Smart System Single Use - Instructions for Use and Warnings

CE 1936

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DESCRIPTION

General – Bone segments fixation comes out of a need for a surgical procedure in grade of rebuild an anatomic segment after a trauma or need of an anatomical correction. Moreover, when deformities are present it is possible to carry out an adequate therapy to treat corrections or lengthening of deformed bone segments.

Smart system - The Smart external fixation kits are composed by the base element, two clamps and four screws. The Smart system fixators are available in two different versions: a system for metacarpus and phalangeal lengthening and an articular system. The base element of the articular fixator is comprised of an articulated hinge and two cylindrical rods for clamps insertion. The lengthener base element is comprised of a millimeter-graduated rod with two cylindrical rods for the clamps sliding.

MATERIALS

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

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

Smart system - Single-use

It is clarified that the indications for use are specific to the hand/wrist district:
• Fracture fixation for the bones within or near the joints of the hand, open or closed.
• Pathologic fractures and tumor resections
• Phalangeal malformations
• Phalangeal lengthening.

CONTRAINDICATIONS

- 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
- Patients with compromised vascularity
- Cancer patients in the area of the fracture
- Amount of insufficient bone tissue
- Quality of insufficient bone tissue

- Patients with osteoporotic bone, as they risk a possible fracturing in the insertion point
- Patients with severe comminution of the fracture due to high-energy trauma
- Patients with contractures due to burns, advanced Dupuytren's disease, congenital hand anomalies and severe crush injuries
- Re-installation.

SURGICAL TECHNIQUE

Hereby are indicated the installation phases (implantation) of a fixation system.
In case of articular rigidity (Smart system for deformity correction), the steps to follow are:
1. Identification of the joint center with a kirschner wire and centering of the fixator.
2. Insertion of 2 pinning elements of 2mm diameter proximally and distally to the joint using as a guide the body of the fixator; the pinning elements must be inserted orthogonally to the axis of the bone segment; use the electric drill to bore the 1° cortex and then advance by hand with the t-handle.
3. Insert the clamps without tightening them with respect to the pinning elements; insert the fixator's body and tighten the clamps with the respective screwdriver. If the fracture is particularly unstable it is advised to use the flat wrench to keep the clamp still while the nut is tighten with the t-screwdriver, therefore avoiding an excessive torque over the screw.
4. Tighten the fixator using the positioning levers.
5. Lock the hinged junction with the corresponding screwdriver and remove the levers.
6. Micrometric revisions post-surgery; insert the positioning levers over the fixator, unblock the joint with the screwdriver, carry out the revision by steps, lock the joint and remove the levers.
In case of corrective osteotomies (Smart system for deformity correction):
1. After performing a clinical and radiological evaluation of the deformity, insert the pinning elements of 2 mm diameter proximally and distally with respect to the deformity with an inclination equivalent to that of the deformity that must be corrected, use the electric drill to bore the 1° cortex and then advance by hand with the t-handle.
2. Perform the osteotomy within the deformity (when possible).
3. Insert the clamps without tightening them with respect to the pinning elements; insert the fixator's body.
4. Correct the deformity by creating a parallelism between the 2 pairs of pinning devices and tighten the clamps with the respective screwdriver. If the fracture is particularly unstable it is advised to use the flat wrench to keep the clamp still while the nut is tightened with the T-screwdriver, therefore avoiding an excessive torque over the screw.
5. Tighten the hinged junction with the corresponding screwdriver and evaluate the obtained correction by putting in motion the patient.
6. Eventual minimal micrometric revisions after the surgery: for eventual rotational defects unblock the clamps (it can be unblocked just one), perform the desired revision and block the clamps; for valgus-varus revisions insert the positioning levers, unblock the junction with the corresponding screwdriver, perform the revision by steps, block the junction and remove the levers.
In case of lengthening (Smart system for lengthening):
1. After performing a clinical and radiological evaluation of the stump to be lengthened, insert the pinning elements of 2 mm diameter as close as possible to the metaphyseal zones, use the electric drill to bore the 1° cortex and then advance by hand with the t-handle.
2. Insert the clamps without tightening them with respect to the pinning elements; insert the fixator's body.
3. Tighten the clamps with the respective T-screwdriver.
4. Increase the distance between clamps by rotating (and thus sliding) the 2 distal nuts with respect to the stump (first the most distal nut and then the most proximal) putting under traction the stump.
5. Perform the osteotomy with multiple perforations.
6. Re-compress the 2 bone segments and then start the lengthening mm by mm after about 7 days.
In case the bone is not able to hold two screws over the length of its body due to the fragment's dimension or the fracture's position:
1. Implant two Kirschner wires laterally and dorsally over the proximal stump of the fracture, the wires must be positioned with a certain angle with respect to the sagittal plane (between 30° and 60°). Avoid any interference with the extension system of the hand. The K-wire must be inserted up to the second cortex, avoiding an excessive protrusion of the tip.
2. Using the bridge clamps mount a bridge of a suitable size to the K-wires and tighten the clamps.
3. Mount the threaded rod to the bridge, the rod must be aligned to the phalanx's axis being stabilized, the rod is blocked through the screw present over the upper body of the bridge.
4. Insert two K-wires over the distal stump of the fracture taking care to position them with the same inclination given to the proximal K-wires implanted on step 1. Mount a second bridge to the threaded rod and position it beside the distal K-wires.
5. Fix the distal K-wires to the bridge through the bridge clamps.
6. Tighten the clamps, tighten the blocking screw of the bridge. Check the fracture's reduction through C-arm and, in case the reduction is satisfactory, proceed with the standard treatment given to this kind of injuries.

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;
- 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.
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- 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 STYLO) should always be readily available before proceeding with the implant;

Intra - Surgery

- Intra-operative fracture 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.
- 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 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;
- 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);

- 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.

PROVISIONS FOR USE

1. The use of external fixation device presumes an in-depth knowledge of external fixation surgery.
2. 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 system comply with the following provisions:
- The implant must be sterile
- Always use genuine accessories approved by the manufacturer
- Implant must always be performed with instruments supplied by the manufacturer
- Implant 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.

CAUTIONS

- 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 fixator **Smart for single-use** is 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.

UNDESIRABLE EFFECTS

The following events may represent undesirable effects after an external fixator implant
- Inflammation affecting the skin
- Inflammation affecting muscle and bone tissue
- Osteolysis with loss of grip between bone and screw
- Instability of the implant caused by slackening of screws and clamps
- Infection in screw insertion sites
- Consolidation and / or non-union delays of the osteotomy site
- DVT (deep venous thrombosis)

Therefore, it is highly recommended to:
- Adopt wound hygiene procedures with weekly controls to reduce the risk of superficial or in-depth infections;
- The effects of osteolysis may be compensated by tightening the screws;
- Periodically ascertain the grip of the tightening elements and screws to avoid instability arising in the implant.

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 SMART SYSTEM system.
The SMART SYSTEM 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.

STERILIZATION

The implantable devices are exclusively SINGLE USE and 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 17664 standard:

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

SAFETY INFORMATION MRI – MR CONDITIONAL

The Smart 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 Smart 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 Smart 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	Smart	
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 Smart system may generate artifacts on the obtained images	

A patient with implanted Smart 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 Smart system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the Smart 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 Smart 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
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.