Instructions for Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. ("KMTI") Tesera SA Anterior Lumbar Interbody Fusion (ALIF), Sterile Packaging.

Caution: United States Federal Law restricts this device to sale by, or on the order of, a physician.

KEY OF RECOGNIZED SYMBOLS

UDI	Unique device identifier		Double sterile barrier system
	Manufacturer		Do not use if package is damaged and consult instructions for use
	Use-by date		Keep away from sunlight
LOT	Batch code		Keep dry
REF	Catalogue number		Do not re-use
STERILE EO	Sterilized using Ethylene oxide		Consult instructions for use
STERILE R	Sterilized using Irradiation	QTY	Quantity of items in package.
	Do not Resterilize	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
NON STERILE	Non-sterile		Store in a cool place. Do not store in environments with the potential for extreme heat or direct sunlight

DESCRIPTION
The Tesera SA ALIF System is an internal spinal fixation system comprised of Titanium Interbody Cages, Titanium Screws and Titanium Cover Plate Assemblies. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Broaches, Sizers, Cage Inserters and Cover Plate Inserters. The titanium interbody cages exhibit KMTI's proprietary Tesera Trabecular Technology® on the inferior and superior endplates which incorporates micro-scale and nano-scale roughness features. The Tesera SA ALIF System is approved for use in the United States and Australia.

Tesera SA ALIF System Implants – Summary Description

Dimensions (mm) A/P M/L H	 26, 28, 30, 32 30, 34, 38, 42 11 – 12 (Δ2mm) heights vary by lordosis
Lordosis	7°, 12°, 16°, 20°,22°, 28°
Number of screws	4
Screw Diameter (mm)	4.5, 5
Screw Length (mm)	20, 25, 30, 35
Cover plate (mm)	8.3 H; 22 W

For implant and instrument part numbers, as well as implant dimensions, refer to the Tesera SA System Surgical Technique (p/n 4128-011).

IMPORTANT NOTE
This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL
All implant components of the Tesera SA ALIF System are made of the following materials:
- Titanium Ally: Ti6Al4V according to ASTM F-136 and F-2924

INDICATIONS FOR USE
The KMTI Tesera SA Anterior Lumbar Interbody Fusion (ALIF) 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). KMTI Tesera SA ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The KMTI Tesera SA ALIF System is a standalone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for the use in the lumbar spine must be used. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°.

GENERAL CONDITIONS OF USE
The safe implantation of Anterior Lumbar Interbody Fusion (ALIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the Tesera SA ALIF System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion.

In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The Tesera SA ALIF System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the Tesera SA ALIF System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. The Tesera SA ALIF System has been tested as a standalone construct.

CONTRAINDICATIONS
Contraindications to using the Tesera SA ALIF System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) Systems and consist of the following:

1. Prior fusion at the level(s) to be treated.
2. Any condition not described in the Indications for Use.
3. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
4. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
5. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
6. Patients with a suspected or documented metal allergy or intolerance.
7. Inadequate tissue coverage over the operative site.
8. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
9. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and pregnancy.

POTENTIAL RISKS
Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal, healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load- sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur in metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

PATIENT SELECTION
The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and

precautions in the device use, leading to the implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

WARNINGS AND CAUTIONS
Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient.

These warnings do not include all possible adverse surgical effects but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage.
4. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
5. The Tesera SA ALIF System implants are provided sterile. Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.
6. The Tesera SA ALIF System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized before each use.
7. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal, healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
9. KMTI implants and instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the Tesera SA ALIF System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
    a. Movement of ferromagnetic components through magnetically induced force and torque.
    b. Localized heating of components caused by radio frequency induction heating.
    c. Image artifacts created by interaction between metallic components and the magnetic field.

MRI SAFETY
1. **Implants**: The KMTI Tesera SA ALIF System implants are manufactured from non-ferromagnetic materials. The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifacts in the MR environment. The safety of the Tesera SA ALIF System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
2. **Instruments**: KMTI instruments used with the Tesera SA ALIF System implants may be manufactured from ferromagnetic materials and may be MR unsafe. Potential risks of placing instruments in or near the magnetic field include:
    a. Movement of ferromagnetic components through magnetically induced force and torque.
    b. Localized heating of components caused by radio frequency induction heating.
    c. Image artifacts created by interaction between metallic components and the magnetic field.

ADVERSE EFFECTS
In addition to the obvious risk that any orthopedic implant may fail, loosen or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals and other materials used in the manufacturing orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long-term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be onco- genic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast digestive system and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation debris may be an inevitable consequence of impaction and/or motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface. Additionally, thoroughly irrigate the wound to prevent debris associated with implantation from remaining within the disc space prior to wound closure.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

HANDLING OF IMPLANTS AND INSTRUMENTS
1. **Receipt**: Carefully unwrap and handle non-sterilized instruments upon receipt to avoid scratching, marking or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration. Implants are provided sterile. Wrappings should not be removed by receiving personnel.
2. **Transport**: Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. **Storage**: Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock rotation – The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility and configuration. Keep implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. **Traceability**: Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting and/or possible traceability to the manufacturer.

IMPLANT STERILITY
All implants are sterilized by exposure to a minimum dose of 25kGy of gamma radiation.

Do not resterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date.

DECONTAMINATION AND CLEANING
All instruments must be thoroughly cleaned before each sterilization (including the first use) and introduction into a sterile field. All devices should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. More information is provided in KMTI Instruments IFU (p/n 4001-001).

Instruments that are specifically designed for use with the Tesera SA ALIF System include trials, sizers, implant/cage inserters and the cover plate inserter. Other instruments are also provided for use with the Tesera SA ALIF System. For a list of all instruments, refer to the KMTI Tesera SA ALIF Surgical Technique manual (p/n 4128-011).

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Keep devices moist and do not allow blood and/or bodily fluids to dry on the devices. The decontamination process should begin immediately after completion of the surgical procedure. Instruments should not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

KMTI rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles and disinfectant type used as instructed by manufacturer of washer-disinfection unit. Devices must be processed separately from trays and cases. All devices must be thoroughly cleaned before use.

Some instruments must be fully disassembled prior to cleaning. Instructions for instruments requiring disassembly prior to cleaning may be found in KMTI Tesera SA ALIF Surgical Technique (p/n 4128-011). In general,

a.) Silicone Handle instruments exhibiting a modular connection (i.e. AO, ¼" Sq., etc.) must be detached from the adjoining instrument connection, such as driver shafts.
b.) Bullet Nose Distractor, Trial, and Broach Instruments should be unthreaded from the Modular Inserter Handle Instrument
c.) Speed Guide Instruments should be detached from the Cage Inserter Instrument.
d.) Inserter Tip Instruments should be detached from the Cage Inserter Instrument.

All devices must be thoroughly cleaned, decontaminated and sterilized as follows (and as per KMTI Instrument IFU, p/n 4001-001):

1. **Pre-Cleaning**: Disassemble devices where applicable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts. The Angled Driver Assembly and Large Modular Handle must be disassembled before cleaning. Instructions for disassembling and reassembling the Angled Driver Assembly are included in the package for the instrument and available upon request, IFU 4001- 004. No other Tesera SA ALIF System instruments require disassembly.
2. **First Rinse**: Rinse devices under running tap water for a minimum of 2 minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris. Actuate devices with moving parts. Clear lumens/cannula/channels/holes of all debris using an appropriately sized bottle brush.
3. **Decontamination**: Soak the devices completely in an enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent). Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct temperature, water quality and concentration. Fully immerse the devices and allow them to soak for a minimum of 20 minutes. Following soak, use a soft-bristled brush to assist in the removal of gross soil, debris or contaminants, ensuring hard to reach areas are accessed and articulating device with moving parts.
4. **Rinsing**: Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Use a syringe, pipette or water jet to flush lumens/cannular/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly.
5. **Washing**: Immerse devices in the ultrasonic washer/cleaner with enzymatic cleaner or detergent solution* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 15 minutes. Follow the manufacturer's specifications for suggested water level, temperature, water quality and concentration of enzymatic cleaner or detergent.
6. **Rinsing**: Thoroughly rinse the devices with purified water for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush lumens/cannula/channels/holes. Articulate devices with moving parts under running water in order to rinse thoroughly. Repeat rinsing a total of three (3) times. Final Rinse water quality should be acceptable per AAMI TIR34.
7. **Inspection**: After cleaning/disinfection, devices should be visually inspected for contamination. If contamination is still visible, repeat steps 2, 3, 4, 5, 6 and 7. If devices continue to have visual contamination, do not use devices and contact KMTI Customer Service for further instructions.
8. **Drying**: Allow devices to air dry for a minimum of 20 minutes prior to sterilization preparation. Devices must be thoroughly dried to remove residual moisture before they are stored.
9. **Preparation and Assembly**: After cleaning/disinfection and inspection, any disassembled devices (Angled Driver Assembly and/or Large Modular Handle) should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Do not use if any of this damage is observed. Mechanically test the working parts to verify that each device functions correctly. Place devices into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines. FDA cleared sterilization wrap must be used.

*Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures.

KMTI has validated the above manual cleaning method with the provided solution examples. Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

CARE AND HANDLING OF INSTRUMENTS

1. General – Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
   - Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing.
   - Only use an instrument for its intended purpose.
   - When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.
2. General Cleaning – Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood. Loosen and/or disassemble instruments with removable parts.
3. Ultrasonic Cleaners – can be used with hot water per the manufacturers' recommended temperature, however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

NOTE: Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

RESPONSIBILITIES OF THE USER

- General – Health care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility.

- Sterility – Users should conduct testing in health care facility to assure that conditions essential to sterilization can be achieved.

STERILIZATION

- **Sterile Implants**: Implants of the Tesera SA ALIF System are provided "STERILE" via gamma irradiation and intended for single patient use only. DO NOT RESTERILIZE THIS PRODUCT. Sterility can only be assured if packaging is intact.
- **Non-sterile Instruments**: Instruments of the Tesera SA ALIF System are provided non-sterile.
- Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid event-related contamination. Storage should be in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes. Care must be taken in handling wrapped cases to prevent damage to the barrier. The shelf life for wrapped instruments cases shall be based on policies and procedures in accordance with ANSI/AAMI ST79. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling. Sterile instrument cases should be carefully examined prior to opening to ensure that the package integrity has not been compromised. If an instrument case sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged, and sterilized.

In a properly functioning calibrated steam sterilizer, testing has shown that effective sterilization may be achieved as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	30 Minute Minimum 40 Minute Maximum

This sterilization cycle (drying time) is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, bio- logical indicators and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid, and a new cycle must be established by the user. The autoclave must be properly installed, maintained and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

Double wrap (2 wraps) instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79. Only FDA-cleared wraps or outer containers should be used. Use only sterile products in the operating field. After surgery, immediately decontaminate, clean, and re-sterilize before handling or (if applicable) return the re-sterilized product to Kyocera Medical Technologies, Inc (KMTI).

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).

Flash sterilization is not recommended.

The shipping packaging in which non-sterile instruments are supplied should not be used for sterilization methods in the hospital.

Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the manufacturer, Kyocera Medical Technologies, Inc (KMTI). Further, if any of the implanted Tesera SA ALIF System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer should be notified immediately. If any KMTI product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone and written correspondence. When filing a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the manufacturer is requested.

FURTHER INFORMATION

Recommended directions for use of this system (Surgical technique manual) are available at no charge upon request.

If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Kyocera Medical Technologies, Inc (KMTI) customer service for current information at 909-557-2360.

If further information is needed or required, please contact:

Kyocera Medical Technologies, INC. (KMTI)
Attn: Regulatory Department
1289 Bryn Mawr Ave., Ste. A
Redlands, CA 92374 USA
(909) 557-2360
Fax: (909) 839-6269
Email: kmti.info@kyocera.com
www.kyocera-medical.com

Australian Sponsor
Evolution Pty Ltd
A 4/12 Chaplin Dr, Lane Cove West, NSW 2066
T +61 2 9428 1084
E evolution@evolutionsurgical.com.au
W evolutionsurgical.com.au

Additional Mailing Address:
4/22 Newstead Terrace, Newstead QLD 4006