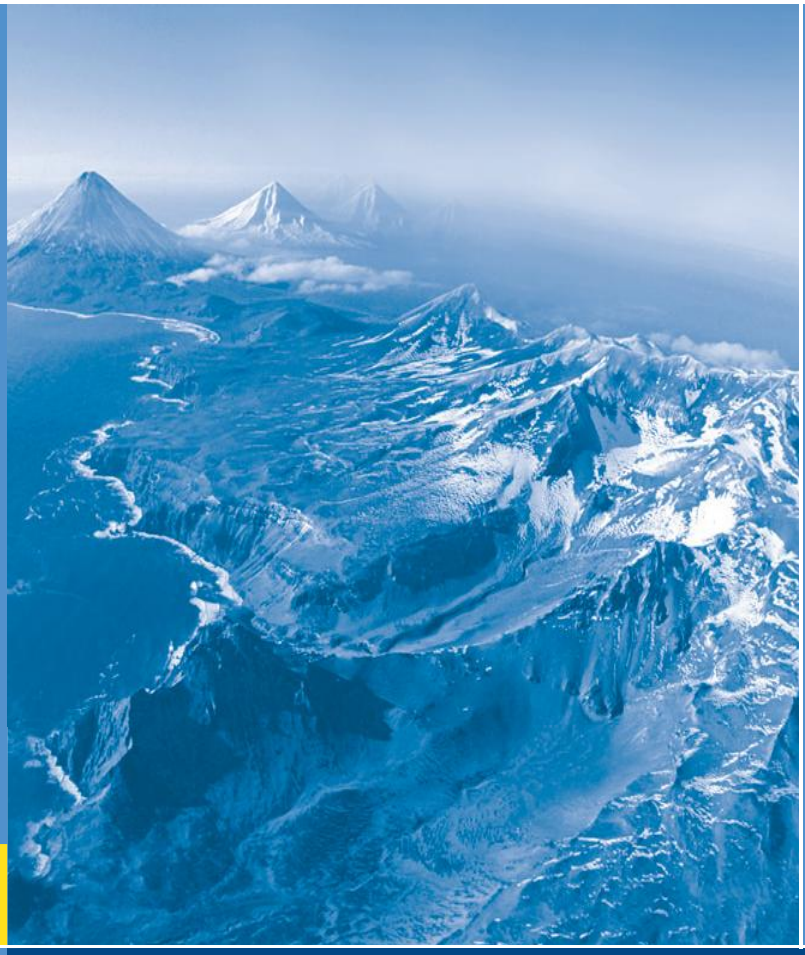


ALEUTIAN®
AN OBLIQUE

aleutian

AN Oblique

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) 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 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 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 and is available with a complete offering of preparation and insertion instruments.

The implant and instrument technology is state-of-the-art, developed to facilitate intra-operative efficiency and ensure the surgeon has multiple options in one, all-inclusive system.

The ALEUTIAN AN 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,

John P. Kostuik, MD
Co-Founder, Past Chairman, & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery

FEATURES & BENEFITS

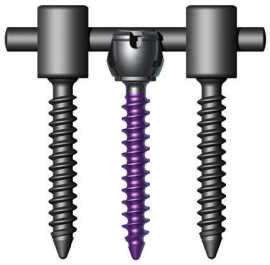
ALEUTIAN® Anatomically-Narrow (AN) Oblique

IMPLANTS

- 8.5 x 28 mm, 8.5 x 32 mm, 10 x 28 mm, 10 x 32 mm, & 12 x 32 mm Footprints Available in Heights Ranging From 7 – 15 mm
- Bulleted Nose for Ease of Insertion
- Large Bone Graft Windows
- Convex Design for Anatomic Fit
- Manufactured of Biocompatible PEEK Polymer

PEDICLE SCREW SYSTEMS

MESA® Spinal & Retractor Systems



IMPLANTS

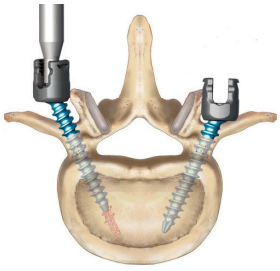
- Zero-Torque Technology®
- No Profile Above the Rod
- One-Step Final Locking
- 60° Range of Motion
- Controlled Compression & Distraction
- Implant & Instrument Design Facilitates Full Rod Reduction Capability

EVEREST® Degenerative Spinal System

IMPLANTS

- 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 & Demonstrates Increased Pull-Out Strength*
- Mixed Material Housing Minimizes Splay & Improves Mechanical Performance When Compared to an Experimental Prototype*
- Polyaxial Range of Motion Provides Intra-Operative Flexibility

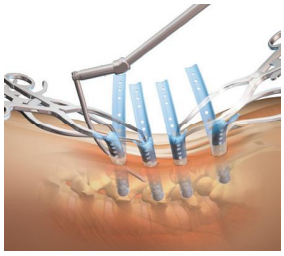
DENALI® Spinal Systems



IMPLANTS

- Off-Axis Screw Height Adjustment
- Low-Volume & Uniquely-Shaped Screw Housing
- Distinct Color-Coded Screws Clearly Indicating Length
- Variety of Easy-to-Use Reduction Instruments
- Torsional Rod Reducers Providing Translation & Reduction

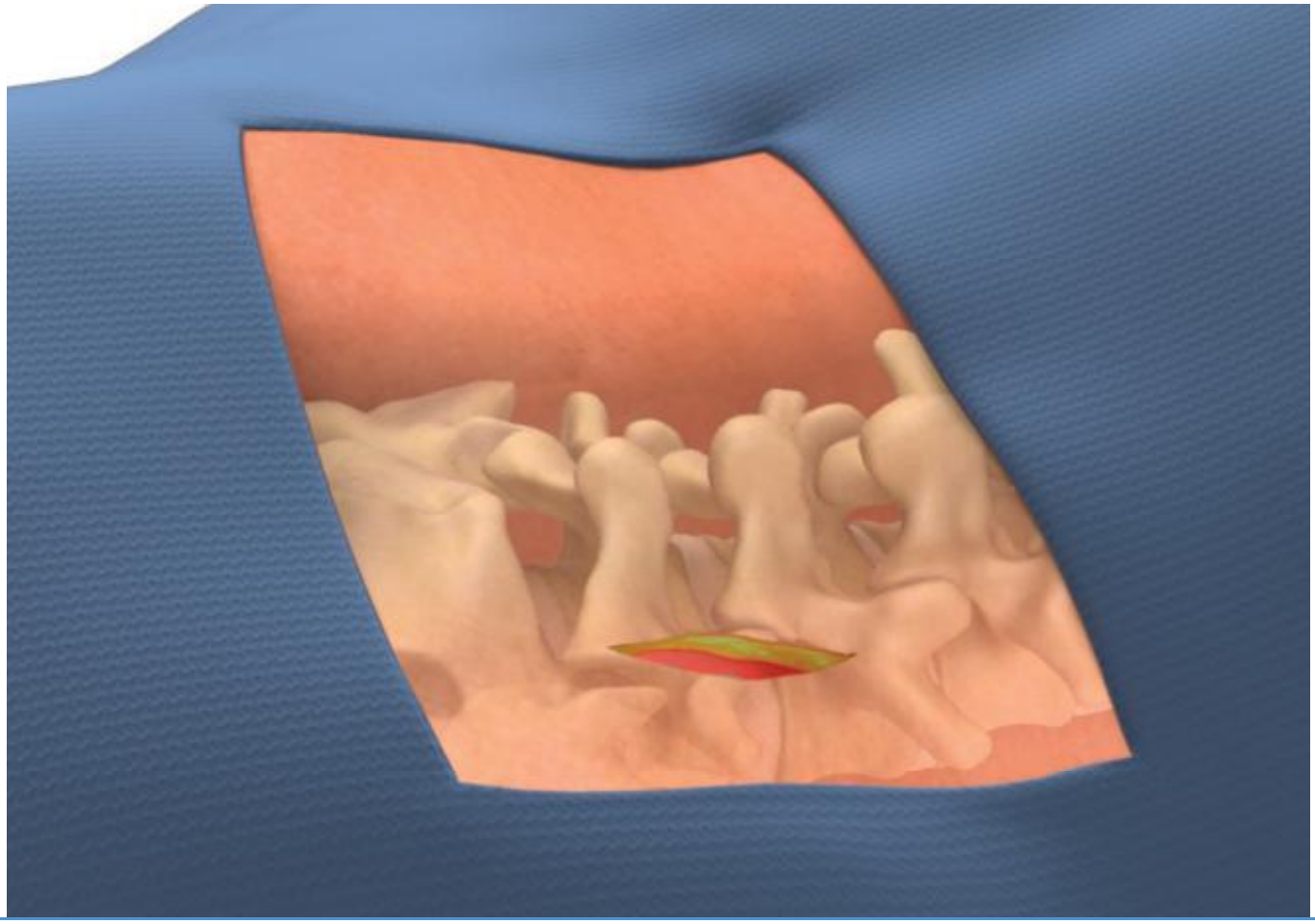
SERENGETI® Minimally Invasive Retractor Systems



- Direct Visualization & Access to the Screw Heads for Simple Rod Insertion
- Flexible Design Simplifying Multi-Level & L5-S1 Rod Insertion
- One-Step, Percutaneous Delivery of the Screw & Retractor Reducing Set-up Time
- Screw-Based Retractor Design Providing a Secure Method of Retraction
- Minimally Invasive Technique Reducing Potential for Musculature & Vascular Disruption
- Polymer Retractor Design Allowing for Neuromonitoring During Screw Insertion
- Used with the TERRA NOVA® Minimally Invasive Access System for Direct Posterior Interbody Access

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

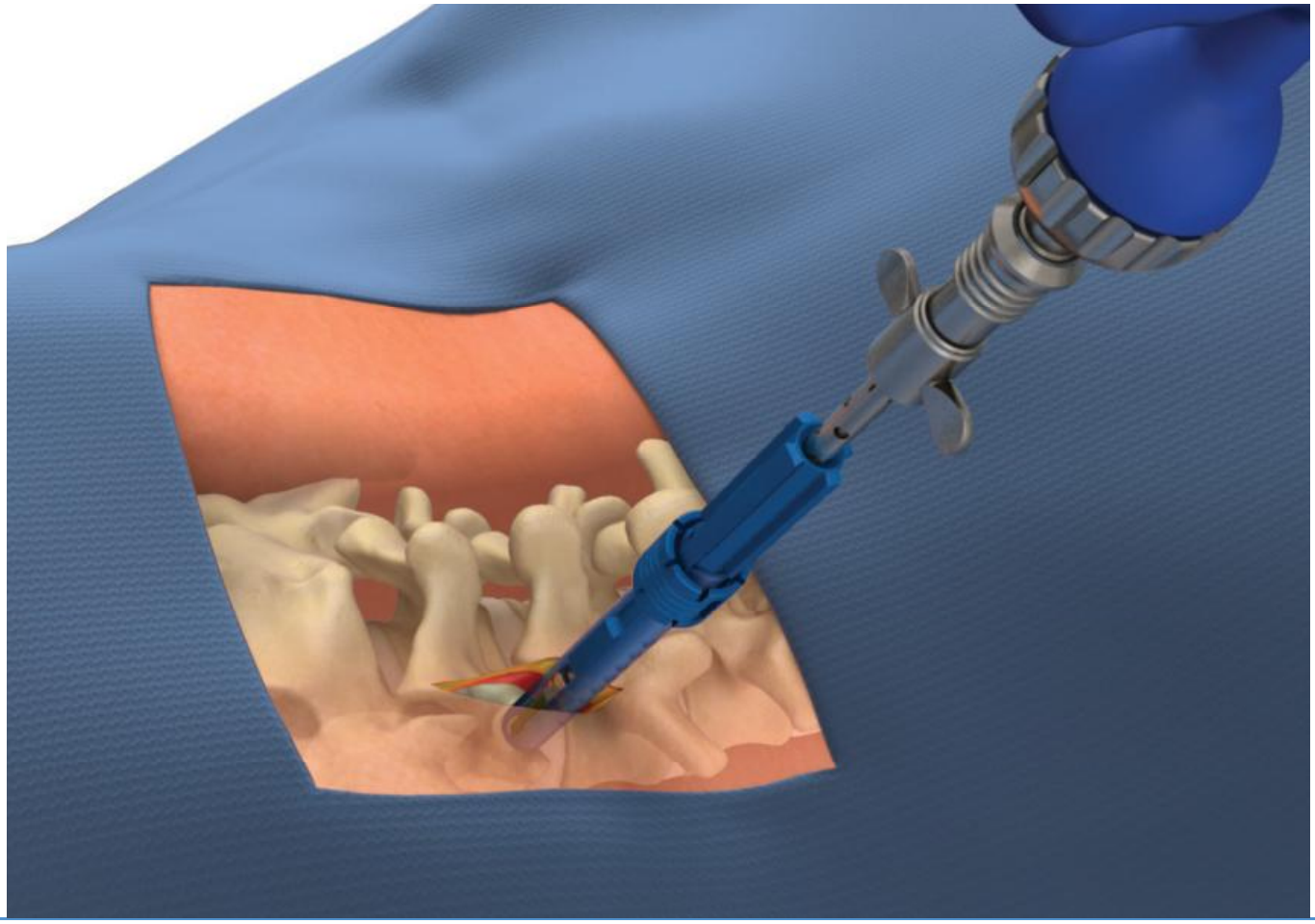
STEP 1 Surgical Technique Steps



PATIENT POSITIONING: POSTERIOR SURGICAL EXPOSURE

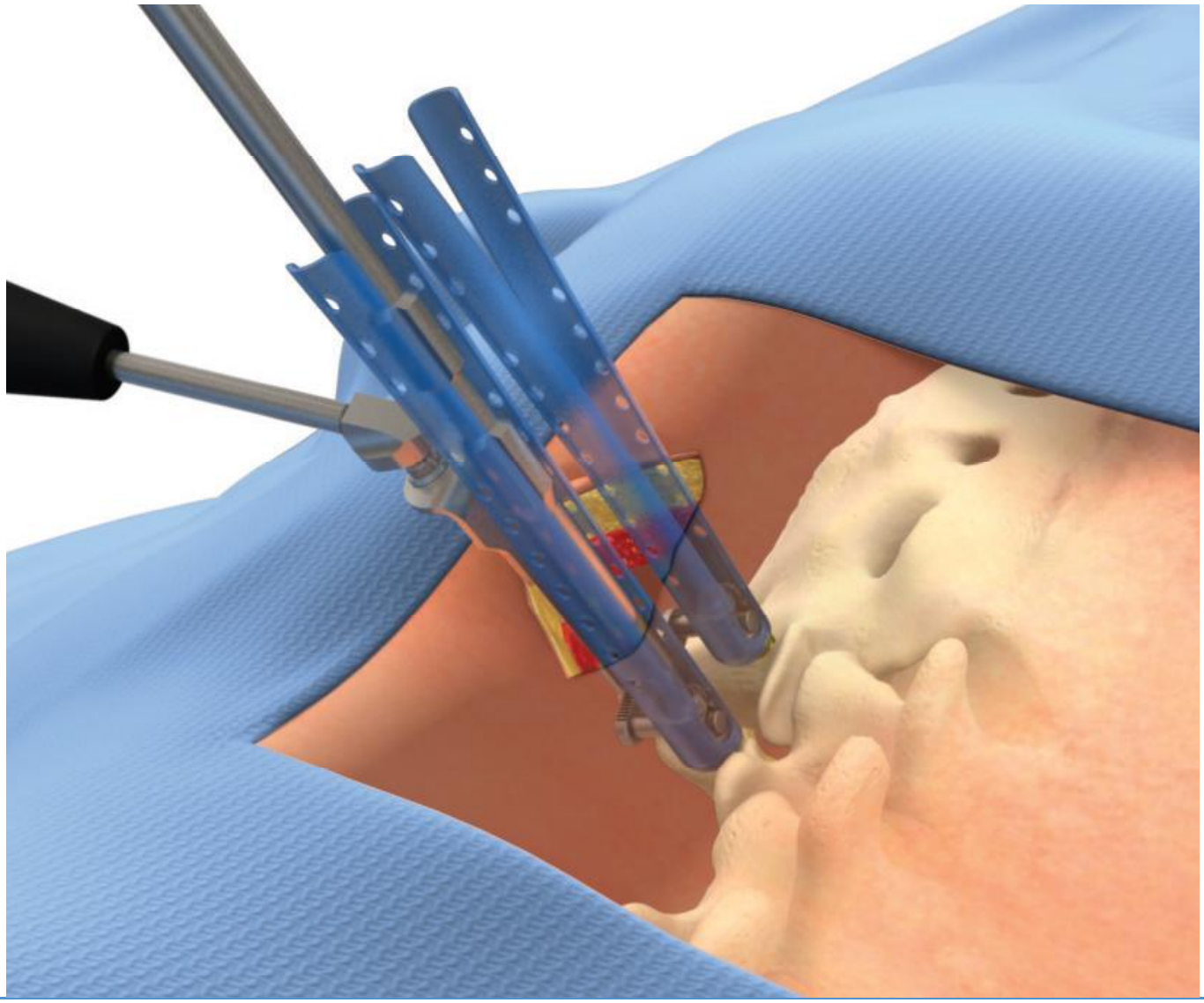
THE PATIENT SHOULD be positioned as appropriate for a posterior approach taking care to preserve or improve sagittal alignment of the spine. To facilitate venous drainage, the abdomen should not be compressed. The decision on operative side is based on the vascular anatomy, the spinal pathology, and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

NOTE: The ALEUTIAN AN Oblique 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.



PEDICLE SCREW PLACEMENT

DENALI® MINIMALLY INVASIVE 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 for proper screw and Retractor placement.

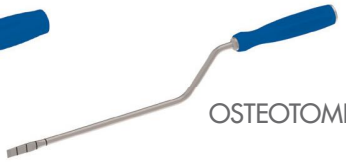


RETRACTOR DISTRACTOR BLADE PLACEMENT

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.

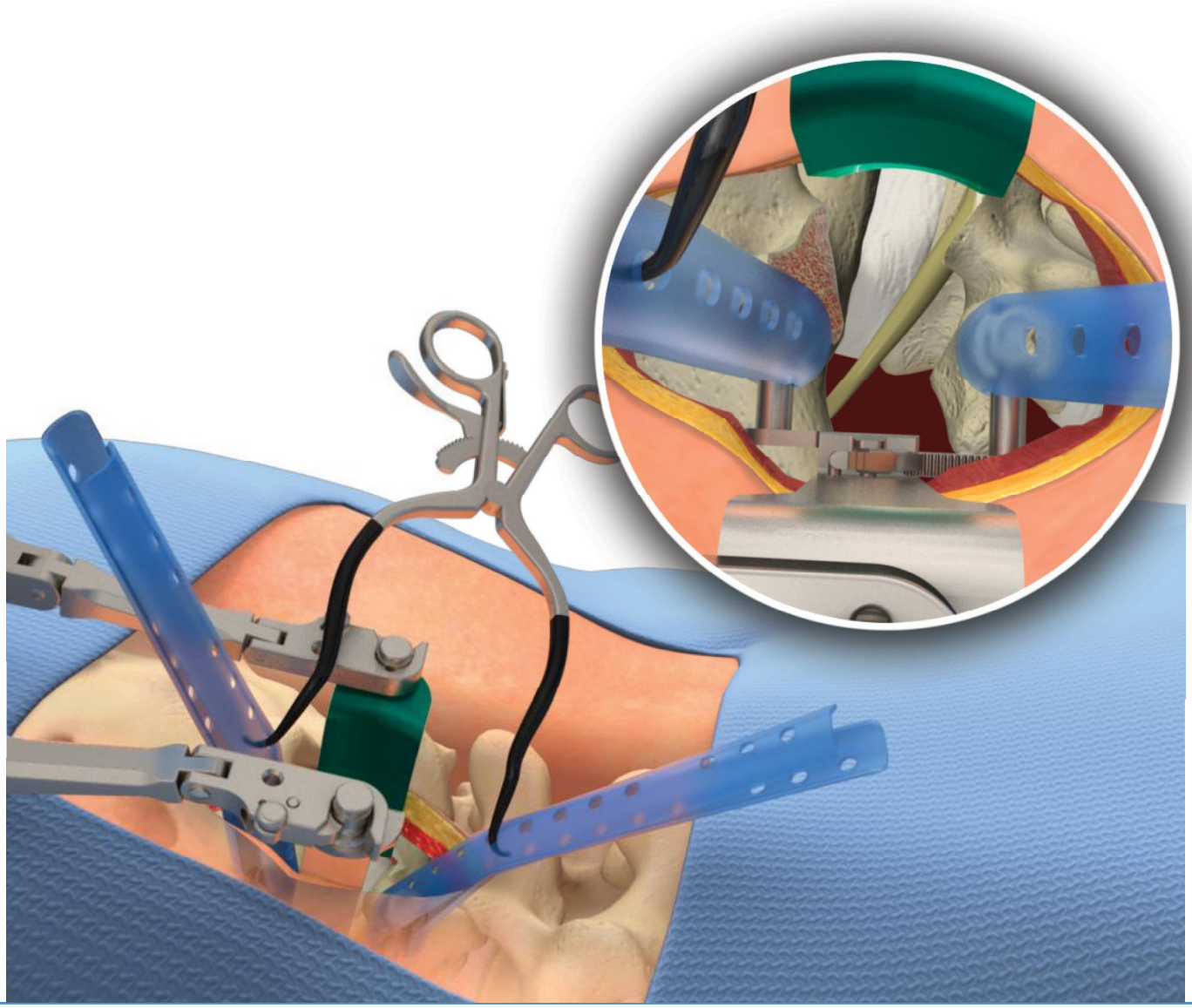
Note: If TERRA NOVA is not being used, the disc space can be distracted using a contralateral rod, lamina spreader or screw-based distractor.

CURETTE



OSTEOTOME

KERRISON RONGEUR



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 Surgical Technique Steps

NERVE ROOT RETRACTOR

DISC SCRAPER

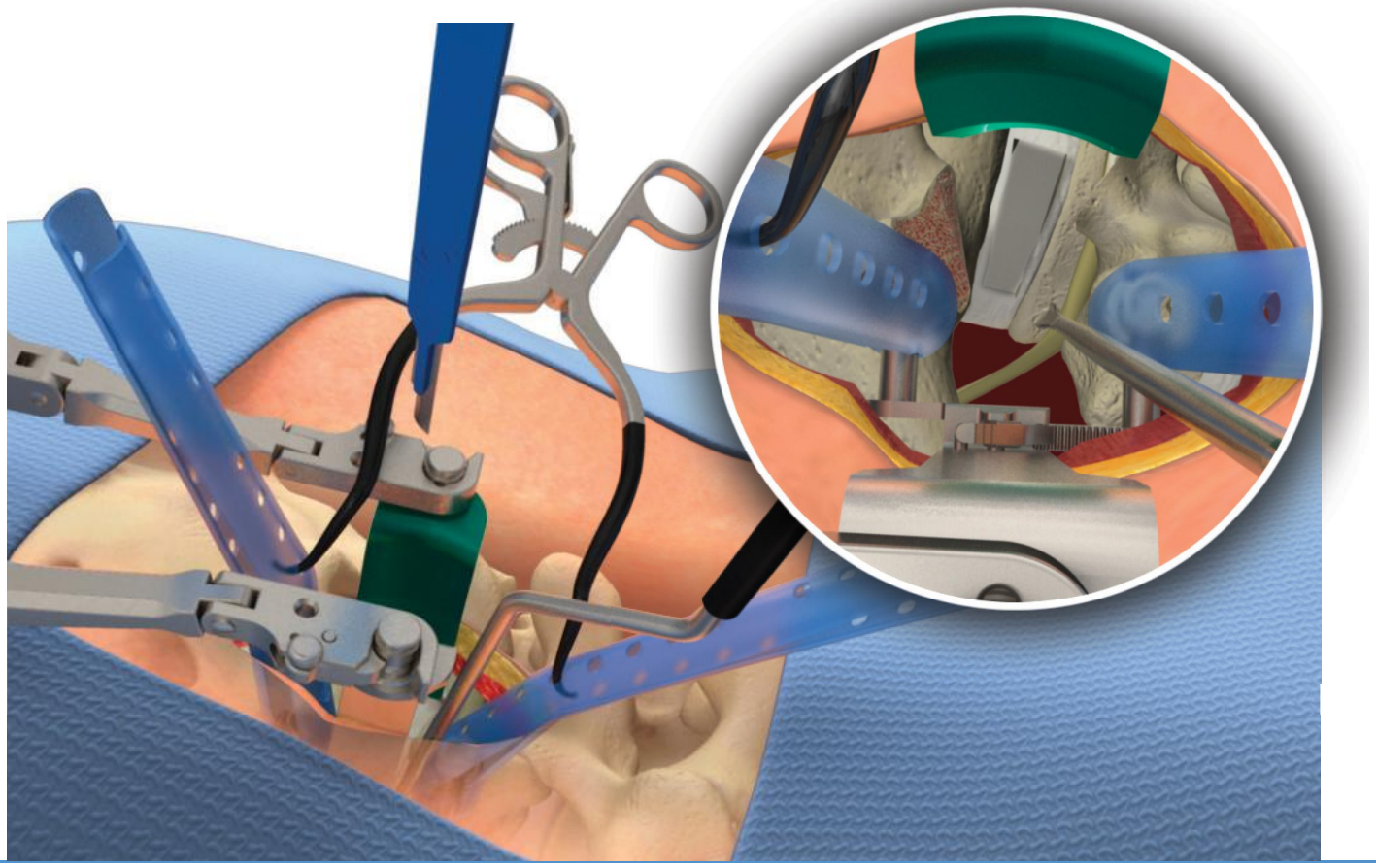
CURETTE

KERRISON RONGEUR

DISC SPREADER

PITUITARY RONGEUR

T-HANDLE



NEURAL ELEMENT RETRACTION/DISC REMOVAL

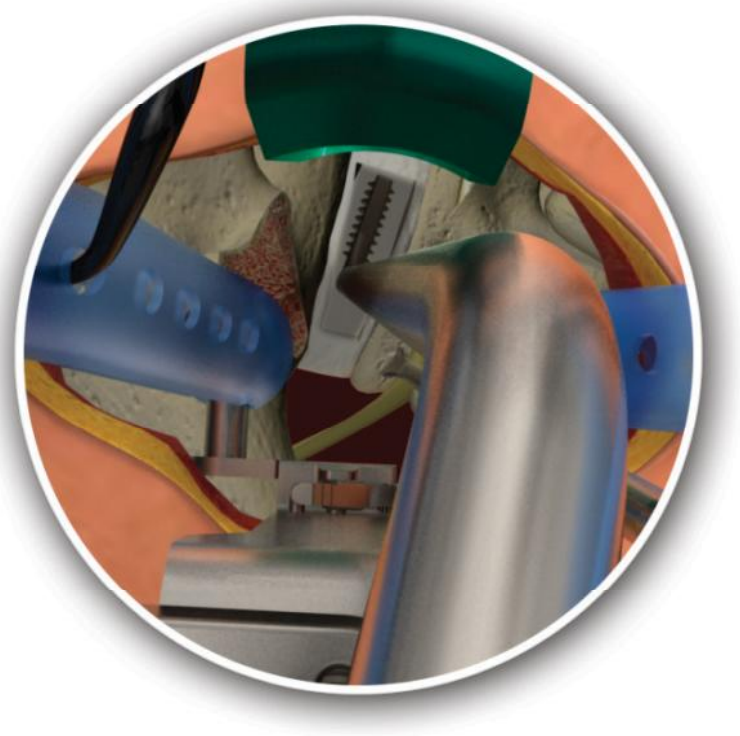
A NERVE ROOT Retractor is used to mobilize the nerve root and expose the annulus of the disc space. A scalpel can then be used to make an incision in the annulus, through which a complete discectomy can be performed. Disc Scrapers, a variety of Curettes, Kerrisons, and Pituitary Rongeurs are included 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.

RASP

CURETTE

DISC SCRAPER

T-HANDLE



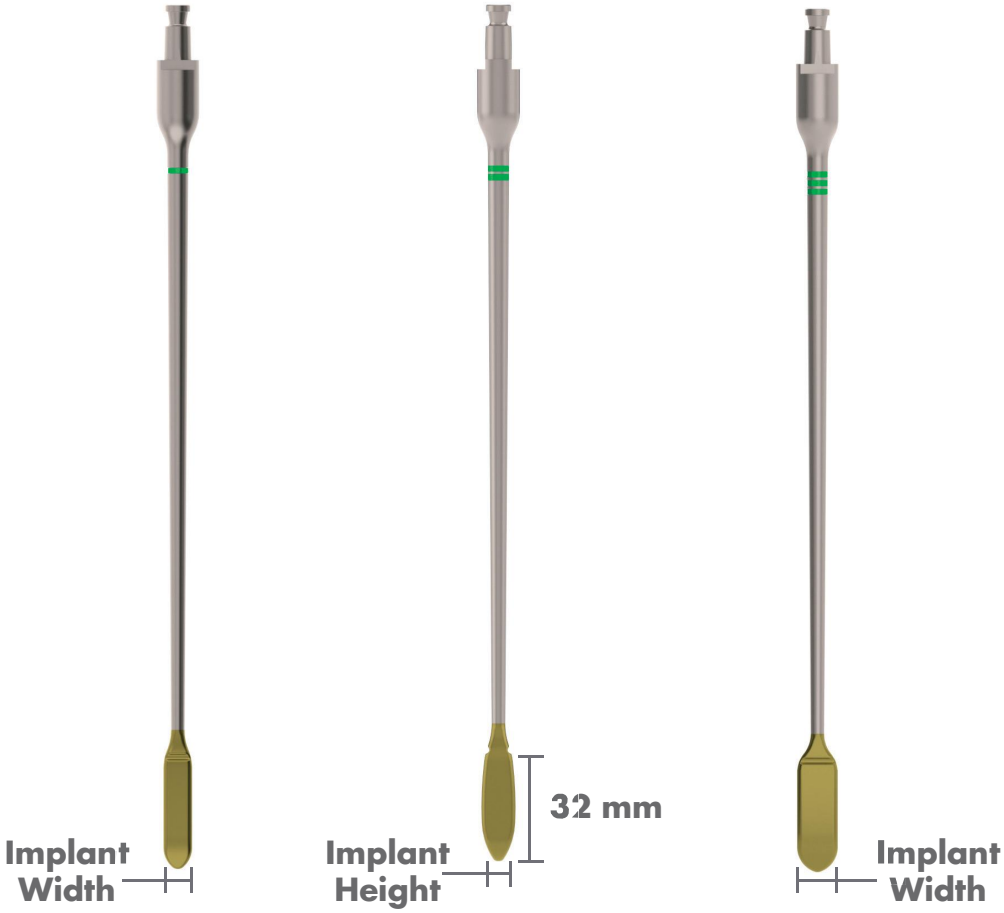
ENDPLATE PREPARATION

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.

Surgical Technique Steps

SLAP HAMMER

SLAP HAMMER ADAPTER



8.5 mm
Indicated by 1 green band

10 mm
Indicated by 2 green bands

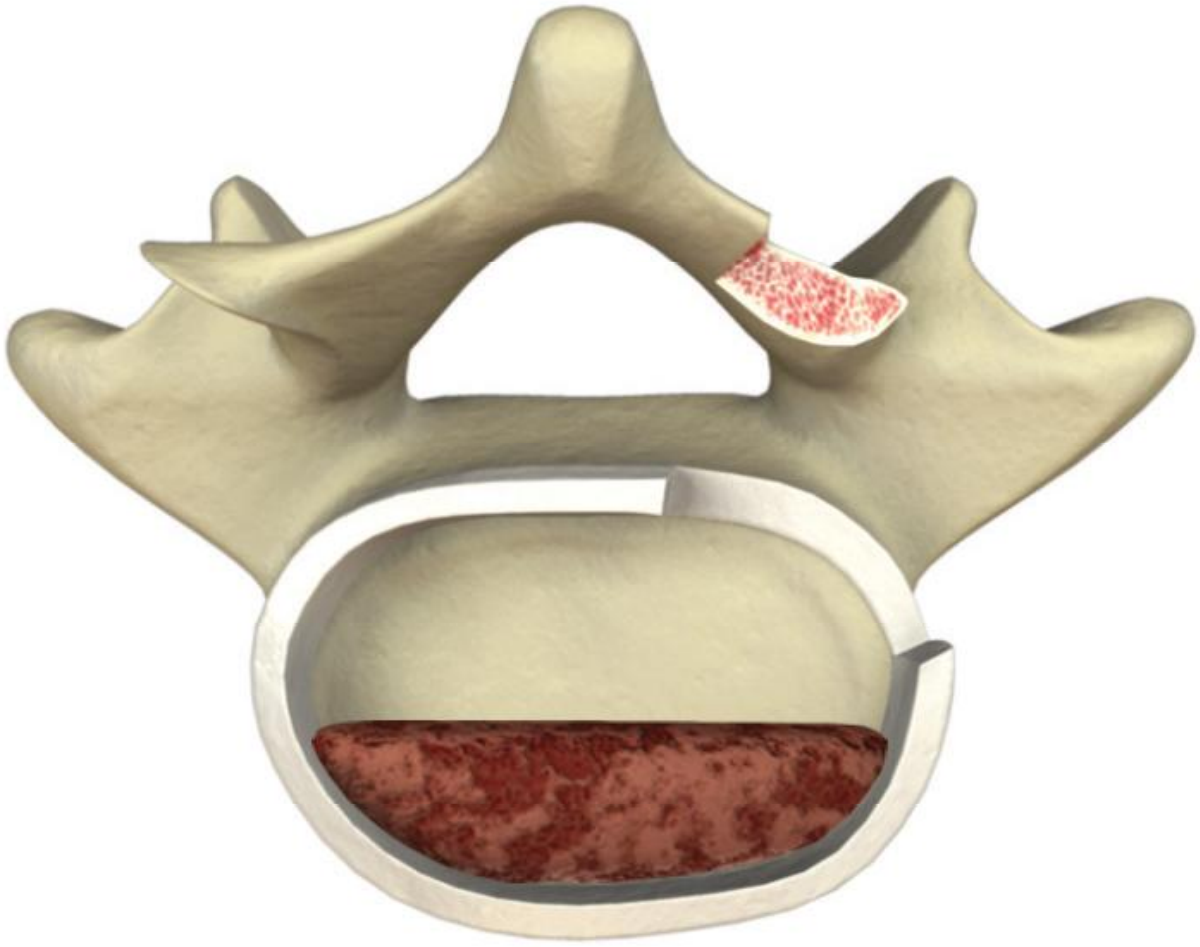
12 mm
Indicated by 3 green bands

IMPLANT SIZING

TRIALS ARE AVAILABLE to determine the proper implant size. The Trials match each of the implant widths and are discernable by the colored rings around the shafts. The scalloped cuts on the Trial body mark 32 mm. The Trials are 0.5 mm less in height than the respective implants to give a slight press fit of the interbody upon impaction. The Trials are intended for use with the included T-Handle. There is also a Slap Hammer Adapter in the Posterior-Lumbar Disc Preparation Instruments Set which can be attached to the Hudson Connection of the Trial for extraction should the Slap Hammer be needed.

BONE GRAFT FUNNEL

BONE GRAFT PUSHER



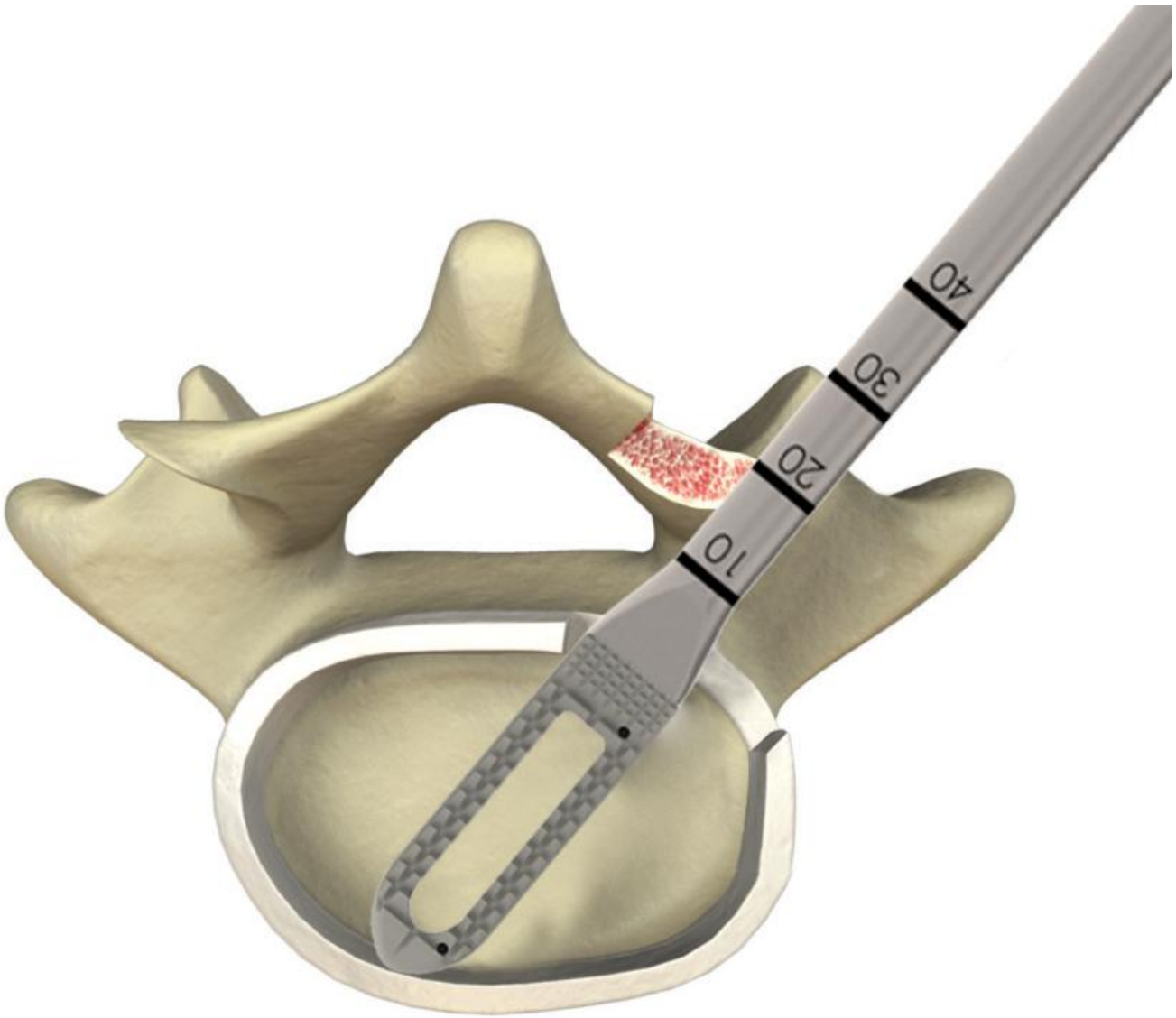
PLACEMENT OF BONE GRAFT

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.

Figure A
The Inserter is assembled by inserting the inner shaft into the Inserter lumen and turning the inner shaft to engage and clear the threads on the inner shaft with those of the Inserter. When the inner shaft is properly assembled, it will be free to slide a few millimeters, but will be retained by the Inserter so it cannot fall out.

IMPLANT INSERTION

THE PROXIMAL END of the implant is threaded onto the stud at the distal end of the Inserter, taking care to ensure the recesses in the implant are aligned with the fingers on the Inserter by turning the thumbwheel at the proximal end of the inner shaft clockwise. **Note**: Each implant width has a specific Inserter.



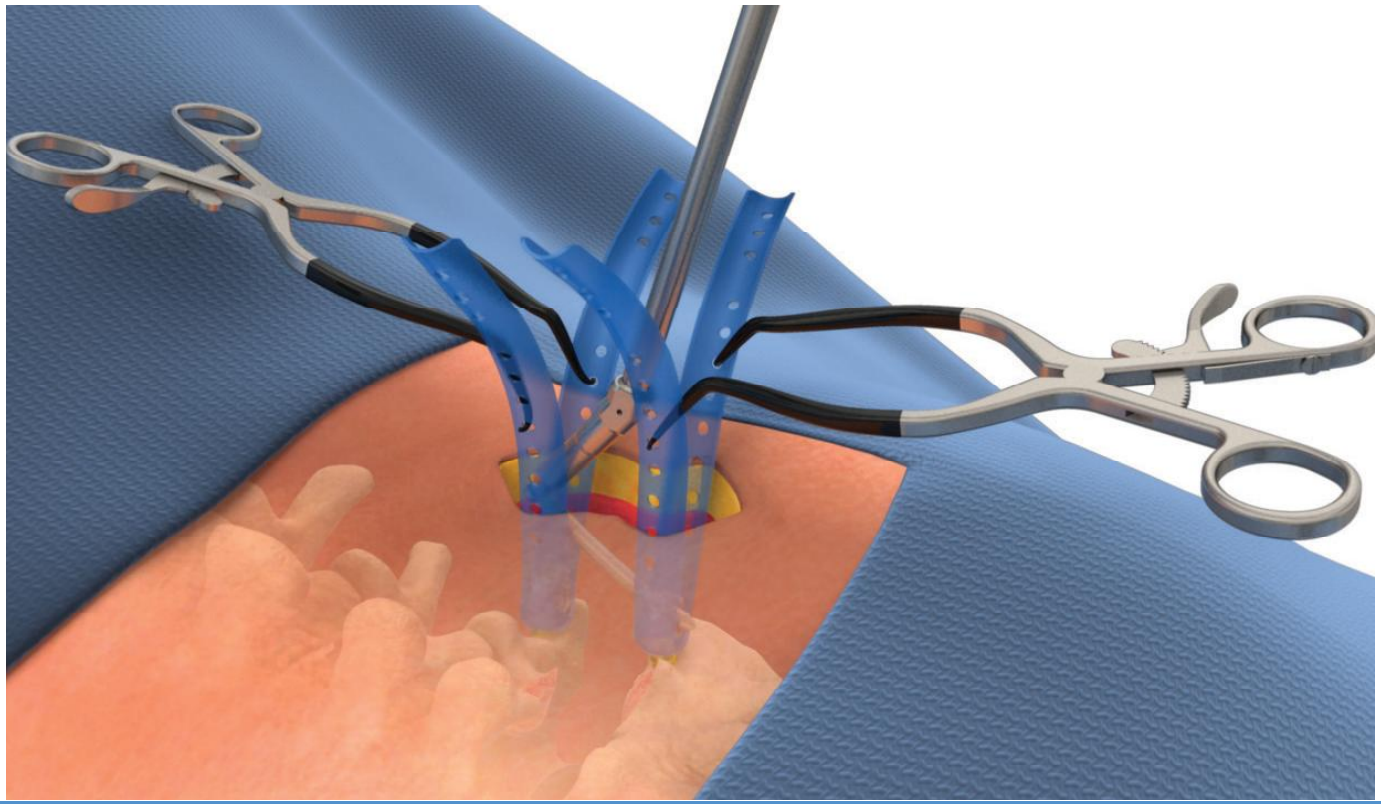
The AN Oblique implants are intended to be placed in a diagonal fashion across the disc space. Ideal placement will have the implant centered across the midline of the disc space. Once proper placement is confirmed with intra-operative x-ray, the Inserter is detached from the implant by turning the thumbwheel on the proximal end of the inner shaft counter-clockwise. The Inserter can subsequently be removed from the wound site.

Surgical Technique Steps


MI ROD CALIPER


MI ROD INSERTER

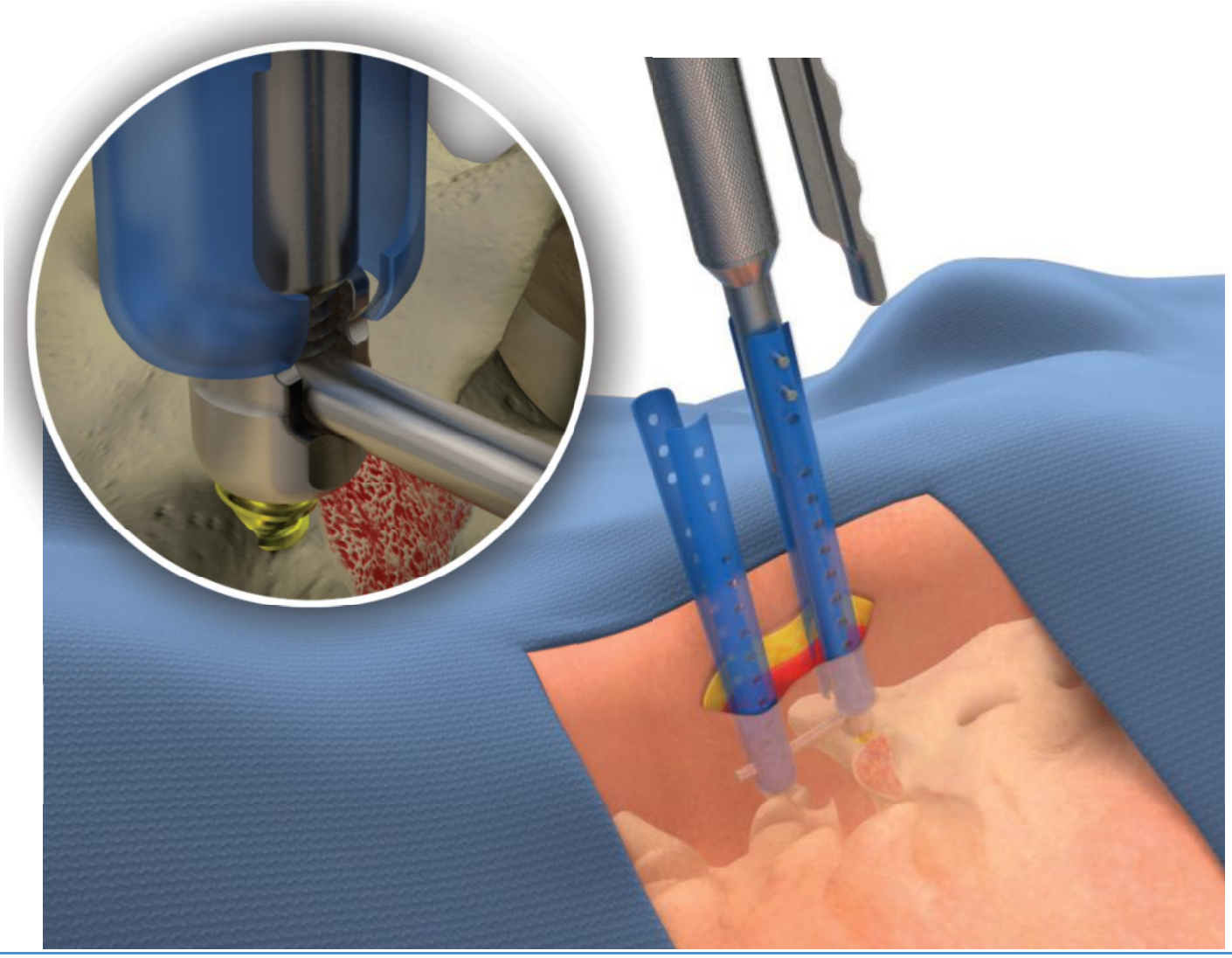

TUBE COMPRESSOR



ROD INSERTION & COMPRESSION

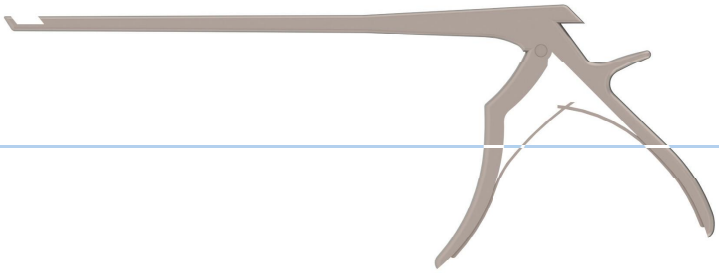
AFTER INTERBODY INSERTION, the Retractor Distractor Blade can be removed from the wound and the screw heads realigned for rod introduction as detailed in the TERRA NOVA Surgical Technique. The MI Rod Caliper can be used to determine the proper rod length. The rod is then inserted into the screw heads 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.

RETRACTOR EXTRACTOR

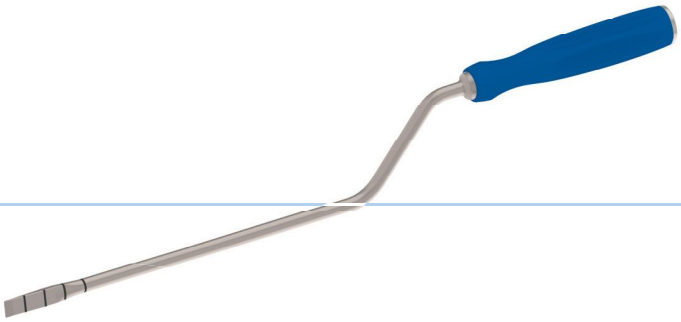


REMOVING THE SERENGETI® RETRACTORS

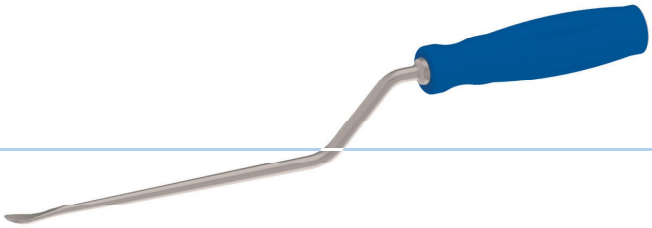
FOLLOWING FINAL TIGHTENING of the set screws, use the Retractor Extractor to remove the SERENGETI Retractors. With the Retractors removed, perform a standard multi-layer wound closure to complete the procedure.



4 & 6 mm 40° UPBITING KERRISON



BAYONETED 8 mm OSTEOTOME*



BAYONETED 10 mm ELEVATOR*

LARGE MALLET

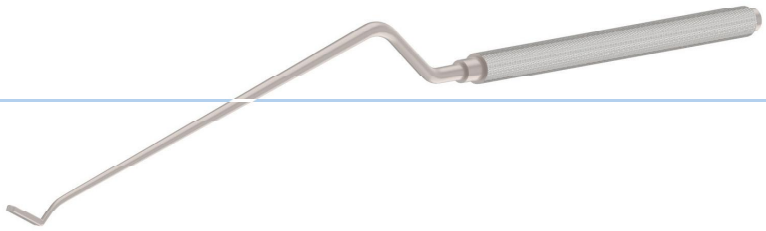
LAMINOTOMY/FACETECTOMY

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

*Also available in straight version

SMALL NERVE ROOT RETRACTOR

PENNFIELD



WOODSON

SCALPEL BLADE HOLDER

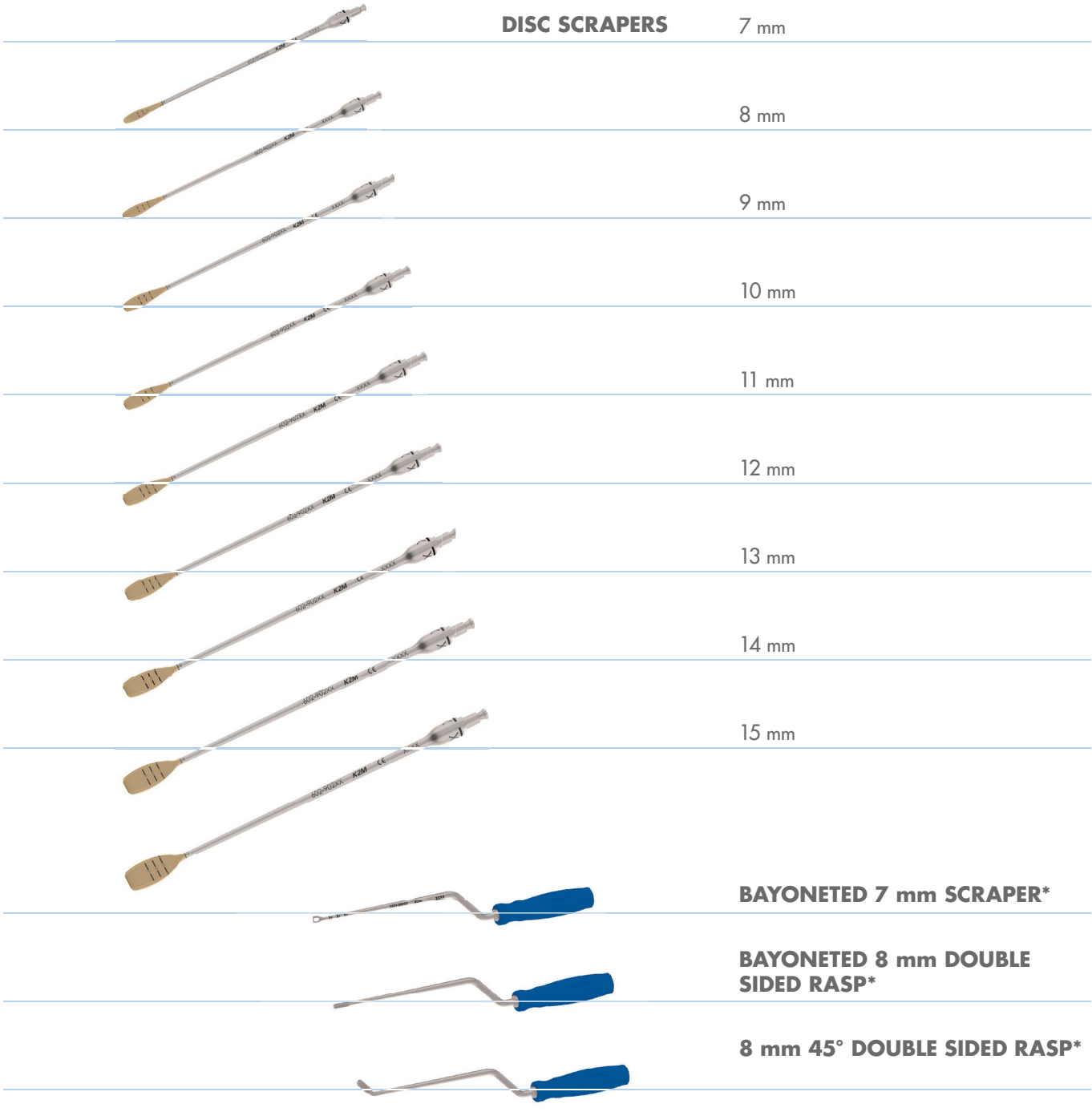
DISC EXPOSURE & ACCESS

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

T-HANDLE WITH STRIKE PLATE

DISC SPACE DISTRACTION

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Disc Spreader – 4 mm	602-90254	Disc Spreader – 11 mm	602-90260
Disc Spreader – 6 mm	602-90255	Disc Spreader – 12 mm	602-90261
Disc Spreader – 7 mm	602-90256	Disc Spreader – 13 mm	602-90262
Disc Spreader – 8 mm	602-90257	Disc Spreader – 14 mm	602-90310
Disc Spreader – 9 mm	602-90258	Disc Spreader – 15 mm	602-90263
Disc Spreader – 10 mm	602-90259	T-Handle with Strike Plate	3303-90058



ENDPLATE PREPARATION

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Disc Scraper – 7 mm	602-90233	Disc Scraper – 13 mm	602-90239
Disc Scraper – 8 mm	602-90234	Disc Scraper – 14 mm	602-90308
Disc Scraper – 9 mm	602-90235	Disc Scraper – 15 mm	602-90240
Disc Scraper – 10 mm	602-90236	Bayoneted 7 mm Scraper	3303-90053*
Disc Scraper – 11 mm	602-90237	Bayoneted 8 mm Double Sided Rasp	3303-90054*
Disc Scraper – 12 mm	602-90238	Bayoneted 8 mm 45° Double Sided Rasp	3303-90055*

**Also available in straight version*

TRIALS

8.5 mm (7 - 15 mm heights)

10 mm (7 - 15 mm heights)

12 mm (7 - 15 mm heights)

IMPLANT SIZING

DESCRIPTION	CATALOG NUMBER
Trial – 8.5 mm (7 - 15 mm heights)	602-90327 – 602-90335
Trial – 10 mm (7 - 15 mm heights)	602-90363 – 602-90371
Trial – 12 mm (7 - 15 mm heights)	602-90399 – 602-90407

REMOVAL TOOL

BONE GRAFT FUNNEL

BONE GRAFT FUNNEL PUSHER

SLAP HAMMER

SLAP HAMMER ADAPTER

BAYONETED STRAIGHT PUSHER*

BAYONETED CURVED PUSHER*

BAYONETED ANGLED PUSHER*

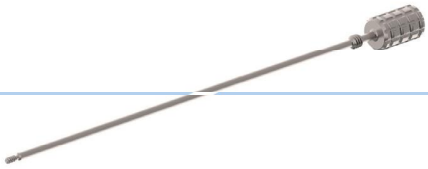
IMPLANT INSERTION

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

DESCRIPTION	CATALOG NUMBER
Bayoneted Curved Pusher	3303-90020*
Bayoneted Angled Pusher	3303-90021*

**Also available in straight version*

AN MI INSERTER*

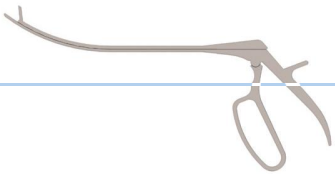


INNER SHAFT

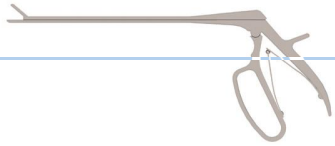
**Available in 8.5, 10, and 12 mm widths*

IMPLANT INSERTION (CONT.)

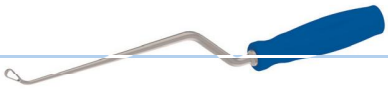
DESCRIPTION	CATALOG NUMBER
AN MIS Inserter - 8.5 mm	602-90448
AN MIS Inserter - 10 mm	602-90450
AN MIS Inserter - 12 mm	602-90451
Inner Shaft for MIS Inserters	602-90449



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*

DISC MATERIAL REMOVAL

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

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

**Also available in straight version*

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT
This booklet is designed to assist in using the ALEUTIAN® Interbody Spacer 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
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 Spacer 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 Spacer 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 surger
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
4. 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.

5. 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 Spacer 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 Spacer 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 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 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.

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K2-06-7035-01 Rev. 0
Actual device color may vary.
Consult product catalog for details.

CE 0086