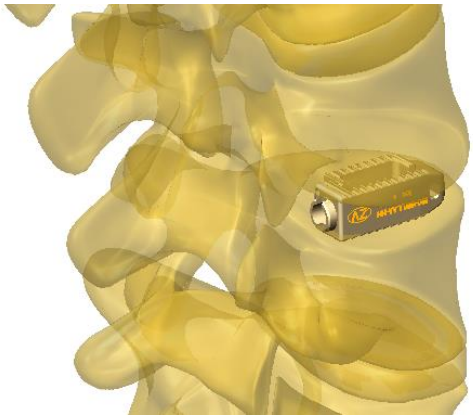
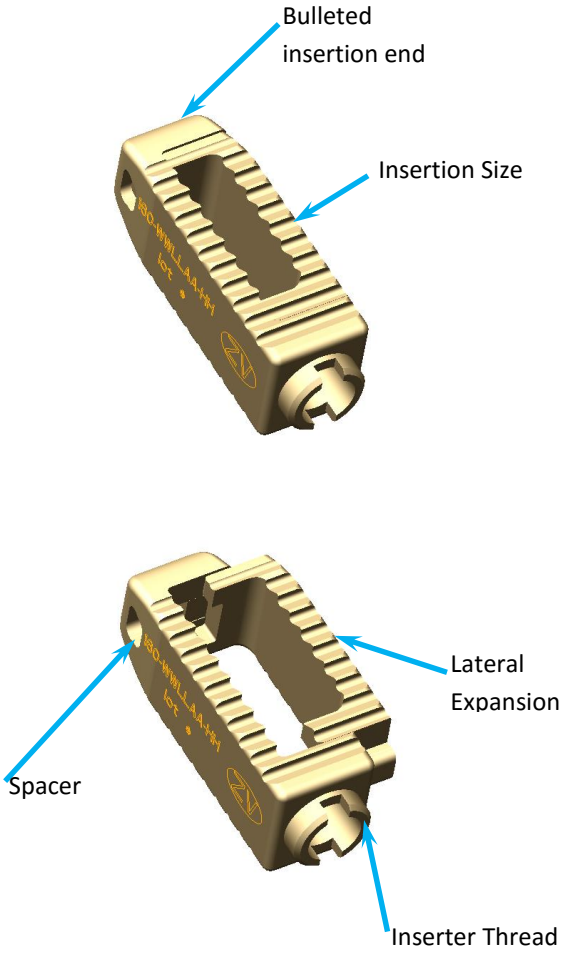
Zavation Posterior LEIF





Posterior Laterally Expanding Interbody Fusion (LEIF):

- Standard PEEK interbody insertion size
- Lateral expansion to increase width footprint after insertion
- Robust threaded connection for insertion
- Inserter provides working cannula for expansion and graft loading
- Bulleted insertion end
- Sizes:
  - Width: 9 or 11mm (initial)
    12.5 or 14.5mm(final)
  - Length: 23mm (bi-lateral use), 27mm, or 32mm
  - Height: 8 to 16mm
- Material
  - Implantable PEEK Zeniva per ASTM F2026
- Markers
  - Spheres: Tantalum per ASTM F560Material
  - Pins: Titanium per ASTM F-136

Surgical Technique for Zavation Posterior LEIF

Step 1

Surgical approach to the disc

A midline incision provides exposure of the interlaminar space and facet joints at the indicated level. Pedicle screws of the surgeons preference are inserted into the pedicles of the vertebrae adjacent to the disc space to be fused. Using a combination of surgical instruments (osteotomes, kerrison rongeurs, curettes, etc.) appropriately selected by the surgeon, a laminotomy, laminectomy and/or facetectomy, is performed, along with the removal of the ligamentum flavum, to gain access to the disc space and identify neural and bony anatomy. Use a standard transforaminal approach for insertion of the the 27mm and 32mm length devices. Use a standard bilateral posterior approach for insertion of the 23mm PLIF devices.

Step 2

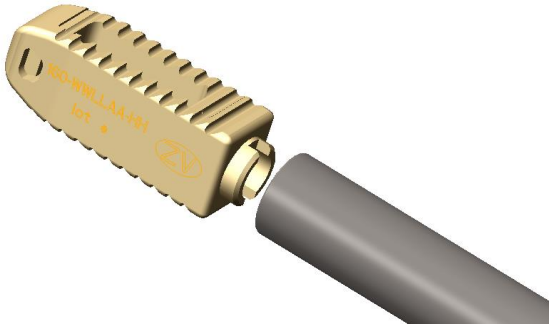
Freshening of the endplate

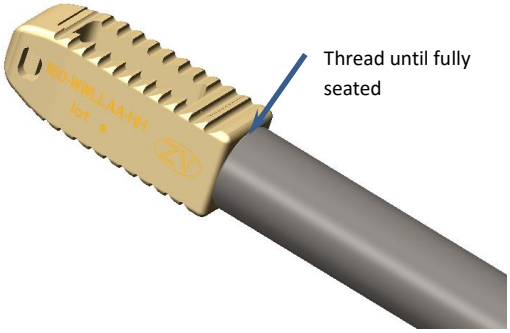
Perform a standard discectomy used with a posterior lumbar discectomy and fusion procedure. Use a curette or rasp to prepare the implant bed and the graft surfaces.

Step 3

Trial for implant size

Introduce the various sized trials into the intervertebral space to determine the height, width and degree of the implant. Note that trials are provided in insertion widths only and that the lateral expansion size is not included in the sizer.

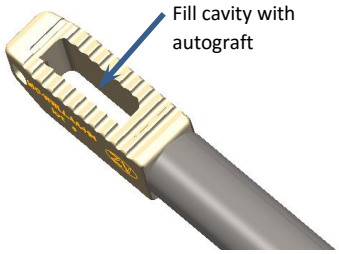




Step 4

Load Implant onto Inserter

Select the appropriate implant and then attach to the inserter instrument. Load implant onto the inserter by threading together until inserter is fully seated on the implant. Be careful not to over tighten.



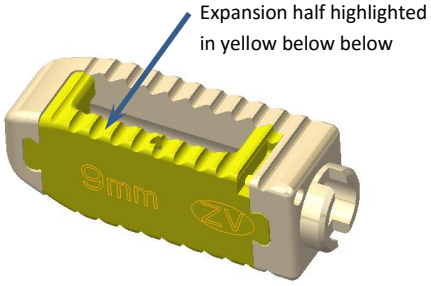
Step 5

Pack the implant with autograft

With the selected implant attached to the insertion instrument, fill the implant with autograft.

Step 6

Insert implant



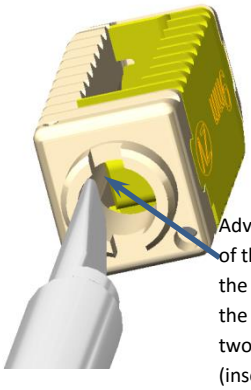
Insure that the “expansion half” is oriented in the direction for desired expansion, and gently insert into the disc space towards its final position. Verify the implant position relative to the vertebral bodies.

X-ray markers in the PEEK spacer enable intraoperative radiographic assessment of the implant position.

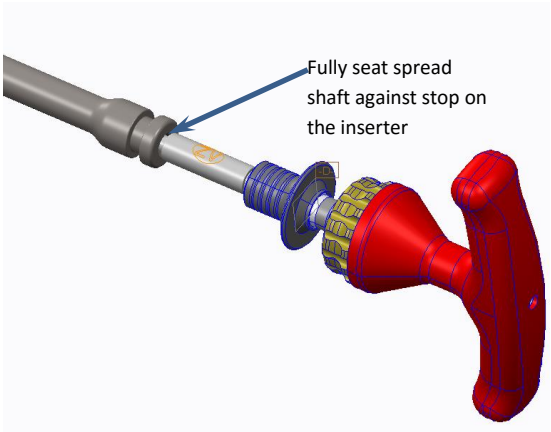
Step 7

Expand Implant

The implant can be expanded laterally. This is accomplished by inserting the Spreader instrument thru the inner cannula of the Inserter and into the cage.



Advance tapered end of the Spreader thru the inserter and into the slot between the two cage halves (inserter not shown in figure)



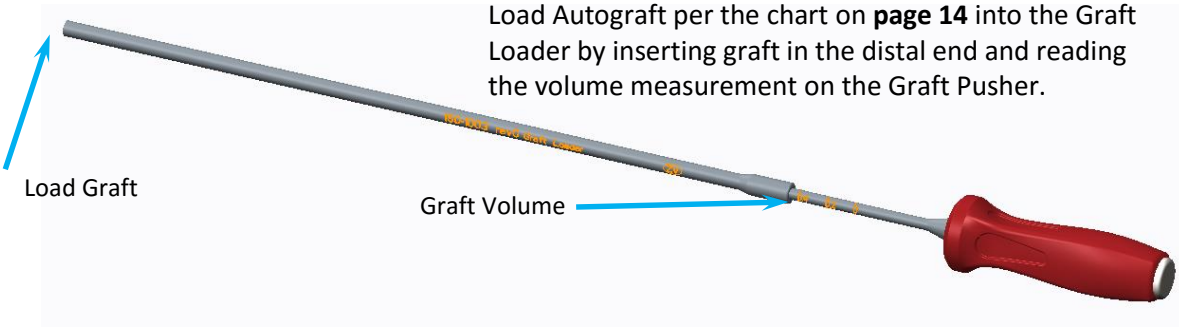
The initial expansion is accomplished by advancing the tapered spreader into the cage. Note that the spreader must be inserted in the location shown in the figure. Correct orientation of the Spreader tip is easily determined by tactile feedback. Insure the Spreader is fully seated as shown before proceeding to the next step.

Expansion is completed by rotating the Spreader instrument. Rotate the Spreader a few degrees alternating clockwise and counter clockwise and gradually increasing the amount of rotation until the spreader can be rotated freely a complete rotation. When the spreader can be rotated freely a full rotation, the implant is fully expanded.

Step 8

Load Autograft

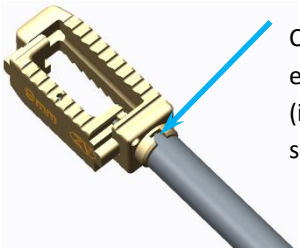
Load Autograft per the chart on **page 14** into the Graft Loader by inserting graft in the distal end and reading the volume measurement on the Graft Pusher.



With the appropriate amount of autograft loaded in the Graft Loader, insert the Graft Loader into the inserter, and then push the Autograft into the implant by advancing the Graft pusher.

Step 9

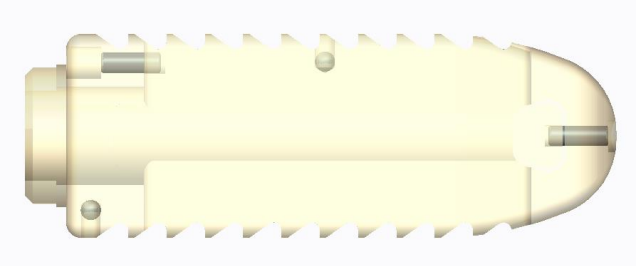
Remove Inserter

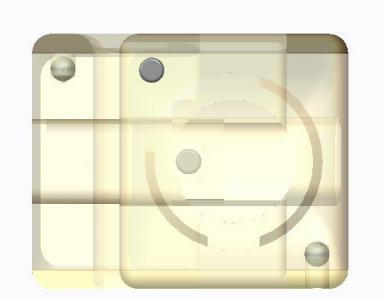


Counter torque engaging slots (inserter not shown)

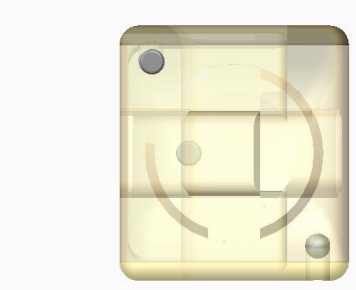
Inserter is removed from the implant by inserting the Counter Torque into the central cannula of the inserter. Rotate the counter torque until it engages the slot in the end of the implant and then unthread the Inserter by rotating it counter clockwise.

Confirm final placement of the implant radiographically.





Open Position



Closed position

Step 10

Implant removal

Thread the inserter onto the implant, and gently remove the implant from disc space. If the implant cannot be easily removed, a cobb elevator or osteotome should be used to loosen the bone to implant interface. The slap hammer can also be connected to the end of the inserter to aid in removal.

If the implant needs to be closed prior to removal, use a small cup curette to remove graft from the implant interior, and then close the implant by compressing from the exterior walls of the implant with two small curettes.

Part#	Description	Graft Volume to add
INSTRUMENTS		
160-1000	Inserter	
160-1001	Counter Torque	
160-1002	Spreader	
160-1003	Graft loader	
160-1004	Graft pusher	
160S-WWLLAA-HH	LEIF Sizers	
100-1008	Slap Hammer	
Z-1009	T-Handle	
IMPLANTS		
160-092300-08	LEIF 9x23x0deg -8	0.43
160-092300-09	LEIF 9x23x0deg -9	0.48
160-092300-10	LEIF 9x23x0deg -10	0.53
160-092300-11	LEIF 9x23x0deg -11	0.59
160-092300-12	LEIF 9x23x0deg -12	0.64
160-092300-13	LEIF 9x23x0deg -13	0.69
160-092300-14	LEIF 9x23x0deg -14	0.75
160-092300-15	LEIF 9x23x0deg -15	0.80
160-092300-16	LEIF 9x23x0deg -16	0.85
160-092305-08	LEIF 9x23x5deg -8	0.43
160-092305-09	LEIF 9x23x5deg -9	0.48
160-092305-10	LEIF 9x23x5deg -10	0.53
160-092305-11	LEIF 9x23x5deg -11	0.59
160-092305-12	LEIF 9x23x5deg -12	0.64
160-092305-13	LEIF 9x23x5deg -13	0.69
160-092305-14	LEIF 9x23x5deg -14	0.75
160-092305-15	LEIF 9x23x5deg -15	0.80
160-092305-16	LEIF 9x23x5deg -16	0.85
160-092700-08	LEIF 9x27x0deg -8	0.54
160-092700-09	LEIF 9x27x0deg -9	0.61
160-092700-10	LEIF 9x27x0deg -10	0.68
160-092700-11	LEIF 9x27x0deg -11	0.74
160-092700-12	LEIF 9x27x0deg -12	0.81
160-092700-13	LEIF 9x27x0deg -13	0.88
160-092700-14	LEIF 9x27x0deg -14	0.95
160-092700-15	LEIF 9x27x0deg -15	1.01
160-092700-16	LEIF 9x27x0deg -16	1.08
160-092705-08	LEIF 9x27x5deg -8	0.54

Part#	Description	Graft Volume to add
160-092705-09	LEIF 9x27x5deg -9	0.61
160-092705-10	LEIF 9x27x5deg -10	0.68
160-092705-11	LEIF 9x27x5deg -11	0.74
160-092705-12	LEIF 9x27x5deg -12	0.81
160-092705-13	LEIF 9x27x5deg -13	0.88
160-092705-14	LEIF 9x27x5deg -14	0.95
160-092705-15	LEIF 9x27x5deg -15	1.01
160-092705-16	LEIF 9x27x5deg -16	1.08
160-093200-08	LEIF 9x32x0deg -8	0.68
160-093200-09	LEIF 9x32x0deg -9	0.77
160-093200-10	LEIF 9x32x0deg -10	0.85
160-093200-11	LEIF 9x32x0deg -11	0.94
160-093200-12	LEIF 9x32x0deg -12	1.02
160-093200-13	LEIF 9x32x0deg -13	1.11
160-093200-14	LEIF 9x32x0deg -14	1.19
160-093200-15	LEIF 9x32x0deg -15	1.28
160-093200-16	LEIF 9x32x0deg -16	1.37
160-093205-08	LEIF 9x32x5deg -8	0.68
160-093205-09	LEIF 9x32x5deg -9	0.77
160-093205-10	LEIF 9x32x5deg -10	0.85
160-093205-11	LEIF 9x32x5deg -11	0.94
160-093205-12	LEIF 9x32x5deg -12	1.02
160-093205-13	LEIF 9x32x5deg -13	1.11
160-093205-14	LEIF 9x32x5deg -14	1.19
160-093205-15	LEIF 9x32x5deg -15	1.28
160-093205-16	LEIF 9x32x5deg -16	1.37
160-112300-08	LEIF 11x23x0deg -8	0.00
160-112300-09	LEIF 11x23x0deg -9	0.43
160-112300-10	LEIF 11x23x0deg -10	0.48
160-112300-11	LEIF 11x23x0deg -11	0.53
160-112300-12	LEIF 11x23x0deg -12	0.59
160-112300-13	LEIF 11x23x0deg -13	0.64
160-112300-14	LEIF 11x23x0deg -14	0.69
160-112300-15	LEIF 11x23x0deg -15	0.75
160-112300-16	LEIF 11x23x0deg -16	0.80
160-112305-08	LEIF 11x23x5deg -8	0.85
160-112305-09	LEIF 11x23x5deg -9	0.43
160-112305-10	LEIF 11x23x5deg -10	0.48
160-112305-11	LEIF 11x23x5deg -11	0.53
160-112305-12	LEIF 11x23x5deg -12	0.59

Part#	Description	Graft Volume to add
160-112305-13	LEIF 11x23x5deg -13	0.64
160-112305-14	LEIF 11x23x5deg -14	0.69
160-112305-15	LEIF 11x23x5deg -15	0.75
160-112305-16	LEIF 11x23x5deg -16	0.80
160-112700-08	LEIF 11x27x0deg -8	0.85
160-112700-09	LEIF 11x27x0deg -9	0.54
160-112700-10	LEIF 11x27x0deg -10	0.61
160-112700-11	LEIF 11x27x0deg -11	0.68
160-112700-12	LEIF 11x27x0deg -12	0.74
160-112700-13	LEIF 11x27x0deg -13	0.81
160-112700-14	LEIF 11x27x0deg -14	0.88
160-112700-15	LEIF 11x27x0deg -15	0.95
160-112700-16	LEIF 11x27x0deg -16	1.01
160-112705-08	LEIF 11x27x5deg -8	1.08
160-112705-09	LEIF 11x27x5deg -9	0.54
160-112705-10	LEIF 11x27x5deg -10	0.61
160-112705-11	LEIF 11x27x5deg -11	0.68
160-112705-12	LEIF 11x27x5deg -12	0.74
160-112705-13	LEIF 11x27x5deg -13	0.81
160-112705-14	LEIF 11x27x5deg -14	0.88
160-112705-15	LEIF 11x27x5deg -15	0.95
160-112705-16	LEIF 11x27x5deg -16	1.01
160-113200-08	LEIF 11x32x0deg -8	1.08
160-113200-09	LEIF 11x32x0deg -9	0.68
160-113200-10	LEIF 11x32x0deg -10	0.77
160-113200-11	LEIF 11x32x0deg -11	0.85
160-113200-12	LEIF 11x32x0deg -12	0.94
160-113200-13	LEIF 11x32x0deg -13	1.02
160-113200-14	LEIF 11x32x0deg -14	1.11
160-113200-15	LEIF 11x32x0deg -15	1.19
160-113200-16	LEIF 11x32x0deg -16	1.28
160-113205-08	LEIF 11x32x5deg -8	1.37
160-113205-09	LEIF 11x32x5deg -9	0.68
160-113205-10	LEIF 11x32x5deg -10	0.77
160-113205-11	LEIF 11x32x5deg -11	0.85
160-113205-12	LEIF 11x32x5deg -12	0.94
160-113205-13	LEIF 11x32x5deg -13	1.02
160-113205-14	LEIF 11x32x5deg -14	1.11
160-113205-15	LEIF 11x32x5deg -15	1.19
160-113205-16	LEIF 11x32x5deg -16	1.28

Part#	Description	Graft Volume to add
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161-0923-09	LEIF-C 9x23 Convex -9	0.00
161-0923-10	LEIF-C 9x23 Convex -10	0.43
161-0923-11	LEIF-C 9x23 Convex -11	0.48
161-0923-12	LEIF-C 9x23 Convex -12	0.53
161-0923-13	LEIF-C 9x23 Convex -13	0.59
161-0923-14	LEIF-C 9x23 Convex -14	0.64
161-0923-15	LEIF-C 9x23 Convex -15	0.69
161-0923-16	LEIF-C 9x23 Convex -16	0.75
161-0927-08	LEIF-C 9x27 Convex -8	0.80
161-0927-09	LEIF-C 9x27 Convex -9	0.85
161-0927-10	LEIF-C 9x27 Convex -10	0.54
161-0927-11	LEIF-C 9x27 Convex -11	0.61
161-0927-12	LEIF-C 9x27 Convex -12	0.68
161-0927-13	LEIF-C 9x27 Convex -13	0.74
161-0927-14	LEIF-C 9x27 Convex -14	0.81
161-0927-15	LEIF-C 9x27 Convex -15	0.88
161-0927-16	LEIF-C 9x27 Convex -16	0.95
161-0932-08	LEIF-C 9x32 Convex -8	1.01
161-0932-09	LEIF-C 9x32 Convex -9	1.08
161-0932-10	LEIF-C 9x32 Convex -10	0.68
161-0932-11	LEIF-C 9x32 Convex -11	0.77
161-0932-12	LEIF-C 9x32 Convex -12	0.85
161-0932-13	LEIF-C 9x32 Convex -13	0.94
161-0932-14	LEIF-C 9x32 Convex -14	1.02
161-0932-15	LEIF-C 9x32 Convex -15	1.11
161-0932-16	LEIF-C 9x32 Convex -16	1.19
161-1123-08	LEIF-C 11x23 Convex -8	1.28
161-1123-09	LEIF-C 11x23 Convex -9	1.37
161-1123-10	LEIF-C 11x23 Convex -10	0.43
161-1123-11	LEIF-C 11x23 Convex -11	0.48
161-1123-12	LEIF-C 11x23 Convex -12	0.53
161-1123-13	LEIF-C 11x23 Convex -13	0.59
161-1123-14	LEIF-C 11x23 Convex -14	0.64
161-1123-15	LEIF-C 11x23 Convex -15	0.69
161-1123-16	LEIF-C 11x23 Convex -16	0.75
161-1127-08	LEIF-C 11x27 Convex -8	0.80
161-1127-09	LEIF-C 11x27 Convex -9	0.85
161-1127-10	LEIF-C 11x27 Convex -10	0.54
161-1127-11	LEIF-C 11x27 Convex -11	0.61

Part#	Description	Graft Volume to add
161-1127-12	LEIF-C 11x27 Convex -12	0.68
161-1127-13	LEIF-C 11x27 Convex -13	0.74
161-1127-14	LEIF-C 11x27 Convex -14	0.81
161-1127-15	LEIF-C 11x27 Convex -15	0.88
161-1127-16	LEIF-C 11x27 Convex -16	0.95
161-1132-08	LEIF-C 11x32 Convex -8	1.01
161-1132-09	LEIF-C 11x32 Convex -9	1.08
161-1132-10	LEIF-C 11x32 Convex -10	0.68
161-1132-11	LEIF-C 11x32 Convex -11	0.77
161-1132-12	LEIF-C 11x32 Convex -12	0.85
161-1132-13	LEIF-C 11x32 Convex -13	0.94
161-1132-14	LEIF-C 11x32 Convex -14	1.02
161-1132-15	LEIF-C 11x32 Convex -15	1.11
161-1132-16	LEIF-C 11x32 Convex -16	1.19

Zavation Posterior LEIF

Device Description:
The Zavation Posterior LEIF(Lateral Expandable Interbody Fusion) devices are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The implants are provided in a shape that accommodates a posterior or transforaminal approach to the lumbar spine. After insertion the implant can be expanded to a larger footprint. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These implants are to be filled with autogenous bone graft material. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

Indications for Use:
The Zavation Posterior LEIF(Lateral Expandable Interbody Fusion) implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation Posterior LEIF 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 I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended to be used in patients who have had six months of non-operative treatment.

The Zavation Posterior LEIF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Spinal System.

Materials:

The spacer component is manufactured from medical grade PEEK Zeniva ZA-500 (ASTM F2026) with a Tantalum alloy position marker (ASTM F560). And pins per titanium alloy (ASTM F136).

Contraindications:
-The Zavation Posterior LEIF is contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, drug/alcohol abuse, mental illness, general neurologic conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity and patients who are unwilling to restrict activities or follow medical advice
-Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation
-This device is not intended for use except as indicated
-Prior fusion at the level(s) to be treated

Potential Adverse Events: Potential adverse events include, but are not limited to:
-Pseudoarthrosis
-Early or late loosening of the components
-Bending, and/or breakage of the components
-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, straining, tumor formation, and/or auto-immune disease
-Post-operative change in spinal curvature, loss of correction, height, and/or reduction
-Infection
-Vertebral body fracture at, above, or below the level of surgery
-Loss of neurological function, including paralysis (complete or incomplete)
-Non-union, delayed union
-Pain, discomfort, or abnormal sensations due to the presence of the device
-Hemorrhage
-Cessation of any potential growth of the operated portion of the spine
-Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions:
-A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without autograft or in cases that do not develop a union will not be successful

-Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion
-Non-sterile, the Zavation Posterior LEIF implants are sold non-sterile, and therefore, must be sterilized before each use
-Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
-Do not reuse implants; discard used, damaged, or otherwise suspect implants
-Single use only
-The Zavation Posterior LEIF components should not be used with components of any other system or manufacturer.
-The Zavation Posterior LEIF has not been evaluated for safety and compatibility in the MR environment. The Zavation Posterior LEIF has not been tested for heating or migration in the MR environment.
-Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Other preoperative, intraoperative and postoperative warnings are as follows:

Implant Selection:
The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Peek surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:
-Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
-Carefully screen the patient, choosing only those that fit the indications described above
-Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
-An adequate inventory should be available at surgery of those expected to be used
-All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need

Intraoperative:
-Instructions should be carefully followed
-Extreme caution should be used around the spinal cord and nerve roots
-The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct
-To assure proper fusion below and around the location of the fusion, autogenous bone graft should be used.
-Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

Postoperative:
-Detailed instructions should be given to the patient regarding care and limitations, if any
-To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process
-The patient should be advised or their limitations and taught to compensate for this permanent physical restriction in body motion
-If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred
-Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):

For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays as long as the inspection criteria provided below are acceptable for the tray.

<table>
<tr><td colspan="2">Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.</td></tr>
<tr><td colspan="2">Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.</td></tr>
<tr><td colspan="2">1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.</td></tr>
<tr><td colspan="2">2-Containment and transportation: Avoid damage and minimize time before cleaning</td></tr>
<tr><td colspan="2">3-Preparation for cleaning: Dis-assemble instruments as required for the Zavation Posterior LEIF System, (note that these items are normally stored in the dedicated trays already disassembled).</td></tr>
<tr><td colspan="2">4 Thoroughly clean instruments per one of the following (Manual or Automated)</td></tr>
<tr><td>Manual</td><td>Automated</td></tr>
<tr><td>4.1 Pre-Cleaning-Manual:
Alcohol wipe
Prepare a pH neutral, enzymatic detergent soak with warm water (approximately 35-40°C) per the instructions of the enzymatic solution manufacturer.
Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
Change the soak solution if the solution becomes visibly soiled.
While still in the soak solution, use a soft brush the remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen
Rinse instruments thoroughly with clean warm deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear</td><td>4.1 Pre-Cleaning-Automated:
Soak in ultrasonic bath
15 minutes
Use nonmetallic brush
Rinse thoroughly in running water</td></tr>
<tr><td>4.2 Cleaning-Manual:
Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under clean running water for a least one</td><td>4.2 Washer Disinfector:
Wash
93°C (200°F) minimum
10 minutes
Rinses; when unloading check cannulations, holes, etc. for complete</td></tr>
</table>

minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear. • Dry the exterior of the instruments with a clean soft cloth. Use clean compressed air or 70% isopropyl to dry any lumens or crevices where water may become trapped.	removal of visible soil. If necessary, repeat cycle or use manual cleaning. • Dry
Inspection: • Visually inspect each device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Check instruments with long slender features for distortion • Inspect the devices for any cracking, pitting, or other signs of deterioration	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Zavation Posterior LEIF should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (121°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.