MEDTRONIC MEDICAL AFFAIRS CORNER

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Medtronic Medical Affairs Corner: A Year in Review

In 2019, challenging cases, reviews of important clinical concerns, and contextualization of various endovascular technologies were at the forefront. Highlights of last year's published articles are described herein.

Jan 2019 — Long Balloons in Practice: Improving Our Treatment Options

By Samuel N. Steerman, MD, FACS, RPVI

Dr. Steerman used a case example to highlight the IN.PACT™ Admiral™ drug-coated balloon (DCB) catheter's (Medtronic) indication expansion for the treatment of lesions ≤ 360 mm and new balloon lengths of 200 and 250 mm. The patient presented with a long chronic total occlusion (CTO) in a previously placed stent in the superficial femoral artery (SFA) and proximal popliteal artery (Figure 1). After treatment with a 6- X 250-mm IN.PACT Admiral DCB, inline flow was returned to the foot without any dissections or stent requirement (Figure 2).

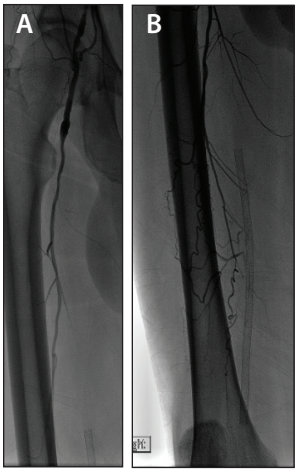

Figure 1. Preintervention angiograms: common femoral artery, profunda, and SFA (A); SFA and occluded popliteal stent (B).

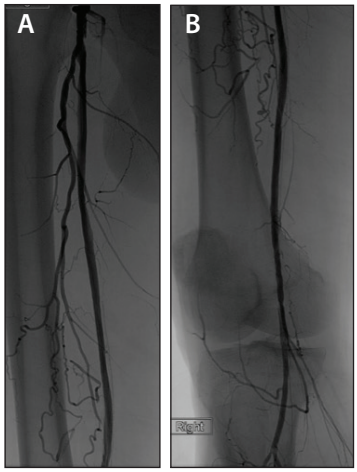

Figure 2. Postprocedure angiograms: patent SFA (A) and patent stent after treatment with the IN.PACT Admiral DCB (B).

Mar 2019 — PAD and the Battle of the Sexes

By Ageliki Vouyouka, MD, FACS, RPVI

Dr. Vouyouka discussed the challenges in diagnosing and treating women with peripheral artery disease (PAD). Many components seem to play a role: intrinsic characteristics, such as vessel size, advanced age, and body habitus, and extrinsic characteristics, such as socioeconomic challenges and misattribution of symptoms to osteoporosis or arthritis. Practice patterns and treatment have also been unequal throughout the years. Overall, endovascular treatment of PAD in women has seemed to lessen the gap between outcome differences among men and women.

Apr 2019 — Treatment Strategies for Femoropopliteal Chronic Total Occlusions

By Harry W. Donias, MD

A high-grade stenosis at the origin of the left SFA and a CTO in the mid-SFA to popliteal artery was crossed with a Viance™ crossing catheter (Medtronic). Several strat-

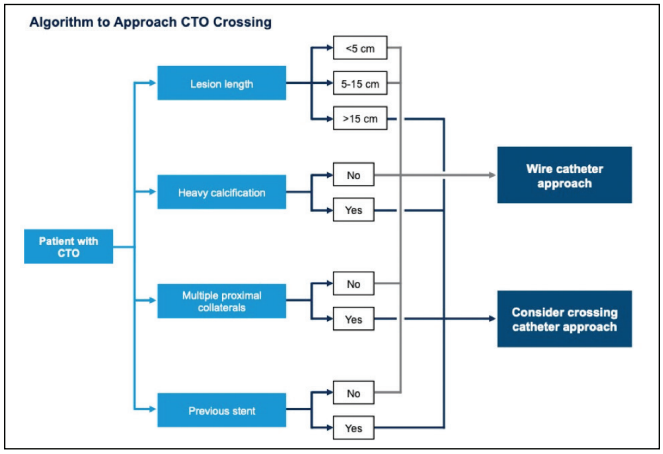

Figure 3. Treatment algorithm for crossing CTOs with varying characteristics.

egies were used for reentry, and a SpiderFX™ embolic protection device (Medtronic) was placed in the popliteal artery. Atherectomy was performed with a HawkOne™ LX directional atherectomy system (Medtronic), and an EverFlex™ self-expanding stent (Medtronic) was placed in the calcified area of the SFA. An algorithm for CTO crossing and revascularization was also presented (Figure 3).

May 2019 — Peripheral Artery Disease Below the Knee: Unique Challenges and Algorithmic Solutions

By Peter P. Monteleone, MD

Dr. Monteleone focused on guiding comprehensive below-the-knee (BTK) treatment—before the procedure and through stringent follow-up. Tips and tricks for crossing lesions BTK were discussed, with a focus on establishing a base of operations near the lesions and preserving current vessels and blood flow. Recommended vascularization techniques included the Chocolate™* percutaneous transluminal angioplasty (PTA) balloon catheter (Medtronic) and the Turbohawk™ SX-C peripheral plaque excision system (Medtronic), as well as the SpiderFX to prevent distal embolization of debris in the already-diseased vessels in the foot. Finally, guidelines for patient follow-up through wound healing were presented, emphasizing that postprocedural care must be approached with the same attention to detail as case planning.

June 2019 — Leveraging Vascular Access Clinical Trial Endpoints to Enhance Innovation

By Prabir Roy-Chaudhury, MD, PhD

This review of the endpoint development process emphasized the importance of including all stakeholders—a particular challenge in vascular access interventions. Dialysis access involves many different physicians, from the nephrologist managing the overall care of end-stage renal disease to the vascular surgeon creating the fistula and the interventionalist maintaining access (whether a vascular surgeon, interventional radiologist, or interventional nephrologist). Dr. Roy-Chaudhury discussed the importance of thoroughly defining the disease state and how the varying components of the disease state should be measured and reported. The positive impact of these efforts and how they can accelerate medical device innovation were presented.

July 2019 — Mixed Ulceration From Arterial and Venous Insufficiency: Is There an Algorithm for Treatment?

By Jon C. George, MD

This article included a case study of a patient with venous and arterial ulcers. Strategies to define disease challenges and appropriately stage patient interventions were discussed, and an algorithm for treating these complex patients was proposed (Figure 4).

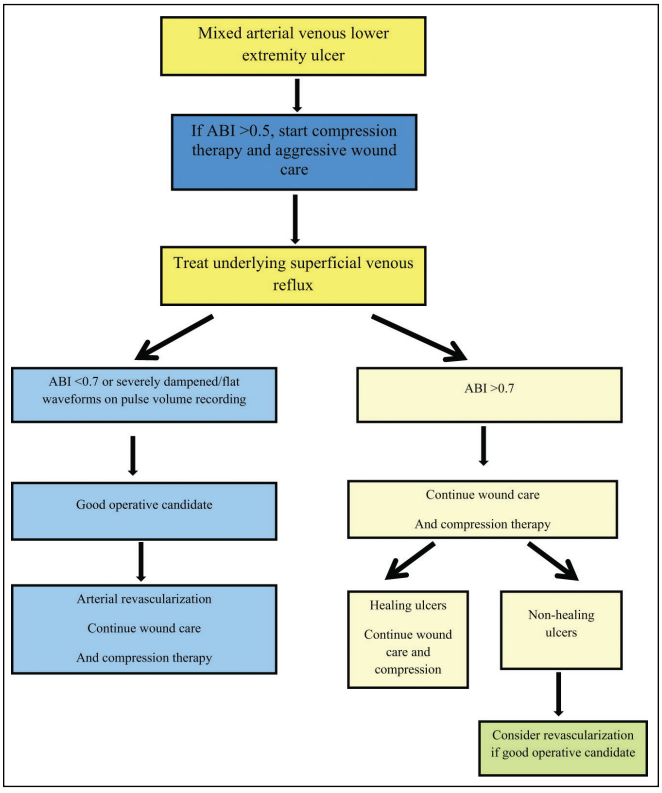

Figure 4. Treatment algorithm for patients with mixed arterial and venous lower extremity ulceration. Hedayati N, Carson JG, Chi WY, et al, Vascular Medicine (Volume 20, Issue 5) pp. 8, copyright © 2015 by (SAGE Publications). Reprinted by permission of SAGE Publications, Ltd.

Aug 2019 — Optimizing Endovascular Treatment for Multilevel Disease in Patients With CLI

By Laiq Raja, MD, FACC, FSCAI, and Lorie Henderson, APRN, MSN, NP-C

The authors presented a complex case handled by their institution's critical limb ischemia (CLI) team, a

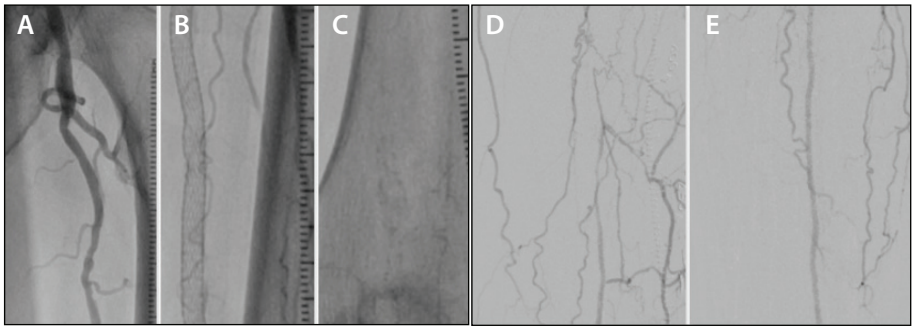

Figure 5. Prevention angiograms showing the SFA bifurcation (A), SFA (B), site of the occlusion (C), and reconstituted peroneal artery through the collaterals (D, E).

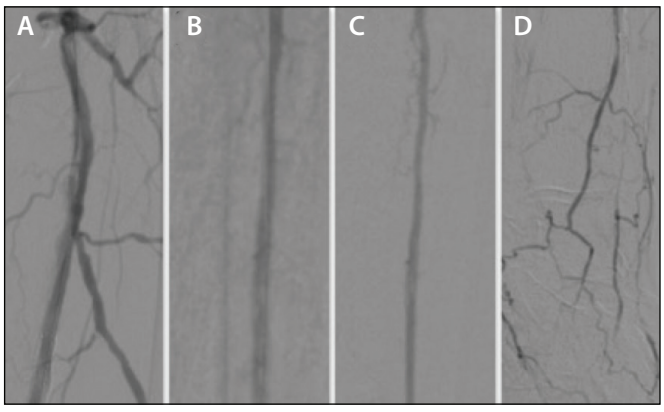

Figure 6. Final angiograms of the common femoral artery and proximal SFA (A), midproximal SFA (B), distal SFA, and peroneal artery (C). The peroneal artery giving collateral flow to the dorsalis pedis and posterior tibial artery (D).

group that has significantly reduced their amputation rates. This patient had a CTO that began at the deep profunda artery and extended into the popliteal artery, with reconstitution at the tibioperoneal trunk and a single runoff vessel to the foot (Figure 5). To further complicate matters, the occlusion in the SFA was partially stented. Techniques for accessing the diseased vessels were discussed, and treatment therapies included HawkOne, SpiderFX to protect the remaining runoff vessel, Chocolate, and the IN.PACT Admiral DCB (Figure 6). The patient's wound was completely healed at 3-month follow-up.

Sept 2019 — IN.PACT Admiral DCB: Safety and Effectiveness in Treating Complex Lesions

By Gary M. Ansel, MD, FACC

An update of the lesion length and 1-year patency scatterplot first presented in November 2018 added four new data points, further contextualizing the core laboratory–adjudicated femoropopliteal studies of FDA class 3 devices and their control arms for 2019. Included in the trends was that PTA is at the low end of the performance range, PTA and bare-metal stents have length-dependent patency outcomes, and DCBs with provisional stenting as needed may yield consistent patency outcomes with less dependence on lesion length.

Oct 2019 — Intraprocedural Monitoring of Blood Flow Using FlowMet-R

By Mahmood K. Razavi, MD, FSIR, FSVM

Dr. Razavi provided a technology review of the FlowMet™*-R intraprocedural monitoring system (Laser Associated Sciences), discussing how the device works and using a case to illustrate how flow values and velocity waveforms can reflect real-time blood flow changes during the procedure (Figures 7 and 8).

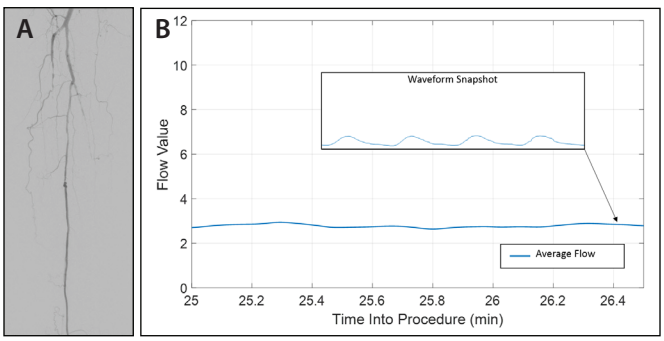

Figure 7. Baseline arteriography showing occlusion of anterior and posterior tibial arteries (A). The FlowMet-R system flow values display showing low blood flow in the CLI range (B).

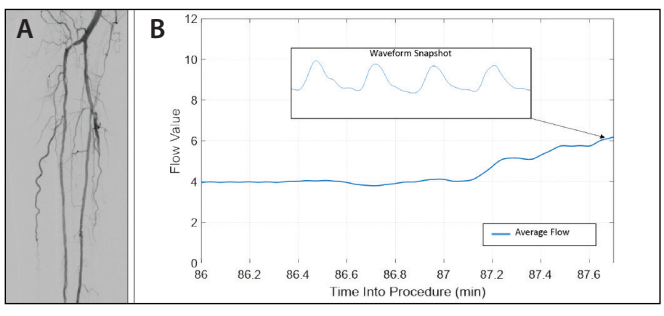

Figure 8. Prolonged balloon dilation with a larger balloon was performed in the anterior tibial artery with improved angiographic appearance (A). The FlowMet-R system flow values show further improvement in flow, close to the normal range (B).

Nov 2019

Transbrachial Access for Stenting of Femoropopliteal Lesions

By Giovanni B. Torsello, MD; Konstantinos Stavroulakis, MD; and Giovanni F. Torsello, MD

This article spoke to the options available for endovascular treatment of SFA lesions when the femoral approach is not feasible. The authors presented a case of a patient with a calcified stenosis of the distal SFA and short occlusion of the popliteal artery (Figure 9). After transbrachial access and treatment with PTA, there was a residual stenosis of 50%. Because atherectomy was not feasible due to the working lengths of these devices, an EverFlex self-expanding stent was implanted using the Entrust™ delivery system, with excellent outcomes (Figure 10). ■

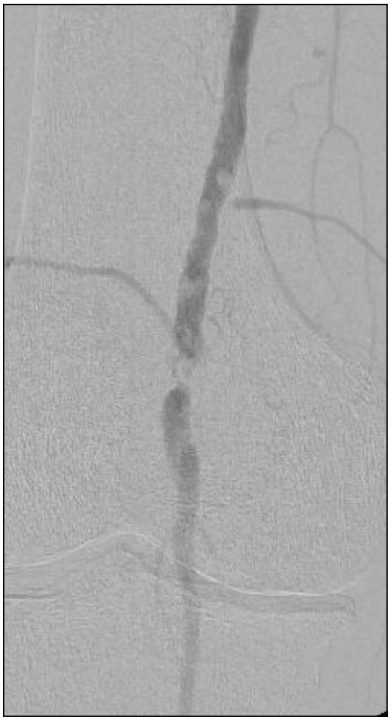

Figure 9. Initial angiogram.

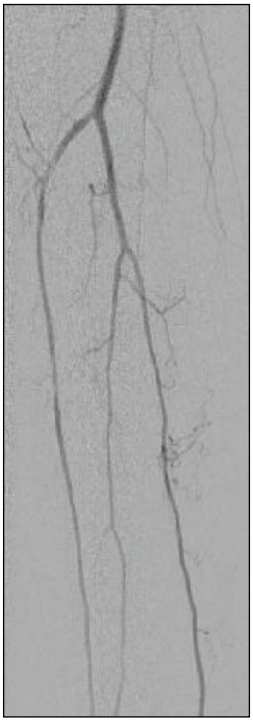

Figure 10. Postinterventional angiogram showing no peripheral thrombosis or dissection.

or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

- Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.
- Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
- Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
- Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

HawkOne™ directional atherectomy system Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The HawkOne directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

TurboHawk™ peripheral plaque excision system Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.
Indications for Use: The TurboHawk peripheral plaque excision system is intended for use in the atherectomy of the peripheral vasculature. The TurboHawk catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.
The TurboHawk catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions (LX-C only).
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

Chocolate™* PTA balloon catheter Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device.
Indications for Use: The Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries.
CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

SpiderFX™ embolic protection device Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use:

- **Lower Extremity (LE) Interventions**
  The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.
- **Carotid Interventions**
  The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.
- **Saphenous Vein Graft (SVG) Interventions**
  The SpiderFX embolic protection device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.

EverFlex™ self-expanding peripheral stent system Reference Statement
Indication: The EverFlex self-expanding peripheral stent system is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 180 mm in length in the native superficial femoral artery and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm – 7.5 mm.

- The EverFlex self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 4.5 mm - 7.5 mm.
- The Protégé™ EverFlex™ self-expanding biliary stent system is intended as a palliative treatment of malignant neoplasms in the biliary tree.

Contraindications: Use of the EverFlex self-expanding peripheral stent system is contraindicated in patients with known hypersensitivity to nickel titanium and in patients contraindicated for anticoagulant and/or antiplatelet therapy, patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Artery perforation or rupture, Bleeding requiring transfusion, Infection, Pseudoaneurysm, Restenosis, Stent collapse or fracture, Stent migration, Surgical or endovascular intervention, Thrombosis/occlusion of the stent.

See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events and device information.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

EverFlex™ self-expanding peripheral stent with Entrust™ delivery system Brief Statement
Indication: The EverFlex™ self-expanding peripheral stent with Entrust™ delivery system is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 140 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 mm - 7.5 mm.
Contraindications: Use of the EverFlex self-expanding peripheral stent with Entrust delivery system is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. The EverFlex self-expanding peripheral stent with Entrust delivery system is contraindicated for use in the carotid artery.
Potential Adverse Events: Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: allergic reaction, amputation, artery perforation or rupture, bleeding requiring transfusion, infection, pseudoaneurysm, restenosis, stent collapse or fracture, stent migration, surgical or endovascular intervention, thrombosis/occlusion of the stent.

See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

Viance™ crossing catheter Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
Indications for Use: The Viance catheter is intended for use with a guidewire to access discrete regions of the peripheral vasculature. When used as part of the peripheral system, the Viance catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.
CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

FlowMet™*-R intraprocedural monitoring system Reference Statement
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The FlowMet-R is a non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.

CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.