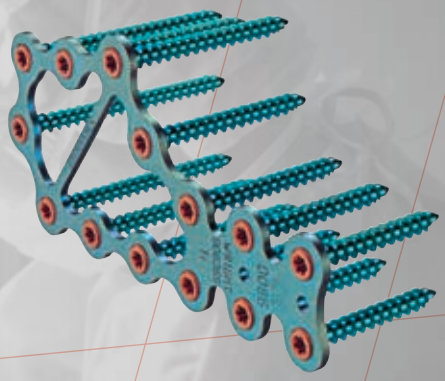
ORTHOLOC®

Calcaneal Fracture System

SURGICAL TECHNIQUE



WRIGHT™

FOCUSED EXCELLENCE

ORTHOLOC®

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SURGICAL TECHNIQUE

Contents

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical.

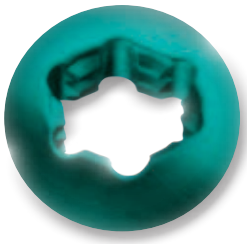
Introduction

chapter 1

The ORTHOLOC® Calcaneal Fracture System marks a new level of surgical flexibility and performance for the complex indication of calcaneal fractures. Featuring the innovative ORTHOLOC® polyaxial locked plate technology; this system gives the surgeon the options of a traditional non-locking plate with the stability of a locking screw/plate construct.

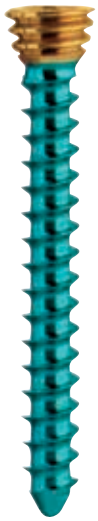
» **Comprehensive Solution:** Perimeter and tab style plates combined with 3.5 and 6.5 headed compression screws provide a complete implant solution in one tray.

» **Strength Without Sacrifice:** ORTHOLOC® polyaxial locking technology allows the surgical flexibility of a non-locking plate while maintaining the strength of a locking construct.



ORTHOLOC® Thread Design

The innovative ORTHOLOC® plate thread creates multiple points of engagement for maximum holding power and stiffness. This feature is key in creating a construct that maintains strength whether engaged on axis or up to 15 degrees off axis.



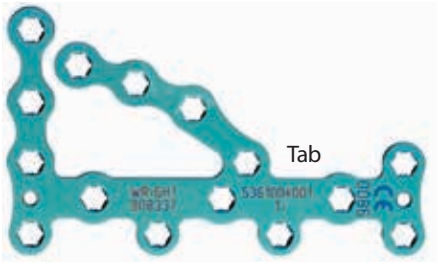
ORTHOLOC® Screw Design

The ORTHOLOC® locking screw is specifically designed for optimum engagement into the ORTHOLOC® Thread. Each locking screw head is covered with titanium nitride coating to create a hardness differential between the plate thread and the screw head. When fully locked into the plate, the harder head re-forms the internal plate threads, creating a secure fit between the plate and the screw.

When used together, these two design features create a construct that maximizes surgical flexibility without sacrificing stability. Coupled with multiple plating and screw styles, the ORTHOLOC® Calcaneal Fracture System offers a comprehensive and innovative approach to calcaneal fractures.

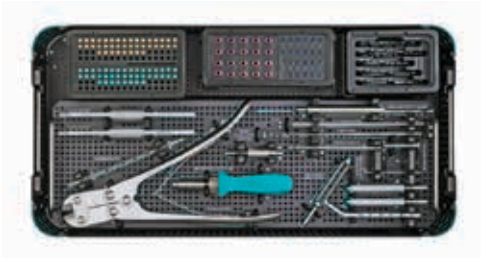
Preoperative Planning

chapter 2



Perimeter

Plate Options



Prior to surgical intervention, thorough evaluation using radiograph and CT imaging of the fracture pattern is needed to accurately plan the complex reduction. A healthy respect for the integrity and condition of the soft tissues is also needed and typically will delay surgery for 10 to 14 days or more after the initial injury.

The ORTHOLOC® Calcaneal Fracture System has been designed to incorporate the instruments and implants needed for the treatment of most calcaneal fractures.

The following instruments and implants are provided:

- Perimeter and Tab Style Plates
- 3.5mm Locking Plate Screws (20-50mm long)
- 3.5mm Non-Locking Plate Screws (20-50mm long)
- 3.5mm Cannulated Compression Screws (30-50mm long)
- 6.5mm Cannulated Compression Screws (40-85mm long)
- Temporary Fixation Pins (for plate)
- 1.2, 1.6, 2.0, 2.5mm K-wires/Steinman Pins
- Straight and Curved Elevators
- Bone Tamp
- Plate Cutters
- Bone Fragment Pick
- Large Tenaculum

In addition to the ORTHOLOC® Calcaneal Fracture System, the following items should be planned for in the OR:

- PRO-DENSE® Injectable Regenerative Graft
- Powered Handpiece with Small and Large-diameter Wire Driver, and Jacobs Chuck
- Intraoperative Flouroscopy
- Lamina Spreader and/or Wire-based Distractor

Patient Positioning

Position the patient in a lateral decubitus position with padding of the appropriate bony prominences. It is recommended that the non-operative foot be scissored forward, and the operative foot positioned behind it and on top of several bulky blankets or sheets. This will allow better visualization with intra-operative C-arm without overlap from the other foot. Hemostasis may be accomplished with a thigh tourniquet.

ORTHOLOC®
Calcaneal Fracture System
Surgical Technique

chapter 3

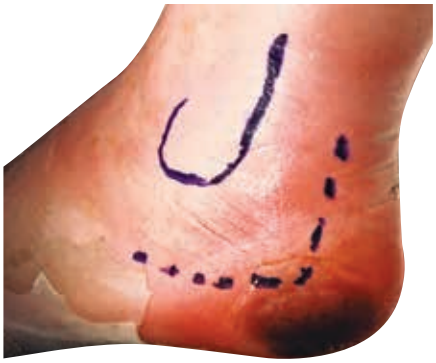


FIGURE 1
Anatomical landmarks and incision markings.

Surgical Approach and Retraction

With a marking pen draw an extensile lateral incision, marking local landmarks and the course of the sural nerve on the skin. | **FIGURE 1** Create a curved skin incision with the vertical limb halfway between the peroneal tendons and Achilles, and the horizontal limb parallel to the plantar surface of the foot.

The sural nerve is protected in both the proximal and distal aspect of the incision.

Bring the incision sharply to bone after identification of the sural nerve. Raise the skin as a full-thickness flap in a subperiosteal plane; take care to protect and elevate the peroneal tendons within the flap.

Direct visualization of the subtalar joint and the calcaneal-cuboid (CC) joint should now be possible. Care should be taken to delicately handle the flap with a "no touch" technique.

1.6mm K-wires may be placed to maintain retraction of the flap while avoiding excessive tension.

Reduction of the Subtalar Joint

Any synovitis or hematoma is carefully removed from within the subtalar joint; this will allow visualization of the intra-articular fractures of the posterior facet.

Often, there is a "blow-out" type fracture of the lateral wall of the calcaneus. This portion of the lateral wall may be carefully removed and held on the back table for later re-implantation.

Decompress the depressed joint fragments to allow reduction of the posterior facet of the subtalar joint. Often the large elevator is used to elevate these fragments to match the opposing talar surface.

Once the posterior facet is reduced, use the 1.6mm K-wires to provisionally fix the joint surface. Realignment of the joint is confirmed with both lateral and calcaneal axial flouroscopic views.

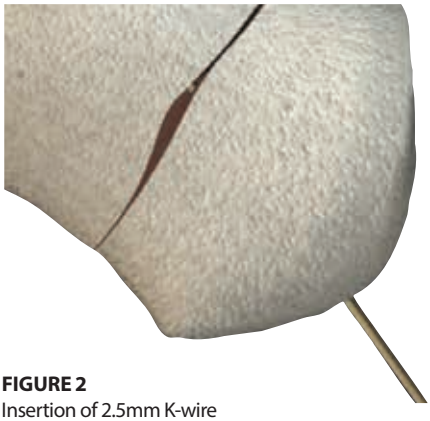


FIGURE 2
Insertion of 2.5mm K-wire into the calcaneus.

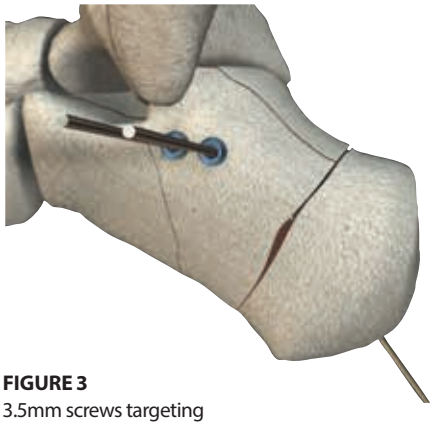


FIGURE 3
3.5mm screws targeting sustentaculum.

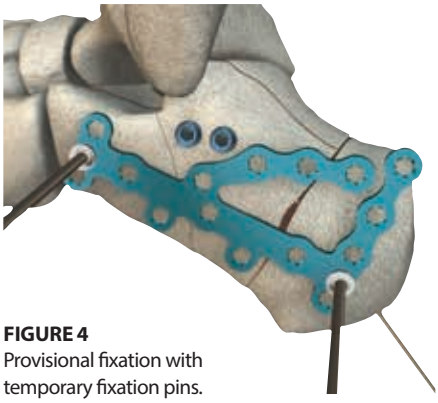


FIGURE 4
Provisional fixation with temporary fixation pins.

Tuberosity Decompression and Realignment

Drive the 2.5mm K-wire axially from the posterior calcaneal tuberosity. This wire may be used as a joystick to aid in decompression and manipulation of the tuberosity. **| FIGURE 2**

Attention is now directed to the position of the posterior tuberosity. Typically this has been displaced superiorly, shortened, and/or rotated into varus. Lever the 2.5mm K-wire to manipulate the tuberosity back down and out of varus, then advance the pin to provide temporary stabilization.

Once the fragments have been stabilized, the 6.5mm cannulated compression screw may be used over the 2.5mm K-wire to fixate and fuse the subtalar joint.

Lateral and calcaneal axial views are used to confirm that the plantar calcaneal cortex is realigned, and the heel is in a neutral position.

If pre-operative CT scan indicated fracture extension into the anterior calcaneal body and/or calcaneal-cuboid (CC) joint, this is now addressed. Inspect the CC joint, reduce as necessary, and provisionally fix with the 1.6mm K-wires. It is important to ensure that the anterior body is reduced and not translated superiorly.

Lateral Wall and Posterior Facet Stabilization

Upon confirmation of posterior facet realignment, drive two 1.2mm guidewires for the 3.5mm cannulated compression screws from posterior lateral to anterior medial in a parallel fashion, just within the dense subchondral bone beneath the posterior facet. These wires target the stable sustentaculum fragment medially. Confirm correct length and placement of these wires with lateral and calcaneal axial views.

Measure the screw length using the cannulated depth gauge, drill with the 2.7mm Cannulated Pilot Drill, and insert the appropriate length screws.

The screws should be advanced in an alternating fashion, and care taken to prevent toggling of the articular fragments. **| FIGURE 3**

Flouroscopy is again performed to confirm correct screw placement within the sustentaculum and reduction of the subtalar joint.

Plate Selection and Temporary Fixation

Replace the lateral wall fragment. Select the appropriate size and style ORTHOLOC® Calcaneal Fracture plate depending on patient anatomy and surgeon preference, using flouroscopy as a reference. The plate may be temporarily held in place with the temporary fixation pins.

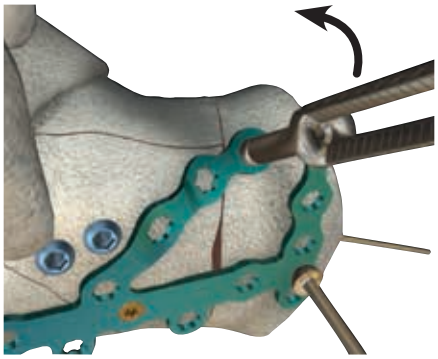


FIGURE 5
Usage of the Fixed Angle Drill Guide.

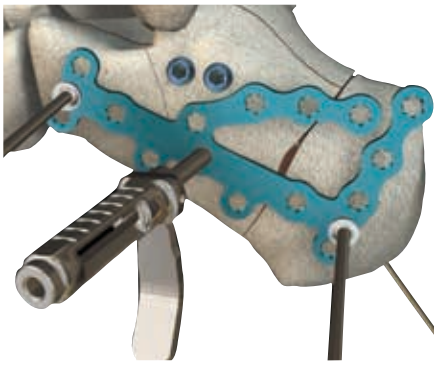


FIGURE 6
Usage of the polyaxial Drill Guide.

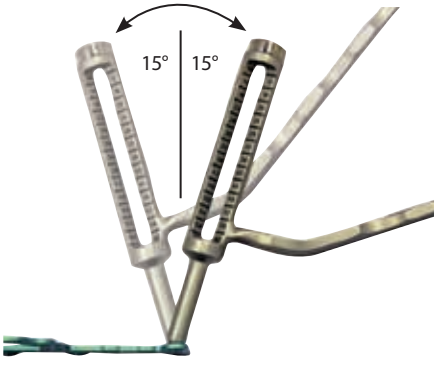


FIGURE 7
30-degree cone of angularity.

Plate Contouring

In-situ contouring of the plate is easily accomplished by threading the Locking Drill Guide into a screw hole and using it as a bender. In this manner, the plate may be anatomically contoured while protecting the locking threads in the plate. | **FIGURE 5**

Locking/Non-Locking Plate Screw Application

The ORTHOLOC® Calcaneal Fracture System permits the usage of either fixed-angle, polyaxial locking or non-locking screws in all screw holes. All polyaxial locking screws can be used up to 15 degrees off axis to the plate threads.

Bicortical fixation is generally not required with locking screws; however, it should always be used with non-locking screws. Non-locking screws may also be used to lag the plate closer to the underlying bone.

When inserting locking screws off axis, determine the appropriate screw angle and place the polyaxial drill guide into the desired screw plate hole. | **FIGURE 6** Take care to keep the locking screws within a 30 degree cone of angularity with respect to the plate threads. | **FIGURE 7** When using the ORTHOLOC® screws at a fixed angle (perpendicular to the plate), thread the locking drill guide into the desired screw hole.

Screw length is determined with the drill and drill guides. Use the appropriate drill to penetrate through the near cortex and continue until the far cortex is reached. Stop drilling just as the far cortex of the bone is penetrated and note where the step in the drill meets the screw gauge on the guide. | **FIGURE 8**

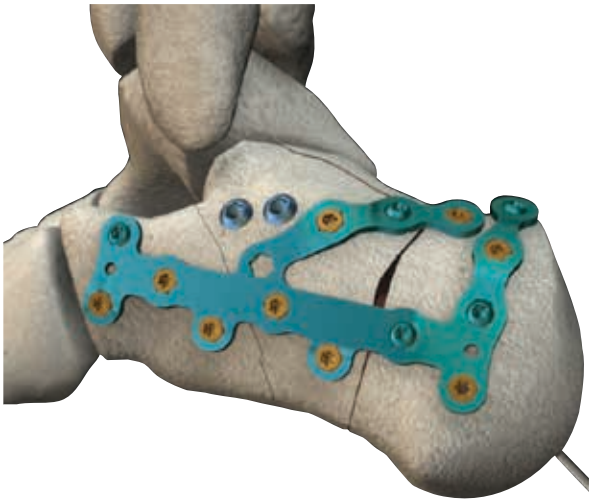
FIGURE 8
Screw length measurement on Drill Guide.

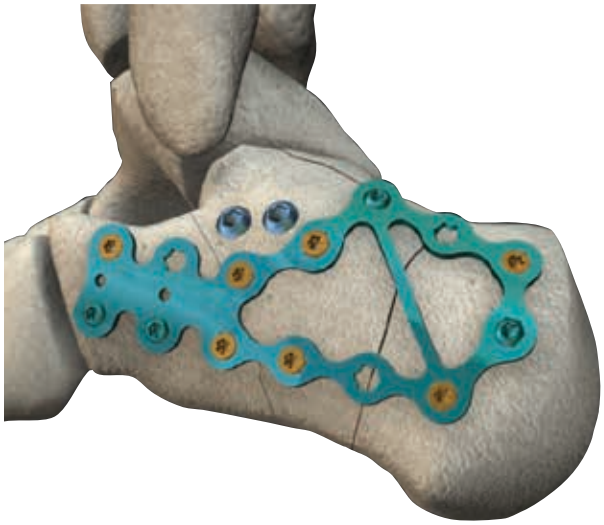
Insert the appropriate screw into the pre-drilled hole and drive until flush with the plate. Repeat the steps described above to prepare more screw locations. As you secure the plate centrally and move distal toward the CC joint, use the bone fragment pick while anchoring the plate to prevent superior displacement of the anterior calcaneal body.

Wound Closure

Final radiographic confirmation of anatomic alignment and hardware position position should be done before closure. Remove the provisional K-wires after final fixation of the fracture.

Deep periosteal tissue may be closed with 0 absorbable suture. The subcutaneous tissue is closed with 2-0 absorbable sutures again using a "no-touch" technique. Sutures are initially placed at the periphery and gradually worked towards the apex of the flap. Skin is closed in an everted fashion.





Explant Information

Removal of the ORTHOLOC® Calcaneal Fracture Plates may be performed by first extracting the plate screws using the STAR 10 Driver (5362000110) and then removing the plate from the bone.

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative Management

Postoperative care is the responsibility of the medical professional.

Ordering Information

ORTHOLOC®
Calcaneal Fracture Plating System

INSTRUMENT KIT: 5361KIT1
IMPLANT KIT: 5361KITA

PLATE OPTIONS

PART NO.	DESCRIPTION	QTY
5361002000	CLC FRAC PLATE, STND, X-SM/SM	1
5361004001	CLC FRAC PLATE, TAB, MED	1
5361004002	CLC FRAC PLATE, TAB, LG	1
5361006001	CLC FRAC PLATE, PERIMETER SM	1
5361006002	CLC FRAC PLATE, PERIMETER LG	1

3.5MM LOCKING PLATE SCREWS

PART NO.	DESCRIPTION	QTY
5351035020	20MM	2
5351035022	22MM	2
5351035024	24MM	2
5351035026	26MM	2
5351035028	28MM	2
5351035030	30MM	3
5351035032	32MM	3
5351035034	34MM	3
5351035036	36MM	3
5351035038	38MM	3
5351035040	40MM	3
5351035042	42MM	3
5351035044	44MM	3
5351035046	46MM	2
5351035048	48MM	2
5351035050	50MM	2

3.5MM NON-LOCKING PLATE SCREWS

PART NO.	DESCRIPTION	QTY
5351135020	20MM	2
5351135022	22MM	2
5351135024	24MM	2
5351135026	26MM	2
5351135028	28MM	2
5351135030	30MM	3
5351135032	32MM	3
5351135034	34MM	3
5351135036	36MM	3
5351135038	38MM	3
5351135040	40MM	3
5351135042	42MM	3
5351135044	44MM	3
5351135046	46MM	2
5351135048	48MM	2
5351135050	50MM	2

INSTRUMENTS

PART NO.	DESCRIPTION	QTY
5362000002	STRAIGHT ELEVATOR	1
5362000004	CURVED ELEVATOR	1
5362000006	BONE TAMP, 10MM	1
5362000012	LOCKING 2.5MM DRILL GUIDE	2
5362000014	POLYAXIAL 2.5MM DRILL GUIDE	1
5362000160	60MM MAX DEPTH GAUGE	1
5272000002	PLATE BENDER	2
40120028	RATCHETING HANDLE	1
41112017	AO/QC ADAPTER, CANNULATED	1
40140015	SCREW GRIPPER	1
49510005	PLATE CUTTER	1
5202000008	BONE FRAGMENT PICK	1
49510010	TENACULUM	1
DC4197	SCREW PICKUP	1

DISPOSABLES

PART NO.	DESCRIPTION	QTY
5362000016	2.5MM DRILL	2
5362000110	DRIVER, STAR 10	2
DC4212	OLIVE WIRE	2
44112008	1.6MM X 150MM K-WIRE	6
56010228	2.0 X 228MM K-WIRE, SMOOTH TIP	4

Ordering Information

Calcaneal Compression Screw System
3.5mm and 6.5mm* DARCO® Headed Screws

3.5MM CANNULATED COMPRESSION SCREWS*

PART NO.	DESCRIPTION	QTY
SCN353032	30MM SHORT	2
SCN353232	32MM SHORT	2
SCN353432	34MM SHORT	2
SCN353632	36MM SHORT	2
SCN353832	38MM SHORT	2
SCN354032	40MM SHORT	2
SCN354232	42MM SHORT	2
SCN354432	44MM SHORT	2
SCN354632	46MM SHORT	2
SCN354832	48MM SHORT	2
SCN355032	50MM SHORT	2

6.5MM CANNULATED COMPRESSION SCREWS*

PART NO.	DESCRIPTION	QTY
SCN654062	40MM	2
SCN654562	45MM	2
SCN655062	50MM	2
SCN655562	55MM	2
SCN656062	60MM	2
SCN656562	65MM	2
SCN657062	70MM	2
SCN657562	75MM	2
SCN658062	80MM	2
SCN658562	85MM	2

INSTRUMENTS*

PART NO.	DESCRIPTION	QTY
IW100627	DRILL SLEEVE 2.7MM DRILL	1
IW120516	2.5MM HEX DRIVER FOR 3.5MM SCREWS	1
IW791503	DEPTH GAUGE FOR 150MM K-WIRE	1
IW200001	TISSUE SLEEVE 6.5MM SCREWS	1
IW101027	DRILL SLEEVE FOR 6.5MM SCREWS	1
IW230532	LARGE COUNTERSINK 6.5MM SCREWS	1
IW240532	5MM HEX DRIVER FOR 6.5MM SCREWS	1
44180025	RATCHETING HANDLE, HUDSON	1
IW792701	DEPTH GAUGE FOR 270MM K-WIRE	1
5362000170	TRAY	1
IW130516	COUNTERSINK	1

DISPOSABLES*

PART NO.	DESCRIPTION	QTY
IW702713	2.7MM DRILL	1
NK011215	1.2MM THREADED TIP K-WIRE 150MM	2
IW706522	4.4MM DRILL BIT FOR 6.5MM SCREWS	1
NK112527	2.5MM K-WIRE	2

**Manufactured by AAP Implantate AG.*

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