SURGICAL TECHNIQUE GUIDE

INCLUDING

AGO MED

AGOSALIS SYSTEM 2.7

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. We work closely with specialists to insure that our implants for trauma and 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, dass 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 zu entwickeln. Wir arbeiten eng mit Spezialisten zusammen, um sicherzustellen, dass unsere Implantate für Traumatologie und Extremitäten die Lebensqualität der Patienten verbessern.

Die Sicherheit der Patienten steht bei uns immer an erster Stelle.

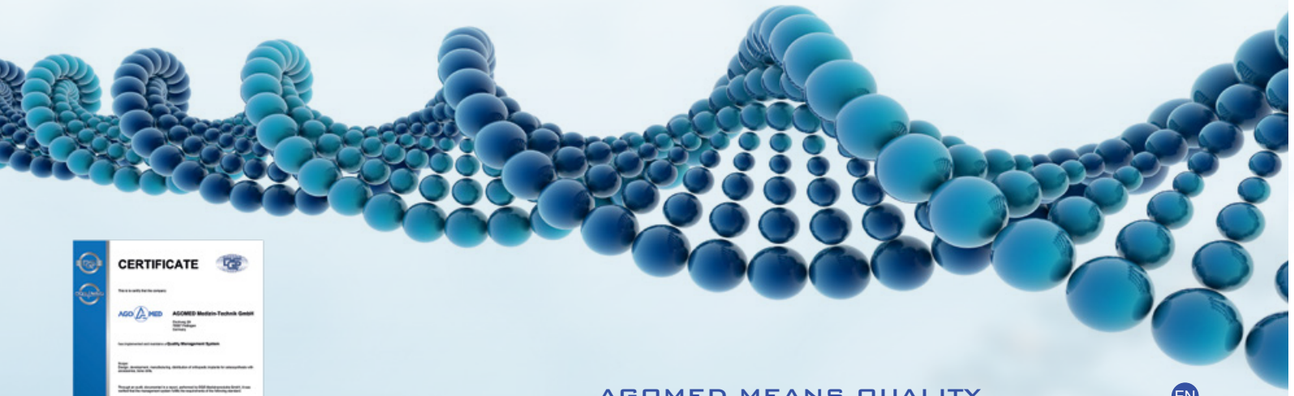
ES *Trabajar con AGOMED significa trabajar con una empresa comprometida con la excelencia. Nuestros productos son diseñados en Alemania, biocompatibles y de vanguardia. Los miembros de nuestro equipo aportan, de manera colectiva, décadas de experiencia en tecnología médica.*

Somos fiables. Somos flexibles. Somos innovadores.

AGOMED colabora con distribuidores, hospitales y doctores a nivel mundial con el objetivo de crear y desarrollar soluciones rigurosas y con tecnología punta. Cooperamos estrechamente con especialistas para garantizar que nuestros implantes para trauma y extremidades 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 ISO 13485


EC-CERTIFICATE

AGOMED Medizin-Technik GmbH

CE CERTIFICATE

EN AGOMED MEANS QUALITY. WE EXCEED ISO 13485 STANDARDS AND HAVE CE CERTIFICATION.

DE AGOMED BEDEUTET QUALITÄT. WIR SIND ZERTIFIZIERT NACH ISO 13485 UND HABEN DIE CE ZERTIFIZIERUNG

ES *AGOMED ES SINÓNIMO DE CALIDAD. SUPERAMOS LOS ESTÁNDARES ISO 13485 Y CONTAMOS CON CERTIFICACIÓN CE.*

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More information about other Agomed products ***Page 18***

AGOSALIS
PLATING SYSTEM 2.7

S-1429

TITANIUM LOCKING PLATE SYSTEM
FOR INTERNAL FIXATION OF THE MIDFOOT

INDICATIONS

- *Arthrodesis of first MPJ*
- *Metatarsal arthrodesis*
- *Pseudarthrosis of Metatarsals*
- *Revision arthrodesis of the MPJ*
- *Iliac crest interposition arthrodesis of first toe*
- *ORIF in trauma cases*
- *Lisfranc arthrodesis*
- *Arthrodesis Lisfranc- Joint (tarso-metatarsal)*
- *Axial corrections and metatarsal shortening*
- *Interposition and revision arthrodesis of Lisfranc joints*
- *Multiple arthrodesis from Metatarsal I to Os naviculare*

ADVANTAGES OF THE SCREWS

Locking and Non-locking screws

Blunt tip design helps to minimize soft tissue irritation. Plate holes accommodate locking screws for instant stability and standard screws for variable-angle fixation.

ADVANTAGES OF THE PLATES

- *Extremely good anatomic fit design*
- *A good internal fixation to the arthrodesis*
- *Anatomical plate dimensions*
- *High stability in the case of slender bones*
- *Variable length*
- *Accomodised screw position*
- *Plates don't cause soft tissue irritation*
- *Unidirektionale looking plates (stabile system)*
- *Combination with lag screws*
- *MRI possible*
- *No interference with scan at the air port*

T-plates available in left and right options for anatomical reduction of Lisfranc fracture dislocation.

Plate ends in shamrock shape provide an excellent stabilization.

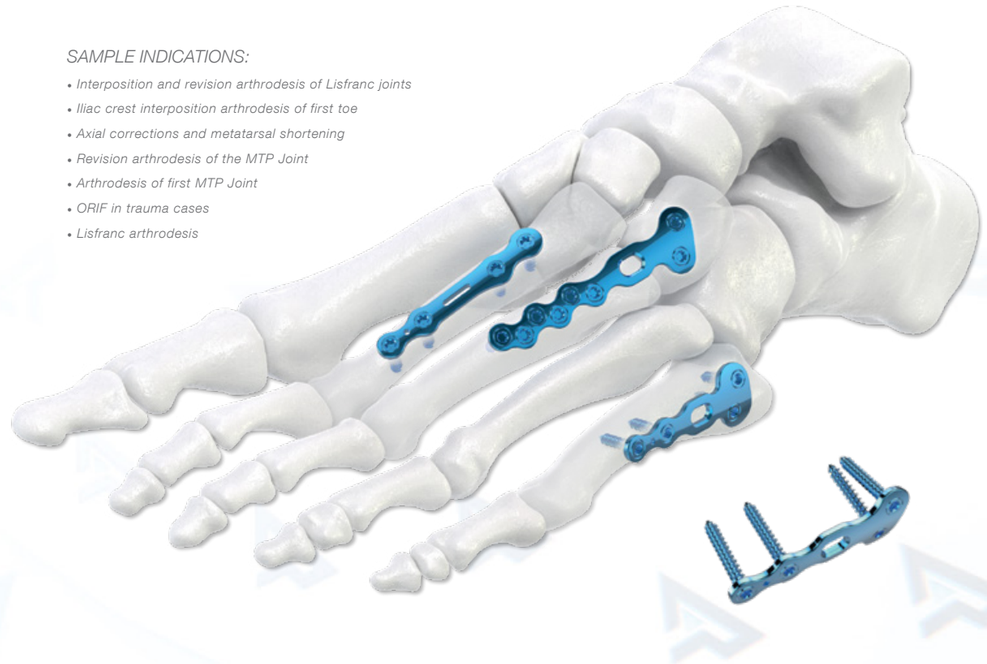
Decreased risk of soft tissue irritation

Low-profile plates with rounded edges and highly polished surface decrease the risk of soft tissue irritation.

AGOSALIS TITANIUM PLATES

SAMPLE INDICATIONS:

- *Interposition and revision arthrodesis of Lisfranc joints*
- *Iliac crest interposition arthrodesis of first toe*
- *Axial corrections and metatarsal shortening*
- *Revision arthrodesis of the MTP Joint*
- *Arthrodesis of first MTP Joint*
- *ORIF in trauma cases*
- *Lisfranc arthrodesis*



STRAIGHT 1.6 mm

4001086
4-holes

4001087
5-holes

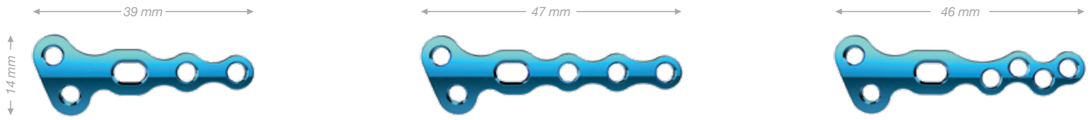
T FORM, STRAIGHT 1.6 mm

4001088
5-holes

4001089
6-holes

4001100
7-holes

T FORM, RIGHT 1.6 mm



4001093
5-holes

4001094
6-holes

4001090
7-holes

4001091
8-holes

4001092
9-holes

T FORM, LEFT 1.6 mm

4001098
5-holes

4001099
6-holes

4001095
7-holes

4001096
8-holes

4001097
9-holes

SAMPLE INDICATIONS:

- *Multiple Arthrodeisis from MT to Os Cuneiforme*

STRAIGHT 1.6 mm

4001101
10-holes, pack/1

4001102
12-holes, pack/1

4001103
14-holes, pack/1

TITANIUM SCREWS 2.7

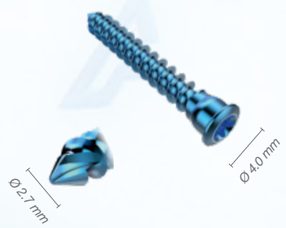
Length

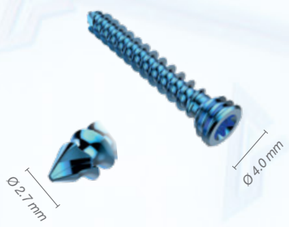
Standard, TX 8

Threaded head, TX 8

L	∅ 2.7 mm	∅ 2.7 mm	Pack
8 mm	**5001108**	**5001008**	**5**
10 mm	**5001110**	**5001010**	**5**
12 mm	**5001112**	**5001012**	**5**
14 mm	**5001114**	**5001014**	**5**
16 mm	**5001116**	**5001016**	**5**
18 mm	**5001118**	**5001018**	**5**
20 mm	**5001120**	**5001020**	**5**
22 mm	**5001122**	**5001022**	**5**
24 mm	**5001124**	**5001024**	**5**
26 mm	**5001126**	**5001026**	**5**
28 mm	**5001128**	**5001028**	**5**
30 mm	**5001130**	**5001030**	**5**

Drill-ø 2.0 mm





OPERATION TECHNIQUE

Patient Positioning

- *Patient positioning per surgeon's technique and preference.*

Osteotomies / Bone Tissue Preparation

- *Joint preparation: Decorticate involved joint surfaces completely by means of appropriate burrs, curettes and osteotomes (e.g. AGOMED Charcot chisel or special osteotomes for joint surface preparation) until the subchondral bone surface is fully exposed on each side.*
- *Only use appropriate saw blades designed for small bone surgery.*

Handling of Implants

- *Use the provided forceps as to remove plates and screws from the tray.*
- *Implants that have been removed from the tray intraoperatively, but were not used in situ, need to be cleaned separately with a validated procedure before being put back into the tray. Afterwards they can be sterilized.*

STEP 1

Plate selection and fixation

- *After choosing the appropriate plate, if necessary, it can be moduled to better fit the patient's anatomy and provisionally fixed in place with K-Wire ø1.1 through the plate.*

Note:
Avoid excessive modeling of the plate as this can compromise its locking mechanism.

Modelling of Locking Plates

- ***Bending:*** *If considered necessary, the bending instruments provided (e.g. plate bending forceps or pliers) may be used to accomplish necessary plate adjustments in order to fit the specific patient anatomy. The plate shaft can be bent up to an angle of 8°.*
- ***Warning:*** *The dedicated thread function of the screw holes may suffer functional reduction or may become inoperative, if located in the bended area(s).*
- ***Tip for maintaining the thread function of screw holes:*** *Prior to bending a near locking thread, it is important to mount the drill guide for protection of the locking threads within the plate.*

STEP 2

Drilling

- *Once the plate is temporary fixed, attach the Drill guide on the plate.*
- *The locking drill guide is threaded into one of the proximal screw holes for drilling and placement of the 2.7 mm locking screw.*
- *The locking hole is drilled with a 2.0 mm drill.*
- **ATTENTION:** *Avoid thermal necrosis using appropriate irrigation.*

Note:
When drilling through plates and drill guides ensure correct guiding (along longitudinal axis) of the drill and the drilling machine! Even slight canting causes premature wear and may result in metal abrasion.

- ***Locking Screw Technique:*** *During drilling the threaded screw holes must not be damaged! The drill guides, part of the system, must be used to avoid damages of the threads and to ensure the correct drill direction for locking screws. The drill bit is to be led through the drill guide's canal.*
- ***Standard Screw Technique:*** *The drill bit may be led through the threaded screw holes without a drill guide. However, the drill bit may suffer high wear during the procedure. Also the threads of the plate may suffer.*
- ***Tip:*** *The drill guides can be used as tissue protectors to a certain degree.*

STEP 3

Depth Measurement

- *To measure the length of the screw use the depth gauge which should be positioned on the plate hole. Its probe is to be forwarded into the pre-drilled intramedullary canal.*
- *If the drill hole reaches through the cortical bone on the opposite site, pull back the measuring gauge until the tip of the gauge catches the bone crest.*
- *Determine the appropriate screw length directly from the scale on the gauge. The reading on the scale is to be understood as the length of the whole screw.*

Warning: *If the drill hole does not reach trough the cortical bone on the opposite site, 1 mm is to be deducted from the read result.*

STEP 4

Screw insertion

- *Attach the provided driver to a handle and insert the selected locking or non-locking screw.*

Note:
Use a non-locking screw for insertion into the plate compression slot.

1001022

1004030

- *Only the appropriate instruments must be used to manipulate and handle the screws. AO system screwdrivers as well as screwdriver handles are provided. Manipulating the screws with inappropriate instruments may result in damage of the threads. The screws may become unusable. Damaged screws must no longer be used and be replaced.*

Tip: *For removing the screws from the tray, the screwdriver blade needs to be pushed firmly in vertical direction into the screw head in order to achieve a good grip of the screw.*

STEP 5

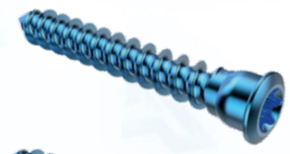
- *Repeat the steps above to fill the second screw hole.*

Note:
The same steps are used regardless if a locking or non-locking screw is used.

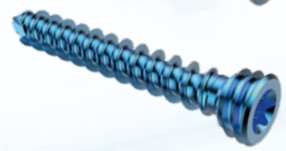
Selection of Screws

- *There are different screw options for the plate fixation:*

Threaded screw holes:

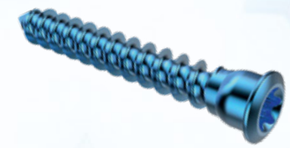


Standard screw 2.7



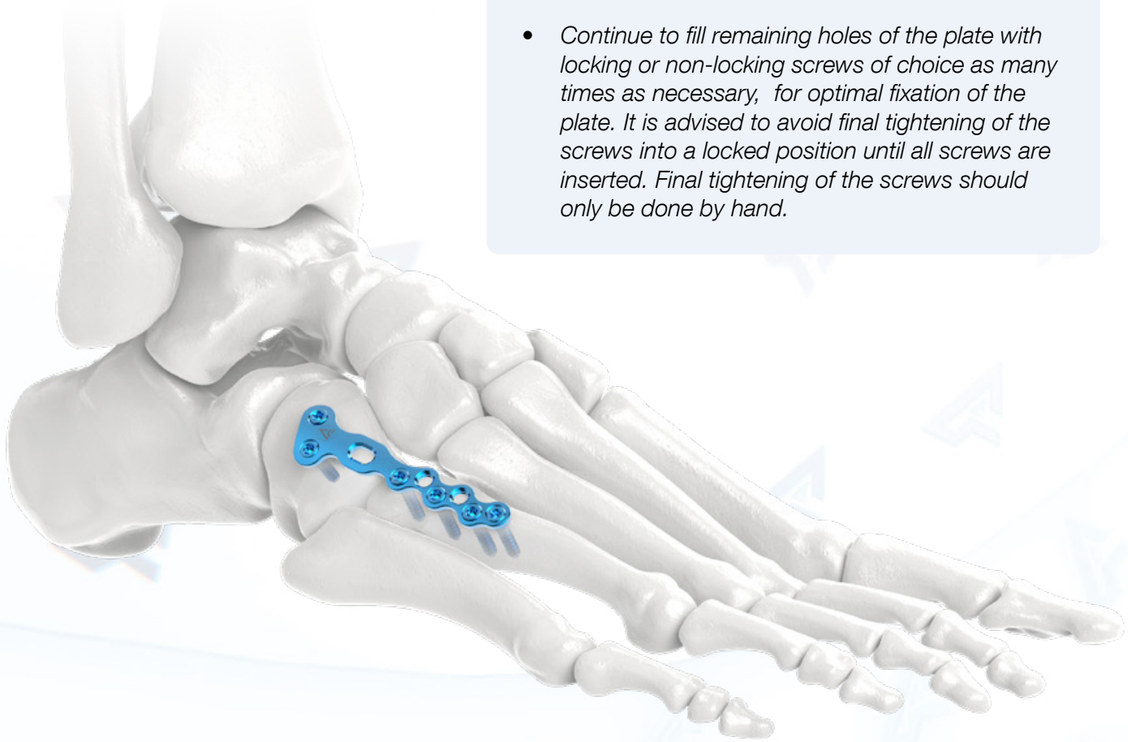
Locking screw 2.7

Gliding screw hole:



Standard screw 2.7

STEP 6



- *Continue to fill remaining holes of the plate with locking or non-locking screws of choice as many times as necessary, for optimal fixation of the plate. It is advised to avoid final tightening of the screws into a locked position until all screws are inserted. Final tightening of the screws should only be done by hand.*

- *Remove temporary fixation of K-wires*
- *Check the final position of the screws through the image intensifier to check if final position is according to initial intention.*
- *Proceed to incision closure or concomitant procedures at this time.*

Wound Closure and Dressing; Post-op positioning

- *The incision is closed per the surgeon's preferred technique.*
  Sterile wound dressing and post-op positioning are carried out according to the surgeon's instruction.

INSTRUMENTS AND TOOLS

1301027	Agopaqx2 instrument tray f. forefoot system 2.7, w/o instruments

1301037	Agopaqx2 tray for implant modules w/ 2 lids, w/o implant modules

1000151	Agopaqx4 forefoot screw tray system 2.7, w/o implants

1000164 Agopaqx4 Agosalis-plates-tray system 2.7, w/o implants

1201053 Twist drill 2,0 x 105 mm, stryker f. 2.7 mm screws, blue code

1201054 Twist drill 2,0 x 103 mm, AO, 23 mm stop, f. 2.7 mm screws, blue code

1001022 Screwdriverblade TX 8, 90 mm AO-shaft

1004030 Silicone screwdriverhandle, blue cannulated, 12 cm, AO-shaft

1006002 Agomed depth gauge 60 mm, round f. 2,0 - 4,5 mm screws

1104009 Agomed K-wire dispenser 15 cm/6” for K-wire 0,8 - 1,6 mm diameter

1101023 Kirschner wire 100 x 1,1 mm trocar/round, pack/6

1002527 Plate- /screwholding forceps angled, 15cm/6”

1008037 Drill-guide only for 2,7 mm screws

1009003 Bending/modelling tool f. 1,5 - 2,0 mm plates

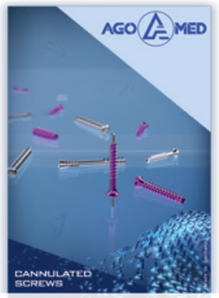
MORE OF OUR PRODUCTS

2010002
Foot & Ankle system

2010033
AgoFix 4.0 system

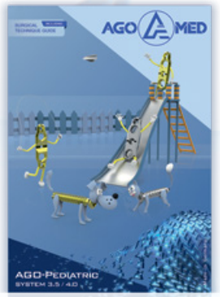
NEW 2010053
Anterior 4.0 system

2010015
Cannulated Screws



2010030
Pediatric Screw system 6.2

2010017
AGO-Pediatric system 3.5 / 4.0



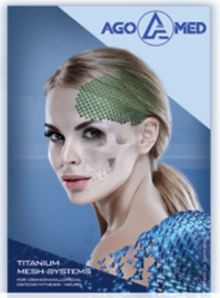
2010007
King Kong Multidirectional Radius system 2.5

2010004
Plating system for Upper Extremities

2010003
Titanium plating system for craniomaxillofacial osteosynthesis

2010008
AgoFix Neuro Plating system 1.5

2010016
Titanium Mesh systems for craniomaxillofacial osteosynthesis / Neuro



S1429 – AGOSALIS 2.7 SYSTEM

Pos.	Cat.No.	Description	Qty.	Picture page
		Containers		
1	1301027	AGOPAQx2 INSTRUMENT TRAY F. FOREFOOT SYSTEM 2.7, W/O INSTRUMENTS	1	15
2	1301037	AGOPAQx2 TRAY FOR IMPLANT MODULES W/ 2 LIDS, W/O IMPLANT MODULES	1	15
3	1000151	AGOPAQx4 FOREFOOT SCREW TRAY SYSTEM 2.7, W/O IMPLANTS	1	15
4	1000164	AGOPAQx4 AGOSALIS-PLATES-TRAY SYSTEM 2.7, W/O IMPLANTS	1	16
		Instruments		
5	1002527	PLATE- /SCREWHOLDING FORCEPS ANGLED, 15CM/6”	1	17
6	1006002	AGOMED DEPTH GAUGE 60 MM, ROUND F. 2,0 - 4,5 MM SCREWS	1	17
7	1009003	BENDING/MODELLING TOOL F. 1,5 - 2,0 MM PLATES	2	17
8	1004030	SILICONE SCREWDRIVERHANDLE, BLUE CANNULATED, 12 CM, AO- SHAFT	1	16
9	1001022	SCREWDRIVERBLADE TX 8, 90 MM AO-SHAFT	1	16
10	1201053	TWIST DRILL 2,0 X 105 MM, STRYKER F. 2.7 MM SCREWS, BLUE CODE	1	16
11	1201054	TWIST DRILL 2,0 X 103 MM, STOP 23 MM AO, F. 2.7 MM SCREWS, BLUE CODE	1	16
12	1008037	DRILL-GUIDE ONLY FOR 2,7 MM SCREWS	2	17
13	1104009	AGOMED K-WIRE DISPENSER 15 CM/6” FOR K-WIRE 0,8 - 1,6 MM DIAMETER	1	17
14	1101023	KIRSCHNER WIRE 100 X 1,1 MM TROCAR/ ROUND, PACK/6	1	17
		Plates		
15	4001086	AGOSALIS TITANIUM PLATE 4-HOLES STRAIGHT	1	5
16	4001087	AGOSALIS TITANIUM PLATE 5-HOLES STRAIGHT	1	5
17	4001090	AGOSALIS TITANIUM PLATE 7-HOLES T-SHAPE RIGHT	1	6
18	4001091	AGOSALIS TITANIUM PLATE 8-HOLES T-SHAPE RIGHT	1	6
19	4001092	AGOSALIS TITANIUM PLATE 9-HOLES T-SHAPE RIGHT	1	6
20	4001093	AGOSALIS TITANIUM PLATE, 5 HOLES T-SHAPE, RIGHT, EACH	1	6
21	4001094	AGOSALIS TITANIUM PLATE, 6-HOLES T-SHAPE, RIGHT	1	6
22	4001098	AGOSALIS TITANIUM PLATE, 5 HOLES T-SHAPE, LEFT	1	6
23	4001099	AGOSALIS TITANIUM PLATE, 6-HOLES T-SHAPE, LEFT	1	6
24	4001095	AGOSALIS TITANIUM PLATE, 7-HOLES T-SHAPE, LEFT	1	6
25	4001096	AGOSALIS TITANIUM PLATE, 8-HOLES T-SHAPE, LEFT	1	6
26	4001097	AGOSALIS TITANIUM PLATE 9-HOLES T-SHAPE LEFT	1	6
27	4001088	AGOSALIS TITANIUM PLATE 5-HOLES T-SHAPED	1	5
28	4001089	AGOSALIS TITANIUM PLATE 6-HOLES STRAIGHT	1	5
29	4001100	AGOSALIS TITANIUM PLATE 7-HOLES T-FORM, STRAIGHT	1	5
30	4001101	AGOSALIS TITANIUM PLATE 10-HOLES STRAIGHT, PACK/1	1	7
31	4001102	AGOSALIS TITANIUM PLATE 12-HOLES STRAIGHT, PACK/1	1	7
32	4001103	AGOSALIS TITANIUM PLATE 14-HOLES STRAIGHT, PACK/1	1	7
		Screws		
33	5001008	TITANIUM SCREW, THREADED HEAD 2,7 X 8 MM, TX 8, PACK/5	1	8
34	5001010	TITANIUM SCREW, THREADED HEAD 2,7 X 10 MM, TX 8, PACK/5	1	8
35	5001012	TITANIUM SCREW, THREADED HEAD 2,7 X 12 MM, TX 8, PACK/5	2	8
36	5001014	TITANIUM SCREW, THREADED HEAD 2,7 X 14 MM, TX 8, PACK/5	2	8
37	5001016	TITANIUM SCREW, THREADED HEAD 2,7 X 16 MM, TX 8, PACK/5	2	8
38	5001018	TITANIUM SCREW, THREADED HEAD 2,7 X 18 MM, TX 8, PACK/5	1	8
39	5001020	TITANIUM SCREW, THREADED HEAD 2,7 X 20 MM, TX 8, PACK/5	1	8
40	5001022	TITANIUM SCREW, THREADED HEAD 2,7 X 22 MM, TX 8, PACK/5	1	8
41	5001024	TITANIUM SCREW, THREADED HEAD 2,7 X 24 MM, TX 8, PACK/5	1	8

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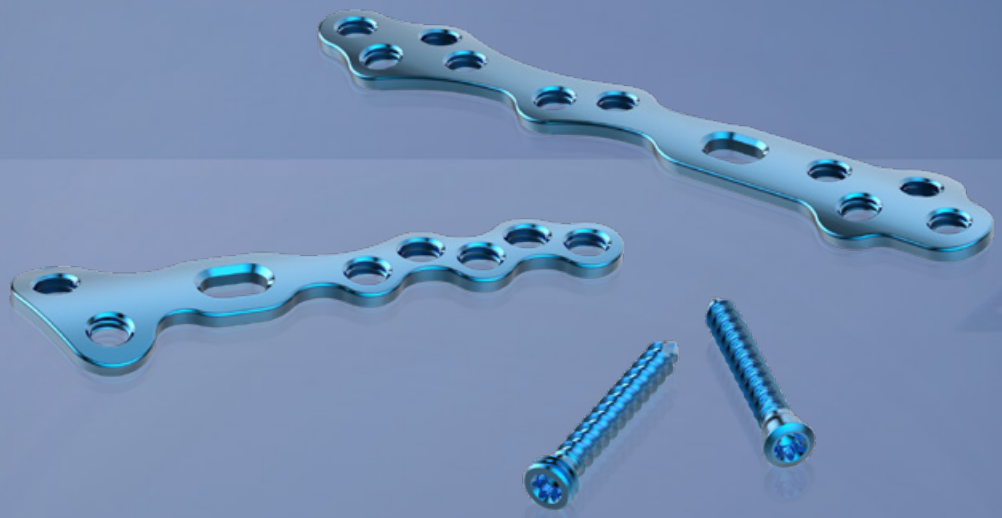
42	5001026	TITANIUM SCREW, THREADED HEAD 2,7 X 26 MM, TX 8, PACK/5	1	8
43	5001028	TITANIUM SCREW, THREADED HEAD 2,7 X 28 MM, TX 8, PACK/5	1	8
44	5001030	TITANIUM SCREW, THREADED HEAD 2,7 X 30 MM, TX 8, PACK/5	1	8
45	5001108	TITANIUM SCREW, STANDARD 2,7 X 8 MM, TX 8, PACK/5	1	8
46	5001110	TITANIUM SCREW, STANDARD 2,7 X 10 MM, TX 8, PACK/5	1	8
47	5001112	TITANIUM SCREW, STANDARD 2,7 X 12 MM, TX 8, PACK/5	2	8
48	5001114	TITANIUM SCREW, STANDARD 2,7 X 14 MM, TX 8, PACK/5	2	8
49	5001116	TITANIUM SCREW, STANDARD 2,7 X 16 MM, TX 8, PACK/5	2	8

Pos.	Cat.No.	Description	Qty.	Picture page
50	5001118	TITANIUM SCREW, STANDARD 2,7 X 18 MM, TX 8, PACK/5	1	8
51	5001120	TITANIUM SCREW, STANDARD 2,7 X 20 MM, TX 8, PACK/5	1	8
52	5001122	TITANIUM SCREW, STANDARD, 2,7 X 22 MM, TX 8, PACK/5	1	8
53	5001124	TITANIUM SCREW, STANDARD 2,7 X 24 MM, TX 8, PACK/5	1	8
54	5001126	TITANIUM SCREW, STANDARD 2,7 X 26 MM, TX 8, PACK/5	1	8
55	5001128	TITANIUM SCREW, STANDARD 2,7 X 28 MM, TX 8, PACK/5	1	8
56	5001130	TITANIUM SCREW, STANDARD 2,7 X 30 MM, TX 8, PACK/5	1	8

NOTES

NOTES



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MADE IN GERMANY

Ref.num. 2010069
Revision 01 / 01.2021

CE
0297