HALF DOME

POSTERIOR LUMBAR INTERBODY SYSTEM

ASTURA MEDICAL

DESIGN RATIONALE

The HALF DOME Posterior Lumbar Interbody Spacer System by ASTURA MEDICAL is a comprehensive system that provides a complete range of anatomic, self-distracting spacers and instrumentation to support all posterior lumbar approaches. The intuitive design of the system provides the versatility to accommodate a wide array of anatomical challenges to ensure an efficient, streamlined procedural sequence.

- ***HALF DOME TLIF spacers are designed specifically for a Transforaminal Lumbar Interbody Fusion (TLIF) approach***
- ***HALF DOME OTLIF spacers are designed for either an Oblique Transforaminal Lumbar Interbody Fusion (OTLIF) or Posterior Lumbar Interbody Fusion (PLIF) approach***
- ***All HALF DOME Spacers are available in PEEK, Acid-Etched Titanium, or HA PEEK***
- ***Heights ranging from 7-15mm in 1mm increments***
- ***Lengths ranging from 22-32mm in 2mm increments***
- ***9 or 10mm widths***
- ***0° or 5° of lordosis***
- ***Bulleted nose allows for self-distraction of the intervertebral space during insertion, while conserving critical structural anatomy***
- ***Large central aperture to pack bone graft to provide a greater opportunity for fusion***

TLIF **OTLIF** **PLIF**

IMPLANT OVERVIEW

HALF DOME PEEK

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

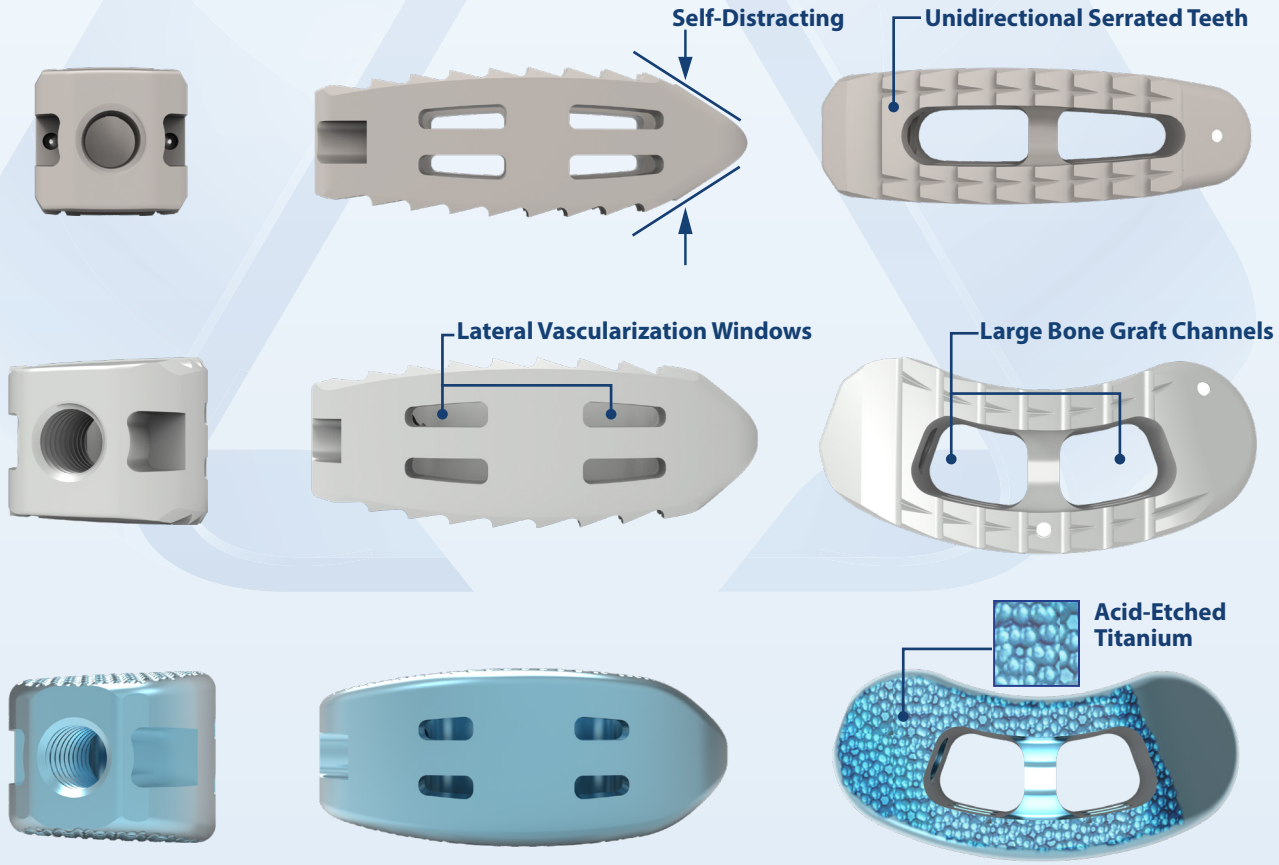
HALF DOME HA PEEK

- HA fully integrated, not coated, making it available on all surfaces of the spacer to provide an osteoconductive surface for bone ongrowth
- Radiographic markers provide fluoroscopic visualization of the exact orientation of the interbody spacer during implantation

HALF DOME Acid-Etched Titanium

- Acid-etched Ti endplates assist with resisting migration postoperatively
- Acid-etched Ti surface technology promotes the necessary factors to enhance the fusion process

IMPLANT SIZING			
	TLIF	PLIF	OTLIF
Length	26-32mm	22-26mm	22-32mm
Width	10mm	9mm	9mm
Height(s)	7-15mm in 1mm increments		
Lordosis	5˚	0˚	0˚



1.0 EXPOSURE

1.1 Identify the affected level using a combination of palpation and fluoroscopy. Using a midline approach, incise the skin to the fascial layer, then use blunt dissection to retract the muscle away from the posterior elements.

2.0 ACCESS

2.1 Decompress the affected neural elements using a combination of laminotomy, facetectomy (Figure 1), and foraminotomy. Carefully resect the superior portion of the inferior facet back to the wall of the pedicle to allow full access to the disc space. Resection of the facet can be accomplished with an Osteotome (BZ5000000), high speed burr, and/or kerrison rongeur. Extreme caution should be used during this step to ensure the neural structures are not compromised during the bone resection process.

3.0 DISTRACTION

3.1 The HALF DOME System offers multiple distraction options. A combination of the following distraction options may be utilized to obtain sufficient access to the disc space: Pedicle screws can be placed above and below the disc space on one side, then the screws can be utilized to distract the disc space. By using the Screw Distractor (BZ6300000) (Figure 2). A Laminar Distractor (BZ6400000) can be utilized in lieu of pedicle screw distraction by gently applying distraction to the base of the spinous process. Another option for producing distraction is to use the Paddle Distractors, which are sized in 1mm increments from 3-15mm (BZ03000XX), with the Modular T-Handle (EBECABBCZ).

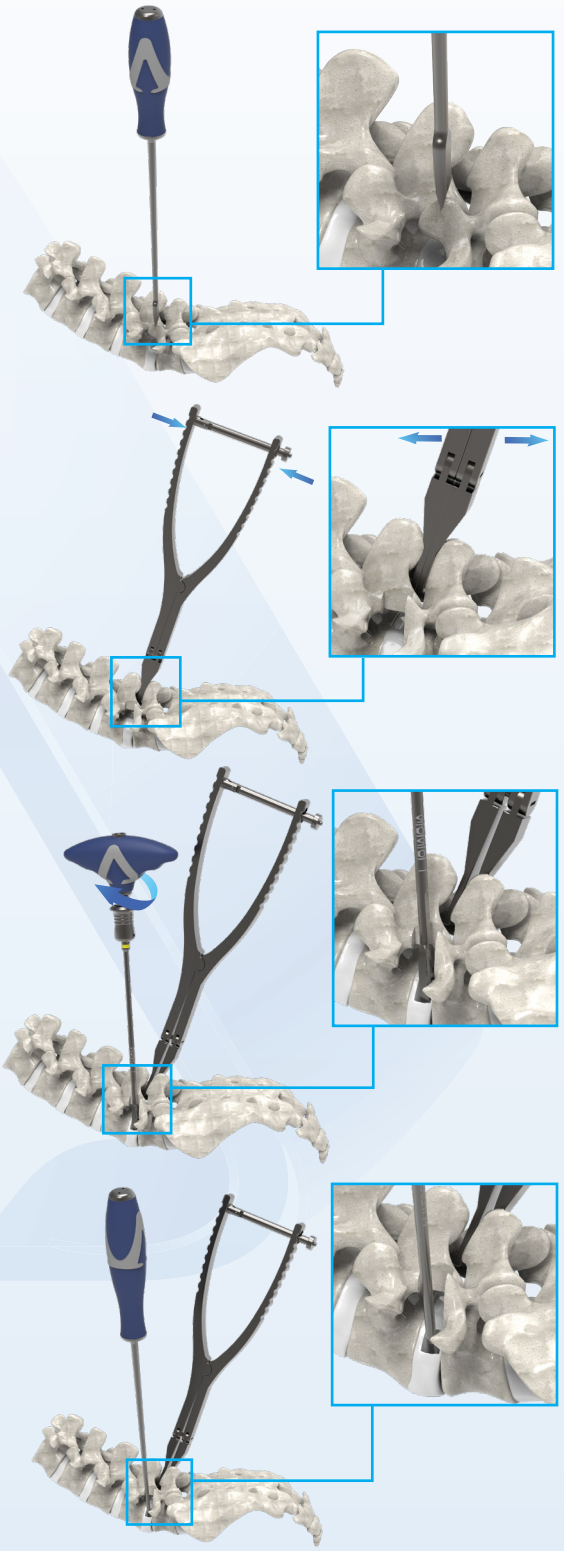
4.0 INTERVERTEBRAL DISC SPACE PREPARATION

4.1 Perform an annulotomy, then remove as much disc material as possible from the disc space. Removal of the intervertebral disc material may be accomplished through the use of the Paddle Shavers (BZ04000XX) and the Pituitaries (BZ5600000), (BZ5700000), (BZ5800000), (BZ5900000) provided in the HALF DOME Posterior Lumbar Instrument System. The Paddle Shavers ranging in size from 3-15mm in 1mm increments, are to be used with modular T-handles. The set includes a 4mm Straight Pituitary, 6mm Straight Pituitary, 4mm Up Angled Pituitary, and 6mm Up Angled Pituitary. It is imperative that all intervertebral disc is completely removed.

5.0 ENDPLATE PREPARATION

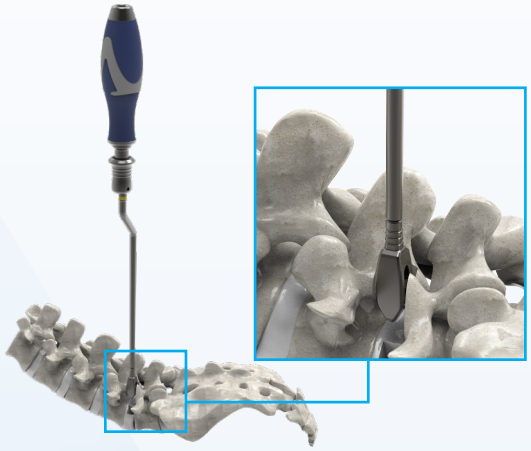
5.1 Endplate preparation can be achieved by the use of the rasps and curettes provided in the system. Use a combination of the following instruments to perform a sufficient preparation of the vertebral endplates: Double-Sided Rasps (Straight - BZ5900000 and Angled - BZ6000000) and/or Cup Curettes (Straight - BZ5100000, Right - BZ5200000, Left - BZ5300000, Up - BZ5400000 and Down - BZ5500000) (Figure 3). Remove any remaining cartilaginous endplates, then create a fusion bed of bleeding bone. Additionally, the use of an Osteotome (BZ5000000) can be utilized to remove any offending superior or inferior osteophyte ridges to improve access to the disc space.

* Extreme caution should be used during this step to avoid neural and vascular compromise.



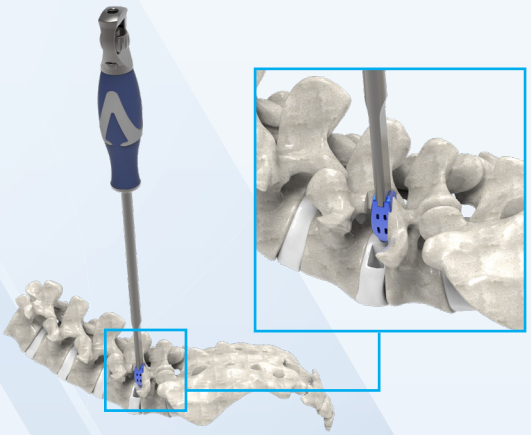
6.0 IMPLANT SELECTION

6.1 The standard HALF DOME Posterior Lumbar Interbody System includes both OTLIF and TLIF Bayonetted Trial Spacers. The OTLIF Trials (BZ6924XXA) are 9mm in width and 24mm in length, with heights ranging from 6-15mm in 1mm increments (Figure 4). The TLIF Trials (BZ7026XXB) are 10mm in width and 26mm in length, with heights ranging from 6-15mm in 1mm increments. The trials contain indicator grooves on the proximal end of the spacer to approximate the appropriate length of the implant. There are 3 grooves which are 2, 4, and 6mm in addition to the length of the trial. The trial is to be used with the Modular Axial Handle (EADCABACZ). Sequentially increase the trial spacer size until the appropriate height is determined (Figure 5). As necessary, utilize fluoroscopy to determine the appropriate trial height, then select the corresponding implant size. The height of the trial spacers is a 1-to-1 ratio to the corresponding implant including teeth height.



7.0 IMPLANT PREPERATION AND INSERTION

7.1 Thread the HALF DOME implant onto the PLIS Straight Inserter (BZ1000000) until the tip of the instrument is flush with the implant body. Pack the selected HALF DOME implant with morselized bone graft material (Figure 6). If necessary, the thecal sac and inferior nerve root may be gently retracted medially with the Nerve Root Retractor (BZ6200000) included in the Half Dome Disc Prep Set. With the implant attached to PLIS Straight Inserter, place the tip of the implant at the prepared opening, then tap it into the prepared disc space with the Mallet (BZ1600000). The bullet-shaped tip assists in distraction and insertion of the implant. Follow the natural curve of the vertebral space when guiding the implant into the space (Figure 7). The Inserter Driver (BZ1100000) can be attached to either of the modular handles to assist with the removal of the implant when the PLIS Inserter knob cannot be turned.



8.0 IMPLANT POSITIONING

8.1 Using HALF DOME's selection of positioning Tamps (Straight - BZ1200010, Angled - BZ1200020), guide the implant to the proper position (Figure 8a and 8b). The custom tamps guide the implant to the final position as shown to the lower right.

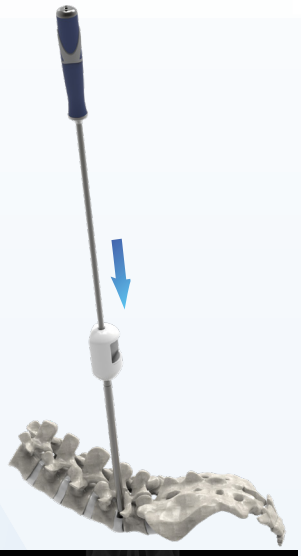
Strive for the following final placement of the OTLIF spacer when using a TLIF approach:
- Midline placement
- Anterior half of the vertebral body
- Long axis of the implant parallel to the coronal plane
- Snug fit utilizing the natural distraction/compression forces of the spine

Strive for the following final placement of the TLIF spacer when using a TLIF approach:
- Midline placement
- Long axis of the implant oblique to the coronal plane
- Snug fit utilizing the natural distraction/compression forces of the spine

Strive for the following final placement of the OTLIF spacer when using a PLIF approach:
- Bilateral placement.
- Snug fit utilizing the natural distraction/compression forces of the spine

9.0 INTERVERTEBRAL GRAFT DELIVERY

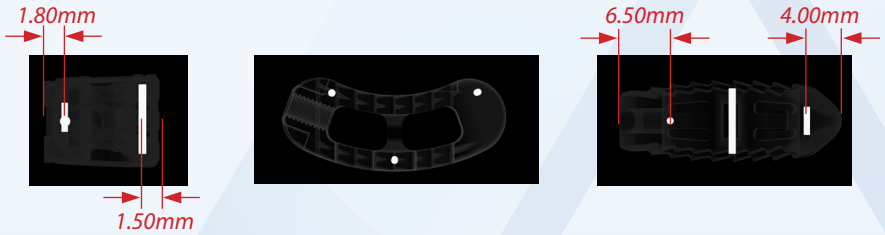
The HALF DOME Bone Graft Delivery Funnel (BZ1700000-10), Graft Tube (BZ1700000-20), and Graft Plunger (BZ1700000-30) can be utilized to pack additional allograft or autograft into the disc space behind and around the spacer to help create a larger fusion mass.

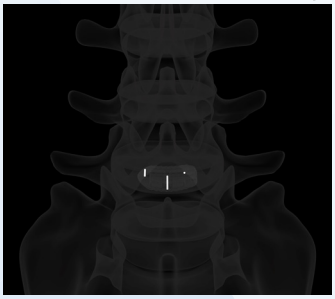


10.0 RADIOGRAPHIC VERIFICATION

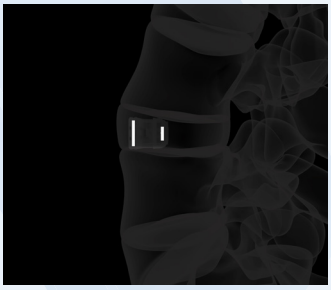
10.1 An intraoperative radiograph showing lateral, the preferred view (Figure 9), or A/P view is suggested. Final placement of the TLIF or OTLIF spacer is confirm by a combination of intraoperative clinical judgment and radiographic appearance.

10.1.1 **PEEK and HA PEEK Spacers:** Radiographically, implant placement can be confirmed on a lateral view with the two vertical markers crossed by the horizontal marker. An A/P view shows the lateral edges of the implant with one radiographic marker in the center. Representative images for various techniques are shown below:





10.1.2 Radiographically, implant placement can be confirmed on a lateral view and A/P view by utilizing the boundaries of the spacer. Representative images for various techniques are shown below:

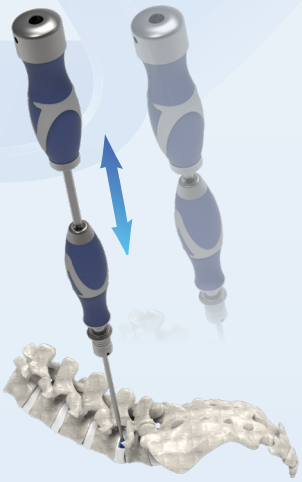


11.0 SUPPLEMENTAL FIXATION

11.1 Supplemental fixation must be used in combination with the HALF DOME spacers to provide sufficient stabilization.

12.0 REVISION AND REMOVAL

12.1 If it is necessary to remove the HALF DOME implant, use the Implant Retriever (BZ2000000) in the HALF DOME Implant Specific set. Attach the implant retriever to the modular handle, then attach it to the implant in situ. Once attached to the implant, the Slaphammer (BZ1500000) is attached to the modular handle, then the implant can be removed.



HALF DOME POSTERIOR LUMBAR INTERBODY HA PEEK OFFERING

TLIF HA PEEK SPACERS

Part Number	Description	Qty
BE102607B	TLIF Spacer, HA PEEK, 10mm x 26mm x 07mm, 5°, Non-Sterile	2 / OPT
BE102608B	TLIF Spacer, HA PEEK, 10mm x 26mm x 08mm, 5°, Non-Sterile	2 / OPT
BE102609B	TLIF Spacer, HA PEEK, 10mm x 26mm x 09mm, 5°, Non-Sterile	2 / OPT
BE102610B	TLIF Spacer, HA PEEK, 10mm x 26mm x 10mm, 5°, Non-Sterile	2 / OPT
BE102611B	TLIF Spacer, HA PEEK, 10mm x 26mm x 11mm, 5°, Non-Sterile	2 / OPT
BE102612B	TLIF Spacer, HA PEEK, 10mm x 26mm x 12mm, 5°, Non-Sterile	2 / OPT
BE102613B	TLIF Spacer, HA PEEK, 10mm x 26mm x 13mm, 5°, Non-Sterile	2 / OPT
BE102614B	TLIF Spacer, HA PEEK, 10mm x 26mm x 14mm, 5°, Non-Sterile	2 / OPT
BE102615B	TLIF Spacer, HA PEEK, 10mm x 26mm x 15mm, 5°, Non-Sterile	2 / OPT
BE102807B	TLIF Spacer, HA PEEK, 10mm x 28mm x 07mm, 5°, Non-Sterile	2 / OPT
BE102808B	TLIF Spacer, HA PEEK, 10mm x 28mm x 08mm, 5°, Non-Sterile	2 / OPT
BE102809B	TLIF Spacer, HA PEEK, 10mm x 28mm x 09mm, 5°, Non-Sterile	2 / OPT
BE102810B	TLIF Spacer, HA PEEK, 10mm x 28mm x 10mm, 5°, Non-Sterile	2 / OPT
BE102811B	TLIF Spacer, HA PEEK, 10mm x 28mm x 11mm, 5°, Non-Sterile	2 / OPT
BE102812B	TLIF Spacer, HA PEEK, 10mm x 28mm x 12mm, 5°, Non-Sterile	2 / OPT
BE102813B	TLIF Spacer, HA PEEK, 10mm x 28mm x 13mm, 5°, Non-Sterile	2 / OPT
BE102814B	TLIF Spacer, HA PEEK, 10mm x 28mm x 14mm, 5°, Non-Sterile	2 / OPT
BE102815B	TLIF Spacer, HA PEEK, 10mm x 28mm x 15mm, 5°, Non-Sterile	2 / OPT
BE103007B	TLIF Spacer, HA PEEK, 10mm x 30mm x 07mm, 5°, Non-Sterile	2 / OPT
BE103008B	TLIF Spacer, HA PEEK, 10mm x 30mm x 08mm, 5°, Non-Sterile	2 / OPT
BE103009B	TLIF Spacer, HA PEEK, 10mm x 30mm x 09mm, 5°, Non-Sterile	2 / OPT
BE103010B	TLIF Spacer, HA PEEK, 10mm x 30mm x 10mm, 5°, Non-Sterile	2 / OPT
BE103011B	TLIF Spacer, HA PEEK, 10mm x 30mm x 11mm, 5°, Non-Sterile	2 / OPT
BE103012B	TLIF Spacer, HA PEEK, 10mm x 30mm x 12mm, 5°, Non-Sterile	2 / OPT
BE103013B	TLIF Spacer, HA PEEK, 10mm x 30mm x 13mm, 5°, Non-Sterile	2 / OPT
BE103014B	TLIF Spacer, HA PEEK, 10mm x 30mm x 14mm, 5°, Non-Sterile	2 / OPT
BE103015B	TLIF Spacer, HA PEEK, 10mm x 30mm x 15mm, 5°, Non-Sterile	2 / OPT
BE103207B	TLIF Spacer, HA PEEK, 10mm x 32mm x 07mm, 5°, Non-Sterile	2 / OPT
BE103208B	TLIF Spacer, HA PEEK, 10mm x 32mm x 08mm, 5°, Non-Sterile	2 / OPT
BE103209B	TLIF Spacer, HA PEEK, 10mm x 32mm x 09mm, 5°, Non-Sterile	2 / OPT
BE103210B	TLIF Spacer, HA PEEK, 10mm x 32mm x 10mm, 5°, Non-Sterile	2 / OPT
BE103211B	TLIF Spacer, HA PEEK, 10mm x 32mm x 11mm, 5°, Non-Sterile	2 / OPT
BE103212B	TLIF Spacer, HA PEEK, 10mm x 32mm x 12mm, 5°, Non-Sterile	2 / OPT
BE103213B	TLIF Spacer, HA PEEK, 10mm x 32mm x 13mm, 5°, Non-Sterile	2 / OPT
BE103214B	TLIF Spacer, HA PEEK, 10mm x 32mm x 14mm, 5°, Non-Sterile	2 / OPT
BE103215B	TLIF Spacer, HA PEEK, 10mm x 32mm x 15mm, 5°, Non-Sterile	2 / OPT

OTLIF HA PEEK SPACERS

Part Number	Description	Qty
BF092207A	OTLIF Spacer, HA PEEK, 09mmx 22mm x 07mm, 0°, Non-Sterile	2 / OPT
BF092208A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 08mm, 0°, Non-Sterile	2 / OPT
BF092209A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 09mm, 0°, Non-Sterile	2 / OPT
BF092210A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 10mm, 0°, Non-Sterile	2 / OPT
BF092211A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 11mm, 0°, Non-Sterile	2 / OPT
BF092212A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 12mm, 0°, Non-Sterile	2 / OPT
BF092213A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 13mm, 0°, Non-Sterile	2 / OPT
BF092214A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 14mm, 0°, Non-Sterile	2 / OPT
BF092215A	OTLIF Spacer, HA PEEK, 09mm x 22mm x 15mm, 0°, Non-Sterile	2 / OPT

HALF DOME POSTERIOR LUMBAR INTERBODY HA PEEK OFFERING

OTLIF HA PEEK SPACERS

Part Number	Description	Qty
BF092407A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 07mm, 0°, Non-Sterile	2 / OPT
BF092408A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 08mm, 0°, Non-Sterile	2 / OPT
BF092409A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 09mm, 0°, Non-Sterile	2 / OPT
BF092410A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 10mm, 0°, Non-Sterile	2 / OPT
BF092411A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 11mm, 0°, Non-Sterile	2 / OPT
BF092412A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 12mm, 0°, Non-Sterile	2 / OPT
BF092413A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 13mm, 0°, Non-Sterile	2 / OPT
BF092414A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 14mm, 0°, Non-Sterile	2 / OPT
BF092415A	OTLIF Spacer, HA PEEK, 09mm x 24mm x 15mm, 0°, Non-Sterile	2 / OPT
BF092607A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 07mm, 0°, Non-Sterile	2 / OPT
BF092608A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 08mm, 0°, Non-Sterile	2 / OPT
BF092609A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 09mm, 0°, Non-Sterile	2 / OPT
BF092610A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 10mm, 0°, Non-Sterile	2 / OPT
BF092611A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 11mm, 0°, Non-Sterile	2 / OPT
BF092612A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 12mm, 0°, Non-Sterile	2 / OPT
BF092613A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 13mm, 0°, Non-Sterile	2 / OPT
BF092614A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 14mm, 0°, Non-Sterile	2 / OPT
BF092615A	OTLIF Spacer, HA PEEK, 09mm x 26mm x 15mm, 0°, Non-Sterile	2 / OPT
BF092807A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 07mm, 0°, Non-Sterile	2 / OPT
BF092808A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 08mm, 0°, Non-Sterile	2 / OPT
BF092809A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 09mm, 0°, Non-Sterile	2 / OPT
BF092810A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 10mm, 0°, Non-Sterile	2 / OPT
BF092811A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 11mm, 0°, Non-Sterile	2 / OPT
BF092812A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 12mm, 0°, Non-Sterile	2 / OPT
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BF092814A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 14mm, 0°, Non-Sterile	2 / OPT
BF092815A	OTLIF Spacer, HA PEEK, 09mm x 28mm x 15mm, 0°, Non-Sterile	2 / OPT
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BF093008A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 08mm, 0°, Non-Sterile	2 / OPT
BF093009A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 09mm, 0°, Non-Sterile	2 / OPT
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BF093011A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 11mm, 0°, Non-Sterile	2 / OPT
BF093012A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 12mm, 0°, Non-Sterile	2 / OPT
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BF093014A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 14mm, 0°, Non-Sterile	2 / OPT
BF093015A	OTLIF Spacer, HA PEEK, 09mm x 30mm x 15mm, 0°, Non-Sterile	2 / OPT
BF093207A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 07mm, 0°, Non-Sterile	2 / OPT
BF093208A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 08mm, 0°, Non-Sterile	2 / OPT
BF093209A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 09mm, 0°, Non-Sterile	2 / OPT
BF093210A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 10mm, 0°, Non-Sterile	2 / OPT
BF093211A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 11mm, 0°, Non-Sterile	2 / OPT
BF093212A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 12mm, 0°, Non-Sterile	2 / OPT
BF093213A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 13mm, 0°, Non-Sterile	2 / OPT
BF093214A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 14mm, 0°, Non-Sterile	2 / OPT
BF093215A	OTLIF Spacer, HA PEEK, 09mm x 32mm x 15mm, 0°, Non-Sterile	2 / OPT

HALF DOME POSTERIOR LUMBAR INTERBODY PEEK OFFERING

TLIF PEEK SPACERS

Part Number	Description	Qty
BA102607B	TLIF Spacer, PEEK, 10mm x 26mm x 07mm, 5°, Non-Sterile	2 / OPT
BA102608B	TLIF Spacer, PEEK, 10mm x 26mm x 08mm, 5°, Non-Sterile	2 / OPT
BA102609B	TLIF Spacer, PEEK, 10mm x 26mm x 09mm, 5°, Non-Sterile	2 / OPT
BA102610B	TLIF Spacer, PEEK, 10mm x 26mm x 10mm, 5°, Non-Sterile	2 / OPT
BA102611B	TLIF Spacer, PEEK, 10mm x 26mm x 11mm, 5°, Non-Sterile	2 / OPT
BA102612B	TLIF Spacer, PEEK, 10mm x 26mm x 12mm, 5°, Non-Sterile	2 / OPT
BA102613B	TLIF Spacer, PEEK, 10mm x 26mm x 13mm, 5°, Non-Sterile	2 / OPT
BA102614B	TLIF Spacer, PEEK, 10mm x 26mm x 14mm, 5°, Non-Sterile	2 / OPT
BA102615B	TLIF Spacer, PEEK, 10mm x 26mm x 15mm, 5°, Non-Sterile	2 / OPT
BA102807B	TLIF Spacer, PEEK, 10mm x 28mm x 07mm, 5°, Non-Sterile	2 / OPT
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BA102812B	TLIF Spacer, PEEK, 10mm x 28mm x 12mm, 5°, Non-Sterile	2 / OPT
BA102813B	TLIF Spacer, PEEK, 10mm x 28mm x 13mm, 5°, Non-Sterile	2 / OPT
BA102814B	TLIF Spacer, PEEK, 10mm x 28mm x 14mm, 5°, Non-Sterile	2 / OPT
BA102815B	TLIF Spacer, PEEK, 10mm x 28mm x 15mm, 5°, Non-Sterile	2 / OPT
BA103007B	TLIF Spacer, PEEK, 10mm x 30mm x 07mm, 5°, Non-Sterile	2 / OPT
BA103008B	TLIF Spacer, PEEK, 10mm x 30mm x 08mm, 5°, Non-Sterile	2 / OPT
BA103009B	TLIF Spacer, PEEK, 10mm x 30mm x 09mm, 5°, Non-Sterile	2 / OPT
BA103010B	TLIF Spacer, PEEK, 10mm x 30mm x 10mm, 5°, Non-Sterile	2 / OPT
BA103011B	TLIF Spacer, PEEK, 10mm x 30mm x 11mm, 5°, Non-Sterile	2 / OPT
BA103012B	TLIF Spacer, PEEK, 10mm x 30mm x 12mm, 5°, Non-Sterile	2 / OPT
BA103013B	TLIF Spacer, PEEK, 10mm x 30mm x 13mm, 5°, Non-Sterile	2 / OPT
BA103014B	TLIF Spacer, PEEK, 10mm x 30mm x 14mm, 5°, Non-Sterile	2 / OPT
BA103015B	TLIF Spacer, PEEK, 10mm x 30mm x 15mm, 5°, Non-Sterile	2 / OPT
BA103207B	TLIF Spacer, PEEK, 10mm x 32mm x 07mm, 5°, Non-Sterile	2 / OPT
BA103208B	TLIF Spacer, PEEK, 10mm x 32mm x 08mm, 5°, Non-Sterile	2 / OPT
BA103209B	TLIF Spacer, PEEK, 10mm x 32mm x 09mm, 5°, Non-Sterile	2 / OPT
BA103210B	TLIF Spacer, PEEK, 10mm x 32mm x 10mm, 5°, Non-Sterile	2 / OPT
BA103211B	TLIF Spacer, PEEK, 10mm x 32mm x 11mm, 5°, Non-Sterile	2 / OPT
BA103212B	TLIF Spacer, PEEK, 10mm x 32mm x 12mm, 5°, Non-Sterile	2 / OPT
BA103213B	TLIF Spacer, PEEK, 10mm x 32mm x 13mm, 5°, Non-Sterile	2 / OPT
BA103214B	TLIF Spacer, PEEK, 10mm x 32mm x 14mm, 5°, Non-Sterile	2 / OPT
BA103215B	TLIF Spacer, PEEK, 10mm x 32mm x 15mm, 5°, Non-Sterile	2 / OPT

OTLIF PEEK SPACERS

Part Number	Description	Qty
BB092207A	OTLIF Spacer, PEEK, 09mm x 22mm x 07mm, 0°, Non-Sterile	2 / OPT
BB092208A	OTLIF Spacer, PEEK, 09mm x 22mm x 08mm, 0°, Non-Sterile	2 / OPT
BB092209A	OTLIF Spacer, PEEK, 09mm x 22mm x 09mm, 0°, Non-Sterile	2 / OPT
BB092210A	OTLIF Spacer, PEEK, 09mm x 22mm x 10mm, 0°, Non-Sterile	2 / OPT
BB092211A	OTLIF Spacer, PEEK, 09mm x 22mm x 11mm, 0°, Non-Sterile	2 / OPT
BB092212A	OTLIF Spacer, PEEK, 09mm x 22mm x 12mm, 0°, Non-Sterile	2 / OPT
BB092213A	OTLIF Spacer, PEEK, 09mm x 22mm x 13mm, 0°, Non-Sterile	2 / OPT
BB092214A	OTLIF Spacer, PEEK, 09mm x 22mm x 14mm, 0°, Non-Sterile	2 / OPT
BB092215A	OTLIF Spacer, PEEK, 09mm x 22mm x 15mm, 0°, Non-Sterile	2 / OPT

HALF DOME POSTERIOR LUMBAR INTERBODY PEEK OFFERING

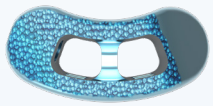
OTLIF PEEK SPACERS

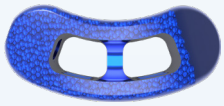
Part Number	Description	Qty
BB092407A	OTLIF Spacer, PEEK, 09mm x 24mm x 07mm, 0°, Non-Sterile	2 / OPT
BB092408A	OTLIF Spacer, PEEK, 09mm x 24mm x 08mm, 0°, Non-Sterile	2 / OPT
BB092409A	OTLIF Spacer, PEEK, 09mm x 24mm x 09mm, 0°, Non-Sterile	2 / OPT
BB092410A	OTLIF Spacer, PEEK, 09mm x 24mm x 10mm, 0°, Non-Sterile	2 / OPT
BB092411A	OTLIF Spacer, PEEK, 09mm x 24mm x 11mm, 0°, Non-Sterile	2 / OPT
BB092412A	OTLIF Spacer, PEEK, 09mm x 24mm x 12mm, 0°, Non-Sterile	2 / OPT
BB092413A	OTLIF Spacer, PEEK, 09mm x 24mm x 13mm, 0°, Non-Sterile	2 / OPT
BB092414A	OTLIF Spacer, PEEK, 09mm x 24mm x 14mm, 0°, Non-Sterile	2 / OPT
BB092415A	OTLIF Spacer, PEEK, 09mm x 24mm x 15mm, 0°, Non-Sterile	2 / OPT
BB092607A	OTLIF Spacer, PEEK, 09mm x 26mm x 07mm, 0°, Non-Sterile	2 / OPT
BB092608A	OTLIF Spacer, PEEK, 09mm x 26mm x 08mm, 0°, Non-Sterile	2 / OPT
BB092609A	OTLIF Spacer, PEEK, 09mm x 26mm x 09mm, 0°, Non-Sterile	2 / OPT
BB092610A	OTLIF Spacer, PEEK, 09mm x 26mm x 10mm, 0°, Non-Sterile	2 / OPT
BB092611A	OTLIF Spacer, PEEK, 09mm x 26mm x 11mm, 0°, Non-Sterile	2 / OPT
BB092612A	OTLIF Spacer, PEEK, 09mm x 26mm x 12mm, 0°, Non-Sterile	2 / OPT
BB092613A	OTLIF Spacer, PEEK, 09mm x 26mm x 13mm, 0°, Non-Sterile	2 / OPT
BB092614A	OTLIF Spacer, PEEK, 09mm x 26mm x 14mm, 0°, Non-Sterile	2 / OPT
BB092615A	OTLIF Spacer, PEEK, 09mm x 26mm x 15mm, 0°, Non-Sterile	2 / OPT
BB092807A	OTLIF Spacer, PEEK, 09mm x 28mm x 07mm, 0°, Non-Sterile	2 / OPT
BB092808A	OTLIF Spacer, PEEK, 09mm x 28mm x 08mm, 0°, Non-Sterile	2 / OPT
BB092809A	OTLIF Spacer, PEEK, 09mm x 28mm x 09mm, 0°, Non-Sterile	2 / OPT
BB092810A	OTLIF Spacer, PEEK, 09mm x 28mm x 10mm, 0°, Non-Sterile	2 / OPT
BB092811A	OTLIF Spacer, PEEK, 09mm x 28mm x 11mm, 0°, Non-Sterile	2 / OPT
BB092812A	OTLIF Spacer, PEEK, 09mm x 28mm x 12mm, 0°, Non-Sterile	2 / OPT
BB092813A	OTLIF Spacer, PEEK, 09mm x 28mm x 13mm, 0°, Non-Sterile	2 / OPT
BB092814A	OTLIF Spacer, PEEK, 09mm x 28mm x 14mm, 0°, Non-Sterile	2 / OPT
BB092815A	OTLIF Spacer, PEEK, 09mm x 28mm x 15mm, 0°, Non-Sterile	2 / OPT
BB093007A	OTLIF Spacer, PEEK, 09mm x 30mm x 07mm, 0°, Non-Sterile	2 / OPT
BB093008A	OTLIF Spacer, PEEK, 09mm x 30mm x 08mm, 0°, Non-Sterile	2 / OPT
BB093009A	OTLIF Spacer, PEEK, 09mm x 30mm x 09mm, 0°, Non-Sterile	2 / OPT
BB093010A	OTLIF Spacer, PEEK, 09mm x 30mm x 10mm, 0°, Non-Sterile	2 / OPT
BB093011A	OTLIF Spacer, PEEK, 09mm x 30mm x 11mm, 0°, Non-Sterile	2 / OPT
BB093012A	OTLIF Spacer, PEEK, 09mm x 30mm x 12mm, 0°, Non-Sterile	2 / OPT
BB093013A	OTLIF Spacer, PEEK, 09mm x 30mm x 13mm, 0°, Non-Sterile	2 / OPT
BB093014A	OTLIF Spacer, PEEK, 09mm x 30mm x 14mm, 0°, Non-Sterile	2 / OPT
BB093015A	OTLIF Spacer, PEEK, 09mm x 30mm x 15mm, 0°, Non-Sterile	2 / OPT
BB093207A	OTLIF Spacer, PEEK, 09mm x 32mm x 07mm, 0°, Non-Sterile	2 / OPT
BB093208A	OTLIF Spacer, PEEK, 09mm x 32mm x 08mm, 0°, Non-Sterile	2 / OPT
BB093209A	OTLIF Spacer, PEEK, 09mm x 32mm x 09mm, 0°, Non-Sterile	2 / OPT
BB093210A	OTLIF Spacer, PEEK, 09mm x 32mm x 10mm, 0°, Non-Sterile	2 / OPT
BB093211A	OTLIF Spacer, PEEK, 09mm x 32mm x 11mm, 0°, Non-Sterile	2 / OPT
BB093212A	OTLIF Spacer, PEEK, 09mm x 32mm x 12mm, 0°, Non-Sterile	2 / OPT
BB093213A	OTLIF Spacer, PEEK, 09mm x 32mm x 13mm, 0°, Non-Sterile	2 / OPT
BB093214A	OTLIF Spacer, PEEK, 09mm x 32mm x 14mm, 0°, Non-Sterile	2 / OPT
BB093215A	OTLIF Spacer, PEEK, 09mm x 32mm x 15mm, 0°, Non-Sterile	2 / OPT

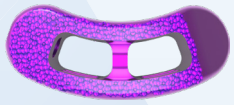
HALF DOME POSTERIOR LUMBAR INTERBODY ACID-ETCHED TITANIUM OFFERING

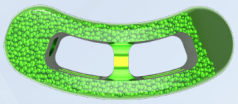
TLIF TITANIUM SPACERS

Part Number	Description	Qty
BC102607B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 07mm, 5°, Non-Sterile	2 / OPT
BC102608B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 08mm, 5°, Non-Sterile	2 / OPT
BC102609B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 09mm, 5°, Non-Sterile	2 / OPT
BC102610B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 10mm, 5°, Non-Sterile	2 / OPT
BC102611B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 11mm, 5°, Non-Sterile	2 / OPT
BC102612B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 12mm, 5°, Non-Sterile	2 / OPT
BC102613B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 13mm, 5°, Non-Sterile	2 / OPT
BC102614B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 14mm, 5°, Non-Sterile	2 / OPT
BC102615B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 26mm x 15mm, 5°, Non-Sterile	2 / OPT
BC102807B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 07mm, 5°, Non-Sterile	2 / OPT
BC102808B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 08mm, 5°, Non-Sterile	2 / OPT
BC102809B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 09mm, 5°, Non-Sterile	2 / OPT
BC102810B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 10mm, 5°, Non-Sterile	2 / OPT
BC102811B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 11mm, 5°, Non-Sterile	2 / OPT
BC102812B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 12mm, 5°, Non-Sterile	2 / OPT
BC102813B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 13mm, 5°, Non-Sterile	2 / OPT
BC102814B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 14mm, 5°, Non-Sterile	2 / OPT
BC102815B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 28mm x 15mm, 5°, Non-Sterile	2 / OPT
BC103007B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 07mm, 5°, Non-Sterile	2 / OPT
BC103008B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 08mm, 5°, Non-Sterile	2 / OPT
BC103009B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 09mm, 5°, Non-Sterile	2 / OPT
BC103010B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 10mm, 5°, Non-Sterile	2 / OPT
BC103011B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 11mm, 5°, Non-Sterile	2 / OPT
BC103012B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 12mm, 5°, Non-Sterile	2 / OPT
BC103013B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 13mm, 5°, Non-Sterile	2 / OPT
BC103014B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 14mm, 5°, Non-Sterile	2 / OPT
BC103015B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 30mm x 15mm, 5°, Non-Sterile	2 / OPT
BC103207B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 07mm, 5°, Non-Sterile	2 / OPT
BC103208B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 08mm, 5°, Non-Sterile	2 / OPT
BC103209B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 09mm, 5°, Non-Sterile	2 / OPT
BC103210B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 10mm, 5°, Non-Sterile	2 / OPT
BC103211B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 11mm, 5°, Non-Sterile	2 / OPT
BC103212B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 12mm, 5°, Non-Sterile	2 / OPT
BC103213B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 13mm, 5°, Non-Sterile	2 / OPT
BC103214B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 14mm, 5°, Non-Sterile	2 / OPT
BC103215B	TLIF Spacer, ACID-ETCHED TITANIUM, 10mm x 32mm x 15mm, 5°, Non-Sterile	2 / OPT



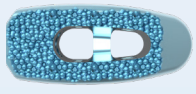






OTLIF TITANIUM SPACERS

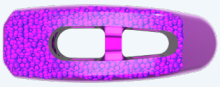
Part Number	Description	Qty
BD092207A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 07mm, 0°, Non-Sterile	2 / OPT
BD092208A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 08mm, 0°, Non-Sterile	2 / OPT
BD092209A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 09mm, 0°, Non-Sterile	2 / OPT
BD092210A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 10mm, 0°, Non-Sterile	2 / OPT
BD092211A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 11mm, 0°, Non-Sterile	2 / OPT
BD092212A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 12mm, 0°, Non-Sterile	2 / OPT
BD092213A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 13mm, 0°, Non-Sterile	2 / OPT
BD092214A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 14mm, 0°, Non-Sterile	2 / OPT
BD092215A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 22mm x 15mm, 0°, Non-Sterile	2 / OPT

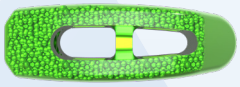


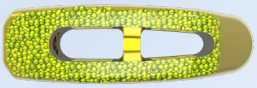
HALF DOME POSTERIOR LUMBAR INTERBODY ACID-ETCHED TITANIUM OFFERING

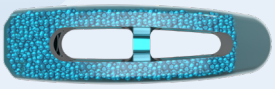
OTLIF TITANIUM SPACERS

Part Number	Description	Qty
BD092407A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 07mm, 0°, Non-Sterile	2 / OPT
BD092408A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 08mm, 0°, Non-Sterile	2 / OPT
BD092409A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 09mm, 0°, Non-Sterile	2 / OPT
BD092410A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 10mm, 0°, Non-Sterile	2 / OPT
BD092411A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 11mm, 0°, Non-Sterile	2 / OPT
BD092412A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 12mm, 0°, Non-Sterile	2 / OPT
BD092413A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 13mm, 0°, Non-Sterile	2 / OPT
BD092414A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 14mm, 0°, Non-Sterile	2 / OPT
BD092415A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 24mm x 15mm, 0°, Non-Sterile	2 / OPT
BD092607A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 07mm, 0°, Non-Sterile	2 / OPT
BD092608A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 08mm, 0°, Non-Sterile	2 / OPT
BD092609A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 09mm, 0°, Non-Sterile	2 / OPT
BD092610A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 10mm, 0°, Non-Sterile	2 / OPT
BD092611A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 11mm, 0°, Non-Sterile	2 / OPT
BD092612A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 12mm, 0°, Non-Sterile	2 / OPT
BD092613A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 13mm, 0°, Non-Sterile	2 / OPT
BD092614A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 14mm, 0°, Non-Sterile	2 / OPT
BD092615A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 26mm x 15mm, 0°, Non-Sterile	2 / OPT
BD092807A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 07mm, 0°, Non-Sterile	2 / OPT
BD092808A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 08mm, 0°, Non-Sterile	2 / OPT
BD092809A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 09mm, 0°, Non-Sterile	2 / OPT
BD092810A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 10mm, 0°, Non-Sterile	2 / OPT
BD092811A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 11mm, 0°, Non-Sterile	2 / OPT
BD092812A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 12mm, 0°, Non-Sterile	2 / OPT
BD092813A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 13mm, 0°, Non-Sterile	2 / OPT
BD092814A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 14mm, 0°, Non-Sterile	2 / OPT
BD092815A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 28mm x 15mm, 0°, Non-Sterile	2 / OPT
BD093007A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 07mm, 0°, Non-Sterile	2 / OPT
BD093008A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 08mm, 0°, Non-Sterile	2 / OPT
BD093009A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 09mm, 0°, Non-Sterile	2 / OPT
BD093010A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 10mm, 0°, Non-Sterile	2 / OPT
BD093011A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 11mm, 0°, Non-Sterile	2 / OPT
BD093012A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 12mm, 0°, Non-Sterile	2 / OPT
BD093013A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 13mm, 0°, Non-Sterile	2 / OPT
BD093014A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 14mm, 0°, Non-Sterile	2 / OPT
BD093015A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 30mm x 15mm, 0°, Non-Sterile	2 / OPT
BD093207A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 07mm, 0°, Non-Sterile	2 / OPT
BD093208A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 08mm, 0°, Non-Sterile	2 / OPT
BD093209A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 09mm, 0°, Non-Sterile	2 / OPT
BD093210A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 10mm, 0°, Non-Sterile	2 / OPT
BD093211A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 11mm, 0°, Non-Sterile	2 / OPT
BD093212A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 12mm, 0°, Non-Sterile	2 / OPT
BD093213A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 13mm, 0°, Non-Sterile	2 / OPT
BD093214A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 14mm, 0°, Non-Sterile	2 / OPT
BD093215A	OTLIF Spacer, ACID-ETCHED TITANIUM, 09mm x 32mm x 15mm, 0°, Non-Sterile	2 / OPT









HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

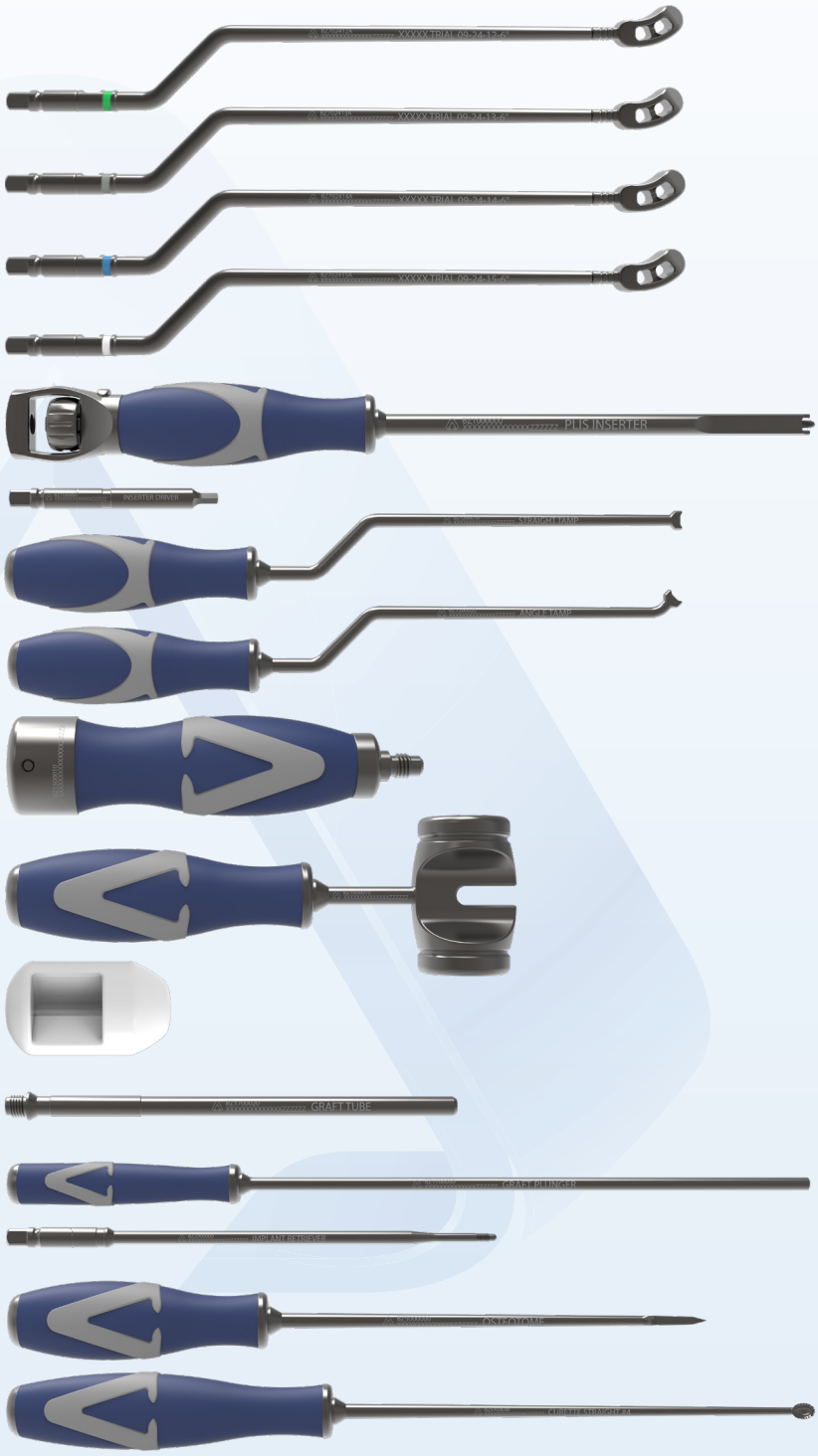
Part Number	Description	Qty
EBECABBCZ	T-Handle, ¼" Square Quick Connect, Slaphammer Impact Cap	2
EADCABACZ	Axial Handle, ¼" Square Quick Connect, Slaphammer Impact Cap	2
BZ0300003	Paddle Distractor, 3mm	1
BZ0300004	Paddle Distractor, 4mm	1
BZ0300005	Paddle Distractor, 5mm	1
BZ0300006	Paddle Distractor, 6mm	1
BZ0300007	Paddle Distractor, 7mm	1
BZ0300008	Paddle Distractor, 8mm	1
BZ0300009	Paddle Distractor, 9mm	1
BZ0300010	Paddle Distractor, 10mm	1
BZ0300011	Paddle Distractor, 11mm	1
BZ0300012	Paddle Distractor, 12mm	1
BZ0300013	Paddle Distractor, 13mm	1
BZ0300014	Paddle Distractor, 14mm	1
BZ0300015	Paddle Distractor, 15mm	1
BZ0400003	Paddle Shaver, 3mm	1
BZ0400004	Paddle Shaver, 4mm	1
BZ0400005	Paddle Shaver, 5mm	1
BZ0400006	Paddle Shaver, 6mm	1
BZ0400007	Paddle Shaver, 7mm	1
BZ0400008	Paddle Shaver, 8mm	1
BZ0400009	Paddle Shaver, 9mm	1
BZ0400010	Paddle Shaver, 10mm	1
BZ0400011	Paddle Shaver, 11mm	1
BZ0400012	Paddle Shaver, 12mm	1

HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ0400013	Paddle Shaver, 13mm	1
BZ0400014	Paddle Shaver, 14mm	1
BZ0400015	Paddle Shaver, 15mm	1
BZ692406A	OTLIF Trial, Bayonetted, 6mm	1 / OPT
BZ692407A	OTLIF Trial, Bayonetted, 7mm	1 / OPT
BZ692408A	OTLIF Trial, Bayonetted, 8mm	1 / OPT
BZ692409A	OTLIF Trial, Bayonetted, 9mm	1 / OPT
BZ692410A	OTLIF Trial, Bayonetted, 10mm	1 / OPT
BZ692411A	OTLIF Trial, Bayonetted, 11mm	1 / OPT
BZ692412A	OTLIF Trial, Bayonetted, 12mm	1 / OPT
BZ692413A	OTLIF Trial, Bayonetted, 13mm	1 / OPT
BZ692414A	OTLIF Trial, Bayonetted, 14mm	1 / OPT
BZ692415A	OTLIF Trial, Bayonetted, 15mm	1 / OPT
BZ702606B	TLIF Trial, Bayonetted, 6mm	1 / OPT
BZ702607B	TLIF Trial, Bayonetted, 7mm	1 / OPT
BZ702608B	TLIF Trial, Bayonetted, 8mm	1 / OPT
BZ702609B	TLIF Trial, Bayonetted, 9mm	1 / OPT
BZ702610B	TLIF Trial, Bayonetted, 10mm	1 / OPT
BZ702611B	TLIF Trial, Bayonetted, 11mm	1 / OPT

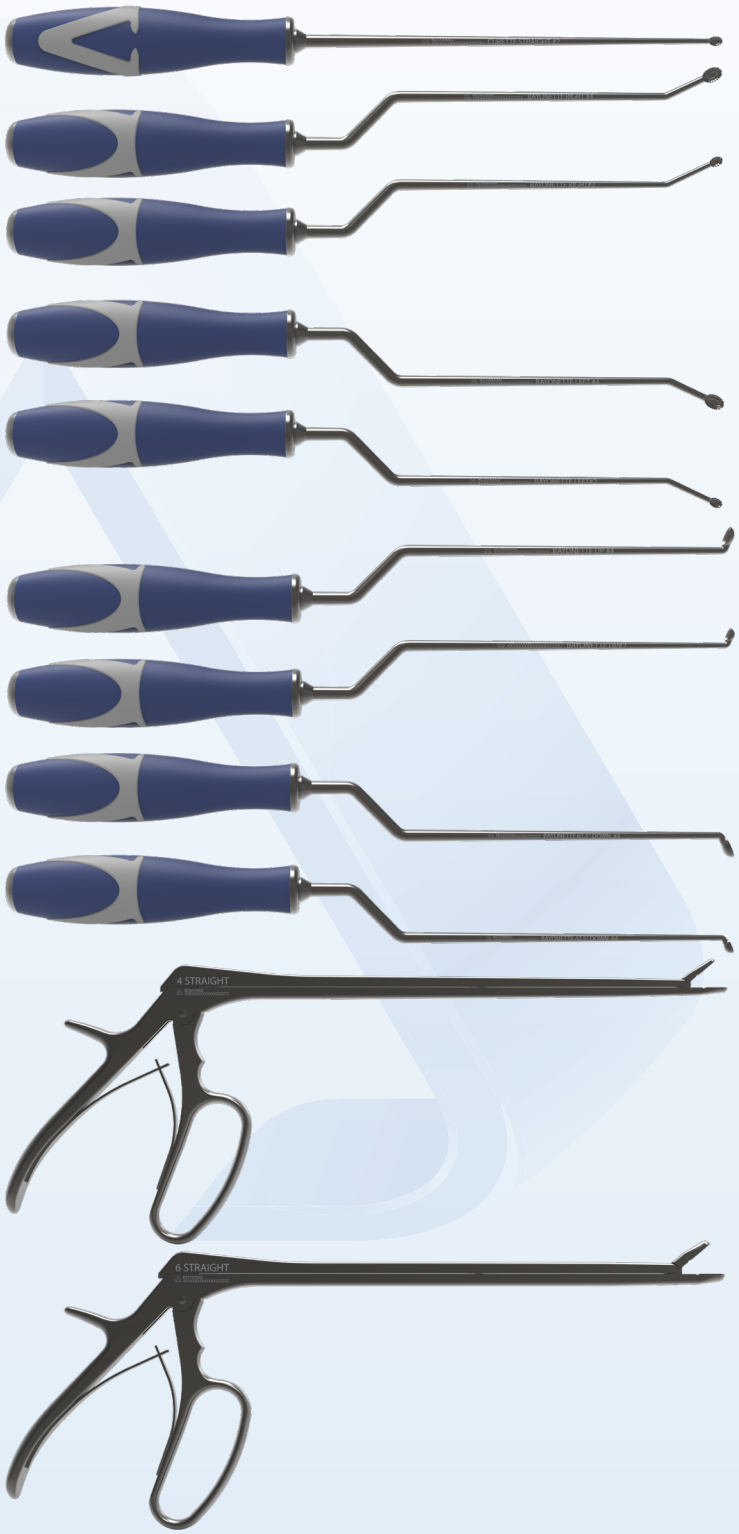
HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ702612B	TLIF Trial, Bayonetted, 12mm	1 / OPT
BZ702613B	TLIF Trial, Bayonetted, 13mm	1 / OPT
BZ702614B	TLIF Trial, Bayonetted, 14mm	1 / OPT
BZ702615B	TLIF Trial, Bayonetted, 15mm	1 / OPT
BZ1000000	PLIS Inserter, Straight	1
BZ1100000	Inserter Driver	1
BZ1200010	Straight Tamp	1
BZ1200020	Angled Tamp	1
BZ1500000	Slaphammer	1
BZ1600000	Mallet	1
BZ1700000-10	Bone Graft Delivery Funnel	1
BZ1700000-20	Graft Tube	1
BZ1700000-30	Graft Plunger	1
BZ2000000	Implant Retriever	1
BZ5000000	Osteotome, Straight, 10mm	1
BZ5100000	Cup Curette, Straight, #4, Teeth	1



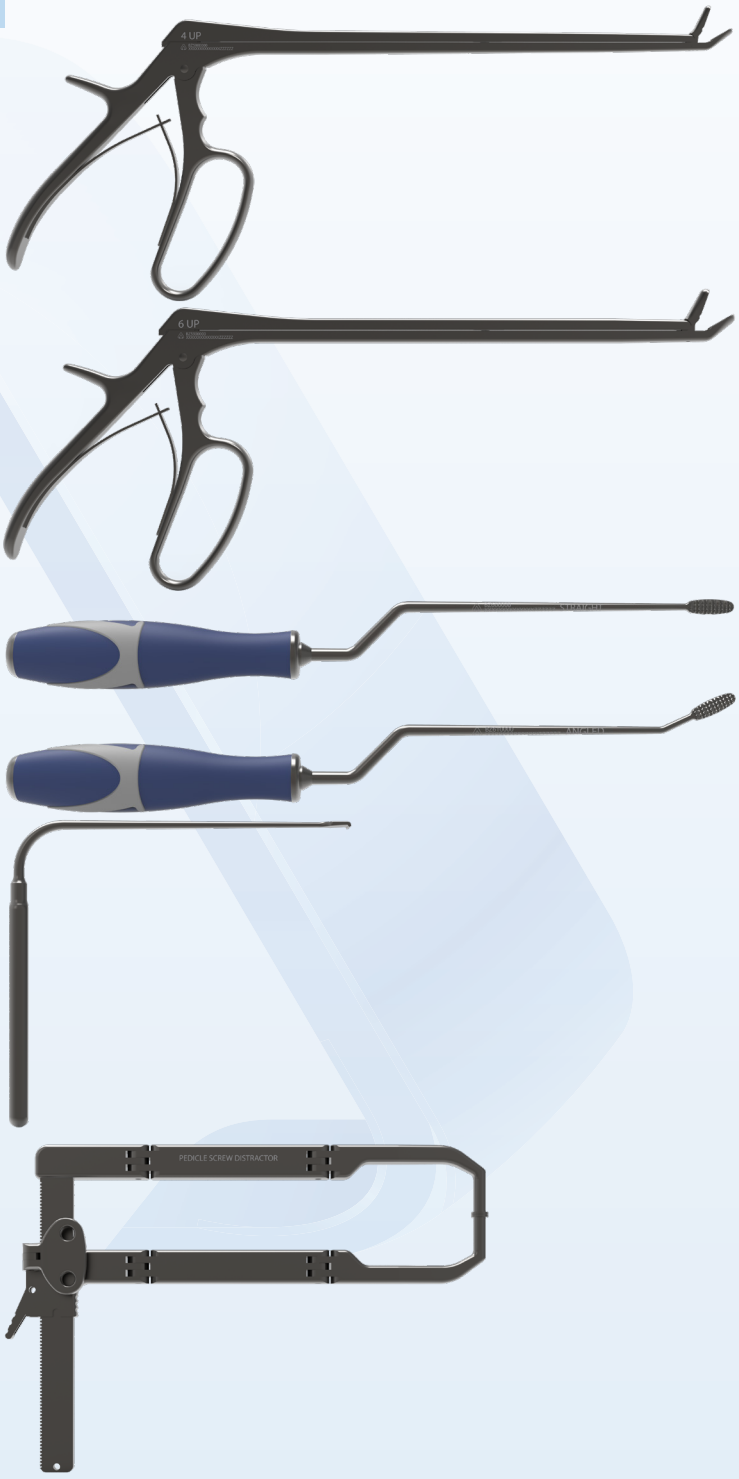
HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ5100002	Cup Curette, Straight, #2, Teeth	1 / OPT
BZ5200000	Cup Curette, Bayonetted, Right, #4, Teeth	1
BZ5200002	Cup Curette, Bayonetted, Right, #2, Teeth	1 / OPT
BZ5300000	Cup Curette, Bayonetted, Left, #4, Teeth	1
BZ5300002	Cup Curette, Bayonetted, Left, #2, Teeth	1 / OPT
BZ5400000	Cup Curette, Bayonetted, Up, #4, No Teeth	1
BZ5400002	Cup Curette, Bayonetted, Up, #2, No Teeth	1 / OPT
BZ5500000	Cup Curette, Bayonetted, 67.5° Down, #4, No Teeth	1
BZ5500002	Cup Curette, Bayonetted, 67.5° Down, #2, No Teeth	1 / OPT
BZ5600000	Pituitary, Straight, #4, No Teeth	1
BZ5700000	Pituitary, Straight, #6, No Teeth	1



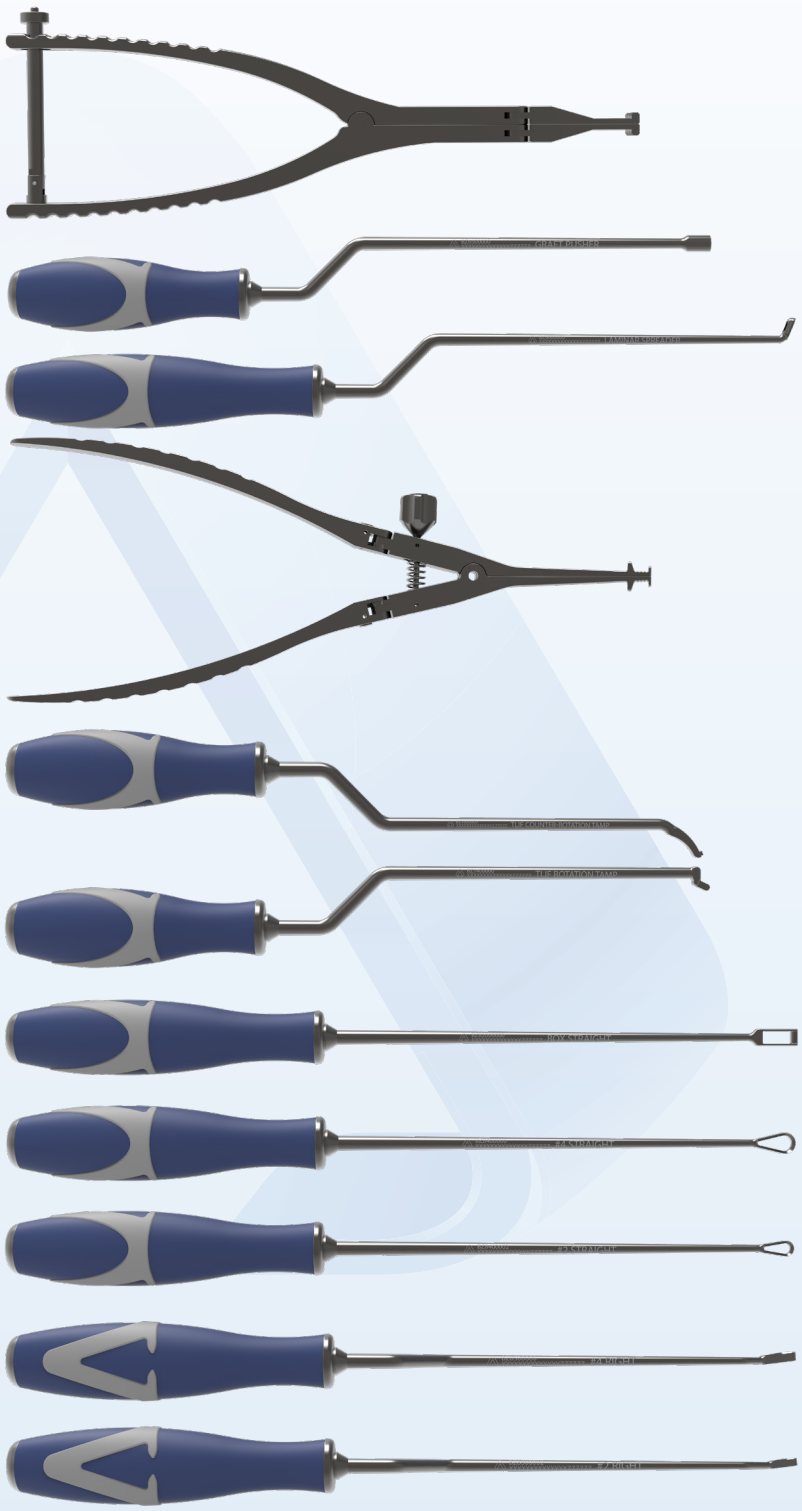
HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ5800000	Pituitary, Up, #4, No Teeth	1
BZ5900000	Pituitary, Up, #6, No Teeth	1
BZ6000000	Endplate Rasp, Bayonetted, Double-sided, Straight	1
BZ6100000	Endplate Rasp, Bayonetted, Double-sided, Angled	1
BZ6200000	Nerve Root Retractor, 90°	1
BZ6300000	Pedicle Screw Distractor	1



HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ6400000	Lamina Spreader	1
BZ6500000	Graft Pusher	1
BZ8000000	Cup Currette, Bayonetted, Downgoing, Pointed Tip	1 / OPT
BZ8100000	Modular Lamina Spreader	1 / OPT
BZ1300000	TLIF Counter-Rotation Tamp	1 / OPT
BZ1400000	TLIF Rotation Tamp	1 / OPT
BZ8200000	Box Curette, Straight	1 / OPT
BZ8400000	Uterine Curette, Bayonetted, Straight, #4, No Teeth	1 / OPT
BZ8400002	Uterine Curette, Bayonetted, Straight, #2, No Teeth	1 / OPT
BZ8500000	Uterine Curette, Bayonetted, Right, #4, No Teeth	1 / OPT
BZ8500002	Uterine Curette, Bayonetted, Right, #2, No Teeth	1 / OPT



HALF DOME POSTERIOR LUMBAR INTERBODY INSTRUMENT OFFERING

Part Number	Description	Qty
BZ8600000	Uterine Curette, Bayonetted, Left, #4, No Teeth	1 / OPT
BZ8600002	Uterine Curette, Bayonetted, Left, #2, No Teeth	1 / OPT
BZ8900006	Rotating Cutter, 06mm	1 / OPT
BZ8900007	Rotating Cutter, 07mm	1 / OPT
BZ8900008	Rotating Cutter, 08mm	1 / OPT
BZ8900009	Rotating Cutter, 09mm	1 / OPT
BZ8900010	Rotating Cutter, 10mm	1 / OPT
BZ4900000	Implant Specific Sterilization Container	1
BZ9900000	Disc Preparation Sterilization Container	1

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The HALF DOME intervertebral body 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 anatomical conditions of the patient. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent implant migration and/or expulsion.

2.0 MATERIAL: VESTAKEEP® i4R PEEK (ASTM F2026), Tantalum (ASTM F560), TI-6AL-4V ELI (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 HALF DOME SYSTEM must not be reused under any circumstances. The HALF DOME SYSTEM 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 HALF DOME SYSTEM and are not a reference for surgical techniques.

4.0 INDICATIONS: The HALF DOME POSTERIOR LUMBAR INTERBODY SYSTEM is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). HALF DOME SYSTEM implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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. 14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
6.1.15 Graft donor site complications including pain, fracture, or wound healing problems.
6.1.16 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
6.1.17 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
6.1.18 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
6.1.19 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
6.1.20 Change in mental status.
6.1.21 Non-union (or pseudarthrosis). Delayed union. Mal-union.
6.1.22 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
6.1.23 Inability to perform the activities of daily living.
6.1.24 Paralysis.
6.1.25 Death.

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

7.0 WARNINGS AND PRECAUTIONS: The HALF DOME SYSTEM 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 HALF DOME SYSTEM 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 HALF DOME SYSTEM 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 intervertebral body fusion device 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 HALF DOME SYSTEM has not been evaluated for safety and compatibility in the MR environment. The HALF DOME SYSTEM 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. HALF DOME SYSTEM components should not be used with components from other manufacturers.only for spinal conditions with significant mechanical instability requiring fusion with instrumentation. These conditions are significant mechanical instability of the cervical spine, objective evidence of neurologic impairment, degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The safety and effectiveness of these devices for any other conditions are unknown.

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 HALF DOME SYSTEM components are not to be combined with the 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 HALF DOME SYSTEM 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 delayed or 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 HALF DOME SYSTEM 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 of the HALF DOME SYSTEM are supplied clean and NOT STERILE, and must be sterilized prior to use.

14.0 CLEANING: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. 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 warm enzymatic detergent 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 water for at least one (1) minute to remove solutions.

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: 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

Wrap tray with a towel placed between tray and FDA cleared wrap.

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.

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 HALF DOME SYSTEM component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.

If any HALF DOME SYSTEM 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

NOTES


ASTURA
MEDICAL