Kyocera Medical's Skyway Anterior Cervical Plate System

Kyocera Medical Technologies, Inc. (KMTI)

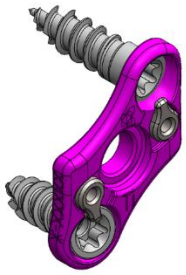
1200 California St. Ste. 210

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 #4140-003 Rev A *09/2023*



SCOPE:

This IFU document applies to KMTI's Skyway Anterior Cervical Plate System 1-level implants (Family 1040-series) and instruments. The System implants include 1-level cervical plates, bone screws, and locking screw. For a full list of all implant part numbers in the scope of KMTI's Skyway Anterior Cervical Plate System, refer to the System's Surgical Technique #4140-004.

The Skyway Anterior Cervical Plate System 1-level cervical plates and locking screw implants are compatible for use with KMTI's Tesera-k SC System's anterior cervical discectomy Fusion (i.e. interbody) cages. Indications for KMTI's Tesera-k SC System are included in KMTI's IFU #4061-001. For a full list of all implant part numbers in the scope of KMTI's Tesera-k SC System, refer to the System's Surgical Technique #4061-002.

The Skyway Anterior Cervical Plate System 1-level and multi-level implants (Family 1140-series), with no optional interbody spacer attachment, are also available; these implants are not compatible for attachment to the Tesera-k SC System cages. For a full list of all implant part numbers and the indications for use in the scope of KMTI's multi-level Skyway Anterior Cervical Plate System, refer to the System's IFU #4140-001 and Surgical Technique #4140-002.

DEVICE DESCRIPTION:

The Kyocera Medical Technologies, Inc. (KMTI) Skyway Anterior Cervical Plate System consists of anterior cervical plates, bone screws, and a locking screw. The implant components are composed of titanium alloy Ti-6Al-4V ELI per ASTM F136. The Skyway Anterior Cervical Plates System is offered in various sizes to accommodate patient anatomical needs.

Skyway Anterior Cervical Plate System Implants – Summary Description

Plate Dimensions (mm) Thickness A / P M / L H Hole-to-Hole Cephalad-to-Caudal	 2.2 3.5 14.8 12 - 16 (Δ2) 19 - 23 (Δ2)
Number of screws	2, 3, or 4
Screw Diameter (mm)	4.0, 4.5
Screw Length (mm)	12 -20, (Δ2)
Center Bolt Length (mm) Before Assembly After Assembly	 13.6 7.8
Locking Screw Diameter (mm)	5.8

For implant and instrument part numbers, as well as implant dimensions, refer to the Skyway Anterior Cervical Plate System Surgical Technique manual (#4140-004).

INDICATIONS:

The Skyway Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis, or scoliosis), tumor, pseudarthrosis or failed previous fusion.

The 4-Hole 1-Level Plates are limited to use at one contiguous level.

The KMTI Tesera-K SC System is indicated for intervertebral body fusion procedures in skeletally mature patients with cervical degenerative disc disease at one or two levels 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. When used with the Skyway Anterior Cervical Plate System plates designed with spacer attachment, the assembly takes on the indications of the KMTI Tesera-K SC Interbody Spacer, with the Skyway Anterior Cervical Plate System acting as the supplemental fixation.

MATERIALS:

The implant plates, bone screws, and construct center bolt are manufactured from Ti-6Al-4V titanium alloy per ASTM F136. Surgical instruments provided with the Skyway Anterior Cervical Plate System are manufactured from stainless steel, aluminum, or silicone.

CONTRAINDICATIONS:

Contraindications to use the Skyway Anterior Cervical Plate System are similar to those of other anterior cervical fixation (ACF) plating systems and include, but are not limited to:

1. Any condition not described in the Indications for Use
2. Patients with conditions that may place excessive stresses on bone and implant, such as severe obesity, pregnancy, neuromuscular deficits, or degenerative diseases. The decision to use this system in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
3. 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.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Any case requiring implants with an interface between stainless steel, cobalt chrome, and/or other metals with titanium implant components.
6. Inadequate tissue coverage over the operative site.
7. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
8. 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.

WARNINGS:

The following are specific warnings and precautions that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Single use only. Reuse of devices labeled as single-use could result in injury or reoperation due to breakage or infection. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
2. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
3. The Skyway Anterior Cervical Plate System is not intended for screw attachment or for fixation to posterior elements (pedicles) of cervical, thoracic, or lumbar spine.
4. Always orient the plate along the midline of the spine.
5. Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. PATIENT SELECTION: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
    a. A patient may have multiple pain generators due to advanced degeneration of the spine (e.g., intervertebral disc. facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record including radiographic studies and applicable diagnostic tests should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
    b. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
    c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
    d. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
    e. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
    f. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
8. Implants Sterility:
    a. Implants are provided sterile and must not be used past expiration date.
9. Instrument Cleaning & Sterilization:
    a. Instruments must be cleaned before use and after use. Prior to sterilization and promptly following each procedure, thoroughly clean all instruments according to the procedures outlined below.
    b. Instruments are critical devices and must be terminally sterilized by steam sterilization prior to surgical use. The parameters for sterilization and sterilization processes listed below are only valid for devices that have been properly cleaned.
    c. 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.
    d. Do not use silicone or oil-based lubricants as these may inhibit sterilization.

e. 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.

10. 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.
11. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

PRE-CAUTIONS:

1. The implantation of spinal fixation devices should be performed only by experienced spinal surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patients.
2. Proper sizing of the implants is important. Based upon the fatigue results, the surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system when selecting the appropriate implant sizes.
3. 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 Skyway Anterior Cervical Plate System implants are available in titanium alloy. It is imperative that the 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.
4. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The devices must be handled and stored carefully to protect from damage. They should be carefully unpacked and inspected for damage prior to use.
5. 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.
6. The Skyway Anterior Cervical Plate System implants are provided sterile. Do not re-sterilize any implant. Do not use any implant from an opened or damaged package. Do not use implants after expiration date.
7. The Skyway Anterior Cervical Plate System instruments are provided non-sterile, and therefore, must be thoroughly cleaned and sterilized per instructions for use before each use.
8. Correct handling of the implants is extremely important. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Do not use the implant if damage is suspected. Do not use implants that exhibit surface or configuration damage.
9. 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. 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 may be particularly at risk during postoperative rehabilitation. A patient that is noncompliant with post-operative guidance is particularly at risk during the early postoperative period.
10. The physician is the learned intermediary between the manufacturer and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.
11. Implants: The Skyway Anterior Cervical Plate System implants are manufactured from nonferromagnetic 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 Skyway Anterior Cervical Plate System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
12. Instruments: KMTI instruments used with the Skyway Anterior Cervical Plate System implants may be manufactured from ferromagnetic materials and may be MR unsafe. 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.

MAGNETIC RESONANCE ENVIRONMENT

The Skyway Anterior Cervical Plate 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 device in the MR environment is unknown. Performing an MR exam on a patient who has this medical device may result in injury or device malfunction.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS:

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

1. Non-bearing, delayed union.
2. Bending or fracture of the implant.
3. Allergic reaction to a foreign body.
4. Infection.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Loss of proper spinal curvature, correction height, and/or reduction.
8. Vascular and/or never damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
9. Paralysis.
10. 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 Skyway Anterior Cervical Plate 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. The vertebral levels to be fixated should be well visualized with a linear anterior surface so that the plate will mount flush with the anterior cervical spine.
5. The components should not be repeatedly or excessively bent more than absolutely necessary. The components should not be reverse bent at the same location. Bending near the screw holes should be avoided.
6. Always orient the plate as close as possible to the spinal midline.
7. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
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. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
2. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
3. Postoperative patients should be instructed to limit activity as determined by their surgeon. The surgeon may advise the patient to wear a brace.
4. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union.
5. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

PREPARATION AT POINT OF USE:

The implants of the Skyway Anterior Cervical Plate System are provided sterile and are single use only. The surgical instruments provided with the Skyway Anterior Cervical Plate 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 dismantlable must be disassembled prior to cleaning. This includes the following:

- Removal of all detachable handles from each instrument
- Removal of inner shafts from outer cannulated shafts
- Removal of Bone Pins from the Bone Pin Driver instrument's distal tip.
- Removal of material from Locking Screw Driver internal tip

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 Skyway Anterior Cervical Plate System. For a list of all System instruments, refer to the KMTI Skyway Anterior Cervical Plate System Surgical Technique manual (P/N 4140-004).

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 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 Skyway Anterior Cervical Plate 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 Skyway Anterior Cervical Plate 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
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.

The System instrument case has a nylon pin mat that is available upon request. The nylon pin mat fits within the instrument case to hold miscellaneous instrumentation during transport and sterilization. When the nylon pin mat is present, the System instrument case requires a 40 minute dry time. It is the responsibility of the end-user (i.e. hospital) to ensure steam sterilization and dry time parameters including a dry time of 40 minutes. Any other modifications to the instrument case and nylon pin mat require the end user to validate appropriate steam sterilizer and dry time parameters.

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 Skyway Anterior Cervical Plate 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 Skyway Anterior Cervical Plate 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 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
	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
	Unique device identifier	5.7.10