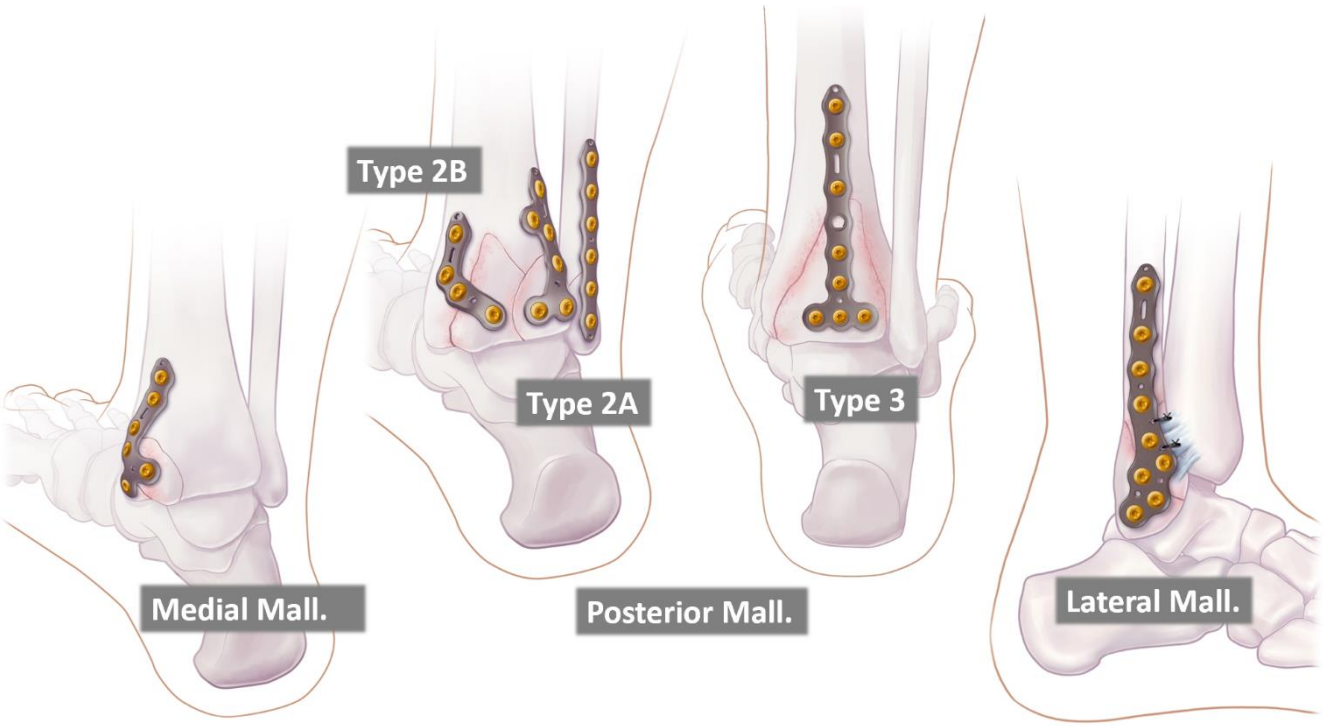
VOLITION™
PLATING SYSTEM

Ankle Fracture Plates

featuring V-Lock™ Technology

Surgical Technique

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.



System Overview

1. Volition™ Ankle Fracture Plates are available in six varieties: anatomic fibula plate, straight fibula plate, anatomic medial malleolar plate, posteromedial tibial plates (Type IIB), posterolateral tibial plates (Type IIA) and posterior tibial plates (Type III). The specific posterior tibial fracture plates are designed around the Mason & Molloy classification [Mason et al. Foot Ankle Int. 2017 Nov;38(11):1229-1235].
2. Volition™ Plating System non-locking screws are compatible with washers and any screw hole in the plates.
3. Volition™ Plating System locking screws are compatible with any screw hole. Locking screws are not compatible with washers.

4. Olive wires may be inserted in any screw hole or wire slot. Alternatively, k-wires may also be used to temporarily affix the plate to the bone thru specific k-wire holes or wire slots within the plates.
5. All plate screws (**Figure 1**) may be inserted through the screw holes in a ±15° conical range of trajectories.

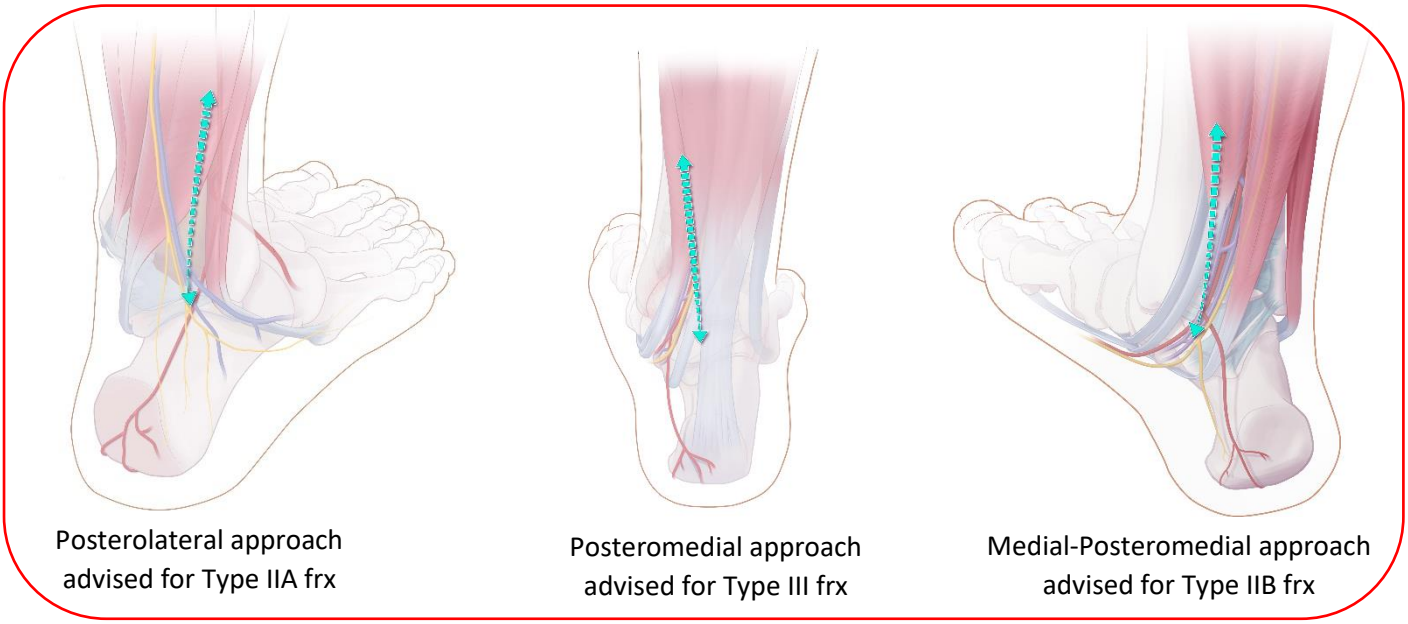
Figure 1

6. Pilot hole drill bits & drill guides include a single-stripe colored band denoting the color of their intended screw. Lag drill bits & drill guides are differentiated with a double-stripe colored band.

   Note: Variable angle (conical) drill guides and the depth gauge extension are compatible with all 3 diameters of pilot hole drill bits and therefore do not have any colored bands.

Approach & Fracture Reduction

7. Use standard approaches and techniques for medial and lateral malleolar fracture fixation. Suggested various posterior tibial approaches depicted below (**Figure 2**) may be used to optimize appropriate exposure relative to specific posterior tibial fracture classifications, based on the fracture specific plates, in accordance with the M&M algorithm.



Posterolateral approach advised for Type IIA frx

Posteromedial approach advised for Type III frx

Medial-Posteromedial approach advised for Type IIB frx

Figure 2

8. Expose the anatomy and then clean and reduce the fracture as per standard fracture care and protocols.
9. Use an appropriately sized powered k-wire driver to advance k-wires to temporarily hold the reduced bone fragments in place, if desired.

   Warning: The k-wires and olive wires are not intended to be left as permanent implants.

Screw and Washer Fixation (Without Plate)

10. Non-locking screws may be used to stabilize fractures without a plate. Compatible washers are also provided for optional use.
11. The Volition™ plate screws are fully threaded so, when used without a plate, lag-drill techniques (**Figure 3)** should be used to apply compression between two bone fragments. Lag technique may also be required for partially threaded cannulated screws.
12. Drill pilot holes and lag (glide) holes for the screw using appropriately sized drill bits and handheld drill guides per the drill bit size compatibility table below. Drill bits feature an AO connector to attach to powered drills with AO couplers and lag guides indicated with double epoxy color bands (**Figure 4**).

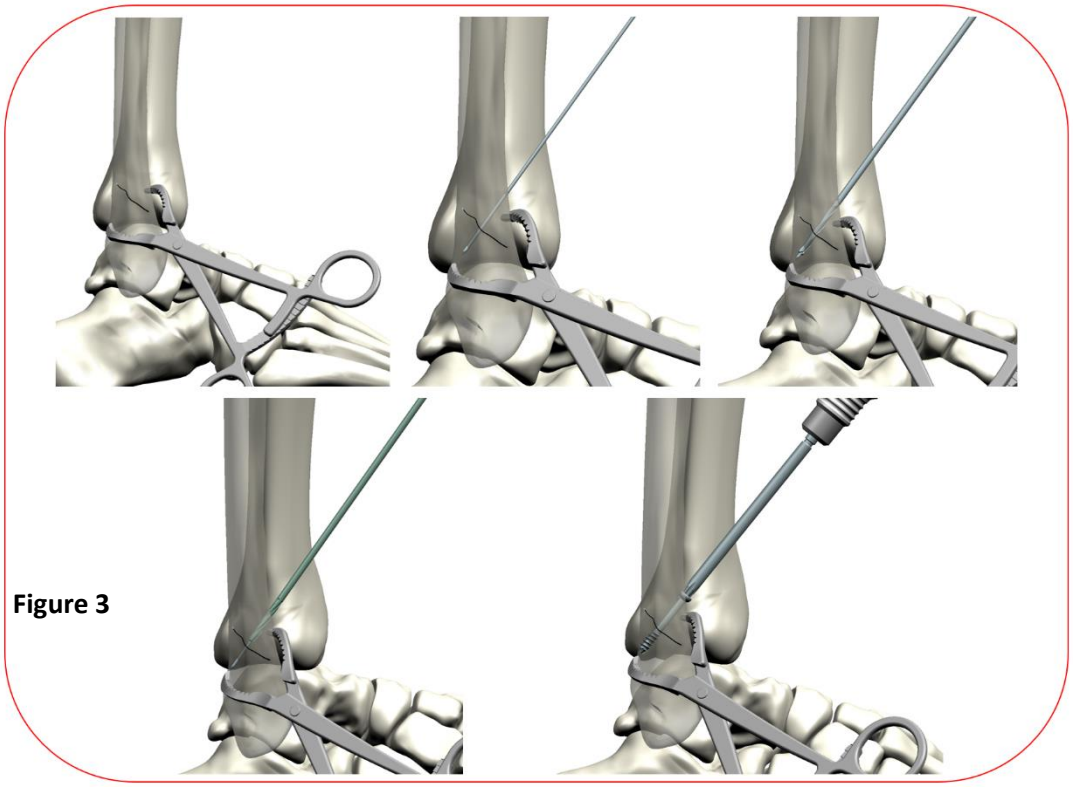


Figure 3

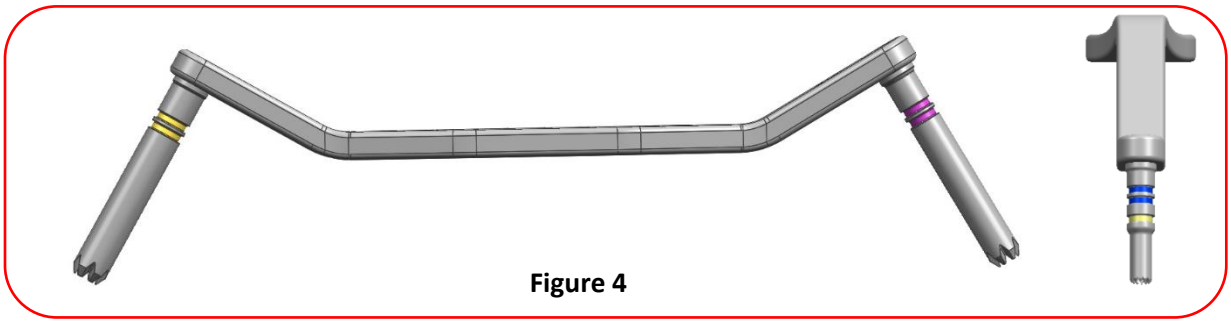


Figure 4

Precaution: When intending to use a washer, do not exceed the ±15° conical range of compatible trajectories.

Precaution: Do not attempt to read depth measurements from the top of the drill guides. Use depth measurement instruments only as instructed in this technique.

Screw Dia. (mm)	Pilot Drill Bit Dia. (mm)	Lag Drill Bit Dia. (mm)
Ø2.7	Ø1.9	Ø2.7[1]
Ø3.5	Ø2.4	Ø3.5
Ø4.0	Ø2.7[1]	Ø4.0

Drill bit size compatibility

Note: A depth gauge extension may be optionally threaded into the top of the handheld pilot hole drill guide to determine the depth during drilling. The depth gauge extension is not compatible with the lag drill guides. The first digit is read from the drill bit and the second digit is read from the drill guide (e.g. "5" on the drill bit and "0" on the guide yields a 50 mm depth) as per **Figure 5**.

Figure 1: *Example depth gauge extension depiction of 50 mm depth*

13. If the pilot hole depth wasn't measured during drilling, use the standard depth probe to measure the drilled depth by placing the narrow end of the outer housing directly against the near cortex and sliding the probe to hook on the far cortex.

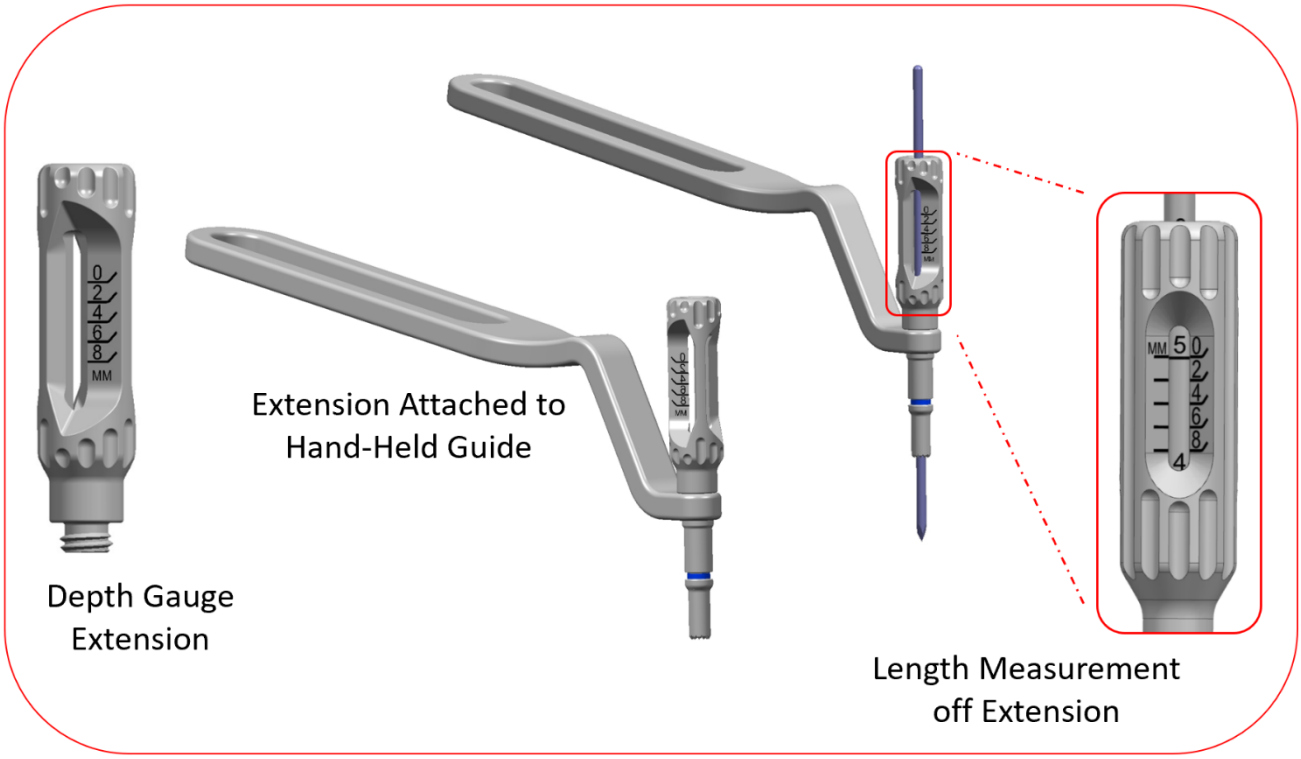


Figure 5

[1] The Ø2.7 mm drill bit and drill guides are dual purpose: for use with Ø4.0 mm screws (pilot hole) and for Ø2.7 mm screws (lag).

14. Countersinks are provided to optionally ream the near cortex to minimize screw head prominence when used without a plate or washer. If desired, attach the AO countersink to either AO handle before countersinking the bone.
    Precaution: Do not use the countersink with powered instruments.
15. Attach the AO screwdriver bit to either AO handle to insert the screw.
    Precaution: Do not use the screwdriver bits with powered instruments.

Plate Fixation

16. Fit the plate to the bone, if needed, to capture the bone fragments.
17. Two styles of plate bending instruments (**Figure 6**) are provided to optionally contour the plates to fit the bone. Plate bending pliers feature flat jaws to grip various positions on the plates. Plate bending irons feature various flat and curved slots to fit the plates in multiple positions.

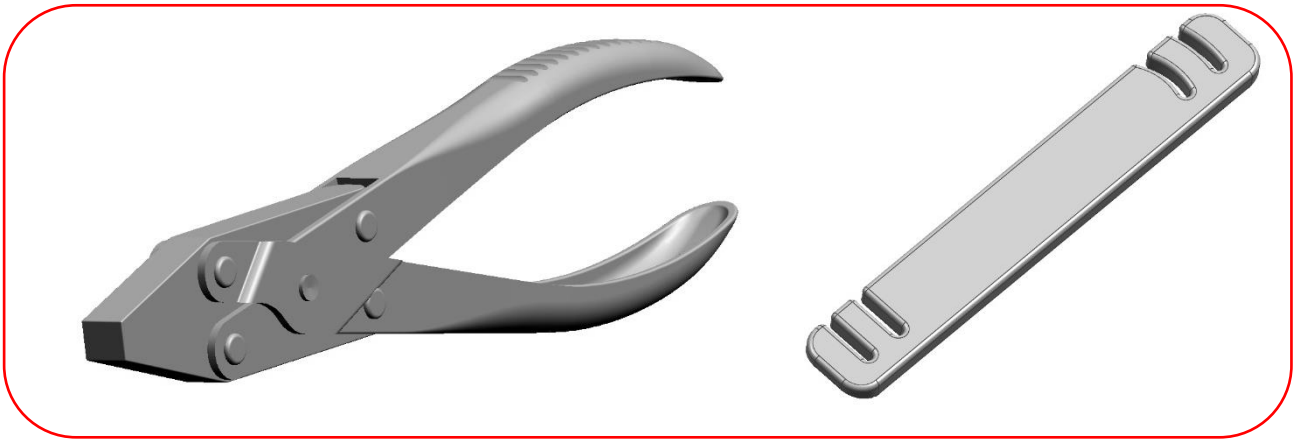


Figure 6

Precaution: Contouring or bending implants should be avoided, where possible, because it may reduce the device's fatigue strength. If contouring is necessary, avoid sharp bends, reverse bends, or bending the device at a screw hole. When contouring implants, only Ortho Solutions instruments must be used in accordance with the specified protocols.

18. Use two or more olive wires, or Ø1.6 mm k-wires, to temporarily affix the plate to the bone before screw insertion. Olive wires may be inserted through any of the plate's screw holes, k-wire holes or wire slots. Alternatively, Ø1.6 mm k-wires may be inserted through any of the plate's k-wire holes or wire slots. Use an appropriately sized powered k-wire driver to advance the olive wires and k-wires.
19. Drill pilot holes for the screws using appropriately sized drill bits and drill guides (**Figure 7**). If off-axis screw trajectory is desired, used the appropriately sized conical drill guides by threading them into the plate hole; each screw size has a corresponding drill guide – tower guides for on-axis drilling or conical guides for off-axis drilling. Alternatively, simple hand-held guides may be used to drill for non-locking screws.
    Note: When loading the olive wires into a wire collet, please note that the proximal end of the olive wires is to 2.0mm.
    Warning: Do not use Ø2.0 mm k-wires through the plates.
20. In the instance of an unstable Wagstaffe fragment, it is suggested to pass the suture thru the two specific holes adjacent to the Wagstaffe fragment and into the AITFL as illustrated in **Figure 8**.

Figure 7

Precaution: Do not exceed the ±15° conical range of compatible trajectories in any screw hole.

Note: The drilled depth may also be measured using the fixed angle drill guide using the same technique as described per Note 1 above and depicted per **Figure 5**.

21. If the pilot hole depth wasn't measured during drilling, use the standard depth probe to measure the drilled depth by placing the narrow end of the outer housing directly against the near cortex/plate hole and sliding the probe to hook on the far cortex.
22. Attach the AO screwdriver bit to either AO handle to insert the screw.

    Precaution: Do not use the screwdriver bits with powered instruments.
23. Implant as many screws as necessary to stabilize the bone fragments. Additional screws may be implanted outside the plate as per **Screw and Washer Fixation (Without Plate)** above.

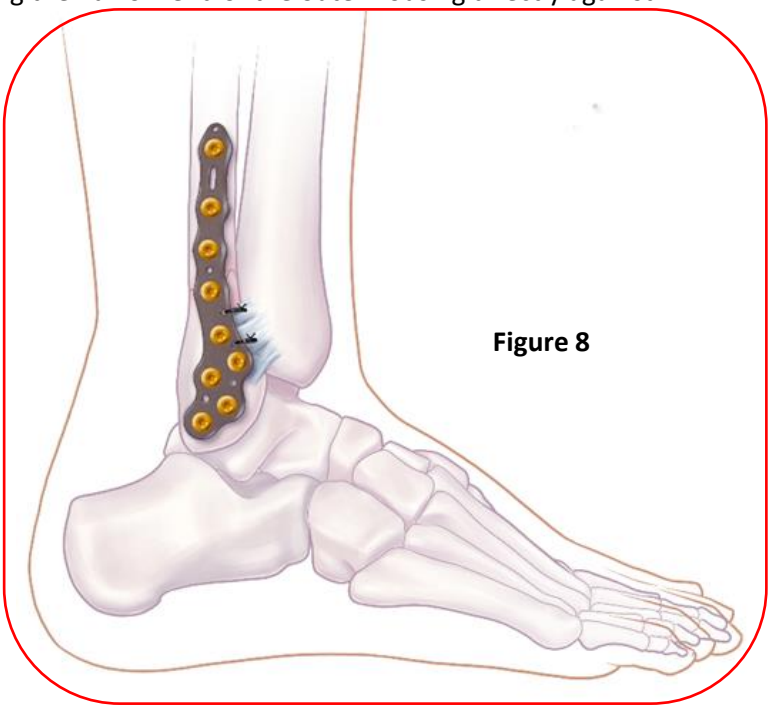


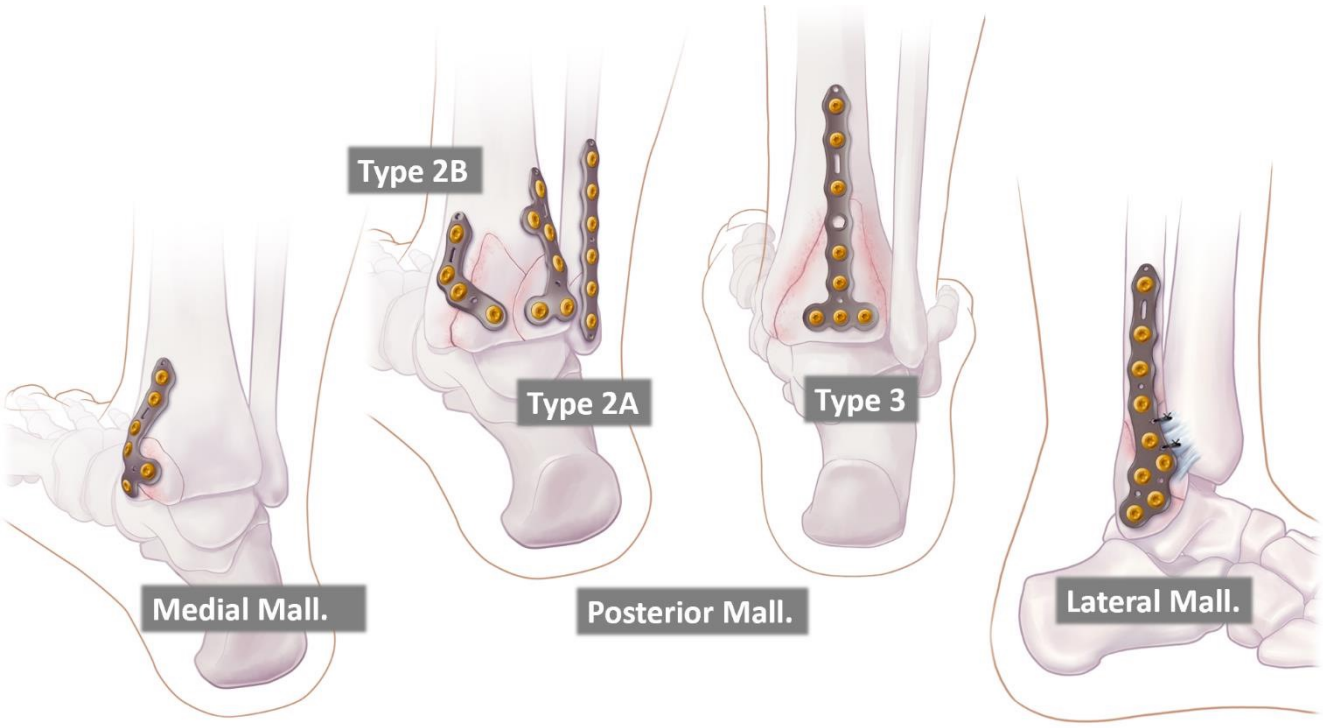
Figure 8

Surgery Completion

24. Remove any temporary fixation wires, instruments, or other non-implantable components from the patient prior to the completion of surgery.
25. Check implant positioning in 2 planes using fluoroscopy.
26. Close the surgical incision using the desired technique.

Contact Information

Report any serious incident that has occurred in relation to the device to Ortho Solutions.



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Ankle Fracture Plates featuring V-Lock™ Technology

THE EVIDENCE-BASED ANKLE FRX SOLUTION

OrthoSolutions Group

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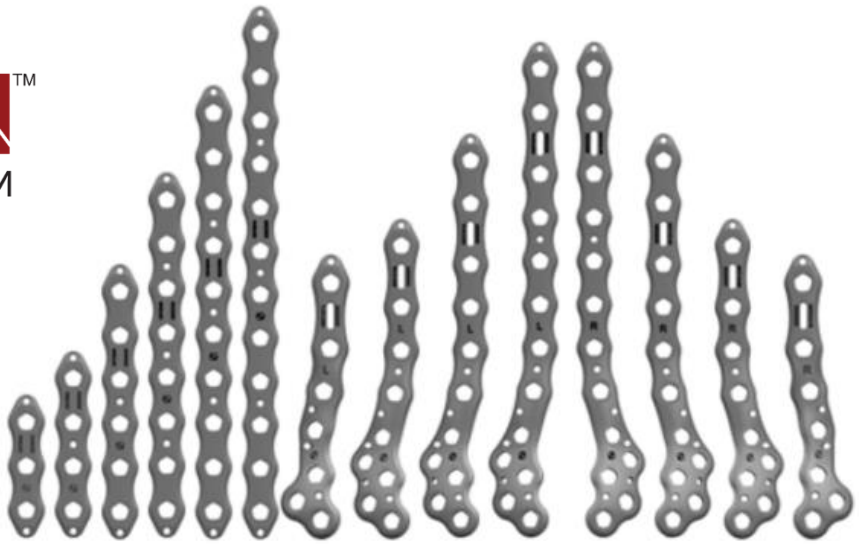
Ankle Fracture Plates



featuring

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Rx only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

www.orthosolutions.com

Consult instructions for use

CE 2797 [2]

Surgeon must be fully trained in the surgical technique

OS TD 00105_19 – Rev 01 –
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[2] CE marking and the notified body number is applied per part number and appears on the device packaging, or the device if applicable.