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Navigating the Ins and Outs of CLI Care During the COVID-19 Pandemic

By Gregory A. Stanley, MD, FACS

The current COVID-19 pandemic has caused unprecedented disruption and strain on the health care system worldwide. Much of the focus and many of the health care resources have been diverted to pandemic management. Challenges arising from this health emergency such as reduced access to care, personnel safety concerns, disruption of the supply chain, and job loss (including loss of health care coverage and financial stress) have led to delays in diagnosis and treatment of many health conditions. Cardiovascular diseases including peripheral artery disease (PAD) require continuous care and, in some cases, rapid intervention to prevent debilitating consequences such as limb loss. The impact of the pandemic is exacerbated in the sicker and vulnerable patient population, including those with critical limb ischemia (CLI).

As the most advanced form of PAD, CLI is defined by ischemic foot pain at rest, nonhealing wounds or ulcers, and/or gangrene in one or both extremities as a result of severe arterial insufficiency. CLI is estimated to be prevalent in approximately 2 million people in the United States,[1] and it is likely to increase in the aftermath of the pandemic as patients defer medical care. Patients with CLI tend to present with multilevel occlusive disease and multiple cardiovascular comorbidities, leading to an increased risk of cardiac events and mortality.[2] The major amputation rates in patients with CLI are as high as 40% within 6 months of presentation.[3] These poor baseline outcomes have only been compounded further by the COVID-19 pandemic. An observational study in Italy reported an almost 50% increase in the rate of amputations during the pandemic compared with the previous year.[4]

CLI is a complex disease that requires a multidisciplinary team approach with the goal of limb salvage and improving quality of life. At our institution, this approach includes aggressive medical management, revascularization, wound care, podiatric and orthotic care, nutritional assessment and supplementation, management of risk factors (eg, smoking cessation), and optimization of home care and other resources. We have streamlined the outpatient care process with urgent preprocedure appointments with all necessary subspecialists to minimize hospitalization and maintain continuity of care. Fortunately, endovascular therapy often offers a suitable revascularization option because of its wide applicability, shorter postoperative recovery time, and reduced infection risk.

To achieve our outpatient goals, we attempt to leverage the most effective endovascular technologies available that provide high patency rates, decreased reinterventions, and significant wound healing potential. Lesion debulking with directional atherectomy is a reliable and effective endovascular strategy that allows the operator to reach their desired level of debulking; in my experience, it has been enhanced further when followed by drug-coated balloon (DCB) angioplasty. The DEFINITIVE LE study, a core-lab adjudicated, multicenter, prospective study, demonstrated the safety and effectiveness of directional atherectomy in 799 patients with PAD (1,022 target lesions).[5] The study included patients with CLI, infrapopliteal lesions, and subcohorts of sicker patients. The 12-month primary patency rate across all anatomic vascular beds was 78% in claudicants, 71% in patients with CLI, and 77% in the diabetic group. There was a 95% rate of freedom from major amputation in patients presenting with CLI, including those with a Rutherford classification of 5 or 6 and tissue loss. With the addition of paclitaxel-based endovascular therapies for superficial femoral artery (SFA)/popliteal lesions based on data reported from the IN.PACT SFA trial,[6] we expect similarly high primary patency rates and single-digit target lesion revascularization rates at 1 year. An examination of this treatment strategy was performed in the DEFINITIVE AR study.[7] Although the study was not powered to provide a statistically significant

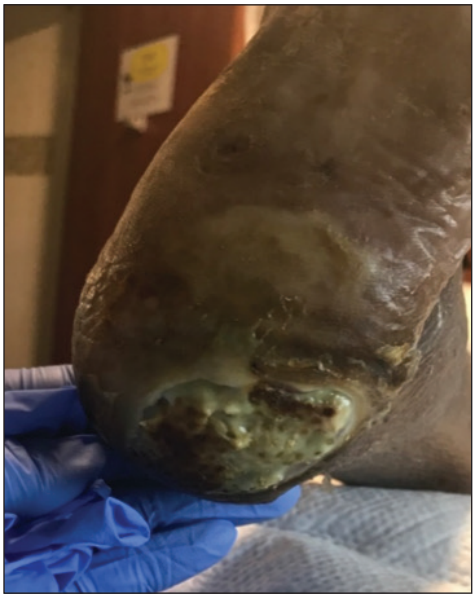

Figure 1. A 3-month-old left heel wound in a patient with CLI.

	Discipline	Strategy
Initial Examination	Imaging	• Left foot MRI shows osteomyelitis of calcaneus
	Ambulatory Status	• Stands to transfer
Risk Factor Management	Smoking Cessation	• Nonsmoker
	Endocrine	• Hgb A1C: 8.1 • Strict blood glucose monitoring, daily goal <200
	Renal	• Cr 1.46
	Nutrition	• Albumin: 2.6 g/dL • CRP: 4.4 mg/dL (elevated) • Initiate Juven and Glucerna supplements
Medications	Infectious Disease	• Intravenous broad-spectrum antibiotics pending bone biopsy for speciation/sensitivity
	Antiplatelet/ Anticoagulation	• Continue warfarin • Initiate clopidogrel daily post-procedure
	Lipids	• Continue high-dose statins
Limb Treatment & Care	Vascular	• Rutherford 6 • Planned revascularization (angiogram with intervention)
	Wound Care	• Debridement with negative pressure dressing placement
	Podiatry	• No urgent needs
	Offloading	• Orthotics consult for heel offloading shoe
	Follow up	• Wound check within 1 week of discharge • Medical specialty follow-up

Figure 2. The limb salvage plan for the patient with CLI in case 1. Cr, creatinine; CRP, C-reactive protein; Hgb, hemoglobin.

conclusion, the combination of directional atherectomy and DCB angioplasty was found to be effective and safe. We await more definitive results of this combination treatment from the REALITY trial, which is currently collecting and analyzing adequate follow-up data.

The following cases demonstrate some of the challenges to CLI care during the COVID-19 pandemic. The standardized and aggressive institutional protocols for CLI patients have been adapted and optimized through positive and negative lessons learned as we continue to cope with the unprecedented obstacles of care amidst the global pandemic.

CASE 1

A woman in her early 70s was admitted with congestive heart failure exacerbation (ejection fraction, 20%) and was found to have a 3-month-old left heel wound (Figure 1).

The patient was a nonsmoker with stage 3 chronic kidney disease, diabetes mellitus, coronary artery disease, and previous stroke with right lower extremity paralysis. She was using her left leg to transfer and therefore remained surprisingly mobile. A left lower extremity arterial duplex ultrasound demonstrated occlusion of the SFA, with reconstitution of the popliteal artery, severe stenosis in the P1 segment, and monophasic tibial waveforms. MRI demonstrated osteomyelitis of the left calcaneus. The decision was made to proceed with limb salvage attempts to maintain her mobility, which would be nonexistent after left leg amputation.

Given her inpatient status and CLI (Rutherford classification 6), she was deemed an essential surgical candidate per our institution's COVID-19 operative case classification. Therefore, she was medically optimized with the initiation of a limb salvage plan (Figure 2) and started on intravenous antibiotics.

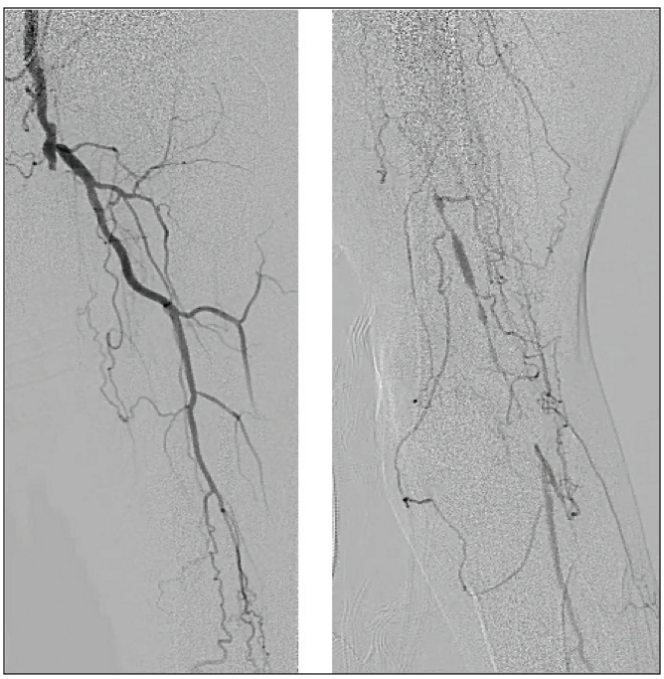

Figure 3. Initial angiograms demonstrating sequential SFA and popliteal artery chronic total occlusions.

The patient underwent heel debridement with bone biopsy and negative pressure wound dressing. The day after debridement, she underwent left lower extremity angiography via right femoral access, which demonstrated severe stenosis of the external iliac artery and SFA/popliteal chronic total occlusions (Figure 3).

Successful recanalization was performed with directional atherectomy of the SFA and popliteal artery using the

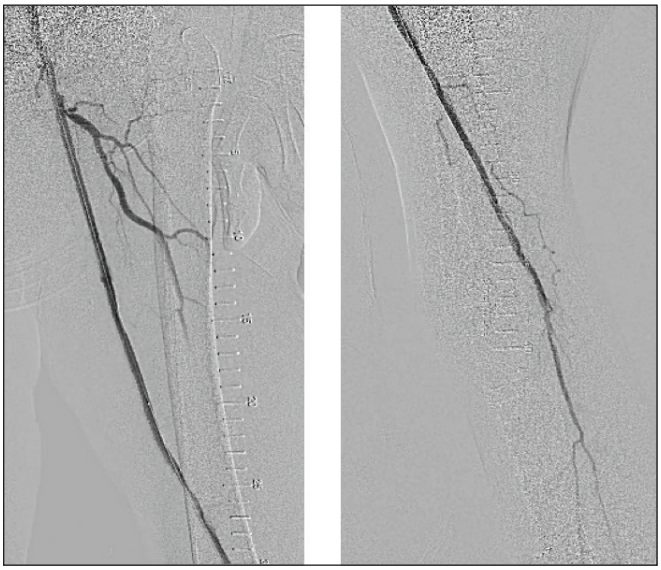

Figure 4. Completion angiograms of the SFA and popliteal artery after directional atherectomy with the HawkOne LX catheter over a 7-mm SpiderFX embolic protection device filter wire, followed by 5- X 250-mm and 5- X 200-mm IN.PACT Admiral DCBs.

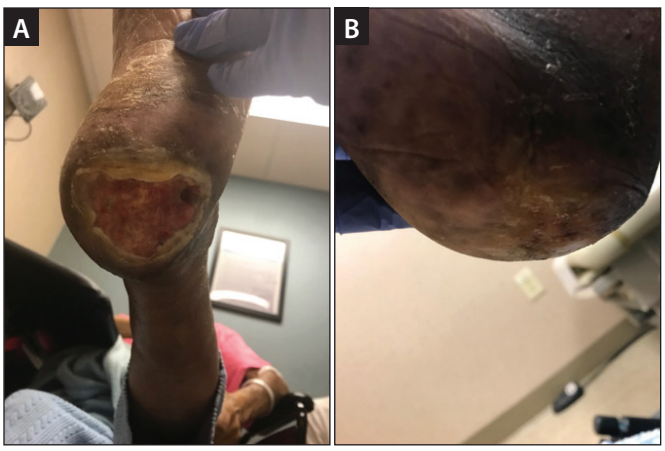

Figure 5. The first follow-up visit after the index procedure within 7 days of discharge showing the heel wound granulating well (A). The healed heel wound at the 2.5-month follow-up visit (B).

HawkOne™ LX directional atherectomy system catheter (Medtronic) over a 7-mm SpiderFX™ embolic protection device filter wire (Medtronic), followed by 5- X 250-mm and 5- X 200-mm IN.PACT™ Admiral™ drug-coated balloons (Medtronic). Completion angiograms are shown in Figure 4. The external iliac artery stenosis was treated with angioplasty and a bare-metal stent.

With a palpable posterior tibial artery pulse after the intervention, the patient had a final inpatient heel debridement 4 days later. She was medically stable, with all limb salvage treatment goals optimized, continued outpatient management was coordinated including intravenous antibiotics, and the patient was then discharged home. Her first follow-up visit was in person and completed within 7 days of discharge, and her heel wound was granulating well (Figure 5A). Our CLI nurse navigator confirmed all outpatient care was continuing as planned. Throughout the COVID-19 pandemic, weekly or biweekly virtual visits were performed using real-time video documentation of the heel wound with assistance from the patient's family members. The patient continued to attend weekly wound care clinic visits with appropriate personal protective equipment. The patient took Juven™* nutritional supplements (Abbott) until wound healing was confirmed. The coordination of virtual visits with medical specialty clinics successfully maintained comorbidity equipoise, and all challenges to care were addressed by our nurse navigator. Over the course of 2.5 months, the patient's left heel wound healed and continues to do well (Figure 5B).

CASE 2

A man in his early 60s with hypertension, poorly controlled diabetes, and severe PAD after a right below-knee amputation 3 years ago presented for evaluation after the development of gangrene on multiple toes of the left foot. He underwent left second toe amputation at an outside hospital 3 weeks before presentation and had breakdown of the incision with several new areas of ulceration. The ankle-brachial index was falsely elevated (0.96), and the toe pressure was 0. A left lower extremity arterial duplex ultrasound showed a patent femoropopliteal segment, with monophasic flow through the anterior tibial and occluded posterior tibial/peroneal arteries. Osteomyelitis of the fifth metatarsal head was confirmed by an MRI.

The patient remained ambulatory with a right lower extremity prosthesis and was motivated to save his left leg to maintain employment. Therefore, we elected to proceed with limb salvage attempts and again applied our systematic approach for limb salvage treatment (Figure 6).

Because the patient presented to the ambulatory clinic early in the COVID-19 outbreak, we elected to treat him via our standard outpatient pathway to preserve inpatient beds for an expected surge of COVID-19–positive patients. The patient was taken to the hybrid operating room and underwent left lower extremity angiography via antegrade left femoral access, which demonstrated severe infrapopliteal occlusive disease (Figure 7) with a dominant anterior tibial artery that occluded distally and reconstitution of the dorsalis pedis artery.

Intervention and recanalization of the anterior tibial artery were performed with directional atherectomy using a HawkOne S catheter (Medtronic) over a 3-mm SpiderFX protection device embolic filter wire (Medtronic) (Figure 8A). Postdilatation was performed with a 2.5-mm angioplasty balloon. Completion angiography is shown in Figure 8B. Mild vasospasm visualized in this angiogram resolved with intra-arterial nitroglycerin administration. The

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	Discipline	Strategy
Initial Examination	Imaging	• Left foot MRI shows osteomyelitis of 5th metatarsal head
	Ambulatory Status	• Ambulatory with RLE prosthesis
Risk Factor Management	Smoking Cessation	• Former smoker • Quit in June 2019
	Endocrine	• Hgb A1C: 8.1 • On metformin
	Renal	• Cr 0.78
	Nutrition	• Juven samples provided
Medications	Antiplatelet/ Anticoagulation	• Aspirin + Atorvastatin + Xarelto
Limb Treatment & Care	Vascular	• Rutherford 5-6 • s/p right below knee amputation • Left lower extremity arterial duplex shows patent femoropopliteal segment with monophasic flow through anterior tibial and occluded posterior tibial/peroneal artery • Plan for left lower extremity revascularization (angiogram with intervention)
	Wound Care	• Multiple toe wounds • Local wound care with Aquacel Ag dressings and santyl to amputation sites • Betadine to necrotic areas • Weekly visits at the nearby wound care center
	Podiatry	• Evaluated pre-COVID-19 at the Local Foot & Ankle Clinic
	Offloading	• Referral to orthotics for front offloading shoe
	Follow up	• Plan for video virtual visit within 1 week of discharge • Medical specialty follow-up

Figure 6. The limb salvage plan for the patient with CLI in case 2. RLE, right lower extremity; s/p, status post.

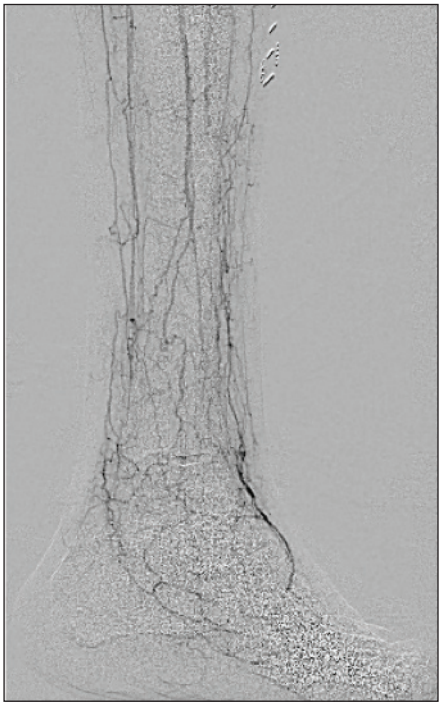

Figure 7. The initial angiogram of the left anterior tibial artery showing distal occlusion with reconstitution of the dorsalis pedis artery.

patient had a palpable dorsalis pedis pulse. He underwent ray amputation of the third, fourth, and fifth toes, as well as debridement of the nonhealing second toe amputation site. The patient was discharged home the same day.

The first planned virtual follow-up visit was within 7 days of discharge, and it was converted from a video visit to a phone visit because the patient was unable to connect adequately. His own assessment of the incision was satisfactory, but he did not have an adequate understanding of how to take or deliver pictures of his incision to our team. We initiated home health wound care and received a poor-quality phone picture demonstrating wound breakdown several days later (Figure 9). The patient was unable to attend requested in-person visits with our clinic or the wound care clinic because of transportation issues during the shelter-in-place order. The patient was also unable to obtain a front offloading shoe due to store closure and transportation issues. Despite good compliance with medications, he did not notify the team that his nutrition supplementation supply was extinguished, and he did not obtain refills.

Ultimately, the patient presented for an in-person visit 4 weeks postprocedure. His dorsalis pedis pulse was palpable and the great toe pressure measured 86 mm Hg. Unfortunately, by that time, the wound breakdown and lack of appropriate wound care left the foot beyond salvage. The patient underwent below-knee amputation shortly thereafter.

> "At the crux of each case is not only a fundamental assessment of the patient's health condition but also an honest judgment of the patient's functional care network and their capacity to operate within that network."

DISCUSSION

Patients with CLI remain a complicated and challenging population to treat, necessitating a successful revascularization procedure followed by strict coordination and oversight of multiple competing treatment plans. An incomplete execution of any one plan addressing the required healing components may be sufficient to derail the entire project and thus result in limb loss. This task is formidable in our standard operating environment and has only been exacerbated by the COVID-19 pandemic.

As the previous cases illustrate, acceptable and successful treatment of CLI patients and limb salvage remains possible amid a crippled health care system during a pandemic. However, we must recognize that the magnitude of obstacles we face to achieve adequate CLI care has mul-

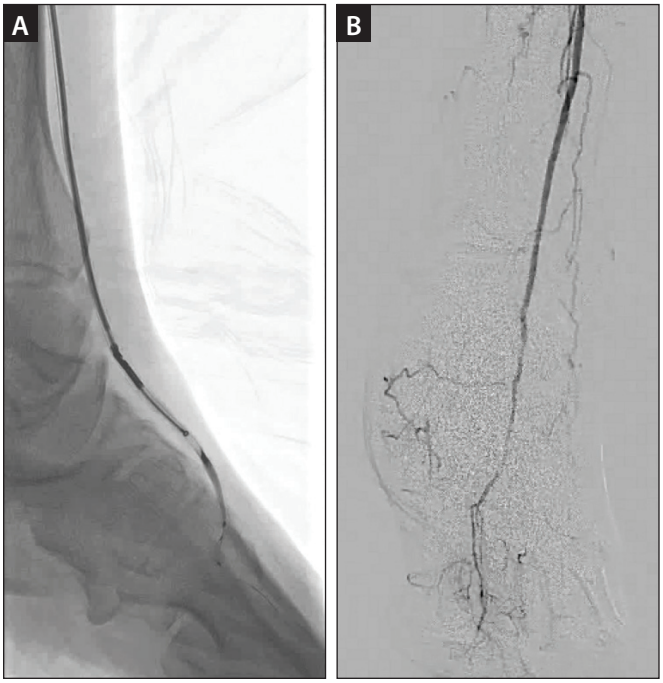

Figure 8. Revascularization of the anterior tibial artery with directional atherectomy using a HawkOne S catheter over a 3-mm SpiderFX embolic filter wire (A). A completion angiogram of the anterior tibial artery (B).

tiplied significantly. At the crux of each case is not only a fundamental assessment of the patient's health condition but also an honest judgment of the patient's functional care network and their capacity to operate within that network. In pre–COVID-19 times, a formal medical assessment (wound status, type of revascularization) would be the driving consideration for inpatient versus outpatient care because, in most instances, we have established and optimized the outpatient care network and treatment plan for CLI patients. However, during the pandemic, the status of the outpatient care network has become the primary driver of inpatient admission. Without a functioning outpatient network and a reliable patient, the likelihood of limb salvage decreases dramatically. Limited in-person clinic visits and closed specialty offices because of social distancing specifications/requirements may lead to suboptimal medication adjustments, improper or nonexistent wound debridement and/or dressing changes, and the inability to obtain prosthetic equipment, among other impediments. Furthermore, elderly patients who do not own smartphones or understand how to adequately use the camera are ill-equipped to provide adequate updates on their progress, whether for virtual visits or wound healing progress. A strong family unit may be able to overcome some of these issues provided they do not become ill themselves, but for solitary patients, any one of these obstacles (including transportation) can be a hindrance to a standard treatment strategy. Ultimately, the expected and required level of care for limb salvage in the outpatient setting may no longer be available.

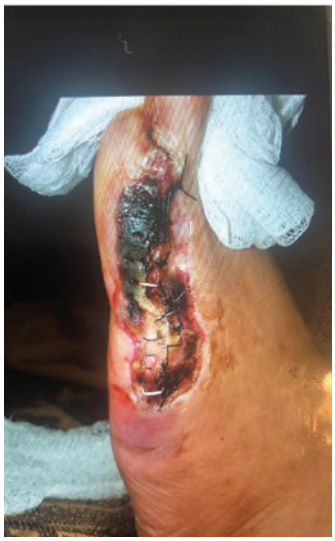

Figure 9. A phone picture taken by the patient showing wound breakdown after initiating home health wound care 7 days post–index procedure.

Understanding that it is impractical and frankly unnecessary to place every CLI patient into inpatient status, it is entirely appropriate to consider a number of these patients as "urgent" cases that justify operative/procedural and inpatient resources. The focus is placed on early medical specialty consultation, expedient revascularization, and wound debridement/care. Active engagement with the functioning outpatient care providers prior to discharge and having contingency plans in place can avoid early missteps and treatment plan failures. Further, an outpatient CLI nurse coordinator may help the patient navigate and troubleshoot obstacles out of the hospital as they arise, which will help keep the treatment plan on track. It is with early and aggressive health care intervention followed by strict and persistent coordination of care that we can provide CLI patients with the best possible opportunity for limb salvage.

CONCLUSION

Patients presenting with CLI require an intense, focused treatment plan to optimize limb salvage. Many of the components in the treatment strategy may be disrupted or nonexistent during the COVID-19 pandemic because of the severe strain placed on the health care system. The reliability of both outpatient care providers and patients has proven to be a significant limiting factor for adequate treatment. As such, the delicate balance of inpatient versus outpatient care of CLI patients may require a paradigm shift during the pandemic to optimize outcomes. ■

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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 an angioplasty 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.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 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 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.

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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.

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SpiderFX™ embolic protection device Brief Statement
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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.

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