National Institute for Health and Care Excellence

IP IP1848 Transcatheter tricuspid valve annuloplasty for tricuspid regurgitation

IPAC date: 12 May 2022

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Edwards Lifesciences Ltd	2.4	Isolated surgery is rarely done because of its high-risk profile. J. Dreyfus et al. (2021)	Thank you for your comment. Dreyfus et al. (2020) Isolated tricuspid valve surgery: impact of aetiology and clinical presentation on outcomes. European Heart Journal 41: 4304–4317 https://doi.org/10.1093/eurheartj/ehaa643 concludes that isolated tricuspid valve surgery is associated with high mortality and morbidity. Section 2.4 of the draft guidance has been amended to 'Isolated tricuspid valve surgery is rarely done **because it is associated with high morbidity and mortality'**.
2	Consultee 1 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 Section 2.5 of the draft guidance has been amended to include improved survival. The key efficacy outcomes in section 3.2 have also been amended.

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3	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p8	64 and not 44 (second sentence in quality-of-life summary)	Thank you for your comment. 44 has been changed to 64
4	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p18	64 and not 44 (EQ-5D-5L score at 30 days)	Thank you for your comment. 44 has been changed to 64
5	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p24	p<0.001 for both comparison tests (Discharge and 30 days)	Thank you for your comment. The overview has been changed to clarify that p<0.001 refers to both time points.

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6	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p26	Moderate or greater in the inclusion criteria but acutally all the patients had severe TR or greater.	Thank you for your comment. The inclusion criteria in the overview state 'moderate or greater chronic functional tricuspid regurgitation', as stated in the paper. The study population section in the overview states 'severe or greater', which reflects the actual population that was described.

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7	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p28	'Major access site and vascular complications needing intervention=0' - 6.7% (n=2)	Thank you for your comment. The overview has been changed to: Major access site and vascular complications needing intervention=6.7% (2/30)
8	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p32	There is the assessment from Carlos III HTA in Spain. Percutaneous repair systems for tricuspid valve insufficiency by annuloplasty. Esther E. García Carpintero, Jordi Gol Freixa, Luis María Sánchez Gómez. Ministry of Health. Agencia de Evaluación de Tecnologías Sanitarias del Instituto de Salud Carlos III, - p. 70; (Collection: Reports, studies and research. Ministry of Health. Series: Health Technology Assessment Reports).	Thank you for your comment. The cited assessment was identified in the literature search but was not included because it is in Spanish, with only a summary in English. The report concludes: 'The available evidence does not yet allow firm conclusions on the efficacy and safety of percutaneous annuloplasty devices for the treatment of tricuspid insufficiency.'
9	Consultee 1 Company Edwards Lifesciences Ltd	Overview – p34	The CARDIOBAND TR EFS trial is still on going.	Thank you for your comment. The trial has been added to the list of ongoing trials in the overview.

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