

Package Insert

LABYRINTH[®] System

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 indicated for spinal fusion procedures 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 indicated for spinal fusion procedures 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). The PEEK implants are available with or without an ion beam assisted deposition (IBAD) coating. The (IBAD) coating is made from Grade 2 Commercially Pure Titanium coating that meets chemical composition requirements of (ASTM F67).

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.
- For implants marked as sterile, do not use if sterile package is opened or damaged.
- 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 are identical to Zavation IBF System components
- LABYRINTH[®] components should not be used with components of any other manufacturer.
- LABYRINTH[®] devices have not been evaluated for safety and compatibility in the MR environment. 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: 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 if 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® System, 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: <ul style="list-style-type: none"> • 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 	4.1 Pre-Cleaning-Automated: <p>Automated washing shall be conducted in a validated washer-disinfector.</p> <p>An example of a validated cycle used for cleaning validation includes:</p> <ul style="list-style-type: none"> • Wash 45°C 4 minutes dose pump 4 (detergent) 5mL

<p>surfaces.</p> <ul style="list-style-type: none"> • 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 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. 	<ul style="list-style-type: none"> • 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
<p>4.2 Cleaning-Manual:</p> <ul style="list-style-type: none"> • 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 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 alcohol to dry any lumens or crevices where water may become trapped. 	<p>4.2 Washer Disinfectant:</p> <p>Automated washing shall be conducted in a validated washer-disinfectant.</p> <p>An example of a validated cycle used for cleaning validation includes:</p> <ul style="list-style-type: none"> • Thermal Disinfection A₀ 93°C • A₀ value: A₀3000 • Dry 123°C air 14 minutes
<p>Inspection:</p> <ul style="list-style-type: none"> • Visually inspect each disassembled device to ensure all visible blood and soil has 	

<p>been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean.</p> <ul style="list-style-type: none"> • Check disassembled instruments with long slender features for distortion. • Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration
<p>Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</p>
<p>Sterilization: See sterilization procedure</p>
<p>Storage: Control environment</p>
<p>Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded.</p>
<p>Manufacturer contact: Contact local representative or call customer service at 601-919-1119</p>

Sterilization: Unless clearly marked as sterile and presented in an unopened sterile package, the LABYRINTH® System components 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 Dr., 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 Dr., 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.



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Approval	ELKE CARTER	VP OF REGULATORY	01-Apr-2025 10:30
Send for Approval	ELKE CARTER		01-Apr-2025 10:30
Approve	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	07-Apr-2025 15:09
QA Approval	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	07-Apr-2025 15:10
Scheduled Release	SARAH DIXON	DOCUMENT CONTROL SPECIALIST	07-Apr-2025 16:08
Send for Review (Written By)	SARAH DIXON	DOCUMENT CONTROL SPECIALIST	25-Mar-2025 14:14
Send for Approval	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	27-Mar-2025 13:10

* Dates are displayed according to the system time zone: (GMT-05:00) Central Daylight Time (America/Chicago)