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: FIXUS88, FIXUS88 Pediatric (P)

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. Fixus BV does not accept liability in the case of non-compliance with this instruction.

1. Product Descriptions / Materials
General
The Fixus RECONSTRUCTION fixators are intended for limb reconstruction within a wide range of indications. They allow for compression, distraction, transport and angulation of mostly the lower extremities of both adult and pediatric patients. Bones or bone fragments are connected to the fixator frame by steel or titanium connecting pins, which are not part of this series.

Considerable weight reduction is achieved by the extensive use of aluminium and carbon fibre. The fixators are designed to be highly flexible and rigid within their intended use.

This IFU is valid for the fixators and instruments covered in the Fixus RECONSTRUCTION series:
- FIXUS88 configurations and instruments;
- FIXUS88P configurations and instruments.

Excluded from this IFU are the RECONSTRUCTION Sterilization Cassettes, for which please refer to 00.8001 - IFU Cassettes.

2. Indications / Contraindications
A. Indications

FIXUS88
- Limb reconstruction and lengthening
- Non-union with major soft tissue defect
- Bone loss with shortening
- Complex tibia and femur fractures
- Periarticular fixation in small fragments and osteoporotic bone
- Proximal and Distal tibia fractures
- Hemicallotasis method

FIXUS88P
Indications for use in pediatric patients:
- Limb reconstruction and lengthening
- Non-union with major soft tissue defect
- Bone loss with shortening
- Complex fractures
- Periarticular fixation in small fragments

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

FIXUS88 (Black)	Lower extremity
FIXUS88P (Black)	Patient weighing up to 45kg

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 FIXUS88 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 approved connection pin following below table:

Diameter

FIXUS88 (Black)	6.0mm
FIXUS88P (Black)	5.0 – 6.0mm

Note:
This system is designed to be used in conjunction with CE-certified pins. 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. Within the EU, Fixus BV can supply 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 system, method of application, instruments, and the recommended surgical technique for this device.
- This device may only be assembled using components and instruments supplied by Fixus BV.

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

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, loosening, stress and excessive activity or weight bearing. The patient must be warned that failure to follow postoperative care instructions can cause the device and/or treatment to fail.
- Improper alignment can cause a malfuction of the device.
- 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.
- All Fixus RECONSTRUCTION fixators and instruments 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.
- The device is not tested on MR compatibility.

6. Adverse Events
In case of serious incidents which occur in relation to this device, directly contact Fixus BV by mail at info@fixus.nl and the competent authority of the country in which the medical device facility and/or patient is established.

7. Cleaning
- Prior to cleaning, the fixator should be disassembled to the extend possible, by removing all screws using the appropriate instruments.
- Parts should be collected and transported in a tray for flushing and ultrasonic treatment. When using a Fixus Sterilization Cassette, please refer to 00.8001 - IFU Cassettes.
- General hospital cleaning rules/protocols shall be applied. Particular attention shall be given to clean cavities.
- When dried, the fixation device shall be assembled using the appropriate instruments.

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. Aluminium parts and coatings can be damaged by acidic (pH<6) and alkaline (pH>8) detergents. Do not clean with detergents and disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions.

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.

9. Storage
Product should be stored in a dry place.

10. Disposal
No special disposal requirements, dispose per hospital protocol.

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»

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