SOFEMED

CE 2803

1. PRODUCT:

External fixator devices

2. RAW MATERIAL OF IMPLANTS CONTACT BONE:
AISI 316L stainless steel in accordance with ISO 5832-1.

3. GENERAL INFORMATION ON THE PRODUCT
Although external fixators are mostly used successfully, the external fixators are made of metal. We can not expect a device can withstand activity level sand loads like a healthy bone after healing.
The surgeon must evaluate each patient to determine the relationship between risks and benefits.
In connection with the use of external fixation implants, the surgeon should be aware of the following:

- It is extremely important to select the correct devices of appropriate size. Selecting a device size, shape and design increases the potential success of the intervention. The devices require precise placement and adequate bone support.
- **Senility, mental illness or alcoholism.** These conditions, among other things, cause the patient to ignore certain limitations and precautions for use of the fixator, which can cause a failure or other complications.
- **Foreign body sensitivity.** When sensitivity is suspected materials should be carried out appropriate tests before the selection or implantation.

4. DESCRIPTION
External fixators of SOFEMED International are available in various configurations for the upper and lower limbs. These fixators require several diameters and lengths of pins or half of pins. The pins/half of pins are available in stainless steel medical quality.

5. INDICATIONS
The unilateral fixators are indicated for stabilizing various fractures, including fractures or comminuted, absence of welding with bone infection, fractures with unequal length of the bone.
Selecting the right type of fixative according to the type of fracture is at the discretion of the surgeon.

PERFORMANCE
Misuse of the device or patient noncompliance may have an adverse effect on performance. This system cannot replace a healthy bone structure.

6. CONTRAINDICATIONS
- Physiologically or psychologically inadequate patient
- Possibility for conservative treatment
- Failure to obtain patient consent

Situations with increased risk of failure include:
- Infection scalable
- Inadequate skin, bone, or neurovascular status
- System irreparable tendon
- Growing patients with open epiphyses
- Patients with a high level of activity
- Fever and white blood cell count inadequate
- Obesity

The contraindications can be relative or absolute and their evaluation is the responsibility of the surgeon.

7. COMPLICATIONS AND ADVERSE REACTIONS
Potential complications exist in any surgery. The risks and complications associated with these external fixators include:
- Infection or pain, swelling or inflammation at the implantation site.
- Fracture of the implant.
- Loosening or dislocation of the implant requiring revision surgery.
- Excessive bone resorption or ossification.
- Allergic reactions to materials.
- Untoward histological responses possibly involving macrophages or fibroblasts.
- Embolism.
- Pain and abnormal sensitivity due to the device.
- Infection.
- Neurological complications.
- Pseudarthrosis.

These external fixators can break when subjected to the increased loading associated with delayed unions and/or non- unions. External fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed, or does not occur, the appliance may eventually break due to fatigue.

8. WARNINGS AND PRECAUTIONS
-External fixators are for single use only.
- Raw material is subject to corrosion. Implantable metal and metal alloy subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals in contact with each other can accelerate the corrosion process that may enhance fracture of devices.
- Conditions attributable to nonunion, osteoporosis, osteomalacia, diabetes, inhibeted revascularization and poor bone formation can cause: loosening, bending, cracking and fracture of the device or premature loss of fixation with the bone.

PRE-OPERATIVE
- It is essential to have a good knowledge of the devices and technology
- Patient selection must be made in accordance with guidance and contraindications for the use of the device
- Fixators are supplied non-sterile. They must be sterilized before use.

Recommendations on fixators components
- SOFEMED International strongly advised not to use any component from another manufacturer with it fixators.
- Use the proper tools especially during insertion and removal.
- Inspect components prior to use to ensure they were not damaged during transport or storage and that they are free from defects at the opening of the package.
- Inspect them immediately upon removal from the patient to ensure they are not broken.

9. INFORMATION ON COMMUNITY MAGNETIC RESONANCE IMAGING
Safety and compatibility of fixators described in this instruction for use have not been evaluated in the MRI environment. The warm-up and migration of the devices described in this manual have not been tested in the MR environment.

10. DEVICE IMPLANTATION
External fixator surgery must be performed by a competent surgeon under the recommendations accompanying the surgical technique used.

11. DEVICE REMOVE
External fixators are intended to remain in place for the purpose of stabilizing until recovery. Then it should be considered withdrawn. However, an early withdrawal is recommended in the following circumstances:
- pain due to implants
- infection
- implant broken

12. PACKAGING
The external fixators of SOFEMED international are supplied non-sterile. All components must be cleaned, decontaminated and steam sterilized in an autoclave before use. Any component whose packaging is damaged should be discarded.

13. HANDLING AND STERILIZATION
Fixator is for single use only. Do not re-sterilize a device was placed in contact with tissues or body fluids.

14. CLEANING
Cleaning and disinfection of fixators may be carried out with solvents containing no aldehydes. Cleaning and decontamination will be performed using neutral detergents and rinsing with deionized water.
Do not use alcaline detergents.
Visual inspection for cleanliness. All visible external and internal surfaces should be inspected visually. If necessary, clean and disinfect the fixator again until it is visibly clean.

15. STERILIZATION
Devices are recommended to be steam sterilized by health institution using the following process parameters:

Cycle	Temperature	Exposure Time
wet steam	134°C (273°F)	20 min

However, each health care institution must validate the technique and sterilization parameters used. Respect the regulations of your country if a law requires the sterilization parameters and technique to use. There is no limit for instruments sterilization. This validation can be carried according to ISO17665-1 standard.

However, it is necessary to check the condition of the device before use. All damaged device must be disposed of immediately. Do not re-sterilize if an implant is likely have been in contact with human tissue or body fluids. Proceed to the immediate disposal to prevent re- use.

16. COMPLAINTS:
Any professional who wishes to claim for a reason of dissatisfaction with the quality of the product, its identity, its durability, its reliability, its effectiveness, and / or its performance, should contact SOFEMED International or its supplier by indicating at least the product number, the name and address of the complainant and the reason for the said claim. SOFEMED International does not engage in a complaint handling process if the product information (such as essentially the batch number) is not provided by the complainant.

Symboles et significations :

Manufacturer	Do not re-use	LOT Batch number
Manufacturing date	Consult accompanying document	REF Code
Expiry date	Consult instructions for use	EC REP Authorised representative in the EC

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