INSTRUCTIONS FOR USE

TRADE NAME: MCI - CMF System
510K: K182758

DESCRIPTION

The MCI - CMF System is a device system consisting of titanium alloy screws (ASTM standard F136) and commercially pure titanium plates and meshes (ASTM standard F67) used for the fixation of bone fragments in humans. The System has many screw and plate sizes suited to different uses. The Cortical Screws are available in self-drilling (Green colored), self-tapping (Golden colored), and self-tapping emergency (Lilac colored) designs.

INDICATIONS FOR USE

MCI - CMF System is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.

GENERAL INSTRUCTIONS

The fact is that no implant is as strong as natural bone, so limitations on biomechanical demands must be considered. Until there is a proper bone consolidation, excessive stress on the implant by the bone must be avoided in order not to cause a new focal fracture. The success of the MCI - CMF System is related to its primary stability after implantation. Its primary stability depends mainly on the implant format and bone quality at the insertion site. Support over the cortical bone is crucial for primary stability as the thinness of cortical bone may result in implant stress failure.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Titanium-specific allergies. physicians must run the required tests and assess the need for surgery.
- Specific patient conditions: senility, alcoholism and infections. These conditions must be carefully investigated by the physician, who should inform the patient of the risks derived from these conditions.
- Device reuse. Device reuse is contraindicated. It is impossible to guarantee the correct performance of screws in the event of reuse.
- Alcoholism or drug addiction. Skeletal immaturity.

WARNINGS AND PRECAUTIONS

The MCI - CMF System must be handled by specialized and duly qualified personnel.

- Before using and sterilizing the MCI - CMF System thoroughly review the material to ensure that all necessary system components are available. Failure to do so may compromise the surgical procedure.
- Do not use instruments that exert excessive force on MCI - CMF System components, as they may cause this device to rupture, fissure, fold, crack or break. They have not been designed to be used this way.
- The surgical instruments are subject to wear during regular use.
- Inspect all implants and instruments carefully before use.

• Every surgical procedure has risks and possible complications. Some risks are common to all procedures, such as infection, bleeding and anesthetic risk, among others. Responsible surgeons must inform patients about these risks.
• MCI - CMF System is bioinert and biocompatible. The materials comprising this device are presented as an option for feasible and well-known internal rigid fixation in reconstruction and orthognathic surgery. There is no scientific evidence of the benefits of routine removal of the apparatus used for internal rigid fixation. Tactility, thermal sensitivity, infection, plate exposure and use on growing patients are the main justifications for a second surgical intervention.
• The fracture or displacement of the osteosynthesis material may be rarely observed after implantation, usually as an intrinsic complication of the procedure and not commonly related to material misuse or structural defect.
• Poor selection, positioning and fixation of MCI - CMF System components may cause undesirable outcomes. The surgeon must be familiar with the product and its surgical handling technique before using it.
• Correct fracture alignment must be observed.
• Whenever using lock screws in surgery requiring anchoring, avoid applying excess force to the anchoring wire and tensing it too much, which may cause lock-screw overload.
• Extremely acute angles along a small folding radius must be avoided due to the potential risk for breakage in the post-surgical period.
• The screws labeled “AP” are self-drilling. Predrilling is not recommended for self-drilling screws.
• The advance of the preformed plates does not mean the exact advance that will be found in the patient.
• Confirm that drill bit length and diameter correspond to selected Cortical Screw length prior to drilling.
• If unsure about the material or technique for use, please contact the manufacturer.
• The manufacturer is not liable for damages caused by the incorrect or unsuitable use of this material. The warranty of this product covers only manufacturing requirements.
• It is the surgeon’s responsibility to assess on a case-by-case basis the removal or not of a titanium surgical implant after fracture consolidation.
• The surgeon must transcribe all product traceability information in the patient’s medical record and inform the patient about traceability and provide free access to this information.
• The MCI - CMF System must be handled with the MCI - CMF System Implantation Instrumental Kit. The warranty of performance is void if unauthorized instruments are used. MCI - CMF System must not be used for any purposes other than those for which the instruments have been designed. The surgical instruments must be specifically used for this sole purpose.
• Patients must be warned about the implant limitations and instructed to adapt their activities to these limitations.
• Special attention must be paid to patient selection. Patients with disorders that may interfere with their ability to adapt to the limitations and follow the precautions must be carefully assessed to ensure that they obtain the beneficial results of this implantation.
• MCI - CMF System IS SOLD DECONTAMINATED BUT NOT STERILIZED.
• MCI - CMF System must be sterilized before use and handled with due care to avoid contamination.
• MCI - CMF System comprises SINGLE-USE implants. After use, these implants shall not be reused under any circumstances.
• The acceptable metal alloys related to the MCI-CMF SYSTEMS are listed below:
Admissible contact alloys - ISO21534
Wrought Titanium 6-Aluminum 4-Vanadium Alloy

Wrought stainless steel 18 Chrome-14 Nickel -2,5 Molybdenum (NBRISO 5832-1 and ASTM F138).
High-nitrogen wrought stainless steel (NBRISO5832-9)
NBRISO5832-4
NBRISO5832-5 Wrought cobalt-chrome-tungsten-nickel alloy
NBRISO5832-6 Wrought cobalt-nickel-chrome-molybdenum alloy
NBRISO5832-7 Cold forged and wrought cobalt-chrome-nickel molybdenum- tungsten-iron alloy
NBRISO5832-8 Wrought cobalt- nickel-chrome-molybdenum-tungsten-iron alloy
NBRISO5832-12 Conformed cobalt-chrome-molybdenum alloy Pure Titanium
These alloys are listed for information purposes. Implants of the same brand, designed for such combinations should be used as the surface finish and surface treatment, among other design factors, may interfere with combinations. The use of metal implants from different manufacturers is not recommended, due to chemical, physical, biological and functional incompatibility.

• The products can only be implanted by surgeons who are familiar with and dominate the surgical techniques for implanting the MCI-CMF Systems. Before using the product, surgeons should carefully study the recommendations, warnings and precautions described in this instruction manual.

• Any complication or other effects that might occur due to reasons such as incorrect indication or surgical technique, inappropriate choice of material, asepsis etc., is under the surgeon's responsibility and may not be attributed to the manufacturer, importers or suppliers of MCI products.

• Before using, it is important to examine the integrity of the implant material and instruments, which should not present fissures or abrasions.

• The products must be correctly cleaned and sterilized before use, as described in the section Cleaning, Disinfection and Sterilization.

• High-impact or high-torque instruments must not be used with MCI - CMF System components because they may cause this device to rupture, fissure, fold, crack or break, as they have not been designed to be used in this way.

• Implants that has been dropped or scratched must not be used.

• The improper use, abuse or excessive force applied with instruments during intrasurgical procedures may cause them to break.

• The following conditions shall be observed during transport and storage: IMPLANTS must not be thrown or touched. Avoid putting excess weight on them.

• Store and transport the product in clean, dry conditions , away from heat and direct light, at a temperature of +10°C to +40°C and maximum relative humidity of 85%.

• Titanium’s solidity increases and ductility decreases with folding. It is crucial to ensure that the desired implant format is achieved with as little folding as possible. Excessive folding may cause the plate to break during the post-surgical period.

• Sharp angles with a small folding radius must be avoided due to the potential risk of post-surgical breakage.

• The bone plates to be implanted may require deburring to prevent soft tissue injury or irritation.

• Micro meshes may be manually adapted to the individual contours of the surface without requiring the use of folding instruments.

• It is crucial to ensure that the screwdriver and screw head are exactly aligned vertically; otherwise, there will be a higher risk of mechanical damage to the implant or screwdriver.

• When introducing the bone screw, the axial pressure exerted by the screwdriver on the screw head must be properly applied, ensuring that the tip of the screwdriver is completely inserted

in the screw head. This ensures axial alignment and full contact between the screwdriver and screw.

• Implants are indicated only up to bone recovery (usually 6 – 10 weeks). Late recovery, non-consolidation or subsequent bone re-absorption or trauma may lead to excessive tension on the implant(s) and cause loosening, arching, fissure or breakage of the device.

EXPECTED PERFORMANCE

MCI - CMF System purpose is to promote reconstruction and fixation of oral maxillofacial fractures.

ADVERSE EFFECTS

Complications may be observed after implanting mini-plates or anchoring screws, such as: local tissue inflammation, gingival hyperplasia around the anchoring screw, difficulty to apply elastic force when the mini-plate or screw are too close to the tooth to be tractioned, damage to roots or adjacent nerves and, finally, traction device fracture or loosening. However, some authors report little tissue inflammation during the treatment of their cases; there was no implant mobility or perioimplant infection, and little radicular re-absorption in the fork and apex region.

INFORMATION TO BE PROVIDED TO PATIENTS

The patient must be warned about:

A. The fact that complications or failures of oral maxillofacial surgery are most common in:

- patients with functional expectancies beyond those provided by surgery.
- patients with systemic or local diseases which may cause bone alterations, such as osteoporosis.

B. Information listed on the topics Indications, Contraindications, Adverse Effects, Precautions and Warnings.

C. The need for periodic medical follow-up to detect possible alterations in the implant and adjacent bone. Only follow-up can detect component loosening or osteolysis.

D. The need to notify technicians of the presence of a prosthesis when undergoing magnetic resonance imaging.

CLEANING, DISINFECTION AND STERILIZATION

MCI - CMF System components are sold non-sterilized; they must be sterilized before implantation. MCI recommends the cleaning and sterilization methods listed below.

All metal implants must be completely decontaminated and cleaned before sterilization.

They must be washed manually or in cleaning appliances using broad-spectrum bactericide and antifungal products.

Before using any cleaning agent, oxidation tests must be performed. Do not use aggressive cleaning agents such as: acid mineral agents (sulphuric, nitric), which may damage devices and, particularly, instruments. Do not use metals or abrasive cleaners and products. This device must be carefully washed after cleaning.

Intensively wash with water, 70% to 80% aqueous ethanol or isopropyl alcohol with subsequent ultrasound treatment, proteolytic enzyme, or a 1:100 sodium hypochlorite solution. If the water available for use has a high ion concentration, use distilled water instead. Dry device immediately after cleaning.

The parameters for sterilization (physical or chemical) for each instrument and component must be analyzed and conducted by people trained and specialized in sterilization processes to ensure the complete efficiency of this procedure. The manufacturer's instructions and methods, in accordance with the internal guidelines of the hospital establishment, must be followed.

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.

CAUTIONS WHEN HANDLING AND TRANSPORTING THE MEDICAL PRODUCT
We recommend that the MCI - CMF System be unpacked and sterilized immediately before the surgical procedure to preserve the integrity of the surface finish and original configuration. The device must be handled as little as possible from this moment on.
Any implant that has been dropped , scratched, dented or otherwise damaged must be discarded; however, the decision regarding its adequacy is always up to the surgeon who uses it.

TRACEABILITY
In order to guarantee the traceability of this product, the surgeon responsible for the implant procedure should notify the distributor of the following data regarding the product implanted:
Name of the Hospital Unit;
Name of the Surgeon;
Surgery Date;
Name of the Patient who has received the implant;
Product Code;
Number of the product batch;

There are two extra labels in each package, one to be affixed to the patient's medical record for internal control of the hospital and another to be given to the patient.
In order to learn more about the information patients must be provided with, see “Information to be provided to patients”.
The MCI - CMF System have a laser engraving of the company logo, batch and manufacturing number, and acronym of material used for implant manufacture. If it is necessary to remove the patient's implant, all this information will remain on the product.
The responsible physician must be notified about the procedures in order to report adverse events and medical product quality deviation, so that this information can be transmitted to patients. The notification of adverse events and/or technical complaints related to the device must be made through the proper health office. In order to learn
more about the information patients should receive, see “Information to be provided to patients”.

DEVICE DISPOSAL

Explanted devices must be disabled before disposal. We recommend filing, bending or cutting the parts to disable them.

Explanted devices are considered medical waste (potentially contaminant products) and must be treated as such, in compliance with the local health authority standards.

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, AWAY FROM HEAT AND DIRECT LIGHT, WITHIN A TEMPERATURE RANGE OF +10°C TO 40°C – MAXIMUM RELATIVE HUMIDITY: 85%

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