ANIKA

CheckMate®

MTP Arthrodesis System

Surgical Technique Guide

The CheckMate MTP Arthrodesis System features low-profile, anatomically pre-contoured Bone Plates with either a combination of locking and non-locking holes or all-locking variable angle holes for primary or revision cases.

CheckMate Introduction

The CheckMate® Metatarsophalangeal (MTP) Arthrodesis System consists of anatomically contoured bone plates, and screws (locking, non-locking, bail-out, and interfragmentar), which are intended to be used for surgical fusion (arthrodesis) of the 1st MTP joint.

The CheckMate surgical instruments are designed to be used in the sizing, location, and delivery of the CheckMate bone plate and bone screw fixation components. These instruments (except the guide pin, drill pin and tack pins i.e. the pin kit) are designed for repeated use, with proper care and handling.

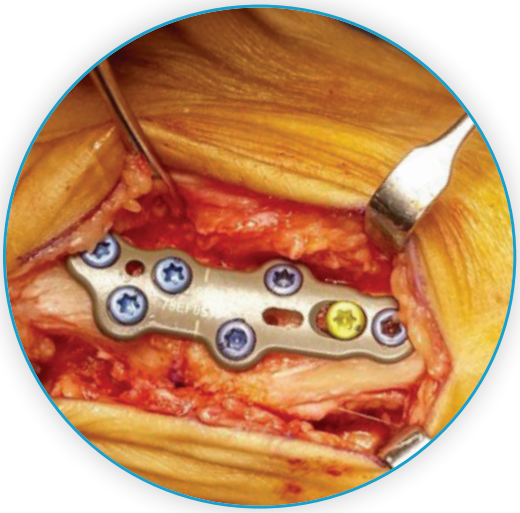
- Low profile & anatomically pre-contoured plates for ease of use and reproducible outcomes
- High stiffness anodized plate for maximum stability
- Interfragmentary Screw Guide provides accurate & rapid installation
- Individual Bone Plates provided completely packaged & sterile

Materials

Materials	
Bone Plates:	Titanium Alloy (Ti-6Al-4V)-Anodized Type II
Locking Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Blue
Non-Locking Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Gold
Bail-out Screws:	Titanium Allow (Ti-6Al-4V)-Anodized Gold
Interfragmentary Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Magenta
Surgical Instruments:	Medical Grade Titanium, Stainless Steel and High Temperature Plastics

Indications for use

The CheckMate® Metatarsophalangeal (MTP) Arthrodesis System is intended for use in stabilization and fixation of the 1st MTP joint in the foot for fusion, osteotomy, nonunion, malunion or revision surgery.

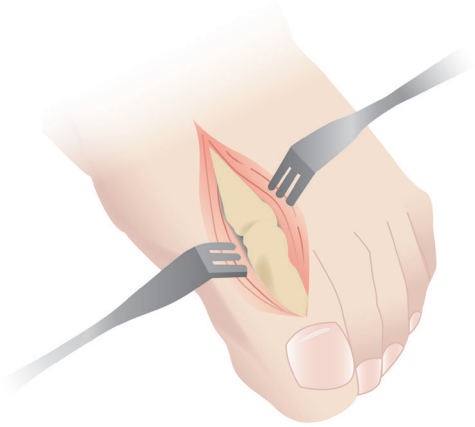


Surgical Technique

CheckMate 1.0 (100 series plate)

Step 1

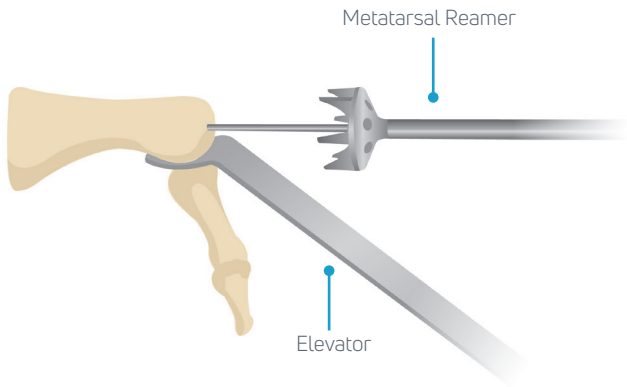
Make a dorsal longitudinal incision to expose 1st MTP joint. Release joint capsule to expose 1st metatarsal and phalangeal bones. Remove all osteophytes/bone spurs before joint surface preparation.



Step 2

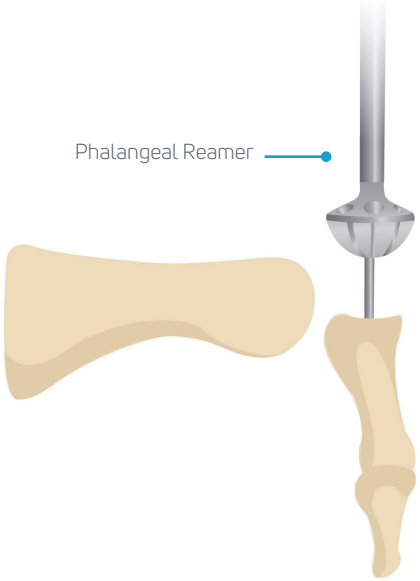
Insert a proximally directed 2.5 mm **Guide Pin** through the center of the metatarsal head and into the diaphysis. Use the **Metatarsal Reamer** to ream the metatarsal head in a dome-shaped fashion until subchondral bone is exposed. Care should be taken to avoid reamer contact with the sesamoids and to prevent excessive metatarsal shortening.

Note: The cannulated power drill should be powered on before advancing **Reamer** onto the bone surface to avoid aggressive bone removal.



Step 3

Similarly, ream the surface of the proximal phalangeal base using a matched **Phalangeal Reamer**. Check that the prepared joint surfaces are congruent. If not, re-ream the joint surface(s) until they are conforming.



Step 4

Using a **Guide Pin**, subchondral drilling (4 to 6 holes) on both sides of the fusion site may be performed at this time to open up bony channels; alternatively, a DBM (demineralized bone matrix) product or graft can be used to fill defects as needed.

Step 5

Reduce and align the 1st MTP joint in the desired orientation of fusion. A k-wire can be used to temporarily stabilize the joint.

Step 6

Select the appropriate **Bone Plate** based on your preference and/or the patient's needs.

Note: Both the standard and all-locking Bone Plates are available in 2 configurations, 145R and 145L. These indicate plate compatibility with orientation of the **IF Screw**. Refer to the following table to select appropriate plate based on your preferred orientation of the **IF Screw**:

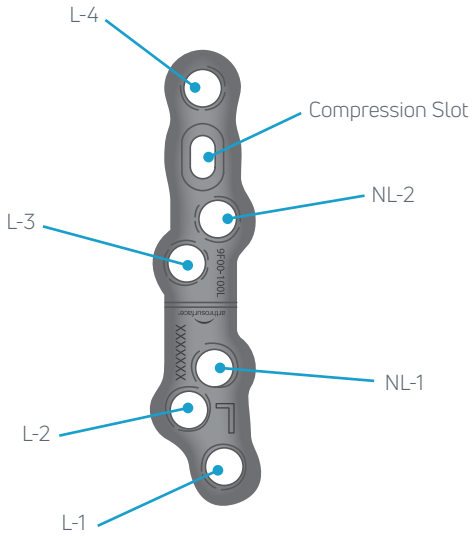
Desired Orientation of Interfragmentary Screw		
Foot	Distal to Proximal	Proxial to Distal
Right Foot	145R	145L
Left Foot	145L	145R

Note: Optional Plate Contouring can be performed using the provided Benders to increase or decrease the dorsiflexion angle to match the patient specific anatomy.

Step 7

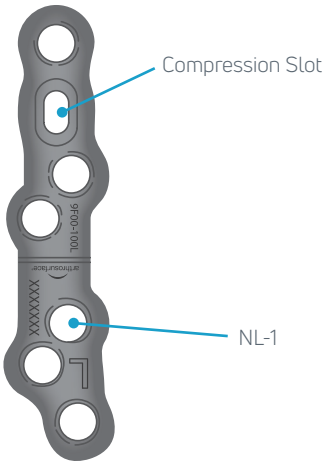
The following technique steps are shown for the 1.0 or 100 series bone plates having a combination of locking and non-locking holes.

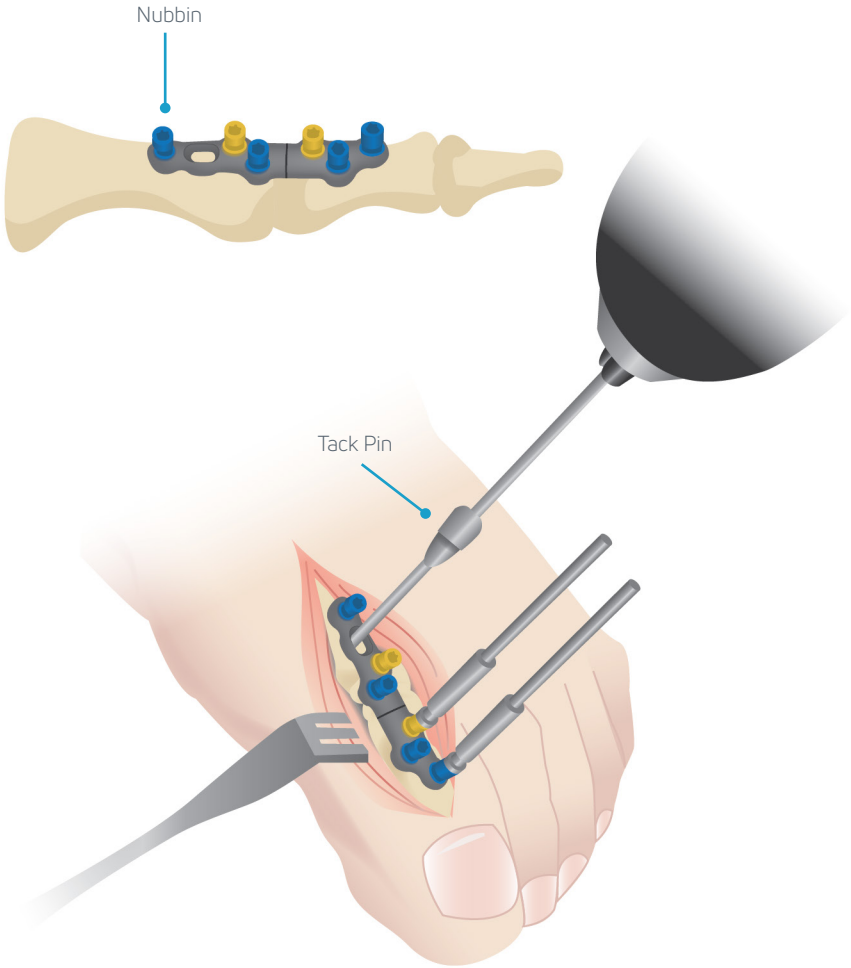
1.0 or 100 Series Plate



Step 8

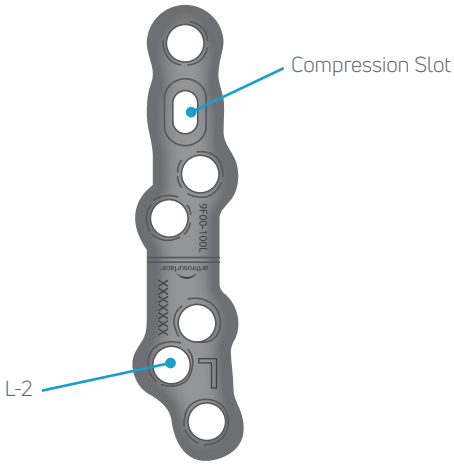
Align the laser etch mark on the plate with the joint and affix the plate to the metatarsal and phalanx in this position by inserting (using a wire driver) one **Threaded Tack Pin** into the proximal most end of the **Compression Slot** and another **Threaded Tack Pin** into hole **NL-1** (the one having a **Gold Nubbin**; for additional stability, tack pins may be inserted in the remaining distal holes at this point).

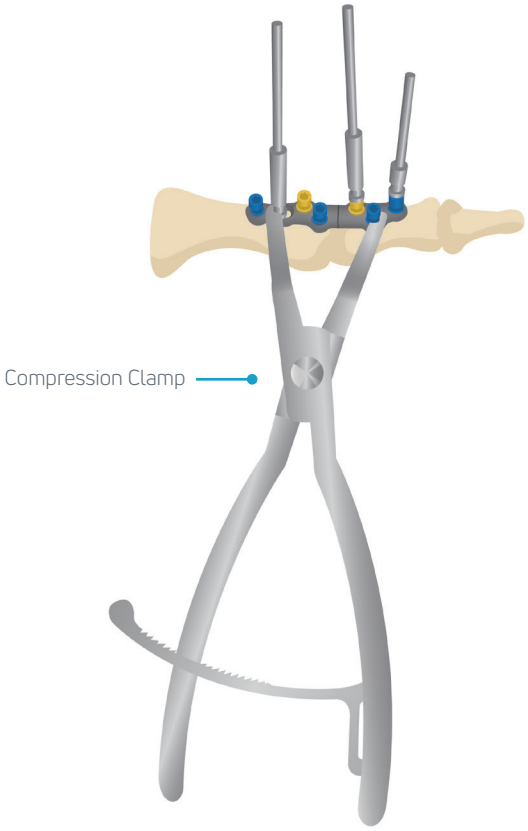




Step 9

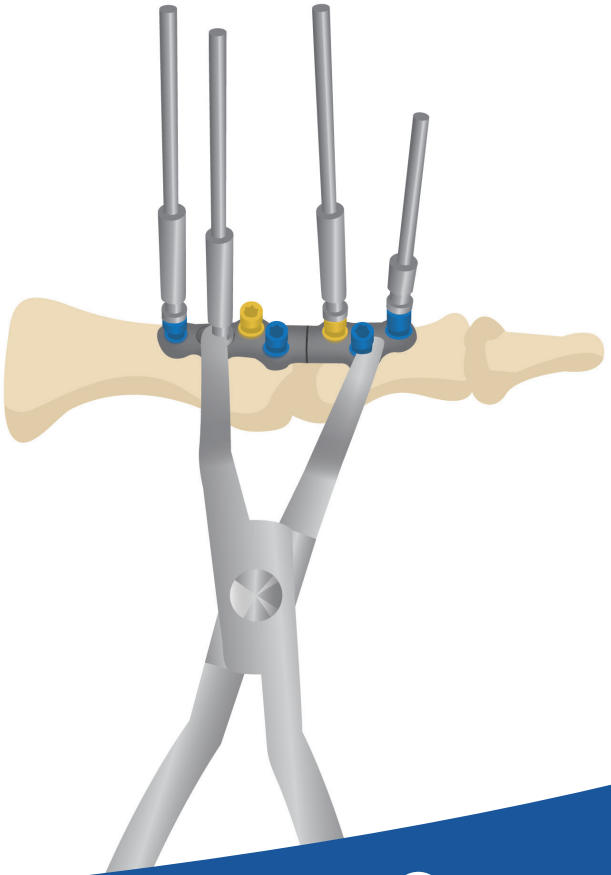
Apply compression to the joint using the **Compression Clamp** positioned on the compression slot tack pin, and hole **L-2 Nubbin (Blue)**.





Step 10

While maintaining compression, insert a **Non-Threaded Tack Pin** in hole **L-4** (the one having a **Blue Nubbin**; tack pins may be inserted in the remaining holes on the proximal segment of the plate at this point for additional stability).

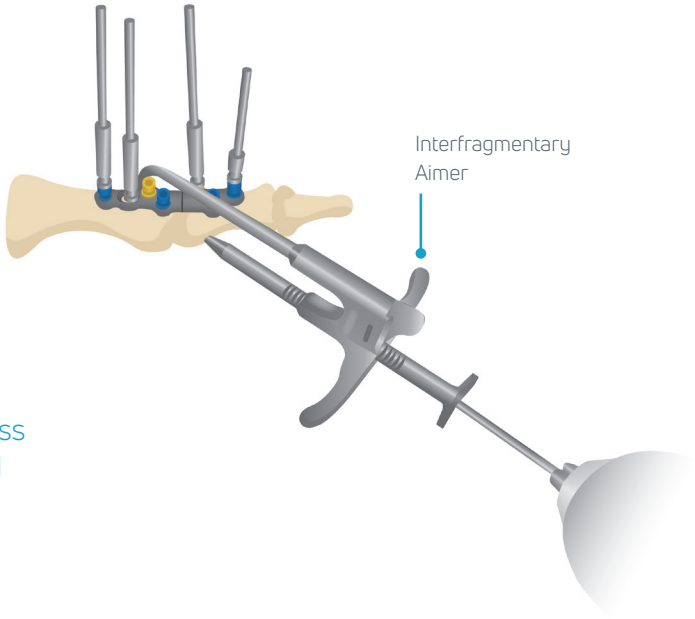


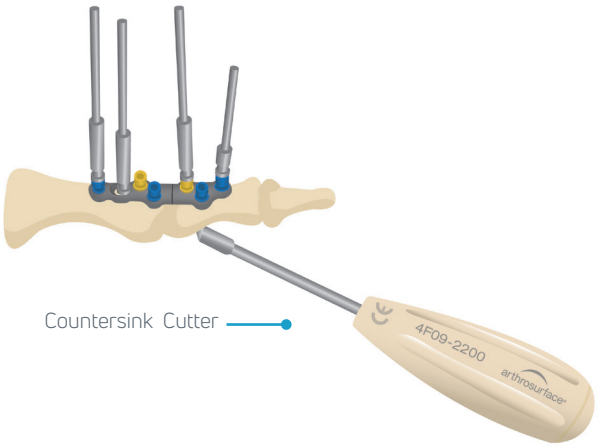
Step 11

Insertion of **Interfragmentary Screw**

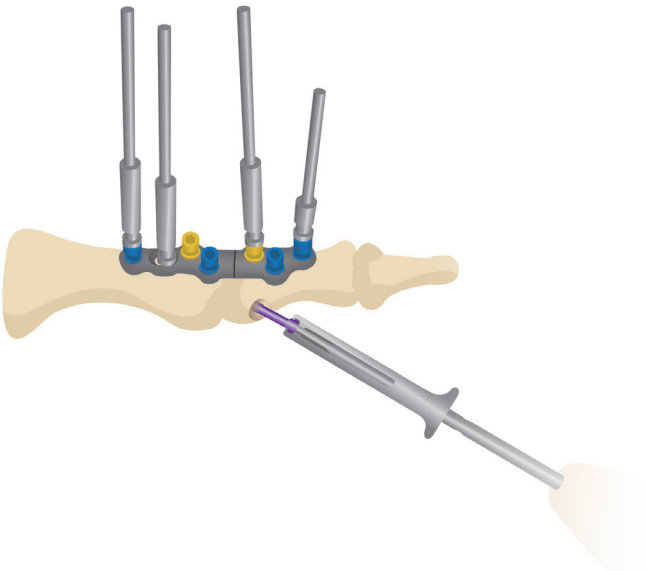
a. Place the **Interfragmentary Aimer*** in a distalmedial to proximal-lateral orientation across the 1st MTP joint. Create pilot hole using provided **Guide Pin** or **Drill Pin**.

***Note:** Alternatively, based on plate selection, the **Interfragmentary Aimer** may be placed in a proximalmedial to distal-lateral orientation across the 1st MTP joint based on the selected foot and place combination. See Step 6 for reference.





b. Countersinking may be performed using the **Countersink Cutter** to create recess for the interfragmentary screw head.



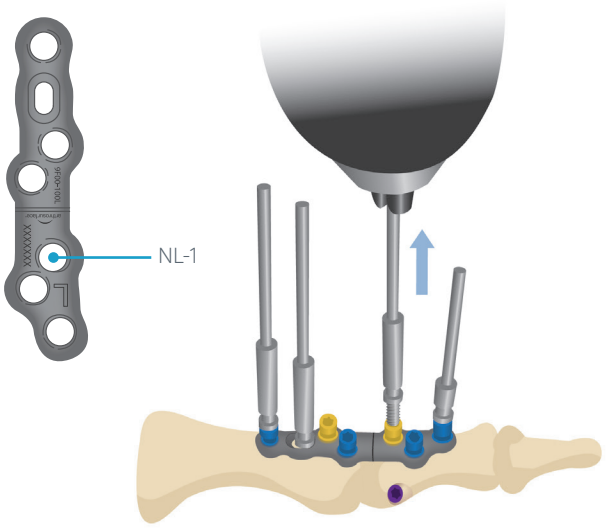
c. Insert the appropriate length **Interfragmentary Screw** in a distal-medial to proximal-lateral orientation using the **Hexalobe Driver** (alternatively, the surgeon may opt to insert it in a proximal-lateral to distal-medial orientation; however, this may cause interference to the adjacent hard and soft tissue structures, and may cause difficulty in using the countersink tool and the depth gauge). Note: Inserting the **Interfragmentary Screw** in any other orientation across the 1st MTP joint will cause interference with the **Locking** and **Non-Locking Bone Screws**.

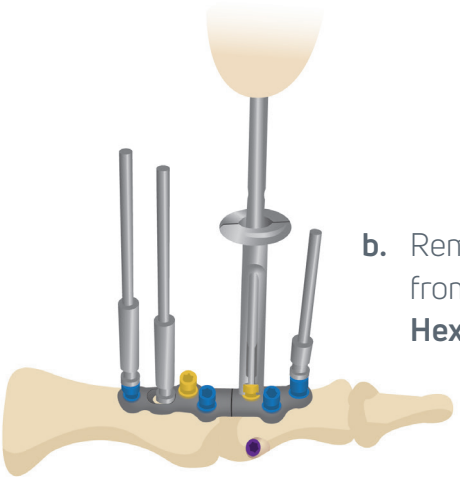
Note: The surgeon may opt to insert the two non-locking (gold) screws prior to placement of the interfragmentary screw.

Step 12

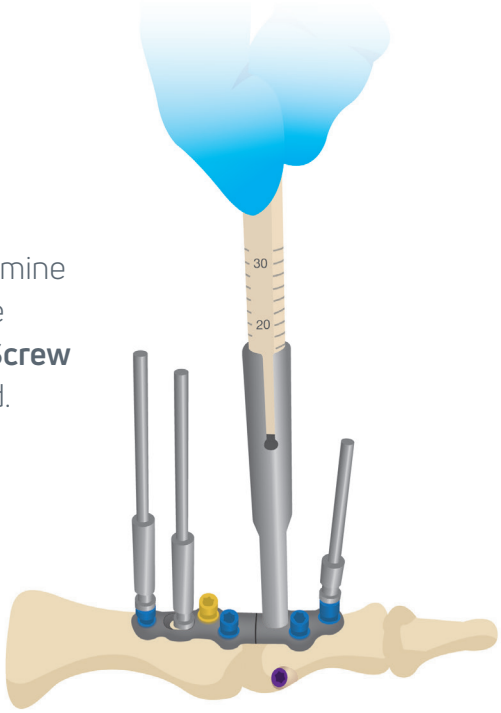
Insertion of **Non-Locking Screw** in **NL-1**

a. Remove the **Tack Pin** from **NL-1**

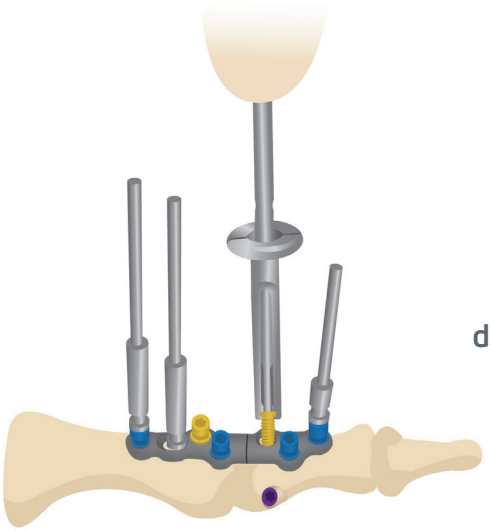




b. Remove the **Nubbin** from **NL-1** using the **Hexalobe Driver**.



c. Use the **Depth Gauge** to determine the appropriate **Non-Locking Screw** length required.

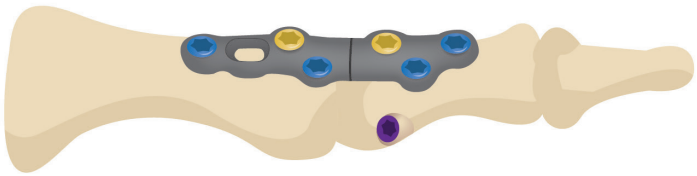


d. Insert the appropriate length **Non-Locking Screw** using the **Hexalobe Driver**.

Step 13

Repeat this procedure for the remaining bone plate holes in the following recommended order (refer to the corresponding image):

- **Non-locking screw** in hole **NL-2**
- **Locking screw** in hole **L-1**
- **Locking screw** in hole **L-2**
- **Locking screw** in hole **L-3**
- **Locking screw** in hole **L-4**

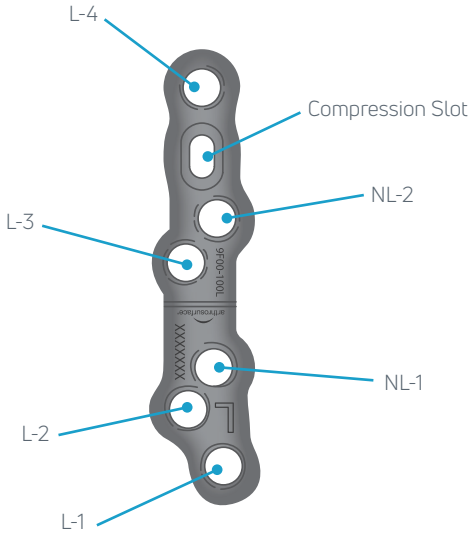


Note: Remove and discard only the corresponding nubbin and/or tack pin as you progress. In the final configuration, the plate should have **2 Non-Locking Screws** and **4 Locking Screws**. A non-locking screw may be inserted in the compression slot for additional stability.

Note: For holes that did not have a tack pin during above steps, pilot holes can be created using the drill pin through the nubbin. Screw length can be measured through the nubbins using the laser markings on the drill pin (in 2 mm increments).

Note: The **Nubbins** are **Color Coded** to match the **Locking** and **Non-Locking** screw colors for easy identification i.e. the holes having a Gold colored Nubbin should receive a Gold colored screw (Non-Locking) and the holes having a Blue colored Nubbin should receive a Blue colored screw (Locking).

Note: It is also important to use the **Depth Gauge** to measure the length of the screws required for each of the holes in the bone plate (i.e. both locking and non-locking) to avoid either too shallow or too deep placement of the screws. These lengths should be measured ONLY after removing the **Nubbins**.



Step 14

Confirm correct placement of implants using intra-operative fluoroscopy or other means.

Step 15

Depending on the approach taken, standard closure of the incision should be performed. It is recommended that a gauze and compression dressing be used to wrap the toe and forefoot.

Step 16

Weight bearing is recommended, as tolerated, in a postoperative boot along with crutches for the first two weeks, following which the crutches can be discarded, but the boot continued for additional six to eight weeks.

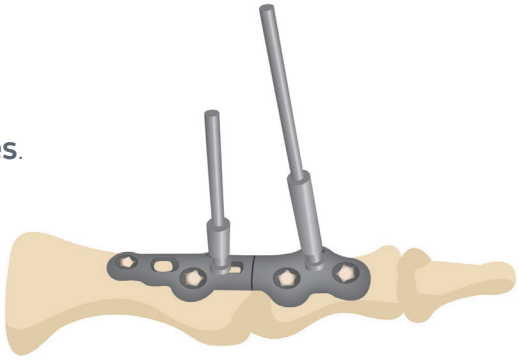
Surgical Technique

CheckMate 2.0 & 3.0 (200 & 300 series plate)

Step 1

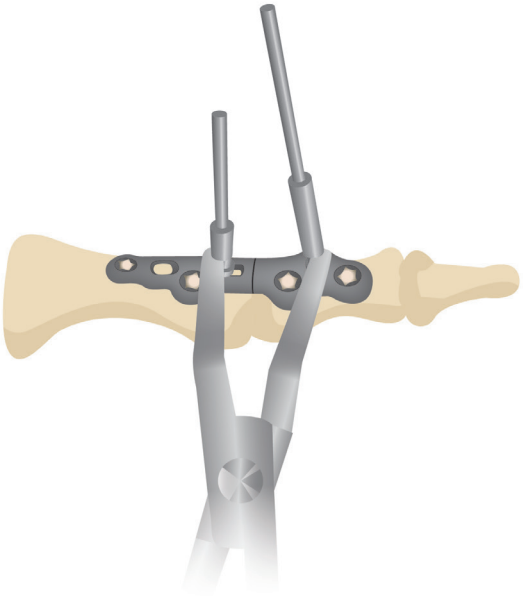
The following technique steps are shown for the **2.0/3.0 or 200/300 Series All-Locking Bone Plates**.

Note: Reference and follow Steps 1 through 6 from Chapter 1 prior to proceeding.



Step 2

Align the laser etch mark on the plate with the joint and affix the plate to the metatarsal and phalanx in this position by inserting (using a wire driver) one **Tack Pin** into the proximal most end of the **Compression Pin Slot** and another **Tack Pin** into the distal Pin Hole.

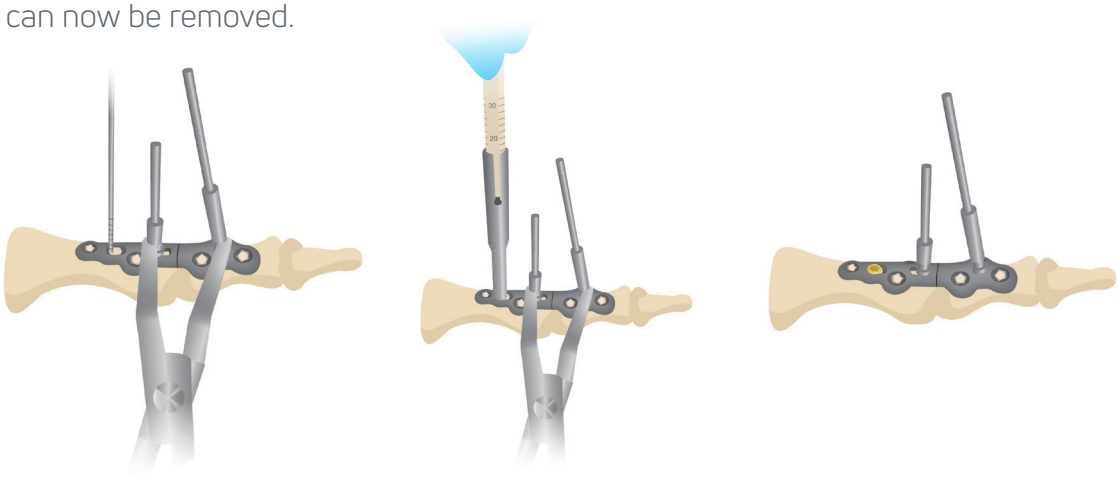


Step 3

Apply compression to the joint using the **Compression Clamp** positioned on the **Tack Pins**.

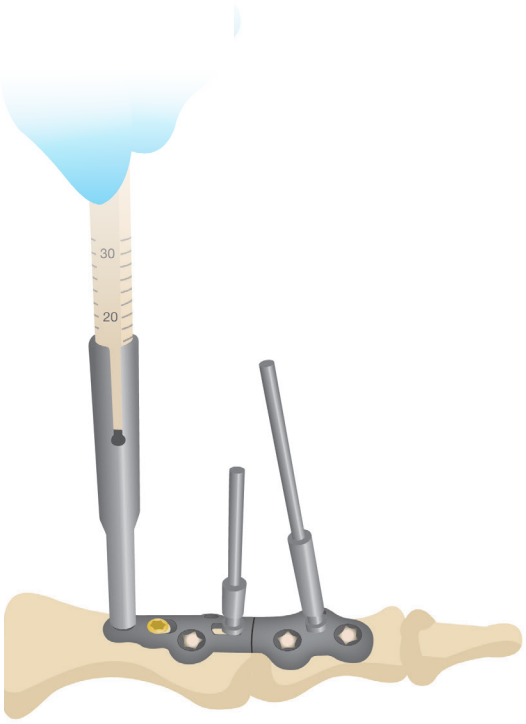
Step 4

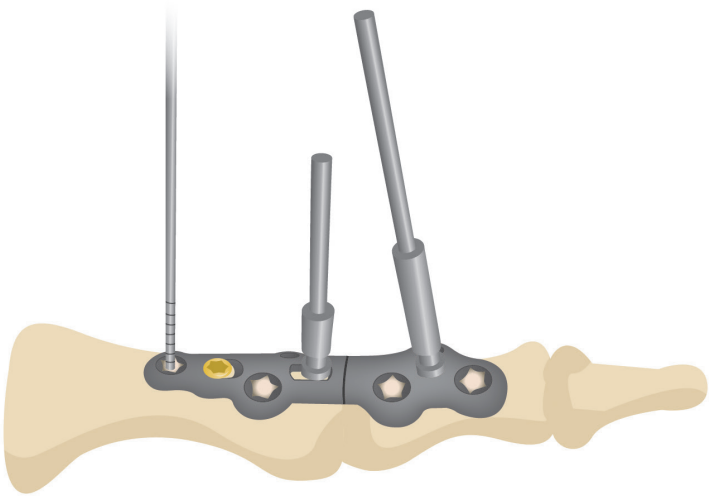
While maintaining compression, drill a pilot hole at the proximal end of the **Compression Screw Hole**, measure the length of the bone screw required using the **Depth Gauge** and insert the appropriate length **Non-Locking** or **Bail-Out Screw**. The **Compression Clamp** can now be removed.



Step 5

Insert the **Locking Screws** alternating between proximal and distal bone segments in the remainder of the bone plate holes. Create a pilot hole using the **Drill Pin**, measure the length of the bone screw required using the **Depth Gauge** and insert the appropriate length **Locking Screw**. The temporary **Tack Pins** can now be removed.





Step 6

Reference and follow Step 11 from Chapter 1 to insert the **Interfragmentary Screw**.

Step 7

Reference and follow Steps 14 to 16 from Chapter 1 to complete the procedure.

Sterility

Bone Plates

The CheckMate® MTP Standard Bone Plate with preassembled nubbins (1.0 or 100 Series) and the All-Locking Bone Plates (without nubbins - 2.0 & 3.0 or 200/300 Series) are provided Sterile. These are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only. Note: Preassembled nubbins are for guidance purposes only. In accordance with the surgical technique, the nubbins are to be disassembled and disposed after intended use.

Bailout Screws, Guide Pin, Drill Pin & Tack Pins

The Bailout Screws are individually packaged and provided sterile. The guide pin, drill pin and tack pins (i.e. the Pin Kit) are provided sterile.

These components are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only. Dispose Pin Kit components after intended use.

Instrument Tray: Screw Caddy with Bone Screws and Surgical Instruments

The CheckMate® MTP bone screws (Locking, Non-Locking and Inter-fragmentary), and surgical instruments are provided Non-Sterile in an instrument tray. These must be cleaned and sterilized before use, as follows:

Cleaning

Remove and discard any plastic caps or tip protectors before cleaning and sterilizing implants and instruments. Cleaning by hand rather than by mechanical cleaning will prolong the life of the implants and instruments. Clean all crevices, flutes, and cannulations of all debris, using a soft bristle brush or cleaning stylet. Remove all traces of blood or other residues immediately. Do not allow these to dry. Implants and instruments should be cleaned while submerged in warm water with an appropriate neutral pH detergent. Always follow the manufacturer's instructions when preparing and using detergents. Do not use steel brushes as they can accelerate wear and corrosion of the implants and instruments. Rinse implants and instruments thoroughly with distilled water. Dry implants and instruments immediately after cleaning.

Sterilization Recommended parameters for steam sterilization are as follows:

Cycle	Temperature	Minimum Exposure Time
Vacuum	270° F/ 132° C	4 minutes
Gravity	250° F/ 121° C	30 minutes

Recommended dry time is 30 minutes.

Parameters may vary based on manufacturer, installation or maintenance of sterilization equipment.On-going testing must be performed by the user toconfirm inactivation of all forms of microorganisms.

Sterilizing in liquid solutions is not recommended. Do not sterilize at temperatures greater than 275° F/ 135° C.

Screw Caddy Assembly

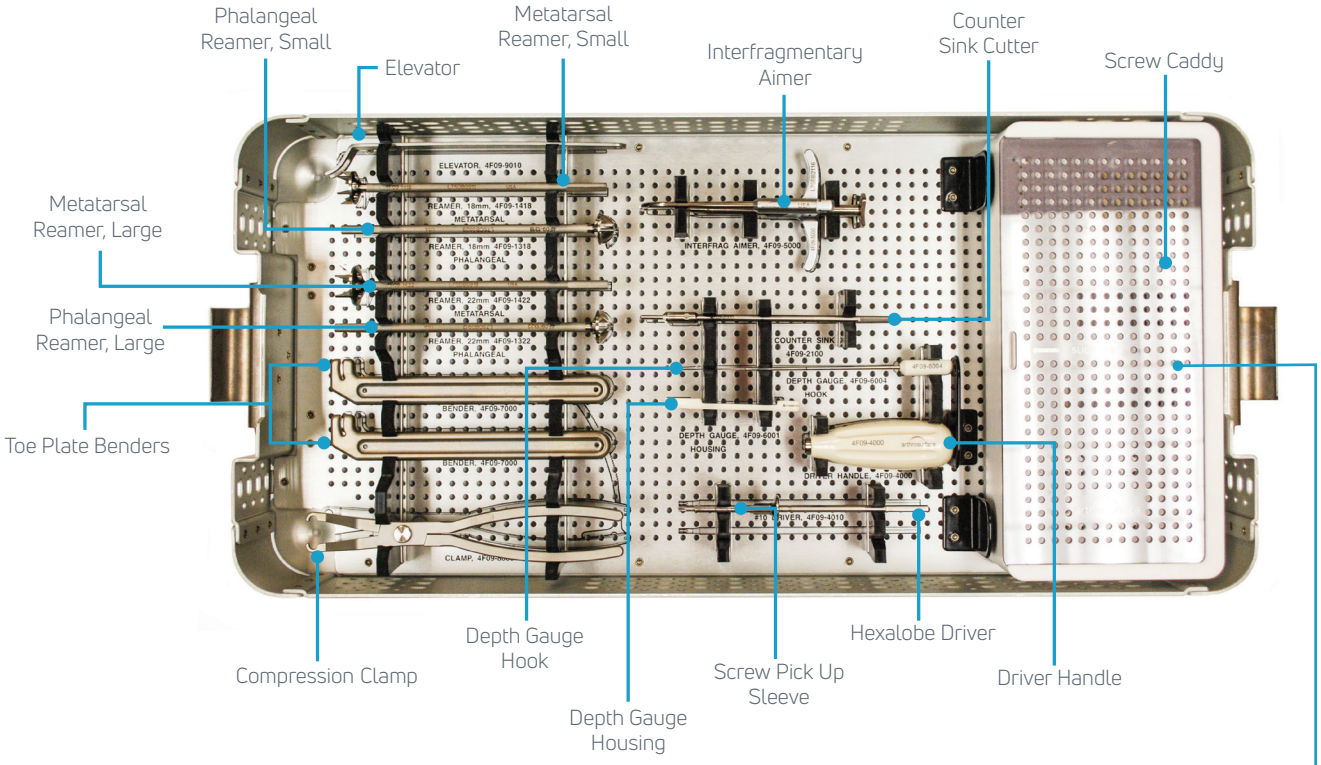
- The bone screw caddy forms a part of the instrument tray, and needs to be populated with bone screws adequately and appropriately, before each cleaning and sterilization cycle.
- The bone screws (locking, non-locking and interfragmentary) are individually packaged, labeled and provided Non-Sterile.
- Each bone screw should be measured for its length (using the measurement scale on the screw caddy) and placed in its designated hole in the screw caddy.
- Before each use (surgical procedure), the screw caddy needs to be completely assembled. The bone screws (in the bone screw caddy) need to be CLEANED and STERILIZED along with the surgical instruments in the instrument tray in accordance with the recommended procedures (see above).

Caution

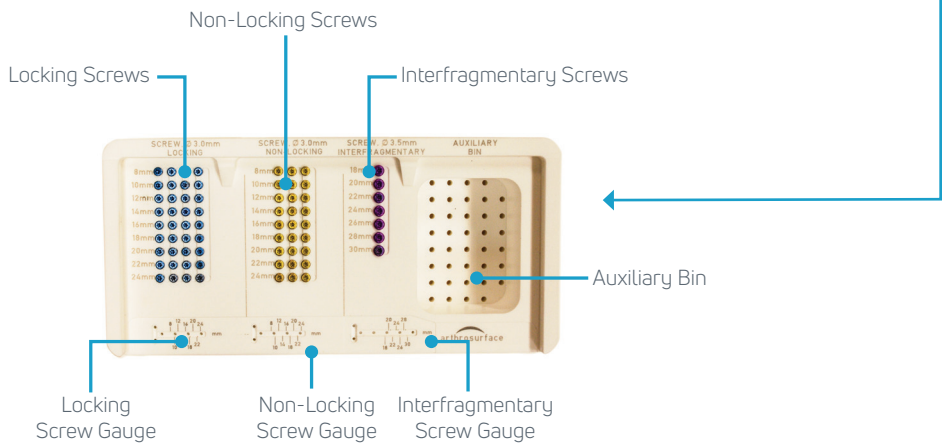
Federal Law (USA) restricts this device to sale by or on the order of a physician.

Instrumentation

CheckMate® Instrument Tray



Instrument Tray Screw Caddy



System Catalog

Plates and Instruments	
9F00-100R	Bone Plate, Standard, Right
9F00-100L	Bone Plate, Standard, Left
9F00-200R	Bone Plate, All-Locking, Right
9F00-200L	Bone Plate, All-Locking, Left
9F00-300R	Bone Plate, All-Locking, Right, Small
9F00-300L	Bone Plate, All-Locking, Left, Small
9F00-1050	Pin Kit (For 1.0 or 100 Series)
9F00-1060	Pin Kit, II (For 2.0/3.0 or 200/300 Series)
9F00-1000	Instrument Kit, Reusable
4F09-9010	MTP Elevator
4F09-5000	Interfragmentary Aimer

Locking Screws	
4F01-1008	Locking Screw, Ø 3.0 mm x 8 mm
4F01-1010	Locking Screw, Ø 3.0 mm x 10 mm
4F01-1012	Locking Screw, Ø 3.0 mm x 12 mm
4F01-1014	Locking Screw, Ø 3.0 mm x 14 mm
4F01-1016	Locking Screw, Ø 3.0 mm x 16 mm
4F01-1018	Locking Screw, Ø 3.0 mm x 18 mm
4F01-1020	Locking Screw, Ø 3.0 mm x 20 mm
4F01-1022	Locking Screw, Ø 3.0 mm x 22 mm
4F01-1024	Locking Screw, Ø 3.0 mm x 24 mm

Non-Locking Screws	
4F01-2008	Non-Locking Screw, Ø 3.0 mm x 8 mm
4F01-2010	Non-Locking Screw, Ø 3.0 mm x 10 mm
4F01-2012	Non-Locking Screw, Ø 3.0 mm x 12 mm
4F01-2014	Non-Locking Screw, Ø 3.0 mm x 14 mm
4F01-2016	Non-Locking Screw, Ø 3.0 mm x 16 mm
4F01-2018	Non-Locking Screw, Ø 3.0 mm x 18 mm
4F01-2020	Non-Locking Screw, Ø 3.0 mm x 20 mm
4F01-2022	Non-Locking Screw, Ø 3.0 mm x 22 mm
4F01-2024	Non-Locking Screw, Ø 3.0 mm x 24 mm

Interfragmentary Screws	
4F01-4018	Interfragmentary Screw, Ø 3.5 mm x 18 mm
4F01-4020	Interfragmentary Screw, Ø 3.5 mm x 20 mm
4F01-4022	Interfragmentary Screw, Ø 3.5 mm x 22 mm
4F01-4024	Interfragmentary Screw, Ø 3.5 mm x 24 mm
4F01-4026	Interfragmentary Screw, Ø 3.5 mm x 26 mm
4F01-4028	Interfragmentary Screw, Ø 3.5 mm x 28 mm
4F01-4030	Interfragmentary Screw, Ø 3.5 mm x 30 mm

Bailout Screws	
9F01-5014	Non-Locking Screw, Ø 3.5 mm x 14 mm
9F01-5016	Non-Locking Screw, Ø 3.5 mm x 16 mm
9F01-5018	Non-Locking Screw, Ø 3.5 mm x 18 mm

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