Sistemi di fissazione esterna pluriuso MIKAI – Informazioni ed Avvertenze d'uso

CE 1936

BRIEF DESCRIPTION OF THE DEVICE

FEP – the FEP external fixation system is a modular component system composed by: the base elements; the clamps, arched connectors, screws, dynamization counter springs. These components, when assembled in their various formats, create a device suited to reconstruction and correction of bone segments in the human skeleton.

Materials

The construction materials for the various components are:
Aluminum Alloy 7012 UNI 9007 3T
Stainless Steel AISI 316 LVM ISO 5832-1
The pins are made of stainless steel AISI 316 LVM ISO 5832-1

The system hereby presented has been tested for MRI compatibility (see "SAFETY INFORMATION MRI – MR CONDITIONAL" section on the present document). Medical personnel must be informed of the composition material of the device and the related provided indications 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 control requirements in MRI.
Furthermore, the patient must also be informed by the hospital staff about the material used in the construction of the implanted device and the specific limitations / contraindications attached to it, as well as the related safety parameters indicated in the present document.

Indications

FEP

Traumatology: Fixation of open and/or closed fractures on long and/or short bones; fractures of the pelvis, pseudoarthrosis, pathological fractures and tumor resections: fractures involving joints (i.e. ankle, wrist, knee).
Orthopedics: pseudoarthrosis, axial correction of limbs, limb hypometria, complex deformities of limbs.

Contraindications

- any form of active infection
- any inflammation in the screw zone
- any mental or neuromuscular disorder
- sensitivity to the screws' material, both documented or suspected (see label)
- obesity, diabetes, vascular pathologies.

Precautions

Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process.
The patient should be informed that any heavy physical activity, involving excessive loading, impacts and stresses on the bone segment fixed with an external fixator or other synthesis system, may cause premature tearing or wear on the device. Any impacts loading the implant or affected limb or bone segment should be absolutely avoided.
The implant choice, correct positioning, surgical technique and instruments are critical factors in conditioning the success of the implant and post-op therapy.
Therefore:

- the working life of the device is strictly linked to biological and biomechanical factors; the correct choice of implant can minimize the risk of failure and this choice must be made considering the dimensions and form of bone segment and the presumed loading it will undergo;
- the patient must always be informed of the implant's limitations and risks it entails; excessive, uncontrolled loading, impacts, tampering and other factors can involve tearing or wearing of the device with consequent failure of the reconstruction and rehabilitation therapy;
- psychologically inhibited, obese or debilitated patients risk failure;
- any implant device requires specific instruments for implanting; the use of unsuitable instruments can damage the device and result in an incorrect implant;
- the device must be inspected for physical and functional integrity before proceeding with the implant;
- it is essential that all information, cautions, indications, contraindications and precautions are respected and that the patient is informed wherever necessary;
- methods and aids or alternative devices should always be readily available before proceeding with the implant.

Provisions for use

1. The use of external fixation devices presumes an in-depth knowledge of external fixation surgery.
2. If the surgeon is not informed on the techniques related to this type of device, it is advisable to consult the scientific and technical documentation on methodologies and devices in order to correctly assess possible risks. Post operatory mobilization on the implant as one of the possible risks must be adequately known and assessed before proceeding with this system. The manufacturer can supply ample documentation both printed and on file to inform and train surgeons on the characteristics of the devices, implant techniques, implant choices and risks/hazards.
3. For the correct use of the Mikai fixation systems abide by the following instructions:

- The implants must be sterile;
- Always use original accessories approved by the manufacturer;
- Implants must always be performed with instruments supplied by the manufacturer;
- Implants must follow adequate operating techniques in suitable conditions;
- When implanting, all the device's accessories must be loose or unlocked in order to position them correctly;
- On completing the implant stage, the surgeon must ensure that all the fixator's elements are fastened, locked and firmly fixed in place;
- In order to retain their lifespan, it is strongly recommended to avoid forcing the threaded elements into place;
- The wound must be thoroughly disinfected before, during and after implanting.

4. To maintain the device's mechanical and physical properties and retain its lifespan we recommend:

- During the implant period control the grip and tightening of the various threaded elements on at least a monthly basis and check that the device operates correctly
- Check, after removal, that each and every part of all components are intact and no surface cracks or oxidation can be seen;
- Make sure that new screws are used for each implant and disposed of on completion of the implant period; the same goes for the clamps that anchor the screws to the rods and the dynamization counter springs;
- Sterilize all parts of the fixator according to the recommended procedure before each implant;
- Store adequately the fixator so that its package cannot undergo damage or alterations;
- Never proceed with the implant if there is visible or assumed damage on any of the fixator's components;
- Comply with the assembly diagrams illustrated in the documentation supplied by the manufacturer.

Cautions

- Never, for any reason whatsoever, use implants with damaged or malfunctioning components; before beginning with the implant make sure that every component is in perfect working order.
- The grasping elements (screws) and the clamps are single-use and must never be reused.
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance.
- It is strongly recommended to use dedicated instruments during implant.
- Keep attention not to cut surgical gloves during the procedure while handling sharp instruments.

Undesirable effects

The following events may represent undesirable effects after an external fixator implant:

- Inflammation affecting the skin;
- Inflammation affecting muscle and bone tissue;
- Osteolysis with loss of grip between bone and screw;
- Instability of the implant caused by slackening of screws and clamps.

Therefore, it is highly recommended to:

- Adopt wound hygiene procedures with weekly controls to reduce the risk of superficial or in-depth infections;
- The effects of osteolysis may be compensated by tightening the screws;
- Periodically ascertain the grip of the tightening elements and screws to avoid instability arising in the implant.

Reuse

Reusable FEP devices can be used up to three (3) times, after which the device must be disposed of in accordance with internal hospital procedures.

Cleaning and disinfection

For the cleaning and disinfection of the reusable elements, perform the standard procedures valid in the medical facility. Do not use detergents or disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions (free halogen ions or sodium hydroxide).
If there is no internal cleaning and disinfection procedure, Mikai recommends washing and disinfection using the following parameters:
Cleaning by hand (immersion)
Equipment required:

- A tray (not a sink) or a container capable of holding a volume of detergent sufficient to completely immerse the element of the equipment to be cleaned;
- A cleaning solution. Mikai recommends immersion for 30 minutes at a temperature of 40 ° C in a 0.3% enzymatic detergent solution;
- A container to hold water for rinsing;
- A drying surface;
- A clean, non-sticky disposable absorbent cloth or mechanical drying device (drying booth or industrial hot air dryer);
- A brush and a jet washing device.

Procedure:

1. Check that the cleaning container is clean and dry.
2. Wearing personal protective equipment, fill the container with sufficient water / detergent solution.
3. With particular care immerse all the components in the solution to release the trapped air; It is important to ensure that the cleaning solution reaches all surfaces, including the surfaces of devices with holes or cavities or cannulated.
4. Brush, dry, shake, irrigate, jet wash or manually spray the element to detach and remove all visible dirt, taking care to perform the operation under the surface of the solution.
5. Remove the elements from the solution and let them drain.
6. Remove all residues with a brush under running water.
7. Immerse in sterile distilled water to remove any traces of tap water.
8. Remove the element from the rinse water and allow it to drip.
9. Paying attention, dry by hand with an absorbent cloth and then in the drying booth.
10. Fill in the required documentation.
11. Proceed with the disinfection procedure.

Disinfection procedure (ultrasound)
Equipment required:

- An ultrasonic cleaner with lid capable of containing a volume of liquid sufficient to completely cover the element of the equipment to be disinfected.
- A sufficient number of racks or trays on which to place the elements to be treated.
- A timer.
- A water / detergent solution compatible with the dilution and temperature recommended by the manufacturer.
- A clean, non-sticky disposable absorbent cloth or a mechanical drying device.

Procedure:

1. Check before use that the ultrasonic cleaner is clean and dry.
2. Wearing personal protective equipment, fill the liquid tank with a sufficient amount of water / disinfectant to ensure complete immersion of the elements. Mikai recommends immersion for 15 minutes at a temperature of 50 ° C in a 0.5% phenolic disinfectant solution (ultrasound frequency of 50/60 Hz).
3. Turn on the cleaner and wait for as long as necessary to degass the water.
4. Remove the cover and paying close attention immerse the element in the fluid checking that the air contained in it is allowed to flow out. Irrigate cannulated devices.
5. Place the cover and wait for the recommended period of time (15 minutes).
6. Turn off the machine, lift the lid, remove the element and let it drip before transferring it to the washing / rinsing container.
7. Rinse thoroughly with clean water, ensuring the irrigation of devices with openings, drain afterwards.
8. Paying attention, dry by hand with an absorbent cloth.
9. Fill in the documentation.
10. Proceed with sterilization.

Paying attention, dry by hand with an absorbent lint-free cloth and then in the drying cabin.
All instruments and components of the products must be visually inspected to check their cleanliness and exclude the presence of signs of deterioration in order to detect malfunctions (cracks or damage to the surface) and to check operation before sterilization. Particular attention should be paid to:

- Cannulated devices.
- Sharp edges: discard instruments that have lost their thread or are damaged.
- Instruments with hinges: check that the movement of the hinges is smooth and that there is no excessive "slack".
- The locking mechanisms must be checked for perfect functioning.
- Do not use a component or instrument where a fault or damage condition is noted or suspected.
- When the instruments are an integral part of an assembly, check the assembly with the various components.
- Lubricate as needed all parts, except for cams, bushes and ball joints with lubricating oil for medical applications.

Rev03_081122 The device is produced by Mikai S.p.A. For any information and communication about the device contact: Mikai S.p.A. - Via P. Gobetti 56r, 16145 Genoa, Italy. Tel: +39-010-30801, Fax: +39-010-3080211, E-Mail: mikai@mikai.it.

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Hospital management of the sterilization process

- PACKAGING FOR STERILIZATION: The instruments must be packed in order to maintain their sterility after the sterilization procedure and avoid damage to the instrument before use. Only appropriate medical grade packaging material should be used. The package must be of sufficient size to contain the instruments without causing these stresses on the seal closures.
- INSTRUMENT GROUPS: The instruments can be collected in MIKAI sterilization cassettes or in universal use sterilization cassettes. Sharp edges must be adequately protected and the recommended content or maximum weight specified by the manufacturer must not be exceeded.
- PRECAUTIONS: The devices can be sterilized assembled on condition that the joints, the locking nut of the central body and the locking screws of the clamp are left untightened. If there are tight joints, they can be damaged by thermal expansion during the sterilization procedure.
- STERILIZATION: Sterilize with steam in an autoclave, using a pre-vacuum cycle. MIKAI recommends the following cycle: Steam sterilization in an autoclave 134 ° C (270-275 ° F), with a minimum residence time of at least 10 minutes. The treated elements must be kept in a clean and safe place to avoid being damaged or tampered with.

Sterile

All the grasping elements (screws) and the clamps are supplied in the sterile state.
All reusable devices in their various configurations are supplied in a NON-STERILE state and sealed, after a cleaning process, in special anti-shock containers that facilitate storage.
Sterilization must be carried out for all NON-STERILE single-use or reusable devices, before implantation; the manufacturer recommends sterilizing the devices by saturated steam autoclave (according to UNI EN ISO 17664):

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 10 min
Temperature	134°C

SAFETY INFORMATION MRI – MR CONDITIONAL

The FEP fixation system devices are marked MR Conditional following the parameters set by the ASTM F2503 standard. In order to mark the devices, the system have been subjected to a risk analysis and the components have been subjected to non-clinical magnetic resonance imaging tests in an MRI environment according to the F2052, F2182 and F2213 ASTM standards. Both the risk analysis and the tests, performed at 1.5 and 3 Tesla, have shown that the devices of the FEP system can be considered as MR Conditionally compatible as long as what is reported below is followed.
The parameters, the systems used and the worst-case results in terms of heating are shown in the following table. The FEP system devices do not present significant risks of displacement, twisting, unwanted movement, or migration in 1.5 and 3 Tesla MR environments, provided the presented parameters are met.

System	FEP	
Nominal value of the static magnetic field	1.5 Tesla [63.6755 MHz]	3 Tesla [127.8 MHz]
Shielding	Active	Active
Maximum spatial field gradient	11 T/m	12 T/m
Coil type	Body coil	Body coil
Scan time for maximum in-vitro temperature variation	15'08"	15'38"
Worst case SAR	2.9 ± 0.36 W/kg	4.66 ± 0.41 W/kg
Maximum in-vitro temperature variation with device inside the bore	14.5 ± 0.5°C	11.2 ± 0.5°C
MR image artifact	The presence of the FEP system may generate artifacts on the obtained images	

A patient with implanted FEP devices can be scanned over the fixator area safely following the previously mentioned conditions. Failure to observe both these conditions and the following warnings and precautions may result in patient injury.

MRI enviroment warnings and precautions:

- The use of parameters other than those listed may cause serious harm to the patient.
- The use of different devices not marked "MR Conditional", even if they belong to any Mikai's system, may 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 FEP system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the FEP system allows to obtain multiple configurations, therefore worse heating conditions cannot be excluded.
- Do not use scan modes higher than SAR = 2 W/kg.
- In normal scan mode (SAR = 2 W/kg), temperatures should be approximately proportionally lower (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 above and below must be followed.
- The continuous times of safe scanning without the risk of localized increases in temperature capable of causing permanent damage to the patient have been determined, the times are equal to 6'37 "for 1.5 T and 8'51" for 3 T, above these times the risk of harmful temperatures, even if minimal, may increase. The patient must be subjected to constant monitoring and continuous communication during the magnetic resonance phase, in case of abnormal increase in temperature, burning sensation or pain, the examination must be immediately suspended.
- The patient must be conscious and able to provide direct feedback to the MRI room staff in order to avoid unexpected heating which, even if unlikely, cannot be ruled out.
- In case the patient is unconscious or unable to provide feedback, Mikai instructs to refrain from placing the fixator inside or within 30 cm of the scanner hole.
- Head and torso scans can be performed if the device is implanted in the legs, as long as the limb with the implanted fixator is held 30 cm out of the MRI scanner bore.
- The FEP system has not been tested for image artifacts and as a result, the MR image quality may be compromised if the image's area of interest is in exactly the same area as the implant.

Handling and storage of the devices:

There are no particular temperature and/or humidity restrictions associated with the storage and handling of the devices.
The supplied devices present a label indicating the contents of the package.
Do not use if the package has been opened or damaged.

	Name and full address of the manufacturer		See instructions for use
REF	Code		Single use only
LOT	Lot No.		Do not use if package is damaged
	Expiration date		Do not resterilize
STERILE EO	Sterilization mode ETO	CE 1936	CE marking and identification number of the Notified Body

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