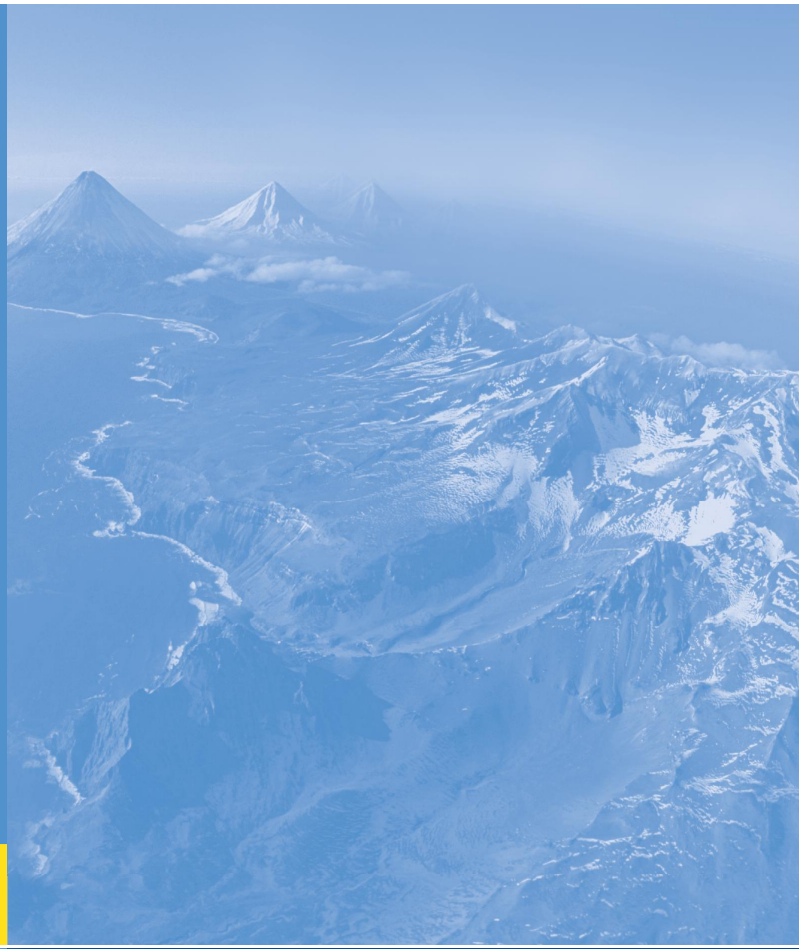


ALEUTIAN®
AN LORDOTIC - OBLIQUE

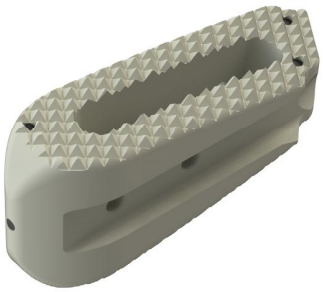
Surgical Technique

aleutian

Anatomically-Narrow Lordotic-Oblique Interbody System

As Described By:

John P. Kostuik, MD
Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS)
& North American Spine Society (NASS)



K2M
COMPLEX SPINE INNOVATIONS™

Surgical Technique

TABLE OF CONTENTS

Dear Colleagues,

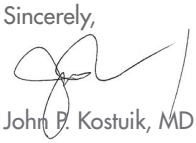
Welcome to K2M and the ALEUTIAN® Anatomically-Narrow (AN) Lordotic-Oblique Interbody System. With this new addition to the ALEUTIAN PEEK interbody product family, K2M continues to strive to attain the highest level of excellence in the medical device industry.

The ALEUTIAN AN Lordotic-Oblique Interbody System is named after a chain of volcanic islands in the Pacific Ocean formed by the fusion of rocks and molten lava. The ALEUTIAN AN Lordotic-Oblique implant is an interbody fusion device indicated for use in the thoracolumbar spine. The system incorporates a full range of unique and anatomically designed PEEK interbodies for multiple spinal applications.

The implant and instrument technology is state-of-the-art and developed to facilitate intra-operative efficiency in the restoration of proper disc height and sagittal alignment.

The ALEUTIAN AN Lordotic-Oblique Interbody System, in my opinion, is a step forward in the design of implants for the treatment of patients. The following technique clearly outlines the procedural details and options, and will help explain the many unique aspects of the system for use in treating patients for Degenerative Disc Disease (DDD) and other indications.

Sincerely,



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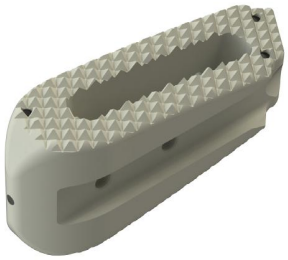
FEATURES & BENEFITS

ALEUTIAN® AN Lordotic-Oblique Interbody System



IMPLANTS

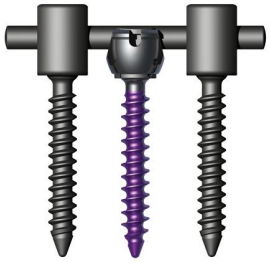
- 8.5 x 28 mm & 8.5 x 32 mm Footprints Available in Posterior Heights Ranging from 4 – 12 mm & Lordosis Angles of 6, 12 & 18°
- Posterior Bone Graft Funnel Provision
- Implant Designed to Match Sagittal Lordosis in an Oblique Orientation
- Convex Design Matches Anatomic Structure of Endplates
- Manufactured of Biocompatible PEEK Polymer
- 35° Angled Posterior Wall to Match Vertebral Anatomy

INSTRUMENTS

- Unique Inserter Built to Support an Insert and Rotate Technique

PEDICLE SCREW SYSTEMS

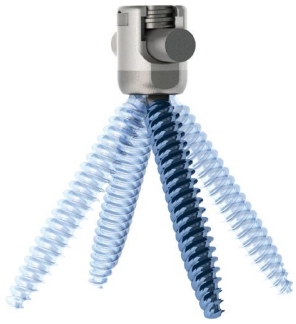
MESA® Spinal Systems



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

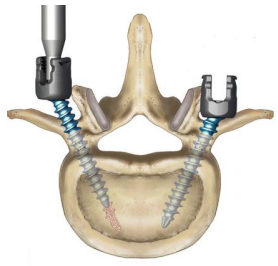
EVEREST® Spinal Systems



IMPLANTS

- Ability to Accept 5.5 mm & 6.0 mm Diameter Rods
- Easy-to-Start Set Screw Facilitating Set Screw Introduction
- Dual Lead Optimized Thread Pattern Allows for Faster Insertion & Increased Pull-Out Strength*
- Mixed Material Housing Designed to Minimize Splay & Improve Mechanical Performance When Compared to an Experimental Prototype*
- Polyaxial Range of Motion Provides Intra-Operative Flexibility

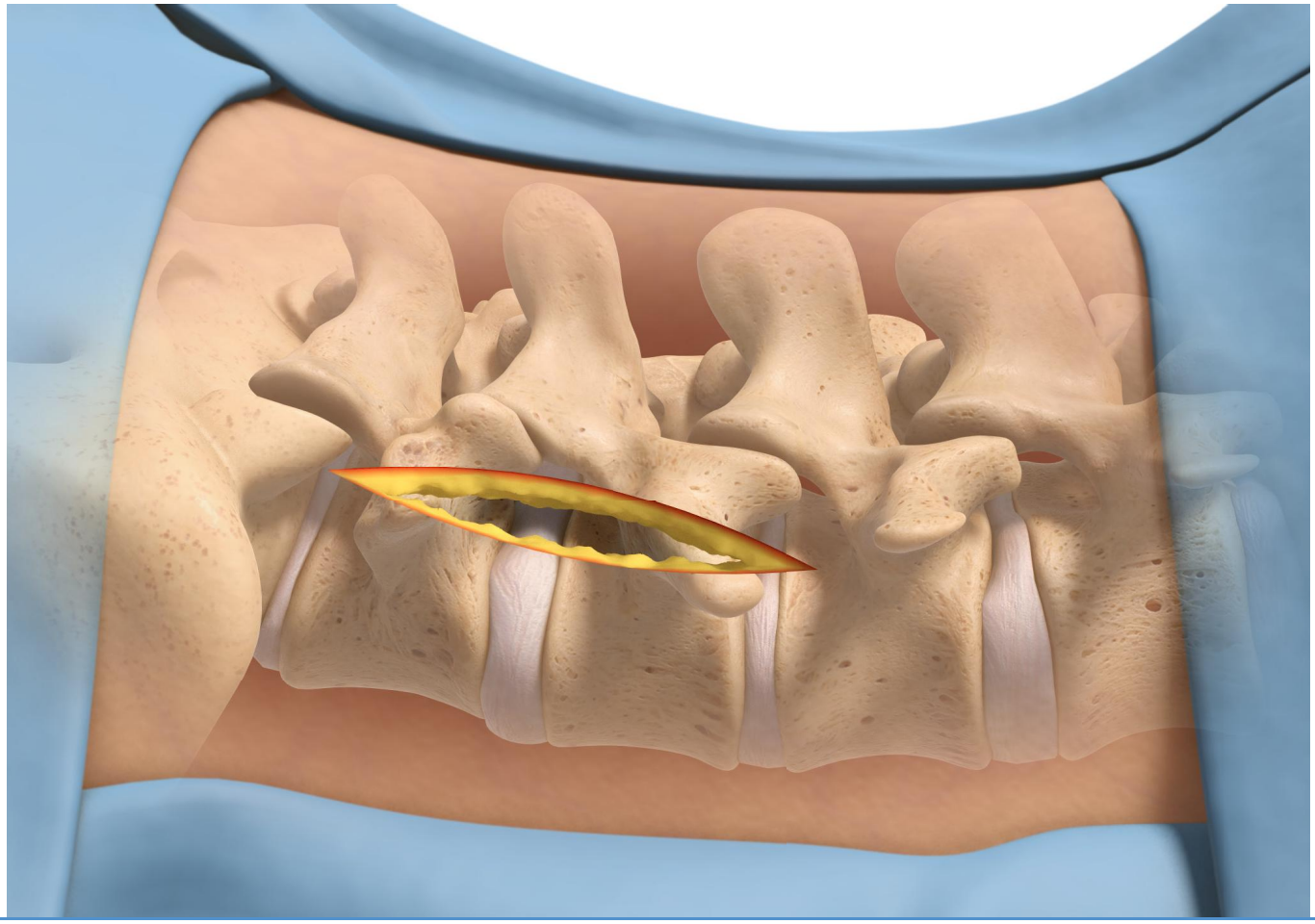
DENALI® Spinal Systems



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

**NOTE: Please reference the Technical Data Insert in the EVEREST Surgical Technique for supporting data.*



PATIENT POSITIONING: POSTERIOR SURGICAL EXPOSURE

THE PATIENT SHOULD BE POSITIONED as appropriate for a posterior approach, taking care to preserve or improve sagittal alignment 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.

POLYAXIAL SCREW INSERTER

T-HANDLE

PEDICLE SCREW PLACEMENT

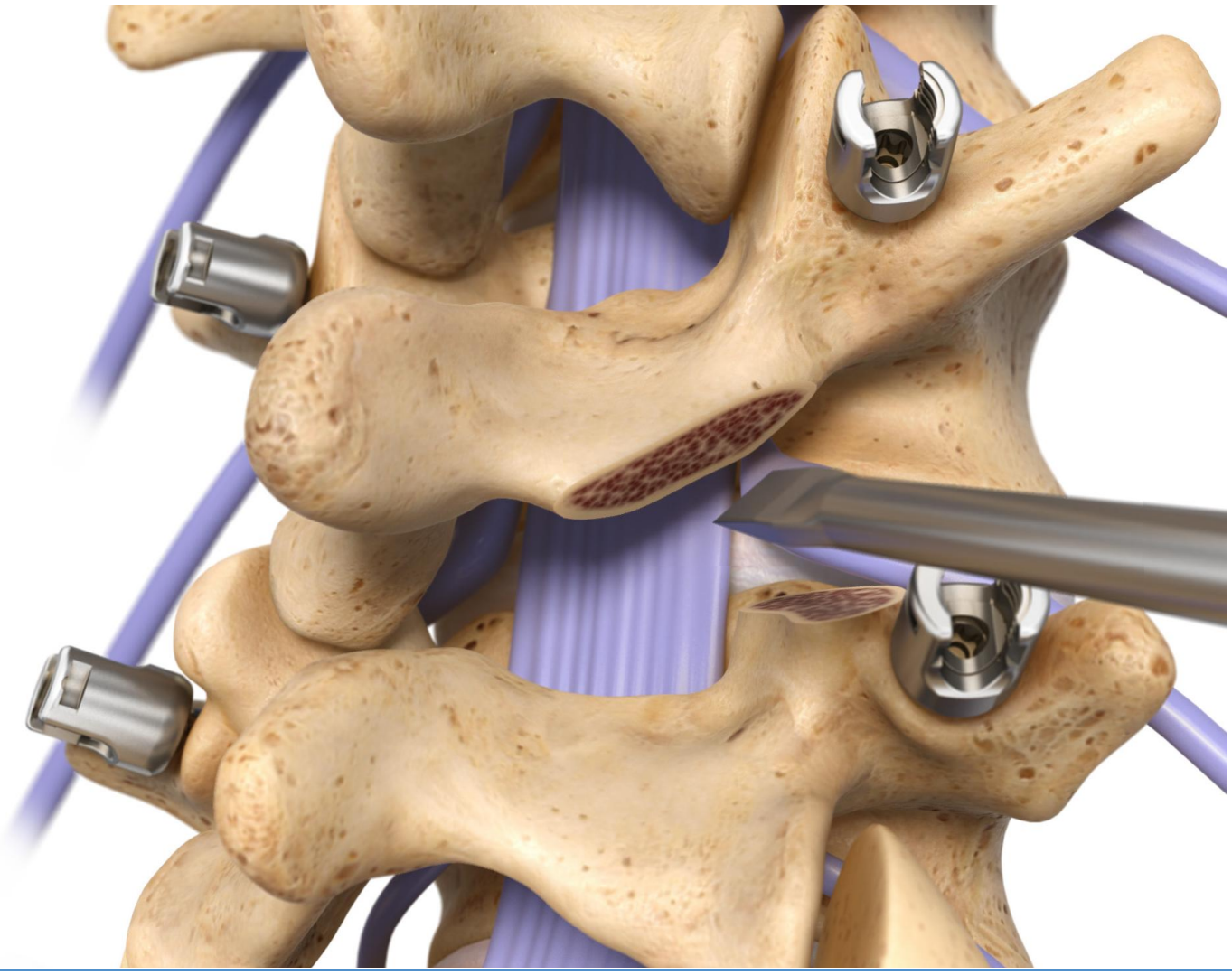
EVEREST® PEDICLE SCREWS are placed in the pedicles adjacent to the operative level. Please refer to the EVEREST Degenerative Surgical Technique (K2-29-7001-01) for proper screw placement techniques.

3

KERRISON RONGEUR

CURETTE

OSTEOTOME



LAMINOTOMY/ FACETECTOMY

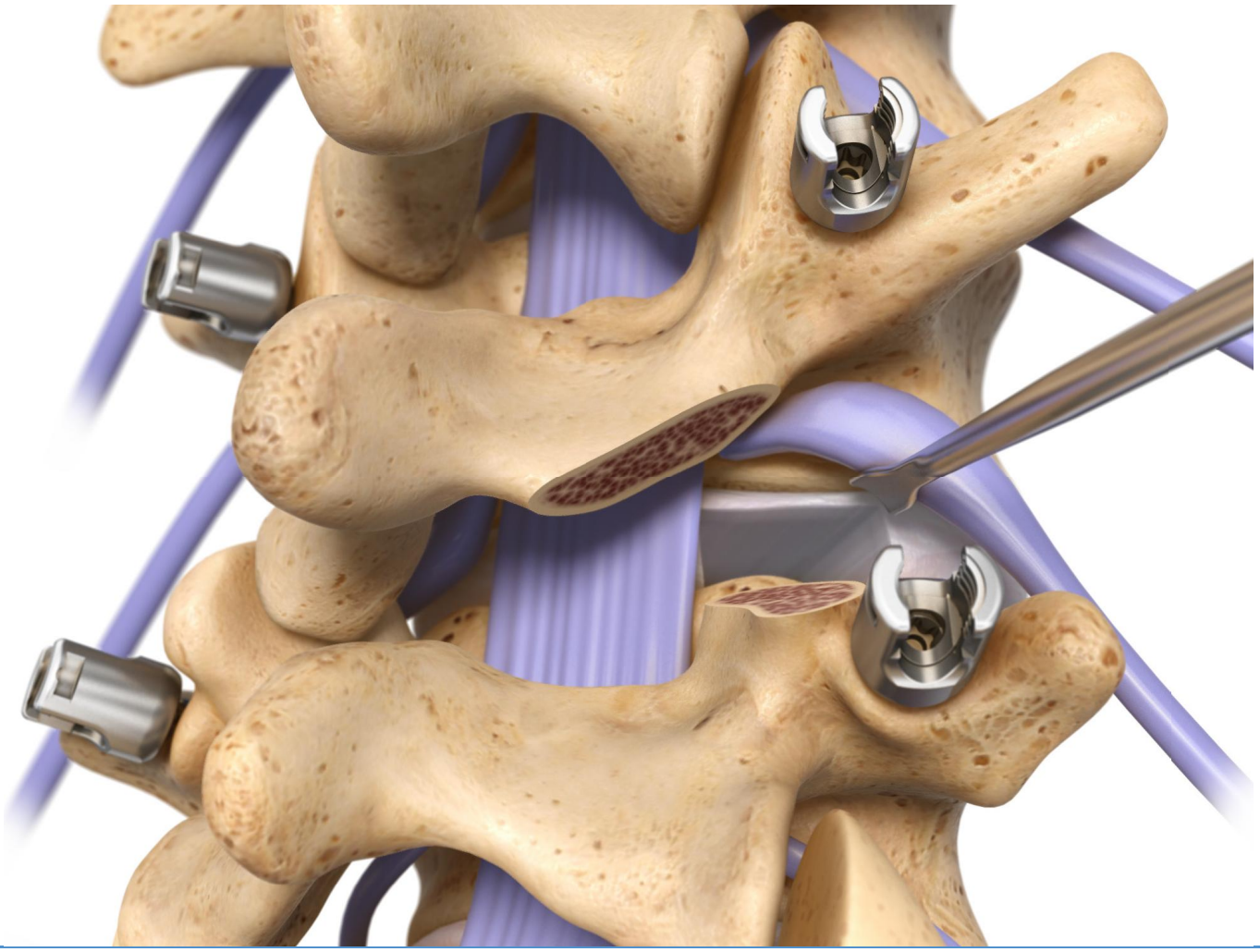
USING A COMBINATION of surgical instruments (Curettes, Osteotomes, Kerrison Rongeurs, etc.) appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy is performed, along with the removal of the ligamentum flavum, to provide access to the disc space.

NERVE ROOT RETRACTOR

CURETTE

PITUITARY RONGEUR

KERRISON RONGEUR



NEURAL ELEMENT RETRACTION/DISC REMOVAL

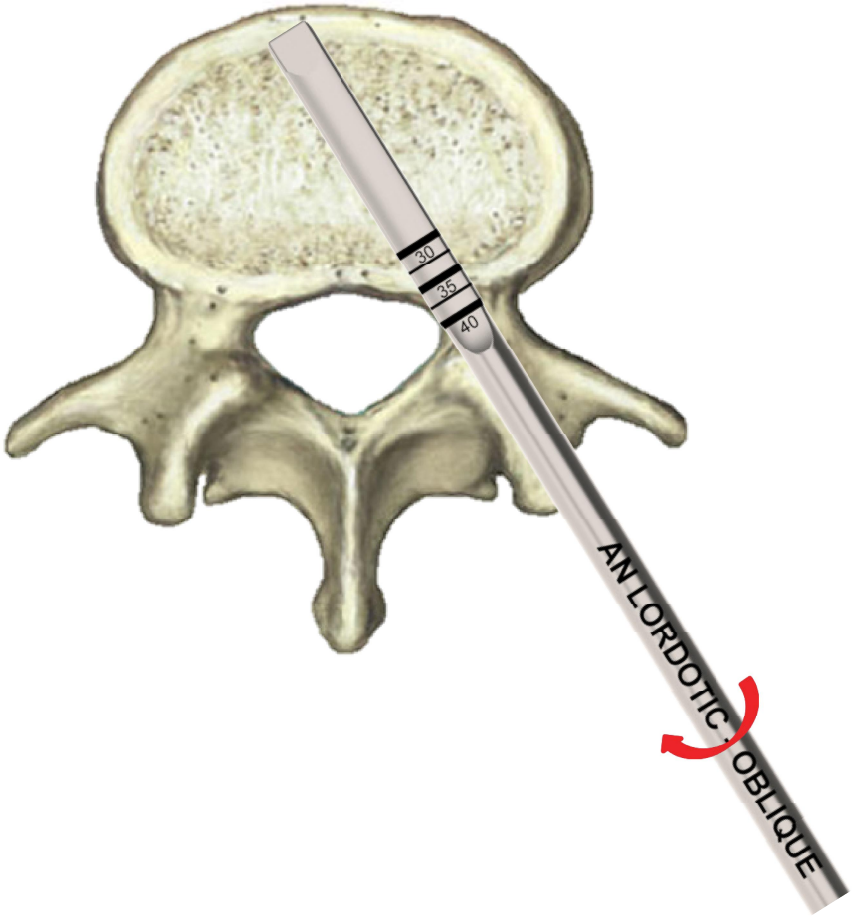
A NERVE ROOT RETRACTOR is used to mobilize the nerve root and expose the annulus of the disc space. A Scalpel can then be used to make an incision in the annulus, through which a complete discectomy can be performed. Disc Scrapers, a variety of Curettes, Kerrisons, and Pitutitary Rongeurs are included in the set to aid in the removal of the disc material and the cartilaginous endplates.

5

T-HANDLE

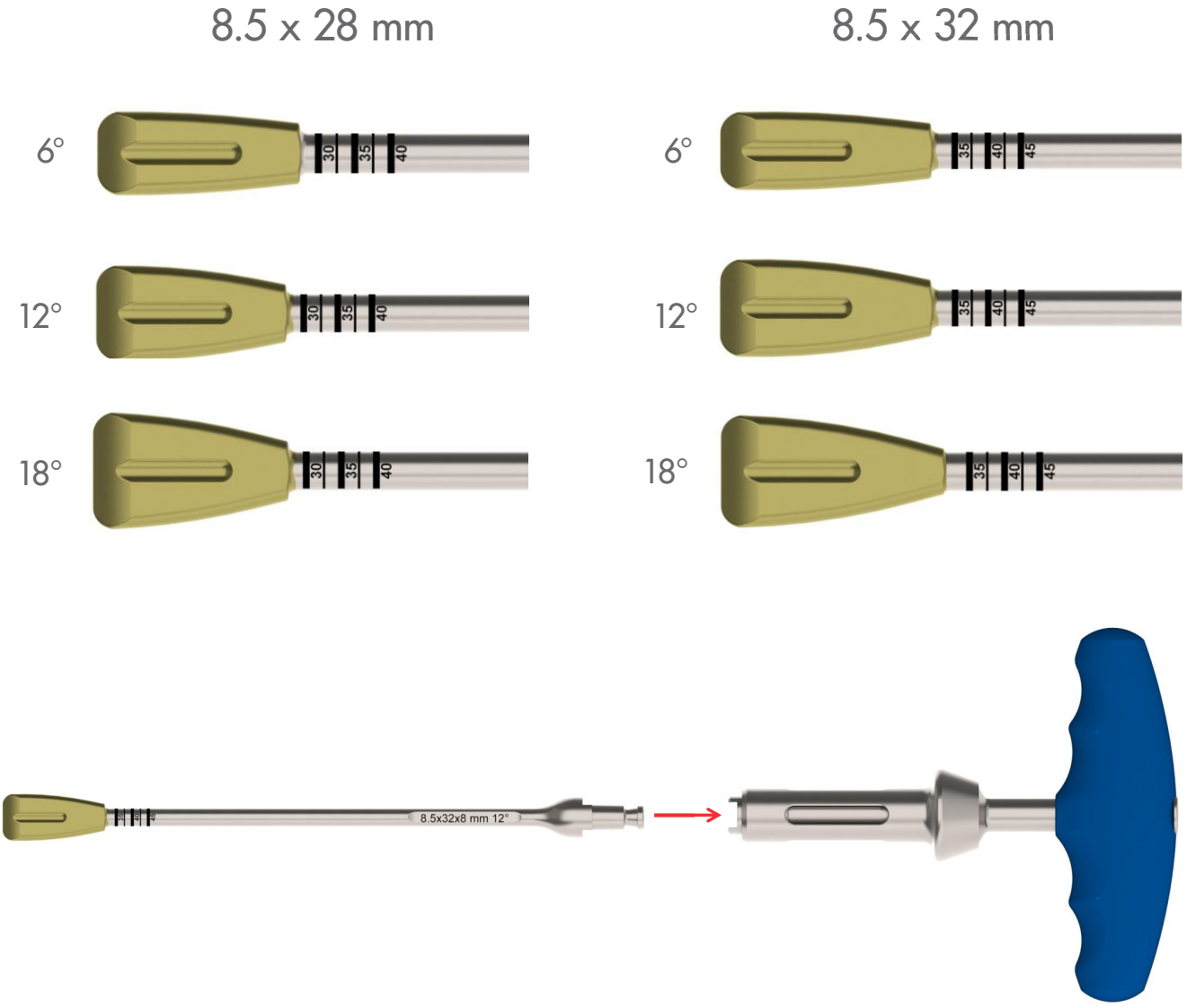
4 MM PARALLEL SPREADER

6 MM PARALLEL SPREADER



IMPLANT SIZING

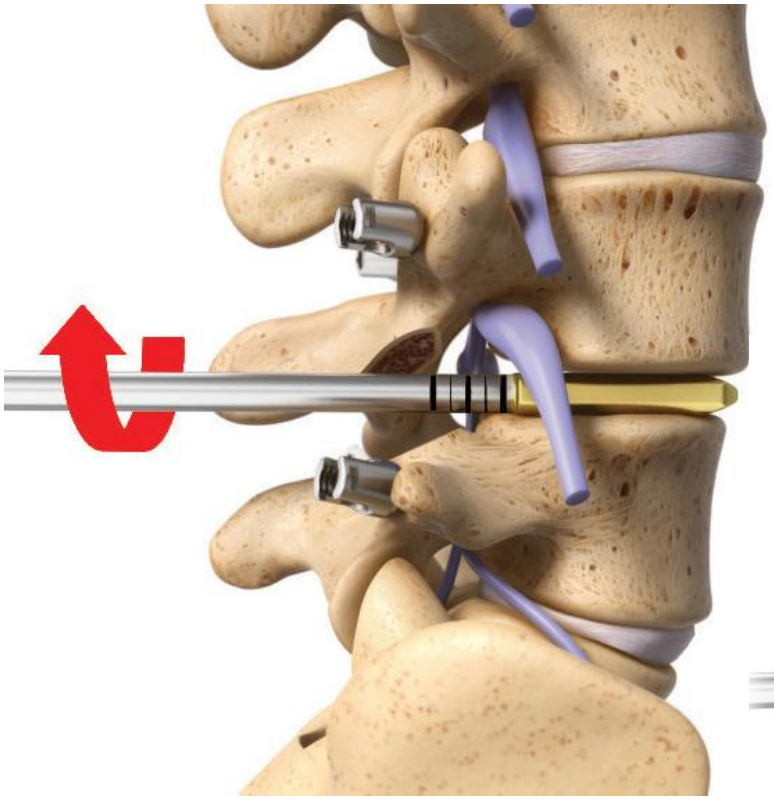
INITIAL DISC SPACE DISTRACTION should be performed using the 4 and/or 6 mm Parallel Spreaders. The Parallel Spreader should be placed into the disc space in an oblique orientation so it spans the endplate to the far anterior cortical rim. Intraoperative x-ray can be used to confirm distractor placement along the cortical rim. The depth markings on the Spreader should be noted as marking the posterior margin of the disc space. This measurement will be used as a reference to ensure all subsequent Spreaders are placed such that the distal tip reaches the anterior annulus and, subsequently, the anterior apophyseal ring.

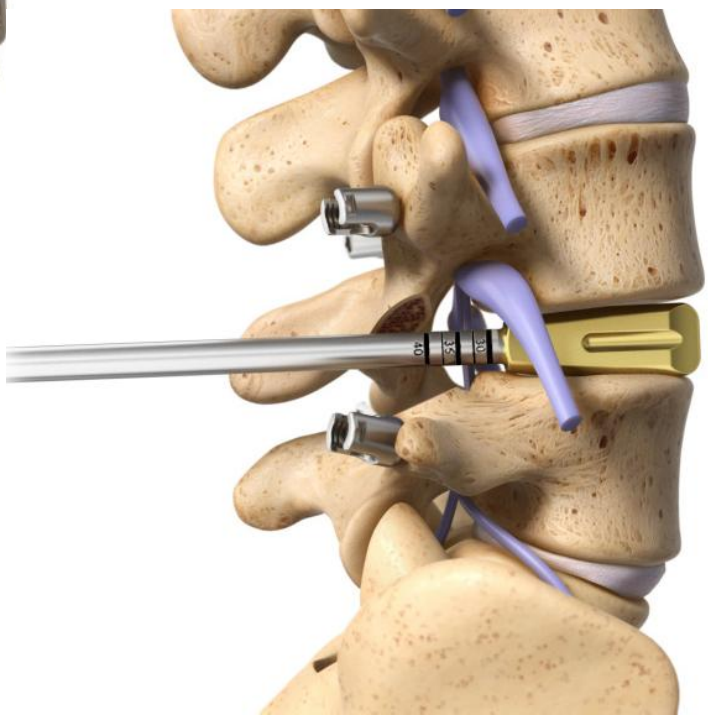


Proper implant size is determined by using the Lordotic-Oblique Rotating Spreaders, which are included in the instrument set. The profile of these Spreaders match the profile of each respective implant, providing an in-situ representation of final anatomic restoration. The Spreaders are intended for use with the extended T-Handle included in the instrument set.

NOTE: All Spreaders should be positioned so the tip of the Spreader portion is in line with the anterior cortical rim of the most anterior vertebral endplate. This positioning ensures the distraction force is applied to the strongest bone of the vertebral body.

NOTE: Labeled Spreader height matches labeled posterior implant height.





IMPLANT SIZING (CONT.)

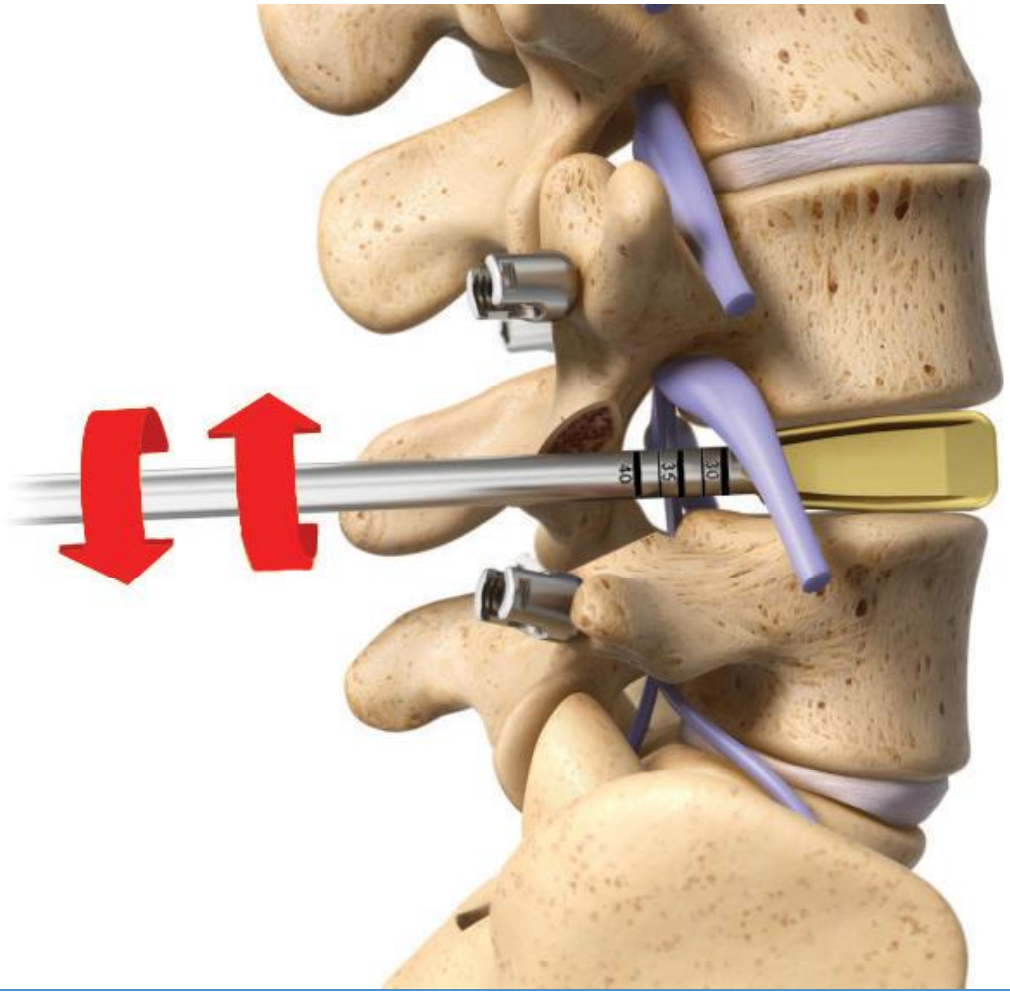
Following initial distraction with the Parallel Spreaders, the Lordotic-Oblique Spreaders can be employed in a sequential manner to determine the optimum implant size based on the individual patient anatomy. Care should be taken to ensure each Spreader be placed to the proper and complete depth in the disc space so the distraction forces are being distributed into the stronger apophyseal bone. If the Spreader is too shallow, it may be possible for the distraction force to be applied to the central portion of the endplate, leading to a potential endplate failure and diminished sagittal restoration. Intraoperative x-ray and/or the length denotations along the distractor shaft can be used to confirm the position of each distractor along the anterior apophyseal ring.

LORDOTIC-OBLIQUE DISC

RASP

CURETTE

T-HANDLE

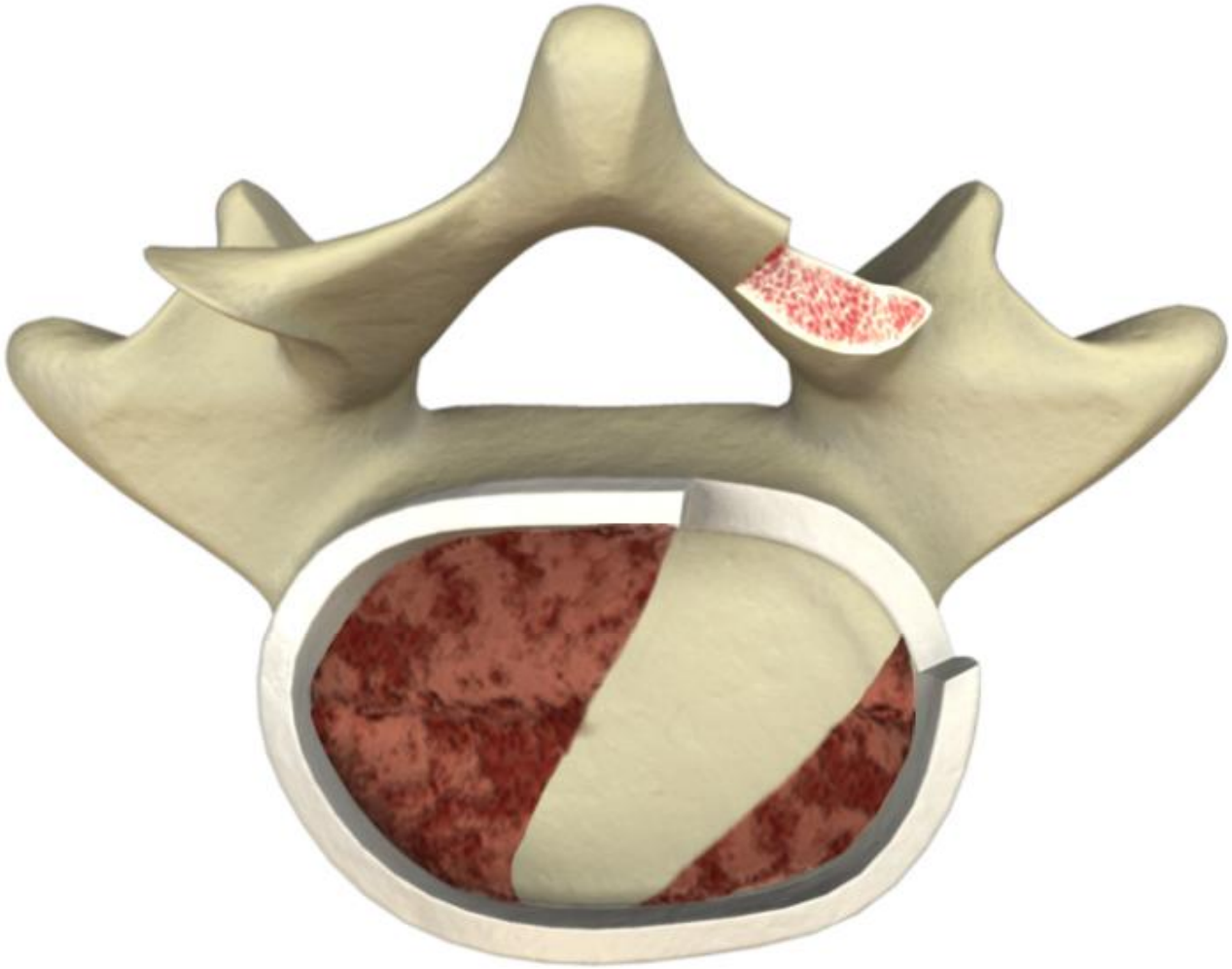


ENDPLATE PREPARATION

ADEQUATE ENDPLATE PREPARATION is essential for a successful fusion. The Posterior-Lumbar Disc Preparation Instrument Sets include Convex Endplate Scrapers, along with a variety of Rasps and Curettes to help ensure proper exposure of the endplates. Additionally, the AN Lordotic-Oblique set includes 6° Lordotic-Oblique Endplate Scrapers should a more aggressive endplate contact be desired. Care should be taken during this step to prevent compromising the integrity of the cortical endplates.

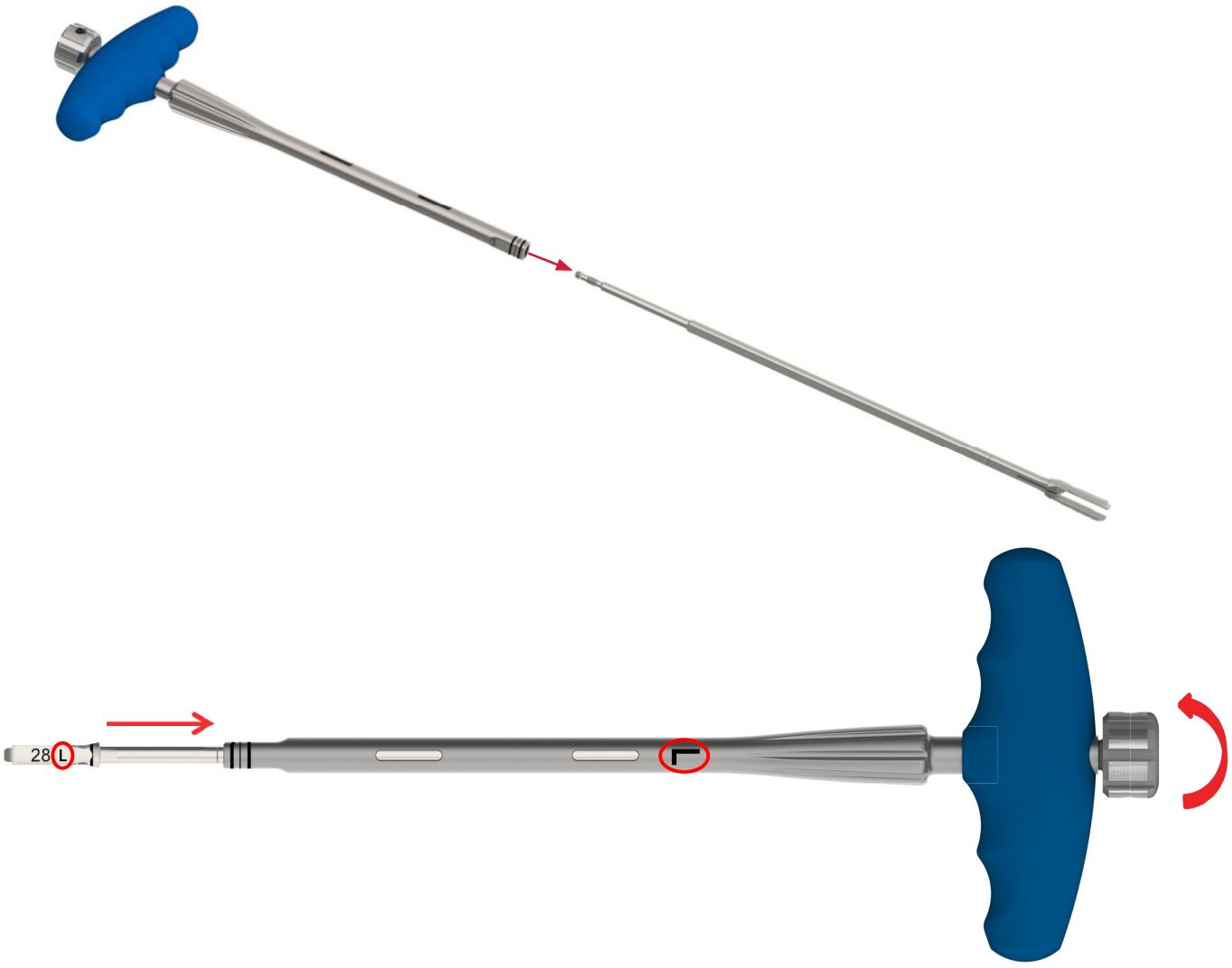
BONE GRAFT FUNNEL

BONE GRAFT PUSHER



PLACEMENT OF BONE GRAFT

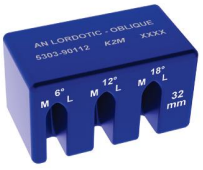
WHEN USED AS A LUMBAR intervertebral body fusion device, the ALEUTIAN implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. A Bone Graft Funnel and Pusher are included in the set to aid with bone graft placement.



INTERBODY INSERTION

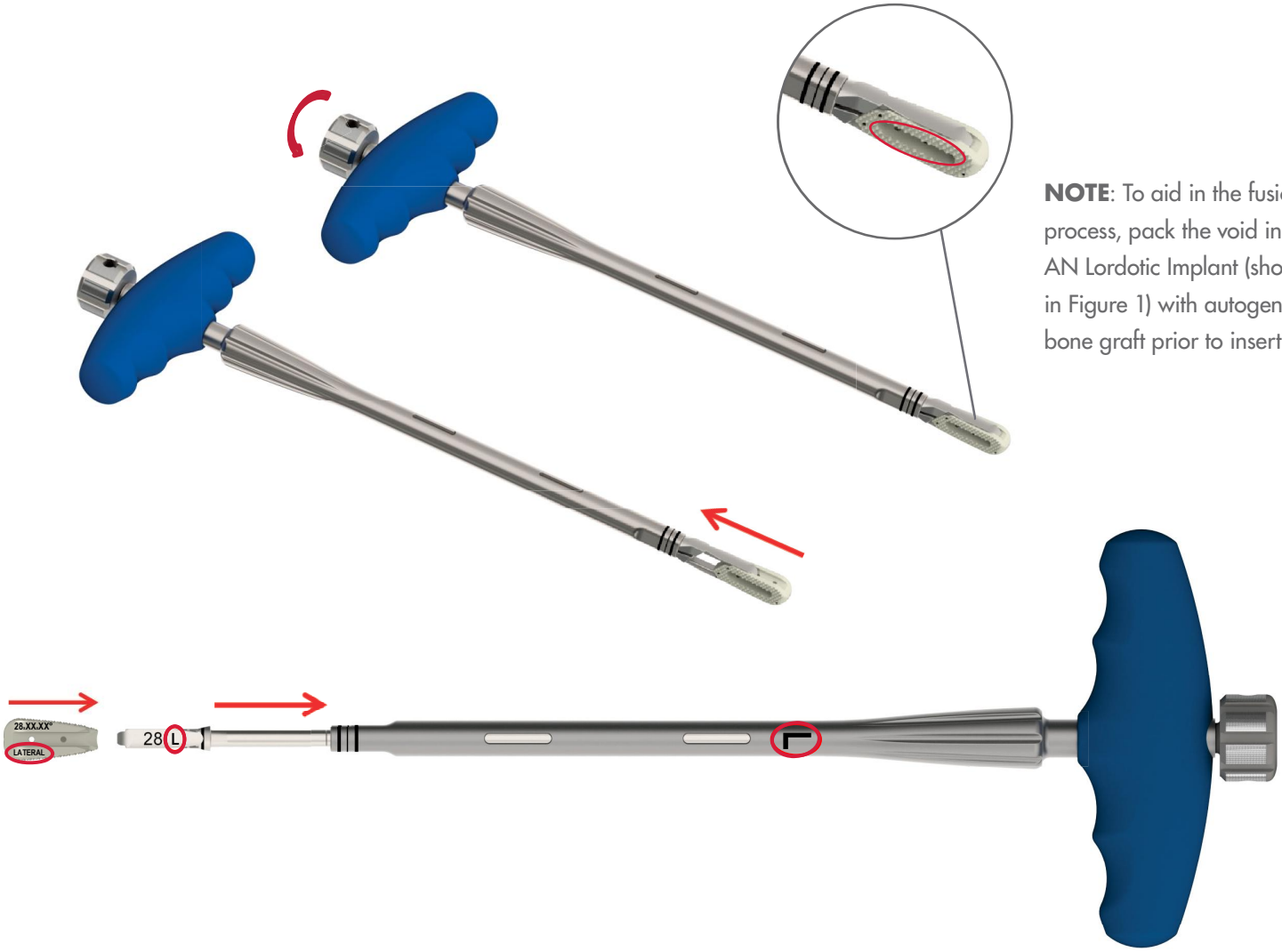
THE ALEUTIAN AN LORDOTIC-OBLIQUE Inserter is designed to be disassembled for cleaning and utilizes modular components for use with both the 28 and 32 mm length implants. To assemble the instrument, identify the Inner Shaft corresponding to the chosen implant length. Insert the Inner Shaft into the Outer Shaft so the threads of the Inner Shaft engage with the internal threads of the knob on the proximal end of the Outer Shaft. Turn the knob in a clockwise direction approximately three turns to retain the Inner Shaft within the Outer Shaft.

NOTE: There are anatomic orientation references on the two Inserter components. Ensure these are properly aligned during assembly as designated in the above image.



BONE GRAFT PACKING MOLD

FIGURE 1.



NOTE: To aid in the fusion process, pack the void in the AN Lordotic Implant (shown in Figure 1) with autogenous bone graft prior to insertion.

INTERBODY INSERTION (CONT.)

To attach the implant to the Inserter, engage the grooves on the side of the implant with the tines of the Inserter. Ensure the angle cut on the proximal end of the implant mates properly with the angle cut in the tip of the Inserter. Slide the implant onto the Inserter tines until the back of the implant is flush with the Inserter. Ensure the orientation references on the implant are properly aligned with those on the Inserter as shown above. To secure the implant, tighten the knob on the proximal end of the Outer Shaft, forcing it down over the Inner Shaft, subsequently squeezing the implant.

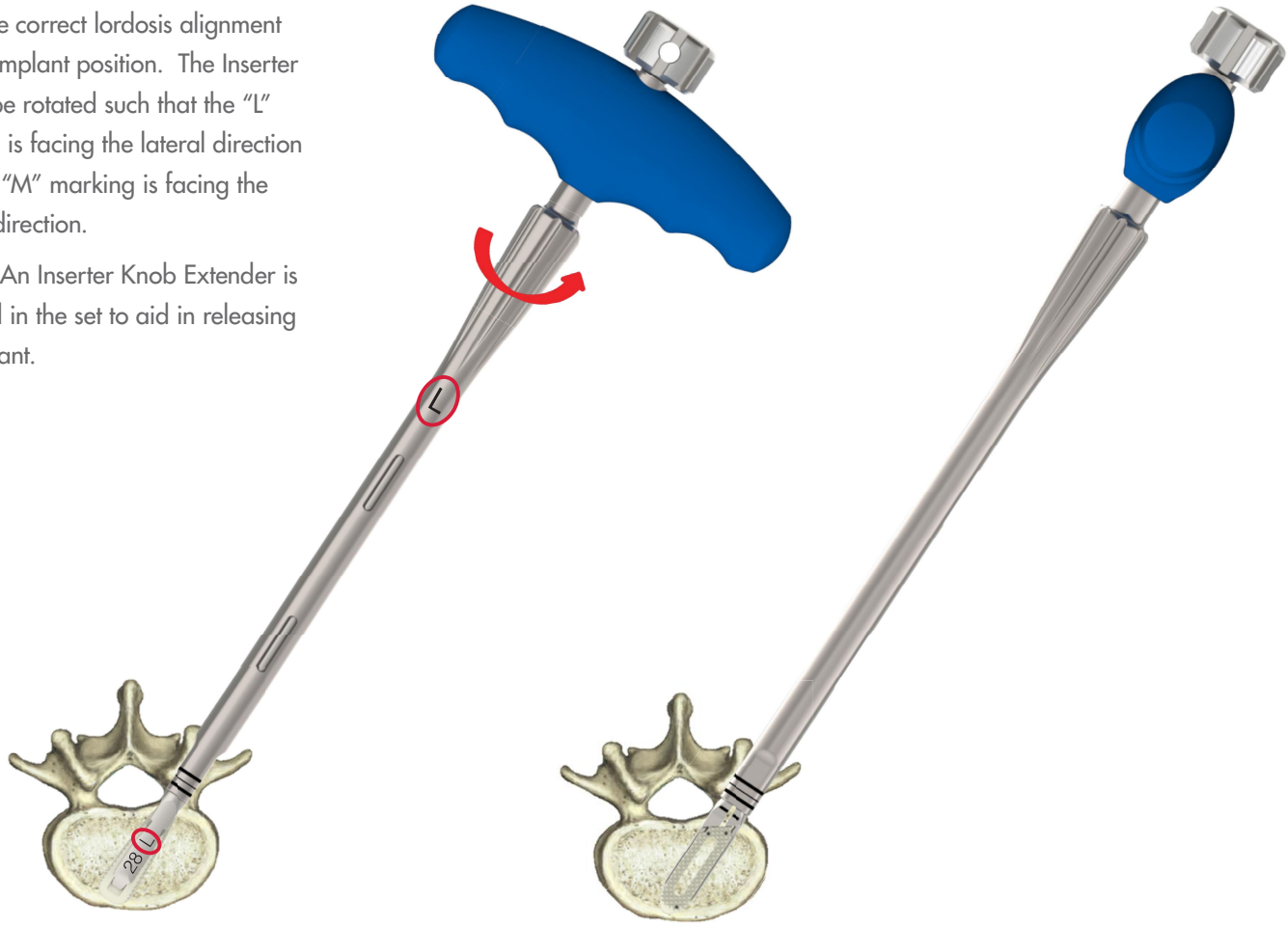
NOTE: Only final tighten the instrument assembly with the implant attached.

LORDOTIC-OBLIQUE ANGLED PUSHER

LORDOTIC-OBLIQUE HORSESHOE PUSHER

NOTE: Observe the anatomic orientation references during insertion to determine proper rotation direction to ensure correct lordosis alignment in final implant position. The Inserter should be rotated such that the "L" marking is facing the lateral direction and the "M" marking is facing the medial direction.

NOTE: An Inserter Knob Extender is included in the set to aid in releasing the implant.



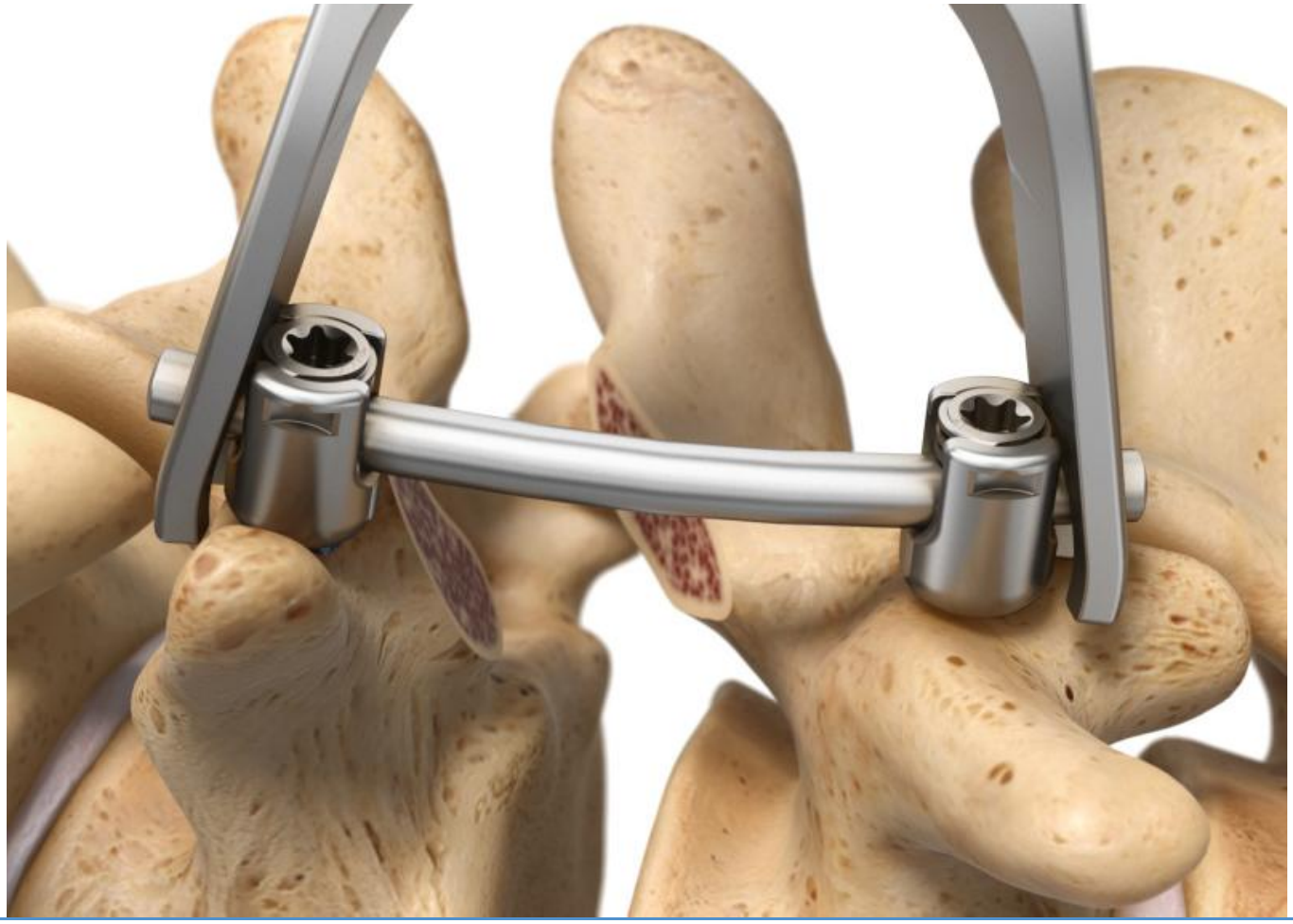
The ALEUTIAN AN Lordotic-Oblique Interbody System is designed to facilitate in-situ rotation of the implants. By inserting the implant on its side, there is no need for overdistraction of the posterior vertebral elements.
Intra-operative imaging and the demarcations along the Inserter Shaft should be used to ensure the implant is fully inserted into the disc space so the tip reaches the anterior annulus and the apophyseal ring.
The implant should be positioned such that it crosses the midline of the disc space in an oblique orientation. Once proper position is confirmed with the implant in its "flat" orientation, the Inserter handle should be carefully rotated 90° to relign the implant into its final vertical position. Intra-operative imaging should again be used to check the implant placement prior to detaching the Inserter. The implant can be released by turning the knob on the proximal end of the Outer Shaft counter-clockwise. Implant Pushers are included in the instrument set to aid in adjusting the implant position following detachment of the Inserter. Should implant removal be necessary, there is a Removal Tool included in the instrument set.

STEP

9

ROD PUSHER

COMPRESSOR



ROD INSERTION & COMPRESSION

FOLLOWING INTERBODY INSERTION, rods should be placed between the pedicle screws as described in the EVEREST surgical technique. Once the rods are placed and any desired compression applied to the construct, a standard multi-layer wound closure is performed to complete the procedure.

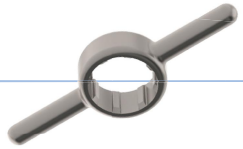
ALEUTIAN® AN LORDOTIC-OBLIQUE PRODUCT CATALOG

Product Catalog

INSERTER INNER SHAFT - 28 mm

INSERTER INNER SHAFT- 32 mm

INSERTER HANDLE/OUTER SHAFT



INSERTER KNOB EXTENDER

LORDOTIC-OBLIQUE SPREADER

PARALLEL SPREADER - 4/6 MM

EXTENDED T-HANDLE

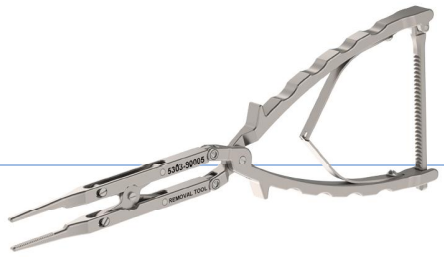
DESCRIPTION	CATALOG NUMBER
Inserter Inner Shaft - 28 mm	5303-90001
Inserter Inner Shaft - 32 mm	5303-90002
Inserter Handle/Outer Shaft	5303-90004
Inserter Knob Extender	5303-90109
Lordotic-Oblique Spreader	5303-9008 - 5303-90080
Parallel Spreader - 4/6 mm	5303-90110/90111
Extended T-Handle	5303-90116

LORDOTIC DISC SCRAPER

ANGLED PUSHER

HORSESHOE PUSHER

BONE GRAFT PACKING MOLD



REMOVAL TOOL

DESCRIPTION	CATALOG NUMBER
Lordotic Disc Scraper	5363-90092 - 5363-90102
Angled Pusher	5303-90007
Horseshoe Pusher	5303-90000
Bone Graft Packing Mold	5303-90112
Removal Tool	5303-90005

Product Insert

⚠ 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 Sytems.

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 associated 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.

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Notes

ALEUTIAN® Anatomically-Narrow Lordotic-Oblique Interbody System

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 lumbarspine, 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 Sytems.

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CE 0086

K2-53-7000-01 Rev. 0
Actual device color may vary.
Consult product catalog for details.