	Instructions for use for External Fixators	Doc. No.: IU/4 Rev. No.:06 Rev. Date:14AUG2017

For use by an Accredited Orthopaedic Surgeon only

1. Purpose:

External fixators are intended to aid in surgical stabilization following operative procedures to treat fractures, enable correction of skeletal deformities or other related interventions. These devices are meant to share load with the bone during the healing and regenerative phase. These devices are subjected to various mechanical forces while in use. The extent to which the device would withstand these forces is limited by the operating surgeon achieving a stable fixation construct, the use of bone graft to supplement the fixation where appropriate, the correct weight bearing regimen prescribed by the operating surgeon based on the progress of healing and the compliance of the patient. These devices, are meant to be removed after they have served their intended purpose.

2. Preparation:

Before the operation, an operative plan must be drawn up by the operating surgeon, ensuring that –

- All external fixator components necessary are available in the required quantities
- Aseptic operating conditions are present.
- The required set of instruments is complete, operable and compatible.
- All pertinent documents related to the set of instruments, implants and the fixator components being used are present and the surgeon and the operating team are, familiar with them.
- The operating surgeon is experienced in performing external fixation procedures to stabilize fractures using implants and in particular with the operative procedure involving the use of this device.

3. Indications:

- Surgical Stabilization following operative procedures to treat fractures, enable correction of deformities or other related interventions, as per the latest fracture management / deformity correction, treatment protocols.

4. Contraindications:

Contraindications for the use of this device include but are not limited to the following:

- Immunological intolerance
- Patients displaying metal sensitivity or allergic reactions to any of the elements in implant grade materials, eg. Nickel or Chromium
- Presence of degenerative diseases
- Mental illness
- Alcohol and/or drug addiction
- Obesity
- Poor patient compliance
- Expected overloading of the implants

5. Device Selection and Handling:

- All external fixator components should be checked for intact packaging on receipt. In case a loaner or consignment set of instruments and external fixator components is used, all instruments and external fixator components must be carefully checked for completeness and all components should be carefully inspected for absence of damage prior to use.
- Selection of the proper size, shape and design of the external fixator device is a crucial parameter for success of the operative procedure and must be ensured by the operative surgeon

- All pre-operative handling on the external fixator components must be done with care to ensure that the handling does not cause scratches, notches or dents on the surface of the components or on the surfaces that interact with other mating devices that may predispose the device to failure.

6. External Fixator Removal

Fixators are external fixation devices. It is intended that these devices assist in the process of stabilizing the operative site during the normal process of healing. Subsequent to healing, these devices do not serve any further functional purpose and need to be removed. Removal is primarily indicated in most cases, as the fixator components are not intended to transfer or support forces applicable during normal activities. If the fixator components are not removed subsequent to completion of their intended use, the following complications may ensue.

1. Migration of position of the fixator components, resulting in injury.
2. Postoperative trauma with the risk of additional injury.
3. Bending, loosening and/or breakage of fixator components, which may make removal more difficult or even impractical.
4. Possibly increased risk of infection.
5. Bone loss due to stress shielding.

7. WARNINGS AND PRECAUTIONS:

The possibility of implant loosening, bending, fissure and/or breakage and other complications can greatly increase if the following instructions and warnings are not considered and followed:

8. SPECIAL NOTE TO USERS:

Implant components that have been implanted and removed must never be re-used even if they appear undamaged due to the high risk of fatigue failure due to internally accumulated material stresses.

9. PACKAGING AND LABELING:

Implant components supplied in pre-sterile condition are packed in double packaging kept inside suitable size of outer box. Sterilisation is carried out using the gamma irradiation process indicated by STERILE R on the label or ETO Sterilisation Process indicated by STERILE EO on the label with a suitable dose of sterilization cycle depending on the materials contained by the implant. Packaging must be carefully checked for perforation or other damage prior to surgery. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery. Implants supplied in unsterile condition are indicated by NON-STERILE or NON STERILE on the label which must be properly sterilized by suitable method prior to surgery.

Metallic components may be re-sterilised using steam or ethylene oxide sterilization process. Re-sterilization of PE components is not permitted.

10. STERILISATION / RE-STERILIZATION:

Sterility and Handling:

- Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed in correspondingly labeled, radiosterilized (gamma sterilization, 25 kGy min.)/ ETO sterilized (Ethylene Oxide) protective packages.

- Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the "sterile" sticker that seals the outer box is intact, the sterility indicator button is of the right colour indicating a properly sterilized implant (red in case of Gamma Irradiation and Green in case of ETO sterilization) and that the implant is within the sterility period indicated on the label.
- Ensure that the surfaces of the implants are not damaged under any circumstances. Under no circumstances may implants that have been damaged, surgically implanted or removed again be reused.

RE-STERILIZATION:

- Re-sterilization of devices supplied in sterile form carries various risks. Various components of joint replacement prosthesis include UHMWPE parts that are known to carry a high risk of oxidative degradation if not packed and sterilized according to closely controlled and monitored conditions. Small imperfections caused on the surfaces of metallic joint replacement components are known to increase the risk of fatigue failure. Such imperfections could be caused by improper handling by untrained staff. In consideration of the above re-sterilization of joint replacement prosthesis components by user facilities is not recommended.

For non-metal components: If packaging appears to be damaged, non-metal components should not be re-sterilized and used.

For metal components only: Adler recommends that if the packaging appears to be damaged, metal components should not be re-sterilized and used. If the packaging appears to be damaged and metal components are to be used however, then the device must be cleaned and re-sterilized prior to implantation, according to the following Instructions:

CLEANING (metal components only):

If packaging of a metal component appears to be damaged and the metal component is to be used, the metal component should be cleaned prior to re-sterilization as follows:

- Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Recommended Steam Sterilisation Cycle Parameters:

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 Minutes and a minimum vacuum drying time of 30 minutes
- Flash Steam Cycle (Reusable Instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in gravity displacement cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilisation evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: This is not a recommendation as to the sterilization parameters to be followed. The adequacy of any sterilization procedure must be suitably tested. It is critical that appropriate process parameters be validated for each

facility's Sterilization equipment and Product/load configuration by persons who have training and expertise in sterilization processes to substantiate the process and its reliability and reproducibility. Flash sterilization may be conducted, if applicable, according to the specific health care facility's policy.

11. STORAGE CONDITIONS:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

12. IMPORTANT INFORMATION:

The operative surgeon is responsible for carrying out the internal fixation procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant. In case of devices such as pins and wires which while implanted, project outside the patient's body, as a part of an external fixator assembly, it is also the responsibility of the operating surgeon to educate the patient on the possibility of pin tract infection and its associated problems, the importance of maintaining general hygiene and methods of maintaining cleanliness and care of the projecting pins and wires and the external fixator assembly.

Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended prior to bony union, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

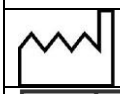
Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components or External Fixator Components predispose such components to premature failure.

Implant components from one manufacturer should not be used with those of another. In case such combinations are necessary, they would be possible only if the surgeon can ascertain that all implants being used are manufactured to correct dimensional specifications and tolerances and from chrome-nickel-molybdenum alloyed austenitic stainless steel complying with or compatible to the relevant standards referred to above.

Manufacturing Traceability Records for the device are available for 15years after the manufacturing date mentioned on the label.

13. Symbols Used in IFUs, Labels and Packaging Materials

Symbol	Definition	Symbol	Definition	Symbol	Definition

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Keep away from heat /sunlight and radioactive sources
	Date of Manufacture YYYY-MM		Manufactured by		Use by Date (Date of Expiry) YYYY-MM
	European Authorised Representative		Do not re-sterilise		Do not use if package is opened or damaged
	Sterilised by radiosterilisation process		Consult instructions for use		Non Sterile
	Caution: check for specific warnings or precautions	REF:	Code Number / Part No.		Avoid moisture or water contact
	Sterilised by ETO Gas Sterilisation process		Recycle		To be sold only against prescription

14. Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to adler-in.info@smith-nephew.com

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