

Device Name: Resolute Integrity Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:

The Resolute Integrity stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanent implant.

Risk Classification: Class III, implantable

Basic UDI-DI: 0763000B00005167N

Model	Type (Codes as per (EU) 2017/2185)	Stent Diameter (mm)	Stent Length (mm)
RSINT22508X	MDN 1101	2.25	08
RSINT22512X	MDN 1101	2.25	12
RSINT22514X	MDN 1101	2.25	14
RSINT22518X	MDN 1101	2.25	18
RSINT22522X	MDN 1101	2.25	22
RSINT22526X	MDN 1101	2.25	26
RSINT22530X	MDN 1101	2.25	30
RSINT25008X	MDN 1101	2.50	08
RSINT25012X	MDN 1101	2.50	12
RSINT25014X	MDN 1101	2.50	14
RSINT25018X	MDN 1101	2.50	18
RSINT25022X	MDN 1101	2.50	22
RSINT25026X	MDN 1101	2.50	26
RSINT25030X	MDN 1101	2.50	30
RSINT27508X	MDN 1101	2.75	08
RSINT27512X	MDN 1101	2.75	12
RSINT27514X	MDN 1101	2.75	14
RSINT27518X	MDN 1101	2.75	18

Model	Type (Codes as per (EU) 2017/2185)	Stent Diameter (mm)	Stent Length (mm)
RSINT27522X	MDN 1101	2.75	22
RSINT27526X	MDN 1101	2.75	26
RSINT27530X	MDN 1101	2.75	30
RSINT30009X	MDN 1101	3.00	09
RSINT30012X	MDN 1101	3.00	12
RSINT30015X	MDN 1101	3.00	15
RSINT30018X	MDN 1101	3.00	18
RSINT30022X	MDN 1101	3.00	22
RSINT30026X	MDN 1101	3.00	26
RSINT30030X	MDN 1101	3.00	30
RSINT30034X	MDN 1101	3.00	34
RSINT30038X	MDN 1101	3.00	38
RSINT35009X	MDN 1101	3.50	09
RSINT35012X	MDN 1101	3.50	12
RSINT35015X	MDN 1101	3.50	15
RSINT35018X	MDN 1101	3.50	18
RSINT35022X	MDN 1101	3.50	22
RSINT35026X	MDN 1101	3.50	26
RSINT35030X	MDN 1101	3.50	30
RSINT35034X	MDN 1101	3.50	34
RSINT35038X	MDN 1101	3.50	38
RSINT40009X	MDN 1101	4.00	09
RSINT40012X	MDN 1101	4.00	12
RSINT40015X	MDN 1101	4.00	15
RSINT40018X	MDN 1101	4.00	18

Model	Type (Codes as per (EU) 2017/2185)	Stent Diameter (mm)	Stent Length (mm)
RSINT40022X	MDN 1101	4.00	22
RSINT40026X	MDN 1101	4.00	26
RSINT40030X	MDN 1101	4.00	30
RSINT40034X	MDN 1101	4.00	34
RSINT40038X	MDN 1101	4.00	38