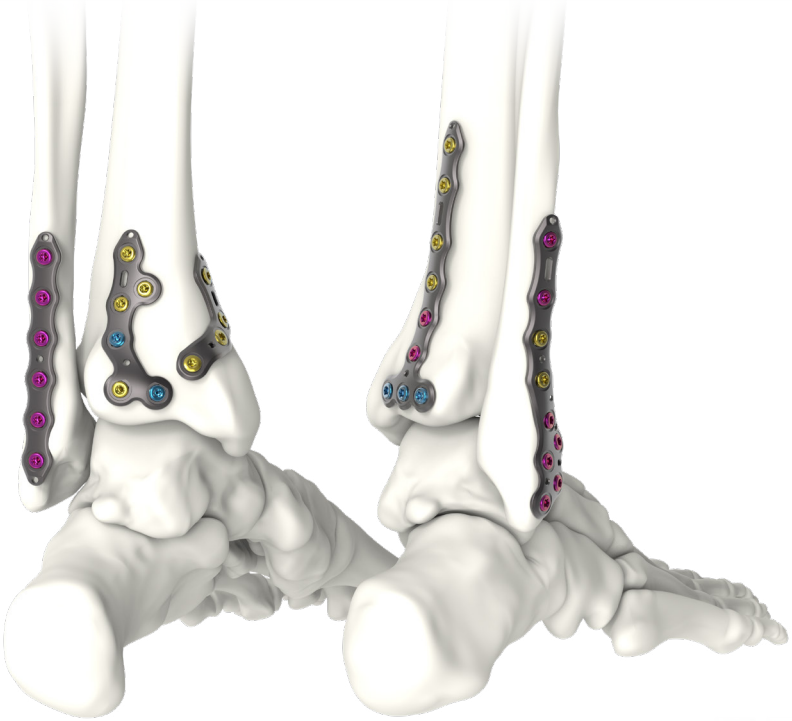
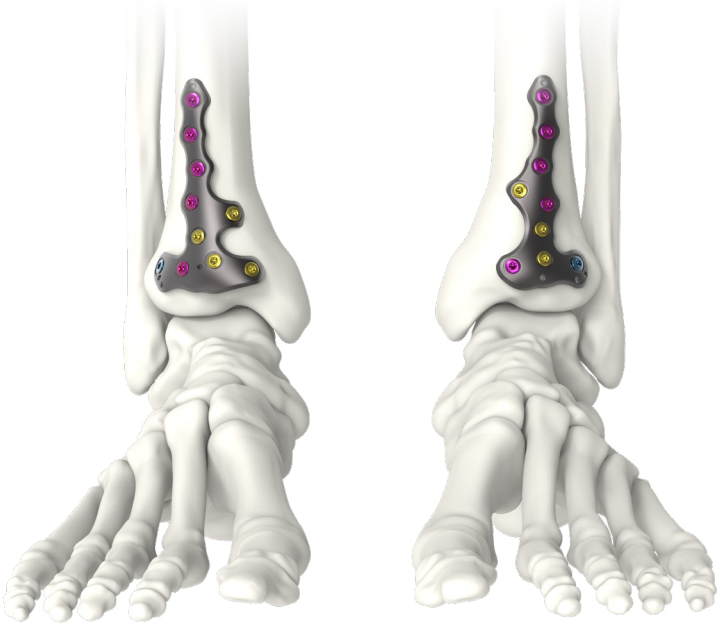




VOLITION® Ankle Fracture Surgical Technique

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

OrthoSolutions Group

Advancing Foot & Ankle Care

CONTENTS

This surgical technique guide is intended as a reference for trained orthopaedic surgeons. It does not replace the full Instructions for Use (IFU), which contains material/allergen/biocompatibility information, indications, contraindications, warnings and precautions, sterilisation/processing instructions, an MRI safety statement and other information critical to safe and effective device usage.

Surgeons should consult the IFU before use. The IFU for the Volition® Plating System is available electronically at www.orthosol.com/eIFU or in paper form upon request by contacting regulatory@orthosol.com.

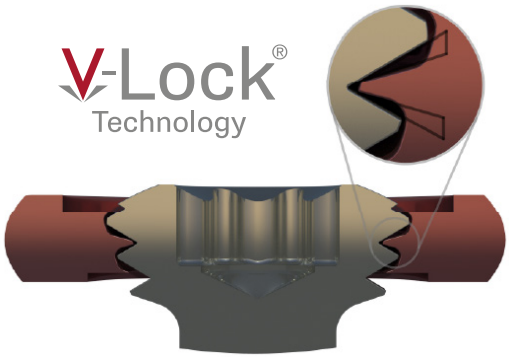
1. VOLITION®
Ankle Fracture Plating System Overview

1.1 VOLITION® Ankle Fracture Plating System

- Comprehensive plating system including lateral malleolus, posterior malleolus, medial malleolus, and anterior plating options
- Several plates feature recessed holes designed to accommodate off-axis screws while minimising screw head prominence
- All threaded screw holes accept 2.7mm, 3.5mm or 4.0mm non-locking and polyaxial locking screws
- All tibia plates feature a low-profile 1.5mm thickness, while fibular plates feature a transitional thickness ranging from 1.3mm to 1.8mm
- All plates feature tapered proximal and distal ends to facilitate smooth percutaneous insertion
- All plates are equipped with V-Lock® Technology which allows easy locking on or off-axis with minimal cross-threading
- All plates are made of titanium and are Type II Anodised

1.2 V-Lock® Technology

V-Lock® Technology provides secure, polyaxial screw locking with up to 30 degrees of conical freedom, giving surgeons the flexibility to optimise screw trajectory. The system allows controlled polyaxial screw placement before locking and offers a simplified technique while maintaining the benefits of a locking construct.

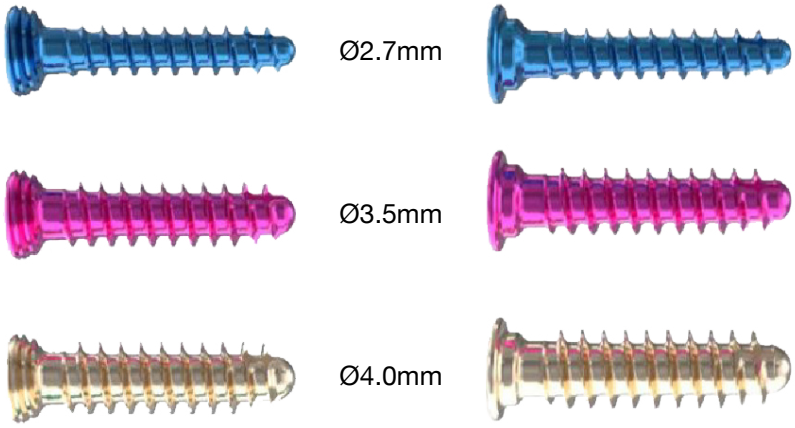


1.3 VOLITION® Screw Fixation

The Volition® Plating System non-locking screws are compatible with washers and any screw hole in the plates.

The Volition® Plating System locking screws are not compatible with any oblong hole; compression slot. Locking screws are also not compatible with washers.

All plate screws may be inserted through the screw holes in a ±15° conical range of trajectories. All plate screws utilise a self-retaining T10 Screwdriver bit (OS721010-NS).



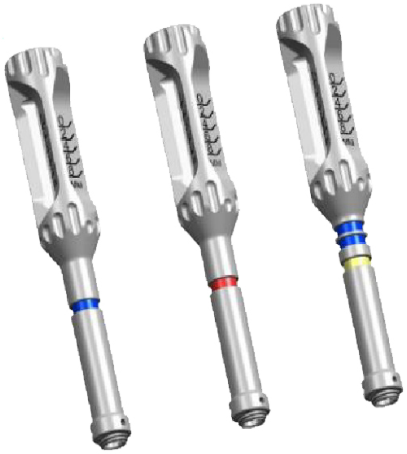
Locking Screws

Non-Locking Screws

30° conical locking capability

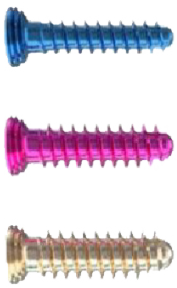
1.4 Drill Guides & Measurement

Drill guide devices correlate specifically to the diameter of the screw which is intended to be used, and hence the appropriately sized drill bit.

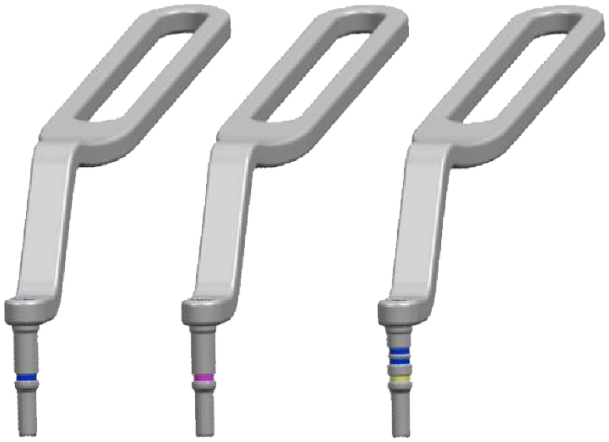


Fixed-Angle Drill Guides (Towers)

Variable-Angle Drill Guides (Cones)



Color Scheme:
Blue: Ø2.7mm
Magenta: Ø3.5mm
Gold: Ø4.0mm



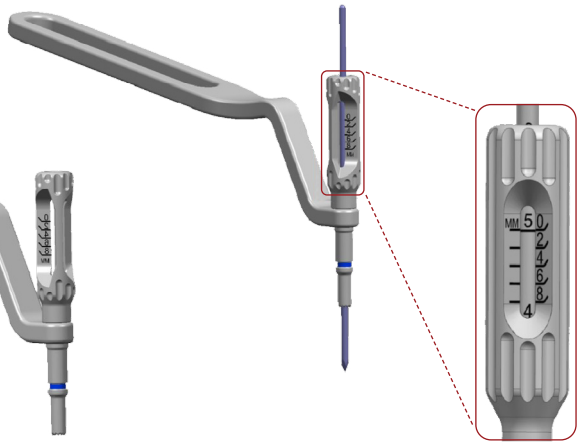
Hand-Held Drill Guides for NL Screws

Depth gauge extensions are compatible with all 3 diameters of pilot hole drill bits and therefore do not have any coloured bands. They are not compatible with lag drill guides.

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 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 50mm depth)

Depth Gauge Extension

Extension Attached to Hand-held Guide



Length Measurement off Extension

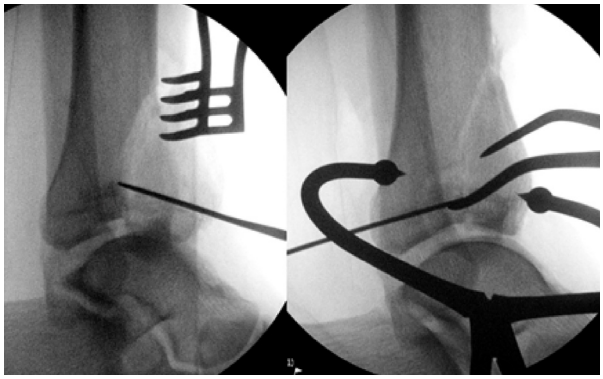
2. Surgical Guidance

2.1 Site Preparation & Temporary Fixation

Use standard approaches and techniques to expose the anatomy.

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 & olive wires are not intended to be left as permanent implants*

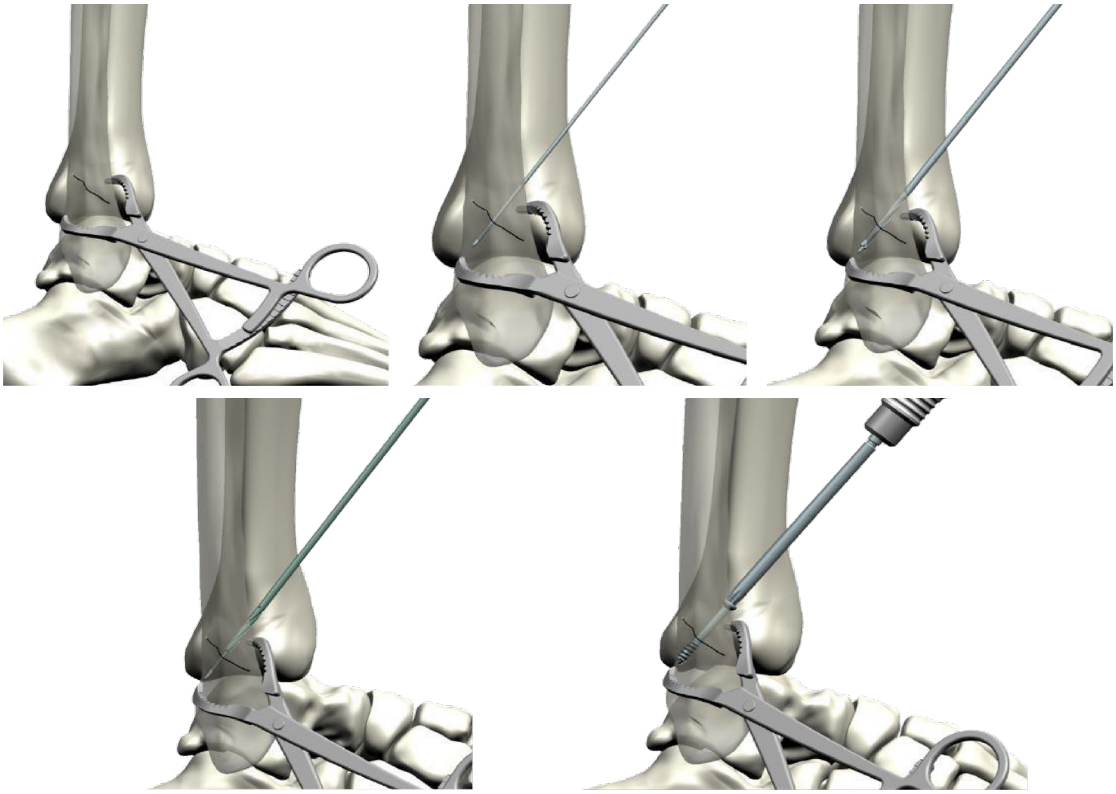


An intra-operative, x-ray example of a typical technique for reducing a fracture fragment

2.2 Screw & Washer Fixation (Outside of Plate)

The Volition® Plating System non-locking plate screws may be used for fixation of fractures, fusions, and osteotomies. Compatible washers are also provided for optional use (OS710000-S). Alternatively, partially threaded 4mm headed or headless cannulated screws are provided within the set for use, if desired.

The Volition® Plating System non-locking plate screws are fully threaded so, when used without a plate, lag-drill techniques should be used to apply compression between two bone fragments.



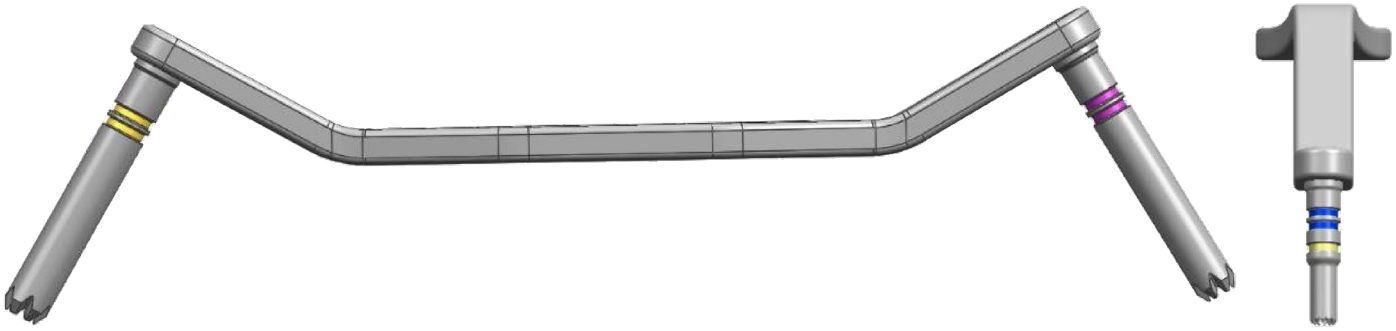
An illustrative example that shows a typical ‘lag-drill’ technique

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.

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

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

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.



Drill bit size compatibility

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

If the pilot hole depth was not measured during drilling, use the UltOS/Volition depth gauge (OS328001-NS) 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.

Countersinks are provided to optionally ream the near cortex to minimise screw head prominence when used without a plate or washer. If desired, attach the relevant AO countersink to either AO handle.

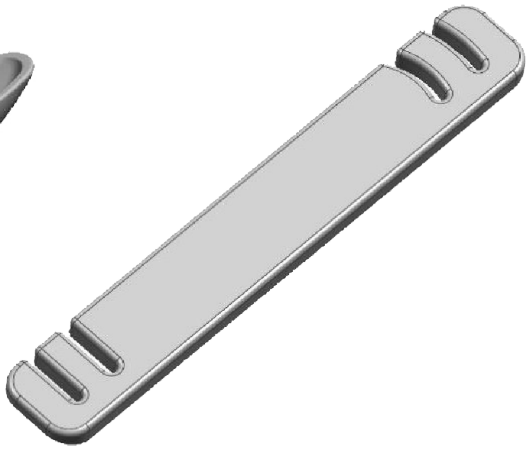
Precaution: Do not use the countersink with powered instruments.

Precaution: Do not use the screwdriver bit with powered instruments.

2.3 Plate Fixation

Choose the desired plate to implant and fit the plate to the bone, if needed, to capture the bone fragments.

Two styles of plate bending instruments 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.

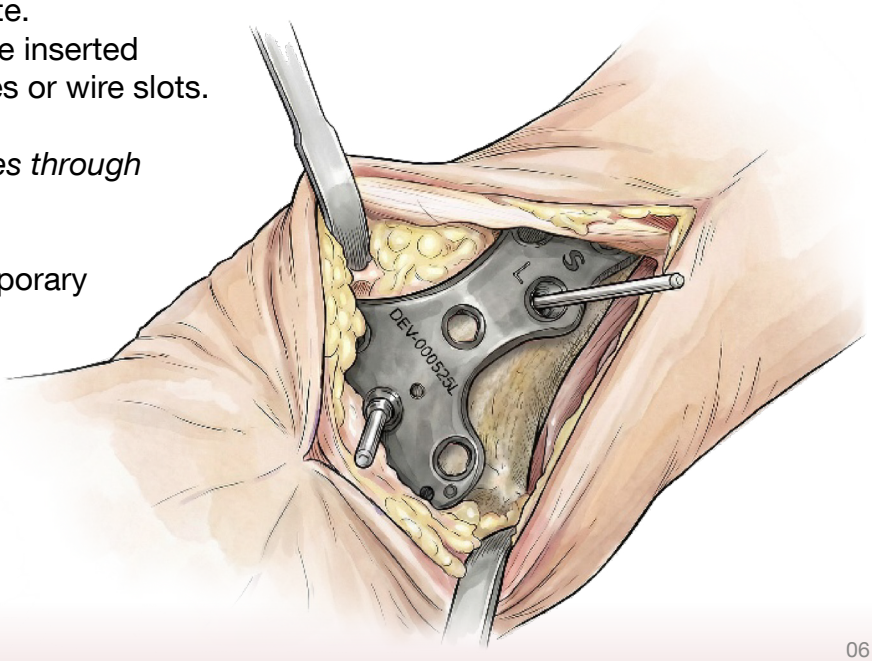


Precaution: Contouring or bending implants should be avoided, where possible, as it may reduce the device's fatigue strength. If contouring is necessary, avoid sharp bends, reverse bends, or bending the device at a screw hole. When contouring implants, only designated Ortho Solutions® instruments are to be used in accordance with the specified protocols (UltOS 3.5mm Parallel Plate Bending Pliers, OS328008-NS or the Plate Bending Iron, OS721004-NS).

Use two or more olive wires (OS722216-S or OS722116-S), or any Ø1.6mm k-wires, to temporarily affix the plate to the bone before screw insertion.
Olive wires (OS722216-S or OS722116-S) may be inserted through any of the screw holes within the plate.
Alternatively, Ø1.6mm k-wires may be inserted through any of the plate's k-wire holes or wire slots.

Warning: *Do not use Ø2.0 mm k-wires through the plates.*

(An illustrative example showing temporary fixation of a plate to bone before screw insertion)



Drill pilot holes for the screws using appropriately sized drill bits and drill guides as previously mentioned. If an ‘off-axis’ screw trajectory is desired, use the appropriately sized conical drill guides by threading them into the plate hole; each screw size has a corresponding drill guide. If an ‘on-axis’ screw trajectory is desired, use the appropriately sized tower drill guides by threading them into the plate hole; each screw size has a corresponding drill guide. Alternatively, simple hand-held guides may be used to drill for non-locking screws.

Precaution: Do not exceed the ±15° conical range of compatible trajectories in any screw hole.
Note: The drilled depth may also be measured via the aforementioned technique from the depth gauge extender, by using the fixed angle drill guide or via a standard depth gauge.

If the pilot hole depth was not measured during drilling, use the UltOS/Volition depth gauge (OS328001-NS) 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. Attach the AO screwdriver bit to either AO handle to insert the screw.

Precaution: Do not use the screwdriver bit with powered instruments.

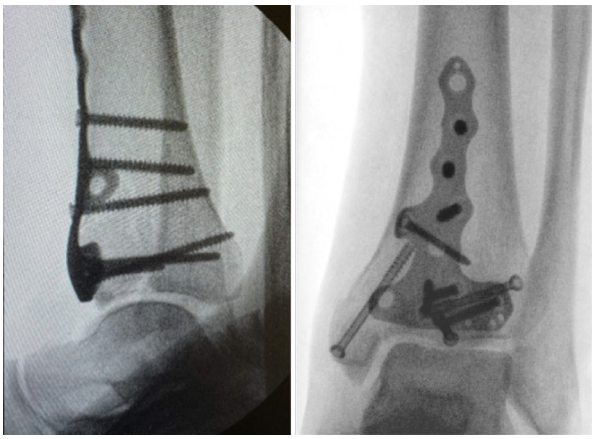
Implant as many screws as necessary to stabilise the bone fragments. Additional screws may be implanted outside the plate as described earlier.

2.4 Surgery Completion

Remove any temporary fixation wires, instruments, or other non-implantable components from the patient prior to the completion of surgery.

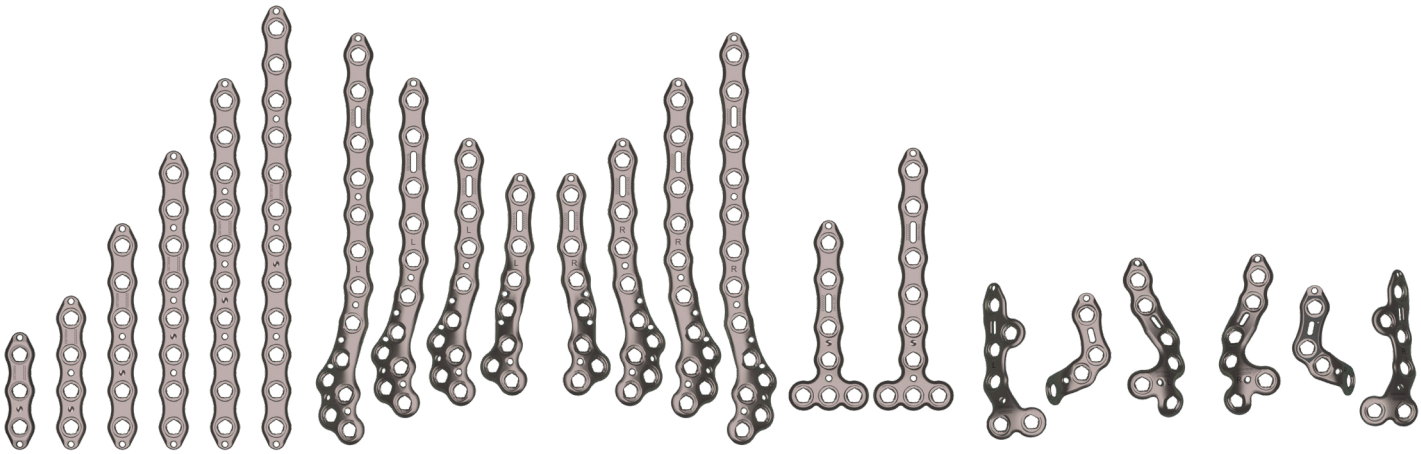
Check implant positioning using fluoroscopy.

Close the surgical incision using the desired technique.



(A typical example showing final implant position using fluoroscopy in a sagittal and antero-posterior plane)

Notes:



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Consult instructions for use

CE 2797 *1

Surgeon must be fully trained in the surgical technique