ENGLISH

Description:

The Universal Lumbar Intuitive System (Ulis® 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 Ulis® system are made from ASTM F136 titanium alloy (Ti-6Al-4V ELI)
The Ulis® System is a single-use device and must never be reused.
Only anchorage implants (pedicle screws) should be in contact with the spine.
Components of the Ulis® system must not be used with components from another manufacturer.

Intended Purpose:

The Universal Lumbar Intuitive System (Ulis® 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.

Intended users:

Surgeon with a good knowledge of the device, its applications, the instruments, and the required surgical technique, e.g., specifically trained in the use of this pedicle screw system (please see surgical technique GIS2-ST).

Patient target group:

Skeletally mature patients, regardless of gender.

Clinical performance:

The Ulis® system provides stabilization of spinal segments and promote fusion (as an adjunct fixation to primary fixation devices).

Device expected lifetime:

The Ulis® system's expected lifetime is 24 months.

Device expected clinical benefits:

The procedure with the implantation of the Ulis® system is aimed to to relieve patients' back and leg pains, reduce their disability and therefore improve their quality of life.
Note: Spinal deformities are not always symptomatic (i.e., back and leg pains or neurologic symtoms), therefore, for these patients, the clinical benefit will be mainly to reduce their disability and improve their quality of life.

Indications:

The Ulis® Spine System is indicated in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine that are secondary to:

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- spondylolisthesis;
- spinal stenosis;
- curvatures (i.e., scoliosis, kyphosis, and/or lordosis);

It can be used from T1-S2 segments. With or without additional iliac fixation.

Contraindications:

Contraindications include:

- Allergy to the implanted material, mainly to metal,
- 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 (leukocytosis) or a tendency to low white blood cell count,
- Localized infection of the operative site,
- All patients with insufficient tissue cover of the operative site,
- Signs of local inflammation,
- Fever,
- Morbid obesity (BMI ≥ 40 kg/m^2),
- Pregnant woman
- Patient's inability to follow practitioner recommendations
- 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 stability of mechanical fixation,
- All cases not requiring bone graft or bone fusion,
- All cases requiring a combination of different metals,
- All patients not agreeing 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 similar to those of other spinal rod instrumentations. This spinal instrumentation is not designed or intended or sold for uses other than those indicated.
These contraindications must be taken into account by the physician when making his decision.

Potential adverse effects:

Some risks associated with non-instrumented spinal surgery have been identified in the state-of-the-art and are described below:

- Dural tears, pseudomeningocele, fistula, persistent Cerebrospinal Fluid Leak (CSF) leakage, meningitis;
- Loss of neurological functions, appearance of radiculopathies, dural injuries and/or pain. Neurovascular insufficiency, including paralysis or other serious lesions;
- Wound infection; Wound dehiscence;
- Gastrointestinal, urological and/or reproductive tract disorders, including sterility, impotence;
- Hemorrhage and/or hematoma;
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status; incapacity to resume the activities of normal everyday life;

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

(i) Adverse events related to the device:

- Implant migration;

- Dismantling, deformity, sliding and/or rupture of one or all components or instruments;
- Pain or abnormal feeling due to the presence of the device;
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.

(ii) Adverse events related to the device and instrumented surgery

- Infection;
- Screw or implant malposition;
- Facet joint violation;
- Lack of bone consolidation (or non-union);
- Loss of curvature or correction of the spine, loss of height;
- 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;
- Early or delayed hardware removal;
- Disk inflammation, arachnoiditis and/or other types of inflammation;
- Deep vein thrombosis, thrombophlebitis and/or pulmonary embolism;
- Soft tissue damage;
- Proximal junctional kyphosis;
- Cervical myelopathy;
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss;
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery;
- Adjacent segment disease or fracture of the vertebral body due to transfer of loads above and below the instrumented zone;
- Osteolysis.

(iii) Adverse events related to instrumented surgery

- Bone graft donor site complications;
- Death.

Note: Some potential adverse events may require an additional surgical revision procedure.
Please refer to the summary of safety and clinical performance (SSCP) for the quantification of the potential adverse events.

Placement of the device:

The Ulis® system is composed of implants designed to be connected by rods 6mm in diameter. 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 SAS.
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 Ulis® 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 SAS 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 or 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 Ulis® System components should be steam sterilized by using a sterilization process according to the international standard for moist heat ISO 17665-1. The following parameters should be followed:

METHOD	CYCLE	TEMPERATURE	MINIMUM EXPOSURE TIME
Steam	Vacuum	134°C (273°F)	18 minutes

The instruments and implants must be completely dried before use.

Please note that according EN ISO 17664-1, It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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 fusion. In the absence of a solid bone fusion between the instrumented vertebrae, 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 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment. The safety and effectiveness of these devices for any other conditions are unknown.

Only anchorage implants (pedicle screws) should be in contact with the spine.

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 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.
- Only skeletally mature patients (i.e., Risser sign of ≥4) can be selected for a treatment with pedicle screw spinal systems.

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 subjected to repeated stresses and their resistance is limited by the dimensions to bone anatomy. This limitation could lead to 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:

Precaution: 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 re-implanted. 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.
- The patient must be informed by the surgeon that summary of safety and clinical performance (SSCP) is available and that it can be asked to the surgeon. Summary of safety and clinical performance (SSCP) can be found directly on EUDAMED database https://ec.europa.eu/tools/eudamed.

Intraoperative: (please see surgical technique GIS2-ST, latest version in force at SPINEVISION SAS)

- 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 hooks and 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.
- Only anchorage implants (pedicle screws) should be in contact with the spine.
- Bone grafting must be performed to enable satisfactory bone fusion between instrumented vertebrae.
- Before closure, all set 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 laterally 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 a tissue reaction 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,
    - high risk of infection and
    - osteolysis due to transfer of mechanical loads.

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

Disposal:
Disposal of all infectious waste (implants) must be in accordance with applicable national and local regulations and the medical waste protocol of the medical center, and do 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 SAS. 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 SAS should be notified immediately. If any SPINEVISION SAS product may have caused or contributed to the death or serious injury of a patient, SPINEVISION SAS should be notified as soon as possible by telephone, fax or written correspondence (see contact details below). 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 SAS.
Any serious incident resulting from the use of the device may be also reported by healthcare professionals and/or patients to the national competent authority in the country where the incident occurred.

Magnetic Resonance (MR) Safety:

Tests have been performed for MRI compatibility. 4 parameters have been tested:

- Inducted Displacement Force according to ASTM F2052-21 standard.
- Inducted Torque according to ASTM F2213-17 standard.
- Heating according to ASTM F2182-19e2 standard.
- Artefact ASTM F2119-07 standard.

Based on the test results, the Ulis® System is conditionally safe under the following MR conditions

MRI Safety Information

MR Conditional

A patient with the SPINEVISION SAS ULIS OR LUMIS devices may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient and/or item malfunction.

Parameter	***Condition of Use / Information***
Static Magnetic Field Strength (B_0)	1.5 T, 3 T
Type of Nuclei	Hydrogen
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	1.5 T: 75.18 T/m (7518 G/cm) 3 T: 37.59 T/m (3759 G/cm)
RF Polarization **(Note: formerly called RF Excitation)**	Circularly Polarized (CP)
RF Transmit Coil	Whole Body and local extremities transmit RF coil can be used
RF Receive Coil	Any receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Whole Body Averaged SAR	Whole Body Averaged SAR ≤ 2 W/kg
Scan Duration and Wait Time	Maximum 15 minutes of continuous scanning followed by a wait time of 15 minutes before resuming scanning. Note: Autoscanning / Autoscan Mode is considered continuous scanning. Note: Short pauses between scan sequences are considered part of the scan time.
Patient characteristics	Patients with uncompromised thermoregulation and under uncontrolled conditions. Or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).
MR Image Artifact	In non-clinical testing, the image artifact caused by the device extends approximately 51 mm from the device edge on gradient echo image, and 58 mm on spin echo images, at 1.5 T.

Ulis® System is therefore labelled as “MR conditional”.

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		Consult instructions for use
	Keep away from sunlight		Batch code
	Do not re-use		Manufacturer
	Keep dry		Catalog number
	Date of Manufacture		Medical Device
	Non-sterile		MR Conditional

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