



# 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  
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ADVICE NOTICE (NI) 99/06

Date: 15 November 1999

Product	:	<b>Thromboembolic Complications involving Silzone® Mechanical Heart Valves</b>
Manufacturer/Models	:	<b>St Jude Medical Inc/AG-701, AHPS-605, AS-601, AECS-602, MS-601 and MECS-602.</b>
Issue	:	<b>High rate of early thromboembolic complications associated with St Jude Medical's Silzone® (silver coated) mechanical heart valve, particularly among mitral valve patients.</b>

**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".



HEALTH ESTATES  
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An Executive Agency of the Department of Health and Social Services

## 2. IMMEDIATE ACTION

- 2.1 Follow up all patients implanted with Silzone® mechanical heart valves to identify any signs of stroke or transient ischemic attack (TIA) and ensure adequate anticoagulation control.
- 2.2 Consider examining patients using Trans-Oesophageal Echocardiography (TOE) to identify any signs of valve thrombus, recognising that there are certain risks associated with TOE. Priority should be given to patients most likely to be at risk, ie those who have suffered thromboembolic complications, those with mitral valve implants, and those who received their implants within the last 6 months.
- 2.3 Consider the information contained in this Notice when making a future choice of mechanical heart valve.
- 2.4 Report all incidents of thromboembolic complications and/or valve thrombus to NIDIC and to the manufacturer.

## 3. BACKGROUND

St Jude Medical applied a silver coating to the sewing cuff of their range of Silzone® mechanical heart valves with the aim of reducing the risk of infective endocarditis, a life-threatening complication. Over 30 thousand Silzone® coated heart valves have been distributed worldwide since early 1997, over 700 of which are within the UK.

Over the last year the Department has received notification that 7 patients suffered a stroke or peripheral embolism among a group of 51 patients implanted with Silzone® heart valves by a number of surgeons at one UK centre. Six of these patients had received a mitral Silzone® valve (including one who had received both mitral and aortic valves). The adverse events occurred within 3 months of valve implantation, and in two cases extensive thrombus was identified on the valve's silver coated sewing cuff. There have been a further 5 suspected incidents of TIA among this patient group.

The 51 patients were enrolled in a clinical study involving different types of prosthetic heart valve, comparing various risk factors for embolic complications. Only one patient among 118 implanted with the standard (uncoated) St Jude heart valve within this study was found to have suffered an embolic complication. There were no significant differences in predisposing risk factors for embolic complications or patient anti-coagulation control between the group of patients with the Silzone® valve and the standard St Jude heart valve. An independent review of these data on behalf of the Society of Cardiothoracic Surgeons of Great Britain and Ireland was requested by the manufacturer to confirm the validity of these events. The review confirmed the statistically greater thromboembolic event rate associated with the Silzone® valve compared with the standard St Jude valve; 22.47(CI 10.71-47.13) and 0.38 (CI 0.05-2.27) percent per patient year respectively. However, in view of the small number of patients, these data should be interpreted with caution.

The same UK centre has reported a further case of mitral valve thrombosis involving a patient implanted with a Silzone® valve outside the scope of this study. The Department has also received notification of the death of a patient who received a Silzone® mitral valve at another UK implanting centre, in which thrombus was found on the valve at post-mortem.

In addition a pathologist outside the UK has reported concerns based upon his evaluation of an unexpectedly high number of Silzone® valve explants. This finding led to a review of all patients implanted with Silzone® valves at one North American hospital. Although complete details of this hospital's findings are not yet available as further patient review is underway, there is concern arising from the high number of thromboembolic complications which have been identified. However, St Jude Medical has informed the Department that their survey of Silzone® patients at two other North American hospitals demonstrated no unusually high complication rates.

St Jude Medical is currently sponsoring a 4,000 patient prospective randomised clinical trial (AVERT) to compare the standard and Silzone® versions of their mechanical heart valve. The aim of this study was to investigate the efficacy of the silver coating in reducing endocarditis, although details of all major complications are being collected. To date this study has not identified a significant difference between the thromboembolic complication rates among patients with the Silzone® and the standard St Jude valve. It will, however, be some time before this study yields adequate data to enable an assessment of the valve's thrombogenicity. Further information will be reviewed as it becomes available enabling additional advice to be provided as necessary.

#### 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 to:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)  
Health Estates  
Estate Policy  
Stoney Road  
Dundonald  
BELFAST BT16 1US *marked for the attention of Mr Brian Godfrey*

Tel: 01232 523714  
Fax: 01232 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.