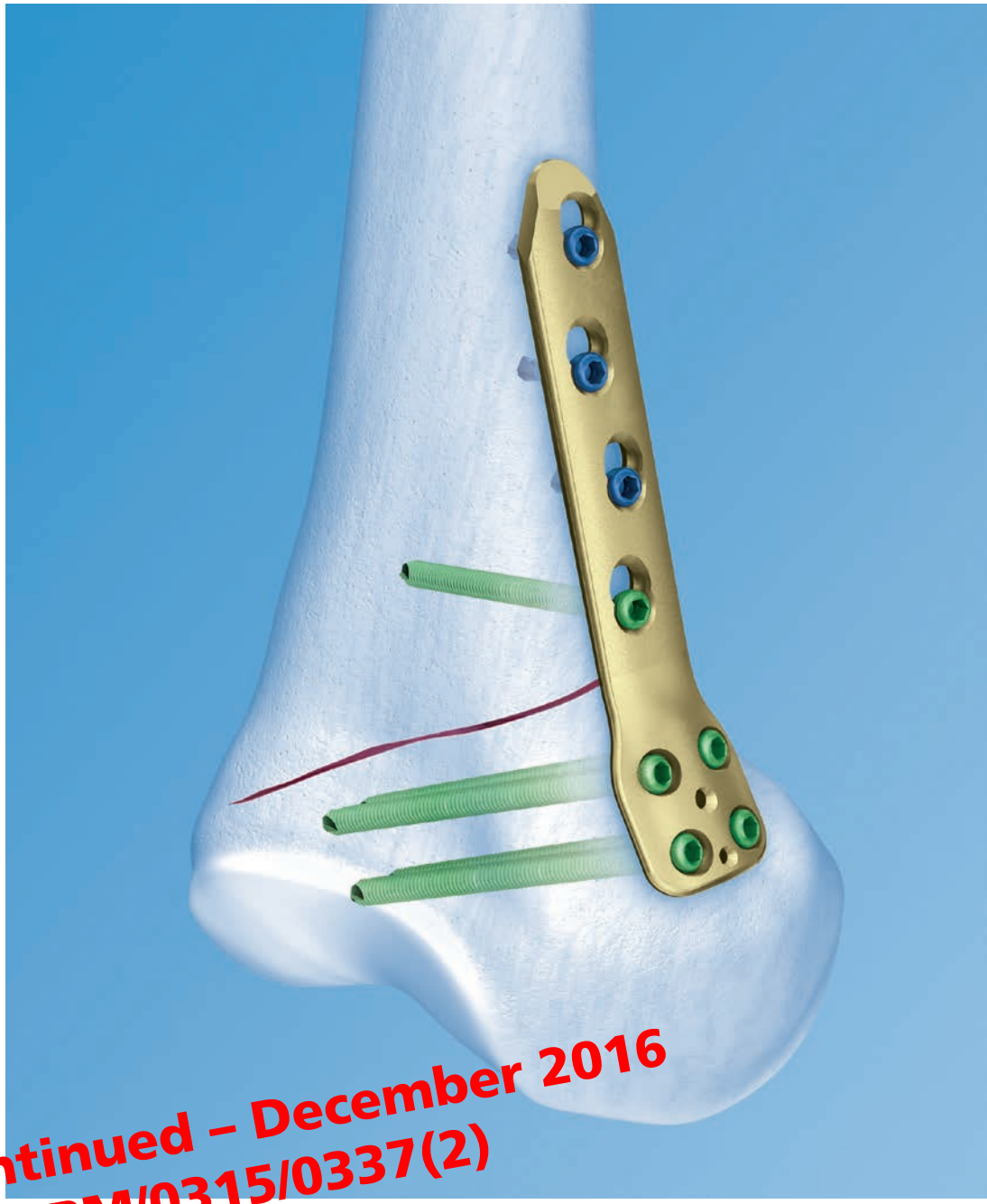
TomoFix Medial Distal Femur (MDF).

For closed-wedge varus femoral osteotomies.

Surgical Technique



Instruments and implants approved by the AO Foundation.

DePuy Synthes
COMPANIES OF Johnson&Johnson

Table of Contents

Introduction	Features and Benefits of the TomoFix Knee Osteotomy System	2
	Osteotomy Principles	3
	Indications and Contraindications	4
Surgical Technique	Preoperative Planning	5
	Osteotomy	8
	Position and Fixation of the Plate	10
	Postoperative Treatment	16
	Implant Removal	16
Product Information	Implants	17
	Instruments	18
Bibliography		19
MRI Information		20

Image intensifier control

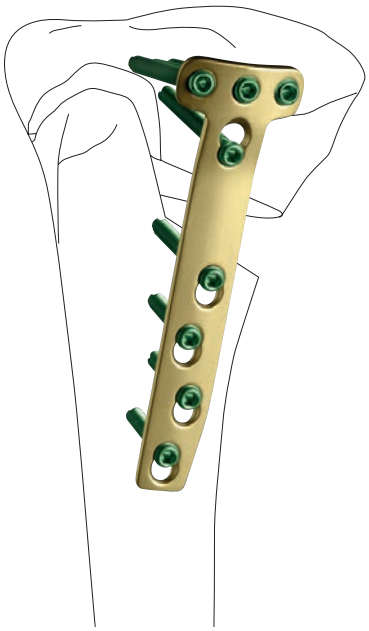
Warning
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

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

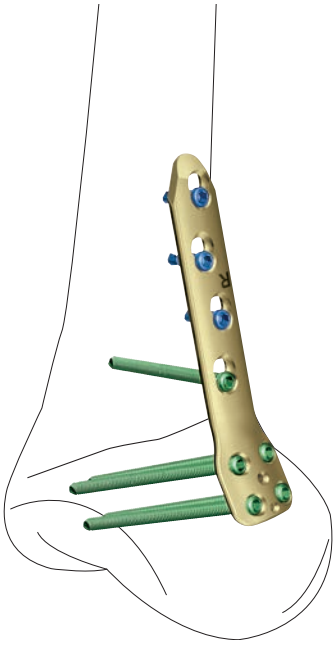
Features and Benefits of the TomoFix Knee Osteotomy System

Angular stability

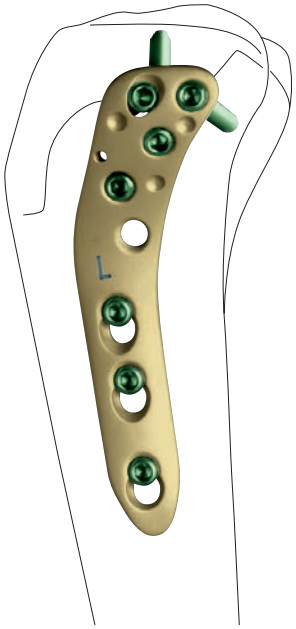
- Improved position of the plate
- Minimally invasive introduction of the plate thanks to tapered shaft end
- Optimised support of the condyle
- Long shaft to support and deflect forces in the diaphysis
- Less risk of a primary and secondary loss of correction
- Reduced impairment of periosteal blood supply due to limited plate-periosteum contact
- Improved retention of the screws in the plate and in the cortical bone
- Stability at all levels



TomoFix tibial head plate medial, proximal
- For open-wedge high tibial osteotomies
- Increased plate strength allows application of the preload technique
- Optimum support for stable bridging



TomoFix Femoral Plate medial, distal
- For closed-wedge osteotomies
- Fixed angle construct for stable fixation
- Plates available in right or left version



TomoFix tibial head plate lateral, proximal
- For closed-wedge osteotomies
- Fixed angle construct for stable fixation
- Plates available in right or left

Osteotomy Principles

Stable Fixation
The angular stability of the locking screw system ensures high biomechanical primary stability and a secure fixation of the osteotomy even in osteoporotic bone. The risk of a secondary loss of correction is significantly reduced.

Preservation of Blood Supply
The temporary use of spacers creates a defined distance between the implant undersurface and bone surface reducing plate-to-bone contact. This does not affect the periosteal blood supply.

Early mobilization
The stable fixation of the osteotomy allows rapid mobilization and early functional postoperative treatment, thus ensuring rapid patient rehabilitation.

Indications and Contraindications

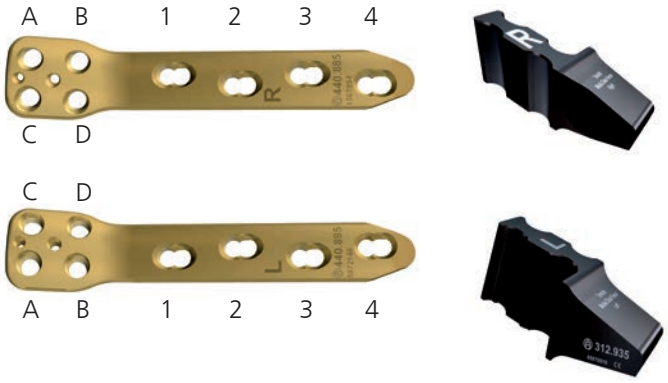
Indications
- Unicompartmental lateral gonarthrosis with valgus malalignment of the distal femur
- Idiopathic or posttraumatic valgus deformity of the distal femur
- Additional fixation for complex distal femoral fractures

Contraindication
- Inflammatory arthritis

1

Preparing the implant

312.934 or 312.935	TomoFix Guiding Block, for right TomoFix Femoral Plate, medial TomoFix Guiding Block, for left TomoFix Femoral Plate, medial
323.042	LCP Drill Sleeve 5.0, for Drill Bits ∅ 4.3 mm
413.309	LCP Spacer ∅ 5.0 mm, length 2 mm, Titanium Alloy (TAN)



To allow uniform orientation the four combination holes in the proximal shaft are numbered 1 – 4 and the four plate holes in the distal segment labelled A - D. Ensure that you have selected the correct implant (right / left).

Use the guiding block as a positioning guide to align the drill sleeves on the distal part of the TomoFix Femoral Plate (MDF). A pictogram on the block shows the correct position.

Insert the drill sleeves exactly along the guiding block. First screw the drill sleeve into hole A, then proceed to screw the drill sleeves into the three remaining holes B-D. Remove the guiding block.

Insert a spacer into hole 4 of the shaft.

2
Positioning of patient

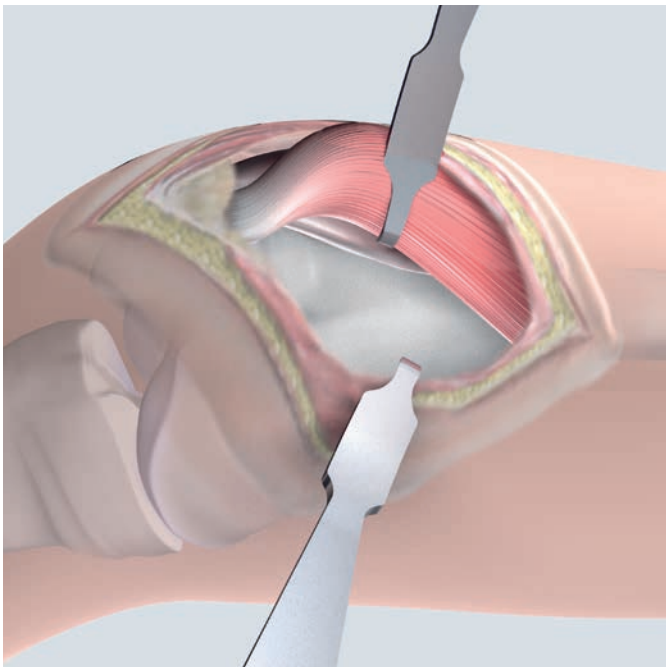
Surgery is performed with the patient in a supine position. Position the patient so that the hip, knee and ankle joint can be visualized with the image intensifier. Lower the contralateral leg at the hip joint to facilitate access to the medial distal femur. The sterile draping also exposes the iliac crest so that the leg axis can be checked intraoperatively. A sterile tourniquet can be used, but is not mandatory.

3
Approach

With the knee joint in extended, position, an anteromedial longitudinal incision is made, starting 10 cm above the patella and ending in the upper third of the patella. This incision has the advantage that it can be used again for any subsequent surgery (i.e. endoprosthesis).

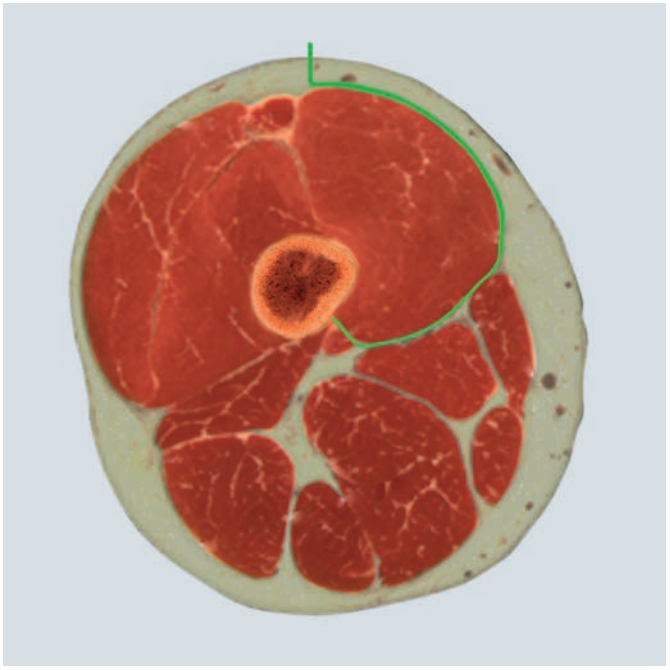
Incise the subcutaneous tissue and dissect the fascia of the vastus medialis muscle. Elevate the muscle and dissect as far as necessary from the intermuscular septum.

Expose the medial patellofermoral ligament at the distal end of the incision. Incise the ligament and the distal insertion of the vastus medialis muscle in order to facilitate mobilization of the muscle. Now expose the intermuscular septum near the condyles. Incise the septum carefully, close to the bone and parallel to the femoral shaft. Use a curved raspatorium to separate the soft tissue of the back of the knee from the distal femur, to allow the use of a wide, blunt-tipped Hohmann retractor behind the femoral shaft.



Precaution: An osteotomy of the distal femur may only be carried out if the neurovascular structures are protected with a blunt retractor. Otherwise there is a high risk of injuring these vital structures.

Use a Hohmann retractor to expose the anteromedial aspect of the supracondylar region of the femur. Expose the shaft proximally so that the TomoFix Femoral Plate (MDF) can be positioned safely.



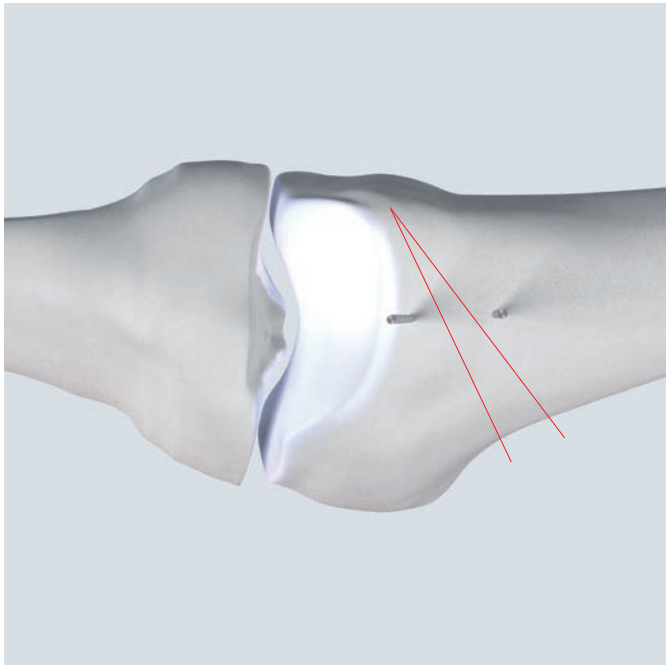
4
Determine the position of the osteotomy

Instrument

292.210	Kirschner Wire ∅ 2.0 mm with trocar tip, length 280 mm, Stainless Steel

The position of the osteotomy is best determined by placing the TomoFix Femoral Plate (MDF) directly on the anteromedial distal femur. It is not necessary to achieve a form fit due to the angular stability. However, it is important to ensure that the distal screws do not penetrate the condyles dorsally.

The osteotomy should be localized under the solid region of the plate, i.e. to allow screws A-D to be positioned distally to the osteotomy. The distal osteotomy cut should be placed approximately 5 mm above the patella groove descending laterally, ending 10 mm from the lateral cortical bone in the lateral condyle of the femur. The proximal osteotomy starts higher in the medial supracondylar region. It is advisable to mark the planned osteotomy site with an electric cautery.

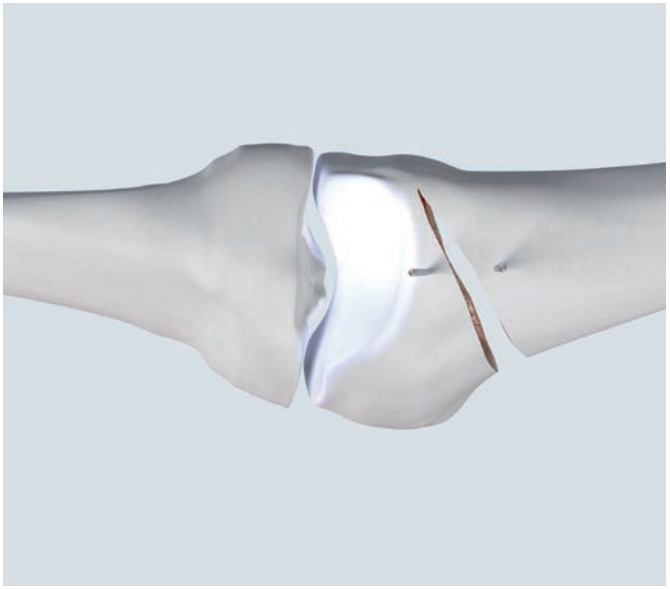


Precaution: In order to avoid a rotational deformity when closing the osteotomy after removing the wedge, place two Kirschner wires in a sagittal direction proximally and distally to the planned osteotomy. Alternatively, longitudinal markings can be made on the medial shaft and on the condyles (using an electric cautery or chisel).

5
Osteotomy

Perform the osteotomies by marking the planned wedge removal with Kirschner wires (check the Kirschner wire placement with the image intensifier before cutting). The wires will then act as a guide for the saw. The osteotomy ends 10 mm before the lateral cortical bone, leaving a lateral hinge and removing a medially based wedge. Perform the osteotomies with an oscillating saw, protecting the soft tissue with a Hohmann retractor and constantly cooling the saw blade.

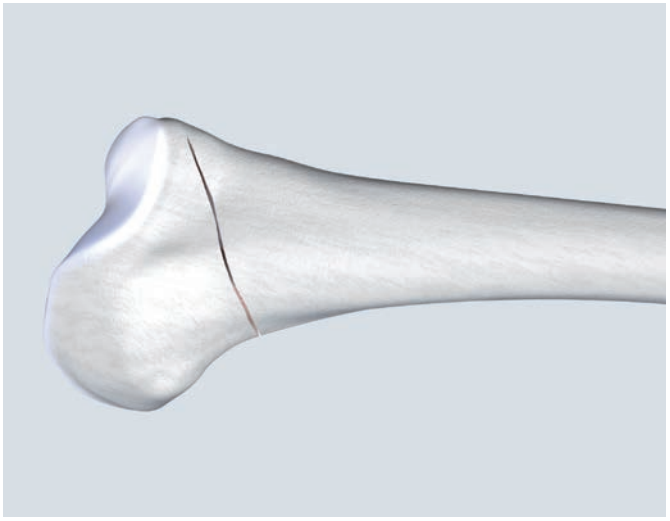
Remove the wedge; check that any residual bone fragments have been removed from the osteotomy. If the bone is very hard, weaken the lateral cortical bone with the 2.5 mm drill bit.



Close the osteotomy carefully by applying continuous pressure to the lateral lower limb while stabilizing the knee joint region. This may take several minutes.

The osteotomy gap can then either be held closed by manual compression or with two crossed Kirschner wires considering the later plate position.

Check the corrected mechanical axis with the image intensifier; position a long metal rod between the center of the femoral head and the center of the ankle joint. The projected axis line passes either centrally or medially through the center of the knee joint, depending on the pre-operative planning.



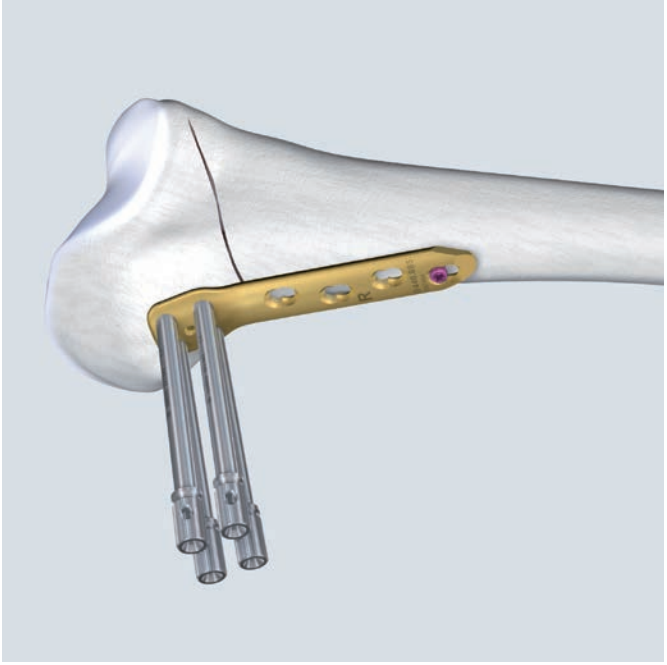
6
Position the implant

Instruments

324.168	Centering Sleeve for Kirschner Wires ∅ 2.0 mm
292.210	Kirschner Wire ∅ 2.0 mm with trocar tip, length 280 mm, Stainless Steel

Position the TomoFix Femoral Plate (MDF) anteromedially on the distal femur using the four distal pre-mounted drill sleeves and the spacer as described above, so that the solid plate segment is bridging the osteotomy and the implant shaft is aligned parallel to the femoral shaft. Temporarily secure the plate through the drill sleeve using a guiding sleeve and a Kirschner wire in plate holes A or C.

Note: The Kirschner wire must not exit the condyles posteriorly. Check by palpation and if necessary modify the plate position or sagital tilt.



7
Distal fixation of the TomoFix Femoral Plate

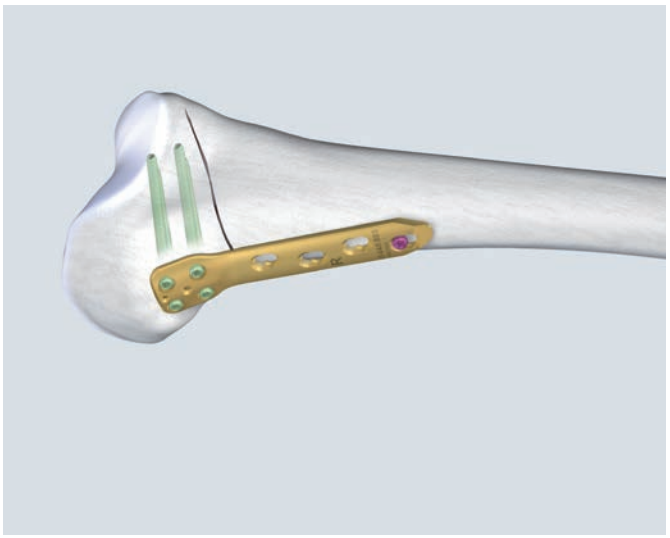
Instruments

310.430	LCP Drill Bit ∅ 4.3 mm with Stop, length 221 mm, 2 flute, for Quick Coupling
319.100	Depth Gauge for Screws ∅ 4.5 to 6.5 mm, measuring range up to 110 mm
324.052	Torque-indicating Screwdriver 3.5
314.152	Screwdriver Shaft 3.5, hexagonal, self-holding

Drill screw holes using the drill sleeves for self-tapping locking screws and the LCP Drill Bit ∅ 4.3 mm. Determine the screw length either by reading the drilled depth from the laser mark on the drill bit or with the depth gauge after removing the drill sleeve. The screws should not protrude from the lateral cortical bone.

Insert the screw using a power tool, but do not fully tighten it. Insert screws in holes B, C and D. Remove the Kirschner wire from hole A and replace by a locking screw.

Finally, lock the screws manually with the torque-limiting screwdriver. After one click, the optimum torque is reached.



8

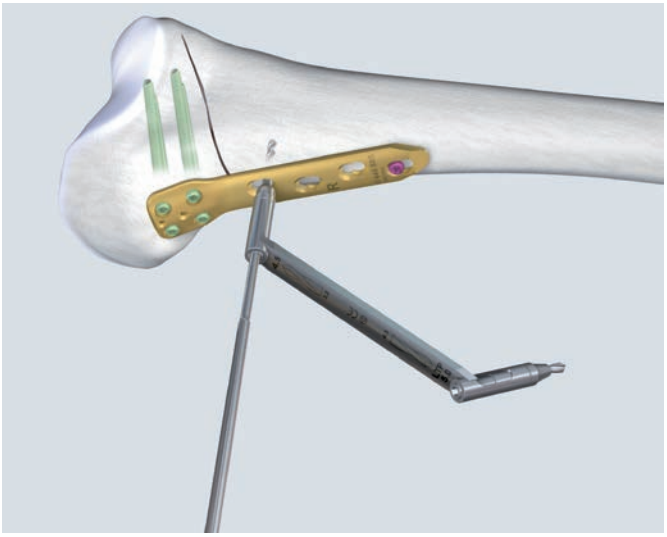
Temporary compression of the osteotomy

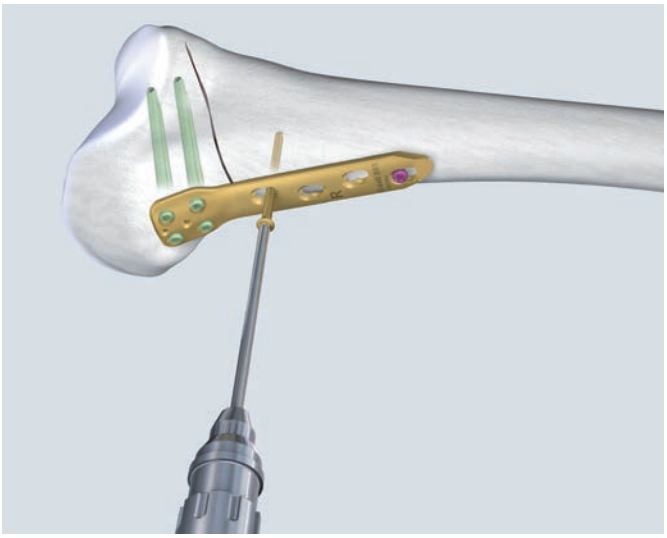
Instruments

323.500	LCP Universal Drill Guide 4.5/5.0
315.310	Drill Bit 3.2 mm, length 145/120 mm, 3-flute, for Quick Coupling
319.100	Depth Gauge for Screws ∅ 4.5 to 6.5 mm, measuring range up to 110 mm
314.152	Screwdriver Shaft 3.5, hexagonal, self-holding

The osteotomy gap can be compressed by eccentrically applying a self-tapping 4.5 mm cortical screw proximal to the osteotomy in the dynamic section of combination hole 1.

The screw should be aimed in a slightly proximal, lateral direction to achieve good interfragmentary compression. This is particularly important if the lateral femoral cortical bone fractured when closing the osteotomy.

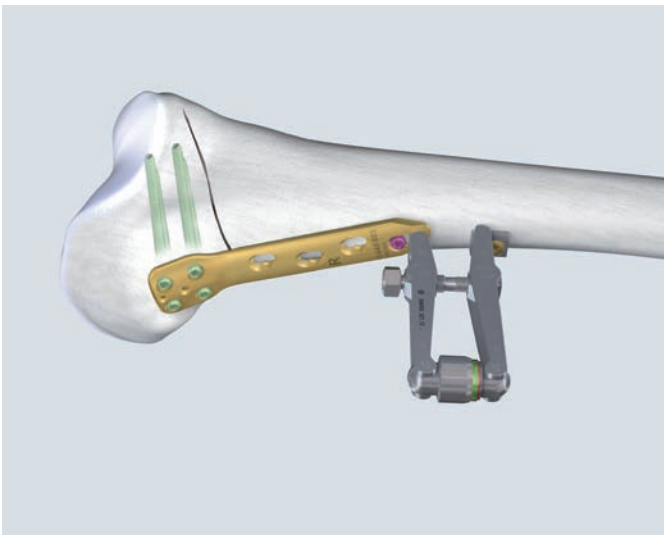




Alternative instrument

321.120	Tension Device, articulated, span 20 mm

Alternatively, the Tension Device, articulated can be used to create compression in the dynamic hole section of plate hole 4. This requires additional proximal soft tissue dissection.

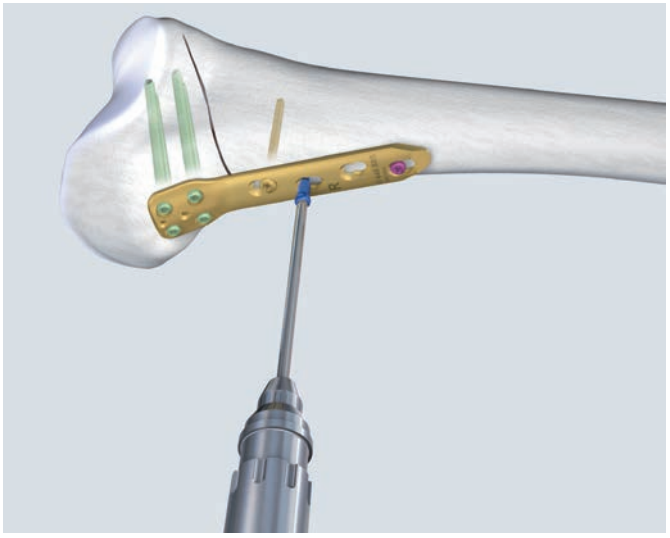


9

Proximal fixation of the TomoFix femoral plate

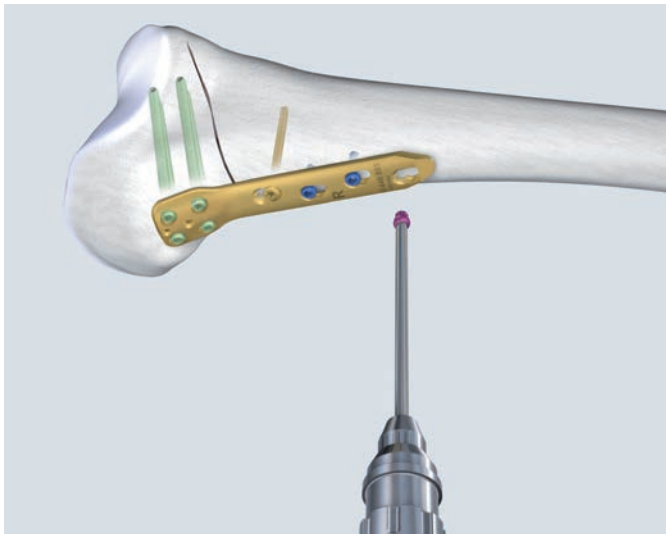
Required instruments

323.500	LCP Universal Drill Guide 4.5/5.0
315.310	Drill Bit 3.2 mm, length 145/120 mm, 3-flute, for Quick Coupling
511.771	Torque Limiter, 4 Nm, for Compact Air Drive and Power Drive
324.052	Torque-indicating Screwdriver 3.5
314.152	Screwdriver Shaft 3.5, hexagonal, self-holding

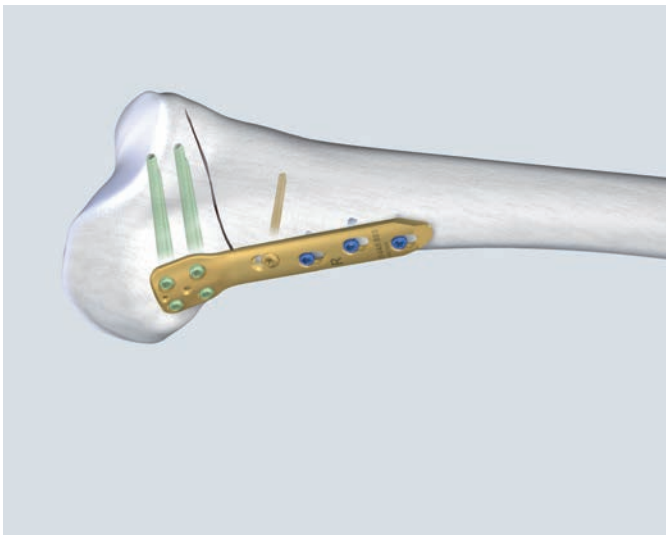


Insert monocortical, self-tapping locking screws into plate holes 2 – 4 of the implant shaft from distal to proximal.

Do not remove the spacer in hole 4 until you are ready to insert a screw in this plate hole.



Use an LCP universal drill sleeve to mark the medial femoral cortical bone with the short drill bit. Screw in the locking screw using a power tool and tighten it using the technique previously described (cf. step 7).

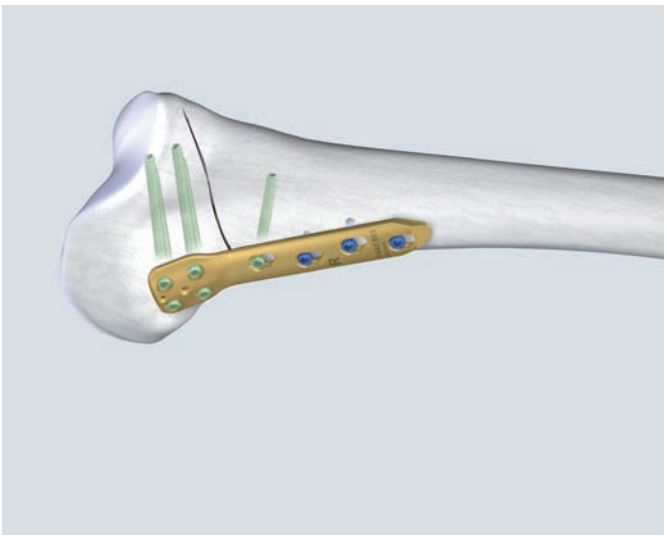


10
Replacing the cortical screw

Instruments

323.042	LCP Drill Sleeve 5.0, for Drill Bits ∅ 4.3 mm
310.430	LCP Drill Bit ∅ 4.3 mm with Stop, length 221 mm, 2 flute, for Quick Coupling
319.100	Depth Gauge for Screws ∅ 4.5 to 6.5 mm, measuring range up to 110 mm
511.771	Torque Limiter, 4 Nm, for Compact Air Drive and Power Drive
324.052	Torque-indicating Screwdriver 3.5
314.152	Screwdriver Shaft 3.5, hexagonal, self-holding

Remove the cortical screw from hole 1 and replace it by a bicortical, self-tapping locking screw. Screw the drill sleeve exactly into the threaded part of the combi-hole and drill the hole with the LCP drill bit ∅ 4.3 mm. Determine the screw length and insert the screw as described in step 7.



11
Radiologic control

Check the result of the correction and the position of the implant using the image intensifier.

12
Wound closure

Close the arthrotomy, reattach the medial patellofemoral ligament and the partially released distal insertion of the vastus medialis muscle on the patella. Close the wound layer by layer.

Postoperative Treatment/ Implant Removal

Postoperative treatment
Early functional postoperative treatment from the 1first postoperative day, partial load bearing of 15 – 20 kg for 6 weeks postoperatively, manual lymphatic drainage, cryotherapy and electrotherapy if necessary. The range of motion is not limited, an orthesis is not necessary, abduction and adduction against resistance should be avoided for the first 6 weeks. Increased load bearing is allowed from the 7th week postoperatively depending on the radiological healing of the osteotomy site.

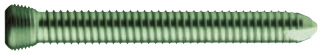
Radiographic control after 2 days, 6 and 12 weeks and 12 months.

Implant removal
Generally, the TomoFix Femoral Plate (MDF) should not be removed earlier than 12 months after surgery. To remove the plate, initially loosen all screws manually and then remove them using power tools.

Implants

The TomoFix Femoral Plate (MDF) is designed according to the principles of the Locking Compression Plate (LCP). In the distal section there are 4 threaded holes, the directions of which are adapted to the anatomy of the supracondylar femur. There are 4 combination holes in the proximal section. A right and left version allow for accurate positioning of the anteromedial section of the distal femur and secure anchoring of the locking screws in the femoral condyles.

Implants

440.885S	TomoFix Femoral Plate, medial, distal, right, 4 holes, Pure Titanium, sterile For the closing osteotomy of the right medial distal femur	
440.895S	TomoFix Femoral Plate, medial, distal, left, 4 holes, Pure Titanium, sterile For the closing osteotomy of the left medial distal femur	
413.314 – 413.390	LCP Locking Screws ∅ 5.0 mm, self-tapping, Titanium Alloy (TAN)	
413.414 – 413.490	LCP Locking Screw ∅ 5.0 mm, self-tapping, Titanium Alloy (TAN)	
414.814 – 414.490	Cortical screw ∅ 4.5 mm, self-tapping, Pure Titanium	

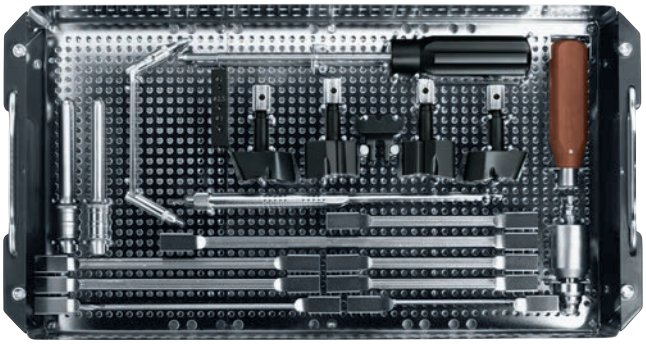
Instruments

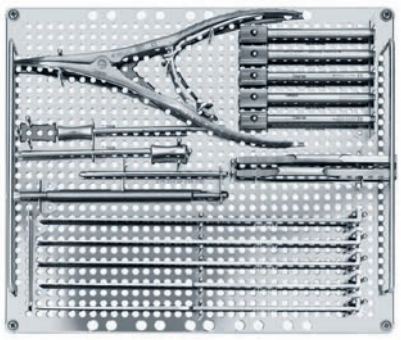
Besides the implant-specific guiding blocks, the full TomoFix Knee Osteotomy System is required for supracondylar closed-wedge osteotomies of the femur.

312.934	TomoFix Guiding Block, for right TomoFix Femoral Plate, medial

312.935	TomoFix Guiding Block, for left TomoFix Femoral Plate, medial

182.630	TomoFix Knee Osteotomy System in Vario Case





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1. Stahelin T, Hardegger F, Ward JC (2000). Supracondylar osteotomy of the femur with use of compression. Osteosynthesis with a malleable implant. J Bone Joint Surg 82A: 712-722

2. Van Heerwarden R, Wymenga A (2006). Die supra-kondyläre varisierende Femurosteotomie mit speziellem Plattenfixateur. In: Lobenhoffer P, JD Agneskirchner, Galla M (Hrsg.). Kniegelenknahe Osteotomien mit Plattenfixateuren – Indikation, Planung und Operationstechnik. Stuttgart, Thieme Verlag

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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