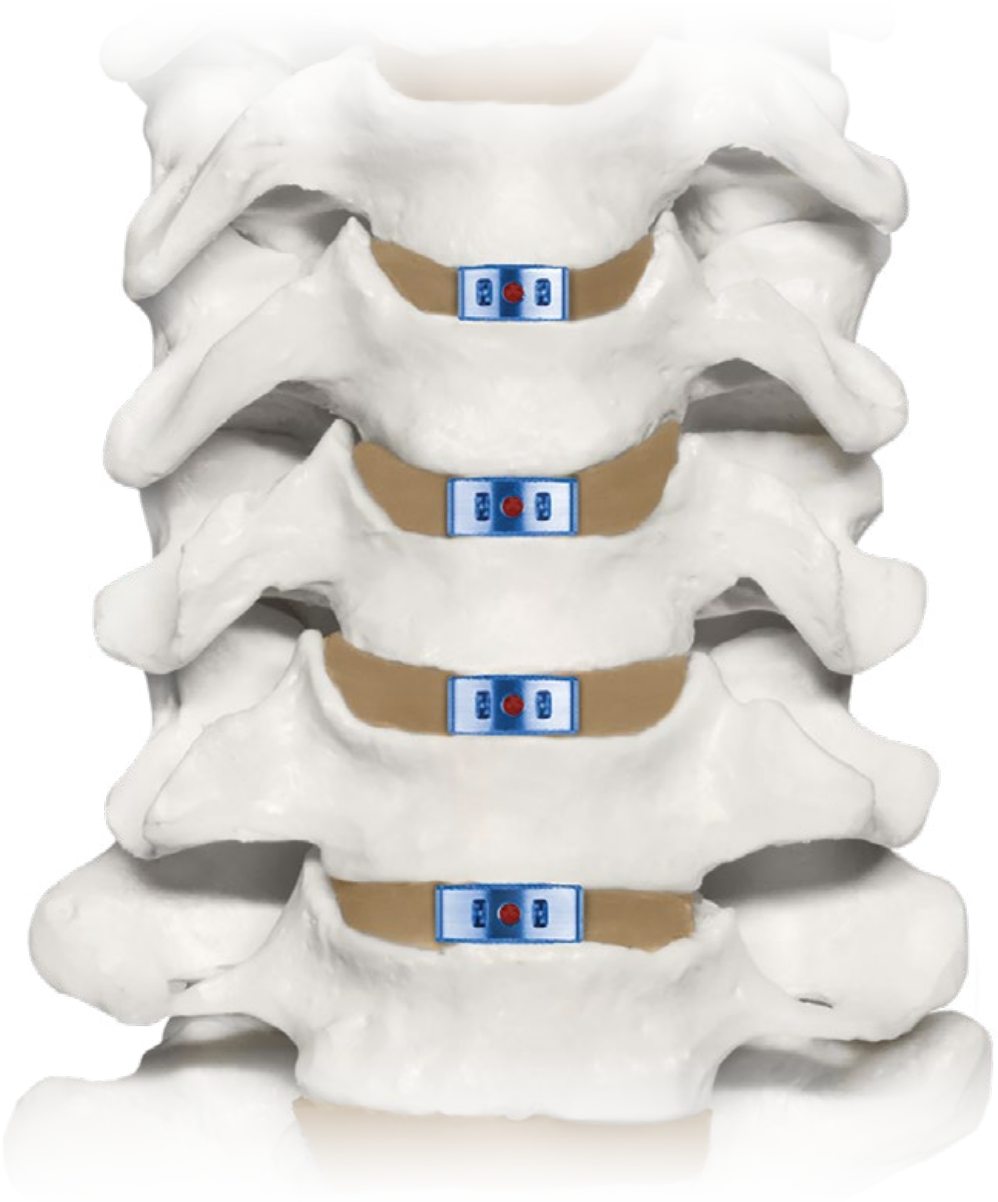
OPTIONAL: REMOVAL AND/OR REVISION

Remove the implant using the Implant/Trial Holder, forceps, or other manual surgical instruments.



MULTI-LEVEL IMPLANT INSERTION

To implant an additional spacer, repeat steps 1-5. A 4-level construct is shown below (prior to insertion of supplemental fixation).



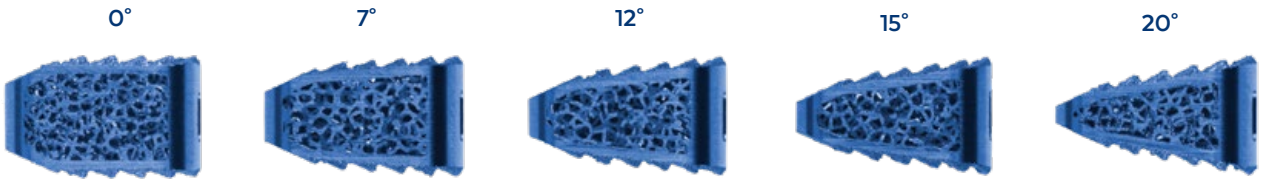
ADDITIONAL SPECIFICATIONS

Bone Graft Volumes

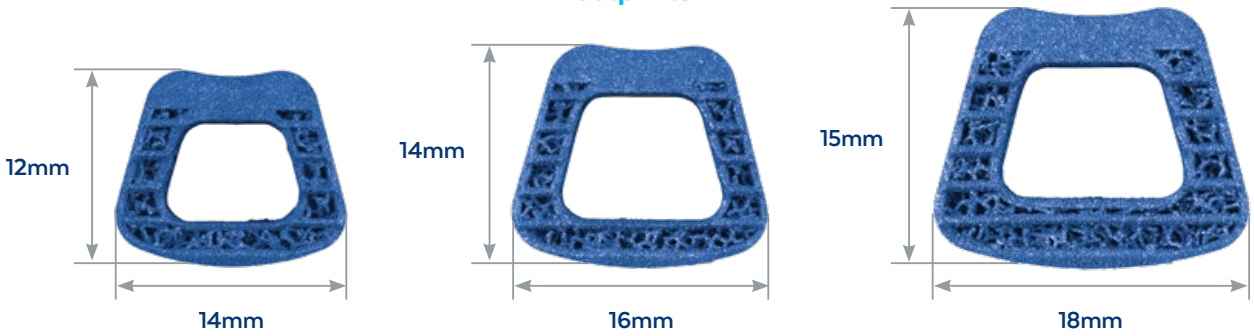
	HEDRON C™ Bone Graft Volume (cc)					
	12x14mm		14x16mm		15x18mm	
	Large		XL		XXL	
Heights	0°	7°	0°	7°	0°	7°
5mm	0.24	0.21	0.38	0.33	0.39	0.33
6mm	0.28	0.26	0.45	0.40	0.46	0.40
7mm	0.32	0.30	0.52	0.47	0.53	0.47
8mm	0.37	0.34	0.59	0.54	0.61	0.54
9mm	0.41	0.39	0.66	0.60	0.68	0.62
10mm	0.45	0.43	0.73	0.67	0.75	0.69
11mm	0.50	0.47	0.80	0.74	0.82	0.76
12mm	0.54	0.52	0.87	0.81	0.89	0.83

	HEDRON C™ Hyperlordotic Bone Graft Volume (cc)								
	12x14mm			14x16mm			15x18mm		
	Large			XL			XXL		
Heights	12°	15°	20°	12°	15°	20°	12°	15°	20°
5mm	-	-	-	-	-	-	-	-	-
6mm	0.24	0.22	-	0.36	-	-	0.36	-	-
7mm	0.28	0.27	0.25	0.43	0.41	-	0.43	0.54	-
8mm	0.32	0.31	0.29	0.50	0.48	0.44	0.50	0.63	0.57
9mm	0.37	0.36	0.33	0.57	0.54	0.51	0.57	0.72	0.67
10mm	0.41	0.40	0.38	0.64	0.61	0.58	0.65	0.81	0.75
11mm	0.46	0.44	0.42	0.71	0.68	0.64	0.72	0.90	0.85
12mm	0.50	0.48	0.46	0.78	0.75	0.72	0.79	0.99	0.94

Sagittal Profiles



Footprints



HEDRON C™ 12x14 and 14x16mm
IMPLANT SET 9211.9001

HEDRON C™ Spacer, 12x14mm, 0°

Part No.	Length	QTY
1211.2405S	5mm	2
1211.2406S	6mm	3
1211.2407S	7mm	3
1211.2408S	8mm	3
1211.2409S	9mm	2
1211.2410S	10mm	2
1211.2411S	11mm	1
1211.2412S	12mm	1

HEDRON C™ Spacer, 14x16mm, 0°

Part No.	Length	QTY
1211.4605S	5mm	2
1211.4606S	6mm	3
1211.4607S	7mm	3
1211.4608S	8mm	3
1211.4609S	9mm	2
1211.4610S	10mm	2
1211.4611S	11mm	1
1211.4612S	12mm	1

HEDRON C™ Spacer, 12x14mm, 7°

Part No.	Length	QTY
1211.2415S	5mm	2
1211.2416S	6mm	3
1211.2417S	7mm	3
1211.2418S	8mm	3
1211.2419S	9mm	2
1211.2420S	10mm	2
1211.2421S	11mm	1
1211.2422S	12mm	1

HEDRON C™ Spacer, 14x16mm, 7°

Part No.	Length	QTY
1211.4615S	5mm	2
1211.4616S	6mm	3
1211.4617S	7mm	3
1211.4618S	8mm	3
1211.4619S	9mm	2
1211.4620S	10mm	2
1211.4621S	11mm	1
1211.4622S	12mm	1

9211.0001	HEDRON C™ 12x14 and 14x16 Spacer Soft Case

HEDRON C™ 15x18mm
IMPLANT SET 9211.9002

HEDRON C™ Spacer, 15x18mm, 0°

Part No.	Length	QTY
1211.5805S	5mm	2
1211.5806S	6mm	3
1211.5807S	7mm	3
1211.5808S	8mm	3
1211.5809S	9mm	2
1211.5810S	10mm	2
1211.5811S	11mm	1
1211.5812S	12mm	1

HEDRON C™ Spacer, 15x18mm, 7°

Part No.	Length	QTY
1211.5815S	5mm	2
1211.5816S	6mm	3
1211.5817S	7mm	3
1211.5818S	8mm	3
1211.5819S	9mm	2
1211.5820S	10mm	2
1211.5821S	11mm	1
1211.5822S	12mm	1

9211.0002 HEDRON C™ 15x18 Spacer Soft Case

HEDRON C™ 12x14mm, 12° and 15° IMPLANT SET 9211.9003

HEDRON C™ Spacer, 12x14mm, 12°

Part No.	Length	QTY
1211.2426S	6mm	3
1211.2427S	7mm	3
1211.2428S	8mm	3
1211.2429S	9mm	2
1211.2430S	10mm	2
1211.2431S	11mm	1
1211.2432S	12mm	1

HEDRON C™ Spacer, 12x14mm, 15°

Part No.	Length	QTY
1211.2436S	6mm	3
1211.2437S	7mm	3
1211.2438S	8mm	3
1211.2439S	9mm	2
1211.2440S	10mm	2
1211.2441S	11mm	1
1211.2442S	12mm	1

9211.0003	HEDRON C™ 12x14 12° and 15° Spacer Soft Case

HEDRON C™ 14x16mm, 12° and 15° IMPLANT SET 9211.9004

HEDRON C™ Spacer, 14x16mm, 12°

Part No.	Length	QTY
1211.4626S	6mm	3
1211.4627S	7mm	3
1211.4628S	8mm	3
1211.4629S	9mm	2
1211.4630S	10mm	2
1211.4631S	11mm	1
1211.4632S	12mm	1

HEDRON C™ Spacer, 14x16mm, 15°

Part No.	Length	QTY
1211.4637S	7mm	3
1211.4638S	8mm	3
1211.4639S	9mm	2
1211.4640S	10mm	2
1211.4641S	11mm	1
1211.4642S	12mm	1

9211.0004	HEDRON C™ 14x16 12° and 15° Spacer Soft Case

HEDRON C™ 15x18mm, 12° and 15° IMPLANT SET 9211.9005

HEDRON C™ Spacer, 15x18mm, 12°

Part No.	Length	QTY
1211.5826S	6mm	3
1211.5827S	7mm	3
1211.5828S	8mm	3
1211.5829S	9mm	2
1211.5830S	10mm	2
1211.5831S	11mm	1
1211.5832S	12mm	1

HEDRON C™ Spacer, 15x18mm, 15°

Part No.	Length	QTY
1211.5837S	7mm	3
1211.5838S	8mm	3
1211.5839S	9mm	2
1211.5840S	10mm	2
1211.5841S	11mm	1
1211.5842S	12mm	1

9211.0005	HEDRON C™ 15x18 12° and 15° Spacer Soft Case

HEDRON C™ 20°
IMPLANT SET 9211.9006

HEDRON C™ Spacer, 12x14mm, 20°

Part No.	Length	QTY
1211.2447S	7mm	3
1211.2448S	8mm	3
1211.2449S	9mm	2
1211.2450S	10mm	2
1211.2451S	11mm	1
1211.2452S	12mm	1

HEDRON C™ Spacer, 14x16mm, 20°

Part No.	Length	QTY
1211.4648S	8mm	3
1211.4649S	9mm	2
1211.4650S	10mm	2
1211.4651S	11mm	1
1211.4652S	12mm	1

HEDRON C™ Spacer, 15x18mm, 20°

Part No.	Length	QTY
1211.5848S	8mm	3
1211.5849S	9mm	2
1211.5850S	10mm	2
1211.5851S	11mm	1
1211.5852S	12mm	1

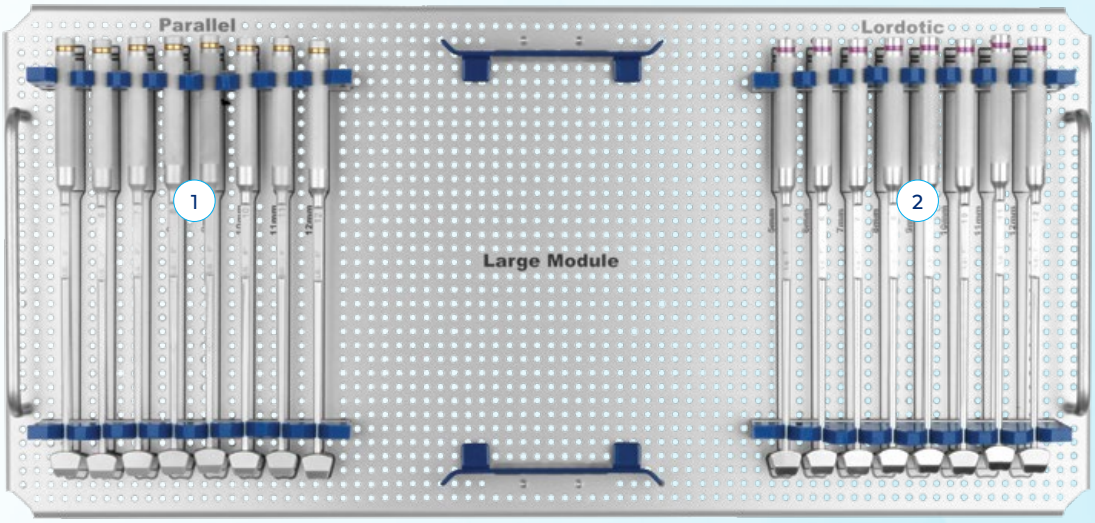
9211.0006	HEDRON C™ 20° Spacer Soft Case

COLONIAL® ACDF
INSTRUMENT SET 965.905

	Part No.	Description	QTY
1	665.305	COLONIAL® Large Trial, Parallel, 5mm	1
	665.306	COLONIAL® Large Trial, Parallel, 6mm	1
	665.307	COLONIAL® Large Trial, Parallel, 7mm	1
	665.308	COLONIAL® Large Trial, Parallel, 8mm	1
	665.309	COLONIAL® Large Trial, Parallel, 9mm	1
	665.310	COLONIAL® Large Trial, Parallel, 10mm	1
	665.311	COLONIAL® Large Trial, Parallel, 11mm	1
	665.312	COLONIAL® Large Trial, Parallel, 12mm	1
2	665.405	COLONIAL® Large Trial, Lordotic, 5mm	1
	665.406	COLONIAL® Large Trial, Lordotic, 6mm	1
	665.407	COLONIAL® Large Trial, Lordotic, 7mm	1
	665.408	COLONIAL® Large Trial, Lordotic, 8mm	1
	665.409	COLONIAL® Large Trial, Lordotic, 9mm	1
	665.410	COLONIAL® Large Trial, Lordotic, 10mm	1
	665.411	COLONIAL® Large Trial, Lordotic, 11mm	1
	665.412	COLONIAL® Large Trial, Lordotic, 12mm	1
	665.413	COLONIAL® Large Trial, Lordotic, 13mm	-
	665.414	COLONIAL® Large Trial, Lordotic, 14mm	-
3	665.326	COLONIAL® Rasp, Large, Parallel, 6mm	1
	665.327	COLONIAL® Rasp, Large, Parallel, 7mm	1
	665.328	COLONIAL® Rasp, Large, Parallel, 8mm	1
	665.329	COLONIAL® Rasp, Large, Parallel, 9mm	1
	665.330	COLONIAL® Rasp, Large, Parallel, 10mm	1
	665.331	COLONIAL® Rasp, Large, Parallel, 11mm	1
	665.332	COLONIAL® Rasp, Large, Parallel, 12mm	1
4	665.426	COLONIAL® Rasp, Large, Lordotic, 6mm	1
	665.427	COLONIAL® Rasp, Large, Lordotic, 7mm	1
	665.428	COLONIAL® Rasp, Large, Lordotic, 8mm	1
	665.429	COLONIAL® Rasp, Large, Lordotic, 9mm	1
	665.430	COLONIAL® Rasp, Large, Lordotic, 10mm	1
	665.431	COLONIAL® Rasp, Large, Lordotic, 11mm	1

	Part No.	Description	QTY
5	601.020	Distractor, Left	1
6	601.021	Distractor, Right	1
7	601.135	MAINTAIN® Holder	1
8	665.500	Implant/Trial Insertion Tool	2
9	665.501	Implant/Trial Insertion Sleeve	2
10	665.502	Box Curette	1
11	665.503	Bone Packing Block	1
12	665.504	Bone Packer	1
13	665.606	Distractor Locking Nuts	4
14	665.607	Impactor	1
15	665.608	Distractor Pin, Driver	1
16	665.612	Distractor Pin, 12mm	2
17	665.614	Distractor Pin, 14mm	2
18	665.616	Distractor Pin, 16mm	2
19	665.618	Distractor Pin, 18mm	2
	965.005	COLONIAL® Graphic Case	

*Items in gray are additionally available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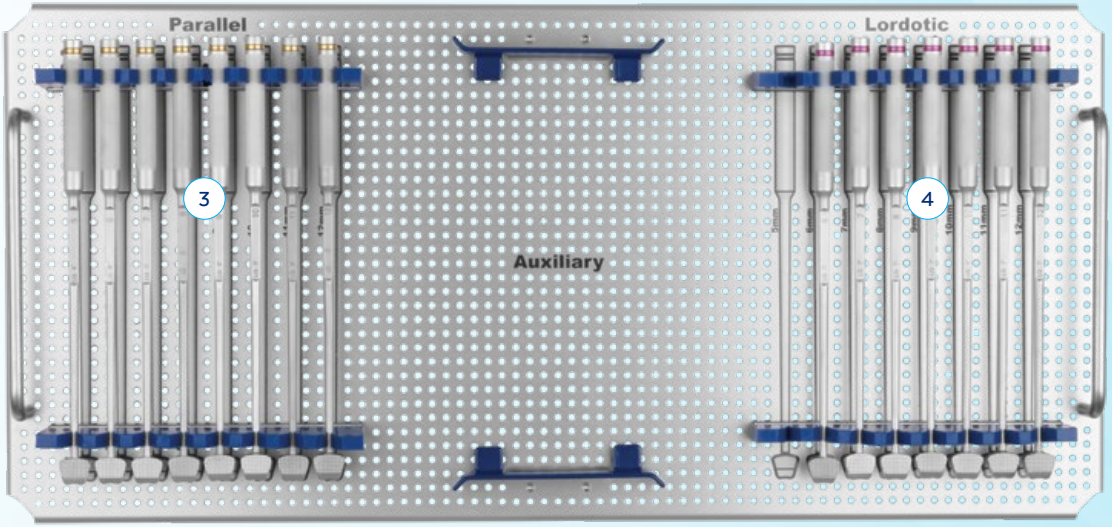
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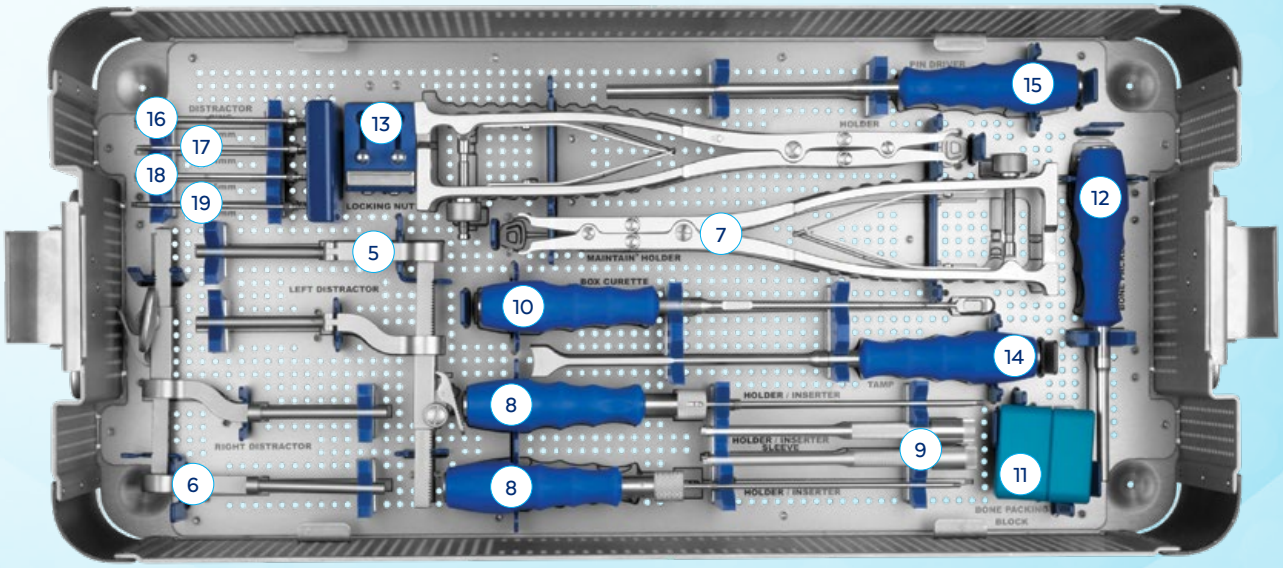
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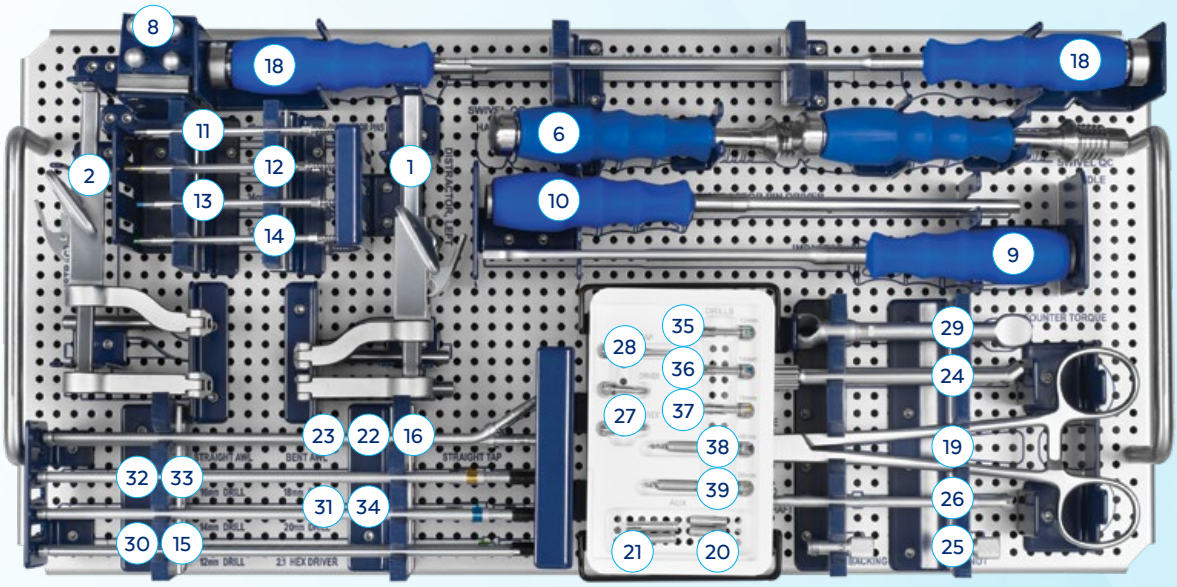
DISTRACTOR
LOCKING NUT
LEFT DISTRACTOR
RIGHT DISTRACTOR
MAINTAIN® HOLDER
BOX CURETTE
HOLDER / INSERTER
HOLDER / INSERTER SLEEVE
HOLDER / INSERTER
TAMP
HOLDER
PIN DRIVER
BONE PACKING BLOCK

UNIVERSAL ACDF
INSTRUMENT SET 9147.9001

	Part No.	Description	QTY
1	601.020	Distractor, Left	1
2	601.021	Distractor, Right	1
3	6147.9001	Trial Holder, Modular Trial / Rasp Heads - Outer Sleeve	3
4	6147.9002	Trial Holder, Modular Trial / Rasp Heads - Inner Shaft Assembly	3
5	6147.9003	Packing Block	1
6	636.450	Quick Connect Handle, Swivel	2
7	665.504	Bone Packer	1
8	665.606	Distractor Locking Nuts	4
9	665.607	Impactor	1
10	665.608	Distractor Pin Driver	1
	665.610	Distractor Pin, 10mm	-
11	665.612	Distractor Pin, 12mm	2
12	665.614	Distractor Pin, 14mm	2
13	665.616	Distractor Pin, 16mm	2
14	665.618	Distractor Pin, 18mm	2
15	671.313	VIP Screwdriver, 2.1mm Hex, QC	1
16	684.004	Tap, Straight	1
17	684.006	Awl with Retractable Sleeve	1
18	684.305	Screwdriver, 2.5mm Hex, Self-Retaining, with Cap	2
19	684.309	Drill Sleeve Adjuster	1
20	684.401	Self-Centering Sleeve-Short	2
21	684.402	Self-Centering Sleeve-Long	2
22	684.403	Awl with Self-Centering Sleeve, Straight	1
23	684.404	Awl with Self-Centering Sleeve, Bent	1
	684.405	Sleeved Driver	-
24	684.415	Angled Sleeve	2
25	684.416	Angled Sleeve with Backing Nut	2
26	684.417	Angled Driving Shaft	2

	Part No.	Description	QTY
27	684.418	Hex Driver Assembly	2
28	684.419	Angled Tap Tip	1
29	684.421	Counter Torque, Angled Instrument	2
	684.425	Angled Driver Tip, Short	-
30	684.422	Straight Drill with Self-Centering Sleeve, 12mm	1
31	684.424	Straight Drill with Self-Centering Sleeve, 14mm	1
32	684.426	Straight Drill with Self-Centering Sleeve, 16mm	1
33	684.428	Straight Drill with Self-Centering Sleeve, 18mm	1
34	684.430	Straight Drill with Self-Centering Sleeve, 20mm	1
35	684.432	Angled Drill with Self-Centering Sleeve, 12mm	1
36	684.434	Angled Drill with Self-Centering Sleeve, 14mm	1
37	684.436	Angled Drill with Self-Centering Sleeve, 16mm	1
38	684.438	Angled Drill with Self-Centering Sleeve, 18mm	1
39	684.440	Angled Drill 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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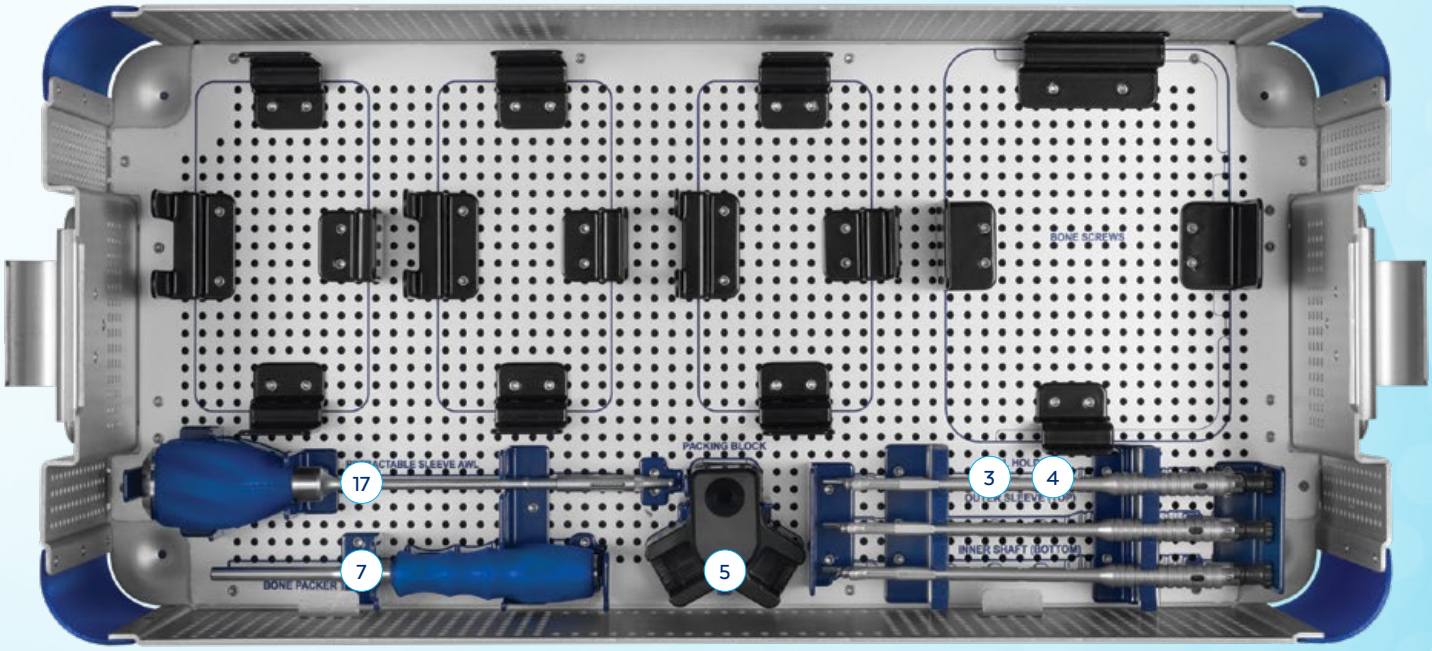
BONE SCREWS
PACKING BLOCK
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5
BONE PACKER

UNIVERSAL ACDF
TRIAL SETS

9147.9013 Universal ACDF 12x14mm, 12° and 15° Trial Set

Part No.	Description	QTY
6147.1206	Modular Trial, 12x14mm, 12°, 6mm	1
6147.1207	Modular Trial, 12x14mm, 12°, 7mm	1
6147.1208	Modular Trial, 12x14mm, 12°, 8mm	1
6147.1209	Modular Trial, 12x14mm, 12°, 9mm	1
6147.1210	Modular Trial, 12x14mm, 12°, 10mm	1
6147.1211	Modular Trial, 12x14mm, 12°, 11mm	1
6147.1212	Modular Trial, 12x14mm, 12°, 12mm	1
6147.1306	Modular Trial, 12x14mm, 15°, 6mm	1
6147.1307	Modular Trial, 12x14mm, 15°, 7mm	1
6147.1308	Modular Trial, 12x14mm, 15°, 8mm	1
6147.1309	Modular Trial, 12x14mm, 15°, 9mm	1
6147.1310	Modular Trial, 12x14mm, 15°, 10mm	1
6147.1311	Modular Trial, 12x14mm, 15°, 11mm	1
6147.1312	Modular Trial, 12x14mm, 15°, 12mm	1
9147.0013	Universal ACDF 12x14mm, 12° and 15° Trial Module	

9147.9014 Universal ACDF 14x16mm, 12° and 15° Trial Set

Part No.	Description	QTY
6147.2206	Modular Trial, 14x16mm, 12°, 6mm	1
6147.2207	Modular Trial, 14x16mm, 12°, 7mm	1
6147.2208	Modular Trial, 14x16mm, 12°, 8mm	1
6147.2209	Modular Trial, 14x16mm, 12°, 9mm	1
6147.2210	Modular Trial, 14x16mm, 12°, 10mm	1
6147.2211	Modular Trial, 14x16mm, 12°, 11mm	1
6147.2212	Modular Trial, 14x16mm, 12°, 12mm	1
6147.2307	Modular Trial, 14x16mm, 15°, 7mm	1
6147.2308	Modular Trial, 14x16mm, 15°, 8mm	1
6147.2309	Modular Trial, 14x16mm, 15°, 9mm	1
6147.2310	Modular Trial, 14x16mm, 15°, 10mm	1
6147.2311	Modular Trial, 14x16mm, 15°, 11mm	1
6147.2312	Modular Trial, 14x16mm, 15°, 12mm	1
9147.0014	Universal ACDF 14x16mm, 12° and 15° Trial Module	

9147.9015 Universal ACDF 15x18mm, 12° and 15° Trial Set

Part No.	Description	QTY
6147.3206	Modular Trial, 15x18mm, 12°, 6mm	1
6147.3207	Modular Trial, 15x18mm, 12°, 7mm	1
6147.3208	Modular Trial, 15x18mm, 12°, 8mm	1
6147.3209	Modular Trial, 15x18mm, 12°, 9mm	1
6147.3210	Modular Trial, 15x18mm, 12°, 10mm	1
6147.3211	Modular Trial, 15x18mm, 12°, 11mm	1
6147.3212	Modular Trial, 15x18mm, 12°, 12mm	1
6147.3307	Modular Trial, 15x18mm, 15°, 7mm	1
6147.3308	Modular Trial, 15x18mm, 15°, 8mm	1
6147.3309	Modular Trial, 15x18mm, 15°, 9mm	1
6147.3310	Modular Trial, 15x18mm, 15°, 10mm	1
6147.3311	Modular Trial, 15x18mm, 15°, 11mm	1
6147.3312	Modular Trial, 15x18mm, 15°, 12mm	1
9147.0015	Universal ACDF 15x18mm, 12° and 15° Trial	

9147.9016 Universal ACDF 20° Trial Set

Part No.	Description	QTY
6147.1407	Modular Trial, 12x14mm, 20°, 7mm	1
6147.1408	Modular Trial, 12x14mm, 20°, 8mm	1
6147.1409	Modular Trial, 12x14mm, 20°, 9mm	1
6147.1410	Modular Trial, 12x14mm, 20°, 10mm	1
6147.1411	Modular Trial, 12x14mm, 20°, 11mm	1
6147.1412	Modular Trial, 12x14mm, 20°, 12mm	1
6147.2408	Modular Trial, 14x16mm, 20°, 8mm	1
6147.2409	Modular Trial, 14x16mm, 20°, 9mm	1
6147.2410	Modular Trial, 14x16mm, 20°, 10mm	1
6147.2411	Modular Trial, 14x16mm, 20°, 11mm	1
6147.2412	Modular Trial, 14x16mm, 20°, 12mm	1
6147.3408	Modular Trial, 15x18mm, 20°, 8mm	1
6147.3409	Modular Trial, 15x18mm, 20°, 9mm	1
6147.3410	Modular Trial, 15x18mm, 20°, 10mm	1
6147.3411	Modular Trial, 15x18mm, 20°, 11mm	1
6147.3412	Modular Trial, 15x18mm, 20°, 12mm	1
9147.0016	Universal ACDF 20° Trial Module	


12 x 14 UNIVERSAL ACDF TRIALS
12°
15°
6mm 7mm 8mm 9mm 10mm 11mm 12mm


14 x 16 UNIVERSAL ACDF TRIALS
12°
15°
6mm 7mm 8mm 9mm 10mm 11mm 12mm


15 x 18 UNIVERSAL ACDF TRIALS
12°
15°
6mm 7mm 8mm 9mm 10mm 11mm 12mm


12 x 14
7mm 8mm 9mm 10mm 11mm 12mm
14 x 16
8mm 9mm 10mm 11mm 12mm
20°
UNIVERSAL
ACDF
TRIALS
15 x 18

ADDITIONALLY AVAILABLE COLONIAL® INSTRUMENTS

Part No.	Description
665.005	COLONIAL® Small Trial, Parallel, 5mm
665.006	COLONIAL® Small Trial, Parallel, 6mm
665.007	COLONIAL® Small Trial, Parallel, 7mm
665.008	COLONIAL® Small Trial, Parallel, 8mm
665.009	COLONIAL® Small Trial, Parallel, 9mm
665.010	COLONIAL® Small Trial, Parallel, 10mm
665.011	COLONIAL® Small Trial, Parallel, 11mm
665.012	COLONIAL® Small Trial, Parallel, 12mm
665.025	COLONIAL® Rasp, Small, Parallel, 5mm
665.026	COLONIAL® Rasp, Small, Parallel, 6mm
665.027	COLONIAL® Rasp, Small, Parallel, 7mm
665.028	COLONIAL® Rasp, Small, Parallel, 8mm
665.029	COLONIAL® Rasp, Small, Parallel, 9mm
665.030	COLONIAL® Rasp, Small, Parallel, 10mm
665.031	COLONIAL® Rasp, Small, Parallel, 11mm
665.032	COLONIAL® Rasp, Small, Parallel, 12mm
665.045	COLONIAL® ACDF Trial, XXL, Parallel, 5mm
665.046	COLONIAL® ACDF Trial, XXL, Parallel, 6mm
665.047	COLONIAL® ACDF Trial, XXL, Parallel, 7mm
665.048	COLONIAL® ACDF Trial, XXL, Parallel, 8mm
665.049	COLONIAL® ACDF Trial, XXL, Parallel, 9mm
665.050	COLONIAL® ACDF Trial, XXL, Parallel, 10mm
665.051	COLONIAL® ACDF Trial, XXL, Parallel, 11mm
665.052	COLONIAL® ACDF Trial, XXL, Parallel, 12mm
665.065	COLONIAL® ACDF Trial, XXL, Lordotic, 5mm
665.066	COLONIAL® ACDF Trial, XXL, Lordotic, 6mm
665.067	COLONIAL® ACDF Trial, XXL, Lordotic, 7mm
665.068	COLONIAL® ACDF Trial, XXL, Lordotic, 8mm
665.069	COLONIAL® ACDF Trial, XXL, Lordotic, 9mm
665.070	COLONIAL® ACDF Trial, XXL, Lordotic, 10mm
665.071	COLONIAL® ACDF Trial, XXL, Lordotic, 11mm
665.072	COLONIAL® ACDF Trial, XXL, Lordotic, 12mm

Part No.	Description
665.105	COLONIAL® Small Trial, Lordotic, 5mm
665.106	COLONIAL® Small Trial, Lordotic, 6mm
665.107	COLONIAL® Small Trial, Lordotic, 7mm
665.108	COLONIAL® Small Trial, Lordotic, 8mm
665.109	COLONIAL® Small Trial, Lordotic, 9mm
665.110	COLONIAL® Small Trial, Lordotic, 10mm
665.111	COLONIAL® Small Trial, Lordotic, 11mm
665.112	COLONIAL® Small Trial, Lordotic, 12mm
665.113	COLONIAL® Small Trial, Lordotic, 13mm
665.114	COLONIAL® Small Trial, Lordotic, 14mm
665.126	COLONIAL® Rasp, Small, Lordotic, 6mm
665.127	COLONIAL® Rasp, Small, Lordotic, 7mm
665.128	COLONIAL® Rasp, Small, Lordotic, 8mm
665.129	COLONIAL® Rasp, Small, Lordotic, 9mm
665.130	COLONIAL® Rasp, Small, Lordotic, 10mm
665.131	COLONIAL® Rasp, Small, Lordotic, 11mm
665.132	COLONIAL® Rasp, Small, Lordotic, 12mm
665.705	COLONIAL® X-Large Trial, Lordotic, 5mm
665.706	COLONIAL® X-Large Trial, Lordotic, 6mm
665.707	COLONIAL® X-Large Trial, Lordotic, 7mm
665.708	COLONIAL® X-Large Trial, Lordotic, 8mm
665.709	COLONIAL® X-Large Trial, Lordotic, 9mm
665.710	COLONIAL® X-Large Trial, Lordotic, 10mm
665.711	COLONIAL® X-Large Trial, Lordotic, 11mm
665.712	COLONIAL® X-Large Trial, Lordotic, 12mm
665.713	COLONIAL® X-Large Trial, Lordotic, 13mm
665.714	COLONIAL® X-Large Trial, Lordotic, 14mm
665.805	COLONIAL® X-Large Trial, Parallel, 5mm
665.806	COLONIAL® X-Large Trial, Parallel, 6mm
665.807	COLONIAL® X-Large Trial, Parallel, 7mm
665.808	COLONIAL® X-Large Trial, Parallel, 8mm
665.809	COLONIAL® X-Large Trial, Parallel, 9mm
665.810	COLONIAL® X-Large Trial, Parallel, 10mm
665.811	COLONIAL® X-Large Trial, Parallel, 11mm
665.812	COLONIAL® X-Large Trial, Parallel, 12mm

**Items in gray are additionally available*

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

DESCRIPTION

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

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

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

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

HEDRON™ Lumbar Spacers are additively manufactured from titanium powder, as specified in ASTM F3001. Screws and anchors are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537.

INDICATIONS

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

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

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

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

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

WARNINGS

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

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

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

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

The components of this system are manufactured from titanium alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical, and functional reasons.

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

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

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

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

MRI SAFETY INFORMATION

The HEDRON™ Spacers are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the HEDRON™ Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

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

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risk versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

PACKAGING

These implants are supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants are available sterile and instruments are nonsterile.

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

Nonsterile instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

IMPORTANT INFORMATION ABOUT HEDRON™ SPACERS

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

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

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

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

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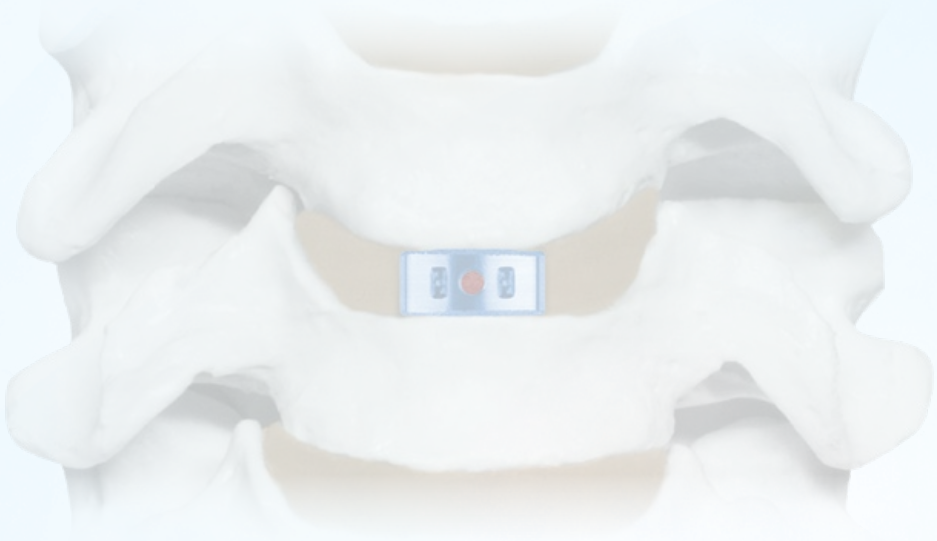

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