

Sonoma WRx® vs. Non-operative Treatment

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Comparison of Range of Motion, Radiographic Parameters and Complications for Minimally Invasive WRx® Surgery vs. Published Non-operative Treatment of Distal Radius Fractures

An analysis was conducted comparing results from six studies of non-operative treatment to a single-surgeon study of patients receiving the WRx® at three months, and one-year post treatment.^{1,2,3,4,5,6}

This data showed treatment with WRx® resulted in significantly better grip strength and range of motion (ROM) for most parameters (when comparing the uninjured to the injured wrist) at three months and one year compared to non-operative treatment. For those parameters that were not significantly improved, results were either equal or showed a trend towards better results for the WRx® group. All patients in the WRx® group experienced union whereas; at least 4.2% resulted in malunion in the non-operative group. In addition, there were no major complications in the WRx® group compared to seven major complications in the non-operative group.

3 month ROM and Radiographic Comparison Non-operative (Cast) vs. Surgical (WRx®)

	Non-op	WRx®	P value
Flexion*	59%	80%	P=0
Extension*	69%	94%	P=0
Pronation*	91%	98%	P=0
Supination*	77%	94%	P=0
Radial Deviation*	74%	86%	P=0.0015
Ulnar Deviation*	63%	86%	P=0
Grip*	44%	66%	P=0
Volar Tilt	-11°	-6°	0.19739
Radial Inclination	17°	24°	0.000026
Ulnar Variation	2.5mm	0.2mm	0.00207

*Ratio of injured wrist/uninjured wrist

1 year ROM and Radiographic Comparison Non-operative (Cast) vs. Surgical (WRx®)

	Non-op	WRx®	P value
Flexion*	80%	99%	P=0.00007
Extension*	93%	99%	P=0.04288
Pronation*	98%	98%	P=1
Supination*	92%	101%	P=0.00006
Radial Deviation*	88%	101%	P=0.14232
Ulnar Deviation*	79%	100%	P=0.00585
Grip*	75%	103%	P=0
Volar Tilt	-5.6°	-5°	P=1
Radial Inclination	18°	21°	P=0.23484
Ulnar Variation	2.675mm	0.1mm	P=0.0021

*Ratio of injured wrist/uninjured wrist

Medicare Reimbursement Information for 2014

(Private insurance is generally higher reimbursement)

Distal Radius Extra-Articular ORIF – CPT Code 25607

Payment to Physician: \$748

Payment to Outpatient Hospital: \$5383

Payment to Ambulatory Surgery Center: \$2974

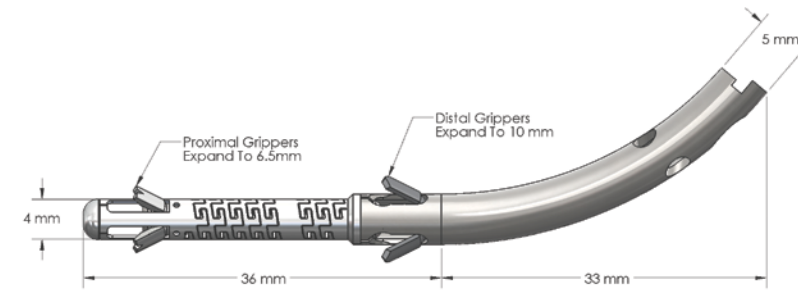
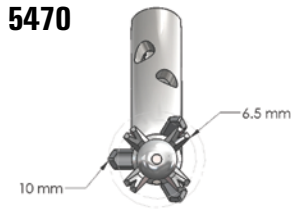
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1. Shauver et al, JHS. Current and Future National Costs to Medicare for the Treatment of Distal Radius Fractures in the Elderly. 1282-7, 2011.
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3. Azzopardi et al, JBJS Unstable extra-articular fractures of the distal radius. p 837-40, 2006.
4. Egol et al, JBJS. Distal Radial Fractures in the Elderly: Operative Compared with Nonoperative Treatment. 1851-7, 2010.
5. Sanchez-Sotelo et al, JBJS (Br) Treatment of fractures of the distal radius with a remodelable bone cement.
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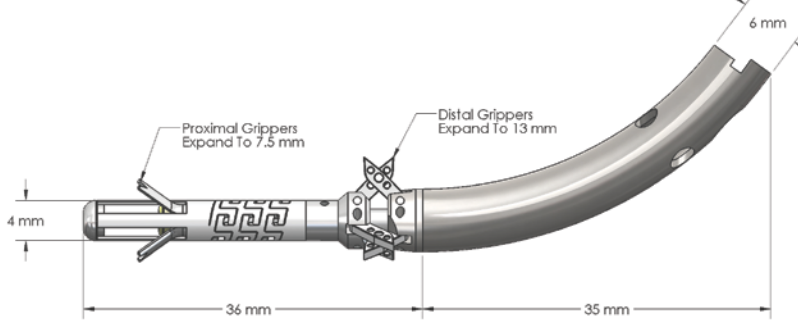


Implant Specifications

WRx® 5470



WRx® 6470



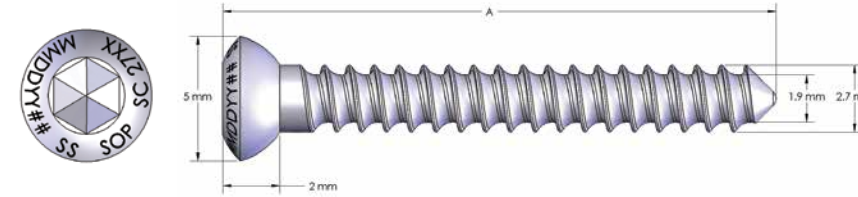
Implant Part Numbers

Sonoma WRx® Implants

WRX-5470 WRx® 5mm x 70mm Implant
WRX-6470 WRx® 6mm x 70mm Implant

Bone Screws

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
SC2728 2.7mm x 28mm Self-Tapping Bone Screw
SC2730 2.7mm x 30mm Self-Tapping Bone Screw
SC2732 2.7mm x 32mm Self-Tapping Bone Screw
SC2734 2.7mm x 34mm Self-Tapping Bone Screw



SONOMA
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STRENGTH FROM WITHIN™

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USA and International Patents Pending
LB-1194 Rev.C



a **BETTER** alternative than casting

SONOMA
Orthopedic Products, Inc
STRENGTH FROM WITHIN™

SONOMA WRx
WRIST FRACTURE ROD

When a Cast Won't Cut It

It is well-recognized that intramedullary rods are advantageous in the treatment of fractures for several reasons:

- ◆ Load-sharing employs Wolff's Law to promote healing
- ◆ Earlier mobilization
- ◆ Smaller incisions and avoidance of soft tissues

The Sonoma WRx[®] is a ground-breaking implant which brings the advantages of intramedullary fixation to distal radius fractures.

Although volar plates have proven to be a successful treatment for distal radius fractures, there are instances where surgeons choose not to use them. For younger patients with simple fractures, some may feel a plate is too excessive a surgery, and will cast them instead.

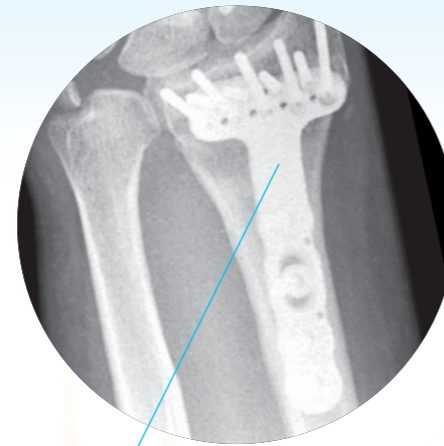
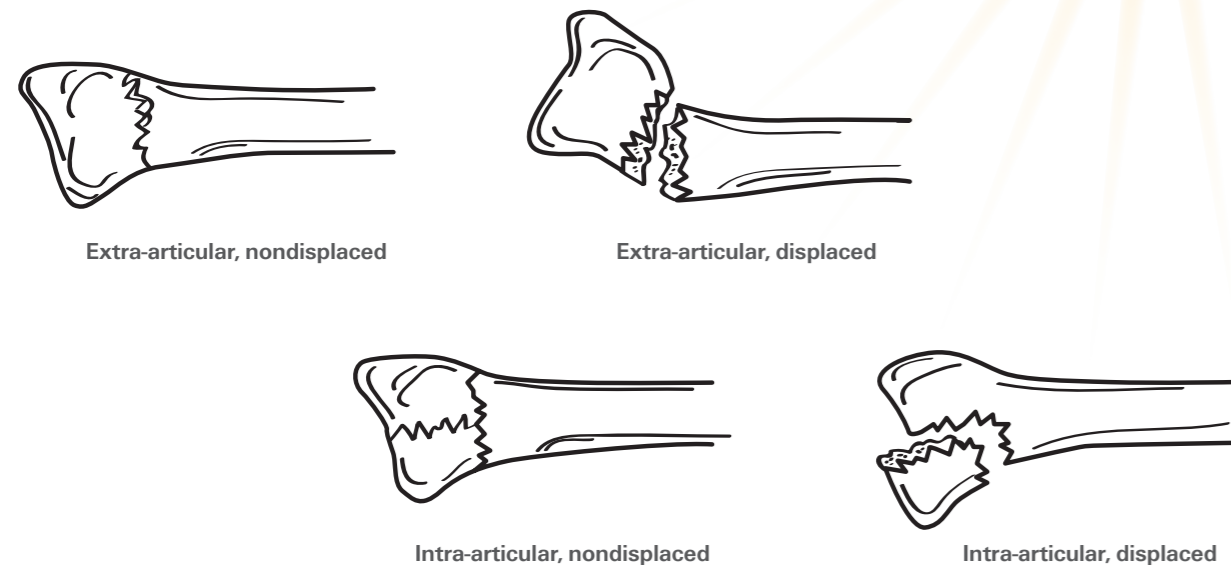
For osteoporotic patients, most surgeons prefer conservative treatments initially. Plates require large incisions, and trauma to soft tissues. In addition, the screws used to affix the plates require strong bone for purchase, and may pull-out of osteoporotic bone.

For both of these patients, the WRx[®] implant may be a better option than conservative treatments.

WRx[®] has been particularly useful with fractures that have features indicative of a high likelihood of displacement with cast treatment alone, or for patients that desire early mobilization and will not tolerate the weeks of immobilization required for cast treatment.

What are the Indications?

The WRx[®] is indicated for extra-articular distal radius fractures or simple intra-articular fractures with minimally displaced intra-articular components.



Plates are excessive for many fractures



Flexible-to-Rigid Wavibody[®]

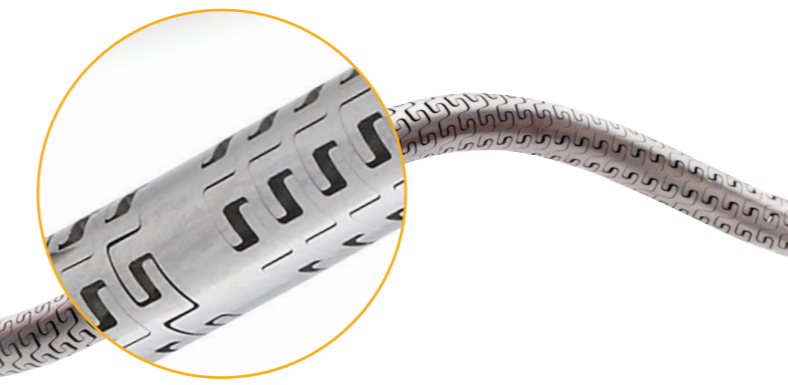
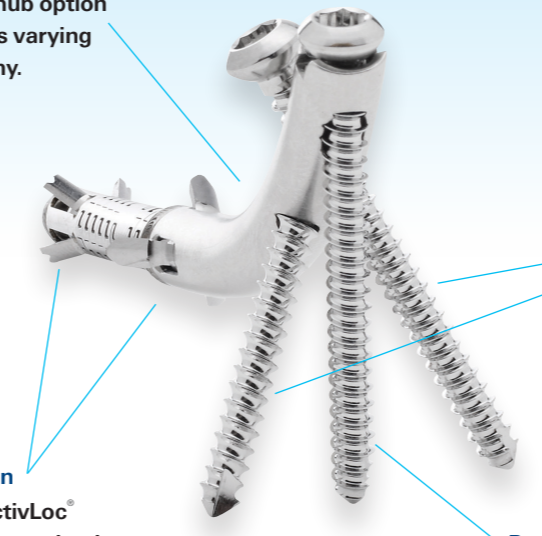
In the WRx[®], the flexibility of the patented Wavibody[®] technology allows the implant to be delivered through the radial styloid into the intramedullary canal without involving soft tissues or additional adjacent cortex penetration. The Wavibody[®] acts as an anchor to maintain the position of the curved hub in the fracture site and allows the grippers to engage in a natural position within the canal.

Curved Hub Design
5mm or 6mm hub option accommodates varying patient anatomy.

Intramedullary Fixation
Proximal and distal ActivLoc[®] grippers engage bone upon implant activation to provide a solid foundation for fracture fixation.

Buttress Screw
Prevents subsidence of the articular surface

Optional Locking Cortical Screws
2.7mm screws lock into implant providing solid fixation of fragments and 3-dimensional subchondral support.



Sonoma WRx[®] Fragility Fracture Case Study

Alexander Shin, MD. Mayo Clinic

Pre-Operative X-Rays



6 Week Follow-Up X-Rays



Incision at 6 Weeks



CASE SUMMARY:

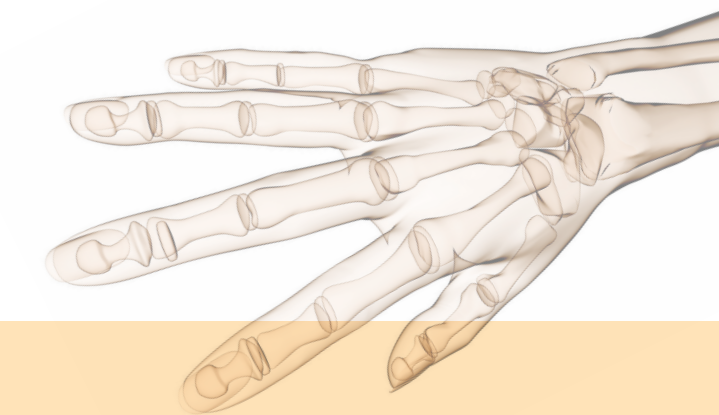
Distal radius fracture in an 82 year old female.

An 82 year old female was referred to the clinic with a distal radius fracture six days after initial closed reduction was performed. The initial fracture occurred after a fall onto her outstretched hand. The patient underwent internal fixation of her right radius with the Sonoma WRx[®] and was released from outpatient surgery.

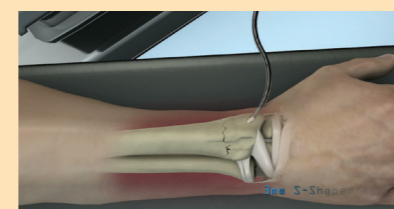
The patient returned for initial follow-up one week post-op at which time her sutures were removed. She was placed into a splint, and was advised to perform gentle range of motion activities.

Four weeks after surgery, the patient had **minimal pain, was able to achieve 50 degrees of extension and flexion, and had full pronation and supination.** At six weeks, the patient was pain free and had returned to normal activity.

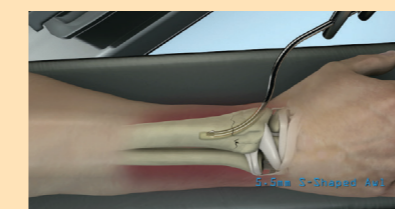
**Dr. Shin is not contractually affiliated with Sonoma Orthopedic Products, Inc. and has provided this case study for educational purposes only.*



Surgical Technique Summary



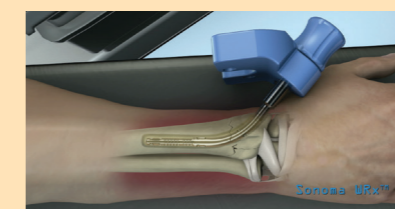
Step 1:
After establishing a distal radial styloid entry point with a K-wire and cannulated drill, introduce the 3mm awl



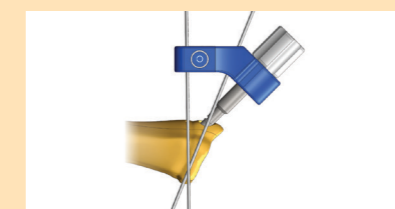
Step 2:
Widen the canal with the 5.5mm awl



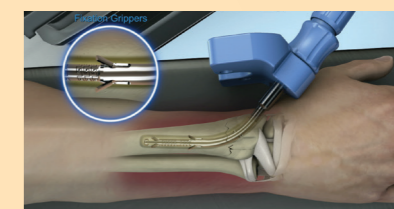
Step 3:
Introduce the guide-wire and ream if further canal preparation is necessary



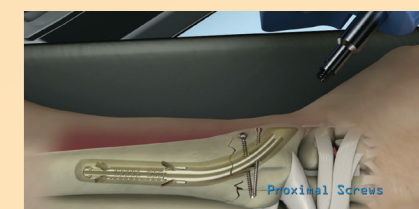
Step 4:
Insert the implant



Step 5:
Provisional K-wires allow visualization of buttress screw position



Step 6:
Activate the grippers. Wavibody[®] converts from flexible to rigid for gentle, press-fit conformity into canal



Step 7:
Insert the buttress screw (and other screws if necessary) by drilling through outrigger