CERCCESS™ – Cervical Retractor System

Product description:
The SIGNUS CERCCESS™ retractor system is adapted to the cervical spine and is used for soft tissue retraction around the ventral cervical spine as well as distraction of one or more intervertebral disc spaces. The system is made up of a longitudinal and lateral distractor with double joint and a multi-segment pin distractor with drill guide. There are blunt or toothed blades with different widths and lengths available to use with the retractor system to cover a wide range of requirements. To use the multi-segment pin distractor, there are P03XAA distractor pins developed by SIGNUS that are available in various sizes. These instruments alone ensure safe application.

Indications:
The CERCCESS™ retractor system is an instrument system for use on the cervical (C3–TH1) spine. For cervical discectomy, it is used with anterior access and for disorders that require segmental spondylodesis such as:
- Degenerative disc diseases
- Mechanical instability
- Ossification of the posterior longitudinal ligament
- Spinal canal stenosis
- Pseudoarthrosis
- Spondylolisthesis
- Deformity

Contraindications:
- Severe osteoporosis, osteopenia
- Spinal fractures
- Spinal tumours
- Infections
- Allergy or intolerance to the instrument material
- 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 disorders, pregnancy, paediatric cases, patients in poor general health, systemic or metabolic diseases, lack of patient compliance)
- Cases that are not mentioned under Indications

Material:
The CERCCESS™ blades consist of the following material:
- Titanium grade 4 as per ASTM F 67 / ISO 5832-2

Composition:
Nickel-free as per per ASTM F 67 / ISO 5832-2
Nitrogen 0.05 % max, carbon 0.08 % max, hydrogen 0.015 % max, iron 0.5 % max, oxygen 0.4 % max, remainder titanium.

Other components of the CERCCESS™ cervical retractor system are made of materials that are established for use as medical devices.

The blades are coated with oxide layers in different colours for easy identification. Colour changes are caused by factors related to production and reprocessing and do not affect the functionality.

Sterility:
The distractor pins are supplied in double sterile packaging and are gamma sterilised in accordance with DIN EN ISO 11137. They are intended for single use only and are not reusable. 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.
Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly.
Instruments supplied non-sterile must be processed before use in accordance with hospital guidelines. The instruments are shipped in instrument trays provided by SIGNUS or in a suitable protective packaging for re-orders. Instruments must be stored in their original packaging or in the instrument tray.

Reprocessing:
Non-sterile instruments must be reprocessed before use.
- Completely remove all components of the packaging prior to reprocessing
- All non-sterile instruments must be reprocessed in the SIGNUS trays
- Observe the validated reprocessing procedure in the instructions included with the tray
- Products 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; 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.

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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	NON STERILE	Non-sterile
	Use by	LOT	Batch code
	Do not resterilise	eIFU	Consult the electronic instructions for use (eifu.signus.com)
0°C 35°C	Temperature limit		Do not use if package is damaged

Storage and transport 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 distractor pins are intended for single use only and must not be re-used. 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.
- The distractor pins must be considered potentially infectious after use. They must therefore be disposed of properly (hazardous medical waste) according to the relevant hygiene and waste disposal guidelines.
- The distractor pins may only be used with the specified instruments. Correct placement of the distractor pins cannot be guaranteed if the distractor pins are placed with other instruments.
- Unless otherwise specified, SIGNUS products must not be combined with materials or components from other systems.

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

Precautions:
- Store sterile instruments in their original packaging.
- Do not remove instruments from their protective packaging until directly before use.
- Check expiry date and integrity of the sterile packaging before use.

Application:
- The attending physician, who must be trained and experienced in carrying out spinal interventions, is responsible for determining the indication, selecting the implant and performing the implantation.
- All information about the surgical technique, the instruments and their use is provided in detail in the SIGNUS product information. This information must be available on site and must be known to the surgical team.
- Before performing the surgery, ensure that all necessary implants and instruments are to hand and fit for purpose.
- If there are any preoperative uncertainties relating to the instrument 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 instruments.
- The CERCCESS™ multi-segment pin distractor may only be used with the distractor pins supplied by SIGNUS.
- To ensure secure positioning of the implant and the clinical outcome, over-distraction of the pin distractor should be avoided
- When positioning the blades, ensures that important organs and muscle layers are not endangered.
- The distractor pins must be placed parallel to the particular endplate. When doing so, ensure that there is adequate distance from the intervertebral disc being evacuated. If the distance between the pins and the endplates is insufficient, this can lead to problems when inserting the implant.
- 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 for an appropriate postoperative period. This applies in particular to the lifting of loads, rotating movements and any type of sport. Falls and sudden, jerky movements of the operated region must be avoided.
- 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.

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 related to the SIGNUS instruments and which may necessitate repeat surgery:
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the implant and instrument materials used
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Pain or recurrent pain

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

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 leaving 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 (potential) malfunction of which the user is aware, including the article number(s) and the lot number(s).

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