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Technique Guide
for PLIF and TLIF, ALIF and LLIF procedures

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Interbody fusion has become increasingly popular among surgeons who are looking to improve patient outcomes following lumbar fusion. The purpose of interbody fusion techniques includes:

1. Anatomic Alignment
   Restoration of normal spinal alignment to improve the biomechanics of the spine
2. Stable Internal Fixation
   Stabilization of the spinal segment to promote spinal fusion
3. Preservation of Blood Supply
   Creation of an optimal environment for fusion
4. Early Pain Free Mobilization
   Minimization of damage to the spinal vasculature, dura and neural elements, which may contribute to pain reduction and improved function for the patient.

K7 provides instrumentation and implants for the following interbody fusion techniques:

- K7A – Anterior Lumbar Interbody Fusion
- K7L – Lateral Lumbar Interbody Fusion
- K7T – Transforaminal Interbody Fusion
- K7P – Posterior Lumbar Interbody Fusion

Caution

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

General Description

The K7 Lumbar Spacers is a collection of lumbar interbody fusion devices constructed from medical grade polyetheretherketone (VESTAKEEP® i4 R) with tantalum markers as described in ASTM F-2026 and ASTM F-560, respectively. The K7 Lumbar Spacers are comprised of various heights and footprints to accommodate individual patient anatomy and to maximize autograft material volume. The K7 Lumbar Spacers are to be used with FDA-cleared supplemental fixation, e.g., facet screws, pedicle screw systems, plate and screw systems, and other fixation systems cleared for use in the lumbar spine as applicable.

Indications for Use

The K7 Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion.

Contraindications

The Use of the K7 Lumbar Spacers and spinal fusion surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Prior fusion at the level(s) to be treated is a contraindication. Any condition not described in the Indications for Use is a contraindication. Condition(s) that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity.

Warning and Precautions

1. The K7 Lumbar Spacers should only be implanted by surgeons experienced in the use of these implants and the associated spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for the implantation of these devices.
2. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
3. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.
4. The K7 Lumbar Spacers are used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used.
5. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
6. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
7. Components of this system should not be used with components of any other system or manufacturer.
8. The K7 Lumbar Spacers has not been evaluated for safety and compatibility in the MR environment. The K7 Lumbar Spacers has not been tested for heating or migration in the MR environment.
9. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury

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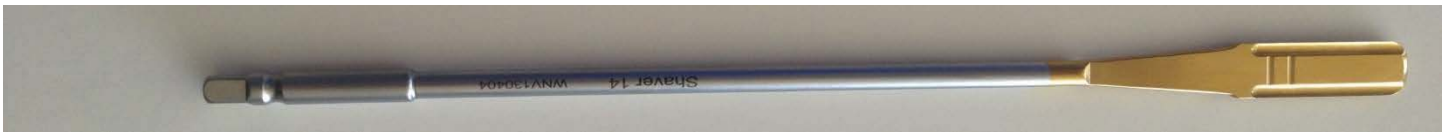
INTERBODY FUSION
K7 Lumbar Spacers

Standard Instruments

Endplate Shaver

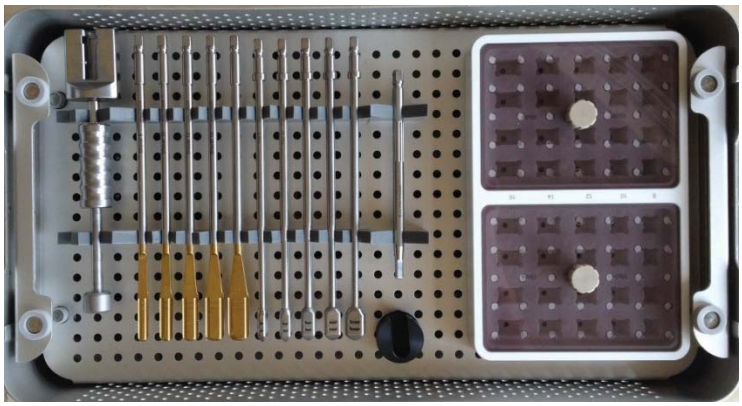


Trial/Distractor

Inserter

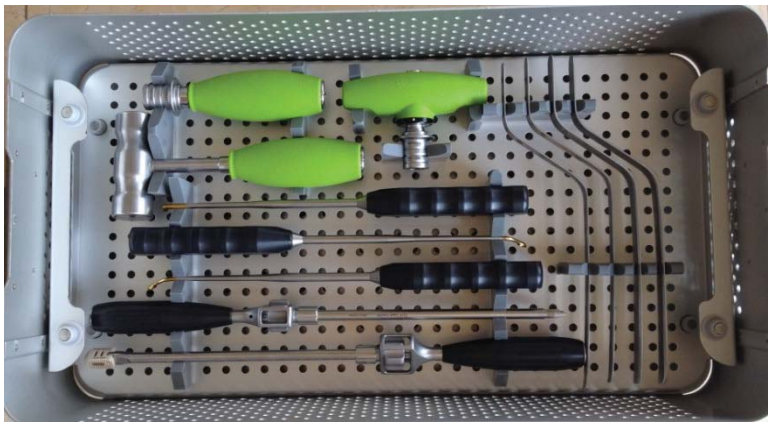
INTERBODY FUSION
K7 Lumbar Spacers

Typical Instrument Trays



Level 1

Implant Caddy
Standard shavers
Trials
Slap Hammer
Bone Chip impactor

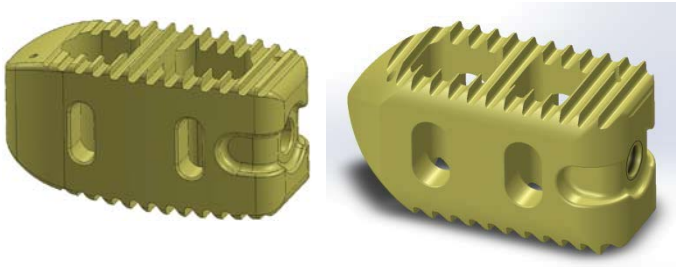


Level 2

Hammer
Nerve root retractors (10 & 14mm)
Implant inserter (2)
T-Handle
I-Handle

POSTERIOR LUMBAR INTERBODY FUSION

PLIF Implants

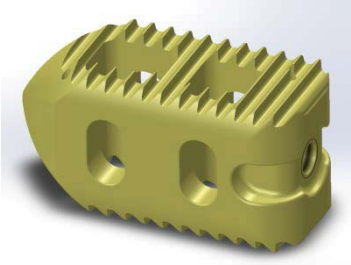


IMPLANT	8	10	12	14	16
Regular 10 x 24	✓	✓	✓	✓	✓
Large 10 X 28	✓	✓	✓	✓	✓

K7 provides implants in a curved and standard design in regular and large implant lengths. All are available in 2mm incremental heights ranging from 8mm to 16 mm.

POSTERIOR LUMBAR INTERBODY FUSION

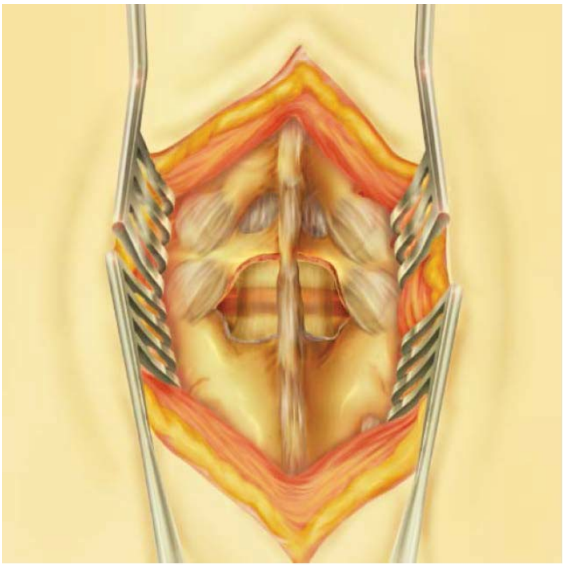
PLIF Surgical Technique



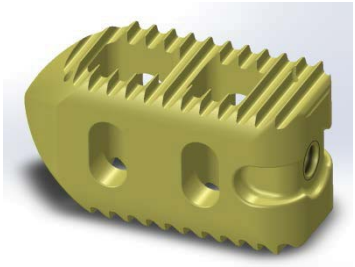
Step 1 - As with any surgical procedure care must be taken to ensure that the patient is adequately positioned. All bony prominences must be padded . The eyes and face should be checked by anesthesia. Chest rolls or special tables may be employed as needed for larger patients. The patient is prepped and draped.

Step 2- After a timeout to verify patient information and the surgical procedure an incision is made and dissection is carried out to the level of the lamina. A self retaining retractor is used for continuous exposure. Fluoroscopy should be used to verify the level of interest. With the correct level identified, the surgery may proceed.

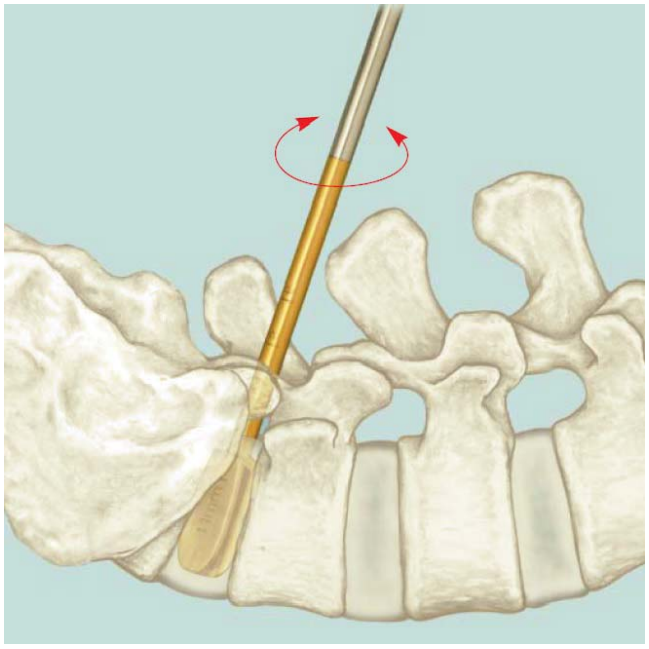
Step 3 - The surgeon, with proper illumination and magnification, may proceed to remove the lamina for exposure. The amount of bone removal will vary by patient and by level. In general a more extensive laminectomy will be necessary for upper lumbar levels than for those closer to the sacrum. It is essential that enough bone is removed to allow for clear visualization throughout the remainder of the procedure. Inadequate bone resection may lead to over retraction of the neurological structures during the remainder of the procedure If necessary, the entire lamina may be removed. On occasion, it may be appropriate to remove the entire facet joints as well.



POSTERIOR LUMBAR INTERBODY FUSION



Step 4 – Once the laminectomy has been accomplished and the foramina have been cleared, a nerve root retractor is used to cautiously retract the dura medially. The dura should never be retracted past the midline. Over retraction can lead to nerve injury



Step 5- With the neurological structures protected, the posterior annulus is resected with a knife and the disc space is cleared with the help of curettes , and pituitary rongeurs. After complete disc removal, the endplates are prepared with the end plate shaver . The shavers are provided in 2mm increments from 8-16 mm. The endplate shaver is rotated both clockwise and counter clockwise to remove the cartilage covering the endplates above and below . Curettes are then used to complete the endplate removal. All loose material should be removed from the disc space.

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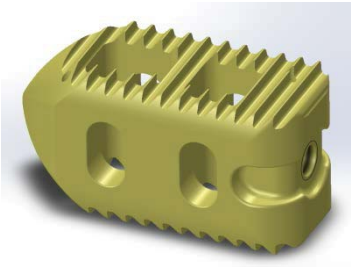
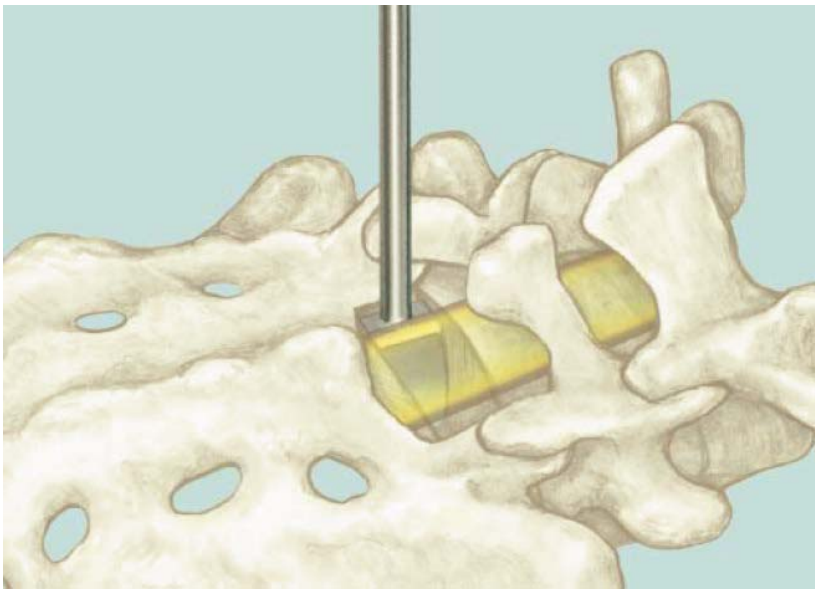
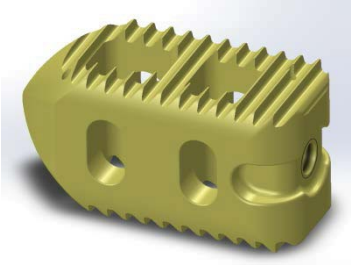
POSTERIOR LUMBAR INTERBODY FUSION



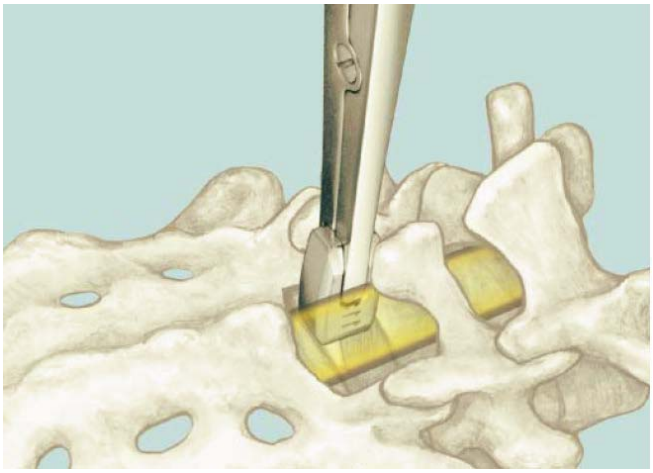


Step 6 - With the disc space properly prepared, the distractor/trials are used to determine the appropriate size implant. The trials are available in 2mm increments from 8-16 mm. The trial can be rotated within the disc space to assist in distraction. The trials are all 24 mm in length. Some distraction is desireable to provide compression of the implant following insertion . An appropriate size implant is selected . Fluoroscopy may be helpful in making a proper selection.

POSTERIOR LUMBAR INTERBODY FUSION

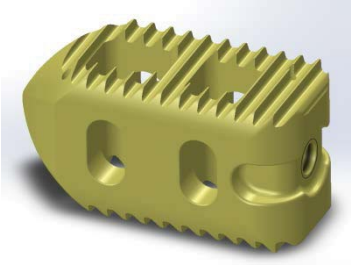


Step 7 - With the trials removed, the disc space is filled anteriorly with bone grafting material. The selected implant is filled with bone grafting material prior to insertion. The implant is then securely attached to the inserted. With the nerve root retractor protecting the nerves, the implant is then inserted into the disc space. The cage should be advanced forward into the disc space. The leading end of the K7P implant is shaped to facilitate insertion, however a few small taps with a mallet may be used as needed. The position of the cage should be confirmed both visually and with fluoroscopy.



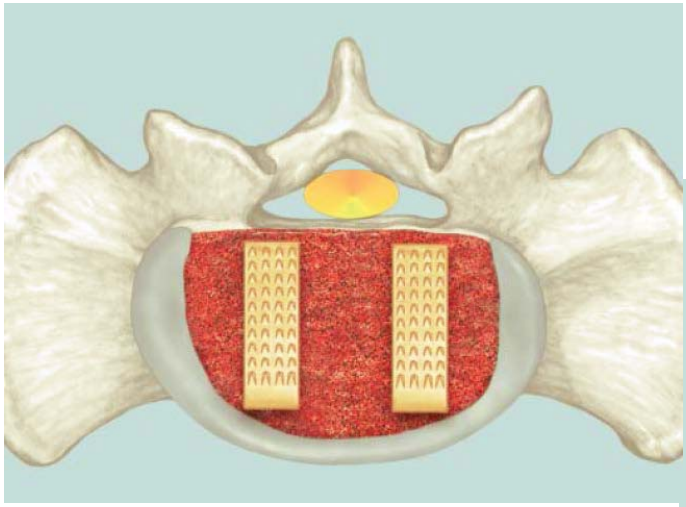
The implant should be fully within the disc space and deep enough to avoid any interaction with the thecal sac or nerve roots. The opposite side is then addressed in the same manner. If sufficient space is available, the contralateral trial may be left in place to facilitate insertion on the opposite side. Care must be taken not to retract the nerves into the shaft of the distractor in this situation.

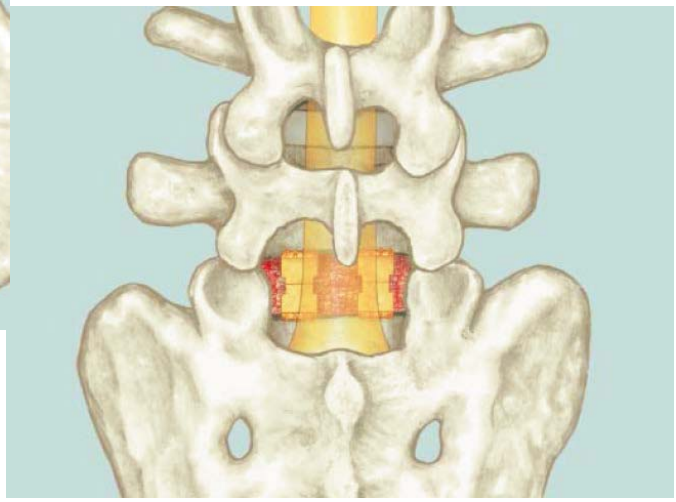
POSTERIOR LUMBAR INTERBODY FUSION



Step 8 - Additional bone grafting of the disc space may then be accomplished. Bone graft may be placed centrally prior to inserting the second implant. After the disc space has been grafted, the retractor is removed.

Step 9 - After confirmation of spacer placement, supplemental fixation is then implanted. The wound is then closed in the standard fashion. Bracing and a mobilization are determined by the operating surgeon.





Removal: Spacer removal can be accomplished by attaching the inserter and gently removing the implant. Vertebral bone overgrowth or scar tissue may need to be addressed to facilitate removal.

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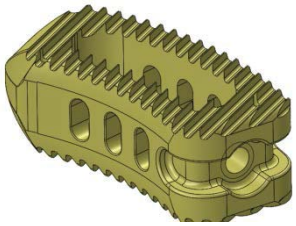
TRANSFORAMINAL LUMBAR INTERBODY FUSION

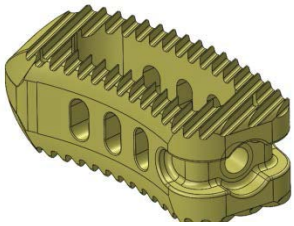


TLIF Implants

IMPLANT	8	10	12	14	16
12 X 30 12 X 36	✓	✓	✓	✓	✓
14 X 30 14 X 36	✓	✓	✓	✓	✓

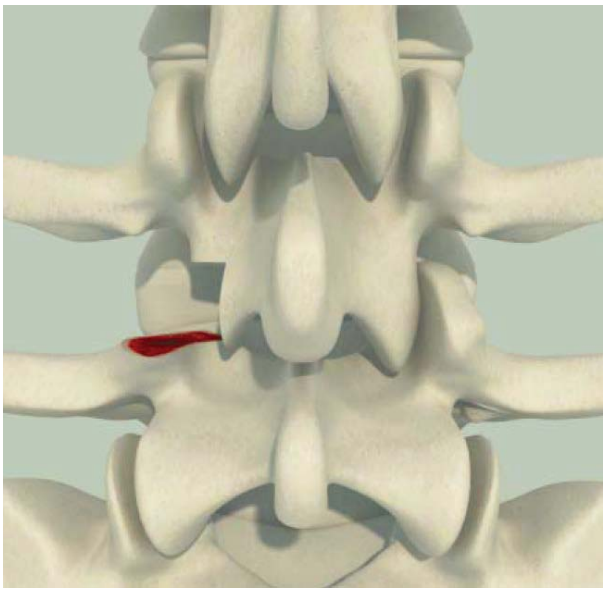
K7 provides TLIF implants in four footprints.
All are available in 2mm incremental heights from 8mm to 16mm.

TRANSFORAMINAL LUMBAR INTERBODY FUSION

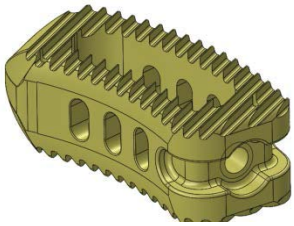


Transforaminal lumbar interbody fusion, or TLIF, is an increasingly popular option among surgeons who wish to support the anterior column while performing a fusion. The general principles discussed for PLIF procedures apply.

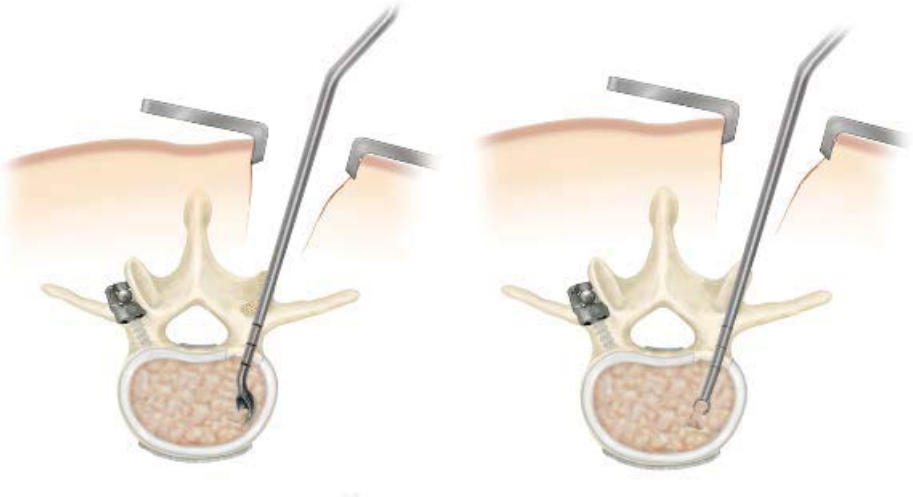
Step 1 – Complete resection of the facet joint is needed for adequate exposure. The lamina should be removed medially to the lateral margin of the dural sleeve.



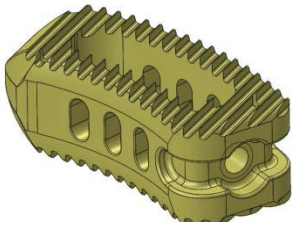
TRANSFORAMINAL LUMBAR INTERBODY FUSION



Step 2 – With the facet joint removed, the postero-lateral disc is exposed as well as the neurological structures. Care must be taken throughout the remainder of the procedure to protect the exiting nerve root. A knife is used to excise the postero-lateral corner of the disc annulus . A nerve root retractor should be used to protect the thecal sac. The disc preparation proceeds with the use of curettes and pituitary ronguers . The cartilage endplates must be resected as thoroughly as possible to facilitate fusion. The anterior and lateral annulus should not be disrupted.

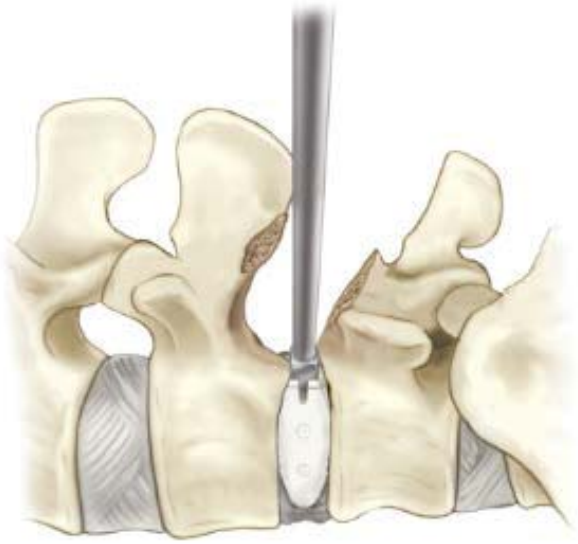


TRANSFORAMINAL LUMBAR INTERBODY FUSION

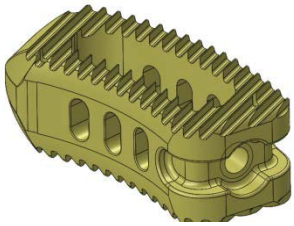


Step 3 - A rotary shaver may be used to assist in endplate removal if necessary. The shavers are identical to those used for the PLIF procedure , however their angle of insertion should coincide with the goal of graft placement. With the endplates prepared, the disc space is filled with bone graft anteriorly . Additional bone graft should be pushed across the disc space if possible to fill the contralateral side of the disc space.

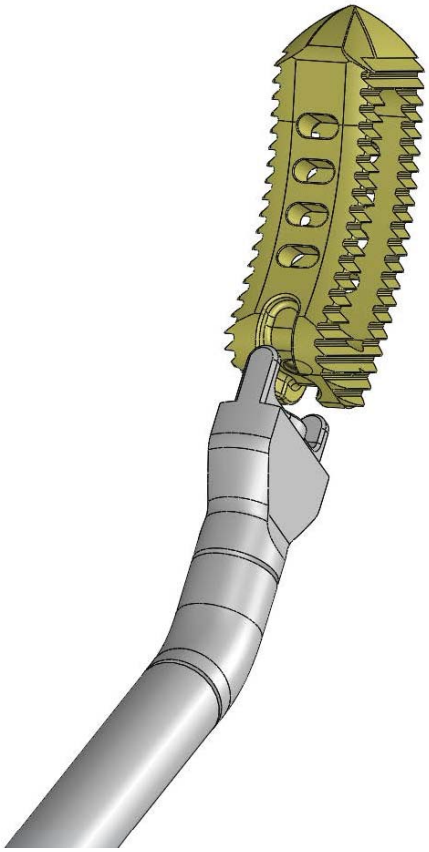
Step 4 - Selection of a properly sized implant is facilitated by placing a distractor/trial into the prepared disc space. The trial should fit securely and provide distraction as needed per the preoperative surgical goals. Special care should be taken to avoid compression of the exiting nerve root during this maneuver. Fluoroscopy may be useful in this evaluation.

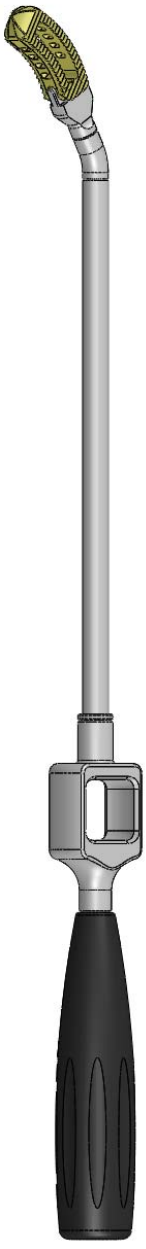


TRANSFORAMINAL LUMBAR INTERBODY FUSION

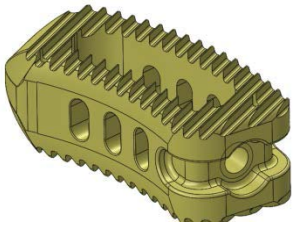


TLIF inserter attached to implant

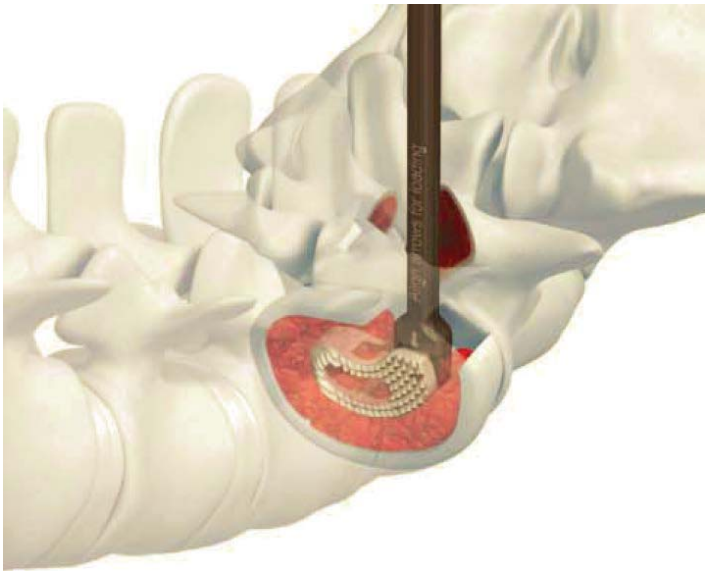




TRANSFORAMINAL LUMBAR INTERBODY FUSION

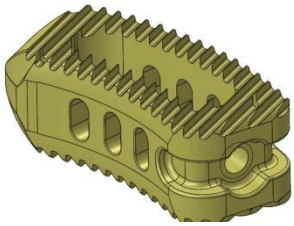


Step 6 – The implant is filled with bone graft material, and carefully inserted into the disc space while protecting the nerve root. The graft should fit securely within the confines of the disc space and should be under some compressive force from the distracted annulus. The position of the graft should be checked under fluoroscopy to ensure proper placement.



The TLIF exposure requires the complete resection of the facet joint on the side of attack.. Because of the instability inherently created with the TLIF procedure, pedicle screw fixation is recommended to achieve postoperative stability The contralateral facet joint is left intact and generally is incorporated into the fusion.

TRANSFORAMINAL LUMBAR INTERBODY FUSION

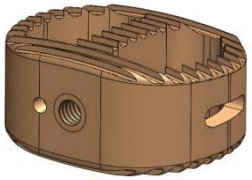


The addition of pedicle screw fixation provides additional stability in patients who undergo the TLIF procedure. After confirmation of spacer placement, supplemental fixation is then implanted.

Removal: Spacer removal can be accomplished by attaching the inserter and gently removing the implant. Vertebral bone overgrowth or scar tissue may need to be addressed to facilitate removal.

ANTERIOR LUMBAR INTERBODY FUSION

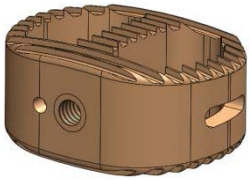
ALIF Implants



IMPLANT	6°	12°
Regular 30 X 24	✓	✓
Large 40 X 28	✓	✓

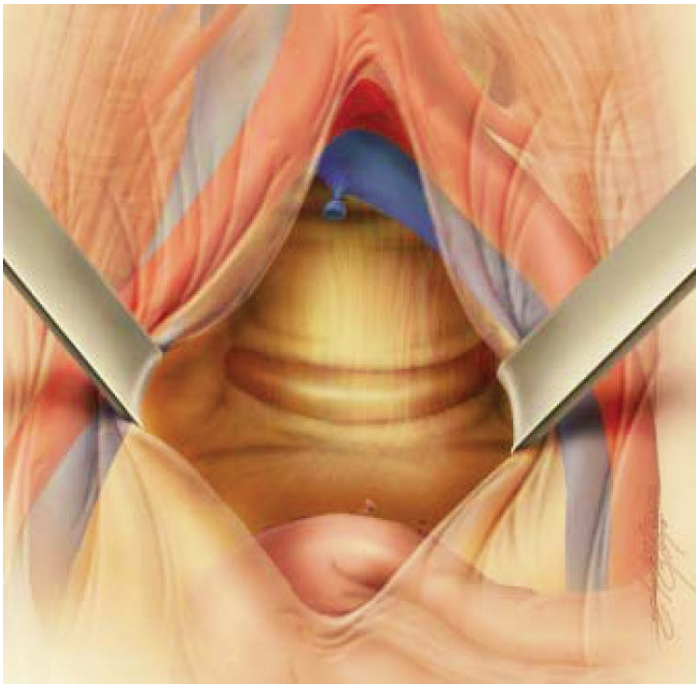
K7 provides ALIF implants in two footprints and two lordotic angles. All are available in 2mm incremental heights from 9 to 19mm.

ANTERIOR LUMBAR INTERBODY FUSION



The ALIF procedure can be accomplished through a retroperitoneal or transperitoneal approach. In either case, it is strongly recommended that the exposing surgeon has expertise in vascular dissection and repair.

Step 1 – The anterior lumbar spine is exposed . Exposure should be sufficient to allow the disc space to be accessed without placing the surrounding vascular structures in jeopardy. Care should be taken to minimize disturbance to the sympathetic plexus . A self retaining retractor is helpful in maintaining exposure throughout the procedure.



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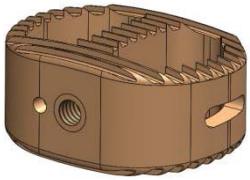
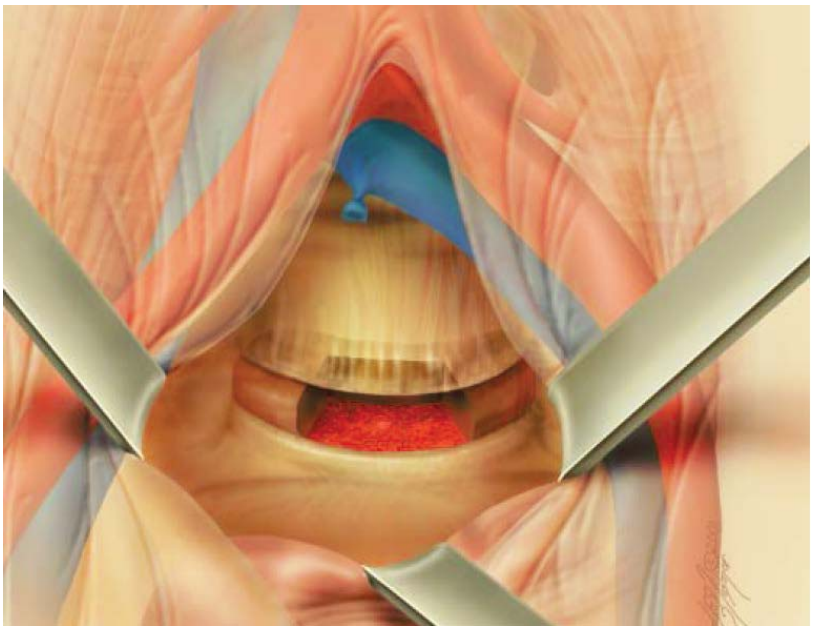
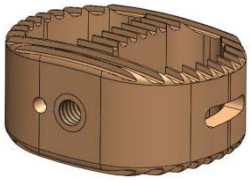
ANTERIOR LUMBAR INTERBODY FUSION



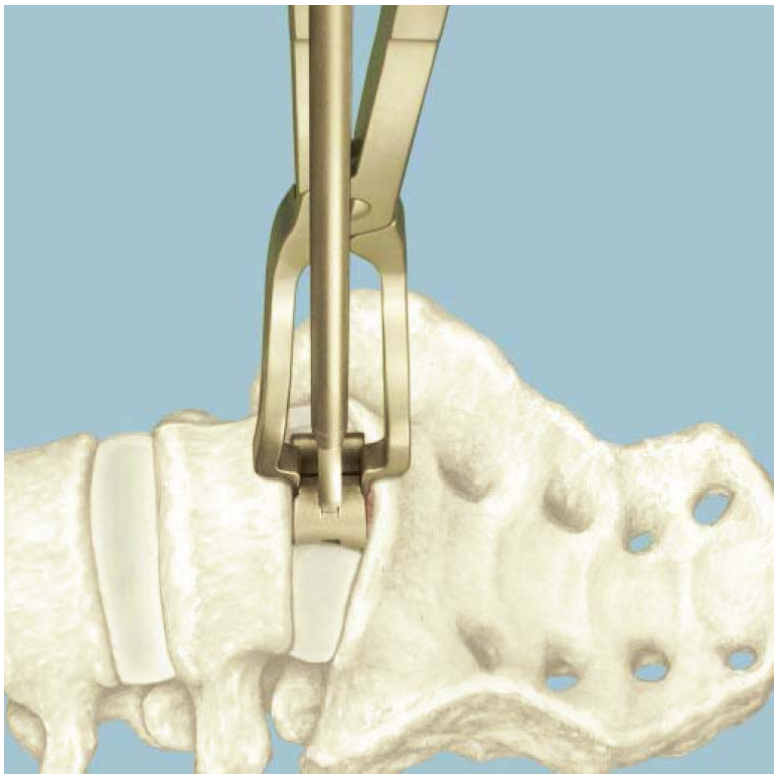
Step2 – The affected lumbar disc and cartilage enpplates are removed with the use of instruments at the surgeon deems appropriate. Cobb elevators are quite effective at separating the endplates from the underlying bone. Pituitary ronguers and currettes are generally sufficient to complete the disc space preparation.



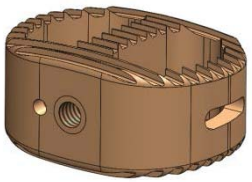
ANTERIOR LUMBAR INTERBODY FUSION



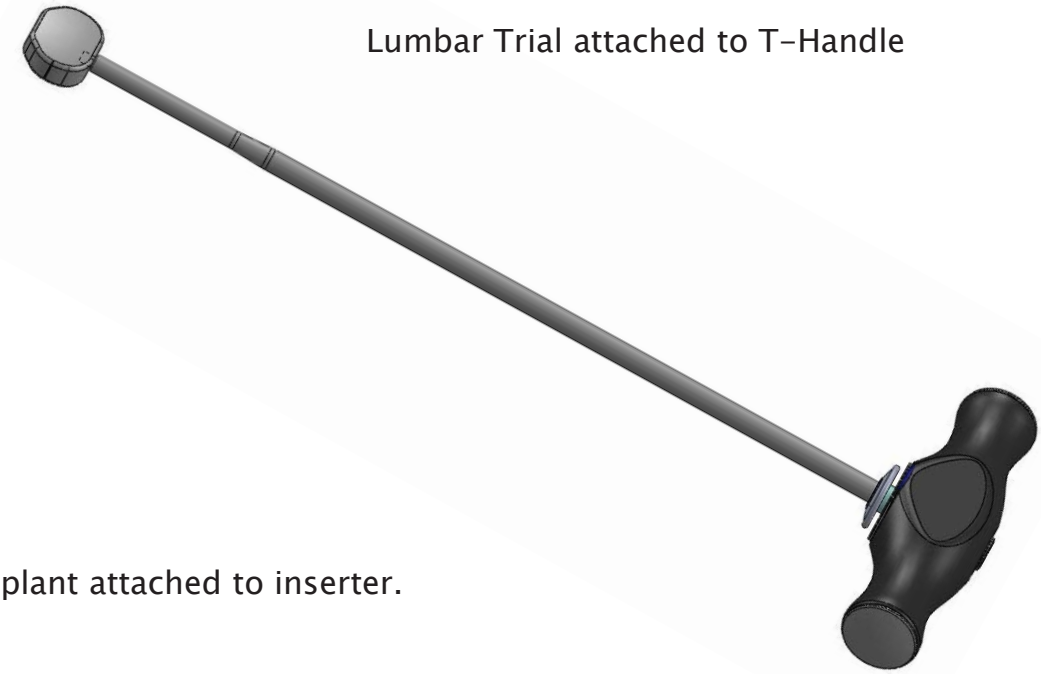
Step 3 – With the disc space adequately prepared, the surgeon should use the trials to select an optimal implant. The K7A ALIF spacer is provided in both standard and large sizes, with 6 and 12 degrees of lordosis. It is imperative that the surgeon fill the disc space as completely as possible with adequate distraction to hold the implant securely in place. A lamina spreader and/or fluoroscopy may be useful in making this determination.



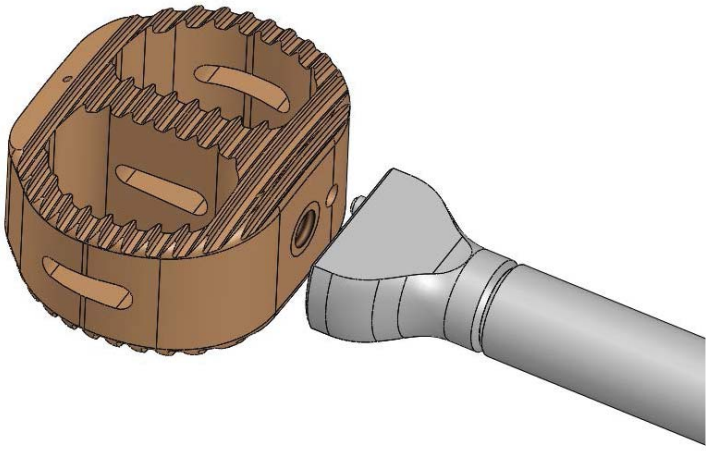
ANTERIOR LUMBAR INTERBODY FUSION



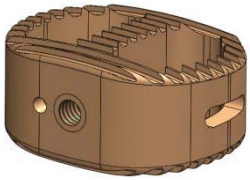
Lumbar Trial attached to T-Handle



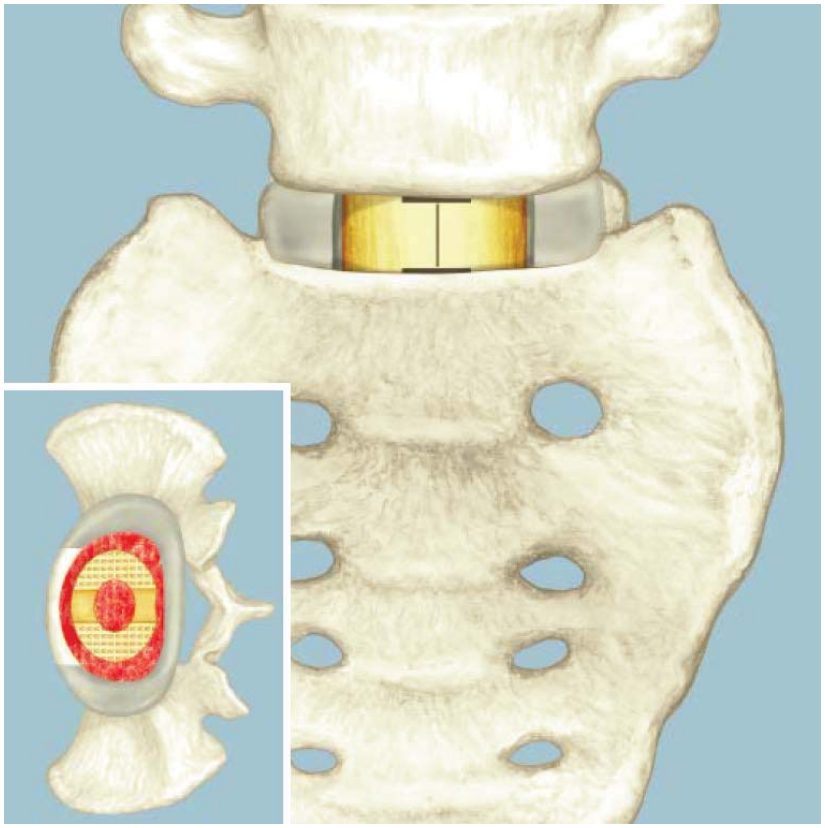
ALIF Implant attached to inserter.

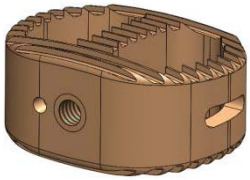


ANTERIOR LUMBAR INTERBODY FUSION

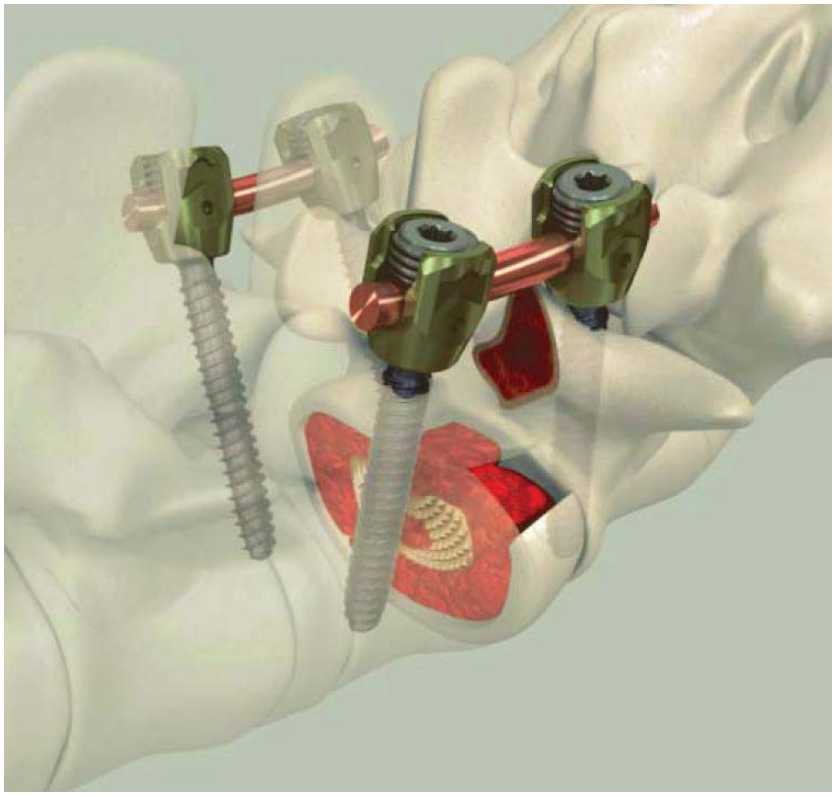


Step 4 – With the appropriate sized implant selected and loaded onto the inserter, the implant is filled with bone graft material. It is not recommended that bone graft be placed within the disc space prior to insertion. The implant is inserted and verified with fluoroscopy. Radiographic markers within the implant are helpful in making this assessment. The implant should be centered within the disc space and secure.





Step 5 – After confirmation of spacer placement, supplemental fixation is then implanted.

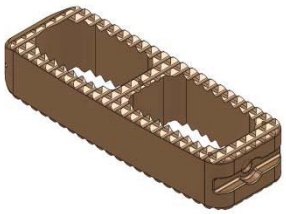


Removal: Spacer removal can be accomplished by attaching the inserter and gently removing the implant. Vertebral bone overgrowth or scar tissue may need to be addressed to facilitate removal.

ortemiz

LATERAL LUMBAR INTERBODY FUSION

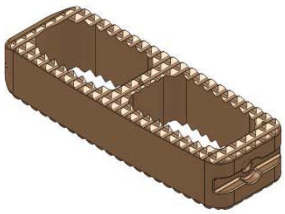
LLIF Implants



IMPLANT	40	45	50	55	60
Standard 16 X 0° and 8°	✓	✓	✓	✓	✓
Large 20 X 0° and 8°	✓	✓	✓	✓	✓

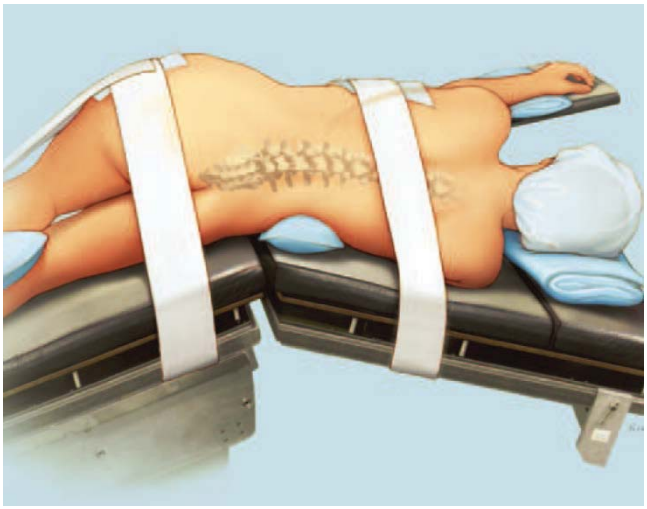
K7 offers LLIF implants in five lengths and two widths providing 10 footprints. Each footprint is available in two lordotic angles (0° and 8°). All are available in 2mm incremental heights from 8 to 18mm.

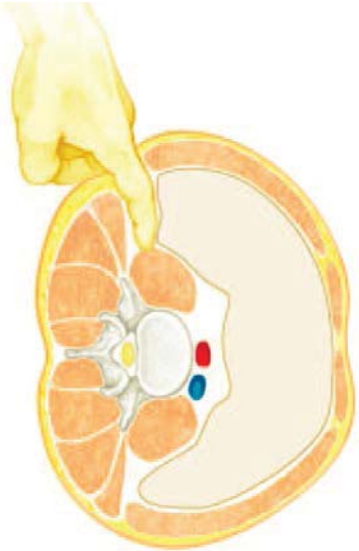
LATERAL LUMBAR INTERBODY FUSION



Over the past several years, lateral approaches to the spine have gained in popularity among spine surgeons. The lateral approach allows excellent access to the lumbar disc spaces from L2-L5. The L1-L2 disc may be approached in this manner, however the cruz of the diaphragm will likely be encountered. The L5-S1 disc can not be accessed through a lateral approach.

With the patient in the decubitus position, the approach is performed by bluntly entering the retro-peritoneum and proceeding through the ileo-psoas muscle to the lateral lumbar spine.





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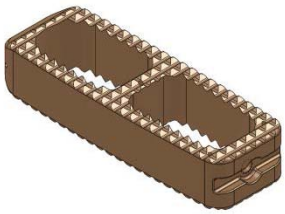
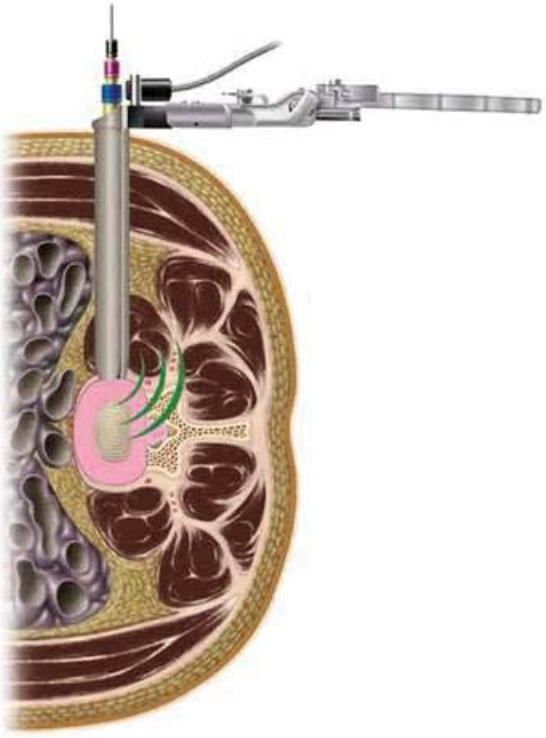
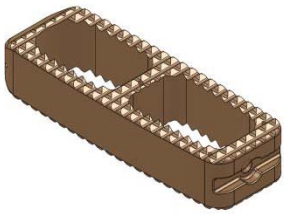


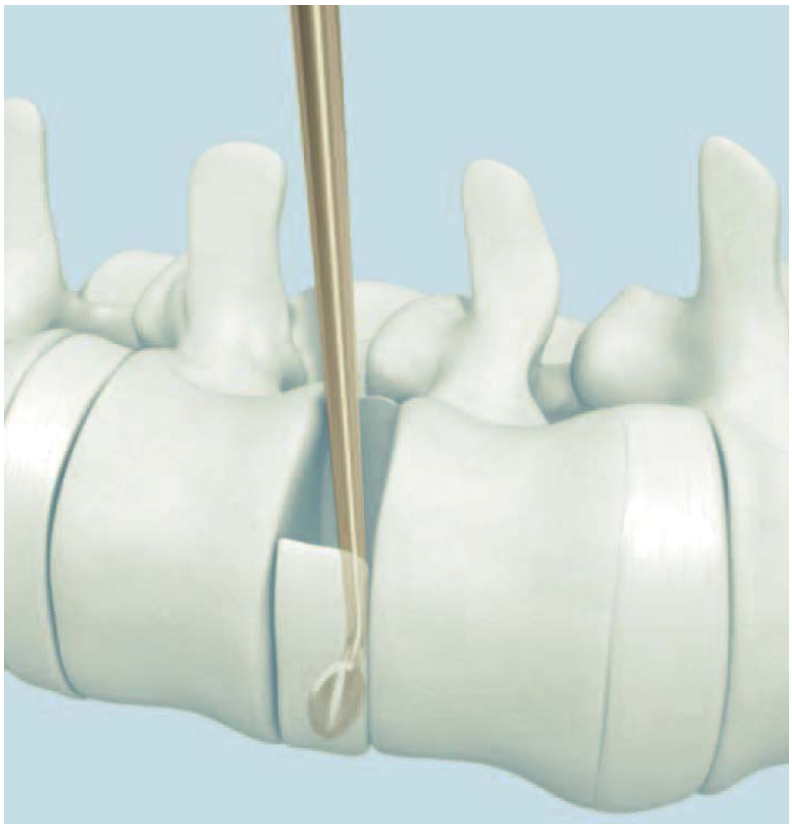
Under fluoroscopic guidance and with the assistance of neuro-monitoring, the lateral aspect of the disc space is identified and a guide wire is placed. Dilators are utilized to enlarge the viewing space and a self retaining retractor is placed. The importance of direct electrical stimulation during this phase can not be underestimated to avoid injury to the lumbar plexus which passes within the psoas muscle. This is particularly important at the L4-L5 level. K7 does not currently provide instrumentation for this purpose.



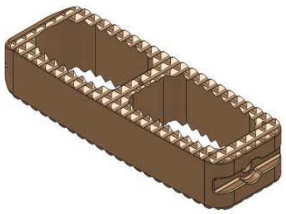
LATERAL LUMBAR INTERBODY FUSION



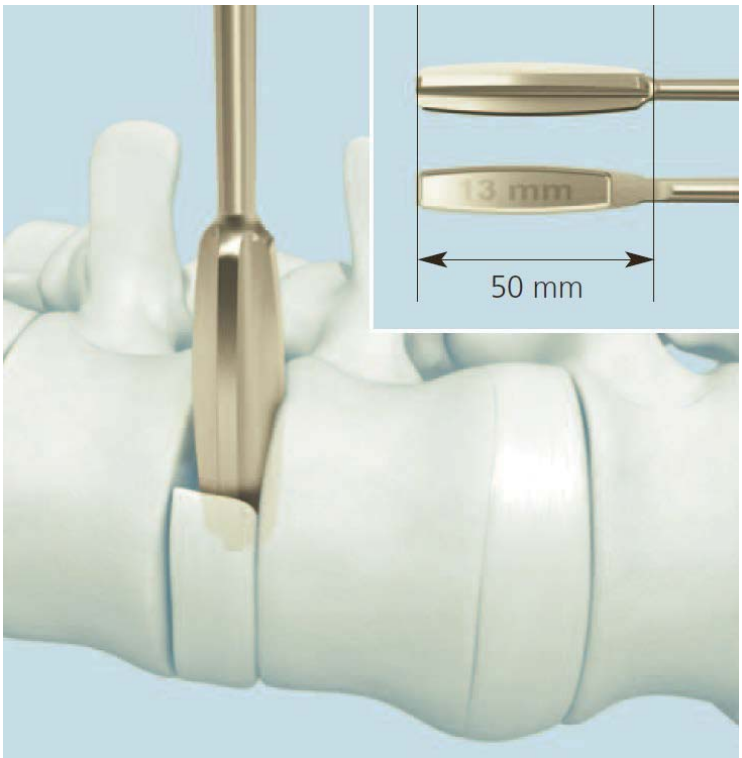
With the retractor securely in place, the surgeon must visualize the lateral annulus of the exposed disc.
The presence of any nerve passing through the retracted space must be excluded before proceeding with the annulectomy. The disc space is then removed with the assistance of elevators, curettes, rongeurs and rasps. The disc should be removed as completely as safely possible.



LATERAL LUMBAR INTERBODY FUSION



With the disc safely removed, the surgeon uses the trial/ distractors to help select an implant. If the disc is not completely removed before the trial is inserted, the trial may push any remaining disc material out the opposite side leading to nerve root irritation. K7 provided lateral fusion implants in sizes 40-60 mm in 5 mm increments. Standard and large sizes are available in both parallel and lordotic forms.



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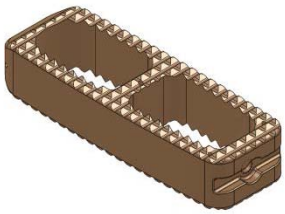
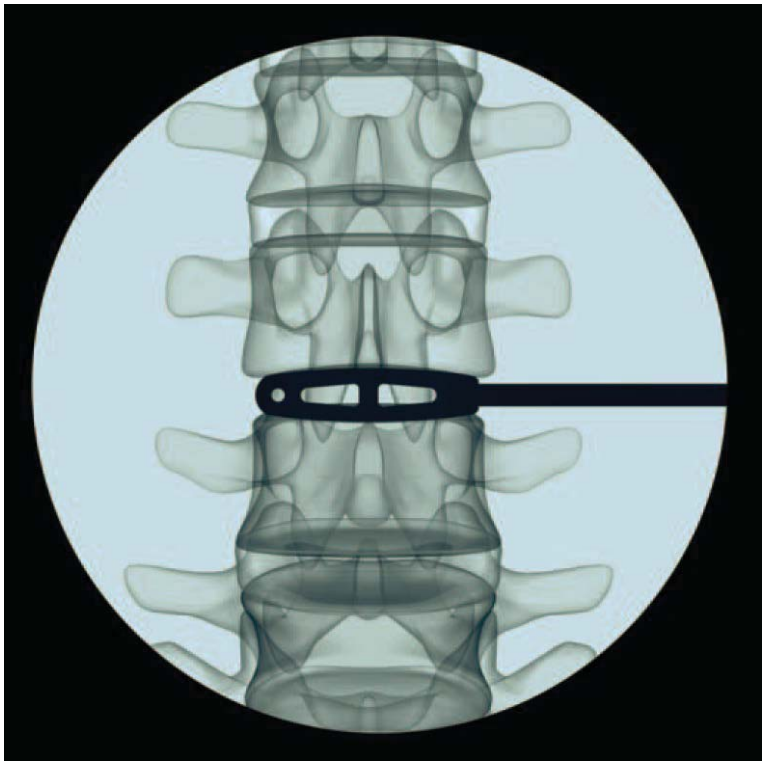


Proper sizing and positioning of the distractor/trial should be confirmed under fluoroscopy. The implant should provide equal support from both sides of the disc space. If needed the contralateral annulus can be released with a sharp elevator. The trial should fit securely within the confines of the disc space.



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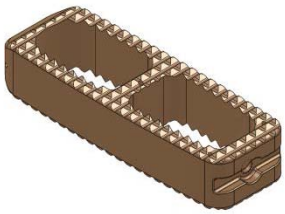
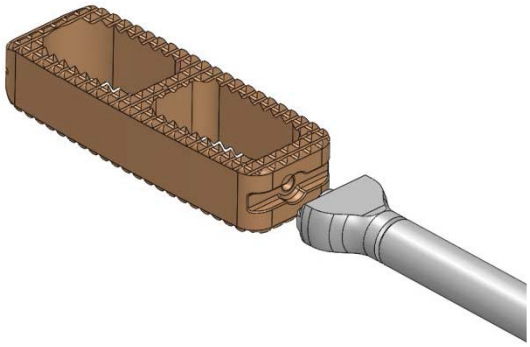


The trial is removed, with the assistance of a slap hammer if needed . The selected implant is attached to the inserter and filled with bone grafting material. The implant is then inserted . The implant should fit securely and be contained within the disc space.

The implant must be fully seated on the inserter before insertion.



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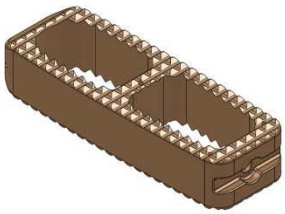
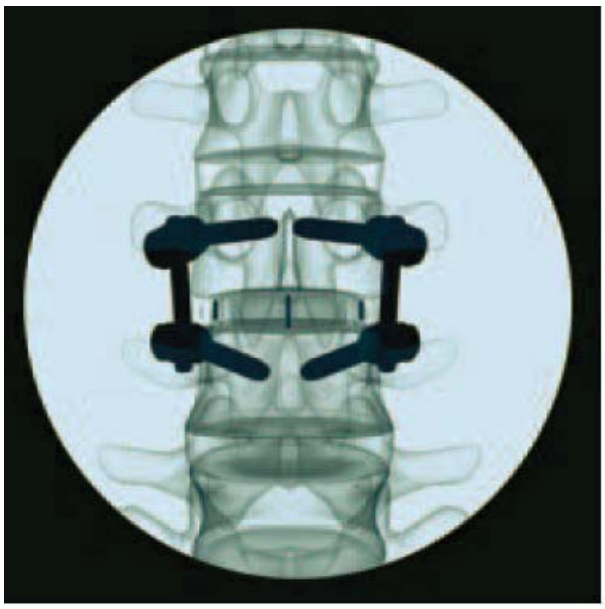
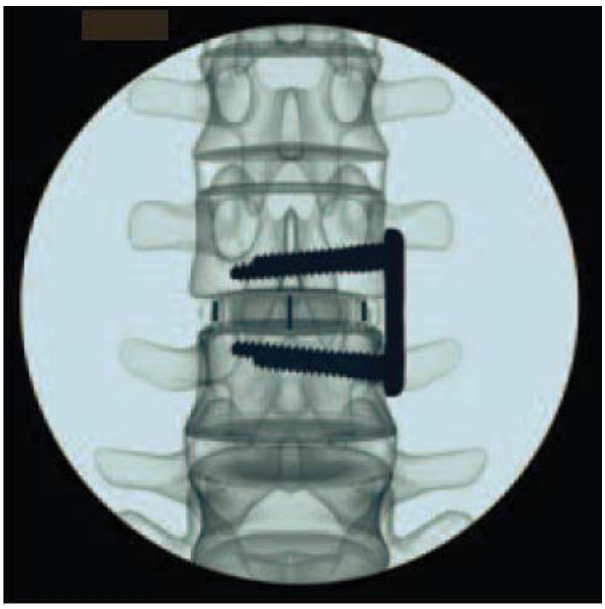


After confirmation of spacer placement, supplemental fixation is then implanted.





Removal: Spacer removal can be accomplished by attaching the inserter and gently removing the implant. Vertebral bone overgrowth or scar tissue may need to be addressed to facilitate removal.

ortemiz

Pragati Maidan, Nadupuru, Visakhapatnam,
Andhra Pradesh 530032.

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Ortemiz Lumbar Spacers Package Insert

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

GENERAL DESCRIPTION
The ortemiz Lumbar Spacers are a collection of lumbar interbody fusion devices constructed from medical grade polyetheretherketone (VESTAKEEP® i4 R) with tantalum markers as described in ASTM F-2026 and ASTM F-560, respectively. The ortemiz Lumbar Spacers are comprised of various heights and footprints to accommodate individual patient anatomy and to maximize autograft material volume. The ortemiz Lumbar Spacers are to be used with FDA-cleared supplemental fixation, e.g., facet screws, pedicle screw systems, plate and screw systems, and other fixation systems cleared for use in the lumbar spine as applicable.

IMPORTANT NOTE TO OPERATING SURGEON
The ortemiz Lumbar Spacers is designed to provide biomechanical environment for lumbar fusion and must be used with supplemental fixation. Without supplemental fixation, its use may not be successful. Spinal fusion should only be undertaken after the surgeon has had hands on training in this method and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure. The surgical technique can be requested by contacting **ortemiz** at the address or phone and fax numbers above.
Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary.

INDICATIONS FOR USE
The ortemiz Lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion.

CONTRAINDICATIONS
Use of the ortemiz Lumbar Spacers and spinal fusion surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Prior fusion at the level(s) to be treated is a contraindication. Any condition not described in the Indications for Use is a contraindication.

Condition(s) that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity.

WARNINGS AND PRECAUTIONS
1. The ortemiz Lumbar Spacers should only be implanted by surgeons experienced in the use of these implants and the associated spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for the implantation of these devices.
2. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
3. These devices are provided as single use only implants and are not to be reused or reimplanted

regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.

4. The ortemiz Lumbar Spacers are used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used.
5. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
6. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
7. Components of this system should not be used with components of any other system or manufacturer.
8. The ortemiz Lumbar Spacers has not been evaluated for safety and compatibility in the MR environment. The ortemiz Lumbar Spacers has not been tested for heating or migration in the MR environment.
9. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

POTENTIAL ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems and include, but are not limited to: Bending, fracture or loosening of implant component(s), nonunion or delayed union, fracture of the vertebra, neurological, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, infection, decrease in bone density due to stress shielding, pain, discomfort or abnormal sensations due to the presence of the device, nerve damage due to surgical trauma, bursitis, dural Leak, paralysis and death.

CLEANING AND DECONTAMINATION

All instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field. The general instructions below provide a sequence of steps required to prepare ortemiz surgical instruments for re-use or to prepare new instruments for use. As a precaution staff should always wear suitable protective clothing and equipment, no matter which method is used.

Point of Use	• Keep devices moist to prevent soil from drying and removing gross soil from the surfaces, crevices, mating surfaces, cannulas, joints, and all other challenging or hard-to-clean design features. • Begin instrument cleaning as soon as possible after use of the device but absolutely within 2 hours. • Following these practices will improve the effectiveness of subsequent cleaning procedures.
Transport to processing area	• Avoid damaging the devices during transport by separating heavy and delicate ones. • Do not overload instrument trays.
Pre-cleaning	• Presoak the surgical devices with an enzymatic solution, such as Enzol® by Advanced Sterilization Products, or equivalent, for a minimum of five minutes. Use the concentration, temperature and time not less than recommended by the enzymatic solution manufacturer. • Remove visible soil and debris from instrument surfaces using a soft-bristled nylon brush. Actuate movable features to expose all areas to solution. • Remove soil and debris from instrument challenging design features (such as cannulations, blind holes and the joints between movable parts) using a soft-bristled bottle brush, pipe cleaner and/or guide wire. Flush challenging design

	features using a syringe or water jet. • Rinse each instrument thoroughly with flowing, warm deionized or purified water for a minimum of one minute. • Inspect instruments for visible soil and repeat the process until no visible debris remains.
Mechanical cleaning	• Prepare a cleaning solution using low foaming, pH neutral detergent, such as Renu-Klenz™ by STERIS Corporation, or equivalent. Use the concentration, temperature and water quality (i.e., hardness, pH) as recommended by the detergent manufacturer. • Sonicate the devices for a minimum of fifteen (15) minutes. • Rinse each instrument thoroughly with flowing, warm deionized or purified water for a minimum of two minutes. Flush cannulations using a syringe or water jet of deionized or purified water. Make sure to irrigate any challenging design features. • Inspect instruments for visible soil. Repeat the cleaning steps until no visible soil remains.
Drying	• Thoroughly dry each device inside and out using a clean, soft, lint-free cloth. • Pay special attention to challenging design features (e.g., threads, ratchets and hinges) • Actuate movable features so that all areas are reached. • Use an air jet (clean compressed air) to reach challenging design features such as cannulas, blind holes and joints between movable parts.

STERILIZATION

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. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Cycle:	Pre-vacuum
Temperature	132°C (270°F)
Exposure time	4 minutes
Drying time	20 minutes

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Ortemiz LLC immediately. ortemiz LLC should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

MANUFACTURED FOR:

Ortemiz, LLC
Pragati Maidan, Nadupuru, Visakhapatnam,
Andhra Pradesh 530032.