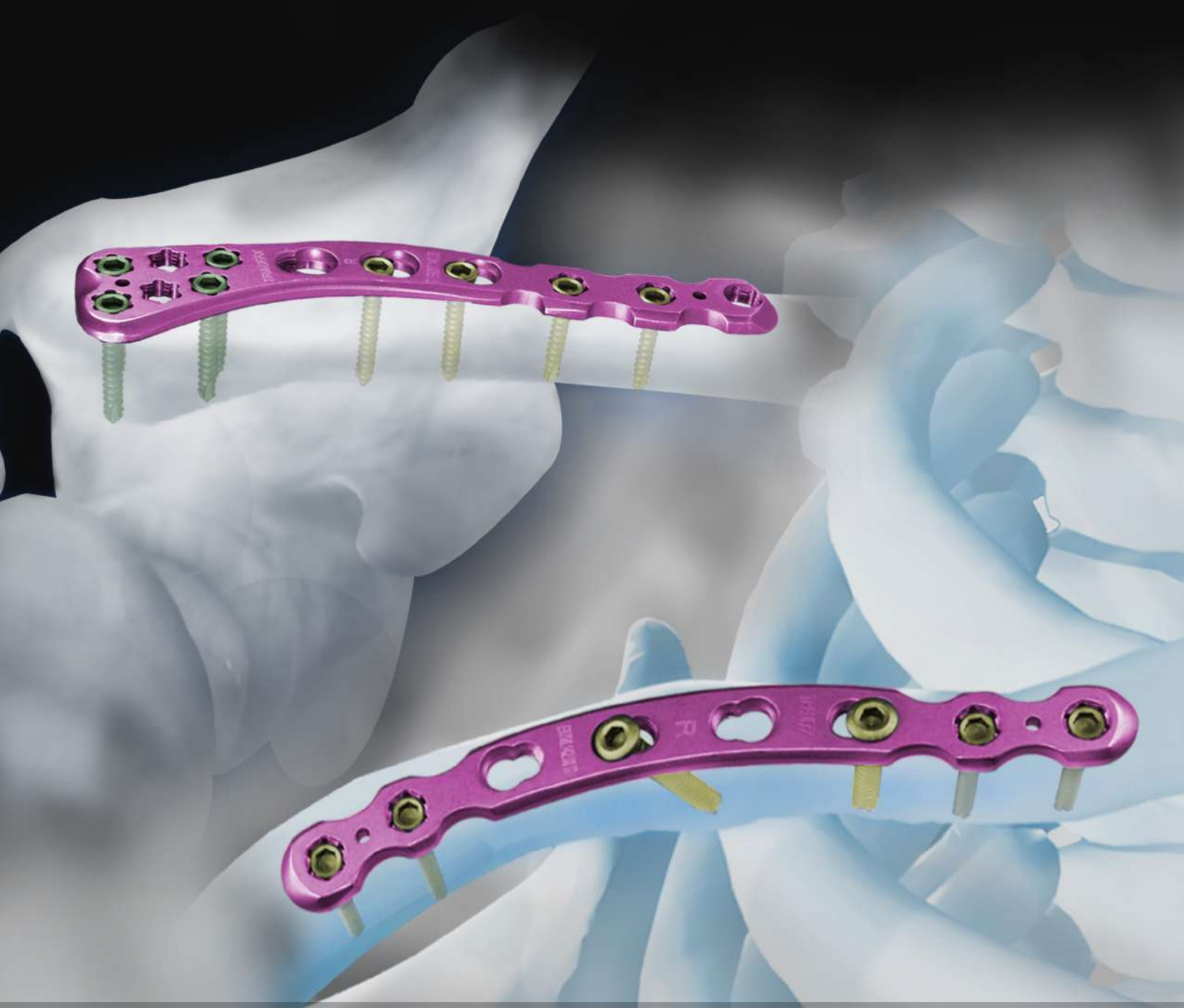
SURGICAL TECHNIQUE

ALP titanium superior anterior clavicle plate with lateral extension and ALP titanium superior anterior clavicle plate **CLAVILOCK**



TRAUFIX
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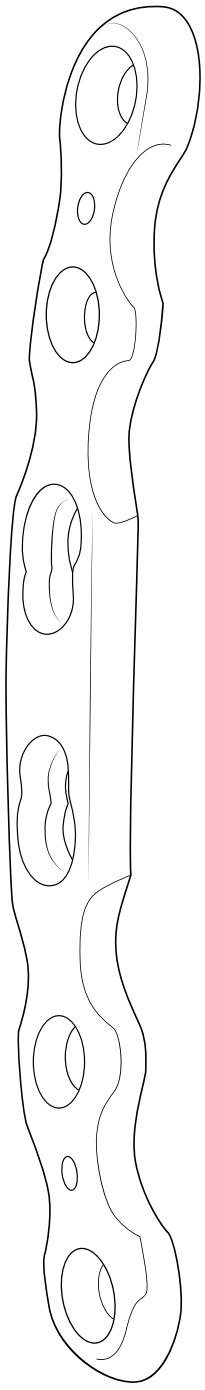
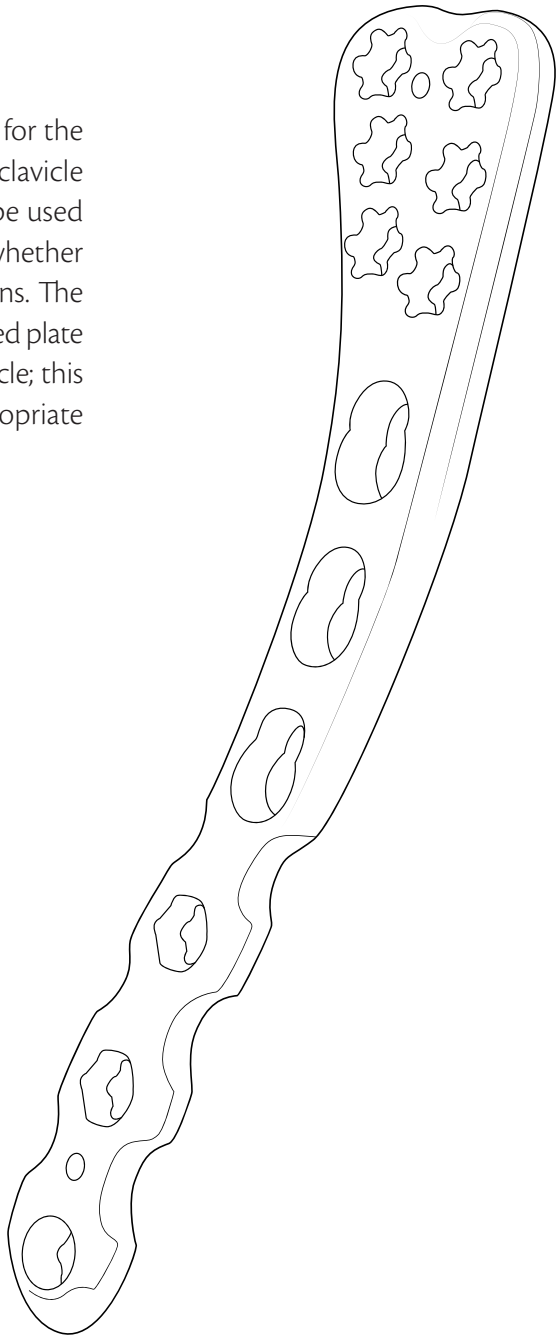


TECHNOLOGICAL ADVANTAGES

One of Traufix's goals is to provide comprehensive solutions for the care and treatment of clavicle fractures, which is why the clavicle osteosynthesis plate system offers great versatility that can be used by surgeons as a first resort in addressing such problems, whether complex and simple fractures, as well as faulty consolidations. The clavicle osteosynthesis plate system offers a set of pre-contoured plate solutions to fit the natural S anatomical contour of the clavicle; this gives specialists the opportunity to choose the most appropriate option depending on the type of patient.



DESCRIPTION OF THE PLATE

- SLeft and right plates are available in titanium alloy (Ti6Al4V ELI).
- Rounded profile shaft
- Plate system for superior anterior clavicle with lateral extension in sizes of 4, 5, and 6 holes.
- Plate system for superior anterior clavicle in sizes of 8, 9 and 10 holes.
- Combined holes for the use of standard screws or locking screws.

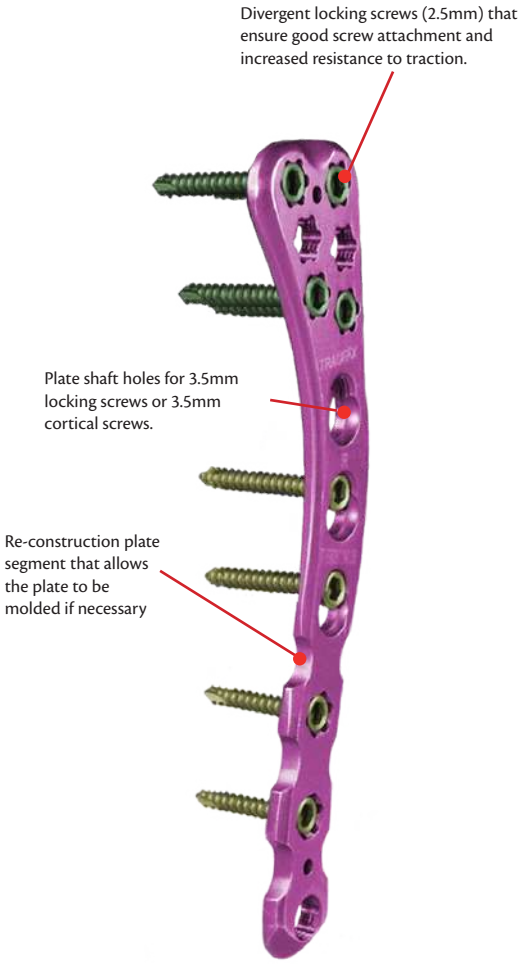
SURGICAL INDICATIONS

It is recommended to use the ALP superior anterior clavicle plate CLAVILOCK in the following cases:

1. Diaphyseal clavicle fractures] limb of the clavicle.
2. Faulty clavicle consolidations.
3. Absence of consolidation (pseudoarthrosis) of the clavicle.

GENERAL CONTRAINDICATIONS

- Systemic inflammatory response syndrome (to be evaluated by the surgeon).
- Septicemia.
- Osteomyelitis.
- Patient unable to comply with post-operation care.
- Hypersensitivity to the materials (titanium).



DESCRIPTION OF SURGICAL TECHNIQUE

Pre-operation Planning

Complete the pre-operation radiographic evaluation and develop the pre-operation plan. Use X-ray templates for superior anterior clavicle plates and determine the plate length and position of the screws.

Patient Placement

Place the patient in supine decubitus, on a radiotransparent operating room table. Leave enough space to rotate the fluoroscope 45 degrees in both directions, this in order to display the clavicle in two planes during the intervention.
Prepare the associated arm so that it can be mobilized during the intervention. Arm mobilization can be used to assist in reduction.
Important: Longer tubes may be needed for anesthesia.

Open approach

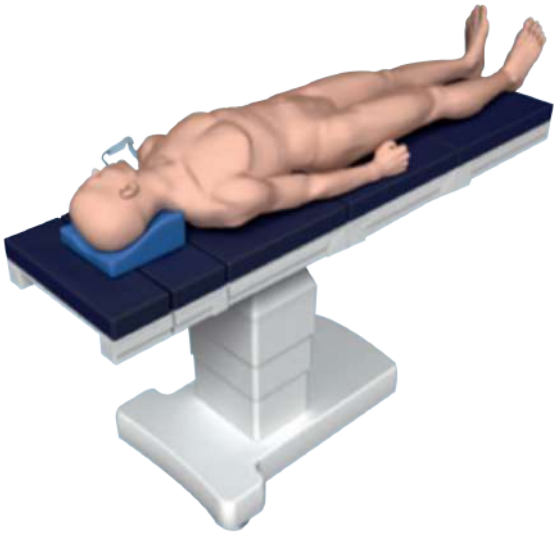
Make a gentle curvilinear incision, parallel to the skin's lines of separation. Subcutaneous dissection allows the identification of supraclavicular sensory nerve branches. The major fibers of these nerves should be identified and protected with small vessel loops throughout the intervention.
Carefully divide the skin muscle of the neck to expose the periosteum of the clavicle in the deltotrapezoid fascia. Perform minimal dissection of the periostio to expose the fracture.

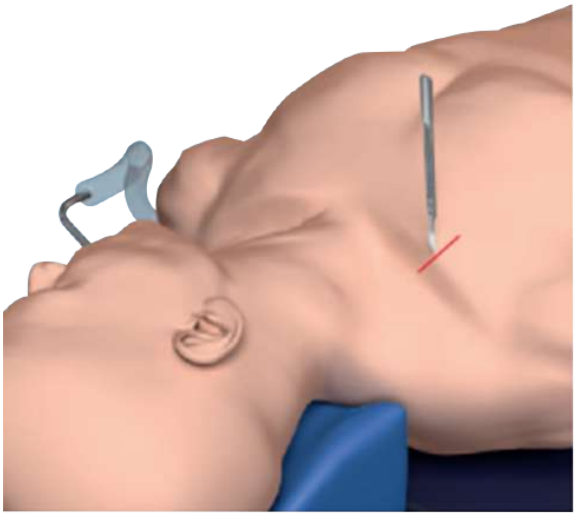
Warning: Bone fragments should not be detached from the petio to facilitate proper bone consolidation. It is essential not to remove any of the fragments of the comminute fracture.

Reducing fracture and temporary fixation

Normal length, axial angle, and rotation must be reset. After exposing the fracture, tract the two main fragments and reset the length of the clavicle. If the ends of the bone form an angle or are oblique, reduce them with pointy reduction tweezers or saw.

Caution
This technique is suggested to describe the use of TRAUFIX instruments and implants, not aiming to interfere with the experience and decisions of the traumatologist considering his/her vast clinical and surgical experience to determine the best proposal for each particular patient.





Any small fragment of the fracture should also be reduced and temporarily fastened with small pointed bone-bearing tweezers or Kirschner wires. Evaluate and plan any temporary fixations so that it does not interfere with the placement of definitive fixing implants. Kirschner wires can be inserted through the distal end of the plate to help temporarily maintain the reduction and place the plate. Another way to maintain reduction is through independent traction screws and traction screws inserted through the plate.

Warning: Bone fragments should not be detached from the periosteum to facilitate proper bone consolidation. It is essential not to remove any of the fragments of the comminute fracture.
Optional process: The superior anterior clavicle plate can be used for biological osteosynthesis with bridge formation. Only the main fragments are reduced, and the actual fracture area does not fit with any screws.

Determination of the length and adaptation of the plate

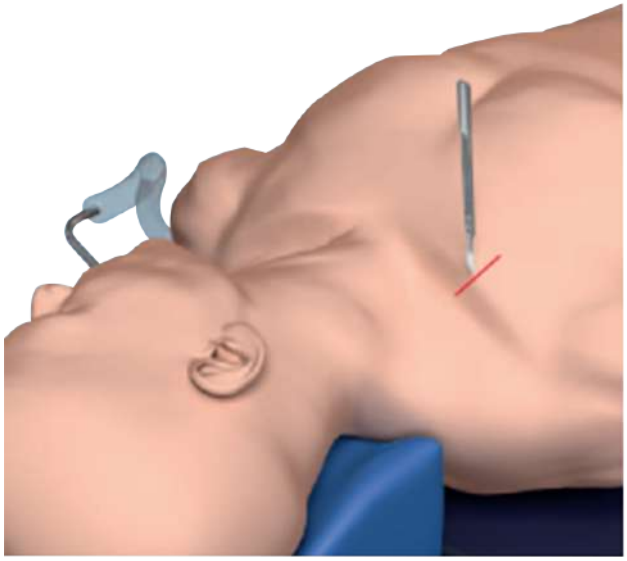
Select a plate of the appropriate size for the fracture.
Note: This plate is anatomically pre-molded to fit the shape of the clavicle.

Temporary placement and fixing of the plate

Place the plate on the reduced bone, and hold it temporarily using a 3.5mm cortical screw or plate reduction clamps.
Once you have inserted the plate, check its alignment on the bone using the fluoroscope..

Minimally invasive approach

The operation is performed in the medial to lateral direction, in order to minimize the risk of damage to the central vessels. Make a 2cm incision over the medial end of the clavicle. Tip: To reduce the risk of post-operation interference between the wound and plate, first push the skin into a cranial direction with one finger before cutting the skin onto the clavicle. When you remove your finger, the skin will go back to its original position and the incision will be placed below the clavicle. Carefully separate and disect the subcutaneous tissue to the cortical of the sterni extreme of the clavicle. Be sure to remove the soft tissue in the anteromedial and superolateral part of the clavicle, so that the plate can be placed.



Reduction of the fracture

Normal length, axial angle, and rotation must be reset. In some cases, it can be done by percutaneous control with your fingers or with pointed tweezers.
Otherwise, make another 3 cm skin incision through the fracture and along the separation lines. If necessary, the reduction is achieved by traction and rotation.
Warning: Bone fragments should not be detached from the periosteum to facilitate proper bone consolidation. It is essential not to remove any of the fragments of the comminute fracture.
Optional process: The superior anterior clavicle plate can be used for biological osteosynthesis with bridge formation. Only the main fragments are reduced, while the actual fracture area does not have any screws.

Determination of the length and adaptation of the plate

Select a plate of the appropriate size for the fracture.
Note: This plate is anatomically pre-molded to fit the shape of the clavicle.

Inserting and placing the plate

Screw the threaded drill guides on the medial part of the plate to serve as insertion handles, this way the plate can be felt and guided percutaneously from the medial fragment to the side. (See image 1). Once you have reduced the fracture, place the plate on the bone and insert 3.5mm cortex screws into the two main fragments, to approximate the bone to the plate. Check its alignment on the bone using the fluoroscope once you have inserted the plate. (See image 2).

Screws insertion:

Determine the combination of screws to be used for fastening.
If you plan on using a combination of locking screws and cortical screws, the locking screws must be inserted first in order to approximate the bone to the plate..
Note: If the plate is used for a bridged osteosynthesis, at least two locking screws must be inserted into each of the two main fragments. Usually, the actual area of the fracture does not have any screws.

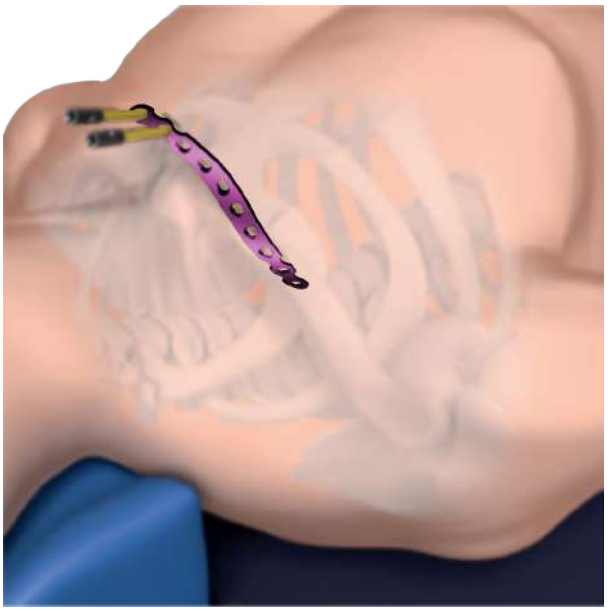


Image 1

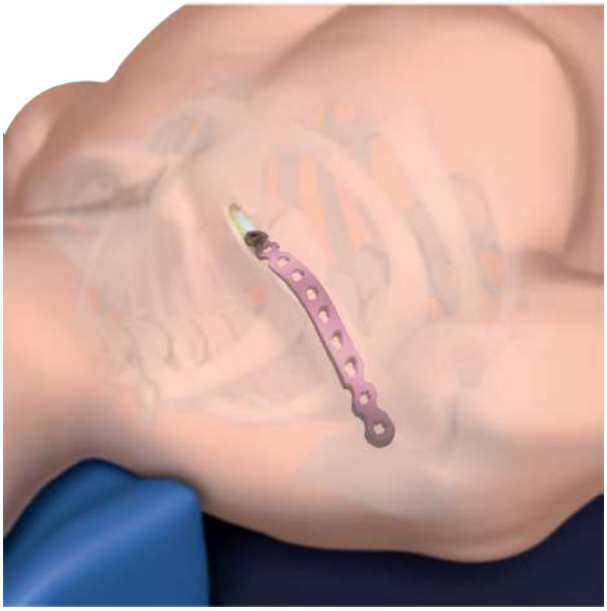


Image 2

Checking the position of the screws

Because the direction of the locking screws depends on the contour of the plate, before inserting the screws it is suggested to check its final position with the help of Kirschner wires under radiological control with the fluoroscope . This is important when applied near a joint or in patients with unusual anatomical peculiarities.

Recommendation: Observe the direction of the bit while drilling under radiological control with the fluoroscope.

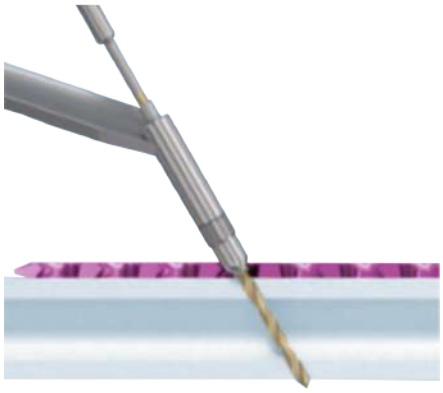


Image 3

Fixing the screws

a) Fixing with cortical 3.5mm screws

Use the 2.5mm bit with the 3.5 universal drill guide to drill the bone bicortically. (See image 3).

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

To tighten the screws in a neutral position, press down the drill guide into the threadless hole. For compression, place the drill guide at the end of the threadless hole away from the fracture, careful not to apply downward pressure to the spring-loaded tip. (See image 4).

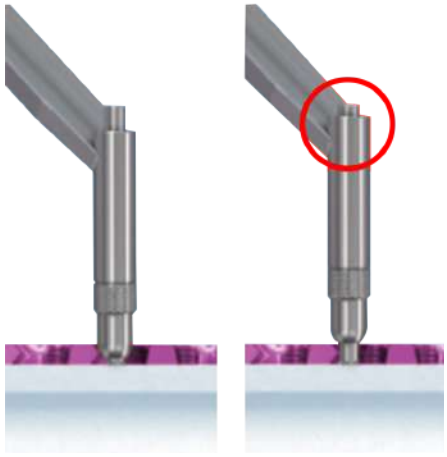


Image 4

Determine the required length of the cortical screw using the depth meter. (See image 5).

Insert the appropriate 3.5mm cortical screw with the help of the hex screwdriver or hexagonal screwdriver part. (See image 6).

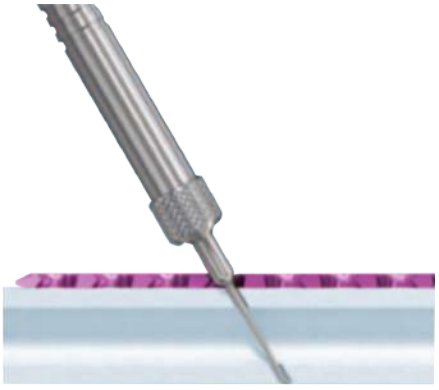


Image 5

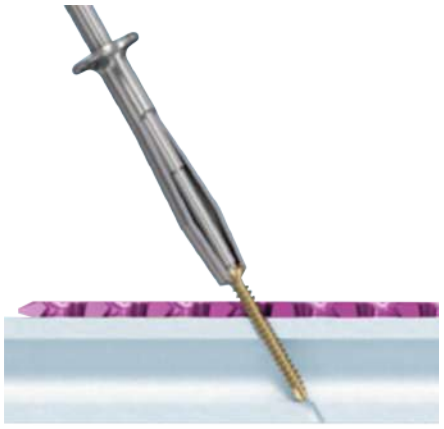


Image 6

b) Fixing with 3.5mm locking screws

Note: If you are first inserting a locking screw, make sure that the fracture is reduced and the plate firmly attached to the bone. This will prevent the plate from turning when the screw locks on the plate.

Screw the drill guide (128.27) into a 3.5mm locking hole until fully seated. Drill with the bit bicortically. (See image 7).

Warning: Avoid contact with the subclavian artery and brachial plexus when drilling through the clavicle.
Remove the drill guide. Use the depth meter to determine the length of the screw. (See image 8).
Insert the locking screw with the hexagonal screwdriver. Tighten until you hear a click. (See image 9).
Repeat with all necessary holes in the plate shaft.

Image 7

Image 8

Image 9

c) Fixing with 2.5mm locking screws

Screw the drill guide (128.20) into a 2.5mm locking hole, until completely joined. Drill with the 2.0mm bit to the desired depth. (See image 10).

Repeat with all necessary holes in the plate shaft but using the drill bit for 2.7mm bit (128.27).

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

Remove the guides.

Determine the required screw length using the bit guide scale and bit guide. If a single mark is visible on the bit, the scale is applied from 0 to 30mm; if two marks are visible, the scale is applied from 30mm to 60mm. (See image 11).

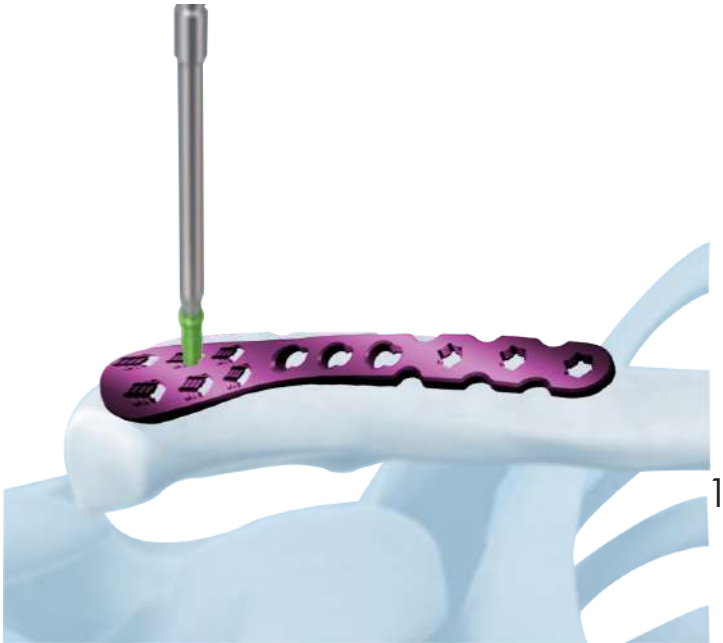
If you use the depth meter for the 2.5mm screws, subtract 4mm from the indicated figure to get the correct screw length.

Note: The above methods result in the insertion of the screws with the tip exactly at the opposite cortical level. If you need to position the screws bicortically, insert screws that measure 1 or 2mm more than the measured length. Screws located near a joint should be somewhat shorter than the measured length.

The 2.5mm locking screws are inserted with the help of the screw-driver. Tighten until you hear a click.

Image 10

Image 11



Implant removal

The decision to remove the implant is up to the treating physician. It is recommended to remove the implant once the consolidation process is complete, provided that it is feasible and suitable for the patient. To remove the screws, first clear the screw head by removing tissue that may have been able to penetrate the hexagonal inlet to ensure that the screwdriver enters properly and reduce the risk of damage to it that may prevent it from being removed. Unscrew all screws and remove them and then remove the plate.

IMPLANTS AND INSTRUMENTS

PLATES

ALP TITANIUM SUPERIOR ANTERIOR CLAVICLE PLATE WITH LATERAL EXTENSION CLAVICLOK RIGHT

140.04 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 4 holes right
140.05 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 5 holes right
140.06 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 6 holes right

ALP TITANIUM SUPERIOR ANTERIOR CLAVICLE PLATE WITH LATERAL EXTENSION CLAVICLOK LEFT

141.04 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 4 holes left
141.05 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 5 holes left
141.06 ALP titanium superior anterior clavicle plate with lateral extension CLAVILOCK 6 holes left

ALP TITANIUM SUPERIOR ANTERIOR CLAVICLE PLATE CLAVICLOK RIGHT

142.06 ALP titanium superior anterior clavicle plate CLAVILOCK 6 holes right
142.07 ALP titanium superior anterior clavicle plate CLAVILOCK 7 holes right
142.08 ALP titanium superior anterior clavicle plate CLAVILOCK 8 holes right

ALP TITANIUM SUPERIOR ANTERIOR CLAVICLE PLATE CLAVICLOK LEFT

143.06 ALP titanium superior anterior clavicle plate CLAVILOCK 6 holes left
143.07 ALP titanium superior anterior clavicle plate CLAVILOCK 7 holes left
143.08 ALP titanium superior anterior clavicle plate CLAVILOCK 8 holes left

SCREWS

3.5mm TITANIUM CORTEX LOCKING SCREW

106.12 3.5mm titanium cortex locking screw 12mm
106.14 3.5mm titanium cortex locking screw 14mm
106.16 3.5mm titanium cortex locking screw 16mm
106.18 3.5mm titanium cortex locking screw 18mm
106.20 3.5mm titanium cortex locking screw 20mm
106.22 3.5mm titanium cortex locking screw 22mm
106.24 3.5mm titanium cortex locking screw 24mm
106.26 3.5mm titanium cortex locking screw 26mm
106.28 3.5mm titanium cortex locking screw 28mm
106.30 3.5mm titanium cortex locking screw 30mm
106.32 3.5mm titanium cortex locking screw 32mm
106.34 3.5mm titanium cortex locking screw 34mm
106.36 3.5mm titanium cortex locking screw 36mm
106.38 3.5mm titanium cortex locking screw 38mm
106.40 3.5mm titanium cortex locking screw 40mm
106.45 3.5mm titanium cortex locking screw 45mm
106.50 3.5mm titanium cortex locking screw 50mm
106.55 3.5mm titanium cortex locking screw 55mm
106.60 3.5mm titanium cortex locking screw 60mm

3.5mm TITANIUM CORTEX SCREW

112.12 3.5mm titanium cortex screw 12mm
112.14 3.5mm titanium cortex screw 14mm
112.16 3.5mm titanium cortex screw 16mm
112.18 3.5mm titanium cortex screw 18mm
112.20 3.5mm titanium cortex screw 20mm
112.22 3.5mm titanium cortex screw 22mm
112.24 3.5mm titanium cortex screw 24mm
112.26 3.5mm titanium cortex screw 26mm
112.28 3.5mm titanium cortex screw 28mm
112.30 3.5mm titanium cortex screw 30mm
112.32 3.5mm titanium cortex screw 32mm
112.34 3.5mm titanium cortex screw 34mm
112.36 3.5mm titanium cortex screw 36mm
112.38 3.5mm titanium cortex screw 38mm
112.40 3.5mm titanium cortex screw 40mm
112.45 3.5mm titanium cortex screw 45mm
112.50 3.5mm titanium cortex screw 50mm
112.55 3.5mm titanium cortex screw 55mm
112.60 3.5mm titanium cortex screw 60mm

2.5mm TITANIUM CORTEX LOCKING SCREW

155.08 2.5mm titanium cortex locking screw 8mm
155.10 2.5mm titanium cortex locking screw 10mm
155.12 2.5mm titanium cortex locking screw 12mm
155.14 2.5mm titanium cortex locking screw 14mm
155.16 2.5mm titanium cortex locking screw 16mm
155.18 2.5mm titanium cortex locking screw 18mm
155.20 2.5mm titanium cortex locking screw 20mm
155.22 2.5mm titanium cortex locking screw 22mm
155.24 2.5mm titanium cortex locking screw 24mm
155.26 2.5mm titanium cortex locking screw 26mm
155.28 2.5mm titanium cortex locking screw 28mm
155.30 2.5mm titanium cortex locking screw 30mm

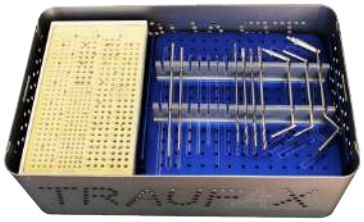
INSTRUMENTS

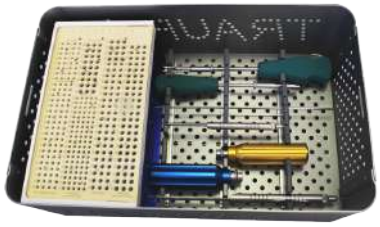
The following instruments are designed to anchor only on Traufix implants, the use of instruments from other brands may damage the product and not anchor properly.

BASIC INSTRUMENTS

CODE	INSTRUMENT
128.27	Drill guide for 2.7mm drill bit
128.20	Drill guide for 2.0mm drill bit

QTY.	DESCRIPTION
2	2.0mm threaded guide-wire
2	1.5mm threaded guide-wire
1	2.5mm hexagonal screwdriver for 3.5mm/4.5mm screw
1	2.5mm eccentric neutral drill guide
1	2.5mm/3.5mm double drill guide
1	2.5mm/3.5mm double drill guide
1	Torque wrench AO of 1.5Nm
1	T-handle with quick coupling (AO)
1	60mm depth gauge
1	6mm countersink tip for 3.5mm/4.0mm screw
1	2.5mm screwdriver hexagonal tip
1	2.5mm hexagonal screw extractor tip
1	3.5mm tap tip
1	6.5mm reamer tip for small fragments
1	2.5mm drill bit quick coupling
1	2.7mm drill bit quick coupling
1	2.0mm drill bit quick coupling





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