

January 21, 2000

URGENT – MEDICAL DEVICE RECALL & ADVISORY

Dear Doctor and other St. Jude Medical Customers:

SUBJECT: **MEDICAL DEVICE RECALL & ADVISORY NOTIFICATION**

Product: All St. Jude Medical Silzone® coated mechanical heart valves and Silzone® coated annuloplasty rings
Lot Numbers: All lot numbers

Issue Description

This letter is to inform you that St. Jude Medical has initiated a voluntary product recall involving all products that have Silzone® coating. These products, which are identified on Attachment A, have a silver coating applied to the sewing cuff.

This recall does not affect St. Jude Medical products without the Silzone® coating.

St. Jude Medical's action in this matter is voluntary, and we have informed the U.S. Food and Drug Administration.

Reason for Recall

St. Jude Medical has received information that indicates there is a statistically significant higher rate of paravalvular leak leading to valve explants in patients implanted with St. Jude Medical® mechanical heart valves with Silzone® coated sewing cuffs.

Action Requested

Please discontinue the use of Silzone® coated products immediately. In addition, please immediately inspect your inventory for any Silzone® products identified on Attachment A and quarantine all the products with Silzone® coating as you follow the instructions below.

Disposition of Product

Once product described on Attachment A has been identified and quarantined, immediately proceed to return this product to:

St. Jude Medical
One Lillehei Plaza
St. Paul, MN 55117
Attention: Silzone® Product Return

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For purposes of returning Silzone® coated product to us, use St. Jude Medical's Federal Express Account Number, 055406871, and request Priority Overnight Service so that St. Jude Medical will cover the cost of the return shipment. You do not need a return authorization number.

St. Jude Medical will make every effort to replenish the product you are returning with non-Silzone® coated product. Your St. Jude Medical representative will be in contact with you with additional information pertaining to your hospital.

Should you have any questions regarding this matter, please contact the following numbers:

- For questions regarding the return of recalled product and replacement product contact St. Jude Medical's Customer Service Department at 800/544-1664.
- For any technical related questions on this product recall, contact St. Jude Medical's Technical Assistance Hotline at 800/922-9219.

In a separate letter, St. Jude Medical is providing you with more information concerning this recall, including the reasons for the recall, background about the clinical issues and the company's recommendations for patient follow-up.

We apologize for any inconvenience or difficulty this recall may cause you, and we appreciate your cooperation and assistance.

Sincerely,

St. Jude Medical, Inc.



Donald S. Guzik
Vice President, Quality Systems and Regulatory Compliance

ATTACHMENT A

Names of St. Jude Medical Products with Silzone® coating:

- **SJM® Masters Series mechanical heart valve with Silzone® coating.**
- **SJM Regent™ valve with Silzone® coating.**
- **SJM® Séguin annuloplasty ring with Silzone® coating.**
- **SJM Tailor™ annuloplasty ring with Silzone® coating.**

St. Jude Medical® mechanical heart valve products with Silzone® coating:

<u>Standard Polyester</u>	<u>Expanded Polyester</u>	<u>HP Cuff</u>	<u>Expanded HP Cuff</u>	<u>Regent™</u>
19AS-601	19AECS-602	17AHPS-605	17AEHPS-605	17-AG-701
21AS-601	21AECS-602	19AHPS-605	19AEHPS-605	19-AG-701
23AS-601	23AECS-602	21AHPS-605	21AEHPS-605	21-AG-701
25AS-601	25AECS-602	23AHPS-605	23AEHPS-605	23-AG-701
27AS-601	27AECS-602	25AHPS-605	25AEHPS-605	25-AG-701
29AS-601	29AECS-602	27AHPS-605	27AEHPS-605	27-AG-701
31AS-601	31AECS-602			29-AG-701
		17MHPS-605	17MEHPS-605	
19MS-601	19MECS-602	19MHPS-605	19MEHPS-605	
21MS-601	21MECS-602	21MHPS-605	21MEHPS-605	
23MS-601	23MECS-602	23MHPS-605	23MEHPS-605	
25MS-601	25MECS-602	25MHPS-605	25MEHPS-605	
27MS-601	27MECS-602	27MHPS-605	27MEHPS-605	
29MS-601	29MECS-602			
31MS-601	31MECS-602			
33MS-601	33MECS-602			
35MS-601				
37MS-601				

St. Jude Medical annuloplasty rings with Silzone® coating:

SJM Tailor™ with Silzone® coating

TAR-25	TAR-31
TAR-27	TAR-33
TAR-29	TAR-35

SJM® Séguin with Silzone® coating

SARS-M24	SARS-M32	SARS-M40
SARS-M26	SARS-M34	
SARS-M28	SARS-M36	
SARS-M30	SARS-M38	