NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1847 Insertion of aortic arch remodelling graft as an adjunct to surgical repair of acute aortic dissection

Your information

Name:	Giovanni Mariscalco
Job title:	Consultant cardiothoracic surgeon-Lead clinician for complex aortic surgery
Organisation:	Glenfield Hospital, Leicester
Email address:	giovanni.mariscalco@uhl-tr.nhs.uk; giovannimariscalco@yahoo.it
Professional organisation or society membership/affiliation:	GMC (7448896) and SCTS (3143)
Nominated/ratified by (if applicable):	Simon Kendall, SCTS president
Registration number (e.g. GMC, NMC, HCPC)	GMC 7448896

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

N/A

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please	In my role as Lead Clinician for Complex Aortic Surgery at the University Hospitals of Leicester NHS Trust, I regularly perform emergency surgery for acute aortic dissections and recognise the implications of a persistent false aortic lumen for outcomes following acute dissection. I therefore fully appreciate the potential advantages that the Ascyrus Medical Dissection Stent (AMDS) prosthesis provides in this life-threatening pathology, by sealing the false lumen and facilitating expansion of the true lumen. I have read the recent published data reporting the mid-term outcomes achieved with the AMDS prosthesis (Boszo SJ, Nagendran J, Chu MWA, et al. Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial. Ann Thorac Surg. 2021;111:463-470.) I have not (personally) yet implanted this prosthesis in a human subject, and it is not available for use at present within my Trust, although we are in the final process to obtaining it. However, I am regularly implanting similar device (Thoraflex) for the treatment of type A acute aortic dissection. The AMDS prosthesis would only be implanted by the cardiac surgical team via sternotomy within an operating theatre environment.

	indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Implantation of the AMDS prosthesis represents a minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. AMDS will be a beneficial device to treat specific type A acute aortic dissections cases, especially those associated with dissection of brachiocephalic vessels and peripheral malperfusion, facilitating the expansion of the true lumen.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	The AMDS prosthesis would be used as an adjunct to the existing surgical standard of care.

Current management

5	Please describe the current standard of care that is used in the NHS.	Emergency surgical repair is the current standard of care in the NHS for acute type A aortic dissection.

6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The Thoraflex and the Evita devices present some characteristics of implantation similar to AMDS (i.e. antegrade deployment of covered stent into the thoracic aorta [arch and descending aorta] via median sternotomy).

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Improvement of malperfusion arising from a patent false lumen, reduced mortality, reduced re-aortic intervention rates and improved long-term survival.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients presenting with acute type A aortic dissection who are candidates for open surgical repair.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. By ensuring sealing of the false aortic lumen, the AMDS prosthesis could lead to a reduction in re-intervention rates, hospital admissions and duration of hospital stay, thereby reducing healthcare expenditure.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	About the same, or possibly less than current standard care. Whilst each AMDS prosthesis costs £13,500, this expense is likely to be offset by the anticipated reduction in future re-intervention rates, hospital admissions and duration of hospital stay.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	About the same, or possibly less than current standard care.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Operating theatre. No changed to existing facilities required.
13	Is any specific training needed in order to	No.

	use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Potential adverse events related to the AMDS prosthesis include aortic injury, aortic branch obstruction, stent fracture and stent failure. However, none of these adverse events have been clearly reported in literature (Boszo SJ, Nagendran J, Chu MWA, et al. Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial. Ann Thorac Surg. 2021;111:463-470.)
15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in total aortic diameter, increase in true lumen size, reduction in false lumen size, mortality, re-intervention rate.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Bozso SJ, Nagendran J, Chu MWA, et al. Single-stage management of dynamic malperfusion utilizing a novel arch remodeling hybrid graft. Ann Thorac Surg. 2019;108:1768-1775. Bozso SJ, Nagendran J, MacArthur RGG, et al. Dissected aorta repair through stent implantation trial: Canadian results. J Thorac Cardiovasc Surg. 2019;157:1763-1771. Boszo SJ, Nagendran J, Chu MWA, et al. Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial. Ann Thorac Surg. 2021;111:463-470.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	DARTS (Dissected Aorta Repair Through Stent Implantation) trial

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Estimated 15-25 cases annually in high aortic volume centre.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your	No.

	organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	**Beneficial/adverse outcome measures:** Short-term clinical outcomes: a) hospital mortality; b) cerebrovascular accident (i.e. stroke, confusion, paraplegia, etc…); c) kidney injury/failure; d) peripheral malperfusion (leg ischemia; bowel complications); e) ITU/hospital length of stay; f) f) blood transfusion Long-term clinical outcome: a) survival b) rate of reintervention (surgical/endovascular) Diagnostic outcomes a) Reduction in total aortic diameter (based on CT scan at 30 days, 6 months and 1 year interval) b) Reduction in false lumen diameter (based on CT scan at 30 days, 6 months and 1 year interval) c) Increase in true lumen diameter (based on CT scan at 30 days, 6 months and 1 year interval) Device related-outcomes: a) Aortic injury due to prosthesis (At 30 days, 6 months, 1 year interval) b) Aortic branch obstruction (At 30 days, 6 months, 1 year interval) c) Stent fracture (At 30 days, 6 months, 1 year interval) d) Stent failure (At 30 days, 6 months, 1 year interval) e) Device-related reintervention (At 30 days, 6 months, 1 year interval)

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	The AMDS device seems to be easier in the implantation compared to other similar devices. IN addition, the surgical strategy and setup does not differ with more traditional surgical approaches to acute aortic syndrome (i.e. arterial cannulation strategy, modality of circulatory arrest, etc…). This seems to suggest that this technology can be adopted by a junior consultants.

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Giovanni Mariscalco**
Dated:	**10/11/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1847 Insertion of aortic arch remodelling graft as an adjunct to surgical repair of acute aortic dissection

Your information

Name:	Prof Andrew Owens
Job title:	Consultant Cardiac Surgeon
Organisation:	South Tees Hospitals NHS Foundation Trust
Email address:	Andrew.owens@nhs.net
Professional organisation or society membership/affiliation:	Member Society for Cardiothoracic Surgery In Great Britain and Ireland
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	3485934

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Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I have been using the technology since February 2021, it is now in routine use by all cardiac surgeons in our unit for all type A aortic dissections and is also in use in 6 units throughout the UK. Given the clinical impact and ease of use of the device I predict rapid and widespread uptake of the technology. It will only be used by cardiac surgeons, currently 35 hospitals in the UK undertake aortic dissection surgery.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The technology is a based on long-standing stent technology however its application in aortic dissection surgery is a novel concept. The use of the device does not alter the fundamental components or manoeuvres of the surgical procedure, it has been designed to be compatible with, and in fact integrate with, the standard surgical approach to this condition. As such, out of the classifications offer in the next question, a minor variation on an existing procedure is the closest description. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It would be an addition to existing standard care.

Current management

5	Please describe the current standard of care that is used in the NHS.	A type A aortic dissection occurs when there is a tear in the lining of the aorta, the main blood vessel that comes out of the heart. This makes it prone to rupture but also results in a 'double-barrelled' aorta beyond the tear which can cause malperfusion of the kidneys or gut and, in the longer term, continue to expand and cause an aneurysm requiring further high risk interventions. It is a well-recognised cardiac surgical emergency with an immediate 50% mortality and subsequent mortality of 1% per hour thereafter, hence the need for rapid surgical intervention.

		As a significant number of patients die before reaching medical care the overall incidence is unknown but in the years 2009-2018 4203 patients in the UK underwent surgical repair of an aortic dissection. The surgery itself essentially involves excising and replacing the part of the aorta that exits the heart, often also part of the aortic arch, to replace the segment with the tear. However this does not typically address the downstream effects of the dissection such as malperfusion or late aneurysm formation.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	In a small number of cases a much more extensive repair operation could be undertaken, replacing not only the ascending aorta but also the aortic arch, disconnecting and reconnecting the head and neck vessels to a more extensive graft. This sort of surgery is typically only undertaken by a small number of specialist aortic surgeons in a limitd number of units. Given the urgencyof surgery it is not a feasible alternative for the majority of patients and would be applicable in a limited proportion of type A dissections. Other than that there is no competing technology.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Studies of the device have demonstrated that its use is associated with a reduction in operative mortality from 18% to 13%, resolution of downstream malperfusion (recognised as an independent mortality risk) in over 95% of patients (58% with standard care) and elimination of aortic arch expansion in the longer term. The latter aspect is arguably the most significant – up to 70% of patients receiving standard surgery are found to have persistence of blood flow in both 'barrels' of the dissected aorta after conventional repair, over 20% have aneurysm formation in the aortic arch. Managing these complications typically involves either high risk redo aortic surgery or stenting, if intervention is even felt feasible.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Most patient with type A aortic dissections undergoing surgical repair.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. It has the potential to improve the outcomes for patients and the system in a number of ways: 1. A reduction in mortality from the initial procedure 2. A reduction in the immediate complications of downstream malperfusion due to aortic dissection 3. A reduction in the need for longer term interventions for aortic arch and descending aortic aneurysms with a further reduction in long term mortality 4. Importantly the technical ease with which the device is deployed and its compatibility with current operative technique means that it can be widely adopted in all cardiac surgical units, unlike complex aortic surgery or stenting, thereby benefiting patients throughout the country.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	In the short term it will add cost, solely due to the device itself as there are no additional staff, capital or diagnostic costs. In the longer term it has the potential to reduce costs as it will reduce the number of patients requiring complex interventions following surgical repair. These interventions typically involve major redo aortic surgery which has a huge impact on theatre time and typically carry long ITU stays and require expensive stents, or endovascular procedures which again carry significant consumable costs.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost	As above – the only cost impact will be the device itself in the immediate surgery.

	more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes are required – it requires no changes in the equipment or facilities currently used to undertake these surgical procedures and no additional follow up investigations beyond the normal standard of care.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	As the device is a variation on the standard operative procedure minimal training is required. A single training session of surgeons and nurses on site is adequate, online resources are available to them 24/7 should a refresher be required pre-op and the device comes with comprehensive instructions. Support is also available from UK specialists.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	No adverse events related to the device have been observed – either published or anecdotally. In theory it could hypothetically enter an aortic tear downstream but the design of the device makes this incredibly unlikely and it has not been observed. As it is otherwise an extension of standard technique I struggle to think of other potential adverse events that are specific to the device as opposed to the overall procedure.
15	Please list the key efficacy outcomes for this procedure/technology?	30 day mortality, resolution of downstream malperfusion, long term incidence of aneurysm formation in the distal aorta.
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None

17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware of. The UK surgical community have been aware of the existence of this device, the published outcomes and widespread use elsewhere in the world for some time, we have been enthusiastically awaiting its arrival in the UK
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	1. Bozso, S. J., et al. (2021). "Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial." Ann Thorac Surg **111**(2): 463-470. 2. Bozso, S. J., & Moon, M. C. (2021). Dissecting the Role of the Ascyrus Medical Dissection Stent. The Annals of thoracic surgery, S0003-4975(21)00845-6. Advance online publication. https://doi.org/10.1016/j.athoracsur.2021.04.077 3. Bozso, S. J., et al. (2019). "Dissected Aorta Repair Through Stent Implantation trial: Canadian results." J Thorac Cardiovasc Surg **157**(5): 1763-1771. 4. Bozso SJ, N. J., Chu MWA, Kiaii B, El-Hamamsy I, Ouzounian M, Kempfert J, Stark C, Shahriari A, Moon MC (2019). "Single-Stage Management of Dynamic Malperfusion Using a Novel Arch Remodeling Hybrid Graft." Ann Thorac Surg **108**(6): 1768-1775. 5. Brinkman, W. (2021). "DARTS Trial." Ann Thorac Surg **111**(2): 470-471. 6. Luthra, S., Tsang, G.M. (2021). Improving outcomes of open stent grafts for Type A acute aortic dissection repair. The Annals of Thoracic Surgery. Advanced online publication. https://doi.org/10.1016/j.athoracsur.2021.02.072 7. Luthra, S., Tsang, G. M. (2021). Concurrent stabilization of "downstream" aorta during acute type A aortic dissection repair. The Journal of thoracic and cardiovascular surgery, S0022-5223(21)00996-X. Advance online publication. https://doi.org/10.1016/j.jtcvs.2021.06.042

		8. Montagner, M., Kofler, M., Heck, R., Buz, S., Starck, C., Kurz, S., Falk, V., & Kempfert, J. (2021). Initial experience with the new type A arch dissection stent: restoration of supra-aortic vessel perfusion. Interactive cardiovascular and thoracic surgery, ivab085. Advance online publication. https://doi.org/10.1093/icvts/ivab085 9. Montagner, M., Heck, R., Kofler, M., Buz, S., Starck, C., Sündermann, S., Kurz, S., Falk, V., & Kempfert Germany Dzhk German Centre For Cardiovascular Research Partner Site Berlin Germany, J. (2020). New Hybrid Prosthesis for Acute Type A Aortic Dissection. Surgical technology international, 36, 95–97. 10. Waterford, S., Moon, C., Moon, M. (2019). Arch Stenting in Type A Aortic Dissection: Tread Lightly. The Annals of Thoracic Surgery, 108(6), 1593-1595. https://doi.org/10.1016/j.athoracsur.2019.05.025 11. Elbatarny M., Youssef A., Bozso S., Moon M., Chung J., El-Hamamsy I., Dagenais F., Chu M., Ouzounian M (2020). Repair of acute type A dissection with distal malperfusion using a novel hybrid arch device. Multimed Man Cardiothorac Surg. 2020 Nov 19, 2020. doi:10.1510/mmcts.2020.062.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The DARTS I study is a prospective investigational study with 5 sites in Canada and 1 site in Germany. The actual enrolment was 47 patients and the study is in the follow-up phase. The ClinicalTrials.gov record are NCT03035643, NCT03397251. The DARTS Registry is a prospective, post-market study with 7 sites in Canada and 4 sites in Germany. The target enrolment is 100 patients with 5 years of follow-up and the study is still in the enrolment phase. The ClinicalTrials.gov record is NCT03894033.

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	A recent paper reviewed the outcomes of all aortic dissection operations in the UK using NICOR registry data. 4203 patients underwent surgical repair in 35 hospitals by 509 surgeons from 2009-2018 with an average mortality of 18%

22	Are there any issues with the usability or practical aspects of the procedure/technology?	None that I am aware of. It has become standard of care for these patients in my unit and I believe most others that have adopted it.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: - Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. - Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Mortality, end-organ malperfusion, stroke, paralysis – all in-hospital and/or 30 days. Long term freedom from aneurysm formation – yearly review Adverse outcome measures: Long term aneurysm formation

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Proctor for Cryolife – support other units deploying the technology	**March 2021**	
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**W Andrew Owens**
Dated:	**29 Oct 2021**