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Instructions for Use for the Spinal Implants in the System:

ROCCIA® PLIF

CE 0483

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:

- Reprocessing Instructions for Instruments (D30003)
- Instrumentation Guide for ROCCIA PLIF (D30048)

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 attendance at applicable user training courses.

We kindly request timely notification if complications should occur in connection with the implants and instruments used.

These instructions for use do not apply to the USA or its territories.

1 Product Description

The ROCCIA PLIF implant (posterior lumbar interbody fusion) is used for surgical treatment of degenerative disorders of the lumbar spine 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 aim is to eliminate discogenic back pain, correct deformities, remedy instabilities, restore intervertebral height, restore physiological lordosis, and provide biomechanical support for bone fusion in the disc space.

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.

The ROCCIA PLIF implant is manufactured from PEEK in accordance with ASTM F 2026 and tantalum in accordance with ASTM F 560.

The ROCCIA PLIF implant 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 implants must not be resterilized after opening the package—even if they were not used. Resterilization has not been validated for the implants.

When removing the implant from the packaging, the implant must be verified against the description on the packaging.

The patient labels in the primary packaging must be attached to the patient file or the surgical report.

2 General Information and Warnings

The ROCCIA PLIF implant may only be used in the field of human medicine for the indications listed in Section 3.

The ROCCIA PLIF System may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques.

Implants are always part of a system. They may only be combined with the original instruments that form part of the same system unless they are instruments that are generally used in an operating room or instruments described in the surgical technique. For system compatibility, refer to the Instrumentation Guide (D30048). Any liability for third-party instruments used by the purchaser or user is excluded. Exceptions to these rules require the express permission of Silony Medical.

The use of implants for other purposes is prohibited.

Complications or other consequences that may be due to an incorrect indication or surgical technique, unsuitable choice of material or treatment, improper use or treatment of the instruments, asepsis, etc., are the responsibility of the surgeon and cannot be attributed to the manufacturer, the importers, or suppliers of products of Silony Medical.

Preoperative planning:

The implantation of the ROCCIA PLIF implant must be precisely planned using a suitable imaging method. The potential success of surgery depends directly on the correct choice of implant. 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 the patient has an allergy to the implant material.

For the surgical procedure, all possibly required implant types in the combination recommended by the manufacturer as well as the instruments needed for implantation must be available if, for example, a different size or a different implant is required.

Notes on Use:

Implantation should generally only ever be considered if all other conservative 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.

Even a successfully implanted cage is inferior to the healthy motion element(s) of the spine. Conversely, 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.

Any implant is subject to inevitable wear and tear. A cage that was initially stable upon implantation may become loose or functionally impaired over time. This can lead to, e.g., implant fracture, wear, aging, and loosening, which can result in revision surgery.

Removal of the implant is possible, provided it is performed in accordance with the instrumentation guide. The decision must be made by the attending physician. If fusion has already occurred, the implant can be removed without additional measures; however, this is not necessary and is usually not done due to the high levels of stress associated with the surgery.

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 in an unauthorized way must not be implanted under any circumstances. They must be returned to the supplier for checking or proper disposal.

Prior to implantation, the implant must be visually inspected for damage. Damaged implants must not be used.

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. Reusing an implant or implant component that was previously implanted in the body of the patient or reusing an implant that has come into contact with body fluids or tissues of a third person is prohibited.

Even if the implant appears to be intact, it may have defects and invisible damage due to excessive stress that can lead to premature wear and tear.

In the event of overloading, damage, improper implantation, or improper handling, implants may fracture, become loose, wear out excessively, or become functionally impaired. In isolated cases, there may be corrosion of the implant.

Any additional warnings (e.g., warning label on the packaging) must be followed.

Magnetic resonance (MR) compatibility:
The ROCCIA PLIF implant was not tested for migration or warming in an MRI 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 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.

The patient must be informed that implants can have an impact on the outcome of CT scan or MRI examination as well as about 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.

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 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.

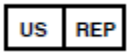
Only the respective Silony Medical instruments and manipulation implants (trial implants) must be used when selecting and adjusting the implants. The implants must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label. Sterile packed 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.

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.

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.

7 Glossary of Symbols

	Manufacturer
	US representative
	Article number
	Lot number
	Number of items
	Store in a dry place
	Keep away from sunlight
	Do not use if the packaging is damaged
	Consult instructions for use
	Caution - consult instructions for use
	The product meets the requirements of EU Directive 93/42/EEC.
	Do not reuse
	Do not resterilize
	Use by *Including the year and month in the following format: YYYY-MM-DD*
	Sterilized using irradiation
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Contact
	Cage angle