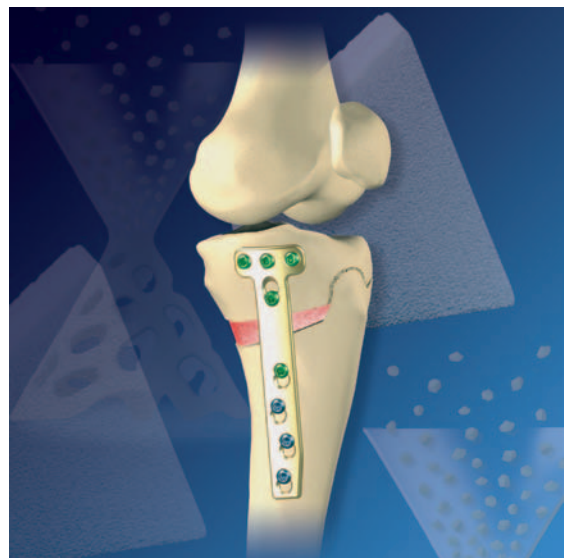
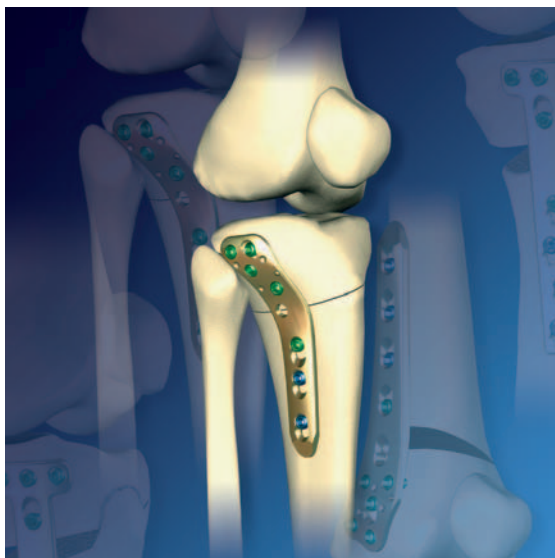
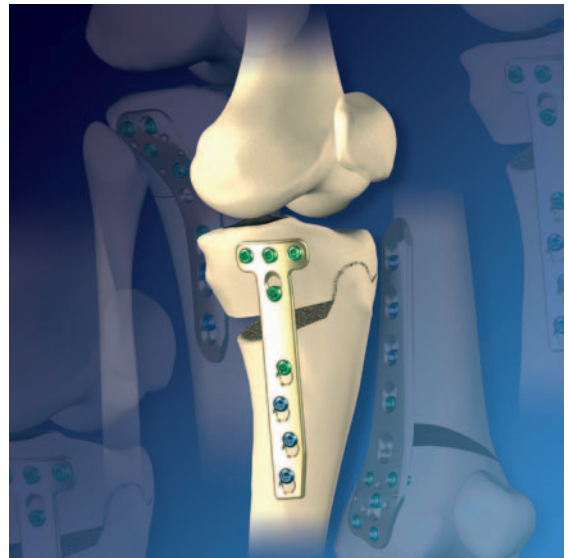
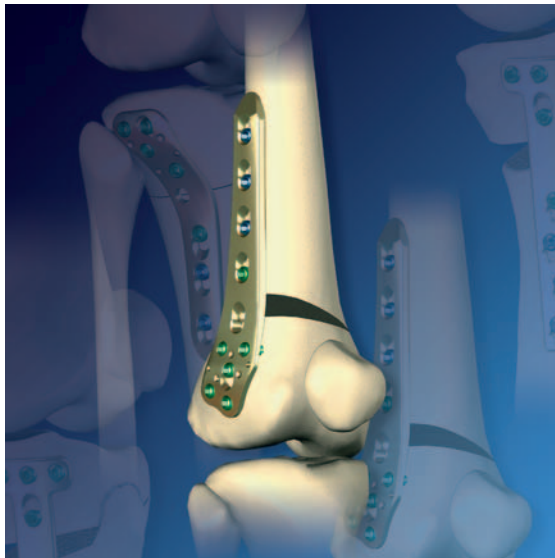


TomoFix™

Application notes



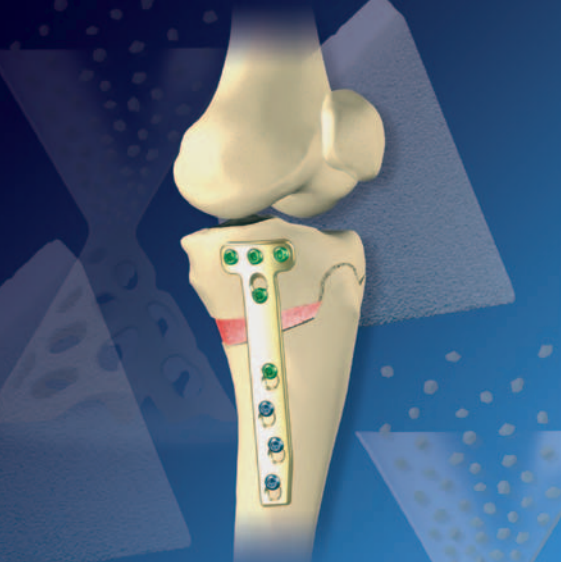
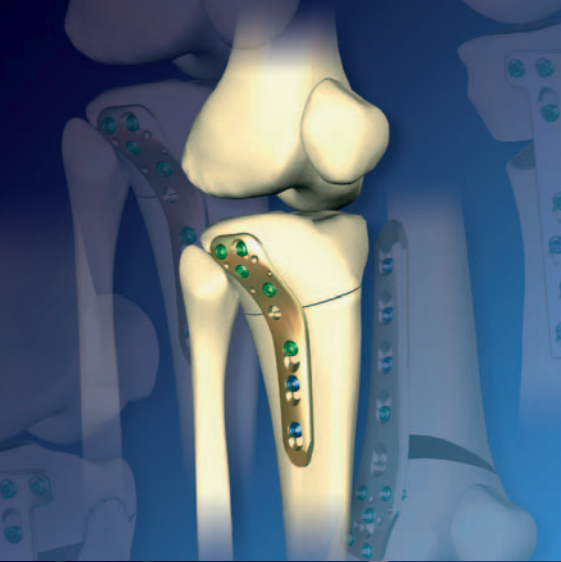
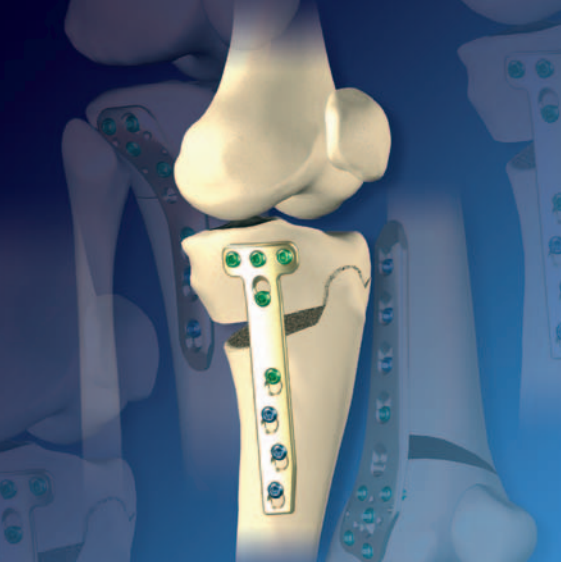
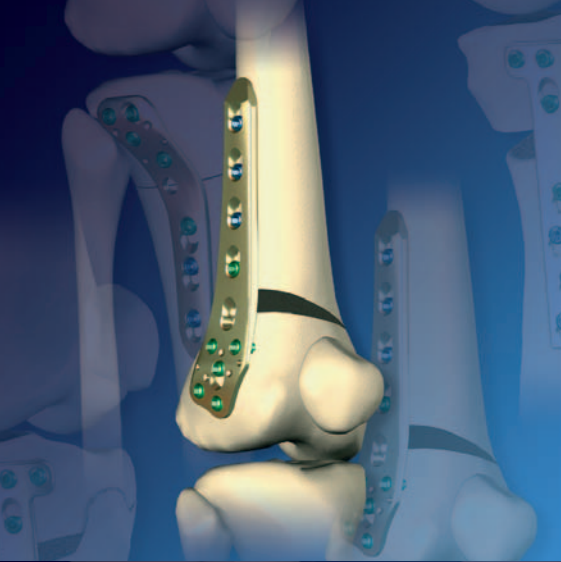


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Warning

This description is not sufficient for an immediate application of the instrumentation. Instructions by an experienced surgeon in handling this instrumentation are highly recommended.

Introduction

The **TomoFix™** system concentrates on the stable fixation of osteotomies close to the knee, irrespective of the osteotomy technique. The high stability of a fixation using **TomoFix™** is particularly effective in open-wedge osteotomies and overweight patients.

These notes inform about the properties of **TomoFix™**, explain the use of the implants and instruments, and provide order information.

A separate AO/ASIF surgical technique – the use of **TomoFix™** medial high tibia – and the medical literature^{1,2,3} include further details on planning and performing osteotomies.

Important!

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

Indications

Open-wedge and closed-wedge osteotomies of the:

- Medial high tibia
- Lateral high tibia
- Lateral distal femur

Case examples

Open-wedge high tibia valgus osteotomy (HTO), without bridging graft

48-year-old woman
(adiposity) with
medial gonarthrosis,
left



Preoperative



Postoperative



Postoperative



6 months postoperative



Following metal removal (15 months postoperative)



Open-wedge high tibia valgus osteotomy (HTO), without bridging graft

23-year-old man,
(sportsman) with
posttraumatic medial,
chondral gonarthrosis,
medial meniscopathy,
varus-morphotype,
left



Preoperative



Postoperative



Postoperative



3 months postoperative



Following metal removal (12 months postoperative)



Open-wedge high tibia valgus osteotomy (HTO) with chronOS™ Osteotomy Wedge

30 year-old man



6 weeks postoperative



3 months postoperative



6 months postoperative



12 months postoperative

Closed-wedge high tibia valgus osteotomy (HTO)

52-year-old woman
with medial
gonarthrosis, left



Preoperative



Postoperative



3 months postoperative



3 months postoperative

Features and benefits of TomoFix™

TomoFix™ is based on the internal fixator principle^{4,5} as well as on LCP, and incorporates the following features and benefits:

The internal fixator

- Tightening of the screws causes no primary loss of reduction and/or correction (Fig. 1), as the Locking Head Screw (LHS) has no tensioning effect.
- The axially and angularly stable screws prevent secondary loss of reduction and/or of correction when active mobilisation occurs (Fig. 2).
- The blood supply to the bone remains preserved, as there is no compression of the periosteum (Fig. 3). To enhance this effect, the use of spacers is recommended.

In an open-wedge medial high tibia valgus osteotomy, the pes anserinus can be freely moved under the plate.

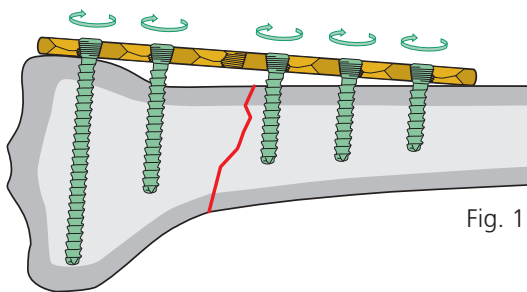


Fig. 1

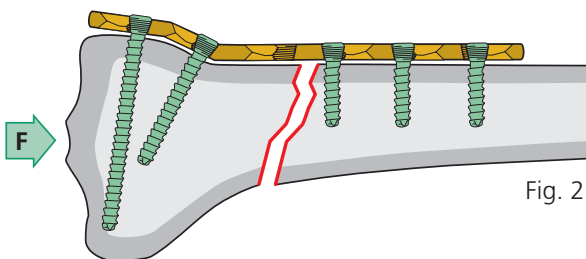


Fig. 2

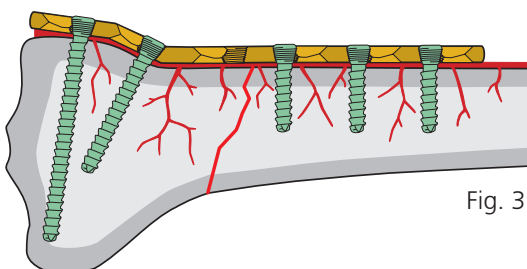
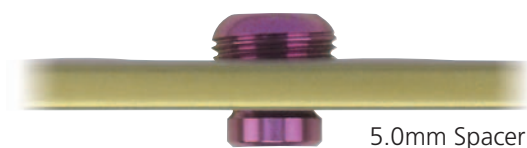


Fig. 3



5.0mm Spacer

The LCP hole

The LCP hole consists of two parts:

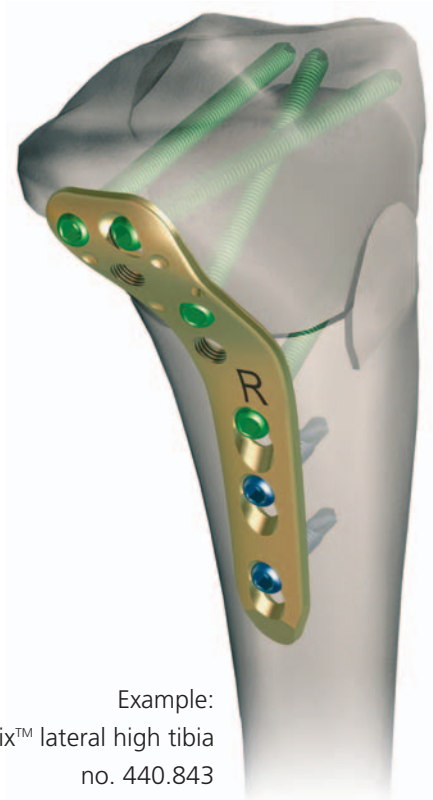
- A** This portion of the hole features a conical thread allowing a secure fixation of the Locking Head Screw (LHS) in the plate (see internal fixator).
- B** This portion corresponds exactly to the DCU⁶ (Dynamic Compression Unit), which is also used in the DCP[®]. As in the DCP[®], dynamic compression can be achieved by an eccentric insertion of standard screws. This portion of the hole is not suitable for the Locking Head Screw.

Important!

If the first screw to be inserted is a Locking Head Screw, it is important to ensure that the plate shows good temporary fixation. Otherwise, the plate rotates simultaneously 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 to remove them in a second step only.

Always use the Torque-limiting Screwdriver (324.052) to lock the LHS.

When fixing the osteotomy using **Tomofix™**, the properties of the LCP hole allow a fine intra-operative adjustment of the correction. Should the open-wedge or closed-wedge osteotomy cause a fracture of the opposite cortex, the latter can be compressed without any problems.



Example:
TomoFix™ lateral high tibia
no. 440.843

TomoFix™ design

Absolute stability⁷

The plates' high strength in combination with the axially and angular stable LHS ensures absolute stability of the osteotomy fixation. This maintains the correction until consolidation occurs, and favours early active mobilisation.

Anatomical shape

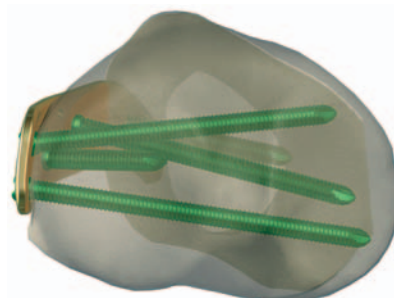
Prevents soft-tissue irritations and increases patient comfort. Pre-operative plate contouring is not required.

Optimum support

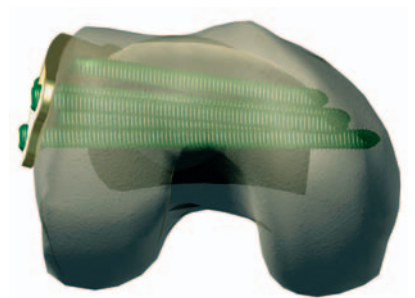
The orientation of the screw meets the requirements of osteotomies, and ensures an optimum support of the articular surfaces.



TomoFix™ medial high tibia,
no. 440.834



TomoFix™ lateral high tibia,
left, no. 440.853



TomoFix™ lateral distal femur,
right, no. 440.864

Features and benefits of chronOS™



chronOS™ wedges can be used in all orthopaedic areas requiring bone replacement as part of osteotomies. Due to its excellent osteoconductive properties, **chronOS™** is particularly well suited for bridging, filling and correcting of bone defects.

Autologous bone harvesting intensifies patient morbidity, prolongs the operating time, increases blood loss and opens another door to possible infections. This is where synthetic bone replacement materials, such as **chronOS™**, provide an alternative.



chronOS™ is synthetic

- Reduced patient morbidity as bone harvesting is unnecessary.
- The use of synthetic β -TCP avoids potential disease transmission risks.
- Standardised and patented production processes ensure reliable mechanical stability values comparable to those of cancellous bone (7.5 ± 1 MPa).



chronOS™ is osteoconductive

- The standardised macroporosity (100–500µm) accelerates the osseous ingrowth.
- Interconnecting pores enable rapid vascular and bone infiltration down to the core of **chronOS™**.

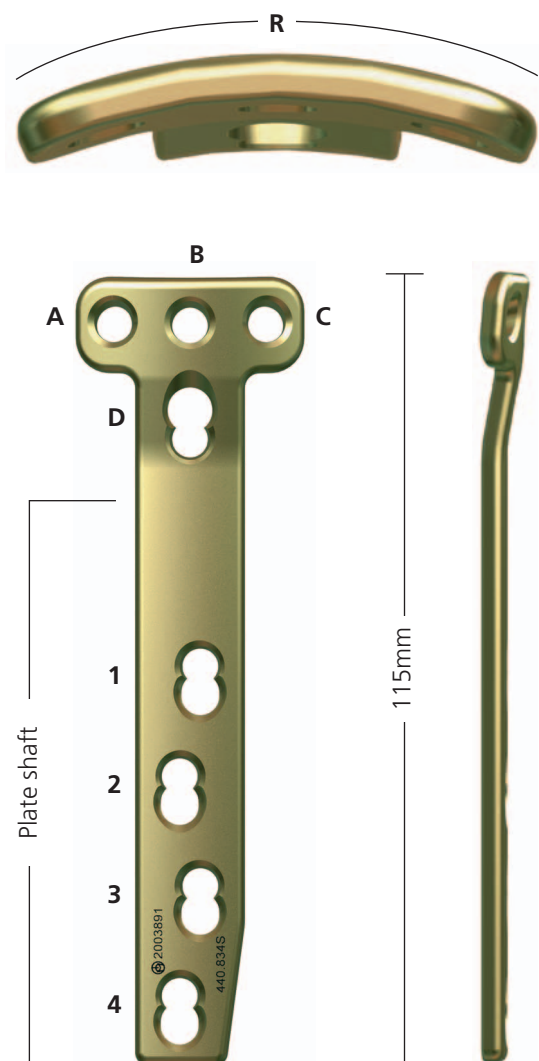


chronOS™ is resorbable

- Pure β -tricalcium phosphate facilitates complete remodelling of **chronOS™** into vital bone within 6 to 18 months.
- The macroporosity increases the specific surface area, and accelerates thus remodelling.

Implants

TomoFix™ medial high tibia



The **TomoFix™** medial high tibia plate (440.834) has been adapted to the anatomy. This applies especially to the radius (R) of the proximal T-bar as well as to the screw axes angled at 4° (Fig. 4) with respect to the plate shaft in the side-by-side holes A, B, and C. The plate shaft closely fits the tibia.

The 2.8mm thickness of the plate and the hole-free area at the osteotomy level ensures high strength. The tapered plate end facilitates the insertion of **TomoFix™** in minimally invasive surgical techniques.

The shaft holes 1 to 4 and hole D in the head area of the plate correspond to LCP and allow choosing (or combining) between an angular-stable fixation with LHS and a dynamic compression with standard screws.

Holes A, B, and C have been designed for the use of LHS.

The plate is made of pure titanium.

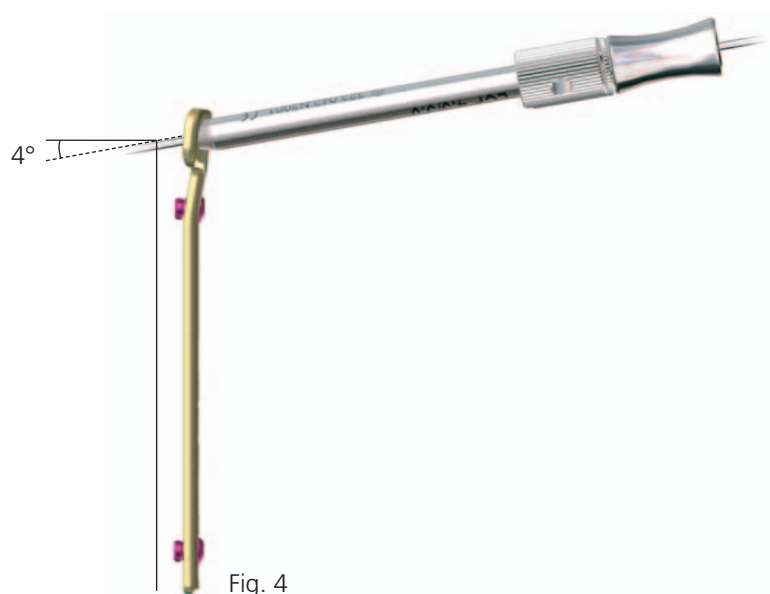
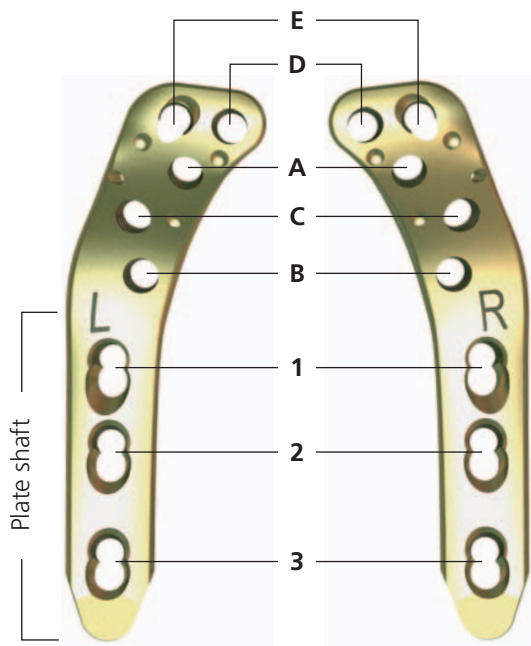


Fig. 4



TomoFix™ lateral high tibia

The **TomoFix™** lateral high tibia plates, right (440.843) and left (440.853) are optimally adapted to the anatomy.

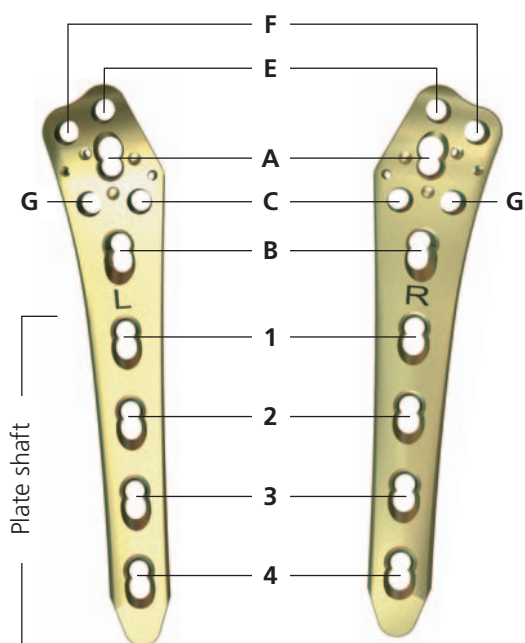
The plate thickness is between 3.1 and 4.5mm and ensures high strength without soft-tissue irritation. Furthermore, the tapered plate end facilitates the insertion of **TomoFix™** in minimally invasive surgical techniques.

Hole E permits the use of LHS as well as standard screws. Holes A, B, C, and D have been designed for the use of LHS.

The shaft holes 1 to 3 correspond to LCP and allow choosing (or combining) between an angular-stable fixation with LHS and a dynamic compression with standard screws.

The plates are made of TAN.





TomoFix™ lateral distal femur

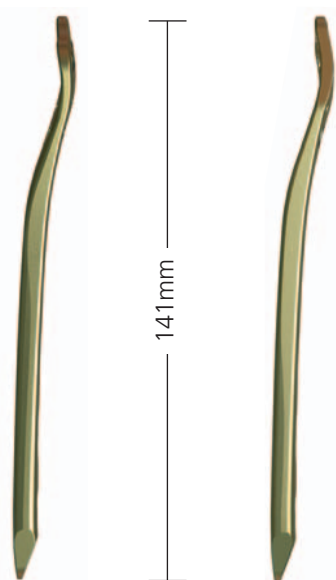
The **TomoFix™** lateral distal femur plates, right (440.864) and left (440.874) have been optimally adapted to the anatomy.

The plate thickness is between 3.0 and 5.5mm, and ensures high strength without soft-tissue irritation. Furthermore, the tapered plate end facilitates the insertion of **TomoFix™** in minimally invasive surgical techniques.

Holes A and B enable the use of LHS as well as standard screws analogous to LCP. Holes C, E, F, and G have been designed for the use of LHS.

The shaft holes 1 to 4 correspond to LCP and allow choosing (or combining) between an angular-stable fixation with LHS and a dynamic compression with standard screws.

The plates are made of TAN.



Instruments

TomoFix™ Instruments



TomoFix™ Guiding Block medial high tibia (312.926)

Ensures that the threaded LCP Drill Guide (323.042) can be screwed easily and correctly into holes A, B, C, and D of **TomoFix™** medial high tibia (440.834).



TomoFix™ Guiding Blocks lateral high tibia, right (312.930) and left (312.931)

Ensure that the threaded LCP Drill Guide (323.042) can be screwed easily and correctly into holes A, B, C, D, and E of **TomoFix™** lateral high tibia, right (440.843) and left (440.853).

The locking nut can be removed for cleaning.

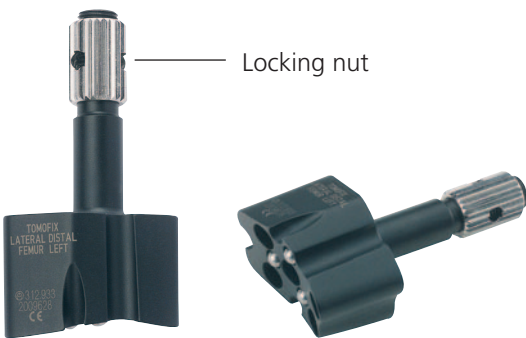




TomoFix™ Guiding Blocks lateral distal femur, right (312.932) and left (312.933)

Ensure that the threaded LCP Drill Guide (323.042) can be screwed easily and correctly into holes A, B, C, E, F, and G of **TomoFix™** lateral distal femur, right (440.864) and left (440.874).

The locking nut can be removed for cleaning.



TomoFix™ Guide Sleeve for 2.0mm Kirschner wires (324.168)

Enables a centric insertion of Kirschner wires up to 2.0mm in diameter into the threaded LCP drill guides. This controls the orientation of the screw axis and the temporary fixation of the plate.





Bone Spreader (399.097), jaw width 8mm, length 220mm, softlock

Ensures a fine adjustment of the correction, and keeps open the osteotomy gap (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 Sleeves (322.440 and 322.430) and the LC-DCP Drill Sleeve (323.450), the current instruments of the large fragment systems continue to be required.

LCP 4.5/5.0 Standard Instruments



Universal Drill Sleeve LCP 4.5/5.0 (323.500)

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

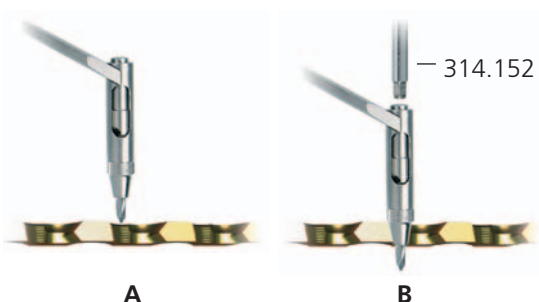
- A** Place the conical part into the threaded part of the LCP combination hole and centre it.
- B** Use the power tool and the self-retaining Screwdriver Shaft (314.152) to drill through the first cortex.

The centring hole is important, as it ensures optimal locking of the self-drilling LHS in the plate. This guarantees maximum angular stability.

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.

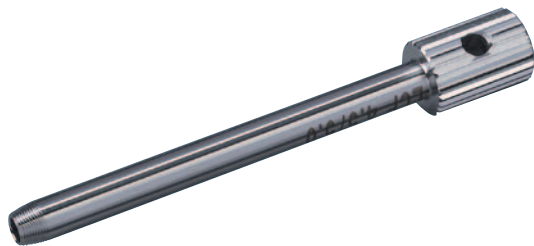
Replace the tip of the drill bit as soon as signs of wear become visible.





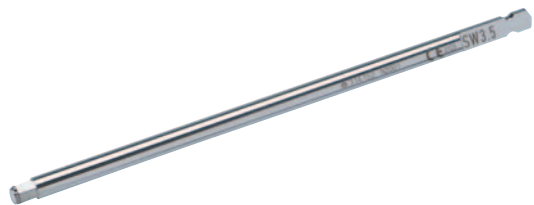
Drill Bit, 4.3mm dia. (310.430)

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



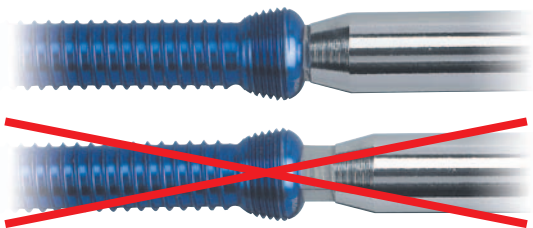
Threaded LCP Drill Guide for 4.3mm drill bits (323.042)

The threaded drill guide permits centric and orthogonal drilling with the 4.3mm drill bit, and protects the soft tissue. This ensures the subsequent correct insertion of self-tapping Locking Head Screws and their optimal angular stability.



Self-retaining Screwdriver Shaft 3.5 (314.152)

Use a power tool to insert the 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.

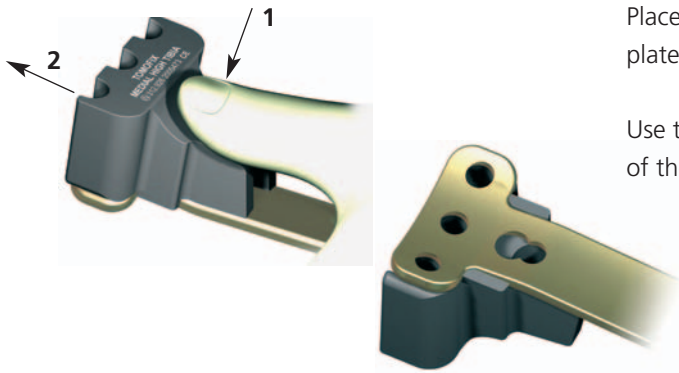


Torque-limiting Screwdriver for 3.5mm hexagon (324.052)

Use the torque-limiting screwdriver to lock the 5.0mm Locking Head Screws. It ensures an optimal tightening moment and prevents excessive tightening of the LHS.

Medial high tibia application

Implant preparation



Place the underside of the Guiding Block (312.926) onto the shaft of the plate back. Lateral guiding aids facilitate 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 Guide (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 5.0mm spacers (413.309) into holes D and 4.



Fixation of the osteotomy

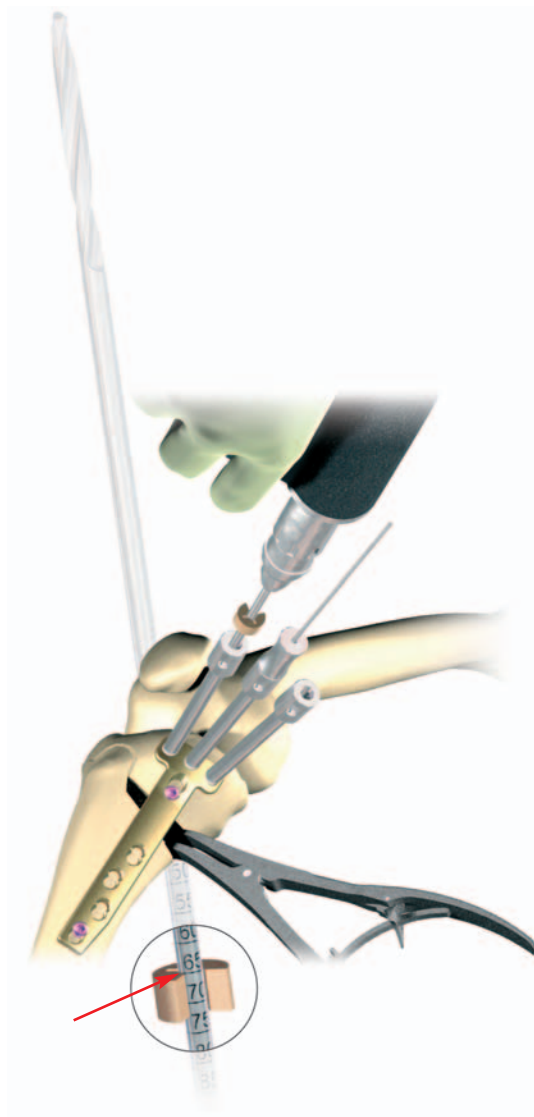
After performing and opening the osteotomy, maintain and finely adjust the correction using the Bone Spreader (399.097). Be careful to ensure that the ventral and dorsal sides are spread identically, if the tibia inclination has to remain unchanged.

Place the prepared implant centrally on the osteotomy; holes A, B, C, and D will be proximal of the correction gap.

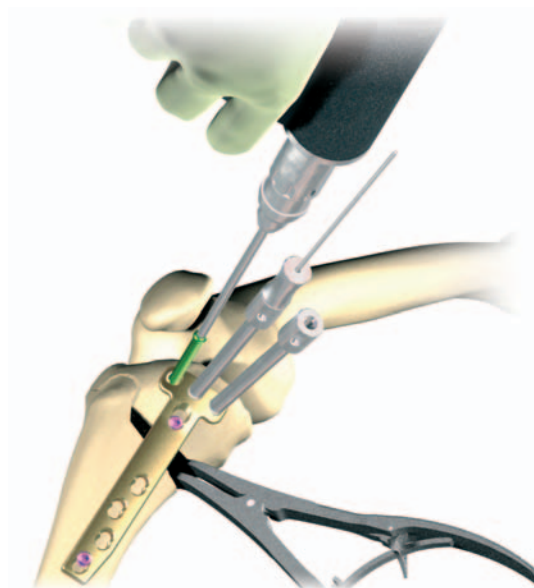


Perform a secure temporary fixation of the plate. Insert the Guide Sleeve for 2.0mm Kirschner wires (324.168) into the middle threaded LCP drill guide and introduce a Kirschner wire. The wire also allows for image-intensifier control of the later screw position. The position of the screw should be parallel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

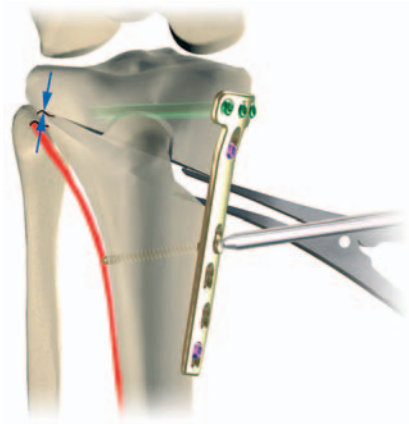




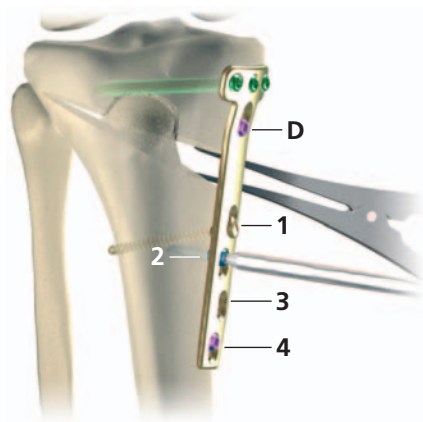
Start the fixation of the plate at the ventral plate hole, analogous to the LCP applications notes. The 4.3mm Drill Bit (310.430) allows direct reading of the drilled depth and/or the required screw length.



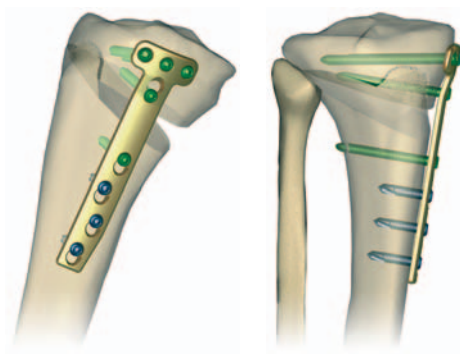
To ensure an optimal support of the tibial plateau, insert the longest possible self-tapping Locking Head Screws (LHS) into holes A, B, and C of the plate. Use the Torque-limiting Screwdriver (324.052) to manually lock the LHS in the plate.



Use a temporary 4.5mm cortex screw inserted in a neutral position in the dynamic part of the LCP hole to perform an indirect reduction of a dislocated tibial shaft. The lateral and ventral cortex compression thus achieved ensures optimal bone contact and high stability, thus promoting osseous consolidation. The spacers will ensure an adequate distance between the plate and the periosteum. The blood supply remains undisturbed and the pes anserinus can be freely moved under the plate. It is important to carry out this surgical step and the ensuing fixation at the tibia shaft, with the leg in full extension.



Start the angular-stable fixation on the tibial shaft. After having inserted LHS into holes 2 and 3, replace the spacer and the temporary cortex screw with angular-stable screws.



Occupy all plate holes with LHS to achieve absolute stability and maintain the correction. 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 of the correction gap. Replace the spacer in hole D onto the osteotomy with a long self-tapping LHS.



Filling the osteotomy gap

After having achieved a stable fixation, the osteotomy gap can be filled with **chronOS™** to ensure faster healing. The semi-circular **chronOS™** osteotomy wedges have been specially designed for osteotomy gaps. The 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 remodelling. Use a standard perfusion syringe that takes the patient blood and the **chronOS™** osteotomy wedge. Expel the air from the syringe, close it, and perfuse the enclosed wedge by pumping several times.

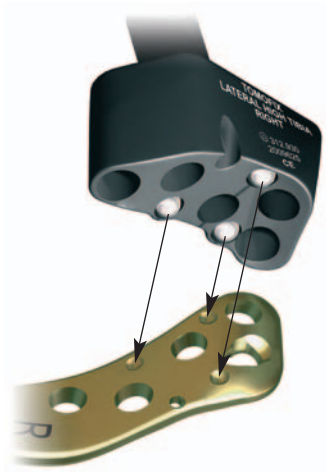
Adapt the perfused **chronOS™** osteotomy wedge to the diameter of the gap. Trim the **chronOS™** osteotomy wedges with a scalpel, a saw, a chisel or a Lindenmann reamer.

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.

The 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 the fragments into the tapered end of the osteotomy gap)

Lateral high tibia application



Implant preparation

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



Screw a first threaded LCP Drill Guide (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 the implant preparation, screw a threaded LCP drill guide into an additional proximal plate hole (D or E). Place a 5.0mm Spacer (413.309) into hole 3.

Fixation of the osteotomy

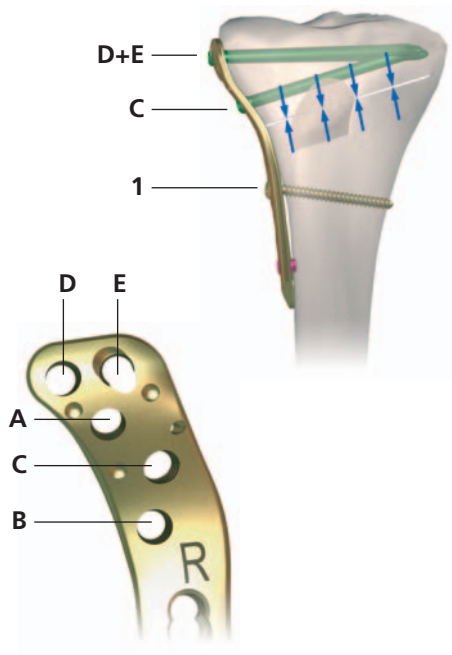
After performing the osteotomy, orientate the prepared implant parallel to the tibial shaft, and fix it temporarily. Insert the Guide Sleeve for 2.0mm Kirschner wires (324.168) into the threaded LCP drill guide. At the same time, the Kirschner wire allows for image-intensifier control of the later screw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

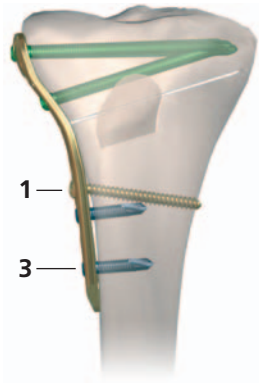
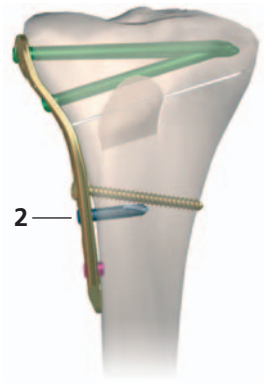


Start the fixation of **Tomofix™** proximal to the correction gap, analogous to the LCP application notes.

To ensure an optimal 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 4.5mm cortex screw in hole 1 to compress the cut bone surfaces. The spacer keeps the blood supply undisturbed by providing an adequate distance between the plate and the periosteum.





Fix the plate in the shaft area with angular stable screws.

After having inserted an LHS into hole 2, replace the spacer (hole 3) and the temporary cortex screw (hole 1) with angular-stable 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 onto the distal part of the correction is a bicortical one. Occupying the two most distal plate holes with monocortical, self-drilling, self-tapping LHS provides sufficient stability.

Lateral distal femur application

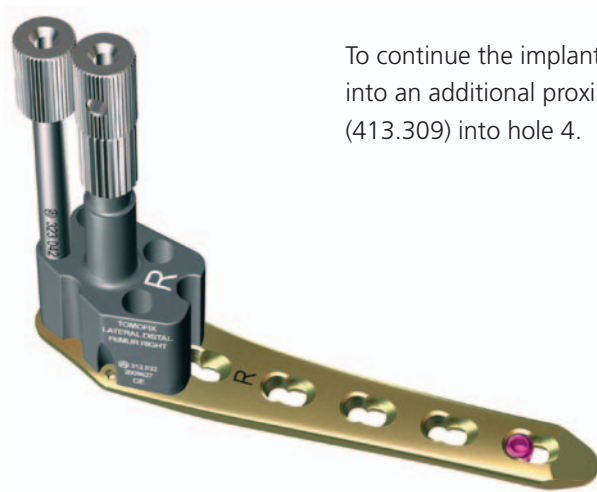


Implant preparation

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



Screw a first threaded LCP Drill Guide (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).

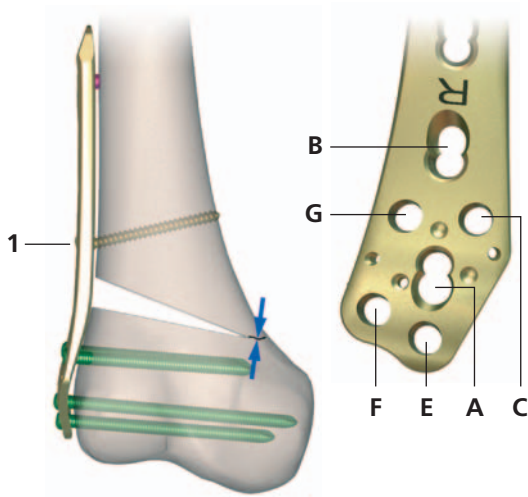


To continue the implant preparation, screw a threaded LCP drill guide into an additional proximal plate hole (F or E). Place a 5.0mm Spacer (413.309) into hole 4.



Fixation of the osteotomy

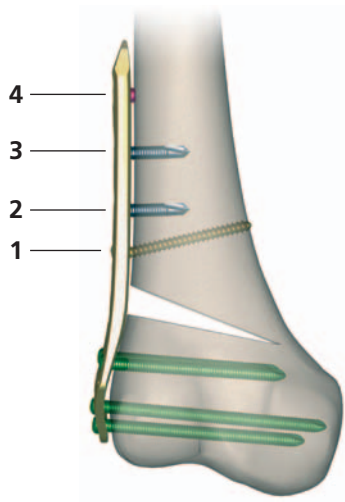
After concluding the osteotomy, orientate the prepared implant parallel to the femoral shaft, and fix it temporarily. Insert the Guide Sleeve for 2.0mm Kirschner wires (324.168) into the threaded LCP drill guide. At the same time, the Kirschner wire allows for image-intensifier control of the later screw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



Start the distal fixation of **TomoFix™** according to the 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 preserves the blood supply by providing an adequate distance between the plate and the periosteum.



Insert self-drilling, self-tapping LHS monocortically into the unoccupied shaft holes (hole 2 and 3) to fix the plate with angular stability.

Subsequently, replace the temporary cortex screw (hole 1) and the spacer (hole 4) with angular-stable screws.

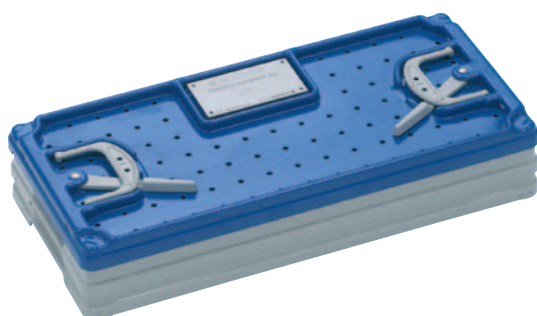


A complete treatment with absolute stability requires the insertion of four LHS distal to the correction gap, as well as the occupation of all plate holes proximal to the osteotomy. Insert a long self-tapping LHS in the hole immediately proximal to the correction gap.



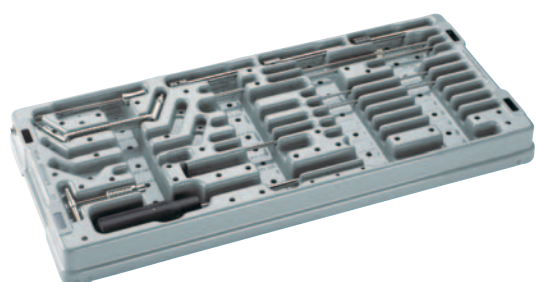
Use semi-circular **chronOS™** osteotomy wedges to fill the osteotomy gap.

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.



Item no.	Description	Units
171.294	TomoFix™ Instrument Set	
671.294	SYNCASE for TomoFix™ Instrument Set, consisting of:	
671.201	Basic Case for Instruments	1
671.203	Case for additional Instruments	1
671.297	Lid to SYNCASE for TomoFix™ Instrument Set	1



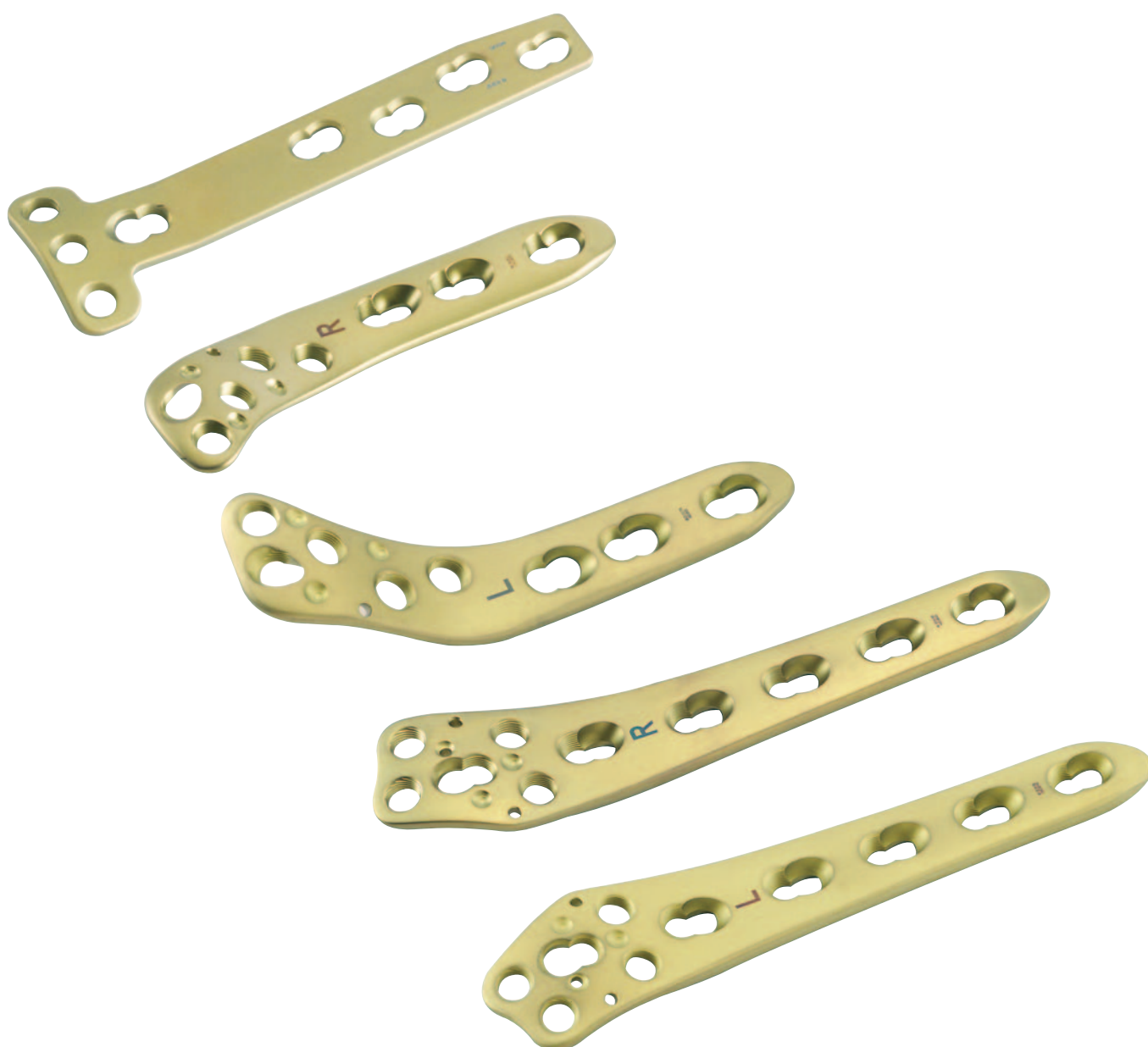
Instruments

Item no.	Description	Units
312.926	TomoFix™ Guiding Block medial high tibia	1
312.930	TomoFix™ Guiding Block lateral high tibia, right	1
312.931	TomoFix™ Guiding Block lateral high tibia, left	1
312.932	TomoFix™ Guiding Block lateral distal femur, right	1
312.933	TomoFix™ Guiding Block lateral distal femur, left	1
323.042	Threaded LCP Drill Guide for 4.3mm drill bits	3
324.168	TomoFix™ Guide Sleeve for 2.0mm Kirschner wires	1
310.430	Drill Bit, 4.3mm dia.	2
314.152	Screwdriver Shaft 3.5, self-retaining	1
324.052	Torque-limiting Screwdriver	1
323.500	Universal Drill Sleeve LCP 4.5/5.0	1
399.097	Bone Spreader, softlock	1
309.530	Extraction Screw, conical	1
309.504S	Drill bit, 3.5mm dia., for metal	1

TomoFix™ Implants

Plates

Item no.	Description	Shaft holes
440.834	TomoFix™ medial high tibia	4
440.843	TomoFix™ lateral high tibia, right	3
440.853	TomoFix™ lateral high tibia, left	3
440.864	TomoFix™ lateral distal femur, right	4
440.874	TomoFix™ lateral distal femur, left	4



TomoFix™ 4.5/5.0mm Screw Set

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

Item no.	Description	Units
171.298	TomoFix™ 4.5/5.0mm Screw Set	
671.298	SYNCASE for TomoFix™ Screw Set, consisting of:	
671.211	Case for Screws	1
679.705	Synthetic Tray with lid	1
671.285	Lid for SYNCASE for TomoFix™ Screw Set	1

Contents of the TomoFix™ Screw Set

Item no.	Description	Units
413.426	5.0mm Locking Head Screw, SD/ST, length 26mm	10
413.336	5.0mm Locking Head Screw, ST, length 36mm	2
413.340	5.0mm Locking Head Screw, ST, length 40mm	4
413.344	5.0mm Locking Head Screw, ST, length 44mm	4
413.350	5.0mm Locking Head Screw, ST, length 50mm	4
413.355	5.0mm Locking Head Screw, ST, length 55mm	4
413.360	5.0mm Locking Head Screw, ST, length 60mm	4
413.365	5.0mm Locking Head Screw, ST, length 65mm	4
413.370	5.0mm Locking Head Screw, ST, length 70mm	4
413.375	5.0mm Locking Head Screw, ST, length 75mm	4
413.380	5.0mm Locking Head Screw, ST, length 80mm	4
413.385	5.0mm Locking Head Screw, ST, length 85mm	4
413.309	Spacer, 5.0mm dia., length 2mm	3
414.824	4.5mm Cortex Screw, ST, length 24mm	2
414.828	4.5mm Cortex Screw, ST, length 28mm	2
414.832	4.5mm Cortex Screw, ST, length 32mm	2
414.836	4.5mm Cortex Screw, ST, length 36mm	2
414.840	4.5mm Cortex Screw, ST, length 40mm	2
414.844	4.5mm Cortex Screw, ST, length 44mm	2
414.848	4.5mm Cortex Screw, ST, length 48mm	2
414.852	4.5mm Cortex Screw, ST, length 52mm	2

chronOS™ Osteotomy Wedges



Item no.	Description
710.057S	chronOS™ β -tricalcium phosphate Wedge, semi-circular, 7° angle, porosity 70%
710.060S	chronOS™ β -tricalcium phosphate Wedge, semi-circular, 10° angle, porosity 70%
710.063S	chronOS™ β -tricalcium phosphate Wedge, semi-circular, 13° angle, porosity 70%

Literature

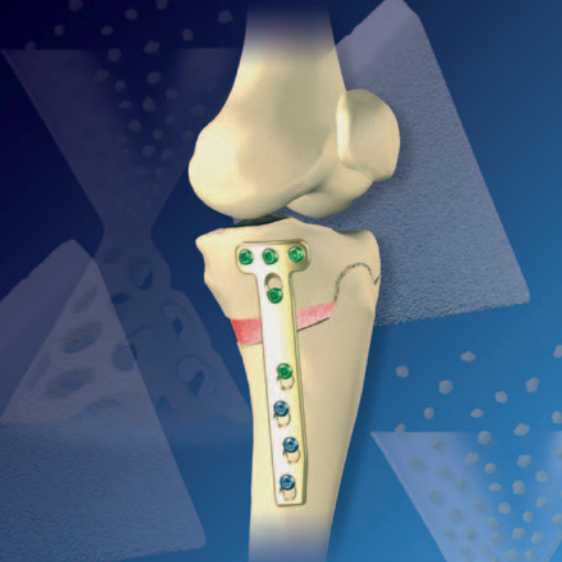
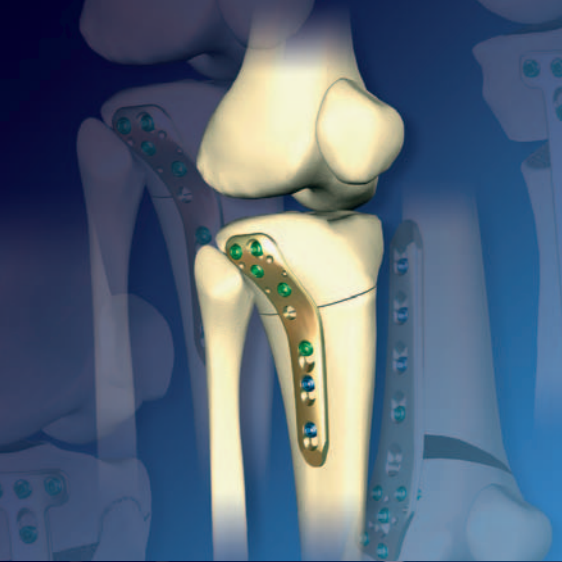
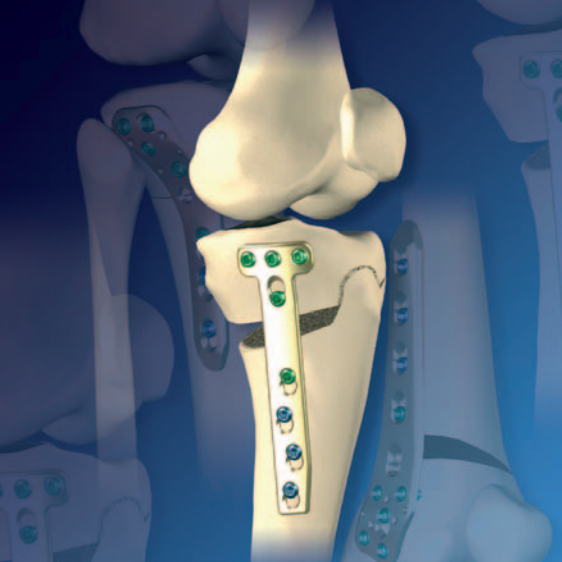
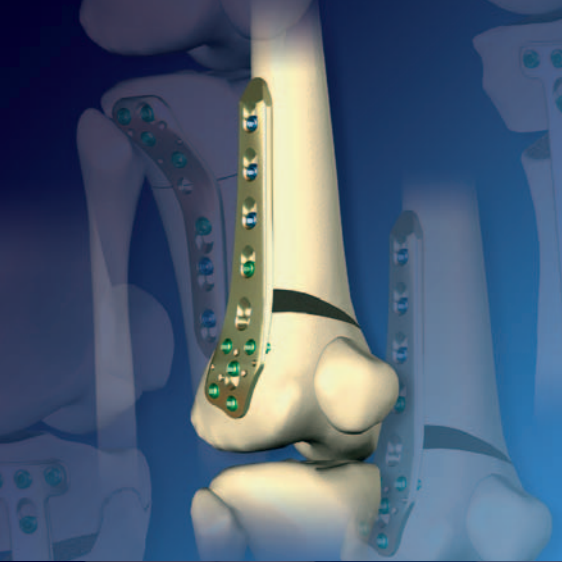
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Notes

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Subject to modifications.