Kyocera Medical's Tesera-K SC System

Tesera-K SC

Kyocera Medical Technologies, Inc. (KMTI)

1289 Bryn Mawr Ave., Ste. A
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 #4061-001 Rev B *10/2024*

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DEVICE DESCRIPTION:

The Kyocera Medical Technologies, Inc. (KMTI) Tesera-K SC System (Tesera-K SC) is an internal spinal fixation system consisting of additively manufactured titanium alloy interbody devices and machined titanium bone screws. It is designed to provide mechanical support to the cervical spine while arthrodesis occurs. The Tesera-K SC System is available in a variety of lordosis and footprint options with a lattice architecture which offers increased room for autogenous bone graft to allow for bone growth and mechanical properties to suit the individual pathology and anatomical conditions of the patient. The Tesera-K SC implants are manufactured from medical grade titanium (Ti-6Al-4V) per ASTM F2924 or per ASTM F136. The titanium interbody cages are designed with KMTI's proprietary Tesera Trabecular Technology® on the inferior and superior endplates which incorporates micro-scale and nano-scale roughness features.

Do not use any of the Tesera-K SC System components with components from any other manufacturer or system unless specifically allowed to do so in this or any other KMTI document. None of the Tesera-K SC System implant components should be reused under any circumstances. The instruments provided with the Tesera-K SC System are provided specifically for the implantation of the Tesera-K SC System implants.

Please refer to the applicable Tesera-K SC Surgical Technique (4167-002) for additional important information.

INDICATIONS:

The KMTI Tesera-K SC System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2-T1. KMTI Tesera-K SC System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six weeks of non-operative treatment prior to implantation.

The KMTI Tesera-K SC System is a stand-alone system when used with the locking bolt and bone screws provided and requires no additional supplemental fixation. When used as a stand-alone system, the cages require the use of two (2) bone screws and the locking bolt.

When used without the locking bolt and two screws, the KMTI Tesera-K SC System is a non-stand- alone system and requires additional supplemental fixation cleared by the FDA for use in the cervical spine to augment stability.

CONTRAINDICATIONS:

- Active systemic infection
- Local infection ant the site of surgery
- Allergy or foreign body sensitivity to any of the implant materials
- Severe osteoporosis as it may prevent adequate fixation and lead to collapse of the vertebral bodies around this and any other orthopedic implant
- Presence of fracture or tumor of the vertebral body
- Prior fusion at the levels to be treated
- Any condition not described in the Indications for Use

Other relative contraindications include:

- Conditions that place great stress on the implant or the interface with the endplates of the vertebral bodies, such as severe obesity, may lead to collapse of the vertebral bodies around the device (subsidence). The treating surgeon must weigh the benefits versus risks of using the device in order to decide what is in the best interest of the patient.

- A patient's occupation or activity level or mental capacity. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as cancer, diabetes, mental illness, alcoholism, drug abuse, or heavy smoker, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

POTENTIAL ADVERSE EFFECTS:

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects. Potential adverse effects include, but are not limited to the following:

- Loss of proper spinal curvature, correction, height and/or reduction
- Non-union (pseudoarthrosis), delayed union, or mal-union
- Cessation of any potential growth of the operated portion of the spine
- Loss of or increase in spinal mobility or function
- Infection
- Wound healing disorders or hematomas
- Bending and or/breaking of any devices
- Fracture, damage, or penetration of any spinal bone
- Pain, skin penetration, irritation, or fibrosis caused by skin pressure by implant components
- Loss of neurological function, dural tear, pain, and/or discomfort
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological, gastrointestinal, and/or reproductive System resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, sterility, consumption, sexual dysfunction etc.
- Change in mental status
- Bone loss and/or bone fracture due to stress shielding
- Bursitis
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia
- Revision surgery
- Death

PRECAUTIONS:

The implantation of the Tesera-K SC System is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique (4167-002) can be requested from KMTI by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the Tesera-K SC System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by KMTI.

CAUTION:

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

MAGNETIC RESONANCE ENVIRONMENT:

1. **Implants: The KMTI Tesera-K SC System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Tesera-K SC System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.**
2. **Instruments: KMTI instruments used with the Tesera-K SC 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.

WARNINGS:

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
- Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, necrosis of the bone, collapse of the vertebral bodies around the device (subsidence), neurological injury, and/or vascular or visceral injury.
- The benefit of spinal fusions utilizing any interbody fusion device has not been adequately established in patients with stable spines.
- Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke, or abuse alcohol, are poor candidates for spinal fusion. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
- The instruments are provided non-sterile and must be cleaned and sterilized before use. Instruments should be sterilized using one of the noted validated sterilization cycle parameters.
- A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions 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.
- Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the Tesera-K SC System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.
- Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
- Do not reuse implants. Discard used, damaged, or otherwise suspected implants. **AN IMPLANT SHOULD NEVER BE RE-USED**. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety. Do not use implants past the expiration date.

HANDLING OF IMPLANTS AND INSTRUMENTS:

- 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.
- Transport: Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
- 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.
- 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 KMTI.

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 SC System should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

PREOPERATIVE:

- The surgeon should consider utilizing the Tesera-K SC System only with those patients that meet the criteria described in the indications.
- The surgeon should avoid utilizing this device with those patients who meet the criteria described in the listed contraindications.
- The surgeon should have a complete understanding of the surgical technique, indications and contraindications.
- The surgeon should have a complete understanding of the surgical technique guide.
- The implants are provided sterile. Do not re-sterilize any implant. Do not use any implant from an opened or damaged package.

- The surgical instruments provided 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 dismantlable must be disassembled prior to cleaning. 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. 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 awls, drivers, drills, and taps for wear, and the inner shafts of any dismantlable instruments. If an instrument is suspected to be damaged it must not be used and KMTI must be contacted for a replacement.

Follow the *Cleaning and Sterilization* procedures later in this document.

INTRAOPERATIVE:

- The instructions in any available applicable surgical technique manual should be carefully followed.
- Damage to the nerves will cause loss of neurological functions. Extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially during endplate preparation, and insertion of the interbody and fixation screws.
- Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel. This includes maintaining the sterility of the implant once opened.
- Bone graft should be packed inside the device prior to insertion and around the device after insertion. Bone graft must be placed in the area to be fused. The bone graft must extend from the upper to the lower vertebrae to be fused.
- Notching and scratching of implants should be avoided.
  Thoroughly irrigate the wound to prevent debris associated with implantation from remaining within the disc space prior to wound closure.

POSTOPERATIVE:

- The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
- For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
- The patient should be warned about the limitation of bending at the point of spinal fusion.
- The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing and/or fusion.
- The removed implants should be properly disposed of and are not to be reused under any circumstance.

PREPARATION AT POINT OF USE:

The implants of the Tesera-K SC System are provided sterile and are single use only. The surgical instruments provided with the Tesera-K SC 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 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.

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.

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.*

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 SC 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-K SC 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.

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

Cycle	Dynamic-air-removal Steam
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 SC System is not recommended.

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

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 SC 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)
1289 Bryn Mawr Ave., Ste. A
Redlands, CA 92374
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

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
℞ ONLY	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 – Indications* 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 and consult *instructions for use*	5.2.8
	Store in cool place. Do not store in environments with the potential for extreme heat of direct sunlight	N/A
QTY	Quantity of items in package	N/A
	Double sterile barrier system	5.2.12
	Consult *instructions for use* or consult electronic *instructions for use*	5.4.3
UDI	Unique device identifier	5.7.10