AUSTRALIA

CLARIANCE

Idys® ALIF ZP 3DTi: Anterior Lumbar Interbody Fusion Device

1. INTENDED USE

The Idys®-ALIF ZP 3DTi cages are interbody fusion devices intended to stabilize 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. DESCRIPTION

The Idys®-ALIF ZP 3DTi is designed for use as a lumbar interbody fusion device. The device is manufactured from medical grade Titanium alloy and is to be used with bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The device has a shape which matches the intervertebral height and lordosis. The device contains two (2) slots to receive the bone graft to promote the fusion process between the endplates. The Idys®-ALIF ZP 3DTi is a standalone system intended to be used with four (4) bone screws, bone graft and requires no additional supplementary fixation. The Idys®-ALIF ZP 3DTi cages are made of compliant ASTM F136 Titanium alloy and screws are made of ASTM F136 Titanium alloy. It is essential to insert implants with instrumentation specifically designed for this purpose. For more description of the instrumentation it is necessary to read the technical documentation associated with Idys®-ALIF ZP 3DTi.

According to the clinical evaluation report, it can be concluded that the benefit-risk ratio is positive.

3. INDICATIONS

The Idys®-ALIF ZP 3DTi system is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous level(s) of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The Idys®-ALIF ZP 3DTi should be used with the integrated fixation screws provided.
The Idys®-ALIF ZP 3DTi System is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone.

4. CONTRA-INDICATIONS

The Idys®-ALIF ZP 3DTi Lumbar Interbody device is not intended for posterior surgical implantation. Contraindications include, but are not limited to:

- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any patient having inadequate bone stock quality or poor bone quality. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication

because this condition may limit the degree of correction and/or or the possibility of mechanical fixation.

- Fever or leukocytosis, infection, local to the operative site, signs of local inflammation.
- Any patient unwilling to co-operate with postoperative instructions, having mental illness
- Any patient withmorbid obesity
- Pregnancy.
- Suspected or documented allergy or intolerance to the constitutive materials.
- These devices must not be used for pediatric cases, or when the patient is still undergoing general skeletal growth.

IMPORTANT NOTE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption and osteoporosis, osteomalacia.

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.

5.PERFORMANCE.

The performance claims of Idys ALIF ZP 3DTi are:

- Provide stability of the lumbar column until fusion occurs
- Promote fusion

6.POTENTIAL ADVERSE EVENTS

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.

7.STORAGE AND PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all instruments sets should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to CLARIANCE.

The handling of the Idys® ALIF ZP 3DTi System components must be done as seldom as possible and always with the utmost care. The Idys®-ALIF ZP 3DTi system components (in their original packaging) must be stored with care in a clean and dry place. Do not expose the Idys®-ALIF ZP 3DTi system components to radiations or extreme temperatures.

Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

8.INSPECTION, CLEANING AND STERILIZATION

The Idys® ALIF ZP 3DTi implants are provided in a sterile state. They must never be resterilized.

The Idys® ALIF ZP 3DTi implants must only be used with the CLARIANCE instruments specially designed for this purpose. Instruments are not supplied sterile and must be sterilized before use. All instruments must be cleaned using alkaline cleaners followed by a deionized water rinse before sterilization. Note that a good cleaning must make necessary the disassembly of some instruments. Refer to document 99REPINS “Manual instruments for Spinal Surgery Instructions for care, Cleaning Maintenance, and Sterilization” to obtain detailed instructions. All products must be sterile prior the introduction into a sterile surgical field, or (if applicable) return of the product to CLARIANCE.

Method	Cycle	Temperature	Exposure time	Drying time[1]
Steam	Dynamic air removal	132°C (270°F)	4 Minutes	20 Minutes
Steam	Gravity	132°C (270°F)	15 Minutes	30 Minutes
Steam	Dynamic air removal	134°C (273°F)	18 Minutes	30 Minutes

[1]The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations**.**

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

9. WARNING AND PRECAUTIONS

PREOPERATIVE

- The implantation of the interbody fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient,
- Only patients that meet the criteria described in the indications should be selected, correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery. The size of device for the case should be determined prior to beginning the surgery.
- Proper function of the surgical instruments should be verified prior to every surgical procedure. All instruments must be cleaned and sterilized before use.
- 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.

INTRAOPERATIVE (Please see surgical technique 45BROUS)

- The instructions in Idys®-ALIF ZP 3DTi System surgical technique manual should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To ensure good fusion of the treated spinal segment, bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone should be used**.**

POSTOPERATIVE

- It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken. 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. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion. It is important that immobilization of union is

established and confirmed by x-rays, CT scans examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.
- 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 Idys® ALIF ZP 3DTi implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Idys® ALIF ZP 3DTi implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

10. 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).

11. 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 CLARIANCE. Further, if any of the implanted Idys® ALIF ZP 3DTi components does not meet any of its performance specifications or otherwise does not perform as intended, or is suspected of doing so, CLARIANCE should be notified immediately.

If any CLARIANCE product may have caused or contributed to the death or serious injury of a patient, CLARIANCE and the National Competent Authority where the incident has occurred 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 CLARIANCE.

For any information, please contact the Australian Sponsor:

Australian Sponsor
Emergo Australia
Level 20 Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
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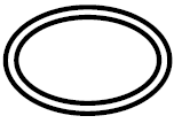
FOR ALL INFORMATION OR COMPLAINTS, CONTACT:

In Europe	In USA
CLARIANCE 18 rue Robespierre 62217 Beaurains, FRANCE Tel: +33 3 21 16 12 15 Email: contact@clariance-spinevision.com	CLARIANCE Inc. 2547 Farrington Street Dallas, TX 75207 P: +1 773 832 7554 contact@clariance-spinevision.com

Symbol	Signifiance	Symbol	Signifiance
	Manufacturer		Lot number or batch code
	Catalog Number		Do not reuse / Single use only
	Unique device identifier		Double sterile barrier system
	Do not re-sterilize		Expiration date
	Attention: See package insert		Non-sterile
	Date and Country of manufacture		Consult instructions for use or consult electronic instructions for use

Symbol	Significance	Symbol	Significance
	Do not use if packaging is damaged		Packaging is sensitive to humidity
	Medical Device		Sterilized by irradiation
	Date of implantation		Patient Name
	Sale of this device is restricted by or on the order of a physician		Information website for patients
	Healthcare institution