ClickIt CF – Circular Fixation System - Instructions for Use and Warnings

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DESCRIPTION
The Circular Fixation System is indicated in the fixation of open and closed fractures, pseudoarthrosis, limb lengthening, correction of deformities and segmental defects of bone or soft tissues.
The frame of the external fixator ClickIt CF, manufactured mainly in 7000 series aluminium alloy, is made up of fixed and moveable rings and spacer elements to be connected to arcs. The rings, available in 5 sizes, are provided with grooves for the spacers that are positioned externally. The fixation systems between the half-rings are retractable to make the assembly extremely functional.
The mobile spacer elements and the fixed ones, designed for fast and practical insertion, are equipped with a quick-connect feature to reduce assembly time.
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
Screws and k-wire: stainless steel AISI 316 LVM ISO 5832-1 available also with HAP coating.
Series 7000 Aluminum Alloy exoskeleton (rings), Struts and accessories in series 7000 Aluminum Alloy, AISI 303/304 / 316L stainless steel and PEEK.
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
The circular fixation system Clickit CF is indicated for:
- Fracture fixation of traumatic and/or pathologic origin in long and short bone, specifically in the following bone segments: radius/ulna, humerus, femur, tibia;
- Foot, knee and ankle fractures with joint involvement
- Luxation or luxation-fracture;
- Infection;
- Limb lengthening;
- Congenital and acquired deformities;
- Congenital and acquired Pseudoarthrosis.

CONTRAINDICATIONS
Absolute contraindications include:
- Lack of consent;
- Unsuitable patient.

Among the conditions that could lead to an increased risk of fixator failure are:
- Osteoporotic bone;
- Infections;
- Malnutrition;
- Prolonged loosening of the structure;
- Neuro vascular disorders.

However, it should be noted that the ClickIt CF system is precisely indicated for greater stability in such pathological situations compared to a possible internal synthesis.

BASE SURGICAL TECHNIQUE
Below are the installation steps (installation) of a circular fixation system.
The fixator is composed of a series of rings that are positioned on the patient's limb and fixed to the bone by means of appropriately tensioned K-wires and/or bone screws. The rings are connected between each other externally in order to allow a stable bone fixation.
The external connection components are threaded bars, fixed and/or mobile quick-attach bars that allow the operator to properly adjust the position of each ring with respect to the others in relation to the treated anatomy and/or fracture.
The correction of a deformity, elongation or mobilization of a segment is obtained by modifying the position of a ring in a micrometric way.
- Assembly of the implant:
Presurgical programming;
In relation to the clinical history, to the rx of the case to be treated and to the weight of the patient an adequate number of rings of the most appropriate shape and diameter is selected. It is recommended to have about 2 cm of space between the ring and the patient's skin.
It is generally advisable to pre-assemble the fixator and position it on the limb inserting it from the foot and sliding it until it is correctly positioned. Alternatively, leaving the structure open it can also be immediately placed on the limb in the desired position and then the whole system can be closed.
Generally, the most used position is the supine one, in any case it is the surgeon who decides the position in relation to personal experience and/or surgical needs.
- Insertion of the bone-gripping elements (screws/k-wires):
Note: always refer to the safety corridors for correct positioning.
Smooth K-wires;
The wire is inserted by motor, generally at reduced speed, and must be orthogonal to the diaphyseal axis or parallel to the joint in the case it is close to the articulation itself. Correct positioning must be evaluated with the C-arm. The wire after passing the bony part and the skin must exceed over the ring adequately on the opposite side of the insertion in order to be correctly tensioned.
It is always advisable to position the wires on the most extreme rings first.
K-wires with stopper
The above applies with the only care to make an incision on the skin on the side of the stopper in order to make it penetrate the skin freely up to the bone.
When placing more wires on each ring, in order to increase the stability of the system, it is preferable to angle the wires as much as possible between them (ideally 90°) always respecting the safety corridors and/or clinical needs.
Insertion of bone screws
Always cut the skin first and separate the tissues with blunt tip scissors to avoid damaging the soft parts.
Use a drill guide and place it on the bone
Perforate the bone beforehand (both cortex walls) with an adequate drill diameter with respect to the diameter of the chosen screw. The screw must be connected to the ring with a dedicated single or multiple clamp.
- Assembly of the wire on the fixator
The wires must be fixed on the rings using the appropriate wire clamps and positioned in the dedicated groove.
Normally the wire is fixed to one end of the ring by locking the nut of the respective clamp and tensioning the opposite end using a wire-tensioning device. The wire tension varies according to the type of ring (complete or open ring), the bone region, the quality of the bone, the anatomical segment and the wire diameter.
- Reduction
The reduction of the fracture can be performed using wires with stopper or smooth wires suitably positioned and moving them with respect to the ring or, in other cases, it can be obtained by moving the rings with respect to the others.
Corrections can be made on all planes (frontal, sagittal and transverse) and translations can be obtained along the diaphyseal axis or ad latus and also rotations can be obtained as well as angular displacements.
During the implant of the fixator on the patient, in addition to the preassembled supporting structure, it is possible to mount accessory parts that are selected on-site.

ADVERSE EVENTS
The following list includes the main complications typically associated with the use of external fixation devices.
- Delayed healing;
- The insertion of the pins can cause damage to the nerves and blood vessels;
- Infection, pain, swelling or inflammation at the implant site;
- Edema;
- Loosening or moving of the system with the need for re-intervention due to incorrect indication or application of the same;
- Device breakage;
- Septic arthritis;
- Loss of range of motion, joint contracture, subluxation and joint dislocation;
- Compartment syndrome;
- Replacement of the system or components with consequent re-intervention;
- Necrosis of the tissues due to the insertion of the pins;
- Pressure on the skin exerted by external components;
- Allergic reaction;
- Laceration of the tendon muscles and excessive bleeding;
- Pseudoatrosis development and failure of satisfactory bone regeneration;
- Bone mass loss;
- Fracture of the regenerated bone after removing the device;
- Discrepancy in the length of the limbs;
- Excessive movement at the fracture site due to improper positioning;
- Joint stiffness;
- Bone deformity;
- 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;
- 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.
- Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process.

The choice, correct positioning, surgical technique and instruments are critical factors in determining the success of the implant and post-op therapy.

Therefore:
- The life span of the device is strictly linked to biological and biomechanical factors; the correct choice of implant can minimize the risk of failure and this choice must be made in relation to the dimension and form of a bone segment and the presumed load it will withstand;
- 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;
- Psychologically inhibited, obese or debilitated patients risk failure;
- Any implant device requires specific instruments for implanting; the use of unsuitable instruments can cause damage to the device and an incorrect implantation;
- The device must be verified for physical and functional integrity before proceeding with the implant;
- It is essential that all information, warnings, indications and contraindications, precautions are respected and the patient is informed wherever necessary;
- Alternative methods and aids or alternative devices should always be readily available before proceeding with the implant.
- Make sure that the sterile devices to be implanted have not exceeded the expiry date;
- Store the product in such a way that the packaging is not damaged or altered and does not use it if the packaging (outer box and inner bags) is damaged.

Intraoperative
- Intra-operative fractures 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.
- 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;
- Any implant device requires specific instruments for implanting provided by MIKAI; the use of unsuitable instruments may cause damage to the device and an incorrect implant;
- Their own accessories must always be used and approved by the manufacturer and must always be installed with the instruments supplied by the manufacturer;
- Never, for any reason whatsoever, use damaged implants;
- Attention must be paid to avoid cutting 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;
- Normally, the strength of the wires varies between 90 and 130 Newtons (N), tensions higher than 155 N can cause wire distension and deformation.
- 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.

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 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 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;
- 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;
- If foot supports are used, the patient must avoid giving the device a full load and must be helped with crutches;
- 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;

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 CF system. The CLICKIT CF 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.

CAUTIONS

Suggestions that the manufacturer strongly recommends to comply with:
- Carefully read the surgical technique supplied by the manufacturer;
- Do not use the device if the packaging (box and inner envelopes) are found to be damaged;
- Make sure that always at least two packs of the same device are available;
- Do not for any reason use damaged devices;
- 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;
- The manufacturer provides the surgeon dedicated instruments for the implantation of the device; instruments other than those listed in the surgical technique must not be used;
- The application of the device must be performed by a medical staff with a good knowledge of orthopedic/trauma surgery. An appropriate training is recommended prior to the implantation of the device. The manufacturer provides the surgeon with documentation in order to give all the details on the surgical technique and the possible risks or hazards;
- Never apply power to the device because it could trigger massive corrosion processes;

COMPATIBILITY

The ClickIt CF system is compatible with the bone screws of Mikai's ClickIt ER and FEP systems.

STERILIZATION

All the ClickIt CF components are supplied **SINGLE USE**, those identified by its respective label as **STERILE** 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 can be sterilized in an autoclave (UNI EN ISO 17665).

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

SAFETY INFORMATION MRI – MR CONDITIONAL

The ClickIt CF 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 CF 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 CF 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 CF	
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 CF system may generate artifacts on the obtained images	

A patient with implanted ClickIt CF 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 CF system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the ClickIt CF 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 CF 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 and expiration date (where applicable). 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;
- HAP or HA: indicates the hydroxyapatite coating of the screw;
- d.: in some cases, indicates the diameter of the device in the description;
- Txx: the letter T followed by a number indicates the length of the main thread in the device;
- Lxx: the letter L followed by a number indicates the main length of the device;
- xxPZ: preceded by a number, indicates the number of devices in the package in the description.