



COUGAR[®] LS Lateral Cage System

DePuy Spine prepares Surgical Technique Manuals showing the use of the implants and instruments for each Spine System. Contact your DePuy Spine sales representative to obtain copies of these Surgical Technique Manuals.

DESCRIPTION

The COUGAR® LS Lateral Cage System consists of the carbon fiber reinforced PEEK (CFRP) cages. Cages are available in parallel or lordotic configurations and are available in various sizes to match patient anatomy. The cage structure is radiolucent with tantalum x-ray wire so that healing can be assessed by normal radiographic methods. The cages have teeth that resist rotation and migration and have cavities to accept packing of autogenous bone graft.

The implants may be utilized in either an open or minimally invasive surgical approach. The implants are placed using a lateral surgical approach. The implants are manufactured from PEEK Optima material.

INDICATIONS

Caution: USA Law restricts this device to sale by or on the order of a physician.

The COUGAR LS Lateral Cage System is indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These 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 and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

CONTRAINDICATIONS

1. Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.

3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated is a contraindication for this system when used for intervertebral body fusion in spine.
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

Following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to devices such as the COUGAR LS implants. General surgical risks should be explained to the patient prior to surgery.

The COUGAR LS implants are intended for use as an intervertebral body fusion cage. These implants are intended to be permanent. The following recommendations for removal of hardware apply to the supplemental internal fixation implants used in this procedure. Neuromonitoring may be considered when performing a lateral surgical approach.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for satisfactory intervertebral body fusion is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

When using the Cougar LS Lateral Cage System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

- 2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing (fusion) occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
- 3. COMPONENTS OF THIS SYSTEM SHOULD NOT BE USED WITH COMPONENTS OF ANY OTHER SYSTEM OR MANUFACTURER.**
- 4. MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Avoid coupling of stainless steel with these implants.
- 5. CLINICAL OUTCOMES MAY VARY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PRECAUTIONS

- 1. SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Polymer/carbon-fiber implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause splitting or fracture of the carbon-fiber implants. When a carbon-fiber implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the carbon-fiber implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.
3. **REMOVAL OF SUPPLEMENTAL FIXATION AFTER HEALING.** If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone fusion is complete. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.
5. **ANY CONDITION NOT DESCRIBED IN THE INDICATIONS FOR USE HAS NOT BEEN STUDIED.** The safety and effectiveness of these implants for conditions not listed in the indications for use has not been established.

POSSIBLE ADVERSE EFFECTS WITH THE COUGAR LS LATERAL CAGE SYSTEM IMPLANTS AND/OR METALLIC INTERNAL FIXATION DEVICES

This list may not include all complications caused by the surgical procedure itself.

1. Bending or fracture of implant. Loosening of the implant.
2. Implant material sensitivity, or allergic reaction to a foreign body.
3. Infection, early or late.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to the presence of the device.
6. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
7. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
8. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
9. Bursitis.
10. Paralysis.
11. Death.
12. Spinal cord impingement or damage.
13. Fracture of bony structures.
14. Reflex sympathetic dystrophy.
15. There is an additional risk if there were to be long term in vivo degradation of the polymer/carbon-fiber composite resulting in possible local or systemic adverse reactions from any potential degradation products.
16. If a pseudarthrosis occurs coupled with a mechanical grinding action this could possibly generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.
18. Subsidence

IMPORTANT NOTE TO OPERATING SURGEON

These procedures should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the COUGAR LS Lateral Cage System for use as an intervertebral body fusion device. The contents of these manuals alone are not adequate for complete instruction in the use of this system. Even for surgeons already experienced in spinal instrumentation and intervertebral body fusion procedures, new skills may be required, that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. The purpose of the COUGAR LS Lateral Cage System is to provide immediate spinal stability and to allow for consolidation of the fusion mass. If any implant of the COUGAR LS Lateral Cage System does break, the decision to remove it must be made by the physician, who must consider the condition of the patient and the risks associated with the presence of the broken implant.

Detailed instructions for placement and removal of COUGAR LS Lateral Cage System implants can be found in the Surgical Technique Manuals for Intervertebral Body Fusion Use. The Surgical Technique Manuals can be obtained from DePuy Spine sales representatives or by contacting the DePuy Spine Customer Service at +1-800-365-6633.

POSTOPERATIVE MOBILIZATION

Postoperative external immobilization (such as bracing or casting) is recommended, at the surgeon's discretion. 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.

CLEANING AND STERILIZATION

These instructions have been validated as being capable of preparing DePuy Spine implants for use. The implants are supplied clean and this is clearly identified on the package label. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Inspect visually for damage or the presence of blood or tissue. If blood or tissue is observed on the implant, it must be thoroughly cleaned manually using a soft brush and neutral pH detergent or discarded.

Cleaning instructions

- Enzyme soak
- Rinse
- Ultrasonic cleaning (10-20 minutes)
- Rinse
- Automated cleaning in a washer disinfectant with lid on to contain implant components
- Dry

Avoid impact, scratching, bending or surface contact with any materials that might affect the implant surface or configuration.

Special attention shall be paid to recesses since both chemicals and rinse water may be entrapped in them.

Implants previously implanted must **not** be re-used.

RECOMMENDATIONS FOR STEAM STERILIZATION:

The sterilization parameters for the devices are as follows:

In a properly functioning calibrated steam sterilizer, independent testing has shown that effective sterilization may be achieved using the following parameters:

Cycle:	Pre-Vacuum
Temperature:	270° F (132° C)
Exposure time:	4 minutes
Drying time:	45 minutes

Wrap implants in accordance with local procedures using standard wrapping techniques and FDA cleared wrap such as those described in ANSI/AAMI ST79:2006.

Post-sterilization drying of the sterilization load within the sterilization vessel is standard practice in hospitals. ANSI/AAMI ST79:2006, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" provides guidance to hospitals for selecting appropriate drying parameters based on the sterilization cycle that is being conducted. Sterilizer manufacturers also typically provide recommendations for drying parameters for their specific equipment.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The COUGAR LS Lateral Cage System(s) implants have not been evaluated for safety and compatibility in the MR environment. The COUGAR LS Lateral Cage System(s) implants have not been tested for heating or migration in the MR environment.

LIMITED WARRANTY AND DISCLAIMER

PRODUCTS FROM DEPUY SYNTHES PRODUCTS, INC. ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/ REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT DEPUY SYNTHES SPINE FOR CURRENT INFORMATION AT +1-800-365-6633 OR AT +1-508-880-8100.

SYMBOL TRANSLATION

LOT LOT NUMBER	 DO NOT RESTERILIZE	 SINGLE USE	STERILE STERILE	 MANUFACTURER
REF REF CATALOG NUMBER			 Lower Limit of temperature = T1 Upper Limit of temperature = T2	
QTY QUANTITY	 STORE AT ROOM TEMPERATURE	 PACKAGE CONTAINS FLAMMABLE LIQUID		STERILE R STERILIZATION BY IRRADIATION
SZ SIZE			 DO NOT USE IF PACKAGE IS DAMAGED	STERILE EO STERILIZATION BY ETHYLENE OXIDE
MADE IN MADE IN	 KEEP AWAY FROM SUNLIGHT	MSR MEASURING DEVICE		LATEX FREE LATEX FREE
NTI NEURAL TISSUE INSTRUMENT			 NONSTERILE NONSTERILE	 XXXX-XX USE BY
IOM NEUROMONITORING INSTRUMENTS	Federal (USA) law restricts this device to sale by or on the order of a physician			

PEEK/C
PEEK/CARBON FIBER COMPOSITE
Polyether Ether Ketone/
Carbon Fiber Composite



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