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IMPORTANT: PLEASE READ

For detailed information on the Southern Transforaminal Interbody Fusion (TLIF), please consult the Surgeons' Manual.

Description:

The Bullet Transforaminal Lumbar Interbody Fusion (TLIF) is a single component device, manufactured from biocompatible poly-ether-ether-ketone (PEEK) (ASTM F2026) and titanium (ASTM F67). The device serves to augment posterior pedicle screw fixation. Surgical instrumentation is manufactured from surgical grade stainless steel (ASTM F899).

The Camber Transforaminal Lumbar Interbody Fusion (TLIF) is manufactured from biocompatible poly-ether-ether-ketone (PEEK) (ASTM F2026) with titanium (ASTM F67) markers and a titanium (ASTM F136) swivel joint. The device serves to augment posterior pedicle screw fixation. Surgical instrumentation is manufactured from surgical grade stainless steel (ASTM F899).

Radioactivity warning:

No radioactive substance or radioactivity.

Intended purpose:

The intervertebral endoprosthesisis intended as a treatment option for pain and functional disorders specific to the lumbar vertebral column. The aim of the device is to provide additional support for pedicle screw fixation between two vertebral bodies and initial immobilization of these bodies whilst simultaneously providing space for bone graft so that a fusion of the two vertebral bodies will in time be attained.

Intended performance and undesirable side-effects:

Preferred patients are those that have instability due to degenerated discs and/or facet joints causing pain, loss of disc height, spondylolisthesis or change in the normal curvature of the spine. The Bullet TLIF is intended for use with bilateral pedicle screw fixation in the lumbar spine, excluding L5-S1. Revision surgery for device retrieval or additional instrumentation must be possible in the event of failure to fuse or poor clinical outcome.

Indications:

- Age between 18 and 60 years
- Degenerative disc disease and instabilities
- Fractures
- Mechanical back pain (usually due to disc degeneration)
- Pseudarthrosis or failed arthrodesis
- Recurrent disc herniation
- Scoliosis
- Segment instability (bulging disc)
- Some tumors
- Spinal instability (spondylolisthesis)
- Spinal Stenosis

Contraindications:

- Certain spinal fractures
- Certain spinal tumors
- Major mental illnesses and psychosocial disorders (Waddell>3/5)
- Primary spinal deformity
- Serious instabilities
- Spinal fractures
- Treatment at L5-S1 level

Surgical Risks:

- Abdominal hernia
- Allergic or other reaction to anesthesia
- Annular ossification
- Blood loss or hemorrhage
- Death
- Degenerative changes in adjacent segment
- Dural injury
- Facet joint deterioration
- Hematoma or seroma
- Heterotopic ossification
- Ileus
- Implant breakage
- Implant collapse or subsidence into adjacent vertebrae
- Implant degradation
- Implant displacement/migration
- Impotence
- Incontinence
- Infection
- Kidney or ureter injury
- Metal ion release
- Myocardial infarction
- Nerve root injury
- Neurologic deterioration:
  - Clumsiness
  - Foot drop
  - Limp
  - Short step
  - Slow moving gait
  - Weakness
- Numbness
- Osteolysis or vertebral inflammation
- Osteophyte resorption
- Pain
- Perineural fibrosis
- Peritonitis
- Pneumonia
- Pneumothorax
- Pulmonary embolism
- 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
- Retrograde ejaculation
- Revision with or without replacement of a component
- RSD (reflex sympathetic dystrophy)
- Spinal instability
- Spinal stenosis (narrowing of the spinal canal)
- Spondylolisthesis acquisita
- Spondylosis acquisita
- Spontaneous fusion
- Sterility
- Supplemental fixation
- Surgical instrument failure
- Thrombosis
- Tumor formation/ carcinogenesis potential
- Vertebral fracture
- Vessel damage
- Wear debris generation

Risks Associated with LumbarSpinal Systems:

- Acute heart failure
- Annular ossification
- Degenerative changes in adjacent segment
- Dural injury
- Facet joint deterioration
- Hematoma or seroma
- Heterotopic ossification
- Implant breakage
- Implant collapse or subsidence into adjacent vertebrae
- Implant degradation
- Implant displacement
- Impotence
- Incontinence
- Kidney or ureter injury
- Metal ion release
- Nerve root injury
- Neurologic deterioration
- Clumsiness
- Foot drop
- Limp
- Short step
- Slow moving gait
- Weakness
- Numbness
- Osteophyte resorption
- Perineural fibrosis
- 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
- Retrograde ejaculation
- RSD (reflex sympathetic dystrophy)
- Spinal cord injury due to instruments being forced too deep
- Spinal instability
- Spinal stenosis (narrowing of the spinal canal)
- Spondylolisthesis acquisita
- Spondylosis acquisita
- Spontaneous fusion
- Sterility
- Supplemental fixation
- Tumor formation/ carcinogenesis potential
- Vertebral fracture
- Vessel damage and
- Wear debris generation

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 the TLIF is limited to spinal surgeons. Refer to surgical procedure and product brochure for more information.

Sterility:

All implants 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. If uncertain be sure to contact a Southern Medical Representative.

STERILIZATION WARNING:

Do not re-sterilize implants produced sterile. Implants are sterilized by gamma irradiation. 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 reused. An explanted implant must never be re-implanted. Reuse or re-implantation may result in cross-contamination or infection.

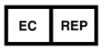
Magnetic Resonance Imaging (MRI)

The Bullet TLIF devices have not been evaluated for adverse effect under MRI. The Bullet TLIF is 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.

Post Implantation:

The surgeon/physician's postoperative directions, indications and warnings to the patient with subsequent patient compliance are vital to successful fusion. The subject must refrain from physical activity for several months. Physical movement must be minimized. Subjects will be instructed not to engage in activities requiring lifting, bending, twisting or excessive movement for several months post-operatively. The subject must not be exposed to electrical shock and/or mechanical vibrations. Directly after the operation, subjects will be placed in a brace until fusion occurs. After a couple of months, the subject may return to the workplace if the work environment does not entail excessive physical activities. Car journey duration must be minimized, preferably avoided.

Descriptions of Symbols Used in Packaging:

USE BY	
LOT NUMBER	
DATE OF MANUFACTURE	
DO NOT REUSE	
STERILIZED USING IRRADIATION	
CAUTION	
AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
CONSULT THE INSTRUCTIONS FOR USE	
DO NOT RESTERILIZE	
DO NOT USE IF PACKAGING IS DAMAGED