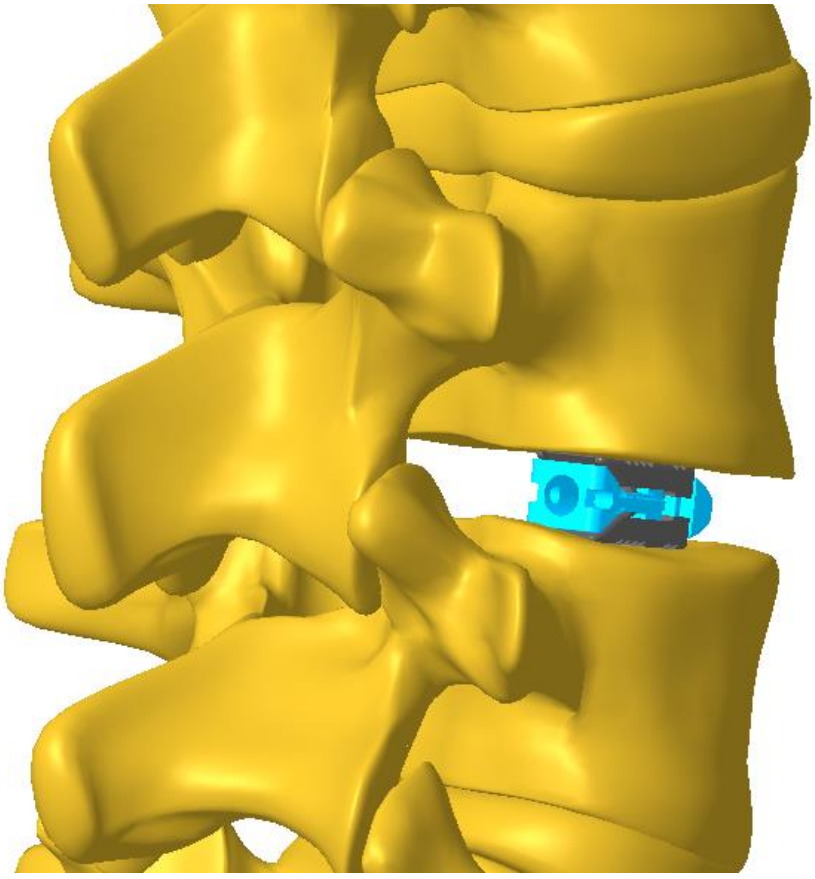
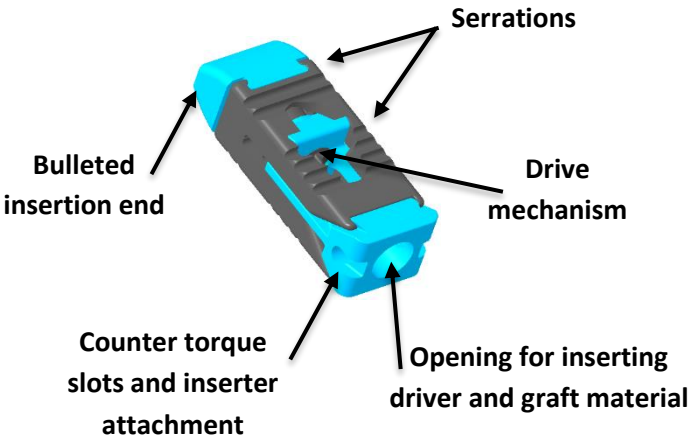
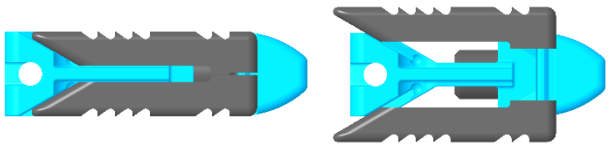
Zavation eZspand® PLIF/T-PLIF
Surgical Technique Guide







Insertion Size

Height Expansion

Zavation eZspand®PLIF/T-PLIF:

- Insertion heights of 0° implants
  - 7 mm
  - 8.5 mm
  - 10.5 mm
- Parallel expansion: 4.5mm
  - 7-11.5 mm
  - 8.5-13 mm
  - 10.5 -15 mm
- Length: 23 (PLIF), 27 & 32mm (T-PLIF)
- Width: 9mm and 11mm
- Lordotic endplates providing lordotic options of 0°, 10°, 15°
- Continuous height adjustment, not incremental
- No secondary locking step required
- Large graft window through the device
- Post expansion packing of graft material through inserter
- Material: Titanium per ASTM F-136

Important Statement: When expanding the cage outside of the body, during a demo for instance, positive pressure needs to be maintained on the endplates of the cage during the demo to prevent the cage's endplates from coming off their tracks.

The endplates can only come off track if the cage is at its fully expanded position and there is no pressure holding them together. This should not be an issue during a case but can occur while demonstrating the cage if you expand it fully, and then try to reduce it back down without holding the endplates down as you start it back down.

Supporting Video: https://photos.app.goo.gl/GvKYmeKsvxzUVgps5

Surgical Technique for Zavation eZspand®PLIF/T-PLIF

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 surgeon's 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 27mm and 32mm length T-PLIF devices. Use a standard bilateral posterior approach for insertion of the 23mm PLIF devices.

Step 2

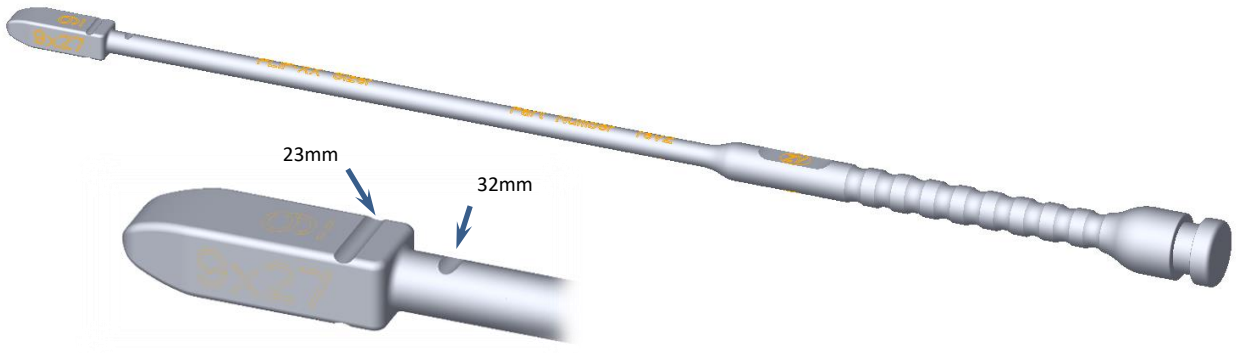
Freshening of the endplate

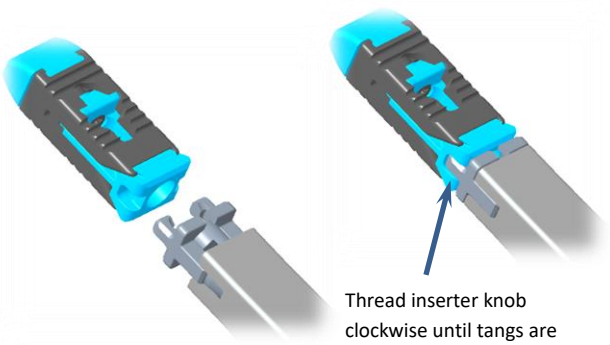
Perform a standard discectomy used with a posterior lumbar discectomy and fusion procedure. Use a curette or rasp to prepare the implant bed and the graft surfaces.

Step 3

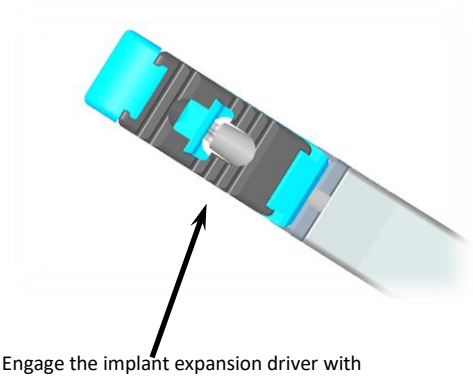
Trial for implant size

Introduce the various sized trials into the intervertebral space to determine the appropriate length and starting height. The footprint for the included trials is 9x27mm; however, notches have been added to the trial to provide indication of 23mm and 32mm lengths under radiographic imaging.





Thread inserter knob clockwise until tangs are fully seated within implant



Engage the implant expansion driver with the drive mechanism.

Step 4

Load Implant onto Inserter

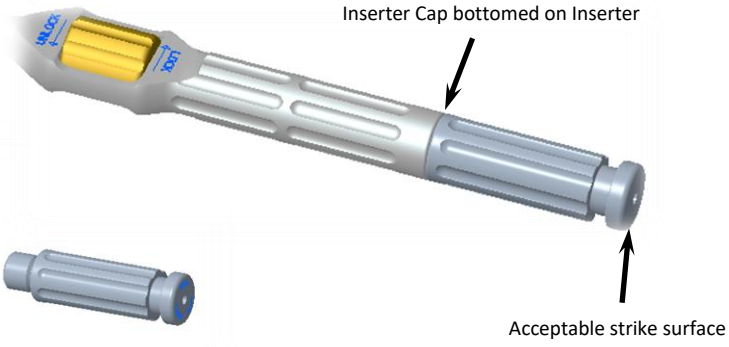
Assemble the implant inserter as outlined on **page 7.**

Rotate the adjustment nut on the inserter counterclockwise to open the inserter tangs that attach to the implant. Select the appropriate implant and then attach to the inserter instrument. Load implant onto the inserter by placing the implant between the inserter tangs and rotate the adjustment nut clockwise until the is fully secured to the inserter.

Select the appropriate expansion driver based on implant length. The implants and drivers are color coded based on implant length. Insert the driver through the inner cannula of the inserter and engage the drive mechanism of the implant.

Install the 360-1000-6 Inserter Cap over the expansion driver by threading clockwise until bottomed.

NOTE: Make sure that the eZspand implant is completely collapsed prior to insertion into the disc space. Inserting an expanded cage will result in damage to the cage and prevent cage expansion.

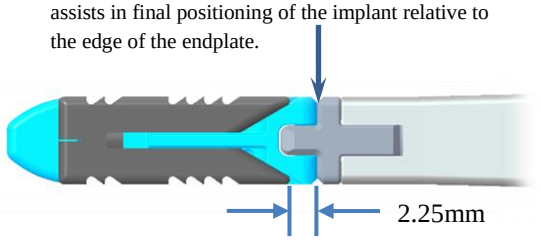


NOTE: Ensure that the inserter cap and expansion driver are installed prior to positioning implant in the disc space. Engaging the driver with the implant expansion mechanisms prevents bone fragments and/or soft tissue from obstructing the drive interface during insertion and provides stability to the implant attachment when changing the trajectory of the implant in the lateral plane.

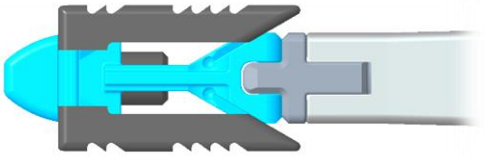
It is acceptable to strike the end of the inserter cap during implant insertion.

DO NOT STRIKE THE EXPANSION DRIVER PRIOR TO INSTALLING THE CAP.

The notch formed between the implant and inserter assists in final positioning of the implant relative to the edge of the endplate.



NOTE: The overall length of the implant is reduced by 2.25mm after expansion to final lengths of 23mm, 27mm and 32mm.



Step 5

Insert implant

The PLIF/T-PLIF device final position should be across the midline with the length of the device perpendicular to the midline. The 27mm and 32mm length T-PLIF devices final position should be across the midline at a 30° to 45° angle from the midline. The 23mm PLIF devices should be placed bilaterally on each side of the midline.

Under fluoroscopy, with the implant mounted on the insertion instrument, gently insert into disc space towards its final position.

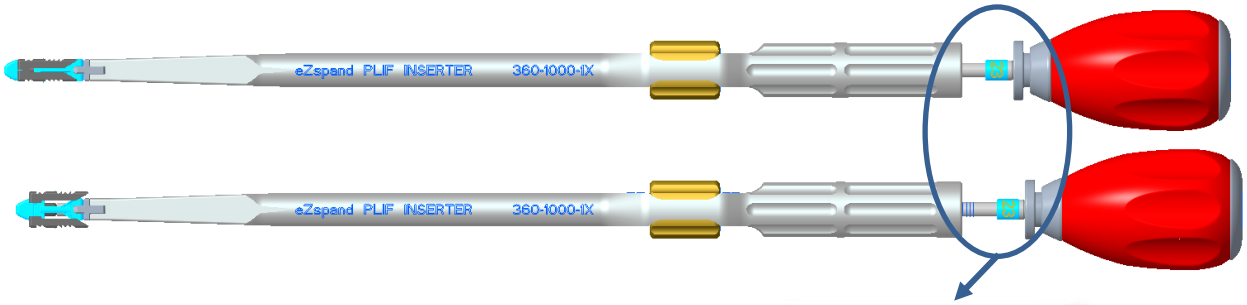
Make sure the cage is fully within the disc space to prevent cage migration. Ensure the cage is fully under load within the disc space to maintain full cage expansion.

Step 6

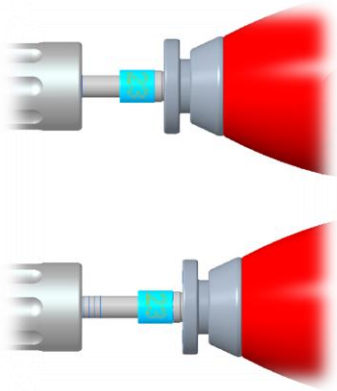
Expand Implant

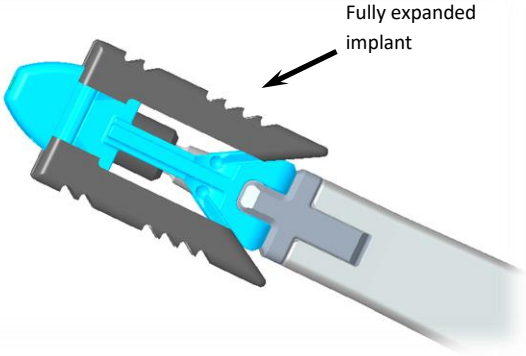
The implant is intended to be expanded in superior/inferior plane to provide controlled distraction and restore disc height. Remove the Inserter Cap and attach the torque limiting handle to the expansion driver.

The implant is expanded to the appropriate height by rotating the implant expansion driver clockwise. The torque limiting driver is designed to limit distraction force applied to the vertebral bodies during expansion and indicate when the implant has been expanded to its maximum design height.



Each implant can be expanded up to 4.5mm from its initial height. Expansion can be quantified by counting the laser mark rings exposed as the implant is expanded. Each line indicates 1mm of expansion.



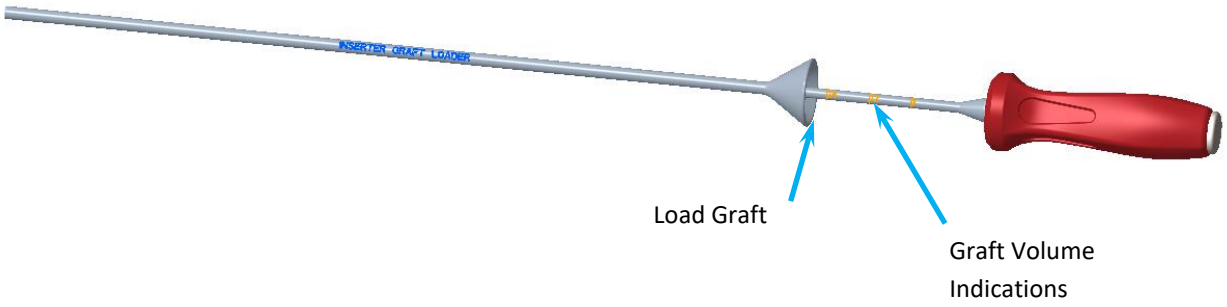


Use caution when expanding the implant to prevent the application of excessive distraction force to the vertebral bodies. Replacing the provided torque limiting handle with any other handle on the implant expansion driver increases the risk of excessive expansion force applied and can cause damage to the vertebral bodies and/or mechanical damage to the eZspand® implant.

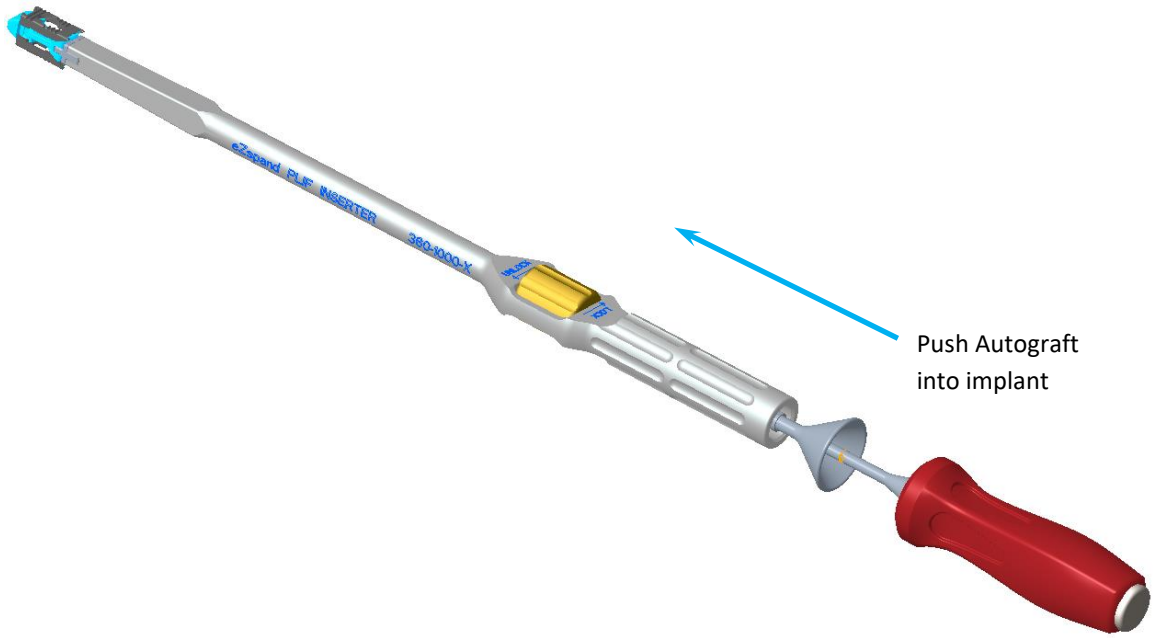
Step 7

Load Autograft

Load Autograft per the chart on **pages 8 and 9** into the Graft Loader by inserting graft material using the funnel at the proximal end of the graft loader. Graft volume can measured by inserting the graft pusher and reading the volume measurement indications marked on the shaft at top of funnel.



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 8

Remove Inserter

Once satisfied with implant placement, remove the inserter by rotating the inserter adjustment nut counterclockwise to disengage the attachment tangs from the implant. Remove the inserter from the implant.

Confirm final placement of the implant radiographically.

Implant Removal Process

Reattach the inserter to the implant as detailed above. Insert the implant expansion driver into the inserter and engage the implant expansion mechanism. Rotate expansion driver counterclockwise to collapse the implant to its initial insertion height. Remove the implant from the disc space. The slap hammer can also be connected to the end of the inserter to aid in removal.

If unable to attached inserter to implant, the expansion driver can be inserted directly into the implant. Rotate the expansion driver counterclockwise to collapse the implant. Forceps or similar surgical equipment may be used to remove the implant.

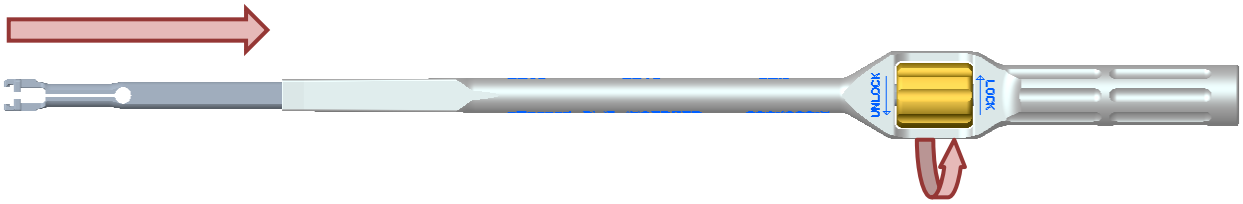
Implant Inserter Assembly Instructions

1) With the inserter components positioned as shown below, align the flats along the length of the **Inserter Sleeve** with the corresponding flats inside the **Inserter Body**.
2) Slide the **Inserter Sleeve** into the **Inserter body** until the **Inserter Sleeve** engages the **Inserter Adjustment Nut**.
3) Rotate the **Inserter Adjustment Nut** clockwise, as viewed from the proximal end, to pull the **Inserter Sleeve** into the **Inserter Body**. Continue rotating the **Inserter Adjustment Nut** until the **Inserter Sleeve** bottoms on the distal end of the **Inserter Body**.

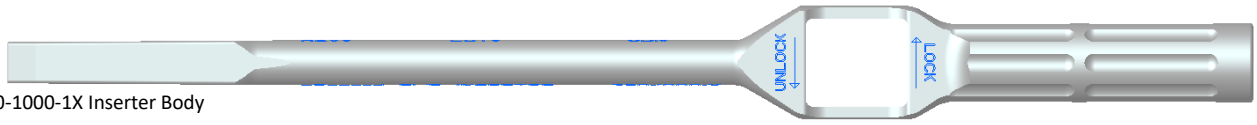
Note: Reverse the above assembly steps for disassembly of the inserter.

Note: 360-1000-5 Inserter cap is installed after loading an implant and engaging the 360-1001-XX driver in the implant.

Note: 360-1000-B and 360-1000-C inserters are provided with the offset handles preassembled.



Implant Inserter Components



360-1000-1X Inserter Body

360-1000-2 Inserter Sleeve

360-1000-3 Inserter Adjustment Nut

360-1000-5 Inserter Cap

Zavation eZspand® Interbody System PLIF/T-PLIF Implants

Part Number	Description	Width [mm]	Length [mm]	Lordotic Angle [°]	Height Expansion	Graft Volume [cc]
360-S092300	eZspand® PLIF/T-PLIF 9x23x0°, 7-11.5mm	9	23	0	7-11.5mm	0.6
360-S092700	eZspand® PLIF/T-PLIF 9x27x0°, 7-11.5mm	9	27	0	7-11.5mm	0.9
360-S093200	eZspand® PLIF/T-PLIF 9x32x0°, 7-11.5mm	9	32	0	7-11.5mm	1.2
360-S092310	eZspand® PLIF/T-PLIF 9x23x10°, 8.5-13mm	9	23	10	8.5-13mm	0.8
360-S092710	eZspand® PLIF/T-PLIF 9x27x10°, 8.5-13mm	9	27	10	8.5-13mm	1.2
360-S093210	eZspand® PLIF/T-PLIF 9x32x10°, 8.5-13mm	9	32	10	8.5-13mm	1.6
360-S092315	eZspand® PLIF/T-PLIF 9x23x15°, 10-14.5mm	9	23	15	10-14.5mm	0.7
360-S092715	eZspand® PLIF/T-PLIF 9x27x15°, 10-14.5mm	9	27	15	10-14.5mm	1.0
360-S093215	eZspand® PLIF/T-PLIF 9x32x15°, 10-14.5mm	9	32	15	10-14.5mm	1.4
360-S112300	eZspand® PLIF/T-PLIF 11x23x0°, 7-11.5mm	11	23	0	7-11.5mm	0.9
360-S112700	eZspand® PLIF/T-PLIF 11x27x0°, 7-11.5mm	11	27	0	7-11.5mm	1.3
360-S113200	eZspand® PLIF/T-PLIF 11x32x0°, 7-11.5mm	11	32	0	7-11.5mm	1.8
360-S112310	eZspand® PLIF/T-PLIF 11x23x10°, 8.5-13mm	11	23	10	8.5-13mm	0.7
360-S112710	eZspand® PLIF/T-PLIF 11x27x10°, 8.5-13mm	11	27	10	8.5-13mm	1.1
360-S113210	eZspand® PLIF/T-PLIF 11x32x10°, 8.5-13mm	11	32	10	8.5-13mm	1.5
360-S112315	eZspand® PLIF/T-PLIF 11x23x15°, 10-14.5mm	11	23	15	10-14.5mm	0.9
360-S112715	eZspand® PLIF/T-PLIF 11x27x15°, 10-14.5mm	11	27	15	10-14.5mm	1.4
360-S113215	eZspand® PLIF/T-PLIF 11x32x15°, 10-14.5mm	11	32	15	10-14.5mm	2.0
360-M092300	eZspand® PLIF/T-PLIF 9x23x0°, 8.5-13mm	9	23	0	8.5-13mm	0.6
360-M092700	eZspand® PLIF/T-PLIF 9x27x0°, 8.5-13mm	9	27	0	8.5-13mm	1.0
360-M093200	eZspand® PLIF/T-PLIF 9x32x0°, 8.5-13mm	9	32	0	8.5-13mm	1.3
360-M092310	eZspand® PLIF/T-PLIF 9x23x10°, 10-14.5mm	9	23	10	10-14.5mm	0.8
360-M092710	eZspand® PLIF/T-PLIF 9x27x10°, 10-14.5mm	9	27	10	10-14.5mm	1.2
360-M093210	eZspand® PLIF/T-PLIF 9x32x10°, 10-14.5mm	9	32	10	10-14.5mm	1.7
360-M092315	eZspand® PLIF/T-PLIF 9x23x15°, 11.5-16mm	9	23	15	11.5-16mm	0.7
360-M092715	eZspand® PLIF/T-PLIF 9x27x15°, 11.5-16mm	9	27	15	11.5-16mm	1.1
360-M093215	eZspand® PLIF/T-PLIF 9x32x15°, 11.5-16mm	9	32	15	11.5-16mm	1.5
360-M112300	eZspand® PLIF/T-PLIF 11x23x0°, 8.5-13mm	11	23	0	8.5-13mm	1.0
360-M112700	eZspand® PLIF/T-PLIF 11x27x0°, 8.5-13mm	11	27	0	8.5-13mm	1.4
360-M113200	eZspand® PLIF/T-PLIF 11x32x0°, 8.5-13mm	11	32	0	8.5-13mm	1.9
360-M112310	eZspand® PLIF/T-PLIF 11x23x10°, 10-14.5mm	11	23	10	10-14.5mm	0.7
360-M112710	eZspand® PLIF/T-PLIF 11x27x10°, 10-14.5mm	11	27	10	10-14.5mm	1.1
360-M113210	eZspand® PLIF/T-PLIF 11x32x10°, 10-14.5mm	11	32	10	10-14.5mm	1.6
360-M112315	eZspand® PLIF/T-PLIF 11x23x15°, 11.5-16mm	11	23	15	11.5-16mm	0.9
360-M112715	eZspand® PLIF/T-PLIF 11x27x15°, 11.5-16mm	11	27	15	11.5-16mm	1.5
360-M113215	eZspand® PLIF/T-PLIF 11x32x15°, 11.5-16mm	11	32	15	11.5-16mm	2.1
360-H092300	eZspand® PLIF/T-PLIF 9x23x0°, 10.5-15mm	9	23	0	10.5-15mm	0.7

Part Number	Description	Width [mm]	Length [mm]	Lordotic Angle [°]	Height Expansion	Graft Volume [cc]
360-H092700	eZspand® PLIF/T-PLIF 9x27x0°, 10.5-15mm	9	27	0	10.5-15mm	1.0
360-H093200	eZspand® PLIF/T-PLIF 9x32x0°, 10.5-15mm	9	32	0	10.5-15mm	1.4
360-H092310	eZspand® PLIF/T-PLIF 9x23x10°, 12-16.5mm	9	23	10	12-16.5mm	0.8
360-H092710	eZspand® PLIF/T-PLIF 9x27x10°, 12-16.5mm	9	27	10	12-16.5mm	1.3
360-H093210	eZspand® PLIF/T-PLIF 9x32x10°, 12-16.5mm	9	32	10	12-16.5mm	1.9
360-H092315	eZspand® PLIF/T-PLIF 9x23x15°, 13.5-18mm	9	23	15	13.5-18mm	0.8
360-H092715	eZspand® PLIF/T-PLIF 9x27x15°, 13.5-18mm	9	27	15	13.5-18mm	1.2
360-H093215	eZspand® PLIF/T-PLIF 9x32x15°, 13.5-18mm	9	32	15	13.5-18mm	1.6
360-H112300	eZspand® PLIF/T-PLIF 11x23x0°, 10.5-15mm	11	23	0	10.5-15mm	1.0
360-H112700	eZspand® PLIF/T-PLIF 11x27x0°, 10.5-15mm	11	27	0	10.5-15mm	1.5
360-H113200	eZspand® PLIF/T-PLIF 11x32x0°, 10.5-15mm	11	32	0	10.5-15mm	2.1
360-H112310	eZspand® PLIF/T-PLIF 11x23x10°, 12-16.5mm	11	23	10	12-16.5mm	0.7
360-H112710	eZspand® PLIF/T-PLIF 11x27x10°, 12-16.5mm	11	27	10	12-16.5mm	1.2
360-H113210	eZspand® PLIF/T-PLIF 11x32x10°, 12-16.5mm	11	32	10	12-16.5mm	1.7
360-H112315	eZspand® PLIF/T-PLIF 11x23x15°, 13.5-18mm	11	23	15	13.5-18mm	0.9
360-H112715	eZspand® PLIF/T-PLIF 11x27x15°, 13.5-18mm	11	27	15	13.5-18mm	1.6
360-H113215	eZspand® PLIF/T-PLIF 11x32x15°, 13.5-18mm	11	32	15	13.5-18mm	2.3

Zavation eZspand®Interbody System Instruments

Part Number	Description
100-1002-092700-07	Sizer, PLIF 9 x 27, 0 Degree, 7mm
100-1002-092700-08	Sizer, PLIF 9 x 27, 0 Degree, 8mm
100-1002-092700-09	Sizer, PLIF 9 x 27, 0 Degree, 9mm
100-1002-092700-10	Sizer, PLIF 9 x 27, 0 Degree, 10mm
100-1002-092700-11	Sizer, PLIF 9 x 27, 0 Degree, 11mm
100-1002-092700-12	Sizer, PLIF 9 x 27, 0 Degree, 12mm
100-1002-092700-13	Sizer, PLIF 9 x 27, 0 Degree, 13mm
100-1002-092700-14	Sizer, PLIF 9 x 27, 0 Degree, 14mm
100-1002-092700-15	Sizer, PLIF 9 x 27, 0 Degree, 15mm
100-1002-092700-16	Sizer, PLIF 9 x 27, 0 Degree, 16mm
100-1008	Slap Hammer
100-1012-07	Paddle Distractor, 7mm
100-1012-08	Paddle Distractor, 8mm
100-1012-09	Paddle Distractor, 9mm
100-1012-10	Paddle Distractor, 10mm
100-1012-11	Paddle Distractor, 11mm
100-1012-12	Paddle Distractor, 12mm
100-1012-13	Paddle Distractor, 13mm
100-1012-14	Paddle Distractor, 14mm
100-1012-15	Paddle Distractor, 15mm
100-1012-16	Paddle Distractor, 16mm
100-1013-07	Shaver, 7mm
100-1013-08	Shaver, 8mm
100-1013-09	Shaver, 9mm
100-1013-10	Shaver, 10mm
100-1013-11	Shaver, 11mm
100-1013-12	Shaver, 12mm
100-1013-13	Shaver, 13mm
100-1013-14	Shaver, 14mm
100-1013-15	Shaver, 15mm
100-1013-16	Shaver, 16mm
360-1000	Inserter
360-1000-8A	In-Line
360-1000-8B	Offset Handle Option-Lateral Plane
360-1000-8C	Offset Handle Option-Superior/Inferior Plane
360-1000-9	Inner Sleeve
360-1000-3	Inserter Adjustment Nut
360-1000-5	Inserter Cap
360-1010	Inserter Removal Tool
ZAV-1236	Cage Removal Tool

Part Number	Description
360-1008-23	23mm Implant Driver
360-1008-27	27mm Implant Driver
360-1008-32	32mm Implant Driver
360-1002	Graft Loader
360-1003	Graft Pusher
360-1006	Graft Adapter
Z-1009	Standard-T Fixed Handle, 1/4"
Z-1030	Torque Limiting Handle, Palm
Z-1032-XX	Torque Limiting Handle, Palm
Z-1033-XX	Torque Limiting Handle, Axial

Zavation eZspand®PLIF/T-PLIF

Device Description:
The Zavation eZspand®Interbody System 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 continuously expanded, within in the limitations of the design, to the desired height to suit the individual anatomical conditions of the patient. The devices are available in various footprints and geometric options to fit the anatomical needs of a wide variety of patients. The implants include an opening through the superior and inferior endplates of the device to facilitate fusion. The posterior opening of the device allows for the packing of autogenous bone graft material post expansion. 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 eZspand®PLIF/T-PLIF implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Zavation eZspand®PLIF/T-PLIF 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 eZspand®PLIF/T-PLIF implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Spinal System.

Materials:
The interbody components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Contraindications:
-The Zavation eZspand®PLIF/T-PLIF 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 eZspand®PLIF/T-PLIF 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 eZspand®PLIF/T-PLIF components should not be used with components of any other system or manufacturer.
-The Zavation eZspand®PLIF/T-PLIF has not been evaluated for safety and compatibility in the MR environment. The Zavation eZspand®PLIF/T-PLIF 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 eZspand®PLIF/T-PLIF 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</td><td>4.1 Pre-Cleaning-Automated:
Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Wash 45ºC 4 minutes dose pump 4 (detergent) 5mL
Wash 60ºC 3 minutes
Rinse with unheated water 1 minute
Rinse 60ºC 1 minute</td></tr>
</table>

<table>
<tr><td>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></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 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.</td><td>4.2 Washer Disinfector:
Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Thermal Disinfection A_0 93ºC
A_0 value: $A_0$3000
Dry 123ºC air 14 minutes</td></tr>
<tr><td colspan="2">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</td></tr>
<tr><td colspan="2">Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</td></tr>
<tr><td colspan="2">Sterilization: See sterilization procedure</td></tr>
<tr><td colspan="2">Storage: Control environment</td></tr>
<tr><td colspan="2">Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded.</td></tr>
<tr><td colspan="2">Manufacturer contact: Contact local representative or call customer service at 601-919-1119</td></tr>
</table>

Sterilization: The Zavation eZspand®PLIF/T-PLIF 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 (132°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 Medical Products, LLC, 3670 Flowood Drive., 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 Medical Products, LLC, 3670 Flowood Drive., 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.