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DESCRIPTION:

The SOLFIX3 Pedicle Screw System consists primarily of poly-axial pedicle screws, rods and locking caps that are intended to be implanted in a bilateral construct using a posterior approach. The device range also includes cross-connectors and rod connectors that may be added to the construct. The screws are made available in three configurations, namely dual-thread with a sharp tip, double-thread with a blunt tip and double-thread with a sharp tip. Each configuration is made available in various diameter and length options. The rods are made available in various lengths and are provided either straight or pre-bent. The length and/or curvature of the rods may, however, be adjusted by the surgeon using the surgical instruments provided by the manufacturer. The pedicle screw system is intended to be implanted in combination with interbody fusion cages at the treated level(s) to provide anterior support and is intended to be used with autograft or allogenic material.

IMPLANT MATERIALS:

Poly-axial Pedicle Screws:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136) Unalloyed Titanium (ASTM F67) Cobalt Chrome (ASTM F1537)
Rods:	Cobalt Chrome (ASTM F1537)
Locking Caps:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)
Connectors:	Ti-6Al-4V ELI Titanium Alloy (ASTM F136)

INDICATIONS FOR USE:

The SOLFIX3 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of skeletally mature patients with acute and chronic instabilities or deformities of the thoracic, lumbar and/or sacral 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,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Spinal tumour,
- Pseudarthrosis, and/or
- Failed previous fusion

Note: The Ø4.4 mm screws are only indicated for use in the thoracic spine and should not be used in the lumbosacral region.

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
- Use of the Ø4.4 mm poly-axial screws in the lumbosacral spinal region.

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(s) 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 tightening torque of 10 Nm should be applied to each locking cap in the construct. Failure to apply the specified torque may lead to loosening or disassembly of the device components.

The SOLFIX3 Pedicle Screw System must not be used in combination with components form other systems or manufacturers in the same construct.

If bone cement is used, intraoperative x-ray screening during cement injection is recommended to detect possible cement leakage.

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 SOLFIX3 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 SOLFIX3 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 adverse events related to the SOLFIX3 Pedicle Screw System 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