Single Use External Fixation System ClickIt STYLO FOOT / DIABETIC FOOT - Instructions for Use and Warnings CE 1936

EN

DESCRIPTION

Kit ClickIt Stylo for single use – The Stylo external fixation sterile complete kits are composed by the base element, clamps and screws. The base element is composed by a multiplanar joint and two cylindrical rods for clamps insertion, the ClickIt Stylo Diabetic Foot has available also an arched connector.

In case of usage of custom kits (5002000FST/SFTS/AST/SAST**X**), please consider that not all the steps of the surgical technique and previously described components might be applicable.

MATERIALS

The construction materials for the various components are:
- Alluminium Alloy 7012 UNI 9007 3T
- Stainless Steel AISI 316 LVM ISO 5832-1
- Titanium alloy Ti6Al4V ELI ISO 5832-3

The system hereby presented has not be tested for MRI compatibility. Medical personnel must be informed of the composition material of the device 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 realization of the implanted device and the specific limitations / contraindications attached to it.
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

KIT ClickIt Stylo Foot / Diabetic Foot for single-use
- Fracture fixation of traumatic/pathologic origin of the foot

The Foot / Diabetic Foot kit of the ClickIt Stylo system are optimized in their contents for their use over the anatomical district of the foot.

CONTRAINDICATION
- Any inflammation in the screw zone
- Patients with previous infections
- any form of active infection
- Sensitivity to the materials constituting the documented or suspected grip elements, it is recommended to perform tests before proceeding with the fixer implantation
- Patients not willing or unable to follow postoperative care instructions, due to particular mental or physiological conditions
- any mental or neuromuscular disorder
- Patients with neuromuscular deficit or other conditions that may have consequences on the healing process
- Senility, mental illness or alcoholism (conditions that can induce the patient not to take into account some limitations and precautions necessary in the use of the implant, giving rise to subsidence or other complications).
- Patients considered heavy smokers
- Cancer patients in the area of the fracture
- Amount of insufficient bone tissue.
- Quality of insufficient bone tissue.

Specific contraindications CLICKIT STYLO
- Extensive trauma to the soft tissue, open fractures, considerable skin area compromised.

BASE SURGICAL TECHNIQUE

CLICKIT STYLO FOOT:
- The two Ø2.5mm screws are implanted in the distal or intermediate phalanges of the first toe, use the double cannula to correctly position the screws. The screws included in the kit can be used on this bone segment or, at the surgeon's discretion, the Ø3mm screws.
- The two Ø3mm screws are then implanted on the proximal segment, positioning can take place at the level of the 1st metatarsal or cuneiform, in particular cases also at the navicular. The use of Ø3 mm screws is recommended on these segments.
- The clamps are inserted on each pair of screws, avoiding to tighten them, then the body of the fixator is inserted. The fracture is reduced and stabilized and, upon reaching the appropriate reduction, the fixator joint and the clamps are fastened with the appropriate wrenches.
- For better implant stability, it is possible to implant an additional screw in the metatarsal of the 3rd or 4th toes, this screw is stabilized by means of the bridge arch, which must be mounted on the fixator body through its special clamp. After assembling the bridge arch, the screw is fixed to it via the single screw clamp.

The Diabetic foot kit has the same approach as the foot kit but uses smaller clamps in order to have a smaller distance between screws and therefore superior maneuverability.

COMPRESSION AND DISTRACTION UNIT
- Hook the fork part of the unit onto the proximal clamp of the fixator. Hook the unit clamp onto the fixator rod and tighten the locking screw.
- Loosen the clamp screw on the proximal clamp of the fixator so as to free the sliding of the clamp over the rod. Turn the wheel of the unit in direction "C" to compress and in the opposite direction to distract. A complete turn of the wheel corresponds to an axial displacement of 2 mm.
- Once the desired reduction has been reached, fasten the previously loosened fixator clamp and loosen the locking screw (A) of the unit clamp to allow removal.

The Mikai system is also equipped with some accessories such as single clamps, double clamps, rail connectors or bridge arches for rear synthesis with a screw and / or K-wire at the heel. These accessories allow the system to be more versatile and modular so to better cope with several types of fractures, anatomical needs and make the implant and synthesis more stable.

Post-operative management

Carry out radiographic and ambulatory checks according to the doctor's criteria. Joint mobilization of the ankle can be granted, in the simplest cases and always following the doctor's criteria, as soon as after a few days of surgery. The granting of the load depends on the type of fracture and must be managed with caution according to the doctor's indications. The treatment period can vary between 6 and 8 weeks and the removal of the fixator, always following the doctor's criteria, can be performed in the ambulatory ward.

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 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.
- Contact the manufacturer for get information on indications, implant techniques, implant choice and risks or hazards.
- For the correct use of the devices under discussion comply with the following provisions:
  - The implants must be sterile.
  - Implants must always be performed with instruments supplied by the manufacturer.
  - Implants must follow adequate operating techniques in suitable conditions.
- 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.

- Early diagnosis and rapid intervention are recommended.
- Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process.
- Psychologically inhibited, obese or debilitated patients risk failure.
- Methods and aids or alternative devices (spare parts or different devices with the same intended use, for example SMART/FEP) should always be readily available before proceeding with the implant.

Intra - Surgery
- Intra-operative fractures or instrument rupture may occur.
- It is strongly recommended to use dedicated instruments during implant and to avoid the use of instruments considered by the surgeon to be worn-out or malfunctioning, in case the instruments are found to be worn-out or malfunctioning they must be shipped back to Mikai that will provide equivalent functioning instruments.
- For components delivered in a sterile package (see the appropriate label on the package), make sure that the sterilization expiration date has not been reached.
- For the components delivered in a sterile package (see the appropriate label on the package), make sure that the casing is free of damage and that the color of the word "GAS" present on the sterilization mark has become green.
- Carefully 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.
- 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.
- 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.
- Before applying the fixator, make sure that the clamps are loose.
- The clamps 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).
- 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.
- 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.
- 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.
- It is necessary to carefully clean the epidermis around the threaded wires (inserting the wires).
- 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.

- Place the adjacent finger on the dorsal component of the fixator, reducing interference with the fingers.
- Avoid pin injuries to the extensor tendons and lateral bands by inserting the gripping elements between these two or on the palm side of the lateral fascia.
- A careful dissection is recommended in the percutaneous insertion of the gripping elements.
- Distraction must reach a maximum gap of 5 mm of the joint even in the most severe contractures.
- Distract the joint gradually (half a turn in the morning and half a turn in the evening) for greater compliance of the pain.
- Position the clamps 10 mm from the skin to allow for post-operative swelling.

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 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.

- Make a strict adherence to physiotherapy and rehabilitation.
- Avviare sin da subito una mobilizzazione del pollice operato tramite opportuni esercizi

PROVISIONS FOR USE

1. The use of external fixation devices presumes an in-depth knowledge of external fixation surgery.
2. If the surgeon should not be 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. Post-operatory mobilization on the implant as one of the possible risks must be adequately known and assessed before proceeding with this system. The manufacturer can supply ample documentation both printed and on file to inform and train surgeons on the potentials, implant techniques, implant choice and risks or hazards.
3. For the correct use of the Mikai fixation systems comply with the following provisions:
- The implants must be sterile.
- Always use genuine accessories approved by the manufacturer.
- Implants must always be performed with instruments supplied by the manufacturer.
- Implants must follow adequate operating techniques in suitable conditions.
- When implanting, all the device’s adjustments must be free or unlocked.
- On completing the implant stage, the surgeon must ensure that all the fixator’s elements are locked and firmly fixed in place.

- In order to retain their lifespan, we strongly recommend against forcing the threaded elements into place.
- The wound must be thoroughly disinfected before, during and after implanting.

4. To maintain the device's mechanical and physical properties and retain its lifespan we recommend:
- During the implant period control the grip and tightening of the various threaded elements on at least a monthly basis and check that the device operates correctly
- Check, after removal, that each and every part of all components are intact and no surface cracks or oxidation can be seen.
- Make sure that new screws are used for each implant and disposed of on completion of the implant period. the same goes for the clamps that anchor the screws to the rods.
- Store the fixator so that its package cannot undergo damage or alterations.
- Never proceed with the implant if there is visible or assumed damage on any of the fixator's components.
- Comply with the assembly diagrams illustrated in the documentation supplied by the manufacturer.

WARNINGS
- Never, for any reason whatsoever, use implants with damaged or malfunctioning components. before beginning with the implant make sure that every component is in perfect working order.
- The grasping elements (screws) and the clamps are for **single use** and must never be reused.
- The **ClickIt Stylo for single-use** fixators are single-use and should never be reused.
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance.
- It is strongly recommended to use dedicated instruments during implant while handling sharp instruments.
- Keep attention not to cut surgical gloves during the procedure.
- 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.

COMPLICATIONS AND ADVERSE EVENTS
The following events may represent undesiderable effects after an external fixator implant:
- Delayed healing.
- Distraction of the fracture.
- The insertion of the pins can cause damage to the nerves and vessels if applied without respecting the anatomical corridors.
- Infection, pain, swelling or inflammation at the implant site.
- Edema.
- Loosening or moving of the system with the need for re-intervention
- Breakage of the device.
- 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.
- Pseudoarthrosis 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.
- Heat accumulation and bone necrosis.
- Ankle stiffness due to the multiple screws used.
- Bone deformity.
- Thrombosis, arteriovenous fistulas.
- Osteomyelitis.

RISKS CAUSED BY RE-USE OF "SINGLE USE" DEVICES
The CLICKIT STYLO FOOT / DIABETIC FOOT kits are 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 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

STERILE
The devices are exclusively supplied sterile. These devices contain a label that indicates said status. The content of the package is STERILE as long as it is not open or damaged. Do not use if the packaging is damaged.
All NON-STERILE products (instruments) must be sterilized using a steam autoclave according to the (UNI EN ISO 17665 standard):

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

SAFETY INFORMATION MRI – MR CONDITIONAL

The Stylo/Ministylo 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 Stylo/Ministylo 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 Stylo/Ministylo 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	Stylo/Ministylo	
Nominal value of the static magnetic field	1.5 Tesla [63.6755 MHz]	3 Tesla [127.8 MHz]
Shielding	Active	Active
Maximum spatial field gradient	11 T/m	12 T/m
Coil type	Body coil	Body coil
Scan time for maximum in-vitro temperature variation	15'08"	15'38"
Worst case SAR	13.99 ± 0.15 W/kg	7.5 ± 0.11 W/kg
Maximum in-vitro temperature variation with device inside the bore	12.6 ± 0.5°C	8.4 ± 0.5°C
MR image artifact	The presence of the Stylo/Ministylo system may	
	generate artifacts on the obtained images	

A patient with implanted Stylo/Ministylo 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.
- 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 Stylo/Ministylo system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the Stylo/Ministylo system allows to obtain multiple configurations, therefore worse heating conditions cannot be excluded.
- 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 9'30 "for 1.5 T and 19'46" 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.
- The Stylo/Ministylo 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.

	Name and full address of the manufacturer		See instructions for use
	Code		Single use only
	Lot No.		Do not use if package is damaged
	Expiration date		Do not resterilize
	Sterilization mode ETO		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.