LCP™ Superior Anterior Clavicle Plate

Internal fracture fixation of the clavicle

Surgical Technique

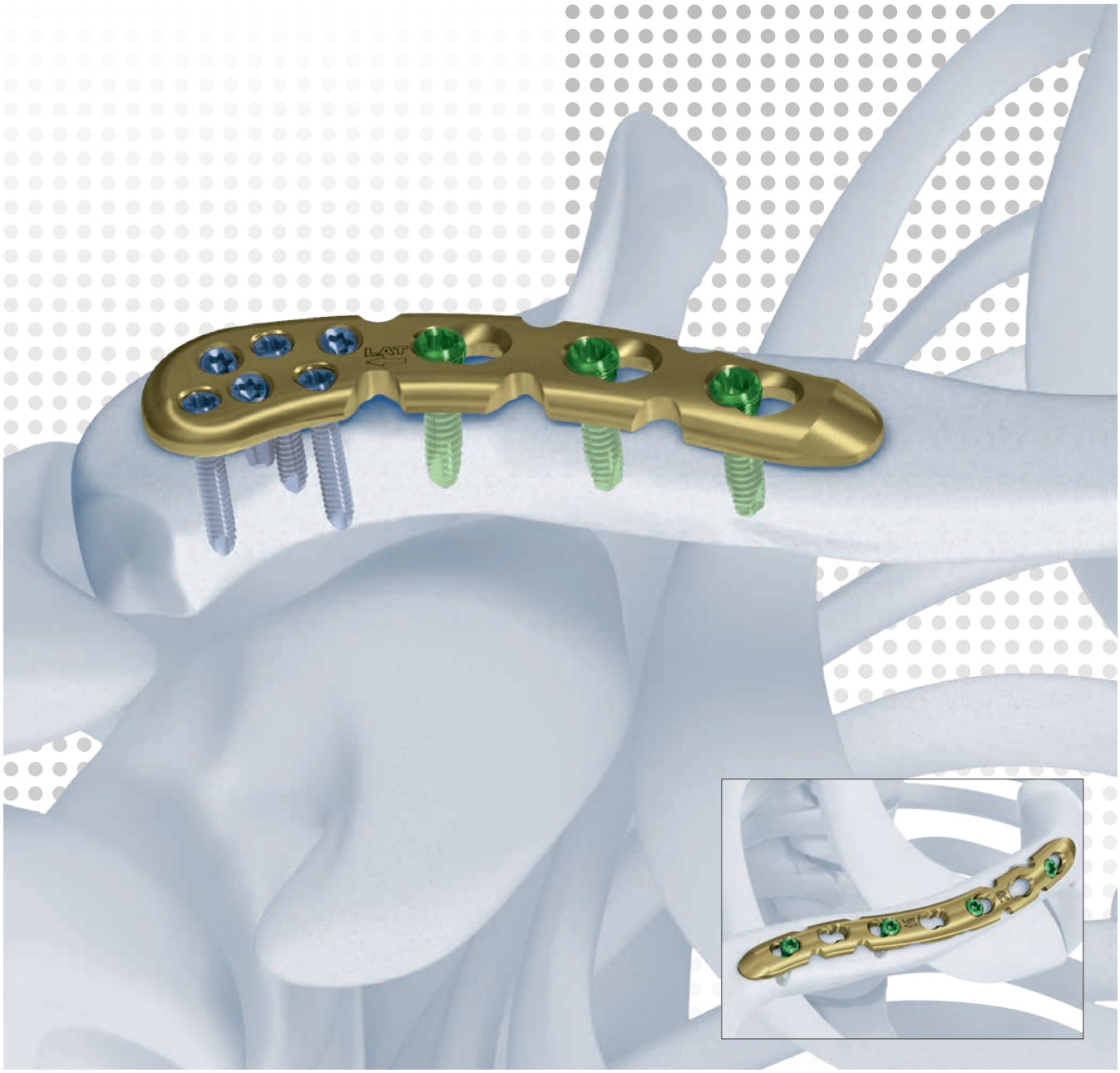

Image intensifier control

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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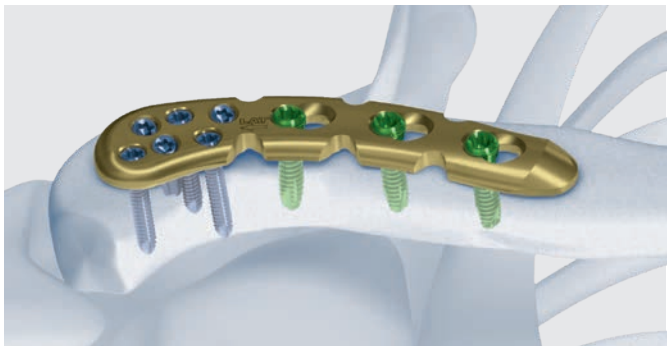
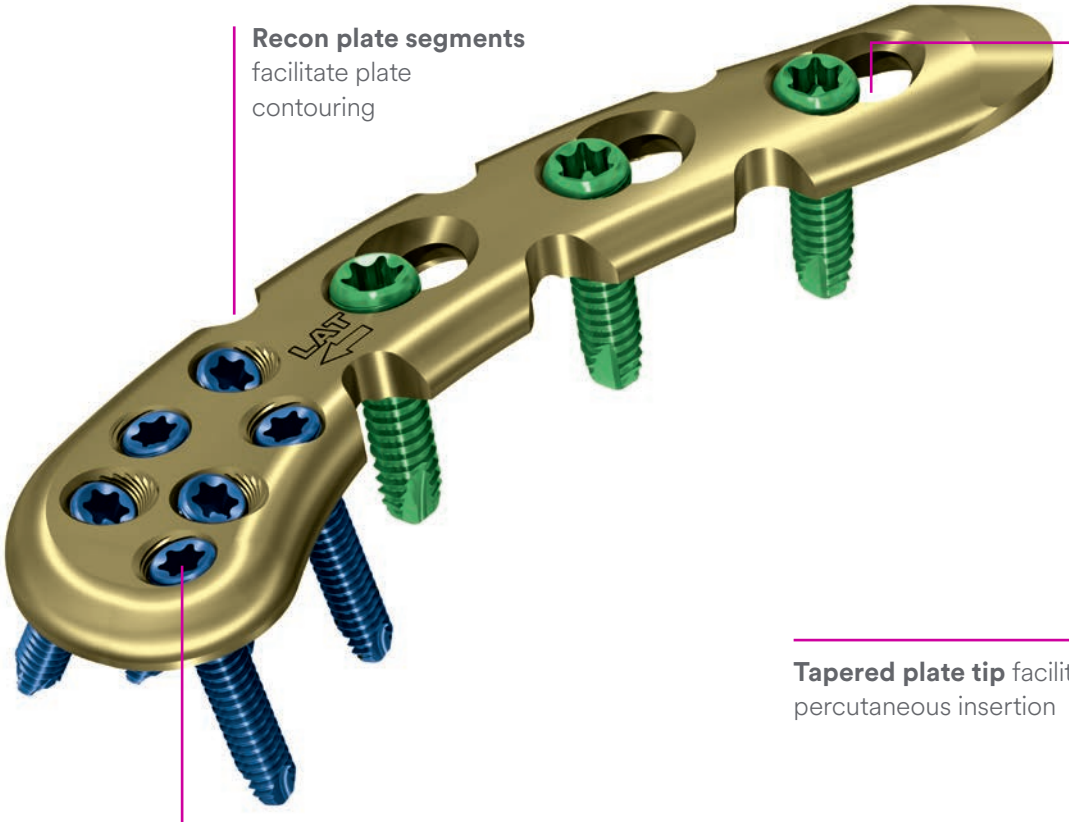
LCP™ Superior Anterior Clavicle Plate

Internal fracture fixation of the clavicle

Overview

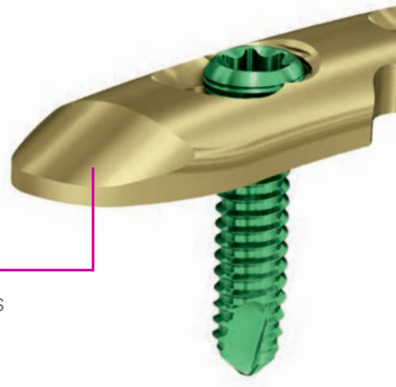


LCP™ Superior Anterior Clavicle Plate with lateral extension



Recon plate segments facilitate plate contouring

Shaft holes 3.5 mm locking or 3.5 mm cortex screws



Tapered plate tip facilitates percutaneous insertion

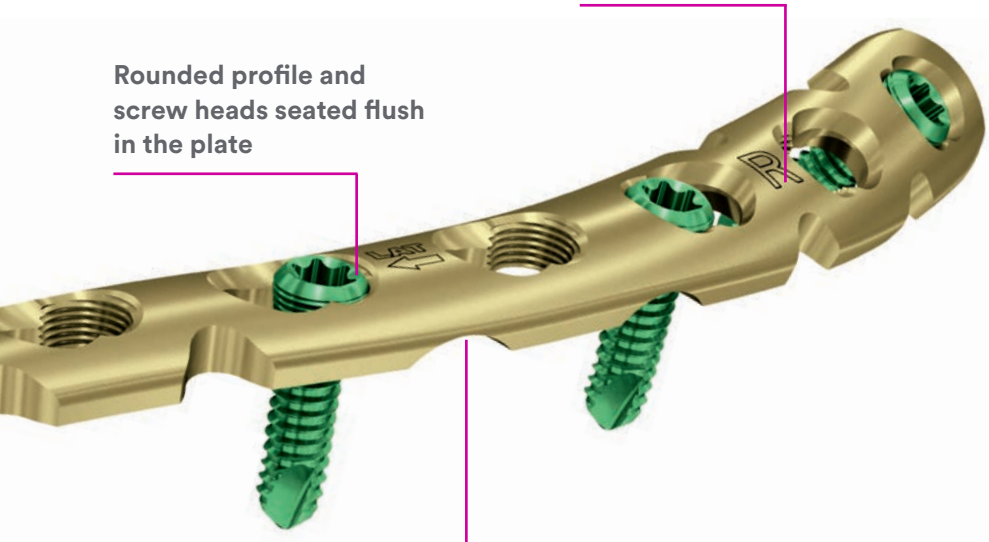
Small (2.7 mm) diverging locking screws in lateral end ensure screw purchase and has pull out strength

Additionally available DePuy Synthes Clavicle Solutions

LCP Superior Anterior Clavicle Plate without lateral extension

Twisted design combines the features of superior and antero-inferior plating

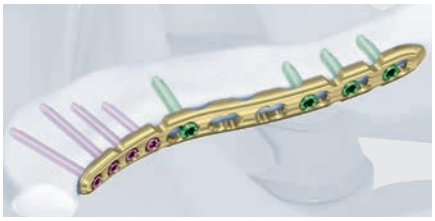
Rounded profile and screw heads seated flush in the plate



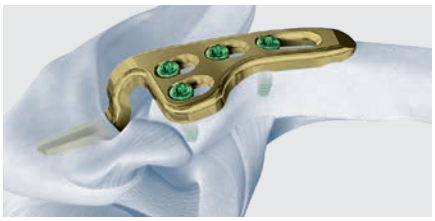
Undercuts

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contra-indications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks. Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

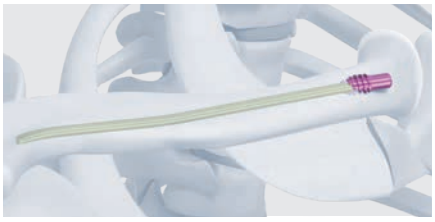
LCP Superior Clavicle Plate



VA LCP™ Anterior Clavicle Plate



LCP Clavicle Hook Plate



Elastic Nail System

The AO Principles of Fracture Management

Mission

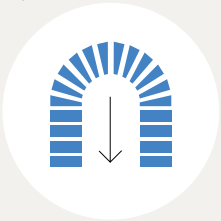
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

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, Allgöwer M, Schneider R, Willenegger H. 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.

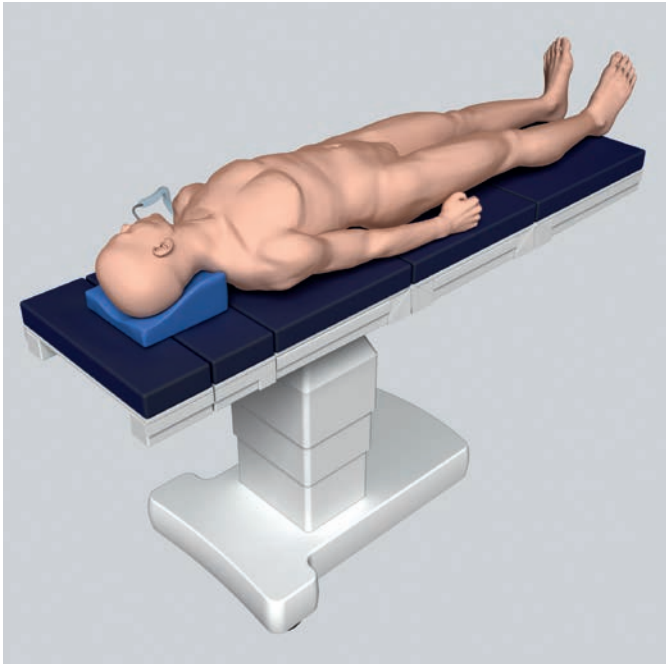
Preparation

1. Preoperative planning

Complete the preoperative radiographic assessment and prepare the preoperative plan.

2. Position and prepare 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 intraoperatively.



Notes:

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

Implantation: Open Approach

1. Surgical approach (open)

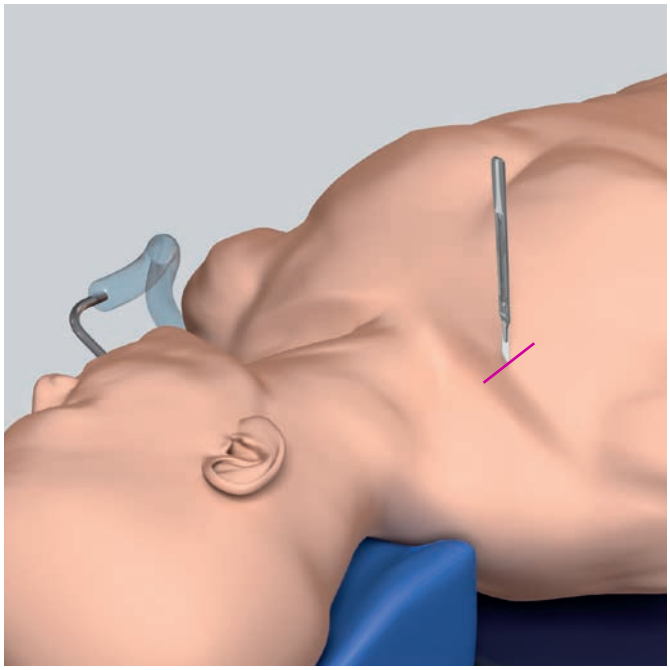
Make a gentle curvilinear incision parallel to the skin cleavage lines.

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.

▲ 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.

Option:

The LCP Superior 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, plate bending may be necessary. Using the bending irons, bending pliers and/or the plate 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, place the plate between the two notches in the front of the jaws of the bending pliers.

To adjust the superior bend, insert the plate all the way toward the back of the jaws of the bending pliers.

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

▲ Precaution:

Avoid bending the plate back and forth, as this can weaken the plate.

■ Notes:

- To avoid damage to the LCP threads from extensive bending, insert a LCP drill sleeve into the threaded hole for protection.
- This locking plate is contoured to fit the clavicle. If the plate contour is changed, it is important to check the position of the screws under image intensifier control.

4. Position plate and attach temporarily

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

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

Implantation: Minimally Invasive Approach

1. Surgical approach (minimally invasive)

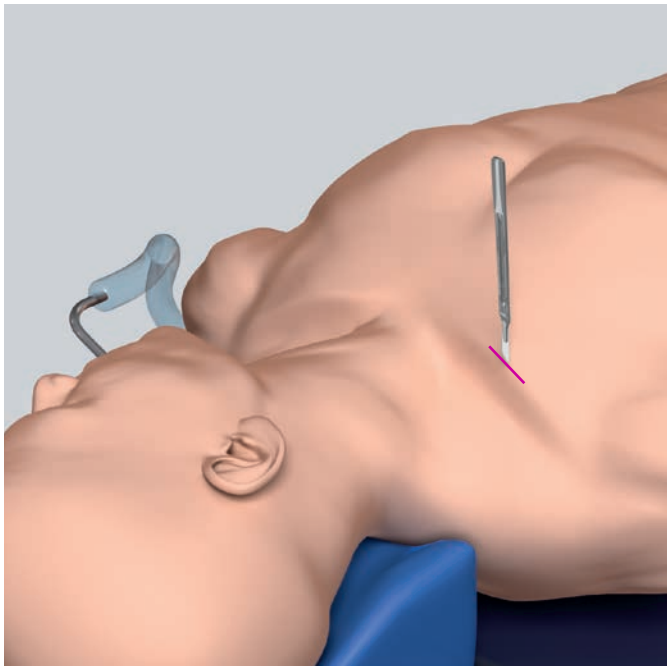
The operation is performed from medial towards lateral to minimize the risk of harming central vessels.

Make a 2 cm incision over the medial end of the clavicle.

■ Note:

To reduce the chance of post-operative interference between the wound and the plate, use a finger to push the skin cranially over the clavicle and cut the skin on the clavicle bone. When removing the finger, the skin will glide back and the cut will be positioned below the clavicle.

The subcutis is carefully spread and dissected to the cortex of the medial clavicle. Ensure that soft tissue is removed from the anterior medial and the superior lateral parts of the bone to enable plate placement.



2. Reduce fracture

Normal length, axis angulation and rotation should be restored. In some cases, this can be controlled percutaneously with one's fingers or with pointed forceps.

Otherwise, an additional 3 cm incision across the fracture and along the cleavage lines is done. Reduction is accomplished through distraction and rotation, if required.

▲ 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.

Option:

The LCP Superior Anterior Clavicle Plate can be used for biological, bridging osteosynthesis. Only the main fragments are reduced while the actual fracture zone is not engaged with any screws.

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. The optimal plate length can be determined by x-ray or by placing it on the skin and palpating.

Due to varying patient anatomy, plate bending may be necessary. Using the bending irons, bending pliers and/or the plate 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, place the plate between the two notches in the front of the jaws of the bending pliers.

To adjust the superior bend, insert the plate all the way toward the back of the jaws of the bending pliers.

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

▲ Precaution:

Avoid bending the plate back and forth, as this can weaken the plate.

■ Notes:

- To avoid damage to the LCP threads from extensive bending, insert a LCP drill sleeve into the threaded hole for protection.
- This locking plate is contoured to fit the clavicle. If the plate contour is changed, it is important to check the position of the screws under image intensifier control.

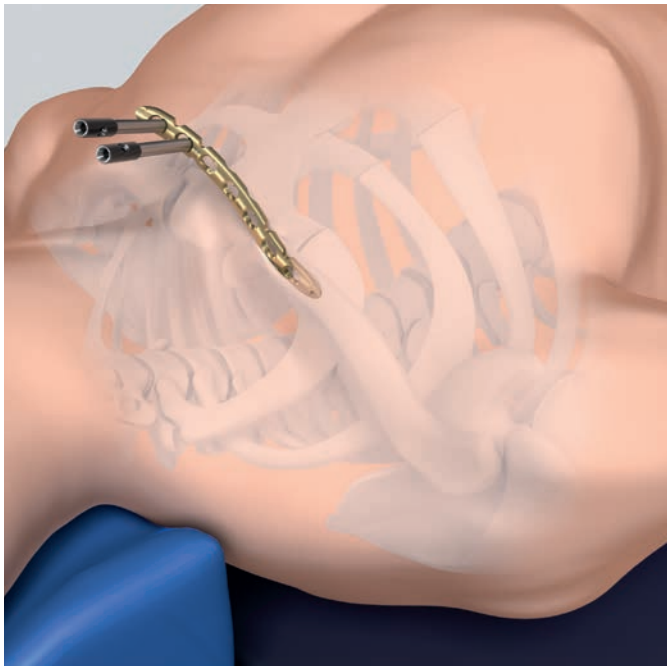
4. Insert and position plate

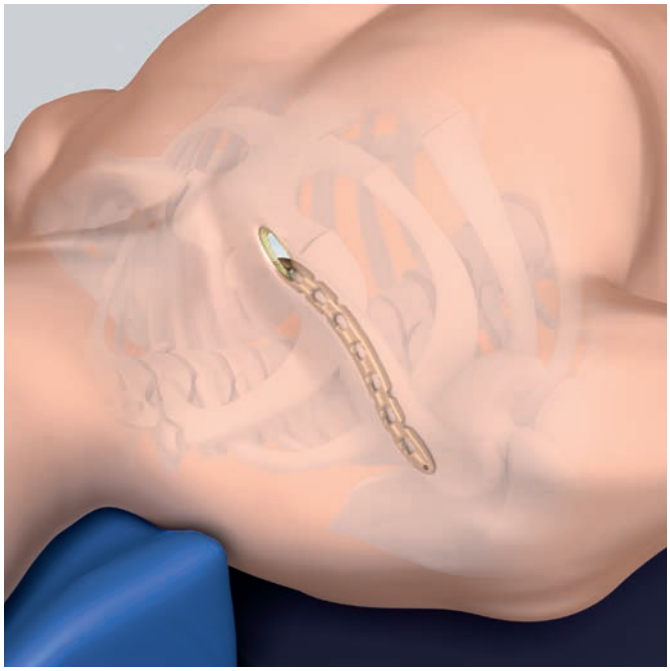
Instrument	
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm

LCP drill sleeves are fixed in the medial part of the plate and used as insertion handles. The plate can be palpated and guided percutaneously from the medial to the lateral fragment.

Position the plate on the reduced bone, and pull the bone to the plate by inserting a 3.5 mm cortex screw in both main fragments (see chapter “Screw Insertion” section 2a).

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 will be used, cortex screws should be inserted first to pull the bone to the plate.

■ Note:

If the LCP Superior Anterior Clavicle Plate is used for bridging osteosynthesis, a minimum of two locking screws should be used in both main fragments. The actual fracture zone is generally not engaged with any screws.

1. Verify screw placement

Since the direction of the locking screws depends on the contour of the plate, final screw position may be verified under image intensifier control with Kirschner wires before insertion. This becomes especially important when the plate has been manually contoured, applied near a joint, or for non-standard anatomy.

Optional:

Observe the direction of the drill bit while drilling under image intensifier control.

2. Screw Fixation

2a. Fixation with ∅ 3.5 mm cortex screws

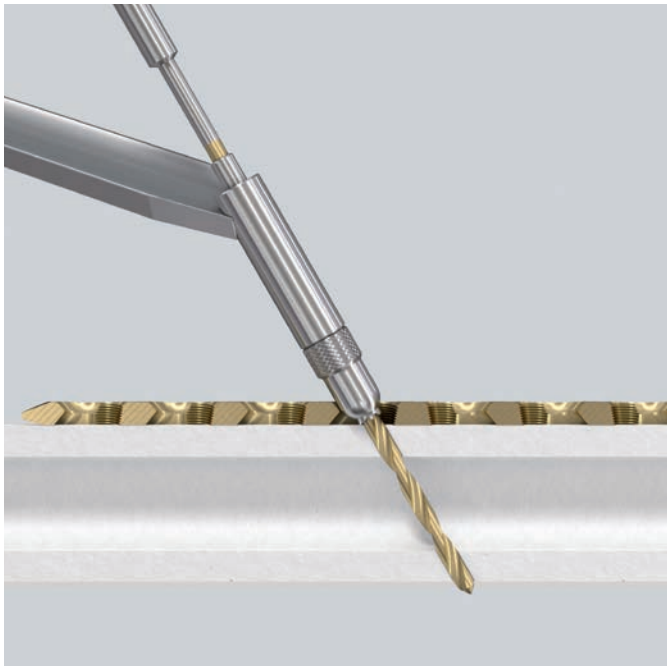
Instruments	
310.250	Drill Bit ∅ 2.5 mm, length 110/85 mm, for Quick Coupling
323.360	Universal Drill Guide 3.5
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
311.431	Handle with Quick Coupling

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

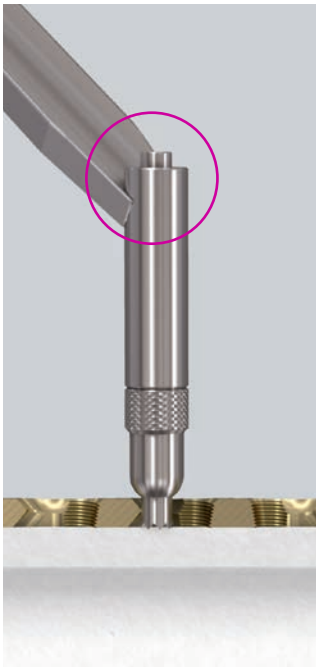
▲ Precaution:

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 or the hexagonal screwdriver shaft.

2b. Fixation with ∅ 3.5 mm locking screws

■ Note:

If a locking screw will be 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.

Instruments	
323.027	LCP Drill Sleeve 3.5, for Drill Bits ∅ 2.8 mm
310.284	LCP Drill Bit ∅ 2.8 mm, length 165 mm
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
or 314.116	Screwdriver Shaft STARDRIVE 3.5, SD15
511.770/773	Torque Limiter, 1.5 Nm
397.705/ 311.431	Handle for Torque Limiter/Handle with Quick Coupling

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

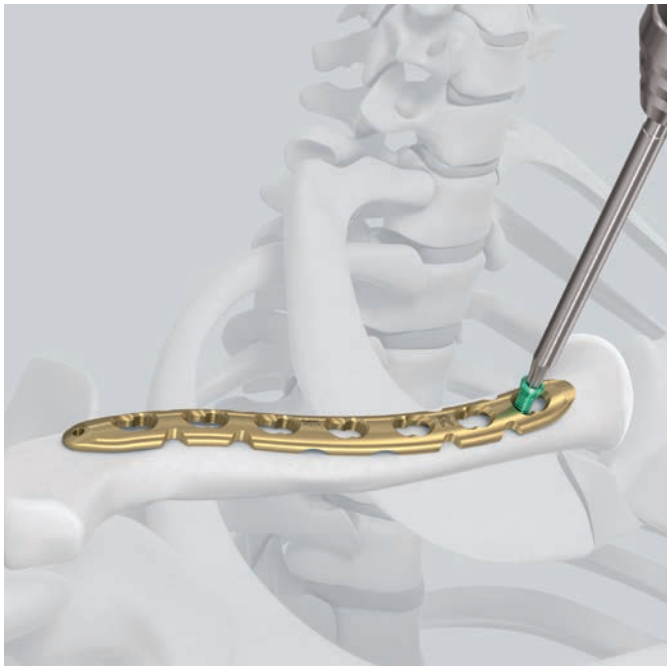
▲ Precaution:

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 locking screws (only in plates with lateral extension)

Instruments	
323.061	LCP Drill Sleeve 2.7 (head LCP 2.4), with Scale up to 60 mm, 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
313.304	Screwdriver Shaft STARDRIVE, SD8, cylindrical, with groove
511.776	Torque Limiter, 0.8 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

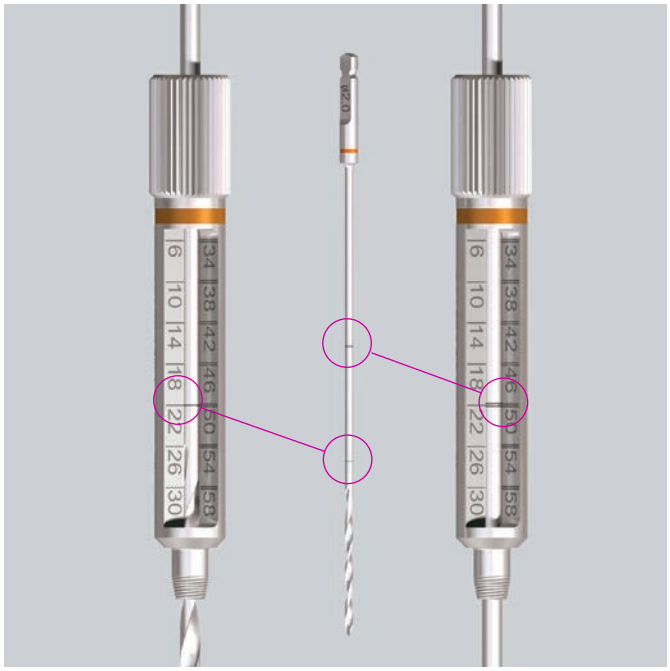
Optional instruments	
03.111.005	Depth Gauge for Screws ∅ 2.0 to 2.7 mm, measuring range up to 40 mm
319.010	Depth Gauge for Screws ∅ 2.7 to 4.0 mm, measuring range up to 60 mm
313.301	Holding Sleeve for LCP Screw STARDRIVE ∅ 2.4/2.7 mm
313.300	Combined Holding Sleeve for Cortex Screws STARDRIVE ∅ 2.4/2.7 mm

Insert the drill sleeve into a 2.7 mm locking hole until fully seated. Use the drill bit to drill to the desired depth.

▲ Precaution:

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

Determine the required length of the screw by using the scale on the drill guide and 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.



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.

■ Note:

The above mentioned methods result in screws that end flush with the opposite cortex. Should bicortical screws be required, insert screws that are 1–2 mm longer than measured. Screws near a joint should be shorter than measured.

The 2.7 mm locking screw can be inserted manually or with power. For manual insertion, use a handle with quick coupling. Use the STARDRIVE screwdriver shaft holding sleeve if necessary.

For powered insertion of the 2.7 mm locking screws, use the screwdriver shaft attached to the 0.8 Nm torque limiting attachment.

▲ Precaution:

Always use a TLA when inserting LCP locking screws to avoid plate, screw and/or screwdriver damage.

Option:

Use 2.4 mm cortex screws.

Repeat the above steps for all lateral holes to be used.

Implant Removal

Instruments

314.030	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm
314.116	Screwdriver Shaft STARDRIVE™ 3.5, SD15
313.304	Screwdriver Shaft STARDRIVE, SD8, cylindrical, with groove, shaft ∅ 3.5 mm, for AO/ASIF 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 LCP 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 LCP 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 lefthanded thread. Loosen the screw by turning the handle counter clockwise.

■ Note:

It is very important to have the correct instrumentation available to ensure trouble free implant removal. The correct screwdrivers (hexagonal or STARDRIVE) and the extraction screws are of special importance.

Plates

LCP Superior Anterior Clavicle Plate 3.5 mm, right

Art. No.	Holes	Length (mm)
0X.112.026	6	94
0X.112.028	7	110
0X.112.030	8	120

LCP Superior Anterior Clavicle Plate 3.5 mm, left

Art. No.	Holes	Length (mm)
0X.112.027	6	94
0X.112.029	7	110
0X.112.031	8	120

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.

LCP Superior Anterior Clavicle Plate 2.7/3.5 mm with lateral extension, right

Art. No.	Holes	Length (mm)
0X.112.006	3	69
0X.112.010	4	81
0X.112.012	5	94
0X.112.008	6	108
0X.112.018*	7	123
0X.112.020*	8	135

LCP Superior Anterior Clavicle Plate 2.7/3.5 mm with lateral extension, left

Art. No.	Holes	Length (mm)
0X.112.007	3	69
0X.112.011	4	81
0X.112.013	5	94
0X.112.009	6	108
0X.112.019*	7	123
0X.112.021*	8	135

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.

*Optionally available

Screws

Lateral

X02.214–230	Locking Screw STARDRIVE ∅ 2.7 mm (head LCP 2.4), self-tapping, length 14–30 mm*	
X01.764–780	Cortex Screw STARDRIVE ∅ 2.4 mm, self-tapping, length 14–30 mm*	

Shaft

X12.102–111	Locking Screw STARDRIVE ∅ 3.5 mm, self-tapping, length 12–30 mm*	
or		
X13.012–030	Locking Screw ∅ 3.5 mm, self-tapping, length 12–30 mm	
X04.812–830	Cortex Screw ∅ 3.5 mm, self-tapping, length 12–30 mm	

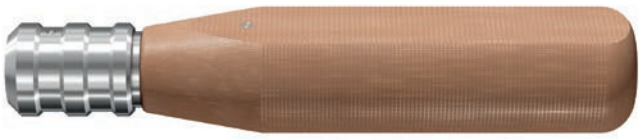
STARDRIVE

Hexagonal

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

* Also available “TS” packed

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	
323.061	LCP Drill Sleeve 2.7 (head LCP 2.4), with Scale up to 60 mm, 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	

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	
511.776	Torque Limiter, 0.8 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	

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

Sets

01.112.009	LCP Superior Anterior Clavicle Plates (Titanium alloy), in Modular Tray, Vario Case System
or	
01.112.011	LCP Superior Anterior Clavicle Plates (Stainless Steel), in Modular Tray, Vario Case System
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 F 2213, ASTM F 2052 and ASTM F 2119

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

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.

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effect and Residual Risks.
Instruction for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

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