MEDICAL CONCEPT INNOVATION

INSTRUCTIONS FOR USE

TRADE NAME: MCI – Neuro Fixation System
510K: K212391

1. DESCRIPTION

The MCI – Neuro Fixation System consists of titanium alloy screws (ASTM F136) and commercially pure titanium plates and meshes (ASTM F67) used for the fixation of cranial bone fragments in humans. The System has many screw and plate sizes suited to different uses. The Auto Drive Screws are green colored (diameter 1.5 mm) or lilac-colored (diameter 1.7) and present a self-drilling design. The plates, meshes and screws are provided non-sterile to end user.

2. INDICATIONS FOR USE

MCI - Neuro Fixation System is indicated for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.

3. 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 to not cause a new focal fracture.

4. 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.

5. WARNINGS AND PRECAUTIONS

The MCI – Neuro Fixation System must be handled by specialized and duly qualified personnel.
• Before using and sterilizing the MCI – Neuro Fixation 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 Neuro Fixation 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 – Neuro Fixation 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, craniotomy, craniectomy and cranial fractures 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 – Neuro Fixation 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.
• Extremely acute angles along a small folding radius must be avoided due to the potential risk for breakage in the post-surgical period.
• The Auto Drive Screws are self-drilling. Predrilling is not recommended for self-drilling screws.
• 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 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 medical record and inform the patient about traceability and provide free access to this information.
• The MCI –Neuro Fixation System must be handled with the MCI – Neuro Fixation System Implantation Instrumental Kit. The warranty of performance is void if unauthorized instruments are used. MCI – Neuro Fixation 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.
• The plates, meshes and screws of MCI – Neuro Fixation System must be clean and sterilized before use and handled with due care to avoid contamination.
• MCI – Neuro Fixation System comprises SINGLE-USE implants. After use, these implants shall not be reused under any circumstances.
•Plates, meshes and screws of MCI – Neuro Fixation System that could possibly be contaminated during a surgical procedure must be treated as described in the DEVICE DISPOSAL item of this instruction for use.

• 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 – Neuro Fixation System. 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 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.
• If provided non-sterile, the products must be correctly sterilized before use, as described in the section Presentation and Sterilization.
• High-impact or high-torque instruments must not be used with MCI – Neuro Fixation 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 maximum temperature of 45 °C and maximum relative humidity of 85%.
• Titanium 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.
• The 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.

6. EXPECTED PERFORMANCE

MCI – Neuro Fixation System purpose is to be used in craniotomy, cranioplasty and fixation of bone fragments of the skull.

7. CLEANING

Before the sterilization process, the devices must be cleaned as described below:

a) Use Alkaline Detergent, like a Valsure® Alkaline Detergent. Dilution should be carried out as recommended by the manufacturer.
b) Immerse the entire device body in the detergent solution, keeping the solution in contact with the device for at least 3 minutes.

c) Rub each device with a soft bristle brush, at least 5 times, from the proximal to the distal direction. Repeat this procedure until the removal of visible dirt, making sure that all recesses have been washed away.
d) Rub the inner surface of each lumen with a soft brush, adjusted to the lumen size, at least 5 times, from the proximal to the distal direction. Repeat this procedure until visible dirt is disposed of.
e) Immerse the products in the ultrasonic washer for at least 5 minutes at a frequency between 40 and 45 KHZ at a temperature between 45 and 55°C.
f) Rinse the device in purified water for at least 1 minute.
g) Never use steel straws or sponges and/ or abrasive products, so as not to damage the instruments in use.
h) Do not accumulate the instruments in large quantity, on each other, to prevent the deformation of the smaller and delicate parts and thus also do not scratch the polished surfaces. Always shave to wear few pieces at a time.
i) Dry the device with soft and clean cloth, which does not loosen lint and/or particles.

8. PRESENTATION AND STERILIZATION

The plates, meshes and screws of MCI – Neuro Fixation System are sold non-sterilized; they must be sterilized before implantation. Sterilize the products the day before or on the day of the procedure. ATTENTION: It is not recommended to autoclave these products in their original packaging. The product must be individually packaged with an FDA-approved wrapper. Please use for sterilization only the steam sterilization according to the following parameters:

Dynamic-Air-Removal Steam Sterilization Cycles[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

The patient must be warned about:
A. The fact that complications or failures of cranial 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, and Warnings and Precautions;
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.

Precautions to take regarding the exposure to magnetic fields:

Non-clinical tests and in vitro electromagnetic simulations have shown that the MCI implantable products are conditional products for magnetic resonance imaging. A patient with this device can be safely examined on an MRI system under the following conditions:

• The static magnetic field of 3 Tesla (3T), only.
• The spatial magnetic field gradient should be less than 153 T/m;
• The product of the static magnetic field and the spatial gradient (force product) must be less than 290 T2/m;
• The maximum magnetic resonance system reported the mean specific absorption rate (SAR) of 2.3 W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system.

Under the scan conditions defined, the prosthesis is expected to produce a maximum temperature rise of up to (0.4+/- 0.1) °C after 15 minutes of continuous scan.
In non-clinical tests, the resulting image artifact by the implant can extend up to approximately 53 mm, when imaged using a gradient echo pulse sequence and a 3 Tesla MRI system. The generation of artifacts affects the images rather than having a physical effect on patients (in other words, they do not threaten patient safety). The contours of metal objects are no longer well delineated and the surrounding area becomes blurred or its signal is altered, which degrades the quality of the images. Initial solutions, such as RF sequence optimization, provide limited corrections to the distortions (mainly in-plane distortions), but the advent of multispectral solutions, namely SEMAC and MAVRIC, have considerably improved image quality.

MCI – Neuro Fixation System, has not been evaluated for RF heating in a 1.5T scanner.

10. CAUTIONS WHEN HANDLING AND TRANSPORTING THE MEDICAL PRODUCT

We recommend that the MCI – Neuro Fixation 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.

11. 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 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 – Neuro Fixation 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 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”.

12. 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.

13. 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.

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

14. SYMBOLOGY

SYMBOL	DESCRIPTION
	Manufactured by
	Date of manufacture
	Catalogue Number

SYMBOL	DESCRIPTION
	Batch Code
	Non-sterile
	Keep dry
	Use-by date
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
	MR Conditional
	Unique Device Identifier

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

Manufactured by:
MCI – Medical Concept Innovation.
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