NUBIC® prefilled with KAINOS®+

Product description:
NUBIC implants are disc replacement implants for use in the cervical spine. They serve as temporary placeholders to restore disc height until firm bony fusion in the affected segment has taken place. They are not explanted again, but remain in the patient.

To achieve optimal adaptation to the intervertebral space, the implants have a trapezoid shape and their upper sides are vaulted. The upper and lower sides of these cages are equipped with small teeth for secure primary stabilisation. Various footprints (14x13 / 17x13) and heights are available to achieve anatomical adaptation to each individual patient.

The implants are made of PEEK-OPTIMA® and their central cavities are filled with KAINOS+. KAINOS+ is a bioactive bone replacement material that is fully absorbed and replaced by newly formed bone. KAINOS+ is a biphasic calcium phosphate ceramic material that is made up of 60% hydroxylapatite (HA) and 40% ß-tricalcium phosphate (ß-TCP). It has a porosity of 70%, 1/3 of the pores being micropores (< 10 x), and 2/3 macropores. Since both PEEK-OPTIMA and KAINOS+ are radiolucent, the cages are equipped with embedded titanium pins for intra- and postoperative monitoring.

Instruments specially developed by SIGNUS, that ensure safe application, are available for application of the implant systems.

Indications:
NUBIC implants are disc replacement implants for use in the cervical spine (C3-C7). They serve as temporary placeholders to restore disc height. They are implanted after cervical discectomy via anterior access to treat disorders that require segmental spondylodesis:
- Soft disc herniation
- Hard disc herniation
- Mechanical instability
- Calcification of the posterior longitudinal ligament
- Osteochondrosis
- Spinal canal stenosis
- Pseudarthrosis or unsuccessful spondylodesis

Contraindications:
- Massive osteoporosis, osteopenia
- Spinal fractures
- Spinal tumours
- Spinal infections
- Allergy or intolerance to implant material
- In cases of additional treatment with corticosteroids or drugs that affect the calcium phosphate metabolism, the use of KAINOS+ must be considered very carefully
- Surgical conditions which 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 not mentioned under Indications

Material:
The NUBIC implants prefilled with KAINOS+ are made from the following materials:

Implants:	Polyether ether ketone (PEEK-OPTIMA) as per ASTM F2026
Filling:	KAINOS+, consisting of hydroxylapatite (ASTM F1185) and beta-tricalcium phosphate (ASTM F1088)
X-ray markers:	Titanium alloy (TI-6AL-4V) as per ASTM F136

The material is an established material for use as an implant. It is biocompatible, corrosion-resistant, non-toxic in the biological environment and allows for interference-free X-ray imaging. It is MRI-compatible with reservations.

Sterility:
All implants are supplied in fully preassembled condition in double sterile packaging, and are gamma-sterilised in accordance with DIN EN ISO 11137.
- Implants with opened primary sterile packaging are not accepted back by SIGNUS.

The cages are intended for single use only and are not reusable. The implants must not be resterilised. Reprocessing and/or reuse can result in infection and/or loss of function, which can in extreme cases lead to the death of the patient.

Reprocessing:
- Instruments must be reprocessed before use
- Observe the validated reprocessing procedure for instruments in the instructions included with the tray
- 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.

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

CE 0499	CE marking		Manufacturer
	For single use only	STERILE R	Sterilised by irradiation
REF	Order number	LOT	Lot number
	Use by		Observe instructions for use
	Do not re-sterilise		Do not use if packaging is damaged

Warnings:
- The spinal implants are intended for single use only and may 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 this device to sale by or on the order of a physician.

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CE 0499

SIGNUS The Spine Sign®

Precautions:
- Store implants in the original packaging.
- Do not remove implants from their protective packing until directly before use.
- Check expiry date and intactness of the sterile packaging before use.
- Do not use the implant if the expiration date has been exceeded or the packaging is damaged
- Before opening the packaging, check that the packaging is intact.
- The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.
- After preparation, carefully inspect the intervertebral disc cavity for bone fragments.
- Particular attention must be paid to the protection of nerve roots.

Application:
- The attending physician, who must be both 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 range of implants, 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 pre-operative 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 from use of the implant.
- When inserting the implant, refrain from using excessive force in order to protect the implant and the adjacent vertebral bodies.
- The surgery must be carried out under fluoroscopic guidance. The correct position of the cages used must be verified radiographically.
- Excessive ablation or even complete removal of the cortical base plates and cover plates of adjacent vertebral bodies must be avoided.
- The cage used must be checked for intactness and correct size before being implanted.
- Care must be taken to ensure maximum contact between the cover plates of the vertebral bodies and the KAINOS+ filling of the implant; if this is not the case, reduced bony ingrowth in this area during the desired fusion phase can result.
- The insert made of KAINOS+ must not be removed from the implant and used without the implant. KAINOS+ does not provide sufficient stability when used as a stand-alone application.
- The KAINOS+ filling should be soaked with patient blood before insertion to stop cell demolition by capillary effects
- The correct and secure seating of the implant must be verified prior to wound closure.
- The implant used must be documented in the patient record, indicating the article number, designation and lot 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.
- 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.
- 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 his individual requirements.

Risiks:
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 cage used and may necessitate repeat surgery:
- Breakage of implant components
- Loss of the fixation, dislocation, subsidence
- 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

These risks may 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.

Product Guarantee:
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).

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