

National Institute for Health and Care Excellence
IP664/2 Percutaneous mitral valve leaflet repair for mitral regurgitation

IPAC 14 February 2019

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Specialist Society British Cardiovascular Society	General	BCS welcomes these guidelines on the limited introduction of this technology into NHS practice and hope that, in time, further evidence will support its use in a wider patient population.	Please respond to all comments Thank you for your comment.
2	Consultee 2 Specialist Society British Cardiovascular Intervention Society	General	<p>BCIS welcomes the positive NICE IPG on Mitraclip.</p> <p>We believe Mitraclip is a valuable treatment option for patients with degenerative MR who are considered unsuitable for cardiac surgery. Recent randomised controlled data show powerful prognostic benefit in defined patients with functional MR.</p> <p>We hope that this IPG will aid completion of commissioning decisions and process such that provision of Mitraclip can be supported in the UK for the benefit of appropriate patients.</p> <p>BCIS feels that in addition to “specialist training” and mentoring for 20 cases mentioned in section 1.4, careful consideration should be given to find the balance between adequate centre (not just operator) volume and thus experience and geographic availability of the procedure for the UK population.</p> <p>BCIS would be keen to produce a set of standards for centres covering both the procedure itself and patient selection in order to ensure that future funding for this technology is used appropriately.</p>	<p>Thank you for your comment.</p> <p>Section 1.3 of the guidance states that the procedure should only be done in specialised centres with access to both cardiac surgical and vascular surgical support in case emergency treatment of complications is needed.</p>

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3	Consultee 3 Company Edwards Lifesciences	General	<p>In general we are very pleased to see an update of this important guidance for a prevalent condition with high morbidity and mortality and limited treatment options. However, there has been substantial progress in the treatment of mitral regurgitation and a number of alternative approaches to treatment are available and/or in development. For example, the percutaneous Cardioband Mitral Reconstruction system (Edwards Lifesciences, USA) can also affect repair of a faulty mitral valve. Other chordal repair systems are also available (e.g. Neochord) and some pending regulatory approval (HARPOON) as well as transcatheter mitral repair systems such as PASCAL (Edwards Lifesciences, USA).</p> <p>Although clearly this original IPG was a response to MitraClip we would like to suggest that it may be timely to expand the scope of this to include other similar products and techniques to address mitral repair.</p>	<p>Thank you for your comment.</p> <p>This guidance is specific to percutaneous mitral valve leaflet repair for mitral regurgitation.</p> <p>Therefore, the committee decided not to change the title.</p>
4	Consultee 3 Company Edwards Lifesciences	General	<p>The draft guidance continually refers to the use of a "clip" for repairing the mitral valve. This is highly specific for the MitraClip product and other systems such as PASCAL (Edwards Lifesciences, USA) are similar but do not utilise the same "clip" technique. To simplify this and allow for a more general guidance applicable to other technologies we would suggest simply changing the use of the term "clip" to the more generic "device".</p>	<p>Thank you for your comment.</p> <p>Committee discussed and changed the word 'clip' to 'device' in the lay description and procedure description (section 2.4 and 2.5) of the guidance.</p> <p>The committee also added a comment to section 3.12 of the guidance as follows:</p> <p><i>The committee noted that most of the evidence comes from one device (MitraClip).</i></p>

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5	Consultee 3 Company Edwards Lifesciences	3	<p>We would comment that in addition to the evidence derived from the comprehensive literature search on MitraClip, a recent publication on data from another percutaneous mitral valve repair system (PASCAL - Edwards Lifesciences, USA) is also available, i.e. Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study: Lancet 2017; 390: 773â€“80.</p> <p>Additionally, other published evidence is available for approved devices used for mitral valve repair, e.g. Transcatheter mitral valve repair for functional mitral regurgitation using the Cardioband system: 1 year outcomes: Eur Heart J. 2018 Aug 16. doi: 10.1093/eurheartj/ehy424</p> <p>Although the original purpose of this guidance was to evaluate the MitraClip technology, we would suggest that the presence of other devices and data would recommend an expansion of the guidance to encompass these as well.</p>	<p>Thank you for your comment.</p> <p>Both of the cited studies are small observational studies with fewer than 100 patients, so they would not have been included in the overview (because of the high volume of literature recovered, non-comparative studies with fewer than 100 participants were excluded).</p> <p>This guidance is specific to percutaneous mitral valve leaflet repair for mitral regurgitation. Other techniques for mitral valve repair could be considered for separate guidance.</p>

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