INSTRUCTIONS FOR USE

TRADE NAME: MCI - CMF System
K182758 – MCI - CMF System

1. DESCRIPTION

The MCI-CMF System is an implantable fixation system composed of titanium alloy screws conforming to ASTM F136 and commercially pure titanium plates and meshes conforming to ASTM F67. The system is intended for the fixation and stabilization of bone fragments in oral and craniomaxillofacial surgical procedures.

The MCI-CMF System includes a variety of plate, mesh, and screw configurations and sizes designed to accommodate different anatomical and surgical requirements.

Cortical screws are available in the following configurations:

* Self-drilling (green color code);
* Self-tapping (gold color code);
* Emergency self-tapping (lilac color code).

2. 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.

3. GENERAL INSTRUCTIONS

No implant can withstand the same mechanical loads as healthy natural bone. Therefore, appropriate biomechanical limitations and postoperative precautions must be observed during the healing period. Until adequate bone healing and consolidation have occurred, excessive mechanical stress on the implant should be avoided, as it may result in implant failure, loss of fixation, or refracture.

4. CONTRAINDICATIONS

Contraindications include, but are not limited to:

a. Titanium-specific allergies. physicians must run the required tests and assess the need for surgery.

b. 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.
c. Device reuse. Device reuse is contraindicated. It is impossible to guarantee the correct performance of screws in the event of reuse.
d. Alcoholism or drug addiction. Skeletal immaturity.

5. WARNINGS AND PRECAUTIONS

a. Before use and sterilization, thoroughly inspect the MCI-CMF System and verify that all required system components are available and in proper condition. Failure to do so may compromise the surgical procedure.
b. The MCI - CMF System must be handled by specialized and duly qualified personnel
c. Do not use instruments or techniques that apply excessive force to the components of the MCI-CMF System, as this may cause the device to deform, crack, fracture, or otherwise fail. The device has not been designed to withstand such misuse.
d. Surgical instruments are subject to wear and degradation during normal use and should be regularly inspected for proper functionality.
e. Carefully inspect all implants and instruments prior to use to ensure they are free from damage, defects, or contamination.
f. All surgical procedures involve inherent risks and potential complications, including but not limited to infection, bleeding, tissue injury, and anesthetic-related complications. The surgeon is responsible for informing the patient of these risks prior to the procedure.
g. The materials used in the MCI-CMF System are biocompatible and commonly used in implantable medical devices intended for rigid internal fixation in reconstructive and orthognathic surgical procedures.
h. Routine removal of implanted fixation devices is generally not required unless clinically indicated. Factors that may justify implant removal include palpability, thermal sensitivity, infection, plate exposure, patient discomfort, or use in skeletally immature patients. The decision to remove the implant should be based on the clinical judgment of the surgeon and the individual condition of the patient.
i. Fracture, loosening, or displacement of osteosynthesis components may rarely occur after implantation as an inherent complication of the surgical procedure and is not typically associated with material defects or device malfunction.

j. Improper selection, positioning, contouring, or fixation of MCI-CMF System components may result in unsatisfactory clinical outcomes. Surgeons should be familiar with the product design, indications, limitations, and recommended surgical techniques prior to use.
k. Proper anatomical reduction and fracture alignment must be achieved and verified during the surgical procedure.
l. When using locking screws in procedures requiring anchorage, avoid applying excessive force or tension to the anchoring wire, as this may overload the locking screw and compromise fixation stability.
m. Avoid creating excessively sharp bends or small bending radii during plate contouring, as this may increase the risk of implant weakening or fracture during the postoperative period.
n. Screws identified with the “AP” designation are self-drilling screws. Predrilling is not recommended when using self-drilling screws.
o. Prior to drilling, verify that the selected drill bit diameter and drilling depth are appropriate for the intended cortical screw size and length.
p. If there are any questions regarding the proper use of the device, materials, or surgical technique, contact MCI – Medical Concept Innovation before use.
q. MCI is not responsible for damages resulting from improper use, misuse, inappropriate surgical technique, or use of the device outside its intended purpose. MCI is responsible only for manufacturing-related defects.
r. The decision to remove a titanium implant after bone healing and consolidation must be based on the surgeon’s clinical judgment and the individual condition of the patient.
s. The surgeon is responsible for recording all applicable product traceability information in the patient’s medical record and for informing the patient about the availability of this information.
t. The MCI-CMF System must be used only with instruments specifically designed and authorized for use with the system. The performance and compatibility of the device cannot be guaranteed when non-authorized instruments are used.
u. The MCI-CMF System and its associated instruments must be used only for their intended purpose and in accordance with the recommended surgical techniques.
v. Patients must be informed about the limitations of the implant and instructed to adapt their activities accordingly during the healing period and throughout the implant service life, when applicable.

w. Careful patient selection is essential. Patients presenting conditions that may impair healing, compromise fixation stability, or limit compliance with postoperative instructions and precautions should be thoroughly evaluated prior to implantation.
x. The MCI-CMF System is supplied non-sterile and must be sterilized before use.
y. Prior to implantation, the device must be handled and sterilized using appropriate procedures to prevent contamination and preserve device integrity.
z. The MCI-CMF System includes single-use implants only. Implants that have been implanted or otherwise used must not be reused or reprocessed under any circumstances.
aa. Only implants and components designed and authorized for use together by MCI should be combined. Differences in design, material composition, surface finish, or surface treatment between products from different manufacturers may result in mechanical, chemical, or biological incompatibility. The use of implants from different manufacturers in the same construct is not recommended.
bb. The products should be implanted only by surgeons who are trained, qualified, and experienced in the surgical techniques applicable to the MCI-CMF System. Prior to use, surgeons should carefully review all recommendations, warnings, precautions, and instructions provided in this Instructions for Use.
cc. Any complication or adverse event resulting from improper indication, inadequate surgical technique, improper handling, failure to maintain aseptic conditions, inappropriate product selection, or misuse of the device is the responsibility of the surgeon and healthcare provider and shall not be attributed to MCI or its authorized distributors.
dd. Prior to use, all implants and instruments must be carefully inspected to verify their integrity and ensure they are free from damage, deformation, scratches, fissures, corrosion, or other visible defects.
ee. The products must be properly cleaned and sterilized before use in accordance with the instructions provided in the section “Cleaning, Disinfection and Sterilization.”
ff. High-impact or high-torque instruments must not be used with MCI-CMF System components, as excessive force may damage, deform, crack, or fracture the device. The system components have not been designed for such use conditions.
gg. Implants that have been dropped, scratched, deformed, or otherwise damaged must not be used.
hh. Improper handling, misuse, abuse, or the application of excessive force with surgical instruments during the procedure may result in damage to the implant or instrument failure.

ii. During transport and storage, implants must be protected from impact, excessive force, improper handling, and conditions that may compromise product integrity or packaging condition.
jj. Store and transport the product in clean and dry conditions, protected from contamination and physical damage.
kk. Repeated or excessive bending of titanium implants may reduce their mechanical strength and increase the risk of postoperative fracture. Plate contouring should therefore be performed carefully and with the minimum amount of bending necessary to achieve the desired anatomical fit.
ll. Avoid creating sharp bends or small bending radii during plate contouring, as this may increase the risk of implant weakening or postoperative fracture.
mm. Bone plates may require deburring prior to implantation in order to minimize the risk of soft tissue irritation or injury.
nn. Micro meshes may be manually contoured to conform to the patient's anatomy without the use of dedicated bending instruments.
oo. Ensure that the screwdriver is properly aligned with the screw head during insertion to minimize the risk of damage to the implant or surgical instrument.
pp. During screw insertion, adequate axial pressure must be applied to maintain full engagement between the screwdriver tip and the screw head. Proper alignment and complete seating of the screwdriver tip are essential to ensure effective torque transmission and minimize the risk of damage to the screw interface.
qq. The implants intend to provide fixation support during the bone healing period. Delayed healing, nonunion, bone resorption, excessive loading, or subsequent trauma may increase mechanical stress on the implant and may result in loosening, deformation, or fracture of the device.

6. EXPECTED PERFORMANCE

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

7. ADVERSE EFFECTS

Potential complications associated with the use of mini-plates or anchoring screws may include, but are not limited to, local tissue inflammation, gingival hyperplasia around the anchoring screw, difficulty in applying orthodontic traction forces when the implant is positioned too close to adjacent teeth, injury to dental roots or nearby nerves, and loosening or fracture of the fixation or traction components.

Additional potential adverse events may include infection, pain, soft tissue irritation, delayed healing, implant exposure, or mechanical failure of the device.

8. PRESENTATION AND STERILIZATION

MCI-CMF System components are supplied non-sterile and must be sterilized prior to implantation in accordance with the validated sterilization instructions provided in this IFU. Sterilization should be performed on the day of the procedure or as otherwise permitted by the healthcare facility's sterilization procedures and policies.

CAUTION: Do not sterilize the products in their original packaging. Prior to sterilization, the devices should be packaged using an FDA-cleared sterilization wrap or an equivalent validated sterilization packaging system.

Use only steam sterilization according to the validated parameters provided below:

VACUUM FRACTIONATED/DYNAMIC AIR REMOVAL PARAMETERS[1]	
Sterilization time	4 minutes
Temperature	132°C
Drying Time	20 minutes[2]

[1] At least three vacuum steps.

[2] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

9. INFORMATION TO BE PROVIDED TO PATIENTS

Patients should be informed of the following:

a. Complications or failure of oral and maxillofacial surgical procedures may be more likely in:

* Patients with functional expectations beyond those achievable through the surgical procedure;
* Patients with systemic or local conditions that may impair bone healing or bone quality, such as osteoporosis or other metabolic bone disorders.

b. The information provided in the sections titled Indications for Use, Contraindications, Warnings, Precautions, and Potential Adverse Effects.

c. The importance of periodic postoperative follow-up examinations to evaluate bone healing and monitor the condition and stability of the implant and surrounding tissues. Such follow-up may assist in the early detection of implant loosening, bone resorption, or other complications.

d. The need to inform healthcare professionals of the presence of an implanted device prior to undergoing magnetic resonance imaging (MRI) or other medical procedures involving strong electromagnetic fields.

10. MAGNETIC RESONANCE IMAGING (MRI) - SAFETY INFORMATION

MR Conditional

Non-clinical testing and electromagnetic simulations demonstrated that the MCI - CMF System is MR Conditional. A patient with this device can be safely scanned under the following conditions:

Static magnetic field of 3 Tesla or less
Spatial gradient magnetic field of 153 T/m or less
Whole-body averaged SAR of 2.3 W/kg for 15 minutes of scanning

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of 0.4 °C after 15 minutes of continuous scanning.

In non-clinical testing, image artifacts caused by the device extended approximately 53 mm from the implant when imaged with a gradient echo pulse sequence using a 3 Tesla MRI system.

The device has not been evaluated for RF-induced heating in a 1.5 Tesla MRI system.

11. CAUTIONS WHEN HANDLING AND TRANSPORTING THE MEDICAL PRODUCT

To preserve device integrity and surface condition, the MCI-CMF System should be removed from its packaging and sterilized as close as practical to the time of the surgical procedure. After sterilization, the device should be handled using appropriate aseptic techniques and with minimal unnecessary manipulation.

Any implant that has been dropped, scratched, dented, deformed, or otherwise damaged must not be used. The final determination regarding the suitability of the device for use remains the responsibility of the surgeon.

12. TRACEABILITY

To ensure product traceability, the surgeon responsible for the implantation procedure should record and/or communicate the following information regarding the implanted device to the distributor or healthcare institution, as applicable:

- Name of the healthcare institution or hospital unit;
- Name of the surgeon;
- Date of surgery;
- Patient identification;
- Product code/catalog number;
- Product batch/lot number.

The MCI-CMF System components are laser marked with the batch/lot manufacturing number to ensure traceability throughout the product lifecycle. If implant removal becomes necessary, this information will remain identifiable on the device.

Healthcare professionals must inform patients about the device traceability information and maintain the corresponding records in the patient's medical file.

Any adverse event or product quality issue related to the device must be reported through the appropriate health authority channels, in accordance with applicable local regulations.

For additional information regarding patient information and follow-up, refer to the section "Information to be Provided to Patients".

13. DEVICE DISPOSAL

Explanted devices must be rendered unusable prior to disposal. This may be accomplished by filing, bending, cutting, or otherwise deforming the device components.

Explanted devices are considered potentially contaminated medical waste and must be handled and disposed of in accordance with applicable local regulations and healthcare facility procedures.

14. COMPLAINTS/CUSTOMER SERVICE

Customers or users of this medical device who have questions or require additional information regarding MCI products or services may contact MCI – Medical Concept Innovation using the contact information provided in this Instructions for Use and on the product packaging labels.

If any issue is identified that may compromise the safety, quality, or performance of the device, the product should be returned to the manufacturer in packaging adequate to preserve its physical integrity during transportation. The returned package must include all information necessary for proper product identification and traceability.

NON-STERILE DEVICE – STERILIZE BEFORE USE.
SINGLE-USE DEVICE – DO NOT REUSE OR REPROCESS.

Store and transport the product in clean and dry conditions, protected from contamination and physical damage.

SYMBOLOGY

SYMBOL	DESCRIPTION
	Manufacturer
	Manufacturing Date
REF	Catalogue Number
LOT	Batch Code
	Non-sterile product
	Keep dry
	Do not re-use (Single use)
Rx only	U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.
	Consult instructions for use
Qty	Quantity per package
	MR Conditional
UDI	Unique Device Identification

Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician.

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