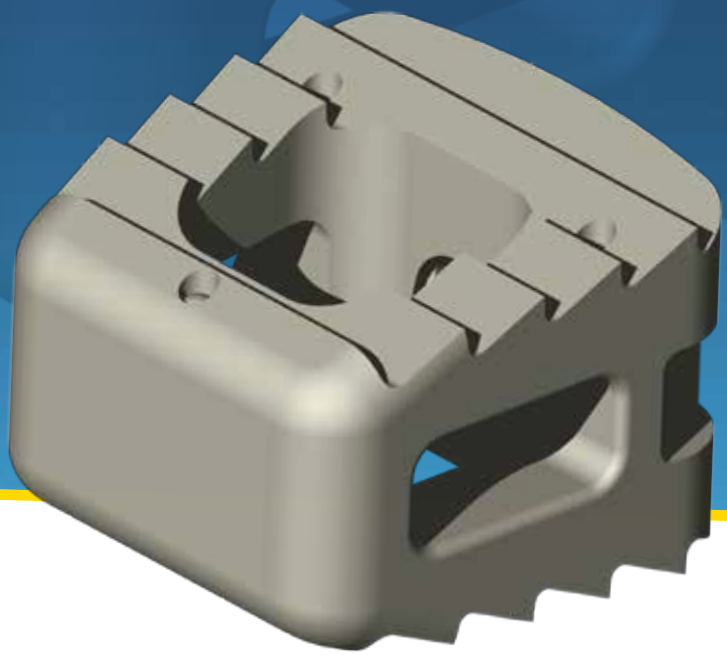
K2M

COMPLEX SPINE INNOVATIONS™

SURGICAL TECHNIQUE

ALEUTIAN®

CERVICAL INTERBODY SYSTEM



ALEUTIAN®
CERVICAL

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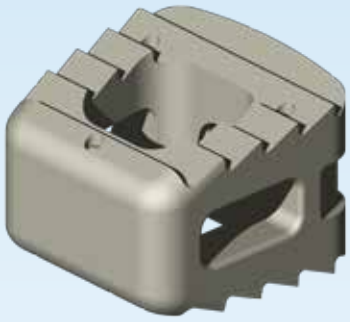
FEATURES & BENEFITS

ALEUTIAN® CERVICAL INTERBODY SYSTEM



IMPLANTS:

- Manufactured From Biocompatible PEEK Polymer
- Elastic Modulus Close to That of Cortical Bone, With the Goal of Allowing for Load Sharing While Minimizing Stress Shielding
- Radiolucency Allowing for More Accurate Fusion Assessment
- Bulleted Nose Allowing for Ease-of-insertion
- Available in Both Lordotic & Convex Designs, Minimizing Endplate Preparation
- Large Range of Implant Heights to Accommodate Differing Anatomy Sizes
- Self-retaining Teeth for Gripping the Endplates & Resisting Expulsion
- Radiopaque Tantalum Markers at Both Ends of the Implants,

INSTRUMENTS:

- Easily Identifiable Insertion Tools
- Color-coded Rasps & Trials to Quickly & Accurately Identify Sizes
- Rasps, Trials, & Pusher Fitted with Stops to Ensure Accurate Placement
- Fixed Handles to Avoid Intraoperative Assembly

FEATURES & BENEFITS

CERVICAL PLATE SYSTEMS

BLUE RIDGE® Hybrid Cervical Plate System

IMPLANTS
- Large Graft Window for Ample Visualization
- Flexibility to Insert Variable Screws Conically up to 30°
- One-step Locking Mechanism
- Clear Visibility of Final Lock

PYRENEES® Constrained Cervical Plate System

IMPLANTS
- Revolutionary *tifix*® Locking Technology
- Flexibility to Insert Screws Conically Up to 45°
- Screws Lock to the Plate Upon Insertion
- No Extra Locking Mechanism Needed

PYRENEES® Translational Cervical Plate System

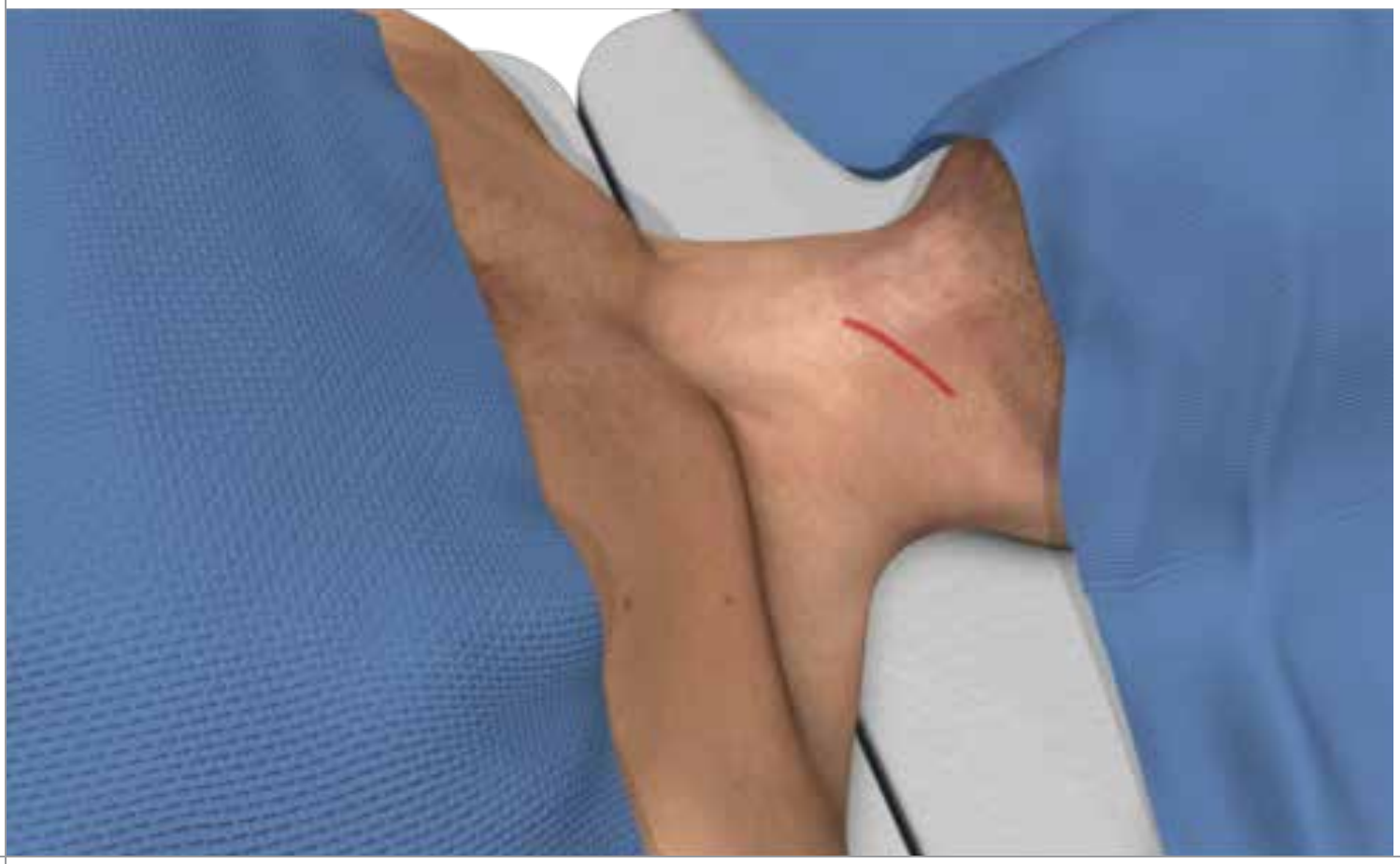
IMPLANTS
- Unidirectional Translational Plates
- Revolutionary *tifix*® Locking Technology
- Flexibility to Insert Screws Conically up to 30°
- Screws Lock to the Plate Upon Insertion
- No Additional Locking Mechanism Needed

SURGICAL TECHNIQUE

STEP 1

PLANNING, APPROACH & PATIENT POSITIONING

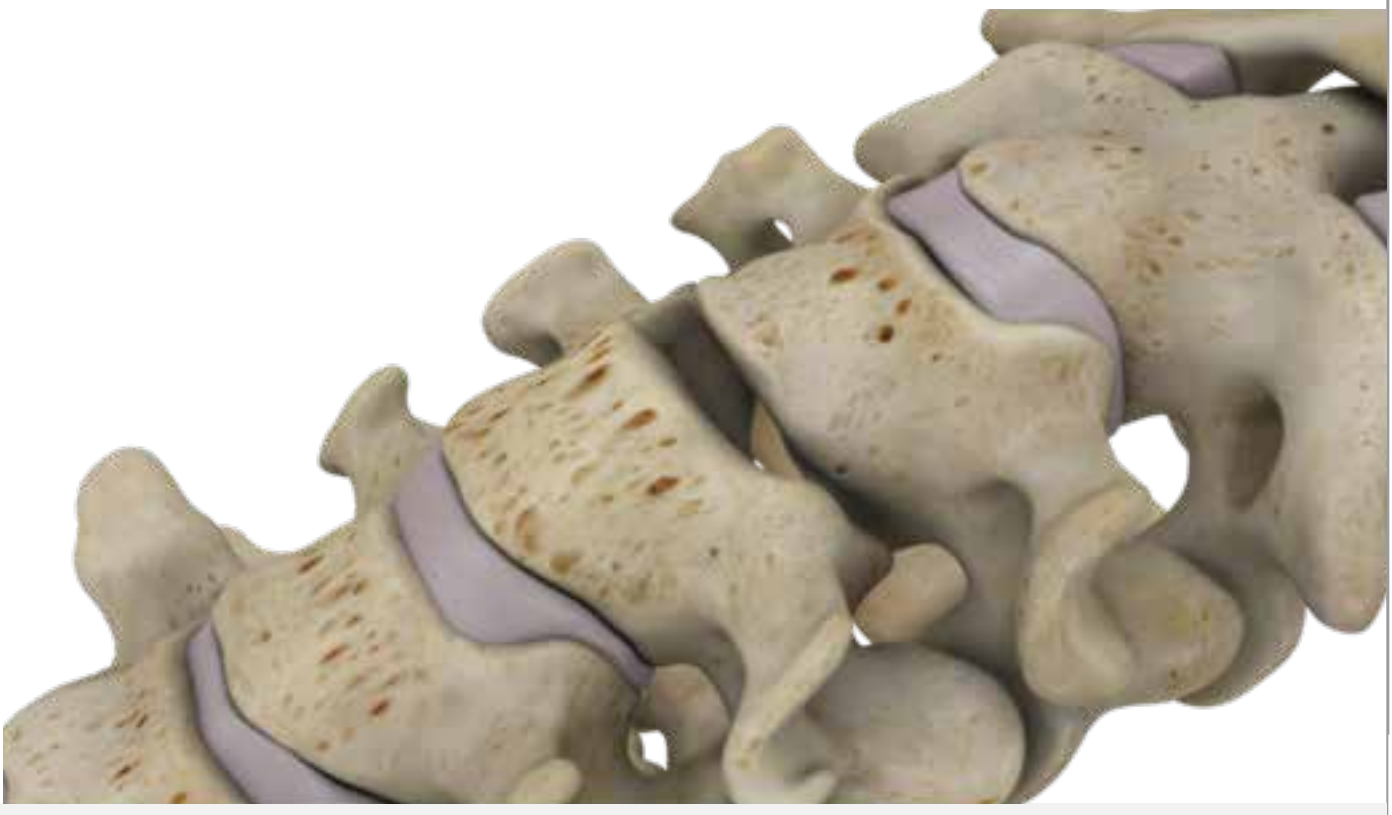
Pre-surgical planning defines the type of construct, the most appropriate implants, and the optimal implant location. The ALEUTIAN® Cervical set is designed to facilitate the anterior surgical approach.



STEP 2

DISCECTOMY & ENDPLATE PREPARATION

Perform a standard incision and exposure of the ventral cervical spine and then complete a standard discectomy. Various Rasps are available to help prepare the vertebral endplates. Rasps are color-coded to quickly and accurately identify heights. Removal of the superficial layers of cartilaginous endplates results in exposure of bleeding bone.

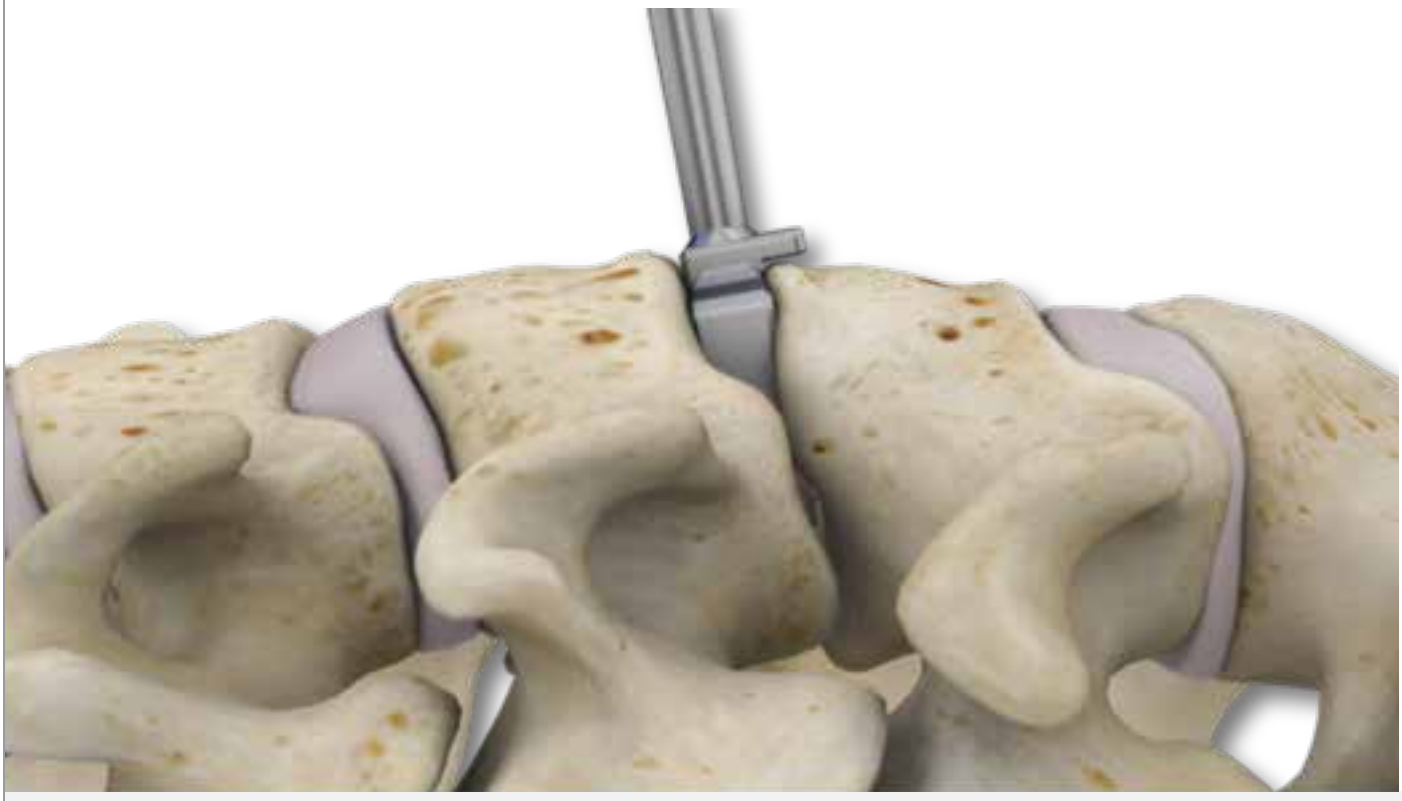


RASP

STEP 3

DETERMINING INTERBODY SIZE

Trials are available in 7° of lordosis to aid in the initial test fitting and size confirmation of the interbody. Trials are 0.5 mm undersized to allow for a slight press fit of the interbody. If the Trial appears to be too small, gradually increase the size until a secure fit is achieved.



TRIAL

STEP 4

INTERBODY SELECTION

An appropriately sized interbody is chosen at the discretion of the surgeon; one which is securely seated with a tight fit between the endplates when the segment is fully distracted. Interbodies are sized at 11 x 11, 11 x 14, and 13 x 16 mm and are available with 7° of lordosis. Heights range from 5—14 mm in 1 mm increments.*

The height of the interbody is measured from the tip-of-tooth to tip-of-tooth. The implant is indicated for spinal fusion procedures to be used with autogenous bone in skeletally mature patients.

*PLUS sizes ranging from 11—4 mm only available upon request. 13 x 16 mm footprints range in heights from 5—12 mm.

STEP 5

INTERBODY INSERTION

11 x 11 & 11 x 14 mm Inserters

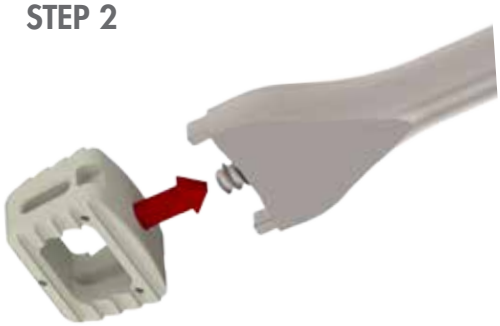
1. Choose the Inserter of the corresponding interbody footprint.
2. Load the interbody onto the distal end of the Inserter, making sure the interbody is loaded onto the tongs.
3. Lightly push the thumbwheel distally, while turning it in a clockwise direction to engage the interbody.
4. After the interbody is properly seated in the disc space, turn the thumbwheel in a counter-clockwise direction to disengage the interbody.
5. The Small Mallet and Straight Impactor may be used to aid in implant placement. X-ray or fluoroscopy may be used live or periodically to verify placement.

STEP 1

11 x 11 mm Inserter

11 x 14 mm Inserter

STEP 2

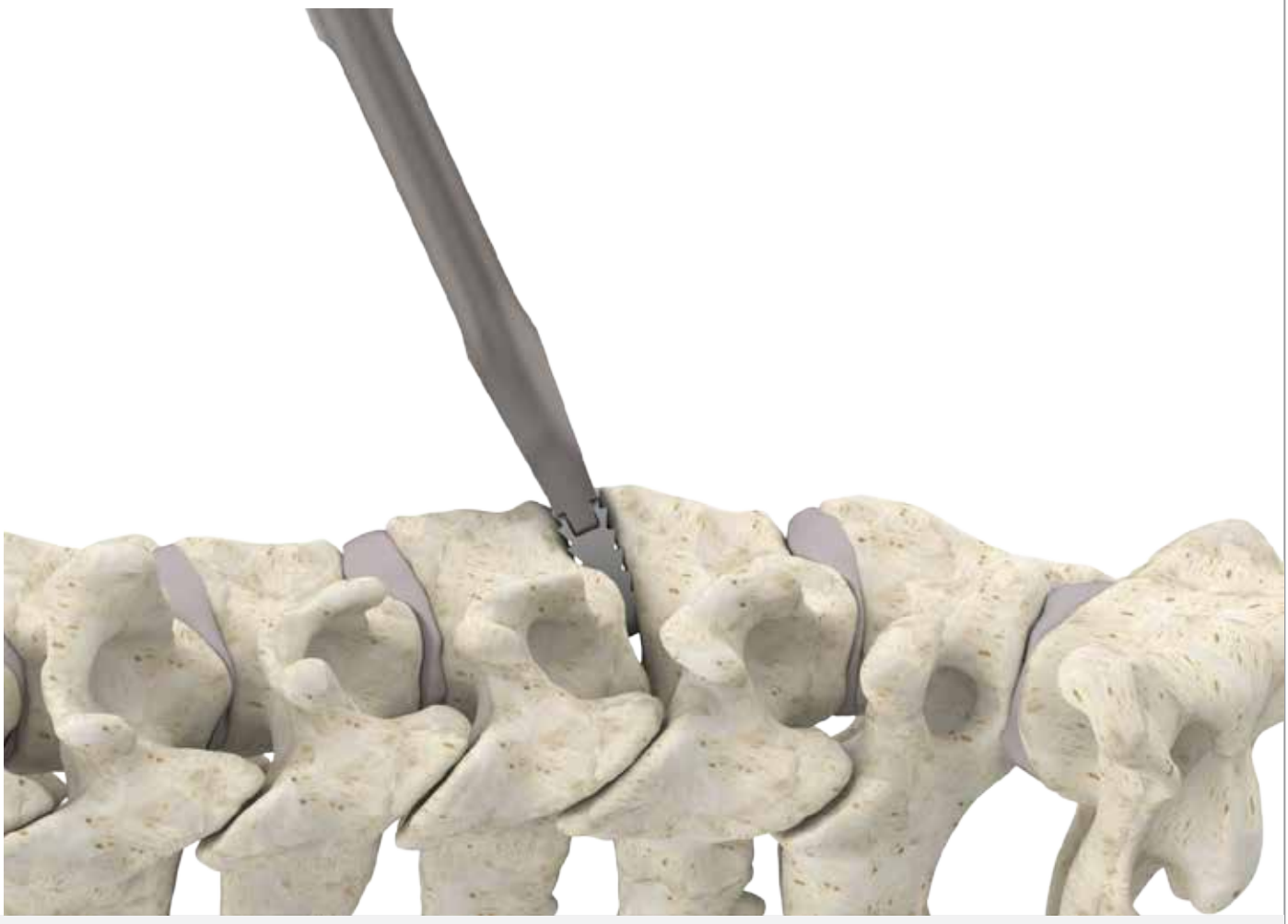


STEP 3

13 x 16 mm Inserter

1. Insert the Inner Shaft through the proximal end of the Inserter and rotate clockwise 1 to 2 turns to engage the threads.
2. Load the interbody onto the distal end of the Inserter, making sure the interbody is loaded onto the tongs.
3. Turn the Inner Shaft thumbwheel on the proximal end in a clockwise direction to secure the implant.
4. After the interbody is properly seated in the disc space, turn the Inner Shaft thumbwheel in a counter-clockwise direction to disengage the interbody.
5. The Small Mallet and Straight Impactor may be used to aid in implant placement. X-ray or fluoroscopy may be used live or periodically to verify placement.

If implant removal is required, the implant can be reattached to the Inserter and pulled out from the disc space.




13 x 16 mm INSERTER

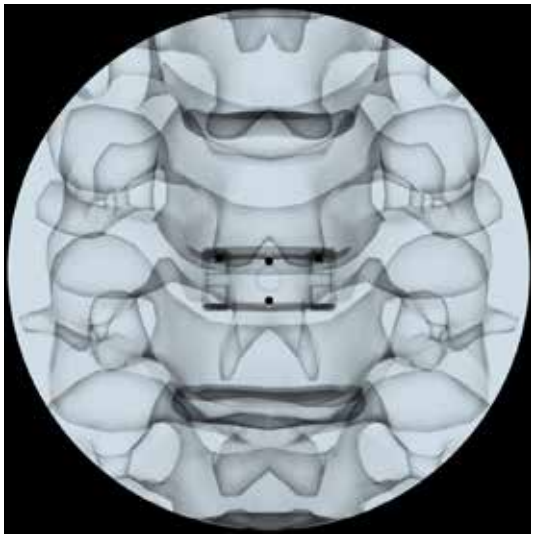

INNER SHAFT

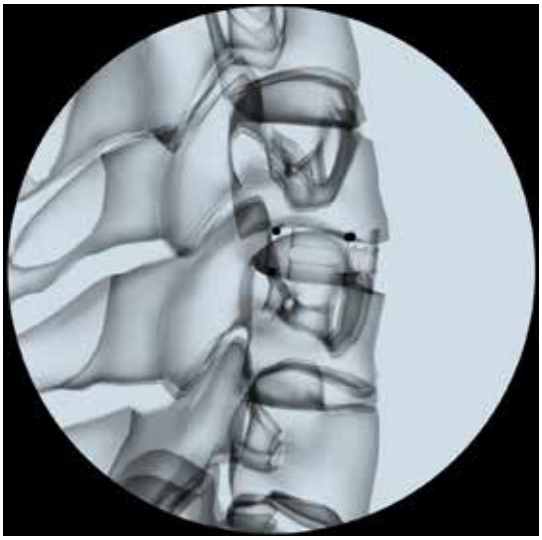
STEP 6

WOUND CLOSURE

When the construct is complete, perform a standard, multi-layer wound closure.

NOTE: To help prevent graft expulsion and for additional anterior support, use the PYRENEES or BLUE RIDGE Cervical Plate Systems. See the PYRENEES or BLUE RIDGE Surgical Techniques for additional instructions.





PRODUCT CATALOG

TRIALS

CATALOG #	DESCRIPTION
402-90013	Trial – 6 mm, 11 x 11 mm
402-90014	Trial – 7 mm, 11 x 11 mm
402-90015	Trial – 8 mm, 11 x 11 mm
402-90016	Trial – 9 mm, 11 x 11 mm
402-90017	Trial – 10 mm, 11 x 11 mm
402-90074	Trial – 5 mm, 11 x 14 mm

CATALOG #	DESCRIPTION
402-90024	Trial – 6 mm, 11 x 14 mm
402-90025	Trial – 7 mm, 11 x 14 mm
402-90026	Trial – 8 mm, 11 x 14 mm
402-90027	Trial – 9 mm, 11 x 14 mm
402-90028	Trial – 10 mm, 11 x 14 mm

PLUS sizes ranging from 11—14 mm available upon request only

6 mm, 11 x 11 mm

7 mm, 11 x 11 mm

8 mm, 11 x 11 mm

9 mm, 11 x 11 mm

10 mm, 11 x 11 mm

5 mm, 11 x 14 mm

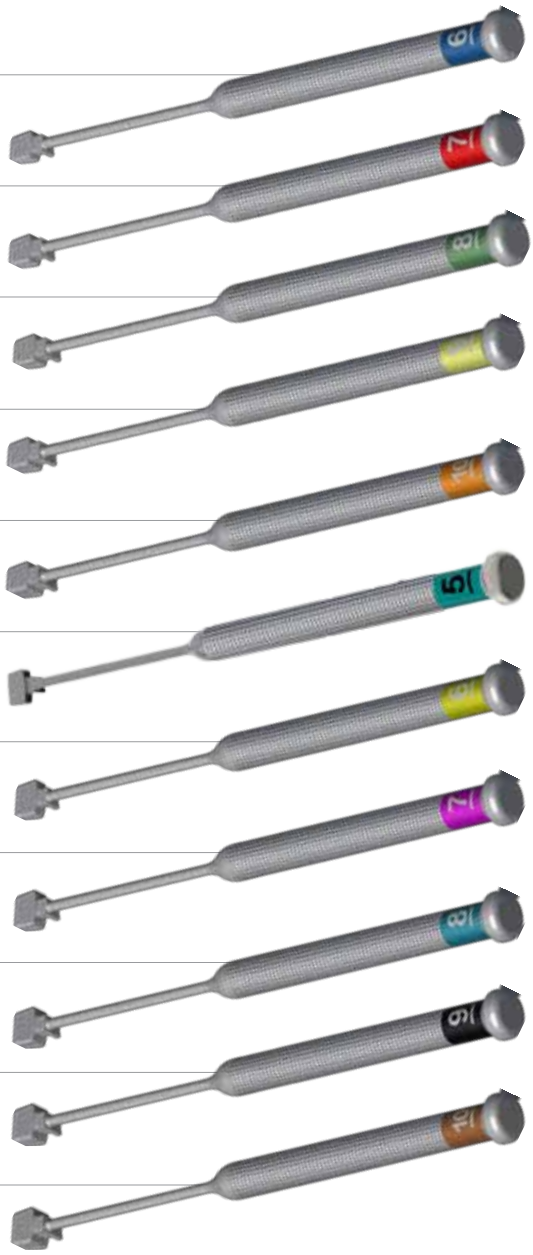
6 mm, 11 x 14 mm

7 mm, 11 x 14 mm

8 mm, 11 x 14 mm

9 mm, 11 x 14 mm

10 mm, 11 x 14 mm



CATALOG #	DESCRIPTION
402-90188	Trial – 5 mm, 13 x 16 mm
402-90189	Trial – 6 mm, 13 x 16 mm
402-90190	Trial – 7 mm, 13 x 16 mm
402-90191	Trial – 8 mm, 13 x 16 mm
402-90192	Trial – 9 mm, 13 x 16 mm

CATALOG #	DESCRIPTION
402-90193	Trial – 10 mm, 13 x 16 mm
402-90194	Trial – 11 mm, 13 x 16 mm
402-90195	Trial – 12 mm, 13 x 16 mm

5 mm, 13 x 16 mm

6 mm, 13 x 16 mm

7 mm, 13 x 16 mm

8 mm, 13 x 16 mm

9 mm, 13 x 16 mm

10 mm, 13 x 16 mm

11 mm, 13 x 16 mm

12 mm, 13 x 16 mm

RASPS

CATALOG #	DESCRIPTION
402-90011	Rasp – 6 mm, 11 x 11 mm
402-90037	Rasp – 7 mm, 11 x 11 mm
402-90038	Rasp – 8 mm, 11 x 11 mm
402-90039	Rasp – 9 mm, 11 x 11 mm
402-90040	Rasp – 10 mm, 11 x 11 mm
402-90073	Rasp – 5 mm, 11 x 14 mm
402-90036	Rasp – 6 mm, 11 x 14 mm

CATALOG #	DESCRIPTION
402-90041	Rasp – 7 mm, 11 x 14 mm
402-90042	Rasp – 8 mm, 11 x 14 mm
402-90043	Rasp – 9 mm, 11 x 14 mm
402-90044	Rasp – 10 mm, 11 x 14 mm
402-90314	Rasp – 5 mm, 13 x 16 mm

PLUS sizes ranging from 11—14 mm available upon request only

6 mm, 11 x 11 mm

7 mm, 11 x 11 mm

8 mm, 11 x 11 mm

9 mm, 11 x 11 mm

10 mm, 11 x 11 mm

5 mm, 11 x 14 mm

6 mm, 11 x 14 mm

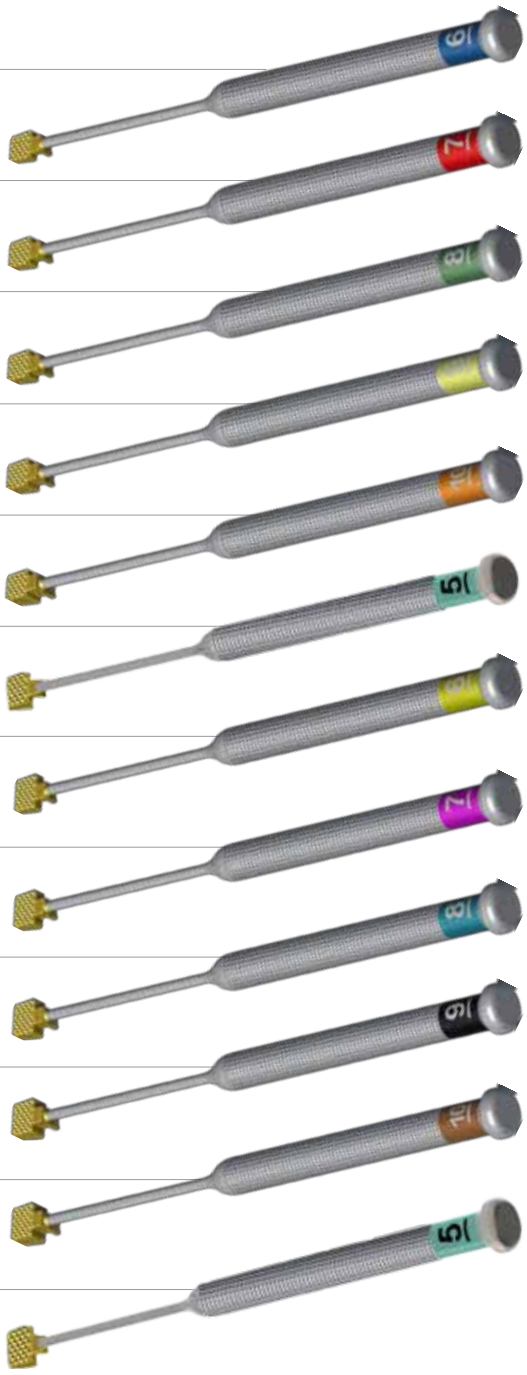
7 mm, 11 x 14 mm

8 mm, 11 x 14 mm

9 mm, 11 x 14 mm

10 mm, 11 x 14 mm

5 mm, 13 x 16 mm



CATALOG #	DESCRIPTION
402-90048	Small Mallet
402-90035	Impactor
402-90010	11 x 11 mm Inserter
402-90090	11 x 14 mm Inserter
402-90232	13 x 16 mm Inserter
402-90237	Inner Shaft

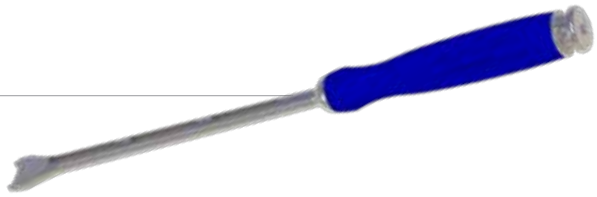
SMALL MALLET

IMPACTOR

11 x 11 mm INSERTER

11 x 14 mm INSERTER

13 x 16 mm INSERTER



INNER SHAFT

⚠ 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 accordingto 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 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 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®

CERVICAL INTERBODY SYSTEM

The ALEUTIAN Cervical Interbody System has a full range of unique and anatomically-designed PEEK interbodies for cervical spinal applications. The system is available with a complete offering of preparation and insertion instruments.

K2M

www.K2M.com

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