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 to 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.

DynaClip Features

- **24° of bridge curvature to maximize compression**
- **Superelastic NiTiNOL construction allows for dynamic post-operative compression**
- **Variable length teeth for improved pullout resistance**
- **Low-profile continuous cross section along entire bridge eliminates any prominence or patient irritation**
- **Broad bridge design provides additional stiffness and durability**

Technical Specifications

- **Legend**
  - Dimensions in millimeters (mm)
- **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 1.5 x 2.5
- **26 x 20 x 20**
  - 4.8 x 1.8 x 2.5

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 the demanding loading conditions in the foot & ankle.
Universal Drill Guide

- Serves as both implant sizer and drill guide
- Compatible with ALL size offerings by using adjustable Slide
- Ergonomic, low-profile handle to maximize 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 and 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**

The DynaClip is indicated for osteotomy or fracture fixation and joint arthrodesis for a variety of pathologies in the hand and foot.

**CONTRAINDICATIONS**

1. Infection
2. Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
4. 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 Implants by procedure.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Bridge Width x Leg Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Hallux IPJ Fusion</td>
<td>8 x 8, 10 x 10, 12 x 12</td>
</tr>
<tr>
<td>2 Lesser PIPJ Fusion</td>
<td>8 x 8, 10 x 10</td>
</tr>
<tr>
<td>3 Akin Osteotomy</td>
<td>8 x 8, 10 x 10</td>
</tr>
<tr>
<td>4 MTPJ Fusion</td>
<td>10 x 10, 12 x 12, 14 x 14, 18 x 18</td>
</tr>
<tr>
<td>5 Chevron Osteotomy</td>
<td>14 x 14, 18 x 18</td>
</tr>
<tr>
<td>6 General MT Osteotomy</td>
<td>12 x 12, 14 x 14, 18 x 18</td>
</tr>
<tr>
<td>7 Base Wedge Osteotomy</td>
<td>10 x 10, 12 x 12, 14 x 14, 18 x 18</td>
</tr>
<tr>
<td>8 Lapidus Fusion</td>
<td>12 x 12, 14 x 14, 18 x 18, 20 x 18</td>
</tr>
<tr>
<td>9 Cotton Osteotomy</td>
<td>18 x 18, 18 x 20, 20 x 18, 20 x 22</td>
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<tr>
<td>10 TMT Fusion</td>
<td>18 x 18, 18 x 20, 20 x 18, 20 x 22</td>
</tr>
<tr>
<td>11 Naviculocuneiform Fusion</td>
<td>14 x 14, 18 x 18, 18 x 20</td>
</tr>
<tr>
<td>12 Talonavicular Fusion</td>
<td>20 x 18, 20 x 22, 26 x 20</td>
</tr>
<tr>
<td>13 Calcaneocuboid Fusion</td>
<td>20 x 18, 20 x 22, 26 x 20</td>
</tr>
<tr>
<td>14 Evans Osteotomy</td>
<td>20 x 18, 20 x 22, 26 x 20</td>
</tr>
<tr>
<td>15 Dyer Osteotomy</td>
<td>20 x 18, 20 x 22, 26 x 20</td>
</tr>
</tbody>
</table>
Prepare the Fusion Site
Create the osteotomy and/or prepare the fusion site needed to implant the DynaClip.

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 (refer to image A). See page 2 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 image A). If desired, the placement of the Guide Sleeves on the bone surface can be checked on fluoroscopy.

Drill the First Hole
Use the appropriate size Drill to drill a pilot hole through the Fixed Guide Sleeve. 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.

**Table 1. Recommended Drill Diameter by DynaClip Size**

<table>
<thead>
<tr>
<th>8 x 8 x 8</th>
<th>18 x 18 x 18</th>
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</thead>
<tbody>
<tr>
<td>10 x 10 x 10</td>
<td>18 x 20 x 20</td>
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<tr>
<td>12 x 12 x 12</td>
<td>20 x 18 x 18</td>
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<tr>
<td>14 x 14 x 14</td>
<td>20 x 22 x 22</td>
</tr>
<tr>
<td>—</td>
<td>26 x 20 x 20</td>
</tr>
</tbody>
</table>

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.
**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. 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.

**Insert the DynaClip Staple**

Select the appropriate 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. If necessary lightly tap with a mallet on the Strike Surface of the Inserter until the Inserter Tip is flush to the bone.

**TECH TIPS**

- 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 (Inset A).

**Release the DynaClip Staple**

Grip the Sliding Neck of the Inserter and pull upward to expose the Inserter Tip.

Slide the Inserter away from the DynaClip Implant in the direction of the blue DynaClip logo, as indicated by the Blue Arrow. Do NOT rotate or twist the Inserter while releasing.
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.

Finish Procedure
Check final positioning of the DynaClip using fluoroscopy.

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

TECH 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.

REMOVAL & RE-INSERTION
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.
MedShape would like to thank Sam Adams, M.D. (Duke University) for his contributions to this surgical technique guide. This brochure was created in collaboration with Dr. Adams and represents his own surgical technique using the DynaClip Bone Fixation System.

IMPORTANT NOTE: MedShape, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. MedShape is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Always refer to the package insert, product label and/or product instructions prior to using any MedShape product.

For further product information or to arrange a product demonstration, please contact your local MedShape representative or call Customer Service at 877-343-7016. You can also visit www.medshape.com.

ORDERING INFORMATION

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<th>Description</th>
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<td>3000-00-080808</td>
<td>DynaClip, 8 mm x 8 mm x 8 mm</td>
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<tr>
<td>3000-00-101010</td>
<td>DynaClip, 10 mm x 10 mm x 10 mm</td>
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<tr>
<td>3000-00-121212</td>
<td>DynaClip, 12 mm x 12 mm x 12 mm</td>
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<td>3000-00-262020</td>
<td>DynaClip, 26 mm x 20 mm x 20 mm</td>
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<tr>
<td>3000-01-000</td>
<td>Universal Procedure Pack</td>
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