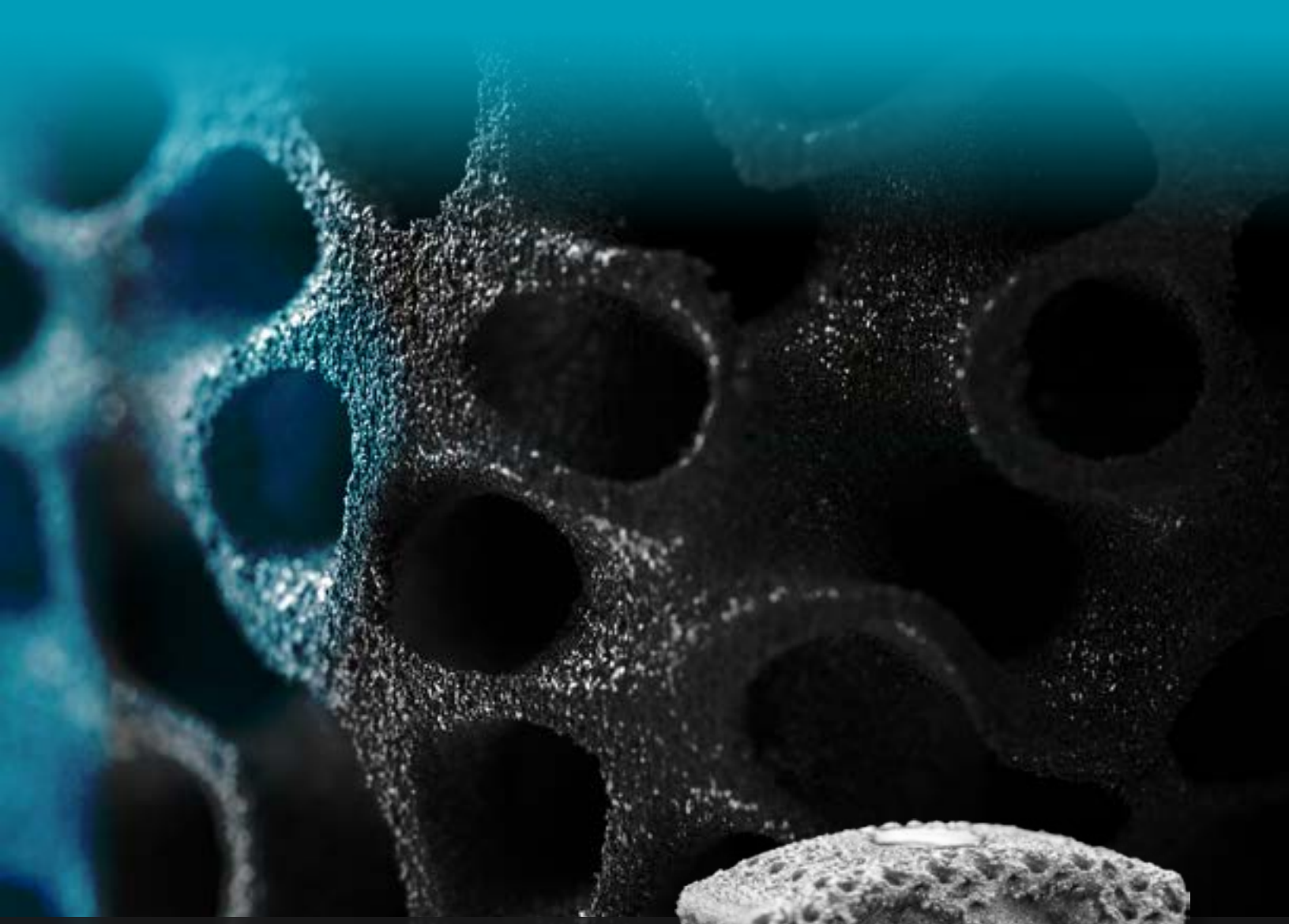


TIDAL™ Cervical Fusion Cage

Fusion in the Cervical Spine (C3-C7)

SURGICAL TECHNIQUE

restor3d

restor3d

Personalized Orthopaedics
Enabling Surgeons to Repair and
Reconstruct the Human Body

Backed by Science
Driven by Outcomes

THIS IS AN INTERACTIVE DOCUMENT

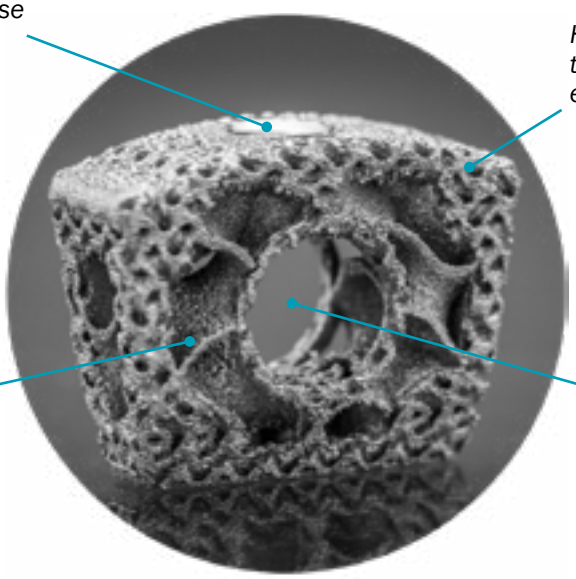
Contents

IMPORTANT NOTE: restor3d, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. restor3d is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Always refer to the package insert, product label and/or product instructions prior to using any restor3d product.

For further product information or to arrange a product demonstration, please contact your local restor3d representative or call Customer Service toll-free in the U.S. at (984) 888-0593 or email customerservice@restor3d.com. You can also visit www.restor3d.com.

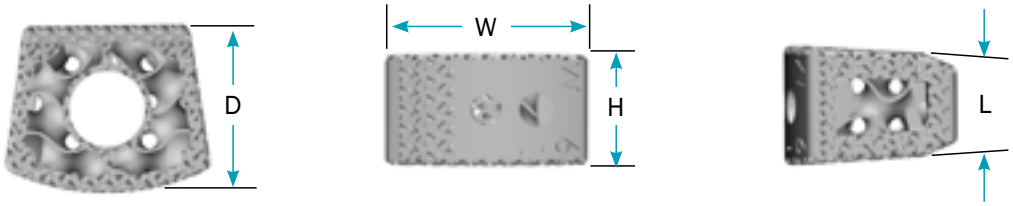
Product Overview

restor3d's TIDAL™ Cervical Fusion Cage is a spinal intervertebral fusion device designed for use in anterior cervical discectomy and fusion procedures in the cervical spine (C3-C7). Manufactured using laser powder bed fusion of medical grade titanium alloy, it's available in a variety of sizes to accommodate differences in patient anatomy.



Available in multiple footprints and heights to accommodate various patient anatomies

Sizing Options

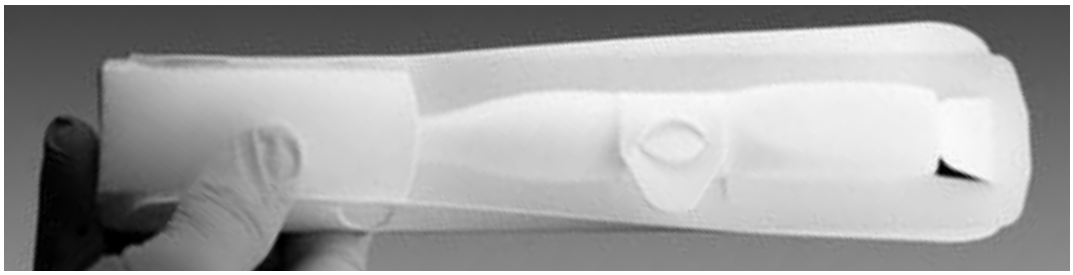


DEPTH (MM)	WIDTH (MM)	HEIGHT* (MM)	LORDOSIS
11mm	14mm	5mm-12mm	7°
13mm	16mm	5mm-12mm	7°
15mm	17mm	5mm-12mm	7°

**Heights are in 1mm increments.*

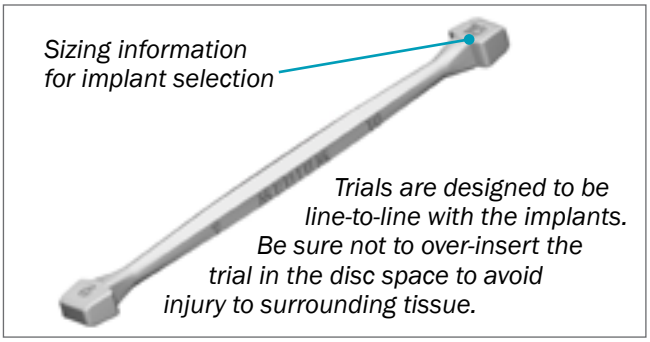
Disposable Instrumentation

Instrumented with single-use, sterile-packed trials and inserters. restor3d's TIDAL™ Cervical Fusion Cage screws onto a threaded inserter for accurate placement. Once implant is in place, simply unscrew the inserter to release.



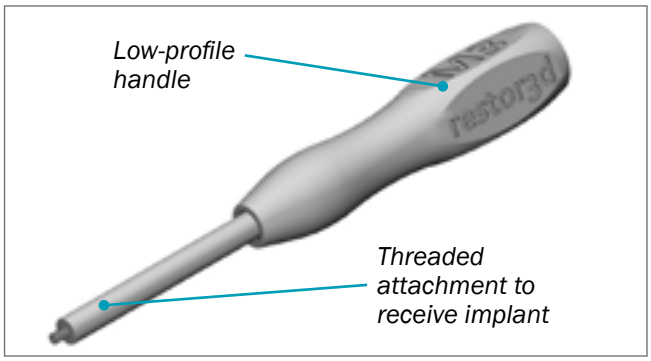
Sizing Trials

- Radiodense material for clear visibility intraoperatively.
- Allows for determination of the correct size of implant.
- Provided in all sizes to match implant offering.



Inserter

- Ergonomic, low-profile handle to maximize visibility of fusion site.
- Rigid fixation with threaded attachment to implant and anti-rotation feature on implant-inserter interface.

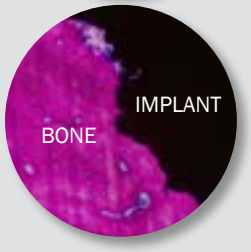


TIDAL Technology

Backed by years of scientific research and development

restor3d's TIDAL Technology is an optimized porous architecture designed for osseointegration. Derived from sinusoidal functions, TIDAL Technology guides bone growth through the fully interconnected structure with maximized surface area.

- 100% interconnectivity and up to 80% porosity[1]
- Mesoscale pores support graft retention and bony ingrowth[2]
- Direct bony apposition to implant surface guided by surface topography and curvature demonstrated in preclinical model[2,3]



1. Kelly, et al. Acta Biomaterialia (2019) 94, 601-626.
2. Kelly, et al. Journal of the Mechanical Behavior of Biomedical Materials (2021) 116, 104380.
3. Kelly et al. Biomaterials (2021) 279, 121206.

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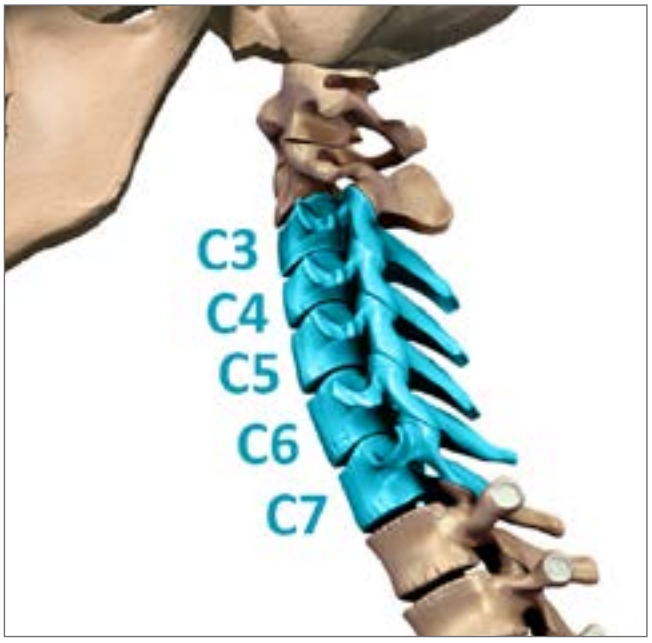
Indications

The restor3d's TIDAL™ Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or more level(s) of the cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the central aperture. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine.



Contraindications

- Surgical procedures other than those listed in the indications for use.
- Patients with an active local or systemic infection.
- Conditions which tend to retard healing such as blood supply limitations or previous infections.
- Skeletally immature patients where the implanted device would cross open epiphyseal plates.
- Grossly distorted anatomy due to congenital abnormalities.
- Inadequate tissue coverage over surgical site.
- Insufficient quality or quantity of bone, comminuted bone surfaces or pathologic conditions such as cystic change or severe osteopenia that would impair the ability of the restor3d Cervical Interbody Fusion Cage to securely fixate to the bone.
- Inadequate neuromuscular status (e.g. paralysis, inadequate muscle strength).
- Patients with conditions such as mental illness, senility, or alcoholism that tend to restrict his or her willingness to follow postoperative instructions during the healing process.
- Patients with foreign body sensitivity, suspected or documented material allergy or intolerance. Where material sensitivity is suspected, appropriate tests should be conducted, and sensitivity ruled out prior to implantation.

Surgical Technique

1. **Expose the disc space and distract the segment per standard procedure.**
2. **Prepare the disc space per surgeon preference.**
3. **Determine the correct implant size and shape with the implant trial(s).**

   Trial selection depends on the height, width, and depth of the intervertebral space, the preparation technique, and the patient's anatomy. Based on the preoperative imaging and surgical technique, choose a trial of the appropriate size and carefully insert it into the disc space (Fig. 1). Sequentially trial until a desired fit within the disc space is achieved. Verify correct sizing via fluoroscopy and select the implant that corresponds to the footprint and height determined using the implant trial(s).

   NOTE: Trials are designed to be line-to-line with the implants.

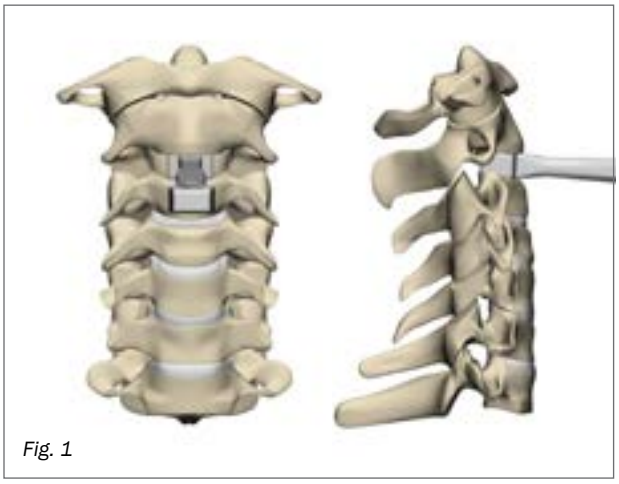


Fig. 1

4. **Prepare the implant, including packing with bone graft material, if desired.**

   Pack the interior of the cage with bone graft material. Note that the large, central graft window, in addition to the porous lattice, can be packed with graft material (Fig. 2).

   PRECAUTION: It is important to fill the implant graft volume fully to ensure optimal contact with the vertebral endplates.

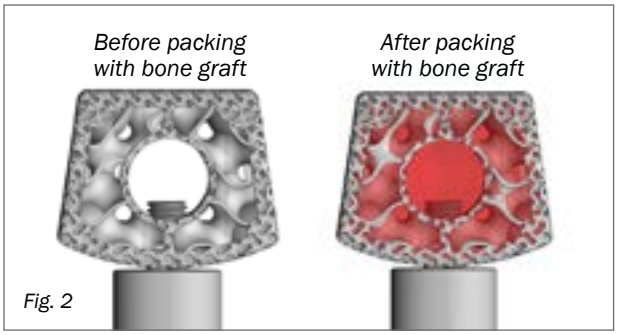


Fig. 2

5. **Place the implant on the inserter handle**

   While holding the implant in place, thread the implant onto the inserter by turning the handle clockwise (Figs. 3 and 4).

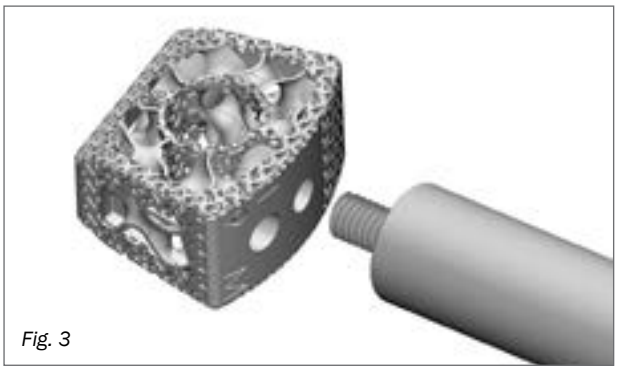


Fig. 3

Fig. 4

Tighten until the knob just touches the back of the handle and some resistance is felt. Ensure the implant is held flush against the inserter and securely in place (Fig. 5).

PRECAUTION: Take caution to not overtighten when threading the implant onto the inserter as overtightening could result in failure to disengage the implant after insertion.

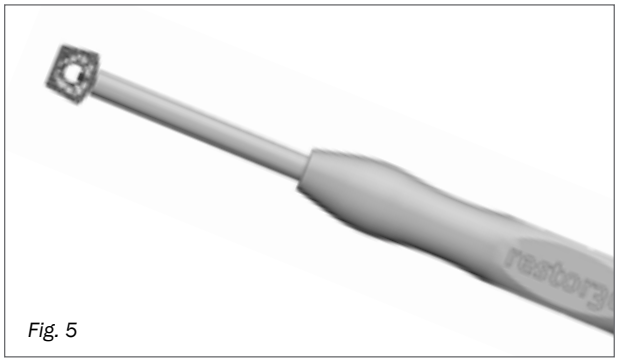


Fig. 5

6. **Orient the implant and inserter in the correct alignment and carefully insert the implant into the distracted segment.**

   Carefully insert the implant into the distracted segment. If necessary, use light impaction to advance the implant into the intervertebral disc space (Fig. 6).

   PRECAUTION: When inserting the implant, take care to avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

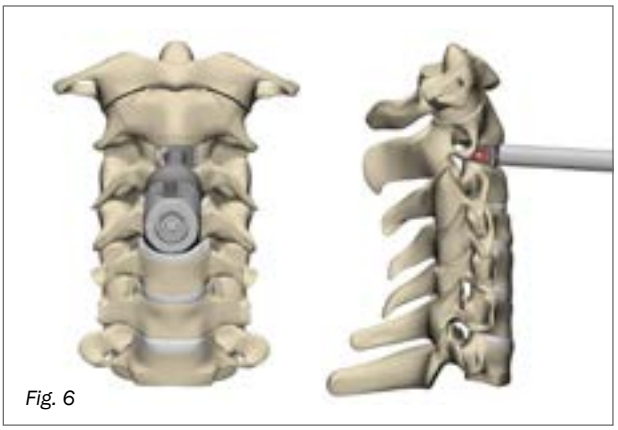


Fig. 6

7. **Verify implant position.**

   Confirm the final position of the implant under radiographic imaging via fluoroscopy (Figs. 7-9).

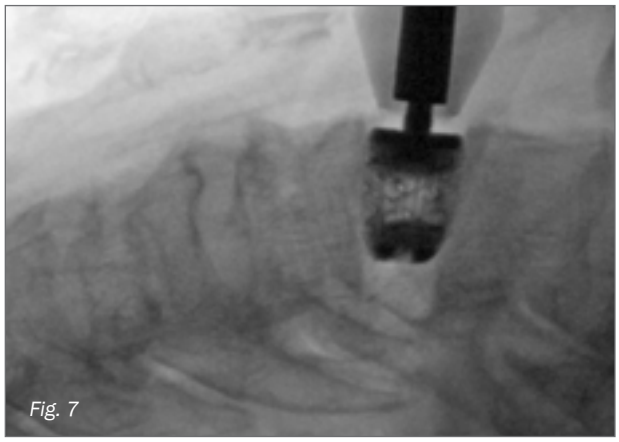


Fig. 7

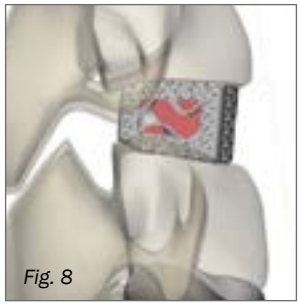


Fig. 8

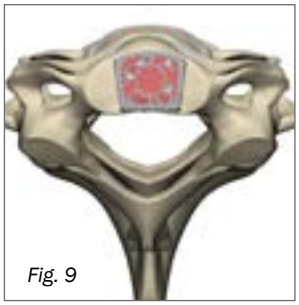


Fig. 9

8. **Remove the inserter handle from the disc space.**

   Turn the knob in a counterclockwise direction to release the implant from the implant inserter.

9. **Complete surgical procedure as required.**

Explant Information

If this implant needs to be removed due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering Information – Implants

TIDAL™ Cervical Fusion Cages

IMPLANT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	HEIGHT	ANGLE
	1110-001-14110507	Small Footprint	11mm	14mm	5mm	7°
	1110-001-14110607				6mm	
	1110-001-14110707				7mm	
	1110-001-14110807				8mm	
	1110-001-14110907				9mm	
	1110-001-14111007				10mm	
	1110-001-14111107				11mm	
	1110-001-14111207				12mm	
	1110-001-16130507	Medium Footprint	13mm	16mm	5mm	7°
	1110-001-16130607				6mm	
	1110-001-16130707				7mm	
	1110-001-16130807				8mm	
	1110-001-16130907				9mm	
	1110-001-16131007				10mm	
	1110-001-16131107				11mm	
	1110-001-16131207				12mm	
	1110-001-17150507	Large Footprint	15mm	17mm	5mm	7°
	1110-001-17150607				6mm	
	1110-001-17150707				7mm	
	1110-001-17150807				8mm	
	1110-001-17150907				9mm	
	1110-001-17151007				10mm	
	1110-001-17151107				11mm	
	1110-001-17151207				12mm	

Ordering Information – Instrumentation

TIDAL™ Cervical Fusion Cage Instrumentation

INSTRUMENT	PRODUCT CODE	FOOTPRINT	DEPTH	WIDTH	STERILE OR NON-STERILE	STOP OR NO STOP	HEIGHT	ANGLE
 *Sizing Trial*	4110-S011	Small Footprint	11mm	14mm	Sterile	Stop	5-10mm	7°
	4110-S021					No-Stop		
	4110-S012	Medium Footprint	13mm	16mm	Sterile	Stop	5-10mm	7°
	4110-S022					No-Stop		
	4110-S013	Large Footprint	15mm	17mm	Sterile	Stop	5-10mm	7°
	4110-S023					No-Stop		
 *Inserter*	6110-INSRTRM3	M3 Cervical Inserter						

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