Manufactured by:
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IMPORTANT: PLEASE READ

For detailed information on the Southern Anterior Cervical Fusion Cages (SPICCA), please consult the Surgeons' Manual.

Description:
The SPICCA (Southern Cervical Fusion Cages for Anterior Placement) range of devices includes SPICCA, SPICCA 2, SPICCA-F, SPICCA S2 and SPICCA-SP. All devices consist of a PEEK cage with an interior opening for bone graft and markers made from either titanium (SPICCA, SPICCA 2) or tantalum (SPICCA-SP, SPICCA S2 and SPICCA-F).
The SPICCA, SPICCA 2 and SPICCA-F devices are not stand-alone devices. The SPICCA S2 and SPICCA-SP devices are stand-alone devices and are fixated with Titanium screws. The SPICCA, SPICCA 2 and SPICCA-SP devices are available with Titanium surface coating (ASTM F1580) for osseointegration. All PEEK components conform to the material specification described by ASTM F2026 and titanium components conform to ASTM F67 and ASTM F136 specifications. Markers manufactured from tantalum conform to the material specification described by ASTM F560.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The SPICCA devices are an adjunct to interbody fusion and intended for immobilisation and/or stabilisation of the cervical spine in the treatment of instabilities/deformities. The devices are intended for anterior approach/placement and multiple levels.

Intended performance and undesirable side-effects:
Fusion of the cervical vertebrae is achieved by bone bridging through the allo/autograft space resulting in stability and immobility of the cervical spine from the C2-C3 to C7-T1 disc. The SPICCA S2 and SPICCA-SP devices have additional internal screw fixation to increase spinal stability during the bone bridging process. Since the SPICCA, SPICCA 2 and SPICCA-F devices are not stand-alone devices and it is recommended that the AXIS2™ Cervical Plate system is used in combination. The SPICCA, SPICCA 2, SPICCA-F, SPICCA-S2 and SPICCA-SP devices must not be used with components from other systems or manufacturers in the same construct, specifically not with stainless steel implantable components.

Indications:
- Anterior decompression
- Confirmed cervical Degenerative Disc Disease (DDD)
- Discopathy
- Herniated disc
- Ossification of Posterior Longitudinal Ligament
- Posterior osteophyte accretion
- Revision surgery
- Spinal stenosis

Contraindications:
- Active systemic infection; active malignancy or history of metastatic malignancy; terminal or autoimmune disease
- Any case where implant utilization may not result in expected physiological performance
- Any disease, condition or surgery which might impair healing
- Any neck pain of unknown origin
- Any patient unwilling to follow postoperative instructions
- Bone diseases (e.g., osteoporosis, gout, osteomalacia, Paget's disease)
- Fever
- Inadequate tissue coverage over operative site
- Inflammation local to operative site
- Leukocytosis
- Sizes of implants not sufficient (too large or too small)
- Morbid obesity
- Muscular/skeletal pathologic/morphologic abnormalities
- Posterior surgical approach
- Pregnancy at time of surgery
- Presence of free nucleus fragment
- Previous trauma to the study treated level, resulting in compression or bursting
- Sufficient previous surgeries that would preclude using an anterior approach
- Titanium/Titanium Alloy, Tantalum allergy/intolerance
- The patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure

Surgical Risks:
- Mechanical Failure of Implant
- Bone resorption (including bone loss and decrease in bone density)
- Cardiovascular system compromise (including vessel damage)
- Change in mental status
- Changes in spinal mobility/immobility
- Death
- Degenerative changes in adjacent segment, facet joint deterioration
- Esophageal perforation
- Dysphagia
- Dural tear/damage (possible cerebrospinal fluid (CSF) leak)
- Foreign body (allergic) reaction
- Gastrointestinal system compromise
- Graft site complications
- Hematoma, seroma and/or thrombosis
- Heterotopic ossification
- Infection
- Loss of neurological function (e.g. anesthesia, complete or incomplete paralysis, dysesthesia, hyperesthesia, paraesthesia, radiculopathy and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms
- Metal ion release
- Osteophyte formation/resorption
- Peridural fibrosis
- Postoperative removal/revision of the device
- Pseudarthrosis
- Reproductive system compromise (including sterility and sexual dysfunction)
- Respiratory compromise/problems
- RSD (reflex sympathetic dystrophy)
- Spinal instability
- Spinal stenosis
- Spondylolisthesis
- Subsidence of the device into vertebral body(ies)
- Supplemental fixation as a result of improper primary and secondary fixation.
- Tumor formation/ carcinogenesis potential
- Vocal cord palsy
- Vertebral fracture

Recommended Surgical Procedure:
Refer to the surgical procedure provided by Southern Medical (Pty) Ltd.

USAGE WARNING:
Improper technique in implant placement can result in implant failure. The SPICCA and SPICCA-F devices are not intended as the sole means of spinal support. In absence of bone graft or fusion the implant or implant components can be expected to pull out, bend or fracture as a result of everyday mechanical stresses. Placement of devices is limited to surgeons. Refer to the surgical procedure and product brochure for more information.

Sterility:
All implants are supplied sterile, and are for single use only before the labeled expiration date. Do not re-use implants. Do not use implants if the packaging has been damaged or previously opened, or if the expiration date has passed. If uncertain be sure to contact a Southern Medical Representative.

STERILIZATION WARNING:
Do not re-sterilize implants produced sterile. Implants are sterilized by gamma irradiation. Re-sterilization could cause material degradation and could result in surgical rejection and/or post-operative infection.
The implant is designed for single patient use only and must never be reused. An explanted implant must never be re-implanted.

Magnetic Resonance Imaging (MRI)
The SPICCA devices have not been evaluated for safety and compatibility in the MR environment. They not been tested for heating, migration, or image artefact in the MR environment. The safety of the SPICCA devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localised heating of components caused by radio frequency induction heating and (3) image artifacts created by interaction between metallic components and the magnetic field.

Post Implantation:
The surgeon/physician's postoperative directions, indications and warnings to the patient with subsequent patient compliance are vital to successful fusion. The subject must refrain from physical activity for several months. Physical movement must be minimized. Subjects will be instructed not to engage in activities requiring lifting, bending, twisting or excessive movement for several months post-operatively. The subject must not be exposed to electrical shock and mechanical vibrations. Directly after the operation, subjects will be placed in a brace until fusion occurs. After a couple of months, the subject may return to the workplace if the work environment does not entail excessive physical activities. Car journey duration must be minimized, preferably avoided.

Explanation:
Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Disposal:
Devices that came into contact with blood or body fluids must be decontaminated before disposal. Disinfectants such as peroxide or enzymatic cleaning agents must be used before the device is disposed of as part of medical waste. The user must take care to avoid sharp edges and wear protective gloves."

Descriptions of Symbols Used in Packaging:

USE BY		*LOT NUMBER*	LOT
DATE OF MANUFACTURE		DO NOT REUSE	
STERILIZED USING IRRADIATION	STERILE R	CAUTION	
AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	EC REP	CONSULT THE INSTRUCTIONS FOR USE	
DO NOT RESTERILIZE		DO NOT USE IF PACKAGING IS DAMAGED	

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Approved By:

(CO-336) Removal of CE on IFUs

Description

CE Mark removed from IFU

Justification

CE Mark is no longer permitted on the IFU's

Assigned To:	Initiated By:	Priority:	Impact:
Helen Bosma	Helen Bosma	High	Major

Version History:

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