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 manufacturer's instructions are available containing information required for application of the system. The additional information, such as Instrumentation Guides, inserts containing useful information, and other product-specific information, may be viewed under the following two links:

- https://elabeling.silony-medical.com
- www.silony-medical.com

Instructions for Use D30003 may be used as reference for reprocessing instruments.

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's information.

Prior to using a product distributed by Silony Medical, the surgeon is expected to closely study the following recommendations, warnings, and advice as well as the product-specific information. Silony Medical also recommends the attendance of corresponding user training courses.

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

1 Product Description

The Silony ROCCIA ACIF (anterior cervical interbody fusion) Cage is used for primary stabilization and restoration of physiological lordosis in the lumbar spine. The cage is designed for ventral approach. The cage is a spacer that is inserted for load support and fusion. The disc space must be prepared by discectomy for this purpose. This is followed by distraction of the disc space and decompression of the neural structures for the purpose of arthrodesis.

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. Implants delivered by the manufacturer in a sterile condition may not be resterilized!

The product designation, article number and lot number are indicated on the product label. When removing the implant from the packaging, the implant must be verified against the description on the packaging (article number / lot number / size).

2 Intended purpose

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.

The objectives:

- To eliminate discogenic pain
- To correct deformities
- To remedy instabilities
- To decompress neural structures
- To restore intervertebral height
- To reestablish physiological lordosis
- To support bony fusion in the disc space

3 Indications

The ROCCIA ACIF system can be used for the following indications on the cervical spine:

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

There are no restrictions regarding the gender and age of the patient. The decision on use lies with the experienced surgeon.

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

Preoperative planning

Correct selection of the implant is very important. The potential success of surgery depends directly 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. Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome.
Prior to the surgery, it must also be clarified whether that patient has an allergy to the implant material.
For the surgical procedure, all implants that may be required in the combination recommended by the manufacturer, as well as the instruments needed for implantation, must be available in the event that a different size or a different implant becomes necessary.

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.

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 implanting the ROCCIA ACIF. ROCCIA ACIF is a system in which the physician can select the implant size on a patient-specific basis. Filling the ROCCIA ACIF with autologous or homologous bone material is an important precondition for reliable fusion. 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).

Removal of the implant is possible, provided 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.

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.

Magnetic resonance compatibility

ROCCIA ACIF was not tested for migration or warming in an MRI environment. As the cage is made of a non-metallic material (PEEK polymer), there can be no migration or heating of the surrounding bone tissue in the MR field. The four titanium markers are also non-magnetic, which excludes migration. On account of the small size and geometry of the markers, heating of the titanium markers and therefore the surrounding bone tissue is unlikely. Artifacts are significantly reduced as a result of the implant material used.

Patient information

The physician is responsible for informing the patient about the risks of implantation and about the outcome of the surgery and any adverse 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 given an implant pass.

All information given to the patient should be documented by the surgeon in writing.

Warnings

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 without authorization, must not be implanted under any circumstances.

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 non-visible 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.

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.

7 Storage and handling

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.

Only the corresponding Silony Medical instruments and trial implants must be used when selecting and adjusting the implants.
The surfaces of implants must be neither labelled 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. The integrity of the packaging must always be checked in order to ensure that sterility has not been impaired. If the protective packaging of sterile packed products has been opened but the product was not used for the surgical procedure, the product is considered used and must not be used. The rules of asepsis must be observed during removal from the sterile packaging.

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. Implants and instruments may only be returned to Silony Medical if the products are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment is to be attached to the outermost packaging.

When transferring Silony Medical products (for payment or free of charge), every entity transferring a product must ensure that the product can be traced at all times (lot tracking).

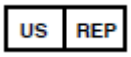
The information and symbols on the packaging must be observed..

8 Reporting of incidents

Users and/or patients are obliged to report all serious incidents involving the device to the manufacturer and the competent authority of the Member State.

9 Glossary of symbols

The CE mark with the code number of the Notified Body applies to all class IIb implants in the ROCCIA ACIF system.

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	US representative
	Swiss agent
	The device meets the requirements of EU Regulation MDR 2017/745
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Article number
	Lot number
	Number of items
	Medical device
	Unique Device Identification
	Use by *Including the year and month in the following format: YYYY-MM-DD*
	Consult Instructions for Use
	Important – consult the Instructions for Use
	Double sterile barrier system sterilized by irradiation with additional protective packaging
	Do not reuse
	Do not resterilise

	Do not use if the packaging is damaged
	Store in a dry place
	Keep away from sunlight
	Contact
	Cage angle
	Anatomic cage
	Wedge-shaped cage
	MR* safe
	Caution MR* conditional safe
	Attention MR* unsafe
	Metal detectors can trigger alarm due to the implant

*the term MR is synonymous with MRI and means magnetic resonance imaging

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