

LCP Low Bend Medial Distal Tibia Plates 3.5 mm

Anatomic plates with low profile head for distal tibia fractures

Surgical Technique

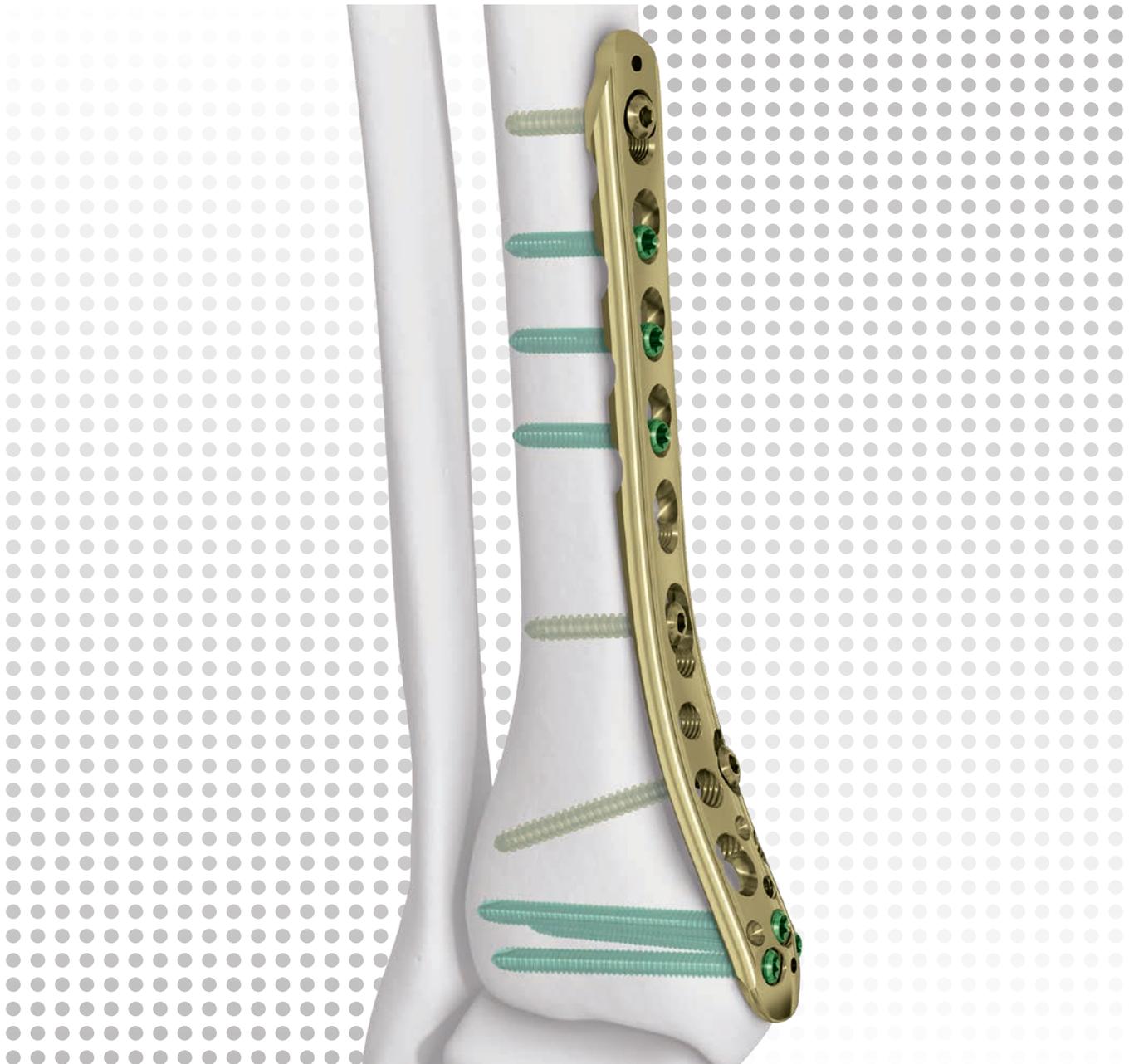


 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

<http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance>

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LCP Low Bend Medial Distal Tibia Plates 3.5 mm

The LCP Low Bend Medial Distal Tibia Plate 3.5 mm is part of the DePuy Synthes Small Fragment 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.

Locking screws provide the ability to create a fixed-angle construct while using standard AO plating techniques. These screws do not rely on plate-to-bone compression to resist patient load.

■ **Note:**

For information on fixation principles using conventional and locked plating techniques, please refer to the LCP Locking Compression Plate Surgical Technique.



Plate overview

- Head of plate is low profile
- 3.5 mm cortex and 4.0 mm cancellous bone screws sit flush with plate in the nonlocking portion of distal combi-holes
- Limited-contact shaft profile
- Available in stainless steel or titanium

Combi-holes in the shaft and head accept the following:

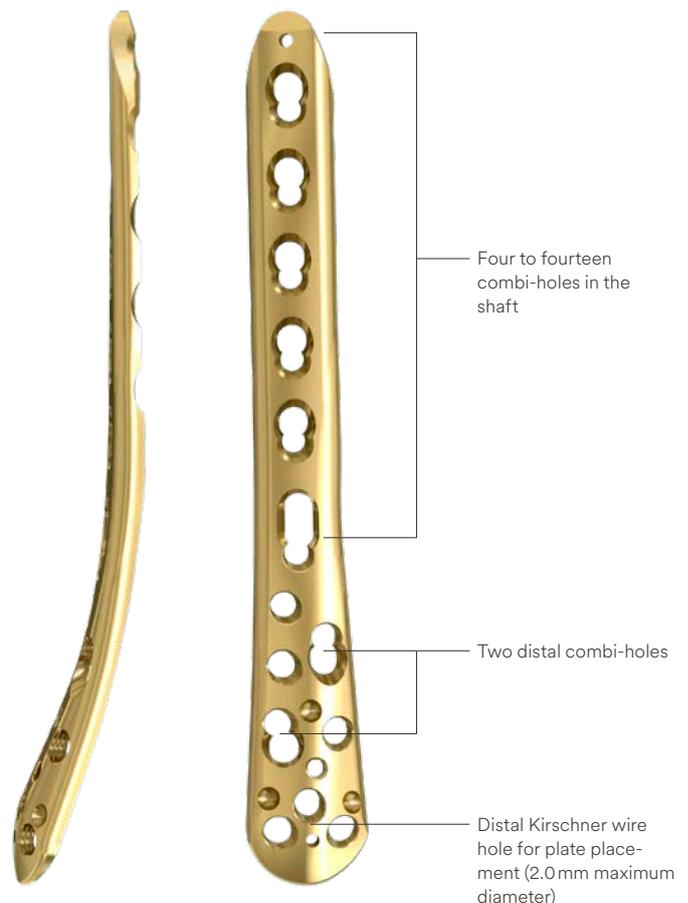
- 3.5 mm cortex screws
- 3.5 mm locking screws
- 4.0 mm cancellous bone screws

Six round locking holes in the head accept the following:

- 2.7 mm cortex screws
- 3.5 mm cortex screws
- 3.5 mm locking screws
- 4.0 mm cancellous bone screws



Three distal locking screws diverge across subchondral bone and are parallel to joint



Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

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, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991

² Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Preparation

Complete the preoperative radiographic assessment and prepare the preoperative plan. Determine plate length and instruments to be used.

Position the patient supine on a radiolucent operating table.

Required set

3.5 mm LCP Low Bend Medial Distal Tibia Plates set

01.112.062	LCP Medial Distal Tibia Low Bend Plates 3.5 (Titanium), in Modular Tray, Vario Case System
01.112.063	LCP Medial Distal Tibia Low Bend Plates 3.5 (Stainless Steel), in Modular Tray, Vario Case System

Modular small fragment instrument trays*

68.122.013	Modular Small Fragment Basic Instruments, size 1/2, without Contents, Vario Case System
68.122.015	Modular Small Fragment 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.

▲ WARNING:

The direction of locking screws is predetermined by the design of the plate. If manual contouring is necessary, verify new screw angles using the screw placement verification technique on section.

Optional modular small fragment Instrument trays

68.122.019	Modular 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

Additionally available

117.700	Instrument Set for Large Distractor
321.120	Tension Device, articulated, span 20 mm

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

Reduction

Reduce articular surface

Approach

An open or a percutaneous approach may be used depending on the fracture.

Reduction

■ Note:

Application of an external fixator or large distractor may facilitate visualization and reduction of the joint.

Reduce the fracture fragments and confirm reduction using image intensification. Methods of stabilizing reduction include the following:

- Independent Kirschner wires
- Kirschner wires through the plate
- Independent lag screws
- Lag screws through the plate
- Locking screws through the plate

Locking screws do not provide interfragment compression; therefore, any desired compression must be achieved with standard lag screws. The articular fractures must be reduced and compressed before fixation of the 3.5 mm LCP low bend medial distal tibia plate with locking screws.

▲ Precautions:

- To verify that independent lag screws will not interfere with plate placement, evaluate placement intraoperatively with AP and lateral fluoroscopic images.
- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.



Plate Insertion

1. Insert plate

Percutaneous insertion

For a percutaneous approach, make an incision to access the medial malleolus and slide the plate under the soft tissue.

■ Note:

Thread a bending pin or LCP drill guide into one of the distal holes as a handle for percutaneous insertion.

Open insertion

Open the area as necessary to expose the joint. Carefully push the plate under the soft tissue for placement on the shaft.

Center the plate on the medial malleolus.

▲ Precaution:

When choosing a percutaneous approach take care not to damage the saphenous nerve or saphenous vein.



Saphenous vein (blue)
Saphenous nerve (yellow)

2. Position plate and fix provisionally

- After plate insertion, check alignment on the bone using fluoroscopy. Make any adjustments before inserting screws.

Note:

This locking plate is contoured 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 section.

Optional instrument

324.024 Instrument for temporary reduction

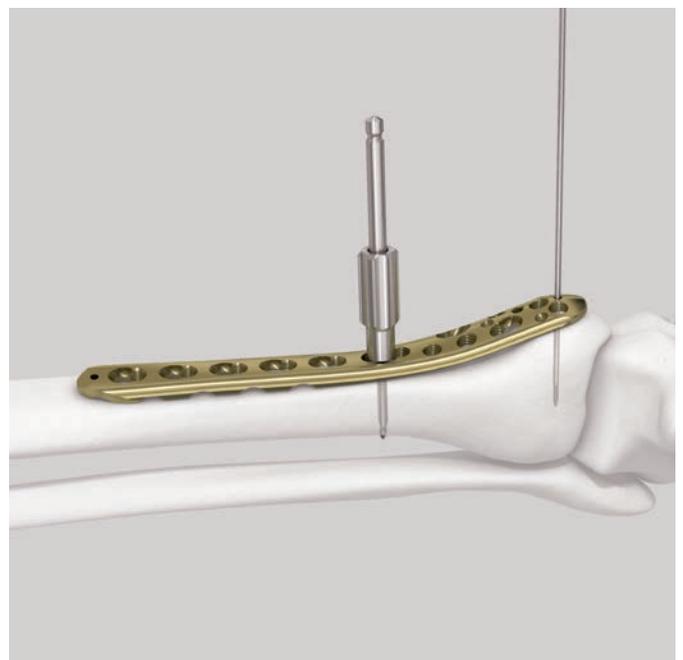
The plate may be temporarily held in place using any of the following options:

- Instrument for temporary reduction (push-pull reduction device)
- 4.0mm 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 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 the locking screws are inserted, further reduction is not possible without loosening the locking screws.



Optional: Screw placement verification technique

Instruments

X92.710	Kirschner Wire Ø 1.6 mm with threaded tip, length 150/5 mm
310.284	LCP Drill Bit Ø 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling
323.027	LCP Drill Sleeve 3.5, for Drill Bits Ø 2.8 mm
323.055	Centering Sleeve for Kirschner Wire Ø 1.6 mm, length 70 mm, for Nos. 323.027 and 323.054
323.060	PHILOS Direct Measuring Device for Kirschner Wire Ø 1.6 mm

X=2: Stainless Steel
X=4: Titanium

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



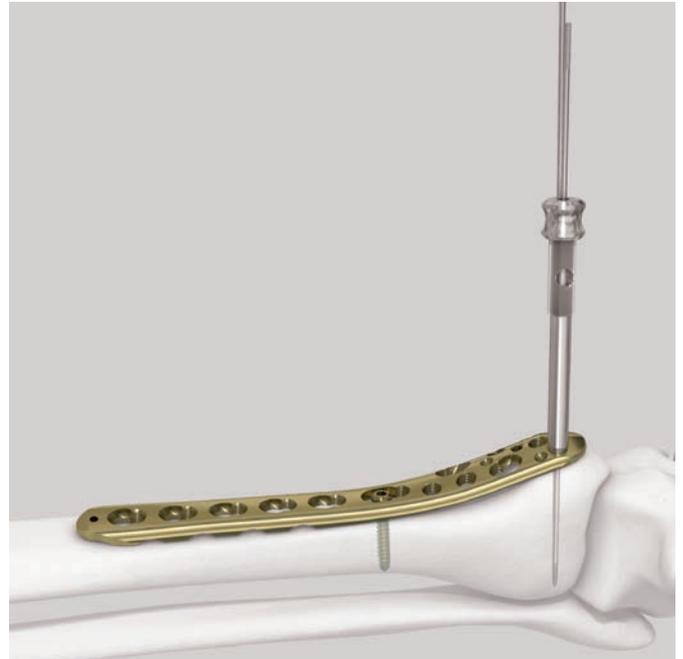
Thread a 3.5 mm LCP drill sleeve into the desired locking hole and insert the 1.6 mm centering sleeve for Kirschner wire into the drill guide.

Insert a 1.6 mm threaded Kirschner wire through the centering sleeve and drill to the desired depth.

- ① 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.



Optional: Screw placement verification technique

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

Remove the direct measuring device, Kirschner wire and 1.6mm wire sleeve, leaving the threaded drill guide in place.

Use the 2.8mm drill bit to drill. Remove the drill guide. Insert the appropriate length locking screw.



Screw Insertion

1. Insert distal screws

Instruments

310.284	LCP Drill Bit Ø 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling
323.027	LCP Drill Sleeve 3.5, for Drill Bits Ø 2.8 mm
311.431	Handle with Quick Coupling
314.115	Screwdriver Stardrive 3.5, T15
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling
314.070	Screwdriver, hexagonal, small, Ø 2.5 mm, with Groove
314.030	Screwdriver Shaft, hexagonal, small, Ø 2.5 mm
319.010	Depth Gauge for Screws Ø 2.7 to 4.0 mm, measuring range up to 60 mm
511.770	Torque Limiter, 1.5 Nm, for Compact Air Drive and for 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. The two combi-holes in the plate head accept 3.5mm cortex, 3.5mm locking or 4.0mm cancellous bone screws. When using a cortex or cancellous bone screw in these combi-holes, the screwhead will be recessed in the hole.

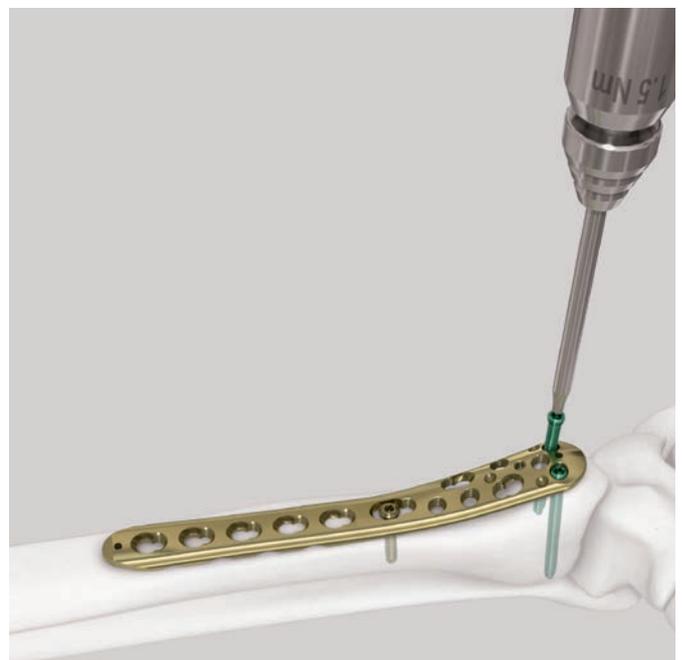
Thread the 3.5mm LCP drill guide into a distal locking hole until fully seated.

Use the 2.8mm drill bit to drill to the desired depth.

Remove the drill guide. Insert the locking screw under power, using the torque limiting attachment and a corresponding screwdriver shaft, or insert manually, using a corresponding screwdriver. Be sure the plate is held securely to the bone to prevent plate rotation as the screw is locked to the plate.

■ Notes:

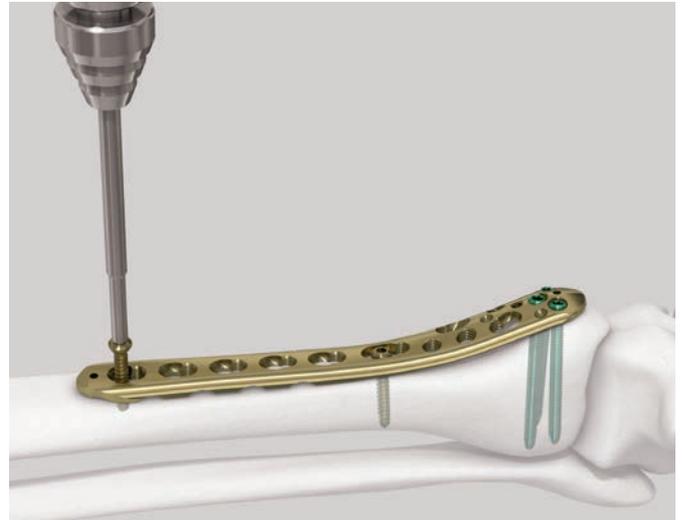
- When using the torque limiting attachment, the screw is securely locked into the plate when a “click” is heard.
- Always use a torque limiting attachment when using power with a screwdriver shaft.



2. Insert screws in shaft

If using the threaded portion of the combi-holes, repeat the steps as described for distal locking screw insertion.

For non-locking screws, use the standard AO screw insertion technique.



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.

* Can be placed in Modular Small Fragment Screw Insertion Tray (68.122.015).

Implants

Sets and Plates

Sets

3.5 mm LCP Low Bend Medial Distal Tibia Plate sets

01.112.062	LCP Medial Distal Tibia Low Bend Plates 3.5 (Titanium), in Modular Tray, Vario Case System
01.112.063	LCP Medial Distal Tibia Low Bend Plates 3.5 (Stainless Steel), in Modular Tray, Vario Case System

Plates

3.5 mm LCP Low Bend Medial Distal Tibia Plates, right

Stainless Steel	Titanium	Holes	Length (mm)
02.112.510	04.112.510	4	109
02.112.514	04.112.514	6	135
02.112.518	04.112.518	8	161
02.112.522	04.112.522	10	187
02.112.526	04.112.526	12	213
02.112.530	04.112.530	14	239

3.5 mm LCP Low Bend Medial Distal Tibia Plates, left

Stainless Steel	Titanium	Holes	Length (mm)
02.112.511	04.112.511	4	109
02.112.515	04.112.515	6	135
02.112.519	04.112.519	8	161
02.112.523	04.112.523	10	187
02.112.527	04.112.527	12	213
02.112.531	04.112.531	14	239

■ Note:

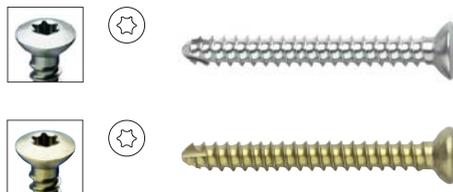
All plates are also available in sterile. Add suffix "S" to article number to order sterile product.

Screws

Cortex Screws 2.7 mm

X02.870– Cortex Screw Stardrive Ø 2.7 mm,
X02.969 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

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

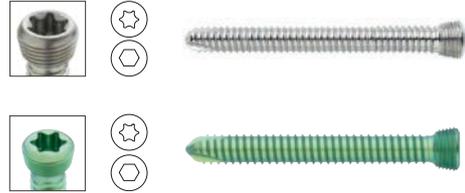


X=2 Stainless Steel
X=4 Titanium

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 Ø 3.5 mm, self-tapping, length 10–65 mm
or	
X13.010– X13.060	Locking Screw Ø 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 Ø 4.0 mm, fully threaded, length 10–60 mm
X07.010– X07.060	Cancellous Bone Screw Ø 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.

Instruments

292.710	Kirschner Wire \varnothing 1.6 mm with threaded tip, length 150/5 mm, Stainless Steel	
310.284	LCP Drill Bit \varnothing 2.8 mm with Stop, length 165 mm, 2-flute, for Quick Coupling	
311.431	Handle with Quick Coupling	
314.030	Screwdriver Shaft, hexagonal, small, \varnothing 2.5 mm	
314.070	Screwdriver, hexagonal, small, \varnothing 2.5 mm, with Groove	
314.115	Screwdriver Stardrive 3.5, T15	
314.116	Screwdriver Shaft Stardrive 3.5, T15, self-holding, for AO/ASIF Quick Coupling	

319.010 Depth Gauge for Screws \varnothing 2.7 to 4.0 mm, measuring range up to 60 mm



323.027 LCP Drill Sleeve 3.5, for Drill Bits \varnothing 2.8 mm



323.055 Centering Sleeve for Kirschner Wire \varnothing 1.6 mm, length 70 mm, for Nos. 323.027 and 323.054



323.060 PHILOS Direct Measuring Device for Kirschner Wire \varnothing 1.6 mm



324.024 Instrument for temporary reduction



511.770 Torque Limiter, 1.5 Nm, for Compact Air Drive and for Power Drive



511.773 Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling



MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F 2119

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

Radio-Frequency-(RF-)induced heating according to ASTM F 2182

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

▲ Precautions:

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

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

Not all products are currently available in all markets.
This publication is not intended for distribution in the USA.
Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.
All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu



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