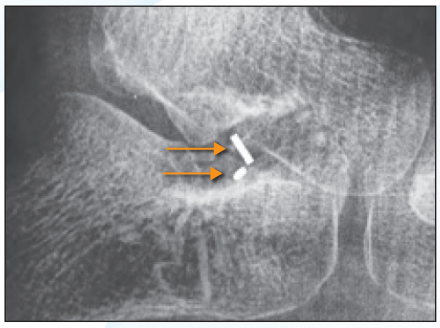
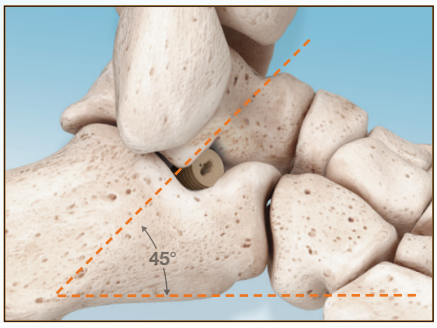
PitStop®

Subtalar Implant

Invisible on x-ray





Anatomical Shape with Lock-in Flanges

Biocompatible, PEEK Radiolucence (invisible on x-ray)

X-ray Markers for Placement Confirmation

In2Bones

A GLOBAL EXTREMITY COMPANY

PitStop®

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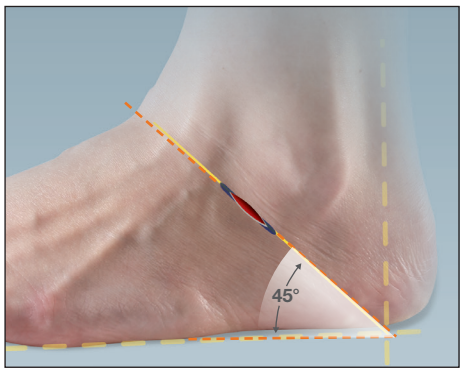
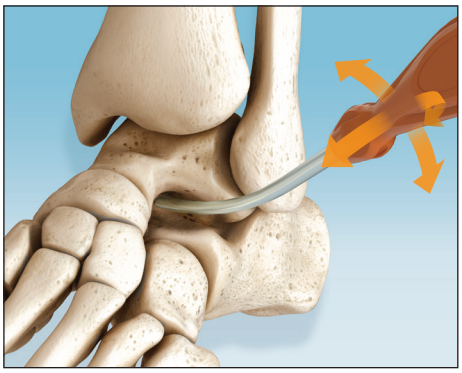


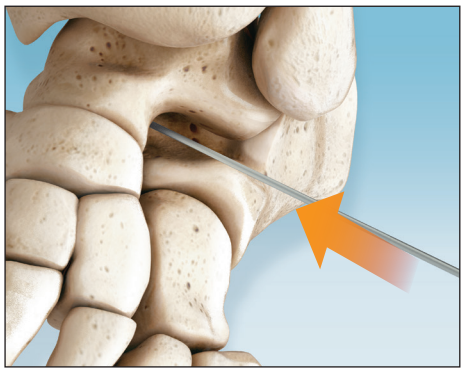
INCISION

A 1-3 cm incision is made on the lateral side of the foot in the skin overlying the sinus tarsi. Blunt dissection with a hemostat to level of joint capsule.



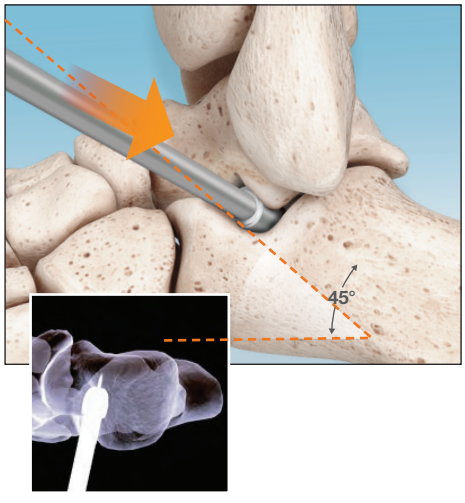
OPTIONAL USE OF VILADOT'S LEVER

The Viladot's Lever is introduced through the sinus tarsi. Move the lever slightly dorsal / medial and anterior / posterior to dilate the tarsal canal.



GUIDE-WIRE INTRODUCTION

Once the talus is positioned on the calcaneus, the 1.6mm Guide-wire is introduced into the axis of the sinus tarsi until the wire is felt on the medial aspect of the hindfoot. Accurate placement may be confirmed with fluoroscopy.



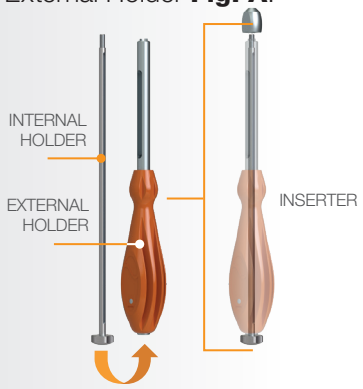
TRIAL SIZER

The first Trial Implant is placed over the Guide-wire and seated in the sinus tarsi. Hindfoot mobility is assessed and the size may be adjusted accordingly. Correct position of the Trial Implant may be verified by fluoroscopy. It is recommended to advance the leading edge of the Trial Implant close to but not past the talonavicular bisection on the AP view. The corresponding flat surfaces of the Trial and Inserter handle are aligned parallel to the lateral talar process which is an approximate 45° angle to the fibula and the plantar aspect of the foot on the lateral view.

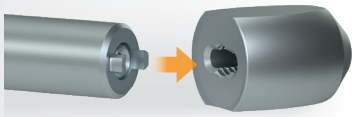
See Inserter preparation

INSERTER* / HOLDER PREP FOR TRIALS

Insert the Internal Holder through the base of the External Holder **Fig. A**.



INSERTER - *Combined External Holder and Internal Holder referred to as the "INSERTER"



Trial aligns with pins in **External Holder**

Fig. B Then attach the Trial Implant to the end of the External Holder by aligning the pins of the Holder to the holes of the Trial Implant. The flat sides of the Trial Implant and the Inserter handle are aligned.

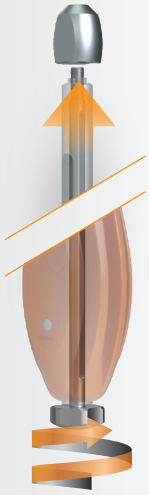
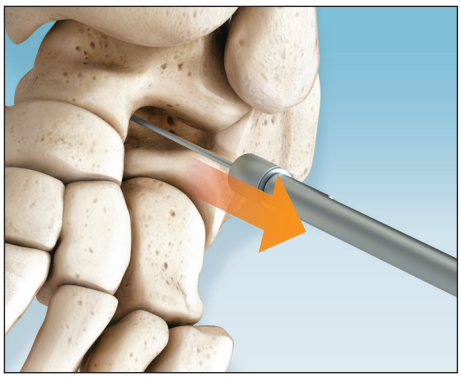


Fig. C Next screw the Internal Holder through the External Holder into the Trial Implant and tighten.



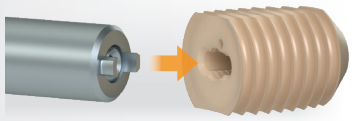
The Trial Implant is removed leaving the Guide-wire in place.

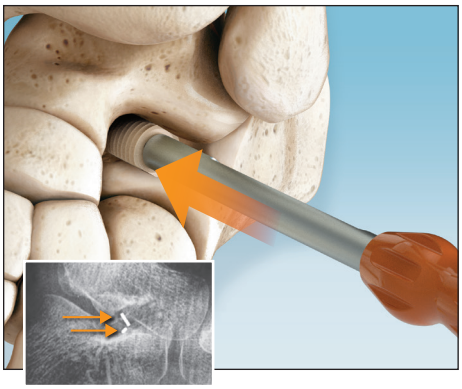
See Inserter preparation

INSERTER PREPARATION FOR IMPLANT

As with the trial, the Implant is fixed to the External Holder **Fig. D**.

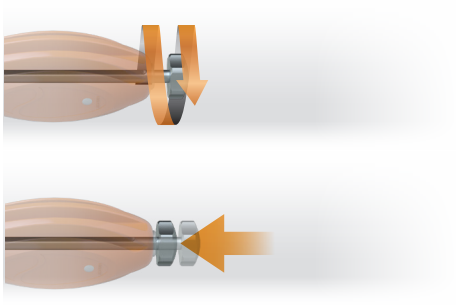
Implant aligns with pins on **External Holder**

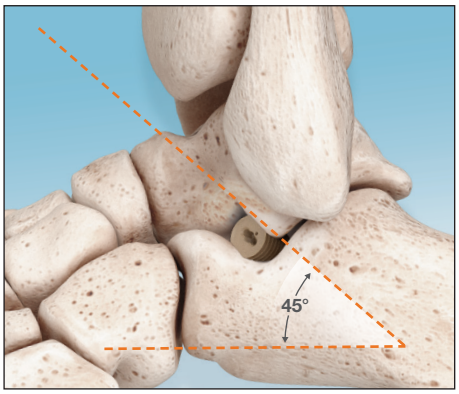




CANNULATED INSERTION

The Inserter is used to "press fit" the Implant in the correct position with a pushing motion. ***"Do not screw Implant into place."*** X-ray markers at each end of the Implant help achieve the adequate depth with fluoroscopy visualization. The corresponding flat surfaces of the Implant and Inserter handle are aligned parallel to the lateral talar process which is an approximate 45° angle to the fibula and the plantar aspect of the foot on the lateral view.





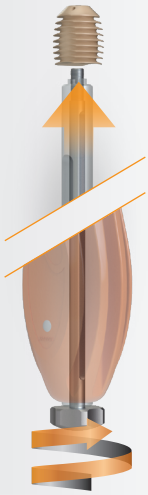
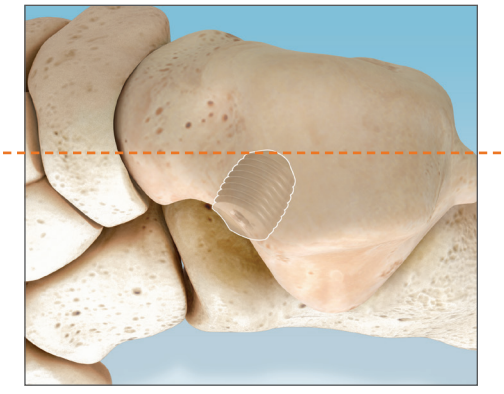


Fig. E Then tightened onto the Internal Holder by turning the bottom knob to engage the Implant.



Unscrew the Internal Holder to release the Implant and push with finger pressure to remove the Holder from the Implant.

Hind-foot mobility is assessed to verify adequate correction. The wound should be closed according to surgeon preference.

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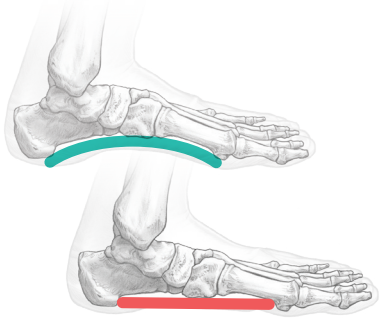
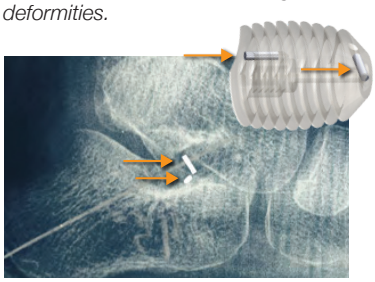
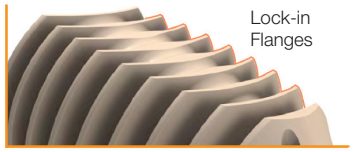
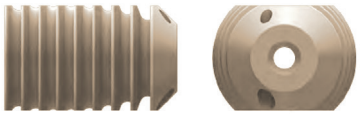
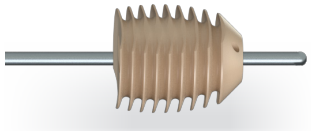


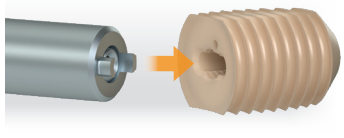
The PitStop Subtalar Implant facilitates the correction of pes plano valgus deformities.











The PitStop Implant is made of PEEK. This biocompatible and inert polymer is flexible, which allows for placement in the sinus tarsi with better load distribution on bone surfaces versus stiffer materials such as titanium and stainless steel.

X-RAY MARKERS

Two X-Ray markers made of tantalum are located at each end of the implant to help guide the positioning of the implant

LOCK-IN FLANGES

Lock-in flanges, (small blades) are designed to provide primary stability in the sinus tarsi.

ANATOMICAL SHAPE

The anatomical shape with the two symmetrical and flattened sides are designed to reduce the compressive constraints and to improve distribution of stress. This may help to decrease incidence of reactive synovitis and improve patient tolerance.

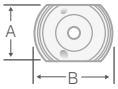
CANNULATED IMPLANT

The PitStop is cannulated to facilitate and secure accurate positioning of the implant over a guide wire.

IMPLANT-INSTRUMENT ASSEMBLY

The easy keyed insertion device allows for a tight assembly between the implant and the instrument.

ORDERING INFO/ SIZING CHART



CAT NUMBER	DESCRIPTION	IMPLANT SIZE A x B IN MM
M20 SP010	PitStop Implant	6.8 x 10
M20 SP011	PitStop Implant	7.8 x 11
M20 SP012	PitStop Implant	8.7 x 12
M20 SP013	PitStop Implant	9.9 x 13
M20 SP014	PitStop Implant	10.1 x 14
M20 SP015	PitStop Implant	11.7 x 15
M20 SP017	PitStop Implant	12.8 x 17

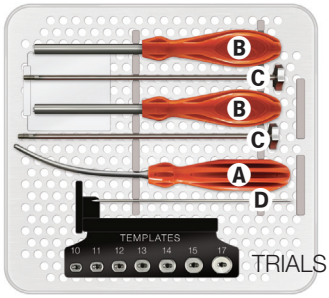
TRIAL IMPLANTS

CAT NUMBER	DESCRIPTION	TRIAL SIZE [MM]
M02 00011	PitStop Trial	6.8 x 10
M02 00021	PitStop Trial	7.8 x 11
M02 00031	PitStop Trial	8.7 x 12
M02 00041	PitStop Trial	9.9 x 13
M02 00051	PitStop Trial	10.1 x 14
M02 00061	PitStop Trial	11.7 x 15
M02 00071	PitStop Trial	12.8 x 17

INSTRUMENTS

CAT NUMBER	DESCRIPTION	
M02 00081	Viladot's lever	A
M02 00091	External holder	B
M02 00101	Internal holder	C
C01 N0015	Guide wire Diam. 1.6mm - Lg. 9in / 228mm	D

INSTRUMENT TRAY



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