

# ARROW-LOK™ DIGITAL FUSION SYSTEM

## INSTRUCTIONS FOR USE

### DESCRIPTION

The ARROW-LOK implant features a three-dimensional arrow shape at each end joined by a solid shaft. The implants are available in multiple lengths and in 2 different angles. The implant is manufactured from stainless steel per ASTM F138.

### INDICATIONS

The ARROW-LOK implant is indicated for fixation of osteotomies, arthrodeses and reconstruction in the lesser toes following corrective procedures. It is not intended for use in the spine.

### CONTRAINDICATIONS

1. Comminuted bone surfaces that may prevent correct device placement.
2. Pathological conditions of bone such as osteopenia or tumor which would impair the ability of the bone to securely engage the device.
3. Sensitivity of the patient to metals used in implant alloys.
4. Infection of either bone or soft tissue.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. A patient presenting a phalanx with a diameter of the intramedullary canal measuring less than 2.5mm.

### WARNING

The ARROW-LOK implant has not been evaluated for safety and compatibility in the MR environment. The ARROW-LOK implant has not been tested for heating or migration in the MR environment.

### PRECAUTIONS

#### PRE-OPERATIVE PRECAUTIONS

1. The surgeon must evaluate each patient's clinical presentation when determining implant selection as correct selection of the implant is extremely important.
2. Prior to performing surgery, the surgeon must be familiar with the implant, instruments, and surgical procedure. If needed, the surgeon should contact the manufacturer for surgical technique information.

3. The ARROW-LOK implant should be used in accordance with its labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
4. During the patient evaluation, the surgeon must consider the ability and willingness of the patient to follow post-operative instructions regarding weight bearing and activity levels.
5. The surgeon should explain the surgical risks and possible adverse effects to the patient. The patient should be warned that the ARROW-LOK implant does not replace healthy normal bone and that the implant can become damaged or fracture as a result of certain activities or trauma and subsequently may need to be removed. The surgeon should also advise the patient of any other risks that the surgeon believes should be disclosed.
6. Inspect devices prior to surgery for damage during storage or shipment.

#### INTRA-OPERATIVE PRECAUTIONS

1. The ARROW-LOK Reamer, Broach and Insertion Forceps are available and must be used as suggested by the manufacturer to assure the accurate implantation of the implant.
2. While rare, extensive use or excessive force may cause breakage of instruments. Instruments should be examined for wear or damage prior to surgery.
3. Patient should be immobilized during implantation.
4. Using aseptic OR technique, remove device from package only after the correct size has been determined and the operative site has been prepared for final implantation. Always avoid contact with hard objects that may damage the product and handle the product with powder-free gloves.
5. The ARROW-LOK implant is for single-use only and should never be reused. Reuse of these devices may seriously harm the patient.
6. The device should never be reused or re-sterilized after contact with body tissues or fluids. Arrowhead Medical Device Technologies, LLC does not take any responsibility for the use of implants re-sterilized after contact with body tissues or fluids.

#### POST-OPERATIVE PRECAUTIONS

1. The surgeon must advise the patient of the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred.

2. Periodic follow-up is recommended to monitor the implant position as well as the bone condition. Post-operative x-rays should be taken periodically to compare with early post-op conditions to detect long term evidence of implant loosening, cracking, bending, or changes in position.

### ADVERSE EFFECTS

The following device-related adverse effects may occur:

- Allergic reactions to materials or metal sensitivity.
- Pain.
- Infections, both deep and superficial.
- Device fracture or migration.

Additional adverse effects may occur related to general surgical procedures (delayed wound healing, hematoma or damage to blood vessels, nerve damage, peripheral neuropathies, cardiovascular disorders, etc.).

### DIRECTIONS FOR USE

1. Examine the pre-op radiographs to estimate the inner diameter of the intramedullary canal of the affected phalanges at the location where you expect the implant's arrow tip to engage. Determined with a ruler and taking into consideration radiographic magnification, the inner diameter at the point of engagement in the bone should be at least 2.5mm to ensure an effective fit, ease of insertion and mitigation of the possible impingement of the arrow tip upon the cortices. Use the ruler to determine the length of ARROW-LOK implant that will engage each phalanx at the intended point of contact and the broaching depth for each phalanx.
2. Create a standard 3cm central incision over the surgical toe.
3. Dissect through the skin and subcutaneous tissues down to the extensor tendon at the deep fascial level. Perform a transverse tenotomy/capsulotomy at the dorsal crown of the proximal phalanx. Dissect and transect the medial and lateral collateral ligaments away from the bone to expose the head of the proximal phalanx into the surgical site.
4. Dissect the soft tissue away from the base of the intermediate phalanx, exposing the cartilaginous surface for resection and arthrodesis preparation.

5. Resect the head of the proximal phalanx and base of the intermediate phalanx bones.
6. Smooth all rough edges of bone.
7. Create a pilot hole down the center of the intramedullary canals of both the proximal and intermediate phalanx with the ARROW-LOK Reamer.
8. Because a phalanx being prepared for the smaller 2.5mm diameter arrowhead needs only to be reamed, skip the next step (broaching) for phalanges expected to receive a 2.5mm diameter arrowhead.
9. Prepare the pilot hole with the recommended ARROW-LOK Broach for each phalanx that will accept at least a 3.5mm diameter arrowhead. Broach each phalanx as deeply as the anatomy will permit while carefully considering the depth estimated during pre-op planning. Make note of the depth marking to which the broach was inserted in each phalanx.
10. Grasp the ARROW-LOK implant with the ARROW-LOK Insertion Forceps at the depth corresponding to the broaching depth of the proximal phalanx.
11. Insert the implant into the proximal phalanx, locking it into the intramedullary canal.
12. Grasp the digit and insert the distal aspect of the implant into the entry portal prepared in the intermediate phalanx locking the implant into the intramedullary canal.
13. Release and remove the Insertion Forceps. Grasping the digit firmly, compress the two bones together to advance the implant both proximally and distally to its final and locked position.
14. Close the wound in accordance with generally accepted surgical technique.
15. Radiographically evaluate the final positions of the implant and ensure that the proximal and intermediate phalanges are in close contact without gapping.

## PACKAGING

Only accept components if received with the factory packaging and labeling intact.

## STERILIZATION

The ARROW-LOK implant is provided sterile and has been sterilized by gamma radiation. Devices are considered sterile unless the inner package has been opened or damaged.

NEVER steam sterilize or re-sterilize an ARROW-LOK implant should it inadvertently become contaminated. The implant should be discarded according to hospital procedures.

Instruments are provided non-sterile. Prior to use, the instruments should be removed from the packaging and shipping material. Prior to sterilization, the parts should be thoroughly cleaned. Parts should be manually cleaned using lukewarm water (between 27°C and 44°C) with an appropriate detergent that is labeled as safe for use on stainless steel. Follow the detergent manufacturer instructions as provided on the labeling. All parts can be wiped or brushed with a soft cleaning cloth or brush. The parts should be thoroughly rinsed after cleaning to remove debris and detergent residue. A final rinse with treated water (i.e. de-ionized, distilled or reverse osmosis water) is recommended. Dry with a clean, disposable, absorbent cloth. The parts should be visually inspected (internal and external) to assure cleanliness. If necessary, the steps above should be repeated until the part is visibly clean.

The cleaned instruments should be placed in the sterilization tray. The tray is not a sterile barrier and must be wrapped. The following steps should be used to sterilize the components.

| Method     | Exposure Time | Exposure Temperature | Drying Time |
|------------|---------------|----------------------|-------------|
| Pre-vacuum | 4 minutes     | 132°C (270°F)        | 30 minutes  |

The specified sterilization parameters result in a sterility assurance level (SAL) of  $10^{-6}$ .

At any time, if any instrument appears to have any pitting, corrosion or other signs of degradation, the instrument should be disposed of or returned to the manufacturer and a replacement instrument should be used.

If alternative cleaning and/or sterilization methods are used, it is the user's responsibility to qualify these methods as effective with the ARROW-LOK instruments.

## STORAGE CONDITIONS

All implants must be stored in the original unopened packaging, away from moisture.

## MANUFACTURER



**ARROWHEAD**  
MEDICAL DEVICE TECHNOLOGIES

Arrowhead Medical Device Technologies, LLC  
328 Poplar View Lane East, Suite 2  
Collierville, TN 38017  
Phone: (901) 853-4366  
Fax: (206) 222-9173

[www.ArrowheadDevices.com](http://www.ArrowheadDevices.com)

**Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

| Symbol | Definition                     | Symbol | Definition                         |
|--------|--------------------------------|--------|------------------------------------|
|        | Batch code                     |        | Do not re-use                      |
|        | Catalog number                 |        | Caution, consult product documents |
|        | Consult operating instructions |        | Use by                             |
|        | Date of manufacture            |        | Manufacturer                       |
|        | Sterilized using radiation     |        | Non-sterile                        |
|        | For prescription use only      |        |                                    |