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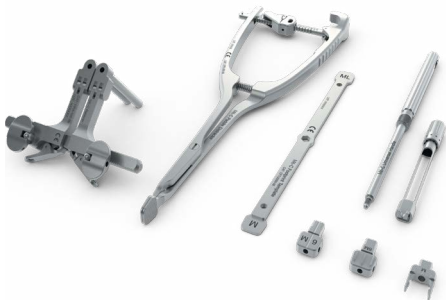


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M6-C™ Artificial Cervical Disc Surgical Instruments

English **EN**

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DEVICE DESCRIPTION

The surgical implantation of the M6-C Artificial Cervical Disc requires specific surgical instruments including: a footprint template and a trial to determine the appropriate size and position of the implant; a fin cutter to create tracks in the superior and inferior vertebral endplates; and an implant inserter to place the disc into the desired position to aid in and ensure correct placement within the intervertebral space. Additionally, there is a tamp to independently adjust the posterior position of the M6-C endplates, a removal tool to remove the disc from the disc space, and general surgical instruments to assist in the distraction and mobilization of the disc space. The instruments are composed primarily of surgical stainless steel coated with ME-92 coating to increase corrosion resistance, with some instrument handles also featuring aluminum and Radel materials. Surgical instruments are provided non-sterile and are intended to be reusable.

The instruments provided in the kit include Footprint Templates, Trials, Inserters, Fin Cutters, a Tamp, Removal Tools, an Intervertebral Distractor, a Paddle Distractor, a Distractor Spacer, a Slide Hammer, a Retainer, Retainer Pins and Locking Nuts.

The M6-C Instrument Tray is multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The instrument tray is perforated to allow steam to penetrate which will allow sterilization of the contents to occur in a steam autoclave.

INDICATIONS FOR USE

The M6-C™ Artificial Cervical Disc Surgical Instruments are intended for the placement and positioning of the M6-C™ Artificial Cervical Disc.

DISCLAIMER

The M6-C Instrument Tray is intended to protect the M6-C Surgical Instruments and facilitate the sterilization process by allowing steam penetration and drying. Laboratory testing has verified that the instrument tray is suitable for the specific sterilization methods and cycles for which it has been tested. Health care personnel bear the ultimate responsibility 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 a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Orthofix does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Orthofix that should have been properly cleaned and/or sterilized by the end user prior to use.

RECOMMENDATIONS

- The instruments are provided non-sterile. Clean instruments before each use. After cleaning, sterilize as directed prior to use.
- As soon as possible after surgery, instruments should be cleaned and sterilized.
- Clean the instruments per the instructions below. Strictly follow the dosage, temperature, exposure time, and material compatibility specifications for the cleaning agent.
- Sterilize the instruments using the steam sterilizer operating conditions below.
- Stainless steel instruments can become stained or corroded if the cleaning and sterilization instructions are not followed. If excessive staining is observed use demineralized water for cleaning and sterilization. Staining may be eliminated by scrubbing the device following standard cleaning procedures. Instruments with corrosion should be removed from use.
- Repeated reprocessing of the instruments has minimal effect. End of life is normally determined by wear and damage due to use.
- After each use inspect all instruments for any damage. Discard and replace instruments as necessary.
- After cleaning and sterilization, verify functionality prior to use.

CAUTION:

- If sterilizing for the first time, remove all vinyl caps and packing foam prior to autoclaving.
- Soak or rinse instruments immediately after use. To avoid risk of corrosion or staining, DO NOT exceed 15 minutes soaking time.
- Do not use Glutaraldehyde, Chlorine, or Ammonium for soaking; this may cause damage to the instrument finish.
- Do not use dry heat sterilization, as this may damage the instrument finish.
- Only sterilize clean instruments; sterilization is only effective on clean items.
- Store instruments in a clean, dry area.

▲ WARNING:

- Only trained personnel should clean and sterilize instruments as described in these Instructions for Use. Use appropriate personal protection equipment when handling contaminated instruments.
- Instruments should be dried after cleaning and after any exposure to water.
- Only sterile instruments may be used for surgery.
- Do not use these instruments for purposes other than those for which they are intended.
- Do not bend, pry, or use excessive force; breakage or failure of the instrument could occur resulting in possible harm to the patient or user.
- Use extreme care during handling and cleaning of delicate or sharp instruments as injury or damage could occur.

RESPONSIBILITIES OF THE USER

General. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance.

Cleaning/Decontamination. The health care facility is responsible to ensure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings and ISO 15883-1 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests provide relevant guidelines.

Sterility. Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities and ISO 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices provide relevant guidelines.

PRECAUTIONS:

- When handling sharp instruments use extreme caution to avoid injury.
- Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.
- Unless otherwise indicated, instruments and tray are NOT Sterile and must be thoroughly cleaned and sterilized prior to use.
- An unwrapped instrument tray DOES NOT maintain sterility.
- Instruments must be removed from tray for manual or automated cleaning procedures. Instrument trays and lids must be cleaned separately from the instruments. Instrument trays must be thoroughly cleaned until visually clean prior to sterilization. If tray is not visually clean, then repeat the entire cleaning process.

Manual Cleaning Process:

- Prior to cleaning, disassemble any instrument capable of being disassembled.
 - For kits which include the Universal Handle with Adjustable Stop, unscrew all instrument heads from the Universal Handle and unscrew the Adjustable Stop by the threaded knob.
 - Remove the arms of the retainer from the gear rack.

- Rinse the instruments under running tap water. Use a syringe to flush lumens and hard to reach areas. A wire guide and/or pipe cleaner should be used to aid in cleaning lumens and other hard to reach areas. Actuate any knobs, clamps, or joints while performing this process.
- Prepare an enzymatic cleaning solution, such as Enzol®, per the manufacturer's instructions.
- Fully immerse the instruments in the prepared enzymatic cleaning solution and allow them to soak for a minimum of one minute.
- After the soak, use a soft bristle brush to thoroughly clean any crevices or other difficult to clean areas of the instruments. Flush lumens and small spaces with a syringe. A wire guide and/or pipe cleaner should be used to aid in cleaning lumens and other hard to reach areas. Actuate any knobs, clamps, or joints while performing this process.
- Remove the instruments from the enzymatic cleaning solution and rinse them with reverse osmosis or de-ionized (RO/DI) water for a minimum of one minute. Use a syringe to flush lumens and hard to reach areas. Actuate any knobs clamps or joints while performing this process.
- Prepare a neutral detergent, such as ValSure® Neutral Detergent, according to the manufacturer's recommendations using warm tap water in an ultrasonic bath.
- Fully immerse the instruments into the sonication bath and sonicate for two minutes.
- Remove the instruments from the neutral detergent solution and rinse them with RO/DI water for a minimum of one minute. Use a syringe to flush lumens and hard to reach areas. Actuate any knobs, clamps, or joints while performing this process.
- Dry the instruments using a clean, lint-free cloth to avoid damage to the surface. Pressurized air (20psi) may be used to assist in drying.
- Visually inspect the surgical instruments for cleanliness. If instruments are not visually clean, then repeat the entire cleaning process.

Automated Cleaning Process:

- Prior to cleaning, disassemble any instrument capable of being disassembled.
 - For kits which include the Universal Handle with Adjustable Stop, unscrew all instrument heads from the Universal Handle and unscrew the Adjustable Stop by the threaded knob.
 - Remove the arms of the retainer from the gear rack.
- Rinse the instruments under running tap water. Use a syringe to flush lumens and hard to reach areas. A wire guide and/or pipe cleaner should be used to aid in cleaning lumens and other hard to reach areas. Actuate any knobs, clamps, or joints while performing this process.
- Prepare an enzymatic cleaning solution, such as Enzol®, per the manufacturer's instructions.
- Fully immerse the instruments in the prepared enzymatic cleaning solution and allow them to soak for a minimum of one minute.
- After the soak, use a soft bristle brush to thoroughly clean any crevices or other difficult to clean areas of the instruments. Flush lumens and small spaces with a syringe. A wire guide and/or pipe cleaner should be used to aid in cleaning lumens and other hard to reach areas. Actuate any knobs, clamps, or joints while performing this process.
- Remove the instruments from the enzymatic cleaning solution and rinse them with reverse osmosis or de-ionized (RO/DI) water for a minimum of one minute. Flush lumens and small spaces with a syringe. Actuate any knobs, clamps, or joints while performing this process.
- Place the instruments into the washer for processing.
- Run the validated cycle parameters below.

Validated Automated Cleaning Cycle

Phase:	Recirculation Time: (minutes)	Water Temperature:	Detergent Type and Concentration: (if applicable)
Pre-wash 1	2:00	Cold Tap Water	N/A
Enzyme Wash	2:00	Hot Tap Water	Enzol® 1 oz/gallon
Wash 1	2:00	65.5 °C	ValSure® Neutral Detergent ¼ oz/gallon
Thermal Rinse (PURW Rinse)	1:00	90 °C	N/A
Drying	7:00	90 °C	N/A

- Remove the instruments from the washer following the cycle.
- Visually inspect the instruments for cleanliness. If instruments are not visually clean, then repeat the entire cleaning process.

STERILIZATION PROCESS

Since Orthofix is not familiar with individual hospital handling procedures, cleaning methods, bioburden levels, and other conditions, Orthofix assumes no responsibility for sterilization of product by a hospital even if the specified guidelines are followed.

When sterilizing multiple instruments in an autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

Do not stack another instrument tray on top of the M6-C Instrument Tray during the sterilization process.

The following sterilization cycle parameters were validated under laboratory conditions; however, these cycles must be re-validated by the end user to ensure that sterility can be achieved on site.

- Instruments should be placed in the designated location for each instrument in the instrument tray. The lock nut of the intervertebral distractor should be used to slightly open the jaws of the intervertebral distractor.
- Wrap the M6-C Surgical Instrument Tray in two layers of an FDA-cleared sterilization wrap such as Halyard Health H600.

	Sterilizer Type: Pre-vacuum Preconditioning Pulses: 4 Temperature: 132°C (270°F) Full Exposure Time: 4 min. Dry Time: 60 min (45 minute cycle time followed by a 15 minutes dwell in the sterilizer after cycle completion with the sterilizer door opened for cooling)	Sterilizer Type: Pre-vacuum Preconditioning Pulses: 4 Temperature: 132°C (270°F) Full Exposure Time: 4 min. Dry Time: 130 min (70 minute cycle time, 30 minutes dwell in the sterilizer after cycle completion with the sterilizer door opened for cooling, 30 minutes cool down on a wire rack)
CIK-200-06 - M6-C Instrument Kit, G6	X	
CIK-200-07 - M6-C Instrument Kit, G7		X

STORAGE AND SHELF LIFE

Instrument trays 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 exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument 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. Handling over time increases the probability of a contaminating event.

PRODUCT COMPLAINTS

Any health care professional (i.e., customer or user of this system), that has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix immediately using the contact information listed on the first page of these instructions. Further, if the device (implant or instruments) "malfunctions," (i.e. does not meet all of its performance specifications or otherwise does not perform as intended) or may have caused or contributed to the death or serious injury of a patient, Orthofix should be notified immediately. When filing a complaint, please provide the device name and serial number, lot number, your name and address, and the nature of the complaint. Complaints may also be reported directly to Medwatch at <http://www.fda.gov/medwatch>.



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