Comments form

EUnetHTA JA3 WP4 - Other technologies, OTCA20, Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair (EVAR/TEVAR)

Comments form for manufacturers – Fact Check

Comments should be submitted not later than Wednesday *02/10/2019*

Please use this form for submitting your comments to the project manager: Jesús González jgonza@isciii.es and Maria del Carmen Sanchez Gonzalez: mcsanchez@isciii.es

1. Please use the checklist for fact check and follow the instruction provided via e-mail when checking the document.
2. Please put each new comment in a new row.
3. Please insert the page number and section number to which your comment applies.
4. Please provide a description of your comment as specific as possible and provide a suggestion for amendment.
5. All comments (either on your own product or on the product of a competitor) must be validated by published sources (full reference).
6. Please **do not** comment on typos or wording as long as they do not lead to inaccuracy.

All comments will be formally responded to in a combined document that will be published on the EUnetHTA website, company names disclosed. Comments that are outside the scope of a fact check are neither considered nor answered by the authors.

Comment from *Insert your company's name*	Page number	Line or 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".*	Authors' reply
Medtronic	8	Line 152	Please correct the company name to (Medtronic, Minneapolis, MN, USA) on this line and throughout the document whenever the company is referenced.	2	Corrected.
Medtronic	9	Lines 186-189	The reimbursement section states that no EU countries provide separate reimbursement for Heli-FX. This is incorrect, "endovascular fixation devices" are currently listed under the "endovascular stent grafts" category of the High-Cost Devices (HCD) list, meaning NHS England reimburses the hospital if Heli-FX is used. In Germany, Heli-FX has a specific OPS code (5-98c.4) and currently has NUB status 1 for repair intervention, meaning that the hospital is reimbursed at a negotiated rate.	1	Thank you for the update, this has been modified as suggested.
Medtronic	30	Lines 549-557	Same comment on reimbursement as above regarding page 9. Please correct the reimbursement status to clarify that there is reimbursement in England and in Germany.	1	Corrected as in previous comment.
Medtronic	35	Line 753	There seems to be some words missing in the start of this paragraph, making it unclear	3	The sentence has been clarified.
Medtronic	36	Lines 786-797	The NICE guideline on AAA, referenced as number 38, is still in draft form. The timeline for this guideline has been extended and the guideline has not yet been issued. Comments about the NICE guideline and the reference to it should be removed from this section unless the final NICE guideline is published prior to the release of this assessment.	1	Thank you for your comment. The assessment team considered that maintaining this reference is relevant for the report. Nevertheless, we have referenced it as a draft, and this is

					explained through the report. Some documents supporting the sentences are finished and the Committee work has been completed though.
Medtronic	39	Lines 954-959	Based on 2018 data, the units per million inhabitants should be as follows: Netherlands (13.2), Switzerland (10.4), Austria (6.2), Spain (5.7), United Kingdom (5.4), Germany (5.4), Ireland (5.4). In line 958, Austria is listed twice.	2	Thank you. This is now corrected.
Medtronic	41	Map	Please correct the colour coding on the map in line with the revised units per million inhabitants in the above comment about page 39.	2	Corrected.
Medtronic	81	Table A1	The NICE guideline on AAA, referenced as number 38, is still in draft form. The timeline for this guideline has been extended and the guideline has not yet been issued. Comments about the NICE guideline and the reference to it should be removed from this section unless the final NICE guideline is published prior to the release of this assessment.	1	Please, see answer to comment on lines 786-797, p36.
Medtronic	132	Table A73	The following specified contraindications are contained in the approved EU labeling, but are missing from the table: • In patients with a condition that threatens to infect the endograft • In patients with a bleeding diathesis	2	Added.
Medtronic	132	Table A73	An expiration date is given for the United States; however, there is no expiration date associated with the 510(k) clearance	2	Added.
Medtronic	133	Table A73	The following specified contraindications are contained in the approved EU labeling, but are missing from the table: • In patients with a condition that threatens to infect the endograft • In patients with a bleeding diathesis	2	Added.

Medtronic	133	Table A73	An expiration date is given for the United States; however, there is no expiration date associated with the 510(k) clearance	2	Added.
Medtronic	134	Table A84 Germany	Germany: please correct the text to reflect that Heli-FX has a specific OPS code (5-98c.4) and currently has NUB status 1 for repair intervention, meaning that the hospital is reimbursed at a negotiated rate.	1	The information has been added.
Medtronic	134	Table A84 Italy	Italy: please change the first sentence so that it reads "the device **is** reimbursed within the DRG in hospital system". The second sentence"At the moment the device is not included in the authorised for acquisition list" should be deleted. It is not relevant as the reimbursement system is not based on positive/negative lists. In agreement with the regional HTA of RER, the technology is purchased by hospitals which are currently collecting clinical data within a registry. Reference: http://assr.regione.emilia-romagna.it/it/servizi/pubblicazioni/rapporti-documenti/heli-fx-endoanchor	1	Modified. We have added the information about the agreement. We considered to leave the sentence about the list in the report as it was reported by RER-Italy.
Medtronic	134	Table A84 UK	UK: Please change the text to state that "endovascular fixation devices" are currently listed under the "endovascular stent grafts" category of the High-Cost Devices (HCD) list, meaning NHS England reimburses the hospital if Heli-FX is used.	1	Changed.
Medtronic	134	Table A84 Switzerland	Switzerland: please remove the sentence "However, there are no products specified". The Swiss DRG system never specifies products. DRGs are based on procedure codes (not products) and there is a procedure code for endoanchoring systems: 00.9A.41 (The description in German of that procedure code is "Einsatz eines Geräts zur Fixierung von Stentgraftprothesen durch Verschraubung").	1	Specified.

Please add extra rows as needed.

[1] a “major”: the comment points to a highly relevant aspect and a thorough answer is expected from the author(s)
b “minor”: the comment does not necessarily have to be answered in a detailed manner
c“linguistic“: grammar, wording, spelling or comprehensibility, only if they lead to inaccuracy.