ClickIt ER – Emergency Fixator – ClickIt Pelvis kit - Instructions for Use and Warnings

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DESCRIPTION

The Clickit ER system is an emergency fixator intended for temporary stabilization.

It allows to perform the general and district-specific Damage Control Orthopedics approach in a safe and secure manner, delivering a substantial stability

It is considerably light, easy to use, fast, versatile and remarkably stable. It has an advantage with respect to the competitors in that it has available an universal clamp that may contain all the sizes of screws present on the system, it contains as well radiotransparent carbonium rods.

It allows for a multiplanar stabilization, free-positioning of the pins and it consents a comprehensive respect of the soft tissues.

The devices of the Clickit ER system are single use.

The clickit Pelvis kit has been prepared with the required elements for a successful facture stabilization in the pelvic area.

The xxxxxxxST***XX*** custom kits may be supplied with a different device composition with respect to the specific target market, this composition however respects the steps of this surgical technique and includes one only Mikai compatible medical devices.

The appropriate instruments (instruments set) provided by the manufacturer must be used with the implant. In case of non-sterile reusable instruments available, wash and sterilize them before each procedure.

The instruments supplied in a sterile kit are SINGLE-USE (disposable) and must not be reused or re-sterilized.

MATERIALS

The components of the fixator system are made of several materials including: aluminum, stainless steel, and carbon fiber (bars). Screws are made of stainless steel AISI 316 LVM ISO 5832-1 and Titanium alloy Ti6Al4V ELI ISO-5232-3.

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

External fixation system for the stabilization of open and/or unstable fractures where the soft tissues preclude the use of other treatment methods such as intramedullary rods or plating.

The ClickIt ER device is indicated for:

- Fixation of fractures of traumatic and/or pathologic origin associated to the following bone segments: hand, radius/ulna, humerus, femur, tibia, hip, elbow, foot, knee and ankle;
- In case of extremity deformity and axial corrections associated to the tibia and femur bones;
- For the stabilization of hip fractures;
- As instrument for the intraoperatory temporary stabilization of hand, radius/ulna, humerus, femur, tibia, hip, elbow, foot, knee and ankle bones.

The contents of the kit hereby presented have been optimized for the treatment of fractures over the Pelvis district

CONTRAINDICATION

Since external fixators are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use.

Among the conditions that have an increased risk of fixator yielding there are:

- Active or suspected infection;
- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device;
- Patient physiologically or psychologically inadequate;
- Compromised vascularity;
- Inadequate skin status and/or unsuitable soft tissue dressing;
- Sensitivity to materials in the screws, both documented or suspected (nickel allergy);
- Fever and leukocytes;
- Obesity, diabetes, vascular disease;
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing;
- Any neuromuscular deficit, which places an unusually heavy load on the device during the healing period.

SURGICAL TECHNIQUE

Hereby are indicated the specific installation phases (implatation) for the ER system's clickit Pelvis kit.

A. PATIENT POSITIONING

The patient is placed in a supine position on the flat radiolucent surgical table. The placement of a pillow under the knees, which should cause a slight flexion of the hips and a consequent reduction of the pelvic nutation, can facilitate the implant of the screws in an anteroinferior position (see below).

B. PLACEMENT OF PIN ELEMENTS

The pin elements consist of self-drilling and self-tapping screws, Ø 6 mm, length 250 mm and threaded for 55 mm.

The screws can be implanted in 3 configurations:

- Anteriorsuperior, with 2 or 3 screws positioned on the iliac crest
- Anteroinferior, with 2 supraacetabular screws
- Combined, with one supraacetabular screw and one screw on the iliac crest.

C. ANTEROSUPERIOR POSITION IMPLANT

1. The anterior superior iliac spine (ASIS) and the iliac crest are identified by touch.
2. At a distance of about 4 cm from the ASIS, two Kirchner wires are inserted at a depth of circa 4-5 cm laterally and medially to the iliac crest so that their tips can slide inside the flat structure of the bone. The outer portion of the more medial wire indicates the implant direction of the screw.
3. Perform an incision of about 1.5 cm at the implant area.
4. The cannula with the trocar is brought into contact with the bone surface: the trocar is removed.
5. The screw, introduced through the cannula in contact with the iliac crest, is screwed with a drill until the thread is no longer visible.
6. Repeat the steps 2 to 5 to implant the posterior screws.
7. Screw positioning is controlled by C-arm.

D. ANTEROINFERIOR POSITION IMPLANT

1. The ASIS is identified.
2. The gap between the sartorius and tensor muscles of the fascia lata is identified by touch at about 3 cm distal to the SIAS; this identification is facilitated by the intrarotation of the limb.
3. Perform an incision of approximately 1.5 cm in line with the identified gap.
4. The fascia is perforated with the blunt scissors: the bone surface is then identified at the anterior inferior iliac spine (AIIS).
5. The cannula with the trocar is brought into contact with the bone surface: the trocar is removed.
6. The screw is brought into contact with the bone through the cannula; the position is controlled by C-arm before implanting the screw.
7. Implant the screw with a drill having a caudocranial inclination of about 10° (the operator's hand is brought towards the feet by about 10 ° with respect to a plane perpendicular to the operating table); the correct position is controlled via C-arm.
8. A second incision is performed about 3 cm distal to the first incision; then steps 4 to 6 are repeated.
9. The screw is positioned through the cannula mounted on the most suitable clamp, which will act as a directional guide.
10. The screw is screwed with a drill until the thread is no longer visible the correct position is controlled via C-arm.

E. COMBINED POSITION IMPLANT

1. The screw on the iliac crest is implanted as described in paragraphs C 1 to 6.
2. The screw is then implanted in the supra-acetabular region as described in paragraphs D 1 to 7.

F. FIXATOR MOUNTING

1. The clamps of the fixator are positioned distant from the skin to avoid decubitus and allow the flexion of the hips; fix the rods to the screws by tightening the clamps.
2. The fixator rods are connected via 4 clamps to the small (distal) and large (proximal) arch supports through the Ø12mm housings of said clamps.
3. After the reduction maneuvers have been carried out, the locking nuts are partially tightened; after the radioscopic assessment of the reduction has taken place, they are fully tightened.
4. The surgeon must check that all locking elements are tightened.

G. CHANGES IN THE SEMIARCHS SHAPE

To carry out abdominal or urological surgical maneuvers it may be necessary to modify the structure of the semi-arches. To avoid loss of reduction, proceed to the assembly of a third semi-arch in an intermediate position; the upper and lower semi-arches may then be moved. At the end of the procedure the third semi-arch is removed

ADVERSE EVENTS

The following list includes potential complications typically associated with external fixation devices.

- Prolonged healing;
- Distraction of the fracture site;
- Screw insertion can result in damage to nerves and vessels;
- Infection, painful, swollen or inflamed implant site;
- Edema;
- Loosening or dislocation of the implant requiring revision surgery;
- Device fracture;
- Septic arthritis;
- Delay of consolidation or pseudoarthrosis;
- Loss of range of motion, joint contracture, joint dislocation and subluxation;
- Compartment Syndrome;
- Replacement of apparatus or components resulting in reoperation;
- Pin insertion leading to tissue necrosis;
- External components leading to skin pressure;
- Allergic reaction;
- Muscle tendon impalement and excessive operative bleeding;
- Failure satisfactory bone regeneration;
- Loss of bone mass;
- Bone fracture of the regenerated bone after device removal;
- Discrepancy in limb length;
- Excessive motion at the fracture site to improper placement;
- Heat build-up and bone necrosis;
- Ankle stiffness due to multiple transfixion screws used in tibial fractures;
- Knee stiffness;
- Bone deformities;
- Thrombosis, arteriovenous fistulas;
- Osteomyelitis.

RECOMMENDATIONS AND PRECAUTIONS

Pre - Surgery

- The use of external fixation devices presumes an in-depth knowledge of external fixation surgery;
- 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;
- If foreign body sensitivity is suspected, testing must be performed to rule out this possibility prior to implant;
- The patient must be informed on how the device is used and potential complications associated with external fixation devices;
- The patient must always be informed of the implant's limitations and the risks it entails; excessive, uncontrolled loading, impacts, tampering and other factors can involve breakdown or wear of the device with subsequent failure of the reconstruction and rehabilitation therapy;
- It is important to correctly select the device components. The correct choice of implant can minimize the risk of failure and this choice must be made in relation to the dimension and form of a bone segment and the presumed load it will withstand;
- Preoperative frame assembly is recommended to decrease OR time and to ensure that components are available as needed;
- Always use accessories approved by the manufacturer and implants must always be performed with instruments supplied by the manufacturer;
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance;
- The device must be verified for physical and functional integrity before proceeding with the implant;
- Verify that the implants are sterile before proceeding with the implant;
- Store the fixator so that the package cannot undergo damage or alterations and never proceed with the implant if there is visible or presumed damage of any of the fixator's components.

Intraoperative

- Intra-operative fracture or instrument breakage may occur;
- It is strongly recommended to use dedicated instruments during implant and to avoid the use of instruments considered by the surgeon to be worn-out or malfunctioning, in case the instruments are found to be worn-out or malfunctioning they must be shipped back to Mikai that will provide equivalent functioning instruments.
- 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" present on the sterilization mark has become green;
- Carefully place screws to avoid damage to nerves, muscles, tendons, and vessels;
- Slowly drill through the bone to avoid heat necrosis of surrounding tissues and bone;
- The device must be implanted in a sterile environment;
- Careful not to cut surgical gloves during the procedure;
- Before applying the fixator, make sure that the clamps are loose;
- The clamps must not be disassembled;
- Any device implanted in the patient, such as bone screws, wires and in general any device marked as "single use": MUST NOT BE REUSED;
- Select the length of the bone screws and the thread according to the size of the bone and soft tissue. Avoid excessive penetration of the second cortex, which could cause damage to the soft tissues;
- The maximum screw thread diameter should not exceed one third of the bone diameter (for example, use 6 mm bone screws for bones with a diameter greater than 20 mm);
- Do not use electric devices to screw the self-drilling screws with a diameter of 5.00mm or more; screw them by hand or using a manual drill. Self-drilling screws with a smaller diameter thread can be inserted with a low speed screwdriver. In the case of bones with particularly thick and hard cortical we recommend the use of a perforator to perform a pre-perforation before introducing the screw;
- It is necessary to apply the fixator at a certain distance from the skin in order to allow post-operative swelling and cleaning, without forgetting that the stability of the system depends on the distance bone-fixator. In case the fixator is positioned at

more than 4cm from the bone, the surgeon will decide the number of bars and bone screws necessary to obtain a correct assembly stability;
- The components are not compatible with all Mikai Fixation systems. For more information on the compatibility of the various components it is recommended to consult the specific operating techniques;
- It may be necessary to use additional instrumentation for application and removal, such as a cutter, wire bending pliers and power drill;
- Check the integrity of the screws and assembly at regular intervals. To avoid any risk of injury, it is recommended to protect (ex: with caps) the ends of the threaded threads, bone screws that have been cut with the cutter;

Post-Surgery
- Instruct the patient on the daily management of the skin near the screws to the reduce risk of infection;
- The patient must be instructed that the system assembly will not be as strong as healthy bone;
- All patients must be informed about the use and maintenance of external fixation mounting and the care of screw mounting sites;
- Patients must be instructed to report any abnormal or unforeseen effects to the surgeon;
- Proper fixation and secure assembly of components are essential. Parts should be securely fastened with the appropriate instruments;
- Evaluate the gap of the fracture during healing. Changes to the construct must only be implemented if necessary. Regularly check the integrity of the device and the tightness of the screws;
- Weight bearing should be avoided for the first three weeks postoperatively. After this time, touch down weight bearing is acceptable when there is bone to bone apposition resulting in inherent stability to the limb. In the absence of such stability, all weight bearing should be avoided until bridging callous is visible radiographically;
- 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.
- Do not use system components with products from other manufacturers unless otherwise indicated, as combined use is not covered by the required validation;

UNDESIDERABLE EFFECTS
- Damage to nerves or blood vessels, resulting from the insertion of wires and screws;
- Superficial or deep bone infection, osteomyelitis or septic arthritis along the passage of the screw and / or wires, including the chronic drainage of the seats for insertion of the bone screws after removal of the device;
- Edema or tumefaction, possible compartment syndrome;
- Joint contracture, subluxation, dislocation or loss of range of motion;
- Failure of bone regeneration, development of nonunion or pseudoarthrosis;
- Fractures of the regenerated bone or caused by the holes of the bone screws, following the removal of the device;
- Loosening or breakdown of the installations;
- Bone damage due to the choice of inadequate implants;
- Bone deformity;
- Persistence or reappearance of the initial condition that required treatment;
- Repetition of the intervention to replace a component or the entire assembly configuration;
- Rejection of installations or components of assembly;
- Tissue necrosis after implant insertion;
- Pressure on the epidermis caused by external components in case of inadequate distance;
- Discrepancy in the length of the limbs;
- Excessive surgical bleeding;
- Intrinsic risks associated with anesthesia;
- Uncontrollable Pain;
- Bone sequestration, derived from excessive speed of the perforation of the cortical bone with heat generation and bone necrosis;
- Vascular disorders, including thrombophlebitis, pulmonary embolus, wound hematoma, avascular necrosis.

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 have positive outcomes. Further complications may develop at any time due to improper use, medical reasons or device failures resulting in a need for a new surgical procedure to remove or replace the device. The pre-surgical and surgical procedures, which include the knowledge of surgical techniques, the correct choice and positioning of the devices, are important factors for the success of the use of Mikai devices by the surgeon. Proper selection of the patient, his ability to follow the doctor's instructions and follow the prescribed treatment regimen greatly influence the results. It is important to subject the patient to a careful examination and to choose the optimal therapy in relation to physical and / or mental requirements and / or limitations. If a candidate for the intervention shows contraindications or predisposition to the same, it is recommended NOT TO USE the CLICKIT ER system. The CLICKIT ER instruments set has not been tested for maximum number of cleaning cycles, in case of presence of oxidation, superficial defects that might compromise the functionality of the instruments or disappearance of the marking, the instrument set must be sent back to Mikai in order to proceed with its correspondent maintenance/substitution.

STERILIZATION
All the ClickIt ER components are supplied **STERILE and SINGLE USE** and are EtO sterilized. If the device packaging appears to be damaged in any manner, it is recommended not to use the device. The device cannot be re-sterilized.
All NON-STERILE products (instruments) can be sterilized in an autoclave (UNI EN ISO 17665).

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 min
Temperature	134°C

SINGLE USE
The implants are strictly single use. The reuse of the devices may lead to the fixator failure due to the alteration of the functional mechanical properties.
The instruments can be reused if corresponding precautions are observed and if they are undamaged and uncontaminated and following appropriate resterilization as indicated above.
No liability is assumed by the manufacturer in case of non-observance.
Mikai recommends if products are exposed to pathogens that are difficult to identify such as variations of Creutzfeldt-Jakob's disease (confirmed or suspected pathogen), they must be discarded.

SAFETY INFORMATION MRI – MR CONDITIONAL

The ClickIt ER 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 ClickIt ER 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 ClickIt ER 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	ClickIt ER	
Nominal value of the static magnetic field	1.5 Tesla [63.85 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	16'05"	14'46"
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 ClickIt ER system may generate artifacts on the obtained images	

A patient with implanted ClickIt ER 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 ClickIt ER system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the ClickIt ER 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 2'57 "for 1.5 T and 3'36" 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.
- Patients with impaired thermoregulation, impaired ability to provide meaningful feedback and/or body temperature above 37 °C should ONLY be scanned on direct orders from the responsible physician and only if the scan mitigates a greater risk to the patient's integrity. This examination must be constantly and strictly monitored and suspended if an abnormal increase in global or local body temperature is noticed.
- The ClickIt ER 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.

DEVICE IDENTIFICATION
The device external pouch and packaging box is identified by labels listing the contents, product code, lot number, expiration date and materials composition. Also listed on the label are symbols (single use, expiration date, warnings, lot number) whose meanings are indicated below.

	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

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;
- 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.