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This package leaflet applies to

Spinal implants of the system
ROCCIA® TLIF

Separate package leaflets are available: for the reprocessing of the instruments (D6007) and instrumentation guide (D60012) needed for implantation.

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1. Description

The ROCCIA TLIF (Transforaminal Lumbar Interbody Fusion) cage is an implant for the primary stabilization and restoration of the physiological lordosis of the lumbar and thoracic spine. The cage is designed for posterior approach.

The aim is to eliminate the discogenic back pain, to correct deformities, to correct instabilities, to restore the intervertebral height, to achieve a physiological re-lordosis and to biomechanically support a bony fusion in the disc space.

The system is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA TLIF is manufactured from titanium alloy conforming to ASTM F136 and ISO 5832-3. The implants are available in various sizes to suit the individual pathology and anatomical conditions of the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

2. Warnings, Cautions and Precautions

The ROCCIA TLIF cage is to be exclusively applied within the indications listed under point 3.

Products of Silony Medical may only be implanted by surgeons who are familiar with the intricacies of spinal surgery and experienced in the product-specific instrumentation guide.

Compatibility: The ROCCIA TLIF cages should be used only with the appropriately designated instruments as referred in the instrumentation guide (D60012). All components should be finally used as specified in the instrumentation guide.

The correct selection of the implant is extremely important. The potential for success of a surgery directly depends on the correct selection of the proper size and design of the implant. The radiographs provide important information about the appropriate implant selection. The omission of a preoperative planning can have a negative impact on the operating result.

While the right selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. An implant cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials. These devices can break when subjected to the increased load associated with delayed union or nonunion.

Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Implants must neither be mechanically adapted nor modified in any other form. Contaminated, non-sterile, damaged, scratched, improperly treated or unauthorized changed implants must never be implanted.

Even if the implant appears to be intact, there may be minor defects and nonvisible excessive stress that can lead to premature wear and tear.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. Over-distraction of the disc space can lead to facet over-distraction and spinous process contact. Confirm lateral fluoroscopy shows proper sagittal alignment.

The TLIF cage is delivered sterile and must not be reprocessed again. If the package is damaged or the expiry date is expired, the implant is unusable.

Implants are for single use only and must not be reprocessed after use in a patient and contamination with blood or tissue. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

End of life of each implant is normally determined by unavoidable wear. A stable implanted device at the beginning can become loose over time or be functionally impaired, and this can lead breakage, wear, aging and loosening of the implant which may require a new surgery.

Even a successfully implanted cage is defeated the healthy musculoskeletal system of the spine. Conversely, an implant for the patient may be an advantageous substitute for one or more pathological(s) and / or symptomatic(s) movement element(s).

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion.

Magnetic Resonance Imaging (MRI) Safety Information: The ROCCIA TLIF implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the ROCCIA TLIF implants in the MR environment is unknown. Scanning a patient who has this device may results in patient injury.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

2.1 Preoperative warnings

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
- Instruments are delivered non-sterile and should be cleaned and sterilized before use.
- Inspect all components for damage before use.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

2.2 Post-operative warnings

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

3. Indications for Use

The ROCCIA TLIF Cage is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. The device is to be used in patients who have had at least six months of non-operative treatment.

The ROCCIA TLIF Cage implants are intended for use in interbody fusions at one or two contiguous levels in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), following discectomy for the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

The ROCCIA TLIF Cage implants are intended for use at one or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The ROCCIA TLIF Cage implants can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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 the use of the implant would be in conflict with the anatomical structures
- Missing bone structures that render good anchoring of the implants impossible (e.g. in fractures, tumors, osteoporosis or infections).

4.2 Relative Contraindications

- Overweight patient
- Malfunctions
- Fever or leukocytosis
- Systemic diseases and metabolic disorders
- Unbalanced diet, abuse of pharmaceutical drugs, consumption of nicotine, alcohol, or Drugs
- Physical activity involving strong vibrations during which the implant is exposed to impact and /or excessive stress (e.g. heavy physical work, competitive sport, marathons
  alpine skiing, jumping and team sports)
- Patients who are mentally unable to understand and to follow the physician's instructions
- If possible, surgery on pregnant women should be avoided or require particular care or procedures. They should only be performed at the discretion of the surgeon
- Any condition which could exclude the potential benefit of a spinal implantation must be clarified by the responsible physician. This may include tumors, unexplained increase of the erythrocyte sedimentation rate by other diseases, a substantial shift in the complete blood count or other parameters.

5. Potential adverse events and complications

As with all major surgical procedures, there are risks in orthopedic surgery. Irregular operative and postoperative complications that may lead to the need for further operations include:

- Permanent damage of the spinal cord by full / spinal anesthesia;
  Allergic reaction to anesthetic or drugs
- Cardiovascular disease (with blood clots, blood pressure drop, myocardial infarction, stroke, death)
- Early and late Infections, delayed wound healing, cross-infection
- Damage to blood vessels, damage to spinal cord or peripheral nerves
- Disruption in motor function and sensitivity due (to nerve lesions, dural lesion with cerebrospinal fluid loss, neuropathy, paraplegia)
- Thrombosis, pulmonary embolism
- Soft tissue injury → loss of function of the nerve-supplied muscles
- Pleural effusions, atelectasis
- Subcutaneous emphysema

- Rib fracture
- Temporary to permanent pain
- Bleeding, secondary bleeding, hematoma, anemia
- Circulatory disorders
- Infection, sepsis, abscess formation
- Postoperative scarring.

Rarely, can some complications be fatal.

Possible risks identified in relation with the use of this system and which may require further treatment include:

- Implants can break or become loose or displaced (as a result of overstress, nonphysiological use, damages, improper handling or implantation)
- Loosening of the implant / shifting of the implant (due to unchanged conditions of load transmission, destruction of the bone bed and /or reaction of the tissue to the implant) up to dislocation, subluxation
- Connection degeneration
- Restricted freedom of movement
- Lack of healing of bone tissue (formation of the pseudarthrosis) up to bone fracture
- Malpositions
- Injury of vascular, visceral or neurological structures up to intermittent or persistent injury resulting from pressure, hematoma or lesion, which lead to motor deficits and nerve damage
- Metal intolerance or allergic reaction to a foreign body
- Decrease of bone density by stress-shielding
- Discomfort or paresthesia (disturbed sensations such as numbness, tingling, hot or cold sensation)
- Paralysis
- Death.

6. Application notes

A surgical-invasive procedure is only to be taken into consideration when all other conservative treatment options have been carefully weighed and not recognized as being better.

The ROCCIA TLIF cage is intended for implantation. The ROCCIA TLIF cages should be used only with the appropriately designated instruments as referred in the instrumentation guide (D60012).

The surgery must be precisely planned based on the X-ray findings. The X-ray images provide information about the suitable type of implant, its size and about possible combinations. The omission of a preoperative planning can lead to mistakes.

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

It is the responsibility of the treated surgeon to consider the possibility of the implantation. With the ROCCIA TLIF Cage the physician can choose the implant personalized matched to the patient.

Prior to the surgery it must also be confirmed whether that patient has an allergy to the implant material. Failure to perform adequate preoperative planning can lead to errors (e.g. with regard to misalignment, the choice of implant, and its size).

For the procedure of implantation of the device please refer to the Instrumentation guide (D60012).

The removal of the implant is possible according to the instrumentation instructions, whereas must be decided by the treated surgeon.

Patient information

The physician is responsible for informing the patient about the risks of an implantation and about the possible effects on the success of the surgical procedure and on the negative consequences. Furthermore, the patient must be informed about the measures he/she can take to minimize the possible effects of these factors. An implant pass must also be issued to the patient.

7. Cleaning / Decontamination und Sterilization

ROCCIA TLIF implants are delivered sterile (gamma radiation sterilization, ISO 11137-2 VDmax 25) and must not be reprocessed.

All instruments of the ROCCIA TLIF system must first be thoroughly cleaned using the validated methods prescribed in the Silony Reprocessing guideline for surgical instruments (D60007.) before introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization.

8. Packaging, Handling and Storage

Packages for each of the components should be intact upon receipt. Implants are delivered sterile and should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Silony.

Implants are extremely sensitive to damage. Even small scratches or impact points on the surfaces can already lead to excessive wear, tear and may cause complications. Extremely careful handling is therefore indicated.

The surfaces of implants must be neither labeled nor come into contact with metal or hard objects, unless this is expressly provided in the description of the surgical technique.

Sterile implants must be stored unopened in the original package.

The selection of an implant size is to exclusively be made by using the sample implants. No longer applicable implants, can be returned to the manufacturer free of charge for professional disposal. Please take notice of the instructions and symbols on the packaging.

9. Glossary of Symbols

Symbol	Title of Symbol /Explanatory Text	Standard Reference
REF	Catalogue number	ISO 15223-1, Clause 5.1.6
LOT	Batch code	ISO 15223-1, Clause 5.1.5
	Use by Date	ISO 15223-1, Clause 5.1.4
	Manufacturer	ISO 15223-1, Clause 5.1.1
US REP	U.S. Representative	ISO-15223-1, Clause 5.1.2
	Follow Instructions for Use	ISO 15223-1, Clause 5.4.3
	Attention – read instruction for use	ISO 15223-1, Clause 5.4.4
STERILE R	Sterilized using irradiation	ISO 15223-1, Clause 5.2.4
	Do not re-use	ISO 15223-1. Clause 5.4.2
	Do not resterilize	ISO 15223-1, Clause 5.2.6
	Do not use if package is damaged	ISO 15223-1, Clause 5.2.8
	Keep dry / Keep away from rain	ISO 15223-1, Clause 5.3.4
	Keep away from sunlight	ISO 15223-1, Clause 5.3.2
CE 0483	The device complies with European Directive MDD 93/42/EEC	MDD 93/42/EEC
Rx only	Prescription Use Only	21 CFR 801.109