Shoulder external fixation system "KIT FEP® SPALLA" - Instructions for Use and Warnings CE 1936

EN

DESCRIPTION

The KIT FEP SHOULDER system is designed to be modular in its components and used together with Mikai bone grasping devices (screws, wires, etc.). The structure configuration is guaranteed by the modularity of the system.

The components of the KIT FEP SPALLA system are not intended to replace a normal and healthy bone or to withstand the stresses of a full load, particularly in the case of unstable fractures or in the presence of pseudarthrosis, consolidation delays or incomplete healing. It is recommended to integrate the treatment with the use of external supports (e.g. braces). The system consists of various modules, applicable in different anatomical sites of the upper limb. If properly used, the KIT FEP SHOULDER system maintains the functionality of the limb, minimizes surgical trauma to the anatomical structures and preserves blood circulation and the osteogenic potential of the tissues. All Mikai devices are intended for professional use only. Surgeons responsible for supervising the use of Mikai devices must be fully aware of orthopedic procedures, as well as have an adequate understanding of the philosophy of the Mikai modular system.

MATERIALS

The KIT FEP SHOULDER system is made up of elements in stainless steel and anodized aluminum alloy. The components that come into contact with the patient are the screws (bone screws), the Kirchner wires, the drill bits, the guides used during the insertion of the screw and/or wires. These components are made of stainless steel for surgical use. Some Mikai bone screws (screws) can be supplied with the threaded portion coated with hydroxyapatite (HA).

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

he KIT FEP SHOULDER system has been designed to obtain bone stabilization in cases of trauma and reconstructive procedures, on adult and pediatric patients (excluding 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
- - Fractures of the proximal humerus;

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

CONTRAINDICATIONS

The KIT FEP SHOULDER system was not designed nor can it be sold for any type of use other than those indicated.

The use of the system is contraindicated in the following situations:

- Patients unwilling or unable to follow postoperative care instructions, due to particular mental or physiological conditions
- Patients with severe osteoporosis *
- Patients with severe or poorly controlled diabetes mellitus
- Patients with compromised vascularity
- Patients with previous infections
- Patients with tumors within 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 material, it is recommended to carry out the required tests before proceeding with the fixator implantation

Possible contraindications for a percutaneous procedure, both for the technical difficulty of positioning the wires and for the final stability of the implant:

- Portion of comminuted bone
- Level and/or extension of the fracture too distal

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

BASE SURGICAL TECHNIQUE

This section contains the essential steps of the surgical technique, for more 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: Open reduction and closed reduction. In order to determine the conformation, position and size of the various bone fragments, the radiographs indicated to be performed are: AP, Trans-thoracic or outlet view projection and when possible: Axillary projection and CT scan of the humeral head.

Assess the external distal metaphyseal integrity (2/3 of the external bone circumference), which represents the entry point of the osteosynthesis devices.

Fracture reduction

Reduction maneuvers must be tested before preparing the surgical field and must be performed following standard procedures. To carry out radiological checks, 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-arm can move freely. NOTE: if the reduction is not satisfactory or cannot be achieved with external maneuvers, open surgery is necessary. In this case, it will be necessary to change the patient's position from supine to semi-seated

Preparation of the surgical field

The area of the acromioclavicular joint must be visible: this is important for the percutaneous insertion of the wires. The consequence of a suboptimal surgical field will be a skin entrance too low. The upper limb must be free in case of mobilization by the surgeon

Surgical technique

a) Closed reduction

The supine position of the patient is recommended with the image intensifier placed on the contralateral side of the fracture and the radiological source orthogonal to the operating bed. In order to allow good management of the image intensifier, the use of a modular bed for shoulder surgery with removable proximal components is recommended.

b) Open reduction

the patient must be placed in a semi-sitting position.

In order to determine the conformation, position and size of the various bone fragments, the radiographs indicated to be performed are:

• AP projection,
• Trans-thoracic or outlet view

and when possible:

• Axillary projection
• CT scan of the humeral head. The latter is particularly suitable for more complex fractures and more than 2 fragments

Fracture reduction

Reduction maneuvers must be tested before preparing the surgical field and must be performed following standard procedures. To carry out radiological checks, the image intensifier must be positioned with the X-ray beam above the glenoid to allow for correct AP projection.

In case of difficulty in obtaining a satisfactory reduction, you can try to improve it percutaneously with mini-accesses and the use of hooks and/or wires.

If the reduction under closed conditions is not satisfactory or cannot be obtained, open surgery must be performed. In this case it is recommended to change the patient's position from supine to semi-seated.

Preparation of the operating field

The area of the acromioclavicular joint must be visible: this is important for the percutaneous insertion of the wires. The upper limb must be free in case of mobilization by the surgeon.

Positioning of percutaneous wires and bone screws

Before introducing the grasping elements, make an adequate incision of the skin using a scalpel

The insertion of the wires must be at low speed

The insertion point of the first thread is about 4/5 cm proximal to the deltoid-pectoral sulcus anterior to the line that runs parallel to the humeral shaft that starts from the apex of the V-shaped insertion of the deltoid. The wire must have an inclination on the frontal plane of about 20 ° with respect to the humeral shaft to reach the head of the humerus. The correct choice of the insertion point of the wire avoids the surgeon from creating iatrogenic neurological lesions of the axillary nerve.

Check with the image intensifier the correct positioning of the wire. The proximal apex of the wire must be in the subchondral area of the head of the humerus.

Insert the second threaded wire in an appropriate direction to obtain a good reduction and stabilization of the fracture positioning it on a different plane than the first but always with direction towards the coracoid process.

Introduction of intramedullary wires

Insert manually using a T-handle or a hammer 2 wires with a lancet-shaped tip from the head of the humerus to the intramedullary canal until you have a good bone hold (diaphyseal area of the canal). Check the correct positioning radiographically

Screw placement

Insert the first self-drilling, self-tapping screw of adequate length at diaphyseal level under the V deltoid. Insert the second diaphyseal screw about 3 - 4 cm distal to the first. The screw diameters can vary from 4 mm to 5 mm depending on the patient's build.

In the case of complex fractures with several fragments, the versatility of the system allows to introduce other possible threaded threads on the large tuberosity and also a possible third intramedullary smooth thread.

Fixator's mounting

After assembling the bridge to the rail body, the wires and screws are mounted to the fixator.

The intramedullary wires are hooked onto the proximal bridge and locked in tension with each other to increase the mechanical stability of the implant. The diaphyseal screws are connected to the fixator rail body using the relative clamps. The first two threaded wires are anchored to the connecting pin that is positioned on the rail body and also locked in tension to improve stability through dedicated clamps.

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.

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. the positioning of the patient must be modified from supine to semi-sitting in case of proximal humerus fracture.
- 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.
- The maximum diameter of the thread of the screw must not exceed a third of the bone diameter (i.e. use bone screws of 6mm with a bone with a body diameter over 20mm).
- Do not use electrical devices to screw self-drilling screws with a diameter of 5 mm or greater; screw them by hand or using a manual drill. Self-drilling screws with a smaller diameter thread can be inserted with a low speed drill. In the case of bones with particularly thick and hard cortices, the use of a perforator is recommended to perform a pilot hole 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 bone-fixator distance. In the event that the fixator is positioned at a distance greater than 4cm from the bone, the surgeon will decide on the number of bars and bone screws necessary to obtain 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.

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- For the SPALLA fixation system: the tip of the wire must be positioned at around 5-10 mm from the articular surface of the humerus' head
- When inserting the wire, it is recommended to use the wire guide to avoid damaging soft tissues and/or joint impingement. After inserting the wire, check joint function.
- To avoid damaging the anatomical structures, insert the wires along the anatomical safety corridors.
- It is recommended not to insert the threads into the soft tissues with a power drill, but to push them through the epidermis to the bone. Use the low speed power drill to insert the wires into the bone.
- The threads are cylindrical and can be retracted if necessary.
- It is recommended to use the dedicated Mikai instrumentation for inserting the threaded wires.
- It is necessary to carefully clean the epidermis around the threaded wires (inserting the wires).

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 wires must be kept in place for an average of 6-8 weeks depending on the fracture with the limb contained in an arm holder.
- In the first 15 days the patient must keep the shoulder absolutely at rest: the arm support can be removed to allow personal hygiene and elbow mobilization.
- From the third week, passive mobilization can be started 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.

UNDESIRABLE 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 tract of passage of the screw and/or wires, including the chronic drainage of the insertion sites of the bone screws after the removal of the device.
- Edema or swelling, possible compartment syndrome.
- Joint contracture, subluxation, dislocation or loss of range of motion.
- Failure of bone regeneration, development of non-union or pseudoarthrosis.
- Fractures of the regenerated bone or caused by the holes of the bone screws, following the removal of the device.
- Loosening or breaking of the implants.
- 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 the implants or assembly components.
- Tissue necrosis following implant insertion.
- Pressure on the epidermis caused by external components in case of inadequate distance.
- Discrepancy in the length of the limbs.
- Excessive operative bleeding.
- Intrinsic risks associated with anesthesia.
- Intractable pain.
- Bone seizure, derived from excessive speed of bone cortical perforation 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 KIT FEP SPALLA system.

RISKS CAUSED BY THE REUSE OF "SINGLE-USE" DEVICES

The whole KIT FEP SPALLA device (clamp, rods, screws and wires) is DISPOSABLE, therefore each individual component must be disposed of after the first use on the patient.

ATTENTION Never reuse devices labeled "SINGLE-USE". MIKAI is solely responsible for the safety and efficacy of individual disposable devices on first use in the patient. Any subsequent use of these devices is forbidden and falls entirely under the responsibility of the Institute or doctor.

It is also essential to follow hospital protocols for the disposal of contaminated materials and biological waste. All surgical instruments used 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 MIKAI "SINGLE USE" implantable device* can be identified by the "  " symbol on the product label. After removal from the patient, as with all the other components that make up the KIT FEP SPALLA product, the implantable device* must be demolished. Reuse of an implantable device* presents contamination risks for users and patients. Reuse of an implantable device* cannot guarantee the original mechanical and functional performance, compromising the effectiveness of the products and presenting health risks for patients.

(*): Implantable device - Any device that has been designed to be fully 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

STERILIZATION

All of the grasping elements (screws) and clamps are supplied sterile. The kit **FEP SPALLA is** supplied in a sterile kit complete with clamps and screws.

Sterilization must be carried out for all NON-STERILE devices (instruments) before implantation; the manufacturer recommends sterilizing the devices by saturated steam autoclave (according to UNI EN ISO 17664):

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

SAFETY INFORMATION MRI – MR CONDITIONAL

The FEP 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 FEP 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 FEP 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	FEP	
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	7.4 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	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 FEP system may generate artifacts on the obtained images	

A patient with implanted FEP 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 FEP system to MRI may cause an unexpected rise in temperature and an increased risk of causing severe patient harm.
- The modularity of the FEP 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 6'37 "for 1.5 T and 8'51" 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 FEP 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.

HANDLING AND STORAGE OF THE DEVICES:

There are no particular temperature and/or humidity restrictions associated with the storage and handling of the devices.

The supplied devices present a label indicating the contents of the package.

Do not use if the package has been opened or damaged.

	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;
- 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.