ENGLISH

INSTRUCTIONS FOR USE

DIGIFIX® EXTERNAL FIXATION SYSTEM

MANUFACTURER

Virak Orthopedics LLC
620 Essex Street
Harrison, NJ 07029 USA
+1 888-316-6798

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

DEVICE DESCRIPTION

Implants

The DIGIFIX® External Fixation System includes various elements including brackets, locking pin, set screws and k-wires. The elements are used to create an assembled frame which capture and support the k-wires on the medial and lateral aspect of finger. The brackets, locking pins and set screws are assembled intraoperatively. Components are manufactured from 6061-T6 Aluminum (bracket, non-patient contacting), stainless steel that conformsto ASTM F-138 (K-wires and distal locking pins) and 18-8 stainless steel (proximal and distal locking screws). External fixator components are provided non-sterile and are intended for single use only.

Instrument System

Instruments used with the DIGIFIX® External Fixation System include the following: Pin Placement Guide, Bracket Expander, Bracket Compressor, Hex Driver, Wire Bender and Wire Cutter. The instruments are reusable and provided non-sterile.

INDICATIONS

The DIGIFIX® External Fixation System is intended to be used in skeletally mature patients in treatment of:

DYNAMIC MODE:

1) complex fracture-dislocations or fracture-subluxation, unstable dislocations, and pilon fractures of the interphalangeal (IP) joint;
2) Post-traumatic joint contracture of the proximal interphalangeal (PIP) joint;

STATIC MODE:

1) Fractures of the phalanges and
2) interphalangeal (IP) joint arthrodesis.

CONTRAINDICATIONS

Contraindications for the DIGIFIX® External Fixation System are as follows:

- Active or suspected infection
- Conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status

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

WARNINGS

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
- K-wire security in bone and device integrity should be routinely checked by the surgeon or hand therapist. Pin track infections need prompt recognition and treatment and may require early device removal.
- As with all percutaneous skeletal fixation, pin care is important in reducing the incidence and severity of pin track infections.
- K-wire placement in bone requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons. Use caution when handling the sharp tip of the K-wires.
- Fracture reduction may be compromised and/or the device may be damaged if the patient accidentally hits the hand against an object or catches the device on clothing or bedding. Instruct the patient to use care to protect the hand.
- For each case, the *Diamond* should be allowed to change shape in one direction (ie either distraction or compression) to avoid breakage.
- The DIGIFIX® External Fixation has not been evaluated for safety and compatibility in the MR environment. The DIGIFIX® External Fixation has not been tested for heating or migration in the MR environment.

Dispose of used device in accordance with healthcare facility policy and local regulations.

COMPLICATIONS

Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision.

The anticipated adverse device effects are the same as those anticipated devices and surgical techniques associated with the currently available external fixation procedures.

Adverse Events

The following list includes potential complications typically associated with external fixation devices.

- Prolonged healing
- Distraction of the fracture site
- Pin insertion can result in damage to nerves and vessels
- Infection, painful, swollen or inflamed implant site
- Device fracture
- Loosening or dislocation of the implant requiring revision surgery
- Edema
- Loss of range of motion, joint contracture, joint subluxation, and joint dislocation
- Compartment Syndrome
- Septic Arthritis
- Delayed unions and intractable pain
- Initial condition may persist or recur requiring further treatment
- Replacement of apparatus or components resulting in reoperation
- Pin insertion leading to tissue necrosis
- External components leading to skin pressure
- Allergic reaction(s) to implant material(s)
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Loss of bone mass
- Abnormal growth plate development
- Bone fractures of regenerated bone after device removal
- Discrepancy in limb length
- Excessive motion at the fracture site due to improper device set-up

- Heat build-up and bone necrosis with bone sequestration due to rapid drilling of the bony cortex
- Bone deformity
- Thrombosis, late erosion or arteriovenuos fistulas
- Osteomyelitis and persistent drainage at wire site after wire removal
- Inability to compress the bone surface due to poorly secured pins seated in the bone

Adverse Events related to DIGIFIX® External Fixator
No additional risks are associated with DIGIFIX® External Fixator.

HOW SUPPLIED, CLEANING AND STERILIZATION
Implants
- The implants are provided non-sterile and are intended to be sterilized by the end user according to the steam sterilization parameters set forth in the table below.
- Implants should be inspected to ensure there is no damage. If the implants' integrity has been compromised, contact the manufacturer for further instructions.
- Implants are for single use only.

Instrument System
Instruments are provided non-sterile and must be cleaned and sterilized before each use in accordance with the instructions below.

Cleaning
1. **Disassemble** all components as per manufacturer instructions (if appropriate).**Open** all hinged instruments.
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 reclean 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.

The minimum recommended steam sterilization conditions for reusable instruments are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:
1. Insert the assembled tray into the AESCULAP solid-bottom container and attach lid.
2. Autoclave according to the following parameters:

Steam Sterilization – PREVACUUM

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 ˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20-30 minutes

FOR GRAVITY DISPLACEMENT STEAM STERILIZATION ONLY:
1. Double wrap the assembled tray in a CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization – GRAVITY DISPLACEMENT

Cycle Type	Parameter	Minimum Set Point
Gravity Displacement 270 ˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	15 minutes
	Dry Time	15-30 minutes

3. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79:2010 guidelines and have been developed and tested using specific equipment.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

OTHER SUPPLIES AND EQUIPMENT NEEDED
- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with pin driver attachment.

RECOMMENDED PROCEDURE
Steps for application of the DIGIFIX® *EXTERNAL FIXATION System* are as follows:

1. Using fluoroscopy, a true lateral of the PIP joint is obtained.
2. A 0.054" or 0.062" K-wire (ie. axis pin) is inserted through the axis of rotation of the PIP joint.
3. Once the axis pin is in place, slide the DIGIFIX® Bracket over the axis pin, through the *Axis Pin Hole*. Next, using the DIGIFIX® Bracket as a guide, percutaneously insert a 0.045" or .054" K-wire through the most proximal of the *Distal K-wire Holes* and drive it across the middle phalanx to exit on the other side of the finger.
4. After placing the first K-wire distally, a second **same-diameter** K-wire is then inserted in a similar manner through one of the remaining *Distal K-wire Holes*. The hole is chosen such that the second K-wire is in the middle phalanx (not the DIP joint or distal phalanx).
5. Before cutting the wires, check to see that the DIGIFIX® is not too close to the skin.
6. Tighten the *Distal Set Screw* to lock the K-wires to the DIGIFIX® Bracket.
7. A second DIGIFIX® Bracket is placed on the other side of the finger for multiplanar stabilization. The Bracket is slid over the axis pin and K-wires using the corresponding holes. In a similar manner, the Bracket is kept 3mm off the skin to allow for post-operative swelling.
8. The K-wires are cut flush with the outer portion of the DIGIFIX®, and the *Distal Set Screw* tightened.

Step 9 is for DYNAMIC MODE ONLY:

9. The axis pin is bent 90° over the outside portion of the DIGIFIX® on each side of the finger to prevent the bracket from sliding off the pin. Each *Diamond* is crimped in dorsal-volar plane to achieve the desired amount distraction. In most cases, 1 – 2 mm of distraction is sufficient. Fluoroscopy is used to confirm that the joint is symmetrically distracted on the AP view and concentrically reduced on the lateral view. The PIP joint is passively ranged to ensure that the joint is freely moving and reduced throughout the arc of motion.

Step 10 is for STATIC MODE ONLY:

10. In certain clinical scenarios, the surgeon may want to have static fixation of the finger. In such cases, with the DIGIFIX® brackets already secured on each side of finger, an additional K-wire is inserted through the *Proximal K-wire Hole* in each bracket. The joint or bone segment is held in the desired position during insertion of this K-wire. The K-wire is cut flush with the Bracket and the *Proximal Set Screw* is tightened to fasten the K-wire to the Bracket.

    If compression is required, the *Diamond* is expanded using the Compression-Spreader instrument. Providone-Iodine sponge dressing is placed around the pins, between the skin and Brackets.

SYMBOLS

Refer to package labels to determine which symbols are relevant to the device in the package.

	Caution
	Catalogue number
	Consult instructions for use
	Contents of package
	Do not reuse
	Lot number
	Manufacturer
	Non-sterile
	Prescription only - device restricted to use by or on the order of a physician

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON THE VIRAK ORTHOPEDIC RESEARCH L.L.C. PRODUCT(S) DESCRIBED IN THIS PUBLICATION. UNDER NO CIRCUMSTANCES SHALL VIRAK ORTHOPEDIC RESEARCH L.L.C. BE LIABLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW. NO PERSON HAS THE AUTHORITY TO BIND VIRAK ORTHOPEDIC RESEARCH L.L.C. TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH HEREIN.

Descriptions or specifications in Virak Orthopedics LLC printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties.

Virak Orthopedics LLC will not be responsible for any direct, incidental, or consequential damages resulting from reuse of the product.

Product and/or its use are covered by U.S. Patents: 8,277,449; 8,282,636; 9,066,757