DI126A-EN (Rev K)	SECURE™-C CERVICAL ARTIFICIAL DISC

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IMPORTANT INFORMATION ON THE SECURE™-C CERVICAL ARTIFICIAL DISC

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For symbols glossary, please refer to www.globusmedical.com/eIFU

ENGLISH

OUTSIDE THE UNITED STATES ONLY

IMPORTANT INFORMATION ON THE SECURE™-C CERVICAL ARTIFICIAL DISC

DESCRIPTION

The SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Disc implants are inserted using an anterior cervical approach. The SECURE™-C assembly consists of two cobalt-chrome-molybdenum alloy endplates with plasma sprayed multiple serrated keels and a moving polyethylene core. The SECURE™-CR implant consists of two polyetheretherketone (PEEK) endplates with plasma sprayed multiple serrated keels and a moving PEEK core. The SECURE™-C3 consists of two PEEK endplates with plasma sprayed multiple serrated keels and a fixed PEEK and PCU core.

The SECURE™-C endplates are manufactured from cobalt-chrome-molybdenum alloy, CoCrMo, as specified in ASTM F1537 (and ISO 5832-12). The superior and inferior surfaces of the SECURE™-C endplates are plasma sprayed with commercially pure titanium, as specified in ASTM F1580, F1978, F1147 and C633 (and ISO 5832-2).

The SECURE™-C cores are manufactured from ultra-high molecular weight polyethylene, UHMWPE, as specified in ASTM F648 (and ISO 5834-2).

The SECURE™-CR endplates and cores are manufactured from PEEK as specified in ASTM F2026. The superior and inferior surfaces of the SECURE™-CR endplates are plasma sprayed with commercially pure titanium, as specified in ASTM F1580, F1978, F1147 and C633.

The SECURE™-C3 endplates are manufactured from PEEK, as specified in ASTM F2026. The superior and inferior surfaces of the endplates are plasma sprayed with commercially pure titanium, as specified in ASTM F1580, F1978, F1147 and C633. The SECURE™-C3 superior core is manufactured from PEEK, as specified in ASTM F2026. The SECURE™-C3 inferior fixed core is manufactured from Bionate 90A polycarbonate urethane (PCU).

INDICATIONS

The SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Discs are indicated for treatment of symptomatic cervical disc disease (SCDD) from C3-C7. SCDD is defined as neck or arm pain, or functional or neurological deficit confirmed by patient history and radiographic studies demonstrating primary or recurrent disc herniation, radiculopathy or myelopathy, spondylosis, spinal stenosis, and/or loss of disc height.

CONTRAINDICATIONS

The SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Discs are contraindicated for patients with the following:

- Local infection;
- Fever, or leukocytosis;
- Morbid obesity;
- Mental illness;
- Distorted anatomy caused by congenital abnormalities;
- Any medical or surgical condition which would preclude the potential benefit or spinal implant surgery, such as the presence of tumors or congenital abnormalities, rapid joint disease, bone absorption osteopenia, and/or osteoporosis;
- Any case where the implant components selected for use would be too large or too small to achieve a successful result;
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance;
- Prior fusion surgery adjacent to the vertebral level being treated;
- Prior surgery at the level to be treated;
- Clinically compromised vertebral bodies at the affected level(s) due to current or past trauma;
- Radiographic confirmation of facet joint disease or degeneration;
- Osteoporosis, osteopenia, Paget's disease, osteomalacia or any other metabolic bone disease;
- Suspected or documented allergy, intolerance or foreign body sensitivity to any of the implant materials;
- Any patient unwilling to follow postoperative instructions;
- Conditions that may place excessive stress on the cervical spine and implant, such as severe obesity or degenerative disease;
- Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place the patient at a particular risk during postoperative rehabilitation. Factors such as patient's weight, activity level, and adherence to weight bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected; and
- Any case not described in the indications.

WARNINGS

Risks associated with this device and with the surgical procedure are not known but may include:

- Injury to nerves, vessels, and organs;
- Allergic or tissue reaction to implant materials;
- Hematoma and impaired wound healing;
- Migration or loosening of the device;
- Fracture of the device;
- Heterotopic ossification and fusion;
- Venous thrombosis, lung embolism, and cardiac arrest; and
- Death

PRECAUTIONS

The implantation of SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Disc should be performed only by experienced spinal surgeons with special training in the use of this cervical artificial disc because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

The implants are provided sterile and for single use only. Surgical implants must never be reused. An explanted cervical disc must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stresses patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI SAFETY INFORMATION

MR

Non-clinical testing on SECURE™-C has demonstrated that the SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Discs are MR Conditional. A patient with these device can be scanned safely in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg (Normal Operating Mode)

Under the scan conditions defined above, SECURE™-C, SECURE™-CR and SECURE™-C3 Cervical Artificial Discs are expected to produce a maximum temperature rise of 1.4°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by SECURE™-C Cervical Artificial Disc extends approximately 20 mm from the device when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

HANDLING/DISPOSAL

This device is for single patient use and should never be reused.

The implant/device must be disposed of in accordance with applicable local regulations for handling of biological medical waste.

ATTENTION

Under no circumstances should the SECURE™-C, SECURE™-CR and SECURE™-C3 device components be used in combination with components from other suppliers. Damage to weight bearing structures can give rise to loosening of the device components, dislocation, and migration, and other serious complications; the implant should be checked periodically.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

The SECURE™-C, SECURE™-CR and SECURE™-C3 implants are provided STERILE, and the surgical instruments are provided NON-STERILE.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile implants are packaged in a heat sealed, double foil pouch. Shelf life was determined to be 5 years. The expiration date is provided on the package label. Do not use if expired. These implants are considered sterile unless the packaging has been opened or damaged.

Non-sterile SECURE™-C, SECURE™-CR, and SECURE™-C3 instruments have been validated to ensure an SAL of 10^{-6}.

Instruments:

These instruments are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	15 minutes	45 minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 minutes	30 minutes

Accessing the Summary of Safety and Clinical Performance (SSCP)
The SSCP will be available in the European database on medical devices (Eudamed), where it will be linked to the Basic UDI-DI 0193982CERVICALDISCGH. The web address for the Eudamed public website is: https://ec.europa.eu/tools/eudamed

Until Eudamed becomes mandatory, the SSCP is available upon request to: inquiries@globusmedical.com