CENTINEL SPINE®

Instructions for use

pro**disc® C Nova (oUS)** cervical disc prosthesis

guides.centinelspine.com

Instructions for use

pro**disc C Nova (oUS)** – Cervical disc prosthesis

Information Regarding this IFU

The latest version or revision of this IFU can be found at guides.centinelspine.com or contact Centinel Spine Customer Service [Call: (1) 484-887-8810, E-mail: cs@centinelspine.com].

The IFU can be opened using a PDF reader, a web browser, or free online PDF Viewers.

Summary of Safety and Clinical Performance (SSCP) is available through the European Database on Medical Devices (EUDAMED): https://ec.europa.eu/tools/eudamed.

Description

The pro**disc C Nova** cervical disc prosthesis is a Total Disc Replacement Implant consisting of Tripod keel anchorage fixation that provides high primary stability and multilevel capability. The components of the pro**disc C Nova** consist of superior and inferior endplates, a cobalt chrome alloy (CoCrMo) calotte insert, and an ultra-high molecular weight polyethylene (UHMWPE) inlay. The endplate's bone contacting surfaces are coated with rough titanium surface to promote integration and increase stability. The endplates are manufactured from Titanium alloy TAN (Ti-6Al-7Nb) per ISO 5832-11 and ASTM F1295 with pure titanium coating per ASTM F1580. The cobalt chrome alloy (CoCrMo) calotte insert is manufactured per ISO 5832-12 and ASTM F1537. The inlay ultra-high

molecular weight polyethylene (UHMWPE) is manufactured per ISO 5834-1/2 and ASTM F648. The pro**disc C Nova** is available in eighteen anatomical sizes, six footprints and three heights, 5, 6 and 7 mm to facilitate an accurate match with the patient's anatomy.

Intended use

The pro**disc C Nova** cervical disc prosthesis is used to replace a cervical intervertebral disc from C3 to C7 at one or two levels and to restore disc height and segmental motion for the patients with symptomatic cervical disc disease (SCDD).

Expected Clinical Benefits

- Reduction in pain (VAS score)
- Improved function (NDI score)
- Improved quality of life (SF-36 score)

Indications for Use

The pro**disc C Nova** cervical disc prosthesis is indicated for symptomatic cervical disc disease (SCDD), including cervical degenerative disc disease, which 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)
- Loss of disc height

Intended Users

- Spine Surgeons

Target Population

The device is intended for skeletally mature patients.

The following parameters should be considered for patient selection, as they 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)
- Substantial loss of disc height, where applied segmental distraction may lead to damage of the great vessels
- 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)

This device has not been evaluated in pediatrics or pregnant women.

Storage Condition

No specific storage or handling conditions applies.

Instructions for Use

Use of the pro**disc C Nova** cervical disc prosthesis should only be considered when the following pre-operative, intra-operative and post-operative conditions exist:

Pre-operative

- Patient meets the indication criteria described and does not have any contraindications.
- The surgeon should determine the construct prior to surgery to ensure that the required components in the necessary sizes are available.

Intra-operative

- The surgeon follows surgical techniques and instructions for use of the device. Care should be taken to determine the correct implant size using the trial sizers provided. The Surgical Technique Guide is available from Centinel Spine Customer Service [Call: (1) 484-887-8810 or E- mail: cs@centinelspine.com].
- All components are inspected and determined to be free of damage.
- Once the pro**disc C Nova** cervical disc prosthesis has been introduced and securely positioned, additional anterior or posterior instrumentation is employed if deemed appropriate by the surgeon, who should consider factors such as the stability of the spinal column after fixation and potential risk associated with a subsequent surgical procedure to remove and/or replace these surgical appliances.

Post-operative

- The choice to administer post-operative antibiotics is at the discretion of the surgeon.
- Post-operative mobilization and rehabilitation is at the discretion of the surgeon dependent on clinical and radiological progress.
- The need for external orthotic support is not mandatory with the final choice based on surgeon preference, patient condition and intra-operative findings that might influence implant security.
- The patient is to be instructed to reduce undue stress on the implant as a precaution to avoid clinical problems that could result in fixation failure.
- The patient is to be instructed to follow the post-operative regime.

State of Sterility

The pro**disc C Nova** cervical disc prosthesis is provided sterile for single use only and supplied sterile by gamma irradiation. The shelf life of the components is five years.

Lifetime

The current estimated functional lifetime, or survivorship, of the pro**disc C** family of implants is 10 years, based on wear testing conducted in accordance with ISO 18192.

The expected lifetime of the pro**disc C Nova** is aligned with the State of the Art for cervical disc protheses. Based on literature review,

10-year revision rates for cervical disc protheses range from 2.1% to 16%, with a weighted mean of 8.9% (95% CI: 0 – 19.3%).

Patients who have concerns or have had their implant for ten years or more may consider seeking their physician's assessment regarding device status and the potential for a device removal. Subsequently, annual yearly assessments may be utilized to ascertain on-going device status.

Performance Characteristics

The pro**disc C Nova** cervical disc prosthesis is designed to address the demands and complexity of minimally invasive cervical lateral interbody motion-preservation/disc arthroplasty procedures. The pro**disc C Nova** cervical disc prosthesis are modular implants consisting of two endplates, a cobalt chrome alloy calotte insert and one polyethylene inlay. The pro**disc C Nova** cervical disc prosthesis utilize a ball and socket articulation design of metal on ultra-high molecular weight polyethylene. The pro**disc C Nova** cervical disc prosthesis have a rough surface coating of pure titanium to support bone-to-implant contact and designed to restore disc height and maintain segmental motion. The pro**disc C Nova** is available in eighteen anatomical sizes to facilitate an accurate match with the patient's anatomy, six footprints and three heights, 5, 6 and 7 mm.

Contraindications

- Fractures, infections, tumors
- Spinal stenosis by hypertrophic spondylarthrosis
- Severe facet joint degeneration
- Increased segmental instability
- Ossification of posterior longitudinal ligament (OPLL)
- 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
- Skeletally immature patients

Warnings and Precautions

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- Assembling and implanting the implant components 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 surgical techniques.

- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile implants.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- Re-usable surgical instruments must be decontaminated and sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or surgical techniques, the limitations of treatment methods, or inadequate asepsis.
- Under no circumstances may implant components from different suppliers be combined.
- 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.
- The implant components applied (name, article number, lot number) must be documented in each patient's record.

Potential Adverse Effects with the prodisc C Nova Cervical Disc Prosthesis

- Those commonly associated with any surgical procedure.
- Those specifically associated with cervical spinal surgery using an anterior approach.
- Those associated with a cervical disc prosthesis (including the pro**disc C Vivo**).
- 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.
- Vertebral body fracture.

- Spine alignment changes.
- Degenerative changes of the index or adjacent level.
- Degenerative changes or instability and loss of any bone at, above and/or below the level of surgery.
- Spinal cord impingement or damage.
- Soft tissue injuries.
- Blood loss.
- Loss or impairment of bowel, sexual, and/or bladder function.
- Additional surgery.
- Pain.
- Loss of Motion.
- Implant subsidence.
- Heterotopic ossification.
- Death as a potential risk associated with any surgical procedure.

Safe Disposal of Devices

Any Centinel Spine implant that has been contaminated by blood, tissue, and/or bodily fluid/matter should never be used again and should be handled to the hospital protocol.

Devices must be disposed of as a health care medical device in accordance with hospital procedures.

Reporting of Incident to Manufacturer and Competent Authority

In case of any patient/user experiencing serious incident contact Centinel Spine Customer Service [Call: (1) 484-887-8810 or E-mail: cs@centinelspine.com].

Packaging

The pro**disc C Nova** cervical disc prosthesis are packaged in a double sterile barrier method utilizing a PETG Tray with Tyvek lid. Packaging of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to Centinel Spine.

Implant cards and patient labels are provided within the sales unit carton.

MRI Safety Information

Non-clinical testing of the worst-case scenario has demonstrated that articles of the pro**disc C Nova** system are MR conditional. These products can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla
- Spatial gradient magnetic field of 300 mT/cm (3000 G/cm)
- Maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning

In non-clinical testing, the pro**disc C Nova** implant will produce a temperature rise not greater than 3.2 ºC at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the pro**disc C Nova** device.

Information About Substances

The pro**disc C Nova** cervical disc prosthesis does not contain substances of biological or animal origin, medicinal substances, or substances derived from human blood. They do not contain CMR 1A, 2, nor BPA, phthalates, or endocrine disruptors at a rate greater than 0.1% of the device's mass. They also do not contain natural or dry latex caoutchouc. The pro**disc C Nova** cervical disc prothesis contains Cobalt which is classified as CMR 1B.

Qualitative and Quantitative Information on the Materials and Substances

Component	Composition	
Endplates	**Element**	**Mass Fraction %**
	Titanium	84.9% to 88%
	Aluminum	5.5 to 6.5
	Niobium	6.5 to 7.5
Inlay	Ultra-High Molecular Weight Polyethylene (UHMWPE)	
	Chain of Carbon & Hydrogen	
Insert	**Element**	**Mass Fraction %**
	Cobalt	58.86% to 79%
	Chromium	26.0% to 30.0%
	Molybdenum	5.0% to 7.0%
	Manganese	1.0% max.
	Silicon	1.0% max.
	Nickel	1.0% max.

Accessing the Summary of Safety and Clinical Performance (SSCP)

- The Summary of Safety and Clinical Performance (SSCP) for this device is available on the European Database on Medical Devices (EUDAMED).
- You can find the SSCP by visiting the EUDAMED public website: https://ec.europa.eu/tools/eudamed.
- To locate the SSCP, use the following Basic UDI-DI: 08431931PRODISCCNOVA34

Patient Information Provided with This Device

The following important documents and labels are provided with this medical device. It is essential that these materials are reviewed and kept for future reference:

1. Device Label:
   - The label, found on the device or its packaging, contains essential information such as the name of the device, the manufacturer's details, and a unique device identifier (UDI) for tracking and identification purposes.
2. Patient Label:
   - A specific label intended for the patient is included. This label contains important identification details.
3. Instructions for Use (IFU):
   - Detailed instructions on the correct and safe use of the device are provided in this document. Step-by-step guidance is included to ensure proper use of the device.

4. Patient Guide:
   - In addition to the IFU, a Patient Guide is provided. This leaflet offers a simplified version of the instructions, highlighting key points in an easily understandable format.

5. Safety and Risk Information:
   - Information on potential risks or side effects associated with the use of the device is included. This section should be reviewed carefully to ensure safe usage.

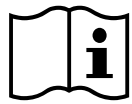
6. Implant Card:
   - An Implant Card is provided. The card contains essential information about the implant, including the model, manufacturer, and UDI. This card should be kept for future reference, particularly during medical appointments.

7. Summary of Safety and Clinical Performance (SSCP)
   - The SSCP is available on the European Database on Medical Devices (EUDAMED). This summary provides detailed information about the device's safety and performance.

8. Contact Information:
   - Contact details for customer support or medical advice are provided within this document. These should be used if assistance is required related to the device.

Symbols:

MD	**EN:** Medical Device
	**EN:** Manufacturer
REF	**EN:** Catalogue Number
UDI	**EN:** Unique Device Identifier
LOT	**EN:** Batch Code
	**EN:** Date of Manufacture
STERILE R	**EN:** Sterilized Using Irradiation
	**EN:** Do Not Re-use
	**EN:** Do Not Resterilize
	**EN:** Do Not Use if Opened or Damaged

	**EN:** Caution
	**EN:** Consult Instructions for Use
CE 2797	**EN:** CE Marked Device
	**EN:** MRI Conditional (usable under magnetic ray with conditions)
	**EN:** Use By Date
℞ ONLY USA Only	**EN:** Restricted Sale as Directed by a Physician (United States of America)
	**EN:** Double Sterile Barrier System
 Cobalt	**EN: Contains Hazardous Substances**
EU REP	**EN:** Authorized Representative in the European Union

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