

Device Schedule:

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

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

Risk Classification: Class III

Basic UDI-DI: 695848140061MB

Device Name	Model	Balloon Size
Mars PTCA Balloon Dilatation Catheters	37-1005	1.0 x 5 mm
	37-1008	1.0 x 8 mm
	37-1010	1.0 x 10 mm
	37-1012	1.0 x 12 mm
	37-1015	1.0 x 15 mm
	37-1020	1.0 x 20 mm
	37-1025	1.0 x 25 mm
	37-1030	1.0 x 30 mm
	37-1205	1.25 x 5 mm
	37-1208	1.25 x 8 mm
	37-1210	1.25 x 10 mm
	37-1212	1.25 x 12 mm
	37-1215	1.25 x 15 mm
	37-1220	1.25 x 20 mm
	37-1225	1.25 x 25 mm
	37-1230	1.25 x 30 mm
	37-1505	1.5 x 5 mm
	37-1508	1.5 x 8 mm
	37-1510	1.5 x 10 mm
	37-1512	1.5 x 12 mm
	37-1515	1.5 x 15 mm
	37-1520	1.5 x 20 mm

Device Name	Model	Balloon Size
Mars PTCA Balloon Dilatation Catheters	37-1525	1.5 x 25 mm
	37-1530	1.5 x 30 mm
	37-1705	1.75 x 5 mm
	37-1708	1.75 x 8 mm
	37-1710	1.75 x 10 mm
	37-1712	1.75 x 12 mm
	37-1715	1.75 x 15 mm
	37-1720	1.75 x 20 mm
	37-1725	1.75 x 25 mm
	37-1730	1.75 x 30 mm
	37-2005	2.0 x 5 mm
	37-2008	2.0 x 8 mm
	37-2010	2.0 x 10 mm
	37-2012	2.0 x 12 mm
	37-2015	2.0 x 15 mm
	37-2020	2.0 x 20 mm
	37-2025	2.0 x 25 mm
	37-2030	2.0 x 30 mm
	37-2205	2.25 x 5 mm
	37-2208	2.25 x 8 mm
	37-2210	2.25 x 10 mm
	37-2212	2.25 x 12 mm
	37-2215	2.25 x 15 mm
	37-2220	2.25 x 20 mm
	37-2225	2.25 x 25 mm
	37-2230	2.25 x 30 mm
	37-2505	2.5 x 5 mm
	37-2508	2.5 x 8 mm
	37-2510	2.5 x 10 mm
	37-2512	2.5 x 12 mm
	37-2515	2.5 x 15 mm
	37-2520	2.5 x 20 mm
	37-2525	2.5 x 25 mm
	37-2530	2.5 x 30 mm
	37-2705	2.75 x 5 mm
	37-2708	2.75 x 8 mm

Device Name	Model	Balloon Size
Mars PTCA Balloon Dilatation Catheters	37-2710	2.75 x 10 mm
	37-2712	2.75 x 12 mm
	37-2715	2.75 x 15 mm
	37-2720	2.75 x 20 mm
	37-2725	2.75 x 25 mm
	37-2730	2.75 x 30 mm
	37-3005	3.0 x 5 mm
	37-3008	3.0 x 8 mm
	37-3010	3.0 x 10 mm
	37-3012	3.0 x 12 mm
	37-3015	3.0 x 15 mm
	37-3020	3.0 x 20 mm
	37-3025	3.0 x 25 mm
	37-3030	3.0 x 30 mm
	37-3205	3.25 x 5 mm
	37-3208	3.25 x 8 mm
	37-3210	3.25 x 10 mm
	37-3212	3.25 x 12 mm
	37-3215	3.25 x 15 mm
	37-3220	3.25 x 20 mm
	37-3225	3.25 x 25 mm
	37-3230	3.25 x 30 mm
	37-3505	3.5 x 5 mm
	37-3508	3.5 x 8 mm
	37-3510	3.5 x 10 mm
	37-3512	3.5 x 12 mm
	37-3515	3.5 x 15 mm
	37-3520	3.5 x 20 mm
	37-3525	3.5 x 25 mm
	37-3530	3.5 x 30 mm
	37-3705	3.75 x 5 mm
	37-3708	3.75 x 8 mm
	37-3710	3.75 x 10 mm
	37-3712	3.75 x 12 mm
	37-3715	3.75 x 15 mm
	37-3720	3.75 x 20 mm

Device Name	Model	Balloon Size
Mars PTCA Balloon Dilatation Catheters	37-3725	3.75 x 25 mm
	37-3730	3.75 x 30 mm
	37-4005	4.0 x 5 mm
	37-4008	4.0 x 8 mm
	37-4010	4.0 x 10 mm
	37-4012	4.0 x 12 mm
	37-4015	4.0 x 15 mm
	37-4020	4.0 x 20 mm
	37-4025	4.0 x 25 mm
	37-4030	4.0 x 30 mm