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IMPORTANT: PLEASE READ

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

DESCRIPTION

The Phoenix Cervical Disc (KCDX) is a weight-bearing implant comprised of two keeled Titanium (ASTM F1580) plasma-sprayed PEEK (ASTM F2026) endplates and one semi-constrained, fully articulating zirconia ceramic core (ISO 13356).

KCDX are available in two footprint options: 14mm X 16mm and 16mm x 18mm. Both footprints are available in heights 4.2mm to 6.2mm and lordotic angles of 2° and 5°. Disc sizing gauges and trials are supplied to determine the appropriate footprint and heights of the implant construct.

The KCDX devices are assembled by the surgeon in the operating room prior to implantation. These devices are implanted as a single unit via an anterior approach. Longer-term fixation of the device to the vertebral bodies is intended to be achieved through bone growth, with initial stabilization by keels on the endplates. The KCDX is supplied sterile.

INDICATIONS FOR USE

KCDX Is indicated for use in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy. Patients must have intractable radiculopathy and/or myelopathy, due to a single-level abnormality localised to one cervical level and confirmed radiographically. These abnormalities encompass symptomatic post-discectomy syndrome, degenerative disc disease (DDD), visible loss of disc height compared to adjacent levels, spondylosis and herniated nucleus pulposus.

Patients eligible to receive KCDX must have undergone and experienced failure of conservative treatment for a minimum of 6 weeks.

CONTRAINDICATIONS

- Patients with active infection, systemic infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit a beneficial surgical outcome
- Any disease, condition or surgery which might impair healing (e.g. diabetes mellitus requiring daily insulin management, active malignancy or history of metastatic malignancy)
- Intractable radiculopathy or myelopathy necessitating surgical treatment at more than one cervical level.
- Osteoporosis or osteopenia
- Significant cervical anatomical deformity at the index level or clinically compromised cervical vertebral bodies at the index level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion, or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis).
- Marked cervical instability on neutral lateral or flexion/extension radiographs
- Rheumatoid arthritis or other autoimmune disease systemic disease
- Use with components from other manufacturers
- Taking medications known to potentially interfere with bone/soft tissue healing
- Clinically compromised vertebral bodies at the affected level due to current or past trauma or disease
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Patients with known or probable intolerance or allergy to the materials used in the manufacture of this device
- Severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height
- Significant kyphotic deformity or significant reversal of lordosis
- Symptoms attributed to more than one cervical level
- Any case not described in the indications for use
- Patients resistant to following post-operative instructions and restrictions, especially in athletic and occupational activities

RISKS & UNDESIRABLE SIDE-EFFECTS

- Implant breakage / fatigue / fracture / failure
- Implant dislodgement, loosening or migration
- Implant component separation
- Allergic reaction and / or foreign body reaction
- Inflammation and / or infection 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)
- Soft tissue injury
- Damage to surrounding organs and / or vasculature
- Temporary or permanent damage to surrounding neural structures
- Excessive bleeding
- Endplate damage or vertebral body damage
- Spinal encroachment
- Subsidence
- Compromised spinal mobility and / or flexibility
- Facet joint degeneration
- Annular ossification
- Spondylolisthesis and / or spondylolysis
- Spontaneous fusion due to heterotopic ossification, bridging trabecular bone or osteophytes
- Calcification resulting in bridging trabecular bone and fusion
- Expulsion or retropulsion, potentially causing pain, paralysis, vascular or neurological damage, spinal cord impingement or damage
- Dysphagia
- Osteolysis, bone loss or bone resorption
- Removal, revision, reoperation or supplemental fixation of the disc
- Death

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

STERILE R

The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection.

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 handling of the device(s) is extremely important. The desired clinical outcome may not be achieved if the usage instructions are not followed.

Correct placement of the device is essential to optimal performance. Correct midline and anterior-posterior placement must be confirmed radiographically

The KCDX devices should not be used with bone cement.

INSTRUMENTS

Only the instruments provided by the manufacturer should be used. 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 they are cleared to do so by their physician.

MRI SAFETY INFORMATION

The KCDX 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 KCDX 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

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