ABBOTT EDUCATION NETWORK

VASCULAR

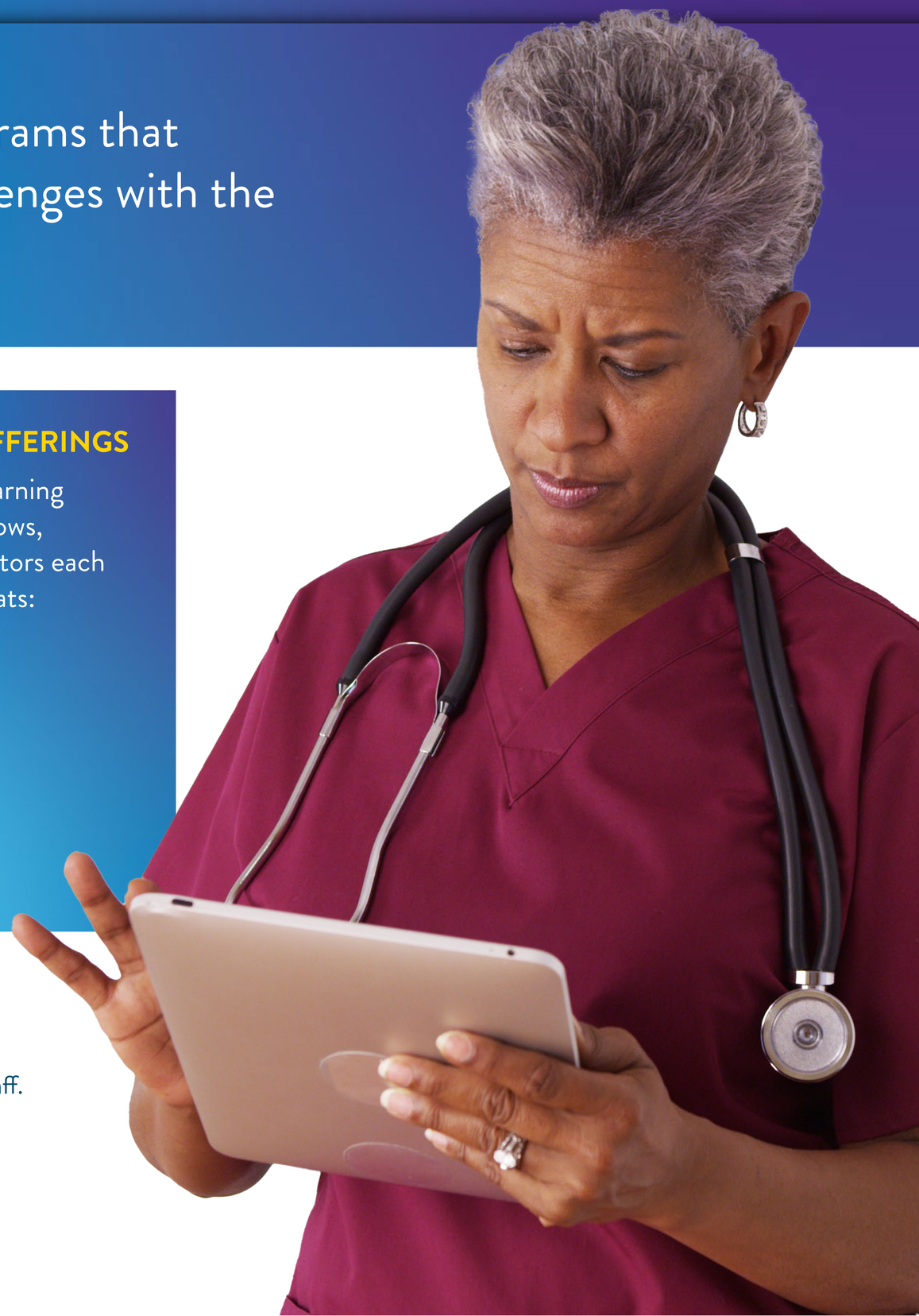
SCIENCE • INNOVATION • PRACTICE

Clinical Pathways

MEDICAL EDUCATION COURSE CATALOG

Abbott

Our mission is to provide exceptional educational programs that address today's clinical, technical, and procedural challenges with the ultimate end goal of improving patient outcomes.



CUSTOMIZED MEDICAL EDUCATION

Thoughtful, engaging curricula grouped to support relevant topics:

- Intravascular Imaging/ OCT & Physiology
- Microvascular Dysfunction
- Complex PCI
- CTOs
- Vessel Closure
- Peripheral Artery Disease
- Iliac/SFA/BTK Treatment
- Carotid Artery Disease

COMPREHENSIVE OFFERINGS

Tailored to the specific learning needs of Physicians, Fellows, Lab Staff, and Administrators each available in multiple formats:

- On-demand
- Virtual
- In-person

The Abbott Education Network (AEN) is a premier educational resource program that was developed in partnership with healthcare professionals to provide best-in-class training courses. As a leader in innovative training programs, AEN offers an impressive educational portfolio for both Endovascular and Coronary Interventions for today's cardiovascular interventional teams that include physicians, fellows, and cath lab staff. AEN offers the broadest array of educational opportunities related to Vascular*, Structural Heart, Heart Failure, Electrophysiology, Cardiac Rhythm Management, Neuromodulation, Diabetes Care and Nutrition.

*Educational opportunities featured herein.

IN-PERSON

- CAS Fundamentals and Advanced Management
- CEUs
  - Coronary
  - Endovascular
- CTO Programs
- EndoFellows Program
- EndoMasters™ Medical Education Program
- PCI Fellows Program
- PCI Masters™ Medical Education Program
- PCI Optimization Courses
- Proctorship Programs
- Product Training
- OCT Virtual Reality
- Regional Speakers
- Vessel Closure Hands-On Practicum

VIRTUAL

- CEUs
  - Coronary
  - Endovascular
- National Webcasts
- OCT Skills Lab
- Regional Speakers

ON-DEMAND

- Abbott Cardiovascular Website
- Med Ed Now
- Vessel Closure Resource Center

Pathways are a way of grouping educational offerings based on a topic of interest or specialty. The options for each Pathway can be taken in any order.

PERIPHERAL ARTERY DISEASE

- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

PERIPHERAL INTERVENTIONS

- EndoMasters™ Medical Education Program
- Endovascular Proctorship Program
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CAROTID ARTERY DISEASE – STENTING & MANAGEMENT

- CAS Proctorship Program
- CAS Fundamentals & Advanced Management
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

THROMBECTOMY

- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

ENDOVASCULAR FELLOWS

- EndoFellows Medical Education Program
- Society-Based Workshops
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

ENDOVASCULAR LAB STAFF

- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Cardiovascular Website
- National Webcasts
- Product Training
- CEUs

VESSEL CLOSURE

- EndoMasters™ Medical Education Program
- Society-Based Workshops
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Med Ed Now
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

Pathways are a way of grouping educational offerings based on a topic of interest or specialty. The options for each Pathway can be taken in any order.

CORONARY IMAGING & OCT

- PCI Masters™ Medical Education Program
- OCT Proctorship
- PCI Optimization
- OCT Virtual Reality
- OCT Skills Lab
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CORONARY PHYSIOLOGY

- PCI Masters™ Medical Education Program
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Society-Based Workshops
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CORONARY MICROVASCULAR DYSFUNCTION

- PCI Masters™ Medical Education Program
- CMD Peer to Peer
- Society-Based Workshops
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CTO-PCI MANAGEMENT

- PCI Masters™ Medical Education Program
- CTO 202 Proctorship
- CTO 101
- Med Ed Now
- Cardiovascular Website
- Product Training
- CEUs

COMPLEX PCI

- PCI Masters™ Medical Education Program
- Complex PCI Proctorship
- Complex PCI Course
- PCI Optimization
- OCT Skills Lab
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

PCI FELLOWS

- PCI Fellows Medical Education Program
- Society-Based Workshops
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Med Ed Now
- Regional Speakers
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CATH LAB STAFF

- OCT Skills Lab
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Med Ed Now
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

VESSEL CLOSURE

- EndoMasters™ Medical Education Program
- Society-Based Workshops
- Vessel Closure Hands-On
- Vessel Closure Resource Center
- Med Ed Now
- National Webcasts
- Cardiovascular Website
- Product Training
- CEUs

CEUs

Continuing Education Credits awarded across dozens of topics

IN-PERSON AND VIRTUAL | 1-HOUR INCREMENTS

OVERVIEW

CEU courses delivered by Abbott Subject Matter Experts across a variety of clinical categories.

DESIGNED FOR

Lab staff including Nurses and Techs; Fellows interested in expanding their understanding of interventional procedures.

ENDOVASCULAR CURRICULUM

Topics include:

Thrombectomy

Vascular Access and Closure

PAD Basics

Endovascular Guide Wire Basics

Stroke and Carotid Artery Disease

Endovascular BDCs and Strategy

Diagnosis & Treatment of Critical Limb Ischemia

Diagnostic Evaluation & Treatment of Carotid Artery Disease

Manual Compression

Understanding the Diabetic World

...and many more topics

CORONARY CURRICULUM

Topics include:

A Small Vessel Perspective

Ideal DES

What is FFR?

Guide Wire Design and Strategy

OCT Image Interpretation

Hemodynamics

Plaque Modification

Restenosis Process

CTO Definition and Patient Care

...and many more topics

PRODUCT TRAINING

In-depth training on Abbott products

IN-PERSON AND VIRTUAL | 1-HOUR INCREMENTS

OVERVIEW

Product-specific training on Abbott tools and medical devices across a variety of clinical categories.

DESIGNED FOR

Physicians, Fellows and Lab Staff interested in product training.

CURRICULUM

Balloon Dilatation Catheters

Carotid Artery Stents

Drug-Eluding Stents (DES)

Embolic Protection Devices

Guide Wires

Imaging / OCT

MLD MAX

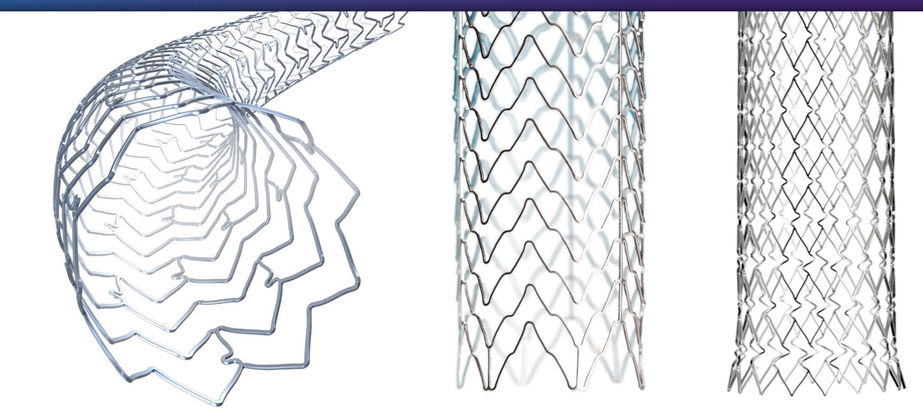
Peripheral Stents

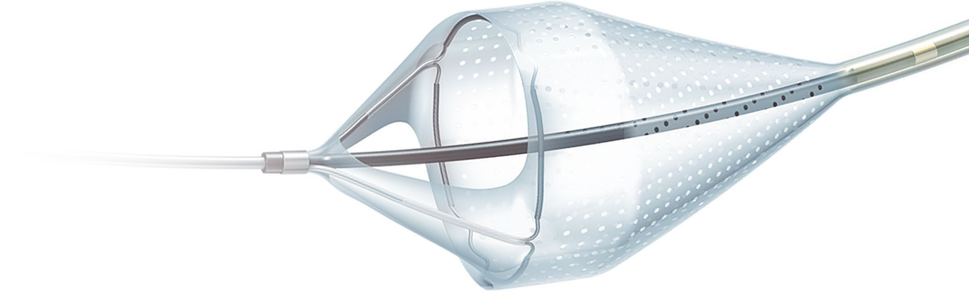
Supera™ Peripheral Stent System

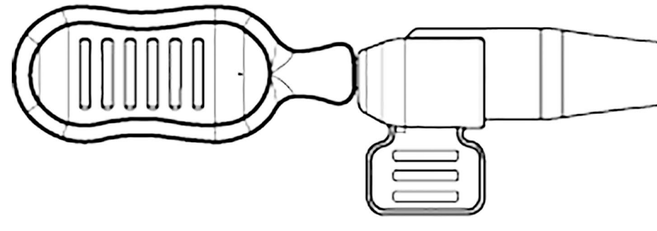
Ultreon™ 1.0 Software

Vessel Closure

XIENCE™ DES







ABBOTT CARDIOVASCULAR

Frequently updated, clinically relevant topics for self-directed medical education

ON-DEMAND | 24/7

OVERVIEW

Access the latest Abbott educational webinars, training videos and course descriptors on Coronary and Endovascular related topics at www.cardiovascular.abbott, including best practices and detailed treatment options for patients.

DESIGNED FOR

Interventional Cardiologists, Vascular Surgeons, Interventional Radiologists, Fellows, Advanced Practitioners, Lab Staff, and Administrators.

CURRICULUM

Anatomical Differences and Similarities of Arteries and Veins

Complications in the Vascular Patient

Hemostasis Management

Imaging/OCT

Indications (various)

Lab Efficiency

MLD MAX

Percutaneous Closure of the Femoral Vessel

Tips and Techniques (various)

Vascular Access Sites

NATIONAL WEBCASTS

Remote presentations on a variety of clinical topics

LIVE-VIRTUAL | 1 HOUR

OVERVIEW

Live virtual presentations with thought leaders on clinically relevant topics (available to all-comers). Webinars are made available on-demand at www.cardiovascular.abbott

DESIGNED FOR

Interventional Cardiologists, Vascular Surgeons, Interventional Radiologists, Fellows, Lab Staff, and Administrators.

CURRICULUM

Didactic presentations on relevant topics related to Coronary and Peripheral procedures, clinical data, and market-related topics.

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

REGIONAL SPEAKERS

Local, custom-tailored subject matter expert speaker opportunities

IN-PERSON AND LIVE-VIRTUAL | 1-2 HOURS

OVERVIEW

Speakers can be made available for delivering custom-designed topics for small groups of clinicians. The Abbott Education Network has access to subject matter experts who are local, national and international thought leaders.

DESIGNED FOR

Interventional Cardiologists, Vascular Surgeons, Interventional Radiologists, and Fellows

CURRICULUM

Didactic content and case reviews

MED ED NOW

Just-in-time, bite-sized clinical webinars

ON-DEMAND | 24/7

OVERVIEW

A diverse curricula of micro-learning modules for self-study on critical clinical topics, techniques, and approaches to patient care.

DESIGNED FOR

Interventional Cardiologists, Vascular Surgeons, Interventional Radiologists, Fellows, Cath Lab Staff, and Administrators.

CURRICULUM

Access and Closure

CLI Diagnostics

Complex PCI

Guide Wire Escalation

High Bleed Risk

Imaging/OCT

PAD

Peripheral Use of EPD

Side Branch Access

Supera™ Peripheral Stent System Deployment

Vessel Closure

Vessel Prep

OCT SKILLS LAB

Remote hands-on, case-based practice session

VIRTUAL | 2 HOURS

OVERVIEW

A fully remote, faculty-led, hands-on OCT training that allows physicians to control the software and collaborate with expert faculty on real case scenarios

DESIGNED FOR

Physicians who wish to advance their OCT skillset

CURRICULUM

Attendees will learn how to:

Acquire images properly

Interpret OCT pullbacks using the MLD MAX algorithm

Apply sound clinical decision-making during OCT cases

Ensure successful incorporation of OCT in your lab workflow

OCT VIRTUAL REALITY

Oculus Go‡ VR goggles for OCT education

IN-PERSON | HALF DAY

OVERVIEW

Comprehensive OCT education for Staff and Fellows.

Training with Oculus Go‡ VR Headsets, OCT Demo Laptop practice, and other hands-on activities.

DESIGNED FOR

Fellows, Lab Staff, and Institutions with OCT systems

CURRICULUM

Gain general familiarity with OCT procedures

Understand procedure workflow and image acquisition

Interpret OCT images

Make clinical decisions using the MLD MAX algorithm

‡ Indicates a third party trademark, which is property of its respective owner.

PCI OPTIMIZATION

Complete case-based overview of OCT PCI

IN-PERSON | 1 DAY

OVERVIEW

This PCI Optimization course will describe the process for image acquisition, interpretation, and understanding the benefits of pre- and post-PCI OCT assessments using the new MLD MAX algorithm.

DESIGNED FOR

Physicians who want to expand their OCT skills and learn how to apply the new optimization algorithm system.

CURRICULUM

This course utilizes an innovative teaching method that includes:

Didactic, Case-Based Presentations

Hands-on case reviews with Faculty on Laptops

Live Case Viewing in Lab

VESSEL CLOSURE RESOURCE CENTER (VCRC)

On-demand Vessel Closure training and certification materials

VIRTUAL | 24/7

OVERVIEW

Access tips and techniques in the VCRC for successful vascular closure, also available as an app.

Content includes information on Abbott's Perclose™ ProStyle™ Suture-Mediated Closure & Repair (SMCR) System, Perclose ProGlide™ SMC System and StarClose SE™ Vascular Closure System.

DESIGNED FOR

Attending Physician, Fellow, Resident or Clinician interested in mastering vascular suture-mediated or clip closure.

CURRICULUM

Product training

Recorded cases

Teaching animations

Additional educational materials to prepare for successful vessel closure certification

VESSEL CLOSURE

Hands-on vessel closure practicum

LIVE | 30 - 90 MINUTES

OVERVIEW

This course can be customized to cover a variety of didactic topics such as safe femoral arterial access, alternative access techniques and/or discussion around potential complications.

Workshops may include ultrasound or hands-on deployment of vascular closure devices, but do not satisfy the device training requirements for Abbott's vessel closure products.

DESIGNED FOR

Interventional Cardiologists, Interventional Radiologists, Vascular Surgeons and Electrophysiologists who would like to practice their deployment skills for large-bore access and closure.

CURRICULUM

Practice the optimal procedural technique for one and two-device closure in flat-plate and wet models.

PROCTORSHIP PROGRAMS

One-on-one, in-lab proctoring

VIRTUAL AND IN-PERSON | 1-2 DAYS

OVERVIEW

A specialized training opportunity typically limited to small groups (no more than 4 trainees) with a Faculty proctor.

DESIGNED FOR

Interventional Cardiologists, Interventional Radiologists, Vascular Surgeons and Electrophysiologists with a specific interest in local or individualized training to enhance their own skills.

CURRICULUM

Clinical areas of focus can include:

Endovascular treatment of Iliac, SFA, BTK, CLI

Carotid Artery Stenting

Small-group OCT proctorships

CTO Proctoring

Vessel Closure Techniques

CAS FUNDAMENTALS
& ADVANCED MANAGEMENT

Complete introduction to Carotid Artery Stenting

LIVE | 2 DAYS

OVERVIEW

This course focuses on the tools to tackle clinical challenges and to review the indications for use of Abbott's carotid products in today's environment.

Completion of this course will satisfy the first step required by the FDA for Abbott's Carotid Stent Systems. Please speak with your Abbott representative post-course about the follow-up requirement of three supervised cases to complete the training process.

DESIGNED FOR

Interventional Cardiologists, Interventional Radiologists, Vascular Surgeons, Neuro-Interventional Radiologists, Neurologists, and other Clinical Staff.

CURRICULUM

Didactic training with participant discussion

Case-based learning

Hands-on workshops

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

COMPLEX PCI COURSE

Advanced PCI skills in cath lab setting

IN-PERSON | 2 DAYS

OVERVIEW

Complex PCI courses offer an extended (and customized) experience focused on therapeutic assessment and technical skill development in a clinical setting for high-risk PCI planning and intervention.

DESIGNED FOR

Interventional Cardiologists who want to advance their skill set into highly complex procedures.

CURRICULUM

Didactic, Case-based presentations and Live Case Viewing in Lab

Barriers to Optimal Revascularization

Hemodynamic Support

Side Branch Access

Expanding Role of Atherectomy

Large Hole Closure

Case review

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

CTO PROGRAMS

Lab-based learning and proctorships

IN-PERSON | 1.5 - 2 DAYS

OVERVIEW

Learn the “Hybrid Algorithm” approach to CTO-PCI with individualized attention for the operating physician.

CTO courses are case-based and offered in a small-group format as an on-site visit and also for 1:1 proctorships.

DESIGNED FOR

Interventional Cardiologists who perform 100 or more PCIs annually and want to learn CTO-PCI.

CURRICULUM

Pre-lab case reviews and intervention planning

Didactic content

Live case observation

Proctorships

CTO 101

Small group comprehensive CTO program introduction

IN-PERSON | 2 DAYS

OVERVIEW

Small format case-based course to elevate CTO knowledge utilizing the "Hybrid Algorithm" approach.

DESIGNED FOR

Interventional Cardiologists who want to learn CTO-PCI, and perform 100 or more PCIs annually.

CURRICULUM

Didactic content

Case reviews

Live case observation

SOCIETY-BASED WORKSHOPS

Hands-on product workshops

VIRTUAL AND IN-PERSON | 1 DAY

OVERVIEW

Abbott partners with societies and conferences to give attendees access to hands-on practice with Abbott products while attending the conference. Most sessions offer access to key opinion leaders in the field in addition to product specialists.

DESIGNED FOR

Physicians who wish to have hands-on time with Abbott products, procedures and techniques.

CURRICULUM

Varies based on society. Past topics include:

Clinical Application of Guidewires

Large Bore Vascular Access & Closure

PCI Optimization with OCT.

PCI FELLOWS PROGRAM

Comprehensive introduction for Fellows

VIRTUAL AND IN-PERSON | 3 DAYS

OVERVIEW

This unique, non-traditional and highly interactive Coronary program enables Fellows to interact and collaborate with high-volume operators to discuss topics relevant in today's clinical setting.

DESIGNED FOR

Interventional Cardiology Fellows

CURRICULUM

This course utilizes an innovative teaching method that includes:

Didactic modules

Interactive case reviews

Hands-on product modeling workshops

A case-based approach is used to elicit in-depth discussion between participants and the Faculty panel.

Fellows will be challenged to rethink treatment strategies and product selection based on the clinical insight and treatment rationale from the program Faculty.

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

ENDOFELLOWS
MEDICAL EDUCATION PROGRAM

Comprehensive case-based, hands-on, peer-to-peer program

VIRTUAL | 2 DAYS

OVERVIEW

This unique, non-traditional and highly interactive Endovascular program enables Fellows to interact and collaborate with multi-disciplinary, high-volume operators to discuss topics relevant in today's clinical setting. Using data and case reviews, attendees will be challenged to rethink treatment strategies and tool selection. A case-based approach is used to elicit in-depth discussion between participants and the panel.

DESIGNED FOR

Final year Interventional Cardiology, Vascular Surgery, and Interventional Radiology Fellows.

CURRICULUM

Hands-on workshops covering:

Complex Case Review

Guide Wires

Pedal Access

Supera™ Stent System Deployment

Vessel Closure

PCI MASTERS™
MEDICAL EDUCATION PROGRAM

Comprehensive case-based, hands-on Peer-to-Peer program

IN-PERSON | 2.5 DAYS

OVERVIEW

This course offers unique interactive case-based learning in a group format practicum, hands on complications management, technical skills labs, and product training workshops that utilize OCT, DES, guide wires and vessel closure.

DESIGNED FOR

Interventional Cardiologists performing 100 or more PCIs annually looking to develop their skills.

CURRICULUM

Hands-on workshops covering:

OCT

Physiology

Side Branch Access

Tips and tricks for using Guide Extensions/Micro Catheters

Trapping/Hydroplaning

Vessel Closure

ENDOMASTERS™
MEDICAL EDUCATION PROGRAM

Comprehensive case-based, hands-on Peer-to-Peer program

IN-PERSON | 2.5 DAYS

OVERVIEW

This unique, non-traditional and highly interactive endovascular program, enables participants to interact and collaborate with multi-disciplinary, high-volume operators to identify treatment modalities and algorithms to utilize in everyday practice to enhance patient outcomes. A case-based approach is used to elicit in-depth discussion between participants and the panel.

DESIGNED FOR

Interventional Cardiologists, Interventional Radiologists, and Vascular Surgeons looking to improve skills and increase their understanding of the disease they are treating. Fellows in current practice are encouraged to attend the EndoFellows course.

CURRICULUM

Hands-on workshops covering:

Cadaveric SFA/Peroneal Access

Complex Case Review

Guide Wires

Pedal Access

Supera™ Stent System Deployment

Vessel Closure

IMPORTANT SAFETY INFORMATION

℞ ONLY XIENCE SKYPOINT™ , XIENCE SIERRA™, XIENCE ALPINE™ (XIENCE™ FAMILY) EVEROLIMUS ELUTING CORONARY STENT SYSTEMS

INDICATIONS

The XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are indicated for improving coronary artery luminal diameter in patients, including those at high risk for bleeding and those with diabetes mellitus, with symptomatic heart disease due to de novo native coronary artery lesions (length ≤ 32 mm) with reference vessel diameters of ≥ 2.25 mm to ≤ 4.25 mm.. In addition, the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are indicated for treating de novo chronic total coronary occlusions.

CONTRAINDICATIONS

The XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are contraindicated for use in:

Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.

Patients with hypersensitivity or contraindication to everolimus or structurally-related compounds, or known hypersensitivity to stent components (cobalt, chromium, nickel, tungsten, methacrylic polymer, fluoropolymer), or with contrast hypersensitivity.

WARNINGS

Each stent and the delivery system are for single use only. Do not reuse, reprocess, or resterilize. Note the product "Use by" date on the package. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and / or delivery system and / or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device and / or delivery system may lead to injury, illness, or death of the patient.

It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon.

Antiplatelet therapy should be administered post-procedure.

This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

Judicious selection of patients is necessary, since the use of this device carries the associated risk of stent thrombosis, vascular complications, and/or bleeding events.

The XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are coated with an everolimus and polymer coating at the full implant stent length. The distal and intermediate portions of the device, the tip, and tapers of the balloon are coated with HYDROCOAT™ Hydrophilic Coating.

Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS

Implantation of the stent should be performed only by the physicians who have received appropriate training.

Stent placement should be performed at centers where emergency coronary artery bypass graft surgery (CABG) can be readily performed.

To confirm sterility has been maintained, ensure that the inner package sterile barrier has not been opened or damaged prior to use.

Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of the stent is unknown at present.

Care should be taken to control the guiding catheter tip during stent delivery, deployment, and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.

When the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of clinical trials.

Compared to use within the specified indications for use, the use of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems in patients and lesions outside of the labeled indications, including more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.

The extent of the patient's exposure to drug and polymer is directly related to the number of stents implanted. See Instructions for Use for current data on multiple stent implantation.

Safety and effectiveness of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems have not been established for subject populations with the following clinical settings:

Patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated site restenosis.

Conjunctive use of the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems with either mechanical atherectomy devices or laser angioplasty catheters.

Unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters < 2.25 mm or > 4.25 mm or lesion lengths > 32 mm, lesions located in saphenous vein grafts, lesions located in unprotected left main coronary artery, ostial lesions, or lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI < 1) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent Acute Myocardial Infarction (AMI) or evidence of thrombus in target vessel, multivessel disease, and in-stent restenosis.

Formal drug interaction studies have not been performed with the XIENCE Skypoint™, XIENCE Sierra™ or XIENCE Alpine™ Stent Systems because of limited exposure to everolimus eluted from XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems.

Everolimus, the active ingredient in the stents, is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.

Oral everolimus use in renal transplant and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglyceride levels, which in some cases required treatment.

Nonclinical testing has demonstrated that the XIENCE Skypoint™, XIENCE Sierra™ and XIENCE Alpine™ Stent Systems in single and in overlapped configurations up to 71 mm in length, are MR Conditional. See Instructions for Use for detailed scanning conditions.

POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with PCI treatment procedures and the use of a stent in native coronary arteries include, but are not limited to, the following:

• Allergic reaction or hypersensitivity to latex, contrast agent anesthesia, device materials, and drug reactions to everolimus, anticoagulation, or antiplatelet drugs • Vascular access complications which may require transfusion or vessel repair, including: Catheter site reactions, Bleeding, Arteriovenous fistula; pseudoaneurysm, aneurysm, dissection, perforation/ rupture, Embolism, Peripheral nerve injury, Peripheral ischemia • Coronary artery complications which may require additional intervention, including: Total occlusion or abrupt closure, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection. Perforation/rupture, Tissue prolapse/plaque shift, Embolism, Coronary or stent thrombosis, Stenosis or restenosis • Pericardial complications which may require additional intervention, including: Cardiac tamponade, Pericardial effusion, Pericarditis. • Cardiac arrhythmias • Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction (including acute), coronary artery spasm, and unstable or stable angina pectoris) • Stroke/ Cerebrovascular Accident (CVA) and Transient Ischemic Attack (TIA) • System organ failures: Cardio-respiratory arrest, Cardiac failure, Cardiopulmonary failure, Renal Insufficiency/failure, Shock • Bleeding • Blood cell disorders • Hypotension and/or hypertension • Infection • Nausea and vomiting • Palpitations • Dizziness • Syncope • Chest Pain • Fever • Pain • Death

The risks described below include the anticipated adverse events relevant for the cardiac population referenced in the contraindications, warnings and precaution sections of the everolimus labels / SmPCs and / or observed at incidences ≥ 10% in clinical trials with oral everolimus for different indications. Please refer to the drug SmPCs and labels for more detailed information and less frequent adverse events.

• Abdominal pain • Anemia • Angioedema • Arterial Thrombotic Events • Bleeding and coagulopathy • Constipation • Cough • Diabetes mellitus • Diarrhea • Dyspnea • Embryo-fetal toxicity • Erythema • Erythroderma • Headache • Hepatic artery thrombosis • Hepatic disorders • Hypersensitivity to everolimus active substance, or to other rapamycin derivates • Hypertension • Infections (bacterial, fungal, viral or protozoan infections, including infections with opportunistic pathogens). Polyoma virus-associated nephropathy (PVAN), JC virus-associated progressive multiple leukoencephalopathy (PML), fatal infections and sepsis have been reported in patients treated with oral everolimus • Kidney arterial and venous thrombosis • Laboratory test alterations • Lymphoma and skin cancer • Male infertility • Menstrual irregularities • Nausea • Nephrotoxicity • Non-infectious pneumonitis • Oral ulcerations • Pain • Pancreatitis • Pericardial effusion • Peripheral edema • Pleural effusion • Pneumonia • Pyrexia • Rash • Renal Failure • Upper respiratory tract infection • Urinary tract infection • Venous thromboembolism • Vomiting • Wound healing complications

Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time.

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION

℞ ONLY OPTIS™ IMAGING SYSTEMS AND SOFTWARE

INDICATIONS

The OPTIS™ Software and AptiVue™ E Series Software are intended to be used only with compatible OPTIS™ Imaging Systems.

The OPTIS™ Imaging System with a compatible Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly™ Imaging Catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ Imaging Catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The OPTIS™ Imaging System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic interven4tion is indicated.

CONTRAINDICATIONS

The OPTIS™ Integrated System and Mobile System with Software are contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure

NOTE: The systems have no patient alarm functions. Do not use for cardiac monitoring.

WARNINGS

Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.

Observe all advancement and movement of the Dragonfly™ Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.

Leave the Guide Wire engaged with the catheter at all times during use. Do not withdraw or advance the Guide Wire prior to withdrawing the catheter.

If resistance is encountered during advancement or withdrawal of the Dragonfly™ Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and Guide Wire together.

The Dragonfly™ Imaging Catheter should never be forced into lumens that are narrower than the catheter body or forced through a tight or heavily calcified lesion.

The Dragonfly™ Imaging Catheter should not be advanced through abnormally tortuous anatomy.

When advancing or retracting a catheter with a monorail tip through a stented vessel, the catheter may engage the stent between the junction of the Dragonfly™ Imaging Catheter and Guide Wire, resulting in entrapment of catheter/Guide Wire, catheter tip separation, and/or stent dislocation.

Refer to the contrast media's instructions-for-use for general warnings and precautions relating to use of the contrast media.

To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment.

Do not use the OPTIS™ Imaging System if there is reason to believe the system's security has been compromised or if the system was unaccounted for a period of time (i.e. misappropriated, modified or tampered with).

PRECAUTIONS

Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.

For optimal imaging, only use 100% contrast media.

Store the Dragonfly™ Imaging Catheter at ambient temperature in a dry location out of direct sunlight.

Never attempt to attach or detach a Dragonfly™ Imaging Catheter to the DOC while the "lock" LED is lit.

Do not kink, sharply bend, pinch, or crush the Dragonfly™ Imaging Catheter at any time.

The Dragonfly™ Imaging Catheter is for single use only. Do not reuse, re-sterilize, or reprocess.

The Dragonfly™ Imaging Catheter is sterilized by ethylene oxide and is intended for one time use only. Non-pyrogenic. Do not use if the package is opened or damaged.

After use, the Dragonfly™ Imaging Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

The Dragonfly™ Imaging Catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION

℞ ONLY SUPERA™ PERIPHERAL STENT SYSTEM

INDICATIONS

The Supera™ Peripheral Stent System is indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and / or proximal popliteal artery with reference vessel diameters of 4.0 to 7.5 mm, and lesion lengths up to 140 mm.

CONTRAINDICATIONS

The Supera™ Peripheral Stent System is contraindicated in:

- 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.
- Patients who cannot receive antiplatelet or anticoagulation therapy. Based on in vivo thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation.

WARNINGS

- This device is intended for single-use only. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged.
- Use this device prior to the "Use by" date as specified on the device package label.
- Store in a dry, dark, cool place.
- **DO NOT** use if it is suspected that the sterility of the device has been compromised.
- Persons with known hypersensitivities to Nitinol and / or its components (e.g., nickel-titanium) may suffer an allergic reaction to this implant.
- Administer appropriate antiplatelet therapy pre- and post-procedure.
- Careful attention should be paid when sizing and deploying the stent to prevent stent elongation. In the SUPERB clinical study, stent elongation was associated with a decrease in patency at 12 months.

PRECAUTIONS

The Supera™ Peripheral Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques and trained on the use of this device.

- The long-term safety and effectiveness of the Supera Peripheral Stent System has not been established beyond three years.
- The safety and effectiveness of the Supera Peripheral Stent System has not been established in patients who:
  - are less than 18 years old
  - are pregnant or lactating
  - have in-stent restenosis of the target lesion
  - have known hypersensitivity to any component of the stent system (e.g., nickel)
  - cannot tolerate contrast media and cannot be pre-treated
  - have uncontrolled hypercoagulability and / or another coagulopathy
- This device is not designed for use with contrast media injection systems or power injection systems.
- The flexible design of the Supera stent may result in variation in the deployed stent length.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Nonclinical testing has demonstrated that the Supera stent, in single and in overlapped configurations up to 250 mm in length, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions :

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient magnetic field of 2,500 Gauss/cm (25 T/m)
- Maximum MR whole-body-averaged specific absorption rate (SAR) of
  - 2 W/kg for landmarks (i.e., center of RF coil) above the umbilicus
  - 1 W/kg for landmarks below the umbilicus and above the mid-thigh
  - 0.5 W/kg for landmarks below the mid-thigh

Under the scan conditions defined above, the Supera stent is expected to produce a maximum temperature rise of 7.6 C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact caused by the device extends approximately 2 cm from the Supera stent when imaged with a gradient echo or spin echo sequence and a 3T MRI system.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

- Abrupt closure
- Allergic reaction (contrast medium; drug; stent material)
- Amputation or limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina or coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- Arteriovenous fistula
- Bleeding complications requiring transfusion or surgical intervention
- Death
- Detachment of a system component or implantation in an unintended site
- Embolization, arterial or other (e.g. air, tissue, plaque, thrombotic material, or stent)
- Emergent surgery
- Fever
- Hematoma or hemorrhagic event, with or without surgical repair
- Hyperperfusion syndrome
- Hypertension / Hypotension
- Infection
- Myocardial infarction
- Pain (leg, foot, and/or insertion site)
- Partial stent deployment
- Peripheral nerve injury
- Pulmonary embolism
- Renal failure or insufficiency
- Restenosis of vessel in stented segment
- Shock
- Stent malapposition or migration, which may require emergency surgery to remove stent
- Stent strut fracture
- Thrombosis or occlusion
- Stroke
- Transient ischemic attack
- Venous thromboembolism
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION

℞ ONLY EMBOSHIELD NAV6™ EMBOLIC PROTECTION SYSTEM

INDICATIONS

The Emboshield NAV6™ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries and while performing atherectomy, during standalone procedures or together with PTA and/or stenting, in lower extremity arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

CONTRAINDICATIONS

The **Emboshield NAV6™ Embolic Protection System** is contraindicated for use in:

- Patients in whom anticoagulant and / or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the Guiding Catheter / Introducer Sheath, Embolic Protection System.
- Patients with a known allergy or hypersensitivity to device materials (Nitinol, Nickel, Titanium) or contrast medium, who cannot be adequately premedicated.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.
- Inability to cross the lesion with the BareWire™ Filter Delivery Wire.
- Diffusely diseased vessels where there is no disease-free section in which to deploy the Filtration Element
- Insufficient straight section of vessel distal to the lesion to permit Filtration Element deployment.

WARNINGS

Use of the device should be restricted to physicians trained to the specifics of the device and to the Instructions for Use. Operators must be knowledgeable of the current medical literature and familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid and lower extremity interventional procedures.

Refer to instructions supplied with all interventional devices to be used with the Emboshield NAV6™ Embolic Protection System for their intended uses, contraindications, and potential complications.

The Emboshield NAV6™ System is supplied sterile. Do not use if the package has been opened or is damaged. Carefully inspect the system components prior to use to verify that they have not been damaged and that the size, shape and condition are suitable for the procedure for which they are to be used. A device or access device that is kinked or damaged in any way should not be used.

Safety and effectiveness of this device as an embolic protection system has not been established in the coronary or cerebral vasculature.

The safety and efficacy of the Emboshield NAV6™ Embolic Protection System has not been demonstrated with carotid stent systems other than the Xact™ or Acculink™ Carotid Stent Systems.

The safety and efficacy of the Emboshield NAV6™ Embolic Protection System has not been demonstrated with atherectomy devices other than Turbo-Elite‡ Laser Atherectomy Catheter, Jetstream‡ Single Cutter (SC) Atherectomy Catheter, Jetstream‡ eXpandable Cutter (XC) Atherectomy Catheter and TurboHawk‡ Peripheral Plaque Excision System.

The Emboshield NAV6™ devicecan only be used with the BareWire™ Filter Delivery Wire. Use of the device with any guide wire other than the BareWire™ Filter Delivery Wire will lead to loss of the Filtration Element during the procedure or an inability to retrieve the Filtration Element.

To reduce the potential for the liberation of emboli during lesion crossing, the device should be carefully manipulated and not advanced against resistance.

If the Filtration Element moves into the stented vessel segment prior to retrieval, DO NOT RETRIEVE. Use the Retrieval Catheter to gently maneuver the Filtration Element distally until it is situated in an unstented portion of vessel. Retrieval should then proceed.

Maintain proper guiding catheter / sheath support throughout the procedure. Ensure that there is enough distance between the proximal tip of the Filtration Element and the most distal tip of any interventional device to be introduced over the Filter Delivery Wire to avoid engagement. The tip of a balloon catheter or a stent delivery system or an atherectomy device should not contact the Filtration Element. Failure to maintain adequate distance could result in inadvertent Filtration Element movement and Stent Delivery System tip / Filtration Element entanglement and / or Filtration Element / Stent entanglement if guide catheter or sheath prolapse occurs.

PRECAUTIONS

Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with heparinized normal saline or alternative anticoagulant, prior to use.

The Emboshield NAV6™ Embolic Protection System must be used with a guiding catheter or introducer sheath to maintain adequate support for the BareWire™ Filter Delivery Wire throughout the procedure.

Venous access should be available during carotid stenting in order to manage bradycardia and / or hypotension by either pharmaceutical intervention or place of a temporary pacemaker, if needed.

Removal of the BareWire™ Filter Delivery Wire with the Emboshield NAV6™ Filtration Element through any interventional devices other than the Emboshield NAV6™ RX Retrieval Catheter has not been tested.

The minimum expanded stent internal diameter required for retrieval of a large embolic load is 2.5 mm.

ADVERSE EVENTS

As reported in the literature, the following adverse events are potentially associated with carotid stents and embolic protection systems:

- Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, stent material (Nitinol, Nickel, Titanium) and drug reactions to anticoagulation, or antiplatelet drugs
- Vascular access complications which may require transfusion or vessel repair, including:
  - Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage)
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation/rupture, and laceration
  - Embolism (air, tissue, plaque, thrombotic material or device)
  - Thrombophlebitis

Target artery complications which may require additional intervention, including:

- Total occlusion or abrupt closure
- Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation/rupture
- Embolism (air, tissue, plaque, thrombotic material or device)
- Stenosis or restenosis
- Artery, stent, or filter thrombosis / occlusion thrombosis
- Vessel spasm
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
- Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction, and unstable or stable angina pectoris)
- Stroke/Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA)
- System organ failures:
- Cardio Pulmonary failure
- Renal failure / insufficiency
- Blood cell disorders including heparin induce thrombocytopenia and other coagulopathy
- Other ischemic conditions/infarct
- Infection - local and systemic (including postprocedural)
- Nausea and vomiting
- Chest pain
- Edema/Cerebral edema and fluid overload
- Fever
- Pain, including headache
- Hyperperfusion syndrome
- Other neurologic and systemic complications
- Cerebral hemorrhage
- Death

Any adverse event occurring involving the Emboshield NAV6™ Embolic Protection System should be reported immediately to Abbott Vascular, Customer Service: 1-800 227-9902.

See Important Safety Information referenced within. **Information contained herein for DISTRIBUTION in the U.S. ONLY.**

IMPORTANT SAFETY INFORMATION

Rx ONLY PERCLOSE PROGLIDE™ SUTURE-MEDIATED CLOSURE (SMC) SYSTEM

INDICATIONS

The Perclose ProGlide™ SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide™ SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott Vascular.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F, it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to close the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the WARNINGS and PRECAUTIONS sections.

WARNINGS

Do not use the Perclose ProGlide™ SMC device or accessories if the packaging or sterile barrier has been previously opened or damaged or if the

components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose ProGlide™ SMC device and accessories are intended for single use only.

Do not use the Perclose ProGlide™ SMC System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO)

angiogram to adequately visualize where the sheath enters the femoral artery or vein.

Do not use the Perclose ProGlide™ SMC System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral artery or vein.

PRECAUTIONS

1 Prior to use, inspect the Perclose ProGlide™ SMC System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.

2 As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide™ SMC System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.

3 Use a single wall puncture technique. Do not puncture the posterior wall of the vessel.

4 Do not deploy the Perclose ProGlide™ SMC device at an angle greater than 45 degrees, as this may cause a cuff miss.

5 There are no reaccess restrictions if previous access site repairs were achieved with Abbott Vascular SMC devices.

6 If significant blood flow is present around the Perclose ProGlide™ SMC device, do not deploy needles. Remove the Perclose ProGlide™ SMC device over a 0.038" (0.97mm) (or smaller) Guide Wire and insert an appropriately sized introducer sheath.

7 When pushing the plunger assembly to advance the needles, stabilize the device to ensure the device does not twist or move forward during deployment. Twisting the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger assembly. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.

8 Do not apply excessive force to the lever when returning the foot to its original position (marked #4) down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever of the device or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.

9 Do not advance or withdraw the Perclose ProGlide™ SMC device against resistance until the cause of that resistance has been determined (see Section 11.3 Single SMC DEVICE PLACEMENT section). Excessive force used to advance or torque the Perclose ProGlide™ SMC device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.

10 If excessive resistance in advancing the Perclose ProGlide™ SMC device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) Guide Wire and reinsert the introducer sheath or use manual compression.

11 Remove the Perclose ProGlide sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.

12 In using this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.

13 During closure of access sites using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC device.

14 During closure of access sites using a procedural sheath > 8F, in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC devices, the physician should assess the situation. Based on the physician assessment of the amount of bleeding use manual compression, compression assisted devices and / or a surgical repair to obtain hemostasis.

15 During closure of access sites using a procedural sheath > 8F, in those cases where the implanting physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of suture mediated closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Anemia
- Arterial stenosis / occlusion
- Arteriovenous fistula
- Bleeding / hemorrhage
- Bruising / hematoma
- Death
- Deep vein thrombosis
- Device entrapment
- Device failure / malfunction / misplacement
- Diminished pulses distal to closure site
- Embolism
- Hypotension / hypertension
- Infection / sepsis
- Inflammation
- Intimal tear / dissection
- Ischemia distal to closure site
- Nerve injury
- Numbness
- Pain
- Perforation
- Pseudoaneurysm
- Pulmonary embolism
- Retroperitoneal hematoma / bleeding
- Thrombus formation
- Vascular injury
- Vasoconstriction / vasospasm
- Vasovagal episode
- Wound dehiscence

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IMPORTANT SAFETY INFORMATION

Rx ONLY STARCLOSE SE™ VASCULAR CLOSURE SYSTEM

INDICATIONS FOR USE

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis, ambulation, and dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

The StarClose SE™ Vascular Closure System is indicated for use to allow patients who have undergone diagnostic endovascular catheterization procedures to ambulate and be eligible for discharge as soon as possible after device placement.

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation in patients who have undergone interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and therapeutic catheterization procedures and who has been trained by an authorized representative of Abbott Vascular. Prior to use, the operators must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

CONTRAINDICATIONS

The StarClose SE™ Vascular Closure System is contraindicated for use in patients with known hypersensitivity to nickel-titanium.

WARNINGS

Do not use the StarClose SE™ Vascular Closure System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The StarClose SE™ Vascular Closure System and accessories are intended for single use only.

Do not use the StarClose SE™ Vascular Closure System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection. Do not use the StarClose SE™ Vascular Closure System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site.

Do not use the StarClose SE™ Vascular Closure System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a retroperitoneal hematoma.

Do not use the StarClose SE™ Vascular Closure System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site.

PRECAUTIONS

1. The StarClose SE™ Vascular Closure System should be used only by operators trained in diagnostic and interventional catheterization procedures who have been certified by an authorized representative of Abbott Vascular Inc.
2. The StarClose SE™ Vascular Closure System is provided sterile and non-pyrogenic in unopened, undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. Store in a cool, dry place.
3. The StarClose SE™ Vascular Closure System is provided sterile and non-pyrogenic in unopened, undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. Store in a cool, dry place.
4. Prior to use, inspect the StarClose SE™ Vascular Closure System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
5. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the StarClose SE™ Vascular Closure System. Employ appropriate groin management, as per hospital protocol, post-procedure and post-hospital discharge to prevent infection.
6. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.
7. Do not use the StarClose SE™ Vascular Closure System to close vessels with diameters less than 5 mm.
8. Do not deploy the Clip in areas of calcified plaque.
9. The StarClose SE™ Vascular Closure System can ONLY be used with the StarClose Exchange System (included in the StarClose SE™ Vascular Closure System packaging).
10. **Do not advance or withdraw the StarClose SE™ Vascular Closure Device against resistance until the cause of that resistance has been determined.** Excessive force used to advance or torque the StarClose SE™ device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate interventional and / or surgical removal of the device and vessel repair.

ADVERSE EVENTS

Potential adverse events that could be associated with the use of this device include:

Major Vascular Complications

- Vascular Injury Requiring Repair
- Surgery
- Angioplasty
- Ultrasound Guided Compression
- Thrombin Injection or Other Percutaneous Procedure
- New Ipsilateral Lower Extremity Ischemia
- Access Site-related Bleeding Requiring Transfusion
- Access Site-related Infection Requiring Intravenous Antibiotics or Prolonged Hospitalization
- Access Site-related Nerve Injury Requiring Intervention
- Death

Minor Vascular Complications

- Pseudoaneurysm
- Arteriovenous Fistula
- Hematoma (≥ 6 cm)
- Late Access Site-related Bleeding
- Transient Lower Extremity Ischemia
- Ipsilateral Deep Vein Thrombosis
- Transient Access Site-related Nerve Injury
- Access Site-related Vessel Injury
- Access Site Wound-related Dehiscence
- Access Site-related Bleeding Requiring ≥ 30 minutes to Re-achieve Hemostasis
- Localized Access Site Infection Treated with IM or Oral Antibiotics
- UADE

See Important Safety Information referenced within. Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION

Rx ONLY PERCLOSE™ PROSTYLE™ SUTURE-MEDIATED CLOSURE AND REPAIR (SMCR) SYSTEM

INDICATIONS FOR USE

The Perclose™ ProStyle™ Suture-Mediated Closure and Repair (SMCR) System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access sites of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose™ ProStyle™ SMCR System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this medical device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F, it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to repair the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device.

WARNINGS

Do not use the Perclose™ ProStyle™ SMCR System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose™ ProStyle™ SMCR System is intended for single use only.

Do not use the Perclose™ ProStyle™ SMCR System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose™ ProStyle™ SMCR System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral vessel.

Do not use the Perclose™ ProStyle™ SMCR System in arterial access if the puncture is through the posterior wall or if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose™ ProStyle™ SMCR System in venous access if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose™ ProStyle™ SMCR System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a right anterior oblique (RAO) and left anterior oblique (LAO) angiogram to adequately visualize where the sheath enters the vessel.

PRECAUTIONS

1. Prior to use, inspect the Perclose™ ProStyle™ SMCR System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose™ ProStyle™ SMCR System. Employ appropriate groin management, as per hospital protocol, post procedure, and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel in arterial access.
4. Do not deploy the Perclose™ ProStyle™ Device at an angle greater than approximately 45 degrees, as this may cause a cuff miss.
5. There are no reaccess restrictions if previous arteriotomy / venotomy repairs were achieved with Abbott Medical SMC or SMCR systems.
6. If significant blood flow is present around the Perclose™ ProStyle™ SMCR Device, do not deploy needles. Remove the device over a 0.038" (0.97 mm) (or smaller) guide wire and insert an appropriately sized introducer sheath.
7. Prior to pushing the plunger to advance the needles, stabilize the device by the body to ensure the foot is apposed to the vessel wall and the device does not twist during deployment. Twisting (torquing) of the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when returning the foot to its original position down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose™ ProStyle™ SMCR Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose™ ProStyle™ SMCR Device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose™ ProStyle™ SMCR Device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guide wire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose™ ProStyle™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Care should be taken to avoid damage to the suture from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. For catheterization procedures using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
14. For catheterization procedures using a procedural sheath > 8F, use manual compression, compression assisted devices, surgical repair, and / or other appropriate treatment methods in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
15. For catheterization procedures using a procedural sheath > 8F, where the operating physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary vascular surgical intervention.

ADVERSE EVENTS

Potential adverse events associated with use of suture mediated closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
  - Anemia
  - Aneurysm
  - Arteriovenous fistula
  - Bleeding / hemorrhage / re-bleeding
  - Bruising / hematoma
  - Embolism
  - Inflammation
  - Intimal tear / dissection
  - Perforation
  - Pseudoaneurysm
  - Retroperitoneal hematoma / bleeding
  - Scar formation / calcification
  - Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
  - Atrial arrhythmias
  - Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
  - Arterial / venous stenosis
  - Arterial / venous occlusion
  - Arteriovenous fistula
  - Intimal tear / dissection
  - Ischemia distal to closure site
  - Nerve injury
  - Numbness
  - Thrombus formation
  - Vascular injury
- Peripheral ischemic conditions (including deep vein thrombosis, pulmonary embolism, post-procedure pulmonary embolism):
  - Deep vein thrombosis
  - Pulmonary embolism
- Infection:
  - Infection / sepsis
  - Pain
- Hemodynamic instability:
  - Hypotension / hypertension
  - Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

See Important Safety Information referenced within. **Information contained herein for DISTRIBUTION in the U.S. ONLY.**

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

The information provided is not intended for medical diagnosis or treatment or as a substitute for professional medical advice. Consult with a physician or qualified healthcare provider for appropriate medical advices. This material is intended for use with healthcare professionals only.

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