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IMPORTANT: PLEASE READ

For detailed information on the Southern AXIS™ 2 Cervical Plate and Screw System, please consult the Surgical Manual

Description: *The AXIS™ 2 Cervical Plate and the fixed and variable angle screws are manufactured from Grade 23 Titanium (ASTM F136).*

***RADIOACTIVITY WARNING*:** No radioactivity substance or radioactivity.

***Intended purpose*:** The Southern AXIS™ 2 Anterior Cervical Plate System (ACP) arthrodesis device is intended for fixation to the anterior cervical spine (C2-T1) to relieve painful motion by immobilizing and stabilizing the affected cervical spinal region during the development of a cervical spinal fusion. The ACP system is to be used in conjunction with a bone graft, interbody or vertebrectomy cage. The range of implants consists of one to four level plates with lengths from 19.5 mm up to 93 mm. The ACP system is intended to be used for treatment of degenerative disk disease and trauma in the cervical spine. The device consists of a plate that is fixated to the vertebral body by means of anchoring screws.

Indications for the use of arthrodesis cervical plates and screws are:

- Deformity (defined by kyphosis, lordosis, or scoliosis)
- Degenerative spondylosis (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.)
- Failed previous fusions
- Pseudarthrosis
- Trauma including fractures
- Tumors

Contraindications for the use of arthrodesis cervical plates and screws are:

- Failure of anterior plate fixation
- Active systemic infection; active malignancy or history of metastatic malignancy; terminal or autoimmune disease
- Any case where implant utilization may not result in expected physiological performance
- Any disease, condition or surgery which might impair healing
- Any patient unwilling to follow postoperative instructions
- Bone diseases (e.g., osteoporosis, gout, osteomalacia, Paget's disease)
- Fever
- Inadequate tissue coverage over operative site
- Inflammation local to operative site
- Leukocytosis
- Morbid obesity
- Pregnancy at time of surgery
- Sufficient previous surgeries that would preclude using an anterior approach
- Titanium/Titanium Alloy allergy or intolerance
- 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

Risks Associated with surgery

- Allergic or other reaction to anesthesia
- Approach related injury
- Blood loss or hemorrhage
- Cerebrospinal fluid leak (CSF)
- Death
- Disease progression
- Dysphagia, Hoarsness and swallowing difficulties
- Infection
- Injury to the jugular vein, carotid artery, trachea, laryngeal nerve, thyroid gland, oesophagus and pharynx
- Malnutrition
- Morbidity
- Osteolysis or vertebral inflammation
- Pulmonary embolism
- Shock
- Thrombosis, Hypotension
- Myocardial infarction

Risks Associated with Cervical Spinal Systems

- Annular ossification
- Bone graft migration
- Dural injury
- Facet joint deterioration
- Failed back syndrome
- Hematoma or Seroma
- Heterotopic ossification
- Hypopharyngeal screw migration
- Implant degradation
- Myocardial infarction
- Nerve damage
- Neurologic deterioration; clumsiness, foot drop, limp, short step, slow moving gait, weakness
- Numbness
- Osteophyte resorption
- Perineural fibrosis
- Plate size may not be inclusive of range/incorrect plate length selection.
- Reflex sympathetic dystrophy (RSD)
- Removal of the device in the post-op or follow-up period
- Reoperation at the study treatment level with or without removal or modification of any or all components of the device
- Revision with or without replacement of a component/device
- Screw back out
- Spontaneous fusion
- Supplemental fixation
- Transitional syndrome
- Tumor formation/ carcinogenesis potential
- Vertebral fracture
- Vessel damage
- Failed fusion
- Mechnanical Failure of Implant (Breaking or bending of screws and/or plates)

If re-used:

- Infection
- Non-oesteointegration

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. Do not reuse implantable devices (screws and plates).

STERILITY:

Plates
All implant plates are supplied sterile, and 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. Re-sterilization could cause material degradation and could result in surgical rejection and/or post-operative infection. 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.

Screws
Cleaned Implant screws are packed onto instrument sets as non-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. Screws provided separate to the screws on instrument sets are supplied sterile and are for single use only before the labeled expiration date. 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.

Magnetic Resonance Imaging (MRI)

The AXIS™ 2 devices have not been evaluated for adverse effect under MRI. The AXIS™ 2 implants are manufactured from non-ferromagnetic materials. Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localised heating of components caused by radio frequency induction heating and (3) image artifacts created by interaction between metallic components and the magnetic field.

Point of use
- Thorough cleaning and rinsing should begin as soon as possible after use of the device
- These practices include keeping devices moist after use to prevent soil from drying and removing gross soil from the surfaces, crevices, mating surfaces, joints, and all other hard-to-clean design features.

Containment and transportation
- No particular requirements.

Preparation for cleaning
- Devices capable of disassembly must be disassembled prior to cleaning
- Dried-on soil is difficult to remove with automatic washing, especially at challenging design features on devices like interfaces, crevices, joint etc. The removal of gross soil from these areas prior to washing in the automatic washer is critical for achieving adequate cleaning

Cleaning: Automated
1. Pre-cleaning should be through soaking in enzymatic detergent for 5 minutes and scrub surfaces including brackets and hinges with cleaning brush
2. Rinse with warm water
3. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain).
4. Run the automatic wash cycle: Minimum cycle parameters:

Phase	Function	Duration (min)
2 Rinse cold + warm water	Rinse, mixed water	2
5Wash I detergent	Wash with detergent	7
13 Rinse warm water	Rinse, warm water	2
16 Disinfection temperature is set at A0=600; 90˚C (+1˚C)/1 min	Disinfection	1 + heating

5. Check instruments for visible soil
6. Long narrow cannulations and blind holes require particular attention during cleaning
7. Repeat cleaning if soil is visible and re-inspect.
8. Thermal disinfection Minimum cycle parameters: one (1) minute at 91° C

Cleaning: Manually
1. Immerse instrument and soak for a minimum of ten (10) minutes in enzymatic detergent
2. Blind holes should be repeatedly filled and emptied
3. Long narrow cannulations and blind holes require particular attention during cleaning
4. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features
5. Scrub interfaces several times using a twisting action. If components of the instrument can be disassembled or moved, it is necessary to retract or open the part in order to access and clean these areas.
6. Scrub inside holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached
7. Scrub around hinged surface areas with a brush or pipe cleaner
8. Scrub crevices using a cleaning brush or pipe cleaner
9. Rinse thoroughly with warm water, making sure to wet the challenging design features
10. Check instruments for visible soil
11. Repeat cleaning if soil is visible

Disinfection:
- Disinfectant solution (EndoZyme®) may be used in accordance with label instructions.
- 3% hydrogen peroxide may be used on difficult to reach areas

Drying
- When drying is achieved as part of a washer disinfector cycle do not exceed 120°C.

Maintenance, Inspection and Testing of Instrumentation
- Visually inspect for damage or wear
- Hinged instruments should be check for smooth movement of hinge without excessive "play."
- Locking mechanisms should be checked for action
- All surfaces should be smooth and free of cracks and deep nicks
- Reamer/drill bits should be inspected for deformities and distortion that might hinder insertion into a drill
- Metal surfaces Inspect for corrosion and major deformation
- Blunt or damaged instruments should be returned to sales representatives

Packaging
- Instrument tray should be double wrapped with Steriwrap.

Sterilization Instructions

Instruments and instrument trays:
- It is important that adequate cleaning of instrument cases/trays be performed prior to sterilization. Preparation for Sterilization Single-Use
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Instrument should be placed in Instrument Trays prior to sterilization
- Sterilization trays must be wrapped with an approved autoclave wrap prior to sterilization. The tray by itself does not provide a sterile barrier.
- **Do not stack sterilization trays in the sterilizer!**

Devices Only:
- Screws are supplied non-sterile unless otherwise specified on the screw packaging.
- 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., 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 instruments. End of life is normally determined by wear and damage due to use.

Recommended Sterilization Parameters:
- Instrument 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
- Some health care authorities recommend sterilization according to these parameters to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system. Should this be required, the following temperature and time is required: 134ºC, 20 minutes exposure, 30 minute drying time.

Storage
- If stored between cleaning and sterilization, dry instruments with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet storage.
- Containment devices can be stacked for storage.

The instructions provided above have been validated by Southern Medical. 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.

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

Description of Symbols Used in Packaging

Use by		Sterility		Consult the Instructions For Use	
Lot Number	LOT	Do not reuse (implant devices)		European Representative	EC REP
Sterilization (Gamma)	STERILE R	Manufacturer address		Date Of Manufacture	
Do not resterilize		Do not use if packaging is damaged		Caution	