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| <ul style="list-style-type: none"><li>• Please read this document carefully before using the product</li><li>• Follow the safety instructions to avoid injuries</li></ul> |
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## 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. Fixus BV does not accept liability in the case of non-compliance with this instruction.

## 1. Product Descriptions / Materials

### General

The Fixus TRAUMA fixators are intended to fixate, distract and/or compress the bone within a broad range of indications, with applications in hand, wrist, elbow, upper and lower arm, pelvis upper and lower leg and ankle surgeries, using dedicated instruments. Bones or bone fragments are connected to the 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 TRAUMA series:

- FIXUS22 configurations and instruments;
- FIXUS33 configurations and instruments;
- FIXUS66 configurations and instruments.

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

## 2. Indications / Contraindications

### A. Indications

#### FIXUS22

Indications for its use in the hand and foot include:

- Metacarpal fractures
- Metatarsal fractures
- Phalangeal fractures
- Soft Tissue Correction
- Delays in Consolidation
- Small joint arthrodesis
- Finger PIP joint ligamentotaxis

#### FIXUS33

- (Unstable) radius and ulnar fractures
- Wrist reduction
- Wrist stabilization
- Humerus fractures (pediatric)
- Congenital conditions and dislocation around the wrist

#### 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
FIXUS33 (Green)	Wrist / Ulna / Radius / Humerus
FIXUS66 (Red/Gold)	Tibia / Elbow / Ankle / Humerus / Femur

### 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 information material may use products of Fixus BV.
- The devices shall be used with any normal suitable connection pin following below table:

#### Diameter

FIXUS22 (Blue)	1,2 – 2,0 mm
FIXUS22 (Ligamentotaxis)	Only 1,2 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. 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 Fixus system, the method of application, instruments and the information material available for the relevant device.
- The device shall only be assembled using components and instruments supplied by Fixus BV.

#### B. Postoperative

- The external fixator cannot be expected to withstand activity levels similar to that of the average 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 malfunction 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 operated 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 stresses similar to that of average healthy bone. Device removal should be followed by adequate postoperative management to avoid re-fracture.
- All Fixus TRAUMA fixators and instruments are single use products which may fail when used more than once.
- Instruments which have experienced extensive use or excessive force are susceptible to breakage.
- 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 facility and/or patient is established.

## 7. Cleaning

- Prior to cleaning, the fixator shall be disassembled by removing all screws using the appropriate instruments.
- Parts shall 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 paid to ensure 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»