READY-FOR-SURGERY[™]

Calcaneus Plate System

Surgical Technique Guide





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READY-FOR-SURGERY[™]

BUILDING A MORE EFFICIENT CASE

Conventus-Flower Orthopedics is the leader in Ready-For-Surgery[™] bone fixation. The FlowerCube[™] produces clinically equivalent outcomes while generating cost savings and surgical efficiencies when compared to traditional orthopedic implant and instrument sets.

- Innovative System that is pre-packaged and ready for use
- Contains single-use, sterile packaged implants & instruments required for specific surgical indications
- Eliminates pre-op handling and post-op reprocessing



FlowerCube[™] Surgical Efficiency Study Results¹:



Faster Case Time

Time saving of nearly 20 minutes per case with the FlowerCube compared to procedures using traditional implants



3rd Party Reimbursement Savings

Over \$1,300 savings in third party reimbursement costs for procedures performed at an ASC compared to those done in an outpatient hospital setting



Joint Union

84.51% of study patients experienced union of the joints by 8 weeks post-surgery and 98.59% by 12 weeks post-surgery



Opportunity Savings

Sterilization, reprocessing and packaging of surgical trays would add \$45 per instrument tray

1: Data on file at Flower Orthopedics

• IRB approved, prospective, multi-center clinical trial • Evaluating arthodesis of first MPJ • 71 patients at both hospital and ASC locations

• Primary Outcome Measure - Fusion rate 12 weeks post surgery • Secondary Outcome Measure - Cost & Time Efficiency

SYSTEM OVERVIEW

Indications For Use

The Calcaneus Plate System is intended to be used for internal fixation of fractures and reconstruction of bones of the rearfoot, including the calcaneus. Examples of these internal fixations and reconstructions include, but are not limited to extra-articular fractures, intra-articular fractures, joint depression fractures, tongue type fractures, severely comminuted fractures, and osteotomies.





Contraindications

Do not use the Flower Orthopedics implants in cases of:

- Inadequate bone quantity and/or bone quality
- Foreign body sensitivity to implant material
- Acute localized infections
- Patients with limited blood supply
- Patients with unstable physical and/or mental health conditions

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SYSTEM FEATURES

The Calcaneus Plate System includes multiple plate types to accommodate a variety of fracture patterns and patient anatomy. Each plate hole accepts either variable angle locking or variable angle compression screws. The Calcaneus Plates are made of commercially pure titanium and are offered in left and right configurations.

CALCANEUS PLATE OPTIONS:

- Minimally Invasive (MIS) plates offer optional insertion posts and MIS insertion guides for implantation through sinus tarsi approach
- Extensile plates are designed for lateral extensile approach; facilitates visualization and grafting

LOW PROFILE DESIGN:

Construct profile minimizes soft tissue disruption

VARIABLE PLATE THINNESS:

- Locking hole spacing and bending zones on the extensile implants ease plate contouring
- Extensile plate thinness: 1.75mm around locking holes, 1.25mm at bend zones
- MIS plate thinness: 1.75mm

ANATOMIC HOLE LOCATIONS:

 Supporting screws for the subtalar joint and posterior tuberosity

FLOWERGROOVE™ LOCKING TECHNOLOGY:

- The FlowerGroove is an innovative, patented locking mechanism that accepts a variety of screw diameters and types.
- The Calcaneal Plates are made of commercially pure titanium and the Variable Angle Locking Screws are made of titanium alloy.
- The locking threads of the screw head engages the "petals" of the locking hole to create a thread-form in the plate.
- 30° cone of angulation





EXTENSILE PLATE DESIGN

The Extensile Calcaneus Plate is designed for implantation through a lateral extensile approach with care given to retract the soft tissues, peroneal tendons, and sural nerve.

STEP 1: Patient Positioning

The recommended patient positioning is a lateral position with a well-padded axillary roll and knee padding around the contralateral limb.

STEP 2: Surgical Approach

A traditional L-shaped incision is made on the lateral aspect of the ankle and hindfoot approximately 10-12cm in length and approximately 2-3cm posterior to the fibula and posterior to the sural nerve. Dissection is carried down to bone at the apex of the incision site and a subperiosteal dissection is performed with care being taken to create a full thickness flap avoiding injury to the lateral soft tissue including the sural nerve. Attention is made to avoid disruption of the comminuted fragments of the lateral wall of the calcaneus.

STEP 3: Fracture Reduction

Using direct and indirect reduction techniques, reduce the fracture and ensure that Bohler's Angle and the Critical Angle of Gissane have been reestablished using fluoroscopy. Insert provisional K-wires as needed to maintain anatomic reduction. Take care to avoid future plate and screw locations with provisional K-wires. Confirm reduction radiographically.

SURGICAL TECHNIQUE EXTENSILE PLATE

STEP 4: Trial for Implant Size & Contour

Instrument:

CPF 996 Calcaneus Plate Trial, Extensile

Extensile Calcaneus Plate Trials are available for all plate sizes and are provided to aid with proper plate selection and contouring. Each trial size can be used for either a right or left plate.

Open and select the appropriate Extensile Calcaneus Plate Trial. Apply the trial to the lateral wall of the calcaneus and contour appropriately to ensure proper positioning of the subchondral line and the corresponding screw holes.

Technique Tip:

The trials are malleable and can be contoured by hand to the desired shape.



STEP 5: Plate Contouring

Instrument:

FIS 231 Plate Benders, Small

Select and open the appropriate sized calcaneal plate based upon the previous trial. If needed, contour the plate using the Plate Benders to replicate the shape of the trial.

Confirm appropriate contour and placement radiographically prior to screw insertion.



CPF 101 Left, Small



CPF 201 Right, Small



CPF 102 Left, Medium



CPF 202 Right, Medium



CPF 103 Left, Large



CPF 203 Right, Large

SURGICAL TECHNIQUE

EXTENSILE PLATE

STEP 6: Screw Insertion

Instruments:

Ontional Instruments:		
EWK 201	E-Kit, Medium, Advanced	
DBK 040	Drill Bit Kit, 4.0mm	
DBK 135	Drill Bit Kit, 3.5mm	

Optional instruments:

FIM 115 Large Bone K-Wire Kit

Each calcaneal locking hole accepts either Variable Angle Locking or Variable Angle Compression screws. Open the appropriate Drill Bit Kit based on the screw size to be inserted as indicated below:



Part #	Description	Drill Bit Kit
FRP 3XX	Locking Screw, 3.5mm x XXmm	DBK 135
FCS 5XX	Compression Screw, 3.5mm x XXmm	DBK 135
FCS 6XX	Compression Screw, 4.0mm x XXmm	DBK 040

Insert the locking end of Drill Guide into the FlowerGroove of the plate hole and to the bone. Drill to the appropriate length.

Note:

When inserting a Locking Screw do not drill more than 15° in any direction from the given trajectory of the hole.

The E-Kit contains the following instruments: T15 Cannulated Screwdriver, Cannulated Depth Gauge & Countersink, Olive Wires, 1.1mm CoCr Guide Wires, and Plating Depth Gauge.

Open the E-Kit and use the Plating Depth Gauge to determine screw length. Ensure the Plating Depth Gauge is fully seated into the FlowerGroove of the plate hole and to the bone in order to obtain an accurate screw measurement.

Insert the appropriate screw using the self-retaining T15 Screwdriver. The Compression Screws can be used first to pull the plate towards the bone. Locking screws should seat fully into the plate hole. Repeat Step 6 as needed. Confirm all screw lengths with fluoroscopy.

Optionally, the screws can be inserted using power with the solid T15 Screwdriver Shaft found in FIM 115. If inserting screws with power, ensure that final tightening is performed by hand using the T15 screwdriver.





SURGICAL TECHNIQUE MIS PLATE

The Minimally Invasive (MIS) Calcaneus Plate is designed for implantation through a sinus tarsi approach with peroneal tendons and sural nerve remaining inferior to the incision. Benefits of using the MIS technique include: smaller incision, minimal soft tissue dissection, potentially faster healing, and potentially decreased chance of infection when compared to open technique.

STEP 1: Patient Positioning

The recommended patient positioning is a lateral position with a well-padded axillary roll and knee padding around the contralateral limb.

STEP 2: Surgical Approach

An incision is made over the sinus tarsi approximately 3-5cm in length. Careful dissection to expose the lateral articular surface of the posterior facet of the subtalar joint. Attention is made to retract and protect the sural nerve and peroneal tendons.

STEP 3: Fracture Reduction

Using direct and indirect reduction techniques, reduce the fracture and ensure that Bohler's Angle and the Critical Angle of Gissane have been reestablished using fluoroscopy. Insert provisional K-wires as needed to maintain anatomic reduction. Take care to avoid future plate and screw locations with provisional K-wires. Confirm reduction radiographically.

STEP 4: Trial for Implant Size & Contour

Instrument:

CPF 997 Calcaneus Plate Trial, MIS

The MIS Calcaneus Plate Trial is available for all plate sizes and is provided to aid with proper plate selection and contouring. The trial can be used for either a right or left plate.

Open the MIS Calcaneus Plate Trial. Insert the trial into the incision and over the lateral wall of the calcaneus to verify appropriate length and anatomic fit. Contour to ensure proper positioning of the subchondral line and the corresponding screw holes.

Technique Tip:

The trial is malleable and can be contoured by hand to the desired shape.



SURGICAL TECHNIQUE MIS PLATE

STEP 5:	Plate Contouring		
Instrument:			
FIS 231 Plate Benders, Small			

Select and open the appropriate sized calcaneal plate based upon the previous trial. If needed, contour the plate using the Plate Benders to replicate the shape of the trial.

Confirm appropriate contour and placement radiographically prior to screw insertion.



STEP 6: Plate Insertion

Instruments:

Optional Instruments:		
CPF 994	MIS Calcaneus Plate Insertion/Incision Guide (Large)	
CPF 993	MIS Calcaneus Plate Insertion/Incision Guide (Medium)	
CPF 992	MIS Calcaneus Plate Insertion/Incision Guide (Small)	

PTK 400 Cal	aneus Plate Tack/Support Pin
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Select the appropriately sized MIS Calcaneus Plate Insertion/Incision Guide that corresponds to the correct plate size (Small, Medium, or Large).

Carefully thread the insertion posts into the 2 small threaded plate holes (as indicated by the red arrows in the image above). Verify that the insertion posts are parallel to each other and fully seated.

Precaution:

The threaded insertion post holes ONLY accept the insertion posts. They are not to be used for screw placement.

The insertion posts can be used as a handle to insert the plate into the minimally invasive incision and position the plate onto the bone.

Confirm plate placement radiographically.

Note:

The insertion posts are not radiolucent while the incision guide is made of radiolucent PEEK.

To facilitate provisional fixation and minimally invasive screw placement, slide the PEEK incision guide over the 2 insertion posts.

The Plate Tack/Support Pin or K-Wires from the E-Kit can be inserted into the plate holes to provisionally secure the plate to the bone.







SURGICAL TECHNIQUE MIS PLATE

STEP 7: Screw Insertion

Instruments:

DBK 135	Drill Bit Kit, 3.5mm			
DBK 040	Drill Bit Kit, 4.0mm			
EWK 201 E-Kit, Medium, Advanced				
Optional Instruments:				
FIM 115	Large Bone K-Wire Kit			

Each calcaneal locking hole accepts either Variable Angle Locking or Variable Angle Compression screws. Open the appropriate Drill Bit Kit based on the screw size to be inserted as indicated below:

Part #	Description	Drill Bit Kit
FRP 3XX	Locking Screw, 3.5mm x XXmm	DBK 135
FCS 5XX	Compression Screw, 3.5mm x XXmm	DBK 135
FCS 6XX	Compression Screw, 4.0mm x XXmm	DBK 040

Using the Incision Guide holes, approximate the minimally invasive screw incisions. Carefully make stab incisions. Dissect down to the plate and bone taking care not to disrupt the plate placement on the bone.

Insert the locking end of Drill Guide through the soft tissue and into the FlowerGroove of the plate hole and to the bone. Drill to the appropriate length.

When drilling, it is recommended to monitor drill depth using fluoroscopy.

Note:

When inserting a Locking Screw do not drill more than 15° in any direction from the given trajectory of the hole.



The E-Kit contains the following instruments: T15 Cannulated Screwdriver, Cannulated Depth Gauge & Countersink, Olive Wires, 1.1mm CoCr Guide Wires, and Plating Depth Gauge.

Open the E-Kit and use the Plating Depth Gauge to determine screw length. Ensure the Plating Depth Gauge is fully seated into the FlowerGroove of the plate hole and to the bone in order to obtain an accurate screw measurement.

Insert the appropriate screw using the self-retaining T15 Screwdriver. The Compression Screws can be used first to pull the plate towards the bone. Locking screws should seat fully into the plate hole. Repeat Step 7 as needed. Confirm all screw lengths with fluoroscopy.

Optionally, the screws can be inserted using power with the solid T15 Screwdriver Shaft found in FIM 115. If inserting screws with power, ensure that final tightening is performed by hand using the T15 screwdriver.





PRODUCT INFORMATION

Additionally Available Implants:

Large Cannulated FlowerCube[™]

Contains 5.5mm, 6.5mm, and 7.3mm cannulated screws and all required instruments to treat fusions, osteotomies and fractures of the foot, ankle, and long bones.

Titanium Cannulated Screws (5.5mm)

CSP 630 – CSP 670 (30mm – 70mm length) Cannulated Screw, Partially Threaded

Titanium Cannulated Screws (6.5mm)

CSP 740 – CSP 798 (40mm – 120mm length) Cannulated Screw, Partially Threaded

CSF 740 – CSP 780 (40mm – 80mm length) Cannulated Screw, Fully Threaded

HCS 740 – HSC 792 (40mm – 100mm length) Headless Compression Screws

Titanium Cannulated Screws (7.5mm)

CSP 850 – CSP 898 (50mm – 120mm length) Cannulated Screw, Partially Threaded

CALCANEUS FLOWERCUBE[™]

Extensile Calcaneus Plates (Small, Medium, & Large)

PRODUCT #	ORIENTATION	WIDTH (mm)	LENGTH (mm)	THINNESS (mm)	HOLES
CPF 101	Left (S)	32.7	57	1.25-1.75	12
CPF 102	Left (M)	35.4	64.1	1.25-1.75	13
CPF 103	Left (L)	36.5	71.5	1.25-1.75	13
CPF 201	Right (S)	32.7	57	1.25-1.75	12
CPF 202	Right (M)	35.4	64.1	1.25-1.75	13
CPF 203	Right (L)	36.5	71.5	1.25-1.75	13



MIS Calcaneus Plates (Small, Medium, & Large)

PRODUCT #	ORIENTATION	WIDTH (mm)	LENGTH (mm)	THINNESS (mm)	HOLES
CPF 112	Left (S)	32.4	59.5	1.75	10
CPF 113	Left (M)	33.9	65.8	1.75	10
CPF 114	Left (L)	36.5	69.6	1.75	11
CPF 212	Right (S)	32.4	59.5	1.75	10
CPF 213	Right (M)	33.9	65.8	1.75	10
CPF 214	Right (L)	36.5	69.6	1.75	11



Calcaneus Plate Trials



CPF 996 - Extensile Plate Trial



CPF 997 - MIS Plate Trial

CALCANEUS FLOWERCUBE[™]

MIS Insertion/Incision Guides

- CPF 992 MIS Calcaneus Plate Insertion/Incision Guide (Small)
- CPF 993 MIS Calcaneus Plate Insertion/Incision Guide (Medium)
- CPF 994 MIS Calcaneus Plate Insertion/Incision Guide (Large)



Variable Angle Screws

3.5MM LOCKING SCREWS (FRP 320 - FRP 350)

Length	Quantity
20mm	3
22mm	3
24mm	3
26mm	6
28mm	6
30mm	6
32mm	6
34mm	6
36mm	3
38mm	3
40mm	3
45mm	3
50mm	3

3.5MM COMPRESSION SCREWS (FCS 520 - FCS 550)

Length	Quantity
20mm	3
22mm	3
24mm	3
26mm	3
28mm	3
30mm	3
32mm	3
34mm	3
36mm	3
38mm	3
40mm	3
45mm	3
50mm	3

4.0MM

COMPRESSION SCREWS (FCS 620 - FCS 650)

Length	Quantity
20mm	2
22mm	2
24mm	2
26mm	2
28mm	2
30mm	2
32mm	2
34mm	2
36mm	2
38mm	2
40mm	2
45mm	2
50mm	2

Instruments

Product #	Instruments	Quantity
PTK 400	Calcaneus Plate Tack/ Support Pin	2
DBK 135	Drill Bit Kit, 3.5mm	2
DBK 040	Drill Bit Kit, 4.0mm	1
LSK 035	Lag Screw Kit, 3.5mm	1
LSK 040	Lag Screw Kit, 4.0mm	1
FIS 231	Plate Benders, Small	1
EWK 201	E-Kit, Medium, Advanced	2
RMD 200	T15 Screwdriver	1
FIM 115	Large Bone K-Wire Kit	1



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