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IMPORTANT: PLEASE READ

For detailed information on the Southern TLIF & PLIF devices, please consult the applicable Surgical Manual.

DESCRIPTION:

The Southern Transforaminal Lumbar Interbody Fusion (TLIF) family including the PLIF Caliber Lordotic, the TLIF Bullet, and the TLIF Camber, are straight or curved, narrow wedge-shaped devices intended to replace intervertebral discs in the lumbar spine and to aid posterior lumbar spinal fixation systems in supporting, stabilising and immobilising the spinal column and restoring normal anatomy while fusion occurs. The TLIF Bullet and Camber devices are intended for a transforaminal surgical approach. The Caliber Lordotic devices are intended for a posterior surgical approach (i.e. PLIF). The devices are not stand-alone devices and must be used with supplementary spinal fixation systems. The devices have a central cavity intended to be filled with autograft.

TLIF Bullet devices are manufactured from radiolucent polyether ether ketone (PEEK ASTM F2026) with radiopaque tantalum (ASTM F560) radiographic markers.
PLIF Caliber Lordotic devices are manufactured from radiolucent PEEK (ASTM F2026) with radiopaque tantalum (ASTM F560) markers. Two PLIF Caliber Lordotic devices per intervertebral level are intended to be implanted bi-laterally following a posterior approach.
TLIF Camber devices are manufactured from radiolucent PEEK (ASTM F2026) with radiopaque tantalum (ASTM F560) markers and a titanium (ASTM F136) hinge.
Instruments: Surgical instrumentation is manufactured from stainless steel (ASTM F899).

INDICATIONS FOR USE:

The Southern Transforaminal Lumbar Interbody Fusion (TLIF) family (PLIF Caliber Lordotic, TLIF Bullet, and TLIF Camber) are indicated for use as interbody fusion devices in the lumbar spine, auxiliary to supplementary lumbar spinal fixation systems, such as posterior pedicle screw and rod systems. The PLIF Caliber Lordotic devices are designed to be implanted bi-laterally following a posterior approach. The devices are intended to be used with autograft to facilitate fusion.

The devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L1 to S1. DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The devices may also be used in patients with pseudarthrosis / non-union from previous unsuccessful fusion surgery. Patients should have undergone at least six months of non-operative treatment.

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)
- Cage subsidence
- Pseudarthrosis or delayed fusion
- Vertebral or adjacent segment fracture/degeneration
- Infection, inflammation, allergic reaction or adverse tissue reaction
- Neurological injury (incl. damage to the spinal cord / neural structures)
- Dural tear or CSF leakage
- Vascular injury and/or damage to surrounding organs / structures
- Soft tissue or visceral injury and/or spinal encroachment
- Endplate damage
- Thrombosis / thromboembolic event
- Spinal instability, loss of correction or function (incl. mobility / disc height)
- General surgical complications (including postoperative ileus, incisional hernia and cyst formation)
- Recurrence and/or aggravation of pre-operative symptoms, incl. pain, neurological deficits
- Reoperation
- Death

USAGE WARNING:

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 device(s) and the associated instrumentation. If uncertain, contact a Southern Medical Representative.

The TLIF & PLIF devices are intended to be with autograft and as accessory devices to primary lumbar fixation systems, such as a pedicle screw and rod system. The PLIF Caliber Lordotic devices must be used in pairs, implanted bilaterally per intervertebral space.

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:

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

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 for specific use with the device(s) and no other instrumentation is intended to be used for the placement of the device(s). Instruments are provided non-sterile and must be cleaned and sterilised using the validated methods prescribed in IFU-100 before use.

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):

The Southern 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 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 serious incidents related to the Southern TLIF devices to the manufacturer.

Descriptions of Symbols Used in Packaging:

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 BARRER		CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx ONLY