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Instructions for Use of the Spinal Implants of the System

ROCCIA® ACIF

Important Information – Please Read Before Use!

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These Instructions for Use apply to ROCCIA ACIF Cages.
Other sets of instructions for use are available, the information in which is required for application of the system:

- Reprocessing Instructions for Instruments (D30003)
- Instrumentation Guide ACIF (D30038)

These Instructions for Use do not apply to the USA or its territories.

1 Product Description

The Silony ROCCIA ACIF Cage (anterior cervical interbody fusion) is used for the surgical treatment of degenerative disorders of the cervical spine requiring surgery. The cage is a spacer that is inserted in a disc space for ventral load support and fusion, usually after prior spreading of the disc space and decompression of the neural structures, for the purpose of arthrodesis. The aim is to eliminate discogenic pain, correct deformities, remedy instabilities, decompress neural structures, restore intervertebral height, restore physiological lordosis, and biomechanically support bone fusion in the disc space.

ROCCIA ACIF is manufactured from PEEK in accordance with ASTM F 2026 and titanium in accordance with ASTM F 136. It is available in various sizes and shapes (anatomic and wedge-shaped) in order to enable appropriate, patient-specific selection.

ROCCIA ACIF is delivered in a sterile condition and can be used without any further preparations. The cages were packaged in accordance with EN ISO 11607 Parts 1+2 and sterilized with gamma radiation at a minimum dose of 25 kGy.

2 General Information and Warnings

ROCCIA ACIF is solely intended for use in the field of human medicine and is employed in the treatment of damage to or diseases of the musculoskeletal system. Implants of the ROCCIA ACIF system are intended for use on the cervical spine (C2-T1) and must be applied within the indications listed in section 3.
ROCCIA ACIF may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques. The surgical technique for Silony Medical implants can be learned within the scope of guest visits, workshops, and courses at a clinic familiar with these implants.

Depending on stability and the sagittal profile, ROCCIA ACIF can be combined with additional stabilization.

Implants and instruments are always part of a system. They may only be combined and implanted with original parts belonging to the same system. For system compatibility refer to the Instrumentation Guide (D30038).

Correct selection of the implant is very important. The potential success of surgery is directly dependent on the correct choice of implant. Surgery must be planned in detail by the attending physician, based on x-ray findings. X-ray images provide important information for an appropriate choice of implant. Omission of preoperative planning can have a negative impact on the surgical outcome.

Implants that do not fit the patient can cause damage to health, or may only function to a limited extent, and therefore only implants with a size that fits the patient may be used.

Implants must not be mechanically processed or modified in any other way. Implants that are contaminated, non-sterile, damaged or scratched, or implants that have been improperly treated or processed in an unauthorized way must under no circumstances be implanted.

Implants are single-use products that must not be reprocessed or reused after application on a patient and after being contaminated with blood or tissue.
Even if the implant appears to be intact, it may have minor defects and invisible damages due to excessive stress that can lead to premature wear and tear.

Any implant is subject to inevitable wear and tear. A cage that was at first stable after implantation can, in the course of time, become loose or functionally impaired and thus lead to, e.g., implant fracture, wear, aging, and loosening, which can result in revision surgery.

Even a successfully implanted cage is inferior to the healthy musculoskeletal system of the spine. Conversely, an implant can be a beneficial replacement of one or multiple pathological and/or symptomatic movement element(s) for the patient.

ROCCIA ACIF was not tested for migration or warming in an MRI environment. In CT or MRI examinations, the implant may become displaced or surrounding bone tissue may become warm. The formation of artifacts due to the in-situ implant can make it more difficult to evaluate the examination result.

Implants delivered by the manufacturer in a sterile condition may not be resterilized! The integrity of the packaging must always be checked in order to ensure that sterility has not been impaired. If an implant is non-sterile, it must be disposed of.

3 Indications

- Symptomatic cervical discopathy
- Cervical spinal canal stenosis
- Clinical signs and symptoms of radiculopathy, myelopathy, or symptoms of myeloradiculopathy

4 Contraindications

4.1 Absolute Contraindications

- Anticipated or documented allergy or intolerance to the materials (e.g. PEEK, titanium).
- Missing bone structures that render good fixation of the implant impossible (e.g. in connection, amongst others, with fractures, tumors, osteoporosis, or infections).

4.2 Relative Contraindications

- Overweight patient
- Deformities
- Fever or leukocytosis
- Systemic diseases and metabolic disorders
- Unbalanced diet, medicinal drug abuse; nicotine, alcohol or drug consumption
- Physical activities involving violent vibrations during which the implant is exposed to impacts and/or excessive loads (e.g., heavy physical work, competitive sports, marathons, alpine skiing, jumping and team sports)
- Patient who is mentally unable to understand and follow the physician's instructions
- Any patient for whom use of the implant would be in conflict with the anatomical structures.
- Operations on pregnant women must be avoided if possible. If they are nevertheless performed, they require special care or procedures. This is at the discretion of the surgeon.

5 Possible Negative Consequences

Possible risks that were identified in connection with use of this system, and that may require further treatments, include the following:

- Damage to, fracturing of or loosening of implants or implant components due to overloading / incorrect exposure to stresses / improper handling or implantation.
- Dislocation, break-out, or sinking in of the implant in base plates and/or cover plates of the adjacent vertebral body.
- Subluxation.
- Loosening of the implant due to a changed bone structure or on account of tissue reaction to the implant.
- Fracture of the vertebra due to unilateral overloading or weakened bone tissue.
- Early and late infections, cross-infection.
- Impaired radius of movement, deformities.
- Transient or permanent nerve damage due to implant-induced pressure or due to hematomas.
- Temporary or permanent pain.
- Wound hematoma and delayed wound healing, cicatrization.

Sporadic operative and postoperative complications that can lead to a need for further surgery include the following:

- Sensitivity to the material or allergic reaction to a foreign body
- Implant fracture
- Injury to the spinal cord, the blood vessels and/or peripheral nerves, up to paralysis
- Dura leakage due to dura injury
- Lesions of the trachea and esophagus
- Pulmonary embolism
- Infections, sepsis
- Motor deficits and paresthesia (paresthesias such as numbness, tingling, feeling of warmth or cold)
- Hoarseness and swallowing disorders (dysphagia) due to nerve paresis or on account of additional plate osteosynthesis
- Heterotrophic ossification
- Secondary instability on the operated segment
- Lack of or delay in bone healing / fusion (development of pseudarthrosis)
- Disease of the adjacent segments (connection degeneration / degradation)
- General surgical risks: bleeding, hematoma, thrombosis, anesthetic risks, cardiovascular disorders (with blood clot, blood pressure drop, heart attack, cardiac arrest, stroke)

In rare cases, some complications can be lethal.

6 Notes on Use

Generally speaking, invasive surgery should only be considered when all other treatment options have been carefully assessed and established as not being the better option.

The attending physician is responsible for weighing the option of implant surgery. ROCCIA ACIF is a system in which the physician can select the implant on a patient-specific basis.

Removal of the implant is possible, provided it is performed in accordance with the Instrumentation Guide. The decision has to be taken by the attending physician. This may be

the case if there is an infection and the intervertebral space has to be cleared out in order to remove the infectious parts.

Patient Information

The physician is responsible for informing the patient about the risks of implantation and about the outcome of the surgery and any negative effects. In addition, the patient must be informed about the measures he/she can take to minimize the possible effects of these factors. The patient must also be issued with an Implant Pass.

7 Handling and Storage

Implants are extremely sensitive to damage. Even minor scratches or impact sites on the surfaces lead to excessive wear and tear and can give rise to complications. Extremely careful handling is therefore required.

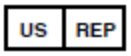
The surfaces of implants must be neither labeled nor allowed to come into contact with hard objects, unless this is expressly stipulated in the Instrumentation Guide.

Sterile implants must be stored in the original packaging without the packaging having been opened. Until use, they can be stored in accordance with the storage conditions indicated on the product label, unless the packaging has been damaged or opened, or the use-by date on the product label has expired.

Implant sizes must only be selected by application of the trial implants.
Implants that can no longer be used can be disposed of in accordance with the regulations applicable at the place of use, or be returned to the manufacturer free of charge for proper disposal.

The information and symbols on the packaging must be heeded.

8 Glossary of Symbols

	Manufacturer
	US representative
	The product meets the requirements of EU Directive 93/42/EEC
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Article number
	Batch number
	Use by
	Number of items
	Observe the Instructions for Use
	Important – heed the Instructions for Use
	Sterilized by irradiation
	Do not reuse
	Do not resterilize
	Do not use if the packaging is damaged
	Store in a dry place
	Protect from sunlight
	Cage angle
	Anatomic cage
	Wedge-shaped cage