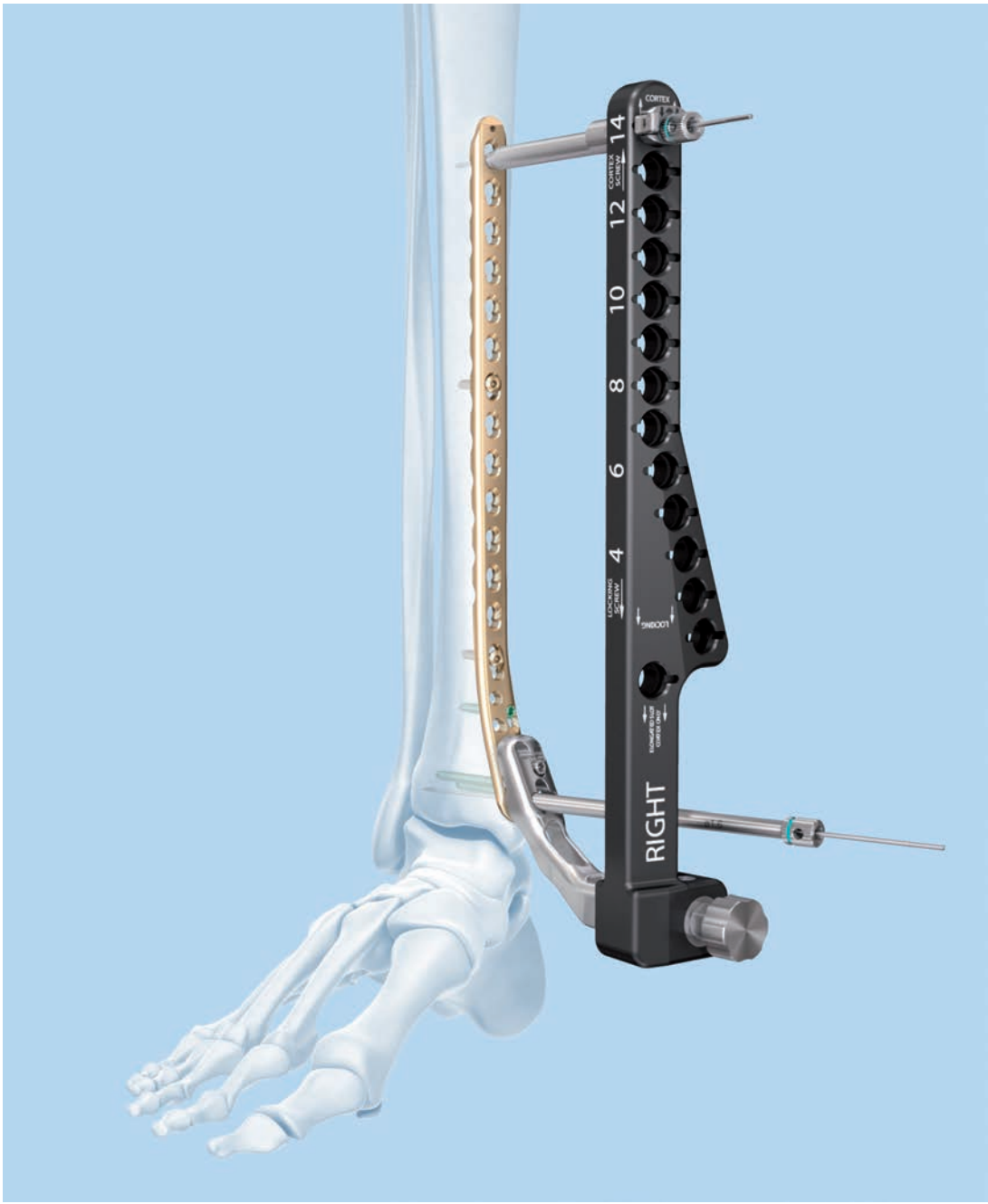
LCP Low Bend Medial Distal Tibia Plate Aiming Instruments 3.5 mm.

Part of the LCP Percutaneous Instrument System 3.5 mm.

Surgical Technique



Instruments and implants approved by the AO Foundation.

DePuy Synthes
COMPANIES OF Johnson&Johnson

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 Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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LCP Low Bend Medial Distal Tibia Plate Aiming Instruments 3.5 mm.

Part of the LCP Percutaneous Instrument System 3.5 mm.

The LCP Percutaneous Instrument Set 3.5 mm consists of a comprehensive series of aiming arms and instrumentation to facilitate the percutaneous, submuscular insertion of various plates.

The LCP Small Fragment Percutaneous Instrument Set 3.5 mm provides common instrumentation throughout the system including:

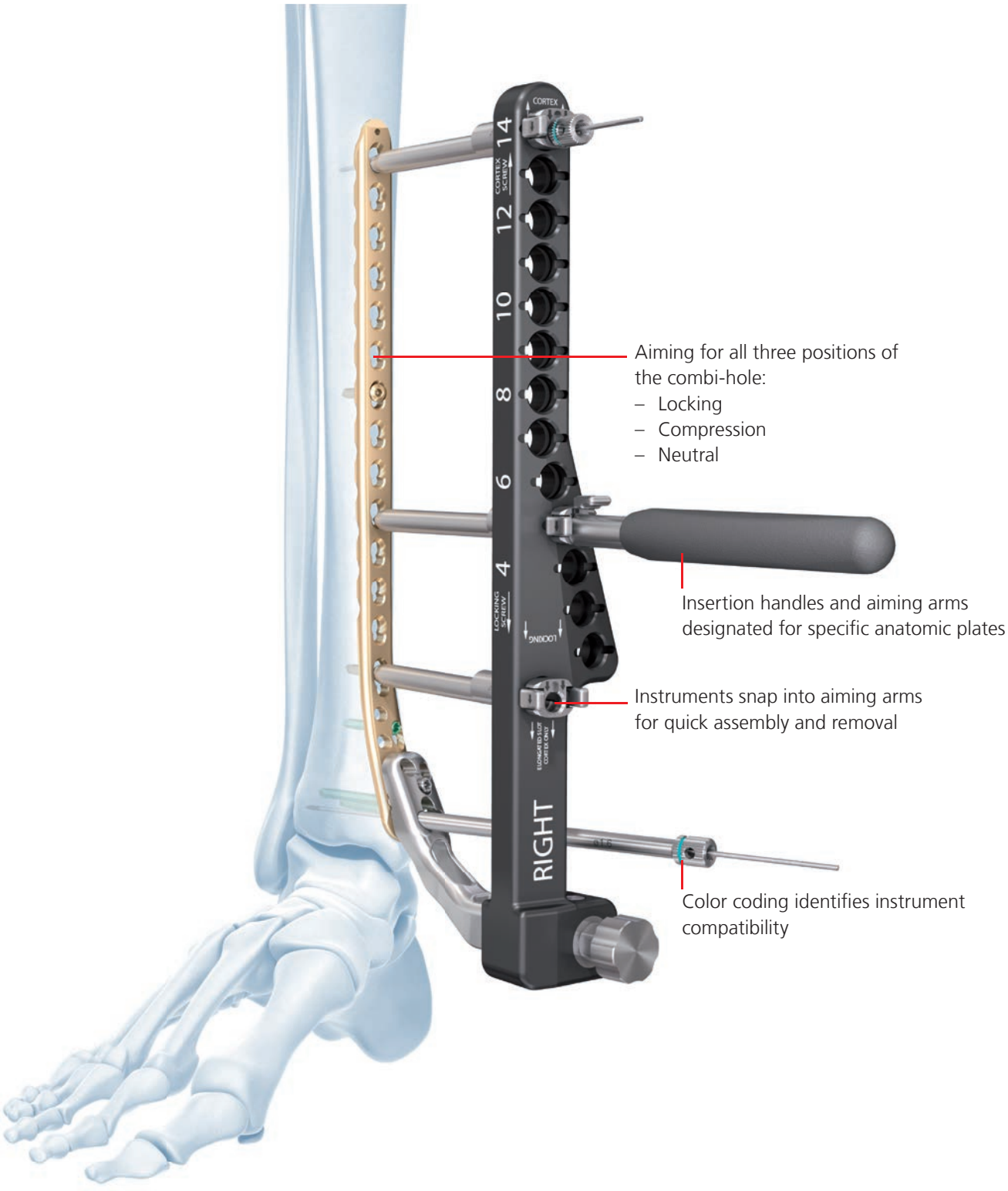
- Screwdrivers
- Locking/neutral and compression drill guides
- Drill bits
- Trocars
- Pull reduction devices
- Depth measuring devices

LCP Low Bend Medial Distal Tibia Plates 3.5 mm

The LCP Low Bend Medial Distal Tibia Plate 3.5 mm is part of the Synthes Locking Compression Plate (LCP) system that merges locking screw technology with conventional plating techniques.

The combi-holes in the LCP plate shaft combine a dynamic compression unit (DCU) hole with a locking screw hole. Combi-holes provide the flexibility of axial compression and locking capability throughout the length of the plate shaft. Fixation with the LCP Low Bend Medial Distal Tibia Plate 3.5 mm has many similarities to traditional plate fixation methods, with a few important improvements. Locking screws provide the ability to create a fixed-angle construct while using standard AO plating techniques. Locking capability is important for fixed-angle constructs in osteopenic bone or multifragment fractures where screw purchase is compromised. These screws do not rely on plate-to-bone compression to resist patient load, but function similarly to multiple, small, angled blade plates.

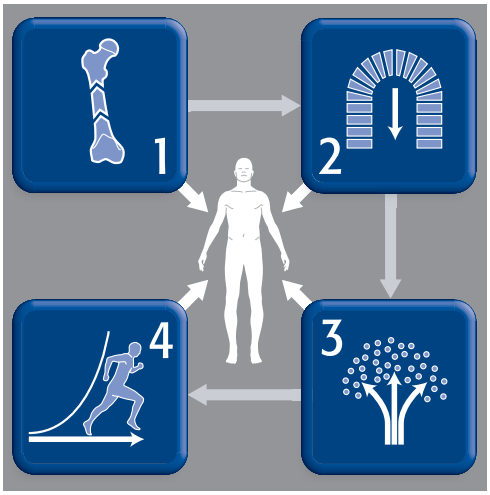
Note: For information on fixation principles using conventional and locked plating techniques, please refer to the LCP Locking Compression Plate Surgical Technique (DSEM/TRM/0115/0278).


Aiming for all three positions of the combi-hole:
– Locking
– Compression
– Neutral
Insertion handles and aiming arms designated for specific anatomic plates
Instruments snap into aiming arms for quick assembly and removal
Color coding identifies instrument compatibility
RIGHT
CORTEX
LOCKING

AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation[1,2].

Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.



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

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

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

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991.
[2] Rüedi TP, Buckley RE, Moran CG. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Indications

The Synthes LCP Low Bend Medial Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia, as a part of the Synthes Small Fragment LCP System.

Preparation

Required sets

Small fragment percutaneous instruments and aiming arms	
01.113.007	LCP Percutaneous Aiming System 3.5, in Modular Tray, for distal tibia, Vario Case System
01.113.008	Percutaneous Aiming Arms for LCP Distal Tibia Low Bend Plates 3.5, in Modular Tray, Vario Case System

Modular small fragment instrument trays*	
68.122.013	Modular Tray for Small Fragment Basic Instruments, size 1/2, without Contents, Vario Case System
68.122.015	Modular Tray for Screw Insertion 3.5/4.0, size 1/2, without Contents, Vario Case System

Modular screw rack
All screws are available in a modular screw rack which can be arranged as needed.

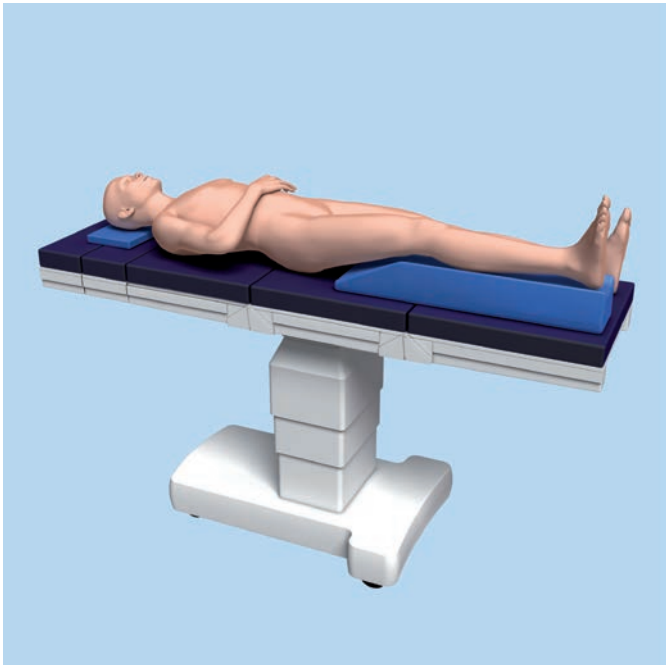
Optional modular small fragment instrument trays

68.122.019	Modular Tray for Small Fragment Bending Instruments, size 1/2, without Contents, Vario Case System
68.122.014	Modular Tray for Small Fragment Reduction Instruments, size 1/2, without Contents, Vario Case System

Complete a preoperative radiographic assessment and prepare the preoperative plan.

* It is also possible to use non modular LCP Small Fragment Instrument Sets.

Note: For information on fixation principles using conventional and locked plating techniques, please refer to the LCP Locking Compression Plate Surgical Technique (DSEM/TRM/0115/0278).



1
Position patient

- Position the patient supine on a radiolucent table. Viewing the distal tibia under fluoroscopy in both the lateral and AP views is necessary.

2
Attach insertion handle

Instruments	
311.431	Handle with Quick Coupling
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling
03.113.025	Percutaneous Insertion Handle for Aiming Arm, right, for LCP Medial Distal Tibial Plates 3.5, Low Bend
03.113.026	Percutaneous Insertion Handle for Aiming Arm, left, for LCP Medial Distal Tibial Plates 3.5, Low Bend

Attach the appropriate insertion handle to the plate by aligning the three locating tabs on the handle with the three dimples in the plate. Use the appropriate screwdriver to tighten the insertion handle connecting screw to secure the handle to the plate.

Precaution: Excessive tightening of the connecting screw may damage the threads in the plate, resulting in loss of fixation.

Note: The insertion handles are not compatible with the LCP Medial Distal Tibia Plates 3.5 mm, without tabs (238.700–238.711 or 438.700–438.711).

3

Secure aiming arm to plate distally

Instrument	
03.113.001	Percutaneous Aiming Arm, right, for LCP Medial Distal Tibial Plates 3.5
or	
03.113.003	Percutaneous Aiming Arm, left, for LCP Medial Distal Tibial Plates 3.5

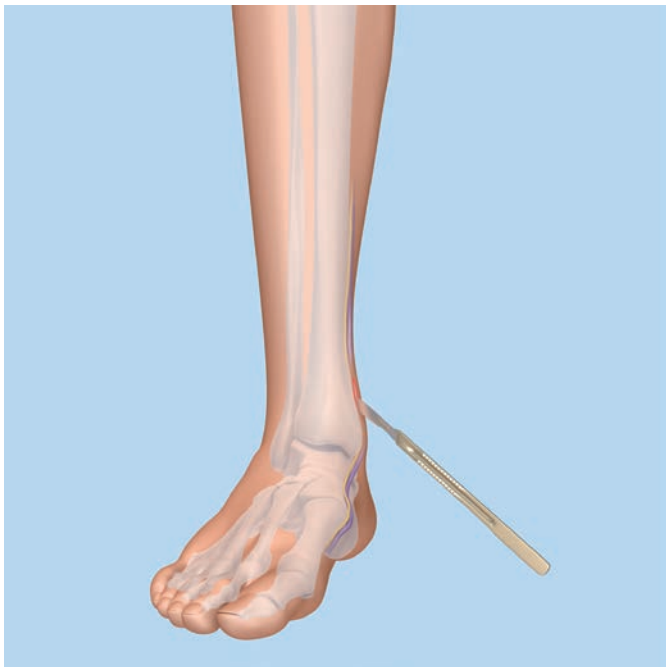
Attach the appropriate aiming arm to the insertion handle. Align the body of the aiming arm with the shaft of the plate. Finger-tighten the connection bolt to secure the aiming arm to the insertion handle.

Note: Flats on the connection bolt allow use of the 11 mm combination wrench for removing the aiming arm. Do not use the wrench to tighten the connecting bolt during assembly. Doing so could damage the connecting bolt.

Approach

Make a medial incision through the skin and subcutis slightly above the level of the ankle joint.

Precaution: Take care not to damage the saphenous nerve or saphenous vein.



Reduce Articular Surface

Reduce the fracture fragments and confirm reduction using image intensification. Secure fragments with appropriately placed bone screws. The plate may be secured temporarily with one of the following:

- Reduction forceps
- Independent Kirschner wires
- Independent lag screws
- Large distractor
- External fixator
- Kirschner wires through the plate
- Lag screws through the plate
- Locking screws through the plate

Note: Locking screws do not provide interfragment compression; therefore, any compression must be achieved with standard lag screws. The articular fractures must be reduced and compressed before fixation of the plate with locking screws.

Plate Insertion

1
Insert plate

Optional instruments

325.010	Soft Tissue Retractor, small, extendible
328.010	Soft Tissue Retractor, large, extendible

Prior to insertion of the plate, use a round smooth periosteal elevator or soft tissue retractor.

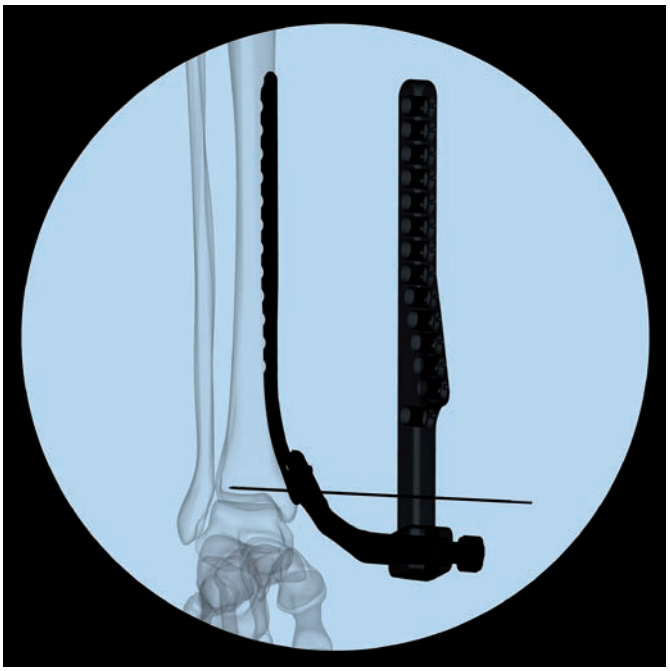
Carefully insert the plate under the soft tissues and along the anteromedial face of the tibia. The aiming arm and insertion handle can be used to control the plate orientation during insertion. Be careful to avoid deviation of the plate from the tibia itself.

Center the plate on the medial malleolus.

2
Position plate and fix provisionally

Optional instrument

03.113.015	Pull Reduction Device for Outer Sleeve, for LCP Percutaneous Aiming Instruments 3.5



Confirm the plate orientation, length, and distal location with fluoroscopy in the anteroposterior and lateral planes. Confirm the fracture reduction. Make any adjustments before inserting screws.

Note: This locking plate is precontoured to fit the medial distal tibia. If the plate contour is changed, it is important to check the position of the screws relative to the joint, using the screw placement verification technique (page 16).

If the plate contour is changed, the aiming arm may not properly target the holes in the plate.

The plate may be temporarily held in place using:
- Pull reduction device
- 4.0 mm cancellous bone screw in a distal combi-hole
- Standard plate holding forceps
- Kirschner wires through the plate

Any of these options will allow moving the plate into a final position, and will also prevent plate rotation while inserting the first locking screw.

Note: Ensure proper reduction before inserting the first locking screw. Once locking screws are inserted, further reduction is not possible without loosening the locking screws.

3

Secure aiming arm to plate proximally

Instruments	
03.113.009	Outer Sleeve for percutaneous LCP Aiming Instruments 3.5
03.113.010	Trocar with Handle ∅ 6.0 mm
03.113.011	Scalpel for Percutaneous Aiming Arm Instruments
03.113.022	Centering Sleeve, percutaneous, for Kirschner Wire ∅ 1.6 mm
03.113.014	Handle for Drill Sleeves with thread
Implant	
02.113.001	Kirschner Wire ∅ 1.6 mm, with drill tip, length 200 mm

Determine the hole in the aiming arm corresponding to the most proximal hole in the plate.

Attach a number 10 blade to the scalpel holding end of the handle. The scalpel will pass through the aiming arm holes and assist in performing a minimally invasive and accurate incision. (The scalpel will pass through the aiming arm only as far as the top surface of the plate.)

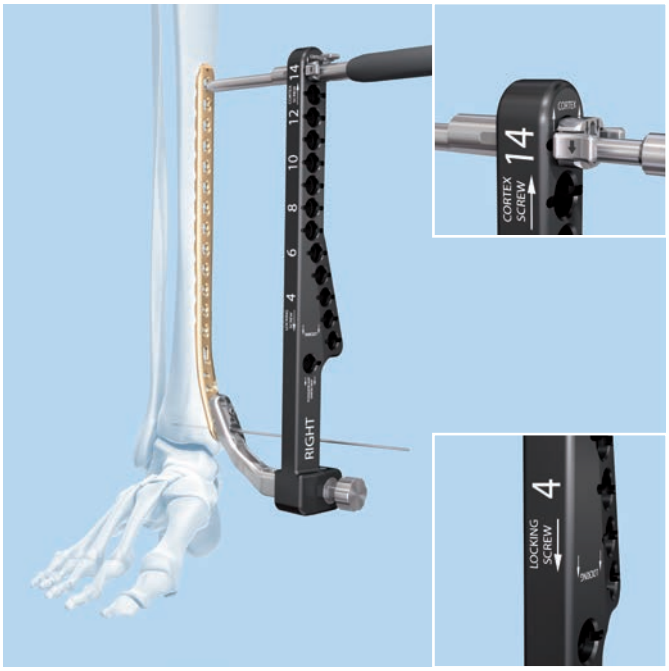
Remove the scalpel from the aiming arm.

Note: Remove the scalpel blade before storing the handle in the case. Assemble an outer sleeve onto the trocar with handle until it seats fully.

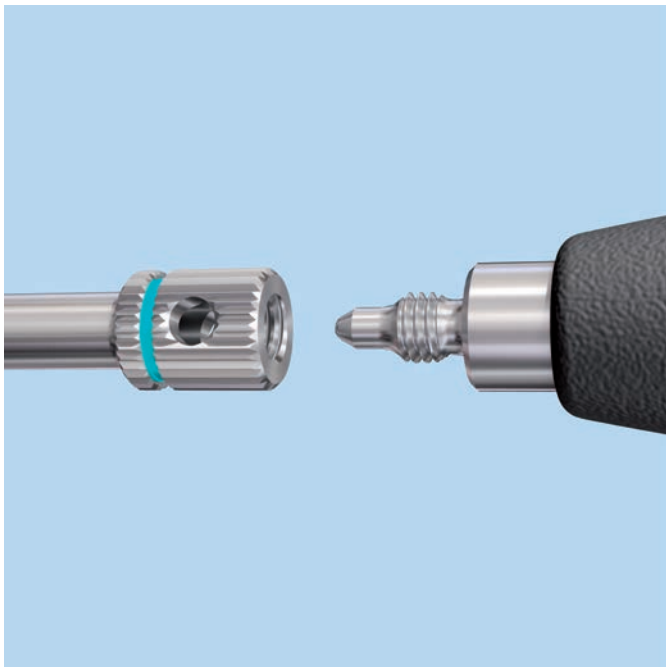
While squeezing inward on the two latches of the outer sleeve, insert the trocar assembly into the appropriate aiming arm hole with the arrows on the outer sleeve oriented in the same direction as the "LOCKING" arrow on the aiming arm.

Push the trocar assembly down to the plate through the incision until the trocar tip contacts the plate and the two latches of the outer sleeve securely snap into the aiming arm.

Remove the trocar.



Thread the handle into the centering sleeve. Insert the handle and centering sleeve assembly through the outer sleeve, and securely thread it into the plate. Turn the handle counter-clockwise to disengage and remove it from the centering sleeve.



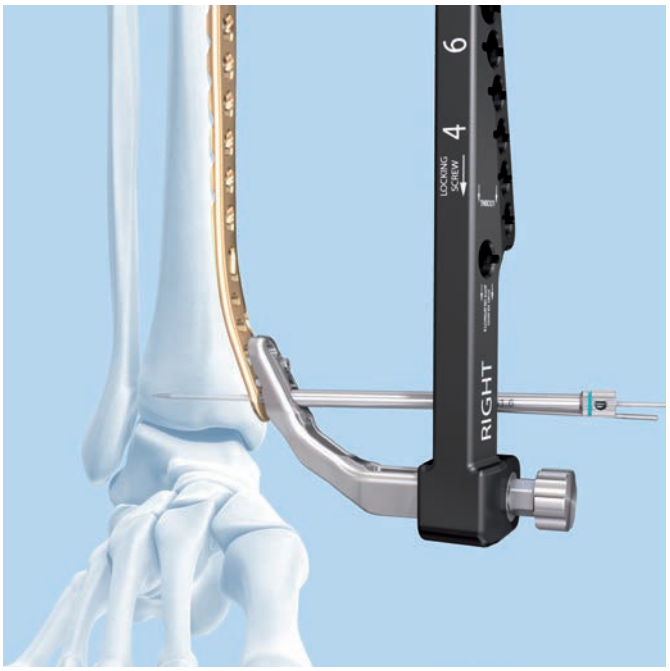
Note: Securely tighten the centering sleeve to the plate, to achieve a stable construct between the aiming arm and the plate.

Insert a 1.6 mm drill tip guide wire into the bone through the percutaneous centering sleeve.

Screw Insertion

1
Option: Verify screw placement

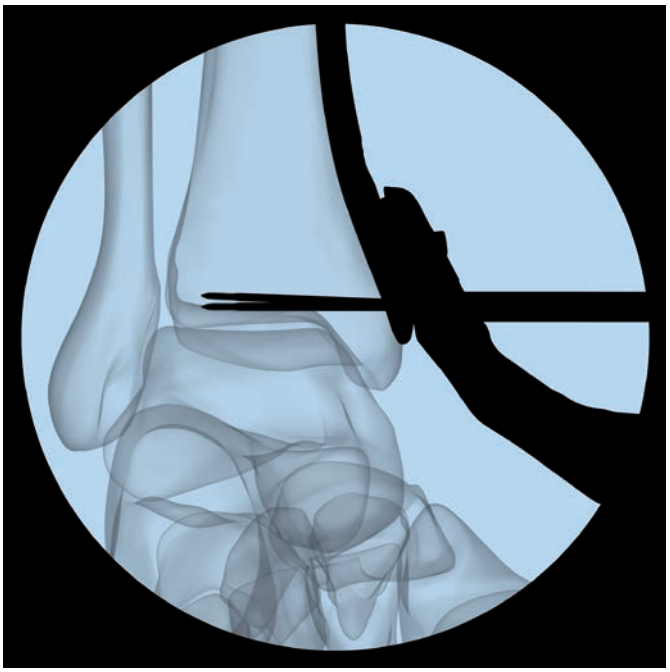
Instruments	
03.113.020	Locking Drill Sleeve ∅ 2.8 mm, percutaneous
03.113.022	Centering Sleeve, percutaneous, for Kirschner Wire ∅ 1.6 mm
03.113.024	Drill Bit ∅ 2.8 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
323.060	PHILOS Direct Measuring Device for Kirschner Wire ∅ 1.6 mm
Implant	
02.113.001	Kirschner Wire ∅ 1.6 mm, with drill tip, length 200 mm



The direction of the locking screw depends on the plate contour; final screw position may be verified with a Kirschner wire before insertion. This is especially important when the plate has been manually contoured or applied near the joint.

With the 1.6 mm percutaneous centering sleeve in the locking hole, drive a 1.6 mm drill tip guide wire to the desired depth.

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

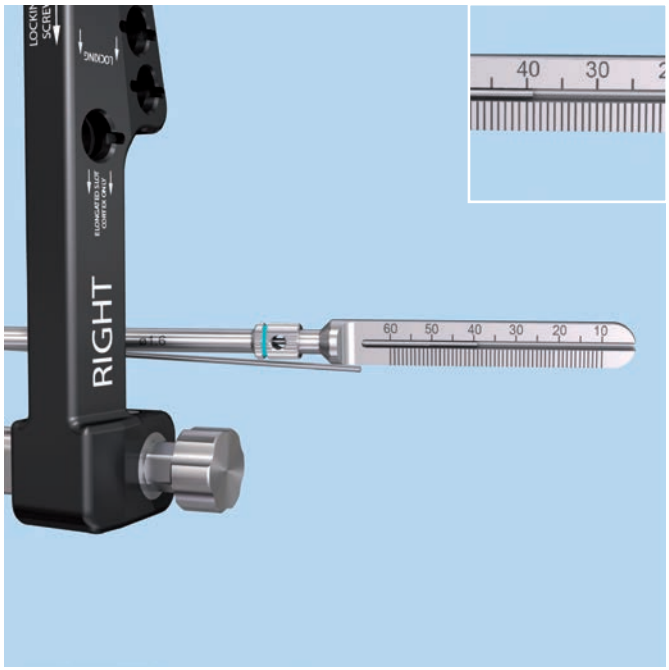


Precaution: The Kirschner wire position represents the final position of the locking screw. Confirm that the Kirschner wire does not enter the joint.

Measure the screw length by sliding the tapered end of the direct measuring device over the Kirschner wire down to the centering sleeve.

Remove the direct measuring device, Kirschner wire and 1.6 mm percutaneous centering sleeve.

Insert a 2.8 mm Locking Drill Sleeve into the locking hole and drill to the measured depth, using the 2.8 mm calibrated drill bit. Remove the drill sleeve and insert the appropriate length locking screw.



2
Insert distal screws

Instruments	
03.113.014	Handle for Drill Sleeves with thread
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling
03.113.020	Locking Drill Sleeve ∅ 2.8 mm, percutaneous
03.113.022	Centering Sleeve, percutaneous, for Kirschner Wire ∅ 1.6 mm
03.113.023	Drill Bit ∅ 2.5 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
03.113.024	Drill Bit ∅ 2.8 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
03.113.028	Depth Gauge for Percutaneous Aiming Arm Instruments
314.550	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm, length 165 mm, for Quick Coupling
323.060	PHILOS Direct Measuring Device for Kirschner Wire ∅ 1.6 mm
511.770	Torque Limiter, 1.5 Nm, for Compact Air Drive and Power Drive
or	
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling

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

If a locking screw will be used as the first screw, ensure the plate is held securely to the bone to prevent plate rotation as the screw is locked to the plate.

In distal combi-holes
For nonlocking screws, use the standard AO screw insertion technique described in the DCP technique guide, 036.001.093. The two combi-holes in the plate head accept 3.5 mm cortex or 4.0 mm cancellous bone screws. When using a cortex or cancellous bone screw in these combi-holes, the screwhead will be recessed in the hole.

Note: When evaluating screw options, remember the 3.5 mm conical screws have a lower profile than the locking screws. 3.7 mm cannulated locking screws are also available.

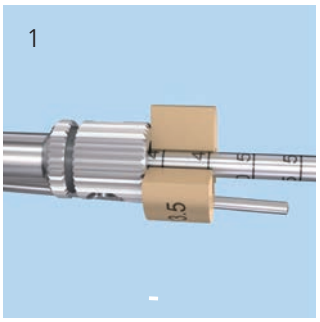
For distal locking screws
Thread the 2.8 mm locking drill sleeve into a distal locking hole until fully seated.

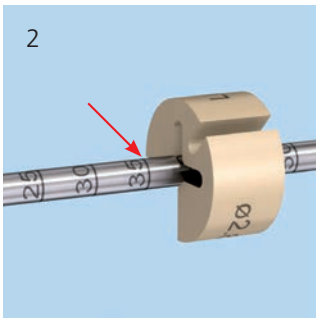
Use the 2.8 mm calibrated drill bit with stop to drill to the desired depth.

Verify that the plastic stop sits (1) on the drill sleeve before removing the drill bit.

Remove the drill bit and read the indicated drill depth below the plastic stop (2). The first visible number indicates the correct depth.

Note: The plastic stop is designed to ride up against the 2.8 mm percutaneous locking drill sleeve. The side of the stop facing the drill sleeve indicates the correct drilling depth.





Note: Use the tip of the handle for drill sleeves as a pin wrench to loosen the drill sleeves from the plate.

Inserting locking screws

Insert the locking screw under power, using the torque limiting attachment. Be sure the plate is held securely to the bone to prevent rotation as the screw is locked to the plate.

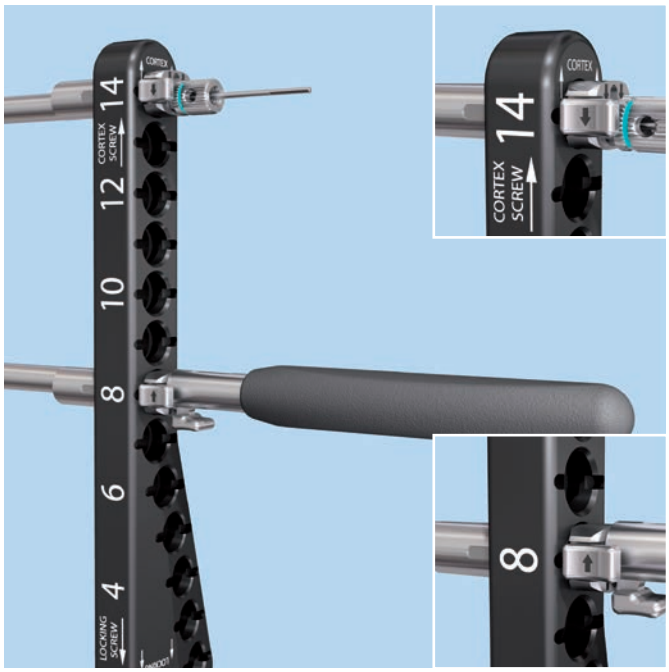
When using the torque limiting attachment, the screw is securely locked into the plate when a click is heard.

Note: Always use a torque limiting attachment when using power or for manual insertion.

3

Insert 3.5 mm cortex screws in shaft

Instruments	
03.113.009	Outer Sleeve for percutaneous LCP Aiming Instruments 3.5
03.113.010	Trocar with Handle ∅ 6.0 mm
03.113.011	Scalpel for Percutaneous Aiming Arm Instruments
03.113.012	Drill Sleeve ∅ 2.5 mm for neutral position, percutaneous
03.113.013	Drill Sleeve ∅ 2.5 mm, for compression position, percutaneous
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling
03.113.023	Drill Bit ∅ 2.5 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
03.113.028	Depth Gauge for Percutaneous Aiming Arm Instruments
314.550	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm, length 165 mm, for Quick Coupling



Create an incision through the appropriate aiming arm hole.

Assemble the trocar with handle with an outer sleeve.

While squeezing inward on the two latches of the outer sleeve, insert the trocar assembly into the appropriate aiming arm hole, with the arrows on the outer sleeve oriented in the same direction as the “CORTEX” arrow on the aiming arm.

Push the trocar assembly down to the plate through the incision until the trocar tip contacts the plate and the two latches of the outer sleeve securely snap into the aiming arm.

Remove the trocar.

Insert the appropriate drill guide, neutral or compression, into the outer sleeve until it securely snaps into place.

Note: When using the compression guide, orient the tab on the compression guide with the slot on the outer sleeve.

Use the 2.5 mm calibrated drill bit with stop to drill to the desired depth. Proper screw length can be determined from the calibration on the drill bit aligned with the top of the drill guide (page 21).

Note: The side of the stop facing the drill guide indicates the correct drilling depth.

Alternative technique
Screw length can also be determined with the use of the depth gauge. Remove the drill guide and insert the depth gauge into the outer sleeve to the previously drilled depth. Proper screw length is indicated by the gauge marking aligned with the top of the outer sleeve.

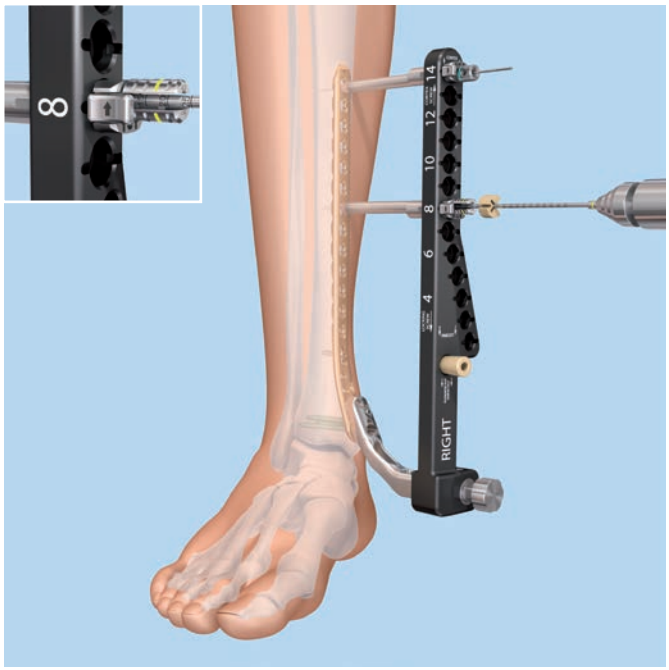
Remove the drill bit and drill guide.

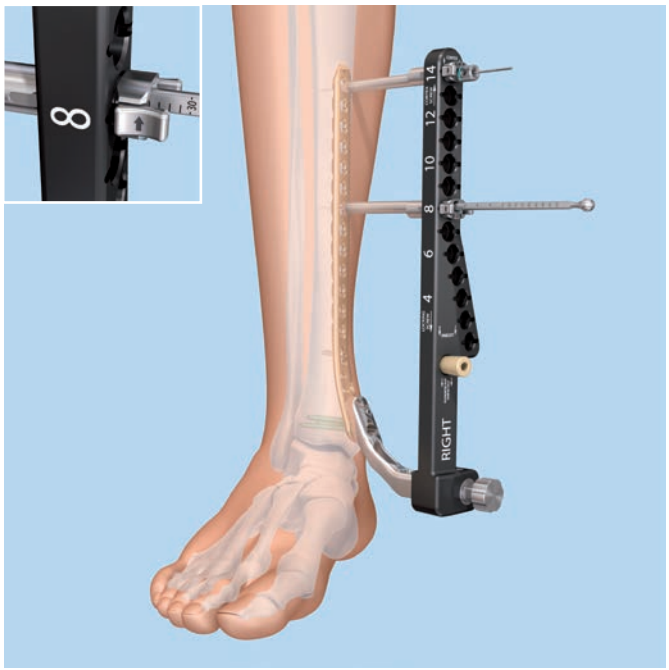
Insert proper length 3.5 mm cortex screw, using the appropriate screwdriver.

Repeat this process to insert as many 3.5 mm cortex screws as necessary into the plate shaft. Mark each screw location in the aiming arm with a stopper.

Precaution: All 3.5 mm cortex screws must be inserted before insertion of locking screws.

Note: Inserting cortex screws into the plate may cause the plate to flex. If the plate contour is changed, the aiming arm may not properly target the holes in the plate.





4

Insert 3.5 mm locking screws in shaft

Instruments	
03.113.009	Outer Sleeve for percutaneous LCP Aiming Instruments 3.5
03.113.010	Trocar with Handle ∅ 6.0 mm
03.113.011	Scalpel for Percutaneous Aiming Arm Instruments
03.113.014	Handle for Drill Sleeves with thread
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling
03.113.020	Locking Drill Sleeve ∅ 2.8 mm, percutaneous
03.113.023	Drill Bit ∅ 2.5 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
03.113.024	Drill Bit ∅ 2.8 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling
03.113.028	Depth Gauge for Percutaneous Aiming Arm Instruments
314.550	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm, length 165 mm, for Quick Coupling
511.770	Torque Limiter, 1.5 Nm, for Compact Air Drive and Power Drive
or	
511.773	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling

Create an incision through the appropriate aiming arm hole. Assemble an outer sleeve onto the trocar with handle until it is fully seated.

While squeezing the two latches of the outer sleeve, insert the trocar assembly into the appropriate aiming arm hole with the arrows on the outer sleeve aligned in the same direction as the "LOCKING" arrow on the aiming arm.

Push down to the plate through the incision until the trocar tip contacts the plate. Push the outer sleeve down the trocar shaft the remainder of the way until the latches of the outer sleeve securely snap into the aiming arm.

Remove the trocar.

Thread the 2.8 mm percutaneous locking drill sleeve into a combi-hole until fully seated.

Use the 2.8 mm calibrated drill bit with stop to drill to the desired depth.

Remove the drill and read the indicated drill depth below the plastic stop.

Insert the proper length 3.5 mm locking screws in the same manner described for the distal locking screws.

5
Remove aiming arm and insertion handle

Instruments	
311.431	Handle with Quick Coupling
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling
Optional instrument	
321.160	Combination Wrench, ∅ 11 mm

Remove all outer sleeves.

Turn the connecting bolt on the aiming arm counter-clockwise to loosen and remove the aiming arm from the insertion handle. The 11 mm combination wrench may be used, if necessary.

Remove the insertion handle from the plate by loosening the connecting screw with the T15 screwdriver.

Remove any remaining guide wires.

Implant removal

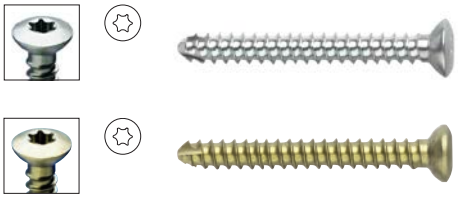
Unlock all screws from the plate, then remove the screws completely from the bone. This prevents simultaneous rotation of the plate when unlocking the last locking screw. If a screw cannot be removed with the screwdriver (e.g. if the hexagonal or Stardrive recess of the locking screw is damaged or if the screw is stuck in the plate), use the T-Handle with Quick-Coupling (311.440) to insert the conical Extraction Screw (309.520 or 309.521) into the screw head, and unscrew the screw in a counter-clockwise direction.

Screws

Screws used with the LCP Low Bend Medial Distal Tibia Plate 3.5 mm

Cortex Screws 2.7 mm

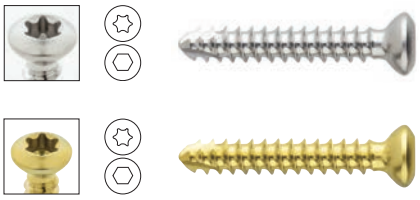
X02.870– X02.969	Cortex Screw Stardrive ∅ 2.7 mm, self-tapping, length 10–60 mm



- May be used in the distal locking holes
- Compresses the plate to the bone
- Fully threaded shaft

Cortex Screws 3.5 mm

0X.200.010– 0X.200.060 or	Cortex Screw Stardrive ∅ 3.5 mm, self-tapping, length 10–60 mm
X04.810– X04.860	Cortex Screw ∅ 3.5 mm, self-tapping, length 10–60 mm



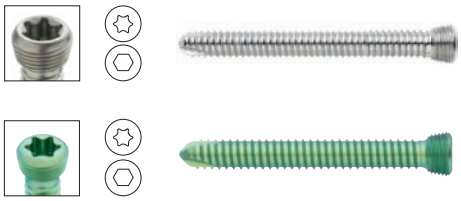
- May be used in the DCU portion of the combi-holes in the plate shaft
- Compresses the plate to the bone or creates axial compression
- Fully threaded shaft

X=2 Stainless Steel
X=4 Titanium

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

Locking Screws 3.5 mm

X12.101– X12.125	Locking Screw Stardrive ∅ 3.5 mm, self-tapping, length 10–65 mm
or	
X13.010– X13.060	Locking Screw ∅ 3.5 mm, self-tapping, length 10–60 mm



- Creates a locked, fixed-angle screw/plate construct
  Fully threaded shaft
- Self-tapping tip
- Used in the locking portion of the combi-holes or in round locking holes

Cancellous Bone Screws 4.0 mm

X06.010– X06.060	Cancellous Bone Screw ∅ 4.0 mm, fully threaded, length 10–60 mm
X07.010– X07.060	Cancellous Bone Screw ∅ 4.0 mm, length 10/5–60/16 mm

- May be used in the DCU portion of the combi-holes in the plate shaft
- Compresses the plate to the bone or creates axial compression
- Fully or partially threaded shaft

X=2 Stainless Steel
X=4 Titanium

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

Implants: Kirschner Wires

02.113.001	Kirschner Wire ∅ 1.6 mm, with drill tip, length 200 mm, Stainless Steel

Kirschner wires are available sterile packed. For sterile implants add suffix "S" to article number.

Instruments

03.113.001	Percutaneous Aiming Arm, right, for LCP Medial Distal Tibial Plates 3.5	
03.113.003	Percutaneous Aiming Arm, left, for LCP Medial Distal Tibial Plates 3.5	
03.113.009	Outer Sleeve for percutaneous LCP Aiming Instruments 3.5	
03.113.010	Trocar with Handle ∅ 6.0 mm	
03.113.011	Scalpel for Percutaneous Aiming Arm Instruments	
03.113.012	Drill Sleeve ∅ 2.5 mm for neutral position, percutaneous	
03.113.013	Drill Sleeve ∅ 2.5 mm, for compression position, percutaneous	
03.113.014	Handle for Drill Sleeves with thread	

03.113.015	Pull Reduction Device for Outer Sleeve, for LCP Percutaneous Aiming Instruments 3.5	
03.113.016	Nut for Pull Reduction Device	
03.113.017	Peg for Aiming Arm, small	
03.113.019	Screwdriver Shaft 3.5 Stardrive, T15, long, self-holding, for AO/ASIF Quick Coupling	
03.113.020	Locking Drill Sleeve ∅ 2.8 mm, percutaneous	
314.550	Screwdriver Shaft, hexagonal, small, ∅ 2.5 mm, length 165 mm, for Quick Coupling	
03.113.022	Centering Sleeve, percutaneous, for Kirschner Wire ∅ 1.6 mm	
03.113.023	Drill Bit ∅ 2.5 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling	
03.113.024	Drill Bit ∅ 2.8 mm with Stop, calibrated, length 250/225 mm, for Quick Coupling	

03.113.025	Percutaneous Insertion Handle for Aiming Arm, right, for LCP Medial Distal Tibial Plates 3.5, Low Bend	
03.113.026	Percutaneous Insertion Handle for Aiming Arm, left, for LCP Medial Distal Tibial Plates 3.5, Low Bend	
03.113.028	Depth Gauge for Percutaneous Aiming Arm Instruments	
311.431	Handle with Quick Coupling	

319.350	Cleaning Stylet ∅ 1.6 mm, for Cannulated Instruments	
319.460	Cleaning Stylet ∅ 2.8 mm, for Cannulated Instruments	
321.160	Combination Wrench ∅ 11 mm	
323.060	PHILOS Direct Measuring Device for Kirschner Wire ∅ 1.6 mm	

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

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