VA LCP™ Clavicle Plate 2.7 System

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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VA LCP™ Clavicle Plate 2.7 System

System Overview

Bending notch facilitates plate contouring when needed.

Suture holes

The VA Combi holes combine a dynamic compression unit (DCU) hole with a VA locking hole. The VA Combi hole allows fixation with VA locking screws in the threaded section for angular stability and cortex screws in the non-threaded DCU section for compression.

Plate shapes are contoured to fit the clavicle.

Tapered edges and low-profile design.

All screw holes accept 2.7 mm screws.

Plate Types

The system consists of three plate types: lateral, shaft and medial. Each plate is available in left and right.

Plate Shapes

Lateral and shaft plates are available in different shapes

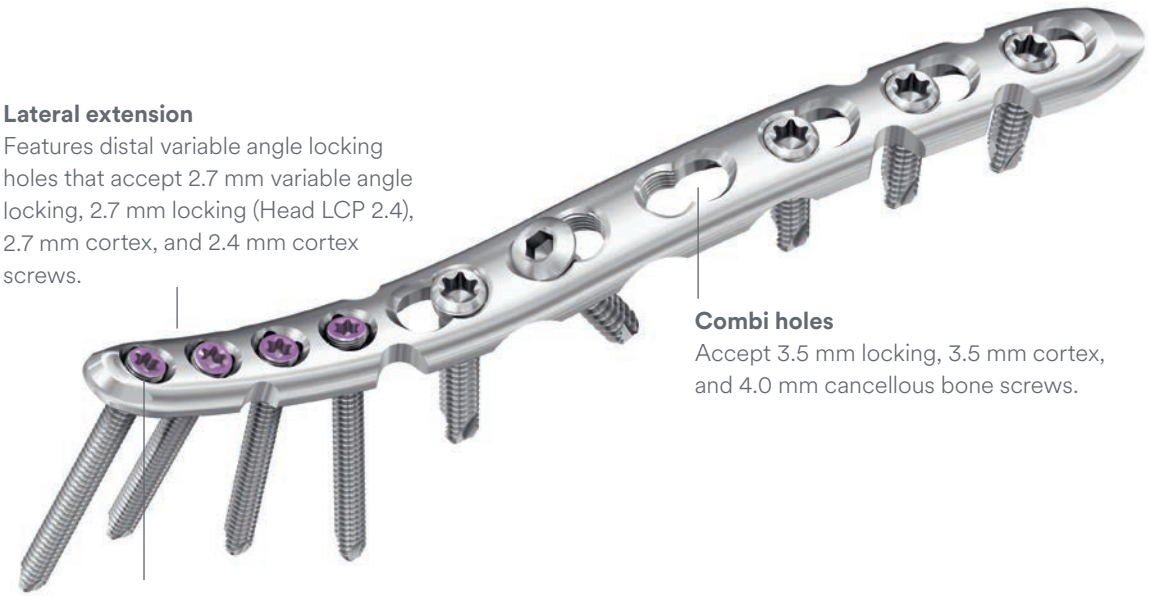
Lateral Plates	Shaft Plates	Medial Plate
CS1 Plate 	CS1 Plate 	
CS2 Plate 	CS2 Plate 	(available in one size)
CS3 Plate 	CS3 Plate 	
	XL Plate 	

DePuy Synthes Clavicle Portfolio

DePuy Synthes offers a portfolio of complementary plating systems for clavicle fractures and acromioclavicular (AC) joint injuries. In addition to the VA LCP™ Clavicle Plate 2.7 system described in this surgical technique guide, DePuy Synthes offers the VA LCP Anterior Clavicle Plates 2.7/3.5 and the VA LCP Clavicle Hook Plates 2.7.

VA LCP Anterior Clavicle Plates

- Plates fit on the anterior aspect of the clavicle
- VA locking holes in the lateral portion of the plate for screw targeting of lateral bone fragments
- Combi holes allow fixation with locking screws in the threaded section for angular stability and with cortex screws in the DCU section for compression.



Lateral extension
Features distal variable angle locking holes that accept 2.7 mm variable angle locking, 2.7 mm locking (Head LCP 2.4), 2.7 mm cortex, and 2.4 mm cortex screws.

Combi holes
Accept 3.5 mm locking, 3.5 mm cortex, and 4.0 mm cancellous bone screws.

Variable angle screw holes
Recess for screwhead minimizes screw prominence to create a low-profile construct.

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.

VA LCP Clavicle Hook Plate system

- Long and Short Hook Plate and Button Plate options available
- Each Plate is available in 3 hook depths
- Plates with low construct prominence
- Plate angulations and hook depths facilitates fit

Hook Plate, Long

Hook Plate, Short

Button Hook Plate

Available in 9 mm, 12 mm, and 15 mm hook depths

The AO Principles of Fracture Management

Mission

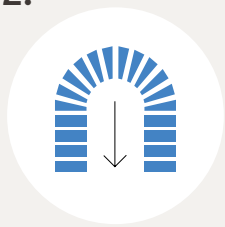
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.

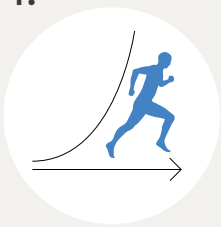


Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

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.

▲ Precaution:

The VA LCP Clavicle Plates 2.7 are designed for patients where the growth plates have fused or will not be crossed. The use of the clavicle plates in patients where the growth plates have not fused or will be crossed may result in premature closure of the physis and bone growth inhibition and therefore plates must be removed upon fracture healing.

Preparation

1. Preparation

Patient Positioning

Patient positioning is based on surgeon preference. A supine position on a radiolucent operating table or a beach chair position with 30°–45° of tilt can be used to provide appropriate access to the clavicle.

A small roll or folded towel placed between the scapulae allows retraction of the shoulders and assists with reduction. The head of the patient should be turned away from the operative side and may be supported with a head rest. Prepare the entire upper extremity, the upper chest wall, and hemithorax. This includes the sternum and sternoclavicular articulation.

Anteroposterior and axial visualization of the clavicle with fluoroscopy is recommended. For medial fractures, position the c-arm perpendicular to the sternoclavicular joint. It is recommended to check access with the c-arm and take trial images prior to draping to ensure appropriate views can be obtained.

Approach

2. Approach

Determine the most appropriate incision length and location along the dotted line, based on the fracture pattern, fracture location, and planned fixation method.

The medial, intermediate, and lateral supraclavicular nerves travel deep to the platysma then cross the clavicle, dividing into medial, intermediate, and lateral branches. Subcutaneous dissection is performed carefully and permits identification of the supra-clavicular sensory nerve branches. The major fibers of these nerves should be identified and protected with small vessel loops throughout the case.

Division of the platysma is performed carefully as the supraclavicular nerves may still be deep to the platysma depending on the cephalad level of the dissection. The platysma is carefully divided to expose the clavicle periosteum at the deltotrapezial fascia and the pectoralis origin. Dissection should be epiperiosteal to preserve the periosteum. Minimal periosteal dissection is carefully done to allow exposure of the fracture.

For medial fractures, elevate the sternocleidomastoid muscle.

▲ Precaution:

The periosteum of bone fragments must not be completely detached in order to preserve available bony blood supply thus enabling proper bone healing. It is critical not to strip any comminuted fragments.

Longitudinal incision

Vertical incision

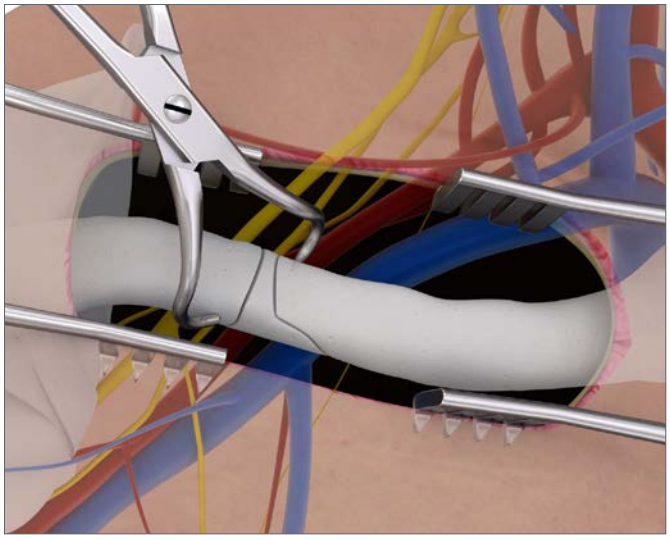
Reduce Fracture and Temporary Fixation

3. Reduce Fracture and Temporary Fixation

After fracture exposure, distract the two main fragments and restore the length of the clavicle. If the bone ends are angled or oblique, reduction with pointed or serrated reduction forceps is recommended. Normal length, axis angulation, and rotation should be restored. Any large comminuted fragments should also be reduced and temporarily held with small pointed bone clamps. Plan temporary fixation so that it does not interfere with placement of definitive fixation.

Additional options for maintaining reduction include:

- Continuous compression implants (see Continuous Compression Implant Brochure)
- Independent lag screws (see Universal Small Fragment Technique Guide)
- Lag screws through the plate (see Universal Small Fragment Technique Guide)
- Temporary K-wire fixation can be useful. If K-wires are employed be certain to protect all critical structures.



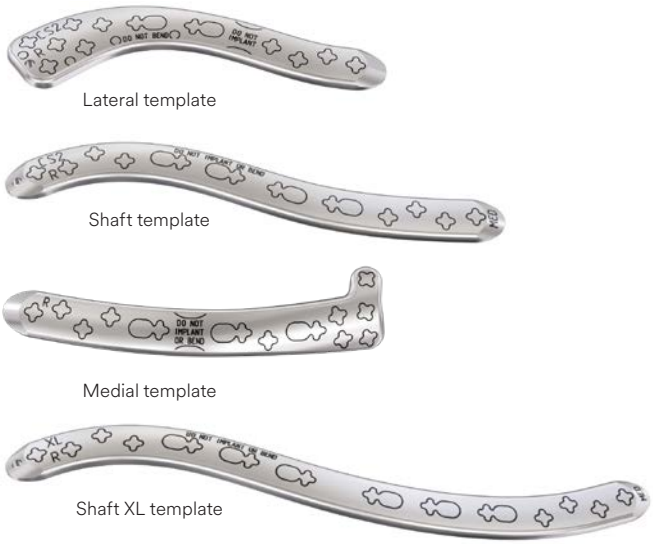
■ Option:

The plates can be used for biological, bridging osteosynthesis. With this technique, only the main fragments are reduced, and the actual fracture zone is not engaged with any screws.

Determine Plate Type and Shape

4. Determine Plate Type and Shape

Instruments	
03.112.610– 03.112.615	Templates for VA LCP Clavicle Plate 2.7, Lateral
03.112.620– 03.112.625	Templates for VA LCP Clavicle Plate 2.7, Shaft
03.112.630– 03.112.631	Templates for VA LCP Clavicle Plate 2.7, Medial
03.112.712– 03.112.713	Templates for VA LCP Clavicle Plate 2.7, XL*

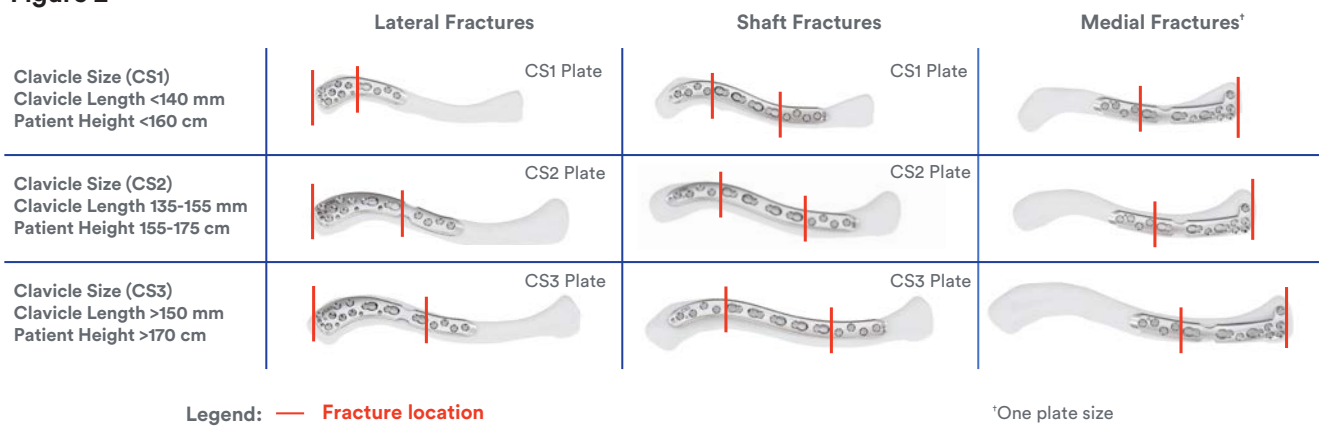


Use the templates to determine the appropriate plate type and shape.

Types: Plates are available in 3 different types: lateral, shaft, and medial. (Figure 2)

Shapes: Plate shapes match the bow and curvatures of the clavicle size. Plate shapes are based on patient stature and clavicle size. Lateral and shaft plate types are available in 3 sizes: CS1, CS2, and CS3. The medial plate is available in one size. (Figure 2)

Figure 2



*Corresponding plates available sterile only.

4. Determine Plate Type and Shape continued

Extended Shaft Fractures: For shaft fracture patterns that require a longer working length, the Shaft XL plate spans from the lateral aspect to the medial aspect of a large size clavicle (clavicle size 3). For extended fractures, use a plate one size larger than the clavicle size. The shaft CS3 plate can be used to span from the lateral aspect to the medial aspect of a mid-size clavicle (clavicle size 2). The shaft CS2 plate can be used to span small size clavicles (clavicle size 1). (Figure 3)

The lateral and shaft templates and corresponding plates fit on the superior aspect of the clavicle. The medial end of the medial template and corresponding plate fit on the anterior aspect of the clavicle.

With the fractured bone segments in proper anatomic alignment, insert the template and assess if it fits the clavicle and is appropriate for fixation of the main fragments. The screw hole positions of the corresponding plate are marked on the template.

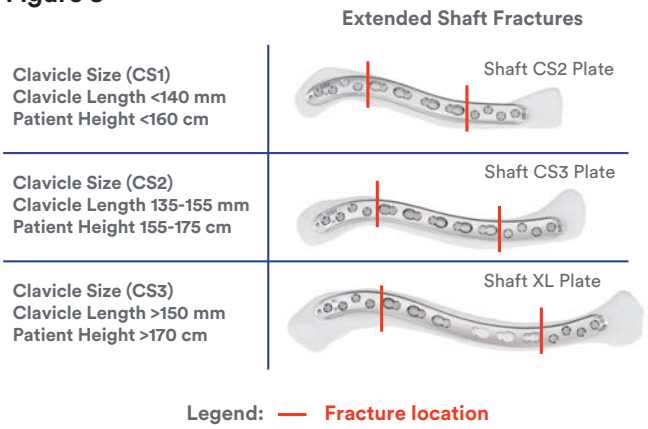
■ Note:

The recommended construct will achieve fixation with four 2.7 mm screws placed bicortically per main fracture fragment. For fractures in the medial clavicle, consider monocortical screw placement in the most medial screw holes to prevent perforation of neurovascular structures or the sternoclavicular joint.

Templates can be temporarily fixed to the bone using clamps or in the lateral clavicle by placing a K-wire (up to 2.0 mm) or compression wire through the hole in the template. Confirm reduction, template fit, planned screw positioning, and shoulder function. If needed use fluoroscopy.

If the surgical plan calls for axial dynamic compression, ensure that the template is positioned so there is at least one VA Combi hole in each main fragment.

Figure 3



4. Determine Plate Type and Shape continued

If the fracture pattern is simple and absolute stability can be achieved, a shorter plate may be selected. For complex fractures with an extensive area of comminution, a longer plate should be selected.

After confirmation of correct alignment and implant size, remove the template.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

■ Note:

To help determine the necessary amount of clavicular length to restore, prior to the patient being draped, measure the distance between the acromioclavicular joint and the sternoclavicular joint on the contralateral side and refer to Figure 2 under section “Determine Plate Type and Shape”. The template can also be placed on the contralateral clavicle to check length.

▲ Precaution:

Do not bend or implant the templates.

Select Plate Type and Shape

5. Select Plate Type and Shape

Select the plate type and shape that corresponds to the template that was used.

If templates were not used, select a plate type and shape based on the clavicle morphology and fracture location. See Figures 2 and 3 under section “Determine Plate Type and Shape” for plate options and instructions on sizing and positioning of the plate.

With the fractured bone segments in proper anatomic alignment, confirm that the plate fits the clavicle and is appropriate for fixation of the main fragments.

■ Note:

Plates are available in Stainless Steel and Titanium alloy.

Adapt Plate to Bone (Optional)

6. Adapt Plate to Bone (Optional)

Instruments	
03.133.200	Bending Iron f/Plates, closed, f/Plates 2.7/3.5 mm
03.133.201	Bending Iron f/Plates, open, f/Plates 2.7/3.5 mm
329.291	Bending Pliers f/Clavicular Plates, L 227 mm

Check if the plate fit is satisfactory. Due to the high degree of variability of the clavicle shape and length, slight plate bending may be necessary.

In-Plane Bending: Use the bending pliers for in-plane bending. In-plane bending can only be performed with the lateral and medial plates at the bending notch. Insert the plate in the slots in the front of the plier jaws and center over the bending notch.

For additional leverage and control, loosen the adjustment screw on the bending pliers so that the handles are closer together. Make a series of small bends, threading the adjustment screw roughly one-half turn each time.

Out-of-Plane Bending: Use bending pliers or bending irons for out-of-plane bending. For bending irons, place the plate in the middle slot of the closed bending iron to hold the plate. Position the middle open bending iron slot at any location along the plate in order to bend that segment of the plate.

Plates may be contoured up to 10° in-plane or out-of-plane.

In-plane bending

Out-of-plane bending

6. Adapt Plate to Bone continued

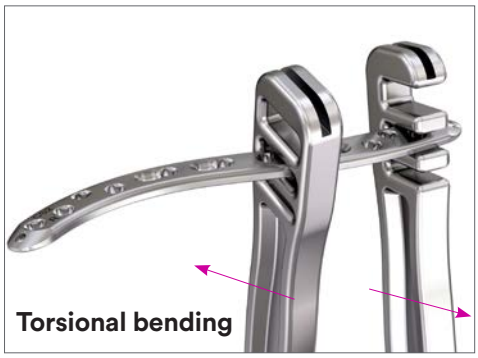
Tab Bending: The bending pliers may also be used to adjust the tab on the medial plates.

Torsional Bending: Use bending irons for torsional bending, i.e., twisting. Place the plate in the middle slot of the closed bending iron to hold the plate. Position the middle open bending iron slot at any location along the plate and rotate the two irons.

Plates may be twisted up to 10°.

▲ Precautions:

- Do not bend the plate more than 10° as it may impact the mechanical performance. Excessive bending may weaken the plate and lead to premature plate failure.
- Avoid reverse bending (i.e., bending and then straightening the plate) as it may compromise the strength of the plate or cause it to break.
- Do not make an acute bend directly over a screw hole as it may damage the thread or deform the screw hole. Check the VA portion of holes adjacent to the bending site with a variable angle drill guide after bending to ensure holes have not been deformed.
- Nominal screw angle is determined by plate design and screw length. If the plate is contoured and/or a screw longer than 40 mm is selected, take care to ensure that the screws do not collide with one another. The use of image intensification is recommended.



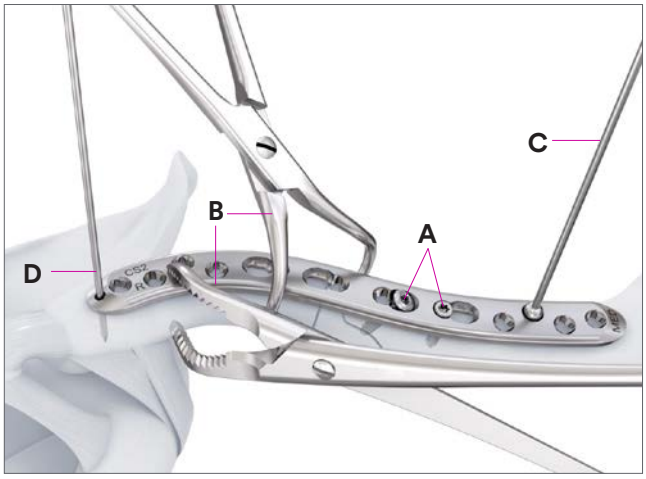
Correct handling

Correct handling of the implant is extremely important. If the shape of the implant must be altered, the device should not be bent sharply, bent backwards, notched, or scratched. Such manipulations, in addition to all other improper handling or use, can produce surface defects and/or concentrate stress in the core of the implant. This, in turn, may eventually cause the product to fail.

Plate Insertion and Temporary Fixation

7. Plate Insertion and Temporary Fixation

Instruments	
292.160S	Kirschner Wire Ø 1.6 mm, w/trocar tip, L 150 mm
03.211.410.01	Compression Wire Ø 1.6 mm, L 150 mm, thread length 10 mm
03.211.415.01	Compression Wire Ø 1.6 mm, L 150 mm, thread length 15 mm



Position the plate on the reduced bone and attach it temporarily using any of the following techniques:

A. Cortex screw or metaphyseal screw
B. Reduction forceps/serrated clamps
C. Compression wire
D. K-wire

It is important to center the compression wire within the plate holes to minimize shifting of the plate position as the wire pulls the plate to the bone.

A K-wire up to 2.0 mm can be inserted in the lateral suture hole or K-wire hole as a reference to visualize the lateral aspect of the clavicle and aid in proper plate placement.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

After plate insertion, confirm fit and alignment of the bone using fluoroscopy.

■ Note:

The suture holes on the lateral plate (see section “Soft Tissue Attachment [Optional]”) have an undercut to allow for suture needle passage. However, depending on the individual patient’s anatomy, the undercut may be blocked and no needle passage possible. In this case, insert the suture through the suture holes before starting with final plate fixation.

Screw Configuration

8. Screw Configuration

All screw holes in the VA LCP Clavicle Plates accept 2.7 mm screws.

■ Note:

The recommended construct will achieve fixation with four 2.7 mm screws placed bicortically per main fracture fragment. For fractures in the medial clavicle, consider monocortical screw placement in the most medial screw holes to prevent perforation of neurovascular structures or the sternoclavicular joint.

Determine the combination of 2.7 mm screws required for fixation. Any of the screws listed on the reference chart can be used with the corresponding instrumentation.

When planning screw location and length, consider screw collision and over-penetration.

■ Note:

If a combination of VA locking, cortex, or metaphyseal screws will be used, it is recommended to insert cortex or metaphyseal screws first, next to the fracture. This will pull the plate to the bone to ensure that the plate sits flush on the clavicle and enhance construct stability, especially in configurations where a high implant load is expected.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

Screw direction at nominal angle.

Screw Reference Chart

Screw Size (mm)	Screw Type	Drill Bit (mm)	Torque Limit (Nm)	Driver Options
2.7	Variable Angle Locking	2.0	1.2	T8
	Metaphyseal		Do Not Use	T8
	Cortex		Do Not Use	T8

Lateral Plate

Shaft Plate


Medial Plate

8. Screw Configuration continued

Cortex Screws

Cortex screws can be used in the non-threaded DCU portion of the VA Combi hole (1) (Figure 4) in the neutral/centered position or in the eccentric position for compression. Cortex screws can be used in VA locking hole (2) in the nominal position only. If a cortex screw is placed in a VA locking hole, it cannot be placed in an eccentric position and the screw head will not sit flush with the plate surface.

VA Locking Screws

VA locking screws can be used in VA locking holes (2) (Figure 4) at either a nominal angle or at variable angles (Figure 5). VA locking screws can also be used in the threaded portion of VA Combi holes. VA locking screws should not be used in the non-threaded DCU portion of VA Combi holes.

Metaphyseal Screws

Metaphyseal screws provide compression with a low-profile screw head that sits flush with the plate. Metaphyseal screws have the same screw shaft thread as the VA locking screws and can be used in VA locking holes (2) (Figure 4) and the threaded portion of VA Combi holes (1) at the nominal angle. They cannot be used in the non-threaded DCU portion of VA Combi holes.

■ Note:

2.7 mm locking screws with Head LCP 3.5 are not compatible with the VA locking holes of the DePuy Synthes VA LCP Clavicle Plate 2.7 System.

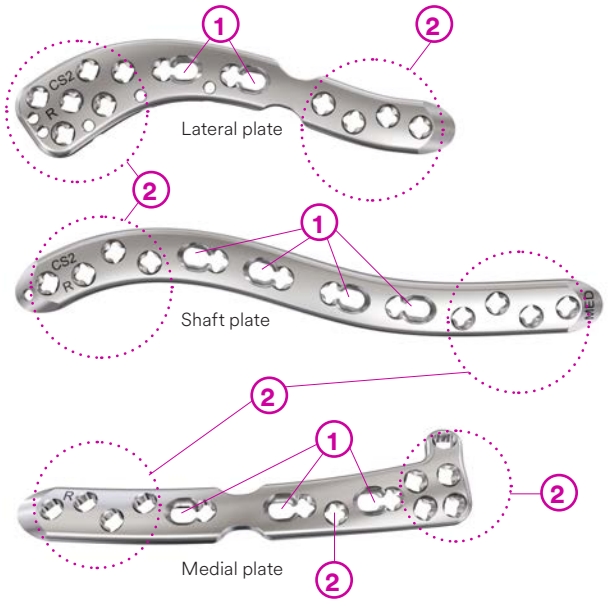
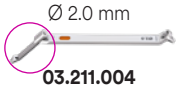
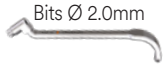
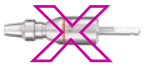
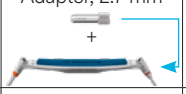
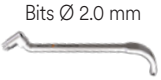


Figure 4

Figure 5: VA locking screw +/-15° of angulation

8. Screw Configuration continued

Screw Type	Plate Hole Type	Application Options			Drill Sleeve		Torque Limiter
		Angulation	Reduction Plate to Bone	DCU Options	Universal Small Fragment	Additional	
Variable Angle Locking 	**VA Locking in VA Combi hole** 	**Variable**	**No**	**No**	**03.133.007** VA Drill Guide, 2.7 mm 	**03.211.002*** VA LCP Drill Sleeve 2.7, f/Drill Bits Ø 2.0 mm 	**03.110.002** Torque Limiter, 1.2 Nm, w/AO/ASIF Quick Coupling 
	VA Locking 	**Fixed (nominal angle)**	**No**	**No**	**03.133.008** Threaded Drill Guide 2.0 mm, f/ Screw 2.7 mm, f/VA and LCP™ 	**03.211.002*** VA LCP Drill Sleeve 2.7, f/Drill Bits Ø 2.0 mm  **03.211.004** VA LCP Drill Sleeve 2.7, coaxial, f/Drill Bits Ø 2.0mm 	
Metaphyseal 	**VA Locking in VA Combi hole**  **VA Locking** 	**Fixed (nominal angle)**	**Yes**	**No**	**03.133.008** Threaded Drill Guide 2.0 mm, f/ Screw 2.7 mm, f/VA and LCP™ 	**03.211.002*** VA LCP Drill Sleeve 2.7, f/Drill Bits Ø 2.0 mm  **03.211.004** VA LCP Drill Sleeve 2.7, coaxial, f/Drill Bits Ø 2.0 mm 	**Do not use** 
Cortex 	**DCU of VA Combi Hole** 	**Yes**	**Yes**	**Axial Compression**	**03.133.006** Non-Locking Drill Guide, 2.7 mm 	**323.260*** Universal Drill Guide 2.7 	**Do not use** 
			Yes	**Neutral No compression**	**03.133.006** Non-Locking Drill Guide, 2.7 mm + **03.133.005** Neutral Sleeve Adapter, 2.7 mm + 		
	VA Locking 	**No**	**Yes**	**No**	**03.133.008** Threaded Drill Guide 2.0 mm, f/ Screw 2.7 mm, f/VA and LCP™ 	**03.211.004** VA LCP Drill Sleeve 2.7, coaxial, f/Drill Bits Ø 2.0 mm 	

*Also available. Not included in set 01.133.273/01.133.473. Not all 2.7 mm VA compatible instruments shown in this table.

Screw Insertion – 2.7 mm Cortex Screws

9. Screw Insertion – 2.7 mm Cortex Screws

Screw Hole Preparation

Instruments

03.133.005	Neutral Sleeve Adapter 2.7 mm, f/Non-Locking Drill Guide 2.7 mm
03.133.006	Non-Locking Drill Guide, 2.7 mm
03.133.100*	Drill Bit Ø 2.0 mm, QC, L 110 mm, Calibration 30 mm
323.260†	Universal Drill Guide 2.7
310.534†‡	Drill Bit Ø 2.0 mm, w/marking, L 110/85 mm, 2-flute, f/Quick Coupl.
323.062†‡	Drill Bit Ø 2.0 mm, w/double marking, L 140/115 mm, 3-flute, f/Quick Coupl.

For neutral/centered screw placement (Figure 6), thread the neutral sleeve adapter, 2.7 mm onto the 2.0 mm end of the non-locking drill guide, 2.7 mm. Place the drill guide tip in the center of the DCU screw hole. Compression will not occur across the fracture.

Dynamic compression can be achieved by eccentric insertion of a cortex screw. To drill a hole for dynamic compression using a 2.7 mm cortex screw, do not use the neutral sleeve adapter. Place the 2.0 mm end of the drill guide tip eccentrically at the edge of the DCU portion of the screw hole away from the fracture (Figure 7). Compression will occur as the cortex screw is tightened and the screw head slides across the compression hole.

Use the drill bit Ø 2.0 mm,to drill to the desired depth. The 2.0 mm drill bits are calibrated so the depth measurements can be read directly from the drill bit shaft (Figure 8).

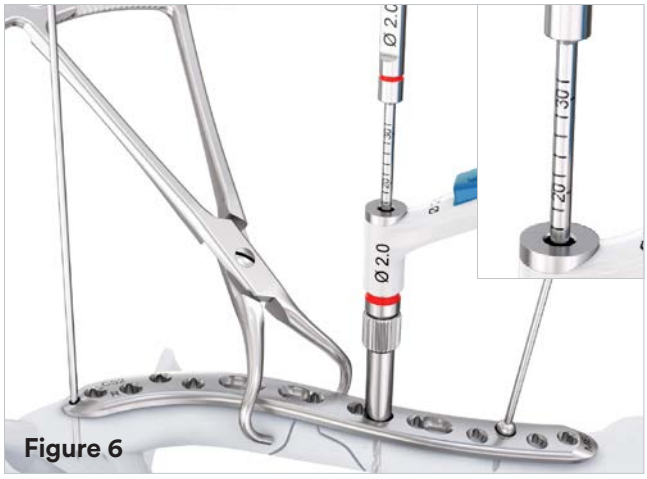


Figure 6

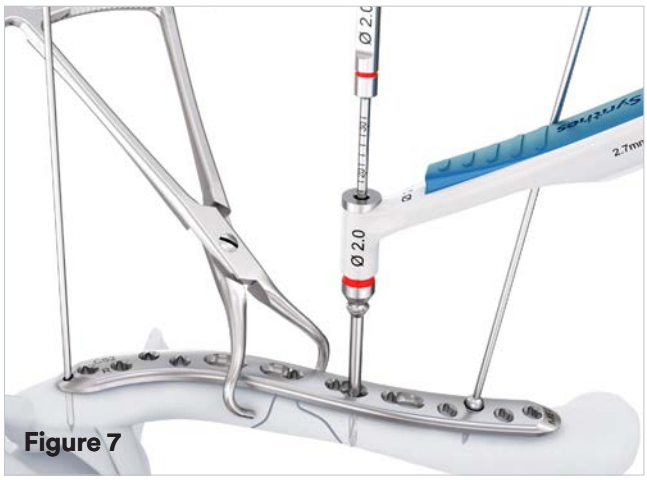


Figure 7

Figure 8

*For use with 03.133.006/323.260.

†Additionally available instruments.

‡For use with 323.260.

9. Screw Insertion – 2.7 mm Cortex Screws continued

■ Note:

Irrigate and apply suction for removal of debris potentially generated during implantation and to avoid heat generation during drilling.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

Hole Depth Measurement

Instruments	
03.111.005	Depth Gauge f/Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm
03.133.080	Depth Gauge 2.7/3.5 mm, 0 to 60 mm

After drilling and removing the drill guide, insert the depth gauge tip through the drilled hole and measure. For bi-cortical measuring, insert the depth gauge tip through both cortices and hook onto the far cortical bone.

Using the depth gauge for screws Ø 2.0 to 2.7 mm (03.111.005), slide the black portion of the gauge toward the bone until it stops. Length is read from the line marked on the silver slider.

Using the depth gauge f/screws Ø 2.0 to 2.7 mm (03.133.080), pull the knob up until it stops. Depth marks are provided on both sides and length is read from the top edge of the metal sleeve.

03.111.005

03.133.080

9. Screw Insertion – 2.7 mm Cortex Screws continued

Screw Insertion

Instruments	
03.133.150	Screwdriver Handle, Universal
314.467	Screwdriver Shaft, StarDrive™ T8, self-holding
314.453	Screwdriver Shaft StarDrive™ 2.4, short, self-holding, f/Quick Coupling
311.260*	Tap f/Cortex Screws, Ø 2.7 mm, L 100/33 mm

To manually insert a cortex screw, attach the T8 StarDrive™ screwdriver shaft onto the Screwdriver Handle, Universal (03.133.150). Insert the screwdriver (314.467) tip into the recess of the desired screw to retrieve it from the screw caddy. Advance the screw into the screw hole until it is fully seated in the plate. Cortex screws can also be inserted using power.

■ Optional Technique:

If inserting screws into very dense bone, use taps after drilling to facilitate screw insertion.

*Additionally available instruments.

Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws

Screw Hole Preparation

Instruments – Nominal Angle Drilling

03.133.008	Threaded Drill Guide 2.0 mm, f/Screw 2.7 mm, f/VA and LCP™ (Figure 9)
03.211.004	VA LCP Drill Sleeve 2.7, coaxial, f/Drill Bits Ø 2.0 mm (Figure 10)
03.133.100*	Drill Bit Ø 2.0 mm, QC, L 110 mm, Calibration 30 mm
314.467	Screwdriver Shaft, StarDrive™ T8, self-holding
314.453	Screwdriver Shaft StarDrive™ 2.4, short, self-holding, f/Quick Coupling
03.211.002†	VA LCP Drill Sleeve 2.7, f/ Drill Bits Ø 2.0 mm
310.534†‡	Drill Bit Ø 2.0 mm, w/marking, L 110/85 mm, 2-flute, f/Quick Coupl.
323.062†‡	Drill Bit Ø 2.0 mm, w/double marking, L 140/115 mm, 3-flute, f/Quick Coupl.

Nominal angle drilling

Screw the threaded guide 2.0 mm into the screw hole, perpendicular to the plate, until fully seated (Figure 9). To ease threading, engage the drill guide with the screw hole by making a quarter turn counterclockwise until the starting thread of the drill guide engage the threads of the screw hole. Turn clockwise once the threads are fully engaged.

The T8 StarDrive screwdriver shaft may be used to help insert the threaded drill guide into the screw holes. Insert the screwdriver shaft into the back of the threaded drill guide and rotate.

Figure 9

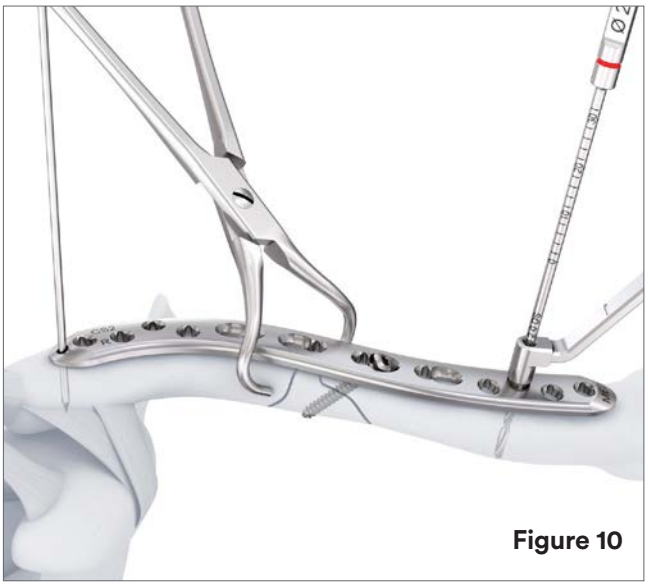


Figure 10

*For use with 03.133.008 or 03.211.004. Depth marks on drill bit do not correspond to drill guide 03.211.004.

†Additionally available instruments.

‡For use with 03.211.002. Mates with scale on 03.211.002.

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws continued

The nominal angle of each screw hole is determined by the plate design. Cortex screw heads will not be flush with the plate when inserted in a locking hole.
To reduce the screw head protrusion, a low-profile Metaphyseal screw may be used at a nominal angle.

Use the drill bit Ø 2.0 mm to drill to the desired depth. Drill bit (03.133.100) is calibrated so that depth measurements can be read directly from the drill bit shaft when used with the corresponding drill guide (03.133.008) (Figure 9).

▲ Precaution:

Nominal screw angle is determined by plate design and screw length. If the plate is contoured and/or a screw longer than 40 mm is selected, take care to ensure that screws do not collide with one another. The use of image intensification is recommended.

■ Note:

Irrigate and apply suction for removal of debris potentially generated during implantation and to avoid heat generation during drilling.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws continued

Instruments – Variable Angle Drilling (VA locking screws only)

03.133.007	VA Drill Guide, 2.7 mm
03.133.100*	Drill Bit Ø 2.0 mm, QC, L 110 mm, Calibration 30 mm
03.211.002†	VA LCP Drill Sleeve 2.7, f/ Drill Bits Ø 2.0 mm (VA side)
310.534†‡	Drill Bit Ø 2.0 mm, w/marking, L 110/85 mm, 2-flute, f/Quick Coupl.
323.062†‡	Drill Bit Ø 2.0 mm, w/double marking, L 140/115 mm, 3-flute, f/Quick Coupl.

Variable angle drilling (VA locking screws only)

Insert the desired VA drill guide into the VA locking screw hole. The VA drill guide features a VA cone on one side and a VA spherical tip on the other side.

When using the cone end of the drill guide, press firmly to ensure the drill guide tip keys securely into the cloverleaf portion of the VA locking screw hole. The notches on top of the cone are visual markers for the drill guide tip orientation. The cone will provide +/-15° of angulation.

When using the spherical tip end for freehand drilling, gently press the instrument into the VA hole. The lip portion of the spherical tip end engages with the VA locking hole to provide tactile feedback of the angulation. Continue to provide light pressure while holding the drill guide at the desired angle. The spherical tip end of the drill guide provides freedom to choose angulation. To ensure 15° angulation, use the cone end of the Variable Angle Drill Guide.

■ Reminder:

Metaphyseal screws can only be inserted in VA locking holes at the nominal angle.

*For use with 03.133.007. Depth marks on drill bit do not indicate screw length in cone drill guide.

†Additionally available instruments.

‡For use with 03.211.002. Mates with scale on 03.211.002.

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws continued

▲ Precaution:

Verify the drill bit angle under image intensification to ensure the desired angle has been achieved. Drilling consecutive screw holes off-axis can cause screws to collide.

■ Note:

Irrigate and apply suction for removal of debris potentially generated during implantation and to avoid heat generation during drilling.

▲ WARNING:

Avoid penetration of the vital neurovascular structures that lie posterior to the clavicle. Perforation of these structures with any instrument or fixation device can lead to major complications including death.

Hole Depth Measurement

Instruments	
03.111.005	Depth Gauge f/Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm
03.133.080	Depth Gauge 2.7/3.5 mm, 0 to 60 mm

See Hole Depth Measurement section under step "9. Screw Insertion – 2.7 mm Cortex Screws continued" for instructions on how to measure screw hole depth.

■ Note:

If using the depth gauge 2.7/3.5 mm (03.133.080) for 2.7 mm VA locking screws, subtract 2 mm from the indicated length on the depth gauge to obtain the correct screw length. The depth gauge for 2.0–2.7 mm screws (03.111.005) does not require subtraction from the reading.

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws continued

Screw Insertion

Instruments	
03.133.150	Screwdriver Handle, Universal
03.110.002	Torque Limiter, 1.2 Nm, w/AO/ASIF Quick Coupling
314.467	Screwdriver Shaft, StarDrive™ T8, self-holding
03.111.906*	Tap f/LCP™ Locking Screws Ø 2.7 mm, L 100/33 mm

Instruments for shorter screwdriver construct with torque limiting attachment	
03.110.005	Handle f/Torque Limiters, 0.4/0.8/1.2 Nm
03.110.002	Torque Limiter, 1.2 Nm, w/AO/ASIF Quick Coupling
314.453	Screwdriver Shaft StarDrive™ 2.4, short, self-holding, f/Quick Coupling

To manually insert a VA locking screw, attach the torque limiter onto the universal screwdriver handle. Insert the screwdriver shaft tip into the recess of the desired screw to retrieve it from the screw caddy. Advance the screw into the screw hole.

▲ Precaution:

Nominal screw angle is determined by plate design and screw length. If the plate is contoured and/or a screw longer than 40 mm is selected, take care to ensure that screws do not collide with one another. The use of image intensification is recommended.

*Additionally available instruments.

10. Screw Insertion – 2.7 mm VA Locking Screws and Metaphyseal Screws continued

Screw Insertion continued

Advance the screw and lock it in the plate. The TLA will provide an audible click once torque value is reached indicating that the screw is seated and locked.

To insert under power, use the T8 StarDrive screwdriver shaft attached to the 1.2 Nm TLA. Confirm screw position and length prior to final tightening. Final tightening must be done manually or at a low speed using the 1.2 Nm TLA.

■ Optional Technique:

If inserting screws into very dense bone, use taps after drilling to facilitate screw insertion.

■ Note:

VA locking screws will not be flush with the plate unless placed at a nominal angle.

▲ Precautions:

- Always use a 1.2 Nm torque limiting attachment (TLA) when inserting VA locking screws.
- Do not lock screws using power tools without the 1.2 Nm TLA or at high speeds as this may damage the screwdriver and cause the screw head to strip, making it difficult to remove the implant.

Soft Tissue Attachment (Optional)

11. Soft Tissue Attachment (optional)

Lateral plates have suture holes on the lateral and anterior aspects of the plate to reattach ruptured ligaments or muscles if necessary.

Pass suture through the holes on the anterior side to attach the anterior part of the deltoid. Pass suture through the holes on the lateral side to attach the superior acromioclavicular ligament or other soft tissue structures. For added stability use multiple suture holes.

Taper point suture needles sized 26 mm ½ C radius are recommended. Search Ethicon Wound Closure Resource Center for applicable suture options.

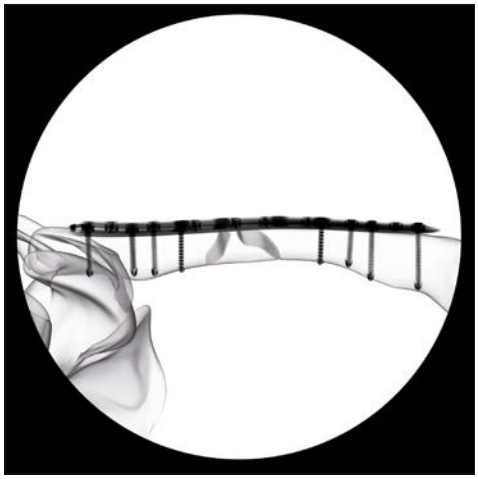
Notes:

- Use suture holes to reattach deltoid and accomplish deltoid stabilization. For added stability use multiple suture holes.
- The suture holes have an undercut to allow for suture needle passage. However, depending on the individual patient's anatomy, the undercut may be blocked and no needle passage possible. In this case, insert the suture through the suture holes before starting with final plate fixation (see section "Plate Insertion and Temporary Fixation").

Reduction and Fixation Confirmation

12. Reduction and Fixation Confirmation

Carefully assess the final reduction and fixation by both direct visualization and image intensification. Inspect the construct by rechecking each screw before closing to verify that the screws are secure. AP and additional views, using fluoroscopic visualization, can be used to confirm reduction and appropriate positioning of plate and screws. Confirm full range of motion of the shoulder and stability of the fixation.



■ Note:

VA locking screw will not be flush with the plate unless placed at a nominal angle. Cortex screw heads will not be flush with the plate when inserted into VA locking holes.

Surgical Closure

13. Surgical Closure

Thoroughly irrigate the wound prior to closure. A careful layered closure should be performed. The trapezial-deltoid fascia can often be approximated over the plate. The platysma and the subcutaneous tissue should be closed as separate layers.

Implant Removal (Optional)

Implant Removal (optional)

Instruments	
03.133.150	Screwdriver Handle, Universal
314.467	Screwdriver Shaft, StarDrive™ T8, self-holding

Unlock all screws from the plate, then remove the screws completely from the bone. This prevents simultaneous rotation of the plate when unlocking the last locking screw.

If the screws cannot be removed with the screwdriver, insert the conical extraction screw with left-handed thread into the screw head using the handle with quick coupling, and loosen the locking screw by turning it counterclockwise.

For additional instructions on screw removal consult the Operace Technique Guide.

▲ Precautions:

- Do not use the torque limiting attachment for screw removal.
- The VA LCP Clavicle Plates 2.7 are designed for patients where the growth plates have fused or will not be crossed. The use of the clavicle plates in patients where the growth plates have not fused or will be crossed may result in premature closure of the physis and bone growth inhibition and therefore plates must be removed upon fracture healing.

Implants

VA LCP Clavicle Plates 2.7*

Stainless Steel	Titanium	Plate Type	Plate Size	Left/ Right
02.112.610	04.112.610	Lateral	CS1	Left
02.112.611	04.112.611	Lateral	CS1	Right
02.112.612	04.112.612	Lateral	CS2	Left
02.112.613	04.112.613	Lateral	CS2	Right (shown)
02.112.614	04.112.614	Lateral	CS3	Left
02.112.615	04.112.615	Lateral	CS3	Right
02.112.620	04.112.620	Shaft	CS1	Left
02.112.621	04.112.621	Shaft	CS1	Right
02.112.622	04.112.622	Shaft	CS2	Left
02.112.623	04.112.623	Shaft	CS2	Right (shown)
02.112.624	04.112.624	Shaft	CS3	Left
02.112.625	04.112.625	Shaft	CS3	Right
02.112.630	04.112.630	Medial	N/A	Left
02.112.631	04.112.631	Medial	N/A	Right (shown)
02.112.712S†	04.112.712S†	Shaft	XL	Left
02.112.713S†	04.112.713S†	Shaft	XL	Right (shown)

Lateral Plate

Shaft Plate

Medial Plate


Shaft XL Plate

*Implants available non-sterile and sterile packed. Add “S” to the article number to order sterile products.

†Available sterile only.

2.7 mm Variable Angle Locking Screws*

02.211.010– 02.211.040	VA Locking Screw StarDrive™ Ø 2.7 mm, self-tapping, Stainless steel Available in 10 mm–40 mm lengths, in 2 mm increments
04.211.010– 04.211.040	VA Locking Screw StarDrive™ Ø 2.7 mm, self-tapping, Titanium alloy Available in 10 mm–40 mm lengths, in 2 mm increments

For use in VA locking holes and the threaded portion of VA Combi holes.

2.7 mm Cortex Screws*

202.870– 202.900	Cortex Screw StarDrive™ Ø 2.7 mm, self-tapping, Stainless steel Available in 10 mm–40 mm lengths, in 2 mm increments
402.870– 402.900	Cortex Screw StarDrive™ Ø 2.7 mm, self-tapping, Titanium alloy Available in 10 mm–40 mm lengths, in 2 mm increments

For use in the non-threaded portion of VA Combi screw holes. If used in VA locking holes the screw head will not sit flush with the plate surface.

2.7 mm Metaphyseal Screws*

02.118.510– 02.118.540	Low Profile Metaphyseal Compression Screw, StarDrive™ Ø 2.7 mm, self-tapping, Stainless Steel Available in 10 mm–40 mm lengths, in 2 mm increments
04.118.510– 04.118.540	Low Profile Metaphyseal Compression Screw, StarDrive™ Ø 2.7 mm, self-tapping, Titanium alloy Available in 10 mm–40 mm lengths, in 2 mm increments

For use in VA locking holes and the threaded portion of VA Combi holes at the nominal angle. They cannot be used in the non-threaded portion of VA Combi holes.

*Screws available non-sterile and sterile packed.
Add “S” or “TS” to the article number to order sterile products.

Templates

VA LCP Clavicle Plates 2.7*

Stainless Steel	Plate Type	Plate Size	Left/Right
03.112.610	Lateral	CS1	Left
03.112.611	Lateral	CS1	Right
03.112.612	Lateral	CS2	Left
03.112.613	Lateral	CS2	Right (shown)
03.112.614	Lateral	CS3	Left
03.112.615	Lateral	CS3	Right
03.112.620	Shaft	CS1	Left
03.112.621	Shaft	CS1	Right
03.112.622	Shaft	CS2	Left
03.112.623	Shaft	CS2	Right (shown)
03.112.624	Shaft	CS3	Left
03.112.625	Shaft	CS3	Right
03.112.630	Medial	N/A	Left
03.112.631	Medial	N/A	Right (shown)
03.112.712	Shaft	XL	Left
03.112.713	Shaft	XL	Right (shown)

Lateral Template

Shaft Template

Medial Template

Shaft XL Template

*Templates available non-sterile only.

Instruments

03.110.002	Torque Limiter, 1.2 Nm, w/AO/ASIF Quick Coupling	
03.110.005	Handle f/Torque Limiters, 0.4/0.8/1.2 Nm	
03.111.005	Depth Gauge f/Screws Ø 2.0 to 2.7 mm, measuring range up to 40 mm	
03.133.005	Neutral Sleeve Adapter 2.7 mm, f/Non-Locking Drill Guide 2.7 mm	
03.133.006	Non-Locking Drill Guide, 2.7 mm	
03.133.007	VA Drill Guide, 2.7 mm	
03.133.008	Threaded Drill Guide 2.0 mm, f/Screw 2.7 mm, f/VA and LCP™	
03.133.080	Depth Gauge 2.7/3.5 mm, 0 to 60 mm	

03.133.100	Drill Bit Ø 2.0 mm, QC, L 110 mm, Calibration 30 mm	
03.133.101	Drill Bit Ø 2.0 mm, QC, L 140 mm, Calibration 60 mm	
03.133.150	Screwdriver Handle, Universal	
03.133.200	Bending Iron f/Plates, closed, f/Plates 2.7/3.5 mm	
03.133.201	Bending Iron f/Plates, open, f/Plates 2.7/3.5 mm	
03.211.004	VA LCP Drill Sleeve 2.7, coaxial, f/Drill Bits Ø 2.0 mm	
03.211.410.01	Compression Wire Ø 1.6 mm, L 150 mm, thread length 10 mm	
03.211.415.01	Compression Wire Ø 1.6 mm, L 150 mm, thread length 15 mm	

292.160.01	Kirschner Wire Ø 1.6 mm, w/trocar tip, L 150 mm	
292.200.01	Kirschner Wire Ø 2.0 mm, w/trocar tip, L 150 mm	
314.467	Screwdriver Shaft, StarDrive™ T8, self-holding	
314.453	Screwdriver Shaft StarDrive™ 2.4, short, self-holding, f/Quick Coupling	
329.291	Bending Pliers f/Clavicular Plates, L 227 mm	

Also Available

03.111.906	Tap f/LCP™ Locking Screws Ø 2.7 mm, L 100/33 mm	
03.211.002	VA LCP Drill Sleeve 2.7, f/Drill Bits Ø 2.0 mm	
310.534	Drill Bit Ø 2.0 mm, w/marking, L 110/85 mm, 2-flute, f/Quick Coupl.	
311.260	Tap f/Cortex Screws, Ø 2.7 mm, L 100/33 mm	
323.062	Drill Bit Ø 2.0 mm, w/double marking, L 140/115 mm, 3-flute, f/Quick Coupl.	
323.260	Universal Drill Guide 2.7	

MRI Safety Information

Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119

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 138 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

Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 12.1 °C (1.5 T) and 6.0 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

▲ 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.

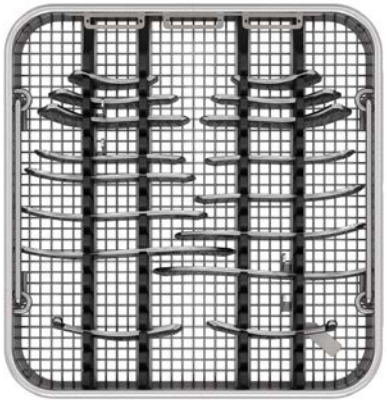
Instruments (including templates)

MR Safety Information is not applicable to instruments. Instruments are not intended to be used in an MR environment.

Cases & Trays

Stainless Steel Case Options

68.033.114	NTOC Cassette for Universal Small Fragment System
68.033.116	NTOC Cassette for USFS Reduction Instruments
68.033.119	NTOC Cassette for USFS Screw Racks 68.100.101 & 68.100.102
68.033.121	NTOC Cassette for Trial Implants, ½-size
68.100.101	NTOC Cassette for Screw Rack 2.7
68.133.007	NTOC Cassette for USFS VA LCP Clavicle Instruments

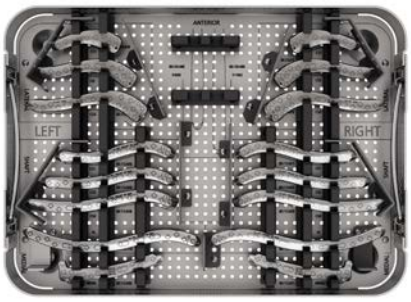


68.033.121

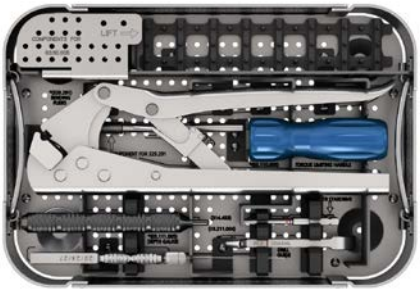
68.133.007

Aluminum Case Options

60.133.000	Outer Case Lid, 3/3 Width
60.133.003	Outer Case, 3 Level High, 3/3 Width
60.133.100	Universal Small Fragment Tray, f/Insertion Instruments
60.133.130	Universal Small Fragment Tray, f/Reduction Instruments
60.133.145	Universal Small Fragment Tray, f/ VA LCP Clavicle Anatomy Implants
60.133.147	Universal Small Fragment Tray, f/ VA LCP Clavicle Templates
60.133.150	Universal Small Fragment Screw Rack
60.133.190	Universal Small Fragment Tray, f/ VA LCP Clavicle Instruments



60.133.147



60.133.190

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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