vizient®

Vascular technologies

Coronary, peripheral and neurovascular devices
Technology Watch | 2019 Volume 1

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Disclaimer: Members of the Vizient® cardiovascular staff attend clinical sessions at important cardiovascular meetings throughout the year. The staff meets with suppliers, reviews new technologies and monitors data from pertinent clinical trials. The information is consolidated into this overview of product and practice trends in the various cardiovascular segments. This document is intended to educate nonclinical hospital staff by offering them insights into new and innovative technologies. Vizient staff members have no personal financial connections with the suppliers and no conflicts of interest in the development of this document. The products presented are for educational purposes. Vizient does not endorse any of the products described in this document.

Introduction

The development of innovative medical devices in the vascular space has shifted as cardiovascular device suppliers turn their research and development focus in other higher-growth areas like transcatheter heart valves and neuromodulation. This does not mean that new vascular medical devices are not being developed. Suppliers are continuing to invest, and the beneficiaries are the hospitals, which receive greater choices and lower pricing.

Changes under way in Europe have the potential to affect the U.S. medical device marketplace. In the early 1990s, the U.S. Food and Drug Administration (FDA) changed its medical device approval requirements. The more restrictive requirements in part motivated U.S. medical device suppliers to move medical device development and manufacturing outside the United States. Faster approval processes outside the U.S. allowed suppliers to market medical devices sooner, in some cases, years in advance of their being approved in the U.S. Now the European medical device approval system is on a journey to increase requirements on medical devices, potentially resulting in slower approvals. The changes are set to influence the speed of approvals beginning this year, with full implementation set for 2020. At the same time, the FDA is looking to revise its approval process. The changes could mean a narrower gap in new medical device availability around the world.

The coronary, peripheral vascular and neurovascular market segments will continue to experience procedural growth over the next several years. As the U.S. population continues to age, hospitals will experience increasing procedural volumes, but at shrinking profit margins. Medical device suppliers will experience moderate growth. Medical device innovation will slow in cardiology, but increase in neurovascular for acute stroke. The future growth in procedures and the increasing reimbursement trend for these categories will allow hospitals to incorporate these technologies and keep the respective procedures' profitability.

Market watch

The 12-month price trend and current average market pricing by product segment is presented in Tables 1-5.

Table 1. Changes in pricing trends over the last 12 months

Coronary products

Category	Change (%)
Drug-eluting stents	↓ 10.4%
Bare metal stents	↓ 7.6%
PTCA dilatation catheters	↓ 0.9%
Cutting/scoring balloons	↑ 0.4%
Interventional guidewires	↓ 11.1%
Guiding catheters	↓ 0.6%
Diagnostic catheters	↑ 4.7%

Neurovascular products

Category	Change (%)
Detachable coils	↓ 4.5%
Liquid embolics	↑ 0.5%
Flow diversion	0.0%
Clot retrieval	↓ 40.7%

Neurovascular products (continued)

Category	Change (%)
Cerebral stents	↑ 2.3%
Neuro guidewires	↓ 17.2%
Microcatheters	↓ 2.1%

Peripheral products

Category	Change (%)
Self-expanding stents	↓ 5.4%
Balloon expandable stents	↓ 7.6%
Carotid stents	↓ 4.7%
Covered stents	↓ 11.2%
PTA dilatation catheters	↓ 6.3%
Drug-coated balloons	↑ 0.8%
Interventional guidewires	↑ 2.2%

Venous products

Category	Change (%)
Vena cava filters	↑ 3.7%

Table 2. Average prices for coronary devices

Bare metal stents

Supplier	Average price
Abbott Vascular	$470
Biotronik	$310
Boston Scientific	$545
Medtronic	$535

Cutting/scoring balloon catheters

Supplier	Average price
Boston Scientific	$755
Philips	$810
Trireme	$430

Diagnostic catheters

Supplier	Average price
Boston Scientific	$10
Cordis	$10
Medtronic	$10
Merit Medical	$15
Terumo Medical	$35

Drug-eluting stents

Supplier	Average price
Abbott Vascular	$960
Boston Scientific	$1,125
Cordis	$780
Medtronic	$1,010

Guiding catheters

Supplier	Average price
Boston Scientific	$70
Cordis	$45
Medtronic	$45
Terumo Medical	$185

Interventional guidewires

Supplier	Average price
Abbott Vascular	$85
Boston Scientific	$90
Cordis	$60
Terumo Medical	$85

PTCA dilatation catheters

Supplier	Average price
Abbott Vascular	$110
Biotronik	$90
Boston Scientific	$115
Cordis	$80
Medtronic	$120

Table 3. Average prices for peripheral interventional devices

Balloon expandable stents

Supplier	Average price
Abbott Vascular	$880
Bard Vascular	$820
Boston Scientific	$875
Cook Medical	$1,000
Cordis	$935
Medtronic	$700

Carotid stents

Supplier	Average price
Abbott Vascular	$1,975
Boston Scientific	$2,200
Cordis	$1,685
Medtronic	$1,630
Silk Road	$2,830

Covered endoprosthesis

Supplier	Average price
Bard Vascular	$2,180
Boston Scientific	$1,000
W.L. Gore	$3,285

Drug-coated balloons

Supplier	Average price
Bard Vascular	$1,480
Medtronic	$1,475
Philips	$1,420

Drug-eluting stents

Supplier	Average price
Cook Medical	$1,760
Boston Scientific	Data not yet available

PTA dilatation catheters

Supplier	Average price
Abbott Vascular	$145
Bard Vascular	$210
Boston Scientific	$180
Cook Medical	$145
Cordis	$170
Medtronic	$150
Terumo	$215

Self-expanding stents

Supplier	Average price
Abbott Vascular	$1,265
Bard Vascular	$1,425
Biotronik	$750
Boston Scientific	$870
Cook Medical	$865
Cordis	$750
Medtronic	$890

Table 4. Average prices for neurovascular devices

Clot aspiration

Supplier	Average price
Medtronic	$2,050
MicroVention	$1,740
Penumbra	$2,415

Clot retrieval

Supplier	Average price
Medtronic	$6,540
Penumbra	$5,235
Stryker	$6,900

Detachable coils

Supplier	Average price
Blockade	$580
Cerenovus	$1,535
Microvention	$1,550
Medtronic	$1,200
Penumbra	$1,605
Stryker	$1,610

Liquid embolics

Supplier	Average price
Cerenovus	$2,855
Medtronic	$2,320

Stents

Supplier	Average price
Cerenovus	$6,215
Microvention	$6,545
Stryker	$6,545

Table 5. Average prices for venous devices

Clot aspiration

Supplier	Average price
Aln Implants	$950
Argon Medical	$960
Bard Vascular	$1,165
Boston Scientific	$815
Cook Medical	$710
Cordis	$870
Getinge	$1,210

Abbreviations: PTA = percutaneous transluminal angioplasty; PTCA = percutaneous transluminal coronary angioplasty.

All estimated selling pricing is the averaged pricing over a category of products. This is not selling pricing for a specific product. Pricing may vary given considerations such as rebates, quality and volumes that are not included.

Economic watch

Economic impact of new technologies

The economic impact of new technologies remains complex, with variability based on the markets.

New device regulations are changing, so that what was old is new again. In the early 1990s, the FDA, under its then-commissioner, David A. Kessler, implemented new regulations on the clearances and approvals of medical devices. These regulations slowed the flow of new devices. At the same time, a changing business and regulatory environment resulting from the formation of the European Union in 1993, especially Ireland, created a movement of medical device development from the United States. Since that time, medical devices have been approved for use in Europe sooner than in the United States. Companies can generate sales while waiting for their U.S. 510(k) clearances or pre-market approvals (PMA). In some cases, early device limitations can be uncovered and corrected before the device is sold in the United States.

This scenario is changing. New European Union regulations[1] passed in 2017 will soon require medical device manufacturers to provide increased information on the safety and efficacy of the devices prior to being approved. These new requirements are set to be fully implemented in May 2020. Even today, some medical device suppliers are beginning to use the new requirements when submitting to the EU regulatory authority.

Hospitals, physicians and patients need these new regulatory requirements. In the past, many new medical devices were cleared for use with little to no real clinical data supporting their safety and efficacy. Clinicians relied on experience or trusted their sales representative that

these new devices were an improvement. But did the patient benefit outweigh the premium price? The new regulations will increase the amount of clinical data that is required before approval. This increase in data is hoped to help hospitals, physicians and clinical staff make better choices for their patients. It may also mean a shorter gap between when medical devices are available for use outside the United States versus inside the United States.

Coronary market

The coronary market should experience slowly declining pricing. Procedural volumes, which had been on a decline, have stabilized and are beginning to trend up as the aging population increases. The new device pipeline is not as robust as it had been in the past. Less funding is being invested in products for this market. Rather, companies are shifting development dollars into faster-growth markets like transcatheter heart valves and acute stroke therapies. Adding pressure, new competitors are beginning to enter the U.S. coronary marketplace, targeting the stent and dilatation balloon segments. Combined, these factors will result in continued downward price pressure.

Peripheral vascular market

The peripheral vascular market is growing. Procedural numbers and emerging technologies will increase a hospital's overall expenditures. The current controversy in the use of paxlitaxel-coated PTA dilatation catheters may result in a slight shift in product usage mix. In the long term due to increased incidence of peripheral artery disease, the procedural rate will support its continued growth.

Neurovascular market

Growth in the neurovascular market will result in the largest increase to hospitals' expenditures. A combination of rapidly growing neurovascular procedures and introduction of innovative neurovascular medical devices will significantly increase hospital expenses. Neurovascular devices are being introduced at premium prices. The rapid acceptance of clot-retriving devices, flow diversion and other new neurointerventional technologies are creating a shift from embolic coils and other older devices. Yet, the use of coils remains strong due to the overall growth in procedures and hospitals offering stroke care.

Reimbursement landscape

Almost all vascular procedures are eligible for reimbursement. Upcoming changes in reimbursement may reduce the overall level of profitability. It is forecast that for the next several years, these procedures will continue to generate profits for hospitals.

Coronary market

Reimbursement for coronary procedures will increase slightly in 2019. This represents a continuation of small but positive reimbursements. When combined with substantial medical device price decreases, the reimbursement picture for the coronary market is positive.

Peripheral vascular market

Similar to the coronary market, reimbursement for the peripheral interventional market is increasing. Since the types of procedures vary widely within the market segment, the actual increase will vary. For major procedures like opening clogged arteries and total chronic occlusions, reimbursement rates for 2019 will increase by 2% to 4%. An increase in reimbursement combined with product prices for stents and balloons continuing to decrease 5% to 6% will result in a minimal increase in profitability for hospitals. This is forecast to continue for the next several years.

Neurovascular market

The Medicare DRG codes 20 through DRG 22 cover the majority of complex patient and procedures for intravascular neurovascular procedures. In 2019, these procedures are reimbursed from $25,000 to $52,000. These rates have been slowly increasing over the past five years. Yet the reimbursement for neurovascular procedures varies. Currently, Medicare does not have a national policy on the use of medical devices to treat neurovascular conditions such as aneurysms. For some, humanitarian device exceptions exist and reimbursement varies by insurer. For other rapidly emerging neurovascular medical devices like clot retrieval systems, reimbursement exists. The reimbursement is limited to DRG 23/24. While neurovascular procedure reimbursement is profitable for hospitals, the use of multiple coils or flow diversion devices per procedure can quickly deteriorate that profitability.

Supplier watch

Penumbra, Inc.

Penumbra is a relative newcomer to the neurovascular marketplace, having entered the U.S. neurovascular market in 2007. Its early growth was slow, focusing on its detachable neuro coil technology. Over time, the company has grown, focusing primarily on the ischemic stroke segment but also expanding into the peripheral vascular embolic segment with its detachable coil technology. Penumbra has had a strong track record of organic product development and commercial expansion that has given the company a solid fourth-place market share position. Some of their innovative accomplishments include:

- Launching the first FDA-cleared, aspiration catheter for the treatment of ischemic stroke patients in 2008
- Launching a revascularization device that allows physicians to combine direct aspiration with "stent retriever" technology in 2017

The company sells to hospitals through a direct sales organization in the United States and it achieved over $200 million in U.S. sales in 2017. This is an increase of almost 25% over the prior year and the company is on pace for a similar performance again in 2018.[2]

Penumbra concentrates on the ischemic stroke market segment. Their main product technologies include thrombectomy devices to remove clots and embolization devices to treat aneurysms and to occlude vessels. According to a Medtech 360 report, the 2018 U.S. ischemic stroke market value is estimated at $725 million, with procedural growth of the aspiration thrombectomy devices and stent retriever segment continuing to increase at a healthy 16.2% forecast through 2026.[3] This strong procedural growth will provide continued fuel and innovative opportunities for Penumbra.

Table 6. Current products

Market category	Product type	Product name	Comments
Neurovascular	Access	Neuron Neuron Max Select Benchmark DDC	Various vascular access devices
	Embolization	Coil 400 Smart Coil	Detachable neuroembolization coils
	Evacuation	Artemis	Neurosurgical aspiration system for the removal of tissues and fluids
	Thrombectomy	Ace 3D	Aspiration-based thrombectomy systems
Peripheral vascular	Embolization	Ruby Pod	Detachable large volume embolic coils and devices
	Thrombectomy	Indigo	Aspiration-based thrombectomy system
	Delivery	Lantern	Microcatheter

Future innovations

Penumbra is investing in new devices. Its research and development pipeline will continue to focus on creating devices to both complete and expand its product portfolio. One such device is:

Liberty neuro stent system (Penumbra)

The Liberty stent is a self-expanding nitinol neuro stent. It is designed to provide structural support across a wide-mouth aneurysm to keep the detachable neuro coils inside the aneurysm. The stent utilizes a double-weave construction. Two thicker support struts provide support and radiopacity, with thinner struts closed cell filling the space between the larger struts. The result is a stent that provides improved coverage and support positioned between existing neuro stents and flow diversion stents. The stent is investigational and is not available for use or sale in the United States.

Technology watch

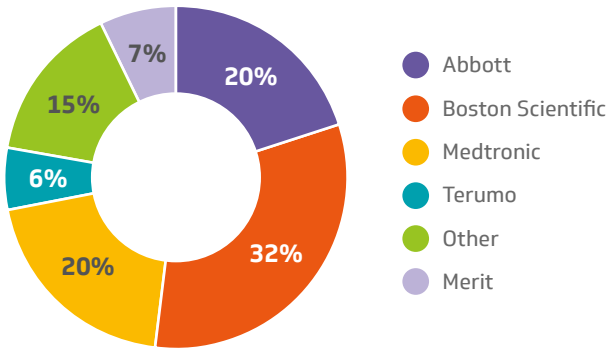
Coronary device market

The coronary market had lost some of its luster following the failed launch of the bioresorbable scaffold in 2017. Outside the United States, the coronary bioresorbable coated drug-eluting stent, like Boston Scientific's Synergy, became the most prevalent stent being used within percutaneous coronary intervention (PCI) procedures. Suppliers are now bringing these products into the United States, recognizing that the next-generation devices can provide additional clinical benefits. New suppliers to this market, including Biotronik and Terumo, have made investments in the U.S. market and are conducting clinical trials to gain FDA approvals and clearances.

The coronary device market is forecast to increase slowly. It is estimated coronary procedures will grow at a sustained rate of less than 1% through 2027, increasing from 2.5 million to 2.8 million procedures.[4] While procedural rates are being forecast to grow, pricing pressure continues to drive average prices lower. The failure of the bioresorbable scaffold and the introduction of the bioresorbable coated stent had resulted in a market share shift toward Boston Scientific. The successful introduction of new Medtronic and Abbott drug-eluting stents has caused a shift in market share within the U.S. and has increased the pricing pressure on stents like Boston Scientific's Synergy. Current Vizient price trending shows stent prices are down about 10% from a year ago.[5] Over the next five years, stent and balloon dilatation catheter prices are forecast to decline more slowly, at a rate of 3%.[6]

In the future, new competitors may emerge. Biotronik is beginning to conduct clinical trials with the ultimate focus on launching their magnesium bioresorbable scaffold in the United States. In the meantime, the company is introducing coronary and peripheral stents, dilatation balloon catheters and other devices. Cordis has re-entered the coronary market with a stent. A number of companies are developing drug-coated balloons for coronary application. These new suppliers may give the established suppliers increased competition. These trends—slowing growth in procedures, product introductions and increasing competition—will be beneficial to hospitals.

Figure 1. Coronary supplier market share (US$)



Source: Vizient Intellisource data

Recently FDA approved or cleared devices

The FDA approves and clears medical devices continually throughout the year. Some recent medical devices in the coronary market segment are listed below.

Table 7. Companies with recent FDA approvals for coronary devices[a]

Vendor	Product	Device	FDA #
		PMA approvals	
Angel Medical Systems	Guardian System	ACS event detection system	P150009, 4/9/18
Biotronik	Orsiro	Coronary drug eluting stent	P170030, 2/22/19
		HDE approvals	
Biotronik	PK Papyrus	Covered coronary stent system	H170004, 9/14/18
		510(k) cleared	
Radial Medical	TBD	Radial compression system	K181651, 10/12/18
Avenu Medical	Ellipsys System	Arteriovenous fistula creation	K181725, 10/5/18
Medos International	Symphony	Optical coherence tomography system	K181949, 10/4/18
Imediplus	Cardiart	Electronic stethoscope	K182196, 9/11/18
Bio Compression Systems	VascuEase	Treatment of deep vein thrombosis	K180248, 8/7/18
Greatbatch Medical	RadialSeal	Radial introducer	K181855, 7/26/18
Asahi Intecc	Gladius Mongo	Interventional guidewire family	K180784, 7/18/18
Asahi Intecc	Sion Black	Interventional guidewire family	K173277, 7/5/18
OrbusNeich	Sapphire II Pro	Coronary dilatation catheter	K180921, 6/28/18
Boston Scientific	iSleeve	Introducer sheath	K180785, 6/22/18
Cordis	Mozec	Coronary dilatation catheter	K181023, 5/17/18
Terumo Medical	Glidesheath Slender	Introducer sheath	K173831, 5/8/18
Abbott	PressureWire X	Pressure guidewire for fractional flow reserve measurement	K180558, 3/28/18
AtriCure	AtriClip Flex-V	Left atrial appendage device	K180010, 1/31/18
Medinol	Gallant	Coronary dilatation catheter	K173581, 1/25/18
Boston Scientific	OptiCross 6 HD	Coronary imaging catheter	K173820, 1/17/18
Abbott	Hi Torque TurnTrac	Interventional guidewire family	K173795, 1/12/18
TZ Medical	ARC	Adjustable radial cuff	K173563, 1/10/18

[a]510(k) Clearances. U.S. Food & Drug Administration website. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/. Accessed November 29, 2018.

Abbreviations: PMA = pre-market approval; HDE = humanitarian device exemption.

Orsiro coronary drug-eluting stent (Biotronik)

The Orsiro is a cobalt chromium metal stent coated with sirolimus and a proprietary poly-l-lactide (PLLA) bioresorbable polymer, Biolute. A second amorphous silicon carbide polymer coating, called proBio, covers the metal struts. The stent features ultrathin stent struts without compromising radial strength and a low crossing profile. It is available in 52 sizes ranging from 2.25 mm to 4.0 mm in diameter and lengths up to 40 mm. The stent is the second bioresorbable stent available in the U.S. The stent was approved for use in the United States in February 2019.

Safety and Effectiveness of the Orsiro Sirolimus-Eluting Coronary Stent System in Subjects With Coronary Artery Lesions (Bioflow-V)

NCT: 02389946

Dr. David Kandzari (Piedmont Heart Institute), co-principal investigator

N = 1,334 patients

Prospective, randomized, multicenter, controlled, non-inferiority clinical study

The primary purpose of this study was to compare the Biotronik Orsiro coronary drug-eluting stent system with the Abbott Xience Prime coronary drug-eluting stent system with respect to in-stent late lumen loss in a non-inferiority study in de novo coronary lesions at 9 months. The trial demonstrated significantly lower rates for target lesion failure (TLF) and target vessel myocardial infarction (MI) at one year in comparison to Xience. At two years, the results showed a 37% lower TLF rate in favor of Orsiro (7.5% vs. 11.9% TLF rate, *P* value = .015), a 47% lower ischemia-driven TLR rate, and a 70% lower rate of spontaneous MI (landmark analysis 31 days to two years follow-up). The promising clinical data may make this stent a potential to the currently available coronary drug-eluting stents.

Xience Sierra coronary drug-eluting stent (Abbott)

The Xience Sierra coronary stent is the next generation of the Xience stent family indicated for coronary artery use in de novo native coronary artery lesions (length ≤ 32 mm) with reference vessel diameters of ≥ 2.25 mm to ≤ 4.25 mm. Like the other Xience stents, it is an everolimus-eluting coronary stent system. The advances in this generation include a thinner profile, increased flexibility, longer lengths and small diameters. A new stent and delivery system was developed for the treatment of complex cases, including people with multiple or totally blocked vessels. The stent family is available in stent diameters from 2.25 mm to 4 mm and stent lengths from 8 mm to 38 mm. The stent was FDA approved in May 2018.

Mynx Control Vascular Closure Device (Cordis)

The Mynx Control is an evolution of the company's control device, integrating active extravascular sealing and bioresorbability with a next-generation delivery system. The device features an improved deployment system with a tension indicator for visual confirmation and an ergonomic handle with a two-button deployment. It is available in 5, 6 and 7 French sizes. The closure device was cleared by the FDA in November 2018.

Developing coronary devices

Agent paclitaxel-coated PTCA balloon catheter (Boston Scientific)

The Agent drug-coated balloon is designed for the coronary arteries. The drug-coated balloon catheter has a proprietary TransPax coating technology that provides a targeted, therapeutic dose of proven, anti-proliferative Paclitaxel to the lesion. The balloon has been designed to provide a drug dose of 2 µg/mm^2 compared to 3 µg/mm^2 of other drug-coated balloons. The device is based on the company's Emerge coronary dilatation catheter technology. The balloon family comes in lengths of 12 mm to 30 mm with diameters of 2 mm to 4 mm. The balloon is available outside the United States but is investigational and not available for use or sale within the U.S.

Comparison of Agent and Sequent Please Paclitaxel-Coated Balloon Catheters in Coronary In-Stent Restenosis (Agent-ISR) Trial

NCT: 02151812

Dr. Christian W. Hamm (Germany) (University Giessen), principal investigator

N = 123 patients

Prospective, randomized European multicenter non-inferiority clinical study

The primary objective of this study was to determine the safety and performance of the Agent paclitaxel-coated PTCA balloon catheter compared to the Sequent Please paclitaxel-releasing coronary balloon catheter (B. Braun) for the treatment of patients with narrowed previously-stented coronary arteries (in-stent restenosis). The study was randomized 1:1 to the two different drug formulations. Data from the study demonstrated the Agent catheter showed lower event rates and 21% lower target lesion failure (TLF) at 12 months (9.2% vs. 11.7%), met its primary endpoint of non-inferiority and was numerically better in all clinical endpoints including target vessel failure (TVF) and stent thrombosis (ST).

Magmaris bioresorbable magnesium scaffold (Biotronik)

Magmaris is a magnesium alloy, sirolimus-eluting bioresorbable coronary scaffold. It has relatively thick struts at 150 µm. The scaffold's magnesium alloy construction breaks down and 95% is resorbed by one year. The construction also allows it to be delivered in a similar manner to existing coronary stents. The edges of the scaffold are electropolished to smooth out any irritating spots and the overall shape is designed to optimize coverage as well as resorption. The scaffold received Conformité Européenne (CE) mark approval but is investigational in the United States and not available for use or sale.

Biotronik—Safety and Performance in De Novo Lesion of Native Coronary Arteries with Magmaris—Registry (Biosolve-IV)

NCT: 02817802

Dr. Michael Kang-Yin Lee (Hong Kong) (Queen Elizabeth Hospital), co-principal investigator

N = 2,054 patients

European multicenter registry

The primary objective of this registry was to determine the clinical performance and long-term safety of Magmaris in a real-world setting. Data reported at 12 months of the first 400 patients was that the rate of target lesion failure was 4.6%, which was up from 2.5% at six months, and there was only one case of scaffold thrombosis.

Coronary Intravascular Lithotripsy (IVL) (Shockwave Medical)

The Shockwave IVL for calcified coronary artery disease is a therapy designed to treat calcified artery blockages using sonic pressure waves. This therapy is currently used in the United States to treat patients with kidney stones. The technology minimizes trauma within the artery by delivering pulsatile sonic pressure waves locally to effectively fracture both intimal and medial calcium in the artery wall but pass through surrounding soft vascular tissue. The therapy requires no specialized training, and it allows physicians to use their own guidewire of choice. The device received CE mark approval in May 2018 but is investigational and not available for sale or use in the United States.

Fantom Encore Bioresorbable Scaffold (Reva Medical)

The Fantom Encore is a sirolimus-eluting bioresorbable coronary scaffold. The company uses Tyrocore, a tyrosine-derived polymer, which is different from the polylactic acid polymer used to construct Absorb. The proprietary design was developed specifically for vascular scaffold applications. The benefit of this material is it allows for a thinner strut profile (95 µm), similar to drug-eluting stents and thinner than that of other scaffolds. The scaffolds are available in diameters of 2.5 mm, 3.0 mm and 3.5 mm and lengths of 12 mm, 18 mm and 24 mm. The scaffold received CE mark approval in October 2018 but is investigational and not available for sale or use in the United States.

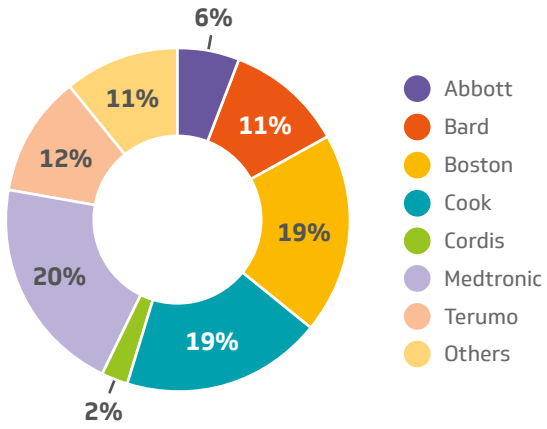
Ultimaster Tansel coronary drug-eluting stent (Terumo)

The Ultimaster Tansel drug-eluting stent is Terumo's entry into the U.S. coronary stent market. The stent system has a rapid-exchange balloon consisting of a balloon expandable intra-coronary L605 cobalt chromium (CoCr) stent with abluminal drug-eluting coating, that consists of a blend of sirolimus and poly (D,L-lactide-co-caprolactone), pre-mounted onto a high-pressure, semi-compliant balloon delivery catheter. The stent has an 80-µm strut thickness. The drug is 3.9 µg/mm. The device family is available in stent diameters of 2.25 mm to 4.0 mm and stent lengths of 9 mm to 38 mm. The device received CE mark approval but is investigational and not available for sale or use in the United States.

Peripheral vascular device market

The peripheral vascular device market continues its steady growth, with a rich pipeline of new devices. This market's growth is driven with a focus on treatments for peripheral artery disease (PAD). PAD affects about 8 million Americans, with its prevalence doubling to 10% in our 70s and doubling again to 20% in our 80s.[7] The most common symptoms of PAD 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 market is complex. Peripheral vascular procedures are made up of numerous procedures, for example vascular stenting, atherectomy, chronic total occlusions, transcatheter embolization and vena cava filter implantation and many more. For each procedure, a variety of unique medical devices may be used. Increasing complexity, similar procedures might be performed in different locations within a hospital by different physician specialists. For example, vascular stenting can be performed in the interventional radiology labs, catheterization labs or the hybrid operating rooms. The treatment of vascular artery blood flow is the largest segment in the peripheral vascular device market.

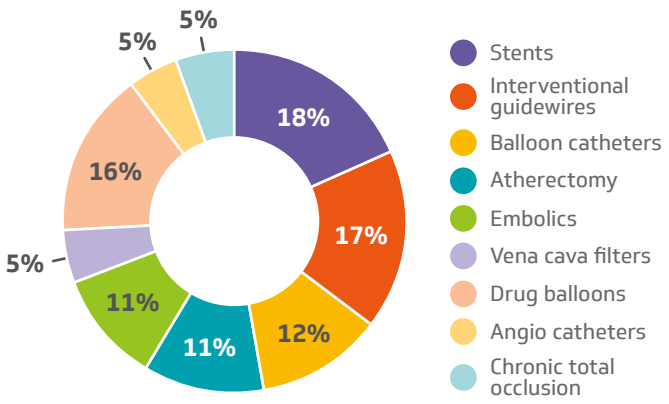
Figure 2. Peripheral vascular supplier market share (US$)



Source: Vizient Intellisource data

The peripheral vascular segment continues its solid procedural growth. Estimates continue to point to a 3% to 4% sustained procedural growth rate through 2025[8] in the angioplasty, stent and atherectomy segments. While procedural rates continue to grow, pricing pressure continues to drive unit prices lower. As shown in the Economic Watch section, prices are down 5% to 7% annually.

Figure 3. Peripheral device market (US$)

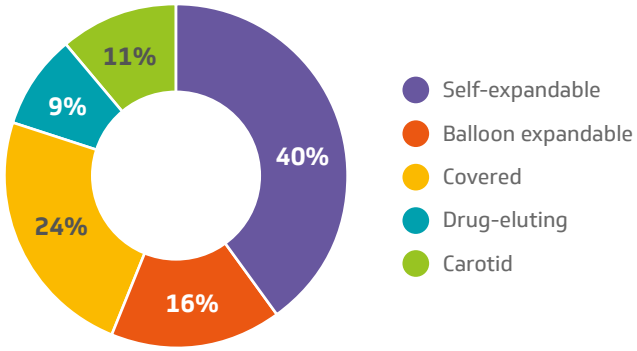


Source: Vizient Intellisource data

The introduction of the second drug-eluting peripheral vascular stent combined with termination of the drug-coated balloon pass-through payment will make for an interesting market dynamic in 2019. It remains to be seen whether the rapid increase in use of the drug coated balloon will slow despite its positive clinical evidence.

The peripheral vascular segment has experienced a unique mix of supplier changes with Cordis and C.R. Bard being acquired to new entrants like Biotronik, Asahi Intecc and others. Despite the declining stent and balloon prices, new competitors are in clinical trials to gain FDA approval or clearance to sell their peripheral vascular device in the United States.

Figure 4. Peripheral vascular stent market (units)



Source: Vizient Intellisource data

Table 8. Companies with recent FDA approvals for peripheral vascular devices[a]

Vendor	Product	Device	FDA #
PMA approvals			
Boston Scientific	Eluvia	Drug-eluting vascular stent system	P180011, 9/18/18
Veryan Medical Limited	Biomimics 3D Stent	Peripheral vascular stent system	P180003, 10/4/18
W.L. Gore	Gore Carotid Stent	Carotid stent	P180010, 11/1/18
510(k) cleared			
Cook Medical	Gunter Retrieval Set	Vena cava filter retrieval set	K181757, 11/6/18
Corin Medical	Corin	Femoral positioning system	K181061, 9/7/18
Contego Medical	Paladin	Carotid dilatation balloon	K181128, 9/6/18
Vascular Solutions	Octane	Mechanical thrombectomy system	K182232, 9/11/18
ReFlow Medical	Wingman 35	Crossing catheter	K173661, 3/18/18
Cordis	Railway	Sheathless access system	K180081, 4/18/18
Vascular Solutions	Trapliner	Guidewire exchange catheter	K180088, 4/4/18
Boston Scientific	Embozene	Color-advanced microspheres	K180102, 4/19/18
Cook Medical	Ultraxx	Nephrostomy balloon catheter	K171601, 2/23/18
Access Vascular	HydroPICC	Venous access catheter	K172885, 2/20/18
OrbusNeich	Jade	Peripheral dilatation catheter	K173894, 2/9/18
Vascular Solutions	Warrior	Interventional guidewire	K180128, 2/16/18

[a]510(k) Clearances. U.S. Food & Drug Administration website. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/. Accessed November 29, 2018.

Abbreviations: FDA = U.S. Food and Drug Administration; PMA = pre-market approval.

Eluvia drug-eluting vascular stent system (Boston Scientific)

The Eluvia stent is a peripheral vascular device developed for the treatment of peripheral artery disease. It uses a drug-polymer combination to offer sustained release of the drug paclitaxel for one year and is designed to prevent tissue regrowth that might otherwise block the stented artery. The stent system is built on the company's Innova stent system platform, a self-expanding nitinol stent that has been designed for use in the superficial femoral and proximal popliteal arteries, the main arteries that supply blood to the legs. This drug-eluting stent was awarded FDA PMA approval for use in the U.S. in September 2018.

Eluvia Drug-Eluting Stent Versus Zilver PTX Stent (Imperial)

NCT: 02574481

Dr. William Gray (USA) (Main Line Health), co-principal investigator

N = 465 patients

Global, prospective, multicenter worldwide clinical study

The primary objective of this study is to determine the safety and performance of the Eluvia drug-eluting stent compared to the Zilver PTX drug-eluting stent (Cook Medical). The Eluvia demonstrated superior results in the first superficial femoral artery head-to-head drug-eluting stent trial. In this trial, patients treated with the Eluvia stent experienced a significantly greater 12-month primary patency of 88.5%, compared to 79.5% in patients treated with competitive stent (*P* = .0119). In addition, patients treated with the Eluvia stent experienced half the target lesion revascularization rate (TLR) of the competitive stent at 12 months, a 4.5% TLR rate for Eluvia versus 9.0% TLR rate for the Zilver PTX cohort.

Gore Carotid Stent (W.L. Gore)

The Gore carotid stent consists of a self-expanding carotid stent. The stent is designed as a flexible open-cell nitinol structure and a 500-µm pore polytetrafluoroethylene (ePTFE) lattice mesh on the outside of the stent to stabilize plaque on the wall of the artery. The device is coated with a heparin bioactive surface to reduce the risk of thrombosis. This feature should reduce the risk of procedural and post-procedural neurological events due to plaque embolization. The FDA approved the stent in November 2018.

BioMimics 3D vascular stent system (Veryan Medical Ltd)

The BioMimics 3D stent is a self-expanding, nitinol bare metal vascular stent. It was approved for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery. It has a three-dimensional helical shape, which is designed to impart natural curvature to the artery. The helical shape of the stent is also designed to facilitate shortening of the stented segment during knee flexion and mitigate the risk of stented segment compression causing localized strains that in other stents might lead to stent fracture. The company is marketing the stent as "the swirling flow" stent. This bare metal vascular stent was awarded FDA PMA approval for use in the U.S. in October 2018.

Zilver PTX 5-mm SFA drug-eluting stent (Cook Medical)

The Zilver PTX 5-mm and longer length drug-eluting stents are an extension to the existing portfolio. The 5-mm drug-eluting stent is available in lengths up to 140 mm and is indicated to treat vessels as small as 4 mm in diameter. The expanded range of peripheral drug-eluting stent diameters will address treatment of vessel sizes from 4 mm to 7 mm in diameter. The longer-length stents are approved to treat total lesion lengths up to 300 mm per patient. In addition, the product also received an extended shelf life of two years. The stents are still indicated for the treatment of patients with lesions in their superficial femoral arteries. The larger drug-eluting stent was awarded FDA approval for use in the U.S. in September 2018.

Vascade vascular closure system (Cardiva Medical)

The Vascade has been an approved vascular closure system for femoral arterial closure since 2013. The expanded indication of the device can now be used in 5-7 French femoral venous closures. The device consists of a thrombogenic bioabsorbable collagen patch and proprietary collapsible disc technology used to stop access site bleed following a catheterization procedure. It works by placing a small, collapsible mesh disc against the inside of the vessel wall to temporarily stop the bleeding, releasing a collagen patch into the tissue and then removing the mesh disc. The collagen patch expands, providing a mechanical and physiological seal to stop the bleeding, and then absorbs into the body, leaving nothing behind and allowing further access to the vessel if additional procedures are required. The expanded indication to venous access was cleared by the FDA for use in the U.S. in April 2018.

Vanguard IEP peripheral angioplasty system (Contego Medical)

The Vanguard is a peripheral balloon angioplasty system and distal embolic filter on the same catheter. The peripheral balloon system has an over-the-wire design with an integrated 150-micron pore filter distal to the angioplasty balloon. The filter features in-vivo adjustability to suit varying vessel sizes and maximize capture efficiency and removal of embolic material during angioplasty, for the femoral, iliac, popliteal and profunda arteries. The system is not intended for use in the renal, cerebral, coronary or carotid vasculature. This medical device was FDA 510(k) cleared for use in the U.S. in December 2018.

Sentry IVC Filter (BTG International)

The Sentry bioconvertible inferior vena cava (IVC) filter provides temporary protection against pulmonary embolism (PE). It is a resorbable filter designed to provide protection from PE during the period that a patient is at risk and then dissolve into a non-filtering configuration after a minimum of 60 days. The filter's cylindrical frame reduces the reported complications of existing IVC filter technologies, including tilt, migration, strut fracture and vessel perforation. The filter was FDA 510(k) cleared for use in the U.S. in December 2018.

The Sentry Clinical Study (Sentry)

NCT: 01975090

Dr. Michael D. Dake (USA) (Stanford Medical Center), principal investigator

N = 123 patients

Prospective, single-arm, multicenter registry trial

In the study, 129 patients requiring temporary protection against PE were enrolled at 23 sites in the United States, Europe and Chile. The 12-month clinical results demonstrated that the rate of new symptomatic pulmonary embolism through 12 months was 0% (0/129). There were no instances of filter tilting, migration, embolization, fracture or IVC perforation through 12 months, and there were no filter-related deaths. The rate of successful filter bioconversion was 95.7% (110/115) at six months and 96.4% (106/110) at 12 months.

Implantable System for Remodulin (ISR) (Medtronic)

The ISR uses the existing Syncomed II implantable drug infusion pump and a new intravascular catheter that is designed to deliver Remodulin intravenously to patients.

The prostacyclin Remodulin (treprostinil), made by United Therapeutics, is a vasodilator and has been shown to widen blood vessels and reduce blood pressure. The ISR is indicated for adult patients. The FDA's clearance of the pump and delivery device was based on data collected from the DelIVery for Pulmonary Arterial Hypertension (PAH) clinical trial (NCT01321073), which was conducted at 10 sites in the U.S. with 60 PAH patients successfully implanted with the device. The device was cleared for use in the United States in August 2018.

Developing peripheral vascular devices

Lutonix 014 drug-coated BTK balloon (Becton, Dickinson and Company)

The Lutonix 014 drug-coated balloon is a smaller version of its drug-coated balloon already approved for use in larger peripheral vessels. The balloon delivers paclitaxel to the arterial wall in a single, short inflation. The balloon's formulation of paclitaxel and carriers, polysorbate and sorbitol, allows it to deliver a therapeutic dose to the artery wall, while keeping the dose of paclitaxel on the balloon as low as possible. The 035" device has proven safe and effective in thousands of patients when used in the superficial femoral artery and popliteal arteries above the knee. The device is CE mark approved but is investigational and not available for sale or use in the United States.

Lutonix DCB Versus Standard Balloon Angioplasty for Treatment of Below-The-Knee (BTK) Arteries

NCT: 01870401

Dr. Patrick Geraghty (USA) (Washington University School of Medicine), co-principal investigator

N = 442 patients

Prospective, global, multicenter, randomized, controlled clinical study

The clinical study was designed to assess the safety and efficacy of the Lutonix drug-coated balloon for treatment of stenosis or occlusion of native below-the-knee arteries. The six-month data showed positive results in the treatment of patients with critical limb ischemia. There was an improvement in primary efficacy of 10.2% (drug-coated balloon: 73.7% and percutaneous transluminal angioplasty: 63.5%, $P = .0273$, not-significant). The more commonly used Kaplan-Meier analysis of the primary efficacy endpoint demonstrated a significant difference of 14.6% (DCB: 85.3%, PTA: 70.7%, $P < .001$). Additional analyses are planned for 12-, 24- and 36-month follow-ups.

Surveil drug-coated SFA balloon (Surmodics)

The Surveil drug-coated balloon is a peripheral vascular drug-coated balloon catheter to treat peripheral artery disease in the superficial femoral artery. The device combines a proprietary drug-delivery and surface technology. The balloon features the company's proprietary durable coating made of a proprietary blend of poly-butyl methacrylate (PBMA) and polyethylene vinyl acetate (PEVA) polymers. The drug is not specific at this time. Abbott will have exclusive worldwide commercialization rights for the drug-coated balloon. Separately, Abbott also received options to negotiate agreements for the company's below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which are currently in pre-clinical development. The device has been given CE mark approval but is investigational and not available for sale or use in the United States.

Safety and Efficacy of the Surveil Drug-Coated Balloon (Transcend)

NCT: 03241459

Dr. William Gray (USA) (Main Line Health), co-principal investigator

N = 446 patients

Global, prospective, multicenter worldwide clinical study

The study is a prospective, multicenter, single-blind, randomized, non-inferiority clinical trial. The trial is randomizing approximately 446 subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. Patients will be randomized 1:1 to treatment with either the Surveil drug-coated balloon or the Inpact Admiral drug-coated balloon (Medtronic) and followed for 60 months. The study is currently enrolling patients. The six-month clinical results demonstrated 100% procedural success. Patients demonstrated primary patency of 100% and mean late lumen loss of 0.27 ± 0.54 mm. Subjects experienced significant improvement in Rutherford classification, ankle-brachial/toe-brachial index, six-minute walk test, and walking impairment questionnaire at 30 days and six months.

Admiral drug-coated AVF balloon (Medtronic)

The Inpact Admiral drug-coated balloon approved for use in peripheral arteries is in clinical trials for a potential use in patients with end-stage renal disease. The study will evaluate the safety and efficacy of the drug-coated balloon as a treatment for failing arteriovenous (AV) fistulas in patients with end-stage renal disease compared with standard balloon angioplasty. The study will aim to enroll 330 patients at approximately 30 institutions in the United States, Japan and New Zealand. Patients will be randomized 1:1 for either treatment with Inpact Admiral drug-coated balloon or standard balloon angioplasty. The primary efficacy endpoint is patency of dialysis fistulas through six months, and the primary safety endpoint is major adverse events through 30 days. Additional endpoints include reducing access circuit-related events, including repeat procedures. The study is planned to last up to two years. The balloon has been given CE mark approval for the AV fistula use but is not available for the indicated use in the United States.

Ranger drug-coated SFA balloon (Boston Scientific)

The Ranger drug-coated balloon catheter is a paclitaxel-coated PTA balloon catheter on a 0.018" Sterling balloon platform. It is designed for angioplasty for femoropopliteal artery lesions. The drug is loaded onto the company's proprietary polymer coating. The coating is designed for optimal drug transfer, minimizing risk for particulate loss downstream, and is able to use approximately half the drug load that is used in previous-generation drug-coated balloon catheters. The product family will be available in balloon diameters ranging from 2 mm to 8 mm and balloon lengths ranging from 30 mm to 200 mm. The Ranger drug-coated balloon catheter is manufactured by Hemoteq AG and will be distributed by Boston Scientific Corporation. The device has been awarded CE mark approval but is investigational and not available for sale or use in the United States.

Safety and Efficacy of the SurVeil Drug-Coated Balloon (Ranger II SFA)

NCT: 03064126

Dr. Thomas Zeller (Germany) (Universitaets-Herzzentrum), co-principal investigator

N = 446 patients

Randomized, global, prospective, multicenter worldwide clinical study

The clinical trial is a global, prospective, multicenter study enrolling approximately 446 subjects at up to 80 study centers worldwide. The study is designed to evaluate the safety and efficacy of the Ranger balloon versus standard percutaneous transluminal angioplasty (PTA) balloons for treating lesions located in the superficial femoral and proximal popliteal arteries. One-year data from a small European trial reported in May 2018 demonstrated the drug-coated balloon group had a greater primary patency rate at 12 months compared with the control group (Kaplan-Meier estimate, 86.4% vs. 56.5%) with a significantly longer time to patency failure. The estimated freedom from target lesion revascularization rate was 91.2% in the drug-coated balloon group and 69.9% in the control group at 12 months, with a significantly longer time to re-intervention (P = .01). There were no target limb amputations or device-related deaths in either group. These results are similar to prior studies on the drug-coated balloon from other studies.

Saval drug-eluting BTK stent (Boston Scientific)

The Saval drug-eluting stent is being developed on a 0.014" platform for use in smaller arteries below the knee. The stent uses a paclitaxel-polymer combination to facilitate sustained release of an anti-restenotic drug. Due to the absence of effective treatment options for patients suffering from chronic limb ischemia, the FDA granted the Expedited Access Pathway (EAP) designation to the Saval BTK stent system. This program is intended to provide patients timely access to medical devices that demonstrate the potential to address unmet clinical needs in treating life-threatening or irreversibly debilitating diseases or conditions. A clinical trial (Saval NCT03551496) (a global, prospective, multicenter, 2:1 randomized trial) will evaluate the safety and effectiveness of the stent system compared to standard percutaneous transluminal angioplasty to treat infrapopliteal artery lesions in patients with critical limb ischemia. The first phase of the trial will begin with one size of the device: 3.5 mm by 80 mm. The trial began enrolling patients in September 2018. The stent is investigational and not available for use or sale anywhere.

Kanshas drug-coated SFA balloon (Terumo Medical)

The Kanshas drug-coated balloon catheter is for use in the treatment of lower extremity peripheral arterial disease. The catheter platform is 0.018", rapid exchange balloon with drug eluting coating of paclitaxel. The drug is 3.2 µg/mm². The device family is available in balloon diameters ranging from 4 mm to 7 mm and balloon lengths ranging from 40 mm to 200 mm. The balloon has a proprietary uniform micro-crystal coating that has been designed so that the coated drug is less likely to migrate before it reaches the lesion and then transfers swiftly to vascular tissue when the balloon is expanded. The balloon received CE mark approval in June 2018 but is not available for sale or use in the United States.

Manta vascular closure system (Teleflex)

The Manta is a vascular closure device designed to close punctures ranging from 10 French to 25 French at femoral arterial access sites after percutaneous cardiac and peripheral catheterization procedures that use a large-bore device, such as transcatheter aortic valve implantation, endovascular aneurysm repair, ventricular assist device and balloon aortic valvuloplasty. The device is available in two sizes: 14 and 18 French. The 14 French device is indicated for closure of femoral arterial access sites following the use of 10 to 14 French devices or sheaths (maximum outer diameter profile of 18 French). The 18 French device is indicated for closure of femoral arterial access sites following the use of 15 to 18 French devices or sheaths (maximum OD/profile of 25 French). Enrollment in the U.S. pivotal investigational device exemption (IDE) trial of 321 patients was completed in October 2017. European clinical data of 50 patients resulted in one major complication and no minor complications. The mean and median time to hemostasis was two minutes and 23 seconds and 24 seconds, respectively, with 74% of patients achieving hemostasis in less than a minute. The closure device received CE mark approval in June 2018 but is not available for sale or use in the United States.

LifePearl Micro (Terumo Medical)

The LifePearl Micro is a drug-elutable microsphere for chemoembolization. The device is made of PEG (polyethylene glycol) embolization microspheres that can be loaded with chemotherapeutic agents (such as doxorubicin, irinotecan, idarubicin and epirubicin). The product is intended for use in interventional oncology. The spheres are available in 100 µm, 200 µm or 400 µm. The device has been given CE mark approval but is investigational and not available for sale or use in the United States.

PerQseal Large Bore Closure Device (Vivasure Medical Ltd.)

PerQseal is a sutureless, fully absorbable synthetic implant for large bore arterial puncture closure. The technology consists of an intravascular bioabsorbable synthetic polymer patch that seals the vessels up to 24 French from the inside. The device is delivered over-the-wire and positioned at the arteriotomy site. Once hemostasis has been confirmed, the wire is removed and the device is deployed. The device is designed to enable transcatheter vessel closure for transcatheter aortic valve replacement and endovascular aneurysm repair procedures. The closure device received CE mark approval in November 2018 but is not available for sale or use in the United States.

LimFlow Percutaneous Deep Vein Arterialization (pDVA) system (LimFlow SA)

LimFlow Percutaneous Deep Vein Arterialization (pDVA) System is designed to bypass blocked arteries in the leg and establish blood flow back into the foot. The system uses proprietary ultrasound-guided catheters and covered nitinol stents designed to restore perfusion to the ischemic foot by bypassing diseased arteries and diverting blood flow into the tibial vein to vascularize the foot. The therapy is intended for "no-option" critical limb ischemia patients when all other revascularization efforts have been exhausted and a patient is facing a major amputation. The system contains an arterial catheter with an embedded ultrasound plate that aligns with a venous catheter indicating optimal crossing for the beveled crossing needle. It also has two stents—a polytetrafluoroethylene (PTFE)-covered nitinol Extension Stent and a PTFE-covered nitinol Crossing Stent. These stents are available in lengths of 60, 100 and 150 mm and diameters of 3.5, 4 and 5.5 mm. The FDA has accepted the LimFlow System into its Breakthrough Device Program. The designation is intended to speed patient access to breakthrough technologies that provide for more effective treatment of life-threatening or irreversibly debilitating diseases, for which no approved or cleared treatment exists or that offers significant advantages over existing approved or cleared alternatives. The system has received CE mark approval but is not available for sale or use in the United States.

Blueleaf Endovenous Valve (Intervene, Inc.)

The Blueleaf system is an endovenous valve formation system that doesn't require an implant to address deep vein reflux. The device is intended to form new vein valves out of the layers of tissue that naturally make up a patient's vein wall. The procedure is done under intervascular ultrasound guidance. The system uses a nitinol dissector and needle assembly. The catheter contains a balloon on one side to create tension and hold the catheter in place. A needle is inserted into the sub-intimal plane and a space is created using hydro-dissection. The nitinol-scoring blades are used to create a new valve or valves. The device is a 16 French system. The system is investigational and is not available for sale or use in the United States

Neurovascular device market

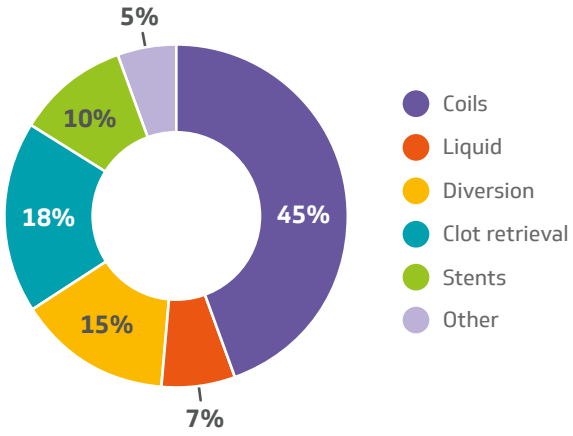
Stroke is the fifth-leading killer of American adults. Strokes fall into one of two categories: hemorrhagic or ischemic. Hemorrhagic stroke results when a blood vessel ruptures, allowing blood to escape into the brain, or when the vessel weakens, creating an aneurysm. Ischemic stroke results from a blood clot within one of the vessels, depriving a segment of the brain of blood. Ischemic strokes account for about 87% of all strokes.[9] Both cause significant neurologic issue for survivors.

Strokes affect almost 800,000 Americans each year, killing nearly 130,000, according to the National Stroke Association. Stroke survivors typically require lengthy and expensive care. Annual costs for stroke in the U.S. are estimated at over $34 billion in related medical expenses.[9] Strokes are not an old-age concern, with almost one-quarter of stroke patients under 65 years old.

The Centers for Disease Control and Prevention estimates about 87% of all strokes are caused by the blockage of blood flow to the brain.[9] If treated early, patients have an increasing chance of surviving with reduced side effects. The American Heart Association/American Stroke Association now recommends using a stent retrieval device to remove blood clots in select stroke patients who have clot-obstructing strokes. The increasing numbers of trained physicians and improving technologies have combined to rapidly evolve this market. The U.S. neurovascular market has experienced high single digit growth for the past five years. This once-niche market, which was centered only in academic medical centers and the largest medical centers by a small group of neurointerventional radiologists, has expanded into mid-sized medical centers now including neurointerventionalists and neurosurgeons. As the orthopedic suppliers have acquired these neurovascular device companies, pricing strategies have emerged, focused on premium pricing and annual increases. Strong physician preference and supplier relationships make pricing control challenging. Supply chain executives must focus on the rapidly growing neurovascular market and develop strategies with their physicians to manage procedural cost and growth.

Great strides have been made in the treatment of both types of stroke. Medical devices are improving to treat a wider array of conditions. Hospitals and trained operators are also growing their capabilities to provide greater access to these treatments.

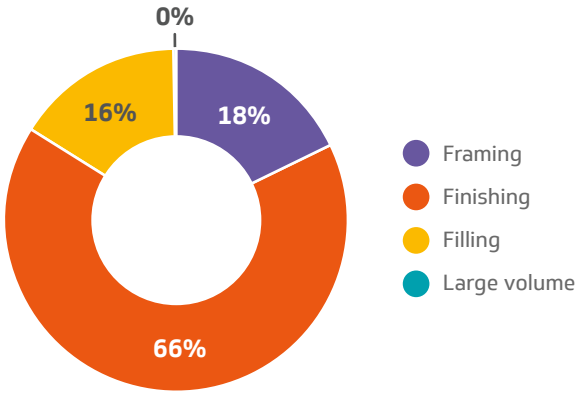
Figure 5. Neuroendovascular device market (US$)



Source: Vizient Intellisource data

The neurovascular devices market encompasses embolic devices (platinum coils and liquid embolic agents), stent retrievers, neurothrombectomy devices (suction and aspiration devices), stenting systems (carotid, cerebral and flow diversion stents), support devices (microcatheters and micro guidewires) and others. Suppliers in the space are relatively limited. Suppliers are actively expanding their product offerings to compete. Medtronic has the broadest product offering. Others like Stryker, Codman and Terumo are expanding their product portfolios primarily through product acquisition strategies. Stryker, Codman and Medtronic are influenced by the large orthopedic company pricing strategies. The result is increasing prices. Last year, prices increased in the microcatheter, interventional wire, liquid embolic and flow diversion segments. Only coils and stents experienced modest price decreases of less than 2%.

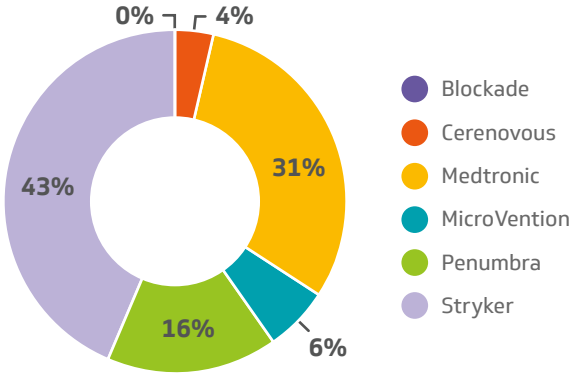
Figure 6. Embolic coil market (units)



Source: Vizient Intellisource data

According to a Medtech 360 report, the 2018 U.S. market value is estimated at $735 million, with procedural growth forecast to increase at a healthy 2.25% through 2026.[3] The growth is being generated from an increasing use of stent retrievers for active clot removal.

Figure 7. Neurovascular supplier market share (US$)



Source: Vizient Intellisource data

Table 9. Companies with recent U.S. FDA approvals for neurovascular devices[a]

Vendor	Product	Device	FDA #
PMA approvals			
Microvention	LVIS	Flow restoration device	P170013, 5/30/18
HDE approvals			
Pulsar Vascular, Inc.	PulseRider	Aneurysm neck reconstruction device	H160002, 6/19/17
Stryker	Neuroform Atlas	Cerebral stent	H020002, 11/9/17
510(k) cleared			
OrbusNeich	Teleport	Microcatheter	K182360, 11/9/18
Micro Therapeutics	React 71	Microcatheter	K182097, 11/14/18
Micro Therapeutics	Solitaire Platinum	Stent retriever	K181186, 10/25/18
Inari Medical	ClotTriever	Stent retriever	K182531, 10/18/18
Biosphere Medical	EmboCube	Embolization gelatin	K181021, 9/27/18
Penumbra	Jet 7	Reperfusion catheter	K173761, 8/17/18
Embolix	Sniper	Infusion catheter	K180904, 6/8/18
Wallaby Medical	Wallaby Avenir	Embolic coil system	K173711, 5/4/18
Inari Medical	FlowTriever	Microcatheter	K180466, 5/17/18
MicroVention	Wedge	Microcatheter	K172014, 4/5/18
Penumbra	Ruby	Embolic coil system	K173614, 4/17/18
Merit Medical	Pursue	Microcatheter	K173548, 3/30/18
Rapid Biomedical	Flex Coil	Embolic coil system	K163661, 3/21/18
Blockade Medical	Optima	Embolic coil system	K172390, 2/18/18
Accurate Medical Therapeutics	Sequre	Microcatheters	K173430, 1/26/18
Surmodics	TBD	Microcatheter	K173560, 1/12/18

[a]510(k) Clearances. U.S. Food & Drug Administration website. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/. Accessed November 29, 2018.

Abbreviations: FDA = U.S. Food and Drug Administration; HDE = humanitarian device exemption; PMA = pre-market approval.

Riptide aspiration system (Medtronic)

The Riptide aspiration system is intended for use in the revascularization of patients with acute ischemic stroke within eight hours of symptom onset. The system is designed to actively retrieve thrombus through the Arc catheter and restore blood flow. The system is comprised of the catheter, aspiration tubing, pump and collection canister with intermediate tubing. The procedure involves inserting a catheter through an incision in the leg and up to the blocked artery, allowing the physician to remove the blood clot. This device was FDA 510(k) cleared for use in the U.S. for acute ischemic stroke patients in January 2018.

Sentinel Cerebral Protection System (Boston Scientific)

The Sentinel Cerebral Protection System is a 6-French filter system indicated to protect patients against the risk of stroke in transcatheter aortic valve replacement (TAVR) procedures. It has two intraluminal filters. One is a proximal embolic basket filter delivered to the brachiocephalic artery and the other is a distal basket embolic filter delivered to the left common carotid artery at the beginning of the TAVR procedure. The filters collect debris released during the procedure and prevent the debris from traveling to the brain. At the completion of the procedure, the filters and collected debris are recaptured into the catheter and

removed. The device is designed to be delivered through a radial artery approach. This product received the U.S. Centers for Medicare & Medicaid Services' new technology add-on payment beginning in October 2018. The maximum payment will be $1,400. It should be coded with ICD-10-PCS procedure code X2A5312. This device was initially FDA 510(k) cleared for use in the U.S. in June 2017.

EmboTrap II stent retriever (Cerenovus)

The EmboTrap II is a stent retriever designed to remove blood clots in ischemic stroke patients. The retriever has a proprietary dual-layer stent-like structure. The design traps the clot with minimal compression, allows rapid delivery of reperfusion and retains the clot during retrieval. Radiopaque markers facilitate optimal positioning relative to the occlusion. Now available in two sizes—5 mm by 33 mm and 5 mm by 21 mm—both of which are 0.021" microcatheter compatible. The company was acquired by Cerenovus to expand their product offering. The device was cleared by the FDA for sale and use in the United States in May 2018.

LVIS neuro stent (Terumo MicroVention)

The LVIS (low profile visualized intraluminal support) stents are indicated for stent-assisted coil embolization of intracranial aneurysms. The stents feature a braided conformable and retrievable design that provides high metal coverage and end-to-end device visualization to provide support for even the smallest neurovascular embolization coils for the treatment of wide-necked saccular intracranial aneurysms. The stents have been approved for use in the United States under humanitarian device exemption (HDE) since 2014 but were FDA pre-market approved for use in the U.S. in May 2018, increasing their potential use.

Surpass Streamline flow diverter (Stryker)

The Surpass Streamline is a flow-diverting stent designed to treat unruptured large and giant wide-neck intracranial aneurysms. It is a small cobalt chromium braided stent that is used to direct blood flow within an intracranial artery away from a weakened blood vessel sac or aneurysm. The diversion of blood flow occludes the aneurysm over time, reducing the risk of future rupture. The device differs from the currently available device due to its balloon expandable delivery. This device was FDA PMA approval for use in the U.S. for acute ischemic stroke patients in February 2018.

AXS Vecta aspiration catheter (Stryker)

The AXS Vectra is a large-bore aspiration catheter. The 0.071" lumen provides great clot aspiration capacity delivered through an 8 French introducer sheath. The catheter uses a unique braid construction of nitinol coil transitioning to a stainless steel cross coil. The construction gives the catheter both a larger inner lumen and good support. The catheter was U.S. FDA cleared for use in March 2018.

Neuroform Atlas stent system (Stryker)

The Neuroform Atlas stent system is the next-generation cerebral stent indicated to treat wide-neck aneurysms. It is a small nitinol stent that is used in conjunction with metal coils to pack weakened blood vessel sacs. A hybrid cell stent design is designed to improve wall apposition. Wide-neck aneurysms represent less than 10% of unruptured aneurysms treated. The stent family was approved for use in the United States under HDE in November 2017.

Galaxy G3 mini coil (Cerenovus)

The Galaxy G3 mini embolic coil is an expansion of the existing Galaxy G3 portfolio. The new coil is the smallest and softest embolic finishing coil in the portfolio for use in the endovascular treatment of cerebral aneurysms and hemorrhagic stroke. The coil is about 25% softer than the Galaxy G3 XSFT coils and have an ultra-low coil profile with a diameter of 0.009 inch. The new coil also features stretch-resistance technology. A proprietary complex random loop design makes the coil conformable and enables it to seek and fill open spaces to achieve higher packing densities. The stent family extension was cleared for use in the United States in January 2018.

PulseRider Aneurysm Neck Reconstruction Device (Cerenovus)

The PulseRider is an aneurysm neck reconstruction device. It is a permanent nitinol (nickel titanium) self-expanding stent implant. The device is indicated for use with neurovascular embolic coils in patients 18 years or over for the treatment of unruptured wide-necked intracranial aneurysms with neck widths of less than 4 mm or a dome-to-neck ratio of less than 2, originating on or near a vessel bifurcation of the basilar tip or carotid terminus with at least a portion of the aneurysm neck overlapping the lumen of the parent artery. The inflow vessels should have diameters from 2.7 mm to 4.5 mm. The device's arch design and Y or T shapes provide concentrated coverage at the neck—designed to allow dense coil packing, minimal coverage in the parent vessel and open architecture in the branch vessels—and eliminate struts crossing through the lumen of the branch vessels versus conventional stenting; selected radial force in the anchor provides stability and prevents migration. This device was approved for use in the United States by the FDA under HDE in June 2017.

Optima coil system (Balt USA)

The Optima embolic coil system is the company's first U.S. device since acquiring Blockade Medical. The coil is designed to be extremely soft with a rapid detachment system. The coil is similar to others on the market with a wide range of implant configurations in three softness profiles. The device's innovation is in the coil delivery design, providing detachment quickly with a reliable thermal detachment system. The coil family was cleared by the FDA in March 2018.

Sofia thrombectomy system (Terumo MicroVention)

The Sofia thrombectomy catheter (soft Torqueable catheter for intracranial access) is designed to allow for a contact aspiration technique. The catheter has a large 0.070" inner lumen for greater clot removal. The catheter was cleared by the FDA in July 2018.

Developing neurovascular devices

Bravo Flow Diverter (Cerenovus)

The Bravo flow diverter is a tightly woven stent indicated for use in the treatment of patients suffering from intracranial aneurysms. The device will divert blood flow from the aneurysm and promote healing, thereby reducing the risk of rupture, a main cause of hemorrhagic stroke. The company claims the innovative design of the device aims to improve clinician ease of use, improve cost effectiveness and reduce length of procedure. The device received CE mark approval in August 2018 but is not available for sale or use in the United States.

Contour Neurovascular System (Cerus Endovascular)

The Contour System is a novel design to treat intracranial aneurysms. The device combines an intra-saccular flow diverter and flow disruptor. The device provides the benefit of a flow diverter without any material in the parent artery. The device is constructed of nitinol and resembles a left atrial appendage device. The device is not available for sale or use anywhere in the world.

Lazarus Effect Cover (Medtronic)

The Lazarus Effect Cover is an innovative differentiating technology that is complementary to a stent retriever. This technology 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 received CE mark approval but is investigational and not available for sale or use in the United States.

Tigertriever 13 (Rapid Medical)

The Tigertriever is an adjustable, fully visible family of clot retrievers designed to treat ischemic stroke patients. The company claims the device's profile is 83% smaller than any other device on the market and it is delivered through a microcatheter with a distal outer diameter of 1.3 French. It is designed to recanalize intracranial vessels of 1 mm to 2.5 mm. These medium vessel occlusions cannot be treated by other devices currently on the market. The device received CE mark approval in July 2018 but is not available for sale or use in the United States.

Eric Stentriever (Terumo Microvention)

The Eric (Embolus Retriever with Interlinked Cages) is a clot-retrieval device. The device is designed to work in conjunction with the company's thrombectomy catheter. The device has a unique design. It contains five spherical elements joined together in a row. The design acts as a conveyor belt to help retrieve the clot into the aspiration catheter. The device comes in sphere sizes ranging from 3 mm to 6 mm, with three to five spheres per device. The spheres are made of nitinol and have an adjustable working length, allowing for the ability to select the number of working spheres deployed. The device has received CE mark approval but is not available for sale or use in the United States.

Neva neurothrombectomy platform (Vesalio)

The Neva is a stent retriever. The device features two "Drop Zones" that are specific areas that allow the clot to drop inside the device. The hybrid stent design with large open cells assists in capturing the blood clot. Multiple markers placed at the leading edge of the Drop Zones are offset 90 degrees to enhance visibility. The 0.014" compatible device is available in four sizes for target vessels, from 2 mm to 4.5 mm and a device working length of 22 mm to 37 mm. Like other stent retrievers, this device is designed to work in combination with aspiration catheters. The company claims the unique multifunctional device design increases the first-pass retrieval success with all clot types. The device was given CE mark approval but is not available for sale or use in the United States.

Rio embolization coil system (Three Rivers Medical)

The Rio is a family of embolization coils. The embolization coils are indicated for endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulas. The device is also indicated for arterial and venous embolization in the peripheral vasculature. The coil system is available in 10 and 18 standard, soft, and ultrasoft coil configurations, ranging in lengths from 22 mm down to 1 mm. The device received CE mark approval in February 2018 but is not available for sale or use in the United States.

Barrel VRD bifurcating/branching aneurysm embolization system (Medtronic)

The Barrel VRD is a self-expandable bifurcation aneurysm-bridging device designed to be used in treating intracranial bifurcation aneurysms. It is intended as an adjunct to embolic coils in patients with wide-necked bifurcating 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 Medical Barrel Device Trial

NCT: 02179190

Dr. J Mocco (USA) (Mount Sinai), principal investigator

N = 164 patients

Prospective, non-randomized, 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-neck, intracranial, bifurcating or branching aneurysms in the middle cerebral and basilar arteries. Patient enrollment has been completed. No other data is available at this time.

Comaneci Remodeling Mesh (Rapid Medical)

The Comaneci device is for the temporary coverage of wide-neck intracranial aneurysms during coil occlusion. It provides the bridging with 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)

The Derivo embolization device is a next-generation flow diverter, providing easy handling, secure repositioning and innovative surface finishing. It is made of a nitinol composite wire with a platinum core. The device allows the treatment of various anatomies with vessel diameters from 2.5 mm to 6 mm. The device comes in a broad range of sizes, with diameters from 3.5 mm to 6 mm and lengths from 15 mm to 50 mm. The device is not available in the United States.

Woven Endobridge (Web) aneurysm embolization system (Terumo MicroVention)

PMA submission P170032

The Web Aneurysm Embolization System is a family of nitinol devices for the treatment of intracranial wide neck bifurcation aneurysms. The company is working to get further indication for bifurcation aneurysms ranging in size from 3 mm to 10 mm in dome diameter. The device uses a dense, microbraid mesh that spans the aneurysm neck, provides inflow disruption and slows intra-saccular flow, resulting in intra-procedural stasis. The company's proprietary braid technology creates a dense mesh constructed from a large number of extremely fine nitinol wires of mixed wire diameters to achieve a balance of compliance, porosity and profile across device sizes. The company presented the clinical findings to the FDA Medical Devices Advisory Committee in September 2018. The device is not available for use or sale in the United States.

Web-IT Study

NCT: 02191618

Dr. Adam Arthur (USA) (Methodist University Hospital, Memphis), co-principal investigator

N = 150 patients

Prospective, non-randomized, single-arm, multicenter, multicountry trial

The study is designed to evaluate the safety and efficacy of the device in patients with wide neck intracranial bifurcation aneurysms having few choices for safe and effective endovascular treatment. In this study, all patients qualifying will be treated with the Web device. The primary effectiveness outcome of the study is the likelihood of complete intracranial aneurysm occlusion on the one-year angiogram as adjudicated by a core laboratory. The study was conducted at 25 investigational sites, including 20 in the United States. The results demonstrated positive results, with the study meeting its primary endpoints. At 12 months, 54.8% of patients met the primary endpoint with 83.2% achieving adequate aneurysm occlusion. Additionally, 99.3% of patients were free of disabling stroke or death.

Flow Re-Direction Endoluminal Device (Fred) (Terumo MicroVention)

The Fred system is the next-generation flow-diversion device intended for the treatment of intracranial aneurysms. The system is a 16-wire outer stent/48-wire inner stent with four atraumatic flared ends. The system is an integrated dual-layer, self-expanding nitinol braided stent (stent within a stent), which is simultaneously deployed. The higher-radial-force outer stent, along with 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 and redirect blood flow away from the aneurysm sac. The device is investigational and not available for use or sale in the United States.

Fred Trial

NCT: 01801007

Dr. Cameron McDougall (USA) (Barrow Neurological Institute), principal investigator

N = 195 patients

Prospective, non-randomized, multicenter U.S. trial

The purpose of this study is to evaluate the safety and effectiveness of the MicroVention Flow Redirection Intraluminal Device (Fred) system when used in the treatment of wide-necked intracranial aneurysms. This is a pivotal U.S. trial to support the device submission to the FDA. The study began in 2013 with over 20 U.S. hospitals participating. The study remains active but is not recruiting new patients. It appears that data from the final patients is being collected. No further clinical data is available.

Luna aneurysm embolization system (AES) (Medtronic)

The Luna AES is an endosaccular embolization device. It is a self-expanding oval ball-like implant with a delivery system. The implant is made from a double layer of nitinol wire mesh secured at both proximal and distal ends and clearly marked with radiopaque platinum markers. The properties of the device allow it to easily compress within a conventional catheter, and then rapidly and easily open to full size once deployed within an aneurysm. The device is intended to treat brain aneurysms by blocking blood flow while providing a scaffold to encourage tissue growth across an aneurysm opening and create a plug. The device is available in nine sizes ranging from 4.5 mm to 8.5 mm. The device has received CE mark approval but is investigational and not available for use or sale in the United States.

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290 E. John Carpenter Freeway
Irving, TX 75062
(972) 830-0000

www.vizientinc.com

For more information, contact us at (800) 842-5146
or vizientsupport@vizientinc.com.

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