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This package leaflet applies to

Spinal implants of the system
ROCCIA® ACIF

Separate package leaflets are available: for the reprocessing of the instruments (D60007) and instrumentation guide (D60001) needed for implantation.

Table of Content

1. Description

The Silony Medical ROCCIA ACIF is manufactured from PEEK conforming to ASTM standard F2026 and titanium alloy conforming to ASTM standard F136 or 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. Indications for use

The ROCCIA ACIF is indicated for intervertebral body fusion of the spine in skeletally mature patients. The ROCCIA ACIF is intended for use for anterior cervical interbody fusion in patients with cervical disc disease (DDD) at up to two contiguous levels from C2 to T1. The System is intended to be used with supplemental fixation; the ROCCIA ACIF device is required to be used with an anterior cervical plate as the form of supplemental fixation. The System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

3. Contraindications

Contraindications include but are not limited to:

- Infection, local on the operative site
- Signs of local inflammation
- Anticipated or documented allergy or intolerance to composite materials
- Patients who are unwilling to restrict activities or follow medical advice
- Patients with inadequate bone stock or quality
- Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
- Patient for whom the use of the implant would be in conflict with anatomical structures
- Any case in which the chosen implants would be too large or too small to achieve a successful result
- Use with components of other systems
- Reusable or multiple uses
- Resterilization of the implants

4. Potential adverse events and complications

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early and late infection, cross infection, damage to blood vessels, damage to spinal cord or peripheral nerves, epidural hematoma, pulmonary emboli, loss of sensory and motor function and permanent pain and deformity. Rarely some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include: bending, fracture or loosening of the device, loss of fixation, non or delayed union, epidural hematoma, neurological, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, infection, decrease in bone density due to stress shielding, pain, discomfort or

abnormal sensations, nerve damage due to surgical trauma, bursitis, dural leak, paralysis and death.

5. Warnings, Cautions and Precautions

- The ACIF cage is intended for use only as indicated.
- The ACIF 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 reused and reprocessed after use in a patient and 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 is extremely important. The potential success depends directly on the right selection of the proper size of implant. 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.
- 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 AICF 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 ACIF implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Compatibility: The ROCCIA ACIF cages should be used only with the appropriately designated instruments as referred in the instrumentation guide (D60001). Do not use with components of other systems. All components should be finally used as specified in the instrumentation guide.

- 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.
- 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 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.

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 ACIF cage is for implantation. The ROCCIA ACIF cages should be used only with the appropriately designated instruments as referred in the instrumentation guide (D60001). 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 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.

Prior to the surgery it must also be clarified 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 (D60001).

9. Postoperative Mobilization

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

10. Packaging

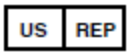
Packages for each of the components should be intact upon receipt. Implants are delivered sterile and should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Silony.

11. Cleaning, Decontamination and Sterilization

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

All instruments of the ROCCIA ACIF 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.

12. 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

	Follow 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 / Keep away from rain	ISO 15223-1, Clause 5.3.4
	Keep Away from Sunlight	ISO 15223-1, Clause 5.3.2
	The device complies with European Directive MDD 93/42/EEC	MDD 93/42/EEC
	Prescription Use Only	21 CFR 801.109