

Important information for the operating surgeon

Caution: These products may only be used by an appropriately qualified and authorised surgeon. Federal Law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer:

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Product groups: Fixus 22, 33, 66 and 99 designs

Introduction

Before using a Fixus 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.

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 (Modified Steinmann's 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 for the surgeon when constructing the actual frame to fit the individual patient.

The resulting stress free fixator offers enhanced rigidity while allowing the use of small diameter pins and other component parts.

Fixus system for external fixation

This Physicians Insert is valid for the following designs:

- Fixus 22 Assembly Complete w. Dynamic Coupling 22100A
- Fixus 22 Assembly Complete Standard 22100B
- Fixus 33 Assembly Complete w. Dynamic Coupling 33100A
- Fixus 33 Assembly Complete Standard 33100B
- Fixus 66 Complete Set 66100A
- Fixus 99 Complete Set 99100A

1.1 Indications/contraindications for Use

A. Indications

Fixus 22

Indications for its use in the hand and foot include:

- Fractures.
- Corrective Osteotomy.
- Lengthening.
- Replantation.
- Soft Tissue Correction.
- Delays in Consolidation.
- When other methods of fracture fixation are not appropriate.

Fixus 33/66/99

- Complex upper and lower extremity fractures.
- Fractures with polytrauma.
- Fractures in patients with pulmonary or cranial complications.
- Temporary cross-leg fixation in plastic soft tissue reconstruction.
- Fixation of tibial pilon fractures.
- Distraction for ligamentotaxis.
- Fixation of Metaphyseal and Diaphyseal Fractures.
- Fracture reduction and compression/distraction.
- Dynamization for callus maturation.
- Angular Corrections.
- Osteotomies.
- Delays in Consolidation
- When other methods of fracture fixation are not appropriate.

Fixus Hybrid 66

- Periarticular fixation in small fragments and osteoporotic bone.
- For comminuted fractures near joints.

Fixus 22 (Blue)	metacarpal or phalangeal fractures
Fixus 33 (Green)	distal radius
Fixus 66 (Red)	femur or tibia
Fixus 66 (Hybrid)	femur or tibia
Fixus 99 (Black)	lower limb extremity

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 Fixus 66 Hybrid)
- Pre-emptive medical condition.

1.2 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
Fixus 22 (Blue)	1,2 - 2,0 mm
Fixus 33 (Green)	3,0 - 3,2 mm
Fixus 66 (Red)	4,0 - 6,0 mm
Fixus 99 (Black)	5,0 - 6,0 mm

2. 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 FIXUS components and instruments as specified in below table;

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.

2.1 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 bearing 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.
- The Fixus 22 is a single use product as well as the Carbon Rod with Dynamic Coupling for both the Fixus 22 and 33. These products may fail when used more than once. Other parts or systems can be used up to the maximum of 6 treatments (approximately 1 year of usage).
- Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage, prior to surgery.

Note:

The Fixus External Fixation System does not provide pins to be placed in the bone. This system is designed to be used in conjunction with CE-certified pins of other manufacturers. 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.

2.2 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.

2.3 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.

2.4 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.

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.

3. Pictograms



Symbol for «Follow User Instructions»



Symbol for «Not to be re-used»



Symbol for «lot number»



Symbol for «catalogue number»