MAINTENANCE OF THE APPARATUS

The apparatus consists of various forms of stainless steel. It is very resistant to mechanical loading if properly assembled. Because the apparatus is used for a long time on patients, equipment integrity is of maximum concern. It is necessary to use a disinfectant cleaning solution that is well tolerated by the stainless steel material. It is also important to protect the equipment with a layer of neutral vaseline or to use a silicone spray that will not produce a skin reaction. The equipment is made to withstand repeated sterilisation using proper autoclaving techniques. At the end of surgery, unused portions of the apparatus should be cleaned well with soapy solution and brushed (especially the pieces which has holes and threaded rods). Equipment used on patients should not be reused since their integrity cannot be guaranteed. During use, the apparatus should be checked periodically for the surface discontinuities of the rings and arches in particular, cracks in or bending of the wires should also be checked. The pieces should be replaced if they are damaged in any way.

INDICATIONS

The device has been approved for the following indications:

1) Fracture fixation (Open & Closed)
2) Pseudoarthroses of long bones (Both congenital and acquired)
3) Limb lengthening by epiphyseal or metaphyseal distraction.
4) Correction of bony or soft tissue deformities.
5) Correction of bony or soft tissue defects.

The new external Ring Fixator developed using essentially a bloodless surgery technique, allows for the treatment of patients with complex diseases and bony defects that otherwise would have been unsuccessfully treated with traditional methods.

CONTRADICTIONS

1. Patients in whom cooperation or mental competence is lacking, thereby reducing patient compliance.

WARNING & PRECAUTIONS

PREOPERATIVE

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 Ring Fixator.
2. Patient selection should be in accordance with the listed indications and contraindications for use of the Ring Fixator.
3. Preliminary frame assembly is recommended to reduce operative time and to assure an adequate supply of components before surgery.
4. Correction of varus, valgus, procuratum, and recurvatum movement of limb segments during distraction should be planned for preoperatively by selecting an appropriate prophylactic ring tilt and strategically positioning wires with stoppers, fulcrums and hinges.
5. All of the device components should be sterilized before use.

INTRAOPERATIVE

1. Wire placement requires strict anatomical consideration avoiding damage to nerves and vessels.
2. The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus. The 1.8mm wires are usually recommended for the tibia and femur in normal adults, while the 1.5mm wire usually recommended for the upper limb and pediatric lower limbapplications.
3. The wire should be gently pushed through soft tissue, not drilled, to reduce the possibility of nerve or vessel injury.
4. Wire drilling of the bone should be done slowly to avoid heat necrosis of surrounding tissue and bone.
5. Caution should be used in handling the sharp tips of the wires.
   The tip of the wire should be held with a surgical sponge or soft cloth when clipped for removal. It is recommended that eye protection devices be worn by operating room personnel.
6. The diameter of the rings or assembled half rings are recommended to be used about 3cm larger than the maximum diameter of the operated limb segment. Ring sizes smaller or larger should not be used.
7. The wires should not be bent, scratched or marred during frame assembly. Bending can be avoided by using various types of washers to build the ring to the wire.
8. Appropriate tension should be applied to the regular wires: atleast 100kg. And no greater than 130kg.
9. Wires with stoppers or " olives " are not always placed under tension, depending upon the application.
10. The limb segments should be twisted carefully to verify completion of the corticotomy: The tibia should only be externally rotated to prevent undue traction on the peroneal nerve.
11. Proper fixation of components is essential. All wires and miscellaneous parts (bolts, rods, nuts, etc.) should be securely fastened with the appropriate instrument.

POSTOPERATIVE

1. Physiologic use of the affected limb and weight bearing when appropriate is advocated.
2. Meticulous wire-site care is crucial in reducing wire- tract infection. A suggested course is to surround the site with antiseptic soaked foam sponges. Persistent infection may necessitate wire removal.
3. The average recommended rate of bone or soft tissue distraction is 1mm/day, accomplished by 1/4mm movement every 6 hours. However, rates slower than this may be needed in situations of delayed consolidation, or faster than this in cases of premature consolidation of hinges are used.
4. Wire tension and frame integrity should be checked routinely. Some component bending or breakage may occur during use.
5. The patient should be instructed to report any adverse or unanticipated effects immediately to the physician. The patient should be instructed about apparatus distraction and adjustment.
6. Weekly to every other week post - operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase.

POSSIBLE ADVERSE EFFECTS

1. Damage to nerves or vessels caused during insertion of the wires or during elongation of an anatomical segment.
2. Superficial or deep wire tract infection.
3. Edema or swelling ; possible compartment syndrome.
4. Joint contracture or loss of range of motion.
5. Septic arthritis and osteomyelitis.
6. Premature consolidation during bone elongation.
7. Loosening or breakage of the wires.
8. Poor result caused by patient non compliance.
9. Bone deformity.
10. Intractable pain.
11. Fracture of regenerated bone.
12. Joint subluxation or dislocation.
13. Foreign body reaction to wires or other components.
14. Tissue necrosis occuring during wire insertion.
15. Persistent drainage after wire removal; chronic wire site osteomyelitis.
16. Skin pressure problems caused by external components.
17. Limb length discrepancy.
18. Inadvertent injury to the patient or operating room personnel caused by the wire
    (eg. Projectile wire from tip cutting during surgery).

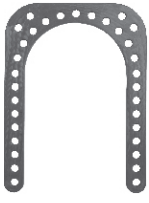
\# Manufactured against Special Order. Contact Mktg.Dept. for accurate delivery schedule.

Note : All composite carbon product range must be used with washers on either end for the expected performance of the product.

This information may be read carefully by end users of Ring Fixation System & Pediatric Ring Fixation System.

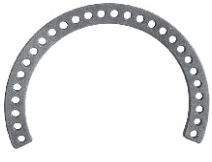
Composite Half Ring

Part No.	Internal Dia.
E 112000080	80mm
E 112000090	90mm
E 112000100	100mm
E 112000110	110mm
E 112000120	120mm



Composite Foot Ring

Part No.	Internal Dia.
E 114000080	80mm
E 114000100	100mm



Composite 3/4 Ring

Part No.	Internal Dia.
E 115000090	90mm
E 115000100	100mm
E 115000110	110mm
E 115000120	120mm

Telescopic Rod

Part No.	Length mm
E 129000040	40
E 129000060	60
E 129000080	80

Oblique Support

Part No. E 161001000

Universal Joint

Part No. E 122001000

Threaded Rods

Part No.	Length mm
E 127000040	40
E 127000060	60
E 127000080	80
E 127000100	100
E 127000120	120
E 127000150	150
E 127000200	200

Threaded Rod -Slotted

Part No.	Length
E 128000040	40
E 128000060	60

Wire fixation buckle

Part No. E 177001000

Bushings

Part No. E 121000000

Post Male

Part No.	Holes
E 135000002	2
E 135000003	3
E 135000004	4

Post Female

Part No.	Holes
E 136000002	2
E 136000003	3
E 136000004	4

Hinges Male

Part No. E 142000001

Hinges Female

Part No. E 143000001

Twisted Plate- 90°

Part No. E 120000090

Wire fixation bolt

Part No.	Type
E 146000001	Cannulated
E 146000002	Slotted

Washers

Part No.	
E 152000010	1 mm
E 152000015	1.5 mm
E 153000000	Slotted

Connection Bolts & Nuts M5

Part No.	mm
E 150000010	10
E 150000016	16
E 151000000	Nut M5
E 151000001	Nylon Nut M5
E 154000000	Triangular Nut

Plate Adaptor

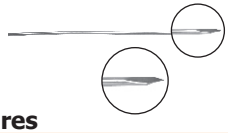
Part No.	Length
E 155000020	20mm
E 155000030	30mm

Block for Half Pins

Part No.	Hole
E 176000001	1
E 176000002	2

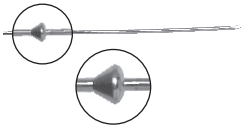
Conical Washer Couple

Part No. E 178001000



Wires

Part No.	Dia	Length
E 159010250	1.0	250
E 159012300	1.2	300
E 159015300	1.5	300



Wires: with Stoppers

Part No.	Dia	Length
E 160001250	1.0	250
E 160012250	1.2	250
D 189015300	1.5	300

INSTRUMENTS

Box wrench 8mm

Part No. E 500000008

Combination wrench 8 mm

Part No. E 501000008

Wire Tensioner Direct Measuring

Part No. E 505001000

Containers for Pediatric Ring Fixation System

Part No.	Container
H842001000	Pediatric ring & plate
H843001000	Pediatric Components