

 **revcon**[™] minimally invasive
screw system

Surgical technique



revcon[™] neutra



revcon[™] anchor

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Two screw lines to fit your patient needs:

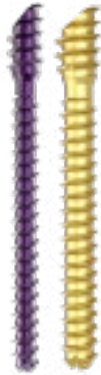
Used exclusively in the Bunionplasty® minimally invasive bunion surgery (MIBS) procedure, the Revcon™ Screw System offers one-screw and two-screw solutions for a variety of orthopedic procedures as indicated in this Surgical Technique.

v1.0

revcon® neutra

The classic two screw solution.

Consistent neutral cancellous pitch, in Ø3mm and Ø4mm options.

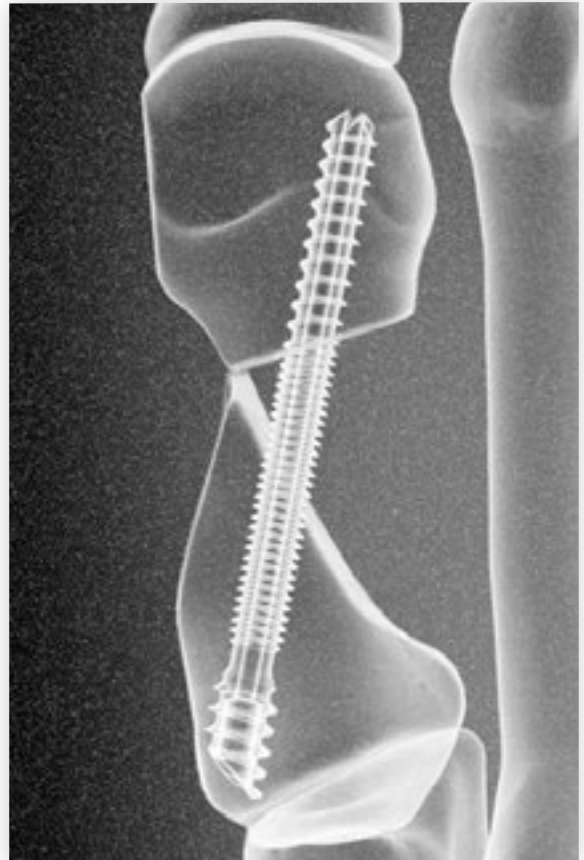


v2.0

revcon® anchor

The tailored single screw solution.

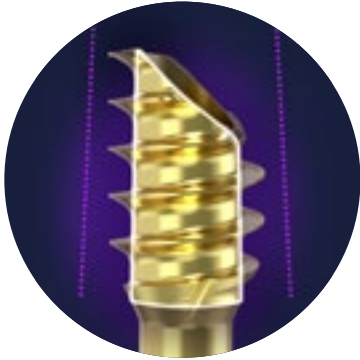
Targeted dual-zone neutral pitch designed for cortical and cancellous fixation.



Patented next-evolution design for minimally invasive bunion surgery (MIBS)

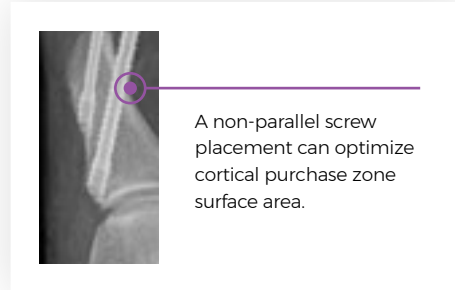
Reverse conical shape

increases thread surface area for bone engagement.



Beveled 42° and 50° angles

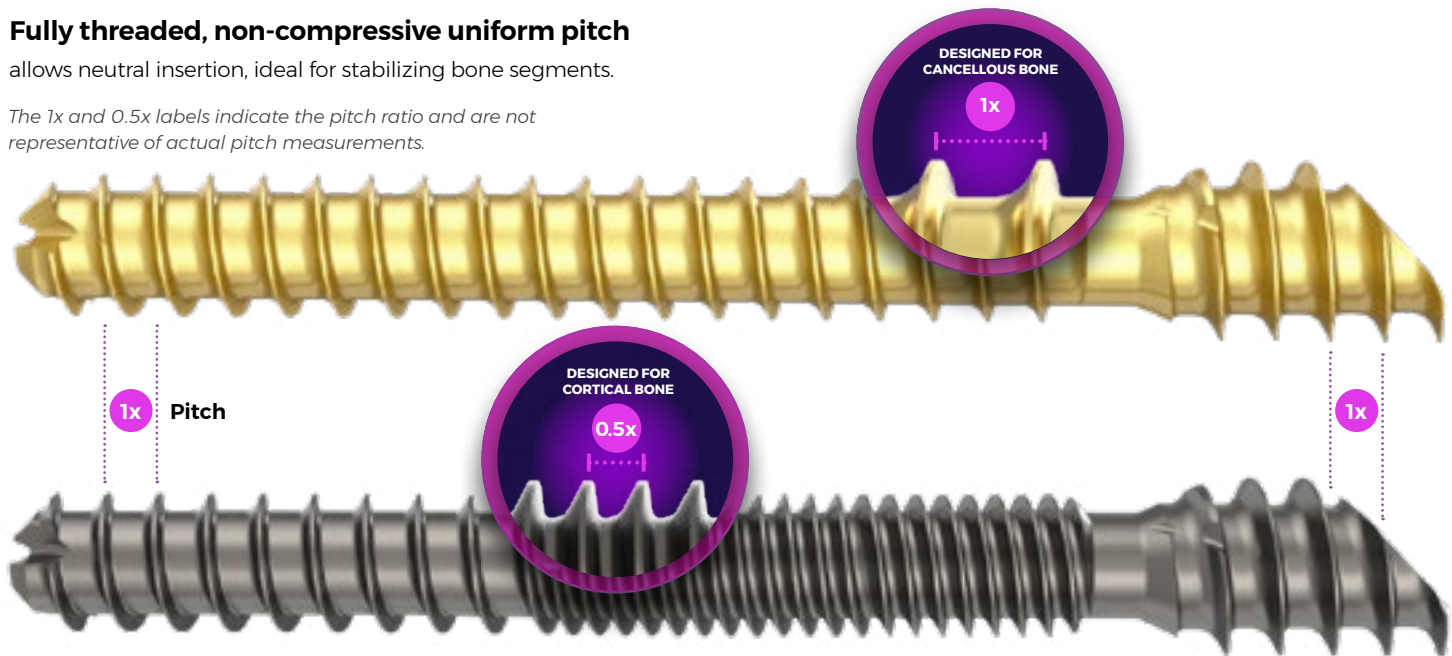
Facilitates divergent screw positioning for capture of the cortical purchase zone (CPZ) and cancellous anchor zone (CAZ).



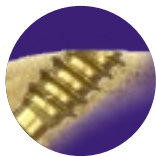
Fully threaded, non-compressive uniform pitch

allows neutral insertion, ideal for stabilizing bone segments.

The 1x and 0.5x labels indicate the pitch ratio and are not representative of actual pitch measurements.



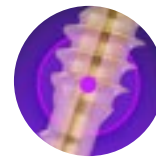
From end to end, the Revcon™ screw is designed for smooth, quick percutaneous insertion, bone purchase, and strength.



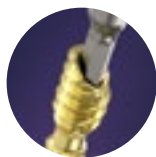
Cancellous pitched head



Forward cutting flutes



Cannulated design



Hexagonal recess



Anodized titanium alloy construction



Quick-turn ratchet handle



Revcon™ Screw System Surgical technique

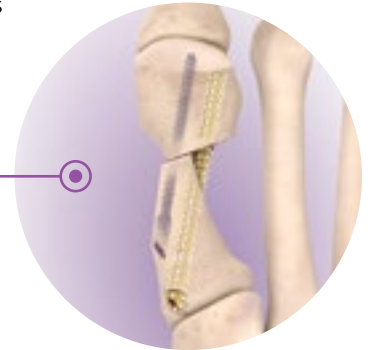
Device description

The Revcon™ screws are intended for use in bone reconstruction, osteotomy, arthrodesis, fracture repair, and fracture fixation of bones appropriate for the size of the device, to allow surgeons to perform a bunion osteotomy and fixation of the osteotomy with a minimally invasive surgical technique.

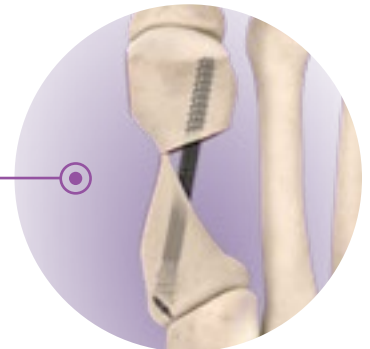
The Revcon™ Screw System contains fully threaded, cannulated screws offered in a variety of diameters and lengths. The screws are manufactured from medical grade titanium alloy (Ti-6Al-4V-ELI) as per ASTM F136 and are provided nonsterile for end user sterilization.

The Revcon™ Screw System includes two screw lines with the following uses:

- **The Revcon™ Neutra** offers Ø3mm and Ø4mm options for single- or multi-screw approaches in orthopedic surgery procedures.



- **The Revcon™ Anchor** is the single screw solution designed for cortical bone purchase in minimally invasive bunion surgery (MIBS).



Indications

The Revcon™ Screw System is indicated for fixation of bone surgery involving reconstruction. Examples include:

- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition and stabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis.

The Revcon™ Screw System is not intended for spinal use.

Precautions

The Revcon™ Screw System has not been evaluated in the Magnetic Resonance environment for safety and/or use.

Before use of the Revcon™ Screw System, see IFU insert for warnings, indications, contraindications, precautions, and possible adverse effects. Instructions for use package inserts are also available by contacting the manufacturer.

Surgeons must communicate contraindications, surgical risks, precautions, warnings, and surgical risks to patients. Patients shall be informed that the Revcon™ Screw System has an expected service life and can be damaged or broken by vigorous activity, and that the Revcon™ Screw System does not replicate healthy bone. Revision surgery or removal may be required in the future.

Contraindications

The Revcon™ Screw System should not be used in the following scenarios:

- Infection
- Physiologically or psychologically inadequate patient;
- Irreparable tendon system;
- Possibility for conservative treatment;
- Growing patients with open epiphyses;
- Patients with high levels of activity
- Vascular insufficiency
- Poor bone quality
- Open epiphyses
- Noncompliant patient
- Allergy to device components
- Possibility for non-surgical treatment

Patient positioning + set up

A fluoroscopic unit is placed on the same side as the operative extremity. When operating on a right foot, the fluoroscopic unit should be placed on the right. When operating on a left foot, the fluoroscopic unit should be placed on the left.

The patient should be positioned supine on the operating table with the feet placed slightly off the end of the table. A bump is placed under the ankle of the operative extremity.

These measures allow easy access of the fluoroscopic unit during critical points during the surgery. The unit should be perpendicular to the operating table allowing for the surgeon to swiftly switch between anterior-posterior views to lateral views.

Surgical technique – Distal first metatarsal osteotomy

1 Step 1: Identifying landmarks + marking

Under fluoroscopic guidance and using a metallic instrument for triangulation, the locations for the incisions should be marked out.

It may be helpful to also draw a medially based longitudinal dotted line bisecting the metatarsal shaft to help orient guidewire placement.

The distal incision location is medially at the first metatarsal neck, just proximal to the flare of the medial eminence.

The proximal incision location is slightly proximal to the first tarsometatarsal joint directly over the medial flare of the first metatarsal base.



Figure 1 The procedure is performed through three tiny incisions designed to minimize scarring.

2 Step 2: Incisions

After the longitudinal incisions are made, blunt dissection is carried down to the bone. Care is taken to avoid any neurovascular structures related to the incision placement.

The periosteal elevator (*Figure 2*) is used to create a plane between the bone of the first metatarsal neck and dorsal soft tissue structures. Avoid aggressive plantar dissection as this may increase risk for injury to the blood supply to the first metatarsal head.

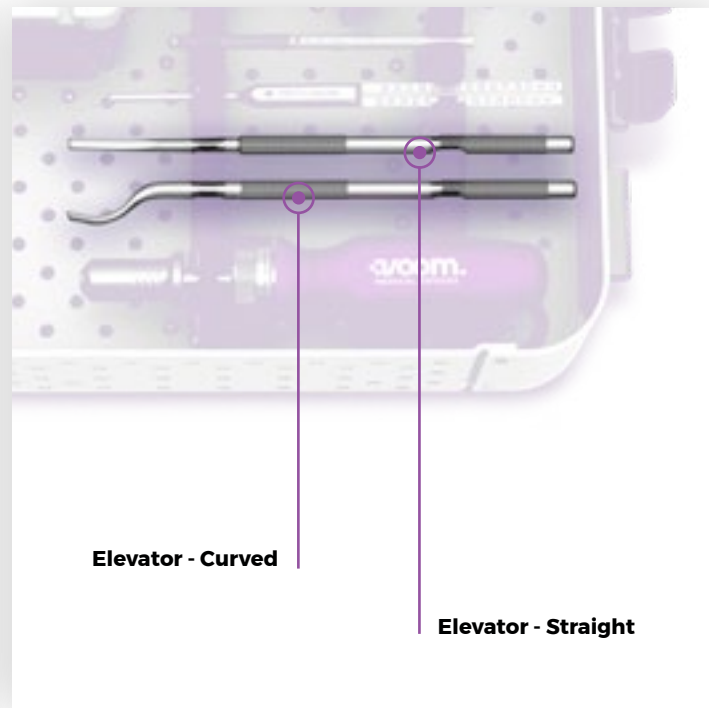


Figure 2 The Revcon™ Guided Instrumentation Tray includes curved and straight periosteal elevators.

3

Step 3: Midshaft osteotomy

The procedure is performed using a transverse, Chevron, or cortical-cancellous Transveron™ midshaft osteotomy, according to surgeon preference (*Figures 3 & 4*), erring toward the capital fragment. The osteotomy can be performed with a rotary Shannon-type burr or a saw, under irrigation. Depending on the surgeon's goal for correction, orienting the osteotomy distally will lengthen the first metatarsal whereas orienting the osteotomy proximal will shorten it.

The osteotomy should be performed under fluoroscopic guidance and irrigation.

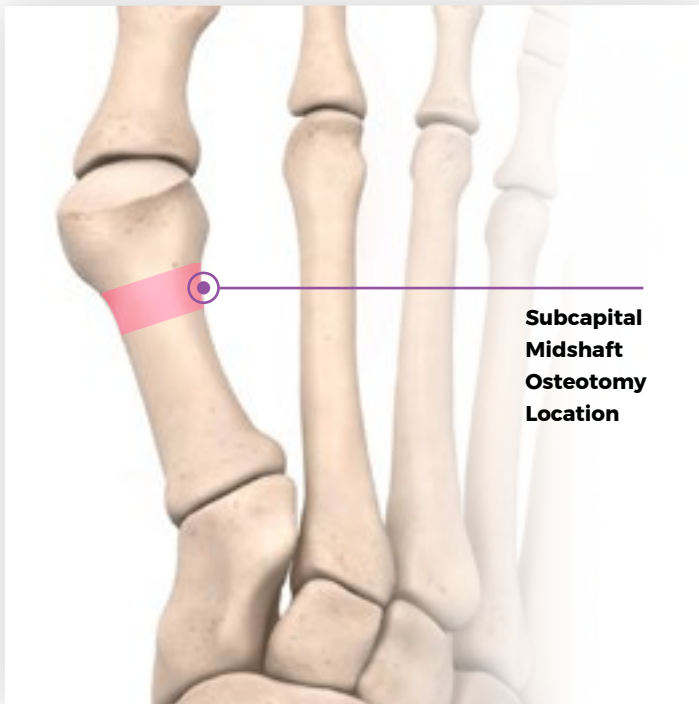


Figure 3 The Transveron™ osteotomy may be placed distally or proximally in the apical transition zone of the first metatarsal.

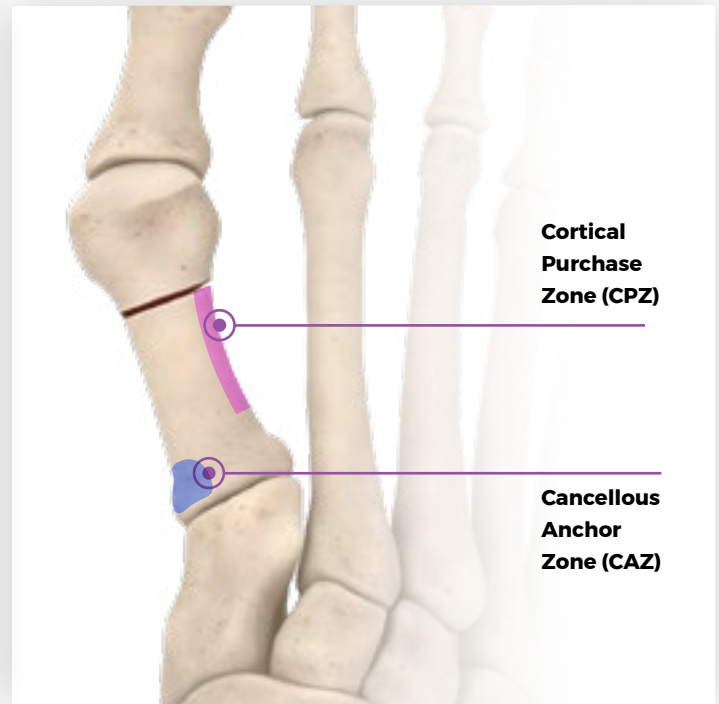


Figure 4 The Revcon™ Screw System is designed for capture of cortical and cancellous bone.

4

Step 4: Metatarsal head positioning + guide wire placement

After the osteotomy is complete and verified by mobility of the metatarsal head, the curved periosteal elevator is placed across the osteotomy site to mobilize the lateral soft tissue allowing for metatarsal head translation.

The straight periosteal elevator is then inserted into the distal incision and deeply into the metatarsal shaft.

Using the medial diaphyseal cortex as a fulcrum for the elevator and applying medial pressure on the hallux, the first metatarsal is translated laterally on the plane of the osteotomy. Care is taken to protect the medial cortex of the first metatarsal from fracturing by monitoring the amount of force applied to through the elevator.

Once the desired lateral translation is achieved, the surgeon should take mental note of this translation as it will assist with guidewire and screw placement.

The final position of the first screw is to engage both the lateral cortex of the first metatarsal shaft and the first metatarsal head.

The first screw to be placed will be the Ø4.0mm Revcon™ screw through the proximal incision using the Ø1.4mm guidewire. Using intraoperative fluoroscopy, the guidewire

is inserted into the flare of the medial base and bisecting the first metatarsal in the sagittal plane. The guidewire is angled into the first interspace, penetrating the lateral cortex proximal to the osteotomy site.

The larger the translation the more proximal the exit point may be on the lateral first metatarsal cortex. It is preferred to engage the diaphyseal shaft of the lateral metatarsal which increases strength of the fixation construct.

Confirm the guidewire position in both AP and lateral views before committing to the position and penetrating the lateral cortex. Once the position of the guidewire is acceptable, it should be advanced just slightly past the cortex.

Next, the lateral translation of the first metatarsal is performed in the same manner illustrated above and keeping dorsal pressure on the first metatarsal head to prevent plantarflexion. The guidewire is advanced into the metatarsal head.

revcon® neutra

revcon® anchor



Design Feature	Revcon™ Neutra Ø3.0mm	Revcon™ Neutra Ø4.0mm	Revcon™ Anchor Ø4.0mm
Hex Driver	2.0mm Hex	2.5mm Hex	2.5mm Hex
Guide Wire	Ø 0.9	Ø 1.4	Ø 1.4
Length	20 - 48 mm	38 - 60 mm	38 - 60 mm
Material	Type III Anodized Titanium	Type III Anodized Titanium	Type II Anodized Titanium

5 Step 5: Revcon™ Screw fixation

Single screw fixation construct (Ø4.0mm Revcon™ screw):

Once the position of the correction is confirmed on AP and lateral fluoroscopic views, the depth gauge is used to measure off the guide wire.

Depending on how close the tip of the 1.4mm guidewire (Figure 5) is to the 1st metatarsophalangeal, 2-4mm may be deducted from the screw size to ensure that the screw tip will not be intra-articular. For added security of the guidewire during over drilling, it can be advanced distally through the skin and clamped with a hemostat.

Drill over the Ø1.4mm guidewire with the Ø3.0mm cannulated drill for the Ø4.0mm Revcon™ screw.

Align the flat edge of the screwdriver to the bevel on the screw, which indicates the position of the bevel as the screw is inserted.

Place the Ø4.0mm Revcon™ screw over the guidewire. The head of the screw should be flush with the medial

cortex of the first metatarsal base. The flat edge of the screwdriver should be aligned with the bottom edge of the bevel, indicating the bevel on the screw is appropriately positioned.

Obtain AP and lateral fluoroscopic images to confirm the screw placement and final position, and that the tip of the Revcon™ screw does not invade the first metatarsophalangeal joint. Remove the guidewire.

Frontal Plane Correction

Frontal plane correction can be achieved after the osteotomy, allowing for more rotation.

Rotating the hallux during the Ø4.0mm screw insertion allows the entire first metatarsophalangeal joint complex to rotate as a unit, in either supination or pronation. This is achieved by cupping the hallux and rotating and compressing the osteotomy as the Ø4.0mm screw enters the metatarsal head.

The frontal plane correction can be very powerful. Fluoroscopy is used to dial in the amount of correction intended.



Figure 5 The Revcon™ Anchor screw instrumentation (left); fixation using the Revcon™ Anchor screw, which is design-optimized for single screw fixation (right).

5 Step 5: Revcon™ Screw fixation *Continued*

Double Screw Fixation Construct (Ø4.0mm and Ø3.0mm Revcon™ screws): A second screw can be placed for additional stability and should be the Ø3.0mm Revcon™ screw (*Figure 6*).

Using the same proximal incision or a new percutaneous incision, the Ø0.9mm guidewire is placed using the same overall trajectory as the first screw.

The second screw is placed distal to the first screw (*Figure 7*) allowing for enough space between the screws. The second screw may or may not engage the lateral cortex of the first metatarsal but should always engage the metatarsal head.

The techniques for inserting the second screw are identical and fluoroscopic confirmation should be used throughout.

For the Ø3.0mm Revcon™ screw, drill over the Ø0.9mm guidewire with the 2.2mm cannulated drill. Place the Ø3.0mm Revcon™ screw over the guidewire. Use fluoroscopy to confirm position and that the tip of the screw does not invade the first metatarsophalangeal joint. Remove the guidewire.

Designed for flexibility: Note that the Revcon™ Neutra Ø3.0mm screw may also be used as a secondary screw when using the Revcon™ Anchor Ø4.0mm screw for primary fixation.

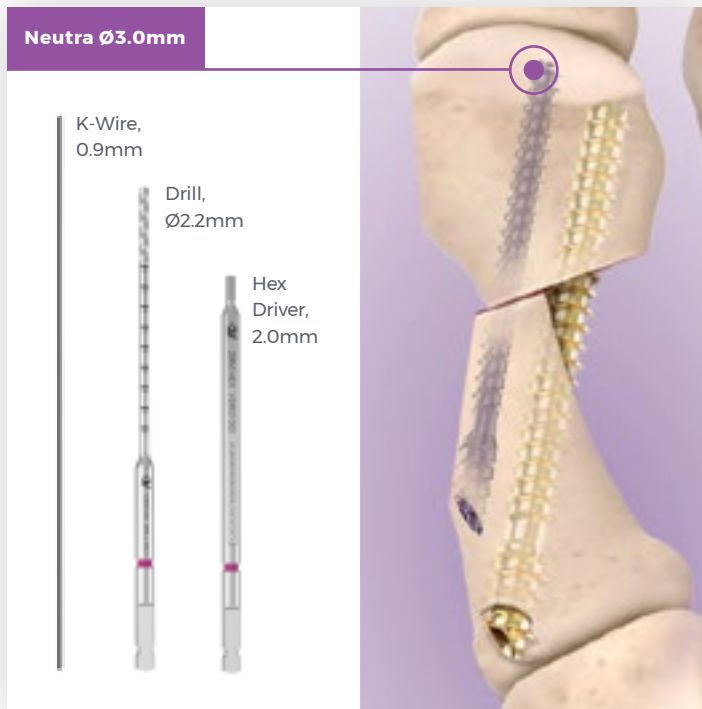


Figure 6 Instrumentation and double screw fixation highlighting the Ø3.0mm Revcon™ Neutra screw.

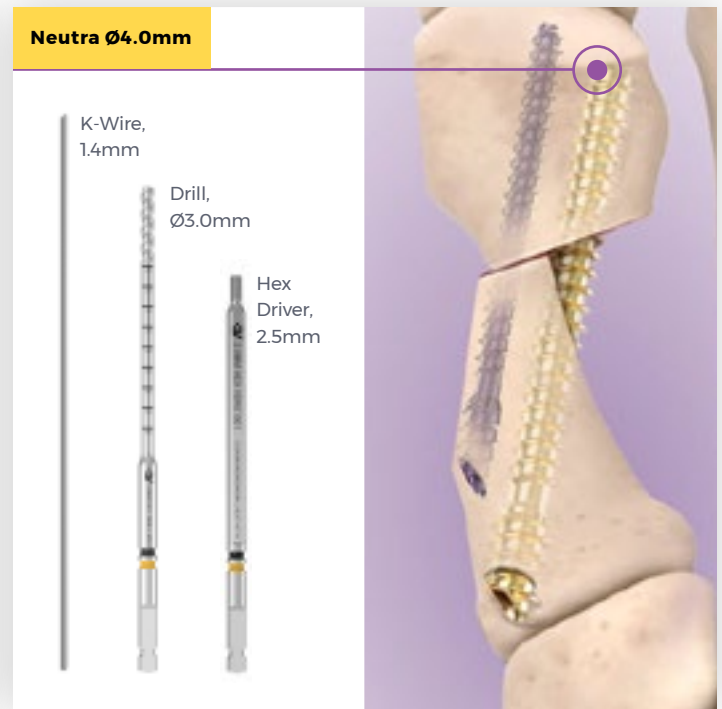


Figure 7 Instrumentation double screw fixation highlighting the Ø4.0mm Revcon™ Neutra screw.

6

Step 6: Bunion + Metatarsal shelf shaving (optional)

The overhanging bone shelf of the proximal medial metatarsal shaft can be resected with a burr or saw, under irrigation. The bone fragment(s) may be removed with a hemostat or pushed into the metatarsal canal as bone graft.

7

Step 7: Lateral release (optional)

The adductor tendon may be percutaneously released using a beaver blade. Using intraoperative fluoroscopy to verify the position of the blade, the adductor tendon is released while also adducting the hallux.

Surgical technique – Akin osteotomy

1 Step 1: Identifying landmarks + incision

After the distal first metatarsal osteotomy procedure is completed there may be residual hallux interphalangeus deformity that the surgeon may deem to correct with an Akin osteotomy (Figure 8). The Akin procedure can also be performed as an independent procedure for isolated hallux interphalangeus.

Under fluoroscopic guidance and using a metallic instrument for triangulation, the medial proximal metaphyseal-diaphyseal junction should be marked out. A small longitudinal incision measuring approximately 2-3mm is made directly over this area and carried down deep to the bone. Care is taken to avoid the dorsomedial cutaneous nerve. The periosteal elevator is used to create a plane between the bone and dorsal extensor tendon complex and plantar flexor complex.

2 Step 2: Osteotomy

The osteotomy can be performed with a rotary shannon-type burr or a saw, under irrigation. A Shannon burr has the advantage of removing bone with cutting allowing for a wedge to be created. The osteotomy should be performed under fluoroscopic guidance and irrigation. The osteotomy can be transverse or angled distal medial to proximal plantar depending on surgeon preference. Perform the osteotomy from medial to lateral and dorsal to plantar, and the lateral cortex can remain intact or broken for additional correction.



Figure 8 Akin osteotomy and 3.0mm screw placement.

3 Step 3: Guide wire placement

The Akin osteotomy is fixated with a Ø3.0mm Revcon™ screw. Percutaneously place a Ø0.9mm guidewire from the medial base of the proximal phalanx to the distal lateral cortex under fluoroscopic guidance. Once the position of the correction is confirmed on AP and lateral fluoroscopic views, the depth gauge is used to measure off of the guide wire. For added security of the guidewire during over drilling, it can be advanced laterally through the skin and clamped with a hemostat.

4 Step 4: Revcon™ screw fixation

Drill over the Ø0.9mm guidewire with the Ø2.2mm cannulated drill for the Ø3.0mm Revcon™ screw. Place the Ø3.0mm Recon™ screw over the guidewire. The head of the screw should be flush with the medial cortex of the proximal phalanx base. Remove the guidewire.

Surgical technique – **Closure + dressings**

1 Closure

After irrigation, incisions are closed with sutures or steri-strips.

2 Dressings

A non-adherent dressing should be placed over the incisions, followed by 4x4 gauze and 4-inch conforming bandage. The hallux should be splinted rectus. A cohesive bandage or ACE wrapped on top.



Ordering information

Revcon™ Screw System

revcon™ neutra



Length	Revcon™ Neutra Ø3.0mm	Qty.	Length	Revcon™ Neutra Ø4.0mm	Qty.
20mm	RSN3020	2	38mm	RSN4038	1
22mm	RSN3022	2	40mm	RSN4040	1
24mm	RSN3024	2	42mm	RSN4042	1
26mm	RSN3026	2	44mm	RSN4044	1
28mm	RSN3028	2	46mm	RSN4046	1
30mm	RSN3030	2	48mm	RSN4048	1
32mm	RSN3032	2	50mm	RSN4050	1
34mm	RSN3034	2	52mm	RSN4052	1
36mm	RSN3036	2	54mm	RSN4054	1
38mm	RSN3038	2	56mm	RSN4056	1
40mm	RSN3040	2	58mm	RSN4058	1
42mm	RSN3042	2	60mm	RSN4060	1
44mm	RSN3044	2			
46mm	RSN3046	2			
48mm	RSN3048	2			

revcon™ anchor



Length	Revcon™ Anchor Ø4.0mm	Qty.
38mm	RSA4038	1
40mm	RSA4040	1
42mm	RSA4042	1
44mm	RSA4044	1
46mm	RSA4046	1
48mm	RSA4048	1
50mm	RSA4050	1
52mm	RSA4052	1
54mm	RSA4054	1
56mm	RSA4056	1
58mm	RSA4058	1
60mm	RSA4060	1



Ordering information

Revcon™ Instrument Tray



Part No.	Description	Qty.
VTR01000	Revcon™ Instrument Tray	1
VTR01001	Revcon™ Instrument Tray Lid	1
VRC01000	Revcon™ Screw Caddy	1
VHA01001	Axial Handle, Cannulated, Ratcheting	1
VEL01000	Elevator - Curved	1
VEL01001	Elevator - Straight	1
VDG01000	Revcon™ Depth Gauge	1
VHA01000	Beaver Handle	1
VDB01000	Drill, Ø2.2mm	2
VDB01001	Drill, Ø3.0mm	2
VKW01000	K-Wire Revcon™ 0.9 x 152.4mm	6
VKW01001	K-Wire Revcon™ 1.4 x 152.4mm	6
VDR01000	Hex Driver, 2.0mm	2
VDR01001	Hex Driver, 2.5mm	2



MEDICAL DEVICES

For more information contact

+844.372.5489

info@voomdevices.com

voomdevices.com

**800A 5th Avenue,
Suite 403
New York, NY 10065**