**Instruction for Use (D20301)**

# ROCCIA® ACIF

**Important Information – please read before use!**

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This Instructions for Use covers the ROCCIA ACIF implants.

This and other product specific information (e.g. instrumentation guides) as well as product accompanying information in other relevant official languages are available under the following links:

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

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

The short summary of safety and performance of Silony implants are available in the European Database for Medical Devices (EUDAMED) and are provided by Silony Spine upon request.

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

Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study the following indications/ contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) adverse events related to the device to the manufacturer and to the state competent authority.

This instruction for use does not apply to the USA or its territories.

# 1 Product description

## 1.1 General Information

The Silony ROCCIA ACIF Cage (Anterior Cervical Interbody Fusion) is used for primary stabilization and restoration of the physiological lordosis of the cervical spine. The cage is designed for the ventral approach. The cage is a spacer that is inserted for load support and fusion. For this purpose, the disc space must be prepared by means of a discectomy. The disc space is then distracted and the neural structures decompressed for the purpose of subsequent fusion.

Filling the ROCCIA ACIF with autologous or homologous bone material is an important requirement for safe fusion. Depending on the stability and sagittal profile, the ROCCIA ACIF can be combined with additional stabilization.

In order to be able to take into account the patient-specific anatomy and to restore the natural intervertebral height and lordosis, the implants are provided in different dimensions and heights. Implant variants with anatomic and wedge shape upper endplate geometry are available.

## 1.2 Performance characteristics

The ROCCIA ACIF Cage system was developed to meet the requirements and complexity of cervical interbody fusion procedures. The chamber system in the cages is used to support interbody fusion and offers the option of inserting either autografts or allografts. Symmetrical pyramid-shaped / truncated pyramid-shaped teeth on the upper and lower end plates of the cages are designed to ensure stable fixation of the implant in the intervertebral disc space.

## 1.3 Material

Implants of the ROCCIA ACIF system are manufactured from PEEK (polyetheretherketone) according to ASTM F2026 and Ti6Al4V ELI (Extra low interstitials) according to ASTM F136, whereby the body of the cage is made of PEEK. In order to achieve better X-ray contrast and primary stability, X-ray markers and spikes made out titanium alloy Ti6Al4V are inserted into the implant.

| Material | Material-specific weight [%] of the total product | Percentage of chemical elements according to standard [%] | | Percentage of chemical elements in the total product [%] |
|---|---|---|---|---|
| PEEK (Polyethe-retherketon) acc. to ASTM F2026 | 84.09 – 90.23 | PEEK | 100 | 84.09 – 90.23 |
| Ti6Al4V ELI acc. to ASTM F136 | 9.77 – 15.91 | [Al] Aluminium | 5.5 to 6.5 | 0.54 – 1.03 |
| | | [V] Vanadium | 3.5 to 4.5 | 0.34 – 0.72 |
| | | [Fe] Iron | 0.25 maximum | 0 – 0.0398 |
| | | [O] Oxygen | 0.13 maximum | 0 – 0.021 |
| | | [C] Carbon | 0.08 maximum | 0 – 0.013 |
| | | [N] Nitrogen | 0.05 maximum | 0 – 0.008 |
| | | [H] Hydrogen | 0.012 maximum | 0 – 0.02 |
| | | [Ti] Titanium | 88.478 to 91 | 8.64 – 14.48 |

## 1.4 Information about special substances

Implants of the ROCCIA ACIF Cage system does not contain substances of biological or animal origin, medicinal substances, or substances derived from human blood.

# 2 Clinical application

## 2.1 Intended use

The ROCCIA ACIF is intended for the use in humans only and is intended for the treatment of damage or diseases of the musculoskeletal system. Implants of the ROCCIA ACIF system are intended for use in the cervical spine (C2-T1).

The aim is to
- Eliminate discogenic pain
- Correct deformities
- Correct instabilities
- Decompress neural structures,

- Restore intervertebral height,
- Establishment of physiological re-lordosation
- Support bony fusion in the disc space.

### 2.2 Indications

The ROCCIA ACIF system can be used to treat the following indications in the cervical spine (C2 - T1):

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

### 2.3 Contraindications

There may be absolute or relative contraindications for not using the product. The decision to use a particular implant must be carefully considered, taking into account the patient's anamnesis. The following circumstances can affect the success of the treatment.

#### 2.3.1 Absolute contraindications

- Expected or documented allergy or intolerance to the materials used (e.g. PEEK, titanium)
- Missing bone structures, which would render stable fixation of the implant impossible (e.g. due to fractures, tumours, diagnosed osteoporosis or infections)

#### 2.3.2 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.

### 2.4 Expected clinical benefit

As clinical benefits for the patient, the quality of life should be increased by reducing pain and a clinically relevant improvement in function, as well as decompressing neural structures and increasing the intervertebral height.

### 2.5 Target patient group

The implants are intended for use in human medicine in patients with a mature skeleton.
There is no restriction regarding the intended patient population additional to the indications/contraindications. This device has not been evaluated in paediatrics or pregnant women.

### 2.6 Target user group

The implants are intended for use by orthopaedic surgeons and neurosurgeons familiar with spinal surgery and experienced in the product-specific surgical techniques.

### 2.7 Use environment

The implants are to be used in a standard surgical environment.

## 3 Risks and possible negative side effects

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 (paresthesia 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, anaesthetic risks, cardiovascular disorders (with blood clot, blood pressure drop, heart attack, cardiac arrest, stroke)

In rare cases, some complications can be lethal.

## 4 Packaging, sterility and storage

### 4.1 Storage

⚠ **Implants must be stored in the sealed packaging according to the storage conditions indicated on the product label until use.**

### 4.2 Packaging

- The product description, article number and LOT number are indicated on the product label. When withdrawing the implant from the packaging, the implant must be verified against the information on the packaging (article number / lot number / size).
- The instructions and symbols given on the packaging must be followed.
- The patient labels in the primary packaging must be attached to the patient file or the surgical report.

### 4.3 Sterilization

- Implants are packaged and sterilized with gamma irradiation at a minimum dose of 25 kGy and delivered sterile. They can be used without further preparation.

⚠ **Implants delivered by the manufacturer in a sterile condition must not be resterilized!**

- Prior to use, secondary packaging, labeling and sterile primary packaging should always be checked for integrity.
- Before using the implant the expiration date (YYYY/MM/DD) and the sterility marker on the packaging must be checked.

⚠ **The implant must not be used if the packaging is damaged, if the expiry date has expired or if the sterility marking is not present or does not indicate that the product has been correctly irradiated (marker must be coloured red).**

- Damaged sterile packaging of products that haven't been used for the surgical procedure are considered as used and must be disposed.

## 5 Notes for application

### 5.1 General

- The surgical technique for Silony Spine implants can be learned by observing surgical procedures for demonstration purposes, workshops, and courses in a hospital familiar with these implants.
- Implants and instruments are part of a system.

⚠ **Only instruments, trials and accessories described in the accompanying manufacturer's instructions (e.g. instrumentation guides or note inserts) must be used in order not to impair the performance of the device or surgical outcome.**

⚠ **Compatibility is only guaranteed with these instruments and accessories.**

### 5.2 Handling of the implants

- Implants are sensitive to damage. Even minor scratches or impact sites on the surfaces lead to premature failure can give rise to complications. Careful handling is required.

⚠ **Implants must not be mechanically processed or modified.**

⚠ **Implants that are contaminated, non-sterile, damaged, or scratched or that have been improperly treated or processed in an unauthorized way must not be implanted under any circumstances.**

- In the event of overloading, damage, improper implantation, or improper handling, implants may fracture, become loose, wear out, or become functionally impaired.
- Any implant is subject to inevitable wear and tear. An implant that was initially stable upon implantation may become loose or functionally impaired over time, which can result in revision surgery.

### 5.3 Reuse

⚠ **Implants are for single use only and strictly must not be reprocessed after use in a patient and contamination with blood, tissue or other body fluids. Reuse, reprocessing or resterilization can lead to limited functionality, transfer of pathogens or cross-infection may lead to patient injuries, diseases or death.**

- 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.

### 5.4 Preoperative use instructions

- Implant surgery should generally only be considered if all other conservative treatment options have been carefully assessed and have not proven to be the better option. The surgeon is responsible for considering the possibility of implant surgery.
- The surgeon is responsible for the proper performance of the surgery, including:
  - Patient-specific selection of size, shape and design of the implant
  - Planning of the surgery based on X-ray images
  - Checking possible allergies of the patient to the implant material
  - Ensure availability of different implant sizes and required instruments for the surgical procedure
- Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome and lead to health damage. The potential success of surgery depends directly on the correct choice of the implant.
- When planning implantation, the patient-specific pathology and anatomy as well as the implantation levels must also be taken into account.

⚠ **Silony Spine bears and accepts no responsibility for complications resulting from an incorrect diagnosis or indication, an unsuitable choice of implant, incorrectly combined implant components and/or an improper surgical technique or asepsis.**

## 5.5 Intra-operative use instructions

- Prior to implantation, the implant must be visually inspected for damage.

⚠ **Damaged implants must not be used.**

- The rules of asepsis must be observed during removal from the protective packaging.
- Depending on the surgeon's decision a bone graft (autograft and/or allograft) may be placed in the area to be fused.

## 5.6 Post-operative use instructions

- Post-operative evaluation of the fusion and the implant status are mandatory.
- Post-operative mobilization and rehabilitation are at the discretion of the surgeon dependent on clinical and radiological progress.
- The need for external orthotic support is not mandatory with the final choice based on surgeon preference, patient condition and intra-operative findings that might influence implant security.

## 5.7 Information to the patient

- Even a successfully implanted cage is inferior to the healthy motion segment(s) of the spine. Similarly, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic motion segment(s) for the patient, as it can help eliminate pain and therefore achieve improved mobility and stability.
- Pre- and post-operative instructions and warnings of the surgeon to the patient and their compliance are essential. The surgeon is responsible for informing the patient about the risks of implantation and about the outcome of the surgery as well as any potential negative consequences. The patient should be made aware of the limitations and the measures to minimize the possible complications. The patient should be instructed to limit the post-operative activity as this will reduce the risk of bending, breaking and/or loosening the implants.
- The patient must be issued with an implant pass.
- The patient must be informed that implants can have an impact on the diagnostic imaging of CT scans or MRI examinations. The patient must also be instructed to inform the examining physician about the implant and to show the implant pass prior to a scheduled CT scan or MRI examination.
- All information given to the patient should be documented in writing by the surgeon.

## 5.8 Magnetic resonance (MR) compatibility

- The implants are MR conditional.

⚠ **The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR 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 prevents migration.
- Heating of the titanium markers and thus of the surrounding bone tissue is unlikely due to the small size and geometry of the markers.
- The formation of artifacts is significantly reduced by the implant material used.

## 5.9 Implant removal and revision

- The implant is not intended to be removed in case of a good outcome.
- Removal of a stable implant can lead to loss of stability and damage to surrounding tissue.
- However, adverse events might warrant removal of the implant.
- Removal of the implant is possible. This should be carefully considered by the surgeon and the patient, evaluating the risks and benefits.

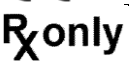
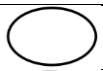
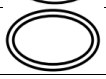
## 5.10 Disposal

- Implants and instruments that can no longer be used can be disposed of in accordance with the national 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 Spine if they are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment must be attached to the outer packaging.

5.11 Traceability

- When passing on Silony Spine products (in return for payment or free of charge), each party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

## 6 Labelling and Symbols

| Symbol | Description according to ISO 15223-1 and Silony specifications |
|---|---|
|  | Manufacturer |
|  | Date of manufacture<br>*Including the date in the following format: YYYY-MM-DD* |
|  | Swiss Authorized Representative |
|  | United Kingdom Representative |
|  | 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<br>*Including the date in the following format: YYYY-MM-DD* |
|  | Consult Instruction for Use |
|  | Caution |
|  | Single sterile barrier system |
|  | Double sterile barrier system |
|  | Sterilized using irradiation |
|  | Do not re-use |
|  | Do not resterilize |
|  | Do not use if the package is damaged |
|  | Keep dry |
|  | Keep away from sunlight |
|  | MR* safe |

| Symbol | Description according to ISO 15223-1 and Silony specifications |
|---|---|
|  | Caution MR* conditional safe |
|  | Attention MR* unsafe |
|  | Metal detectors can trigger alarm due to the implant |
|  | Patient Identification |
|  | Health care centre or doctor |
|  | Date (of implantation) |
|  | Contact |
|  | Silony Logo (for identification of the legal manufacturer in the course of direct marking of products) |
|  | Cage angulation |
|  | Domed cage |
|  | Tapered cage |

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

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