

The Rail & Dynamic External Fixation System

Maintenance of the Apparatus :

The Apparatus consists of various clamps, which are hard anodized on Aluminum Alloy. The Apparatus defined is resistant to mechanical loading if properly assembled. The said Apparatus is used on a patient for a considerable time, resulting into fragile in terms of equipment integrity at the end of the treatment.

Once the equipment is completely used, the entire fixation assembly must be disassembled completely. The Bone screws (Tapered Half pins) used before must be discarded since they cannot be reused.

Once the unit is entirely dissembled for its various components, the parts that are damaged, cracked should not be reused. Ideally cams, bushes should also be discarded.

Such dissembled parts should be immersed in 36 volume of hydrogen peroxide for more than 12 hours and any residue remaining should be brushed in running water.

The said Apparatus should be soaped in the distilled water after this to remove traces of hard water. The Components may be dried and then cleaned in ultrasonic equipment prior to re-sterilization for the next usage.

It should be well understood that equipment one used on a patient should be reused only after thorough checking and conforming the integrity of the Apparatus. Even during the use, the Apparatus should be checked periodically for the surface defects if any like cracks and bending. The pieces found problematic even during treatment, should be replaced immediately.

Description of intended use :

The apparatus has been designed with the following goals in mind:

- Anatomical reduction of bony injuries.
- High stability of the bone fracture segments.
- Preservation of injured limb function.
- Early mobilization of the patient.

Indications :

The devise should be used for following indications:

- 1) Fracture fixation
- 2) For correcting diaphyseal deformities, metaphyseal deformities with or without shortenings
- 3) Correction of bony or soft tissue deformities
- 4) Limb Lengthening
- 5) For treating nonunion and malunion
- 6) Bone transport application

The newly developed Rail Fixation System has been conceptualized using bloodless surgery technique and minimal disruption of soft tissues that contribute to external callus formation. The apparatus allows the treatment of patient with complex bony defects and permits conversion from static to dynamic mode by activating integral telescopic facility. The weight bearing and intermittent axial loading at fraction site enhances bone formation.

Contra-indications :

Patients, in whom co-operation or mental competence is lacking, thereby reducing patient compliance.

Warning & Precautions :

1. Pre-Operative:

- 1.1 Proper understanding of the device and technique are essential. Physicians are strongly encouraged to obtain instructions from experienced clinicians or to observe surgical application of the apparatus prior to initial use of the Rail Fixation system.
- 1.2 Patient selection should be in accordance with the listed indications and contraindications for use of

the Rail Fixation system.

- 1.3 Preliminary frame assembly is recommended to reduce operative time and to assure an adequate supply of components before surgery.
- 1.4 All of the device components should be sterilized before use.
2. Intra-Operative :
 - 2.1 Select an appropriate size of the fixator and template.
 - 2.2 Select an appropriate type of Clamp to suit application.
 - 2.3 Select Tapered half pins of correct lengths.
 - 2.4 Select an appropriate size of Drill bits
 - 2.5 Proper fixation of components is essential.
 - 2.6 Ensure that all components are securely tightened or fastened with appropriate Instruments.
 - 2.7 Taper half pin placement should be in strict anatomical consideration avoiding damage to nerves and vessels.
 - 2.8 The selection of the taper half pin should be to ensure sufficient pin strength and to maintain appropriate axial stiffness of the apparatus.
 - 2.9 The taper half pin should be gently pushed through soft tissue, not drilled.

3. Post-Operative :

- 3.1 Physiologic use of the affected limb and weight bearing when appropriate is advocated.
- 3.2 Apparatus integrity should be checked routinely.
- 3.3 The patient should be instructed to report any adverse or unanticipated effects immediately to the physician.
- 3.4 The post-operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase.
- 3.5 Adequate care should be taken during the treatment. The skin around the tapered half pin should be cleaned with saline. The skin around the pin should then be covered with sterile gauze.
- 3.6 The joint function should be checked regularly while the fixator is in place. Should there be a degree of joint stiffness, it should be overcome by regular programme of physiotherapy.
- 3.7 Dynamization: The time point at which dynamisation should commence will depend upon various factors like type of fracture, bone fixator distance, weight of the patient, the extent of fracture repairs and physical condition of the patient.
- 3.8 The fixator should be removed only after clinical radiolucence evidence of fracture healing.
- 3.9 To ensure full follow up of the case, X-ray should be taken at one or two months from final healing and removal of fixator.

Possible adverse effects :

1. Edema or swelling; possible compartment syndrome.
2. Joint contracture or loss of range of motion.
3. Premature consolidation during bone elongation.
4. Loosening of the taper half pin or joining of the pin.
5. Poor result caused by patient non-compliance.
6. Bone deformity.
7. Intractable infection
8. Fracture of regenerated bone.
9. Skin pressure problems caused by external components.
10. Limb length discrepancy