

Device Schedule:

Device name: Amplatzer™ Duct Occluder II and Amplatzer Piccolo™ Occluder

Intended Purpose as per the Instructions for Use:

The Amplatzer™ Duct Occluder II is a device intended for the occlusion of a patent ductus arteriosus.

The Amplatzer Piccolo™ Occluder is a device intended for the occlusion of a patent ductus arteriosus.

Type (Codes as per (EU) 2017/2185): MDN 1101

Risk Classification: Class III, Implantable

Basic UDI-DI: 5415067AMP1400EC

Device Name	Model	Retention Disc Diameter mm (in)	Waist Diameter mm (in)	Occluder Length mm (in)
Amplatzer™ Duct Occluder II	9-PDA2-03-04	9 (0.35)	3 (0.12)	4 (0.17)
	9-PDA2-03-06	9 (0.35)	3 (0.12)	6 (0.25)
	9-PDA2-04-04	10 (0.39)	4 (0.16)	4 (0.17)
	9-PDA2-04-06	10 (0.39)	4 (0.16)	6 (0.25)
	9-PDA2-05-04	11 (0.43)	5 (0.20)	4 (0.17)
	9-PDA2-05-06	11 (0.43)	5 (0.20)	6 (0.25)
	9-PDA2-06-04	12 (0.47)	6 (0.24)	4 (0.17)
	9-PDA2-06-06	12 (0.47)	6 (0.24)	6 (0.25)

Device Name	Model	Retention Disc Diameter mm (in)	Waist Diameter mm (in)	Occluder Length mm (in)
Amplatzer Piccolo™ Occluder	9-PDAP-03-02-L	4.00 (0.157)	3.00 (0.118)	2.00 (0.079)
	9-PDAP-03-04-L	4.00 (0.157)	3.00 (0.118)	4.00 (0.157)
	9-PDAP-03-06-L	4.00 (0.157)	3.00 (0.118)	6.00 (0.236)
	9-PDAP-04-02-L	5.25 (0.207)	4.00 (0.157)	2.00 (0.079)
	9-PDAP-04-04-L	5.25 (0.207)	4.00 (0.157)	4.00 (0.157)
	9-PDAP-04-06-L	5.25 (0.207)	4.00 (0.157)	6.00 (0.236)
	9-PDAP-05-02-L	6.50 (0.256)	5.00 (0.197)	2.00 (0.079)
	9-PDAP-05-04-L	6.50 (0.256)	5.00 (0.197)	4.00 (0.157)
	9-PDAP-05-06-L	6.50 (0.256)	5.00 (0.197)	6.00 (0.236)