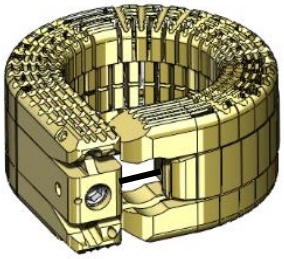
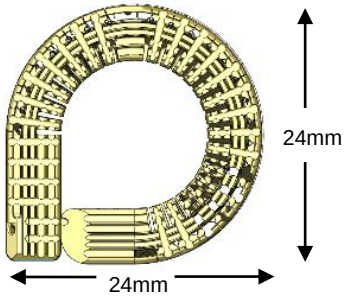
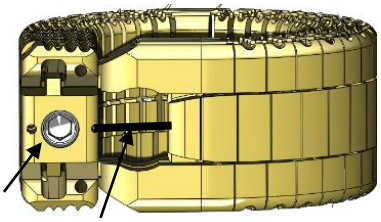
Luna 3D™ Interbody Fusion System

Important: Read all instructions, cautions and warnings prior to use, including the Luna 3D Interbody Fusion System Surgical Technique Guide. These instructions provide guidance to the experienced physician using the Luna 3D Interbody Fusion System for the treatment of symptomatic degenerative disc disease. This is not a reference to spine surgery technique. **Failure to properly follow the instructions or to heed any warnings or precautions could result in patient injury. Do not attempt to use the Luna 3D Interbody Fusion System prior to receiving training from Benvenue Medical personnel.**

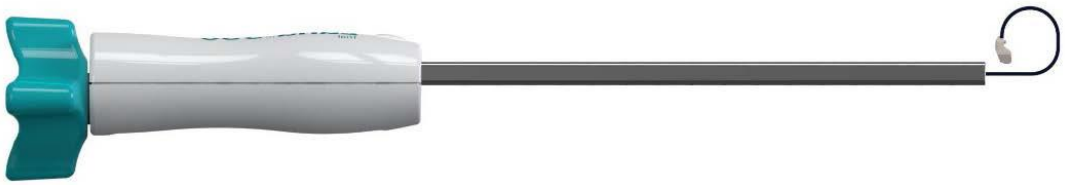
SYSTEM DESCRIPTION:
The Luna 3D Interbody Fusion System is comprised of an Implant and disposable instruments. The Luna 3D Implant is made of PEEK (polyetheretherketone) polymer with stainless steel, tantalum markers, and a thin coating of silicone (polydimethyl siloxane). The instruments consist of the Luna 3D Inserter (containing the Luna 3D Implant), Luna 3D Trial/Scout, Pusher Tool, Lock Driver and Graft Injector with Hopper. These instruments are designed to assist placement of the Implant within the disc space to facilitate fusion when used in conjunction with posterior instrumentation and autogenous bone graft.







Inserter with Luna 3D Implant



Luna Trial

Luna Scout

Pusher Tool

Lock Driver

Graft Injector with Hopper

INDICATIONS:
The Luna 3D Interbody Fusion System consists of a Luna 3D Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic 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 I spondylolisthesis or retrolisthesis at the involved level(s). The Luna 3D Interbody Fusion System is to be used with autogenous bone graft. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Luna 3D Implant. The Luna 3D Interbody Fusion System is to be used with supplemental fixation.

CONTRAINDICATIONS

- Active systemic or local infection in the proposed area of surgery.
- Involved level is a revision of a previous intervertebral fusion procedure(s).
- Known allergy to the device materials.
- Severe osteoporosis, osteopenia, and/or osteomalacia.
- A medical condition that interferes with postoperative management program.
- Active malignancy.
- Morbid obesity.
- Grade II or greater spondylolisthesis or retrolisthesis at involved spine level.
- DDD affecting three or more spine motion segments.
- Abnormal anticoagulation status.
- Any condition not described in the Indications for Use.

WARNINGS

Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

MRI Safety Information

Non-clinical testing has demonstrated that the Luna 3D Implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the Luna 3D Implant is expected to produce a maximum temperature rise of 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10mm from the Luna 3D Implant when imaged with gradient echo pulse sequence and a 1.5 or 3.0 Tesla MRI system.

GENERAL PRECAUTIONS

- Do not use the sterile, single use device if the packaging appears to be damaged or if there is evidence of tampering.
- The single-use devices are intended for single-use only. Do not re-sterilize or reuse. Reuse of the device could result in infection, cross-contamination, and failure to perform in a safe manner as intended.
- The user should inspect the device for damage prior to use. If the device appears damaged, do not use. Discard or return to the manufacturer.
- It is important to read the Instructions For Use and these precautions prior to device operation.
- Use the Luna 3D Interbody Fusion System prior to the Use By date noted on the package.
- The physician shall be trained in the use of the Luna 3D Interbody Fusion System prior to surgery.
- The physician should be familiar with the anatomy and pathology being treated with this device.
- This device must be inserted using fluoroscopic guidance. Failure to use fluoroscopic guidance could result in serious patient injury.
- Failure to observe recommendations may contribute to serious patient injury.
- Always carefully prepare the disc space by using appropriate tools (not provided) to remove all nucleus material and prepare the endplates for fusion.
- Always use sizing paddles to determine the appropriate disc distraction height and to ensure the appropriate size of Luna 3D Implant is available.
- Never attempt to advance the Implant without the use of the Implant Inserter and Pusher Tool.
- Never attempt to remove the Implant without the use of the Extraction Instrument.
- Always use posterior instrumentation to supplement the Luna 3D Implant.
- Do not use a mallet or hammer on the Implant or any of the Luna Instruments.
- Do not rotate the Insertion Instrument while the Implant is out of the cannula. This may break the Implant.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Use caution when manipulating the lock wire or using instruments near it. If it is damaged, then the lock mechanism may not hold the implant in a circular shape. A new implant should be used.

CAUTION:

℞ Federal law restricts this device to sale by or on the order of a physician.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contradictions should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Components of the system should be protected during storage, especially from corrosive environments.
4. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment.

INTRAOPERATIVE

1. The instructions in the Luna 3D Interbody Fusion System Surgical Technique Guide should be carefully followed.
2. Extreme caution should be used around the spinal cord and nerve root. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Use great care to insure that the implant surfaces and lock wire are not scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower endplates being fused.
6. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal fusion applications, and this material will make removal of the components, if necessary, difficult or impossible.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, 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 or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock 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 utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction of body motion.
4. 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 the eventual bending, 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. If a state of non-union persists or if the components loosen, bend and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures) prophylactic antibiotics may be considered, especially for high-risk patients.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. The Luna 3D Implant components should never be reused under any circumstances.

POSSIBLE ADVERSE EFFECTS

The following are potential adverse events or complications associated spinal fusion surgery with instrumentation. Possible adverse events with use of the Luna 3D Interbody System include, but are not limited to:

- Infection, early or late
- Implant migration, breakage, or subsidence
- Hemorrhage of blood vessels and/or hematomas
- Decrease in bone density due to stress shielding
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, or cerebral spinal fluid leakage,
- Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
- Failure to relieve back pain or increased back pain
- Non union (or pseudoarthritis), delayed union
- Death

Standard medical practice and procedures should be followed prior to use and following the use of the Luna 3D Interbody System. These practices are not within the scope of this document.

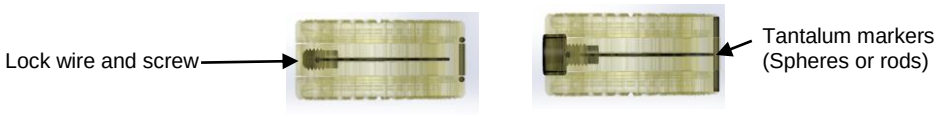
LUNA 3D INTERBODY FUSION SYSTEM INSTRUCTIONS FOR USE

Implant Selection

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Unless 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, bending or loosening of the device and/or the supplemental fixation before the healing process is complete. The Luna 3D Implant is available in lordotic angles of 0 and 8 degrees and select heights ranging from 8mm to 15mm, which correspond to the final height of the Implant at the anterior location. The lateral and A-P dimensions are 24mm each.

Fluoroscopic Markers

The Luna 3D Implant contains distinct radiopaque markers to facilitate position and orientation tracking. As shown in the figure below, the lock screw and lock wire are oriented perpendicular to the axis of the implant, while the tantalum post of the middle implant member until it reaches its final position and is aligned with the tantalum markers of the top and bottom members, which may be either spheres or rods.



Additionally, the Luna 3D Trial delivers a PEEK tip mounted on a nitinol ribbon, which is radiopaque. The Luna 3D Scout delivers a pair of radiopaque PEEK components that mimic the Top and Bottom components of the Implant. Either of these instruments are used in the same manner to assess adequate discectomy.

Surgical steps (refer to Luna 3D Surgical Technique Guide for full details)

1. **Disc Sizing:** Use sizing paddles, determine the proper height of the Luna 3D Interbody Spacer to implant.
2. **Luna 3D Trial/Scout Insertion:** Assess the discectomy of the space by inserting the distal end of the Trial/Scout into the prepared disc. Deploy Trial/Scout under fluoroscopy. If it can make a full circle, then proceed to implantation. Otherwise, perform additional discectomy to remove potential blockages to Luna 3D Implant.
3. **Luna 3D Implant Insertion:** Place the distal end of the Insertion Instrument into the prepared disc. Insert the Outer Implant components by turning the Insertion Knob clockwise. Verify the position using fluoroscopy. Once the initial position is established, insert the Pusher into the proximal end of the Insertion Knob. Turn the Pusher clockwise to insert the middle component. Advance the middle component until locked into the outer components and the radiographic markers are aligned as shown above. Verify the final position using fluoroscopy.
4. **Insertion Instrument Removal:** Cut the retention cables completely by activating the 2 levers on the side of the Inserter. Remove Inserter from patient and dispose. Remove retention cables 1 at a time, leaving Lock Wire in place. Pull the slack from the Lock Wire.
5. **Bone Graft Placement:** Fill distal end of Graft Injector using Hopper. Gently dock Graft Injector at opening of Luna 3D Implant and push plunger to insert bone graft. Repeat as necessary to completely fill interior volume with bone graft.
6. **Locking Luna 3D Implant:** While pulling with moderate tension on lock wire, tighten Lock Screw with Lock Driver until the excess portion of lock wire is severed. Remove excess wire and Lock Driver wrench. The insertion is now complete.
7. **Extraction (if necessary):** Use the Lock Driver to remove the Lock Screw completely from the Luna 3D Implant. Screw the Extractor instrument into the hole from which the Lock Screw came. Use a slap-hammer to slowly remove the implant in a controlled manner while protecting all nearby neural tissue.

HOW SUPPLIED: The Luna 3D Implant and associated disposable instruments of the Luna 3D Interbody Fusion System are supplied sterile in peel open packages and should not be re-sterilized. Do not use device if package is damaged or opened, if product is accidentally contaminated before use, or, if beyond expiration date.

MATERIALS NOT SUPPLIED

The surgical access systems, disc preparation instruments, posterior instrumentation implants and instruments are not provided. Refer to those manufacturers "Instructions for Use" for proper use, contraindications, adverse events, warnings and precautions.

STORAGE: Store in a cool, dry place. Proper care should be taken to ensure that the Luna 3D Interbody Fusion System will not be damaged.

DISPOSAL: No unique requirements. Dispose of in accordance with hospital clinic requirements.

LIMITATION OF LIABILITY: IN NO EVENT SHALL BENVENUE MEDICAL BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE LUNA 3D INTERBODY SYSTEM, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

SERVICE REPRESENTATIVES AND REQUESTS FOR INFORMATION

For service, technical support, requests for information or reorder information, contact, in the United States:

Benvenue Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA, 95054 – USA
Phone: (800) 997-7463
Fax: (855) 774-6305
www.benvenuemedical.com

BENVENUE MEDICAL

Any device-related-incident or problem which is believed to represent a safety issue should be immediately reported to Benvenue Medical, Inc.

PRODUCT RETURNS

To return Benvenue Product, contact Benvenue Medical Inc. at (800) 997-7463.

SYMBOL DEFINITIONS

Do not reuse		Manufacturer	
Do not use if package damaged		Sterile by irradiation	STERILE R
Lot Number	LOT	Use by	
Latex Free	LATEX	Keep Dry	
Do Not Re-sterilize		Read the Documentation	
MR Conditional	MR	By Prescription Only	Rx
Caution			