

Device Schedule:

Device Name: Apollo / Aperi NC / Origin NC Balloon Dilatation Catheters

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.

Risk Classification: Class III

Basic UDI-DI: 695848140004LX

Type (EU 2017/2185): MDN 1203

Description (Balloon size)	Apollo Model Number	Aperi NC Model Number	Origin NC Model Number
2.0 x 6mm	802-2006	442006	ON2006
2.0 x 8mm	802-2008	442008	ON2008
2.0 x 10mm	802-2010	442010	ON2010
2.0 x 12mm	802-2012	442012	ON2012
2.0 x 15mm	802-2015	442015	ON2015
2.0 x 18mm	802-2018	442018	ON2018
2.0 x 20mm	802-2020	442020	ON2020
2.0 x 22mm	802-2022	442022	ON2022
2.0 x 25mm	802-2025	442025	ON2025
2.0 x 30mm	802-2030	442030	ON2030
2.25 x 6mm	802-2206	442206	ON2206
2.25 x 8mm	802-2208	442208	ON2208
2.25 x 10mm	802-2210	442210	ON2210
2.25 x 12mm	802-2212	442212	ON2212
2.25 x 15mm	802-2215	442215	ON2215

Description (Balloon size)	Apollo Model Number	Aperi NC Model Number	Origin NC Model Number
2.25 x 18mm	802-2218	442218	ON2218
2.25 x 20mm	802-2220	442220	ON2220
2.25 x 22mm	802-2222	442222	ON2222
2.25 x 25mm	802-2225	442225	ON2225
2.25 x 30mm	802-2230	442230	ON2230
2.5 x 6mm	802-2506	442506	ON2506
2.5 x 8mm	802-2508	442508	ON2508
2.5 x 10mm	802-2510	442510	ON2510
2.5 x 12mm	802-2512	442512	ON2512
2.5 x 15mm	802-2515	442515	ON2515
2.5 x 18mm	802-2518	442518	ON2518
2.5 x 20mm	802-2520	442520	ON2520
2.5 x 22mm	802-2522	442522	ON2522
2.5 x 25mm	802-2525	442525	ON2525
2.5 x 30mm	802-2530	442530	ON2530
2.75 x 6mm	802-2706	442706	ON2706
2.75 x 8mm	802-2708	442708	ON2708
2.75 x 10mm	802-2710	442710	ON2710
2.75 x 12mm	802-2712	442712	ON2712
2.75 x 15mm	802-2715	442715	ON2715
2.75 x 18mm	802-2718	442718	ON2718
2.75 x 20mm	802-2720	442720	ON2720
2.75 x 22mm	802-2722	442722	ON2722
2.75 x 25mm	802-2725	442725	ON2725
2.75 x 30mm	802-2730	442730	ON2730

Description (Balloon size)	Apollo Model Number	Aperi NC Model Number	Origin NC Model Number
3.0 x 6mm	802-3006	443006	ON3006
3.0 x 8mm	802-3008	443008	ON3008
3.0 x 10mm	802-3010	443010	ON3010
3.0 x 12mm	802-3012	443012	ON3012
3.0 x 15mm	802-3015	443015	ON3015
3.0 x 18mm	802-3018	443018	ON3018
3.0 x 20mm	802-3020	443020	ON3020
3.0 x 22mm	802-3022	443022	ON3022
3.0 x 25mm	802-3025	443025	ON3025
3.0 x 30mm	802-3030	443030	ON3030
3.25 x 6mm	802-3206	443206	ON3206
3.25 x 8mm	802-3208	443208	ON3208
3.25 x 10mm	802-3210	443210	ON3210
3.25 x 12mm	802-3212	443212	ON3212
3.25 x 15mm	802-3215	443215	ON3215
3.25 x 18mm	802-3218	443218	ON3218
3.25 x 20mm	802-3220	443220	ON3220
3.25 x 22mm	802-3222	443222	ON3222
3.25 x 25mm	802-3225	443225	ON3225
3.25 x 30mm	802-3230	443230	ON3230
3.5 x 6mm	802-3506	443506	ON3506
3.5 x 8mm	802-3508	443508	ON3508
3.5 x 10mm	802-3510	443510	ON3510
3.5 x 12mm	802-3512	443512	ON3512

Description (Balloon size)	Apollo Model Number	Aperi NC Model Number	Origin NC Model Number
3.5 x 15mm	802-3515	443515	ON3515
3.5 x 18mm	802-3518	443518	ON3518
3.5 x 20mm	802-3520	443520	ON3520
3.5 x 22mm	802-3522	443522	ON3522
3.5 x 25mm	802-3525	443525	ON3525
3.5 x 30mm	802-3530	443530	ON3530
3.75 x 6mm	802-3706	443706	ON3706
3.75 x 8mm	802-3708	443708	ON3708
3.75 x 10mm	802-3710	443710	ON3710
3.75 x 12mm	802-3712	443712	ON3712
3.75 x 15mm	802-3715	443715	ON3715
3.75 x 18mm	802-3718	443718	ON3718
3.75 x 20mm	802-3720	443720	ON3720
3.75 x 22mm	802-3722	443722	ON3722
3.75 x 25mm	802-3725	443725	ON3725
3.75 x 30mm	802-3730	443730	ON3730
4.0 x 6mm	802-4006	444006	ON4006
4.0 x 8mm	802-4008	444008	ON4008
4.0 x 10mm	802-4010	444010	ON4010
4.0 x 12mm	802-4012	444012	ON4012
4.0 x 15mm	802-4015	444015	ON4015
4.0 x 18mm	802-4018	444018	ON4018
4.0 x 20mm	802-4020	444020	ON4020
4.0 x 22mm	802-4022	444022	ON4022
4.0 x 25mm	802-4025	444025	ON4025
4.0 x 30mm	802-4030	444030	ON4030

Description (Balloon size)	Apollo Model Number	Aperi NC Model Number	Origin NC Model Number
4.5 x 6mm	802-4506	444506	ON4506
4.5 x 8mm	802-4508	444508	ON4508
4.5 x 10mm	802-4510	444510	ON4510
4.5 x 12mm	802-4512	444512	ON4512
4.5 x 15mm	802-4515	444515	ON4515
4.5 x 18mm	802-4518	444518	ON4518
4.5 x 20mm	802-4520	444520	ON4520
4.5 x 22mm	802-4522	444522	ON4522
4.5 x 25mm	802-4525	444525	ON4525
4.5 x 30mm	802-4530	444530	ON4530
5.0 x 6mm	802-5006	445006	ON5006
5.0 x 8mm	802-5008	445008	ON5008
5.0 x 10mm	802-5010	445010	ON5010
5.0 x 12mm	802-5012	445012	ON5012
5.0 x 15mm	802-5015	445015	ON5015
5.0 x 18mm	802-5018	445018	ON5018
5.0 x 20mm	802-5020	445020	ON5020
5.0 x 22mm	802-5022	445022	ON5022
5.0 x 25mm	802-5025	445025	ON5025
5.0 x 30mm	802-5030	445030	ON5030