# External Fixation System for Single Use - Instructions for Use and Warnings CE

EN

**DESCRIPTION**
**FEP for single use** - The FEP external fixation devices are composed by the base element and clamps. The base element is composed by two rods for clamps insertion, the joint and the distraction-compression unit.
**PTA** - The PTA external fixation kit is composed by the base element and two clamps. The base element is comprised of a tower for screw insertion, a distraction-compression unit and a rod for clamps insertion.

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

**INDICATIONS FOR USE**
**FEP for single-use**
Traumatology: Fixation of fractures on long and/or open bones; fractures of the pelvis, pseudoarthrosis, pathological fractures and tumour resections: fractures involving of joints (i.e. ankle, wrist, and knee).
Orthopaedics: pseudoarthrosis, axial correction of limbs, limb hypometria, complex deformities of limbs.
**PTA**
Orthopedics: Correction of tibial varus and femoral valgus.

**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
- Patients with compromised vascularity
- Cancer patients in the area of the fracture
- Amount of insufficient bone tissue;
- Quality of insufficient bone tissue;
- **PTA** - Deformity of knee varism above 18 °, arthritis greater than stage 2 of Ahlback, presence of autoimmune pathology such as rheumatoid arthritis or chondrocalcinosis, severe osteoporosis or obesity, diabetes, vasculopathies.

**PRECAUTIONS**
Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process. The patient should be informed that any heavy physical activity, involving excessive loading, impacts and stresses on the bone segment fixed with an external fixator or other synthesis system, may cause undue tearing or wear on the device. Any impacts loading the implant or affected limb or bone segment should be absolutely avoided. The choice, correct positioning, surgical technique and instruments are critical factors in conditioning the success of the implant and post-op therapy.
Therefore:
- The working life 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 dimensions and form of bone segment and the presumed loading it will undergo;
- The patient must always be informed of the implant's limitations and risks it entails; excessive, uncontrolled loading, impacts, tampering and other factors can involve tearing or wearing of the device with consequent 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 implant;
- The device must be controlled for physical and functional integrity before proceeding with the implant;
- It is essential that all information, cautions, indications and contraindications, precautions are respected and the patient is informed wherever necessary;
- Methods and aids or alternative devices should always be readily available before proceeding with the implant.
- Check the cleaning of the screws to avoid infections.

- **PTA** - During the application of the device, the position of the fixator and the application of proximal screws are of utmost importance to avoid changes in the tibial slope.
- 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.

**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 b 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.

**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 **FEP for single-use and PTA** 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.

**UNDESIDERABLE EFFECTS**
The following events may represent undesiderable effects after an external fixator implant:
- Inflammation affecting the skin;
- Inflammation affecting muscle and bone tissue;
- Osteolysis with loss of g rip 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)
- **PTA** - Stiffness of the knee
- **PTA** - Fracture of the lateral cortex during the distraction phase

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.

**STERILIZATION**
Sterilization must be carried out for all NON-STERILE devices 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 | ≥ 10 min |
| Temperature | 134°C |

**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 |
| REF | Code | | Single use only |
| LOT | Lot No. | | Do not use if package is damaged |
| NON STERILE | Non sterile | | Do not resterilize |
| CE | CE marking | MD | Medical device |