National Institute for Health and Care Excellence

IP1824 Endoanchoring systems in endovascular aortic aneurysm repair

IPAC date: 10 March 2022

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Company Medtronic Ltd	**1.1**	Medtronic would like to thank NICE for the opportunity to comment on the draft recommendations for this procedure. The recommendation is largely robust however we believe that there is a clear patient subgroup that is missing from the patients outlined. Specifically, the patient subgroup that may initially present as favourable, but due to perioperative complications, would greatly benefit from added reinforcement at the proximal seal with the use of an endoanchor. This is particularly important in urgent/emergency cases, for unforeseen complications such as Type 1 endoleaks, where time does not permit for a customised device. Based on current practice and clinical feedback, we believe that it is of high clinical importance for the use of endoanchors in this patient subgroup to be considered, as these patients may not fall into either category stipulated within draft recommendation 1.1 or 1.2. Therefore, we would like to respectfully ask that the committee amend the recommendation to include this patient subgroup. We have suggested the wording below, as this may be more appropriate for the defined group: “For people with unfavourable aneurysm morphology needing an endovascular aortic aneurysm repair (EVAR) as a primary procedure, for people presenting with perioperative complications, or for people with an existing EVAR who need a secondary procedure, evidence on the safety of using endoanchoring systems is adequate.”	Thank you for your comment. A committee comment has been added, to note that the procedure is also used in patients with favourable anatomy who develop an intraoperative complication such as an endoleak during primary EVAR.

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2	Consultee 1 Company Medtronic Ltd	**1.2**	Medtronic do acknowledge that 'Evidence on efficacy is limited in quantity and quality' for people with favourable aneurysm morphology. However, the use of this device is typically focused for people with unfavourable aneurysm morphology, hence the majority of the clinical research trials has been completed for this patient group. As indicated in the European Network for Health Technology Assessment report on 'Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair (EVAR/REVAR)' (Agencia de Evaluación de Tecnologías Sanitarias-Instituto de Salud Carlos III, 2019): "Their use is indicated in patients whose anatomical features may predispose them to suboptimal positioning of the endoprosthesis and consequent endovascular losses (endoleaks) and/or migration of the endoprosthesis itself (unfavourable anatomy or hostile neck-related issues)." Therefore, we would like to respectfully ask that the committee amend the recommendation to include the reason for the limited evidence on efficacy. We have suggested the wording below: "For people with favourable aneurysm morphology needing an EVAR as a primary procedure, evidence on the safety of using endoanchoring systems is adequate. This cohort is not the target population of endoanchoring system, and consequently clinical evidence is limited in quantity and quality. Therefore, for these people, this procedure should only be used in the context of research."	Thank you for your comment A committee comment has been added, to note that the procedure is primarily intended to be used for patients with unfavourable anatomy and this is where most of the evidence came from.
3	Consultee 1 Company Medtronic Ltd	**2.5**	The word 'of' has been used instead of 'or' in the first sentence. We would respectfully ask that the committe amend the wording to: "Endoanchoring implants can be inserted during a primary EVAR procedure or as a secondary procedure under general OR local anaesthesia"	Thank you for your comment. Section 2.5 has been changed, to say 'general **or** local anaesthesia'.

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