Instruction for Use (D30284)

ROCCIA® MultiLIF
ROCCIA® ALIF
ROCCIA® TLIF

Important Information – please read before use!

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This Instructions for Use covers the ROCCIA MultiLIF, ROCCIA ALIF und ROCCIA TLIF Implants (ROCCIA Titanium Cage Systems).

This and other product specific information (e.g. instrumentation instructions) 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 Products (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 instructions for use does not apply to the USA or its territories.

1 Product description

1.1 General Information

Implants of the titanium cage systems ROCCIA MultiLIF, ROCCIA ALIF and ROCCIA TLIF are intervertebral body fusion implants for the treatment of degenerative diseases of the thoraco-lumbar and lumbar spine. Various implants with different surgical approaches are available for the respective area of application within the spine.

The aim of the bony fusion is to treat instabilities, correct deformities and support a physiological lordosis.
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.

In combination with autograft or allograft the implants of ROCCIA titanium cage systems shall support fusion.

1.2 Performance characteristics

The ROCCIA Titan Cage systems were developed to meet the requirements and complexity of thoracolumbar and lumbar 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. The wide contact surface of the cages is intended to counteract subsidence.

1.3 Material

Implants of ROCCIA titanium cage systems are manufactured from titanium alloy Ti6Al4V ELI (ELI = extra low interstitials) in accordance to ASTM F-136 / ISO 5832-3.

Chemical composition (elements) according to ASTM F136	Limit content [%] (proportion by mass)
[Al] Aluminum	5.5 to 6.5 (5.5 to 6.75)*
[V] Vanadium	3.5 to 4.5
[Fe] Iron	0.25 maximum (0.3 maximum)*
[O] Oxygen	0.13 maximum (0.2 maximum)*
[C] Carbon	0.08 maximum
[N] Nitrogen	0.05 maximum
[H] Hydrogen	0.012 maximum (0.015 maximum**)*
[Ti] Titanium	88.478 – 91 (88,105 – 91)*

** Specification according to ISO 5832-3*
***(from ISO 5832-3) for using blocks as raw material, the maximum hydrogen content must not exceed 0.01%.*

1.4 Information about special substances

Implants of the ROCCIA titanium cage systems do not contain substances of biological or animal origin, medicinal substances, or substances derived from human blood.

2 Clinical application

2.1 Intended use

The spinal cage implants ROCCIA MultiLIF, ALIF and TLIF are used as interbody fusion devices. Implants of the ROCCIA Cage systems are intended for surgical application in the thoraco-lumbar and lumbar spine.

- The ROCCIA MultiLIF (lumbar interbody fusion) is designed for the lateral, anterior or posterior approaches in the thoraco-lumbar and lumbar spine.
- The ROCCIA TLIF (transforaminal lumbar interbody fusion) is designed for the posterior approach in the thoraco-lumbar and lumbar spine.
- The ROCCIA ALIF (anterior lumbar interbody fusion) is designed for the anterior approach in the lumbar spine.

The ROCCIA cage systems must be used with an additional stabilisation, for example with the VERTICALE posterior spinal fixation system.

2.2 Indications

The ROCCIA MultiLIF, TLIF and ALIF systems can be used to treat the following indications:

- Degenerative disc diseases
- Deformities
- Segmental dysfunctions of the lumbar spine (for MultiLIF and TLIF also thoracolumbar spine)
- Spondylolisthesis
- Segmental instabilities
- Stenosis

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
- 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

- Patient overweight
- 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
- Pregnant women: surgeries should be avoided if possible or require special care. This is at the discretion of the surgeon.
- Any condition that could exclude the potential benefit of a spinal implantation must be clarified by the physician using the implant.

2.4 Expected clinical benefit

As clinical benefit for the patient quality of life should be increased through pain reduction and a clinically relevant improvement in function as well as support in physiological relordosis.

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

As with any major surgical procedures there is a risk for adverse events. Prevalence of the possible negative side effects may vary depending on patient specific pathology and anatomy, as well as implantation levels. Possible negative consequences include among others:

- General surgery risks (pain, delayed wound healing, (post-operative) bleeding, hematoma, abscesses, thrombosis, post-operative scar proliferation)
- Cardiovascular complications (knot blood, pressure drop, cardiac arrest, stroke)

- Infections, inflammations, sepsis
- Pulmonary complications (pneumonia, embolus, atelectasis, pleural effusion)
- Neurologic complications (dural lesion, CSF leakage, (transient) neurologic impairment / deficits, abnormal sensations, numbness, nerve root compression / irritation, injury to the spinal cord, (temporary) partial or complete paralysis)
- Urological complications (injury to the ureters, sexual dysfunction)
- Gastrointestinal complications (injury to the testine, ileus)
- material intolerance or allergic reaction
- Epidural bleeding / fibrosis
- Loosening, wear, corrosion, malposition, dislocation, (sub)luxation, aging, degradation and fracture of the implant or implant parts.
- Subsidence of the implant in the inferior and /or superior endplates of the adjacent vertebral body
- Vascular / visceral injuries
- Soft tissue or muscle injury / impairment
- Restricted range of motion
- Absence or delay of bony healing (pseudoarthrosis formation) up to vertebral fracture
- Reduction in the bone density due to stress shielding
- Damage / fracture of vertebral bones or endplates
- Skin emphysema
- Rib fracture
- Adjacent segment degeneration
- Deformities
- In rare cases, some complications can be lethal.
- Note: Using the ALIF method for implantation poses a higher risk for blood loss, ileus, incisional hernia, injury of peritoneum or diaphragm and in men a higher risk for retrograde ejaculation.

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, labelling 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 is 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. In rare cases, there may be corrosion of the implant.
- 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 postoperative 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.**

- Patients with these implants can be scanned safely immediately after placement under the following conditions:
  - Static magnetic field of 3-Tesla or less
  - Maximum spatial gradient magnetic field of 720-Gauss/cm (a higher value for the spatial gradient magnetic field may apply if properly calculated)
  - Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).
- MRI-Related Heating: Possible heat generation is acceptable for a whole body averaged specific absorption rate (SAR) of 2W/kg for 15-minutes (per pulse sequence) of scanning using a 3-Tesla MR system.
- Migration: Due to the material used (titanium alloy), no forces or moments are to be expected which cause the implant to migrate during the MR examination.
- Artifacts: MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant.
- In all cases, the surgeon is responsible for MR conditions, MR imaging quality and patient safety.

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

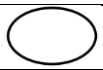
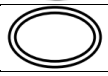
- Implants and instruments that can no longer be used can be disposed of in accordance with the national regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.

- Implants and instruments may only be returned to Silony Spine if they are still in their 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 Silony 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 *Including the date in the following format: YYYY-MM-DD*
CH REP	Swiss Authorized Representative
UK REP	United Kingdom Representative
CE 0483	The device meets the requirements of EU Regulation MDR 2017/745.
Rx only	Federal law in the USA restricts this device to sale by or on the order of a physician.
REF	Article number
LOT	Lot number
QTY	Number of items
MD	Medical device
UDI	Unique device identification
	Use by *Including the date in the following format: YYYY-MM-DD*
	Consult Instruction for Use
	Caution
	Single sterile barrier system
	Double sterile barrier system
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Do not use if the package is damaged
	Keep dry
	Keep away from sunlight

Symbol	Description according to ISO 15223-1 and Silony specifications
	MR*** safe
	Caution MR*** conditional
	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

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

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