

34-TIMES fewer
REMOVALS
for discomfort
than plates



Compared to Plates:

- Equal union rates¹
- 34-times fewer removals for discomfort²
- Leaves bone 230% stronger if removed³

The Breakthrough You Worry About?

The average clavicle patient is an active male between the ages of 30 and 40-years old. Despite preoperative counselling, 88% complain of discomfort from their clavicle plate.⁴ After the bone has healed, approximately 18% of these patients have their plates removed, revealing 6 to 12 holes in the narrow clavicle.⁵

- ◆ Will the patients return to activities before bone fills in the holes?
- ◆ What are the options if the clavicle refractures?

CRx[®] – The Breakthrough You've Been Looking For!

Complications Requiring Hardware Removal

Complications Requiring Hardware Removal	Plate Studies n=558		Sonoma CRx [®] n=342		Sonoma VELOX [™] n=407	
	#Surgical interventions	Percentage	#Patients	Percentage	#Patients	Percentage
Infections	16	2.87%	6	1.75%	6	1.47%
Hardware Failures	14	2.51%	8	2.34%	3	0.74%
Non Union/malunion	24	4.30%	10	2.92%	3	0.74%
Refractures	3	0.54%	3	0.88%	0	0.00%
Irritation/prominence/other	47	8.42%	3	0.88%	1	0.25%
Total	104	18.64%	30	8.77%	13	3.19%

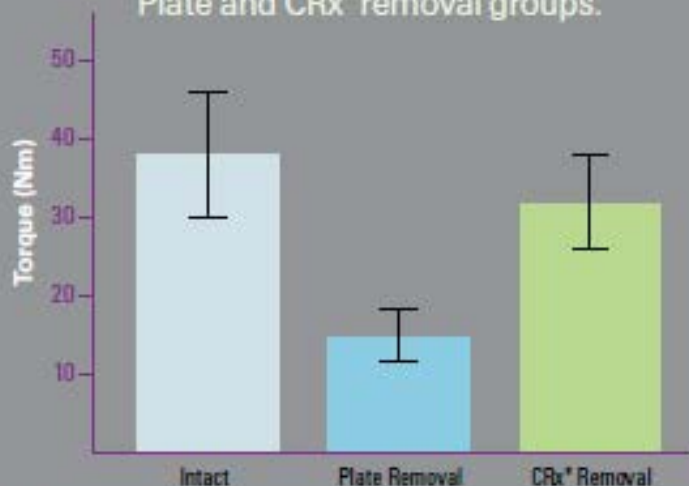
⁵Plate Studies[®] data is referenced from Wjodick et al. Systematic review of the complications of plate fixation of clavicle fractures. Arch Orthop trauma Surg (2012) 132:617-625

Sonoma CRx[®] and VELOX[™] data has been captured from Sonoma CRx[®] and VELOX[™] removal records

Plates are removed **34-times more** for discomfort than the CRx[®] Nail[®]

In a 12-study meta-analysis by Terry Whipple, MD, clavicle fractures treated with plates demonstrated an 18.64% removal rate for complications. Fractures treated with the CRx[®] using first generation instrumentation resulted in 8.77% device removal. This was further decreased by the use of CRx[®] with the VELOX[™] procedure, which resulted in a 3.19% removal rate. Additionally, the VELOX[™] procedure resulted in 34-times fewer removals for irritation/prominence than plates.

Failure torque (Nm) comparison of Plate and CRx[®] removal groups.



Holes in the Bone vs. a Whole Bone

After removal of a plate, there is a documented fracture rate of 7%.⁷ This is supported by laboratory testing on fourth generation sawbones at Steadman-Philippon Research Institute (SPRI). Testing determined a clavicle with a removed plate is 283% weaker than a normal clavicle. After a CRx[®] was removed, bone strength was statistically the same as unfractured bone and was 230% stronger than the plated bone due to the lack of stress risers caused by bone screws.



Clavicle after the Plate has been removed (283% weaker than a normal clavicle)

REFERENCES:

1. King. Clavicle shaft fractures: intramedullary locked fixation vs anatomically contoured locked plating. Presented ADSSM, July 2013
2. Whipple. Complications leading to surgical intervention following ORIF of clavicle fractures: a comparison between plate and intramedullary fixation. Sonoma, March 2012
3. Wjodick et al. Stability of mid-shaft clavicle fractures after plate fixation versus intramedullary repair and after hardware removal. Knee Surg Sports Traumatol Arthrosc. Aug 2012
4. Formani N, et al. Superior versus inferior plating of clavicle fractures. Orthopedics. 2013 Jul
5. Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am. 2007
6. Whipple. Complications leading to surgical intervention following ORIF of clavicle fractures: a comparison between plate and intramedullary fixation. Sonoma, March 2012
7. Wjodick et al. Complications after plate fixation and elastic stable intramedullary nailing of displaced midshaft clavicle fractures: a retrospective comparison. SICOT 2012

The First Intramedullary Nail to *Go the Distance*

Intramedullary rods are advantageous to use in the treatment of long bone fractures for a number of well-recognized reasons. Rods share the load with the bone, rather than shield it for more rapid return to function. In addition, intramedullary fixation is less invasive, which is advantageous for recovery and cosmesis.

The CRx[®] is the first implant capable of following the curvature of the clavicle and providing the benefits expected from intramedullary fixation.

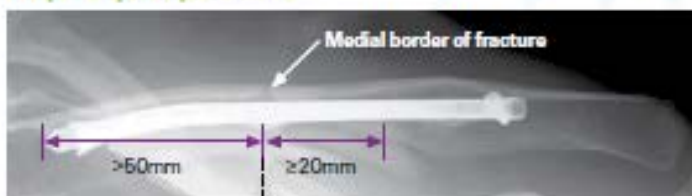
- ◆ Dual-locking implant is fixed at both ends to provide stable fixation
- ◆ Periosteum blood supply is retained to facilitate healing
- ◆ Micromotion at the fracture site promotes healing



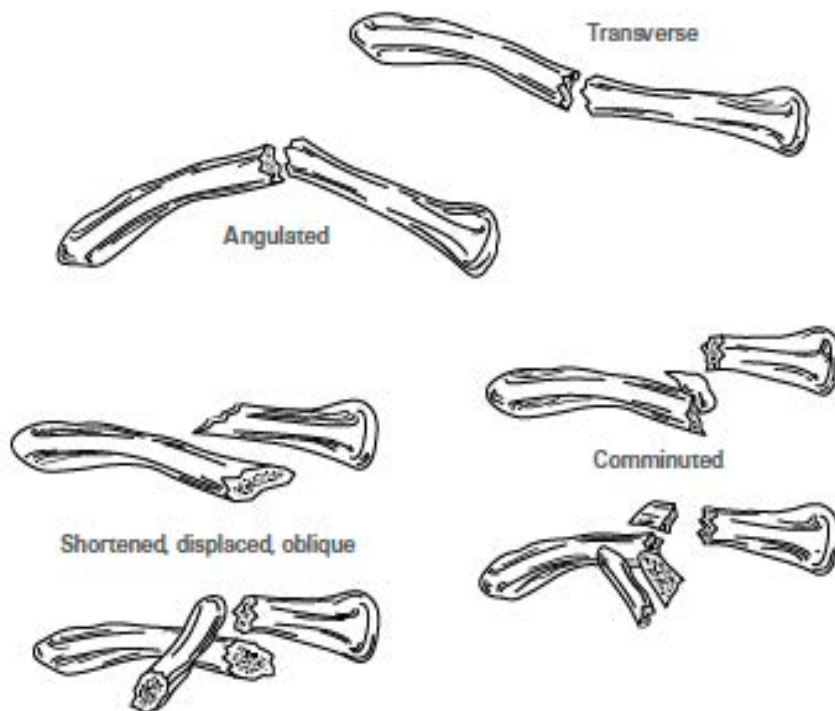
What are the **Indications?**

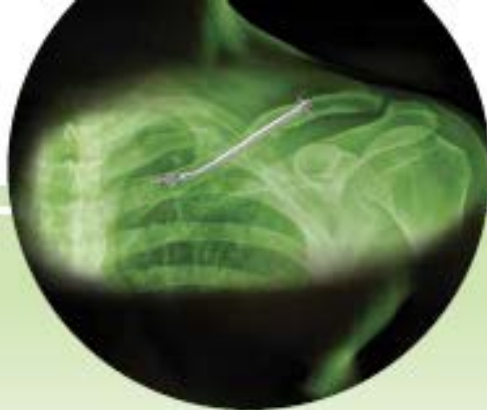
The CRx[®] is utilized for many different types of mid-shaft fractures. The only requirements are that the implant extends a minimum of 50mm beyond the most medial edge of the fracture and 20mm beyond the most lateral edge of the fracture to ensure bone support.

Proper implant placement



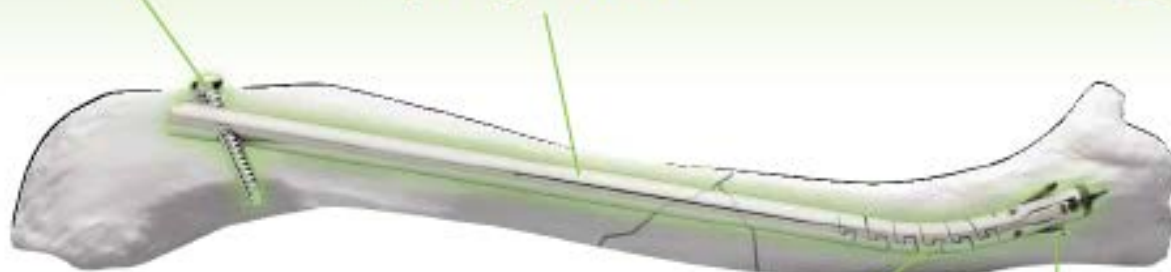
The CRx[®] is used effectively for fresh fractures, malunions, nonunions and plate revisions.





Lateral 2.7mm stainless steel screw for locking and rotational stability

4.2mm diameter; implant lengths 100-130mm



35mm Wavibody® allows navigation of S-shaped bone

During activation, talons open up to 8mm for stability



Flexible-to-Rigid Wavibody®

The difference between the CRx® nail and other clavicle repair devices is the ability of the CRx® to reproducibly follow the natural curvature of the clavicle. This is made possible by our proprietary flexible-to-rigid Wavibody®. The laser cut pattern in the Wavibody® is specifically engineered for the anatomical requirements of the clavicle. It allows the nail to navigate the bowed medial side of the clavicle and span the entire length of the bone, providing greater strength at the fracture site. When in position, the Wavibody® is "activated" and transitions from flexible to rigid for an anatomic reduction. This rigid curvature cooperates with the talons to resist torsion and axial displacement.

Surgical Technique Summary



Step 1:
2mm pilot drill in medial segment



Step 2:
2mm pilot drill in lateral segment



Step 3:
Rear trocar tip of guidewire navigates lateral segment



Step 4:
Reduction of clavicle fragments
rearrangement of segments



With **CRx[®]**, removal is **Your** choice.

Pre-Operative



Six-Months Post Operative



Bilateral Symmetry After Removal



Incisions from CRx[®] removal



Although most surgeons choose not to remove the CRx[®], a small percentage of surgeons electively remove the CRx[®] in all of their patients. However, it is extremely rare for a CRx[®] patient to request removal. CRx[®] removal is **generally a 15-minute procedure** performed under intravenous anesthesia. The implant is extracted after withdrawing the lateral screw and deactivating the talons through two small stab-incisions in the rear of the shoulder. No additional rehabilitation is required and the bone has been shown to remodel completely.

Medicare Reimbursement Estimate (varies by location)

Clavicle Fracture ORIF – CPT Code 23515

Payment to Physician: \$739

Payment to Outpatient Hospital: \$5383

Payment to Ambulatory Surgery Center: \$2974

Hardware Removal – CPT Code 20680

Payment to Physician: \$435

if removal performed in hospital

Payment to Outpatient Hospital: \$1737

Payment to Ambulatory Surgery Center: \$959

NOTE:

Private insurance is generally higher reimbursement.



Step 4:
Clavicle fracture. Drive wire and flexible CRx[®] over 50cm into medial side of the fracture.



Step 5:
Insert the implant. Activation causes the implant to transform from flexible to rigid.

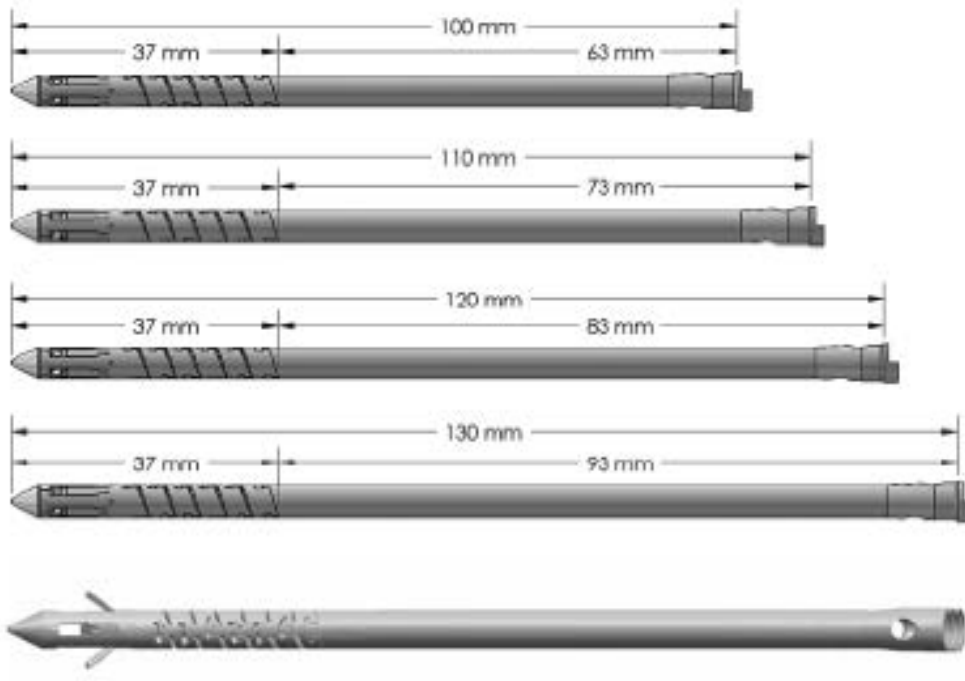


Step 6:
Insert the anti-rotation screw in the lateral side.



Step 7:
Cerclage butterfly fragments to the CRx[®]/bone strut.

Implant Specifications



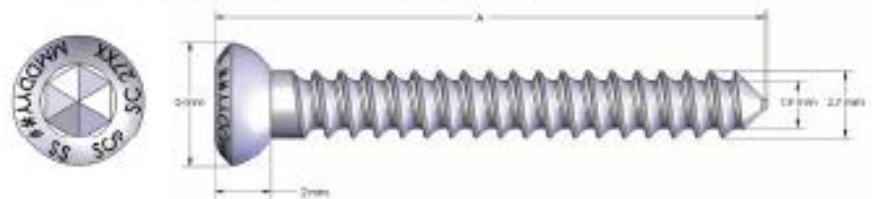
Implant Part Numbers

Sonoma CRx* Implants

CRXWG2-40100-S	4.2mm x 100mm Sonoma CRx* WG
CRXWG2-40110-S	4.2mm x 110mm Sonoma CRx* WG
CRXWG2-40120-S	4.2mm x 120mm Sonoma CRx* WG
CRXWG2-40130-S	4.2mm x 130mm Sonoma CRx* WG

Bone Screws

SC2714	2.7mm x 14mm Self-Tapping, Bone Screw
SC2716	2.7mm x 16mm Self-Tapping, Bone Screw
SC2718	2.7mm x 18mm Self-Tapping, Bone Screw
SC2720	2.7mm x 20mm Self-Tapping, Bone Screw
SC2722	2.7mm x 22mm Self-Tapping, Bone Screw
SC2724	2.7mm x 24mm Self-Tapping, Bone Screw
SC2726	2.7mm x 26mm Self-Tapping, Bone Screw



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