

OPERATIVE TECHNIQUE

# Sole™

Medial Column Fusion Plate





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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

## GENERAL DESCRIPTION

SOLE™ Medial Column Fusion Plate (hereinafter SOLE MCF) is an internal fixation system designed to address the specific demands of stabilization, fixation and fusion of small bones and small joints within the anatomical area of the foot and ankle. The SOLE MCF Systems consist of 2 different plate designs, identified as STANDARD PLATE and WIDE PLATE, which differ in length and number of holes. Each plate has a LEFT and a RIGHT version. Plates accept 2 different bone screw sizes (4.0mm and 5.0mm) that are available in different lengths as well as locking and non-locking options. Application of SOLE MCF can be performed with Orthofix general orthopedic instrumentation.

## INDICATIONS FOR USE

The SOLE MCF is intended to provide bone fixation. The SOLE MCF is indicated for orthopedic applications within the anatomical area of the foot and ankle, including but not limited to the medial column (consisting of the first metatarsal, medial cuneiform, navicular and talus). Specific indicated procedures include:

- Arthrodesis
- Joint depression stabilization
- Fracture and/or osteotomy fixation
- Reconstruction
- Revision

to be performed for conditions such as Charcot neuroarthropathy.

## CONTRAINDICATIONS

Do not use SOLE MCF if a surgical candidate exhibits or is predisposed to any of the following contraindications:

- Active osteomyelitis or deep tissue infections at surgical site
- Infected ulcerations at the surgical site
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the device
- Inadequate coverage of the surgical site
- Suspected or documented metal allergy or intolerance
- Other medical or surgical conditions that would preclude the potential benefit for surgery
- Any mental or neuromuscular disorder that could create an unacceptable risk of fixation failure or complications in postoperative care

as it could result in a treatment failure in the intended population.

## INTENDED PATIENTS

Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations.

The SOLE MCF is intended for adult patients. The SOLE MCF is not intended for pediatric patients.

## INTENDED USERS

The product is intended for use by Healthcare Professionals (HCP) only and such HCP must have full awareness of the appropriate orthopedic fixation procedures and must be familiar with the devices, instruments and surgical procedures (including application and removal).

## FEATURES AND BENEFITS

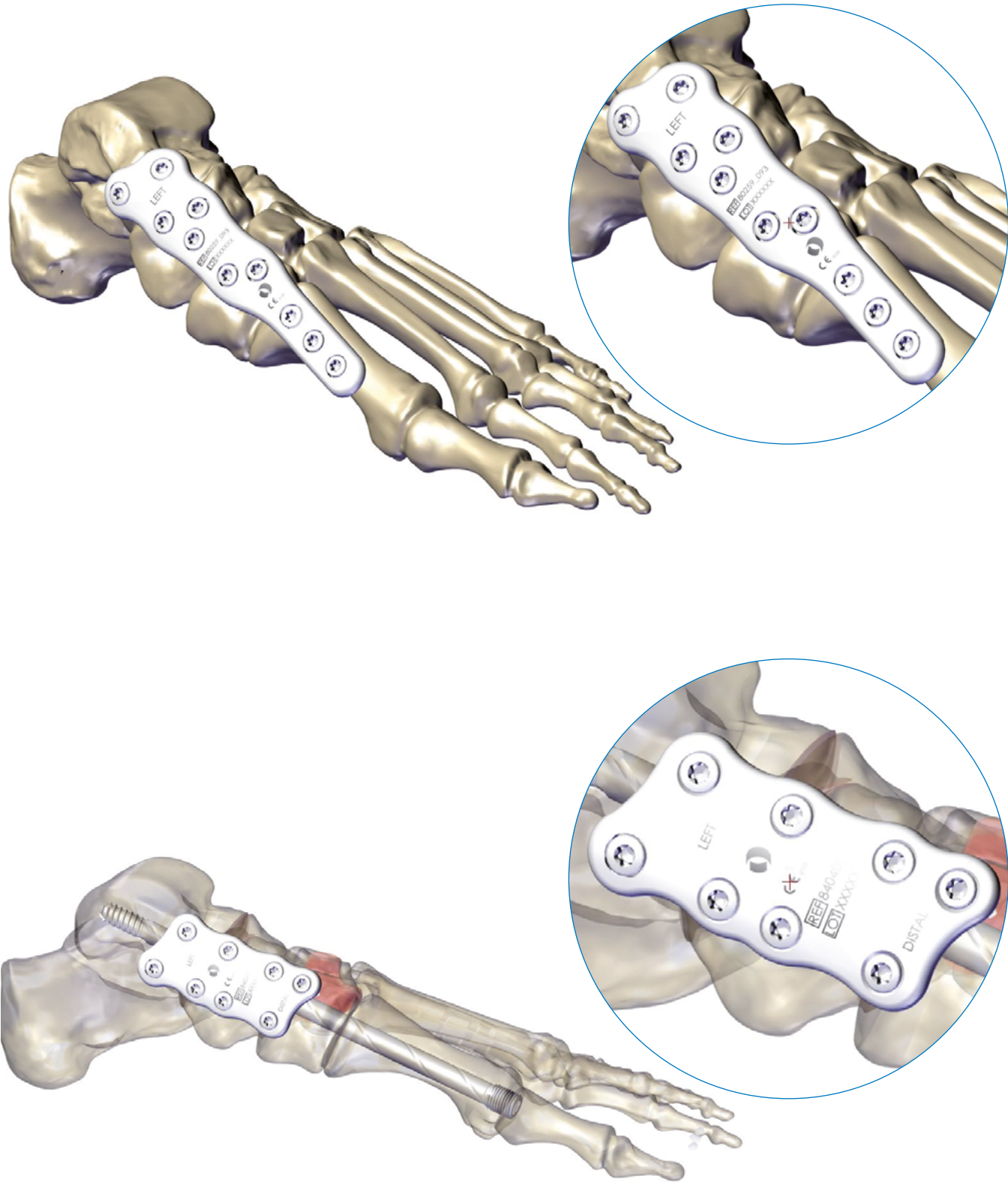
### Features

- Stainless Steel Manufacturing Material
- Variable Angle Locking for screws
- Anatomical Design
- Wide variety of screw lengths
- Dedicated Reduction Rail

### Benefits

- The manufacturing material is chosen for improved stiffness of the plate and screw constructs
- The screw locking mechanism is designed to provide flexibility in screw placement in difficult anatomical positions
- The plates are designed for left and right in standard and wide versions for optimal implant placement
- The variety of screw lengths are designed to provide optimal implant selection

EXAMPLES OF SOLE™ MEDIAL COLUMN FUSION PLATE APPLICATIONS



## SALES CONFIGURATION/KIT CONFIGURATION

### SOLE™ Medial Column Fusion Plate Implants

Part #	Description
99-84010L	SOLE MCF SS PLATE STANDARD LARGE LEFT STERILE
99-84020L	SOLE MCF SS PLATE STANDARD SMALL LEFT STERILE
99-84030L	SOLE MCF SS PLATE STANDARD EXTENDED LARGE LEFT STERILE
99-84040L	SOLE MCF SS PLATE WIDE 8-HOLES LEFT STERILE
99-84050L	SOLE MCF SS PLATE WIDE 4-HOLES LEFT STERILE

Part #	Description
99-84010R	SOLE MCF SS PLATE STANDARD LARGE RIGHT STERILE
99-84020R	SOLE MCF SS PLATE STANDARD SMALL RIGHT STERILE
99-84030R	SOLE MCF SS PLATE STANDARD EXTENDED LARGE RIGHT STERILE
99-84040R	SOLE MCF SS PLATE WIDE 8-HOLES RIGHT STERILE
99-84050R	SOLE MCF SS PLATE WIDE 4-HOLES RIGHT STERILE

### STANDARD PLATE (stainless steel)

#### SMALL (R&L)



#### LARGE (R&L)



#### LARGE WITH EXTENTION (R&L)



### WIDE PLATE (stainless steel)

#### TALUS-NAVICULAR-CUNEIFORM (R&L)



#### TALUS-NAVICULAR (R&L)





## SOLE™ Medial Column Fusion Plate Locking and Non-locking Screws

Part #	Description
99-841510	SS VA LOCKING SCREW L10MM D5MM STERILE
99-841512	SS VA LOCKING SCREW L12MM D5MM STERILE
99-841514	SS VA LOCKING SCREW L14MM D5MM STERILE
99-841516	SS VA LOCKING SCREW L16MM D5MM STERILE
99-841518	SS VA LOCKING SCREW L18MM D5MM STERILE
99-841520	SS VA LOCKING SCREW L20MM D5MM STERILE
99-841522	SS VA LOCKING SCREW L22MM D5MM STERILE
99-841524	SS VA LOCKING SCREW L24MM D5MM STERILE
99-841526	SS VA LOCKING SCREW L26MM D5MM STERILE
99-841528	SS VA LOCKING SCREW L28MM D5MM STERILE
99-841530	SS VA LOCKING SCREW L30MM D5MM STERILE
99-841534	SS VA LOCKING SCREW L34MM D5MM STERILE
99-841538	SS VA LOCKING SCREW L38MM D5MM STERILE
99-841542	SS VA LOCKING SCREW L42MM D5MM STERILE
99-841546	SS VA LOCKING SCREW L46MM D5MM STERILE
99-841550	SS VA LOCKING SCREW L50MM D5MM STERILE
99-841555	SS VA LOCKING SCREW L55MM D5MM STERILE
99-841560	SS VA LOCKING SCREW L60MM D5MM STERILE
99-841410	SS VA LOCKING SCREW L10MM D4MM STERILE
99-841412	SS VA LOCKING SCREW L12MM D4MM STERILE
99-841414	SS VA LOCKING SCREW L14MM D4MM STERILE
99-841416	SS VA LOCKING SCREW L16MM D4MM STERILE
99-841418	SS VA LOCKING SCREW L18MM D4MM STERILE
99-841420	SS VA LOCKING SCREW L20MM D4MM STERILE
99-841422	SS VA LOCKING SCREW L22MM D4MM STERILE
99-841424	SS VA LOCKING SCREW L24MM D4MM STERILE
99-841426	SS VA LOCKING SCREW L26MM D4MM STERILE
99-841428	SS VA LOCKING SCREW L28MM D4MM STERILE
99-841430	SS VA LOCKING SCREW L30MM D4MM STERILE
99-841434	SS VA LOCKING SCREW L34MM D4MM STERILE
99-841438	SS VA LOCKING SCREW L38MM D4MM STERILE
99-841442	SS VA LOCKING SCREW L42MM D4MM STERILE
99-841446	SS VA LOCKING SCREW L46MM D4MM STERILE
99-841450	SS VA LOCKING SCREW L50MM D4MM STERILE
99-841455	SS VA LOCKING SCREW L55MM D4MM STERILE
99-841460	SS VA LOCKING SCREW L60MM D4MM STERILE
99-842510	SS NON-LOCKING SCREW L10MM D5MM STERILE
99-842512	SS NON-LOCKING SCREW L12MM D5MM STERILE
99-842514	SS NON-LOCKING SCREW L14MM D5MM STERILE
99-842516	SS NON-LOCKING SCREW L16MM D5MM STERILE
99-842518	SS NON-LOCKING SCREW L18MM D5MM STERILE
99-842520	SS NON-LOCKING SCREW L20MM D5MM STERILE
99-842522	SS NON-LOCKING SCREW L22MM D5MM STERILE
99-842524	SS NON-LOCKING SCREW L24MM D5MM STERILE
99-842526	SS NON-LOCKING SCREW L26MM D5MM STERILE

### LOCKING SCREW

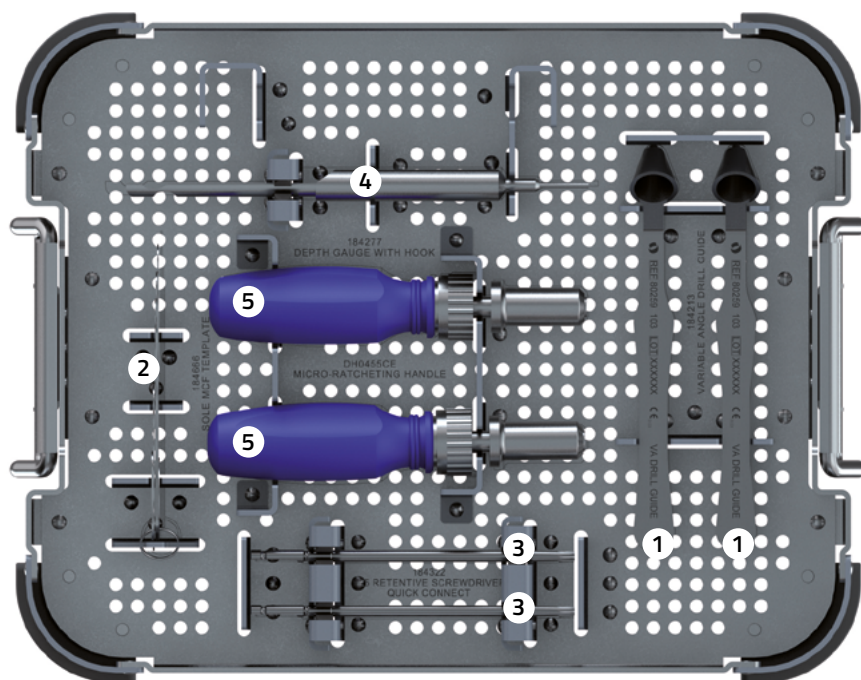


### NON-LOCKING SCREW



Part #	Description
99-842528	SS NON-LOCKING SCREW L28MM D5MM STERILE
99-842530	SS NON-LOCKING SCREW L30MM D5MM STERILE
99-842534	SS NON-LOCKING SCREW L34MM D5MM STERILE
99-842538	SS NON-LOCKING SCREW L38MM D5MM STERILE
99-842542	SS NON-LOCKING SCREW L42MM D5MM STERILE
99-842546	SS NON-LOCKING SCREW L46MM D5MM STERILE
99-842550	SS NON-LOCKING SCREW L50MM D5MM STERILE
99-842555	SS NON-LOCKING SCREW L55MM D5MM STERILE
99-842560	SS NON-LOCKING SCREW L60MM D5MM STERILE
99-842410	SS NON-LOCKING SCREW L10MM D4MM STERILE
99-842412	SS NON-LOCKING SCREW L12MM D4MM STERILE
99-842414	SS NON-LOCKING SCREW L14MM D4MM STERILE
99-842416	SS NON-LOCKING SCREW L16MM D4MM STERILE
99-842418	SS NON-LOCKING SCREW L18MM D4MM STERILE
99-842420	SS NON-LOCKING SCREW L20MM D4MM STERILE
99-842422	SS NON-LOCKING SCREW L22MM D4MM STERILE
99-842424	SS NON-LOCKING SCREW L24MM D4MM STERILE
99-842426	SS NON-LOCKING SCREW L26MM D4MM STERILE
99-842428	SS NON-LOCKING SCREW L28MM D4MM STERILE
99-842430	SS NON-LOCKING SCREW L30MM D4MM STERILE
99-842434	SS NON-LOCKING SCREW L34MM D4MM STERILE
99-842438	SS NON-LOCKING SCREW L38MM D4MM STERILE
99-842442	SS NON-LOCKING SCREW L42MM D4MM STERILE
99-842446	SS NON-LOCKING SCREW L46MM D4MM STERILE
99-842450	SS NON-LOCKING SCREW L50MM D4MM STERILE
99-842455	SS NON-LOCKING SCREW L55MM D4MM STERILE
99-842460	SS NON-LOCKING SCREW L60MM D4MM STERILE

## SOLE™ MEDIAL COLUMN FUSION PLATE INSTRUMENTATION



### SOLE™ Medial Column Fusion Plate Instrumentation






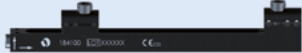
Part #	Description	Qty
184213	1 SS VARIABLE ANGLE DRILL GUIDE	2
184666	2 SOLE MCF SS TEMPLATE	1
184322	3 SS T15 RETENTIVE SCREWDRIVER QUICK CONNECT	2
184277	4 DEPTH GAUGE WITH HOOK	1
DH0455CE	5 MICRO-RATCHETING HANDLE	2
184990	SOLE MCF TRAY COMPLETE EMPTY	
184991	SOLE MCF TRAY BASE	
184992	SOLE MCF TRAY LID	

### SOLE™ MCF Sterile Instruments

Part #	Description
99-184281	SS THREADED OLIVE WIRE D2.0MM PACK OF 2 STERILE
99-184183	SS DRILL BIT D2.8MM QUICK CONNECT STERILE
99-184100	REDUCTION RAIL STERILE*
99-M311M	SELF DRILLING CORTICAL SCREW L60/20MM D3.0-2.5MM PACK OF 2 STERILE*
99-M314M	SELF DRILLING CORTICAL SCREW L70/20MM D3.0-2.5MM PACK OF 2 STERILE*

\* Optional instruments

### Instruments

	Part #	Description
	184213	SS VARIABLE ANGLE DRILL GUIDE
	184666	SOLE MCF SS TEMPLATE
	184322	SS T15 RETENTIVE SCREWDRIVER QUICK CONNECT
	184277	DEPTH GAUGE WITH HOOK
	DH0455CE	MICRO-RATCHETING HANDLE
	184100	REDUCTION RAIL*

\* Optional instruments

## MRI INFO

The Orthofix SOLE MCF has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Orthofix SOLE MCF in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## PREOPERATIVE PLANNING

The SOLE MCF is composed of a variety of plates and bone screws. Detailed preoperative planning is important for determining appropriate screw and plate size and location for the desired procedure(s) to be performed.

## SURGICAL TECHNIQUE

The operative technique listed below is designed to provide a general recommendation on the instruments and procedure required for the plating of the medial column of the foot with the SOLE MCF.

## PATIENT POSITIONING

Place the patient in the supine position. Placement of a bump under the contralateral hip facilitates visualization of the medial side. It is also helpful to place the operative leg on a stack of sheets or premade commercial positioner to raise it above the contralateral extremity. This will aid in easier lateral fluoroscopic imaging. A tourniquet is to be used at the surgeon's discretion.

## SURGICAL APPROACH

Make a medial utility incision 1 cm below the medial malleolus, from the talus down to the medial or plantar medial first metatarsal. The deep dissection can be categorized into proximal, middle, and distal segments. The proximal extent of the approach is in the interval between the tibialis anterior and tibialis posterior tendons. Once these tendons are protected, careful dissection is performed down to and through the capsules of the tibiotalar, talonavicular, and naviculocuneiform joints. In the middle extent of the dissection, the tibialis anterior crosses the wound and inserts on the plantar aspect of the first metatarsal. The surgeon must make a decision on what to do with this tendon. The options are to leave it intact and attempt to slide the plate underneath the tendon. Alternatively, the tendon can be transected if it will aid in deformity correction and hardware placement. In this scenario, it is helpful to leave a stump of the tendon at its insertion or to make a "Z" lengthening cut in the tendon. Both of these techniques allow for repair of the tendon at the end of the case. Continue the deep dissection through the first tarsometatarsal joint. Distally, the abductor tendon should be reflected off of the first metatarsal from dorsal to plantar. If performing a midfoot osteotomy, continue the deep dissection along the dorsal and plantar foot, raising full thickness flaps directly off of the bone.

## JOINT PREPARATION AND DEFORMITY CORRECTION

Perform a midfoot osteotomy, if needed. Carefully protect the soft-tissues. Next, prepare the surfaces of the joints to be fused. Remove joint cartilage and any fibrous tissue from the joints down to the level of bleeding subchondral bone. Next perform deformity correction aligning the first medial column in both the anteroposterior and lateral fluoroscopic images. Biologic adjuvants are used at the surgeon's discretion. In cases of lack of bony opposition, bone graft should be used.



## JOINT COMPRESSION

Perform joint compression.

### ADDITIONAL COMPRESSION

(optional step)

Part #	Description
99-184100	REDUCTION RAIL STERILE
DH0455CE	MICRO-RATCHETING HANDLE
184100	REDUCTION RAIL (optional)
184322	SS T15 RETENTIVE SCREWDRIVER QUICK CONNECT (optional)
99-M311M	SELF DRILLING CORTICAL SCREW L60/20MM D3.0-2.5MM PACK OF 2 STERILE (optional)
99-M314M	SELF DRILLING CORTICAL SCREW L70/20MM D3.0-2.5MM PACK OF 2 STERILE (optional)

If additional compression is desired and the user is familiar with the device, the reduction rail (available on demand) can be used. Insert a self-drilling cortical screw 3.0-2.5mm thread diameter/shaft diameter 3.0mm into the talus.

**(Fig. 1a)**

The screws should be inserted in a dorsomedial to plantar lateral direction in a location that will not interfere with plate placement. During insertion of the screws avoid tibialis anterior and extensor hallucis longus. Slide the proximal clamp of the reduction rail over the inserted self-drilling screw and secure it by tightening the screw of the clamp with the screwdriver.

Using the distal clamp of the reduction rail as template, insert a second self-drilling cortical screw in the metatarsal. **(Fig. 1b)** Close the distal clamp as previously described.

Attach the screwdriver to the ratcheting handle and provide the desired compression by tightening the compression/distraction screw. **(Fig. 1c)**



**PRECAUTION:** Monitor the compression. Over compressing could dorsally displace the distal bones and create a rocker bottom deformity.



**PRECAUTION:** Use the image intensifier to verify correct placement of the screws.

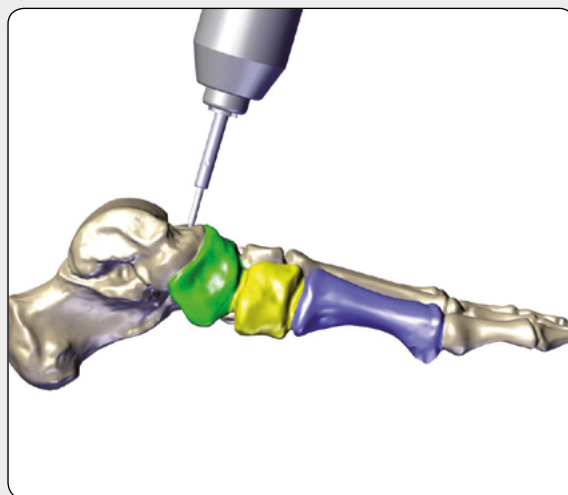


Fig. 1a

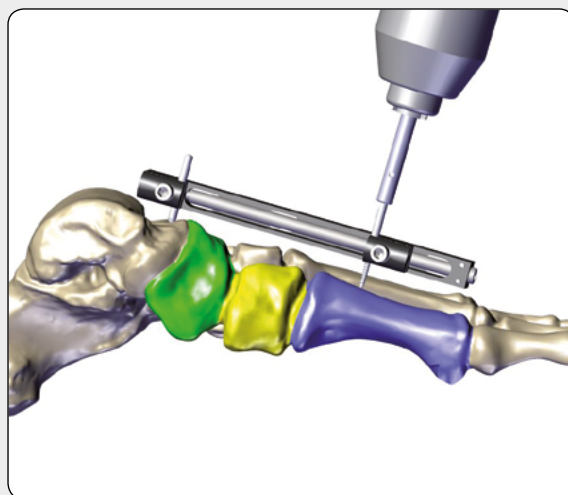


Fig. 1b

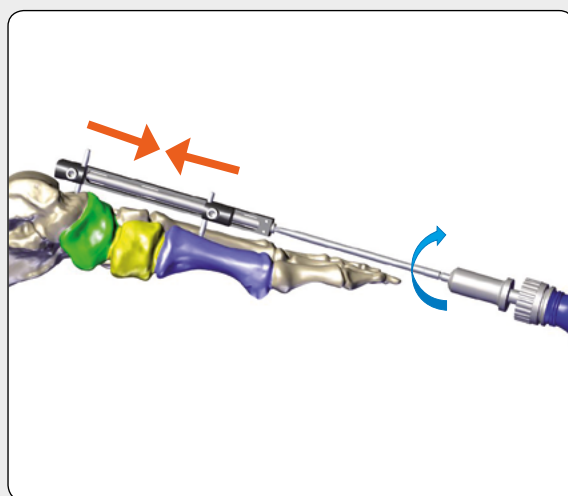


Fig. 1c

## PLATE SELECTION

Part #	Description
184666	SOLE MCF SS TEMPLATE

Use the templates found in the SOLE MCF instrumentation to evaluate the appropriate plate size to fit individual patient anatomy. Once the best plate fit has been identified, open the corresponding sterile packed plate.

## PLATE POSITIONING

Part #	Description
99-184281	SS THREADED OLIVE WIRE D2.0MM PACK OF 2 STERILE

Provisionally fix the plate to the bone by inserting the threaded olive wires in the screw holes. Confirm proper plate positioning prior to screw insertion with biplanar fluoroscopy.



**PRECAUTION:** Use the image intensifier to verify correct placement of the wires.

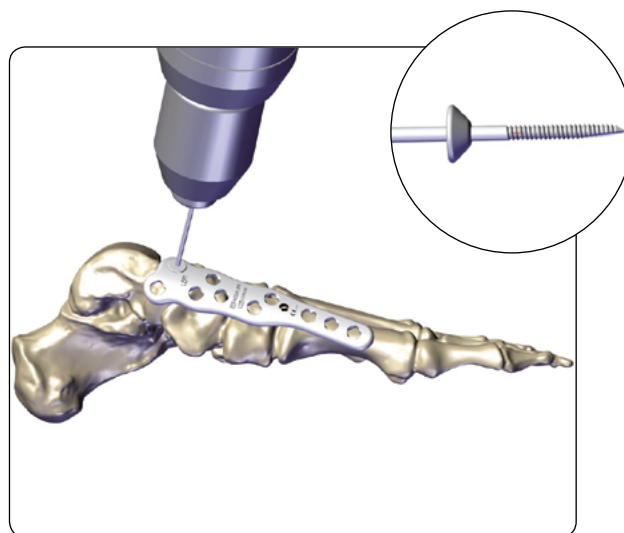


Fig. 2a

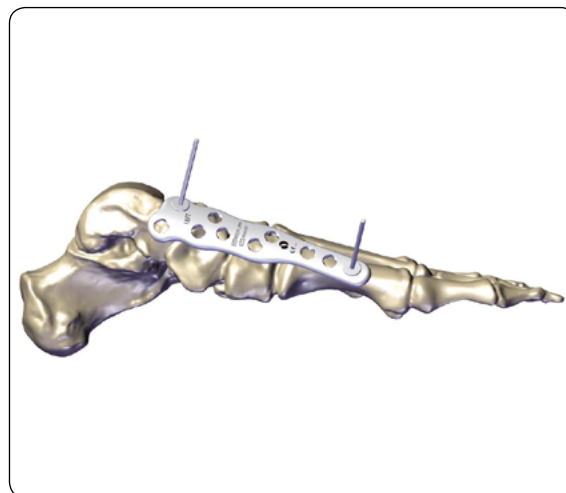


Fig. 2b



Fig. 2c

## PRE-DRILLING AND SCREW LENGTH DETERMINATION

Part #	Description
184213	SS VARIABLE ANGLE DRILL GUIDE
99-184183	SS DRILL BIT D2.8MM QUICK CONNECT STERILE
184277	DEPTH GAUGE WITH HOOK

Use the sterile packed drill bit with the variable angle drill guide to prepare screw holes. The funnel of the variable angle drill guide allows a drilling angle within a 30° cone. Insert the variable angle drill guide completely in the plate hole. (Fig. 3a)

When drilling needs to be performed not axial to the plate hole, the variable angle drill guide should remain in place and the drill bit should be angled to the desired direction within the cone (Fig. 3b). Drill to the desired depth. Bicortical fixation is desired when possible. Use the depth gauge with hook to determine the correct screw length (Fig. 4). Use the image intensifier to visualize the depth gauge and confirm correct screw position.



**PRECAUTION:** Use the image intensifier to ensure correct pre-drilling of the desired depth and to avoid interference with the reduction rail screws.

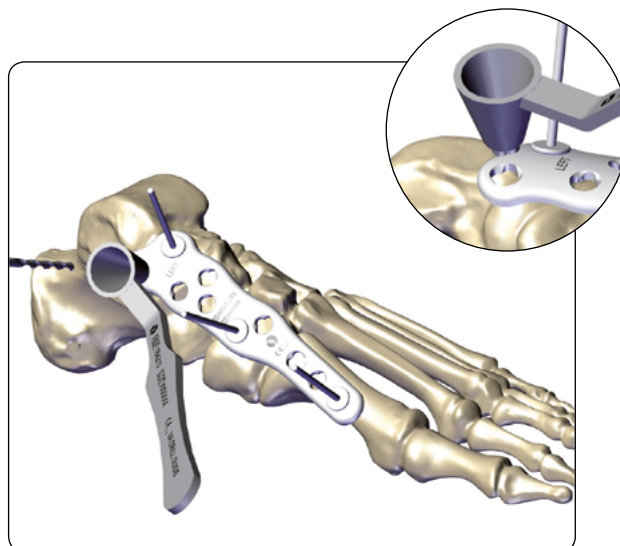


Fig. 3a

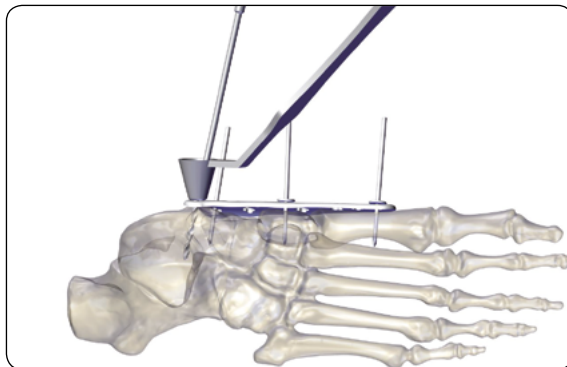
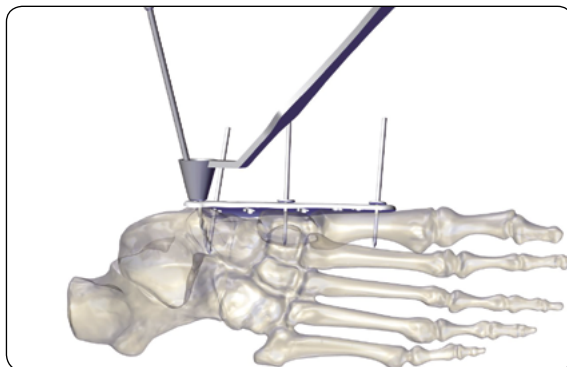
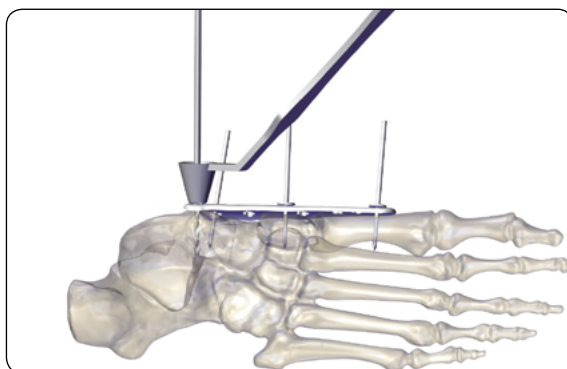


Fig. 3b

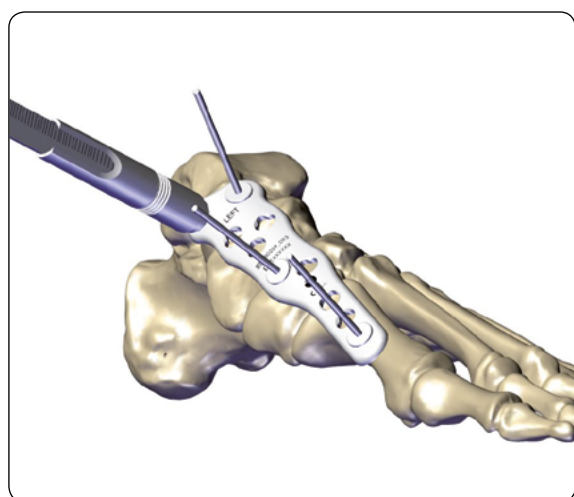


Fig. 4



## SCREW INSERTION

Part #	Description
184322	SS T15 RETENTIVE SCREWDRIVER QUICK CONNECT
DH0455CE	MICRO-RATCHETING HANDLE

Once the appropriate screw length is determined, open the corresponding sterile packed screw.

### Option 1: Manual insertion

Attach the screwdriver to the ratcheting handle to manually advance the screw into place.

### Option 2: Insertion under power

Insert the screw partially under power, then complete insertion by hand.



**WARNING:** Screws must not be over-tightened during insertion. Over-tightening may cause damage to the implant or bone stripping.



**WARNING:** In the event that locking screw head threads strip out, replace the locking screw with a non-locking screw.



**PRECAUTION:** Use the image intensifier to verify correct placement of the screws.



**PRECAUTION:** Complete each locking screw insertion entirely before inserting the next screw to avoid a possible incorrect engagement of the screw to the plate.

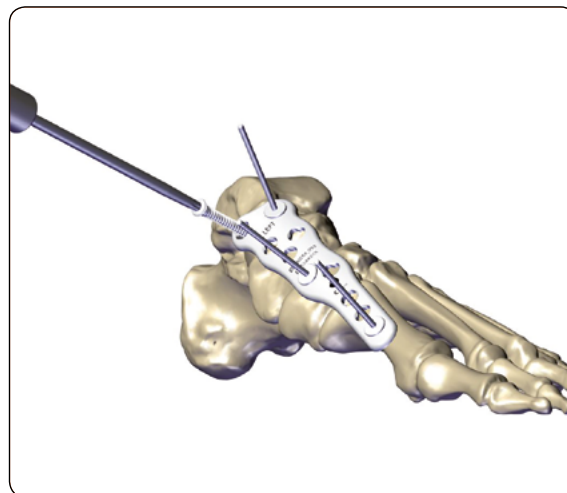


Fig. 5

## COMPLETION OF SCREW INSERTION

Part #	Description
184213	SS VARIABLE ANGLE DRILL GUIDE
99-184183	SS DRILL BIT D2.8MM QUICK CONNECT STERILE
184277	DEPTH GAUGE WITH HOOK
DH0455CE	MICRO-RATCHETING HANDLE

Repeat pre-drilling, measuring and placement of the screws in the remaining holes as required to complete plate fixation (**Fig. 6-7**) and if previously used, remove the reduction rail. To remove the reduction rail screws, put the drill in reverse to avoid inserting them further into the bone.

Interference with converging screws and with the reduction rail screws should be avoided.



**PRECAUTION:** In the event that the reduction rail interferes with screw insertion and needs to be removed before implantation of all the screws, ensure that compression is maintained.



**PRECAUTION:** Use the image intensifier to ensure pre-drilling of the desired depth, to avoid interference with converging screws, to avoid interference with reduction rail screws, and to verify correct screw placement.



**PRECAUTION:** Use the image intensifier to verify correct placement of the screws.

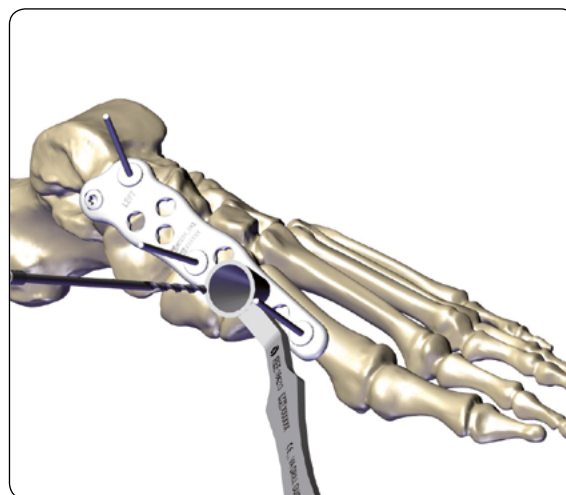


Fig. 6a

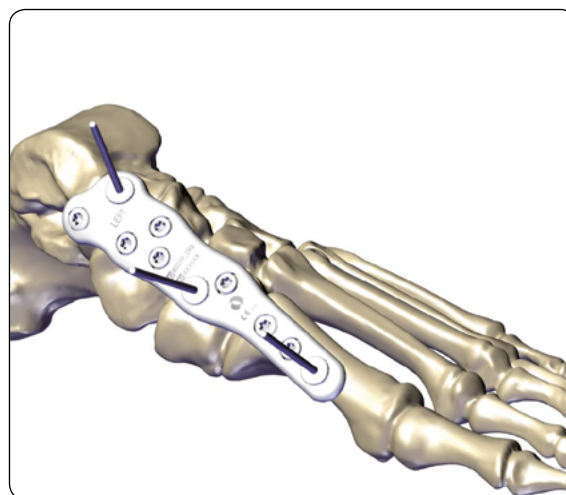


Fig. 6b

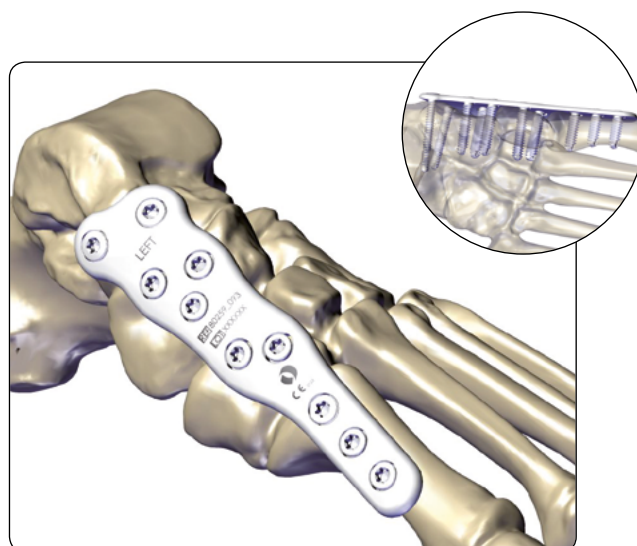


Fig. 7

## FINAL FLUOROSCOPIC CONTROL

Use fluoroscopy to ensure the correct implant positioning.

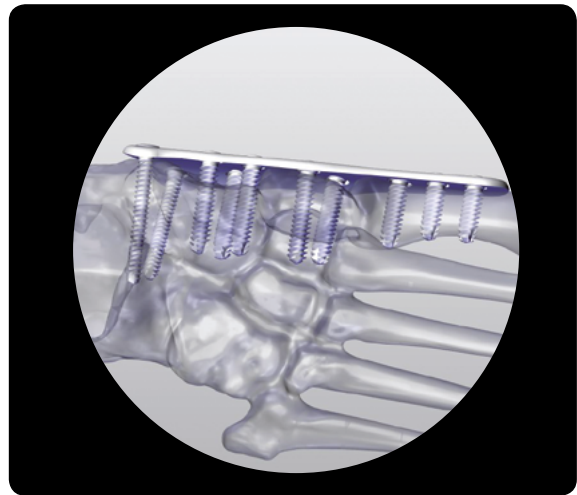


Fig. 8 representation of a possible screw placement.

## PLATE AND SCREW REMOVAL

Part #	Description
184322	SS T15 RETENTIVE SCREWDRIVER QUICK CONNECT
DH0455CE	MICRO-RATCHETING HANDLE

Perform appropriate surgical incisions to adequately expose the implantation site.

If necessary, remove overgrown bone to expose entire screw heads. Use the screwdriver to remove each screw from the plate. **(Fig. 9)**

Use a general surgical grasping instrument to lift off the plate from the bone.

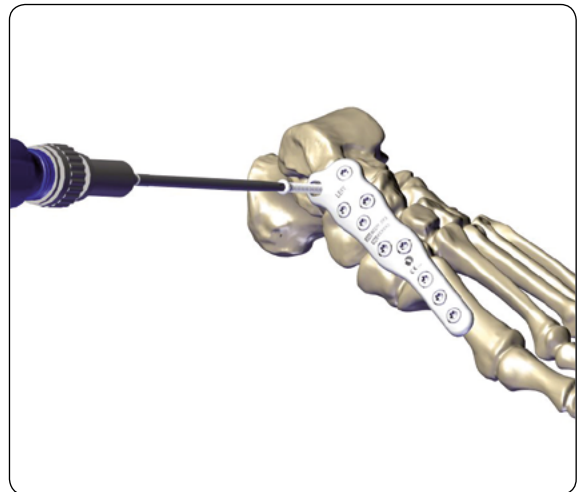


Fig. 9



## USE OF THE SOLE MCF PLATE IN COMBINATION WITH G-BEAM FUSION BEAMING SYSTEM™

The Wide Plate of the SOLE MCF Plating System may be used with G-Beam when necessary to provide additional fixation. In these cases, insert the G-Beam first and then apply the SOLE MCF. In this order, longitudinal compression can be achieved with the G-Beam prior to applying the SOLE MCF. Next, apply the SOLE Plate and use the variable angle drill guide to aim the screws around the G-Beam.



**PRECAUTION:** Use the image intensifier to ensure predrilling of the desired depth, to avoid interference with converging screws, to avoid interference with the reduction rail screws and/or additional fixation elements present at surgical site.

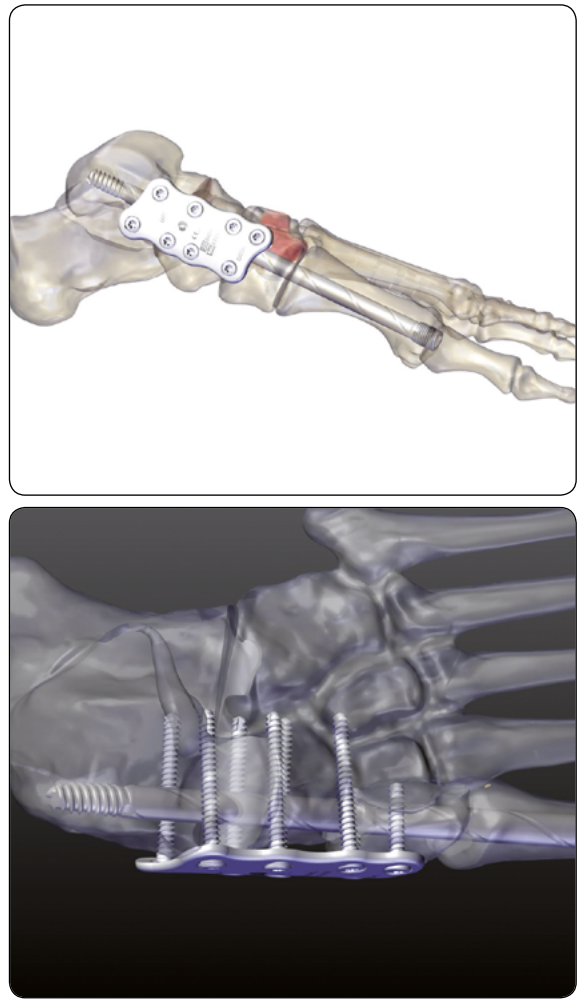


Fig. 10

Please refer to the “Instructions for Use” supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):

tel +39 045 6719301, fax +39 045 6719370,

e-mail: [customerservice@orthofix.it](mailto:customerservice@orthofix.it)

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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