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PRECISION IN FIXATION

SURGICAL TECHNIQUE

Minimally Invasive Surgery

Extension of the Distal Radius System 2.5



APTUS Wrist

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

Introduction

Product Materials

Plates	Pure titanium, titanium alloy
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 Wrist

Fractures, osteotomies and arthrodesis of the bones of the wrist

- Distal Radius plates
 - Extraarticular fractures of the distal radius

Contraindications

- Preexisting or suspected infection at or near the implantation site
- Known allergies and/or hypersensitivity to implant 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

System Size	Color Code
2.5	Purple

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)

Possible Combination of Plates and Screws

Plates and screws can be combined within one system size:

2.5 TriLock Plates

- 2.5 Cortical screws, HexaDrive 7
- 2.5 TriLock screws, HexaDrive 7

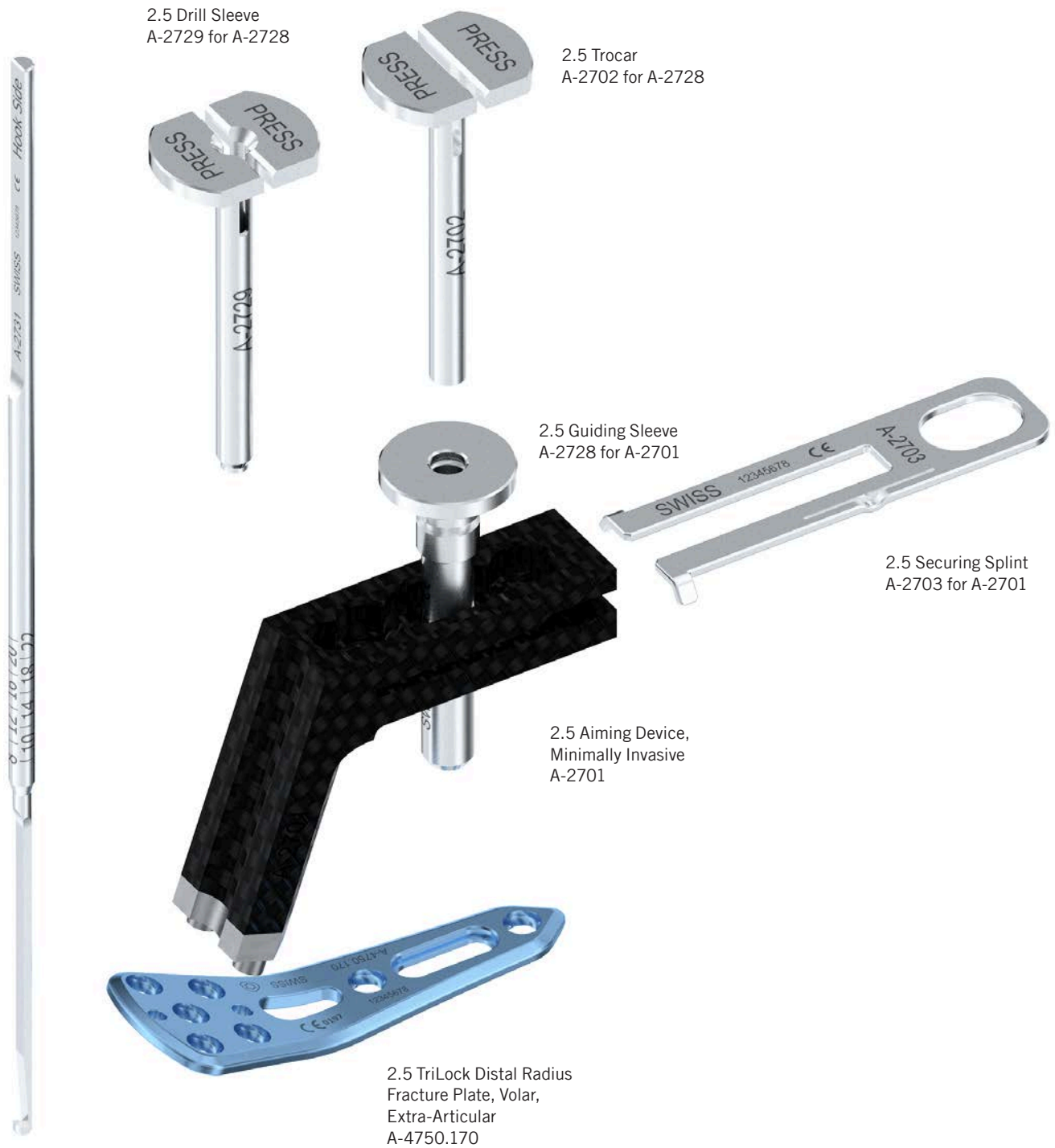
Symbols



HexaDrive




System Overview



2.5 Direct Gauge
A-2731

Treatment Concept

The table below lists typical clinical findings which can be treated with the implant plate for minimally invasive surgery (A-4750.170) of the Distal Radius System 2.5.

Plate Type	
Fracture Type	
A1	
A2	
A3	
B1.1	
B1.2	
B1.3	
B2	
B3	
C1	
C2	
C3	
Volar lunate facet fragment	
Avulsed small distal fragments	
Diaphyseal-metaphyseal fracture	
Correction osteotomy	

- Primary recommendation
- Recommendation
- Possible

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.

* Soft tissue protecting plate position along the watershed line to be respected, according to Soong et al. (Soong et al.; Volar locking plate implant prominence and flexor tendon rupture; J Bone Joint Surg Am. 2011; 93: 328–335)

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
2.5	Purple

There are two different types of twist drills for the system size 2.5: The core hole drills are characterized by one colored ring, the gliding hole drills (for lag screw technique) are characterized by two colored rings.

Warning

The twist drill must always be guided by the drill guide (A-2722) or in the case of proximal screw hole drilling (see chapter Specific Surgical Technique) by the drill sleeve (A-2729). 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-3713



A-3723



A-3733

Core hole drills with \varnothing 2.0 mm = one colored ring



A-3711



A-3721



A-3731

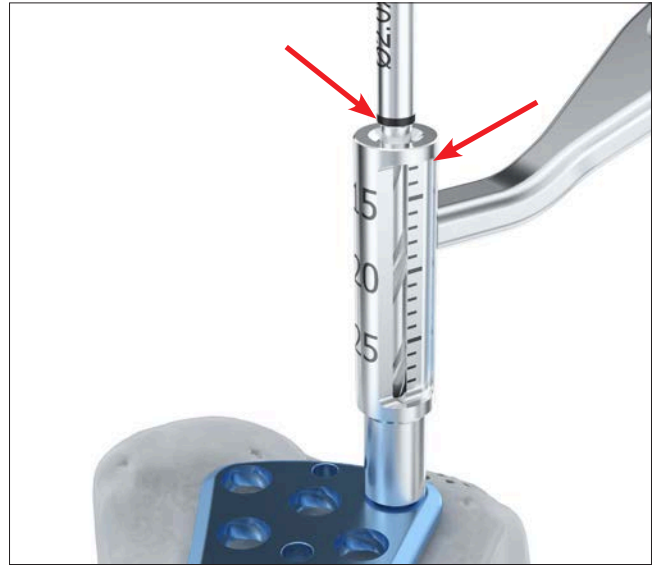
Gliding hole drills with \varnothing 2.6 mm = two colored rings



A-2722
2.5 Drill Guide, Scaled

After positioning the plate, insert the drill guide and the twist drill into the screw hole.

You can read the required screw length at the scale of the drill guide (A-2722) in connection with the black markings on the drill shaft of the twist drills (A-3713, A-3723 or A-3733).



Warning

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



Assigning the Screw Length

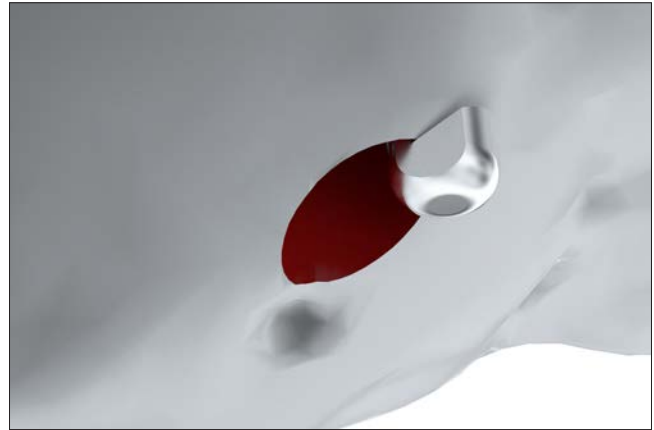
The depth gauge (A-2730) is used to assign the ideal screw length for use in monocortical or bicortical screw fixation of TriLock screws and cortical screws. .

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.



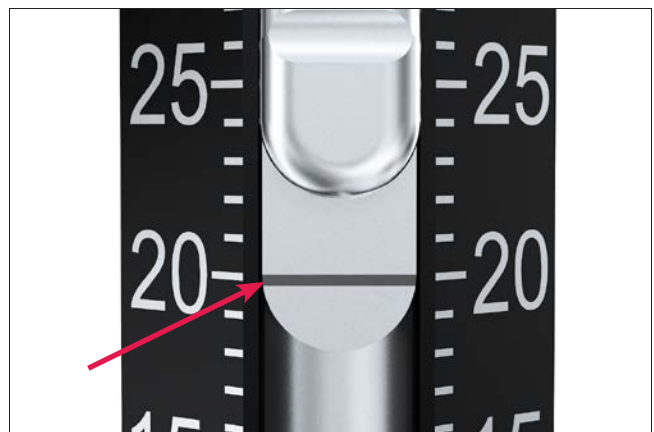
A-2730
2.5 Depth Gauge



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.



Screw Pick-Up

The screwdriver (A-2710) and the screwdriver blade (A-2013) feature the patented HexaDrive self-holding system.



A-2710
2.5 Screwdriver, HD7, Self-Holding



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

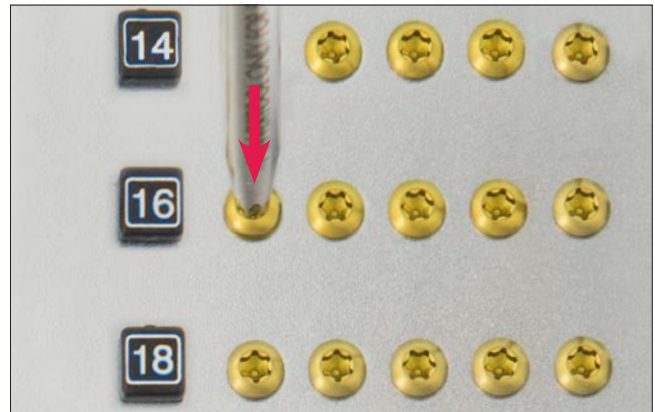


A-2073
Cannulated Handle with Quick Connector, AO

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.

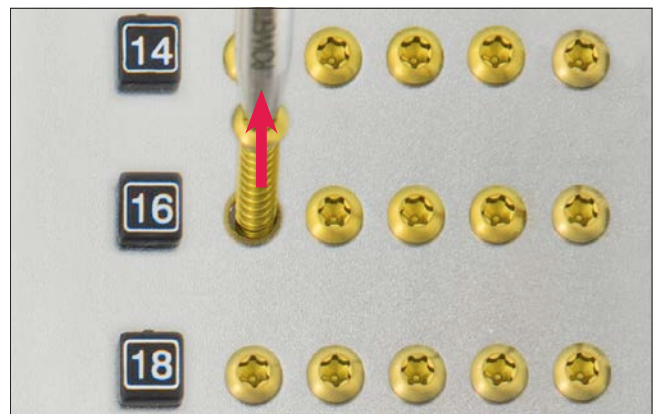
Notice

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.



Surgical Techniques

General Surgical Techniques

Lag Screw Technique

Warning

Incorrect application of the lag screw technique may result in postoperative loss of reduction.

1. Drilling the gliding hole

Drill the gliding hole using the APTUS twist drill marked with two purple rings (A-3711, A-3721, A-3731, Ø 2.6 mm) in combination with the end of the drill guide (A-2721) labeled with two purple bars. Drill perpendicular to the fracture line.

Do not drill further than to the fracture line.



2. Drilling the core hole

Insert the other end of the drill guide (A-2721) into the drilled gliding hole and use the twist drill for core holes with one purple ring (A-3713, A-3723, A-3733, Ø 2.0 mm) to drill the core hole.



3. Compressing the fracture

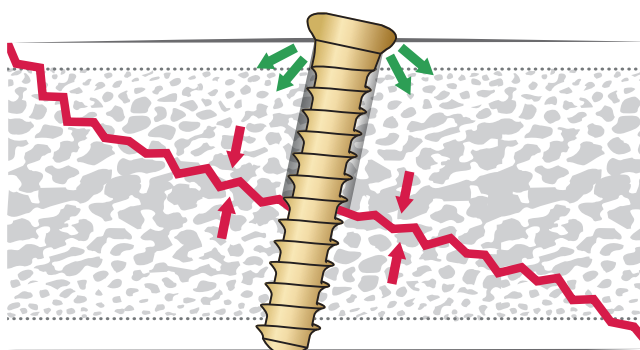
Compress the fracture with the corresponding cortical screw (A-5700.xx).

4. Optional steps before compression

If required, use the countersink (A-3830) to create a recess in the bone for the screw head.

Caution

Use the handle (A-2073) instead of a power tool to reduce the risk of countersinking too far through the near cortex.



Distal Two-Row Screw Allocation

During application on the distal radius, ensure that screws are inserted in two rows at the distal end of the plate. This not only increases stability, but also provides the best possible subchondral support of the radiocarpal joint. Drill the two distal screw rows as subchondrally as possible, which automatically leads to the screws crossing over.

Warning

Insert at least three TriLock screws into the most distal row and two TriLock screws into the second distal row.



Specific Surgical Technique

1. Surgical approach

Make a transverse skin incision of approximately 15 mm in length proximal to the proximal wrist crease, over the tendon of the flexor carpi radialis muscle (FCR).

Open the tendon sheath of the FCR, the flexor carpi radialis tendon is being held to the side ulnarly. Open the bottom of the tendon sheath to expose the pronator quadratus muscle (PQ). Make an incision at the distal margin of the PQ to expose the distal fragment.

Make a blunt separation of the PQ to create a submuscular pocket which corresponds to the size of the plate.

Reduction of the fragments is performed with longitudinal traction by dorsal pressure on the fragments to align the volar cortex.

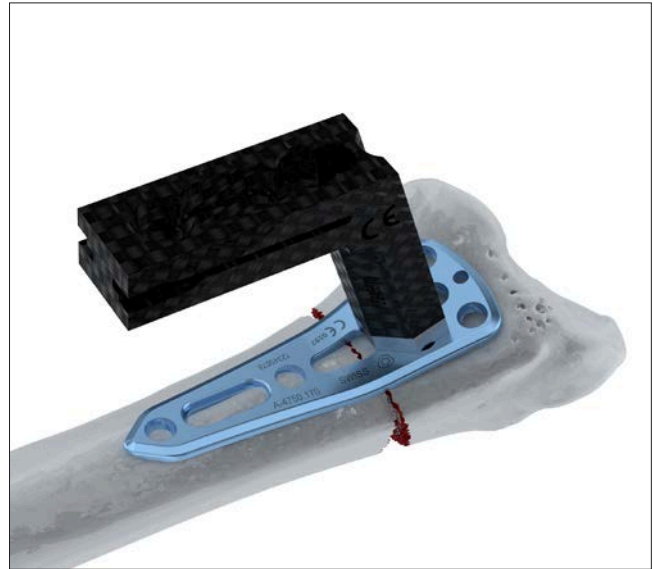
2. Mounting the aiming device on the plate

Insert the aiming device (A-2701) into the second distal screw row (see red dots) of the plate (A-4750.170). Tighten the integrated screw using the 2.5 screwdriver blade (A-2013) in combination with the handle (A-2073) or use the 2.5 screwdriver (A-2710).



3. Positioning the plate and distal fixation

Use the aiming device (A-2701) to insert the plate (A-4750.170) underneath the pronator quadratus muscle.



Use intraoperative X-ray control to verify the correct position of the plate (A-4750.170).

Ensure the longitudinal alignment of the plate to the radius shaft.

With the drill guide (A-2722) and the core hole drill with \varnothing 2.0 mm (A-3713, A-3723, A-3733, one purple ring) drill a core hole through the distal screw hole.



Assign the screw length using the depth gauge (A-2730) and insert a cortical screw \varnothing 2.5 mm (A-5700.xx) as first screw. Ensure that the screw is inserted bicortically.

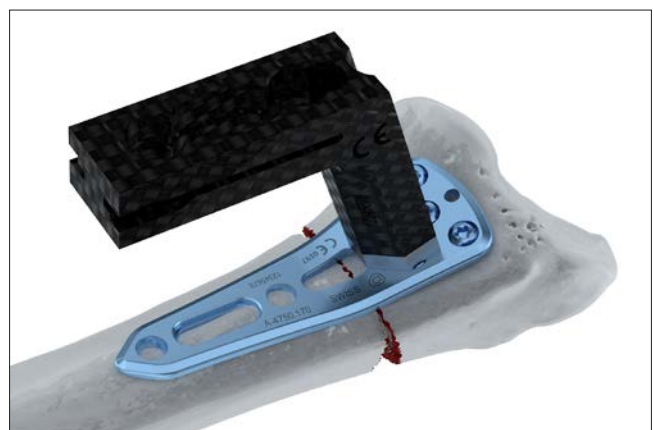


This cortical screw is used to pull the plate (A-4750.170) to the fragment. If pulling of the fragment is not found to be necessary, use a TriLock screw (A-5750.xx) as first screw.



Drill, assign the screw length and fill the remaining distal screw holes with TriLock screws \varnothing 2.5 mm (A-5750.xx).

If a cortical screw (A-5700.xx) was inserted initially, it can now be replaced with a TriLock screw.



4. Stab incision and inserting the trocar

Perform a stab incision into the skin through the oblong slot of the aiming device (A-2701) and spread the soft tissue using a mosquito clamp to create a sufficiently large approach for the guiding sleeve (A-2728).

Make a blunt dissection with the clamp down to the bone, sliding the mosquito clamp radially to the flexor carpi radialis.



Insert the trocar (A-2702) into the guiding sleeve (A-2728) until it snaps into place.

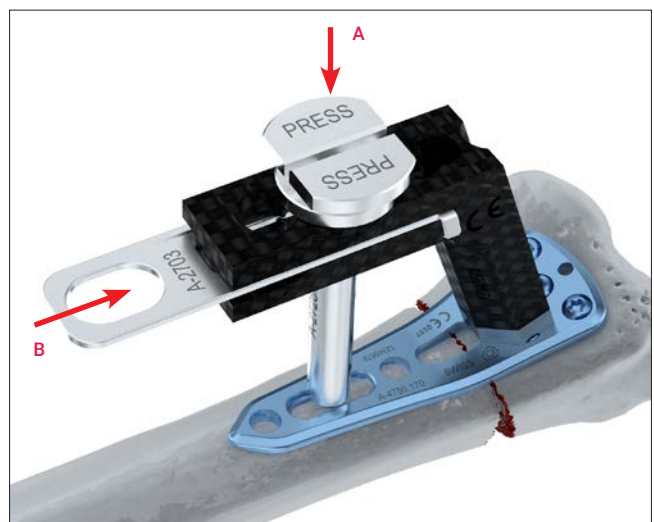


Insert the trocar (A-2702) together with the guiding sleeve (A-2728) into the oblong slot of the aiming device (A-2701) towards the bone. The oblong slot aims to the oblong hole of the plate.

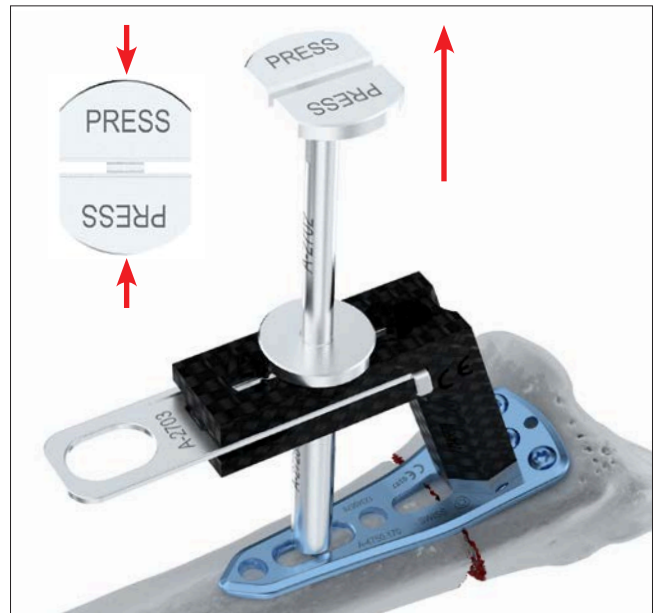
Fix the guiding sleeve and the trocar using the securing splint (A-2703) until it snaps into place.

Caution

During the insertion of the securing splint, hold the trocar down onto the aiming device.



Press the head of the trocar (A-2702) together and remove it from the guiding sleeve (A-2728).



5. Proximal fixation

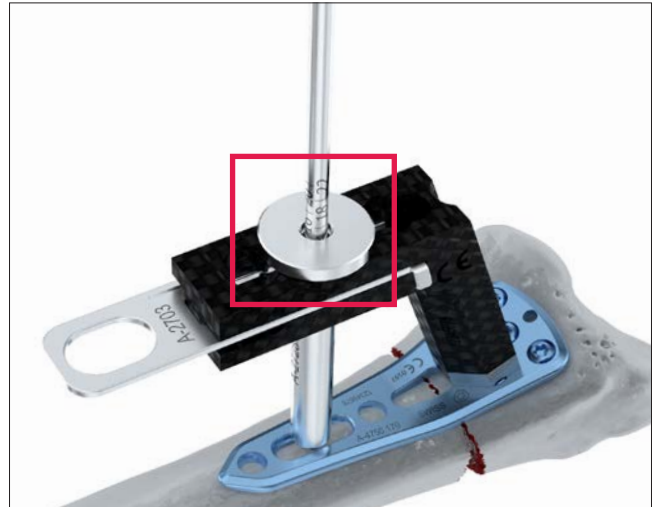
Insert the drill sleeve (A-2729) into the guiding sleeve (A-2728) until it snaps into place.



Drill a hole through the drill sleeve (A-2729) and the oblong hole using the core hole drill with \varnothing 2.0 mm (A-3713, A-3723, A-3733, one purple ring).



Remove the drill sleeve (A-2729) and determine the screw length using the direct gauge (A-2731).



The screw length can be read on the scale of the direct gauge (A-2731).



Insert a cortical screw (A-5700.xx) through the guiding sleeve (A-2728). Use intraoperative X-ray control to verify the anatomic reduction and the correct position of the plate (A-4750.170).

If necessary, the position of both plate and distal radius fragment can be corrected by moving the plate longitudinally.



Remove the securing splint (A-2703) and the guiding sleeve (A-2728). Reinsert the guiding sleeve through the distal or proximal hole of the aiming device (A-2701) and fix it again with the securing splint.



Slide the skin aside to avoid a new skin incision. Repeat the above steps for proximal fixation and insert two TriLock screws (A-5750.xx) into the remaining two shaft holes.

6. Removing the aiming device

Remove the aiming device (A-2701) together with the guiding sleeve (A-2728) and securing splint (A-2703).

7. Final distal fixation

Drill the two remaining holes in the second distal screw row using the drill guide (A-2722) and the core hole drill with \varnothing 2.0 mm (A-3713, A-3723, A-3733, one purple ring).

Determine the screw lengths using the depth gauge (A-2730) and insert two TriLock screws (A-5750.xx).

Use intraoperative X-ray control to verify the correct position of the plate (A-4750.170), the screws and the distal radioulnar joint.



Explantation

Explantation of the Plate

1. Removing the screws

Unlock all screws and remove them.

The order in which the screws are removed is not relevant.

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

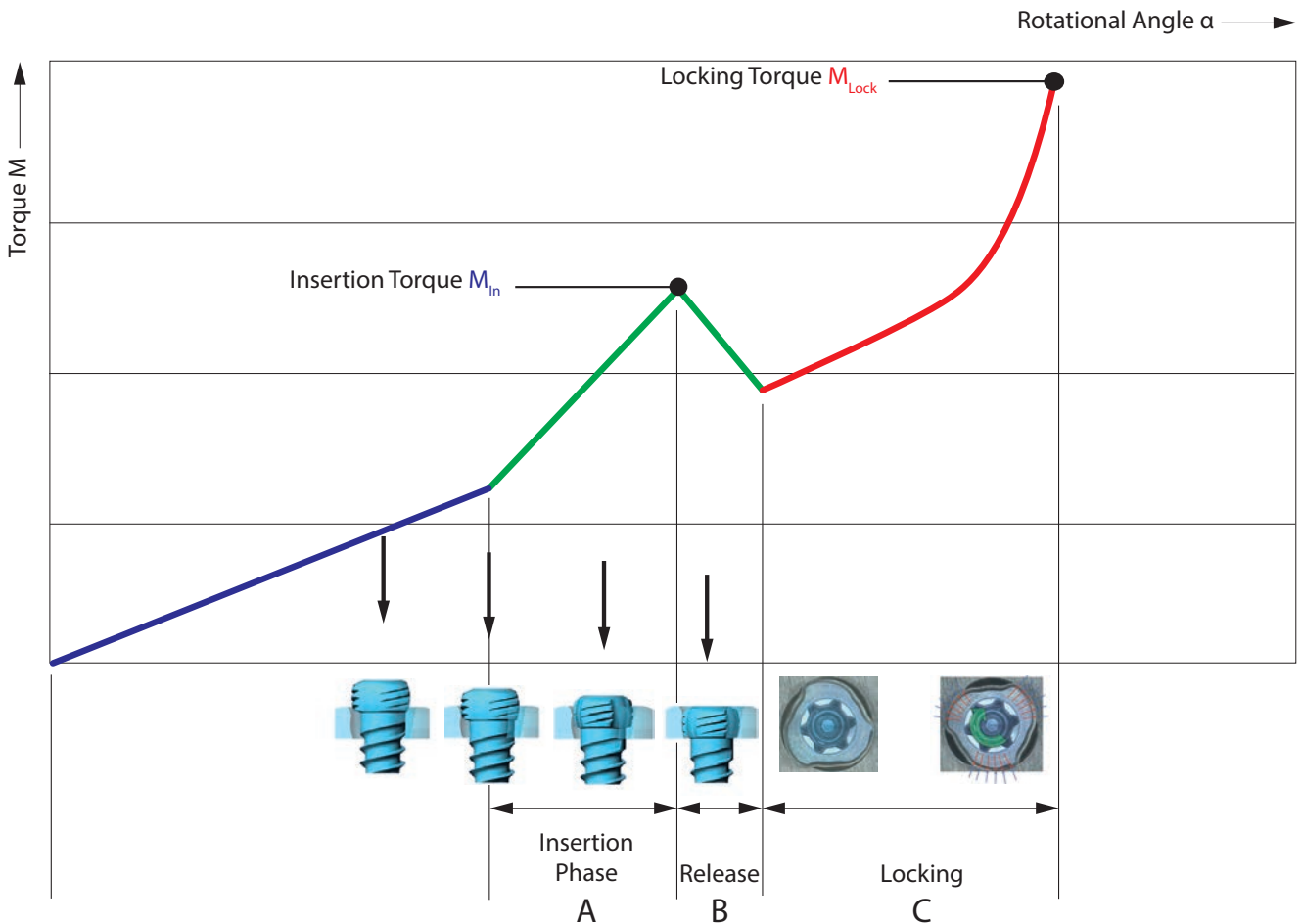
Correct Application of the TriLock Locking Technology

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 ($\pm 15^\circ$) of the TriLock Screws in the Plate

The example below representatively depicts the correct locking position of a 2.5 mm screw in a straight 1.6 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 contour of the plate.

In this case, the screw has to be tightened further 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

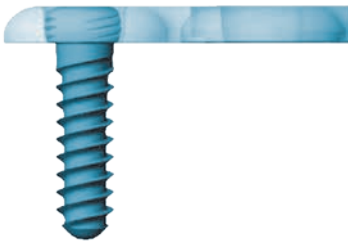


Figure 1

Incorrect: UNLOCKED

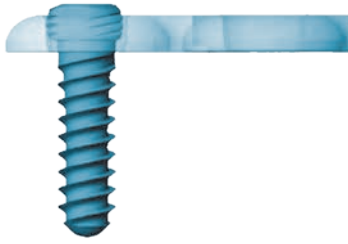


Figure 2

Correct: LOCKED

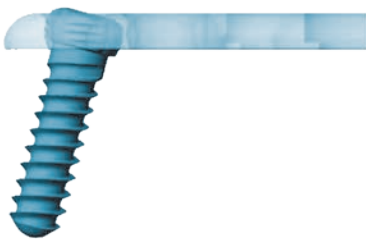


Figure 3

Incorrect: UNLOCKED

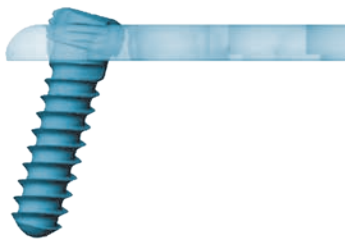


Figure 4

Implant, Instruments and Container

2.5 TriLock Distal Radius Fracture Plate, Volar, Extra-Articular

Material: Titanium (ASTM F67)
Plate thickness: 1.6 mm



Art. No.	Holes	Pieces/Pkg
A-4750.170	8	1

2.5 Aiming Device, Minimally Invasive



A-2701

Art. No.	Description	Pieces/Pkg
A-2701		1
A-2701.1	screw for aiming device 2.5, minimally invasive (spare part)	1

2.5 Securing Splint



Art. No.	Description	Length	Pieces/Pkg
A-2703	for A-2701	43 mm	1

2.5 Guiding Sleeve



Art. No.	Description	Length	Pieces/Pkg
A-2728	for A-2701	35 mm	1

2.5 Trocar



Art. No.	Description	Length	Pieces/Pkg
A-2702	for A-2728	38 mm	1

2.5 Drill Sleeve



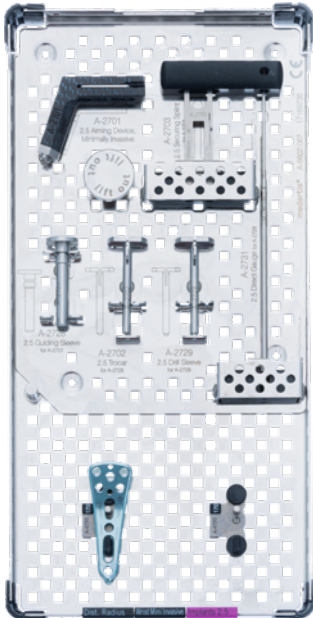
Art. No.	Description	Length	Pieces/Pkg
A-2729	for A-2728	38 mm	1

2.5 Direct Gauge



Art. No.	Description	Length	Pieces/Pkg
A-2731	for A-2728	125 mm	1

Case, Tray



A-6602.066 containing A-6602.067
(excl. implant and instruments)

Art. No.	Description	Dimension (W x L)	Pieces/Pkg
A-6602.066	implant case APTUS Radius, minimally invasive	120 x 240 mm	1
A-6602.067	instrument tray APTUS Radius, minimally invasive	114 x 154 mm	1
M-6706	lid for implant and instrument case 120 x 240 mm	120 x 240 mm	1

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