Kyocera Medical's Tesera-k ALIF Anterior Lumbar Interbody Fusion (ALIF) System

Tesera-k SA ALIF

Tesera-k A ALIF

Kyocera Medical Technologies, Inc. (KMTI)

1200 California St. Ste. 210
Redlands, CA 92374
909-557-2360

CAUTION: United States Federal law restricts this device to sale by or on the order of a physician.

IFU Document #4167-001 Rev B *05/2022*

DEVICE DESCRIPTION:

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k Anterior Lumbar Interbody Fusion (ALIF) System consists of implants to support foraminal height and decompression between lumbar or lumbosacral vertebral bodies during spinal correction and fusion as well as reusable instruments to assist in endplate preparation and implantation. The Tesera-k ALIF System implants are available as a monolith without integrated fixation (Tesera-k A) or as a standalone with integrated fixation (Tesera-k SA) and are additively manufactured from Ti-6Al-4V per ASTM F2924. The Tesera-k SA construct includes screws and a coverplate manufactured from Ti-6Al-4V per ASTM F136 from the Tesera SA ALIF System. The Tesera-k ALIF implants are sterile packaged and inserted via a direct anterior or oblique anterior surgical approach. The Tesera-k ALIF implants are offered in a variety of sizes and lordosis options to meet patient anatomical needs.

INDICATIONS:

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-k Anterior Lumbar Interbody Fusion (ALIF) System is indicated for interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine at one or two contiguous levels from L2 to S1. DDD 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-k 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 Tesera-k ALIF System implants are available in standalone (Tesera-k SA) and non-standalone (Tesera-k A) configurations.

Tesera-k SA ALIF cages are intended to be implanted from a direct anterior surgical approach only. Tesera-k SA ALIF cages are intended to be used with the coverplate and screws provided. Tesera-k SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles less than 20° and use all four screws are standalone and require no supplemental fixation. Tesera-k SA ALIF assemblies (cage, screws, coverplate) that contain cages with lordotic angles greater than or equal to 20° or if the surgeon chose to use fewer than four screws are considered non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine.

Tesera-k A ALIF cages are monolithic and do not interface or mate with any additional implants. Tesera-k A ALIF cages may be implanted from direct anterior or oblique insertion angle. Tesera-k A ALIF cages are non-standalone and require supplemental fixation cleared by the FDA for use in the lumbosacral spine.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

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. 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.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
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:

1. Implants are provided sterile. Do not use implants past expiration date.
2. Instruments are provided non-sterile.
3. Instruments must be cleaned before use and after use.
4. Instruments are critical devices and must be terminally sterilized by steam sterilization prior to surgical use.
5. Prior to sterilization and promptly following each procedure, thoroughly clean all instruments according to the procedures outlined below. The parameters for sterilization and sterilization processes listed below are only valid for devices that have been properly cleaned.
6. All instruments should not be allowed to dry before reprocessing to effectively clean and remove contaminants including blood, body fluids, bone and tissue debris, and other contaminants.
7. Do not use silicone or oil-based lubricants as these may inhibit sterilization.
8. Do not use metal cleaning tools such as metal or wire brushes, scouring pads, etc to clean the instruments as these may damage the surface of the instruments.
9. 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.
10. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

11. Corrosion from Mixed Metals. Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion for implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The Tesera-k ALIF implants are available in titanium alloy. It is imperative that the Tesera-k ALIF implants do not come into contact in-vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment. Corrosion may accelerate failure of implants. Corrosion also causes metal compounds to be released into the body.
12. Smoking. Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

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. Do not subject implant to excessive loading or trauma. 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 Tesera-k ALIF System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS:

Potential complications and adverse effects include, but are not limited to:

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. Cessation of growth of the fused portion of the spine.
4. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
5. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis Tissue damage caused by improper positioning and placement of implants or instruments.
6. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
7. Infection and/or wound complications.
8. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or meningitis.
9. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
10. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
11. Loss of bowel and/or bladder control, or other types of urological system compromise.
12. Scar formation possibly causing neurological compromise around nerves and/or pain.
13. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
14. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
15. Non-union (or pseud-arthrosis). Delayed union. Mal union.
16. Loss of spinal mobility or function. Inability to perform the activities of daily living.
17. Malalignment of anatomical structures (i.e. loss of normal spine contours or change in height).
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Subsidence of the device into the vertebral body.
21. Pain or discomfort.
22. Atelectasis, ileus, gastritis, herniated nucleus pulposus, and/or retropulsed graft.
23. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
24. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
25. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
26. Change in mental status.

27. Revision surgery.
28. Death.

NOTE: Additional surgery may be necessary to correct some of these potential adverse effects.

CAUTION:

FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

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 SELECTION:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete. This may result in further injury or the need to remove the device prematurely.

Use of the Tesera-k ALIF System should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

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 instruments 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 Kyocera Medical Technologies, Inc (KMTI).
7. The type of implant to be used for the case should be determined prior to beginning the surgery.
8. All instruments 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. Care must be taken to maintain implant sterility once sterile packaging is opened.
3. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
4. Thoroughly irrigate the wound to prevent debris associated with implantation from remaining within the disc space.
5. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
6. 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.
7. 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.
8. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
9. 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.

PREPARATION AT POINT OF USE:

The implants of the Tesera-k ALIF System are provided sterile and are single use only. The surgical instruments provided with the Tesera-k ALIF System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual instruments may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. All instruments that are fully or partially dismantleable must be disassembled prior to cleaning. This includes the following:

- Removal of all detachable handles from each instrument

Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients.

Instruments must be placed into their respective locations in the sterilization tray to ensure proper steam sterilization. Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. This includes inspecting the tips of drivers and awls for wear, checking the function of modular handles, and inspecting inserters for wear or damage. If an instrument is suspected to be damaged it must not be used and, and Kyocera Medical Technologies, Inc (KMTI) contacted for a replacement.

Follow the Cleaning and Sterilization procedures below.

CLEANING AND STERILIZATION

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. KMTI Instrument IFU (P/N 4001-001) provides more detailed information about proper cleaning of the instruments in the Tesera-k ALIF System. For a list of all instruments, refer to the KMTI Tesera-k ALIF Surgical Technique manual (P/N 4167-002).

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.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments.)

Either manual cleaning or automated cleaning may be utilized by the end-user. Both methods are validated and acceptable. It is not necessary to utilize manual cleaning in conjunction with automated cleaning methodologies, or vice versa.

MANUAL CLEANING INSTRUCTIONS.

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.
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 devices 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/cannula/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. Water quality used for final rinsing should be acceptable per AAMI TIR34. 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.
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 inspection and 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 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 instrument functions correctly.

* 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.

AUTOMATED CLEANING INSTRUCTIONS

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.
2. First Rinse: Rinse devices under cold, running tap water (<43° C) for a minimum of 2 minutes to remove gross soil and debris.
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 5 minutes.
4. Second Rinse: 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/cannula/channels/holes. Actuate devices with moving parts under running water in order to rinse

thoroughly. 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 devices with moving parts. Scrub all surfaces using brushes paying particular attention to moving parts, lumens, cannulas, channels, holes, crevices, and rough surfaces.

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 10 minutes. Follow the manufacturer's specifications for suggested water level, temperature, water quality and concentration of enzymatic cleaner or detergent.
6. Third Rinse: Rinse thoroughly with warm water while irrigating challenging cleaning features.
7. Automated Cleaner: Load instruments in automated washer and run standard instrument cycle. KMTI has validated the following cycle parameters:

STAGE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE AND CONCENTRATION (IF APPLICABLE)
Pre-wash 1	02:00	Cold tap water	N/A
Wash 1	02:00	43º C Tap water (Set Point)	Enzol 1 oz./gallon
Rinse 1 (final rinse)	02:00	43º C (Set Point) [1]	N/A
Dry Time	15:00	90º C	N/A

[1] Water quality used for final rinsing should be acceptable per AAMI TIR34.

8. Inspection: After cleaning/disinfection, devices should be visually inspected for contamination. If contamination is still visible, repeat steps 2, 3, 4, 5, 6, 7, and 8. If devices continue to have visual contamination, do not use devices and contact KMTI Customer Service for further instructions.
9. Preparation and Assembly: After cleaning/disinfection and inspection, any disassembled devices 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 instrument functions correctly.

* 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 automated 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 INSTRUCTIONS

- **Sterile Implants**: Implants of the Tesera-k 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 Implants and Instruments**: Instruments of the Tesera-k 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 extremes in temperature and moisture. Care must be taken in handling wrapped cases to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instruments cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. 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.

Sterilization: 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, biological 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 cases, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the Tesera-k ALIF System 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-k 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.

DISCLAIMER

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*.

FURTHER INFORMATION:

Recommended directions for use of this system (surgical technique manual) are available at no charge upon request. If further information is needed or required, please contact:

Kyocera Medical Technologies, Inc. (KMTI)
1200 California St. Ste. 210
Redlands, CA 92374
909-557-2360
Fax: 909-839-6269
Email: kmti.info@kyocera.com
www.kyocera-medical.com

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Use-by-Date – Indicates the date after which the medical device is not to be used.	5.1.4
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Sterilized via Irradiation – Indicates a medical device has been sterilized using irradiation	5.2.4
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	5.4.2
	Do not re-sterilize	5.2.6
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself * *per ISO 15332-1:2016	5.4.4
	Keep Dry	5.3.4
	Keep away from sunlight	5.3.2
	Do not use if package is damaged	5.2.8
	Store in cool place. Do not store in environments with the potential for extreme heat of direct sunlight	N/A