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IMPORTANT: PLEASE READ

DESCRIPTION
The Thoracic Vertebrectomy Cages are height-adjustable vertebral body replacement devices manufactured from Ti6Al-4V ELI (ASTM F136).
The cages are available in various extendable heights, and angles to accommodate different anatomic requirements. Serrations on the superior and inferior endplate surfaces provide increased stability during placement.
Fenestrations on the cage cavity allow for packing of autograft or allogenic bone graft into the cage and to promote bony in-growth.
The implant is required to be used with supplementary spinal fixation systems.

INDICATIONS FOR USE
The devices are indicated for use in the cervical or thoracic spine in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body resulting from trauma, osteomyelitis, revision surgery, tumors or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders in the cervical and thoracic spine.

The devices are intended to be packed with autograft or allogenic bone graft and are intended to be used with supplementary spinal fixation systems.

CONTRAINDICATIONS
- Active systemic or local infection and/or inflammation
- Pregnancy
- Bone diseases, such as severe osteoporosis, osteopenia, osteomalacia or Paget's disease, that compromise bone quality and may interfere with device placement, healing and/or fusion
- Pregnancy
- Patient anatomy or pathology that prevents full insertion and correct usage of the device
- Allergy or sensitivity to the implant materials
- Inadequate patient compliance
- Severe osteoporosis or similar loss of bone density
- Severe damage to bone structures that would prevent the stable implantation of system components
- Any other conditions that may place excessive stress on the device and/or bone, such as morbid obesity, tumours, fractures, inadequate tissue coverage or wound healing disorders. The decision to use a device in patients with such conditions must be made by a healthcare professional after taking into consideration the benefits and risks to the patient.
- 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.
- Cases not listed under indications
- Use with components of other systems.
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RISKS & UNDESIRABLE SIDE-EFFECTS
- Implant failure or fracture or breakage
- Implant loosening or migration or dislodgement.
- Injury to surrounding vertebrae or spinous processes.
- Injury to neurological or vascular anatomy
- Injury to surrounding organs or the spinal cord
- Thrombosis / thromboembolic events
- Allergic and/or inflammatory response to implant material and/or foreign body and/or particulates
- Infection and / or inflammation
- Revision surgery
- Paralysis
- Wound dehiscence or delayed healing.
- Incorrect positioning of the device
- General surgical complications (including pain, discomfort, postoperative ileus, incisional hernia and cyst formation)
- Death

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

STERILE R

The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection.

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 potential for success is increased by the proper selection of implant size, shape, and design. 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.

Failure to use supplemental fixation may lead to mechanical failure of the device, collapse 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 supplemental fixation, mechanical failure of the implant can be expected as a result of everyday mechanical loads and stresses.

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
The surgeon/physician should provide appropriate postoperative care instructions to the patient and should ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimize physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement. Follow-up consultations should be arranged with the patient at appropriate intervals, as deemed necessary by the physician. The patient should only resume their normal activities once cleared to do so by their physician.

MRI SAFETY INFORMATION
The Thoracic vertebrectomy devices have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the 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.

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	REF
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	LOT
DATE OF MANUFACTURE		STERILIZED USING IRRADIATION	STERILE R
DO NOT USE IF PACKAGING IS DAMAGED		CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY