MADE IN CHINA

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

INSTRUCTIONS FOR USE

DIGIFIX™ EXTERNAL FIXATION SYSTEM

MANUFACTURER
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Dispoze 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
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- Heat build-up and bone necrosis with bone sequestration due to rapid drilling of the bony cortex
- Bone deformity
- Thrombosis, late erosion or arteriovenous 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, 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.

The minimum recommended steam sterilization conditions for reusable instruments and single-use implants 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

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
</table>
| 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 (i.e. axis pin) is inserted through the axis of rotation of the PIP joint.
3. Once the 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 2-3mm 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 squeezed in the dorsal-volar direction with pliers to achieve the desired amount of 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 Bracket Expander instrument. Light gauze dressing is placed around the finger.

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>!</td>
<td>Caution</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>i</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>CONT</td>
<td>Contents of package</td>
</tr>
<tr>
<td>2</td>
<td>Do not reuse</td>
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<tr>
<td>LOT</td>
<td>Lot number</td>
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<tr>
<td>Manufacturer</td>
<td></td>
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<tr>
<td>Non-sterile</td>
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<tr>
<td>R</td>
<td>Prescription only - device restricted to use by or on the order of a physician</td>
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