MERIT MEDICAL SYSTEMS INC
Form 10-K
March 12, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2013,

or

o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

MERIT MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Utah	0-18592	87-0447695
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

1600 West Merit Parkway
South Jordan, Utah 84095
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: (801) 253-1600

Securities registered pursuant to Section 12(b) of the Act: Common Stock, No Par Value
Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, on June 30, 2013, which is the last day of the registrant's most recently completed second fiscal quarter (based upon the closing sale price of the registrant's common stock on the NASDAQ National Market System on June 30, 2013), was approximately $452,137,252. Shares of common stock held by each officer and director of the registrant and by each person who may be deemed to be an affiliate have been excluded.

As of March 10, 2014, the registrant had 42,862,172 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following document are incorporated by reference in Part III of this Report: the registrant's definitive proxy statement relating to the Annual Meeting of Shareholders scheduled for May 22, 2014.

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PART I

Unless otherwise indicated in this report, “Merit,” “we,” “us,” “our,” and similar terms refer to Merit Medical Systems, Inc. and our consolidated subsidiaries.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This report includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements in this report, other than statements of historical fact, are “forward-looking statements” for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of our management for future operations, any statements concerning proposed new products or services, any statements regarding the integration, development or commercialization of the business or any assets acquired from other parties, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All forward-looking statements included in this report are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any forward-looking statement. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “intends,” “believes,” “estimates,” “potential,” or “continue,” or the ne thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results will differ, and could differ materially, from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including risks relating to possible infringement of our technology or the assertion that our technology infringes the rights of other parties; risks relating to product recalls or product liability claims; potential restrictions on our liquidity or our ability to operate our business by our current debt agreements; potential for significant adverse changes in, or our failure to comply with governing regulations; healthcare reform legislation affecting our financial results and its effects on our business, operations or financial condition; greater governmental scrutiny and increasing regulation of the medical device industry; expenditures relating to research, development, testing and regulatory approval or clearance of our products and the risk that such products may not be developed successfully or approved for commercial use; reforms to the 510(k) process administered by the U.S. Food and Drug Administration (the “FDA”); modification or limitation of governmental or private insurance reimbursement policies; laws targeting fraud and abuse in the healthcare industry; the potential imposition of fines, penalties, or other adverse consequences if our employees or agents violate the U.S. Foreign Corrupt Practices Act or other laws or regulations; increases in the prices of commodity components or loss of supply; negative changes in economic and industry conditions in the United States and other countries; termination or interruption of relationships with our suppliers or failure of such suppliers to perform; our potential inability to successfully manage growth through acquisitions, including the inability to commercialize technology acquired through completed, proposed, or future acquisitions; fluctuations in foreign currency exchange rates; our need to generate sufficient cash flow to fund our debt obligations, capital expenditures, and ongoing operations; concentration of our revenues among a few products and procedures; development of new products and technology that could render our existing products obsolete; volatility in the market price of our common stock (the “Common Stock”); manufacturing facilities may be negatively impacted by certain factors, including severe weather conditions and natural disasters; changes in key personnel; work stoppage or transportation risks; international economic conditions affecting business and results of operations; failures to comply with applicable environmental laws; and other factors referenced in our press releases and in our reports filed with the Securities and Exchange Commission (the “SEC”). All subsequent forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Actual results will differ, and may differ materially, from anticipated results. Financial estimates are subject to change and are not intended to be relied upon as predictions of future operating results, and we assume no obligation to update or disclose revisions to those estimates. Additional factors

that may have a direct bearing on our operating results are described under Item 1A “Risk Factors” beginning on page 15.

Item 1. Business.

GENERAL

Merit Medical Systems, Inc. is a worldwide designer, developer, manufacturer and marketer of medical devices used in a vast array of interventional and diagnostic procedures. Our mission is to provide innovative high-quality products to physicians and healthcare professionals to enhance patient care and enable them to perform procedures safely and effectively.

Our operations are divided into the following principal markets: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology, interventional pulmonology, vascular surgery, interventional nephrology, and thoracic

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surgery. We believe we have been able to introduce new products and capture significant market share because of our expertise in product design, our proprietary technology and our skills in injection and insert molding.

In October 2013, we acquired from Radial Assist, LLC ("Radial Assist"), the Rad Board®, Rad Board Xtra™, Rad Trac™ and Rad Rest® devices which are used for patient positioning during radial access procedures.

Also in October 2013, we acquired from Datascope Corp. ("Datascope"), the Safeguard® Pressure Assisted Device, which assists in obtaining and maintaining hemostasis after a femoral procedure, and the Air-Band™ Radial Compression Device, which is indicated to assist hemostasis of the radial artery puncture site while maintaining visibility.

Merit was organized in July 1987 as a Utah corporation. We also conduct our operations through a number of domestic and foreign subsidiaries. Our principal offices are located at 1600 West Merit Parkway, South Jordan, Utah, 84095, and our telephone number is (801) 253-1600. See Item 2. “Properties.” We maintain an Internet website at www.merit.com.

PRODUCTS

We design, develop, manufacture and market innovative products that offer a high level of quality, value and safety to our customers, as well as the patients they serve. We have devoted our attention to four primary areas: diagnostic and interventional cardiology, interventional radiology, interventional gastroenterology and interventional pulmonology. Our products are also used in other clinical areas such as thoracic surgery, interventional nephrology, vascular surgery, oncology and pain management.

The success of our products is enhanced by the extensive experience of our management team in the healthcare industry, our experienced direct sales force and distributors, our ability to combine and customize devices, kits, trays and procedural packs at the request of our customers, and our dedication to offering facility-unique solutions in the markets we serve worldwide.

Cardiology and Radiology Products

Interventional cardiology and interventional radiology are specialty disciplines that use many common visualization techniques and therapeutic approaches to treat vascular disease. These shared techniques give us the opportunity to gain product line efficiencies by serving two distinct therapeutic needs with very similar product platforms. We recognize the unique demands of the two disciplines and provide very specific products to serve the unique product needs of physicians practicing in these fields.

Interventional cardiology is a branch of the medical specialty of cardiology that deals specifically with the catheter-based diagnosis and treatment of heart diseases. A large number of procedures that can be performed by catheterization involve the insertion of a sheath into the femoral, radial, or brachial artery. Fluoroscopy (real-time moving X-ray images) and computed tomography (“CT”) or three-dimensional computer generated images are most often used to visualize the vessels and chambers of the heart during these diagnostic and interventional procedures. Percutaneous coronary interventions (“PCI”) are used to treat coronary atherosclerosis and the resulting narrowing of the arteries of the heart.

Interventional radiology is related to the minimally invasive treatment of disease in peripheral vessels and organs of the body. Percutaneous peripheral interventions (“PPI”) are used to treat peripheral vascular disease conditions outside the heart.

Vascular Access Products and Accessories. We offer a broad line of devices used to gain and maintain vascular access while protecting the clinician from accidental cuts and needle sticks during procedures. These effective and useful devices and kits include the Futura® Safety Scalpel and an improved line of angiography needles such as the Merit Advance® and the SecureLoc™ Safety Introducer Needle. In addition, we offer an extensive line of sheath introducers (Prelude®) and mini access kits (MAK™ and S-MAK™), which are designed to provide clinicians with smooth, less traumatic, and convenient access to the patient's vasculature. Merit’s sheath introducers are designed for radial and femoral approach when performing diagnostic and interventional procedures. We expanded our line of radial (mini-access) sheath introducers with the addition of a 7 French size Prelude Sheath Introducer during the year ended December 31, 2013.

In October 2013, we acquired the assets of Radial Assist, which include the Rad Board, Rad Board Xtra, Rad Trac, and Rad Rest devices.The Rad Board is designed to provide a larger work space for physicians and an area for patients to rest their arms during radial procedures and has a section of lead-free Xenolite embedded in the Rad Board to help reduce scatter radiation exposure. The Rad Board Xtra is designed to work in conjunction with the Rad Board by extending the usable work space and allowing for a 90-degree perpendicular extension of the arm for physicians who prefer to perform procedures at a 90-degree angle. The Rad Trac is also designed to be used with the Rad Board and facilitates placement and removal of the Rad Board with the patient still on the table. The Rad Rest is a disposable, single-use product designed to stabilize the arm by ergonomically supporting the elbow, forearm and wrist during radial procedures.

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Safety and Waste Management Systems. We offer a variety of safety-related products and kits. Our ShortStop® and ShortStop Advantage® Temporary Sharps Holders address the potential safety issues associated with accidental needle sticks. Our extensive line of color-coded Medallion® Syringes and the PAL™ Pen and Label Medication Labeling System comply with the latest patient safety initiatives of The Joint Commission (formerly known as "JCAHO") and are designed to help minimize mix-ups in administering medication. We also offer waste management products to help avoid accidental exposure to contaminated fluids. These include our Occupational Safety and Health Administration ("OSHA")-compliant waste disposal basins: the BackStop®, BackStop+™, MiniStop®, MiniStop+™, and DugOut®. These products have been designed to complement other Merit devices and are included in many of our kits and procedure trays in order to make the clinical setting safer for both clinicians and the patients.

Hemostasis Management Devices. In recent years, radial artery catheterization has become increasingly popular as an alternative to femoral artery access when performing diagnostic and interventional cardiology procedures. There are many ways to achieve hemostasis after a diagnostic or interventional procedure. In 2013, we acquired several pressure assisted devices from Datascope, including the Air-Band,™ which we have re-branded as the Safeguard Radial™ Compression Device (the "Safeguard Radial"). The Safeguard Radial is a self-adhesive wristband designed to assist hemostasis of the radial artery after a transradial procedure. The Safeguard Radial delivers adjustable compression of the radial puncture site with an inflatable bulb and standard luer valve for easy inflation and deflation with any standard luer syringe. Through the Datascope acquisition, we also acquired the Safeguard® Pressure Assisted Device, which is designed to obtain and maintain hemostasis after femoral access. The Safeguard Pressure Assisted Device offers hands-free adjustable pressure of the puncture site with an inflatable bulb.

We offer the Clo-Sur PLUS P.A.D™, which is intended for the local management of bleeding wounds and the creation of a barrier to bacterial penetration. Non-invasive devices, including topically applied hemostatic dressings, are used primarily in diagnostic procedures; however, radial access sites use compression devices on both diagnostic and interventional procedures. As a result, we have developed and offer two independent, highly differentiated radial compression systems, the Finale® Compression Device and the RADStat® Radial Artery Compression Device.

Guide Wires and Accessories. Our diagnostic guide wires are used to traverse vascular anatomy and aid in placing catheters and other devices. Our pre-coated, high performance InQwire® Diagnostic Guide Wires are lubricious and are available in a wide range of configurations to meet clinicians' diagnostic needs. These wires provide enhanced maneuverability through tortuous anatomy. The Merit Laureate® Hydrophilic Guide Wire has a consistent, lubricious coating intended to promote rapid catheter exchanges and minimize friction. The Merit Laureate was designed with one-to-one torque to reduce wire whipping. We also offer the BowTie™ Guide Wire Insertion Device, which is used to facilitate alignment of the proximal end of a micro guide wire into the tip of a device such as a dilator, introducer, or catheter. The BowTie has two funneled ends and a tear-away slit for easy removal. We also offer a line of torque devices (SeaDragon™ and H2O Torq™), which are guide wire steering tools that can be used on both standard and hydrophilic guide wires in both large and small diameters and are often included as a component in our angioplasty packs.

Diagnostic Catheters. We offer diagnostic catheters for use during both cardiology and radiology angiographic procedures. Our diagnostic catheter offering includes our Impress® line of peripheral catheters and the Performa® line of cardiology catheters. These catheters offer interventional radiologists and cardiologists superior performance during a variety of angiography procedures. During 2013, we introduced the MIV™ Radial Ventriculogram Pigtail Catheter to address the difficulty in accessing the left ventricle from the radial artery when using standard femoral approach catheters. MIV Radial Catheters are designed to angle toward the left cusp from the radial approach, facilitating easier insertion into the ventricle.

Hemostasis Valves. We have developed a broad line of technically sophisticated, clinically acclaimed, hemostasis valves, MAP™ Merit Angioplasty Packs and angioplasty accessories. Hemostasis valves connect to catheters and allow passage of additional guide wires, balloon catheters and other devices into the vasculature, while reducing the amount of blood loss during the procedures. Our hemostasis valve line includes the Honor®, AccessPLUS™, Access-9™, DoublePlay™, MBA™, and the Passage®.

Inflation Devices. During PCI and PPI procedures, balloons and/or stents are placed within the vasculature. The balloons must be carefully placed, inflated, and deflated within the vessel in order to achieve optimal results without injury to the patient. For more than two decades, we have offered an extensive, innovative line of inflation devices that accurately measure pressures during balloon and stent deployment. In 2013, we introduced the BASIXTouch™ Inflation Syringe, offering clinicians one-handed preparation and priming for faster preparation time. The Blue Diamond™ Digital Inflation Device features an angled gauge for better viewing. Additionally, our IntelliSystem® and Monarch® Inflation Devices (state-of-the-art digital inflation systems), as well as the BasixCOMPAK™ Inflation Syringe, offer clinicians a wide range of features and prices.

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Drainage Catheters and Accessories. We have a broad line of catheters for nephrostomy, abscess and other drainage procedures. The ReSolve® Locking Drainage Catheter's unique, convenient locking mechanism is appreciated by clinicians and patients who often comment on the enhanced comfort that the catheter provides them. We also offer a range of catheter fixation devices, including the Revolution™ Catheter Securement Device, which was designed to save time, enhance patient comfort and improve cost-effectiveness. We also provide a wide selection of accessories that complement our drainage catheters, including tubing sets and drainage bags. For non-vascular applications, we offer mini access kits (MAK-NV™) designed for easy visualization and quick access into the drainage area. For enhanced visibility, the device features an echo-enhanced needle and radiopaque marker tip on the introducer.

Paracentesis, Thoracentesis and Pericardiocentesis Catheters. Paracentesis is a procedure to remove fluid that has accumulated in the abdominal cavity (peritoneal fluid). Our One-Step™ Drainage Catheter, Safety Paracentesis Procedure Tray (“SPPT”) and Thoracentesis and Paracentesis Set (“TAPS”) are designed to provide clinicians with a safe, convenient and cost-effective method for removing this fluid accumulation. Thoracentesis is a procedure to remove fluid that has accumulated in the pleural space. Our One-Step™ product line includes a valved version of the device. The Valved One-Step™ Centesis Catheter and TAPS may also be used to remove excess fluid in the pleural space during a thoracentesis. Pericardiocentesis is a procedure in which fluid is aspirated from the pericardial sac (the sac enveloping the heart). Our pericardiocentesis kit is designed as an organized, ready-to-use, convenient tray to assist the clinician in draining fluid quickly from the pericardial sac.

Thrombosis Products. We offer an extensive line of products designed to treat clots that block the flow of blood in veins and arteries. Our therapeutic thrombolytic infusion systems include the Fountain® Infusion System and the Mistique® Infusion Catheter. These catheters are used to treat thrombus (blood clot) formation in the peripheral vessels of the body, including native dialysis fistula and synthetic grafts. A new low-profile aspiration catheter, the ASAP LP™ has been added to the ASAP® line of Aspiration Catheters, giving clinicians two options for the safe and efficient removal of fresh, soft emboli and thrombi from the vessels of the arterial system.

Multipurpose Microcatheters. We offer specialty catheters designed for intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, a microcatheter can be used for the controlled and selective infusion of diagnostic, embolic microspheres or particles, or therapeutic agents into vessels. The Merit Maestro® microcatheter has a swan neck design to seat catheters in the vessel and to reduce the recoiling effect of the embolic agent as it is introduced. The EmboCath® Plus infusion microcatheter was part of the BioSphere acquisition.

Embolic Particles and Products. We offer embolic microspheres and particles and embolic delivery systems. These products include:

Embosphere® Microspheres and EmboGold® Microspheres, which are marketed for symptomatic uterine fibroids, hypervascularized tumors, and arteriovenous malformations in the United States, the European Union, and several other markets outside the United States;

HepaSphere™ Microspheres, which are marketed in the European Union, Brazil, and Russia and other emerging markets for drug delivery in the treatment of primary and metastatic liver cancer. We received regulatory approval in the European Union in 2013 to sell HepaSphere Microspheres in a smaller size (30-60 μm), giving physicians the ability to achieve more distal occlusions when embolizing hypervascular tumors and arteriovenous malformations; and

QuadraSphere® Micropsheres, which are marketed for the treatment of hypervascularized tumors and arteriovenous malformations in the United States.

Bearing nsPVA™ Particles, introduced in 2013 and also marketed for symptomatic uterine fibroids, hypervascularized tumors, and arteriovenous malformations in the United States, the European Union, and several other markets outside

the United States.

Vascular Retrieval Devices. Our snares or vascular retrieval devices are single-use products designed for foreign body manipulation and retrieval and can be used to retrieve inferior vena cava filters, reposition indwelling venous catheters, strip fibrin sheath formation, and assist in central venal access venipuncture. We offer the ONE Snare®, a single loop device, and the EN Snare® Endovascular Snare System, which has three interlaced loops. Both are offered in multiple sizes to accommodate a broad range of vessels throughout the body.

Angiography and Angioplasty Accessories. We offer the Ostial PRO® Stent Positioning System, a medical-grade disposable guide wire system designed to provide consistent and precise stent implantation in aorto-ostial lesions during coronary or peripheral interventional procedures. The Ostial PRO can be used to introduce and position stents and other interventional

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devices within the coronary and peripheral vasculature and function as an alignment tool. Additional angiographic accessories include the Flow Control Switch™, an integrated, one-handed, single-channel switch designed with clinician and patient safety in mind. Since the introduction of the CCS™ Coronary Control Syringe line in 1988, we have continued to develop innovative, problem-solving devices, accessories, kits and procedure trays for use during minimally invasive diagnosis and treatment of coronary artery and peripheral disease. We now offer a broad range of specialty syringes, including color-coded Medallion® Syringes and the proprietary VacLok® Vacuum Pressure Syringe. The most recent line extensions to our syringe product family are frosted and sword-handled Medallion® syringes. Additionally, we offer an extensive line of kits containing fluid management products such as syringes, manifolds, stopcocks, tubing, and disposable pressure transducers (Meritrans®) for measurement of pressures within the vessels and chambers of the heart. The TRAM® and TRAM-P™ Manifolds with Integral Transducers combine a low torque manifold with the transducer. We also provide devices, kits and procedure trays to effectively and safely manage fluids, contrast media and waste during angiography and interventional procedures. The Miser® Contrast Management System complements our comprehensive line of fluid management products used in angiography procedures.

Hemodialysis and Peritoneal Dialysis.We offer peritoneal dialysis catheters and accessories as part of our dialysis and interventional nephrology product line, including the Flex-Neck® and ExxTended™ Peritoneal Dialysis Catheters and Y-TEC® Implantation Kits. The Centros® and CentrosFLO® Long-Term Hemodialysis Catheters anchor our chronic dialysis line. The ProGuide™ is considered a “workhorse” catheter for chronic dialysis and provides a platform for the development of additional Merit products in the dialysis and interventional nephrology market. For example, the new Prelude® Short Sheath provides vascular access to dialysis grafts, along with our extensive line of micro access devices such as the MAK™ and S-MAK™ line of mini access kits. We also offer a wide range of guide wires, diagnostic catheters, therapeutic infusion systems and safety products that can be used during dialysis-related procedures. The OuTake® Catheter Extractor is used to remove tunneled chronic dialysis catheters from dialysis patients. A curved introducer needle aids clinicians who choose to place a tunneled dialysis catheter over a wire with a single stick. The Slip-Not® Suture Retention Device provides a unique and effective method for securing a purse-string suture that controls bleeding after an arteriovenous (“AV”) fistula intervention. In addition, we offer the Impress® 30 cm Fistula Catheters, which can be used by interventional nephrologists. Our dialysis and interventional nephrology products are designed to provide comprehensive coverage for completing AV fistula interventions.

Electrophysiology ("EP") Products. With our acquisition of Thomas Medical Products, Inc. ("Thomas Medical") in 2012, we now offer innovative solutions to address lead implantation and therapeutic delivery in the rapidly-expanding cardiac rhythm management and electrophysiology fields.

Cardiac rhythm management is the field of cardiovascular disease therapy that relates to the detection and treatment of abnormally fast (tachycardia) and abnormally slow (bradycardia) heart rhythms, or electrical patterns in the heart, and heart failure. We offer products that improve lead delivery and vessel access. The ClassicSheath™ Splittable Hemostatic Introducer System allows for insertion of cardiac pacer leads for pacemakers and implantable cardioverter defibrillators. Its robust valve design reduces the risk of air embolism and backbleed. We also offer the Worley™ Advanced LV Delivery System to aid in the insertion and implantation of left ventricular leads, which are wire electrodes inserted into the coronary sinus to the left lateral wall of the heart to pace the left side of the heart for heart failure patients. The Worley™ Advanced LV Delivery System has been shown to reduce lead failure, improve target lead location and reduce procedure times.

Cardiac electrophysiology is the study of diagnosing and treating the electrical activities of the heart. Common procedures include diagnostic EP studies and therapeutic ablation procedures designed to deter arrhythmia. We offer the HeartSpan® Transseptal Needle, which is designed with a larger ergonomic handle, unique unibody needle design and optimal needle sharpness; the Heartspan® Transeptal Sheath, which features an improved hemostasis valve for reduced blood loss and air embolism, smooth sheath to dilator transition for easier transeptal crossing, and reinforced

stainless steel tubing for excellent torque response; and the Heartspan® Resiliance Dilator, which is designed to minimize the risk of the needle cutting out small pieces of plastic inside the dilator.

Endoscopy Products for Gastroenterology, Pulmonology, and Thoracic Surgery

Airway Stents. Through our Merit Endotek division, we sell a variety of non-vascular stents. Our AERO® and AERO DV® Fully Covered Tracheobronchial Stents are used by interventional pulmonologists and thoracic surgeons. These products offer our customers patented, fully covered, self-expanding metal stents used to improve patency of patient airways-both tracheal and bronchial-and to offer palliation to patients suffering from strictures caused by cancer.

Esophageal Stents. The Alimaxx-ES® and the new EndoMAXX® Fully Covered Esophageal Stents are used by interventional gastroenterologists, ENTs and thoracic surgeons to palliate symptoms associated with malignant tumors and strictures affecting the esophagus, as well as to treat concomitant tracheoesophageal fistulae.

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Biliary Stents. The Alimaxx-B® Biliary Stent System is used by interventional gastroenterologists to palliate symptoms associated with malignant tumors affecting the bile duct. Additionally, we sell a plastic biliary stent that is used to restore patency and relieve symptoms associated with strictures and blockages within the biliary system. These stents are often used to "stage" treatment of malignant tumors such as pancreatic cancer and other serious conditions.

Stent Sizing Device. Merit Endotek also sells the AEROSIZER® tracheobronchial stent sizing device which is used in interventional pulmonology procedures. This proprietary product allows length and diameter measurement accuracy, thus minimizing the possibility of stent mis-sizing and associated cost and complications.

Guide Wires for Non-Vascular Procedures. MAXXWIRE® is a line of specialty guide wires that have pulmonology and gastroenterology applications.

Bipolar Coagulation Probes. Bipolar probes are used by physicians as one means of controlling bleeding within the gastrointestinal tract. Our Brighton® Bipolar Probe is now sold directly by our Merit Endotek division and our original bipolar probe is sold on an original equipment manufacturer ("OEM") basis to customers who market them to a large number of gastroenterologists.

Inflation Devices. Merit Endotek's BIG60® Inflation Device is a 60 mL device designed to inflate and deflate non-vascular balloon dilators while monitoring and displaying inflation pressures up to 12 atmospheres. Merit Endotek also offers Endotek-labeled versions of the BasixCOMPAK™ and Monarch Inflation Devices to customers in pulmonology, gastroenterology, and thoracic surgery.

Cholangiography Rapid Refill Continuous Injection Kits. Merit Endotek's BiliQUICK™ Cholangiography Rapid Refill Continuous Injection Kit incorporates a convenient all-in-one kit that is used in gastroenterology to deliver contrast media both quickly and efficiently while eliminating unnecessary time spent refilling the injection syringe. Our Inject10^{n}™ Coronary Control Syringe is included in the kit.

Oropharyngeal Airway, Bite Block and Oxygen Administration Device. The TIO™ Three-in-One is a combination product that incorporates the benefits of an oropharyngeal airway, bite block and oxygen administration device into one convenient, easy to use device, enhancing procedure efficiency.

Specialty Procedure Products

In addition to the procedures and devices detailed above, interventional radiology and other special procedure labs perform a variety of additional minimally invasive diagnostic and interventional procedures. We offer a variety of devices and accessories used during these procedures.

Discography Products. Discography is a technique used to determine whether a disc is the source of pain in patients with back or neck pain. During discography, contrast medium is injected into the disc and the patient's response to the injection is noted. Due to their quality and accuracy, our digital inflation devices (IntelliSystem and Monarch) are used in many pain management clinics.

Coated Wires and Tubes. We provide coating services for medical tubes and wires under the Merit Medical OEM brand. We offer coated tubes and wires to customers on a spool or as further manufactured components like hypotubes, guide wire components, coated mandrels/stylets and coated needles. Our coating operation facility is located in Venlo, The Netherlands, where PFOA-free PTFE and Hydrophilic coatings are applied to bulk lengths of bare wire and tubing, prior to cutting, using a proprietary spool-to-spool coating method. Our coating technology, developed more than 20 years ago, results in consistently coated medical tubes and wires with tight tolerances. In the summer of 2013, we opened a state-of-the-art hypotube manufacturing Center of Excellence in Galway, Ireland,

including advanced laser cutting and ablation, passivation, cleaning and other hypotube manufacturing processes. The Merit Hypotube™ is used as the catheter shaft in PTCA and PTA balloon catheters, as well as functional guide wires.

Pressure Sensors. Our sensor division manufactures and sells microelectromechanical systems ("MEMS") pressure sensor components focusing on piezoresistive pressure sensors in various forms, including bare silicon die, die mounted on ceramic substrates, and custom assemblies for specific customers.

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MARKETING AND SALES