

TECHNICAL SPECIFICATIONS, cont.

Distance of Marker from Shoulder (balloon overhang)	Proximal balloon shoulder located within the width of the proximal balloon marker +/- 1 mm (for all sizes with 2 markers). Distal balloon shoulder located within the width of the distal balloon marker (for all sizes with 2 markers).
0.014" GW Compatibility	Yes
Catheter Shaft Length	145 cm +/- 2 cm
Distal Shaft Diameter (max)	2.4 French
Proximal Shaft Diameter (max)	2.1 French
Diameter of RX Notch	2.5 French average* (3.00 mm Ø) 2.7 French maximum (all Ø)
Minimum Guiding Catheter	5 French (1.20 mm – 4.00 mm Ø) 6 French (4.50 mm & 5.00 mm Ø)
Sterilization Method	EtO (Ethylene Oxide Gas) sterilized
Shelf Life (from sterilization date)	36 months
Storage Recommendation	Cool, Dark & Dry
Latex Free Declaration	Latex free
Heavy Metals	No
Chlorine Bleached Materials	No
Recyclable Materials	Yes

COMPLIANCE CHART

Pressure (atm)	1.20 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm	4.50 mm	5.00 mm
2	1.10	1.34	1.69	1.87	2.15	2.16	2.49	2.91	2.93	3.06	3.24	3.69	4.10
3	1.12	1.36	1.80	1.95	2.20	2.35	2.56	2.98	3.04	3.22	3.46	3.91	4.28
4	1.13	1.38	1.85	2.00	2.27	2.41	2.66	3.05	3.11	3.31	3.56	4.04	4.43
5	1.14	1.40	1.90	2.06	2.34	2.49	2.73	3.12	3.20	3.41	3.67	4.17	4.59
6	1.17	1.43	1.94	2.12	2.40	2.56	2.81	3.19	3.28	3.50	3.78	4.29	4.73
7	1.18	1.45	1.98	2.17	2.45	2.63	2.87	3.25	3.38	3.59	3.89	4.40	4.86
8 NP	1.20	1.47	2.01	2.21	2.51	2.70	2.93	3.31	3.45	3.67	3.99	4.49	4.98
9	1.21	1.49	2.03	2.25	2.55	2.75	2.97	3.36	3.51	3.74	4.06	4.56	5.05
10	1.23	1.51	2.07	2.28	2.58	2.80	3.01	3.39	3.56	3.79	4.11	4.62	5.13
11	1.24	1.52	2.09	2.31	2.60	2.83	3.04	3.42	3.60	3.84	4.18	4.68	5.20
12	1.25	1.54	2.12	2.33	2.62	2.86	3.07	3.45	3.64	3.87	4.23	4.73	5.25
13	1.26	1.55	2.14	2.35	2.64	2.88	3.09	3.48	3.67	3.91	4.28	4.80	5.31
14 RBP	1.27	1.56	2.17	2.37	2.67	2.91	3.11	3.50	3.70	3.94	4.32	4.86	5.36
15	1.28	1.57	2.19	2.39	2.69	2.92	3.14	3.53	3.73	3.99	4.38	4.92	5.41
16	1.29	1.59	2.21	2.41	2.71	2.96	3.16	3.56	3.75	4.02	4.44	4.98	5.50
17	1.30	1.60	2.24	2.43	2.73	2.99	3.18	3.58	3.78	4.05	4.49	5.04	5.56

*Tests performed by and data on file at Abbott.
Data on file at Abbott.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.
©2021 Abbott. All rights reserved. MAT-2114609 v1.0

Tender Specification

TREK™ Coronary Dilatation Catheter & MINI TREK™ Coronary Dilatation Catheter Rapid Exchange (RX) Platform

INDICATIONS

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
- Balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarctions.
- Balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only).
- Balloon dilatation of *de novo* chronic total coronary occlusions (CTO) (MINI TREK™ only).

TECHNICAL SPECIFICATIONS

Balloon Lengths (mm)	6, 8, 12, 15, 20, 25, 30
Balloon Diameters (mm)	MINI TREK™ Dilatation Catheter: 1.20 - 2.00 TREK™ Dilatation Catheter: 2.25 - 5.00
Platform	Rapid Exchange (RX)
Compliance Type	Semi-compliant, measured by radial growth mm/ATM
Balloon Material	Pebax [‡]
Marker Material	Flexible Tungsten/Pebax [‡]
Number of Markers	Single markers on all lengths for 1.20 mm & 1.50 mm diameters and all 6 mm lengths. All other sizes have 2 markers.
Balloon Coating	Hydrophilic; 42 cm in length starting at tip
Folding	1.20 – 1.50 mm diameters are bi-fold. All other sizes are tri-fold.
Nominal Pressure (NP)	8 ATM
Rated burst Pressure (RBP)	14 ATM
Tip Entry Profile	0.017 inch* (3.0 mm Ø)
Tip Crossing Profile	0.021 inch average* (3.0 mm Ø) 0.023 inch maximum (all Ø)
Folded Balloon Crossing Profile (OD)	0.032 inch average* (3.0 mm Ø) 0.036 inch maximum (3.0 mm Ø)
Refolded Balloon Crossing Profile (OD)	0.056 inch maximum (3.0 mm Ø)
Tip Length	<3 mm
Inflation Time to RPB	5 seconds maximum
Deflation Time	17 seconds average* (3.0 mm Ø)

* Tests performed by and data on file at Abbott.
Data on file at Abbott.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

©2021 Abbott. All rights reserved. MAT-2114609 v1.0