





Operative Technique





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This publication sets forth detailed recommended procedures for using Novastep PECA implants and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery.

Indications & Contraindications

Indications

• Mild to severe hallux valgus deformities where proximal or distal osteotomies are appropriate

Contraindications

- Infection
- Open physes
- Patients in whom hallux valgus surgical correction is not appropriate due to physical limitations or inability to participate in required recovery
- Have not attempted non operative treatment

Percutaneous Chevron Akin Implant System

Indications: PECA implants are indicated

for small bone fragment osteosynthesis for extremity surgeries. Examples of use: Hallux Valgus with Percutaneous Chevron and Akin osteotomies.



Allows Exact driver positioning and provides optimal torque.

Reduction Wire

translation (CKW03001).

Flexible stem

Fully threaded, constant pitch:

Facilitates purchase for stable fixation.

Self-drilling

40 Degree Chamfer Cut Head: Anatomically contours to the medial cortex of the first metatarsal.





flutes: Eases insertion.







Exact-T - Patent Pending

Facilitates correct placement of implant upon insertion.

Exact-T® Recess

Keyed recess connection. Ensures driver inserts implant in only one direction.



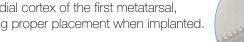


resection and removal without violating soft tissue structures. **Visual Guideline**

The black laser marking aligns with the chamfer head of the implant, identifying the medial cortex of the first metatarsal, ensuring proper placement when implanted.













Intelligently designed cutting flutes offer precision bone

Sterile Percutaneous Burrs

The single-use reduction wire offers the simplicity of a flexible

stem with a rigid and sharpened tip for hands free metatarsal

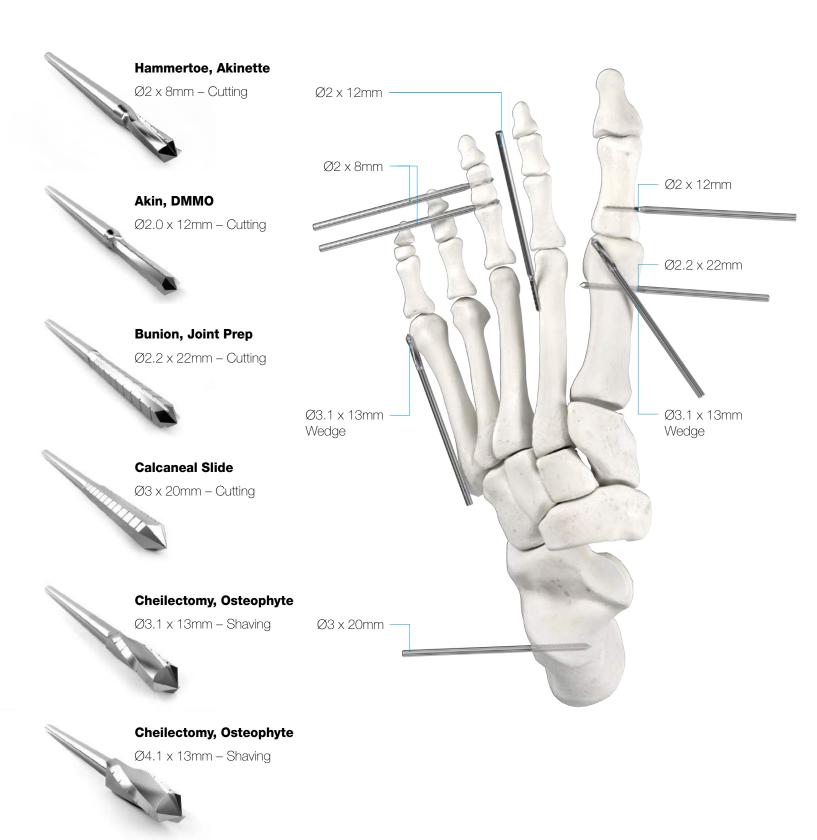
Rigid, Sharp tip

QuickStep Reamers

Reamers designed for immediate setup on a wire-driver to maximize Operating Room efficiency.



Sterile Burrs



Percutaneous, Chevron and Akin Technique

Distal First Metatarsal Osteotomy

The procedure may be performed with or without a tourniquet.

Use of tourniquet may increase the chance of bone necrosis so adequate irrigation is necessary.



Draw the contour of the first metatarsal with a marking pen. Using fluoroscopic guidance, draw the center line bisecting the first metatarsal and great toe longitudinally. In addition, mark out the first tarsometatarsal and metatarsal phalangeal joints. This will help guide percutaneous wire placement.





The patient is positioned with the foot off the end of bed to facilitate AP and lateral fluoroscopy views of the forefoot with minimal adjustment of the mini C-arm.

The operative leg is elevated relative to the contralateral extremity on blankets or a bump.

The surgeon's dominant hand dictates C-arm location. For a right-handed surgeon, the C-arm should be positioned on the right side of the patient; for a left-handed surgeon, C-arm is on the left.

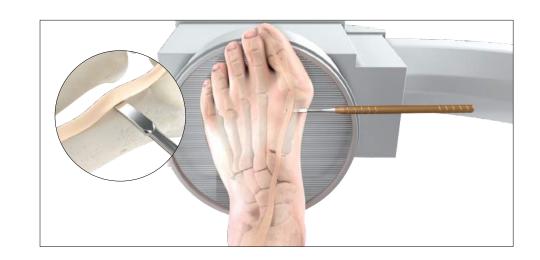


Using fluoroscopic guidance, a dorsomedial, percutaneous, 4-5mm longitudinal incision is made at the meta-diaphyseal junction of the medial first metatarsal. A hemostat is used to bluntly dissect down to bone.

Take care to avoid damaging the dorsomedial sensory nerve branch. A periosteal elevator is used to clear periosteum and soft tissue dorsally in line with the proposed osteotomy.

Do not clear soft tissue from the plantar surface to avoid damaging the blood supply to the first metatarsal head.





Technique Tips

With use of the burr, the surgeon should use gentle irrigation of the incision to prevent burning the skin. Bone paste may be expressed from the skin incision or removed with a large catheter, or left in place as bone graft for healing.

The Ø2.2 x 22mm Shannon Burr is then inserted under AP fluoroscopic guidance into the base of the medial first metatarsal head.

Angling the burr distally or proximally will allow for elongating or shortening of the first metatarsal depending on the surgeon's goals for correction. In order to prevent shortening of the first metatarsal due to use of the 2.2mm, angle 10 degrees distally relative to the central axis of the first metatarsal.



Neutral



Elongated



Shortened

For Chevron Osteotomy

Start burr slightly more dorsal than plantar (1/3 dorsal and 2/3 plantar) and angle 10 degrees plantarly (to reduce the risk of first ray dorsiflexion and transfer, second metatarsalgia) and perpendicular to the shaft of the first metatarsal in order to prevent shortening of the first ray.

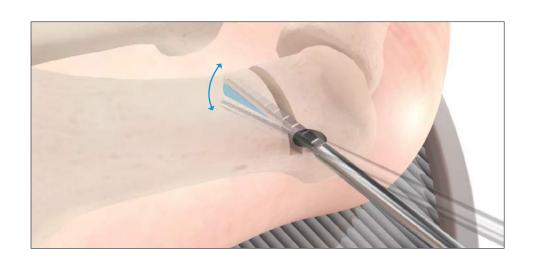
Once the burr tip has reached the lateral cortex, an AP fluoroscopy view is obtained to confirm the trajectory of the burr. The burr is then passed through the lateral cortex to create the apex of the Chevron Osteotomy.

For each limb of the osteotomy, the surgeon should envision the end point of their hand position prior to each cut.

Complete the dorsal vertical limb of the short Chevron Osteotomy by rotating the hand plantarly, using the medial cortex osteotomy hole as the center of rotation (fulcrum).

As the osteotomy is performed, the surgeon should gently oscillate the burr in and out to ensure that they have cut the far cortex.

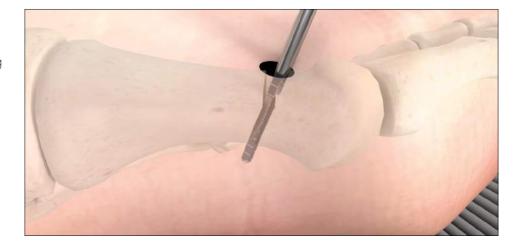




Next return the burr to the apex of the osteotomy. Complete the plantar limb of the Chevron Osteotomy by rotating the hand dorsally and slightly distal, using the medial cortex osteotomy hole as the center of rotation for the osteotomy.

Take care to keep the plantar limb short and fairly vertical.

Prior to each step, fluoroscopy should be used to confirm position on the burr.



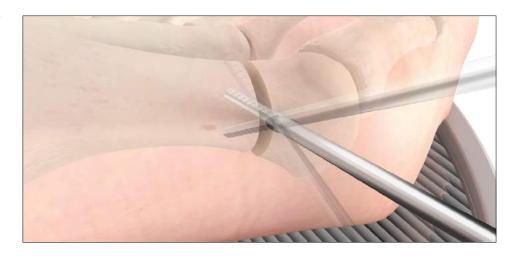
Place a varus stress on the metatarsal head to create the lateral shift, taking care to maintain proper dorsal/plantar alignment of the head relative to the shaft.



Alternative Transverse Osteotomy

A transverse osteotomy may be performed if more rotational correction is desired for pronation deformities.

A Ø2 x 12mm or Ø2.2 x 22mm burr may be used to perform the transverse osteotomy. With larger shifts, the type of osteotomy becomes less relevant given there is less bony contact.



Once the capital fragment is mobile, pull traction on the hallux and insert the thick end of the head-shifting tool through the same first metatarsal medial eminence incision and into the first metatarsal shaft. Bend the flexible wire portion under the base of the hallux proximal phalanx to prevent plantar migration of the capital fragment.



The Ø1.4mm guidewire for the Ø4.0mm PECA implant is inserted through the proximal medial cortex of the first metatarsal shaft angling 1cm lateral to the first metatarsal head. Alternatively the Ø1.4mm guidewire may be inserted after the amount of head shift is approximated initially with use of the head-shifting tool. Check AP and lateral fluoroscopy views to ensure that the trajectory of the wire is correct.

More proximal placement of the guidewire and implant increases stability of the construct. The Ø1.4mm guidewire must be placed through the proximal medial and distal lateral first metatarsal shaft cortices prior to engaging the capital fragment for stability of the construct.

Tip of screws are not within the first metatarsophalangeal joint.



Obtain AP and lateral fluoroscopy views to check to tentative first metatarsal position. Next drive the Ø1.4mm guidewire into the capital fragment after correction of intermetatarsal angle, distal metatarsal articular angle, and pronation.



Overdrill the proximal lateral guidewire using the Ø3.2mm cannulated drill.

Take care to drill across both the medial and lateral first metatarsal shaft cortices and gently into the first metatarsal head while stabilizing the correction manually. Be careful not to remove the guidewire when removing the drill bit.



Next insert a second Ø1.4mm guidewire just distal to the first through the medial proximal first metatarsal cortex and into the capital fragment. Alternatively, a Ø1.0mm guidewire for the Ø3.0mm PECA implant may be used if the patient has a smaller deformity or smaller diameter of the metatarsal.

The Ø1.4mm guidewire is recommended over the Ø1.0mm guidewire because it is easier to place and the larger implant provides more stability to the construct. Check AP and lateral fluoroscopy views to confirm guidewire position. Small 0.5mm incisions are made around each wire and soft tissue is freed up down to the bone.

Each guidewire is then measured and a PECA implant is chosen that is 2-4mm shorter than the measured length to ensure that the implant is fully recessed after insertion.









Place the Ø4.0mm PECA screw over the wire to secure the osteotomy.

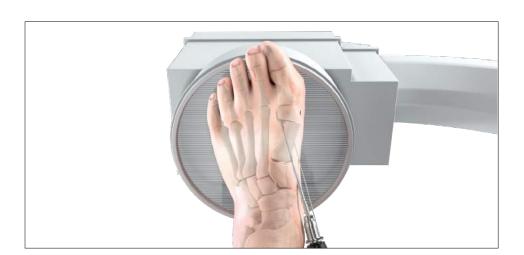
Again, take care to maintain the position of the correction both in the sagittal and horizontal planes.

The screwdriver will only engage the head of the PECA screw in one direction, corresponding to the chamfer of the screw.

The chamfer of the screw head should sit flush with the medial cortex of the first metatarsal shaft after insertion.
Use AP and oblique fluoroscopy views to confirm.

Overdrill the second wire with the corresponding drill and place the second PECA screw over the wire for final fixation as described above.

AP, oblique, and lateral fluoroscopic views are checked to confirm proper hallux valgus correction ensuring implant heads are not prominent and tips of the implant are not violating the metatarsophalangeal joint.







Finally, the medial spike of first metatarsal shaft bone is excised with the Ø3.1mm Wedge Burr through the medial distal incision on the first metatarsal.

The piece of bone may either be removed with a hemostat or pushed into the osteotomy site as bone graft.

Alternatively, a small rongeur may be used to remove the spike. If a medial eminence resection was not performed at the beginning of the case, the Ø3.1mm Wedge Burr may be used to complete the resection at this point.

(Optional)

A percutaneous release of the phalangeal-sesamoid ligament may be performed through a dorsal lateral first metatarsophalangeal joint incision using a beaver blade with AP fluoroscopic guidance. Avoid cutting the collateral ligament.



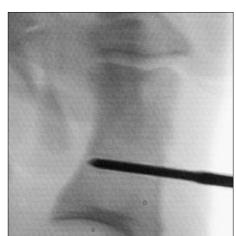


Akin Osteotomy

If interphalangeous deformity is noted after the chevron, an Akin may be performed. Under fluoroscopic guidance, the position of the osteotomy is marked at the metadiaphyseal margin of the medial proximal phalanx.

The Ø2 x 12mm Shannon burr is inserted midaxially perpendicular to the diaphysis while preserving the lateral cortex.





The dorsal limb is completed while holding the hallux interphalangeal joint dorsiflexed to prevent damage to the extensor hallucis longus tendon.

The plantar limb is completed with the hallux interphalangeal joint plantarflexed to prevent damage to the flexor hallucis longus tendon.

The hallux is placed in varus to correct any remaining valgus deformity, the 1mm guidewire for the Ø3.0mm PECA implant is then inserted percutaneously from the medial base of the hallux proximal phalanx across the Akin osteotomy site and through the distal lateral cortex. The position is checked on AP and lateral fluoroscopic views. The wire is then measured and over drilled through both cortices using the Ø2.0mm cannulated drill bit. A Ø3.0mm PECA implant that is 2mm shorter than the measured length is then inserted, and final AP and lateral fluoroscopy views of the hallux are checked.

The incisions are closed with sutures or sterile strips.



Final Bunion









Dressing

The incisions are dressed with a non-adherent layer and 4 x 4inch gauze.

Gauze strips are placed in each of the webspaces and wrapped around the medial forefoot to maintain a varus stress.

A 2inch kling bandage is then wrapped around each toe sequentially from medial to lateral with a slight varus stress to maintain hallux valgus correction.

The cling is overwrapped with an ACE wrap.

This dressing is left in place for two weeks and then a new dressing is placed for another two weeks at the first posteroperative visit.





Implant removal

If Exact[™] T-10 and T-8 drivers are not available, a standard cannulated T-8 Driver may be used to remove Ø4.0mm implant, and a standard cannulated T-6 driver may be used to remove 3.0mm implant.

Ordering Information

PECABunion Implants

Length (mm)	PECA Implant Ø3.0mm	PECA Implant Ø4.0mm	Qty.
16mm	PS020016	-	2
18mm	PS020018	-	2
20mm	PS020020	_	2
22mm	PS020022	-	2
24mm	PS020024	_	2
26mm	PS020026	PS050026	2
28mm	PS020028	PS050028	2
30mm	PS020030	PS050030	2
32mm	PS020032	PS050032	2
34mm	PS020034	PS050034	2
36mm	PS020036	PS050036	2
38mm	PS020038	PS050038	2
40mm	PS020040	PS050040	2
42mm	PS020042	PS050042	2
44mm	PS020044	PS050044	2
46mm	PS020046	PS050046	2
48mm	PS020048	PS050048	2
50mm	-	PS050050	2
52mm	_	PS050052	2
54mm	-	PS050054	2
56mm	_	PS050056	2
58mm	-	PS050058	2
60mm	_	PS050060	2

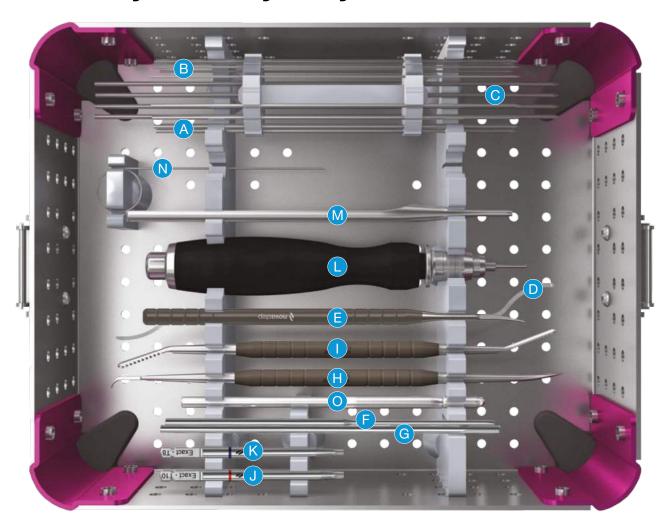
Sterile Burrs

Ref	Description	Qty.
CRE12008	Shannon Coria 2.0 x 8mm	2
CRE12012	Shannon Recla 2.0 x 12mm	2
CRE12222	Shannon Longa 2.2 x 22mm	2
CRE13020	Shannon Larga 3.0 x 20mm	2
CRE23113	Wedge 3.1	2
CRE24113	Wedge 4.1	2

K-Wires, Reduction Wires



Standard System Tray – Layout



PECA Instrument Tray

	Part#	Description	Qty.
	XTR10026	PECA Instrument Tray	
A	CKW02005	K-Wire Ø1.4 lg150 TR/RD CoCr*	6
В	CKW02004	K-Wire Ø1.0 lg150 TR/RD CoCr*	6
C	CKW03001	PECA Reduction Wire*	4
D	XMS01027	Reduction Device Double Tip	1
E	XMS01011	Periosteal Elevator Single Tip	1
F	XDB01017	2.0 Quick Step Reamer*	2
G	XDB01018	3.2 Quick Step Reamer*	2
Н	XMS01008	Periostial Elevator Double Tip	1
1	XMS01009	Percutaneous Rasp	1
J	XSD04004	Exact T10 Driver	2
K	XSD02003	Exact T8 Driver	2
L	XHA01001	AO handle	1
М	XGA01009	Nexis / PECA Depth Gauge Length 150mm	1
N	XKW01001	Cleaning pin	1
0	SF13	Beaver handle	1

*Disposable instrumentation

Notes



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

This document is intended solely for the use of healthcare professionals. This technique was developed in conjunction with healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Novastep does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate a Novastep product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any Novastep product.

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