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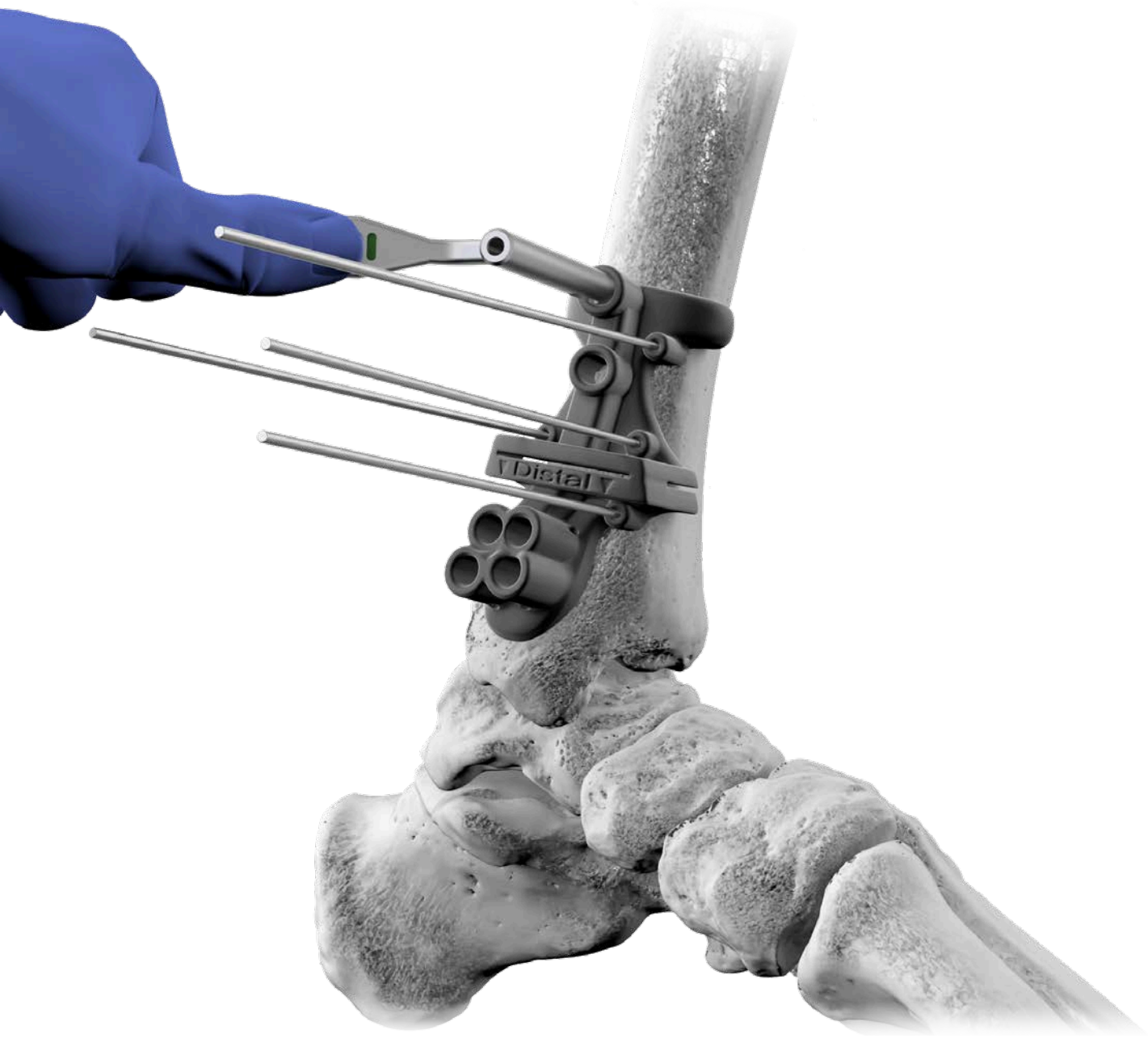
PRECISION IN FIXATION

SURGICAL TECHNIQUE

CMX Ankle



CMX Ankle

Contents

For further information on CMX, visit www.medartis.com.

Introduction

Product Materials

CMX Custom-Made Devices
All CMX APTUS guides and bone models are made of PA12 (polyamide/Nylon 12). The polyamide used is biocompatible for the intended type and time of application during surgery (see "Intended Purpose") and non-toxic in a biological environment.

Compatible APTUS Ankle Plates, Screws and Instruments

Product	Material
Plates	Pure titanium, titanium alloy
Washers	Titanium alloy
Screws	Titanium alloy
K-wires	Stainless steel
Instruments	Stainless steel, PEEK, aluminum, Nitinol, silicone or titanium

Notice
Alongside the CMX APTUS guides, the necessary APTUS plates, screws and the corresponding twist drills as well as the necessary instruments must be available and sterile. These are not included in the CMX delivery.

Intended Purpose

Guides
CMX APTUS guides are intended for use as surgical instruments for guiding purposes when marking, drilling or sawing the bone of a specific patient.

Bone Models
CMX APTUS bone models are intended to illustrate preoperative and/or postoperative anatomical structures of a specific patient.

Contraindications

- Preexisting or suspected infection at or near the implantation site
- Known allergies and/or hypersensitivity to product materials
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Growth plates are not to be blocked with plates and screws

Color Coding

CMX APTUS Guides and Bone Models
CMX APTUS guides and bone models are not color coded.

System Size	Color Code
2.8	Orange
3.5	Green

Plates and Screws
Special implant plates and screws have their own color:

Implant plates blue	TriLock plates (locking)
Implant screws gold	Cortical screws (fixation)
Implant screws blue	TriLock screws (locking)

Compatible APTUS Plates and Screws

Plates and screws can be combined within one system size:

2.8/3.5 TriLock Distal Tibia Plates
2.8 Cortical Screws, HexaDrive 7
2.8 TriLock Screws, HexaDrive 7
3.5 Cortical Screws, HexaDrive 15
3.5 TriLock Screws, HexaDrive 15

3.5 TriLock Distal Tibia T + L Plates
3.5 Cortical Screws, HexaDrive 15
3.5 TriLock Screws, HexaDrive 15

2.8/3.5 TriLock Distal Fibula Plates
2.8 Cortical Screws, HexaDrive 7
2.8 TriLock Screws, HexaDrive 7
3.5 Cortical Screws, HexaDrive 15
3.5 TriLock Screws, HexaDrive 15

Symbols

HexaDrive

Instrument Application

General Instrument Application

Drilling

Color-coded twist drills are available for every APTUS system size. All twist drills are color coded with a ring system.

System Size	Color Code
2.8	Orange
3.5	Green

There are different types of twist drills for every system size: The core hole drills are characterized by one colored ring, the gliding hole drills (for lag screw technique) are characterized by two colored rings.

Hole Drilling for 2.8 Screws

A-3832
Twist Drill Ø 2.35 mm, AO

Core hole drill with Ø 2.35 mm = one colored ring

A-3834
Twist Drill Ø 2.9 mm, AO

Gliding hole drill with Ø 2.9 mm = two colored rings

Hole Drilling for 3.5 Screws

3.5 Cortical

A-3934
Twist Drill Ø 2.6 mm, AO

Core hole drill with Ø 2.6 mm = one colored ring

3.5 TriLock

A-3931
Twist Drill Ø 3.0 mm, AO

Core hole drill with Ø 3.0 mm = one colored ring

A-3933
Twist Drill Ø 3.6 mm

Gliding hole drill with Ø 3.6 mm = two colored rings

For 2.8 screws, the twist drill must always be guided by the drill guide (A-2820) or the self-holding drill sleeve (A-2826).

A-2820
2.8 Drill Guide

A-2826
2.5/2.8 Drill Sleeve, Self-Holding

For 3.5 screws, the twist drill must always be guided by the drill guide (A-2925, A-2927) or the self-holding drill sleeve (A-2921).

A-2925
3.5 Drill Guide, Cortical, Drill Ø 2.6/3.6 mm

A-2927
3.5 Drill Guide, TriLock, Drill Ø 3.0 mm

A-2921
3.5 Drill Sleeve, Self-Holding

The double-ended drill guides (A-2820, A-2925) are used to perform the classic lag screw technique according to AO/ASIF.

Warning
The twist drill must always be guided by the drill guide (A-2820 for 2.8 screws or A-2925, A-2927 for 3.5 screws) or the self-holding drill sleeve (A-2826 for 2.8 screws or A-2921 for 3.5 screws). This prevents damage to the screw hole and protects the surrounding tissue from direct contact with the drill. The drill guide also serves to limit the pivoting angle.

Warning

For TriLock plates ensure that the screw holes are predrilled with a pivoting angle of no more than ±15°. For this purpose, the drill guide features a limit stop of ±15°. A predrilled pivoting angle of >15° no longer allows the TriLock screws to correctly lock in the plate.

A-2921
3.5 Drill Sleeve, Self-Holding

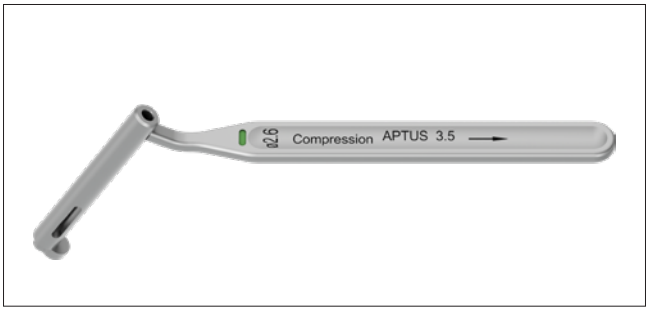
A-2927
3.5 Drill Guide, TriLock

Compression Drill Guide

The single-ended 3.5 drill guide for compression (A-2926) is used in the compression hole of the 2.8/3.5 TriLock distal tibia plate medial and provides compression up to 3 mm across the fracture or osteotomy site.

Warning

The arrow "→" indicates the direction of the compression and must always point towards the fracture/osteotomy line.



A-2926
3.5 Drill Guide, Compression

Assigning the Screw Length

The depth gauges (A-2836, A-2931) are used to assign the ideal screw length for use in monocortical or bicortical screw fixation.

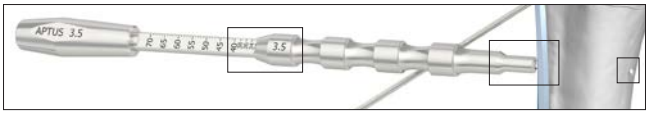
A-2931
3.5/4.0 Depth Gauge, 10–70 mm

A-2836
2.8 Depth Gauge

Warning
It is important to use the correct depth gauge for the corresponding screw diameter, which is indicated on the slider and handle of the depth gauge.

Retract the slider of the depth gauge.

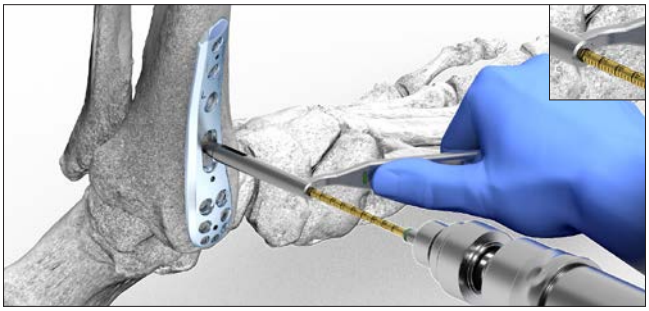
The depth gauge caliper has a hooked tip that is either inserted to the bottom of the hole or is used to catch the far cortex of the bone. When using the depth gauge, the caliper stays static, only the slider is adjusted.



To assign the screw length, place the end of the slider onto the plate or directly onto the bone. When using the lag screw technique, place the end of the slider directly onto the bone.

The ideal screw length for the assigned drill hole can be read on the scale of the depth gauge.

When inserting a 3.5 cortical screw, the screw length may also be assigned directly from the scale on the twist drill ⌀ 2.6 mm (A-3934) in combination with the drill guide (A-2925). The length is assigned from the end of the drill guide.



Screw Pick-Up

Both the 2.8 screwdriver blade (A-2013) and the 3.5 screwdriver blade (A-2911) feature the patented HexaDrive self-holding system.

A-2013
2.5/2.8 Screwdriver Blade, HD7, AO

A-2911
3.5/4.0 Screwdriver Blade, HD15, AO

2.8 Screws

For 2.8 screws, attach only the orange color-coded 2.5/2.8 screwdriver blade (A-2013) to the cannulated handle with quick connector (A-2073).

A-2073
Cannulated Handle with Quick Connector, AO

3.5 Screws

For 3.5 screws, attach only the green color-coded 3.5/4.0 screwdriver blade (A-2911) to either the handle with quick connector (A-2074) or the T-handle with quick connector (A-2075).

A-2074
Handle with Quick Connector, AO

A-2075
T-Handle with Quick Connector, AO

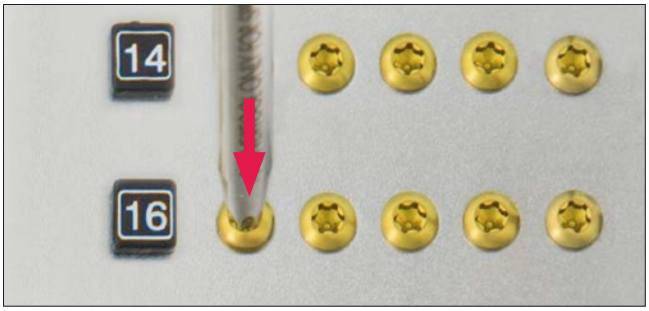
Warning

Do not use the orange color-coded 2.5/2.8 screwdriver blade (A-2013) with the large handle (A-2074) or with the T-handle (A-2075), as the high forces generated can damage the locking of the screw head in the plate hole.

To remove the screws from the implant container, insert the screwdriver blade perpendicularly into the screw head of the desired screw and pick up the screw with axial pressure.

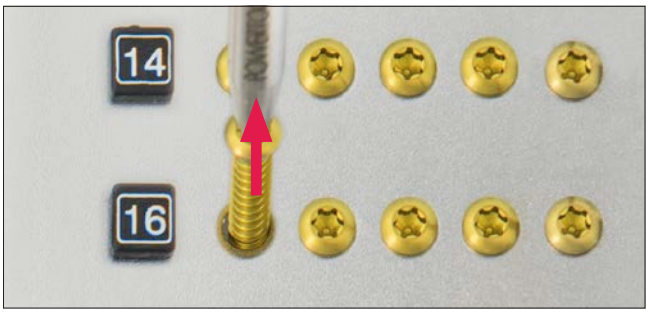
Notice

The screw will not hold without axial pressure.



Caution

Vertically extract the screw from the compartment. Picking up the screw repeatedly may lead to permanent deformation of the self-retaining area of the HexaDrive inside the screw head. Therefore, the screw may no longer be able to be picked up correctly. In this case, a new screw has to be used.



Notice

Check the screw length and diameter at the scale of the measuring module. The screw length is determined at the end of the screw head.

Surgical Techniques

CMX APTUS Guide

The CMX APTUS guides can be fixed in the designated holes with K-wires or 2.8 cortical screws. Please refer to the case-specific design freeze document for further details.

CMX APTUS Guide with K-Wire Fixation

Placing and fixing the CMX guide
Before placing the CMX guide on the bone, ensure that the bone is fully exposed to ensure an optimum contact surface.

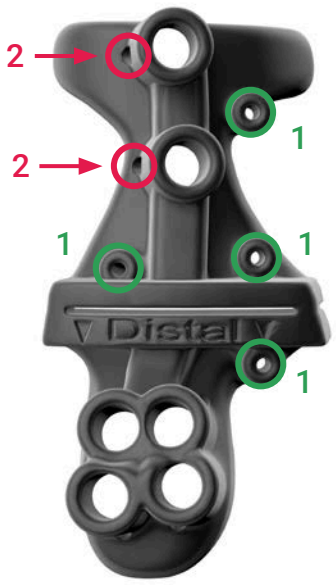
Caution
The CMX guide itself features orientation markings. Additionally, there are consecutive numberings in case more than one CMX guide is needed. These must be taken into account when using the guide. Please refer to the case-specific design freeze document for further details.

To identify the previously defined position of the CMX guide on the bone, it should be placed in various positions. The correct position can be determined based on the fit with the bone or by using the bone model as a reference. Illustrations are provided in the case-specific design freeze document as a guide.

Once the defined position is found, the CMX drill guide is fixed in the designated holes (1) with K-wires (A-5040.41, A-5042.41) according to the case-specific design freeze document.

Caution
Irrigation ports (2) must not be used to fix the guide.

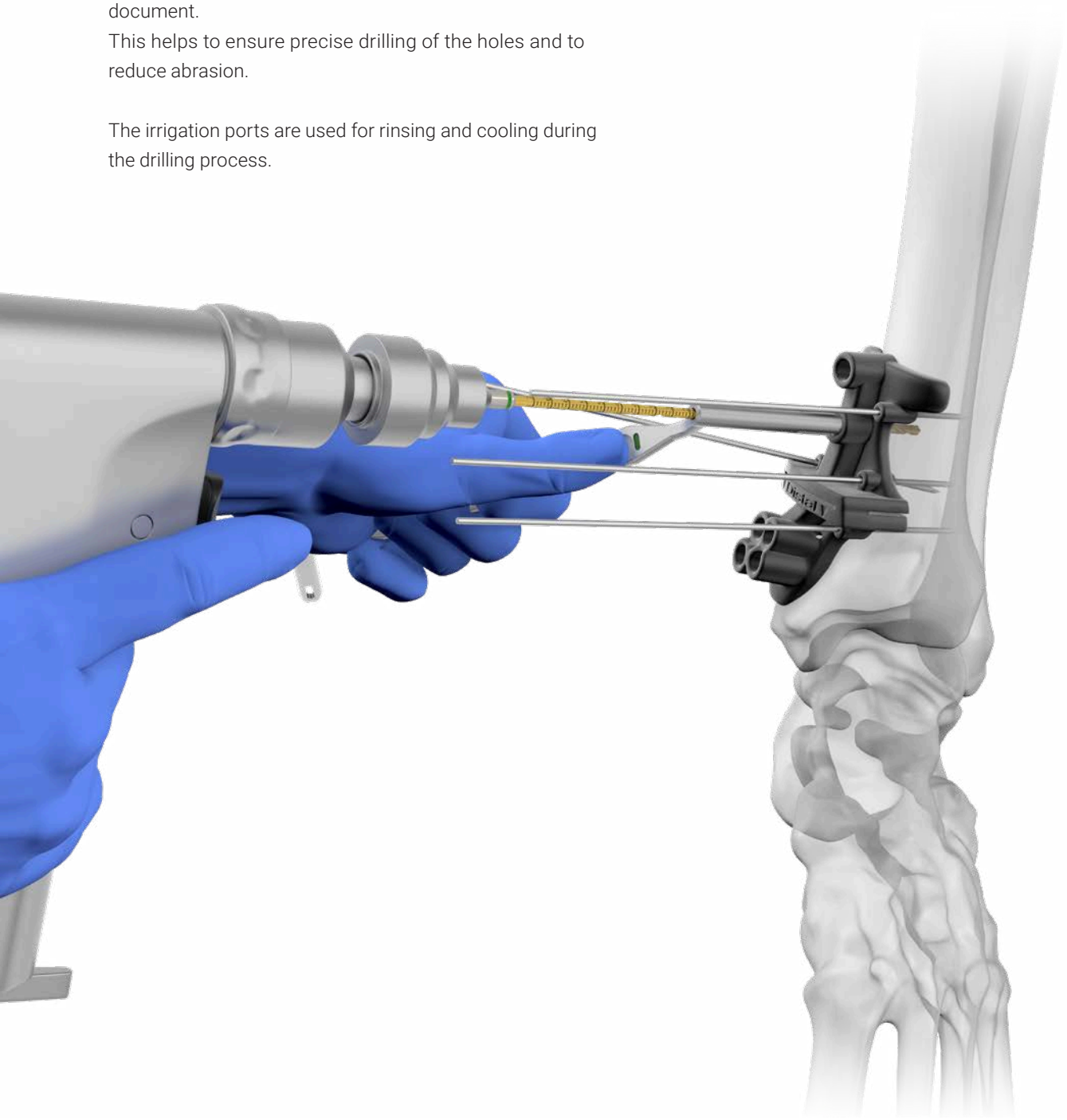
Caution
Throughout the application, it is important to ensure that no excess force is applied to the product as this could cause damage.



Drilling the screw holes for the plate
After the CMX guide is safely fixed to the bone, all predefined screw holes are drilled.

Use the 3.5 cortical drill guide (A-2925) with the twist drill ∅ 2.6 mm (A-3934, one colored ring) or the 3.5 TriLock drill guide (A-2927) and the twist drill ∅ 3.0 mm (A-3931, one colored ring) according to the case-specific design freeze document.
This helps to ensure precise drilling of the holes and to reduce abrasion.

The irrigation ports are used for rinsing and cooling during the drilling process.



Osteotomy of the near cortex

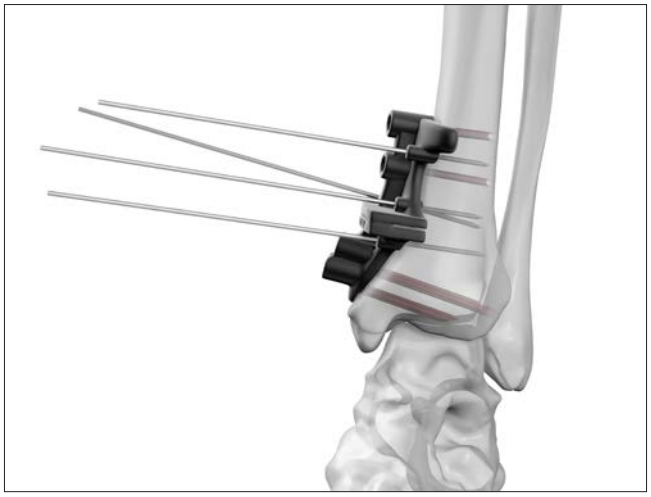
After the holes are drilled, the osteotomy of the near cortex is performed.

Take care not to break the lateral cortex at the apex of the distal part of the tibia so that it can be used as a hinge.

Caution

Avoid drilling or sawing into the guide as this can cause abrasion on the guide. The abrasive material should not enter the tissue. The surgical site must be thoroughly flushed during and after drilling and sawing and any particles must be suctioned away.

The guide may not be adapted either before or during surgery.



Removing the CMX guide

Remove the K-wires and the CMX guide.

Fixing the plate

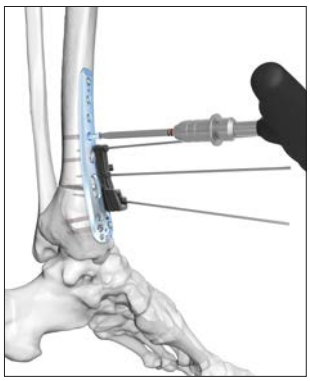
Insertion of 3.5 TriLock screws:

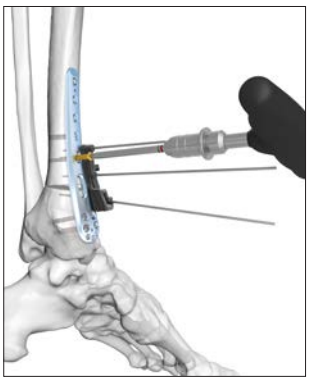
Assign the screw length using the 3.5/4.0 depth gauge (A-2931) in the predrilled distal holes and insert 3.5 TriLock screws (A-5950.xx).

In an open wedge osteotomy, it is recommended to insert 3.5 TriLock screws in the shaft section of the plate first.

In a closing wedge osteotomy, it is recommended to insert 3.5 TriLock screws in the distal section of the plate first.

Open or close the osteotomy manually.





Filling the remaining screw holes

Fill the remaining screw holes preferably with 3.5 TriLock screws (A-5950.xx).

Caution

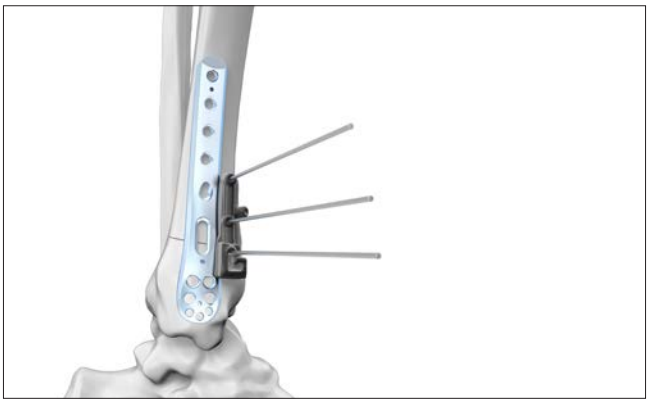
The T-handle (A-2075) must always be used to lock 3.5 TriLock screws.

Warning

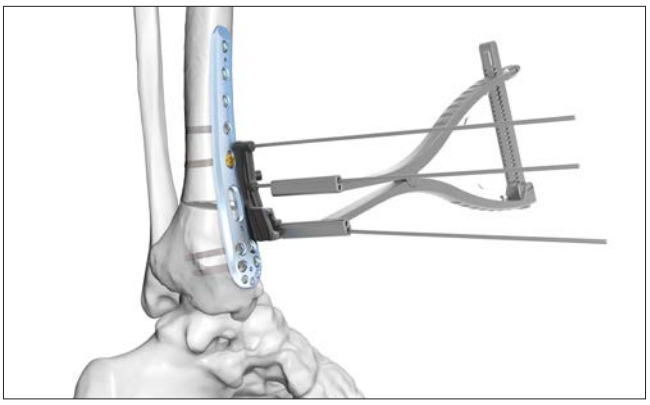
Make sure correct locking has been achieved (see chapter TriLock Locking Technology).

Warning
Depending on the level of open wedge correction, some cases may require bone grafting between the proximal and the distal fragments, autologous bone is recommended. Insufficient bone grafting can increase the risk of breakage of the plate.

Optionally – Using a reposition guide
Placing and fixing the CMX reposition guide.
The parallel K-wires support to identify the defined position. The CMX reposition guide is fixed in the designated holes with one additional K-wire (A-5040.41, A-5042.41) according to the case-specific design freeze document.



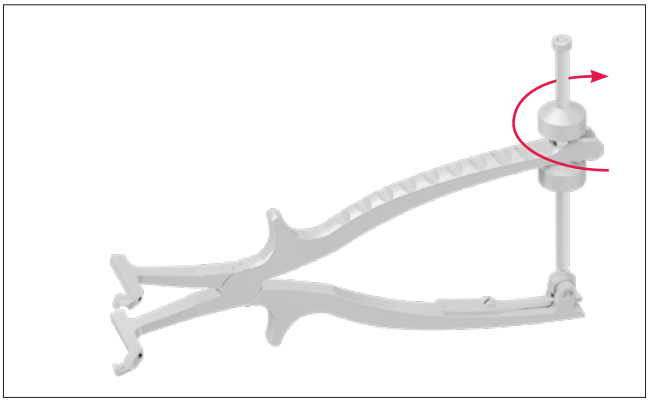
Depending on the procedure, a K-wire spreader (open wedge osteotomy) or compression forceps (closed wedge osteotomy) can be used.



K-wire spreader for 1.6 or 2.0 mm K-wires (open wedge osteotomy)
To perfom a distraction using the K-wire spreader for 1.6 mm or 2.0 mm K-wires (A-2056), press the handle together.
To keep the distraction of the osteotomy, the ratchet of the spreaders can be fixed. The slot in the reposition guide serves as a guide for the K-wire.

Caution
Overdistraction could damage the bone and/or the K-wires. If the forceps are placed at a too high distance from the bone, the K-wires may possibly bend.

Compression forceps for K-wires ∅ 2.0 mm (closed wedge osteotomy)
When using the compression and distraction forceps (A-2049), slide the knurled nut into the slot of the handle. Turn the nut clockwise to gradually apply additional compression and to sustain the interfragmentary compression.



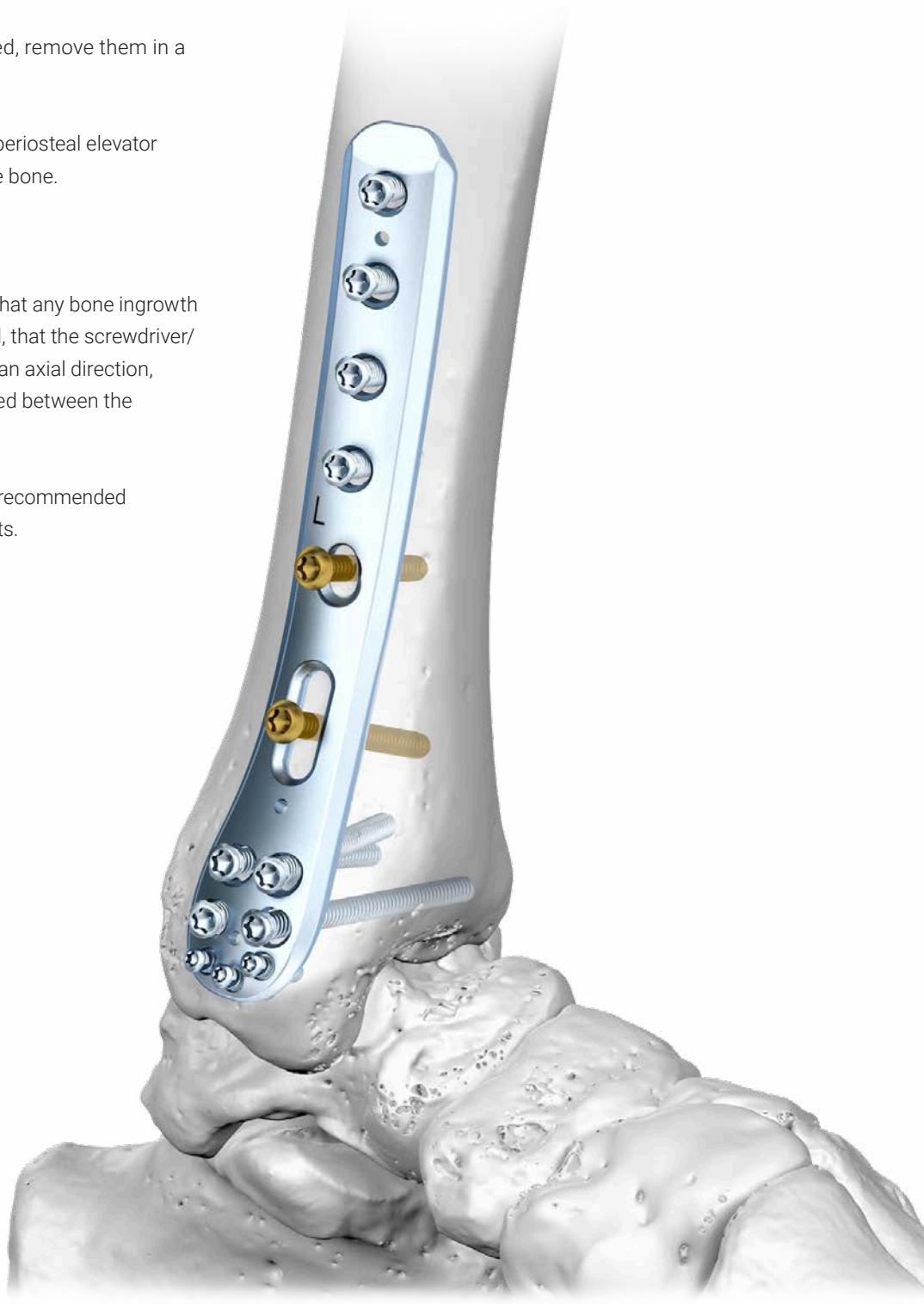
Explantation

Removing the screws
Unlock all screws from the plate.
When all screws have been unlocked, remove them in a random order.

If the plate sticks to the bone, use a periosteal elevator to carefully lift and detach it from the bone.

Caution
When removing the screws, ensure that any bone ingrowth in the screw head has been removed, that the screwdriver/screw head connection is aligned in an axial direction, and that a sufficient axial force is used between the blade and the screw.

Only original APTUS instruments are recommended for the explantation of APTUS implants.



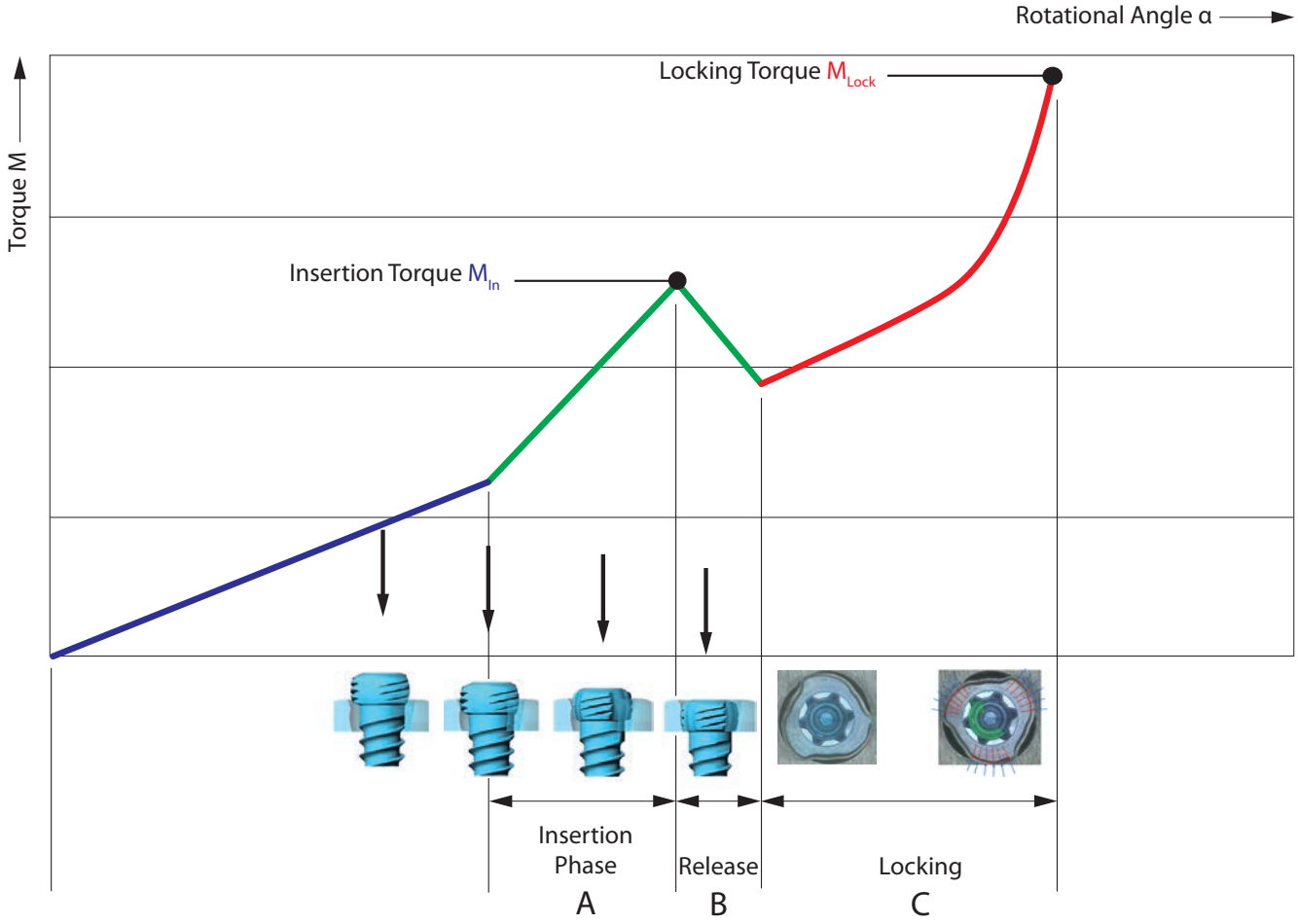
TriLock Locking Technology

Correct Application of the TriLock Locking Technology — 2.8 TriLock Screws

The screw is inserted through the plate hole into a predrilled canal in the bone. An increase of the tightening torque will be felt as soon as the screw head gets in contact with the plate surface.

This indicates the start of the "Insertion Phase" as the screw head starts entering the locking zone of the plate (section "A" in the diagram). Afterwards, a drop of the tightening torque occurs (section "B" in the diagram). Finally, the actual locking is initiated (section "C" in the diagram) as a friction connection is established between screw and plate when tightening firmly.

The torque applied during fastening of the screw is decisive for the quality of the locking as described in section "C" of the diagram.

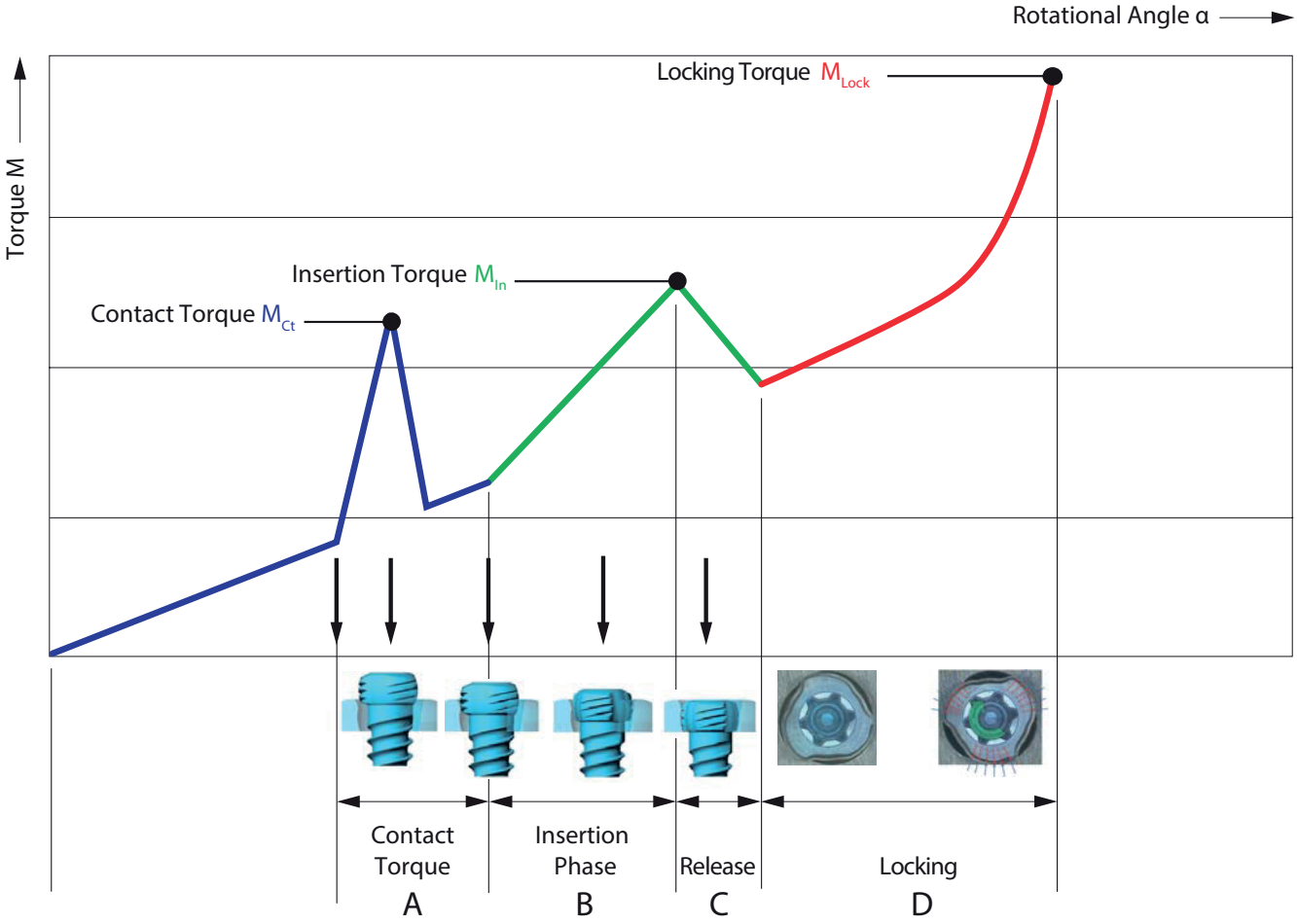


Correct Application of the TriLock Locking Technology — 3.5 TriLock Screws

The screw is inserted through the plate hole into the predrilled bone. A “contact torque” will be felt once the screw head makes contact with the plate surface; for the 3.5 TriLock screws this torque increase is easily perceived (section “A” in the diagram).

The torque then decreases before it starts increasing again during the “Insertion Phase”, as the screw head enters the locking hole (section “B” in the diagram). Once the screw head has entered the locking hole, a second decrease of torque occurs (section “C” in the diagram). Finally, the actual locking is initiated (section “D” in the diagram) as a friction connection is established between screw and plate when tightening firmly The torque applied in section “D” is decisive for the quality of the locking.

In summary, two intermediate torque maxima have to be overcome before there is the final locking of the screw.



Correct Locking (±15°) of the TriLock Screws in the Plate

Correct locking occurs only when the screw head has locked flush with the locking contour (fig. 1 and 3).

However, if there is still a noticeable protrusion (fig. 2 and 4), the screw head has not completely reached the locking position. In this case, the screw has to be retightened to obtain full penetration and proper locking. In case of poor bone quality, a slight axial pressure might be necessary to achieve proper locking.

After having reached the locking torque (MLock), do not further tighten the screw, otherwise the locking function cannot be guaranteed anymore.

Correct: LOCKED

Figure 1

Incorrect: UNLOCKED

Figure 2

Correct: LOCKED

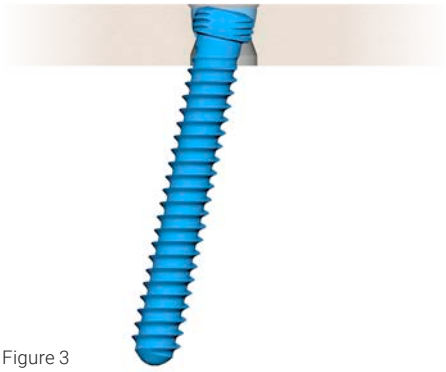


Figure 3

Incorrect: UNLOCKED

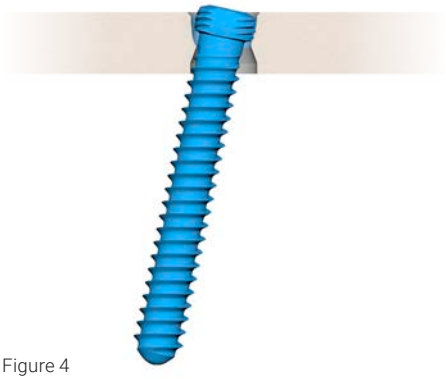


Figure 4

Appendix

CMX APTUS Guides and Bone Models

For all CMX APTUS guides, bone models and compatible APTUS Ankle plates, screws and instruments according to the case-specific design freeze document, see CMX Portal at cmx.medartis.com.

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