



VIA™ Spinous Process Fixation System

DESCRIPTION

The VIA Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion, and is not intended for stand-alone use. When the VIA Spinous Process Plate is used as a supplemental fixation in interbody fusion procedures, its use is limited to the treatment of degenerative disc disease DDD) of the lumbosacral spine (L2-S1).

INDICATIONS

The VIA Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device, intended for single level use in the non-cervical spine (T1 – S1). It is intended for single level plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Trauma (i.e., fracture or dislocation)
- Spondylolisthesis
- Tumor

The VIA Spinous Process Fixation System is not intended for stand-alone use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality (i.e. prior laminectomy, or pars defect.)
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

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

- Early or late loosening of any or all of the components; device migration.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the spinous process, lamina, 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.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Infection.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

PRECAUTION

The implantation of this device should be performed only by experienced spinal surgeons with specific training in the use of systems of this type because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will 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, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. 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, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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.

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

MRI WARNING

The VIA Spinous Process Fixation System has not been evaluated for safety, heating, migration, or and compatibility in the MR environment. Other pre-operative, intraoperative, and postoperative warnings and precautions 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. Metallic 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 metal 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.

Implant Handling

Exercise care in handling implants. Protect the implants from contact with objects that may damage the surface. Inspect each implant prior to use and do not use if any damage is suspected.

Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- 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.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative

- Refer to the surgical technique guide regarding instrument use, implant size selection and further instructions.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. Utilize an imaging system to facilitate surgery.

Postoperative

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

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing 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 or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock 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 tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the device and its components should never be reused under any circumstances. Any device which has been placed in the body and removed should be discarded.
- Contact Spineology to discuss Revision / Retrieval.

Packaging

Packages for each of the components should be intact upon receipt. Implant packaging should be inspected for continuity and components should be handled appropriately to ensure sterility. Do not use if packaging has been damaged or shelf life exceeded. 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 Spineology.

Cleaning and Decontamination

Cleaning and decontamination of surgical instruments are required before introduction into the sterile field. Instruments that exhibit signs of damage or deterioration should not be used. Ensure that all components are available for use prior to surgery.

Following use, disassemble devices as instructed for cleaning. Preventing drying will facilitate later cleaning.

- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for one (1) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean tubes. Pay special attention to inner diameters and crevices during cleaning. Ultrasonic cleaning is acceptable.
- Rinse each part thoroughly under running water for one (1) minute or longer.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Sterilization

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery 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 products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

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

FDA cleared wraps are recommended for use with the sterilization tray. These instructions have been qualified by the manufacturer as being CAPABLE of preparing a device for re-use. Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

FURTHER INFORMATION OR PRODUCT COMPLAINTS

Contact Spineology
at: Spineology Inc.
7800 3rd Street N., Suite 600
Saint Paul, MN 55128-5455
Phone: 1.651.256.8500
Fax: 1.651.256.8505

Please contact your local Spineology representative for a complete surgical technique manual or further cleaning instructions.

Manufactured by:



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Do Not
Reuse