

CLAW[®] II

Polyaxial Compression Plating System

SURGICAL TECHNIQUE



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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 events. Package inserts are also available by contacting Wright Medical Technology, Inc.

Introduction



The CLAW® II Polyaxial Compression Plating System represents the next evolution of Wright's proprietary CLAW® technology for osteotomies and arthrodeses of the foot. The system incorporates ORTHOLOC® 3DSi Polyaxial Locking Screw Technology into a variety of anatomic-specific stainless steel compression plates, allowing versatile implant solutions for both simple and complex indications of the foot.

This new system now provides the foot and ankle surgeon:

- » Expanded Offering of 5 Plate Styles, Including the Indication Specific U-Plates Designed for 1st & 2nd TMT Fusions
- » Plate Holes Accept Both 2.7mm and 3.5mm ORTHOLOC® 3DSi Locking Screws
- » 3.5mm Screws Available in Cortical and Cancellous Designs
- » Polyaxial Locking Engagement with up to 15-degrees Off-Axis
- » Surgeon-Controlled Compression of the Joint using Redesigned Spreader

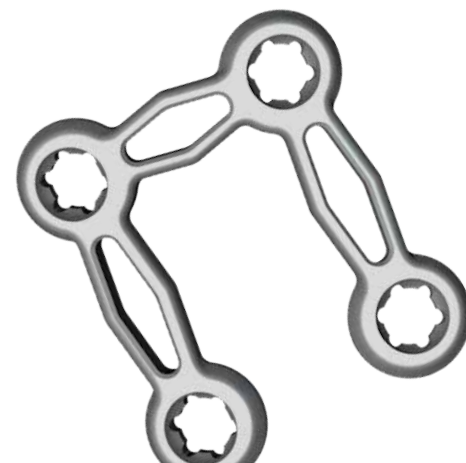
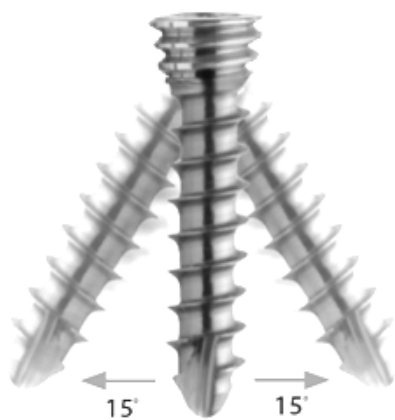
ORTHOLOC® 3DSi Polyaxial Locking Screw Technology

ORTHOLOC® 3DSi polyaxial locking screw technology is the combination of two advanced designs: a plate thread designed to maximize polyaxial screw engagement, and a stainless-steel locking screw manufactured with a hardened metal to re-form the internal plate threads to the angle of the locking screw. The result is ORTHOLOC® 3DSi – an advanced polyaxial screw technology providing versatility without sacrificing the advantages of a locked plate construct.

The ORTHOLOC® 3DSi plate thread design features a locking thread that has been segmented into multiple engagement levels. When used on axis, this design performs as a traditional locking mechanism, providing a reliable construct interface frequently required for a compression plate. Additionally, when placed up to 15-degrees off-axis, the ORTHOLOC® 3DSi design allows a secure polyaxial engagement between the screw and plate interface, which provides versatility in screw placement and orientation.

- » 30° conical polyaxial locking capability
- » Multi-point screw/plate engagement
- » Versatility in screw placement, orientation and selection

3DSi



Intended Use

Indications

Wright's CLAW® II Polyaxial Compression Plating System is intended to be used for fixation including:

- » Midfoot and hindfoot arthrodeses or osteotomies
- » Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, Lapidus)
- » Intercuneiform arthrodeses
- » Naviculocuneiform arthrodeses
- » Talonavicular arthrodeses
- » Calcaneocuboid arthrodeses
- » Lisfranc arthrodeses
- » Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- » Fixation of osteotomies for hallux valgus treatment (e.g., Scarf and Chevron)
- » Akin osteotomies
- » First metatarsophalangeal arthrodeses

Contraindications

While the CLAW® II Polyaxial Compression Plating System can be used in multiple indications as described above, it is contraindicated for several general surgical circumstances:

- » Infection
- » Physiologically or psychologically inadequate patient
- » Inadequate skin, bone, or neurovascular status
- » Irreparable tendon system
- » Possibility for conservative treatment
- » Growing patients with open epiphyses

Implant Selection: Plates

The CLAW® II Polyaxial Compression Plates are made out of stainless steel for maximum strength and stiffness. The system is composed of 5 different plate styles, with multiple options in sizing and configuration. The universal-style 2-hole, 4-hole and Series plates provide the surgeon with surgical flexibility of implant size and geometry for a variety of indications. The 3- and 4-hole T-Plates are designed to provide optimal screw fixation for fusions of the individual tarsometatarsal joints. The indication specific U-Plate is designed to provide a unified compression plating construct for fusions of the 1st and 2nd tarsometatarsals. Together, this comprehensive array of CLAW® II plates combine versatility with a locking screw compression plate that provides robust strength and stability.

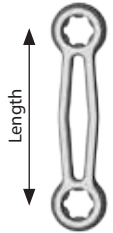
Like any lower extremity arthrodesis procedure, preoperative planning and adequate joint preparation/positioning are vital to the overall outcome of the procedure. Careful consideration must be given to implant selection, with particular attention to the individual anatomic variables of the patient.

Each plate features a locking thread that will accept both 2.7mm and 3.5mm diameter cortical locking screws on-axis and up to 15-degrees off-axis. Additionally, the 3.5mm screws are available with a cancellous threadform.



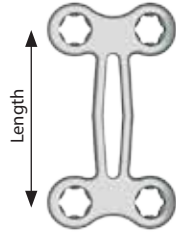
Universal Plates

2-Hole Plate



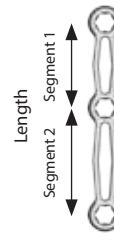
Size	Length
XSmall	15mm
Small	20mm
Medium	25mm
Large	30mm

4-Hole Plate



Size	Length
Small	20mm
Medium	25mm
Large	30mm

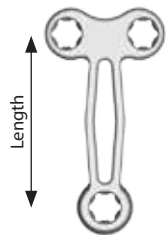
Series Plate



Size	Length	
	Segment 1	Segment 2
Small	20mm	20mm
Medium	20mm	25mm
Large	25mm	25mm

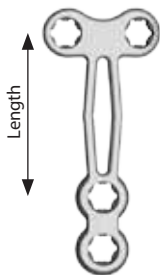
Alphabet Plates

3-Hole T-Plate



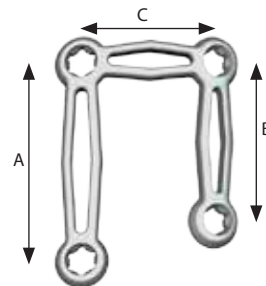
Size	Length
Small	20mm
Medium	25mm
Large	30mm

4-Hole T-Plate



Size	Length
Small	20mm
Medium	25mm
Large	30mm

U-Plate



Size	Segment Length		
	A	B	C
Small	18	18	16
Medium	22	22	19
Large	30	24	22

Large available in Left and Right



FIGURE 1 Recommended placement and orientation of U-Plate Styles.

Implant Selection: Plates

The following tables may assist with implant selection based on the supported indications for the CLAW® II Polyaxial Compression Plating System. **Table 1** details the general indication categories, while **Table 2** identifies the particular mid- & hind-foot indications for which each plate was designed. **FIGURE 1** demonstrates the recommended orientation and placement of the U-Plate for 1st and 2nd TMT fusions.

Table 1 - Indications

Plate Type	Plate Design	Mono-or-Bi-Cortical Osteotomies of the Forefoot	First Metatarsophalangeal Arthrodesis	Akin Osteotomy	Mid- & Hind-foot Arthrodeses or Osteotomies	Fixation of Osteotomies for Hallux Valgus	Tarsometatarsal (TMT) Fusions	Lisfranc Arthrodesis
2-Hole		+	+	+	+	+	+	+
4-Hole			+		+	+	+	+
Series			+		+	+	+	+
T-Plate		+	+		+	+	+	+
U-Plate					+		+	+

Table 2 - Midfoot & Hindfoot Arthrodesis Procedures

Plate Type	Plate Design	Tarsometatarsal (TMT) Fusions					Intercuneiform	Naviculo-cuneiform	Talo-navicular	Calcaneo-cuboid
		1st	2nd	3rd	4th	5th				
2-Hole		+	+	+	x	x	+	+	+	+
4-Hole		+	x	x	x		+	+	+	+
Series		+	+	+	x	x	+	+	+	x
T-Plate		+	+	+	+	+	x	+	+	+
U-Plate		+	+	x			+	x		

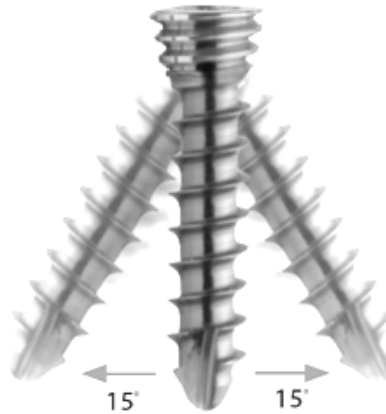
+ Primary x Secondary

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the product and procedure used based on personal medical training and experience.

Implant Selection: Screws

The ORTHOLOC® 3DSi polyaxial locking screw hole within the CLAW® Compression Plate has been designed to provide the surgeon with a variety of fixation options, from two screw diameters and threadforms to the ability to insert the screw off-axis. With a uniform locking head design, all stainless steel screw holes will accept either a 2.7mm or 3.5mm diameter locking screw. Additionally, the 3.5mm diameter screw is available in both cortical and cancellous threadforms. Screw diameter, size, and threadform are determined by the anatomy and fixation goals. All screws are self-tapping, but do require the use of a color-coded pre-drill and provided instrumentation.

The locking screws can be locked on-axis with the plate threads or up to 15-degrees off-axis in any direction. | **FIGURE 2** The screws are manufactured from a hardened metal, which allows strong polyaxial fixation into the stainless steel plate.



| **FIGURE 2** Polyaxial capabilities of the ORTHOLOC® 3DSi Locking Screw

Preoperative Planning

The CLAW® II Polyaxial Compression Plating System comprises a variety of plating styles and sizes, many designed for a particular indication. Preoperative selection of the appropriate size and style of plate will facilitate a streamlined surgical procedure.

Joint Preparation

The joints to be fused are prepared by thoroughly debriding the articular surfaces, and manually reducing the anatomy to ensure good bony apposition of the joint surfaces. Provisional fixation of the reduction can be accomplished with a 1.6mm K-wire (P/N 44112008).

Plate Fixation

Plate Contouring

General plate contouring may be required with the Plate Bending Irons (P/N 40140020) to obtain proper fit between the plate and bone surface. | **FIGURE 3** The U plates have a pre-existing medial-lateral contour to match the general anatomy of the metatarsals and cuneiforms, and the large sizes are available in left and right configurations. Modification in multiple dimensions, particularly proximal-distal, may be needed to match a patient's particular anatomy. Close attention should be taken to protect the screw holes when bending. The plate should only be bent in one direction and should not exceed 10-degrees of bending.

1.6mm K-wire
44112008



Plate Bending Iron
40140020



1.1mm Temporary Fixation Pin
DC4212



Plate Tack
40250010



In Situ Bender
49510032



| **FIGURE 3** Contouring of a 2-Hole Plate using the Plate Bending Irons

Provisional Fixation

The desired CLAW® II compression plate is placed on the bone, ensuring adequate points of fixation. 1.1mm Temporary Fixation Pins (P/N DC4212) or Plate Tacks (P/N 40250010) can be placed either through any locking screw hole or between the compression arms. Plates will compress the joint linearly along the compression arms, so plate positioning should account for this. Fluoroscopy should be used to verify accurate plate placement prior to screw fixation.

In Situ Contouring

Due to variations in foot anatomy, additional minor contouring of the plate may be necessary to allow direct apposition of the plate to the bone. The CLAW® II Polyaxial Compression Plating System does not utilize non-locking screws to facilitate plate lagging, so contouring must be accomplished prior to screw placement. *In Situ* Benders (P/N 49510032) are threaded into the locking screw holes, ensuring full engagement with the plate threads. The Benders are then levered down, contouring the plate flush to the bone.

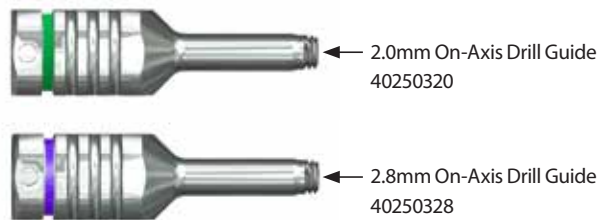
Locking Screw Placement

In order to achieve a unified plating construct for compression, every screw hole on the plate must be utilized with an ORTHOLOC® 3DSi locking screw. It is recommended to place the distal locking screws before the proximal screws to facilitate plate positioning and contouring.

The CLAW® II Polyaxial Compression Plates' Locking Screw Holes have been designed to accept both 2.7mm and 3.5mm ORTHOLOC® 3DSi locking screws. All locking screws can be placed on-axis with the internal plate threads or up to 15-degrees off-axis in any direction.

When using a locking screw on-axis, the appropriate Locking Drill Guide is threaded into the screw hole on the plate, and the corresponding Drill Bit is used through the guide to the appropriate depth. | **FIGURE 4** Screw length can be determined with the Drill Bit and Drill Guides. The Drill Bit is used to penetrate the proximal cortex and continued until the distal cortex is reached. Drilling is stopped as the distal cortex is breached, and the screw length reference on the Drill Bit is examined at the end of the Drill Guide. | **FIGURE 5** Alternatively, a traditional screw Depth Gauge (P/N 49510036) is provided in the system.

Note that the Drill Guide should not be used to contour the plate.



Locking Screw	Drill/Guide Size	Color Code	Guide P/N	Drill P/N
2.7mm	2.0mm	Green	40250320	40250020
3.5mm	2.8mm	Purple	40250328	40250028

| **FIGURE 4** On-Axis Drill and Drill Guide Selection



2.0mm Drill Bit for 2.7mm Screw
40250020



2.8mm Tissue Protector for 3.5mm
Screw 40250028



Depth Gauge
49510036



| **FIGURE 5** Screw Length Determination

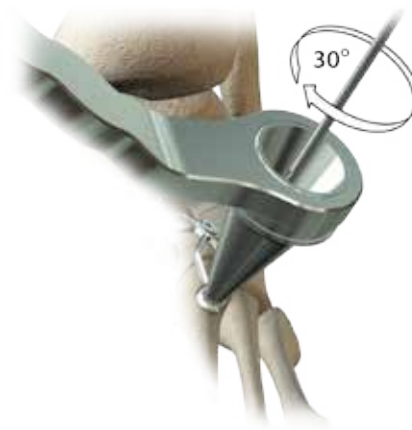
All ORTHOLOC® 3DSi locking holes and locking screws have polyaxial locking capabilities. To engage a locking screw off-axis to the plate threads, the appropriately sized Polyaxial Drill Cone is assembled to the Polyaxial Guide Handle (P/N 40250100), and inserted into the desired locking hole. | **FIGURE 6 & 7** Ensure the guide mates properly with the locking feature. Alternatively, a Tissue Protector for the selected Drill Bit may be inserted into the Guide Handle. The corresponding Drill is used through the Drill Guide to the appropriate depth, as described above, ensuring that the drill trajectory stays within the 30-degree guide cone.

Avoidance of screw divergence is highly recommended, as this may create plantar gapping of the joint. Slight convergence of screw trajectories might mitigate any plantar gapping during compression.



Locking Screw	Drill/Guide Size	Color Code	Guide P/N	Drill P/N
2.7mm	2.0mm	Green	40250120	40250220
3.5mm	2.8mm	Purple	40250128	40250228

| **FIGURE 6** Polyaxial Drill and Drill Guide Selection



Polyaxial Tissue Protector
40250220 & 40250228



Self Retaining
STAR 10 Driver 40251100



Non-Retaining
STAR 10 Driver 40251101



Screw Gripper
58870004

The STAR 10 Driver is used to advance the screw into the plate using the Ratcheting Driver Handle (P/N 40120028). The Self Retaining Driver (P/N 40251100) can be used to select and remove the screw from the caddy by firmly pressing the driver tip into the head of the screw while it is within the tray. Alternatively, a non-self-retaining Driver (P/N 40251101) can be used with the Screw Gripper (P/N 58870004) to transport the screw to the operative field. The screw is tightened until it locks securely into the plate, following the on- or off-axis trajectory of the drill hole. The process is repeated until all the screw holes on the CLAW® plate have been filled.



Plate Spreader
40250030

Plate Expansion

The plate arms are then distracted by using the Plate Spreader (P/N 40250030) to create compression of the joint. The tips of the Spreader are inserted in between the arms of the plate, and firm pressure is applied to the Spreader to expand the arms and achieve compression at the joint. | **FIGURE 8** For plates involving multiple spans it is recommended to maintain an order of compression from proximal to distal and then medial to lateral, although the specific order is left to the judgement of the surgeon, and may depend on specific factors such as patient anatomy, surgeon preference and indication.



| **FIGURE 8** Compression of the Joint Using the 4-Hole CLAW® Compression Plate



Non-Retaining STAR 10 Driver
40251101

Explant Information

Removal of the compression plate may be performed by first extracting the locking screws using the STAR10 Driver (P/N 40251101) and then removing the plate from the bone.

If 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 manufacture for investigation.

Postoperative Care

Postoperative protocol is at the discretion of the medical professional.

Ordering Information

Sterile part numbers are available upon request for specific markets.



Part Number	Description
40240215	CLAW® II - 2-HOLE - 15MM
40240220	CLAW® II - 2-HOLE - 20MM
40240225	CLAW® II - 2-HOLE - 25MM
40240230	CLAW® II - 2-HOLE - 30MM



Part Number	Description
40240420	CLAW® II - 4-HOLE - 20MM
40240425	CLAW® II - 4-HOLE - 25MM
40240430	CLAW® II - 4-HOLE - 30MM



Part Number	Description
40241320	CLAW® II - 3-HOLE T-PLATE 20MM
40241325	CLAW® II - 3-HOLE T-PLATE 25MM
40241330	CLAW® II - 3-HOLE - 30MM



40241420	CLAW® II - 4-HOLE T-PLATE 20MM
40241425	CLAW® II - 4-HOLE T-PLATE 25MM
40241430	CLAW® II - 4-HOLE T-PLATE 30MM



Part Number	Description
40242020	CLAW® II - SERIES - 20 X 20MM
40242025	CLAW® II - SERIES - 20 X 25MM
40242525	CLAW® II - SERIES - 25 X 25MM



Part Number	Description
40243010	CLAW® II - U-PLATE - SMALL
40243020	CLAW® II - U-PLATE - MEDIUM
4024303L	CLAW® II - U-PLATE - LARGE LT
4024303R	CLAW® II - U-PLATE - LARGE RT

**ORTHOLOC® 3DSi –
2.7mm Cortical Locking Screws**



Part Number	Description
40232712	2.7 x 12mm
40232714	2.7 x 14mm
40232716	2.7 x 16mm
40232718	2.7 x 18mm
40232720	2.7 x 20mm
40232722	2.7 x 22mm
40232724	2.7 x 24mm
40232726	2.7 x 26mm
40232728	2.7 x 28mm
40232730	2.7 x 30mm
40232732	2.7 x 32mm
40232734	2.7 x 34mm
40232736	2.7 x 36mm

**ORTHOLOC® 3DSi –
3.5mm Cortical Locking Screws**



Part Number	Description
40233512	3.5 x 12mm
40233514	3.5 x 14mm
40233516	3.5 x 16mm
40233518	3.5 x 18mm
40233520	3.5 x 20mm
40233522	3.5 x 22mm
40233524	3.5 x 24mm
40233526	3.5 x 26mm
40233528	3.5 x 28mm
40233530	3.5 x 30mm
40233532	3.5 x 32mm
40233534	3.5 x 34mm
40233536	3.5 x 36mm
40233538	3.5 x 38mm
40233540	3.5 x 40mm

**ORTHOLOC® 3DSi –
3.5mm Cancellous Screws (Optional)**

Part Number	Description
40223510	3.5 x 10mm
40223512	3.5 x 12mm
40223514	3.5 x 14mm
40223516	3.5 x 16mm
40223518	3.5 x 18mm
40223520	3.5 x 20mm
40223522	3.5 x 22mm
40223524	3.5 x 24mm
40223526	3.5 x 26mm
40223528	3.5 x 28mm
40223530	3.5 x 30mm
40223532	3.5 x 32mm
40223534	3.5 x 34mm
40223536	3.5 x 36mm
40223538	3.5 x 38mm
40223540	3.5 x 40mm

CLAW® II Instrument Kit – 4024KIT1

Part Number	Description
40120028	CLAW® RATCHETING DRIVER HANDLE
40140020	CLAW® 3.5MM PLATE BENDER
40250030	CLAW® II - PLATE SPREADER
40250100	CLAW® II - POLYAXIAL GUIDE
40250120	CLAW® II - POLYAXIAL 2.0MM CONE
40250128	CLAW® II - POLYAXIAL 2.8MM CONE
40250220	CLAW® II- 2.0MM TISSUE PROTECTOR
40250228	CLAW® II- 2.8MM TISSUE PROTECTOR
40250320	CLAW® II - 2.0MM DRILL GUIDE
40250328	CLAW® II - 2.8MM DRILL GUIDE
49510032	IN-SITU BENDERS
58870004	SCREW GRIPPER – 4 PRONG
49510036	DEPTH GAUGE EVOLVE EPS

Consumables

Part Number	Description
DC4212	Temporary Fixation Pin 1.1mm
44112008	Single Trocar Wire 1.6x150mm
40250020	CLAW® II - 2.0MM DRILL BIT
40250028	CLAW® II - 2.8MM DRILL BIT
40250010	CLAW® II - PLATE TACK
40251100	DRIVER STAR10 SELF RETAINING
40251101	DRIVER STAR10

Bone Taps (Optional)

Part Number	Description
49513310	Bone Tap 2.7mm Cortical
49513311	Bone Tap 3.5mm Cortical
49513312	Bone Tap 3.5mm Cancellous



2525011060

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