

Device Schedule:

Device Name: Artimes / Aperi SC / Origin SC Balloon Dilatation Catheters

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.

Risk Classification: Class III

Basic UDI-DI: 695848140003LV

Type (EU 2017/2185): MDN 1203

Description (Balloon size)	Artimes Model Number	Aperi SC Model Number	Origin SC Model Number
1.0 x 5mm	801-1005	431005	OS1005
1.0 x 8mm	801-1008	431008	OS1008
1.0 x 10mm	801-1010	431010	OS1010
1.0 x 12mm	801-1012	431012	OS1012
1.0 x 15mm	801-1015	431015	OS1015
1.0 x 20mm	801-1020	431020	OS1020
1.0 x 25mm	801-1025	431025	OS1025
1.0 x 30mm	801-1030	431030	OS1030
1.25 x 5mm	801-1205	431205	OS1205
1.25 x 8mm	801-1208	431208	OS1208
1.25 x 10mm	801-1210	431210	OS1210
1.25 x 12mm	801-1212	431212	OS1212
1.25 x 15mm	801-1215	431215	OS1215

Description (Balloon size)	Artimes Model Number	Aperi SC Model Number	Origin SC Model Number
1.25 x 20mm	801-1220	431220	OS1220
1.25 x 25mm	801-1225	431225	OS1225
1.25 x 30mm	801-1230	431230	OS1230
1.5 x 5mm	801-1505	431505	OS1505
1.5 x 8mm	801-1508	431508	OS1508
1.5 x 10mm	801-1510	431510	OS1510
1.5 x 12mm	801-1512	431512	OS1512
1.5 x 15mm	801-1515	431515	OS1515
1.5 x 20mm	801-1520	431520	OS1520
1.5 x 25mm	801-1525	431525	OS1525
1.5 x 30mm	801-1530	431530	OS1530
1.75 x 5mm	801-1705	431705	OS1705
1.75 x 8mm	801-1708	431708	OS1708
1.75 x 10mm	801-1710	431710	OS1710
1.75 x 12mm	801-1712	431712	OS1712
1.75 x 15mm	801-1715	431715	OS1715
1.75 x 20mm	801-1720	431720	OS1720
1.75 x 25mm	801-1725	431725	OS1725
1.75 x 30mm	801-1730	431730	OS1730
2.0 x 5mm	801-2005	432005	OS2005
2.0 x 8mm	801-2008	432008	OS2008
2.0 x 10mm	801-2010	432010	OS2010
2.0 x 12mm	801-2012	432012	OS2012
2.0 x 15mm	801-2015	432015	OS2015
2.0 x 20mm	801-2020	432020	OS2020

Description (Balloon size)	Artimes Model Number	Aperi SC Model Number	Origin SC Model Number
2.0 x 25mm	801-2025	432025	OS2025
2.0 x 30mm	801-2030	432030	OS2030
2.25 x 5mm	801-2205	432205	OS2205
2.25 x 8mm	801-2208	432208	OS2208
2.25 x 10mm	801-2210	432210	OS2210
2.25 x 12mm	801-2212	432212	OS2212
2.25 x 15mm	801-2215	432215	OS2215
2.25 x 20mm	801-2220	432220	OS2220
2.25 x 25mm	801-2225	432225	OS2225
2.25 x 30mm	801-2230	432230	OS2230
2.5 x 5mm	801-2505	432505	OS2505
2.5 x 8mm	801-2508	432508	OS2508
2.5 x 10mm	801-2510	432510	OS2510
2.5 x 12mm	801-2512	432512	OS2512
2.5 x 15mm	801-2515	432515	OS2515
2.5 x 20mm	801-2520	432520	OS2520
2.5 x 25mm	801-2525	432525	OS2525
2.5 x 30mm	801-2530	432530	OS2530
2.75 x 5mm	801-2705	432705	OS2705
2.75 x 8mm	801-2708	432708	OS2708
2.75 x 10mm	801-2710	432710	OS2710
2.75 x 12mm	801-2712	432712	OS2712
2.75 x 15mm	801-2715	432715	OS2715
2.75 x 20mm	801-2720	432720	OS2720
2.75 x 25mm	801-2725	432725	OS2725
2.75 x 30mm	801-2730	432730	OS2730

Description (Balloon size)	Artimes Model Number	Aperi SC Model Number	Origin SC Model Number
3.0 x 5mm	801-3005	433005	OS3005
3.0 x 8mm	801-3008	433008	OS3008
3.0 x 10mm	801-3010	433010	OS3010
3.0 x 12mm	801-3012	433012	OS3012
3.0 x 15mm	801-3015	433015	OS3015
3.0 x 20mm	801-3020	433020	OS3020
3.0 x 25mm	801-3025	433025	OS3025
3.0 x 30mm	801-3030	433030	OS3030
3.25 x 5mm	801-3205	433205	OS3205
3.25 x 8mm	801-3208	433208	OS3208
3.25 x 10mm	801-3210	433210	OS3210
3.25 x 12mm	801-3212	433212	OS3212
3.25 x 15mm	801-3215	433215	OS3215
3.25 x 20mm	801-3220	433220	OS3220
3.25 x 25mm	801-3225	433225	OS3225
3.25 x 30mm	801-3230	433230	OS3230
3.5 x 5mm	801-3505	433505	OS3505
3.5 x 8mm	801-3508	433508	OS3508
3.5 x 10mm	801-3510	433510	OS3510
3.5 x 12mm	801-3512	433512	OS3512
3.5 x 15mm	801-3515	433515	OS3515
3.5 x 20mm	801-3520	433520	OS3520
3.5 x 25mm	801-3525	433525	OS3525
3.5 x 30mm	801-3530	433530	OS3530
3.75 x 5mm	801-3705	433705	OS3705
3.75 x 8mm	801-3708	433708	OS3708

Description (Balloon size)	Artimes Model Number	Aperi SC Model Number	Origin SC Model Number
3.75 x 10mm	801-3710	433710	OS3710
3.75 x 12mm	801-3712	433712	OS3712
3.75 x 15mm	801-3715	433715	OS3715
3.75 x 20mm	801-3720	433720	OS3720
3.75 x 25mm	801-3725	433725	OS3725
3.75 x 30mm	801-3730	433730	OS3730
4.0 x 5mm	801-4005	434005	OS4005
4.0 x 8mm	801-4008	434008	OS4008
4.0 x 10mm	801-4010	434010	OS4010
4.0 x 12mm	801-4012	434012	OS4012
4.0 x 15mm	801-4015	434015	OS4015
4.0 x 20mm	801-4020	434020	OS4020
4.0 x 25mm	801-4025	434025	OS4025
4.0 x 30mm	801-4030	434030	OS4030