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IMPORTANT: PLEASE READ

For detailed information on the Southern Spinal Fixator, please consult the Surgeons' Manual.

Description:
The implant arrangement consists of fixed and poly-axial screw heads, screw caps, stems, rods, rod connectors, cross linkage blocks and lamina and pedicle hooks. The SOLFIX and TSG screw stems are modular and available in various stem lengths and stem diameters. The stems are screwed into the pedicle arch of vertebrae from a posterior approach with the heads positioned above the vertebrae. A rod (fixed to the screw heads with screw caps) passes through and connects the screw heads. This results in rigid connection of the screw system, leading to immobilisation and stabilisation of the intended spinal segments/ vertebrae. The system allows for scoliosis correction through extended profiled heads. All components are manufactured from surgical grade titanium/titanium alloy described by ASTM F136 and ASTM F67.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The SOLFIX and TSG implant are intended to provide immobilisation and stabilisation of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and/or sacral vertebrae.

Intended performance and undesirable side-effects:
Fusion of the lumber vertebrae is achieved through immobilisation and stabilisation of one or more spinal motion segment while stable boney attachment is achieved. The Southern Spinal Fixator is intended to stabilize segments T11-S1. It is recommended that the Southern Spinal Fixator is used in combination with a lumber interbody cage, such as the SASCA™, Unity / Unity+ LLC, Camber TLIF and Caliber TLIF. A bilateral construct is recommended. If anterior support is not used, nonunion may occur which may lead to implant fatigue or breakage. The Southern Spinal Fixator devices must not be used with components from other systems or manufacturers in the same construct.

Indications:
- Extensive facet arthritis or degeneration of the facets
- Evidence of degenerative disc disease (DDD) as defined by back pain of discogenic origin with DDD confirmed by patient history and radiographic studies
- Failed previous fusion
- Hyper/hypo lordosis
- Kyphosis
- Spondylolisthesis
- Pseudarthrosis
- Scoliosis
- Spinal stenosis
- Trauma (fracture or dislocation)
- Tumor resection

Contraindications:
- Active systemic infection; active malignancy or history of metastatic malignancy; terminal or autoimmune disease
- Any back or leg pain of unknown origin
- Any case where implant utilization may not result in expected physiological performance
- Any disease, condition or surgery which might impair healing or the possibility of fusion
- Any patient unwilling to follow postoperative instructions
- Bone diseases (e.g., severe osteoporosis, gout, osteomalacia, Paget's disease)
- Current or extensive use of any drug known to interfere with bone or soft tissue healing
- Documented presence of free nuclear fragment
- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
- Fever
- Leukocytosis
- Mental illness
- Modular sizes of implants not sufficient (too large or too small)
- Morbid obesity
- Muscular/skeletal pathologic/morphologic abnormalities
- Not requiring bone graft fusion
- Pregnancy at time of surgery
- Previous trauma to the study treated level, resulting in compression or bursting
- Signs of local inflammation
- Skeletally immature patients
- Sufficient previous surgeries that would preclude using a posterior approach
- Titanium allergy or intolerance

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
- Inadequate tissue coverage over the implant
- Infection
- Loosening of components
- Metal ion release
- Nerve root injury
- Neurologic deterioration such as; clumsiness, foot drop, limp short step, slow moving gait, weakness, Improper bladder control
- Numbness
- Reproductive system compromise (including sterility and sexual dysfunction)
- Respiratory compromise and or 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)
- Disassembly of components
- Facet joint deterioration
- Foreign body (allergic) reaction
- Gastrointestinal system compromise
- Graft site complications
- Hematoma or Seroma
- Heterotopic ossification
- Implant degradation
- Osteophyte formation/resorption
- Perineural fibrosis
- Postoperative change in spinal curvature, height and reduction
- Pseudarthrosis
- Removal/Revision of the device in the post-op or follow-up period
- Spinal instability
- Spinal stenosis
- Spondylolisthesis
- Stress shielding
- Supplemental fixation or fixation failure
- Tumor formation/ carcinogenesis potential
  Vertebral fracture, or resorption

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. Surgical instrumentation is provided for specific use with the implant and no other instrumentation is intended to be used for the placement of the implant. Placement of this device is limited to qualified surgeons. Refer to surgical procedure and product brochure for more information.

STERILITY:
Implants are cleaned and packed onto trays but are not supplied sterile and require sterilization by an ISO 17665 validated steam sterilization (autoclave) method. It is the responsibility of the hospital to ensure equipment and cycles are validated on site. Personnel responsible for the cleaning and sterilization of the instruments must be a fully trained hospital staff member. Unless marked sterile and clearly labeled as such in an unopened sterile package, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Sterilization must be done in time before implanting the prosthesis. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below. If uncertain contact a Southern Medical representative.

INSTRUMENTATION
Refer to IFU-100 for instrumentation handling and sterilization information

Magnetic Resonance Imaging (MRI)
The Southern Spinal Fixator devices have not been evaluated for adverse effect under MRI. The components are manufactured from non-ferromagnetic materials. Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localized heating of components caused by radio frequency induction heating and (3) image artefacts created by interaction between metallic components and the magnetic field. The Southern Spinal Fixator has not been tested for heating, migration or image artifact in the MR environment. The safety of the devices are unknown. Scanning a patient who has this device may result in patient injury.

Post Implantation:
Movement of the operation site will be restricted according to the discretion of the surgeon. 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.

Sterilization Devices Only
- Prior to sterilization of the device, remove all original packaging and labeling inserts. Place the device in suitable packaging for the sterilization process, i.e., implant trays, central supply wrap, autoclave pouches, etc.
- Special care should be taken to protect the device from contact with other metal or hard objects that could damage the implant
- Packaging should be inspected for punctures or other damage before and after sterilization

Limitations on reprocessing:
- Repeated processing has minimal effect on these implants. End of life is normally determined by wear and damage due to use

Recommended Sterilization Parameters:
- Implant sets produced by Southern Medical can be sterilized to a sterility assurance level (SAL) of 10E-6 in a pre-vacuum, 4 pulse, 132º-135ºC (270º-275ºF), 12 minute exposure, 30 minute vacuum dry, steam sterilization cycle

Storage
It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

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Bone Cement Application
It is recommended to perform intraoperative x-ray monitoring during the cement injection procedure to detect possible cement leakage

Descriptions of Symbols Used in Packaging:

USE BY		**NON-STERILITY**	NON STERILE	**DO NOT RESTERILIZE**	
LOT NUMBER	LOT	**CAUTION**		**DO NOT REUSE**	
DATE OF MANUFACTURE		**AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**	EC REP	**CONSULT THE INSTRUCTIONS FOR USE**	
MANUFACTURER ADDRESS					