MARQUARDT
Medizintechnik

TWIN - CF
Screw System

Table of Contents

Note:

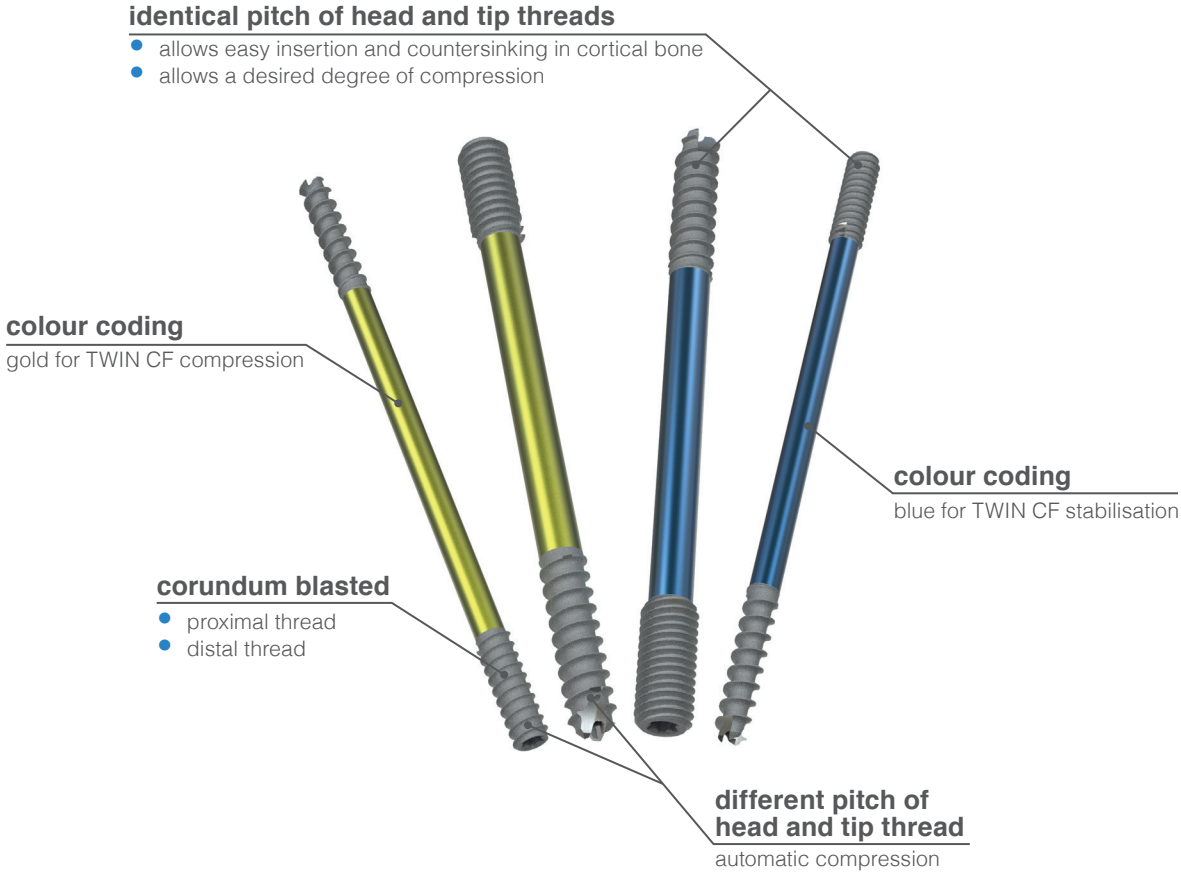
The surgical technique outlined below reflect the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.

Introduction

System Characteristic

The ***TWIN CF Screw System*** is dedicated to address the unique demands of advanced mid/hint foot reconstruction. It is designed to specifically address these patients, while providing easy to use instrumentation that assists in attaining reproducible results. The surface structure of the screw threads is created by subtractive corundum blasting. The enhanced roughness supports osseointegration and leads to an enlarged implant surface which results in increased primary stability. The TWIN CF system offers two types of cannulated screws:

- TWIN CF Compression screw for automatic compression based on different thread pitches of the tip and the head.
- TWIN CF Stabilisation screw for manual compression with a specific instrumentation maintaining a desired compression by a stabilization screw.



Indication - TWIN CF Ø 7.5 mm

Fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of bones in the foot and ankle. Medial and Lateral Column fusion resulting from neuropathic osteoarthropathy (Charcot).

Indication - TWIN CF Ø 5.0 mm

Fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of bones in the foot and ankle. Lateral Column fusion resulting from neuropathic osteoarthropathy (Charcot).

Surgical Technique - TWIN CF Ø 7.5 mm

Preparation

- A gastrocnemius slide or percutaneous tendo–achilles lengthening can help to minimize stress across the midfoot.
- Make a medial incision along the axis of the medial column to allow access to the medial column joints.
- Expose and prepare the joints to be fused.
- Identify and avoid the tibialis anterior tendon, during the procedure.

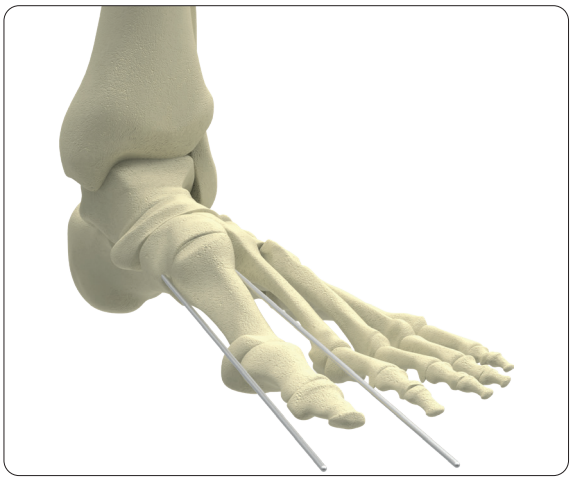
TWIN CF Stabilisation Screw Ø 7.5 mm Insertion

Prepare Joints

Instruments

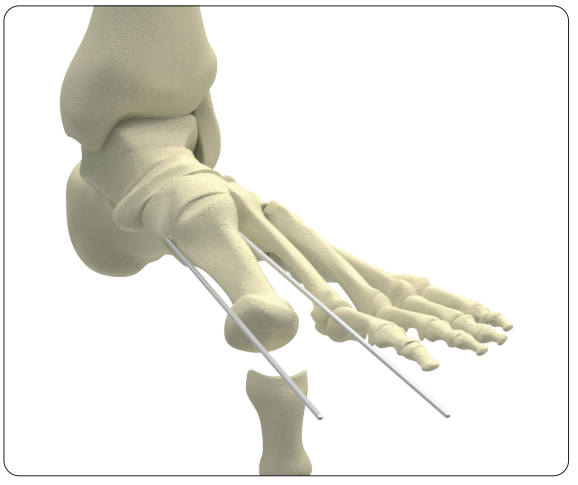
REF 11.90020.150 *Kirschner Wire Ø 2.0 mm, L 150 mm*

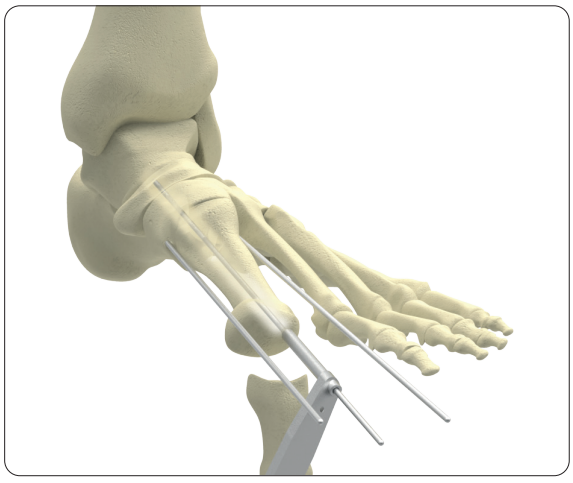
- Correct deformities with resections, where necessary.
- These corrections should be performed to the estimated final shape of the foot.
- Place temporary K-wires to hold the joints in place, taking care not to place them in the path of the final implant.



Prepare Metatarsal

- The first metatarsal phalangeal joint is exposed with an incision from dorsal.



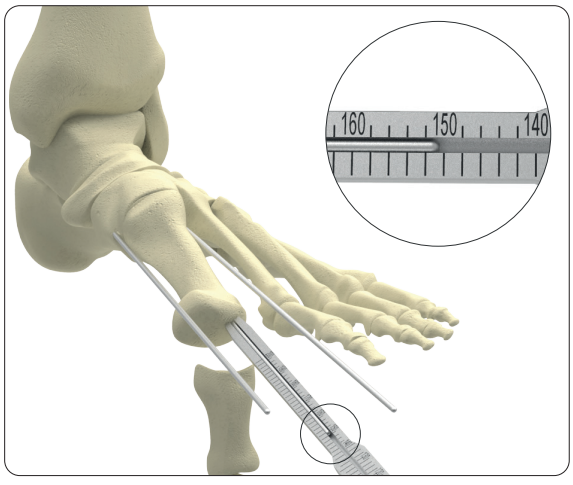


Insert K-wire

Instruments

REF 11.90220.230	*Kirschner Wire Ø 2.0 mm, L 230 mm*
REF 12.20060.070	*Double Drill Guide 2.0 / 7.0*

- The Ø 2.0 mm K-wire is inserted using the double drill guide during plantarflexion of the first phalanx.
- The K-wire is inserted across the cuneiform, navicular into the talus under image intensifier control.
- Advance the K-wire until the tip is in the desired implant position in the talus.



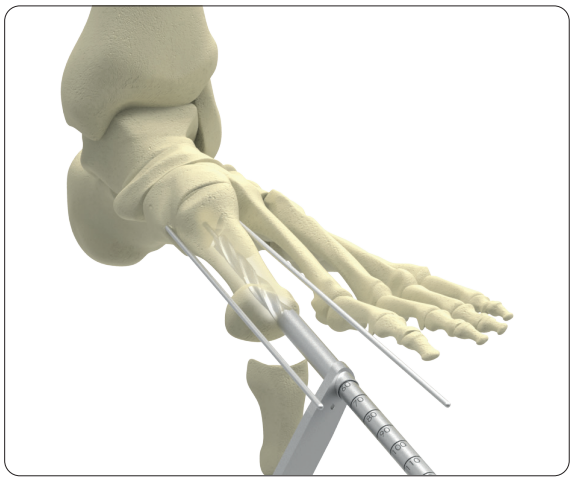
Measuring Implant Length

Instruments

REF 08.20100.070	*Length Determination Instrument for K-Wire Ø 2.0 mm x 230 mm*

- The required screw length is determined using the length determination instrument for the K-wire.
- The end of the Kirschner wire indicates the length of the required screw.

Please note:
For final implant length the space between joints, compression and countersinking should be considered.



Pre-Drill

Instruments

REF 12.20010.069	*TWIN CF Step Reamer*

- Remove the direct measuring device and pre-drill over the K-wire with the step reamer.
- Ensure under image intensification that the step reamer is not advanced further than the K-wire.

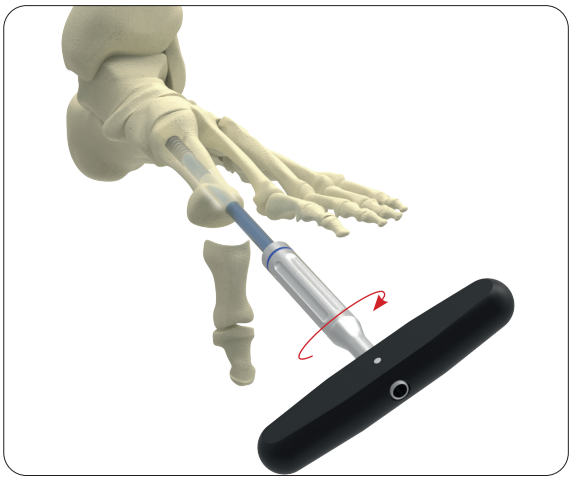
Please note:
It should be verified with the help of image intensifier that the step reamer follows the desired path and does not penetrate the end of the talus.

Insertion of the TWIN CF Stabilisation Screw Ø 7.5 mm

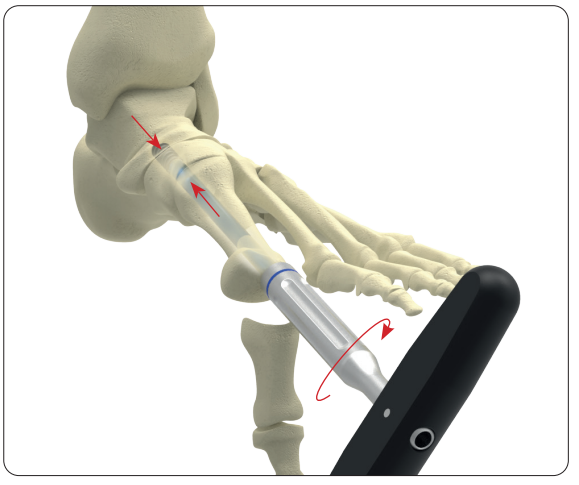
Instruments

REF 12.20040.069 *TWIN CF Compression Screwdriver*

- The distal thread of the TWIN CF Screw is connected to the compression screwdriver.
- Insert the TWIN CF Screw over the K-wire into the metatarsal head.
- Control screw insertion with an image intensifier.



- Advance the TWIN CF Screw until the compression screwdriver contacts the articular surface of the metatarsal.
- Continue to advance the compression screwdriver to compress the medial column until desired compression is achieved.

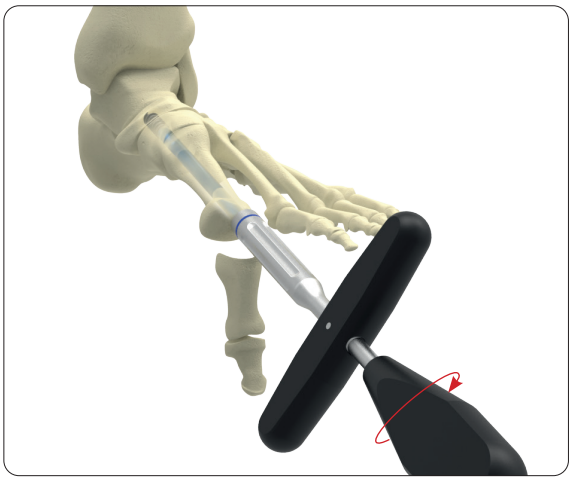


Countersink TWIN CF Stabilisation Screw Ø 7.5 mm

Instruments

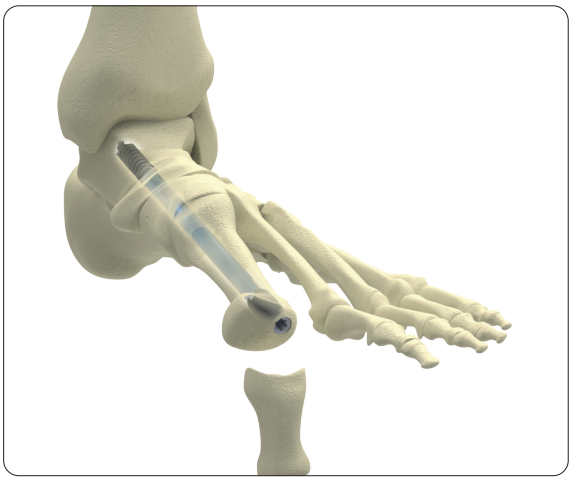
REF 12.20045.027 *Screwdriver T27*

- To countersink the screw and to deconnect it from the compression screwdriver use the screwdriver T27 thorugh the cannulation of the T-handle.
- The compression screwdriver is kept in position and the screwdriver is used to screw the head of the implant into the metatarsal.
- When the stop of the screwdriver shaft reaches the T-handle, it indicates that the top end of the TWIN CF Screw thread is even with the articular surface.



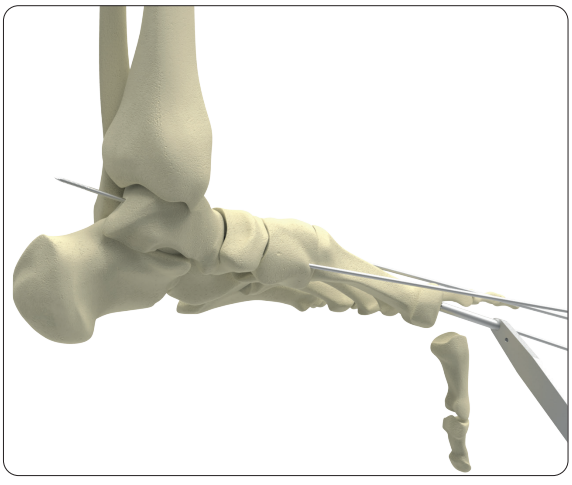
Please note:

Remove the screwdriver and the compression screwdriver after reaching the stop of the screwdriver.



- Check the position of the TWIN CF Screw in two planes with the image intensifier, to ensure that it is well inserted into the body of the talus.

Please note:
It is important to use the right length of the TWIN CF Screw to avoid cut-outs along the plantar aspect of the distal talus.

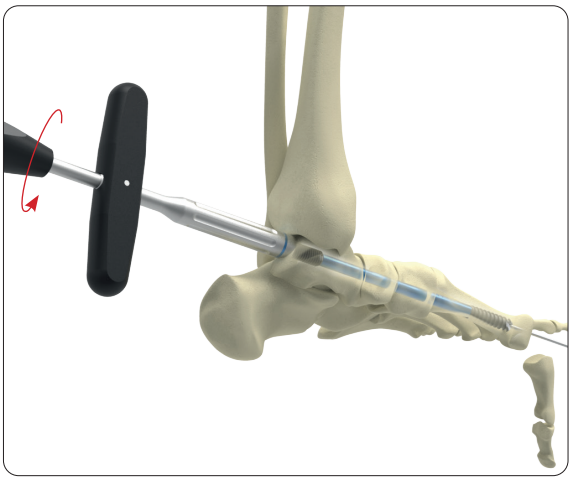


Alternative Reverse Technique
Insert K-Wire

Instruments

REF 11.90220.230	*Kirschner Wire Ø 2.0 mm, L 230 mm*
REF 12.20060.070	*Double Drill Guide 2.0 / 7.0*

- The Ø 2.0 mm K-wire is inserted using the double drill guide during plantarflexion of the first phalanx.
- The K-wire is inserted across the cuneiform, navicular into the talus under image intensifier control.
- Advance the K-wire until the tip emerges posteriorly from the talus without injuring the subtalar joint.



Countersink TWIN CF Stabilisation Screw Ø 7.5 mm

Instruments

REF 12.20045.027	*Scewdriver T27*
REF 12.20040.069	*TWIN CF Compression Screwdriver*

- The further procedure for inserting the TWIN CF Screw corresponds to the points described above.

Please note:

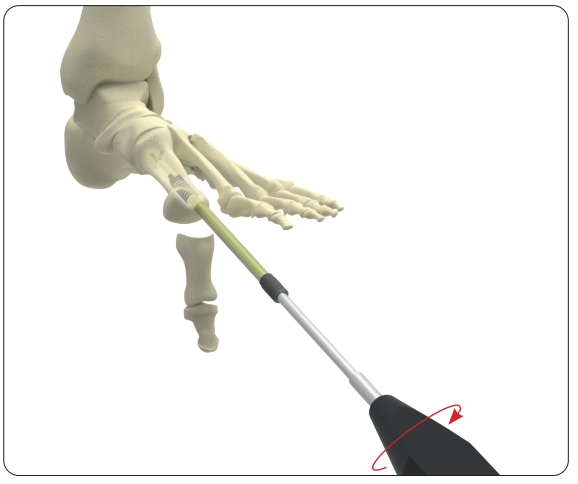
Finally, after reaching the stop of the screwdriver, the compression screwdriver and the screwdriver are removed.

TWIN CF Compression Screw Ø 7.5 mm Insertion

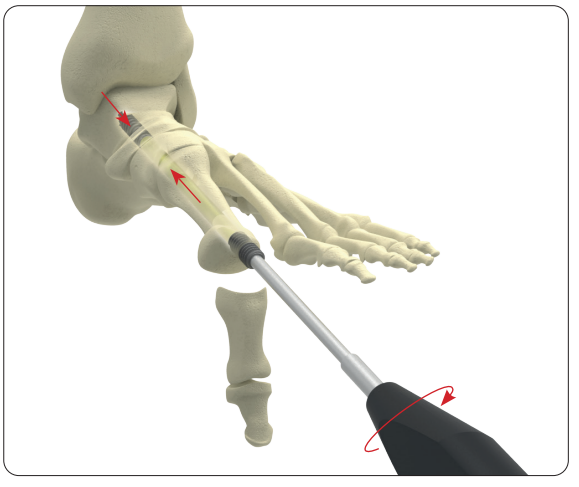
Instruments

REF 12.20045.027 *Screwdriver T27*

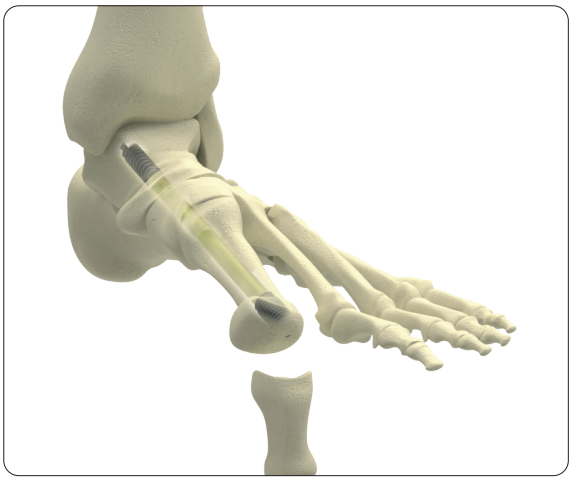
- Apply steps „Insert K-wire, Measuring Implant Length and Pre-Drill“ as described before.
- Insert the TWIN CF Screw over the K-wire into the metatarsal head using the screwdriver.
- Use image intensification to visualize and control screw insertion.



- Turn the screwdriver until the head of the TWIN CF Screw is seated below the articular surface of the metatarsal.



- Check the position of the TWIN CF Screw in two planes with the image intensifier, to ensure that it is well inserted into the body of the talus.



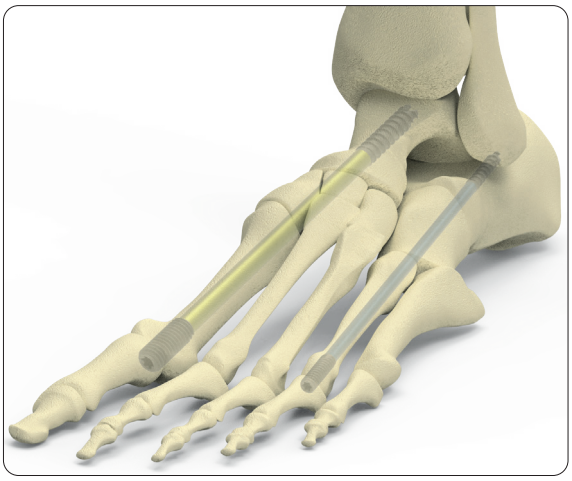
Please note:

It is important to use the right length of the TWIN CF Screw to avoid cut-outs along the plantar aspect of the distal talus.

Please note:

The TWIN CF Screw can also be inserted in the reverse technique. Here, the procedure corresponds to the points described above (Alternative Reverse Technique and TWIN CF Compression Screw Ø 7.5 mm Insertion).

Surgical Technique - TWIN CF Ø 5.0 mm



TWIN CF Stabilisation and Compression Screw Ø 5.0 mm

Instruments

REF 12.20010.049	*TWIN CF Step Reamer Ø 3.6 / 4.9 mm*
REF 12.20045.020	*Scewdriver T20*
REF 12.20040.049	*TWIN CF 5.0 Compession Screwdriver*

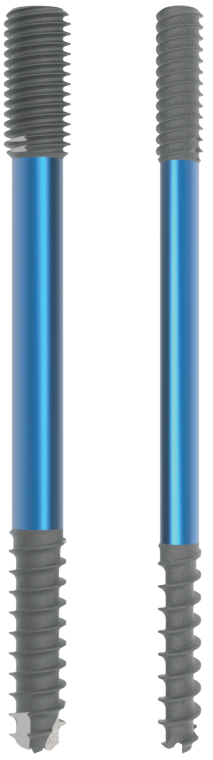
- The insertion of the TWIN CF Stabilisation Screw Ø 5.0 mm and the TWIN CF Compression Screw Ø 5.0 mm corresponds to the points described above.

Product Information

Implants

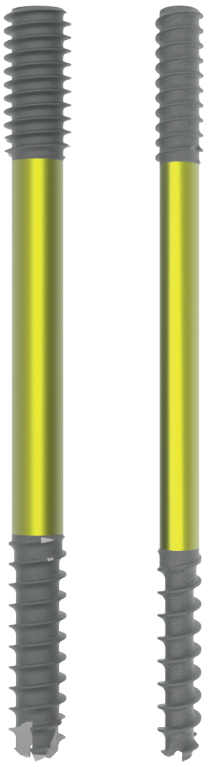
TWIN CF Stabilisation Screw

	TWIN CF Ø 7.5 mm	TWIN CF Ø 5.0 mm
Screw diameter:	7.5 / 8.9 mm	5.3 / 5.8 mm
Cannulation:	2.2 mm	2.2 mm
Pitch:	2.75 / 2.75 mm	2.75 / 2.75 mm
Hexalobe:	T27	T20
Material:	Ti6Al4V	Ti6Al4V



TWIN CF Ø 7.5 mm Article Number *	TWIN CF Ø 5.0 mm Article Number *	Length	TWIN CF Ø 7.5 mm Article Number *	TWIN CF Ø 5.0 mm Article Number *	Length
12.03719.060	12.03519.060	60 mm	12.03719.115	12.03519.115	115 mm
12.03719.065	12.03519.065	65 mm	12.03719.120	12.03519.120	120 mm
12.03719.070	12.03519.070	70 mm	12.03719.125	12.03519.125	125 mm
12.03719.075	12.03519.075	75 mm	12.03719.130	12.03519.130	130 mm
12.03719.080	12.03519.080	80 mm	12.03719.135	12.03519.135	135 mm
12.03719.085	12.03519.085	85 mm	12.03719.140	12.03519.140	140 mm
12.03719.090	12.03519.090	90 mm	12.03719.145	12.03519.145	145 mm
12.03719.095	12.03519.095	95 mm	12.03719.150	12.03519.150	150 mm
12.03719.100	12.03519.100	100 mm	12.03719.155	12.03519.155	155 mm
12.03719.105	12.03519.105	105 mm	12.03719.160	12.03519.160	160 mm
12.03719.110	12.03519.110	110 mm	12.03719.165	12.03519.165	165 mm
			12.03719.170	12.03519.170	170 mm

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.



TWIN CF Compression Screw

	TWIN CF Ø 7.5 mm	TWIN CF Ø 5.0 mm
Screw diameter:	7.5 / 8.9 mm	5.3 / 5.8 mm
Cannulation:	2.2 mm	2.2 mm
Pitch:	2.75 / 1.80 mm	2.75 / 1.80 mm
Hexalobe:	T27	T20
Material:	Ti6Al4V	Ti6Al4V

TWIN CF Ø 7.5 mm Article Number *	TWIN CF Ø 5.0 mm Article Number *	Length	TWIN CF Ø 7.5 mm Article Number *	TWIN CF Ø 5.0 mm Article Number *	Length
12.03718.060	12.03518.060	60 mm	12.03718.115	12.03518.115	115 mm
12.03718.065	12.03518.065	65 mm	12.03718.120	12.03518.120	120 mm
12.03718.070	12.03518.070	70 mm	12.03718.125	12.03518.125	125 mm
12.03718.075	12.03518.075	75 mm	12.03718.130	12.03518.130	130 mm
12.03718.080	12.03518.080	80 mm	12.03718.135	12.03518.135	135 mm
12.03718.085	12.03518.085	85 mm	12.03718.140	12.03518.140	140 mm
12.03718.090	12.03518.090	90 mm	12.03718.145	12.03518.145	145 mm
12.03718.095	12.03518.095	95 mm	12.03718.150	12.03518.150	150 mm
12.03718.100	12.03518.100	100 mm	12.03718.155	12.03518.155	155 mm
12.03718.105	12.03518.105	105 mm	12.03718.160	12.03518.160	160 mm
12.03718.110	12.03518.110	110 mm	12.03718.165	12.03518.165	165 mm
			12.03718.170	12.03518.170	170 mm

***** All implants are also available in sterile. Therefor, add suffix "S" to article number.

Instruments

11.90020.150 Kirschner Wire Ø 2.0 mm, trocar tip, L 150 mm, stainless steel

11.90220.230 Kirschner Wire Ø 2.0 mm, threaded tip, L 230 mm, stainless steel

08.20120.170 Cleaning Wire Ø 2.0 mm, L 250 mm

08.20100.070 Length Determination Instrument for Kirschner Wires Ø 2.0 mm x 230 mm

12.20060.070 Double Drill Guide 2.0 / 7.0

TWIN CF Ø 7.5 mm

12.20010.069 TWIN CF 7.5 Step Reamer Ø 5.8 / 6.9 mm, cannulated, scaled, Jacobs Chuck

12.20045.127 Screwdriver Shaft, T27, cannulated

12.20045.027 Screwdriver, T27, cannulated, L 233 / 123 mm

12.20040.069 TWIN CF 7.5 Compression Screwdriver, cannulated, T-Handle

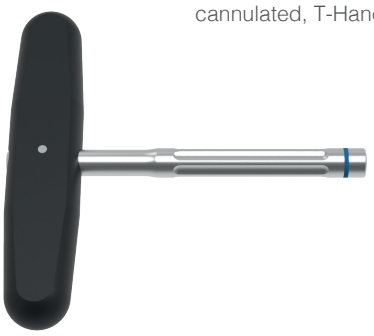
TWIN CF Ø 5.0 mm

12.20010.049 TWIN CF 5.0 Step Reamer Ø 3.6 / 4.9 mm, cannulated, scaled, Jacobs Chuck

12.20045.120 Screwdriver Shaft, T20, cannulated

12.20045.020 Screwdriver, T20, cannulated, L 233 / 123 mm

12.20040.049 TWIN CF 5.0 Compression Screwdriver, cannulated, T-Handle



12.20060.150 Reduction Sleeve 5.0 / 7.0

MRI Safety Information

Non-clinical testing has demonstrated that the screw range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field (B_0)
- Spatial field gradient lower than or equal to
  - **1.5 T:** 23.45 T/m (2345 G/cm)
  - **3.0 T:** 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg.
  - Scan duration and wait time:

    1.5 T: 2 W/kg whole-body average SAR for **10min and 55s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **10min and 55s** if this limit is reached.

    3.0 T: 2 W/kg whole-body average SAR for **7min and 54s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **7min and 54s** if this limit is reached.
- The screws are expected to produce a maximum temperature rise of 6.2 °C at 1.5 T and 6.5 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

Note:

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.

Release date: 10.06.2024 • 12.99100.702 • Rev.: 010/00

MARQUARDT
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