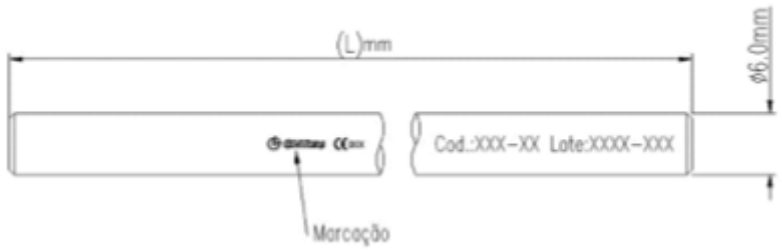
3. INSTRUCTIONS FOR USE

3.1. General Information of Product Identification

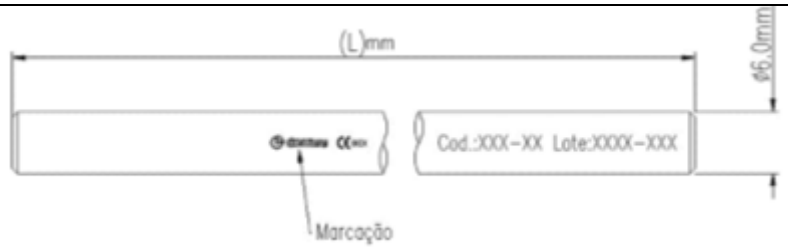
3.1.1.a. Technical Name: Rear spine system for blade, apophysis pedicle or articulate mass.
3.1.1.b. Commercial Name: Pedimax II – Pedicle screws system.

3.1.1.c. Table 1. Implantable components relation which compose the product with the graphic details: draws, descriptions, dimensional characteristics, tolerances, composition and technical standard of the raw material for each product. These details allow the products visualization in the way they are delivered for consumption.

Table 1. Draws, descriptions, dimensional characteristics, tolerances, composition to the respective technical standard and the marking location of the products.

	TECHNICAL DRAWINGS			
				
RAW MATERIAL – Pure Titanium ASTM F67 Gr.4				
CODE	**PRODUCT DESCRIPTION**			
112-(L)	**ROD Ø6.0 x (L)mm (L)mm**		**(L)mm**	

112-18	ROD Ø6.0 x 40.0mm		**40.0mm**	
112-19	ROD Ø6.0 x 50.0mm		**50.0mm**	
112-20	ROD Ø6.0 x 60.0mm		**60.0mm**	
112-21	ROD Ø6.0 x 70.0mm		**70.0mm**	
112-22	ROD Ø6.0 x 80.0mm		**80.0mm**	
112-23	ROD Ø6.0 x 90.0mm		**90.0mm**	
112-122	ROD Ø6.0 x 100.0mm		**100.0mm**	
112-24	ROD Ø6.0 x 110.0mm		**110.0mm**	
112-25	ROD Ø6.0 x 130.0mm		**130.0mm**	
112-26	ROD Ø6.0 x 150.0mm		**150.0mm**	
112-27	ROD Ø6.0 x 180.0mm		**180.0mm**	
112-28	ROD Ø6.0 x 210.0mm		**210.0mm**	
112-85	ROD Ø6.0 x 380.0mm		**380.0mm**	
112-86	ROD Ø6.0 x 450.0mm		**450.0mm**	

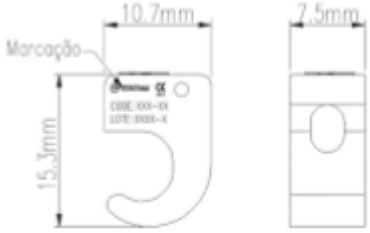


RAW MATERIAL –Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**		
112-06-(L)	**ROD Ø6.0 x (L)mm**		**(L)mm**
112-06-40	ROD Ø6.0 x 40.0mm		**40.0mm**
112-06-50	ROD Ø6.0 x 50.0mm		**50.0mm**
112-06-60	ROD Ø6.0 x 60.0mm		**60.0mm**
112-06-70	ROD Ø6.0 x 70.0mm		**70.0mm**
112-06-80	ROD Ø6.0 x 80.0mm		**80.0mm**
112-06-90	ROD Ø6.0 x 90.0mm		**90.0mm**
112-06-100	ROD Ø6.0 x 100.0mm		**100.0mm**
112-06-110	ROD Ø6.0 x 110.0mm		**110.0mm**
112-06-130	ROD Ø6.0 x 130.0mm		**130.0mm**
112-06-150	ROD Ø6.0 x 150.0mm		**150.0mm**
112-06-180	ROD Ø6.0 x 180.0mm		**180.0mm**
112-06-210	ROD Ø6.0 x 210.0mm		**210.0mm**
112-06-380	ROD Ø6.0 x 380.0mm		**380.0mm**
112-06-450	ROD Ø6.0 x 450.0mm		**450.0mm**

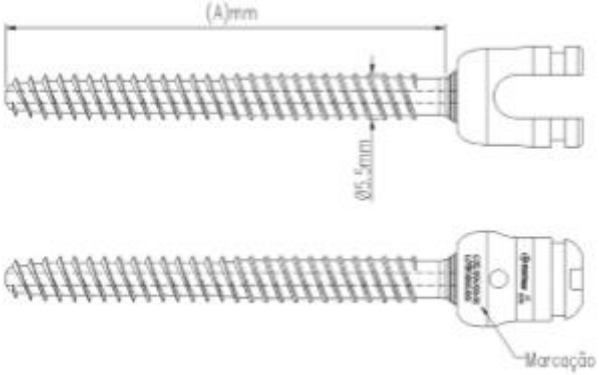
RAW MATERIAL –Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
	TRANSVERSAL ROD Ø3.2x(L)mm		**(L)mm**	
112-46	TRANSVERSAL ROD Ø3.2x60.0mm		60.0mm	
112-47	TRANSVERSAL ROD ∅3.2x80.0mm		80.0mm	
112-48	TRANSVERSAL ROD ∅3.2x100.0mm		100.0mm	



RAW MATERIAL –Titanium 6Al 4V ELI ASTM F136

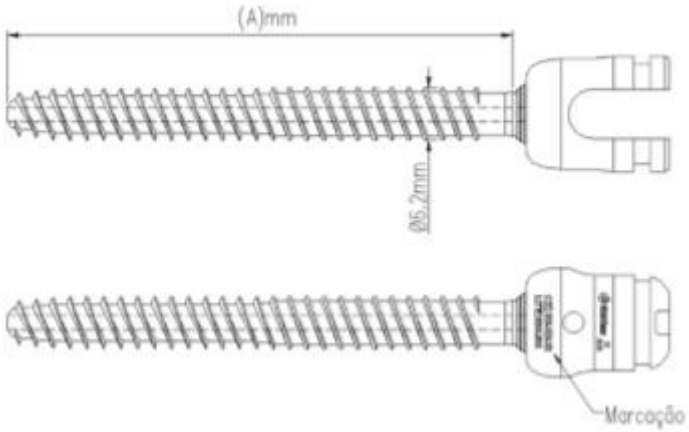
CODE	PRODUCT DESCRIPTION			
112-44	CROSSLINK HOOK PEDIMAX II			



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

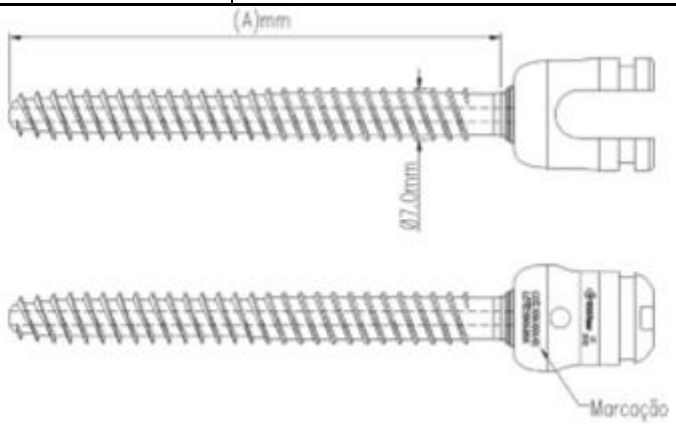
CODE	PRODUCT DESCRIPTION			
152-55-(A)	**POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅5.5x(A)mm**		**(A)mm**	
152-55-30	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅5.5x30.0mm		**30.0mm**	
152-55-35	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅5.5x35.0mm		**35.0mm**	

152-55-40	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅5.5x40.0mm		**40.0mm**	
152-55-45	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅5.5x45.0mm		**45.0mm**	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

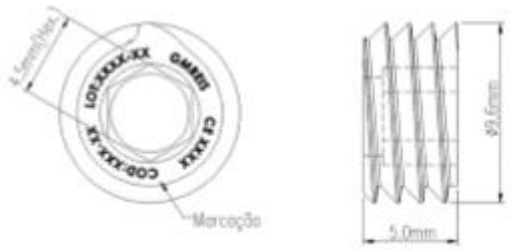
CODE	**PRODUCT DESCRIPTION**			
152-62-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅6.2x(A)mm		**(A)mm**	
152-62-35	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅6.2x35.0mm		**35.0mm**	
152-62-40	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅6.2x40.0mm		**40.0mm**	
152-62-45	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅6.2x45.0mm		**45.0mm**	
152-62-50	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅6.2x50.0mm		**50.0mm**	



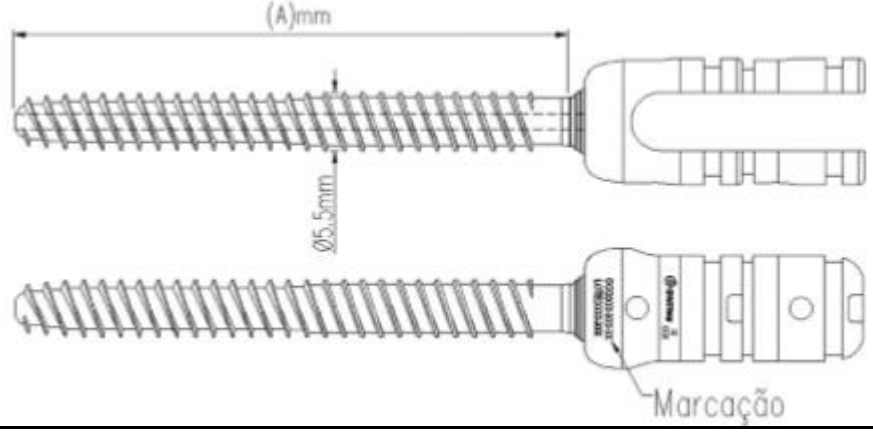
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**	

152-70-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x(A)mm		**(L)mm**	
152-70-30	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x30.0mm		**30.0mm**	
152-70-35	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x35.0mm		**35.0mm**	
152-70-40	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x40.0mm		**40.0mm**	
152-70-45	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x45.0mm		**45.0mm**	
152-70-50	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS ∅7.0x50.0mm		**50.0mm**	

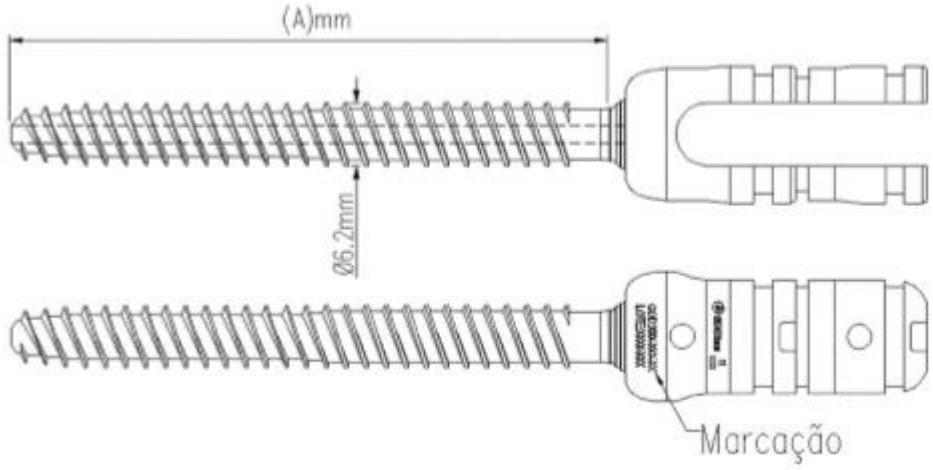


RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136				
CODE	**PRODUCT DESCRIPTION**			
152-50-96	BLOCKER PEDIMAX II PERCUTANEOUS			



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136				
CODE	**PRODUCT DESCRIPTION**			
152-55-(A)-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅5.5x(A)mm		(A)mm	

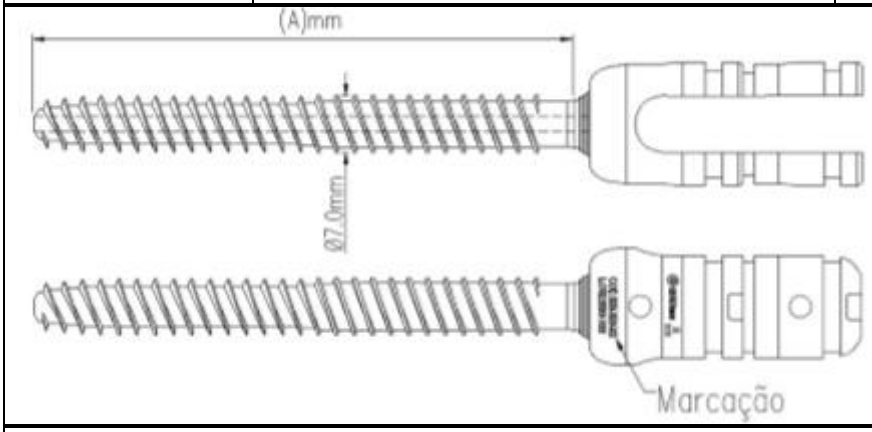
152-55-30-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅5.5x30.0mm		30.0mm	
152-55-35-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅5.5x35.0mm		35.0mm	
152-55-40-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅5.5x40.0mm		40.0mm	
152-55-45-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅5.5x45.0mm		45.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

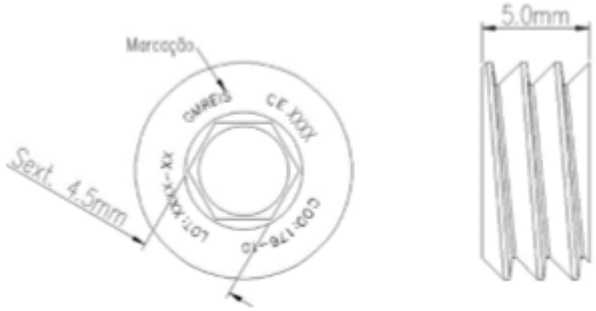
CODE	**PRODUCT DESCRIPTION**			
152-62-(A)-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅6.2x(A)mm		(A)mm	
152-62-35-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅6.2x35.0mm		35.0mm	
152-62-40-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅6.2x40.0mm		40.0mm	
152-62-45-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅6.2x45.0mm		45.0mm	

152-62-50-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅6.2x50.0mm		50.0mm	



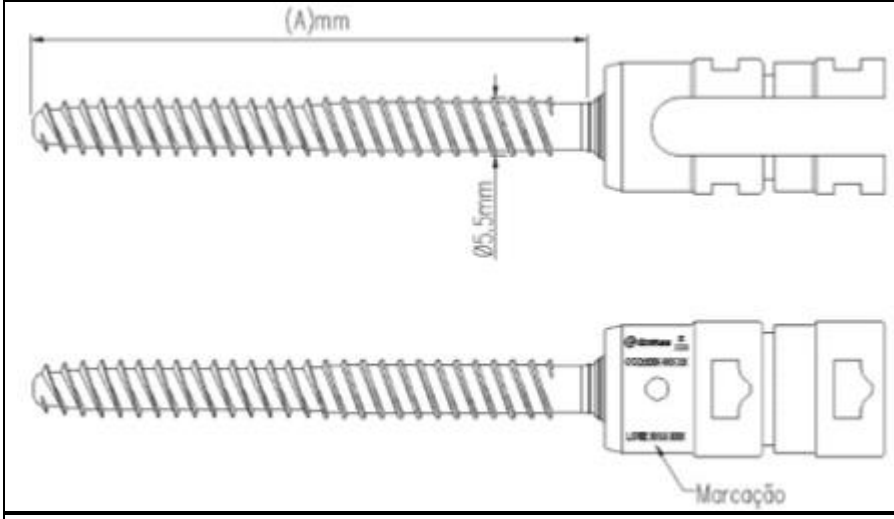
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**			
152-70-(A)-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x(A)mm		(A)mm	
152-70-30-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x30.0mm		30.0mm	
152-70-35-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x35.0mm		35.0mm	
152-70-40-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x40.0mm		40.0mm	
152-70-45-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x45.0mm		45.0mm	
152-70-50-E	POLYAXIAL PEDICLE SCREW PEDIMAX II PERCUTANEOUS FOR SPONDYLOLISTHESIS ∅7.0x50.0mm		50.0mm	



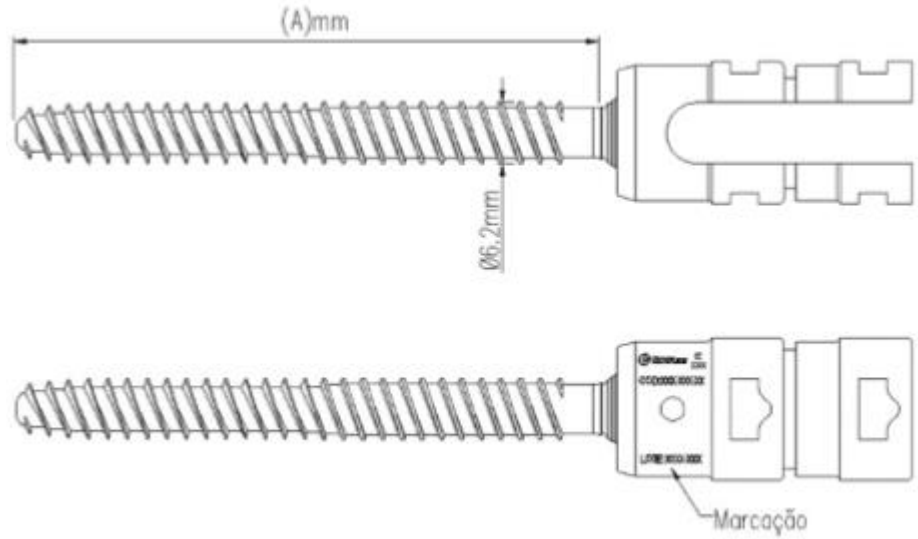
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
176-10	PEDIMAX BLOCKER II			



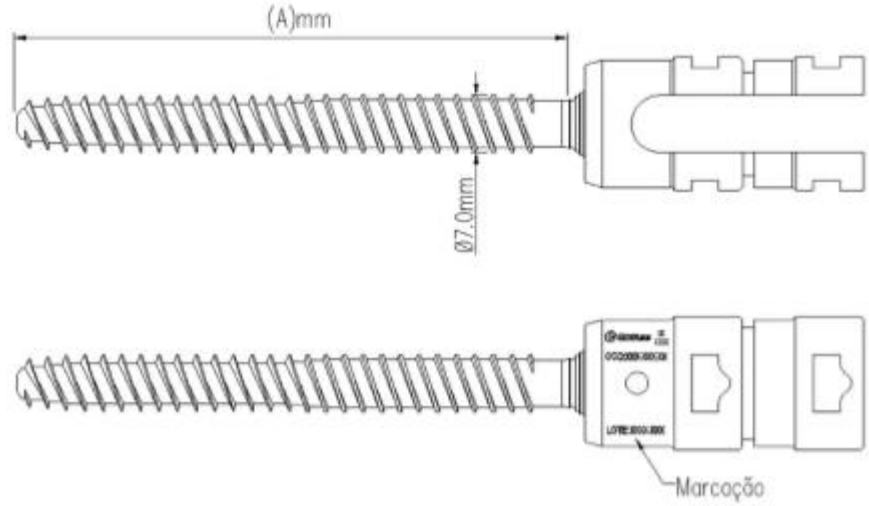
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
175-55-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x(A)mm		(A)mm	
175-55-30	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x30.0mm		30.0mm	
175-55-35	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x35.0mm		35.0mm	
175-55-40	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x40.0mm		40.0mm	
175-55-45	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x45.0mm		45.0mm	
175-55-50	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅5.5x50.0mm		50.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

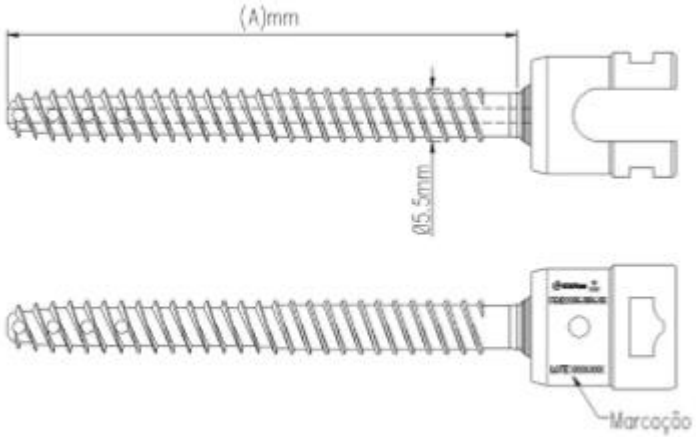
CODE	PRODUCT DESCRIPTION			
175-62-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅6.2x(A)mm		(A)mm	
175-62-35	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅6.2x35.0mm		35.0mm	
175-62-40	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅6.2x40.0mm		40.0mm	
175-62-45	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅6.2x45.0mm		45.0mm	
175-62-50	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅6.2x50.0mm		50.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION	

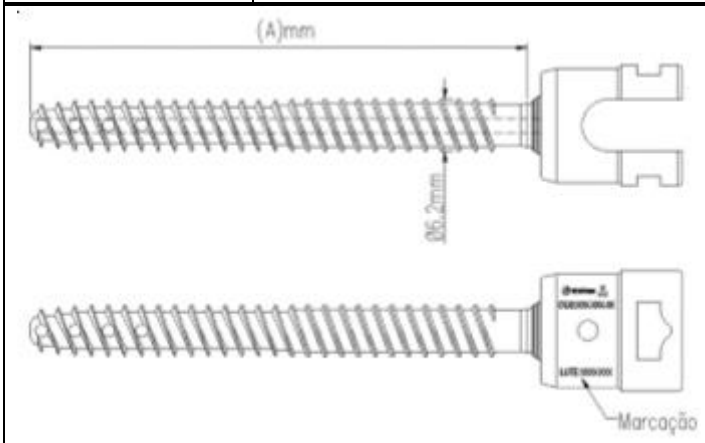
175-70-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x(A)mm SPONDYLOLISTHESIS ∅6.2x(A)mm		(A)mm	
175-70-30	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x30.0mm		30.0mm	
175-70-35	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x35.0mm		35.0mm	
175-70-40	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x40.0mm		40.0mm	
175-70-45	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x45.0mm		45.0mm	
175-70-50	POLYAXIAL PEDICLE SCREW PEDIMAX II FOR SPONDYLOLISTHESIS ∅7.0x50.0mm		50.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

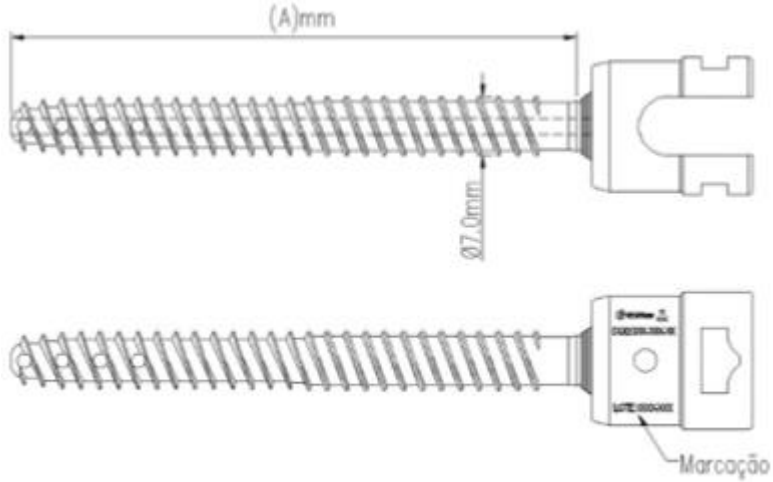
CODE	**PRODUCT DESCRIPTION**			
221-55-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x(A)mm SPONDYLOLISTHESIS ∅7.0x(A)mm SPONDYLOLISTHESIS ∅6.2x(A)mm		(A)mm	
221-55-30	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x30.0mm		30.0mm	
221-55-35	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x35.0mm		35.0mm	
221-55-40	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x40.0mm		40.0mm	
221-55-45	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x45.0mm		45.0mm	

221-55-50	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x50.0mm		50.0mm	
221-55-55	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x55.0mm		55.0mm	
221-55-60	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅5.5x60.0mm		60.0mm	



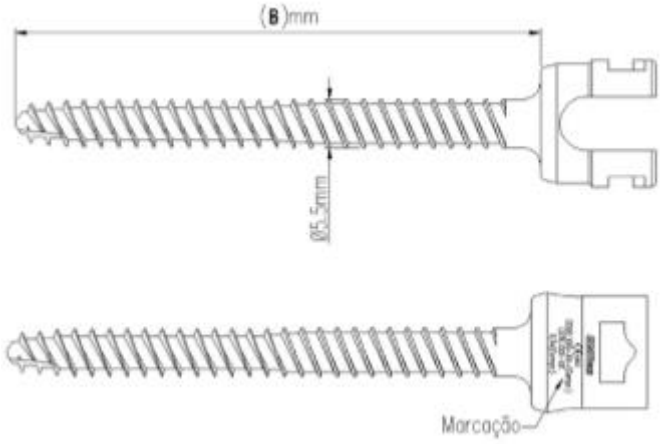
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**			
221-62-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅6.2x(B)mm SPONDYLOLISTHESIS ∅7.0x(A)mm SPONDYLOLISTHESIS ∅6.2x(A)mm		(A)mm	
221-62-35	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅6.2x35.0mm		35.0mm	
221-62-40	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅6.2x40.0mm		40.0mm	
221-62-45	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅6.2x45.0mm		45.0mm	
221-62-50	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅6.2x50.0mm		50.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

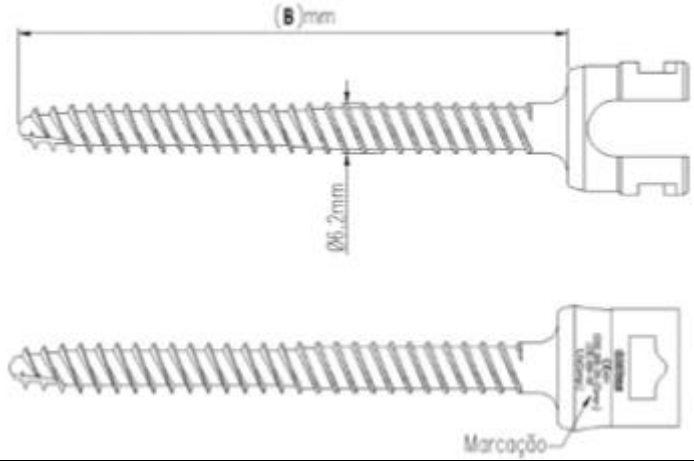
CODE	PRODUCT DESCRIPTION			
221-70-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS POROUS ∅7.0x(B)mm		(A)mm	
221-70-40	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅7.0x40.0mm		40.0mm	
221-70-45	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅7.0x45.0mm		45.0mm	
221-70-50	POLYAXIAL PEDICLE SCREW PEDIMAX II POROUS ∅7.0x50.0mm		50.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

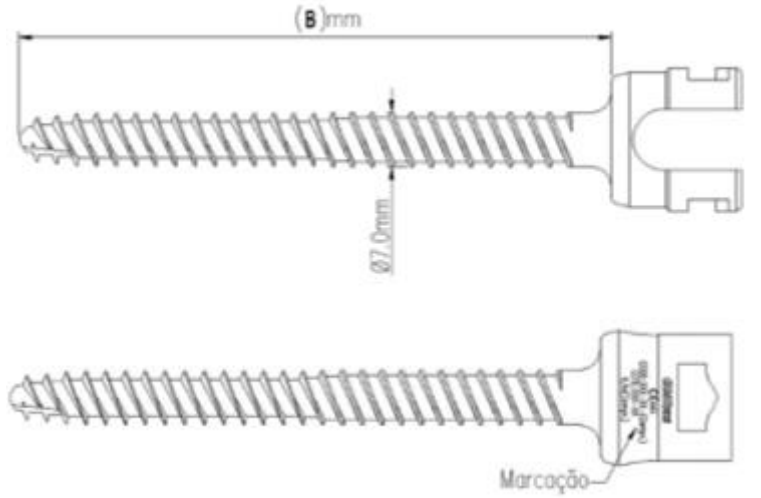
CODE	PRODUCT DESCRIPTION			
176-10-(B)	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x(B)mm		(B)mm	
176-10-30	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x30.0mm		30.0mm	

176-10-35	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x35.0mm		35.0mm	
176-10-40	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x40.0mm		40.0mm	
176-10-45	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x45.0mm		45.0mm	
176-10-50	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x50.0mm		50.0mm	



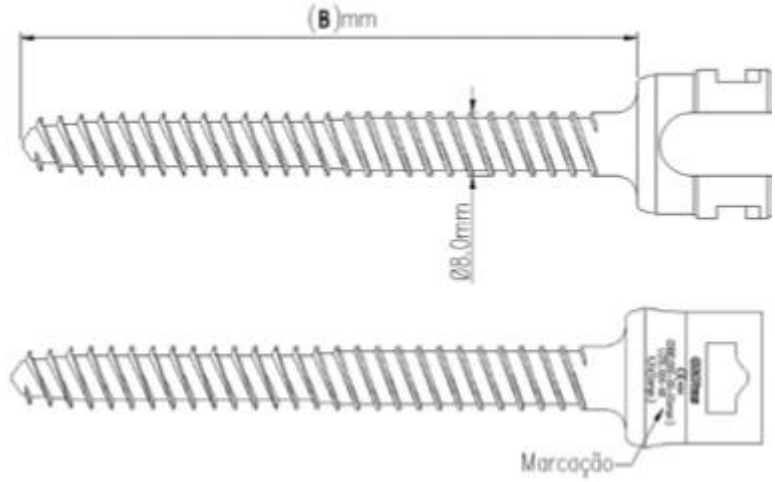
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**			
176-11-(B)	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x(B)mm		(B)mm	
176-11-30	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x30.0mm		30.0mm	
176-11-35	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x35.0mm		35.0mm	
176-11-40	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x40.0mm		40.0mm	
176-11-45	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x45.0mm		45.0mm	
176-11-50	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x50.0mm		50.0mm	
176-11-55	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x55.0mm		55.0mm	
176-11-60	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x60.0mm		60.0mm	



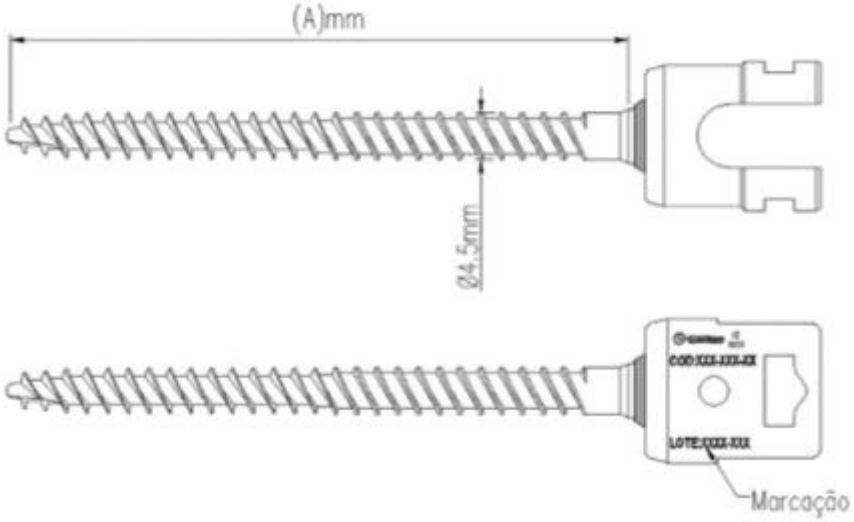
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
176-12-(B)	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x(B)mm		(B)mm	
176-12-30	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x30.0mm		30.0mm	
176-12-35	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x35.0mm		35.0mm	
176-12-40	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x40.0mm		40.0mm	
176-12-45	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x45.0mm		45.0mm	
176-12-50	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x50.0mm		50.0mm	
176-12-55	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x55.0mm		55.0mm	
176-12-60	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x60.0mm		60.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

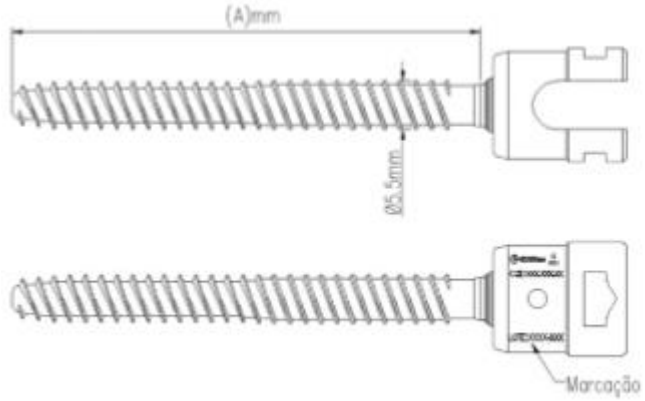
CODE	PRODUCT DESCRIPTION			
176-13-(B)	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅8.0x(B)mm		(B)mm	
176-13-40	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅8.0x40.0mm		40.0mm	
176-13-45	MONOAXIAL PEDICLE SCREW PEDIMAX II ∅8.0x45.0mm		45.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
176-45-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x(A)mm		(B)mm	

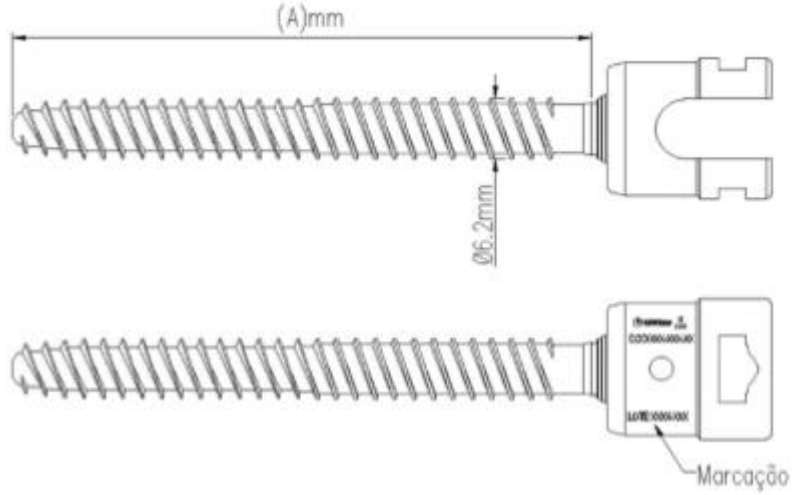
176-45-20	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x20.0mm		20.0mm	
176-45-25	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x25.0mm		25.0mm	
176-45-30	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x30.0mm		30.0mm	
176-45-35	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x35.0mm		35.0mm	
176-45-40	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x40.0mm		40.0mm	
176-45-45	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅4.5x45.0mm		45.0mm	



RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

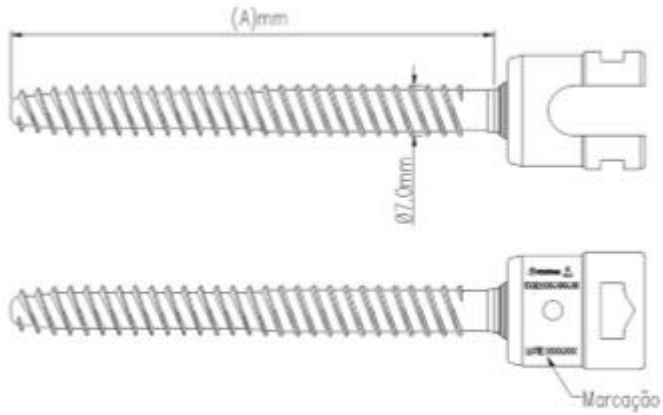
CODE	**PRODUCT DESCRIPTION**			
176-50-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x(A)mm		(A)mm	
176-50-30	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x30.0mm		30.0mm	
176-50-35	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x35.0mm		35.0mm	
176-50-40	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x40.0mm		40.0mm	
176-50-45	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x45.0mm		45.0mm	
176-50-50	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x50.0mm		50.0mm	
176-50-55	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x55.0mm		55.0mm	

176-50-60	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅5.5x60.0mm		60.0mm	



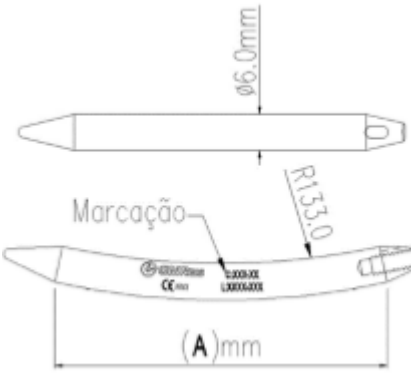
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	**PRODUCT DESCRIPTION**			
176-60-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x(A)mm		(A)mm	
176-60-30	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x30.0mm		30.0mm	
176-60-35	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x35.0mm		35.0mm	
176-60-40	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x40.0mm		40.0mm	
176-60-45	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x45.0mm		45.0mm	
176-60-50	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x50.0mm		50.0mm	
176-60-55	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x55.0mm		55.0mm	
176-60-60	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅6.2x60.0mm		60.0mm	



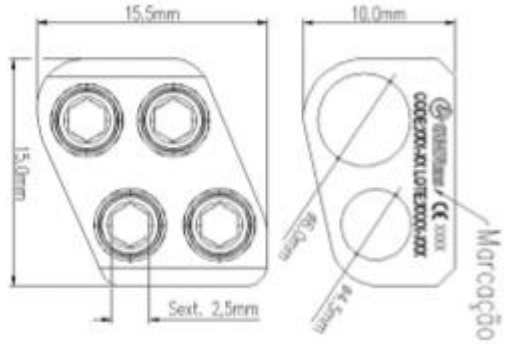
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
176-70-(A)	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x(A)mm		(A)mm	
176-70-30	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x30.0mm		30.0mm	
176-70-35	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x35.0mm		35.0mm	
176-70-40	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x40.0mm		40.0mm	
176-70-45	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x45.0mm		45.0mm	
176-70-50	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x50.0mm		50.0mm	
176-70-55	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x55.0mm		55.0mm	
176-70-60	POLYAXIAL PEDICLE SCREW PEDIMAX II ∅7.0x60.0mm		60.0mm	

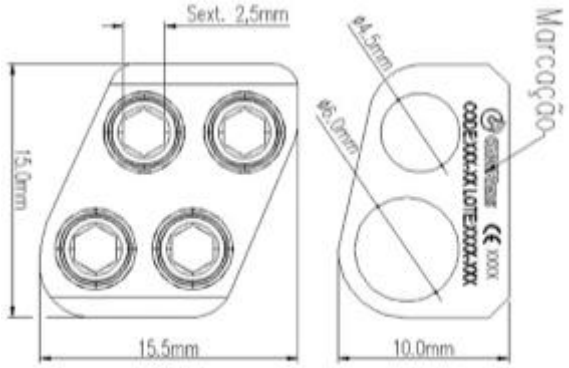


RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION			
	PERCUTANEOUS FENESTRATED ROD Ø		6.0x(A)mm (A)mm	
152-75	PERCUTANEOUS FENESTRATED ROD Ø6.0x50.0mm		50.0mm	
152-76	PERCUTANEOUS FENESTRATED ROD Ø6.0x55.0mm		55.0mm	
152-88	PERCUTANEOUS FENESTRATED ROD Ø6.0x80.0mm		80.0mm	
152-89	PERCUTANEOUS FENESTRATED ROD Ø6.0x90.0mm		90.0mm	

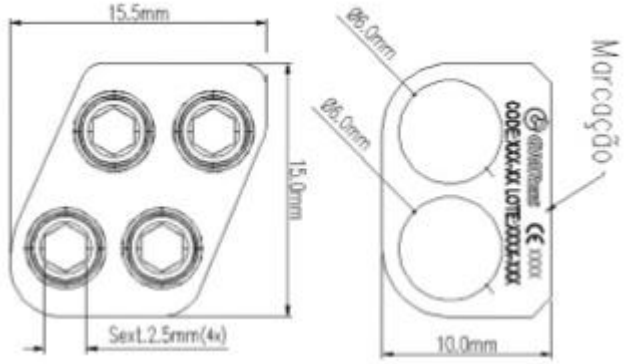


CODE	PRODUCT DESCRIPTION			
136-97	ROD CONNECTOR / ROD Ø6.0 / 4.5mm LEFT			



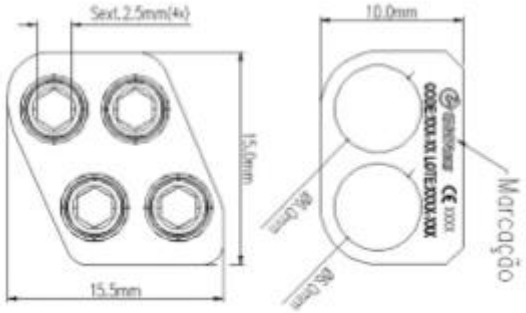
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION		
136-98	ROD CONNECTOR/ROD Ø6.0 / 4.5mm RIGHT		



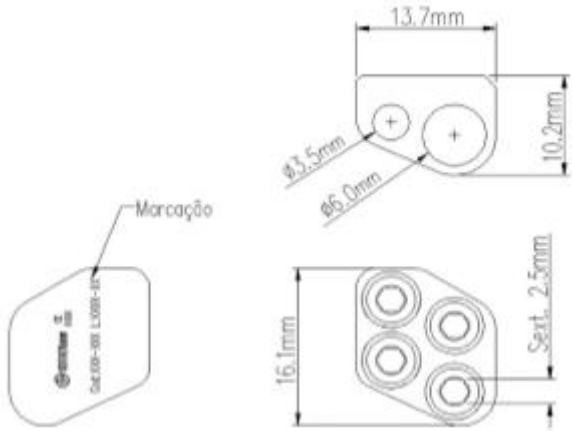
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION		
136-06-06-D	ROD CONNECTOR/ROD Ø6.0 / 6.0mm RIGHT		



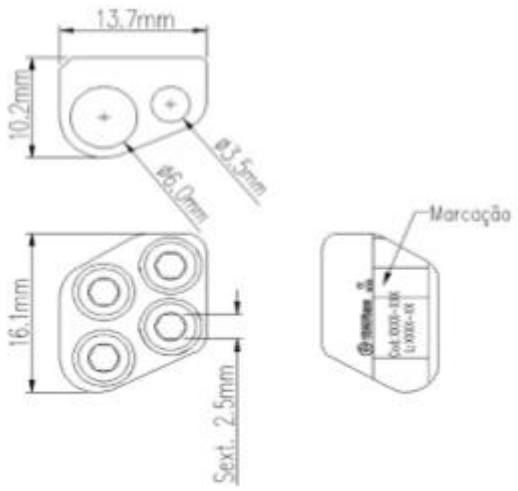
RAW MATERIAL - Titanium 6Al 4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION		
136-06-06-E	ROD CONNECTOR/ROD Ø6.0 / 6.0mm LEFT		



RAW MATERIAL - Ti 6AL4V ELI ASTM F136

CODE	PRODUCT DESCRIPTION		
134-229	ROD CONNECTOR/ROD Ø3,5 / 6,0mm RIGHT		



RAW MATERIAL - Ti 6AL4V ELI ASTM F136			
CODE	**PRODUCT DESCRIPTION**		
134-228	ROD CONNECTOR/ROD Ø3,5 / 6,0mm LEFT		

3.1.1.d. Physical principle and technology fundamentals description, applied to its working and action

Pedimax II – Pedicle Screws System is based by pedicle screws, rods, block elements

The pedicle screws system is composed of pedicle screws, rods, blocking elements and hooks which, when associated form a system, that is, a biomechanics physical structure with the ability to provide a stabilization in the segment of treaty vertebra, thus enabling the arthrodesis of the segment.

3.1.1.e. Ancillary components necessary to the implementation of the product

There are no ancillary components.

3.1.1.f. Technical specification of the Material Manufacturing

- Titanium Alloy Ti6Al4V, in accordance with the standard ASTM F136 “Standard Specification for *Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”*

Format: Bar

Condition: Annealed

- *Pure Titanium Degree 2 and Degree 4,* in accordance with the standard *ASTM F67 “Standard Specification for Unalloyed Titanium, for Surgical Implant Applications”*

Format: Bar

Condição: Annealed

3.1.1.g. Marking

The implantable components are identified by marking laser with the following information:

• Batch of product;

• Product Code;

• Logo of the brand GMReis and,
The location of laser marking of each product is shown in the drawings presented in **table 1.**

3.1.1.h. Product Traceability Procedure
The Identification and traceability of the product are ensured through a set of 05 adhesive tags contained in the package (see illustration below), along with the instruction of use and the implant, such as: name, model, code, allotment, product registration and manufacturer identification. In this way it is possible to make the reverse path and reach a production, raw material, suppliers and other quality controls established in the GMReis Quality System.
Traceability tags shall be fixed to the following locations:
- The tag number 1, obligatorily, in the patient's medical record;
- The tag number 2, in the report delivered to the patient;
- The tag number 3, in the tax documentation that generates the collection to the paying source;
- The tag number 4, available for supplier control (registration distribution history);
- The tag number 5, provided for the control of the doctor.
It is a responsibility of the medical and hospital staff (the custodians of patient information and records), the tag fixation on the surgical description sheet or a section of the medical chart. GMReis recommends that the patient receive this information, receiving a certificate stating one of the traceability adhesive wheels.

3.1.1.1. Presentation form of the medical product
3.1.1.1.1. Individual Presentation Form
The product is supplied non-sterile, properly identified, ie laser-marked with your GMReis code, allotment number and logo.
It is an open system, having as a commercial presentation the stowage in individual packaging of surgical grade paper, where the product is supplied separately with its instruction, the 5 tags of traceability and properly labeled on the back, as shown in the next figure:


Product packaging (front and back)
The supplied models and marking locals are described on chart 1.
<u>The product shall be sterilized according to “Sterilization Method”</u>
3.1.2. Handling, conservation, storage and transport
The hospital is responsible for the steps of handling, conservation and storage of products from receipt, ensuring that the manufacturer's recommendations are respected to and that the product maintains the original characteristics established.
The product must be preserved, handled and transported in order to prevent any damage or modification to its characteristics and packaging.

The medical product must be handled with care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect the product quality and the user safety.
It must be preserved and stored in its original packaging or in specific surgical boxes until the moment of use, with the proper care of the medical and hospital area, in a clean, dry, ventilated environment protected from sunlight and free of contaminants (acid vapors), temperature (≤ 40 ° C) and humidity (≤70% RH).
Exclusively professionals in the hospital area, properly trained, empowered and familiar with the technique and the procedures involved, must do the handling of the product.
Vibrations effects, shocks, defective seating and improper stacking during transportation should be avoided.
Storage outside these conditions may create risk to the procedure, and patient.

3.1.3. Instruction for correct use of the product and indication of training

3.1.3.1. Instruction for the correct use

1- Perform the pre-operative clinical planning;
2- Perform the pre-operative radiological planning and select the sizes of the implantable components to be used;
3- Perform the access and perforate the pedicle in the anatomical angulation;
4- Insert the pedicle screws into the perforated pedicle with the radiological control and when necessary insert the hook into the most appropriate anatomical positions;
5- Insert the longitudinal element (rods) on the pedicle screws, hooks or through connectors;
6- Fix the locking elements on the pedicle Screws and/or hooks; If necessary perform the distraction or compression before the final tightening.
7- Perform final radiological control and,
8- Close access.

3.1.3.2. Indication of training

Only properly trained, empowered in procedures of column may use the product.

Note 1: The surgeon should be aware of all recommendations described in the product "Use instructions" and other information on the label.

3.1.4. Precautions, restrictions, warnings, special cares, explanation about the use of the product, storage, handling and transportation,

3.1.4.a. General information

• Single-use product, do not reuse, even if it is in perfect condition;
• Non-sterile supplied product;
• Sterilize before use, according to recommended sterilization method;
• Prohibited reprocessing.
• Conditional for MR: Pedimax II is safe for the patient undergoing Magnetic Resonance (MR), if the following specific conditions are present;
• Static magnetic fields of 1,5 - 3,0 Tesla, only;
• Maximum space magnetic field gradient of 4,000 Gauss/cm (40 T/m);
• Weighted specific absorption rate of all body, as indicated by the MR scanner of 2,0 W/kg for 15 min of scanning (e.g. by pulse) in normal operating mode.

3.1.4.b. Load Restrictions

The use of implants for the internal fixation allows the spine surgeon the establishment of the vertebral segments in the closest position of natural anatomy. The implants allow early mobility

of patients, but limited to movements without load until the surgeon confirm the bone consolidation through X-rays, which usually occurs in 12 months after surgery. These implants are designed as an assistant to the natural process of bone consolidation, but cannot be used to replace anatomical structures or supporting the body weight in the presence of bone comprehensive.
During recovery, the spine surgeon along with the physiotherapist controls the applied load, increasing this load according to the process of consolidation and the general condition of the patient.
It is very important to perform a careful reduction and a stable fixation for the complete bone healing. The implants used in surgery serve to promote a normal process of bone regeneration. They are not intended to replace the original anatomical structures and nor to sustain permanently mechanical stresses caused by regions that showed no bone consolidation.
The surgeon should instruct the patient about care and physical support appropriate to be used during the period of the implant use.
In the face of a spinal segment with the osseous consolidation completes, the load can be released. If the segment of the column is not with the bone completely, no charge can be given to the implanted system. The load release is the surgeon responsibility, and depends on the bone consolidation.

3.1.4.c. Criteria for size selection, shape and design associated with the bone consolidation success

It is the responsibility of the surgeon in charge of the procedure, the size selection of the implantable component most appropriate for the use, which must be done based on radiological studies pre-operative and the indication of the correct use. The right selection of the implant is extremely important and should take into account the biomechanical aspects, the size and shape of the bone structure to be treated, which corresponds to the size and the model of the implant selected.

Size of the Screws	Regions of Indication
Ø4,5mm	Thoracic Vertebrae
Ø5,5mm	Thoracic Vertebrae and lumbar, and sacrum
Ø6,2mm	Thoracic Vertebrae and lumbar, and sacrum
Ø7,0mm	Thoracic Vertebrae and lumbar, and sacrum
Ø8,0mm	Thoracic Vertebrae and lumbar, and sacrum

3.1.4.D. Mechanical conformation limit for aptness for use of the product

The products are designed to properly fit into the bone to be treated.
It is only permitted the modeling of implants of the type rods, with the objective of bringing anatomy. If the modeling is required, the surgeon must avoid excessive mechanical, the limit for modeling is the bone anatomy in which it will be used. The rod should not be folded to the contrary, scratched and warped, and once modeled cannot be returned to its original form, which may cause a fracture on the rod and consequent failure in the system function.

3.1.4.e. Patient instructions

The patient should be warned about the limits of its initial activities and about their rehabilitation to protect the surgery performed by the surgeon in charge.
Excessive activities and/or trauma may affect the positioning of the implant, which may result in migration, loosening, wear and/or early rupture of the implant, as well as affecting the support bone structure, making the review procedure more difficult and premature.
The patient should be warned about the risks of surgery, secondary effects or undesirable side effects and that the reconstruction carried out with the implant will not present the same physical characteristics of the vertebral column, and that there might be fatigue, breaks or migration of the implant, resulting from abnormal physical activities, trauma or degenerative diseases and other diseases, or metabolic disorders, failure in indication, in surgical technique or lack of cooperation of the patient regarding postoperative recommendations.
It is important to the patient be aware that the implant has a life time of 12 months, until bone consolidation and that should be replaced as soon as the surgeon deems necessary. The patient should be warned that the product could fail (i.e.: break, release and/or migrate), if the bone consolidation does not occur in up to 12 months or in cases of falls and/or accidents of the patient.
Smokers, diabetics, with metabolic disorders and/or making use of anabolic steroids, as well as making use of medication that could impair the consolidation and/or who have other diseases that may lead to a consolidation delay, should take science that the bone consolidation may not occur within the schedule time and that the implants may be loose or broken. If the patient has an accident, he must be advised that the implant can rupture, releasing and/or migrate.
The surgeon in charge is responsible to make the postoperative recommendations, accompaniments, clinical evolution and radiological of the patient.
The professional responsible for the surgical procedure should warn the patient that components implanted were designed to provide stability to the vertebral segment treaty and support loads until the arthrodesis at treaty, this period should not exceed 12 months in a healthy individual; experiencing the arthrodesis, the product loses its function, and the bone structures begins to absorb the normal workloads of the patients column. If the arthrodesis does not occur, by some health problem of the patient, the product will be exposed to constant fatigue loads, which could lead it to fail due to lack of bone consolidation, with the need for replacing the same. If the focus is not consolidate in 12 months, is the surgeon responsible for corrective action to be taken.
It is important to the patient being aware that the failure of the postoperative recommendations may lead to unsuccessful treatment and that the implant can suffer migration, release and/or breaks.
The patient should be informed that, despite of the raw material used for the implant manufacturer is biocompatible, side effects may occur or adverse reactions in more sensitive patients, such as:
Sensibility to the material;
Allergic reactions;
Bone deformity in the place of the implementation;
Incomplete bone consolidation;
Conditional to MR (See item 3.12 – “Use instructions”.)

3.1.4.f. Warning regarding the product condition which restrict the use

The product should not present any visual abnormality in its surface, as risks, failures, dirt or other.

The implantable components that exhibit abnormalities in their surface should be destroyed and disposed of according to the procedure of "Destruction and disposal".

3.1.4.g. Caution associated in case of fall of some component

In case of fall of any component or suffer any kind of damage, it should be destroyed and disposed of according to the Procedure of disposal.

3.1.4.h. Factors that may cause the implant to a possible breach, loosening, displacement or heating which should be informed to the patient

The following are the main factors that, alone or in combination, can lead the implantation of a premature failure (breakage, loosening or migration).

Disregard with the postoperative recommendations;

Metabolic disorders;

Diabetes

Smoking

Patients accident (e.g. falls, accidents, …);

Pseudo arthrosis;

Delay in bone consolidation;

Failure in surgical technique;

Inappropriate choice of implant;

Early releasing of the load;

The no use of external prostheses, when recommended;

Excessive load or inappropriate activity;

Drugs ingestions that can lead to a delay of the bone consolidation and pseudo arthrosis;

Osteoporosis;

Practice of intense physical activity;

Practice of physical activity prior to the surgeon release;

Exposure to an environment of magnetic resonance, e.g.: examination of MR (see precations 3.12 “Instructions of use”).

3.1.4.i. Procedure for disposal to ensure the destruction of the product

The implants which for some reason were not used during the surgery and had the package open, or suffered damage and/or falls may not be re-used and/or re-sterilized and should be discarded in the hospital as the medical procedure hospital and/or local law or as instructed by the Commission of Hospital Infection Control - CHIC.

The methods and procedures for product disposing should ensure the complete mischaracterization of same, preventing any possibility of reuse. The adulteration of the product is the sole responsibility of the hospital institution, as well as the methods and procedures for disposing used.

It is recommended that they be deformed with molders or twisters until be clearly identified that the product is inappropriate for your use, ensuring that the product may not be used or improperly reused.

3.1.4.j. Removing and handling of implants removed from patients for Analysis

The implant must not be removed, except in the case of surgical revision.

If the implant should be removed and need to be subjected to analysis, it must be in accordance with NBR ISO 12891-1 "Removal and analysis of surgical implantation - Part 1 - Removal and Handling", following the instructions below:
It is recommended that the implants, and in applicable cases, samples of tissue, are removed in a way that causes minimal damage in both tissue and implant.
It is especially important that functional surfaces, such as surfaces of joints of prostheses and surfaces of fractured implants are protected.
It is also of extreme importance to list the parties of the fractured implant and other removed components, leaving clear positioning in the deployment place.
The most important part of the implant removal is the prevention of damage that may lead to a scientific examination useless. For an appropriate scientific examination, the implant must be preserved as close as possible of the state, which existed at the time of the patient removal. Consequently, it is important that there be taken care during handling, storage and transport of the implants removed in order to ensure that no damage occurs or changes on the surfaces that will be analyzed.
The same care should be taken with the instruments, which eventually fail during its use.
The implants removed must go through process of cleaning and disinfection, under the responsibility of the health service. Subsequently, must be packaged separately in plastic bags or plastic containers/glass and labelled. The packaging should be designed to minimize the possibility of breakage, damage to surface and possible contamination of the implant by the environment. The labelling of products, which will be forwarded for analysis, should ensure their accurate identification, being that the NBR ISO 12891-1 recommends the use of labels non-removable (that tear in the case of attempted removal).
It is extremely important, for an accurate evaluation failure cause of the product that the X-rays pre, post-operative and the verification of the implant failure are sent together with the material sent for analysis.

3.2. Indications, purpose or intended use of the product

The Pedimax II - System of pedicle screws is a universal pediculate system designed to treat a variety of diseases of the thoracic spine and lumbar-sacral. The specific indications of the product are:

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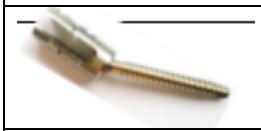
3.2.1.1. Specific indications

THORACIC FIXATION, LUMBAR-SACRAL INFORMATION CHART BY PRODUCT
THORACIC FIXATION, LUMBAR-SACRAL DUCT – REGIONS OF INDICATION BY COMPONENT

	Pedicle screws Monoaxiais Poliaxial and Pedimax II	Discs degenerative diseases (DDD), trauma (i.e. fractures and dislocations), deformities (i.e. hyperlordosis and Hyperkyphosis), tumors, root stenosis or spinal canal, and failure of previous fusion (pseudoarthrosis), by open way.
	Pedicle screws Pedimax Poliaxial II for Spondylolisthesis	Spondylolisthesis, open channel.
	Pedicle Screws Pedimax Poliaxial percutaneous II	Discs degenerative diseases (DDD), trauma (i.e. fractures and dislocations), deformities (i.e. hyperlordosis and Hyperkyphosis), tumors, root stenosis or spinal canal, and failure of previous fusion (pseudoarthrosis), open channel, by percutaneous way
	Pedicle Screws Pedimax Poliaxial percutaneous II for spondylolisthesis	Spondylolisthesis, by percutaneous way
	Pedicle screws Pedimax Poliaxial II Porous	Discs degenerative diseases (DDD), trauma (i.e. fractures and dislocations), deformities (i.e. hyperlordosis and Hyperkyphosis), tumors, root stenosis or spinal canal, and failure of previous fusion (pseudoarthrosis), in patients with osteoporosis, by open way.
	Rod	Joint use with pedicle screws (all) for the fixing of the thoracic spine, lumbar and sacral.
	Transversal rod	Joint use with the hooks crosslink pedimax to unite

		the rods longitudinal, increasing the stiffness of the mounting and biomechanical stability.
	Percutaneous Fenestrated Rod	Joint use with the screws percutaneous fenestrated rod percutaneous pedicles for fixing of the column lumbar-sacral.
	Crosslink Hook Pedimax	Use in pair, and in conjunction with the transversal rod to attach the rods longitudinal, increasing the stiffness of the mounting and biomechanical stability.
	Pedimax blocker II	Blockade of the longitudinal rods in the pedicle screws: Poliaxial and Monoaxiais Pedimax II Pedimax Poliaxial II for spondylolisthesis Poliaxial and Pedimax II Porous.
	Pedimax Blocker Percutaneous II	Blockade of the longitudinal rods in the pedicle screws: Polyaxial Pedimax II Percutaneous and Percutaneous for Spondylolisthesis.
	Rod/Rod connector	Union of the longitudinal rods of the system Pedimax II with the longitudinal rods of other diameters or even, in the case of an extension of the treatment area.

Size of the Screws	**Regions of Indication**
Ø4,5mm	Thoracic vertebrae
Ø5,5mm	Thoracic and lumbar vertebrae and sacrum

Ø6,2mm	Thoracic and lumbar vertebrae and sacrum
Ø7,0mm	Thoracic and lumbar vertebrae and sacrum
Ø8,0mm	Sacrum

3.2.2. Side effects or undesirable side effects and contraindications

3.2.2.a. Side effects or undesirable side effects

Consolidation delay or pseudo arthrosis, may lead to loosening or fracture of the implant when no consolidation occur after 12 months of surgery;
Rupture or loosening of the implants for not following the guidelines of postoperative rehabilitation and/or excessive load during the physiotherapy and/or incorrect positioning of the implant;
Decrease in bone density;
Pain, discomfort and abnormal sensations due to the presence of the implant;
Nerve Injury due to surgical trauma;
Bone necrosis;
Vascular changes and other factors inherent to the surgical procedure;

Note 1: A second surgery may be needed to repair the secondary effects;
Note 2: Smokers with metabolic disorders have greater difficulties in achieving the osseous consolidation, consequently there is a greater chance to occur deformation, rupture or loosening of the implants and does not reach the bone and suffer more progressive degeneracy.

3.2.2.a.1. Side effects or undesirable side effects related to conditional for MR

Torsion forces can cause the device to spin on the MR field.
Displacement forces can extract the device from the MR field.
The radio frequency (RF) induces currents that can cause heating of the product implanted in the patient.

3.2.2.B. Contraindications

The patients, who present some clinical condition described below, should not be subject to the procedure with the use of the product. The contraindications include those listed below, but are not limited to:
Active infection or history of recent infection of bone tissue or of soft parts locations;
Osteometabolic diseases that cause weakness or reduction of bone mass;
Insufficient bone mass or of poor quality;
Inadequate vascularization in the implant placement local that could compromise the adequate blood supply in the place of deployment;
Patients with previously implants that may compromise the deployment and/or interfere with the product;
Mental diseases;
Drugs abuse and alcoholism;
Fever;
Allergy and/or sensitivity to metals (pure titanium and titanium aluminum alloy-Vanadium)

Patients without conditions to follow the medical advice and the health team at any time of their treatment.
The MR exam is contraindicated for patients with a system of implant "**Conditional for RM**", if one of the specific conditions presented in the labelling, as well as in item "precautions to take regarding exposure to magnetic fields," is not fulfilled.

3.3. Detailed information on the characteristics of all parts, accessories and materials destined to be used with the product

3.3.1. Admissible combinations with other materials

The materials used to manufacture the products are:
- Pure titanium grade 2 and grade 4 CPTi - according to ASTM F67 "*Standard Specification for Unalloyed Titanium for Surgical Implant Applications*";
- Alloy of Titanium Ti6Al4V according to ASTM F136 "*Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*".

The materials in question are highly resistant to corrosion of the solution. Despite this, the product **cannot** be used in conjunction with any product from another manufacturer, or any metallic product with different chemical composition, because this association may generate chemical incompatibilities (producing galvanic corrosion and others), physical, biological and functional, early fatigue and possible risks to the patient.
In the event of any undue combination by the surgeon, he will be responsible for the risks associated with such combination.
The product should only be deployed with the specific instruments, by GMReis brand, presented in table 3.

Table 3: Instrumentals of Pedimax II – Pedicle Screws System (NOT OBJECT OF THIS RECORD)

Code	Description
112-111	Cross Link Clamp
112-148	Spondylo Screw Breaker
112-150	Template 150mm
112-37	Compression Clamp 6.0mm
112-40	Pedicle Neutralizer for Screw Nut
112-42	Rod Pusher
112-77	Clamp of Huge Distraction
112-78	3 Points Modeler
112-84	Rod Clamp of 6.0mm
116-17	Cross Link Wrench
135-05	Guidewire 2.5x280mm
144-08	Interchangeable Cable
150-08A	Spanner Wrench T

151-01	BPS-A Cable
151-06	Vertebral Probe
151-08	Guidewire coat BPS
151-13	Nut Driver Endopedimax
151-23	Double Impactor BPS
152-24	Endopedimax Guide 3 Levels
152-01	Lumbar Macho Endopedimax 6.7mm
152-04	Trocar Point Endopedimax
152-101	Polyaxial Wrench Endopedimax
152-103	Small Cable
152-104	Depth Gage Endopedimax
152-105	Middle Open Cannula Endopedimax
152-106	Middle Closed Cannula Endopedimax
152-107	Milling Cutter of Ø13mm Endopedimax
152-108	Rod Integrator Wrench Endopedimax
152-109	Extra Large Chamber 19mm
152-14	Polyaxial Wrench Endopedimax
152-15	Cable T Endopedimax
152-16	Guidewire Endopedimax
152-22	Blocker Holder Endopedimax
152-57	Integrator Wrench
152-58	Big Exchange Tip
152-59	Pedicle Neutralizer Endopedimax
152-63	Mandrel of Fast Coupling with Sraight Cable
152-91	Extra Large Chamber
152-92	Large Chamber
152-93	Middle Chamber
152-94	Small Chamber
152-95	Extra small Chamber
152-99	Spondylo Screw Breaker
169-455	Hexagonal Wrench of 4.5mm with Large Torquemeter
176-01	Reducer
176-02	Straight Probe
176-03	Exchange Tip
176-04	Lever
176-05	Neutralizer
176-06	Monoaxial Screw Wrench
176-07	Polyaxial Screw Wrench
176-08	Blocker Final Wrench
176-09	Blocker Holder
176-11	Pedicle Orientation Pin with Spherical Head

176-12	Pedicle Orientation Pin
176-17	Mandrel of Fast Coupling with Straight Cable
176-18	Template 210mm

3.3.3. Accessories

None.

3.5. Useful information to prevent risks arising out of the implementation

3.5.1. Implementation risk

In spite of the raw materials used for the manufacture of products are biocompatible and normalized according to the rules Pure Titanium - Degrees 2 and 4 – CPTI – in accordance with the standard ASTM F67 “Standard Specification for Unalloyed Titanium for Surgical Implant Applications” and Titanium Alloy Ti6Al4V in accordance with the standard ASTM F136 “Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications”, the patient may experience sensitivity to the product or allergic reaction. It is known that, even if a raw material presents the chemical requirements, mechanical and microstructural determined by rules (which ensures its purity and biomechanical performance, making it suitable for use as material for the manufacture of implants), there is no material that shows completely free of adverse reactions in the human body.

To prevent others risks of deployment, other care could be taken, such as:

- Total Aseptic Condition;
- Radiologic Pre-Assessment, intraoperative;
- Follow the instructions for use;
- Proper selection of the type and size of the implant based on pre-operative radiological planning.

Others risks of deployment:

- Failure in the surgical indication,
- Failure in the surgical technique, and/or
- Lack of patient cooperation regarding postoperative recommendations

3.5.2. Assessment of the product deployed

After the deployment, in the intra-operative the responsible professional should perform radiological control to verify the correct positioning of the product. The professional responsible must make, and it is his/her responsibility, the clinical and radiological assessments after the surgical procedure, in the frequency stipulated by him, to check the condition of the implant and the bone healing. If the product find itself outside the correct placement, or present any non-compliance, it is the responsibility of the surgeon take the more appropriate corrective action.

3.7. The necessary instructions in the damage event of the protective packaging of the sterility of a medical product sterile, and, where applicable, the indication of the appropriate methods and resterilization.

3.7.1. Restrictions and instructions on the damage of the packaging

In the circumstances described below, the product must be unusable and discarded, as the procedure of destruction and disposal:
- The sealing area of the package is violated.
- Any one of the packages present physical damage;
- The label or identification code is unreadable and
- Date of validity is expired.

3.7.2. Procedure of the packaging opening

Procedure of the surgical paper grade opening

1. Use hands and gloves drought;
2. Hold the product firmly;
3. Hold the surgical paper grade with your other hand;
4. To open the packaging pull the surgical paper grade with strength;
5. Hold the inner package firmly, and
6. With the other hand pull the product.

3.7.3. Restrictions on reuse

It is not allowed in any reuse of the product, even if this present to be in perfect condition. The reuse does not guarantee the performance given by GMReis to the product, being free of any responsibility about this act.

3.8. Method of Sterilization

The products are non-sterile supplied, with the hospital responsible for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical norms and current regulations of the ANVISA and Ministry of Health. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service.
GMReis recommends that products must be sterilized by the following method:
Type: humid heat
Cycle: gravitational
Temperature: 121oC (250oF)
Exposure Time: 60 minutes

Additional information regarding sterilization are described in ABNT NBR ISO *17665-1- "Esterilização de Produtos para a Saúde – Vapor. Parte 1: Requisitos para o desenvolvimento, validação e controle de rotina nos processos de esterilização de produtos para a saúde".*

3.9. Additional information about the procedure before using the product

Upon opening the package, check the superficial condition of the product as the deformations, stains, scratches or any other type of superficial alteration or defect, then forward the product for sterilization, by following the recommendations as indicated in the topic "Method of Sterilization".

The product packaging must be disposed in accordance with the medical-hospital procedure and/or local law or as instructed by the Hospital Infect Control Commission (Comissão de Controle de Infecção Hospitalar - CCIH.)

3.12. Precautions to take regarding the exposure to magnetic fields

The non-clinical testing in the magnetic resonance environment performed accomplished to evaluate the behavior of the product components Pedimax II – Pedicle Screws System, under these conditions, demonstrated that the product is Conditional for Magnetic Resonance, providing safe performance in the magnetic resonance exams of the whole body, on the following conditions:

- Static Magnetic Fields of 1,5-3,0 Tesla, only;
- Maximum gradient of the spatial magnetic field of 4.000 Gauss/cm (40 T/m);
- Specific pondered absorption rate of the entire body, indicated by the MRI scanner, of 2.0 W/kg for 15 min of scanning (i.e. per pulse sequence), in normal operating mode.

In the conditions described, the product Pedimax II – Pedicle Screws System presents a maximum increase of temperature of 5,5oC after 15 minutes of continuous scanning.
The artifact generated by the product has approximately 15mm from the product, when use a pulse echo gradient sequence in a resonance system of 3.0 Tesla. It should be emphasized that the quality of MRI image can be compromised if the area of interest is the same area or relatively close to the positioning of the implant.

Other Precautions:

The product is safe to be used in a magnetic resonance environment when used within the established specifications.
It is recommended that always verify the procedures information for the magnetic resonance before performing an examination of this type.

The test performed on the product is based on non-clinical testing. The increase in the actual temperature on the patient will depend on factors beyond the SAR (specific absorption rate) and the duration of the administration of radio frequency (RF), which induces currents that can cause heating of the product implanted in the patient.
Therefore, it is recommended to pay attention in particular on the following points:
- Monitor the patients carefully
- Patients with impaired thermoregulation or perception of temperature should not be submitted to magnetic resonance imaging;
- The specific absorption rate (SAR) that will be used should be reduced as much as possible.
- Use a ventilation system helps to reduce the increase in the body temperature.

3.13. Specific guidance to the physician regarding the reporting of adverse events
If the product presents adverse events not reported in the instruction of use or there are technical complaints about the product, the physician should immediately contact the manufacturer through the GM Reis Customer Service (SAC), in addition to notifying the competent sanitary authority, ANVISA, via e-mail: tecnovigilancia@anvisa.gov.br. More information can be found in the National System of Notifications to the Sanitary Surveillance – NOTIVISA (Sistema Nacional de Notificações para a Vigilância Sanitária) (web: http://www.anvisa.gov.br/hotsite/notivisa/apresenta.htm). To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 labels of traceability, provided within the packaging, along with the instruction of use, as described in the topic "Product Traceability Procedure".

3.14. Customer Complaint
If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, notify directly the GM Reis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address:
Avenida Pierre Simon de Laplace, 600 - ***Lote:3-Quadra: F Quarteirão: 9677- TechnoPark – Zup Code:13069-320 Campinas – São Paulo – Brazil or directly notify at Telephone Number:(0xx19)3765-9900/ Fax.:(0xx19)3283- 9065 / E-mail: sac@gmreis.com.br***

Symbolism of labelling
The graphic symbols used in labelling are in accordance with the NBR ISO 15223 Standard and ASTM F2503-13, as follows:

Symbols	Descriptions	Symbols	Descriptions
	Manufacturing Date		Product For Single Use "Do not reuse"

	Expiration Date		Additional information "See instructions for use"
	Keep dry		Keep away from light
	MR Conditional		

User Warning

These Instructions for Use are available in format that is not printed, through the electronic address of the manufacturer: http://www.gmreis.com.br/produtos/IFU, and can be checked in the search field by trade name and registration number at Anvisa, described on the label of the product packaging.

The Instructions of use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br.

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