Manufacturer:
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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

1. Introduction
The VAR*II*S system is a product consisting of modular parts for the assembly of an external fixator. The VAR*II*S consist of a minimal amount of different parts and components. The parts can be used with 3th party medical products specially designed and used for external fixation (pins, wires, instruments).
The various modules are designed to be applied in different anatomical sites of the upper and lower limb as well as the pelvis and allow the surgeon to:
- position screws where the condition of the bone and soft tissues permits;
- peduce the fracture in order to restore alignment;
- stabilize the fracture safely.

The VAR*II*S components are not intended to replace or withstand the stress of normal healthy bone for example full weightbearing. The use of external support during treatment is advised (e.g. walking aids). The system can be used for stabilization of fractures in a variety of anatomical sites like upper and lower limbs as well the pelvis. All Fixus products and supporting accessories are for professional use only. Fixus BV does not accept liability in the case of non-compliance with this instructions. This includes, but shall not be limited to, the following:
- assembling this device with components, other than recommended by Fixus BV;
- using instrumentation other than recommended by Fixus staff or appointed distributors.

2. Product Descriptions / Materials

The VAR*II*S system is partly or fully produced from stainless steel, aluminium alloys, plastics and/or carbon fiber. None of the VAR*II*S branded parts come in direct contact with the patient or enter into the body. The VAR*II*S products should be connected to bone screws provided by Fixus BV or a 3th party.

3. Indications / Contraindications
The VAR*II*S is intended to be used for bone stabilization in trauma and orthopedic procedures, both in adult and pediatric (not newbornes) 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
The VAR*II*S is only sold to be used for its intended use and as indicated. Use of the system is contraindicated in the following situation:
- patients with mental or physiological conditions who are unwilling or unable of following 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.

4. 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: 3.0 – 4.0mm for the small 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. Fixus supplies pins non-sterile.

5. 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.

6. 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 load 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.
- 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).

7. Adverse Events
- Nerve or vessel damage.
- Superficial or deep done infections.
- Oedema or swelling.
- Joint contracture, subluxation, dislocation or loss of range of motion.
- Premature bone consolidation during distraction.
- Failure of bone regenerate satisfactorily, non-unions.
- Fracture at bone screw holes.
- Loosening or breakage of device/implant.
- Bone deformity.
- Persistence or recurrence of initial condition.
- Reoperation replacing component or entire system.
- Foreign body reactions.
- Limb length discrepancy.

In many instances, adverse results may be clinically related rather than device related.

8. Cleaning
- Prior to cleaning, the fixation device shall be disassembled -where possible- by removing all screws using the appropriate 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 given to clean cavities.
- When dried, the fixation device shall be assembled using the appropriate driver.

9. 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.

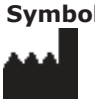
Note:
When using cleaning agents, agents to be used shall be the same as in the hospital's cleaning protocol for surgical instruments. For assembly and disassembly, a protocol should be made by the individual/department maintaining the device.

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

11. Disposal
No special disposal requirements

12. Single-use
- All VAR*II*S assemblies and parts are single use products, products may fail when used more than once.

13. 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»