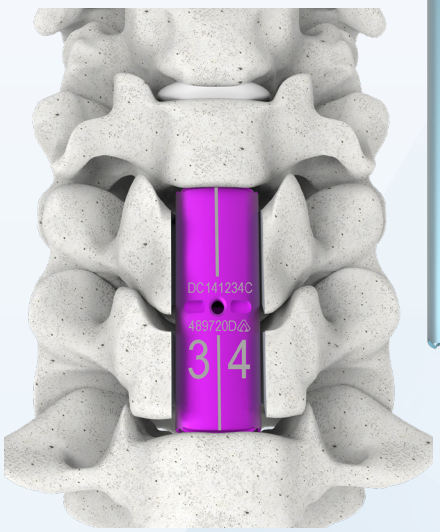
ALTA

ANTERIOR CERVICAL CORPECTOMY SPACER

ASTURA MEDICAL

DESIGN RATIONALE

The ALTA Anterior Cervical Corpectomy Spacer System is a simple and efficient set of instruments and implants that provide the intraoperative flexibility necessary to accommodate the wide array of anatomical challenges consistently encountered when performing an anterior cervical corpectomy. The intuitive design ensures an efficient and streamlined procedural sequence.



ACID-ETCHED TITANIUM

HA PEEK

IMPLANT OVERVIEW

ALTA HA PEEK

- HA is fully integrated, not coated, making it available on all surfaces of the spacer to provide an osteoconductive surface for bone ongrowth

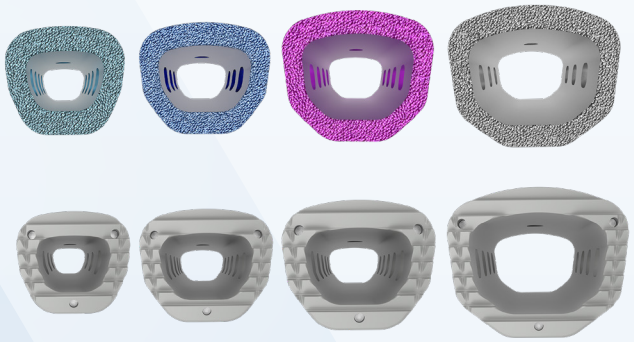
ALTA Acid-Etched Titanium

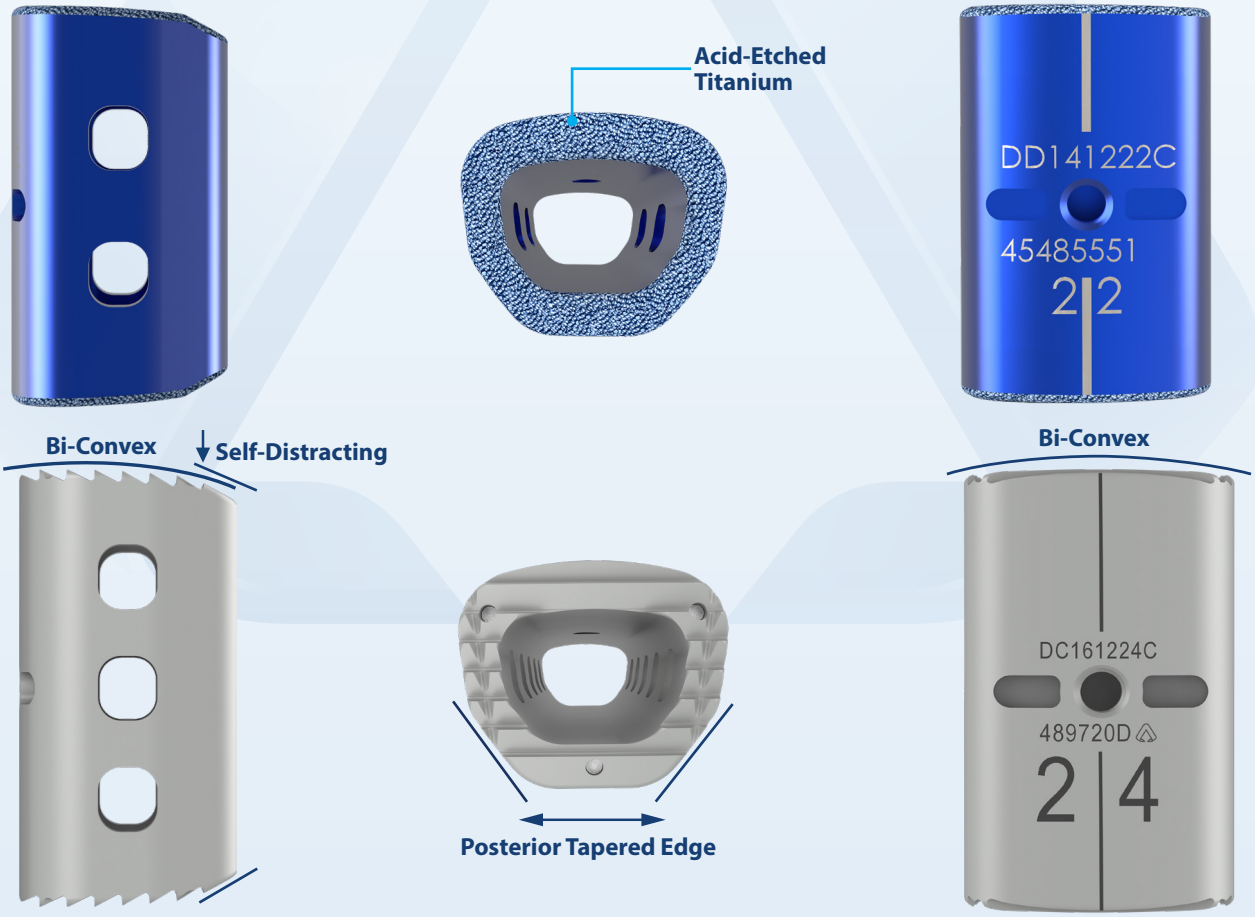
- Acid-etched endplates to resist migration postoperatively
- Acid-etched surface enhances and increases the effeciency of bone growth

All ALTA Anterior Cervical Corpectomy Spacers provide:

- Four different axial footprint options to accommodate varied patient anatomy
- Large central aperture to pack bone graft to provide a greater opportunity for fusion
- Lateral windows to provide additional graft vascularization
- Tapered posterior edge allows for self-distraction of intervertebral space during insertion, as well as conservation of critical structural anatomy
- Tapered posterior/lateral faces contour to bony geometry, improve posterior/lateral resection, and increase insertion safety

IMPLANT OFFERING				
Dimension	Small	Medium	Large	Xlarge
Width	12mm	14mm	16mm	18mm
Depth	11mm	12mm	14mm	15mm
Height	18-50mm in 1mm increments			
Lordosis	7˚	7˚	7˚	7˚





1.0 EXPOSURE

1.1 Identify the affected level using a combination of palpation and fluoroscopy.
1.2 Select either a left or right-sided approach. Using a standard anterior cervical surgical technique, expose the midline of the affected site.
1.3 Use tissue retractors to perform a blunt dissection, then retract the trachea and esophagus accordingly.

2.0 DISTRACTION

2.1 A variety of distraction techniques are available for the cervical spine. Based on preference, a selected technique will be used to distract the two adjacent vertebrae to provide sufficient access to the disc space.

3.0 INTERVERTEBRAL DISC SPACE PREPARATION

3.1 Perform an annulotomy and discectomy to remove the intervertebral disc.

4.0 ENDPLATE PREPARATION

4.1 Endplate preparation can be achieved by the use of the ACIS Lordotic Rasp (DZ0100000). Prepare endplates by removing any remaining cartilaginous endplates to create a fusion bed of bleeding bone.
4.2 The use of an osteotome can be utilized to remove any offending superior or inferior osteophyte ridges to improve access to the disc space.

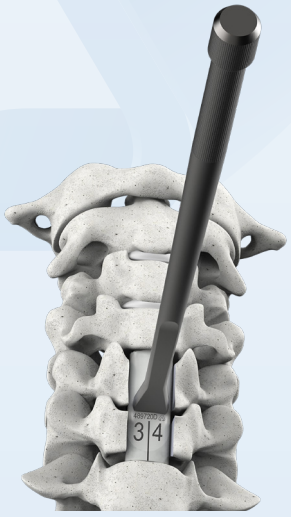
**Note that extreme caution must be taken during this step to avoid any neural or vascular compromise, as well as overly weakening the adjacent cervical discs.*

5.0 IMPLANT SELECTION

5.1 Implant height is determined by placing the tips of the Caliper (DZ8000000) on the two opposing end plates, then recording the size shown within the window of the device. Ensure the recessed portion of the tips are fully seated on the anterior cortex and end plate junction.

6.0 IMPLANT PREPARATION AND INSERTION

6.1 Select the desired size implant.
6.2 Thread the ACIS Inserter (DZ0350000) onto the selected ALTA Anterior Cervical Corpectomy Spacer until the tip of the instrument is flush with the implant.
6.3 Pack the selected implant with morselized bone graft material.
6.4 With the implant attached to the ACIS Inserter, place the tip of the implant at the prepared opening, then impact the implant into the prepared disc space. The tapered tip of the implant assists in distraction and insertion.
6.5 Once inserted to the proper depth, unthread the ACIS Inserter from the implant.



7.0 IMPLANT POSITIONING

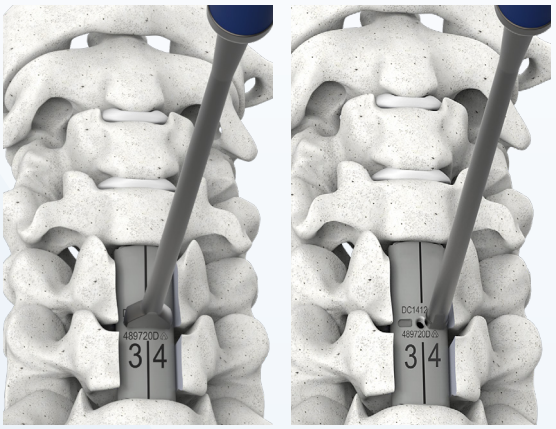
7.1 If necessary, use the ACIS Recess Tamp (DZ0400000) or ACIS Rotation Tamp (DZ0500000) to impact the implant to the proper position.

7.2 Strive for the following for the final placement of the ALTA Anterior Cervical Corpectomy Spacer:

7.2.1. Midline placement

7.2.2. Anterior face of implant recessed past the anterior face of the vertebrae

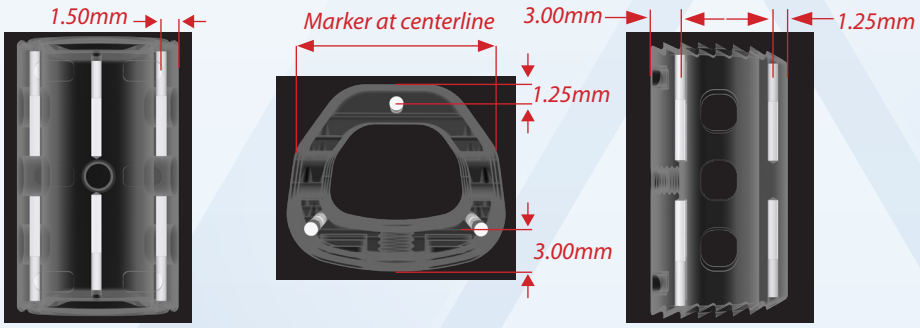
7.2.3. Snug fit utilizing the natural distraction/compression forces of the spine

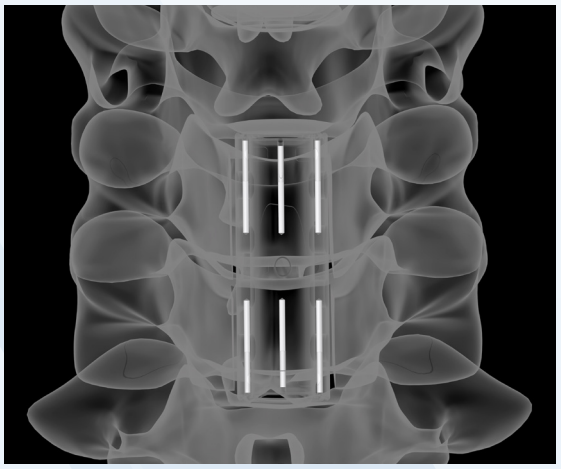


8.0 RADIOGRAPHIC VERIFICATION

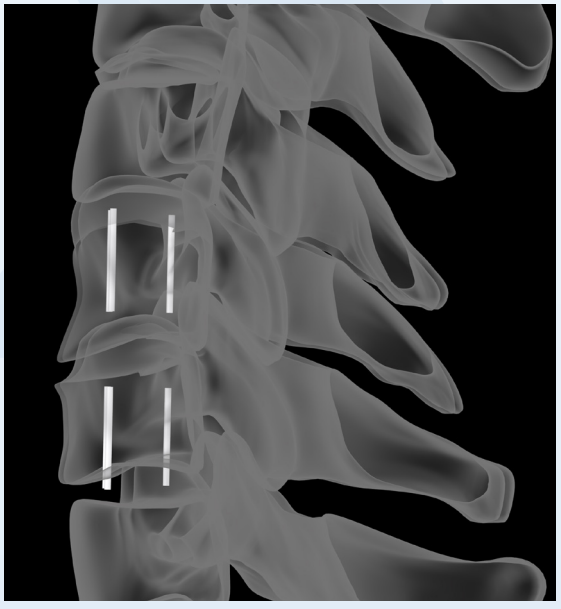
8.1 An intraoperative radiograph showing A/P and M/L views are suggested. Final placement of the ALTA Anterior Cervical Corpectomy Spacer is a combination of intraoperative clinical judgment and radiographic appearance.

8.2 For the HA PEEK Implants, the placement can be radiographically located by two vertical tantalum markers in the anterior region of the implant, in conjunction with a vertical posterior marker located in the posterior tapered tip. See below for marker location:





Since the titanium implant is not radiolucent, the implant body will be completely visible during fluoroscopy. The lateral windows will allow for radiographic visualization of the fusion process postoperatively.



9.0 SUPPLEMENTAL FIXATION

9.1 Supplemental fixation, such as the Zion Anterior Cervical Plating System, must be used in combination with the ALTA Anterior Cervical Corpectomy Spacer System to provide sufficient stabilization.

10.0 REVISION AND REMOVAL

10.1 If it is necessary to remove the ALTA Anterior Cervical Corpectomy Spacer, attach the ACIS Inserter (DZ0300000) to the implant by threading the ACIS Inserter until the tip of the instrument is flush with the implant.

10.2 Extract the implant from the disc space. Refer to Section 1.0 if exposure is required.

ALTA ANTERIOR CERVICAL CORPECTOMY SPACER HA PEEK OFFERING

Part Number	Description	Qty
DE121115C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 15mm, 7°, Non-Sterile	1
DE121116C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 16mm, 7°, Non-Sterile	1
DE121117C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 17mm, 7°, Non-Sterile	1
DE121118C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 18mm, 7°, Non-Sterile	1
DE121119C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 19mm, 7°, Non-Sterile	1
DE121120C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 20mm, 7°, Non-Sterile	1
DE121121C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 21mm, 7°, Non-Sterile	1
DE121122C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 22mm, 7°, Non-Sterile	1
DE121123C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 23mm, 7°, Non-Sterile	1
DE121124C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 24mm, 7°, Non-Sterile	1
DE121125C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 25mm, 7°, Non-Sterile	1
DE121126C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 26mm, 7°, Non-Sterile	1
DE121127C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 27mm, 7°, Non-Sterile	1
DE121128C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 28mm, 7°, Non-Sterile	1
DE121129C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 29mm, 7°, Non-Sterile	1
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DE121131C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 31mm, 7°, Non-Sterile	1
DE121132C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 32mm, 7°, Non-Sterile	1
DE121133C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 33mm, 7°, Non-Sterile	1
DE121134C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 34mm, 7°, Non-Sterile	1
DE121135C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 35mm, 7°, Non-Sterile	1
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DE121138C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 38mm, 7°, Non-Sterile	1
DE121139C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 39mm, 7°, Non-Sterile	1
DE121140C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 40mm, 7°, Non-Sterile	1
DE121141C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 41mm, 7°, Non-Sterile	1
DE121142C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 42mm, 7°, Non-Sterile	1
DE121143C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 43mm, 7°, Non-Sterile	1
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DE121146C	Corpectomy Spacer, HA PEEK, 12mm x 11mm x 46mm, 7°, Non-Sterile	1
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DE141231C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 31mm, 7°, Non-Sterile	1
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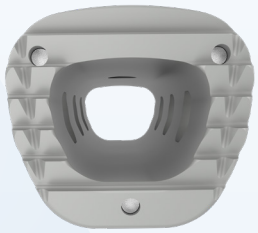

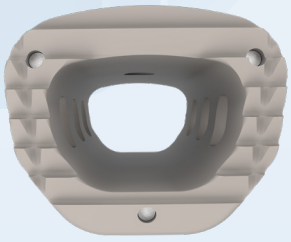

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DE141234C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 34mm, 7°, Non-Sterile	1
DE141235C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 35mm, 7°, Non-Sterile	1
DE141236C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 36mm, 7°, Non-Sterile	1
DE141237C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 37mm, 7°, Non-Sterile	1
DE141238C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 38mm, 7°, Non-Sterile	1
DE141239C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 39mm, 7°, Non-Sterile	1
DE141240C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 40mm, 7°, Non-Sterile	1
DE141241C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 41mm, 7°, Non-Sterile	1
DE141242C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 42mm, 7°, Non-Sterile	1
DE141243C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 43mm, 7°, Non-Sterile	1
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DE141246C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 46mm, 7°, Non-Sterile	1
DE141247C	Corpectomy Spacer, HA PEEK, 14mm x 12mm x 47mm, 7°, Non-Sterile	1
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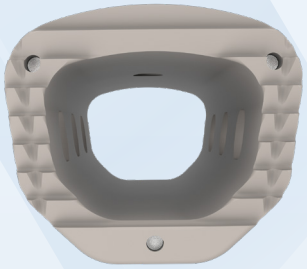
DE161448C	Corpectomy Spacer, HA PEEK, 16mm x 14mm x 48mm, 7°, Non-Sterile	1
DE161449C	Corpectomy Spacer, HA PEEK, 16mm x 14mm x 49mm, 7°, Non-Sterile	1
DE161450C	Corpectomy Spacer, HA PEEK, 16mm x 14mm x 50mm, 7°, Non-Sterile	1



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Part Number	Description	Qty
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DE181518C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 18mm, 7°, Non-Sterile	1
DE181519C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 19mm, 7°, Non-Sterile	1
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DE181521C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 21mm, 7°, Non-Sterile	1
DE181522C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 22mm, 7°, Non-Sterile	1
DE181523C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 23mm, 7°, Non-Sterile	1
DE181524C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 24mm, 7°, Non-Sterile	1
DE181525C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 25mm, 7°, Non-Sterile	1
DE181526C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 26mm, 7°, Non-Sterile	1
DE181527C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 27mm, 7°, Non-Sterile	1
DE181528C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 28mm, 7°, Non-Sterile	1
DE181529C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 29mm, 7°, Non-Sterile	1
DE181530C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 30mm, 7°, Non-Sterile	1
DE181531C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 31mm, 7°, Non-Sterile	1
DE181532C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 32mm, 7°, Non-Sterile	1
DE181533C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 33mm, 7°, Non-Sterile	1
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DE181544C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 44mm, 7°, Non-Sterile	1
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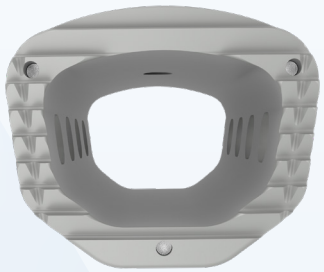
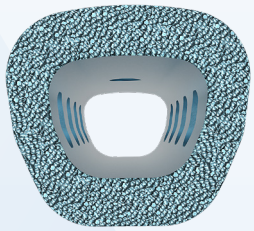
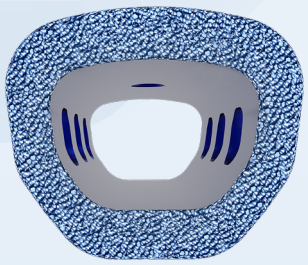
DE181548C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 48mm, 7°, Non-Sterile	1
DE181549C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 49mm, 7°, Non-Sterile	1
DE181550C	Corpectomy Spacer, HA PEEK, 18mm x 15mm x 50mm, 7°, Non-Sterile	1



ALTA ANTERIOR CERVICAL CORPECTOMY SPACER
ACID-ETCHED TITANIUM OFFERING

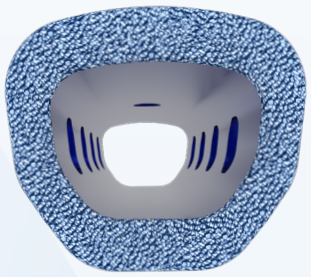
Part Number	Description	Qty
DD121115C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 15mm, 7°, Non-Sterile	1
DD121116C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 16mm, 7°, Non-Sterile	1
DD121117C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 17mm, 7°, Non-Sterile	1
DD121118C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 18mm, 7°, Non-Sterile	1
DD121119C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 19mm, 7°, Non-Sterile	1
DD121120C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 20mm, 7°, Non-Sterile	1
DD121121C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 21mm, 7°, Non-Sterile	1
DD121122C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 22mm, 7°, Non-Sterile	1
DD121123C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 23mm, 7°, Non-Sterile	1
DD121124C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 24mm, 7°, Non-Sterile	1
DD121125C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 25mm, 7°, Non-Sterile	1
DD121126C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 26mm, 7°, Non-Sterile	1
DD121127C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 27mm, 7°, Non-Sterile	1
DD121128C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 28mm, 7°, Non-Sterile	1
DD121129C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 29mm, 7°, Non-Sterile	1
DD121130C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 30mm, 7°, Non-Sterile	1
DD121131C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 31mm, 7°, Non-Sterile	1
DD121132C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 32mm, 7°, Non-Sterile	1
DD121133C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 33mm, 7°, Non-Sterile	1
DD121134C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 34mm, 7°, Non-Sterile	1
DD121135C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 35mm, 7°, Non-Sterile	1
DD121136C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 36mm, 7°, Non-Sterile	1
DD121137C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 37mm, 7°, Non-Sterile	1
DD121138C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 38mm, 7°, Non-Sterile	1
DD121139C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 39mm, 7°, Non-Sterile	1
DD121140C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 40mm, 7°, Non-Sterile	1
DD121141C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 41mm, 7°, Non-Sterile	1
DD121142C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 42mm, 7°, Non-Sterile	1
DD121143C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 43mm, 7°, Non-Sterile	1
DD121144C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 44mm, 7°, Non-Sterile	1
DD121145C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 45mm, 7°, Non-Sterile	1
DD121146C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 46mm, 7°, Non-Sterile	1
DD121147C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 47mm, 7°, Non-Sterile	1
DD121148C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 48mm, 7°, Non-Sterile	1
DD121149C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 49mm, 7°, Non-Sterile	1
DD121150C	Corpectomy Spacer, Acid-Etched Titanium, 12mm x 11mm x 50mm, 7°, Non-Sterile	1
DD141215C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 15mm, 7°, Non-Sterile	1
DD141216C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 16mm, 7°, Non-Sterile	1
DD141217C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 17mm, 7°, Non-Sterile	1
DD141218C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 18mm, 7°, Non-Sterile	1
DD141219C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 19mm, 7°, Non-Sterile	1
DD141220C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 20mm, 7°, Non-Sterile	1
DD141221C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 21mm, 7°, Non-Sterile	1
DD141222C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 22mm, 7°, Non-Sterile	1
DD141223C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 23mm, 7°, Non-Sterile	1
DD141224C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 24mm, 7°, Non-Sterile	1
DD141225C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 25mm, 7°, Non-Sterile	1
DD141226C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 26mm, 7°, Non-Sterile	1
DD141227C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 27mm, 7°, Non-Sterile	1
DD141228C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 28mm, 7°, Non-Sterile	1
DD141229C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 29mm, 7°, Non-Sterile	1
DD141230C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 30mm, 7°, Non-Sterile	1
DD141231C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 31mm, 7°, Non-Sterile	1
DD141232C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 32mm, 7°, Non-Sterile	1



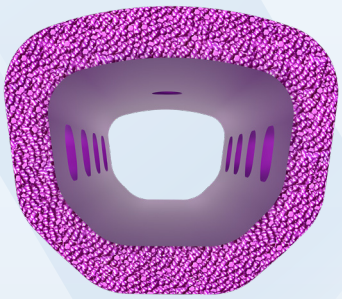


ALTA ANTERIOR CERVICAL CORPECTOMY SPACER
ACID-ETCHED TITANIUM OFFERING

Part Number	Description	Qty
DD141233C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 33mm, 7°, Non-Sterile	1
DD141234C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 34mm, 7°, Non-Sterile	1
DD141235C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 35mm, 7°, Non-Sterile	1
DD141236C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 36mm, 7°, Non-Sterile	1
DD141237C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 37mm, 7°, Non-Sterile	1
DD141238C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 38mm, 7°, Non-Sterile	1
DD141239C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 39mm, 7°, Non-Sterile	1
DD141240C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 40mm, 7°, Non-Sterile	1
DD141241C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 41mm, 7°, Non-Sterile	1
DD141242C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 42mm, 7°, Non-Sterile	1
DD141243C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 43mm, 7°, Non-Sterile	1
DD141244C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 44mm, 7°, Non-Sterile	1
DD141245C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 45mm, 7°, Non-Sterile	1
DD141246C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 46mm, 7°, Non-Sterile	1
DD141247C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 47mm, 7°, Non-Sterile	1
DD141248C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 48mm, 7°, Non-Sterile	1
DD141249C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 49mm, 7°, Non-Sterile	1
DD141250C	Corpectomy Spacer, Acid-Etched Titanium, 14mm x 12mm x 50mm, 7°, Non-Sterile	1

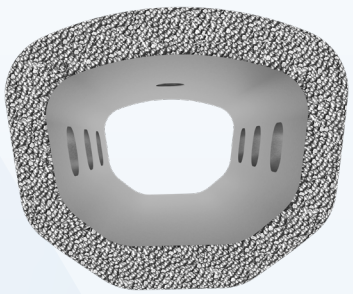


DD161415C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 15mm, 7°, Non-Sterile	1
DD161416C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 16mm, 7°, Non-Sterile	1
DD161417C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 17mm, 7°, Non-Sterile	1
DD161418C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 18mm, 7°, Non-Sterile	1
DD161419C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 19mm, 7°, Non-Sterile	1
DD161420C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 20mm, 7°, Non-Sterile	1
DD161421C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 21mm, 7°, Non-Sterile	1
DD161422C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 22mm, 7°, Non-Sterile	1
DD161423C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 23mm, 7°, Non-Sterile	1
DD161424C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 24mm, 7°, Non-Sterile	1
DD161425C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 25mm, 7°, Non-Sterile	1
DD161426C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 26mm, 7°, Non-Sterile	1
DD161427C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 27mm, 7°, Non-Sterile	1
DD161428C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 28mm, 7°, Non-Sterile	1
DD161429C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 29mm, 7°, Non-Sterile	1
DD161430C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 30mm, 7°, Non-Sterile	1
DD161431C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 31mm, 7°, Non-Sterile	1
DD161432C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 32mm, 7°, Non-Sterile	1
DD161433C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 33mm, 7°, Non-Sterile	1
DD161434C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 34mm, 7°, Non-Sterile	1
DD161435C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 35mm, 7°, Non-Sterile	1
DD161436C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 36mm, 7°, Non-Sterile	1
DD161437C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 37mm, 7°, Non-Sterile	1
DD161438C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 38mm, 7°, Non-Sterile	1
DD161439C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 39mm, 7°, Non-Sterile	1
DD161440C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 40mm, 7°, Non-Sterile	1
DD161441C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 41mm, 7°, Non-Sterile	1
DD161442C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 42mm, 7°, Non-Sterile	1
DD161443C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 43mm, 7°, Non-Sterile	1
DD161444C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 44mm, 7°, Non-Sterile	1
DD161445C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 45mm, 7°, Non-Sterile	1
DD161446C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 46mm, 7°, Non-Sterile	1
DD161447C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 47mm, 7°, Non-Sterile	1
DD161448C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 48mm, 7°, Non-Sterile	1
DD161449C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 49mm, 7°, Non-Sterile	1
DD161450C	Corpectomy Spacer, Acid-Etched Titanium, 16mm x 14mm x 50mm, 7°, Non-Sterile	1



ALTA ANTERIOR CERVICAL CORPECTOMY SPACER
ACID-ETCHED TITANIUM OFFERING

Part Number	Description	Qty
DD181515C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 15mm, 7°, Non-Sterile	1
DD181516C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 16mm, 7°, Non-Sterile	1
DD181517C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 17mm, 7°, Non-Sterile	1
DD181518C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 18mm, 7°, Non-Sterile	1
DD181519C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 19mm, 7°, Non-Sterile	1
DD181520C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 20mm, 7°, Non-Sterile	1
DD181521C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 21mm, 7°, Non-Sterile	1
DD181522C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 22mm, 7°, Non-Sterile	1
DD181523C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 23mm, 7°, Non-Sterile	1
DD181524C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 24mm, 7°, Non-Sterile	1
DD181525C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 25mm, 7°, Non-Sterile	1
DD181526C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 26mm, 7°, Non-Sterile	1
DD181527C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 27mm, 7°, Non-Sterile	1
DD181528C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 28mm, 7°, Non-Sterile	1
DD181529C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 29mm, 7°, Non-Sterile	1
DD181530C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 30mm, 7°, Non-Sterile	1
DD181531C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 31mm, 7°, Non-Sterile	1
DD181532C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 32mm, 7°, Non-Sterile	1
DD181533C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 33mm, 7°, Non-Sterile	1
DD181534C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 34mm, 7°, Non-Sterile	1
DD181535C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 35mm, 7°, Non-Sterile	1
DD181536C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 36mm, 7°, Non-Sterile	1
DD181537C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 37mm, 7°, Non-Sterile	1
DD181538C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 38mm, 7°, Non-Sterile	1
DD181539C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 39mm, 7°, Non-Sterile	1
DD181540C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 40mm, 7°, Non-Sterile	1
DD181541C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 41mm, 7°, Non-Sterile	1
DD181542C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 42mm, 7°, Non-Sterile	1
DD181543C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 43mm, 7°, Non-Sterile	1
DD181544C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 44mm, 7°, Non-Sterile	1
DD181545C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 45mm, 7°, Non-Sterile	1
DD181546C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 46mm, 7°, Non-Sterile	1
DD181547C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 47mm, 7°, Non-Sterile	1
DD181548C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 48mm, 7°, Non-Sterile	1
DD181549C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 49mm, 7°, Non-Sterile	1
DD181550C	Corpectomy Spacer, Acid-Etched Titanium, 18mm x 15mm x 50mm, 7°, Non-Sterile	1



ALTA ANTERIOR CERVICAL CORPECTOMY SPACER INSTRUMENT OFFERING

OPTIONAL INSTRUMENTS

Part Number	Description	Qty	
DZ8000000	Corpectomy Caliper	1	
DZ0350000	Metal Inserter	1	
DZ0400000	ACIS Recess Tamp	1	
DZ0500000	ACIS Rotation Tamp	1	
DZ8900000	ACIS Sterilization Container	1	

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The ALTA Anterior Cervical Corpectomy Spacer is a vertebral body replacement system manufactured from PEEK-OPTIMA LT120HA (HA PEEK) or titanium alloy (Ti6Al4VELI). The devices have trapezoidal footprints and multiple sizes to accommodate patient anatomy and graft windows to help facilitate bony integration. The HA PEEK spacers have unidirectional teeth on both of their inferior and superior surfaces to prevent migration/expulsion and X-ray markers in the form of tantalum pins. The titanium alloy spacers have roughened superior and inferior surfaces to prevent migration/expulsion.

2.0 MATERIALS: Titanium (ASTM F136), PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced), Tantalum (ASTM F560)

3.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician. All implants are intended for single use only. The ALTA Cervical Corpectomy Spacer must not be reused under any circumstances. The ALTA Cervical Corpectomy Spacer is not a stand-alone device and must be utilized in conjunction with supplemental posterior fixation. These instructions for use are designed to assist in use of the ALTA Cervical Corpectomy Spacer and are not a reference for surgical techniques.

4.0 INDICATIONS: The ALTA Anterior Cervical Corpectomy Spacer is indicated for vertebral body replacement in the cervical spine (C3-C7) in skeletally mature patients. The Alta Anterior Cervical Corpectomy Spacer is intended to replace a diseased or damaged vertebral body caused by fracture, osteomyelitis, or tumor, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The System is intended to be used with supplemental fixation that has been cleared by the FDA for use in the cervical spine. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. The System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectance is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

5.0 CONTRAINDICATIONS

5.1 Acute or chronic infectious diseases of any etiology and localization
5.2 Signs of local inflammation
5.3 Fever or leukocytosis
5.4 Morbid obesity
5.5 Pregnancy
5.6 Metal/polymer sensitivity/allergies to the implant materials
5.7 Mental illness, alcoholism, drug abuse
5.8 Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
5.9 Grossly distorted anatomy due to congenital abnormalities
5.10 Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
5.11 Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
5.12 Any case not needing a bone graft and fusion or where fracture healing is not required
5.13 Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
5.14 Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
5.15 Any case not described in the Indications.
5.16 Any patient unwilling to cooperate with the post-operative instructions.
5.17 Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
5.18 Symptomatic cardiac disease.
5.19 Systemic or terminal illness.
5.20 Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

6.0 POSSIBLE ADVERSE EVENTS:

6.1 A listing of possible adverse events includes, but is not limited to:
6.1.1 Bending or fracture of implant. Loosening of the implant.
6.1.2 Implant material sensitivity, or allergic reaction to a foreign body.
6.1.3 Infection, early or late.
6.1.4 Decrease in bone density due to stress shielding.
6.1.5 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.1.6 Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
6.1.7 Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6.1.8 Dural tears.
6.1.9 Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
6.1.10 Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
6.1.11 Loss of bowel and/or bladder control or other types of urological system compromise.
6.1.12 Scar formation possibly causing neurological compromise around nerves and/or pain.
6.1.13 Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
6.1.14 Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
6.1.15 Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
6.1.16 Graft donor site complications including pain, fracture, or wound healing problems.
6.1.17 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
6.1.18 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
6.1.19 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
6.1.20 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
6.1.21 Change in mental status.
6.1.22 Non-union (or pseudarthrosis). Delayed union. Mal-union.
6.1.23 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
6.1.24 Inability to perform the activities of daily living.
6.1.25 Paralysis.
6.1.26 Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

7.0 WARNINGS AND PRECAUTIONS: The ALTA Cervical Corpectomy Spacer is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the ALTA Cervical Corpectomy Spacer is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the ALTA Cervical Corpectomy Spacer by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

The implantation of the ALTA Cervical Interbody Spacer should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.

The ALTA Cervical Corpectomy Spacer has not been evaluated for safety and compatibility in the MR environment. The ALTA Cervical Corpectomy Spacer has not been tested for heating or migration in the MR environment.

8.0 IMPLANT SELECTION: The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion. ALTA Cervical Corpectomy Spacer components should not be used with components from other manufacturers.

9.0 PREOPERATIVE:

9.1 Only patients that meet the criteria described in the indications should be selected.
9.2 Patient conditions and/or predispositions such as those addressed in the aforementioned

contraindications should be avoided.

9.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

9.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

9.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.

9.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The ALTA Cervical Corpectomy Spacer components are not to be combined with components from another manufacturer.

9.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

9.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

9.9 A surgical technique manual may be obtained from ASTURA MEDICAL or from any of its representatives.

10.0 INTRAOPERATIVE

10.1 Any instruction manual should be carefully followed.

10.2 At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

10.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

10.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.

10.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.

10.6 Before closing the soft tissues, all of the devices should be securely seated.

10.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

11.0 POSTOPERATIVE: **The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.**

11.1 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

11.2 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

11.3 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

11.4 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

11.5 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.

11.6 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved ALTA Cervical Corpectomy Spacer components should ever be reused under any circumstances.

12.0 PACKAGING: Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to ASTURA MEDICAL.

13.0 CLEANING AND DECONTAMINATION: Instruments and implants of the ALTA Cervical Corpectomy Spacer are supplied clean and NOT STERILE, and must be sterilized prior to use.

14.0 CLEANING: All instruments must first be thoroughly cleaned before sterilization and introduced into a sterile surgical field. Reference LIT-00007 for disassembly and reassembly instructions. All cleaning processes must conform to Advancement of Medical Instrumentation (AAMI) guideline TIR30 Section 5.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile or tap water and transport to a decontaminate environment. An enzymatic cleaner bath (soak) composed of lukewarm tap water and percent (%) volume of enzymatic cleaner per manufacturer's guidelines is effective in removing organic material from instruments. Instruments should be fully submerged for at least ten (10) minutes.

Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Once instruments are cleaned and disassembled, place instruments in an ultrasonic cleaner with an enzymatic cleaner mixture composed of lukewarm tap water and percent (%) volume of enzymatic cleaner per manufacturer's guidelines for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running tap water for at least one (1) minute to remove solutions. Drying methods are not necessary.

Instruments should never be exposed to cleaning agents containing any peroxides.

Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

15.0 STERILIZATION: Instruments and implants of the ALTA Cervical Corpectomy Spacer are supplied clean and NOT STERILE, and must be sterilized as specified below using the Astura provided sterilization container (Part #: DZ9900000). Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	30 minutes

The Sterility Assurance Level (SAL) is 1 x 10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL. Instruments are to be in the assembled during sterilization.

This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications. **This statement is not required for the parameters listed above.**
It has not been determined if reprocessing affects the chemical, phase, or structural properties of the hydroxyapatite on the ALTA Cervical Corpectomy Spacer.

16.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted ALTA Cervical Corpectomy Spacer component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.
If any ALTA Cervical Corpectomy Spacer product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing.
For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint.

If further information is needed or required, please contact using the company information listed below.

17.0 COMPANY INFORMATION

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