

ST. JUDE MEDICAL
Global Leadership in Medical Technology
St. Jude Medical, Inc.
Corporate Relations
One Lillehei Plaza
St. Paul, Minnesota 55117 U.S.A.
651-481-7790
Fax: 651-490-4333



Contacts:	Laura Merriam	Peter Gove
	Investor Relations	Media Relations
	(651) 766-3029	(651) 481-7790

St. Jude Medical Recalling Heart Valve Products with Silzone® Coating

St. Paul, MN, January 24, 2000 - - St. Jude Medical, Inc. (NYSE: STJ) announced today that on January 21 it had initiated a worldwide voluntary recall of all field inventory of heart valve replacement and repair products incorporating its proprietary Silzone® coating on the sewing cuff fabric, and will no longer distribute products with Silzone. The Company is advising all of its clinician customers, after consultation with the U.S. Food and Drug Administration (FDA) and other regulatory agencies, of its decision to voluntarily recall and cease distribution of Silzone. St. Jude Medical is not recommending explants of its products with Silzone coating unless routine patient monitoring detects specific complications.

These actions follow reports in an independently managed clinical trial evaluating SJM mechanical heart valve products with Silzone coating of an unacceptable level of product explants as a result of a specific postoperative complication known as Paravalvular leak. This trial, sponsored by St. Jude Medical and designed to compare the incidence of endocarditis (a life-threatening, postoperative infection) in valves with and without Silzone coating, also captured all normally reported complications common to heart valve replacement surgery.

The Silzone technology was first introduced in 1997 with the potential to reduce the incidence of endocarditis in valve procedures. St. Jude Medical estimates there have been approximately 36,000 implants worldwide of St. Jude Medical heart valve replacement and repair products with Silzone coating. The Company emphasized the reported complication does not involve the valve mechanism itself. Rather it appears to be associated with the Silzone-coated sewing cuff fabric.

Non-Silzone coated products, which represent 75% of the Company's heart valve shipments, are not affected by this announcement.

This clinical trial, known as AVERT (Artificial Valve Endocarditis Reduction Trial), was designed as the largest, most rigorous, prospective clinical trial ever in the prosthetic heart valve industry. It is an independent, multi-year, multi-center randomized study intended to follow 4,400 patients to study the efficacy of Silzone coating on the valve sewing cuff fabric in reducing infection following valve replacement surgery.

Based on data from the 792 patients enrolled in AVERT as of January 6, 2000, an independent Data and Safety Monitoring Board advised St. Jude Medical on January 21 that further enrollment in the AVERT study was suspended, given an unacceptable level of explants due to paravalvular leakage in the Silzone “arm” of AVERT. Eight explants for paravalvular leak have been reported out of a total of 398 patients enrolled in the Silzone “arm” of AVERT. One explant for paravalvular leak has been reported out of a total of 394 patients in the non-Silzone “arm” of AVERT.

This complication occurs even though the valve is properly manufactured. Silzone coating is impregnated in the valve sewing cuff fabric and is not related to the design, manufacture or function of the valve mechanism. These valve explants are a physician response to paravalvular leakage, which occurs where blood leaks at one or more points around the outside of the implanted valve, between the sewing cuff of the valve and the heart tissue.

St. Jude Medical, as a result of the recommendation from the Data and Safety Monitoring Board, made the decision to immediately recall all field inventory and cease distribution of all products with Silzone coating.

The reported complications requiring intervention were detected as part of standard patient follow-up and were treated by a reoperation. St. Jude Medical is recommending to its clinician customers that normal postoperative monitoring will detect this complication. If this complication arises, it typically does not present an emergency situation.

As a precautionary step, St. Jude Medical is also recalling and ceasing distribution of tissue valve and repair products with Silzone coating not involved in AVERT. No abnormal trends have been identified from the reports of complications associated with these products. The Company plans to replace customer inventories of products with Silzone coating on the sewing cuff fabric with its products without Silzone.

Dr. Robert W. Frater, a cardiac surgeon from New York City and Medical Director of the Company’s Heart Valve Division, said, “Despite its promise to reduce endocarditis, given the higher explant rates related to paravalvular leakage recently reported in AVERT of products with Silzone on the sewing cuff, it is prudent for St. Jude Medical to recall these products. Patients with Silzone products should not be concerned, as the usual monitoring of heart valve patients is sufficient to detect this complication. They should contact their physician with any questions.”

St. Jude Medical will record a non-recurring charge against first quarter 2000 earnings in the range of \$16-20 million for the write-off of inventory and other costs related to this recall and product discontinuation. Other than this non-recurring charge, the Company believes at this time that the Silzone actions will not materially impact its year 2000 earnings outlook.

On behalf of St. Jude Medical, Steven J. Healy, President of the St. Jude Medical Heart Valve Division, said, “Given the action of the Data and Safety Monitoring Board, we made the correct decision to recall products with Silzone® coating on the sewing cuff fabric and discontinue the use of this technology. Patient safety is our number one priority. The AVERT study, although

Designed to compare the effect of Silzone in reducing endocarditis, provided the detailed data that led to our decision. Without the randomized, prospective design of AVERT, this trend would have been much more difficult to identify.

“We regret that heart valve recipients may be affected by this announcement. We urge patients with prosthetic heart valves who are concerned to contact their physician. We anticipate only a very small number of patients with heart valves with Silzone sewing cuff fabric will require medical intervention other than the normal patient monitoring that is standard for individuals with prosthetic heart valves. As the global market leader in heart valve disease management, we have a profound responsibility to respond promptly and appropriately when information such as this emerges from a rigorous clinical study. We believe the actions we are announcing today are in the very best interest of patients and our surgeon customers,” Healy concluded.

Any statements made regarding the Company’s anticipated revenues, earnings and potential clinical success are forward-looking statements which are subject to risks and uncertainties, such as those described in the Company’s Annual Report on Form 10-K for the year ended December 31, 1998 (see pages 28-29). Actual results may differ materially from anticipated results.

St. Jude Medical, Inc. (www.sjm.com) is dedicated to the design, manufacture and distribution of innovative medical devices of the highest quality, offering physicians, patients and payers unmatched clinical performance and demonstrated economic value.