



EXTERNAL FIXATION SYSTEMS

150860-0

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Rx ONLY

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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION
EXTERNAL FIXATION SYSTEMS
(150860-0)

OUTLINE

DEFINITIONS














GENERAL PRODUCT INFORMATION


- A. PATIENT SELECTION
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DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide

STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
 ONLY	For prescription use only
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
Al	Aluminum

I. GENERAL PRODUCT INFORMATION

Through the advancement of surgical hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured

from metal, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after healing occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

In using external fixation implants, the surgeon should be aware of the following:

- **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.
- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
 3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

DESCRIPTION

The external fixators are available in various configurations for upper limbs and various configurations for lower limbs. These fixators (i.e. Rearfoot, Circular, and Unilateral) use several pin designs of various diameters and lengths. Pins are available in implantable stainless steel.

The fixators are made of several materials: aluminum, stainless steel and composite materials.

A. PATIENT SELECTION

Use of surgical hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

B. INDICATIONS

REARFOOT FIXATOR

The Rearfoot Fixator system is intended to be used on adults or pediatric patients as required and are intended to be used for ankle and foot joints fusion; to stabilize fractures of the foot bones, (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union of foot bones; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue foot defects; joint arthrodesis; and management of comminuted intra-articular foot bone fractures.

CIRCULAR FIXATOR

The Circular Fixator system is indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The Circular Fixator is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

UNILATERAL FIXATORS

The Unilateral Fixators are indicated for stabilizing various fractures including open and/or comminuted fractures, infected non-unions, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal, metatarsal, ulnar, and calcaneal bones.

The selection of the appropriate type of fixator is left to the discretion of the surgeon, according to the type of fracture.

PERFORMANCE

Misuse of the device or patient noncompliance may adversely affect performance. In no case will this system replace a healthy bone structure.

C. CONTRAINDICATIONS

Absolute contraindications include:

- Physiologically or psychologically inadequate patient
- Possibility for conservative treatment
- Failure to obtain patient's consent

Conditions presenting increased risk of failure include:

- Active Infection
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Growing patients with open epiphyses
- Patients with high levels of activity
- Fevers and white blood cells
- Obesity

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

D. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Embolism

- Abnormal pain and sensations due to the device
- Infection
- Neurologic complication with possible palsy
- Pseudarthrosis

E. WARNINGS AND PRECAUTIONS

External fixators are intended for single use only.

PREOPERATIVE

- Proper understanding of the devices and technique is essential
- Patient selection should be in accordance with the listed indications and contraindications for use of the device
- Nonsterile implants should be sterilized before use

Recommendations Regarding Device Fragments

- Wright Medical Technology strongly advises against the use of another manufacturer's device with any Wright Medical Technology external fixators.
- Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.

- If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

FRAME ASSEMBLY

Preliminary frame assembly should be performed by the surgeon as recommended in the surgical technique.

IMPLANT REMOVAL

External fixators are intended to be left in place for stabilization until complete healing. After that, removal should be considered. However, early removal is recommended in the following situations:

- pain due to implants
- infection
- implant breakage

POSTOPERATIVE

Directions and warnings to patients regarding

- restricted physical activity
- adverse effects
- knowing that no metal device will ever be as strong as a healthy bone structure

CHECKING

- Implantation under image intensifier control
- Assessment of motor activity
- Check proper tightening of all locking elements

INTERFERENCE

Check compatibility of implants with all the materials of the fixator.

PACKAGING

Unless specifically labeled "STERILE" the external fixators are provided nonsterile; all components should be cleaned, decontaminated and sterilized by steam autoclaving before use. Any component with damaged packaging should be discarded.

- Pin Covers are provided Sterile packaged.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants described in this package insert are either provided sterile or non-sterile as indicated on the individual product's label. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. If the inner package integrity has been compromised, contact the manufacturer for further instructions. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions
10. **Rinse** thoroughly /flush with RO/DI water.

11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

STERILIZATION

Autoclave according to the following parameters:

Method: Steam Sterilization

Type: Prevacuum

Minimum Preconditioning Pulses: 3

Minimal time: 18 minutes

Minimal temperature: 132 °C (270 °F)

Minimum Dry Time: 45 minutes

The specified steam sterilization parameters result in a sterility assurance level (SAL) of 10^{-6} . These parameters were validated according to EN 554 “Sterilization of medical devices - Validation and routine control of sterilization by moist heat”. This cycle is not for use in prion inactivation.

For additional information see WMT's Cleaning and Handling of Wright Medical Instruments.

G. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

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