National Institute for Health and Care Excellence

IP865/2 Sutureless Aortic Valve Replacement for aortic stenosis

IPAC 14/06/18:

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional	**1.1**	*1.1 Current evidence on the safety and efficacy of sutureless aortic valve replacement for aortic stenosis is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.* I agree with this statement. There is now good seven year data which shows equivalence with surgical AVR.	Thank you for your comment.
2	Consultee 1 NHS professional	**1.2**	*1.2 Patient selection should be done by a multidisciplinary team, including cardiologists and cardiac surgeons.* I agree with this statement.	Thank you for your comment.
3	Consultee 1 NHS professional	**1.3**	*1.3 Specific training is important for this procedure and surgeons should do their initial procedures with an experienced mentor.* I agree with this statement. There should be a structured training and proctoring programme and only when signed off should this be performed solo.	Thank you for your comment.
4	Consultee 1 NHS professional	**1.4**	*1.4 Clinicians should enter details about all patients having sutureless aortic valve replacement for aortic stenosis onto the UK National Institute for Cardiovascular Outcomes Research database.* This is already being done via NICOR &SCTS database	Thank you for your comment.

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5	Consultee 2 Company (LivaNova)	**2.3**	Sutureless aortic valve replacement (SAVR) for aortic stenosis is an alternative to both conventional surgical aortic valve replacement *and TAVI.*	Thank you for your comment. The committee acknowledged the typo error and amended 2.3 as follows *Sutureless aortic valve replacement (SUAVR) for aortic stenosis is an alternative to conventional surgical aortic valve replacement.* As TAVI is not a direct comparator to SAVR the surgical procedure, it has been deleted as an alternative treatment from section 2.3.
6	Consultee 2 Company (LivaNova)	**2.4**	With the patient under general anaesthesia, access to the heart is usually made through a full- or mini-sternotomy *or right anterior thoracotomy*.	Thank you for your comment. IPAC considered this comment and amended 2.4 as follows: *With the patient under general anaesthesia, access to the heart is usually* made through a full- or mini-sternotomy or *right anterior thoracotomy.*
7	Consultee 2 Company (LivaNova)	**3.7**	The committee was informed that *one device currently on the market for this procedure utilizes temporary guide sutures to assist with device positioning. These sutures are removed prior to completion of the procedure, making it a truly sutureless implantation.*	Thank you for your comment. IPAC amended 3.7 as follows: *The committee was informed that one device currently on the market for this procedure uses temporary guide sutures to assist with device positioning.*

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8	Consultee 3 Company (Boston Scientific)	**2.3**	We would ask NICE to change the sentence '*'Sutureless aortic valve replacement (S-AVR) for aortic stenosis is an alternative to both conventional surgical aortic valve replacement'* which does not read correctly as follows *'Sutureless aortic valve replacement (S-AVR) for aortic stenosis is an alternative to conventional surgical aortic valve replacement'.* Considering that S-AVR is a surgical procedure, we believe it is important to highlight that TAVI is not a direct comparison to the surgical procedure for all patients and therefore should not be included in this statement. We ask NICE to provide a more specific definition of the alternative treatments available as linked to the patients risk profiles and suitability to open-chest surgery as this will make clear which patients each alternative is suitable for.	Thank you for your comment. The committee acknowledged the typo error and amended 2.3 as follows *Sutureless aortic valve replacement (SUAVR) for aortic stenosis is an alternative to conventional surgical aortic valve replacement.* As TAVI is not a direct comparator to SAVR the surgical procedure, it has been deleted as an alternative treatment from section 2.3. Section 1.2 of the guidance states that '*patient selection should be done by a multidisciplinary team, including cardiologists and cardiac surgeons'.*
9	Consultee 4 Company Edwards Lifesciences	**Title**	Factual inaccuracy: We reiterate that the intervention should be called Rapid Deployment Aortic Valve Replacement (RADVR) as this would more closely describe all products under this guidance. Sutureless Aortic Valve Replacement is a product specific descriptor.	Thank you for your comments. IPAC added a statement to section 2.5 as follows: 2.5 The procedure is sometimes described as sutureless aortic valve replacement and sometimes as rapid deployment aortic valve replacement.
10	Consultee 4 Company Edwards Lifesciences	**General**	If the Sutureless Aortic Valve Replacement descriptor is used we would recommend that the acronym used is SUAVR and not S-AVR which will be confused with Surgical Aortic Valve Replacement, SAVR.	Thank you for your comments. The committee considered this comment and changed the acronym for Sutureless Aortic Valve Replacement to SUAVR.
11	Consultee 4 Company Edwards Lifesciences	**3.1**	Factual inaccuracy: We had mentioned in the last review that Medtronics 3F Enable valve is no longer on the market but you have mentioned it as an available product in the overview document.	Thank you for your comments. Information on availability of products is deleted from the overview document.

12	Consultee 4 Company Edwards Lifesciences Ltd	**3.1**	Additional relevant evidence, with references: The overview document overwhelmingly cites data on the Perceval valve. The Edwards INTUITY Elite Valve System has a good body of evidence that should also be cited. Most notably the TRITON, CADENCE-MIS, TRANSFORM trials and the FOUNDATION Registry. **References:** Di Eusanio M, et al. Sutureless and Rapid-Deployment Aortic Valve Replacement. International Registry (SURD-IR): early results from 3343 patients. Eur J Cardiothorac Surg 2018; doi:10.1093/ejcts/ezy132. Romano MA, et al. Permanent Pacemaker Implantation Following Rapid Deployment Aortic Valve Replacement, The Annals of Thoracic Surgery (2018), doi: 10.1016/j.athoracsur.2018.03.055. Young C, et al. One-year outcomes after rapid-deployment aortic valve replacement. J Thorac Cardiovasc Surg 2018;155:575-85. Rahmanian PB, et al. Rapid Deployment Aortic Valve Replacement: Excellent Results and Increased Effective Orifice Areas. Ann Thorac Surg 2018;105:24-30. Accola KD, et al. Step-by-Step Aortic Valve Replacement With a New Rapid Deployment Valve. Ann Thorac Surg. 2018 Mar;105(3):966-971. Barnhart GR, Accola KD, Grossi EA, Woo YJ, Mumtaz MA, Sabik JF, et al. TRANSFORM (Multicenter Experience with Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: performance of a rapid deployment aortic valve. J Thorac Cardiovasc Surg. 2017; 153:241-51. Laufer G, et al. Long-term outcomes of a rapid deployment aortic valve: data up to 5 years. European Journal of Cardio-Thoracic Surgery 0 (2017) 1â€“7. Bening C, et al. Rapid deployment valve system shortens operative times for aortic valve replacement through right	Thank you for the list of references. 13 studies (Eusanio 2018, Accola 2018 identified in update search and Rahmanian 2018, Roman 2018, Lino 2017, Glenn 2016, Santana 2011, Barnhart 2017, Bening 2017, Borger 2016, Wahlers 2016, Kocher 2013 and Haverich 2014) have been added to appendix in the overview. 1 study (Laufer 2017) has been added to table 2 in the overview. Glauber 2016 has been added to the overview (on page 38). Borger MA 2015 has been included in the systematic review (Qureshi 2018) added to table 2 in the overview. Details of this primary study have been added to appendix in the overview.

			anterior minithoracotomy, J Cardiothorac Surg. 2017; 12: 27. Iino K, et al. Prolonged Cross-Clamping During Aortic Valve Replacement Is an Independent Predictor of Postoperative Morbidity and Mortality: Analysis of the Japan Cardiovascular Surgery Database. Ann Thorac Surg 2017;103:602â€“9. Borger MA, Dohmen PM, Knosalla C, Hammerschmidt R, Merk DR, Richter M, et al. Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial. Eur J Cardiothorac Surg. 2016;50:713-20. Wahlers TC, Haverich A, Borger MA, Shrestha M, Kocher AA, Walther T, et al. Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve. J Thorac Cardiovasc Surg. 2016;151:1639-47. Glenn R. Barnhart, Malakh Lal Shrestha. Current Clinical Evidence on Rapid Deployment Aortic Valve Replacement: Sutureless Aortic Bioprostheses. Innovations (Phila) 2016 Jan; 11(1): 7“14. Glauber M, et al. International Expert Consensus on Sutureless and Rapid Deployment Valves in Aortic Valve Replacement Using Minimally Invasive Approaches. Innovations (Phila) 2016 May; 11(3): 165“173. BorgerMA,MoustafineV, Conradi L, Knosalla C, Richter M, Merk DR, et al. A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. Ann Thorac Surg. 2015;99:17-25.	

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12	Consultee 4 Company Edwards Lifesciences Ltd		Continued from comment above: Haverich A, Wahlers TC, Borger MA, et al. Three-year hemodynamic performance, left ventricular mass regression, and prosthetic-patient mismatch after rapid deployment aortic valve replacement in 287 patients. J Thorac Cardiovasc Surg 2014;148:2854-60. Kocher AA, Laufer G, Haverich A, Shrestha M, Walther T, Misfeld M, et al. One year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System. J Thorac Cardiovasc Surg. 2013;145:110-6. Santana O, et al. Outcomes of Minimally Invasive Valve Surgery Versus Standard Sternotomy in Obese Patients Undergoing Isolated Valve Surgery. Ann Thorac Surg 2011;91:406-10.	
13	Consultee 4 Company Edwards Lifesciences	**1.3**	*"initial procedures with an experienced mentor."* Please can you clarify this requirement. Does the mentor include a company clinical specialist?	Thank you for your comments. IP guidance does not go into the level of detail about training. IPAC considered your comment and added a comment to section 3.10 as follows: 'The committee was informed that manufacturers deliver a specific training programme for surgeons using this procedure'.

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14	Consultee 4 Company Edwards Lifesciences	**2.4**	*"One or more stitches may be needed to guide correct positioning of the new valve. The valve prosthesis, loaded into a delivery device, is inserted into the native annulus. The valve is then released and guide stitches are removed. Balloon dilatation of the new valve may be used to maximise the area of contact between the prosthesis and the aortic annulus. "* This section clearly relates to the IFU for the LivaNova Perceval Valve and is at variance with the Edwards INTUITY Elite IFU. Please genericise.	Thank you for your comments. IPAC considered your comment and amended 2.4 as follows: *"With the patient under general anaesthesia, access to the heart is usually made through a full- or mini-sternotomy or right anterior thoracotomy. Once cardiopulmonary bypass and cardioplegia are established, the diseased aortic valve is accessed and removed through a cut in the aorta. Bulky calcifications around the native aortic annulus are removed to achieve a smooth round annulus for valve implantation. The valve prosthesis with self-expanding or balloon expanding frame, loaded into a special delivery device, is deployed into the native annulus. Once in position the valve is released. The exact deployment method varies between the different devices available for this procedure and with some devices; one or more temporary guiding or securing sutures may be used. Balloon dilatation of the new valve may be used to maximise the area of contact between the prosthesis and the aortic annulus. Once the valve is deployed, the delivery system is removed and the aortotomy is closed. All of the devices used in this procedure contain material derived from animal sources"*

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15	Consultee 4 Company Edwards Lifesciences Ltd	**3.1**	The following recent publications were included in our first submission but are omitted in the consultation document: Young C, et al. One-year outcomes after rapid-deployment aortic valve replacement. J Thorac Cardiovasc Surg 2018;155:575-85. Laufer G, et al. Long-term outcomes of a rapid deployment aortic valve: data up to 5 years. European Journal of Cardio-Thoracic Surgery 0 (2017) 1“7. Eusanio MD, et al. Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry (SURD-IR): early results from 3343 patients: European Journal of Cardio-Thoracic Surgery 0 (2018) 1“6. Romano MA, et al. Permanent Pacemaker Implantation Following Rapid Deployment Aortic Valve Replacement, The Annals of Thoracic Surgery (2018), doi: 10.1016/j.athoracsur.2018.03.055.	Thank you for your comments. 1 study (Laufer 2017) had been added to table 2 in the overview and 3 studies (Eusanio 2018 Roman 2018, Young 2018) have been added to appendix in the overview.

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16	Consultee 4 Company Edwards Lifesciences Ltd	**3.8**	*"The committee was informed that the risk of heart block leading to pacemaker implantation was higher with sutureless aortic valve replacement compared with conventional aortic valve replacement "* Eusanio MD et al (2018) found that the rate of pacemaker implantation significantly decreased over time [from 17.2% (2007-2008) to 5.4% (2016); P = 0.02]. Romano MA et al. (2018) states: The rapid deployment INTUITY valve is associated with increased PPI rates in the setting of pre-existing cardiac conduction abnormalities, similar to that seen with other commercially available rapid deployment aortic valves. However, in the absence of baseline conduction abnormalities, the PPI rate is similar to that of published data for standard sutured AVR prostheses.	Thank you for your comments. IPAC amended 3.8 as follows: *"The committee was informed that the risk of heart block leading to pacemaker implantation may be higher with sutureless aortic valve replacement compared with conventional aortic valve replacement, but the incidence may be falling as experience with the procedure increases".*

"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."