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IMPORTANT: PLEASE READ

For detailed information on correct & safe device use, please consult the Surgical Manual.

DESCRIPTION

The SPICCA-SG devices are wedge-shaped anterior cervical interbody fusion cages that are additively manufactured from Ti-6Al-4V ELI Titanium Alloy (ASTM F3001). The cages have a central "bone pocket" that is intended to be filled with autograft or allogenic bone graft. The cages include two pre-assembled PEEK rings (ASTM F2026) that are intended to prevent screw backout. The SPICCA-SG cages are to be anchored with two Ti-6Al-4V ELI Titanium Alloy (ASTM F136) screws. A Ti-6Al-4V ELI Titanium (ASTM F136) locking plate is provided that may be added at the surgeon's discretion. The SPICCA-SG range includes two types of cages - one with screw holes angled towards the midline of the cage and one with screw holes that are parallel to the midline. Each cage type is made available in four footprint and six height options.

INDICATIONS FOR USE

The SPICCA-SG Stand-Alone Cervical Fusion Cages are stand-alone interbody fusion devices intended for spinal fusion procedures at one or two levels from the C2/C3 disc space to the C7/T1 disc space in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices. The implant is designed to accommodate two screws and a locking plate.

CONTRAINDICATIONS

- Patients with known or probable intolerance to the materials used in the manufacture of this device
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit a beneficial surgical outcome
- Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
- Use with components from other manufacturers.
- Grossly distorted anatomy caused by congenital abnormalities.
- Rapid joint disease, bone absorption or osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction or stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple use.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.

RISKS & UNDESIRABLE SIDE-EFFECTS

- Damage to the vertebral endplates and/or fracture of the vertebrae.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Soft tissue injury.
- Esophageal injury/perforation.
- Dural tears, persistent CSF leakage, or meningitis.
- Bone loss or decrease in bone density.
- Graft site complications (if autograft is used).
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise.
- Infection.
- Foreign body allergic reaction or rejection to implant/ foreign particulate.
- Post-operative change in spinal curvature, loss of correction, height and/or reduction.
- Loss of neurological function including paralysis, radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
- Transient or permanent neurological deficits, reflex deficits, irritation, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Non-union (or pseudarthrosis), delayed union or mal-union.
- Disassembly, bending, and/or breakage of the implant.
- Implant loosening and/or migration
- Subsidence of the device into the vertebral body(ies).
- Transient or persistent dysphagia (swallowing difficulties).
- Sore throat and/or hoarseness.
- Development of respiratory problems.
- Loss of spinal mobility or function.
- Wound necrosis or wound dehiscence.
- Inability to perform the activities of daily living.
- Change in mental status.
- Death.

Additional surgical intervention may be required to correct/prevent some of these possible adverse events.

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

STERILE R

The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device.

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

The devices are **SINGLE-USE**. Do not re-use implants. An explanted implant must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

WARNINGS & PRECAUTIONS: CORRECT & SAFE USE

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 device is intended to be used with two screws provided by the manufacturer. Failure to use two screws may lead to mechanical failure of the device, non-union and/or cage migration/expulsion.

Bone graft should be used in combination with the device

Correct placement of the device should be verified radiographically

INSTRUMENTS

Only the instruments provided by the manufacturer should be used. Instruments are provided non-sterile and should be cleaned and sterilized before use in accordance with the instructions provided in IFU-100.

STORAGE

There are no special storage instructions. Storage conditions must not lead to degradation or contamination of the packaging or its contents. Handle with care.

POST-OPERATIVE CARE INSTRUCTIONS

The surgeon/physician should provide appropriate postoperative care instructions to the patient and should ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimize physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Follow-up consultations should be arranged with the patient at appropriate intervals, as deemed necessary by the physician. The patient should only resume their normal activities once cleared to do so by their physician.

MRI SAFETY INFORMATION

The SPICCA-SG devices have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the SPICCA-SG cervical fusion devices 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.

DEVICE REMOVAL

Surgical removal of the device is possible. A 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. Refer to the Surgical Manual for removal instructions.

DISPOSAL

Single-use devices that have been in contact with blood or bodily fluids/tissues should be disposed of in accordance with the hospital's procedure for disposal of hazardous and/or biological waste. Users must wear surgical gloves and take care to avoid sharp edges. Devices that cannot be used because the packaging has been damaged but have not been in contact with blood or bodily fluids/tissues, should be returned to the manufacturer.

REPORTING

Any device-related adverse events must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER		USE BY	
CONSULT INSTRUCTIONS FOR USE		CATALOGUE NUMBER	REF
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	LOT
DATE OF MANUFACTURE		STERILIZED USING IRRADIATION	STERILE R
DO NOT USE IF PACKAGING IS DAMAGED		DOUBLE STERILE BARRIER SYSTEM	
CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY		