

ENGLISH (EUROPE ONLY)

SpineVision®

Intended Use

The Lumbar Universal Minimally Invasive System (LUMIS® System) instrumentation is designed for correction and surgical stabilization of the spine during development of solid bone fusion. It is recommended to remove the device as soon as effective solid bone fusion has been achieved.

Description

The Lumbar Universal Minimally Invasive System (LUMIS® System) instrumentation is composed of pedicle screws and fixation rods. Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient.

These constructs are assembled using specific instruments.

The components of the LUMIS® system are made from ASTM F136 titanium alloy (Ti-6Al-4V ELI) and ASTM F1537 Cobalt Chromium.

Implants must never be reused.

Components of the LUMIS® system must not be used with components derived from another manufacturer.

According to the clinical evaluation report, it can be concluded that the benefice-risk ratio is positive.

Indications

The LUMIS® System is indicated to provide immobilization and stabilization of spinal segments in skeletally mature patients, regardless of gender, as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The LUMIS® System is indicated for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); and tumor. It can be used from T1-S2 segments. With or without additional iliac fixation.

This device can only be implanted by a surgeon with a good working knowledge of the device, its applications, the instruments, and the required surgical technique (please see surgical technique MS2-STG01).

Contraindications

- Contraindications include:
- Allergy to the implanted material, mainly to metal (e.g. cobalt, chromium, nickel, etc.)
- Any other medical or surgical condition likely to compromise the success of instrumented surgery, such as the presence of a malignant tumor or serious congenital abnormalities, raised erythrocyte sedimentation rate not explained by other diseases, high white blood cell count or a tendency to low white blood cell count, leukocytosis
- Localized infection of the operative site, signs of local inflammation,
- All patients with insufficient tissue cover of the operative site.
- Morbid obesity (BMI $\geq$ 40 kg/m²)
- Pregnant woman
- Rapidly evolving joint diseases, bone absorption, osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication, as this medical condition can limit the expected correction gain and/or the strength of the bone/implant interface, leading to jeopardized mechanical fixation
- All cases not requiring bone graft or bone fusion.
- All cases requiring a combination of metals different to ASTM F136 titanium alloy (Ti-6Al-4V ELI) and ASTM F1537 Cobalt Chromium.
- All patients not agreeing or enable to comply with postoperative instructions.
- The use of pedicular screws above T1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance

The contraindications of these devices are like those of other spinal posterior fixation instrumentations. This spinal instrumentation is not designed or intended or sold for uses other than those indicated.

These contraindications must be considered by the physician when making his decision.

Potential Adverse Events

In addition to the risks associated with spinal surgery without instrumentation, the following potential adverse events can occur:

- Early or delayed hardware removal.
- Implant migration.
- Dismantling, deformity, sliding and/or rupture of one or all components or instruments.
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.
- Subcutaneous pressure by the components, possibly causing alteration of the skin in places in which the tissue cover is insufficient. Skin complications, including perforation of the skin by the implant or the graft.
- Loss of curvature or correction of the spine, loss of height.
- Infection.
- Fracture of the vertebral body due to transfer of loads above and below the instrumented zone.
- Lack of bone consolidation (or non-union).
- Loss of neurological functions, appearance of radiculopathies, dural injuries and/or pain. Neurovascular insufficiency, including paralysis or other serious lesions. Cerebrospinal fluid leak.
- Gastrointestinal, urological and/or reproductive tract disorders, including sterility, impotence.
- Haemorrhage and/or haematoma.
- Disk inflammation, arachnoiditis and/or other types of inflammation.
- Deep vein thrombosis, thrombophlebitis and/or pulmonary embolism.
- Bone graft donor site complications.
- Incapacity to resume the activities of normal everyday life.
- Soft tissue damage.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle strength loss.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Change in mental status.
- Pain or abnormal feeling due to the presence of the device.
- Osteolysis.
- Death.

Note: Some potential adverse events may require an additional surgical revision procedure.

Placement of the device

The LUMIS® system is composed of implants designed to be connected by 6.0mm diameter rods. They are designed to be used with instruments specifically intended for these devices.

Packaging

The packaging of each component must be intact on reception. The operating room personnel must thoroughly verify, before use, that all devices are complete and that no component presents any signs of damage. Damaged packaging and/or products must not be used but must be returned to SpineVision® or distributor.

All packaging and labelling materials must be removed prior to sterilization. Only sterile implants and instruments must be used in surgery.

Inspection, Cleaning and Sterilization

The LUMIS® system instruments and implants are supplied not sterile. They must be sterilized before use. Surface decontamination and cleaning of reusable instruments must be completed prior to sterilization. Further information regarding cleaning and sterilization of SpineVision products are available in the “Instructions for cleaning, sterilization, inspection and maintenance of SpineVision medical devices” I-LG09.

• Decontamination, Cleaning

For the initial and any subsequent cleaning, the recommended general protocol for the pre-disinfection, decontamination and cleaning of **the implants and instruments** is:

- Disassemble necessary implants and instruments. Articulated instruments must be opened.

- It is recommended to use a neutral pH, enzymatic and alkaline (pH < 11) cleaning agents' solution and deionized or distilled warm (room temperature) water of soaking, cleaning and rinsing.
- Inspect each device and repeat the washing in the presence of any residual debris, paying close attention to threads, cannulas, hinges and hard to reach areas.

• Verification

Devices must always be verified before use: any devices presenting signs of weakness or surface scratches must not be used. (Return to the manufacturer or distributor any implants showing deterioration).

• Sterilization

Prior to use, the LUMIS® system components should be steam sterilized according to the following parameters:

Method	Cycle	Temperature	Minimum exposure time
Steam	Vacuum	134° (273°F)	18 minutes
Steam	Vacuum	134° (273°F)	5 minutes
Steam	Vacuum	134° (273°F)	3 minutes
Steam	Vacuum	132° (270°F)	4 minutes

The first cycle (134°C) is validated in Europe and the second (132°C) in the USA.

The instruments and implants must be completely dried before use.

WARNINGS

This instrumentation is not designed to be the only means of long-term support of the spine. The use of this product cannot be successful without a mechanically solid bone graft. In the absence of a solid bone graft, the implanted devices can become deformed, loose, dismantled and/or may break.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and more) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture and spinal tumor. The safety and effectiveness of these devices for any other conditions are unknown.

Compliance with preoperative and intraoperative procedures and recommendations, a good knowledge of surgical techniques, correct selection and positioning of implants as well as the quality of the reduction obtained are important factors determining success of the operation. Appropriate patient selection and patient cooperation also have a major influence on the results. High non-fusion rates have been demonstrated in smokers, obese subjects, alcoholics, patients with poor quality bone or muscle and/or suffering from paralysis. These patients must be informed of this risk and its consequences.

In the case of a major bone defect of the anterior vertebral column, the surgeon must consider the use of additional support devices (e.g: intervertebral lumbar interbody, cement, anterior plate...).

Patient selection

- Particular attention must be paid to patient selection criteria, correct placement of the implant and postoperative care in order to minimize the mechanical stresses to which the implants are submitted.
- Only patients satisfying the criteria described in the indications must be selected.
- Patients corresponding to criteria described in the contraindications must not be selected.

Implant Use

- Adequate selection of the type, shape and size of the implant for each patient is crucial to the success of the operation. After implantation, implants are bearing repeated mechanical stresses and their resistance is limited by adaptation of their dimensions to bone anatomy. When these dimensions are not adapted, repeated stresses can induce excessive loading of the hardware, resulting in deformity, rupture or dismantling of the device before bone consolidation has been achieved, which may cause damage or require premature removal of the instrumentation.
- Mixing of dissimilar metals can accelerate the corrosion process. The components of this system are not to be used with implants of other material in building a construct. Components of this system should NOT be used with components from any other system or manufacturer.

PRECAUTIONS

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

SURGICAL IMPLANTS MUST NEVER BE REUSED; An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage.

Preoperative

- Implants must be handled and stored very carefully. They must not be scratched or damaged. Implants and instruments must be protected during storage, especially from corrosive environments.
- The surgeon must be familiar with all components before using this instrumentation and must personally manipulate the components to ensure that all implants and instruments are available before starting surgery.
- The type of construct to be performed for each case must be determined before starting the surgical operation. An adequate range of implant sizes must be available at the time of the operation, including smaller sizes and larger sizes than those initially planned.
- All components must be sterilized before use. Supplementary sterile components must be available if required unexpectedly.

Intraoperative (Please see surgical technique MS2-STG01, latest version in force at SpineVision)

- The surgeon must strictly comply with the instructions for use of the spinal instrumentation.
- The surgeon must always exert extreme caution in relation to the spinal cord and nerve roots. This warning is particularly important during insertion of screws. All nerve lesions can induce loss of neurological function.
- Rupture, sliding or incorrect use of the instruments or components of the implant can injure the patient or operating room personnel.
- Rods must not be repeatedly or excessively bent beyond that which is absolutely necessary. Very thoroughly verify that the surfaces of the implant are neither scratched nor damaged. If the rods must be cut to a certain length, they must be cut to obtain a flat, blunt surface, perpendicular to the axis of the rod. **Cut the rod outside of the surgical field.**
- Do not use screws of inappropriate dimensions (length, diameter) due to the risk of damage to the nerve roots or causing haemorrhage and/or avulsion.
- Bone graft must be performed to ensure satisfactory fusion. Autologous bone grafts are essentially used with this instrumentation.
- Before closure, all tightening screws must be tightened according to the instructions.

Postoperative

- The postoperative advice given by the surgeon to the patient and the patient's compliance with this advice are extremely important.
- The patient must be informed about the limits of use of the device. If premature and/or excessive loading of the spine occurs prior to complete bone consolidation, the patient must be informed that complications such as deformity, dismantling and/or rupture of the device can occur.
- The patient or the device must not be exposed to mechanical vibrations which could induce dismantling of the device. The patient must be informed about this risk and must be advised to limit his or her physical activities, particularly lifting and torsion movements, as well as any sports activities. The patient must be advised to refrain from smoking and drinking alcohol during the process of consolidation of the bone graft.
- Patients must be informed that they will be unable to flex their spine at the level of fusion and must be trained to compensate for this permanent physical limitation of their body's movements.
- Persistent absence of bone consolidation that cannot be immobilized places repeated and excessive stresses on the implant. Due to the mechanism of fatigue, these stresses can finally result in dismantling, deformity or rupture of the device. It is important to immobilize the zone of fusion and confirm this consolidation by radiological examination. If an abnormal absence of consolidation is observed or if the components become dismantled, deformed and/or broken, the device must be removed immediately, before it causes a serious lesion.
- Spinal implants are internal fixation devices designed to stabilize the operative zone during the normal consolidation process. Once consolidation has been achieved, these devices no longer have any useful function and can be removed by the surgeon. If the device is not removed after having completed its role, one of the following complications can occur:

- corrosion, with potential tissue reaction and/or localized pain,
- migration of the implant resulting in a lesion,
- risk of additional lesions due to postoperative trauma,
- deformity, dismantling and/or rupture may make hardware removal difficult or impossible,
- pain or abnormal feelings due to the presence of the device,
- risk of infection
- osteolysis due to transfer of mechanical loads

All explanted devices must be managed in order to prevent reuse in another surgical procedure.

Disposal

Disposal of all infectious wastes (implants) must be in accordance with applicable national and local regulations and the medical waste protocol of the medical center, and not endanger the security or the health of patient, user, or another person until its complete disposal (including cleaning, decontamination and waste).

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, reliability, durability, safety, effectiveness and/or performance should notify SpineVision®. Further, if any of the implanted spinal instrumentation components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, SpineVision® should be notified immediately. If any SpineVision® product may have caused or contributed to the death or serious injury of a patient, SpineVision® should be notified as soon as possible 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 is requested from SpineVision®.

Magnetic Resonance (MR) Safety: The LUMIS® has not been evaluated for safety and compatibility in the MR environment. The LUMIS® has not been tested for heating or migration in the MR environment.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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	Caution		Federal law (US) restricts this device to sale by or on the order of a physician.
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Medical device		Batch code
	Do not re-use		Manufacturer
	Keep dry		Catalog number
	Keep away from sunlight		Non-sterile