MANUFACTURED BY:
Southern Medical (Pty) Ltd.
55 Regency Drive
Route 21 Corporate Park
Irene, 0062
South Africa

P O Box 17198
Lyttelton, 0140
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za
www.southmed.co.za

IMPORTANT: PLEASE READ

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

DESCRIPTION

The SPICCA Corpectomy Cage is a spinal vertebral body replacement device that is comprised of a PEEK (ASTM F2026) body with four Tantalum (ASTM F560) radiographic markers. The devices are intended to be used in combination with the AXIS anterior cervical plate system, as well as autograft or allogenic bone graft packed into its central “bone pocket”. The device has a trapezoidal footprint and is made available in a variety of height options.

INDICATIONS FOR USE

The SPICCA Corpectomy Cages are vertebral body replacement devices intended for use in the cervical spine (C2-T1). The cages are intended for use in skeletally mature patients to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders. The device is intended to be used with an anterior cervical plate system, and the interior of the cage is intended to be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.

These cages are intended to restore integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon’s discretion.

CONTRAINDICATIONS

- Patients with known or probable intolerance to the materials used in the manufacture of this device
- Patients with infection, inflammation, fever, obesity, pregnancy, drug/alcohol abuse, 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.
- 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

- Fracture, micro-fracture, resorption, damage or penetration of any spinal bone.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- 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 to implant.
- Post-operative change in spinal curvature, loss of correction, height and/or reduction.
- Loss of neurological function including paralysis, radiculopathy, spinal cord impingement or damage 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.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Death.

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

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection.

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 in combination with the AXIS anterior cervical plate system. Failure to use supplemental fixation may lead to mechanical failure of the device, non-union and/or cage migration/expulsion.

Autograft or allogenic bone graft should be used in combination with the device. Failure to use bone graft may result in non-union.

Modification of the device must be done outside of the patient before implantation.

The clamp provided must be used when modifying the implant outside of the patient

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 Corpectomy 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 Corpectomy 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		CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY