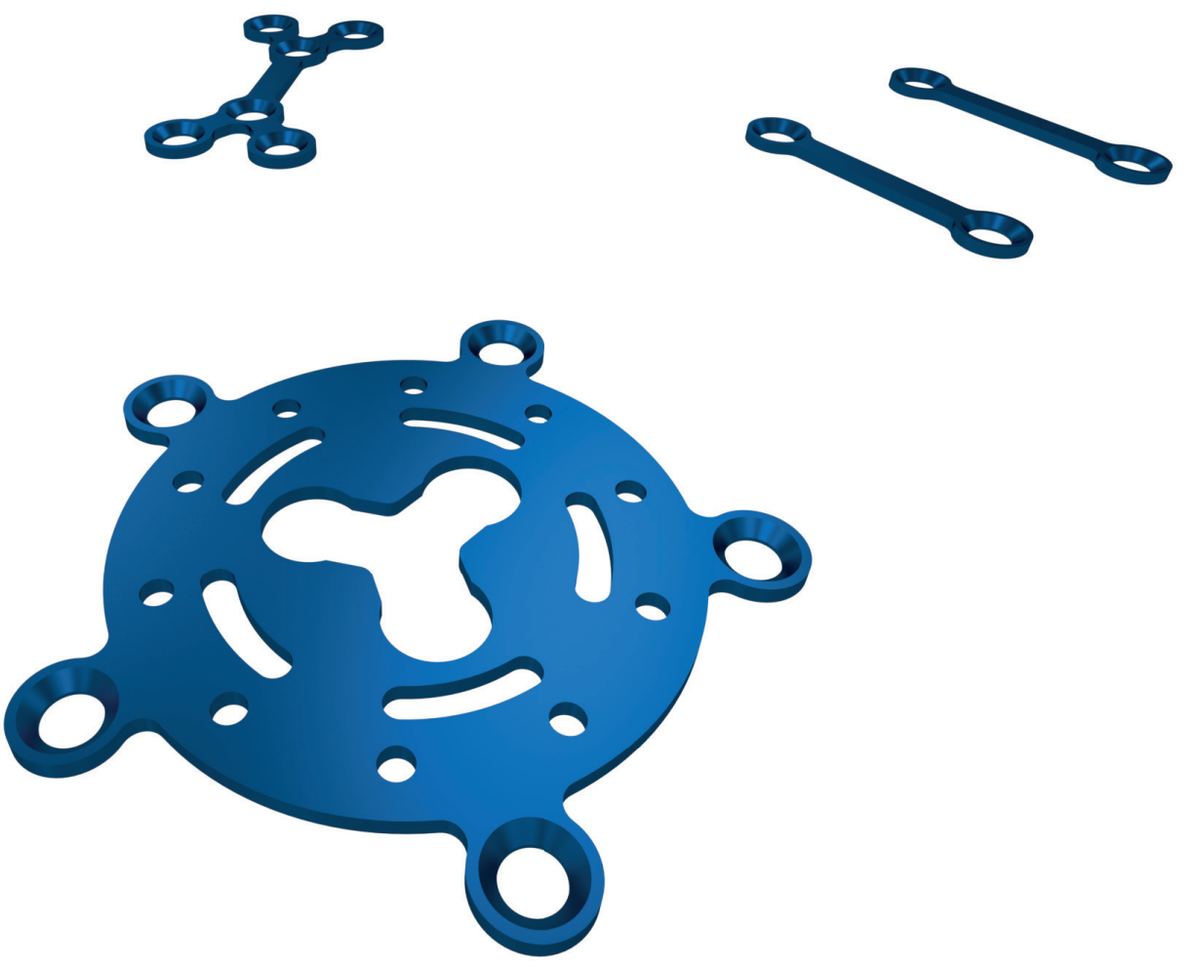
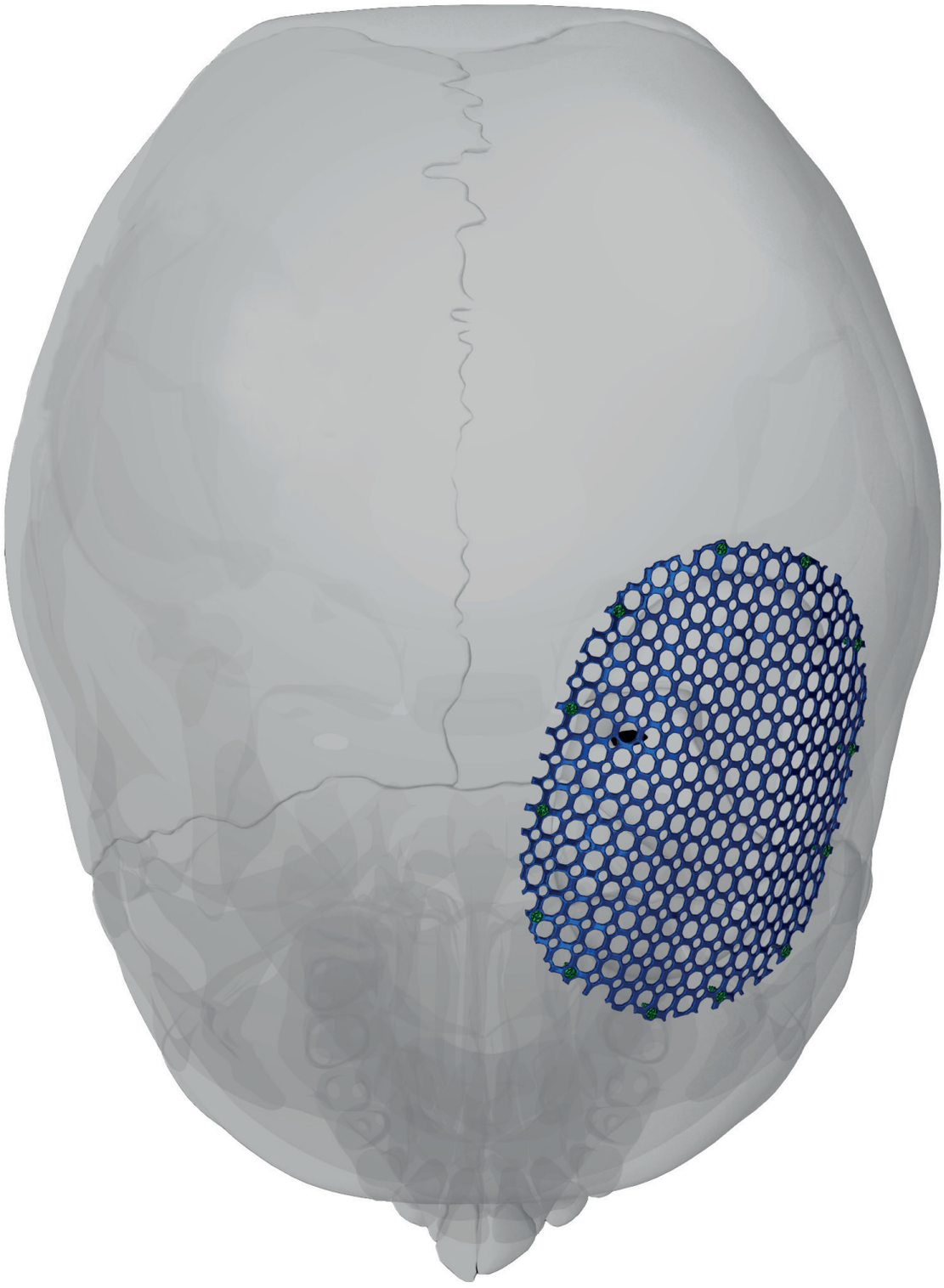
Neuro Fixation System

Surgical Technique

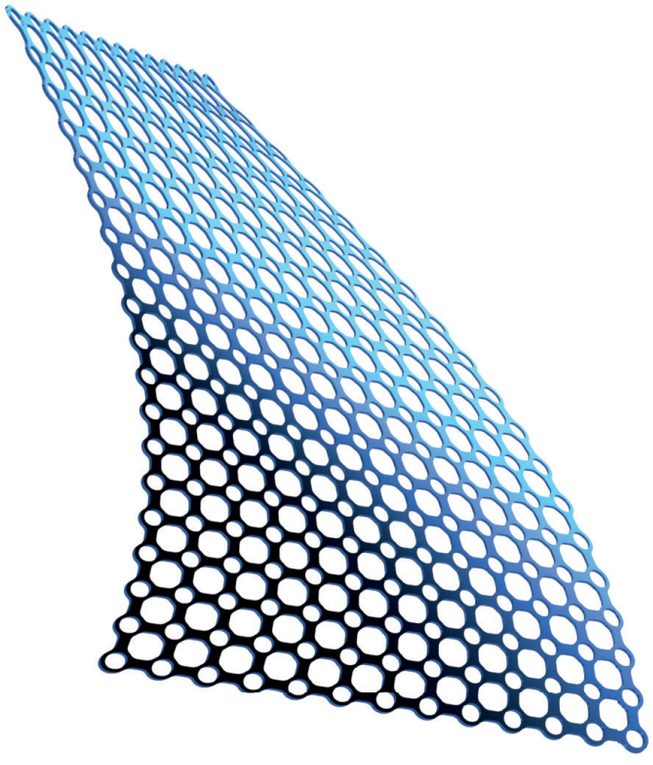


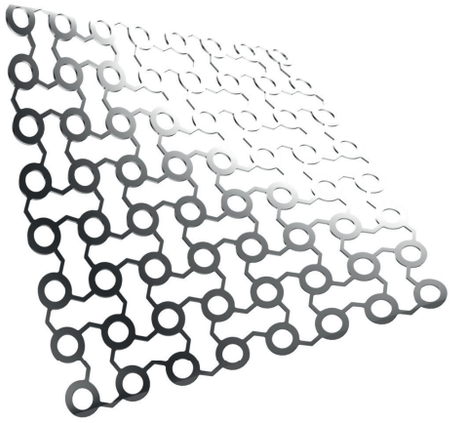
MEDICAL CONCEPT INNOVATION



This Surgical instruction does not replace the previous and necessary knowledge of the professional surgeon to perform any surgical procedure, it only describes the functionality and instruction of use of MCI products.
For More informations:
www.mci-medical.com

Index





1. Introduction

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 intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.

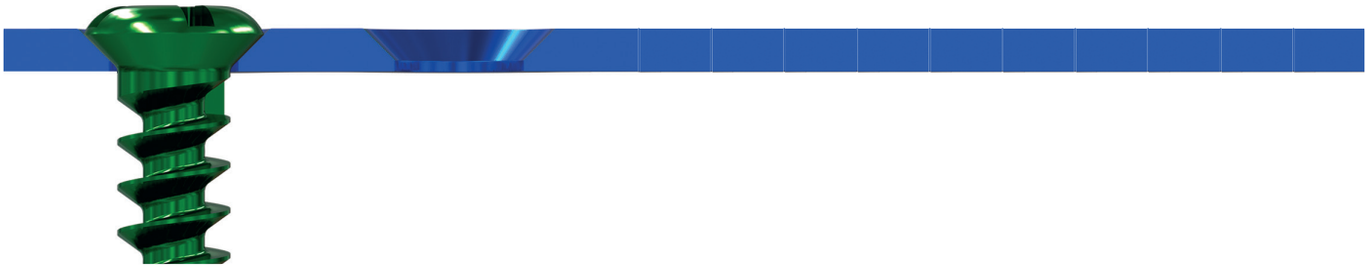
3. Screws

Auto Drive Screw N 1.5mm

A01.02.0000	3mm
A01.02.0006	3mm | 5pc
A01.02.0007	3mm | 20pc
A01.02.0001	4mm
A01.02.0008	4mm | 5pc
A01.02.0009	4mm | 20pc
A01.02.0002	5mm
A01.02.0010	5mm | 5pc
A01.02.0011	5mm | 20pc
A01.02.0003	6mm
A01.02.0012	6mm | 5pc
A01.02.0013	6mm | 20pc

Auto Drive Screw N 1.7mm

A01.02.0004	4mm
A01.02.0014	4mm | 5pc
A01.02.0015	4mm | 20pc
A01.02.0005	5mm
A01.02.0016	5mm | 5pc
A01.02.0017	5mm | 20pc



4. Plates

1.5 Module
Micro Plate | Blue Colouring | Screw Ø 1.5 mm

Micro Plates (1.5 mm Module)

Square Micro Plate N

A01.02.1106	2X2H
A01.02.1135	2X2H | 5pc

Clover Micro Plate N

A01.02.1109	
A01.02.1139	5pc

Rectangular Micro Plate N

A01.02.1112	2x2H
A01.02.1138	2x2H | 5pc
A01.02.1107	3X2H
A01.02.1136	3X2H | 5pc
A01.02.1108	4X2H
A01.02.1137	4X2H | 5pc

Z Micro Plate Bridge

A01.02.1130	10mm
A01.02.1131	10mm | 5pc

Triangular Micro Plate N

A01.02.1119	
A01.02.1141	5pc

Straight Micro Plate N 16H

A01.02.1115	
A01.02.1163	5pc

Straight Micro Plate N 4H

A01.02.1111	
A01.02.1142	5pc

TR Straight Micro Plate N Bridge

A01.02.1116	8mm | 2H
A01.02.1149	8mm | 2H | 5pc
A01.02.1113	10mm | 2H
A01.02.1147	10mm | 2H | 5pc
A01.02.1114	12mm | 2H
A01.02.1148	12mm | 2H | 5pc
A01.02.1117	14mm | 2H
A01.02.1150	14mm | 2H | 5pc

Straight Micro Plate N Bridge

A01.02.1120	6mm | 2H
A01.02.1144	6mm | 2H | 5pc
A01.02.1161	7mm | 2H
A01.02.1162	7mm | 2H | 5pc
A01.02.1121	8mm | 2H
A01.02.1145	8mm | 2H | 5pc
A01.02.1122	10mm | 2H
A01.02.1146	10mm | 2H | 5pc
A01.02.1123	12mm | 2H
A01.02.1143	12mm | 2H | 5pc

X Micro Plate N Bridge

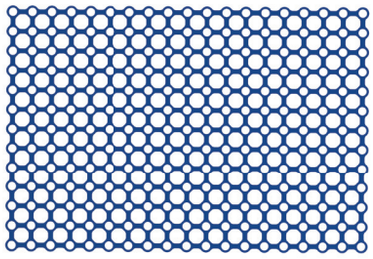
A01.02.1103	5mm
A01.02.1132	5mm | 5pc
A01.02.1104	7mm
A01.02.1133	7mm | 5pc
A01.02.1105	9mm
A01.02.1134	9mm | 5pc

Y Micro Plate N Bridge

A01.02.1110	6mm | 5H
A01.02.1140	6mm | 5H | 5pc

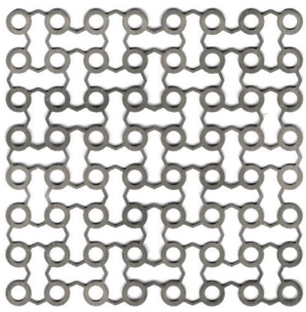
TR Micro Mesh

A01.02.1000	50.6mm X 74.6mm | 0.3mm



I Micro Mesh

A01.02.1011	40mm X 40mm | 0.3mm
A01.02.1012	90mm X 90mm | 0.3mm
A01.02.1013	120mm X 120mm | 0.3mm



Micro Plate N for Craniotomy

A01.02.1100	Ø18mm | Drain 6mm
A01.02.1151	Ø18mm | Drain 6mm | 5pc

Micro Plate N for Craniotomy

A01.02.1129	Ø22mm | 0.3mm
A01.02.1155	Ø22mm | 0.3mm | 5pc

Micro Plate N for Craniotomy

A01.02.1128	Ø18mm | Drain 3.2mm
A01.02.1154	Ø18mm | Drain 3.2mm | 5pc

Micro Plate N for Craniotomy

A01.02.1125	Ø17mm | 0.3mm
A01.02.1159	Ø17mm | 0.3mm | 5pc

Cranial Micro Plate N

A01.02.1118	Ø18.5mm | 5H
A01.02.1157	Ø18.5mm | 5H | 5pc

Micro Plate N for Craniotomy

A01.02.1127	Ø12mm | 0.3mm
A01.02.1156	Ø12mm | 0.3mm | 5pc

Micro Plate N for Craniotomy

A01.02.1102	Ø15mm
A01.02.1153	Ø15mm | 5pc

Micro Plate N for Craniotomy

A01.02.1101	Ø20mm
A01.02.1152	Ø20mm | 5pc

5.Instrumental

Drill

A02.01.0020 Ø1.1mm X 50mm | 5mm

Drill

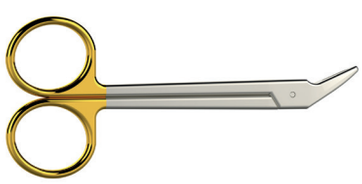
A02.01.0022 Ø1.1mm X 100mm | 5mm

Plate Holding Forceps n2

A02.01.1412

Small Scissors Cutting Pliers

A02.02.0004



Cable Quick Coupler

A02.01.0801

Tip Cross drive 1.5mm

A02.01.0600

Bending Pliers 1.5 - 2.0

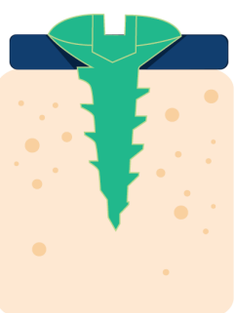
A02.01.0003

Mesh Modeling Pliers

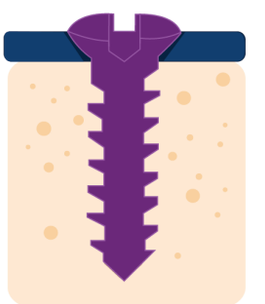
A02.01.0007

Drills

Drill Ø1.1 mm



Auto Drive Cortical Screw Ø1.5 mm Cross Drive



Auto Drive Cortical Screw Ø1.7 mm Cross Drive

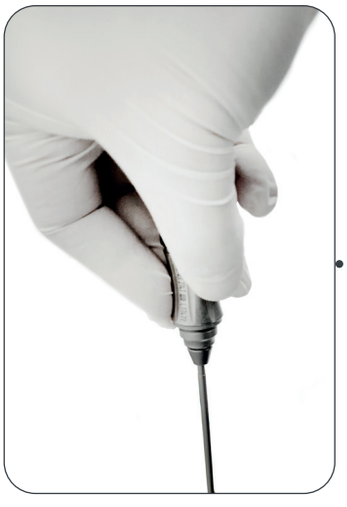
Note: Auto drive screws do not require pre-drilling for insertion due to their self-drilling feature, but if pre--drilling is required, use only Ø1.1mm drills. emergency screws (1.7) are indicated in case of poor fastening (for various reasons) of the standard screw (1.5).

6. Schematic outline of important steps

During manipulation of the instruments and implants at the time of fixation of the Screws to bone tissue are required some practices to ensure good product performance and its integrity.

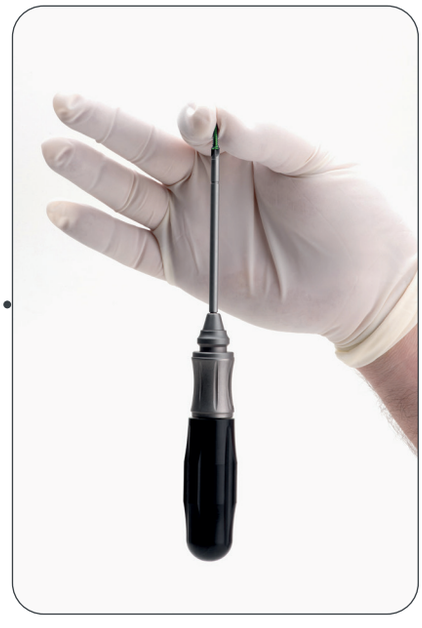
First step is the correct handgrip of the quick coupling wrench. The base of the cable must be between the two transverse arches, the third, fourth and fifth finger must press the cable, and the primary clamp of the first and second finger should rotate the drum of the cable.

Proper wielding



Vertical pressure for perfect connection between screw and screwdriver

After carrying the handle, the wrench must be inserted into the screw fitting, the wrench can be rotated to ensure that the ferrule is actually attached to the Screw, after which a slight vertical pressure is required to ensure the perfect Component fitting.



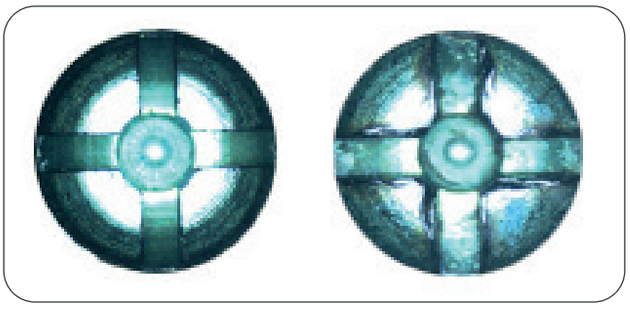
By doing these steps it is possible to observe the quality of the stability achieved between the two components of the system.

Correct Connection

Incorrect connection

During the choice of screws it may be necessary to return the screws to the case, this should be done with circular movements without acute angulation as they may damage the fitting of the screws and the tips.

Returns of screws to the case are not indicated, butif necessary, should be made with little angulation and circular movements.



Screw intact

Screw damaged by numerous returns to the case.

7. 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.

8. Warnings and Precautions

The MCI – Neuro Fixation System must be handled by specialized and duly qualified personnel.

• Before using and sterilizing (if applicable) 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 IS ARE SOLD DECONTAMINATED BUT NOT STERILIZED.

• The plates, meshes and screws of MCI – Neuro Fixation System must be 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.

• 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 Sterilizatio n.

• 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.

9. Expected Performance

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

10. 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.

11. Information to be provided to the patient

The patient must be warned about:

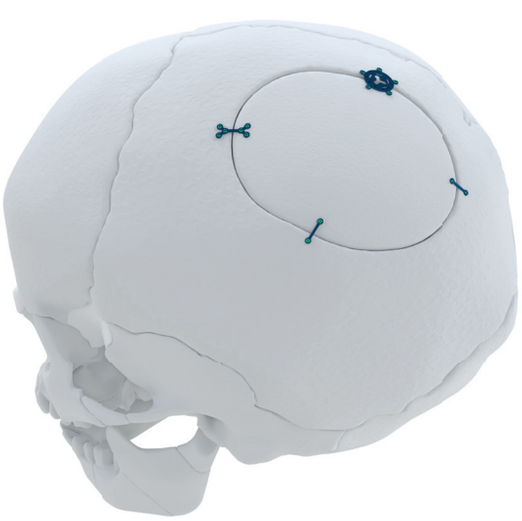
A. The fact that complications or failures of cranial surgery are most common in:

• 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.



MEDICAL CONCEPT INNOVATION

4592 North Hiatus Road, Sunrise, FL 33351 - USA
Fone/ Fax: +01 954.306.2521
mci-medical.com| customer.service@mci-medical.com

rev01 | 2023