National Institute for Health and Clinical Excellence

739/1 – Percutaneous mitral valve annuloplasty
Consultation Comments table

IPAC date: Thursday 13th April 2010

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Healthcare Other	**1**	Fully agree. Â More data will be coming forth the back half of 2010, however.	Thank you for your comment. NICE may consider reviewing this procedure upon publication of new evidence in accordance with the process described in the Interventional Procedures Programme Process Guide.
2	Consultee 2 3 Specialist Advisers nominated by BCIS	**2.1**	Suggest 2.1.1 Â Mitral regurgitation is characterised.... Causes include cusp retraction often due to rheumatic heart disease, leaflet prolapse and and annular dilation which causes 'functional' mitral regurgitation from failure of leaflet apposition. Left untreated, ...	Thank you for your comment. The Committee considered this comment but decided not to change the guidance**.**
3	Consultee 2 3 Specialist Advisers nominated by BCIS	**2.1 (cont'd)**	2.1.2 Â Treatment of severe mitral regurgitation may include surgical placement of a supporting ring around the base of the mitral valve to reduce annular dilation (annuloplasty), bringing the mitral valve leaflets closer together so that valve competence can be restored.	Thank you for your comment. Section 2.1.2 of the guidance will be changed.

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4	Consultee 2 3 Specialist Advisers nominated by BCIS	**2.1 (cont'd)**	2.1.3 Â Percutaneous mitral valve annuloplasty is suitable for patients with at least moderate symptomatic functional mitral regurgitation, where the valve leaflets themselves are anatomically normal without retraction or prolapse as demonstrated by trans-oesophageal echocardiography. Moderate to severe calcification of the mitral valve annulus restricts the effectiveness of percutaneous annuloplasty and is therefore a contraindication. Â	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
5	Consultee 2 3 Specialist Advisers nominated by BCIS	**2.1 (cont'd)**	2.1.4 The selection of patients for mitral valve annuloplasty must involve a MDT meeting involving a cardiac surgeon who performs mitral valve repair procedures	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
6	Consultee 2 3 Specialist Advisers nominated by BCIS	**2.2**	Suggest 2.2.2 Â The procedure is carried out with the patient under general or local anaesthesia. Under fluoroscopic and in some cases transoesophageal echocardiographic guidance, the device is advanced on a catheter via the femoral or jugular vein towards the coronary sinus. It is deployed and anchored in the coronary sinus. Residual mitral regurgitation is assessed and further percutaneous manipulation of the device may be used to reduce mitral regurgitation by changing the shape and size of the mitral valve annulus. Â Access to immediate on site emergency cardiac surgery is required in all cases because of the risk of complication	Thank you for your comment. Section 2.2.2 of the guidance will be changed but the consultee's comment regarding access to on-site emergency cardiac surgery will not be added to the recommendations.

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7	Consultee 1 Healthcare Other	**2.2**	Not all coronary-sinus approaches utilize femoral or juglar vein access. Â The PTMA system utilizes subclavian vein access. Â Further, the PTMA system does not require use of anchors to reach stable position within the venous anatomy it utilizes up to 3 Nitinol rods (sized to fit patient anatomy) to exert push at the area of P2 by pulling / flexing out in the region of the trigones. Â An unbiased description of the device can be found at Sack et al, Circ Cardiovasc Intervent. 20092:277-284.	Thank you for your comment. Section 2.2.2 of the guidance will be changed. The study referenced by the consultee was identified in the updated literature search, brought to the attention of the Committee and will be added to the overview.
8	Consultee 1 Healthcare Other	**2.3**	The PTMA system is currently being evaluated in a CE-Mark study in 5 countries in Europe. Â Enrollment is expected to be completed during 2010. Â First-in-man data with the PTMA system can be found in Sack et al, Circ Cardiovasc Intervent. 20092:277-284.	Thank you for your comment. The study referenced by the consultee was identified in the updated literature search, brought to the attention of the Committee and will be added to the overview.
9	Consultee 2 3 Specialist Advisers nominated by BCIS	**General**	Comments made on behalf of BCIS they are a summation of advice fro our experts: [redacted] each of whom advised on this topic on behalf of BCIS initially.	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."