

Device Schedule:

Intended Purpose as per the Instructions for Use: The balloon dilatation catheter is intended for dilatation of stenosis and post-deployed stent in the coronary artery or bypass graft.

Type: (Code as per (EU) 2017/2185): MDN 1203

Risk Classification: Class III

Basic UDI-DI: 695848140062MD

Device Name	Model	Balloon Size
Mars NC PTCA Balloon Dilatation Catheters	38-2006	2.0 x 6 mm
	38-2008	2.0 x 8 mm
	38-2010	2.0 x 10 mm
	38-2012	2.0 x 12 mm
	38-2015	2.0 x 15 mm
	38-2018	2.0 x 18 mm
	38-2020	2.0 x 20 mm
	38-2025	2.0 x 25 mm
	38-2030	2.0 x 30 mm
	38-2206	2.25 x 6 mm
	38-2208	2.25 x 8 mm
	38-2210	2.25 x 10 mm
	38-2212	2.25 x 12 mm
	38-2215	2.25 x 15 mm
	38-2218	2.25 x 18 mm
	38-2220	2.25 x 20 mm
	38-2225	2.25 x 25 mm
	38-2230	2.25 x 30 mm
	38-2506	2.5 x 6 mm
	38-2508	2.5 x 8 mm
	38-2510	2.5 x 10 mm
	38-2512	2.5 x 12 mm

Device Name	Model	Balloon Size
Mars NC PTCA Balloon Dilatation Catheters	38-2515	2.5 x 15 mm
	38-2518	2.5 x 18 mm
	38-2520	2.5 x 20 mm
	38-2525	2.5 x 25 mm
	38-2530	2.5 x 30 mm
	38-2706	2.75 x 6 mm
	38-2708	2.75 x 8 mm
	38-2710	2.75 x 10 mm
	38-2712	2.75 x 12 mm
	38-2715	2.75 x 15 mm
	38-2718	2.75 x 18 mm
	38-2720	2.75 x 20 mm
	38-2725	2.75 x 25 mm
	38-2730	2.75 x 30 mm
	38-3006	3.0 x 6 mm
	38-3008	3.0 x 8 mm
	38-3010	3.0 x 10 mm
	38-3012	3.0 x 12 mm
	38-3015	3.0 x 15 mm
	38-3018	3.0 x 18 mm
	38-3020	3.0 x 20 mm
	38-3025	3.0 x 25 mm
	38-3030	3.0 x 30 mm
	38-3206	3.25 x 6 mm
	38-3208	3.25 x 8 mm
	38-3210	3.25 x 10 mm
	38-3212	3.25 x 12 mm
	38-3215	3.25 x 15 mm
	38-3218	3.25 x 18 mm
	38-3220	3.25 x 20 mm
	38-3225	3.25 x 25 mm
	38-3230	3.25 x 30 mm

Device Name	Model	Balloon Size
Mars NC PTCA Balloon Dilatation Catheters	38-3506	3.5 x 6 mm
	38-3508	3.5 x 8 mm
	38-3510	3.5 x 10 mm
	38-3512	3.5 x 12 mm
	38-3515	3.5 x 15 mm
	38-3518	3.5 x 18 mm
	38-3520	3.5 x 20 mm
	38-3525	3.5 x 25 mm
	38-3530	3.5 x 30 mm
	38-3706	3.75 x 6 mm
	38-3708	3.75 x 8 mm
	38-3710	3.75 x 10 mm
	38-3712	3.75 x 12 mm
	38-3715	3.75 x 15 mm
	38-3718	3.75 x 18 mm
	38-3720	3.75 x 20 mm
	38-3725	3.75 x 25 mm
	38-3730	3.75 x 30 mm
	38-4006	4.0 x 6 mm
	38-4008	4.0 x 8 mm
	38-4010	4.0 x 10 mm
	38-4012	4.0 x 12 mm
	38-4015	4.0 x 15 mm
	38-4018	4.0 x 18 mm
	38-4020	4.0 x 20 mm
	38-4025	4.0 x 25 mm
	38-4030	4.0 x 30 mm
	38-4506	4.5 x 6 mm
	38-4508	4.5 x 8 mm
	38-4510	4.5 x 10 mm
	38-4512	4.5 x 12 mm
	38-4515	4.5 x 15 mm

Device Name	Model	Balloon Size
Mars NC PTCA Balloon Dilatation Catheters	38-4518	4.5 x 18 mm
	38-4520	4.5 x 20 mm
	38-5006	5.0 x 6 mm
	38-5008	5.0 x 8 mm
	38-5010	5.0 x 10 mm
	38-5012	5.0 x 12 mm
	38-5015	5.0 x 15 mm
	38-5018	5.0 x 18 mm
	38-5020	5.0 x 20 mm
	38-5506	5.5 x 6 mm
	38-5508	5.5 x 8 mm
	38-5510	5.5 x 10 mm
	38-5512	5.5 x 12 mm
	38-5515	5.5 x 15 mm
	38-5518	5.5 x 18 mm
	38-5520	5.5 x 20 mm
	38-6006	6.0 x 6 mm
	38-6008	6.0 x 8 mm
	38-6010	6.0 x 10 mm
	38-6012	6.0 x 12 mm
	38-6015	6.0 x 15 mm
	38-6018	6.0 x 18 mm
	38-6020	6.0 x 20 mm