vizient™

Vascular technologies

Coronary, peripheral and neurovascular devices

Technology Watch | 2016 Volume 1

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Introduction

Recent years have been an exciting time in the vascular technologies segment and the health care market as a whole. As forecasted, revolutionary new medical devices have been or are being approved by the U.S. Food and Drug Administration (FDA) and are being introduced into the United States. Early in 2015, the drug-coated balloon and the left atrial appendage device were approved. In 2016, the bioresorbable scaffold, minimally invasive aortic heart valve, and bifurcation stent are expected to become available. Each represents a significant advance in patient care options, especially for patients who are very sick or have inoperable conditions.

These revolutionary technologies grabbed the headlines, but other exciting technologies are also in development in the neuroendovascular and peripheral vascular segments. This report covers several of these technologies and provides insight into potential new devices that may improve patient care, change clinical practice or increase competition.

Also grabbing headlines this year were the vena cava filter devices. At the Cardiovascular Interventional Radiology Society of Europe meeting in December 2015, Lee et al published retrieval success rates with inferior vena cava (IVC) filters using CIRSE's retrievable IVC filter registry of 628 patients from Dec. 1, 2010, through June 30, 2012.[1] The investigators concluded that, based on the registry data, the retrieval rate was 92% across a range of filter types and the rate of major complications was low, reflecting current practice. They also found that use of retrievable filters for relative and prophylactic indications was increasing. This and other publications offer proof that older technologies continue to provide patient care benefit.

Also this year, Congress passed a bipartisan bill that repealed Medicare's sustainable growth rate formula for calculating physician reimbursement for Medicare patients. The Medicare Access and CHIP Reauthorization Act (MACRA) eliminated the potential 21% Medicare pay cut. The law also shifted Medicare physician compensation from fee-for-service to the Merit-based Incentive Payment System. The law directs that physicians and other health care professionals shall receive annual payment increases or decreases based on their performance as measured by standards the government shall establish. Section 101 of the law links improving physician-related outcomes, reporting requirements, and support for cost savings to physician pay beginning in 2019. Section 512 eliminates civil monetary penalties for inducements to physicians to limit services that are not medically necessary. It requires the secretary of the U.S. Department of Health and Human Services to report to Congress on permitting gainsharing arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency. This law will have significant impact in the coming years when combined with the emerging bundled payment and population health initiatives promoted by the Affordable Care Act and taking place under the auspices of the Centers for Medicare & Medicaid Services (CMS).

For the markets covered in this report, competition has created an environment of decreasing prices. There are exceptions, principally in the neuroendovascular market where a combination of new devices and a shift in supplier ownership to an orthopedic-like pricing strategy is resulting in rising average selling prices. As the emerging health care market transitions from volume-based to value-based reimbursement, providers and suppliers will need to collaborate to achieve improved patient outcomes, satisfactory economic outcomes and their own individual objectives.

Disclaimer Vizient cardiovascular staff attend clinical sessions at cardiovascular meetings through the year. The staff meet with suppliers, review new technologies, and monitor key clinical trial data. The information is consolidated into this overview of product and practice trends in cardiology, rhythm management, endovascular, neurovascular and structural heart for a review of the technology pipeline and information about the newest innovations. This document is intended to educate nonclinical hospital staff, giving them insight into emerging technologies that have a high probability of affecting a health care facility both positively, by enhancing patient care, and also negatively, by increasing supply-chain cost. The report is not intended to reflect detailed clinical trial information nor its potential clinical impact. Discussions with the hospital's physicians should always be conducted for a complete understanding of new technologies. Vizient staff have no personal financial connections with the suppliers and no conflicts of interest in the development of this document. The information about the products presented is for educational purposes and not for promotion. Most of the products presented in this document are investigational and not approved for sale in the United States.

Market watch

The 12-month price trend and current average market pricing by product segment is shown in the tables that follow.

Pricing trends

Coronary products

Category	Change (%)
Drug-eluting stent	↓ 7.8
Bare-metal stent	↓ 6.7
PTCA balloon catheters	↓ 6.4
Interventional wires	↑ 3.8
Guiding catheters	↓ 6.7
Diagnostic catheters	↓ 3.1

PTCA = percutaneous transluminal coronary angioplasty

Peripheral products

Category	Change (%)
Self-expanding stents	↓ 6.1
Balloon-expandable stents	↓ 10.7
Carotid stents	↓ 1.6
PTA balloon catheters	↑ 1.6
Drug-coated balloons	↑ 2.3
Atherectomy	↑ 3.6

PTA = percutaneous transluminal angioplasty

Neuroendovascular products

Category	Change (%)
Detachable coils	↓ 1.0
Liquid embolics	↑ 7.4
Flow diversion devices	↑ 5.5
Cerebral stents	↓ 1.8
Neuro wires	↑ 1.4
Microcatheters	↑ 16.8

Venous products

Category	Change (%)
Vena cava filters	↓ 4.0

All prices in the tables that follow are the average prices for that category of products, not selling prices for specific products. Individual hospital pricing may vary given considerations such as rebates, quality and volumes that are not included in these estimates.

Coronary devices

Drug-eluting stents

Supplier	Average price
Abbott Vascular	$1,270
Boston Scientific	$1,260
Medtronic	$1,320

Bare-metal stents

Supplier	Average price
Abbott Vascular	$560
Boston Scientific	$580
Medtronic	$620

PTCA balloon catheters

Supplier	Average price
Abbott Vascular	$130
Boston Scientific	$130
Cordis	$145
Medtronic	$135

PTCA = percutaneous transluminal coronary angioplasty

Interventional wires

Supplier	Average price
Abbott Vascular	$85
Boston Scientific	$80
Cordis	$60
Medtronic	$60
Terumo Medical	$80

Guiding catheters

Supplier	Average price
Boston Scientific	$50
Cordis	$45
Medtronic	$45
Merit Medical	$40
Terumo Medical	$75

Diagnostic catheters

Supplier	Average price
Boston Scientific	$8
Cordis	$9
Medtronic	$8
Merit Medical	$9
Terumo Medical	$30

Cutting balloon catheters

Supplier	Average price
Boston Scientific	$775
Angioscore	$810

Peripheral interventional devices

Self-expanding stents

Supplier	Average price
Abbott Vascular	$1,130
Bard Vascular	$1,140
Boston Scientific	$940
Cook Medical	$1,010
Cordis	$780
Medtronic	$950

Balloon-expandable stents

Supplier	Average price
Abbott Vascular	$1,090
Bard Vascular	$930
Boston Scientific	$1,000
Cook Medical	$960
Cordis	$970
Medtronic	$750

Carotid stents

Supplier	Average price
Abbott Vascular	$2,240
Boston Scientific	$2,350
Cordis	$1,890
Covidien	$1,780

Covered endoprostheses

Supplier	Average price
Bard Vascular	$2,510
Boston Scientific	$1.010
WL Gore	$3,240

Drug-eluting stents

Supplier	Average price
Cook Medical	$1,650

Drug-coated balloons

Supplier	Average price
Bard Vascular	$1,580
Medtronic	$1,490

PTA balloon catheters

Supplier	Average price
Abbott Vascular	$185
Bard Vascular	$220
Boston Scientific	$200
Cook Medical	$185
Cordis	$270
Medtronic	$165

PTA = percutaneous transluminal angioplasty

Neuroendovascular devices

Detachable coils

Supplier	Average price
Blockade	$600
Codman	$1,480
MicroVention	$1,450
Medtronic	$800
Penumbra	$1,430
Stryker	$1,400

Liquid embolics

Supplier	Average price
Codman	$2,960
Medtronic	$2,290

Clot retrieval devices

Supplier	Average price
Medtronic	$6,650
Stryker	$7,220

Venous devices

Vena cava filters

Supplier	Average price
ALN	$990
Argon Medical	$1,020
B. Braun Medical	$1,180
Bard Vascular	$1,010
Boston Scientific	$920
Cook Medical	$1,040
Cordis	$980

Supplier watch

Terumo Medical

Terumo Corporation was founded in Japan in 1921 by a group of medical scientists to produce medical thermometers. The company is one of the worldwide leaders in cardiovascular medical devices and a leader in the U.S. in cardiac surgery market; it is best known for its Glidewire product platform. Terumo has had a presence in the United States since 1971, but remained relatively unknown until the early 2000s. In 2005, the company terminated its distribution agreement with Boston Scientific, creating Terumo Interventional Systems. Terumo has increased its worldwide leadership position through acquisitions, including its 2006 acquisition of MicroVention, which allowed the company to solidify its position in the neuroendovascular market. Outside the United States, Terumo Interventional Systems markets a full line of medical devices for a wide variety of coronary, endovascular, and neuroendovascular procedures, including peripheral embolization and transradial vascular access. It was the company's strategy to aggressively promote the transradial access technique in the United States that firmly established the company and allowed it to build a strong brand image here. Their breadth and depth of products and technologies makes them a solid global competitor. Terumo remains a company to watch as it brings its many technologies and products to the U.S. market in the coming years.

The tables below list many of the Terumo technologies available outside the United States.

FDA specialty approvals in 2015

Name	Device type	Device description
Coronary devices		
ART	Coronary scaffold	A bioresorbable scaffold to be developed and marketed in partnership with Arterial Remodeling Technologies
Nobori	Bioabsorbable polymer stent	A cobalt chromium coronary stent with bioabsorbable polymer and biolimus A9 drug
Finecross MG	Micro guiding catheter	A microcatheter specifically designed for coronary interventions to support a guidewire to navigate through the artery
Peripheral vascular devices		
Misago	Vascular stent	A self-expanding, rapid-exchange stent system for use with superficial femoral artery and/or proximal popliteal artery catheters
Tsunami	Vascular stent	A balloon-expandable, premounted peripheral stent on a balloon at the distal tip of a rapid-exchange–type delivery catheter
Lifepearl	Microsphere	Drug-elutable microspheres designed to be loaded with chemotherapy drugs for delivery to cancerous tumors

Name	Device type	Device description
Azur	Hydrophilic coils	A platinum coil and an expandable hydrogel polymer for peripheral embolization
Neuroendovascular devices		
FRED	Flow-diversion stent	An integrated dual-layer, self-expanding nitinol braided stent to help reduce blood flow and redirect it away from the aneurysm sac
ERIC	Mechanical thrombectomy	A clot-retrieving catheter used to restore cerebral blood flow
LVIS	Neurovascular stent	An FDA-approved self-expanding nitinol stent used to repair brain aneurysms
PHIL	Liquid embolic	A nonadhesive, dimethyl-sulfoxide liquid embolic system
Roadsaver	Carotid stent	A nitinol double-layer micromesh design carotid artery stent system indicated for use in patients with carotid arterial atherosclerotic disease
Casper Rx	Carotid stent	A self-expanding, nitinol stent indicated for use in patients with carotid arterial atherosclerotic disease
Sofia	Aspiration catheter	A soft, torqueable catheter designed to optimize intracranial access
Eliminate	Aspiration catheter	An aspiration catheter designed to offer an optimal balance between crossing performance, kink resistance, and thrombus-aspiration capability
Vascular imaging systems		
Visiwave	IVUS imaging system	An intravascular ultrasound system catheter and imaging console to acquire luminal surface and cross-sectional images of blood vessels
Lunawave	OCT imaging system	An optical technology-based imaging system catheter and imaging console to acquire luminal surface and cross-sectional images of blood vessels

Name	Device type	Device description
Renal denervation		
Iberis	Renal denervation	A radiofrequency delivery system with a single point of contact for renal artery ablation

FDA = U.S. Food and Drug Administration

Terumo has a robust product portfolio and is likely to introduce a number of innovative medical devices into the United States over the next several years, making the company a comprehensive supply chain provider offering clinical and economic solutions.

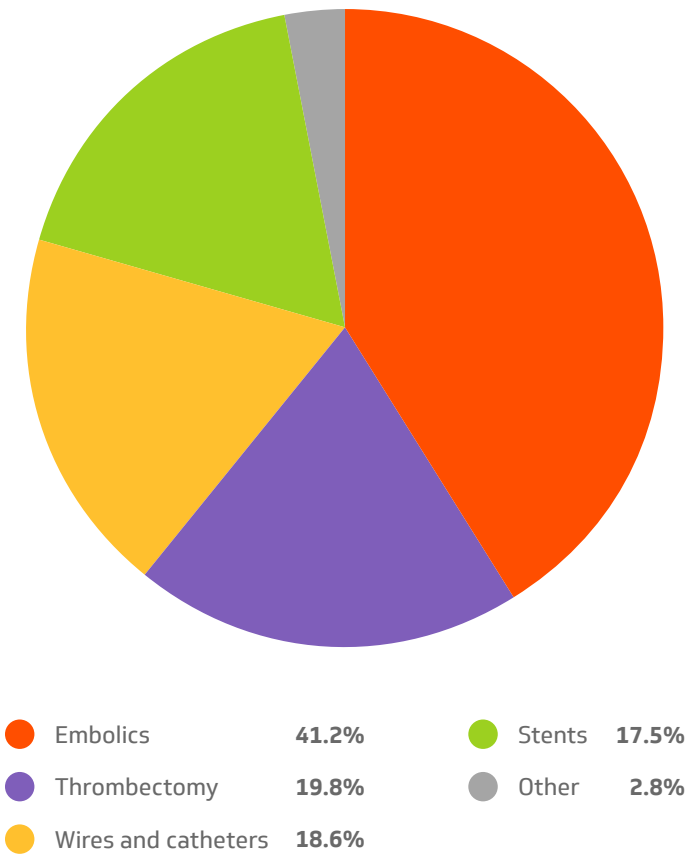
Technology watch

Neuroendovascular devices

The neuroendovascular device market, which has been growing rapidly, encompasses embolic devices (platinum coils and liquid embolic agents), neural thrombectomy devices (suction/aspiration devices, clot retrievers and snares), stent systems (carotid, cerebral and flow diversion), support devices (microcatheters and micro guidewires), and other devices. Technology for transluminal treatment of acute ischemic stroke has continued to evolve. The number of operators has expanded, driving market growth, although supplier consolidation and acquisition are complete. Suppliers in the space—Stryker, Codman and Medtronic—are influenced by the pricing strategies of the large orthopedic companies. The result is increasing prices. Last year prices increased in the microcatheter, interventional wire, liquid embolic and flow-diversion stent segments. Only coils and stents saw modest price decreases (less than two percent).

Old supplier name	New supplier name
Boston Scientific	Stryker Neuro
Micrus	Codman Neurovascular
MicroVention	Terumo MicroVention
Covidien/ev3	Medtronic Neuro

Neuroendovascular device market



During the past year, Medtronic has strengthened its product portfolio in the neuroendovascular market through the acquisition of several companies. Following its acquisition of Covidien, Medtronic also acquired Medina Medical (3D mesh implant), Lazarus Effect (nitinol mesh cover) and Reverse Medical (bifurcation aneurysm bridge device). These product additions position Medtronic well to protect its leading market position in the flow-diversion and clot-removal segments.

The statistics on stroke are alarming. Almost 800,000 Americans have a stroke each year and nearly 130,000 of those die from it, making stroke the fifth leading cause of death in the United States, according to the American Heart Association/American Stroke Association (AHA/ASA).[2] Survivors often require lengthy and expensive care. The AHA estimates that the cost to the United States of stroke-related care is more than $70 billion annually.[3] Given the aging population, these numbers are expected to increase.

The Centers for Disease Control and Prevention estimates that 87% of all strokes are caused by blockage of blood flow to the brain.[4] With early treatment, survival with few or no deficits is increasingly possible. The AHA/ASA now recommends using a stent-retrieval device to remove blood clots in select stroke patients.

The increasing numbers of trained physicians and improvements in technology have contributed to rapid evolution in this market. The U.S. neuroendovascular market has experienced high single-digit growth for the past five years, and is expected to continue to grow at a mid–single-digit rate, to over $600 million by 2020, according to iData Research.[5] This once niche market, which was centered in academic medical centers and the largest community medical centers and comprised a small group of interventional neuroradiologists, has expanded into mid-sized medical centers and now includes both neuroradiologists and neurosurgeons.

As orthopedic suppliers have acquired neuroendovascular device companies, pricing strategies have emerged focused on premium pricing and annual increases. Strong physician preference and supplier relationships make price control challenging. Supply chain executives must begin to focus on this rapidly growing market and work with their physicians to develop cost management strategies.

Devices recently approved by the FDA

ACE64 Aspiration Thrombectomy System (Penumbra, Inc., USA)

ACE64 is a large-lumen aspiration thrombectomy device with a 0.064" distal inner diameter and a 0.068" proximal inner diameter for evacuating large cerebral clots. The device is intended for use in patients with acute ischemia and large-vessel occlusive disease within eight hours of symptom onset. The device works with other devices to simplify procedures and lower procedural costs. This device received FDA 510(k) approval for use in the United States for patients with acute ischemic stroke in May 2015.

Enroute Transcarotid Neuroprotection System (Silk Road Medical, USA)

The Enroute Transcarotid NPS is an innovative device used to directly access the common carotid artery and induce high-rate temporary blood flow reversal to protect the brain from stroke while performing carotid angioplasty and stenting. The system allows stenting and balloon angioplasty to be performed while blood flow is reversed. After the stent is placed, flow reversal is turned off and normal blood flow to the brain resumes. The device and stent are indicated for use in patients for whom surgery carries a high risk. The device received FDA 510(k) approval in May 2015.

Wirion Embolic Protection Device (Allium Medical, Israel)

The Wirion Embolic Protection System is a temporary embolic protection system that filters distal to the intervention site. The system is a rapid-exchange, preloaded filter that can be used with any 0.014" interventional guidewire. The filter is delivered and deployed on the wire and the locking mechanism is activated, allowing unencumbered guidewire performance and support. At the end of the procedure, the filter is retrieved along with the wire. Embolic material including blood clots, plaque, and other solid substrates is trapped by the device. The device received approval from the FDA for the clinical indication of embolic protection during carotid artery catheterization procedures in June 2015.

Companies with recent FDA approvals for neuroendovascular devices

Vendor name	Product name	Device type	FDA no. Approval date
Premarket Approval			
Silk Road	Enroute	Transcarotid neuroprotection system	P140026 5/18/15
510(k) approval			
Sequent Medical	Via 21	Microcatheter	K150894 8/28/15
Penumbra	Smart	Coil	K151572 7/10/15
Scientia Vascular	Plato	Microcatheter	K143398 6/26/15
Roxwood Medical	Microcross	Microcatheter	K151082 6/7/15
Asahi INTECC	Asahi Corsair	Microcatheter	K151103 6/23/15
Penumbra	Ace64	Aspiration thrombectomy	K142458 5/22/15
Texas Medical Technologies	Intranovo 25	Microcatheter	K142817 4/23/15
MicroVention	Sofia	Catheter	K150366 3/27/15
Cardiogard Medical	Cardiogard	Embolic protection cannula	K141465 1/9/15

FDA = U.S. Food and Drug Administration

Companies developing neuroendovascular devices

Vendor name	Product name	Device type	Target indication
Acandis	Derivo	Flow diversion	Aneurysm occlusion
Codman	Enterprise2	Aneurysm stent	Occlusion assist
InspireMD	CGuard	Micromesh stent	Carotid artery
Medtronic	Barrel	Bifurcation stent	Occlusion assist
Medtronic	Solitaire2	Mechanical thrombectomy	Clot retrieval

Vendor name	Product name	Device type	Target indication
MicroVention	Eric	Mechanical thrombectomy	Clot retrieval
MicroVention	Roadsaver	Micromesh stent	Carotid artery
MicroVention	Scepter C	Occlusion balloon	Occlusion assist
MicroVention	Sofia	Aspiration catheter	Clot retrieval
Neuravi	EmboTrap	Mechanical thrombectomy	Clot retrieval
Phenox GmbH	pCONus	Bifurcation stent	Occlusion assist
Pulsar Vascular	PulseRider	Aneurysm bridge	Occlusion assist
Rapid Medical	Comaneci	Aneurysm bridge	Occlusion assist
Sequent Medical	WEB	Flow diversion	Aneurysm occlusion
WL Gore	Gore Carotid	PTFE-covered stent	Carotid artery

PTFE = polytetrafluoroethylene

Economic impact

The economic impact of device development in the neuroendovascular segment is growing. The combination of growth in the number of procedures and higher prices has resulted in increasing supply costs for hospitals. This trend is in opposition to the emerging reimbursement environment established by the CMS.

Reimbursement

Reimbursement for neuroendovascular procedures exists; DRG codes 20 and 21 cover complex patients and procedures. In 2015, the reimbursement amounts for those codes of $55,453 and $42,023, respectively, could be profitable for a hospital. However, the use of multiple coils or flow-diversion devices can quickly eliminate profitability when combined with other high-cost devices and the typically long hospital stays of patients with acute stroke, and neuroendovascular procedures will not be exempt from reduced reimbursement in the coming years.

Promising new neuroendovascular devices

Clot-retrieving devices

Aperio Thrombectomy Device (Acandis GmbH, Germany)

The Aperio is a nitinol stent-retriever system designed for the removal of thrombus. The device is equipped with a nitinol transport wire with a checked surface to enhance the grip and push of the wire to allow controlled and safe device placement. The device is suitable for vessel diameters from 1.5 mm to 5.5 mm and is available in four sizes with diameters of 3.5, 4.5, and 6.0 mm. The device is not available in the United States.

EmboTrap Revascularisation System (Neuravi, Ireland)

The EmboTrap Revascularization System is designed to trap the clot inside a proprietary structure that the company calls a “stent-trap” while the device restores blood flow to the brain. The stent-trap structure is engineered to retain the clot with minimal compression during the retrieval process and features a multidimensional fragment protection zone. The device also allows rapid reperfusion, improving patient outcomes and advancing the treatment of acute ischemic stroke. The device is not available for use or sale in the United States.

ARISE II Trial
NCT 02488915
Sam Zaidat, MD (St. Vincent Mercy Hospital, Toledo, OH, USA), co-principal investigator
N = 210 patients
Open label U.S. and European multicenter study

The study objective is to prove the safety and efficacy of the EmboTrap device to remove cerebral blood clots in large-vessel occlusions. The study will enroll 210 patients at up to 25 sites across Europe and the United States. Data from the study will be submitted as part of an application to the FDA for approval of the device for marketing in the United States. The study began enrolling patients in November 2015.

Lazarus Cover (Medtronic, Ireland)

The Lazarus Cover device is an innovative differentiating technology that complements Medtronic's Solitaire stent retriever platform. The Lazarus device is designed to address clinical needs with a novel nitinol "mesh cover" that folds over a stent retriever device during clot retrieval and "candy wraps" the stent with the clot inside. The device is not available for use or sale in the United States.

Tigertriever (Rapid Medical, Israel)

The Tigertriever uses Rapid Medical's proprietary technology to make it fully visible and controllable. The device can be adjusted by the physician to fit the dimensions of the blood vessel containing the clot. The Tigertriever is based on the company's adjustable remodeling mesh technology. The device received CE marking in January 2016; it is not available for use or sale in the United States.

Embolization assist devices

Barrel VRD (Reverse Medical/Medtronic, Ireland)

The Barrel VRD is a self-expandable bifurcation aneurysm-bridging device designed to be used in treating intracranial bifurcation aneurysms. The device reduces the neck size of wide-neck bifurcation aneurysms to enable traditional coil embolization. The device is not available for use or sale in the United States.

Reverse Barrel VRD Trial
NCT 02179190
Eric Sauvageau, MD (Baptist Medical Center, Jacksonville, FL, USA), co-principal investigator
N = 164 patients
Prospective, nonrandomized, single-arm, multicenter U.S. study

The single-arm study is to evaluate the safety and effectiveness of the Barrel VRD and to evaluate the outcomes of treatment with the Barrel VRD device as an adjunctive treatment to coiling for wide-necked, bifurcating/branching aneurysms in the middle cerebral and basilar arteries. No data is available at this time.

Comaneci Remodeling Mesh (Rapid Medical, Israel)

The Comaneci device is for temporary coverage of wide-necked intracranial aneurysms during coil occlusion. It provides bridging and has the advantage of averting flow arrest during deployment. The device is designed to confer the same benefits as balloon remodeling but without the risks of parent artery occlusion. This alleviates time pressure on the physician and may reduce the risk of parent artery thrombosis. The device is not available for use or sale in the United States.

Derivo Embolization Device (Acandis GmbH, Germany)

The Derivo embolization device is a next-generation flow diverter that offers easy handling, secure repositioning, and innovative surface finishing. It reduces flow velocity in the aneurysm and supports progressive thrombosis, thus contributing to possible long-term regression of the aneurysm. The device is suitable for treatment of vessel from 2.5 mm to 6.0 mm in diameter. It is available in diameters ranging from 3.5 mm to 6.0 mm and lengths from 15 mm to 50 mm. The device is not available in the United States.

eClips (Evasc Medical Systems, Canada)

eClips is an innovative device for the treatment of saccular bifurcation aneurysms. The device secures the aneurysm by bridging the neck, creating flow effect and providing scaffolding for endothelial coverage. In situ, it causes no side-branch caging and does not require anchoring in the trunk vessel. Coiling can be accomplished through the mesh of the device. The device is not available for use or sale in the United States.

Medina Embolization Device (Medina Medical/Medtronic, Ireland)

The Medina Embolization Device is an intrasaccular three-dimensional mesh implant that fills the inside of an intracranial aneurysm. This technology features self-expandable mesh that provides a scaffold across the aneurysm neck, conforms to the shape of the aneurysm and reduces blood flow into the aneurysm. The device is not available for use or sale in the United States.

Neuroform Atlas Stent (Stryker, USA)

The Neuroform Atlas stent is the fourth generation of the Neuroform stent platform. The stent features an innovative adaptive cell architecture that is designed to optimize conformability and stability when treating wide-necked intracranial aneurysms. The stent is indicated for use with bare-metal embolic coils for the treatment of wide-necked intracranial saccular aneurysms arising from a parent vessel with a diameter between 2 mm and 4.5 mm. The stent, like the current Neuroform platform, is available in diameters from 3.0 mm to 4.5 mm. Neuroform Atlas received CE marking in August 2015; it is not available in the United States.

p64 Flow Modulation Device (Phenox GmbH, Germany)

The p64 Flow Modulation Device is the only flow diverter that allows complete deployment and full recoverability. The device, an extremely fine-mesh stent because of its 64 nitinol wire braids, maximizes hemodynamic flow effect when placed across the neck of a small aneurysm and alters the flow sufficiently to allow thrombosis of the aneurysm. The p64 device, available in diameters up to 6 mm, is deployed through a microcatheter. The device is not available for use or sale in the United States.

PulseRider Neuro Platform (Pulsar Vascular, USA)

The PulseRider Neuro Platform is a minimally invasive device intended for use with embolic coils in the treatment of unruptured wide-necked intracranial aneurysms originating on or near a bifurcation. The device, a self-expanding nitinol implant that bridges the wide neck of the aneurysm, provides a new endovascular option to patients and physicians. The device is not available for use or sale in the United States.

ANSWER Clinical Trial
NCT 02312856
Alejandro Spiotta, MD (Medical University of South Carolina, Charleston, SC, USA), principal investigator
N = 30 patients
Prospective, nonrandomized, multicenter U.S. study

This study, conducted at 10 U.S. hospitals, is designed to evaluate the safety of the PulseRider in patients undergoing treatment for bifurcation basilar or carotid terminus aneurysms for potential FDA approval. Enrollment was completed in Oct. 2015. No data is available yet on the study outcomes.

Uno Neurovascular Embolization System (Reverse Medical/Medtronic, Ireland)

The Uno Neurovascular Embolization System is a self-expanding vessel occlusion device designed to rapidly obstruct blood flow in the neurovasculature. The device is deployed within the vessel, sacrificing the vessel while reducing blood flow to the aneurysm and the time that would otherwise be required for multiple coil deployments. The device is not available for use or sale in the United States.

WEB Aneurysm Embolization Device (Sequent Medical, USA)

The WEB Aneurysm Embolization System is a family of nitinol devices for the treatment of both ruptured and unruptured aneurysms. The device uses a dense, microbraid mesh spanning the aneurysm neck providing inflow disruption, slowing intrasaccular flow and resulting in intraprocedural stasis. The company's proprietary braid technology creates a dense mesh constructed from a large number of extremely fine nitinol wires of mixed diameters to achieve a balance of compliance, porosity, and profile across device sizes. The device is not available for use or sale in the United States.

WEB-IT Study
NCT 02191618
Adam Arthur, MD (Methodist University Hospital, Memphis, USA), co-principal investigator
N = 150 patients
Prospective, nonrandomized, single-arm, multicenter, multicountry trial

The study is designed to evaluate the safety and efficacy of the WEB device in patients with ruptured or unruptured wide-necked intracranial bifurcation aneurysms for which there otherwise would be few choices for safe and effective endovascular treatment. In this study, all patients who qualify will be treated with the WEB device. The primary effectiveness outcome of the study is the rate of complete aneurysm occlusion on the one-year angiogram, as adjudicated by a core laboratory. The study will be conducted at 25 investigational sites, including 20 in the United States.

Flow-diversion devices

Flow Re-Direction Endoluminal Device (FRED) (MicroVention Terumo, Japan)

The FRED system is a next-generation flow diversion device intended for the treatment of intracranial aneurysms. The device consists of a 16-wire outer stent and a 48-wire inner stent with four atraumatic flared ends. The system is an integrated dual-layer, self-expanding nitinol braided stent-within-a-stent. The high radial force outer stent and the low-porosity/high metal surface area inner stent combine to provide enhanced stent opening, improved vessel apposition, and fluoroscopic visibility. The device is designed to help reduce blood flow and redirect it away from the aneurysm sac. The system offers an additional benefit over first-generation flow diversion devices: its ability to be partially deployed, retrieved, and accurately redeployed without the need for a torque device. The device is not available for use or sale in the United States.

FRED Trial
NCT 01801007
Cameron McDougall, MD (Barrow Neurological Institute, Phoenix, AZ, USA), principal investigator
N = 137 patients
Prospective, nonrandomized, multicenter U.S. trial

The purpose of this study is to evaluate the safety and effectiveness of the FRED system when used in the treatment of wide-necked intracranial aneurysms. This is a pivotal trial to support the submission to the FDA. The study began in 2013 with more than 20 U.S. hospitals participating. The study is ongoing but not accepting new patients. No clinical data is yet available.

Other neuroendovascular devices

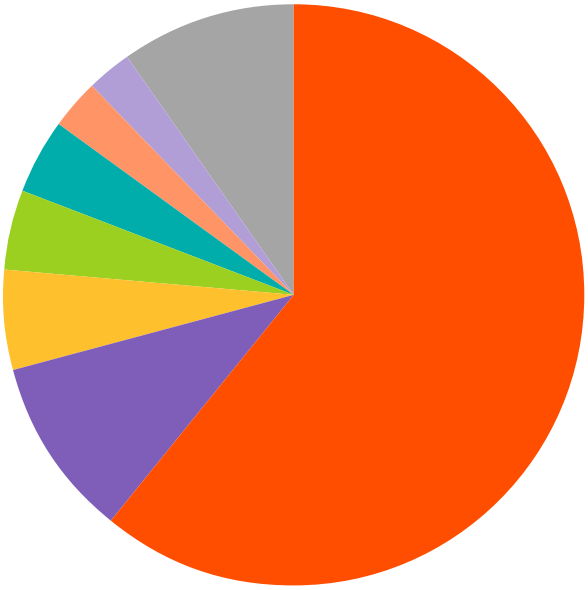
CGuard MicroNet Embolic Protection System (InspireMD, Germany)

The CGuard Embolic Prevention System is designed to prevent periprocedural and late embolization by trapping potential emboli against the arterial wall while maintaining perfusion to the external carotid artery and branch vessels. The stent combines a nitinol stent structure with a MicroNet polyethylene terephthalate inner cover, and is available in lengths of 20, 30, 40 and 60 mm and in diameters of 6 mm to 10 mm. The stent is not yet available in the United States.

Coronary stents and scaffolds

The coronary stent market is on the verge of exciting change. Late last year, bioabsorbable polymer-coated drug-eluting stents became available in the United States. Based on European experience, this class of stent has become the workhorse. This year the bioabsorbable scaffold is likely to enter the U.S. market. On March 15, the Circulatory System Devices Panel of the FDA's Medical Devices Advisory Committee is scheduled to discuss, make recommendations and vote on the premarket approval application for the Absorb GT1 Bioresorbable Vascular Scaffold System. The potential availability of these new coronary devices will provide patients and clinicians with innovative options that have the potential to improve outcomes.

Coronary device market



Coronary stents	**61.0%**	Arthrectomy	**4.1%**
Baloon catheters	**10.1%**	Guiding catheters	**2.8%**
Interventional wires	**5.6%**	Angio catheters	**2.6%**
Sheaths	**4.5%**	Other	**9.5%**

Coronary stents continue to dominate the overall coronary market, commanding the majority of the market spend. This dominance has been declining, however, as pricing pressure continues. Prices of drug-eluting stents continue to fall by five to seven percent annually; coronary drug-eluting stent prices are now under $1,000 net per unit. Many hospitals have negotiated a combination of reduced pricing and rebates. (The next largest product segment, coronary balloon dilation catheters, has also seen four to six percent annual price reductions.)

Stent pricing decreases are expected to slow somewhat as new stents and scaffolds enter the market. In the long term, however, prices will continue to decline overall. According to data from iData Research, Inc., procedural volumes are projected to increase after years of decline, although the rate of increase is expected to be marginal—one to two percent annually.[6] The growth in volume is offset by the faster decline in product prices, as noted above.

Potential changes within the larger health care environment are affecting the coronary stent market. The influence of physician employment, the 28-day readmission penalty and CMS experiments with alternative models such as bundled payments for cardiovascular procedures are combining to drive these changes. The need to use medical devices that can potentially keep patients out of the hospital longer and demonstrate improved economic and outcomes data to payers is driving hospitals to look at product procurement differently. Suppliers are spending more to add economic outcomes measures to clinical trials. Many suppliers have introduced health care economics groups, consulting and risk-share options. The coronary stent market will be at the forefront of change in the coming year. Despite the remaining uncertainty, efforts today to improve outcomes and lower costs will pay dividends as the changes in health care solidify.

Devices recently approved by the FDA

Synergy Bioabsorbable Polymer Drug-Eluting Stent System (Boston Scientific, USA)

The Synergy drug-eluting stent is the first coronary stent available in the United States that has a bioabsorbable polymer coating. The stent is made of a platinum chromium alloy that consists of platinum, chromium, iron, nickel, and molybdenum. The stent uses a bioabsorbable poly(lactic-co-glycolic acid) polymer and everolimus drug combination to create a thin, abluminal coating. The drug is released over the first three months and the coating dissolves over several additional months, leaving only a bare metal stent in the vessel and thereby reducing the risk of very late stent thrombosis. The device was launched in the United States in October 2015.

Companies with recent FDA approvals for coronary products

Vendor name	Product name	Device type	FDA no. Approval date
Premarket approval			
Boston Scientific	Synergy	Drug-eluting stent	P150003 10/2/15
Boston Scientific	Watchman	Left atrial appendage closure	P130013 3/13/15
Abiomed	Impella 2.5	Coronary hemodynamic support	P140003 3/13/15
510(k) approval			
Vascular Solutions	Fluent	Inflation device	K152387 12/18/15
Cook Medical	Flexor Radial	Hydrophilic introducer access set	K152044 8/14/15
Datascope	Cardiosave	Hybrid intra-aortic balloon pump	K151254 7/2/15
Medtronic	Euphora Rx	PTCA balloon catheter	K143480 4/2/15
Shanghai MicroPort Medical	Foxtrot NC	PTCA balloon catheter	K143160 3/5/15

FDA = U.S. Food and Drug Administration; PTCA = percutaneous transluminal coronary angioplasty.

Companies developing bioresorbable coronary scaffold devices

Vendor name	Product name	Origin	Material type	Drug	CE marking
PLLA–based					
Abbott Vascular	Absorb	USA	PLLA	Everolimus	Yes
Amaranth Medical	Fortitude	USA	PLLA	Sirolimus	No

Vendor name	Product name	Origin	Material type	Drug	CE marking
Arterial Remodeling Technologies (Terumo)	ART BRS	France	PLDL	None	Yes
Arterius	Arteriosorb	UK	PLLA	Sirolimus	No
Boston Scientific	Fast	USA	PLLA	Everolimus	No
Cardionovum	Renatural P	Germany	PLLA	Sirolimus	No
Elixir Medical	Desolve	USA	PLLA	Novolimus	Yes
Huaan Biotech	Xinsorb	China	PLLA + PCL + PLGA	Sirolimus	No
Icon Interventional	Biosorb	USA	PLA	None	No
Kyoto Medical	Igaki-Tamai	Japan	PLLA	None	No
Meril Life Sciences	Meres	India	PLA	Merilimus	No
MicroPort	BSS	China	PLLA	Sirolimus	No
OrbusNeich	On-Abs	USA	PLLA + PDLA ε-caprolactone	Sirolimus + CD34 antibodies	No
S3V Vascular	Avatar	India	PLLA	Multi	No
Sahajanand	None	India	Heparinized PLLA	Genistein	No
Stron Medical	None	Germany	PLA	Sirolimus	No
Metal-based					
Biotronik	DREAMS	Germany	Magnesium	Paclitaxel	No
Boston Scientific	BSC BRS	USA	Magnesium	Everolimus	No
Cardionovum	Renatural M	Germany	Magnesium alloy	Sirolimus	No
Medtronic	DFS	Ireland	Magnesium alloy	Zotarolimus	No
Zorion Medical	Zorion BRS	USA	Magnesium alloy + PGA	None	No
Other polymer-based					
Reva Medical	Fantom	USA	Desaminotyrosine-derived polycarbonate	Sirolimus	No
Tepha Inc.	TephaFlex	USA	TephaFlex biopolymer (P4HB)	None	No
Xenogenics	Ideal Biostent	USA	Salicylic acid	Sirolimus	No

BRS = bioresorbable scaffold; DFS = drug-filled stent; PCL = polycaprolactone; PGA = poly-glycolic acid; PLA = polylactic acid; PLDL = poly-L,D-lactic acid; PLGA = poly-lactide-co-glycolide; PLLA = poly-L-lactic acid.

Companies developing biodegradable coated drug-eluting stents

Vendor name	Product name	Origin	Material type	Drug	CE marking
Balloon-expandable stent					
Alvimedica	Coracto	Italy	Stainless steel	Amphilimus	Yes
Biosensors	Biomatrix Flex	Germany	Stainless steel	Biolimus A9	Yes
Biotronik	Orsiro	Germany	Cobalt chromium	Sirolimus	Yes
B Braun	Coroflex Isar	Germany	Chromium cobalt	Sirolimus + probucol	Yes
Elixir Medical	Desyne BD	USA	Cobalt chromium	Novolimus	Yes
Medtronic	Onyx	Ireland	Cobalt alloy	Zotarolimus	Yes
Micell Technologies	Mistent	USA	Cobalt chromium	Sirolimus	Yes
Microport	Firehawk 2	China	Chromium cobalt	Sirolimus	No
Rontis	Abrax	Switzerland	Carbonized stainless steel	Sirolimus	Yes
S3V Vascular	Avatar	India	Stainless steel	Sirolimus	Yes
Stron Medical	Galaxy	Germany	Carbonized stainless steel	Sirolimus	Yes
Terumo	Ultimaster	Japan	Chromium cobalt	Sirolimus	Yes
Self-expandable stent					
Stentys	Self-apposing	Germany	Nitinol	Sirolimus	Yes

Economic impact

The economic impact of stent development will be marginal. The recently released Synergy drug-eluting stent was released at a premium price. The release of the absorbable scaffold will also be at a premium, but significantly less than originally projected. Combined, these new devices may have the potential to increase catheterization lab spend by approximately seven to nine percent.

Reimbursement

Reimbursement for the stent products exists. At the time the bioabsorbable scaffold is introduced, no unique reimbursement will exist. Based on the experience with the drug-coated balloon, it is possible that reimbursement for the scaffold may become available soon after its introduction. If the bioabsorbable scaffold is approved by the FDA before July 1, the device will be eligible for a new technology add-on payment beginning in October 2016, assuming a new coding category is not created. Over the next several years the most significant impact on reimbursement for coronary devices will be reduced reimbursement as a result of changes in the health care industry as a whole. In the longer term, the potential for a bundled payment for percutaneous coronary intervention or other value-based procedural pricing will have an additional impact on this category of products.

Promising new coronary stents and scaffolds

Coronary scaffolds

Absorb Drug-eluting Scaffold (Abbott Vascular, USA)

The Absorb bioresorbable vascular scaffold is a new generation of coronary device. Like a drug-eluting coronary stent, it is designed to open blocked coronary arteries. The Absorb is made of a naturally dissolvable material, poly-L-lactide (PLLA), which has been safely used in medical products for many years. The scaffold works by opening a coronary artery blockage and restoring blood flow to the heart. After the vessel heals, the device dissolves, leaving the vessel free of a permanent implant and allowing it to return to natural function. The scaffold also features a bioresorbable coating made of poly-D,L-lactide (PDLLA) and everolimus, a cell-growth–inhibiting drug, which helps give the vessel time to heal after it is opened. The scaffold will be available in diameters of 2.5, 3.0 and 3.5 mm and lengths of 8, 12, 18, 23 and 28 mm. The device will be reviewed and potentially recommended for FDA approval by the FDA's Cardiovascular Committee in February 2016.

ABSORB III Trial
NCT 01751906
Stephen Ellis, MD (Cleveland Clinic, Cleveland, Ohio, USA), co-principal investigator
N = 2,250 patients
Prospective, randomized, single-blind, multicenter U.S. trial

The ABSORB III trial is a prospective randomized, single-blind trial at 193 U.S. and non-U.S. sites comparing the safety and effectiveness of the Absorb system with that of Xience stents to demonstrate noninferiority of Absorb. It is the pivotal trial to support the U.S. premarket approval of the Absorb Bioresorbable Vascular Scaffold. The one-year data demonstrated that the device is safe and effective. It also showed that there are no statistically significant differences between Absorb and Xience. The primary endpoint of the study, target lesion failure, was 7.8 percent for Absorb and 6.1 percent for Xience ($P < .007$; not statistically significant). None of the other results for the prespecified secondary endpoints showed statistically significant differences, including incidence of angina. The data from this trial will be used on March 15, 2016, to support application for FDA committee approval.

Drug-filled Stent (Medtronic, Ireland)

The Medtronic drug-filled stent is both a drug-eluting stent and a bare-metal stent built on the platform of the Resolute Onyx drug-eluting stent with Continuous Sinusoid technology that molds one single strand of wire into a sinusoidal wave enabling a continuous range of motion. The new drug-filled stent features a novel triple-layer wire design that allows the innermost core layer to be removed so that the hollow strut lumen functions as an internal drug reservoir. The drug is eluted from the core through small, laser-drilled, abluminal side holes on the surface of the stent, allowing controlled, polymer-free drug elution over a desired period of time directly into the arterial wall to help prevent chronic inflammation and adverse vascular responses. The clinical trial, intended to support application for CE marking, began enrolling patients in October 2015.

DREAMS (Biotronik, Germany)

The DREAMS (Drug-Eluting Absorbable Metal Scaffold) device is a fully bioresorbable scaffold made from a magnesium alloy covered with a polymer and sirolimus drug coating. This new class of absorbable metal scaffolds has the potential to become available in the United States. The scaffold resorbs within 12 months, faster than polymer-based bioresorbable scaffolds. The BIOSOLVE-II trial is investigating the safety and clinical performance of the magnesium-based bioresorbable scaffold.

Resorbable Scaffold (Boston Scientific, USA)

The resorbable polymer scaffold incorporates several design elements from the Boston Scientific Synergy Stent System, including a resorbable polymer and an ultrathin everolimus coating which is applied on the exterior surface to the scaffold. It also features a delivery system designed to facilitate improved acute performance. A study of the scaffold initiated in July 2015, the Fully Absorbable Scaffold Feasibility (FAST) study (NCT 02470884), is a prospective, single-arm study designed to assess the safety and performance of the scaffold for the treatment of coronary lesions.

Coronary bioabsorbable polymer stents

Resolute Onyx Drug-Eluting Stent Systems (Medtronic, Ireland)

The Resolute Onyx drug-eluting stent features the company's proprietary CoreWire technology, a dense metal inner core surrounded by cobalt alloy. A single strand of wire is molded into a sinusoidal wave and then wrapped and soldered at specific contact points to create a stent with a continuous range of motion. The new materials allow the stent to have thinner struts and a lower profile, but more visibility during the procedure.

Resolute Onyx 2.0 mm Trial
NCT 02412501
Matthew J. Price, MD (Scripps Green Hospital, San Diego, CA, USA), co-principal investigator
N = 100 patients
Prospective, randomized, multicenter U.S. trial

The first patient was enrolled in this randomized clinical study in March 2015. The first phase of the study will evaluate the stent's safety and effectiveness in coronary arteries with small vessel diameters (2 mm). Other stent sizes will be studied separately. The study will be used to obtain FDA approval. No data is available at this time.

Slender IDS (Svelte Medical, USA)

The Slender IDS (integrated delivery system), also called a "stent-on-a-wire," is a unique drug-eluting coronary stent fixed-wire system. It combines the latest guidewire, delivery balloon and drug-eluting stent technologies into a single, "all-in-one" fixed-wire system. Asahi Actone wire technology provides precise steering while proprietary balloon technology allows controlled balloon growth to safely perform direct stenting and high-pressure postdilatation. A sirolimus drug coating is applied to a highly conformable cobalt chrome stent and a natural, amino acid-based polyesteramide bioresorbable drug carrier. The device gained CE marking in December 2015. The company hopes to submit an application for premarket approval to the FDA in 2016.

Other coronary stents

Tryton Side Branch Stent (Tryton Medical, USA)

The Tryton Side Branch Stent is a bifurcation stent system designed to actively treat, protect, and secure arterial bifurcations. The stent's proprietary design, known as Tri-Zone Technology, provides scaffolding within the side branch, radial strength in the transition and minimal coverage in the main vessel. The bare-metal coronary cobalt chromium stent is deployed in the side-branch artery using a standard single-wire balloon-expandable stent delivery system. The stent is intended to treat and maintain patency in the side branch/carina by providing better ostial side branch conformability and is intended for use in conjunction with currently approved balloon-expandable drug-eluting stents for treatment of the main branch.

Tryton Study
NCT 01258972
Martin B. Leon, MD (Columbia University Medical Center, New York, NY, USA), principal investigator
N = 133 patients
Prospective, randomized, single-blind, multicenter U.S. trial

This pivotal study will be used to support the company's application for FDA approval. Patient enrollment was complete in late in 2015. Recent clinical data established an acceptable acute safety profile for the treatment of coronary bifurcation lesions in vessels appropriate for a ≥ 2.5-mm stent. In addition, a post-hoc analysis of the Tryton Randomized Clinical Trial (n = 704) by Grundeken et al showed that the Tryton side branch stent reduced target vessel failure and improved side-branch stenosis compared with provisional stenting in the intended treatment population (i.e., patients for whom a ≥ 2.5-mm stent was appropriate).[7] The company hopes to submit data to the FDA in early 2016.

PK Papyrus Covered Stent (Biotronik, Germany)

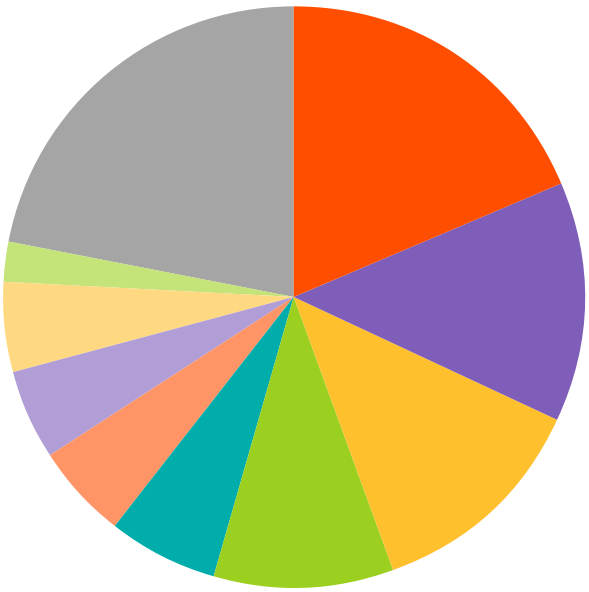
The PK Papyrus covered coronary stent system is intended for the treatment of acute coronary artery perforation. The manufacturer claims the device has greater flexibility than Abbott's Jostent Graftmaster as a result of its innovative "electrospun" membrane. The technology allows for a proprietary single-layer covered stent design rather than the traditional "sandwich technique," allowing the device to be 5F compatible. The single-layer, 90-µm polyurethane membrane combines high flexibility and a low crossing profile for exceptional deliverability while sealing vessel defects in acute situations. Severe acute perforations are rare. When one occurs, a covered stent compatible with existing devices can save the physician valuable time. The stent is available in a wide range of sizes (diameters of 2.5-5.0 mm, lengths of 15-26 mm), allowing a broad range of vessels to be treated confidently and efficiently. The device is not available for use or sale in the United States.

Peripheral vascular devices

Peripheral vascular devices are used to treat peripheral arterial disease, which affects about eight million Americans and becomes more common with age. The most common symptoms of peripheral arterial disease are cramping and pain or tiredness in the leg or hip muscles while walking or climbing stairs. The disease is characterized by hardening and thickening of the artery walls due to fatty deposits or blood clots.

The peripheral vascular device market is complex, encompassing numerous procedures such as vascular stenting, atherectomy, chronic total occlusion repair, transcatheter embolization and vena cava filter implantation. For each procedure, a variety of medical devices may be used. Procedures may be performed in multiple locations in the hospital, further complicating the management of patients and device usage. The treatment of problems with arterial blood flow continues to be the largest segment in the peripheral vascular device market. Increasing awareness and diagnosis of peripheral artery disease along with the introduction of improved devices is driving an annual growth rate of four to six percent in this market.

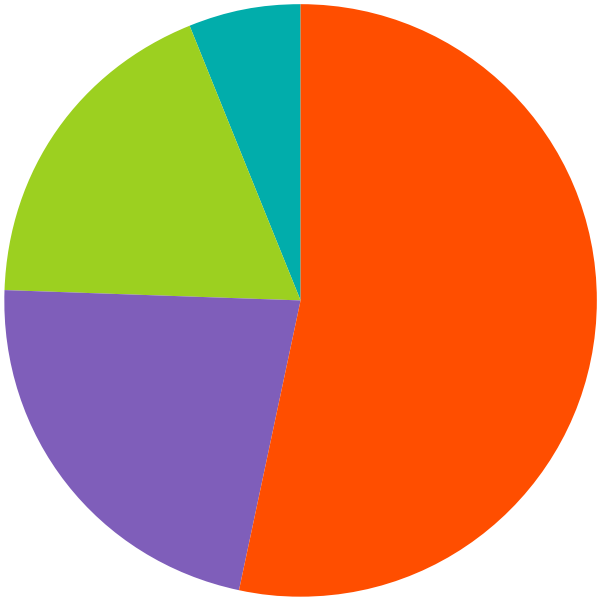
Peripheral device market



Stents	18.7%	Vena cava filters	5.3%
Interventional wires	13.3%	Drug balloons	5.1%
Baloon catheters	12.7%	Angio catheters	5.0%
Arthrectomy	9.9%	CTO devices	2.2%
Embolics	6.0%	Other	21.8%

CTO = chronic total occlusion.

Peripheral stent market



Self-expandable	53.4%	Covered	18.3%
Balloon-expandable	22.3%	Drug-eluting	6.1%

Peripheral stents comprise the largest segment of the peripheral device market, accounting for 20 percent of devices. This figure has been declining, however, as pricing pressure continues to drive unit prices lower. Prices for self-expanding stents continue to fall by five to seven percent annually. Balloon-expandable stent prices are declining at a faster rate. The introduction of drug-coated balloons late in 2014 is having an impact on stent unit volume growth. These devices have emerged as one of the fastest growing segments in the peripheral vascular device market. Drug-coated balloons are in their first year of U.S. availability with a high-single-digit market share. Strong U.S. growth in this segment is expected to continue based on positive clinical data, availability of outpatient reimbursement and a new technology add-on payment for inpatient procedures. In addition to new devices, new competitors are entering the U.S. market, including the newest arrivals in the already-crowded stent segment, Terumo and Biotronik. At least three new competitors are currently conducting clinical trials of drug-coated balloons in support of applications for FDA approval.

Devices recently approved by the FDA

IN.PACT Admiral Drug-Coated Balloon (Medtronic, Ireland)

The IN.PACT Admiral drug-coated balloon is designed to treat patients with peripheral arterial disease who suffer from blockages in the upper leg including the superficial femoral and popliteal arteries. The balloon is coated with a combination of two substances: a drug (paclitaxel) and a natural substance (urea) that aids in the transfer of the drug from the balloon to the artery wall. The balloon is available in diameters of 4 mm to 7 mm and lengths of 40 mm to 150 mm. The product was approved in February 2015.

VenaSeal Closure System (Medtronic, Ireland)

The VenaSeal closure system is designed to provide permanent treatment of varicose veins in the legs by sealing the affected superficial veins using an adhesive agent. A health care professional monitors the placement of the catheter into the vein using ultrasound imaging and delivers a clear adhesive liquid that polymerizes into a solid material within the vein. The system is made up of an adhesive, a specially formulated n-butyl-2-cyanoacrylate, and delivery system components that include a catheter, guidewire, dispenser gun, dispenser tips, and syringes. The stent was approved in February 2015.

Misago Vascular Stent System (Terumo Medical, Japan)

The Misago stent system consists of a nitinol stent premounted on the distal portion of a rapid-exchange delivery catheter. The stent is approved for treatment of peripheral artery disease in the superficial femoral artery and proximal popliteal artery. The stent is available in a range of sizes to treat vessels with diameters from 4 mm to 7 mm and lesion lengths up to 150 mm. The stent was approved in May 2015.

Innova Vascular Stent System (Boston Scientific, USA)

The Innova vascular stent system is an evolutionary design of the company's peripheral stent platform. The self-expanding stent is indicated to treat narrowing or blockages in the superficial femoral artery or proximal popliteal artery. The platform consists of a nitinol self-expanding bare-metal stent with an advanced delivery system. It is available in a range of sizes, including diameters from 5 mm to 8 mm and lengths of 20 mm to 200 mm. It features mixed-cell architecture with open cells along the stent body and closed cells at each end for uniform and accurate deployment. This stent platform serves as the foundation for the new Elivia drug-eluting vascular stent. The stent was approved by the FDA in July 2015.

AngioJet ZelanteDVT thrombectomy catheter (Boston Scientific, USA)

The AngioJet ZelanteDVT thrombectomy catheter is designed to treat deep vein thrombosis in large-diameter upper- and lower-limb peripheral veins. The device can deliver four times the suction power of previous AngioJet catheters and so is able to remove larger clots with more consistency. The device is intended for removing thrombi from veins of at least 6 mm in diameter, but can also be used for infusion of thrombolytic and other agents into the vasculature. The catheter is the company's first catheter specifically designed to treat deep vein thrombosis. The catheter was approved by the FDA in December 2015.

Companies with recent FDA approvals for peripheral vascular products

Vendor name	Product name	Device type	FDA no. approval date
Premarket approval			
Cook Medical	Zenith Alpha	Thoracic endograft	P140016 9/15/15
Boston Scientific	Innova	Self-expanding stent	P140028 7/21/15
Terumo Medical	Misago	Self-expanding stent	P14002 5/22/15
Medtronic	Venaseal	Venous closure device	P140018 2/20/15

Vendor name	Product name	Device type	FDA no. approval date
510(k) approval			
MicroVention	Hydropearl	Microspheres	K150870 12/21/15
Boston Scientific	Stingray LP	CTO catheter	K152401 12/4/15
Biotronik	Passeo-18	PTA 18 balloon catheter	K151744 10/8/15
MicroVention	Lifepearl	Microspheres	K150958 9/17/15
Kaneka Corp	Metacross	PTA balloon catheter	K152080 9/24/15
Abbott	Hi-Torque Command	18 guidewire	K152404 9/21/15
AccessClosure Cardinal Healthcare	PaxWire	Occlusion balloon system	K143613 8/14/15
Kaneka Corp	Metacross Rx	PTA balloon catheter	K150865 8/3/15
Abbott	Armada 18	PTA balloon catheter	K151317 7/6/15
Hotspur Technologies	Arrow GPSCath	PTA 18 balloon catheter	K143093 6/24/15
Asahi Intecc	Asahi	Peripheral guidewire series	K150445 6/30/15
Texas Medical Technologies	TBD	PTA 14 balloon catheter	K142954 5/28/15
Vector Corp	Vector	PTA balloon dilatation catheter	K143652 2/26/15

CTO = chronic total occlusion; FDA = U.S. Food and Drug Administration; PTA = percutaneous transluminal angioplasty; TBD = to be determined.

Companies developing drug-coated balloon dilatation catheters

Vendor name	Product name	Origin	Drug	CE marking
Peripheral vascular				
Aachen Resonance	Elutax	Germany	Paclitaxel	Yes
Bayer Interventional	Cotavance	USA	Paclitaxel	Yes

Vendor name	Product name	Origin	Drug	CE marking
B. Braun	Sequent Please	Germany	Paclitaxel	Yes
Biosensors International	Biopath	Singapore	Paclitaxel	Yes
Biotronik	Pantera Lux	Germany	Paclitaxel	Yes
Boston Scientific	Ranger	USA	Paclitaxel	Yes
Concept Medical	Magic Touch	USA	Sirolimus	No
Cook Medical	Advance 18 PTX	USA	Paclitaxel	Yes
Covidien	Stellarex	Ireland	Paclitaxel	No
Eurocor	Freeway	Germany	Paclitaxel	Yes
Hemoteq	Agent	Germany	Paclitaxel	No
iVascular	Oceanus 14	Spain	Paclitaxel	Yes
Coronary				
Biosensors International	Biostream	Singapore	Paclitaxel	Yes
Cardionovum	Restore DEB	Germany	Paclitaxel	Yes
EuroCor	Dior	Germany	Paclitaxel	Yes
Micell Technologies	TBD	USA	Sirolimus	No
Minvasys	Danubio	France	Paclitaxel	Yes
QualiMed	TBD	Germany	Paclitaxel	Yes

TBD = to be determined

Economic impact

The economic impact of peripheral vascular device development will be marginal. Innovative new devices are being introduced at marginally premium prices. The average cost of the drug-coated balloon is approximately $1,500, compared with the average cost of $800 to $1,100 for a traditional percutaneous transluminal angioplasty catheter plus balloon-expandable stent.

Reimbursement

Reimbursement exists for the majority of peripheral vascular procedures. Reimbursement for the outpatient use of the drug-coated balloon was made available soon after the device's introduction; a new add-on payment was approved for inpatient use in October 2015. Over the next several years the most significant impact on reimbursement will be a reduction as a result of overall changes in the health care market.

Promising new peripheral vascular devices

Drug-coated balloons

Ranger DCB (Boston Scientific, USA)

The Ranger drug-coated balloon for the treatment of peripheral artery disease combines the deliverability of the Sterling balloon platform and the proven drug paclitaxel. The balloon features proprietary TransPax coating technology and an innovative loading tool designed to maintain drug-coating integrity and maximize drug-transfer efficiency, resulting in consistent and predictable drug delivery. The device is not available for use or sale in the United States.

Advance 18 PTX Drug-Eluting PTA Balloon Dilation Catheter (Cook Medical, USA)

The Advance 18 PTX combines the mechanical therapy of the Advance peripheral balloon platform with the drug paclitaxel. No polymers or excipients are used during manufacturing and the balloon is coated before being folded, allowing for more drug-to-vessel contact. The balloon will be available in a range of sizes, including diameters of 3 mm to 7 mm and lengths of 40 mm to 100 mm. The balloon has not been approved for use or sale in the United States.

Drug-Coated Chocolate PTA Balloon (TriReme Medical, USA)

The drug-coated Chocolate PTA balloon is intended for treatment of peripheral artery disease. The balloon's uniqueness lies in its external constraining mesh, which prevents overinflation and potential dissections of the vessel. The balloon itself has rings positioned along its tract that prevent it from expanding into a uniform shape and form "valleys" that prevent large bits of particularly hard calcification from being pushed into the vessel wall where they might cause damage. The balloon uses a paclitaxel-based coating to reduce the buildup of tissue in the vessel. The non–drug-coated version of the balloon is being distributed in the United States through Cordis, a Cardinal Healthcare company. The ENDURE Trial (NCT02129127) is currently enrolling patients. The device is not available for use or sale in the United States.

Drug-eluting stents

Eluvia Drug-Eluting Vascular Stent System (Boston Scientific, USA)

The Eluvia stent system is indicated to treat narrowing or blockages in the superficial femoral artery or proximal popliteal artery. The stent is built on the Innova stent system platform (approved for use in the United States in July 2015). The stent consists of a self-expanding nitinol stent and a 6F low-profile triaxial delivery system. The stent architecture features a closed-cell design at each end of the stent for more predictable deployment and an open-cell design along the stent body for improved flexibility, strength and fracture resistance. The stent uses paclitaxel. Data from the MAJESTIC trial will be used to gain CE marking. The device is not available for use or sale in the United States.

MAJESTIC Trial
NCT 01820637
Stefan Müller-Hülsbeck, MD, PhD (Ev Luth Diakonissenanstalt, Flensburg, Germany), principal investigator
N = 57 patients
Prospective, randomized, multicenter European trial

The 12-month trial results were presented the September 2015. The trial included a high percentage of complex lesions with an average lesion length of 70.8 mm; 46 percent of the lesions were classified as total occlusions and 5 percent were identified as severely calcified. The target lesion revascularization rate was 3.8 percent; there were no observed stent fractures and no amputations. The stent demonstrated a primary patency rate of more than 96.1 percent. These results represent the highest 12-month primary patency reported for an interventional treatment of femoropopliteal artery lesions among comparable trials.

Other devices

Embozene Tandem Drug-Elutable Microspheres (CeloNova Biosciences, USA)

The Tandem drug-elutable microspheres are Embozene microspheres with the potential for full integration of drugs. The microspheres are designed to be loaded with chemotherapy drugs for delivery to cancerous tumors and spherical embolic products used to treat uterine fibroids and other conditions. The microspheres are capable of loading doxorubicin HCl, idarubicin HCl epirubicin HCl, and irinotecan HCl microspheres up to 50 mg/mL. The microspheres are also color-coded to improve patient safety. Boston Scientific purchased this product line and others in November 2015. The device is not available for sales or use in the United States.

SOLACE Trial
NCT 02460991
Ghassan Abou-Alfa, MD (Memorial Sloan Kettering, New York, NY, USA), co-principal investigator
N = 244 patients
Prospective, randomized, multicenter U.S. and European trial

The trial is designed to compare Oncozene embolic microspheres loaded with doxorubicin with sorafenib for the treatment of unresectable, locally advanced hepatocellular carcinoma. The study will evaluate patients' medical condition after being treated with Oncozene and compare it with that of patients treated with sorafenib alone. The study is currently enrolling patients. No clinical data is available.

SurefirePrecision High-Flow Microcatheter (Surefire Medical, USA)

The Surefire Precision catheter is designed specifically for direct-to-tumor treatment delivery in primary liver cancer employing a transcatheter interventional technique. The catheter is designed to deliver therapy with higher infusion efficiency. The catheter has a covered, expandable nitinol tip. The catheter's ultra-thin construction and lubricious hydrophilic coating allow it to pass through tortuous vessels. The catheter provides a safe and effective delivery method for drug-eluting and yttrium-90 microspheres for patients with unresectable liver tumors. The catheter received FDA 510(k) approval in July 2015.

PaxWire Occlusion Balloon System (Cardinal Health, USA)

The PaxWire occlusion balloon is indicated for temporary flow occlusion in the iliofemoral artery to provide bleeding control in the management of complications of mid- and large-bore procedures (above 8F). The 0.035" fixed-wire chronoprene-compliant balloon can be inserted through the procedural sheath and quickly inflated up to 12 mm for temporary flow occlusion in the iliofemoral artery while the procedural sheath is removed to control bleeding while repair is performed. This balloon is designed to support vessel closure for transcatheter heart valve and endograft procedures. The PaxWire System received FDA 510(k) approval in August 2015.

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