SPINEVISION
INNOVATION THAT MATTERS

Patient information leaflet – Hexanium® TLIF

Item	Title	Information on device
1.a	Device Name	Hexanium® TLIF
1.b	Model of the device	 *Figure 1: Hexanium® TLIF curved version*  *Figure 2: Hexanium® TLIF straight version*
2.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®.
2.b	Intended patient population	Hexanium® TLIF is intended to be used in skeletally mature patients, regardless of gender.
3	Any special operating instructions for the use of the device	It is important to reduce the stresses exerted on implants in order to avoid the clinical problems that can accompany poor fixation. Strictly following your surgeon's instructions is one of the most important aspects of successful bone healing. Prohibited physical activity and full weight-bearing can lead to premature failure of the internal stabilising devices through migration, loosening or fracture. The implant does not have the strength of normal, healthy bone, and failure of the device may occur if excessive load is placed on it. This internal stabilising device is intended to share the load until normal healing occurs. If normal healing does not occur or is delayed, the device may break due to fatigue.
4.a	Intended performance of the device	Hexanium® TLIF provides primary stability of the cervical column until fusion occurs and promote fusion between two continuous levels of the cervical vertebrae.
4.b	Undesirable side effects	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 – 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 – dysphagia – adjacent level degenerative changes – 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

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		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
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted	Please refer to the item 3 on "Any special operating instructions for the use of the device".
6.a	Warnings about risks that could arise from the interaction of the device with other equipment	The Hexanium® TLIF has not been evaluated for safety and compatibility in the MR environment. The Hexanium® TLIF has not been tested for heating or migration in the MR environment.
6.b	Precautions and other measures that, because of those risks, should be taken by the patient or a health professional.	Please refer to the advice of the surgeon after implantation of the Hexanium® TLIF.
7.a	The nature and frequency of monitoring of the patient by a health professional	It is very important to monitor the patient carefully for the first two to four months after the operation, while the fusion is taking place.
7.b	Symptoms that could indicate that the device is malfunctioning;	Symptoms such as prolonged pain or neurological deficit after surgery could be signs of Hexanium® TLIF malfunction.
7.c	Precautions and other measures to be taken by the patient if the device malfunctions or if the patient experiences any of the symptoms mentioned in paragraph (b).	In case of any symptoms that indicate that the device is malfunctioning, the patient should contact a healthcare professional.
7.d	Expected device lifetime	The expected lifetime of Hexanium® TLIF is 24 months (time for bone fusion to occur) but Hexanium® TLIF will remain implanted for life.
7.e	Anything that could shorten or lengthen the device lifetime	Failure to carefully follow your surgeon's instructions for your post-operative care and recovery may lead to shorten the device lifetime
7.f	Precautions and other measures that should be taken at, or near, the end of the expected device lifetime	The patient should be monitored by his surgeon at the end of the expected device lifetime.
7.g	Any other cases in which the patient should contact a health professional	In case of prolonged pain or neurological deficit after surgery, the patient should contact a health professional.
8.a	Materials and substances included in the device	Hexanium® TLIF is manufactured from implant grade Titanium (Ti6Al4V ELI compliant with ASTM F3001).
8.b	Any manufacturing residuals that could pose a risk to the patient	Hexanium® TLIF does not contain any manufacturing residuals that could pose a risk to the patient.
9.a	Contact in case of any serious incident	In the event of any serious incident related to the Hexanium® TLIF, please report it immediately to SPINEVISION SAS at the following email address: corp.quality@spinevision.com and to the national competent authority where the incident occurred. SPINEVISION SAS website address: https://spinevision.net/

	Patient identification		Unique device identifier
	Date of medical procedure		Catalog number
	Healthcare center or doctor		Batch number
	Patient information website		Manufacturer
	Medical device		