ROTAIO® – Cervical Disc Prosthesis

Product description:
ROTAIO is a disc replacement implant for use in the cervical spine. In addition to restoring height of the vertebral disc, its primary function is to preserve physiological mobility in the affected segment.

The prosthesis consists of a superior and an inferior endplate on which the sliding elements are anchored and secured by means of a fixation pin. The implant design provides an optimum fit to the anatomy of the intervertebral space. For optimum primary stabilisation, the endplates have a toothed surface, and special surface treatment of the endplates to increase the surface area assists bony integration. To provide maximum coverage of the vertebral body endplates, a total of 16 different disc prostheses are available with various footprints and heights.

Instruments specially developed by SIGNUS to ensure safe application are available for use with the implant system.

Indications:
ROTAIO is a disc replacement implant for use in the cervical spine (C3–C7). In addition to restoring height of the vertebral disc, this implant, in contrast to a cage, serves to preserve physiological mobility. The implant is used for the following indications following cervical discectomy via anterior access:
- Discopathy
- Disc herniation
- Foraminal and spinal canal stenosis

Contraindications:
- Instability
- Severe facet joint and spinal disc degeneration
- Immobility of the affected segment
- History of surgery to the affected segment
- Deformity
- Ossification of the posterior longitudinal ligament
- Traumatic lesions of the cervical spine
- Tumour
- Osteoporosis, osteopenia
- Acute or chronic systemic, spinal or localised infections
- Systemic or metabolic diseases
- Allergy or intolerance to implant material (e.g. nickel)
- Surgical conditions that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental illness, pregnancy, paediatric cases, patients in poor general health, lack of patient compliance)
- Cases that are not mentioned under Indications

Material:
The disc prosthesis is made of the following materials:
- Superior and inferior endplates: Titanium aluminium vanadium (TI-6AL-4V) as per ISO 5832-3
- Sliding components: Cobalt chromium-28 molybdenum-6 forging alloy as per ISO 5832-12

Composition:
Titanium alloy (Ti6Al4V) as per ASTM F 136 / ISO 5832-3.
For all products made of titanium alloy Ti6Al4V:
Nickel-free as per ASTM F 136 / DIN ISO 5832-3
Nitrogen 0.05% max., carbon 0.08% max., hydrogen 0.012% max., iron 0.25% max., oxygen 0.13% max., aluminium 5.5–6.5%, vanadium 3.5–4.5%, remainder titanium.

Cobalt chromium molybdenum alloy as per
ASTM F 1537 / ISO 5832-12:
Carbon: 0.14% max., chrome 30.0% max., molybdenum 7.0% max., nickel 1.0% max., iron 0.75% max., silicon 1.0% max., manganese 1.0% max., nitrogen 0.25% max., remainder cobalt.

The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant and non-toxic in the biological environment and enable interference-free X-ray imaging.
The implants are MRI-compatible with reservations and have been tested at 1.5 T. There are no results for testing at 3 T available.

Sterility:
All implants are supplied in fully preassembled condition in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137.
ROTAIO is intended for single use only and is not reusable.
The instruments GB0006, GB14 and GB58, which are supplied in sterile condition as part of the set, are intended for single use only and are not reusable.
The implant must not be resterilised.
- Implants with opened primary sterile packaging will not accepted by SIGNUS and must be disposed of properly
- Reprocessing and / or reuse can result in infection and / or loss of function and in extreme cases may lead to the death of the patient.

Reprocessing:
Non-sterile instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing
- All non-sterile implants and instruments must be reprocessed in the SIGNUS trays
- Observe the validated reprocessing procedure in the instructions included with the tray (valid version: eifu.signus.com)
- Instruments with cavities as well as gaps, threads, joints and springs must be placed in an ultrasonic bath for 10 minutes at 40°C in a 0.5% alkaline cleaning solution and then rinsed/flushed for 20 seconds with cold mains water at about 4 bar static pressure (mains pressure)
- During sterilisation the following must be noted:
  - Procedure: Steam sterilisation method (fractionated pre-vacuum method)
  - Temperature: Minimum 132°C, maximum 137°C
  - Cycles: At least 4 pre-vacuum pulses
  - Sterilisation duration: At least 4 minutes
  - Drying time: Adjust the drying time in accordance with the loading of the steriliser; the items to be sterilised must be dry
- The instrument tray must undergo a validated cleaning process before being returned to SIGNUS. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

Sterile implants:
Implants that are supplied sterile must not be resterilised. Reprocessing can result in infection and / or loss of function, which in extreme cases can lead to the death of the patient.

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CE 0483

SIGNUS The Spine Sign®

Labelling:
Explanation of the symbols that may be used on the packaging of SIGNUS products:

CE 0483	CE marking		Manufacturer and date of manufacture
	Do not re-use	STERILE R	Sterilised using irradiation
REF	Item number	LOT	Batch code
	Use by		Consult instructions for use
	Do not resterilise		Do not use if package is damaged
0°C 35°C	Temperature limit		

Storage conditions:
Store the products between 0°C and 35°C. During transport, temperatures of up to 40°C for short periods can be tolerated.

Warnings:
- The spinal implants are intended for single use only and must not be re-used. Re-use of an implant can cause implant failure, infections and/or death.
- Implants must be considered as potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines.

USA: Federal law restricts the sale of this device by or on the order of a physician.

Precautions:
- Store implants and sterile instruments in their original packaging.
- Do not remove implants from their protective packaging until directly before use.
- Check expiration date and intactness of the sterile packaging before use.
- Before opening the packaging, check that the packaging is intact.
- The implant must likewise be checked for integrity before being implanted. A damaged implant must not be used.

Application:
- The attending physician, who must be experienced in the implementation of surgical interventions and instructed in the use of the instruments, is responsible for determining the indication, selecting the implant and performing the implantation.
- All information about the surgical technique, the range of implants, the instruments and their use is provided in detail in the SIGNUS product documentation. This information must be available on site and must be known to the surgical team.
- Before performing the surgical intervention, it must be ensured that all required implants and instruments are to hand and fit for purpose.
- If there are any preoperative uncertainties relating to the implant system, information must be obtained from SIGNUS.
- Before the surgical intervention, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and with use of the implant.
- The correct position of the spinal implant must be verified with the aid of imaging procedures both during the intervention and upon completion.
- The implant must be checked for integrity and correct size before being implanted. Footprint: Compare the footprint information on the adapter with the information indicated on the selected trial instrument. Height: observe the dots marked on the posterior endplate of the implant (1 / 2 / 3 / 4 dot(s) = 5 / 6 / 7 / 8 mm, respectively)
- The sterile-packaged ROTAIO disc prosthesis is fitted with an adapter that facilitates insertion into the intervertebral space. This adapter must be removed after implantation and must not remain in the patient.
- If the prosthesis is to be re-positioned, it must be grasped carefully with the extraction forceps and withdrawn. For withdrawal, the distraction in the affected segment must be increased. Do not under any circumstances exert excessive force (e.g. by using the slotted hammer) to avoid damaging the prosthesis. Before re-mounting the implant onto the insertion adapter, the intactness of the implant must be verified.
- If the implant has to be re-mounted onto the insertion adapter, the instructions in this regard provided in the tray or in the product information must be followed.
- The implant used must be documented in the patient record, indicating the article number, designation and batch number. All necessary data are indicated on the labels in the original packaging and must be pasted into the patient record to ensure lot traceability.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to the patient's individual requirements.
- The implant must be checked for correct size prior to the intervention.
- Particular attention must be paid to the protection of nerve roots.
- After preparation, carefully inspect the intervertebral disc cavity for bone fragments.
- Excessive ablation or even complete removal of the cortical base plates and cover plates of adjacent vertebral bodies must be avoided.
- When inserting the implant, refrain from using excessive force in order to protect the adjacent vertebral bodies.
- Do not forcibly hammer the implant into place.
- Aftercare and follow-up examinations must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity. This applies in particular to the lifting of loads, rotating movements and sporting activities of any kind. Falls and sudden, jerky movements of the spine must be avoided.

Risks:
These instructions for use do not list the general risks associated with surgery or the complications that can arise from spinal surgery. The following are potential risks and complications that are related to the intervertebral disc prosthesis and may necessitate repeat surgery:

- Wear or breakage of implant components
- Loss of fixation, dislocation, subsidence
- Temporary or permanent noise production
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant materials used
- Incorrect placement
- Infection
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Fusion of the segment that underwent surgery

These risks can potentially lead to injuries of all degrees of severity to the surrounding tissue, the nerves and blood vessels, which can in extreme cases even lead to death.

Product warranty:
SIGNUS Medizintechnik GmbH guarantees that every spinal implant has been manufactured, packaged and tested with the greatest possible care using selected materials and that all processes involved are subject to continuous quality control. Since SIGNUS Medizintechnik GmbH has no influence on the conditions under which a spinal implant is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the spinal implant after it has left the factory, SIGNUS Medizintechnik GmbH gives no warranty either for the success of the procedure or for the non-occurrence of complications. Please inform SIGNUS immediately of any (possible) malfunction that has become known, indicating the article number(s) and the lot number(s).