ST. JUDE MEDICAL

January 16, 2008

Important Device Upgrade Information

Epic and Atlas Family of ICDs

Dear Doctor,

St. Jude Medical is making a programmer software upgrade available to resolve and eliminate a very rare occurrence (incidence of 8 in 143,000 devices) that could lead to a ventricular sensing anomaly in our Epic and Atlas families of Implantable Cardioverter Defibrillators (ICDs). The new programmer software (version 6.4.1 for Merlin PCS and version 6.5.1 for Model 3510) will allow a programmer to automatically identify a device that can benefit from a firmware upgrade to resolve and eliminate the potential issue with a simple, one time device software upgrade.

St. Jude Medical Field Sales Staff and Field Clinical Engineers will install this software upgrade in Merlin PCS and Model 3510 programmers in the field. Thereafter, upon initial interrogation of an Epic or Atlas family ICD, the Merlin or 3510 programmer will automatically identify implanted devices that require a firmware upgrade and will inform the clinician with a message that an upgrade should be performed. The programmer will complete the device upgrade in approximately 10-20 seconds. During the upgrade process the device continues to function as programmed, with all bradycardia and tachycardia functions fully available.

Approximately 143,000 Epic and Atlas family ICDs have been implanted worldwide since July 2002; approximately 123,000 of these devices remain in service. To date, 8 out of 143,000 of the subject device population (an incidence of 0.00006) have been found to exhibit a loss of ventricular sensing, with a risk of patient harm estimated to be on the order of 1 in 1 million (0.000001).

The loss of ventricular sensing has been attributed to a well defined, yet extremely rare timing sequence that occurs in a very small (61 microsecond) timing window. No patient injuries or deaths have been reported to St. Jude Medical as the result of a device entering the described loss of sensing state. As mentioned above, the potential issue can be fully resolved and eliminated by a programmer initiated upgrade to the device.

In summary:

- A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available.
- St. Jude Medical along with our independent Medical Advisory board members have determined that no other action is recommended.

If you have any questions or would like to discuss this topic in greater detail, please do not hesitate to contact your local Sales Representative or Technical Services at 800-722-3774.

Sincerely,

Kathleen M. Chester

Kathleen Chester
Vice President, Regulatory Affairs and Quality Assurance

PHYSICIAN DEVICE ADVISORY NOTICE
LOSS OF VENTRICULAR SENSING
Advisory Date: January 16, 2008

Manufacturer(s)	**St. Jude Medical**	
Product(s)	**Trade Name** **Epic ICDs** **Atlas ICDs**	**Model Number** **Epic V-197, V-235, V-337, V-338, V-339** **Epic+ V-196, V-233, V-236, V-239, V-350** **Epic II V-158, V-255, V-258, V-355, V-356, V-357** **Atlas+ V-340, V-341, V-343, V-193, V-242, V-243** **Atlas II V-168, V-265, V-268, V-365, V-366, V-367**
Manufactured on or before (Date)	**Not applicable (N/A)**	
Performance Failure	**A very rare condition that could lead to a ventricular sensing anomaly in Epic and Atlas family of Implantable Cardioverter Defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia.**	
Root Cause (if known)	**The loss of ventricular sensing has been attributed to a random, yet understood extremely rare timing sequence that may occur in a very small (61 microsecond) timing window.**	
Date Manufacturer Corrected Product Available (if known)	**A programmer software/device firmware upgrade will eliminate this issue and prevent future occurrences. This upgrade is available in the field starting Jan. 16, 2008.**	
Has all affected product been retrieved?	**☐ Yes ☑ No**	**When?** **Devices do not need to be retrieved or replaced. An update to programmer software will eliminate this anomaly when the device is interrogated.**

FDA CLASSIFICATION STATUS

Advisory classification **Class:** ☑ **Decision Pending**

CLINICAL ACUITY

	(USA)	*(Worldwide)*
a) Total number of units currently implanted	**Approximately 114,000 currently implanted. This is based on US patient registration information provided to the company.**	**Approximately 123,000 currently implanted. This is based on worldwide patient registration information provided to the company.**
b) Estimated number of potentially affected devices of this model	**This is a random occurrence potentially affecting all of the units identified in a) above.**	**This is a random occurrence potentially affecting all of the units identified in a) above.**
c) Estimated incidences of this performance failure over the projected life of the device	**None -this issue will be eliminated in all devices following programmer software update.**	**None -this issue will be eliminated in all devices following programmer software update.**
d) Total number with observed Performance Failure	**6**	**8**
% of Performance Failures d/b x 100=	**0.005%**	**0.007% (based on 8 failures out of 123,000 currently implanted devices worldwide)** **(Note: the 0.006% identified in the Doctor letter is based on 8 failures out of 143,000 total worldwide implants)**
e) Mean age of product in implanted population	**1.8 years**	**1.8 years**

f) Patient deaths reported	**☐ Yes**	**☑ No**
Number of deaths =	**0**	**0**
g) Patient deaths with probable relationship to device failure	**☐ Yes**	**☑ No**
Number of deaths =	**0**	**0**

* The data analysis provided in this report was generated by the manufacturer and may be subject to change.