LUX™ Expandable Lumbar Interbody System

Product Instructions for Use

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Xenix Medical
149 W. Michigan Street
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STERILE PRODUCT and NON-STERILE SURGICAL INSTRUMENTATION

ALL **IMPLANTS** ARE INTENDED FOR ***SINGLE USE ONLY***

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE AND USE BY, OR ON THE ORDER OF A PHYSICIAN

BEFORE USING THIS PRODUCT
READ THE FOLLOWING THOROUGHLY.

IMPORTANT INFORMATION ON THE LUX™ EXPANDABLE LUMBAR INTERBODY SYSTEM

Description:
The LUX™ Expandable Lumbar Interbody System is used to maintain disc space distraction in skeletally mature patients requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit the patient's pathology and anatomical conditions of the patient. The implant contains interconnected porosity and allows for radiological evaluation. The implants include large central, vertical graft windows, and smaller interconnected graft pathways, which may be packed with bone graft material prior to implantation. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent implant migration and/or expulsion.

The LUX™ Expandable Lumbar Interbody System implants are manufactured from Titanium 6Al-4V ELI per ASTM F136 and F3001. Endplates are additively manufactured from titanium alloy powder per ASTM F3001 and internal components are manufactured from titanium alloy per ASTM F136. To achieve the best results, unless otherwise specifically described in another LUX™ Expandable document, do not use lumbar components in conjunction with components from any other system or manufacturer. LUX™ Expandable warrants that these devices are fabricated from the foregoing material specification. No other warranties expressed or implied, are made.

Devices incorporate proprietary NANOACTIV™ micro and nano-roughened surface designed to improve fixation to adjacent bone. The Xenix Medical implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document. *In vitro* results may not be representative of clinical performance. Note: Supporting Study Data will be provided upon request.

Caution:
Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

All implants are intended for single use only. The LUX™ Expandable Lumbar Interbody System implants must not be reused under any circumstances. The LUX™ Expandable Lumbar Interbody System is not a stand-alone device and must be utilized in conjunction with supplemental fixation. These instructions for use are designed to assist in use of the LUX™ Expandable Lumbar Interbody System and are not a reference for surgical techniques.

Indications:

The LUX™ Expandable Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The LUX™ Expandable Lumbar Interbody System implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft implanted via a transforaminal approach or an open posterior approach. The LUX™ Expandable Lumbar Interbody System implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Contraindications:
- Spondylolisthesis higher than grade I (not for the use with a pedicle screw fixation system).
- Reduced bone density, which does not guarantee a sufficient resting stability (e.g. osteoporosis).
- Fractures.
- Tumors.
- Scoliosis.
- Active infection.
- Metal/polymer sensitivity/allergies to the implant materials
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- 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 case that requires the mixing of metals from two different components or systems.
- Any patient 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 to be treated.
- Any other condition which would preclude the potential benefit of spinal implant 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.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Possible Adverse Effects:
A listing of possible adverse events includes, but is not limited to:
- Bending or fracture of implant. Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- 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.
- 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.
- Dural tears experienced during surgery could result in need for further surgery fordural repair, a chronic CSF leak or fistula, and possible meningitis.
- Bursitis.
- Paralysis.
- Death.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- If a pseudarthrosis occurs coupled with the LUX™ Expandable Lumbar Interbody System, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:
The LUX™ Expandable Lumbar Interbody System is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the LUX™ Expandable Lumbar Interbody System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. The risk of device expulsion and migration is higher without the use of supplemental fixation. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the LUX™ Expandable Lumbar Interbody System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. An entirely satisfactory result is not always achieved in every surgical case. This particularly applies to spinal surgery, in which numerous external factors may compromise the results.

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation,

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pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.

The implantation of the LUX™ Expandable Lumbar Interbody System should be performed only by experienced spinal surgeons with specific training in the use of lumbar cage systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Never use a STERILE implant if the packaging is damaged. Never use a STERILE implant that is past its expiration date.

PHYSICIAN NOTE: *Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.*

CAUTION: *The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.*

CAUTION: *The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.*

MRI Safety Information:

The LUX™ Expandable Lumbar Interbody 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 LUX™ Expandable Lumbar Interbody System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury**.**

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Implant Selection:
The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion. LUX™ Expandable Lumbar Interbody implants should not be used with components from other manufacturers.

Preoperative:
- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions 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 implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.
- A surgical technique manual may be obtained from Xenix Medical or any of its representatives.

Intraoperative:
- Any instruction manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the devices should be securely seated.
- Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

Postoperative:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved LUX™ Expandable Lumbar Interbody implants should ever be reused under any circumstances.

Packaging and Storage:

Packaging for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used and should be returned immediately to Xenix Medical.

The implants are delivered in sterile packages; these must be intact at the time of receipt. The implants are provided STERILE and are individually packed in protective packaging that is labeled according to its contents. Instruments are provided as NON-STERILE and shall be clean and sterilized prior to each use.

Additional Notes:

- Do not remove the STERILE implant from the packaging until immediately before use.
- The STERILE implant should be stored in ambient temperature in a secure location.
- Instruments shall be handled with extreme care and stored in a controlled environment location that prevents extreme conditions or other eminent dangers to the integrity and fitness of the instruments.
- Instruments are provided in secure trays that contain retention positions within the tray. Instruments should only be moved (transported) when using their individual trays unless authorized by Xenix Medical.
- Instruments shall be cleaned and sterilized before use.

Both inner and outer packaging of STERILE implants, including seals, should be thoroughly inspected prior to implantation. Do not use if package is opened or damaged or if the expiration date has passed.

Cleaning and Decontamination:

Instruments of the LUX™ Expandable Lumbar Interbody System are supplied clean and NOT STERILE and must be sterilized prior to use.

These instructions are provided in accordance with AAMI TIR12, AAMI TIR30, and ISO 17665 and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols. Use of these guidelines does not remove or limit the end-user's ultimate responsibility for the cleanliness and sterility of any surgical device used at their facility.

It is recommended to rinse the device components with critical water that meets specifications for AAMI TIR34 for example, DI/RO water.

Point of Use Cleaning:
Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Taking measures to prevent the drying of soil on the device will facilitate subsequent cleaning steps.
Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.
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Cleaning:
All instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field. Xenix Medical instrument trays have been validated for either manual or automated cleaning procedures. It is recommended that a manual processing be performed prior to any automated cleaning to remove gross contaminants. Complex instruments such as those with lumens or hinges may require special attention.

MANUAL CLEANING STEPS

1	Remove debris from instruments and rinse in ambient temperature tap water to remove visible soil. NOTE: Disassembly of instrumentation is not required
2	Prepare enzymatic solution, such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's directions and submerge device in enzyme solution. Fill all cannulations with enzymatic cleaner. Actuate the device while it is submerged and sonicate for a minimum of 15 minutes.
3	Scrub the device using an appropriately sized soft-bristled brush while fully immersed in solution. Pay special attention to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 60 mL, 3 times) or water jet is recommended for hard-to-reach areas, rinsing until exiting water runs clear.

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4	Rinse devices in warm water for a minimum of 1 minute.
5	Prepare cleaning solution, such as Prolystica® 2X Concentrate Alkaline Detergent, per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
6	Thoroughly rinse devices with DI/RO water to remove all detergent residues for a minimum of 2 minutes. All cannulations must be fully flushed until rinse water runs clear.
7	Visually inspect each instrument for contamination. If there is any visual soil, repeat cleaning steps until the instruments are visibly clean.
8	Dry devices with a clean, lint free cloth and/or allow to air dry.

AUTOMATED CLEANING STEPS

1	Rinse devices in ambient temperature tap water to remove visible soil. Complex instruments, such as those with lumens and hinges require special attention during cleaning. Actuate devices where appropriate. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped. NOTE: Disassembly of instrumentation is not required
2	Prepare enzymatic solution, such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's recommendations and submerge devices in enzyme solution. Fill all cannulations with enzymatic cleaner and soak for a minimum of 15 minutes.
Place devices into a Washer/Disinfector and process through a surgical instrument cycle as follows:	
3	Enzyme wash using cleaner such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's recommendations, using hot tap water (66°C/150°F minimum) for a minimum of 4 minutes.
4	Detergent wash using detergent such as Prolystica® 2X Concentrate Alkaline Detergent or equivalent, per manufacturer's recommendations, using hot tap water (66°C/150°F minimum) for a minimum of 2 minutes.
5	Rinse with hot DI/RO water (66°C/150°F minimum) for a minimum of 2 minutes.
6	Dry using hot air (115°C/239°F minimum) for a minimum of 12 minutes.
7	Visually inspect each instrument for contamination. If there is any visual soil, repeat cleaning steps until the instruments are visibly clean.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The instruments should be inspected and checked to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Sterilization:

The implants are clearly labeled STERILE and are provided clean and sterile. These devices are sterilized using gamma irradiation processes validated by AAMI/ANSI/ISO 11137-2 – method VDmax[25].

The implants should never be cleaned or otherwise reprocessed and should be discarded if they become soiled. Verify the expiration data and return or discard any expired devices.

Instruments are provided NON-STERILE and must be cleaned and sterilized before use. Non-sterile instruments should be autoclaved in accordance with the sterilization parameters previously validated by ANSI/AAMI/ISO 17665-1. These parameters were validated to sterility assurance level (SAL) of 10^{-6}.

Using the Xenix Medical Instrument Tray, Steam Sterilization prior to use according to the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	30 minutes

Double wrap tray with using an FDA cleared wrap.

No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all instruments used in surgery. This process must be performed before handling or returning to Xenix Medical.

It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

Product Complaints:
Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Xenix Medical or its representative. Further, if any implanted LUX™ Expandable Lumbar Interbody implant ever malfunctions, Xenix Medical or its representative must be notified immediately.

If any Xenix Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Xenix Medical must be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Xenix Medical understand the cause of the complaint.

If further information is needed or required, please contact:

Xenix Medical
149 W. Michigan Street Phone: 888-594-6433
Orlando, FL 32806

GRAPHIC SYMBOLS:



Catalog Number



Lot Number/Batch Code


Manufacturer


Use by Date



Sterilized using Irradiation


Do not use if package is damaged


Consult electronic Instructions for use
www.xenixmedical.com



Non-sterile


Single Use Only; Do not re-use


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