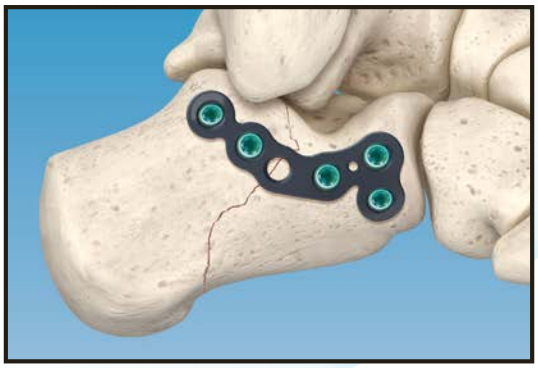
COMPREHENSIVE LOW-PROFILE CALCANEAL FIXATION SYSTEM

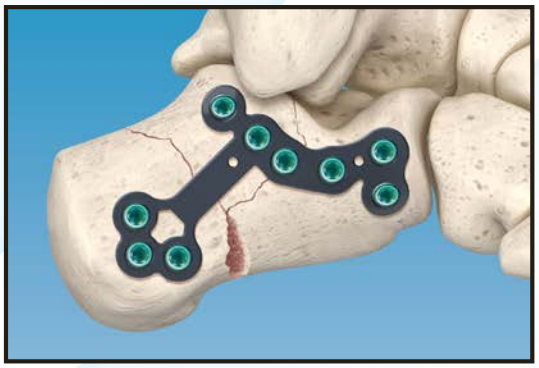
CoLink® Cfx

Minimally Invasive Fracture and Osteotomy Plates

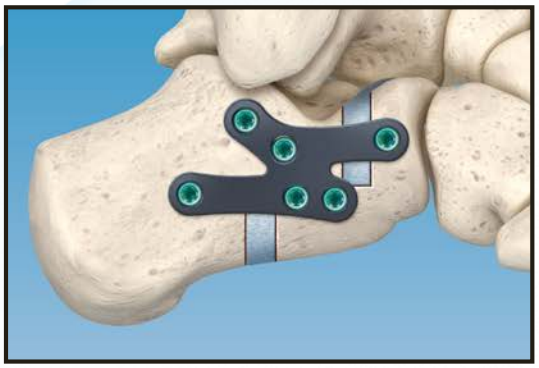
MIS Plates



MIS Extended Plates



Perimeter Plates



Z-Plasty® Osteotomy Plates

Plates and Screws OR Ready, Delivered Sterile

• Anatomic Design • Type II Anodized •

Unique Z-Plasty® Osteotomy Guided System

In2Bones

A GLOBAL EXTREMITY COMPANY

CoLink® Cfx

CALCANEAL FIXATION SYSTEM

System Overview

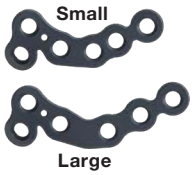
The **CoLink® Calcaneal Fixation System** is a collection of plates and screws targeted at orthopaedic indications of the calcaneus. The system has four plate families to address traumatic fractures and osteotomies of the calcaneus. The system consists of MIS, MIS Extended, Perimeter fracture, and Z-Plasty™ Osteotomy plates in various sizes to account for anatomical variations. Associated cortical screws are 3.5mm locking and non-locking, and 4.0mm cancellous non-locking screws.

All implants are provided sterile packaged. This system utilizes a set of reusable instruments, inclusive of plate trials, for proper size determination prior to selecting the plate. The system also uses a set of single-use, sterile wires and drills to assist with implant placement.

CoLink® Cfx Plates

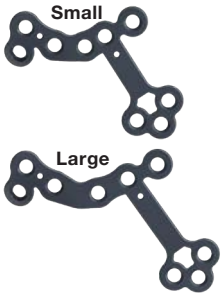
MIS Plates*

- Guided system for sinus tarsi approach
- Low-profile, left and right specific plates
- Small and large sizes



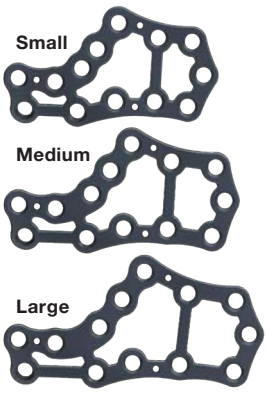
MIS Extended Plates*

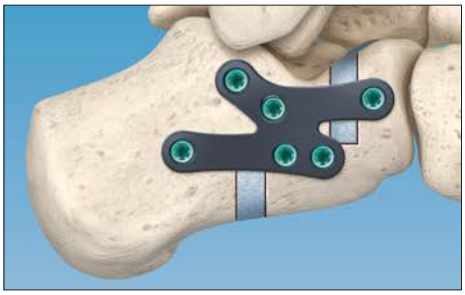
- Guided system for sinus tarsi approach
- Extended lateral calcaneal support
- Low-profile, left and right specific plates
- Small and large sizes



Perimeter Plates

- Lateral extensile approach
- Low-profile, left and right specific plates
- Small, medium, and large sizes





Z-Plasty™ Plate

- Fixation for Z lateral column lengthening osteotomy
- Guided instrumentation for reproducible outcomes
- Left and right specific plates, in one size

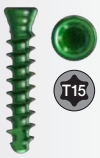
***MIS / MIS Extended Plate Marking Guide**

Ensuring orientation when locating distal screws. See page 5 for details.

CoLink® Cfx Screws

3.5mm Locking & Non-Locking Screws

- Drill Guides = **Light Blue band**
- Depth measurement with Drill Laser Markings or via standard Depth Gauge.

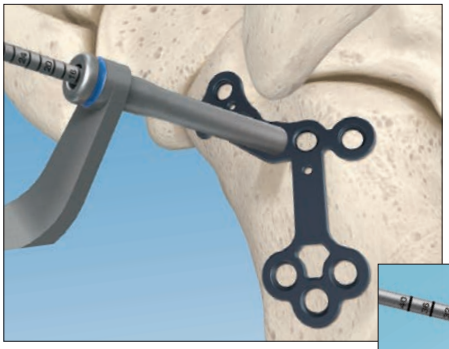


4.0mm Cancellous Screw

- Drill Guides = **Light Blue band**
- Depth measurement with Drill Laser Markings or via standard Depth Gauge.

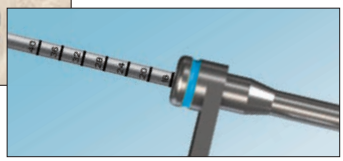
NOTE: Non-locking screws may be placed up to 15° in any direction off the center axis of the screw hole.

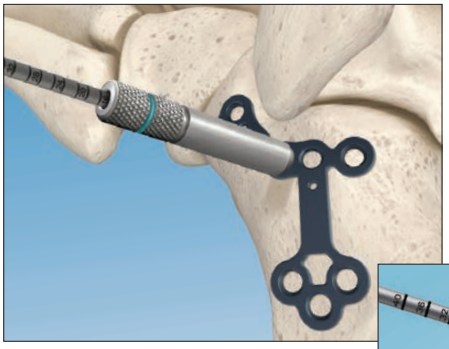
CoLink® Cfx Drill Guides and Screw Sizing Options



Double-ended Non-locking Drill Guide

- Use the blue end for non-locking, off-axis, 3.5mm cortical and 4.0mm cancellous screws

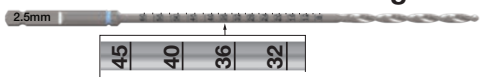




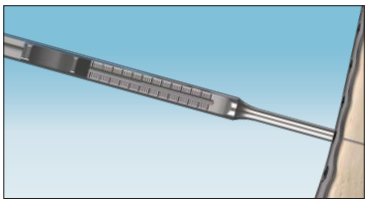
Locking Drill Guide

- For on-axis 3.5mm locking screws

Calibrated Drill Screw Sizing



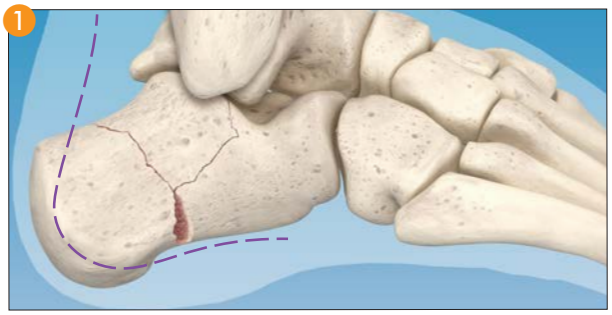
Determine the screw length from the calibrated markings on the Drill relative to the top the Drill Guide.



Depth Gauge Screw Sizing

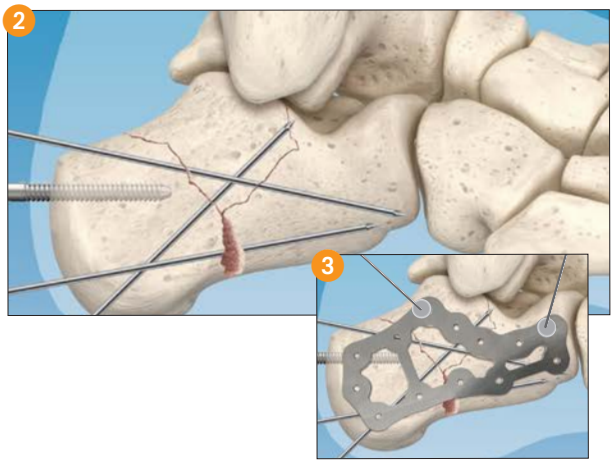
- Place the nose of the Depth Gauge into the screw hole. Hook the far cortex with the probe. Read the measurement on the Depth Gauge body for bi-cortical screw length.

CoLink® Cfx
General Insertion Technique



Incision

1 Use a standard technique for incision, exposure, and preparation of the joint, osteotomy, or fracture site.



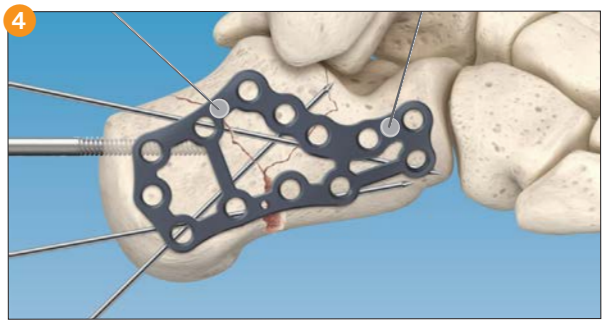
Provisional Fixation

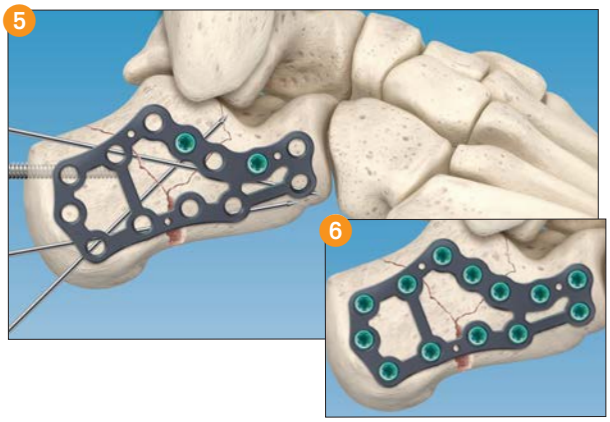
2 Utilize K-Wires and the supplied Schanz Pin to reduce the fracture and provisionally fix in place. Take care not to interfere with plate positioning.

Trialing

3 Determine the appropriate plate selection using the supplied plate trials. Position the selected plate in the desired location.

General Insertion Technique cont.





Provisional Plate Fixation

4 Provisionally fix the corresponding plate with Olive Wires on the distal and proximal ends of the plate. The provided Reduction Forceps may maintain alignment and compression of the fracture or osteotomy while achieving provisional plate fixation.

Note: *If additional contouring is needed, use the supplied Plate Benders or Threaded Bending Bars to contour, taking care not to bend across a hole.*

Screw Preparation and Insertion

Using the associated Drill Guide and calibrated Drill, prepare the first screw hole. Drill to the desired depth and identify the screw length and preferred type.

5 Load the selected screw onto the T15 Driver and seat to the plate through the prepared hole.

While repeating the process, prepare the second screw hole and assemble the selected screw to the plate. Remove the Olive Wires.

6 Prepare and assemble the remaining screws to the plate.

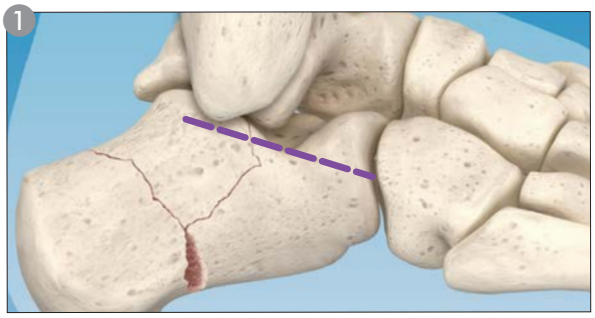
Closure

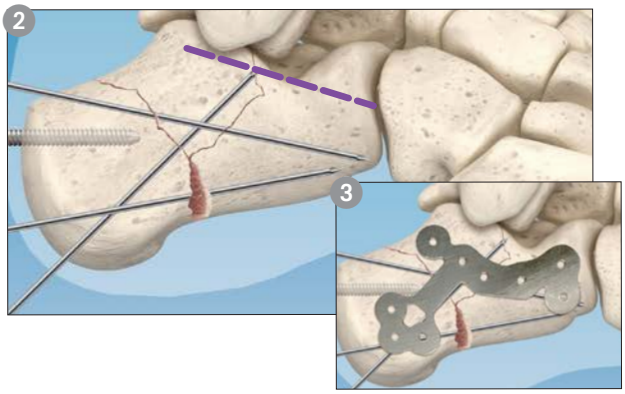
Close by preferred methods.

Removal Technique

Use the supplied CoLink Calcaneal Fixation System instrument set to remove the plate screws, followed by removal of the plate from the bone.

Sinus Tarsi Surgical Technique - **MIS / MIS Extended Plates**





Approach and Incision

1 Initiate an Ollier's type incision posterior-distal to the distal tip of the fibula, extending distally towards the 4th metatarsal (3-5cm). The incision should cross the anterior process of the calcaneus, superior to the peroneal tendons.

Note: *Take precautions to protect the sural nerve throughout the procedure. Inspect the peroneal tendons and repair if needed.*

Alignment and Provisional Fixation

Utilizing K-Wires and the supplied Schanz Pin, reduce the fracture and provisionally fix in place while ensuring the wire and pin positions do not interfere with plate positioning 2.

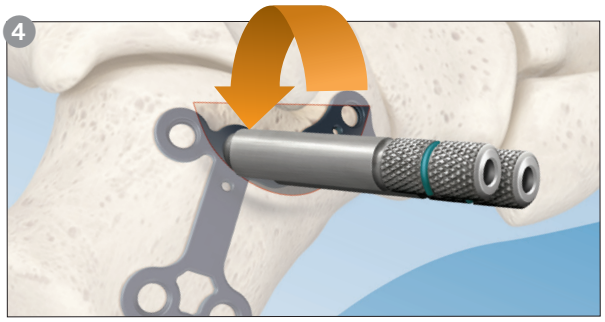
Note: *Use the appropriate K-Wires from the corresponding set when placing cannulated screws.*

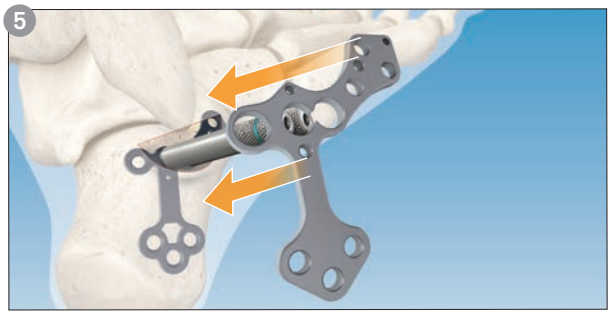
Trialing

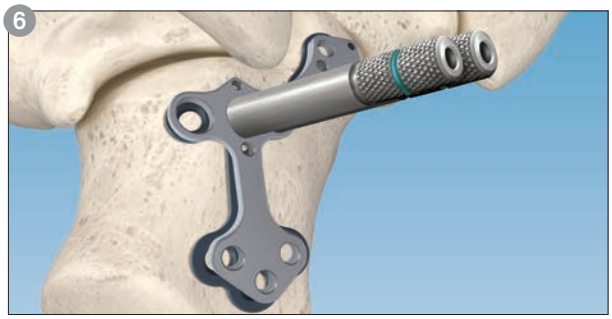
3 Determine the appropriate plate with the supplied plate trials and select the corresponding sterile implant package.

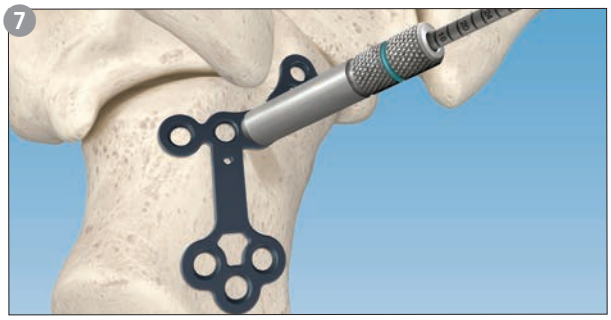
Note: *It is recommended to place the plate trial over the skin of the lateral calcaneus and confirm the size with the use of fluoroscopy prior to final plate size selection.*

Sinus Tarsi Surgical Technique cont. - **MIS / MIS Extended Plates**









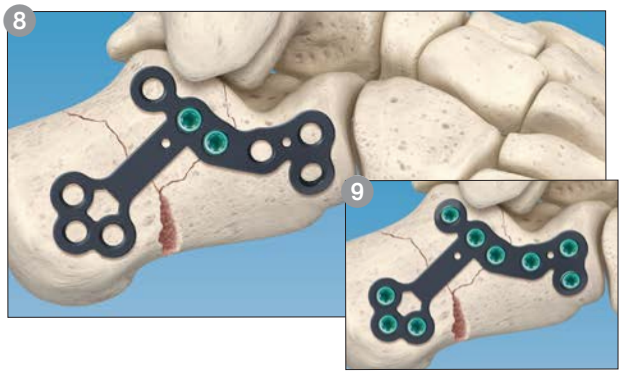


Plate Insertion

Assemble the Locking Drill Guides into superior-central screw holes A.

4 Insert the plate through the incision and position in the desired location, confirming placement under fluoroscopy.

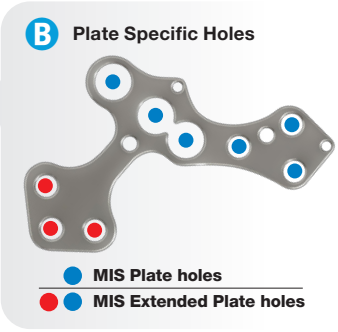
Note: *Should additional dissection be needed, the 7.25" Periosteal Elevator or 3/8" Cobb Elevator may be used to separate soft tissue from the lateral aspect of the calcaneus.*

If contouring is required, remove the plate from the incision and contour with the supplied Plate Benders or CoLink Cfx Threaded Bending Bars; take care not to bend across a plate hole.

Preparation and Implantation

5 Slide the appropriately sized MIS Extended Plate Marking Guide over the Locking Drill Guides ensuring orientation and side are correct 6.

Provisionally fix the plate to the bone with Olive Wires. Mark the hole locations with a skin marker or K-Wire as indicated B.



Note: *Pin holes may be used to check plate placement to the borders of the subtalar and calcaneocuboid joints.*

Prepare the first screw through one of the Locking Drill Guides using the calibrated Drill.

Drill to the desired depth and determine screw length; remove the Drill Guide 7.

Select the appropriate screw package based on the indicated length, screw type, and size preference. Seat to the plate with the T15 AO Driver.

While repeating the process, prepare the second screw through the remaining Locking Drill Guide and assemble to the plate; remove the Olive Wires 8.

Drill for the remaining screws as permitted by the existing sinus tarsi incision using the double-ended Non-Locking Drill Guide and calibrated Drill; size and fill as appropriate.

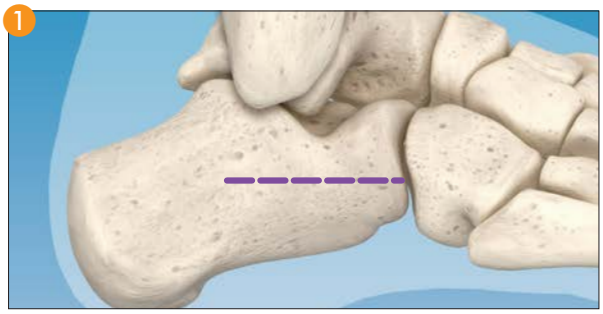
Note: *In order to protect surrounding tissue, screw hole preparation without a drill guide is not recommended.*

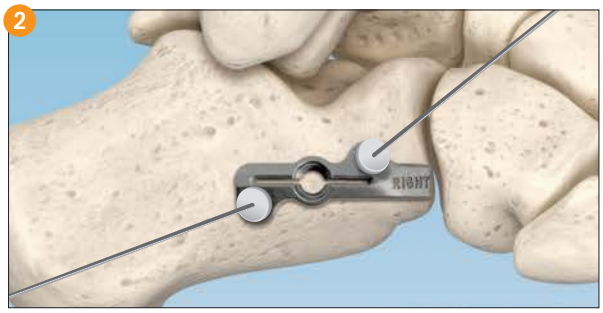
Create stab incisions to gain access to the remaining holes as indicated by the previously marked locations; a single straight incision may be preferable to gain access to the posterior holes on the MIS Extended Plate.

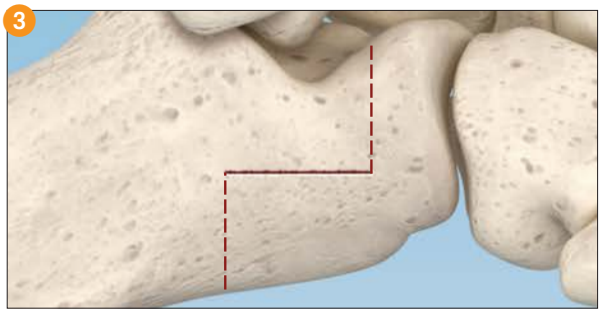
Using the double-ended Drill Guide, prepare, size, and fill each of the remaining holes 9.

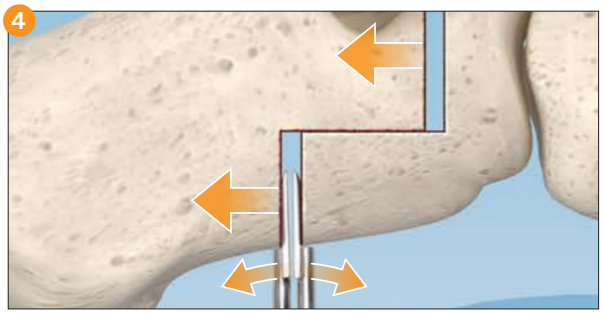
Confirm final implant placement with the use of fluoroscopy and close by preferred methods.

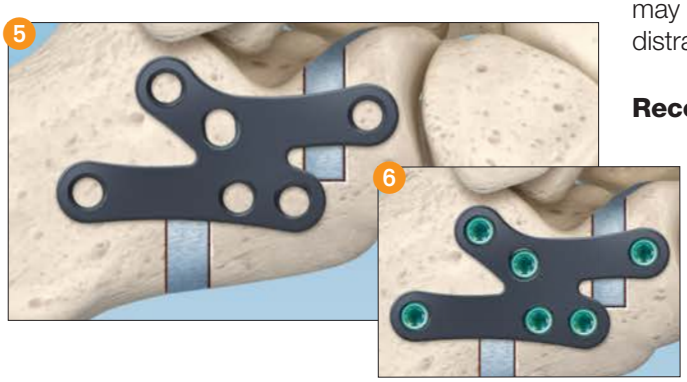
Z-Plasty™ Technique - **Z-Plasty Plates**











Incision/Exposure

Place a lateral, linear incision over the peroneal tendons overlying the anterior body of the calcaneus from the calcaneocuboid joint to the peroneal tubercle 1. Carefully dissect, retract, and protect any neurovascular structures including the sural nerve. Expose, examine, and repair the peroneal tendons as necessary.

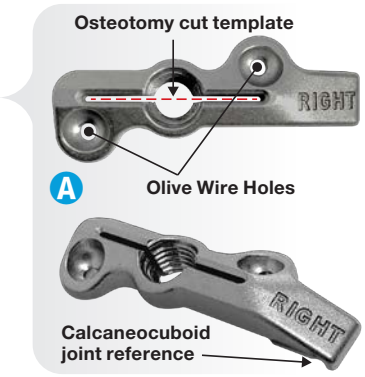
Expose the lateral calcaneal body for planning of the Z-osteotomy.

Z-Plasty Cutting Guide

Template the "Z" using the provided side-specific saw Cut Guide. This guide is referenced off the calcaneocuboid joint to begin the saw cut 13 mm proximal to the joint line A.

Pin the guide in place with two Olive Wires and verify with imaging 2.

Note: *Ideal placement of the guide is centered at the midline of the calcaneus.*



Initial Osteotomy Cut

Perform the initial osteotomy via the cutting guide; remove the guide 3.

Superior/Inferior Osteotomies

Starting at the anterior-superior Olive Wire hole, make a vertical osteotomy extending from the transverse osteotomy to the superior aspect of the calcaneus.

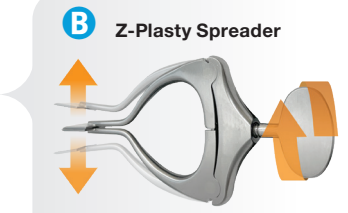
The proximal osteotomy will reference the posterior-inferior Olive Wire hole and extend distally to the inferior aspect of the calcaneus.

Tip: *The Peroneals may need to be retracted inferiorly during the performance of the anterior portion of the osteotomy and superiorly during the creation of the proximal osteotomy.*

Z-Plasty Spreader Use

Use the Z-Plasty Spreader B in either the distal or proximal osteotomy to distract and lengthen to desired correction 4.

This lengthening may be 'dialed in' and reviewed with AP imaging; TN coverage may be used to determine the amount of distraction lengthening desired.



Note: Take care not to over-tighten in the closed position for insertion into the osteotomy or loading into the instrument tray.

Recommended Bone Grafting

5 Bone or wedge grafting of the osteotomy site is recommended per surgeon preference.

Use the supplied plate trials to determine plate selection; place and secure the corresponding implant in place with the supplied Olive Wires through any of the plate holes.

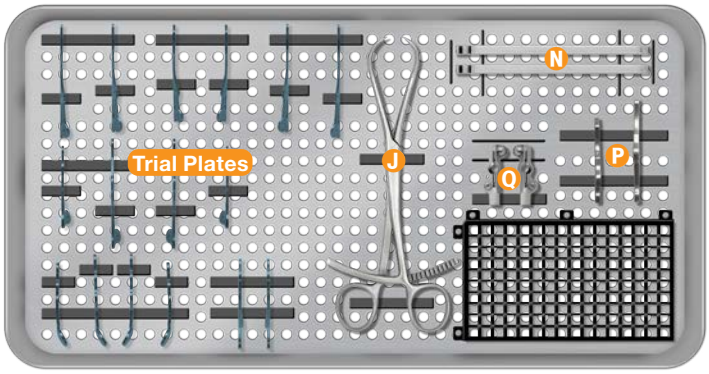
6 Follow the screw placement technique to place screws in all available plate holes.

Close the incision by preferred methods.

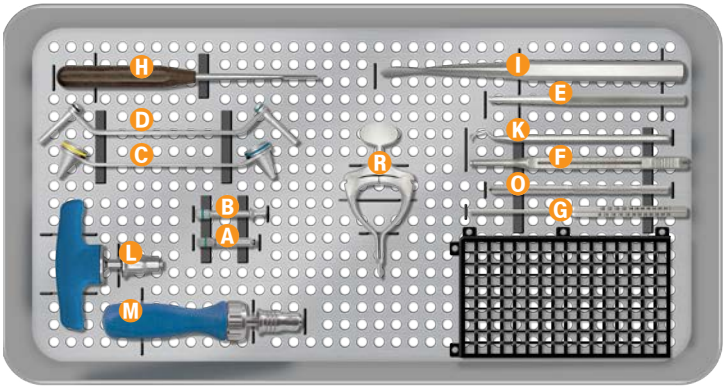
CoLink® Cfx
Instrument Set

- **A** P08 N0081..... Locking Drill Guide, 2.5mm
- **B** P07 N0231..... Lag Guide, 2.5mm
- **C** P07 N0291..... VA NL Drill Guide, 1.9 & 2.5mm
- **D** P07 N0151..... NL Drill Guide, 2.5 & 3.5mm
- **E** P08 N0091..... Bone Tamp, 5mm X 6"
- **F** P07 N0251..... Easy Clean Depth Gauge
- **G** P06 N0661..... Lag Screw Sizer, 6"
- **H** P07 N0261..... Periosteal Elevator, 7.25" 6mm Straight Blade
- **I** P08 N0021..... Cobb Elevator, 3/8"
- **J** P08 N0011..... 8" Reduction Bone Forceps
- **K** P07 N0221..... Dental Pick
- **L** P08 N0041..... T-Handle, AO, QC
- **M** P04 N0063..... Ratcheting Handle, AO QC
- **N** P07 N0121..... Plate Bender
- **O** P08 N0031..... Threaded Bending Bar
- **P** P08 N0071/2 .. MIS Extended Marking Guide; Sm/Lg
- **Q** P08 N0061/2 .. Cfx Z-Plasty Cutting Guides; L/R
- **R** P08 N0101..... Z-Plasty Spreader

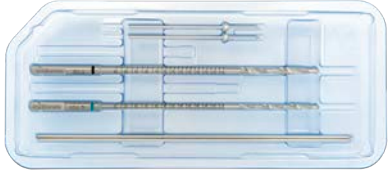
Top Reusable Tray



Bottom Reusable Tray



Single-Use, Sterile Kit - P08 S0001



- 2 - Guide Wire, Single Trocar 0.06 X 6”
- 1 - 2.5 X 60mm Drill
- 2 - Olive Wire 0.045 X 2.5”
- 1 - Lag Drill, 3.5mm

In separate, single-use sterile packs:

P04 S0221 ..... Olive Wire - 0.045 X 2.5", 2 Pack, Sterile
P06 S2333 ..... Guide Wire - Single Trocar, 0.06 X 6", 2 Pack, Sterile
P07 S0041 ..... T15 Driver, AO, Sterile
P08 S0051 ..... Schanz Pin - threaded, 5 X 175mm, Sterile

COMPREHENSIVE LOW-PROFILE CALCANEAL FIXATION SYSTEM

CoLink® Cfx

All Sterile, Minimally Invasive Fracture /Osteotomy Plating

CoLink® Cfx Calcaneal Plates

	CATALOG NO	DESCRIPTION
MIS S / MIS L	P80 ST111	MIS Plate, Small, **R**ight
	P80 ST211	MIS Plate, Small, **L**eft
	P80 ST112	MIS Plate, Large, **R**ight
	P80 ST212	MIS Plate, Large, **L**eft
MIS EXT S / MIS EXT L	P80 ST121	MIS Plate, Ext, Small, **R**ight
	P80 ST221	MIS Plate, Ext, Small, **L**eft
	P80 ST122	MIS Plate, Ext, Large, **R**ight
	P80 ST222	MIS Plate, Ext, Large, **L**eft
SMALL / MEDIUM / LARGE	P80 ST131	Perimeter Plate, Small, **R**ight
	P80 ST231	Perimeter Plate, Small, **L**eft
	P80 ST132	Perimeter Plate, Medium, **R**ight
	P80 ST232	Perimeter Plate, Medium, **L**eft
	P80 ST133	Perimeter Plate, Large, **R**ight
	P80 ST233	Perimeter Plate, Large, **L**eft
	P80 ST141	Z-Plasty Plate, **R**ight
	P80 ST241	Z-Plasty Plate, **L**eft

CoLink® Cfx Instruments

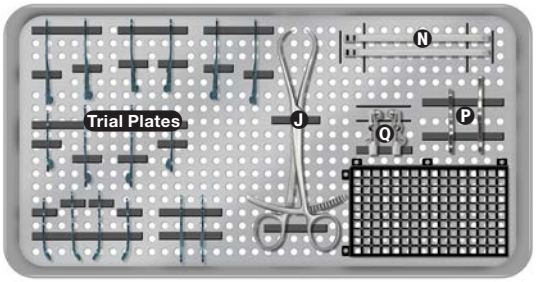
Single-Use, Sterile Kit - P08 S0001

2 - Guide Wire, Single Trocar, 0.06 X 6”
1 - 2.5 X 60mm Drill
2 - Olive Wire 0.045 X 2.5”
1 - Lag Drill, 3.5mm

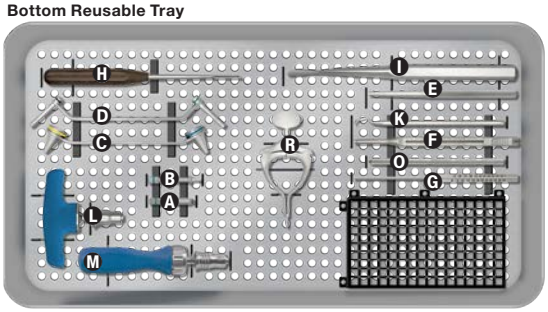
In separate, single-use sterile packs:

P04 S0221 .... Olive Wire - 0.045 X 2.5", 2 Pack, Sterile
P06 S2333 .... Guide Wire - Single Trocar, 0.06 X 6", 2 Pack, Sterile
P07 S0041 .... T15 Driver, AO, Sterile
P08 S0051 .... Schanz Pin - threaded, 5 X 175mm, Sterile

Top Reusable Tray



Bottom Reusable Tray



CoLink® Cfx 3.5mm Low-Pro Cortical Screws

Color code T15

CATALOG NO	DIA x LENGTH	STYLE
P73 ST010	3.5 x 10mm	Non-Locking
P73 ST012	3.5 x 12mm	Non-Locking
P73 ST014	3.5 x 14mm	Non-Locking
P73 ST016	3.5 x 16mm	Non-Locking
P73 ST018	3.5 x 18mm	Non-Locking
P73 ST020	3.5 x 20mm	Non-Locking
P73 ST022	3.5 x 22mm	Non-Locking
P73 ST024	3.5 x 24mm	Non-Locking
P73 ST026	3.5 x 26mm	Non-Locking
P73 ST028	3.5 x 28mm	Non-Locking
P73 ST030	3.5 x 30mm	Non-Locking
P73 ST032	3.5 x 32mm	Non-Locking
P73 ST034	3.5 x 34mm	Non-Locking
P73 ST036	3.5 x 36mm	Non-Locking
P73 ST038	3.5 x 38mm	Non-Locking
P73 ST040	3.5 x 40mm	Non-Locking
P73 ST042	3.5 x 42.5mm	Non-Locking
P73 ST045	3.5 x 45mm	Non-Locking
P73 ST047	3.5 x 47.5mm	Non-Locking
P73 ST050	3.5 x 50mm	Non-Locking
P73 ST052	3.5 x 52.5mm	Non-Locking
P73 ST055	3.5 x 55mm	Non-Locking
P73 ST057	3.5 x 57.5mm	Non-Locking
P73 ST060	3.5 x 60mm	Non-Locking

CoLink® Cfx 3.5mm Locking Screws

T15

P73 ST110	3.5 x 10mm	Locking
P73 ST112	3.5 x 12mm	Locking
P73 ST114	3.5 x 14mm	Locking
P73 ST116	3.5 x 16mm	Locking
P73 ST118	3.5 x 18mm	Locking
P73 ST120	3.5 x 20mm	Locking
P73 ST122	3.5 x 22mm	Locking
P73 ST124	3.5 x 24mm	Locking
P73 ST126	3.5 x 26mm	Locking
P73 ST128	3.5 x 28mm	Locking
P73 ST130	3.5 x 30mm	Locking
P73 ST132	3.5 x 32mm	Locking

CoLink® Cfx 3.5mm Locking Screws - cont.

P73 ST134	3.5 x 34mm	Locking
P73 ST136	3.5 x 36mm	Locking
P73 ST138	3.5 x 38mm	Locking
P73 ST140	3.5 x 40mm	Locking
P73 ST142	3.5 x 42.5mm	Locking
P73 ST145	3.5 x 45mm	Locking
P73 ST147	3.5 x 47.5mm	Locking
P73 ST150	3.5 x 50mm	Locking
P73 ST152	3.5 x 52.5mm	Locking
P73 ST155	3.5 x 55mm	Locking
P73 ST157	3.5 x 57.5mm	Locking
P73 ST160	3.5 x 60mm	Locking

CoLink® Cfx 4.0mm Cancellous Screws

T15

P74 ST010	4.0 x 10mm	Cancellous
P74 ST012	4.0 x 12mm	Cancellous
P74 ST014	4.0 x 14mm	Cancellous
P74 ST016	4.0 x 16mm	Cancellous
P74 ST018	4.0 x 18mm	Cancellous
P74 ST020	4.0 x 20mm	Cancellous
P74 ST022	4.0 x 22mm	Cancellous
P74 ST024	4.0 x 24mm	Cancellous
P74 ST026	4.0 x 26mm	Cancellous
P74 ST028	4.0 x 28mm	Cancellous
P74 ST030	4.0 x 30mm	Cancellous
P74 ST032	4.0 x 32mm	Cancellous
P74 ST034	4.0 x 34mm	Cancellous
P74 ST036	4.0 x 36mm	Cancellous
P74 ST038	4.0 x 38mm	Cancellous
P74 ST040	4.0 x 40mm	Cancellous
P74 ST042	4.0 x 42.5mm	Cancellous
P74 ST045	4.0 x 45mm	Cancellous
P74 ST047	4.0 x 47.5mm	Cancellous
P74 ST050	4.0 x 50mm	Cancellous
P74 ST052	4.0 x 52.5mm	Cancellous
P74 ST055	4.0 x 55mm	Cancellous
P74 ST057	4.0 x 57.5mm	Cancellous
P74 ST060	4.0 x 60mm	Cancellous

Reusable Tray Components

- **A** P08 N0081 ..... Locking Drill Guide, 2.5mm
- **B** P07 N0231 ..... Lag Guide, 2.5mm
- **C** P07 N0291 ..... VA NL Drill Guide, 1.9 & 2.5mm
- **D** P07 N0151 ..... NL Drill Guide, 2.5 & 3.5mm
- **E** P08 N0091 ..... Bone Tamp, 5mm X 6"
- **F** P07 N0251 ..... Easy Clean Depth Gauge
- **G** P06 N0661 ..... Lag Screw Sizer, 6"
- **H** P07 N0261..... .. Periosteal Elevator, 7.25" 6mm Straight Blade
- **I** P08 N0021 ..... Cobb Elevator, 3/8"
- **J** P08 N0011 ..... 8" Reduction Bone Forceps
- **K** P07 N0221 ..... Dental Pick
- **L** P08 N0041 ..... T-Handle, AO, QC
- **M** P04 N0063 ..... Ratcheting Handle, AO QC
- **N** P07 N0121 ..... Plate Bender
- **O** P08 N0031 ..... Threaded Bending Bar
- **P** P08 N0071/2 .... MIS Extended Marking Guide; Sm/Lg
- **Q** P08 N0061/2 .... Cfx Z-Plasty Cutting Guides; L/R
- **R** P08 N0101 ..... Z-Plasty Spreader

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