Product Overview and Features

The VELOX™ Procedure with Sonoma CRx® is faster, streamlined, and designed for reproducible, minimally invasive clavicle fracture repair. The Sonoma CRx nail eliminates plate prominence, uniquely conforms to your patient’s anatomy, and locks to length for potentially earlier return to activities of daily living.

1. **Lateral Unicortical Screw**
   2.7mm Locking Screw secures implant and lateral fracture segment.

2. **ACTIVLOC® Grippers**
   ACTIVLOC grippers engage bone upon implant actuation, providing fixation.

3. **WAVIBODY® Technology**
   WAVIBODY segment adapts to the curvature of the intramedullary canal and transitions from flexible to rigid upon implant actuation.
**STEP 1**

**Pre-Operative Evaluation**

Using anterior to posterior (AP) and 45° cephalic tilt fluoroscopic views, determine if a minimum depth of 50mm (from the most medial edge of the fracture on the medial fragment) can be achieved in the medial segment intramedullary canal.

**STEP 2**

**Patient Positioning**

Position the patient in a modified beach chair position. Use an Allen table to gain access to the posterior shoulder.

Position the C-Arm from behind the patient to allow for AP and cephalic tilt views.

Expose and prep the entire aspect of the clavicle from medial to lateral, including the AC joint and posterior shoulder.
**STEP 3**
**Medial Segment Preparation**

For accurate implant placement, the medial segment canal must be prepared to a depth of 50mm from the most medial aspect of the fracture on the medial segment.

Make a 2-3cm oblique incision directly over the fracture site along Langer’s Lines.

Elevate the medial fracture segment and establish a starter hole in the canal of 20mm depth using 2.0mm then 3.5mm Drills.

**Using both AP and cephalic views, ensure the 3.5mm Drill does not violate the anterior cortex.**

Advance the Spade-Tip Guide Wire until the 50mm gold section is completely past the most medial edge of the fracture.

Use the 4.5mm Flexible Banded Reamer on power to ream the canal to the tip of the Guide Wire.

Alternatively: Use the 3.0mm Curved Trocar and 4.5 Curved Cutting Awl to prepare the medial canal to a depth of 50mm. Make sure the curves of the Trocar and Awl are aligned with the curvature of the clavicle. Ensure the anterior cortex was not punctured by the awls.
STEP 4

Lateral Segment Preparation

Optimal lateral exit point is posterior along the centerline of the bone, lateral and posterior to conoid tubercle.

Elevate the lateral segment and establish a 20mm deep starter hole in the canal using the 2.0mm Drill. Use fluoroscopy in an AP view to ensure optimal trajectory to exit point.

Advance the 3.5mm Drill just to cortex.

Under fluoroscopic guidance, insert the 4.5mm Aimer Awl to complete the exit trajectory.

Drive the 1.6mm K-Wire through the Aimer Awl, tenting the skin posteriorly.

Make a small incision over the palpable K-Wire. Remove the Aimer Awl and retain the K-Wire.
**STEP 5**  
**Fracture Reduction**

Using the 4.5mm Cannulated Drill, drill over the K-Wire from lateral to medial to the fracture site. Remove the K-Wire and retain the Drill.

Reduce the fracture.

Insert the Spade-Tip Guide Wire through the Drill and into the medial segment by hand or with power.

Remove the Drill and advance the 4.5mm Flexible Banded Reamer over the Guide Wire. Ream to the tip of the Guide Wire and confirm that the 50mm indicator band on the Reamer is beyond the most medial edge of the fracture on the medial segment.
STEP 6
CRx Implant Insertion

Place the Reamer Depth Gauge over the Reamer and advance it until it contacts bone. Read the length on the scale to determine implant length. If implant measurement falls between two sizes, choose the longer implant, and ensure you have adequate depth to accommodate the Lateral Screw.

Remove the Reamer. Advance the Implant Insertion Guide over the Guide Wire and into the lateral segment no more than 25mm.

Remove the Guide Wire and Implant Insertion Guide Inner Handle, retaining the Guide Channel.
STEP 6
CRx Implant Insertion (Cont.)

Attach the CRx Implant to the Outrigger and insert the Actuation Driver into the hub of the Implant.

Advance the CRx Implant along the Guide Channel and into the lateral fragment. Withdraw the Guide Channel BEFORE advancing the Implant to final position. Confirm position with fluoroscopy.

Position the Outrigger in parallel plane with the top of the shoulder.

Expand the Implant’s ACTIVLOC grippers by turning the Actuation Driver clockwise until the white lines become colinear. Remove the Actuation Driver.
STEP 7
Lateral Screw Placement

Insert the Soft Tissue Trocar into the External Sheath. Make a stab incision and advance the Sheath with inserted Trocar until it rests firmly against posterior bone. Lock the position of the Sheath using the Thumb Screw.

Remove the Soft Tissue Trocar and insert the Drill Guide into the External Sheath.

Under fluoroscopic guidance, use the 2.0mm Drill to drill through the CRx Implant down to the edge of the anterior cortex.

Measure screw length on the Drill Guide and subtract 2mm for countersinking. Insert the screw using the 2.5mm Captive Screwdriver.

Verify that the Lateral Screw has passed through the CRx Implant by reinserting the Actuation Driver.
**STEP 8**
Confirm Reduction and Fixation

Evaluate the reduction and fixation of the fracture, including the deployment of the grippers, in both AP and 45° cephalic views. Clerclage to hold bony apposition for oblique or comminuted fractures.

Use appropriate soft tissue and wound closure procedures.

**STEP 9**
Post-Operative Care

Fit the patient with a sling or shoulder immobilizer.

Patients should avoid repetitive forward flexion or abduction past 90° until there is evidence of healing.

**STEP 10**
Implant Removal

Implant removal is an optional procedure. Sonoma Orthopedic Products® recommends removal of the Sonoma CRx from highly active patients after radiographic healing has been verified, or before 12 months from implantation has been reached.

**Lateral Screw Removal**

Use fluoroscopy to locate the Lateral Screw. Make an incision directly over the screw, and dissect down to expose the screw head.

Use the Hex Driver to remove the screw.

**Implant Removal**

Use fluoroscopy to locate the hub of the CRx Implant at the lateral insertion point. Make an incision directly over the CRx Implant Hub, and dissect down to expose the Implant Hub.

Insert the De-Actuating Device into the CRx Implant Hub.

Rotate the De-Actuating Device counterclockwise to deactivate the CRx Implant ACTIVLOC grippers. It will take 30-40 rotations to fully de-activate.

Remove the De-Actuating Device and insert the Long Hub Attachment. Rotate clockwise into the Implant Hub until firm. Slide the Removal Paddle onto the Long Hub Attachment. Use gentle blows to slap the CRx Implant entirely out of the bone.
Sonoma Orthopedic Products, Inc. has made these technique guidelines available for informational purposes only and to illustrate the physician authors’ suggested treatment for an uncomplicated procedure. Proper surgical procedures and techniques are the responsibility of the surgeon, who must evaluate the appropriateness of the procedures described, based upon his/her own personal medical training, experience and the needs of the individual patient. Prior to the use of the Sonoma Orthopedic Products system, the surgeon should refer to the product instruction for use (IFU) for complete indications, warnings, precautions and contra indications. Package inserts are also available by contacting Sonoma Orthopedic Products, Inc.