medartis

PRECISION IN FIXATION

SURGICAL TECHNIQUE

CMC-I Fusion System 2.0, 3.0

APTUS Hand

Contents

For further information regarding the APTUS product line visit: www.medartis.com

Introduction

Product Materials

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

Indications

APTUS CMC-I Fusion Plate System
The APTUS CMC-I Fusion Plate System is intended to be used for fusion of the trapezium with the first metacarpal

Contraindications

- Preexisting or suspected infection at or near the implantation site
- Known allergies and/or hypersensitivity to foreign bodies
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- The treatment of at-risk groups is inadvisable

Specific Complications

Specific complications that may be associated with the arthrodesis of the thumb carpometacarpal joint include:

- Non-union
- Decreased thumb opposition
- Inability to flatten the palm

Color Coding

System Size	Color Code
2.0	Blue
3.0	Yellow

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

Implant plates blue	TriLock plates (locking)
Implant screws blue	TriLock screws (locking)
Implant screws gold	Cortical screws (fixation) and cannulated compression screws

Possible Combination of Plates and Screws

Plates and screws can be combined within one system size:

2.0 TriLock CMC-I Fusion Plate
2.0 Cortical screws, HexaDrive 6
2.0 TriLock screws, HexaDrive 6

Caution
3.0 cannulated compression screws (CCS) must not be inserted into the plate.

Symbols


HexaDrive


See Instructions for Use
www.medartis.com

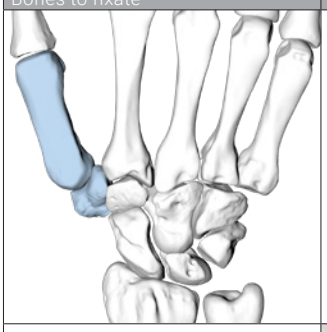
System Overview

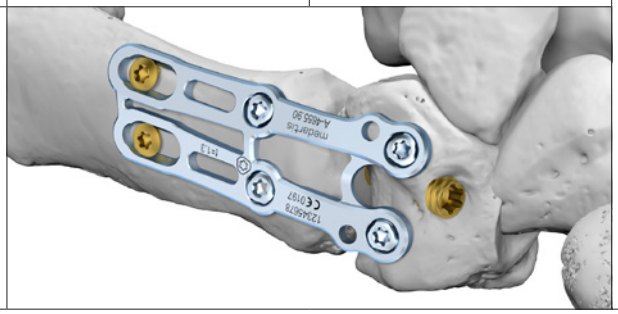
The APTUS CMC-I Fusion System 2.0, 3.0 consists of one 2.0 TriLock plate (A-4655.90) combined with a 3.0 cannulated compression screw (A-5880.xx).

Treatment Concept

The table below lists typical clinical findings which can be treated with the implants of the APTUS CMC-I Fusion System 2.0, 3.0.

Bones to fixate	Plate	Cannulated Compression Screw	Recommended patient population[1-3]

	 A-4655.90	 A-5880.xx	- Patients younger than 65 years
			- Heavy laborer and still very active patients requiring a stable thumb and high strength
			- Patients with Stage II and Stage III osteoarthritis (classification after Eaton and Littler)
			- Typical anamnesis
			  - Advanced arthritis: degenerative/ post-traumatic
			  - Pain, deformity
			  - Reduced mobility and activity (max. force)
			
			Arthrodesis of the thumb carpometacarpal joint in case of significant osteoarthritis at the scaphotrapezotrapezoidal joint (Stage IV) is **not** recommended.

- Metacarpal I - Trapezium			1. Fulton DB and Stern PJ, J Hand Surg Am. 2001;26(1):109-14 2. Bamberger HB et al, J Hand Surg Am. 1992 Jul;17(4):605-11 3. Stark HH et al, J Bone Joint Surg Am. 1977 Jan;59(1):22-6

The above-mentioned information is a recommendation only. The operating surgeon is solely responsible for the choice of the suitable implant for the specific case.

Instrument Application

General Instrument Application

Inserting the K-Wire

Cannulated compression screws are inserted over a K-wire. The percutaneous K-wire guide (A-2007) or the drill guide with the end marked “K-WIRE” (A-2825) are used to insert the K-wire for the cannulated compression screw.

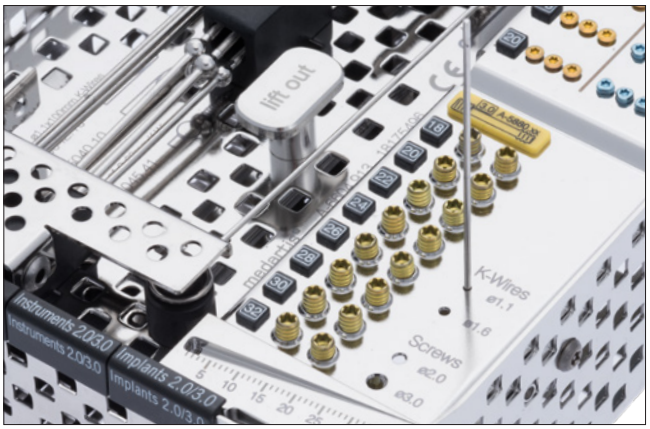
Caution
To ensure that the lengths of the screws to be used are assigned correctly, only original APTUS K-wires may be used. If alternative wires are used, the correct screw length assignment cannot be assured.

3.0 CCS: A-5040.10 (trocar) or A-5042.10 (lancet)
Ø 1.1 mm × length 100 mm

Check the K-wire diameter in the measuring module of the container.

A-2007
2.2/3.0 K-Wire Guide, Percutaneous

A-2825
3.0 Drill Guide



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
2.0	Blue
3.0	Yellow

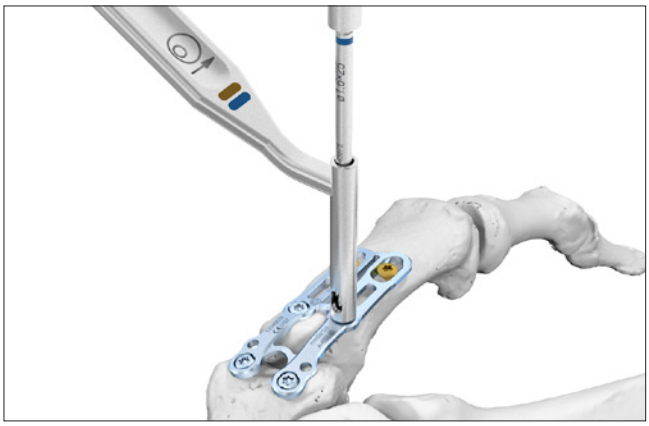
Warning
The twist drill must always be guided by a drill guide. This prevents damage to the screw hole and protects the surrounding tissue from direct contact with the drill. The drill guide also serves to limit the pivoting angle.

A-3430
Twist Drill Ø 1.6 mm, AO

A-3836
3.0 Cannulated Twist Drill Ø 2.1 mm, AO

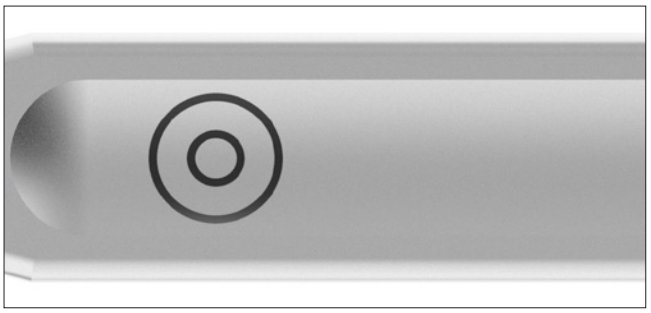
A-2020
2.0/2.3 Drill Guide, Centric/Excentric

After positioning the plate, insert the drill guide (A-2020) and the twist drill (A-3430) into the screw hole.



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 guides feature a limit stop of ± 15°. A predrilled pivoting angle of > 15° no longer allows the TriLock screws to correctly lock in the plate.

This symbol marks the end of the drill guide used for centric drilling (A-2020). This end is used for all fixation and TriLock holes, as well as for lag screws.



This symbol marks the end of the drill guide used for eccentric drilling (A-2020). It is used for compression holes only.

Warning
The arrow " ← " indicates the direction of the compression and must always point towards the fracture/osteotomy line resp. fusion site/line.

For the cannulated compression screws, use the drill guide with the end marked "DRILL" (A-2825) to drill as far as the opposite cortex.

A-2825
3.0 Drill Guide

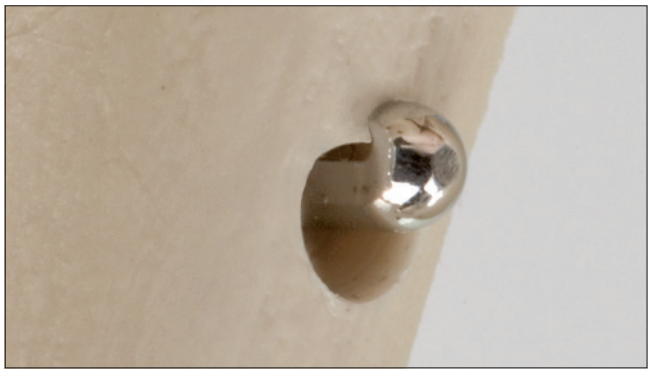
Caution
The use of the twist drill (A-3836) is recommended in the case of particularly hard bone.

Assigning the Screw Length

The depth gauge (A-2032) is used to assign the ideal screw length for use in monocortical or bicortical screw fixation of TriLock screws and cortical screws.

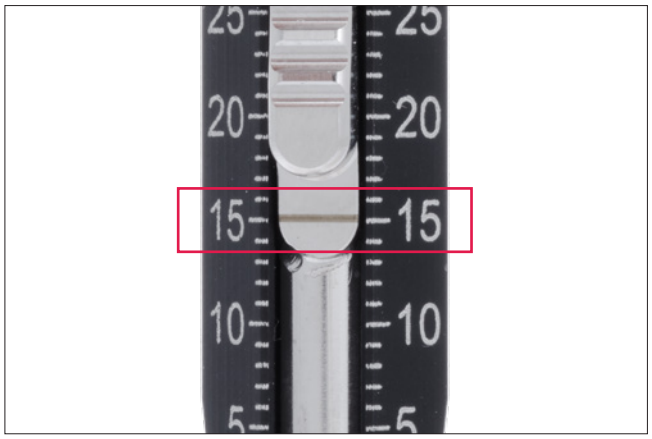
A-2032
2.0 / 2.3 Depth Gauge

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 distal end of the slider onto the implant plate or directly onto the bone (e.g. for fracture fixation with lag screws).

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

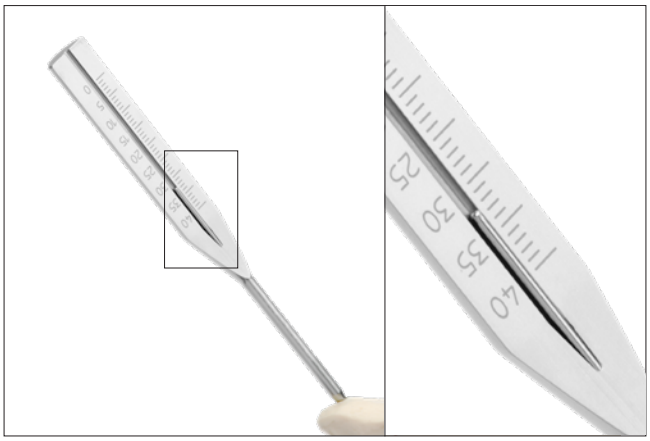


Assigning the Length of the Cannulated Compression Screw

The depth gauge for cannulated compression screws (A-2835) is used to assign the appropriate screw length.

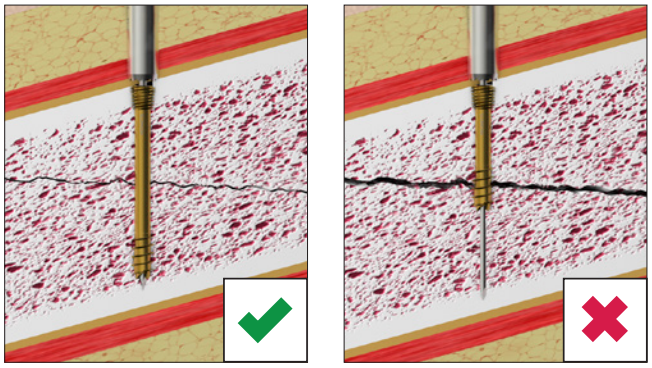
A-2835
2.2 / 3.0 Depth Gauge

Slide the depth gauge over the previously inserted K-wire (A-5040.10, A-5042.10) until it touches the bone. The length can be read from the end of the K-wire. The length corresponds to the distance between the entry point of the K-wire into the bone and the K-wire tip.



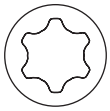
Select a screw that is slightly shorter than the length determined above to allow for shortening through compression of the fusion gap.

Warning
When selecting the screw, it is mandatory that the distal thread is not positioned within the fusion gap, as otherwise no compression can be achieved.



Screw Pick-Up

The screwdriver blades (A-2611, A-2816) feature the patented HexaDrive self-holding system.



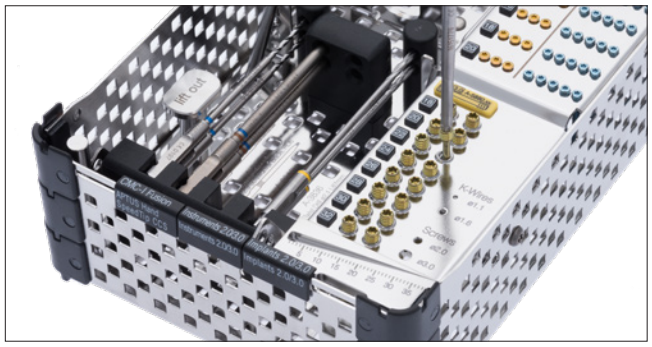
A-2611
2.0/2.3 Screwdriver Blade, HD6, AO

A-2816
3.0 Cannulated Screwdriver Blade, HD10, AO

A-2073
Cannulated Handle with Quick Connector, AO

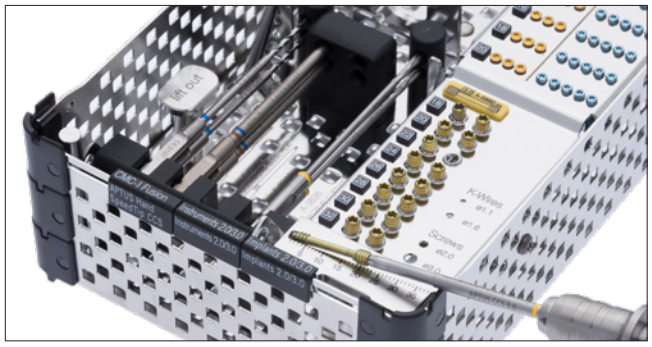
Caution
CCS screws have sharp threads and need to be picked up from the implant container by means of the screwdriver. Be cautious touching the screws directly.

To remove the screws from the implant container, insert the appropriately color-coded screwdriver 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.

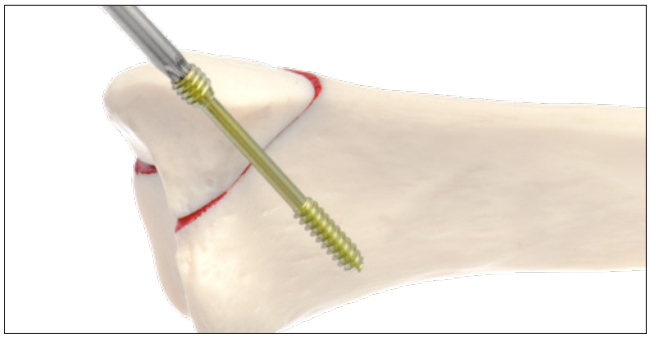
Caution
Vertically extract the screw from the compartment.
Picking up the screw repeatedly may lead to permanent deformation of the self-retaining area of the HexaDrive inside the screw head. Therefore, the screw may no longer be able to be picked up correctly. In this case, a new screw has to be used.



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.

Inserting the Cannulated Compression Screw

When inserting the cannulated compression screw over the K-wire, apply sufficient axial pressure in order to allow for proper cutting and good thread forming.



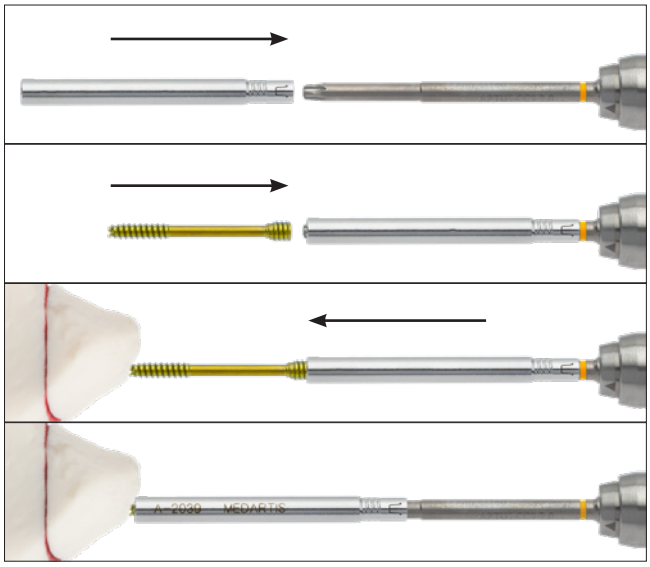
If required, the 2.2/3.0 protection sleeve (A-2039) can be used to protect the surrounding soft tissue.

A-2039
2.2/3.0 Protection Sleeve

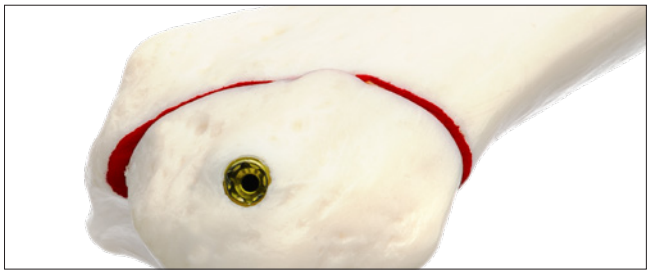
Slide the protection sleeve onto the screwdriver blade.

Put the screw onto the screwdriver.

Slide the protection sleeve to the bone. During screw insertion the protection sleeve slides back.



Caution
Turn the screw until the screw head is completely inserted into the bone.
Remove the K-wire.



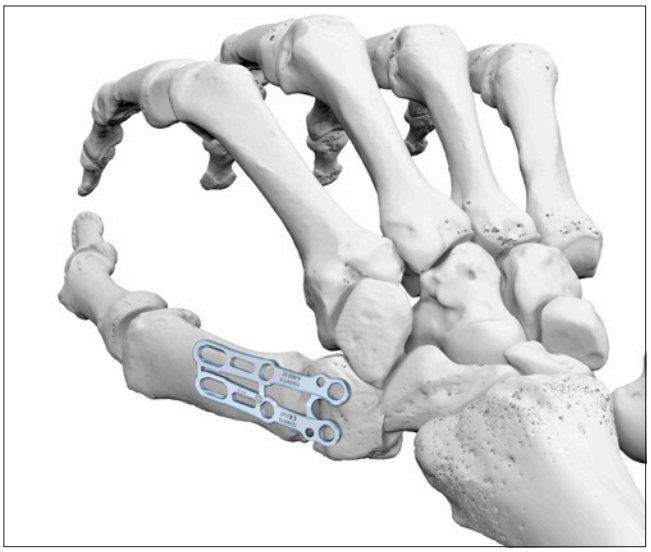
Warning
The correct position of the screw and screw tip as well as the screw length always have to be verified using X-ray control.

Surgical Techniques

General Surgical Techniques

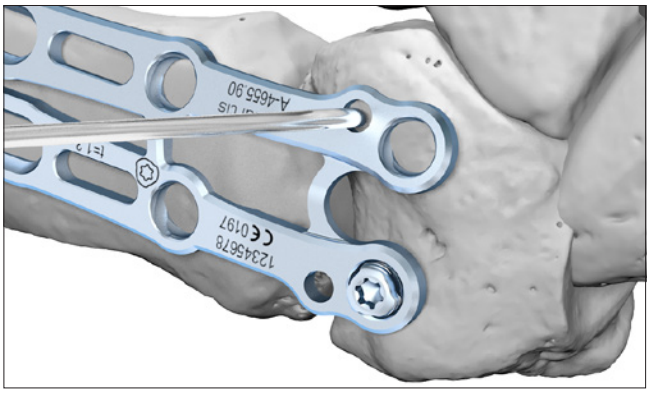
CMC-I Fusion System

A-4655.90 2.0 TriLock CMC-I Fusion Plate
A-5880.xx 3.0 Cannulated Compression Screws (CCS)

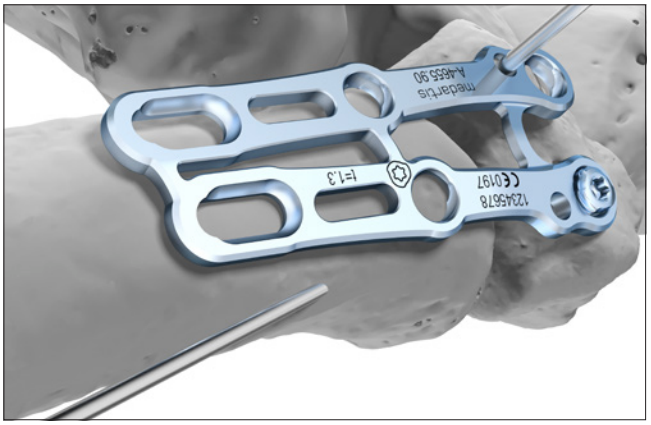


1. Preparing the joint surfaces
Expose and decorticate the surfaces between trapezium and metacarpal. Completely remove the cartilage and the osteoarthritic tissue to expose soft cancellous bone. Flatten the dorsal surfaces with a rongeur, resecting any prominent protuberances.

Fill the fusion site with bone graft.



2. Positioning and prefixation of the plate
Place and align the CMC-I fusion plate (A-4655.90) on the trapezium and first metacarpal.
Insert the first TriLock screw (A-5450.xx) within the trapezium, typically radially as it is better exposed. Do not lock it to still allow some adjustment.
Insert a 1.1 mm K-wire (A-5040.10, A-5042.10) through the ulno-proximal aspect of the plate into the trapezium, without compromising the later insertion of the second TriLock screw.



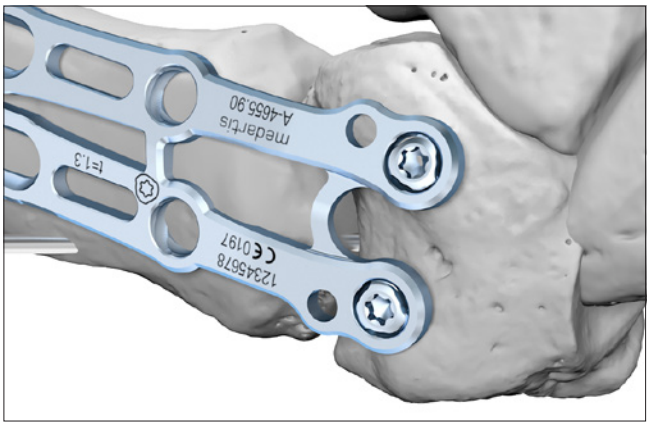
3. Bone alignment and temporary transfixation with K-wire
Insert a 1.1 mm K-wire for transfixation across the joint, obliquely from the metacarpal into the trapezium (or in the opposite direction) while manually precompressing and aligning bones in the desired position for fusion. Use X-ray control to verify the correct alignment.

If needed, realign the plate by adjusting the K-wire position. Use X-ray control to verify the correct alignment.

4. Fixation of the plate on the trapezium

Complete the fixation of the plate on the trapezium. Insert the second TriLock screw (A-5450.xx) within the trapezium. Use X-ray control to verify the correct alignment.

Lock both TriLock screws.



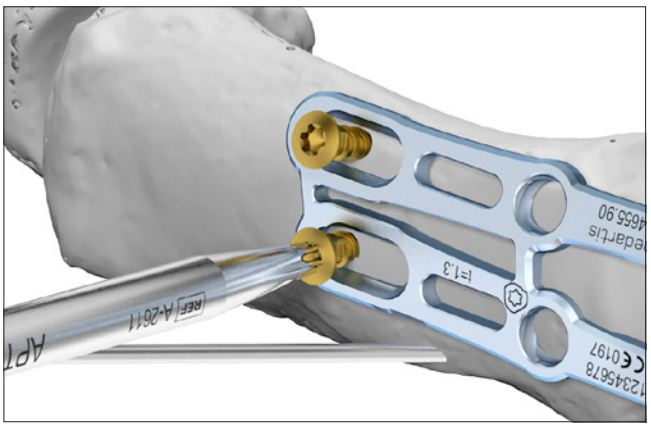
Notice

Add more bone graft if necessary.

5. Prefixation of the plate on the metacarpal

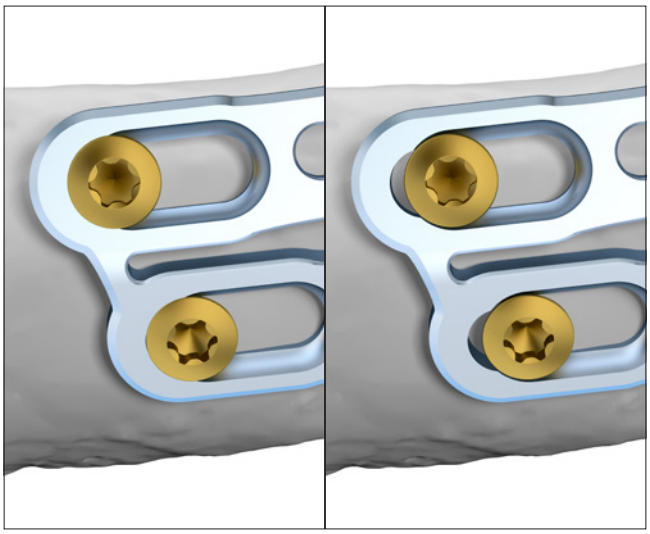
In the distal compression holes of the plate, drill both holes eccentrically using the drill sleeve (A-2020) with the end marked for eccentric drilling.

Insert both cortical screws (A-5400.xx) partially into the drilled holes.



6. Compressing with the cortical screws

Remove the transfixation K-wire. Tighten both screws to apply compression. Use X-ray control to verify the correct screw positions.

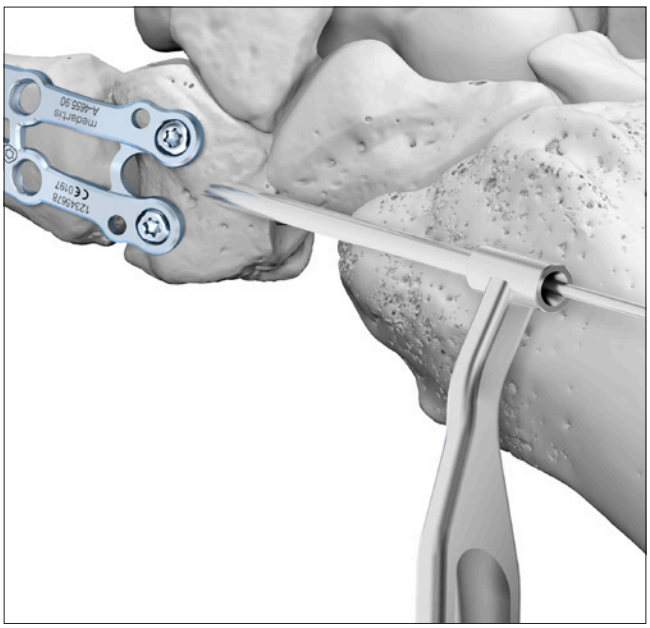


7. Inserting the guide wire for the CCS

Insert the 1.1 mm K-wire using the percutaneous K-wire guide (A-2007):

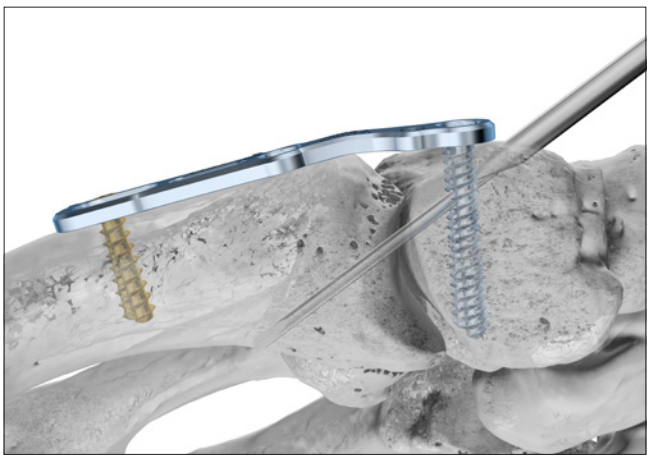
- at a 25°–30° angle to the long axis of the metacarpal,
- through the trapezium, from a point just proximal to and in the area between the two trapezial locking screws.

Use X-ray control to verify the correct position of the guide wire.



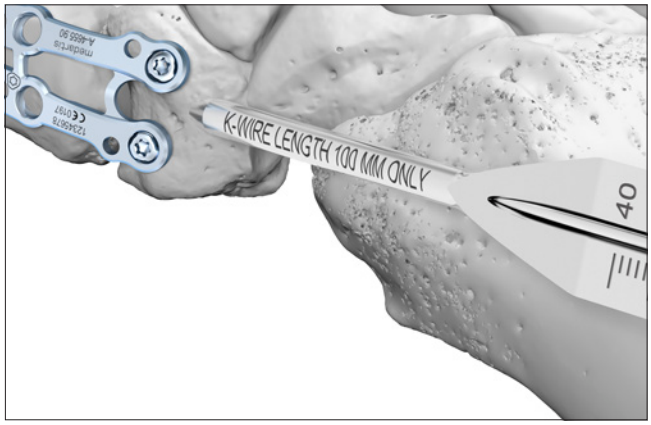
Notice

Position the wrist in ulnar deviation to allow for the appropriate insertion of the CCS.



8. Assigning the length of the CCS

Use the depth gauge (A-2835) to assign the length of the CCS (see chapter “Assigning the Length of the Cannulated Compression Screw”).



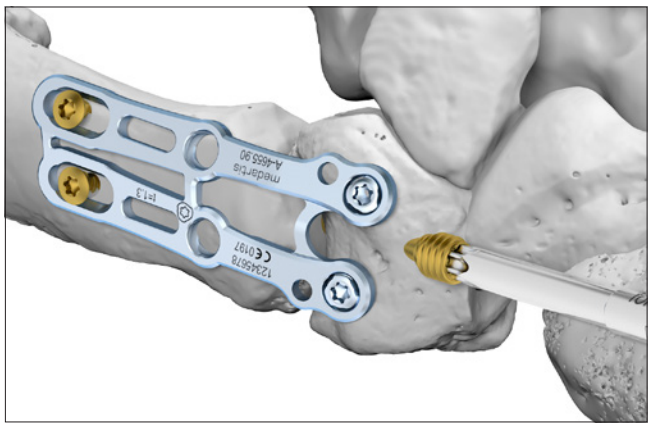
Caution

The tip of the CCS should not exit the far cortex.

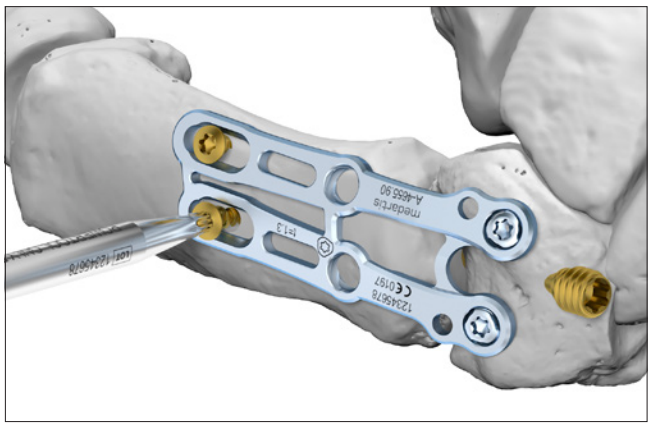
9. Inserting the CCS and applying additional compression

Insert the CCS (A-5880.xx) over the guide wire until the thread of the screw head contacts the cortical shell of the trapezium.

Use the protection sleeve (A-2039) to protect surrounding soft tissues (e.g. nerves, arteries).

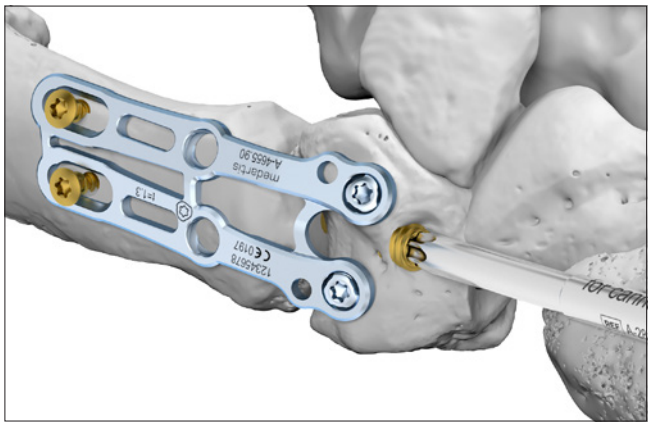


Untighten the two cortical screws by ¼ – ½ turn to allow for further sliding during the insertion of the CCS screw.

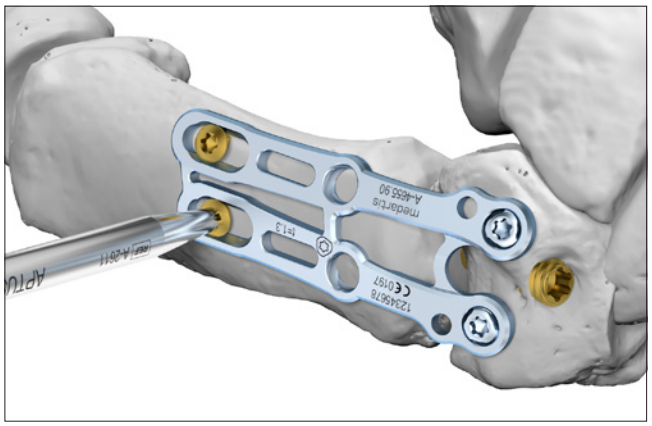


Complete the insertion of the CCS.
Monitor the CCS insertion and use X-ray control to check the compression and alignment of bones.
Remove the guide wire used for the CCS.

Caution
Monitor while inserting, not only after complete insertion.

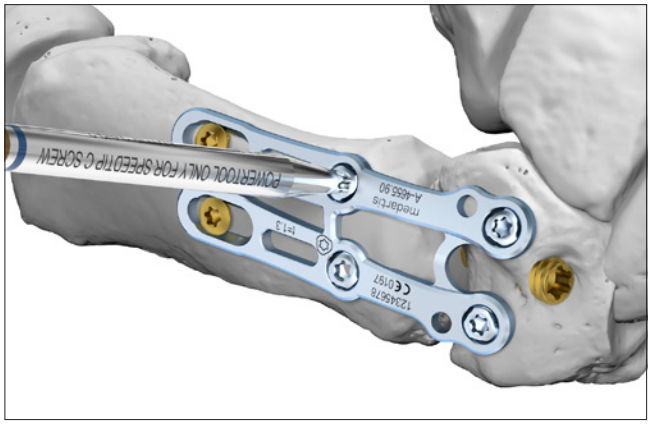


10. Fixation of the plate on the metacarpal
Fully tighten the cortical screws.



Fill the screw holes above the proximal part of the metacarpal with two TriLock screws.

Caution
Use X-ray control to perform a final check of all implants.



Explantation

For implant removal, it is recommended that the implants are removed by using only original APTUS instruments.

Generally, the order in which the screws are removed is not relevant. However, the sequence described for the screw **implantation** should be reversed for the **explantation**.

Explantation of the CCS 3.0

Notice
It is recommended to insert a K-wire into the screw cannulation. The screwdriver/screw head connection must be aligned in an axial direction. Ensure that the cannulated screwdriver blade is fully inserted into the HexaDrive recess of the screw head.

Explantation of the CMC-I Fusion Plate

1. Removing the screws
Unlock/loosen all screws and remove them. In case 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 axial direction, and that a sufficient axial force is used between blade and screw.

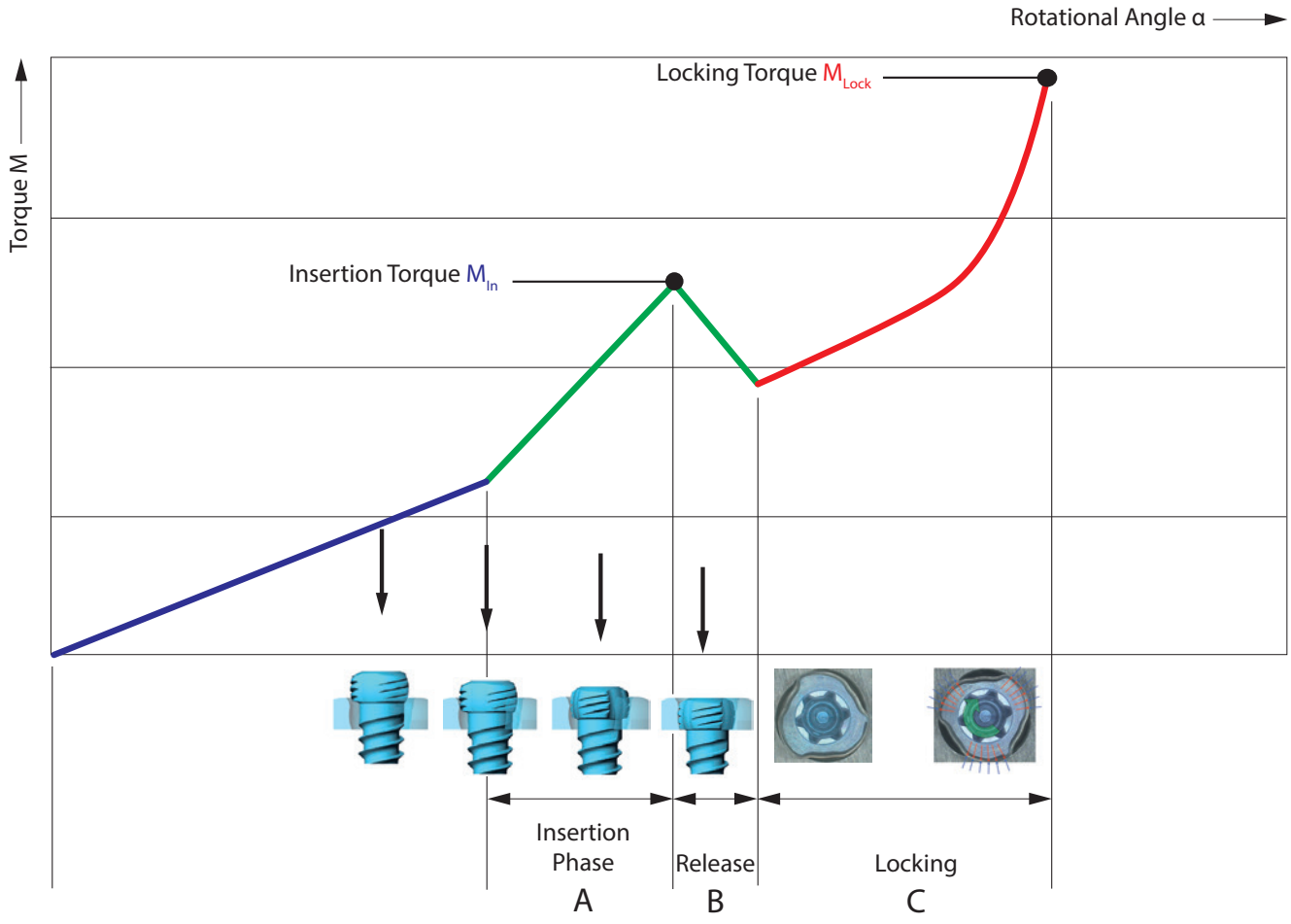
TriLock Locking Technology

Correct Application of the TriLock Locking Technology

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

The example below representatively depicts the correct locking position of a 2.0 mm screw in a straight 1.0 mm thick plate.Correct locking occurs only when the screw head is 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

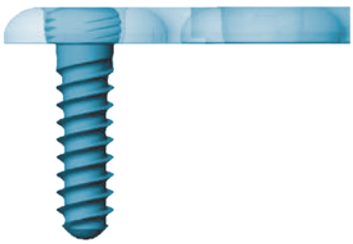


Figure 1

Incorrect: UNLOCKED

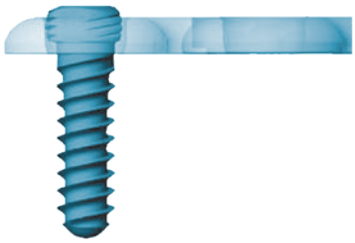


Figure 2

Correct: LOCKED

Figure 3

Incorrect: UNLOCKED

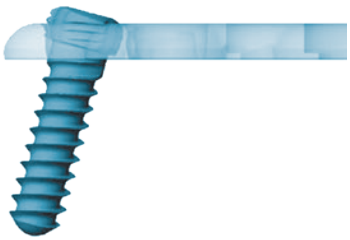


Figure 4

MANUFACTURER & HEADQUARTERS

Medartis AG | Hochbergerstrasse 60E | 4057 Basel / Switzerland

P +41 61 633 34 34 | F +41 61 633 34 00 | www.medartis.com

USA

Medartis Inc. | 1195 Polk Drive | Warsaw IN 46582

P +1 574 376 2404 | Toll free 877 406 BONE (2663) | F +1 574 966 1396

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