National Institute for Health and Clinical Excellence

IP 392/2 Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction

Consultation Comments table IPAC date: 8 November 2012

Com.	Consultee name and	Sec. no.	Comments	Response
110.	organisation			Please respond to all comments
1	Consultee 1 Manufacturer Edwards Lifesciences	1.1	"Patients having this procedure are often very unwell and might otherwise need open heart surgery (frequently always reoperative) with its	Thank you for your comment. The evidence was unclear whether the procedures were always reoperative.
			associated risks."	The Committee considered the comment and section 1.1 of the guidance was changed to: 'Patients having this procedure are often very unwell and might otherwise need open heart surgery (<i>typically</i> reoperative) with its associated risks.'
2	Consultee 1 Manufacturer Edwards Lifesciences	2.2.2	"Angiography is used to identify the anatomy of the RVOT and coronary arteries." This is not quite correct. We would suggest the omission as described above.	Thank you for your comment. Use of angiography to identify the coronary arteries in relation to the anatomy of the RVOT is reported in the literature.
				The Committee considered the comment and section 2.2.2 of the guidance has been changed to: 'Angiography is used to identify the anatomy of the RVOT and <i>its</i> relation to the coronary arteries.'
3	Consultee 1 Manufacturer Edwards Lifesciences	2.4.2	there are other publications reporting endocarditis cases.	Thank you for your comment. We have made references to additional publications reporting endocarditis in the main extraction table and Appendix A of the Overview.

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