X-PAC® N-GAGE™ Lumbar Plate System
Package Insert

DEVICE DESCRIPTION

X-PAC® N-GAGE™ Lumbar Plate System is a spinal fixation system intended to provide temporary stabilization of the thoracolumbar spine during interbody fusion. The system's components include implants manufactured from titanium alloy (Ti-6Al-4V or Ti-6Al-4V ELI) and corresponding instrumentation.

X-PAC® N-GAGE™ Lumbar Plate System implants are comprised of:

- 1-hole, 2-hole, and 4-hole plates.
- Multiple screw diameters in 35mm to 60mm lengths.
- Plate Couplers designed for attachment to the X-PAC® LLIF Expandable Cage System.

INDICATIONS FOR USE

X-PAC® N-GAGE™ Lumbar Plate System is indicated for temporary stabilization during spinal fusion via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via a lateral or anterolateral surgical approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability in skeletally mature patients for the treatment of symptomatic degenerative disc disease (DDD), degenerative spondylolisthesis, spinal stenosis, disc herniation, pseudoarthrosis, multilevel degenerative scoliosis, sagittal deformity and/or failed previous fusion. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

N-GAGE™ 2-Hole and 4-Hole Plates are indicated for use as supplemental fixation. When attached to the X-PAC® LLIF Expandable Cages, N-GAGE Plates are intended to remain attached following implantation to provide further stabilization of the fusion construct. In this configuration, the Plate -Cage assembly takes on the indications of the interbody device as a stand-alone interbody implant..

N-GAGE™ 1-Hole Plates include a built-in coupler intended for attachment to the X-PAC® LLIF Expandable Cages. N-GAGE 1-Hole Plates are intended as anti-migration plating and indicated for use in conjunction with supplemental fixation (e.g., posterior fixation).

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Patients with bone resorption related disease (e.g., osteopenia), bone and/or joint disease, or deficient soft tissue at the wound site.
2. Patients with active infection, inflammation, fever, tumors, elevated white blood count, pregnancy, mental illness, drug abuse, and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients with known allergy or intolerance to titanium.
4. Patients with prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS

Potential adverse events may be related to surgery in general, spine surgery specifically or the device. These may include, but are not limited to the following:

1. Adverse events related to any surgery: Infection, reactions to anesthesia, blood loss, soft tissue damage, wound dehiscence or incisional hernia, hematoma, embolism, heart attack, stroke, or death.
2. Adverse events related to the spinal procedure: Non-union or delayed union, vertebral body damage or fracture, ligament damage, vascular injury, visceral injury, urological problems, retrograde ejaculation, adjacent intervertebral disc injury, dural tear and/or CSF leak, neurological injury, radiculopathy, myelopathy, paraparesis, paresthesia or paralysis, pain, discomfort, or abnormal sensations due to the device's presence.
3. Adverse events related to device: Implant crack or fracture, implant migration, loss of fixation, titanium sensitivity or allergic reaction, or bone resorption. In some instances, additional surgery may be required for implant removal, repositioning, or replacement.

WARNINGS AND PRECAUTIONS

1. Implants are provided non-sterile. All N-GAGE™ Implants must be sterilized prior to use. Refer to the STERILIZATION INSTRUCTIONS section for details.

2. Reusable instrumentation must be cleaned and steam sterilized before procedural use by the end user.
3. Components of this system should not be used with components from other systems or manufacturers.
4. X-PAC® N-GAGE™ Lumbar Plate System implants are for single use only. Implants that are explanted must not be reused. Implants that came in contact with blood or other bodily fluids must NOT be reused. While an implant may appear undamaged, it may contain small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-contamination and/or early device failure.
5. Caution must be taken before using this product on patients with known sensitivity to materials. Do not implant in patients with known or suspected sensitivity to titanium alloy.
6. This device is only indicated for use on the anterior column of the thoracolumbar spine. This device should NEVER be used on the posterior elements of the spine.
7. This system is intended to be used as an adjunct to interbody fusion. These devices are not designed to be used on their own to withstand normal stresses within the spinal column.
8. These implants are used only to provide internal fixation during the period of bone formation. A successful result may not be achieved in every instance. No spinal implant is designed to withstand body loads for an indefinite period without the support of bone. In the event of pseudoarthrosis or delayed fusion, the risk of the implant loosening, bending, or breaking increases. 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.
9. NEVER use a mallet to seat the plate on the vertebral bodies. Attempting the use of a mallet to seat the plate will potentially damage the inserter and/or plate and require implant replacement.
10. Always use the N-GAGE™ Adjustable Awl to make pilot holes. Free-hand insertion is not recommended. It is important to closely monitor Screw depth using A/P fluoroscopy to prevent over-insertion. Screws exceeding the maximum angulation in any plane may lead to improper or insufficient locking of the construct.
11. All components should be final tightened per the specifications in the Surgical Technique Manual. Implants should not be forcibly tightened past the locking point, as dictated by the torque-limiting handles and Surgical Technique Manual. Overpowering the systems built in torque limits could lead to device failure.
12. Implantation should only be performed by experienced spinal surgeons with specific training in the use of this spinal system.
13. Proper implant selection based on patient needs and interbody height is extremely important. Refer to the Surgical Technique Manual for proper guidance on implant selection. Care should be taken to avoid under sizing N-GAGE™ Plates.
14. During implant removal, care should be taken to ensure all implant components are removed from the patient.

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 taken when handling and during storage of the implants and implant instruments. Prior to use, implants should be inspected for visual damage that could result from shipping, reprocessing, and/or storage. Damaged implants should be removed from the system and replaced by contacting your Expanding Innovations representative or Customer Service. Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. The use of damaged system components could lead to device failures or bodily harm.
4. Implants and instruments should be protected during storage especially from corrosive environments.
5. All implants and instruments are delivered non-sterile and should be both cleaned and sterilized before use.

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. Detailed instructions on the use and limitations of the device must be given to the patient.

1. Patients should be informed regarding the purpose and limitations of the implanted devices.
2. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implanted devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibratory motion, falls, jolts, or other movements preventing proper healing and/or fusion development.
3. Patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implanted device in case of delayed, malunion, or nonunion of bone. Immobilization should continue until a complete bone fusion mass has developed

and been confirmed.

5. To ensure the earliest possible detection of pseudoarthrosis or non-unions, periodic postoperative assessment of the devices should be performed using appropriate radiographic techniques. If a non-union develops or if the components loosen, migrate, and/or break, the devices must be revised and / or removed immediately before serious injury occurs.

DIRECTIONS FOR USE

Refer to the Surgical Technique Manual for surgical instructions.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

X-PAC® N-GAGE™ Lumbar Plate 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 X-PAC® N-GAGE™ Lumbar Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

COMPATIBILITY

X-PAC® N-GAGE™ Lumbar Plate System is designed for use in conjunction with X-PAC® LLIF Expandable Lateral Cage System. Use with components from other systems is not intended, unless otherwise stated. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

PACKAGING

X-PAC® N-GAGE™ Lumbar Plate System components (implants and instruments) are supplied in trays or caddies that should be used for steam sterilization prior to use, according to the STERILIZATION INSTRUCTIONS section included below. In the case of instrument and implant restock, individual items will be sent in a plastic bag, labeled for that device, and require sterilization prior to use.

STORAGE

Expanding Innovations 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 contamination, including dust, insects and chemical vapors.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS AND IMPLANTS:

All implants and instruments of the X-PAC® N-GAGE™ Lumbar Plate System are delivered non-sterile and therefore, must be cleaned and sterilized prior to surgical use. Strict compliance with the instructions for use pertaining to initial cleaning and sterilization of implants and instruments is mandatory, as well as reprocessing of reusable instruments.

WARNINGS

- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Avoid exposure to hypochlorite solutions, as these will promote corrosion.
- Scratches or dents can result in breakage.
- Sterilization by Flash, Ethylene Oxide or Chemical methods have not been established and is not recommended.

CARE AT THE POINT OF USE

- Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Thoroughly clean instruments as soon as possible after use.
  If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and purified water to prevent drying and encrustation of surgical soil.
- Avoid prolonged exposure to saline to minimize the chance of corrosion

DISASSEMBLY

Disassemble instruments prior to cleaning and sterilization, as follows.

- N-GAGE™ Adjustable Awl, unscrew the gold thumb nut to release the outer shaft.
- Optional N-GAGE Drill, unscrew the gold thumb nut to release the outer shaft.

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MANUAL CLEANING INSTRUCTIONS

1. Rinse the articles under cool running tap water for at least 90 seconds.
   1.1. Remove all gross soil with a clean lint-free cloth (such as a microfiber, chamois or equivalent).
   1.2. While rinsing, use an appropriately sized syringe, such as a 50 cc BD dispensing syringe or similar, filled with tap water to flush any hard-to-reach areas of the inserter device.
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. Use an appropriately sized syringe filled with enzymatic cleaning solution to flush any hard-to-reach areas of the inserter device.
4. Remove the articles from the cleaning solution and wipe away any soil debris with a clean lint-free cloth (such as a microfiber, chamois or equivalent).
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 nylon 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 of the inserter device.
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 of the inserter device with an appropriately sized syringe filled with RO/DI water.
7. Dry all articles with a clean lint-free cloth (such as microfiber, chamois or equivalent).

AUTOMATED CLEANING INSTRUCTIONS

- Follow manual cleaning steps 1-6 outlined above.
- Load instruments into automatic washer, such as a STERIS Reliance Genfore Washer-Disinfector (or equivalent) per manufacturer's recommended orientation.
- Select the appropriate cycle as listed below:

Motor speed: High

STAGE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION (IF APPLICABLE)
Pre-wash 1	2 minutes	Cold tap water	N/A
Enzyme Wash	5 minutes	Hot tap water	MetriZyme or equivalent per the manufacturer's recommendation
Wash 1	5 minutes	43°C tap water	MetriZyme or equivalent per the manufacturer's recommendation
Thermal Rinse	2 minutes	64°C RO/DI water	N/A
Drying	15 minutes	66°C	N/A

CLEANING INSPECTION:
Inspect all instruments to verify that all visible soil is removed during cleaning and prior to sterilization. If soiling is still visible after cleaning, repeat the cleaning process. Return devices to their proper location within the carrying case. Do not reassemble devices prior to sterilization.

STERILIZATION INSTRUCTIONS

- All components of the X-PAC® N-GAGE™ Lumbar Plate System are sterilizable by steam autoclave using standard hospital practices.
- Device carrying cases containing the trays and caddies are to be packaged in an FDA-cleared woven sterilization wrap prior to placement in an autoclave.

- Double-wrap carrying cases in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/ AAMI ST79.
- Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.
- When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
- Always sterilize the instruments in the disassembled, open, unlocked position, and implants in the applicable implant caddy.

In a validated, properly functioning, maintained, and calibrated steam sterilizer, effective sterilization can 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	30 minutes

- After sterilization, remove the wrapped carrying case from the sterilizer unit. Avoid sudden cooling of the device components.
- To preserve sterility, the carrying case should remain wrapped until ready for immediate use.
- Before proceeding with surgery, verify that all instruments are correctly assembled and function properly and that all instruments and implants are undamaged.

NOTE: STERILIZATION DOES NOT REPLACE CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

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

MAINTENANCE INSPECTION AND FUNCTIONAL TESTING:
The instruments used to implant the X-PAC® N-GAGE™ Lumbar Plate System do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, functional use, cleaning, and sterilization processes. Instruments should be carefully inspected before use.

- Visually inspect all instruments to ensure no damage and wear.
- Ensure there are no cracked handles and shafts are secure in handles.
- Ensure long instruments are free of any bending and distortion.
- Ensure instrument tips are free of defects or burrs.
- Ensure complex instruments with moving parts function appropriately.

MAINTENANCE AND REPAIR

WARNING:
Do not attempt to repair or modify any Expanding Innovation instruments.

If your Expanding Innovations instrument requires repair or maintenance, return the instrument in the Expanding Innovations shipping container or another suitable, protective container with adequate packaging material to protect the instrument. Send the packaged instrument to:

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

Note: Instruments returned to Expanding Innovations 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.

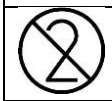
MANUFACTURER INFORMATION

For further information regarding X-PAC® N-GAGE™ Lumbar Plate System or for a copy of the Surgical Technique manual,

please contact Expanding Innovations or your local Expanding Innovations Distributor.

Manufacturer:
Expanding Innovations
110 Pioneer Way, Suite I
Mountain View, California 94041
Phone: +1.650.861.3129

SYMBOL LEGEND

	**Catalog Number**		**Manufacturer**
	**Lot Number**		**Non-sterile**
	**Do not reuse**		**Caution, consult accompanying documents**

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