ENGLISH

SPINEVISION SAS

Hexanium® ACIF: Anterior Cervical Interbody Fusion device

Intended purpose

The Hexanium® ACIF (Anterior Cervical Interbody Fusion) system is intended as a standalone intervertebral body fusion device of the cervical spine (C3-C7). It is intended to be implanted via an anterior approach to give a primary stability of the cervical column (with or without restoring disc height) until fusion occurs.

Description

The Hexanium® ACIF consists of a 3D-printed, honeycomb cage containing a single-step screw blocking system made of two bone screws for standalone intervertebral body fusion of the cervical spine (C3-C7).

The Hexanium® ACIF cages are available in two different endplate shapes (lordotic [6°] and convex [6°]), various heights (5, 6, 7, 8, 9, 10, 11 and 12 mm), as well as various widths and depths (width x depth: 15 x 12 mm, 17 x 14 mm and 19 x 15 mm).
The Hexanium® ACIF screws are available in various lengths (10, 12, 14 and 16 mm) and diameters (3.5 mm and 3.8 mm). The orientation of the endplate screws is: 38° cranial/caudal, 10° lateral/medial.
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 0.25 mm. The rugosity of the surface is 6.4 µm.
All cages and bone screws are manufactured from implant grade Titanium (Ti6Al4V ELI compliant with ASTM (American Society for Testing and Materials) F3001 and F136, respectively).
Of note, Hexanium® ACIF implants do not contain any substance which may be considered as a medicinal substance, nor a human blood derivative, and are not manufactured using tissues of animal origin.

Hexanium® ACIF implants are provided sterile.

Indications

The Hexanium® ACIF (Anterior Cervical Interbody Fusion) system is an intervertebral body fusion device indicated for use in:

- Patients with Degenerative Disc Disease (DDD) at one level from C3 to C7 of the cervical spine, and up to 2 consecutive levels.
- Patients with DDD who may also have symptoms of radiculopathy and/or myelopathy, or spondylosis at the involved level(s) and must be resistant to conservative management.

Contraindications

This device is not intended for thoracic or lumbar 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 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.

Implants are 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 Events

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

- hemorrhage of blood vessels and/or hematomas;
- disc disruption or degeneration above, or below the level of surgery;
- dysphagia;
- 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;

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:

- foreign body reaction due to the implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring;

(ii) adverse events related to the device and instrumented surgery:

- 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, or other types of serious injury, cerebral spinal fluid leakage;
- injury of muscular or neurological 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;
- pain, discomfort, or other abnormal sensations due to the presence of the device;
- herniated nucleus pulposus,
- adjacent level degenerative changes;
- loss of or increase in spinal mobility or function;
- pressure on the surrounding tissues or organs;
- scar formation possibly causing neurological compromise or compression around nerves and/or pain;
- stenosis;

(iii) adverse events related to instrumented surgery

- bone graft donor site complication;

- death;

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

Intended user
The use of the Hexanium® ACIF shall be performed by a trained orthopedic surgeon or neurosurgeon familiar with these recommendations as well as with the operating techniques relating to these implants.

Patient target groups
Hexanium® ACIF is intended to be used in skeletally mature patients, regardless of gender.

Clinical benefit
The procedure with the implantation of the Hexanium® ACIF system will provide patients relief of their neck and arm pain, and reduce their disability.

Performances
The Hexanium® ACIF 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 cervical lordosis.

Hence the performance claims of Hexanium® ACIF are:
- Provide primary stability of the cervical column until fusion occurs
- Promote fusion between two continuous levels from C3-C7

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. Carefully check that the seal between the lid and the blister pack is intact. (Red arrow on the picture below) and with no bubbles prior to use. Carefully check if the inner pouch is intact and under vacuum.
Damaged packages or products must not be used.

Inspection, cleaning and sterilization
Hexanium® ACIF implants are delivered sterile by exposure to a minimum dose of 25kGy of gamma radiation. They must be never resterilized.
Hexanium® ACIF implants must only be used with the Hexanium® ACIF ancillary equipment. Hexanium® ACIF ancillary equipment is not supplied sterile and 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 SAS 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 and alkaline (pH < 11) cleaning agents 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® ACIF instruments should be steam sterilized according to the following parameters:

Method	Cycle	Temperature	Minimum exposure time	Minimum drying time
Steam	Prevacuum	134° (273°F)	3 minutes	30 minutes
Steam	Prevacuum	134° (273°F)	18 minutes	30 minutes
Steam	Prevacuum	132° (270°F)	4 minutes	30 minutes

The second cycle (134°C during 18minutes) is the recommended cycle in several European countries.
Validations were performed with dynamic-air-removal steam sterilization process.

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. 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.
- The surgeon can have training at the time of the commercial phase.

- **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 (Please see surgical technique GAC2-ST)

- Hexanium® ACIF system must be used with the dedicated Hexanium® ACIF instrumentation.
- The combination of the cage and the screws is mandatory for Hexanium® ACIF system.
- 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® ACIF implants, 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). Hexanium® ACIF must be filled with bone graft material. The choice of the type of bone graft will always be the surgeon's responsibility.

- 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® ACIF components have been designed for use with this system. Do not use the Hexanium® ACIF with any components not specifically recommended, or with any components from another manufacturer.
- The Hexanium® ACIF has to be inserted and not impacted.
- The Hexanium® ACIF cannot be inserted via a posterior approach.
- The Hexanium® ACIF cannot be used in thoracic and lumbar 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**.**
- Implant card shall be handed out to the patient by the surgeon
- Patient information leaflet shall be handed out to the patient by the surgeon.

Magnetic Resonance (MR) Safety: The Hexanium® ACIF has not been evaluated for safety and compatibility in the MR environment. The Hexanium® ACIF 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 SAS. Further, if any of the implanted Hexanium® ACIF 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 and the National Competent Authority where the incident has occurred should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report is requested from SPINEVISION SAS.

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
	Expiration date		Batch code
	Do not re-use		Manufacturer
	Keep dry		Catalog number
	Keep away from sunlight		Do not re-sterilize
	Sterilized using Irradiation		Medical Device
	Unique Device Identifier		Single Sterile Barrier System with protective packaging inside
	Date of Manufacture		Patient identification
	Date of medical procedure		Health care centre or doctor
	Patient information website		

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IMPORTANT INFORMATION CONCERNING HEXANIUM® ACIF INSTRUMENTATION