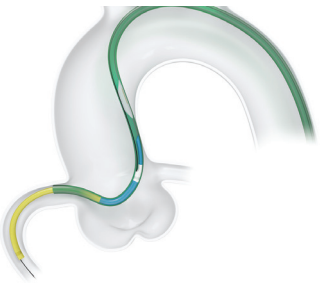
TrapLiner Catheter

Teleflex
(888) 240-6001
www.vasc.com

KEY FEATURES

- Coil reinforced guide extension
- Integrated balloon for guidewire trapping
- Half-pipe channel
- Hydrophilic coating



The TrapLiner Catheter is a guide extension catheter with a trapping balloon in an all-in-one device. The straight, flexible extension provides deep-seating for extra backup support and coaxial alignment in challenging anatomies. The integrated balloon adds the ability to trap a guidewire during over-the-wire (OTW) catheter exchanges. This eliminates the extra step of deploying a percutaneous transluminal coronary angioplasty balloon to trap a guidewire when exchanging OTW microcatheters.

Dimitri Karmpaliotis, MD, PhD, Director of Chronic Total Occlusion, Complex and High-Risk Angioplasty at Columbia University Medical Center, was the first to use the device in the United States. "The primary clinical use for the TrapLiner is during cases in which OTW microcatheters are required to cross calcified lesions, navigate bifurcations, or cross tortuous anatomy," stated Karmpaliotis. "During these procedures, the TrapLiner not only provides added backup support and deep-seating for the guide catheter, but also allows the operator to maintain guidewire positioning when exchanging the microcatheter."

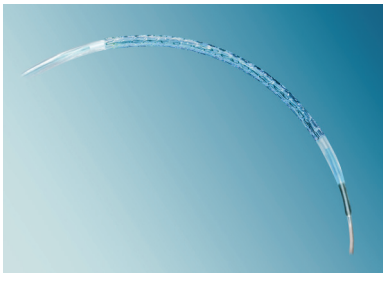
The TrapLiner Catheter received 510(k) clearance by the US Food and Drug Administration (FDA) and is available for sale in the United States and Canada.

PRO-Kinetic Energy CoCr Coronary Stent System

Biotronik
(800) 547-0394
www.biotronik.com

KEY FEATURES

- 60 µm ultrathin struts—the thinnest available in the US*
- Best-in-class flexibility, crossability, and pushability†
- Numerically, the lowest target vessel failure across FDA investigational device exemption studies‡;1-4



The Biotronik PRO-Kinetic Energy Cobalt Chromium (CoCr) Coronary Stent System recently launched in the United States after it received FDA approval. The device is available in diameters from 2.25 to 4 mm and lengths from 9 to 35 mm. PRO-Kinetic Energy system has ultrathin 60 µm struts, the thinnest available in the United States. Thinner struts have been shown to have clinically lower rates of restenosis[5,6]; the double helix stent design maintains sufficient radial strength to provide vessel support.

PRO-Kinetic Energy outperforms other stents in flexibility, crossability, and pushability and has the lowest crossing profile on the United States market.† In the BIOHELIX-I study, PRO-Kinetic Energy demonstrated the lowest numerical target vessel failure outcome of 9.06% across FDA investigational device exemption studies from leading bare-metal stent competitors.‡;1-4 ■

*Applicable for diameters 2.25 to 3 mm.
†3 mm diameter, when compared with key competitors. Biotronik data on file.
‡Results from different trials are not directly comparable. Differences in outcomes may be the result of differences in protocol design, patient populations, or other factors.

1. Biotronik: US Food and Drug Administration, Center for Devices and Radiological Health. PRO-Kinetic Energy Cobalt Chromium (CoCr) Coronary Stent System, P160003; https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160003B.pdf. Accessed March 30, 2017.
2. Medtronic: US Food and Drug Administration, Center for Devices and Radiological Health. Driver Over-TheWire, Rapid Exchange and Multi-Exchange Coronary Stent System, P030009; https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030009B.pdf. Accessed November 16, 2016.
3. Abbott Vascular: US Food and Drug Administration, Center for Devices and Radiological Health. Multi-Link Vision OTW Coronary Stent System, P020047; https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020047B.pdf. Accessed November 16, 2016.
4. Boston Scientific: US Food and Drug Administration, Center for Devices and Radiological Health, Rebel Platinum Chromium Coronary Stent System (Monorail and Over-the-Wire), P130030; https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130030B.pdf. Accessed November 16, 2016.
5. Kastrati A, Mehilli J, Dirschinger J, et al. Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO) trial. Circulation. 2001;103:2816-2821.
6. Pache J, Kastrati A, Mehilli J, et al. Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO-2) trial. J Am Coll Cardiol. 2003;41: 283-1288.