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IMPORTANT: PLEASE READ

DESCRIPTION:
The Genesis SASCA (Southern Anterior Screw Fixated Cage) devices, including SASCA-G and SASCA-2G, are wedge-shaped stand-alone lumbar interbody fusion cages that are additively manufactured from Ti-6Al-4V ELI Titanium Alloy (ASTM F3001). These devices are intended for use in anterior lumbar interbody fusion (ALIF) procedures to immobilise and stabilise the spinal column, restore and maintain spinal curvature and intervertebral disc height, and facilitate fusion at the treated level(s). The cages include three pre-assembled PEEK rings (ASTM F2026) that are intended to prevent screw back-out. The cages must be implanted with three Ti-6Al-4V ELI Titanium Alloy (ASTM F136) screws. Supplementary spinal fixation is not required. The cages have a central cavity that is intended to be filled with autograft or allogenic bone graft.

INDICATIONS FOR USE:

The devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L1 to 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 at the involved level(s). The devices may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Patients should have undergone at least six months of non-operative treatment.

CONTRA-INDICATIONS:

Contra-indications include, but are not limited to:

- Allergy or hypersensitivity to any of the implant materials
- Active systemic or localised infection and/or inflammation
- Spondylolisthesis greater than Grade I
- Bone diseases, such as severe osteoporosis, osteopenia, osteomalacia or Paget's disease, that compromise bone quality and may interfere with device placement, healing and/or fusion
- Pregnancy
- Bilateral isthmic spondylolisthesis at L5-S1 without supplementary posterior fixation
- Patient anatomy or pathology prevents full insertion and correct usage of the device
- Any other conditions that may place excessive stress on the device and/or bone, such as morbid obesity, tumours, fractures or inadequate tissue coverage. The decision to use a device in patients with such conditions must be made by a healthcare professional after taking into consideration the benefits and risks to the patient.
- Use of this device is relatively contra-indicated in patients whose activity, occupation, mental capacity, history of substance abuse or other lifestyle factors may prohibit their ability to comply with post-operative care instructions. These patients may place undue stress on the device and may be at higher risk of implant failure.

ADVERSE EFFECTS AND RISKS OF USE:

- Device failure / fracture
- Loss of fixation (e.g. cage loosening or migration)
- Pseudarthrosis or delayed fusion
- Fracture of the vertebrae
- Adjacent segment disease / degeneration
- Infection and/or inflammation
- Allergic response to foreign body/foreign particulate
- Neurological injury
- Vascular injury
- Thrombosis / thromboembolic event
- Visceral injury
- Loss of spinal mobility and/or function at the treated level(s)
- General surgical complications (including postoperative ileus, incisional hernia, and cyst formation)
- Reoperation
- Death

USAGE WARNING:
The device should only be implanted by qualified surgeons with knowledge of the correct and safe use of the device and associated instrumentation. Refer to the Surgical Manual provided by Southern Medical (Pty) Ltd. If uncertain, please contact a Southern Medical Representative.

The SASCA-G & SASCA-2G devices are intended to be used with a sufficient quantity of autograft or allogenic material. At the surgeon's discretion, additional fixation systems may be used supplementary to the SASCA Genesis devices.

Placement of the titanium screws must be guided by the drill guide provided. Failure to use the drill guide during screw placement may result in mispositioning or damage to the screws.

Correct placement of the device should be verified radiographically.

Correct handling of the device(s) is extremely important. The desired clinical outcome may not be achieved if the usage instructions are not followed.

STERILITY:
Implants are sterilised by gamma irradiation and are supplied **STERILE**. **DO NOT RE-STERILISE** devices supplied sterile. Re-sterilisation can cause material degradation and could result in surgical rejection and/or post-operative infection.

Do not use if the packaging has been damaged or opened, or if the expiry date on the label has been exceeded.

RE-USE WARNING:
The implants are intended for **SINGLE USE** only and **MAY NOT BE RE-USED**. An explanted device must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

INSTRUMENTATION:
Surgical instrumentation is provided for specific use with the device(s) and no other instrumentation is intended to be used for the placement of the device(s).

Instruments are provided non-sterile and must be cleaned and sterilised using the validated methods prescribed in IFU-100 before use.

STORAGE:
No special storage instructions. Storage conditions must not prematurely deteriorate device packaging or degrade/contaminate the packaging or the contents thereof in any way. Handle with care.

RADIOACTIVITY WARNING:
No radioactive substance or radioactivity.

MAGNETIC RESONANCE IMAGING (MRI):
The SASCA Genesis devices have not been evaluated for safety in the MR environment. The devices have not been tested for heating or unwanted movement in the MR environment. The safety of the devices in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POST-OPERATIVE CARE INSTRUCTIONS:
The surgeon, physician or other healthcare professional must provide appropriate post-operative care instructions to the patient and must ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimise physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Normal physical activities may only be resumed upon approval from a healthcare professional. It is recommended to schedule patient follow-up consultations as necessary.

DEVICE REMOVAL:
The devices are intended to remain in place for the duration of the patient's life. Surgical removal of the device is possible. Any decision to remove the device must be made by a healthcare professional after taking into consideration the patient's general medical condition and the potential risk of a subsequent surgical procedure.

DEVICE DISPOSAL:
Single-use devices that have been in contact with blood or bodily fluids/tissues must be decontaminated and discarded following the standard hazardous and/or biological waste disposal procedures of the healthcare facility. Users must wear gloves and take care to avoid sharp edges.

REPORTING:
Adverse events related to the device must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING:

USE BY		CAUTION	
LOT NUMBER	LOT	CONSULT THE INSTRUCTIONS FOR USE	
MANUFACTURER		DO NOT RESTERILISE	
DATE OF MANUFACTURE		DO NOT USE IF PACKAGING IS DAMAGED	
DO NOT REUSE		STERILISED USING IRRADIATION	STERILE R
CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY		