



Operative Technique

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Fracture Plating System

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This document offers technical guidance pertaining to the Apollo Ankle Fracture Plating System. As with any medical device, surgeons should rely on their training, making any necessary adjustments based on the needs of the patient.

Indications

Indications for Use and Intended Use:

The Apollo Ankle Fracture Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

The Apollo Ankle locking and non-locking screws are intended for use with Apollo Ankle Fracture Plating System.

Apollo non-locking screws are indicated for use of bone in reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Apollo 1/3 tubular plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Apollo washer is intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

Contraindications Precautions

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and / or fixation of the devices
- Material sensitivity, documented or suspected

See package insert for warnings, precautions, adverse effects and other essential product information.

The Apollo Ankle Fracture Plating System has not been evaluated for safety in (MR) environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Apollo Ankle Fracture Plating System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

- Obesity: an overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

Special syndesmotic holes are designed for the 4.3mm screws and standard suture buttons. They are anatomically angled 35°, posterior to anterior

Tapered proximal end easily and comfortably fits under soft tissue upon insertion

Screw heads sit below the plate surface when fully engaged

The plates are built with a patented hybrid construction of 3D printed titanium and injection molded PEEK. The combination of these manufacturing techniques, along with a blend of proprietary surface treatments, creates a lightweight, bendable plate with strength equal to traditional machined titanium plates with Type II anodization.

Ø2.9mm and Ø3.7mm locking and non-locking screws can be inserted up to 15° off-axis

> Plate holes allow for Ø2.9mm and Ø3.7mm locking / non-locking screws, and 4.3 non-locking screws

Proprietary Hybrid Titanium/ PEEK construction is ortholucent and malleable

*PEEK pellets are melted and injected into a custom mold. Any left over sprues or scrap can be reground into the raw material and used again. Components produced using additive manufacturing require minimal to no additional machining and create no titanium waste.

Hybrid Materials and Manufacturing

The plates are not only visually green, but also environmentally green. Produced using a zero waste process, these plates are made through a proprietary additive manufacturing (3D printing) and injection molding process.

Additive manufacturing offers the capability to mirror complex anatomy and create very smooth contours that minimize soft tissue irritation. This technology creates the shell structure of the plate which offers the thinnest section of titanium on the market, giving Apollo its radiolucent properties.*



Low-profile, contoured plate offers strength while reducing soft tissue irritation Distal fibula screw cluster allows for multiple points of fixation

Screw Technology

The unique combination of additive manufactured titanium and injection molded PEEK leads to the patented screw locking technology of PEEKLOC[™].

The PEEK construct allows for a quick thread engagement, and smooth tactile feel, while the proprietary hidden titanium structure enforces the solid locking strength. PEEKLOC[™] technology creates the elastic locking friction and greatly reduces the risk of cold-welding during screw insertion.



PEEKLOC[™] and Self-countersinking Screws



This thin cross-sectional structure of titanium gives the plates "ortholucency", a unique advantage over traditional metal implants where the radiolucent properties drastically improve the visualization of bones and joint spaces. Intraoperatively, surgeons benefit from improved fracture and joint reduction imaging, while postoperatively they can better assess if bone is healing properly, potentially leading to earlier weight bearing decisions. 0

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Apollo Ankle Fracture Plating System





Contoured to the bone and smooth radius on the edges for less soft tissue irritation

1. Posterior Tibial Plate

- Left/Right anatomical designs.
- Distal holes angled away from tibiotalar joint.

2. Fibular Plate

- Syndesmotic holes positioned to aim 35°, posterior to anterior.
- Syndesmotic holes designed to accept typical suture buttons.
- Multiple points of fixation in the distal cluster.

3. One-third Tubular Plate

• Versatile plate with hole choices from 4 to 12 holes.

4. Medial Malleolar Plate

• Extra thin distal portion to minimize soft tissue irritation.

5. Hook Plate

- Versatile design for both lateral and medial malleoli.
- Compression slot with 2mm compressive action.

6. Syndesmotic Plate

- 2 and 4 hole designs.
- Syndesmotic hole designed for typical suture button.

Design Features

Plate Options

	Plate	Length	Shaft Width	Head With	Total Hole Count	Shaft Hole Count	Orientation
office (Standards	Lateral Fibula	67 89 111	9.6	18	9 11 13	4 6 8	Left / Right
00000000000000	One Third Tubular	51 62 73 84 95 117 139	9.6	N/A	4 5 6 7 8 10 12	4 5 6 7 8 10 12	Universal
	Hook	48 59 70 81	10	N/A	3 4 5 6	3 4 5 6	Universal
0000000	Medial Malleolar	60 71 83	9.6	21	6 7 8	3 4 5	Universal
80000	Posterior Tibia	48 59	10.6	23	5 6	3 4	Left/Right
0000	Syndesmosis	29 51	10.8	N/A	2 4	2 4	Universal
	Material			Ti6Al4V / F	PEEK		

Plate Features

Fibular plate

- Syndesmotic holes positioned to aim 35 degrees P to A.
- Syndesmotic holes designed to accept typical suture buttons.
- Multiple points of fixation on the distal cluster.

One-third Tubular plate

• Versatile plate with hole choices from 4 to 12 holes.

Medial Malleolar plate

• Extra thin distal portion to minimize soft tissue irritation.

Posterior Tibial plate

- Left/Right anatomical designs.
- Distal holes angled away from tibiotalar joint.

Syndesmotic plate

- 2 and 4 holes designs.
- Syndesmotic hole designed for typical suture button.

Hook Plate

- Versatile design for both lateral and medial malleoli.
- Compression slot with 2mm compressive action.

Design Features – Technical Specifications



Ø Size range	2.9mm	3.7mm	4.3mm
Туре	Locking and Non-Locking		Non-Locking
Length	8–40mm	10–60mm	25-70mm
Material	Ti6Al4V		
Color	Fuchsia	Green	Blue
Core drill sizes	2.4mm (Purple)	3.1mm (Green & Blue)	3.1mm (Green & Blue)
Over drill sizes (lag drills)	3.35mm (Purple)	4.0mm (Green)	4.5mm (Blue)

Screw Angulations

All Apollo locking and non-locking screws can be placed up to 15° off-axis.

Advanced hybrid design of 3D printed Ti and PEEK create unique locking feature where thread forming is occurring in both the PEEK and titanium enhancing locking and minimizing cold welding.

Note:

During bone screw insertion the surgeon should rely on tactile feedback to prevent excessive torque which may result in thread / bone stripping, screw damage / pull through, or screwdriver damage. Proper observation of bone quality, screw size and instrumentation can help determine the appropriate insertion torque during insertion and final tightening of the screw in the plate. Do not use power when locking the screws. When the screw is fully seated during final tightening, an increase of resistance indicates sufficient screw fixation.

Note:

It is not recommended to engage the poly-axial locking mechanism more than three times during screw insertion. Repeated use or damage to screw locking interface can cause:

- Screws may not lock to plate.
- Screws may pass through plate.

Note:

If plate is off the bone, use non-locking screw to pull it down.

Note:

+15°

- 15'

Excessive angulation of screw over 15° may prevent locking screws from locking into plate.

Design Features - Ortholucent Implants

Ortholucent Hybrid Technology – plates and screws

- See accurate reduction of fractures behind the plates and screws.
- See post-op healing more clearly.
- •Less scatter from MRI/CT's.
- Equivalent strength to other low profile Titanium plates.
- Proprietary 3D printed structures and surface treatment with Anodization for better fatigue strength.
- Anatomical contoured shape for minimal contouring.
- Hybrid construction just as malleable as any titanium plate - Contour to any shape.
- Low profile shape with rounded edges to prevent soft tissue irritation.
- Tapered noses on all plates.
- Locking interface with PEEK no cold welding of screw to plate.
- Self-countersinking screw heads – no countersinking step needed.
- Standard T15 hexa-lobular socket on the screws.
- Variable screw entry angle up to +/- 15 degrees.
- Washer for lag screws fits all sizes.





Hexalobular socket uses standard sized T15 screwdriver.

Locking heads will be color coated gray to easily differentiate from non-locking screws.

Forward Ratcheting

Design Features Single-Use Convenience Kit & 2 starter screws

Instrumentation Philosophy

Innovation driven designs to drive value while simultaneously enhancing experience. Optimizing work flow within the care provider while maintaining high quality.



Design Features Single-Use Convenience Kit & 2 starter screws

Drill Guide

- Sized to accommodate both Ø2.4mm and Ø3.1mm drills.
- Dual sided depth measurement accommodates 8 – 70mm depths within a low profile.
- Drill guide allows 15° conical off-axis drilling of screws (15° cone (30°)).



Countersink Depth Gauge

- Can be read from both front and back.
- Equipped with a countersinking tip. Note this is optional step since all screw heads have a self-countersinking feature.



Plate Benders / Tamp

Plate bender slots fit various portions of all plates. The opposite end can be used as a tamp for the hook plate.



Olive wires / K-wires / Drills

- Self-centering olive wires guarantee center hole placement.
- Movable olive guides placement of wire in center of hole, preventing unwanted plate movement.
- Slide olive back to shoulder to use olive wire for traditional use.
- Provisional K-wires.
- Drills for all sizes of screws.
- All Drills are color coded for matching the color coded screws.



Design Features – Lag Kit 2.9/3.7/4.3mm screws

Lag Drill Guide

The lag drill guides are color coded for each screw size.



Lag Drill Bits

Drill bits are color coded for each screw size. Distal end interfaces with a standard AO connect.



Washers

Washers are available for lag screws if desired. The one size, 7.5mm OD, fits all screw sizes.



Design Features – Instruments

Hook Plate Kit

The hook plate instrument kit comes with K-wires that are stored on the guide. The hook plate guide anatomical aligns to either lateral or medial malleoli. It matches the hook plate and properly locates two drill holes for the hook plate tines.

Sterile Trials

Plastic anatomically formed trials match each plate.

Adjust plate size as needed by breaking off end.

Special plastic blend is radio opaque for easy determination of size under fluoroscopy.





Surgical Procedure – Distal Lateral Fibula Plate

The Operative Technique listed below is designed to provide a general overview on the instruments and procedure required to implant a plate in the distal fibula. This operative technique will focus on the placement and fixation of the Distal Lateral Fibula Plate, One Third Tubular Plate, Syndesmosis Plate, Hook Plate, Medial Malleolus Plate, and Posterior Tibia Plate.

Step 1 – Planning and Preparation

Identification and classification of the fracture site should be established preoperatively using appropriate techniques and imaging modalities. A formed sterile trial can be placed on the bone to determine plate size and any additional contouring that may be needed. Trials have break away sections to adjust for different plate sizes.

Several incision options are available for ankle fractures, which should be selected based on the fracture type and anatomy. A lateral incision is typically used to perform extra-periosteal exposure of the distal fibula.





Step 2 – Fracture Reduction

Direct reduction with traditional bone reduction forceps can often provide anatomic reduction.

Care should be taken to ensure the location of the forceps do not interfere with implant positioning. Reduction should be confirmed fluoroscopically.



Step 3 – Plate Contouring

The Apollo Ankle Fracture Plates are designed anatomically to reduce the need for interoperative contouring. Slight contouring can be performed with plate benders provided in the single-use kit and the ratcheting handle is equipped with slots for plate bending as well. Use minimal bending to achieve further anatomic contouring.

Note:

Always avoid excessive and reverse bending or over bending motions to prevent stress risers. Plate contouring can affect the functionality of the locking mechanism. Avoid bending or contouring directly over a hole that will eventually be used for a locking screw.

Step 4 – Provisional Plate Fixation

Self-centering olive wires are provided for provisional plate fixation. With the plate positioned in the desired location and the self-centering olive wire loaded onto a standard pin driver, place the sliding olive tip into the chosen plate hole.

The olive wire will automatically center the pin to the hole and will provide plate reduction once the olive wire reaches the stop flange of the pin. Once both olive wires are in place, plate placement can be confirmed fluoroscopically.

Note:

If self-centering feature is not desired, simply pull the olive portion back onto the shoulder of the pin.





Surgical Procedure – Distal Lateral Fibula Plate

Step 5 – Screw

Preparation

The Apollo plate screw hole has been designed to accept the Ø2.9mm and Ø3.7mm Apollo locking and non-locking screws and Ø4.3mm non-locking screws provided in the system.

All screws (locking and non-locking) can be placed on-axis or up to 15° off axis in any direction. Refer to the table for the corresponding drill to be used to pre-drill hole for the selected screw.

The single-use drill guide is designed to accommodate both drill diameters.

Drill guide offers straight and polyaxial drilling.

Step 6 – Determining Screw Length

Two options are available for determining screw length: (1) drill markings matched with their respective drill guide markings and (2) hooking depth gauge.

Method 1 – Drill and drill guide measurement

Using the appropriate drill through drill guide, penetrate through the near cortex until the far cortex is reached.

Take note of depth indicated on the drill guide by referencing the laser line on the drill as the far cortex is breached.

A solid laser line on the drill is used to measure depths 8-40mm, and a dashed laser line is used to measure depths of 40-70mm.

Note:

To ensure accurate angles to the plate either side of the drill guide should be 90 degrees to the hole surface.

Note:

Excessive angulation of screw over 15° may prevent locking screws from locking into plate.





For screw lengths 8mm-40mm use solid laser line



For screw lengths 40mm-70mm use dashed laser line.

Method 2 – Hooking

depth gauge

Measure the depth of the drilled hole using the hooking depth gauge. The depth gauge must be inserted first through the plate and then into the drilled hole.

Ensure the sleeve of the depth gauge is fully inserted into the respective plate hole prior to measuring. Measuring without a plate will result in a false reading.

Note:

Depth gauge also has a countersinking tip and may be used to create a countersink for the screw. This is an optional step since all screw heads are designed with self-countersinking heads.







Surgical Procedure – Distal Lateral Fibula Plate

Step 7 – Inserting the Screw

Assemble the T15 self-retaining driver to the ratcheting handle. Assemble the desired screw onto the distal tip of the T15 driver using the Quick Caddy screw delivery system, or using single used packaged screws. For fibular fractures, the Quick Caddy is recommended where the 2.9 Quick Caddy is used for smaller patients, and the 3.7 Quick caddy is used for larger patients. When using the Quick Caddy select the size of screw and insert the T15 self-retaining driver in the socket. Push and lift the screw through the clips of the Quick Caddy card.

Insert the screw into the drilled hole using the screwdriver assembly. As the screw head begins to engage the plate, feel for a natural endpoint and then stop insertion.

Note:

For non-locking screws, the screw head should sit approximately flush with the plate. It is possible to strip the pre-drilled hole through bone if excessive torque is applied to the screw. For locking screws, resistance will begin as the screw head engages the plate. Resistance will gradually increase until screws are locked to the plate.

Excessive torque application may cause stripping of the screw head at the plate.

Note:

For shorter locking head screws, more axial force is needed when the locking head engages the plate to start the thread forming process.







Optional: Syndesmotic Fixation Technique

The Apollo fibula and syndesmosis plates feature dedicated anatomic syndesmosis holes for use with Ø4.3mm (blue) non-locking screws.

In addition, suspensionary fixation devices with rounded lateral buttons of outer diameters between Ø5.0mm and Ø6.35mm can be used. These syndesmotic holes have been positioned to allow for screw insertion closer to the posterolateral edge of the fibula, and allows approximately 35 degrees of posterior to anterior angulation.

Use the Ø2.4mm drill for the Ø2.9mm screw and the Ø3.1mm drill for the Ø4.3mm and Ø3.7mm screw through the syndesmosis hole on either plate, and measure for screw length. Insert the selected screw through the syndesmotic hole until fully seated and confirm syndesmotic fixation fluoroscopically. One or two tri-cortical or tetra cortical Ø3.7mm or Ø4.3mm non-locking screws can be used for syndesmotic fixation based on patient factors, injury factors, and surgeon preference.

Optional: Lag Screw Technique using the Lag Kit

The Ø2.9mm, Ø3.7mm and Ø4.3mm non-locking screws can be used as independent lag screws to reduce fibula fractures, prior to fixation of an Apollo plate. The lag kit provides lag drills and guides for all three non-locking screw sizes. Also provided as desired is a washer that fits all screw heads. The core drill sizes are provided in the standard single use kit The near fragment should be drilled first with the drill matching the screw diameter. The corresponding top hat should be fully inserted into the near fragment hole and then the appropriate core drill should be used for the far fragment.



Note:

The 4.3 non-locking screw is recommended for syndesmotic fixation. The 2.9 and 3.7 non-locking screws can be used, but are not as strong as the 4.3 screw so a minimum of 2 screws are recommended.



Note:

Washers are strongly recommended for use with screws when using the lagging technique.

Surgical Procedure - One Third Tubular Plate

The Apollo one third tubular plate is a low profile plate that is designed for use in the surgical treatment of most fibular fractures, and may be used for any appropriate sized bone. The rounded ends allow for easy percutaneous insertion on the fibular shaft. All screw holes accept the Ø2.9mm and Ø3.7mm locking and non-locking screws.

Note:

If the plate is used for a fibular fracture, the most common screws sizes are available in the Quick Caddy screw delivery system.

Step 1 – Planning and Preparation

The patient is positioned on the operating room table in the supine or lateral decubitus position based on surgeon preference or fracture pattern.

A longitudinal incision is made over the distal fibula. Careful soft tissue dissection is then performed to expose the fracture site.

Step 2 – Fracture Reduction

The fracture reduction is performed using standard techniques and temporary stabilization is achieved using a K-wire (provided in the single-use kit) or a bone reduction clamp. Confirm reduction with fluoroscopy.

Step 3 – Plate sizing

Select the appropriate plate size for the fracture pattern. Sterile Trials are available to assist in determining the appropriate length of the plate. Olive wires can be used to secure the plate to the bone. Confirm plate placement using fluoroscopy.







Step 4 – Closure

Fill the screw holes with appropriate screws as described above. Confirm plate and screw placement using fluoroscopy. Proceed to incision closure or adjunctive procedures at this time.

The postoperative protocol is per surgeon preference.



Surgical Procedure – Syndesmosis Plates

The Apollo 2 and 4 hole syndesmosis plates are low profile plates designed for use in the surgical treatment of isolated syndesmosis injuries or in association with other fractures around the ankle. The screw holes accept Ø2.9mm and Ø3.7mm locking and non-locking screws, as well as Ø4.3mm non-locking screws. A suture button implant can also be used to maintain reduction of the syndesmosis.

Step 1 – Planning and Preparation

The patient is positioned on the operating room table in the supine or lateral decubitus position based on surgeon preference or fracture pattern.

A longitudinal incision is made over the distal fibula depending on the size of the plate selected.

Step 2 – Fracture Reduction

The syndesmosis is then reduced using a large bone reduction clamp such as a Weber clamp or a syndesmotic tenaculum clamp. A small indentation on the center of the plate is for use with the clamp if desired.

Small stab incisions can be made to allow placement of the reduction clamp on the medial and lateral malleolus. Confirm reduction with fluoroscopy.

Step 3 – Plate Selection

The appropriate plate size is selected and secured to the fibula with olive wires. Placement of one or two syndesmosis screws is then performed. A suture button can be used alone or in conjunction with screws to maintain syndesmotic reduction. Confirm plate and screw placement as well as maintenance of syndemsosis reduction with fluoroscopy.

Note:

The 4.3 non-locking screw is recommended for syndesmotic fixation. The 2.9 and 3.7 non-locking screws can be used, but are not as strong as the 4.3 screw so a minimum of 2 screws are recommended.







Step 4 – Closure

Proceed with wound closure or other adjunctive procedures. The postoperative protocol is per surgeon preference.





Surgical Procedure – Hook Plates

The Apollo hook plates are low profile plates designed for use in treating significantly distal or comminuted fractures or avulsion fractures of the medial and lateral malleolus that cannot be fixed with traditional plates or screws. The hooks are designed to hold the small fracture fragments while the proximal screws maintain the reduction. The screw holes accept Ø2.9mm and Ø3.7mm locking and non-locking screws as well as Ø4.3mm non-locking screws. There is a hook guide that assists with insertion of the plate. The hook guide also features two parallel drill guides to accomodate Ø2.0mm drill bits or K-wires.

Step 1 – Planning and Preparation

The patient is positioned supine on the operating room table. A longitudinal incision is made over the malleolus to expose the fracture. The fracture is then reduced.



Step 2 - Plate Placement

The hook drill guide can also be used as a drill guide for holes that allow for easier insertion of the hooks. Mate the hook plate to the drilled holes and slide the hook plate along the malleolus. The hook tamp provided as part of the handle on the plate bender can be used to seat the hooks flush with the bone. Olive wires are used to secure the plate. Fluoroscopy is performed to assess plate placement and fracture reduction.



Step 3 – Drill and Measure

For additional compression use the oblong hole. A drill hole is first drill in the proximal aspect of the oblong hole for placement of a Ø2.9mm or Ø3.7mm or Ø4.3mm non-locking screws.

This allows for compression at the fracture site up to 2mm.



Step 4 - Screw Insertion

Drill and insert appropriately sized locking or non-locking screws in the remaining screw holes. Confirm screw placement and fracture reduction using fluoroscopy.



Step 6 – Closure

Proceed with wound closure or other adjunctive procedures. The postoperative protocol is per surgeon preference.



Surgical Procedure – Medial Malleolus Plates

The Apollo medial malleolus plates are low profile plates designed for use in treating displaced medial malleolus fractures that are not amenable to lag screw fixation alone due to the fracture pattern. Most screw holes accept the Ø2.9mm and Ø3.7mm locking and non-locking screws and Ø4.3mm cancellous screws.

Step 1 – Planning and Preparation

The patient is positioned supine on the operating room table. A longitudinal incision is made over the medial malleolus. The fracture site is then exposed and the fracture is reduced. Temporary fixation is then performed using bone reduction clamps or K-wires.



Step 2 - Plate Placement

The medial malleolus plate is placed medially and can be secured with olive wires. Confirm the plate placement and fracture reduction using fluoroscopy.



Step 3 – Screw Insertion

Drill and insert appropriately sized locking or non-locking screws in the remaining screw holes. Confirm screw placement using fluoroscopy.



Step 4 – Closure

Proceed with wound closure or other adjunctive procedures. The postoperative protocol is per surgeon preference.



Surgical Procedure - Posterior Tibia Plates

The Apollo posterior tibia plates are low profile plates designed for treatment of displaced intra-articular posterior tibia fractures. All screw holes accept the Ø2.9mm and Ø3.7mm locking and non-locking screws. The distal screw holes have been designed to avoid drilling into the articular surface.

Step 1 – Planning and Preparation

The patient is placed on the operating room table in the lateral decubitus or prone position. The posterolateral approach to the ankle is used.

A longitudinal incision is made along the posterior border of the fibula. The posterior tibia is accessed by anterior retraction of the peroneal tendons. Dissect the interval between the flexor hallucis longus (FHL) tendon and peroneal tendons and then elevate the the FHL tendon off the posterior tibia. Retract the FHL tendon medially to expose the posterior tibia fracture.

It is important not to release the posterior inferior tibiofibular ligament. The fracture is then reduced and temporary fixation is done using K-wires or a bone reduction clamp.



Step 2 - Plate Placement

The appropriately size plate is placed posteriorly and temporarily fixed with olive wires. The plate placement and fracture reduction is confirmed with fluoroscopy.



Step 3 – Screw Insertion

Drill and insert a screw in the proximal hole first. This assists in reducing the fracture when the remaining distal holes are filled with appropriately sized screws. The distal hole may require drilling in the superior direction to avoid inserting the screw into the joint. Confirm the screw and placement with fluoroscopy.

Note:

The two distal holes are angled superiorly to avoid the tibiotalar joint.



Step 4 – Closure

Proceed with wound closure or other adjunctive procedures. The postoperative protocol is per surgeon preference.



Surgical Procedure – 3.7mm CREED Medial Malleolar Implant, Fully threaded and partially threaded

As an option to using the Medial Malleolar plate for fracture fixation, the 3.7mm CREED Medial Malleolar implant may be used. The CREED system has a separate dispenser box for the specialized single use instruments and implants.



3.7mm CREED Medial Malleolar Instrument Kit

Step 1 - K-wire Selection

Select 1.6mm K-wire from the CREED medial malleolar implant single use instrument kit.



Step 2 - K-wire Insertion

Insert the supplied K-wire to the proper depth. If necessary, utilize fluoroscopy to maintain reduction and control K-wire position.

In hard or sclerotic bone, perforating the cortex with the Countersink / Depth Gauge (and driver handle) prior to K-wire insertion can reduce the risk of wire deviation and heat escalation.

Note:

Please ensure there is no visible bending of the K-wire before inserting the screw. Correct K-wire placement if required.



Step 3 – Screw Length Selection

Screw length can be read directly from the Countersink / Depth Gauge at the end of the K-wire. It is dependent upon proper positioning of K-wire and seating of the Countersink / Depth Gauge against the bone.



Step 4 – Drill over K-wire

Select the 3.2 drill and drill over the k-wire to the desired depth. For poor bone quality the depth of the drilling may be shortened to gain better thread engagement on the distal end.

The screws are designed with forward cutting flutes, so depth of drill may be varied based on bone quality and best medical judgment.



Surgical Procedure – 3.7mm CREED Medial Malleolar Implant, Fully threaded and partially threaded

Step 5 – Screw Insertion

Select partially threaded or fully threaded implant and appropriate length.

Attach the provided Cannulated Screwdriver Bit to the Universal Handle, AO small to insert the appropriate screw over the previously placed K-wire.

Ensure the laser marking on the driver is aligned to the laser marking on the screw. Use this marking to appropriately align the chamfer to be flush to the bone. If power insertion is preferred the drivers are compatible.

Note:

When necessary, fluoroscopy may be used to verify K-wire and screw placement.





Step 6 – Final Reduction

Final position of the reduction and screw should be verified. The K-wire is removed and discarded. Repeat these steps as needed for additional screws.

Note:

K-wire removal can be assisted with the Countersink / Depth Gauge instruments.



Catalog Information – Implants

Distal Lateral Fibula Plates



REF	Hole Count	Orientation
F3-1001-004S	9-Hole	Left
F3-2001-004S	9-Hole	Right
F3-1001-006S	11-Hole	Left
F3-2001-006S	11-Hole	Right
F3-1001-008S	13-Hole	Left
F3-2001-008S	13-Hole	Right

One Third Tubular Plates

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REF	Hole Count	Orientation
F3-0004-004S	4-Hole	Universal
F3-0004-005S	5-Hole	Universal
F3-0004-006S	6-Hole	Universal
F3-0004-007S	7-Hole	Universal
F3-0004-008S	8-Hole	Universal
F3-0004-010S	10-Hole	Universal
F3-0004-012S	12-Hole	Universal

Syndesmosis Plates



REF	Hole Count	Orientation
F3-0005-002S	2-Hole	Universal
F3-0005-004S	4-Hole	Universal

Catalog Information – Implants

Posterior Tibial Plates



REF	Hole Count	Orientation
F3-1002-003S	5-Hole	Left
F3-2002-003S	5-Hole	Right
F3-1002-004S	6-Hole	Left
F3-2002-004S	6-Hole	Right

Medial Malleolar Plate



REF	Hole Count	Orientation
F3-0003-003S	6-Hole	Universal
F3-0003-004S	7-Hole	Universal
F3-0003-005S	8-Hole	Universal

Hook Plates

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REF	Hole Count	Orientation
F3-0006-003S	3-Hole	Universal
F3-0006-004S	4-Hole	Universal
F3-0006-005S	5-Hole	Universal
F3-0006-006S	6-Hole	Universal
3.7mm Sterile Quick Caddy



F4-3014-000S

QTY	Description
2	Ø3.7mm x 12mm Non-Locking
2	Ø3.7mm x 14mm Non-Locking
2	Ø3.7mm x 12mm Locking
2	Ø3.7mm x 14mm Locking





F4-3013-000S

QTY	Description
1	Ø2.9mm x 10mm Non-Locking
2	Ø2.9mm x 12mm Non-Locking
1	Ø2.9mm x 14mm Non-Locking
1	Ø2.9mm x 10mm Locking
2	Ø2.9mm x 12mm Locking
1	Ø2.9mm x 14mm Locking

Ø2.9mm Locking and Non-locking Screws

D: mmmme	Bannums	
Locking Ø2.9mm	Non-locking Ø2.9mm	Length
F3-1029-008S	F3-0029-008S	8mm
F3-1029-010S	F3-0029-010S	10mm
F3-1029-012S	F3-0029-012S	12mm
F3-1029-014S	F3-0029-014S	14mm
F3-1029-016S	F3-0029-016S	16mm
F3-1029-018S	F3-0029-018S	18mm
F3-1029-020S	F3-0029-020S	20mm
F3-1029-022S	F3-0029-022S	22mm
F3-1029-024S	F3-0029-024S	24mm
F3-1029-026S	F3-0029-026S	26mm
F3-1029-028S	F3-0029-028S	28mm
F3-1029-030S	F3-0029-030S	30mm
F3-1029-032S	F3-0029-032S	32.5mm
F3-1029-035S	F3-0029-035S	35mm
F3-1029-037S	F3-0029-037S	37.5mm
F3-1029-040S	F3-0029-040S	40mm

Catalog Information – Implants

Ø3.7mm Locking and Non-locking Screws

	Bumme	
Locking Ø3.7mm	Non-locking Ø3.7mm	Length
F3-1037-010S	F3-0037-010S	10mm
F3-1037-012S	F3-0037-012S	12mm
F3-1037-014S	F3-0037-014S	14mm
F3-1037-016S	F3-0037-016S	16mm
F3-1037-018S	F3-0037-018S	18mm
F3-1037-020S	F3-0037-020S	20mm
F3-1037-022S	F3-0037-022S	22mm
F3-1037-024S	F3-0037-024S	24mm
F3-1037-026S	F3-0037-026S	26mm
F3-1037-028S	F3-0037-028S	28mm
F3-1037-030S	F3-0037-030S	30mm
F3-1037-032S	F3-0037-032S	32mm
F3-1037-034S	F3-0037-034S	34mm
F3-1037-036S	F3-0037-036S	36mm
F3-1037-038S	F3-0037-038S	38mm
F3-1037-040S	F3-0037-040S	40mm
F3-1037-042S	F3-0037-042S	42.5mm
F3-1037-045S	F3-0037-045S	45mm
F3-1037-047S	F3-0037-047S	47.5mm
F3-1037-050S	F3-0037-050S	50mm
F3-1037-052S	F3-0037-052S	52.5mm
F3-1037-055S	F3-0037-055S	55mm
F3-1037-057S	F3-0037-057S	57.5mm
F3-1037-060S	F3-0037-060S	60mm

Ø4.3mm Non-locking Screws

Non-locking Ø4.3mm	Length
F3-0043-025S	25mm
F3-0043-027S	27.5mm
F3-0043-030S	30mm
F3-0043-032S	32.5mm
F3-0043-035S	35mm
F3-0043-037S	37.5mm
F3-0043-040S	40mm
F3-0043-042S	42.5mm
F3-0043-045S	45mm
F3-0043-047S	47.5mm
F3-0043-050S	50mm
F3-0043-052S	52.5mm
F3-0043-055S	55mm
F3-0043-057S	57.5mm
F3-0043-060S	60mm
F3-0043-062S	62.5mm
F3-0043-065S	65mm
F3-0043-067S	67.5mm
F3-0043-070S	70mm



Washer	Size
F3-0075-000S	7.5mm - Fits all screws

Catalog Information – Instruments





Tray Layout - Instruments



Tray Layout - Optional Reduction Instruments



	REF	Description	Quantity
1	F5-9002-000	Tray	1
2	F5-9005-000	Syndesmotic Clamp	1
3	F5-9022-000	Parallel Pin Distractor	1
4	F5-9006-000	Verbrugge Clamp	1
5	F5-9004-000	Lobster Clamp	2
6	F5-9020-000	Reduction Forceps – 8"	2
7	F5-9003-000	Reduction Forceps – 5"	2
8	F5-9009-000	Dental Pick	1
9	F5-9024-000	Tissue forcep	1
10	F5-9021-000	Hohmann Retractor – 15mm	2
11	F5-9007-000	Hohmann Retractor – 8mm	2
12	F5-9008-000	Periosteal Elevator	1
13	F5-9010-000	Curette, size 00	1
14	F5-9023-000	Distraction Pins, Tube	10

Portfolio Information



Instruments

Part No	Description	Qty
F4-3008-000	APOLLO Ankle Fracture Dispenser System	1
F4-3000-000S	Convenience Kit with 2 starter screws	1
F3-1029-010S	2.9mm / Locking Screw / 2.9 mm X 10	1
F3-1029-012S	2.9mm / Locking Screw / 2.9 mm X 12	1
F4-3002-000S	Single Use Lag Kit 2.9	1
F4-3003-000S	Single Use Lag Kit 3.7	1
F4-3004-000S	Single Use Lag Kit 4.3	1
F4-3005-000S	Single Use Hook Kit	1
F4-3006-000S	Single Use Trials	1
F4-3009-000S	K-wire Kit	2
F4-3013-000S	Quick Caddy, 2.9	2
F4-3014-000S	Quick Caddy, 3.7	2
F4-3007-000	Reduction Tray	1

Plates

Part No	Description	Qty
F3-1001-004S	Fibular Plate / Left / 9 holes	2
F3-2001-004S	Fibular Plate / Right / 9 holes	2
F3-1001-006S	Fibular Plate / Left / 11 holes	2
F3-2001-006S	Fibular Plate / Right / 11 holes	2
F3-1001-008S	Fibular Plate / Left / 13 holes	2
F3-2001-008S	Fibular Plate / Right / 13 holes	2
F3-1002-003S	Posterior Plate / Left / 5 holes	1
F3-2002-003S	Posterior Plate / Right / 5 holes	1
F3-1002-004S	Posterior Plate / Left / 6 holes	1
F3-2002-004S	Posterior Plate / Right / 6 holes	1
F3-0003-003S	Medial Mal. Plate / 6 holes	1
F3-0003-004S	Medial Mal. Plate / 7 holes	1
F3-0003-005S	Medial Mal. Plate / 8 holes	1
F3-0004-004S	1/3 Tubular Plate / 4 holes	1
F3-0004-005S	1/3 Tubular Plate / 5 holes	2
F3-0004-006S	1/3 Tubular Plate / 6 holes	2
F3-0004-007S	1/3 Tubular Plate / 7 holes	2
F3-0004-008S	1/3 Tubular Plate / 8 holes	2
F3-0004-010S	1/3 Tubular Plate / 10 holes	2
F3-0004-012S	1/3 Tubular Plate / 12 holes	2
F3-0005-002S	Syndesmotic Plate / 2 holes	1
F3-0005-004S	Syndesmotic Plate / 4 holes	1
F3-0006-003S	Hook Plate / 3 holes	1
F3-0006-004S	Hook Plate / 4 holes	1
F3-0006-005S	Hook Plate / 5 holes	1
F3-0006-006S	Hook Plate / 6 holes	1









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Portfolio Information

2.9mm Non-locking screws

Part No	Description	Qty
F3-0029-008S	2.9mm / Non-Locking Screw / 2.9 mm X 8	1
F3-0029-010S	2.9mm / Non-Locking Screw / 2.9 mm X 10	2
F3-0029-012S	2.9mm / Non-Locking Screw / 2.9 mm X 12	2
F3-0029-014S	2.9mm / Non-Locking Screw / 2.9 mm X 14	2
F3-0029-016S	2.9mm / Non-Locking Screw / 2.9 mm X 16	2
F3-0029-018S	2.9mm / Non-Locking Screw / 2.9 mm X 18	2
F3-0029-020S	2.9mm / Non-Locking Screw / 2.9 mm X 20	2
F3-0029-022S	2.9mm / Non-Locking Screw / 2.9 mm X 22	1
F3-0029-024S	2.9mm / Non-Locking Screw / 2.9 mm X 24	1
F3-0029-026S	2.9mm / Non-Locking Screw / 2.9 mm X 26	1
F3-0029-028S	2.9mm / Non-Locking Screw / 2.9 mm X 28	1
F3-0029-030S	2.9mm / Non-Locking Screw / 2.9mm X 30	1
F3-0029-032S	2.9mm / Non-Locking Screw / 2.9 mm X 32.5	1
F3-0029-035S	2.9mm / Non-Locking Screw / 2.9mm X 35	1
F3-0029-037S	2.9mm / Non-Locking Screw / 2.9 mm X 37.5	1
F3-0029-040S	2.9mm / Non-Locking Screw / 2.9mm X 40	1

2.9mm Locking screws

Part No	Description	Qty
F3-1029-008S	2.9mm / Locking Screw / 2.9 mm X 8	2
F3-1029-010S	2.9mm / Locking Screw / 2.9 mm X 10	4
F3-1029-012S	2.9mm / Locking Screw / 2.9 mm X 12	4
F3-1029-014S	2.9mm / Locking Screw / 2.9 mm X 14	4
F3-1029-016S	2.9mm / Locking Screw / 2.9 mm X 16	2
F3-1029-018S	2.9mm / Locking Screw / 2.9 mm X 18	2
F3-1029-020S	2.9mm / Locking Screw / 2.9 mm X 20	2
F3-1029-022S	2.9mm / Locking Screw / 2.9 mm X 22	1
F3-1029-024S	2.9mm / Locking Screw / 2.9 mm X 24	1
F3-1029-026S	2.9mm / Locking Screw / 2.9 mm X 26	1
F3-1029-028S	2.9mm / Locking Screw / 2.9 mm X 28	1
F3-1029-030S	2.9mm / Locking Screw / 2.9 mm X 30	1
F3-1029-032S	2.9mm / Locking Screw / 2.9 mm X 32.5	1
F3-1029-035S	2.9mm / Locking Screw / 2.9 mm X 35	1
F3-1029-037S	2.9mm / Locking Screw / 2.9 mm X 37.5	1
F3-1029-040S	2.9mm / Locking Screw / 2.9 mm X 40	1

3.7mm Non-locking screws

Part No	Description	Qty
F3-0037-010S	3.7mm / Non-Locking Screw / 3.7 mm X 10	2
F3-0037-012S	3.7mm / Non-Locking Screw / 3.7 mm X 12	2
F3-0037-014S	3.7mm / Non-Locking Screw / 3.7 mm X 14	2
F3-0037-016S	3.7mm / Non-Locking Screw / 3.7 mm X 16	2
F3-0037-018S	3.7mm / Non-Locking Screw / 3.7 mm X 18	2
F3-0037-020S	3.7mm / Non-Locking Screw / 3.7 mm X 20	2
F3-0037-022S	3.7mm / Non-Locking Screw / 3.7 mm X 22	1
F3-0037-024S	3.7mm / Non-Locking Screw / 3.7 mm X 24	1
F3-0037-026S	3.7mm / Non-Locking Screw / 3.7 mm X 26	1
F3-0037-028S	3.7mm / Non-Locking Screw / 3.7 mm X 28	1
F3-0037-030S	3.7mm / Non-Locking Screw / 3.7 mm X 30	1
F3-0037-032S	3.7mm / Non-Locking Screw / 3.7 mm X 32	1
F3-0037-034S	3.7mm / Non-Locking Screw / 3.7 mm X 34	1
F3-0037-036S	3.7mm / Non-Locking Screw / 3.7 mm X 36	1
F3-0037-038S	3.7mm / Non-Locking Screw / 3.7 mm X 38	1
F3-0037-040S	3.7mm / Non-Locking Screw / 3.7 mm X 40	1
F3-0037-042S	3.7mm / Non-Locking Screw / 3.7 mm X 42.5	1
F3-0037-045S	3.7mm / Non-Locking Screw / 3.7 mm X 45	1
F3-0037-047S	3.7mm / Non-Locking Screw / 3.7 mm X 47.5	1
F3-0037-050S	3.7mm / Non-Locking Screw / 3.7 mm X 50	1
F3-0037-052S	3.7mm / Non-Locking Screw / 3.7 mm X 52.5	1
F3-0037-055S	3.7mm / Non-Locking Screw / 3.7 mm X 55	1
F3-0037-057S	3.7mm / Non-Locking Screw / 3.7 mm X 57.5	1
F3-0037-060S	3.7mm / Non-Locking Screw / 3.7mm X 60	1

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3.7mm Locking screws

Part No	Description	Qty
F3-1037-010S	3.7mm / Locking Screw / 3.7 mm X 10	2
F3-1037-012S	3.7mm / Locking Screw / 3.7 mm X 12	2
F3-1037-014S	3.7mm / Locking Screw / 3.7 mm X 14	2
F3-1037-016S	3.7mm / Locking Screw / 3.7 mm X 16	2
F3-1037-018S	3.7mm / Locking Screw / 3.7 mm X 18	2
F3-1037-020S	3.7mm / Locking Screw / 3.7 mm X 20	2
F3-1037-022S	3.7mm / Locking Screw / 3.7 mm X 22	1
F3-1037-024S	3.7mm / Locking Screw / 3.7 mm X 24	1
F3-1037-026S	3.7mm / Locking Screw / 3.7 mm X 26	1
F3-1037-028S	3.7mm / Locking Screw / 3.7 mm X 28	1
F3-1037-030S	3.7mm / Locking Screw / 3.7 mm X 30	1
F3-1037-032S	3.7mm / Locking Screw / 3.7 mm X 32	1
F3-1037-034S	3.7mm / Locking Screw / 3.7 mm X 34	1
F3-1037-036S	3.7mm / Locking Screw / 3.7 mm X 36	1
F3-1037-038S	3.7mm / Locking Screw / 3.7 mm X 38	1
F3-1037-040S	3.7mm / Locking Screw / 3.7 mm X 40	1
F3-1037-042S	3.7mm / Locking Screw / 3.7 mm X 42.5	1
F3-1037-045S	3.7mm / Locking Screw / 3.7 mm X 45	1
F3-1037-047S	3.7mm / Locking Screw / 3.7 mm X 47.5	1
F3-1037-050S	3.7mm / Locking Screw / 3.7 mm X 50	1
F3-1037-052S	3.7mm / Locking Screw / 3.7 mm X 52.5	1
F3-1037-055S	3.7mm / Locking Screw / 3.7 mm X 55	1
F3-1037-057S	3.7mm / Locking Screw / 3.7 mm X 57.5	1
F3-1037-060S	3.7mm / Locking Screw / 3.7 mm X 60	1

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4.3mm Non-locking screws

Part No	Description	Qty
F3-0043-025S	4.3mm / Non-Locking Screw / 4.3mm X 25 mm	1
F3-0043-027S	4.3mm / Non-Locking Screw / 4.3mm X 27.5 mm	1
F3-0043-030S	4.3mm / Non-Locking Screw / 4.3mm X 30 mm	1
F3-0043-032S	4.3mm / Non-Locking Screw / 4.3mm X 32.5 mm	1
F3-0043-035S	4.3mm / Non-Locking Screw / 4.3mm X 35 mm	1
F3-0043-037S	4.3mm / Non-Locking Screw / 4.3mm X 37.5 mm	1
F3-0043-040S	4.3mm / Non-Locking Screw / 4.3mm X 40 mm	1
F3-0043-042S	4.3mm / Non-Locking Screw / 4.3mm X 42.5 mm	1
F3-0043-045S	4.3mm / Non-Locking Screw / 4.3mm X 45 mm	1
F3-0043-047S	4.3mm / Non-Locking Screw / 4.3mm X 47.5 mm	1
F3-0043-050S	4.3mm / Non-Locking Screw / 4.3mm X 50 mm	1
F3-0043-052S	4.3mm / Non-Locking Screw / 4.3mm X 52.5 mm	1
F3-0043-055S	4.3mm / Non-Locking Screw / 4.3mm X 55 mm	1
F3-0043-057S	4.3mm / Non-Locking Screw / 4.3mm X 57.5 mm	1
F3-0043-060S	4.3mm / Non-Locking Screw / 4.3mm X 60 mm	1
F3-0043-062S	4.3mm / Non-Locking Screw / 4.3mm X 62.5mm	1
F3-0043-065S	4.3mm / Non-Locking Screw / 4.3mm X 65 mm	1
F3-0043-067S	4.3mm / Non-Locking Screw / 4.3mm X 67.5 mm	1
F3-0043-070S	4.3mm / Non-Locking Screw / 4.3mm X 70 mm	1

Washer

Part No	Description	Qty
F3-0075-000S	Washer / 7.5 mm OD	2



Catalog Information – 3.7mm CREED Medial Malleolar Implants

Ø3.7mm Partially threaded

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	REF	Dimensions
	F1-0737-020S	Ø3.7 x 20 mm/Thread 7mm
	F1-0737-022S	Ø3.7 x 22 mm/Thread 7mm
	F1-0737-024S	Ø3.7 x 24 mm/Thread 7mm
	F1-0737-026S	Ø3.7 x 26 mm/Thread 7mm
	F1-0737-028S	Ø3.7 x 28 mm/Thread 7mm
	F1-1137-030S	Ø3.7 x 30 mm/Thread 11mm
	F1-1137-032S	Ø3.7 x 32 mm/Thread 11mm
	F1-1137-034S	Ø3.7 x 34 mm/Thread 11mm
	F1-1137-036S	Ø3.7 x 36 mm/Thread 11mm
	F1-1137-038S	Ø3.7 x 38 mm/Thread 11mm
	F1-1137-040S	Ø3.7 x 40 mm/Thread 11mm
	F1-1537-042S	Ø3.7 x 42 mm/Thread 15mm
	F1-1537-044S	Ø3.7 x 44 mm/Thread 15mm
	F1-1537-046S	Ø3.7 x 46 mm/Thread 15mm
	F1-1537-048S	Ø3.7 x 48 mm/Thread 15mm
	F1-1537-050S	Ø3.7 x 50 mm/Thread 15mm
	F1-1537-055S	Ø3.7 x 55 mm/Thread 15mm
	F1-2237-060S	Ø3.7 x 60 mm/Thread 22mm

Catalog Information – 3.7mm CREED Medial Malleolar Implants

Ø3.7mm Fully threaded

REF	Dimensions
F1-0037-020S	Ø3.7 x 20 mm/Fully Threaded
F1-0037-022S	Ø3.7 x 22 mm/Fully Threaded
F1-0037-024S	Ø3.7 x 24 mm/Fully Threaded
F1-0037-026S	Ø3.7 x 26 mm/Fully Threaded
F1-0037-028S	Ø3.7 x 28 mm/Fully Threaded
F1-0037-030S	Ø3.7 x 30 mm/Fully Threaded
F1-0037-032S	Ø3.7 x 32 mm/Fully Threaded
F1-0037-034S	Ø3.7 x 34 mm/Fully Threaded
F1-0037-036S	Ø3.7 x 36 mm/Fully Threaded
F1-0037-038S	Ø3.7 x 38 mm/Fully Threaded
F1-0037-040S	Ø3.7 x 40 mm/Fully Threaded
F1-0037-042S	Ø3.7 x 42 mm/Fully Threaded
F1-0037-044S	Ø3.7 x 44 mm/Fully Threaded
F1-0037-046S	Ø3.7 x 46 mm/Fully Threaded
F1-0037-048S	Ø3.7 x 48 mm/Fully Threaded
F1-0037-050S	Ø3.7 x 50 mm/Fully Threaded
F1-0037-055S	Ø3.7 x 55 mm/Fully Threaded
F1-0037-060S	Ø3.7 x 60 mm/Fully Threaded
F1-0037-065S	Ø3.7 x 65 mm/Fully Threaded
F1-0037-070S	Ø3.7 x 70 mm/Fully Threaded
F1-0037-075S	Ø3.7 x 75 mm/Fully Threaded
F1-0037-080S	Ø3.7 x 80 mm/Fully Threaded

Catalog Information – 3.7mm CREED

Medial Malleolar Instruments





Shipping Container



Notes



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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Ref: APO-OT-Ed1-07-25-EN