Karen Dilks
Senior Coroner for the City of Newcastle Upon Tyne

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO: Chief Executive, Newcastle Upon Tyne NHS Foundation Health Trust** C/O Legal Services Level 2, Peacock Hall Royal Victoria Infirmary Newcastle Upon Tyne NE1 4LP
1	**CORONER** I am Karen Dilks, Senior Coroner for the City of Newcastle Upon Tyne
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 9 April 2015 I commenced an investigation into the death of Sheila Mary Hynes, aged 72 years whose death was confirmed on the 2 April 2015 within the Freeman Hospital, Newcastle upon Tyne. The investigation concluded at the end of the inquest, which was heard between the 19 and 21 June 2017 inclusive. The conclusion of the inquest was a Narrative: Sheila Hynes died due to an aortic and mitral valve replacement procedure during which sutures securing the mechanical aortic valve snapped. The valve was explanted, remounted on it's holder (contrary to manufacturers instructions) in an inverted position, leading to reimplantation of that valve in an inverted position. Opportunities were missed to identify and rectify the position of the valve causing Mrs Hynes acute heart damage from which she could not recover.
4	**CIRCUMSTANCES OF THE DEATH** Sheila Mary Hynes suffered from rheumatic aortic and mitral valve disease and had previously undergone mitral valvuloplasty. As a consequence of disease progression, Mrs Hynes underwent an Aortic and Mitral Valve Replacement procedure on the 26 March 2015 within the Freeman Hospital in Newcastle. Mechanical valves were considered the most appropriate given Mrs Hynes clinical history. The primary surgeon selected a Sorin Carbomedics 23 mm mechanical by-leaflet prosthetic heart valve to replace Mrs Hynes native aortic valve. The said valve was supplied on a holder. The manufacturer's instructions for use clearly state that the valve should not be remounted on the holder. The valve holder **was not a unidirectional holder. It was therefore possible for the valve, if remounted, to be remounted in an inverted position.** **This fact was not known by the primary surgeon or any member of the operating team.** **During the replacement of Mrs Hynes aortic valve, a suture snapped, necessitating the**

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	explanting of the valve. The valve was handed, still within the sterile field, to a scrub nurse. The scrub nurse was directed by a surgical registrar to remount the valve. The scrub nurse had neither training in or experience of remounting valves, but nevertheless remounted the valve as instructed. The valve was remounted in an inverted position. The valve was then handed back to the primary surgeon who re-implanted the valve in an inverted position. **Opportunities to identify the mistake and take appropriate remedial action were missed. Mrs Hynes suffered acute heart damage, which led directly to her death.** **The Medicines and Healthcare Products Regulatory Agency were informed of the circumstances above on the 27 March 2015. They identified an opportunity for possible improvement of the design of certain valve holders and have confirmed that it is expected that by mid 2019 all such valves will be supplied only on unidirectional holders.**
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – (1) During Mrs Hynes operation a direction was given to remount the Sorin Corbomedics 23mm mechanical aortic valve on its holder whilst preparations to implant the valve were undertaken. Remounting the valve on its holder is contrary to the manufacturer's instructions for use. Concerns arising are: a) The rational for departing from the manufacturer's instructions for use was neither discussed nor recorded. b) The primary surgeon and operating team were unaware of the risks of departing from the manufacturer's instructions for use namely potential inverted remount. c) A scrub nurse with neither training nor experience was instructed to remount the valve contrary to the manufacturer's instructions for use. The rational for this direction was neither discussed nor recorded. d) The primary surgeon with overall responsibility for the procedure did not instruct remounting of the valve; There are no recorded discussions with the primary surgeon on this issue.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths as follows: 1) Extensive training should be undertaken at all levels to ensure knowledge and understanding of the significance of manufacturer's instruction for use of medical products and any product design factors that may influence their use. 2) A protocol should be established to facilitate junior members of an operating team to raise concerns when instructed to act outwith their experience and training. 3) The Trust should direct that in all future mechanical valve replacement procedures any valve explanted should be discarded and a new valve re-implanted. I believe you Chief Executive of Newcastle Upon Tyne NHS Foundation Health Trust have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 28 August 2017. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons [redacted] on behalf of the family of Sheila Hynes. I have also sent it to Hudgell Solicitors for [redacted] family. And to Sintons Solicitors on behalf of the Newcastle upon Tyne NHS Foundation Health Trust. And [redacted] at the Medicine's and Health Products Regulation Agency. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	Dated 3 July 2017 Signature _____ Senior Coroner for the City of Newcastle Upon Tyne

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