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This package leaflet applies to

Spinal implants of the system
ROCCIA® PLIF

Separate package leaflets are available: for the reprocessing of the instruments (D60007) and instrumentation guide (D60015) needed for implantation.

Table of Content

1. Description

The Silony Medical ROCCIA PLIF cage is manufactured from Polyetheretherketone (PEEK) conforming to ASTM F2026 and Tantal according to ASTM F 560. The ROCCIA

PLIF cages 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. Indications for use

The ROCCIA PLIF System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the ROCCIA PLIF System is indicated in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open posterior approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

3. Contraindications

Contraindications include, but are not limited to:

- Infection local to the operative site
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Any other condition which would preclude the potential benefit of spinal surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Suspected or documented allergy or intolerance to composite materials
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery

- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
- Spondylolisthesis unable to be reduced to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level(s) to be treated

4. Potential adverse events and complications

Adverse effects may occur when the device is used with or without associated instrumentation. The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration
- Breakage of the device(s)
- Foreign body reaction to the implants including possible tumor formation, auto immune diseases, and scarring
- Pressure on the surrounding tissue or organs
- Loss of proper spinal curvature, correction, height, and reduction
- Infection
- Bone fracture or stress shielding at, above, or below the level of surgery
- Non-union (or pseudoarthrosis)
- Loss of neurological function, appearance of radiculopathy, dural tears, and development of pain
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury
- Cerebral spinal fluid leakage
- Haemorrhage of blood vessels and hematomas
- Discitis, arachnoiditis, and/or other types of inflammation
- Deep venous thrombosis, thrombophlebitis, and pulmonary embolus
- Bone graft donor site complication
- Inability to resume activities of normal daily living
- Early or late loosening or movement of the device(s)
- Urinary retention or loss of bladder control or other types of urological system compromise
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and vertebral body) and bone graft harvest site at, above, or below the level of surgery

- Retropulsed graft
- Herniated nucleus pulposus, disc disruption, or degeneration at, or below the level of surgery
- Loss of increase in spinal mobility or function
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status
- Cessation of any potential growth of the operated portion of the spine
- Death

5. Warnings, Cautions and Precautions

- The ROCCIA PLIF cage is intended for use only as indicated.
- The ROCCIA PLIF 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. ROCCIA PLIF cages are for single use only and must not be reprocessed after use in a patient and/or contamination with blood or tissue.
- 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.
- Correct selection of the implant may be critical for a successful result. While the correct selection could help reduce risks, the size and shape of human bones present limitations to the size and strength of implants. An implant cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. ROCCIA PLIF cages 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. ROCCIA PLIF cages may fracture when subjected to increased loads associated with a delayed union or nonunion.
- Internal fixation pedicle screw systems are load-sharing devices that hold bony structures in alignment until healing occurs. In case healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the ROCCIA PLIF cage produced by load bearing and by the patient's activity level will dictate the longevity of the implant.
- Single Use: 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.

- Magnetic Resonance (MR) Safety: The ROCCIA PLIF cage has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.
- Compatibility: The ROCCIA PLIF cages should be used only with the appropriately designated instruments as referred to in the instrumentation guide (D60015). All components should be finally used as specified in the instrumentation guide.
- Notching, striking, and/or scratching of ROCCIA PLIF cages 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.
- 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.
- 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.

6. 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 taken 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 each ROCCIA PLIF cage for damage before use.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

7. 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.

8. Method of Use

The ROCCIA PLIF cage is for implantation. The ROCCIA PLIF cages should be used only with the appropriately designated instruments as referred in the instrumentation guide (D60015). 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. For the surgical procedure, all possibly required ROCCIA PLIF cage 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 ROCCIA PLIF cage is required.

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

For the procedure of implantation of the device please refer to the instrumentation guide (D60015).

9. Packaging

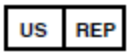
Packaging for each ROCCIA PLIF cage should be intact upon receipt. ROCCIA PLIF cages are delivered sterile and should be carefully examined for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Silony Medical Corp.

10. Cleaning, Decontamination and Sterilization

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

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

11. Glossary of Symbols

Symbol	Title of Symbol/Explanatory Text	Standard Reference
	Catalogue Number	ISO 15223-1, Clause 5.1.6
	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
	U.S. Representative	ISO 15223-1, Clause 5.1.2
	Consult Instructions for Use	ISO 15223-1, Clause 5.4.3
	Attention – read instruction for use	ISO 15223-1, Clause 5.4.4
	Sterilized using Radiation	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	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