ClickIt SHOULDER - External Shoulder Fixation System - Instructions for Use and Warnings

CE 1936

EN

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

DESCRIPTION
The CLICK IT ER SHOULDER kit, part of the ClickIt ER system, is an emergency external fixator for temporary stabilization, it is designed to be modular in its components and used as an adjunct to the Mikai anchoring devices (screws, wires, etc.). The configuration of the structure is guaranteed by the modularity of the system.
The components of the CLICK IT ER SHOULDER system are not intended to replace a normal and healthy bone or to withstand the stresses of a complete load, particularly in the case of unstable fractures or in the presence of nonunion, delays in consolidation or incomplete healing. It is recommended to integrate the treatment with the use of external support.
The system consists of various modules, applicable in various anatomic sites of the upper limb. When properly used, the CLICK IT ER SHOULDER system maintains the function of the extremity, minimizes the surgical trauma of the anatomical structures and preserves the blood circulation and the osteogenic potential of the tissues.
The 5000630ST**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.
All Mikai devices are intended for professional use only. Surgeons who supervise the use of Mikai devices must be fully aware of orthopedic procedures, as well as have an adequate understanding of the Mikai modular system philosophy.
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 CLICK IT ER SHOULDER system consists of elements in stainless steel, aluminum alloy, titanium alloy and carbon fibers. The components that come into contact with the patient are the screws (bone screws), threaded wires, drill bits, and guides used when inserting the screws and / or wires. These components are made of surgical stainless steel. Some Mikai bone screws (screws) can be supplied with the threaded section coated with hydroxyapatite (HA).
QUALITATIVE AND QUANTITATIVE INFORMATION
The implantable alloys used by Mikai are:
- Titanium alloy Gr5 Ti6Al4V-ELI (ISO 5832-3)
- Stainless steel AISI316LVM (ISO 5832-1)

The ISO 5832-3 standard identifies the following limits for the Titanium alloy Gr5 Ti6Al4V-ELI:

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).

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

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

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;
- Elbow;
- Foot;

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/LST: 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.

KIT CLICKIT ER AND CUSTOM KIT
The ClickIt ER system provides kits containing different devices in predefined quantities for the optimal treatment of certain anatomical areas.
The devices contained in the kits, the quantities and the sizes were determined based on the material used most frequently for the treatment of pathologies linked to each anatomical district.
Furthermore, there are also custom kits (xxxxxxxST**X** / xxxxxxxST**XX**), which can be supplied with compositions different from the starting kits, optimized for the reference markets/customers. This composition respects, however, the steps of the below mentioned surgical technique and includes exclusively Mikai compatible medical devices.

SURGICAL TECHNIQUE
This section contains the essential steps of the surgical technique, for further information consult the specific documentation.
Positioning of the patient in the operating room
For the positioning of the patient two different ways can be followed: Closed-sky synthesis and Open-air synthesis. In order to determine the conformation, position and size of the various bone fragments, the x-rays to be performed are: AP Projection, Trans-thoracic or outlet view and when possible: Axillary projection and CT scan of the humeral head.
Evaluate the external distal metaphyseal integrity (2/3 of the outer bone circumference), which represents the entry point of the osteosynthesis means.

Fracture reduction
The reduction techniques must be tested before preparing the surgical field and must be performed according to standard procedures. To perform radiological verification, the image intensifier must be positioned at the level of the patient's head on the same side of the injured limb so that the C-shaped arch can move freely. NOTE: if the reduction is not satisfactory or cannot be performed with external maneuvers, it is necessary to perform open surgery. In this case, it will be necessary to change the positioning of the patient from supine to semi-sitting.

Preparation of the surgical field
The area of the acromioclavicular joint must be visible: this is important for percutaneous insertion of the threads. The consequence of a non-optimal surgical field will be a cutaneous entry that is too low. The upper limb must be free in case of mobilization by the surgeon.

Positioning of percutaneous threads
The system has proven to have achieved good stability regardless of the order in which the wires are inserted. However, the placement of the first 2 or 3 threads is constrained by the position of the upper limb to maintain the reduction. In 3 or 4 fragments fractures or in fractures that show some instability after reduction, it is necessary to add 2 wires in the proximal distal direction to fix the trochitis to the head and to the humeral diaphysis, whether the synthesis is done in the closed you do it in the open air. This procedure requires further assembly to connect the distal and proximal osteosynthesis.

Inserting the wires with the help of the wire pointing device
1. Proceed with inserting the wires at a slow speed. Place the first thread using the soft tissue protection guide. The verification of the correct position of the wires must be performed by radiographic verification.
2. Tighten the thread pointing device on the first thread guide by turning the knob clockwise.
3. Insert the second thread guide into the thread pointing device at the position most appropriate to fracture reduction and lock it with the upper knob.
4. Insert the second thread into the newly positioned thread guide.
5. Repeat the operation for the remaining wires. The system must have at least 4 wires not crossed between each other. If the reduction is not satisfactory, retract the threads until the fracture is released, without removing them completely from the diaphysis. Improve the reduction with external positioning and insert the wires again until the fragments of the humeral head are fixed.

Once the reduction has been obtained, bend the threads at about 90 ° with the appropriate thread-folding pincer, leaving about 3cm away from the skin: this will facilitate dressing and removal at the end of the treatment. The wires are oriented in pairs of 2 so that they are running with a good approximation parallel to the same plane. The flexibility of the system and the small rotational movements still possible with a single wire allow an appropriate wire orientation

Wire stabilization
1. Holding the clamp, clamp wire in place with the 10mm spanner, tighten the top disc of the clamp using the universal T-wrench with relative accessories.
2. Repeat the same operation for the remaining pairs of wires. Cut the wire distally near the wire lock terminal.
3. Connect each wire clamp terminal with a clamp, then connect the latter with a 6mm diameter bar. Test the stability of the synthesis under the image intensifier.
4. Cover the wires with the cover caps.

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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;
- Bone malformation
- Thrombosis, arteriovenous fistulas;
- Osteomyelitis.

RECOMMENDATIONS AND PRECAUTIONS
Pre – Surgery
- The use of external fixation devices requires a thorough knowledge of the surgery and the specific technique of this method;
- If material susceptibility is suspected, do not use the device;
- The patient should be informed of how the device is used and of potential complications associated with external fixators;
- The patient must always be informed of the implant's limitations and risks it entails; impacts, and other factors can involve tearing or wearing of the device with consequent failure of the reconstruction and rehabilitation therapy;
- It is important to select the components of the device correctly. The correct choice of the implant can minimize the risks of failure and this choice must be made in relation to the size and shape of the affected bone segment and to the loads it is subjected to;
- The dedicated accessories must always be used and approved by the manufacturer and must always be installed with the instruments supplied by the manufacturer;
- The device must be inspected for physical, superficial and functional integrity before proceeding with the implant;
- Marked deformation of an implant can cause a marked reduction in fatigue resistance;
- Make sure that the devices to be implanted are sterile;
- Store the product in such a way that the packaging is not damaged or altered and do not use it if the packaging (outer box and inner bags) is damaged.

Intra - Surgery
- 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;
- For components delivered in sterile packaging (see specific label on the package), make sure that the packaging is free from damage;
- 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 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;
- 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;
- 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 pins 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;

- When inserting the wire, use the wire guide to avoid damaging the soft tissue and / or the articular impingement. After inserting the thread, check the joint function;
- To avoid damaging the anatomical structures, insert the wires along the anatomical safety corridors;
- It is not recommended to insert the threads in soft tissues with a power drill, but to push them through the epidermis up to the bone. Use the low-speed motor drill to insert the wires into the bone;

Post-Surgery
- Patients should 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 should only be implemented if necessary. Regularly check the integrity of the device and the tightness of the screws;
- The devices under discussion are for single use and must never be reused; the re-use of the devices involves on the one hand the risk of causing a re-infection or cross-infection, on the other hand compromising 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 CLICK IT SHOULDER system.
The CLICKIT SHOULDER 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.

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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.

RISKS CAUSED BY RE-USE OF "SINGLE USE" DEVICES

The CLICK IT SHOULDER system (bars clamps, screws and wires) is SINGLE USE, therefore every single component must be destroyed and properly disposed after the first use on a patient.
CAUTION: Never reuse devices labeled "SINGLE USE". MIKAI is solely responsible for the safety and efficacy of single disposable devices when first used in the patient. Any subsequent use of these devices is improper and absolutely contraindicated by the manufacturer.
It is also essential to follow hospital protocols for the disposal of contaminated materials and biological waste. All used surgical instruments must be considered contaminated. It is therefore necessary to handle, collect and transport these instruments with rigorous care to minimize potential risks for patients, staff and all areas of the hospital

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	e-IFU	See instructions for use available at https://www.mikai.us/downloads/
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
	Single sterile barrier with internal protection	MD	Medical device
	Keep in a cool, dry place	UDI	Unique device identifier

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.