



Abbott

THE POWER OF  
YOUR HEART

PG. 12

A JOURNEY WITH  
CHRONIC PAIN

PG. 20

A DIABETES CARE  
REVOLUTION

PG. 25



SHAPING THE FUTURE OF HEALTH

EDGE

WINTER 2020

# LEADING EDGE



14



16



20



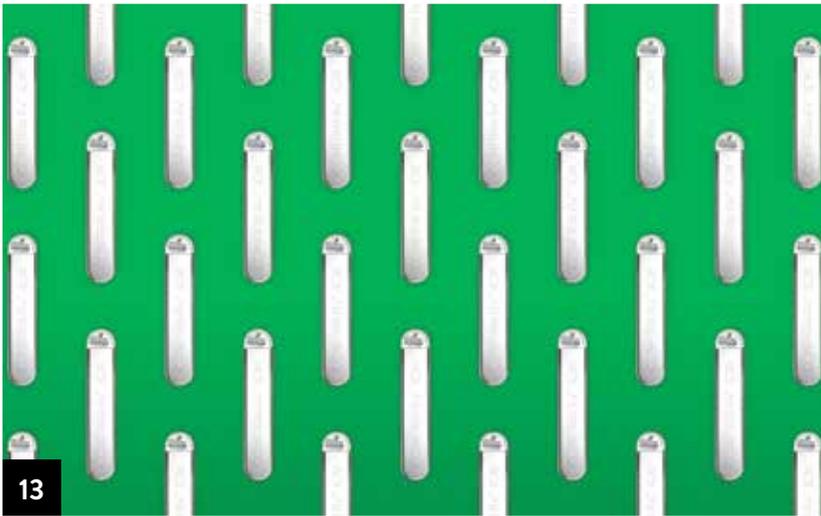
25

## CONTENT

THE “SPARKLE” IN HER HEART.....	6	STAYING ONE STEP AHEAD OF HIV.....	19
THE WEIGHT OF THE WAIT .....	8	A JOURNEY WITH CHRONIC PAIN .....	20
A TINY HEART. A BIG BREAKTHROUGH.....	10	THE SCIENCE BEHIND GOOD NUTRITION.....	22
THE POWER OF YOUR HEART .....	12	FAST RESULTS FOR THE FLU.....	24
HEART MONITORING, EVERYWHERE YOU GO.....	13	A DIABETES CARE REVOLUTION .....	25
AGAINST THE GRAIN IN PARKINSON’S FIGHT .....	14	THE FUTURE OF DIABETES CAREGIVING.....	26
SHE WON’T STOP FIGHTING VIRUSES .....	16	BIG DATA ARE CHANGING DIABETES MANAGEMENT .....	28

## CONNECT WITH US

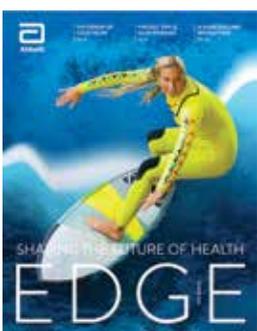
- ONLINE [abbott.com](http://abbott.com) | [lifetothe fullest.abbott](http://lifetothe fullest.abbott)
- FACEBOOK <https://www.facebook.com/abbott>
- TWITTER <https://twitter.com/abbottnews>
- INSTAGRAM <https://www.instagram.com/abbottglobal/>
- YOUTUBE <https://www.youtube.com/c/abbott>
- LINKEDIN <https://www.linkedin.com/company/abbott/>



13



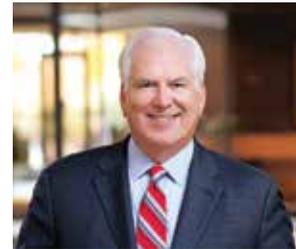
6



DOWNLOAD THIS MAGAZINE.



SUBSCRIBE TO ABBOTT EDGE MONTHLY NEWSLETTER.



**MILES WHITE**  
Chairman and  
Chief Executive Officer

## WELCOME TO THE FUTURE OF HEALTHCARE

You may be new to Abbott, so I'd like to tell you a bit about our company.

As you know, digital technology has huge implications for the way we'll manage health in the years ahead. The data and insight we can now provide people about their general health status or about highly specific conditions and measures is revolutionizing the way we monitor health and treat illness.

Abbott is one of the leaders in connected care — the vanguard of this revolution — with medical devices that can be implanted in the body, or worn on it, to provide critical information to users and their physicians, easily, continually, and painlessly.

So, welcome to Abbott. We're pleased to meet you and invite you to learn more about us and the future of healthcare that we're helping to make possible.

All the best,

Miles White

## PODCAST: INNOVATION IN A HEARTBEAT

Join Dr. Jack Kreindler (physician and health tech entrepreneur), Dr. Andreas Fleischli (Abbott) and host Mike Rugnetta as they tackle humanity's desire to increase not only the length of life but the quality of those added years. Modern technology is building on the progress being made in health innovations. They discuss the process by which remarkable ideas become medical realities — and where they're going next.

FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 30.



LISTEN HERE.



LISTEN, DOWNLOAD AND SUBSCRIBE TO OUR PODCAST CHANNEL:



© 2020 ABBOTT. ALL RIGHTS RESERVED.

Unless otherwise specified, all product and service names appearing in this publication are trademarks owned by or licensed to Abbott, its subsidiaries or affiliates. No use of any Abbott trademark, trade name, or trade dress may be made without the prior written authorization of Abbott, except to identify the product or services of the company.

A TINY HEART.  
A BIG BREAKTHROUGH.  
**AN ENTIRE LIFETIME  
OF POSSIBILITY.**

Every year, thousands of newborn babies enter the world with a hole in their hearts. When that happens, an already-fragile life can become a house of cards.

Now, Abbott has invented the world's first device small enough to close that hole, in even the tiniest, most delicate of hearts, keeping open a lifetime of possibility.

The most personal technology is technology with the power to change your life.

DIAGNOSTICS | MEDICAL DEVICES | NUTRITION



*life. to the fullest.®*

**Abbott**

WATCH VIDEO HERE.



## ABBOTT AT A GLANCE



Discovering new ways to make life better for more than 130 years



Making a difference in over 160 countries

# 103K

Employees working around the world to make a lasting impact on health

## MARKET LEADER

GLUCOSE MONITORING

BLOOD AND PLASMA SCREENING

ADULT NUTRITION

PEDIATRIC NUTRITION IN MANY MARKETS

HEART PUMPS (LVADs)

REMOTE HEART FAILURE MONITORING

POINT OF CARE TESTING

CHRONIC PAIN DEVICES

## ADVANCING INNOVATION



### CARDIOVASCULAR

Keeping your heart healthy with breakthrough medical technologies



### DIABETES

Pioneer diabetes management with groundbreaking sensing technologies that display glucose trends with a scan



### DIAGNOSTICS

An unprecedented approach bringing accurate, timely information in more efficient solutions to better manage your health



### NEUROMODULATION

Innovative devices and solutions for movement disorders and chronic pain



### NUTRITION

Nourishing your body at every stage of life



### MEDICINES

Helping people get and stay healthy with quality medicines you can trust

## LEADERSHIP

**AMONG FORTUNE'S MOST ADMIRED**

Since 1984

**SCIENCE TOP EMPLOYER**

for 16 years

**DIVERSITYINC TOP 50 COMPANY FOR DIVERSITY**

for 16 consecutive years

**INDUSTRY LEADER**

Dow Jones Sustainability Index's industry group leader every year since 2013

**WORKING MOTHER TOP 100 BEST COMPANY**

for 19 years in a row

**HONORED FOR WORKPLACE LEADERS**

in more than 25 countries

## OUR HERITAGE

In 1888, physician and drug store proprietor Dr. Wallace C. Abbott began producing accurate, scientifically formulated medications with the goal of providing more effective therapies to patients and the physicians providing their care.

Under the pioneering leadership of Dr. Abbott, our company was among the founders of the scientific practice of pharmacy, expanding its business to meet rising global health needs by championing new areas of medical research. By continually entering new areas — both scientific and geographic — we've established a now long-standing tradition of helping people live healthier lives around the world. Dr. Abbott's spirit of entrepreneurship, innovation and caring lives on in our culture, our business and our contributions to medical science.

For more than 130 years, we've adapted to an increasingly complex healthcare environment by keeping our focus where it belongs — on helping people achieve their best possible health, in all stages of life, around the world.

And that's a goal we'll continue to pursue far into the future.

# THE “SPARKLE” IN HER HEART

“ONCE SHE GOT THE VALVE,  
THE NEXT DAY SHE WAS A TOTALLY  
DIFFERENT KID.”

— DR. JONATHAN CHEN



## Baby Sadie received the world's smallest mechanical heart valve, and her life instantly changed.

Sadie Rutenberg is a 5-year-old who likes the color pink and loves penguins. She's happy, spunky and very friendly.

But Sadie isn't like most children her age — she was the first child in the United States to receive a revolutionary pediatric mechanical heart valve when she was a baby as part of a clinical trial. The dime-sized valve is the world's smallest, and suitable for treating the tiniest patients including newborns and babies 1-year-old and younger.

Before Sadie was born, an ultrasound showed the walls between her heart's left and right chambers were not forming properly. As a newborn, she was diagnosed with a congenital heart problem called complete atrioventricular canal defect.

"Imagine a giant hole in the upstairs chamber of your heart, and a giant hole in the downstairs chamber, so the middle is essentially missing," explained Dr. Jonathan Chen, who was chief of pediatric cardiovascular surgery and co-director of Seattle Children's Heart Center.

When Sadie's parents took her to the cardiologist for what they thought was a routine visit, the doctor told them she had to be admitted to the hospital. At that moment, Sadie's parents realized just how sick she was.

She needed surgery right away.

But given the replacement valves that were available at the time, it would take years until Sadie's heart was big enough to make the surgery a success. Sadie didn't have that time. Over the next two weeks, Sadie underwent two surgeries to repair the defect. It wasn't enough, and Sadie was still unable to thrive the way a growing and healthy newborn should.

Dr. Chen suggested a clinical trial for Sadie, which was evaluating the world's smallest mechanical heart valve, made by Abbott, in pediatric patients five years of age or younger. Seattle Children's Hospital was one of 40 sites nationwide participating in Abbott's trial. Sadie's age and size made her the perfect candidate.

And, it was her only option.

"We wanted Sadie to be a part of the trial because it could hopefully save her life," said Wendy Rutenberg, Sadie's mom. "I remember Dr. Chen coming out after the surgery. That initial moment where we're looking at him and wondering, 'Is he going to give us good news or bad news?' Then he broke into a smile. It was like winning the lottery," Wendy shared.

"When Dr. Chen told us the Abbott valve worked, and that it improved her heart function as much as it did ... as a parent, I can't put into words the happiness and emotion I felt. It's a moment I'll never forget," said Sadie's dad, Lee'or.

The surgery to place the valve couldn't have gone better. Instantly, Sadie's heart function improved dramatically. She quickly began gaining weight and became more alert and active. Soon, her parents were able to bring her home where she's continued to grow and now is enjoying life as a 5-year-old should, playing with toys, running around at the playground and going to the zoo.

"Once she got the valve, the next day she was a totally different kid. It was amazing to watch how just fixing that problem can completely change you," Dr. Chen said.

"I think the future is really bright. She is going to have some limitations, but she has so much opportunity ahead of her now. If that clinical trial hadn't been available, we would have started planning for her death rather than planning for her life, setting up a college fund and all the things that parents typically do," Wendy expressed.

Sadie is aware she has a heart issue, but it doesn't bring her down. Instead, "she says she has a 'sparkle' in her heart, something she and Dr. Chen came up with together.

"She's a firecracker. You would never know she's been through the heart surgeries she has," Lee'or said. "That valve saved her life."

**FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 30.**



**WATCH SADIE'S VIDEO HERE.**

# THE WEIGHT OF THE WAIT

When you're waiting for a heart replacement, time drags on. But with HeartMate 3, you can live your life again.

There are times when you're just going to wait.  
You'll be delayed.  
Immediate expectations? Unmet.  
Instant gratification? Postponed.  
This is that lag.  
So you bide your time.  
Deferred if not detoured.  
What's to come? Just wanting for word of what's to come.  
You can't leave.  
So you linger. And loiter. And lurk.  
There is no stay from the staying put.  
The moment is always overdue.  
And so are you.  
Anxiousness builds.  
Reading this?  
Patience.



It's just a small taste of what it feels like when you're living with heart failure and waiting — extolling the universe for the fortune of a new heart.

Tens of thousands in the U.S. are diagnosed every year needing heart transplants. Just a fraction are available to meet the demand. So they wait, hoping for the day good news comes their way — which means bad news already came to someone else.

That is the weight of their wait.

Tyrone Morris knows it well. He's in line for a new heart, but he's not waiting for anyone. Not now that his HeartMate 3™ left ventricular assist device (LVAD) — commonly known as a heart pump — is extending and improving his time between now and whenever a suitable heart comes.

HeartMate 3 was built to get patients like him back to living their life. Approved for bridge-to-transplant (short-term) and destination therapy (long-term) use, the device takes the place of a new heart. HeartMate 3 is the leading heart pump available with unparalleled results in overall survival, quality of life and a reduction in adverse events (such as stroke and thrombosis). That is the intent of HeartMate 3, to take some of the weight off the wait.

For Tyrone, to remove the delay of living his life again.

His expectations met.

Gratification propelled.

No lag.

Imbibing his time.

Delivered, not deferred.

What's to come? He's out living his life.

He can't leave.

His moment has arrived.

And so has yours.

**FOR IMPORTANT SAFETY INFORMATION,  
PLEASE SEE PAGE 30.**



**WATCH TYRONE'S VIDEO HERE.**



A TINY HEART.

# A BIG BREAKTHROUGH.

AN ENTIRE LIFETIME OF POSSIBILITY.



## CLOSING A HOLE IN THE MOST FRAGILE OF HEARTS

Every baby is born with a hole in their heart. This blood vessel, called the ductus arteriosus, allows them to receive oxygen-rich blood from their mother while in the womb. After birth, the hole should naturally close over the first few days of life, letting the lungs and heart take over. But for thousands of babies each year, the hole doesn't close properly — known as a PDA (patent ductus arteriosus). When that happens, it can threaten their already fragile life and become a house of cards.

## HOW IT WORKS

In an infant's heart, the ductus arteriosus remains open while in the womb so a mother's oxygenated blood can bypass the lungs and flow directly into her child's heart.

For most babies, their ductus arteriosus closes shortly after birth.

But in some cases, this hole fails to close and can inhibit growth and become life-threatening.

Abbott's Amplatzer Piccolo™ is inserted through a small incision in the leg, through the ductus, to seal the opening in the heart.

## ONE OF HEALTH'S BIGGEST BREAKTHROUGHS, THAT'S ALSO ONE OF THE SMALLEST

Sometimes solving the biggest challenges means thinking small — very small. At no bigger than a pea, our Amplatzer™ Piccolo is one of the smallest heart devices ever. Most importantly, Piccolo is the first U.S.-approved device small enough to close a hole in the heart of a premature infant weighing as little as 700 grams (about 1.5 pounds). And because Piccolo is a minimally invasive device, it can eliminate the need for riskier surgery.

A breakthrough that, for thousands of future newborn lives, will keep open a lifetime of possibility.

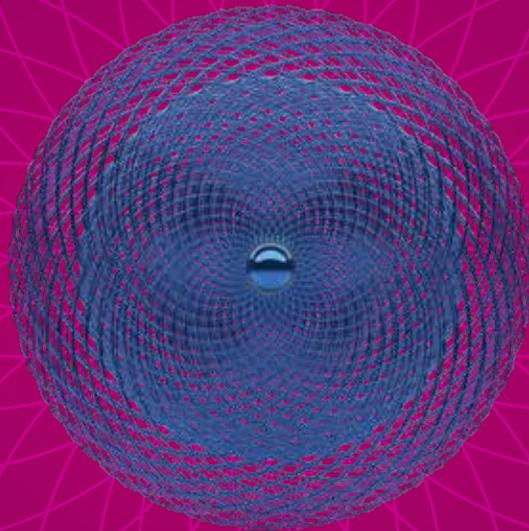
A PDA is present in approximately 1 in 2,000 births.<sup>1</sup>  
PDA risk is considerably higher 20–60% in preterm babies.<sup>2</sup>

## A FUTURE WITH BETTER HEALTH AND FULLER LIVES

For every breakthrough, there's another, even greater breakthrough, waiting to be discovered. The possibilities for human health and life's potential are wide open. Whether it's a life just starting out or one that's experienced, Abbott's technology can help create a future with better health. It's the most personal technology, technology with the power to change your life.

<sup>1</sup> Krasuki, R. A. (2006). Patent ductus arteriosus closure. *Journal of Interventional Cardiology*, 19 (5 Suppl), S60-S66.

<sup>2</sup> Dice JE, Bhatia J. Patent ductus arteriosus: an overview. *J Pediatr Pharmacol Ther* 2007;12(3):138–46.



THE WORLD'S FIRST DEVICE  
THAT CAN CLOSE A HOLE IN EVEN  
THE TINIEST OF HEARTS.



WATCH  
VIDEO  
HERE.



# THE POWER OF YOUR HEART

Harnessing our life-changing technology,  
we're helping hearts around the world power on.

Home is where the heart is. An old proverb, sure. But as true as ever. Here's a twist, where that philosophy meets some science: With the power generated by all of the hearts benefitting from our life-changing technology, you could power that home. And the neighbor's next door. We'll illuminate.

More than 1.5 million people around the world receive our stents each year, clearing clogged arteries to get blood flowing again.

Add to that the more than 75,000 of our catheter technologies used last year in the U.S. alone for ablation procedures, helping hearts get back to and maintain their beat.

Then tack on the more than 26,000 people whose hearts are pumping more efficiently thanks to the help of our lineup of HeartMate left ventricle assist devices.

Don't leave out the 10,000 people living well with the peace of mind that their heart's performance is being constantly monitored by CardioMEMS™.

Include the 12,000 premature babies born in the U.S. each year suffering from a persistent heart defect requiring treatment with our Amplatzer Piccolo™ Occluder.

It all adds up to about 1.6 million hearts and cardiovascular systems kept in good health by our devices, every day. A big number that's growing all the time.

As big as it is, it doesn't include the more than 15 million blood tests each year helping doctors diagnose heart disease, heart attack and heart failure.

But take those 1.6 million hearts. On average, each one generates about 1.3 watts. Collectively, more than 2,000 kilowatts of power are churned out.

Like firing up a generator after a storm, you'd have harnessed enough juice to run about 98,000 average U.S. homes for a month. That's some power. And that's the community we want to work in. Because helping your heart is where we call home.

**FOR IMPORTANT SAFETY INFORMATION ABOUT OUR STENTS, PLEASE SEE PAGE 31. FOR IMPORTANT SAFETY INFORMATION ABOUT OUR CARDIAC ABLATION, LEFT VENTRICLE ASSIST DEVICES AND CARDIOMEMS™, PLEASE SEE PAGE 32. FOR IMPORTANT SAFETY INFORMATION ABOUT OUR AMPLATZER PICCOLO™ OCCLUDER, PLEASE SEE PAGE 30.**

# HEART MONITORING, EVERYWHERE YOU GO

**“The stakes are very high. It gives both me and my patient peace of mind that we’ve got them covered.”**

You’ve felt this dizziness before. The heart palpitations. Maybe chest pains. Shortness of breath. It comes and goes but when it comes, you know it because you feel it. You’re not completely sure what’s behind it. You’ve never been diagnosed with any heart issues. Or maybe you have but this ... this is different.

If these symptoms continue, you should get with your doctor to check it out. Of course, just like visiting a mechanic when your car is making a noise, when you get there ... nothing happens. You’re fine. Ticking like a clock. It’s impractical to sit and wait it out for hours, not exactly hoping it happens again but wanting answers. It’s also unlikely you’ll be close to your doctor the next time it does. It’s just how the world tends to work.

“Whenever you’re dealing with rhythm problems in the heart, being able to identify risk can sometimes mean the difference between life and death. The key is finding out what happened: What’s the cause of your symptoms?” said Sean C. Beinart, M.D., FACC, FHRS, cardiologist.

How can you diagnose these nomadic symptoms from your body? Especially if you’ve experienced cardiac problems before? An insertable cardiac monitor (ICM), which is placed just under the skin during a minimally invasive procedure to continuously monitor your heart’s rhythm for signs of atrial fibrillation.

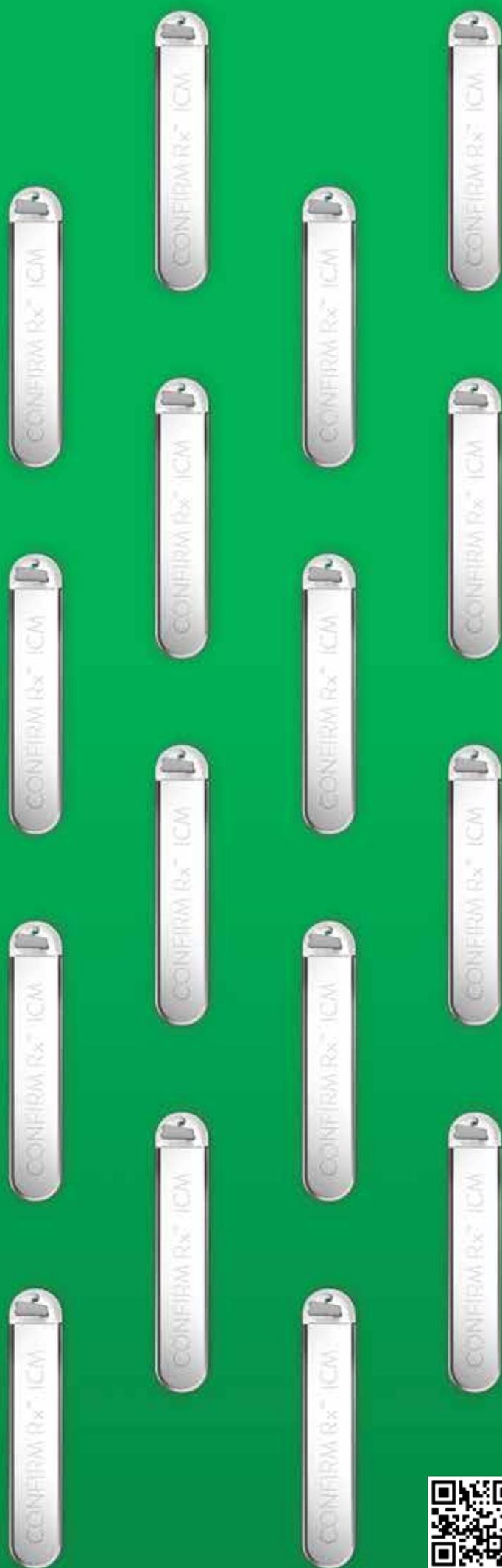
“Prior to the evolution of this technology, the ability to monitor patients was really short-lived. But this allows the monitoring to continue and allows the patient to continue to live their lives unhindered,” Beinart said.

Even better: Abbott’s Confirm Rx™ ICM, which is designed not only to detect arrhythmias but also to wirelessly transmit data via Bluetooth® to your smart phone for data transmission to the Merlin.net™ Patient Care Network so your doctor has real-time access anywhere in the world to how your heart is performing.

Abbott’s ICM is small and slim. It continuously monitors the heart — taking the onus off you — but offers the capability to instantly record events through one-touch programming via a smartphone app, should you choose to do so.

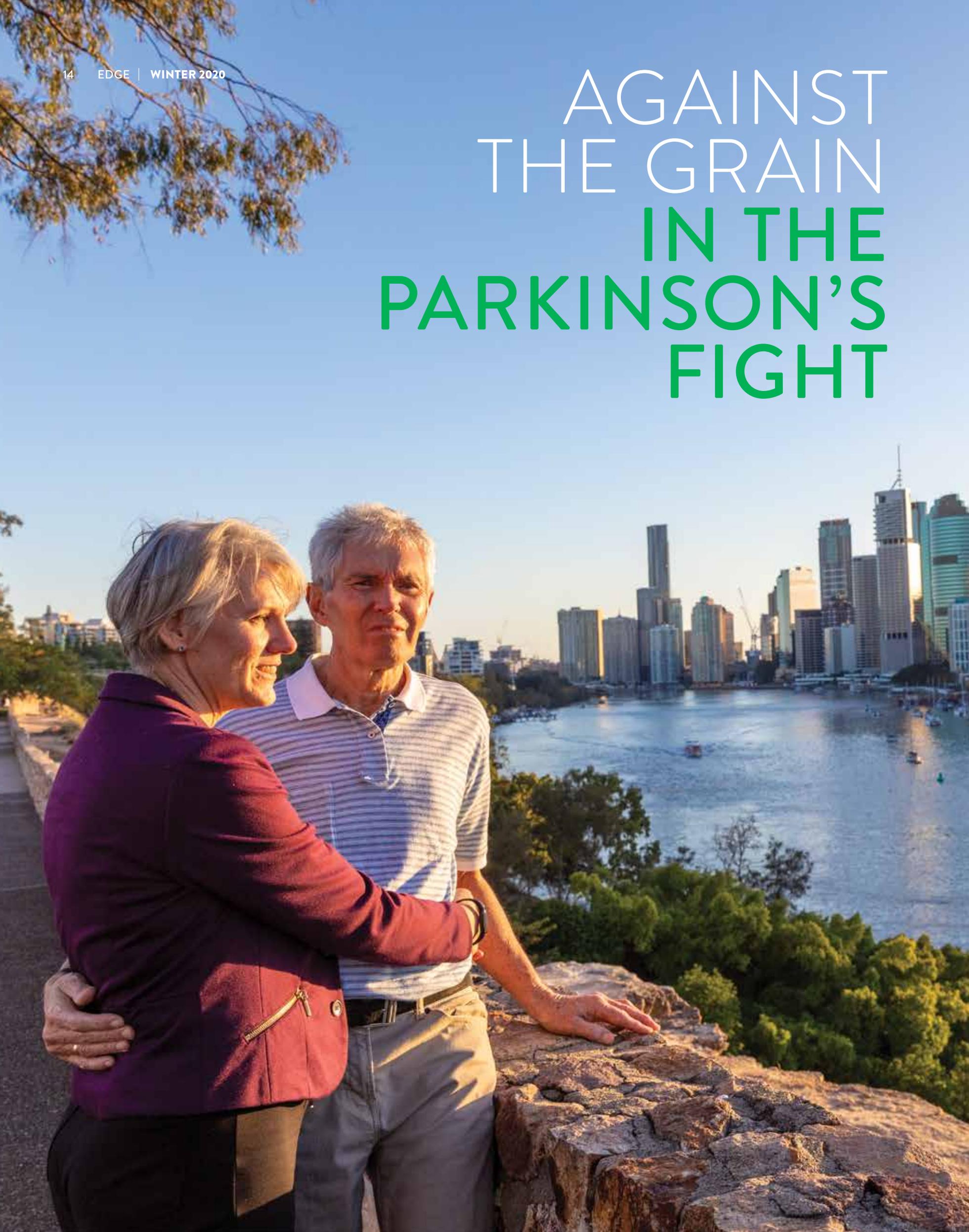
“The stakes are very high,” Beinart said. “What the Confirm Rx does is it gives both me and my patient peace of mind that we’ve got them covered.”

FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 32.



WATCH  
VIDEO  
HERE.

# AGAINST THE GRAIN IN THE PARKINSON'S FIGHT



## When medication proved less effective, deep brain stimulation helped Clive leave his symptoms in the sawdust.

The table saw — screaming now at tens of thousands of revolutions a minute — makes easy work ripping that board.

In the workshop, the warm scents of helpless grain giving way to a blade's teeth fill the air as sawdust falls to the floor.

The tools, of course, have no awareness of their satisfying the senses. Their job is stone simple: Cut. Whatever comes, cut it in two. That includes wayward fingers and hands.

It's steady work — even if it's not something you do all the time.

Don't take our word for it. Here's Clive Couperthwaite.

"I've always loved working with wood. I like the smell of woodworking. To do this takes skill. And to do that properly, you need to have the hand coordination. And with Parkinson's, that is all gone."

Couperthwaite had been a practicing psychologist who specialized in forensic psychology. It was his job to figure what happened at the scene. In 2007, when his Parkinson's first showed itself, it was all still a mystery.

"The diagnosis of having Parkinson's disease was, at first, stunning. And it felt like I was somehow responsible for my condition," Couperthwaite said.

It wasn't long before Parkinson's seemed to take everything: his work, his relationships, his hobbies.

"He would often say, 'You could just put me on a desert island and leave me alone and I'd be happy.' He didn't want to engage," said Felicity, his wife.

"He wasn't telling as many jokes and he didn't have a lot of energy. I was just really worried about him," said Alana, his daughter.

He was splintering. He struggled to control his moods as much as his body, lumbering through his day. Medication, according to Clive, "was starting to have less and less effect and I had to have higher and higher doses."

And then he found Abbott's directional deep brain stimulation (DBS).

His implanted, battery-operated neurostimulator sends mild electrical impulses to the regions of the brain that control movement. With its directional leads, the system allows a neurologist to customize stimulation and optimize therapy while helping limit potential side effects.

Doctors can more precisely steer electrical current toward targeted areas of the brain to lessen symptoms such as tremors. The system can also be conveniently and discreetly adjusted via an iPod Touch controller.

"Suddenly I felt like a new dawn had come about. I could move around, I could walk, I felt happy, I felt cheerful," Couperthwaite said. "Now I was able to do things I wasn't able to do before."

**"I NOTICED THE DIFFERENCE IMMEDIATELY. I'VE GOT MY HUSBAND BACK."**

— FELICITY COUPERTHWAITE

Things like working confidently with his saws and sharp tools again to build his works of art from wood.

"I noticed the difference immediately. I've got my husband back," Felicity said.

"It feels like I have my childhood back. Like, the father I didn't have for so many years is finally back," Alana said.

They're with him, through thick and thin. And with the help of this precision technology, he's cutting through, leaving his symptoms in the sawdust and helping others who are suffering as he had.

"The future you had planned or thought about for yourself can come back into focus again. I didn't know that's what the technology would provide. And that's just been phenomenal," he said.

**FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 32.**



**WATCH CLIVE'S VIDEO HERE.**

# SHE WON'T STOP FIGHTING VIRUSES

**Mary Rodgers: Scientist, mother, colleague,  
wife, friend, driven by compassion and curiosity.**

A pilot dizzied by aviophobia, the extreme fear of flying. A racecar driver slowed by tachophobia, the fear of speed. The cruel daily double: A clergyman living with ecclesiophobia (the fear of churches) and uranophobia (the fear of heaven). A chef simmering in cibophobia, the fear of food. Kids who claim didaskaleinophobia, the fear of school. (Indicated cure: Summer.) Ridiculous, right?

Patently absurd. Couldn't happen. Wouldn't happen. It's illogical, Watson.

How about a scientist whose passion and profession demand that she work in identifying, cataloging and tracking pathogens in blood who has such pronounced hemophobia — the fear of blood — that she was regularly overcome at the sight of it?

"Throughout my life, I have always fainted at the sight of blood up until really only probably five years ago," said Mary Rodgers, an Abbott principal scientist who spends her work life hunting viruses as part of the company's diagnostics business. "When I was in high school, I would always pass out when anyone started talking about blood. And when I got my blood drawn.

"When I first started working at a lab in college, they showed me where the biohazard waste was for when they were collecting blood and discarding the samples. And I had to sit down. 'I'm sorry, I'm going to pass out.' I was so embarrassed.

"And after that, I worked really hard to find a way that I could work around blood that wouldn't make me feel this way.

"Mary Rodgers isn't one to let an overbearing dread get in the way of her calling, not when that work is so crucial to keeping the world's blood supply safe.

## **SCIENTERRIFIC UPBRINGING**

Born in southern Wisconsin, Mary is the first of two daughters to Dirk and Kathy Rodgers, an electrical engineer and nurse, respectively. Growing up, their father read Jules Verne and Sir Arthur Conan Doyle to Mary and sister Jane. While they found Verne quite boring, Doyle's Sherlock Holmes captivated.

"As you hear the story, you have all the same information as Sherlock Holmes. But he puts it together because he notices the parts that are important. And in a way, that's what science is like," Mary said. "There's a wealth of information, especially in the age of genomics. There's too much information. The good scientist can pick apart which part is actually important, the same way Sherlock Holmes does."



Their father hoped his daughters would follow in his footsteps. “I tried to convince them. They just laughed. They both wanted to be scientists,” said Dirk, adding, “Mary wanted to be a scientist from a very early age.”

But what kind of scientist, Mary wasn’t sure. Her father-in-law was unexpectedly and particularly helpful. “I was just starting out, trying to figure out what I wanted to even major in. I was thinking I was going to major in chemical engineering, and I was having a hard time. I was like, ‘I don’t know, I’m not getting into this,’” Mary said. She turns to her husband Matt, who is hearing this for the first time.

“And your dad was like, ‘I don’t know, I just don’t see you as a chemistry person, you seem more like a biology person.’ And I said, ‘Well maybe I’ll take a biology class.’ And then I became a biology person.”

Matt’s reaction: “Wow.”

“That’s some intuition he has,” Matt said. “He didn’t say that to me. He said, ‘You want to go to film school? Fine.’”

Mary graduated with her bachelor’s in biochemistry at Wisconsin-Madison. She earned her Ph.D. from Harvard in biological and biomedical science. Her post-doc came during her years at Southern California.

Jane, two-and-a-half years younger, is also a scientist. She works as a medical writer at a pharmaceutical company. It was on Jane’s advice that Mary came back to the Midwest to work for Abbott after years on the coasts. Their mother sees influences of mom and dad in both. “I used to tell the kids they got their work habits from me and their intelligence from their dad,” Kathy said.

As a child, it was clear to her family that Mary was born with her mother’s natural instinct as a nurse to care for others. It’s a trait that would drive her work to improve humanity’s health as an adult.

“My father tried to quit smoking for many years and multiple times. She climbed up on his lap (at 3) and she said, ‘Grandpa, you stink.’ And he just quit cold turkey after that. He didn’t want to smell like cigarette smoke around his grandkids,” Kathy said.

“This is a very famous story in our family,” Mary said. “When my grandpa used to tell it, he said that all I did was ask, ‘Why do you smoke? Why do you smoke?’ And he just didn’t have a good answer. And he quit.”

That concern for those in her immediate world as well as people around the globe is evident in Mary’s work.

“I remember vividly telling her to use her intelligence to help other people,” Kathy said. “And she would seek out a way to do that.”

She found it at Abbott.

## A WORLD OF POSSIBILITIES

The development of many of Abbott's diagnostics tools is bolstered by the work done by Abbott's Global Surveillance Program.

The program is a one-of-a-kind collection of HIV and hepatitis strains from around the world. It includes 78,000 samples collected since 1994 from 45 countries on six continents. It's utterly massive. And it's growing, new strains added all the time.

And without it, the company's tests could potentially miss new pathogens or strains of established bugs.

"I am absolutely in love with viruses," said Mary.

(She's totally serious. Here she is waxing philosophical on viral paradox: "Viruses can't really do anything on their own; they're completely dependent on people. And yet they take over our lives, and to me that juxtaposition of inability to fend for themselves and the ability to make someone ill is really interesting to me.")

When samples are added to Abbott's viral library — kept safe in a deep, frozen state — they're checked and rechecked to see how the diseases are mutating. That sorting and cataloging is done by Mary and her team.

Here's how it works.

Medical workers from around the world "take little tubes, put them in one giant box, put it in on dry ice and ship it all the way over here to Abbott Park," said Mary, who manages the program. "Then we test them. We look to see if we can confirm the results that our collaborators found.

"Both the sample and the sequences are very valuable, because we can now say that if a strain such as this is found, this is the kind of test result you would expect."

Abbott's institutional knowledge, understanding those expectations, is critical to the public's health. It's an investment that has far surpassed the usual R&D timeline of five years.

But it really is elementary: If a virus can't be found in testing, it can't be treated. That's how outbreaks happen.

"So if we have a test that can really detect every single strain of the virus, then we can say for sure, 'Yes, you have this,' or, 'No, you do not,'" Mary said.

"We can really challenge our tests and determine how well they perform. So that goes into the design of new tests for FDA approval. And then that test now goes back out into the world and is used at the same clinics where the first sample was collected."

## IT ALL ADDS UP

Erin Lyons and Lorena Mora-Blanco have known Mary for more than a decade, since their days in and around Harvard Yard. They're friends and confidants, participants in late-night sessions of science and philosophy, as one does in college.



Independently, they describe Mary similarly.

Lorena: "Quiet strength."

Erin: "Unflappable. Even-keeled."

Lorena: "Her passion for public health is apparent."

Erin's turn. A story stands out, about how Mary knows when she's done with an experiment: "Either when I can't see — can't focus my eyes — or when I start crying."

("It was Lorena who said that!" Mary said later.)

Erin adds: "She has such a capacity for hard work."

Mary elaborates: "To be a scientist, you're never not working. You're always thinking about your project and what you need to do next. You're always mulling it over in the back of your mind. It's your whole life. It's every minute of your day. It's not just your job."

Said Mary's husband Matt: "She's always wanted to do something that's bigger than herself. What she's doing at Abbott is really fascinating. And it's really important. It's just really great work."

It's her mission to do her part at Abbott to make a better life for people suffering the effects of HIV and hepatitis, to make a better world for her family, for her kids and — someday — her grandkids.

So, Sherlock Holmes, have you figured out who Mary Rodgers is?

"Unflappable. Even-keeled. And just very down-to-Earth," Erin said.

"She would be the person I would turn to" during a viral outbreak, Lorena said.

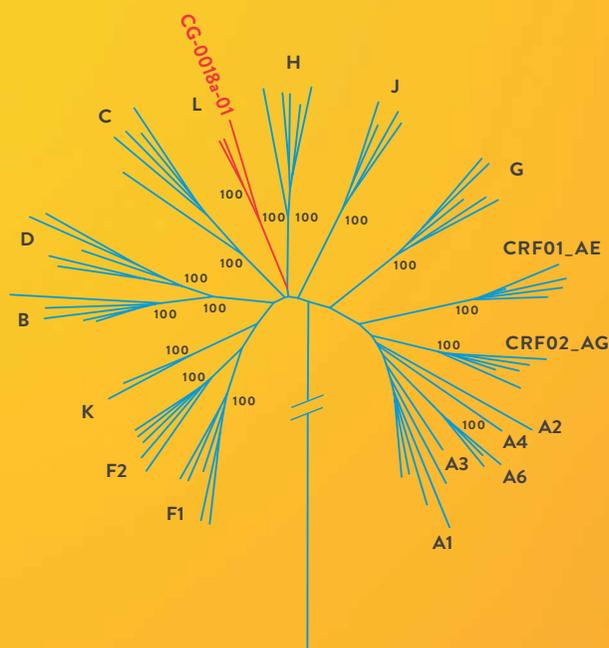
She certainly is. Elementary.



WATCH MARY'S VIDEO HERE.

# STAYING ONE STEP AHEAD OF HIV

Meet Abbott's team of Virus Hunters who hunt down mutating viruses that could pose a new risk.



## DISCOVERING A NEW STRAIN: HIV-1 GROUP M, SUBTYPE L

ADAPTED FROM YAMAGUCHI J., ET AL. JAIDS. 2019

“Like looking for a needle in a haystack.”

That's the kind of difficult detective work Abbott's Virus Hunters tackle every day as they track down mutating viruses from around the globe.

By developing new techniques and using next-generation sequencing, this team recently announced the discovery of a new strain of HIV or human immunodeficiency virus.

Abbott's announcement of the discovery, published in the *Journal of Acquired Immune Deficiency Syndromes (JAIDS)*, marks the first time a new subtype of HIV-1 has been identified in nearly two decades.<sup>1,2</sup>

Called HIV-1 Group M, subtype L, this new HIV subtype is part of the same group of viruses responsible for the global HIV pandemic, which has infected 75 million people to date and claimed an estimated 32 million lives.<sup>3</sup>

“This discovery reminds us that to end the HIV pandemic, we must continue to outthink this continuously changing virus and use the latest advancements in technology and resources to monitor its evolution,” says Carole McArthur, Ph.D., M.D., professor in the departments of oral and craniofacial sciences, University of Missouri-Kansas City, and one of the study authors.

## FINDING ONE IN A BILLION

Discovery of this new HIV strain culminated a process that began nearly four decades ago.

To determine whether an unusual virus is in fact a new HIV subtype, three cases must be discovered independently.<sup>1</sup> The first two samples of this subtype were discovered in the Democratic Republic of Congo (DRC) in the 1980s and the 1990s.<sup>2</sup> The third, collected in 2001, was difficult to sequence at that time because of the amount of virus in the sample and the existing technology.<sup>2</sup>

Today's next-generation sequencing technology allows researchers to build an entire genome at higher speeds and lower costs. Abbott scientists had to develop and apply new techniques in order to leverage next-generation sequencing, which helped narrow in on the virus portion of the sample to fully sequence and complete the genome.<sup>2</sup>

“Identifying new viruses such as this one is like searching for a needle in a haystack,” says Mary Rodgers, Ph.D., a principal scientist and head of Abbott's Global Viral Surveillance Program, and one of the study authors. “By advancing our techniques and using next-generation sequencing technology, we are pulling the needle out with a magnet.”

“We're making this new strain accessible to the research community to evaluate its impact to diagnostic testing, treatments and potential vaccines.”

## TWENTY-FIVE YEARS OF HUNTING VIRUSES ACROSS THE GLOBE

Abbott created its Global Viral Surveillance Program 25 years ago to monitor HIV and hepatitis viruses and identify mutations, which helps ensure the company's diagnostic tests remain up to date.<sup>4</sup>

“All of the viruses that we study really are just a plane ride away,” Rodgers says. “The discovery of this new strain of HIV reminds us of why the work we do at Abbott is so important. If we can prevent even one person from becoming infected with HIV or hepatitis, then we've done our jobs.”



WATCH VIDEO HERE.

1 Robertson DL, Anderson JP, Bradac JA, et al. HIV-1 nomenclature proposal. *Science*. 2000;288(5463):55-56.

2 Yamaguchi J, Vallari A, McArthur C, Sthresley L, Cloherty G, Berg M, Rodgers MA. Complete genome sequence of CG-0018a-01 establishes HIV-1 subtype L. *Journal of Acquired Immune Deficiency Syndromes*. 2019; [https://journals.lww.com/jaids/Abstract/publishahead/Complete\\_genome\\_sequence\\_of.CG\\_0018a\\_01.96307.aspx](https://journals.lww.com/jaids/Abstract/publishahead/Complete_genome_sequence_of.CG_0018a_01.96307.aspx)

3 Global Health Observatory Data. HIV/AIDS. World Health Organization. Available at: <https://www.who.int/gho/hiv/en/>

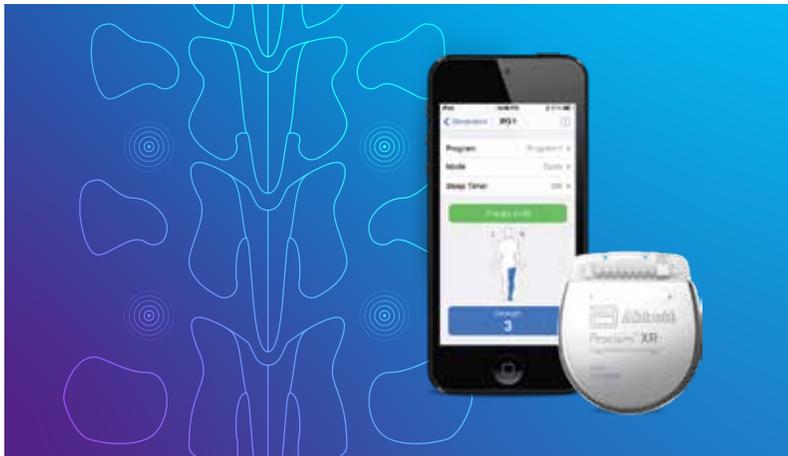
4 Abbott Global Viral Surveillance Program. Abbott's diagnostics business. Available at: <https://www.corelaboratory.abbott/int/en/offerings/global-surveillance>

# A JOURNEY WITH CHRONIC PAIN

This chef tried everything — even amputation — before discovering the technology that helped him manage his chronic pain.

Tony Lawless is no stranger to perseverance. He was diagnosed with rheumatoid arthritis at 19, but he didn't let the condition stop him from pursuing his dream of becoming a chef. His culinary talents landed him top chef spots at restaurants across the country, where he worked tirelessly — but not without pain.

Over the years, anti-inflammatory medication did only so much to soothe the searing pain in his joints, Lawless says. It would be years before he was introduced to the life-changing technology of dorsal root ganglion (DRG) stimulation therapy.



“I just pushed through,” he said. “Working so much probably saved me, because my joints didn’t get a chance to fuse up. My attitude was always: Keep moving through [the pain].”

## IF YOU WANT TO BE MOBILE — CUT IT OFF

After enduring numerous surgeries and fusing procedures to try and keep his arthritis under control, Lawless made the difficult decision at age 40 to have his left leg amputated below the knee in the hopes of increasing his mobility.

“Most people don’t elect to have an amputation,” he said. “But after I fused my ankle in 1991, I was never really that mobile. I dragged my leg around. My idea [with the amputation] was that I wanted to be more mobile.”

The amputation, performed in 2000, helped alleviate Lawless’ pain, and with physical therapy, he learned how to get around on one leg; he was even able to ski by using an adaptive chair. But five years later, severe nerve pain caught up with Lawless, and he searched once again for medical options that could help control his pain. That’s when he came across DRG therapy.

The life-changing technology is a novel treatment that uses neurostimulation therapy to treat chronic pain in areas of the lower body, such as the knee, foot and groin. Lawless heard about the DRG stimulator when he was visiting an interventional pain specialist. His years-long journey with rheumatoid arthritis and chronic pain (including diagnosis of complex regional pain syndrome) and the lack of relief provided by traditional treatments made Lawless a prime candidate for a DRG stimulator.

## A LIFE-ALTERING DEVICE

Lawless first experienced DRG therapy with a temporary test stimulator, a small external device that sent mild electrical currents through inserted wires, or leads, to his dorsal root ganglia that he could control with a hand-held remote allowing him to adjust the stimulation strength. The first day he got the temporary DRG stimulator, Lawless felt so good that he walked five miles around New York City.

“It felt great,” he said. “Up to that point, I had not walked five miles in about five or six years.” Lawless has since had a permanent DRG therapy system implanted, and he says he’s never felt better. The DRG stimulator has alleviated the majority of his nerve pain, and the therapy system has allowed him to hike again and return to stand-up skiing. Lawless is also an avid motorcyclist and boater, and he’s a ski instructor for disabled people.

“For me, it’s been a life-changing device,” he said of his DRG stimulator. “I only found it because I don’t give up.” Lawless shares his story with DRG therapy in the hopes that more people will learn about the life-changing technology and consider how the device might work for them. “What people need to know is that if you have nerve pain, this has a huge potential to change the quality of your life,” he said. “For me, it has completely changed the quality of my life.”

*The placement of a neurostimulation system requires surgery, which exposes patients to certain risks. Complications such as infection, swelling, bruising and possibly the loss of strength or use in an affected limb or muscle group (e.g. paralysis) are possible. Additional risks such as undesirable changes in stimulation may occur over time. Be sure to talk to your doctor about the possible risks associated with neurostimulation. This reflects one person’s story; not everyone will experience the same results. Talk to your doctor about the benefits and risks of your treatment options.*

**FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 35.**

**“FOR ME,  
IT HAS COMPLETELY  
CHANGED THE QUALITY  
OF MY LIFE.”**

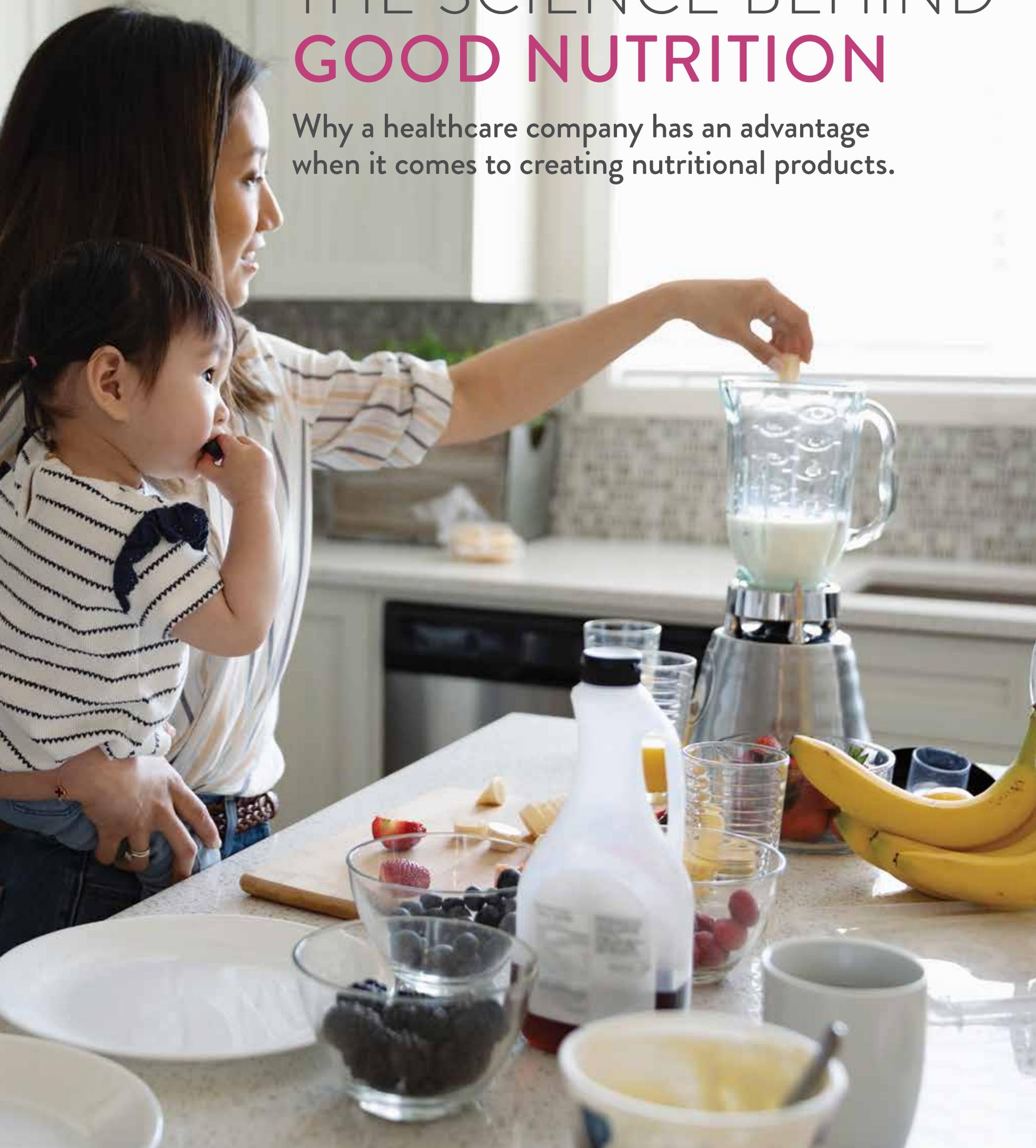
— TONY LAWLESS



WATCH TONY'S VIDEO HERE.

# THE SCIENCE BEHIND GOOD NUTRITION

Why a healthcare company has an advantage when it comes to creating nutritional products.



While many large food and beverage companies and startups have jumped into nutritional products, healthcare companies have a major advantage when it comes to product development: Scientific research is in their DNA.

“Science has shown us, again and again, the right nutrition can provide us with the strength, energy, immunity and focus we need to help us live our best and healthiest lives,” said Dr. Hakim Bouzamondo, divisional vice president of global nutrition research and development at Abbott. “As a health, science and technology company with a 130-year legacy, we are committed to using validated scientific evidence and comprehensive research when developing nutritional products.”

### RESEARCH-BACKED INNOVATION

Abbott scientists work with world-renowned research partners to conduct and publish laboratory, preclinical and clinical research before developing or enhancing many of their nutritional products.

Take Similac Pro-Advanced with 2'-FL HMO, for example. In 2016, Abbott was the first company in the world to add 2'-FL HMO to infant formula. 2'-FL HMO, or 2'-fucosyllactose human milk oligosaccharide, has been found to enhance the development of babies' immune systems by helping to increase the healthy bacteria already living in their gastrointestinal tract — supporting their gut and immune health. Before introducing 2'-FL HMO to Similac, Abbott scientists spent nearly two decades researching and publishing more than 20 preclinical studies on the impact of HMOs on babies' health with top research partners around the world. The major breakthrough came in 2016, when Abbott published the first-of-its-kind clinical study in the *Journal of Nutrition* showing babies fed formula enriched with 2'-FL HMO had immune responses similar to breastfed babies, compared to those fed a formula without 2'-FL HMO.

The company has five research and development centers around the world with more than 650 nutrition scientists, physicians and engineers focused on nutritional innovation and product development.

“Every day, our teams are focused on bringing the nutritional benefits of breastmilk to formula-fed babies,” said Daniel Salvadori, executive vice president of nutritional products at Abbott. “When you discover important evidence-based benefits of an ingredient like HMO that can help improve the immune health of formula-fed babies in a way no other formula has done before — bringing their immune system closer to that of a breastfed baby — it's both rewarding and revolutionary.”

### DATA-DRIVEN CONSUMER NEEDS

While science is in the Abbott DNA, product innovations don't always come from decades of research.

Last year, for example, Abbott introduced Ensure Max, a high-protein nutritional shake designed to fill nutritional gaps for active adults. Before launching the product, Abbott scientists looked closely at peer-reviewed research and data from various sources — including the National Health and Nutrition Examination Survey — to better understand nutritional gaps, nutritional needs and habits among older adults.

“We know protein plays a critical role in building and maintaining muscle as we age,” Bouzamondo said. “To determine the right level of protein needed for this consumer, we evaluated the nutritional needs of aging Americans. Understanding this data helped us to develop a product that serves the specific needs for this specific group.”

### UNDERSTANDING HUMAN HEALTH

When it comes to understanding the full nutritional needs of patients with specific health conditions, healthcare companies have a big advantage. Abbott, for example, can efficiently leverage its expertise in human health to create nutritional products that support a wide range of products — from providing human milk fortifier to premature babies to nutritional shakes specifically designed for patients preparing for and recovering from surgery.

“We understand better than anybody else the challenges patients go through as they are diagnosed with various conditions and treated with a broad range of nutritional products, medications or devices,” Salvadori said. “We are continually working to ensure we're providing the optimal product for each patient, each consumer, at every stage of their life.”

Research has also shown that by focusing on nutrition, Abbott's science-based nutritional products can help improve health outcomes, reduce the risk of hospital readmissions and ultimately save costs for both the consumer and the healthcare systems.

In a multiyear study Abbott conducted with Advocate Health Care, one of the nation's largest health systems, researchers followed more than 1,200 patients with serious conditions such as heart failure to see how nutrition education and the use of nutritional products affected their time at the hospital. Researchers found that patients who received more active and comprehensive nutrition consultation and intervention with oral nutritional supplements, including Abbott's Ensure, had 25% shorter hospital stays and a 27% reduction in 30-day readmission rates. The researchers also found a significant impact on hospital cost savings of more than \$3,800 per hospitalized patient.

A similar study conducted with more than 1,500 home health patients found an 18% reduction in admission rates over 90 days. This reduction resulted in an estimated \$1,500 cost savings per patient treated.

“Our goal is to improve the health and the lives of people globally, through the power of nutrition,” Bouzamondo said. “This study — as well as many of the studies we have done around the world — reveal the profound impact nutrition can have on patient outcomes and on human health. When healthcare professionals and consumers simply focus on nutrition, the health of entire populations and the economic burden of healthcare costs can be improved around the world.”



# FAST RESULTS FOR THE FLU

Within minutes, the ID NOW™ flu test can get you and your child on the way to feeling better now.

“Mom, I feel cold and achy...”

As a parent, you dread hearing those words. Chills and body aches could mean the flu, especially at this time of year. And if it’s a weekday, that means keeping your child home from school. But then what?

First of all, make sure you recognize the typical flu symptoms: fever, chills, cough, muscle or body aches, vomiting and diarrhea. These symptoms can come on suddenly and often point to influenza, although it doesn’t mean that all these symptoms have to be present. Children, for example, are more likely to experience vomiting and diarrhea than adults. And not everyone with the flu spikes a fever.<sup>1</sup>

To get a quick, official confirmation that it’s really the flu virus and not, say, a cold or stomach bug, your child should have a flu test. Traditionally, the most accurate flu tests had to be sent to central labs for processing, but today’s molecular tests — like Abbott’s ID NOW™ Influenza A & B 2 — provide accurate, on-the-spot diagnosis within minutes.

The simple swab test is available in doctors’ offices as well as urgent care centers, pharmacy clinics and emergency rooms. Getting the right diagnosis right away means starting treatment early on, when those treatments work best.

## THE ROAD TO FEELING BETTER

Once a diagnosis of the flu is confirmed, call the school nurse or the school’s parent coordinator with the information. “It can be more helpful to tell the school that it is because of influenza that your child will be out for a few days,” said Norman Moore, Ph.D., director of infectious diseases scientific affairs for Abbott.

“Influenza is highly contagious, which makes it a community health concern. It’s important to let the school know that the virus is present so that others in the school community can take precautions.

The school may have a protocol in place, such as informing the staff and other parents about potential exposure to the flu virus, scheduling hand washing breaks throughout the day or reminding students to cough into their elbows or to use a tissue when coughing.<sup>2</sup>

The fact is, someone with the flu can spread the virus to others even before severe symptoms are evident, and classrooms are flu-friendly environments. The school nurse might also take the opportunity to remind members of the school community to get a flu shot if they haven’t already.

The Centers for Disease Control and Prevention (CDC) recommends annual flu vaccination for everyone over six months of age. While there are still a lot of misconceptions about the flu vaccine, it remains the single most important way to help reduce flu illness.<sup>3</sup>

“Identifying the virus early on and being prepared as soon as you notice symptoms will not just speed up your own child’s recovery, it will help keep others in your family and community healthy this flu season,” Moore said.

1 Centers for Disease Control and Prevention (CDC). Flu symptoms & diagnosis. Available at: <https://www.cdc.gov/flu/symptoms/index.html>

2 CDC. Guidance for school administrators to help reduce the spread of seasonal influenza in K-12 schools. Available at: <https://www.cdc.gov/flu/school/guidance.htm#schoolage>

3 CDC. Who needs a flu vaccine and when. Available at: <https://www.cdc.gov/flu/prevent/vaccinations.htm>

# A DIABETES CARE REVOLUTION

Routine glucose monitoring demanding painful and inconvenient fingersticks is a thing of the past.

Daily diabetes monitoring hurts. If you or someone you love has diabetes, you're probably familiar with the tedious routine of glucose monitoring, the painful fingersticks to draw a drop of blood and the bulky traditional glucose monitoring equipment requiring daily calibrations. These inconveniences can make it difficult to stick to a diabetes management plan, opening the door for complications to arise.

## What if you could take the pain and inconvenience out of glucose monitoring and experience a better way of managing the condition?

For the 30.3 million Americans who have diabetes, FreeStyle® Libre is that life-changing experience. The revolutionary system eliminates the hurdles of traditional glucose monitoring and requires no routine fingersticks or fingerstick calibrations.

Across the globe, more than 1.5 million people are using the FreeStyle Libre, 14 day, and the system has been clinically proven to be accurate, stable and consistent.

## How does continuous glucose monitoring with the FreeStyle Libre system work?

The FreeStyle Libre 14 day system measures glucose levels through a small sensor — the size of two stacked quarters — applied to the back of your upper arm. It provides real-time glucose readings for up to 14 days, both day and night. The sensor can also read glucose levels through clothes, making testing discreet and convenient.

The FreeStyle Libre 14 day system provides three critical pieces of data with each scan:

- A real-time glucose result.
- An eight-hour historical trend.
- A directional trend arrow showing where glucose levels are headed.

The touchscreen reader also holds up to 90 days of data, which allows people to track their glucose levels over time.

## How does the FreeStyle Libre 14 day system help improve treatment?

The data generated by the FreeStyle Libre system is designed to provide actionable trends and patterns that help you make better decisions about your health, such as adjustments to your diet or how much insulin you need to take. For example, the reader's snapshots can reveal if a person is experiencing hypoglycemic trends (low glucose levels) patterns or hyperglycemic trends (high glucose levels), which can aid in choosing the right diabetes management.

Studies show that FreeStyle Libre users who scan more frequently spend less time in hypoglycemia and experience improved average glucose levels. According to a study published in *The Lancet*, people using the FreeStyle Libre 14 day system spent 38 percent less time within hypoglycemia as compared with those who managed their glucose with traditional self-monitoring glucose system.

Diabetes doesn't have to control your life. It's time to live freely.

FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 35.



WATCH VIDEO HERE.



# THE FUTURE OF DIABETES CAREGIVING

FreeStyle Libre 14 day and its apps are enabling caregivers to better monitor their loved ones with diabetes. This is how.

Behind every person with diabetes — and there are 30.3 million of them in the U.S., and another 84.1 million with prediabetes — are countless caregivers who play an important role in keeping their loved ones healthy. Caregivers remind their loved ones to take their insulin, help them with their glucose testing and suggest lifestyle changes to help them better manage their glucose. Caregiving for a person with diabetes is a noble endeavor, but it can be time-consuming and taxing.

Luckily, managing diabetes is easier thanks to breakthroughs in continuous glucose monitor technology. The FreeStyle® Libre 14 day system is making glucose testing painless<sup>1</sup>, through its mobile apps, allowing people with diabetes to easily share their results with their caregivers with compatible apps.

## A MORE CONVENIENT MONITORING SYSTEM

Fingersticking and poking that comes with the job isn't fun for anyone, caregivers included. Testing glucose is necessary, but inflicting even minor pain upon your loved one with diabetes is never easy.

Enter FreeStyle Libre 14 day system.

FreeStyle Libre 14 day system frees users from the pain and tedium of fingersticks.<sup>2</sup> The system instead measures and stores glucose readings through a small sensor, about the size of two stacked quarters, that you wear on the back of your upper arm and can scan with a hand-held reader through your clothing.<sup>3</sup> With just a quick, one-second scan, users can see real-time glucose readings, as well as identify glucose trends with a directional arrow and review eight hours of glucose history — providing actionable information to make better informed health decisions.



Additionally, users can use the FreeStyle LibreLink mobile app, which lets users swipe their iPhone®<sup>4</sup> on their FreeStyle Libre 14 day sensor to instantly capture and view their real-time glucose levels. The app also includes a series of reports that visualize trends and patterns to help people understand how they're keeping their glucose in check.

### A MORE CONVENIENT ROAD FOR CAREGIVERS

We live in a mobile society, so it can be challenging to care for a person with diabetes when you're on opposite sides of town — let alone on the other side of the world. That's where the LibreLinkUp app comes in handy. The app lets caregivers and/or parents see glucose data shared by people who use the FreeStyle LibreLink app<sup>5</sup> and FreeStyle Libre sensors, whenever they scan their sensor. LibreLinkUp lets as many as to 20 people check the numbers on a single FreeStyle LibreLink account.

Because the app provides real-time glucose information and a recent glucose history, caregivers can help pinpoint how and when certain foods, activities and insulin injections are affecting glucose levels. This powerful knowledge can help caregivers identify troubling trends and can assist in getting their loved one to make the necessary lifestyle changes, pronto. The app is currently supported in more than 30 countries, including the U.S.

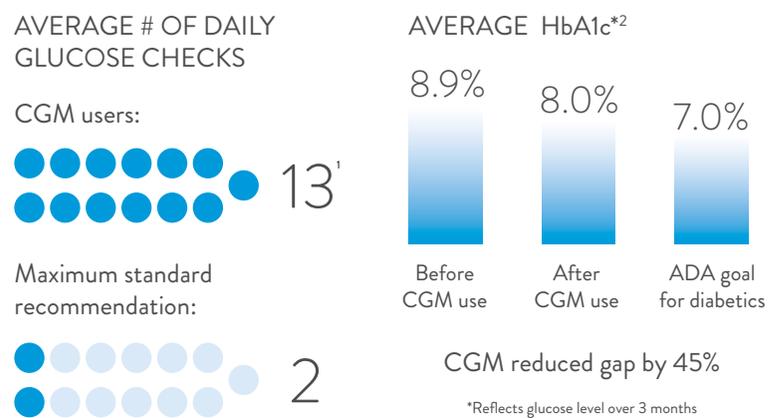
The FreeStyle LibreLink and LibreLinkUp apps are giving people with diabetes more freedom by making it easier than ever to monitor glucose levels.

1 Data on File. Abbott Diabetes Care.  
 2 Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.  
 3 The reader can capture data from the sensor when it is within 1 cm to 4 cm of the sensor.  
 4 The FreeStyle LibreLink app and the FreeStyle Libre and FreeStyle Libre 14 Day reader have similar but not identical features. Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose. When using FreeStyle LibreLink app, access to a blood glucose monitoring system is required as the app does not provide one.  
 5 The FreeStyle LibreLink app is compatible with iPhone 7 and later running iOS 11 and later. Use of the FreeStyle LibreLink app requires registration with LibreView, a service provided by Abbott and Newyu, Inc.

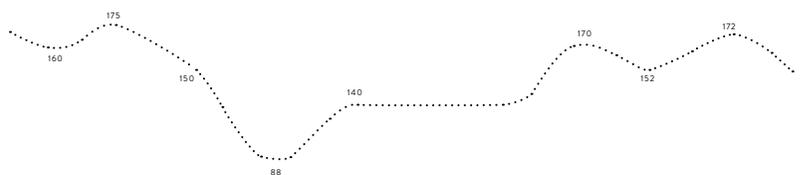
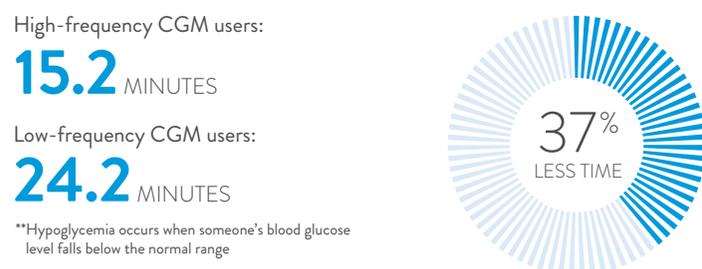
FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 35.

## IMPROVING DIABETES CARE

CGM systems like the FreeStyle Libre 14 day system have been found to enhance diabetes management in these ways:



### AVERAGE TIME DAILY IN HYPOGLYCEMIC RANGE<sup>\*\*3</sup>



1. FreeStyle Libre system users scanned on average 13 times per day to check their glucose levels.  
<https://abbott.mediaroom.com/2018-06-25-New-Late-Breaking-Data-at-ADA-Underscore-Significant-Benefits-of-Abbotts-FreeStyle-Libre-System-for-People-Living-with-Diabetes>  
 2. Data specific to FreeStyle Libre 14 day system users.  
<https://abbott.mediaroom.com/2019-06-08-New-Data-Show-Use-of-Abbotts-FreeStyle-R-Libre-System-Significantly-Reduces-HbA1c-Levels-in-People-Living-with-Type-2-Diabetes>  
 3. Data specific to FreeStyle Libre 14 day system users.  
<https://abbott.mediaroom.com/2018-06-25-New-Late-Breaking-Data-at-ADA-Underscore-Significant-Benefits-of-Abbotts-FreeStyle-Libre-System-for-People-Living-with-Diabetes>

A woman with long dark hair is smiling and looking down at a tablet device she is holding. The background is a blurred city street at night with warm bokeh lights. The text is overlaid on the lower left portion of the image.

BIG DATA ARE  
CHANGING  
DIABETES  
MANAGEMENT  
IN BIG WAYS

## Big data are helping people with diabetes get better care that's tailor-made for them.

When you're faced with a big decision, it's natural to want all of the relevant information right there in front of you so that you can make the best choice possible. And if that included information from hundreds or thousands of other people who've made similar decisions — and the results of those decisions — wouldn't that help immensely?

That's big data, in a nutshell — an enormous amount of information gathered from many sources, compiled in a computing system and run through advanced analytics and algorithms to reveal underlying trends and patterns.

Using big data in healthcare could change the future of diabetes and other health conditions.

### BIG DATA AND PRECISION MEDICINE

On the healthcare front, big data has helped source the Electronic Health Record (EHR), a broad record of patient health information culled from doctor's visits, inpatient hospital stays and data from wearable devices. EHR streamlines a provider's workflow by using big data to improve research and patient care. EHR has also been used to develop an algorithm that can, with 82 percent accuracy, determine whether a person would need an inpatient hospitalization a year in advance of the actual admission.

By gathering big data, hospitals can now more quickly identify which patients would benefit from a shift in treatment and potentially preventing serious complications of chronic diseases. This phenomenon of tailor-made medical treatment is called precision medicine — when massive amounts of information are processed and mined for specific patterns, putting patient profiles into sharp relief. For patients that fit a certain profile, a physician can prescribe a certain medication that the data suggests is a better fit or encourage increased monitoring based on the patient's symptoms.

By delivering personalized care, improving patient outcomes and possibly even preventing debilitating complications, big data in healthcare could improve the quality of life for patients, reduce disability from conditions and save millions of dollars spent on healthcare — especially when it comes to chronic conditions such as diabetes.

### BIG DATA AND THE FUTURE OF DIABETES

According to the Centers for Disease Control and Prevention, 9 percent of the U.S. population has diabetes. The need for valuable insight into treating and managing the disease is more pressing than ever. A broad approach to data analysis can help healthcare providers better understand the disease, its attendant prognoses and the potential complications it presents.

Big data analysis is predicated on large amounts of data, and people with diabetes are creating a huge amount of data just by living their daily lives. Glucometers create data; so do wearable exercise monitors, smart blood pressure cuffs, Bluetooth®-enabled bathroom scales and smart insulin pens.

The FreeStyle® Libre 14 day system, for instance, allows people with diabetes to track their glucose levels in real time, with ease and without fingersticks<sup>1</sup>. And when using the FreeStyle LibreLink iPhone® app<sup>2</sup> in conjunction with their monitor, they're able to access reports that show how well they're managing their glucose and review their glucose levels from the past 90 days. All of this data can also be shared easily with their doctor and diabetes support team.

Technologies such as the FreeStyle Libre 14 day system are a prime example of how big data can transform diabetes management. Not only can they help people improve their glucose control and better manage their condition, but they also generate a wealth of information. Aggregating, analyzing and interpreting that information can lead to best practices that can be distilled into actionable changes to help people live their best lives.

Big data has the potential to be the next wave of improvement for disease management, and though the technology is still somewhat in its infancy, we can already see some of the benefits of machine learning and artificial intelligence in the agriculture and healthcare fields. The future of diabetes is looking brighter every day because of breakthroughs in this growing field.

<sup>1</sup> Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.

<sup>2</sup> The FreeStyle LibreLink app is compatible with iPhone 7 and later running iOS 11 and later. Use of the FreeStyle LibreLink app requires registration with LibreView, a service provided by Abbott and Newyu, Inc.

**FOR IMPORTANT SAFETY INFORMATION, PLEASE SEE PAGE 35.**

# IMPORTANT SAFETY INFORMATION

## (INNOVATION IN A HEARTBEAT PODCAST)

### HEARTMATE 3™ AND HEARTMATE II™ LVAS

#### IMPORTANT SAFETY INFORMATION

Rx Only

#### BRIEF SUMMARY

Prior to using these devices, please review the Instructions For Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

#### HEARTMATE 3™ LVAS INDICATIONS

The HeartMate 3 Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

#### HEARTMATE II™ LVAS INDICATIONS

The HeartMate II Left Ventricular Assist System is indicated for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

#### HEARTMATE 3 AND HEARTMATE II LVAS CONTRAINDICATIONS

The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

#### HEARTMATE 3 AND HEARTMATE II LVAS ADVERSE EVENTS

Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System include, but are not limited to those listed below: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS), thromboembolism, pericardial fluid collection, pump pocket or pseudo pump pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and pump thrombosis.

## (THE “SPARKLE” IN HER HEART)

### SJM™ MASTERS SERIES MECHANICAL HEART VALVE MECHANICAL HEART VALVE SIZER

#### IMPORTANT SAFETY INFORMATION

Rx Only

#### INDICATIONS FOR USE

The SJM™ Masters Series Mechanical Heart Valve is intended for use as a replacement valve in patients with a diseased, damaged, or malfunctioning mitral or aortic heart valve. This device may also be used to replace a previously implanted mitral or aortic prosthetic heart valve.

The sizer model 905-15 is indicated to confirm size selection of the 15AHPJ-505 and 15MHPJ-505 valves.

#### CONTRAINDICATIONS

The SJM™ Masters Series Mechanical Heart Valve is contraindicated for individuals unable to tolerate anticoagulation therapy.

The sizer model 905-15 is contraindicated for use with any devices other than the 15 AHPJ-505 and 15MHPJ-505 valves. Any sizer sterilization method other than steam is contraindicated.

#### WARNINGS

##### Valve

- For single use only. Attempts to reuse the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Use only St. Jude Medical™ mechanical heart valve sizers.
- Do not use if:
  - The valve has been dropped, damaged, or mishandled in anyway.
  - The expiration date has elapsed.
  - The tamper-evident container seal or inner/outer tray seals are damaged, broken, or missing.
- Remove any residual tissue that may impair valve size selection, correct seating of the valve, rotation of the valve, or leaflet motion.
- Proper valve size selection is crucial. Do not oversize the valve. If the native annulus measurement falls between two SJM™ Masters Series Mechanical Heart Valve sizes, use the smaller prosthetic valve size.
- The outer tray is not sterile, and should not be placed in the sterile field.
- To minimize direct handling of the valve during implantation, do not remove the holder/rotator until the valve has been seated in the annulus.
- Do not use hard or rigid instruments to test leaflet mobility, as this may result in structural damage to the valve or thromboembolic complications. Use a St. Jude Medical™ leaflet tester to gently test valve leaflet mobility.
- Place sutures in the outer half of the valve sewing cuff.
- Never apply force to the valve leaflets. Force may cause structural damage to the valve.
- Use only SJM™ Valve Holder/Rotators to perform valve rotation. Use of other instruments could result in structural damage. The valve holder/rotator is intended for single use only and should be discarded after surgery.
- The two retention sutures on the valve holder/rotator must be cut and removed before the valve can be rotated.
- Do not pass catheters or other instruments through St. Jude Medical™ mechanical heart valves. This could result in scratched or damaged valve components, leaflet fracture, or dislodgment.
- Cut suture ends short, especially in the vicinity of the pivot guards, to prevent leaflet impingement.

#### PRECAUTIONS

##### Valve

- Do not touch the prosthetic valve unnecessarily, even with gloved hands. This may cause scratches or surface imperfections that may lead to thrombus formation.
- Be careful not to cut or tear the valve sewing cuff when removing the identification tag and the holder/rotator from the valve.
- Before placing sutures in the valve sewing cuff, verify that the valve is mounted correctly on the valve holder/rotator.
- To avoid structural damage, the valve must be rotated in the fully open position.
- To minimize rotational torque, verify that the valve holder/rotator is properly seated in the valve, and that the valve holder handle is perpendicular to the valve.
- Remove any loose suture or thread, which may be a source of thrombus or thromboembolism.
- Implantation of a prosthetic valve too large for the annulus may result in increased risk of damage to the conductive system, obstruction of the left ventricular outflow tract, impairment of valve mobility, damage to the left circumflex artery, and damage to surrounding tissues or cardiac structures including obstruction and/or distortion of adjacent cardiac structures.
- NOTE: PROSPECTIVE DATA TO SUPPORT SAFETY AND EFFECTIVENESS OF THE 15-mm HP VALVE IMPLANTED IN THE AORTIC POSITION ARE NOT CURRENTLY AVAILABLE.

##### Sizer

- Instruments must be cleaned and sterilized prior to use.
- Do not use cracked, deformed, discolored/rusted, or damaged instruments.
- Improper cleaning may result in an immunological or toxic reaction.
- Instrument sterilization temperature must not exceed 280°F (138°C).
- Do not bend flexible instrument handles beyond a 90° angle.

- Instruments must be sterilized in a tray or container that is permeable to steam.
- Do not expose instruments to cleaning or rinse agents that are not compatible with polysulfone or polyphenylsulfone.

#### POTENTIAL ADVERSE EVENTS

Complications associated with replacement mechanical heart valves include, but are not limited to, hemolysis, infections, thrombus, or thromboembolism, valve dehiscence, unacceptable hemodynamic performance, hemorrhagic complications secondary to anticoagulation therapy, heart block requiring pacemaker implant, prosthetic failure, adjacent cardiac structure interference, heart failure, stroke, myocardial infarction, or death. Any of these complications may require reoperation or explantation of the device.

## (THE WEIGHT OF THE WAIT)

### HEARTMATE 3™ LVAS

#### IMPORTANT SAFETY INFORMATION

Rx Only

#### BRIEF SUMMARY

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

#### HEARTMATE 3™ LVAS INDICATIONS

The HeartMate 3 Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

#### HEARTMATE 3™ LVAS CONTRAINDICATIONS

The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

#### HEARTMATE 3™ LVAS ADVERSE EVENTS

Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) or pump thrombosis.

™ Indicates a trademark of the Abbott group of companies.

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

© 2019 Abbott. All Rights Reserved.

MAT-1901418 v1.0 | Item approved for U.S. use only.

## (A TINY HEART. A BIG BREAKTHROUGH; THE POWER OF YOUR HEART)

### AMPLATZER PICCOLO™ OCCLUDER

#### IMPORTANT SAFETY INFORMATION

Rx Only

#### INDICATIONS AND USAGE

The AMPLATZER Piccolo™ Occluder is a percutaneous, transcatheter occlusion device intended for the nonsurgical closure of a patent ductus arteriosus (PDA).

#### CONTRAINDICATIONS

- Weight < 700 grams at time of the procedure
- Age < 3 days at time of procedure
- Coarctation of the aorta
- Left pulmonary artery stenosis
- Cardiac output that is dependent on right to left shunt through the PDA due to pulmonary hypertension

- Intracardiac thrombus that may interfere with the implant procedure
- Active infection requiring treatment at the time of implant
- Patients with a PDA length smaller than 3 mm
- Patients with a PDA diameter that is greater than 4 mm at the narrowest portion

#### WARNINGS

- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to re-sterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use the device if the sterile package is open or damaged.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- Prepare for situations that require the removal of this device. Preparation includes access to a transcatheter snare kit and an on-site surgeon.
- Accurate measurements of the ductus are crucial for correct occluder size selection.
- Do not release the occluder from the delivery wire if either a retention disc protrudes into the pulmonary artery or aorta; or if the position of the occluder is not stable.
- Remove embolized devices. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter.

#### PRECAUTIONS

- This device should be used only by physicians who are trained in standard transcatheter techniques. Determine which patients are candidates for procedures that use this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants and antiplatelet drugs before, during, and/or after the use of this device.
- Patients should have an activated clotting time (ACT) of greater than 200 sec prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anti-coagulated.
- The device may be delivered via an antegrade (venous) or a retrograde (arterial) approach. However, in small infants ( $\leq 2$  kg), the device should be delivered using the antegrade (venous) approach since small infants are at an increased risk for arterial injury.
- The AMPLATZER Piccolo™ Occluder contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days following implant. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should seek immediate medical attention if there is suspicion of an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data are currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.
- Use in specific populations
  - Pregnancy — Minimize radiation exposure to the fetus and the mother.
  - Nursing mothers — There has been no quantitative assessment for the presence of leachables in breast milk.
- Store in a dry place.
- Do not use contrast power injection with delivery catheter.

#### POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur during or after a procedure placing this device include, but are not limited to:

- Air embolus
- Allergic dye reaction
- Allergic drug reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Bacterial endocarditis
- Bleeding
- Cardiac perforation
- Cardiac tamponade
- Chest pain

- Device embolization
- Device erosion
- Death
- Fever
- Headache/migraine
- Hemolysis
- Hematoma
- Hypertension
- Hypotension
- Infection
- Myocardial infarction
- Palpitations
- Partial obstruction of aorta
- Partial obstruction of pulmonary artery
- Pericardial effusion
- Pericarditis
- Peripheral embolism
- Pleural effusion
- Pulmonary embolism
- Re-intervention for device removal
- Respiratory distress
- Stroke
- Thrombus
- Transient ischemic attack
- Valvular regurgitation
- Vascular access site injury
- Vascular occlusion
- Vessel perforation

Abbott 3200 Lakeside Dr., Santa Clara, CA. 95054 USA,  
Tel: 1.800.227.9902

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

™ Indicates a trademark of the Abbott group of companies.  
‡ Indicates a third-party trademark, which is property of its respective owner.  
[www.Cardiovascular.Abbott](http://www.Cardiovascular.Abbott)  
©2019 Abbott. All rights reserved. AP2947244-US Rev. B

#### (THE POWER OF YOUR HEART)

The XIENCE V®, XIENCE nano®, XIENCE PRIME®, XIENCE PRIME® LL, XIENCE Xpedition®, XIENCE Xpedition® SV and XIENCE Xpedition® LL, XIENCE Alpine®, and XIENCE Sierra™ (XIENCE Family) of Everolimus Eluting Coronary Stents on the MULTI-LINK VISION® or MULTI-LINK MINI VISION® Delivery System  
Rx Only

#### INDICATIONS

The XIENCE Sierra stent system is indicated for improving coronary artery luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease due to de novo native coronary artery lesions (length  $\leq 32$  mm) with reference vessel diameters of  $\geq 2.25$  mm to  $\leq 4.25$  mm. In addition, the XIENCE Sierra stent system is indicated for treating de novo chronic total coronary occlusions.

#### CONTRAINDICATIONS

The XIENCE Sierra stent system is contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally related compounds, or known hypersensitivity to stent components (cobalt, chromium, nickel, tungsten, acrylic, fluoropolymers), or with contrast sensitivity.

#### WARNINGS

- It is not recommended to treat patients having a lesion that prevent complete inflation of an angioplasty balloon.
- Judicious patient selection is necessary because the use of this device carries the associated risk of stent thrombosis, vascular complications, and/or bleeding events.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

#### PRECAUTIONS

- Ensure that the inner package sterile barrier has not been opened or damaged prior to use.
- Stent implantation should only be performed by physicians who have received appropriate training.
- Stent placement should be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) is accessible.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. Long-term outcomes following repeat dilatation of the stent are presently unknown.
- Care should be taken to control the guiding catheter tip during stent delivery, deployment and balloon withdrawal. Before withdrawing the stent delivery system, visually confirm complete balloon deflation by fluoroscopy to avoid guiding catheter movement into the vessel and subsequent arterial damage.
- When DES are used outside the specified Indications for Use, patient outcomes may differ from the results observed in the SPIRIT family of trials.
- Compared to use within the specified Indications for Use, the use of DES in patients and lesions outside of the labeled indications may have an increased risk of adverse events, including stent thrombosis, stent embolization, MI, or death.
- Orally administered everolimus combined with cyclosporine is associated with increased serum cholesterol and triglycerides levels.
- A patient's exposure to drug and polymer is proportional to the number and total length of implanted stents. See Instructions for Use for current data on multiple stent implantation.
- Safety and effectiveness of the XIENCE Family of stents have not been established for subject populations with the following clinical settings:
  - Patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated site restenosis, patients in whom mechanical atherectomy devices or laser angioplasty catheters are used in conjunction with XIENCE Family stents, women who are pregnant or lactating, men intending to father children, pediatric patients, unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters  $< 2.25$  mm or  $> 4.25$  mm or lesion length  $> 32$  mm, lesions located in saphenous vein grafts, unprotected left main coronary artery, ostial lesions, lesions located at a bifurcation or previously stented lesions, diffuse disease or poor flow (TIMI  $< 1$ ) distal to the identified lesions, excessive tortuosity proximal to or within the lesion, recent Acute Myocardial Infarction (AMI) or evidence of thrombus in target vessel, multivessel disease, and in-stent restenosis.
- Everolimus has been shown to reduce the clearance of some prescription medications when administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with the XIENCE Family of stents because of limited systemic exposure to everolimus eluted from the stent.
- Everolimus is an immunosuppressive agent. Consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant patients and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglycerides, which in some cases required treatment.
- Non-clinical testing has demonstrated that the XIENCE Sierra stent, in single and in overlapped configurations up to 71 mm in length, is MR Conditional. It can be scanned safely under the conditions in the Instructions for Use.
- The XIENCE Family of stents should be handled, placed, implanted, and removed according to the Instructions for Use.

**POTENTIAL ADVERSE EVENTS**

Adverse events (in alphabetical order) which may be associated with percutaneous coronary intervention treatment procedures and the use of a coronary stent in native coronary arteries include, but are not limited to, the following:

- Abrupt closure, hematoma, or hemorrhage, Acute myocardial infarction, Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, device materials (platinum, polymer, cobalt, chromium, nickel, tungsten, acrylic, fluoropolymers), and drug reactions to everolimus, anticoagulation, or antiplatelet drugs, Arterial rupture, Arteriovenous fistula, Arrhythmias, atrial and ventricular, Bleeding complications, which may require transfusion, Cardiac tamponade, Coronary artery spasm, Coronary or stent embolism, Coronary or stent thrombosis, Death, Dissection of the coronary artery, Fever, Hypotension and/or hypertension, Ischemia (myocardial), Myocardial infarction (MI), Nausea and vomiting, Palpitations, Peripheral ischemia, Pseudoaneurysm, Renal Failure, Restenosis, Shock/pulmonary edema, Stroke/cerebrovascular accident (CVA), Total occlusion of coronary artery, Unstable or stable angina pectoris, Vascular access complications which may require vessel repair, Vessel dissection

The risks described below include, but are not limited to, the anticipated adverse events relevant for the cardiac population referenced in the contraindications, warnings, and precautions sections of the everolimus labels.

- Abdominal pain; Anemia; Angioedema; Constipation; Cough; Diarrhea; Dyslipidemia (including hyperlipidemia and hypercholesterolemia); Dyspnea; Edema (peripheral); Headache; Hyperglycemia; Hypertension; Hypokalemia; Elevations of serum creatinine; Infections: bacterial, viral, fungal, and protozoan infections (may include opportunistic infections); Lymphoma and skin cancer; Male infertility; Oral ulcerations; Nausea; Non-infectious pneumonitis; Pain; Proteinuria; Pyrexia; Rash; Thrombotic microangiopathy (TMA)/Thrombotic thrombocytopenic purpura (TTP)/Hemolytic uremic syndrome (HUS); Urinary tract infection; Upper respiratory tract infection; Vomiting
- Live vaccines should be avoided and close contact with those that have had live vaccines should be avoided. Fetal harm can occur when administered to a pregnant woman. There may be other potential adverse events that are unforeseen at this time.

AP2946524-WBU Rev. A

**(THE POWER OF YOUR HEART)****ABLATION****IMPORTANT SAFETY INFORMATION**

Catheter ablation uses high frequency electrical energy or other energy to correct fast heartbeats by scarring or destroying tissue that affects the electrical signals that travel through the heart. Your doctor is the best source of information about the risks of having a catheter ablation procedure. Be sure to talk about all of your questions and concerns. The following is a summary of risk information. Procedure risks may include esophageal perforation, coronary artery injuries, phrenic nerve paralysis, infection, damage to the heart or blood vessels and blood clots. Bleeding, swelling or bruising may occur at the catheter insertion sites.

It is also possible that the heart's normal electrical system could be damaged during this procedure. Generally, risks depend on age, general health, specific medical conditions and heart function. If this occurs, an artificial pacemaker may be necessary. Following the procedure, you will be moved to a recovery area where you will be monitored for complications from the procedure. Although all types of anesthesia involve some risk, individual side effects and complications from anesthesia can vary. Specific risks can differ depending on various health factors. Any potential concerns should be discussed with your physician. Catheter ablation is often successful; however some people require repeat procedures. You may also need to take medication, even after you have had an ablation procedure. Your doctor will determine the best option for you. This procedure is available by prescription only and is not right for everyone. Individual results may vary.

**(THE POWER OF YOUR HEART)****LEFT VENTRICULAR ASSIST DEVICE (LVAD)****IMPORTANT SAFETY INFORMATION**

Complications of surgery to receive an LVAD are similar to the potential complications of any open heart surgery procedure. You will be asked to sign a surgical consent form prior to the operation, as well as a consent form for blood transfusions. Your surgeon will discuss potential risks and benefits with you prior to the procedure.

Possible serious adverse events include death, bleeding (during surgery or after surgery), cardiac arrhythmia (irregular heartbeat), local infection, respiratory failure, device malfunction, sepsis (serious infection), right heart failure, driveline or pocket infection, renal failure (inability of the kidneys to remove waste from the blood), stroke, neurologic dysfunction (problems affecting the brain or nervous system), psychiatric episode, thromboembolic event, peripheral (blood clots), hemolysis (breakdown of red blood cells), hepatic dysfunction (liver problems), device thrombosis (formation of a blood clot inside the device) and myocardial infarction (heart attack).

Individual experiences, symptoms, situations, and circumstances may vary. Please consult your physician or qualified healthcare provider regarding your condition and appropriate medical treatment.

**(THE POWER OF YOUR HEART)****CARDIOMEMS™ HF SYSTEM****INDICATIONS, SAFETY & WARNINGS**

Rx Only

**BRIEF SUMMARY**

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**INDICATIONS AND USAGE**

The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

**CONTRAINDICATIONS**

The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

**POTENTIAL ADVERSE EVENTS**

Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

**(HEART MONITORING, EVERYWHERE YOU GO)****CONFIRM Rx INSERTABLE CARDIAC MONITOR****IMPORTANT SAFETY INFORMATION**

Rx Only

**INDICATIONS**

The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Confirm Rx™ ICM has not been specifically tested for pediatric use.

**CONTRAINDICATIONS**

There are no known contraindications for the insertion of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

**ADVERSE EVENTS**

Possible adverse events (in alphabetical order) associated with the device, include the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

**ADDITIONAL INFORMATION**

Clinicians must log onto Merlin.net™ Patient Care Network to view transmissions from patients' Confirm Rx™ ICM. On Merlin.net™ PCN they can configure transmission schedules and enable or disable features on a patient's myMerlin™ for Confirm Rx™ ICM mobile app. Review of transmissions is dependent on the clinician and may not happen immediately following delivery of such transmissions.

**LIMITATIONS**

Patients may use their own Apple® or Android® mobile device to transmit information from their Confirm Rx™ ICM using the myMerlin™ for Confirm Rx™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology enabled and data coverage (cellular or WiFi®) available. The myMerlin™ for Confirm Rx™ mobile app provides periodic patient monitoring based on clinician configured settings. Data is resent if the transmission was not sent successfully. However, there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes, or data processing.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

™ Indicates a trademark of the Abbott group of companies.

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

**(AGAINST THE GRAIN IN THE PARKINSON'S FIGHT)****DEEP BRAIN STIMULATION**

St. Jude Medical is now Abbott Medical

**PRESCRIPTION AND SAFETY INFORMATION**

Read this section to gather important prescription and safety information. For specific indications, contraindications, instructions, warnings, precautions, and adverse effects about system components available in your country or region, see the approved clinician's manual for those components.

**INTENDED USE**

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

**INDICATIONS FOR USE****United States:**

The neurostimulation system is indicated for the following conditions:

- Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications.
- Unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

**International:**

The neurostimulation system is indicated for the following conditions:

- Unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease.
- Unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the management of disabling tremor.

- Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for the management of intractable, chronic dystonia, including primary and secondary dystonia, for patients who are at least 7 years old.

## CONTRAINDICATIONS

### United States:

This system is contraindicated for patients who meet the following criteria:

- Are unable to operate the system
- Have unsuccessful test stimulation

The following procedures are contraindicated for patients with a deep brain stimulation system. Advise patients to inform their healthcare professional that they cannot undergo the following procedures:

- Diathermy (short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy)
- Electroshock therapy and transcranial magnetic stimulation (TMS)

### International:

Implantation of this neurostimulation system is contraindicated for the following:

- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the system.

The following procedures are contraindicated for patients that have been implanted with this device:

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in a severe injury or death. Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. All patients are advised to inform their healthcare professional that they should not be exposed to diathermy treatment.

## MRI SAFETY INFORMATION

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. Scanning under different conditions may cause device malfunction, severe patient injury, or death. For more information about MR Conditional deep brain stimulation (DBS) components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for DBS systems (available online at [manuals.sjm.com](http://manuals.sjm.com)). For more information about MR Conditional products, visit the Abbott product information page at [sjm.com/MRIReady](http://sjm.com/MRIReady).

## WARNINGS

The following warnings apply to this neurostimulation system.

**Pregnancy and nursing.** Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established. Patients should not use this neurostimulation system if they are pregnant or nursing.

**Magnetic resonance imaging (MRI).** Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

If any component of the implanted neurostimulation system, such as an IPG, lead, or extension, does not meet the requirements for an MR Conditional system, do not perform an MRI scan. If a system does not meet the MR Conditional requirements, consider it MR Unsafe.

**High stimulation outputs and charge density limits.** Avoid excessive stimulation. A risk of brain tissue damage exists with parameter settings using high amplitudes and wide pulse widths.

**High amplitudes and wide pulse widths should only be programmed with due consideration of the warnings concerning charge densities.** The system can be programmed to use parameter settings outside the range of those used in the clinical studies. If the programming of stimulation parameters exceeds the charge density limit of 30  $\mu\text{C}/\text{cm}^2$ , a screen will appear warning you that the charge density is too high. Charge density can be reduced by lowering the stimulation amplitude or pulse width. For more information, see the clinician programmer manual.

Higher amplitudes and wider pulse widths may indicate a system problem or a suboptimal lead placement. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render the patient incapable of controlling the patient controller. If unpleasant sensations occur, the device should be turned off immediately using the patient magnet.

**Risk of depression, suicidal ideations, and suicide.** Depression, suicidal ideation, and suicide have been reported in patients receiving deep brain stimulation therapy for movement disorders, although no direct cause and effect relationship has been established. Preoperatively assess patients for suicide risk and carefully balance this risk with the potential clinical benefit. Postoperatively monitor patients for the presence of any of the following symptoms and manage these symptoms appropriately: depression, suicidal thoughts or behaviors, changes in mood, and impulse control. Emphasize the importance of sustained follow-up and support with all patients and their caregivers and family members.

**Poor surgical risks.** Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

**Explosive or flammable gases.** Do not use the clinician programmer or patient controller in an environment where explosive or flammable gas fumes or vapors are present. The operation of the clinician programmer or patient controller could cause them to ignite, causing severe burns, injury, or death.

**Operation of machinery and equipment.** Patients should not operate potentially dangerous machinery, power tools, or vehicles or engage in any activity that could be unsafe if their symptoms were to unexpectedly return.

**Device components.** The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

**Electrosurgery.** To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the device in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure.

During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.
- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

**Radiofrequency or microwave ablation.** Careful consideration should be used before using radiofrequency (RF) or microwave ablation in patients who have an implanted neurostimulation system since safety has not been established. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

**Implanted cardiac systems.** Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing

the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

**Other active implanted devices.** The neurostimulation system may interfere with the normal operation of another active implanted device, such as a pacemaker, defibrillator, or another type of neurostimulator. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

**Case damage.** If the case of the implantable pulse generator (IPG) is pierced or ruptured, severe burns could result from exposure to battery chemicals.

**Cremation.** The IPG should be explanted before cremation because the IPG could explode. Return the explanted IPG to Abbott Medical.

**Component disposal.** Return all explanted components to Abbott Medical for safe disposal. IPGs contain batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

**Coagulopathies.** Physicians should use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should also consider underlying factors, such as previous neurological injury or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

**Low frequencies.** Stimulation frequencies at less than 30 Hz may cause tremor to be driven (meaning that tremor occurs at the same frequency as the programmed frequency). For this reason, programming at frequencies less than 30 Hz is not recommended.

**IPG placement.** The IPG should be placed into the pocket, at a depth not to exceed 4 cm (1.57 in), with the logo side facing toward the skin surface. Placing the IPG deeper than 4 cm (1.57 in) can impede or prohibit IPG communications with the clinician programmer or patient controller.

**Return of symptoms and rebound effect.** The abrupt cessation of stimulation for any reason will probably cause disease symptoms to return. In some cases, symptoms may return with a greater intensity than what a patient experienced before system implantation (rebound effect). In rare cases, this can create a medical emergency.

## PRECAUTIONS

The following precautions apply to this neurostimulation system.

### GENERAL PRECAUTIONS

**Surgeon training.** Implanting physicians should be experienced in stereotactic and functional neurosurgery.

**Clinician training.** Clinicians should be familiar with deep brain stimulation therapy and be experienced in the diagnosis and treatment of the indication for which the deep brain stimulation components are being used.

**Patient selection.** Select patients appropriately for deep brain stimulation. The patient should be able and willing to use the patient controller and correctly interpret the icons and messages that appear on the screen.

Especially consider the following additional factors when selecting patients:

- Level of available support from a caregiver.
- Expected effect from cessation of therapy, should disease symptoms return unexpectedly.
- Patient's age, as very young or very old patients may have difficulty performing required monitoring of the device.
- Patient's mental capacity, as patients with cognitive impairment or those prone to developing dementia would likely have difficulty performing device-related tasks without assistance.
- Patient's physical ability, as patients with higher degrees of motor impairment might have difficulty with the physical requirements of monitoring the device.
- Patient's visual ability to read the patient controller screen.

**Infection.** Follow proper infection control procedures. Infections may require that the device be explanted.

**Electromagnetic interference (EMI).** Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

**Security, antitheft, and radiofrequency identification (RFID) devices.** Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients should cautiously approach such devices and should request help to bypass them. If they must go through or near a gate or doorway containing this type of device, patients should move quickly and then check their IPG to determine if it is turned on or off.

**Unauthorized changes to stimulation parameters.** Caution patients to not make unauthorized changes to physician-established stimulation parameters.

**Damage to shallow implants.** Falling and other traumatic accidents can damage shallowly implanted components such as the leads and extensions.

**Keep programmers and controllers dry.** The clinician programmer and patient controller are not waterproof. Keep them dry to avoid damage. Advise patients to not use the patient controller when engaging in activities that might cause it to get wet, such as swimming or bathing.

**Handle the programmers and controllers with care.** The clinician programmer and patient controllers are sensitive electronic devices that can be damaged by rough handling, such as dropping them on the ground.

**Battery care.** Batteries can explode, leak, or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

**Long-term safety and effectiveness.** The long-term safety and effectiveness of this neurostimulation system has not been established beyond 5 years. Safety and effectiveness has not been established for patients with a neurological disease other than Parkinson's disease or essential tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients under 22 years; implantation in targets other than the STN for Parkinson's disease and the VIM for essential tremor; patients with an active implantable device; patients requiring MRI.

## STERILIZATION AND STORAGE

**Single-use, sterile device.** The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

**Storage environment.** Store components and their packaging where they will not come in contact with liquids of any kind. Detailed information on storage environment is provided in the appendix of this manual.

## HANDLING AND IMPLANTATION

**Expiration date.** An expiration date (or "use-before" date) is printed on the packaging. Do not use the system if the use-before date has expired.

**Care and handling of components.** Use extreme care when handling system components. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

**Package or component damage.** Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

**Exposure to body fluids or saline.** Prior to connection, exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

**Skin erosion.** To avoid the risk of skin erosion, implant components at the appropriate depth and inform patients to avoid touching their skin where components are implanted. The IPG should be placed into the pocket, at a depth not to exceed 4.0 cm (1.57 in), with the logo side facing toward the skin surface.

**System testing.** To ensure correct operation, always test the system during the implant procedure, before closing the neurostimulator pocket, and before the patient leaves the surgery suite.

**Device modification.** The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

**Multiple leads.** When multiple leads are implanted, route the lead extensions so the area between them is minimized. If the lead extensions are routed in a loop, the loop will increase the potential for electromagnetic interference (EMI).

**Abandoned leads and replacement leads.** The long-term safety associated with multiple implants, leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

**Placement of lead connection in neck.** The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture.

## HOSPITAL AND MEDICAL ENVIRONMENTS

**Electrical medical treatment.** In the case that a medical treatment is administered where an electrical current is passed through the body from an external source, first deactivate the IPG by setting all electrodes to off, turning stimulation off, and setting amplitude to zero. Regardless if the device is deactivated, take care to monitor the device for proper function during and after treatment.

**High-output ultrasonics and lithotripsy.** The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

**Ultrasonic scanning equipment.** The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

**External defibrillators.** The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

**Therapeutic radiation.** Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead. Damage to the system may not be immediately detectable.

**Electrocardiograms.** Ensure the neurostimulator is off before initiating an electrocardiogram (ECG). If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

## HOME AND OCCUPATIONAL ENVIRONMENTS

**Patient activities and environmental precautions.** Patients should take reasonable care to avoid devices that generate strong EMI, which may cause the neurostimulation system to unintentionally turn on or off. Patients should also avoid any activities that would be potentially unsafe if their symptoms were to return unexpectedly. These activities include but are not limited to climbing ladders and operating potentially dangerous

machinery, power tools, and vehicles. Sudden loss of stimulation may cause patients to fall or lose control of equipment or vehicles, injure others, or bring injury upon themselves.

**Control of the patient controller.** Advise patients to keep the patient controller away from children and pets in order to avoid potential damage or other hazards.

**Activities requiring excessive twisting or stretching.** Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component.

**Component manipulation by patient.** Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Manipulation may cause device inversion, inhibiting the ability to use the magnet to start or stop stimulation.

**Scuba diving or hyperbaric chambers.** Patients should not dive below 30 m (100 ft) of water or enter hyperbaric chambers above 4.0 atmospheres absolute (ATA). Pressures below 30 m (100 ft) of water (or above 4.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

**Skydiving, skiing, or hiking in the mountains.** High altitudes should not affect the neurostimulator; however, the patient should consider the movements involved in any planned activity and take precautions to avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.

**Wireless use restrictions.** In some environments, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on. (Bluetooth® is a registered trademark of Bluetooth SIG, Inc.)

**Mobile phones.** The effect of mobile phones on deep brain stimulation is unknown. Patients should be advised to avoid carrying mobile phones in their shirt pocket or otherwise placing them directly over the deep brain stimulation system components. If interference occurs, try holding the phone to the other ear or turning off the phone.

**Household appliances.** Household appliances that contain magnets (e.g., refrigerators, freezers, inductive cooktops, stereo speakers, mobile telephones, cordless telephones, standard wired telephones, AM/FM radios, and some power tools) may unintentionally cause the neurostimulation system to turn on or turn off.

**Therapeutic magnets.** Patients should be advised to not use therapeutic magnets. Therapeutic magnets (e.g., magnets used in pillows, mattress pads, back belts, knee braces, wrist bands, and insoles) may unintentionally cause the neurostimulation system to turn on or off.

## ADVERSE EFFECTS

Deep brain stimulation potentially has the following adverse effects:

**Possible surgical complications.** Surgical complications include, but are not limited to, the following: intracranial hemorrhage (which can lead to stroke, paralysis, or death); subcutaneous hemorrhage or seroma; hematoma; cerebrospinal fluid leakage or cerebrospinal fluid abnormality; brain contusion; infection or inflammation; antibiotic anaphylaxis; skin disorder; edema; persistent pain at surgery site or IPG site; erosion; brachial plexus injury (nerves to chest, shoulder and arm); postoperative pain, stress, or discomfort; neuropathy (nerve degeneration); hemiparesis (muscular weakness or partial paralysis on one side of body); ballism or hemiballism (uncontrollable movements on both or only one side of the body); confusion—transient, nocturnal or ongoing; cognitive impairment, including delirium, dementia, disorientation, psychosis and speech difficulties; aphasia; deep vein thrombosis; complications from anesthesia;

phlebitis (vein inflammation); pulmonary embolism (sudden blood vessel obstruction); aborted procedures (air embolism, unable to find target, surgical complication, etc.); complications from unusual physiological variations in patients, including foreign body rejection phenomena; pneumonia, seizure or convulsions; paralysis (loss of motor function, inability to move); stroke and death.

**Possible deep brain stimulation complications.** Deep brain stimulation complications include, but are not limited to, the following:

- Device-related complications
  - Undesirable changes in stimulation related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, or lead fracture
  - Loss of therapeutic benefit as a result of change in electrode positions, loose electrical connections, or lead or extension fracture
  - Initial jolt or tingling during stimulation; jolting or shocking sensations
  - Infection
  - Paresthesia
  - Lead fracture, migration, or dislodgement
  - Misplaced lead
  - Extension malfunction, fracture, or disconnect
  - Deep brain stimulation system failure or battery failure within the device
  - Deep brain stimulation system malfunction or dislodgement
  - Spontaneous turning on or off of the IPG
  - Allergic or rejection response to implanted materials
  - Persistent pain, tightness, or redness at the incision sites or general pain
  - General erosion or local skin erosion over the IPG
  - Persistent pain, tightness, or discomfort around the implanted parts (e.g., along the extension path in the neck)
  - Impaired wound healing (e.g., incision site drainage) or abscess formation
  - Additional neurosurgical procedure to manage one of the above complications or to replace a malfunctioning component
- Stimulation-related complications or other complications
  - Worsening of motor impairment and Parkinson's disease symptoms including dyskinesia, rigidity, akinesia or bradykinesia, myoclonus, motor fluctuations, abnormal gait or incoordination, ataxia, tremor, and dysphasia
  - Paresis, asthenia, hemiplegia, or hemiparesis
  - Dystonia
  - Sensory disturbance or impairment including neuropathy, neuralgia, sensory deficit, headache, and hearing and visual disturbance
  - Speech or language impairment including, aphasia, dysphagia, dysarthria, and hypophonia
  - Cognitive impairment including attention deficit, confusion, disorientation, abnormal thinking, hallucinations, amnesia, delusions, dementia, inability to act or make decisions, psychic akinesia, long term memory impairment, psychiatric disturbances, depression, irritability or fatigue, mania or hypomania, psychosis, aggression, emotional lability, sleep disturbance, anxiety, apathy, drowsiness, alteration of mentation, postural instability and disequilibrium
  - Restless leg syndrome
  - Supranuclear gaze palsy
  - Hypersexuality or increased libido
  - Decreased therapeutic response
  - Urinary incontinence or retention
  - Diarrhea or constipation
  - Cardiac dysfunction (e.g., hypotension, heart rate changes, or syncope)
  - Difficulty breathing
  - Increased salivation
  - Weight gain or loss
  - Eye disorder including eye apraxia or blepharospasm
  - Nausea or vomiting
  - Sweating
  - Fever
  - Hiccups
  - Cough

- Cramps
- Worsening existing medical conditions

#### (A JOURNEY WITH CHRONIC PAIN)

### PROCLAIM™ ELITE RECHARGE-FREE SCS SYSTEM

#### IMPORTANT SAFETY INFORMATION

Rx Only

While neurostimulation helps most patients experience at least some reduction in chronic pain, not everyone responds in the same way. The amount of pain relief varies with each individual. Complications related to placement and/or use of the device may occur. Be sure to talk to your doctor about the risks associated with the placement of a neurostimulation system.

#### BRIEF SUMMARY

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

#### INDICATIONS FOR USE

Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

#### CONTRAINDICATIONS

Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

#### WARNINGS/PRECAUTIONS

Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

#### ADVERSE EFFECTS

Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). Clinicians manual must be reviewed for detailed disclosure.

#### (A DIABETES CARE REVOLUTION)

### FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM

#### INDICATIONS AND IMPORTANT SAFETY INFORMATION

The FreeStyle Libre Flash Glucose Monitoring system is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for single patient use and requires a prescription.

#### CONTRAINDICATIONS

Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

#### WARNINGS/LIMITATIONS

Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The FreeStyle Libre system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The FreeStyle Libre system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of bloodborne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis,

neonates, critically-ill patients, or for diagnosis or screening of diabetes. Review all product information before use or contact Abbott Toll-Free (855-632-8658) or visit [www.freestylelibre.us](http://www.freestylelibre.us) for detailed indications for use and safety information.

#### (THE FUTURE OF DIABETES CAREGIVING; BIG DATA ARE CHANGING DIABETES MANAGEMENT IN BIG WAYS)

### FREESTYLE LIBRE AND FREESTYLE LIBRE 14 DAY FLASH GLUCOSE MONITORING SYSTEMS

#### INDICATIONS AND IMPORTANT SAFETY INFORMATION

FreeStyle Libre and FreeStyle Libre 14 day Flash Glucose Monitoring systems are continuous glucose monitoring (CGM) devices indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The systems are intended for single patient use and require a prescription.

#### CONTRAINDICATIONS

Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment.

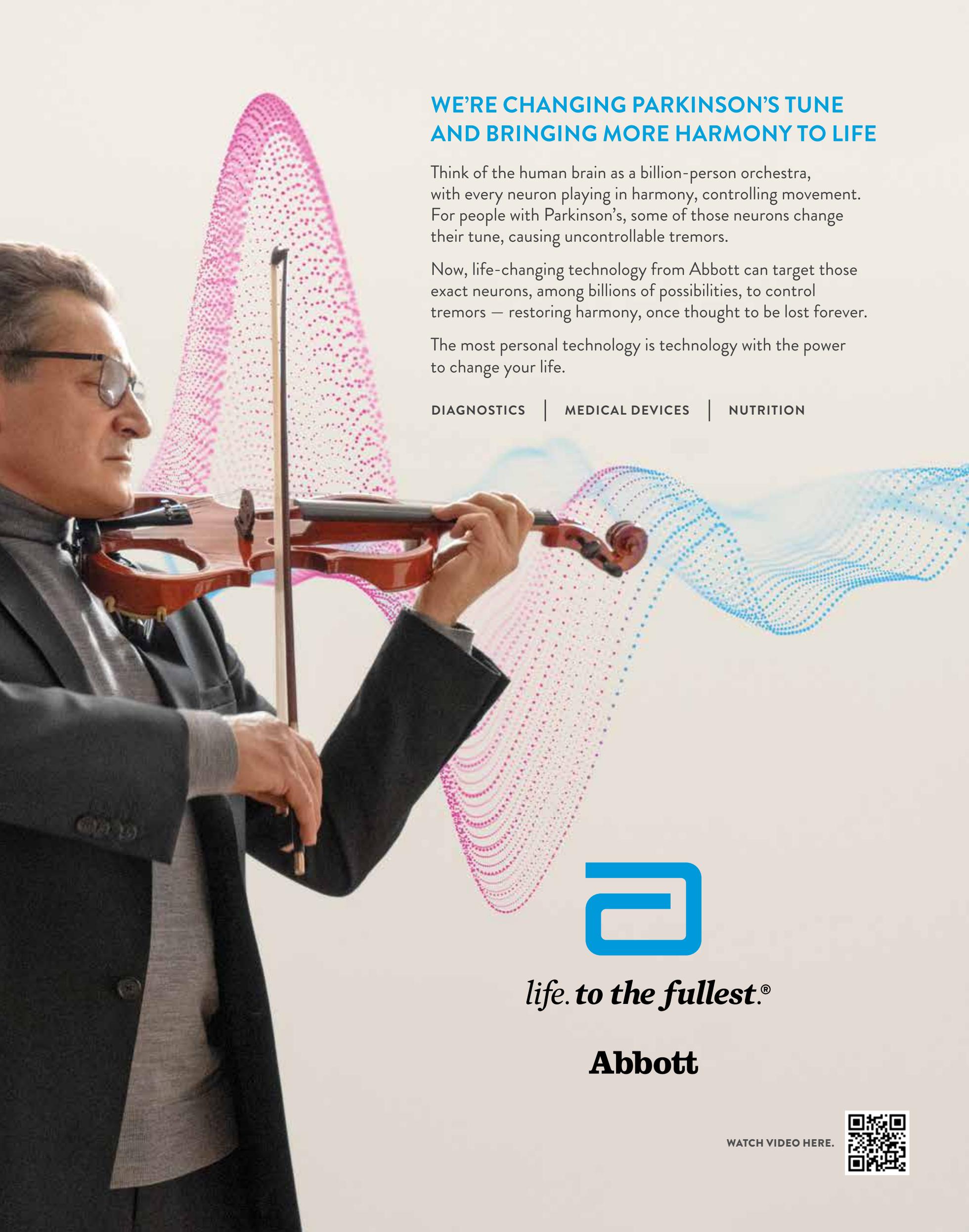
#### WARNINGS/LIMITATIONS

Do not ignore symptoms that may be due to low or high blood glucose, hypoglycemic unawareness, or dehydration. Check sensor glucose readings with a blood glucose meter when Check Blood Glucose symbol appears, when symptoms do not match system readings, or when readings are suspected to be inaccurate. The system does not have alarms unless the sensor is scanned, and the system contains small parts that may be dangerous if swallowed. The system is not approved for pregnant women, persons on dialysis, or critically-ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken. The built-in blood glucose meter is not for use on dehydrated, hypotensive, in shock, hyperglycemic-hyperosmolar state, with or without ketosis, neonates, critically-ill patients, or for diagnosis or screening of diabetes. When using FreeStyle LibreLink app, access to a blood glucose monitoring system is required as the app does not provide one. Review all product information before use or contact Abbott Toll Free (855-632-8658) or visit [www.freestylelibre.us](http://www.freestylelibre.us) for detailed indications for use and safety information.

FreeStyle, Libre, and related brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions. Other trademarks are the property of their respective owners.

No use of any Abbott trademark, trade name, or trade dress in this site may be made without the prior written authorization of Abbott Laboratories, except to identify the product or services of the company. The product images are for illustrative purposes only.

This publication and the information contained herein is intended for use by residents of the United States.



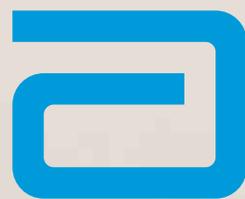
## WE'RE CHANGING PARKINSON'S TUNE AND BRINGING MORE HARMONY TO LIFE

Think of the human brain as a billion-person orchestra, with every neuron playing in harmony, controlling movement. For people with Parkinson's, some of those neurons change their tune, causing uncontrollable tremors.

Now, life-changing technology from Abbott can target those exact neurons, among billions of possibilities, to control tremors — restoring harmony, once thought to be lost forever.

The most personal technology is technology with the power to change your life.

DIAGNOSTICS | MEDICAL DEVICES | NUTRITION



*life. to the fullest.®*

**Abbott**

WATCH VIDEO HERE.

