EUnetHTA JA3 WP4 - Other technologies, OTCA20
Review by external experts & fact check by manufacturer of the 2nd draft Project Plan for Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair (EVAR/TEVAR)

Comments from experts

Comment from *Insert your name and organisation*	**Page number** *Insert 'general' if your comment relates to the whole document*	**Line/ section number**	**Comment and suggestion for rewording** *Please insert each new comment in a new row.*	**Character of comment** • 'major'[a] =1 • 'minor'[b] = 2 • 'linguistic'[c] =3 *Please indicate your choice by writing the according number in this field, e.g. for major choose "1".*	**Author's reply**
Dr Tambyraja Royal Infirmary of Edinburgh (Scotland)	6		It would be nice to have a patient representative. They may not be able to contribute significantly, but any input they may have would be valuable. I can try to recruit a patient if you wish.	2	Patient involvement is always a valuable input to any assessment. Action. We will continue inviting patients to pass a questionnaire and incorporate the opinion of individual patients as additional information in the assessment.
	9		Prosthesis failure would be better rephrased as graft failure.	2	Prosthesis failure is a MeSH term. We do not detail here all free text terms of our Search strategy. Action: We will include in our assessment (Search strategy section) the free text term "graft failure".
	10		There are several duplicate publications in the literature. Care must be taken not to regard these as unique series of patients.	1	Besides excluding duplicates with reference manager, the Project Plan states on page 10 table 2-3 ".When the same institution had published sequential studies, in order to avoid overlap, the study with the largest number of cases will be chosen". Action: Modify an add. "In order to avoid possible patient overlap in the studies, if the same institution has

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					published sequential studies, the study with the largest number of cases will be chosen, strengthen the assessment elements for the identification and exclusion of duplicate publications."
Dr Guerra. Guadalajara Hospital. (Spain)	Page 18. DOO17	Doo17	I think our patients are not able to realise about this technical aspect. They will just be able to appreciate if this surgery is comfortable or not	2	We understand the difficulty here to differentiate the satisfaction with the procedure from the specific technical aspect. We will try to answer this question despite its complexity considering the limitations Action: None
	Page20..	4 Legal 4.1 Answer Legal requirements..	This technique is another intraoperative tool, and It`s possible to use as unplanning way. In other situations, the surgeon explains EVAR/ TEVAR surgery but not associated use of endoanchor and for this reason the surgeons only give to the patients one informed consent about de EVAR/TEVAR. In fact, for example, there isn`t a specific informed consent for Endoanchor nowadays from the Endovascular Chapter of Spanish Society. On the other hand in Spain the use Endoanchor is not specifically reimbursed.	2	We know the complexity to inform with detail all that is implied in EVAR/TEVAR procedures, especially treatment options of unplanned intraoperative complications. However, it would be important to inform patients if it is planned the use of Endoanchor in the elective treatment on endoleaks/migrations of stents/endografts. Action: Add. "Informed consent should be implemented in health care institutions *especially <u>if the use</u>*

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					of Endoanchor is planned".

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eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Comments from Manufacturer

Comment from ***Insert your company's name***	**Page number**	**Line/ section number**	**Description of factual inaccuracy and proposed amendment** ***Please insert each new comment in a new row.***	**Character of comment** • **'major'[a] =1** • **'minor'[b] = 2** • **'linguistic'[c] =3** ***Please indicate your choice by writing the according number in this field, e.g. for major choose "1".***	**Author's reply**
Medtronic	11	141, Intervention section	Product brand name should be corrected to match the IFU: Aptus™ Heli-FX™ & Heli-FX Thoracic EndoAnchor™ Systems /Medtronic	2	We identified the wrong terms in the PP. Action: Correct the name as suggested.
	11	141, Comparison section	Clinical Scenario 1 or primary intervention: the "1" next to complications should be a superscript, and the description of high risk of complications should be inserted, similar to the section on the population. Otherwise, it is not clear that high risk refers to "hostile neck".	1	We think this suggestion could improve understanding the comparison group. Action: Add High risk for migration/endoleak note for comparison clinical Scenario 1
	11	141, Comparison section	Rationale section: The sentence "Almost all new generation aortic endografts/stents include anchors or other internal mechanisms to fix and avoid migration or endoleak formation" is misleading and may lead to misunderstandings. It needs to be reworded to: "Almost all new generation aortic endografts/stents include active fixation mechanisms to avoid migration".	1	We accept the suggested sentence. Action: Modified in the PP: "Almost all new generation aortic endografts/stents include active fixation mechanisms to avoid migration".
	12	141, Study design section	Please be aware that the current wording of the effectiveness study designs would exclude most Heli-FX studies including the largest, ANCHOR. We suggest deleting the word "comparative" to ensure you review all the relevant literature.	1	This comment is not related to a factual inaccuracy and is, therefore, outside the scope of a fact check. Action: None

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	19	232, Ethical section 1.1.	Ethical considerations – As stated in EUnetHTA's HTA CORE Model for Rapid Relative Effectiveness (page 10): "only those issues for which a difference exists between the technology to be assessed and its major comparator(s) should be described". The same concern about equal access to treatment applies to EVAR/TEVAR (clinical scenario 1) and to secondary repair of EVAR/TEVAR complications (clinical scenario 2). The answer to ethical question 1.1 should, therefore, be "No".	1	This comment is not related to a factual inaccuracy and is, therefore, outside the scope of a fact check. Action: None

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