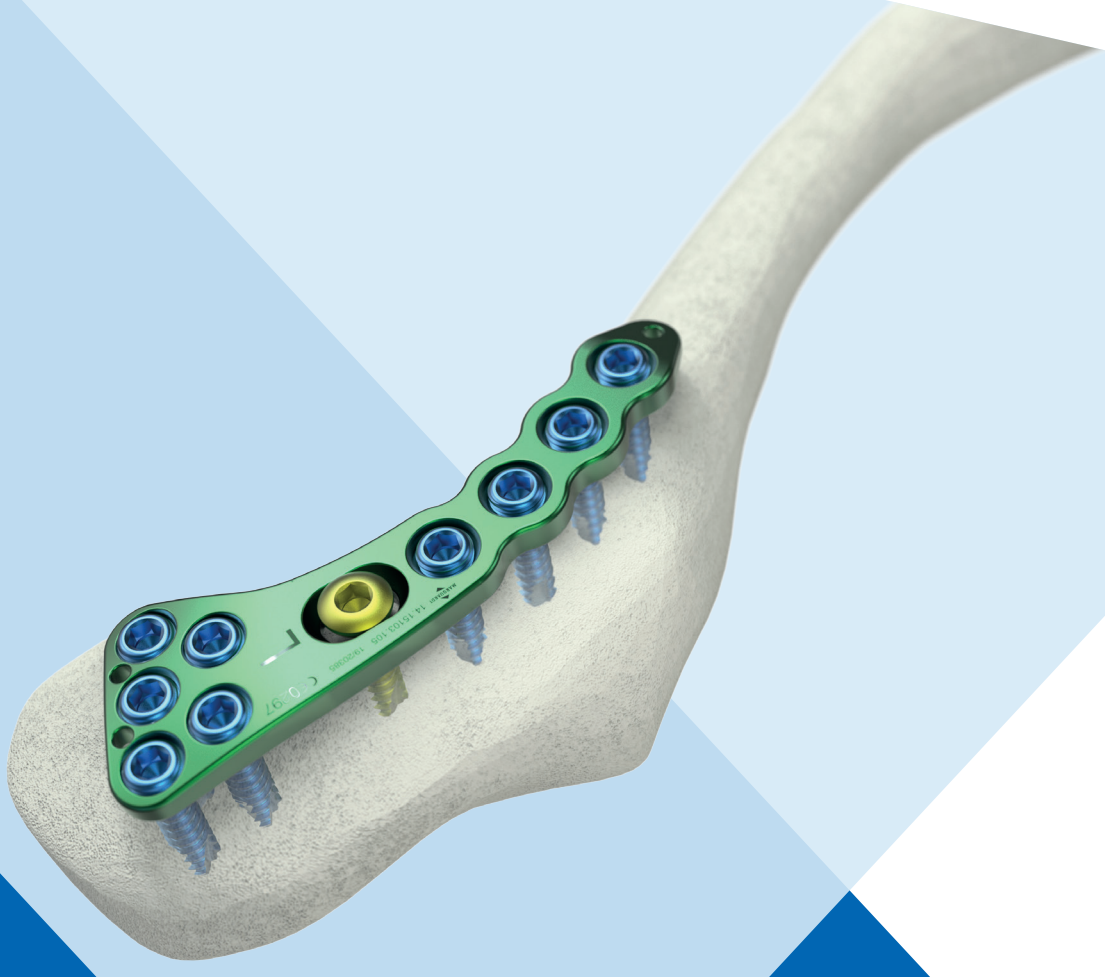
MARQUARDT
Medizintechnik



WINSTA-C

Clavicle Plating System

Clinical Advisor

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North Middlesex University Hospital NHS Trust

Table of Contents

Introduction	Implant Specifications	2
	Indications	3
Surgical Technique	Imaging	4
	Positioning	4
	Access	4
	Reduction and Positioning	5
	Fixation with S-Shaped and J-Shaped Plates	7
	Fixation with Lateral Clavicle Plates	9
	Fixation with Hook Plates	11
	Post-OP Protocol	12
	Implant Removal	12
Product Information	Implants	13
	Instruments	16
	Templates	17
	MRI Safety Information	18

Note:

The surgical technique outlined below reflects the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.

Introduction

Produktspezifikation

The anatomical variance of the clavicle is very high, therefore the Marquardt ***WINSTA-C Clavicle Plating System*** offers plates in three different lengths and three different curvatures. The skid-shaped plate tips allow percutaneous insertion, while waists enable good modeling of the plates.
The plate holes are filled with cortical screws, locking screws or non-locking screws, multi- or monoaxial. The screw heads are seated flush in the plate, reducing the risk of soft tissue irritation.

WINSTA-C
Clavicle Plate, S-Shaped
Minimum Bend

MED and LAT labeling
for correct medial and lateral placement

Lateral laser marking
with curvature typ

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

WINSTA-C
Clavicle Plate, S-Shaped
Medium Bend

Lateral laser marking
with curvature typ

MED and LAT labeling
for correct medial and lateral placement

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

WINSTA-C
Clavicle Plate, S-Shaped
Maximum Bend

Lateral laser marking
with curvature typ

MED and LAT labeling
for correct medial and lateral placement

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

WINSTA-C
Clavicle Plate , J-Shaped

J-Plate shaped
especially for the transition zone between middle and lateral part of the clavicle

MED and LAT labeling
for correct medial and lateral placement

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

WINSTA-C
Clavicle Plate, lateral

Plate shape
especially for the lateral part of the clavicle

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

WINSTA-C
Clavicle Hook Plate

3 different hook depths
12, 15 und 18 mm

Hook angle 100°

Screw holes suitable for:
- Cortical Screws
- Locking Cortical Screws
- Multiaxial Locking Cortical Screws

Indications

Clavicle Plate S- and J-shaped:
- Fixation of fractures and mal-unions of the clavicle shaft.

Lateral Clavicle Plate:
- Fixation of fractures and mal-unions of the lateral clavicle.

Clavicle hook plates:
- Fractures of the lateral clavicle.
- Acromioclavicular joint separation, type: Rockwood III, IV or V and Tossy III

Surgical Technique

Imaging

- Radiographic diagnostic with x-ray in AP and 45° plane.
- If necessary additional diagnostic with CT or MRI.

Positioning

- The patient is placed in the beach chair position.
- A standard operating table with head up positioning may be used.
- A longitudinal sand bag placed just medial to the affected scapula, will assist in reduction.
- Before draping, check that adequate x-ray imaging is possible and that no metal is blocking the view of the clavicle.
- The patient's head is turned away from the operative site to improve access to the clavicle.
- The affected arm should be toweled and kept free to enable intraoperative mobilization.
- The operative site is disinfected and toweled.

Access

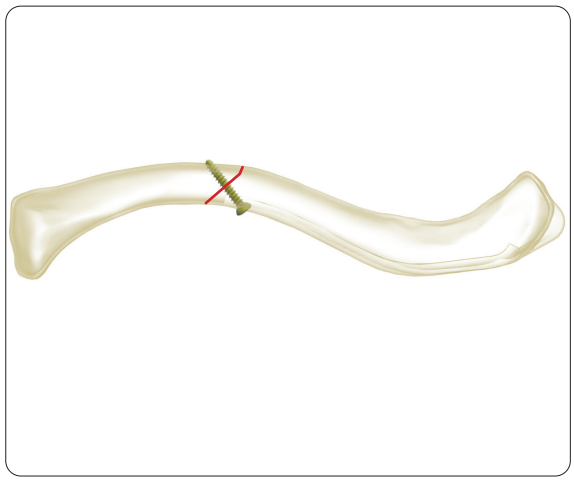
- A transverse incision is recommended for accessing the clavicle.
- A horizontal incision is made from medial to lateral and centered over the fracture site.
- When using a lateral plate, the incision is centered over the fracture site and ending lateral to the AC joint.
- When using a minimal invasive approach, locking drill guides can be used to insert the plate from medial to lateral.

- As an alternative a vertical incision, which is placed over the fracture site and along Langer´s lines, is possible.

Please note:

- Branches of the Supraclavicular nerves (usually 2) should be identified and protected during subcutaneous dissection.
- During subperiosteal preparation of the platysma muscle the fiber orientation should be considered.
- Small individual bone fragments should not be removed from their periosteum to protect their blood supply.

Reduction and Positioning



Instruments

REF 14.40060.025	*Drill Bit Ø 2.5 mm*
REF 03.20010.035	*Drill Bit Ø 3.5 mm*
REF 03.20060.025	*Double Drill Guide 3.5 / 2.5*

- Fracture ends are exposed and the fracture is reduced
- After restoration of the anatomical position, temporary fixation can be achieved with K-wires.
- Prior to the application of the plate, lag screw fixation perpendicular to the fracture line is often helpful to stabilize and compress the main fragments.
- There are Ø 3.5 mm and Ø 2.5 mm drills and a double drill guide to facilitate this.
- The clavicle plate can then be placed
- K-wires can be used for temporary fixation of the plate through the provided K-wire holes.

Please note:

If plate contouring is necessary, the following aspects have to be considered:

Instruments

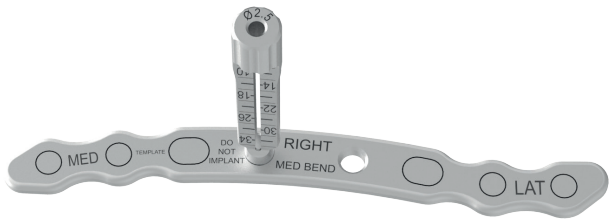
REF 03.20110.035	Bending Iron for Plates 2.7 to 3.5, right
REF 03.20110.135	Bending Iron for Plates 2.7 to 3.5, left

- For contouring of the plates the bending irons may be used.
- To avoid weakening of the implant material the plates should be bent only once and only in one direction.
- Bending of the implant across a screw hole should be avoided.
- To protect the threads of the plate during bending, drill sleeves should be inserted into the threads.

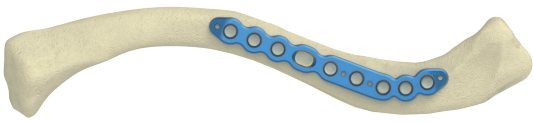
Clavicle Plate S-Shaped

- The plate is placed on the middle part of the clavicle with its center located over the fracture site.
- The required plate size and the appropriate plate bend type can be determined using the templates. The templates are available in all variations. The top and bottom side of the template can be used for the left and right clavicle. By using the templates, it is possible to check which plate size and bend type corresponds to the anatomy and should be used.

Please note:



- The drill guide can be attached to all templates for better handling.



Clavicle Plate J-Shaped

- The J-shaped clavicle plate is placed in the transition zone between the middle and lateral parts of the clavicle.
- The plate should be placed so that the strengthened part of the plate is located over the fracture site.
- The plate positioning can also be determined with the help of a template.

Lateral Clavicle Plate

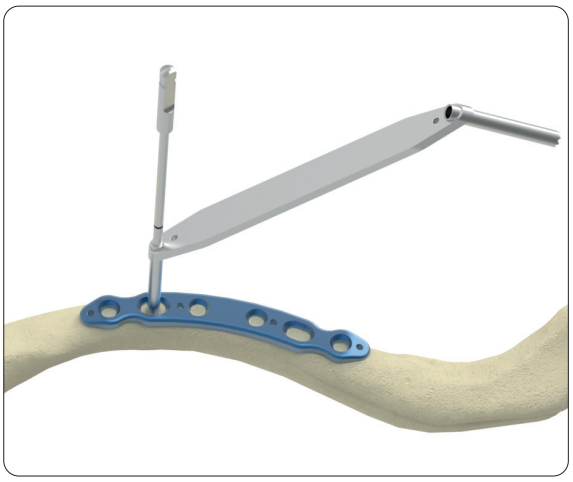
- The fracture is reduced and the AC joint is identified. It may be helpful to mark this with a needle.
- The required plate size and the plate positioning can be determined with the help of templates.
- The plate is placed medial but close to the AC joint so as to gain maximum purchase in the lateral fragment. Ideally the part which is between the oval hole and the lateral holes is located over the fracture site.
- The final plate position should be checked with x-ray control. Guide wires which can be placed in the lateral K-wire holes of the plate can help to verify that the lateral screws do not penetrate into the AC joint.
- Multiaxial screws can help to prevent perforation of the joint space.

Fixation with Clavicle Plates S-Shaped and J-Shaped

Instruments

REF 14.40060.025 *Drill Bit Ø 2.5 mm*
REF 03.20060.025 *Double Drill Guide 3.5 / 2.5*

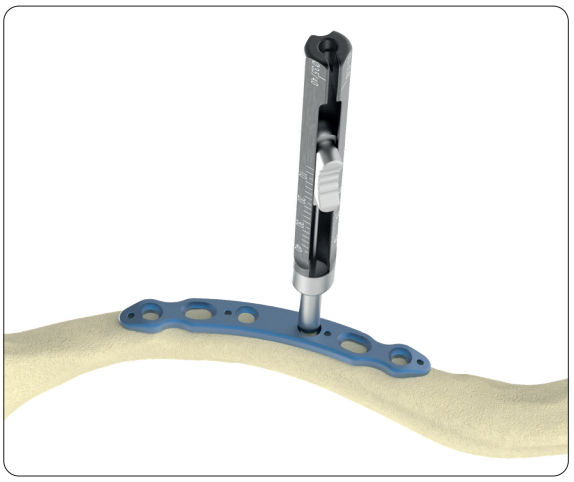
- It is recommended to place a non-locking Ø 3.5 mm screw into the oval hole as a first step. Minor adjustment of the plate position is possible by loosening that screw and moving the plate around the oval hole.
- The pilot hole for Ø 3.5 mm screws is drilled with a Ø 2.5 mm drill bit and the double drill guide.



Instruments

REF 03.20100.040 *Length Determination Instruments for Screws up to 40 mm*

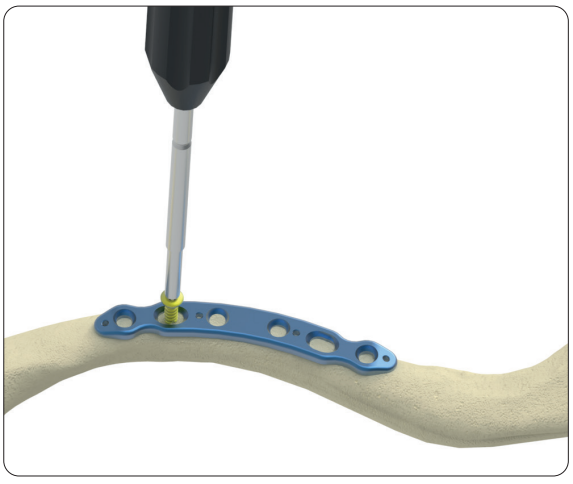
- The screw length is measured with the depth gauge.
- The hook of the measuring device is hooked into the far cortex and the appropriate screw length is given by the scale.
- The screws must be placed through both cortices in order to achieve bicortical fixation.

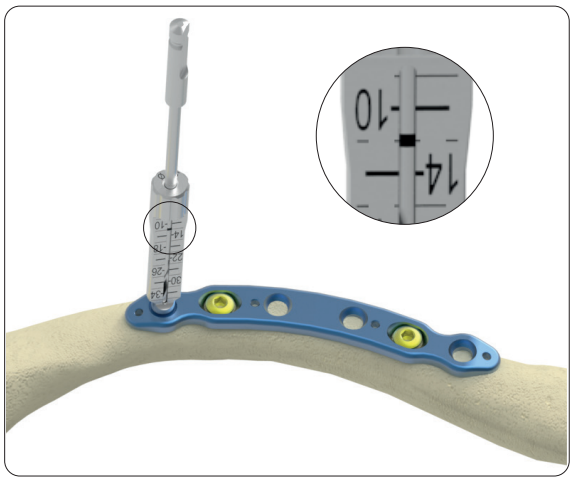


Instruments

REF 03.20040.030 *Screwdriver, hex 2.5 mm*

- An appropriate screw can be inserted by using the screwdriver.
- If the value of the measured screw is between sizes, the longer screw option should be chosen but its length and position must be checked with the image intensifier and further adjustment made if necessary.
- After placing screws into the oval holes medial and lateral to the fracture site, the remaining screw holes can be filled with either locking or non-locking screws.
- If the insertion of a non-locking lag screw through the plate is planned, it is important to remember that the non-locking screw(s) should always be placed prior to any locking screws.

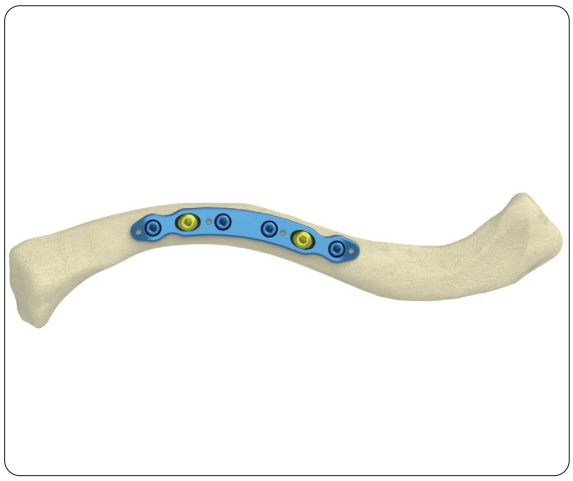




Instruments

REF 14.40060.047 *Drill Guide 2.5, calibrated*

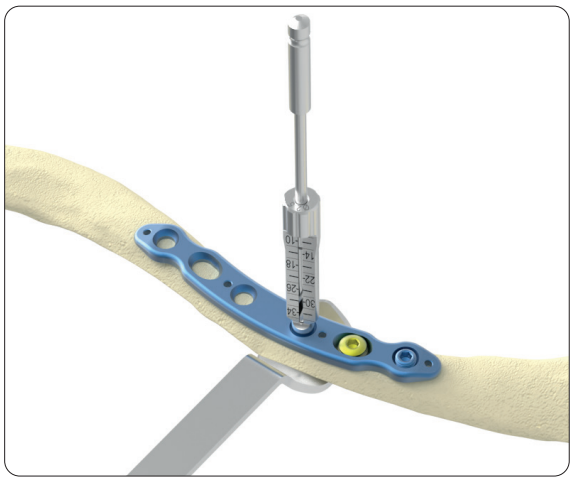
- In order to place Ø 3.5 mm locking screws into the circular holes, the scaled drill guide is screwed into the thread of the hole.
- Subsequently the pilot hole can be drilled and the screw length can be measured as described above.
- When using a scaled drill guide it is possible to read off the required screw length directly from the drill guide.



Instruments

REF 03.20040.325 *Torque Screwdriver, hex 2.5 mm*

- Final tightening of the locking screws should be done by hand using the torque-limiting screwdriver.
- As soon as all desired screws are placed into the corresponding screw holes, an intraoperative radiograph is recommended to check the implant positions and the anatomical reduction of the fracture and the lengths of the screws.



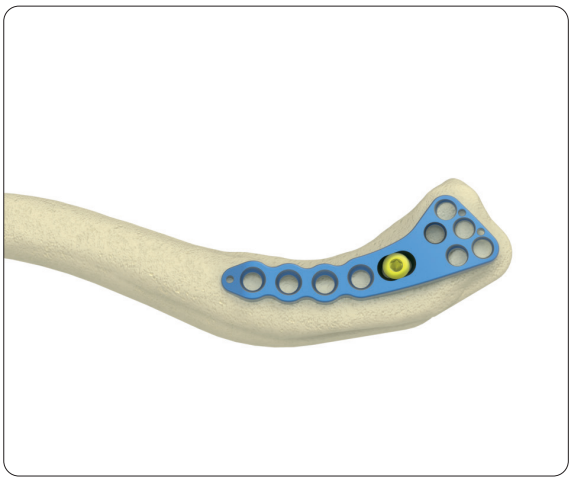
Instruments

REF 14.40060.010 *Clavicle Retractor*

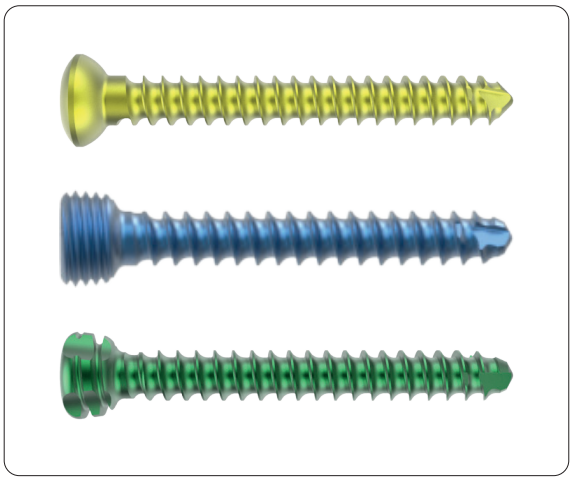
Please note:

- To avoid trauma to the subclavian artery and the brachial plexus, drilling should always be done with caution.
- The clavicle retractor (neurovascular protector) should be placed under the inferior cortex of the clavicle, to prevent over-penetration.

Fixation with Lateral Clavicle Plates



- To achieve initial stabilization it is recommended to place first two screws, one medial and one lateral to the fracture site.
- As described above, a Ø 3.5 mm non-locking cortical screw is placed into the oval hole of the plate.
- Locking or non-locking screws can be used in the other holes of the plate according to the procedure described before.



- There are three choices of self-tapping Ø 2.7 mm screws available to be used within the lateral screw holes:

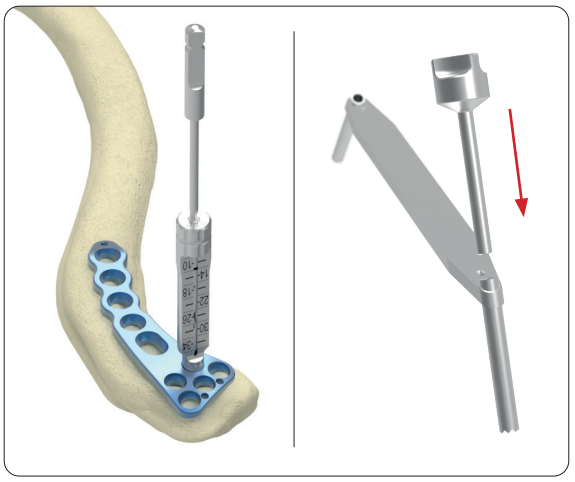
  Yellow: Non-locking cortical screws

  Blue: Locking cortical screws

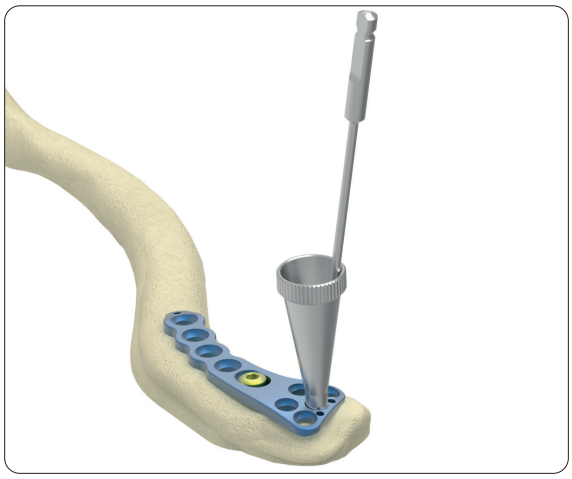
  Green: Multiaxial locking cortical screws (***ML***)

Instruments

REF 03.20060.025 *Double Drill Guide 3.5 / 2.5*
REF 10.20010.020 *Drill Bit Ø 2.0 mm*
REF 10.20060.047 *Drill Guide 2.0, calibrated*
REF 14.40060.030 *Drill Sleeve Insert 3.5 / 2.0*



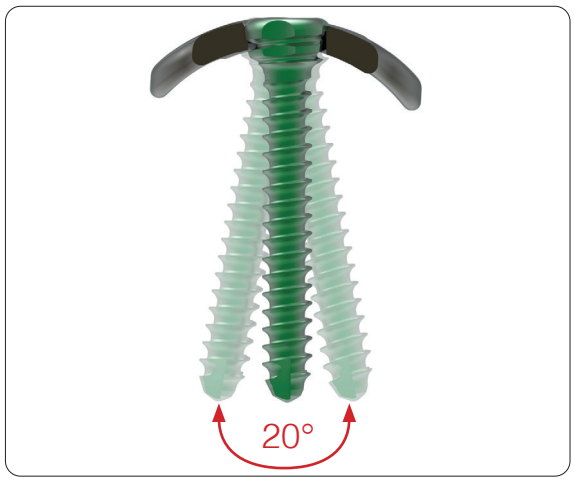
- To drill the hole for a locking Ø 2.7 mm cortical screw the locking drill sleeve is placed into the desired hole and screwed into the thread of the plate (left).
- A Ø 2.0 mm drill bit is used and precautions should be taken to avoid over-penetration of the inferior cortex of the clavicle.
- For non-locking Ø 2.7 mm cortical screws it is also possible to use the locking drill sleeve (left). Alternatively the reduction drill sleeve insert for Ø 2.0 mm drills can be placed into the double drill guide (right).



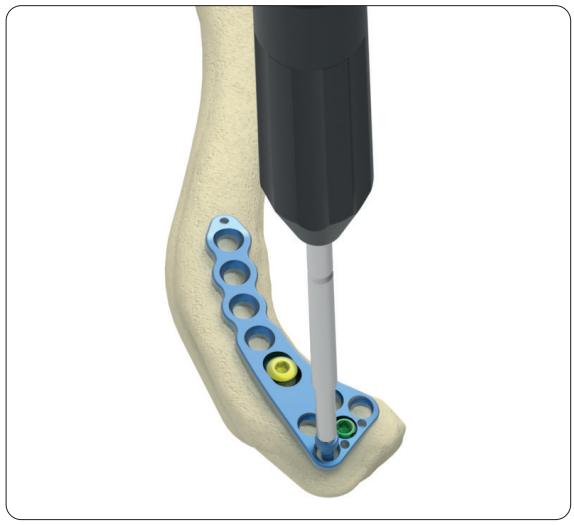
Instruments

REF 10.20010.020 *Drill Bit Ø 2.0 mm*
REF 10.20050.025 *ML Drill Guide 2.0*

- To ensure a proper and safe locking of the screw into the plate, the angulation of the screw should not be more than 20°.
- Drilling of the Ø 2.7 mm multiaxial screw holes is performed with the specific ML drill guide which is screwed into the desired plate hole.
- With the ML drill guide in place, it is possible to drill using the drill bit Ø 2.0 mm within 20° of the original screw axis.
- When using the ML drill guide it is necessary to ensure that the axis of drilling is chosen correctly and that the AC joint is not penetrated with the drill.



- Multiaxial Ø 2.7 mm screws can be used in order to reach certain bone fragments, if the defined screw axis is not sufficient.
- When using multiaxial locking screws, it is possible to place and lock the screw within a cone of 20° around the original screw axis.

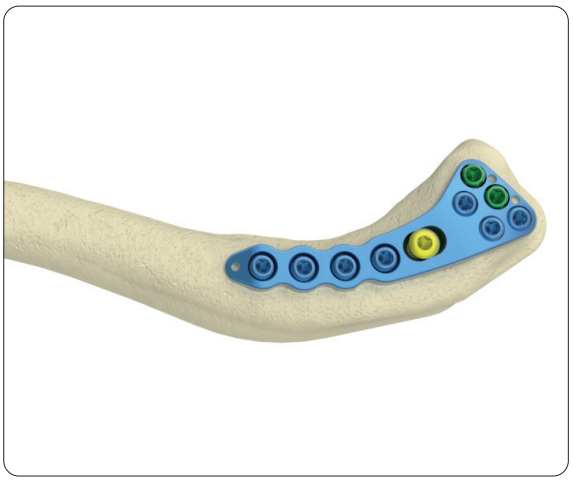


Instruments

REF 03.20040.030 *Screwdriver, hex 2.5 mm*
REF 03.20040.325 *Torque Screwdriver, hex 2.5 mm*

- The ML drill guide is removed, and the screw length is then determined as described above via the depth gauge.
- In the event that screws are positioned near the AC joint and the measured value is between two available screw lengths, choose the shorter one and then check the length and position with the aid of an X-ray and make any corrections as required.
- The insertion of the Ø 2.7 mm screws is done using the screwdriver.
- Final tightening of the locking screws should be done by using the torque-limiting screwdriver.

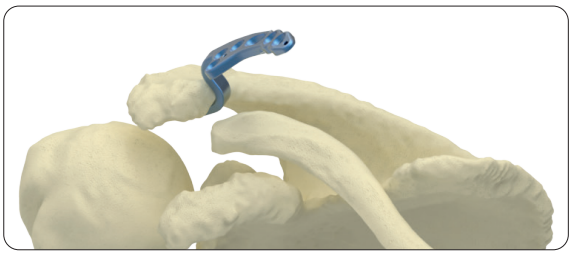
- As soon as all desired screws are placed into the corresponding screw holes an intraoperative radiograph should be performed to check the plate and screw positions and the anatomical reduction of the fracture.

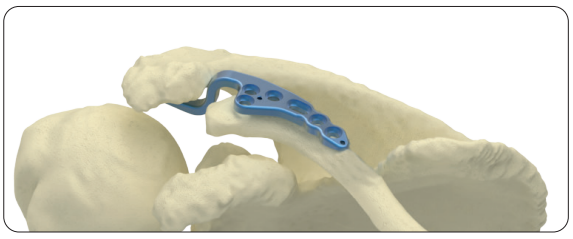


Fixation with Hook Plates

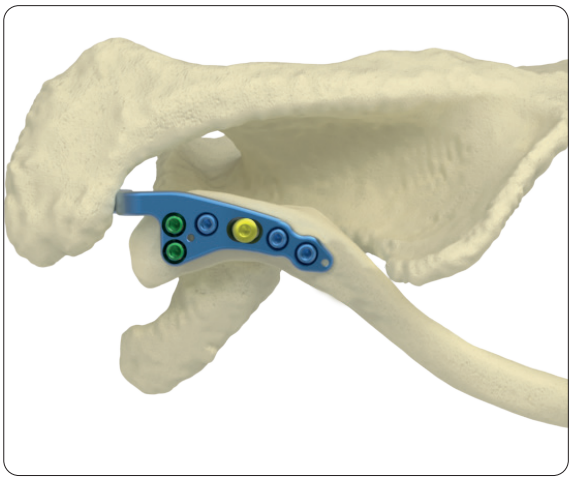
Access, Reduction and Positioning of the Clavicle Hook Plate

- The exposure of the delto trapezial fascia is performed via a transacromial incision; the lateral supraclavicular nerves must not be damaged in the process.
- Temporary fixing of the fracture can be performed with K-wires or reduction forceps.
- Afterwards the capsule of the acromioclavicular joint is identified.
- In order to enable positioning of the hook under the acromion, the insertion of the trapezius muscle must be detached from the medial edge of the acromion.
- The required plate size and the exact plate positioning can be determined with the help of templates.
- The hook can now be positioned under the acromion and the shaft of the plate can be positioned on the lateral clavicle.
- The clavicle hook plate can be temporarily fixed with K-wires.





- The oval hole of the plate is filled with a Ø 3.5 mm cortical screw according to the procedure described above.
- Locking or non-locking screws can also be placed in the shaft holes according to the procedure described above.
- For the lateral screw holes, non-locking, locking and multiaxial locking Ø 2.7 mm screws are available.



Post-OP Protocol

- Postoperative management will be determined by various factors such as fracture type, bone quality or age of the patient.
- Generally, passive movement only is recommended during the first four weeks.
- Heavy lifting, pushing or pulling must be avoided by the patient.
- Depending on the healing process the patient can start with supported active exercises from four to six weeks postoperatively.
- Depending on the stability of the fixation and after radiological assessment, it is possible to start with an active physical load increasement from the eighth week.

Implant Removal

Instruments

REF 03.20040.030 Screwdriver, hex 2.5 mm

- The removal of the implant takes place via one of the accesses described.
- When removing a plate located in the middle area of the clavicle, special care should be taken to avoid damaging any cutaneous nerves.
- After loosening and removal of all screws with the screwdriver, the plate can be removed.

Product Information

Implants

Clavicle Plate S-shaped

- Material: Ti6Al4V

Article Number * left	Article Number * right	Holes	Bend
14.15100.106	14.15100.006	6	min
14.15100.108	14.15100.008	8	min
14.15100.110	14.15100.010	10	min
14.15101.106	14.15101.006	6	med
14.15101.108	14.15101.008	8	med
14.15101.110	14.15101.010	10	med
14.15102.106	14.15102.006	6	max
14.15102.108	14.15102.008	8	max
14.15102.110	14.15102.010	10	max

left

right

Clavicle Plate J-shaped

- Material: Ti6Al4V

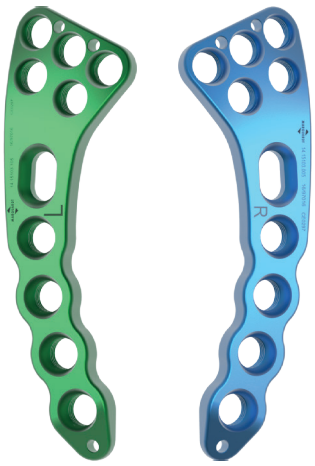
Article Number * left	Article Number * right	Holes
14.15100.109	14.15100.009	9

left

right

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

left right



Lateral Clavicle Plate

- Material: Ti6Al4V

Article Number * left	Article Number * right	Holes
14.15103.105	14.15103.005	5
14.15103.107	14.15103.007	7
14.15103.109	14.15103.009	9

left right

Clavicle Hook Plate

- Hook angle: 100°
- Hook depth: 12mm, 15mm, 18mm
- Material: Titan

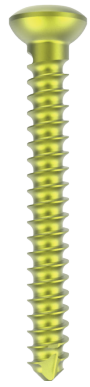
Article Number * left	Article Number * right	Holes	Depth in mm
14.15105.103	14.15105.003	3	12
14.15105.105	14.15105.005	5	12
14.15104.103	14.15104.003	3	15
14.15104.105	14.15104.005	5	15
14.15106.103	14.15106.003	3	18
14.15106.105	14.15106.005	5	18

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Article Number 3.5 mm	Article Number 2.7 mm	Length
03.03612.010	03.03527.010	10 mm
03.03612.012	03.03527.012	12 mm
03.03612.014	03.03527.014	14 mm
03.03612.016	03.03527.016	16 mm
03.03612.018	03.03527.018	18 mm
03.03612.020	03.03527.020	20 mm
03.03612.022		22 mm
03.03612.024		24 mm

Cortical Screw, self-tapping

	3.5 mm	2.7 mm
• Thread diameter:	3.5 mm	2.7 mm
• Core diameter:	2.4 mm	1.9 mm
• Head diameter:	6.0 mm	5.0 mm
• Hexagon socket:	2.5 mm	2.5 mm
• Material:	Ti6Al4V	



Article Number 3.5 mm	Article Number 2.7 mm	Length
03.05612.010	03.05527.010	10 mm
03.05612.012	03.05527.012	12 mm
03.05612.014	03.05527.014	14 mm
03.05612.016	03.05527.016	16 mm
03.05612.018	03.05527.018	18 mm
03.05612.020	03.05527.020	20 mm
03.05612.022		22 mm
03.05612.024		24 mm

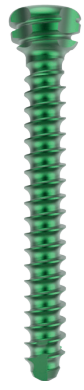
Locking Cortical Screw, self-tapping

	3.5 mm	2.7 mm
• Thread diameter:	3.5 mm	2.7 mm
• Core diameter:	2.4 mm	1.9 mm
• Head diameter:	4.75 mm	4.75 mm
• Hexagon socket:	2.5 mm	2.5 mm
• Material:	Ti6Al4V	

Article Number 2.7 mm	Length
03.03540.010	10 mm
03.03540.012	12 mm
03.03540.014	14 mm
03.03540.016	16 mm
03.03540.018	18 mm
03.03540.020	20 mm

ML Screw, self-tapping

	2.7 mm
• Thread diameter:	2.7 mm
• Core diameter:	1.9 mm
• Head diameter:	4,75 mm
• Hexagon socket:	2.5 mm
• Material:	Ti6Al4V



Instruments

11.90016.150 Kirschner Wire Ø 1.6 mm, trocar tip, L 150 mm, steel

10.20010.020 Drill Bit Ø 2.0 mm, 2-flute, AO Coupling, L 112 / 82 mm

14.40060.025 Drill Bit Ø 2.5 mm, 2-flute, AO Coupling, L 112 / 82 mm

03.20010.035 Drill Bit Ø 3.5 mm, 2-flute, AO Coupling, L 110 / 80 mm

10.20060.047 Drill Guide 2.0, calibrated

14.40060.047 Drill Guide 2.5, calibrated

14.40060.030 Drill Sleeve Insert 3.5 / 2.0

03.20060.025 Double Drill Guide 3.5 / 2.5

10.20050.025 ML Drill Guide 2.0

03.20100.040 Length Determination Instruments for Screws up to 40 mm

03.20040.030 Screwdriver, hex 2.5 mm, ball handle, L 200 / 85 mm

03.20040.325 Torque Screwdriver, hex 2.5 mm short

03.20080.006 Periosteal Elevator, curved blade, round edge, width 6 mm

03.20070.133 Reduction Forceps, toothed, ratchet lock, L 140 mm

02.20120.015 Screw Forceps, self-holding

03.20110.035 Bending Iron for Plates 2.7 to 3.5, right
03.20110.135 Bending Iron for Plates 2.7 to 3.5, left

14.40060.010 Clavicle Retractor

Templates

Clavicle Plate S-Shaped Templates

Article Number Left / Right	Holes	Bend
14.25100.006	6	min
14.25100.008	8	min
14.25100.010	10	min
14.25101.006	6	med
14.25101.008	8	med
14.25101.010	10	med
14.25102.006	6	max
14.25102.008	8	max
14.25102.010	10	max

Clavicle Plate J-Shaped Templates

Article Number Left / Right	Holes
14.25100.009	9

Lateral Clavicle Plate Templates

Article Number Left / Right	Holes
14.25103.005	5
14.25103.007	7
14.25103.009	9

Clavicle Hook Plate Templates

Article Number left	Article Number right	Holes	Depth in mm
14.25105.103	14.25105.003	3	12
14.25104.103	14.25104.003	3	15
14.25106.103	14.25106.003	3	18

MRI Safety Information

Non-clinical testing has demonstrated that the plates range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B_0)
- Spatial field gradient lower than or equal to
  - **1.5 T:** 23.45 T/m (2345 G/cm)
  - **3.0 T:** 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg.
  - Scan duration and wait time:

    1.5 T: 2 W/kg whole-body average SAR for **8min and 15s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **8min and 15s** if this limit is reached.

    3.0 T: 2 W/kg whole-body average SAR for **6min and 19s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **6min and 19s** if this limit is reached.
- The plates are expected to produce a maximum temperature rise of 8.5 °C at 1.5 T and 6.9 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.

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MARQUARDT
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