Medtronic

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Recomendações para pacientes portadores com eletrodos Sprint Fidelis®

São Paulo, 15 de outubro de 2007

Prezado Doutor,

A Medtronic sempre comprometida em assegurar o mais alto padrão de confiabilidade de seus produtos, divulga uma informação relevante sobre o desempenho do eletrodo Sprint Fidelis e recomenda uma observação rigorosa no acompanhamento dos pacientes, portadores deste dispositivo. Os nossos registos indicam que o sr. implantou ou acompanha pacientes portadores de eletrodos Sprint Fidelis (Modelos 6930, 6931, 6948, 6949). Após consultar o nosso " Comite de Médicos Independentes para a Qualidade", e o Dr. Bruce Lindsay M.D. Professor of Medicine at Washington University School of Medicine e atual presidente do Heart Rhythm Society (HRS- USA) , decidimos interromper voluntariamente a distribuição, em todo o mundo, dos eletrodos Sprint Fidelis. Esta decisão foi tomada apoiada em vários fatores detalhados na presente carta, que em conjunto indicam, e se justifica a interrupção dos implantes destes eletrodos. Desaconselhamos a implantar eletrodos modelo Sprint Fidelis e recomendamos a utilização de outros modelos.

Através de uma avaliação detalhada, identificamos dois locais primários onde fraturas do condutor têm sido observadas: 1) porção distal do eletrodo; 2) próximo ao ponto de fixação do manguito. As fraturas do condutor distal afetam o anodo (anel do eletrodo) e as que acontecem ao redor do ponto de fixação do manguito, afetam o catodo (espiral do eletrodo). A ocorrência deste fato, em ambos os locais, apresentam-se, clinicamente, como "over-sensing", contagens de intervalos aumentadas e choques inapropriados. A Medtronic tem trabalhado com médicos que relataram estas ocorrências, tendo conduzido testes importantes em bancada na tentativa de reproduzir a situação observada e identificar a causa. Neste momento, nossa investigação sugere que variáveis dentro do procedimento de implante possam contribuir significativamente para isso.

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Recomendações

A Medtronic recomenda o seguinte como parte integrante do acompanhamento de rotina de cada paciente: Reduzir o risco de detecção e de terapias inapropriadas, motivada por oversensing, programando a detecção de FV, ajustando o Número de Intervalos a Detectar (NID) inicial para parâmetros nominais (18/24) ou superior conforme avaliação do médico e NID de Re-detecção para parâmetros nominais (12/16).

Ligar (ON) o Patient Alert™ para as impedâncias de Pacing do VD , de desfibrilhação do VD e de desfibrilação da VCS.

Para a otimização da eficácia do alerta de impedância do eletrodo:

- Rever a curva de comportamento de estimulação V do eletrodo para calcular o valor habitual da impedância cronica do paciente (os valores habituais dos eletrodos Fidelis devem estar entre 350-1000 ohms).
- Limite máximo de alerta de impedância do eletrodo para estimulação do VD de 1000 ohms, no caso da impedância cronica normal do paciente ser ≤ 700 ohms, ou
- Limite máximo do alerta de impedância do eletrodo para estimulação do VD de 1.500 ohms, no caso de impedância cronica normal do paciente ser ≥ 700 ohms.
- Limite máximo do alerta de impedância do eletrodo para desfibrilhação do VD e da VCS de 100 ohms.

Estima-se que as recomendações relativas ao tratamento do paciente acima referidas aumentem a probabilidade da fratura ser detectada pelo Alerta do Paciente e reduzam a possibilidade de administração de terapias inapropriadas. Conforme a revisão dos dados disponíveis, um acompanhamento mais frequente não parece trazer um benefício adicional

O Comitê de Médicos Independentes para a Qualidade da Medtronic, o Dr. Bruce Lindasy, e o EHRA Board, consideram pouco apropriado a remoção profilática dos eletrodos Sprint Fidelis, com a exceção de alguns casos individuais. A Medtronic apoia esta posição.

Medtronic é comprometida em assegurar os mais altos padrões de confiabilidade do produto. Com o avanço das nossas descobertas, compartilharemos informações adicionais e orientação técnica através de nossos representantes de vendas e assessores técnicos. Em caso de dúvida, nos colocamos à disposição.

Cordialmente,

Dr. Roberto Takeda
Gerente Médico da Medtronic do Brasil

Milton Munhoz
Gerente de Marketing da Medtronic Brasil

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European Heart Rhythm Association (EHRA)

Sprint Fidelis Implantable Cardiac Leads

"Medtronic, Inc informed today that it has decided to suspend the distribution of the Sprint Fidelis® defibrillation leads because of the potential for lead fractures. The company today also recommends physicians to stop the implant of the leads.

The decision has been taken by the company as a consequence of the evaluation of the performance data of the Sprint Fidelis leads showing that at 30 months the viability of Sprint Fidelis is 97.7% as compared to the viability of the Sprint Quattro leads that at the same time point is 99.1%. The estimate regarding the Sprit Fidelis leads comes from the company's System Longevity Study data and it is confirmed by the monitoring through the Carelink Network on 25000 devices.

Based on data available at present time, EHRA Board agrees with the opinion of the Independent Physician Quality Panel of Medtronic that the risk of removal or of the insertion of another lead is greater than the risk associated with lead fracture according to recent literature's data (Bracke et al. Europace May 2004; 6(3):243-247 Kennergren et al. Europace. August 2007; 9(8):651-656.)

The standard follow-up of three months of the leads is recommended.

The following actions recommended by the company seem reasonable to increase appropriate detection of a lead fracture by Patient Alert and/or Medtronic CareAlert notifications and they may also reduce the probability of the delivery of inappropriate shocks:

Turn ON Patient Alert™ for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance. For Concerto® and Virtuoso® devices enrolled on the Medtronic CareLink™ Network, turn ON the CareLink CareAlert® notifications for these same parameters.
To reduce the risk of inappropriate detection and therapy due to oversensing, program VF detection for initial Number of Intervals to Detect (NID) to nominal settings (18/24) or longer at physician discretion and Redetect NID to nominal settings (12/16).
To optimize effectiveness of the lead impedance alert:

* Review V Pacing Lead Performance Trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms).
* Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is ⩽ 700 ohms, or
* Program lead impedance alert threshold for RV Pacing to 1,500 ohms, if the typical chronic impedance for the patient is > 700 ohms.
* Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.

EHRA board will continue to carefully monitor information as they become available and will issue updates of this statement as they become appropriate."

Josep Brugada
EHRA President

Silvia G Priori
Immediate Past President of EHRA

Panos Vardas
EHRA President Elect

Angelo Auricchio
Chairman of the Committee for Scientific Documents

FDA Statement

FOR IMMEDIATE RELEASE
October 15, 2007

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Statement on Medtronic's Voluntary Market Suspension of Their Sprint Fidelis Defibrillator Leads

Statement by Daniel Schultz, M.D., director of the Center for Devices and Radiological Health:

Medtronic's decision to voluntarily remove its Sprint Fidelis defibrillation leads from the market is in the best interest of patient safety.

These electronic wires are prone to fracture in a small number of patients which can cause the defibrillator to deliver unnecessary shocks or not operate at all. Based on our initial review of reported adverse events, some deaths and major complications have occurred after the leads have fractured.

Defibrillators are life-saving products for patients with a heart rhythm abnormality. We know it can be frightening for a patient to learn that a product they rely on so much might have a serious defect. However, patients can be assured that the likelihood of fracture is very low and FDA is committed to ensuring that the risk to patients is minimized.

Background:

Today, Medtronic announced it was voluntarily suspending distribution of its Sprint Fidelis defibrillation leads because a small number of fractures have been detected. As a result of Medtronic's action, no more Sprint Fidelis leads will be sold or manufactured and any remaining product should be pulled from inventory and returned to the company. Patients who are implanted with this lead are encouraged to contact their physicians for further information.

Medtronic first notified physicians in March about the fracture rate at that time and the proper method for implantation. Additional data on adverse events accumulated since then has prompted today's action.

Implantable cardioverter defibrillators (ICDs) and Cardiac Resynchronization Therapy-Defibrillators (CRT-Ds) are used to treat abnormal heart rhythms that can cause the heart to stop suddenly. ICDs and CRT-Ds shock the heart back into normal rhythm by sending a pulse of energy through an electronic wire or lead that is connected to the heart.

When a defibrillator lead is slightly more prone to fracture, it doesn't mean that every lead will break. Most leads will function well, as is the case with Sprint Fidelis. In the infrequent circumstance where a lead actually breaks, or "fractures," the lead may send false signals that cause inappropriate defibrillator shocks, or therapies such as pacing or shocks may not be delivered.

Current adverse event information indicates that fractures have occurred in less than 1 percent of the approximately 268,000 of these leads implanted worldwide. We don't know if this rate of adverse events will remain constant or increase over the life of these leads.

FDA considers Medtronic's action to be a product recall, as defined by FDA regulations, and we will soon be issuing a recall classification for this action. We recognize that some patients and health care professionals might inappropriately interpret the word "recall" to mean that the devices must be surgically removed and returned to the manufacturer. Although the leads should no longer be implanted in patients, we do not mean to imply that these leads should be surgically removed.

The leads continue to function properly in the vast proportion of patients. Although there is no test to predict which lead will fracture, FDA agrees with Medtronic's recommendation that defibrillator settings be adjusted at the patient's next scheduled follow-up visit with their doctor. Doing so may increase the likelihood that a fracture will be detected before a patient is harmed.

Neither FDA, Medtronic, nor representatives of the Heart Rhythm Society, recommend the routine surgical removal of a fractured lead because removal carries risks. Instead, physicians should weigh the benefits and risks of either continuing to use the lead with careful monitoring or capping the lead so it is no longer useable and implanting a different model.

Patients should recognize that a small number of Sprint Fidelis leads are used with defibrillators made by manufacturers other than Medtronic. If patients have reason to believe that they have a Sprint Fidelis lead or if they do not know the model of their lead, they should contact their health care professional.

FDA will continue to monitor information on these devices and will take whatever other actions may be necessary.

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