UNITED STATES OF AMERICA

Hexanium PLIF: Posterior Lumbar Interbody Fusion

Intended Purpose:

The Hexanium PLIF (Posterior Lumbar Interbody Fusion) is intended to give a primary stability of the anterior column, via a posterior approach, with or without restoring disc height until fusion occurs.

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

Description:

The Hexanium PLIF (Posterior Lumbar Interbody Fusion) system is an intervertebral body fusion device of the lumbar spine (L2-S1).

The Hexanium PLIF system consists of cages of various widths, heights, and angulations, which can be inserted between two vertebral bodies 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 Hexanium PLIF system, two cages must be used per segment for fusion in order to stabilize the segment concerned.

The Hexanium PLIF is indicated for use with autogenous bone.

All cages are manufactured from implant grade Titanium (Ti6Al4V compliant with ASTM F3001).

Indications:

The Hexanium PLIF (Posterior Lumbar Interbody Fusion) system is an intervertebral body fusion device indicated for use with autogenous bone graft in skeletally mature patients with Degenerative Disc (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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least 6 months of non-operative treatment prior to treatment with the Hexanium PLIF system. This device has to be filled with autogenous bone graft material. This device is implanted via the posterior approach. The Hexanium PLIF system must be used in combination with supplemental internal spinal fixation which has been cleared by the FDA for use in the lumbar spine.

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;
- fever;
- morbid obesity (BMI ≥ 40 kg/m²);
- pregnant woman should not undergo a surgery;
- 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 materials;
- 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.
- previous 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.

Potential adverse effects:

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 the sacrum, 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;
- infection;
- hemorrhage of blood vessels and/or hematomas;
- 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;
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus, disc disruption or degeneration above, or below the level of surgery;
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- foreign body reaction due to the presence of implants, such as a mass, auto-immune disease, and/or impaired healing;
- cessation of any potential growth of the operated portion of the spine,
- deep venous thrombosis, thrombophlebitis;
- development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.;
- bone graft donor site complication;
- urinary retention or loss of bladder control or other types of urological system compromise;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- change in mental status;
- incapacity to resume the activities of normal everyday life;
- death.

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

Intended users:

Trained orthopedic surgeon or neurosurgeon on the Hexanium PLIF use, and familiar with its recommendations as well as with the operating techniques.

Patient target groups:

Skeletally mature patients, regardless of gender.

Storage and packaging:

Packages for each of the components should be intact upon receipt. Care should be taken not to damage the implants when opening the packaging. For implant supplied in a sterile form, carefully check that the seal on the cardboard box is intact before you open the box. Damaged packages or products must not be used. If in doubt, please send them back to SpineVision® or to the distributor.

Inspection, cleaning and sterilization:

Hexanium PLIF implants are delivered sterile by exposure to a minimum dose of 25kGy of gamma radiation. They must be never resterilized.

Hexanium PLIF implants must only be used with the Hexanium PLIF ancillary equipment. Hexanium PLIF ancillary equipment are supplied not sterile. They must be sterilized before use.

All packaging and labeling materials must be removed prior to sterilization. Decontamination and cleaning must be performed before sterilization. Further information regarding cleaning and sterilization of SpineVision products are available in the instruction I-LG09 “Instructions for cleaning, sterilization, inspection and maintenance of SpineVision medical devices”.

- **Cleaning and decontamination of the non-sterile instruments at the Healthcare facility**:

It is recommended to use a neutral pH, enzymatic or alkaline (pH < 11) cleaning agent solution and deionized or distilled warm (room temperature) water of soaking, cleaning and rinsing.

Dismantle the necessary instruments. Articulated instruments must be opened.

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.

Note: Certain cleaning solutions, such as those containing bleach or formaldehyde, may damage certain components and must not be used.

- **Verification**

The 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, Hexanium PLIF instruments should be double wrapped using FDA-cleared sterilization wraps and steam sterilized according to the following parameters:

METHOD	CYCLE	TEMPERATURE	MINIMUM EXPOSURE TIME	MINIMUM DRYING TIME
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Validations were performed with dynamic-air-removal steam sterilization process.

Warnings and precautions:

PREOPERATIVE

- The use of the Hexanium PLIF has to be done using dedicated adequate instrumentation by a trained orthopedic surgeon or neurosurgeon familiar with these recommendations as well as with the operating techniques relating to these implants.

- 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 PLIF 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, mental illness, 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 (please see surgical technique GPL2-ST, latest applicable version at SpineVision)

- 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 PLIF 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 PLIF components have been designed for use with this system. Do not use the Hexanium PLIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium PLIF cannot be inserted via an anterior approach.
- The Hexanium PLIF 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

- Careful patient monitoring for the first two to four months following the operation is very important while 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.

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

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, identification, durability, reliability, safety, effectiveness and/or performance, should notify SpineVision® or the distributor. Further, if any of the implanted Hexanium PLIF 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, 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®.

FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

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	See package insert for labeling limitation	Rx only	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
	Expiration date	LOT	Batch code
	Do not re-use		Manufacturer
	Keep dry	REF	Catalog number
	Keep away from sunlight		Do not re-sterilize
STERILE R	Sterilized using Irradiation	MD	Medical Device

IMPORTANT INFORMATION CONCERNING HEXANIUM PLIF INSTRUMENTATION