ENGLISH (EUROPE ONLY)

SpineVision®

Intended Use:
The Lumbar Universal Minimally Invasive System (LUMIS® System) instrumentation is designed for correction and support of the posterior and anterior lumbar vertebrae 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 fastener clips. 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.
Implants of the LUMIS® system must not be used with components derived from another manufacturer.
Nothing in the clinical evaluation report, it can be concluded that the beneficia-risk ratio is positive.

Indications:
The LUMIS® system is indicated to provide immobilization and stabilization of spinal segments in skeletal 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 by back pain of discogenic origin with degeneration of the disc confirmed by history and radiography), spondylolisthesis, degenerative scoliosis, kyphosis, kyphosis, vertebral fracture, fracture or dislocation, spinal stenosis, curvature (i.e., scoliosis, kyphosis, and/or lordosis), and tumor. It can be used from T1 to S2 segments. Write or without medical bone graft.
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).

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 severe cardiopulmonary abnormalities, raised erythrocyte sedimentation rate not explained by other diseases, high white blood cell count or a tendency to low white blood cell count, leukopenia.
- Localized infection of the operative site, signs of local inflammation.
- All patients with severe infection or infection tendency.
- Morbid obesity (BMI ≥ 40 kg/m2).
- Pregnancy and lactation.
- 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 implanted fixation to withstand the forces of healing and mechanical loading, 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 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.
- 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 to be used for any other use or purpose than those indicated. These contraindications must be considered by the physician when making his decision.

Potential adverse effects:
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, deforming, sliding and/or rupture of one or all components or instruments.
- Implant breakage. Implant breakage includes including possible screw breakage, screw avulsion, metal breakage, and/or metal fatigue.
- Subcutaneous pressure by the components, possibly causing alteration of the skin in places in which the tissue cover is insufficient. Over time, subcutaneous pressure may cause the skin to necrose.
- Dura damage, dural tear, cerebrospinal fluid leakage, nerve damage, root damage, cauda equina syndrome, neuroma, paresthesia, weakness, paralysis (partial or permanent), paraplegia, alteration in strength, reflexes, muscle mass, neuropathy, or other neurological disorders.
- Vascular injury, hemorrhage, blood loss, blood disorder or alteration 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 components are designed to be connected by rods 6mm in diameter rods. They are designed to be used with instruments specifically intended for these devices.
Connections for the U.L.I.S.™ and LUMIS™ systems must be tightened to a value of 8.5 N.m whatever the rod material is.

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. Instruments must be cleaned prior to distribution.
The 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. The instructions for cleaning, sterilization, inspection and maintenance of SpineVision medical devices: I-LG09.
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- **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 modular implants and instruments. Articulated instruments must be opened.
- It is recommended to use a neutral pH, enzymatic or alcaline (pH < 12) cleaning agents solution as recommended by the detergent manufacturer's instructions for use. Avoid foaming.
- Inspect each device, and repeat the washing in the presence of any residual debris, paying close attention to threads, crevices, fringes 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	Prevacuum	134°C (273°F) **See Note 1**	18 minutes
Steam	Prevacuum	132°C (270°F) **See Note 1**	4 minutes
Steam	Vacuum	132°C (270°F)	4 minutes
Steam	Vacuum	134°C (273°F)	3 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 construct will eventually fail because of material fatigue.

Prior to use:
- Check that all components are of the correct size.
- Check that all components are not damaged.
- Check that all components are not deteriorated.

During surgery:
- Do not use damaged components.
- Do not use components of different manufacturers.
- Do not use components of different sizes.
- Do not use components of different designs.
- Do not use components of different materials.
- Do not use components of different sterilization methods.
- Do not use components of different packaging.
- Do not use components of different lots.
- Do not use components of different expiration dates