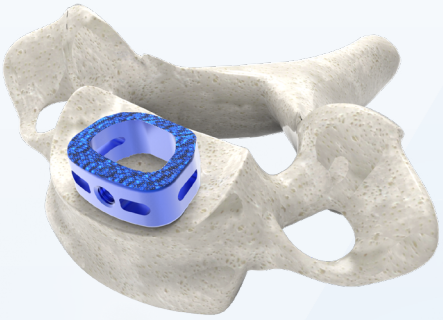
ALTA

ANTERIOR CERVICAL INTERBODY
SPACER SYSTEM

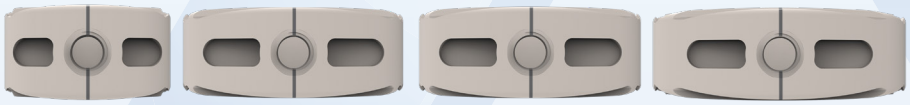
ASTURA MEDICAL

DESIGN RATIONALE

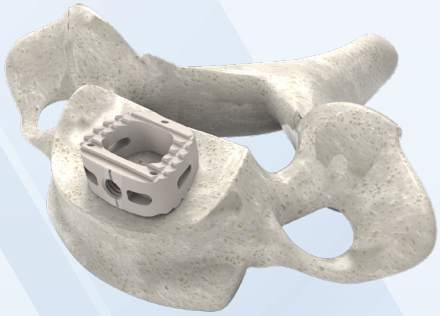
The ALTA Anterior Cervical Interbody Spacer System by ASTURA MEDICAL is a comprehensive system designed to provide a complete range of anatomic, self-distracting spacers and instrumentation to support the Anterior Cervical Discectomy Fusion (ACDF) procedure. This intuitive design ensures an efficient and streamlined procedural sequence.

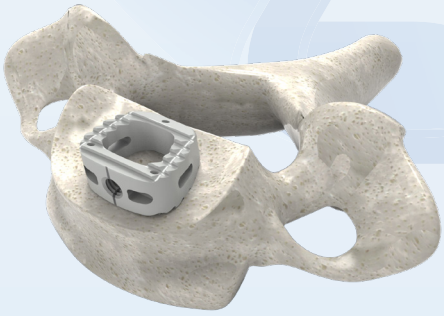


ACID-ETCHED TITANIUM



PEEK





HA PEEK

IMPLANT OVERVIEW

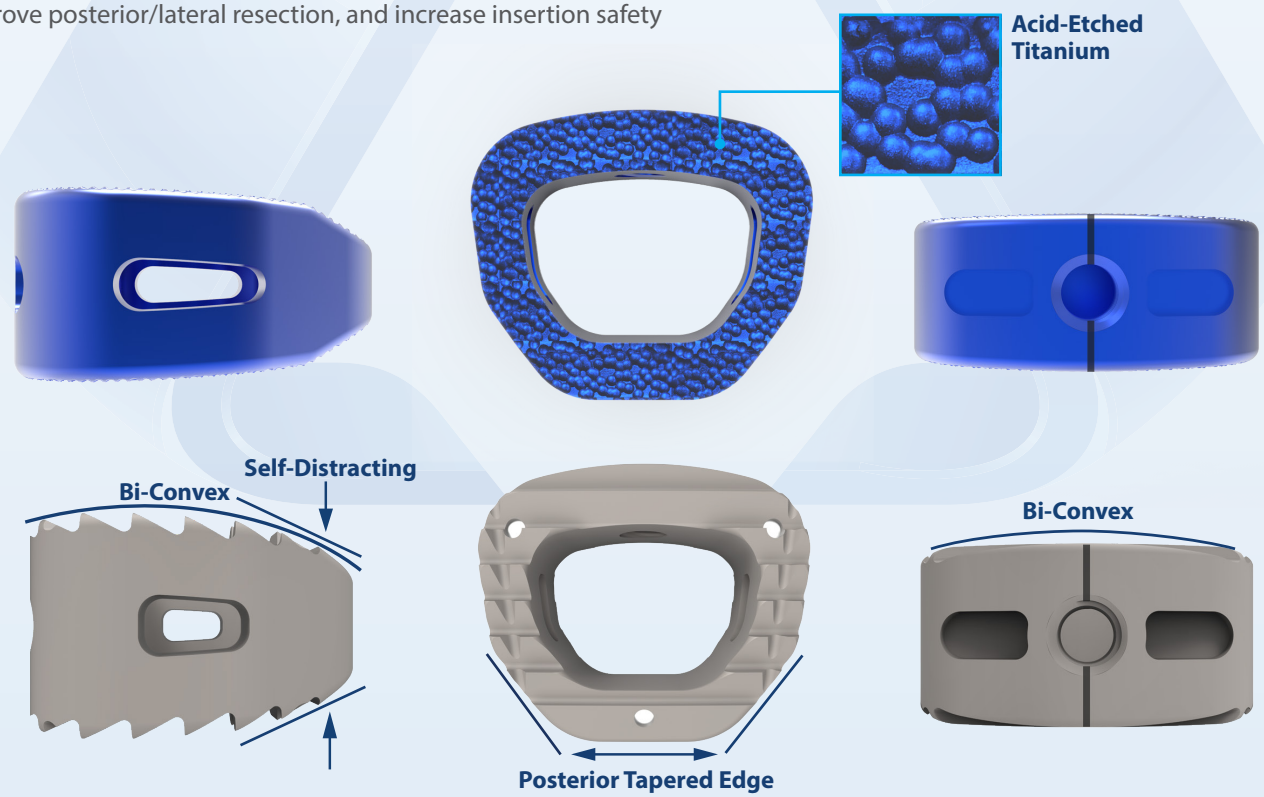
ALTA PEEK
- Unidirectional serrated teeth to resist migration postoperatively
- Radiographic markers provide fluoroscopic visualization of exact orientation of the interbody spacer during implantation

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

ALTA Titanium
- Acid-etched endplates to resist migration postoperatively
- Acid-etched surface enhanced increase the effeciency of bone growth

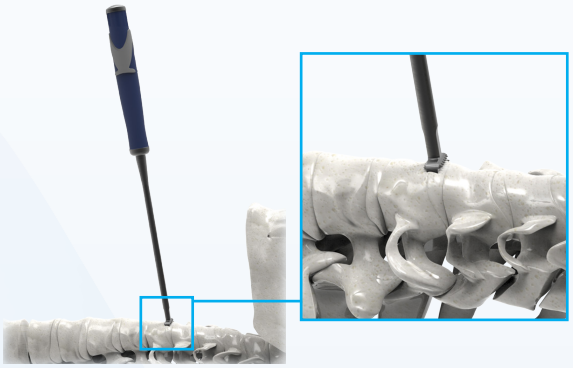
All ALTA Anterior Cervical Interbody Spacers are:
- 7° Lordotic
- Available in 1mm height increments from 5-14mm
- Four different axial footprint options to accommodate varied patient anatomy
- Large central aperture to pack bone graft to provide a greater opportunity for fusion
- Lateral windows to 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	5-14mm in 1mm increments			
Lordosis	7°	7°	7°	7°
Graft Volume (CC)	0.23-0.61	0.31-0.89	0.46-1.33	0.57-1.68



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 surgeon's preference, a selected technique will be used to distract the two adjacent vertebrae to provide sufficient access to the disc space.

3.0 INTERVERTEBRAL 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.*

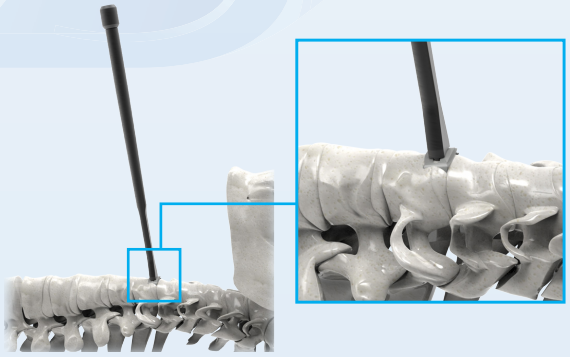
5.0 IMPLANT SELECTION

5.1 The ALTA Anterior Cervical Interbody Spacer System includes four axial footprints in a wide variety of heights.
5.2 All sizes of implants are paired with a matching ACIS Trial for proper implant selection. The ACIS Trials are designed with a depth stop to prevent over insertion into the disc space posteriorly. The depth stop allows for an additional 2mm of recess if needed past the anterior face of the Implant.
5.3 Sequentially increase the ACIS Trial size until the appropriate height is determined. If necessary, utilize fluoroscopy to determine appropriate trial size.

**Note: trials are 1:1 true to size.*

6.0 IMPLANT PREPARATION AND INSERTION

6.1 Select the desired size implant.
6.2 Thread the ACIS Inserter (DZ0350000) onto the selected the ALTA Anterior Cervical Interbody Spacer Implant 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

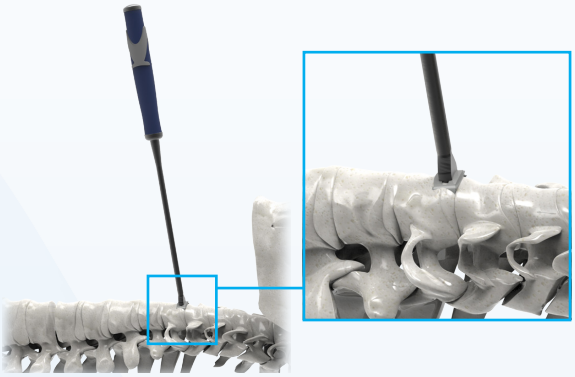
7.1 If necessary, use the ACIS Recess Tamp (DZ0400000) or ACIS Rotation Tamp (DZ0500000) to impact the implant to the proper position.

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

7.2.1. Midline placement

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

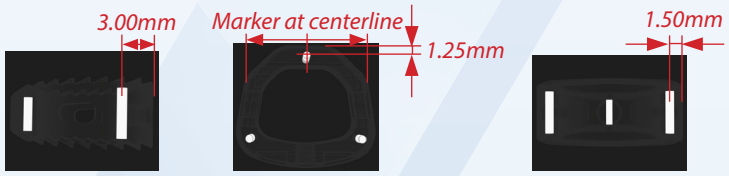
7.2.3. Snug fit utilizing the natural distraction/compression forces of the spine

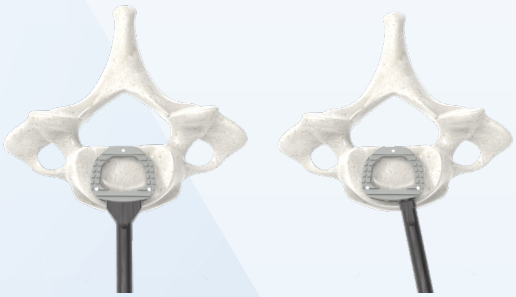


8.0 RADIOGRAPHIC VERIFICATION

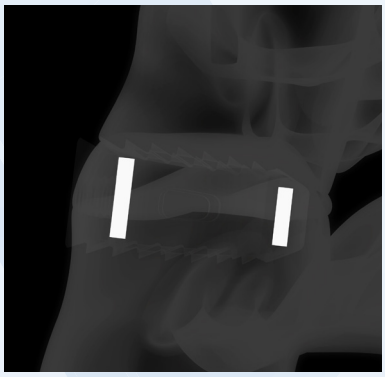
8.1 An intraoperative radiograph showing A/P and M/L views are suggested. Final placement of the ALTA Anterior Cervical Interbody Spacer System Implant is a combination of intraoperative clinical judgment and radiographic appearance.

8.2 For the PEEK and 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 Interbody Spacer System to provide sufficient stabilization.

10.0 REVISION AND REMOVAL

10.1 If it is necessary to remove the ALTA Anterior Cervical Interbody Spacer System Implant, 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 INTERBODY HA PEEK OFFERING

Part Number	Description	Qty
DC121105C	ACIS Spacer, HA PEEK, 12mm x 11mm x 05mm, 7°, non-sterile	4
DC121106C	ACIS Spacer, HA PEEK, 12mm x 11mm x 06mm, 7°, non-sterile	4
DC121107C	ACIS Spacer, HA PEEK, 12mm x 11mm x 07mm, 7°, non-sterile	4
DC121108C	ACIS Spacer, HA PEEK, 12mm x 11mm x 08mm, 7°, non-sterile	4
DC121109C	ACIS Spacer, HA PEEK, 12mm x 11mm x 09mm, 7°, non-sterile	4
DC121110C	ACIS Spacer, HA PEEK, 12mm x 11mm x 10mm, 7°, non-sterile	2
DC121111C	ACIS Spacer, HA PEEK, 12mm x 11mm x 11mm, 7°, non-sterile	OPT
DC121112C	ACIS Spacer, HA PEEK, 12mm x 11mm x 12mm, 7°, non-sterile	OPT
DC121113C	ACIS Spacer, HA PEEK, 12mm x 11mm x 13mm, 7°, non-sterile	OPT
DC121114C	ACIS Spacer, HA PEEK, 12mm x 11mm x 14mm, 7°, non-sterile	OPT
DC141205C	ACIS Spacer, HA PEEK, 14mm x 12mm x 05mm, 7°, non-sterile	4
DC141206C	ACIS Spacer, HA PEEK, 14mm x 12mm x 06mm, 7°, non-sterile	4
DC141207C	ACIS Spacer, HA PEEK, 14mm x 12mm x 07mm, 7°, non-sterile	4
DC141208C	ACIS Spacer, HA PEEK, 14mm x 12mm x 08mm, 7°, non-sterile	4
DC141209C	ACIS Spacer, HA PEEK, 14mm x 12mm x 09mm, 7°, non-sterile	4
DC141210C	ACIS Spacer, HA PEEK, 14mm x 12mm x 10mm, 7°, non-sterile	2
DC141211C	ACIS Spacer, HA PEEK, 14mm x 12mm x 11mm, 7°, non-sterile	OPT
DC141212C	ACIS Spacer, HA PEEK, 14mm x 12mm x 12mm, 7°, non-sterile	OPT
DC141213C	ACIS Spacer, HA PEEK, 14mm x 12mm x 13mm, 7°, non-sterile	OPT
DC141214C	ACIS Spacer, HA PEEK, 14mm x 12mm x 14mm, 7°, non-sterile	OPT
DC161405C	ACIS Spacer, HA PEEK, 16mm x 14mm x 05mm, 7°, non-sterile	4
DC161406C	ACIS Spacer, HA PEEK, 16mm x 14mm x 06mm, 7°, non-sterile	4
DC161407C	ACIS Spacer, HA PEEK, 16mm x 14mm x 07mm, 7°, non-sterile	4
DC161408C	ACIS Spacer, HA PEEK, 16mm x 14mm x 08mm, 7°, non-sterile	4
DC161409C	ACIS Spacer, HA PEEK, 16mm x 14mm x 09mm, 7°, non-sterile	4
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DC161411C	ACIS Spacer, HA PEEK, 16mm x 14mm x 11mm, 7°, non-sterile	OPT
DC161412C	ACIS Spacer, HA PEEK, 16mm x 14mm x 12mm, 7°, non-sterile	OPT
DC161413C	ACIS Spacer, HA PEEK, 16mm x 14mm x 13mm, 7°, non-sterile	OPT
DC161414C	ACIS Spacer, HA PEEK, 16mm x 14mm x 14mm, 7°, non-sterile	OPT
DC181505C	ACIS Spacer, HA PEEK, 18mm x 15mm x 05mm, 7°, non-sterile	4
DC181506C	ACIS Spacer, HA PEEK, 18mm x 15mm x 06mm, 7°, non-sterile	4
DC181507C	ACIS Spacer, HA PEEK, 18mm x 15mm x 07mm, 7°, non-sterile	4
DC181508C	ACIS Spacer, HA PEEK, 18mm x 15mm x 08mm, 7°, non-sterile	4
DC181509C	ACIS Spacer, HA PEEK, 18mm x 15mm x 09mm, 7°, non-sterile	4
DC181510C	ACIS Spacer, HA PEEK, 18mm x 15mm x 10mm, 7°, non-sterile	2
DC181511C	ACIS Spacer, HA PEEK, 18mm x 15mm x 11mm, 7°, non-sterile	OPT
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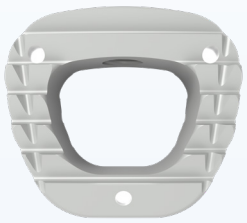

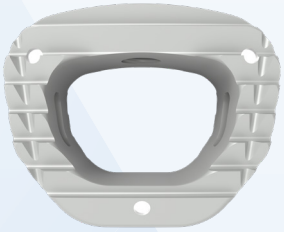

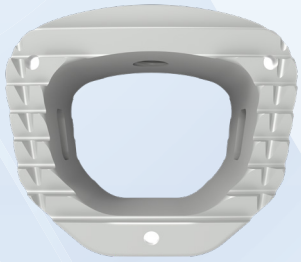

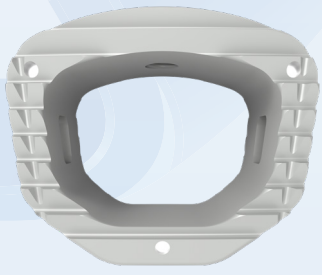

ALTA ANTERIOR CERVICAL INTERBODY PEEK OFFERING

Part Number	Description	Qty
DA121105C	ACIS Spacer, PEEK, 12mm x 11mm x 05mm, 7°, non-sterile	4
DA121106C	ACIS Spacer, PEEK, 12mm x 11mm x 06mm, 7°, non-sterile	4
DA121107C	ACIS Spacer, PEEK, 12mm x 11mm x 07mm, 7°, non-sterile	4
DA121108C	ACIS Spacer, PEEK, 12mm x 11mm x 08mm, 7°, non-sterile	4
DA121109C	ACIS Spacer, PEEK, 12mm x 11mm x 09mm, 7°, non-sterile	4
DA121110C	ACIS Spacer, PEEK, 12mm x 11mm x 10mm, 7°, non-sterile	2
DA121111C	ACIS Spacer, PEEK, 12mm x 11mm x 11mm, 7°, non-sterile	OPT
DA121112C	ACIS Spacer, PEEK, 12mm x 11mm x 12mm, 7°, non-sterile	OPT
DA121113C	ACIS Spacer, PEEK, 12mm x 11mm x 13mm, 7°, non-sterile	OPT
DA121114C	ACIS Spacer, PEEK, 12mm x 11mm x 14mm, 7°, non-sterile	OPT
DA141205C	ACIS Spacer, PEEK, 14mm x 12mm x 05mm, 7°, non-sterile	4
DA141206C	ACIS Spacer, PEEK, 14mm x 12mm x 06mm, 7°, non-sterile	4
DA141207C	ACIS Spacer, PEEK, 14mm x 12mm x 07mm, 7°, non-sterile	4
DA141208C	ACIS Spacer, PEEK, 14mm x 12mm x 08mm, 7°, non-sterile	4
DA141209C	ACIS Spacer, PEEK, 14mm x 12mm x 09mm, 7°, non-sterile	4
DA141210C	ACIS Spacer, PEEK, 14mm x 12mm x 10mm, 7°, non-sterile	2
DA141211C	ACIS Spacer, PEEK, 14mm x 12mm x 11mm, 7°, non-sterile	OPT
DA141212C	ACIS Spacer, PEEK, 14mm x 12mm x 12mm, 7°, non-sterile	OPT
DA141213C	ACIS Spacer, PEEK, 14mm x 12mm x 13mm, 7°, non-sterile	OPT
DA141214C	ACIS Spacer, PEEK, 14mm x 12mm x 14mm, 7°, non-sterile	OPT
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DA161406C	ACIS Spacer, PEEK, 16mm x 14mm x 06mm, 7°, non-sterile	4
DA161407C	ACIS Spacer, PEEK, 16mm x 14mm x 07mm, 7°, non-sterile	4
DA161408C	ACIS Spacer, PEEK, 16mm x 14mm x 08mm, 7°, non-sterile	4
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DA161410C	ACIS Spacer, PEEK, 16mm x 14mm x 10mm, 7°, non-sterile	2
DA161411C	ACIS Spacer, PEEK, 16mm x 14mm x 11mm, 7°, non-sterile	OPT
DA161412C	ACIS Spacer, PEEK, 16mm x 14mm x 12mm, 7°, non-sterile	OPT
DA161413C	ACIS Spacer, PEEK, 16mm x 14mm x 13mm, 7°, non-sterile	OPT
DA161414C	ACIS Spacer, PEEK, 16mm x 14mm x 14mm, 7°, non-sterile	OPT
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DA181506C	ACIS Spacer, PEEK, 18mm x 15mm x 06mm, 7°, non-sterile	4
DA181507C	ACIS Spacer, PEEK, 18mm x 15mm x 07mm, 7°, non-sterile	4
DA181508C	ACIS Spacer, PEEK, 18mm x 15mm x 08mm, 7°, non-sterile	4
DA181509C	ACIS Spacer, PEEK, 18mm x 15mm x 09mm, 7°, non-sterile	4
DA181510C	ACIS Spacer, PEEK, 18mm x 15mm x 10mm, 7°, non-sterile	2
DA181511C	ACIS Spacer, PEEK, 18mm x 15mm x 11mm, 7°, non-sterile	OPT
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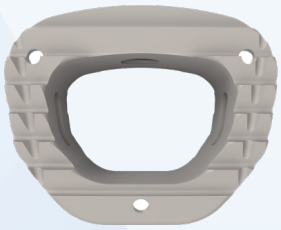

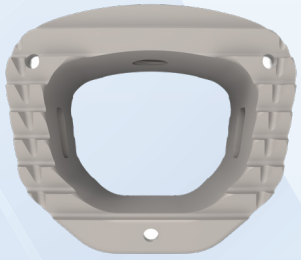

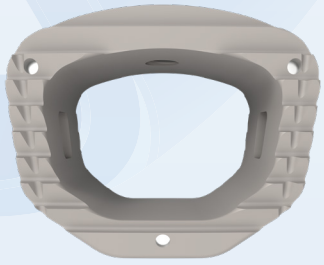

ALTA ANTERIOR CERVICAL INTERBODY
ACID- ETCHED TITANIUM OFFERING

Part Number	Description	Qty
DB121105C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 05mm, 7°, non-sterile	4
DB121106C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 06mm, 7°, non-sterile	4
DB121107C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 07mm, 7°, non-sterile	4
DB121108C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 08mm, 7°, non-sterile	4
DB121109C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 09mm, 7°, non-sterile	4
DB121110C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 10mm, 7°, non-sterile	2
DB121111C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 11mm, 7°, non-sterile	OPT
DB121112C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 12mm, 7°, non-sterile	OPT
DB121113C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 13mm, 7°, non-sterile	OPT
DB121114C	ACIS Spacer, ACID-ETCHED TITANIUM, 12mm x 11mm x 14mm, 7°, non-sterile	OPT
DB141205C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 05mm, 7°, non-sterile	4
DB141206C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 06mm, 7°, non-sterile	4
DB141207C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 07mm, 7°, non-sterile	4
DB141208C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 08mm, 7°, non-sterile	4
DB141209C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 09mm, 7°, non-sterile	4
DB141210C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 10mm, 7°, non-sterile	2
DB141211C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 11mm, 7°, non-sterile	OPT
DB141212C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 12mm, 7°, non-sterile	OPT
DB141213C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 13mm, 7°, non-sterile	OPT
DB141214C	ACIS Spacer, ACID-ETCHED TITANIUM, 14mm x 12mm x 14mm, 7°, non-sterile	OPT
DB161405C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 05mm, 7°, non-sterile	4
DB161406C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 06mm, 7°, non-sterile	4
DB161407C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 07mm, 7°, non-sterile	4
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DB161412C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 12mm, 7°, non-sterile	OPT
DB161413C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 13mm, 7°, non-sterile	OPT
DB161414C	ACIS Spacer, ACID-ETCHED TITANIUM, 16mm x 14mm x 14mm, 7°, non-sterile	OPT
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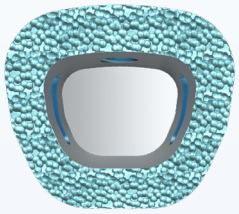
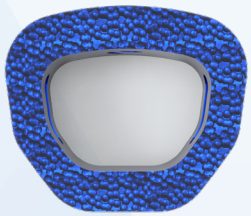
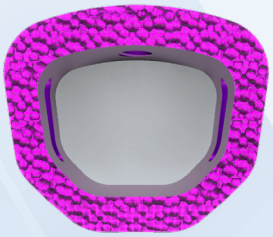
DB181506C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 06mm, 7°, non-sterile	4
DB181507C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 07mm, 7°, non-sterile	4
DB181508C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 08mm, 7°, non-sterile	4
DB181509C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 09mm, 7°, non-sterile	4
DB181510C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 10mm, 7°, non-sterile	2
DB181511C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 11mm, 7°, non-sterile	OPT
DB181512C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 12mm, 7°, non-sterile	OPT
DB181513C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 13mm, 7°, non-sterile	OPT
DB181514C	ACIS Spacer, ACID-ETCHED TITANIUM, 18mm x 15mm x 14mm, 7°, non-sterile	OPT







ALTA ANTERIOR CERVICAL INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
DZ0100000	ACIS Lordotic Rasp	1
DZ121105C	ACIS Trial, 12mm x 11mm x 05mm, 7°	1
DZ121106C	ACIS Trial, 12mm x 11mm x 06mm, 7°	1
DZ121107C	ACIS Trial, 12mm x 11mm x 07mm, 7°	1
DZ121108C	ACIS Trial, 12mm x 11mm x 08mm, 7°	1
DZ121109C	ACIS Trial, 12mm x 11mm x 09mm, 7°	1
DZ121110C	ACIS Trial, 12mm x 11mm x 10mm, 7°	1
DZ141205C	ACIS Trial, 14mm x 12mm x 05mm, 7°	1
DZ141206C	ACIS Trial, 14mm x 12mm x 06mm, 7°	1
DZ141207C	ACIS Trial, 14mm x 12mm x 07mm, 7°	1
DZ141208C	ACIS Trial, 14mm x 12mm x 08mm, 7°	1
DZ141209C	ACIS Trial, 14mm x 12mm x 09mm, 7°	1
DZ141210C	ACIS Trial, 14mm x 12mm x 10mm, 7°	1
DZ161405C	ACIS Trial, 16mm x 14mm x 05mm, 7°	1
DZ161406C	ACIS Trial, 16mm x 14mm x 06mm, 7°	1
DZ161407C	ACIS Trial, 16mm x 14mm x 07mm, 7°	1
DZ161408C	ACIS Trial, 16mm x 14mm x 08mm, 7°	1
DZ161409C	ACIS Trial, 16mm x 14mm x 09mm, 7°	1
DZ161410C	ACIS Trial, 16mm x 14mm x 10mm, 7°	1
DZ0350000	Metal Inserter	1
DZ0400000	ACIS Recess Tamp	1
DZ0500000	ACIS Rotation Tamp	1
DZ9900000	ACIS Sterilization Container	1

ALTA ANTERIOR CERVICAL INTERBODY INSTRUMENT OFFERING

OPTIONAL INSTRUMENTS

Part Number	Description	Qty
DZ121111C	ACIS Trial, 12mm x 11mm x 11mm, 7°	OPT
DZ121112C	ACIS Trial, 12mm x 11mm x 12mm, 7°	OPT
DZ121113C	ACIS Trial, 12mm x 11mm x 13mm, 7°	OPT
DZ121114C	ACIS Trial, 12mm x 11mm x 14mm, 7°	OPT
DZ141211C	ACIS Trial, 14mm x 12mm x 11mm, 7°	OPT
DZ141212C	ACIS Trial, 14mm x 12mm x 12mm, 7°	OPT
DZ141213C	ACIS Trial, 14mm x 12mm x 13mm, 7°	OPT
DZ141214C	ACIS Trial, 14mm x 12mm x 14mm, 7°	OPT
DZ161411C	ACIS Trial, 16mm x 14mm x 11mm, 7°	OPT
DZ161412C	ACIS Trial, 16mm x 14mm x 12mm, 7°	OPT
DZ161413C	ACIS Trial, 16mm x 14mm x 13mm, 7°	OPT
DZ161414C	ACIS Trial, 16mm x 14mm x 14mm, 7°	OPT

INSTRUCTIONS FOR USE

ALTA
ANTERIOR CERVICAL INTERBODY SPACER SYSTEM

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The ALTA Cervical Interbody Spacer fusion device is used to maintain disc space distraction in skeletally mature adults requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit each individual's pathology and anatomy. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. This device is offered in two material choices: PEEK and Titanium. Ridges on the superior and inferior surfaces of the peek device help to grip the endplates and prevent implant migration and/or expulsion. Roughened surfaces of the Titanium device help to grip the endplates and prevent implant migration and/or expulsion.

2.0 MATERIALS: VESTAKEEP® i4R PEEK (ASTM F2026), Tantalum (ASTM F560), Titanium (ASTM F136), PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced)

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 Interbody Spacer must not be reused under any circumstances. The ALTA Cervical Interbody 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 Interbody Spacer and are not a reference for surgical techniques

4.0 INDICATIONS: The ALTA Anterior Cervical Interbody Spacer is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ALTA Anterior Cervical Interbody Spacer is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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 Interbody 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 Interbody 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 Interbody 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 Interbody Spacer has not been evaluated for safety and compatibility in the MR environment. The ALTA Cervical Interbody 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 Interbody 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 Interbody 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 Interbody 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 Interbody 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 Interbody 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 HALF DOME Posterior Lumbar Interbody 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 Interbody Spacer component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.
If any ALTA Cervical Interbody 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

Astura Medical
4949 W Royal Lane
Irving, TX 75063
Phone: (469) 501-5530
Email: info@asturamedical.com

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