

pecaplasty®

Percutaneous Bunion Correction







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In Memory of Lilian Gazonnet

Lead Designer of Pecaplasty Percutaneous Bunion Correction System.

September 30th, 1976 - February 26th, 2022. "The engineer who turned a concept into a reality"

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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 symptomatic hallux valgus deformities in which distal or proximal osteotomies are traditionally indicated.
- Surgically appropriate patient that has failed previous nonoperative treatments.

Contraindications

- Active infection.
- · Open physes.
- · Allergy to metallic implants.
- Patients unable to undergo anesthesia, unable to navigate postoperative process, or deemed surgically inappropriate.

Preoperative Considerations

The preoperative indications for percutaneous hallux valgus correction mirror open procedures. Once a patient is determined to be a satisfactory surgical candidate and has failed conservative treatment, then he or she is evaluated preoperatively for Pecaplasty® procedural planning. Pecaplasty® is appropriate for primary or revision hallux valgus surgical deformity correction.

Furthermore, in certain revision cases the Pecaplasty® approach could be considered a significant benefit to avoid further scarring. When evaluating a candidate for Pecaplasty®, a thorough physical examination of the patient's hallux valgus deformity should be performed and standard weightbearing pedal radiographs obtained.

The first intermetatarsal angle, hallux valgus angle, sesamoid position, and any metatarsus primus elevatus should be noted and documented. Concurrent frontal plane deformity of the first ray should also be assessed, as triplanar deformity correction is possible when indicated.

The transverse osteotomy and Pecaplasty® percutaneous approach permits the surgeon to control the length of the first metatarsal, adjust the capital fragment dorsal or plantar in the sagittal plane, reduces the first intermetatarsal angle in the transverse plane, and can correct frontal plane rotation. Additionally, the integrity of the first metatarsophalangeal joint should be evaluated for degenerative changes and evaluating for crepitus or intra-articular joint pain on range of motion of the joint during physical exam.

Another critical radiographic factor to consider when evaluating a patient for possible Pecaplasty® candidacy is examining the width of the distal first metatarsal metaphysis compared to the distance between the surgical necks of the first and second metatarsals. This is used as a predictor of success and potential reducibility of the overall hallux valgus deformity more so than the first intermetatarsal angle. For example, if the width of the distal first metatarsal metaphysis (A to B in figure 1) is equal or greater than the distance between the surgical necks of the first and second metatarsals (C to D in figure 1), then the Pecaplasty® procedure will be reliable to obtain full correction of the hallux valgus deformity (fig 1).



Figure 1: The width of the distal metaphyseal region of the first metatarsal (A to B) is equal to the distance between the surgical necks of the first and second metatarsals (C to D).

Percutaneous Chevron Akin Implant System



Reduction Wire

The single-use reduction wire offers the simplicity of a flexible stem with a rigid and sharpened tip for hands free metatarsal translation (CKW03001).



Sterile Percutaneous Burrs

Intelligently designed cutting flutes offer precision bone resection and removal without violating soft tissue structures.



QuickStep Reamers

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



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.





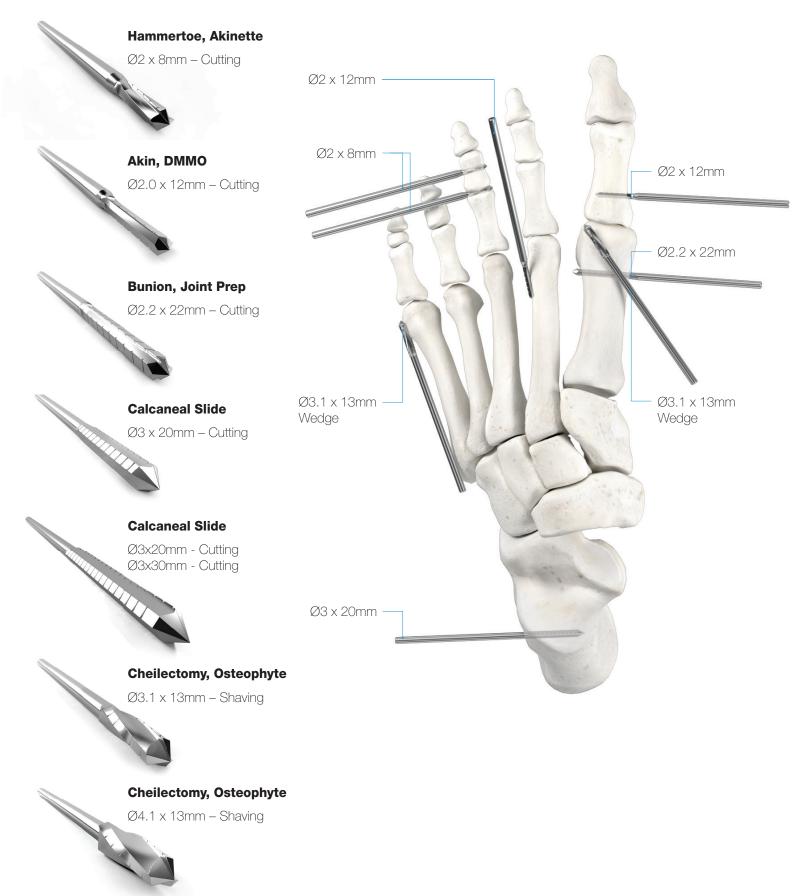
Visual Guideline

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.



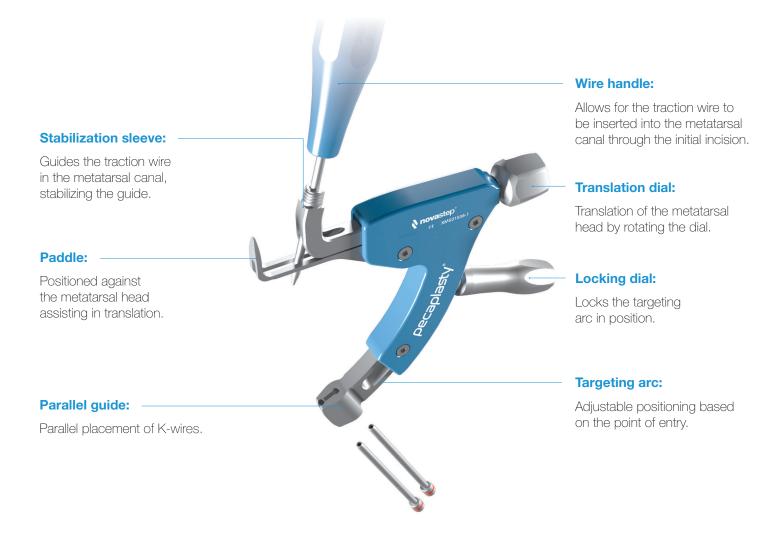


Sterile Burrs



Pecaplasty® System

Patent pending



Pecaplasty® System

Guided & reproducible procedure

1. Easy positioning on the foot

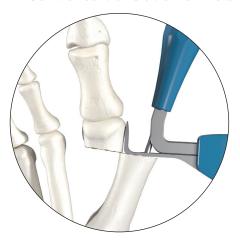




Position:

the guide after a transverse osteotomy by inserting the paddle beneath the medial capsule.

2. Controlled translation of metatarsal head





Translate:

the metatarsal head using the translation dial.

3. Accurate placement of K-wires





Adjust:

the arc around its center of rotation to allow K-Wires insertion. Insertion point must be as proximal as possible. Aiming point is fixed, always 14mm from the paddle.

Patient positioning

Once a patient is appropriately evaluated and deemed a satisfactory Pecaplasty® candidate for percutaneous hallux valgus surgery they are taken to the operating theatre.

Patient positioning is the first, and most critical, initial step related to the percutaneous surgical procedure. The patient is positioned with the heel of the operative limb extending approximately six to ten inches off the end of the surgical bed. This allows for fluid unobstructed use of surgical instruments and placement of the operative foot onto the intraoperative fluoroscopy unit with manipulation ability throughout the entire procedure. A right-handed surgeon is seated on the left side of the patient's operative foot and fluoroscopy is positioned to the right of the patient regardless of which limb is being operated upon.

For left-handed surgeons this positioning is reversed. When operating on the right foot the left foot will be protected and bolstered out of the surgical field, while the right lower extremity will not be in the way for surgery on the left foot. The procedure may be performed with or without use of a tourniquet and is at the discretion of the surgeon. If tourniquet is utilized, periodic irrigation should be considered when using the percutaneous burrs in order to limit potential for thermal soft tissue injury or osseous necrosis.



Landmarks & incision

Once the foot is appropriately prepped and draped, attention is directed to the operative foot where the landmarks of the first ray are identified and marked by using palpation or fluoroscopy.

Key landmarks that should be drawn include the first tarsometatarsal joint, the first metatarsophalangeal joint, and the longitudinal bisection of the first metatarsal on the sagittal plane. If a percutaneous Akin osteotomy is being considered, then marking the longitudinal bisection of the proximal phalanx of the hallux is also helpful.

Using a beaver blade or similar small scalpel, a 1-2 mm percutaneous incision is made through the skin along the medial aspect of the distal first metatarsal metaphysis. A periosteal elevator is utilized to create a working space along the dorsal capsule, but the plantar capsule is not stripped or violated to prevent disrupting the blood flow entering the first metatarsal head.

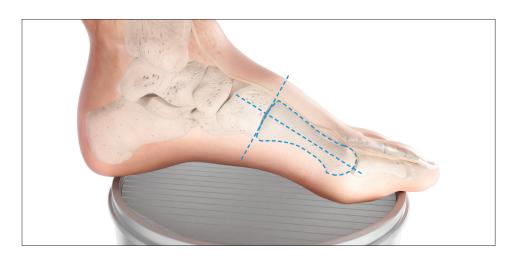


Using the Novastep 2.2 mm by 22 mm percutaneous cutting burr, a straight transverse osteotomy is made within the metaphyseal bone of the distal first metatarsal located slightly proximal to the sesamoid complex.

Note:

It's important to remember that a burr will take 2-3mm of bone with its cut, as opposed to 1mm with a traditional saw, thus the surgeon should ensure proper burr orientation and angle that will result in the desired first ray length following the osteotomy.

Upon completion of the osteotomy a distraction tool is then inserted into the first metatarsal medullary canal and the first metatarsal head is shifted laterally to loosen capsular and periosteal soft tissue attachments.







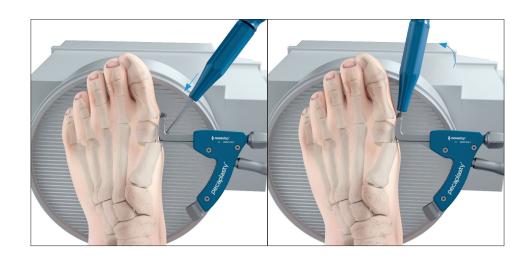
Pecaplasty® guide placement

Once the lateral shift of the head can be clinically appreciated or visualized under fluoroscopic guidance, the Pecaplasty[®] jig is inserted through the initial percutaneous incision with the paddle placed deep to the first metatarsal capsule along the medial aspect of the capital fragment.

The Pecaplasty® is then stabilized and secured by inserting the first metatarsal wire, screwed into the wire handle and inserted through the stabilization sleeve. It is directed from distal to proximal through the initial percutaneous incision into the first metatarsal medullary canal.

It is critical that the surgeon ensures proper positioning of the Pecaplasty® jig prior to capital fragment translation and placement of fixation. Specifically, the Pecaplasty® should be held parallel to the longitudinal bisection of the first metatarsal, the paddle should be oriented parallel with the second metatarsal, and the paddle arm should be perpendicular with the second metatarsal.







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Controlled translation

Through ligamentotaxis, the operative hallux may be rotated in the frontal plane at this time to correct for any first metatarsal frontal plane deformity.

The translation paddle is then engaged against the capital fragment by turning the dial in clockwise fashion, and the capital fragment is translated laterally until the appropriate correction is achieved. This is confirmed through direct clinical visualization and with fluoroscopy.

Note:

The hallux is held into varus against the wire handle in order to control the rotation and dorso-plantar position of the metatarsal head until K-wires are placed.





K-wire placement

The distal guide wire sleeve is entered through the parallel guide on the targeting arc. A percutaneous incision is made to allow insertion of the proximal and distal guide wire sleeves down to bone along the proximal medial first metatarsal ensuring that the proximal guide wire sleeve contacts the first metatarsal along its most proximal medial extent.

The locking dial is turned clockwise to lock the targeting arc in extension once the guide sleeves are aligned in appropriate position. A 1.4 mm guide wire for a 4.0 mm PECA implant is then inserted into the distal guide wire sleeve down to bone. The distal guide wire is then driven through the proximal first metatarsal and into the central portion of the first metatarsal head. The distal guide wire will typically end within the central portion of the capital fragment and is usually uni-cortical prior to entering the capital fragment.

Depending on the amount of lateral translation of the capital fragment, this wire can (but does not have to) purchase the distal first metatarsal lateral cortex prior to entering the first metatarsal head.

A second 1.4 mm guide wire for a 4.0 mm PECA implant is then inserted through the proximal guide sleeve within the parallel guide of the targeting arc. The proximal guide wire is then driven bicortical exiting the lateral first metatarsal diaphysis about 1 cm proximal to the osteotomy prior to entering into the lateral aspect of the capital fragment.

This step is key for the proximal PECA implant to provide stability to the osteotomy and capital fragment, as well as limit the potential for fracture adjacent to the osteotomy site. The distal PECA implant will increase the stability of the construct, but is also there to maintain alignment and prevent rotation of the capital fragment.





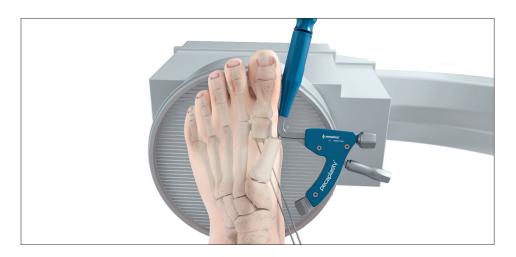


Care must be taken to assure the proximal guide wire does not pass through the lateral cortex too close to the osteotomy site and the sesamoids should be checked on the AP view to ensure they are fully corrected to normal positioning. The tips of the guide wires should stop just proximal to the first metatarsophalangeal joint and proper position of the wires should be confirmed on anterior-posterior (AP) view as well as lateral view using fluoroscopy. The position of the first metatarsal head, reduction of the deformity, and proper position of the guide wires is then again confirmed under multiple planes of fluoroscopy (typically AP and lateral views). If the positions of the guide wires are satisfactory, the Pecaplasty jig is then disassembled and removed from the percutaneous incisions.



The Pecaplasty guide can be easily disassembled. The locking dial is turned counterclockwise to unlock the guide and the sleeves are removed.

The K-wires pass through the notch of the parallel guide, the targeting arc is retracted to remove the guide.



Implants insertion

The remaining calibrated guide wires are then measured for two appropriately sized 4.0mm PECA implants. The PECA implants chosen are 2-4mm shorter than the measured length to ensure that the implants are fully recessed after insertion.

The wires are then over-drilled with the \emptyset 3.2mm 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.

The two 4.0mm PECA implants are inserted while simultaneously holding the first metatarsal head to resist rotation of the capital fragment.

Note: The Exact 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.



Medial spike removal

Using the Novastep 2.2mm x 22mm cutting burr, the medial first metatarsal osseous spike/shelf created by the capital fragment shift is osteotomized and removed through one of the percutaneous incisions.

At this point if there is any residual osseous prominence present at the medial first metatarsal head, it can be reduced with the Novastep 3.1mm x 13mm percutaneous wedge burr.



Optional

Following completion of the aforementioned Pecaplasty® procedure, the surgeon should then evaluate for any need to augment the procedure with a percutaneous soft tissue lateral release and/or a percutaneous hallux Akin osteotomy. The operative forefoot is loaded and the hallux position critically evaluated clinically and under fluoroscopy. If the decision to perform a percutaneous proximal phalangeal Akin type osteotomy is made, then this can be initiated by making a 1-2mm percutaneous skin incision created on the medial aspect of the proximal metaphysis of the hallux proximal phalanx. Using the Novastep 2.0mm x 12mm percutaneous cutting burr a medially-based closing wedge osteotomy is created in the proximal phalanx of the hallux and feathered incrementally to obtain ideal transverse plane correction while maintaining the lateral cortex intact. If indicated, further frontal plane rotation of the hallux can be obtained by completing the Akin osteotomy through the lateral cortex of the proximal phalanx and rotating the hallux in the frontal plane until the deformity is fully corrected.

A 1.0mm guide wire for a 3.0mm PECA implant is then inserted bi-cortical and perpendicular to the osteotomy while manually compressing the osteotomy closed.



The wire can be inserted through the initial percutaneous incision of the first metatarsal osteotomy starting it along the proximal medial aspect of the proximal phalanx and directing it distal lateral. The 1.0mm calibrated guide wire is then measured with depth gauge and the guide wire is then over-drilled with an appropriately sized cannulated drill. This is then followed by placement of an appropriately sized 3.0 mm PECA implant. Fluoroscopy is again utilized to confirm appropriate implant placement and correction of hallux valgus deformity on AP and lateral views.

All incisions are copiously irrigated, taking care to remove any residual bone paste or debris.

Dressing and post-operative management

The wounds are closed according to surgeon's preference. If a first metatarsophalangeal joint lateral soft tissue release is indicated, this can be employed percutaneously after the osteotomies are complete.

A local anesthetic block is provided for postoperative analgesia. The operative hallux is splinted into a corrected position and a compression dressing is applied to the foot and ankle.

The patient is discharged with the appropriate pain control regimen and a surgical shoe to wear whenever weight bearing on the operative foot. Patients are instructed to initially bear weight to their heel only or flat-footed with the rigid surgical shoe but are instructed to avoid a propulsive type gait.





Pre & Post Op X-rays





Ordering Information

PECA Bunion 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

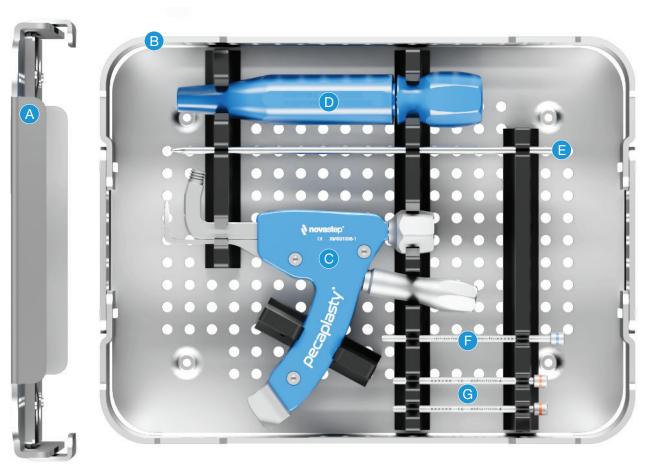
| Ref | Description | Qty. |
|----------|--------------------------|------|
| CRE12008 | Shannon Corta 2.0 x 8mm | 2 |
| CRE12012 | Shannon Recta 2.0 x 12mm | 2 |
| CRE12222 | Shannon Longa 2.2 x 22mm | 2 |
| CRE13020 | Shannon Larga 3.0 x 20mm | 2 |
| CRE13030 | Shannon Xlarga 3.0 x30mm | 2 |
| CRE23113 | Wedge 3.1 | 2 |
| CRE24113 | Wedge 4.1 | 2 |

K-Wires, Reduction Wires



| Ref | Description | Qty. |
|----------|--|------|
| CKW02005 | K-Wire Ø1.4 lg 150mm TR/RD CoCr | 4 |
| CKW02004 | K-Wire Ø1.0 lg 150mm TR/RD CoCr | 4 |
| CKW07001 | Threaded K-wire Ø1.4 lg 150mm TR/RD CoCr | 4 |
| CKW03001 | PECA Reduction wire | 4 |

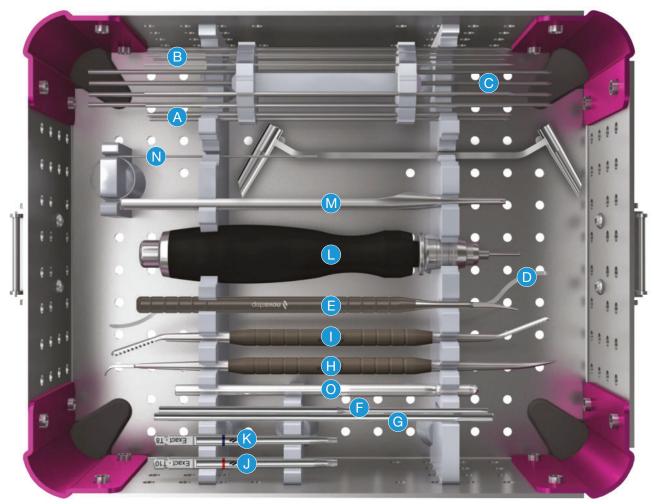
Pecaplasty® Tray – Layout



Pecaplasty Instrument Tray

| | Part# | Description | Qty. |
|---|--------------|---|------|
| A | ACC1019P0001 | Pecaplasty® Targeting guide tray | 1 |
| В | ACC1019P0002 | Pecaplasty® Targeting guide lid | 1 |
| С | XMS01038-1 | Pecaplasty® Targeting guide | 1 |
| D | XMS01038-2 | Pecaplasty® Targeting guide wire handle | 1 |
| E | CKW06001 | Traction wire for Pecaplasty® targeting guide | 1 |
| F | XMS01038-3 | Pecaplasty® Ø4mm K-Wire sleeve | 2 |
| G | XMS01038-4 | Pecaplasty® Ø3mm K-Wire sleeve | 1 |

Peca[®] Instrument Tray – Layout



PECA Instrument Tray

| | Part# | Description | Qty. |
|----|-----------|--|------|
| | XTR10026 | PECA Instrument Tray | |
| A | CKW02005 | K-Wire Ø1.4mm lg150 TR/RD CoCr* | 4 |
| В | CKW02004 | K-Wire Ø1.0mm lg150 TR/RD CoCr* | 4 |
| C | CKW07001 | Threaded K-Wire Ø1.4 lg150 TR/RD CoCr* | 4 |
| C1 | CKW03001 | Peca Reduction Wire 3mm* | 2 |
| C2 | CKW03002 | Peca Reduction Wire 5mm* | 2 |
| D | XMS01027 | Reduction Device Double Tip | 1 |
| E | XMS01011 | Periosteal Elevator Single Tip | 1 |
| F | XDB01017D | 2.0 Quick Step Reamer* | 2 |
| G | XDB01018D | 3.2 Quick Step Reamer* | 2 |
| Н | XMS01008 | Periostial Elevator Double Tip | 1 |
| I | 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 |
| P | XDG01024 | PECA Tissue Protector | 1 |
| | | | |

*Disposable instrumentation 19



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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