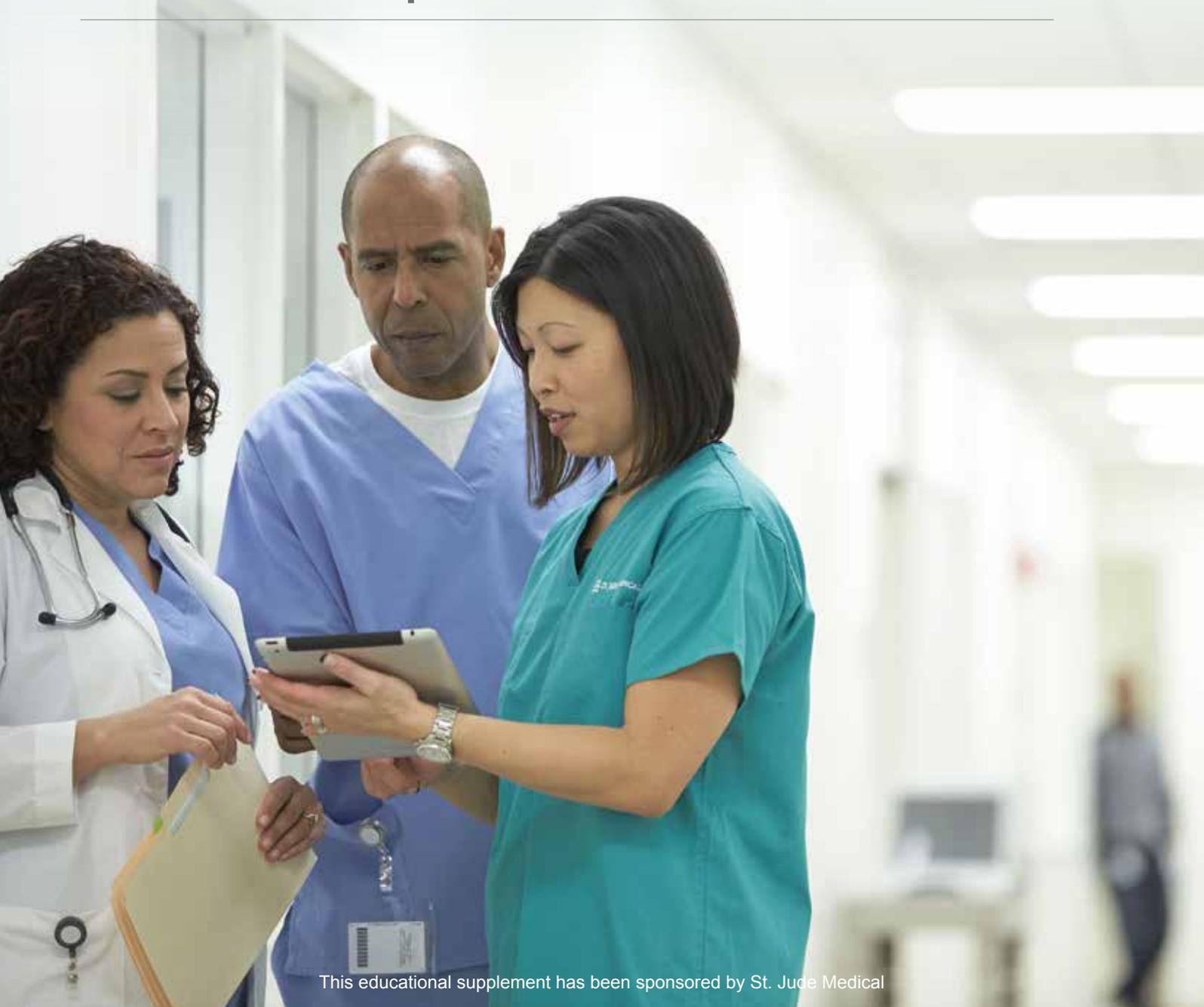


NeuroNews

EDUCATIONAL SUPPLEMENT

St. Jude Medical: Returning innovation to chronic pain treatment



This educational supplement has been sponsored by St. Jude Medical



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Introduction

St. Jude Medical: Returning innovation to chronic pain treatment

With a series of acquisitions and recent product approvals, St. Jude Medical has further solidified its place as a leading provider of treatment options for patients suffering from chronic pain and the symptoms associated with movement disorders. The company is now the only medical device manufacturer in the world to offer radiofrequency ablation (RFA), spinal cord stimulation (SCS) and dorsal root ganglion (DRG) stimulation therapy solutions for the treatment of chronic pain, as well as deep brain stimulation (DBS) products for patients battling Parkinson's disease, tremor and dystonia.

With physician feedback and the development of patient-centric solutions central to the company's expansion and consistently driving the company's innovation, St. Jude Medical is developing products that address profound patient needs.

This educational supplement provides a thorough look at some of the highlights from within St. Jude Medical's neuromodulation portfolio, focusing on new product features and providing insight from key physicians from across international markets.



Investigational device limited by Federal or U.S. law to investigational use. Not available for sale in the U.S.

The St. Jude Medical approach to innovation

St. Jude Medical is the only device manufacturer in the world to offer patients outside the USA the company's Burst stimulation waveform and traditional tonic stimulation in one device. A trio of systems offer international patients access to both stimulation waveforms: the Prodigy™ Chronic Pain System, the Prodigy MRI™ Chronic Pain System and the Proclaim™ Chronic Pain System, all of which are CE mark approved.

In the USA, St. Jude Medical offers the Protégé™ and Protégé MRI™ spinal cord stimulation systems. Both options are upgradeable, which gives patients immediate access to new therapy options as they are approved without the need for additional surgery.

St. Jude Medical has also changed how patients worldwide assess spinal cord stimulation with the St. Jude Medical™ Invisible Trial System, the industry's first SCS trial system to utilise Apple™ mobile digital devices and Bluetooth® wireless technology. The system is patient-focused and has been designed to improve the SCS trial experience for patients suffering from the debilitating effects of chronic pain.

St. Jude Medical has also expanded its product portfolio to address the needs of pain patients for whom conventional spinal cord stimulation is not suitable and who may need more targeted therapy. Outside

the USA, St. Jude Medical offers the Axiom™ Neurostimulator System, which targets the dorsal root ganglion, a sensory structure that plays a critical role in the development and maintenance of chronic pain.

In addition to chronic pain therapy options, St. Jude Medical has also focused the company's attention on developing more intuitive DBS systems for patients suffering from Parkinson's disease, tremor and dystonia. The St. Jude Medical Infinity™ Deep Brain Stimulation System and directional DBS lead recently received CE mark approval and will soon be available in select international markets.

In this educational supplement, we hope to provide you an in-depth look at a number of new St. Jude Medical therapy op-



tions and a look at how the company is committed to innovation.

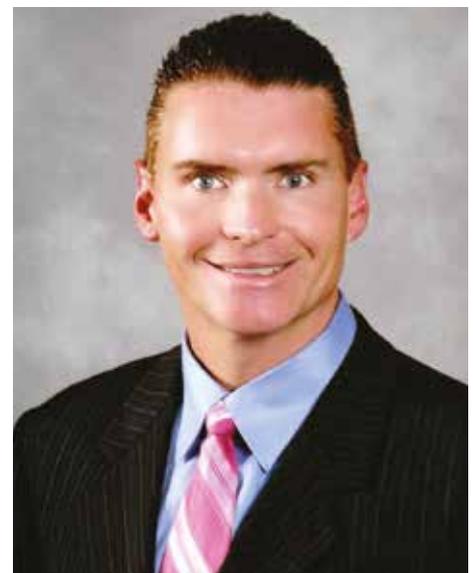
The importance of upgradeability

As chronic pain treatment options evolve, St. Jude Medical has made upgradeability a core benefit of their latest internal pulse generators (IPG). By offering upgradeable technology, St. Jude Medical hopes to allow patients to access new therapy options and software updates upon approval without the need for surgery to replace their IPG. New therapy may address the 20% to 30% of pain patients who do not respond to traditional tonic stimulation or who develop new pain who may not be able to be covered by tonic SCS.

According to Timothy Deer from West Virginia University, USA, new waveforms and treatment options and updated software will expand the ability of physicians to treat their patients effectively.

“New therapy options could play an important role in the treatment of those who are failing stimulation using conventional stimulation, and will ultimately be very valuable tools to salvage patients who have failed with tonic stimulation,” he said.

Commenting on the unique upgradeable technology of the Protégé™ Neurostimulation System, Deer said the concept of upgradeability is important in minimising the need for additional surgeries and invasive techniques. “It will also be important to continue to offer the newest evidence-based therapies as soon as they are approved for use in the United States,” he said. “This will be a significant advantage for those patients who are receiving spinal cord stimulation.”



Timothy Deer



Radiofrequency ablation

Providing physicians and patients more options across the chronic pain care continuum

Since its acquisition of NeuroTherm in August of 2014, St. Jude Medical has become the only medical device company to offer both SCS and RFA to chronic pain sufferers. The RFA products offered by St. Jude Medical can be used for a wide array of pain management procedures including facet denervation, sacroiliac denervation, and treatment of chronic knee pain.

Paul Lynch, from Arizona Pain Specialists in Phoenix, USA, provided *NeuroNews* an in-depth overview of how RFA works for the treatment of chronic pain. He explained that during an RFA procedure, radio waves are used to generate heat that can be applied to nerve clusters responsible for causing a person's pain. This controlled, targeted heat destroys the nerve's ability to transmit pain while avoiding damage to nearby nerves that control movement and non-painful sensations. According to Lynch, many patients who undergo an RFA procedure will experience pain relief for six to 12 months and some may experience pain relief for longer periods of time. *NeuroNews* asked Lynch for more detail around RFA and how physicians can leverage this therapy option.

How has radiofrequency ablation technology changed the face of chronic pain treatment?

Radiofrequency technology provides a treatment for chronic pain that creates significant long-term relief for appropriately selected patients. The therapy is also inexpensive compared to many other chronic pain treatments such as surgery or opioids.

Who are the ideal patients for radiofrequency ablation?

Ideal patients for radiofrequency ablation have moderate to severe chronic pain of a distinct anatomical region (eg., axial low back pain) that has not been relieved by appropriate conservative methods but receives temporary relief from anaesthetic injections of



Paul Lynch

the targeted nerves.

How does a physician go about prescribing radiofrequency ablation vs. spinal cord stimulation? Is one a stepping stone to the other?

Some chronic pain conditions can be appropriately treated with either radiofrequency ablation or spinal cord stimulation. Typically, radiofrequency ablation would come earlier in the treatment algorithm. Patients who have failed to get adequate relief from interventional therapies such as radiofrequency ablation may be appropriate candidates for spinal cord stimulation.

Do you think radiofrequency ablation for the treatment of chronic pain should be more widely used?

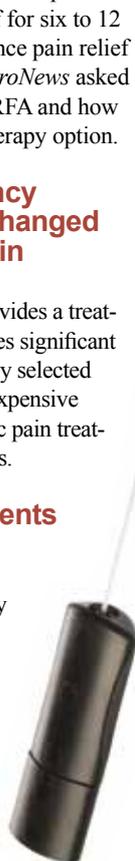
Yes. Radiofrequency ablation helps fill the gap between conservative care for pain (eg., physical therapy, chiropractor, bracing) and surgical treatments. Many physicians utilise radiofrequency ablation for basic treatments, such as lumbar facet disease, but fail to realise it is also highly effective in the cervical and thoracic spine, as well as for a variety of other conditions through peripheral nerve ablation.

What are some of the less known indications for radiofrequency ablation, and how far-reaching of a therapy to do think it has the potential to be?

Some less known indications for radiofrequency ablation include treating knee pain with genicular radiofrequency ablation, sacroiliac joint pain with sacroiliac lateral branch nerve ablation, or headache pain with occipital ablation. Radiofrequency ablation of peripheral nerve targets such as these have a high rate of success; for some of our patients RFA provides the highest rate of relief of any interventional pain procedures.

What is the future of radiofrequency ablation for the treatment of chronic pain?

In the future, the number of nerve groups targeted by radiofrequency ablation will increase. Future developments will also make the pain relief from radiofrequency ablation more consistent. Having one company offer multiple therapy options across the care continuum can help bring these effective therapies to more physicians, and therefore, more patients. A company such as St. Jude Medical also working with physicians to best identify which patients may benefit most from each therapy is also important. In this area, it is very valuable to have St. Jude Medical consistently working with physicians to understand our challenges in managing chronic pain and adapting their therapies with our feedback in mind.



The St. Jude Medical™ Invisible Trial System

A series of “firsts” designed to improve the SCS trial experience

With FDA and CE mark approval of the St. Jude Medical™ Invisible Trial System, the company is bringing patients a series of “firsts.”

Unlike any spinal cord stimulation trial system currently available, the St. Jude Medical Invisible Trial System is the industry’s first trial system to combine Bluetooth® wireless technology and the first to leverage Apple™ iPod touch™ and iPad mini™ mobile digital devices for patient and physician programmers.

Prior to receiving a permanently implanted SCS device, patients undergo a minimally invasive “trial” period to evaluate the therapy. Yet for some patients, complex controllers and bulky programming cables can disrupt the trial experience and act as barrier to SCS therapy.

With the Invisible Trial System, St. Jude Medical has removed these barriers, allowing patients to focus on evaluating their SCS therapy. The system relies on Bluetooth® wireless technology to provide patients a safe, secure and entirely wireless SCS trial experience. Rather than a complex controller, the St. Jude Medical Invisible Trial System provides patients with a more intuitive iPod touch™ mobile digital device as a controller, while physicians will utilise an iPad mini™ mobile digital device to programme and evaluate their patient’s therapy.

“I expect that the St. Jude Medical Invisible Trial System will significantly improve the trial experience for my patients,” said Stefan Schu, specialist for neurosurgery and senior physician for neuromodulation at the Sana Clinic in Duisburg, Germany. “The new system will be discreet, familiar and require no cables that can be uncomfortable. Perhaps the most important feature is that in some geographies the system will expand the range of stimulation modes available in the trial phase and thereby potentially improve the trial success rate for my patients suffering from chronic pain.”

One of the key system features of the St. Jude Medical Invisible Trial System is the use of a small external pulse generator (EPG) as the system’s power source. Because the EPG uses Bluetooth® wireless technology to communicate between the patient’s



Leonardo Kapural

iPod touch controller and the stimulation system, the overall device profile has been reduced so the system can be worn discreetly under a patient’s clothing. The effect is that the system feels essentially “invisible” to the wearer, providing a more comfortable trial experience that allows patients to focus entirely on their system’s therapeutic impact during their trial.

According to Leonardo Kapural, professor of Anaesthesiology and medical director, Chronic Pain Center, Wake Forest University School of Medicine, Winston-Salem, USA, there is great

importance in conducting a trial for spinal cord stimulation. If conducted long enough, Kapural says that a trial can help predict long-term successes of therapy in improvements of pain scores.

Comparing the St. Jude Medical Invisible Trial System to others currently available, Kapural pointed to the improved patient experience that has been achieved with the St. Jude Medical Invisible Trial System.

“Every other system today uses cables to connect the leads that are placed in the back to a power source. That power source is programmed by the company representative under the direction of the physician. Often times, patients struggle to access all of the capability that the system could offer to address their pain because the device is unfamiliar and the trial period is often too short for them to become adept at its use. This leaves them with a less than ideal experience that could result in failure of the therapy.

“What is unique about the Invisible Trial System is that it uses the familiar iPod touch as the patient controller to reduce the learning curve, and eliminates the use of excess cables reducing the potential for cables to catch on something inadvertently. If leads move out of position, the stimulation can move off of the intended anatomical target and provide less than adequate relief,” Kapural said.

Outside of the United States, where Burst SCS technology is approved, the St. Jude Medical Invisible Trial System offers both tonic and burst stimulation during the trial period, offering the patient the full experience.

Reinforcing the improvement to patient experience with the St. Jude Medical Invisible Trial System, Kapural added that this new system is “a more discreet system that is familiar and provides a patient-friendly option for their care, and we would expect compliance to our treatment plan should increase. I think the patients will find this approach particularly comfortable and I suspect patients will forget they are wearing this device and focus more on pain relief without distraction.”



MR-conditional labelling

Providing more patients access to leading technologies

With the recent FDA approval of the Protégé MRI™ Neurostimulation System and Proclaim Elite™ Chronic Pain System in the USA and CE mark approval for the Prodigy MRI™ Neurostimulation System and Proclaim Elite™ Chronic Pain System in Europe, St. Jude Medical is taking new steps to ensure patient access to their industry-leading spinal cord stimulation therapy options while removing a traditional barrier to spinal cord stimulation therapy. With the approval of updated MR-conditional labelling, patients will now be able to undergo head and extremity MRI imaging in MRI scanners with strength of up to 1.5 Tesla.

St. Jude Medical has also said that it plans to seek updated labelling in key markets around the world for several existing products and recently received FDA approval for MR-conditional labelling of their flagship Penta™ paddle lead. According to the company, the approvals of MR-conditional labelling for products within their chronic pain portfolio represent a critical component to growing their neuromodulation business and improving access to industry-leading chronic pain therapies for patients who may need future head and extremity MRI scans.

“Clinical experience suggests that while relief from chronic pain remains the primary need for patients seeking spinal cord stimulation therapy, some patients who may benefit from SCS therapy may also need future MRI scans,” said Athanasios Koulousakis, head of the Department

Functional Neurosurgery, Spasticity and Pain, University Hospital in Cologne, Germany.

“So while the number of SCS patients requiring future MRIs may be limited, it is still

critical to remove barriers to diagnostic options. Yet just as critical is providing MRI capability in SCS solutions that provide access to new therapy options. The new Prodigy MRI system helps put all such requirements into one package for our patients.”

NeuroNews recently spoke to Jason Pope, president of the Summit Pain Alliance, USA, about the importance of MRI compatibility and the value in patients having options of choosing SCS systems with MR-conditional labelling.

Why is MR-compatibility important?

MRI is an imaging modality that aids in the diagnosis of neurodegenerative disorders and extremity joint pain. For these patient challenges, MRI is the imaging modality of choice for these conditions, like malignant brain tumours and Multiple Sclerosis. Further, extremity MRI can aid in orthopaedic diagnoses.

Before this technology, how large of a barrier was the need for MRI scans to patients who would potentially benefit from spinal cord stimulation?

MRI is an important diagnostic tool for a select group of patients. The philosophy of adding MR-conditional labelling to an upgradeable system and eliminating

some of the imaging restrictions imposed on other healthcare management tools speaks to a patient-centric innovation model St. Jude Medical has taken.

How do you think MR-conditional labelling will change current practice and decision-making in terms of the option of spinal cord stimulation?

My practice has expanded to provide the best technology available to my patients, focused on patient safety and efficacy, with MR-conditional labelling. In the past, if patients were asked to choose between the best available technologies to treat their pain most effectively or access to MRI testing, the vast majority would choose the chance to have their pain most effectively managed. Now, with MR-conditional labelling, patients do not have to make such a polarised decision.

How has the MRI conditional device changed from the original Prodigy™ and Protégé™ Neurostimulation Systems?

Through the activation of multiple MRI dependent components as well as a new patient programmer the implanted pulse generator (IPG) can be placed into MRI Mode to protect against lead heating, device damage, and patient harm.



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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. Radiofrequency Ablation: Rx Only. Brief Summary: Please review the instructions for use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. Indications for Use: The NT2000iX™ generator is intended for lesioning neural tissue. The NT2000iX™ generator is intended to be used for pain management. The NT2000iX™ generator is to be used only with separately cleared/approved lesion/temperature probes (NeuroTherm™ radiofrequency probes and

SPINECATH™ and ACUTHERM™ catheters). The NT2000iX™ generator is indicated for use in the peripheral nervous system.

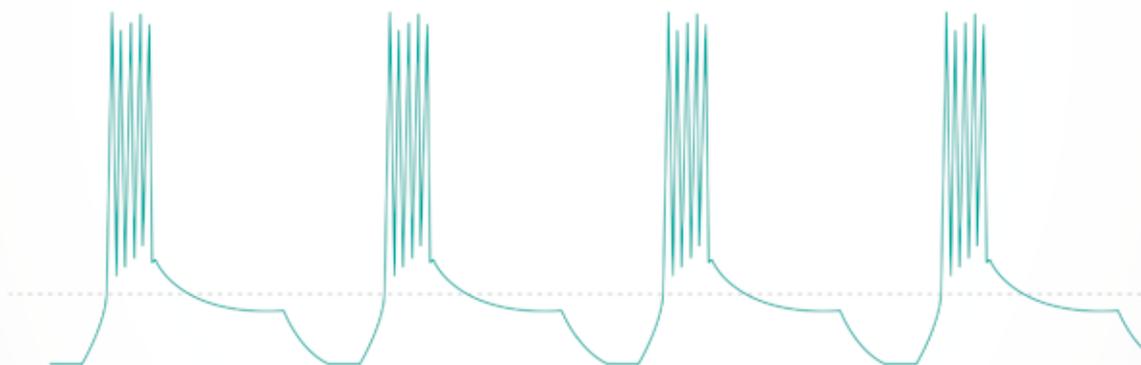
Warnings/Precautions: Physicians must read the instructions for use before operating Neurotherm radiofrequency ablation products. Potential risks include: hazardous electrical output, electric shock, fire hazard, pooling hazard, ignition hazard, and the risk of burn or injury to patients. SJM-COR-1015-0172 - Item approved for global use.

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Innovation means nothing without results. So while others may try to replicate the St. Jude Medical Burst waveform, ours is being supported by a growing body of evidence* and rigorous product development. At St. Jude Medical, we don't just advertise our innovation—we prove it.



[*Learn more at SJM.com/Burst](http://SJM.com/Burst)



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