



SURGICAL
TECHNIQUE

enovis™

DYNACLIP®

BONE FIXATION THAT EMPOWERS ACTIVE, ADAPTIVE HEALING

STAPLE SYSTEM





**NEXT GENERATION
STRENGTH THAT CLIPS
THE COMPETITION**

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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.

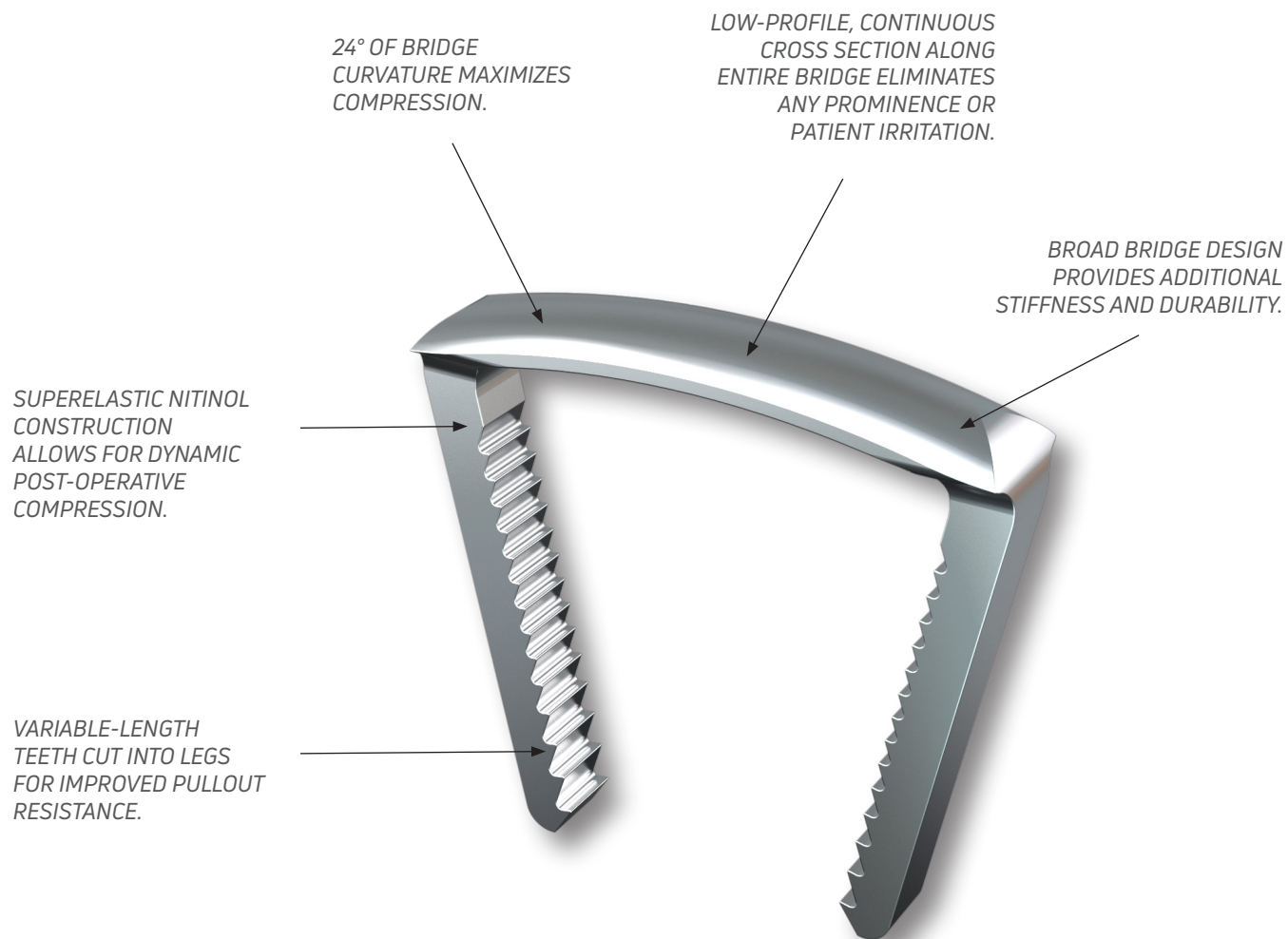
See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

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.

The DynaClip® Bone Fixation System is an innovative bone staple system, manufactured from superelastic nickel titanium (NiTiNOL), that provides dynamic post-operative compression and reliable durability to withstand demanding loading conditions in the foot and ankle.



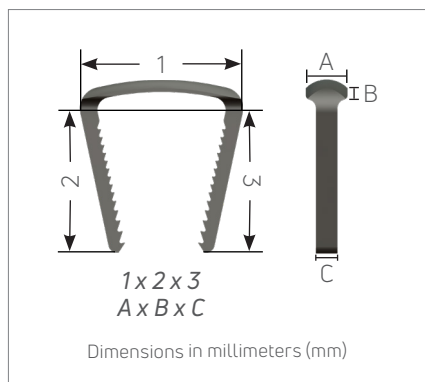
DYNACLIP® INSERTER

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

- 1. Inserter Tip:** Retains the DynaClip 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 Neck to expose the DynaClip 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.



LEGEND



8 x 8 x 8
3.8 x 1 x 2



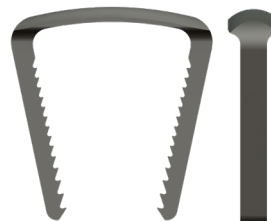
10 x 10 x 10
3.8 x 1.1 x 2



12 x 12 x 12
3.8 x 1.2 x 2



14 x 14 x 14
3.8 x 1.3 x 2



18 x 18 x 18
4.8 x 1.4 x 2.5



18 x 20 x 20
4.8 x 1.4 x 2.5



20 x 18 x 18
4.8 x 1.5 x 2.5



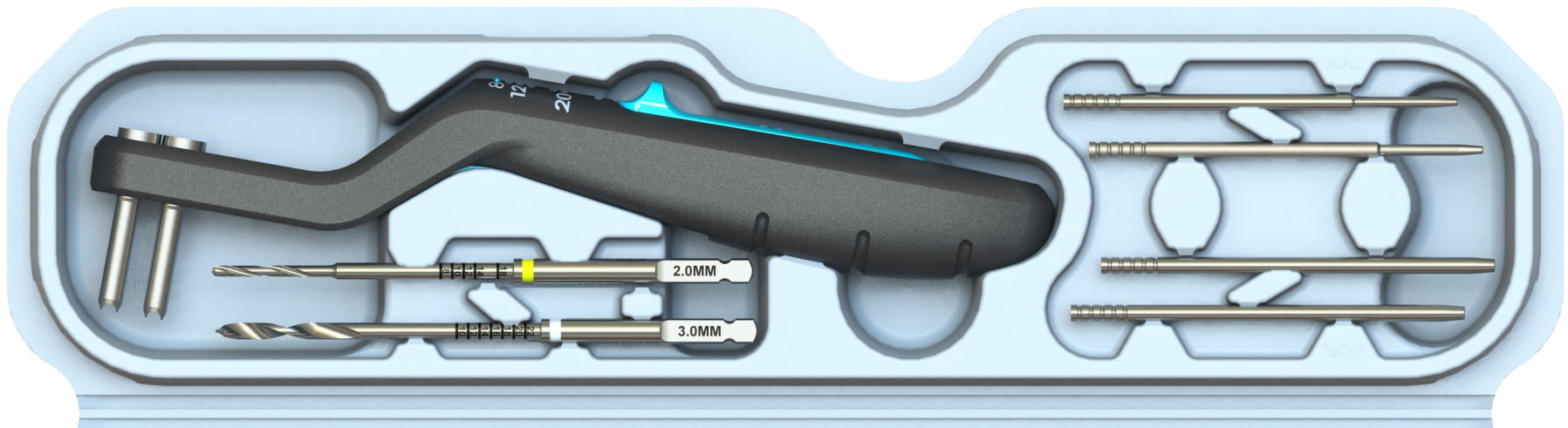
20 x 22 x 22
4.8 x 1.4 x 2.5



26 x 20 x 20
4.8 x 1.8 x 2.5

UNIVERSAL PROCEDURE PACK

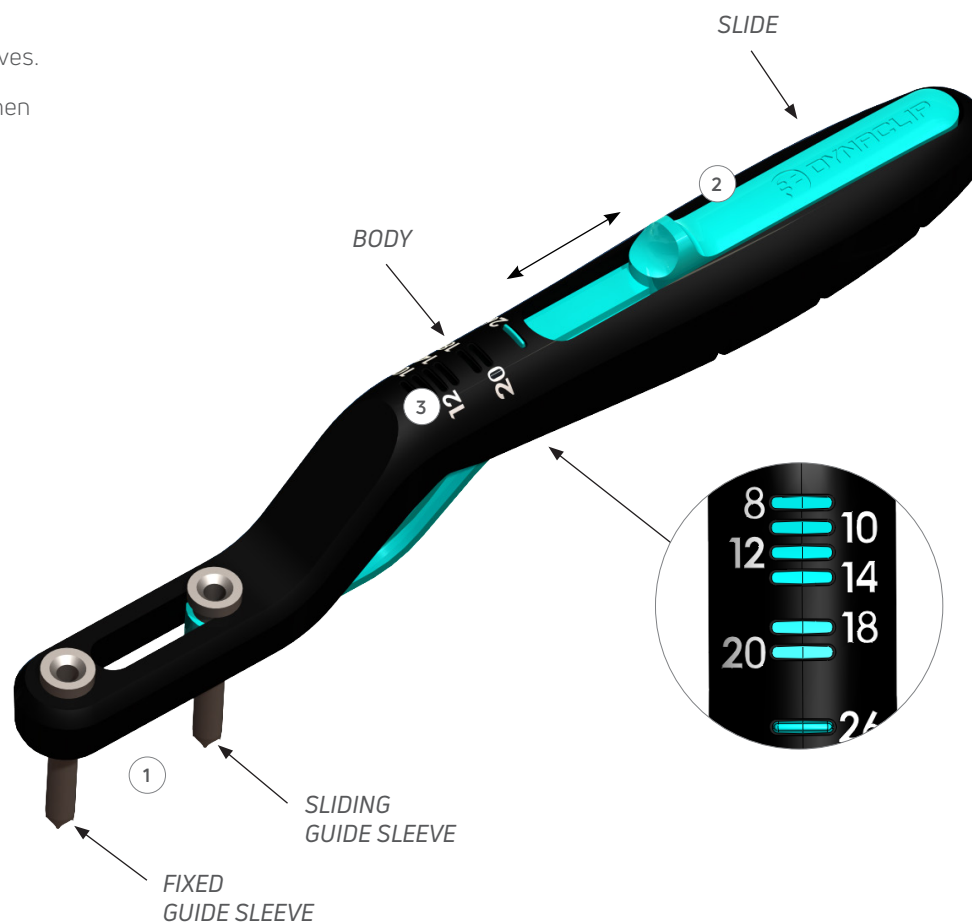
Disposable, single-use sterile kit contains all instruments required to implant the DynaClip®. No need to open multiple packs!



UNIVERSAL DRILL GUIDE

- Serves as both implant sizer and drill guide
- Compatible with ALL size offerings by using adjustable Slide
- Ergonomic, low-profile handle maximizes visibility of fusion site

- 1. Guide Sleeves:** Use the Guide Sleeves to determine desired DynaClip® bridge width, then use the Sleeves as guides for the Drill.
- 2. Slide:** Move the Slide to adjust the separation distance between the Guide Sleeves.
- 3. Bridge Width Markings:** Determine the distance between the Guide Sleeves when adjusting.



DRILLS & PINS

- 1. Drills:** Provided in two different diameters depending on DynaClip® size. Laser markings can be used to measure drill depth.
- 2. Locator Pins:** Provided in two different diameters depending on DynaClip size. Fixate the Universal Drill Guide in place during drilling to ensure accurate distance between drill holes and for visualization under fluoroscopy.



2.0 MM DRILL (8 MM - 14 MM STAPLES)



3.0 MM DRILL (18 MM - 26 MM STAPLES)



2.0 MM PIN (8 MM - 14 MM STAPLES)



3.0 MM PIN (18 MM - 26 MM STAPLES)

INDICATIONS

DYNACLIP® BONE FIXATION SYSTEM

The DynaClip® Bone Fixation System is indicated for:

- Osteotomy or fracture fixation and joint arthrodesis for a variety of pathologies in the hand and foot.

CONTRAINDICATIONS

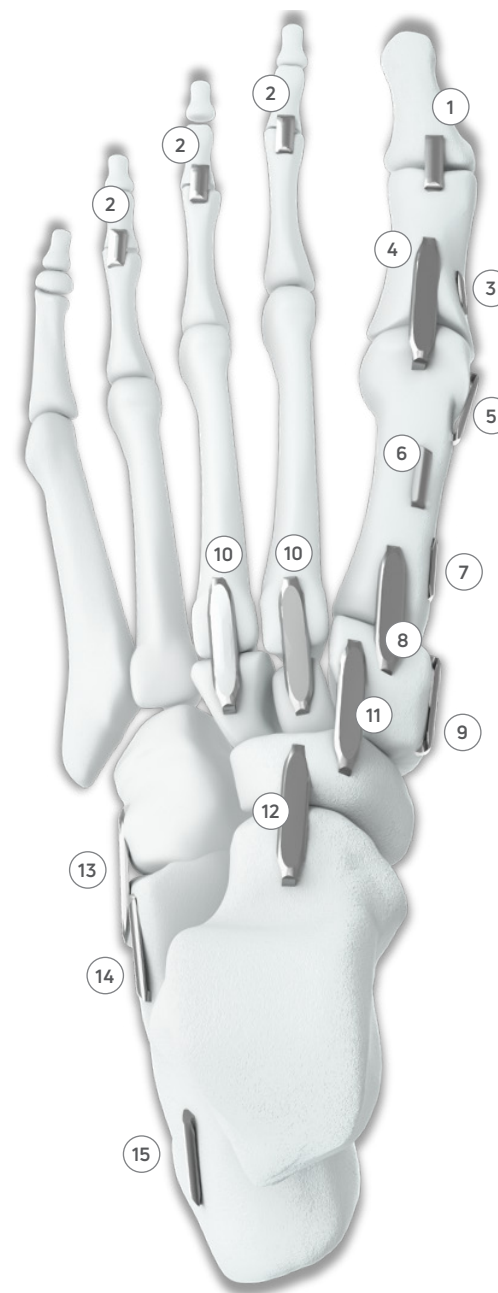
DYNACLIP BONE FIXATION SYSTEM

The DynaClip Bone Fixation System is contraindicated for:

- Patients with 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.
- Patients with foreign body sensitivity. Where material sensitivity is suspected, testing should be completed prior to implantation of device.

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

INDICATION		BRIDGE LENGTH X LEG LENGTH
1	HALLUX IPJ FUSION	8 x 8, 10 x 10, 12 x 12
2	LESSER PIPJ FUSION	8 x 8, 10 x 10
3	AKIN OSTEOTOMY	8 x 8, 10 x 10
4	MTPJ FUSION	10 x 10, 12 x 12, 14 x 14, 18 x 18
5	CHEVRON OSTEOTOMY	14 x 14, 18 x 18
6	GENERAL MT OSTEOTOMY	12 x 12, 14 x 14, 18 x 18
7	BASE WEDGE OSTEOTOMY	10 x 10, 12 x 12, 14 x 14, 18 x 18
8	1ST TMT (LAPIDUS FUSION)	12 x 12, 14 x 14, 18 x 18, 20 x 18
9	COTTON OSTEOTOMY	18 x 18, 18 x 20, 20 x 18, 20 x 22
10	TMT FUSION	18 x 18, 18 x 20, 20 x 18, 20 x 22
11	NAVICULOCUNEIFORM FUSION	14 x 14, 18 x 18, 18 x 20
12	TALONAVICULAR FUSION	20 x 18, 20 x 22, 26 x 20
13	CALCANEOCUBOID FUSION	20 x 18, 20 x 22, 26 x 20
14	EVANS OSTEOTOMY	20 x 18, 20 x 22, 26 x 20
15	DYER OSTEOTOMY	20 x 18, 20 x 22, 26 x 20



INDICATION		BRIDGE LENGTH X LEG LENGTH
1	DIP ARTHRODESIS	8 x 8, 10 x 10
2	METACARPOPHALANGEAL (MCP) ARTHRODESIS	8 x 8, 10 x 10, 12 x 12, 14 x 14
3	CARPOMETACARPAL (CMC) ARTHRODESIS	10 x 10, 12 x 12, 14 x 14
4	SCAPHOTRAPEZIOTRAPEZOID ARTHRODESIS (STT)	10 x 10, 12 x 12, 14 x 14
5	CAPITATE SHORTENING	10 X 10, 12 X 12, 14 X 14
6	RADIOCHAPHOLUNATE (RSL) ARTHRODESIS	12 x 12, 14 x 14, 18 x 18, 20 x 18
7	LUNOTRIQUETRAL (LT) JOINT ARTHRODESIS	10 x 10, 12 x 12, 14 x 14
8	RADIOLUNATE ARTHRODESIS	12 x 12, 14 x 14, 18 x 18, 20 x 18
9	THUMB METACARPAL EXTENSION OSTEOTOMY	10 x 10, 12 x 12, 14 x 14
10	SCAPHOID FRACTURE REPAIR PRIMARY/REVISION	10 x 10, 12 x 12, 14 x 14
11	LIMITED INTERCARPAL JOINT ARTHRODESIS (INCLUDING 4-CORNER ARTHRODESIS)	14 x 14, 18 x 18, 18 x 20



1. PREPARE THE FUSION SITE

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

2. SIZE AND PREPARE FOR DRILLING

Determine the appropriate DynaClip bridge width by placing the Universal Drill Guide Sleeves perpendicular across the osteotomy or fusion site. Adjust the distance between the Guide Sleeves by moving the Drill Guide Slide to the necessary width (**FIGURE 1**). See page 5 for all available DynaClip size offerings.

The width of the DynaClip corresponds to the sizing indicated by the white numbering on the Drill Guide Body (red arrow in inset **A**). If desired, the placement of the Guide Sleeves on the bone surface can be checked on fluoroscopy.

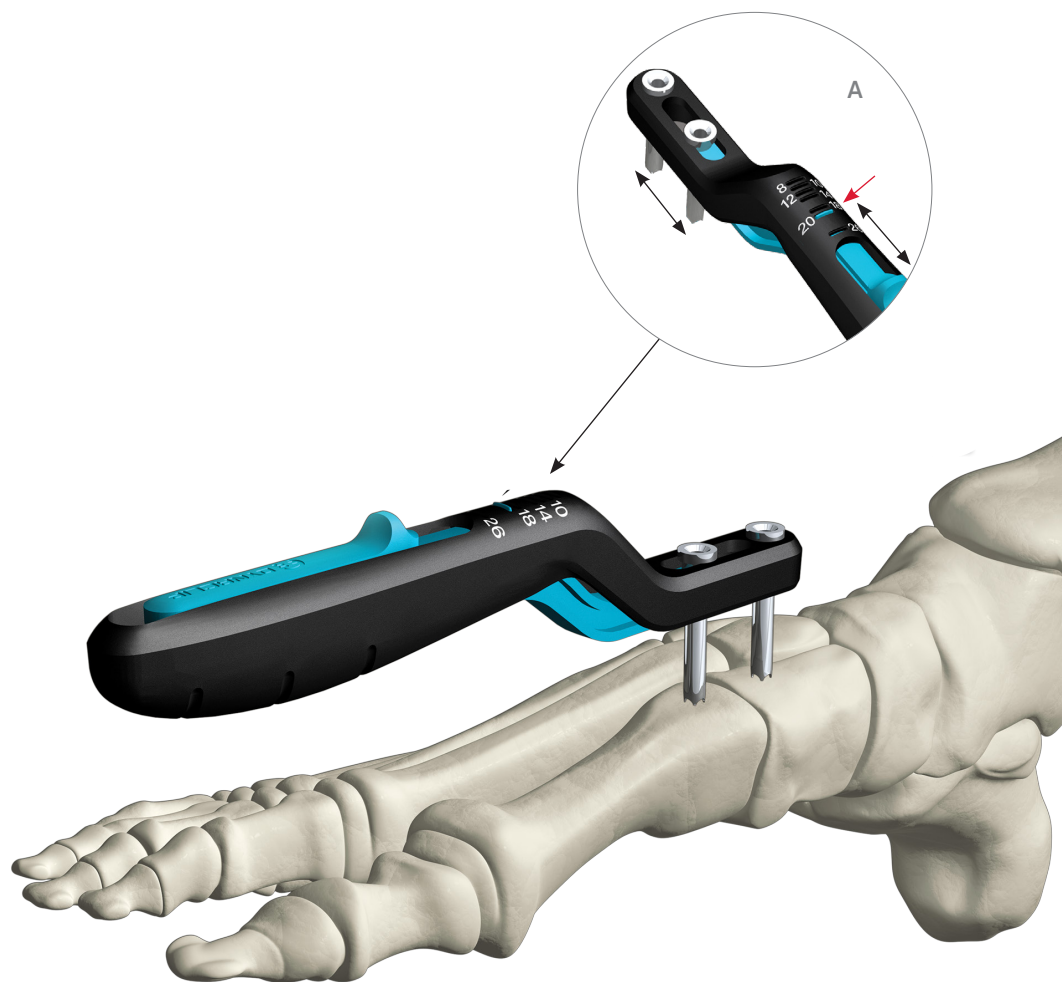


FIGURE 1

3. DRILL THE FIRST HOLE

Use the appropriate size Drill to drill a pilot hole through the Fixed Guide Sleeve (**FIGURE 2**). Refer to Table 1 for drill diameter recommendations. Use the laser markings on the Drill to measure drill depth. It is recommended to drill to the same depth as the leg length of the chosen DynaClip® staple size.

Before drilling the second hole, place a corresponding diameter Locator Pin in the first hole through the Fixed Guide Sleeve to stabilize the positioning of the Universal Drill Guide (**FIGURE 3**).

TABLE 1

2 MM DRILL	3 MM DRILL
8 x 8 x 8	18 x 18 x 18
10 x 10 x 10	18 x 20 x 20
12 x 12 x 12	20 x 18 x 18
14 x 14 x 14	20 x 22 x 22
—	26 x 20 x 20

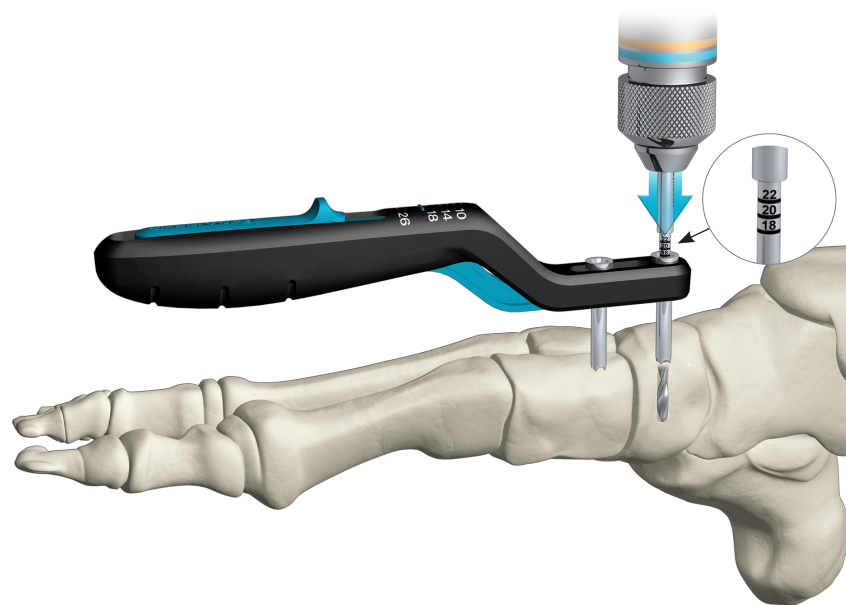


FIGURE 2

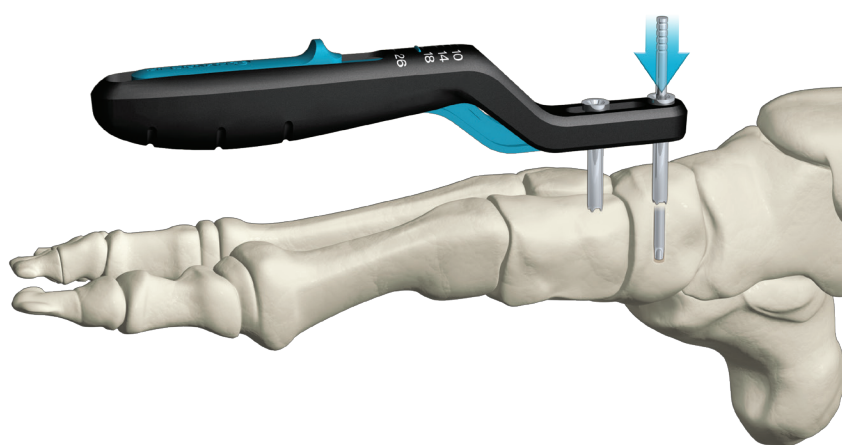


FIGURE 3

4. DRILL THE SECOND HOLE

Drill the second pilot hole through the Sliding Guide Sleeve, using the laser marks on the Drill to determine drill depth (**FIGURE 4**). Remove Locator Pins and Universal Drill Guide before proceeding to next step.

OPTIONAL: Place a second Locator Pin in the hole of the Sliding Guide Sleeve. Remove the Universal Drill Guide but keep the Locator Pins in place. Check the positioning of the holes using fluoroscopy. When satisfied with placement, remove Locator Pins from the pilot holes.

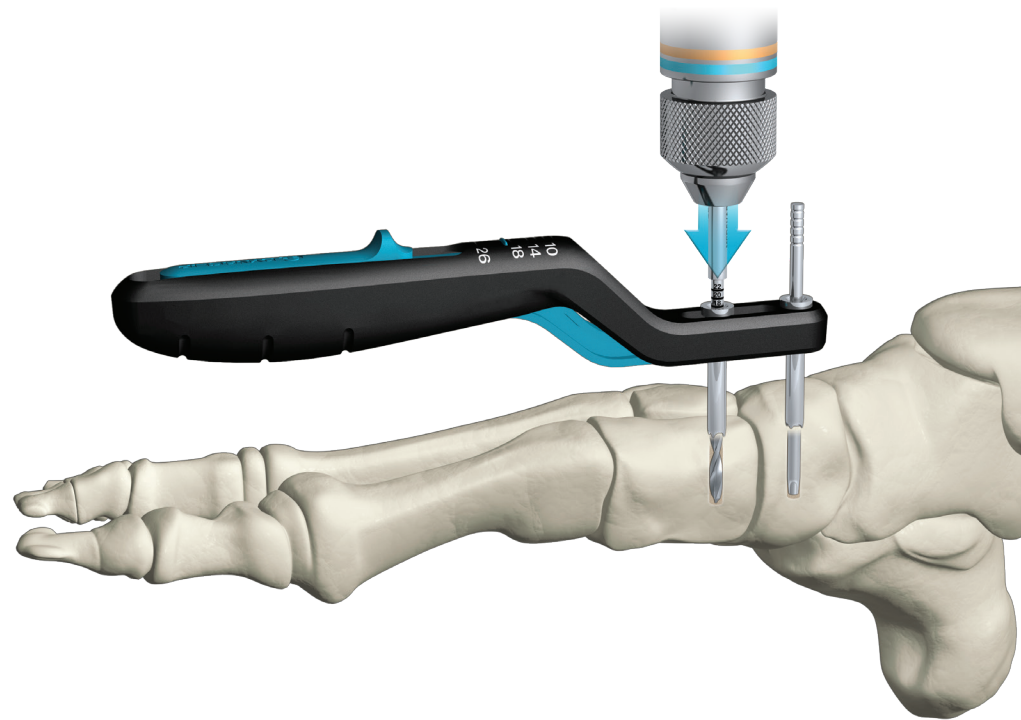


FIGURE 4

5. INSERT THE DYNACLIP® STAPLE

Select the appropriately sized DynaClip® pre-loaded on the Inserter. Position the legs of the DynaClip over the pilot holes and advance the staple into the surgical holes by hand (FIGURE 5). If necessary, lightly tap with a 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).

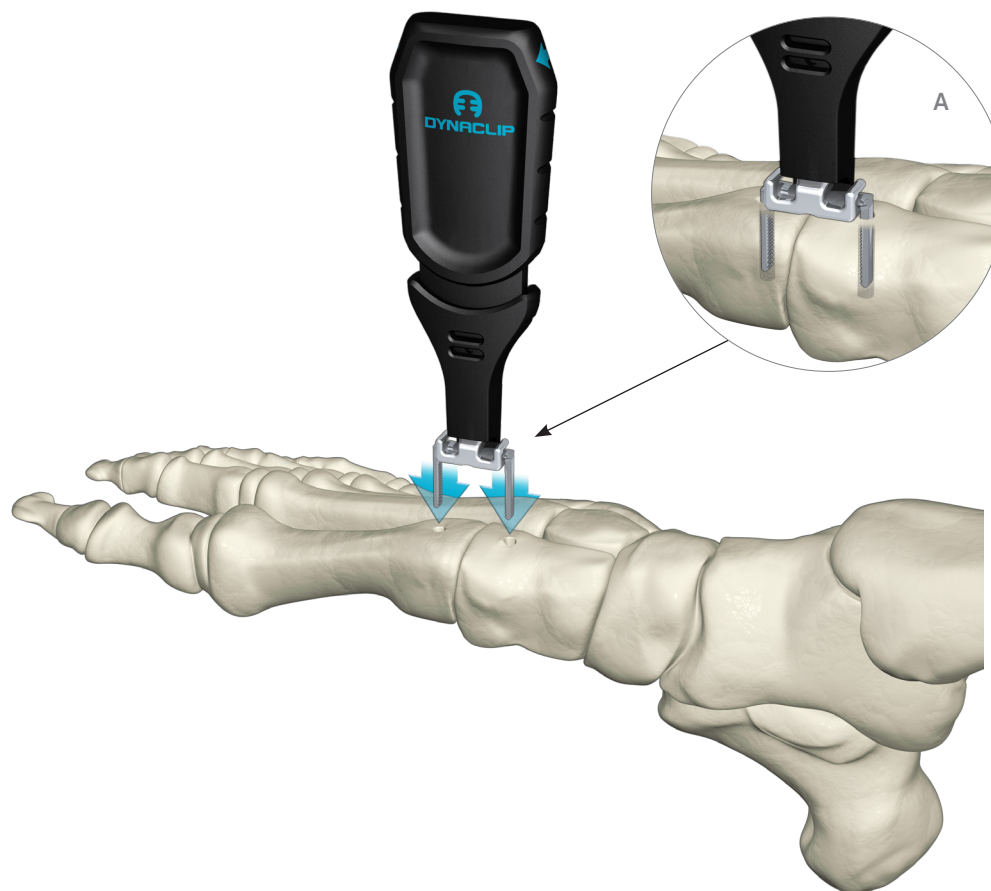


FIGURE 5

6. RELEASE THE DYNACLIP® 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® Implant in the direction of the blue DynaClip logo, as indicated by the Blue Arrow (**FIGURE 7**). Do NOT rotate or twist the Inserter while releasing.

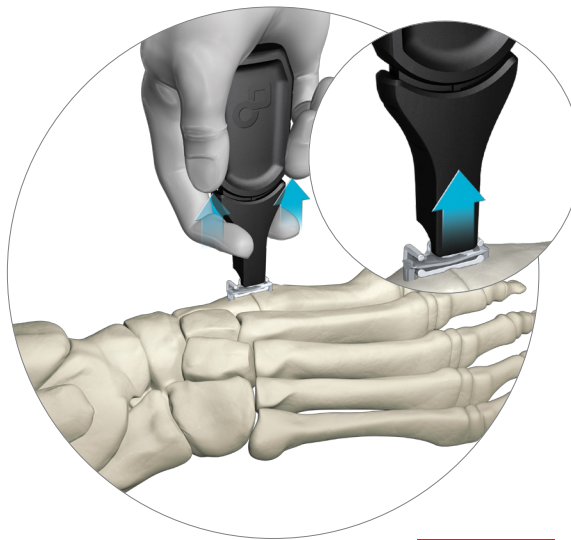


FIGURE 6

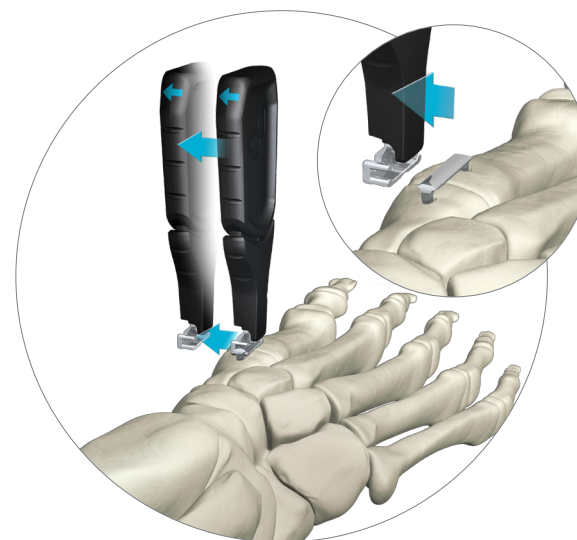


FIGURE 7

7. TAMP INTO PLACE

Place the tamping edge of the Inserter Tip over the bridge of the DynaClip® Implant and lightly mallet the top of the Inserter to tamp the Implant until fully seated on the bone (**FIGURE 8**).

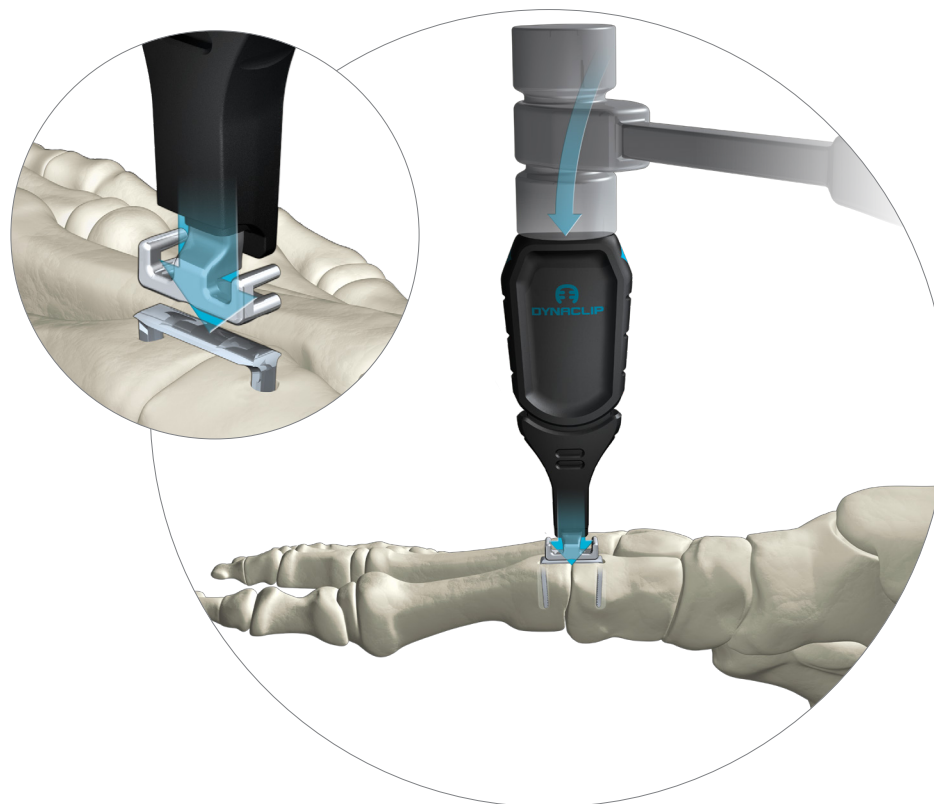
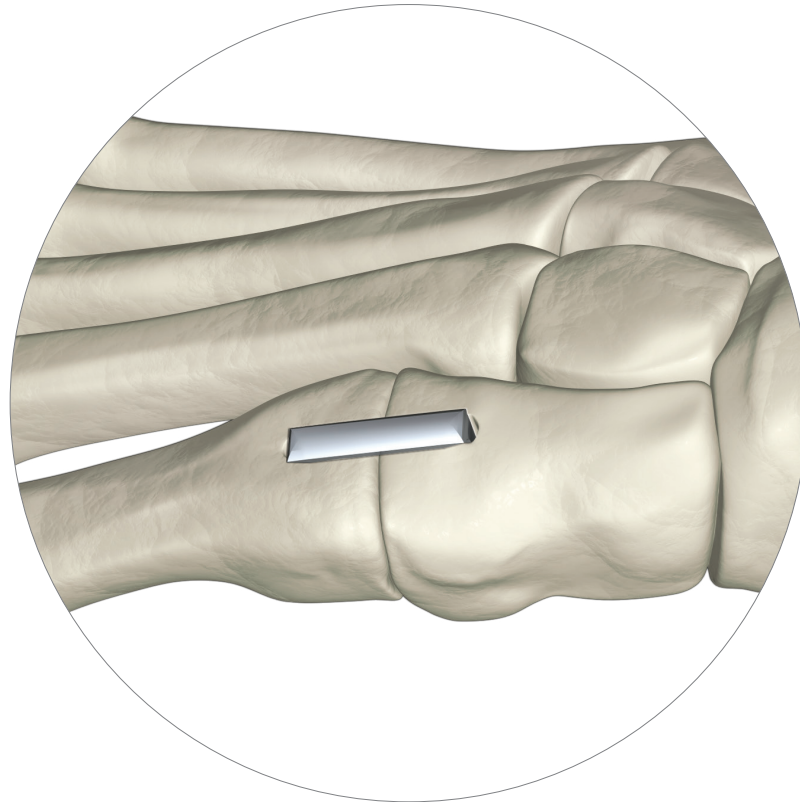


FIGURE 8

8. FINISH PROCEDURE

Check final positioning of the DynaClip® using fluoroscopy.



9. PLACE ADDITIONAL DYNACLIP® IMPLANTS

Repeat Steps 2-8 for each additional DynaClip® Implant used. Then finish procedure and close wounds.

TIP:

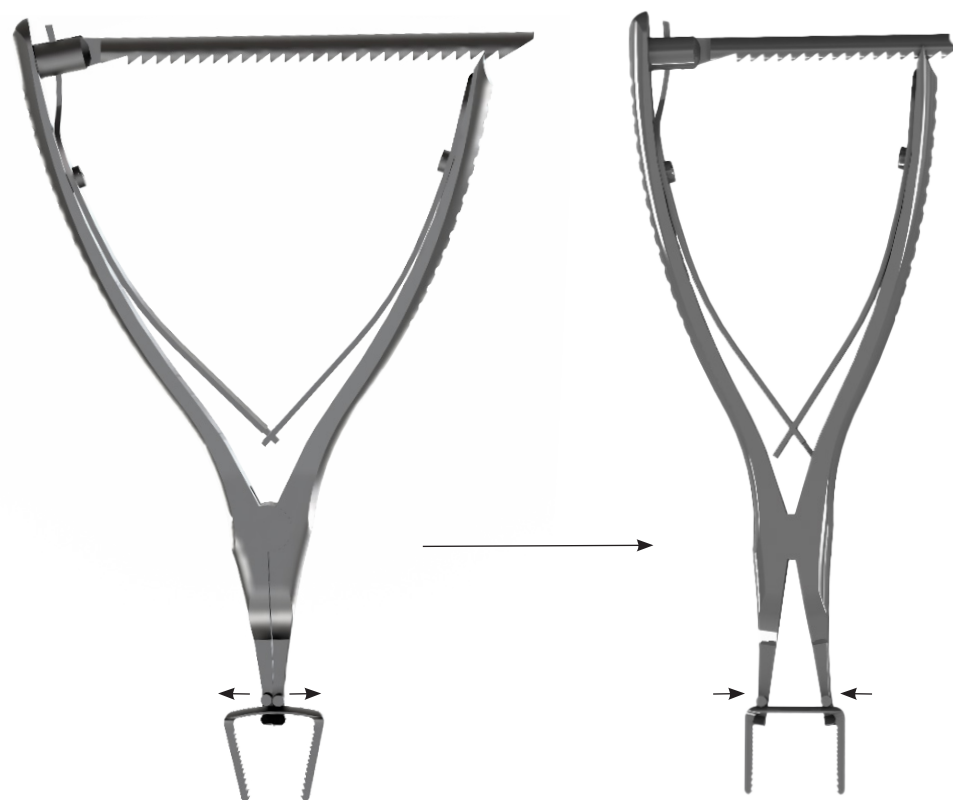
If placing two DynaClip Implants 90 degrees to each other, stagger placement so that the legs do not obstruct each other in the bone.



The DynaClip® implant can be removed and re-positioned in bone using the reusable Re-Load Tool.

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

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



DYNACLIP® IMPLANTS & SINGLE-USE INSTRUMENTS

DESCRIPTION	PART #
DYNACLIP, 8 MM x 8 MM x 8 MM	3000-00-080808
DYNACLIP, 10 MM x 10 MM x 10 MM	3000-00-101010
DYNACLIP, 12 MM x 12 MM x 12 MM	3000-00-121212
DYNACLIP, 14 MM x 14 MM x 14 MM	3000-00-141414
DYNACLIP, 18 MM x 18 MM x 18 MM	3000-00-181818
DYNACLIP, 18 MM x 20 MM x 20 MM	3000-00-182020
DYNACLIP, 20 MM x 18 MM x 18 MM	3000-00-201818
DYNACLIP, 20 MM x 22 MM x 22 MM	3000-00-202222
DYNACLIP, 26 MM x 20 MM x 20 MM	3000-00-262020
DISPOSABLE PROCEDURE PACK, STERILE	3000-01-000

enovis

T 800.495.2919 F 877.778.3864

Medshape, Inc.
1575 Northside Drive NW | Suite 440 | Atlanta, GA 30318 | U.S.A.
enovis.com/foot-and-ankle

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