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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 screw stems are modular and available in various stem lengths and stem diameters. The stems are screwed into the pedicle from a posterior approach with the heads positioned above the vertebrae. A rod passes through the screw heads and locked with caps. 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 implants 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:
- Evidence of degenerative disc disease (DDD) as defined by back pain of discogenic origin with DDD confirmed by patient history and radiographic studies
- Extensive facet arthritis or degeneration of the facets
- Failed previous fusion
- Hyper/hypo lordosis
- Kyphoscoliosis
- Spondylolisthesis
- Scoliosis
- Spinal stenosis
- Trauma (fracture or dislocation)
- Tumour resection
- Disc collapse or secondary instability after lumber decompression
- Patients with adjacent level degeneration after previous lumbar fusion
- Herniation

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
- 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
- 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
- Titanium allergy or intolerance
- Modular sizes of implants not sufficient (too large or too small)
- Morbid obesity
- Muscular/skeletal pathologic/morphologic abnormalities
- Pregnancy at time of surgery
- Previous trauma to the study treated level, resulting in compression or bursting
- Sufficient previous surgeries that would preclude using a posterior approach
- Skeletally immature patients
- The patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure

Surgical Risks:
- Mechanical failure of implanted components
- Pseudarthrosis
- Infection
- Perineural and epidural fibrosis
- Graft site complications
- Hematoma or Seroma
- Degenerative changes in adjacent segments and facet joins
- Foreign body (allergic) reaction
- Spondylolisthesis
- Osteophyte formation or resorption
- Vertebral fracture, or resorption
- Bone resorption (including stress shielding and Heterotopic ossification)
- Comptonisation of systems: cardiovascular, gastrointestinal, reproductive, respiratory
- Depression and anxiety
- RSD (reflex sympathetic dystrophy)
- Death
- Spinal stenosis
- Changes in spinal mobility/immobility, curvature, height and reduction
- Metal ion release
- Neurologic deterioration such as; clumsiness, foot drop, limp short step, slow moving gait, weakness, improper bladder control, numbness
- Removal / revision of the device in the post-op or follow-up period

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.

STERILE IMPLANTS:
Implants that are supplied sterile are for single use only before the labeled expiration date. Do not re-use implants. Do not use implants if the packaging has been damaged or previously opened, or if the expiration date has passed. Do not re-sterilize implants provided sterile. The implant is designed for single patient use only and must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection. If uncertain be sure to contact a Southern Medical Representative.

NON-STERILE IMPLANTS:
Implants are cleaned and packed onto trays but are not supplied sterile. They require sterilization by an ISO 17665 validated steam sterilization (autoclave) method by the hospital in time before implanting the prosthesis. 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 implants must be a fully trained hospital staff member. 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 parameters below. If uncertain contact a Southern Medical representative.

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.
Special care should be taken to protect the device from contact with other metal or hard objects that could damage to the implant.

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

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 is 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.

Explanation
After solid fusion occurs, these devices serve no functional purpose and may be removed. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Disposal
Devices that came into contact with blood or body fluids must be decontaminated before disposal. Disinfectants such as peroxide or enzymatic cleaning agents must be used before the device is disposed of as part of medical waste. The user must take care to avoid sharp edges and wear protective gloves."

Descriptions of Symbols Used in Packaging:

USE BY		**STERILIZED USING IRRADIATION**	STERILE R	**DO NOT REUSE**	
LOT NUMBER	LOT	**CAUTION**		**DO NOT RESTERILIZE**	
DATE OF MANUFACTURE		**AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**	EC REP	**DO NOT USE IF PACKAGING IS DAMAGED**	
MANUFACTURER ADDRESS		**CONSULT THE INSTRUCTIONS FOR USE**		**NON-STERILITY**	