

Arcus[®] Staple System

Surgical Technique



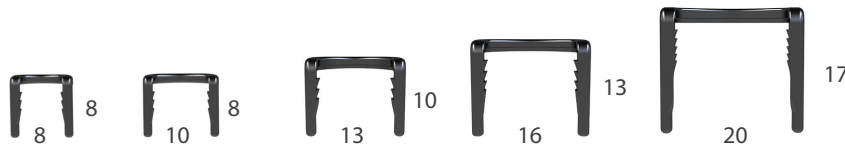


- **Unique arc design creates greater proximal-to-distal compression than tested conventional and nitinol staples***
- **Proven to retain compression over time and after 600 cycles***
- **Internal barbs function to help create compression and to resist migration****
- **Single-pack sterile instrumentation kit**
 - Staple pre-loaded on inserter for ease of use
- **Optional stacking capability**



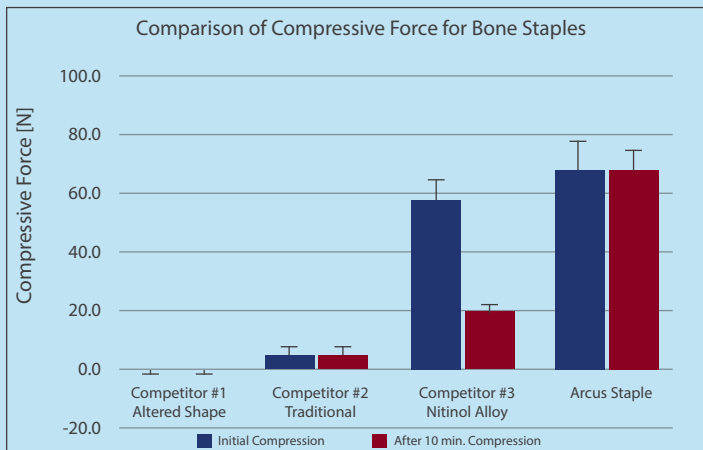
The Arcus Staple System is manufactured using Ti 6-4 ELI.

**Actual
Sizes
(mm)**



Mechanical Evaluation of the Interfragumentary Compressive Forces of the Arcus® Staple System*

The results showed the Arcus Staple System successfully maintained compressive forces across the simulated fracture site after ten minutes of relaxation and after cyclic bending of the staple.



- Demonstrated compressive integrity across the fracture site with no loss of compressive force during staple bending
- No statistically significant loss in applied compressive force measured after ten minutes
- No significant loss in compressive force across the fracture site after six hundred cycles of staple bending, with no significant loss in compression when the construct was removed from the test machine and in a relaxed state

*Reference: *A Mechanical Evaluation of the Interfragumentary Compressive Forces of the Arcus Staple System*, Lisa A. Ferrara, Ph.D., et. al. Orthokinetic Technologies and Orthokinetic

**Reference: ASTM F564-10 "Standard Specification and Test Methods for Metallic Bone Staples".

Arcus® Staple System Surgical Technique Overview

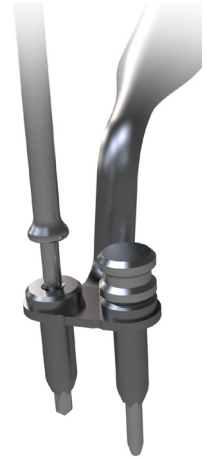
1. Sizing & Bone Preparation

The optional **Arcus Staple Sizing Guide** may be used to determine staple size needed. Open size-specific **Instrument/Implant Kit**. Place **Drill Guide** evenly over osteotomy. Drill first hole until the stop meets **Drill Guide** bushing.



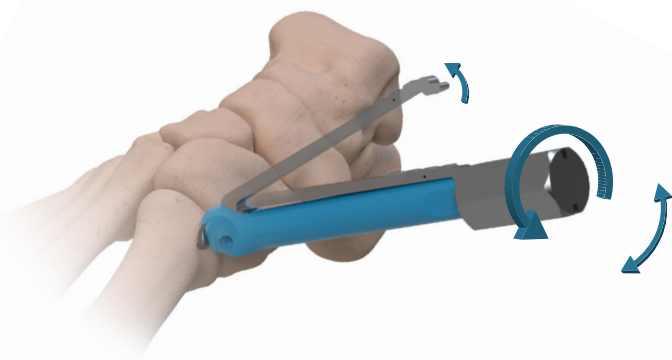
2. Stabilize

Insert **Stabilization Pin**. Prior to drilling second hole, ensure osteotomy/fracture is fully reduced. Drill second hole. Remove **Pin** and **Drill Guide**.



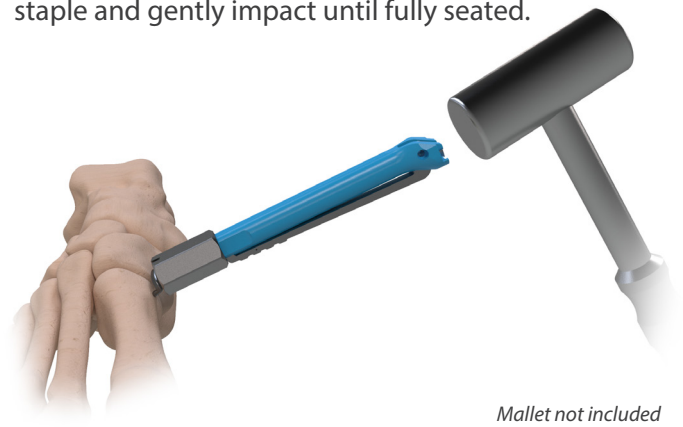
3. Insert Staple

Using **Staple Inserter Assembly**, insert staple. Remove **Inserter** from **Staple** by twisting knob counter-clockwise until lever arm is free, then tilt **Inserter** forward or backward.

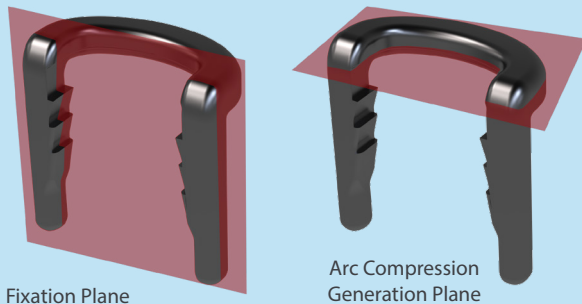


4. Optional Tamping

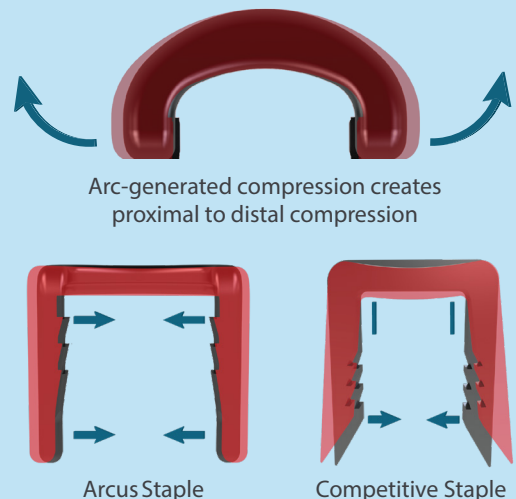
If **Staple** bridge is not fully seated on bone, **Inserter** may be used as a tamp. First re-engage lever arm under knob and twist clockwise. Place flat end of knob on staple and gently impact until fully seated.



Arc-Generated Compression



Compression is created in the **Arc Compression Plane**. Staple tines are narrower than guided drill holes.



Arcus® Staple System Stacking Options

	8x8	10x8	13x10	16x13	20x17
8x8					
10x8					
13x10					
16x13					
20x17					

ORDERING INFORMATION

Part No.	Description		
KITS	Each Kit Contains: Arcus Staple and Size-Specific Inserter, AO Drill, Drill Guide & Temporary Pin	ASSEMBLY	Each Individual Assembly Contains: Arcus Staple & Size-Specific Inserter
ARC-0808K	8mm x 8mm Arcus Staple System Sterile Procedure Kit	ARC-0808A	8mm x 8mm Arcus Staple Individual Assembly
ARC-1008K	10mm x 8mm Arcus Staple System Sterile Procedure Kit	ARC-1008A	10mm x 8mm Arcus Staple Individual Assembly
ARC-1310K	13mm x 10mm Arcus Staple System Sterile Procedure Kit	ARC-1310A	13mm x 10mm Arcus Staple Individual Assembly
ARC-1613K	16mm x 13mm Arcus Staple System Sterile Procedure Kit	ARC-1613A	16mm x 13mm Arcus Staple Individual Assembly
ARC-2017K	20mm x 17mm Arcus Staple System Sterile Procedure Kit	ARC-2017A	20mm x 17mm Arcus Staple Individual Assembly
		ARC-SSTK	Arcus Staple Sizing Guide

INDICATIONS: Arcus Staple System is indicated for fixation of bone fractures, bone reconstruction, ligament, soft tissue and tendon. Examples included: (1) Fixation of bone fragments or small bones fractures; (2) Fracture management in the foot and hand.

CONTRAINDICATIONS: (1) Patient conditions including insufficient quantity or quality of bone; (2) Blood supply limitations and previous or active infections that may inhibit healing; (3) Surgical procedures other than for the indications listed; (4) Patients with conditions that limit their ability or willingness to follow postoperative care instructions; (5) The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature; (6) Foreign-body sensitivity. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to implantation.

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert. Check for country product clearances and reference product-specific instructions for use.

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The Arcus Staple System is manufactured using TI 6-4 ELI.

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