

### SINGLE USE FEP KIT

CODE	DESCRIPTION	Q.TY	DESCRIPTION
5000030MST	Single use Large FEP	1	Large FEP fixator
		6	Self-drilling cortical screws 6x180mm
		6	Single clamp for large fixator
5000001MST	Single use Standard FEP	1	Standard FEP fixator
		6	Self-drilling cortical screws 5x160mm
		6	Single clamp for standard/small fixator
5000060MST	Single use Small FEP	1	Small FEP fixator
		4	Self-drilling cortical screws 4x140mm
		4	Single clamp for standard/small fixator

### ACCESSORIES

CODE	DESCRIPTION	CODE	DESCRIPTION
5000003ST	Standard/small double-hole clamp	5000506ST	Self-drilling cortical screws 06x100mm
5000032ST	Large double-hole clamp	5000507ST	Self-drilling cortical screws 06x120mm
5000521ST	Self-drilling cancellous screws 06x100mm	5000508ST	Self-drilling cortical screws 06x140mm
5000522ST	Self-drilling cancellous screws 06x120mm	5000509ST	Self-drilling cortical screws 06x160mm
5000523ST	Self-drilling cancellous screws 06x140mm	5000510ST	Self-drilling cortical screws 06x180mm
5000524ST	Self-drilling cancellous screws 06x160mm	5000586ST	Self-drilling cortical screws 06x200mm
5000525ST	Self-drilling cancellous screws 06x180mm	5000587ST	Self-drilling cortical screws 06x220mm
5000526ST	Self-drilling cancellous screws 06x200mm	5000588ST	Self-drilling cortical screws 06x240mm
5000527ST	Self-drilling cancellous screws 06x220mm	5000536ST	Self-drilling cortical screws 05x80mm
5000528ST	Self-drilling cancellous screws 06x240mm	5000537ST	Self-drilling cortical screws 05x100mm
5000551ST	Self-drilling cancellous screws 05x80mm	5000538ST	Self-drilling cortical screws 05x120mm
5000552ST	Self-drilling cancellous screws 05x100mm	5000539ST	Self-drilling cortical screws 05x140mm
5000553ST	Self-drilling cancellous screws 05x120mm	5000540ST	Self-drilling cortical screws 05x160mm
5000554ST	Self-drilling cancellous screws 05x140mm	5000566ST	Self-drilling cortical screws 04x80mm
5000555ST	Self-drilling cancellous screws 05x160mm	5000567ST	Self-drilling cortical screws 04x100mm
5000581ST	Self-drilling cancellous screws 04x80mm	5000568ST	Self-drilling cortical screws 04x120mm
5000582ST	Self-drilling cancellous screws 04x100mm	5000569ST	Self-drilling cortical screws 04x140mm
5000583ST	Self-drilling cancellous screws 04x120mm	5000595ST	Double threaded wire 0 2x250mm, 4mm thread
5000584ST	Self-drilling cancellous screws 04x140mm	5000596ST	Double threaded wire 0 2,5x250mm, 4mm thread

### STERILIZATION

Single use FEP Kit is supplied sterile as indicated on the label.  
For the instruments autoclave sterilization (saturated steam) is recommended with the following guidelines:

Temperature: 135°C    Pressure: 2 atm    Exposure: 45 min  
Mikai does not recommend using EtO or other cold sterilization methods.

Technique and instruments developed in collaboration with Dr. Domenico Amato  
Cover image by Orthopedic Department - Santa Corona Hospital - Pietra Ligure



**MIKAI S.p.A.**

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Reg. No: 3106-A

È conforme alla norma/ is in compliance with the standard: UNI EN ISO 9001:2008

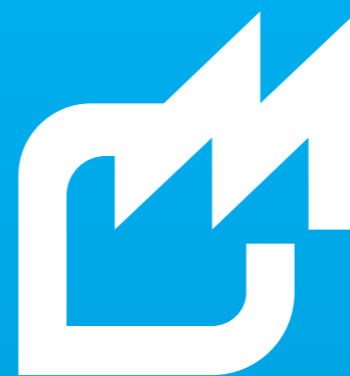
Per i seguenti prodotti-servizi/ For the following products-services:

Progettazione e produzione di dispositivi medici per ortopedia e traumatologia.  
Commercializzazione di dispositivi medici nei seguenti settori: ortopedia e traumatologia, neurochirurgia, radiologia e artroscopia.

Design and production of medical devices for orthopaedy and traumatology. Sales of medical devices in orthopaedy, traumatology, neurosurgery, radiology and arthroscopy.

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# FEP KIT

Polytrauma External Fixator

### INSTRUMENTS

CODE	DESCRIPTION
5000127	Double-head wrench 30-26mm
5000123	Double-head wrench 23-19mm
5000121	T- wrench Ø 12mm
5000122	Double-head wrench 12mm
5000600	T- wrench for Ø 4mm screws
5000601	T- wrench for Ø 5mm screws
5000602	T-wrench for Ø 6mm screws
5000120	Reduction wrench for 4-5-6mm screws (n.2)*
5000124	Hexagonal screwdriver Ø 3mm
5000140	L-wrench Ø12mm
5000144	Cannula Ø 4mm for guide (n. 3)*
5000145	Cannula Ø 5mm for guide (n. 3)*
5000146	Cannula Ø 6mm for guide (n. 3)*
5000141	Cannula Ø 2.5mm for drill
5000142	Cannula Ø 3.5mm for drill
5000143	Cannula Ø 4.5mm for drill
5000148	Guide for screws insertion
5000135	Micrometric ad uster (n. 2)*
5000125	Feeler rod Ø 4mm whit slide mass
5000126	Feeler rod Ø 6mm whit slide mass
5000131	Cannula Ø 4mm
5000132	Cannula Ø 5mm
5000133	Cannula Ø 6mm
5000134	Cannula Ø 7mm
5000147	Cannula Ø 7mm for guide
5000178	Empty sterilization tray
5000180	Complete sterilization tray

\* The quantity refers to the number of items in the case.

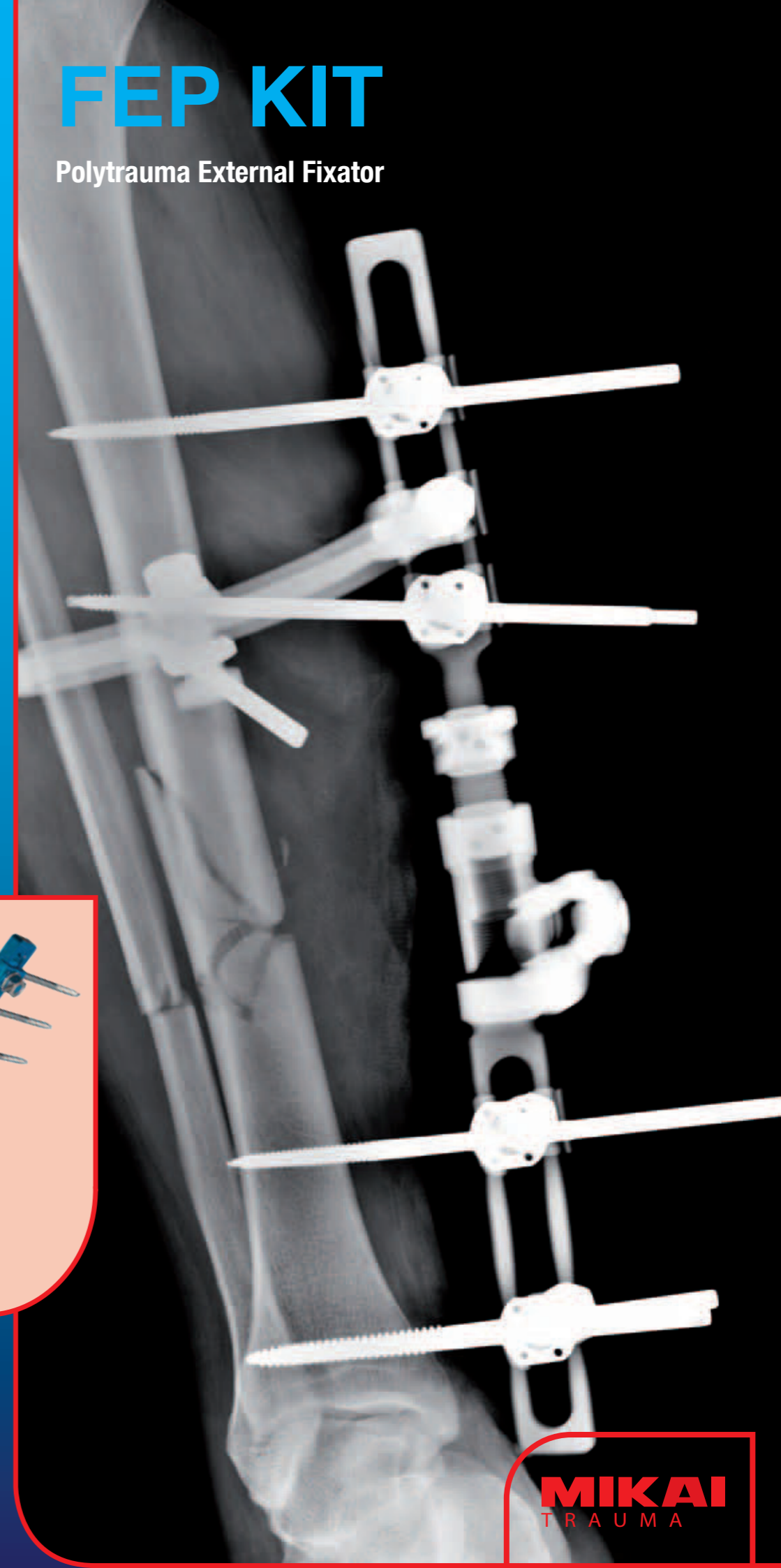
FEP-0005/12



SINGLE USE  
FEP KIT

CE 0476

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**MIKAI**  
TRAUMA

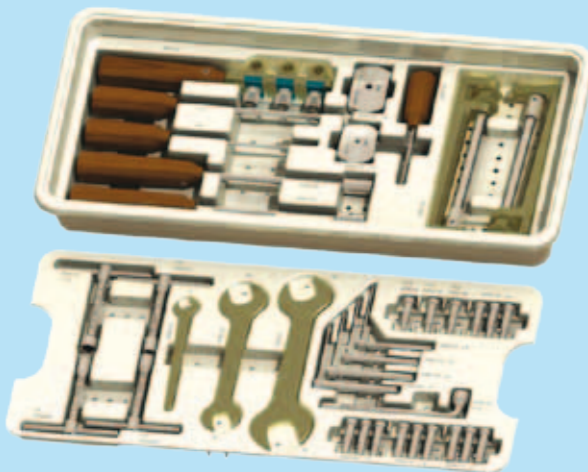
# KIT FEP

Polytrauma external fixator



## FEP KIT Features

- Packaged in a sterile kit including the main body, clamps and screws
- Manufactured of aluminum alloy 7012
- Joint for correction of latero-lateral and pro-curved-recurved shift
- Distraction-compression unit
- Corrections of varo-valgus with micrometric adjusters
- Dedicated instrument tray



## “Damage Control Surgery”

Damage Control Surgery represents a great progress in the treatment of major polytrauma; this procedure, used only for more critical patients (4% of treated cases) requires a complete team dedicated to polytrauma patients in order to be successful. The Damage Control Surgery concept is based on the immediate stabilization by external fixation (Damage Control Orthopaedics) and subsequent conversion, if necessary, using other osteosynthesis methods. The single use FEP kit meets all these requirements.

## Advantages

### Extremely light and resistant fixator

The single-use FEP is resistant yet is very lightweight due to the aluminum alloy material and allows for any type of correction.

### Intrinsically elastic material

The single-use FEP is manufactured of aluminum alloy 7012 which has elastic properties that promote fracture repair while insuring the stability of the skeletal segments

### Magnetically compatible

Subsequent diagnostic exams, such as MRI and CT, can be performed on patients previously treated in emergency situations as the fixator is manufactured entirely of aluminum alloy 7012

### Single-use, ready-to-use fixator according to current Damage Control guidelines

The single-use FEP kit comes in three sizes (large standard, small) with clamps and self-drilling screws and includes a dedicated instrument kit in its own case allowing for stabilization of a trauma patient in the shortest time possible

### Wide range of corrections due to the joint

The joint of the disposable FEP allows for procurved-recurved corrections from 0° to 120° and misalignment corrections in latero-lateral up to 6 cm

### Independent corrections on three planes

The single-use FEP provides a correction on three planes thanks to the characteristics of the fixator and the modularity of its accessories: the joint allows for the procurved - recurved correction, the distraction-compression unit allows correction of the defects of rotation, finally the micrometric adjusters allow for varo-valgus corrections; each correction can be made without losing the previous correction

### Guide to facilitate the insertion of the screws

The guide allows for the coplanar insertion (not necessarily parallel) of screws such to facilitate the surgeon's tasks in emergency and planned activities

### Instruments dedicated to macro and micrometric corrections

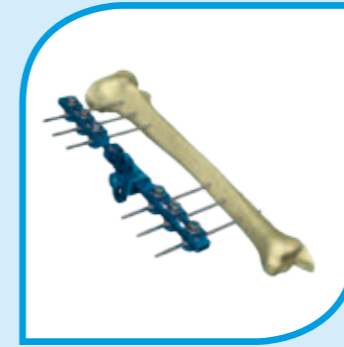
Inside the instrument tray there are 2 levers for macrometric Corrections and 2 “jack” regulators to be used alone or in pairs for the micrometric corrections on the same plane as the screws which is particularly useful in correcting varo-valgus



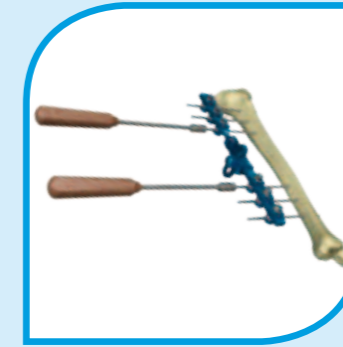
## SURGICAL TECHNIQUE (Example of standard fixator assemblies)



Img. 1. With the patient on the operating table in trans-skeleton traction, perform a reduction on 3 planes. Insert the screws on the frontal plane with the guide from the instrument tray; cross the 1st cortical directly with the screw positioned on the drill, then proceed manually with cross rim T-wrench.



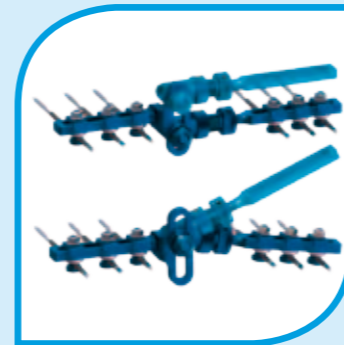
Img. 2. Insert the body of the fixator, opened in all its components (joint and clamps), and place it on the screws. The distraction-compression unit must be opened halfway so that the two actions can be performed.



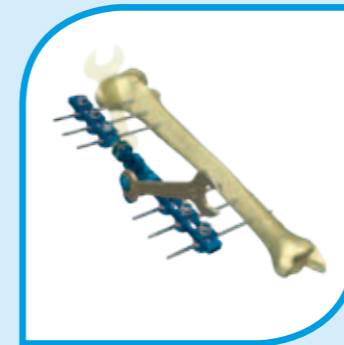
Img. 3. Perform the fracture reduction using the levers for manual reduction applied to the screws; execute strong and gradual pressure or traction on bone fragments until the desired position is reached.



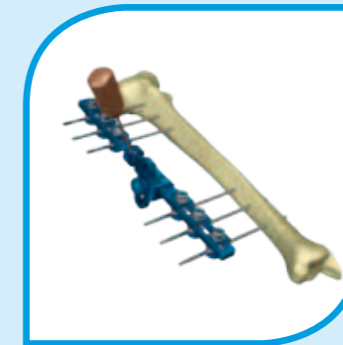
Img. 4. Tighten the nuts with the dedicated T-wrench.



Img. 5. Correct procurved-recurved and latero-lateral on the median joint.



Img. 6. Lock the median joint with the double open wrench. Perform a compression-distraction using the telescopic system. If necessary, perform the adjustment of the rotational position while using the telescopic system.



Img. 7. Close the allen screws of the telescopic system.



Img. 8. If necessary, perform precise adjustments of the varo-valgus with the micrometric regulators. Check and tighten all components.



5000123:  
Wrench 19/23 mm  
Size 19 - Image 6  
For small FEP distraction/compression  
For the joint nuts of the small fixator  
Size 23  
For large FEP distraction/compression  
For the joint nuts of the large fixator



5000121:  
T Wrench, 12 mm for clamp  
Image 4 - For the nuts of all the clamps



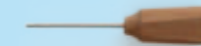
5000122:  
Wrench 12mm  
To tighten the clamp nuts where impossible with the T-wrench



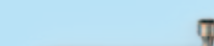
5000600:  
For screws Ø 4mm  
5000601:  
For screws Ø 5mm  
5000602:  
For screws Ø 6mm



5000120:  
Lever for reduction  
Image 3 - For all screw measurements



5000124:  
Image 7 - Hexagonal screwdriver Ø 3mm



5000140:  
L Wrench, 12 mm for clamp  
For all the clamps where impossible with the T-wrench



5000135:  
Micrometer  
Image 8 - For all screw measurements



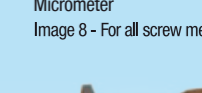
5000141:  
For drills Ø 2.5mm to use with screws Ø 4mm  
5000142:  
For drills Ø 3.5mm to use with screws Ø 5mm  
5000143:  
For drills Ø 4.5mm to use with screws Ø 6mm



5000144:  
Tip Ø 4mm  
5000145:  
Tip Ø 5mm  
5000146:  
Tip Ø 6mm  
5000147:  
Cannula, Ø 7mm for guide  
Tip for spongy bone Ø 6mm



5000148:  
Image 1 - For all the fixators



5000125:  
Punch with pusher, Ø 4mm  
5000126:  
Punch with pusher, Ø 6mm