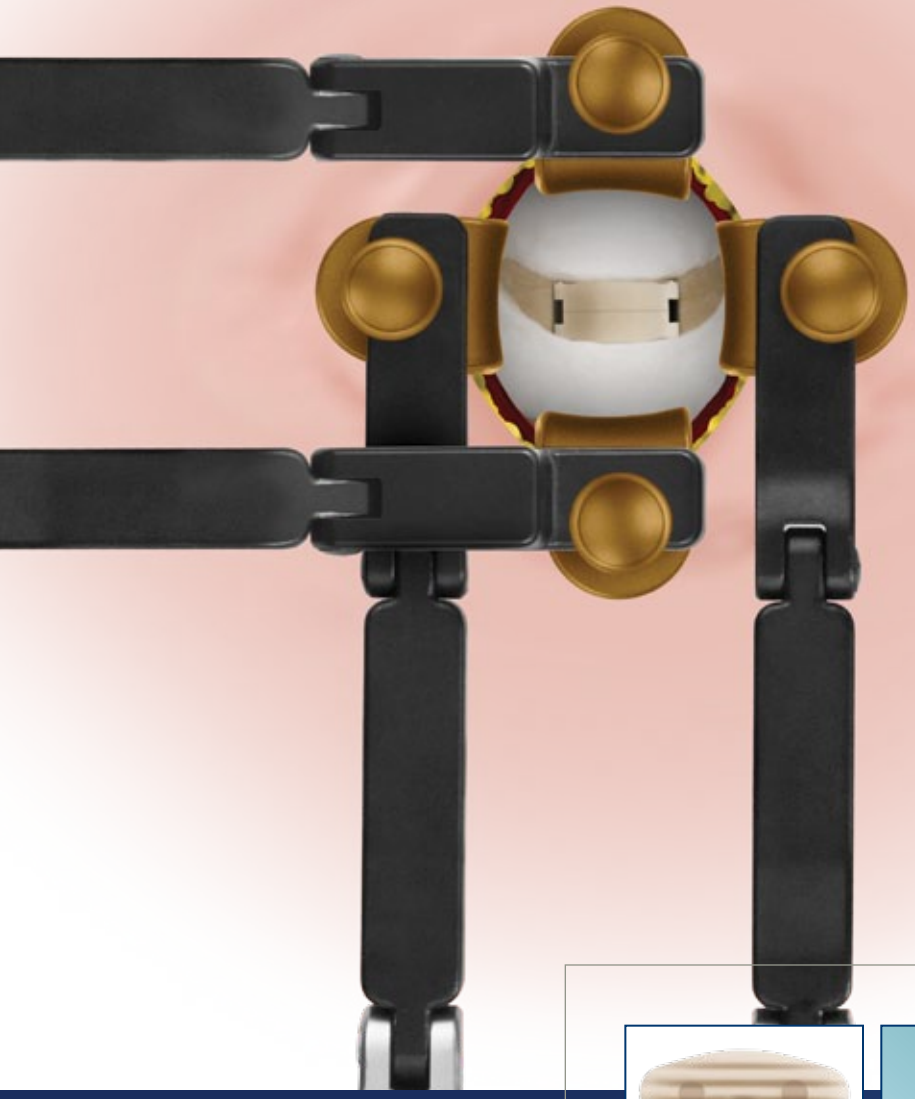
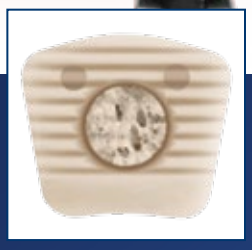
Life moves us



SURGICAL TECHNIQUE



FORGE®

Cervical Allograft Spacer

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

FORGE®

Cervical Allograft Spacer

The FORGE® Cervical Allograft Spacer is a corticocancellous spacer designed to provide a natural option for anterior cervical fusion. This spacer is available in multiple sagittal profiles and heights to accommodate varying patient anatomy and optimize fit. The FORGE® system is designed to be used with innovative instruments to streamline the procedure.

FORGE®
CERVICAL ALLOGRAFT SPACER

Precisely Machined for Strength and Fit

Designed to support cervical loads while maximizing surface contact between the graft and the vertebral endplates

Gradual Bone Incorporation

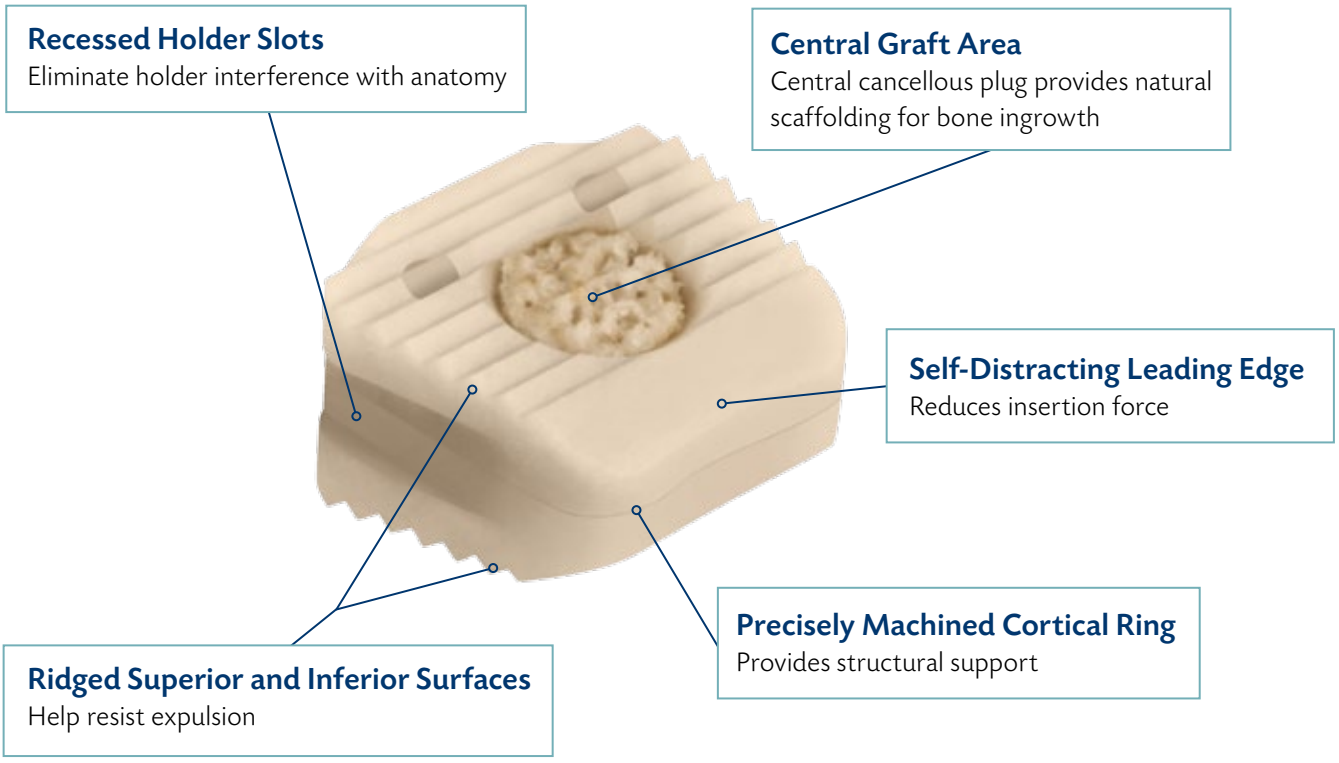
Corticocancellous composition provides a load-bearing scaffold that can be slowly resorbed and simultaneously replaced by the patient's own bone

Osteogenic *In Situ*

Becomes osteogenic upon *in situ* rehydration with blood from adjacent bleeding bone

Sterile-Packed in Freeze-Dried Form

Compact storage and easy shipping



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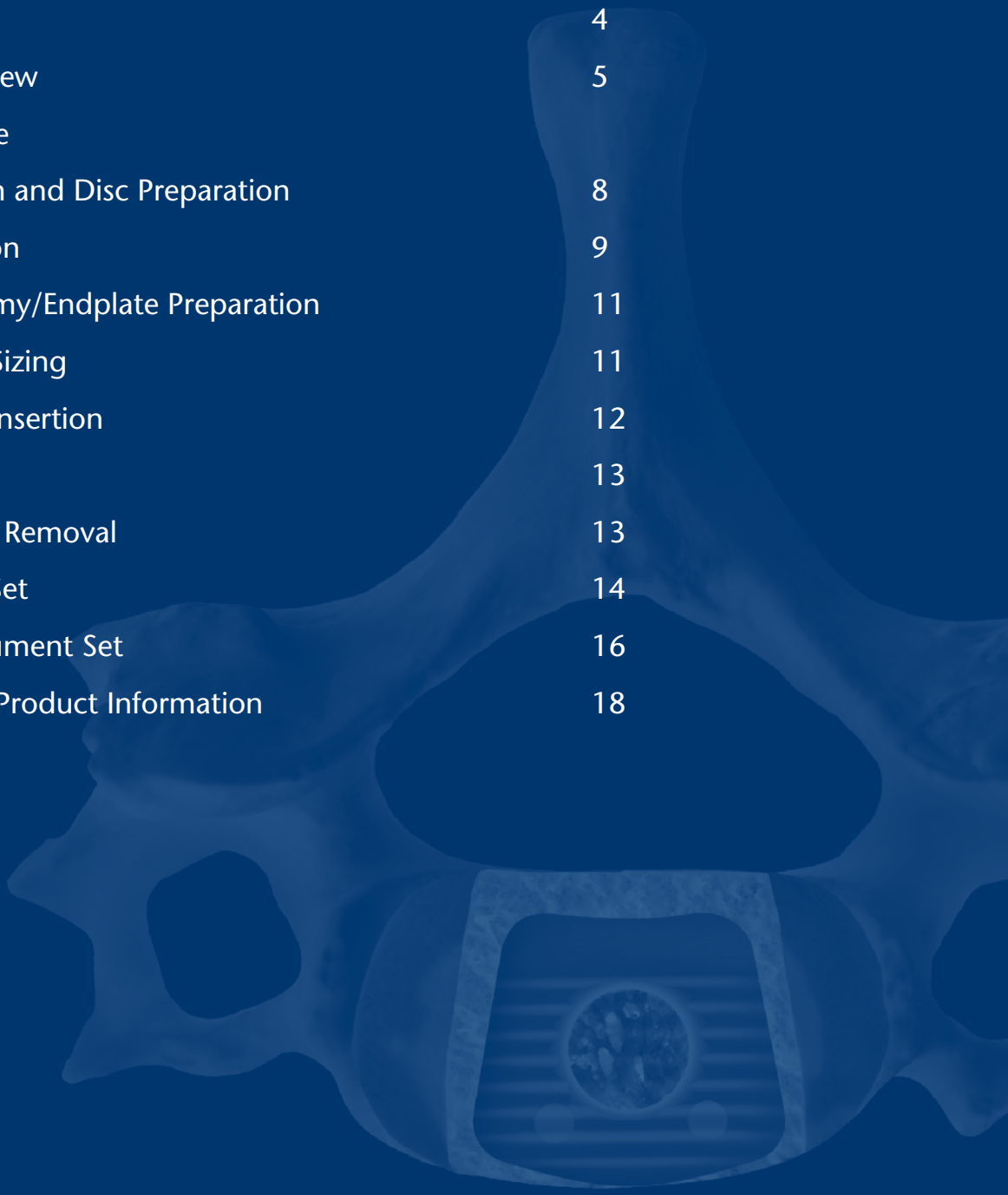
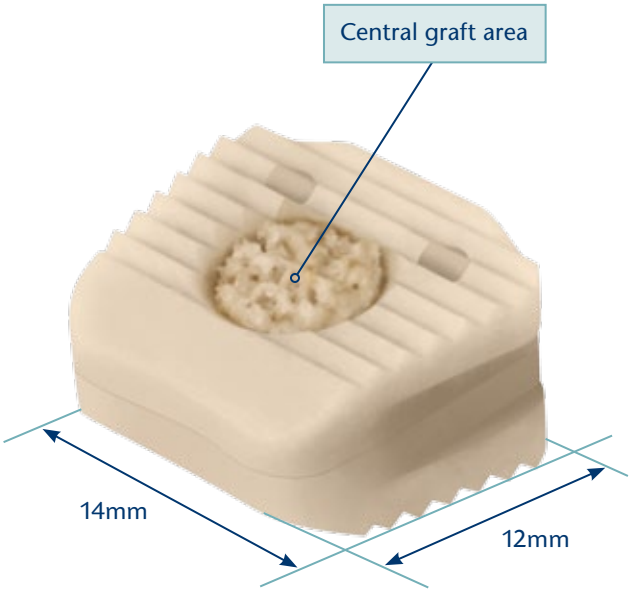


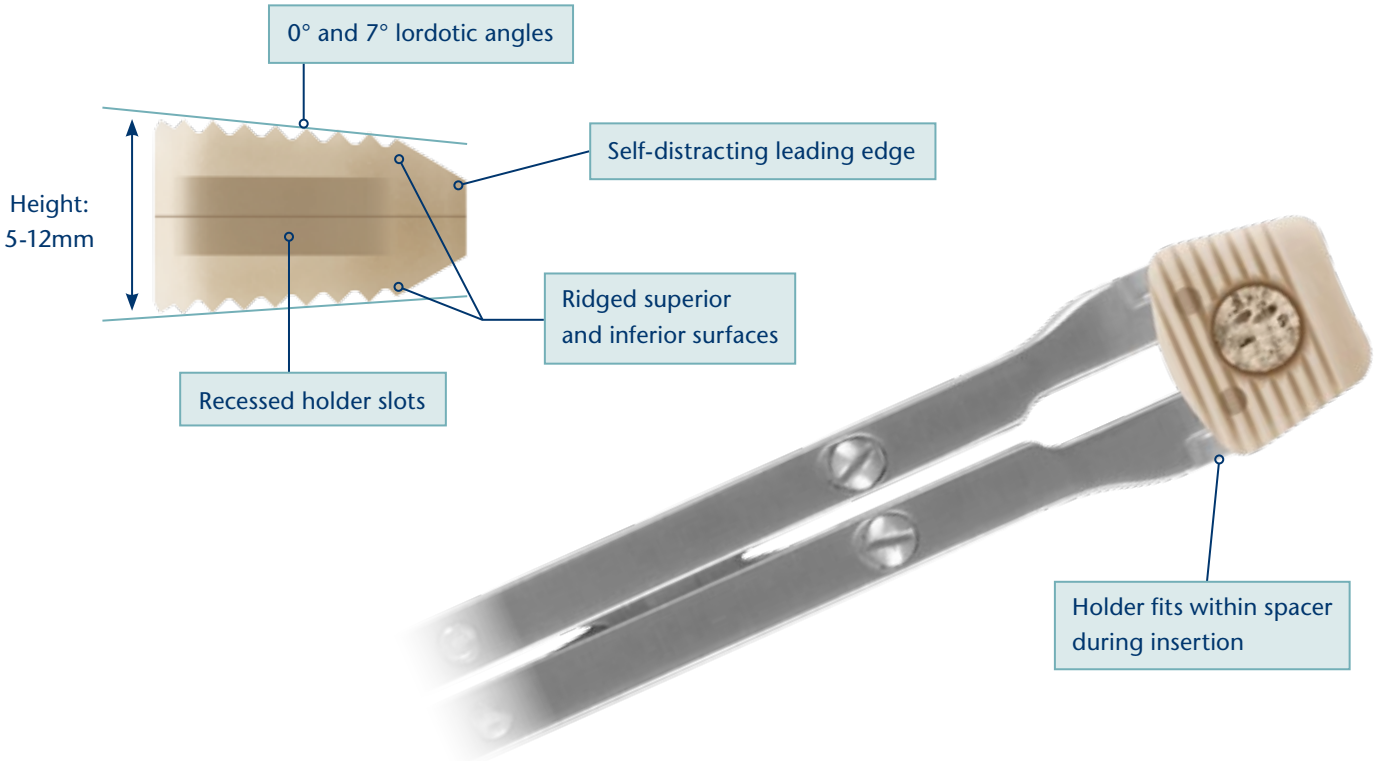
The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be 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.

IMPLANT OVERVIEW

FORGE® Cervical Allograft Spacer

- Footprint: 12x14mm
- Height: 5–12mm, 1mm increments
- Two sagittal profiles (0° and 7° lordotic) for an optimal fit between cervical endplates
- Precisely machined from corticocancellous bone for strength and fit
- Central graft area filled with cancellous bone helps promote fusion
- Self-distracting leading edge reduces insertion force
- Ridged superior and inferior surfaces maintain *in situ* position and help resist expulsion
- Recessed holder slots provide a secure fit with the holder and eliminate holder interference with anatomy
- Compatible with Minimally Invasive Surgical (MIS) techniques





INSTRUMENT OVERVIEW

Note: The FORGE® Cervical Allograft Spacer has the same footprint as the PATRIOT® Large COLONIAL® ACDF Spacer. The COLONIAL® Instrument Set (965.905) may be used to prepare the site for the insertion of a FORGE® Cervical Allograft Spacer.

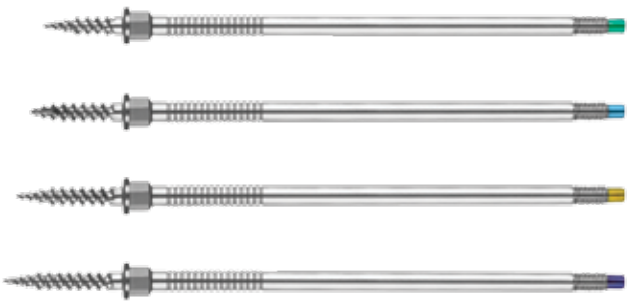
The following instruments will be additionally required:
665.901 FORGE® Cervical Implant Holder
665.907 FORGE® Cervical Impactor

Distraction Instruments

Distractor, Right 601.021
Distractor, Left 601.020

Distractor Locking Nuts 665.606

Distractor Pins

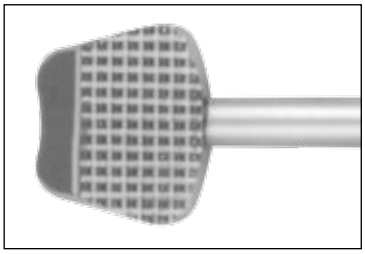


Height	Part Number
12mm	665.612
14mm	665.614
16mm	665.616
18mm	665.618

Distractor Pin Driver 665.608

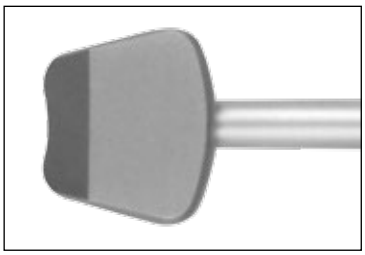
Trials

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



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

Insertion Instruments

FORGE® Cervical Implant Holder 665.901

FORGE® Cervical Impactor 665.907

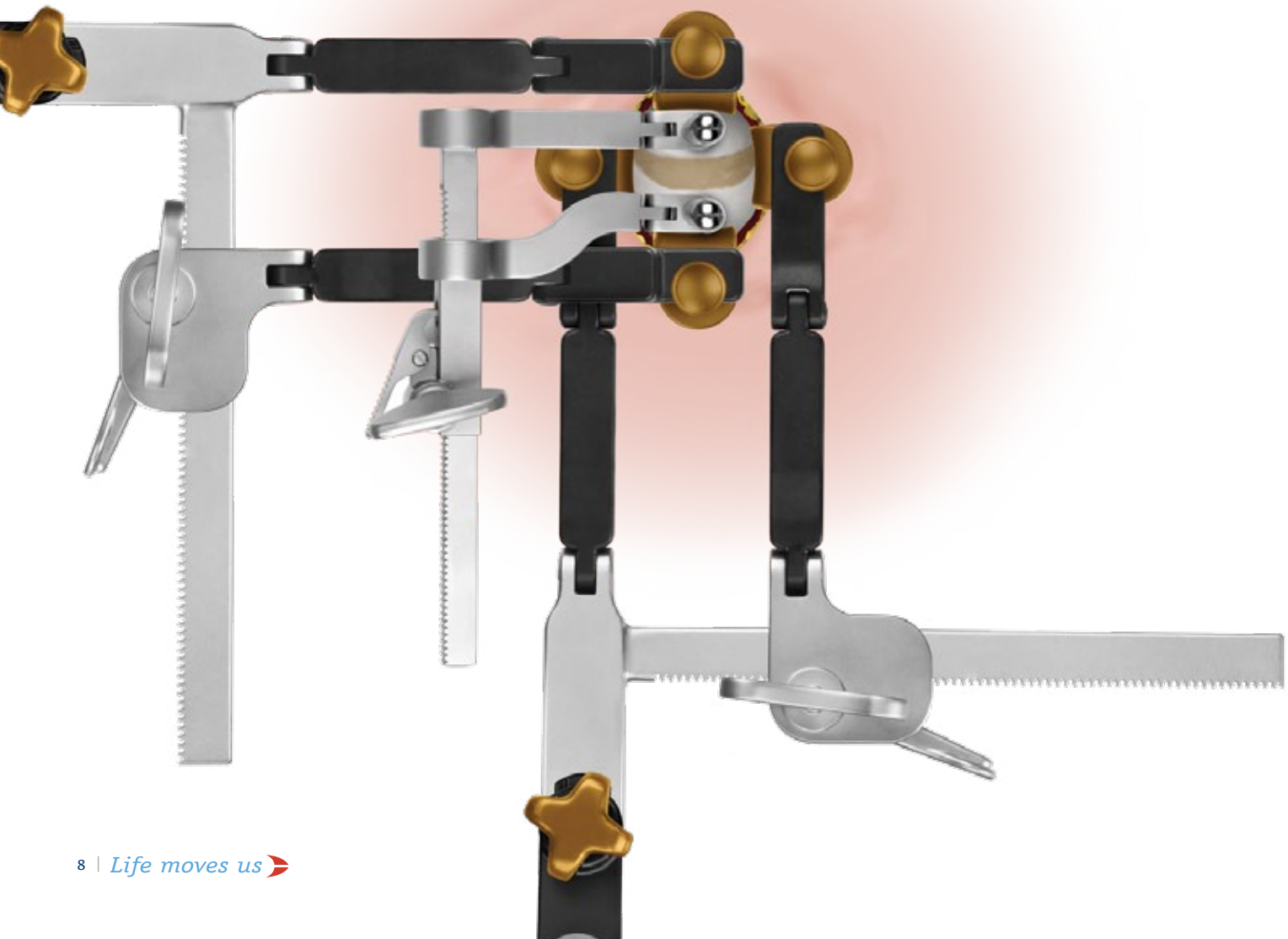
Additional Instruments

Box Curette 665.502

FORGE® Cervical Allograft Spacer
SURGICAL TECHNIQUE

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 cervical level. Please refer to the product information at the end of this technique manual for complete description, indications, contraindications and warnings.



Step 2 Distraction

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

To use the distractor, first 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 in placing pins to avoid interference with supplemental fixation (e.g. anterior cervical plate).

Insertion of distractor pins

Distractor pins positioned

Distraction (Cont'd)

Place the Distractor, Left or Right, as desired until seated. Secure the distractor in place by attaching the **Distractor Locking Nuts** and rotating clockwise until secure. 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.

Distracting the disc space using the 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, **COLONIAL® Trial Rasps** match the trial design and may be used to expose bleeding bone.

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

Endplate preparation using the box curette

Endplate preparation using the trial rasp

Step 4 Implant Sizing

Determine the appropriate implant profile for the desired segment. Insert the 5mm **COLONIAL® Trial** into the disc space first, moving onto taller trials as needed. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. This can be confirmed using fluoroscopy and tactile feedback.

Trialing for implant size

Step 5 Implant Insertion

Select an appropriate size FORGE® Cervical Allograft Spacer.

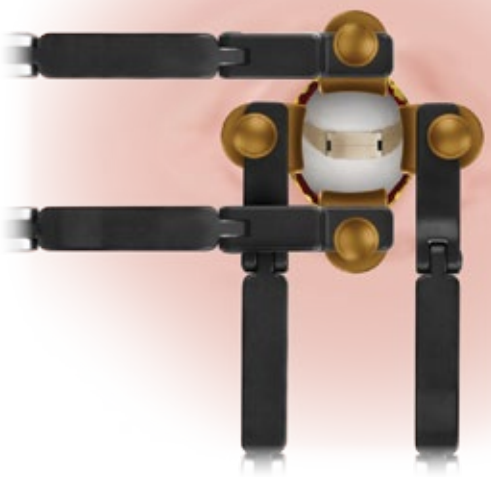
Grip the spacer with the **FORGE® Cervical Implant Holder** and insert into the intervertebral space. The spacer should be slightly recessed into the disc space. If needed, the **FORGE® Cervical Impactor** may be used for light impaction.

Note: Cancellous plug area may be removed if desired and replaced with autograft.

Implant insertion

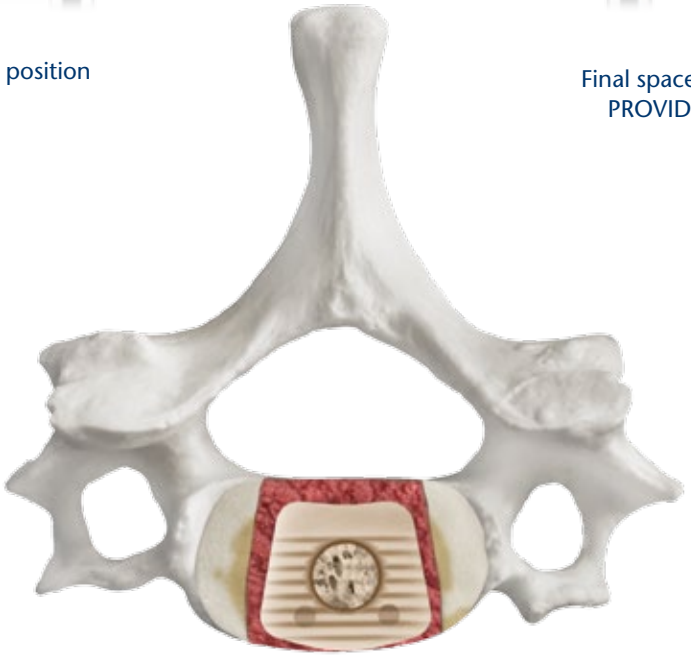
Final Position

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



Final spacer position

Final spacer position with PROVIDENCE™ plate

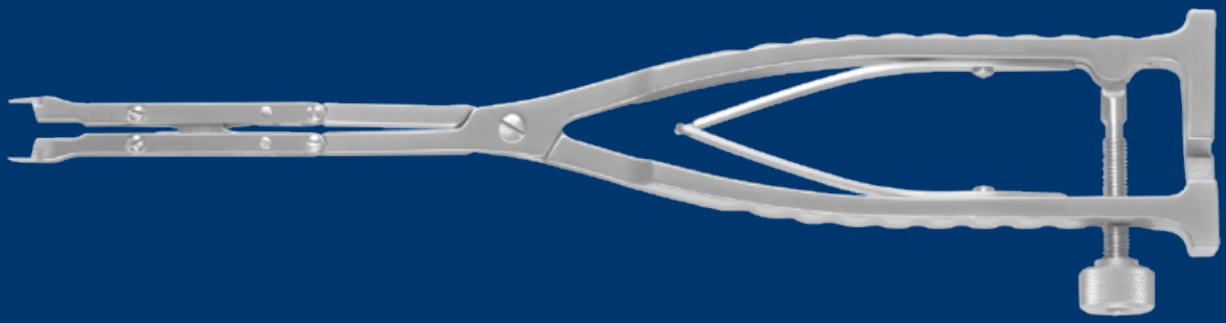


Final Position, Axial View

Optional: Implant Removal

The FORGE® Cervical Implant Holder, forceps or other manual surgical instruments may be used to grasp and extract the spacer.

FORGE® CERVICAL SET



FORGE® Cervical Set 9109.9001

FORGE® Cervical Spacers

Part No.	Height	Lordotic Angle	Qty
865.305S	5mm	0°	1
865.306S	6mm	0°	3
865.307S	7mm	0°	3
865.308S	8mm	0°	3
865.309S	9mm	0°	2
865.310S	10mm	0°	2
865.311S	11mm	0°	0
865.312S	12mm	0°	0
865.405S	5mm	7°	1
865.406S	6mm	7°	3
865.407S	7mm	7°	3
865.408S	8mm	7°	3
865.409S	9mm	7°	2
865.410S	10mm	7°	2
865.411S	11mm	7°	0
865.412S	12mm	7°	0

Part Number	Graft Volume (cc)	Part Number	Graft Volume (cc)
865.305S	0.12	865.405S	0.10
865.306S	0.14	865.406S	0.12
865.307S	0.16	865.407S	0.14
865.308S	0.18	865.408S	0.16
865.309S	0.20	865.409S	0.19
865.310S	0.22	865.410S	0.22
865.311S	0.24	865.411S	0.23
865.312S	0.27	865.412S	0.25

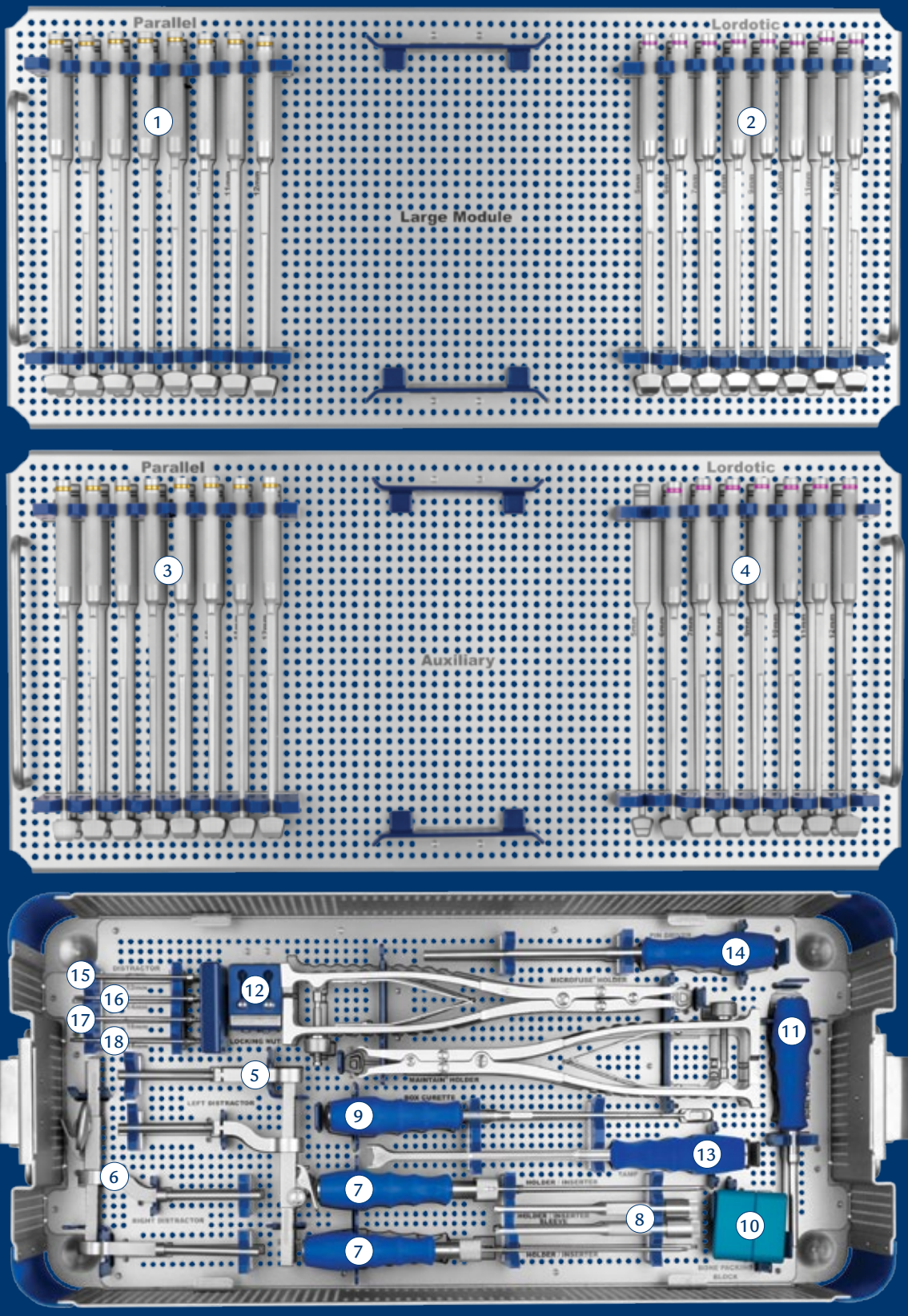
Instruments

Part No.	Description	Qty
665.901	FORGE® Cervical Implant Holder	1
665.907	FORGE® Cervical Impactor	1

Soft Case

965.060	FORGE® Cervical Soft Case	

COLONIAL® INSTRUMENT SET



COLONIAL® Instrument Set 965.905

	Instruments		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
3	665.325	COLONIAL® Rasp, Large, Parallel, 5mm	1
	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

	Instruments		Qty
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
	665.432	COLONIAL® Rasp, Large, Lordotic, 12mm	1
5	601.020	Distractor, Left	1
6	601.021	Distractor, Right	1
7	665.500	Implant/Trial Insertion Tool	2
8	665.501	Implant/Trial Insertion Sleeve	2
9	665.502	Box Curette	1
10	665.503	Bone Packing Block	1
11	665.504	Bone Packer	1
12	665.606	Distractor Locking Nuts	4
13	665.607	Impactor	1
14	665.608	Distractor Pin Driver	1
15	665.612	Distractor Pin, 12mm	2
16	665.614	Distractor Pin, 14mm	2
17	665.616	Distractor Pin, 16mm	2
18	665.618	Distractor Pin, 18mm	2
	965.005	COLONIAL® Graphic Case	

TISSUE SAFETY AND PRODUCT INFORMATION

Tissue Bank

Every tissue bank that processes FORGE® Allograft Spacers is accredited by the American Association of Tissue Banks (AATB), complies with FDA regulations and maintains the highest standards in the recovery, processing, storage and distribution of human allograft tissues. These tissue banks assure unsurpassed safety and the highest quality of FORGE® Allograft Spacers.

Stringent Donor Selection, Testing and Donor Release

Each of Globus' partner tissue banks adheres to strict donor criteria and stringent screening procedures. Every donor undergoes an intense review of medical and social history, along with intensive screening and testing. Donors are tested for HIV 1 and 2, Hepatitis C, Hepatitis B, and Syphilis. In addition, numerous microbiologic cultures are performed and evaluated at tissue recovery and allograft packaging. As a final check, a portion of each donor's tissue is destructively tested for the presence of microorganisms. Donors are determined to be suitable for transplantation only after the tissue bank's Medical Director reviews the medical and social history, relevant hospital records, infectious disease testing, physical exam, and autopsy report (if one was performed).

Controlled Processing and Rigorous Cleaning

AATB certified technicians process FORGE® Allograft Spacers in a highly controlled environment to minimize possible contaminants. FORGE® Allograft Spacers are processed, cleaned and disinfected using proprietary technology which is a combination of treatments of antibiotics, alcohol, peroxide and multiple water rinses to reduce bioburden of the processed tissue. Coupled with a removal of bone marrow, lipids, and proteins, this technology is effective in reducing the risk of viral transmission of processed tissues.

Product-Specific Information

Please refer to the package insert for the specific product for details on storage, handling, and preparation of allograft, as well as tissue handling procedures.

Notes

Notes

Notes

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

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

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