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Important Medical Device Information

July 29, 2014

Subject: Nanostim™ Leadless Pacemaker & Delivery System Catheter, Model S1DLCP

Dear Doctor,

St. Jude Medical is performing a voluntary Field Safety Corrective Action related to the Nanostim™ Leadless Pacemaker System. St. Jude Medical became aware of a limited number of pericardial effusion adverse events during the implant procedure. Those events were observed during our Post Market clinical Follow up (PMCF) study. St. Jude Medical performed a comprehensive investigation into these events and the results were discussed with the PMCF Study Steering Committee. Factors that contributed to the pericardial effusion events during the implant procedure include patient selection and implant technique.

Please refrain from implanting the Nanostim™ Leadless Pacemaker until the below steps are completed.

The actions below are being implemented as part of the Field Safety Corrective Action:

- Revision of the Instructions for Use (IFU) (see change summary Table included in Annex) to include additional warnings, cautions and clarification on implant practices. This revision has been approved by the Notified Body
- Amendment of the PMCF protocol to align with the revised IFU
- Additional training of all implanting physicians and SJM personnel on implant steps and best practices and the revised PMCF protocol

The study will be reinitiated in the PMCF centers upon fulfillment of the following conditions:

- Amended PMCF protocol approved by local Ethics Committee and where appropriate by Competent Authorities
- Retraining of implanting physicians

There is no change to existing patient follow-up requirements.

A detailed description of the significant changes made to the Instructions for Use of the Nanostim™ Leadless Pacemaker and Nanostim™ Delivery System Catheter is provided in the Annex.

Please review this information with all members of your staff who need to be aware of the contents of this communication.

St. Jude Medical is committed to providing the highest quality products and support. This action has been communicated to the appropriate authorities and Ethics Committees.

If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.

Sincerely,

Roland Gerard
VP, Quality and Regulatory Affairs
St. Jude Medical

Nanostim™ Leadless Pacemaker and Nanostim™ Delivery System Catheter **IFU SIGNIFICANT CHANGE SUMMARY**	
Old Instructions For Use	**Revised Instructions For Use**
Contraindications	
CONTRAINDICATION *Use of a leadless pacemaker could involve higher levels of risks, compared to those of conventional pacemakers, due to inadvertent pulmonary embolism of the pacemaker in patients also presenting with elevated right-ventricular pressure or reduced pulmonary reserve.*	***REVISED CONTRAINDICATION*** *The leadless pacemaker is contraindicated for use in patients with pre-existing pulmonary arterial (PA) hypertension (PA systolic pressure > 40 mmHg or RV systolic pressure > 40 mmHg) or significant physiologically-impairing lung disease.*
Warning	
	NEW WARNING *Careful consideration should be given to patients who have had cardiovascular or peripheral vascular surgery/intervention within the last 30 days because these patients may have a higher risk of complications.*
	NEW WARNING *Implant of a Nanostim leadless pacemaker should not be attempted in the presence of an active perforation. Implant sites where a previous clinical event such as perforation or lead extraction with myocardial tissue removal should be avoided as this may result in a higher rate of perforation.*
Room and Patient Preparation	
ROOM AND PATIENT PREPARATION *Implantation should be performed only when:* *• proper emergency facilities for cardioversion and/or defibrillation are available.*	***REVISED ROOM AND PATIENT PREPARATION*** *Implantation should be performed only when:* *• proper emergency facilities for cardioversion, defibrillation and cardio-pulmonary resuscitation are available.* *• proper equipment is available for high resolution fluoroscopy including the ability to record and save images, to zoom, and to obtain images in multiple projections.*
Insert the Nanostim™ Leadless Pacemaker and Nanostim™ Delivery System Catheter	
	NEW CAUTION *Do not independently advance the delivery catheter as this may advance the LP outside of the protective sleeve and leave the LP helix exposed and result in damage to the LP helix. Do not advance the device by pushing the device from the handle or delivery catheter.*

Position the Guide Catheter and Nanostim™Leadless Pacemaker	
CAUTION *If there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle (for example, use of oral steroids, apical right ventricular infarction, history of ARVD), consider a lower septal site for placement of the Nanostim™ Leadless Pacemaker (LP).*	***CAUTION TO WARNING*** *To reduce risk of perforation, consider a lower septal site for placement of the Nanostim™ Leadless Pacemaker (LP), especially if there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle (for example, use of oral steroids, right ventricular infarction, history of ARVD.*
CAUTION *If the awake patient feels a twinge of pain, this may be an early sign of perforation.*	***CAUTION DELETED***
	NEW WARNING *Do not apply excessive forward force to the delivery catheter, because perforation can occur.*
NOTE *Do not advance all the way to the apex with the protective sleeve covering the device (see the picture that follows), because this could result in perforation.*	***NOTE TO WARNING*** *Do not advance the LP to the endocardium until the protective sleeve, is fully retracted because this may result in perforation.*
CAUTION *Maintain LP position as you pull back the guide catheter protective sleeve, because movement could lead to perforation or entanglement.*	***CAUTION TO WARNING*** *Maintain the LP position by holding the delivery catheter handle on the patient table as you slowly pull back the guide catheter protective sleeve, because movement could lead to perforation or entanglement. Fix the delivery catheter handle on the patient table, without bending, so that relative movements can be made in a controlled manner. The protective sleeve should be fully retracted before advancing the LP to the endocardium.*
Affix the Nanostim™ Leadless Pacemaker in the Right Ventricular Area	
NOTE *Turns of the control knob will not necessarily match turns of the device during implantation.*	***NOTE*** *Turns of the control knob will not necessarily match turns of the device during implantation. Do not exceed 16 clicks of the control knob and do not exceed 1.25 turns of the LP device.*
5. Continue to turn the control knob slowly until you have visualized 1 1/4 turns of the device. Count approximately 12-16 total clicks of the control knob. *Do not exceed 16 clicks when affixing, because this may lead to perforation.*	*5. Continue to turn the control knob slowly until you have visualized a minimum of 1 turn and a maximum of 1.25 turns of the device radiopaque marker. Do not exceed 16 clicks of the control knob or rotation of the device radiopaque marker beyond 1.25 turns when affixing, because this may lead to perforation.*
Assess Pacing and Sensing Thresholds	
	NEW WARNING *If the device does not capture at maximum pulse amplitude and pulse width (6.01V/1.5ms) and the impedance is >2000 ohms, consider the possibility that perforation has occurred, leave the device in place, perform an echocardiogram and prepare for possible urgent pericardiocentesis.*