

National Institute for Health and Care Excellence

IP IP1882 Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation

IPAC date: 12 May 2022

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company Abbott Medical	1.1	1. Page 3 point 1.1. 1.1 would be better if the events that constituted 'serious' were defined.	Please respond to all comments Thank you for your comment. The Committee considered this comment but decided not to change the guidance. The key safety outcomes are described in section 3.3 of the draft guidance.
2	Consultee 1 Company Abbott Medical	2.1	2. Page 4 point 2.1. Secondary Tricuspid regurgitation (TR) is not only about stretch of the annulus. The causes of secondary TR include changes in the right ventricle (RV) or distortion of the tricuspid valve leaflets, annulus or chords. The condition typically occurs secondary to left sided heart disease and/or RV remodelling, pulmonary hypertension, tricuspid annular dilation, atrial fibrillation or RV dysfunction.	Thank you for your comment. The last sentence of section 2.1 has been deleted.

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3	Consultee 1 Company Abbott Medical	2.2	3. Page 4 point 2.2. The medical community is moving towards a five grade classification of TR and this should be reflected in the guidance. The current wording may not be sufficiently granular to identify a subset of severe TR patients who may have a worse prognosis than others.	Please respond to all comments Thank you for your comment. Section 2.2 is intended to be a summary of the condition and 'severe' is used in a general context. As noted in section 1.5, "The procedure should only be done in specialised centres with experience of the interventional management of tricuspid regurgitation." It is expected that specialized centres will have relevant expertise to judge the applicability of the term 'severe' to the five grade classification when this becomes standard practice.
4	Consultee 1 Company Abbott Medical	2.3	4. Page 5 point 2.3. It should be stated that medical management options for TR are extremely limited and do not address the underlying pathology of TR. There are no specific pharmaceutical options for treating TR itself, but treatments are available to reduce congestion, volume overload and HF symptoms.	Thank you for your comment. Section 2.3 has been changed to include a statement that there are no specific medical treatments for tricuspid regurgitation itself.
5	Consultee 1 Company Abbott Medical	2.4	5. Page 5 point 2.4. The guidance would be better saying "Isolated tricuspid valve surgery is rarely done because it is associated with a high morbidity and mortality".	Thank you for your comment. 2.4 has been amended to 'Isolated tricuspid valve surgery is rarely done because it is associated with high morbidity and mortality '.
6	Consultee 1 Company Abbott Medical	2.5	6. Page 5 point 2.5. The third sentence does not reflect all of the issues raised in the first. The third sentence would be better if it included that the Tricuspid repair procedure also aims to reduce mortality.	Thank you for your comment. Section 2.5 has been changed to include improved survival.

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7	Consultee 2 Company Edwards Lifesciences Ltd	2.4	Isolated surgery is rarely done because of its high-risk profile. J. Dreyfus et al. (2021)	Please respond to all comments Thank you for your comment. 2.4 has been amended to 'Isolated tricuspid valve surgery is rarely done because it is associated with high morbidity and mortality '.
8	Consultee 2 Company Edwards Lifesciences Ltd	2.5	'The procedure aims to reduce regurgitation, increase quality of life and reduce hospital admissions related to heart failure.' - Improve survival as well.	Thank you for your comment. Section 2.5 has been changed to include improved survival.
9	Consultee 2 Company Edwards Lifesciences Ltd	Overview – p41	The RCTs (CLASP II TR and TRILUMINATE Pivotal) are ongoing.	Thank you for your comment. The 2 trials have been added to the list of ongoing trials in the overview. CLASP II TR is an RCT in US and Canada, with an estimated enrolment of 825 and estimated completion date March 2027. TRILUMINATE Pivotal trial is an RCT in US, Canada and Europe with an estimated enrolment of 700 and estimated completion date March 2027.
10	Consultee 2 Company Edwards Lifesciences Ltd	Overview – p41	CLASP TR, CLASP II TR, TriCLASP and TRILUMINATE Pivotal trials are missing.	Thank you for your comment. The 2 trials have been added to the list of ongoing trials in the overview.

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11	Consultee 2 Company Edwards Lifesciences Ltd	Overview – p48	Löw et al. 2021 and Wild & Hausleiter are missing (not be reviewed at all by NICE - latest is not published yet and has been presented at 2021 ESC congress).	Please respond to all comments Thank you for your comment. Löw et al. (2021) was identified in the updated literature search and has been added to the appendix of the overview. Conference abstracts are not normally considered adequate to support decisions on efficacy and are not generally selected for presentation in the overview.

"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."