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 the distraction of one or more intervertebral disc spaces.
The system is made up of a longitudinal and lateral distractor with double joint, a multi-segment pin distractor 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 distractor system to cover a wide range of requirements.
To use the multi-segment pin distractor, there are Caspar type distractor pins P03XAA developed by SIGNUS that are available in various sizes. These instruments alone ensure safe application.

Indications:
The CERCCESS distractor system is an instrument system for use on the cervical (C3–Th1) spine and is used for soft tissue retraction and distraction of two or more vertebral bodies.
For cervical discectomy, they are used with anterior access and for disorders that require segmental spondylodesis such as:
- Degenerative disc disease
- Spinal canal stenosis
- Spondylolisthesis
- Trauma
- Tumour and inflammation without bone involvement at the site of fixation
- Mechanical instability
- Deformity
- Pseudoarthrosis

Contraindications:
- Active infectious processes at the site of surgery
- Medical conditions that could prevent successful surgery (e.g. obesity, mental illness, pregnancy, patients in poor general health, lack of patient compliance)
- Allergy or intolerance to the instrument material
- Cases that are not mentioned under Indications

Material:
The blades are made from a titanium alloy (Ti6Al4V) as specified in ASTM F1472 / ISO 5832-3.

The blades are coated with oxide layers in different colours for easy identification. Colour changes between different instrument batches are due to production-related factors and do not affect the functionality of the instruments.

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

Sterility:
The CERCCESS retractor system is supplied non-sterile and 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.
The Caspar type distractor pins P03XAA are provided sterile:
- Store sterile instruments in their original packaging
- Check expiry date and intactness of the sterile packaging before use
- Do not remove implants from their protective packaging until directly before use
- Reprocessing (e.g. if the packaging is inadvertently opened) may be carried out using a standard sterilisation procedure provided the procedure is compatible with the hospital guidelines
- Sterile instruments that are returned with opened primary sterile packaging will not be accepted by SIGNUS

Reprocessing:
- Instruments that are supplied non-sterile 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:
  - Method: Steam sterilisation (fractionated 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 implant and 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.

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

CE	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		Consult instructions for use
0°C 35°C	Temperature limit		Do not use if package is damaged

SIGNUS Medizintechnik GmbH | Industriestr. 2 | 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 | f. +49 (0) 6023 9166 161 | info@signus.com | www.signus.com

CE

SIGNUS The Spine Sign®

Warnings:
- The Caspar type distractor pins are intended for single use and must not be re-used or resterilised. Repeated use can cause the fine pin tip to break or may lead to infections and/or death.
- The Caspar type distractor pins 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. Combining SIGNUS products with components/materials from other manufacturers is not permitted.

Application:
- The instruments may only be used for their intended purpose by appropriately trained and qualified personnel. The attending physician, who must be sufficiently trained and experienced in the handling of the instruments, is responsible for the selection and application. To minimise hazards for patients and users as much as possible, the instructions for use must be consulted.
- All information about the surgical technique, the instruments and their use is provided in detail in the corresponding SIGNUS product information. This information must be available on site and must be known to the surgical team.
- The CERCCESS multi-segment pin distractor may only be used with the Caspar type distractor pins supplied by SIGNUS.
- Prior to use, ensure that all instruments belonging to the system are sterile and fit for purpose.
- All components of the CERCCESS retractor system must be checked for intactness before use.
- Before the surgery, the patient must be informed about all potential risks and complications that can arise in connection with the procedure.
- Instruments that do not belong to the system must not be used.

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 associated with the Caspar type distractor pins:
- Sensitivity to foreign bodies, allergic reactions or other local/systemic adverse reactions to the instrument materials used
- Infection

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

Product warranty:
SIGNUS Medizintechnik GmbH guarantees that every medical device 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 medical device is applied and used, nor on the diagnosis of the patient, the method of application or the handling of the medical device 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).

SIGNUS Medizintechnik GmbH I Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161 I info@signus.com I www.signus.com

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