



## **Instructions for use**

prodisc® C SK – Cervical disc prosthesis



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## Safety precautions

Please read these instructions for use and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

## Contents

The prodisc® C SK cervical disc prosthesis is made up of three components:

- prodisc® C SK superior endplate
- prodisc® C SK inferior endplate
- prodisc® C SK inlay

All implant components (the superior endplate and the inferior endplate with the PE inlay snapped in) are packaged together using a double sterile barrier method.

## Description

The components of the prodisc® C SK cervical disc prosthesis are made from:

- (1) Superior and inferior endplate: CoCrMo (Co-28Cr-6Mo) per ISO 5832-12 with pure titanium coating per ASTM F1580
- (2) Inlay: UHMWPE per ISO 5834-2

Contents are supplied sterile.

### **Intended use**

prodisc® C SK implants are used to replace a cervical intervertebral disc and to restore disc height and segmental motion.

### **Indications**

The prodisc® C SK Total Disc Replacement is indicated in skeletally mature patients for reconstruction of a single disc from C3–C7 following discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or loss of disc height. The prodisc® C SK Total Disc Replacement is implanted via an open anterior approach. Patients receiving the prodisc® C SK Total Disc Replacement should have failed at least six weeks of nonoperative treatment prior to implantation of the prodisc® C SK Total Disc Replacement.

### **Specific contraindications**

- Fractures, infections, tumours
- Spinal stenosis by hypertrophic spondylarthrosis
- Facet joint degeneration
- Increased segmental instability
- Ossification of posterior longitudinal ligament (OPLL)
- Advanced cervical anatomical deformity (e.g., ankylosing spondylitis, scoliosis) at the operative or adjacent levels
- Osteopenia

- Advanced cervical degenerative facet joint changes, and
- Cervical spine mal-alignment conditions (e.g. scoliosis or kyphosis.)

### **General contraindications**

- Osteoporosis, Osteochondrosis, and severe Osteopenia
- Acute or chronic systemic, spinal, or localized infections
- Systemic and metabolic diseases
- Any medical and surgical conditions precluding the benefits of spinal surgery
- Foreign body sensitivity to the implant materials
- Dependency on pharmaceutical drugs, drug abuse or alcoholism
- Pregnancy
- Severe obesity (Body Mass Index above 40)
- Lack of patient cooperation

### **Patient exclusion recommendations**

Patient selection is one of the most important factors contributing to the outcome of the total disc replacement procedure. The following may affect clinical outcomes:

- A condition of senility or mental illness, alcoholism or smoking
- Dependency on pharmaceutical drugs or drug abuse
- The patient's occupation or activity level
- Compromised vertebral bodies at affected level due to current or past trauma (fractures)
- Disc height less than 3mm measured from the center of the disc in a

## English

neutral position and disc height less than 20% of the anterior-posterior width of the inferior vertebral body

- Involved vertebral endplate dimensionally smaller than the minimum implant footprint size in both the medial-lateral and the anterior-posterior directions
- Severe abnormality of the endplate (e.g. large Schmorl nodes)

Successful clinical outcomes depend on a number of critical factors, including:

- Completion of a training program on the use of **prodisc C**, **prodisc C Nova**, **prodisc C SK**, or **prodisc C Vivo**
- Proper patient selection
- Adequate bone quality (investigation to determine bone quality is recommended)
- Complete and meticulous discectomy, decompression, and remobilization of the disc space
- Optimal implant sizing and placement
- Postoperative treatment

## Precautions

Proper surgical performance of the implantation is the responsibility of the operating surgeon.

- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- Assembling and implanting the implant components is the responsibility of the operating surgeon.

- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Under no circumstances may implant components from different suppliers be combined.
- The implant components applied (name, article number, lot number) must be documented in each patient's record.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.
- Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other grave complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the cervical disc prosthesis must be checked periodically post operative, using appropriate techniques.
- **prodisc® C SK** device has not been studied in the clinical situation of prior cervical fusion.

## Potential risks

Potential risks to health associated with the use of the **prodisc® C SK** include, but are not limited to:

- Those commonly associated with any surgical procedure
- Death as a potential risk associated with any surgical procedure
- Those specifically associated with cervical spinal surgery using an anterior approach

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- Those associated with a cervical disc prosthesis (including the **prodisc® C SK**)
- Bending, loosening, wear and tear on, or fracture of implant components
- Loss of fixation, dislocation and migration
- Neurological injury
- Injury to vessels, nerves and organs
- Primary and secondary infections
- Allergic reactions to implant materials
- Tissue reaction to implant materials
- Venous thrombosis, lung embolism and cardiac arrest
- Hematoma and impaired wound healing
- Periarticular calcification and fusion
- Subsidence
- Vertebral body fracture
- Spine alignment changes
- Degenerative changes of the index or adjacent level

## Procedure

- The **prodisc® C SK** cervical disc prosthesis must be implanted with the **prodisc® C SK** instruments only.

The operating surgeon draws up an operation plan specifying and documenting the following:

- Implant and the dimensions.
- Proper position of the implant in the intervertebral space.
- Determination of intraoperative orientation points.



The following conditions must be fulfilled prior to application:

- Requisite implant is readily available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments must be available and in working order.
- Damaged or defective instruments should not be used or processed. Contact your local Centinel Spine representative or dealer for repair or replacement.
- The use of an instrument for tasks other than those for which they are intended may result in damaged / broken instruments or patient injury.
- The operating surgeon and operating room team must be thoroughly familiar with the surgical technique, as well as the range of implants and instruments to be applied.
- The operating surgeon must be especially trained in spinal surgery, biomechanical principles of the spine and the relevant surgical techniques.

The operative procedure has been explained to the patient, and the patient's understanding of the following information has been documented:

- The patient is aware of the risks associated with neurosurgery, general surgery, orthopaedic surgery and with general anaesthesia.
- The patient has been informed about the advantages and disadvantages of a cervical disc prosthesis and about possible alternative treatments.
- The cervical disc prosthesis can fail owing to excessive load, wear and tear, or infection.

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- The cervical disc prosthesis must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- In the event corrective surgery is performed, it may not be possible to restore segmental motion.
- The patient must have their physician carry out follow-up examinations of the cervical disc prosthesis at regular intervals.

### **Disinfection, cleaning, care and sterilization**

- The implant comes packed in protective packaging that is labeled according to its contents.
- The implant is radiosterilized (gamma sterilization, minimum 25 kGy).
- Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
- Prior to use, check the product expiration date and verify the integrity of the sterile packaging.
- Do not use implants that are past their expiration dates or whose packaging is damaged.
- Never resterilize or reuse implants.
- The implants are not designed to be disinfected or cleaned by the user.

### **Magnetic Resonance environment**

MR Conditional:

Non-clinical testing of the worst-case scenario has demonstrated that the articles of the **prodisc® C SK** system are MR conditional. These ar-

ticles can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla
- Spatial gradient field of 90 mT/cm (900 Gauss/cm)
- Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning

In non-clinical testing, the pro**disc**<sup>®</sup> **C SK** produced a temperature rise of less than 2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or close to the position of the pro**disc**<sup>®</sup> **C SK** device.

### **For further information**

If further information on this product is needed, please contact your local Centinel Spine representative or dealer.



Technical alterations reserved

### Symbols:



Catalog Number



Lot Number



See Instructions For Use



Do not reuse



Do not re-sterilize



Sterile using irradiation



Expiration Date (YYYY-MM)



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