Manufacturer:
Fixus BV
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The Netherlands

INSTRUCTION FOR USE (IFU)
English

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

Product group(s): VAR*II*S

Introduction
Before using a Fixus BV product, the operating surgeon is asked to study the following recommendations, warnings and instructions carefully, as well as other available product-specific information material. Fixus BV does not accept liability in the case of non-compliance with this instructions.

1. Product Descriptions / Materials
The QUICK FIX system is intended to fixate the bone during acute cases of trauma where quick handling is required. Indications include fixation of upper and lower limb as well as the pelvis, using dedicated instruments. Bones or bone fragments are connected to the configurable 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 QUICK FIX series:
- VAR*II*S configurations and instruments.

Excluded from this IFU and the QUICK FIX Sterilization Cassettes, for which please refer to 00.8001 - IFU Cassettes.

2. Indications / Contraindications
The QUICK FIX system may be used for bone stabilization in trauma and orthopedic procedures in both adult and pediatric (not newborns) appliances as required.

A. Indications
Indications for its use include:
- Open or closed fracture stabilization of the lower extremity bones;
- Open or closed fracture stabilization of the upper extremity bones;
- Stable or vertically instable pelvic fractures;
- Non-union stabilization.

B. Contraindications
- Patients with mental or physiological conditions who are unwilling or unable to follow postoperative care instructions;
- patients with severe osteoporosis;
- patients with severe, poorly controlled diabetes mellitus;
- patients with compromised vascularity;
- patients with previous infections;
- patients with malignancy in the fracture area;
- patients with neuromuscular deficit or any other conditions that could influence the healing process.

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 pin diameters:
- 2.0 – 3.0mm for the small parts;
- 3.0 – 4.0mm for the medium parts;
- 5.0 – 6.0mm for the large parts.

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). The pins are MR conditional per the same parameters as the fixators , please refer to ANNEX I.

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 QUICK FIX 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 fixator parts are MR conditional (refer to ANNEX I).

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 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»

Symbol for «MR conditional»

ANNEX I

Parameter	Condition of Use/Information
MR Compatibility	MR conditional 
Static Magnetic Field Strength (B0)	1.5 T, 3 T
Maximum Spatial Field Gradient (SPG)	12 T/m and 1,200 gauss/cm
RF Polarization	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
MR System (RF) Operating Modes	First Level Operating Mode
Whole-Body Averaged SAR	≤ 4 W/kg
Scan Duration and Wait Time	Scan for 60 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) without cooling period
Patient Position in Scanner	A patient with the Fixus VARIIS components must be positioned in such a way that the VARIIS components are located outside the MR Scanner bore at all times
MR Image Artifact	The presence of this device may produce an image artifact
Item Configuration	The FIXUS VARIIS components shall stay outside the MR Scanner bore at all times
Additional Information	The health state of the patient or the presence of other implants may require reduction of the MRI limits.

Fixus VARIIS components can only be guaranteed for MRI when using the below listed components to build a frame:

Reference	Description	Reference	Description
VAR19001	clamp large	VAR19035	12×500mm rod
VAR19002	clamp medium	VAR19012	8×100mm rod
VAR19004	clamp small	VAR19013	8×150mm rod
VAR19003	X/T clamp large	VAR19014	8×200mm rod
VAR19033	X/T clamp medium	VAR19015	8×250mm rod
VAR19030	12mm angled rod 2×45°	VAR19016	8×300mm rod
VAR19026	8mm angled rod 1×45°	VAR19017	8×350mm rod
VAR19029	12mm angled rod 1×45°	VAR19018	8×400mm rod
VAR19028	8mm angled rod 2×45°	VAR19019	5×100mm rod
VAR19008	12×250mm rod	VAR19020	5×150mm rod
VAR19009	12×300mm rod	VAR19021	5×200mm rod
VAR19010	12×350mm rod	VAR19022	5×250mm rod
VAR19005	12×100mm rod	VAR19023	5×300mm rod
VAR19006	12×150mm rod	VAR19036	5×40mm rod
VAR19007	12×200mm rod	VAR19037	5×60mm rod
VAR19011	12×400mm rod	VAR19038	5×80mm rod
VAR19034	12×450mm rod		

Note: the pins Fixus can supply within the EU are MR conditional to the same parameters as are applicable to the fixators, as listed in the above table.