Manufactured by:
Southern Medical (Pty) Ltd
55 Regency Drive
Route 21 Corporate Park
Irene, Centurion
0178
South Africa

P O Box 17198
Lyttleton, 0140
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za
www.southmed.co.za

IMPORTANT: PLEASE READ

For detailed information on the Axis Anterior Cervical Plate (ACP) System, please consult the Surgical Manual.

DESCRIPTION:

The Southern Medical Axis Anterior Cervical Plate (ACP) system is a spinal plating system intended for screw fixation to the anterior aspect of the vertebral bodies of the cervical spine (C2-T1). It is intended for the treatment of one to four levels in skeletally mature patients as an adjunct to cervical discectomy, corpectomy or vertebrectomy and fusion procedures. It is not a stand-alone system and must be used as intended with cervical fusion cages and/or autograft or allogenic bone graft. The Axis ACP system is designed to provide supplementary support, rigidity and stabilisation while spinal fusion occurs. The system comprises base plates, pre-assembled with locking plates, and two screws per vertebral body. To achieve the desired clinical result, the system must be fully assembled as per the manufacturer's instructions.

The Axis plates and screws are manufactured from radiopaque titanium alloy (Ti-6Al-4V; ASTM F136). Surgical instrumentation is manufactured from stainless steel (ASTM F899) and titanium (ASTM F136).

INDICATIONS FOR USE:

The Axis Anterior Cervical Plate system is intended for use in skeletally mature patients for anterior screw fixation to the cervical spine (C2-T1) as an adjunct to fusion for the treatment of the following indications: (a) degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); (b) trauma (including fractures); (c) tumours; (d) deformity (defined as kyphosis, lordosis or scoliosis); (e) spondylolisthesis; (f) spinal stenosis; (g) pseudarthrosis and (h) revision of previous surgery.

Patients must have undergone at least six weeks of non-operative treatment prior to being treated with this medical device.

CONTRA-INDICATIONS:

Contra-indications include, but are not limited to:

- Allergy or hypersensitivity to any of the implant materials (known or suspected)
- Active systemic or localised infection and/or inflammation
- Pregnancy
- Joint disease or bone absorption syndromes, such as severe osteoporosis, osteopenia, osteomalacia, osteomyelitis or Paget's disease, that compromise bone quality and may interfere with device placement, healing and/or fusion
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality or anatomical definition
- Patient anatomy or pathology that prevents full insertion, assembly and correct usage of the device
- Any medical or surgical condition that would preclude the potential benefit of surgery, such as morbid obesity, heavy smoking, diabetes, cancer, congenital abnormalities, elevated sedimentation rate unexplained by other disease, elevated white blood cells or a marked shift in white blood cell differential count
- 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.
- Any condition not specified in the indications

ADVERSE EFFECTS AND RISKS OF USE:

- Device failure or fracture
- Loss of fixation
- Pseudarthrosis or delayed fusion
- Fracture or other damage to the vertebrae
- Pain, discomfort or abnormal sensations due to the presence of the device
- Infection and/or inflammation
- Allergic response to foreign body
- Neurological injury
- Vascular injury
- Visceral injury
- Thrombosis / thromboembolic event
- Loss of or reduction in spinal mobility and/or function at the treated level(s)
- General surgical complications
- Reoperation
- Death

USAGE WARNINGS:

Implantation of this device(s) is limited to qualified surgeons in a sterile environment. The recommended surgical procedure is provided by the manufacturer. Refer to the surgical manual. Prior to use, the surgeon should be specifically trained in the use of this spinal system and the associated instrumentation. If uncertain, contact a Southern Medical Representative.

A sufficient quantity of autograft or allogenic material must be used to facilitate fusion. The Axis devices can be used with the Southern Medical SPICCA anterior cervical interbody fusion devices.

The Axis ACP System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Do not substitute another manufacturer's device for any components of the Axis ACP system.

Correct handling of the device(s) is extremely important. The desired clinical outcome may not be achieved if the usage instructions are not followed.

STERILITY INFORMATION AND WARNINGS:

The Axis ACP devices are provided either sterile or non-sterile.

For devices supplied STERILE:

Implants are sterilised by gamma irradiation and are supplied **STERILE**. **DO NOT RE-STERILISE** devices supplied sterile. Re-sterilisation could cause material degradation and could result in surgical rejection and/or post-operative infection.

Sterile devices are packaged in a double sterile barrier. Do not use if the packaging is damaged, previously opened or if the expiry date indicated on the packaging has been exceeded.

All devices sold outside South Africa are provided sterile.

For devices supplied NON-STERILE:

Prior to use, non-sterile implants must be sterilised using the validated methods prescribed by the manufacturer in IFU-100.

RE-USE WARNING:

All 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 for specific use with the device(s) and no other instrumentation is intended to be used for the placement of the device(s). Instrumentation is manufactured from stainless steel (ASTM F899) and titanium (ASTM F136).

Instruments are provided non-sterile and must be cleaned and sterilised using the validated methods prescribed by the manufacturer before use. Refer to IFU-100.

STORAGE:

No special storage instructions. Storage conditions must not prematurely deteriorate device packaging or degrade/contaminate the packaging or the contents thereof in any way. Handle with care.

RADIOACTIVITY INFORMATION:

No radioactive substance or radioactivity.

MAGNETIC RESONANCE IMAGING (MRI) WARNING:

The Axis ACP 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 Axis devices 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. 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. Refer to the surgical manual for removal instructions.

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 serious incidents related to the Axis ACP devices to the manufacturer.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING:

USE BY		CAUTION	
LOT NUMBER	LOT	CONSULT THE INSTRUCTIONS FOR USE	
MANUFACTURER ADDRESS		DO NOT RESTERILISE	
DATE OF MANUFACTURE		DO NOT USE IF PACKAGING IS DAMAGED	
DO NOT REUSE		STERILISED USING IRRADIATION	STERILE R
CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY	NON-STERILE	NON STERILE