INCLUDING

SURGICAL
TECHNIQUE GUIDE

AGO MED

IN COOPERATION WITH

FIG FOOT INNOVATION GROUP

ANTERIOR
PLATING SYSTEM 4.0

Made in Germany

INNOVATIVE MEDICAL TECHNOLOGY

EN *Working with AGOMED means working with a company committed to excellence. Our products are German engineered, biocompatible, and cutting-edge. Our team members collectively bring decades of medical technology experience to the table.*

We're reliable. We're flexible. We're inventive.

AGOMED collaborates with distributors, hospitals, and doctors worldwide to create and develop exacting, state-of-the-art solutions for complex surgical problems. We work closely with specialists to insure that our implant systems for Traumatology/Orthopaedics of upper and lower extremities improve the patient's quality of life. Patient safety is always our number one priority.

DE *Mit AGOMED zu arbeiten, bedeutet mit einem Unternehmen zu arbeiten, das sich zur Exzellenz und Hochleistung verpflichtet.*

Unsere Produkte werden von deutschen Ingenieuren entwickelt, sind biokompatibel, innovativ und auf dem neuesten Stand der Technik. Unser Team hat jahrzehntelange Erfahrung im Bereich der Medizintechnik.

Wir sind zuverlässig. Wir sind flexibel. Wir sind innovativ.

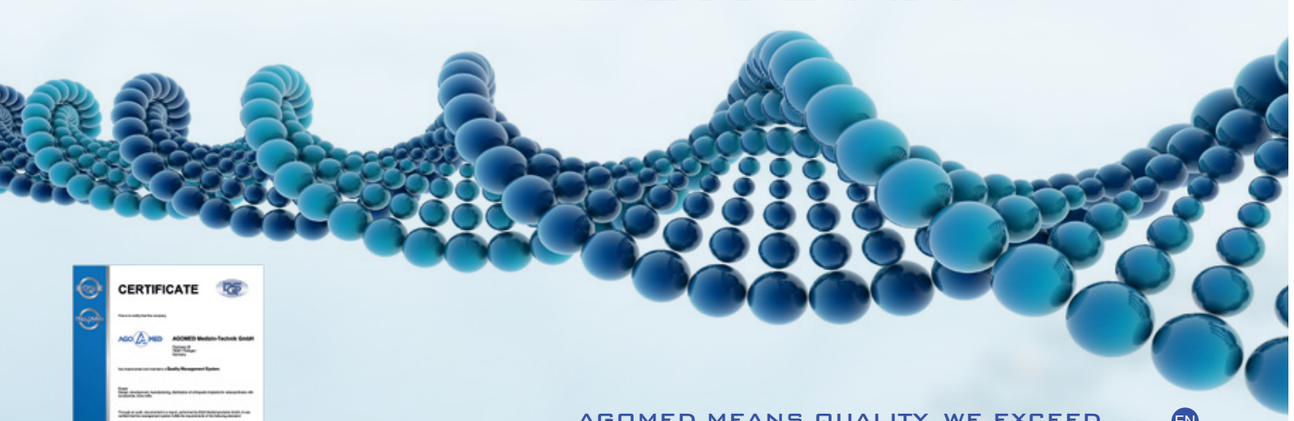
AGOMED arbeitet weltweit mit Unternehmen, Krankenhäusern und Ärzten zusammen, um anspruchsvolle, hochmoderne Lösungen für komplexe chirurgische Probleme zu entwickeln. Wir arbeiten eng mit Spezialisten zusammen, um sicherzustellen, dass unsere Implantat-Systeme für Traumatologie/Orthopädie der oberen und unteren Extremitäten die Lebensqualität der Patienten verbessern. Die Sicherheit der Patienten steht bei uns immer an erster Stelle.

ES *Trabajar con AGOMED significa trabajar con una empresa comprometida con la excelencia. Nuestros productos son diseñados en Alemania, biocompatibles y de vanguardia. Los miembros de nuestro equipo aportan, de manera colectiva, décadas de experiencia en tecnología médica.*

Somos fiables. Somos flexibles. Somos innovadores.

AGOMED colabora con distribuidores, hospitales y doctores a nivel mundial con el objetivo de desarrollar soluciones rigurosas para problemas quirúrgicos complejos con tecnología punta. Cooperamos estrechamente con especialistas para garantizar que nuestros sistemas de implantes y instrumentos para Traumatologia/Ortopedia de las extremidades superiores y inferiores mejoren la calidad de vida de los pacientes. La seguridad de los pacientes siempre es nuestra prioridad.

QUALITY IS PART OF OUR DNA



CERTIFICATE

AGOMED Medizin-Technik GmbH

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

DIN EN ISO 13485

EN AGOMED MEANS QUALITY. WE EXCEED DIN EN ISO 13485 STANDARDS. ALL OUR PRODUCTS BEAR THE CE MARK.


EC-CERTIFICATE
(Full quality assurance system)

AGOMED Medizin-Technik GmbH

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

CE CERTIFICATE

DE AGOMED BEDEUTET QUALITÄT. WIR SIND ZERTIFIZIERT NACH DIN EN ISO 13485. ALLE UNSERE PRODUKTE TRAGEN DAS CE ZEICHEN.

ES AGOMED ES SINÒNIMO DE CALIDAD. SUPERAMOS LOS ESTÁNDARES DIN EN ISO 13485. TODOS LOS PRODUCTOS LLEVAN EL SIGNO CE.

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More information about other Agomed products ***Page 17***

ANTERIOR SYSTEM 4.0

S-1487

FEATURES & BENEFITS

- *Low profile plates with a thickness of 3.0 mm - 4.0 mm*
- *Plate hole accepts 4.0 mm locking and non-locking screws*
- *Maximum fixation points within each plate*
- *Anatomically designed for use surgical approaches: anterior*
- *External Compression Device facilitates controlled compression across the joint*
- *Four compression modes available in the system*

  - Anatomic compression hole

  - Oblong compression hole

Oblong Compression Hole

For eccentric screw placement and compression.

Anatomical Plate Designs

Pre-contoured plate designs closely match the curvature of the anatomy, minimizing the need for additional plate contouring.

Strong low profile plate

Decreases the chance of soft tissue irritation and skin closure

Anatomic Compression Hole

Allows lag compression through the center of the arthrodesis site for maximal compression.

Anterior plates are fully compatible with the Agofix 4.0 System ***S1439***

ANTERIOR PLATES

LEFT 3.0-4.0 mm

RIGHT 3.0-4.0 mm

4001220
9-holes, pack/1

4001221
9-holes, pack/1

4001222
10-holes, pack/1

4001225
10-holes, pack/1

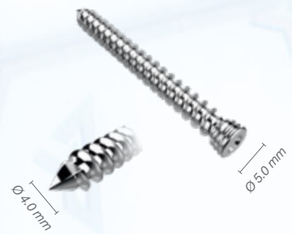
TITANIUM SCREWS 4.0

Threaded head, TX 10

Standard, TX 10

L	∅ 4.0 mm	∅ 4.0 mm	Pack
18 mm	***5004018***	***5004118***	***5***
20 mm	***5004020***	***5004120***	***5***
22 mm	***5004022***	***5004122***	***5***
24 mm	***5004024***	***5004124***	***5***
26 mm	***5004026***	***5004126***	***5***
28 mm	***5004028***	***5004128***	***5***
30 mm	***5004030***	***5004130***	***5***
32 mm	***5004032***	***5004132***	***5***
34 mm	***5004034***	***5004134***	***5***
36 mm	***5004036***	***5004136***	***5***
38 mm	***5004038***	***5004138***	***5***
40 mm	***5004040***	***5004140***	***5***
42 mm	***5004042***	***5004142***	***5***
44 mm	***5004044***	***5004144***	***5***
46 mm	***5004046***	***5004146***	***5***
48 mm	***5004048***	***5004148***	***5***
50 mm	***5004050***	***5004150***	***5***
55 mm	***5004055***	***5004155***	***5***

Drill-ø 3.2 mm



INDICATIONS

- *Arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodeses, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.*

CONTRAINDICATIONS

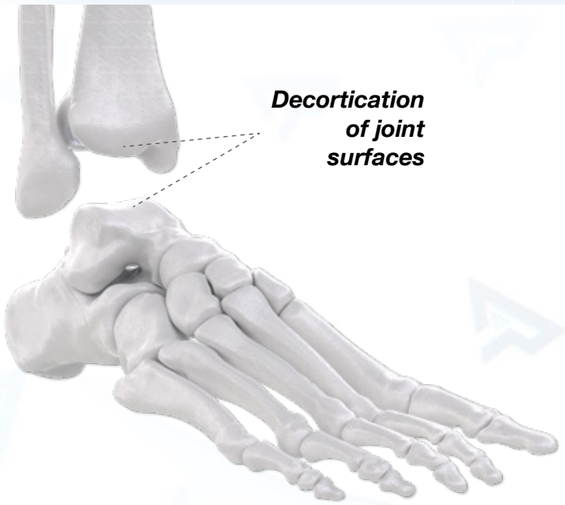
- *Active Infection*
- *Psychologically inadequate patient*
- *Insufficient quantity or quality of bone to permit stabilization of the arthrodesis*
- *Possibility for conservative treatment*
- *Growing patients with open epiphyses*
- *Suspected or documented metal allergy or intolerance*

OPERATION TECHNIQUE

Patient Positioning

- *Position the patient in the supine position, with the heel at end of the table. Place a bump proximal to the ankle.*

STEP 1



Bone Preparation

- *Prepare the joint in the usual manner. Use burrs, curettes, and osteotomes (such as a Charcot chisel or special osteotomes for joint surface preparation) to decorticate the involved joint surfaces. Due to arthritic changes of the ankle, a small portion of the anterior tibia may need to be removed for plate placement.*
- *Ensure that the joint surfaces are prepared congruently.*

STEP 2

- *Provisional fixation of the reduction can be accomplished with a 1.6 mm x 180 mm K-wire (1101058) posterior to where the plate will reside. The wire can be targeted from either the medial or lateral aspect of the tibia.*
- *If necessary, use the appropriate Cannulated Drill Bit to predrill over the Guide Wire. Using the appropriate Driver, insert the cannulated compression 7.5 mm short thread screw (5010036-5010130) to compress the ankle joint. Tighten the screw until the desired compression is achieved, care should be taken to avoid complete penetration of the medial cortex of the tibia.*

STEP 3

Plate Placement

- *Frequently there is an irregular surface remaining over the anterior joint which requires debridement to a smooth surface with either a rongeur or saw. Retrieve the appropriate anterior TT plate based on the patient's anatomy.*
- *If necessary, the anterior metaphyseal flare can be removed along the frontal plane using a saw or chisel. This bone can be translated distally as autograft to fill the void between the plate and anterior margin of the joint. Resect any bony prominence on the dorsal talar neck and check for a proper fit of the plate.*

STEP 4

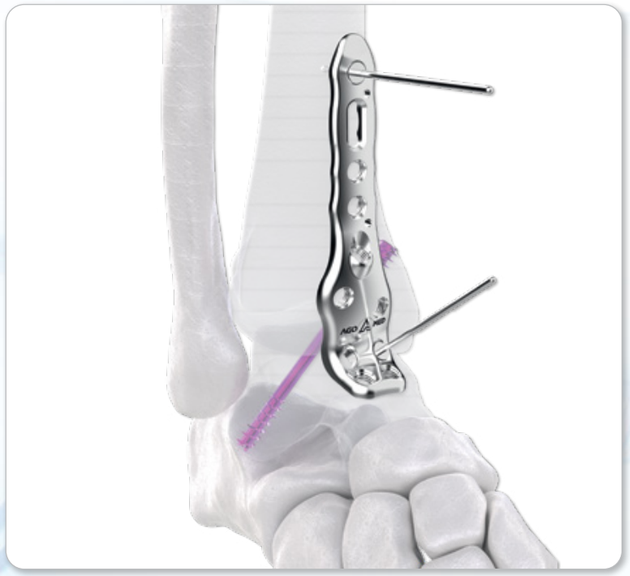
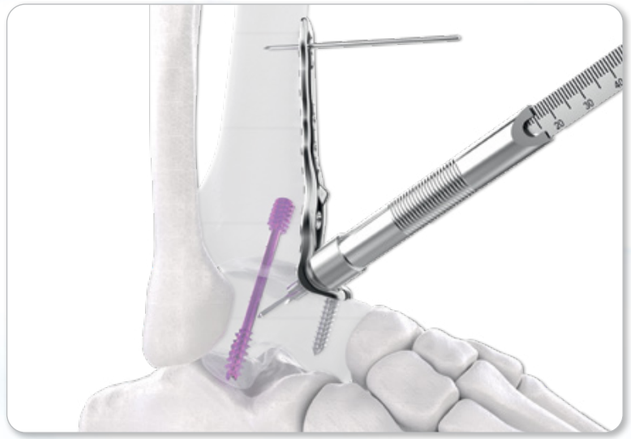


Plate Fixation

- *Fixate the proper anterior plate across the ankle joint and temporarily fix in position using one positioning pin in the talus and the other in the tibia.*

Note: *The plate should be positioned proximal to the dorsal margin of the talonavicular joint to avoid impingement when dorsiflexing the foot.*

STEP 5



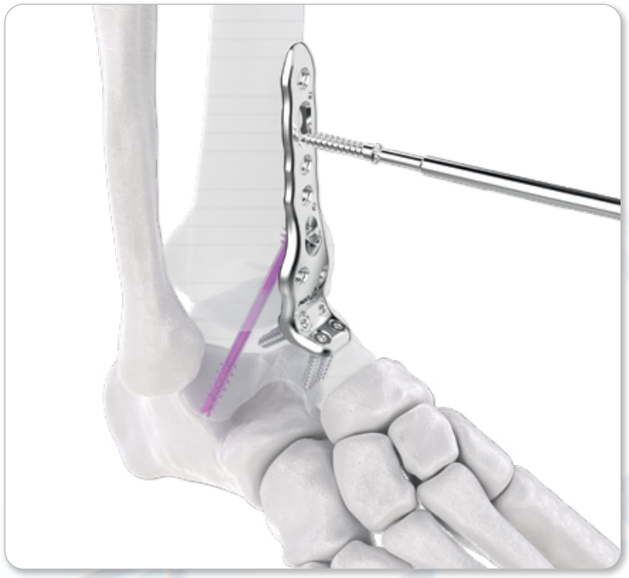
Screw Insertion

- *Secure the plate distally in the talus using a 4.0 mm locking or nonlocking screw drilling with the 3.2 mm drill.*

Tip: *Placing the fixed drill guides in the holes prior to temporary plate fixation may facilitate plate positioning and distal screw drilling.*

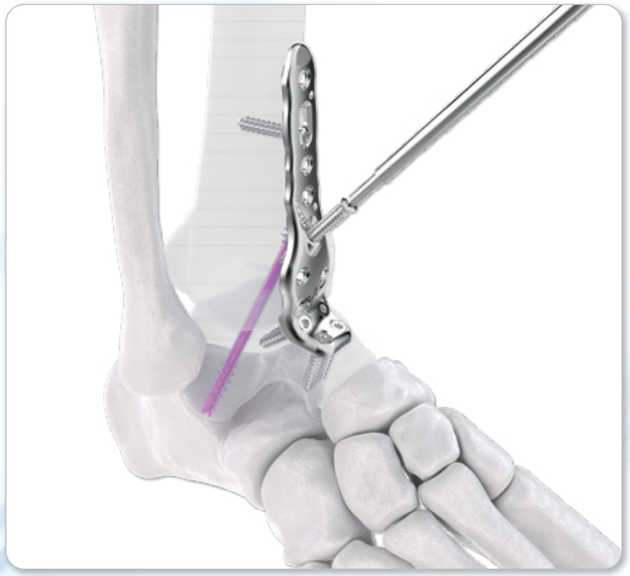
- *Remove the drill guide and measure screw length using the depth gauge. Confirm screw projection and length using the depth gauge under fluoroscopy. Insert the selected screw size into the plate hole using the provided driver and handle.*
- *Continue filling the talar holes until proper fixation is achieved. It is recommended that distal fixation be achieved in advance of proximal fixation of the oblong compression hole in the tibia.*

STEP 6



- *Remove the positioning pin from the tibial screw hole. Use the step outlined in the screw fixation section to drill, measure and fill appropriate 4.0 non-locking screw in the Proximal Slot. Obtain initial compression across the arthrodesis site and secure the tibial portion of the plate to the bone by placing a non-locking screw eccentrically in the oblong compression hole.*

STEP 7



- *In the anatomic lag screw hole use the drill sleeve (K-wire for cannulated drill bits is available) and 3.2 mm drill bit. Overdrill with the drill. Use the depth device to measure and place a screw.*

STEP 8

- *Continue to use either locking or nonlocking screws through the remaining proximal plate holes until the desired fixation is achieved.*

STEP 9

Wound Closure and Dressing

- *Use image intensification to confirm adequate plate and screw placement. Then close the wound in layers, and apply a cast in the usual manner.*

CLINICAL CASE STUDIES

INSTRUMENTS AND TOOLS

1301048	AgoFix agopaq system 4.0 instrument tray

1000150	Agopaqx4 tray for implant modules w/4 lids, w/o implant modules

1000439	Agopaqx4 Ankle Fusion Anterior plate-tray system 4.0, w/o implants

1301038 Agopaqx4 screw tray
system 4.0 w/o implants

1301051 Agopaqx4 AgoFix screw tray 34-55 mm
locking, system 4.0, w/o implants

1301052 Agopaqx4 AgoFix screw tray 34-70 mm
standard, system 4.0, w/o implants

1300980 Silicone ratchet T-handle, AO-shaft
right / left / fixed, 13 cm, cannulated, black

1300977 Silicone ratchet handle, AO-shaft
right / left / fixed, 15 cm,
non-cannulated, black

1300513 Pin w/screw thread 4.0,
AO 140 mm

1101270 Kirschner wires trocar/trocar
2 x 150 mm, pack/10

1006002 Agomed depth gauge 60 mm,
round f. 2.0 - 4.5 mm screws

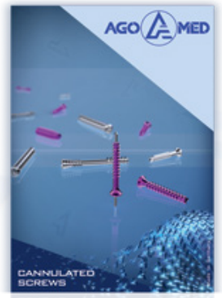
1201114	AgoFix drill-guide f. drill 2.7 sys. 4.0, screwable, black marking, 45 mm	
1201115	AgoFix drill-guide f. drill 3.2 sys. 4.0, screwable, red marking, 65 mm	
1001010	Screwdriver blade TX 10 non-cannulated, interchangeable, AO-shaft	
1201064	Twist drill 2.7 x 125 mm, AO 50 mm thread, black marker	
1201101	Twist drill 3.2 x 145 mm, AO-shaft 50 mm thread, red marker	
1002527	Plate- /screwholding forceps angled, 15cm/6”	

MORE OF OUR PRODUCTS

2010033
AgoFix 4.0 system

2010002
Foot & Ankle system

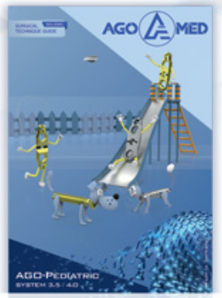
2010015
Cannulated Screws



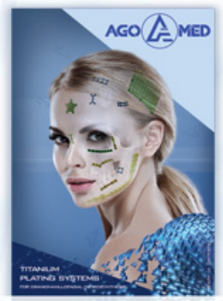
2010007
King Kong Multidirectional Radius system 2.5

2010030
Pediatric Screw system 6.2

2010017
AGO-Pediatric system 3.5 / 4.0



2010003
Titanium plating system for craniomaxillofacial osteosynthesis



2010008
AgoFix Neuro Plating system 1.5

2010016
Titanium Mesh systems for craniomaxillofacial osteosynthesis / Neuro

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