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LUMBAR SPINE IMPLANTS AND INSTRUMENTATION
(LUCENT®, LUCENT® TI-BOND®, LUCENT MAGNUM®, LUCENT MAGNUM® TI-BOND®)

This package insert covers multiple Spinal Elements lumbar spine systems: the Lucent system, the Lucent Ti-Bond system, the Lucent Magnum system, the Lucent Magnum Ti-Bond system, and Manual Surgical Instruments that are used for the implantation of these systems. System-specific sections highlight important user information for only that system. The GENERAL INSTRUCTIONS FOR USE section provides important information for all systems included in this insert.

LUCENT & LUCENT TI-BOND
POSTERIOR LUMBAR INTERBODY SYSTEMS

GENERAL INFORMATION
Spinal Elements' Lucent and Lucent Ti-Bond devices are generally box-shaped devices that have various graft windows throughout their geometry. These devices are made from either titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3, polyetheretherketone (PEEK-Optima®) conforming to ASTM F 2026, or PEEK with a coating of commercially pure titanium conforming to ASTM F 1580. All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

INDICATIONS
Lucent and Lucent Ti-Bond are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

These devices are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

These devices are intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with these devices.

LUCENT MAGNUM & LUCENT MAGNUM TI-BOND
ANTERIOR LUMBAR INTERBODY SYSTEMS

GENERAL INFORMATION
Spinal Elements' Lucent Magnum and Lucent Magnum Ti-Bond devices are generally oval-shaped devices that have various graft windows throughout their geometry. These devices are made from either titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3, polyetheretherketone (PEEK-Optima®) conforming to ASTM F 2026, or PEEK with a coating of commercially pure titanium conforming to ASTM F 1580. All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems.

INDICATIONS
Lucent Magnum and Lucent Magnum Ti-Bond are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

These devices are intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

These devices are intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with these devices.

GENERAL INSTRUCTIONS FOR USE

CONTRAINDICATIONS

1. Patients with known or probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any patient that has had prior fusion surgery at the levels to be treated.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
8. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indications for use.
13. Reuse or multiple use.

WARNINGS

Implants and instruments are provided non-sterile. Instruments must be cleaned and sterilized before use. Implants may be reprocessed prior to use and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative 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 this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

Physician Note: 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.

MAGNETIC RESONANCE ENVIRONMENT

The Lucent, Lucent Ti-Bond, Lucent Magnum and Lucent Magnum Ti-Bond Systems have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants.

5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent CSF leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
13. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Non-union (pseudo-arthrosis), delayed union, mal-union.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Inability to perform the activities of daily living.
19. Death.

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments and implants should be processed and sterilized prior to use.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. 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. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
5. Implants should not be axially rotated with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
4. Contaminated instruments must be cleaned promptly after use per instructions noted in the Cleaning Instruction section of this insert in order to prevent drying and ensure an effective cleaning.

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, mechanical failure, serious injury, transmission of infectious agents and death.

Titanium-Coated Implants:

Titanium-coated implants may be processed by automated means prior to sterilization. Implants that have directly come in contact with the patient or bio-contaminants should be discarded. Separate implant caddies from the instrument tray prior to and during any processing.

CLEANING AND MAINTENANCE

GENERAL INFORMATION

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.

Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

1. Inserters and Offset Inserters should be disassembled before cleaning:
   The Inserters are each comprised of two subassemblies - a shaft and a handle - that disassemble for cleaning. To disassemble each of these instruments, hold the instrument by its shaft in one hand. Depress the button on the larger diameter of the shaft with the first hand while pulling the handle axially away from the shaft with a second hand.
   To disassemble Offset Inserters, hold the instrument by its shaft in one hand. Depress the button on the larger diameter of the shaft with the first hand while pulling the inserter rod axially away from the shaft with a second hand.
2. Follow the cleaning instructions listed in the Cleaning Instruction section of this insert. Pay special attention to the lumens of the external shafts of disassembled instruments.
3. An instrument lubricant should be applied to the ratchet teeth on the internal shaft of inserters and to the ratcheting mechanisms of the Lucent and Lucent Ti-Bond Guns after cleaning.
4. An instrument lubricant should be applied to all hinged instruments (i.e. rongeurs, lamina spreaders, etc.) after cleaning.

AUTOMATED CLEANING INSTRUCTIONS

All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING

1. Disassemble all instruments that come apart for cleaning.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas. Pay special attention to lumens of the external shafts of disassembled instruments.
3. Prepare Enzol® (or equivalent neutral or mild pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 1 minute. While soaking, actuate the instruments through a full range of motion (as appropriate) to allow complete penetration of the cleaning solution. Instruments that do not disassemble may require additional soaking.
4. After the soak, remove the instruments and wipe any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of enzymatic cleaning solution using warm water. Scrub the entire surface of the devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations. Ensure no soil is visible in the rinse stream.
5. Remove from enzymatic cleaner solution and rinse with reverse osmosis or de-ionized (RO/DI) water for a minimum of 30 seconds to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
6. Prepare Prolystica® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
7. Remove from the detergent solution and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds to remove any residual detergent and until no sign of soil is seen in the rinse stream. While rinsing, thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.

AUTOMATED CLEANING

8. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzol or equivalent per manufacturer's instructions
Wash	2 minutes	65.5°C	Prolystica or equivalent per manufacturer's instructions
PURW Rinse	2 minutes	43°C	N/A
Drying	15 minutes	90°C	N/A

9. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
10. Visually examine devices to ensure all visible soil has been removed.
11. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
12. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. Pay special attention to the instruments called out in system specific sections.

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Disassemble all instruments that come apart for cleaning.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide, and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas. Pay special attention to the lumens of the external shafts of disassembled instruments.
3. Prepare Enzol® (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 20 minutes. After the soak, scrub devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations.
4. Remove from enzymatic cleaner solution and rinse with reverse osmosis/de-ionized (RO/DI) water for a minimum of three minutes to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
5. Prepare Prolystica® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
6. Remove from the detergent solution and rinse with RO/DI water for a minimum of three minutes to remove any residual detergent and until no sign of soil is seen in the rinse stream. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
7. Repeat Steps 5 and 6.
8. Dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
9. Visually examine devices to ensure all visible soil has been removed.
10. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
11. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. Pay special attention to the instruments called out in system specific sections.

STERILIZATION

Implants and instruments are provided non-sterile and must be sterilized before use. Non-sterile implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Gravity Displacement	270°F (132°C)	15 minutes	45 minutes
	Steam	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Rigid Container	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

*Note: Rigid containers must have a minimum of 2 filters and require a 30 minute cooldown period post sterilization.

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. These sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as 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 (time and temperature).

INFORMATION

REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Caution, Consult Accompanying Documents		Do Not Re-Use

NON-STERILE Device Not Sterile

℞ Only Prescription Only

Instruction for Use are provided electronically at ifu.spinalelements.com

Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

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