Instructions for Use for the Spinal Implants in the System:

ROCCIA® PLIF

Important Information—Please Read Before Use!

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These Instructions for Use apply to ROCCIA PLIF 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.

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

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

1 Product Description

The Silony ROCCIA PLIF (posterior lumbar interbody fusion) is used for surgical treatment of degenerative disorders of the lumbar spine requiring surgery with additional transpedicular stabilization of the motion segments. The cage is a spacer that is inserted in pairs into a disc space for load support and fusion, usually after prior distraction of the disc space, for the purpose of arthrodesis.

The ROCCIA PLIF is manufactured from PEEK in accordance with ASTM F 2026 and tantalum in accordance with ASTM F 560. It is available in various sizes and shapes in order to enable appropriate, patient-specific selection.

The ROCCIA PLIF 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).

Silony Medical recommends additional posterior fixation of the spinal segment being treated, for example, with the posterior screw-rod system for the thoracic and lumbar spine from the VERTICALE product family.

2 Intended purpose

ROCCIA PLIF 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 PLIF system are intended for use on the lumbar spine:

The objectives:

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

3 Indications

Implants of the ROCCIA PLIF System are intended for use on the lumbar spine for the following indications:

- Degenerative disc diseases
- Deformities
- Segmental dysfunctions of the lumbar spine
- Spondylolisthesis
- Segmental instabilities
- Stenosis

4 Contraindications

4.1 Absolute Contraindications

- Anticipated or documented allergy or intolerance to the materials (e.g., PEEK, tantalum).
- Any case in which the chosen implants would be too large or too small to achieve a successful result.
- Any patient for whom use of the implant would be in conflict with the anatomical structures.
- Missing bone structures, which would render stable fixation of the implant impossible (e.g., associated 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
- 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.
- Any condition that could exclude the potential benefit of a spinal implantation must be clarified by the physician using the implant. This may include tumors, local fractures in the surgical area, unexplained increase in the blood sedimentation rate due to other diseases, increase in leucocytes, or a significant leftward shift in the differential blood count or of other parameters

5 Possible Negative Consequences

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

- Allergic reaction to anesthetic or medications
- Cardiovascular disorders with blood clot, blood pressure drop, heart attack, stroke, death
- Early and late infections, delayed wound healing, cross-infection
- Damage to blood vessels, damage to the spinal cord or peripheral nerves
- Nerve lesions, dura lesions with loss of cerebrospinal fluid, neuropathy, intercostal neuralgia, paraplegia
- Bleeding, secondary bleeding, hematoma, anemia, circulatory disorders
- Impaired motor skills and sensitivity
- Thromboses, pulmonary embolism
- Soft tissue injury, loss of function of the muscles supplied by the nerve
- Neurological, vascular, or visceral injury
- Temporary or permanent pain
- Deformities
- Circulatory disorders
- Infection, sepsis, abscess formation
- Adjacent segment degeneration
- Postoperative overgrowth of scar tissue

In rare cases, some complications can be lethal.

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

- Breakage or loosening of the implant (due to overstress, non-physiological use, damage, improper handling or implantation)
- Loosening of the implant (due to changed conditions of load transmission,or destruction of the bone bed and/or reaction of the tissue to the implant)
- Dislocation, subluxation
- Physiologically restricted movements, pain
- Lack of or delay in healing of bone tissue (development of pseudarthrosis)
- Fracture of the vertebra (due to unilateral overloading or weakened bone substance)
- Disease of the adjacent segments (connection degeneration / degradation)
- Malpositions
- Sensitivity to the metal or allergic reaction to a foreign body
- Reduction in the bone density due to stress shielding
- Symptoms of paresthesia (abnormal sensations such as numbness, tingling, feeling of warmth or cold)

- Transient or permanent nerve damage due to pressure, hematoma, or lesion leading to motor deficits and nerve damage
- Dura injury
- Paralysis

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 considering the possibility of implant surgery. ROCCIA PLIF is a system in which the physician can select the implant on a patient-specific basis. Depending on stability and the sagittal profile, ROCCIA PLIF 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 (D30048).
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 PLIF 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 (MR) compatibility:

The ROCCIA PLIF implant was not tested for migration or warming in an MR environment. In computed tomography (CT) or magnetic resonance imaging (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.

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.

The patient must be informed that implants can have an impact on the outcome of CT scan or MRI examination as well as the possible negative consequences. The patient must also be instructed to inform the examining physician about the implant and to show his/her implant pass prior to a scheduled CT scan or MRI examination.

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 unless this is expressly stipulated in the Instrumentation Guide. 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 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.

Only the respective Silony Medical instruments and manipulation implants (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.

The implants must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label. Sterile packed products for which the expiration date of the sterile packaging has expired must not be used. 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 is damaged, they must not be used. 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 passing on Silony Medical products (in return for payment or free of charge), any party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

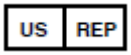
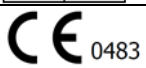
The information and symbols on the packaging must be observed.

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 PLIF 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 / European Directive 93/42/EEC
	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

Symbol	Description according to ISO 15223-1 and Silony specifications
STERILE R	Sterilized using irradiation
	Non-sterile
	Do not reuse
	Do not resterilise
	Do not use if the packaging is damaged
	Store in a dry place
	Keep away from sunlight
MR	MR* safe
	Caution MR* conditional safe
	Attention MR* unsafe
	Metal detectors can trigger alarm due to the implant
	Contact
	Cage angle

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

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Distribution countries / Official language			
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Belgium / Belgian/French/Dutch	Netherlands / Dutch	Spain / Spanish	Cyprus / Greek
Germany / German	Austria / German	Czech Republic / Czech	
Greece / Greek	Switzerland / German/Italian/French	United Kingdom / English	CE 0483