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**DESCRIPTION:**

The TEX Expandable Transforaminal Lumbar Interbody Fusion (TLIF) cage is an interbody fusion device that expands into a wedge-shape. The device is intended to provide structural stability in skeletally mature individuals following discectomy. The device is made available in different footprint options and can be expanded to the appropriate height and degree of lordosis. The screw, wedge and pins are manufactured from Ti-6Al-4V ELI Titanium Alloy (ASTM F136), while the endplates are additively manufactured from Ti-6Al-4V ELI (ASTM F3001)

**INDICATIONS FOR USE:**

The TEX Expandable Transforaminal Lumbar Interbody Fusion (TLIF) cage is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L1 – S1). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These patients may also have up to Grade I spondylolisthesis at the involved level(s).

The devices are indicated for use in skeletally mature patients that have undergone at least six months of non-operative treatment. The device may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Two TEX Expandable TLIF devices should be used per treated level. The device is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation.

**CONTRA-INDICATIONS:**

Contra-indications include, but are not limited to:

- Allergy or hypersensitivity to any of the implant materials
- Active systemic or localised infection and/or inflammation
- Spondylolisthesis greater than Grade I
- 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
- Any other conditions that may place excessive stress on the device and/or bone, such as morbid obesity, tumours, fractures or inadequate tissue coverage. 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.

**ADVERSE EFFECTS AND RISKS OF USE:**

- Device failure / fracture
- Loss of fixation (e.g., cage loosening or migration)
- Pseudarthrosis or delayed fusion
- Fracture of the vertebrae
- Adjacent segment disease / degeneration
- Infection and/or inflammation
- Allergic response to foreign body
- Neurological injury
- Vascular injury
- Thrombosis / thromboembolic event
- Visceral injury
- Loss of spinal mobility and/or function at the treated level(s)
- General surgical complications (including postoperative ileus, incisional hernia and cyst formation)
- Reoperation
- Death

**USAGE WARNINGS:**

This device should be implanted in a sterile environment by a qualified surgeon with knowledge of the correct and safe use of the device and its associated instrumentation. If uncertain, contact a Southern Medical Representative.

Two TEX Expandable TLIF devices should be used per treated level.

The device is intended to be used with autograft and/or allograft and should be used with supplementary fixation.

The 5Nm torque limiting driver should be used for device placement. Do not over-tighten the screw.

Correct placement and sufficient expansion of the device should be verified radiographically.

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

**STERILITY:**

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

Do not use the device if the packaging has been damaged or if the expiry date on the label has been exceeded.

**RE-USE WARNING:**

The 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 by the manufacturer. No other instruments may be used in combination with this device.

The instruments are provided non-sterile and must be cleaned and sterilised before use in accordance with the instructions provided by the manufacturer in IFU-100.

**STORAGE:**

No special storage instructions apply. 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):**

The TEX Expandable TLIF devices have 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 TEX Expandable TLIF 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.

**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 adverse events related to the TEX Expandable TLIF devices to the manufacturer as soon as possible.

**Descriptions of Symbols Used in Packaging:**

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| USE BY | | CAUTION | |
| LOT NUMBER | LOT | CONSULT THE INSTRUCTIONS FOR USE | |
| MANUFACTURER | | DO NOT RESTERILISE | |
| DATE OF MANUFACTURE | | DO NOT USE IF PACKAGING IS DAMAGED | |
| DO NOT REUSE | | STERILISED USING IRRADIATION | STERILE R |
| DOUBLE STERILE BARRIER SYSTEM | | | |