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Instructions for Use of the Spinal Implants in the System

ROCCIA® TLIF

CE 0483

Important Information—Please Read Before Use!

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These Instructions for Use apply to ROCCIA TLIF 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 TLIF (D30080)
- Product-specific inserts

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 TLIF (transforaminal lumbar interbody fusion) Cage is an implant for primary stabilization and restoration of physiological lordosis in the lumbar and thoracic spine. The cage is designed for posterior approaches.

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.

It must be used with additional stabilization. For posterior lumbar stabilization, Silony Medical recommends the use of a posterior spinal fixator (e.g., the VERTICALE system).

The ROCCIA TLIF Cage is manufactured from titanium alloy in accordance with ASTM F136 / ISO 5832-3.

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). The article number is preceded by an "S" on the label of implants delivered sterile.

Implants of the ROCCIA TLIF System are supplied both sterile and non-sterile.

1.1 Sterile Implants

Sterile products are packaged in accordance with EN ISO 11607 Parts 1+2 and sterilized using 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.

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

1.2 Non-sterile Implants

Implants that are supplied non-sterile must not be implanted without prior cleaning/disinfection and sterilization; see Section 6 of these instructions for use.

2 General Information and Warnings

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

The ROCCIA TLIF System may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques. The surgical technique for implants from Silony Medical can be learned as part of guest visits during surgical procedures for demonstration purposes, workshops, and courses at a hospital familiar with these implants.

Implants and instruments 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 instrumentation guide. For system compatibility, refer to the Instrumentation Guide (D30080).

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 TLIF must be precisely planned using a suitable imaging method. The potential success of surgery depends directly on the correct choice of implant. The x-ray images provide important information about the suitable type of implant, its size and possible combinations. Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome. Prior to surgery, it must also be clarified whether the patient has an allergy to the implant material.

For the surgical procedure, all implant types in the combination recommended by the manufacturer that may be required as well as the instruments needed for implantation must be available if a different size becomes necessary.

Notes on Use:

Implantation should 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 TLIF is a system that enables the physician to select the implant on a patient-specific basis.

Even a successfully implanted device is inferior to the healthy movement element(s) of the spinal column. Conversely, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic movement element(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. An implant 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.

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.

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

Implants are for single use only and must not be reprocessed after use in a patient and contamination with blood or tissue. Reusing an implant or implant component that was previously implanted in the body of a patient or reusing an implant that has come into contact with body fluids or tissues of a third person is prohibited.

Violations may result in the following health risks:
- Risk of transfer of pathogens due to inadequate cleaning
- Limited functionality due to cleaning, disinfection and sterilization
- Risk of cross-infection

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.

When removing the implants from the trays, particular attention must be paid to ensure that those implants remaining in the tray are not contaminated with blood, tissue, or other contaminants. Implants must always be removed with the utmost care and never while wearing contaminated gloves.

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 TLIF implants have not been tested for migration or warming in the 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 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 scans or MRI examinations 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.

3 Indications

Implants of the ROCCIA TLIF System are intended for use on the lumbar and thoracolumbar spine for the following indications:

- Degenerative disc diseases
- Deformities
- Segmental dysfunctions of the lumbar or possibly also thoracolumbar spine
- Spondylolisthesis
- Segmental instability
- Stenosis

4 Contraindications

4.1 Absolute Contraindications

- Anticipated or documented allergy or intolerance to the materials (e.g., titanium).
- 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, an increase in the erythrocyte sedimentation rate that cannot be explained by other diseases, or a significant shift in the differential blood count or other parameters.

5 Possible Negative Consequences

Like all major surgical procedures, there are risks associated with orthopedic surgery.
Sporadic operative and postoperative complications that can lead to a need for further surgery include the following:

- Allergic reaction to anesthetic or medications
- Long-term damage to the spinal cord due to general or spinal anesthesia
- 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, the spinal cord, or peripheral nerves
- Bleeding, secondary bleeding, hematoma, anemia

- Impaired motor function or sensitivity (due to nerve lesions, dura lesions with loss of cerebrospinal fluid, neuropathy, paraplegia)
- Thromboses, pulmonary embolism
- Soft tissue injury → loss of function of the muscles supplied by the nerve
- Pleural effusions, atelectasis
- Subcutaneous emphysema
- Rib fracture
- Temporary to permanent pain
- Circulatory disorders
- Infection, sepsis, abscess formation
- 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)
- Loss of fixation / displacement 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) to dislocation, subluxation
- Adjacent segment degeneration
- Restricted movement
- Lack of or delay in bone healing (development of pseudarthrosis) to vertebral body fracture
- Malpositions
- Injury to vascular, visceral, or neurological structures through to temporary or permanent damage as a result of pressure, hematoma, or lesion which lead to motor deficits or nerve damage
- Injury to the ureter
- Metal intolerance 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)
- Paralysis
- Death

6 Cleaning/Disinfection and Sterilization

This section applies only to implants that are supplied non-sterile. Implants delivered by the manufacturer in a sterile condition may not be resterilized.

Implants that are delivered non-sterile must not be implanted without prior cleaning/disinfection and sterilization. The original packaging must be completely removed before cleaning the product for the first time.

Please also comply with the applicable legal provisions and the relevant hygiene regulations of the health authorities in your country.

6.1 Cleaning/Disinfection

The following general rule applies: automated processing must be used for cleaning and disinfection. Manual reprocessing must not be used because of its markedly lower effectiveness.

Requirements for the cleaning and disinfection procedure:

- The cleaning and disinfection equipment (CDE) used must comply with the standard EN ISO 15883 and be CE marked.
- Validated reprocessing procedures
- Regular servicing and testing of the CDE
- The program used must meet the minimum requirements in Table 1.

Selecting cleaning agents and disinfectants:

When selecting the cleaning agent system to be used, please ensure that the chemicals used are compatible with the implants. Non-sterile implants must not come into contact with agents containing chlorine, phosphorus, formaldehyde or fluorine, bleaching agents, detergents containing fats, or strong acids and alkalis (bases).

It is crucial that the concentrations and exposure times indicated by the manufacturer of the cleaning agents and, where applicable, disinfectants are observed.

For cleaning, a cleaning agent with a pH value of > 10 is recommended. The pH value of the Neodisher MediClean forte (Dr. Weigert) product used for the validation is between 10.4 and 10.8 at the dosage indicated in Table 1.

Workflow:

1. Remove the implants from the protective packaging and place them into the fixture in the tray insert.
2. Position the tray according to the validated procedures into the CDE, ensuring that no areas are left unwashed (attention: do not stack multiple trays on top of one another. Automated cleaning in the CDE must always be carried out without the cover.)
3. Starting the program

Level	**Water**	**Cleaning agent**	**Temperature**	**Holding time**
Pre-wash	Tap water	-	unheated	2 min
Emptying	-	-	-	-
Main cleaning	Tap water	DOS 0.5%*	55°C	5 min
Emptying	-	-	-	-
Rinsing	Demineralized water	-	unheated	3 min
Emptying	-	-	-	-
Rinsing	Demineralized water	-	unheated	2 min
Emptying	-	-	-	-
Thermal disinfection	CDE program on thermal disinfection: The country-specific national requirements for the applicable A_0 value must be taken into account. If no other value is specified, an A_0 value of at least 3000 must be used.			
Drying	Program with adequate drying of the products with at least 10 minutes holding time. Please also note the instructions of the CDE device manufacturer!			

Table 1

* Neodisher MediClean forte (Dr. Weigert)
** Demineralized water

4. After the program has ended, remove the tray from the CDE and release the cleaning lot.
5. Pack the tray as soon as possible after removal and, if applicable, cool.

6.2 Sterilization

Only sufficiently cleaned, disinfected implants packaged in a suitable and approved SBS (Sterile Barrier System) may be sterilized. The implants may be sterilized only using a validated steam sterilization method in accordance with EN ISO 17665. A fractioned vacuum procedure must be used.
The following requirements for the parameters apply:

- Steam sterilizer in accordance with EN 13060 and EN 285
- Valid commissioning and performance evaluation
- Minimum sterilization temperature: 134°C
- Maximum sterilization temperature: 137°C (value corresponds to minimum temperature plus tolerance of +3°C in accordance with EN 285)
- Minimum sterilization time (holding time): 3 min
- Sufficient drying of the products at the end of the process of at least 10 min

As a general rule, sterilization with hot air must not be used (implants can be destroyed). The use of other sterilization procedures (e.g., ethylene oxide, formaldehyde, radiation, and low-temperature plasma sterilization) is beyond the manufacturer's responsibility.

6.3. Directions for Recleaning and Resterilization

Implants that are supplied non-sterile can be added to the cleaning and sterilization process multiple times provided that they have not been contaminated with body fluids, blood, or bone.

In the event of contamination of the holders or other points of the storage system supplied by Silony Medical, this must be brushed off thoroughly and rinsed until no more soiling is visible.

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.

Implants must be stored in the unopened original packaging and must not be damaged.

Implants that are supplied sterile must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label. 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.

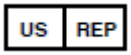
Implants that can no longer be used can be disposed of in accordance with the regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.

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 Glossary of Symbols

	Manufacturer
	US representative
	Catalogue number
	Batch Code
	Keep dry / Keep away from rain
	Keep away from sunlight
	Do not use if the packaging is damaged
	Consult instructions for use
	Attention—read instructions for use
 0483	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
	Non-sterile
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Number of items
	Contact
	Cage angle
Color on the label	The color on the label helps to make the correct choice of cage size: please consult the instrumentation guide for more information.