ClickIt ER – Emergency Fixator - Instructions for Use and Warnings

CE 1936

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

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 a 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 screws and it consents a comprehensive respect of the soft tissues.
The devices of the Clickit ER system are single use.
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 as indicated in the dedicated instructions for use.
The ClickIt ER system is addressed to expert orthopaedic surgeons with experience in external fixation.
The ClickIt ER system is compatible with Mikai's ClickIt CF and FEP systems, for further information contact the manufacturer.

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 5832-11 and Titanium alloy Ti6Al4V ELI ISO-5232-3 and are further discussed in the ClickIt ER Sterile System IFU.
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.

INTENDED USE

External fixation system for stabilization of open and/or unstable fractures and where soft tissue precludes the use of other treatment methods such as intramedullary nailing or plates. Bone stabilization in cases of trauma and reconstructive procedures, on the adult patient.

INDICATIONS FOR USE

Fractures and/or dislocations of traumatic and/or pathological origin which may occur in the following anatomical areas or joints:
- Hand/Wrist;
- Radio/Ulna;
- Humerus;
- Femur;
- Tibia;
- Pelvis;
- Elbow;
- Foot;
- Knee;
- Ankle.

IMPORTANT: Check the "specific devices" section for further indications and contraindications of some specific ClickIt ER devices.

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;
- Incorrectly treated skin injury/opening and/or inadequate soft tissues 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.

TIME OF USE AND IMPLANT REMOVAL

The ClickIt ER fixator can remain implanted from 30 to 180 days, the maximum time in which the intended indications for use are expected to be achieved, or less than 30 days in the case of intraoperative stabilization. To proceed with the implant removal, fist the clamps must be loosen, after which they must be removed together with the rods and external accessories and, lastly, the gripping elements such as screws and wires must be unscrewed and removed using the appropriate instruments of the ClickIt ER system.

SPECIFIC DEVICES

Some devices of the ClickIt ER system have been developed for a specific use, their correct functioning is linked to complete compliance with the following indications:
- Joint 5006538: device developed for use on the upper limbs, specifically for the treatment of fractures and pathologies involving the elbow, the joint presents the possibility of slight micrometric corrections in compression and distraction.
- Arches 5006542S/L: adjustable arches developed for the treatment of fractures and pathologies involving the pelvis.
- Carbon fiber rods Ø6mm: minor diameter rods used for the upper limbs and foot, not suitable for treating fractures and pathologies of the tibia and femur.

The above statements must always be combined with the indications for use and general contraindications of the ClickIt ER system.

BASE SURGICAL TECHNIQUE

Hereby are indicated the installation phases (implatation) of a fixation system over long bones.
1. Effectuate a smal incision over the insertion zone of the screws. Using a small periosteal elevator unstick the tissues until the bone is reached, taking care when elevating the periosteum in order to preserve as much as possible the soft tissues during the use of the drill and the insertion of the screws.
2. The preboring is optional (but advised in cortical bone) as Mikai's screws are self-drilling and self-tapping.
3. Using the drill and the sleeve determine the length of the thread to be used; remove the sleeve and insert the screw until the second cortex is reached.
4. A stable structure is obtained inserting four screws at the maximum possible distance between themselves over the length of the bone. The correct insertion must consider a screw over each stump of the fracture at the maximum obtainable distance of the rim.
5. Insert two additional screws as close as possible over both sides of the fracture.
6. Use the rod/screw clamps to fix the screws to the rods and assemble the rod of the appropriate length.
7. If the fracture reduction is satisfactory, the broad possibility of settings given by the clamps allows the use of a single connecting rod. Once the clamps are fastened the reduction is well kept.
8. If the reduction is hard to keep, the pair of distal and proximal screws can be linked with shorter rods. Using both rods as reduction instruments the fracture can be manipulated in order to obtain reduction and stability. A rod is then connected with the dedicated clamps to the two rods mentioned beforehand in order to join both bone segments.
9. After the assembly and reduction is complete, fasten the central bolt in order to lock all the elements and provide a safe and steady construct.

BASE SURGICAL TECHNIQUE FOR CLICKIT ELBOW KIT

Hereby are indicated the specific installation phases (implatation) for the ER system's clickit elbow kit.
The device is preset to be implanted over the right arm; it is possible however to set it for the left arm following the next steps:
- Using the 5mm hexagonal screwdriver disengage the locking screw of the central fixed body (the part connected to the humeral rod of the device), this in order to loose the central articulated joint.
- Reconnect the articulated joint according to the direction of use as indicated by the marking (R or L) present over the lateral flat surfaces of the central fixed body, the marking corresponding to the limb to be treated (R-Right, L-Left) must remain exposed laterally to the patient.
- Loose the locking screw of the stem of the ulnar rod and rotate said stem until it reaches the position indicated by the marking (R or L).
- Fasten the screw of the stem.
- Stabilize the articulated joint and the slot in neutral position.

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;
- Screw insertion leading to tissue necrosis;
- External components leading to skin pressure;
- Allergic reaction;
- Muscle tendon impalement and excessive operative bleeding;
- Failure of 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 malformation;
- 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 material sensitivity is suspected, do not use the device;
- 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; 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;
- The dedicated accessories must always be used and approved by the manufacturer and must always be installed with the instruments supplied by the manufacturer;
- Always use accessories approved by the manufacturer and implants must always be performed with instruments supplied by the manufacturer;
- 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 have being properly sterilized 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
- Use dedicated instruments during implant and to avoid the use of instruments 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 expiration date has not been reached;
- 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;
- Before applying the fixator, make sure that the clamps are loose;
- The clamps must not be disassembled;
- Any device 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;
- 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;

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- 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;
- At the end of the implant phase, the surgeon must ensure that all the elements of the fixator are fastened and blocked
- Carefully position the bone screws/k-wires to avoid joint surface damage;

Post-Surgery
- 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;
- 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;
- There are 4 detachable labels on the sterile packaging of the device which show the traceability data and can be attached to the patient's record.
- Removal of the device: the final decision about the removal of the device is up to the surgeon

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 malformation;
- 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.

CLEANING AND DISINFECTION

The non sterile devices must be cleaned, disinfected and sterilized before and after each use.
The cleaning and disinfection of Mikai's devices must be carried out by hand and with an ultrasonic washing machine, always wearing personal protective equipment; the parameters for each methodology are shown below:

	Manual cleaning	Ultrasonic cleaning
Active component	Enzymatic disinfectant - 0.3%	Phenol - 0.5%

Manual cleaning:
1. Fill a tank (tray capable of containing enough detergent to immerse the equipment to be washed) with a 0.3% enzymatic detergent solution at 40 ° C. DO NOT USE detergents with fluoride, chloride, bromide, iodide or hydroxyl ions.
2. Immerse the components to be washed taking care to release all the trapped air, leave the components immersed for 60 minutes in the solution.
3. Brush, shake, irrigate, jet wash or spray the elements to loosen and remove all visible dirt, perform all operations below the surface of the solution.
4. Remove the elements from the solution, drain and remove the residues with a brush under running water.
5. Immerse in sterile distilled water to remove any traces of running water.
6. Drain and hand dry with a clean, lint-free, disposable absorbent cloth, then dry in the drying cabin.
7. Fill in the required documentation and proceed with disinfection.

Ultrasonic disinfection:
1. Fill the tank of the ultrasonic cleaning machine to a level sufficient to ensure complete immersion of the elements, use a 0.5% phenolic disinfectant solution at an ultrasonic frequency of 50/60 Hz. DO NOT USE detergents with ions fluoride, chloride, bromide, iodide or hydroxyl.
2. Turn on the machine and wait all the time necessary to degas the water. Then remove the lid and immerse the element in the fluid, checking that the air contained in it is allowed to flow out. Flush cannulated devices. Put the lid back on and wait for the recommended amount of time (15 minutes).
3. Switch off the machine, remove the components and let them drip before transferring them to the wash / rinse container.
4. Rinse thoroughly with clean water, ensuring the irrigation of devices with openings and allow to drain, dry by hand with a clean, disposable non-lint-free absorbent cloth.
5. Fill in the required documentation and proceed with sterilization.

STERILIZATION

All the ClickIt ER components are supplied **SINGLE USE**. If the device packaging appears to be damaged in any manner, it is recommended not to use the device.
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 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.

- 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.

IMPORTANT: The codes 5000610, 5000611 and 5000612 (threaded threads Ø1.8, 2.5 and 3mm) are not covered by these conditions and, consequently, are not considered MR Conditional, always check the symbol on the label and contact Mikai directly for further information clarifications.

DEVICE IDENTIFICATION

Each device is identified through a label placed over the primary and secondary packaging (cardboard box). Over the label are present the symbols presented here afterwards with their own respective meaning.

In case of an important incident, it is necessary to communicate it to the manufacturer Mikai S.p.a and to the relevant authority of the state on which the incident has happened.

The summary relating to safety and clinical performance is updated by the manufacturer where necessary and made available on the EUDAMED database.

As far as disposal is concerned, it is essential to follow hospital protocols regarding contaminated materials and biological waste. All surgical instruments used should be considered contaminated. Therefore, these instruments must be handled, collected and transported with rigorous care to minimize potential risks to patients, staff and all areas of the hospital.

	Name and full address of the manufacturer		Single use only
	Code		Do not use if package is damaged
	Lot No.		Non sterile
	MR CONDITIONAL (ASTM F2503)		CE marking
	Keep in a cool, dry place		Medical device
	Unique device identifier		See instructions for use available at https://www.mikai.us/downloads/

Note: The following device may contain the following non-harmonized symbols (abbreviations) in the description:

- 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;
- xxPCS: preceded by a number, indicates the number of devices in the package in the description.