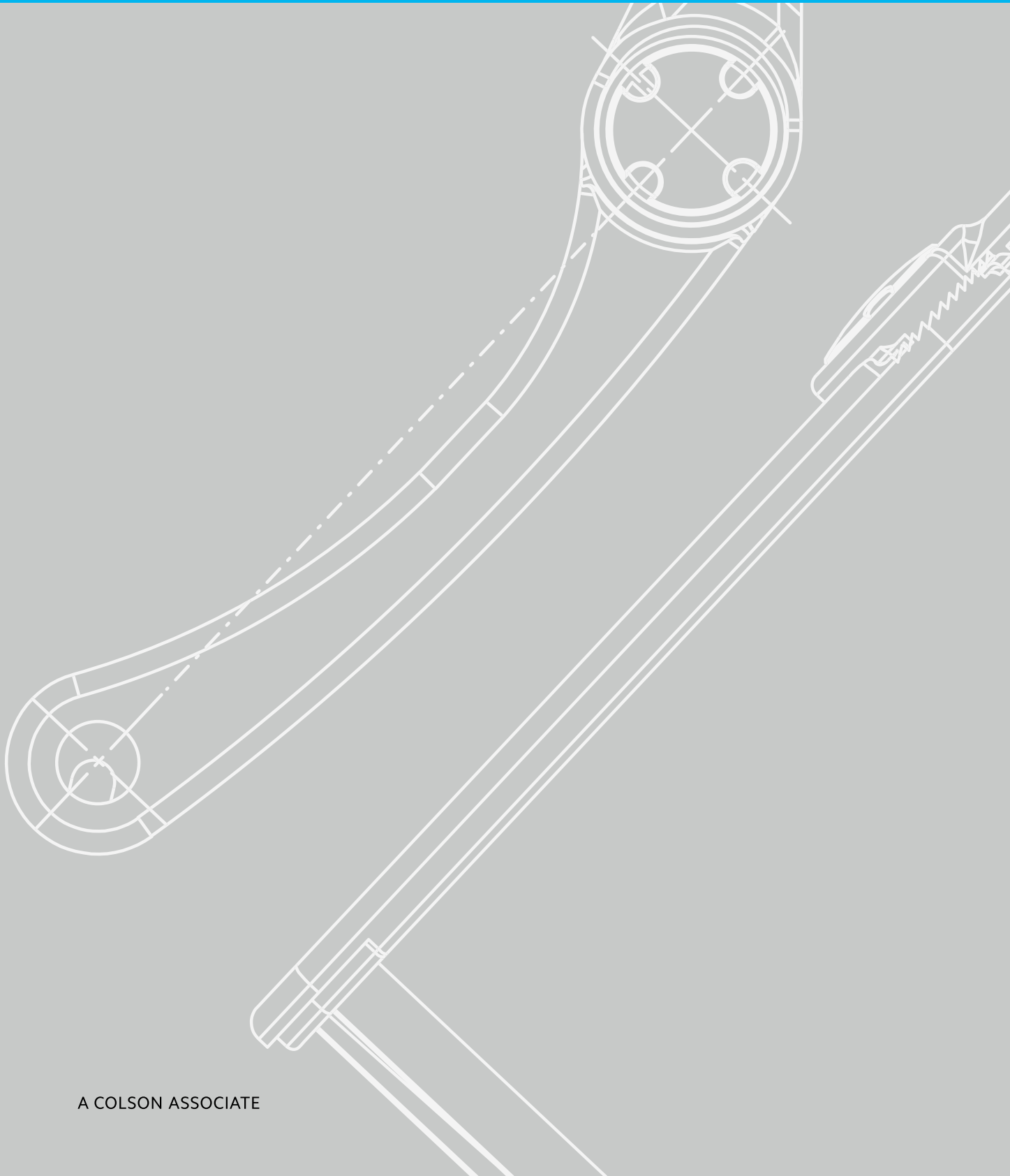


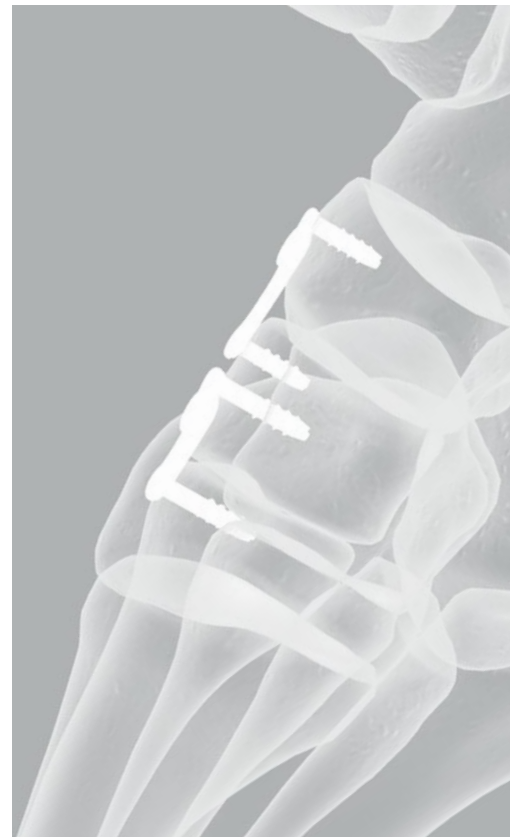
Technical Monograph





Technical Monograph

Acumed® Ratcheting Compression Plating System



ORTHOPAEDIC HISTORY & PROBLEM

Problem Statement/History

Fixation of fusions and osteotomies in the foot are challenging to surgically repair. Various staple and compression plate designs have been implemented to address these challenges. The performance of these solutions are affected by biomechanical challenges in surgeries of the foot and ankle, including:

1. Joint stabilization
2. Compression (initial and retained)
3. Cyclic loading
4. Ease of application

Solution

The Acumed Ratcheting Compression Plating System addresses each of these factors. With appropriate application, the Ratchet Plate solution allows the surgeon to generate, incrementally increase, and retain mechanical compression.

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SOLUTION

Acumed® Ratcheting Compression Plate Description

- An adjustable device which integrates a plate span, cannulated and threaded legs, and ratcheting hub into a stand-alone implant.
- Each Ratcheting Compression Plate utilizes the small ratcheting hub which contains a built-in anti-reversing mechanism. This allows the surgeon to incrementally increase and lock in the final configuration of the device intraoperatively.
- The cannulated legs fit over .045" guide wires for precise placement.
- During activation, the legs travel in line towards each other, allowing the surgeon to control the direction of compression.
- The plate span comes in six sizes to fit a wide variety of indications.



DESIGN RATIONALE FOR SYSTEM

Problem	Feature	Parameter	Benefit
How Compression is Generated	Controlled Compression	Up to 10.8 pounds Acumed Internal Test Report No. TR01279	Surgeon controls how much compression to apply
	Controlled Reduction	3–4 mm in-line leg travel	Audible click indicates linear leg travel
How Much Compression is Retained	Anti-reversing Ratchet Hub	Up to 94% retained compression, 5 hours post application Acumed Internal Test Report No. TR01279	Anti-reversing ratchet hub mechanically locks in compression
Biomechanical Performance	Bending Strength	Bending load to failure Acumed Internal Test Report No. TR01204	Bending strength greater than a competitive bone staple
	Pullout Strength	Force required to pull out Fatigue resistance Acumed Internal Test Report No. TR01204	Pullout strength greater than a competitive bone staple
	Cyclic Loading	Fatigue resistance Acumed Internal Test Report No. TR01204	Greater fatigue strength than a competitive bone staple

Design Characteristics

Ratcheting Compression Plates come in a variety of sizes to fit the requirements of different indications.

Device Sizes & Configuration

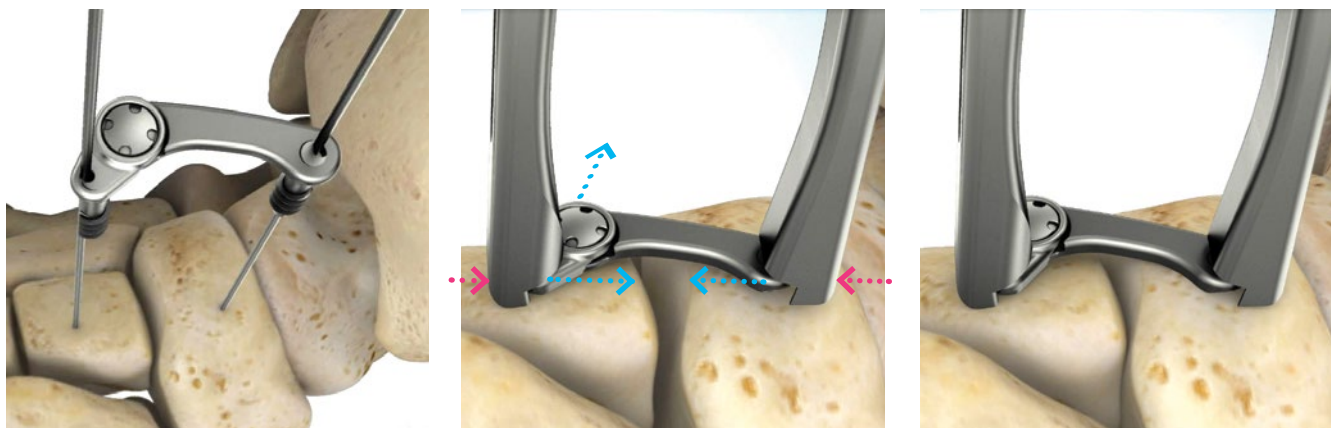
DESCRIPTION	PLATE SPAN	LEG LENGTH	PART NUMBER
Ratcheting Compression Plate, 15 x 11 Sterile	15 mm	11 mm	3701-1511N-S
Ratcheting Compression Plate, 17 x 14 Sterile	17 mm	14 mm	3701-1714N-S
Ratcheting Compression Plate, 20 x 17 Sterile	20 mm	17 mm	3701-2017N-S
Ratcheting Compression Plate, 25 x 17 Sterile	25 mm	17 mm	3701-2517N-S
Ratcheting Compression Plate, 25 x 20 Sterile	25 mm	20 mm	3701-2520N-S
Ratcheting Compression Plate, 30 x 25 Sterile	30 mm	25 mm	3701-3025N-S



- Ratchet Hub: Anti-reversing mechanism allows surgeon to incrementally increase in order to lock in compression
- Plate Span: Designed to span the fusion site while sitting flush to the bone
- Material: Made from BioDur stainless steel
- Plate Legs: Cannulated, slotted, threaded
- Laser-welded assembly
- Sterile implants
- Ratchet hub can be disassembled intraoperatively or postoperatively to aid in explantation

How Actuation Works

After each implant leg is inserted over the guide wire and seated on the surface of the bone, each end of the Compression Tool is threaded over the guide wire. The ends of the tool are seated on either side of the plate span. The finger holes on the Compression Tool are then squeezed together. This action applies pressure (indicated in red) to the sides of the implant and activates the ratchet mechanism. As the ratchet actuates, the ratchet hub rotates and makes an audible “click.” Each click drives the component legs in line closer together (indicated in blue).



Leg Travel per Plate Span

Size	15 mm	17 mm	20 mm	25 mm	30 mm
Total Travel	3.4 mm	3.6 mm	3.7 mm	3.9 mm	4 mm
Per Click	0.5 mm	0.5 mm	0.5 mm	0.5 mm	0.5 mm

Implant Removal

Each Ratcheting Compression Plate is designed to be explantable (removable) from the body. Using the instruments included in the set, the ratchet plate can be unlocked, thereby releasing the compression on the construct. Each side of the plate span can then be unthreaded from the bone.

See the surgical technique for specific instructions.

MOST COMMON INDICATIONS



1. Calcaneo-cuboid Fusion



3. Navicular-cuneiform Fusion



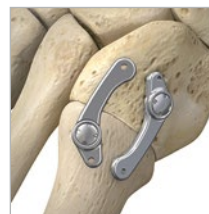
5. Dwyer Osteotomy



2. Talo-navicular Fusion



4. Tarsal-metatarsal Fusion



6. Lapidus

DISCUSSION OF TESTING

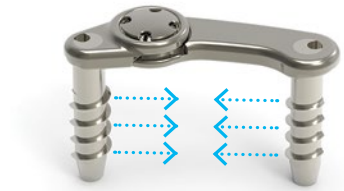
Biomechanical Testing

During biomechanical testing, a competitive bone staple was used as a test control to evaluate the performance of the Ratcheting Compression Plate.

Compression Testing—Ratcheting Compression Plate

This testing method measures the compressive force generated by the device and the retained compressive force five hours later.

- Initial compression measured up to 10.8 pounds
- Retained compression measured up to 94%
- Source: Acumed Internal Test Report No. TR01279



Four-point Bending

A testing method which places a pure bending moment on the device. The results identify device stiffness and peak failure loads.

Test	Size	Mode	Acumed Ratcheting Compression Plate	Competitive Bone Staple
Static Four-Point Bending	S	Stiffness	10 N/mm	10 N/mm
		Peak Load	101 N	75 N
	L	Stiffness	7.5 N/mm	7 N/mm
		Peak Load	85 N	64 N



S=Small, L=Large and N=Newtons | Acumed Internal Test Report No. TR01204

Cyclic Loading

A testing method which determines the fatigue resistance of a device when subjected to repetitive loading for a large number of cycles.

Test	Size	Mode	Acumed Ratcheting Compression Plate	Competitive Bone Staple
Dynamic Four-Point Bending	S	Runout Load at 1 Million Cycles	30 N	15 N
	L		17 N	13 N



S=Small, L=Large and N=Newtons | Acumed Internal Test Report No. TR01204

Pullout

A testing method which determines the axial (pullout) holding strength of a device.

Test	Mode	Acumed Ratcheting Compression Plate	Competitive Bone Staple
Axial Pullout	Peak Load	72 N	40 N



N=Newtons | Acumed Internal Test Report No. TR01204



Acumed Headquarters
5885 NW Cornelius Pass Road
Hillsboro, OR 97124
Office: +1.888.627.9957
Office: +1.503.627.9957
Fax: +1.503.520.9618
acumed.net

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