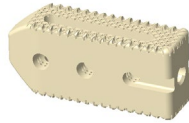


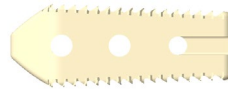
LABYRINTH[®] (TLIF, T-PLIF and PLIF)



TLIF



**Parallel
T-PLIF
PLIF(23mm)**



**Lordotic
T-PLIF-L
PLIF-L(23mm)**

Heights: 7mm-16mm
Widths: 10mm
Lengths: 25 and 30mm

*23mm devices are to be used bi-laterally

**7mm-16mm
9mm, 11mm
27mm, 32mm**

**8mm-16mm
9mm, 11mm
27mm, 32mm**

Implants provided sterile

Surgical Technique for LABYRINTH[®] (TLIF, T-PLIF and PLIF)

Step 1

Surgical approach to the disc (posterior)

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 TLIF and the 27mm and 32mm length T-PLIF devices. Use a standard bilateral posterior approach for insertion of the 23mm PLIF devices.

Step 2

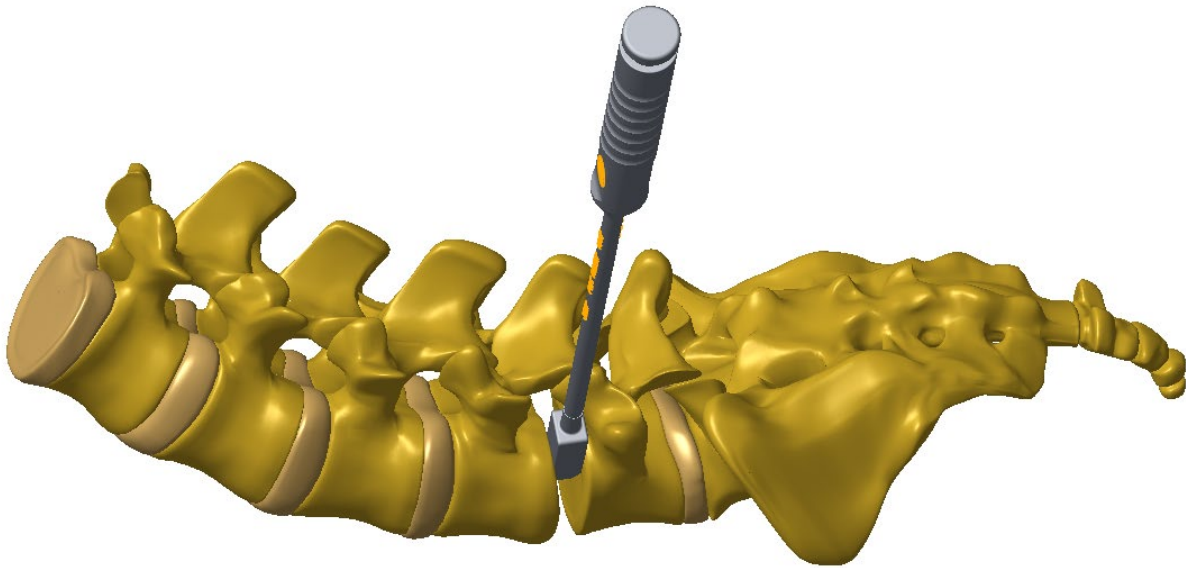
Freshening of the endplate



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

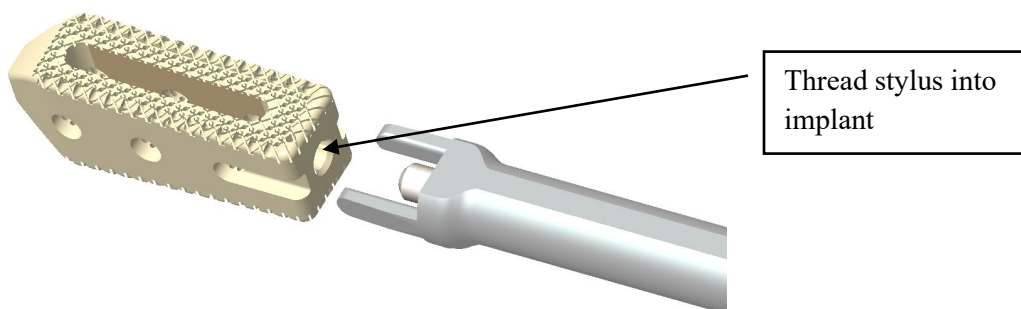


Introduce the various sized trials into the intervertebral space to determine the height, width and degree of the implant.

Step 4

Selection of the implant size

Select the appropriate implant and then attach to the inserter instrument. Load implant onto the inserter by aligning anti-rotation features and threading central stylus into implant.



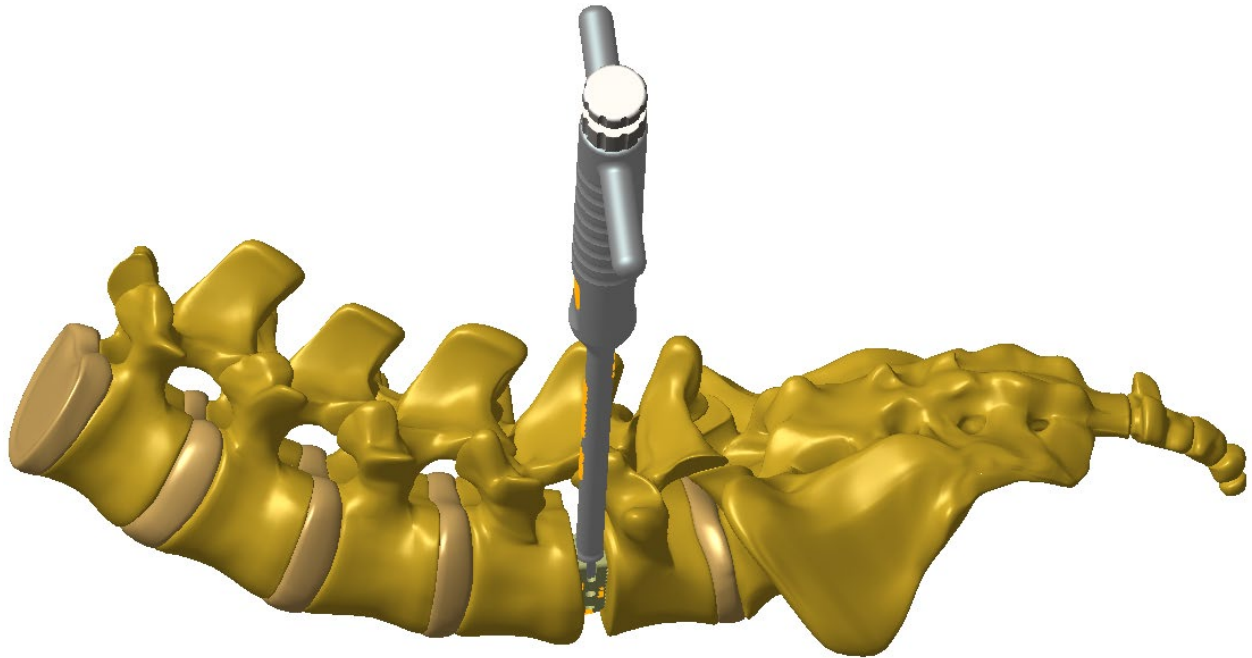
Step 5

Filling implant with autograft

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

Step 6

Insert implant



The TLIF devices 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 degree 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, gentle insert into disc space towards its final position. A tamp is available for tamping the implant into final position.

Step 7

X-ray verification

Remove the inserter instrument by unscrewing the knobs on the end of the inserter to allow X-ray or visual verification of the implant after implantation.

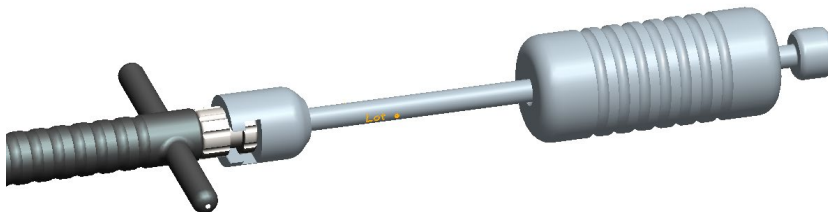
Step 8

Supplemental fixation

Use of supplemental fixation is required with the TLIF, T-PLIF, or PLIF implant. Zavation Spinal System (pedicle screw system) may be used as supplemental fixation.

Implant removal

Attach inserter into implant posteriorly, thread inserter into threads of implant until tightened, gentle remove implant from disc space. If the implant cannot be easily removed, a Cobb elevator, slap hammer or osteotome should be used to loosen the bone to implant interface.



LABYRINTH®

Device Description:

The LABYRINTH® implants offer a variety of heights, widths and lengths. There are six main configurations: ALIF, LLIF, TLIF, T-PLIF, PLIF and CIF. The different configurations allow for multiple surgical technique options. The implants are manufactured from medical grade PEEK (Polyetheretherketone). Subject instruments are intended for use only with Zavation pedicle or OCT screws.

The LABYRINTH® implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the implants as an option to help allow for radiographic visualization. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The LABYRINTH® device includes a porous structure on the endplate and through the device.

Indications for Use:

When used as a cervical intervertebral body fusion device, the LABYRINTH® implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the LABYRINTH® implants are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticancellous bone graft in skeletally mature patients. The lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the LABYRINTH® implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including Zavation Pedicle Screw System and Zavation Cervical Plate System.

Materials:

The devices are manufactured from medical grade PEEK Zeniva ZA-500 or Magnolia PEEK (ASTM F2026) with Tantalum alloy position markers (ASTM F560).

Contraindications:

- The LABYRINTH® devices are 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.
- 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
- LABYRINTH® components should not be used with components of any other manufacturer.
- LABYRINTH® components are identical to Zavation IBF System components.
- LABYRINTH® devices have not been evaluated for safety and compatibility in the MR environment. The LABYRINTH® devices have 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 previous surgery.

Sterilization: The LABYRINTH® implants will be provided sterile in sealed sterile packaging.

Other preoperative, intraoperative, and postoperative warnings are as followed:

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. 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 than those expected to be used

-Unless clearly marked as sterile and presented in an unopened sterile package, 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 of 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.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.	
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.	
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.	
2-Containment and transportation: Avoid damage and minimize time before cleaning	
3-Preparation for cleaning: Dis-assemble instruments as required. For the LABYRINTH® devices, the only instruments requiring disassembly would be the inserter. The inserter is disassembled and reassembled by sliding the stylus through the proximal end of the inserter. (Note that these items are normally stored in the dedicated trays already disassembled).	
4 Thoroughly clean instruments per one of the following (Manual or Automated)	
Manual	Automated
4.1 Pre-Cleaning-Manual: • Prepare a pH neutral, enzymatic detergent soak 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 to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size	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 45°C 4 minutes dose pump 4 (detergent) 5mL • Wash 60°C 3 minutes • Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute. • Rinse 60°C 1 minute

cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen. Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or 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	
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 running critical water, such as reverse osmosis, distilled, and/or deionized water for at least one minute until water runs clear. Use a tubing attachment to the water outlet 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 alcohol to dry any lumens or crevices where water may become trapped.	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 A₀ 93°C - A₀ value: A₀3000 - Dry 123°C air 14 minutes
Inspection: - Visually inspect each disassembled 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 disassembled instruments with long slender features for distortion. - Inspect the disassembled 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: Unless clearly marked as sterile and presented in an unopened sterile package, the LABYRINTH® components should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	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.

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