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IMPORTANT: PLEASE READ

For detailed information on the Kineflex Cervical Disc Prime (KCDP) prosthesis, please consult the KCDP Surgeons' Manual or IFU at southmed.co.za

Description:
The Kineflex Cervical Artificial Disc | Prime (KCDP) is a weight-bearing implant consisting of two keeled endplates and one semi-constrained, fully articulating core. The KCDP is supplied sterile.

The KCDP consists of two poly-ether-ether ketone (PEEK) (ASTM F2026) endplates with titanium plasma (ASTM F1580) sprayed integration surfaces, and a zirconia ceramic core (ISO 13356). Surgical instrumentation is produced from stainless steel (ASTM F899).

Disc sizing gauges are supplied with the instrumentation set to determine the footprint and heights of the endplates. Distraction instruments are also supplied with the instrumentation set, which are used to select the disc height.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The KCDP is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 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 patients 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:
- Age between 18 and 60 years
- Evidence of single level degenerative disc disease (DDD) at only one cervical level from C3 to C7 of one or more of the following; degenerated/dark disc on MRI, decreased disc height compared to adjacent levels on radiographic film, CT, or MRI or disc herniation on CT or MRI
- Failed prior conservative therapy (>6 months)
- Neck Disability Index (score) of at least 40 pre-operatively
- Progressive symptoms or signs of nerve root compression
- Radiculopathy symptoms in neck, one or both shoulders and/or one or both arms (pain or paresthesias, decreased muscle strength or abnormal sensation)

Contraindications:
- Active systemic infection
- Any disease, condition or surgery which might impair healing (e.g. diabetes mellitus requiring daily insulin management, active malignancy or history of metastatic malignancy)
- Any paralysis
- Any terminal, systemic or autoimmune disease
- Arachnoiditis
- Bridging osteophytes
- Cervical spondylosis
- Current or extended use (> 6 months) of any drug known to interfere with bone or soft tissue healing
- Degenerative spondylolisthesis
- Documented presence of free nuclear fragment at any cervical level
- Infection at the site of surgery
- Known metal allergy
- Less than 2° of motion at index level
- Marked cervical instability on resting lateral or flexion/extension X-ray (translation >3mm or >11° rotation to that of either adjacent non-treatment level)
- Metabolic bone disease (e.g. osteoporosis, gout, osteomalacia, Paget's disease)
- Morbid obesity, defined as body mass index ("BMI") >40 or more than 100lbs. over ideal body weight)
- More than one neck surgery via anterior approach
- Non-discogenic neck pain or non-discogenic source of symptoms (e.g., tumor, rotator cuff injury, etc.)
- Pregnancy or planning pregnancy at time of enrollment, which would contraindicate surgery
- Present major mental illness (psychosis, major affective disorder, or schizophrenia), or manifesting physical symptoms suspected to be of psychological rather than physical origin
- Previous trauma to the C3-C7 levels resulting in compression or bursting
- Prior disc space infection or osteomyelitis in the cervical spine
- Prior fusion at any cervical level
- Prior surgery at the level to be treated, except laminotomy without accompanying facetotomy
- Radiographic confirmation of severe facet disease or facet degeneration at index level
- Recent history (within previous 6 months) of chemical or alcohol dependence
- Severe myelopathy (<3/5 muscle strength)
- Spinal stenosis
- Use of spinal stimulator prior to surgery

Surgical Risks:
- Allergic or other reaction to anesthesia
- Annular ossification
- Blood loss or hemorrhage
- Clinical failure of the device in the post-op or follow-up period
- Clumsiness
- Degenerative changes in adjacent segment
- Dural injury
- Dysphagia
- Facet joint deterioration
- Foot drop
- Hematoma or Seroma
- Heterotopic ossification
- Implant breakage
- Implant collapse or subsidence into adjacent vertebrae
- Implant degradation
- Implant displacement
- Incontinence
- Incorrect implant placement
- Infection
- Limp
- Myocardial infarction
- Necrosis
- Nerve root injury
- Neurologic deterioration
- Numbness
- Osteolysis or vertebral inflammation
- Osteophyte resorption
- Pain
- Perineural fibrosis
- 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
- Revision with or without replacement of a component
- RSD (reflex sympathetic dystrophy)
- Short step
- Slow moving gait
- 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
- Thrombosis
- Tumor formation/carcinogenesis potential
- Vertebral fracture
- Vessel damage
- Weakness

Recommended Surgical Procedure:
Refer to the surgical procedure provided by Southern Medical (Pty) Ltd.

USAGE WARNING:
Improper technique of 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 Kineflex 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.

RE-STERILIZATION AND RE-USE 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 KCDP devices have not been tested for adverse effects under MRI. The KCDP is manufactured from non-ferromagnetic materials. Non-clinical evaluations have demonstrated that KCDP devices are MR Conditional based on a Cobalt Chrome worst case device. 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.

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:
Motion should be restricted post operatively as pain allows it. Rehabilitation will be initiated at 2 to 4 weeks postoperatively under the supervision of a physiotherapist as prescribed by the surgeon. Subjects will be instructed not to engage in strenuous activities for six months post-operatively.

Descriptions of Symbols Used in Packaging:

USE BY	
LOT NUMBER	LOT
DATE OF MANUFACTURE	
MANUFACTURER ADDRESS	
DO NOT REUSE	
STERILIZED USING IRRADIATION	STERILE R
CAUTION	
AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	EC REP
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DO NOT RESTERILIZE	STERILIZE
DO NOT USE IF PACKAGING IS DAMAGED	