External Fixation System for Single Use - Instructions for Use and Warnings CE 1936

EN

DESCRIPTION

Kit FEP for single use - The FEP external fixation sterile kits are composed by the base element, clamps and screws. The base element is composed by two rods for clamps insertion, the joint and the distraction-compression unit.

Kit Stylo for single use – The Stylo external fixation sterile kits are composed by the base element, clamps and screws. The base element is composed by a multiplanar joint and two cylindrical rods for clamps insertion which can be extended with lengtheners.

Kit MiniStylo for single use - The MiniStylo external fixation sterile kit is composed by the base element, two clamps and four screws. The base element is composed by a multiplanar joint, a distraction-compression unit and three cylindrical rods for clamps insertion.

Kit Smart for single use - The Smart external fixation kits are composed by the base element, two clamps and four screws. The Smart device is available in two different versions: a system for metacarpus and phalangeal lengthening and an articular system. The base element of the articular fixator is comprised of an articulated hinge and two cylindrical rods for clamps insertion. The lengthener base element is comprised of a millimeter-graduated rod with two cylindrical rods for the clamps sliding.

Kit MiniSmart for single use - The MiniSmart external fixation kit are composed by the base element and two clamps. The MiniSmart device is available in two different versions: with one screw clamp or with two screws clamp. MiniSmart structure is similar to Smart for lengthening System and is used in paediatric surgery.

PTA - The PTA external fixation kit is composed by the base element, two clamps and four screws. The base element is comprised of a tower for screw insertion, a distraction-compression unit and a rod for clamps insertion.

Blue Shark - The Blue Shark external fixation kit is composed by two blister packs, the first contains the fourth fixator elements (the two stirrups and two arched connectors), the other contains six screws and all the instrument used for the implant (two trocars, two cannulas guide, one scalpel, one scissor, one T-wrench for screws, one T-wrench for clamps, one flat wrench for screws and K-wire.

MATERIALS

The construction materials for the various components are:
Alluminium Alloy 7012 UNI 9007 3T
Stainless Steel AISI 316 LVM ISO 5832-1
Nylon (50% glass fibre) GV5 H (Only for the Blue Shark)
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 FOR USE

KIT FEP for single-use

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

KIT Stylo for single-use

Traumatology: Fixation of fractures in bones adjacent or in proximity to wrist joint, closed and/or open, pseudoarthrosis, pathological fractures and tumoural resections.
Orthopaedics: pseudoarthrosis, deformities.

KIT MiniStylo for single-use

Traumatology: Fixation of fractures in bones adjacent or in proximity to hand joint, closed and/or open, pseudoarthrosis, pathological fractures and tumoural resections.
Orthopaedics: pseudoarthrosis, metacarpus and phalangeal deformities.

KIT Smart for single-use

Traumatology: Fixation of fractures in bones adjacent or in proximity to hand joints, closed and/or open, pseudoarthrosis, pathological fractures and tumoural resections.
Orthopaedics: pseudoarthrosis, phalangeal articular correction, phalangeal lengthening.

KIT MiniSmart for single-use

Traumatology: Fixation of fractures in bones adjacent or in proximity to hand joints, closed and/or open, pseudoarthrosis, pathological fractures and tumoural resections in paediatric surgery.
Orthopaedics: pseudoarthrosis, phalangeal articular correction, phalangeal lengthening in paediatric surgery.

PTA

Orthopedics: Correction of tibial varus and femoral valgus.

BLUE SHARK

Traumatology: stabilization of patient with pelvic injury; definitive for B type fractures (unstable only horizontally), temporary in B type fractures (horizontal and vertical unstableness).

CONTRAINDICATION

- Any inflammation in the screw zone
- Patients with previous infections
- any form of active infection
- Sensitivity to the materials constituting the documented or suspected grip elements, it is recommended to perform tests before proceeding with the fixer implantation
- Patients not willing or unable to follow postoperative care instructions, due to particular mental or physiological conditions
- any mental or neuromuscular disorder
- Patients with neuromuscular deficit or other conditions that may have consequences on the healing process
- Senility, mental illness or alcoholism (conditions that can induce the patient not to take into account some limitations and precautions necessary in the use of the implant, giving rise to subsidence or other complications).
- Patients considered heavy smokers
- Patients with compromised vascularity
- Cancer patients in the area of the fracture
- Amount of insufficient bone tissue;
- Quality of insufficient bone tissue;

- **PTA** - Deformity of knee varism above 18 °, arthritis greater than stage 2 of Ahlback, presence of autoimmune pathology such as rheumatoid arthritis or chondrocalcinosis, severe osteoporosis or obesity, diabetes, vasculopathies.

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 undue tearing or wear on the device. Any impacts loading the implant or affected limb or bone segment should be absolutely avoided. The 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 in relation to 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 cause damage to the device and an incorrect implant;
- The device must be controlled for physical and functional integrity before proceeding with the implant;
- It is essential that all information, cautions, indications and contraindications, precautions are respected and the patient is informed wherever necessary;
- Methods and aids or alternative devices should always be readily available before proceeding with the implant.
- Check the cleaning of the screws to avoid infections.

- **PTA** - During the application of the device, the position of the fixator and the application of proximal screws are of utmost importance to avoid changes in the tibial slope.
- The devices are disposable and should NEVER be reused. The reuse of the devices may cause a re-infection or cross infection or compromise the functional performance of the device.

PROVISIONS FOR USE

1. The use of external fixation devices presumes an in-depth knowledge of external fixation surgery.
2. If the surgeon should not b 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 potentials, implant techniques, implant choice and risks or hazards.
3. For the correct use of the Mikai fixation systems comply with the following provisions:
- The implants must be sterile;
- Always use genuine 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 adjustments must be free or unlocked;
- On completing the implant stage, the surgeon must ensure that all the fixator's elements are locked and firmly fixed in place;
- In order to retain their lifespan we strongly recommend against 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;
- Store 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 for **single use** and must never be reused.
- The **FEP for single-use, Stylo for single-use, MiniStylo for single-use, Smart for single-use, MiniSmart for single-use, PTA and Blue Shark** fixators are single use and should 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 while handling sharp instruments.
- Keep attention not to cut surgical gloves during the procedure.
- For components delivered in a sterile package (see the appropriate label on the package), make sure that the sterilization expiration date has not been reached.
- For the components delivered in a sterile package (see the appropriate label on the package), make sure that the casing is free of damage and that the color of the word "GAS" of the color change has become green;

UNDESIDERABLE EFFECTS

The following events may represent undesiderable effects after an external fixator implant:
- Inflammation affecting the skin;
- Inflammation affecting muscle and bone tissue;
- Osteolysis with loss of g rip between bone and screw;
- Instability of the implant caused by slackening of screws and clamps.
- Infection in screw insertion sites
- Consolidation and / or non-union delays of the osteotomy site
- DVT (deep venous thrombosis)
- **PTA** - Stiffness of the knee
- **PTA** - Fracture of the lateral cortex during the distraction phase

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.

STERILIZATION

All of the grasping elements (screws) and clamps are supplied sterile.
The **FEP for single-use, Stylo for single-use, MiniStylo for single-use, Smart for single-use, MiniSmart for single-use, PTA and Blue Shark** fixators are supplied in a sterile kit complete with clamps and screws.
All the grasping elements (screws) and the clamps are supplied in the sterile state.
Sterilization must be carried out for all NON-STERILE devices (instruments) 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	≥ 5 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	7.4 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
	Code		Single use only
	Lot No.		Do not use if package is damaged
	Expiration date		Do not resterilize
	Sterilization mode ETO		CE marking and identification number of the Notified Body

Note: The following device may contain the following non-harmonized 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 hydroxyapatite coating of the screw;
- d.: in some cases, indicates the diameter of the device in the description;
- Txx: the letter T followed by a number indicates the length of the main thread in the device;
- Lxx: the letter L followed by a number indicates the main length of the device;
- xxPZ: preceded by a number, indicates the number of devices in the package in the description.