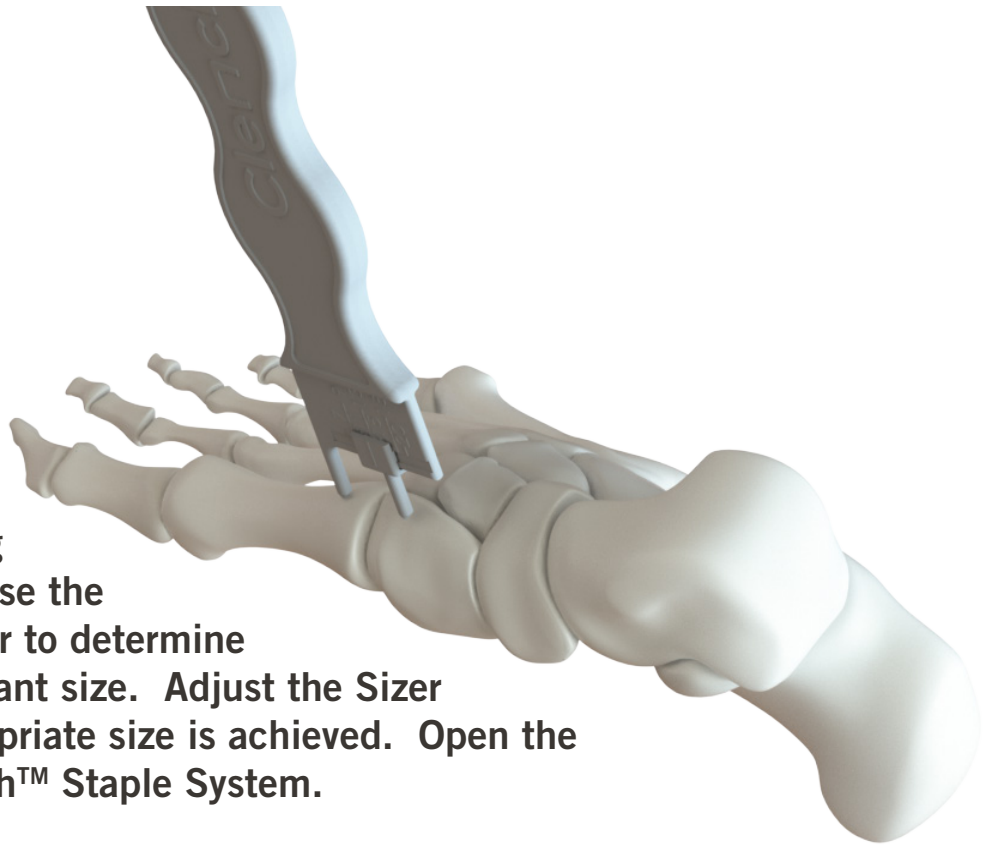




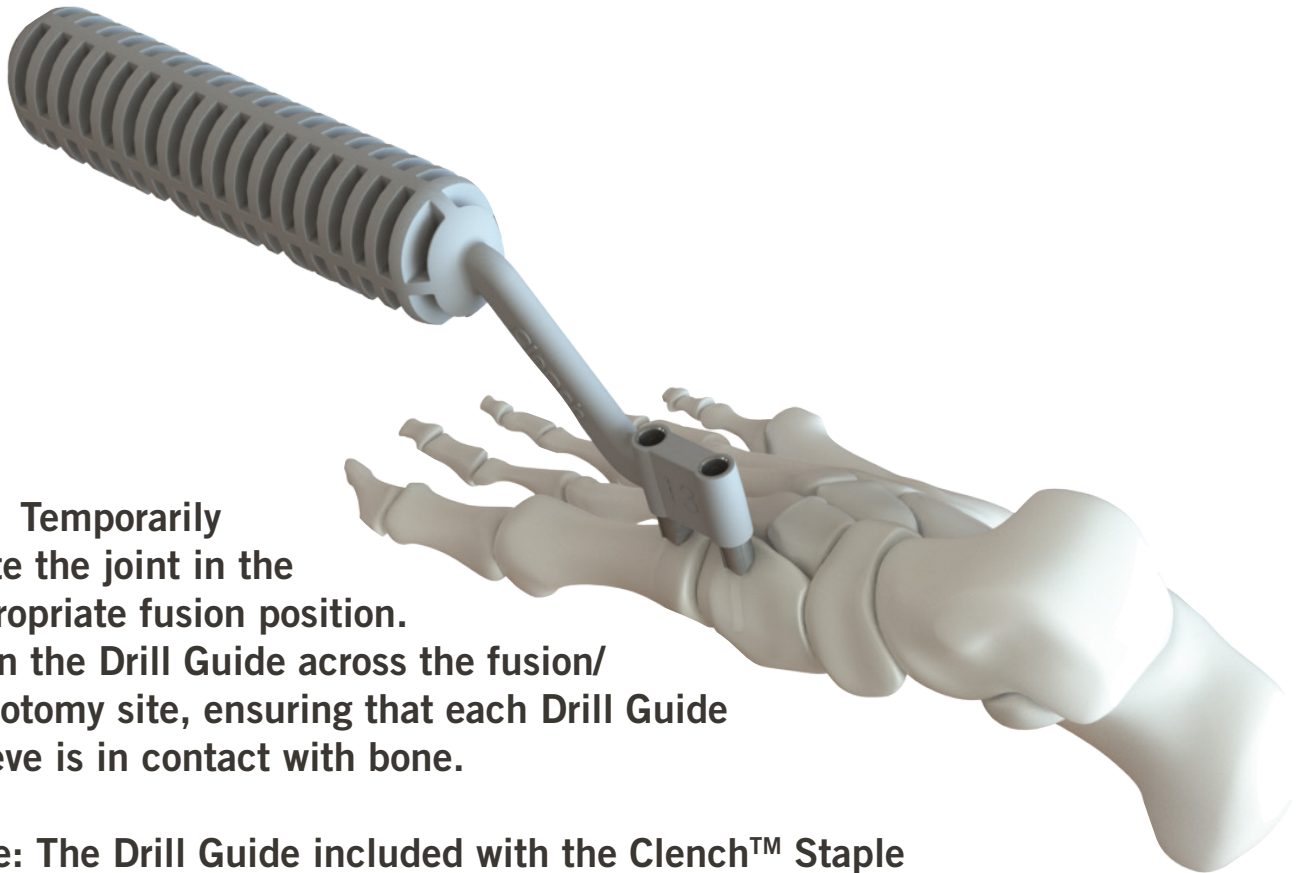
Clench™ Compression Staple



1 After adequately preparing the joint surfaces, use the Clench™ Staple Sizer to determine the appropriate implant size. Adjust the Sizer Slide until the appropriate size is achieved. Open the corresponding Clench™ Staple System.



2 Temporarily fixate the joint in the appropriate fusion position. Align the Drill Guide across the fusion/osteotomy site, ensuring that each Drill Guide Sleeve is in contact with bone.

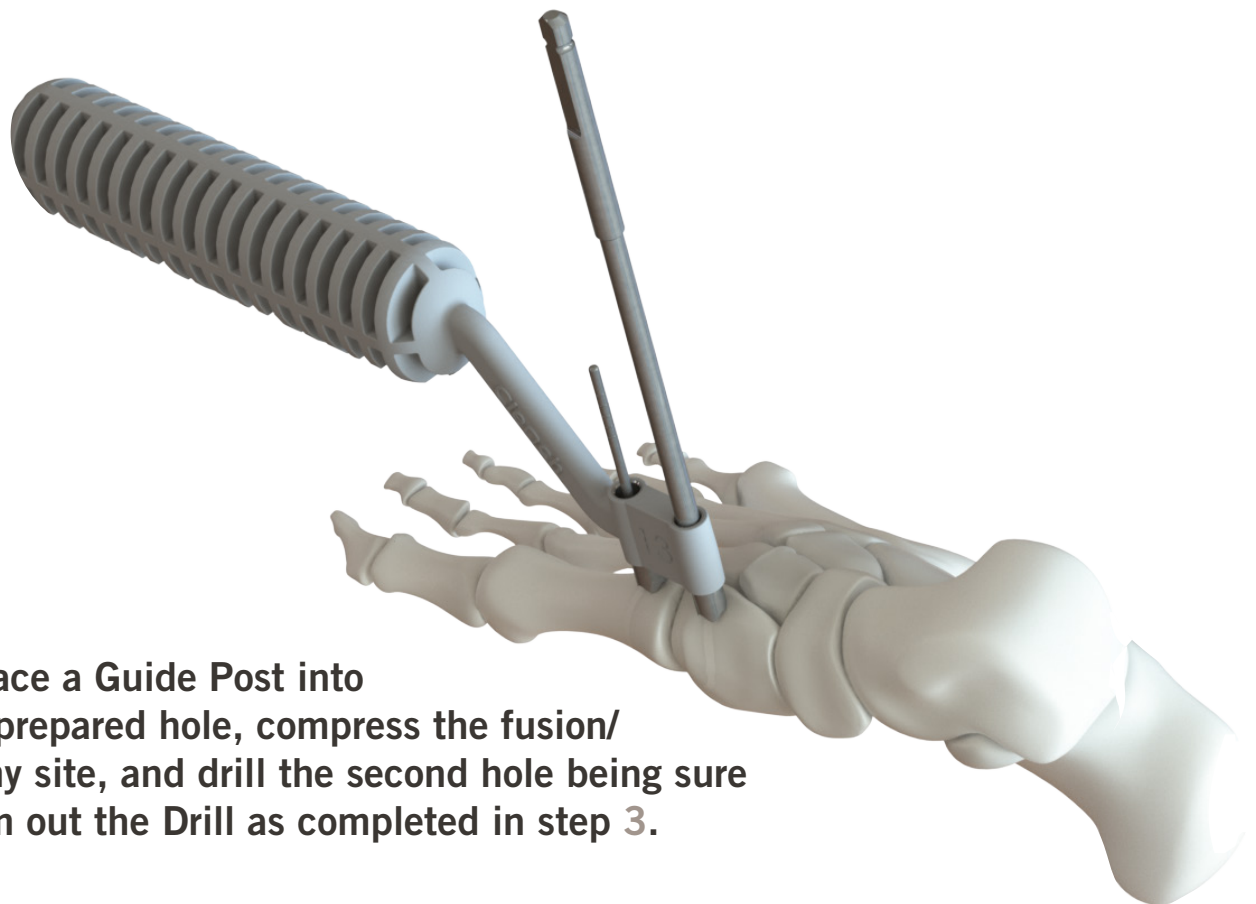
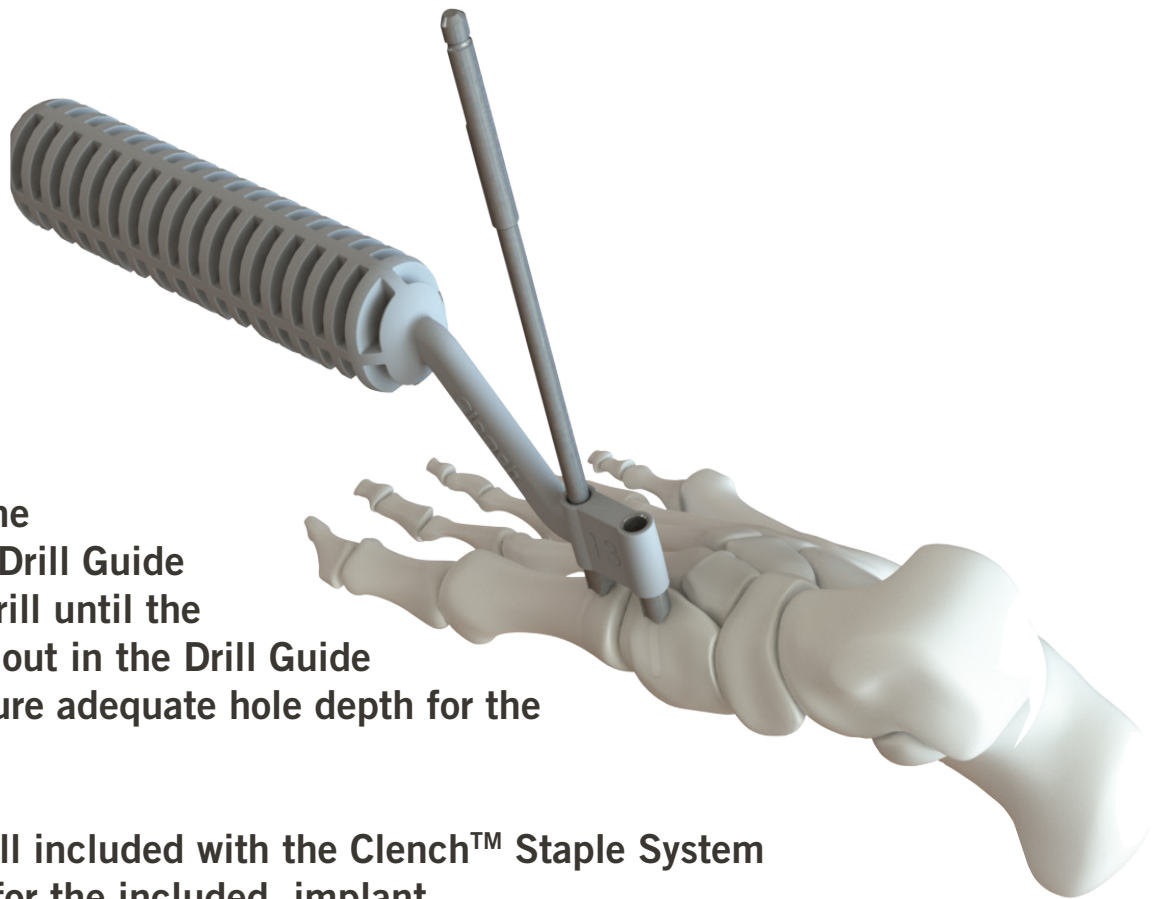


Note: The Drill Guide included with the Clench™ Staple System is calibrated for the included implant.

3 Insert the Drill into the Drill Guide sleeve and drill until the Drill bottoms out in the Drill Guide sleeve to ensure adequate hole depth for the implant.

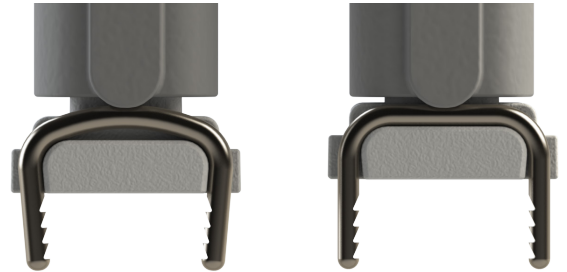
Note: The Drill included with the Clench™ Staple System is calibrated for the included implant.

4 Place a Guide Post into the first prepared hole, compress the fusion/osteotomy site, and drill the second hole being sure to bottom out the Drill as completed in step 3.

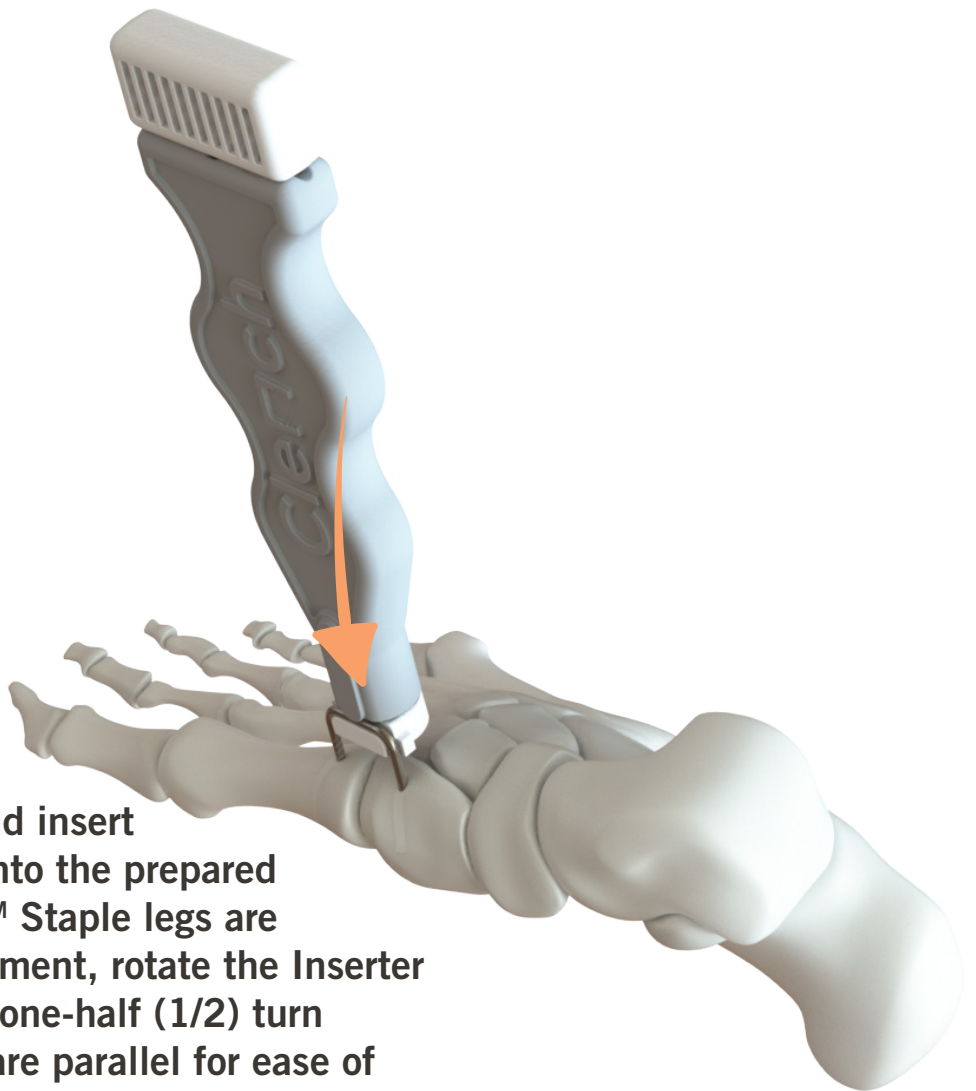


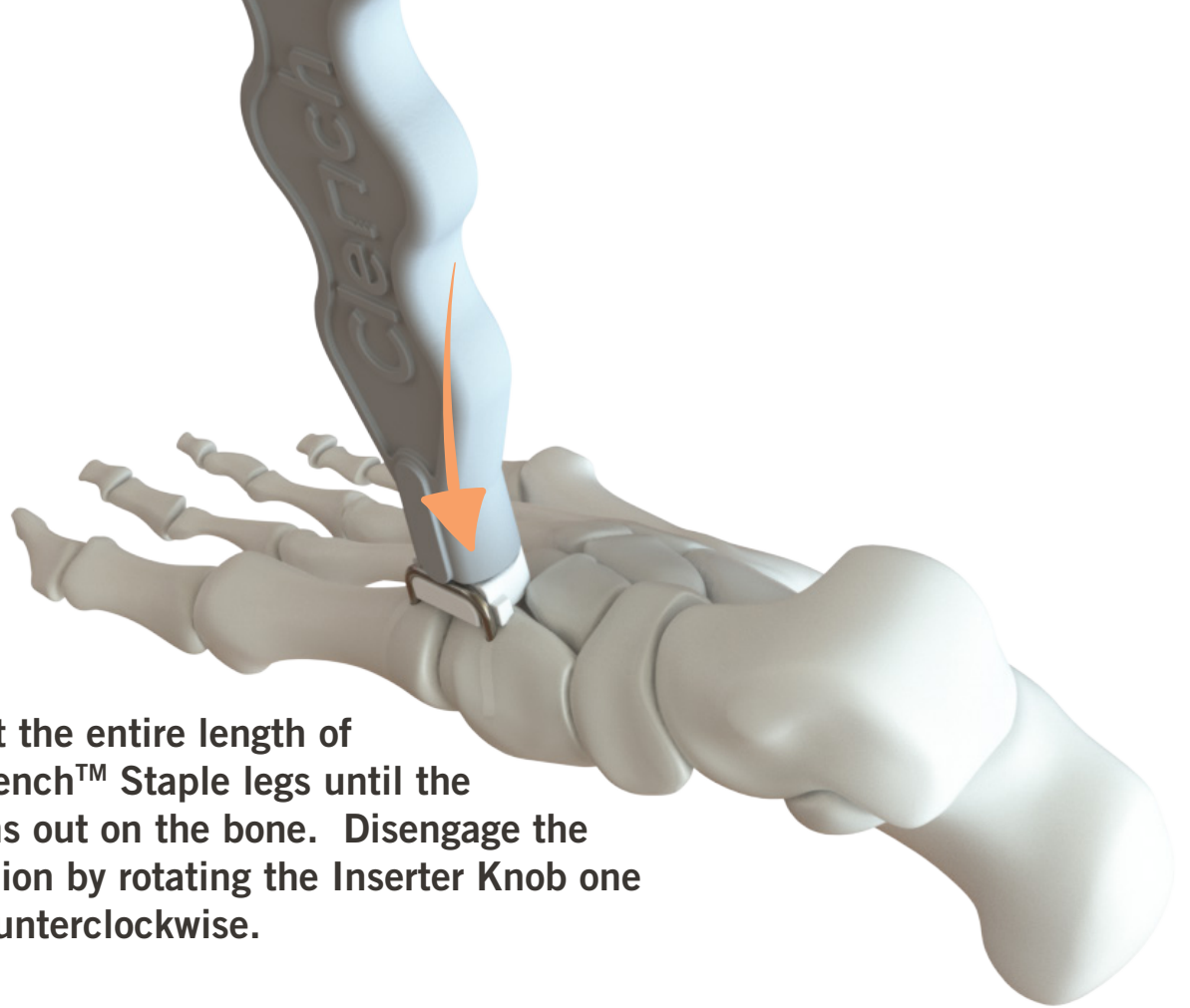


5 Rotate the proximal Inserter Knob one-half (1/2) to one (1) full turn clockwise to expand the implant legs until parallel. If necessary rotate the Inserter Knob in one-half (1/2) turn increments to expand the legs as needed for insertion ease.



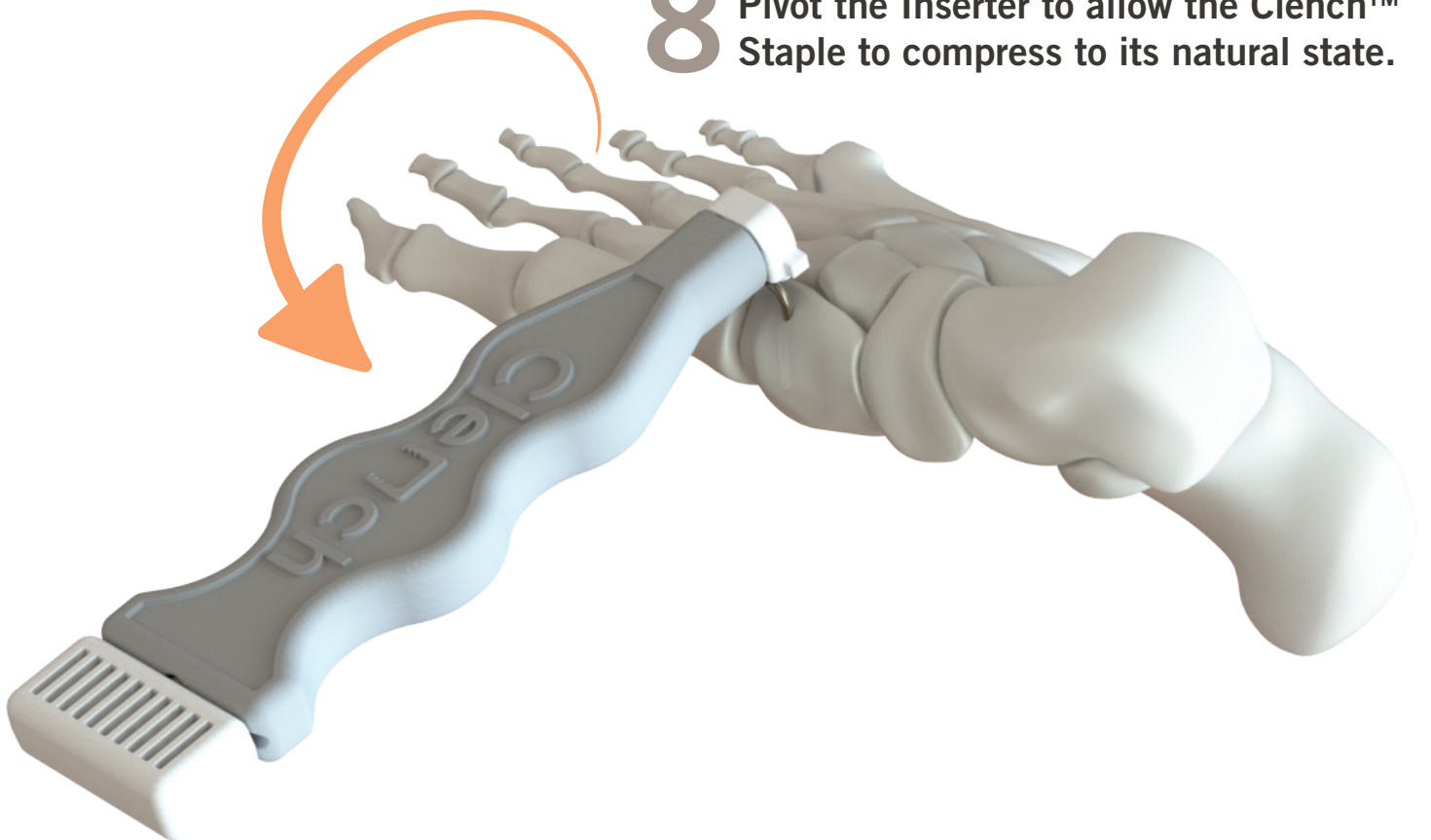
6 Ensure the fusion/osteotomy site is adequately compressed and insert the Clench™ Staple legs into the prepared drill holes. If the Clench™ Staple legs are overextended during placement, rotate the Inserter Knob counterclockwise in one-half (1/2) turn increments until the legs are parallel for ease of insertion.



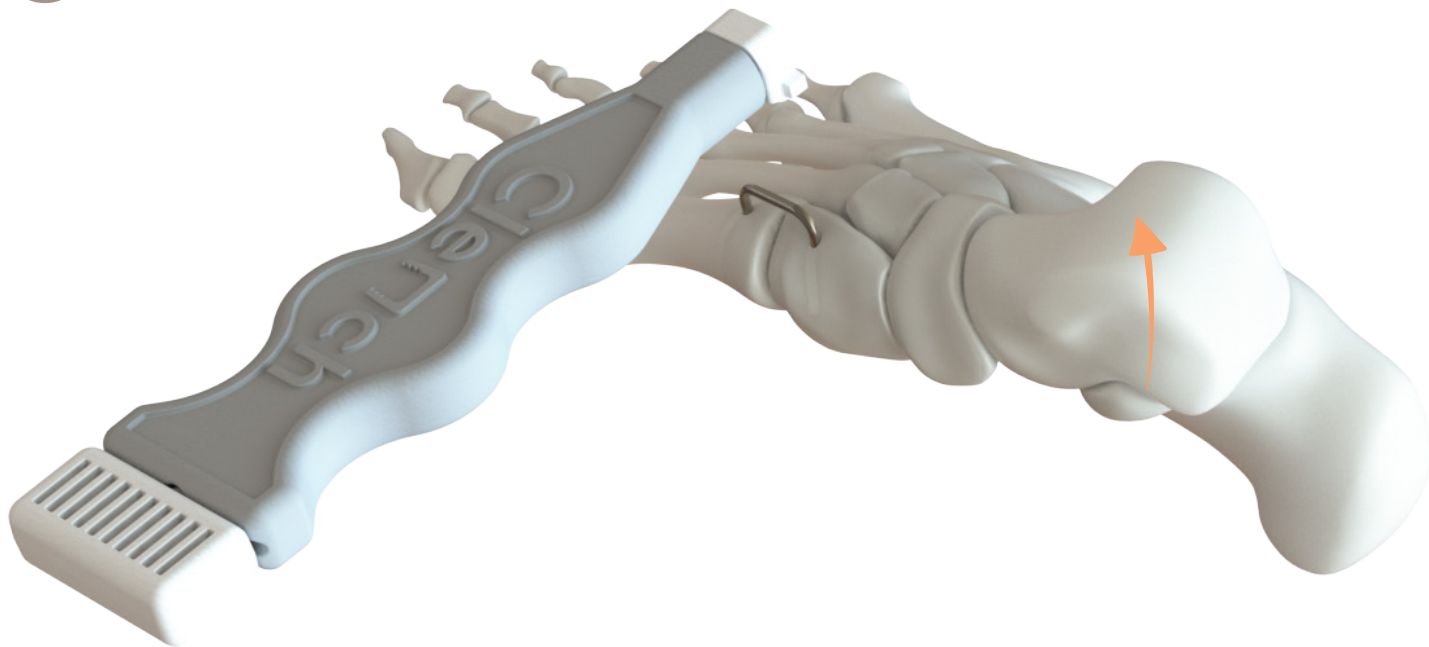


7 Fully insert the entire length of the exposed Clench™ Staple legs until the Inserter bottoms out on the bone. Disengage the implant expansion by rotating the Inserter Knob one (1) full turn counterclockwise.

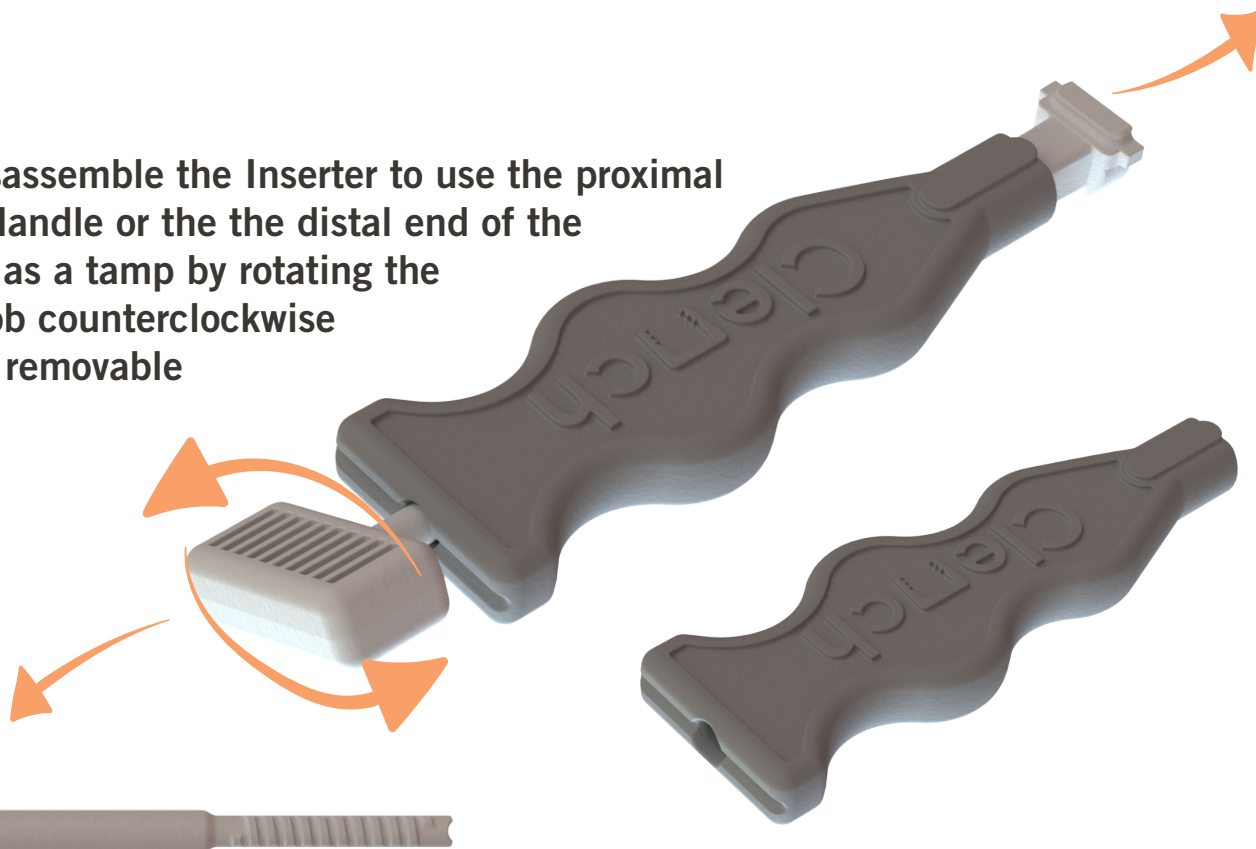
8 Pivot the Inserter to allow the Clench™ Staple to compress to its natural state.



9 Lift the Inserter as shown to release the Clench™ Staple from the Inserter.

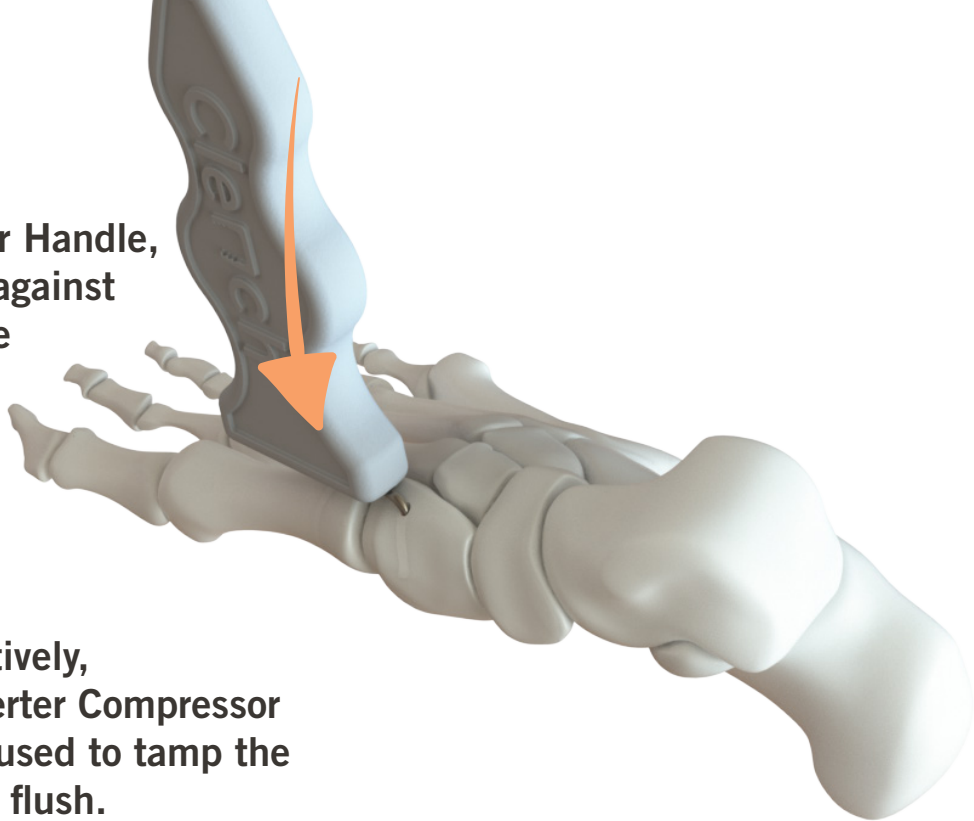


10 Disassemble the Inserter to use the proximal end of the Handle or the the distal end of the Compressor as a tamp by rotating the Inserter Knob counterclockwise until axially removable

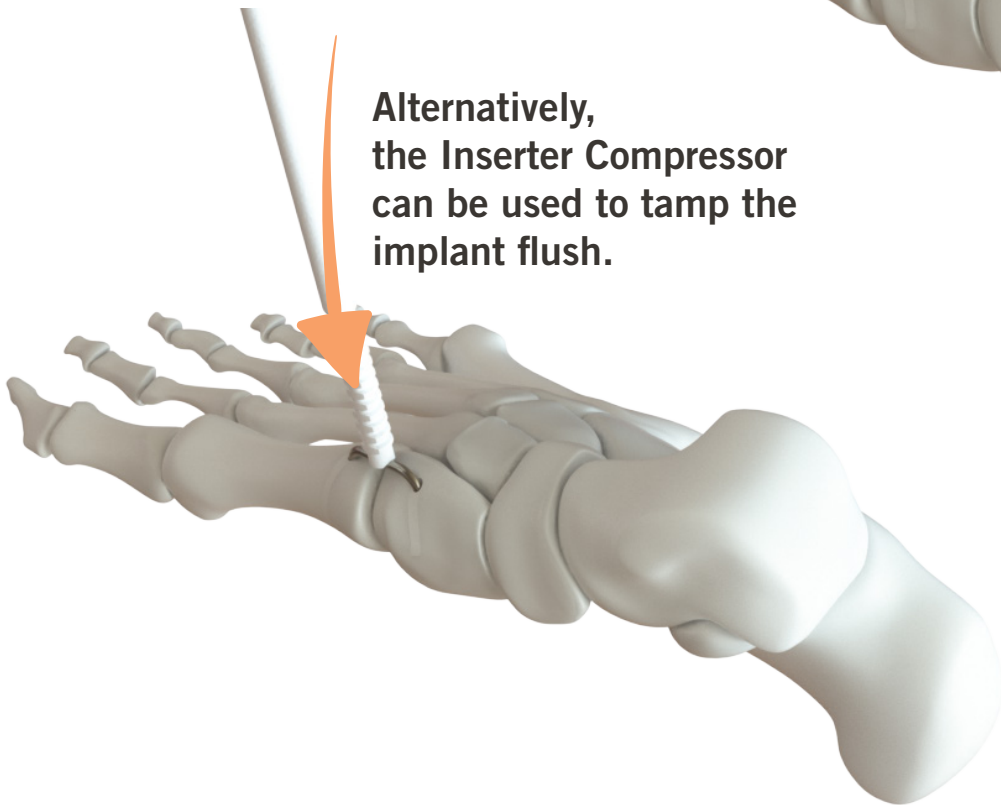


Note: The proximal end of the Handle and the distal end of the Compressor include a notched feature to help prevent slipping off of the bridge during tamping.

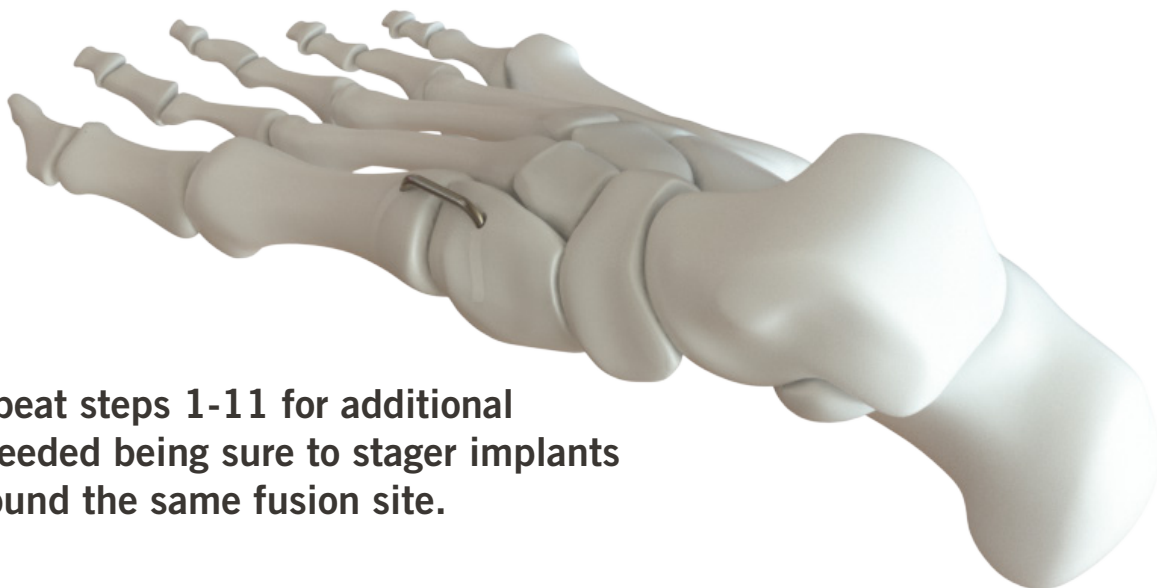
11 Using the Inserter Handle, place the proximal notch against the Clench™ Staple bridge and tamp gently until the implant is flush with the surface bone.



Alternatively, the Inserter Compressor can be used to tamp the implant flush.



12 Repeat steps 1-11 for additional fixation as needed being sure to stagger implants if placed around the same fusion site.



DEVICE REMOVAL:

- 1. Create a surgical incision to expose the bridge of the implant.**
- 2. Dissect tissue away from the bridge of the implant.**
- 3. Using forceps, grasp the bridge of the implant and withdraw the implant from the tissue. If the implant is difficult to remove, cut the bridge with wire cutters and use forceps to grasp and rotate while withdrawing each implant segment.**

For further information, please reference the Instructions for Use insert contained within each implant package. This can also be obtained from your authorized sales representative or customer service.



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