Hexanium® TLIF

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

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Computer filename / *Référence informatique du document* : SSCP TLIF_R-RA81_rev_E_EN

PROJECT INFORMATION *INFORMATIONS DU PROJET*	
SSCP Report Reference *Référence du Rapport RCSPC :*	*SSCP TLIF_R-RA81_rev_E*

CHANGE SUMMARY

Revision	Date	Justification	Revision Validated by the Notified Body
A	26/08/2022	Document creation	☐ Yes Validation language: English ☒ No
B	03/01/2023	Modification following Deficiencies report "DR1_Spinevision_INI_Hexanium TLIF_2022-12-30_713270864"	☐ Yes Validation language: English ☒ No
C	28/09/2023	Modification of BUDI in page 5 and page 18 Update of Harmonized standards applied in page 17 by taking into account harmonized standards under MDR	☐ Yes Validation language: English ☒ No
D	16/10/2023	Change of company name to "SPINEVISION SAS"	☐ Yes Validation language: English ☒ No
E	22/04/2024	Revision of the list of harmonized standards applicable according to the commission implementing decision (EU) 2024/815 of 6 March 2024.	☒ Yes Validation language: English ☐ No

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APPROVAL SIGNATURES

	Issued by Rédaction	Checked by Verification	Approval by Approbation
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Signature :			

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SSCP FOR USERS AND OR HEALTHCARE PROFESSIONALS

1. OBJECTIVE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

Following this information there is a summary intended for patients.

2. DEVICE IDENTIFICATION AND GENERAL INFORMATION

MANUFACTURER	
Name	SPINEVISION SAS
Address	10 rue de la Renaissance – Bâtiment E – 92160 Antony – France
Single Registration Number (SRN)	FR-MF-000001549
NOTIFIED BODY	
Name	TÜV SÜD
Single Identification Number	0123
PRODUCT	
Device trade name	Hexanium® TLIF
Basic UDI-DI	3663136TLIFCAGE5E
Medical Device Nomenclature Description/text	P09070101: Spinal cages
Class of device	Class III
Year when the first certificate (CE) was issued covering the device	2016

3. INTENDED USE OF THE DEVICE

A. INTENDED PURPOSE

The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is intended as intervertebral body fusion device of the lumbar spine (L2-S1). It is intended to be implanted via a transforaminal approach to give a primary stability of the anterior column (with or without restoring disc height) until fusion occurs.

Hexanium® TLIF intervertebral body fusion device must be combined with an appropriate posterior lumbar fixation device, e.g. the SPINEVISION® PLUS®, ULIS® or LUMIS®.

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B. INDICATION(S) AND TARGET POPULATION(S)

The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is an intervertebral body fusion device indicated for use in

- Patients with Degenerative Disc Disease (DDD) at one or two continuous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.
- Patients with DDD who may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Hexanium® TLIF is intended to be used in skeletally mature patients, who do not meet contraindications, and regardless of gender.

C. CONTRAINDICATIONS AND/OR LIMITATIONS

This device is not intended for thoracic or cervical spine use.

Contraindications include:

- infection, local to the operative site, signs of local inflammation, leukocytosis;
- fever;
- morbid obesity (BMI ≥ 40 kg/m^2);
- pregnant women;
- pediatric cases, or patient still having general skeletal growth;
- spondylolisthesis unable to be reduced to Grade I;
- suspected or documented allergy or intolerance to composite metal;
- 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.
- any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- prior fusion at the level to be treated.
- any case not needing a bone graft or fusion;
- any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis;
- 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 segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- senility, unable to understand/unwilling to follow physician's instructions,;
- any patient unwilling to cooperate with postoperative instructions.

The contraindications of these devices are similar to those of other spinal interbody systems. 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.

4. DEVICE DESCRIPTION

A. DESCRIPTION OF THE DEVICE

The Hexanium® TLIF system consists of a cage of various widths and heights, which can be inserted between two vertebral bodies of L2-S1 segment to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with bone graft. For the

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Hexanium® TLIF system, one cage must be used per segment for fusion in order to stabilize the segment concerned.

All cages are manufactured from implant grade Titanium (Ti6Al4V compliant with ASTM F136 and ASTM F3001). According to the previous clinical evaluation report, it was concluded that the benefice-risk ratio is positive.

The cages are composed of a plain part and a honeycomb structure with holes width of 1 mm. On both upper and bottom surfaces there are several rows of teeth with a height of 0.7 mm. Pyramidal teeth on the rear allow to avoid the back out of the cage. The bullet nose eases the insertion between the vertebrae. The rugosity of the surface is 6.4 µm.

Hexanium® TLIF implants were originally available in curved design, in heights of 7 mm to 16 mm in 1 mm increments in a small footprint (28 mm x 9 mm) or a medium footprint (32 mm x 10.5 mm).

Hexanium® TLIF implants of straight designed were also developed, in heights of 7 mm to 16 mm in 1 mm increments in a small footprint (28 mm x 10 mm) or a medium footprint (32 mm x 10 mm).

Hexanium® TLIF implants have a 5° lordosis angle.

For the Hexanium® TLIF system, one cage must be used per segment for fusion in order to stabilize the segment concerned. The Hexanium® TLIF must be filled with autogenous bone graft or a bone graft substitute to enhance the bone fusion. The choice of graft will always be the surgeon's responsibility.

B. PREVIOUS GENERATION(S) OR VARIANT

No previous generation is claimed for the Hexanium® TLIF

C. DESCRIPTION OF ACCESSORIES INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

No accessories are intended to be used in combination with the device.

D. DESCRIPTION OF DEVICES AND PRODUCTS INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

The Hexanium® TLIF must be filled with autogenous bone graft or a bone graft substitute to enhance the bone fusion. The choice of graft will always be the surgeon's responsibility.

Hexanium® TLIF cage must be combined with an appropriate posterior lumbar fixation device, e.g. the SPINEVISION® PLUS®, ULIS® or LUMIS®.

Hexanium® TLIF cage shall be used with a range of associated instruments to the cage. They are provided with the Hexanium® TLIF cage for any surgical procedure.

REFERENCE	DESIGNATION	INTENDED USE	VISUAL
INSTRUMENTS FOR DISC SPACE PREPARATION			
TL3-A033	Straight Rack Curette	*To remove disc material.*	
TL3-A035-R	Ring Curette Right		

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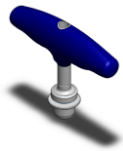
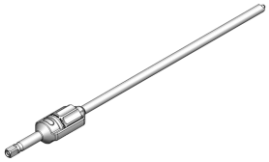
REFERENCE	DESIGNATION	INTENDED USE	VISUAL
TL3-A035-L	Ring Curette Left		
TL3-A037-01	Straight Convex Rasp	*To bleed the endplates.*	
TL3-A037-02	Curved Convex Rasp		
INSTRUMENTS FOR DISC SPACE RESTORATION			
TL3-A010-xx	Spreader (from 7 to 16 mm)	*To restore the height of the disc space and bleed the endplates.*	
TL3-A011-xx	Reamer (from 7 to 16 mm)		
SD-ATSH1169214C5	Snap-On Cannulated Silicon T-Handle	*To be connected to the instruments.*	
INSTRUMENTS FOR CAGE INSERTION/REMOVAL			
TL3-A001	Cage Holder	*To insert curved cages into the disc space.*	
TL3-A012	Ti TLIF Cage & Trial Holder	*To insert straight cages and trials into the disc space.*	
TL3-A002	Cage Holder Handle	*To be connected to the cage holders.*	

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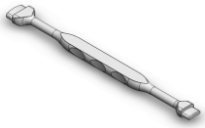
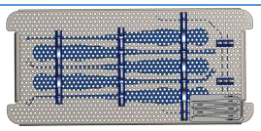
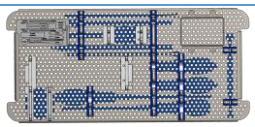
REFERENCE	DESIGNATION	INTENDED USE	VISUAL
TL3-A025	Sliding Hammer	*To ease the insertion/removal of the cage.*	
TL3-A022	Tamp	*To reposition the cage after insertion with the cage holder.*	
INSTRUMENTS FOR BONE GRAFTING (CURVED CAGES)			
TL3-A020	Cage Support for Graft	*To maintain the cage during bone graft compaction.*	
TL3-A021	Graft Compactor	*To compact the bone graft into the cage.*	

Table 1: Instruments intended to be used to implant Hexanium® TLIF cages

REFERENCE	DESIGNATION	DESCRIPTION	PICTURE
SD-BASE1158	SV Common Base DIN 1/1 H68 mm	*To contain trays.*	
SD-BASE11117	SV Common Base DIN 1/1 H117 mm		
SD-MLID	SV Common Lid DIN 1/1		
TL3-TRAY111	Curette Tray	*To hold curettes.*	
TL3-TRAY112	Spreader Tray	*To hold spreaders.*	
TL3-TRAY113	Ti TLIF Instrument Tray	*To hold instruments for TLIF.*	

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REFERENCE	DESIGNATION	DESCRIPTION	PICTURE
TL3-RACK	Ti TLIF Trials Rack	*To hold trials for TLIF.*	

Table 2: Instruments intended to be used to implant Hexanium® TLIF cages

5. RISKS AND WARNINGS

A. RESIDUAL RISKS AND UNDESIRABLE EFFECTS

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

- aortic occlusion with non-fatal cardiac arrest
- bowel injury
- myocardial infarction
- hemorrhage of blood vessels and/or hematomas;
- disc disruption or degeneration above, or below the level of surgery;
- deep venous thrombosis, thrombophlebitis;
- development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.;
- urinary retention or loss of bladder control or other types of urological system compromise;
- change in mental status;
- incapacity to resume the activities of normal everyday life;

This list is not exhaustive. Other risks that may arise during spinal surgery.

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

- delayed union;
- non-union (or pseudoarthrosis);
- bone fracture or stress shielding at, above, or below the level of surgery, microfracture, resorption, or damage of any spinal bone (including pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site;
- retropulsed graft;
- loosening, or migration of implant, that may result in paralysis, neurological disorders or blood vessel erosion due to the proximity of the device;
- 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;
- injury of muscular structures
- infection;
- discitis, arachnoiditis, and/or other types of inflammation;
- subsidence of implant into adjacent vertebral bodies resulting in loss of height and possible impingement of neural structures;
- loss of proper spinal curvature, correction, height, and/or reduction;
- loss of sagittal balance
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus,
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring;

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- bone graft donor site complication;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- pseudarthrosis;
- stenosis;
- inadequate lordosis recovery;
- death

Note: Some potential adverse events may require an additional surgical revision procedure and may increase the operative time.

Quantitative data:

Based on lumbar interbody devices' recognized undesirable side-effects/adverse events (USEs/AEs) and complications identified within the state of the art, it is possible that Hexanium® TLIF may be associated with:

Adjacent segment degeneration/disease

- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)
- Rate from the general state of the art:
  - General: 8.5% - 26.6% (Hashimoto 2018)
  - At five years: 7% (Kuo 2020)

Reoperation

- Rate from the general state of the art:
  - General: 11.1% (Manzur 2020)
  - From 1 to 11 years: 0 – 39% (Lang 2019)
  - At 15 years: 37.5% (Lang 2019)

Cage breakage

- Rate from the general state of the art: 3.7% (Koenders 2019)

Cage migration

- Rate from the general state of the art: 1.3% - 8% (Koenders 2019; Yu 2022)

Cage subsidence

- Rate from the general state of the art: 27.6% (Yu 2022)

Nerve root injury

- No rate reported for non-equivalent similar devices neither from the general state of the art (Lan 2018; Li 2020)

Malposition of pedicle screw:

- Rate from the general state of the art: 3.7% - 4.3% (Koenders 2019)

Adjacent segment instability

- Rate from the general state of the art: 3.3% (Koenders 2019)

Wound infection

- Rate from the general state of the art: 1.3% - 5.8% (Koenders 2019)
- Rate from non-equivalent similar devices: 2% - 3.3% (Mokawem 2019; Belykh 2018)

Pseudarthrosis

- Rate from the general state of the art: 1.7% - 4.7% (Koenders 2019)

Dural tear

- Rate from the general state of the art: 3.3% - 16% (Koenders 2019)
- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Vascular wound

- Rate from the general state of the art: 1.6% - 4.5% (Koenders 2019)

Spinal / Submuscular hematoma

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- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Aortic occlusion with non-fatal cardiac arrest

- Rate from the general state of the art: 2% (Koenders 2019)

Pulmonary embolism

- Rate from the general state of the art: 3.3% - 4.3% (Koenders 2019)

Myocardial infarction

- Rate from the general state of the art: 4% (Koenders 2019)

Acute allergic reaction

- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Urosepsis

- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Bowel injury

- Rate from the general state of the art: 4.5% (Koenders 2019)

Post-operative confusion

- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Urinary tract injury:

- Rate from the general state of the art: 46 documented cases in the literature (Turgut 2020)

Vertebral slippage

- No rate reported for non-equivalent similar devices neither from the general state of the art (Tang 2020)

Worsening of neurological symptoms

- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Leg pain

- Rate from non-equivalent similar devices: 2% (Mokawem 2019)

Iliac deep vein thrombosis

- Rate from non-equivalent similar devices: 2% (Mokawem 2019)

B. WARNINGS AND PRECAUTIONS

PREOPERATIVE

- The surgeon must be aware of not only the medical and surgical aspects of the implant, but also of the material limitations of titanium implants. The patient must be instructed in the limitations of the implant, especially with regard to the weight bearing and other body stresses on the device before a solid fusion occurs. The patient must be instructed that non-compliance with postoperative instructions could lead to failure of the device. The patient must be instructed that device failure could lead to the need for additional surgery to remove failed components.
- Patients should have received at least 6 weeks of non-operative treatment prior to treatment with Hexanium® TLIF system.
- **Only patients that meet the criteria described in the indications should be selected and patients corresponding to the aforementioned contra-indications should not be selected. The following factors may be of importance when selecting patients for internal stabilization devices:**
  - foreign body sensitivity;
  - certain degenerative diseases;
  - senility, unable to understand/unwilling to follow physician's instructions, alcoholism, or drug abuse;

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- obesity;
- patient's occupation or activity level;
- smoking.

- Additional sterile components should be available in case of any unexpected need**.**

INTRAOPERATIVE (Please see surgical technique GTL3-ST, latest applicable version at SPINEVISION SAS)

- Correct handling of the implants is extremely important. The implants must be transported in a way not to incur any damage. The implants must not be scratched and must not collide during handling.
- Care must be taken when picking up the Hexanium® TLIF implant, filling it with bone graft and inserting it between the vertebral bodies. Alterations may produce defects in surface finish and may become the focal point for eventual breakage of the implant or for decreased efficacy in withstanding post-operative migration (e.g. when teeth of implant are damaged).
- Correct selection of the implant size is extremely important. The chance of adequate stabilization is increased by the selection of the proper size of the implant regarding the anatomy and conditions of the patient. Proper selection of the implant can minimize, but not eliminate risks.
- The Hexanium® TLIF components have been designed for use with this system. Do not use the Hexanium® TLIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium® TLIF cannot be inserted via an anterior approach.
- The Hexanium® TLIF cannot be used in cervical and thoracic spine.
- The implant should be placed on the peripheral cortical bone of the endplates to minimize the risk of post - operative subsidence.
- **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

POSTOPERATIVE

- The fusion mass matures and becomes able to share load with the implant. **Adequately instruct the patient in the appropriate postoperative care**. The patient must be instructed to reduce stress on the implants in order to avoid clinical problems that may accompany failed fixation. The patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be instructed in the limitations of the implant, and that physical activity and full weight bearing may cause premature failure of internal stabilization devices by migrating, loosening or fracture. The patient must be instructed that an implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on the implant. An active, debilitated, or demented patient who is unable to use orthotic weight bearing devices may be particularly at risk.
- No internal stabilization device can withstand activity levels equal to those withstood by normal healthy segment. No implant can be expected to withstand unsupported weight-bearing stress indefinitely.
- Implants may fail when subjected to the increased loading associated with delayed union or non-union. Internal stabilization devices are intended as load-sharing devices until normal healing occurs. If normal healing does not occur or is delayed, the device may break due to fatigue. Patients should be informed of the risks of implant failure.

The Hexanium® TLIF has not been evaluated for safety and compatibility in the MRI environment. The Hexanium® TLIF has not been tested for heating or migration in the MRI environment.

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C. OTHER RELEVANT ASPECTS OF SAFETY (i.e., FSCA/FSN)

No other relevant aspects of safety are claimed for Hexanium® TLIF.

6. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

A. SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE (IF APPLICABLE)

N/A. No equivalent device was claimed, current clinical data is based on Hexanium® TLIF (curved design).

It has to be noted that Hexanium® TLIF (straight design) and Hexanium® TLIF (curved design) have identical clinical and biological characteristics. They have similar technical characteristics with some discrepancies due to the design: one being curved the other being straight. However, this difference does not impact the device safety and performance, with no additional risk, as reported in the state-of-the-art.

Hence based on clinical, biological and technical characteristics, Hexanium® TLIF (straight design) is considered to be equivalent to Hexanium® TLIF (curved design). Therefore, all clinical evidence presented are applicable to both designs.

B. SUMMARY OF CLINICAL DATA FROM PRE-MARKET CLINICAL INVESTIGATION(S)

N/A. There were no specific clinical investigations performed on the device before CE-marking.

C. SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

N/A. Clinical data on Hexanium® TLIF can be generated and held by the manufacturer or can be found in the literature. In the clinical evaluation report associated to Hexanium® TLIF, clinical data was generated by Post-Market Clinical Follow-Up (PMCF) studies related to the study device. No publication related to Hexanium® TLIF was found in the literature.

D. AN OVERALL SUMMARY OF THE CLINICAL PERFORMANCE AND SAFETY

SPINEVISION SAS claims that Hexanium® TLIF system provides immediate stabilization of unstable spinal segments, promote a surface area for bony ingrowth while having the biomechanical properties to support the axial skeleton, and maintains interbody space and lordosis of the spine.

Based on the preliminary results of the two PMCF studies, it was confirmed that:

- Hexanium® TLIF system provides immediate stabilization of unstable spinal segments: this was verified by 100% stable system in patients with available data at 2 months (n=22), at 6 months (n=10) and at 12 months (n=67)
- Hexanium® TLIF system promote fusion between two continuous levels from L2-S1: this was verified by total fusion on 98.5% of patients at 12 months

The clinical data and clinical evidence are sufficient to demonstrate the clinical performance of Hexanium® TLIF up to 12 months.

Safety claims for the Hexanium® TLIF system are the following: biocompatible; solid (i.e., resistant to breakage/tear); limited complications associated with the use of the Hexanium® TLIF system.

Based on the preliminary results of the two PMCF studies, it was confirmed that:

- Hexanium® TLIF system is biocompatible: verified following biocompatibility testing conducted by SPINEVISION SAS, according to the standards. Device biocompatibility was also confirmed through the absence of reaction to the device reported during PMS and PMCF activities.

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- Hexanium® TLIF system is solid: verified through PMS activities with no device breakage/tear reported.
- The use of Hexanium® TLIF system does not lead to more complications compared to those observed in the literature.

The clinical data and clinical evidence are sufficient to demonstrate the clinical safety and performance of Hexanium® TLIF over the lifetime of the device.

E. ONGOING OR PLANNED POST-MARKET CLINICAL FOLLOW-UP

SPINEVISION SAS has implemented two PMCF studies for Hexanium® TLIF (curved design) since CE marking under MDD requirements. These studies are ongoing and will still be active after the device CE marking under the MDR requirements. SPINEVISION SAS has also scheduled a PMCF study for Hexanium® TLIF (straight design) which will start after the device CE marking under MDR requirements.

SV005 - Hexanium® TLIF Study (study device: Hexanium® TLIF (curved design))

The Hexanium® TLIF Study goal is to confirm performance and safety of Hexanium® TLIF system in the treatment of skeletally mature patients suffering from degenerative disc disease.

It is an ambispective, non-interventional, multicentric, post market clinical follow up study.

Patients' data will be collected up to 2 years post Hexanium® TLIF implant procedure, at the following time points: 2 months, 6 months, 12 months and 24 months post-surgery, per standard of care.

The primary endpoints are as follows:

- primary safety endpoint: incidence of serious adverse device and/or procedure-related events, within two (2) years of the device implant;
- primary performance endpoint: improvement of the Oswestry Disability Index (ODI) at twelve (12) months after implantation compared to baseline.

To the date of this document, a total of 44 patients have been treated with Hexanium® TLIF and were included in the study after obtaining patients' non-opposition to the collection of their personal data. 19 patients reached the 12 months post-procedure time point but among these 19 patients, only 6 patients had their follow-up visit performed.

SV007 – US Hexanium® TLIF – PMCF study (study device: Hexanium® TLIF (curved design))

The objective of SV007 – US Hexanium® TLIF PMCF Study is to assess of the Hexanium® TLIF and Ulis systems effectiveness in reducing functional disability associated with lumbar pain 12 months post-surgery. The primary endpoint is the Oswestry Disability Index (ODI) at 12 (10-18) months after implantation.

The result of the primary endpoint will allow to show the efficacy of Hexanium® TLIF in patients with DDD. It is a common outcome used to evaluate the performance of an interbody cage in this indication.

Clinical follow-ups are scheduled at 2 to 3 months, 6 months, 12 months and 24 months post-surgery, as performed in the current practice in the participating site.

To the date of this document, 83 Hexanium® TLIF systems were implanted in 66 patients. Baseline data are available for all 66 patients and in total, 81.8% of patients' data (54 patients) were available in the database for the 12-month post-procedure to evaluate the primary endpoint and 77.3% of patients' data (51 patients) for the 24-months post-procedure.

SV012 – LINEAR study (study device: Hexanium® TLIF (straight design))

The LINEAR study is an ambispective, non-interventional, multicentric, post-market clinical follow-up study with the objective to confirm the performance and safety of Hexanium® TLIF (straight design) in the treatment of patients suffering from degenerative disc disease.

The primary endpoints are as follow:

- primary safety endpoint is the incidence of serious and non-serious adverse device and/or procedure-related events, within 12 months of the device implant.

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- Primary performance endpoint is the improvement of the Oswestry Disability Index (ODI) at twelve (12) months after implantation compared to baseline.

To the date of this document, the study has not yet started. It is scheduled to have first patient inclusions after device CE marking under MDR requirements.

7. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Theoretically, some treatment goals can be reached by conservative (nonsurgical) methods and they are generally the first choice for treatment. Conservative treatment options include:

- pharmacotherapy including painkillers, anti-inflammatories, muscle relaxants, antidepressants, local corticosteroid injections, and nerve blocks;
- physiotherapy including spinal traction, electrostimulation of muscles, electromagnetic and magnetic field therapy, massage, manual therapy, acupuncture, and specific exercises;
- cognitive therapy focused on addressing psychological problems, in particular depression and anxiety associated with chronic pain.

Other lumbar interbody fusion approaches exist: Anterior Lumbar Interbody Fusion (ALIF), Lateral Lumbar Interbody Fusion (LLIF), Oblique Lateral Interbody Fusion (OLIF) and Posterior Lumbar Interbody Fusion (PLIF). Interbody cage designs may differ depending on the approach chosen.

In the state-of-the-art, hybrid surgery with combination of fusion and non-fusion technique has emerged as a potential treatment alternative. This technique involves lumbar interbody fusion and either total disc arthroplasty or dynamic stabilization or hybrid instrumentation.

8. SUGGESTED PROFILE AND TRAINING FOR USERS

The use of the Hexanium® TLIF shall be performed by a trained orthopedic surgeon or neurosurgeon familiar with spine surgery as well as with the operating techniques relating to these implants.

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9. REFERENCE TO ANY HARMONISED STANDARDS APPLIED

The list of standards below contains the harmonised standards applied under regulation (EU) 2017/745.

Class	Reference	Description	Publication year
A. Quality Management	EN ISO 13485*	Medical devices - Quality management systems - Requirements for regulatory purposes	2016
B. Risk Management	EN ISO 14971*	Medical devices - Application of risk management to medical devices	2019
B. Risk Management	IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015
C. General Requirements	EN ISO 14630	Non-active surgical implants - General requirements	2013
C. General Requirements	EN ISO 14602	Non-active surgical implants - Implants for osteosynthesis - Particular requirements	2012
E. Manufacturing	ISO 20417	[Labelling] Medical devices — Information to be supplied by the manufacturer	2021
E. Manufacturing	EN ISO 15223-1*	[Labelling] Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
E. Manufacturing	EN ISO 11607-1*	[Packaging] Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020
E. Manufacturing	EN ISO 11607-2*	[Packaging] Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2019
E. Manufacturing	EN ISO 14937	[Sterilization]Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	2009
E. Manufacturing	EN ISO 11137-1*	[Sterilization] Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015

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Class	Reference	Description	Publication year
E. Manufacturing	EN ISO 11137-2*	[Sterilization] Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	2015
E. Manufacturing	EN ISO 11737-1*	[Sterilization] Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2018
E. Manufacturing	EN ISO 11737-2*	[Sterilization] Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020
E. Manufacturing	EN 556-1	[Sterilization]Sterilization of medical devices - Requirements for medical devices to be designated STERILE - Part 1 : requirements for terminally sterilized medical devices	2002
H. Biocompatibility	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
H. Biocompatibility	EN ISO 10993-2	Biological evaluation of medical devices Part 2: Animal welfare requirements	2022
H. Biocompatibility	EN ISO 10993-3	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
H. Biocompatibility	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
H. Biocompatibility	EN ISO 10993-6	Biological evaluation of medical devices Part 6: Tests for local effects after implantation	2016
H. Biocompatibility	EN ISO 10993-10*	Biological evaluation of medical devices Part 10: Tests for skin sensitization	2023
H. Biocompatibility	EN ISO 10993-11	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	2017
H. Biocompatibility	EN ISO 10993-12*	Biological evaluation of medical devices Part 12: Sample preparation and reference materials	2021

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Class	Reference	Description	Publication year
H. Biocompatibility	EN ISO 10993-17*	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents	2023
H. Biocompatibility	EN ISO 10993-18*	Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process	2020
H. Biocompatibility	EN ISO 10993-23*	Biological evaluation of medical devices Part 23: Tests for irritation	2021
I. Clinical Evaluation	EN ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	2020

*Harmonised standards under regulation (EU) 2017/745.

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SSCP PATIENTS

PROJECT INFORMATION	
SSCP Report Reference	*SSCP TLIF_R-RA81_rev_E*
Document Revision	*E*
Date issued	*24/04/2024*

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

MANUFACTURER	
Name	SPINEVISION SAS
Address	10 rue de la Renaissance – Bâtiment E – 92160 Antony – France
PRODUCT	
Device trade name	Hexanium® TLIF
Basic UDI-DI	3663136TLIFCAGE5E
Year when the device was first CE-marked	2016

2. INTENDED USE OF THE DEVICE

A. INTENDED PURPOSE

The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is intended as intervertebral body fusion device of the low spine . It is intended to be implanted via a transforaminal approach to give a primary stability of the anterior column (with or without restoring vertebral disc height) until fusion occurs. Spinal fusion is a surgical procedure that is performed to join two or more bones of the spine together, eliminating movement between them.

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Hexanium® TLIF intervertebral body fusion device must be combined with an appropriate posterior lumbar fixation device, e.g. the SPINEVISION® PLUS®, ULIS® or LUMIS®.

B. INDICATION(S) AND INTENDED PATIENT GROUP(S)

The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is an intervertebral body fusion device indicated for use in:

- Patients with Degenerative Disc Disease (DDD) at one or two continuous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc (a form of low back pain caused by chemically or mechanically damaged intervertebral discs), confirmed by patient medical history and radiographic images.
- Patients with DDD who may also have up to Grade I spondylolisthesis (vertebra sliding forward) or retrolisthesis (vertebra sliding backward) at the involved level(s).

C. CONTRAINDICATIONS

This device is not intended for thoracic or cervical spine use.

Contraindications include:

- infection, local to the operative site, signs of local inflammation, leukocytosis (high white blood cell count);
- fever;
- morbid obesity (BMI ≥ 40 kg/m2);
- pregnant women;
- pediatric cases, or patient still having general skeletal growth;
- spondylolisthesis (slip forward of a vertebrae relative to the one just below) unable to be reduced to Grade I;
- suspected or documented allergy or intolerance to composite metal;
- 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;
- any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- prior fusion at the level to be treated;
- any case not needing a bone graft or fusion;
- any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis;
- 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 segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
- patient's inability to follow practitioner recommendations;
- any patient unwilling to cooperate with postoperative instructions.

The contraindications of these devices are similar to those of other spinal interbody systems. 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.

3. DEVICE DESCRIPTION

A. DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENTS TISSUES

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The Hexanium® TLIF system consists of a cage of various widths and heights (see figure 1), which can be inserted between two vertebral bodies of L2-S1 segment (low back) to give support and correction during lumbar interbody fusion surgeries (see figure 2).

Hexanium® TLIF cage is exclusively composed of Titanium alloy which is biocompatible. Only the titanium is in contact with the patient's tissues.

Figure 1: Visual of Hexanium® TLIF cage (curved version on the left and straight version on the right)

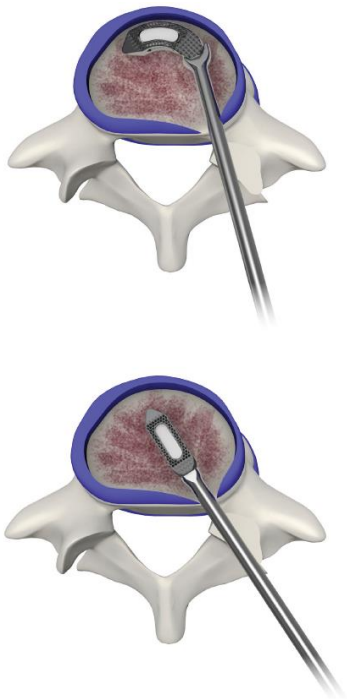

Figure 2: Insertion of the Hexanium® TLIF cage into the intervertebral space

There are 2 versions of Hexanium® TLIF cage. The curved Hexanium® TLIF cage and the straight Hexanium® TLIF cage. Visual of the 2 versions of Hexanium® TLIF cage is available in the figure 1 (curved version on the left and straight version on the right). These device versions have been developed for the following reasons:

- to accommodate the various anatomical differences in patients
- the various correction strategies in terms of endplate shape, lordosis, height, width, and depth.

These 2 versions of Hexanium® TLIF cage are similar from a functional point of view, but their shape allows an adaptation to the anatomical variations of the implanted patients.

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The Hexanium® TLIF must be filled with autogenous bone graft or a bone graft substitute to enhance the bone fusion. The choice of graft will always be the surgeon's responsibility.

Hexanium® TLIF cage must be combined with an appropriate posterior lumbar fixation device, e.g. the SPINEVISION® PLUS®, ULIS® or LUMIS®.

Hexanium® TLIF cage shall be used with a range of associated instruments to the cage. They are provided with the Hexanium® TLIF cage for any surgical procedure.

B. INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

Hexanium® TLIF cage does not contain medicinal substances. Therefore, no medicinal substance is in contact with the patient's tissues.

C. DESCRIPTION OF HOW THE DEVICE IS ACHIEVING ITS INTENDED MODE OF ACTION

Hexanium® TLIF cage achieve its intended mode of action by:

- Mechanically maintaining the height between adjacent vertebrae
- Allowing primary stability is achieved by the upper and lower surface of the cage ridges/teeth resisting backout and supplemental internal spinal fixation.
- Allowing secondary fixation with a material that allows the bone to form around, and internal cavity permits placement of bone graft, in order to facilitate long-term fusion of the motion segment.

D. DESCRIPTION OF ACCESSORIES, IF ANY

No accessories are intended to be used in combination with the device.

4. RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks.
This document is not intended to replace a consultation with your healthcare professional if needed.

A. HOW POTENTIAL RISKS HAVE BEEN CONTROLLED OR MANAGED

In order to control potential risks that could arise when using Hexanium® TLIF cage, SPINEVISION SAS decided to use risk control methods as indicated in ISO 14971.
These control methods consist of:

- Use of medically safe products in design and manufacture
- Protective measures in the medical device itself or in the manufacturing process
- information for safety and, where appropriate, training to users

B. REMAINING RISKS AND UNDESIRABLE EFFECTS

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

- aortic occlusion with non-fatal cardiac arrest
- bowel injury
- myocardial infarction
- hemorrhage of blood vessels and/or hematomas;
- disc disruption or degeneration above, or below the level of surgery;

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- deep venous thrombosis, thrombophlebitis;
- development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.;
- urinary retention or loss of bladder control or other types of urological system compromise;
- change in mental status;
- incapacity to resume the activities of normal everyday life;

This list is not exhaustive. Other risks that may arise during spinal surgery.

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

- delayed union;
- non-union (or pseudoarthrosis);
- bone fracture or stress shielding at, above, or below the level of surgery, microfracture, resorption, or damage of any spinal bone (including pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site;
- retropulsed graft;
- loosening, or migration of implant, that may result in paralysis, neurological disorders or blood vessel erosion due to the proximity of the device;
- 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;
- injury of muscular structures
- infection;
- discitis, arachnoiditis, and/or other types of inflammation;
- subsidence of implant into adjacent vertebral bodies resulting in loss of height and possible impingement of neural structures;
- loss of proper spinal curvature, correction, height, and/or reduction;
- loss of sagittal balance
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus,
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring;
- bone graft donor site complication;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- pseudarthrosis;
- stenosis;
- inadequate lordosis recovery;
- death

Note: Some potential adverse events may require an additional surgical revision procedure and may increase the operative time.

Quantitative data:

Based on lumbar interbody devices' recognized undesirable side-effects/adverse events (USEs/AEs) and complications identified within the state of the art, it is possible that Hexanium® TLIF may be associated with:

Adjacent segment degeneration/disease

- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)
- Rate from the general state of the art:
  - General: 8.5% - 26.6% (Hashimoto 2018)

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- At five years: 7% (Kuo 2020)

Reoperation

- Rate from the general state of the art:
  - General: 11.1% (Manzur 2020)
  - From 1 to 11 years: 0 – 39% (Lang 2019)
  - At 15 years: 37.5% (Lang 2019)

Cage breakage

- Rate from the general state of the art: 3.7% (Koenders 2019)

Cage migration

- Rate from the general state of the art: 1.3% - 8% (Koenders 2019; Yu 2022)

Cage subsidence

- Rate from the general state of the art: 27.6% (Yu 2022)

Nerve root injury

- No rate reported for non-equivalent similar devices neither from the general state of the art (Lan 2018; Li 2020)

Malposition of pedicle screw:

- Rate from the general state of the art: 3.7% - 4.3% (Koenders 2019)

Adjacent segment instability

- Rate from the general state of the art: 3.3% (Koenders 2019)

Wound infection

- Rate from the general state of the art: 1.3% - 5.8% (Koenders 2019)
- Rate from non-equivalent similar devices: 2% - 3.3% (Mokawem 2019; Belykh 2018)

Pseudarthrosis

- Rate from the general state of the art: 1.7% - 4.7% (Koenders 2019)

Dural tear

- Rate from the general state of the art: 3.3% - 16% (Koenders 2019)
- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Vascular wound

- Rate from the general state of the art: 1.6% - 4.5% (Koenders 2019)

Spinal / Submuscular hematoma

- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Aortic occlusion with non-fatal cardiac arrest

- Rate from the general state of the art: 2% (Koenders 2019)

Pulmonary embolism

- Rate from the general state of the art: 3.3% - 4.3% (Koenders 2019)

Myocardial infarction

- Rate from the general state of the art: 4% (Koenders 2019)

Acute allergic reaction

- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Urosepsis

- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Bowel injury

- Rate from the general state of the art: 4.5% (Koenders 2019)

Post-operative confusion

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- No rate reported for non-equivalent similar devices neither from the general state of the art (Koenders 2019)

Urinary tract injury:

- Rate from the general state of the art: 46 documented cases in the literature (Turgut 2020)

Vertebral slippage

- No rate reported for non-equivalent similar devices neither from the general state of the art (Tang 2020)

Worsening of neurological symptoms

- Rate from non-equivalent similar devices: 3.3% (Belykh 2018)

Leg pain

- Rate from non-equivalent similar devices: 2% (Mokawem 2019)

Iliac deep vein thrombosis

- Rate from non-equivalent similar devices: 2% (Mokawem 2019)

The Hexanium® TLIF has not been evaluated for safety and compatibility in the MRI environment. The Hexanium® TLIF has not been tested for heating or migration in the MRI environment.

C. WARNINGS AND PRECAUTIONS

PREOPERATIVE

- The surgeon must be aware of not only the medical and surgical aspects of the implant, but also of the material limitations of titanium implants. The patient must be instructed in the limitations of the implant, especially with regard to the weight bearing and other body stresses on the device before a solid fusion occurs. The patient must be instructed that non-compliance with postoperative instructions could lead to failure of the device. The patient must be instructed that device failure could lead to the need for additional surgery to remove failed components.
- Patients should have received at least 6 weeks of non-operative treatment prior to treatment with Hexanium® TLIF system.
- **Only patients that meet the criteria described in the indications should be selected and patients corresponding to the aforementioned contra-indications should not be selected. The following factors may be of importance when selecting patients for internal stabilization devices:**
  - foreign body sensitivity;
  - certain degenerative diseases;
  - senility, unable to understand/unwilling to follow physician's instructions, alcoholism, or drug abuse;
  - obesity;
  - patient's occupation or activity level;
  - smoking.
- Additional sterile components should be available in case of any unexpected need**.**

INTRAOPERATIVE

- Correct handling of the implants is extremely important. The implants must be transported in a way not to incur any damage. The implants must not be scratched and must not collide during handling.
- Care must be taken when picking up the Hexanium® TLIF implant, filling it with bone graft and inserting it between the vertebral bodies. Alterations may produce defects in surface finish and may become the focal point for eventual breakage of the implant or for decreased efficacy in withstanding post-operative migration (e.g. when teeth of implant are damaged).

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- Correct selection of the implant size is extremely important. The chance of adequate stabilization is increased by the selection of the proper size of the implant regarding the anatomy and conditions of the patient. Proper selection of the implant can minimize, but not eliminate risks.
- The Hexanium® TLIF components have been designed for use with this system. Do not use the Hexanium® TLIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium® TLIF cannot be inserted via an anterior approach.
- The Hexanium® TLIF cannot be used in cervical and thoracic spine.
- The implant should be placed on the peripheral cortical bone of the endplates to minimize the risk of post - operative subsidence.
- **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

POSTOPERATIVE

- The fusion mass matures and becomes able to share load with the implant. **Adequately instruct the patient in the appropriate postoperative care**. The patient must be instructed to reduce stress on the implants in order to avoid clinical problems that may accompany failed fixation. The patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be instructed in the limitations of the implant, and that physical activity and full weight bearing may cause premature failure of internal stabilization devices by migrating, loosening or fracture. The patient must be instructed that an implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on the implant. An active, debilitated, or demented patient who is unable to use orthotic weight bearing devices may be particularly at risk.
- No internal stabilization device can withstand activity levels equal to those withstood by normal healthy segment. No implant can be expected to withstand unsupported weight-bearing stress indefinitely.
- Implants may fail when subjected to the increased loading associated with delayed union or non-union. Internal stabilization devices are intended as load-sharing devices until normal healing occurs. If normal healing does not occur or is delayed, the device may break due to fatigue. Patients should be informed of the risks of implant failure.

D. SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION (FSCA)

No other relevant aspects of safety are claimed for Hexanium® TLIF.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

A. CLINICAL BACKGROUND OF THE DEVICE

The Hexanium® TLIF system is CE marked in December 2017; the CE marking certifies that this medical device has met the European Union (EU) consumer safety requirements and can be freely sold throughout the EU. The Hexanium® TLIF is on the market since 2018 with 3,254 units sold worldwide. The device is not considered as a new technology. Indeed, this technology (interbody cages for spinal fusion) has been used for several years in the medical field with proven safety and efficacy.

B. CLINICAL EVIDENCE FOR THE CE-MARKING

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Since the device is on the market, SPINEVISION SAS has organized two non-interventional clinical studies (observational studies with only standard of care patient's data collection) to confirm the device's safety and performance in patients suffering from degenerative disc disease.

One of the studies is conducted in the USA with 66 patients included and the other one is conducted in Europe with to date 44 patients included in 2 French sites. Both studies are ongoing.

Preliminary results showed that implantation of Hexanium® TLIF system provides immediate stabilization of unstable spinal segments in all patients. Additionally at 12 months, 98.5% of patients had the bones of their spine (2 or more levels) joined together permanently (=spinal fusion). These preliminary results showed that the implantation of Hexanium® TLIF system allow stabilization of spinal segment and promote spinal fusion.

Preliminary results of both studies also showed that implantation of Hexanium® TLIF system is safe with limited complications reported during the course of the studies.

C. SAFETY

Through preliminary analysis of both clinical studies, patients treated by the Hexanium® TLIF system felt that their back and leg pains were reduced even up to 24 months after the index procedure compared to prior they have been implanted with the device. Additionally, their disability was improved as reported during follow-ups (at 2-, 6-, 12- and 24-month post-procedure) compared to baseline. These preliminary results showed that implantation of Hexanium® TLIF improves patients' quality of life with limited risks.

Through these preliminary results, SPINEVISION SAS considers that the benefit/risk ratio of using Hexanium® TLIF in patients with degenerative disc disease is positive.

The two non-interventional clinical studies are still ongoing. Patients' inclusion is completed in the study set up in the USA, but patients' follow-up is ongoing. In the study set up in Europe, patients' inclusion and follow-ups are still ongoing.

Continuous collection of the data provided by both studies will allow to confirm the continuous safety and performance of Hexanium® TLIF.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

Theoretically, some treatment goals can be reached by conservative (nonsurgical) methods and they are generally the first choice for treatment. Conservative treatment options include:

- pharmacotherapy including painkillers, anti-inflammatories, muscle relaxants, antidepressants, local corticosteroid injections, and nerve blocks;
- physiotherapy including spinal traction, electrostimulation of muscles, electromagnetic and magnetic field therapy, massage, manual therapy, acupuncture, and specific exercises;
- cognitive therapy focused on addressing psychological problems, in particular depression and anxiety associated with chronic pain.

The Hexanium® TLIF system implantation is performed via a transforaminal approach (via the opening between the bones of the spine, vertebrae, through which the nerves leave the spinal cord). Other approaches exist when implanting an interbody cage for spinal fusion: anterior, lateral, oblique and posterior. Interbody cage shape may differ depending on the approach chosen.

In the literature, hybrid surgery with combination of fusion and non-fusion technique has emerged as a potential treatment alternative. This technique involves lumbar interbody fusion and either total disc arthroplasty (joint replacement surgery) or dynamic stabilization or hybrid instrumentation.

7. SUGGESTED TRAINING FOR USERS

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The Hexanium® TLIF can be implanted only by a trained orthopedic surgeon or neurosurgeon familiar with spine surgery as well as with the operating techniques relating to these implants.

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