CARE AND HANDLING INSTRUCTIONS

Rx Only

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M6-C™ Single Use, Disposable Instrumentation

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, and general surgical instruments to assist in the distraction and mobilization of the disc space. The instruments are composed primarily of surgical stainless steel and Glass Fiber Reinforced Polyarylamide (PAA) for instrument subcomponents. Surgical instruments are provided sterile and are intended to be single use.

The instruments provided in the kit include Footprint Templates, Trials, Inserters, Fin Cutters, a Tamp, and a Distractor. The M6-C™ Single Use, Disposable Instrumentation come in three separate, pre-sterilized kits: Implantation Kit, Mallet Kit, and Implant Specific Kits.

INDICATIONS FOR USE

The M6-C™ Single Use, Disposable Instrumentation are intended for the placement and positioning of the M6-C™ Artificial Cervical Disc.

RECOMMENDATIONS

- The instruments are provided sterile. After surgery, instruments should be properly disposed of.
- Do not use Single Use Instruments after the last day of the month of the "Use by date" on the label.
- Use sterile technique to carefully remove the instruments from the packaging. Inspect the instruments before use to ensure it exhibits no signs of damage (e.g., metal and plastic damage).

CAUTION:

- 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.
- 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.

Instrument Reprocessing. Instruments covered in this Instruction for Use are intended to be single use ONLY. After use instruments should be disposed of according to local health care procedure.

Reusable instruments are not covered in this Instruction for Use and should reference the correct Instruction for Use.

Sterility. The M6-C Artificial Cervical Disc is supplied sterile and is single use only. Do not re-sterilize or reuse the M6-C Artificial Cervical Disc.

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.

STORAGE AND SHELF LIFE

Shelf Life should be determined based on labeling provided on instrument kits. Instrument kits 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 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.

PK_0336_A1_01