



WINSTA-FiT

Distal Fibula and Tibia Plating System

Clinical Advisor

PD Dr. Fabian Stuby

Medical Director

BG Clinic for Trauma Murnau

Dr. Eike Mrosek

Head of Department

Clinic for Trauma Offenburg

Ortenau Hospital Offenburg-Kehl

► Table of Contents

Introduction	Product Specification	2
	Indication (distal Tibia)	2
	Indication (distal Fibula)	2

Surgical Technique		
Distal Tibia Plate, medial	Positioning of the Patient and Access	3
	Positioning and Fixation of the Plate	3
	Monoaxial Insertion of Locking Screws	4
	Polyaxial Insertion of Locking Screws	5
Distal Tibia Plate, posterior	Positioning of the Patient and Access	6
	Positioning and Fixation of the Plate	6
Distal Tibia Plate, anterolateral	Positioning of the Patient and Access	7
	Positioning and Fixation of the Plate	7

Surgical Technique		
Distal Fibula Plate, lateral	Positioning of the Patient and Access	8
	Positioning and Fixation of the Plate	8

Product Information	Implants	9
	Instruments	14
	Templates	15
	MRI Safety Information	16

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.

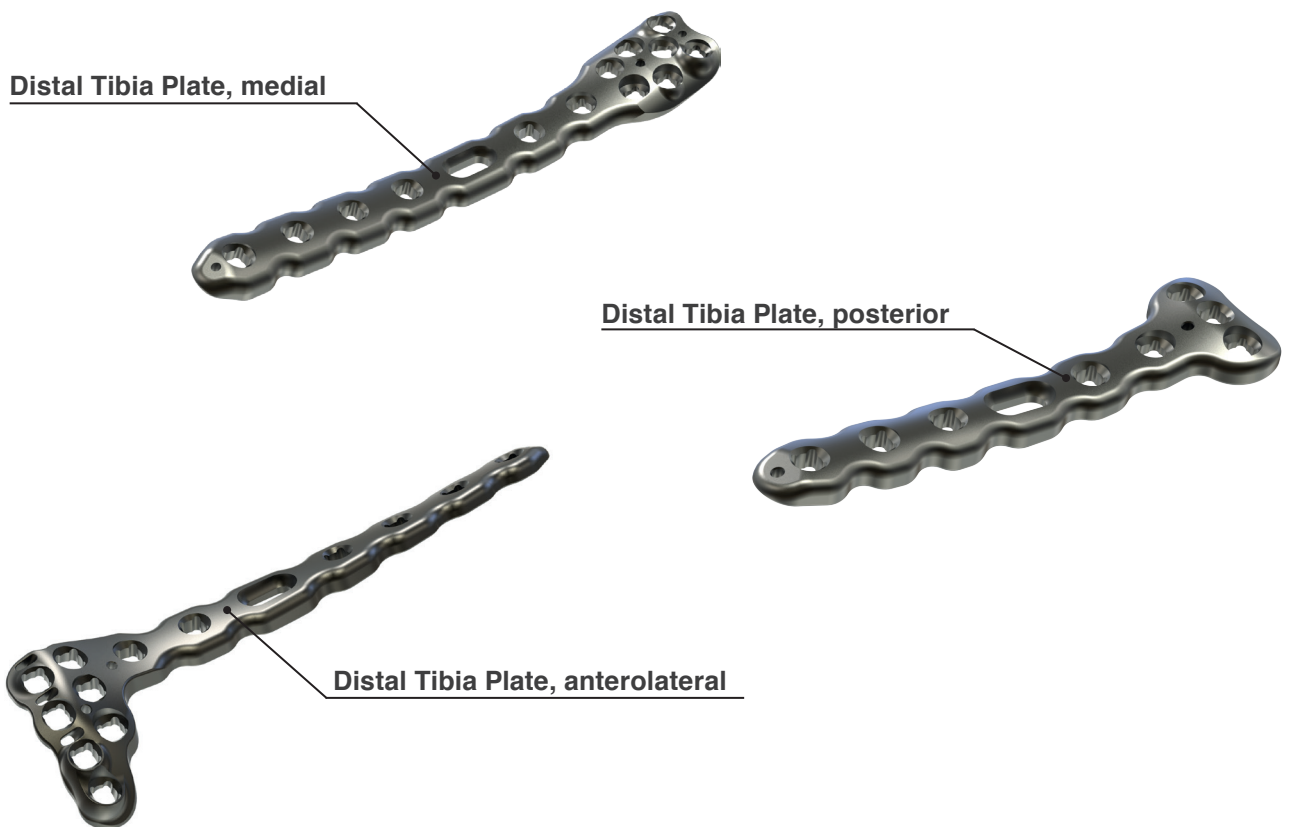
► Introduction

Product Specification

The Marquardt **WINSTA-FiT** System offers anatomically formed plates for fixed-angle locking. The plates are fixed with self-tapping cortical screws. The screws are available in non-locking and locking versions.

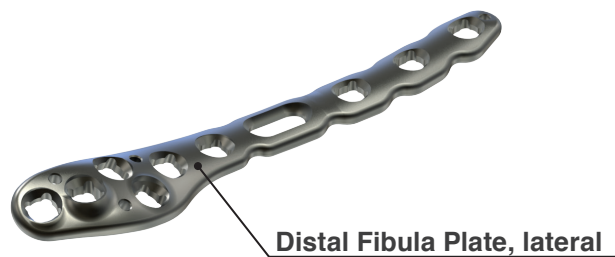
Indication (distal Tibia)

- Complex intra-, extra- and partial articular fractures of distal tibia
- Pseudarthrosis and osteotomies of distal tibia



Indication (distal Fibula)

- Meta- and diaphyseal fractures of distal fibula
- Pseudarthrosis of distal fibula



The following surgical techniques describe the placement of Ø 3.5 mm locking cortical screws. The surgical techniques for the Ø 2.7 mm locking cortical screws are identical in principle but use different instruments (these are stated in brackets).

► Surgical Technique - Distal Tibia Plate, medial

Positioning of the Patient and Access

- The operation is done in supine position on a radiolucent operating table.
- The affected leg of the patient is placed on a special positioning pad with the knee slightly flexed. Thus, the leg can be positioned in a neutral position.
- For access, select a longitudinal incision that passes over the medial malleolus.

Note:

- Be careful not to damage the saphenous vein and the saphenous nerve.



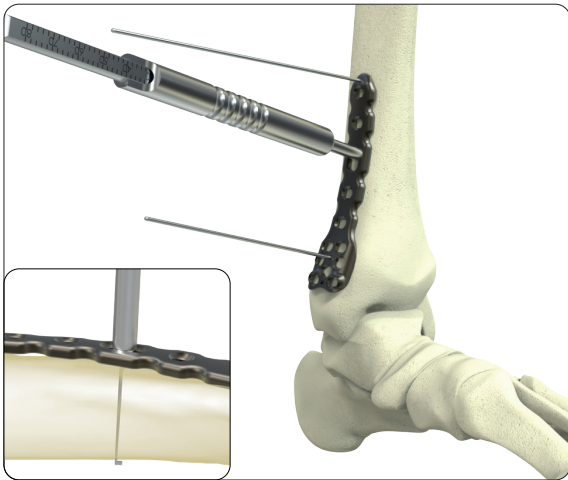
Positioning and Fixation of the Plate

Instruments

REF 03.20011.125	Drill Bit Ø 2.5 mm
(REF 03.20011.120	Drill Bit Ø 2.0 mm)
REF 03.20060.035	Double Drill Guide 2.5 / 3.5
(REF 02.20060.027	Double Drill Guide 2.0 / 2.7)
REF 03.20110.035/135	Bending Iron
REF 11.90016.150	Kirschner Wire Ø 1.6 mm

- The required plate size can be determined using the templates.
- The plate is fixed on the bone with Ø 1.6 mm K-wires.
- Afterwards the plate is fixed in the oval hole. To do this, a Ø 3.5 mm cortical screw is placed in the oval hole.
- The screw hole is pre-drilled bicortically using the drill bit through the double drill guide.
- If required, it may be necessary to adjust the plate to the individual anatomy of the patient. To do this, the plate can be bent with the bending irons. Bending of the implant across a screw hole must be avoided.

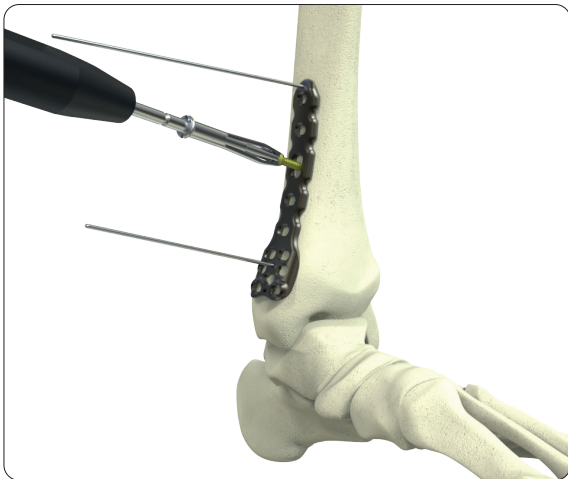




Instruments

REF 03.20100.080 *Length Determination Instrument, for Screw up to 80 mm*

- The length is measured using the length determination instrument.
- The hook is hooked into the opposite cortical bone, and the required screw length is read off the scale.



Instruments

REF 03.20040.025 *Screwdriver, hex 2.5 mm*

REF 03.20040.026 *Holding Sleeve for Screws*

- After the required screw length has been determined, the corresponding cortical screw can be inserted with the screwdriver and the holding sleeve.
- The screw is initially tightened only slightly, so that the plate position can be corrected distally and proximally as required.
- Check the plate position once more and correct it, if necessary, with image amplifier monitoring.
- Once the plate position is correct, the screws are finally tightened, and the plate is thus fixed.



Monoaxial Insertion of Locking Screws

Instruments

REF 03.20011.125 *Drill Bit Ø 2.5 mm*
 (REF 03.20011.120 *Drill Bit Ø 2.0 mm*)

REF 03.20060.325 *Double Drill Guide 2.5 / ML*
 (REF 03.20010.320 *Double Drill Guide 2.0 / ML*)

REF 03.20040.025 *Screwdriver, hex 2.5 mm*

REF 03.20100.080 *Length Determination Instrument, for Screw up to 80 mm*

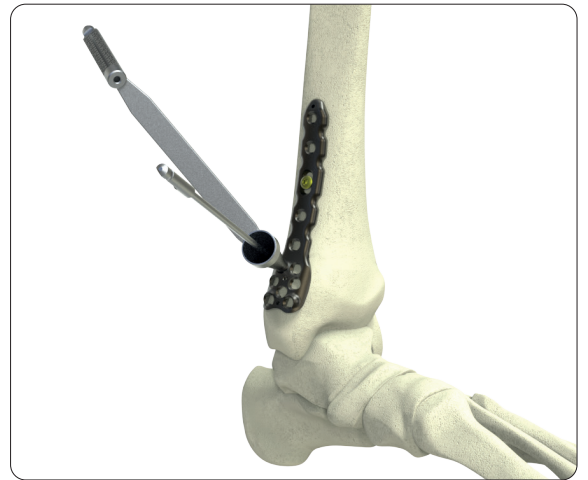
- For monoaxial insertion of Ø 3.5 mm locking cortical screws, the double drill guide 2.5 / ML is inserted into the screw hole.
- The screw hole is pre-drilled bicortically using the Ø 2.5 mm drill bit through the double drill guide.
- The screw length can be determined via the markings of the drill sleeve and the drill bit.
- Alternatively, the screw length can be determined with the length determination instrument.
- The locking cortical screw is tightened with the screwdriver.

Polyaxial Insertion of Locking Screws

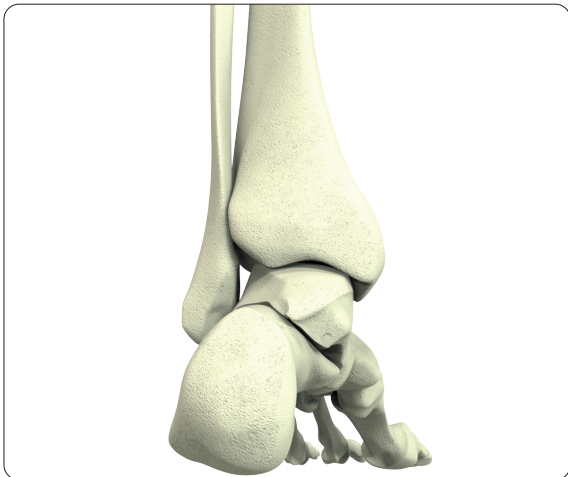
Instruments

<i>REF 03.20011.125</i>	<i>Drill Bit Ø 2.5 mm</i>
<i>(REF 03.20011.120)</i>	<i>Drill Bit Ø 2.0 mm)</i>
<i>REF 03.20060.325</i>	<i>Double Drill Guide 2.5 / ML</i>
<i>(REF 03.20010.320)</i>	<i>Double Drill Guide 2.0 / ML)</i>
<i>REF 03.20040.025</i>	<i>Screwdriver, hex 2.5 mm</i>
<i>REF 03.20100.080</i>	<i>Length Determination Instrument, for Screw up to 80 mm</i>

- The double drill guide 2.5 / ML is used for polyaxial insertion of Ø 3.5 mm locking cortical screws. The double drill guide is inserted into the corresponding screw hole and enables stepless polyaxial drilling in a cone of 20°.
 - The screw hole is pre-drilled bicortically using the Ø 2.5 mm drill bit through the double drill guide.
 - Afterwards the screw length is determined with the length determination instrument.
 - The locking cortical screw is tightened with the screwdriver.
-
- Repeat the procedure for all shaft holes into which screws are to be inserted.
 - Once all of the screw holes have been occupied, a final radiological check is performed.

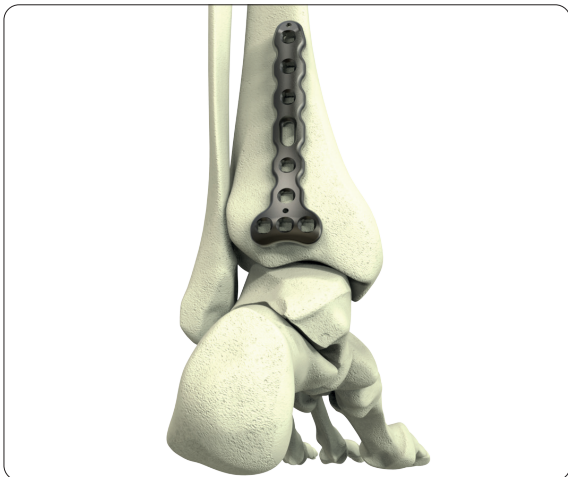


► Surgical Technique - Distal Tibia Plate, posterior



Positioning of the Patient and Access

- The operation is supine on a radiolucent operating table.
- A positioning cushion is placed under the back of the feet to prevent deformation of the feet by lying on the table.
- For posterior access to the tibia, a posterolateral incision is selected.
- Subsequently, the Achilles tendon and the underlying flexor-hallucis-longus tendon are pushed back.

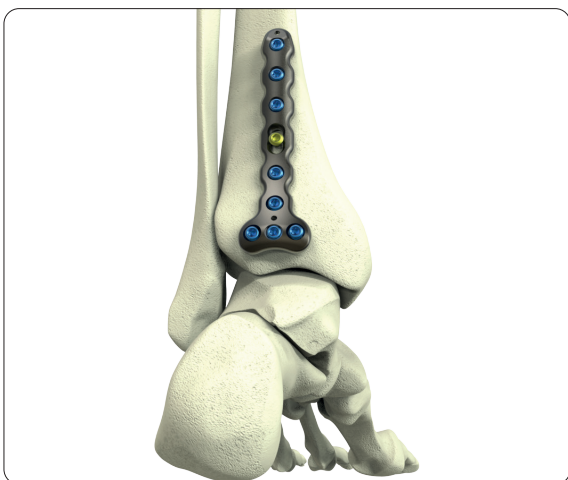


Positioning and Fixation

Instruments

REF 11.90016.150 Kirschner Wire Ø 1.6 mm

- The required plate size can be determined using the templates.
- The plate is fixed on the bone with Ø 1.6 mm K-wires.
- The oval hole is filled following the procedure described above using a Ø 3.5 mm non-locking cortical screw.

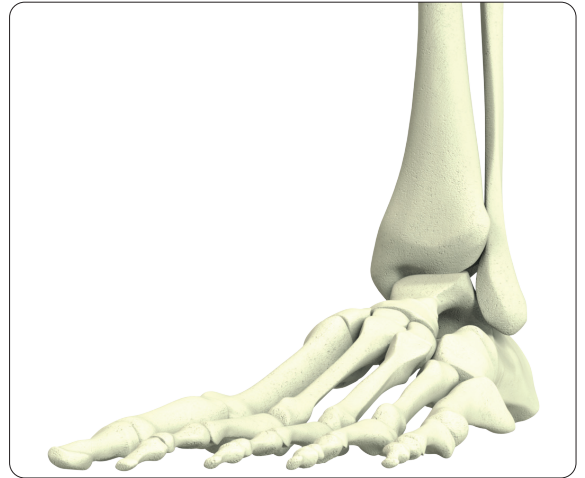


- The locking cortical screws Ø 3.5 mm (Ø 2.7 mm) can also be inserted in the manner described above either monoaxially or polyaxially.
- Once all of the plate holes that are to be occupied have been fixed with screws, a final radiological check is performed in which the plate position and the anatomical repositioning of the fracture are checked.

► Surgical Technique - Distal Tibia Plate, anterolateral

Positioning of the Patient and Access

- The operation is supine on a radiolucent operating table.
- The affected leg of the patient is placed on a special positioning pad with the knee slightly flexed. Thus, the leg can be positioned in a neutral position.
- For the anterior approach, choose a longitudinal incision. This should run distally parallel to the fourth metatarsal bone, then centrally over the ankle and proximally between the tibia and fibula.
- The incision should begin at the level of the talonavicular joint and end up about 7 to 8 cm above the ankle.

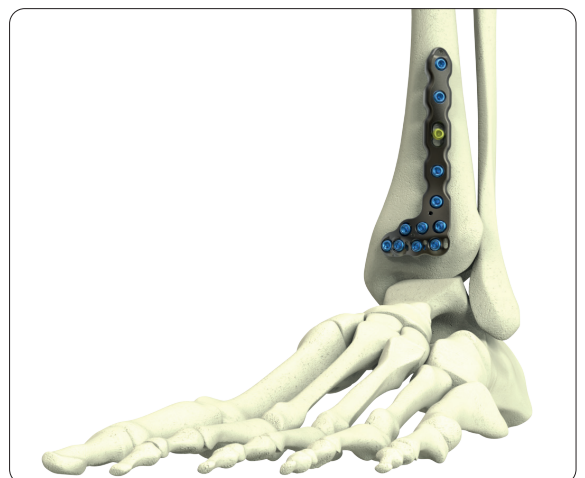
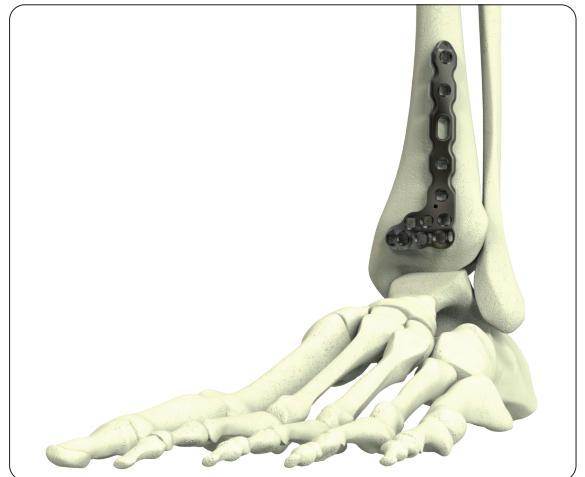


Positioning and Fixation

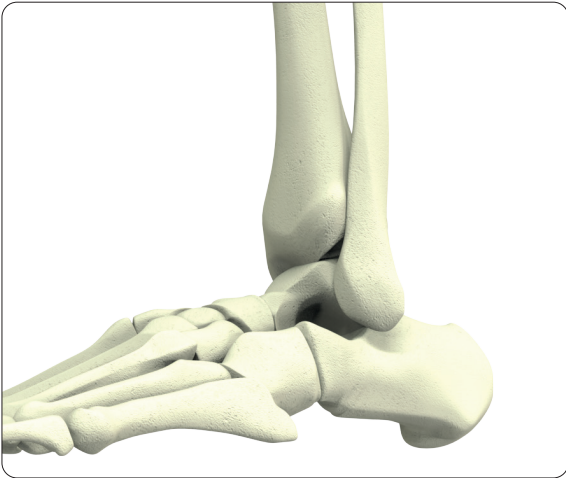
Instruments

REF 11.90016.150 Kirschner Wire Ø 1.6 mm

- The required plate size can be determined using the templates. The templates are available in all variations.
 - The plate is fixed on the bone with Ø 1.6 mm K-wires.
 - The oval hole is filled following the procedure described above using a Ø 3.5 mm non-locking cortical screw.
-
- The locking cortical screws Ø 3.5 mm (Ø 2.7 mm) can also be inserted in the manner described above either monoaxially or polyaxially.
 - Once all of the plate holes that are to be occupied have been fixed with screws, a final radiological check is performed in which the plate position and the anatomical repositioning of the fracture are checked.



► Surgical Technique - Distal Fibula Plate, lateral

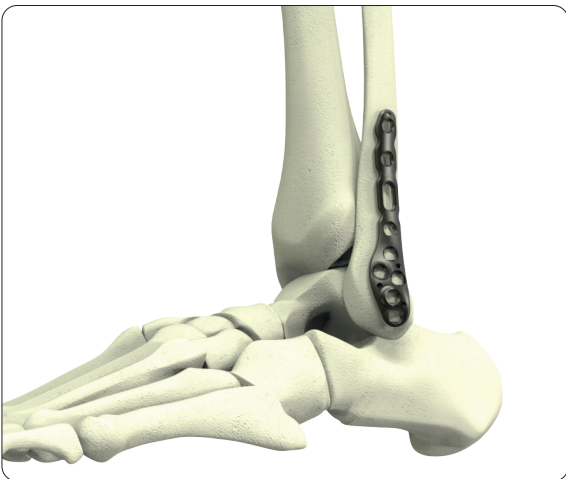


Positioning of the Patient and Access

- The operation is supine on a radiolucent operating table.
- The affected leg of the patient is placed on a special positioning pad with the knee slightly flexed. Thus, the leg can be positioned in a neutral position.
- To access the fibula, select a lateral or posterolateral longitudinal incision.
- A posterolateral incision offers the advantage that better tissue coverage is available at this site, which can lead to better wound healing.

Note:

- Be careful not to damage the superficial peroneal nerve proximally and anteriorly, or the sural nerve posteriorly.

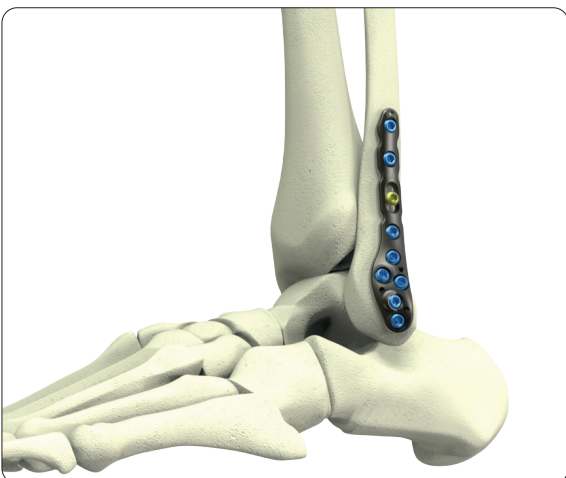


Positioning and Fixation

Instruments

REF 11.90016.150 Kirschner Wire Ø 1.6 mm

- The required plate size can be determined using the templates. The templates are available in all variations.
- The plate is fixed on the bone with Ø 1.6 mm K-wires.
- The oval hole is filled following the procedure described above using a Ø 3.5 mm non-locking cortical screw.



- The locking cortical screws Ø 3.5 mm (Ø 2.7 mm) can also be inserted in the manner described above either monoaxially or polyaxially.
- Once all of the plate holes that are to be occupied have been fixed with screws, a final radiological check is performed in which the plate position and the anatomical repositioning of the fracture are checked.

► Product Information

Implants

Article Number * left	Article Number * right	Holes	Length (mm)
13.15100.105	13.15100.005	5	95
13.15100.107	13.15100.007	7	120
13.15100.109	13.15100.009	9	150
13.15100.111	13.15100.011	11	176
13.15100.115	13.15100.015	15	227

Article Number * left	Article Number * right	Holes	Length (mm)
13.15200.105	13.15200.005	5	88
13.15200.107	13.15200.007	7	116
13.15200.109	13.15200.009	9	147
13.15200.111	13.15200.011	11	174
13.15200.115	13.15200.015	15	229

Article Number *	Holes	Length (mm)
13.15300.003	3	49
13.15300.006	6	87

Article Number * left	Article Number * right	Holes	Length (mm)
13.15500.104	13.15500.004	4	79
13.15500.105	13.15500.005	5	91
13.15500.106	13.15500.006	6	104
13.15500.108	13.15500.008	8	132
13.15500.110	13.15500.010	10	156

WINSTA-FiT Distal Tibia Plate, medial

- Material: Ti6Al4V
- Anodisation: Type II



WINSTA-FiT Distal Tibia Plate, anterolateral

- Material: Ti6Al4V
- Anodisation: Type II



WINSTA-FiT Distal Tibia Plate, posterior

- Material: Ti6Al4V
- Anodisation: Type II

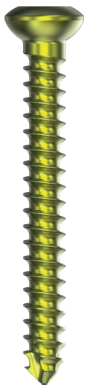


WINSTA-FiT Distal Fibula Plate, lateral

- Material: Ti6Al4V
- Anodisation: Type II



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



Cortical Screw, self-tapping

- Thread diameter:
- Core diameter:
- Head diameter:
- Hexagon socket:
- Material:

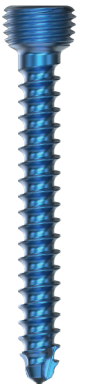
	Ø 2.7 mm	Ø 3.5 mm
Thread diameter:	2.7 mm	3.5 mm
Core diameter:	1.9 mm	2.4 mm
Head diameter:	5.0 mm	6.0 mm
Hexagon socket:	2.5 mm	2.5 mm
Material:	Ti6Al4V	Ti6Al4V

Article Number Ø 2.7 mm	Article Number Ø 3.5 mm	Length (mm)
03.03527.012	03.03612.012	12
03.03527.014	03.03612.014	14
03.03527.016	03.03612.016	16
03.03527.018	03.03612.018	18
03.03527.020	03.03612.020	20
03.03527.022	03.03612.022	22
03.03527.024	03.03612.024	24
03.03527.026	03.03612.026	26
03.03527.028	03.03612.028	28
03.03527.030	03.03612.030	30
03.03527.032	03.03612.032	32
03.03527.034	03.03612.034	34
03.03527.036	03.03612.036	36
03.03527.038	03.03612.038	38
03.03527.040	03.03612.040	40
03.03527.045	03.03612.045	45
03.03527.050	03.03612.050	50
	03.03612.055	55
	03.03612.060	60
	03.03612.065	65
	03.03612.070	70
	03.03612.075	75
	03.03612.080	80

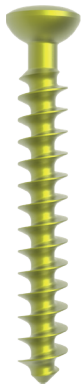
Article Number * Ø 2.7 mm	Article Number * Ø 3.5 mm	Length (mm)
03.05527.012	03.05612.012	12
03.05527.014	03.05612.014	14
03.05527.016	03.05612.016	16
03.05527.018	03.05612.018	18
03.05527.020	03.05612.020	20
03.05527.022	03.05612.022	22
03.05527.024	03.05612.024	24
03.05527.026	03.05612.026	26
03.05527.028	03.05612.028	28
03.05527.030	03.05612.030	30
03.05527.032	03.05612.032	32
03.05527.034	03.05612.034	34
03.05527.036	03.05612.036	36
03.05527.038	03.05612.038	38
03.05527.040	03.05612.040	40
03.05527.042	03.05612.042	42
03.05527.044	03.05612.044	44
03.05527.046	03.05612.046	46
03.05527.048	03.05612.048	48
03.05527.050	03.05612.050	50
03.05527.052	03.05612.052	52
03.05527.054	03.05612.054	54
03.05527.056	03.05612.056	56
03.05527.058	03.05612.058	58
03.05527.060	03.05612.060	60
	03.05612.065	65
	03.05612.070	70
	03.05612.075	75
	03.05612.080	80

Locking Cortical Screw, self-tapping

	Ø 2.7 mm	Ø 3.5 mm
• Thread diameter:	2.7 mm	3.5 mm
• Core diameter:	1.9 mm	2.4 mm
• Head diameter:	4.75 mm	4.75 mm
• Hexagon socket:	2.5 mm	2.5 mm
• Material:	Ti6Al4V	Ti6Al4V



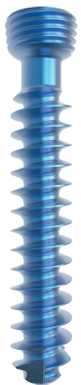
* All implants are also available in sterile. Therefore, add suffix "S" to article number.



Cancellous Bone Screw 4.0 mm

- Thread diameter: 4.0 mm
- Core diameter: 1.9 mm
- Head diameter: 6.0 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article Number *	Length	Article Number *	Length
03.01640.012	12 mm	03.01640.034	34 mm
03.01640.014	14 mm	03.01640.036	36 mm
03.01640.016	16 mm	03.01640.038	38 mm
03.01640.018	18 mm	03.01640.040	40 mm
03.01640.020	20 mm	03.01640.042	42 mm
03.01640.022	22 mm	03.01640.044	44 mm
03.01640.024	24 mm	03.01640.046	46 mm
03.01640.026	26 mm	03.01640.048	48 mm
03.01640.028	28 mm	03.01640.050	50 mm
03.01640.030	30 mm	03.01640.055	55 mm
03.01640.032	32 mm	03.01640.060	60 mm



Locking Cancellous Bone Screw Ø 4.0 mm, self-tapping

- Thread diameter: 4.0 mm
- Core diameter: 2.3 mm
- Head diameter: 4.7 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article Number	Length	Article Number	Length
03.05640.012S	12 mm	03.05640.042S	42 mm
03.05640.014S	14 mm	03.05640.044S	44 mm
03.05640.016S	16 mm	03.05640.046S	46 mm
03.05640.018S	18 mm	03.05640.048S	48 mm
03.05640.020S	20 mm	03.05640.050S	50 mm
03.05640.022S	22 mm	03.05640.052S	52 mm
03.05640.024S	24 mm	03.05640.054S	54 mm
03.05640.026S	26 mm	03.05640.056S	56 mm
03.05640.028S	28 mm	03.05640.058S	58 mm
03.05640.030S	30 mm	03.05640.060S	60 mm
03.05640.032S	32 mm	03.05640.065S	65 mm
03.05640.034S	34 mm	03.05640.070S	70 mm
03.05640.036S	36 mm	03.05640.075S	75 mm
03.05640.038S	38 mm	03.05640.080S	80 mm
03.05640.040S	40 mm		

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

Instruments

11.90016.150 Kirschner Wire Ø 1.6 mm, trocar tip, L 150 mm, stainless steel



02.20010.027 Drill Bit Ø 2.7 mm, AO Coupling, L 100 / 70 mm



03.20010.035 Drill Bit Ø 3.5 mm, AO Coupling, L 110 / 80 mm



03.20011.120 Drill Bit Ø 2.0 mm, AO Coupling, L 165 / 135 mm



03.20011.125 Drill Bit Ø 2.5 mm, AO Coupling, L 165 / 135 mm



03.20060.015 Drill Guide Ø 2.0 for WS Plates



03.20060.020 Drill Guide Ø 2.5 for WS Plates



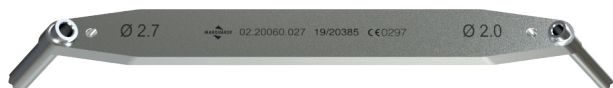
03.20060.320 Double Drill Guide 2.0 / ML



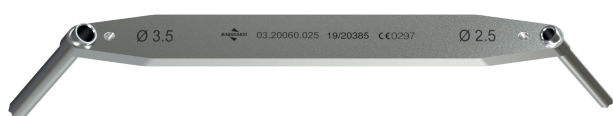
03.20060.325 Double Drill Guide 2.5 / ML



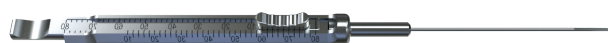
02.20060.027 Double Drill Guide 2.0 / 2.7



03.20060.025 Double Drill Guide 2.5 / 3.5



03.20100.080 Length Determination Instrument, for Screws up to 80 mm



03.20040.125 Screwdriver Shaft, hex 2.5 mm, AO Coupling, L 100 / 70 mm



03.20040.025 Screwdriver, hex 2.5 mm, L 200 / 85 mm



03.20040.026 Holding Sleeve for Screws Ø 2.7 - 4.0 mm



02.20120.015 Screw Forceps, self-holding



03.20110.035 Bending Iron for Plates 2.7 to 3.5, right

03.20110.135 Bending Iron for Plates 2.7 to 3.5, left



Templates

Article Number left	Article Number right	Holes
13.25100.105	13.25100.005	5
13.25100.109	13.25100.009	9

**WINSTA-FiT
Distal Tibia Plate, medial**



Article Number left	Article Number right	Holes
13.25200.105	13.25200.005	5
13.25200.109	13.25200.009	9

**WINSTA-FiT
Distal Tibia Plate, anterolateral**



Article Number left / right	Holes
13.25300.003	3

**WINSTA-FiT
Distal Tibia Plate, posterior**



Article Number left	Article Number right	Holes
13.25500.104	13.25500.004	4
13.25500.106	13.25500.006	6

**WINSTA-FiT
Distal Fibula Plate, lateral**





MRI Safety Information

Non-clinical testing has demonstrated that the plates 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 **8min and 15s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **8min and 15s** if this limit is reached.
 - 3.0 T:** 2 W/kg whole-body average SAR for **6min and 19s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **6min and 19s** if this limit is reached.
- The plates are expected to produce a maximum temperature rise of 8.5 °C at 1.5 T and 6.9 °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.



Dieter Marquardt Medizintechnik GmbH

Robert-Bosch-Straße 1 • 78549 Spaichingen, Germany
Telefon +49 7424 9581-0 • Telefax +49 7424 501441
info@marquardt-medizintechnik.de • www.marquardt-medizintechnik.de

