



TREK & MINI TREK

Coronary Dilatation Catheters

PTKA balioninis kateteris



PRODUCT DESCRIPTION

- TREK and MINI TREK Coronary Dilatation catheter are designed to reach lesions in the coronary artery, cross lesions and then be inflated within the diseased area. Balloon inflation pushes the plaque aside creating a clear lumen for blood flow. TREK and MINI TREK are available in both a rapid exchange and over-the-wire platform.

PRODUCT CHARACTERISTICS

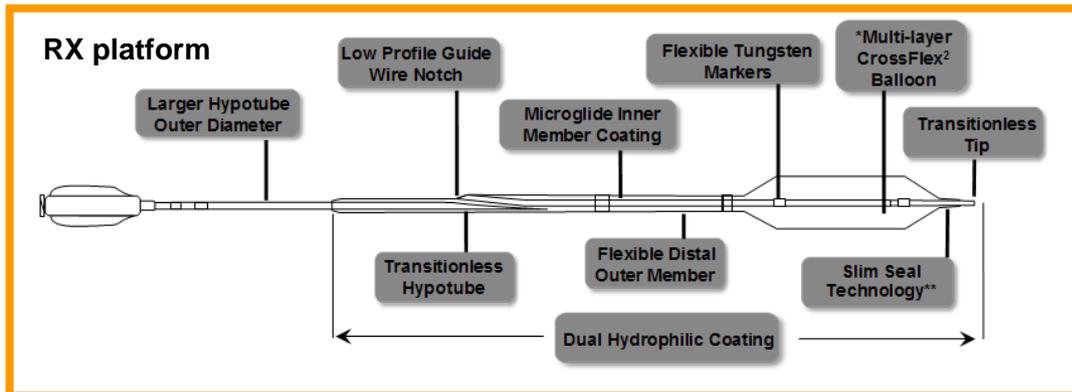
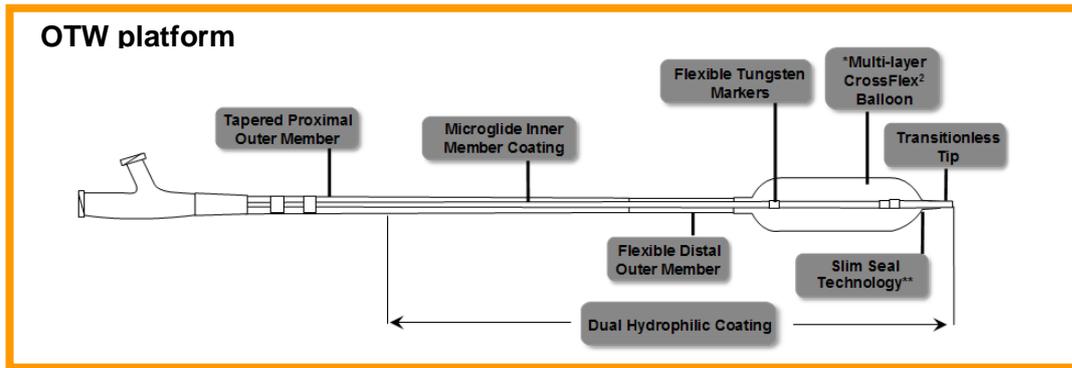
- TREK RX and MINI TREK RX smooth transitions between hypotube and distal shaft drive catheter balance for excellent support and flexibility. Superb tactile feel and less force required to cross challenging anatomy.
- TREK RX/OTW and MINI TREK RX and II OTW feature a smooth, transitionless tip for confident crossing in resistant lesions while minimizing vessel trauma.
- TREK RX/OTW features proprietary multi-layer CrossFlex^{2*} and Slim Seal^{**} technology for advanced flexibility and low profiles.
- MINI TREK RX and II OTW have an ultra low profile design for lesion access. The distinctive small chassis is available in the unique 1.20 mm diameters as well as 1.50 mm and 2.00 mm diameters.

INDICATIONS PER IFU

- **Applies to TREK & MINI TREK RX and MINI TREK II OTW 1.2 mm – 5.0 mm only:**
- TREK and MINI TREK are indicated for:
 - a) balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
 - b) balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarctions.
 - c) balloon dilatation of a stent after implantation (balloon models 2.00 mm – 5.00 mm only).
- **Applies to MINI TREK RX & II OTW 1.20 mm – 2.0 mm sizes only:**
 - a) The MINI TREK RX & OTW Coronary Dilatation Catheters are indicated for balloon dilatation of *de novo* chronic total coronary occlusions (CTO)

NOTE (APPLIES TO TREK AND MINI TREK OTW ONLY): POST-DEPLOYMENT STENT EXPANSION TESTING WAS PERFORMED ON THE BENCH WITH THE MULTI-LINK VISION AND MULTI-LINK ULTRA STENTS. ALL STENTS SHOULD BE DEPLOYED IN ACCORDANCE WITH THE MANUFACTURER'S INDICATIONS AND INSTRUCTIONS FOR USE.

TREK AND MINI TREK INNOVATIONS



TREK and MINI TREK coronary dilatation catheters offers smooth transitionless design for superb conformability and stiffness transition together with ultra low profiles for excellent crossing performance and superb tactile feel and push performance for excellent catheter control.

Key Innovations are:

- **Sidearm:** For improved legibility and sleek shape.
- **Proximal Markers:** Lower profile proximal markers.
- **Larger Hypotube Outer Diameter:** For improved tactile feel and push.
- **Transitionless Hypotube:** To prevent kinking in sharp bends.
- **Low profile Exit Notch:** For improved compatibility in Kissing Balloon techniques.
- **Microglide Inner Member Coating:** To reduce friction over Guide Wire.
- **Distal Outer Member:** Flexible and strong.
- **Dual Hydrophilic Coating:** More Durable. Last Longer.
- **Balloon:** Multi-layer CrossFlex²* Balloon offers maximum flexibility and outstanding rupture strength.
- **Transitionless Tip:** Soft tip extends proximal into the catheter for a smooth transitionless feel and low crossing profile.
- **Tungsten Makers:** For improved flexibility and radiopacity.
- **Balloon Seal:** Slim Seal** Technology enables a reduction in crossing profile.
- **Transitionless Hypotube:** Prevents kinking and provides a smooth transition between the hypotube and distal shaft.

BALLOON TECHNICAL SPECIFICATIONS – TREK & MINI TREK RX

Technical Parameter		
Balloon Lengths	ilgiai	6, 8, 12, 15, 20, 25 and 30 mm
Diameters of Balloons	diametrai	1.20 – 5.0 mm
Construction System		Rapid Exchange (RX)
Compliance Type		Semi-Compliant, measured by radial growth mm/ATM
Balloon Material	baliono medžiaga	Pebax
Balloon Coating	padengimas	Hydrophilic, from tip to mid shaft
Folding		Tri-fold
Nominal Pressure	nominalus slgis	8 atm
Rated Burst Pressure (RBP)	plyšimo slgis	14 atm
Crossing Profile	prajimo profilis	0.0209 inch (3.0 mm x 20 mm balloon)
Inflation / Deflation Time (3.0 mm x 20 mm)		≤ 5 sec. / ≤ 10 sec
Number of Markers	markeriai	Single markers on all lengths for 1.20 mm & 1.50 mm diameters and 6 mm lengths. All other sizes have 2 markers.
Marker Material	markerio medžiaga	Flexible Tungsten/Pebax Wolframas
Width of Marker	markerio matmenys	1.0 mm
Distance of Marker from Shoulder (balloon overhang):		Shoulders located within markers
Lesion Entry Profile	galiuko profilis	0.0168 inch (1.5 mm and 3.0 mm Ø balloon)
Folded Crossing Profile (OD)		0.036" balloon Crossing Profile for 3.0 mm Ø balloon
Refolded Crossing Profile (OD)		0.056" balloon Crossing Profile for 3.0 mm Ø balloon
Tip Length		< 3.0 mm
0,014" Compatability		Yes
Flexibility of Balloon Tip		Medium soft
Tip Construction (laser bounded, tapered etc.)		Tapered
Technical Parameter		
Length of Catheter Shaft:	kateterio ilgis	145 cm
Diameter of Distal Shaft:	distalinis diametras	RX: 2.4 (TREK) 2.3 (MINI TREK) French
Diameter of Proximal Shaft:	proksimalinis diam.	2.1 French
Diameter of RX Notch:		2.4 French
Stiffness of Shaft:		Soft
Kinking Resistance in Transition Zone:		Reinforced transitionless design
Minimum Guiding Catheter		5 French (0.058")
Versatile Treatment Options		6 French (0.070")
Procedural Success Rate (per VIPER) [†]		≥ 95%
Sterilization Method		EtO (Ethylene Oxide Gas) sterilized
Shelf Life (from sterilisation date)		36 months
Storage Recommendation		15 - 30 °C (Cool, Dark & Dry)
Latex Free Declaration		Latex free
Heavy Metals		No
Chlorine Bleached Materials		No
Recyclable Materials		Yes

AP2938849-OUS REV A ©2013 Abbott. All rights reserved. Tests performed by and data on file at Abbott Vascular.
[†]Complaint Handling Database data (4/10-04/13) on file at Abbott Vascular. Information contained herein for use outside of US, France and Japan only.

BALLOON TECHNICAL SPECIFICATIONS – TREK & MINI TREK II OTW

Technical Parameter	
Balloon Lengths	6, 8, 12, 15, 20, 25 and 30 mm
Diameters of Balloons	1.20 – 5.0 mm
Construction System	Over-The-Wire (OTW)
Compliance Type	Semi-Compliant, measured by radial growth mm/ATM
Balloon Material	Pebax
Balloon Coating	Hydrophilic, from tip to mid shaft
Folding	Tri-fold
Nominal Pressure	8 atm
Rated Burst Pressure (RBP)	14 atm
Crossing Profile	0.0209 inch (3.0 mm x 20 mm balloon)
Inflation / Deflation Time (3.0 mm x 20 mm)	≤ 5 sec. / ≤ 10 sec
Number of Markers	Single markers on all lengths for 1.20 mm & 1.50 mm diameters and 6 mm lengths. All other sizes have 2 markers.
Marker Material	Flexible Tungsten/Pebax
Width of Marker	1.0 mm
Distance of Marker from Shoulder (balloon overhang):	Shoulders located within markers
Lesion Entry Profile	0.0168 inch (1.5 mm and 3.0 mm Ø balloon)
Folded Crossing Profile (OD)	0.036" balloon Crossing Profile for 3.0 mm Ø balloon
Refolded Crossing Profile (OD)	0.056" balloon Crossing Profile for 3.0 mm Ø balloon
Tip Length	< 3.0 mm
0,014" Compatibility	Yes
Flexibility of Balloon Tip	Medium soft
Tip Construction (laser bounded, tapered etc.)	Tapered
Technical Parameter	
Length of Catheter Shaft:	145 cm
Diameter of Distal Shaft:	OTW: 2.4 (TREK) 2.3 (MINI TREK II) French
Diameter of Proximal Shaft:	3.4 French
Stiffness of Shaft:	Soft
Kinking Resistance in Transition Zone:	High
Minimum Guiding Catheter	5 French (0.058")
Sterilization Method	EtO (Ethylene Oxide Gas) sterilized
Shelf Life (from sterilisation date)	36 months
Storage Recommendation	15 - 30 °C (Cool, Dark & Dry)
Latex Free Declaration	Latex free
Heavy Metals	No
Chlorine Bleached Materials	No
Recyclable Materials	Yes

COMPLIANCE CHART

Pressure (atm)	Ø Balloon (mm)												
	1,20	1,50	2,0	2,25	2,5	2,75	3,0	3,25	3,5	3,75	4,0	4,5	5,0
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

ORDERING INFORMATION

TREK RX and MINI TREK RX							
Balloon Ø [mm]	References by Length and Diameter						
	6 mm	8 mm	12 mm	15 mm	20 mm	25 mm	30 mm
1.20 mm	1012268-06	1012268-08	1012268-12	1012268-15	1012268-20	-	-
1.50 mm	1012269-06	1012269-08	1012269-12	1012269-15	1012269-20	-	-
2.00 mm	1012270-06	1012270-08	1012270-12	1012270-15	1012270-20	1012270-25	1012270-30
2.25 mm	1012271-06	1012271-08	1012271-12	1012271-15	1012271-20	1012271-25	1012271-30
2.50 mm	1012272-06	1012272-08	1012272-12	1012272-15	1012272-20	1012272-25	1012272-30
2.75 mm	1012273-06	1012273-08	1012273-12	1012273-15	1012273-20	1012273-25	1012273-30
3.00 mm	1012274-06	1012274-08	1012274-12	1012274-15	1012274-20	1012274-25	1012274-30
3.25 mm	1012275-06	1012275-08	1012275-12	1012275-15	1012275-20	1012275-25	1012275-30
3.50 mm	1012276-06	1012276-08	1012276-12	1012276-15	1012276-20	1012276-25	1012276-30
3.75 mm	1012277-06	1012277-08	1012277-12	1012277-15	1012277-20	1012277-25	1012277-30
4.00 mm	1012278-06	1012278-08	1012278-12	1012278-15	1012278-20	1012278-25	1012278-30
4.50 mm	-	-	1012279-12	1012279-15	-	-	-
5.00 mm	-	-	1012280-12	1012280-15	-	-	-

TREK OTW & MINI TREK II OTW							
Balloon Ø [mm]	References by Length and Diameter						
	6 mm	8 mm	12 mm	15 mm	20 mm	25 mm	30 mm
1.20 mm	1012401-06A	1012401-08A	1012401-12A	1012401-15A	1012401-20A	-	-
1.50 mm	1012402-06A	1012402-08A	1012402-12A	1012402-15A	1012402-20A	-	-
2.00 mm	1012403-06A	1012403-08A	1012403-12A	1012403-15A	1012403-20A	-	-
2.25 mm	1012404-06	1012404-08	1012404-12	1012404-15	1012404-20	1012404-25	1012404-30
2.50 mm	1012405-06	1012405-08	1012405-12	1012405-15	1012405-20	1012405-25	1012405-30
2.75 mm	1012406-06	1012406-08	1012406-12	1012406-15	1012406-20	1012406-25	1012406-30
3.00 mm	1012407-06	1012407-08	1012407-12	1012407-15	1012407-20	1012407-25	1012407-30
3.25 mm	1012408-06	1012408-08	1012408-12	1012408-15	1012408-20	1012408-25	1012408-30
3.50 mm	1012409-06	1012409-08	1012409-12	1012409-15	1012409-20	1012409-25	1012409-30
3.75 mm	1012410-06	1012410-08	1012410-12	1012410-15	1012410-20	1012410-25	1012410-30
4.00 mm	1012411-06	1012411-08	1012411-12	1012411-15	1012411-20	1012411-25	1012411-30
4.50 mm	-	-	1012412-12	1012412-15	-	-	-
5.00 mm	-	-	1012413-12	1012413-15	-	-	-