Variable Angle LCP Volar Rim Distal Radius Plate 2.4. For fragment-specific fracture fixation with variable angle locking technology.

Surgical Technique

Instruments and implants approved by the AO Foundation.

DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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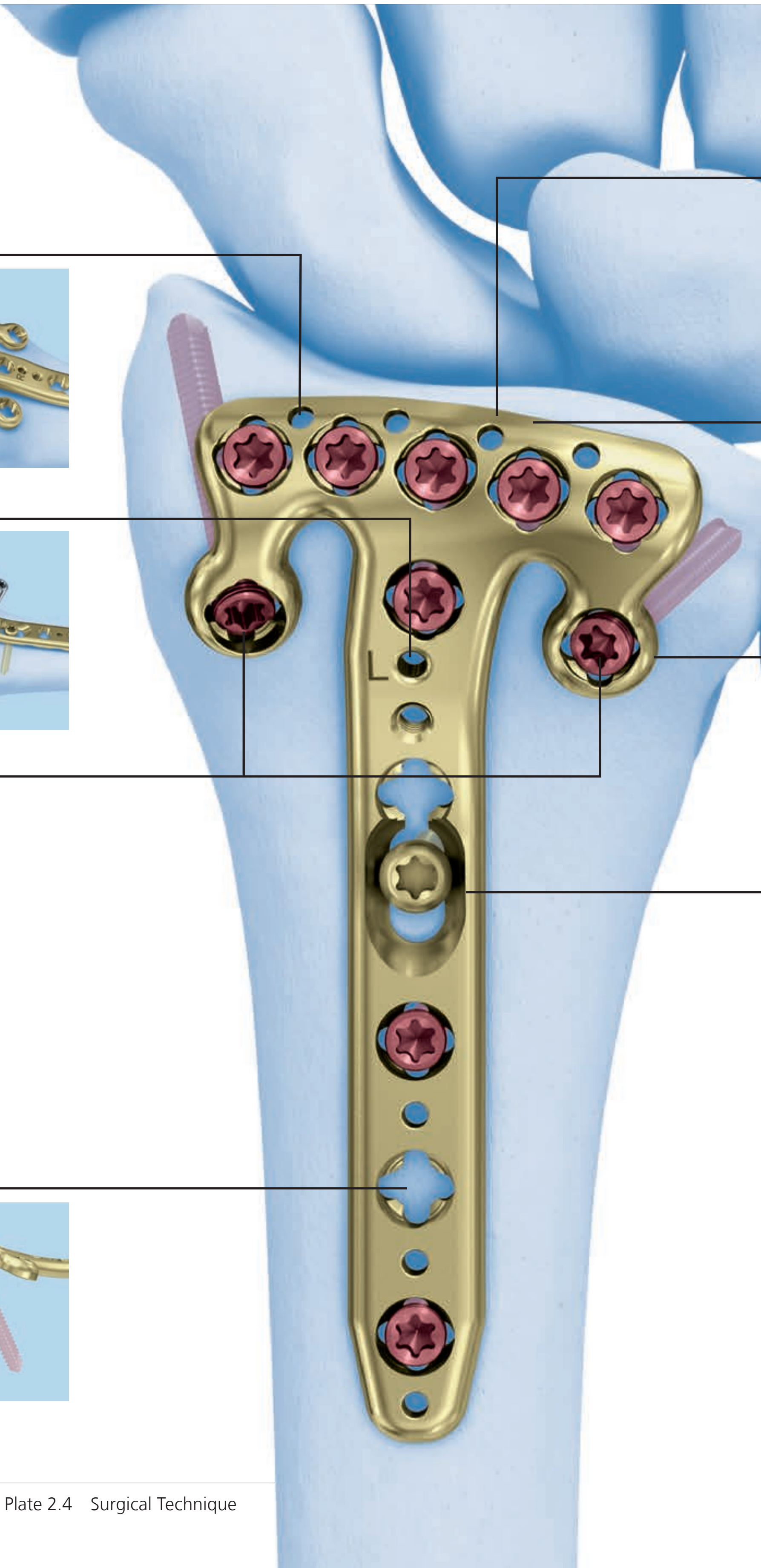
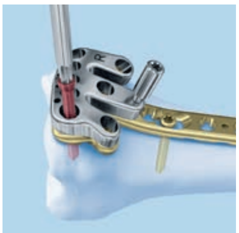
Variable Angle LCP Volar Rim Distal Radius Plate 2.4. For fragment-specific fracture fixation with variable angle locking technology.

The anatomically pre-contoured plates with small plate and screw dimension are indicated for complex intra-articular and extra-articular distal radius fractures. All implants are available in stainless steel and titanium.



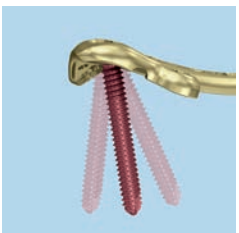
Kirschner wire holes
Enable preliminary plate fixation and indicate screw orientation when using guiding blocks.

Guiding block
Allows guided drilling and screw insertion in the pre-defined nominal angle.



Additional distal screw options
Enable support of radial styloid, lunate facet and DRUJ.

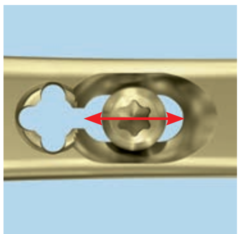
Variable angle locking
Holes allow up to 15° off-axis screw angulation in all directions in order to address the individual fracture patterns.



Low profile construct
Bevelled distal edge, rounded plate edges, polished surface and counter-sunk screws help reduce the risk of soft tissue irritation.

Anatomically pre-contoured
Buttressing of distal fragments due to anatomically pre-contoured plate.

Bendable tabs
If necessary, tabs can be bent in order to suit the individual anatomical conditions of the bone.



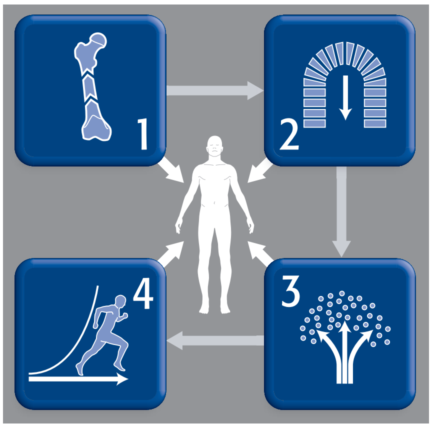
Oblong VA combi-hole
Allows accurate plate positioning on the bone.

AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.[1, 2]

Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.



Stable fixation
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin Heidelberg New York: Springer. 1991.
[2] Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management.2nd ed. Stuttgart, New York: Thieme. 2007.

Intended Use and Indications

Intended Use
The plate and screw implants included in the Radius Plate product family are intended for temporary fixation, correction or stabilization in the radius anatomical region.

Indications
Variable Angle LCP Volar Rim Distal Radius Plate 2.4 is indicated for the fixation of complex intra-articular and extra-articular fractures of the distal radius.

Clinical Cases

Case 1
74-year-old female with AO C3 fracture and distal ulna fracture


Preoperative, AP view


Preoperative, lateral view


Postoperative, AP view


Postoperative, lateral view

Case 2
43-year-old male with AO C2 fracture


Preoperative, AP view

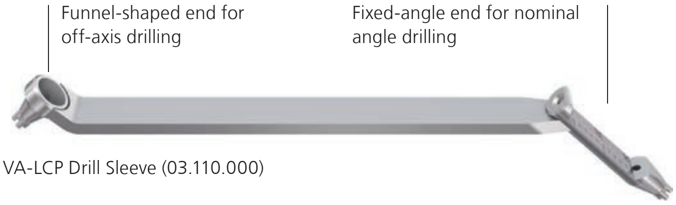

Preoperative, lateral view


Postoperative, AP view


Postoperative, lateral view

Recommendations on Screw and Plate Insertion
Screw Insertion Techniques

Variable angle locking screws can be inserted using two different techniques:
– Variable angle technique
– Pre-defined nominal angle technique



VA-LCP Drill Sleeve (03.110.000)

VA-LCP Drill Sleeve, freehand (03.111.004), for off-axis drilling

Variable angle technique

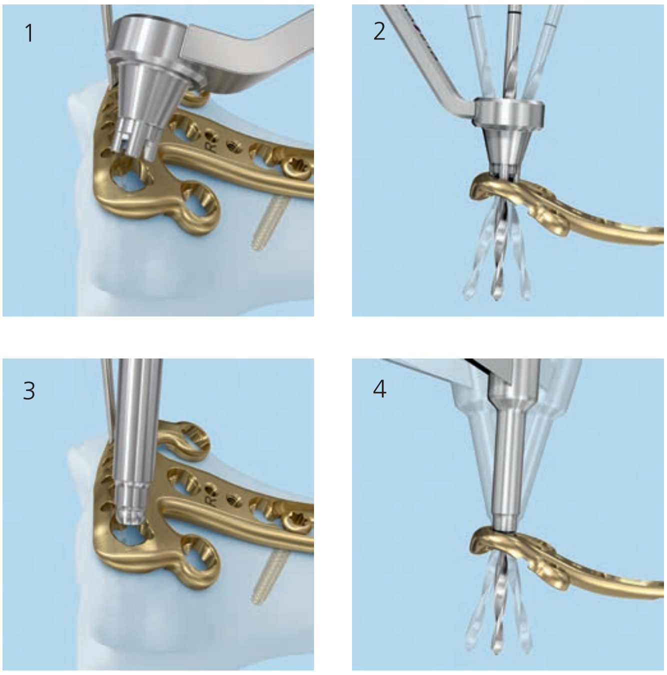
To drill variable angle holes up to 15° deviation from the nominal trajectory of the locking hole, insert the tip of the VA-LCP drill sleeve and key into the cloverleaf design of the VA locking hole. (1)

Use the funnel-shaped end of the VA-LCP drill sleeve to drill variable angle holes at the desired angle. (2)

Alternatively, use the freehand VA-LCP drill sleeve and insert it fully into the VA locking hole. (3)

Drill variable angle holes at the desired angle. (4)

Precaution: It is important not to angulate more than 15° from the central axis of the screw hole. Overangulation could result in inappropriate screw locking. Moreover, the screw head may not be fully countersunk.



Pre-defined nominal angle technique

a) Use of fixed-angle end of VA-LCP drill sleeve
The fixed-angle end of the VA-LCP drill sleeve only allows the drill bit to follow the nominal trajectory of the VA locking hole.

b) Use of guiding blocks
Fixation at the nominal angle of the VA locking holes in the head of the plate may also be facilitated by a guiding block attached to the plate prior to plate fixation.

The guiding blocks are used together with the quick drill sleeve (03.111.000).

Choose the guiding block corresponding to the desired plate (six or seven head hole configuration, left or right). Mount the guiding block to the plate by turning the guiding block attachment screw clockwise.

Quick Drill Sleeve (03.111.000)

Guiding Block, 7 head holes

Precaution: If using guiding blocks, avoid bending the head portion of the plate.

Recommendations on Screw and Plate Insertion
Screw Type Determination

Determine whether standard cortex screws or variable angle locking screws will be used for fixation.

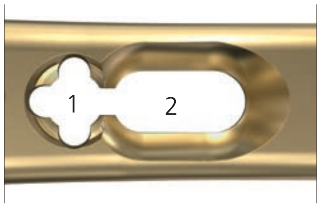
The final screw placement and the use of VA locking and cortex screws are determined by the fracture pattern.

If a VA locking screw is inserted first, ensure that the plate is held securely to the bone to prevent the plate from spinning as the screw locks into the plate.

When using pre-defined nominal angle technique standard locking screws can also be used instead of VA locking screws.

Precaution: When a cortex screw is inserted into a variable angle locking hole the screw head will not be completely countersunk. Only use cortex screws in the most distal row when essential for clinical outcome since a prominent screw head may increase the risk of soft tissue irritation.

VA locking hole:
2.4 mm VA locking screw,
1.8 mm VA locking buttress pin,
2.4 mm locking screw
(only nominal angle)
or 2.4 mm cortex screw applicable

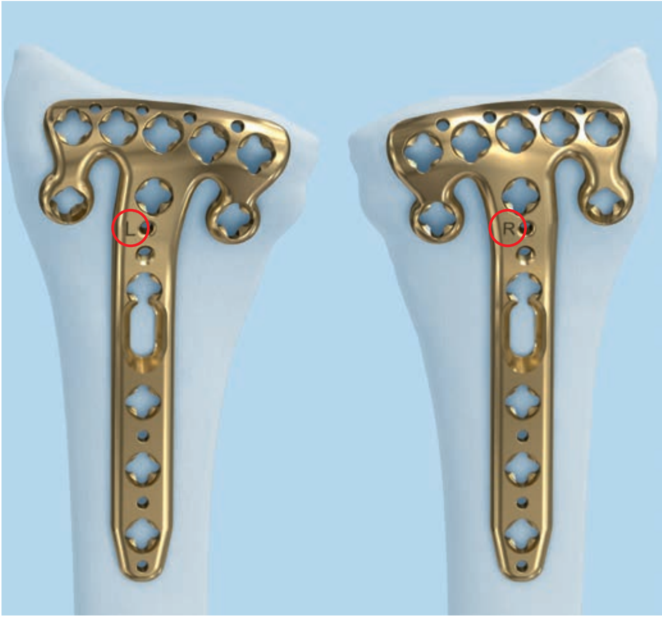


Oblong VA combi-hole:
2.4 mm VA locking screw,
1.8 mm VA locking buttress pin,
2.4 mm locking screw
(only nominal angle)
or 2.4 mm cortex screw applicable in the threaded portion (1)
2.4 mm or 2.7 mm cortex screw applicable in the compression portion (2)

Select implant

Select the plate according to the fracture pattern and anatomy of the bone.

Note: Ensure the proper plate selection by verifying the L (left) and R (right) etching on the plate shaft.



Approach

Make a longitudinal incision slightly radial to the flexor carpi radialis tendon (FCR). Dissect between the FCR and the radial artery, exposing the pronator quadratus. Detach the pronator quadratus from the lateral border of the radius and elevate it toward the ulna.

Precaution: Leave the volar wrist capsule intact to avoid devascularization of the fracture fragments and destabilization of the volar wrist ligaments.

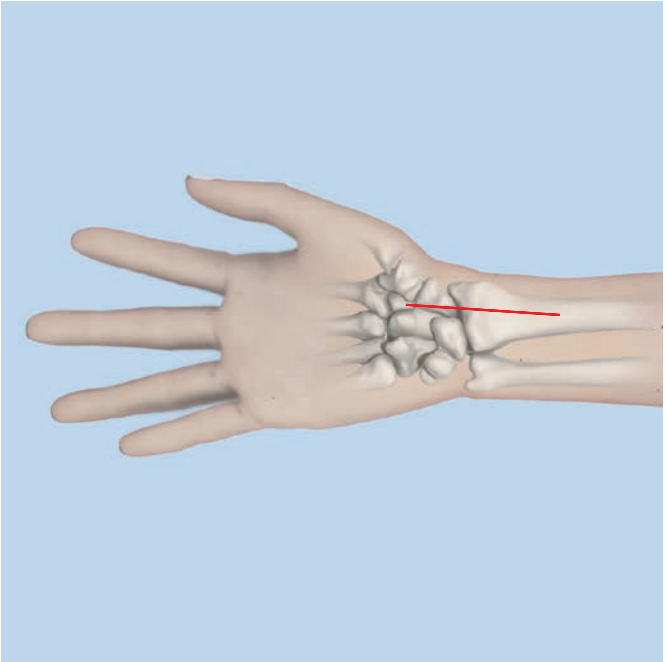


Plate Insertion

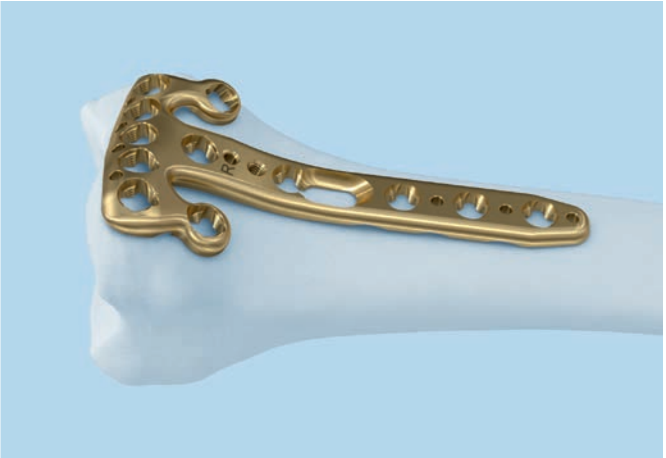
1
Reduce fracture

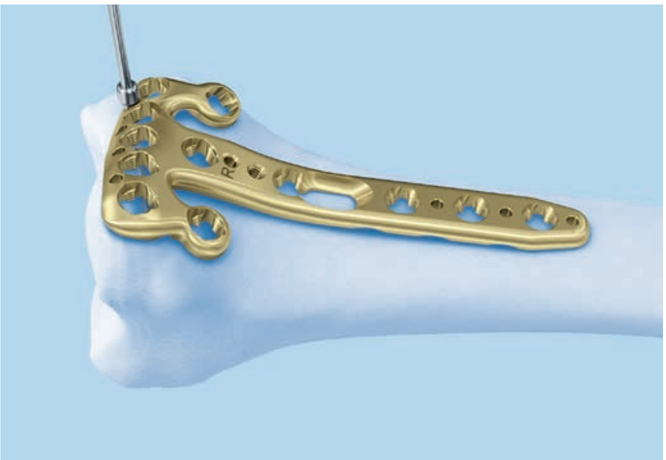
Reduce the fracture under image intensifier control and, if necessary, fix with Kirschner wires or reduction forceps. The reduction method will be fracture-specific.

2
Position plate

Optional instruments

292.120(S)	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm, Stainless Steel
02.111.500.01(S)	Plate Reduction Wire ∅ 1.25 mm, with thread, with Small Stop, length 150 mm, Stainless Steel
02.111.501.01(S)	Plate Reduction Wire ∅ 1.25 mm, with thread, with Large Stop, length 150 mm, Stainless Steel





Apply the plate to fit the volar surface. If necessary, use 1.25 mm Kirschner wires inserted through the desired Kirschner wire hole to temporarily fix the plate.

Option: Plate reduction wires
The 1.25 mm plate reduction wires can be used for preliminary plate fixation.

They must be removed when no longer needed for temporary fixation.

Precaution: The plate reduction wires and Kirschner wires are single use items, do not re-use.

1
Drill screw hole for cortex screw

Instruments – 2.4 mm cortex screws	
310.509	Drill Bit ∅ 1.8 mm with marking, length 110/85 mm, 2-fluted, for Quick Coupling
323.202	Universal Drill Guide 2.4
Instruments – 2.7 mm cortex screws	
310.534	Drill Bit ∅ 2.0 mm, with marking, length 110/85 mm, 2-flute for Quick Coupling
323.260	Universal Drill Guide 2.7

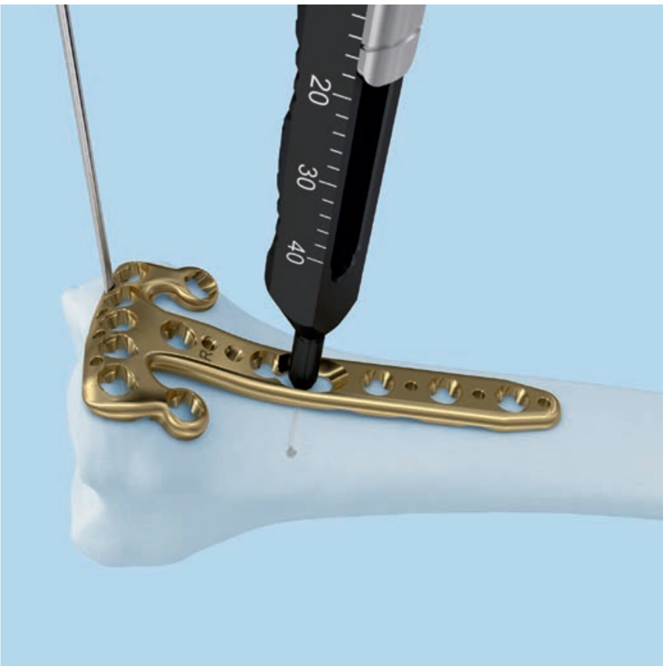
Start with the elongated hole in the shaft of the plate.

For 2.4 mm cortex screws, use the 2.4 universal drill guide and pre-drill the screw hole with the 1.8 mm drill bit.

For 2.7 mm cortex screws, use the 2.7 universal drill guide and pre-drill the screw hole with the 2.0 mm drill bit.

2
Determine screw length

Instrument	
03.111.005	Depth Gauge for Screws ∅ 2.0 to 2.7 mm, measuring range up to 40 mm



Determine screw length with the depth gauge.

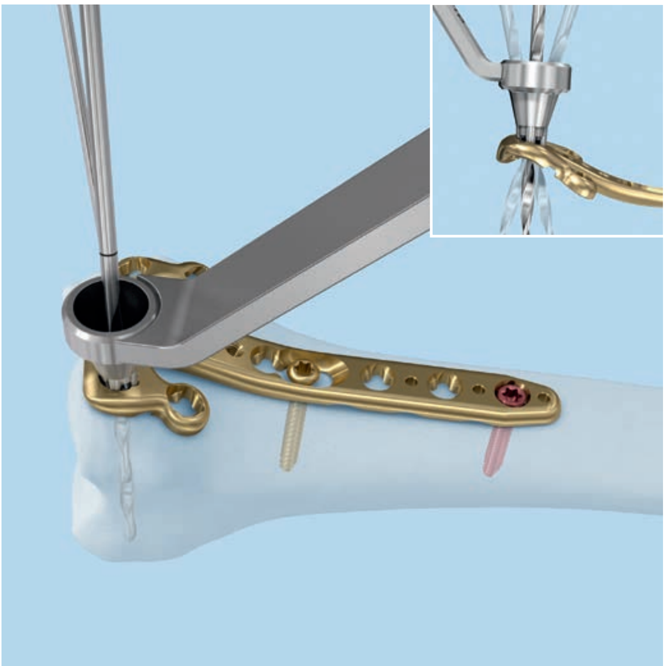
3
Insert cortex screw

Instruments	
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
311.430	Handle with Quick Coupling
Optional instrument	
314.453	Screwdriver Shaft, Stardrive 2.4, short, self-holding, for Quick Coupling

Insert the self-tapping cortex screw using the self-holding T8 Stardrive screwdriver shaft and the quick coupling handle.

Variable Angle Locking Screws

1a
Drill screw hole for VA locking screw using variable angle technique



Instruments

310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-fluted, for Quick Coupling
03.110.000	VA-LCP Drill Sleeve 2.4, for Drill Bits ∅ 1.8 mm

Optional instruments

03.110.023	VA-LCP Drill Sleeve 2.4, conical, for Drill Bits ∅ 1.8 mm
03.111.004	VA-LCP Drill Sleeve 2.4, for Drill Bits ∅ 1.8 mm, freehand useable

Drill using VA-LCP drill sleeve with funnel

Insert and lock the VA-LCP drill sleeve tip into the cloverleaf design of the VA locking hole.

Use the 1.8 mm drill bit to drill to the desired depth at the desired angle.

The funnel of the drill sleeve allows the drill bit to be angled up to 15° around the central axis of the locking hole.

Drill using VA-LCP drill sleeve for freehand use

Alternatively, use the freehand VA-LCP drill sleeve. Fully extend it into the VA locking hole. Drill variable angle holes at the desired angle.

Precaution: It is important not to angulate more than 15° from the central axis of the screw hole. Overangulation could result in inappropriate screw-locking. Moreover, the screw head may not be fully countersunk.

To achieve the desired angle, verify the drill bit angle under image intensifier control. If necessary, drill at a different angle and verify again under image intensifier control.

Note: The previous inserted Kirschner wire can be used as reference for the screw angulation by using the image intensifier.

1b
Drill screw hole for VA locking screw using nominal angle technique

Instruments

310.509	Drill Bit ∅ 1.8 mm with marking, length 110/85 mm, 2-fluted, for Quick Coupling
03.110.000	VA-LCP Drill Sleeve 2.4, for Drill Bits ∅ 1.8 mm

Optional instruments

03.110.024	VA-LCP Drill Sleeve 2.4, coaxial, for Drill Bits ∅ 1.8 mm
03.111.000	Quick Drill Sleeve 2.4 with Scale, for Drill Bits ∅ 1.8 mm, for Guiding Block
03.115.700	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, right, head 6 holes
03.115.701	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, left, head 6 holes
03.115.800	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, right, head 7 holes
03.115.801	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, left, head 7 holes

Drill using VA-LCP drill sleeve

The fixed-angle end of the drill sleeve only allows the drill bit to follow the nominal trajectory of the VA locking hole.

Use the 1.8 mm drill bit to drill to the desired depth.

Read the screw length directly from the laser mark on the drill bit. Alternatively, use the depth gauge to determine the screw length.

Drill using guiding blocks

Alternatively, use the volar rim distal radius plate guiding block in combination with the quick drill sleeve.

Select the corresponding guiding block and secure it to the plate using the attachment screw.

Insert the quick drill sleeve with scale into the guiding block hole. Ensure that the quick drill sleeve is firmly seated in the hole. Drill to the desired depth using the 1.8 mm drill bit.

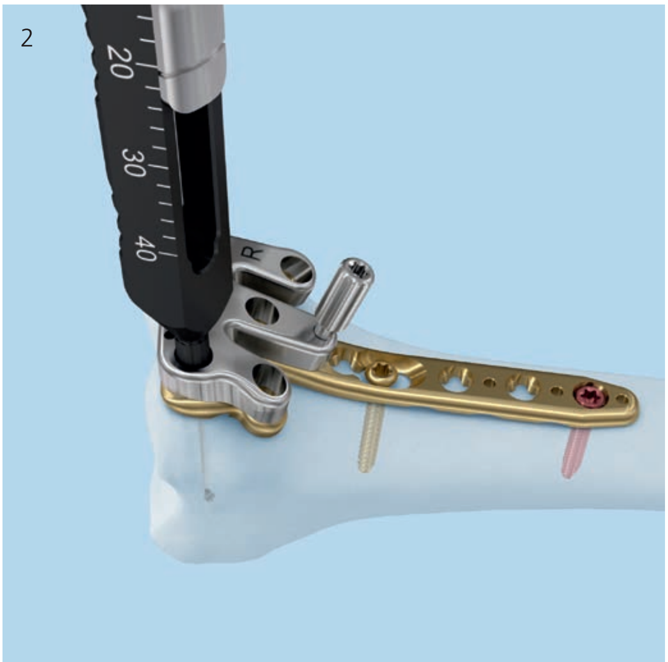
Read the screw length directly from the scale on the instrument or use the depth gauge to determine the screw length (see step 2 on page 20).

2
Determine screw length

Instrument	
03.111.005	Depth Gauge for Screws ∅ 2.0 to 2.7 mm, measuring range up to 40 mm

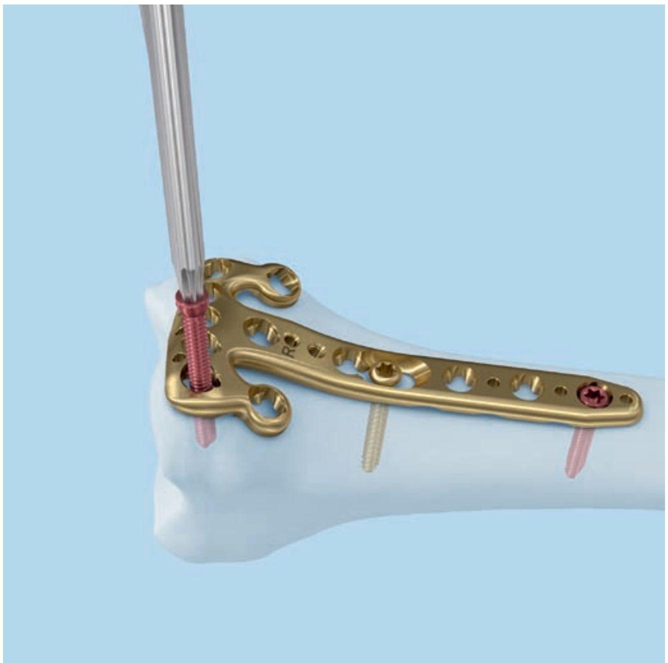
Determine the screw length with the depth gauge. (1)

If the guiding block is applied, measure directly through the guiding block. (2)



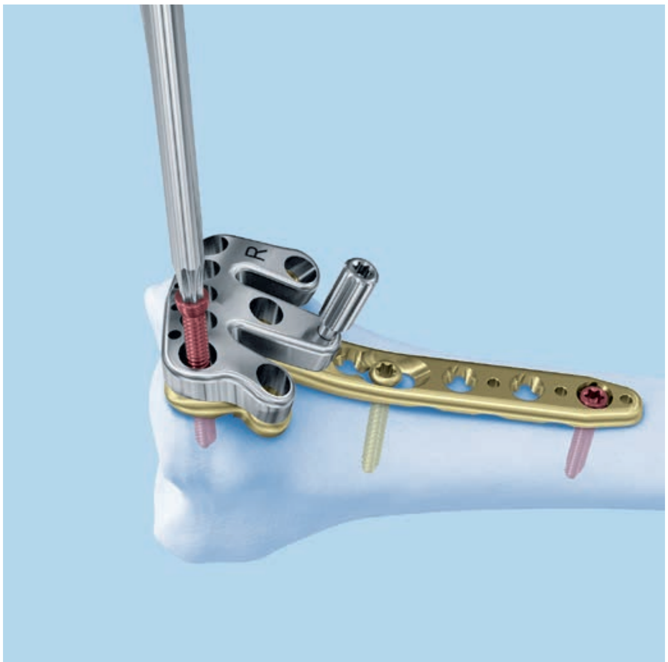
3
Insert VA locking screws

Instruments	
311.430	Handle with Quick Coupling, length 110 mm
314.467	Screwdriver Shaft Stardrive, T8, self-holding
Optional instrument	
314.453	Screwdriver Shaft, Stardrive 2.4, short, self-holding, for Quick Coupling



Insert the VA locking screws manually with the self-holding T8 Stardrive screwdriver shaft and quick coupling handle and tighten just enough for the screw head to be fully seated in the VA locking hole.

When using the pre-defined nominal angle technique, standard 2.4 mm locking screws can also be used instead of VA locking screws.

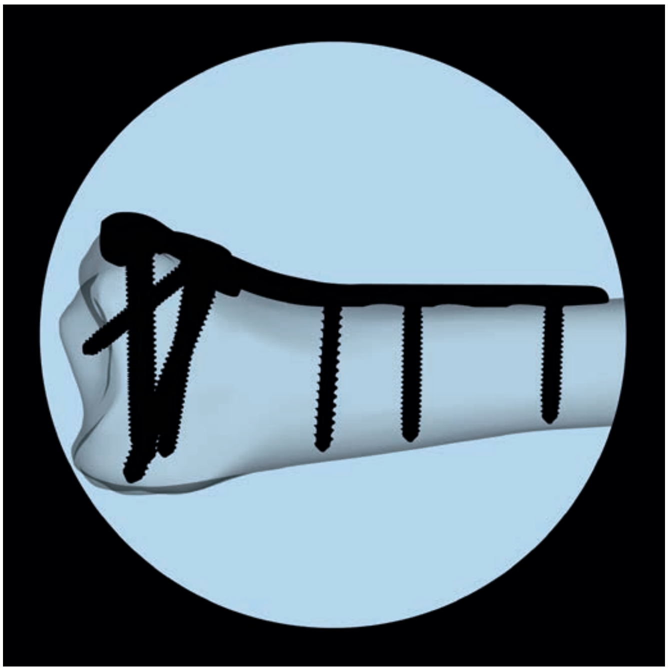


Note: Do not over-tighten the screw. This allows the screws to be easily removed should they not be in the desired position.

Note: When a guiding block is used, the locking screw (VA locking or standard locking) may be inserted with a T8 screwdriver directly through the guiding block.

4
Ensure proper joint reconstruction

After insertion of all screws, ensure proper joint reconstruction, screw placement and screw length using the image intensifier. Verify that the distal screws are not in the joint by using additional views.



5
Final fixation of VA locking screws

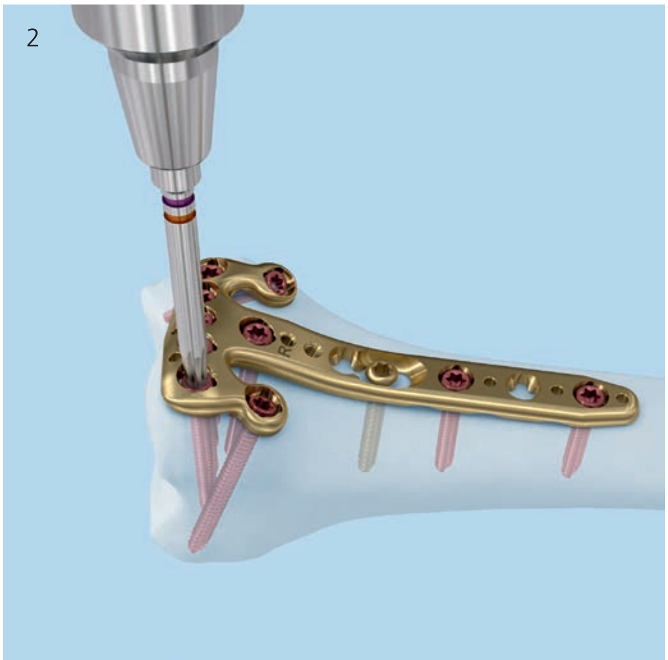
Instruments	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm
511.776	Torque Limiter, 0.8 Nm, with AO Quick Coupling
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
Optional instrument	
314.453	Screwdriver Shaft, Stardrive 2.4, short, self-holding, for Quick Coupling

Precaution: Use of the 0.8 Nm torque limiter (TLA) is mandatory when inserting locking screws into variable angle locking holes to ensure the adequate torque is applied (1). Final locking must be done manually using the TLA.

1

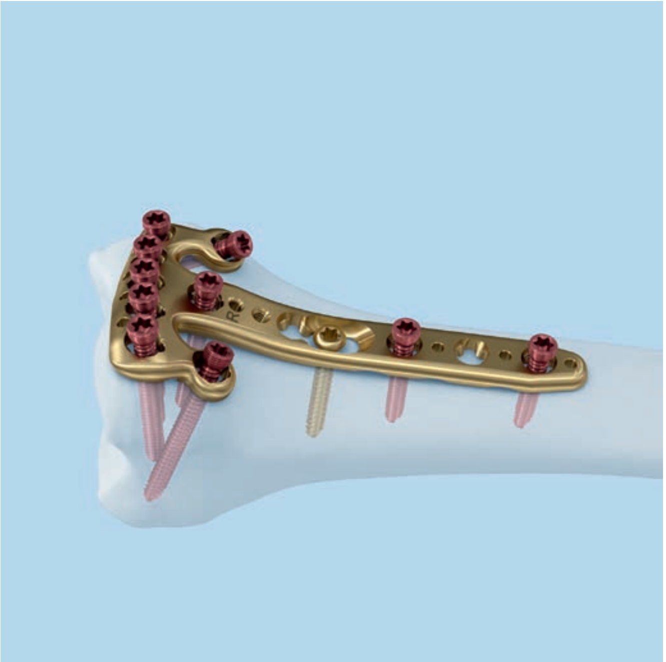

The torque limiter prevents over-tightening and ensures that the VA locking screws are securely locked into the plate. (2)

Note: For dense bone, visually inspect if the screw is countersunk after tightening with the torque limiter. If required, carefully tighten without the torque limiter until the screw head is flush with the plate surface.

2


Postoperative Treatment/ Implant Removal

Postoperative treatment
Postoperative treatment with VA locking compression plates does not differ from conventional internal fixation procedures.



Precaution: The plate was developed to specifically treat very distal radius fractures which require fixation distal to the watershed line. Patients with volar plate prominence should be screened for symptoms of tendon irritation. In symptomatic patients, elective hardware removal should be considered.

Implant removal

Instruments	
311.430	Handle with Quick Coupling, length 110 mm
314.467	Screwdriver Shaft, Stardrive, T8, self-holding

Optional instrument	
314.453	Screwdriver Shaft, Stardrive 2.4, short, self-holding, for Quick Coupling

To remove locking screws, first unlock all screws from the plate; then remove the screws completely from the bone.

The last screw removed should be a non-locking screw on the shaft. This prevents the plate from spinning when locking screws are removed.

Tip: Contour tabs

Instrument

347.901	Pliers, flat-nosed, pointed, for Plates 1.0 to 2.4

If necessary, bend the tabs of the plate to suit anatomical conditions as indicated. Avoid repetitive bending.

Recommendation: Use non-serrated bending pliers for preservation of the plate’s smooth finish.

Precautions:
– The design of the plate holes allows a certain degree of deformation. However, if threaded holes are significantly deformed, locking is not sufficiently efficient.
– Reverse bending or use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage). Do not bend the plate beyond what is required to match the anatomy.
– If using guiding blocks, avoid bending the head portion of the plate.

Plates

VA-LCP Volar Rim Distal Radius Plate 2.4, 6 holes

Part number	Head holes	Shaft holes	Length (mm)	Right/Left
0X.115.750	6	5	57	Right
0X.115.751	6	5	57	Left

VA-LCP Volar Rim Distal Radius Plate 2.4, 7 holes

Part number	Head holes	Shaft holes	Length (mm)	Right/Left
0X.115.850	7	5	57	Right
0X.115.851	7	5	57	Left

All plates are also available sterile packed. Add suffix "S" to article number.

X = 2: Stainless Steel
X = 4: TiCP

Trial Implants

Trial Implant for VA-LCP Volar Rim Distal Radius Plate 2.4, 6 holes, stainless steel

Part number	Length (mm)	Right/Left
03.115.750	57	Right
03.115.751	57	Left

Trial Implant for VA-LCP Volar Rim Distal Radius Plate 2.4, 7 holes, stainless steel

Part number	Length (mm)	Right/Left
03.115.850	57	Right
03.115.851	57	Left

Screws

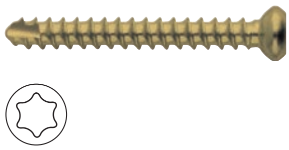
Variable Angle Locking Screws 2.4 mm

0X.210.108 – 0X.210.130	VA Locking Screw Stardrive ∅ 2.4 mm, self-tapping, lengths 8 mm to 30 mm For use in VA locking holes.

Precaution: For final locking the 0.8 Nm torque limiter is required.

Cortex Screws 2.4 mm

X01.756 – X01.780	Cortex Screw Stardrive ∅ 2.4 mm, self-tapping, lengths 6 mm to 30 mm For use in VA locking holes or oblong combi-holes.



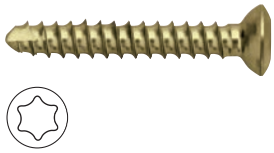
All screws are also available sterile packed. Add suffix "S" to article number.

X = 2: Stainless Steel (SSt)
X = 4: Titanium Alloy (TAN)

Optional

Cortex Screws 2.7 mm

X02.866 – X02.890	Cortex Screw Stardrive ∅ 2.7 mm, self-tapping, lengths 6 mm to 30 mm For use in oblong combi-holes.

Variable Angle Locking Buttress Pins 1.8 mm

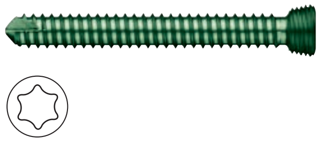
0X.210.078 – 0X.210.100	VA-LCP Buttress Pins, Stardrive, ∅ 1.8 mm, lengths 8 mm to 30 mm For use in VA locking holes.

Precaution: For final locking, the 0.8 Nm torque limiter is required.


Locking Screws 2.4 mm

X12.806 – X12.830	Locking Screw Stardrive ∅ 2.4 mm, self-tapping, lengths 6 mm to 30 mm For use in VA locking holes but only in pre-defined angle using nominal angle technique.

Precaution: For final locking, the 0.8 Nm torque limiter is required.

All screws are also available sterile packed. Add suffix "S" to article number.

X = 2: Stainless Steel (SSt)
X = 4: Titanium alloy (TAN)

Instruments

03.110.000	VA-LCP Drill Sleeve 2.4, for Drill Bits ∅ 1.8 mm	
323.202	Universal Drill Guide 2.4	
310.509	Drill Bit ∅ 1.8 mm with marking, length 110/85 mm, 2-flute, for Quick Coupling	
314.453	Screwdriver Shaft, Stardrive 2.4, short, self-holding, for Quick Coupling	
314.467	Screwdriver Shaft, Stardrive, T8, self-holding	
03.111.005	Depth Gauge for Screws ∅ 2.0 to 2.7 mm, measuring range up to 40 mm	
311.430	Handle with Quick Coupling, length 110 mm	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm	
511.776	Torque Limiter 0.8 Nm, with AO/ASIF Quick Coupling	
292.120(S)	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm, Stainless Steel	

Optional instruments

03.111.038 Handle with Quick Coupling

03.110.023 VA-LCP Drill Sleeve 2.4, conical,
for Drill Bits ∅ 1.8 mm

03.110.024 VA-LCP Drill Sleeve 2.4, coaxial,
for Drill Bits ∅ 1.8 mm

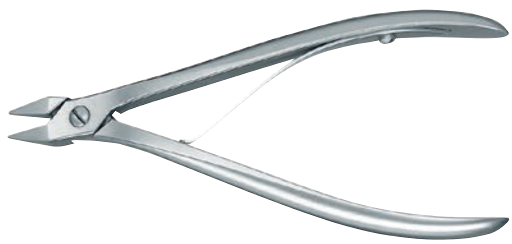
03.111.004 VA-LCP Drill Sleeve 2.4,
for Drill Bits ∅ 1.8 mm, freehand useable

323.260 Universal Drill Guide 2.7

310.534 Drill Bit ∅ 2.0 mm, with marking,
length 110/85 mm, 2-flute,
for Quick Coupling

03.111.000 Quick Drill Sleeve 2.4 with Scale,
for Drill Bits ∅ 1.8 mm, for Guiding Block

347.901 Pliers, flat-nosed, pointed,
for Plates 1.0 to 2.4



02.111.500.01(S)	Plate Reduction Wire ∅ 1.25 mm, with thread, with Small Stop, length 150 mm, Stainless Steel	
02.111.501.01(S)	Plate Reduction Wire ∅ 1.25 mm, with thread, with Large Stop, length 150 mm, Stainless Steel	
03.115.700	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, right, head 6 holes	
03.115.701	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, left, head 6 holes	
03.115.800	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, right, head 7 holes	
03.115.801	Guiding Block for VA-LCP Volar Rim Distal Radius Plate 2.4, left, head 7 holes	

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MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F 2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a
Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

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