

Package Insert

ZAVATION MILC® SYSTEM

PURPOSE

The Zavation MILC® Interbody Device is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations. This system may be implanted via a direct lateral approach.

DESCRIPTION

The Zavation MILC® Interbody device is a PEEK intervertebral body fusion device. Also available with the system are incorporated Titanium locking plates and locking screws for internal fixation.

The Zavation MILC® Interbody device is manufactured from PEEK Optima® LT1 (polyetheretherketone) or PEEK Zeniva ZA-500 or Magnolia PEEK and contains tantalum radiopaque markers. The Locking Plates and Locking Screws used with this device are manufactured from Titanium 6Al-4V alloy.

INDICATIONS

The Zavation MILC® Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The device must be used with supplemental fixation (i.e., lateral plating or pedicle screw systems), which is in addition to the integrated locking plates provided in the system. When used with the integrated locking plates, it is indicated to be used at one level from L2-L5. When used without the integrated locking plates, it is indicated to be used at one or two contiguous levels, from L2-S1. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

CONTRAINDICATIONS

Contraindications may include, but are not limited to the following:

1. Any case where there is translational instability (spondylolisthesis greater than Grade I) at the level(s) treated
2. Severe osteoporosis
3. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
4. Infection, local to the operative site
5. Signs of local inflammation,
6. Fever or leukocytosis,
7. Morbid obesity,
8. Pregnancy,

9. Mental illness,
10. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
11. Suspected or documented allergy or intolerance to titanium alloy or other device materials
12. Any case not needing a fusion,
13. Any case not described in the indications,
14. Any patient unwilling to cooperate with postoperative instructions.
15. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
16. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
17. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
18. Any case that requires the mixing of metals from two different components or systems.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to the following:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, autoimmune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Hemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.

12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Ileus and or small bowel obstruction associated with the anterior approach to the spine.
18. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
19. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
20. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
21. Loss of or increase in spinal mobility or function.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Cessation of any potential growth of the operated portion of the spine.
26. Death.

WARNING(S)

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. The device must be used with supplemental fixation (e.g., plates, pedicle screw systems). The use of the Zavation integrated titanium alloy Locking Plate and Locking Screws with the Zavation MILC® Interbody Device is optional.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction are important considerations in the success of surgery.

Never reuse an internal fixation device under any circumstances.

Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the implant will reduce the stability of the instrumentation. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, long term steroid use, and/or alcohol or narcotic abuse patients are also poor candidates for spine fusion.

The Zavation MILC® Interbody device has not been evaluated for safety and compatibility in the MR environment. The Zavation MILC® Interbody device has not been tested for heating or migration in the MR environment.

The safety and effectiveness of the Zavation MILC® Interbody device with internal fixation has not been established for multiple levels of use.

The safety and effectiveness of the Zavation MILC® Interbody device has not been established for standalone use. Therefore, the device is to be used with supplemental fixation that is in addition to the optional integrated locking plates (i.e., lateral plating or pedicle screw systems).

PRECAUTION(S)

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

FOR US AUDIENCES ONLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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. Plastic polymer 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 material 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

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. All instruments must be cleaned and sterilized before use.
8. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Instructions in the available Zavation MILC® Interbody System surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the fusion, bone graft must be used.
5. Bone cement should not be used, because this material may make removal of these components difficult or impossible. The heat generated from the curing process may damage or deform the PEEK devices.
6. Autogenous bone graft must be used with this system.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If a brace is required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive bending, lifting or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to limit activities or use a lumbar brace. The patient should be warned to avoid falls or sudden jolts in spinal position.

2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone graft healing process.
3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize with a brace may lead to a delayed or non-union of bone, which will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Implants are provided nonsterile. Packages for each of the components should be intact upon receipt. If a loaner or consignment instrument system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Zavation Medical Products, LLC.

CLEANING AND DECONTAMINATION

All instruments must be unpackaged, disassembled (if applicable) and cleaned before sterilization and introduction into a sterile surgical field or, if applicable, return of the product to Zavation. Remove all packaging materials prior to disassembly (if applicable) and cleaning. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care.

Improper use or handling may lead to damage and/or possible improper functioning of the device.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS

Most instrument systems include inserts/trays and a container(s). Many instruments are intended for use with a specific implant. It is essential that the surgeon and operating theater staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

All instruments of the Zavation MILC® Interbody System are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and facilitates the subsequent cleaning stage. Strict compliance with the instructions for use pertaining to decontamination and cleaning is mandatory, particularly the concentration and exposure time requirements.

CAUTION: These instructions DO NOT APPLY to single-use devices.

These reprocessing instructions have been validated as being capable of preparing reusable Zavation MILC® Interbody System instruments for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

Where further information is desired, please contact your local sales representative.

Warnings

- * Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- * Do not exceed 140° C during reprocessing steps.
- * Highly alkaline conditions can damage products with aluminum parts.
- * Complex devices, such as those with tubes, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Manual pre-cleaning of such device features is required before automated cleaning processing.
- * Avoid exposure to hypochlorite solutions, as these will promote corrosion.
- * Scratches or dents can result in breakage.
- * For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
- * Care should be taken to thoroughly remove any debris, tissue or bone fragments that may collect on the instrument.

Limitations on Processing

- * Repeated processing has minimal effects on instrument life and function.
- * End of useful life is generally determined by wear or damage in surgical use.
- * Carefully inspect instruments between uses to verify proper functioning.

- * Damaged instruments should be repaired or replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

Decontamination Considerations – Creutzfeldt-Jakob Disease(CJD)

Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease)

inactivation processing procedures. Consult WHO and local regulations for further information. This risk pertains to use of this device outside the United States.

Reprocessing Instructions Care at the Point of Use

- * Thoroughly clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergent solution or water to prevent drying and encrustation of surgical soil.
- * Avoid prolonged exposure to saline to minimize the chance of corrosion.
- * Remove excessive soil with a disposable wipe.

Preparation for Cleaning

For instruments that require disassembly for cleaning, perform disassembly into component parts.

Manual Cleaning

- * Disassemble instruments that are intended to come apart for cleaning.
- * Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions. (1oz Enzol, or equivalent, per gallon)
- * Soak soiled instruments for 5 minutes in the enzymatic solution.
- * Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
- * When cleaning, fully immerse the instrument in the cleaning solution to avoid aerosol generation. Brush with a soft non-metallic bristle brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, any hard-to-reach areas, textured surfaces, or crevices.
- * Actuate any moveable mechanisms, such as hinged joints, box locks, or spring loaded features, to free trapped blood and debris. If the components of the instrument can be retracted, retract or open the part while cleaning the area. For instruments with flexible shafts, bend or flex the instrument under the cleaning solution while brushing the flexible areas.
- * Rinse the instrument thoroughly with warm tap water for 3 minutes
- * Rinse the instruments thoroughly again with deionized water for 3 minutes.
- * Dry the instrument immediately after final rinse.

Cleaning Inspection

- * Inspect all instruments before sterilization or storage to ensure the complete removal of soil from surfaces, tubes and holes, moveable parts to assure there is no visual contamination.

- * If soil is still present, reclean the instrument.

Functional Inspection

- * Visually inspect the instrument and check for damage and wear.
- * Cutting edges should be free of nicks and have a continuous edge.
- * Jaws and teeth should align properly.
- * Moveable parts should have smooth movement without excessive play.
- * Locking mechanisms should fasten securely and close easily.
- * Long, thin instruments should be free of bending and distortion.

Wrapping Technique

- * If desired, use instrument trays to contain instruments that are provided in sets.
- * Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions.
- * Double wrap using "FDA Cleared Wrap" for instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79.
- * Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system

Sterilization

- * Use a validated, properly maintained and calibrated steam sterilizer.
- * Effective steam sterilization can be achieved using the following cycles.

NOTE: Sterilization does not replace decontamination or cleaning. Only a clean product can be correctly sterilized.

Only sterile implants and instruments may be used for surgery.

STERILIZATION

All implants and instruments used in surgery are provided nonsterile and must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these implants and instruments are recommended to be steam sterilized by the hospital using process parameters below.

Caution: Use only FDA Cleared wrap to wrap the trays prior to sterilization.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Allow sterilized tray to cool for 30 minutes on wire rack prior to storage.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

PRODUCT COMPLAINTS

Any Health Care 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 the Zavation Medical Products, LLC. Further, if any of the implanted spinal system component(s) ever “malfunctions,” (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Zavation Medical Products ever “malfunction” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Zavation Medical Products, LLC. (601) 919-1119.



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 Review (Written By)	FELICIA SMITH	VP OF QUALITY	09-Jan-2025 11:27
Send for Required Approval(s)	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 12:05
Approve	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 12:42
QA Approval	FELICIA SMITH	VP OF QUALITY	09-Jan-2025 13:29

* Dates are displayed according to the system time zone: (GMT-06:00) Central Standard Time (America/Chicago)