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IMPORTANT: PLEASE READ

DESCRIPTION

SPRINT Interspinous devices are a treatment option for spinal instability. SPRINT devices provide an alternative to fusion procedures and allow for the spine to restabilize and/or reduce the pressure on the intervertebral discs. The SPRINT range is available in several anterior heigh options.

Southern Medical (Pty) Ltd manufactures the SPRINT device range from Titanium Grade 23 (ASTM F136).

INDICATIONS FOR USE

The SPRINT devices are indicated for use in skeletally mature patients with evidence of single level degenerative disc disease (DDD) at L4/L5 or L5/S1 with radiographic evidence (such as CT, MRI, plain film, flexion/extension films, myelography, discography, etc.) of one or more of the following; mild to moderate osteophyte formation of vertebral endplates, loss of disc height ≥ 2 mm when compared to adjacent level, herniated nucleus pulposus, loss of water content on MRI (black disc on T2 weighted image), or vacuum phenomenon.

Patients are required to have a history of back and/or radicular pain and have undergone at least six (6) months prior conservative therapy.

CONTRAINDICATIONS

- Degeneration in more than two levels
- Severe osteoporosis
- Severe spondylolysis
- Mobile antelisthesis
- L5/S1 degeneration
- Titanium allergy
- Cauda equine syndrome
- Bone fractures
- Blood infection
- Blood infection

RISKS & UNDESIRABLE SIDE-EFFECTS

- Damage to the vertebral bodies.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Soft tissue injury.
  Dural tears, persistent CSF leakage, or meningitis.
- Bone loss or decrease in bone density.
- 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.
- Disassembly, bending, and/or breakage of the implant.
- Implant migration/dislodgement
- Loss of spinal mobility or function.
- Wound necrosis or wound dehiscence.
- Thrombosis formation
- Pain and discomfort at operative site
- 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

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.

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 SPRINT 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 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.

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	