KYOCERA Medical Technologies, Inc.

4127-001 Rev. C

Instructions For Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. ("KMTI")
Cervical Interbody Implant Inserter

DESCRIPTION

KMTI instrumentation consists of devices and their accessories used in surgical procedures. Before using KMTI instrumentation for any surgical procedure, familiarity with, and attention to the appropriate, recommended surgical technique is imperative. KMTI instrumentation should only be used in combination with other KMTI products.

KMTI instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

INDICATIONS

The KMTI Cervical Interbody Instrumentation system should only be used to assist in the implantation of a cervical intervertebral fusion cage according to the indications and instructions for use (IFU) of the specific device being implanted. Cervical Cage Systems are indicated for intervertebral fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one level from C2 to T1. Degenerative disc disease is defined as discogenic neck pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

This instrumentation should not be used to implant any cervical intervertebral fusion cage in a way that violates the IFU of the specific device to be implanted. Contraindications include, but are not limited to, the following:

1. Signs of local inflammation
2. Fever or leukocytosis
3. Morbid obesity
4. Pregnancy
5. Mental illness
6. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Suspected or documented allergy or intolerance to composite materials
8. Any case not needing a fusion
9. Any case not described in the indications
10. Any patient unwilling to cooperate with postoperative instructions
11. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
12. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
13. Any case where the implant components selected for use would be too large or too small to achieve a successful result
14. Any case that requires the mixing of metals from two different components or systems
15. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
16. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
17. Prior fusion at the level to be treated.
18. Additional contraindications for the use of a cervical interbody spacer shall be determined by a licensed practitioner.

PRECAUTIONS

Use of the KMTI Cervical Interbody Instrumentation System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with spinal fusion procedures; and has had hands-on training in the use of such devices. Use extreme care in handling and storing implant components. At the time of surgery, an adequate inventory of implant sizes should be available. All implants and instrumentation should be inspected prior to surgery. The patient could possibly have an allergic or other adverse reaction to instrument or implant materials. The surgeon should be familiar with the surgical technique for any procedure being performed to ensure the instruments are used appropriately. The following potential adverse events (singly or in combination) could also result from the use of the KMTI Cervical Interbody Instrumentation System:

1. Fracture of bony structures.
2. Infection, early or late.
3. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
4. Spinal cord impingement or damage.
5. Vascular damage could result in catastrophic or fatal bleeding

DISCLAIMER

KMTI has determined that the Cervical Interbody Implant Inserter is suitable for the specific sterilization cycle listed in this document. Heath 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. Testing should be conducted in health care facility to assure that conditions essential to sterilization can be achieved. KMTI and its distributors do not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical device supplied by KMTI that should have been cleaned and sterilized by the end user. All instruments are to be examined for wear and damage prior to surgery.

CLEANING AND DECONTAMINATION

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

KMTI Cervical Interbody Implant Inserter may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap with other devices.
4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. **Preparation and Assembly:** After cleaning/disinfection, the instruments should be visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Wrap with protective sterilization wrap according to AAMI / AORN guidelines. Wrap the instruments individually in two layers of 1-ply polypropylene wrap (Kimguard KC600) using sequential wrapping techniques. Alternatively, the instruments can be individually packaged in any commercially available sterilization pouch cleared by the FDA for the sterilization cycle recommended in this document.

* 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 qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). 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 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.
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.

RESPONSIBILITIES OF THE USER

General – Heath 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.

STORAGE AND SHELF LIFE

Instruments 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 instruments to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instruments, 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.

Sterility: KMTI Instruments are provided non-sterile. Sterilization is recommended as follows:

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

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.

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).

The 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.

References: References to relevant literature may be obtained by calling Kyocera Medical Technologies, Inc. at +1 (909) 557-2360.

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

KYOCERA Medical Technologies, Inc.
1200 California St. Ste. 210
Redlands, CA 92374 USA
+1 (909) 557-2360