X-PAC Expandable LLIF Cage System IFU

EXPANDING INNOVATIONS, INC. X-PAC LATERAL EXPANDABLE CAGE SYSTEM PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE:

The X-PAC LLIF Cage System consists of an intervertebral body fusion device and instruments designed to facilitate implantation and is intended as an interbody fusion device to aid in the surgical correction and stabilization of the spine. The Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System implants are:

1. Constructed from Ti 6Al-4V, as described by ASTM F136
2. Available in multiple configurations of parallel or lordotic expansion.
3. The teeth on the superior and inferior ends resist expulsion in all directions.
4. The implant is fenestrated and contains openings to enhance bony ingrowth.
5. The device is open in the transverse plane to allow insertion of autogenous graft material into the device after placement.
6. For all indications, this device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbar spine.

The Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System is only offered non-sterile and must be steam sterilized before use.

Indications for Use

The Expanding Innovations X-PAC Expandable LLIF Cages are indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft. X-PAC Expandable LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The **X-PAC Lateral Expandable** implants are intended for single use only.

Contraindications

The operation should not be carried out against the following contraindications:

1. Infection local to the operative site
2. Signs of local inflammation
3. Pregnancy
4. Patients with known sensitivity to the materials to be implanted
5. Patients with an unwillingness or inability to follow the instructions for postoperative treatment
6. Muscular. neurological or vascular deficiencies, which compromise the affected extremity
7. Patients with inadequate bone stock or quality
8. Conditions that place excessive demand on the implant (i.e. Charcot's joints. muscle deficiencies, refusal to modify post-operative physical activities, skeletal immaturity)
9. Recurrent disc herniation
10. Severe osteoporosis
11. Paget's disease
12. Renal osteodystrophy
13. Cancer of the spine
14. Advanced diabetes
15. Rheumatoid arthritis
16. Immunological suppression

17. Sustained trauma with instability
18. Fracture of the vertebra
19. Degenerative spondylolisthesis exceeding Grade 1
20. Conditions requiring steroids in excess of usual doses
21. Obesity
22. Patients with physical or medical conditions that would prohibit beneficial surgical outcome
23. Prior fusion at the level(s) to be treated
24. All cases that are not listed under indications

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

Orthopedic surgery is a major surgical procedure, and as such, involves risks. Complications, both operative and postoperative, though infrequent, do occur and may include:

1. infection which may result in the need for additional surgeries
2. damage to blood vessels
3. damage to the spinal cord or peripheral nerves
4. pulmonary emboli
5. loss of sensory and/or motor function
6. impotence
7. permanent pain and/or deformity

Though rare, some complications may be fatal.

WARNINGS, CAUTIONS, AND PRECAUTIONS

The 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 metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

The Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of the Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System. The Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System procedure is technically demanding, presenting a risk of serious injury to the patient.

Potential risks identified with the use of this system which may require additional surgery, include:

1. device component fracture, micro-fracture, resorption, damage, or penetration of any spinal bone
2. disassembly, bending, and/or breakage of implant
3. loss of fixation
4. non-union (pseudoarthrosis), delayed union, mal-union
5. fracture of the vertebra, vertebral endplate injury
6. soft tissue injury
7. neurological injury
8. vascular or visceral injury
9. pain and loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss
10. early or late loosening of any or all of the components
11. failure of the device to provide adequate mechanical stability
12. foreign body (allergic) reaction to implant
13. post-operative change in spinal curvature, loss of correction, height, and/or reduction
14. infection
15. dural tears, persistent CSF leakage, meningitis

16. cauda equine syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss
17. loss of bladder control or other types of urological system compromise
18. scar formation possibly causing neurological compromise or compression around nerves and/or pain
19. herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
20. loss of or increase in spinal mobility or function
21. inability to perform the activities of daily living

The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, the size and shape of the human spine presents limiting restrictions of the size and strength of implants and should be considered.

Metallic internal fixation devices 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 stresses of full weight or load bearing alone. If fusion is delayed or a pseudoarthrosis occurs, the implant may break. The patient should understand that stress on an implant may in some cases result in failure of that implant.

Extremely osteoporotic bone may not be suitable for traditional forms of lateral spinal fixation and may increase the risk of implant failure. Should extremely osteoporotic bone be determined intraoperatively, the device may be removed, and an alternative approach should be considered.

As with all orthopedic implants, Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System implant should never be reused under any circumstances.

Do not implant into patients with known or suspected sensitivities to titanium.

Do not implant into patients with a presence of an active infection.

Do not implant into patients when conservative treatment is appropriate.

Metal implants in the human body are subjected to a chemical environment consisting of salts, acids and proteins that may cause corrosion due to galvanic corrosion effects. Dissimilar metals in contact with each other can accelerate the corrosion process; mixing of implant components from different manufacturers is never recommended for metallurgical, mechanical and functional reasons.
Certain degenerative diseases or physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process and risk implant failure.

These devices can break when subjected to the increased load associated with delayed union or non-union. 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. If a nonunion develops or if the components loosen, bend, and/or break, the implant(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the implant(s).

Implants may loosen, fracture, migrate, increase the risk of infection, cause pain, or stress shield bone, even after normal healing, particularly in young active patients. The surgeon should consider the risks and benefits when deciding whether or not to remove an implant. Implant removal should be followed by careful postoperative management to avoid refractures. If the patient is older and has a low activity level, the surgeon may elect not to remove the implant in order to eliminate the risks of another surgery.

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This device is meant to be used with lateral supplemental fixation (i.e. facet screw fixation systems, facet compression devices, and lateral pedicle screw and rod system). Confirm fusion before removing such fixation systems.

Based on fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.

Extreme care should be taken in the handling of the implants. No bending or changing of the implant's shape should be attempted. These may product internal stresses, which may cause eventual breakage.

A patient's mental or physical impairment, which compromises or prevents a patient's ability to comply with the necessary limitations or precautions of a metallic implant, may place that patient at a particular risk during postoperative rehabilitation.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Additional care should be taken to ensure a thorough discectomy is completed in order to correctly size, place, and expand the device. An incomplete discectomy may result in difficulty to fully deploy and place the device in its intended position.

Do not prepack the implant with autogenous graft material. Prepacking may prevent proper attachment and/or actuation of system.

Do not release the insertion device and/from the expandable cage until the surgeon is satisfied with the position and height of the cage. Once the cage has been released from the insertion device, it is extremely difficult to reattach to the cage.

Do not proceed with packing the expandable cage with autogenous graft material until the location and height of the cage are absolutely final. Once autogenous graft material has been installed in the cage, cage removal is extremely difficult.

Do not remove the cage cannula from the expandable cage until the location, height, and amount of autogenous graft material is satisfactory. Reattachment of the cage cannula to the cage is extremely difficult after removal.

Do not reuse implants. Ensure removed implants are not mixed in with the unused implants. Implants are only intended for a single installation and must never be re-implanted.

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. The patient should understand that a metallic implant is not as strong as a normal, healthy bone, and with time will fracture under normal weight bearing or load bearing in the absence of a fusion.

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:

1. Mechanical failure
2. Material degradation
3. Potential leachables
4. Transmission of infectious agents.

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MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The X-PAC Lateral Expandable Cage System has 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 X-PAC Lateral Expandable Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

COMPATIBILITY

Do not use the X-PAC Lateral Expandable Cage System with components of other systems unless otherwise stated.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the contraindications section should be avoided.
3. Care should be used in the handling and storage of the implants and implant instruments. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All implants and instruments are delivered non-sterile, and as such should be cleaned and sterilized before use.
5. Implants and instruments should be inspected for damage prior to use. Damage to the devices including pitting or corrosion indicates end of life of the device and should be removed from points of use.
6. Care should be taken during surgical procedures to prevent damage to the device(s) and injury to the patient.

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.

DIRECTIONS FOR USE

Refer to the Surgical Techniques manual for use directions.

PACKAGING

Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System is delivered only as non-sterile.
All Expandable Lumbar Cage implants must be cleaned, and steam sterilized (autoclaved) prior to implantation as described in "CLEANING AND DECONTAMINATION" and "STERILIZATION PROCEDURE" included below.

All implant and instrument sets should be carefully examined for completeness and damage, prior to use. Damaged implants or instruments should not be used and should be returned to Expanding Innovations, Inc.

MANUAL CLEANING PROCEDURE

Disassemble instruments (Refer to the user manual section titled Disassembly for Cleaning/Sterilization. Perform the manual cleaning procedure as follows:

1. Rinse the articles under cool running tap water.
   1.1. Remove all gross soil with a clean lint-free cloth.
   1.2. While rinsing, use an appropriately sized syringe filled with tap water to flush any hard to reach areas.
2. Prepare an enzymatic cleaning solution (MetriZyme or equivalent) per manufacturer's specification using warm tap water preferably in an ultrasonic cleaner where available.
3. Allow the articles to soak for 10 minutes with sonication where available.
   3.1. While soaking, actuate all moving parts through a full range of motion.

3.2. For the cannula with a flushing port, thoroughly and aggressively use a luer tip syringe to flush the cannula shaft through the port and observe the cleaning solution exit through all the holes in the distal end of the cannula until no debris is visible.

4. Remove the articles from the cleaning solution and wipe away any soil debris with a clean lint-free cloth.
5. Prepare a fresh bath using MetriZyme or equivalent) per manufacturer's specification using warm tap water. Fully immerse the articles for 10 minutes.
   5.1. While immersed, use a soft bristled brush to brush the exterior surfaces of the articles. Actuate all moving parts through a full range of motion while brushing.
   5.2. Use a lumen brush to reach any hard-to-reach areas.
   5.3. For the cannula with a flushing port, use a luer tip syringe to flush the cannula shaft through the port and observe the cleaning solution exit through all the holes in the distal end of the cannula until no debris is visible.
6. Prepare a bath with RO/DI water. Immerse the articles for a minimum of 30 seconds.
   6.1. While immersed, agitate the bath and actuate all moving parts through a full range of motion.
   6.2. Flush all hard to reach areas with an appropriately sized syringe filled with RO/DI water.
   6.3. Use a luer tip syringe filled with RO/DI water to flush the cannula shaft if a flushing port is available.
7. Dry all articles with a clean lint-free cloth.

AUTOMATED CLEANING PROCEDURE

Disassemble instruments (Refer to the user manual section titled Disassembly for Cleaning/Sterilization. Perform the automated cleaning procedure as follows:

1. Rinse the articles under cool running tap water.
   1.1. Remove all gross soil with a clean lint-free cloth.
   1.2. While rinsing, use an appropriately sized syringe filled with tap water to flush any hard to reach areas.
2. Prepare an enzymatic cleaning solution (MetriZyme or equivalent) per manufacturer's specification using warm tap water preferably in an ultrasonic cleaner where available.
3. Allow the articles to soak for 10 minutes with sonication where available.
   3.1. While soaking, actuate all moving parts through a full range of motion.
   3.2. For the cannula with a flushing port, thoroughly and aggressively use a luer tip syringe to flush the cannula shaft through the port and observe the cleaning solution exit through all the holes in the distal end of the cannula until no debris is visible.
4. Remove the articles from the cleaning solution and wipe away any soil debris with a clean lint-free cloth.
5. Prepare a fresh bath using MetriZyme or equivalent) per manufacturer's specification using warm tap water. Fully immerse the articles for 10 minutes.
   5.1. While immersed, use a soft bristled brush to brush the exterior surfaces of the articles. Actuate all moving parts through a full range of motion while brushing.
   5.2. Use a lumen brush to reach any hard to reach areas.
   5.3. For the cannula with a flushing port, use a luer tip syringe to flush the cannula shaft through the port and observe the cleaning solution exit through all the holes in the distal end of the cannula until no debris is visible.
   5.4. Prepare a bath with RO/DI water. Immerse the articles for a minimum of 30 seconds.
      5.4.1. While immersed, agitate the bath and actuate all moving parts through a full range of motion.
      5.4.2. Flush all hard to reach areas with an appropriately sized syringe filled with RO/DI water.
      5.4.3. Use a luer tip syringe filled with RO/DI water to flush the cannula shaft if a flushing port is available.
   5.5. Select the appropriate cycle as listed below:
   Motor speed: High

STAGE	RECIRCULATION TIME (minutes: seconds)	TEMPERATURE	DETERGENT/Water Type
Pre-wash 1	2:00	Cold	Utility Water
Enzyme Wash	5:00	Hot	½ oz./gallon (MetriZyme or equivalent)
Wash 1	5:00	Heated 43°C	½ oz./gallon (MetriZyme or equivalent)
Rinse 1	0:30	Heated 43°C	Utility Water
Thermal Rinse	2:00	Heated 64°C	Critical Water
Drying	15:00	66°C	N/A

5.6. Dry all articles with a clean lint-free cloth.

Inspect all devices for visible soil. If soil persists, begin cleaning procedure at step 1 again for any offending devices. Return devices to their proper location within the carrying case.

Rinse instruments with saline immediately after surgery for easiest cleaning. Inspect instruments after each use and ensure that all instruments are functional.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Certain cleaning solutions such as those containing bleach or formalin may damage some devices and should not be used.

Contact your Expanding Innovations, Inc. representative for any additional information related to cleaning and sterilization of Expanding Innovations, Inc. surgical instruments.

STERILIZATION PROCEDURE

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components of the Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System are sterilizable by steam autoclave using standard hospital practices. Device carrying cases are to be packaged in an FDA-cleared woven sterilization wrap prior to placement in an autoclave. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved by using the following validated parameters to achieve a Sterility Assurance Level (SAL) of 10^{-6}:

Method:	Cycle:	Temperature:	Exposure Time:	Dry Time:
Steam	Pre-Vacuum	270° F (132°C)	4 minutes	60 minutes

Always sterilize the instruments in the disassembled, open, unlocked position, and implants in the "Cage Caddy". Avoid sudden cooling of the device components. Ensure devices function properly before use.

After sterilization, remove the wrapped carrying case from the sterilizer unit. To preserve sterility, the carrying case should remain wrapped until ready for immediate use.

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed.

Before proceeding with surgery, verify that all devices are correctly assembled and that all instruments and implants are undamaged. Only sterile implants should be used in surgery.

Warning: Expanding Innovations, Inc. does not recommend that the implants or instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

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LIMITATIONS ON PROCESSING

Repeated processing has minimal effect on these implants and instruments. End of life is normally determined by wear and damage due to use (instruments only).

STORAGE

Expanding Innovations, Inc. instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects and chemical vapors.

MAINTENANCE AND REPAIR

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any Expanding Innovations, Inc. instrument.

If your Expanding Innovations, Inc. instrument requires repair or maintenance, return the instrument in the Expanding Innovations, Inc. box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Attn: Expanding Innovations, Inc. Technical Services
Expanding Innovations, Inc., Inc
110 Pioneer Way, Suite I
Mountain View, CA 94041

Note: Instruments returned to Expanding Innovations, Inc. must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

INFORMATION

For further information regarding the Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System or a copy of the Expanding Innovations, Inc. X-PAC Lateral Expandable Cage System Surgical Technique manual, please contact Expanding Innovations, Inc., Inc. or your local Expanding Innovations, Inc. Distributor.

EMERGENCY IMPLANT REMOVAL PROCEDURE (FOR DETAILED INSTRUCTIONS, PLEASE REFER TO THE SURGICAL TECHNIQUES MANUAL)

In the event that the implant needs to be removed after the Cage Insertion device has been removed and/or the Cage Cannula has been removed, follow the following instructions:

1. Attach the T-Handle to the rear Hudson end of the Cage Extractor
2. Is the Cage Cannula still attached to the Cage?
    a. If yes, proceed to step 3
    b. If no, proceed to step 9
3. Slide the Cage Extractor down the center of the Cage Cannula, ensure the T-HANDLE IS ALIGNED WITH THE PATIENT'S SPINE.
4. Push the Cage Extractor down the Cage Cannula until the Cage Extractor stops against the Cage Lock within the implant.
5. Rotate the Cage Extractor clockwise 90 degrees clockwise, until the T-Handle is perpendicular to the patient's spine.
6. Ensure the Cage Extractor is properly attached to the Cage Lock by firmly pulling on the T-Handle. If the Cage Extractor slides back out of the Cannula, repeat steps 3-6.
7. Attach the Slap Hammer to the T-Handle by sliding the Slap Hammer hook over the T-section on the rear of the T-Handle.

8. Grasp the slide and tap to collapse cage. Continue to tap the slide to remove the Cage from the disc space. Withdraw the Cage Cannula, Cage Extractor, and Cage out of the patient.
9. **Cannula Disconnected from Cage**
10. If the implant has already been packed with autograft, removal of some material might be necessary to allow the Cage Extractor to engage. Insert the Cage Extractor into the back of the implant. Ensure the T-HANDLE IS ALIGNED WITH THE PATIENT'S SPINE.
11. Rotate the Cage Extractor clockwise 90 degrees clockwise, until the T-Handle is perpendicular to the patient's spine.
12. Ensure the Cage Extractor is properly attached to the Cage Lock by firmly pulling on the T-Handle. If the Cage Extractor pops out of the implant, repeat steps 10-12.
13. Attach the Slap Hammer to the T-Handle by sliding the Slap Hammer hook over the T-section on the rear of the T-Handle.
14. Grasp the slide and tap to collapse cage. Continue to tap the slide to remove the Cage from the disc space. Withdraw the Cage Extractor and Cage out of the patient.

DO NOT REUSE THE IMPLANT. ENSURE THE CAGE IS NOT MIXED IN WITH THE UNUSED CAGES. CAGES ARE ONLY INTENDED FOR A SINGLE INSTALLATION.

Symbols:

REF	**Catalog Number**
LOT	**Lot Number**
	Do not reuse

	Manufacturer
NON STERILE	**Non-sterile**
	Caution, consult accompanying documents

Manufactured By:
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