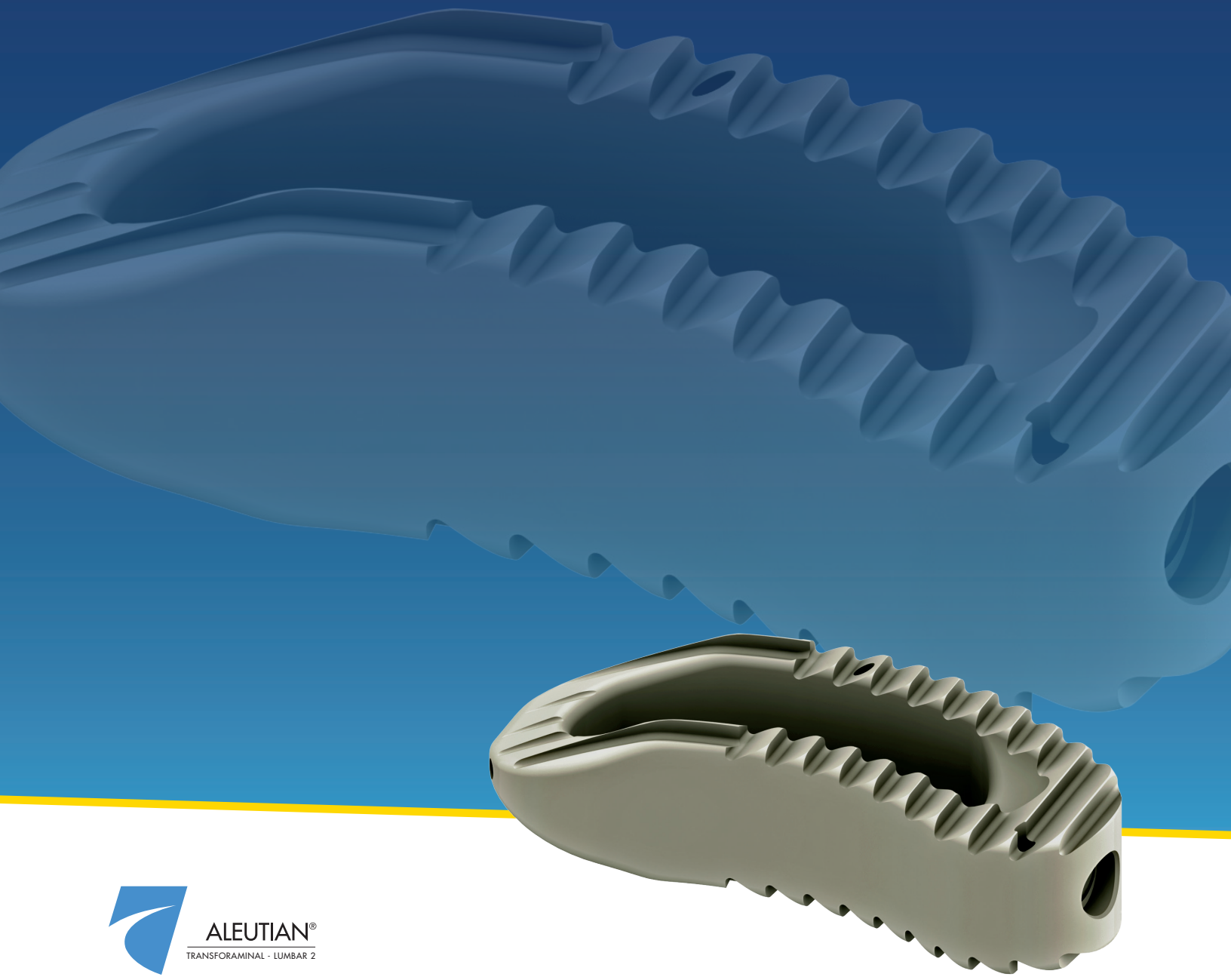
K2M

COMPLEX SPINE INNOVATIONS™

SURGICAL TECHNIQUE

ALEUTIAN®

TRANSFORAMINAL-LUMBAR (TLIF) 2 INTERBODY SYSTEM



ALEUTIAN®
TRANSFORAMINAL - LUMBAR 2

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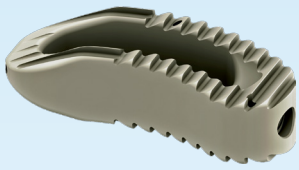
ALEUTIAN® TRANSFORAMINAL-LUMBAR (TLIF) 2 INTERBODY SYSTEM



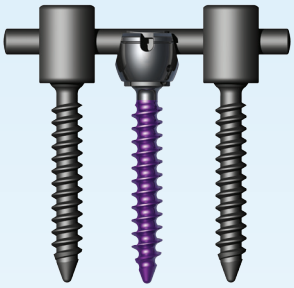
IMPLANTS

- 10 x 28, 10 x 32, 12 x 32 & 12 x 36 mm Footprints Available in 7° Lordotic Options
- Full Selection of Implant Heights Ranging from 7–15 mm
- Bulleted Nose with Grooved Channels for Ease of Insertion
- Designed to Allow for a Large Grafting Space
- Manufactured of Biocompatible PEEK Polymer

FEATURES & BENEFITS

PEDICLE SCREW SYSTEMS

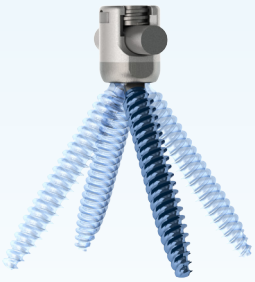
MESA® Spinal Systems



IMPLANTS

- Zero-Torque Technology®
- No Profile Above the Rod
- One-step Final Locking
- 60° Range of Motion
- Controlled Compression & Distraction
- Implant & Instrument Design Facilitates Full Rod Reduction Capability

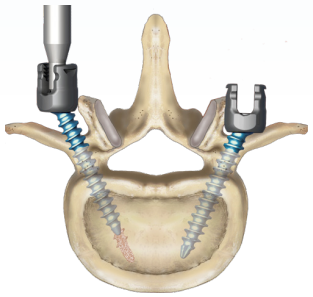
EVEREST® Degenerative Spinal System



IMPLANTS

- Screw Head Accepts Both Ø5.5 & Ø6.0 mm Rods
- Set Screw Features a Modified Square Thread Design, Facilitating Set Screw Introduction
- Dual-lead Thread Pattern for Faster Insertion & Increased Pullout Strength*
- Mixed-metal (Ti/CoCr) Tulip Minimized Head Splay & Improved Biomechanical Performance When Tested Against an All-titanium Alloy Screw*

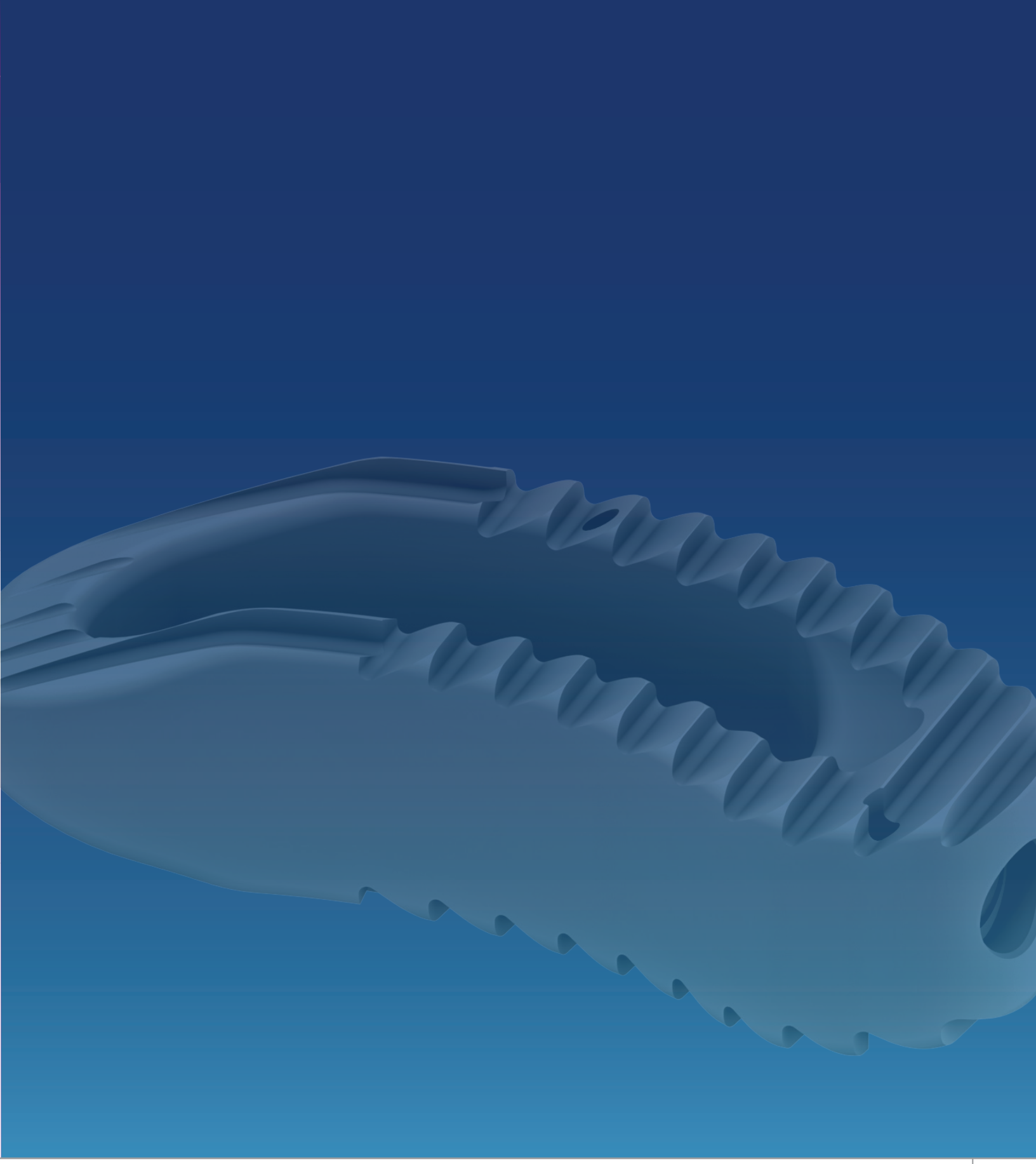
DENALI® Spinal Systems



IMPLANTS

- Off-axis Screw Height Adjustment
- Low-volume Screw Housing
- Distinct Color-coded Screws Clearly Indicating Length
- Variety of Easy-to-use Reduction Instruments
- Torsional Rod Reducers Providing Translation & Reduction

*Support data available upon request. Mechanical testing may not represent clinical results.



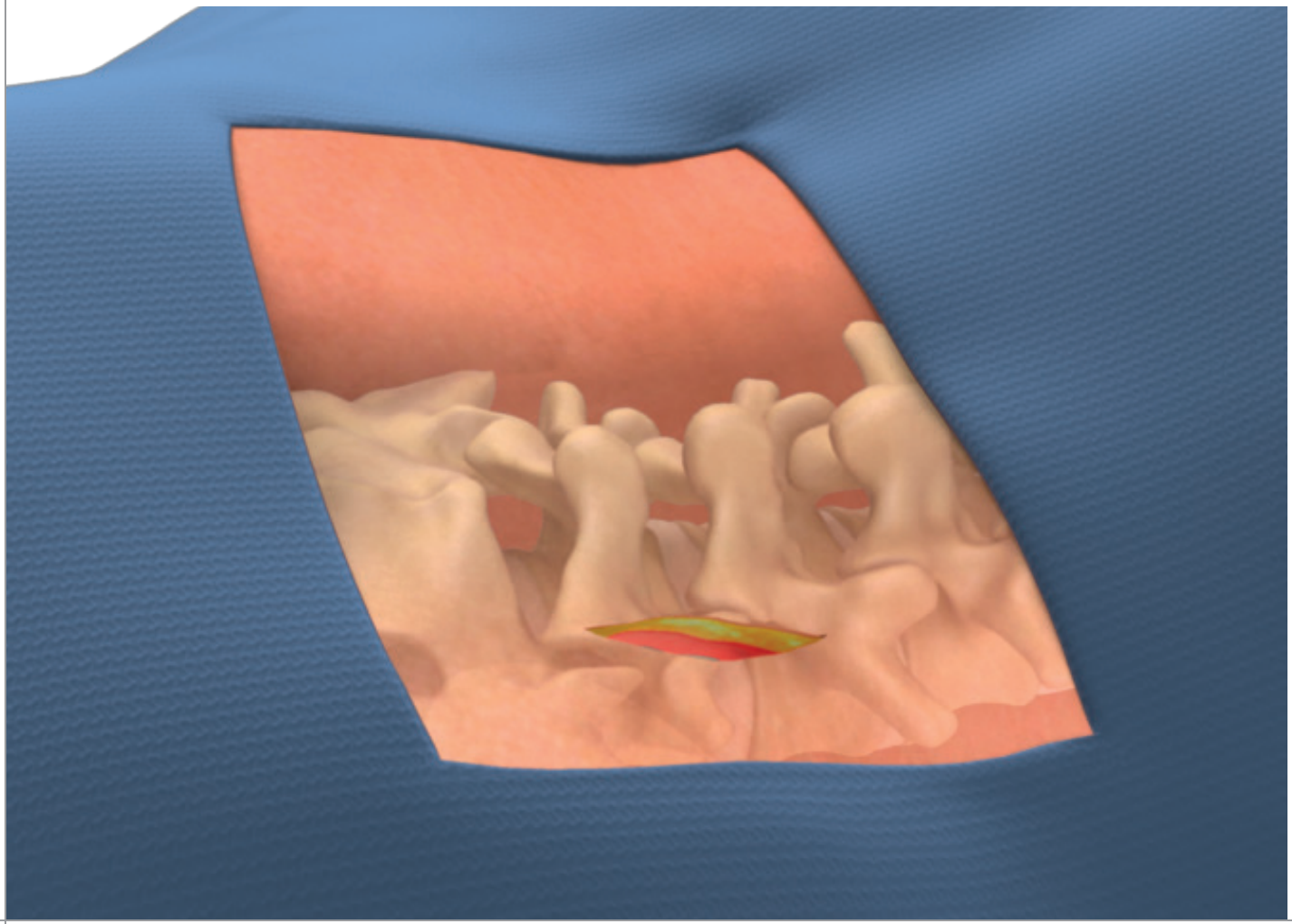
SURGICAL TECHNIQUE

STEP 1

PATIENT POSITIONING: POSTERIOR SURGICAL EXPOSURE

The patient should be positioned as appropriate for a posterior approach, taking care to preserve or improve sagittal balance of the spine. To facilitate venous drainage, the abdomen should not be compressed. The decision on operative side is based on the vascular anatomy, the spinal pathology, and surgeon preference.

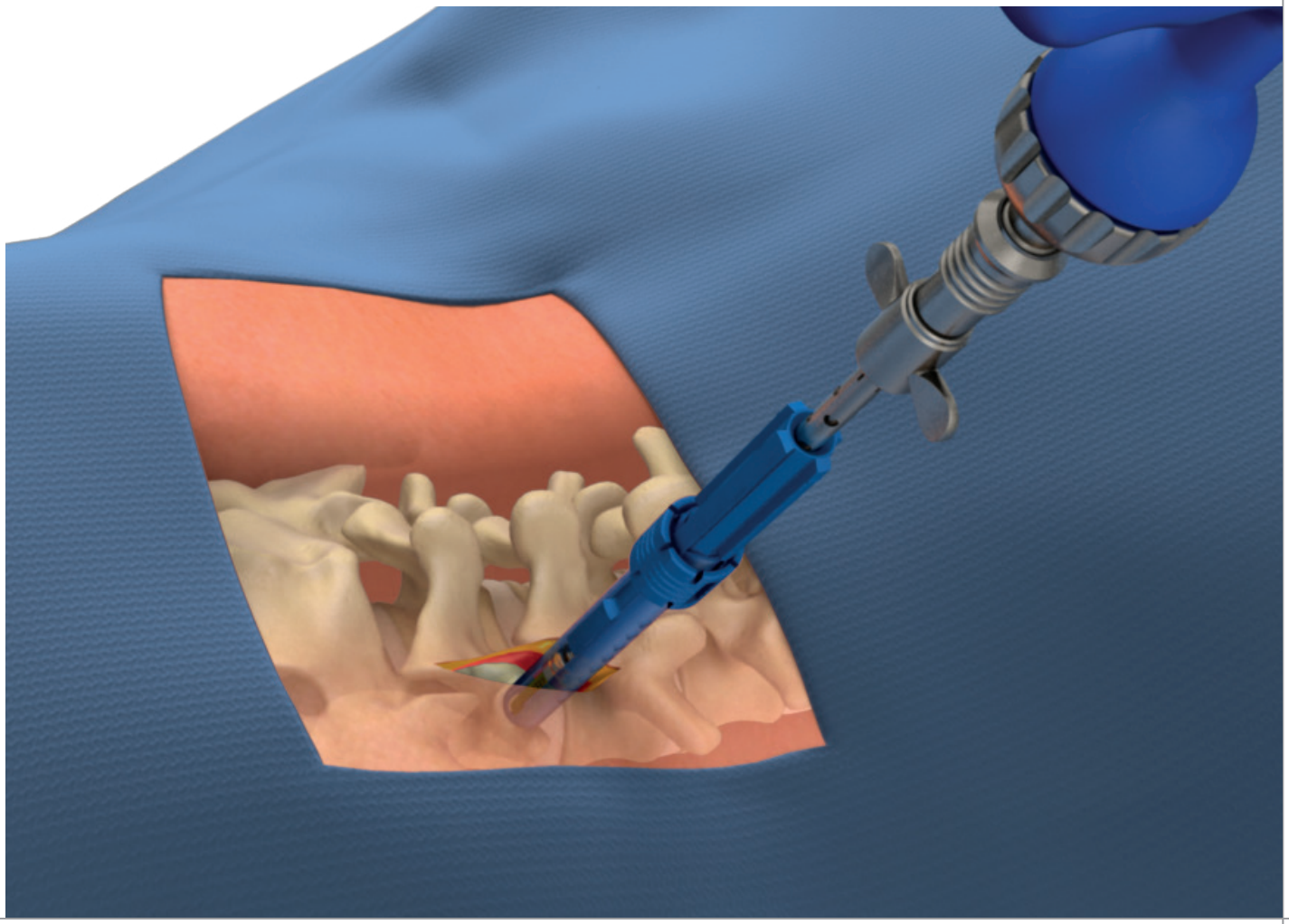
NOTE: The ALEUTIAN TLIF 2 Interbody System is designed to accommodate all open and less invasive surgical techniques. For the purposes of this guide, a minimally invasive technique is detailed, but open and muscle splitting exposures are equally valid and utilize the same surgical principles.



STEP 2

PEDICLE SCREW PLACEMENT

Cannulated DENALI Pedicle Screws and SERENGETI Retractors are placed in the pedicles adjacent to the operative level. Please refer to the SERENGETI Minimally Invasive Retractor System Surgical Technique (K2-10-7009-01) for proper screw and Retractor placement.



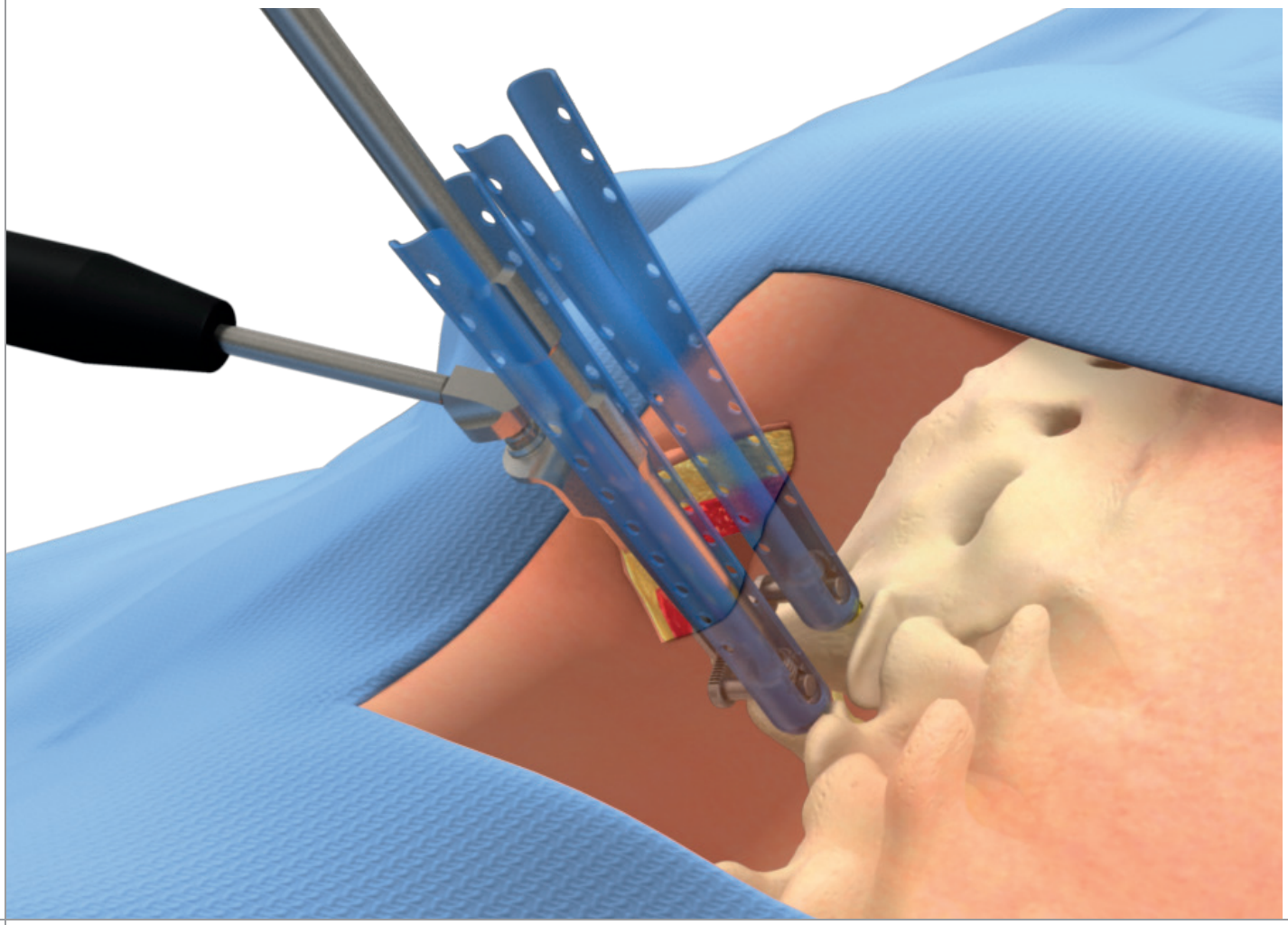
STEP 3

RETRACTOR DISTRACTOR BLADE PLACEMENT

Attach the Blade Handle to the Retractor Distractor Blade. Slide the Retractor Distractor Blade down the SERENGETI Retractors and into the screw saddles. Provisionally tighten the set screws to retain the Retractor Distractor Blade in the screw heads. Pivot the Blade Handle laterally to allow for direct visualization of the targeted level. While holding the Blade Handle, lock one of the set screws to maintain lateral retraction.

Distract the disc space and assemble the remaining Retractor components as detailed in the TERRA NOVA® Minimally Invasive Access System Surgical Technique (K2-15-7005-01).

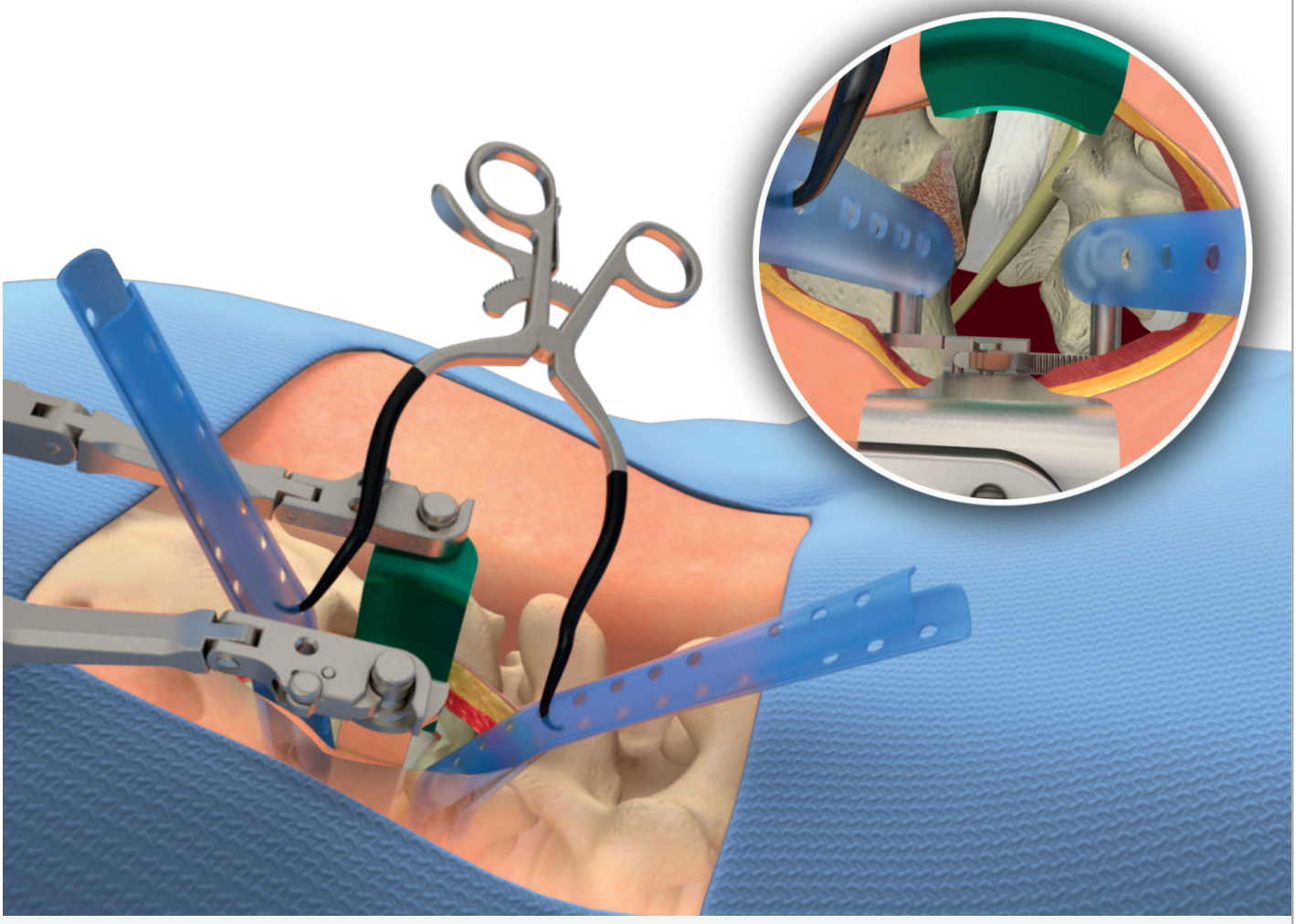
NOTE: If TERRA NOVA is not being used, the disc space can be distracted using a contralateral rod, lamina spreader or screw based distractor.



STEP 4

LAMINOTOMY/FACETECTOMY

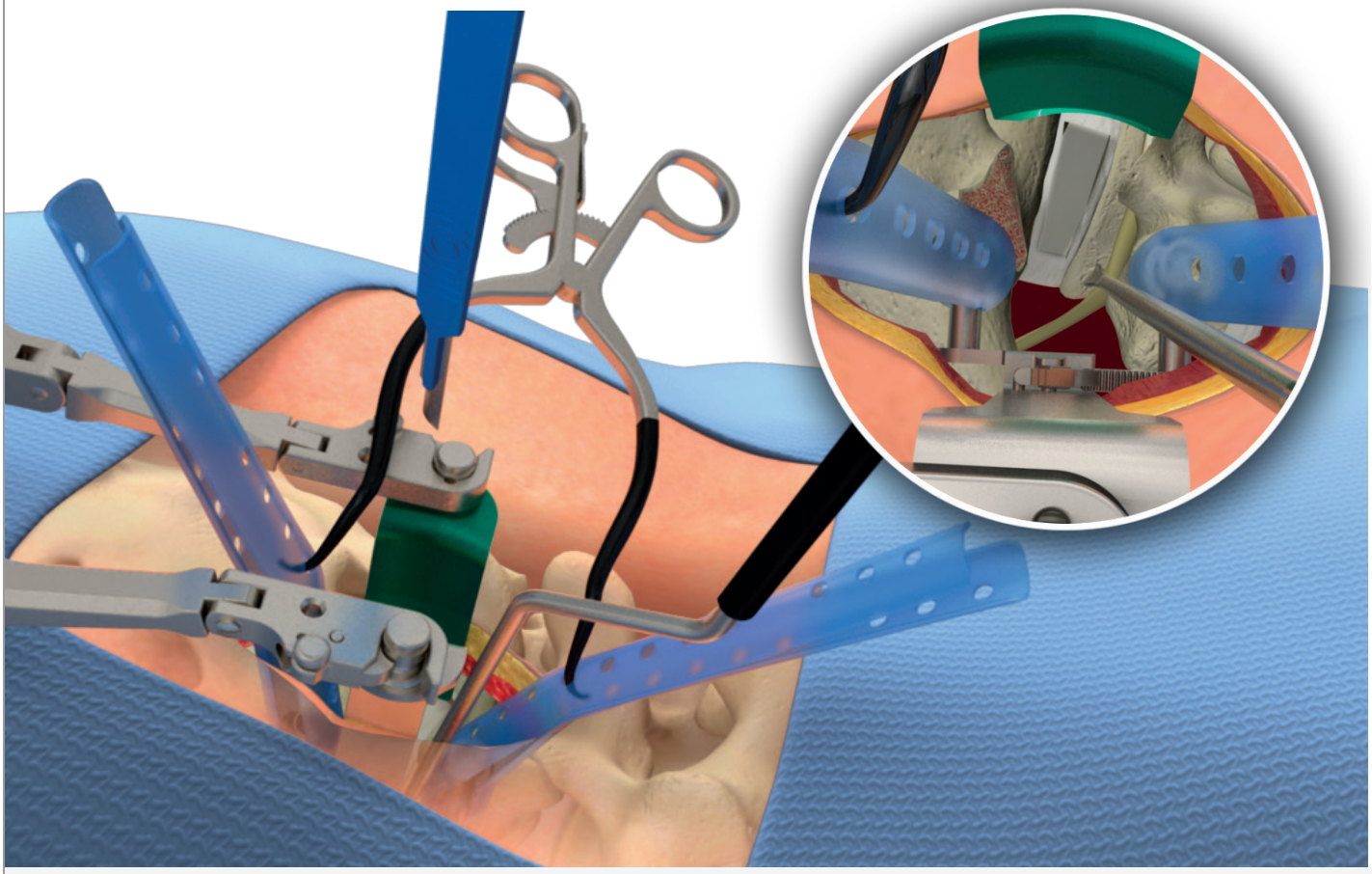
Using a combination of surgical instruments (Curettes, Osteotomes, Kerrison Rongeurs, etc.) appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy is performed, along with the removal of the ligamentum flavum to provide access to the disc space.



STEP 5

NEURAL ELEMENT RETRACTION/DISC REMOVAL

A Nerve Root Retractor is used to mobilize the nerve root and expose the annulus of the disc space. A scalpel can then be used to make an incision in the annulus through which a complete discectomy can be performed. Disc Scrapers, a variety of Curettes, Kerrisons, and Pituitary Rongeurs are included in the set to aid in the removal of the disc material and the cartilaginous endplates. Sequential rotating Disc Spreaders are also available should any additional disc space distraction be desired.



NERVE ROOT RETRACTOR

DISC SCRAPER

CURETTE

KERRISON RONGEUR

DISC SPREADER

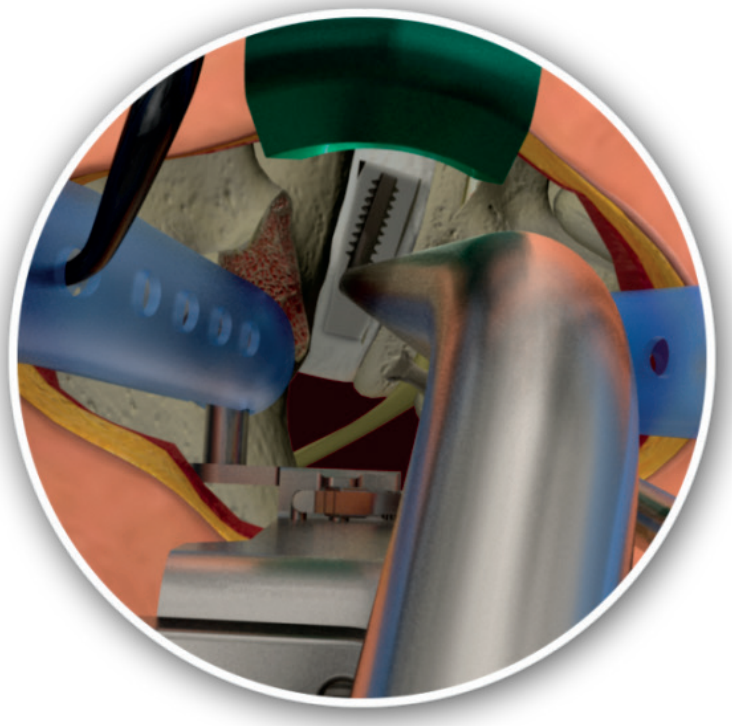
PITUITARY RONGEUR

T-HANDLE

STEP 6

ENDPLATE PREPARATION

Adequate endplate preparation is essential for a successful fusion. The Posterior-Lumbar Disc Preparation Instruments Sets include appropriately sized Disc Scrapers, along with a variety of Rasps and Curettes to help ensure proper decortication of the endplates.




RASP


CURETTE

DISC SCRAPER


T-HANDLE

STEP 7

IMPLANT SIZING

Trials are available to determine the proper implant size. The Trials match each of the four implant footprints and are discernable by the colored rings around the shafts, which correspond to each of the respective footprints. The Trials are 0.5 mm shorter than the respective implants to give a slight press fit of the interbody upon impaction.

12 x 36 mm
Indicated by 3 yellow bands

12 x 32 mm
Indicated by 3 green bands

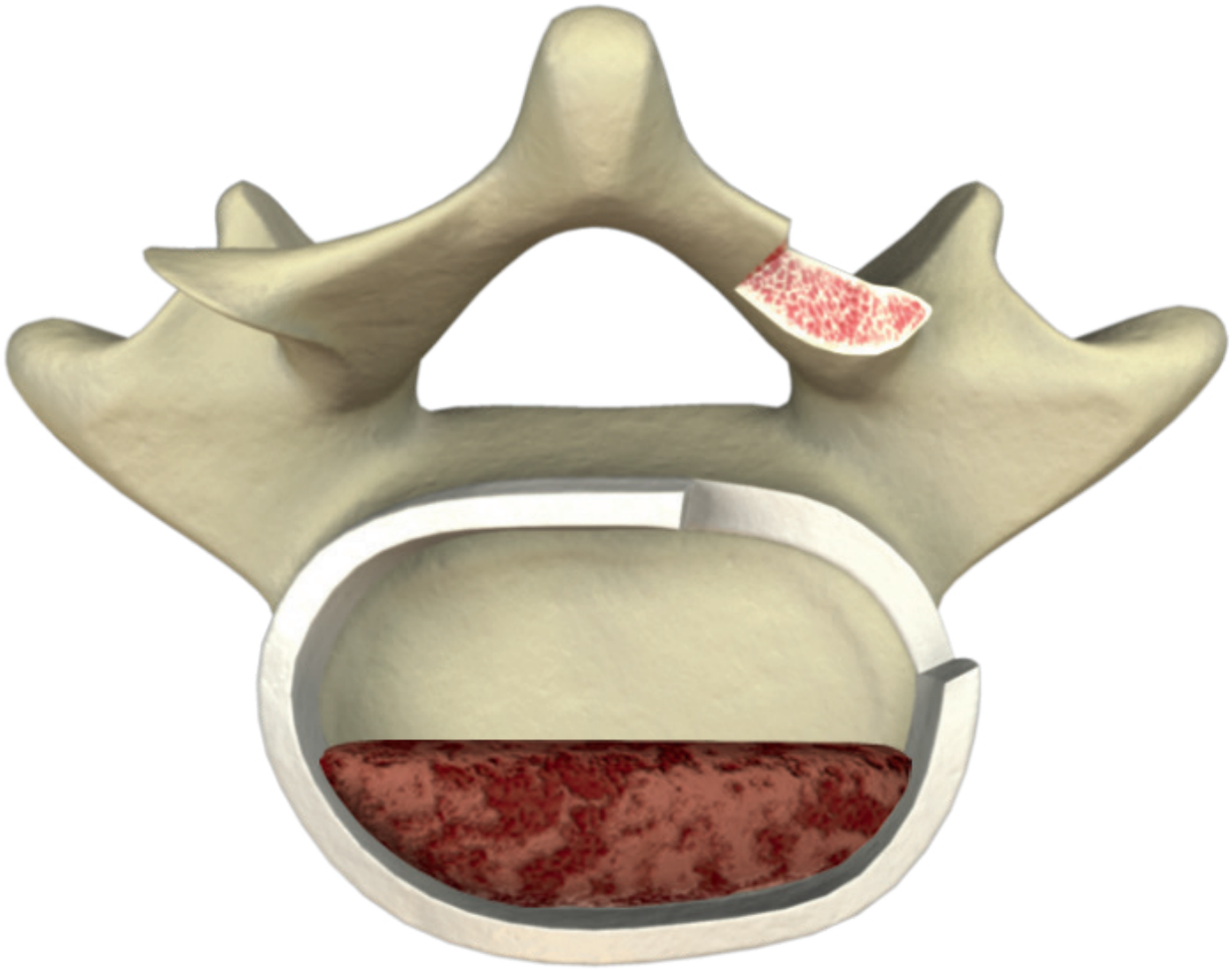
10 x 32 mm
Indicated by 2 green bands

10 x 28 mm
Indicated by 2 blue bands

STEP 8

PLACEMENT OF BONE GRAFT

When used as a lumbar intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. A Bone Graft Funnel and Pusher are included in the set to aid with bone graft placement.



BONE GRAFT FUNNEL

BONE GRAFT PUSHER

STEP 9

IMPLANT INSERTION

There are two Inserter options which may be used with this system: a rigid Straight Inserter and an Adjustable Inserter. The Adjustable Inserter lends itself well to the minimally invasive type exposure detailed here.

Figure A
The proximal end of the implant is threaded onto the stud at the distal end of the Inserter, taking care to ensure the recess in the implant is aligned with the finger on the Inserter by turning the thumbwheel at the proximal end of the inner shaft. The thumbwheel contains a torque limiting mechanism which will skip when the implant is secured to the Inserter. The implant should tangentially touch the Inserter. Following implant attachment, the inner shaft should be removed from the Inserter.

STRAIGHT INSERTER

STRAIGHT INSERTER SHAFT

The implant is inserted into the disc space in the 0° orientation for initial linear introduction. Using a Mallet, the implant is advanced into the disc space. The collar on the Inserter Shaft can be rotated to adjust the incident angle between the Inserter and the implant.

NOTE: The inner shaft should be removed prior to malleting the Inserter.

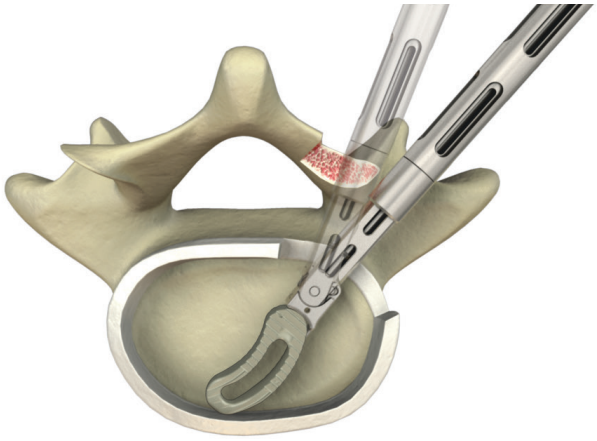
Figure B
The Adjustable Inserter allows for an incident angle between the Inserter and the implant ranging from 0–60°.

STEP 9

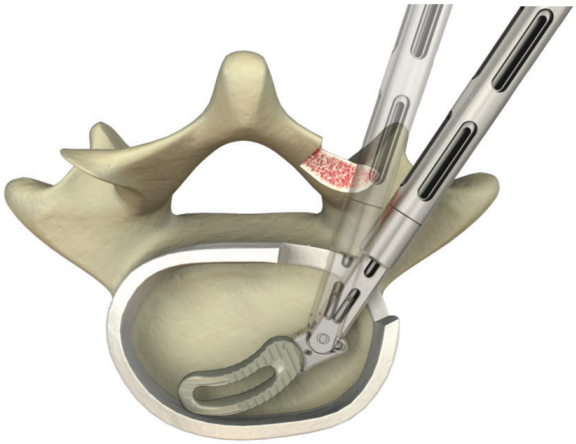
IMPLANT INSERTION (CONT.)

Adjusting the angle in a stepwise fashion during insertion can aid in advancing the implant into position along the anterior annulus. X-ray or fluoroscopy may be used during insertion to verify implant placement. Once the implant is properly positioned, the inner shaft can be reengaged with the Inserter. The Inserter is detached by rotating the thumbwheel on the proximal end counter-clockwise, at which point it can be removed from the wound. In the event that the implant must be removed, there is a removal tool included in the Posterior Lumbar Disc Preparation Instruments Set which can be used to extract the implant from the disc space.

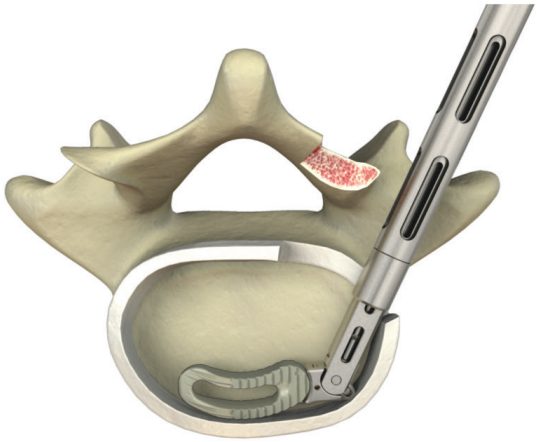
NOTE: After unthreading the Inserter from the implant, the angulation of the Inserter can be returned to 0° to ease extraction from the disc space.



STEP 1



STEP 2



STEP 3

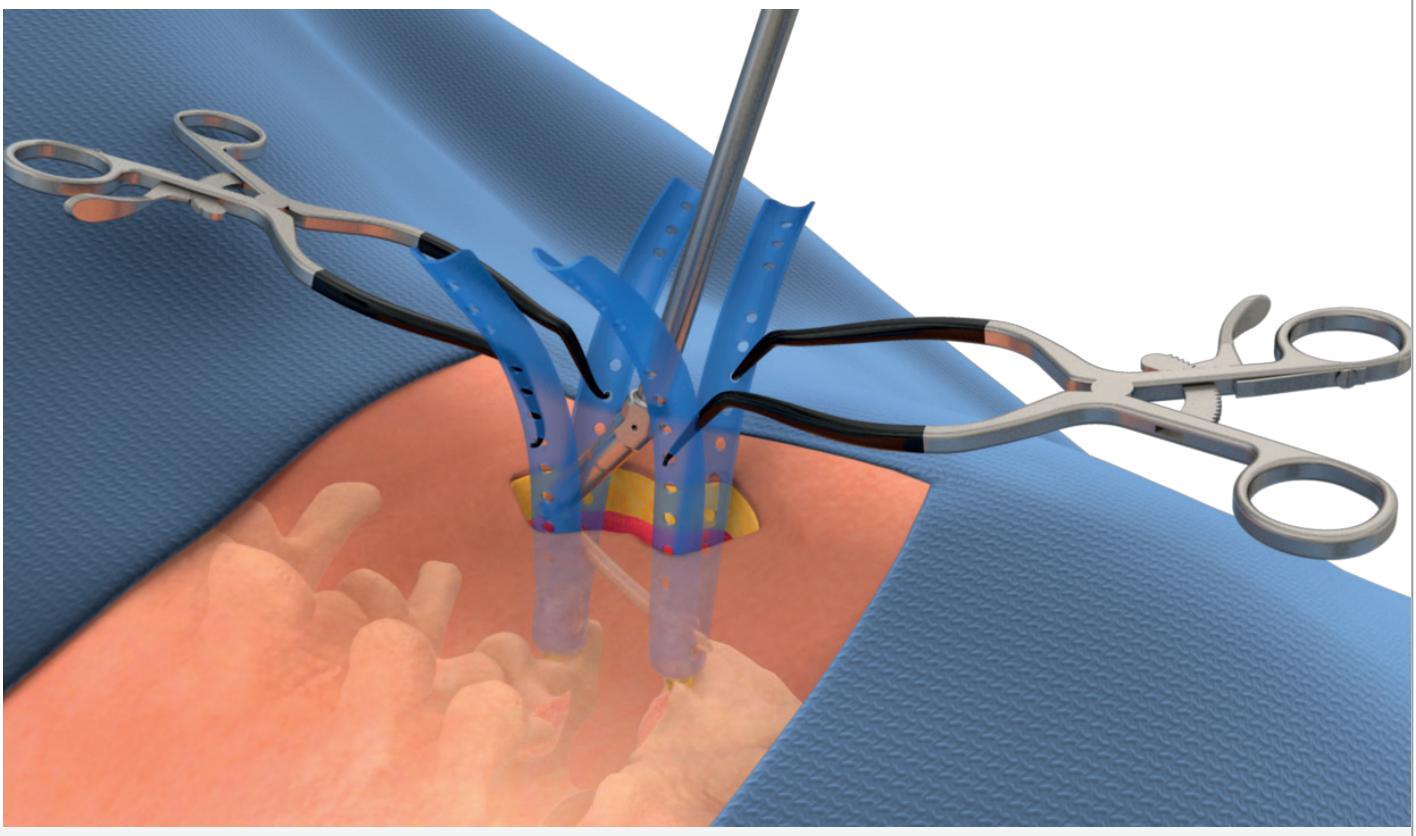
ADJUSTABLE INSERTER

ADJUSTABLE INSERTER INNER SHAFT

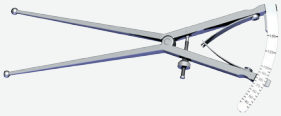
STEP 10

ROD INSERTION & COMPRESSION

After interbody insertion, the Retractor Distractor Blade can be removed from the wound and the screw heads realigned for rod introduction, as detailed in the TERRA NOVA Surgical Technique. The MI Rod Caliper can be used to determine the proper rod length. The rod is then inserted into the screw heads according to the TERRA NOVA Surgical Technique. If compression is desired, leave one set screw provisionally tightened and use the Tube Compressor to apply compression and final tighten the set screw.



MI ROD CALIPER



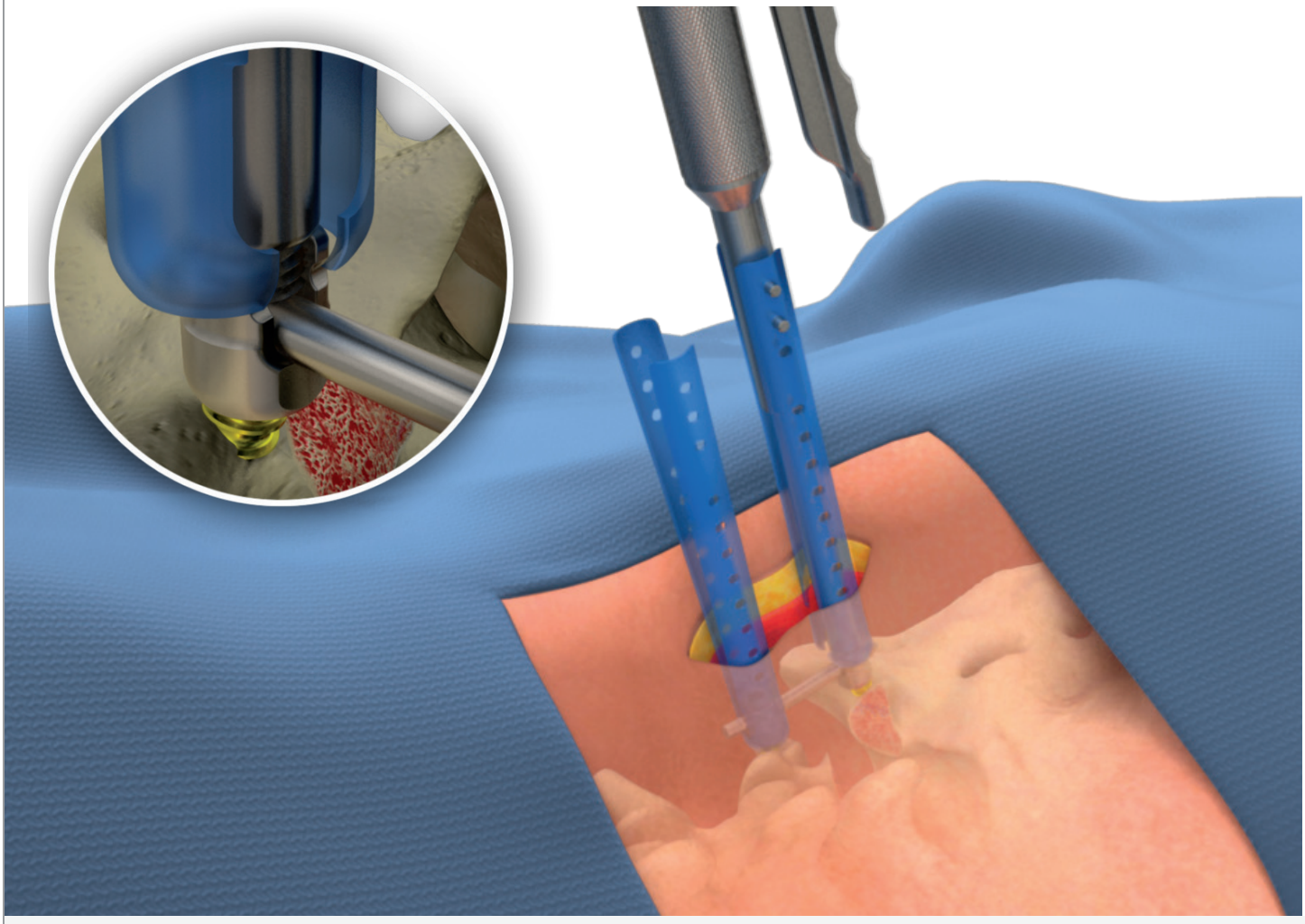
MI ROD INSERTER

TUBE COMPRESSOR

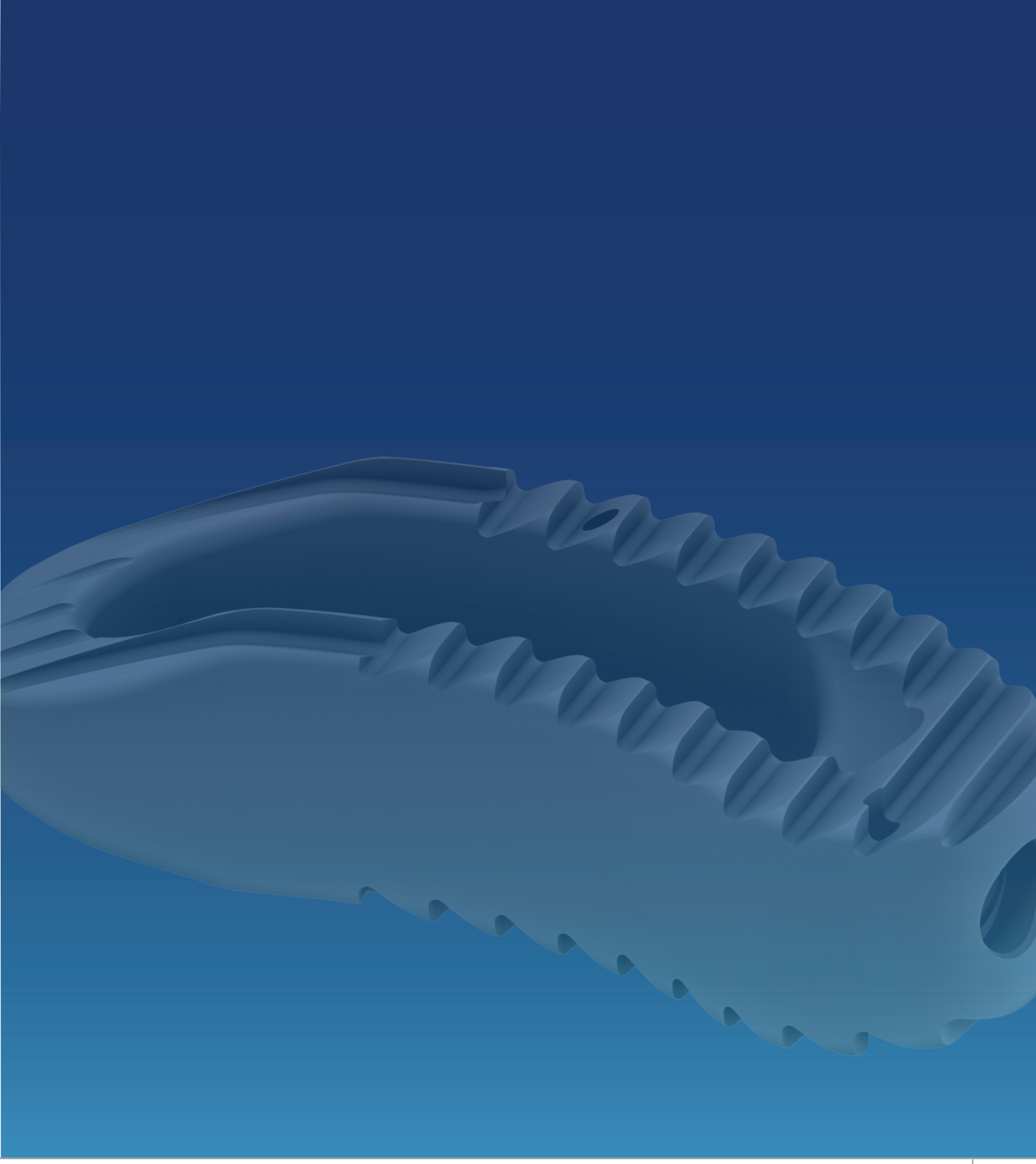
STEP 11

REMOVING THE SERENGETI RETRACTORS

Following final tightening of the set screws, use the Retractor Extractor to remove the SERENGETI Retractors. With the Retractors removed, perform a standard multi-layer wound closure to complete the procedure.



RETRACTOR EXTRACTOR



PRODUCT CATALOG

LAMINOTOMY/FACETECTOMY

CATALOG #	DESCRIPTION
3303-90046	4 mm 40° Upbiting Kerrison
3303-90047	6 mm 40° Upbiting Kerrison
3303-90036*	Bayoneted 8 mm Osteotome
3303-90022*	Bayoneted 10 mm Elevator
702-90052	Large Mallet

*Also available in straight version

4 & 6 mm 40° UPBITING KERRISON

BAYONETED 8 mm OSTEOTOME*

BAYONETED 10 mm ELEVATOR*

LARGE MALLET

DISC EXPOSURE & ACCESS

CATALOG #	DESCRIPTION
3303-90055	Small Nerve Root Retractor
725-1154-3	Pennfield
725-1115-3	Woodson
705-1010-3	Scalpel Blade Holder

SMALL NERVE ROOT RETRACTOR

PENNFIELD

WOODSON

SCALPEL BLADE HOLDER

DISC SPACE DISTRACTION

CATALOG #	DESCRIPTION
602-90254	Disc Spreader – 4 mm
602-90255	Disc Spreader – 6 mm
602-90256	Disc Spreader – 7 mm
602-90257	Disc Spreader – 8 mm
602-90258	Disc Spreader – 9 mm
602-90259	Disc Spreader – 10 mm

CATALOG #	DESCRIPTION
602-90260	Disc Spreader – 11 mm
602-90261	Disc Spreader – 12 mm
602-90262	Disc Spreader – 13 mm
602-90310	Disc Spreader – 14 mm
602-90263	Disc Spreader – 15 mm
3303-90058	T-Handle with Strike Plate

DISC SPREADERS 4 mm

6 mm

7 mm

8 mm

9 mm

10 mm

11 mm

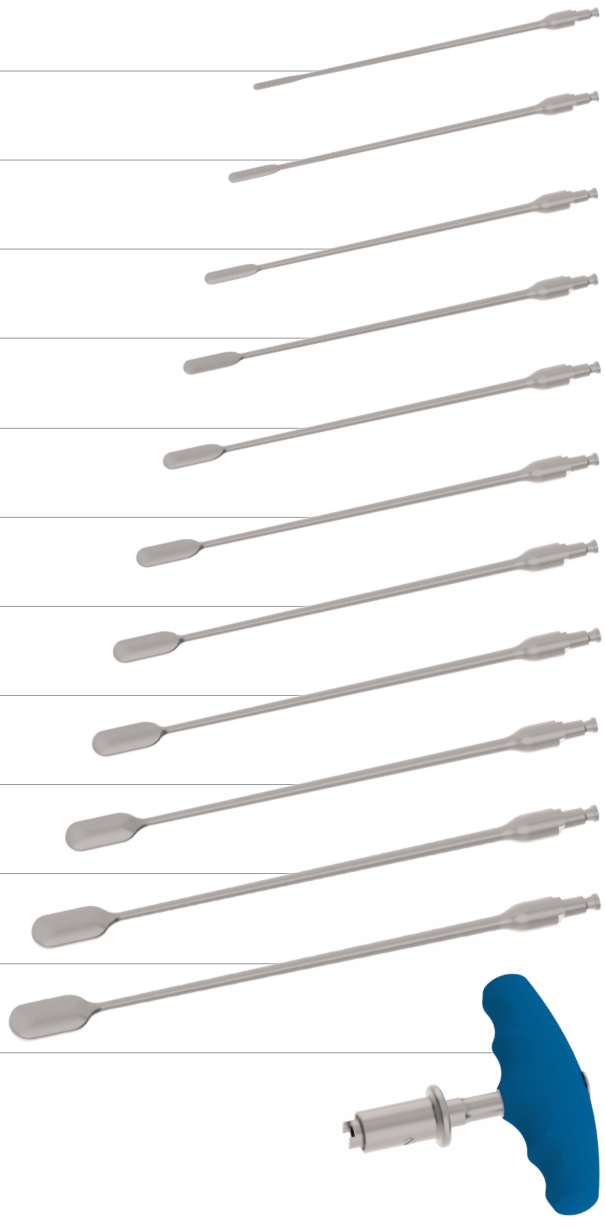
12 mm

13 mm

14 mm

15 mm

T-HANDLE WITH STRIKE PLATE



ENDPLATE PREPARATION

CATALOG #	DESCRIPTION
602-90233	Disc Scraper – 7 mm
602-90234	Disc Scraper – 8 mm
602-90235	Disc Scraper – 9 mm
602-90236	Disc Scraper – 10 mm
602-90237	Disc Scraper – 11 mm
602-90238	Disc Scraper – 12 mm

CATALOG #	DESCRIPTION
602-90239	Disc Scraper – 13 mm
602-90308	Disc Scraper – 14 mm
602-90240	Disc Scraper – 15 mm
3303-90053*	Bayoneted 7 mm Scraper
3303-90054*	Bayoneted 8 mm Double Sided Rasp
3303-90055*	Bayoneted 8 mm 45° Double Sided Rasp

**Also available in straight version*

DISC SCRAPERS 7 mm

8 mm

9 mm

10 mm

11 mm

12 mm

13 mm

14 mm

15 mm

BAYONETED 7 mm SCRAPER*

BAYONETED 8 mm DOUBLE SIDED RASP*

8 mm 45° DOUBLE SIDED RASP*

IMPLANT SIZING

CATALOG #	DESCRIPTION
3303-90080 – 3303-90088	Trial – 10 x 28, 7°
3303-90092 – 3303-90100	Trial – 10 x 32, 7°
3303-90128 – 3303-90136	Trial – 12 x 32, 7°
3303-90140 – 3303-90148	Trial – 12 x 36, 7°

TRIALS

10 x 28, 7°

10 x 32, 7°

12 x 32, 7°

12 x 36, 7°

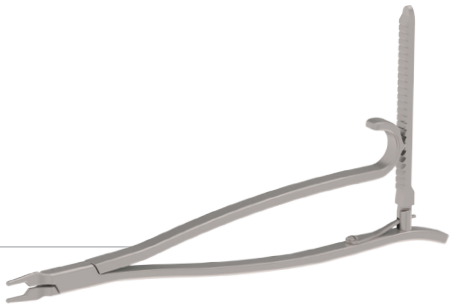
IMPLANT INSERTION

CATALOG #	DESCRIPTION
3303-90051	Removal Tool
3303-90157	Bone Graft Funnel
3303-90160	Bone Graft Funnel Pusher
3303-90052	Slap Hammer
3303-90032	Slap Hammer Adapter
3303-90019*	Bayoneted Straight Pusher

CATALOG #	DESCRIPTION
3303-90019*	Bayoneted Straight Pusher
3303-90020*	Bayoneted Curved Pusher
3303-90021*	Bayoneted Angled Pusher

**Also available in straight version*

REMOVAL TOOL



BONE GRAFT FUNNEL

BONE GRAFT FUNNEL PUSHER

SLAP HAMMER

SLAP HAMMER ADAPTER

BAYONETED STRAIGHT PUSHER*

BAYONETED CURVED PUSHER*

BAYONETED ANGLED PUSHER*

IMPLANT INSERTION (CONT.)

CATALOG #	DESCRIPTION
3303-90151	TLIF 2 Straight Inserter
3303-90152	Straight Inserter Inner Shaft
3303-90603	TLIF 2 Adjustable Inserter
3303-90384	TLIF 2 Adjustable Inserter Inner Shaft

TLIF 2 INSERTER

STRAIGHT INSERTER INNER SHAFT

TLIF 2 ADJUSTABLE INSERTER

TLIF 2 ADJUSTABLE INSERTER INNER SHAFT

DISC MATERIAL REMOVAL

CATALOG #	DESCRIPTION
3303-90040	4 mm Curved Pituitary Rongeur
3303-90041	6 mm Curved Pituitary Rongeur
3303-90043	4 mm Straight Pituitary Rongeur
3303-90044	6 mm Straight Pituitary Rongeur
3303-90023*	Bayoneted 7 mm Left Teardrop Curette
3303-90024*	Bayoneted 7 mm Right Teardrop Curette
3303-90025*	Bayoneted #2 Cup Curette

CATALOG #	DESCRIPTION
3303-90026*	Bayoneted #2 Short Forward Cup Curette
3303-90027*	Bayoneted #2 Medium Forward Cup Curette
3303-90029*	Bayoneted #2 90° Reverse Curette
3303-90056*	Bayoneted #2 Serrated Cup Curette
3303-90030*	Bayoneted 7 mm Ring Curette

**Also available in straight version*

4 & 6 mm CURVED PITUITARY RONGEUR

4 & 6 mm STRAIGHT PITUITARY RONGEUR

BAYONETED 7 mm LEFT & RIGHT TEARDROP CURETTE*

BAYONETED #2 CUP CURETTE*

BAYONETED #2 SHORT FORWARD CUP CURETTE*

BAYONETED #2 MEDIUM FORWARD CUP CURETTE*

BAYONETED #2 90° REVERSE CURETTE*

BAYONETED #2 SERRATED CUP CURETTE*

BAYONETED 7 mm RING CURETTE*

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the ALEUTIAN® Interbody System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS
When used as a cervical intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

When used as vertebral body replacement devices the ALEUTIAN implants are indicated for use in the thoracolumbar spine (T1 to L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body, resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The ALEUTIAN implants are designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

For all the above indications the ALEUTIAN implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

MATERIALS
The implants of the ALEUTIAN Interbody System are manufactured from PEEK-OPTIMA® LT1 Polymer (polyetheretherketone) and Tantalum per ISO and ASTM standards.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS
K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles.

STERILIZATION
Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles are recommended, however sterilization should be in accordance with the sterilizer manufacturer's instructions and the institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes
Outside USA	Prevacuum	273°F (134°C)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions).

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE
(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

The ALEUTIAN Interbody System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

CONTRAINDICATIONS
1. The ALEUTIAN Interbody System is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. This device is not recommended for patients who have received prior fusion at the level(s) to be treated. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS
1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/ or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS
1. The ALEUTIAN Interbody System is intended for use for the indications listed. Safety and effectiveness of the implants have not been established for other applications. The implants are for single use only and are not designed to be combined with devices from other manufacturers.
2. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of this system and the asso-

ciated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of breakage or migration of the device.

3. Patient selection and compliance is extremely important. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a PEEK Polymer implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
4. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
5. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
6. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
7. The ALEUTIAN Interbody implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
8. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative planning should identify degree of correction possible without neurological damage using techniques similar to other Partial Vertebral Body replacement procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.

OPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. The placement of the vertebral body replacement implants should be checked radiographically prior to final tightening of the construct.
3. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone, even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted PEEK implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY


Caution: Consult Accompanying Documentation


Consult Instructions For Use


Do Not Reuse

PI003-0A11-01 Rev 0
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ALEUTIAN®

TRANSFORAMINAL-LUMBAR (TLIF) 2 INTERBODY SYSTEM

The ALEUTIAN TLIF 2 Interbody System has a full range of bulleted PEEK interbodies for posterior-lumbar applications. The system offers innovative instrumentation facilitating more efficient intraoperative use of the system, including the Adjustable Inserter, which allows for variable angulation of the implant from 0° to 60° in-situ.

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