MANUFACTURED BY:
Southern Medical (Pty) Ltd.
55 Regency Drive
Route 21 Corporate Park
Irene, 0062
South Africa

P O Box 17198
Lyttelton, 0140
South Africa
Tel: +27 12 667 6243/4
Email: info@southmed.co.za
www.southmed.co.za

IMPORTANT: PLEASE READ

For detailed information on correct & safe device use, please consult the Surgical Manual.

DESCRIPTION

The Kineflex Prosthetic Disc (KPD) and Lateral Lumbar Disc (LLD) are weight bearing modular implants comprised of three elements: a superior endplate (no retention), an inferior endplate (with retention) and an Ultra-High-Molecular-Weight Polyethylene (UHMWPE) (ASTM F2695) core which is available in one size and configuration. The endplates are manufactured from cobalt-chrome molybdenum (ASTM 1537) with titanium plasma spray coating (ASTM F1580). Longer-term fixation of the KPD and LLD devices to the vertebral bodies is intended to be achieved through bone growth, with initial stabilization by keels on the endplates.

The KPD device endplates are available in three footprint sizes and various heights. The endplates can be assembled in various combinations to obtain a construct of heights ranging from 10mm to 13mm. The constructs' lordotic angle options are 0°, 5° and 10°**.**

The LLD device endplates are available in two footprint sizes and various heights. The endplates can be assembled in various combinations to obtain a construct of heights ranging from 10mm to 11mm. The constructs' lordotic angle options are 0° **and** 5°.

The KPD and LLD devices are assembled by the surgeon in the operating room prior to implantation. The KPD and LLD devices are implanted as a single unit via an anterior and a lateral approach, respectively.

INDICATIONS FOR USE

The KPD and LLD devices ae indicated for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level in the lumbar vertebral spine. KPD is indicated from L3-S 1 and LLD is indicated from L2-L4.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients should have no more than grade 1 spondylolisthesis at the involved level. Patients receiving the KPD or LLD should have failed at least six months of conservative treatment prior to implantation of the device.

CONTRAINDICATIONS

- More than one vertebral level with DDD
- Facet joint disease or degeneration
- Back or leg pain of unknown aetiology
- Paget's disease, osteomalacia, or other metabolic bone disease
- Morbid obesity (BMI>40 or weight more than 100 lbs over ideal body weight)
- Patients with known or probable intolerance to the materials used in the manufacture of this device
- Patients with active infection, inflammation, fever, tumours, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit a beneficial surgical outcome
- Patients resistant to following post-operative instructions and restrictions, especially in athletic and occupational activities.
- Use with components from other manufacturers
- Taking medications known to potentially interfere with bone/soft tissue healing
- Rheumatoid arthritis or other autoimmune disease systemic disease
- Abdominal pathology that would preclude an anterior retroperitoneal approach
- Spinal stenosis or segmental instability or Spinal deformity such as scoliosis or Spondylolysis/isthmic spondylolisthesis
- Clinically compromised vertebral bodies at the affected level due to current or past trauma or disease
- Facet ankylosis or facet joint degeneration
- Preoperative remaining disc height < 3mm
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site /inadequate bone stock / quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use

RISKS & UNDESIRABLE SIDE-EFFECTS

- Implant breakage / failure Implant breakage, dislodgement, or migration
- Inflammation and/or adverse tissue reaction
- Allergic reaction and/or foreign body reaction
- Dural tear and / or CSF leakage
- Damage to the spinal cord and/ or neural structures that may lead to loss of / deterioration of neurological function (incl. paralysis)
- Loss of spinal correction and/or disc height and/or spinal curvature
- Recurrence of preoperative symptoms (incl. pain)
- Heterotopic Ossification
- Soft tissue injury
- Damage to surrounding organs and/or vasculature
- Excessive bleeding
- Endplate damage
- Spinal encroachment
- Subsidence
- Compromised spinal mobility
- Facet joint degeneration
- Annular ossification
- Spondylolisthesis and/or spondylolysis
- Calcification resulting in bridging trabecular bone and fusion
- Expulsion or retropulsion, potentially causing pain, paralysis, vascular or neurological damage, spinal cord impingement or damage
- Death

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

STERILE R

The devices are sterilised via gamma irradiation and are provided **STERILE**. Do not resterilise.

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 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.

Correct selection of the appropriate implant size and correct placement of the device are essential to ensure optimal performance and function of the device.
Correct placement of the device is essential to optimal performance. Correct midline and anterior-posterior placement must be confirmed radiographically.

INSTRUMENTS

Only the instruments provided by the manufacturer should be used and no other instrumentation is intended to be used for the placement of the implant. 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 KPD devices 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.

The LLD 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 LLD 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		DOUBLE STERILE BARRIER SYSTEM	