

Device Schedule:

Device name: Ryurei

Intended Purpose as per the Instructions for Use:

The Ryurei ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries. The Ryurei (balloon models 2.0 mm to 4.0 mm) is also intended for post-deployment expansion of balloon-expandable stents.

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

Risk Classification: Class III

Basic UDI-DI: 498735026DCRRLU

Model	Description (Balloon diameter, Balloon length)
DC-RR1005HH	1.00 mm, 5 mm
DC-RR1205HH	1.25 mm, 5 mm
DC-RR1210HH	1.25 mm, 10 mm
DC-RR1215HH	1.25 mm, 15 mm
DC-RR1220HH	1.25 mm, 20 mm
DC-RR1505HH	1.50 mm, 5 mm
DC-RR1510HH	1.50 mm, 10 mm
DC-RR1515HH	1.50 mm, 15 mm
DC-RR1520HH	1.50 mm, 20 mm
DC-RR2010HHW	2.00 mm, 10 mm
DC-RR2015HHW	2.00 mm, 15 mm
DC-RR2020HHW	2.00 mm, 20 mm
DC-RR2030HHW	2.00 mm, 30 mm
DC-RR2040HHW	2.00 mm, 40 mm
DC-RR2210HHW	2.25 mm, 10 mm
DC-RR2215HHW	2.25 mm, 15 mm
DC-RR2220HHW	2.25 mm, 20 mm

Model	Description (Balloon diameter, Balloon length)
DC-RR2510HHW	2.50 mm, 10 mm
DC-RR2515HHW	2.50 mm, 15 mm
DC-RR2520HHW	2.50 mm, 20 mm
DC-RR2530HHW	2.50 mm, 30 mm
DC-RR2540HHW	2.50 mm, 40 mm
DC-RR2710HHW	2.75 mm, 10 mm
DC-RR2715HHW	2.75 mm, 15 mm
DC-RR2720HHW	2.75 mm, 20 mm
DC-RR3010HHW	3.00 mm, 10 mm
DC-RR3015HHW	3.00 mm, 15 mm
DC-RR3020HHW	3.00 mm, 20 mm
DC-RR3030HHW	3.00 mm, 30 mm
DC-RR3040HHW	3.00 mm, 40 mm
DC-RR3210HHW	3.25 mm, 10 mm
DC-RR3215HHW	3.25 mm, 15 mm
DC-RR3220HHW	3.25 mm, 20 mm
DC-RR3510HHW	3.50 mm, 10 mm
DC-RR3515HHW	3.50 mm, 15 mm
DC-RR3520HHW	3.50 mm, 20 mm
DC-RR3530HHW	3.50 mm, 30 mm
DC-RR3540HHW	3.50 mm, 40 mm
DC-RR3710HHW	3.75 mm, 10 mm
DC-RR3715HHW	3.75 mm, 15 mm
DC-RR3720HHW	3.75 mm, 20 mm
DC-RR4010HHW	4.00 mm, 10 mm
DC-RR4015HHW	4.00 mm, 15 mm
DC-RR4020HHW	4.00 mm, 20 mm