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

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DESCRIPTION
The CLICK IT SHOULDER system is designed to be modular in its components and used as a 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 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 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 500630ST**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.

MATERIALS
The CLICK IT 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).

INDICATIONS FOR USE
The CLICK IT SHOULDER system has been designed to obtain bone stabilization in cases of trauma and reconstructive procedures on adult and pediatric patients (excluded infants).
Indications for use include:
- Closed or exposed fractures of long bones (upper limb);
- Infected or aseptic pseudoarthrosis (upper limb);
- Pathologies / injuries of the joints of the upper limb and in particular;
- Proximal humerus fractures.

NOTE: The shoulder fixation system is designed for use in proximal humeral fractures with two thirds of the metaphysis intact.

CONTRAINDICATION
The CLICK IT SHOULDER system has not been designed and cannot be sold for any use other than those indicated.
Use of the system is contraindicated in the following situations:
- Patients not willing or unable to follow postoperative care instructions, due to mental or physiological conditions;
- Patients suffering from severe osteoporosis*;
- Patients with severe or poorly controlled diabetes mellitus;
- Patients with compromised vascularity;
- Patients with previous infections;
- Patients with a tumor in the fracture area;
- Patients with neuromuscular deficit or other conditions that could have consequences on the healing process;
- HIV-positive patients;
- Patients with hypersensitivity to foreign bodies. In case of suspected allergy to the materials, it is recommended to perform tests before proceeding with the fixator implant;

Possible contraindications for a percutaneous procedure, both due to the technical difficulty of positioning the wires and for the final stability of the implant:
- A portion of comminuted bone;
- Level and / or extent of fracture is too distal.

* As defined by the World Health Organization: "Bone mineral density of 2.5 standard deviations or less below the average peak of bone mass (average of a healthy young adult) in the presence of one or more fragility fractures".

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.

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 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 a foreign body susceptibility is suspected, a test should be performed prior to implantation to exclude this possibility;
- 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; excessive, uncontrolled loading, 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;
- Excessive or 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
- Intra-operative fractures or instrument rupture may occur;
- It is strongly recommended to use dedicated instruments during implant while handling sharp 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" of the color change has become green;
- Carefully position the screws to avoid damage to the nerves, muscles, tendons and vessels;
- Slowly pierce 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;
- Stabilization of the fracture must be performed after having obtained a correct reduction of the fracture. If the reduction is not satisfactory or cannot be accomplished 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-seated in the case of fractures of the proximal humerus;
- Before applying the fixator, make sure that the clamps are loose;
- The terminals must not be disassembled;
- The stability of the assembly must be verified in the intra-operative position, before the patient leaves the operating room (check the closing of all the clamps). Based on the clinical and radiological results, the surgeon will decide the number of bars and bone screws needed in order to obtain the correct assembly stability;
- Any device implanted in the patient, such as bone screws, threaded 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;
- For the shoulder fixation system: the tip of the thread must be 5-10mm from the articular surface of the humeral head;
- When inserting the thread, it is recommended to use the thread 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;
- Use wires with 2.5-3,0 mm thread with the wire lock clamp;
- Insert the first threaded thread in the center of the humeral head and reach its apex;
- The wires are cylindrical and can be retracted if necessary;
- It is recommended to use the dedicated Mikai instrumentation for inserting threaded wires;
- It is necessary to carefully clean the epidermis around the threaded wires (inserting the wires) ;
- 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 that you do it in the open. This intervention requires further assembly to connect the distal and proximal osteosynthesis.

Post-Surgery
- Instruct the patient on the daily management of the skin near the screws to the reduce risk of infection;
- The patient should be informed that the system will not be as strong as healthy bone;
- All patients should be informed about the use and maintenance of external fixation mounting and the care of screw mounting sites;
- Patients should be instructed to report any abnormal or unforeseen effects to the surgeon;
- 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 unless otherwise indicated, as combined use is not covered by the required validation;
- Removal of the device: the final decision about the removal of the device is up to the surgeon;
- The threads should be kept in place on average for 6-8 weeks depending on the fracture with the limb contained in an arm support;
- During the first 15 days, the patient must keep the shoulder completely at rest: the straps can be removed to allow personal hygiene and elbow mobilization;
- From the third week, it is possible to begin to perform a passive mobilization with a degree of freedom proportional to the severity of the fracture;
- The closed reduction of three- and especially four-part fractures is a technically demanding procedure. Before using this technique, it is necessary to understand the nature of the lesion, the number and position of the fragments. In this regard, CT with three-dimensional reconstruction can be useful;
- A disadvantage of the "semi-rigid" fixation techniques is the need for post-operative immobilization of the arm. This device is often applied percutaneously with minimal damage to the soft parts so the shoulder could be mobilized early, as in non-operative treatment.

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 CLICK IT SHOULDER system.

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

IMPLANTABLE DEVICE*
The single use implantable device* by MIKAI is identifiable by the symbol " " shown on the product label. After removal from the patient, as with all other components that make up the CLICK IT SHOULDER product, the implantable device* must be destroyed. Re-use of an implantable device* presents risks of contamination for users and patients. The re-use of an implantable device * cannot guarantee the original mechanical and functional performance, compromising product efficacy and presenting health risks to patients.

(*):Implantable device - Any device that has been designed to be totally or partially introduced into the human body through surgery and to remain in place after the procedure for at least 30 days is considered an implantable device.

STERILIZATION
Devices supplied in the STERILE version have a label indicating this state. The contents of the package are STERILE unless this is opened or damaged. Do not use if the package has been opened or damaged.

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

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.