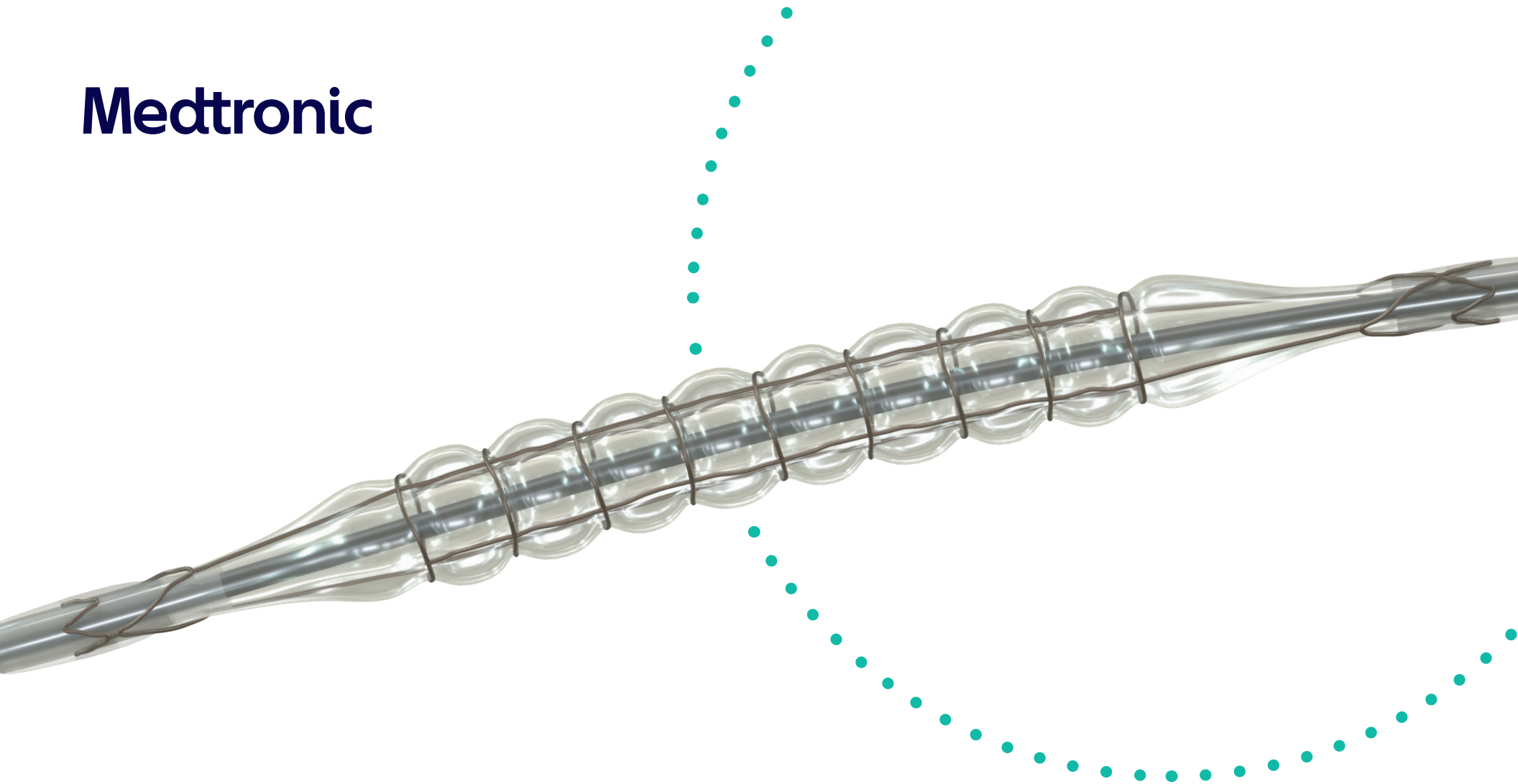
Medtronic



Chocolate™* PTA Balloon

Case book

Chocolate™* PTA Balloon

In the anterior tibial and posterior tibial

Pre-treatment

Post-Chocolate™* PTA balloon

Case note

- 3.0 mm x 40 mm Chocolate™* PTA balloon used in anterior tibial
- 3.0 mm x 40 mm Chocolate™* PTA balloon used in posterior tibial
- 3.0/2.5 mm x 210 mm NanoCross™ Elite PTA balloon used in peroneal
- Chocolate™* PTA balloon was used to alleviate dissection concerns and minimize the need for a bailout stent

Images courtesy of Dr. I. Awais Baig

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the posterior tibial

Pre-treatment

Post-Chocolate™* PTA balloon

Case note

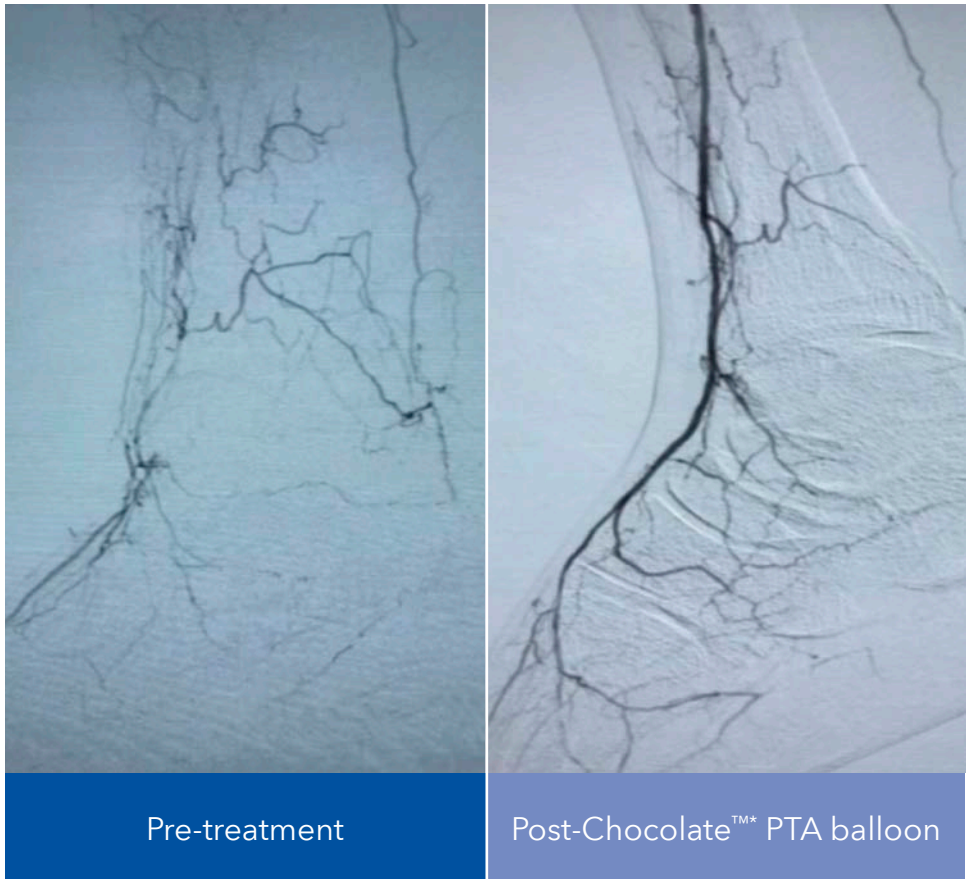
- 3.0 mm x 120 mm Chocolate™* PTA balloon used in the posterior tibial
- Chocolate™* PTA balloon was used to minimize any distal embolization and dissections

Images courtesy of Dr. Sid Rao

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the anterior tibial



Pre-treatment | Post-Chocolate™* PTA balloon

Case note

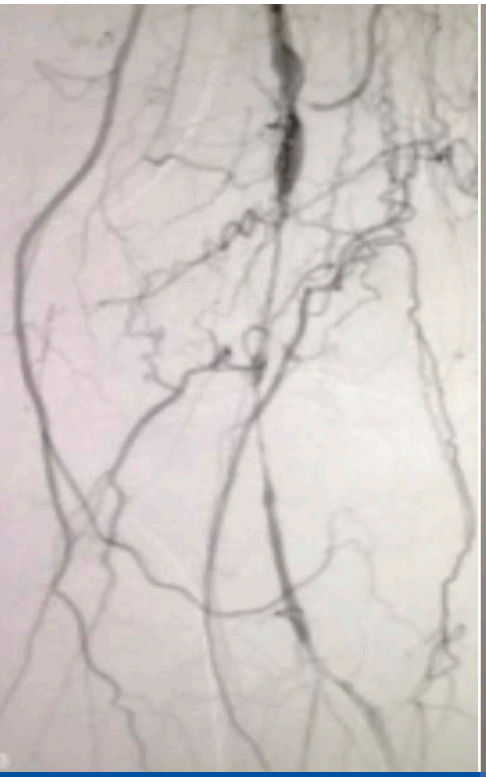
- 2.5 mm x 80 mm Chocolate™* PTA balloon used in the anterior tibial
- Chocolate™* PTA balloon used within highly stenosed distal lesion

Images courtesy of Dr. Ahmad Hussain

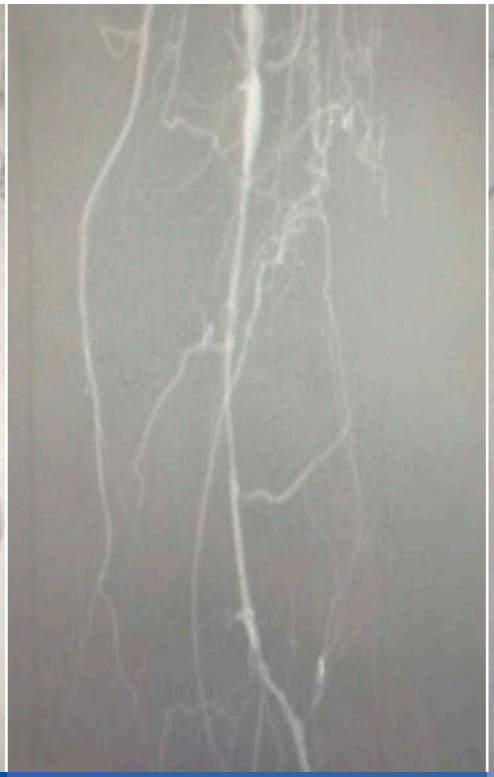
Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

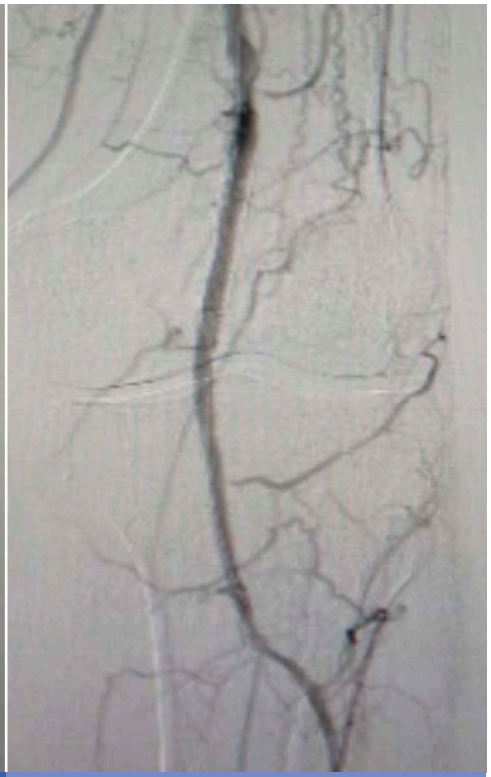
In the popliteal and anterior tibial



Pre-treatment



Post-HawkOne™ S device



Post-Chocolate™* PTA balloon

Case note

- 4.0 mm x 120 mm Chocolate™* PTA balloon used in the distal and proximal popliteal
- HawkOne™ S device used in the popliteal and anterior tibial artery
- PTA balloon used in distal popliteal and anterior tibial artery
- Chocolate™* PTA balloon was used based on low dissection rates from Chocolate BAR Registry[1]

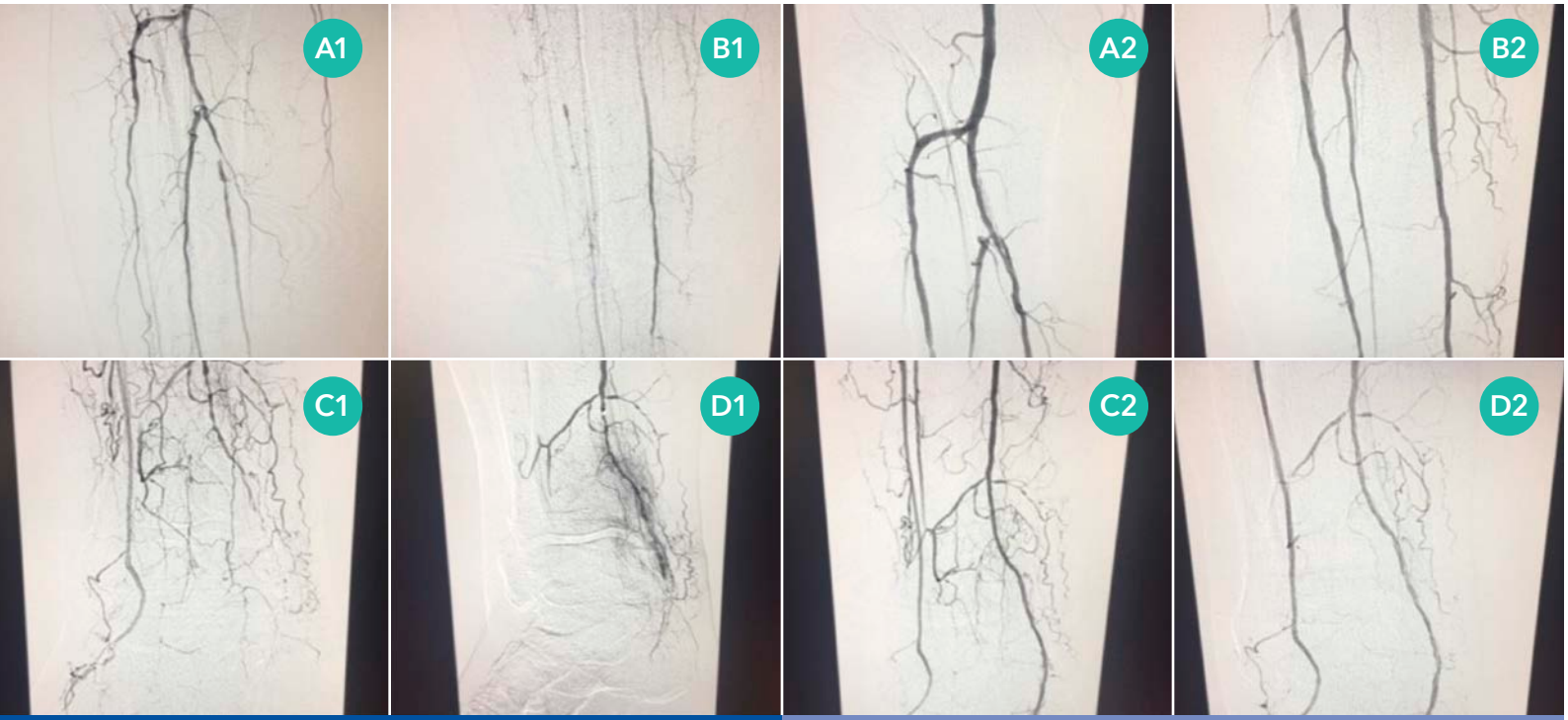
Images courtesy of Dr. Chris Pollock

Results may vary depending on lesion characteristics. Use angiographic assessment to determine treatment.

[1] Mustapha JA, Lansky A, Shishehbor M, et al. A Prospective, Multi-Center Study of the Chocolate Balloon in Femoropopliteal Peripheral Artery Disease: The Chocolate BAR Registry. *Catheter Cardiovasc Interv*. May 1, 2018;91(6):1144-1148.

Chocolate™* PTA Balloon

In the popliteal, anterior tibial, and peroneal



Pre-treatment

Post-Chocolate™* PTA balloon

Case note

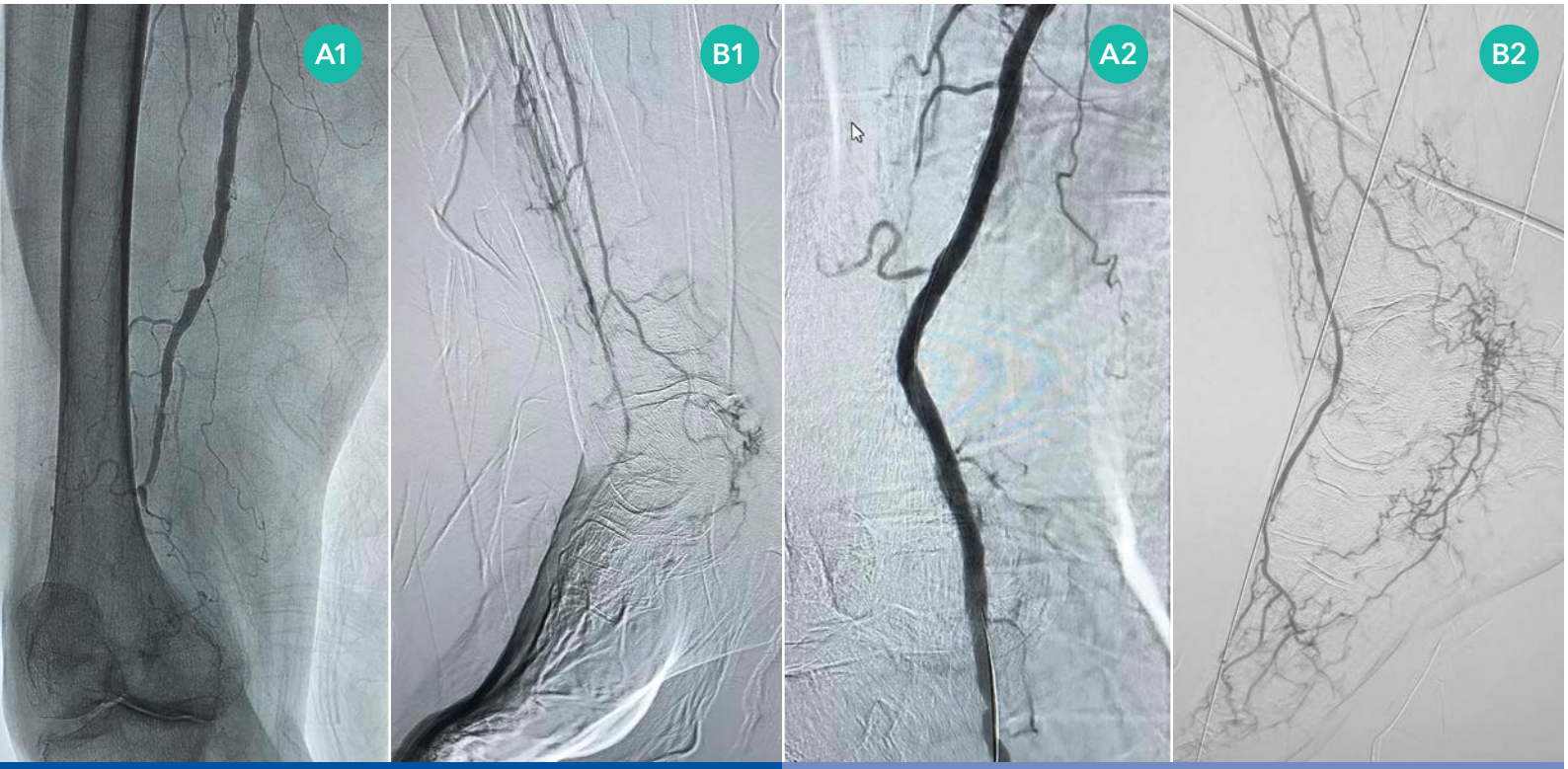
- 4.0 mm x 120 mm Chocolate™* PTA balloon used in the tibioperoneal trunk into the posterior tibial and anterior tibial
- 2.0 mm x 80 mm NanoCross™ Elite PTA balloon used in distal posterior tibial and into the plantar
- 2.5 mm x 120 mm NanoCross™ Elite PTA balloon used in the distal anterior tibial
- Chocolate™* PTA balloon used to minimize flow-limiting dissection BTK and establish perfusion to the foot

Images courtesy of Dr. David Stewart

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the popliteal



Pre-treatment

Post-Chocolate™* PTA balloon

Case note

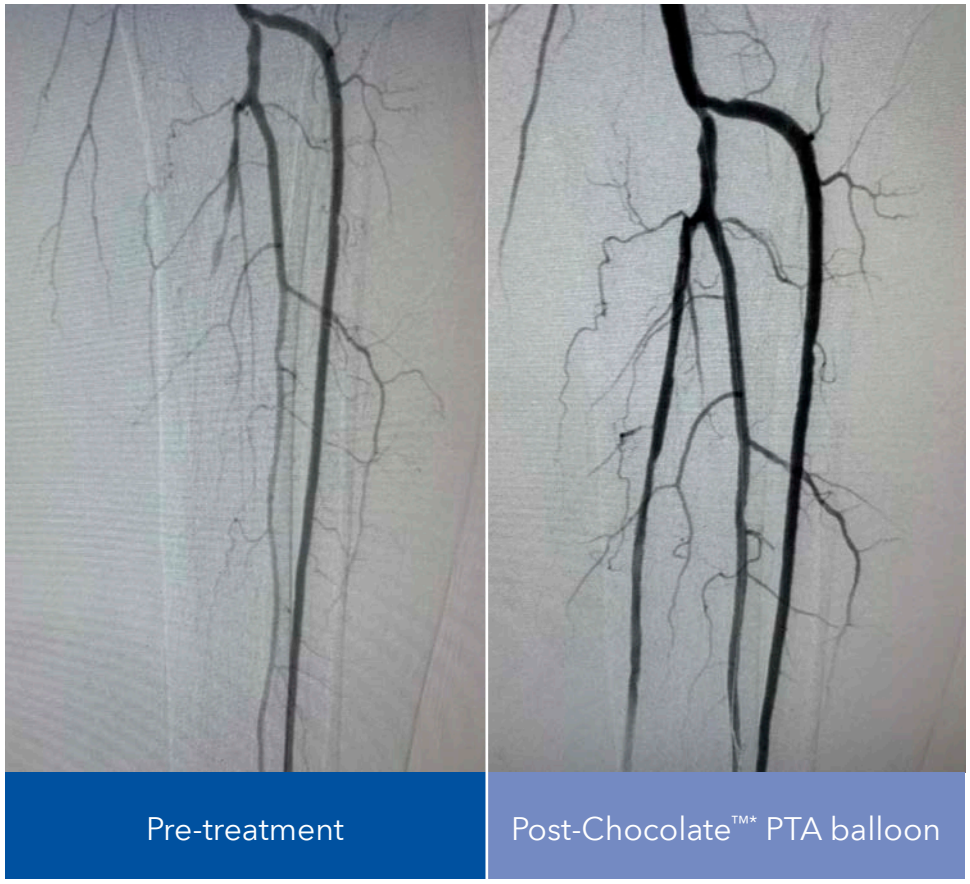
- 5.0 mm x 120 mm Chocolate™* PTA balloon used in the popliteal
- Physician chose to utilize Chocolate™* PTA balloon, based on diabetic patient's age (93), to treat wound on foot

Images courtesy of Dr. Zlatan Stepanovic

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the posterior tibial and peroneal



Pre-treatment | Post-Chocolate™* PTA balloon

Case note

- 2.5 mm x 120 mm Chocolate™* PTA balloon used in the posterior tibial
- 3.0 mm x 120 mm Chocolate™* PTA balloon used in the peroneal
- Chocolate™* PTA balloon used to minimize dissections

Images courtesy of Dr. Robert Corn

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the popliteal

Pre-treatment | Post-Chocolate™* PTA balloon

Case note

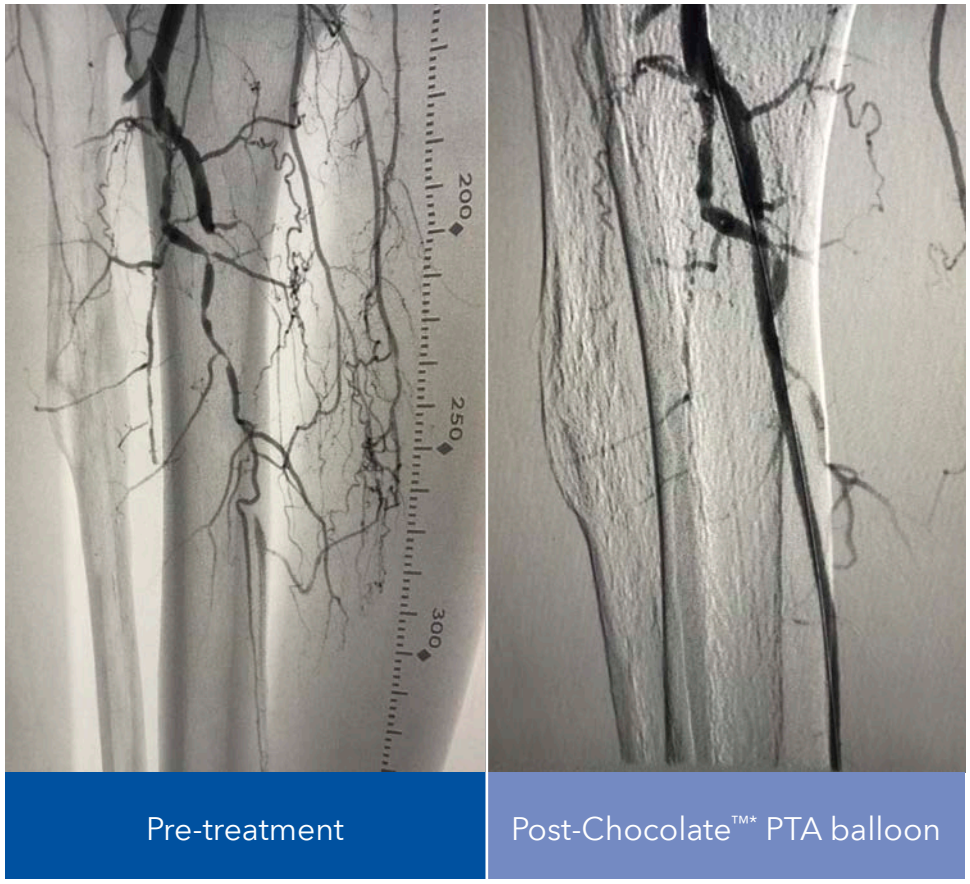
- 4.0 mm x 120 mm Chocolate™* PTA balloon used in the popliteal
- 4.0 mm x 150 mm IN.PACT™ Admiral™ DCB used post-Chocolate™* PTA balloon
- Chocolate™* PTA balloon was used to minimize dissection, prep for IN.PACT™ Admiral™ DCB

Images courtesy of Dr. Anne Henderson

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the posterior tibial



Pre-treatment

Post-Chocolate™* PTA balloon

Case note

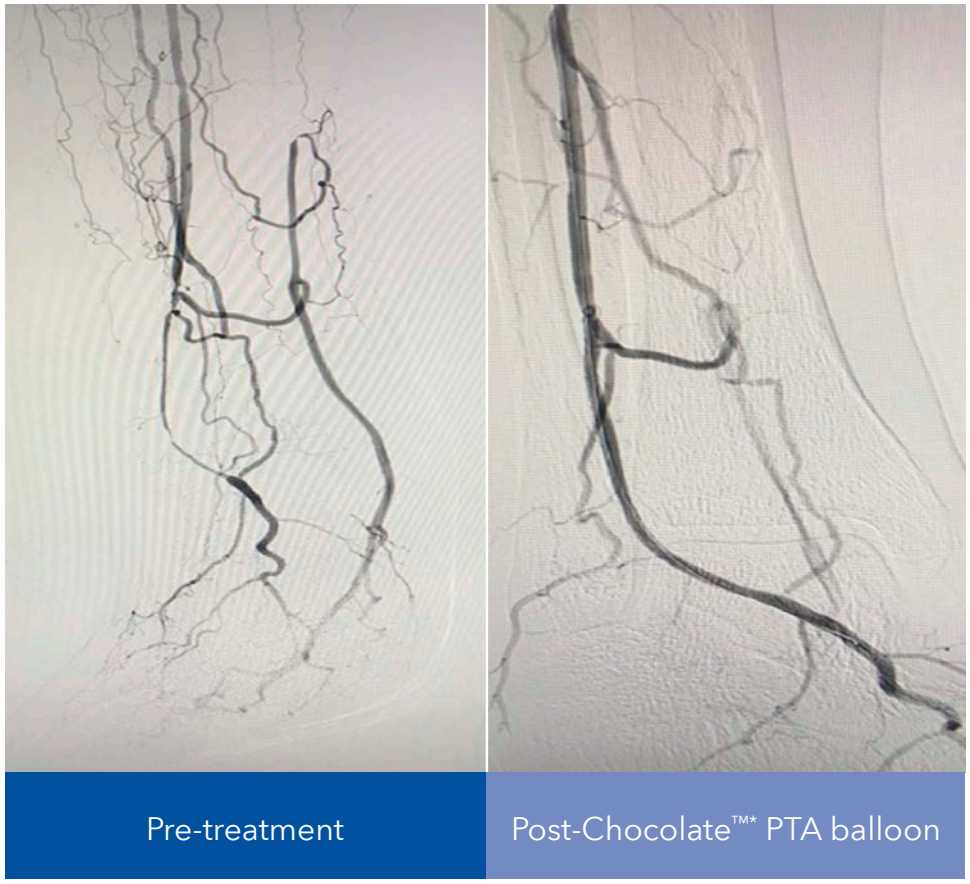
- Distal flow protected with a 3.0 mm SpiderFX™ filter
- HawkOne™ S device was used on posterior tibial before Chocolate™* PTA balloon
- 3.0 mm x 120 mm Chocolate™* PTA balloon used in the posterior tibial
- Chocolate™* PTA balloon used as it was a single-vessel runoff in a critical patient with CLI and extensive tissue loss who could not afford a dissection

Images courtesy of Dr. Laiq Raja

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the peroneal



Pre-treatment | Post-Chocolate™* PTA balloon

Case note

- 4.0 mm x 120 mm Chocolate™* PTA balloon used in the proximal peroneal
- 3.5 mm x 120 mm Chocolate™* PTA balloon used in the distal peroneal
- Chocolate™* PTA balloon used to minimize dissections

Images courtesy of Dr. Dan Dishmon

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Chocolate™* PTA Balloon

In the SFA and popliteal

Pre-treatment | Post-Chocolate™* PTA balloon

Case note

- Distal flow protected with a 5.0 mm SpiderFX™ filter
- 4.0 mm x 80 mm Chocolate™* PTA balloon used in the SFA and popliteal
- HawkOne™ S device was used in the SFA and popliteal before Chocolate™* PTA balloon
- Chocolate™* PTA balloon used due to highly stenosed burden

Images courtesy of Dr. Christian Ochoa

Results may vary depending on lesion characteristics.
Use angiographic assessment to determine treatment.

Brief statements

Chocolate™* PTA Balloon Catheter
Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labeling 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, infra-popliteal, and renal arteries.

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

HawkOne™ Directional Atherectomy System
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™ peripheral 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 to sale by or on the order of a physician.

IN.PACT™ Admiral™ Drug-coated Balloon
Indications for Use
The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of *de novo*, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications
The IN.PACT Admiral DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of anangioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2–3 years post-treatment compared with the use of non-drug-coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.**
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.

Brief statements, cont'd.

- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1,419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1,115 kPa). The RBP is based on the results of *in vitro* testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects

The potential adverse effects (e.g., complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, 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 *Physicians' 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.

NanoCross™ Elite 0.014" PTA Balloon Catheter
Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter is intended to dilate stenosesin the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

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

SpiderFX™ Embolic Protection Device
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 3.0 mm and 7.0 mm.

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 3.0 mm to 6.0 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

Medtronic

medtronic.com/peripheral