ST

SURGICAL
TECHNIQUE

enovis™

# DYNACLIP DELTA™

ACTIVE, ADAPTIVE HEALING FOR FIRST MTP FUSION

STAPLE SYSTEM

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NEXT GENERATION
STRENGTH THAT CLIPS
THE COMPETITION



MedShape, Inc. is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

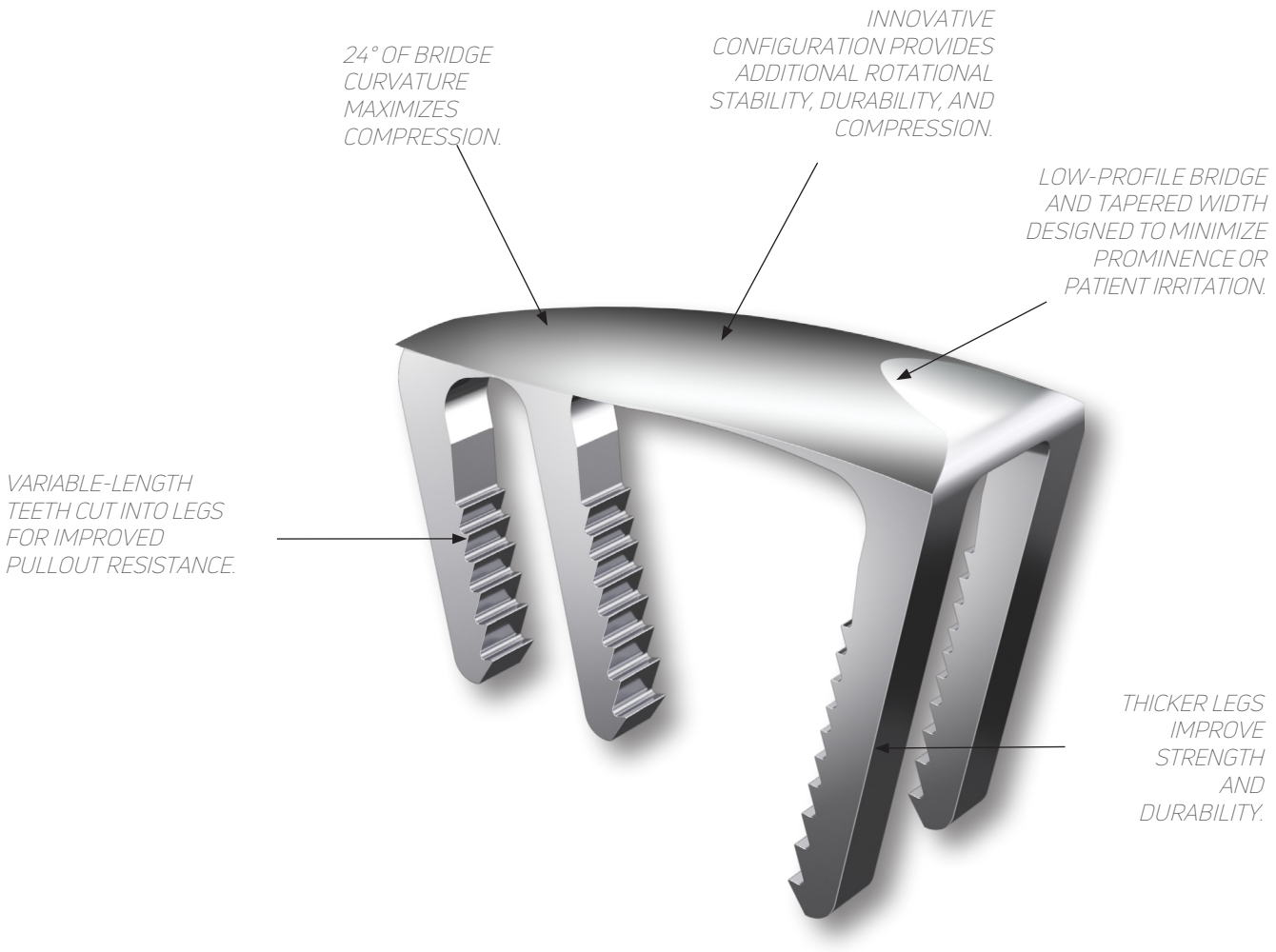
Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

# DESIGN FEATURES



Our latest innovation in NiTiNOL, DynaClip Delta™ is a robust staple system that meets surgeon demands for challenging, high load-bearing applications requiring greater compression and stability than traditional 2-leg designs.



## DYNACLIP DELTA™ INSERTER

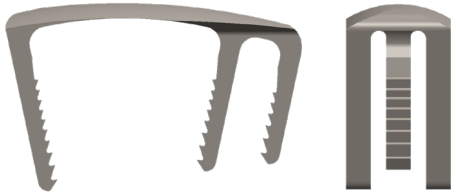
The DynaClip Delta™ comes pre-loaded on a disposable Inserter that allows for fast and easy deployment.

1. **Inserter Tip:** Retains the DynaClip Delta on the Inserter with the bottom also serving as a tamp to impact the staple flush with the bone.
2. **Sliding Neck:** Pull up on the Sliding Neck to expose the DynaClip Delta on the Inserter Tip and release from the Inserter.
3. **Blue Arrow:** Indicates the direction the Inserter slides away during deployment.
4. **Strike Surface:** Mallet the Strike Surface when tamping to fully seat the DynaClip Delta.

# TECHNICAL SPECIFICATIONS

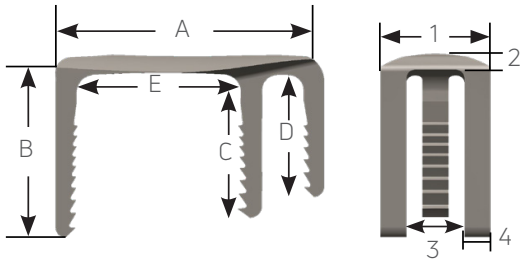


*24 x 16 x 14 x 12 x 16*
*10.5 x 1.8 x 5.5 x 2.5*



*28 x 16 x 14 x 12 x 20*
*10.5 x 1.9 x 5.5 x 2.5*

## LEGEND

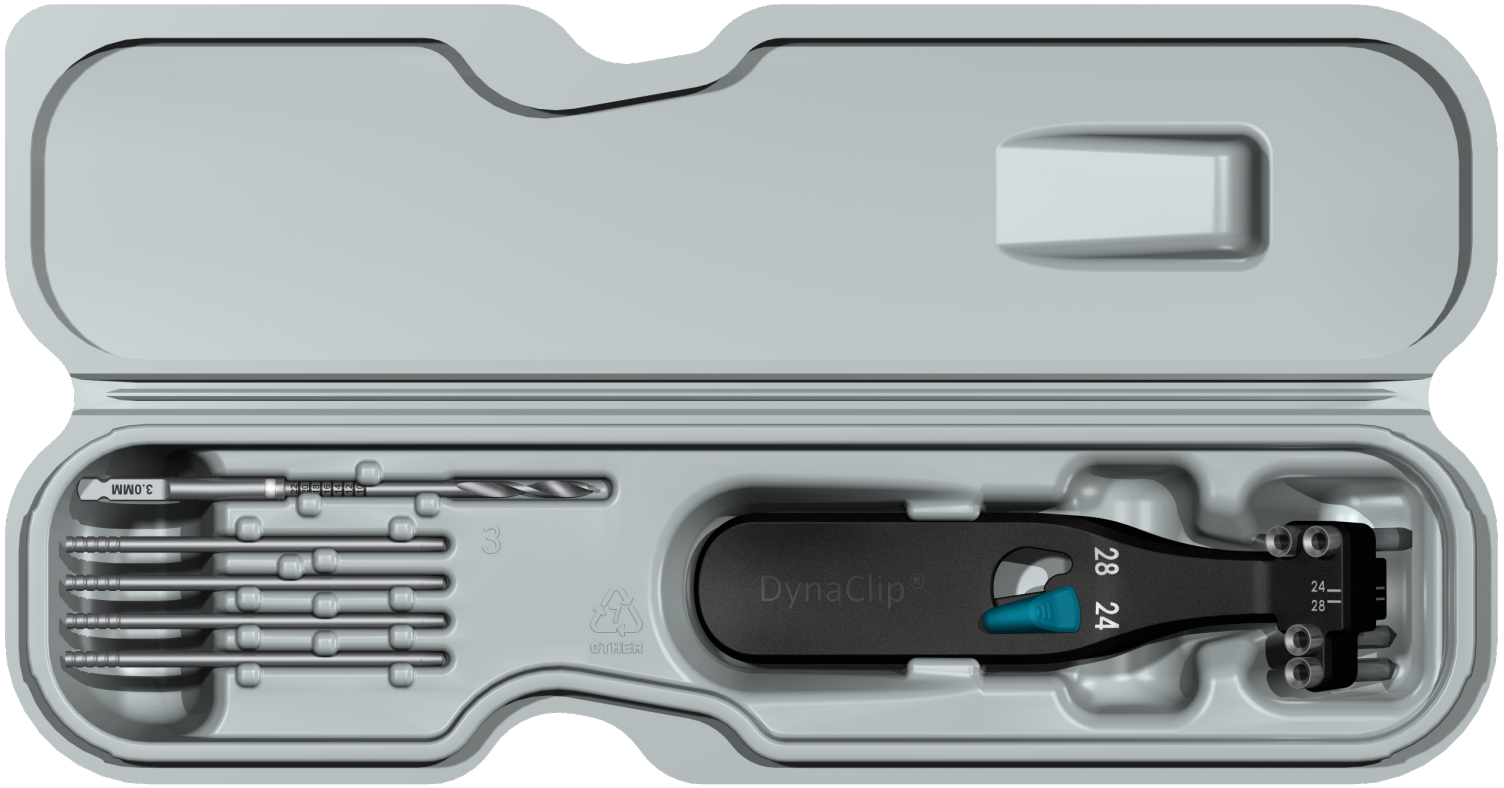



*A x B x C x D x E*
*1 x 2 x 3 x 4*

Dimensions in millimeters (mm)

## PROCEDURE PACK

Disposable, single-use sterile kit contains all instruments required to implant the DynaClip Delta™. No need to open multiple packs.



## DRILL GUIDE

- Serves as both implant sizer and drill guide
- Ergonomic, low-profile handle maximizes visibility of fusion site

1. **Guide Sleeves:** Use the Guide Sleeves to determine desired DynaClip Delta bridge length, then use as guides for the Drill.
2. **Button:** Move the Button to adjust the separation distance between the Guide Sleeves.
3. **Bridge Length Markings:** Determine the appropriate DynaClip Delta bridge length from the marked sizes and Size Indicator.

## DRILLS & PINS

1. **3.0 mm Drill:** Laser Markings may be used to measure Drill depth.
2. **3.0 mm Locator Pin:** Fixate the Drill Guide in place during drilling to ensure accurate distance between drill holes and for visualization under fluoroscopy.


*3.0 MM DRILL*

*3.0 MM PIN*

## INDICATIONS

### DYNACLIP DELTA™ BONE FIXATION SYSTEM

The DynaClip Delta™ Bone Fixation System is indicated for:

- Fracture, osteotomy fixation, and joint arthrodesis of the hand and foot.
- Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle; and in flat bone such as the pelvis and scapula.

## CONTRAINDICATIONS

### DYNACLIP DELTA BONE FIXATION SYSTEM

The DynaClip Delta Bone Fixation System is contraindicated for:

- Infection.
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of device.

# PROCEDURAL SIZING CHART



The diagram and chart highlight some of the suggested indications and recommended sizing for the DynaClip Delta™ implants by procedure.

| INDICATION | | NO. OF STAPLES | BRIDGE LENGTH (MM) x LEG LENGTH (MM) |
|---|---|---|---|
| 1 | FIRST MTP FUSION | 1 | 24 x 16 x 14 x 12,<br>28 x 16 x 14 x 12 |

## 1. PREPARE THE FUSION SITE

Create the osteotomy and/or prepare the fusion site needed to implant the DynaClip Delta™.

## 2. SIZE AND PREPARE FOR DRILLING

Determine the appropriate DynaClip Delta bridge length by placing the Drill Guide Sleeves perpendicular across the osteotomy or fusion site (FIGURE 1). Adjust the distance between the Guide Sleeves by moving the Drill Guide Button to the necessary width (A).

The bridge length of the DynaClip Delta corresponds to the sizing indicated by the white numbering on the Drill Guide Body (red arrow). The white numbering on the front of the Drill Guide (blue arrows) may be referenced for each implant size to center the implant over the joint line. If desired, the placement of the Guide Sleeves on the bone surface can be confirmed under fluoroscopy.

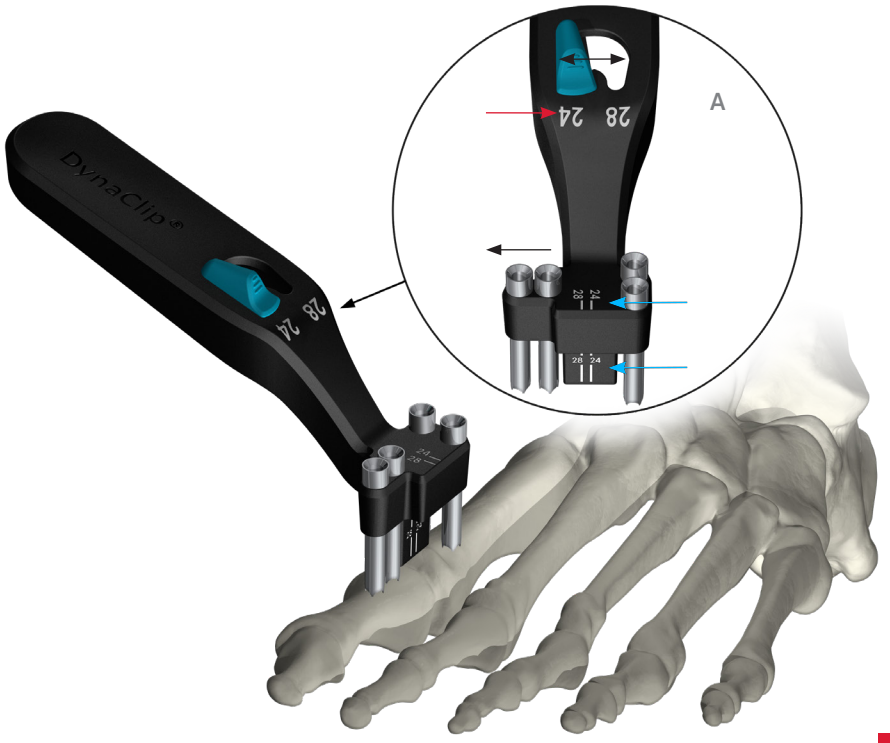



FIGURE 1

## 3. DRILL THE FIRST HOLE

Using the 3.0 mm Drill, drill a pilot hole through Drill Guide Sleeve #1 (FIGURE 2). Use the laser markings on the Drill to measure drill depth. It is recommended to drill to the same depth as the staple leg length.

Before drilling the second hole, place a 3 mm Locator Pin in the first hole through Drill Guide Sleeve #1 to stabilize the positioning of the Drill Guide (FIGURE 3).

**TIP:**

- Ensure the Size Indicator remains in the desired position during drilling.
- The Locator Pins may be lightly malleted to ensure they are fully seated into the drilled holes.

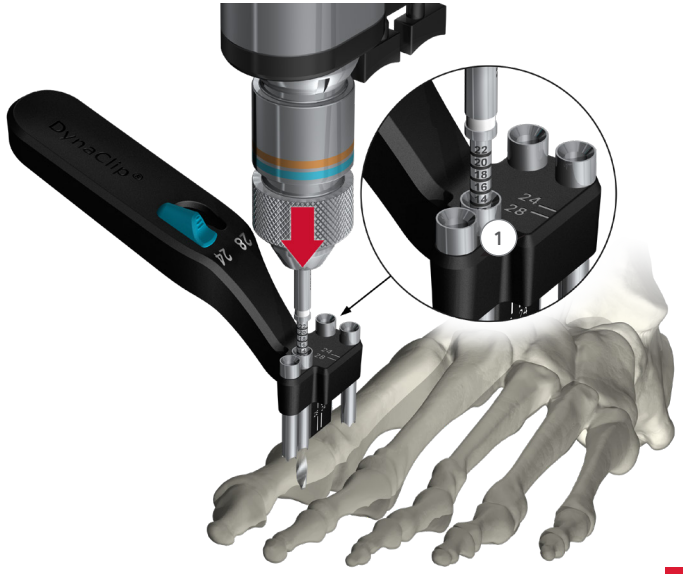



FIGURE 2

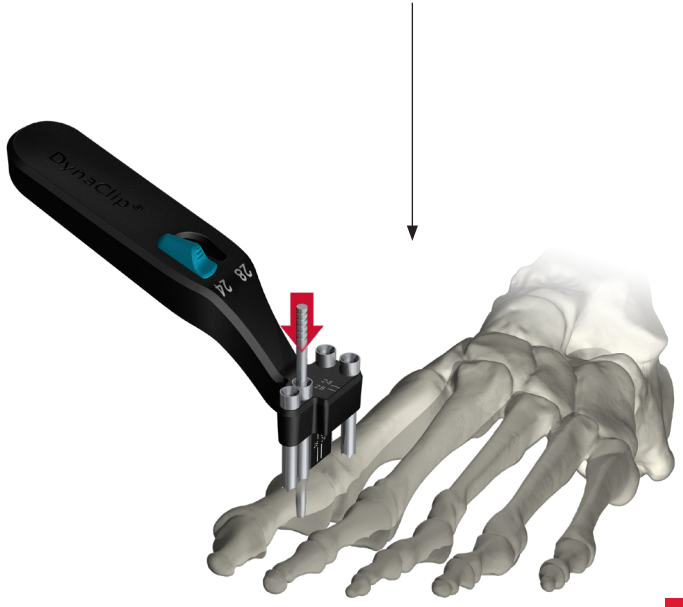



FIGURE 3

## 4. DRILL EACH ADDITIONAL HOLE

Repeat Step 3 for Drill Guide Sleeves #2, #3, and #4 (FIGURE 4, in order indicated), taking care to place a Locator Pin in each drilled hole before drilling through the next Drill Guide Sleeve.

**OPTIONAL:** Place a fourth Locator Pin in Drill Guide Sleeve #4. Remove the Drill Guide but keep the Locator Pins in place to visualize the positioning under fluoroscopy. When satisfied with placement, remove Locator Pins from the pilot holes.

**TIP:** Apply compression across the fusion site before drilling through Drill Guide Sleeve #2.

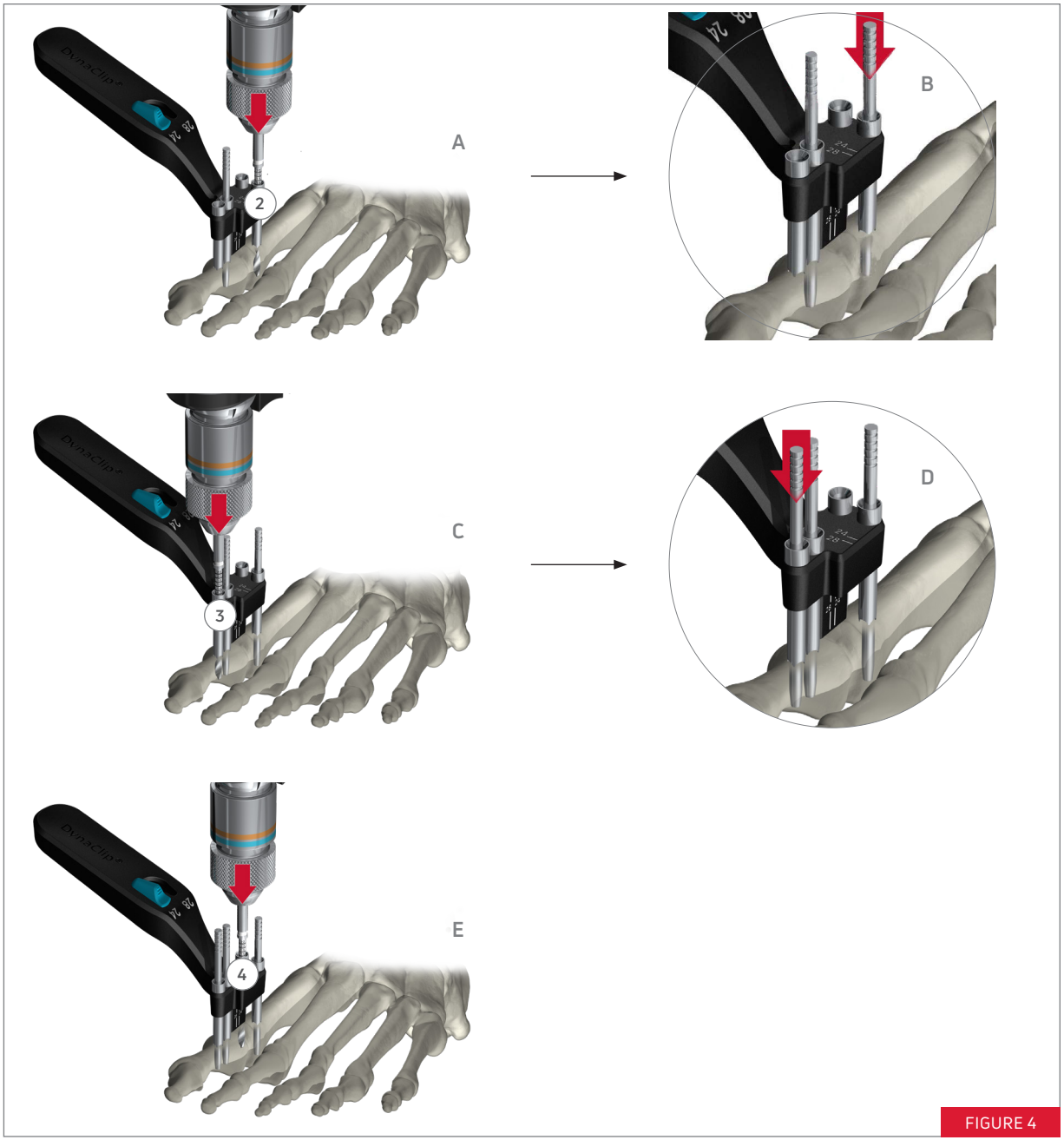



FIGURE 4

## 5. INSERT THE DYNACLIP DELTA™ STAPLE

Select the appropriately sized DynaClip Delta™ pre-loaded on the Inserter. Position the legs of the DynaClip Delta over the pilot holes and advance the staple into the bone by hand (FIGURE 5).

The staple legs should easily slide into the drilled holes without requiring excessive force. If necessary, lightly mallet on the Strike Surface of the Inserter until the Inserter Tip is flush to the bone.

**TIP:**

- If implanting in the forefoot, be sure to hold the phalanges and apply counter pressure while inserting the staple.
- It is important to ensure the bottom of the Inserter Tip is fully seated on the bone prior to deployment to avoid having to overly tamp the staple (A).

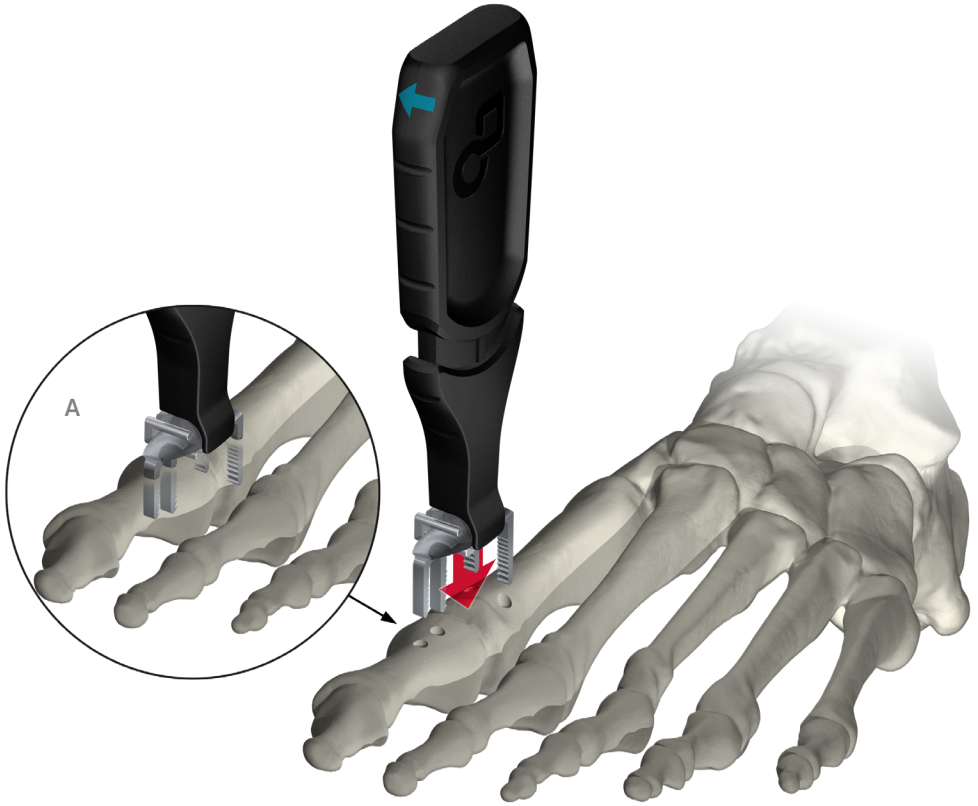



FIGURE 5

## 6. RELEASE THE DYNACLIP DELTA™ STAPLE

### 6A. PULL UP

Grip the Sliding Neck of the Inserter and pull upward to expose the Inserter Tip (FIGURE 6).

### 6B. SLIDE

Slide the Inserter away from the DynaClip Delta™ Implant in the direction of the blue DynaClip logo, as indicated by the Blue Arrow on the Inserter (FIGURE 7).

**TIP:** The Inserter may be twisted slightly to disengage from the implant. Hold the bone in place to keep it stable during removal.

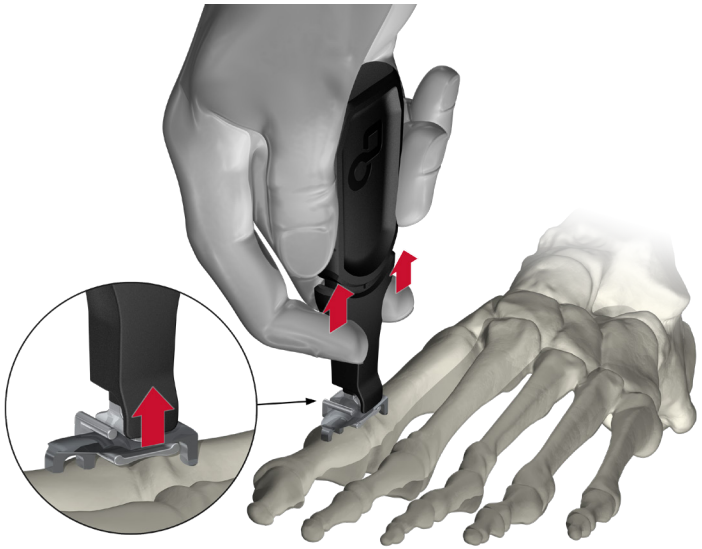


FIGURE 6

FIGURE 7

## 7. TAMP INTO PLACE

Place the tamping edge of the Inserter Tip over the bridge of the Implant and lightly mallet the Strike Surface to tamp the staple until fully seated on the bone (FIGURE 8).

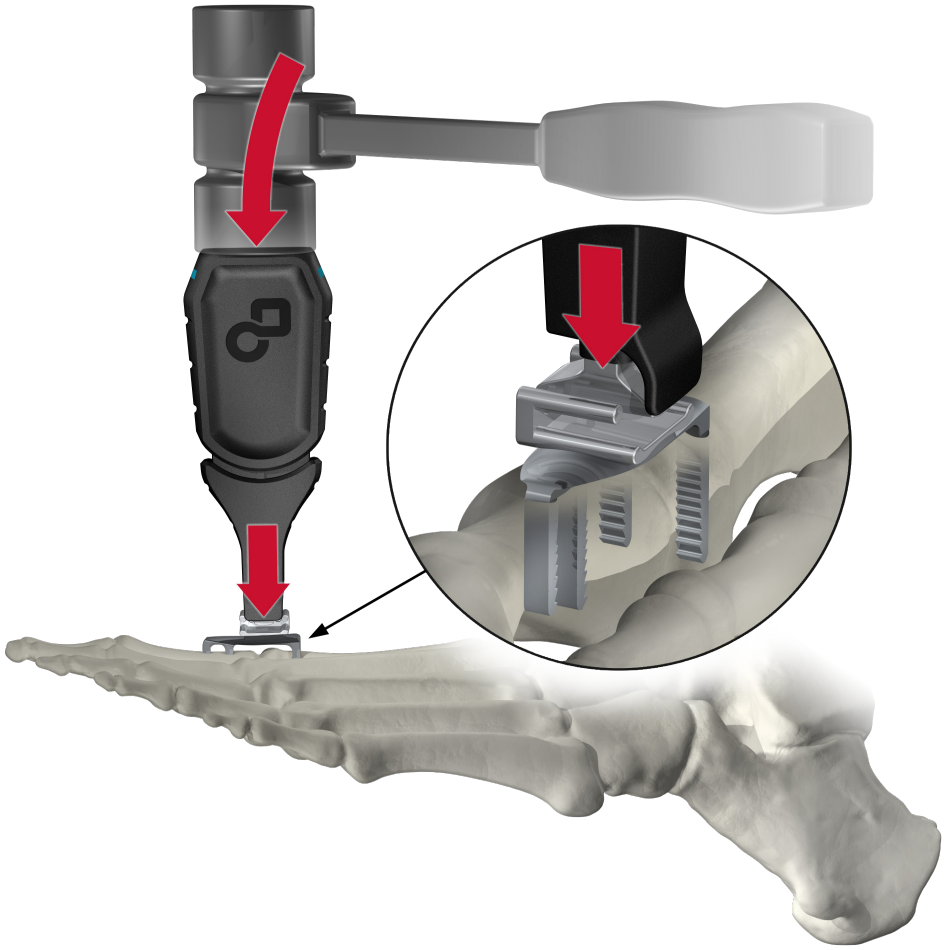


FIGURE 8

## 8. CONFIRM IMPLANT PLACEMENT

Check final positioning under fluoroscopy (FIGURE 9).

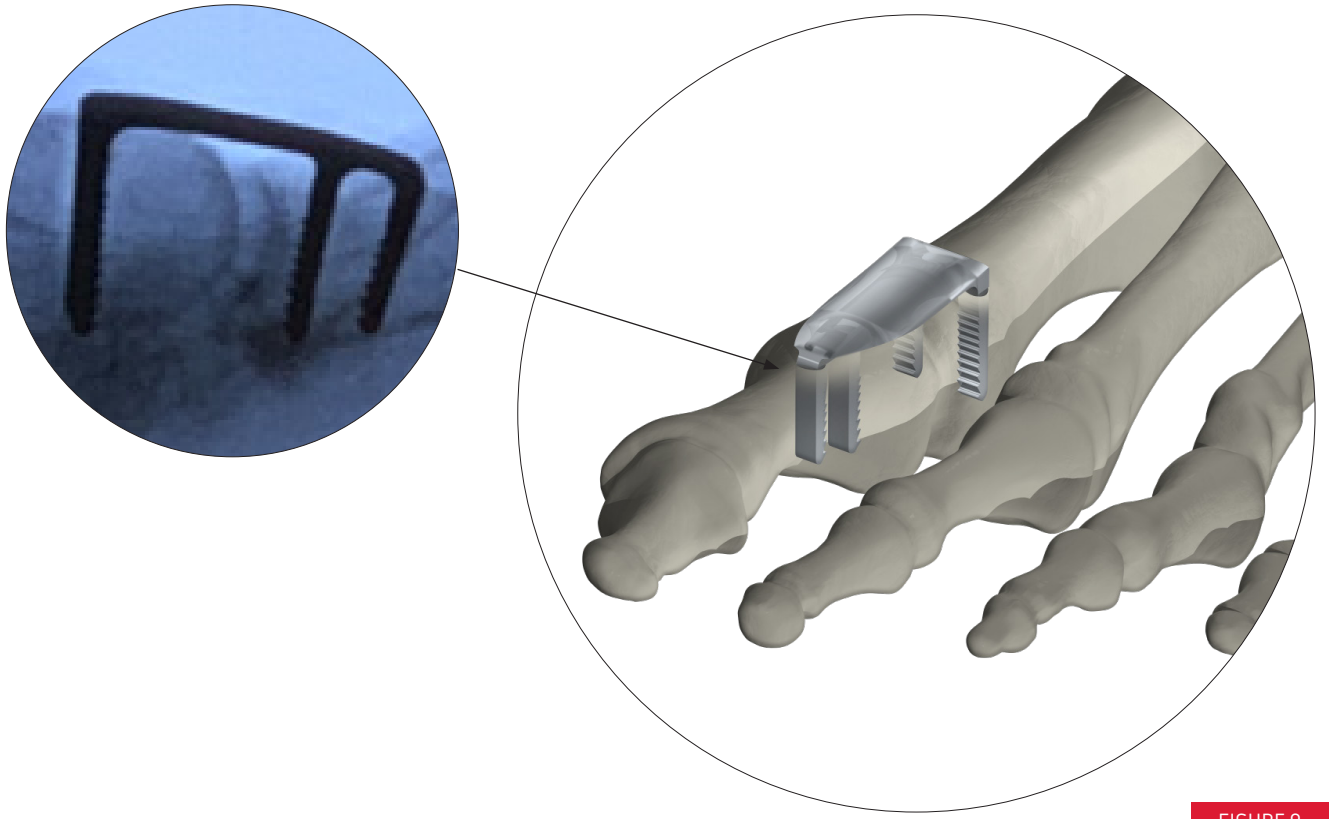


FIGURE 9

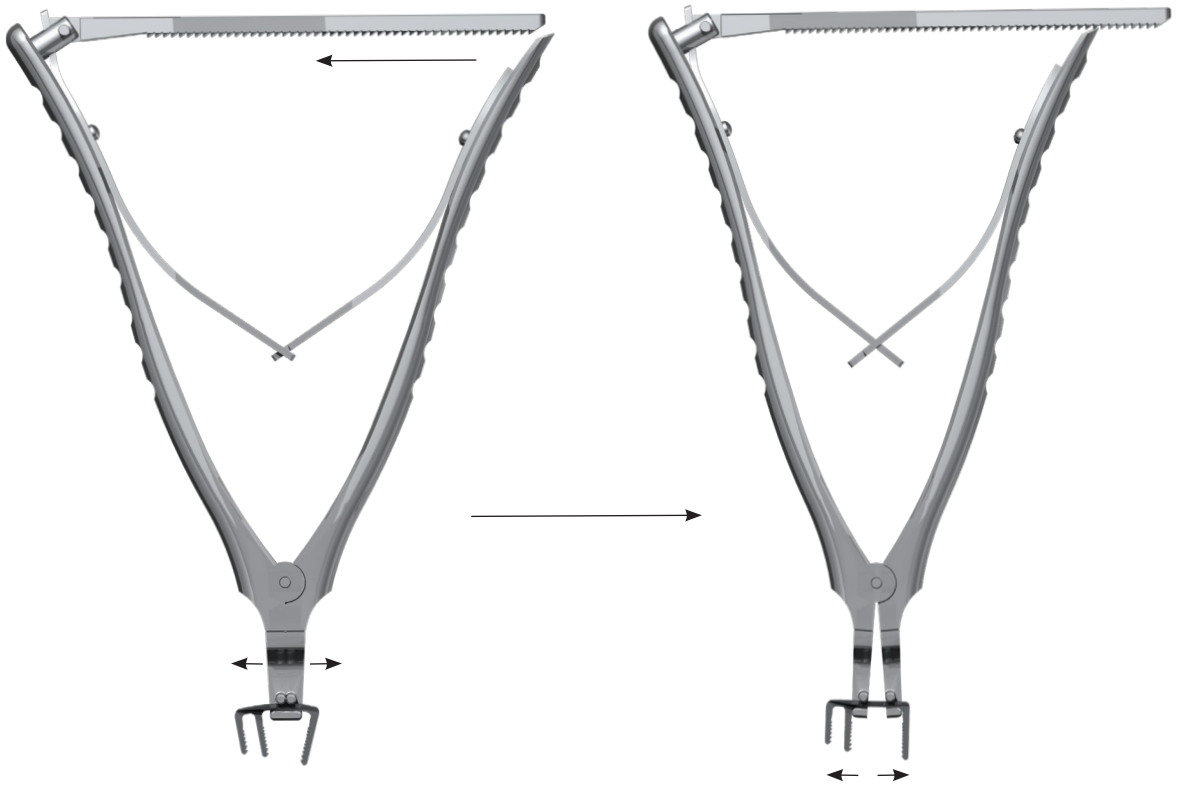
# REMOVAL & RE-INSERTION



The DynaClip Delta™ Implant can be removed and re-positioned in bone using the reusable Removal Tool.

To remove a DynaClip Delta Implant, use a flat sided instrument to wedge the bridge of the DynaClip Delta Implant slightly off the bone. Place the Removal Tool's posts under the implant bridge and adjust the Ratchet Arms of the Removal Tool until the posts are pushing against the staple corners. Pull up on the Removal Tool to remove the staple from the bone.

To reposition the DynaClip Delta implant (if needed), squeeze the arms of the Removal Tool to expand the implant legs until parallel, ensuring the legs do not go past parallel. Re-insert the DynaClip Delta implant into the bone and remove the Removal Tool by releasing the Ratchet Arms. With the original inserter, tamp the DynaClip Delta implant until flush with bone.



# ORDERING INFORMATION



## DYNACLIP DELTA™ IMPLANTS & SINGLE-USE INSTRUMENTS

| PART # | DESCRIPTION |
|---|---|
| 3000-10-24161412 | DYNACLIP DELTA, 24MM x 16MM x 14MM x 12MM |
| 3000-10-28161412 | DYNACLIP DELTA, 28MM x 16MM x 14MM x 12MM |
| 3000-12-000 | DYNACLIP DELTA DISPOSABLE PROCEDURE PACK, STERILE |

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