Manufactured by:
Southern Medical (Pty) Ltd.
55 Regency Drive,
Route 21 Corporate Park
Irene, Centurion, 0062
South Africa
Tel: +27 12 667 6244
Email: info@southmed.co.za

IMPORTANT: PLEASE READ

For detailed information on the Kineflex Prosthetic Disc (KPD) and Lateral Lumbar Disc (LLD) prostheses, please consult the KPD/LLD Surgical Manual and IFU at southmed.co.za

Description:
The Kineflex devices are weight-bearing implants consisting of two keeled endplates and one semi-constrained, fully articulating CCM core. The Kineflex is supplied sterile. The Kineflex endplates and the core are manufactured from cobalt chrome molybdenum alloy (ASTM F799) with titanium (Ti) plasma spray coating (ASTM F1580) on the osseointegrating surfaces of the endplates. Surgical instrumentation is produced from stainless steel (ASTM F899).

Radioactivity warning:
No radioactivity substance or radioactivity.

Intended purpose:
The Kineflex intervertebral arthroplasties are intended as treatment options for pain and functional disorders specific to the lumbar vertebral column.
The Kineflex intervertebral arthroplasties are indicated in skeletally mature patients for reconstruction of the disc in the lumbar spine following single-level discectomy for intractable radiculopathy and/or myelopathy.
The aim is to restore segmental stability and recreate normal vertebral body spacing. Preferred patients are those suffering from post-discectomy syndrome and symptomatic degenerative disc disease.

Intended performance and undesirable side-effects:
The implant is intended to restore segmental stability and recreate normal vertebral body spacing while preserving motion in the spine. Incorrect placement can affect clinical outcome and possibly result in device subsidence and/or failure.

Indications:
- Adjacent segment disease – single level adjacent to previous successful fusion
- Age between 18 and 60 years
- Chronic backache and radiculopathy with a contained disc on MRI
- Disabling back pain due to DDD or lumbar spondylosis
- Evidence of single level degenerative disc disease (DDD) at L4/L5 with radiographic evidence (such as CT, MRI, plain film, flexion/extension films, myelography, discography, etc.) of one or more of the following; mild to moderate osteophyte formation of vertebral endplates, loss of disc height ≥ 2 mm when compared to adjacent level, contained herniated nucleus pulpous, paucity of facet joint degeneration, scarring/thickening of annulus fibrosis with osteophytes indicating osteoarthritis, loss of water content on MRI (black disc on T2 weighted image), or vacuum phenomenon
- Failed prior conservative therapy (at least six (6) months) for discogenic back pain and/or prior nucleolysis, nucleoplasty, discectomy, rhizotomy, intradiscal electro thermal therapy (IDET) or laminotomy at study treatment level
- History of back and/or radicular pain
- Mono-segmental and bi-segmental instability with pseudoradicular symptoms as well as radicular irritation in stenosis of the intervertebral foramina and/or facet symptoms
- Mild or moderate facet joint degenerative changes maybe present, but not significant pain contributor
- Non-radicular leg or back pain in the absence of nerve root compression
- Oswestry Disability Index (ODI) score of at least 40 pre-operatively
- Painful degenerative scoliosis less than 11° in the coronal plane (or prior treatment for scoliosis to correct or lower the coronal curvature to less than 11°)
- Post-discectomy syndrome
- Structural spondylolistheses up to Meyerding 1 in load-bearing structures of the vertebral body
- Visual analog score (VAS score) of at least 40 on a 100 mm scale
-

Contraindications:
- Any back or leg pain of unknown origin
- Any disease, condition or surgery which might impair healing
- Arachnoiditis
- At risk for osteoporosis or osteopenia
- Bilateral retroperitoneal scarring (e.g. abscess or prior surgery). Need for direct posterior decompression through same approach (Second posterior micro-decompression not contraindicated)
- Central canal stenosis or bony lumbar spinal stenosis
- Chronic steroid use or use of bone growth stimulators
- Current or extensive (>6 months) use of any drug known to interfere with bone or soft tissue healing including chemical or alcohol dependence
- Defect in the pars interarticularis
- Degenerative spondylolisthesis with greater than 3 mm slippage (>grade 3)
- Documented abnormal abdominal vessel or muscular/fascial pathology or morphology
- Documented presence of free nuclear fragment
- Documented significant spinal, foraminal or lateral stenosis or disc height ≤3 mm
- Endplate abnormalities (the concave endplates) or interoseous discus rupture
- Extensive facet arthritis or degeneration of the facets noted on MRI, CT or X-ray
- Infection
- Inflammation at intended implant site
- Instability or significant previous posterior decompression surgery
- isolated radicular compression syndromes, especially due to displaced intervertebral disc tissue
- Isthmic (spondylolytic) spondylolisthesis or spondylitis, spondylolysis
- Known metal allergy
- Listhesis (degenerative or lytic), or undisplaced lysis
- Lytic spondylolisthesis or degenerative spondylolisthesis > grade 1 (Moderate to severe spondylolisthesis)
- Major mental illness including psychosis, major affective disorder or schizophrenia, Psychosocial disorders (Waddell >3/5)
- Metabolic bone disease (e.g., osteoporosis, gout, osteomalacia, Paget's disease)
- Morbid obesity; BMI >40 or >100 pounds overweight
- Midsagittal stenosis < 8mm
- Necrosis
- Non-contained herniated disc pathology or extruded herniated nucleus pulpous
- Objective evidence of nerve root compression
- Osteopathy with possible disintegration of the bearing endplates of the vertebral bodies
- Other spinal surgery at affected level (except prior nucleolysis, nucleoplasty, discectomy, or laminotomy)
- Pregnancy at time of surgery previous thoracic or lumbar fusion or previous unsuccessful attempt at fusion
- Previous thoracic or lumbar fusion or previous unsuccessful attempt at fusion
- Previous trauma to the study treatment level, resulting in compression or bursting
- Primary symptom complexes due to vertebral canal stenosis
- Prior resection of the facet joints during laminectomies and decompression operations that will lead to excessive sliding movements
- Prior retroperitoneal surgery, irradiation or sufficient previous surgeries that would preclude using an anterior approach
- Rheumatoid arthritis
- Scoliosis of the lumbar spine with greater than 11° coronal deformity severe facet joint arthrosis
- Severe facet joint arthrosis
- Severe Vascular pathology
- Significant rotatory scoliosis (idiopathic scoliosis), Lumbar deformities with >30° rotation
- Spinal fracture, Post traumatic fracture or vertebral body wedging or when fracture in the thoracolumbar area causes abnormal kyphosis
- Spinal stenosis (foraminal stenosis, may in selected patients be relieved by the use of an intervertebral prosthesis.)
- Straight leg raise producing pain below the knee Transitional vertebrae at level to be treated that has not clearly fused
- Symptomatic multilevel lumbar degeneration
- Systemic infection; active malignancy or history of metastatic malignancy; terminal or autoimmune disease including AIDS and hepatitis
- Transitional vertebrae at level to be treated that has not clearly fused
- Tumours (spinal tumours)

Surgical Risks:
- Anterior longitudinal ligament rupture
- Annular ossification
- Allergic or other reaction to anesthesia
- Atrial fibrillation
- Blood loss or hemorrhage
- Death
- Dissecting psoas major must be done carefully so as not to injure nerves of the lumbar plexus or cause significant trauma to the psoas major
- Dysesthesias: genito/femoral
- Degenerative changes in adjacent segment
- Dural injury
- Endplate fracture
- Facet joint deterioration
- Gastric volvulus
- Hematoma or Seroma
- Heterotopic ossification
- High incidence of transient numbness along the genitofemoral nerve after psoas muscle retraction
- Iatrogenic pseudomeningoceles
- Ileus (and transient ileus)
- Incisional hernia
- Infection
- Incontinence
- Implant breakage
- Implant collapse or subsidence into adjacent vertebrae
- Implant degradation
- Implant displacement
- Impotence
- Iliac vein laceration
- Iliac artery thrombosis
- Kidney or ureter injury
- Loss of fixation
- Meralgia paresthetica
- Motor injury
- Metal ion release
- Myocardial fibrillation
- Myoinfarction
- Nerve root injury
- Neurologic deterioration; clumsiness, foot drop, limp, short step
- Numbness
- Slow moving gait
- Osteolysis or vertebral inflammation
- Osteophyte resorption
- Pain
- Paralysis
- Permanent femoral injury
- Peritoneal catheter occlusion
- Peritoneal or abdominal adhesions
- Pneumonia
- Pneumothorax
- Psoas spasm
- Perineural fibrosis
- Pulmonary embolism
- Quad weakness
- Re-intubation
- 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 instability
- Spinal stenosis (narrowing of the spinal canal)
- Spondylolisthesis acquisita
- Spondylosis acquisita
- Spontaneous fusion
- Sterility
- Supplemental fixation
- Transfusion
- Thrombosis (Iliac artery thrombosis and ileo-femoral venous thrombosis)
- Tumor formation/ carcinogenesis potential
- The inferior edge of the 12th rib and the superior edge of the iliac crest limit potential exposure sites to L1-L5
- Urinary retention
- Vertebral fracture
- Vessel damage
- Weakness
- 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 LLD is limited to spinal surgeons. Refer to surgical procedure and product brochure for more information.
Heavy smokers and alcohol drinkers should have a BMD test done.

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.

Magnetic Resonance Imaging (MRI)

Kineflex Lumbar Discs are manufactured from non-ferromagnetic cobalt-chromium-molybdenum alloy (Co-Cr-Mo). Non-clinical testing has demonstrated that KPD Discs are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 3.0-Tesla (3.0T) or less
- Maximum spatial gradient field less than or equal to 10T/m.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
    - 2 W/kg for 15 minutes of scanning at 1.5T.
    - 2 W/kg for 15 minutes of scanning at 3.0T.

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters.

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 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		**CAUTION**	
LOT NUMBER		**DO NOT RESTERILIZE**	
DATE OF MANUFACTURE		**DO NOT USE IF PACKAGING IS DAMAGED**	
DO NOT REUSE		**CONSULT THE INSTRUCTIONS FOR USE**	
STERILIZED USING IRRADIATION			
MANUFACTURER ADDRESS