



INSTRUCTION FOR USE

Versalock 2,4/2,7 System

Versalock System

Sheet:

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INSTRUCTIONS FOR USE

Single-use product.

Non-sterile – sterilize before use according to the Sterilization Method.

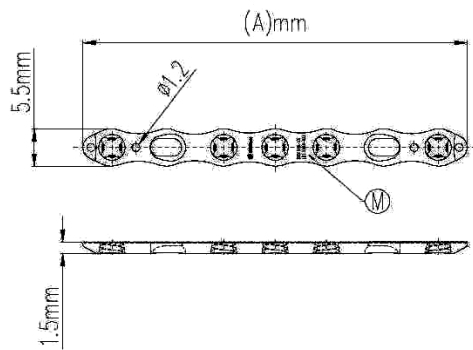
No reprocessing.

3.1.1.a. Technical Name: Versalock 2,4/2,7 System

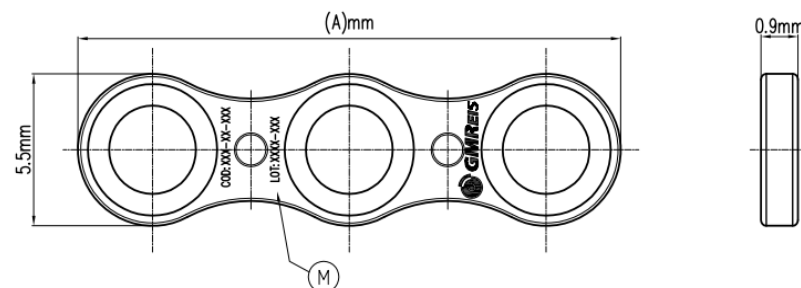
3.1.1.b. Trade Name: Versalock 2,4/2,7 System

3.1.1.c. List of the implantable components that make up the product family with the graphic information: drawings, descriptions, dimensional characteristics, tolerances, composition and technical standard of the raw material for each model, and this information makes it possible to visualize the products in the form that will be delivered to consumption, are presented in table 1.

Table 1 - Drawings, descriptions, dimensional characteristics, composition with respective technical standard.

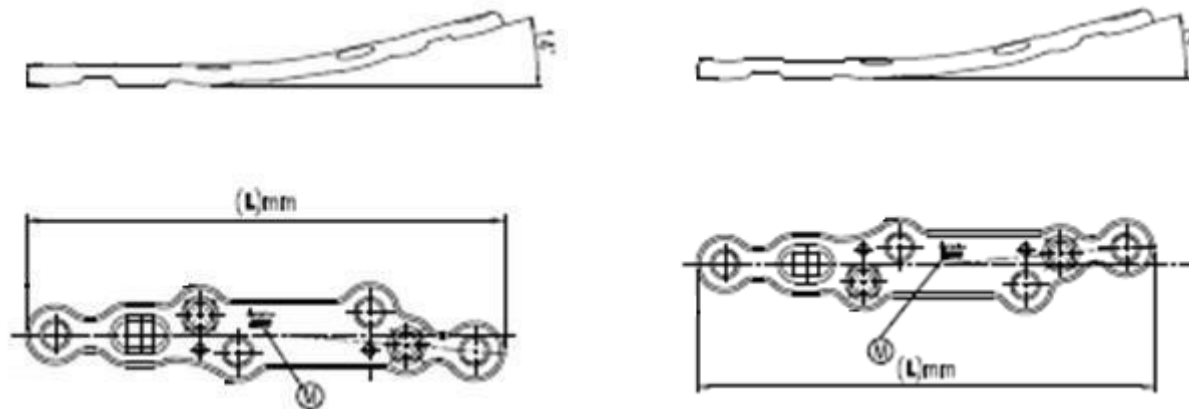
DRAW		
		
Titanium Alloy ASTM F136		
CODE	DESCRIPTION	A (mm)
223-43	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 10 HOLES	90,0
223-44	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 09 HOLES	70,0
223-45	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 07 HOLES	55,0
223-46	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 05 HOLES	45,0
223-47	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 04 HOLES	35,0
223-49	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 03 HOLES	25,0
223-50	VERSALOCK MINI STRAIGHT PLATE FOR FOOT 02 HOLES	18,0

DRAW



Pure Titanium ASTM F67

CODE	DESCRIPTION	A (mm)
223-31-20	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 03 HOLES – 20MM	20,0
223-31-25	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 03 HOLES – 25MM	25,0
223-31-30	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 05 HOLES – 30MM	30,0
223-31-35	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 05 HOLES – 35MM	35,0
223-31-40	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 07 HOLES – 40MM	40,0
223-31-45	VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE 07 HOLES – 45MM	45,0

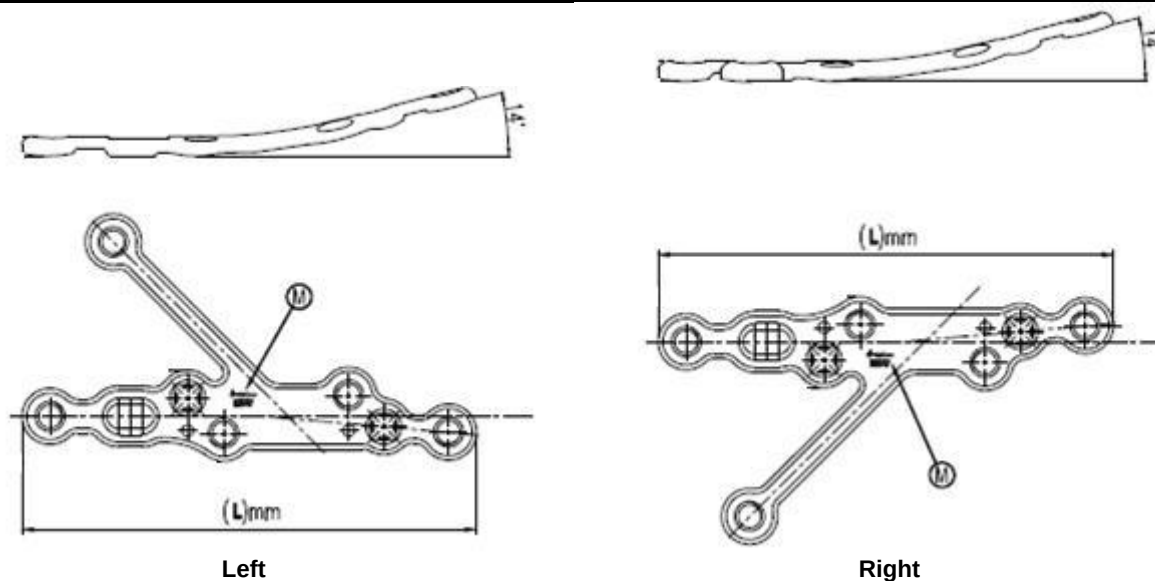
DRAW


Right

Left

Titanium Alloy ASTM F136

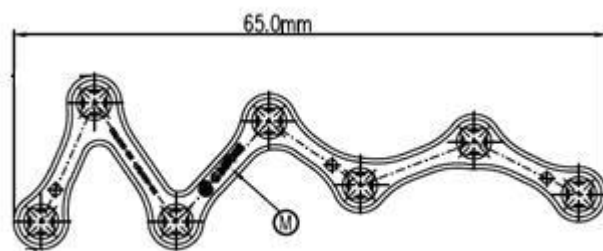
CODE	DESCRIPTION	L(mm)
223-60-45-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT SMALL	45,0
223-60-53-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT MEDIUM	53,0
223-60-57-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT LARGE	57,0
223-60-45-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT SMALL	45,0
223-60-53-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT MEDIUM	53,0
223-60-57-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT LARGE	57,0

DRAW


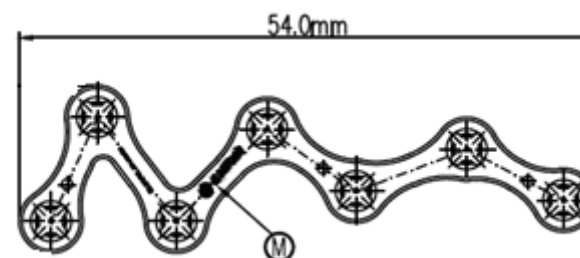
Titanium Alloy ASTM F136

CODE	DESCRIPTION	L(mm)
223-61-45-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT SMALL	45,0
223-61-53-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT MEDIUM	53,0
223-61-57-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT LARGE	57,0
223-61-45-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT SMALL	45,0
223-61-53-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT MEDIUM	53,0
223-61-57-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT LARGE	57,0

DRAW



Medium

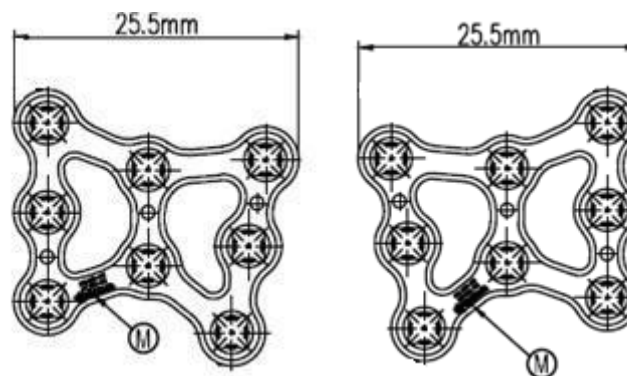


Small

Pure Titanium ASTM F67

CODE	DESCRIPTION
223-35-M	VERSALOCK SERPENT PLATE MEDIUM
223-35-P	VERSALOCK SERPENT PLATE SMALL

DRAW

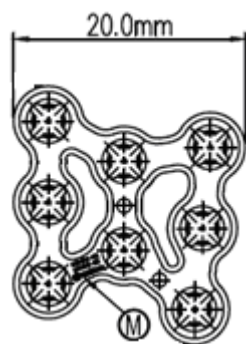


Right

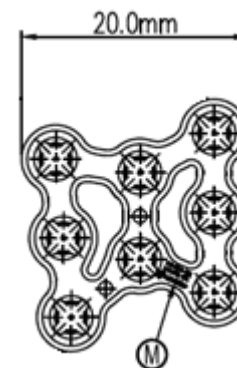
Left

Pure Titanium ASTM F67

CODE	DESCRIPTION
223-36-D	VERSALOCK BUTTERFLY PLATE FOR CUBOID RIGHT LARGE
223-36-E	VERSALOCK BUTTERFLY PLATE FOR CUBOID LEFT LARGE

DRAW


Right

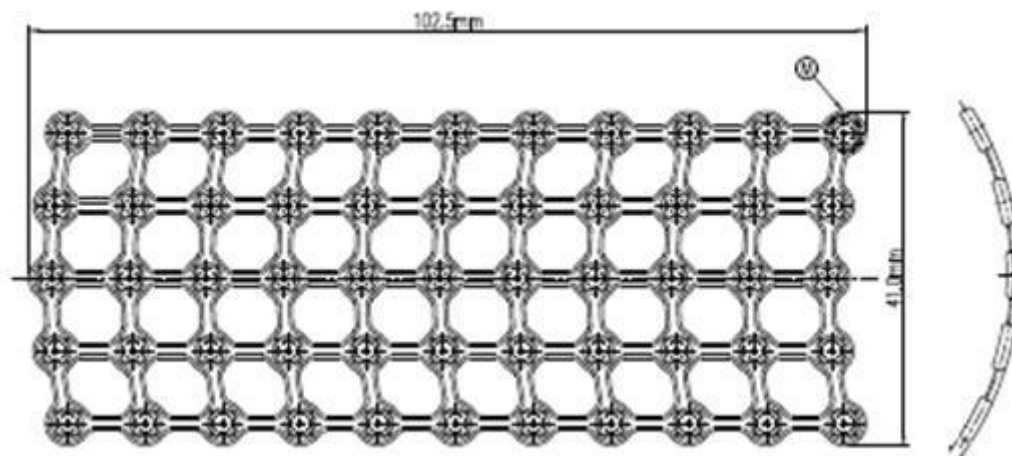


Left

Pure Titanium ASTM F67

CODE	DESCRIPTION
223-37-D	VERSALOCK BUTTERFLY PLATE FOR CUBOID RIGHT MEDIUM
223-37-E	VERSALOCK BUTTERFLY PLATE FOR CUBOID LEFT MEDIUM

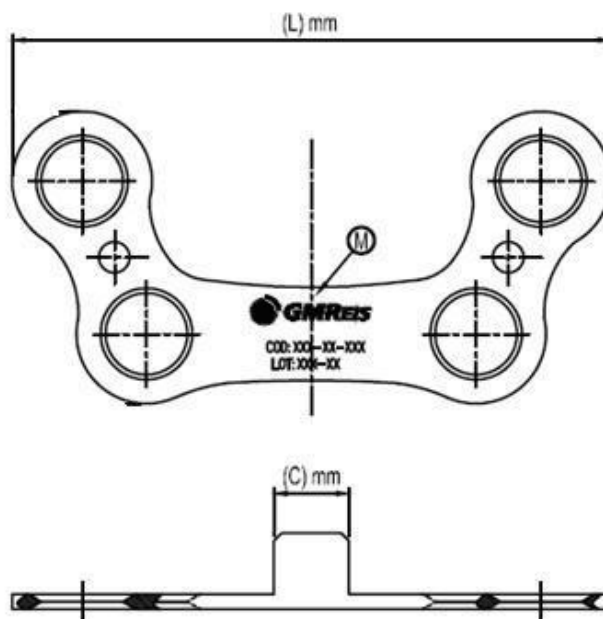
DRAW



Pure Titanium ASTM F67

CODE	DESCRIPTION
223-48	VERSALOCK VERSATILE MESH PLATE

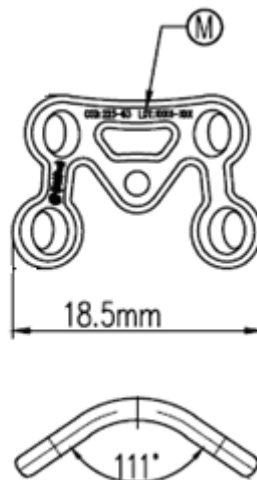
DRAW



Pure Titanium ASTM F67

CODE	DESCRIPTION	L(mm)	C(mm)
223-19-B	LOW PROFILE VERSALOCK "U" PLATE	22,5	-
223-20-B	LOW PROFILE VERSALOCK "U" PLATE 2,0MM	22,5	2,0
223-22-B	LOW PROFILE VERSALOCK "U" PLATE 4,0MM	24,5	4,0
223-24-B	LOW PROFILE VERSALOCK "U" PLATE 6,0MM	26,5	6,0
223-26-B	LOW PROFILE VERSALOCK "U" PLATE 8,0MM	28,5	8,0

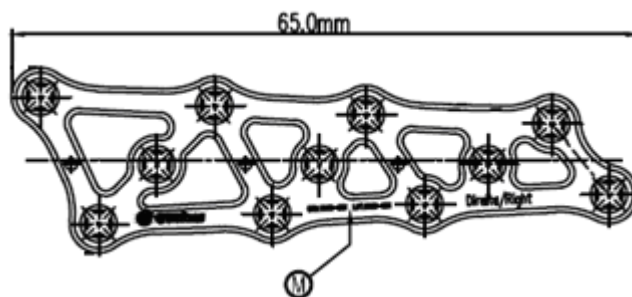
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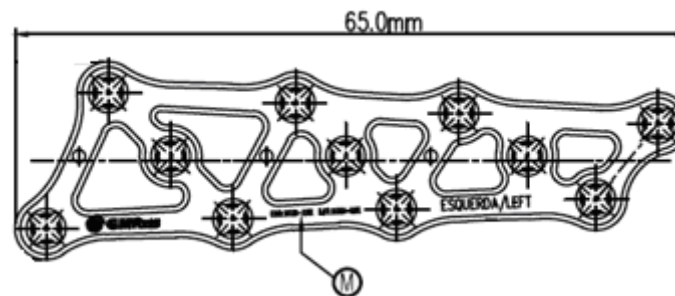
Titanium Alloy ASTM F136

CODE	DESCRIPTION
223-63	VERSALOCK TALAR NECK PLATE

DRAW



Right

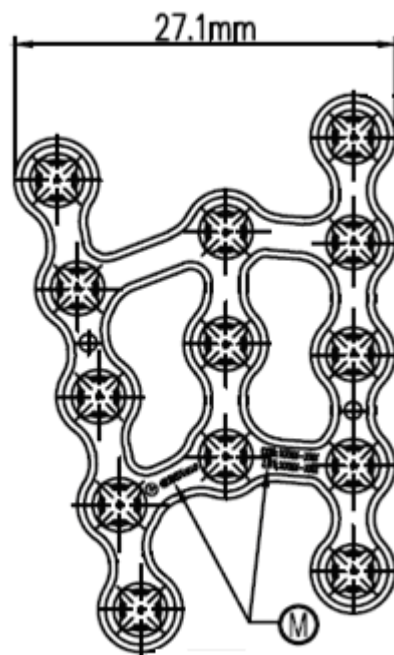


Left

Pure Titanium ASTM F67

CODE	DESCRIPTION
223-35-D	VERSATILE RECTANGULAR VERSALOCK PLATE RIGHT
223-35-E	VERSATILE RECTANGULAR VERSALOCK PLATE LEFT

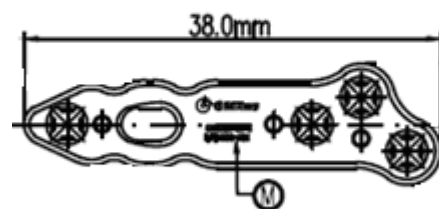
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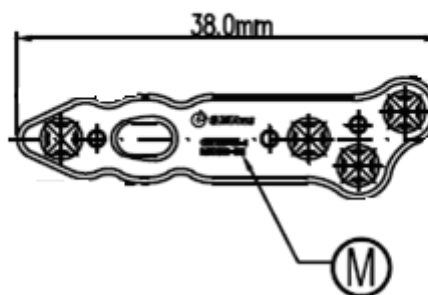
Pure Titanium ASTM F67

CODE	DESCRIPTION
223-36-W	VERSALOCK "W" VERSATILE PLATE

DRAW



RIGHT

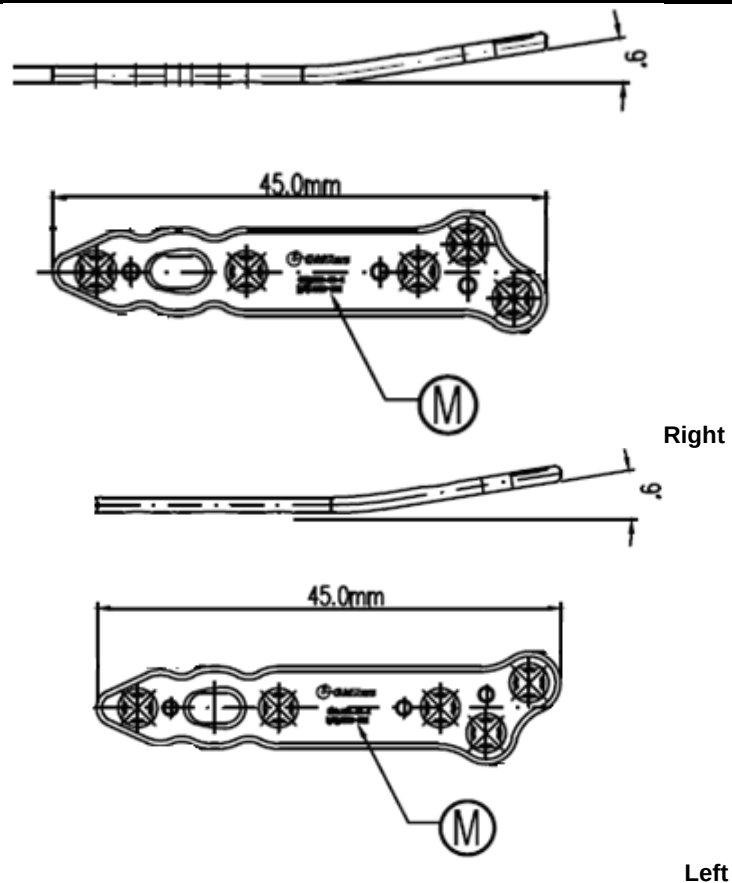


LEFT

Titanium Alloy ASTM F136

CODE	DESCRIPTION
223-41-38	VERSATILE ANGLED "T" PLATE 05 HOLES RIGHT
223-42-38	VERSATILE ANGLED "T" PLATE 05 HOLES LEFT

DRAW

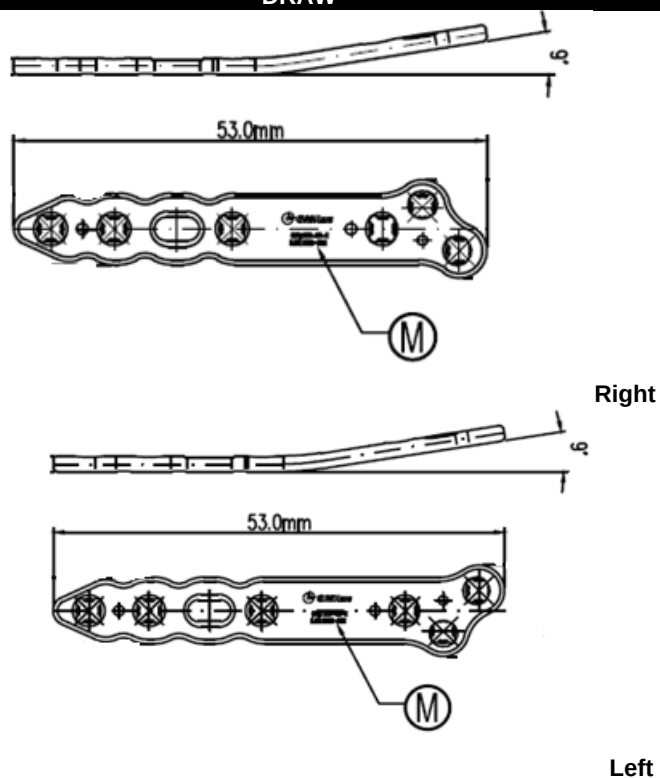


Titanium Alloy ASTM F136

Left

CODE	DESCRIPTION
223-41-45	VERSATILE ANGLED "T" PLATE 06 HOLES RIGHT
223-42-45	VERSATILE ANGLED "T" PLATE 06 HOLES LEFT

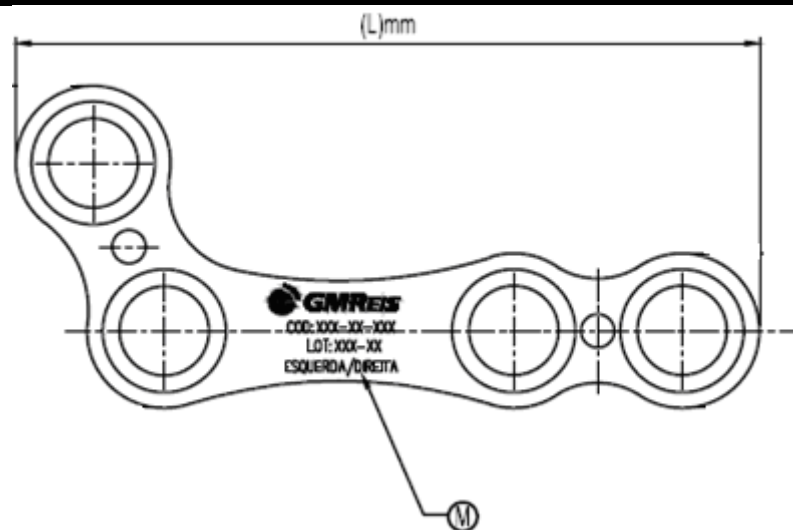
DRAW



Titanium Alloy ASTM F136

CODE	DESCRIPTION
223-41-53	VERSATILE ANGLED "T" PLATE 07 HOLED RIGHT
223-42-53	VERSATILE ANGLED "T" PLATE 07 HOLES LEFT

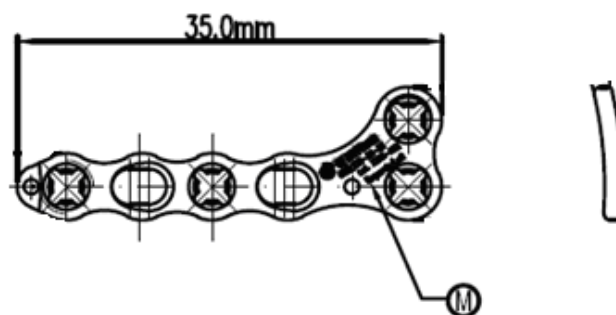
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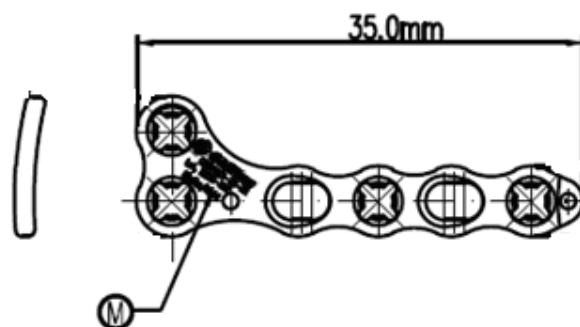
Pure Titanium ASTM F67

CODE	DESCRIPTION	L(mm)
223-12-EB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE LEFT WITH 22,5MM REGULAR	22,5
223-17-EB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE LEFT WITH 26,5MM MEDIUM	26,5
223-18-EB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE LEFT WITH 28,5MM LARGE	28,5
223-12-DB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE RIGHT WITH 22,5MM REGULAR	22,5
223-17-DB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE RIGHT WITH 26,5MM MEDIUM	26,5
223-18-DB	VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE RIGHT WITH 28,5MM LARGE	28,5

DRAW



Left

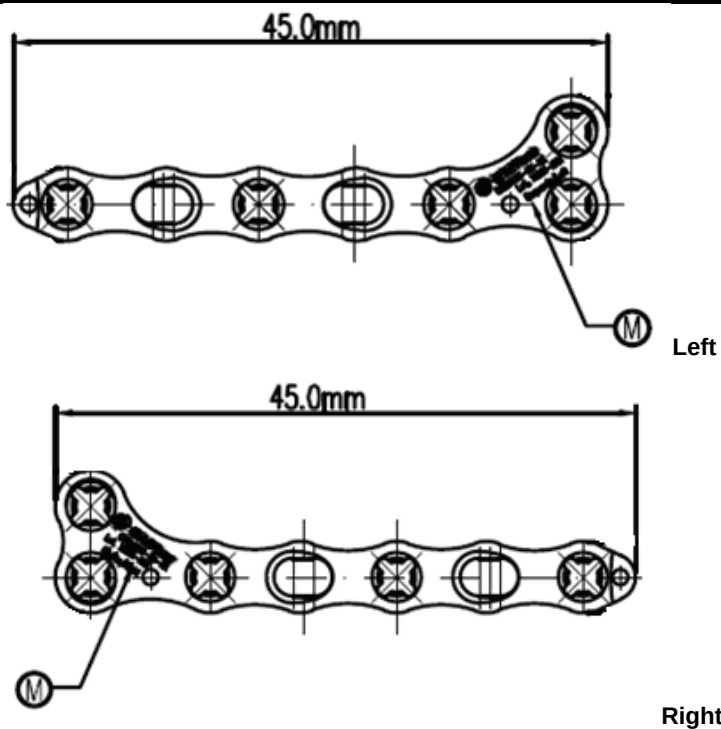


Right

Titanium Alloy ASTM F136

CODE	DESCRIPTION
223-51-35	MINI VERSALOCK PLATE "L" 06 VERSATILE HOLES LEFT
223-52-35	MINI VERSALOCK PLATE "L" 06 VERSATILE HOLES RIGHT

DRAW

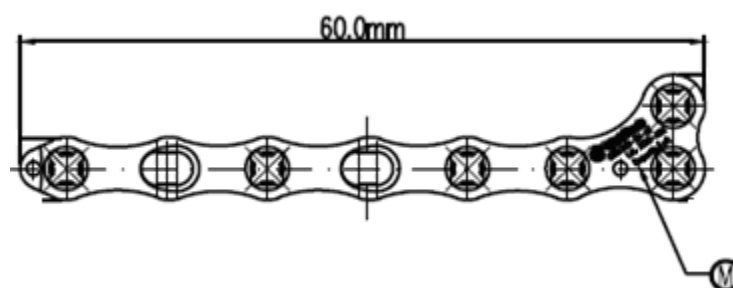


Titanium Alloy ASTM F136

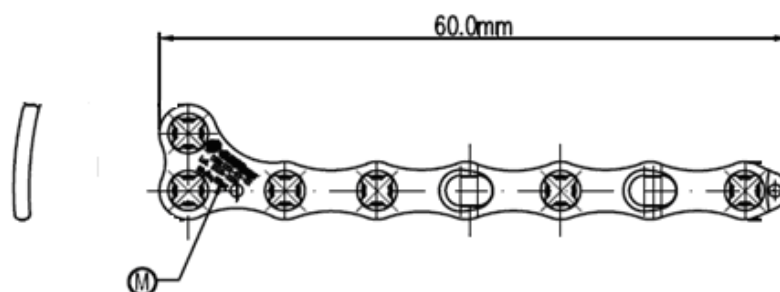
Right

CODE	DESCRIPTION
223-51-45	MINI VERSALOCK PLATE "L" 07 VERSATILE HOLES LEFT
223-52-45	MINI VERSALOCK PLATE "L" 07 VERSATILE HOLES RIGHT

DRAW



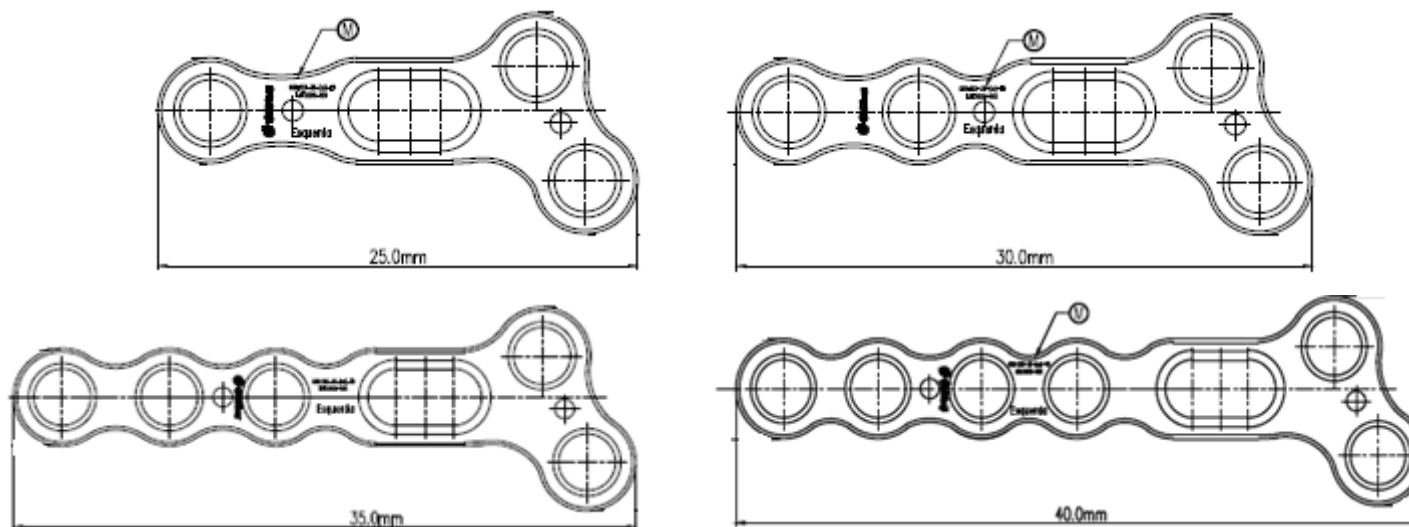
Left



Right

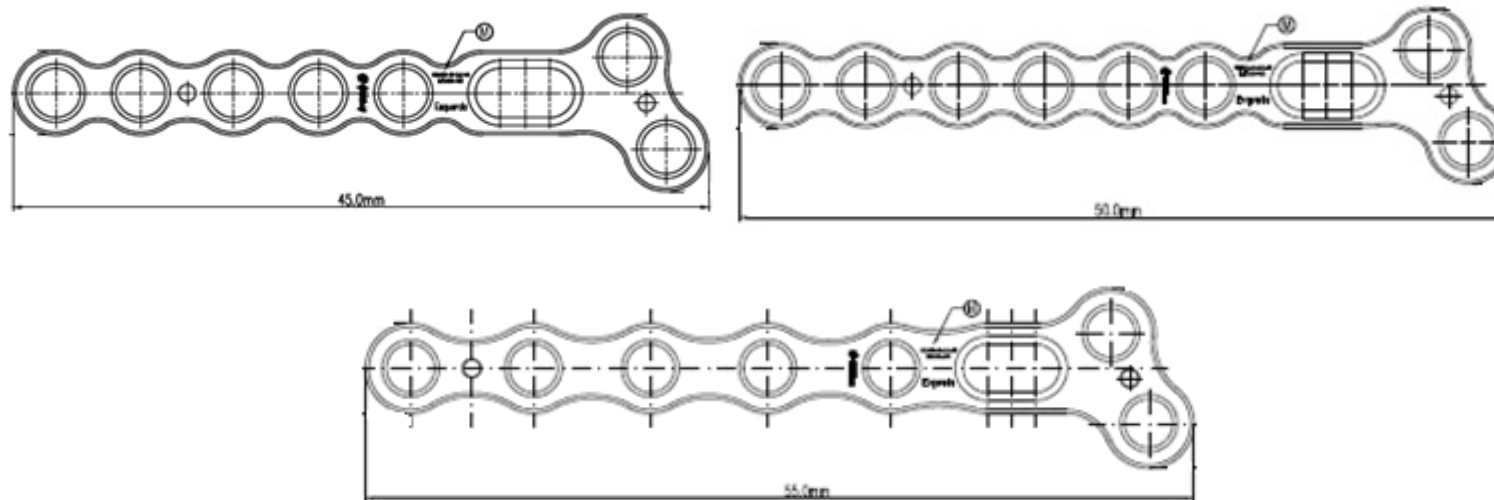
Titanium Alloy ASTM F136

CODE	DESCRIPTION
223-51-60	MINI VERSALOCK PLATE "L" 08 VERSATILE HOLES LEFT
223-52-60	MINI VERSALOCK PLATE "L" 08 VERSATILE HOLES RIGHT

DRAW


Pure Titanium ASTM F67

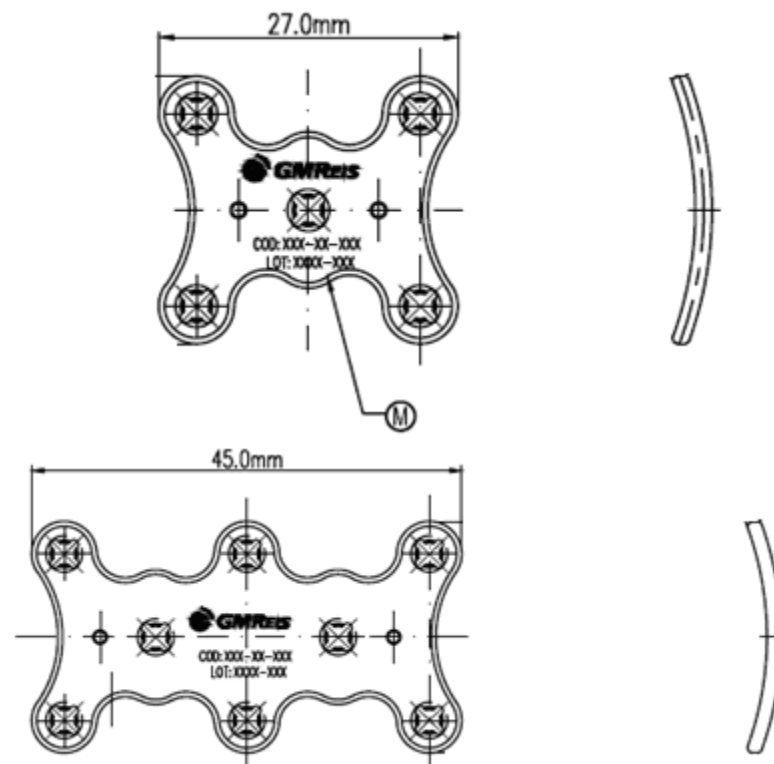
CODE	DESCRIPTION
223-32-25-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 04 HOLES
223-32-30-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 05 HOLES
223-32-35-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 06 HOLES
223-32-40-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 07 HOLES

DRAW


Pure Titanium ASTM F67

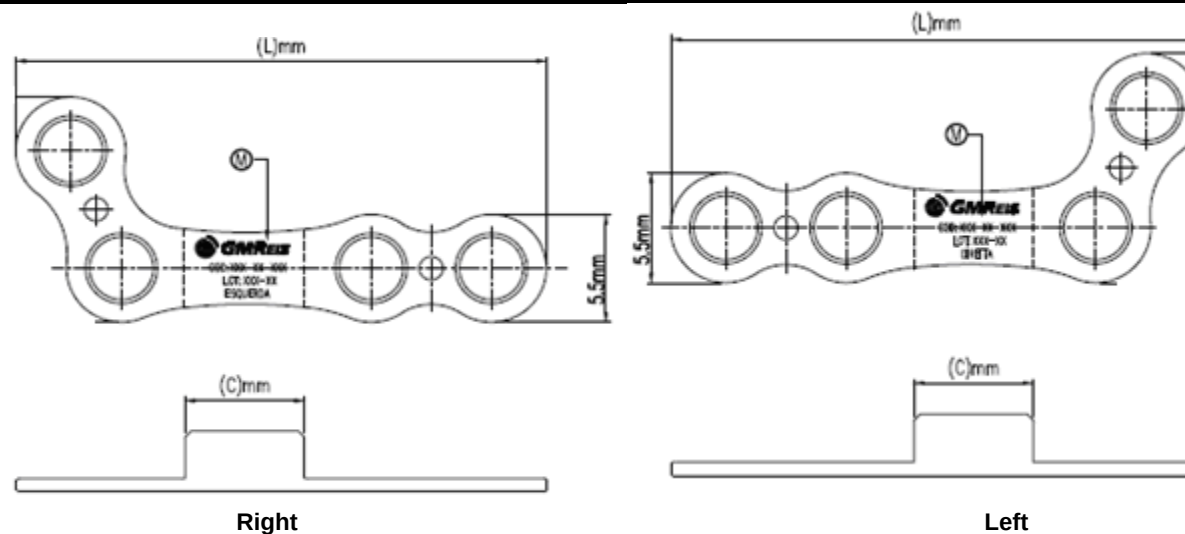
CODE	DESCRIPTION
223-32-45-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 08 HOLES
223-32-50-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 09 HOLES
223-32-55-ED	LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE 08 HOLES LONG

DRAW



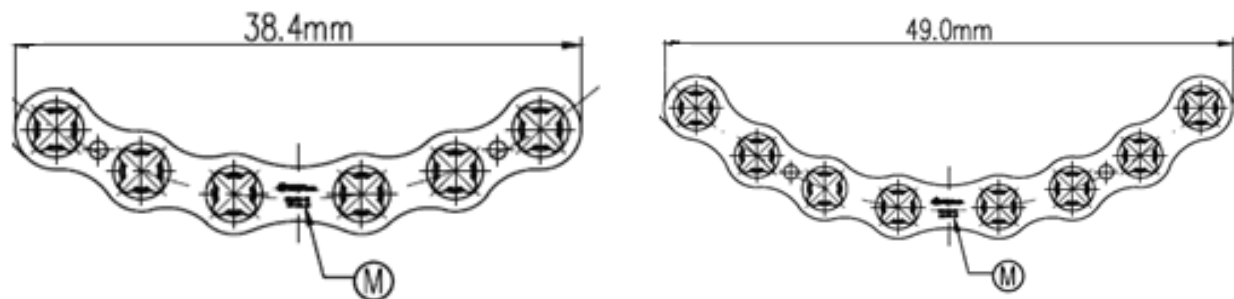
Pure Titanium ASTM F67

CODE	DESCRIPTION
223-56	MINI VERSALOCK "H" VERSATILE PLATE 05 HOLES
223-57	MINI VERSALOCK "H" VERSATILE PLATE 08 HOLES

DRAW


Pure Titanium ASTM F67

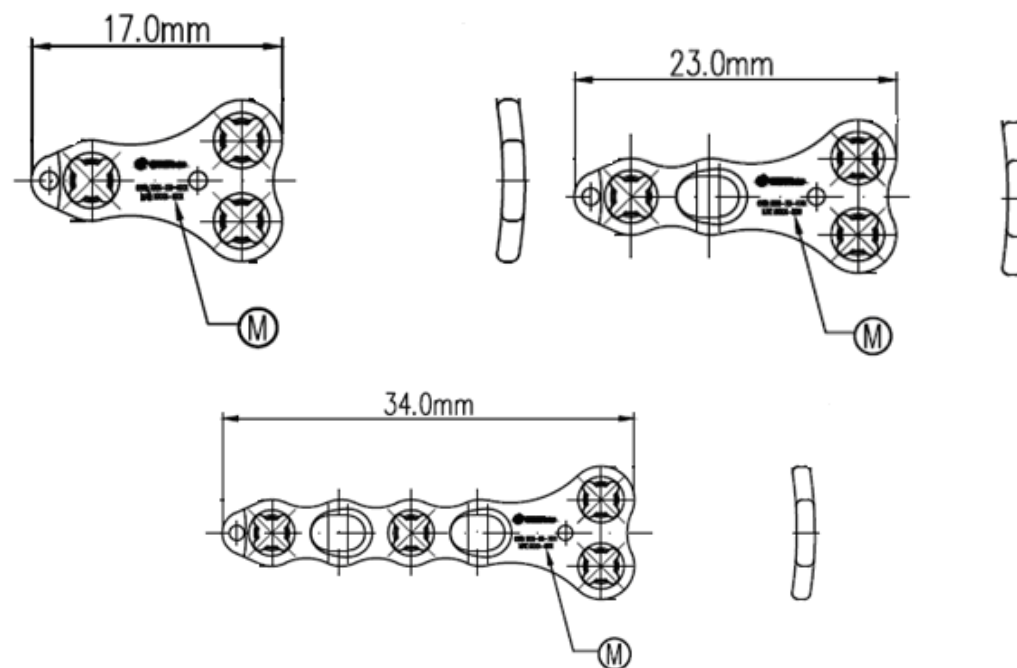
CODE	DESCRIPTION	L(mm)	C(mm)
223-11-DB	VERSALOCK "L" LOW PROFILE MINI PLATE RIGHT	22,5	--
223-13-DB	VERSALOCK "L" LOW PROFILE MINI PLATE RIGHT 2,0MM	22,5	2,0
223-15-DB	VERSALOCK "L" LOW PROFILE MINI PLATE RIGHT 4,0MM	24,5	4,0
223-16-DB	VERSALOCK "L" LOW PROFILE MINI PLATE RIGHT 6,0MM	26,5	6,0
223-19-DB	VERSALOCK "L" LOW PROFILE MINI PLATE RIGHT 8,0MM	28,5	8,0
223-11-EB	VERSALOCK "L" LOW PROFILE MINI PLATE LEFT	22,5	--
223-13-EB	VERSALOCK "L" LOW PROFILE MINI PLATE LEFT 2,0MM	22,5	2,0
223-15-EB	VERSALOCK "L" LOW PROFILE MINI PLATE LEFT 4,0MM	24,5	4,0
223-16-EB	VERSALOCK "L" LOW PROFILE MINI PLATE LEFT 6,0MM	26,5	6,0
223-19-EB	VERSALOCK "L" LOW PROFILE MINI PLATE LEFT 8,0MM	28,5	8,0

DRAW


Pure Titanium ASTM F67

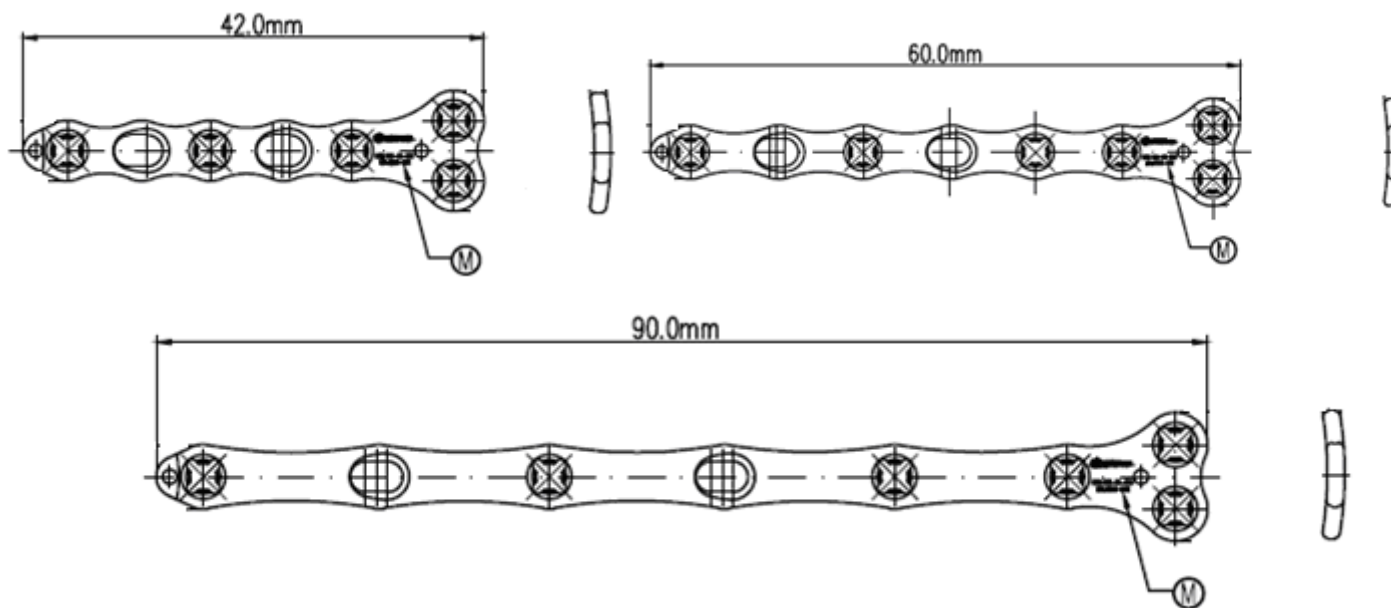
CODE	DESCRIPTION
223-53	VERSATILE SEMILUNAR VERSALOCK PLATE 3+3 HOLES
223-54	VERSATILE SEMILUNAR VERSALOCK PLATE 4+4 HOLES

DRAW



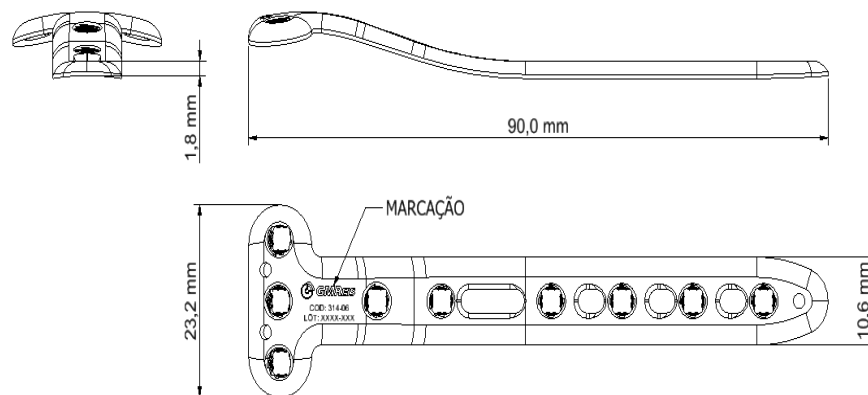
Pure Titanium ASTM F67

CODE	DESCRIPTION
223-55-17	MINI VERSALOCK "T" PLATE VERSATILE 03 HOLES
223-55-23	MINI VERSALOCK "T" PLATE VERSATILE 04 HOLES
223-55-34	MINI VERSALOCK "T" PLATE VERSATILE 06 HOLES

DRAW


Pure Titanium ASTM F67

CODE	DESCRIPTION
223-55-42	MINI VERSALOCK "T" PLATE VERSATILE 07 HOLES
223-55-60	MINI VERSALOCK "T" PLATE VERSATILE 08 HOLES
223-55-90	MINI VERSALOCK "T" PLATE VERSATILE 08 HOLES LONG

DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION
314-06	VERSALOCK PLATE POSTERIOR MALLEOLUS T 06 HOLES 2.7MM

INSTRUCTION FOR USE

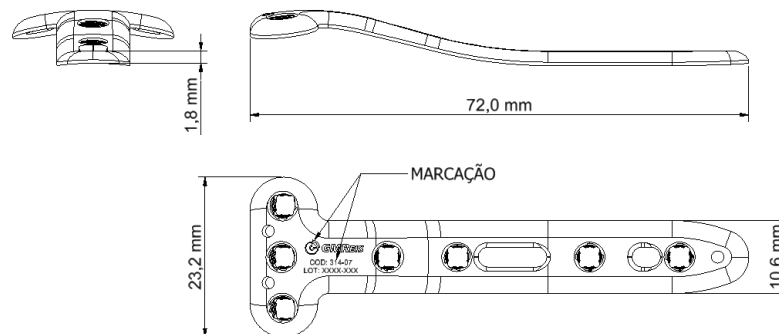
Versalock 2,4/2,7 System

Versalock System

Sheet:

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DRAW



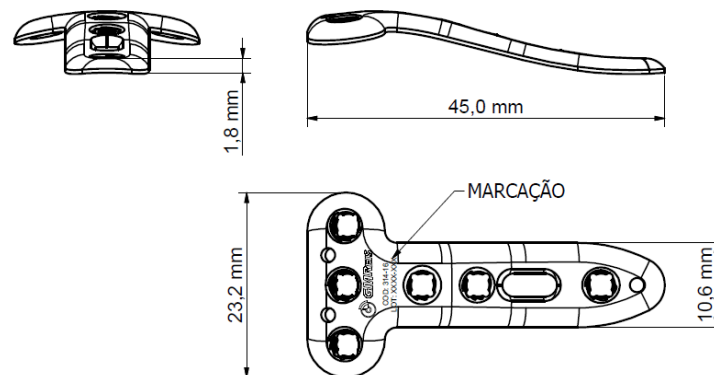
Titanium Alloy ASTM F136

CODE

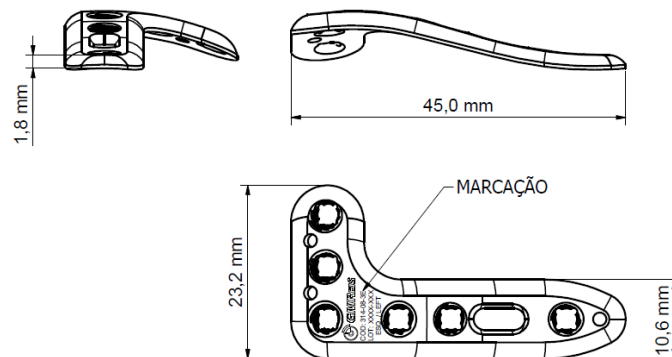
314-07

DESCRIPTION

VERSALOCK PLATE POSTERIOR MALLEOLUS T 0 HOLES 2.7MM

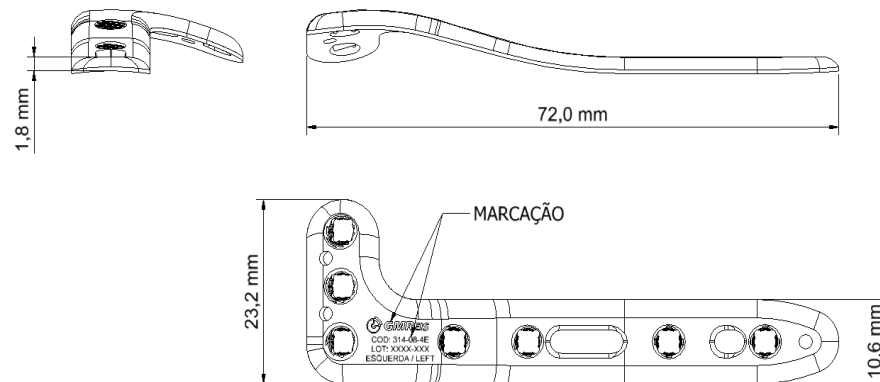
DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION
314-16	VERSALOCK PLATE POSTERIOR MALLEOLUS T 03 HOLES 2.7MM

DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION
314-08-3E	VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 03 HOLES 2.7MM

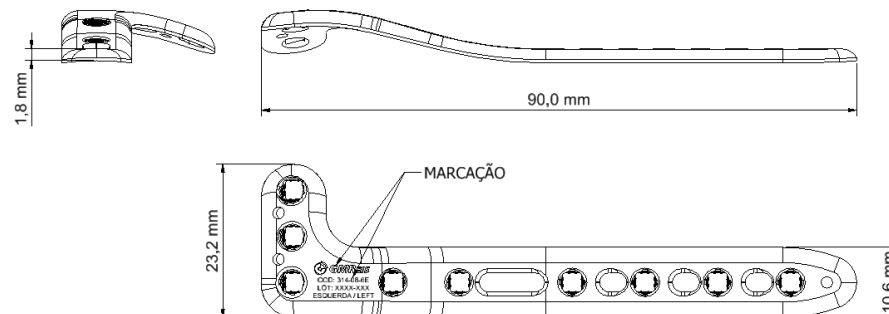
DRAW



Titanium Alloy ASTM F136

CODE	DESCRIPTION
314-08-4E	VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 04 HOLES 2.7MM

DRAW



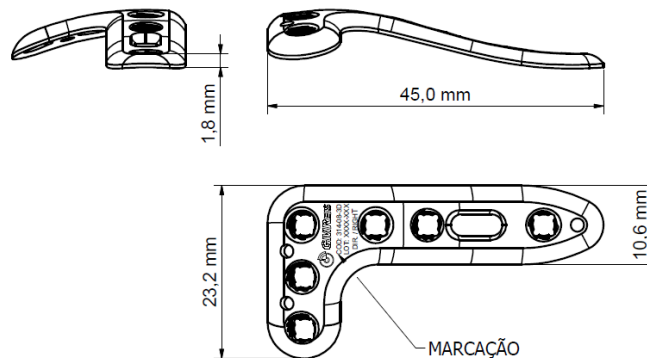
Titanium Alloy ASTM F136

CODE

314-08-6E

DESCRIPTION

VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 06 HOLES 2.7MM

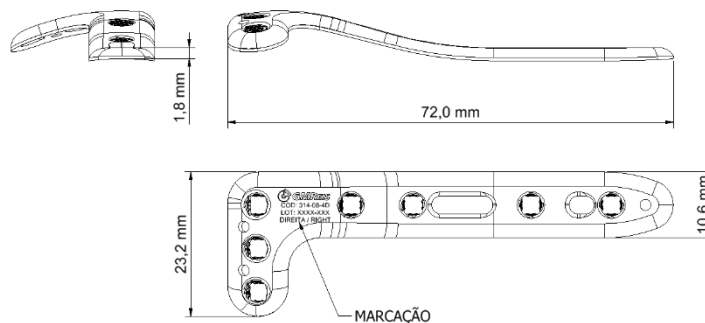
DRAW

Titanium Alloy ASTM F136
CODE

314-08-3D

DESCRIPTION

VERSALOCK PLATE POSTERIOR MALLEOLUS L RIGHT. 03 HOLES 2.7MM

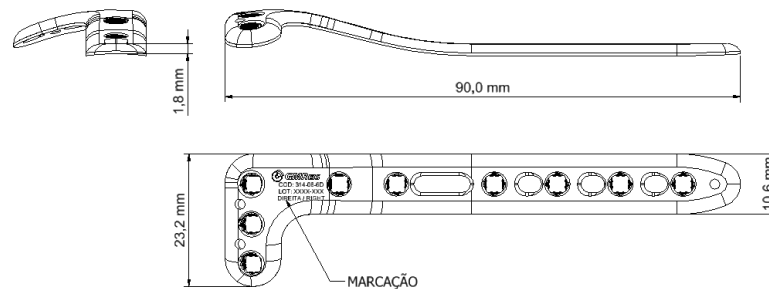
DRAW



Titanium Alloy ASTM F136

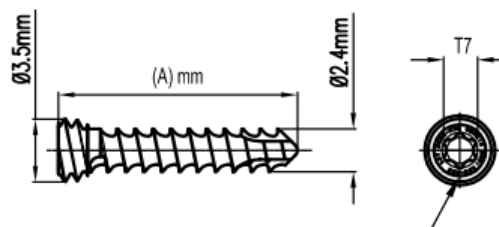
CODE	DESCRIPTION
314-08-4D	VERSALOCK PLATE POSTERIOR MALLEOLUS L RIGHT. 04 HOLES 2.7MM

DRAW



Titanium Alloy ASTM F136

CODE	DESCRIPTION
314-08-6D	VERSALOCK PLATE REAR MALLEOLUS L RIGHT. 06 HOLES 2.7MM

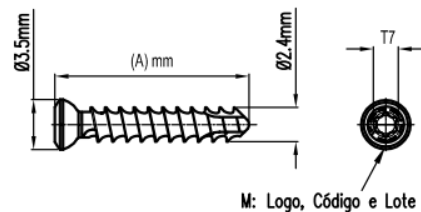
DRAW


M: Logo, Código e Lote

Titanium Alloy ASTM F136

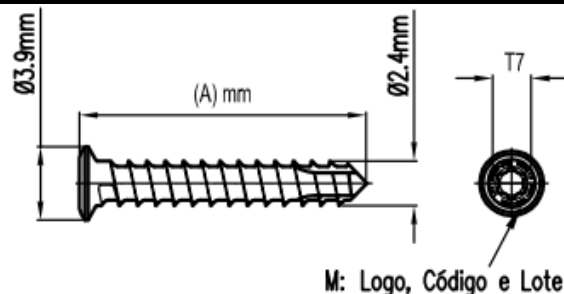
CODE	DESCRIPTION	A (mm)
223-24-08-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X 08,0MM	8,0
223-24-10-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X10,0MM	10,0
223-24-12-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X12,0MM	12,0
223-24-14-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X14,0MM	14,0
223-24-16-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X16,0MM	16,0
223-24-18-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X18,0MM	18,0
223-24-20-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X20,0MM	20,0
223-24-22-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X22,0MM	22,0
223-24-24-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X24,0MM	24,0
223-24-26-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X26,0MM	26,0
223-24-28-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X28,0MM	28,0
223-24-30-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X30,0MM	30,0
223-24-32-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X32,0MM	32,0
223-24-34-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X34,0MM	34,0
223-24-36-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X36,0MM	36,0
223-24-38-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X38,0MM	38,0
223-24-40-BP	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X40,0MM	40,0

DRAW

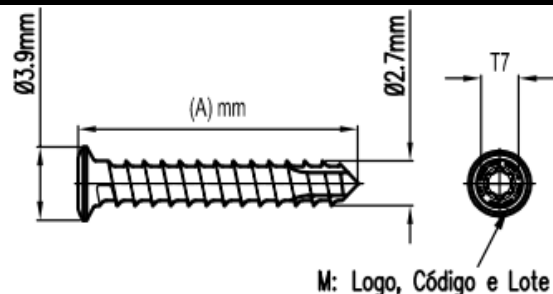


Titanium Alloy ASTM F136

CODE	DESCRIPTION	A (mm)
223-24-08-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X08,0MM	8,0
223-24-10-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X10,0MM	10,0
223-24-12-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X12,0MM	12,0
223-24-14-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X14,0MM	14,0
223-24-16-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X16,0MM	16,0
223-24-18-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X18,0MM	18,0
223-24-20-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X20,0MM	20,0
223-24-22-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X22,0MM	22,0
223-24-24-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X24,0MM	24,0
223-24-26-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X26,0MM	26,0
223-24-28-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X28,0MM	28,0
223-24-30-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X30,0MM	30,0
223-24-32-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X32,0MM	32,0
223-24-34-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X34,0MM	34,0
223-24-36-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X36,0MM	36,0
223-24-38-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X38,0MM	38,0
223-24-40-C	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X40,0MM	40,0

DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION	A (mm)
223-24-10-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X10,0MM LOW PROFILE	10,0
223-24-12-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X12,0MM LOW PROFILE	12,0
223-24-14-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X14,0MM LOW PROFILE	14,0
223-24-16-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X16,0MM LOW PROFILE	16,0
223-24-18-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X18,0MM LOW PROFILE	18,0
223-24-20-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X20,0MM LOW PROFILE	20,0
223-24-22-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X22,0MM LOW PROFILE	22,0
223-24-24-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X24,0MM LOW PROFILE	24,0
223-24-26-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X26,0MM LOW PROFILE	26,0
223-24-28-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X28,0MM LOW PROFILE	28,0
223-24-30-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X30,0MM LOW PROFILE	30,0
223-24-32-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X32,0MM LOW PROFILE	32,0
223-24-34-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X34,0MM LOW PROFILE	34,0
223-24-36-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X36,0MM LOW PROFILE	36,0
223-24-38-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X38,0MM LOW PROFILE	38,0
223-24-40-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X40,0MM LOW PROFILE	40,0
223-24-42-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X42,0MM LOW PROFILE	42,0
223-24-44-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X44,0MM LOW PROFILE	44,0
223-24-46-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X46,0MM LOW PROFILE	46,0
223-24-48-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X48,0MM LOW PROFILE	48,0
223-24-50-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X50,0MM LOW PROFILE	50,0
223-24-52-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X52,0MM LOW PROFILE	52,0
223-24-54-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X54,0MM LOW PROFILE	54,0
223-24-56-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,4X56,0MM LOW PROFILE	56,0

DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION	A (mm)
223-27-10-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X10,0MM LOW PROFILE	10,0
223-27-12-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X12,0MM LOW PROFILE	12,0
223-27-14-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X14,0MM LOW PROFILE	14,0
223-27-16-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X16,0MM LOW PROFILE	16,0
223-27-18-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X18,0MM LOW PROFILE	18,0
223-27-20-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X20,0MM LOW PROFILE	20,0
223-27-22-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X22,0MM LOW PROFILE	22,0
223-27-27-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X24,0MM LOW PROFILE	24,0
223-27-26-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X26,0MM LOW PROFILE	26,0
223-27-28-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X28,0MM LOW PROFILE	28,0
223-27-30-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X30,0MM LOW PROFILE	30,0
223-27-32-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X32,0MM LOW PROFILE	32,0
223-27-34-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X34,0MM LOW PROFILE	34,0
223-27-36-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X36,0MM LOW PROFILE	36,0
223-27-38-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X38,0MM LOW PROFILE	38,0
223-27-40-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X40,0MM LOW PROFILE	40,0
223-27-42-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X42,0MM LOW PROFILE	42,0
223-27-44-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X44,0MM LOW PROFILE	44,0
223-27-46-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X46,0MM LOW PROFILE	46,0
223-27-48-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X48,0MM LOW PROFILE	48,0
223-27-50-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X50,0MM LOW PROFILE	50,0
223-27-52-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X52,0MM LOW PROFILE	52,0
223-27-54-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X54,0MM LOW PROFILE	54,0
223-27-56-CPB	TORXDRIVE CORTICAL SCREW TI T7 Ø2,7X56,0MM LOW PROFILE	56,0

INSTRUCTION FOR USE

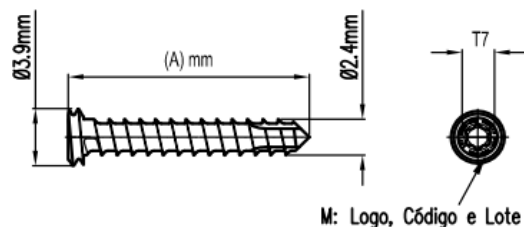
Versalock 2,4/2,7 System

Versalock System

Sheet:

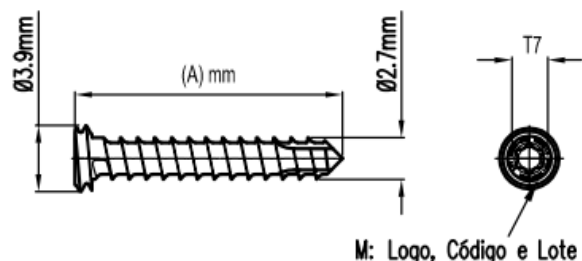
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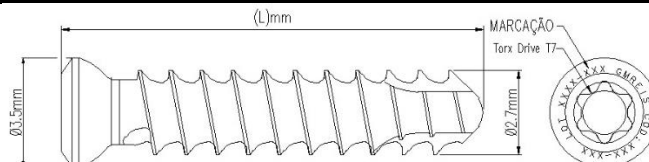
CODE	DESCRIPTION	A (mm)
223-24-12-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X12,0MM LOW PROFILE	12,0
223-24-14-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X14,0MM LOW PROFILE	14,0
223-24-16-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X16,0MM LOW PROFILE	16,0
223-24-18-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X18,0MM LOW PROFILE	18,0
223-24-20-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X20,0MM LOW PROFILE	20,0
223-24-22-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X22,0MM LOW PROFILE	22,0
223-24-24-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X24,0MM LOW PROFILE	24,0
223-24-26-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X26,0MM LOW PROFILE	26,0
223-24-28-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X28,0MM LOW PROFILE	28,0
223-24-30-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X30,0MM LOW PROFILE	30,0
223-24-32-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X32,0MM LOW PROFILE	32,0
223-24-34-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X34,0MM LOW PROFILE	34,0
223-24-36-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X36,0MM LOW PROFILE	36,0
223-24-38-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X38,0MM LOW PROFILE	38,0
223-24-40-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X40,0MM LOW PROFILE	40,0
223-24-42-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X42,0MM LOW PROFILE	42,0
223-24-44-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X44,0MM LOW PROFILE	44,0
223-24-46-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X46,0MM LOW PROFILE	46,0
223-24-48-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X48,0MM LOW PROFILE	48,0
223-24-50-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X50,0MM LOW PROFILE	50,0
223-24-52-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X52,0MM LOW PROFILE	52,0
223-24-54-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X54,0MM LOW PROFILE	54,0
223-24-56-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4X56,0MM LOW PROFILE	56,0

DRAW


Titanium Alloy ASTM F136

CODE	DESCRIPTION	A (mm)
223-27-10-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X10,0MM LOW PROFILE	10,0
223-27-12-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X12,0MM LOW PROFILE	12,0
223-27-14-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X14,0MM LOW PROFILE	14,0
223-27-16-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X16,0MM LOW PROFILE	16,0
223-27-18-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X18,0MM LOW PROFILE	18,0
223-27-20-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X20,0MM LOW PROFILE	20,0
223-27-22-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X22,0MM LOW PROFILE	22,0
223-27-24-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X24,0MM LOW PROFILE	24,0
223-27-26-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X26,0MM LOW PROFILE	26,0
223-27-28-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X28,0MM LOW PROFILE	28,0
223-27-30-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X30,0MM LOW PROFILE	30,0
223-27-32-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X32,0MM LOW PROFILE	32,0
223-27-34-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X34,0MM LOW PROFILE	34,0
223-27-36-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X36,0MM LOW PROFILE	36,0
223-27-38-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X38,0MM LOW PROFILE	38,0
223-27-40-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X40,0MM LOW PROFILE	40,0
223-27-42-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X42,0MM LOW PROFILE	42,0
223-27-44-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X44,0MM LOW PROFILE	44,0
223-27-46-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X46,0MM LOW PROFILE	46,0
223-27-48-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X48,0MM LOW PROFILE	48,0
223-27-50-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X50,0MM LOW PROFILE	50,0
223-27-52-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X52,0MM LOW PROFILE	52,0
223-27-54-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X54,0MM LOW PROFILE	54,0
223-27-56-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X56,0MM LOW PROFILE	56,0
223-27-58-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X58,0MM LOW PROFILE	58,0
223-27-60-BPB	TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7X60,0MM LOW PROFILE	60,0

DRAW



Titanium Alloy ASTM F136

CODE	DESCRIPTION	LENGTH
223-27-08-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 8,0MM	8,0
223-27-10-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 10,0MM	10,0
223-27-12-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 12,0MM	12,0
223-27-14-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 14,0MM	14,0
223-27-16-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 16,0MM	16,0
223-27-18-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 18,0MM	18,0
223-27-20-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 20,0MM	20,0
223-27-22-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 22,0MM	22,0
223-27-24-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 24,0MM	24,0
223-27-26-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 26,0MM	26,0
223-27-28-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 28,0MM	28,0
223-27-30-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 30,0MM	30,0
223-27-32-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 32,0MM	32,0
223-27-34-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 34,0MM	34,0
223-27-36-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 36,0MM	36,0
223-27-38-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 38,0MM	38,0
223-27-40-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 40,0MM	40,0
223-27-42-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 42,0MM	42,0
223-27-44-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 44,0MM	44,0
223-27-46-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 46,0MM	46,0
223-27-48-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 48,0MM	48,0
223-27-50-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 50,0MM	50,0
223-27-52-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 52,0MM	52,0
223-27-54-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 54,0MM	54,0
223-27-55-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 55,0MM	55,0
223-27-56-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 56,0MM	56,0
223-27-58-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 58,0MM	58,0
223-27-60-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 60,0MM	60,0
223-27-62-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 62,0MM	62,0
223-27-64-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 64,0MM	64,0



INSTRUCTION FOR USE

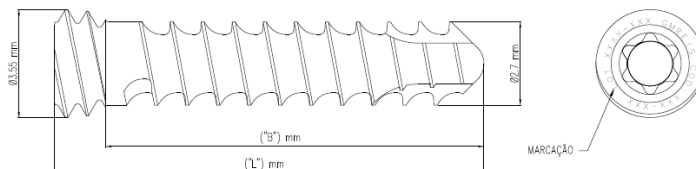
Versalock 2,4/2,7 System

Versalock System

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223-27-65-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 65,0MM	65,0
223-27-66-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 66,0MM	66,0
223-27-68-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 68,0MM	68,0
223-27-70-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 70,0MM	70,0
223-27-72-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 72,0MM	72,0
223-27-74-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 74,0MM	74,0
223-27-75-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 75,0MM	75,0
223-27-76-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 76,0MM	76,0
223-27-78-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 78,0MM	78,0
223-27-80-C	VERSA TORXDRIVE MINI SCREW TI Ø 2,7MM X 80,0MM	80,0

DRAW

Titanium Alloy ASTM F136

CODE	DESCRIPTION	(L)mm
223-27-06-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 6,0MM	6,0
223-27-08-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 8,0MM	8,0
223-27-10-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 10,0MM	10,0
223-27-12-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 12,0MM	12,0
223-27-14-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 14,0MM	14,0
223-27-16-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 16,0MM	16,0
223-27-18-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 18,0MM	18,0
223-27-20-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 20,0MM	20,0
223-27-22-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 22,0MM	22,0
223-27-24-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 24,0MM	24,0
223-27-26-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 26,0MM	26,0
223-27-28-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 28,0MM	28,0
223-27-30-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 30,0MM	30,0
223-27-32-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 32,0MM	32,0
223-27-34-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 34,0MM	34,0
223-27-36-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 36,0MM	36,0
223-27-38-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 38,0MM	38,0
223-27-40-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 40,0MM	40,0
223-27-42-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 42,0MM	42,0
223-27-44-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 44,0MM	44,0
223-27-46-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 46,0MM	46,0
223-27-48-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 48,0MM	48,0
223-27-50-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 50,0MM	50,0
223-27-52-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 52,0MM	52,0
223-27-54-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 54,0MM	54,0
223-27-56-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 56,0MM	56,0
223-27-58-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 58,0MM	58,0
223-27-60-BP	TI VERSALOCK LOCK SCREW T7 Ø2,7 X 60,0MM	60,0



INSTRUCTION FOR USE

Versalock 2,4/2,7 System

Versalock System

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223-27-62-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 62,0MM	62,0
223-27-64-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 64,0MM	64,0
223-27-66-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 66,0MM	66,0
223-27-68-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 68,0MM	68,0
223-27-70-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 70,0MM	70,0
223-27-72-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 72,0MM	72,0
223-27-74-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 74,0MM	74,0
223-27-76-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 76,0MM	76,0
223-27-78-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 78,0MM	78,0
223-27-80-BP	TI VERSALOCK LOCK SCREWT7 Ø2,7 X 80,0MM	80,0

Description of the physical principle and fundamentals of the technology, applied to its operation and action

The Versalock 2.4/2.7 System is a variable angle locking system for reconstructing the bones of the foot and ankle. The physical principle is based on rigid fixation, simulating an internal fixator where the screws have a specific thread profile in their head, which, when fixed with the appropriate instrument, allows the surgeon to fix it with a variable angle of $\pm 15^\circ$ in the hole. threaded from the plate, forming an imaginary cone, as shown in the following illustration.

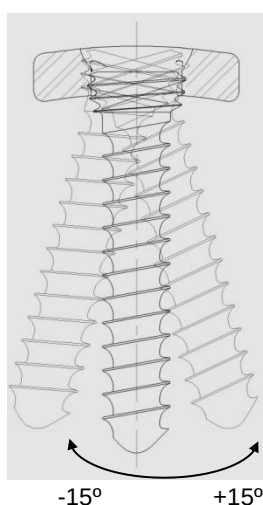


Figure 1: Illustration of the angle variation in the plate hole.

The system also allows fixation with non-threaded cortical and cancellous head screws when the surgeon so desires.

Technical specification of the raw material used for the manufacture of the product

The raw material used for the manufacture of the system is the titanium alloy Ti-6Al-4V ELI, according to the ASTM F 136 standard "*Standard Specification Wrought Titanium-6Aluminium-4Vanadium Alloy (Extra Low Interstitial) for Surgical Implant Applications*" and CPTi according to ASTM F67 standard "*Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*".

Marking

Implantable components are identified by laser marking with the following information:

- Product Lot

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- Product Code
- GMReis brand logo

Product Traceability Procedure

The identification and traceability of the product are ensured through a set of 05 adhesive labels provided in the package (see illustration below), along with the Instruction of Use and the implant, bringing information about the product, such as: name, model, code, batch, product registration and identification of the manufacturer. In this way, it is possible to take the opposite path and reach the production, raw material, suppliers, and other quality control items established in the GMReis Quality System. Traceability labels shall be affixed in the following locations:

- Label number 1, mandatorily, in the patient's medical record:
- Label number 2, in the report delivered to the patient:
- label number 3, on the tax documentation that generates the charge to the paying source;
- label number 4, made available for the supplier's control (historical distribution record);
- label number 5, made available for the surgeon's control.

 GMREIS Qualidade para Vida	AUT. MS: 1.02.477.0 CNPJ: 60.040.599/0001-19 I.E.: 244.342.283.119 Razão Social: G.M. dos Reis Ind. e Com. Ltda Av. Pierre Simon de Laplace, 600, Lote 3 Quadra F CEP: 13069-320 - Campinas/SP - Condomínio Techno Park Telefone: +55 19 3765-9900 E-mail: sac@gmreis.com.br
Afixe nos Prontuários / Attach to the Records	
NOME TÉCNICO / TECHNICAL NAME:	
NOME COMERCIAL / COMMERCIAL NAME:	
Modelo / Model:	
Código / Code:	
Lote / Batch:	
REGISTRO ANVISA Nº: Resp. Técn. Legalmente Habilitado: Geraldo M. dos Reis Jr. CREA/SP : 0682127536	

Figure 2: Traceability label.

It is the responsibility of the medical staff and the hospital (the custodians of the patient's information and medical records) to attach the label to the surgery description sheet or section of the medical record. GMReis recommends that the patient be the depository of this

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information, receiving a certificate with the attachment of one of the adhesive traceability labels.

Form of presentation

The implantable components are supplied non-sterile, duly identified, that is, laser marked with their code, batch number and GMReis logo.

It is an open system, with the commercial presentation being packaging in individual surgical grade paper packaging, duly labeled on the back (as shown in the following figure) where the components are supplied separately. The product is accompanied by 5 traceability labels and a manual on how the user can obtain the product's Instructions for Use, in non-printed format, at no additional cost, including shipping. This information is included in the product labeling.

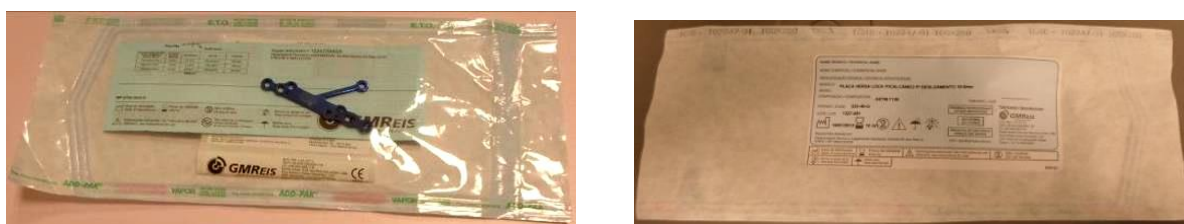


Figure 3: Illustration of the individual packaging of one of the products.

PORTUGUÊS (PT)	ENGLISH (EN)	ESPAÑOL (ES)	
A Instrução de Uso para este produto está disponível no website www.gmreis.com.br/produtos/IFU , (formato não impresso) e sempre estará de acordo com a última versão vigente, aprovada pela Anvisa	The Instruction for USE (IFU) for this product is available on the website: www.gmreis.com.br/produtos/IFU (printed format) and will always be in accordance with the latest version, approved by Anvisa	La Instrucción de Uso para este producto está disponible en el sitio web: www.gmreis.com.br/produtos/IFU (formato impreso) y siempre será con arreglo a la última versión en vigor, aprobado por la Anvisa	
No campo de busca, procure pelo nº do Registro da Anvisa do Produto ou nome comercial, descrito no rótulo, na embalagem do produto. Para visualização do documento é preciso ter o Adobe Reader. Obtenha gratuitamente no website acima.	In the search field, look for ANVISA registration number or commercial name, described on label in the product packaging. In order to view the document, you must have Adobe Reader, which can be downloaded for.free from the website above.	En el campo de búsqueda, busque por el número Registro ANVISA del producto o nombre comercial, descrito en la etiqueta del envase de producto. Para visualizar el documento es necesario tener el Adobe Reader. Reciba gratis en el sitio web arriba.	
Caso necessite receber uma versão impressa da IU, sem custo adicional, inclusive de envio, solicite gratuitamente pelo e-mail: sac@gmreis.com.br ou telefone disponível na rotulagem	If you need a printed copy at no extra cost, including shipping, please contact the e-mail: sac@gmreis.com.br or phone number available on labelling	Caso necesite recibir una versión impresa de IFU, sin costo adicional, incluyendo el envío, solicite gratis por el correo electrónico: sac@gmreis.com.br o teléfono disponible en el etiquetad	PT - Guia para acesso das Instruções de Uso GMReis (IFU) EN - GMReis Instructions for Use (IFU) access guide ES - Guía para acceder a las instrucciones de uso (IFU) IFUGMREIS – Rev.01

Figure 4: Manual that comes with the product.

The models provided and the marking location are described in the item in table 1.

The product must be sterilized according to the item "Sterilization Method".

Handling, conservation, storage, and transport

The product must be handled, preserved, stored, and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

The medical product must be handled with great care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect its quality and also the safety of the user.

It must be preserved and stored in its original packaging, until the moment of use, in a clean, dry, ventilated environment, protected from sunlight, free of contaminants (acid and organic vapors), and with temperature and humidity control.

The handling and storage of the product must be done exclusively by professionals in the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating, improper stacking, and high temperatures during transport should be avoided.

Instruction for use and indication of training

Instruction for use

1. After clinical and imaging evaluation, carry out surgical planning to define treatment techniques and which implants are most appropriate;
2. Position the patient and perform surgical access;
3. Confirm which implant is best suited to the patient's needs, considering model (morphology) and dimensions, and, if necessary, perform small modeling, using the appropriate instruments, to better adapt to the treated region;
4. Reduce the fracture by temporarily fixing the fragments with wires or bone forceps. Position the chosen plate, fixing it with guide wires or support instruments (tweezers).
5. To apply versa (or cortical) screws:
 - a. Position the respective guide in the smooth hole on the plate;
 - b. Carry out drilling with the appropriate drill;
 - c. If necessary, use the thread tap;
 - d. Measure the hole with the depth gauge;
 - e. With the fixed wrench, apply the screw determined by measurement.

6. For application of Versalock screws (variable angle locks):

- a. Position the guide (0° or +/- 15°) in the threaded hole on the plate, drill with the appropriate drill and apply the screw with the wrench accompanied by a torque limiter;
- b. Perform the drilling with the appropriate drill and at the most suitable angle for applying the screw;
- c. Measure the hole with the depth gauge;
- d. Using the wrench accompanied by the torque limiter, apply the screw determined by the measurement, locking it on the plate.

7. Remove any clamps and wires possibly used for temporary fixation of the reduction or plate;

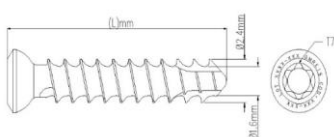
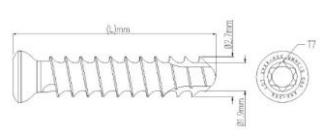
8. Carry out radiological and functional assessment (if necessary) to check the positioning of the implants and quality of the treatment;

9. Close the surgical incisions in their different planes and layers and apply dressings, splints, plaster, or other materials to protect the treated region, as defined by the surgical planning.

The time during which this care must be maintained depends on the specific characteristics of each procedure and must be carefully outlined by the responsible surgeon. Likewise, post-operative care and rehabilitation will depend on countless variables that cannot be outlined in this document and that are the absolute responsibility of the multidisciplinary team that cares for the patient.

The patient should be instructed not to place load on the treated limb before 10 weeks. The release of the load after 10 weeks must be gradual, carried out with the supervision of the surgeon, together with the physiotherapist, who must program and control the rehabilitation process.

Compatibility Table

	
223-24-(L)-C - VERSA TORXDRIVE MINI SCREW TI Ø2.4mm x (L)mm	223-27-(L)-C - VERSA TORXDRIVE MINI SCREW TI Ø2.7mm x (L)mm
180-68 - DRILL Ø1.8x100.0mm	169-403 - DRILL Ø2,0x110mm
180-69 - DRILL Ø2.4x70.0mm	180-89 - DRILL Ø2.7x85.0mm
223-320 - SCREW COUNTERSINK 2,4 - 2,7mm	
223-308 - HEXALOBULAR WRENCH TIP T7	
223-310 - SMALL HANDLE WITH QUICK COUPLE	
223-312 - SMALL DEPTH GAUGE 10.0mm TO 40.0mm	
180-90 - INTERFRAGMENTARY DRILL GUIDE Ø2.4mm	180-91 - INTERFRAGMENTARY DRILL GUIDE Ø2.7mm

Indication of capacity

Only professionals who are properly trained and qualified in osteosynthesis procedures will be able to use the product.

The surgeon should be aware of all the recommendations described in the "instructions for use" of the product and other information described on the label.

Precautions, restrictions, warnings, special care, clarification of product use, storage, handling and transportation
General information

- Single-use product, do not reuse, even if it appears to be in perfect condition.
- Non-sterile product supplied.
- Sterilize before use according to the recommended Sterilization Method.
- Product must not be reprocessed.

Warnings and Restrictions on Correct Implant Choice

The correct choice of implants must be extremely rigorous. The success of the procedure is directly related to the correct choice of the dimensions of the implant to be used. The size and shape of bone structures are limiting factors in the choice of implants. Metal implants cannot withstand levels of activity and loads equivalent to natural bones. Always follow the instructions for use of the product.

Criteria for selecting the implants

The correct selection of the implant is extremely important, considering biomechanical aspects, the size and shape of the bone structure to be treated, which corresponds to the size of the implant to be selected. The success of fixation is related to the correct selection of the implant.

Product Load Restrictions

These implants are designed to support loads distributed on their surface when implanted to stabilize a specific bone structure and may rupture until complete bone consolidation occurs. Overloads and mechanical handling efforts (i.e., twisting, bending, etc.) exerted during its implementation compromise its mechanical characteristics, which may lead to the product failing or breaking due to early fatigue.

The use of implants for internal fixation allows the surgeon to fix bone fragments in the correct anatomical position. The implants allow early mobility for patients, but limited to unloaded movements until the surgeon confirms bone healing of the fracture through X-rays, which normally occurs within 90 days after surgery.

Implants are designed as aids to the natural consolidation process, but they are not intended to replace anatomical structures or support the weight of the body in the presence of incomplete consolidation.

The patient should not place load on the treated limb before 10 weeks. The release of the load after 10 weeks must be gradual, carried out with the supervision of the surgeon, together with the physiotherapist, who must program and control the rehabilitation process.

Product Shaping Limit

Plates

The Versalock 2,4/2,7 System plates are designed to properly adapt to the bone being treated. In certain situations, it is necessary to model the implant to adapt it perfectly to the anatomy of the bone to be treated. Avoid excessive modeling and avoid modeling the product in the same place in opposite directions.

The correct selection of the implant is essential for the success of the surgery and the perfect functioning of the implanted system. After the correct selection of the implant, they can be modeled, and the limit for modeling the implant is the anatomy of the bone in which it will be

used. The implant must not be bent at sharp angles, bent upside down, scratched or deformed.

An implant once modeled cannot be modeled again to its original shape, or to another shape, as this could lead to early fracture of the implant and consequently failure of the product's function.

The plates described below, which make up this system, should not be shaped during surgery, they are already presented at the appropriate angle.

CODE	DESCRIPTION
223-60-45-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT SMALL
223-60-53-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT MEDIUM
223-60-57-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE RIGHT LARGE
223-60-45-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT SMALL
223-60-53-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT MEDIUM
223-60-57-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE LEFT LARGE
223-61-45-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT SMALL
223-61-53-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT MEDIUM
223-61-57-D	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION RIGHT LARGE
223-61-45-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT SMALL
223-61-53-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT MEDIUM
223-61-57-E	VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION LEFT LARGE
223-48	VERSALOCK VERSATILE MESH PLATE
223-63	VERSALOCK TALAR NECK PLATE
223-41-38	VERSATILE ANGLED "T" PLATE 05 HOLES RIGHT
223-42-38	VERSATILE ANGLED "T" PLATE 05 HOLES LEFT
223-41-45	VERSATILE ANGLED "T" PLATE 06 HOLES RIGHT
223-42-45	VERSATILE ANGLED "T" PLATE 06 HOLES LEFT
223-41-53	VERSATILE ANGLED "T" PLATE 07 HOLES RIGHT
223-42-53	VERSATILE ANGLED "T" PLATE 07 HOLES LEFT
223-51-35	MINI VERSALOCK PLATE "L" 06 VERSATILE HOLES LEFT
223-52-35	MINI VERSALOCK PLATE "L" 06 VERSATILE HOLES RIGHT
223-51-45	MINI VERSALOCK PLATE "L" 07 VERSATILE HOLES LEFT
223-52-45	MINI VERSALOCK PLATE "L" 07 VERSATILE HOLES RIGHT
223-51-60	MINI VERSALOCK PLATE "L" 08 VERSATILE HOLES LEFT
223-52-60	MINI VERSALOCK PLATE "L" 08 VERSATILE HOLES RIGHT
223-56	MINI VERSALOCK "H" VERSATILE PLATE 05 HOLES
223-57	MINI VERSALOCK "H" VERSATILE PLATE 08 HOLES
223-55-17	MINI VERSALOCK "T" PLATE VERSATILE 03 HOLES
223-55-23	MINI VERSALOCK "T" PLATE VERSATILE 04 HOLES
223-55-34	MINI VERSALOCK "T" PLATE VERSATILE 06 HOLES
223-55-42	MINI VERSALOCK "T" PLATE VERSATILE 07 HOLES
223-55-60	MINI VERSALOCK "T" PLATE VERSATILE 08 HOLES
223-55-90	MINI VERSALOCK "T" PLATE VERSATILE 08 HOLES LONG
314-06	VERSALOCK PLATE POSTERIOR MALLEOLUS T 06 HOLES 2.7MM
314-07	VERSALOCK PLATE POSTERIOR MALLEOLUS T 0 HOLES 2.7MM
314-16	VERSALOCK PLATE POSTERIOR MALLEOLUS T 03 HOLES 2.7MM
314-08-3E	VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 03 HOLES 2.7MM
314-08-4E	VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 04 HOLES 2.7MM
314-08-6E	VERSALOCK PLATE POSTERIOR MALLEOLUS L LEFT. 06 HOLES 2.7MM
314-08-3D	VERSALOCK PLATE POSTERIOR MALLEOLUS L RIGHT. 03 HOLES 2.7MM
314-08-4D	VERSALOCK PLATE POSTERIOR MALLEOLUS L RIGHT. 04 HOLES 2.7MM
314-08-6D	VERSALOCK PLATE REAR MALLEOLUS L RIGHT. 06 HOLES 2.7MM

Screws

Shaping of screws is not permitted.

Patient Instructions

The patient must be warned about the limits of their initial activities and their rehabilitation to protect the surgery performed by the responsible surgeon.

Excessive initial activities and trauma may affect the positioning of the implant, which may result in migration and premature wear of the implant or its rupture, affecting the supporting bone structure, making the revision procedure more difficult and earlier.

The patient must be warned about the risks of surgery and undesirable secondary or side effects and that the reconstruction performed with the implant will not have the same characteristics as the natural tissue that was reconstructed and that the implant may fail as a result of abnormal physical activities, trauma or degenerative diseases and other illnesses. The patient must be informed that the implant can be replaced when the surgeon deems it necessary. The patient must be instructed by the responsible surgeon to use adequate external support until the fracture is completely consolidated, as well as restrict physical activities that put the implant at risk or that allow movements in the fracture site, delaying bone consolidation.

Patients who are smokers, diabetics, with metabolic disorders and/or who use anabolic steroids, or who are using any medication that may compromise consolidation, and/or who have other diseases that may lead to delayed bone consolidation, should take aware that bone consolidation may not occur within the expected 90 days and that the implants may loosen or rupture, and that a second surgery may be necessary to repair the side effects. If the patient has an accident, he must be informed that the implant may break, loosen and/or migrate.

It is the responsible surgeon's responsibility to make postoperative recommendations, follow-ups, and the patient's clinical and radiological evolution.

It is important for the patient to be aware that failure to follow postoperative recommendations may lead to treatment failure and that the implant may migrate, loosen and/or break.

The patient must be informed that although the raw material used to manufacture the implant is known to be biocompatible, other side effects or adverse reactions may occur in more sensitive patients, such as:

- Sensitivity to the material;
- Allergic reactions;
- Bone deformity at the implantation site; or
- Incomplete bone consolidation.

Warning associated with the case of a falling component

If any implantable component falls or shows any type of damage, it must be discarded and discarded according to the "Disposal Procedure".

Warning regarding the surface condition of the product that restricts use

Implantable components must not visually exhibit any abnormalities on their surface, such as scratches, flaws, dirt, or other defects. Implantable components that present abnormalities on their surface should be discarded and discarded according to the disposal procedure.

Factors that may lead to possible breakage, loosening, or migration of the implant should be reported to the patient

The following are the main factors that, alone or in combination, can lead the implant to an early failure (breakage, loosening or migration):

- Failure to comply with postoperative recommendations;
- Metabolic dysfunctions;
- Diabetes;
- Smoking;
- Ingestion of medications that may affect the success of the surgery;
- Patients who have made or are using anabolic steroids;
- Patient's accident (e.g. falls, car accidents, etc.);
- Pseudarthrosis;
- Failure in surgical technique;
- Inadequate choice of implant;
- Early cargo release;
- Do not use external orthoses, when recommended;
- Excessive load or inadequate physical therapy activity;
- Osteoporosis;

- Practice of intense physical activity;
- Practice of physical activity before the surgeon's clearance and,
- Use outside the intended indications for the product.

Disposal procedure that ensures that the product is rendered unusable

Implants that for some reason were not used during the surgical procedure and had their packaging opened, or suffered damage and/or falls, cannot be reprocessed, and must be discarded at the hospital itself, together with their original packaging, according to the medical-hospital procedure and/or local legislation or according to the instructions of the Hospital Infection Control Commission - CCIH.

The methods and procedures for disposing of the medical product must ensure the complete decharacterization of the same, preventing any possibility of its reuse. The decharacterization of the medical product is the sole responsibility of the hospital institution, as well as the methods and disposal procedures used.

It is recommended that they be deformed with moulders or twistors until it is clearly identified that the product is unfit for their use, ensuring that the product cannot be used or improperly reused.

Removal and Handling of Implants Removed from Patients for Analysis

When the implant is explanted from the patient and has to be submitted to analysis, it must be proceeded in accordance with *ISO 12891-1 "Removal and Analysis of Surgical Implant – Part 1 – Removal and Handling"*, according to the instructions below:

It is recommended that implants, and in applicable cases, adjacent tissue samples, be removed in a manner that causes minimal damage to both tissue and implant. It is especially important that functional surfaces, such as prosthesis joint surfaces and fractured implant surfaces, are protected.

It is also extremely important to list the fractured parts of the implant and other removed components, making their position at the implantation site clear.

The most important part of surgical implant removal is the prevention of damage that could lead to useless scientific examination. For a proper scientific examination, the implant has to be preserved in the state as close as possible to that in which it existed at the time of the patient's removal. Consequently, it is important that care is taken during the handling,

storage and transport of the removed implants in order to ensure that no damage or alteration occurs on the surfaces that will be analyzed.

The same precautions should be taken for instruments that eventually fail during use.

Instruments that failed and implants removed must be cleaned and disinfected. Subsequently, they must be packed separately in plastic bags or plastic/glass containers and labeled. Packaging should minimize the possibility of breakage, surface damage, and possible contamination of the implant by the environment. The labeling of the products that will be sent for analysis must ensure their precise identification, and the ISO 12891-1 standard recommends that non-removable labels (which tear in the event of an attempt to remove them) be used.

It is extremely important, for an accurate assessment of the cause of product failure, that preoperative, postoperative and implant failure verification X-rays are sent together with the material sent for analysis.

Indication for Use

The Versalock 2.4/2.7 System is indicated in surgical procedures to be used in the stabilization of micro and mini bone fragments, reconstruction, and synthesis of the bones of the foot and ankle, associated or not with plates and/or washers, with the purpose to stabilize the fracture for the expected time, in cases of:

- Osteotomies;
- Fractures;
- Bone reconstructions;
- Tumors;
- Deformities and
- Pseudoarthroses.

The correct selection of the implant is extremely important, considering the biomechanical aspects, size, and shape of the bone structure to be treated, which corresponds to the size and model of the selected implant. The success of bone consolidation is related to the correct selection of the implant.

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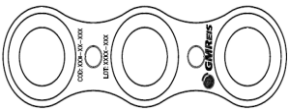
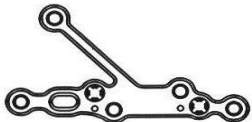
Specific Indication for Use

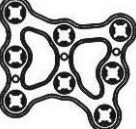
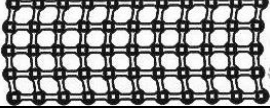
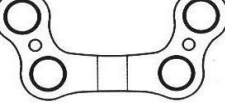
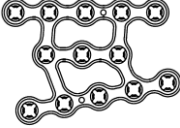
It is the responsibility of the surgeon responsible for the procedure to select the size of the most appropriate implantable component for use, which must be done based on the pre-operative radiological study and the correct indication for use.

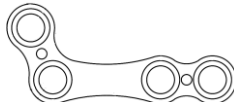
The correct selection of the implant is extremely important, considering the biomechanical aspects, size, and shape of the bone structure to be treated, which corresponds to the size and model of the selected implant.

The success of bone consolidation is related to the correct selection of the implant.

The following table provides information on the Versalock 2.4/2.7 System and the screws that must be used with each plate.

Product	Code	Image	Indication	Screw Type
VERSALOCK MINI STRAIGHT PLATE FOR FOOT	223-43 223-44 223-45 223-46 223-47 223-49 223-50		- Diaphyseal osteotomy of the first metatarsal; - Fractures of the first Metatarsal; - Osteotomies of the lateral metatarsals (II, III, IV and V) – diaphysis and base; - Fractures of the lateral metatarsals (II, III, IV and V); - Isolated tarso-metatarsal arthrodeses (II, III, IV and V); - Lateral metatarsophalangeal arthrodeses (II, III, IV and V);	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP - TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm - 223-24-L-C - TORXDRIVE CORTICAL SCREW T7 Ø2,4x(A)mm - 223-27-L-C - VERSA TORXDRIVE MINI SCREW TI T7 Ø2,7x(A)mm
VERSALOCK MINI STRAIGHT PLATE FOR FOOT LOW PROFILE	223-31-20 223-31-25 223-31-30 223-31-35 223-31-40 223-31-45		- Diaphyseal osteotomy of the first metatarsal; - Fractures of the first Metatarsal; - Osteotomies of the lateral metatarsals (II, III, IV and V) – diaphysis and base; - Fractures of the lateral metatarsals (II, III, IV and V); - Isolated tarso-metatarsal arthrodeses (II, III, IV and V); - Lateral metatarsophalangeal arthrodeses (II, III, IV and V); - Lisfranc fractures and dislocations.	- 223-24-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7x(A)mm LOW PROFILE - 223-24-L-CPB TORXDRIVE CORTICAL SCREW TI T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-CPB - TORXDRIVE CORTICAL SCREW TI T7 Ø2,7x(A)mm LOW PROFILE
VERSALOCK HALLUX MTF ARTHRODESIS PLATE	223-60-45-D 223-60-53-D 223-60-57-D 223-60-45-E 223-60-53-E 223-60-57-E		- Metatarsophalangeal Arthrodesis of the Hallux (forefoot); - Diaphyseal Fractures of the First Metatarsal (forefoot); - Osteotomies of the First Metatarsal (forefoot);	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP – TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm
VERSALOCK HALLUX MTF ARTHRODESIS PLATE WITH EXTENSION	223-61-45-D 223-61-53-D 223-61-57-D 223-61-45-E 223-61-53-E 223-61-57-E		- Metatarsophalangeal Arthrodesis of the Hallux (forefoot);	

VERSALOCK SERPENT PLATE	223-35-M 223-35-P		- Fractures of the Navicular Tarsus (forefoot)	
VERSALOCK BUTTERFLY PLATE FOR CUBOID	223-36-D 223-36-E 223-37-D 223-37-E		- Isolated tarso-metatarsal arthrodeses (midfoot and forefoot) - Cuboid fractures (midfoot) - Calcaneus-Cuboid Arthrodesis (midfoot and hindfoot)	
VERSALOCK VERSATILE MESH PLATE	223-48		- Fractures of the talus (hindfoot) - Calcaneal fractures (hindfoot) - Midfoot fractures	
LOW PROFILE VERSALOCK "U" PLATE	223-19-B 223-20-B 223-22-B 223-24-B 223-26-B		- Calcaneus-Cuboid Arthrodesis (midfoot and hindfoot) - Osteotomy of the Anterior Calcaneal Tuberosity (rearfoot)	- 223-24-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7x(A)mm LOW PROFILE
VERSALOCK TALAR NECK	223-63		- Fracture of the neck of the talus (hindfoot)	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP - TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm
VERSATILE RECTANGULAR VERSALOCK PLATE	223-35-D 223-35-E		- Lisfranc Fractures and Dislocations (midfoot) - Fractures of the Navicular Tarsus (midfoot) - Midtarsal Arthrodesis (Talo-Navicular) – hindfoot and midfoot - Midfoot Fractures	
VERSALOCK "W" VERSATILE PLATE	223-36-W		- Lisfranc Fractures and Dislocations (midfoot) - Cuboid (midfoot) fractures - Midtarsal Arthrodesis (Calcaneus-- Cuboid) – midfoot and hindfoot - Calcaneal fractures (hindfoot) - Midfoot Fractures	
VERSATILE ANGLED "T" PLATE	223-41-38 223-42-38 223-41-45 223-42-45		- Metatarsophalangeal Arthrodesis of the Hallux (forefoot) - Fractures of the First Metatarsal (forefoot)	

	223-41-53 223-42-53			
VERSATILE LOW PROFILE VERSALOCK "L" MINI PLATE	223-12-EB 223-17-EB 223-18-EB 223-12-DB 223-17-DB 223-18-DB		- Base osteotomies of the 1st metatarsal (forefoot) - Diaphyseal Osteotomies of the I Metatarsus (forefoot) - Fractures of the 1st Metatarsal (forefoot) - Lisfranc Dislocation Fractures (midfoot) - Forefoot fractures	- 223-24-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7x(A)mm LOW PROFILE
MINI VERSALOCK PLATE "L"	223-51-35 223-52-35 223-51-45 223-52-45 223-51-60 223-52-60		- Diaphyseal Osteotomies of the I Metatarsus (forefoot) - Fractures of the 1st Metatarsal (forefoot) - Osteotomies of the Lateral Metatarsals (II, III, IV and V) – Diaphysis and Base (forefoot) - Fracture of the neck of the lateral metatarsals (II, III, IV and V) - forefoot - Fracture of the Lateral Metatarsals (II, III, IV and V) - forefoot - Isolated Tarsal-Metatarsal Arthrodeses (II, III, IV and V) – midfoot and forefoot - Lateral Metatarsophalangeal Arthrodeses (II, III, IV and V) - forefoot - Forefoot fractures	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP – TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm
LOW PROFILE ANGLED "T" MINI VERSALOCK PLATE	223-32-25-ED 223-32-30-ED 223-32-35-ED 223-32-40-ED 223-32-45-ED 223-32-50-ED 223-32-55-ED		- Diaphyseal Osteotomies of the I Metatarsus (forefoot) - Fractures of the 1st Metatarsal (forefoot) - Osteotomies of the Lateral Metatarsals (II, III, IV and V) – Diaphysis and Base (forefoot) - Fracture of the neck of the lateral metatarsals (II, III, IV and V) (forefoot) - Fracture of the Lateral Metatarsals (II, III, IV and V) (forefoot) - Isolated Tarsal-Metatarsal Arthrodeses (II, III, IV and V) (rearfoot and forefoot) - Lateral Metatarsophalangeal Arthrodeses (II, III, IV and V) (forefoot) - Lisfranc Dislocation Fractures (midfoot) - Forefoot fractures	- 223-24-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7x(A)mm LOW PROFILE

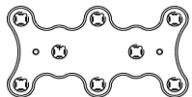
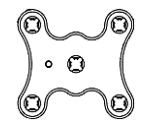
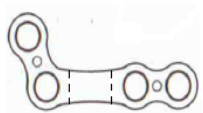
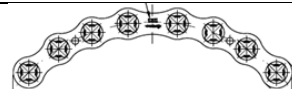
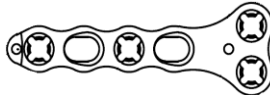
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MINI VERSALOCK "H" VERSATILE PLATE	223-57		- Cuboid (midfoot) fractures - Midtarsal Arthrodesis (Calcaneus- Cuboid) - midfoot and hindfoot - Calcaneal fractures (hindfoot)	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP – TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm
MINI VERSALOCK "H" VERSATILE PLATE	223-56		- Tarsal-Metatarsal Arthrodesis of the I Ray (rearfoot and forefoot) - Lisfranc Fractures and Dislocations (midfoot) - Cuboid (midfoot) fractures - Midtarsal Arthrodesis (Talo-Navicular) – hindfoot and midfoot	
VERSALOCK "L" LOW PROFILE MINI PLATE	223-11-DB 223-13-DB 223-15-DB 223-16-DB 223-19-DB 223-11-EB 223-13-EB 223-15-EB 223-16-EB 223-19-EB		- Forefoot osteotomy	- 223-24-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm LOW PROFILE - 223-27-L-BPB - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,7x(A)mm LOW PROFILE
VERSATILE SEMILUNAR VERSALOCK PLATE	223-53 223-54		- Fractures of the neck of the talus (hindfoot) - Midfoot fractures	
MINI VERSALOCK "T" PLATE VERSATILE	223-55-17 223-55-23 223-55-34 223-55-42 223-55-60 223-55-90		- Diaphyseal Osteotomies of the I Metatarsus (forefoot) - Fractures of the 1st Metatarsal (forefoot) - Osteotomies of the neck of the lateral metatarsals (II, III, IV and V) (forefoot) - Osteotomies of the Lateral Metatarsals (II, III, IV and V) – Diaphysis and Base (forefoot) - Fracture of the neck of the lateral metatarsals (II, III, IV and V) (forefoot) - Fracture of the Lateral Metatarsals (II, III, IV and V) - (forefoot) - Isolated Tarso-Metatarsal Arthrodeses (II, III, IV and V) – (forefoot) - Lateral Metatarsophalangeal Arthrodeses (II, III, IV and V) - (forefoot) - Midfoot fractures	- 223-24-L-BP - TORXDRIVE TI VERSALOCK LOCKING SCREW T7 Ø2,4x(A)mm - 223-27-L-BP – TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm

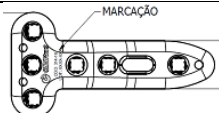
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VERSALOCK PLATE POSTERIOR MALLEOLUS	314-06 314-07 314-16		- Fixation of fragments of the distal region of the tibia – posterior malleolus	- 223-27-L-BP – TI VERSALOCK LOCK SCREW T7 Ø2,7 x L mm - 223-27-L-C – VERSA TORXDRIVE MINI SCREW TI Ø2,7 x L mm
VERSALOCK PLATE POSTERIOR MALLEOLUS L	314-08-3D 314-08-4D 314-08-6D 314-08-3E 314-08-4E 314-08-6E		- Fixation of fragments of the distal region of the tibia – posterior malleolus	

Side Effects

The Versalock 2.4/2.7 System are manufactured with raw materials for recognized biomedical uses, which meet the requirements of the following international standards:

Pure Titanium – CPTi – in accordance with ASTM F67 “Standard Specification for Unalloyed Titanium for Surgical Implant Applications”;

Ti6Al4V Titanium Alloy in accordance with ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”. The chemical, metallographic and mechanical requirements of material standards are used as criteria to ensure the purity of the product and its biomechanical performance, characterizing it as suitable for implantation in the human body. It should be noted, however, that no surgical implant material has been shown to be completely free from adverse reactions in the human body, and that an acceptable level of biological response can be expected when the material is used in appropriate applications. Therefore, the product may generate some undesirable side effects due to the biomaterial:

- Sensitivity to metal or allergic reaction to a foreign body;
- Pain, discomfort, and abnormal sensations due to incorrect use and indication of the implant.

It is recommended that the surgeon assess the patient's possible sensitivity to the use of the biomaterial to be used before implantation. Other undesirable side effects related to the surgical procedure and product placement:

- Rupture or loosening of implants due to not following post-operative rehabilitation guidelines and/or excessive load during physiotherapy and/or incorrect positioning of the implant;
- Shortening of the limb due to fracture compression or bone resorption;
- Decrease in bone density;
- Nerve injuries due to surgical trauma;
- Infections
- Bone necrosis and
- Vascular changes and others inherent to the surgical procedure.

Note 1: Smoking patients (smokers) have greater difficulties in achieving bone consolidation, consequently there are greater chances of deformation, rupture or loosening of the implants.

Note 2: Other interventions may be necessary to repair side effects.

Contraindications

Patients who present any of the clinical conditions described below should not undergo the procedure with the use of Versalock 2,4/2,7 System:

- History of recent infection or active infection;
- Osteometabolic diseases that cause fragility or reduction in bone mass;
- Insufficient or low-quality bone mass;
- Inadequate vascularization at the implant placement site that may compromise adequate blood supply at the implantation site;
- Patients with previously placed implants that could compromise implantation and/or interfere with the product;
- Drug abuse and alcoholism;
- Fever
- Pregnancy;
- Allergy and/or sensitivity to metals and,
- Patients unable to follow postoperative recommendations.

Permissible combinations with other materials

The materials in question are highly resistant to corrosion in the physiological environment. Despite this, the product cannot be used in conjunction with any product from another manufacturer, or any metallic product with a different chemical composition, as this association can generate chemical (producing galvanic and other corrosion), physical, biological, and functional incompatibilities, early fatigue, and possible risks to the patient.

The product should only be implemented with specific instruments, from the GMReis brand, presented in the table below.

If any inappropriate combination occurs by the surgeon, he will be responsible for the risks associated with such combination.

Instrumental non-implantable components

CODE	DESCRIPTION
223-58	Medium Rod
172-19	Plate Cutter Clamp
223-305	Olive Guide Wire Ø1.0x10..0x100.0mm
223-306	Olive Guide Wire Ø1.0x20.0x100.0mm
223-307	Olive Guide Wire Ø1.0x30.0x100.0mm
223-100	Foot Distraction Forceps
223-301	Small Bone Reduction Forceps
223-302	Small Angled Bone Reduction Forceps

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223-303	Small Straight Bone Reduction Forceps
223-304	Hohmann Retractor Small 1.7mm
223-308	T7 Hexalobular Wrench Tip
223-309	Medium Periostome 6.0mm
223-310	Handle with Small Quick Coupling
223-311	Plate and Screw Gripper
223-312	Small Depth Gauge 10.0mm to 40.0mm
223-313	T7 Screw Extractor
223-314	Torque Limiter Handle 1.3 N.m
223-315	Small Erina
223-316	Guide Wire Ø1.6mmx130.0mm Without Thread
223-317	Twist Off Key
223-318	Mini Plate Modeler
223-319	Polyaxial Drill Guide Ø1.7mm 0o – 0o to 15°
223-320	Screwdriver for 2.4-2.7mm Screws
223-321	Drill Ø1.5x100mm
223-322	Mini Plate Protector Screw Ø2.8mm
223-323	Guide Wire Ø1.0x150.0mm Without Thread
223-334	Drill Guide Ø2.3mm
169-165	Toothed Reduction Forceps
232-84	Hexalobular Wrench Tip T15 x 165mm
307-50	Drill Guide Ø2.5mm
223-324	REAMER Ø14.0mm DISTAL
223-325	REAMER Ø16.0mm DISTAL
223-326	REAMER Ø18.0mm DISTAL
223-327	REAMER Ø20.0mm DISTAL
223-328	REAMER Ø22.0mm DISTAL
223-329	REAMER Ø14.0mm PROXIMAL
223-330	REAMER Ø16.0mm PROXIMAL
223-331	REAMER Ø18.0mm PROXIMAL
223-332	REAMER Ø20.0mm PROXIMAL
223-333	REAMER Ø22.0mm PROXIMAL
172-19A	WIRE CUTTER Ø 3.2mm
223-341	DRILL Ø2.7x125.0mm
223-342	DRILL Ø2.4x125.0mm
223-343	MEDIUM DRILL GUIDE
180-19	POLYAXIAL DRILL GUIDE Ø2,0mm
172-17	GUIDE WIRE 2.0 x 150mm
180-63	HANDLE WITH TORQUE LIMITER 0.8 N.m
223-200	BOX FOR PLATES
223-201	BOX
223-206	BOX
223-202	BOX
223-204	BOX
223-207	BOX
711-112	COVER
180-68	DRILL Ø1.8x100.0mm
180-69	DRILL Ø2.4x70.0mm
180-89	DRILL Ø2.7x85.0mm
169-403	DRILL Ø2,0x110mm
180-90	INTERFRAGMENTARY DRILL GUIDE Ø2.4mm
180-91	INTERFRAGMENTARY DRILL GUIDE Ø2.7mm

Deployment risk

Although the raw material used to manufacture the product is biocompatible and standardized according to ASTM F136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications" and Pure Titanium – CPTi – in accordance with ASTM F67 "Standard Specification for Unalloyed Titanium for Surgical Implant Applications"; the patient may suffer sensitivity to the product or allergic reaction. It is known that, even if a raw material meets the chemical,

mechanical and microstructural requirements determined by standards (which ensures its purity and biomechanical performance, making it suitable for use as a material for the manufacture of implants), there is no material that is completely free of adverse reactions in the human body.

To avoid other risks of implantation, other precautions can be taken, such as:

- Total aseptic condition;
- Preoperative and intraoperative radiological evaluation;
- Follow the instructions for use;
- Appropriate selection of implant type and size based on preoperative radiological planning.

Other deployment risks:

- Failure to indicate surgery,
- Failure of surgical technique, and/or
- Lack of patient cooperation regarding postoperative recommendations.

Evaluation of the deployed product

After implantation, intraoperatively, the responsible professional must perform radiological control to verify the correct positioning of the product. The responsible professional must carry out, and is his or her responsibility, clinical and radiological evaluations after the surgical procedure, at the frequency stipulated by him, to check the status of the implant and the progress of bone consolidation. If the product is out of correct positioning, or presents any non-compliance, it is the surgeon's responsibility to take the most appropriate corrective action.

Restrictions and instructions on damage to packaging

In the circumstances described below, the product must be unusable and discarded, according to the item *Procedure related to disposal that ensures the unusability of the product*:

- Sealing area of the package is violated;
- Any of the packages have physical damage;
- The label or identification code is illegible and,
- Expiration date is overdue.



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Surgical Grade Paper Opening Procedure

1. Use dry hands and gloves;
2. Hold the product firmly;
3. Hold the surgical grade paper with the other hand;
4. To open the packaging, pull the surgical grade paper with continuous force;
5. Hold the inner packaging firmly and then
6. With the other hand, pull the product.

Restrictions on reprocessing

Reprocessing of the product is not allowed, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, not presenting the expected performance for the intended use, which may put the health of patients and health professionals at risk.

Sterilization Method

Products should be sterilized by the following method:

Type: Moist Heat

Cycle: Gravitational

Temperature: 121°C (250°F)

Exposure Time: 60 minutes

Additional information regarding sterilization is described in the ISO 17665-1:2010 standard - "Sterilization of health products - Steam Part 1: Requirements for the development, validation and routine control of sterilization processes of health products".

Additional information on the procedure before using the product

When opening the package, check the surface condition of the product for deformations, stains, scratches or any other type of superficial alteration or defect; then send the product for sterilization, following the recommendations as indicated in the item "Sterilization Method". The packaging of the product must be discarded according to medical-hospital procedure and/or local legislation or according to the instructions of the Hospital Infection Control Commission - CCIH.

Specific guidelines for physicians regarding the reporting of adverse events and technical complaints

If the product presents adverse events not reported in the instruction for use or has technical complaints about the product, the physician must immediately contact the manufacturer through the GM Reis Customer Service (SAC), in addition to notifying the competent health authority, ANVISA, through the E-mail: tecnovigilancia@anvisa.gov.br. More information can be found in the National System of Notifications for Health Surveillance – NOTIVISA (web: <http://www.anvisa.gov.br/hotsite/notivisa/apresenta.htm>). To ensure product traceability, the physician must proceed according to the "product traceability procedure". The traceability of the product is ensured through the 05 traceability labels, provided inside the package, along with the Instruction for Use, as described in the item "Product Traceability Procedure".

Customer's Complaint

If the medical product presents a specific unforeseeable risk, is out of its specifications or is generating any dissatisfaction, notify GM Reis Customer Service (SAC) directly. The product must be sent clean and packed in a plastic bag, duly identified and with a description of the non-conformity, to the following address: Rua Pierre Simon de La Place, 600, Lote 3, Quadra F, Quarteirão 9677 – TechnoPark – CEP: 13069-320, Campinas – SP, Brazil, or notify directly at Tel.: (0XX19) 3765-9900 / Fax.: (0XX19) 3765-9111 / E-mail: sac@gmreis.com.br.

Labeling Symbolology

The graphic symbols used in the labeling are in accordance with the NBR ISO 15223 Standard as follows:

SYMBOLS	DESCRIPTIONS	SYMBOLS	DESCRIPTIONS
	Date of manufacture		Single-Use Product "Do not reuse"
	Shelf Life		Additional information "See instructions for use"
	Keep dry		Keep away from light

ALERT TO THE USER:

These Instructions for Use are available in non-printed format, through the manufacturer's electronic address: <http://www.gmreis.com.br/produtos/IFU>, and can be checked on the website, in the search

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field, by the trade name or registration number with Anvisa, described on the label of the product packaging. The Instructions for Use provided will always be in accordance with the latest version in force, approved by Anvisa. If the user is interested, the Instructions for Use may be made available in printed format, at no additional cost, including shipping. Request it free of charge by e-mail: sac@gmreis.com.br or phone available on the label.

GM dos Reis Indústria e Comércio Ltda.

Avenida Pierre Simon de Laplace, nº 600 - Lote 3 - Quadra F - Quarteirão 9677

TECHNOPARK District - CEP: 13069-320 – Campinas – SP - BRAZIL

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