

# COLONIAL<sup>®</sup> and COLONIAL<sup>®</sup> TPS<sup>®</sup>

ACDF System



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

***Life moves us*** 

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

# SURGICAL TECHNIQUE GUIDE

## COLONIAL<sup>®</sup> and COLONIAL<sup>®</sup> TPS<sup>®</sup>

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# COLONIAL<sup>®</sup> and COLONIAL<sup>®</sup> TPS<sup>®</sup>

## ACDF System

COLONIAL<sup>®</sup> ACDF spacer is an anterior cervical interbody fusion device made from PEEK radiolucent polymer and available with titanium plasma spray (TPS) coating.

The implants are offered in numerous footprints, heights, and sagittal profiles to accommodate various patient anatomies with innovative instruments designed to streamline the anterior cervical fusion procedure.

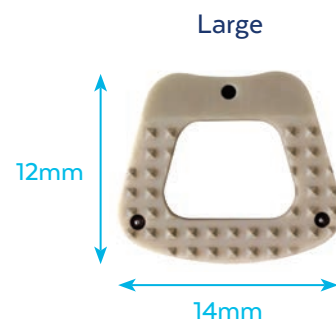
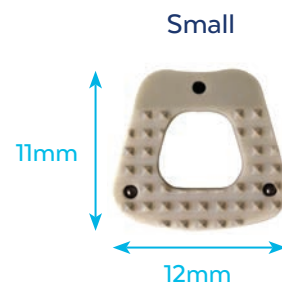


## COLONIAL<sup>®</sup> Instruments

- Smooth and rasp trials match implant geometry
- Distraction pin locking nuts facilitate rigid and parallel distraction
- Holder provides easy implant disengagement
- Crescent-shaped tamp for implant positioning



COLONIAL<sup>®</sup>

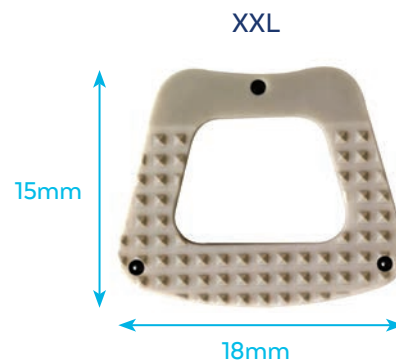
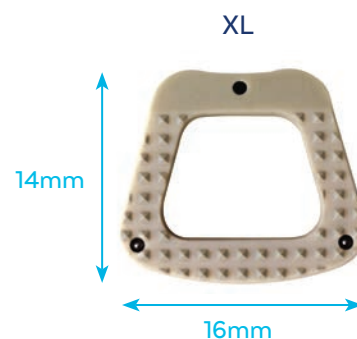


## COLONIAL<sup>®</sup> ACDF Spacers

- Made from PEEK radiolucent polymer, available with titanium plasma spray (TPS) coating
- Self-distracting leading edge
- Modulus of elasticity between cortical and cancellous bone for optimal load sharing
- Four axial footprints
- Six sagittal profiles: convex, parallel, 7° lordotic, 12° lordotic, 15° lordotic, and 20° lordotic
- Heights of 5–14mm in 1mm increments
- Three tantalum beads for visualization



COLONIAL<sup>®</sup> TPS<sup>®</sup>







# INSTRUMENT OVERVIEW

## DISTRACTION INSTRUMENTS



Distractor Locking Nuts 665.606

Distractor Pins

	Height	Part No.
	12mm	665.612
	14mm	665.614
	16mm	665.616
	18mm	665.618



Distractor Pin Driver 665.608

## TRIALS

### COLONIAL® Trial Rasps



11x12mm		
Height	0°	7°
5mm	665.025	665.125
6mm	665.026	665.126
7mm	665.027	665.127
8mm	665.028	665.128
9mm	665.029	665.129
10mm	665.030	665.130
11mm	665.031	665.131
12mm	665.032	665.132

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

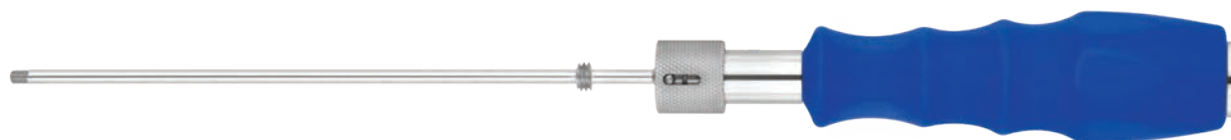
### COLONIAL® Trials



11x12mm			
Height	0°	7°	
5mm	665.005	665.105	
6mm	665.006	665.106	
7mm	665.007	665.107	
8mm	665.008	665.108	
9mm	665.009	665.109	
10mm	665.010	665.110	
11mm	665.011	665.111	
12mm	665.012	665.112	
13mm	-	665.113	
14mm	-	665.114	
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	
13mm	-	665.413	
14mm	-	665.414	

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	
13mm	-	665.713	
14mm	-	665.714	
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



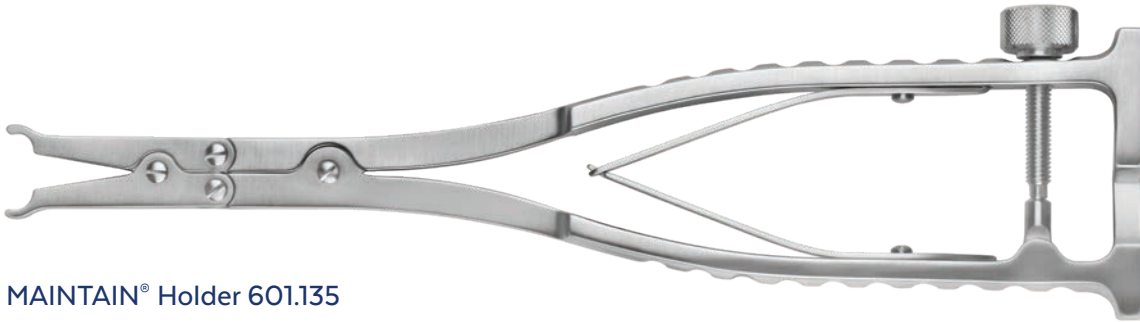
Implant/Trial Insertion Sleeve 665.501



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

## SURGICAL TECHNIQUE

# COLONIAL<sup>®</sup> and COLONIAL<sup>®</sup> TPS<sup>®</sup>

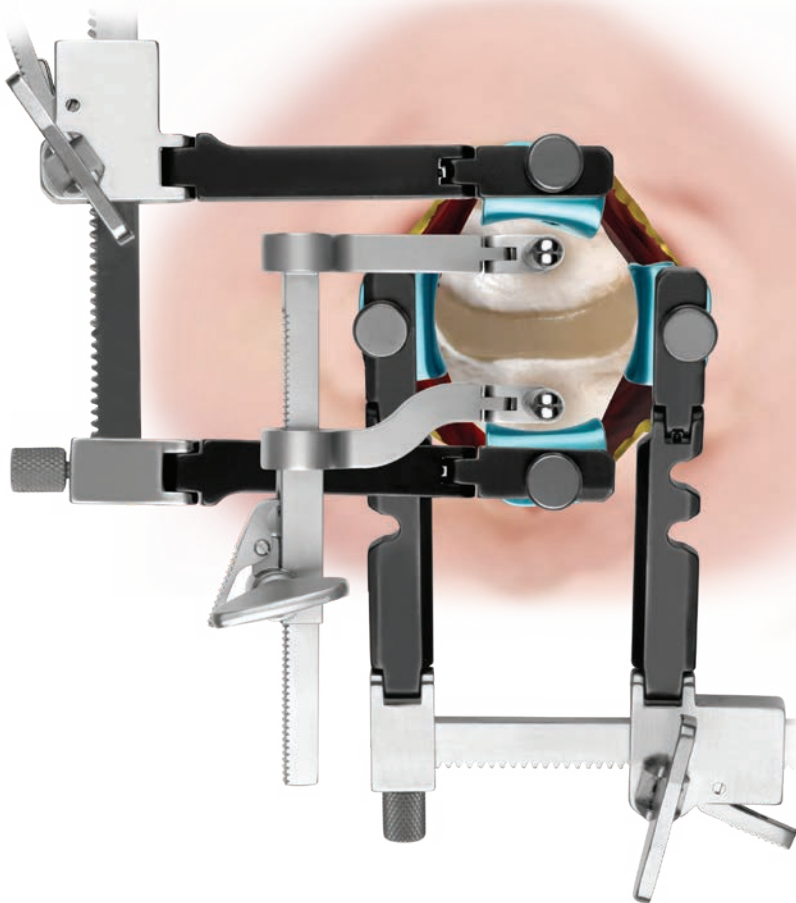
Please refer to the product information at the end of this technique manual for a complete description, indications, contraindications, and warnings associated with this system.

### STEP

### 1

## APPROACH AND DISC PREPARATION

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. The COLONIAL<sup>®</sup> ACDF and COLONIAL<sup>®</sup> TPS<sup>®</sup> Systems may be used in the cervical spine from C2 to T1.



## STEP

## 2

## DISTRACTION

Distraction may be accomplished using the **Distractor** available in this system or other standard methods.

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



Insertion of Distractor Pins



Distractor Pins positioned

## DISTRACTION (CONT'D)

Place the Distractor, Right or Left, as desired over the Distractor Pins until seated. When seated, secure the Distractor by attaching the **Distractor Locking Nuts** and rotating clockwise until finger tight. Rotate the ratchet handle to distract to the desired amount, being careful not to over-distract the segment. Distraction may be used throughout the technique to provide visualization and access to the disc and osseous structures.



Using Distractor

## STEP

## 3

## DISCECTOMY/ENDPLATE PREPARATION

Leaving the lateral annulus intact, remove the intervertebral disc and osteophytes as needed, using rongeurs and other discectomy instruments. The **Box Curette** may be used to remove the disc, as well as superficial layers of the cartilaginous endplates to expose bleeding bone. Alternatively, **Trial Rasps** match the trial design and may be used to expose bleeding bone.

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



Endplate preparation using Box Curette



Endplate preparation using Trial Rasp

## STEP

## 4

## IMPLANT SIZING

Determine the appropriate implant 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 stabilize the segment. Confirm placement using fluoroscopy and tactile feedback.



Trialing for implant size



## STEP 5 IMPLANT INSERTION

Select an appropriate size COLONIAL® or COLONIAL® TPS® ACDF spacer. Pack with autograft and/or allogenic bone graft material using the **Bone Packing Block** and **Bone Packer**, as shown at right.

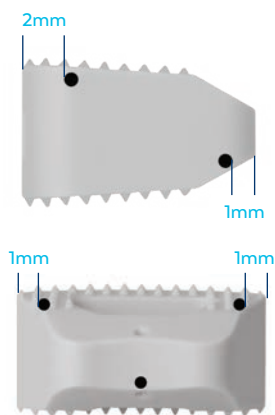
Thread the implant onto the **Implant/Trial Holder** and insert into the intervertebral space. The spacer should be slightly recessed into the disc space. If needed, the **Impactor** may be used for light impaction.

Use the three radiographic beads for proper placement during fluoroscopy.

*Note: COLONIAL® 5mm implants require the MAINTAIN® Holder.*



Implant insertion



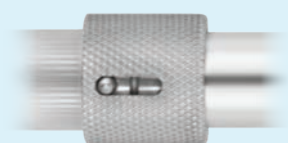
Radiographic markers



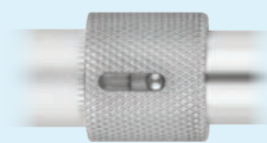
Using the Bone Packing Block

### ⚙️ 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

# IMPLANT INSERTION (CONT'D)

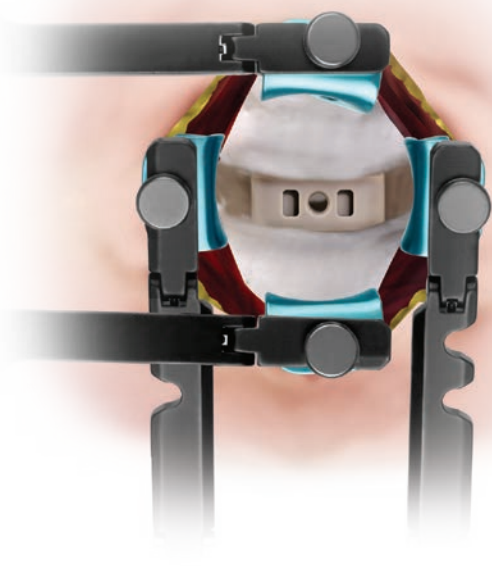
## Multi-Level Implant Insertion

To implant an additional spacer, repeat the steps from distraction to implant insertion. A 4-level construct is shown below.

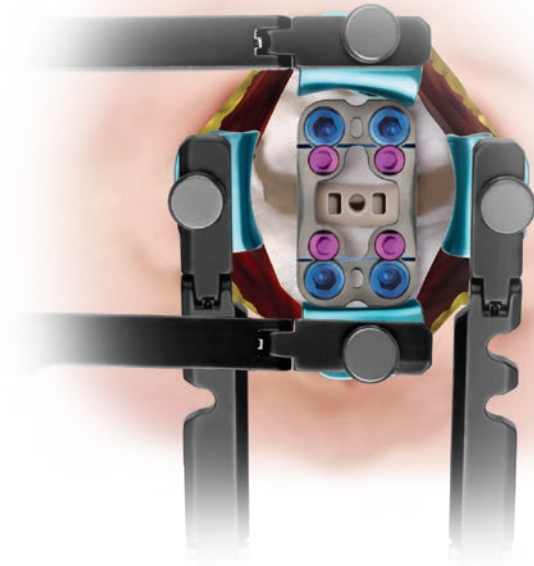


# FINAL POSITION

Supplemental fixation using an anterior cervical plate, such as ASSURE®, PROVIDENCE™ or VIP®, is required.



Final implant position



Final implant position with PROVIDENCE™ plate



Final implant position  
- axial view

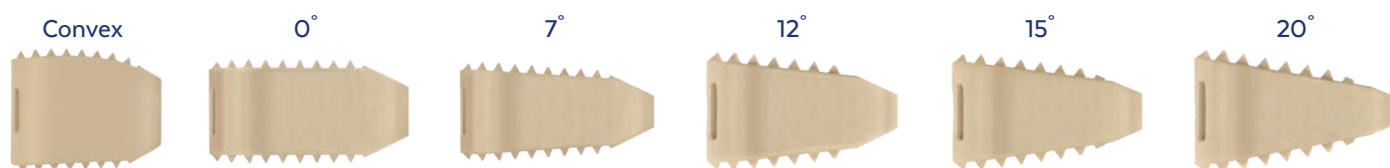


## ADDITIONAL SPECIFICATIONS

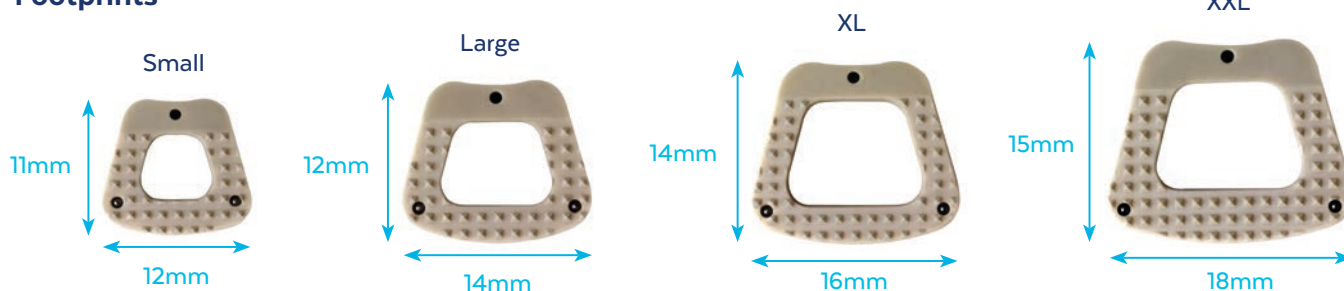
COLONIAL® Bone Graft Volume (cc)												
Heights	11mmx12mm			12mmx14mm			14mmx16mm			15mmx18mm		
	Small			Large			XL			XXL		
	0°	7°	Convex	0°	7°	Convex	0°	7°	Convex	0°	7°	Convex
5mm	0.14	0.13	0.13	0.24	0.21	0.22	0.38	0.33	0.35	0.39	0.33	0.35
6mm	0.17	0.15	0.15	0.28	0.26	0.26	0.45	0.40	0.41	0.46	0.40	0.41
7mm	0.19	0.18	0.18	0.32	0.30	0.30	0.52	0.47	0.48	0.53	0.47	0.48
8mm	0.22	0.20	0.21	0.37	0.34	0.35	0.59	0.54	0.55	0.61	0.54	0.55
9mm	0.24	0.23	0.24	0.41	0.39	0.39	0.66	0.60	0.62	0.68	0.62	0.63
10mm	0.27	0.26	0.26	0.45	0.43	0.44	0.73	0.67	0.69	0.75	0.69	0.70
11mm	0.30	0.28	0.29	0.50	0.47	0.48	0.80	0.74	0.75	0.82	0.76	0.77
12mm	0.32	0.31	0.31	0.54	0.52	0.52	0.87	0.81	0.82	0.89	0.83	0.84
13mm	0.35	0.33	-	0.59	0.56	-	-	0.88	-	-	-	-
14mm	0.38	0.36	-	0.63	0.60	-	-	0.95	-	-	-	-

COLONIAL® Hyperlordotic Bone Graft Volume (cc)												
Heights	11mmx12mm			12mmx14mm			14mmx16mm			15mmx18mm		
	Small			Large			XL			XXL		
	12°	15°	20°	12°	15°	20°	12°	15°	20°	12°	15°	20°
5mm	-	-	-	-	-	-	-	-	-	-	-	-
6mm	0.14	0.14	-	0.24	0.22	-	0.36	-	-	0.36	-	-
7mm	0.17	0.16	0.15	0.28	0.27	0.25	0.43	0.41	-	0.43	0.54	-
8mm	0.20	0.19	0.18	0.32	0.31	0.29	0.50	0.48	0.44	0.50	0.63	0.57
9mm	0.22	0.22	0.20	0.37	0.36	0.33	0.57	0.54	0.51	0.57	0.72	0.67
10mm	0.25	0.24	0.23	0.41	0.40	0.38	0.64	0.61	0.58	0.65	0.81	0.75
11mm	0.27	0.27	0.26	0.46	0.44	0.42	0.71	0.68	0.64	0.72	0.90	0.85
12mm	0.30	0.29	0.28	0.50	0.48	0.46	0.78	0.75	0.72	0.79	0.99	0.94

### Sagittal Profiles



### Footprints



# COLONIAL® ACDF IMPLANT SETS

## 965.901 COLONIAL® ACDF 11x12mm Implant Set

Part No.	Description	Qty
365.005	COLONIAL® ACDF Spacer, 11x12, 0°, 5mm	1
365.006	COLONIAL® ACDF Spacer, 11x12, 0°, 6mm	3
365.007	COLONIAL® ACDF Spacer, 11x12, 0°, 7mm	3
365.008	COLONIAL® ACDF Spacer, 11x12, 0°, 8mm	3
365.009	COLONIAL® ACDF Spacer, 11x12, 0°, 9mm	2
365.010	COLONIAL® ACDF Spacer, 11x12, 0°, 10mm	2
365.011	COLONIAL® ACDF Spacer, 11x12, 0°, 11mm	1
365.012	COLONIAL® ACDF Spacer, 11x12, 0°, 12mm	1
365.013	COLONIAL® ACDF Spacer, 11x12, 0°, 13mm	-
365.014	COLONIAL® ACDF Spacer, 11x12, 0°, 14mm	-
365.105	COLONIAL® ACDF Spacer, 11x12, 7°, 5mm	1
365.106	COLONIAL® ACDF Spacer, 11x12, 7°, 6mm	3
365.107	COLONIAL® ACDF Spacer, 11x12, 7°, 7mm	3
365.108	COLONIAL® ACDF Spacer, 11x12, 7°, 8mm	3
365.109	COLONIAL® ACDF Spacer, 11x12, 7°, 9mm	2
365.110	COLONIAL® ACDF Spacer, 11x12, 7°, 10mm	2
365.111	COLONIAL® ACDF Spacer, 11x12, 7°, 11mm	1
365.112	COLONIAL® ACDF Spacer, 11x12, 7°, 12mm	1
365.113	COLONIAL® ACDF Spacer, 11x12, 7°, 13mm	-
365.114	COLONIAL® ACDF Spacer, 11x12, 7°, 14mm	-
965.001	COLONIAL® 11x12, Small Implant Module	

## 965.903 COLONIAL® ACDF 14x16mm Implant Set

Part No.	Description	Qty
365.705	COLONIAL® ACDF Spacer, 14x16, 7°, 5mm	1
365.706	COLONIAL® ACDF Spacer, 14x16, 7°, 6mm	3
365.707	COLONIAL® ACDF Spacer, 14x16, 7°, 7mm	3
365.708	COLONIAL® ACDF Spacer, 14x16, 7°, 8mm	3
365.709	COLONIAL® ACDF Spacer, 14x16, 7°, 9mm	2
365.710	COLONIAL® ACDF Spacer, 14x16, 7°, 10mm	2
365.711	COLONIAL® ACDF Spacer, 14x16, 7°, 11mm	1
365.712	COLONIAL® ACDF Spacer, 14x16, 7°, 12mm	1
365.713	COLONIAL® ACDF Spacer, 14x16, 7°, 13mm	-
365.714	COLONIAL® ACDF Spacer, 14x16, 7°, 14mm	-
365.805	COLONIAL® ACDF Spacer, 14x16, 0°, 5mm	1
365.806	COLONIAL® ACDF Spacer, 14x16, 0°, 6mm	3
365.807	COLONIAL® ACDF Spacer, 14x16, 0°, 7mm	3
365.808	COLONIAL® ACDF Spacer, 14x16, 0°, 8mm	3
365.809	COLONIAL® ACDF Spacer, 14x16, 0°, 9mm	2
365.810	COLONIAL® ACDF Spacer, 14x16, 0°, 10mm	2
365.811	COLONIAL® ACDF Spacer, 14x16, 0°, 11mm	1
365.812	COLONIAL® ACDF Spacer, 14x16, 0°, 12mm	1
965.003	COLONIAL® 14x16, X-Large Implant Module	

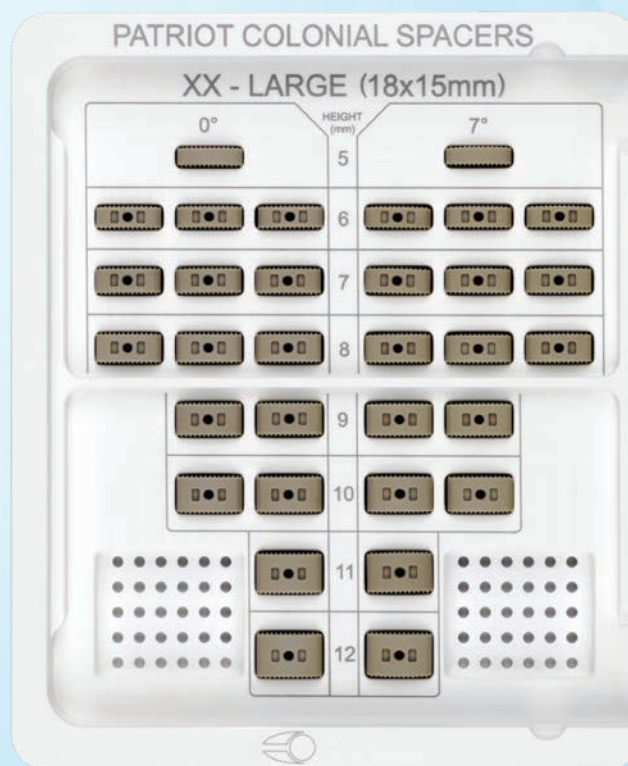
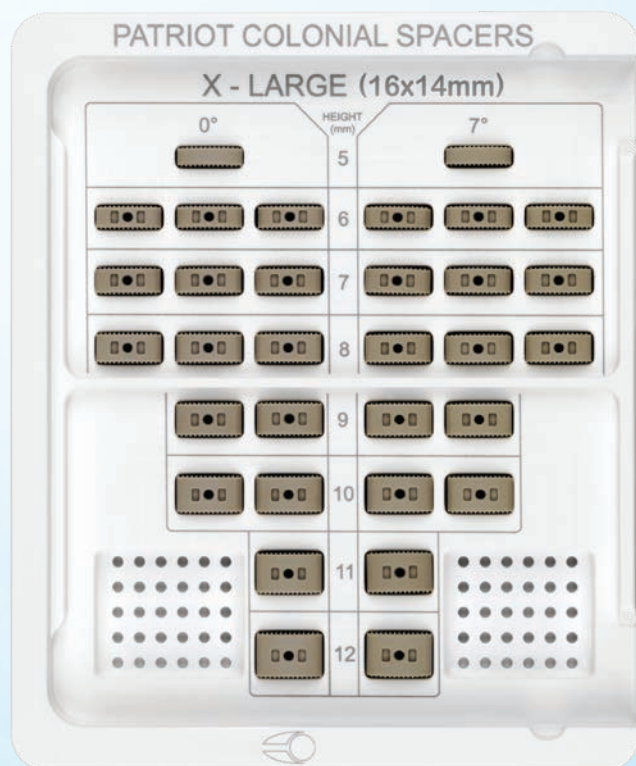
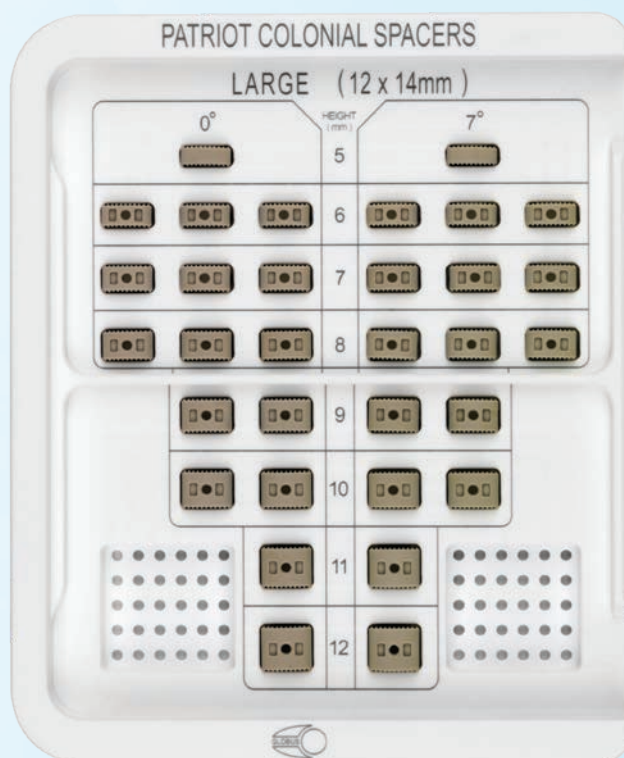
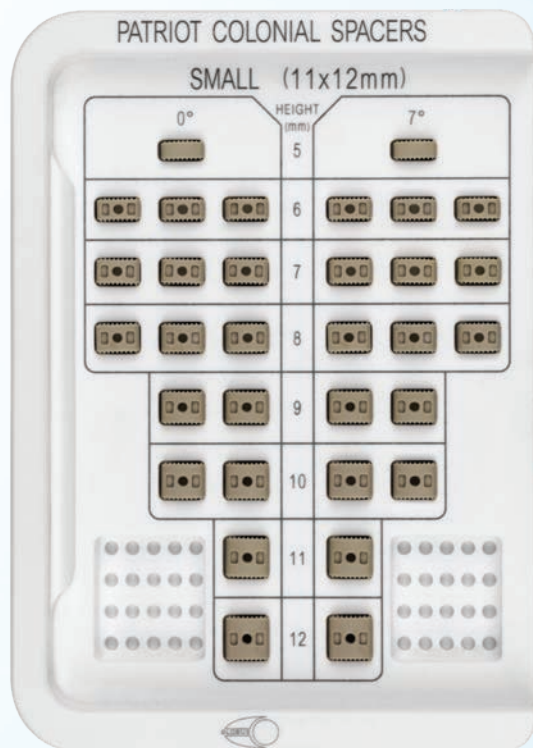
## 965.902 COLONIAL® ACDF 12x14mm Implant Set

Part No.	Description	Qty
365.305	COLONIAL® ACDF Spacer, 12x14, 0°, 5mm	1
365.306	COLONIAL® ACDF Spacer, 12x14, 0°, 6mm	3
365.307	COLONIAL® ACDF Spacer, 12x14, 0°, 7mm	3
365.308	COLONIAL® ACDF Spacer, 12x14, 0°, 8mm	3
365.309	COLONIAL® ACDF Spacer, 12x14, 0°, 9mm	2
365.310	COLONIAL® ACDF Spacer, 12x14, 0°, 10mm	2
365.311	COLONIAL® ACDF Spacer, 12x14, 0°, 11mm	1
365.312	COLONIAL® ACDF Spacer, 12x14, 0°, 12mm	1
365.313	COLONIAL® ACDF Spacer, 12x14, 0°, 13mm	-
365.314	COLONIAL® ACDF Spacer, 12x14, 0°, 14mm	-
365.405	COLONIAL® ACDF Spacer, 12x14, 7°, 5mm	1
365.406	COLONIAL® ACDF Spacer, 12x14, 7°, 6mm	3
365.407	COLONIAL® ACDF Spacer, 12x14, 7°, 7mm	3
365.408	COLONIAL® ACDF Spacer, 12x14, 7°, 8mm	3
365.409	COLONIAL® ACDF Spacer, 12x14, 7°, 9mm	2
365.410	COLONIAL® ACDF Spacer, 12x14, 7°, 10mm	2
365.411	COLONIAL® ACDF Spacer, 12x14, 7°, 11mm	1
365.412	COLONIAL® ACDF Spacer, 12x14, 7°, 12mm	1
365.413	COLONIAL® ACDF Spacer, 12x14, 7°, 13mm	-
365.414	COLONIAL® ACDF Spacer, 12x14, 7°, 14mm	-
965.002	COLONIAL® 12x14, Large Implant Module	

## 965.904 COLONIAL® ACDF 15x18mm Implant Set

Part No.	Description	Qty
365.045	COLONIAL® ACDF Spacer, 15x18, 0°, 5mm	1
365.046	COLONIAL® ACDF Spacer, 15x18, 0°, 6mm	3
365.047	COLONIAL® ACDF Spacer, 15x18, 0°, 7mm	3
365.048	COLONIAL® ACDF Spacer, 15x18, 0°, 8mm	3
365.049	COLONIAL® ACDF Spacer, 15x18, 0°, 9mm	2
365.050	COLONIAL® ACDF Spacer, 15x18, 0°, 10mm	2
365.051	COLONIAL® ACDF Spacer, 15x18, 0°, 11mm	1
365.052	COLONIAL® ACDF Spacer, 15x18, 0°, 12mm	1
365.065	COLONIAL® ACDF Spacer, 15x18, 7°, 5mm	1
365.066	COLONIAL® ACDF Spacer, 15x18, 7°, 6mm	3
365.067	COLONIAL® ACDF Spacer, 15x18, 7°, 7mm	3
365.068	COLONIAL® ACDF Spacer, 15x18, 7°, 8mm	3
365.069	COLONIAL® ACDF Spacer, 15x18, 7°, 9mm	2
365.070	COLONIAL® ACDF Spacer, 15x18, 7°, 10mm	2
365.071	COLONIAL® ACDF Spacer, 15x18, 7°, 11mm	1
365.072	COLONIAL® ACDF Spacer, 15x18, 7°, 12mm	1
965.004	COLONIAL® 15x18, XX-Large Implant Module	

# COLONIAL<sup>®</sup> ACDF IMPLANT SETS



# COLONIAL<sup>®</sup> TPS<sup>®</sup>

## IMPLANT SETS

### 965.953 COLONIAL<sup>®</sup> TPS<sup>®</sup> 11x12mm, Implant Set

Part No.	Description	Qty
365.005CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 5mm	1
365.006CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 6mm	3
365.007CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 7mm	3
365.008CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 8mm	3
365.009CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 9mm	2
365.010CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 10mm	2
365.011CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 11mm	1
365.012CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 0°, 12mm	1
365.105CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 5mm	1
365.106CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 6mm	3
365.107CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 7mm	3
365.108CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 8mm	3
365.109CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 9mm	2
365.110CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 10mm	2
365.111CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 11mm	1
365.112CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 11x12, 7°, 12mm	1
965.007	Soft Case PATRIOT COLONIAL <sup>®</sup> TPS <sup>®</sup>	(32 Box)

### 965.959 COLONIAL<sup>®</sup> TPS<sup>®</sup> 14x16mm, Implant Set

Part No.	Description	Qty
365.705CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 5mm	1
365.706CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 6mm	3
365.707CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 7mm	3
365.708CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 8mm	3
365.709CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 9mm	2
365.710CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 10mm	2
365.711CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 11mm	1
365.712CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 7°, 12mm	1
365.805CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 5mm	1
365.806CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 6mm	3
365.807CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 7mm	3
365.808CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 8mm	3
365.809CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 9mm	2
365.810CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 10mm	2
365.811CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 11mm	1
365.812CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 0°, 12mm	1
965.007	Soft Case PATRIOT COLONIAL <sup>®</sup> TPS <sup>®</sup>	(32 Box)

### 965.952 COLONIAL<sup>®</sup> TPS<sup>®</sup> 12x14mm, Implant Set

Part No.	Description	Qty
365.305CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 5mm	1
365.306CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 6mm	3
365.307CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 7mm	3
365.308CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 8mm	3
365.309CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 9mm	2
365.310CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 10mm	2
365.311CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 11mm	1
365.312CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 0°, 12mm	1
365.405CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 5mm	1
365.406CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 6mm	3
365.407CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 7mm	3
365.408CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 8mm	3
365.409CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 9mm	2
365.410CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 10mm	2
365.411CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 11mm	1
365.412CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 7°, 12mm	1
965.007	Soft Case PATRIOT COLONIAL <sup>®</sup> TPS <sup>®</sup>	(32 Box)

### 965.954 COLONIAL<sup>®</sup> TPS<sup>®</sup> 15x18mm, Implant Set

Part No.	Description	Qty
365.045CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 5mm	1
365.046CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 6mm	3
365.047CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 7mm	3
365.048CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 8mm	3
365.049CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 9mm	2
365.050CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 10mm	2
365.051CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 11mm	1
365.052CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 0°, 12mm	1
365.065CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 5mm	1
365.066CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 6mm	3
365.067CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 7mm	3
365.068CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 8mm	3
365.069CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 9mm	2
365.070CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 10mm	2
365.071CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 11mm	1
365.072CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 7°, 12mm	1
965.007	Soft Case PATRIOT COLONIAL <sup>®</sup> TPS <sup>®</sup>	(32 Box)



# COLONIAL<sup>®</sup> TPS<sup>®</sup> IMPLANT SETS



# COLONIAL® HYPERLORDOTIC IMPLANT SETS

## 965.913 COLONIAL® 12x14mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.426	COLONIAL® ACDF Spacer, 12x14, 12°, 6mm	3
365.427	COLONIAL® ACDF Spacer, 12x14, 12°, 7mm	3
365.428	COLONIAL® ACDF Spacer, 12x14, 12°, 8mm	3
365.429	COLONIAL® ACDF Spacer, 12x14, 12°, 9mm	2
365.430	COLONIAL® ACDF Spacer, 12x14, 12°, 10mm	2
365.431	COLONIAL® ACDF Spacer, 12x14, 12°, 11mm	1
365.432	COLONIAL® ACDF Spacer, 12x14, 12°, 12mm	1
365.436	COLONIAL® ACDF Spacer, 12x14, 15°, 6mm	3
365.437	COLONIAL® ACDF Spacer, 12x14, 15°, 7mm	3
365.438	COLONIAL® ACDF Spacer, 12x14, 15°, 8mm	3
365.439	COLONIAL® ACDF Spacer, 12x14, 15°, 9mm	2
365.440	COLONIAL® ACDF Spacer, 12x14, 15°, 10mm	2
365.441	COLONIAL® ACDF Spacer, 12x14, 15°, 11mm	1
365.442	COLONIAL® ACDF Spacer, 12x14, 15°, 12mm	1
965.013	COLONIAL® Hyperlordotic 12x14, Spacer Module	

## 965.914 COLONIAL® 14x16mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.726	COLONIAL® ACDF Spacer, 14x16, 12°, 6mm	3
365.727	COLONIAL® ACDF Spacer, 14x16, 12°, 7mm	3
365.728	COLONIAL® ACDF Spacer, 14x16, 12°, 8mm	3
365.729	COLONIAL® ACDF Spacer, 14x16, 12°, 9mm	2
365.730	COLONIAL® ACDF Spacer, 14x16, 12°, 10mm	2
365.731	COLONIAL® ACDF Spacer, 14x16, 12°, 11mm	1
365.732	COLONIAL® ACDF Spacer, 14x16, 12°, 12mm	1
365.737	COLONIAL® ACDF Spacer, 14x16, 15°, 7mm	3
365.738	COLONIAL® ACDF Spacer, 14x16, 15°, 8mm	3
365.739	COLONIAL® ACDF Spacer, 14x16, 15°, 9mm	2
365.740	COLONIAL® ACDF Spacer, 14x16, 15°, 10mm	2
365.741	COLONIAL® ACDF Spacer, 14x16, 15°, 11mm	1
365.742	COLONIAL® ACDF Spacer, 14x16, 15°, 12mm	1
965.014	COLONIAL® Hyperlordotic 14x16, Spacer Module	

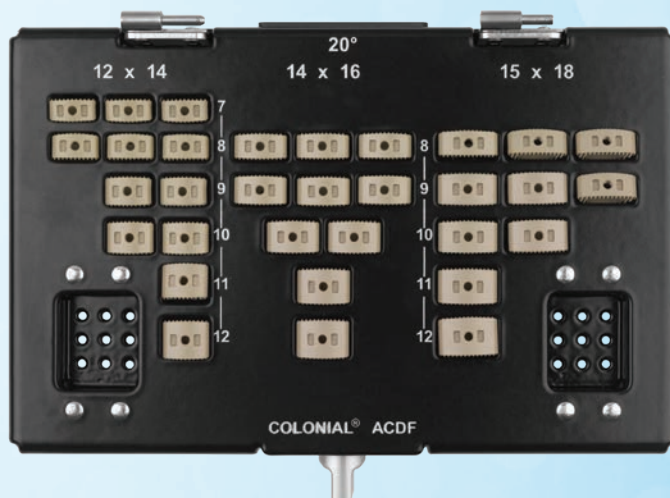
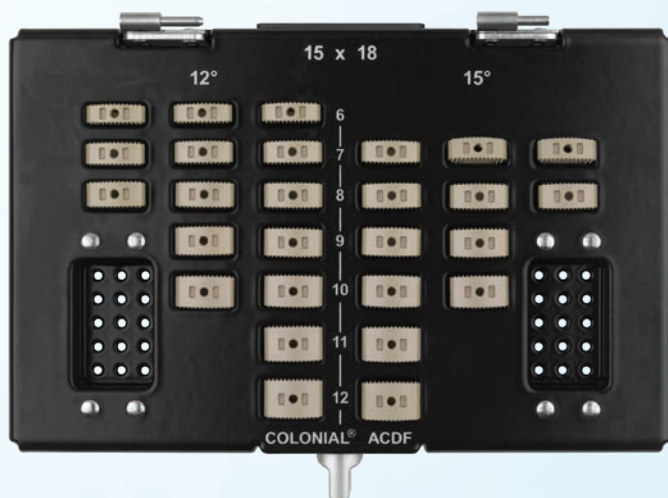
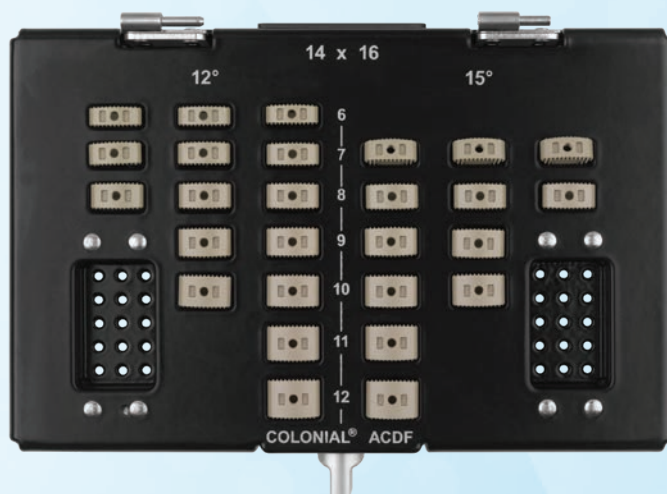
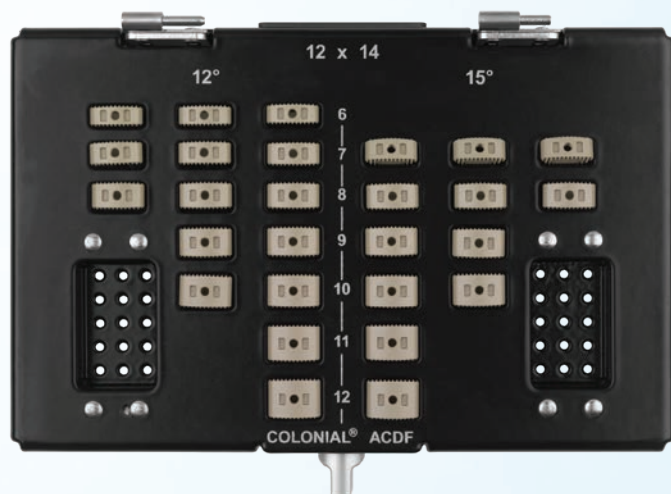
## 965.915 COLONIAL® 15x18mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.026	COLONIAL® ACDF Spacer, 15x18, 12°, 6mm	3
365.027	COLONIAL® ACDF Spacer, 15x18, 12°, 7mm	3
365.028	COLONIAL® ACDF Spacer, 15x18, 12°, 8mm	3
365.029	COLONIAL® ACDF Spacer, 15x18, 12°, 9mm	2
365.030	COLONIAL® ACDF Spacer, 15x18, 12°, 10mm	2
365.031	COLONIAL® ACDF Spacer, 15x18, 12°, 11mm	1
365.032	COLONIAL® ACDF Spacer, 15x18, 12°, 12mm	1
365.037	COLONIAL® ACDF Spacer, 15x18, 15°, 7mm	3
365.038	COLONIAL® ACDF Spacer, 15x18, 15°, 8mm	3
365.039	COLONIAL® ACDF Spacer, 15x18, 15°, 9mm	2
365.040	COLONIAL® ACDF Spacer, 15x18, 15°, 10mm	2
365.041	COLONIAL® ACDF Spacer, 15x18, 15°, 11mm	1
365.042	COLONIAL® ACDF Spacer, 15x18, 15°, 12mm	1
965.015	COLONIAL® Hyperlordotic, 15x18, Spacer Module	

## 965.916 COLONIAL® 20° Implant Set

Part No.	Description	Qty
365.447	COLONIAL® ACDF Spacer, 12x14, 20°, 7mm	3
365.448	COLONIAL® ACDF Spacer, 12x14, 20°, 8mm	3
365.449	COLONIAL® ACDF Spacer, 12x14, 20°, 9mm	2
365.450	COLONIAL® ACDF Spacer, 12x14, 20°, 10mm	2
365.451	COLONIAL® ACDF Spacer, 12x14, 20°, 11mm	1
365.452	COLONIAL® ACDF Spacer, 12x14, 20°, 12mm	1
365.748	COLONIAL® ACDF Spacer, 14x16, 20°, 8mm	3
365.749	COLONIAL® ACDF Spacer, 14x16, 20°, 9mm	3
365.750	COLONIAL® ACDF Spacer, 14x16, 20°, 10mm	2
365.751	COLONIAL® ACDF Spacer, 14x16, 20°, 11mm	1
365.752	COLONIAL® ACDF Spacer, 14x16, 20°, 12mm	1
365.248	COLONIAL® ACDF Spacer, 15x18, 20°, 8mm	3
365.249	COLONIAL® ACDF Spacer, 15x18, 20°, 9mm	3
365.250	COLONIAL® ACDF Spacer, 15x18, 20°, 10mm	2
365.251	COLONIAL® ACDF Spacer, 15x18, 20°, 11mm	1
365.252	COLONIAL® ACDF Spacer, 15x18, 20°, 12mm	1
965.016	COLONIAL® 20° Spacer Module	

# COLONIAL<sup>®</sup> HYPERLORDOTIC IMPLANT SETS





# COLONIAL<sup>®</sup> TPS<sup>®</sup> HYPERLORDOTIC IMPLANT SETS

## 965.923 COLONIAL<sup>®</sup> TPS<sup>®</sup> 12x14mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.426CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 6mm	3
365.427CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 7mm	3
365.428CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 8mm	3
365.429CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 9mm	2
365.430CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 10mm	2
365.431CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 11mm	1
365.432CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 12°, 12mm	1
365.436CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 6mm	3
365.437CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 7mm	3
365.438CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 8mm	3
365.439CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 9mm	2
365.440CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 10mm	2
365.441CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 11mm	1
365.442CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 15°, 12mm	1
965.023	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup> 12x14mm, 12° and 15°	

## 965.924 COLONIAL<sup>®</sup> TPS<sup>®</sup> 14x16mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.726CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 6mm	3
365.727CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 7mm	3
365.728CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 8mm	3
365.729CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 9mm	2
365.730CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 10mm	2
365.731CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 11mm	1
365.732CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 12°, 12mm	1
365.737CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 7mm	3
365.738CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 8mm	3
365.739CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 9mm	2
365.740CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 10mm	2
365.741CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 11mm	1
365.742CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 15°, 12mm	1
965.024	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup> 14x16mm 12° and 15°	



# COLONIAL<sup>®</sup> TPS<sup>®</sup> HYPERLORDOTIC IMPLANT SETS

## 965.925 COLONIAL<sup>®</sup> TPS<sup>®</sup> 15x18mm, 12° and 15° Implant Set

Part No.	Description	Qty
365.026CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 6mm	3
365.027CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 7mm	3
365.028CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 8mm	3
365.029CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 9mm	2
365.030CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 10mm	2
365.031CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 11mm	1
365.032CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 12°, 12mm	1
365.237CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 7mm	3
365.238CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 8mm	3
365.239CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 9mm	2
365.240CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 10mm	2
365.241CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 11mm	1
365.242CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 15°, 12mm	1
965.025	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup> 15x18mm 12° and 15°	

## 965.926 COLONIAL<sup>®</sup> TPS<sup>®</sup> 20° Implant Set

Part No.	Description	Qty
365.447CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 7mm	3
365.448CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 8mm	3
365.449CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 9mm	2
365.450CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 10mm	2
365.451CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 11mm	1
365.452CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 12x14, 20°, 12mm	1
365.748CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 20°, 8mm	3
365.749CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 20°, 9mm	3
365.750CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 20°, 10mm	2
365.751CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 20°, 11mm	1
365.752CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 14x16, 20°, 12mm	1
365.248CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 20°, 8mm	3
365.249CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 20°, 9mm	3
365.250CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 20°, 10mm	2
365.251CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 20°, 11mm	1
365.252CS	COLONIAL <sup>®</sup> ACDF TPS <sup>®</sup> Spacer, 15x18, 20°, 12mm	1
965.026	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup> 20°	

# COLONIAL® ACDF CONVEX IMPLANT SETS

## 965.906 COLONIAL® 11x12 Convex Implant Set

Part No.	Description	Qty
365.205	COLONIAL® ACDF Spacer, 11x12, Convex, 5mm	1
365.206	COLONIAL® ACDF Spacer, 11x12, Convex, 6mm	3
365.207	COLONIAL® ACDF Spacer, 11x12, Convex, 7mm	3
365.208	COLONIAL® ACDF Spacer, 11x12, Convex, 8mm	3
365.209	COLONIAL® ACDF Spacer, 11x12, Convex, 9mm	2
365.210	COLONIAL® ACDF Spacer, 11x12, Convex, 10mm	2
365.211	COLONIAL® ACDF Spacer, 11x12, Convex, 11mm	1
365.212	COLONIAL® ACDF Spacer, 11x12, Convex, 12mm	1

## 965.907 COLONIAL® 12x14 Convex Implant Set

Part No.	Description	Qty
365.505	COLONIAL® ACDF Spacer, 12x14, Convex, 5mm	1
365.506	COLONIAL® ACDF Spacer, 12x14, Convex, 6mm	3
365.507	COLONIAL® ACDF Spacer, 12x14, Convex, 7mm	3
365.508	COLONIAL® ACDF Spacer, 12x14, Convex, 8mm	3
365.509	COLONIAL® ACDF Spacer, 12x14, Convex, 9mm	2
365.510	COLONIAL® ACDF Spacer, 12x14, Convex, 10mm	2
365.511	COLONIAL® ACDF Spacer, 12x14, Convex, 11mm	1
365.512	COLONIAL® ACDF Spacer, 12x14, Convex, 12mm	1

## 965.908 COLONIAL® 14x16 Convex Implant Set

Part No.	Description	Qty
365.905	COLONIAL® ACDF Spacer, 14x16, Convex, 5mm	1
365.906	COLONIAL® ACDF Spacer, 14x16, Convex, 6mm	3
365.907	COLONIAL® ACDF Spacer, 14x16, Convex, 7mm	3
365.908	COLONIAL® ACDF Spacer, 14x16, Convex, 8mm	3
365.909	COLONIAL® ACDF Spacer, 14x16, Convex, 9mm	2
365.910	COLONIAL® ACDF Spacer, 14x16, Convex, 10mm	2
365.911	COLONIAL® ACDF Spacer, 14x16, Convex, 11mm	1
365.912	COLONIAL® ACDF Spacer, 14x16, Convex, 12mm	1

## 965.909 COLONIAL® 15x18 Convex Implant Set

Part No.	Description	Qty
365.085	COLONIAL® ACDF Spacer, 15x18, Convex, 5mm	1
365.086	COLONIAL® ACDF Spacer, 15x18, Convex, 6mm	3
365.087	COLONIAL® ACDF Spacer, 15x18, Convex, 7mm	3
365.088	COLONIAL® ACDF Spacer, 15x18, Convex, 8mm	3
365.089	COLONIAL® ACDF Spacer, 15x18, Convex, 9mm	2
365.090	COLONIAL® ACDF Spacer, 15x18, Convex, 10mm	2
365.091	COLONIAL® ACDF Spacer, 15x18, Convex, 11mm	1
365.092	COLONIAL® ACDF Spacer, 15x18, Convex, 12mm	1

# COLONIAL<sup>®</sup> TPS<sup>®</sup> ACDF CONVEX IMPLANT SETS

## 965.951 COLONIAL<sup>®</sup> TPS<sup>®</sup> 12x14 and 14x16 Convex Implant Set

Part No.	Description	Qty
365.505CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 5mm	1
365.506CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 6mm	3
365.507CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 7mm	3
365.508CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 8mm	3
365.509CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 9mm	2
365.510CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 10mm	2
365.511CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 11mm	1
365.512CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 12x14, Convex, 12mm	1
365.905CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 5mm	1
365.906CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 6mm	3
365.907CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 7mm	3
365.908CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 8mm	3
365.909CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 9mm	2
365.910CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 10mm	2
365.911CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 11mm	1
365.912CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 14x16, Convex, 12mm	1
965.007	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup>	

## 965.957 COLONIAL<sup>®</sup> TPS<sup>®</sup> 11x12 Convex Implant Set

Part No.	Description	Qty
365.205CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 5mm	1
365.206CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 6mm	3
365.207CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 7mm	3
365.208CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 8mm	3
365.209CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 9mm	2
365.210CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 10mm	2
365.211CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 11mm	1
365.212CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 11x12, Convex, 12mm	1
965.007	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup>	

## 965.958 COLONIAL<sup>®</sup> TPS<sup>®</sup> 15x18 Convex Implant Set

Part No.	Description	Qty
365.085CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 5mm	1
365.086CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 6mm	3
365.087CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 7mm	3
365.088CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 8mm	3
365.089CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 9mm	2
365.090CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 10mm	2
365.091CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 11mm	1
365.092CS	COLONIAL <sup>®</sup> TPS <sup>®</sup> ACDF Spacer, 15x18, Convex, 12mm	1
965.007	Soft Case PATRIOT <sup>®</sup> COLONIAL <sup>®</sup> TPS <sup>®</sup>	

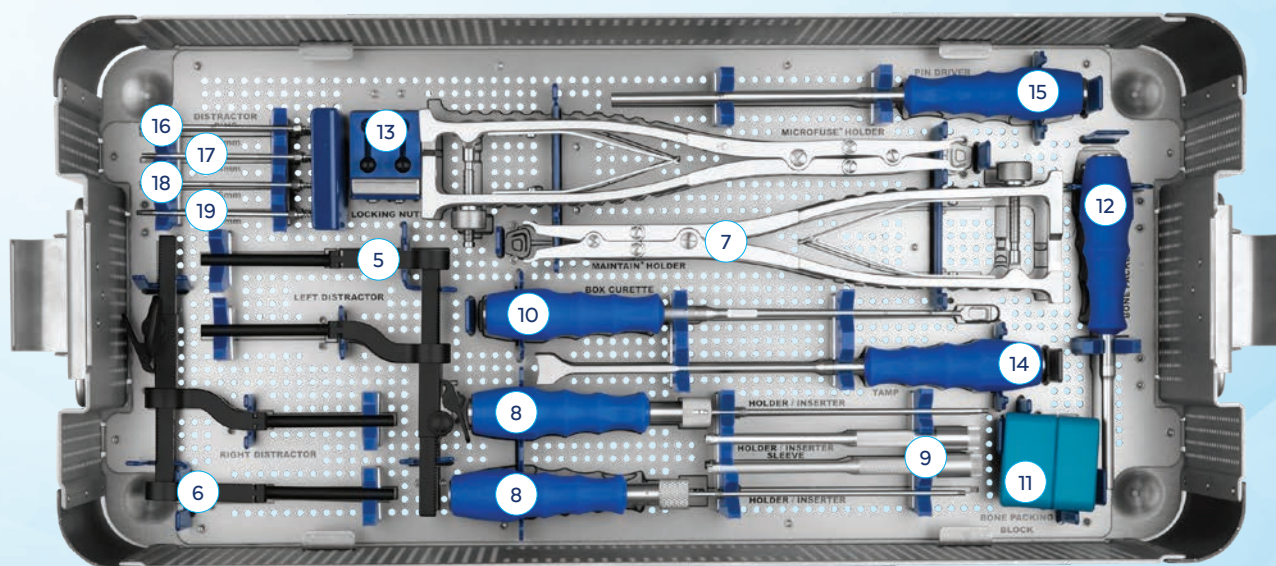
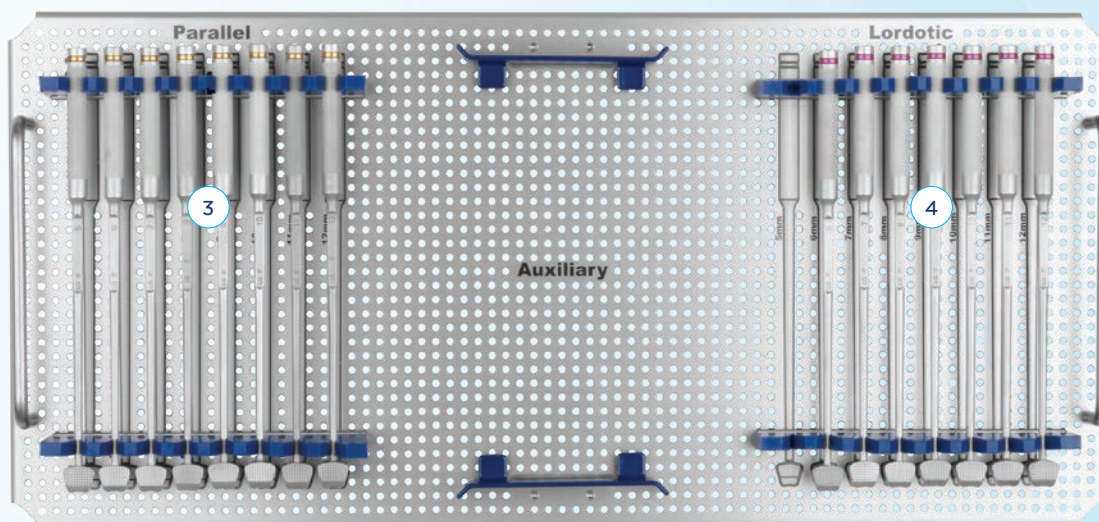
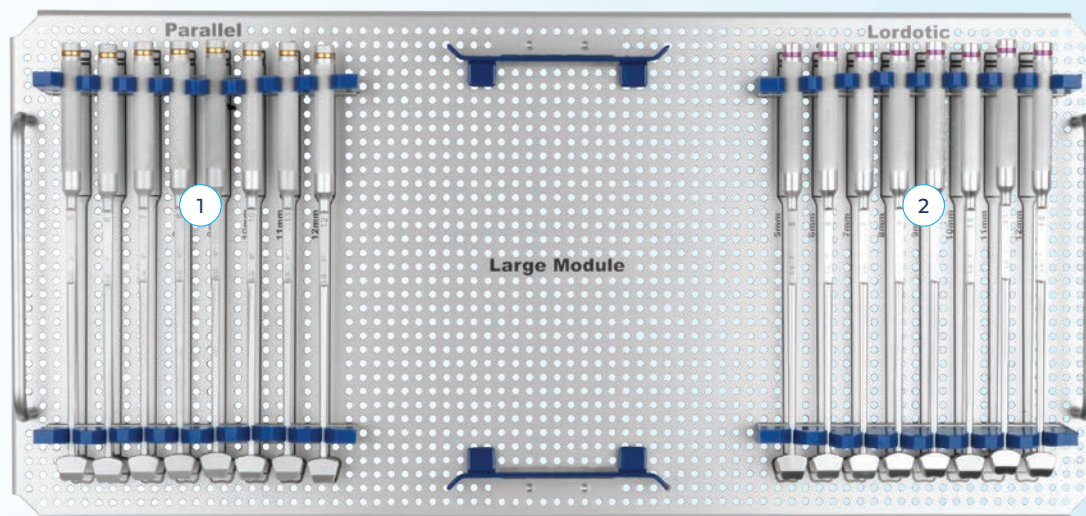
# COLONIAL® ACDF

## INSTRUMENT SET 965.905

	Part No.	Description	Qty		Part No.	Description	Qty
1	665.305	COLONIAL® Large Trial, Parallel, 5mm	1	5	601.020	Distractor, Left	1
	665.306	COLONIAL® Large Trial, Parallel, 6mm	1	6	601.021	Distractor, Right	1
	665.307	COLONIAL® Large Trial, Parallel, 7mm	1	7	601.135	MAINTAIN® Holder	1
	665.308	COLONIAL® Large Trial, Parallel, 8mm	1	8	665.500	Implant/Trial Insertion Tool	2
	665.309	COLONIAL® Large Trial, Parallel, 9mm	1	9	665.501	Implant/Trial Insertion Sleeve	2
	665.310	COLONIAL® Large Trial, Parallel, 10mm	1	10	665.502	Box Curette	1
	665.311	COLONIAL® Large Trial, Parallel, 11mm	1	11	665.503	Bone Packing Block	1
	665.312	COLONIAL® Large Trial, Parallel, 12mm	1	12	665.504	Bone Packer	1
2	665.405	COLONIAL® Large Trial, Lordotic, 5mm	1	13	665.606	Distractor Locking Nuts	4
	665.406	COLONIAL® Large Trial, Lordotic, 6mm	1	14	665.607	Impactor	1
	665.407	COLONIAL® Large Trial, Lordotic, 7mm	1	15	665.608	Distractor Pin, Driver	1
	665.408	COLONIAL® Large Trial, Lordotic, 8mm	1	16	665.612	Distractor Pin, 12mm	2
	665.409	COLONIAL® Large Trial, Lordotic, 9mm	1	17	665.614	Distractor Pin, 14mm	2
	665.410	COLONIAL® Large Trial, Lordotic, 10mm	1	18	665.616	Distractor Pin, 16mm	2
	665.411	COLONIAL® Large Trial, Lordotic, 11mm	1	19	665.618	Distractor Pin, 18mm	2
	665.412	COLONIAL® Large Trial, Lordotic, 12mm	1		965.005	COLONIAL® Graphic Case	
	665.413	COLONIAL® Large Trial, Lordotic, 13mm	-				
	665.414	COLONIAL® Large Trial, Lordotic, 14mm	-				
	665.326	COLONIAL® Rasp, Large, Parallel, 6mm	1				
3	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				
	665.426	COLONIAL® Rasp, Large, Lordotic, 6mm	1				
4	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				



# COLONIAL<sup>®</sup> ACDF INSTRUMENT SET 965.905



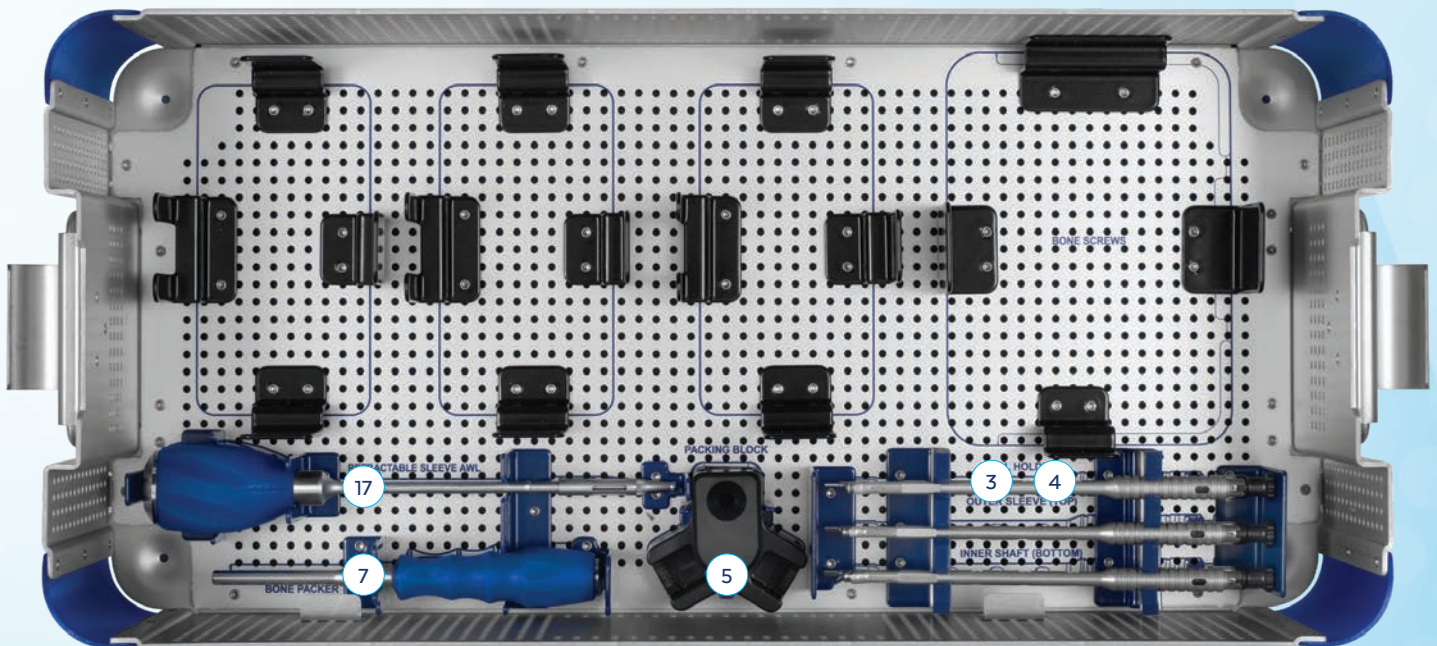
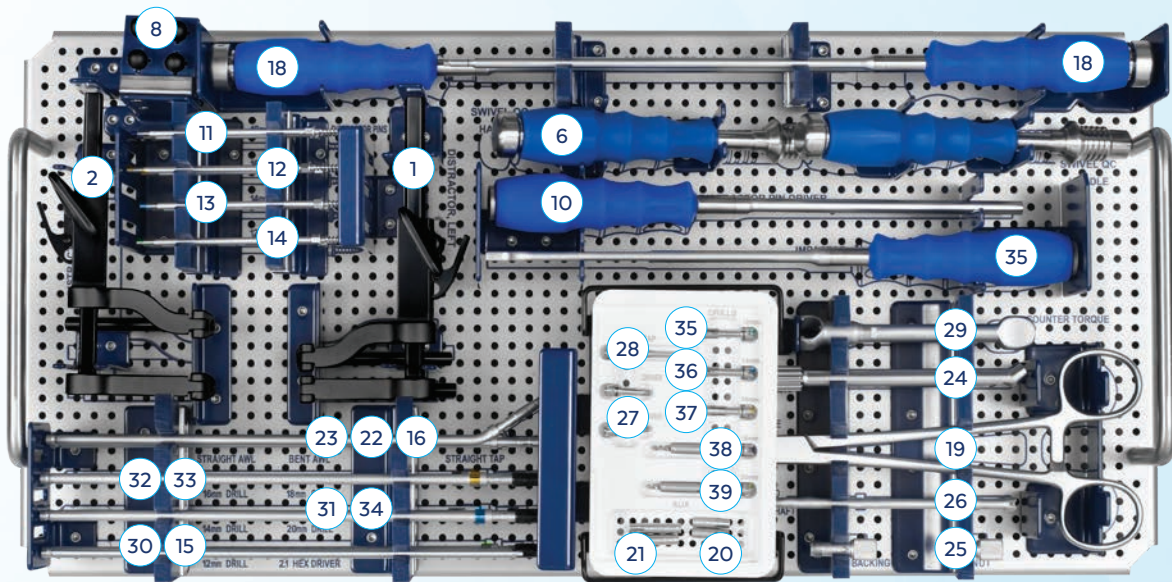
# UNIVERSAL ACDF

## INSTRUMENT SET 9147.9001

Part No.	Description	Qty	Part No.	Description	Qty
1	601.020 Distractor, Left	1	27	684.418 Hex Driver Assembly	2
2	601.021 Distractor, Right	1	28	684.419 Angled Tap Tip	1
3	6147.9001 Trial Holder, Modular Trial / Rasp Heads - Outer Sleeve	3	29	684.421 Counter-Torque, Angled Instrument	2
4	6147.9002 Trial Holder, Modular Trial / Rasp Heads - Inner Shaft Assembly	3	684.425	Angled Driver Tip, Short	-
5	6147.9003 Packing Block	1	30	684.422 Straight Drill with Self-Centering Sleeve, 12mm	1
6	636.450 Quick-Connect Handle, Swivel	2	31	684.424 Straight Drill with Self-Centering Sleeve, 14mm	1
7	665.504 Bone Packer	1	32	684.426 Straight Drill with Self-Centering Sleeve, 16mm	1
8	665.606 Distractor Locking Nuts	4	33	684.428 Straight Drill with Self-Centering Sleeve, 18mm	1
9	665.607 Impactor	1	34	684.430 Straight Drill with Self-Centering Sleeve, 20mm	1
10	665.608 Distractor Pin Driver	1	35	684.432 Angled Drill with Self-Centering Sleeve, 12mm	1
	665.610 Distractor Pin, 10mm	-	36	684.434 Angled Drill with Self-Centering Sleeve, 14mm	1
11	665.612 Distractor Pin, 12mm	2	37	684.436 Angled Drill with Self-Centering Sleeve, 16mm	1
12	665.614 Distractor Pin, 14mm	2	38	684.438 Angled Drill with Self-Centering Sleeve, 18mm	1
13	665.616 Distractor Pin, 16mm	2	39	684.440 Angled Drill with Self-Centering Sleeve, 20mm	1
14	665.618 Distractor Pin, 18mm	2			
15	671.313 VIP® Screwdriver, 2.1mm Hex, QC	1	9147.0001	Universal ACDF Instrument Graphic Case	
16	684.004 Tap, Straight	1	984.004	COALITION® Module, Angled Instruments	
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			



# UNIVERSAL ACDF INSTRUMENT SET 9147.9001



# 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	

## 9147.9015 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	

## 9147.9014 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	

## 9147.9016 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	



# UNIVERSAL ACDF TRIAL SETS



# ADDITIONALLY AVAILABLE COLONIAL<sup>®</sup> INSTRUMENTS

## Part No. Description

665.005	COLONIAL <sup>®</sup> Small Trial, Parallel, 5mm
665.006	COLONIAL <sup>®</sup> Small Trial, Parallel, 6mm
665.007	COLONIAL <sup>®</sup> Small Trial, Parallel, 7mm
665.008	COLONIAL <sup>®</sup> Small Trial, Parallel, 8mm
665.009	COLONIAL <sup>®</sup> Small Trial, Parallel, 9mm
665.010	COLONIAL <sup>®</sup> Small Trial, Parallel, 10mm
665.011	COLONIAL <sup>®</sup> Small Trial, Parallel, 11mm
665.012	COLONIAL <sup>®</sup> Small Trial, Parallel, 12mm
665.025	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 5mm
665.026	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 6mm
665.027	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 7mm
665.028	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 8mm
665.029	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 9mm
665.030	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 10mm
665.031	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 11mm
665.032	COLONIAL <sup>®</sup> Rasp, Small, Parallel, 12mm
665.045	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 5mm
665.046	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 6mm
665.047	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 7mm
665.048	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 8mm
665.049	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 9mm
665.050	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 10mm
665.051	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 11mm
665.052	COLONIAL <sup>®</sup> ACDF Trial, XXL, Parallel, 12mm
665.065	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 5mm
665.066	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 6mm
665.067	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 7mm
665.068	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 8mm
665.069	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 9mm
665.070	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 10mm
665.071	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 11mm
665.072	COLONIAL <sup>®</sup> ACDF Trial, XXL, Lordotic, 12mm

## Part No. Description

665.105	COLONIAL <sup>®</sup> Small Trial, Lordotic, 5mm
665.106	COLONIAL <sup>®</sup> Small Trial, Lordotic, 6mm
665.107	COLONIAL <sup>®</sup> Small Trial, Lordotic, 7mm
665.108	COLONIAL <sup>®</sup> Small Trial, Lordotic, 8mm
665.109	COLONIAL <sup>®</sup> Small Trial, Lordotic, 9mm
665.110	COLONIAL <sup>®</sup> Small Trial, Lordotic, 10mm
665.111	COLONIAL <sup>®</sup> Small Trial, Lordotic, 11mm
665.112	COLONIAL <sup>®</sup> Small Trial, Lordotic, 12mm
665.113	COLONIAL <sup>®</sup> Small Trial, Lordotic, 13mm
665.114	COLONIAL <sup>®</sup> Small Trial, Lordotic, 14mm
665.126	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 6mm
665.127	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 7mm
665.128	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 8mm
665.129	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 9mm
665.130	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 10mm
665.131	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 11mm
665.132	COLONIAL <sup>®</sup> Rasp, Small, Lordotic, 12mm
665.705	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 5mm
665.706	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 6mm
665.707	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 7mm
665.708	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 8mm
665.709	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 9mm
665.710	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 10mm
665.711	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 11mm
665.712	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 12mm
665.713	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 13mm
665.714	COLONIAL <sup>®</sup> X-Large Trial, Lordotic, 14mm
665.805	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 5mm
665.806	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 6mm
665.807	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 7mm
665.808	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 8mm
665.809	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 9mm
665.810	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 10mm
665.811	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 11mm
665.812	COLONIAL <sup>®</sup> X-Large Trial, Parallel, 12mm

# IMPORTANT INFORMATION ON PATRIOT® CERVICAL SPACERS

## DESCRIPTION

PATRIOT® COLONIAL® Spacers are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COLONIAL® ACDF Spacers are inserted through an anterior cervical approach, and are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® COLONIAL® Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in F2026, F136, F1295, and F560. PATRIOT® PEEK Spacers are available with a commercially pure titanium plasma spray (TPS) coating, as specified in ASTM F67 and F1580. COLONIAL® Ti Spacers are manufactured from titanium alloy per ASTM F136.

## INDICATIONS

PATRIOT® COLONIAL® ACDF 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 weeks of non-operative treatment. All PATRIOT® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

PATRIOT® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation, such as the ASSURE® or PROVIDENCE® Anterior Cervical Plate Systems.

## 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 levels to be treated may have different clinical outcomes compared to those without previous surgery.

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 PATRIOT® 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 PATRIOT® 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:

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 levels 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. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any case that requires the mixing of metals from two different components or systems.
17. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
18. 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

## IMPORTANT INFORMATION ON PATRIOT® CERVICAL SPACERS

- 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 and instruments may be 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 accidentally 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 Enzo® 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 Enzo® 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 and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level SAL of 10<sup>-6</sup>. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10<sup>-6</sup>. 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<sup>2</sup> total, or a minimum of four (4) 7.5in diameter filters.
- No more than one 1 loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.











For implants and 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
Steam	Pre-vacuum	134°C (273°F)	3 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 (U.S.A.) Law Restricts this Device to Sale by or on the Order of a Physician.

## IMPORTANT INFORMATION ON PATRIOT® CERVICAL SPACERS

	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

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## NOTES

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