



# DEFECT & INVESTIGATION CENTRE

**FOR ACTION BY:**

Chief Executive of each HSS Trust  
General Manager/Chief Executive of each HSS Board  
General Manager/Chief Executive of each Agency  
General Practitioners

Stoney Road Dundonald  
Belfast  
Northern Ireland BT16 1US

**ADVICE NOTICE (NI) 2000/01**

**Date: 3 February 2000**

Telephone 01232 523745  
Facsimile 01232 523900  
GTN Code 440

Product	:	Silzone® Prosthetic Heart Valves and Annuloplasty Rings
Manufacturer/ Supplier	:	St Jude Medical Inc Master Series™ & Regent™ Mechanical Heart Valves with Silzone® coating:  Aortic: XXAS-601, XXAECS-602, XXAHPS-605, XX-AG-701, XXAEHPS-605 Mitral: XXMS-601, XXMECS-602, XXMHPS-605, XXMEHPS-605 Epic™ Tissue Heart Valve with Silzone®: ELS-XXA, ELS-XXM Annuloplasty Rings with Silzone®: TAR-XX (Tailor Ring), SARS-MXX (Sequin ring)  XX = valve size
Issue	:	Recall of prosthetic heart valves and annuloplasty rings with Silzone® coated sewing cuffs due to high rate of paravalvular leak leading to valve explant.

**ADVICE NOTICE**

**1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS**

This Advice Notice should be brought to the immediate attention of all who need to know, or be aware of it including those listed below, in accordance with local procedures, and immediate action should be taken as detailed overleaf:

- ◆ Nursing Directors
- ◆ Medical Directors
- ◆ Directors of Cardiothoracic Surgery
- ◆ Cardiothoracic Surgeons
- ◆ Directors of Cardiology
- ◆ Cardiologists
- ◆ Risk Managers
- ◆ Safety Liaison Officers

Boards/Trusts should ensure that if appropriate, this information is passed to ALL persons having the responsibility for premises registered under "THE REGISTERED HOMES (NI) ORDER 1992".



**2. IMMEDIATE ACTION**

- 2.1 Do not implant Silzone® coated prosthetic heart valves or annuloplasty rings.
- 2.2 Identify and isolate any remaining stocks of Silzone® coated prosthetic heart valves or annuloplasty rings and return them to a St Jude Medical representative.
- 2.3 Identify all patients implanted with Silzone® coated prosthetic heart valves or annuloplasty rings. Patients should undergo early review for signs of worsening cardiac symptoms or heart failure. Asymptomatic patients should be instructed to make an early future appointment if they experience onset of signs of cardiac failure.
- 2.4 Examine symptomatic patients or those with murmurs of insufficiency using appropriate diagnostic techniques including transthoracic or transeosophageal echocardiography (TTE/TOE).
- 2.5 Consider periodic TTE/TOE assessment or valve/annuloplasty ring replacement for patients with evidence of paravalvular leak, dependent upon the severity of cardiac symptoms and the size of the leak. Consider urgent valve replacement if there is evidence of valve thrombosis or infective endocarditis.
- 2.6 Elective explantation without evidence of paravalvular leak or other serious implant-related complications is not recommended.

### 3. BACKGROUND

St Jude Medical applied a silver coating to the sewing cuff of their range of Silzone® mechanical and tissue heart valves and annuloplasty rings with the aim of reducing the incidence of infective endocarditis. Approximately 37 thousand Silzone® heart valves have been distributed worldwide since early 1997, some 1,300 of which are within the UK. One tissue valve with Silzone® coated sewing cuff (Epic™ valve) and 45 Silzone® coated annuloplasty rings have been distributed in the UK.

In November 1999 we issued Advice Note (NI) 99/06 highlighting possible risks of thromboembolic complications involving Silzone® heart valves. The advice resulted from an investigation triggered by information from a leading UK cardiothoracic surgeon on a high rate of thromboembolic complications among patients with Silzone® heart valves within a study being conducted at his hospital. The Notice provided recommendations for patient follow-up which focused upon the typical symptoms and diagnoses of valve thrombosis and stroke.

At that time no recommendation was made to cease further implantations, and instead information was issued to help clinicians make an informed choice about the future use of these valves. However further information has just become available from a large international multi-centre study (AVERT) sponsored by St Jude Medical which found a statistically significant higher rate of paravalvular leak leading to explant among patients implanted with Silzone® valves, compared to those implanted with the St Jude Medical mechanical valves with the conventional (uncoated) sewing cuff. Eleven incidents of paravalvular leak among 398 Silzone® valve patients were identified, 8 of which required valve explant. Only 4 paravalvular leaks were identified among a comparable number of patients implanted with valves with the conventional cuff, one of which resulted in explant. As a result, St Jude Medical recently initiated a voluntary worldwide recall of all their prosthetic heart valves and annuloplasty rings which have Silzone® coated sewing cuffs. The Company issued information to their customers in a Recall Notification (dated 21<sup>st</sup> January 2000) including a list of the serial numbers of the valves they had received, and has taken steps to retrieve unused stocks. Although enrolment of patients in the AVERT study has ceased, patients are continuing to be closely monitored and up-dated information will be issued to clinicians if there are new findings of relevance to patient management.

Paravalvular leak can be detected by routine patient monitoring techniques, and is a well known complication of heart valve replacement often causing haemolysis and sometimes associated with infective endocarditis. It is not yet known how many of the 11 Silzone® valve patients with paravalvular leak within the AVERT study, also suffered from other such complications.

The risk to patients with paravalvular leak will depend upon the size of the leak, and increases significantly in the presence of infective endocarditis. The need for valve replacement is proportional to the haemodynamic disturbance and should be determined on an individual patient basis following patient assessment. Prophylactic valve replacement without confirmed valve-related complications is not recommended.

The risk of complications and recommendations for management of patients implanted with Silzone® coated annuloplasty rings are probably similar to those for patients with the Silzone® heart valves, although there are currently no data available to support this.

This Notice applies to St Jude Medical's Silzone® coated prosthetic heart valves and annuloplasty rings, only.

4. ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mrs S Goodband  
St Jude Medical (UK) Ltd  
Bow Court  
Fletchworth Gate  
Coventry CV5 6SP

Tel: 01203 716226  
Fax: 01203 716212

Enquiries regarding this notice should be addressed as follows:

DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates

Estate Policy

Stoney Road

Dundonald

Belfast BT16 1US

*marked for the attention of Mr Brian Godfrey*

Tel: 028 90 523714

Fax: 028 90 523900

Email: [brian.godfrey@dhssni.gov.uk](mailto:brian.godfrey@dhssni.gov.uk)

Yours faithfully

Brian Godfrey  
Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant, medical devices and other medical and non medical equipment and supplies.