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 range includes SPICCA, SPICCA-F, SPICCA-S, SPICCA-S2, SPICCA-SP, SPICCA-SP2 and the relevant fixation screws. All cages have an interior opening for bone graft. The SPICCA cages are made of PEEK and are radiolucent except for radiopaque markers. The SPICCA-SP/-SP2 have radiopaque Titanium Plasma Coating. The SPICCA-S/-S2 and SPICCA-SP/-SP2 screws are also radiopaque.
The SPICCA and SPICCA-F devices are not stand alone devices. The SPICCA-S/-S2 and SPICCA-SP/-SP2 devices are stand-alone devices and are fixated with Titanium screws. The SPICCA-SP/-SP2 devices are coated with Titanium (ASTM F1580) to increase osseointegration. All PEEK components are manufactured according to ASTM F2026 and Titanium components according to ASTM F67 and ASTM F136.

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-S/-S2 and SPICCA-SP/-SP2 devices have additional internal screw fixation to increase spinal stability during the bone bridging process. Since the SPICCA 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-F, SPICCA-S/-S2 and SPICCA-SP/-SP2 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
- Mental illness
- 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 nuclear fragment
- Previous trauma to the study treated level, resulting in compression or bursting
- Sufficient previous surgeries that would preclude using an anterior approach
- Titanium allergy/intolerance
- Use of any drug known to interfere with bone or soft tissue healing

Surgical Risks:
- Bending or breakage of implanted components
- 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
- Disassembly of components
- Dural tear/damage
- Dysphagia
- Esophageal perforation
- Facet joint deterioration
- Foreign body (allergic) reaction
- Gastrointestinal system compromise
- Graft site complications
- Hematoma, seroma and/or thrombosis
- Heterotopic ossification
- Implant degradation
- Inadequate tissue coverage over the implant
- Infection
- Loosening of components
- 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
- Nerve or nerve root injury
- Non-Union, delayed union or mal-union
- Numbness
- Osteophyte formation/resorption
- Perineural fibrosis
- Postoperative change in spinal curvature, height and reduction
- Postoperative removal/revision of the device
- Pseudarthrosis
- Reproductive system compromise (including sterility and sexual dysfunction)
- Respiratory compromise/problems
- Revision at the adjacent level with or without removal or modification of any or all components of the device
- Revision with or without replacement of a component
- RSD (reflex sympathetic dystrophy)
- Scar formation possibly causing neurological compromise around nerves and/or pain
- Spinal instability
- Spinal stenosis
- Spondylolisthesis
- Subsidence of the device into vertebral body(ies)
- Supplemental fixation
- Tumor formation/ carcinogenesis potential
- Vertebral fracture
- Vocal cord palsy

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.

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.

Descriptions of Symbols Used in Packaging:

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