Idys® ALIF ZP 3DTi Cages

Approvals

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History

Revision	Date	Comments
01	23/04/2025	Creation

Patient information leaflet – Idys® ALIF ZP 3DTi

Item	Title	Information on device
1.a	Device Name	Idys® ALIF ZP 3DTi
1.b	Model of the device	 *Figure 1: Idys® ALIF ZP 3DTi, assembled with screws.*
		 *Figure 2: Idys® ALIF ZP 3DTi cage,without screws.*
2.a	Intended purpose	The Idys®-ALIF ZP 3DTi cages are interbody fusion devices intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is knowledgeable in the implant's material and surgical aspects and who has been trained as to its mechanical and material applications and limitations
2.b	Intended patient population	Idys-ALIF ZP 3DTi device should be implanted in patients skeletally mature and who have six months of non-operative treatment.
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 prematurefailure of internal stabilization devices by migrating, loosening or fracture. The implant does not have the strength of normal healthy bone, and that device failuremay 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	The performance claims of Idys ALIF ZP 3DTi are: ▪ Provide stability of the lumbar column until fusion occurs ▪ Promote fusion
4.b	Undesirable side effects	Secondary and possible side effects may occur when the device is used either with or without associated instrumentation. The potential risk of side effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential secondary and possible side effects include but are not limited to: ▪ Infection, non-union (or pseudarthrosis). ▪ Implant migration, implant subsidence, implant malposition, loss of correction height, and/or reduction of the spinal curvature, breakage of the device(s), foreign body reaction to the implants. ▪ Bone fracture or stress shielding at, above, or below the level of surgery, bone graft donor site complication. ▪ Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain, neurovascular compromise including temporary paralysis, or other types of serious injury. ▪ Cerebral spinal fluid leakage, hemorrhage of blood vessels and/or hematomas, deep venous thrombosis, thrombophlebitis, vascular injury, and/or pulmonary embolus. ▪ Discitis, and/or other types of inflammation. ▪ Inability to resume activities of normal daily living. Early or late loosening or movement of the device(s). Scar formation possibly causing neurological compromise or compression around nerves and/or pain.

		▪ Fracture, micro fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery, graft expulsion. ▪ Herniated nucleus pulposus, disc disruption or degeneration at above, or below the level of surgery. ▪ Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction. ▪ Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, pleural effusion. ▪ Urinary complication including urinary infection, bladder dysfunction. ▪ Gastrointestinal complications including ileus, bowel obstruction, peritoneal tears, Incisional hernia, retroperitoneal hematoma. ▪ Other visceral injury. Change in mental status, death. **Note**: Additional surgery may be necessary to correct some of these anticipated adverse events
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 Idys® ALIF ZP 3DTi has not been evaluated for safety and compatibility in the MR environment. The Idys® ALIF ZP 3DTi has not been tested for heating ormigration 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 Idys® ALIF ZP 3DTi
7.a	The nature and frequency of monitoring of the patient by a health professional	It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider actions to be taken. 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 Idys® ALIF ZP 3DTi. It is important that immobilization of union is established and confirmed by X-rays, CT scans examination.
7.b	Symptoms that could indicate that the device is malfunctioning	Symptoms such as prolonged pain or neurological deficit (numbness, tingling, temporary paralysis) after surgery could be signs of with Idys® ALIF ZP 3DTi 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 patientshould contact a healthcare professional.
7.d	Expected device lifetime	An interbody fusion device is intended to be implanted permanently. The lifetime of such devices varies from patient to patient. According to publicly available national registries data, a mean implantation time of 36 years could be estimated for these devices.
7.e	Anything that could shorten or lengthen the device lifetime	There are many factors affecting the outcomes and the lifetime of the device. These factors include, but are not limited to: patient's physical condition, patient's activity level and the progression of the disease. 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 devicelifetime.
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 shouldcontact a health professional.
8.a	Materials and substances included in the device	Idys® ALIF ZP 3DTi is manufactured from implant grade Titanium (Ti6Al4V ELI compliant with F136).

8.b	Any manufacturing residuals that could pose a risk to the patient	Idys® ALIF ZP 3DTi does not contain any manufacturing residuals that could pose arisk to the patient.
9.a	Contact in case of any serious incident	In the event of any serious incident related to the Idys® ALIF ZP 3DTi, please report it immediately to CLARIANCE at the following email address: contact@clariance-spine.com and to the Therapeutic Goods Administration. CLARIANCE website address: https://www.clariance-spine.com/int/ TGA website address: https://www.tga.gov.au/