SPINEVISION
INNOVATION THAT MATTERS

Patient information leaflet – Hexanium® ACIF

Item	Title	Information on device
1.a	Device Name	Hexanium® ACIF
1.b	Model of the device	 *Figure 1: Hexanium® ACIF, assembled with screws*
		 *Figure 2: Hexanium® ACIF lordotic cage, without screws*  *Figure 3: Hexanium® ACIF convex cage, without screws*
2.a	Intended purpose	The Hexanium® ACIF (Anterior Cervical Interbody Fusion) system is intended as a standalone intervertebral body fusion device of the cervical spine. It is intended to be implanted via an anterior cervical approach to give a primary stability of the cervical column (with or without restoring disc height) until fusion occurs.
2.b	Intended patient population	Hexanium® ACIF 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 that stress must be reduced on the implants to avoid clinical problems that may accompany failed fixation. Following your surgeon's instructions carefully is one of the most important aspects of successful bone healing. Disallowed physical activity and full weight bearing may cause premature failure of internal stabilization devices by migrating, loosening or fracture. The implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on it. This internal stabilization device is 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.
4.a	Intended performance of the device	Hexanium® ACIF 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

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		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
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® 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.
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® ACIF.
7.a	The nature and frequency of monitoring of the patient by a health professional	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 Hexanium® ACIF.
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® ACIF 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® ACIF is 24 months (time for bone fusion to occur) but Hexanium® ACIF 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® ACIF is manufactured from implant grade Titanium (Ti6Al4V ELI compliant with ASTM F3001 and F136, respectively).
8.b	Any manufacturing residuals that could pose a risk to the patient	Hexanium® ACIF 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® ACIF, please report it immediately to SPINEVISION at the following email address: corp.quality@spinevision.com and to the Therapeutic Goods Administration. SPINEVISION website address: https://spinevision.net/ TGA website address: https://www.tga.gov.au/