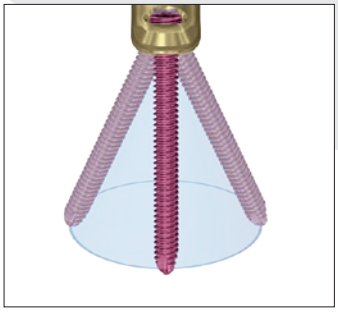
VA-LCP Anterior Clavicle Plate

Surgical Technique



DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

AO approved by AO Technical Commission

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 DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy 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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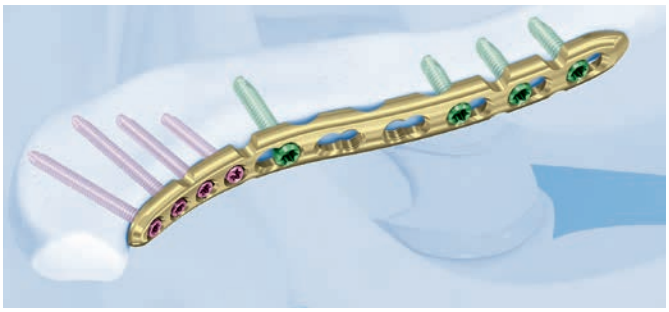
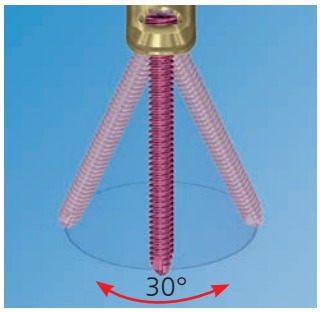
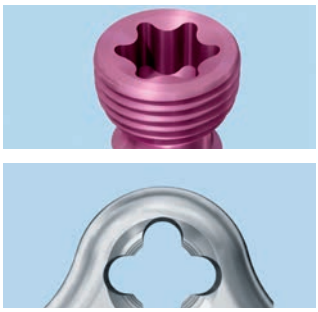
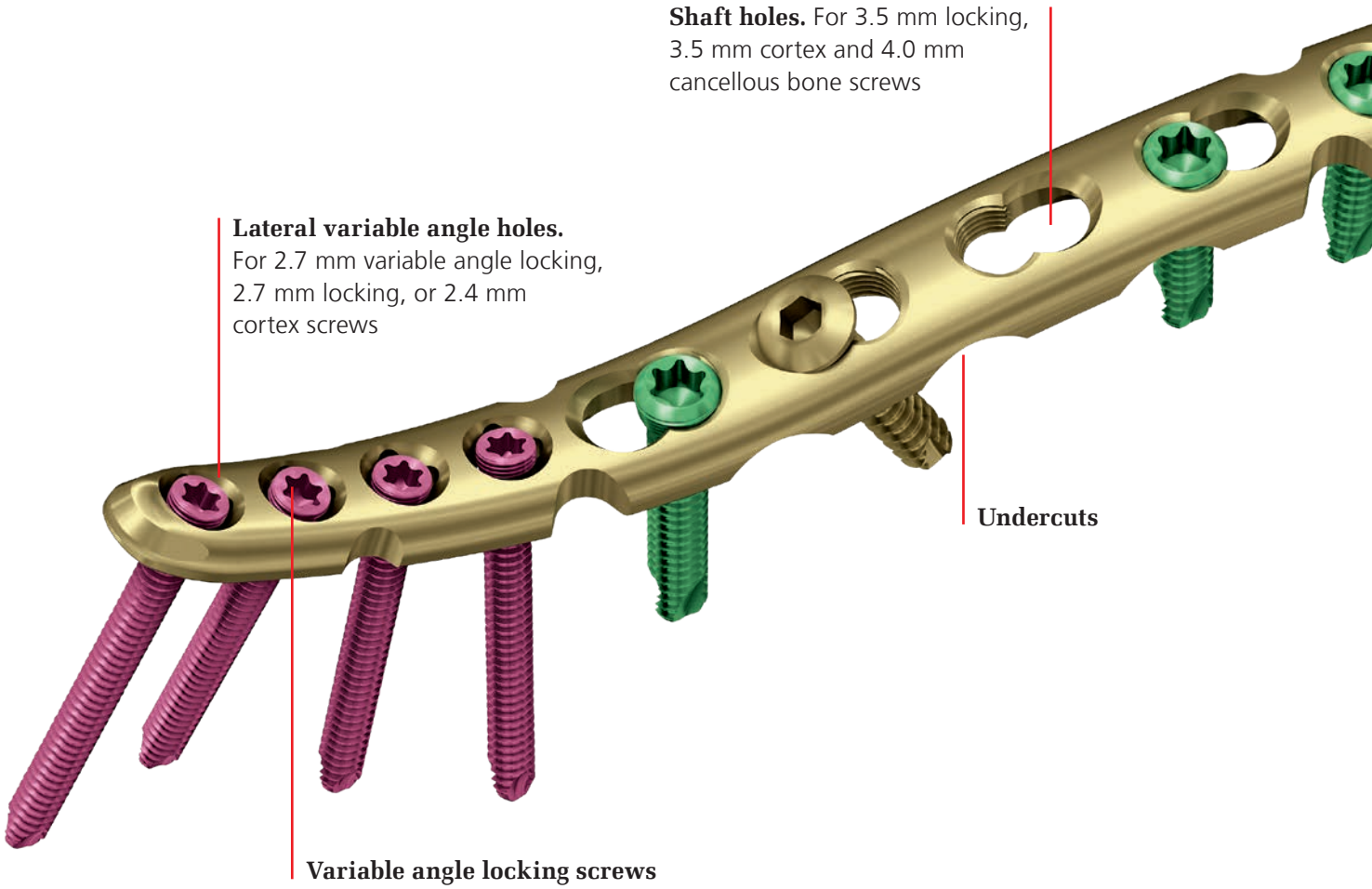




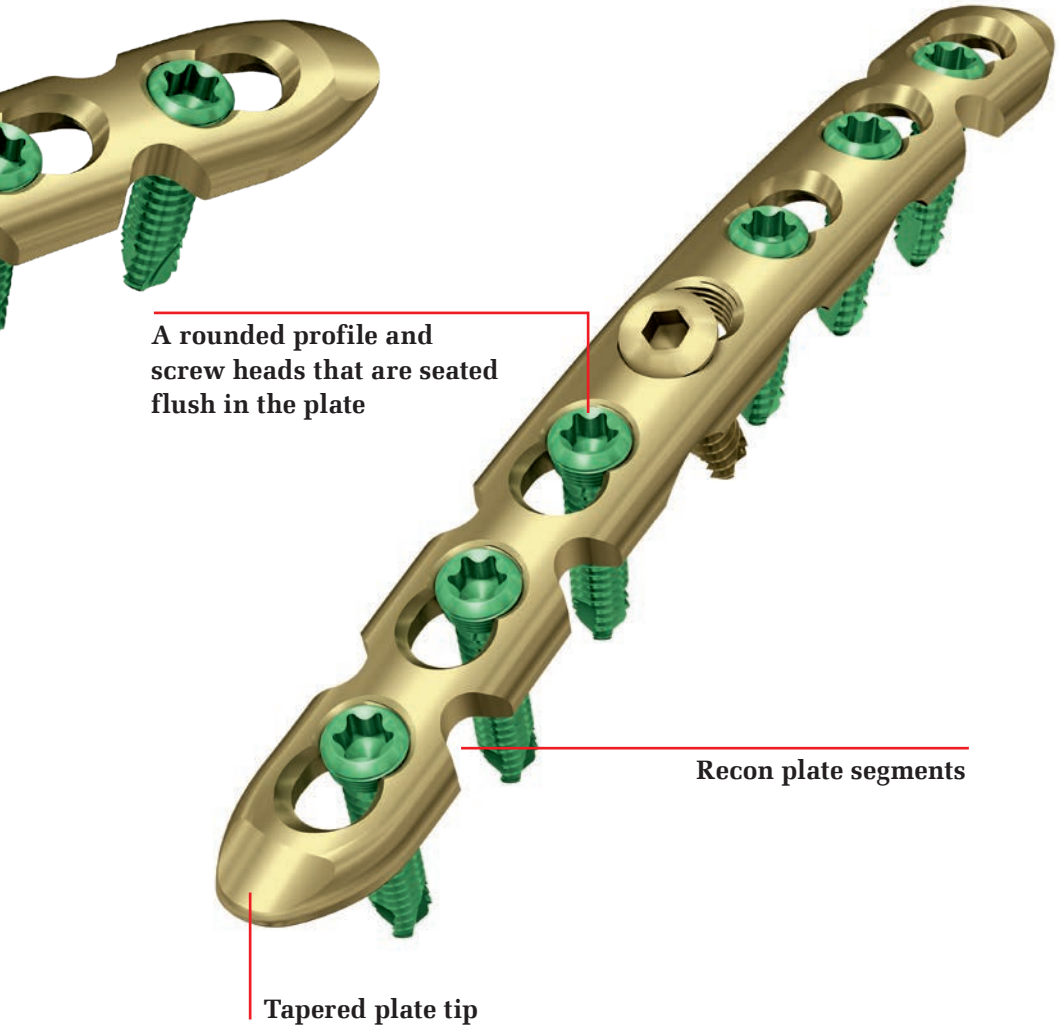


VA-LCP Anterior Clavicle Plate 2.7/3.5, lateral (7, 9, 10, 11 and 12 holes)



Additionally Available DePuy Synthes Clavicle System

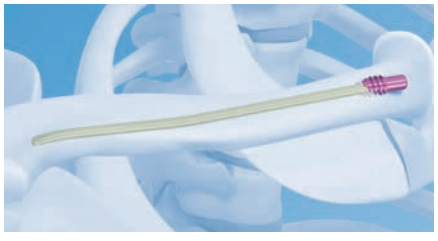
LCP Anterior Clavicle Plate 3.5, medial (6, 7 and 8 holes)



LCP Superior Clavicle Plate

LCP Superior Anterior Clavicle Plate

LCP Clavicle Hook Plate



Elastic Nail System

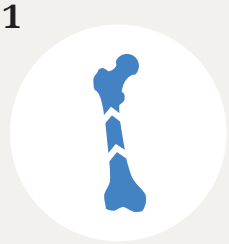
Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

The AO Principles of Fracture Management

Mission
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

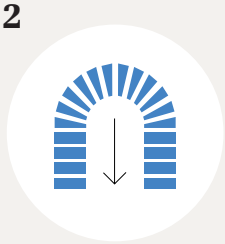
AO Principles [1,2]

1



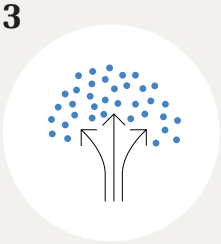
Fracture reduction and fixation to restore anatomical relationships.

2



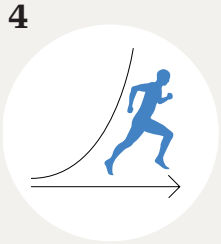
Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3



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

4



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

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

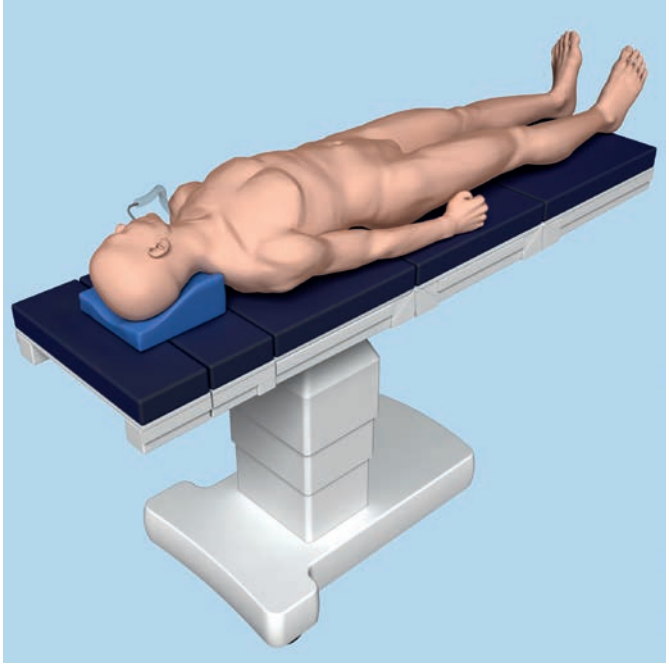
Preparation

1. Preoperative planning

Complete the preoperative radiographic assessment and prepare the preoperative plan.

2. Position patient

Position the patient in a supine position on a radiolucent operating table. Provide enough room to swing the image intensifier 45° in both directions to view the clavicle in two planes intra-operatively.



Notes

- **Longer tubes for anesthesia may be required.**
- **Prepare the associated arm so that it can be intra-operatively mobilized. The mobilization of the arm can be used as reduction aid.**

Plate Insertion

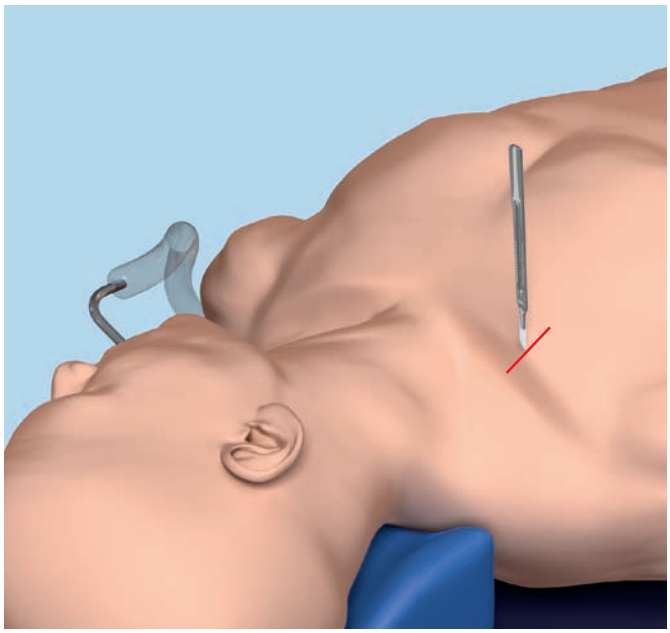
1. Approach

Make a gentle curvilinear incision parallel to the skin cleavage lines.

Subcutaneous dissection permits identification of the supraclavicular sensory nerve branches. The major fibers of these nerves should be identified and protected with small vessel loops throughout the surgery.

Carefully divide the platysma to expose the clavicle periosteum at the deltotrapezial fascia. Minimally dissect the periosteum to expose the fracture.

Precaution: **Bone fragments must not be detached from the periosteum in order to enable proper bone healing. It is critical not to strip any comminuted fragments.**



2. Fracture reduction and temporary fixation

Normal length, axis angulation and rotation should be restored.

After exposing the fracture, the two main fragments are distracted and the length of the clavicle is restored. If the bone ends are angled or oblique, reduce with a pointed or serrated reduction forceps.

Any large comminuted fragments should also be reduced and held temporarily with small pointed bone clamps or Kirschner wires. Assess and plan for any temporary fixation so as to not interfere with the placement of the definitive fixation implants.

Kirschner wires can be placed through the distal end of the plate to assist with temporary maintenance of the reduction and for plate placement.

Additional options for maintaining the reduction include independent lag screws and lag screws inserted through the plate.

Option: The VA-LCP Anterior Clavicle Plate can be used for biological, bridging osteosynthesis. Only the main fragments are reduced and the actual fracture zone is not engaged with any screw.

3. Determine plate length and adapt plate

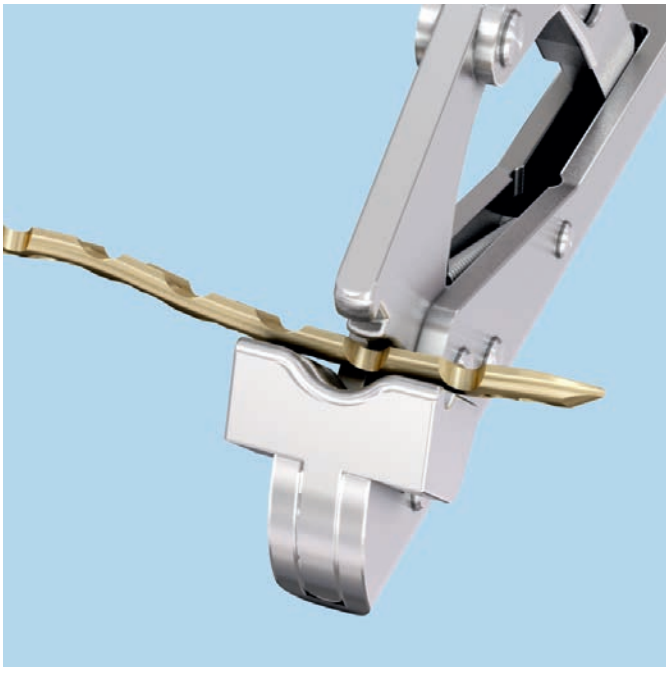
Optional instruments	
329.291	Bending Pliers for Clavicular Plates, length 227 mm
329.040/ 329.050	Bending Iron for Plates 2.4 to 3.5, length 145 mm
329.300	Bending Press, length 400 mm

Select a plate length appropriate for the fracture.

Due to varying patient anatomy, the plate may not be perfectly anatomical and slight plate bending may be necessary. Using bending irons, bending pliers, and/or the bending press, contour the plate as needed. For an optimum fit, the plate can be bent at each notch in the plane of the shaft.

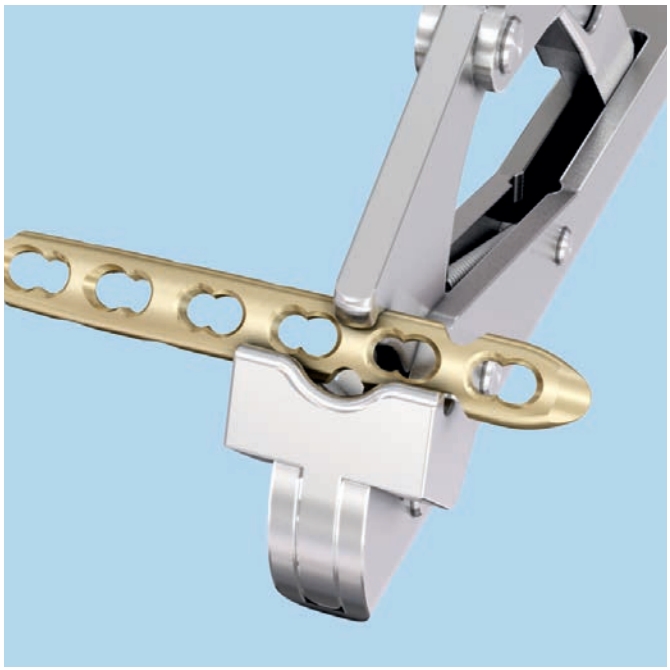
To bend the plate, insert it into the jaws of the bending pliers for clavicle plates at the appropriate notch.

To adjust the S-curve, insert the plate at the back of the jaws of the bending pliers.



To adjust the superior inferior bend, place the plate between the two notches in the front of the jaws of the bending pliers.

For more leverage and control when bending, loosen the adjustment screw on the bending pliers so that the handles are closer together. If more adjustment is needed, make a series of small bends, threading the adjustment screw roughly half a turn at a time.



4. Insert plate

Position the plate on the reduced bone, and attach it temporarily with the plate holding forceps or a 3.5 mm cortex screw.

After plate insertion, check alignment on the bone using an image intensifier.

Screw Insertion

Determine the combination of screws to be used for fixation. If a combination of locking and cortex screws is used, cortex screws should be inserted first to pull the bone to the plate.

1. Verify screw placement

Since the direction of the 3.5 mm locking screw depends on the contour of the plate, final screw position may be verified with Kirschner wires before insertion. This becomes important when the plate has been manually contoured, applied near the acromioclavicular joint, or for unusual anatomy.

- Verify Kirschner wire placement under image intensification to determine if final screw placement will be acceptable.

2. Screw fixation

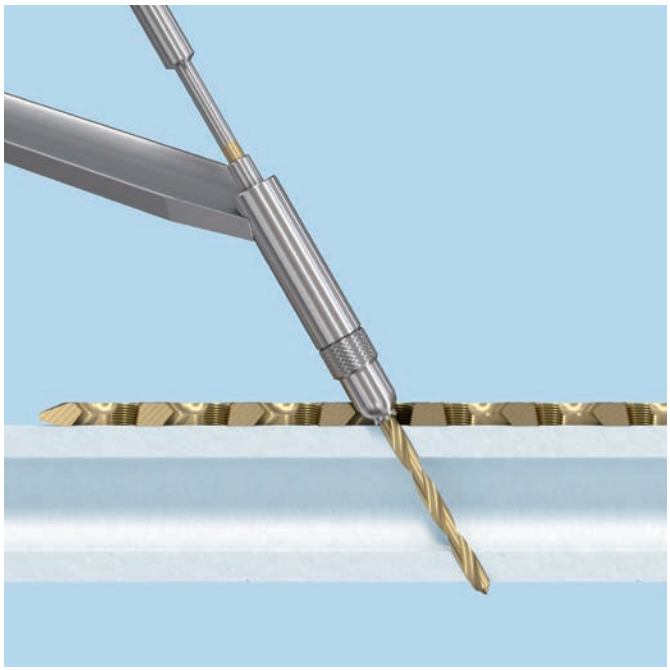
2a. Fixation with ∅ 3.5 mm cortex screws

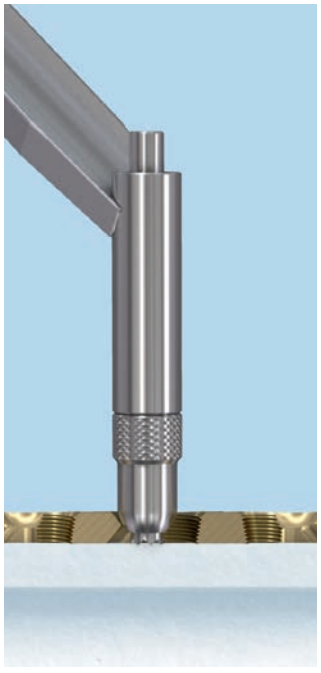
Instruments	
310.250	Drill Bit 2.5 mm, length 110/85 mm, 2-flute,for Quick Coupling
323.360	Universal Drill Guide 3.5
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.070	Screwdriver, hexagonal, small, ∅ 2.5 mm, with Groove

Use the 2.5 mm drill bit with the 3.5 universal drill guide to pre-drill the bone through both cortices.

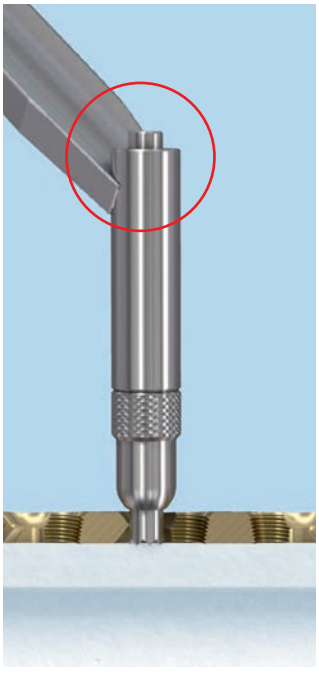
Precaution: **Avoid contact with the subclavian artery and brachial plexus when drilling through the clavicle.**

To set screws in a neutral position, press the drill guide down in the non-threaded hole. To obtain compression, place the drill guide at the end of the non-threaded hole away from the fracture, being sure not to apply downward pressure on the spring loaded tip.



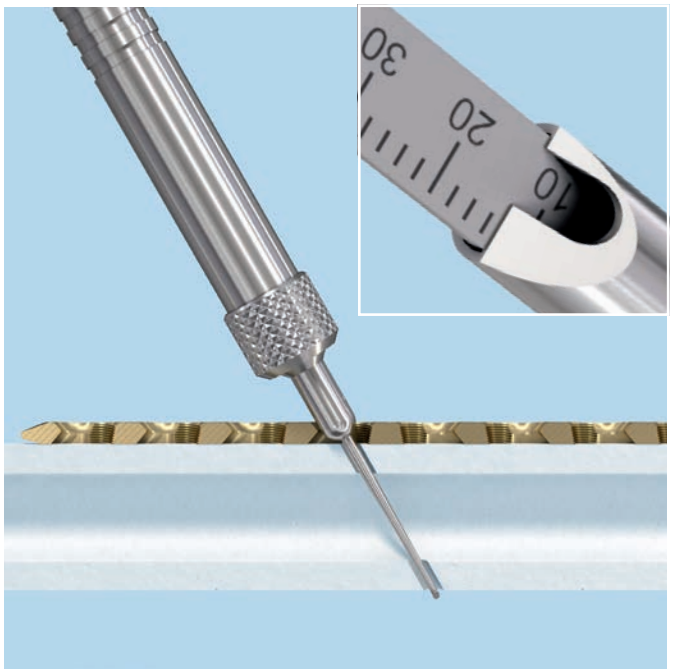


For neutral position

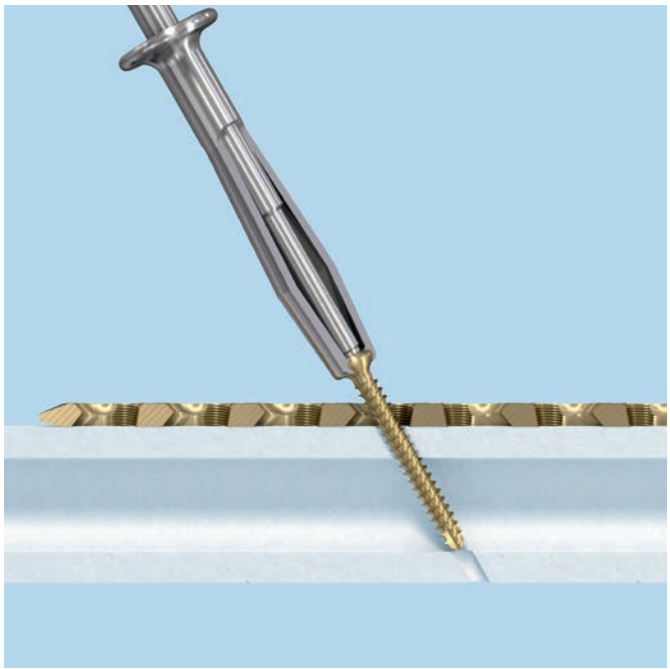


For compression

Determine the required length of the cortex screw using the depth gauge.



Insert the appropriate 3.5 mm cortex screw using the hexagonal screwdriver.



2b. Fixation with ∅ 3.5 mm locking screws

Instruments	
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm
310.284	LCP Drill Bit ∅ 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.030 or 314.116	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm Screwdriver Shaft Stardrive 3.5, SD15, self-holding, for AO/ASIF Quick Coupling
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling

Note: **If a locking screw is used as the first screw, be sure that the fracture is reduced and the plate is held securely to the bone. This prevents plate rotation as the screw is locked to the plate.**

Insert the drill sleeve into a 3.5 mm locking hole until fully seated. Drill through both cortices with the drill bit.

Precaution: **Avoid contact with the subclavian artery and brachial plexus when drilling through the clavicle.**

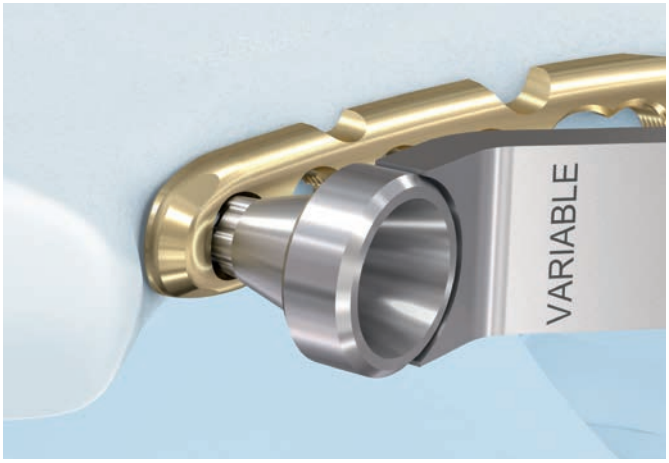
Remove the drill guide. Use the depth gauge to determine the screw length.

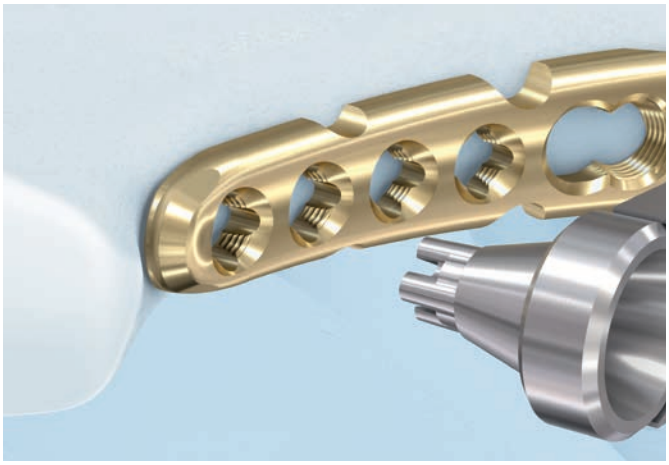
Insert the locking screw with the appropriate screwdriver shaft (hexagonal or Stardrive recess) mounted on the 1.5 Nm torque limiter. Insert the screw manually or by power until a click is heard. If a power tool is used,- reduce speed when tightening the head of the locking screw into the plate.

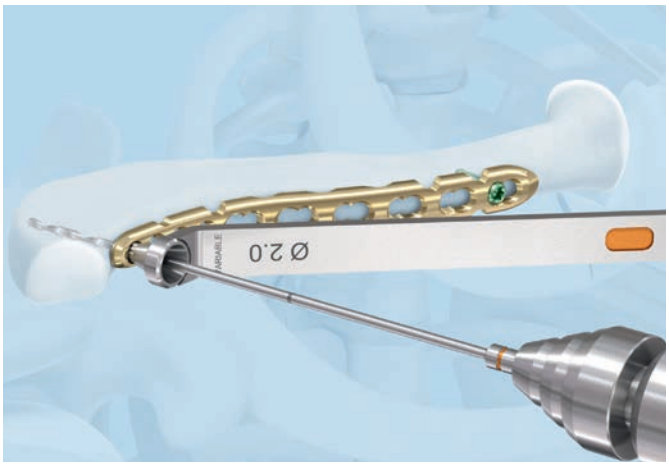
Repeat the above steps for all required shaft holes.

2c. Fixation with ∅ 2.7 mm variable angle locking screws (only for lateral plates)

Instruments	
03.211.002	VA-LCP Drill Sleeve 2.7, for Drill Bits ∅ 2.0 mm
323.062	Drill Bit ∅ 2.0 mm, with double marking, length 140/115 mm, 3-flute, for Quick Coupling
03.111.005	Depth Gauge for Screws ∅ 2.0 to 2.7 mm, measuring range up to 40 mm
313.304	Screwdriver Shaft Stardrive, SD8, cylindrical, with groove, shaft ∅ 3.5 mm, for AO/ASIF Quick Coupling
03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm







Precaution: **Avoid contact with the subclavian artery and brachial plexus when drilling through the clavicle.**

Insert the 2.7 VA-LCP drill sleeve into the variable angle screw hole, ensuring that the drill sleeve tip keys into the cloverleaf portion of the hole.

Use the cone-shaped end of the drill sleeve to drill variable angle holes at the desired angle. The cone allows the drill bit a total variation in angulation of 30°.

Use the 2.0 mm drill bit to drill at the desired angle and to the desired depth.

- Verify the drill bit angle under image intensification to ensure the desired angle has been achieved.

Remove the drill sleeve and use the depth gauge to measure the screw length.

Note: **If the depth gauge 319.010 is used for 2.7 mm screws, subtract 4 mm from the indicated length to obtain the correct screw length.**

Use the SD8 Stardrive screwdriver shaft attached to the 1.2 Nm torque limiter to insert the ∅ 2.7 mm variable angle locking screw. For manual insertion, use the handle for torque limiters.

Repeat for all lateral holes to be used.

Option

The drill sleeve can also be inserted coaxially into the variable angle hole. The fixed-angle end of the drill sleeve ensures that the drill bit follows the nominal trajectory of the locking hole. Determine the required length of the screw by using the scale on the drill sleeve. If a single marking is visible on the drill bit, the scale from 6–30 mm applies; if a double marking is visible, the scale from 34 –58 mm applies.

Implant Removal

Instruments

314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
	or
314.116	Screwdriver Shaft Stardrive 3.5, SD15, self-holding, for AO/ASIF Quick Coupling
313.304	Screwdriver Shaft Stardrive, SD8, cylindrical, with Groove, shaft ∅ 3.5 mm, for AO/ASIF Quick Coupling
311.431	Handle with Quick Coupling
309.521	Extraction Screw for Screws ∅ 3.5 mm
309.510	Extraction Screw for Screws ∅ 1.5 mm and 2.0 mm

To remove the implants, unlock all locking screws before removing them completely. The plate may otherwise rotate while the last screw is being removed, which may damage the soft tissue. If the locking screws cannot be removed with the screw driver (e.g. the recess of the screw is damaged or the locking screw is stuck in the plate), use an extraction screw with left-handed thread. Loosen the screw by turning the handle counter-clockwise.

Note: Verify that the correct instrumentation is available to ensure trouble free implant removal. The correct screwdrivers (hexagonal or Stardrive) and the extraction screws are of special importance.

Plates

Medial

0X.112.040	LCP Anterior Clavicle Plate 3.5, 6 holes, length 79 mm	
0X.112.041	LCP Anterior Clavicle Plate 3.5, 7 holes, length 90 mm	
0X.112.042	LCP Anterior Clavicle Plate 3.5, 8 holes, length 102 mm	

Lateral

0X.112.045	VA-LCP Anterior Clavicle Plate 2.7/3.5, 7 holes, length 77 mm	
0X.112.046	VA-LCP Anterior Clavicle Plate 2.7/3.5, 9 holes, length 89 mm	
0X.112.047	VA-LCP Anterior Clavicle Plate 2.7/3.5, 10 holes, length 101 mm	
0X.112.048	VA-LCP Anterior Clavicle Plate 2.7/3.5, 11 holes, length 113 mm	
0X.112.049	VA-LCP Anterior Clavicle Plate 2.7/3.5, 12 holes, length 124 mm	

X = 2: stainless steel
X = 4: titanium alloy

All plates and screws are also available sterile packed.
For sterile implants, add suffix "S" to article number.

Screws

Lateral

0X.211.016 – 0X.211.032	VA Locking Screw Stardrive ∅ 2.7 mm (head 2.4), self-tapping, length 16–32 mm

Shaft

X12.102 – X12.111	Locking Screw Stardrive ∅ 3.5 mm, self-tapping, length 12–30 mm
	or
X13.012– X13.030	Locking Screw ∅ 3.5 mm, self-tapping, length 12–30 mm

X04.812– X04.830	Cortex Screw ∅ 3.5 mm, self-tapping, length 12–30 mm
	or
0X.200.012– 0X.200.030	Cortex Screw Stardrive ∅ 3.5 mm, self-tapping, length 12–30 mm

X = 2: stainless steel
X = 4: titanium alloy

All plates and screws are also available sterile packed.
For sterile implants, add suffix "S" to article number.

Instruments

309.521	Extraction Screw for Screws ∅ 3.5 mm	
309.510	Extraction Screw, conical, for Screws ∅ 1.5 and 2.0 mm	
310.250	Drill Bit ∅ 2.5 mm, length 110/85 mm, 2-flute, for Quick Coupling	
310.284	LCP Drill Bit ∅ 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling	
311.431	Handle with Quick Coupling	
313.304	Screwdriver Shaft Stardrive, SD8, cylindrical, with Groove, shaft ∅ 3.5 mm, for AO/ASIF Quick Coupling	

314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm	
314.116	Screwdriver Shaft Stardrive 3.5, SD15, self-holding, for AO/ASIF Quick Coupling	
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm	
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm	
323.062	Drill Bit ∅ 2.0 mm, with double marking, length 140/115 mm, 3-flute, for Quick Coupling	
323.360	Universal Drill Guide 3.5	

329.291	Bending Pliers for Clavicular Plates, length 227 mm	
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling	
03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling	
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm	
03.111.005	Depth Gauge for Screws ∅ 2.4 to 2.7 mm, measuring range up to 40 mm	
03.211.002	VA-LCP Drill Sleeve 2.7, for Drill Bits ∅ 2.0 mm	

Optional Instruments

399.071	Reduction Forceps w/Points, soft lock, L 126 mm
399.074	Reduction Forceps w/Points, wide, soft lock
399.082	Reduction Forceps, toothed, soft lock, L 146 mm
399.770	Reduction Forceps w/Points, speed lock
399.790	Reduction Forceps, toothed, speed lock
399.970	Reduction Forceps w/Points, ratchet lock, L 130 mm
399.990	Reduction Forceps, toothed, L 140 mm
398.410	Reduction Forceps w/Points, wide, L 132 mm
292.120	Kirschner Wire ∅ 1.25 mm w/trocar tip, L 150 mm
292.160	Kirschner Wire ∅ 1.6 mm w/trocar tip, L 150 mm

Sets

01.112.041	Tray for VA-LCP Anterior Clavicle Plates (Stainless Steel), with Contents, for Vario Case
	or
01.112.040	Tray for VA-LCP Anterior Clavicle Plates (Titanium Alloy), with Contents, for Vario Case
01.122.013	Small Fragment Basic Instruments, in Modular Tray, Vario Case System
01.122.015	Screw Insertion Instruments 3.5/4.0, in Modular Tray, Vario Case System
01.104.007	Screw Insertion Instruments 2.7/2.4, in Modular Tray, Vario Case System

Optional sets

01.122.019	Small Fragment Bending Instruments, in Modular Tray, Vario Case System
01.122.014	Small Fragment Reduction Instruments, in Modular Tray, Vario Case System

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-14 and ASTM F2119-07

Non-clinical testing of a 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 F2182-11a

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 an MRI 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

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

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