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IMPORTANT: PLEASE READ

For detailed information on correct & safe device use, please consult the Surgical 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.

INDICATIONS FOR USE

The Southern Spinal Fixator is intended to stabilize segments T11-S1 in skeletally mature patients. Fusion of the lumber vertebrae is achieved through immobilisation and stabilisation of one or more spinal motion segment while stable bony attachment is achieved. 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, non-union 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 for use include:

- Extensive facet arthritis or degeneration of the facets
- Degenerative disc disease (defined by back pain of discogenic origin with confirmed by patient history and radiographic studies)
- Failed previous fusion
- Hyper/hypo lordosis
- Kyphosis
- Spondylolisthesis
- Pseudarthrosis
- Spinal stenosis
- Trauma (fracture or dislocation)
- Tumour 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

RISKS & UNDESIRABLE SIDE-EFFECTS

- 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
- Disassembly of components
- Facet joint deterioration
- Foreign body (allergic) reaction
- Gastrointestinal system compromise
- 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
- Osteophyte formation/resorption
- Perineural fibrosis
- Postoperative change in spinal curvature, height and reduction
- 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)
- Spinal instability
- Spinal stenosis
- Spondylolisthesis
- Stress shielding

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

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 labelled 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. **Refer to IFU-100**

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.

The device is intended to be used in combination with the AXIS anterior cervical plate system. Failure to use supplemental fixation may lead to mechanical failure of the device, non-union and/or cage migration/expulsion.

Autograft or allogenic bone graft should be used in combination with the device. Failure to use bone graft may result in non-union. In the absence of osseous fusion, mechanical failure of the implant can be expected as a result of everyday mechanical stresses.

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

Do not manipulate the tulip without disengaging the locking mechanism

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

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.

MRI SAFETY INFORMATION

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.

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	
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	
DATE OF MANUFACTURE		NON-STERILITY	
DO NOT USE IF PACKAGING IS DAMAGED