

Device Schedule:

Device Name: RevoEdge High Pressure Cutting Balloon Dilatation Catheters

Intended Purpose as per the Instructions for Use:

The balloon dilatation catheter is intended for dilatation of stenosis in the coronary vasculature.

Risk Classification: Class III

Basic UDI-DI: 695848140068MR

Type (EU 2017/2185): MDN 1203

Model	Balloon Size
39-1510	1.5 x 10 mm
39-1515	1.5 x 15 mm
39-1520	1.5 x 20 mm
39-1710	1.75 x 10 mm
39-1715	1.75 x 15 mm
39-1720	1.75 x 20 mm
39-2010	2.0 x 10 mm
39-2015	2.0 x 15 mm
39-2020	2.0 x 20 mm
39-2210	2.25 x 10 mm
39-2215	2.25 x 15 mm
39-2220	2.25 x 20 mm
39-2510	2.5 x 10 mm
39-2515	2.5 x 15 mm
39-2520	2.5 x 20 mm
39-2710	2.75 x 10 mm
39-2715	2.75 x 15 mm
39-2720	2.75 x 20 mm
39-3010	3.0 x 10 mm
39-3015	3.0 x 15 mm

Device Schedule:

Model	Balloon Size
39-3020	3.0 x 20 mm
39-3210	3.25 x 10 mm
39-3215	3.25 x 15 mm
39-3220	3.25 x 20 mm
39-3510	3.5 x 10 mm
39-3515	3.5 x 15 mm
39-3520	3.5 x 20 mm
39-4010	4.0 x 10 mm
39-4015	4.0 x 15 mm
39-4020	4.0 x 20 mm