	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** British Cardiac Intervention Society and the British Society of Interventional Radiology
1	**CORONER** I am Emma Brown Area Coroner for **Birmingham and Solihull**
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.
3	**INVESTIGATION and INQUEST** On 25/09/2015 I commenced an investigation into the death of Ronald Reginald BENTLEY. The investigation concluded at the end of the inquest on 25th February 2016. The conclusion of the inquest was that the death was a result of an unforeseen complication of a medical procedure.
4	**CIRCUMSTANCES OF THE DEATH** The Deceased passed away at the Queen Elizabeth Hospital Birmingham on the 20th September 2015 as a result of a complication during an elective percutaneous closure of an atrial appendage on the 17th September 2015. During the procedure which was being performed under conscious sedation air was introduced into the vascular system when the Deceased took a deep breath whilst the sheath into the left atrium was open to allow the appendage occlusion device to be introduced. This caused an air embolism which resulted in a hypoxic brain injury. The procedure was required for the treatment of atrial fibrillation and flutter and was being performed under conscious sedation because the Deceased had a significant vascular lesion on his tongue and there was a concern that a tracheal tube could cause this to haemorrhage if a general anaesthetic was used. The medical cause of death was: 1(a) HYPOXIC BRAIN INJURY 1(b) AIR EMBOLISM SECONDARY TO LEFT HEART CATHETERISATION 2 DIABETES MELLITUS, ATRIAL FLUTTER
5	**<u>CORONER'S CONCERNS</u>** 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. – During the inquest the Consultant Cardiologist, [redacted] gave evidence that before the procedure it had not occurred to him that in performing the procedure with conscious sedation there is a risk that if the patient breathes deeply at the 4 or so points when the sheath is open air could enter the vascular system. He stated that there was no warning of this risk that he was aware of at the time and he has since made enquiries of the manufacturers of the TorqVue sheath system used, St. Jude, and they have stated that they had not identified this as a risk of conscious sedation. [redacted] has since canvassed colleagues both nationally and internationally and this risk of the procedure when proceeding with conscious sedation had not been identified by anyone he had spoken to. [redacted] stated that as

	a result of Mr. Bentley's death the University Hospital of Birmingham NHS Trust has taken the following stops to reduce the risk of these events arising again: (a) all such procedures to be undertaken with a general anaesthetic unless an absolute need for conscious sedation; (b) ensuring that LA pressure is above 10mmHg before introducing the sheath; (c) all exchanges on to the sheath to be done in a water bath so if suction does occur it is sterile solution sucked not air; (d) the amount of time the TorqVue sheath is within the left atrium has been reduced by changing to a smaller sheath as soon as possible in conjunction with introducing the occlusion device as soon as the left atrium is entered. However, the Coroner's concern is that unless this risk is widely known, and safeguards introduced as a consequence, there continues to be a risk that patients at other Cardiac Centres could suffer the same complication.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you 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 28th April 2016. 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 the family of Mr. Bentley. 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	03/03/2016 Signature__________________________ Emma Brown Area Coroner **Birmingham and Solihull**