TomoFix

Application Notes

approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY 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 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

Table of Contents

■ **Notes**
▲ **Precautions**
▲ **WARNINGS**

Introduction

This document explains the use of Tomofix implants and instruments, and provides ordering information.

A separate AO/ASIF Application Note – the use of TomoFix medial high tibia include further details on planning and performing osteotomies.

■ Note:

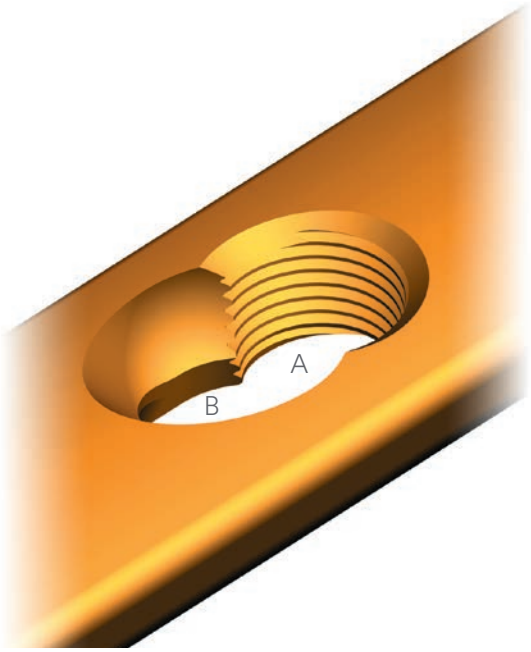
A thorough introduction to the application of LCP has to precede the use of TomoFix.
The surgeon has to be familiar with LCP principles.

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

Overview

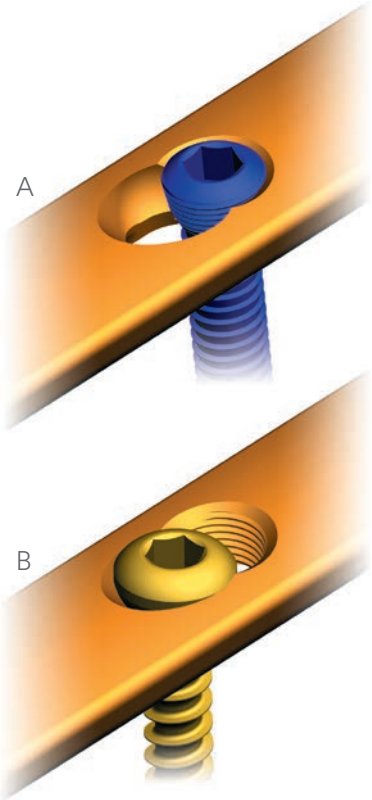
The LCP hole consists of two parts:

A Conical thread hole with Locking Head Screw (LHS) insertion (see internal fixator)
B Dynamic Compression Unit (DCU) with standard screw insertion, similar to DCP



■ Note:

If the first screw to be inserted is a Locking Head Screw, it is important to ensure that the plate demonstrates good temporary fixation. Otherwise, the plate rotates when locking the screw, and might cause soft-tissue injuries. When removing the plate, it is strongly recommended to manually unlock all screws first, and only remove them as a second step.
Always use the Torque-limiting Screwdriver (324.052) to lock the LHS.



The AO Principles of Fracture Management

Mission

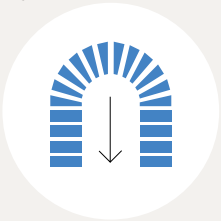
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.



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

3.

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

4.

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

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

TomoFix medial high tibia

The Tomofix medial proximal tibial head plate (440.834) is anatomically contoured to the tibia. The radius (R) of the proximal T-bar is curved and the plate holes A, B and C are angled at 10° (Fig. 4) with respect to the plate shaft. The plate is 3.0 mm thick and has a tapered plate end. LCP shaft holes 1 to 4 and hole D can be used with LHS and/or standard screws.

Holes A, B, and C are for use with LHS.

The plate is made of commercially pure titanium.

The TomoFix medial proximal tibial head plate is also available in a smaller version (440.831).

■ Note:

When making a decision about using the small plate (440.831) several factors have to be taken into consideration: osteotomy size and type, body weight, post-operative weight-bearing scheme and patient's compliance to this, and patient's healing capacity.

The small version of the TomoFix Medial High Tibial Plate does not reach the same degree of stability as the standard plate.

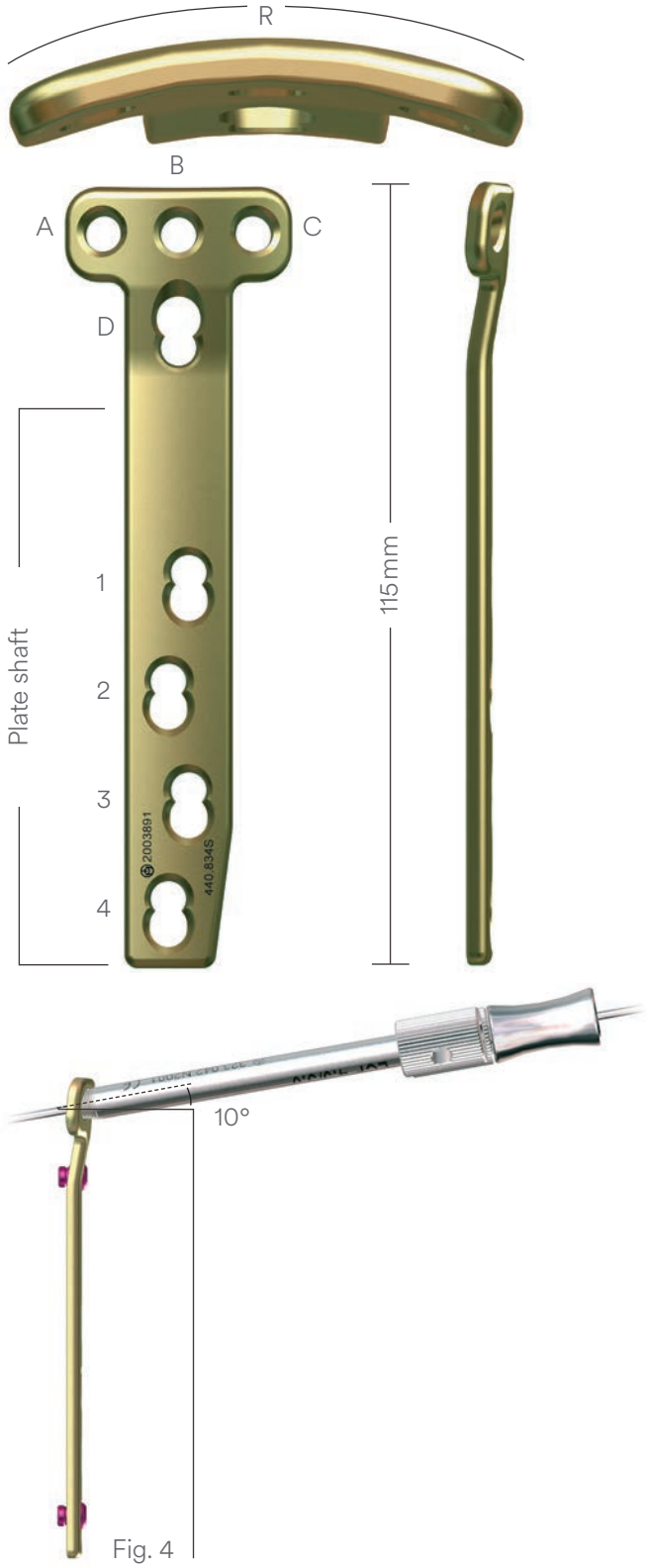


Fig. 4

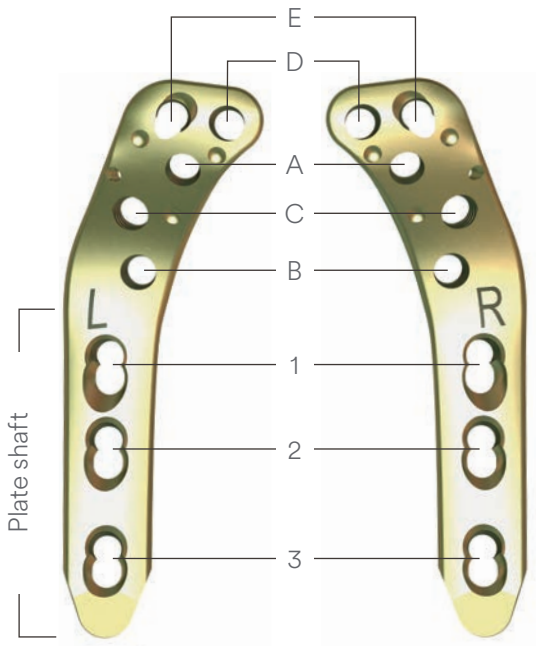
TomoFix Plates are available nonsterile and sterile packed.
For sterile implants, add suffix S to article number.

TomoFix lateral high tibia

The Tomofix lateral tibial head plates proximal are available in right (440.843) and left (440.853) version. Plate thickness is between 3.1 and 4.5 mm and has a tapered plate end.

The plates are made of Titanium Alloy (TAN).

Hole E can be used with LHS or standard screw.
Holes A, B, C, D can be used with LHS.
LCP shaft holes 1–3 can be used with LHS and/or standard screws.



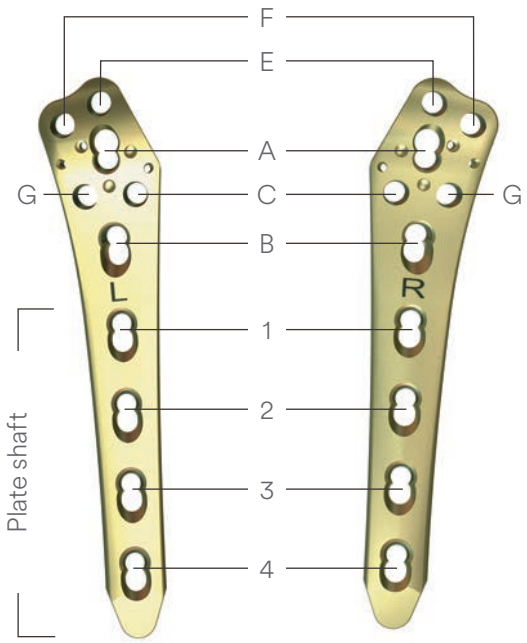
TomoFix Plates are available nonsterile and sterile packed.
For sterile implants, add suffix S to article number.

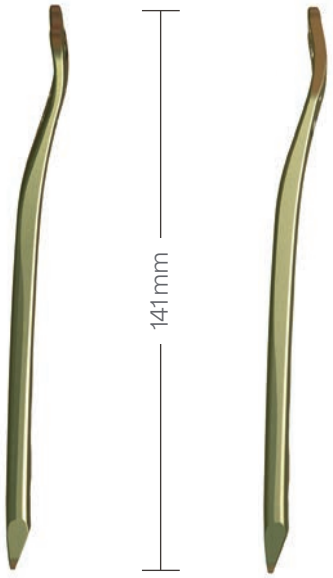
TomoFix lateral distal femur

The Tomofix lateral distal femoral plates are available in right (440.864) and left (440.874) version. Plate thickness is between 3.0 mm and 5.5 mm and has a tapered plate end.

The plates are made of Titanium Alloy (TAN).

LCP holes A, B and shaft holes 1–4 can be used with LHS and/or standard screws. Holes C, E, F and G can be used with LHS.





TomoFix Plates are available nonsterile and sterile packed.
For sterile implants, add suffix S to article number.

Instruments

TomoFix Guiding Block for TomoFix medial proximal Tibial Head Plate (312.926)

Tomofix Guiding block for Tomofix medial proximal Tibial Head plate is used to thread the LCP Drill sleeve (323.042) into holes A, B, C and D of Tomofix medial high tibia (440.834).

TomoFix Guiding Block for TomoFix medial proximal Tibial Head Plate small stature plate (312.924)

TomoFix Guiding Block for Tomofix medial proximal Tibial Head Plate small stature plate is used to thread the LCP Drill Sleeve (323.042) into holes A,B,C and D of TomoFix medial proximal Tibial Head Plate, small (440.831).

TomoFix Guiding Blocks for TomoFix lateral proximal Tibial Head Plates, right (312.930) and left (312.931)

Tomofix Guiding Blocks for TomoFix lateral proximal Tibial Head plates, right and left is used to thread the LCP Drill sleeve (323.042) into holes A, B, C, D and E of the Tomofix lateral proximal Tibial head plates, right (440.843) and left (440.853).

The locking nut can be removed for cleaning.

TomoFix Guiding Blocks for TomoFix Femoral Plate, lateral distal right (312.932) and left (312.933)

Tomofix Guiding Blocks for TomoFix Femoral plate, lateral distal right and left is used to thread the LCP Drill Sleeve (323.042) into holes A, B, C, D, E, F and G of the Tomofix lateral distal Femoral Plates, right (440.864) and left (440.874).

The locking nut can be removed for cleaning.

Centering Sleeve for Kirschner Wires 2.0 mm (324.168)

Enables a centric insertion of Kirschner wires up to 2.0 mm in diameter into threaded LCP drill guides.

Bone Spreader, soft lock, width 8 mm, length 220 mm (399.097)

Facilitates adjustment of the correction, and keeps osteotomy gap open (open-wedge osteotomy).

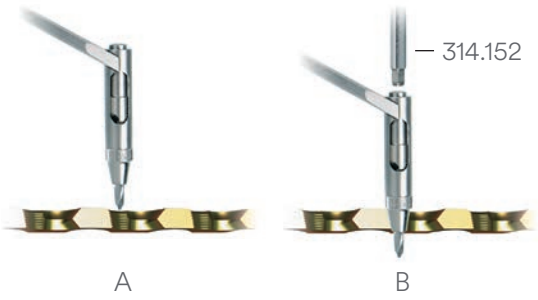
The instruments described below are used for Locking Head Screws or specifically applied in the LCP 4.5/5.0 systems. Except for the DCP Drill Guides (322.440 and 322.430) and the LC-DCP Drill Guide (323.450), the current large fragment system instruments are still required.

LCP 4.5/5.0 Standard Instruments

LCP Universal Drill Guide 4.5/5.0 (323.500)

On one side, the universal drill sleeve consists of a 3.2 mm universal drill sleeve allowing centric and eccentric pre-drilling with the 3.2 mm drill bit for 4.5 mm cortex screws. The other side has a short integrated 4.3 mm drill bit permitting centric pre-drilling of the cortex for self-drilling 5.0 mm Locking Head Screws.

A Place the conical part into the threaded part of the LCP combination hole and center it.
B Use the power tool and the self-retaining Screwdriver Shaft (314.152) to drill through the first cortex.



The Centering hole supports locking of the self-drilling LHS in the plate.

Maintenance and cleaning

The universal drill sleeve can be disassembled for cleaning. The lock on the drill-bit side has a left-handed thread. For this reason, turn it clockwise to open it.

Replace drill bit tip as soon as signs of wear become visible.

LCP Drill Bit, ∅ 4.3 mm with Stop, length 221 mm, 2-flute, for Quick Coupling (310.430)

Use the 4.3 mm drill bit to drill the hole for the self-tapping 5.0 mm LHS.

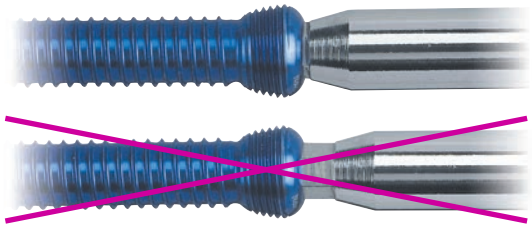
LCP Drill Sleeve 5.0, for Drill Bits ∅ 4.3 mm (323.042)

The threaded drill guide permits centric and orthogonal drilling with the 4.3 mm drill bit.

Screwdriver Shaft 3.5, hexagonal, self-holding (314.152)

Use a power tool to insert the Locking Head Screws (LHS). However, avoid locking the screws by power tool, as its maximum torque is higher than the recommended tightening moment of the LHS. Always use the Torque-limiting Screwdriver (324.052) for final tightening.

To prevent damage to the hexagonal recess of the screw, be careful to ensure that the screwdriver sits properly in the screw head.



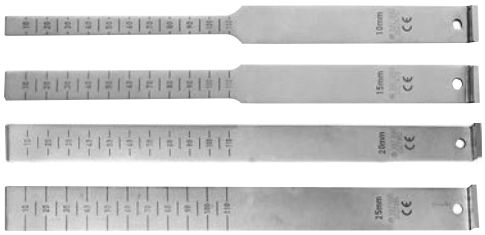
Torque-limiting Screwdriver, 3.5 self-holding, for Locking Screws ∅ 5 mm (324.052)

Use the torque-limiting screwdriver to lock the 5.0 mm Locking Head Screws (LHS). It facilitates tightening to the nominal torque and potentially prevents excessive tightening of the LHS.

Optional Instruments

TomoFix Osteotomy Chisels (397.992–397.995)

Use the Osteotomy Chisels for performing an osteotomy.

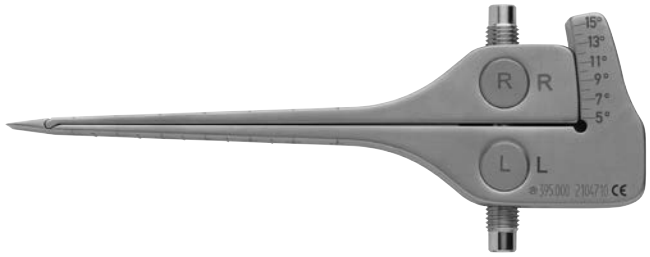


Tension Device, articulated, span 20 mm (321.120)

Use the Tension Device to achieve osteotomy gap compression when performing closing-wedge osteotomies.

TomoFix Bone Spreader (395.000)

Use the Bone Spreader for opening an open-wedge osteotomy

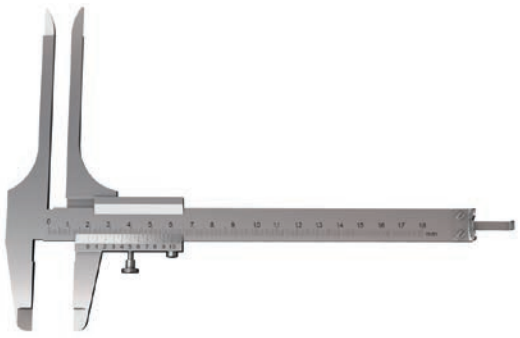


TomoFix Osteotomy Gap Measuring Device, Stainless Steel (395.001)

Use the Osteotomy Gap Measuring Device for measuring the opening height of opening-wedge osteotomies.

Calliper for Corpectomy, short, Stainless Steel (324.060)

Use the Calliper for measuring the wedge height of closing-wedge osteotomies or the opening height of opening-wedge osteotomies.

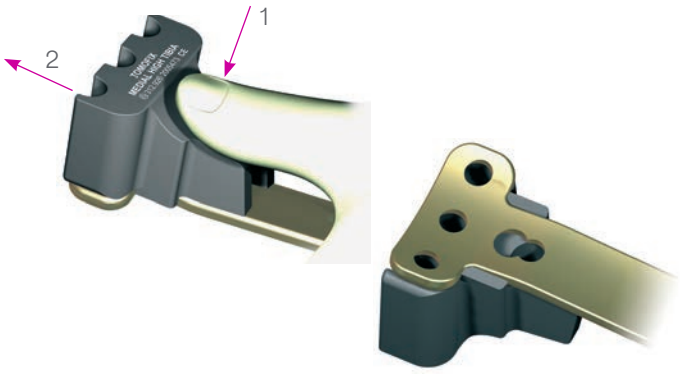


Medial High Tibia Application

Implant preparation

Place the underside of the Guiding Block (312.926 for standard plate, 312.924 for small plate) onto the shaft of the plate back. Lateral guiding facilitates correct positioning.

Use the thumb (1) to push the guiding block as far as possible in direction of the proximal plate end (2).



Screw the first threaded LCP Drill Sleeve (323.042) into the middle plate hole (B). Use the thumb to hold the guiding block in the correct position on the plate.

To continue the implant preparation, screw threaded LCP drill guides into the proximal plate holes A and C.

Place LCP Spacers ∅ 5.0 mm (413.309) into holes D and 4.

Determine osteotomy position

Plan osteotomy type and position. The TomoFix medial high Tibial Plate is indicated for fixation of osteotomies of the proximal tibia.

Mark the osteotomy position by placing two parallel 2.5 mm Kirschner wires along the osteotomy plane. For closing-wedge osteotomies, the definition of a proximal and a distal osteotomy plane is necessary in order to form a wedge. The wires must end exactly at the opposite cortex. The osteotomy should end approximately 15 mm before the opposite cortex in order to leave a bony hinge (important for the next step). Use fluoroscopic control to check correct insertion of the Kirschner wires.

The following illustrations show examples of opening-wedge osteotomies.

■ Note:

When placing the two wires, it is important to ensure that there is sufficient space for all plate screws.

Biplanar Osteotomy

Perform osteotomy according to the preoperative plan. Kirschner wires serve as a guide for the saw blade. Transverse osteotomy should run across the posterior two thirds of the bone, leaving the ventral third intact for performing a second, ascending osteotomy in the coronal plane (biplanar technique).

Protect anatomical structures dorsal to posterior bone surface with a Hohmann retractor. Perform the entire sawing procedure slowly, with very little pressure and constant cooling of the saw blade by irrigation. When the planned depth is achieved in the posterior two thirds of the bone, perform the anterior ascending saw cut with a thin saw blade. The ascending cut consists of a complete osteotomy including the opposite cortex.

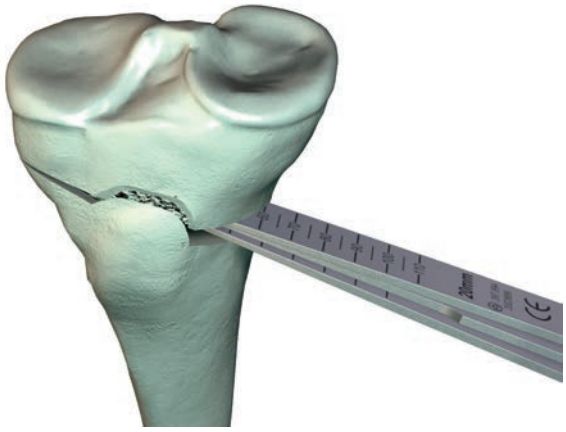
■ Note:

Observe caution with neurovascular structures. Saw slowly and maintain full control since the blade could deviate into the back of the knee, and always use a sharp saw blade.

After performing the osteotomy, close the osteotomy carefully by applying continuous pressure to the lateral lower limb while stabilizing the knee joint region (closing-wedge osteotomy), or open the osteotomy by using one of the techniques described in the following section (opening-wedge osteotomy). This may take several minutes.

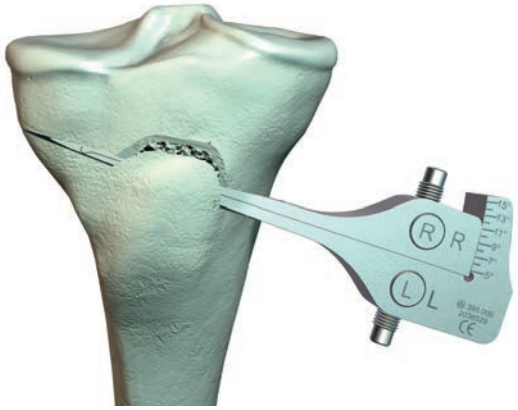
Techniques for performing an opening-wedge osteotomy

Insert an osteotomy chisel into the transverse osteotomy up to the lateral bony bridge. Insertion depth corresponds to cutting depth; mark it on the first osteotomy chisel. Then slowly hammer in a second osteotomy chisel distally to the first chisel around 10 mm less deep than the first chisel. If necessary, continue with a third, fourth and fifth between the two first chisels, thereby gradually spreading the osteotomy until the desired opening height is reached. Monitor the width of the osteotomy gap during the opening procedure using a caliper. Open the osteotomy slowly over a period of several minutes in order to prevent fracturing of the opposite cortex.



Alternative technique:

Alternatively, the TomoFix Bone Spreader (395.000) can be used for spreading the osteotomy and measuring the gap opening in degrees. Use at least two chisels to gain an initial osteotomy gap. Remove chisels and carefully hammer in the TomoFix Bone Spreader until it reaches the hinge. To avoid any inaccuracies, the spreader must be inserted absolutely parallel to hinge. Osteotomy depth can be read from the scale on the spreader blades. To open, slowly turn the screw spindle with a screwdriver clockwise until the desired value in degrees is reached. Countercheck correction either with a caliper, radiologically with the alignment rod as described in handling technique, or a cable.



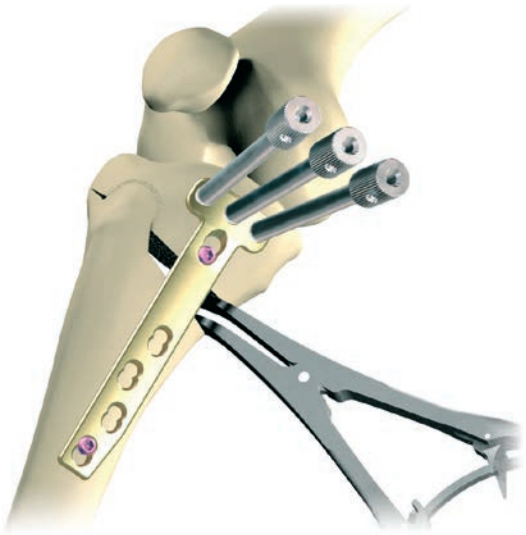
■ Note:

When opening the osteotomy, take special care not to put too much strain on the lateral hinge, to prevent it from breaking.

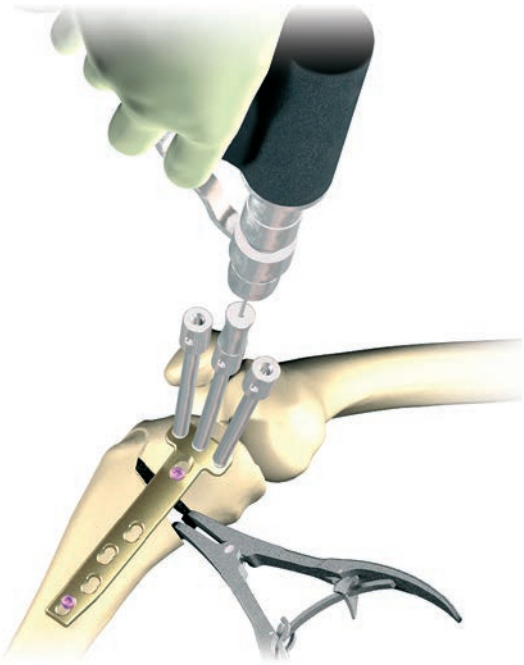
Osteotomy Fixation

After performing and adjusting osteotomy, maintain and finely adjust the correction. In case of an opening-wedge osteotomy, do this using the Bone Spreader (399.097). Be careful to ensure that the ventral and dorsal sides are adjusted identically, if the tibial inclination has to remain unchanged. Osteotomy opening can be measured with the TomoFix Osteotomy Gap Measuring Device (395.001). Therefore, hammer the Gap Measuring Device into the opened osteotomy gap until it is gripped. Then slide the sledge towards the gap until it has reached the cortex. The opening value in millimeters can be read from the scale.

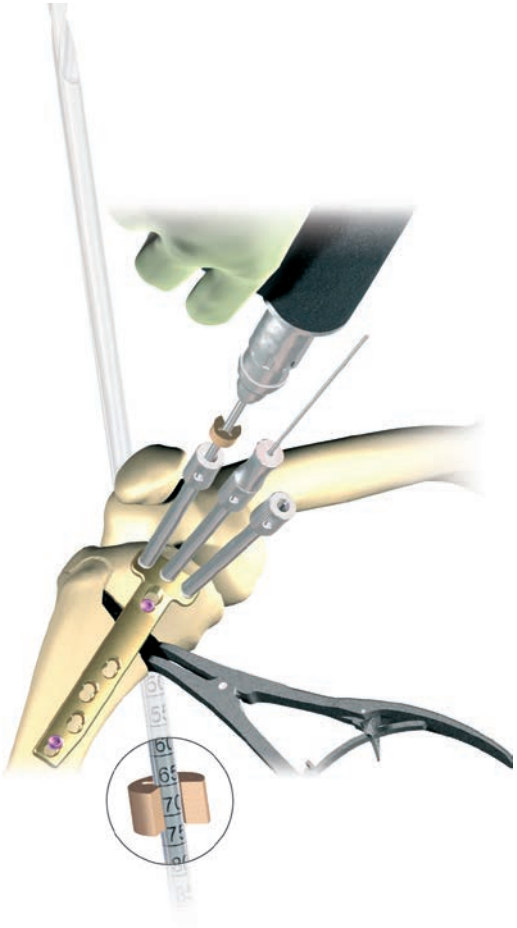
Place the prepared implant centrally on the osteotomy; holes A, B, C, and D will be proximal to the cut.



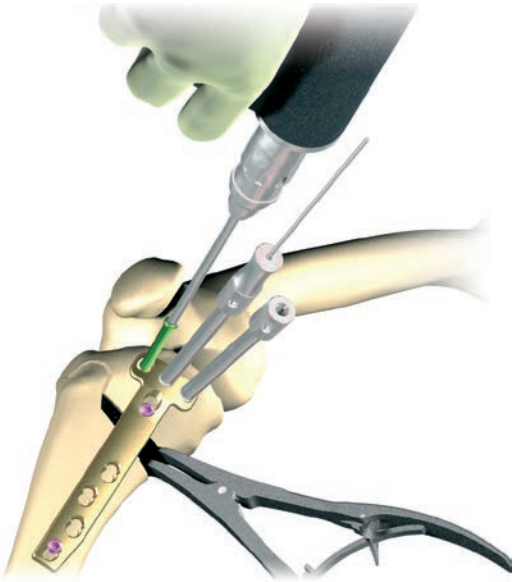
Perform a secure temporary fixation of the plate. Insert the Centering Sleeve for Kirschner Wires ∅ 2.0 mm (324.168) into the middle threaded LCP drill guide and introduce a Kirschner wire. The wire also allows for image-intensifier control of the later screw position. Screw position should be parallel to the articular surface.



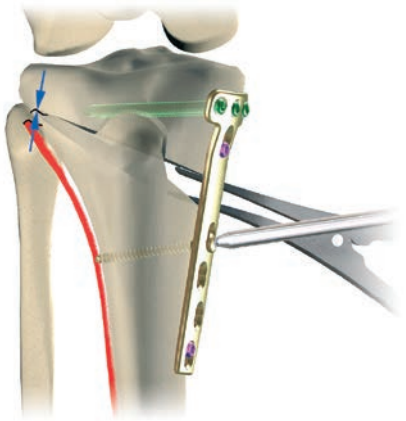
Start plate fixation at the ventral plate hole, analogous to the LCP Application Notes. The LCP Drill Bit ∅ 4.3 mm (310.430) allows direct reading of the drilled depth and/or required screw length.



To ensure support of the tibial plateau, insert the longest possible self-tapping Locking Head Screws (LHS) into holes A, B, and C of the plate. Use the Torque-limiting Screwdriver (324.052) to manually lock the LHS in the plate.



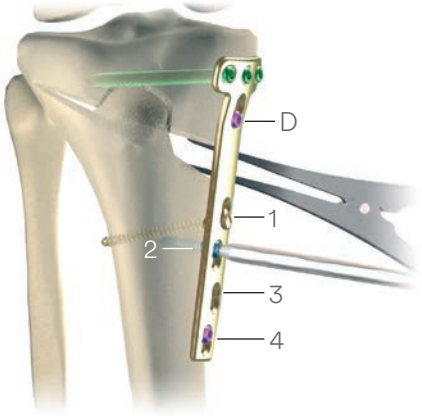
Use a temporary 4.5 mm cortex screw inserted in a neutral position in the dynamic part of the LCP hole 1 to perform an indirect reduction of a displaced tibial shaft in an opening-wedge osteotomy. In the case of a closing-wedge osteotomy, the osteotomy is compressed by placing this 4.5 mm cortex screw in an eccentric position (dynamic compression) through LCP hole 1. Compression can also be achieved by using the Tension Device (321.120). When using the Tension Device, special care must be taken to avoid fracturing the bone by over-compressing the gap.



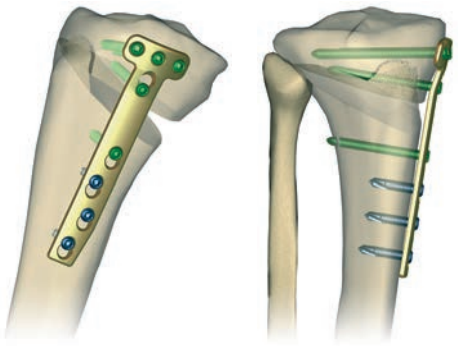
Spacers facilitate adequate distance between plate and periosteum and the pes anserinus which can be moved under the plate.

It is important to carry out this surgical step and ensuing fixation at the tibial shaft, with the leg in full extension.

Start the fixation on the tibial shaft. After having inserted LHS into holes 2 and 3, replace the spacer in hole 4 and the temporary cortex screw in hole 1 with LHS screws.



Occupy all plates holes with LHS to provide correction and fracture stability. In holes 2, 3, and 4 of the plate, a monocortical screw fixation with self-drilling and self-tapping LHS is sufficient, whereas a bicortical self-tapping LHS is recommended for hole 1 distal to the osteotomy. Replace the spacer in hole D through a long self-tapping LHS.



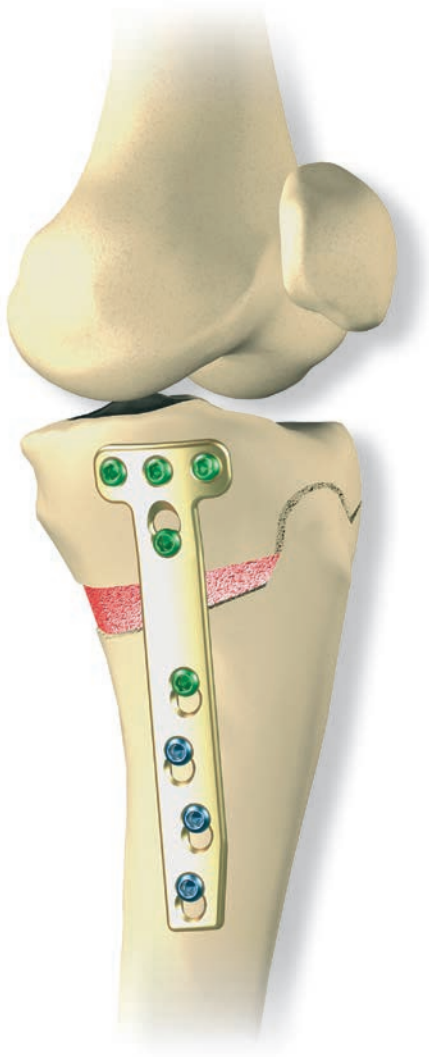
Filling osteotomy gap (opening-wedge osteotomy)

After having achieved a stable fixation, the osteotomy gap of an opening-wedge osteotomy can be filled with chronOS Semi-Circular chronOS Wedge Bone Void Filler. Maximum wedge height in mm corresponds to the wedge angle in degrees (°). Determine the size of the chronOS osteotomy wedge to be used by measuring the osteotomy gap in mm or in degrees. Select a wedge that matches the size of the correction gap or a larger one. Perfuse the chronOS bone substitute with patient blood to ensure optimal remodeling. Use a standard perfusion syringe to perfuse the chronOS wedge with patient blood.

Expel the air from the syringe, close it, and perfuse the enclosed wedge by pumping several times.

Adapt the perfused chronOS osteotomy wedge to the diameter of the gap. Trim the chronOS osteotomy wedges with scalpel, saw, chisel, or Lindenmann reamer.

Wedge the chronOS osteotomy wedge into the osteotomy gap, seating it firmly in the cortical bone of the gap. Remove any projecting chronOS material and insert it into the tapered end of the osteotomy gap.



Individual steps:

- Measure the osteotomy gap
- Select the appropriate chronOS osteotomy wedge
- Perfuse the osteotomy wedge with patient blood
- Adapt the size
- Wedge chronOS bone substitute into the cortical bone of the osteotomy gap
- Remove any projecting chronOS bone substitute (insert fragments into the tapered end of the osteotomy gap)

Lateral High Tibia Application

Implant preparation

Place the underside of the TomoFix Guiding Block (right 312.930, left 312.931) onto the proximal part of the plate. Three-point seating ensures correct positioning.

First, screw a threaded LCP Drill Sleeve (323.042) through the drill guide of the guiding block into hole A of the plate (1). Tighten the locking nut of the guiding block to lock the drill guide (2).

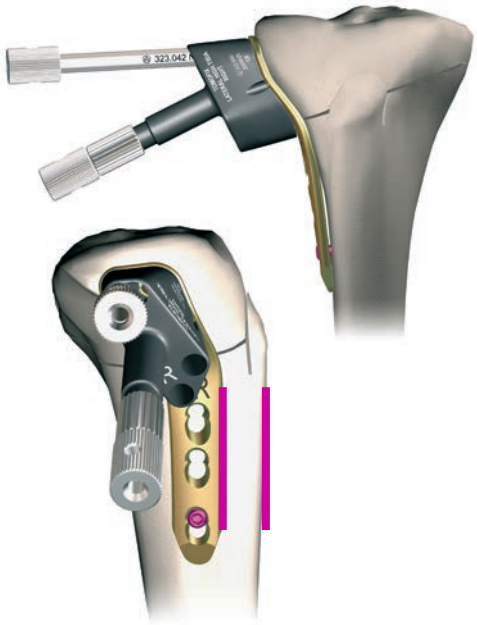
To continue implant preparation, screw a threaded LCP drill guide into an additional proximal plate hole (D or E). Place a LCP Spacer ∅ 5.0 mm (413.309) into hole 3.

Performing osteotomy

Please refer to Techniques for performing an opening-wedge osteotomy section on how to perform and open or close an osteotomy.

Osteotomy fixation

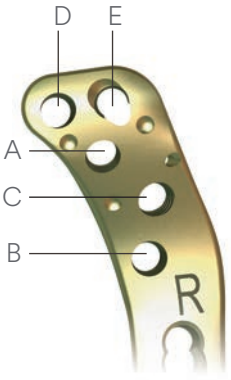
After performing osteotomy, orientate the prepared implant parallel to the tibial shaft, and fix it temporarily. Insert the Centering Sleeve for Kirschner Wire ∅ 2.0 mm (324.168) into the threaded LCP drill guide. At the same time, the Kirschner wire allows for image intensifier control of the later screw position.

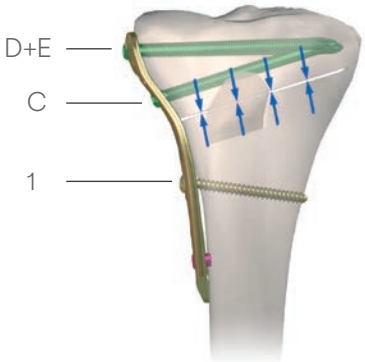


Start TomoFix fixation proximal to the correction gap, analogous to the LCP Application Notes.

For support of the tibial plateau after pre-drilling, insert two long, self-tapping Locking Head Screws (LHS) into holes D and E of the plate. Insert another self-tapping LHS into hole A or C, as desired.

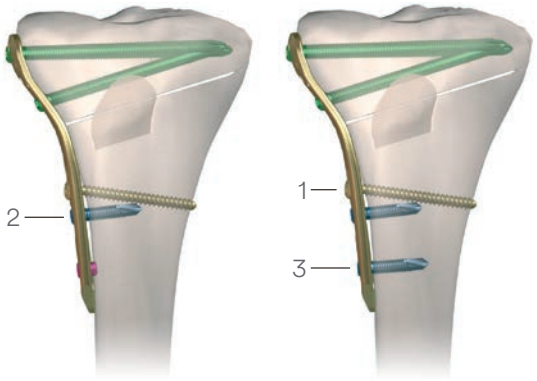
Use a distally-angulated, temporary 4.5 mm cortex screw in hole 1 to compress the cut bone surfaces. The spacer provides distance between the plate and periosteum.





Fix the plate in the shaft area with locking screws.

After having inserted an LHS into hole 2, replace the spacer (hole 3) and the temporary cortex screw (hole 1) with LHS screws.



A complete treatment with absolute stability requires the insertion of three LHS in the proximal part of the osteotomy, as well as the occupation of all plate holes in the plate shaft. Be careful to ensure that the first screw inserted into the distal part of the correction is bicortical. Insert monocortical, self-drilling, self-tapping LHS into the two most distal plate holes.

Lateral Distal Femur Application

Implant preparation

Place the underside of the TomoFix Guiding Block (right 312.932, left 312.933) onto the proximal part of the plate. Three-point seating ensures correct positioning.

Screw a previously-threaded LCP Drill Sleeve (323.042) through the drill guide of the guiding block into hole A of the plate (1). Tighten the locking nut of the guiding block to lock the drill guide (2).

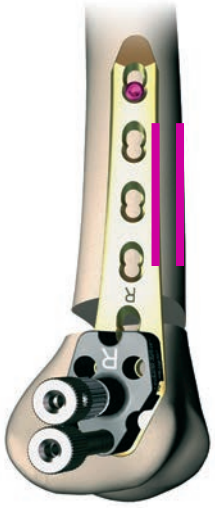
To continue implant preparation, screw a threaded LCP drill guide into an additional proximal plate hole (F or E). Place LCP Spacer ∅ 5.0 mm (413.309) into hole 4.

Performing osteotomy

Please refer to Techniques for performing an opening-wedge osteotomy section on how to perform and open or close an osteotomy.

Osteotomy fixation

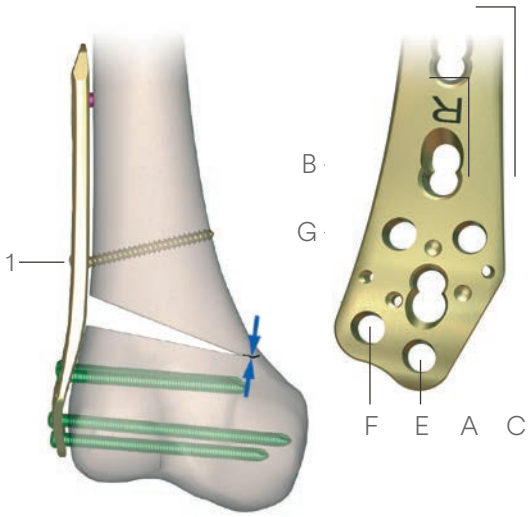
After concluding osteotomy, orientate the prepared implant parallel to the femoral shaft, and fix it temporarily. Insert the Centering Sleeve for Kirschner Wires ∅ 2.0 mm (324.168) into threaded LCP drill guide. At the same time, the Kirschner wire allows for image-intensifier control of the later screw position.



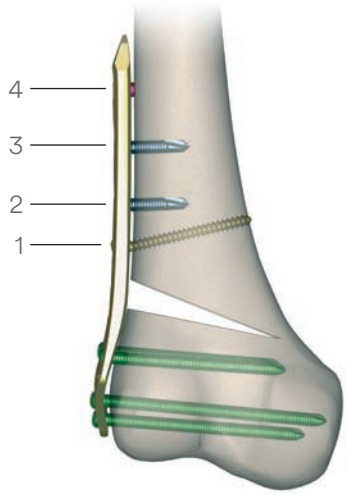
Start the distal fixation of TomoFix according to LCP Application Notes.

After pre-drilling, insert four long, self-tapping Locking Head Screws (LHS) into holes C, E, F, and G.

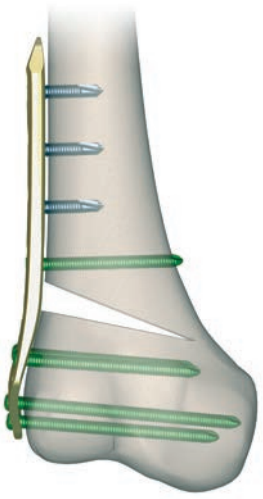
Opening of the correction gap can burst the far cortex. Use a Cranially-ascending, temporary cortex screw in hole 1 to achieve indirect reduction and compression of the fracture. The spacer provides distance between the plate and periosteum.

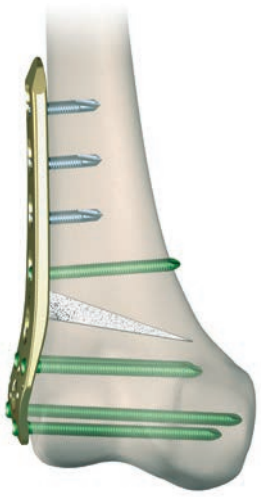


Insert self-drilling, self-tapping LHS monocortically into unoccupied shaft holes (hole 2 and 3) to fix the plate with angular stability. Subsequently, replace the temporary cortex screw (hole 1) and spacer (hole 4) with LHS screws.



A complete treatment with absolute stability requires the insertion of four LHS distal to the correction gap, as well as the occupation of all plate holes proximal to the osteotomy. Insert a long, self-tapping LHS in the hole immediately proximal to the correction gap.

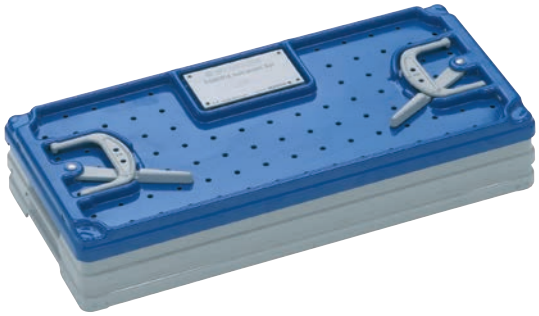


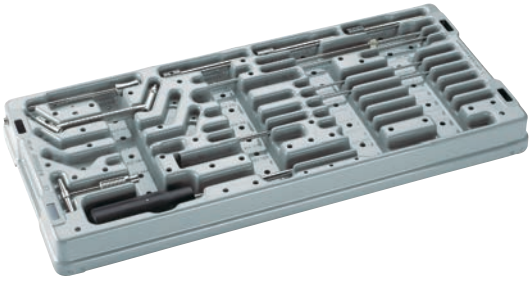


TomoFix Instrument Set

The TomoFix Instrument Set consists of 2 synthetic cases and a lid. The cases can be stacked and locked using the two levers integrated in the lid. Once locked, they form a complete, solid SynCase.

The basic equipment of the TomoFix Instrument Set (171.294) includes only instruments for the use of TomoFix with locking head screws.





Art. Nr.	Description	Units
171.294	TomoFix Instrument Set	
671.294	SynCase for TomoFix Instrument Set	
671.201	Basic Tray for LCP Instruments 4.5/5.0	1
671.203	Case for LCP Instruments 3.0 and 4.5/5.0	1
671.297	Lid to SynCase for TomoFix Instrument Set	1

Instruments

Art. Nr.	Description	Units
312.926	TomoFix Guiding Block for TomoFix Tibial Head Plate, medial, proximal	1
312.930	TomoFix Guiding Block for right TomoFix Tibial Head Plate, lateral, proximal	1
312.931	TomoFix Guiding Block for left TomoFix Tibial Head Plate, lateral, proximal	1
312.932	TomoFix Guiding Block for right TomoFix Femoral Plate, lateral, distal	1
312.933	TomoFix Guiding Block for left TomoFix Femoral Plate, lateral, distal	1
323.042	LCP Drill Sleeve 5.0, for Drill Bits ∅ 4.3 mm	3
324.168	Centering Sleeve for Kirschner Wires ∅ 2.0 mm	1
310.430	DCP Hip Drill Guide 4.5, for neutral and load position	2
314.152	Screwdriver Shaft 3.5, hexagonal, self-holding	1
324.052	Torque-limiting Screwdriver 3.5, self-holding, for Locking Screws ∅ 5.0 mm	1
323.500	LCP Universal Drill Guide 4.5/5.0	1
399.097	Bone Spreader, soft lock, width 8 mm, length 220 mm	1
309.530	Extraction Screw, conical, for Screwsoft lock, width 8 mm, length 220 mm	1
309.504S	HSS Drill Bit ∅ 3.5 mm for Implant Steel, sterile	1

TomoFix Implants

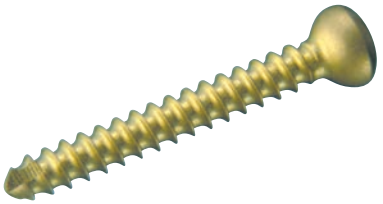
Plates

Art. Nr.	Description	Shaft holes
440.834	TomoFix Tibial Head Plate, medial, proximal, Commercially Pure Titanium	4
440.831	TomoFix Tibial Head Plate, small, medial, proximal, head 4 holes, length 112 mm, Commercially Pure Titanium	4
440.843	TomoFix Tibial Head Plate, lateral, proximal, right, Titanium Alloy (TAN)	3
440.853	TomoFix Tibial Head Plate, lateral, proximal, left, Titanium Alloy (TAN)	3
440.864	TomoFix Femoral Plate, lateral, distal, right, Titanium Alloy (TAN)	4
440.874	TomoFix Femoral Plate, lateral, distal, left, Titanium Alloy (TAN)	4

TomoFix Plates are available nonsterile and sterile packed.
For sterile implants, add suffix S to article number.

TomoFix 4.5/5.0 mm Screw Set

The TomoFix Screw Set consists of a synthetic case and a lid. It accommodates 5.0 mm Locking Head Screws as well as standard large fragment screws.



Art. Nr.	Description	Units
171.298	TomoFix Screw Set ∅ 4.5/5.0 mm in SynCase	
671.298	SynCase for TomoFix (Screw s ∅ 4.5/5.0 mm)	
671.211	Case for LCP Screws ∅ 4.5/5.0 mm	1
679.705	Tray synthetic, with Lid	1
671.285	Lid for No. 671.298	1

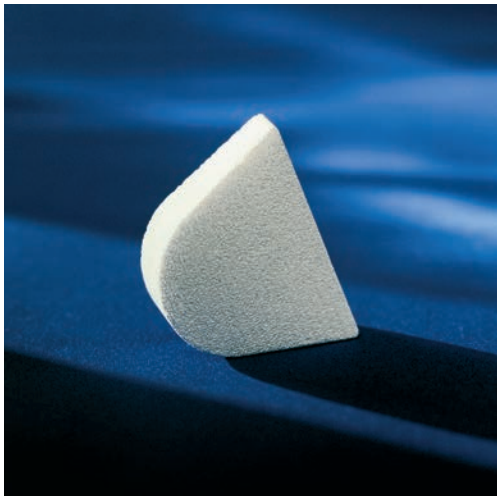
Contents of the TomoFix Screw Set

Art. Nr.	Description	Units
413.426	Locking Screw ∅ 5.0 mm, self-drilling, length 26 mm, Titanium Alloy (TAN)	10
413.336	Locking Screw ∅ 5.0 mm, self-tapping, length 36 mm, Titanium Alloy (TAN)	2
413.340	Locking Screw ∅ 5.0 mm, self-tapping, length 40 mm, Titanium Alloy (TAN)	4
413.344	Locking Screw ∅ 5.0 mm, self-tapping, length 44 mm, Titanium Alloy (TAN)	4
413.350	Locking Screw ∅ 5.0 mm, self-tapping, length 50 mm, Titanium Alloy (TAN)	4
413.355	Locking Screw ∅ 5.0 mm, self-tapping, length 55 mm, Titanium Alloy (TAN)	4
413.360	Locking Screw ∅ 5.0 mm, self-tapping, length 60 mm, Titanium Alloy (TAN)	4
413.365	Locking Screw ∅ 5.0 mm, self-tapping, length 65 mm, Titanium Alloy (TAN)	4
413.370	Locking Screw ∅ 5.0 mm, self-tapping, length 70 mm, Titanium Alloy (TAN)	4
413.375	Locking Screw ∅ 5.0 mm, self-tapping, length 75 mm, Titanium Alloy (TAN)	4
413.380	Locking Screw ∅ 5.0 mm, self-tapping, length 80mm, Titanium Alloy (TAN)	4
413.385	Locking Screw ∅ 5.0 mm, self-tapping, length 85 mm, Titanium Alloy (TAN)	4
413.309	LCP Spacer ∅ 5.0 mm, length 2 mm, Titanium Alloy (TAN)	3
414.824	Cortex Screw ∅ 4.5 mm, self-tapping, length 24 mm, Pure Titanium	2
414.828	Cortex Screw ∅ 4.5 mm, self-tapping, length 28 mm, Pure Titanium	2

414.832	Cortex Screw ∅ 4.5 mm, self-tapping, length 32 mm, Pure Titanium	2
414.836	Cortex Screw ∅ 4.5 mm, self-tapping, length 36 mm, Pure Titanium	2
414.840	Cortex Screw ∅ 4.5 mm, self-tapping, length 40 mm, Pure Titanium	2
414.844	Cortex Screw ∅ 4.5 mm, self-tapping, length 44 mm, Pure Titanium	2
414.848	Cortex Screw ∅ 4.5 mm, self-tapping, length 48 mm, Pure Titanium	2
414.852	Cortex Screw ∅ 4.5 mm, self-tapping, length 52 mm, Pure Titanium	2

chronOS Osteotomy Wedges

Art. Nr.	Description
710.057S	chronOS Wedge, semicircular, 7°, 25 × 35 × 7 mm, sterile
710.060S	chronOS Wedge, semicircular, 10°, 25 × 35 × 10 mm, sterile
710.063S	chronOS Wedge, semicircular, 13°, 25 × 35 × 13 mm, sterile



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

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11

www.depuysynthes.com

SE_836562 AB (DSEM/TRM/0115/0287) EOS: 167029-220120 03/2022

CE
0123