INSTRUCTIONS FOR USE

TRADE NAME: CMF System Instrumets

MEDICAL USE PRODUCT
NON-STERILE PRODUCT

ATTENTION: Read all instructions carefully before use. Observe all warnings and precautions mentioned in this instruction. Failure to observe the information stated here may lead to complications when using this product.

1. DESCRIPTION OF THE MEDICAL PRODUCT

The MCI CMFInstrumental Kit, are medical devices specifically developed to be used in conjunction with implantable devices, assisting the surgeon in their implementation. The components of the MCI CMFInstrumental Kit are practical, easy to handle with specific characteristics that reduce the risks during surgery.
The MCI CMFInstrumental Kit, is supplied non-sterile.
The MCI CMFInstrumental Kit is a product that can be reprocessed.

1.2. COMPOSITION OF THE MEDICAL DEVICE

The Table below shows the classification of the raw material used in the products.

1.3. HOW TO USE

Preoperative:
The selection of instruments is an integral part of surgical planning and must be carried out by means of a formal medical request that indicates the intended technique, as well as the characteristics of the implant to be used and the specifications of the components that are part of the set of instruments. It is of fundamental importance, to perform a thorough inspection on each medical device, paying attention to the conditions of use and cleaning. Sterilization is mandatory and must have proven efficiency. To make the surgical procedure more efficient, it is recommended to review the surgical instrumentation technique before the operation.
Intraoperative:
The instruments serve exclusively for medical assistance, and will never be an integral part of the implants as to the permanence in the body after the procedure. They must be selected and made compatible only for the device to be implanted, aiming at the adequacy of the orthopedic implant with the implantation site. Instruments from different manufacturers can be used only when their compatibility and suitability between them has been previously evaluated.
The use of surgical instruments should be done under the technical guidance and restricted to clinical and hospital environments, following some precautions:
- Handling and handling: the instrument must be transported and handled in order to prevent any damage or alteration in its characteristics. It must be handled carefully, in small batches, avoiding falls and bumps. Any instruments that have fallen or been improperly handled, or suspected of having suffered damage, must be separated, identified and forwarded to the technician responsible for inspection, even if he has already passed this stage.
- technical inspection: before being made available for use, the instruments, including the assembly of the set, must be subjected to technical inspection by a responsible person. Failed

devices must be separated for review and maintenance by the supplier or destined for disposal. The inspection must verify the characteristics associated with the conservation and the functionality of the instrument, including superficial aspects, such as stains, oxidation and damage, in addition to characteristics pertinent to each instrument, such as ease of articulation, apprehension capacity, cutting capacity and food of tips.
- sterilization: instruments must be sterilized before use. The appropriate parameters of the sterilization process for each device and volume, must be analyzed and conducted by people trained and specialized in sterilization processes, ensuring the complete efficiency of this procedure.

- reuse: the process for reusing surgical instruments involves at least five basic steps: prior cleaning, decontamination, washing, rinsing and drying. It is recommended that all instruments be cleaned immediately after the surgical procedure, avoiding the hardening of dirt from this procedure. Cleaning should be standardized, avoiding the spread of contamination and damage to the instruments. Any manual cleaning procedure must be performed using appropriate personal protective equipment. In cleaning operations on automatic equipment, the manufacturers' instructions must be strictly followed, especially regarding the products and the quality of the water to be used. The instruments, when pertinent, must be introduced in the equipment, opened or disassembled. Under no circumstances should metal brushes, steel wool or other abrasive products, even soap products, be used to remove any remaining dirt from any step in the cleaning process. Do not use aggressive cleaning agents, such as minerals and acids (sulfuric, nitric). It must be ensured that the instruments, as well as their components, when pertinent, are free from any preservation product, as well as from any dirt arising from storage or repair procedures. The presence of non-water-soluble products can lead to the formation of physical barriers, protecting microorganisms from the action of germicides, as well as providing the retention of undesirable soils to later use of the instrument.
Water quality is essential for both cleaning and instrument conservation. The presence of particulate elements, the concentration of elements or chemicals, and the pH imbalance, can deteriorate the instrument during the cleaning process. The combination of some of these parameters can lead to the incrustation of mineral precipitates, which cannot be eliminated in the phase of removing organic matter incrustations, as well as to the induction of the corrosion process of stainless steel, as in the case of a heavy presence of chlorides. It is recommended that the water used to wash the instruments is in accordance with the quality requirements established in the sterilization
Note: all instruments must be cleaned after the end of the surgical procedure, thus avoiding the hardening of liquids originating from the surgical work. Every cleaning process must be done with utmost care, avoiding falls, bumps, which could compromise the instruments.
-prior cleaning: the instruments should be dipped, opened or disassembled, when appropriate, in an appropriate container containing water and detergent, preferably enzymatic, at room temperature. Then it must be thoroughly washed under running water, preferably warm. This phase should always be carried out with water at temperatures below 45 ° C, as higher temperatures cause protein coagulation, making the process of removing inscriptions from the instrument more difficult.
- decontamination: it is done by immersing the instrument, open or disassembled, when appropriate, in an appropriate container containing a disinfectant solution in water, at room temperature (chemical disinfection), pu in a heated bath (thermochemical disinfection). The immersion time of the instrument depends on both the operating temperature and the dilution, and the type of disinfectant used.

-washing: the parts must be completely brushed, with soft bristle brushes, paying special attention to the joints, serration and racks. The instruments, when pertinent, must be disassembled and each component washed separately. In areas that are difficult to access, attention should be doubled, since there may be retention of organic tissues and deposition of secretions or disinfectant solutions.
-rinse: the instruments must be rinsed thoroughly, under running water, and the articulated instruments must be opened and closed a few times during the rinse. The use of heated water is recommended.
-drying: it must be ensured that the drying processes do not introduce moisture, particles or lint on the surface of the instrument. Special care must be given to joints, serrations and racks. It is recommended that the fabric is absorbent, soft and that each component of a dismountable instrument be dried separately; if there are cavities or entrails, its interior must be completely dry.
-disposal: Disposal of unqualified parts must be done under evaluation and technical guidance. After replacement, destroy damaged components, avoiding improper use afterwards. When it is necessary to discard the instrument, it must be discarded immediately. Disposal of instruments must comply with the rules on the disposal of contaminating medical waste. We recommend that the parts be cut and damaged for destruction.

1.4. STORAGE CONDITIONS

The MCI CMF Instrumental Kit must be stored in a clean and dry place, Special conditions for storage, handling and conservation of the product must be followed in order to ensure that the components remain intact for the surgical procedure. Be careful with the receipt, storage, transport, cleaning and conservation of the lot's references, which must be adopted in conjunction with good practices for the storage and distribution of medical products.

1.5. CONDITIONS OF TRANSPORT AND HANDLING

The MCI CMFInstrumental Kit must be transported and handled in a clean and dry place, away from heat and sheltered from direct light and in its original packaging, under Temperature: + 15 ° to + 45 ° C - Relative Humidity: 75% of form to prevent any damage or alteration in its characteristics. Note: Any product that has been dropped or improperly handled, or suspected of having suffered damage, must be identified and segregated.
After unpacking, the components of the MCI CMF Instrumental Kit must be handled carefully and individually, avoiding contamination. Any product that has been dropped or improperly handled, or suspected of being damaged, must be identified and segregated.

1.6. CONTRAINDICATIONS

- Do not use MCI instruments along with other brand products.
- MCI surgical instruments are to be used in human bein.

1.7. WARNINGS

There are appropriate surgical instruments for each stage of the surgery. Usual wear, the exercise of excessive forces and the use of instruments for purposes exclusive to the project can impair the evolution of the surgical procedure and cause damage to the implant. The use of different instruments can carry risks of improper fixation and other technical complications. The instruments are metallic components that are subject to important mechanical stresses during continued use for a variable and indefinite period; requiring inspection and review of the conditions of use of the instruments or their parts. If there is varying performance, loss of precision, instability, or lack of cut, the part must be replaced immediately.

The advance of the preformed plates does not mean the exact advance that will be found in the patient

1.8. PRECAUTIONS

Instrumentals must be kept in their original packaging until sterilized and used.
After each use, perform a correct cleaning in order to avoid encrustation and corrosion.
Only professionals specialized and trained in the corresponding surgical technique may use these instrumentals.
Check, with each use, that the instruments have not suffered any damage.
Always use the appropriate instruments for each type of implant, never try to replace any element with another that is not appropriate for the intended use.
Instrumentals must not be stored together with chemical products, which can exhale corrosive vapors causing possible damage to them.

It is recommended that the following physical sterilization parameters in autoclaves (saturated vapor) be applied:
• Temperature: 134 °C;
• Sterilization time: seven minutes;
• Pre-vacuum pressure: 0.30 barA;
• Pre-steam pressure: 1.15 barA;
• Vacuum pulses: four pulses;
• Drying time: 15 minutes.

As reference standards used are:
ISO 17665-1: 2006 - Sterilization of health products - Wet heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
ISO 17665-2: 2009 - Sterilization of health products - Wet heat - Part 2: Guidance on the application of ISO 17665-1.

1.9. COMPLAINTS/CUSTOMER SERVICE

Customers or users of this medical device who have questions or want to learn more about the services and/or products offered may reach MCI - Medical Concept Innovation, through the contact information given in the instruction manual and product packaging labels.
If there are any problems that may make the device unsuitable for further use, the customer shall return it to the manufacturer in a package that can ensure the physical integrity of the medical product. The package shall contain all the information required to identify the medical product: handling conditions, cleaning and disinfection methods, and the lot description and number.

NON-STERILE PRODUCT – STERILIZE BEFORE USE. SINGLE-USE PRODUCT – DO NOT REPROCESS. STORE AND TRANSPORT THE PRODUCT IN A CLEAN AND DRY PLACE,

Manufactured by:
MCI – Medical Concept Innovation.
Address: 4592 North Hiatus Roads
Sunrise, FL 33351 - USA
www.mci-medical.com
E-mail: customer.service@mci-medical.com