TRANSFORMING MEDTRONIC TO SUPPORT PROGRESS IN HEALTHCARE

2019

PERSPECTIVE SYNOPSIS: Healthcare is facing immense challenges. From shifting payment models to problems of access, providers and payers are struggling to improve patient outcomes and lower overall costs. While there is no single solution, we recognize that those who deliver care are at the center of this transformation — and that technology can help propel them forward. At Medtronic, we know we don't have all of the answers, but we are committed to collaborating with others to take healthcare Further, Together.

During the six decades of Medtronic existence, our Mission has remained the same: to alleviate pain, restore health, and extend life for people around the world.

We are a technology company deeply rooted in pushing the limits of innovation, and we have worked hard to be at the forefront of medical technology development, reinvention and disruption — challenging ourselves to create high-quality therapies that positively impact people's lives. And we have accomplished a lot: today more than 75 million people benefit from our technologies each year, equating to more than two people every second.

But we also know that we participate in a global healthcare environment that faces intense clinical and economic challenges. If not corrected, these challenges may undermine progress while leaving millions around the world untreated. We believe the approach that got us to the current state of healthcare is not necessarily what will push us ahead. The future of healthcare requires new approaches and new forms of innovation.

Medtronic has contributed to human welfare by partnering with others to create medical technologies that improve patients' lives. The full power of these technologies and the information and insight we know they generate, however, has not been fully realized. Our technologies, services, and people are powerful tools for those seeking to drive more seamless, integrated care and better patient outcomes. Fundamentally, we believe the world would be a better, healthier place if we were able to more fully capture and apply the power of technology to integrate care and generate better outcomes for patients.

HEALTHCARE'S GROWING CHALLENGES

In many ways, the history of medicine is the story of a continuous quest to ensure that people receive the life-saving or life-enhancing treatments they need to return to a full life. As we have moved along this journey, those who provide care to patients have cultivated a core set of beliefs that healthcare systems around the world now hold as common fundamental goals: improving clinical outcomes, expanding access, and optimizing cost and efficiency.

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The ability to achieve these goals, however, is complicated by a range of challenges, including an aging global population, an increasing burden of chronic disease, payment and delivery systems with misaligned incentives, and government policies and regulations that, at times, can be cumbersome. Total healthcare spend in the world's major regions is expected to reach $8.7 trillion by 2020.[1] Much of this spending comes from treating non-communicable diseases[2] — like stroke, heart disease, and diabetes — which account for 88 percent of all deaths in high-income countries.[3]

What has made tackling these challenges even more difficult is the disjointed and inefficient nature of how healthcare is delivered. While physicians and healthcare practitioners perform exceedingly well and with the utmost expertise, they operate in healthcare systems that have traditionally rewarded volume of care over value of care. These fee-for-service or procedure-based payment and delivery systems are typically highly fragmented, siloed and disconnected — leading to one of our new challenges: health economists estimate that 20 percent of healthcare spend in countries of the Organization for Economic Co-operation (OECD), including the U.S., is ineffective.[4]

In short, our current system is struggling to deliver what we all want to accomplish: high-quality and affordable care that returns people to fuller, more productive lives.

What we need is a more coordinated, connected network where technology empowers providers to deliver better care to patients throughout their health journey and where outcomes that matter to patients are prioritized relative to the cost. But what will this look like? For patients undergoing a complex procedure, this might mean therapy optimization that protects them from harmful complications and readmissions. In common surgeries that have a wide variance in outcomes, such as hip and knee replacements, this could mean bundling services for patients and physicians throughout the entire episode of care to ensure consistent and positive results. And for people with chronic diseases, this vision will entail collaboration with patients and their clinicians to help manage the condition.

Medtronic
Further, Together

SHIFT IN FOCUS FROM VOLUME TO VALUE

Around the world, healthcare systems are in the early stages of experimenting with different ways to address these challenges. In many countries, new models of care are emerging that promote integration or care coordination across a patient's care continuum. Take the United Kingdom, for example, where the National Health Service (NHS) made a commitment to bring together local authorities, care and support providers, housing services, public health workers, and others to make further steps toward better integrated care.

Similarly, the U.S. Centers for Medicare & Medicaid Services (CMS) has put into place new financial incentives that reward the quality of care provided rather than the volume of care. In 2018, CMS announced the launch of the voluntary Bundled Payments for Care Improvement (BPCI) Advanced model. "To accelerate the value-based transformation of America's healthcare system, we must offer a range of new payment models so providers can choose the approach that works best for them," said CMS Administrator Seema Verma. The BPCI Advanced model currently includes nearly 1,300 participants that are receiving episode-based payments for various episodes of care.[5] Additionally, in November 2018, the U.S. Department of Health and Human Services (HHS) announced it would also reinstate a number of mandatory bundled payment models.[6]

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TAKING HEALTHCARE "FURTHER, TOGETHER"

Though we firmly believe Medtronic is already playing a unique role in facilitating the move toward a more aligned, value-based environment, we know we can and will do more. We call this new approach "Further, Together." "Further," because we will continue to drive progress in innovation, and devise powerful solutions with proven clinical and economic value as the basis of our offerings and value proposition. And "Together," because we will collaborate with providers, policymakers, payers and other new links in the healthcare chain to help our customers achieve their goal of delivering more seamless, integrated care across the healthcare continuum.

The main tenets of "Further, Together" focus on applying our technologies, capabilities and expertise to align value among the various stakeholders in the healthcare system; creating meaningful innovations at the therapy, procedural, and system level; and expanding global access to healthcare — all while developing new collaborations with those who are committed to transforming and improving patient care.

USING TECHNOLOGY TO ALIGN VALUE

At Medtronic, we fully support the healthcare systems around the world that have or are seeking to adopt value-based healthcare delivery and payments systems. And though we remain focused on developing technologies, services and solutions that drive more clinical value into existing health systems, we are also dedicated to working with others to help drive economic value and bring about the transformation to value-based care. This endeavor will take time, but we're confident that this approach offers the best pathway to putting the patient at the center of care — leading to better outcomes, greater coordination from all healthcare players, and reduced costs.

One way we're actively moving in this direction is sharing accountability for patient outcomes. In 2018, Medtronic and the eight hospitals in the Lehigh Valley Health Network (LVHN) in Pennsylvania began a first-of-its-kind partnership, designed to bring better medical care to more people at a lower cost. The work is initially focused on 10 to 15 health conditions, including bariatrics, heart disease, stroke and diabetes. Part of the financial structure of the arrangement is based on whether the technology or service demonstrates better outcomes for patients or reduces costs. Ultimately, Medtronic and LVHN expect to team up on at least 70 medical conditions, impact as many as half a million people, and save at least $100 million dollars in healthcare costs over five years.

"This is the kind of forward thinking we'll need in reaching out with our partners at Medtronic to improve our community," said Brian Nester, President and CEO of Lehigh Valley Health Network. "This is the future of healthcare, and we're about to begin developing it right here."

And we won't stop there. Medtronic is working with the global healthcare community to leverage our skillsets to develop and implement a comprehensive portfolio of offerings across our businesses. Ultimately, this will help stakeholders align value across the care continuum and improve system performance, including clinical care optimization, operational efficiency and patient management.

Enhancing technologies to optimize care and provide more value. For example, for all the good a pacemaker can do, if a patient experiences an infection from the implantation of the device, the positive effects of the technology can be mired by serious medical complications. Cardiovascular implantable electronic device (CIED) infections also impose a substantial financial burden resulting from prolonged hospital stays, long duration of antibiotic therapy, management of sepsis and complications, device extraction and reimplantation.[7]

To help providers avoid these costly events, Medtronic now offers the TYRX™ absorbable antibacterial envelope — which has been shown to reduce the chances of infection among high-risk patients by 70 to 100 percent — within a shared accountability arrangement to providers and payers.[8] This arrangement in the implantable cardiac device space enables us to absorb some of the risk if a patient with a Medtronic device and the TYRX envelope gets an infection associated with the device implantation.

Fighting operational inefficiency and waste at the system level to help align more value across stakeholders. Operational efficiency has been a focus of Medtronic for a number of years given the significant unmet needs in this area. At the heart of the matter, it comes down to the fact that hospital margins today require systematic efficiencies to be maximized on a daily basis for hospitals not to lose money. Unfortunately, few care providers are successful in their efforts. This was illustrated in a recent report by the Ponemon Institute of more than 400 U.S healthcare providers. The analysis found hospitals' and health systems' workflows wasted a significant amount of time because

of inefficient communication, costing $1.75 million per hospital and more than $11 billion industry-wide.[9]

To address this need for hospitals and systems, we created the Medtronic Integrated Health Solutions (IHS) business to help providers optimize costs and outcomes and produce higher value and patient satisfaction across the care continuum. In an operational excellence transformational program conducted at Maastricht University Medical Center in the Netherlands, Medtronic provided on-site program management and seasoned consultants to optimize processes and clinical pathways and to engage staff for successful knowledge transfer. We worked with Maastricht leaders and clinical teams to embed a performance improvement culture and drive advancements in efficiency, quality, clinical outcomes, and patient experience though a combination of classroom work, mentoring, and on-the-job learning to ensure lasting, transformational change. Within one year of a five-year partnership, $2.5M in value[8] was generated by efficiency gains through optimized resource use, which also lead to productivity and capacity increases.

Improving the effectiveness of care delivery through disease management. Another opportunity to align value in healthcare systems around the globe is to focus our efforts on improving the way we care for patients with chronic conditions — such as diabetes — who are often the most challenging and costly to treat. While many different solutions will be needed to address the vast array of chronic conditions, we're focusing on a few strategies to prevent condition escalation in chronic disease patients. We're working with healthcare practitioners to establish a baseline assessment, bundle episodic intensive care with outcome measures tailored to the disease, and incorporate periodic outcome measurements to monitor the condition.

Case in point — we offer high-tech and high-touch solutions through our Diabetes Management clinics — known as "Diabeter Clinics" — where we manage the care of 2,400 children and young adults living with Type 1 diabetes in the Netherlands. These clinics leverage personalized medicine by making use of specially developed technologies, such as an electronic system that links patient and physician. This encourages self-management with diabetes care team support. Diabeter data shows that their patients have achieved significant reductions in HbA1c levels, a key measurement used to assess blood glucose control. More consistent blood glucose control has been shown to reduce long term complications of diabetes and in a recent analysis, Diabeter was able to showcase that its unique approach saved 8.7 percent[10] in annual costs to its patients. The savings were mainly driven by a much lower patient hospitalization rate than that of other Dutch pediatric diabetes clinics.

Medtronic also addresses the global obesity crisis by offering a holistic approach to bariatric surgery within our Nederlands Obesitas Kliniek (NOK) clinics. At least 650 million people worldwide are obese — and if current trends continue, almost half the world's adults could be obese by 2030.[11] It's the leading cause of chronic health conditions such as high blood pressure, diabetes, kidney disease, and stroke. In spite of these staggering figures, less than 1 percent of patients eligible for bariatric surgery undergo the procedure, a proven way to effectively treat obesity and the associated co-morbidities.[12]

The NOK model gives providers an opportunity to offer bariatric surgery with an accountable partner. The approach spans patient identification, the acute episode and chronic management, and focuses on differentiated outcomes for patients, providers and payers. These include weight loss that will be more durable in the long term, achieved by using periodic outcome measures to monitor and manage a patient's condition. The multidisciplinary program gives the patient and the surgeon the expertise and support they need to be successful, including standardized and measured nutritional, psychological, exercise, and medical support. It is also designed for expansion globally to the benefit of many other countries struggling to deal with the obesity crisis.

CREATING MEANINGFUL INNOVATIONS AND INCREASING GLOBAL ACCESS TO HEALTHCARE

The power of technology not only helps align value for providers and stakeholders, it also drives innovation. Meaningful innovations at the therapy, procedural and system levels are those that deliver better patient outcomes at appropriate costs, lead to enhanced quality of life, and can be validated by both clinical and economic evidence. Medtronic is exploring many ways to rethink what this means along the full continuum of care.

This year alone we have invested $2.3 billion in research and development to bring meaningful innovations to market. Out of all the innovations developed, there is one that's closest to our heart — most likely because it's in so many of our patients. Medtronic was founded shortly after our founder invented the first external and battery-operated pacemaker to help patients who had a slow heartbeat. What was a significant advancement 60 years ago is only superseded today by something just as notable. The Micra™ Transcatheter Pacing System (TPS) is the first FDA-approved device with miniaturized pacing technology that makes it cosmetically invisible and small enough to be implanted directly into the heart. Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical "pocket" under the skin. As a result, potential sources of costly complications related to the leads and pocket are eliminated, thereby improving clinical outcomes and reducing costs for the patient and system.[13]

The power of technology not only helps align value for providers and stakeholders, it also drives innovation.

The technologies we design are meant to improve patient outcomes, but if we are to improve outcomes around the world, global access to quality healthcare must also be a critical area of focus for the company. Equity is a matter of concern across nearly all indicators in many parts of the world. According to a 2017 report from the World Bank and the World Health Organization (WHO), at least half of the world's population cannot obtain essential health services, and nearly 100 million people are pushed into poverty each year because of out-of-pocket healthcare expenses.[14]

In developed markets, we're working with governments and providers on care delivery and efficiency. In emerging markets, we're assisting with infrastructure development, therapy awareness and education, and

capacity management. One service that stretches across all geographies and is imperative to improving outcomes is physician training. In the last year we invested $142 million in capacity building and training for medical professionals, reaching a record 89,000 people.

Emerging markets face unique obstacles in their quest to stand up and establish sustainable, high-quality, and cost-effective health systems. Access is typically impacted by location and proximity to quality health institutions, a lack of quality trained specialists and healthcare practitioners, and a lack of infrastructure or facilities.

Recognizing these dynamics, Medtronic is focusing on developing market models and partnerships that establish centers of excellence where specialized tasks and procedures are housed to increase quality outcomes, develop physician expertise, and minimize expenditures and costs. These centers are then connected to satellite or field entities focused on patient screening, diagnosis, and post-procedure patient management. These total disease-specific patient care pathway models are showing promise around the world.

Now with a larger global footprint, we're positioned as a stronger partner for physicians, hospital systems, patients, payers, and governments around the world.

For example, in Brazil — heart failure, myocardial infarction, atrial fibrillation, and hypertension affect 45.7 million people and account for $17.5 billion in healthcare expenditures[15] — we're working with local government officials, leading physicians, emergency care personnel, and hospital systems to put into place the appropriate infrastructure to provide optimal care for heart attack patients. It's making a difference in Sao Paulo, one of the world's busiest cities, where patients suffering from one of the worst forms of heart attacks previously have had little chance to reach an appropriate hospital in time to alleviate their heart blockages.

The infrastructure program is called "LATIN" (Latin America Telemedicine Infarct Network), and we're offering telemedicine technologies that help key stakeholders develop localized protocols and educate both cardiologists and emergency care physicians on the most appropriate care pathway for ST-elevation myocardial infarction (STEMI), a serious type of heart attack. Coupled with a large-scale public education initiative to better inform the community, the LATIN program has significantly improved outcomes for heart attack patients in Sao Paulo.[16] Today, the "hub and spoke" infrastructure spans 120 clinics and 19 hospitals across Colombia and Brazil. In remote parts of Mexico, 35 primary care centers and three hospitals have also adopted the model.

THE WAY FORWARD: JOINT ACCOUNTABILITY FOR OUTCOMES

Our technologies, services and solutions — coupled with our commitment to aligning value, developing meaningful innovations and improving global access — are merely the latest examples of Medtronic's six-decade commitment to serving those who provide care. Since our founder Earl Bakken and his groundbreaking work on pacemakers, our dedication to providing clinicians with the technologies they need to deliver high quality care has never wavered.

There have been many steps in this journey, including our acquisition of Covidien that doubles our portfolio of innovative products, and expands our clinical and economic expertise. And now with a larger global footprint, we're positioned as a stronger partner for physicians, hospital systems, patients, payers, and governments around the world. Our growing team and capabilities have also given us the opportunity to think beyond just the products we've typically focused on and put into place the policies and system to develop product-agnostic offerings. These new services and solutions allow us to think holistically about the entire patient journey and offer greater value to our partners across their continuum for care, including awareness, prevention, diagnosis, treatment and management.

Yet with the constantly evolving transformation of healthcare, we know providers need more than technology and service innovations.

That's why we're fashioning some of our key offerings into outcomes-based arrangements with providers and payers. In other words, we are entering into agreements with customers where the costs of the products, services and integrated solutions we provide are directly linked to the quantifiable clinical, patient and economic outcomes.

To come up with these value-based healthcare solutions, Medtronic has spent a lot of time and investment to create a framework and methodology to identify outcomes and cohorts that help our partners succeed in risk-sharing models. Across the company — in different groups and geographies — we're using a seven-step framework that defines these new models in which we share direct accountability for system costs and patient outcomes with our customers. And, in some instances, we have gone as far as entering outcomes-based agreements that tie payment or reimbursement to these clinical outcomes.

Now is a truly exciting time to be working in healthcare, as fundamental shifts are occurring that will change how patients receive care and how we think about what real value — for patients and providers— means. These changes will only come to fruition if we all work together and evolve with the new framework that our healthcare system needs.

These new capabilities — along with our "Further, Together" mindset of driving healthcare transformation in partnership with like-minded players across the industry — are a transformative opportunity for Medtronic to improve the ways we help others in healthcare and also fulfill our mission to alleviate pain, restore health and extend life.

Learn more about how we collaborate with others to take healthcare Further, Together.

INDICATIONS, SAFETY, AND WARNINGS

TYRX™ Absorbable Antibacterial Envelope

INDICATIONS FOR USE

The TYRX™ Absorbable Antibacterial Envelope is intended to hold a pacemaker pulse generator or defibrillator securely in order to provide a stable environment when implanted in the body. The absorbable antibacterial envelope contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of the generator or defibrillator. This device is only intended to be used in conjunction with pacemakers and implantable defibrillators.

CAUTIONS

Only physicians qualified in the placement of pulse generators or defibrillators should use this prosthesis.

CONTRAINDICATIONS

The Absorbable Antibacterial Envelope is NOT indicated for use in the following situations:

- Allergy or history of allergy to tetracyclines, rifampin, or resorbable sutures
- In patients with systemic lupus erythematosus (SLE) because minocycline has been reported to aggravate this condition
- Contaminated or infected wounds

POTENTIAL COMPLICATIONS

Possible complications for these procedures include bleeding and infection. (See also WARNINGS.) There is currently no long-term data available to determine whether tissue reactions to the absorbable antibacterial envelope will be equivalent to the Parsonnet™ pacemaker pouch. As with any surgical procedure involving the implantation of a pacemaker/defibrillator, there may be complications, including seroma, adhesions, hematoma, inflammation, extrusion, or fistula formation. If infection develops, treat the infection aggressively as per standard practice, including removal of the prosthesis, if indicated. Please report any device-related adverse events to Medtronic, Inc. at 1-800-848-9300.

WARNINGS

This device is supplied sterile. Inspect the packaging to be sure that it is intact and undamaged prior to use.

This device is for single use only. Do not re-sterilize. Product should be used once the exterior foil wrapper has been broken. Do not store for later use. Unused portions of the prosthesis should be discarded.

If the unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent risk of transmission of any disease.

The use of any surgical mesh in a contaminated or infected wound could lead to fistula formation and extrusion of the prosthesis. If infection develops, treat the infection aggressively as per standard practice, including removal of the prosthesis, if indicated.

As in any antimicrobial therapy, the possible teratogenic potential in women capable of having children should be carefully weighed against the benefit of therapy.

This device has not been evaluated in pediatric patients.

The use of this product in patients with compromised hepatic and renal function, or in the presence of hepatotoxic or renal toxic medications, should be carefully considered because rifampin and minocycline can cause additional stress on the hepatic and renal systems. Patients who are implanted with this device and are also receiving methoxyflurane should also be carefully monitored for signs of renal toxicity.

Patients who are implanted with this device who are also taking warfarin should have their International Normalized Ratio (INR) monitored because tetracyclines have been reported to potentiate the anticoagulant effect of warfarin. The use of this product in patients being treated with thionamides, isoniazid, or halothane should be carefully considered due to potential hepatic side effects that have been reported in patients using these drugs and higher doses of rifampin.

The contraindications, warnings, and precautions applicable to the use of specific antibiotic prophylaxis should be followed when prophylaxis is administered in conjunction with implantation of a pacemaker pulse generator or defibrillator enclosed in an absorbable antibacterial envelope.

Development of a hypersensitivity reaction should be followed by removal of the device and appropriate treatment initiated at the discretion of the attending physician.

Use of the absorbable antibacterial envelope in contaminated wounds is not recommended. The device is not indicated for the treatment of infection. Because the absorbable antibacterial envelope is impregnated with a combination of the antimicrobial agents rifampin (a derivative of rifamycin B) and minocycline (a derivative of tetracycline), the contraindications, warnings, and precautions regarding the use of these antimicrobials apply and should be adhered to when using this device.

Micra™

INDICATIONS

Micra™ Model MC1VR01 is indicated for patients with:

- Symptomatic paroxysmal or permanent high grade AV block in the presence of AF
- Symptomatic paroxysmal or permanent high grade AV block in the absence of AF as an alternative to dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses), as an alternative to atrial or dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

CONTRAINDICATIONS

Micra Model MC1VR01 is contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated.

Steroid use — Do not use in patients for whom a single dose of 1.0 mg of dexamethasone acetate cannot be tolerated.

WARNINGS AND PRECAUTIONS

End of Service (EOS) — When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use — Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. Asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explantation of the Micra device, which should be turned off.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, acceleration of tachycardia, myocardial infarction, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, death, device embolization, access site hematoma and AV fistulae, vessel spasm, infection, inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at **www.medtronic.com**.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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16. TBD by LATAM Team

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