MEP - Multipurpose External Fixator - Instructions and warnings for use

CE 1936

IT

Mikai S.p.a. Via P. Gobetti 56R – 16145 Genoa (Italy)

DESCRIPTION

The MEP multipurpose external fixator is a monolateral fixation system that allows the bone stumps to be manipulated in all planes and angles thanks to its articulated body and the use of multifunctional sliding clamps. The free positioning of the screws guarantees maximum respect for the soft tissues thanks to the possibility given to the surgeon to position them in spaces and angles that are less traumatic for the patient.
The MEP system devices are single use only.
The appropriate instruments (set of instruments) provided by the manufacturer must be used for the implant. If non-sterile multi-use instruments are available, wash and sterilise them before each procedure as indicated in the dedicated instructions for use.
The instruments supplied in sterile kits are SINGLE-USE and must not be reused or resterilised.
The MEP system is intended for orthopaedic surgeons who are experts in the field of external fixation.
The MEP system is compatible with Mikai's ClickIt ER and ClickIt CF systems, for further information contact the manufacturer.

MATERIALS

The fastener elements are made of different materials including: aluminium, stainless steel, PEEK, UHMWPE, Nylon, Teflon, ABS, POM and carbon fibre
The gripping elements are made of AISI 316 LVM ISO 5832-1 stainless steel (also available coated in hydroxyapatite) and Ti6Al4V ELI ISO 5832-3 titanium alloy.
This system has been tested for magnetocompatibility (see section "MRI SAFETY INFORMATION - MR CONDITIONAL" in this document). Medical staff must be informed of the composition material of the device and the respective indications provided so that they can make appropriate considerations regarding the exposure of the patient equipped with the implanted device to strong electromagnetic fields, as in the case of MRI control needs.
Furthermore, the patient must also be informed by the hospital staff about the material used in the manufacture of the implanted device and the specific limitations/contraindications attached to it, in addition to the safety parameters provided in this document.

QUALITATIVE AND QUANTITATIVE INFORMATION

The implantable alloys used by Mikai are:
- Titanium alloy Gr5 Ti6Al4V-ELI (ISO 5832-3)
- AISI 316 LVM stainless steel (ISO 5832-1)

ISO 5832-3 identifies the following limits for the Gr5 Ti6Al4V-ELI titanium alloy:

Element	Compositional limits % (*m/m*)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max.[a]
Titanium	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 % (*m/m*).

ISO 5832-1 identifies the following limits for AISI 316 LVM stainless steel:

Element	Mass fraction %
Carbon	0,030 max.
Silicon	1,0 max.
Manganese	2,0 max.
Phosphorus	0,025 max.
Sulfur	0,010 max.
Nitrogen	0,10 max.
Chromium	17,0 to 19,0 max.
Molybdenum	2,25 to 3,00
Nickel	13,0 to 15,0
Copper	0,50 max.
Iron	Balance

The limits for hydroxyapatite are shown in the following table:

Test	Method	Unit	Requirements min	Requirements max
Crystallinity ratio	ISO 13779-6: 2015	%	95	100
Ca/P ratio	ISO 13779-3: 2018 (Annex H)	/	1,66	1,71
Foreign phases				
α-TCP*	ISO 13779-6: 2015 ISO 13779-3: 2018 (Annex H)	%	/	∑5,0
β-TCP*			/	
TTCP*			/	
CaO*			/	
CaO*			/	1,0
**detection limit for each foreign phase <1*				
Trace Elements				
Arsenic (As)	ISO 13779-6: 2015	mg/kg	/	3,0
Cadmium (Cd)			/	5,0
Mercury (Hg)			/	5,0
Lead (Pb)			/	30,0
Heavy Metals (as Lead)			/	30,0
Sodium (Na)			/	/
Magnesium (Mg)			/	/
Morphology	ISO 13779-6: 2015	/	atomized	
Granulometry	ISO 13779-6: 2015	micron	< 200	

INTENDED USE

Family of medical devices for external fixation for the treatment of bone stabilisation and correction in the event of trauma or disease, in adult and paediatric patients.

INDICATIONS FOR USE

Fractures of traumatic and/or pathological origin that may occur in the following anatomical regions or joints:
- Wrist
- Radius/Ulna;
- Humerus;
- Femur;
- Tibia;
- Pelvis;
- Knee;
- Ankle;
- Elbow.

Pseudoarthrosis that may occur in the following anatomical regions or joints:
- Wrist;
- Radius/Ulna;
- Humerus;
- Femur;
- Tibia;
- Foot.

Protection or external support for localised infections that may occur in the following anatomical areas or joints:
- Tibia;
- Ankle;
- Foot;
- Wrist;
- Radius/Ulna;
- Humerus;
- Femur;
- Knee;
- Elbow.

Need for elongations that may occur in the following anatomical regions:
- Radius/Ulna;
- Humerus;
- Femur;
- Tibia.

Deformities that may occur in the following anatomical regions and joints:
- Wrist;
- Radius/Ulna;
- Humerus;
- Femur;
- Tibia;
- Knee;
- Ankle;
- Elbow;
- Foot.

CONTRAINDICATIONS

Conditions that present an increased risk of error include:
- Insufficient quantity or quality of bone that prevents proper fixation of the device;
- Physiologically or psychologically unsuitable patient;
- Impaired vascularisation;
- Skin injury or opening not properly treated;
- Sensitivity to the materials constituting the gripping elements, whether documented or suspected (nickel allergy);
- Fever and leukocytosis;
- Malignant neoplasm in the fracture area;
- Insertion of implantable elements in an area subject to infection;
- Any neuromuscular deficit that could interfere with the patient's ability to limit the load;
- Any neuromuscular deficit that places an unusually heavy load on the device during the healing period;
- Neurovascular disorders.

DURATION OF USE AND EXPLANTATION

The MEP fixators can remain implanted from 30 up to 180 days, the maximum time in which the intended uses are expected to be achieved. To proceed with the explant, the dedicated clamps must first be loosened, after which they must be removed together with the fixator body and the additional external accessories. Finally, the gripping elements such as screws and wires must be unscrewed and removed using the appropriate tools of the MEP system.

CUSTOM MEP KIT

The MEP system provides custom kits (50000**AA**ST***XX***) containing various devices in predefined quantities for the treatment of certain anatomical areas and optimised according to the reference market/customer. This composition respects, however, the steps of the following surgical technique and includes only Mikai compatible medical devices.
The description of the custom kit is for information purposes only and may correspond to a word or synthetic phrase. This refers to the indications for use (which must be included among those attributed to the MEP fixator) if it is a kit commercially aimed at treating a district or pathology (e.g. TIBIA or TIBIA PLUS).

BASIC SURGICAL TECHNIQUE

The installation steps (implant) of a monolateral fixation system are listed below.
1. Carry out a preliminary reduction on the three planes. After having carried out the relative pre-drilling, insert the screws on the frontal plane, passing the first cortical with the screw mounted on the motor drill;
2. Proceed by hand with the appropriate T-wrench for bone screws, until the second cortical is passed;
3. The central joint allows for translations and/or angular corrections;
4. Use the handles on the bone screws to obtain a macrometric reduction on the frontal plane;
5. When the correction is complete, tighten the clamps with the dedicated wrench;
6. The possible use of the regulators on the bone screws allows a micrometric correction to be made on the frontal plane;
7. If the reduction is acceptable in the sagittal plane, lock the joint with the appropriate key;
8. If a reduction in the sagittal plane is necessary, use the handles anchored on the bone screws and perform the reduction maneuvers, taking advantage of the articulation of the central joint. When the reduction is complete, lock the central joint;
9. Lock the compression-distraction complex with the dedicated hexagonal screwdriver. Further rotational corrections and/or further micrometric compression-distraction can be performed;
10. Once the correction is complete, tighten the grub screws again.

Use of hybrid MEP fitting 5.2109.00S/L:
The hybrid MEP fitting allows the standard MEP body to be transformed into a hybrid MEP body by performing the following steps:
1. Loosen the male track grub screws (compression/distraction module side), loosen only the row of grub screws closest to the track.
2. Unscrew the track anticlockwise, avoiding rotating the compression/distraction module.
3. Insert the hybrid MEP fitting 5.2109.00S/L by screwing it clockwise until it reaches the support base.
4. Adjust the height with the compression/distraction module and tighten the grub screws.

WARNINGS AND PRECAUTIONS

Pre-operative
- The use of external fixation devices requires a thorough knowledge of external fixation surgery;
- Do not use the device if material hypersensitivity is suspected;
- The patient must be informed of how the device is used and of the potential complications associated with external fixators. Furthermore, they must always be informed about the limits of the implant; shocks, excessive uncontrolled loading, tampering with the device and other factors can lead to failure or wear of the device with consequent failure of reconstructive and rehabilitative therapy;
- If the surgeon is not familiar with the techniques related to such devices, consultation of the scientific and technical documentation on the methods and devices is recommended, in order to correctly assess the possible risks;
- Pre-operative assembly of the system is recommended to reduce operating times and ensure that all components are available;
- Store the product so that the packaging does not suffer damage or alteration and do not use it if the (primary or secondary) packaging is damaged;
- The duration of the device's operating period is closely related to biological and biomechanical factors;
- The correct choice of implant can minimise the risk of failure and this choice must be made in relation to the size and shape of the bone segment involved and the anticipated loads it will be subjected to;
- Psychologically compromised, obese or debilitated patients are at risk of failure;

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- Only manufacturer-approved accessories should be used and they must always be implanted with the instruments supplied by the manufacturer;
- The evident deformation of an implant can cause a marked reduction in fatigue resistance;
- It is necessary to check the physical and functional integrity of the device before proceeding with its implantation;
- Alternative methods, aids or devices must always be available before proceeding with the implant.

Intra-Operative

- Intraoperative fractures or instrument breakage may occur;
- It is strongly recommended to use dedicated instruments during implantation and to avoid using instruments that, according to the surgeon's experience, are considered worn or malfunctioning. should any worn or malfunctioning devices be identified, they must be returned to Mikai which will promptly replace them with equivalent suitable material;
- For components delivered in sterile packaging (see specific label on the packaging), make sure that the expiry date has not been exceeded;
- For components delivered in sterile packaging (see the specific label on the packaging), make sure that the packaging is free from damage;
- Pre-drill before inserting the screws;
- Carefully position the screws to avoid damage to nerves, muscles, tendons and vessels;
- Implantation must take place in a sterile environment;
- Drill the bone slowly to avoid heat necrosis of the surrounding tissues and bone;
- Before applying the fixator, make sure that the clamps are loose;
- Do not use damaged implants for any reason;
- Be careful not to cut the surgical gloves during implantation by handling sharp instruments.
- The clamps must not be disassembled;
- The devices are single-use and must NEVER be reused. The reuse of the devices entails the risk of causing a re-infection or a cross-infection, as well as compromising the functional performance of the device;
- Select the length of the bone screws and thread according to the size of the bone and soft tissues. Avoid excessive penetration of the far cortex, which could cause damage to soft tissues;
- It is necessary to apply the fixator at a certain distance from the skin in order to allow for post-operative swelling and cleaning, without forgetting that the stability of the system depends on the bone-fixator distance. It is at the discretion of the surgeon to apply any accessories to the fixator to increase the stabilisation of the construct;
- Additional instrumentation may be required for implantation and removal, such as cutters, wire bending pliers and a power drill;
- Check the integrity of the screws and the assembly at regular intervals. To avoid any risk of injury, it is recommended to protect (e.g. with caps) the ends of the threaded wires, bone screws that have been cut with the wire cutter;
- At the end of the implant phase, the surgeon must ensure that all the elements of the fixator are fixed and locked;
- The maximum diameter of the screw thread must not exceed one third of the bone diameter (for example, use 6 mm bone screws for bones with a diameter greater than 20 mm);
- Be careful not to protrude from the articular surface with the screws/bone wires.

Post-operative

- Instruct the patient on the daily management of the skin near the screws to reduce infections;
- The patient should be informed that the system will not be comparable to healthy bone;
- All patients must be informed about the use and maintenance of the external fixation assembly;
- Patients should be instructed to report any abnormal or unintended effects to the surgeon;
- Correct and stable assembly of the system is essential. The components must be firmly fixed with the appropriate tools;
- Weight-bearing should be avoided for the first 3 weeks after surgery. After this time, it is possible to apply light loads in cases where there is bone-bone contact with consequent intrinsic stability of the limb. In lack of such stability, loading should be avoided until the callus becomes visible radiographically;
- If slides are used, the patient must avoid putting the implant under full load and must use crutches;
- Assess the fracture gap during healing. Changes to the construct should only be implemented if necessary;
- Regularly check the integrity of the device and the tightness of the screws;
- Do not use system components with products from other manufacturers;
- The sterile packaging of the device contains 4 detachable labels bearing traceability data, which can be affixed to the patient's medical record;
- Removal of the device: the final decision regarding the removal of the fixation device rests with the surgeon.

POSSIBLE ADVERSE EVENTS OR SIDE EFFECTS

- Damage to nerves or blood vessels, resulting from the insertion of wires and screws;
- Excessive movement at the fracture site due to improper positioning;
- Superficial or deep bone infection, osteomyelitis or septic arthritis along the screw and/or wire passage tract, including chronic drainage of the bone screw insertion sites after removal of the device;
- Oedema or swelling, possible compartment syndrome;
- Joint contracture, subluxation, joint dislocation, deformity or loss of range of motion;
- Failure of bone regeneration, development of non-union or pseudoarthrosis;
- Delayed healing;
- Osteolysis;
- Tendon muscle laceration;
- Fractures of the regenerated bone or caused by the holes of the bone screws, following the removal of the device;
- Loosening or breakage of the devices;
- Bone damage due to the choice of inadequate implants;
- Bone malformation;
- Persistence or reappearance of the initial condition that required treatment;
- Repeat surgery to replace a component or the entire assembly configuration;
- Repeat surgery due to inadequate synthesis;
- Rejection of implants or assembly components;
- Tissue necrosis following the insertion of implantable elements;
- Pressure on the epidermis caused by external components in the event of inadequate distance;
- Discrepancy in limb length
- Excessive surgical bleeding;
- Inherent risks associated with anaesthesia;
- Allergic reaction;
- Intractable pain;
- Swelling or inflammation at the implant site;
- Heat build-up and bone necrosis;
- Bone sequestration, resulting from excessive speed of bone cortex perforation with heat generation and bone necrosis;
- Damage to the cartilage at the joint;
- Loss of reduction;
- Migration of implanted elements
- Heterotopic ossification;
- Formation of keloids over the surgical incision scar;
- Hypoesthesia;
- Vascular disorders, including thrombophlebitis, pulmonary embolism, wound haematoma, vascular necrosis, thrombosis and arteriovenous fistulas.

Warning: this device is not approved for fixation or attachment with screws to the posterior elements (peduncles) of the cervical, thoracic or lumbar spine.

IMPORTANT

Not all surgical procedures are successful. Further complications may develop at any time due to misuse, for medical reasons or due to device failures resulting in the need for new surgery to remove or replace the external fixation device. Pre-operative and operative procedures, which include knowledge of surgical techniques, correct choice and placement of external fixation devices, are important factors for the successful use of Mikai external fixation devices by the surgeon. Proper patient selection, the patient's ability to comply with the doctor's instructions and to follow the prescribed treatment regimen greatly influence the results. It is important to subject the patient to a thorough examination and choose the optimal therapy in relation to the physical and/or mental requirements and/or limitations. If a candidate for surgery shows contraindications or a predisposition to them, it is recommended NOT TO USE the devices of the MEP system.

The MEP system instruments have not been tested for a maximum number of washing cycles. In the event of oxidation, surface defects that compromise the functionality of the instruments or disappearance of the marking, the instruments must be returned to Mikai to proceed with their maintenance/replacement.

STERILISATION

All the components of the MEP monolateral external fixator are supplied in **STERILE and SINGLE-USE** packaging and are subjected to a sterilisation process using Ethylene Oxide. If the packaging is damaged, it is recommended not to use its contents. The devices are not intended to be re-sterilised.

All NON-STERILE products (instruments) must be steam sterilised in an autoclave (according to the UNI EN ISO 17665 standard).

Procedure	Fractional and/or dynamic pre-vacuum procedure
Exposure duration	≥ 5 minutes
Temperature	134°C

SINGLE USE

The components of the fixator are for single use only. Reuse of the device can lead to failure of the fixator due to alteration of the functional mechanical properties.

The instruments can be reused provided that: rules for their correct storage have been observed; the instruments are not damaged and/or contaminated, and the guidelines for resterilisation indicated above are followed.

The aforementioned instruments refer exclusively to non-sterile devices belonging to the reusable instrument set supplied by Mikai.

In the event of non-compliance with this requirement, the manufacturer accepts no liability.

Mikai recommends that the products be disposed of if they come into contact with pathogens that are difficult to detect, such as the variant of Creutzfeldt-Jakob disease (confirmed or suspected pathogen).

MRI SAFETY INFORMATION - MR CONDITIONAL

The devices of the MEP fixation system bear the "MR Conditional" symbol in compliance with the parameters of the ASTM F2503 standard. In order to submit the trademark, the system was subjected to a risk analysis and the components were subjected to non-clinical MRI tests in an MRI environment according to ASTM F2052, F2182 and F2213 standards. The risk analysis and tests, performed at 1.5 and 3 Tesla, have shown that the components of the MEP system can be considered conditionally compatible for use in an MR environment provided that the following is respected.

The parameters, the systems used and the worst cases in terms of heating are shown in the table below. The devices of the MEP system do not present significant risks of displacement, torsion, unwanted movement or migration in 1.5 and 3 Tesla MR environments, provided that the parameters presented are met.

MEP	System	
Nominal value of the static magnetic field	1.5 Tesla [63.85 MHz]	3 Tesla [127.8 MHz]
Screen	Active	Active
Maximum field gradient	7.4 T/m	12 T/m
Coil type	Body coil	Body coil
Maximum in-vitro temperature variation scan time	15'08"	15'38"
SAR worst case	8.51 ± 0.13 W/kg	11.18 ± 0.16 W/kg
Maximum in-vitro temperature variation with the device inside the scanner	3.9 ± 0.4°C	5.8 ± 0.4°C
Artifact on the MR image	The presence of the MEP system can generate artefacts on the images obtained	

A patient with implanted MEP devices can be safely scanned in the area of the fixator under the aforementioned conditions. Failure to follow these conditions and the following warnings and precautions may result in injury to the patient.

MRI warnings and precautions:

- The use of parameters other than those listed can cause serious harm to the patient.
- The use of other devices not marked "MR Conditional", even if they belong to Mikai systems, can cause serious harm to the patient.
- Avoid aligning the implanted components of the device (bone screws, Kirschner wires) with the main axis of the scanner bore to reduce the risk of induced heating.
- Subjecting a patient with other implanted medical devices in addition to the MEP system to MRI can cause an unexpected increase in temperature and an increased risk of causing serious harm to the patient.
- The modularity of the MEP system allows for multiple configurations; therefore, worse heating conditions cannot be excluded.
- Do not use scanning modes higher than SAR = 2 W/kg.
- In normal scan mode (SAR = 2 W/kg), the temperatures should be lower in an approximately proportional way (about 12°C for 1.5 T and 6°C for 3 T), this, however, should not be taken as a certainty and all the precautions listed below must be followed.
- Safe continuous scan times with no risk of localized temperature increases capable of causing patient harm have been determined; these times are 6'37" for 1.5 T and 8'51" for

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3 T. Beyond these times, the risk of harmful temperature levels, although minimal, may increase. The patient must be subject to constant monitoring and continuous communication throughout the MRI scan; in the event of abnormal temperature increase, burning sensation or pain, the examination must be immediately discontinued.

- The patient must be conscious and able to provide direct feedback to the MRI room staff in order to avoid unexpected heating which, although unlikely, cannot be excluded.
- In the event that the patient is unconscious or unable to provide feedback, Mikai indicates that the fixator should not be placed inside or within 30 cm of the scanner bore.
- Head and torso scans can be performed if the device is implanted in the legs, as long as they are kept 30 cm outside the bore of the MRI scanner.
- Patients with impaired thermoregulation, impaired ability to provide meaningful feedback and/or body temperature above 37°C should be scanned ONLY on the direct order of the attending physician and only if the scan mitigates a greater risk to the patient's integrity. This examination must be constantly and rigorously monitored and discontinued if an abnormal increase in global or local body temperature is noted.
- The MEP ClickIt system has not been tested for image artefacts and, as a result, the quality of the MRI image may be compromised if the area of interest of the image is located in exactly the same area as the implant.

IDENTIFICATION OF DEVICES

Each device is identified by a label placed on the primary or secondary packaging (cardboard box). The following symbols are present on the label with their explanation.

In the event of a serious accident, the manufacturer Mikai S.p.A. and the competent authority of the state in which the accident occurred must be informed.

The manufacturer keeps the summary of safety and clinical performance up to date when necessary, which is made available on the Eudamed portal at the following address: https://ec.europa.eu/tools/eudamed. To consult this document, select the section relating to devices, systems and procedural packages and carry out a search by filling in the "Reference number/catalogue" field.

With regard to disposal, it is essential to follow hospital protocols relating to contaminated materials and biological waste. All surgical instruments should be considered contaminated. Therefore, these instruments must be handled, collected and transported with the utmost care to minimise potential risks to patients, staff and all areas of the hospital.

	Name and full address of the manufacturer		Single use
REF	Code		Do not use if the packaging is damaged
LOT	Batch No.		Do not resterilise
	Expiry date	CE 1936	CE mark and identification number of the Notified Body
STERILE EO	Sterilised by Ethylene oxide	MD	Medical device
MR	MR CONDITIONAL (According to ASTM F2503)		Single sterile barrier with internal protection
UDI	Unique device identification	e-IFU	Read the instructions for use available at https://www.mikai.us/downloads/
	Store in a cool, dry place		

Note: This device may have the following non-harmonised symbols (abbreviations) in the description:

- ST: indicates the sterility status of the device;
- Ti: indicates that the device is made of titanium;
- HAP or HA: indicates the coating of the screw in hydroxyapatite;
- Fxx: the letter F followed by a number indicates the length of the main thread present in the device;
- Lxx: the letter L followed by a number indicates the main length of the device;
- xxPZ: preceded by a number, indicates in the description the number of devices in the package