2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius System.

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.

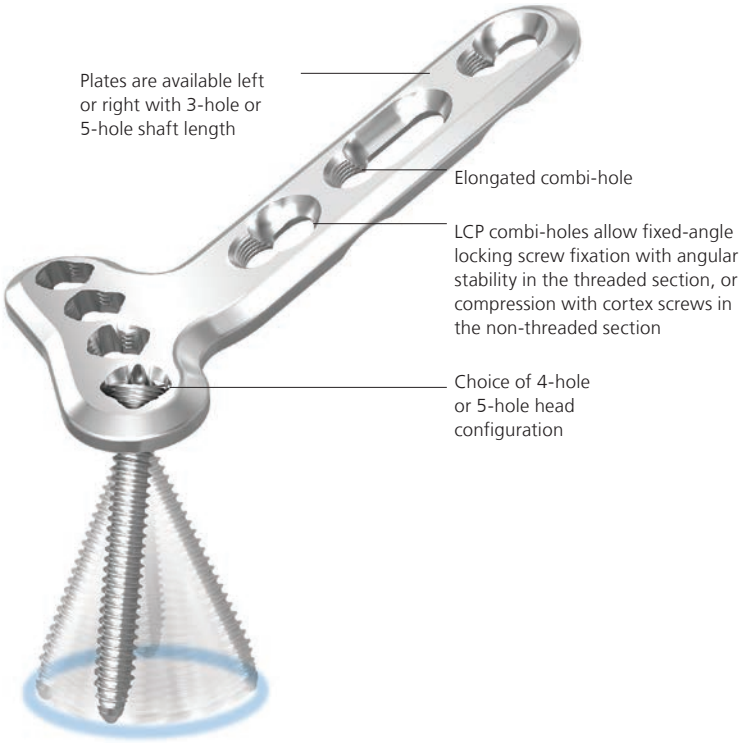
Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
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

Table of Contents

2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius System

Variable Angle LCP (VA-LCP)

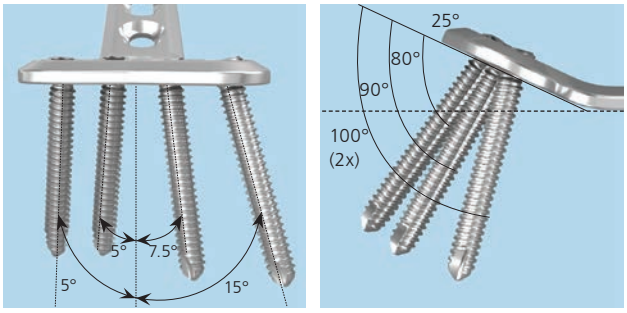
- The variable angle LCP (VA-LCP) holes combined with variable angle locking screws allow up to 15° off-axis angulation in all directions
- The variable angle (VA) locking screws offer a fixed-angle construct to support the articular surface
- Fixation can be achieved in osteoporotic bone
- Manufactured in stainless steel and pure titanium



Fragment-specific fixation

- Due to the 15° off the central axis the surgeon can perform fragment-specific fixation with a fixed-angle construct (1).
- The nominal angles of the VA locking screws are identical to the fixed-angle 2.4 mm LCP extra-articular volar distal radius plate (2).

(1)



(2)

Variable angle (VA) locking hole

- The VA locking hole contains four columns of threads. These columns provide four points of threaded locking between the VA-LCP plate and the variable angle locking screw, forming a fixed-angle construct at the desired screw angle (1).
- The head of the 2.4 mm VA locking screw has rounded shape that facilitates various angles within the locking hole (2). The shafts of the 2.4 mm VA locking screw and the standard 2.4 mm locking screw are identical.
- The combi-hole accepts a 2.4 mm VA locking screw or a cortex screw (3).

VA locking hole

(1)

(2)

Combi-hole

(3)

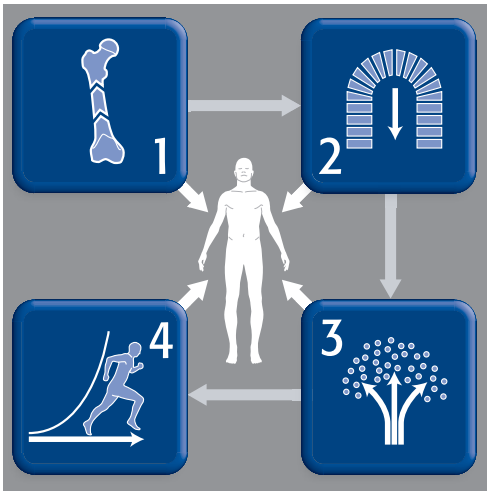
VA-LCP Drill Guide

- The drill guide allows up to a 15° angulation around the central axis of the locking hole.

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.



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

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

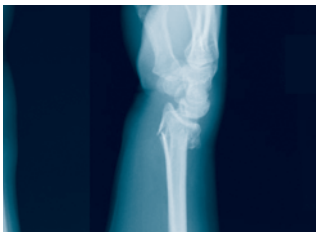
Preservation of blood supply
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

[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
The 2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius Plates are indicated for fixation of intra- and extra-articular fractures and osteotomies of the distal radius.



Clinical Cases

Case 1
48-year-old female, cause of injury unknown


Preoperative AP


Preoperative lateral


Postoperative AP


Postoperative lateral

Case 2
71-year-old female, cause of injury unknown


Preoperative AP

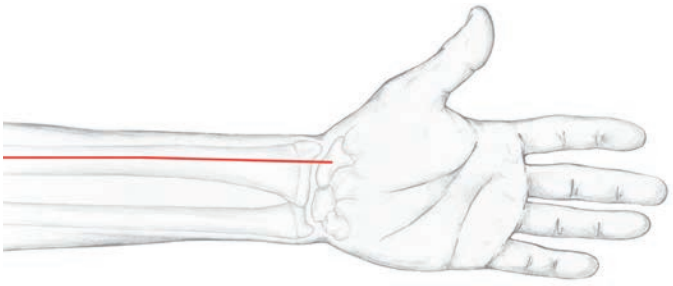

Preoperative lateral


Postoperative AP


Postoperative lateral

Preparation

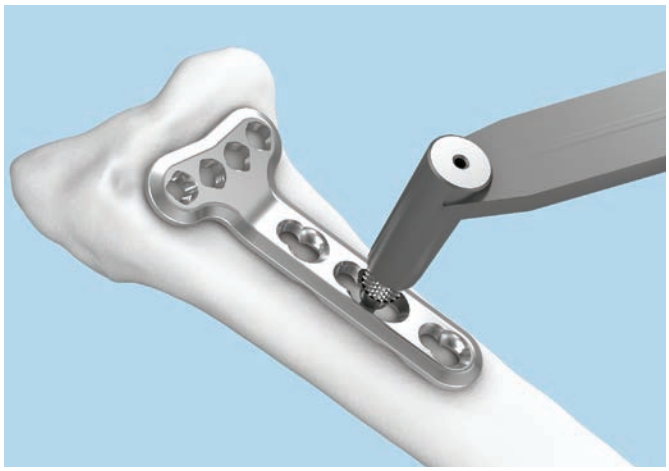
Approach
Make a longitudinal incision slightly radial to the flexor carpi radialis tendon (FCR). Dissect between the FCR and the radial artery, exposing the pronator quadratus. Detach the pronator quadratus from the lateral border of the radius and elevate it toward the ulna.

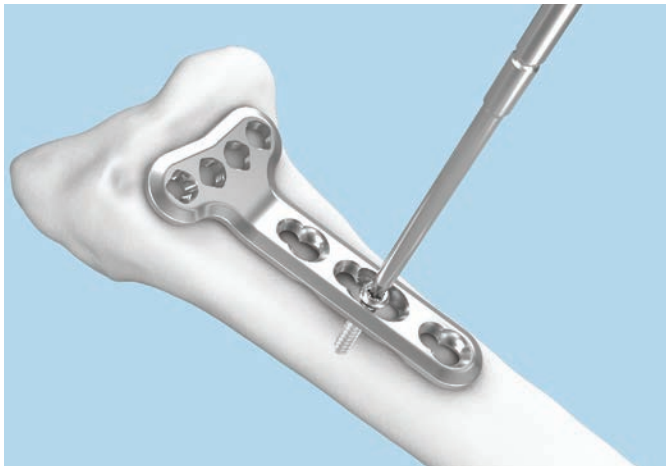


Precaution: Leave the volar wrist capsule intact to avoid devascularization of the fracture fragments and destabilization of the volar wrist ligaments.

1
Reduce fracture and position plate

Instruments for 2.4 mm Cortex screws	
310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling
311.430	Handle with Quick Coupling, length 110 mm
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
319.005	Depth Gauge for Screws ∅ 2.0 and 2.4 mm
323.202	Universal Drill Guide 2.4
Optional	
310.534	Drill Bit ∅ 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
323.260	Universal Drill Guide 2.7





Reduce the fracture. The reduction method will be fracture-specific. Beginning with the elongated hole in the shaft of the plate, drill with the 1.8 mm drill bit using the Universal Drill Guide 2.4. Insert a 2.4 mm cortex screw in the elongated hole in the plate shaft. Adjust the plate position if necessary and tighten the screw.

The order of screw insertion in the shaft and metaphysis may vary depending on the fracture pattern and reduction technique.

Note: Alternatively, insert 2.7 mm cortex screws into the shaft. Use the Universal Drill Guide 2.7 in the unthreaded part of the hole. Drill with the drill bit 2.0 mm.

Precaution: 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.

2
Insert proximal screws

Instruments for 2.4 mm VA locking screws	
310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling
323.029	LCP Drill Sleeve 2.4, with Scale up to 30 mm, for Drill Bits ∅ 1.8 mm
319.005	Depth Gauge for Screws ∅ 2.0 and 2.4 mm
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
511.776	Torque Limiter 0.8 Nm
311.430	Handle, with Quick Coupling

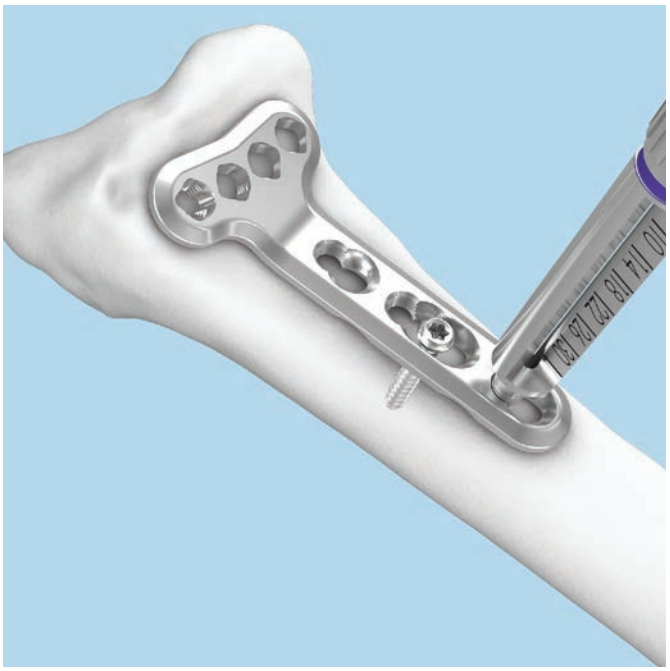
Optional instrument	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

Instruments for 2.4 mm cortex screws	
310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling
311.430	Handle, with Quick Coupling
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
319.005	Depth Gauge for Screws ∅ 2.0 and 2.4 mm
323.202	Universal Drill Guide 2.4

Determine where 2.4 mm VA locking screws or 2.4 mm cortex screws will be used in the shaft of the plate. Insert these screws beginning with the most proximal screw.

For VA locking screws, carefully insert the LCP drill sleeve 2.4 in line with the hole's axis until it is seated in the desired locking hole. Use the 1.8 mm drill bit.

Read the screw length directly from the laser mark on the drill bit, or use the corresponding depth gauge to determine the screw length. To insert the screw use the T8 screwdriver shaft in combination with the torque limiter 0.8 Nm.



Precaution: Use of the TLA is mandatory when inserting locking screws into variable angle locking holes, to ensure the adequate torque is applied.

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.

For 2.4 mm cortex screws use the Universal Drill Guide 2.4 and drill with the 1.8 mm drill bit. Measure the screw length with the corresponding depth gauge. Insert the screw with the T8 screwdriver shaft.

3
Insert VA locking screws distally

Instruments	
03.110.000	VA-LCP Drill Guide 2.4, for Drill Bits ∅ 1.8 mm
314.467	Screwdriver Shaft, Stardrive, T8, self-holding
310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling
311.430	Handle, with Quick Coupling
319.005	Depth Gauge for Screws ∅ 2.0 and 2.4 mm

The VA-LCP drill guide tip is inserted and keyed into the cloverleaf design of the VA-LCP hole.

Use the funnel-shaped end of the VA-LCP drill guide to drill variable angle holes at the desired angle.

Precaution: Do not use the threaded LCP drill sleeve (323.029) in variable angle locking holes.

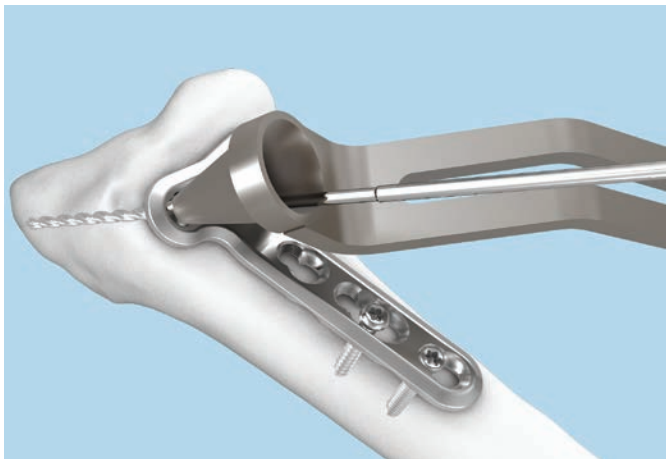
4
Drill for VA screw distally

When the VA-LCP drill guide is engaged in the VA locking hole, use the 1.8 mm drill bit to drill to the desired depth at the desired angle.

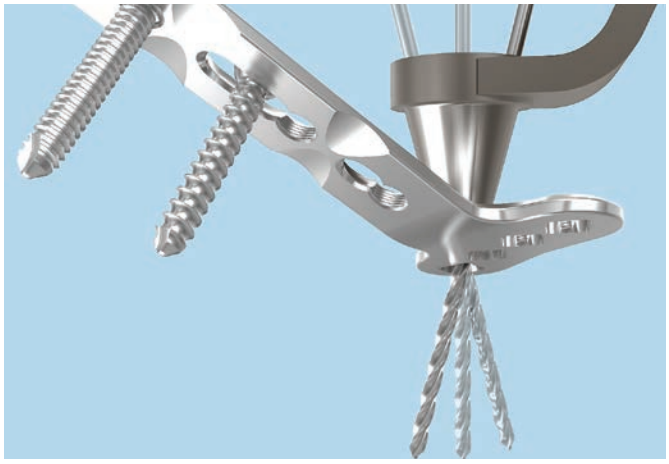
The funnel of the drill guide allows the drill bit a total angle variation of 30° (1, 2).

Verify the drill bit angle under C-arm to ensure the desired angle has been achieved. If necessary, drill at a different angle and verify again under C-arm.

Use the depth gauge for 2.0 mm and 2.4 mm screws to measure the correct screw length.

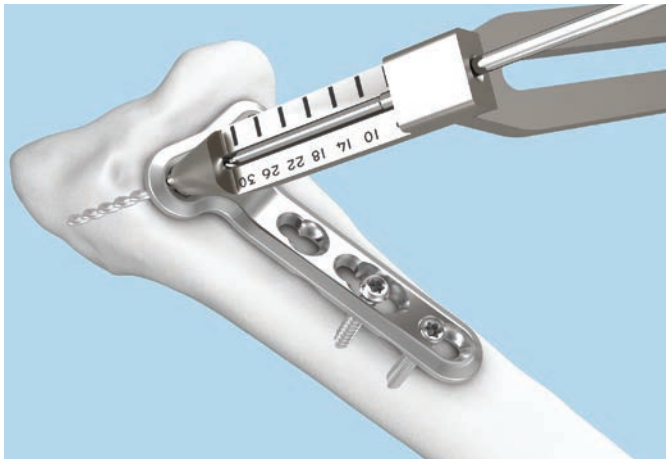


(1)



(2)

The fixed-angle end of the drill guide only allows the drill bit to follow the nominal trajectory of the locking hole (3).

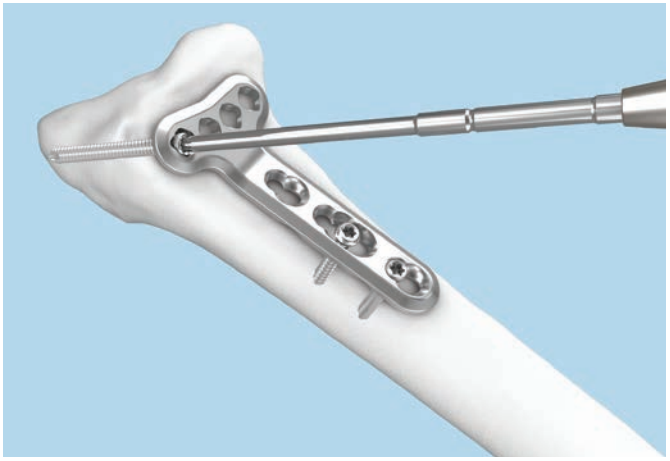


(3)

5
Preliminary screw placement

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

Insert the VA locking screws manually with the self retaining T8 Stardrive screwdriver shaft and Quick Coupling handle until just before the screw head is seated in the locking hole. Do not over-tighten the screw so they can be easily removed if necessary.



6
Confirm proper joint reconstruction

Confirm proper joint reconstruction, screw placement and screw length using multiple C-arm views. Ensure that the distal screws are not in the joint using additional views such as a 10° dorsally tilted, 20° inclined lateral, and 45° pronated oblique view.

7
Locking of variable angle screws in VA holes

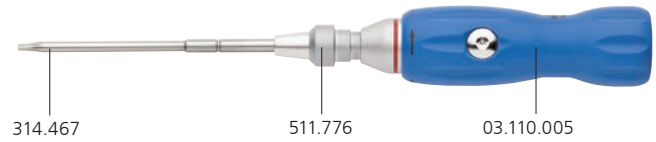
Instruments	
511.776	Torque Limiter, 0.8 Nm, with AO/ASIF Quick Coupling
311.430	Handle with Quick Coupling, length 110 mm
314.467	Screwdriver Shaft, Stardrive, T8, self-holding

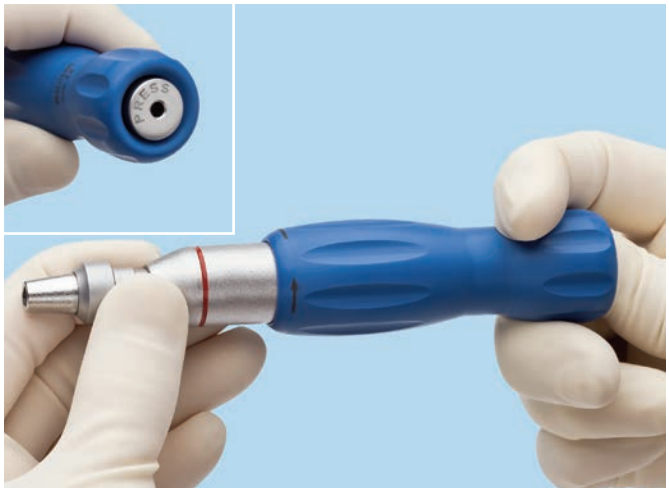
Optional instrument	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

Use the torque limiting attachment to perform the final locking step for the VA locking screws.

Precaution: Use of the torque limiter is mandatory when inserting locking screws into variable angle locking holes, to ensure the adequate torque is applied.

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.





Closing of Incision

Closing of incision
Use the appropriate method for surgical closure of the incision.

Implant removal

To remove locking screws, first unlock all screws from the plate; then remove the screws completely from the bone. This prevents rotation of the plate when removing the last locking screw.

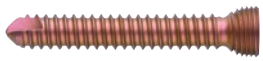
Screw Overview

Variable angle locking screws

2.4 mm Variable angle locking screws, with Stardrive recess
- Threaded, spherical head locks securely into the threaded VA-LCP holes to provide angular stability at angles determined by the surgeon
- 6 mm to 30 mm lengths (2 mm increments)
- Self-tapping tip

0X.210.108–0X.210.130

Precaution: Use of 0.8 Nm TLA torque limiting attachment required.



0X.210.108–0X.210.130

Cortex screws

2.4 mm Cortex screws, self-tapping, with Stardrive recess
- For use in round or combi-holes
- Low-profile head in the plate holes
- 6 mm to 30 mm lengths (2 mm increments)
- Self-tapping tip

X01.756–X01.780

X01.756-X01.780

2.7 mm Cortex screws, self-tapping, with Stardrive recess

- For use in combi-holes
- Used to provide compression or neutral fixation
- 10 mm to 30 mm lengths (2 mm increments)
- Self-tapping tip

X02.870–X02.890

Note: For information on fixation principles using conventional and locked plating techniques, please refer to the LCP Surgical Technique (036.000.019/DSEM/TRM/0115/0278).

X02.870–X02.890

Available in stainless steel (X=2) or titanium alloy (X=4).

All implants are available non-sterile or sterile packed. Add suffix "S" to article number to order sterile product.

Plate Overview

2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius Plates, Stainless Steel

Left plates

02.110.203

02.110.204

02.110.207

02.110.208

Right plates

02.110.201

02.110.202

02.110.205

02.110.206

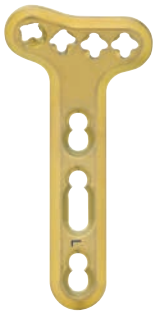
All implants are available non-sterile or sterile packed.
Add suffix "S" to article number to order sterile product.

2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius Plates, Titanium

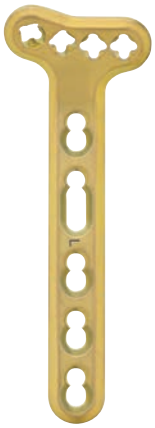
Left plates

04.110.203

04.110.204



04.110.207



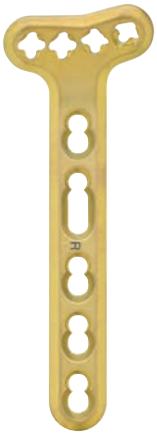
04.110.208

Right plates

04.110.201

04.110.202

04.110.205



04.110.206

All implants are available non-sterile or sterile packed. Add suffix "S" to article number to order sterile product.

03.110.000	VA-LCP Drill Guide 2.4, for Drill Bits ∅ 1.8 mm	

310.509	Drill Bit ∅ 1.8 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling	
311.430	Handle with Quick Coupling, length 110 mm	
314.467	Screwdriver Shaft, Stardrive, T8, self-holding	
314.468	Holding Sleeve for Screws Stardrive ∅ 2.4 mm, T8, for Screwdriver Shafts ∅ 3.5 mm, for No. 314.467	
319.005	Depth Gauge for Screws ∅ 2.0 and 2.4 mm, measuring range up to 40 mm	
323.029	LCP Drill Sleeve 2.4, with Scale up to 30 mm, for Drill Bits ∅ 1.8 mm	
323.202	2.4 mm Universal Drill Guide	
511.776	Torque Limiter, 0.8 Nm, with AO/ASIF Quick Coupling	

Optional instruments

310.260	Drill Bit ∅ 2.7 mm, length 100/75 mm, 2-flute, for Quick Coupling	
310.530	Drill Bit ∅ 2.4 mm, length 100/75 mm, 2-flute, for Quick Coupling	
310.534	Drill Bit ∅ 2.0 mm, with marking, length 110/85 mm, 2-flute, for Quick Coupling	
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm	
323.260	Universal Drill Guide 2.7	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm	

2.4 mm Variable Angle LCP Module

The module contains the following plates, screws and instruments:

Module with content	
01.111.416	VA-LCP Distal Radius Plates 2.4, extraarticular, Pure Titanium
01.111.417	VA-LCP Distal Radius Plates 2.4, extraarticular, Stainless Steel

Implants in module

2.4 mm Variable Angle LCP Volar Extra-Articular Distal Radius Plates

Stainless Steel	Titanium	Head Holes	Shaft Holes	
02.110.201	04.110.201	5	3	right
02.110.203	04.110.203	5	3	left
02.110.202	04.110.202	5	5	right
02.110.204	04.110.204	5	5	left
02.110.205	04.110.205	4	3	right
02.110.207	04.110.207	4	3	left
02.110.206	04.110.206	4	5	right
02.110.208	04.110.208	4	5	left

2.4 mm Variable Angle Locking Screws, with Stardrive recess

Stainless Steel	Titanium	Length (mm)	Quantity
02.210.106	04.210.106	6	optional
02.210.108	04.210.108	8	optional
02.210.110	04.210.110	10	3
02.210.112	04.210.112	12	3
02.210.114	04.210.114	14	3
02.210.116	04.210.116	16	3
02.210.118	04.210.118	18	3
02.210.120	04.210.120	20	3
02.210.122	04.210.122	22	3
02.210.124	04.210.124	24	3
02.210.126	04.210.126	26	3
02.210.128	04.210.128	28	3
02.210.130	04.210.130	30	3

Instruments in module

03.110.000	VA-LCP Drill Guide 2.4, for Drill Bits ∅ 1.8 mm
X92.120*	Kirschner Wire ∅ 1.25 mm with trocar tip, length 150 mm
511.776	Torque Limiter, 0.8 Nm, with AO/ASIF Quick Coupling

Additionally available

X92.160*	Kirschner Wire ∅ 1.6 mm with trocar tip, length 150 mm

* Legend: X = 2 for Stainless Steel Wire
X = 4 for Titanium Alloy (TAV) Wire

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.

DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES
People inspired™

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

All surgical techniques are available as PDF files at
www.depuysynthes.com/ifu

CE
0123

 036.000.575 DSEM/TRM/0815/0457(2) 05/16