Manufacturer:
Fixus BV
Spoorstraat 9 | 7261 AE, Ruurlo
The Netherlands

INSTRUCTION FOR USE (IFU)
English

- Please read this document carefully before using the product
- Follow the safety instructions to avoid injuries

Product groups: FIXUS22, FIXUS33, FIXUS66

Introduction
Before using a Fixus BV product, the operating surgeon is asked to study the following recommendations, warnings and instructions carefully, as well as the product-specific information (technical product description, description of the surgical technique, catalogue sheet, etc.).
The manufacturer does not accept liability in the case of non-compliance with this package insert. This includes but shall not be limited to the following cases:
- assembling this device with components, other than recommended by Fixus BV.
- using instrumentation other than recommended by Fixus BV staff or appointed distributors.

1. Product Descriptions / Materials
General
The modern External Fixator is a mechanical, frame-like structure assembled close to the skin, but outside the body. Bones or bone fragments are connected to the frame by steel or titanium connecting pins. The frame requires adjustments to influence the position of the bone fragments.

A bi-lateral pin insertion is catered for in long bone applications, and a high degree of rigidity is guaranteed. Considerable weight reduction is achieved by the extensive use of aluminium and carbon fibre.

The refined pin clamping mechanisms allow for a bi-lateral (V) form pin configuration resulting in an unsurpassed degree of flexibility.

This IFU is valid for the following designs according to the catalogue list:
- FIXUS22 Complete sets;
- FIXUS33 Complete sets;
- FIXUS66 Complete Sets;
- all accessories as specified in the catalogue referring to the FIXUS22/33/66 series.

2. Indications / Contraindications
A. Indications

FIXUS22
Indications for its use in the hand and foot include:
- Metacarpal fractures
- Metatarsal fractures
- Phalangeal fractures
- Open fractures
- Soft Tissue Correction
- Delays in Consolidation
- Small joint arhrodesis

FIXUS33
- Distal radius fractures
- Pediatrics
- Humerus fractures
- Open fractures

FIXUS66
- Upper and lower extremity fractures
- Fractures with polytrauma
- Inter-articular fractures
- Post-traumatic stiffness
- Treatment of dislocated and rigid elbows
- Unstable elbow fractures
- Unstable ankle fractures
- Periarticular fixation in small fragments and osteoporotic bone
- Proximal and Distal tibia fractures

Specific instructions per indication can be found in the Basic technique guides per fixator

FIXUS22 (Blue)	Hand & Foot
FIXUS33 (Green)	Distal radius / Humerus
FIXUS66 (Red/Gold)	Tibia

B. Contraindications
- If uncertainty exists with regard to the anatomic location of the neurovascular structure due to post-traumatic destruction.
- Local sepsis.
- The presence of internal fracture fixation devices.
- Psychiatric Patients.
- Osteoporotic Bone (except for FIXUS66 Hybrid).
- Pre-emptive medical condition.

3. Assembly Instructions / Directions for Use
- Only surgeons who are familiar with the general problems of fracture management and who master the product specific surgical techniques may use products of Fixus BV.
- The external fixator shall be used with any normal suitable connection pin following below table:

Diameter

FIXUS22 (Blue)	1,2 – 2,0 mm
FIXUS33 (Green)	3,0 – 4.0 mm
FIXUS66 (Red)	3,0 – 6,0 mm

Note:
This system is designed to be used in conjunction with CE-certified pins or wires. Physiological dimensions limit the size of pin appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support. Fixus BV supplies pins and wires non-sterile.

4. Warnings
A. Preoperative
- For safe and effective use of this device, the surgeon must be thoroughly familiar with the Fixus External Fixation system, the method of application, instruments, and the recommended surgical technique for this device.
- This device shall only be assembled using components and instruments supplied by Fixus BV.

B. Postoperative
- The external fixator, subject to metal fatigue, cannot be expected to withstand activity levels in the same way as would a normal human bone.

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5. Precautions

- The patient must be cautioned, preferably in writing, about the use, limitations and possible adverse effects of this device including the possibility of the device failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight hearing or lead bearing. The patient must be warned that failure to follow postoperative care instructions can cause the device and/or treatment to fail.
- Patients should be instructed to report any unusual changes to the operated site to their physician. The patient should be closely monitored if a change at the fracture site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity in order to aid fracture healing.
- After a fracture fixation appliance has been removed, the patient should be cautioned to govern their activity levels, as re-fracture can occur. Voids left in the bone after appliance explants, or bone that has not yet fully healed, cannot be expected to withstand stress as would normal healthy bone. Device removal should be followed by adequate postoperative management to avoid re-fracture.
- A fracture fixation appliance should never be reused. While it may appear undamaged, a used appliance may have acquired blemishes or latent compromise of its integrity which would reduce its service life.
- All Fixus Trauma fixators and parts are single use products, products may fail when used more than once.
- Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.
- Device is not to be used in magnetic fields (MRI or other).

6. Adverse Events

- In many instances, adverse results may be clinically related rather than device related.
- These devices can break when subjected to the increased loading associated. Loads on the device produced by load bearing, and the patient's activity level, will dictate the prolonged existence of the device.
- Improper alignment can cause a malfunction of the device.

7. Cleaning

- Prior to cleaning, the fixation device shall be disassembled by removing all screws using the appropriate hexagonal driver.
- Parts shall be collected and transported in a tray for flushing and ultrasonic treatment.
- General hospital cleaning rules/protocols shall be applied. Particular attention shall be paid to clean cavities.
- When dried, the fixation device shall be assembled using the appropriate hexagonal driver.

8. Sterilization and Re-sterilisation

Products are delivered non-sterile. For initial or re-sterilisation of components a steam autoclave is recommended following in-house sterilisation protocols.

Note:

When using cleaning agents, agents to be used shall be the same as in the hospital's cleaning protocol for surgical instruments.
For assembly and disassembly, a protocol should be made by the individual/department maintaining the device.

9. Storage

No special storage requirements are needed. Product should be stored in a dry place.

10. Disposal

No special disposal requirements

11. Symbols


Symbol for «Manufacturer»


Symbol for «Date of Manufacturing»


Symbol for «Consult instructions for use»


Symbol for «Caution»

Symbol for «Non-Sterile»


Symbol for «Do not use if package is damaged»

Symbol for «Catalogue number»

Symbol for «Batch code»

Symbol for «Unique Device Identifier»


Symbol for «Declaration of conformity according to the applicable European directive»


Symbol for «Do not reuse, single use only»

Symbol for «Medical Device»