





# SURGICAL TECHNIQUE GUIDE



WHAT'S YOUR T-SCORE?





### **Table of Contents**

<b>Description</b>
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Indications

Instruments

**Implant Options** 

### Surgical Technique

Approach

Discectomy

Sizing

Engaging the Inserter

Packing the Graft

Initial Insertion

Disengaging the Inserter

Final Positioning

Implant Removal

#### Instructions for Use

#### 4

4

5

6

7

8

10

11

12

13

### **Description**

The DEXA-C™ Cervical Interbody System is a porous 3D-printed intervertebral body fusion device that incorporates low, mid, or high-density lattice pattern options. The profile of the device is rectangular with a hollow core for bone graft to promote bone integration and fusion between the endplates. The implant is available in various footprints and heights to accommodate variability among patients and is manufactured from titanium alloy per ASTM F3001.

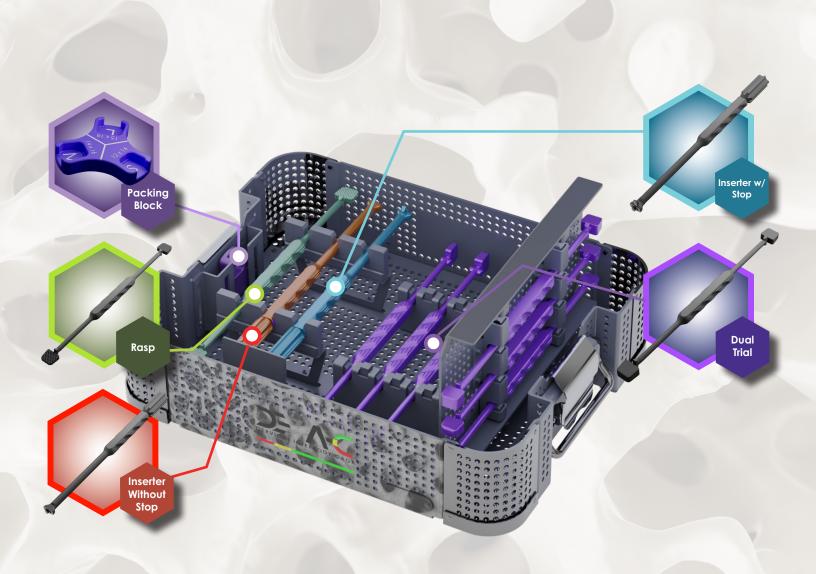
#### **Indications**

The DEXA-C™ Cervical Interbody System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. The implant system is designed for use with supplemental fixation and autograft and/or allogenic bone graft composed of cancellous, cortical, and/orcortico-cancellous bone to facilitate fusion and is to be implanted via an open, anterior approach.



## Instruments

Part Number	Description			
105-317	Packing Block			
116-313-07	Dual Trial			
116-314-1	Rasp			
116-317-1	Inserter w/ Stop			
116-317-2	Inserter Without Stop			



### **Implant Options**

DEXA-C<sup>TM</sup> Cervical Interbody System implants are offered in multiple sizes, as well as three porous lattice pattern density options to accommodate variations in patient anatomy and physiology. The high, mid, and low density lattice implants are color-coded for additional ease of identification.

Lattice Density	Pore Size	Color-Code	Compressive Stiffness (% of PEEK)	t-Score	
Low Density	Larger	Red	37%	-4.0 to -2.5	
Medium Density	Medium	Yellow	49%	-2.5 to -1.0	
High Density	Smaller	Green	71%	-1.0 to +4.0	

Catalog #	Description (L X W X H, A°)	Heights (XX)
116-12147-XX-LD	Low Density 12mm x 14mm x XXmm x 7°	5-9mm
116-14167-XX-LD	Low Density 14mm x 16mm x XXmm x 7°	5-9mm
116-12147-XX-MD	Mid Density 12mm x 14mm x XXmm x 7°	5-9mm
116-14167-XX-MD	Mid Density 14mm x 16mm x XXmm x 7°	5-9mm
116-12147-XX-HD	High Density 12mm x 14mm x XXmm x 7°	5-9mm
116-14167-XX-HD	High Density 14mm x 16mm x XXmm x 7°	5-9mm

<sup>\*</sup>Sizes and availability may vary. Please contact an Aurora representative for additional information.

### **Implant Options Notes:**

Recommended implant densities are based on TR (Test report) Aurora 16 Rev. 2, page 6, ASTM 2077 Mechanical Strength comparisons to bone and other similar devices.

The selection of the lattice density is based on the physician's clinical opinion.



#### 1. Approach

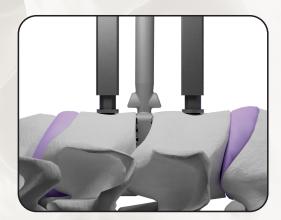
Patient should be placed in the supine position, with the posterior cervical spine supported to maintain normal lordosis. A incision should be made on the right or left side, medially between the trachea and the esophagus, and the carotid sheath laterally. Use retractors to access and expose the anterior vertebral column.





#### 2. Discectomy

Using preferred surgical instruments, remove necessary disc material at affected level. The Dual Rasps can be used to remove superficial layers of cartilaginous endplates. Removal of these layers will result in the exposure of bleeding bone.

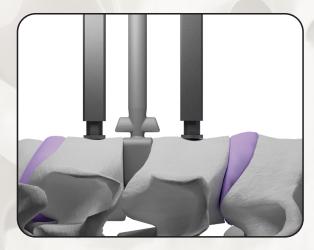


The Rasp has a  $12 \times 14$  and  $14 \times 16$  side indicated by the laser markings on the handle.



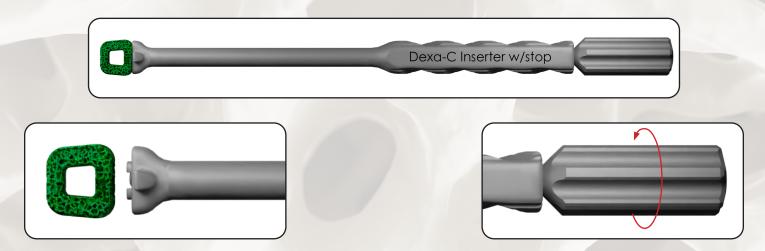
#### 3. Sizing

Determine which implant profile is appropriate for the affected segment using the Dual Trials until the desired spinal orientation is achieved.



### 4. Engaging the Inserter

The Inserter will secure the implant by threading the stylet into the center thread of the implant.

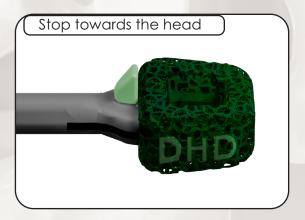


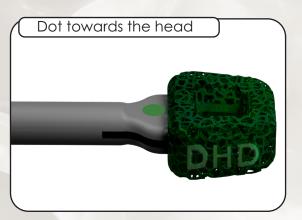
After engaging the inserter with the implant, rotate the handle clockwise to secure the prongs within the implant.

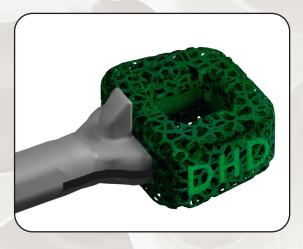


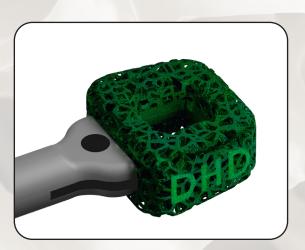


Laser marking on the Dexa- $C^{\mathsf{TM}}$  Inserters may be used to implant the cage with the radiographic identification right-side-up. Align the lettering on the cage with the laser marked line on the side of the Dexa- $C^{\mathsf{TM}}$  Inserter. Point the stop towards the head of the patient to insert with lettering right-side-up. If using the Dexa- $C^{\mathsf{TM}}$  Inserter without Stop, point the laser marked dot towards the head of the patient.











### 5. Packing the Graft

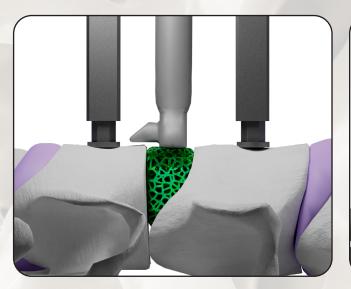
With the implant attached to the Rotating Inserter, place the implant in the appropriate pocket in the Packing Block.

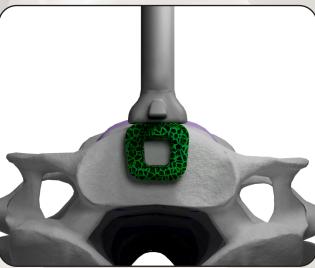


Add the preferred graft material to the center opening of the implant. The Tamp can be used to compress the graft material. Grafting material can also be placed in the surrounding area of the disc space prior to inserting the implant.

#### 6. Initial Insertion

Gently impact the implant into the prepared disc space.



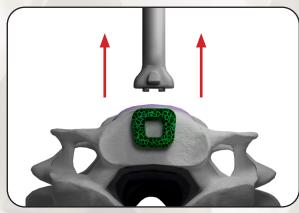




### 7. Disengaging the Inserter

Rotate the Inserter handle counter-clockwise to loosen the thread and release the Inserter from the implant.

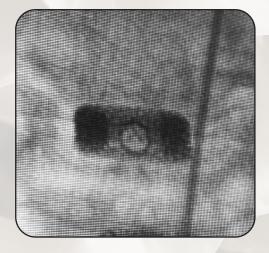


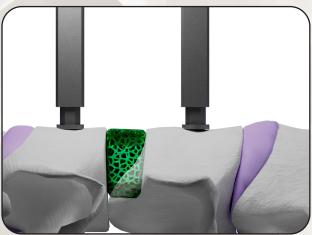


### 8. Final Positioning

Once the implant has been inserted, confirm final positioning with Anterior/Posterior and Lateral fluoroscopy.

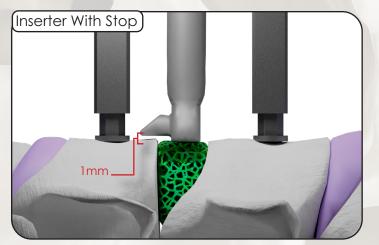








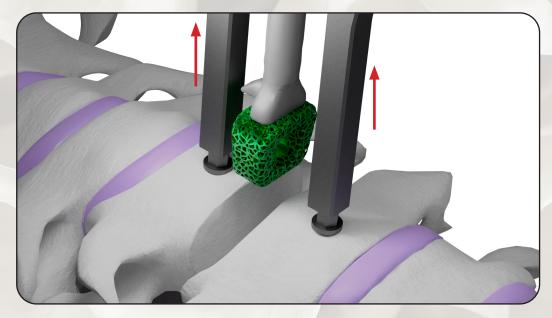
The inserter with stop allows countersinking the implant no more than 1 mm beyond the anterior border of the vertebral body. Fine adjustments to the implant position can be made using the inserter as a Tamp by removing the stylet. When using the Tamp, apply gentle force, and ensure that the Tamp surface is seated flush against the implant. Optionally, an inserter without stop is provided and may be used.





#### 9. Implant Removal

For implant removal, engage the Inserter with the implant, rotate the handle clockwise to secure the stylet within the implant and remove the implant from the surgical site.





#### Instructions for Use

#### **Indications for Use**

The DEXA-C<sup>TM</sup> Cervical Interbody System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. The implant system is designed for use with supplemental fixation and autograft and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone to facilitate fusion and is to be implanted via an open, anterior approach.

#### **Material**

DEXA-C<sup>™</sup> Cervical Interbody System implants are constructed titanium alloy per ASTM F3001. System instruments are made primarily of surgical grade stainless steel (ASTM F899).

#### **Sterilization**

DEXA-C<sup>TM</sup> Cervical Interbody System impants are delivered sterile. All sterile implants are gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. Do not re-sterilize.

#### Contraindications

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the implants
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

#### **Customer Service**

For further information regarding the DEXA-C<sup>™</sup> Cervical Interbody System or Surgical Technique Guide, please contact Aurora Spine, Inc. or your local Aurora Spine Distributor.

CAUTION: Federal (USA) Law restricts this implant to sale by or on the order of a physician.

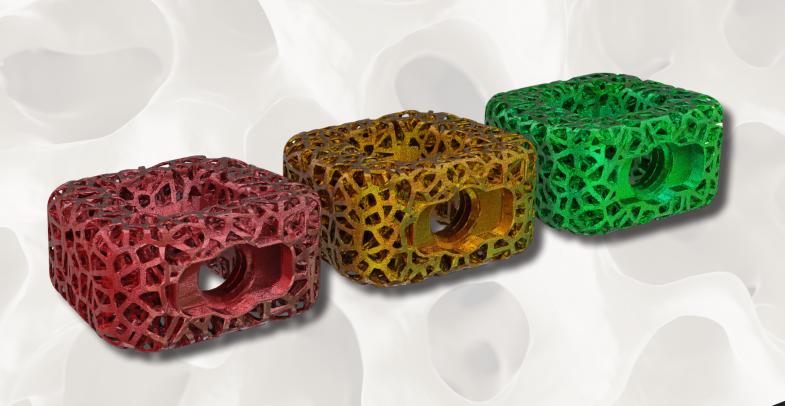
DEXA-CTM Cervical Interbody System implants are supplied sterile. | STERILE | R



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# WHAT'S YOUR T-SCORE?



Reference the website for current clearances and approvals.

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Aurora is ISO 13485 certified.



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