DUALX® LLIF expanding IBFD

Product Information and Instructions for Use

Description

The **AMPLIFY SURGICAL DUALX® LLIF Expanding Titanium Lateral Lumbar Interbody Fusion System** (dualX® LLIF) is a comprehensive interbody cage system that provides structural stability of the anterior vertebral column. It is comprised of expanding titanium interbody cages of various sizes. The instruments provided with the system include implant trials, a bone graft tamp and graft funnel, a screwdriver, and an inserter to facilitate placement and expansion of the interbody device.

Material

The device is made of Ti 6AL-4V ELI per ASTM F136. The instrumentation is made from various grades of stainless steel, Radel 5500 PPSU, nitinol, titanium, peek, aluminum, medical grade adhesive, and medical grade silicone.

Clinical Indications

The **AMPLIFY SURGICAL DUALX® LLIF** is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation.

The **dualX® LLIF** implants are intended for single use only.

Contraindications

Contraindications may be relative or absolute. The choice to implant the **dualX® LLIF** must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the likelihood of a successful outcome. Contraindications include, but are not limited to:

1. Allergy or sensitivity to implant material or foreign body allergic reaction
2. Active or suspected infection
3. Patients who are immune compromised
4. Any condition that may affect the process of normal bone remodeling, including, but not limited to, osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis
5. Morbid obesity
6. Signs of local infection or inflammation
7. Fracture of vertebrae
8. Spondylolisthesis > grade 1
9. Alcoholism
10. Heavy smoking
11. Pregnancy
12. Any patients exhibiting disorders which would cause the patient to ignore the limitations of fixation implants
13. Prior fusion at the level(s) to be treated
14. Any condition not described in the Indications for Use

Possible Complications

Possible complications specific to the device may include:

1. Implant breakage, failure, loosening, or migration
2. Bone fracture or fracture to a lumbar vertebra
3. Allergic reaction to the implant material
4. Delayed or non-union

Other general complications associated with any spinal surgery may include:

1. Pseudoarthrosis
2. Pain
3. Revision surgery
4. Bleeding
5. Infection, early or late
6. Tissue or nerve damage
7. Spinal fluid leakage
8. Spinal cord impingement or damage resulting in potential paresthesia or paralysis
9. Scar formation
10. Complications due to the use of bone grafting, including donor site complications.

Warnings

1. Use of an inappropriately sized device in an area of high functional stresses may lead to implant fracture and failure.
2. **dualX®** has not been evaluated for safety and compatibility in the MR environment nor has it been tested for heating or migration in the MR environment.
3. Evaluating the safety and compatibility of the device in the MR environment, the following concerns were determined: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.
4. When more than two involved spinal levels are treated, longer operative times and greater blood loss are likely to occur.
5. As the number of previous surgeries at the involved spinal level(s) increases, the potential for intra-operative tears of the dura increases.
6. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system.
7. **dualX® LLIF** is intended to fill the disc space, only. Using the implant to distract the disc space may cause damage to the lumbar vertebra, or to the implant.
8. If the user wants to adjust the **dualX® LLIF** implant after the first placement, the implant must be collapsed to allow repositioning and re-expansion of the implant.
   NOTE: These devices are single use only. Do not reuse an implant that has been previously removed.
9. Using instruments that have not been properly maintained may lead to inadequate performance and damage to the implant, or to the lumbar vertebra.
10. Components of this system should not be used with components of any other system or manufacturer.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of expandable fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which implant sizes to use for specific indications.
3. The **dualX® LLIF** is not intended to endure excessive abnormal functional stresses.
4. Failure to use dedicated, unique **AMPLIFY SURGICAL DUALX®** Instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
5. Carefully inspect **AMPLIFY SURGICAL DUALX®** instruments before and after each procedure to ensure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to **AMPLIFY SURGICAL INC.** for disposition and repair.
6. **AMPLIFY SURGICAL** recommends the use of **AMPLIFY SURGICAL** products in a sterile environment.

Attention: Instructions for Use are in the Surgical Technique Guide (ML10004)

Instructions for Use, dualX® LLIF Expandable Lateral Lumbar Interbody Fusion System

1. With the patient in a direct lateral decubitus position and secured in place, identify the location of the disc space with AP and lateral fluoroscopic images.
2. Repeat fluoroscopy using two guide wires to determine initial skin incision location.
   NOTE: If multiple levels will be fused, the initial incision may be biased in the direction of the vertebral body between the two spine fusion levels.
3. Identify landmarks and mark the position of a second posterolateral incision.
4. Make a posterolateral incision and palpate using a finger and blunt instruments to find the psoas muscle.
5. Once the psoas muscle is identified, ensure the abdominal wall is palpated out of the path of the lateral incision using the index finger.
6. Make the lateral incision using the index finger as a guide.
7. Use a probe or hospital neuromonitoring probe to palpate through the lateral incision.
8. Verify the positioning of the probe using both AP and lateral fluoroscopy images.
9. Palpate through the psoas muscle using a probe or hospital neuromonitoring probe.
10. Place an appropriate retractor and retract the musculature and soft tissue to allow for proper visualization and placement of the **dualX® LLIF** implant.
11. Verify positioning and determine preliminary implant size using fluoroscopy.
12. Excise annulus according to the estimated size of the collapsed implant required for the patient. Remove freed annular tissues.
    NOTE: Maintain distraction during implant placement.
    NOTE: Distraction of the intervertebral space is only intended to provide just enough space to slip the collapsed **dualX® LLIF** implant into position.
13. Perform standard discectomy using preferred instrumentation/technique.
14. Prepare end plate surfaces for Interbody Fusion Device implantation.
15. Use **dualX® LLIF** trials to determine the correct implant size. Begin trialing with a conservatively smaller sized trial to avoid over stressing soft tissues.
16. Place implant trial through retractor with the collapsed height orientation against the vertebral bodies. Ensure the orientation and initial location of the trial is correct. Rotate the trial 90° clockwise to simulate expanded height of the implant. Rotate the trial counterclockwise to return to the collapsed height prior to removal.
    WARNING: do not continue to rotate the trial clockwise from the expanded height position. Rotating the trial more than 90° could cause overexpansion of the disc space and/or damage to the vertebrae or soft tissues.
17. Determine implant length using grooves in the trial. Each groove in the trial represents a 5mm increase in implant length the proximal end of the trial head represents the 60mm implant length.
18. Repeat step 15-17 using sequentially larger trials until the appropriate implant size has been determined.
19. Attach the appropriately sized implant to the dualX® inserter.
    a. Push the implant into the pocket at the tip of the inserter.
    b. Turn the inserter thumbwheel clockwise until wheel is finger tight.
    c. Install the drawbar.
    d. Turn the drawbar knob clockwise until it is finger tight.
20. Engage the lever by rotating / pushing it flat against the inserter handle.
21. Insert the implant into the disc space.
    NOTE: Care must be taken to avoid over insertion of the implant.
    a. Confirm initial position using fluoroscopy.
22. Lateral expansion
    a. Turn inserter handle clockwise until the laser marking under "LATERAL" is visible.
23. Vertical expansion
    a. Continue to turn inserter handle clockwise until the laser marking under "VERTICAL" is visible.
    b. Confirm position and expansion using fluoroscopy.
       NOTE: Audible clicks or pops may be heard as the implant provisional locks are engaged.
24. Determine placement via fluoroscopy to verify placement within the disc space.
25. Drawbar and handle removal
    a. Disengage the drawbar by lifting and pulling the lever to the disengaged position.
       NOTE: The lever may initially be easy to lift, but the if the internal mechanism is under load, additional force may be necessary to fully disengage the drawbar. Rotating the inserter handle slightly counterclockwise will relieve the internal forces on the inserter mechanism.
    b. Unthread (counterclockwise) and remove the drawbar.
    c. Press the handle removal tabs and remove the inserter handle.
26. Bone graft insertion
    a. Install the funnel onto the hex-shaped shaft.
    b. Insert bone graft material into the disc space using the tamp.
27. Install the **dualX® LLIF** lockout screw (provided in the implant packaging).
    a. Install the lockout screw onto the screwdriver and insert through the funnel into the implant.
    b. Apply a lockout torque of 14 in-lbs. using the screwdriver and torque limiting screwdriver handle.
28. Remove inserter shaft and funnel.
    a. Remove screwdriver and torque limiting handle.
    b. Remove inserter shaft and funnel by using the funnel as a wrench and turning it counterclockwise to unthread the implant retainer shaft until the implant retainer shaft and inserter outer shaft are free to be removed.

Repositioning / removal of the dualX® LLIF

NOTE: An implant can be removed or repositioned only after initial placement, not after fusion has taken place.

1. Reattach screwdriver to lockout screw.
   NOTE: The screwdriver acts as a guide to allow for easy alignment and attachment of the implant retainer shaft and inserter outer inserter shaft.
2. Reattach the outer shaft by sliding it over the screwdriver shaft and then rotating slowly until the shaft pocket drops over the attachment boss of the implant.
   NOTE: Installing the outer shaft and implant retainer shaft simultaneously over the screwdriver shaft will improve alignment and ease of attachment onto the implant.
3. Thread the implant retainer shaft into the back of the implant using the funnel as a wrench.
4. Reattach the torque limiting screwdriver handle and remove the lockout screw.
5. Remove the funnel and reattach the inserter handle.
6. Reattach the drawbar and engage the lever as done previously in steps 19-20
7. Collapse the implant by rotating the inserter handle counterclockwise until the "COLLAPSED" laser marking is aligned with the top of the inserter handle.
8. Reposition or remove the implant as necessary. Re-expand and lockout the implant again in desired location by following steps 21-27

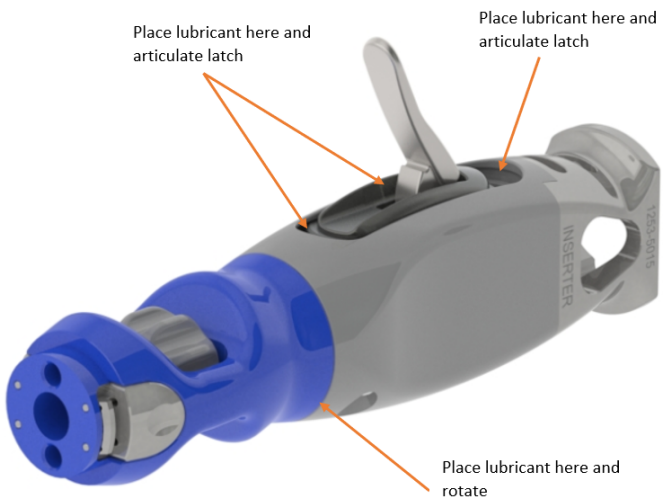
Cleaning

- Instruments must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- It is the responsibility of the facility/user to qualify any deviations from the recommended method of processing.
- **AMPLIFY SURGICAL** recommends the following cleaning and sterilization instructions for Instrumentation:

1. Disassemble the inserter into separate components, including:
   a. Drawbar
   b. Inserter Handle
   c. Implant Retainer Shaft
   d. Inserter Outer Shaft
2. Disassemble the screwdriver into separate components, including:
   a. Screwdriver Shaft
   b. Torque Limiting Handle
3. Rinse instruments in cool tap water for a minimum of 2 minutes for each disassembled component. Actuate all buttons and levers while rinsing to facilitate debris removal.
4. Brush (with a soft-bristled nylon brush) and flush (with a 60mL syringe) instruments during rinsing until they are free of visible debris.
5. Enzymatic Soak/Brush/Flush
   a. Completely submerge instruments in pH Neutral enzymatic cleaner (US: e.g. Steris Prolystica 2X) prepared according to the manufacturer's instructions, using warm (110° F Min) tap water.
   b. Rotate the instruments below the surface of the cleaner and actuate all buttons and levers while submerged to facilitate debris removal and to eliminate any trapped air bubbles.
   c. Ensure there is no contact between the instruments, and allow instruments to soak in enzymatic cleaner for a minimum of 20 Minutes
   d. Following the soak, and while still submerged, brush each disassembled component of the instruments for a minimum of 2 minutes. Pay special attention to orifices, cracks, crevices, and all lumens of the instruments. Use soft nylon (e.g. See Below) bristle brushes while flushing with enzymatic cleaner. Actuate all buttons and levers a minimum of 4 times while submerged.
6. Fresh Enzymatic Cleaner Flush
   a. Prepare a fresh cleaning solution per Step 5a. Use a 60ML syringe to jet flush all joints/cracks and gaps in the instruments with the cleaning solution a minimum of 5 times. Actuate all buttons and levers while flushing.
7. Ultrasonic Clean
   a. Place instruments in ultrasonic cleaner, ensuring that all instruments are disassembled and submerged with a freshly prepared solution of pH Neutral enzymatic cleaner (prepared per step 5a). Ensure there is no contact between the instruments and rotate the instruments below the surface of the cleaner and actuate all buttons and levers while submerged to facilitate debris removal and to eliminate any trapped air bubbles.
   b. Allow instruments to soak in the solution while sonicating for a minimum of 20 Minutes.
8. Rinse in hot water

a. Rinse instruments under hot (110° F minimum) running water and rinse for a minimum of 3 minutes
b. Actuate all buttons and levers while rinsing, and ensure water penetrates all cracks, crevices, lumens, and orifices.
c. Jet Flush with hot water
d. Use a 60ML syringe filled with hot water (110° F minimum) to jet flush all joints/cracks and gaps in the instruments two (2) times. Actuate all buttons and levers while flushing

9. Final Rinse
   a. Rinse all instruments using AAMI TIR34 compliant rinse water for 2 minutes.
10. Dry
    a. Dry instruments with a soft, lint-free cloth
    b. Dry the instruments with filtered pressurized air
    c. Optional: Heated dry in a 90-120° instrument dryer
11. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
12. Lubrication
    a. Hinged, rotating, sliding, or articulating instruments should be lubricated with water-soluble product (e.g. Instrument Milk or equivalent).



13. Steam autoclave per sterilization instructions.

Storage

- Sterile packaged implants should be stored at controlled room temperature out of direct sunlight.
- Product Tyvek package should be inspected prior to use for signs of damage or tampering.
- Sterile implants have a shelf life of 5 years.

Sterilization Instructions

1. Implants are supplied STERILE and NON-STERILE. System instruments are supplied NON-STERILE.
2. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Non-sterile devices should be sterilized by steam sterilization (autoclaving). For sterilization of **dualX® LLIF** implants and instruments, the following parameters should be used.

Tray System

Pre-Vacuum Steam Sterilization
Cycle: 3
Temperature: 270ºF (132ºC)
Time: 4 minutes
Dry Time: 30 minutes

Configuration: Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554 or equivalent) using sequential wrapping techniques.
Do not exceed 275ºF (135ºC), to avoid compromising functions of polymeric instrumentation.

Caution

- **Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.**
- **Do not attempt a surgical procedure with faulty, damaged, or suspect Amplify Surgical instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.**

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Symbols and Definitions

	Single Use Only		**REF**	Catalogue Number
	Use By (Date)		STERILE R	Sterile, Method of Sterilization Using Irradiation
LOT	Batch Code (Lot Number)			Consult Instructions for Use
	Date of Manufacture (MFG DATE)			Manufacturer (MFR)
	Attention, See Instructions for Use Caution, Consult Accompanying Documents			Do not use if sterile package is damaged
Rx ONLY	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.			