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DESCRIPTION:

The S3-FR Pedicle Screw System consists of two fixed head pedicle screws with pre-assembled rods (S3-FR screws), two mono- or poly-axial pedicle screws, and locking caps. The construct is intended to be implanted bilaterally using a posterior approach, with the two S3-FR screws placed inferiorly and the two mono-/poly-axial screws placed superiorly. The pre-assembled rods in the S3-FR screws are intended to pivot into the adjacent mono-/poly-axial screw tulips, after which four caps should be used to lock the construct. The screws are made available in various size options. The S3-FR screws are also made available with 40-50 mm pre-assembled rod options. The length and/or curvature of the rods may, however, be adjusted by the surgeon using the surgical instruments provided by the manufacturer. This pedicle screw system is intended to be implanted in combination with and interbody fusion cage at the treated level to provide anterior support and is intended to be used with autograft or allogenic material.

IMPLANT MATERIALS:

S3-FR screws:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136) Cobalt Chrome (ASTM F1537)
Mono-/poly-axial screws:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136) Unalloyed Titanium (ASTM F67) Cobalt Chrome (ASTM F1537)
Locking Caps:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)

INDICATIONS FOR USE:

The S3-FR Pedicle Screw System is intended to provide immobilization and stabilization of a spinal segment as an adjunct to one-level fusion in the treatment of skeletally mature patients with acute and chronic instabilities or deformities of sacrolumbar spine, including the following:

- Degenerative Disc Disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- Spondylolisthesis,
- Trauma (e.g., fracture or dislocation),
- Spinal stenosis,
- Spinal tumour, and/or
- Pseudarthrosis.

CONTRA-INDICATIONS:

- Active systemic or localised infection and/or inflammation
- Allergy, sensitivity or intolerance to any of the implant materials
- Bone diseases, such as severe osteoporosis, osteopenia, osteomalacia or Paget's disease, that compromise bone quality and may interfere with device placement, healing and/or fusion
- Pregnancy
- Mental illness
- Fever or leucocytosis
- Unavailability of appropriate implant sizes
- Patient anatomy or pathology that prevents adequate fixation and/or correct usage of the device
- Any other conditions that may place excessive stress on the device and/or significantly reduce the likelihood of fusion, such as morbid obesity, diabetes, or inadequate tissue coverage.
- The use of this device is relatively contra-indicated in patients whose activity, occupation, mental capacity, history of substance abuse or other lifestyle factors may prohibit their ability to comply with post-operative care instructions. These patients may place undue stress on the device and may be at higher risk of implant failure.
- Skeletally immature patients
- Sufficient previous surgeries that would preclude using a posterior approach
- Deformities or curvatures, including scoliosis & kyphosis
- Failed previous fusion
- Fusion of two or more levels

ADVERSE EFFECTS AND RISKS OF USE:

- Device failure, including bending, breakage, loosening and/or disassembly
- Bone resorption (including bone loss and decreased bone density)
- Pseudarthrosis, non-union or delayed union
- Fracture of the vertebrae
- Change in mental status
- Adjacent segment disease / degeneration
- Facet joint deterioration
- Osteophyte formation/resorption
- Infection and/or inflammation
- Allergic response to foreign body
- Loss of neurological function (e.g., bowel or bladder dysfunction, paralysis, dysesthesia, hyperesthesia, paraesthesia, pain, weakness, numbness, spasms, sensory loss, drop foot)
- Vascular or visceral injury
- Thrombosis / thromboembolic event
- Gastrointestinal and/or reproductive system compromise (including sterility and sexual dysfunction)
- Post-operative change in normal spinal curvature; loss of correction, height and/or reduction
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site
- Peridural fibrosis
- Loss of spinal mobility and/or function at the treated level(s)
- Spinal instability
- Spinal stenosis
- Spondylolisthesis
- Respiratory system compromise
- General surgical complications
- Reoperation / revision surgery
- Death

USAGE WARNINGS:

This device should be implanted in a sterile environment by a qualified surgeon with knowledge of the correct and safe use of the device and its associated instrumentation. Improper technique in implant placement can result in implant failure. If uncertain, contact a Southern Medical Representative.

The pedicle screw system is intended to be implanted in a bilateral construct in combination with a lumbar interbody fusion cage at the treated level to provide anterior support. If these instructions are not followed, non-union may occur which may lead to implant fatigue or breakage.

The pedicle screw system is intended to be used with autograft or allogenic material.

The selection of the appropriate screw size, as well as the size and curvature of the rods, are at the discretion of the surgeon.

A locking cap must be used for each screw in the construct. A tightening torque of 10 Nm should be applied to each locking cap. Failure to apply the specified torque may lead to loosening or disassembly of the device components.

The pedicle screw system must not be used in combination with components form other systems or manufacturers in the same construct.

Intraoperative x-ray screening is recommended to confirm that the construct has been implanted correctly.

STERILITY:

Implants are supplied **NON-STERILE**. The implants must be decontaminated and sterilized prior to use in accordance with the instructions provided by the manufacturer in IFU-100.

RE-USE WARNING:

The implants are intended for **SINGLE USE** only and **MAY NOT BE RE-USED**. An explanted device must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

INSTRUMENTATION:

Surgical instrumentation is provided by the manufacturer. No other instruments may be used in combination with this device. The instruments are provided non-sterile and must be cleaned and sterilised before use in accordance with the instructions provided by the manufacturer in IFU-100.

STORAGE:

The implants should be stored on an implant tray in a clean, dry, and well-ventilated environment. The implants may be decontaminated and sterilized while still on the tray. Refer to IFU-100. Handle with care.

MAGNETIC RESONANCE IMAGING (MRI):

The pedicle screw system has not been evaluated for safety in the MR environment. The devices have not been tested for heating or unwanted movement in the MR environment. The safety of the pedicle screw system 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.

POST-OPERATIVE CARE INSTRUCTIONS:

The surgeon, physician or other healthcare professional must provide appropriate post-operative care instructions to the patient and must ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimise physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Normal physical activities may only be resumed upon approval from a healthcare professional. It is recommended to schedule patient follow up consultations as necessary.

DEVICE REMOVAL:

The devices are intended to remain in place for the duration of the patient's life. Surgical removal of the device is possible using the surgical instruments provided by the manufacturer. Any 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.

DEVICE DISPOSAL:

Single-use devices that have been in contact with blood or bodily fluids/tissues must be decontaminated and discarded following the standard hazardous and/or biological waste disposal procedures of the healthcare facility. Users must wear gloves and take care to avoid sharp edges.

REPORTING:

Report any device-related adverse events to the manufacturer as soon as possible.

Descriptions of Symbols Used in Packaging:

USE BY		CAUTION	
LOT NUMBER	LOT	CONSULT THE INSTRUCTIONS FOR USE	
MANUFACTURER		DO NOT RESTERILISE	
DATE OF MANUFACTURE		DO NOT USE IF PACKAGING IS DAMAGED	
DO NOT REUSE		NON-STERILE	NON STERILE