EUnetHTA Joint Action 3 2016-2020

Prophylactic or therapeutic use of endoanchoring systems in endovascular aortic aneurysm repair (EVAR/TEVAR)

Project ID: ***OTCA20***

Project description and planning

Agencia de Evaluación de Tecnologías Sanitarias-Instituto de Salud Carlos III

REPUBLIC OF SLOVENIA
MINISTRY OF HEALTH

Republika Slovenija
Ministrstvo za Zdravje

Version Log

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Version number	Date	Modification	Reason for the modification
V1	29/10/2018	Preliminary version	Scoping meeting and manufacturer´s comments
V2	20/11/2018	First version	Dedicated reviewers
V3	18/12/2018	Second version	Experts and manufacturer comments
V4	21/01/2019	Third version	

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1 Project organisation

1.1 Participants

Table 1-1: Project participants

	Agency	Role in the project	Country	Distribution of work
Assessment team				
1.	Agencia de Evaluación de Tecnologías Sanitarias-Instituto de Salud Carlos III	Author	Spain	Develop first draft of EUnetHTA project plan, amend the draft if necessary. Perform the literature search Carry out the assessment: answer assessment elements (Production of CUR, TEC, EFF and SAF domains), fill in checklist regarding potential "ethical, organisational, patient and social and legal aspects" of the HTA Core Model R for rapid REA (see table 6) Send "draft versions" to reviewers, compile feedback from reviewers and perform changes according to reviewers comments Prepare final assessment and write a final summary of the assessment
2.	Republika Slovenija Ministrstvo za Zdravje	Co-Author	Slovenia	Review the project plan draft. Support the production of all domains (Focus on CUR and TEC domains) and quality check the steps of their production (data, information, sources). Contribute to answering questions related to potential ethical, organisational, patient, social, and legal aspects if needed. Approve/endorse conclusions drawn as well as all draft versions and the final assessment including the executive summary.
3.	Università Cattolica del Sacro Cuore GEMELLI	Dedicated Reviewer	Italy	Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. •Review methods, results, and conclusions based on the original studies included. •Provide constructive comments in all the project phases
4.	Swiss Network for Health Technology Assessment	Dedicated Reviewer	Switzerland	Guarantee quality assurance by thoroughly reviewing the

				project plan and the assessment drafts. •Review methods, results, and conclusions based on the original studies included. •Provide constructive comments in all the project phases
Contributors				
5.	Dr Guerra Chief of Vascular Surgery Department at University Hospital of Guadalajara (Spain) and President of Chapter of Endovascular Surgery of Spanish Society of Angiology and Vascular Surgery.	External expert		Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts; •Review methods, results, and conclusions based on the original studies included; •Provide constructive comments in all the project phases
6.	Dr Tambyraja Consultant Vascular Surgeon at Royal Infirmary of Edinburgh (Scotland) and Honorary Clinical Senior Lecturer at University of Edinburgh	External expert		Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts; •Review methods, results, and conclusions based on the original studies included; •Provide constructive comments in all the project phases
7.	TBD	Medical Editor		
8.	Agencia de Evaluación de Tecnologías Sanitarias-Instituto de Salud Carlos III	Project Manager	Spain	Project management

1.2 Project stakeholders

Table 1-2: Project stakeholders

Organisation	**Role in the project**
Medtronic	Manufacturer-fact check of project plan, 2nd draft assessment; submission template
Patient/consumer representative groups	None: no group or individual patient available.

1.3 Milestones and Deliverables

Table 1-3: Milestones and Deliverables

Milestones/Deliverables	***Start date***	***End date***
Project duration	***06/08/2018***	***02/07/2019***
Scoping phase	*06/08/2018*	*22/01/2019*
Identification of manufacturers and external experts; *optional: identification of patients*	*06/08/2018*	*15/10/2018*
Scoping and development of draft Project Plan incl. preliminary PICO	*06/08/2018*	*15/10/2018*

Share the preliminary PICO with external experts *(and patients)* for comments	*16-10-2018*	*22-10-2018*
Internal Scoping e-meeting with the assessment team	*23-10-2018*	*29-10-2018*
Share the preliminary PICO for comments to manufacturer(s)	*7-11-2018*	*13-11-2018*
Consultation of draft Project Plan with dedicated reviewers	*21-11-2018*	*18/12/2018*
Consultation of draft Project Plan with external experts *(and patients)* and fact check by manufacturers	*19-12-2018*	*15-1-2019*
Amendment of draft Project Plan & final Project Plan available	*16-1-2019*	*22-1-2019*
Assessment phase	*23-1-2019*	*2-7-2019*
Writing first draft rapid assessment	*23-1-2019*	*12-3-2019*
Review by dedicated reviewer(s)	*13-3-2019*	*26-3-2019*
Writing second draft rapid assessment	*27-3-2019*	*16-4-2019*
Review by ≥ 2 external clinical experts and fact check by manufacturers	*17-4-2019*	*13-5-2019*
Writing third draft rapid assessment	14-5-2019	28-5-2019
Medical editing	29-5-2019	4-6-2019
Writing of final version of rapid assessment	5-6-2019	18-6-2019
Formatting	19-6-2019	25-6-2019
Final version of REA		**[week** from 26/06/ to 02/07/2019

2 Project Outline

2.1 Project Objectives

The rationale of this assessment is to collaboratively produce structured (rapid) core HTA information on other technologies. In addition, the aim is to apply those collaboratively produced assessments in the national or regional context.

Table 2-1: Project objectives

	List of project objectives	**Indicator (and target)**
1.	To jointly produce health technology assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies.	Production of 1 (rapid) relative effectiveness assessment for the use of endoanchoring systems in endovascular aortic aneurysm repair.
2.	To apply this collaboratively produced assessment into local (e.g. regional or national) context.	Production of ≥2 local (e.g. national or regional) reports based on the jointly produced assessment.

This rapid assessment addresses the research question whether:

1. The primary use of endoanchoring systems in patients with EVAR/TEVAR with high risk for endoleak Type I or migration is more effective and safer (or at least as safe) than primary endovascular aortic aneurysm repair without use of endoanchoring system.
2. The secondary use of endoanchoring systems to treat complications in patients with primary EVAR/TEVAR is more effective and safer (or at least as safe) than other endovascular aortic aneurysm repair without use of anchoring system (other endovascular treatments to treat endoleaks or endograft migration) or open surgical repair.

This topic is of relevance for the Spanish common services portfolio of the National Health System. The use of EVAR/TEVAR with external anchor systems in aortic aneurysm patients is increasing, and there are few systematic reviews or HTA reports about the efficacy and safety of this procedure for anchoring endografts in EVAR/TEVAR. Although this endovascular device is used in some Hospitals included in “EVAR/TEVAR procedures”, this technique is not yet in the Spanish common services portfolio of the National Health System.

2.2 Project Method and Scope

2.2.1 Approach and Method

Table 2-2: Project approach and method

Project approach and method
The HTA Core Model Application for rapid Relative Effectiveness Assessment (REA) (4.2) will be the primary source for selecting assessment elements. The selected assessment element generic questions will be translated into research questions. For Description and technical characteristics of technology (TEC) and Health problem and current use of technology (CUR) domains a descriptive analysis will be performed, based on information from different sources: • Input from manufacturers, particularly related to questions on CE mark, marketing, availability and current use. The Medical Devices Evidence Submission template will be sent to all relevant manufacturers of the technology under assessment. Manufacturers will be asked to submit non-confidential documents, focusing on the technical characteristics and current use of the technology and on unpublished trial results. • Input from clinical experts, particularly related to description of disease, current treatment, current use and best available epidemiological data. The clinical experts will be asked to verify the relevance and accuracy of the information and citations. • Clinical guidelines: A search for current clinical guidelines in the Guidelines International database (G-I-N) will be performed by the author. • Relevant literature identified by the literature search for the EFF and SAF domains. A quality assessment would be conducted depending on the type of studies or information sources included in these two domains. For Effectiveness (EFF) and Safety (SAF) domains, we will perform a systematic literature search. Two authors will independently screen the titles and abstracts and select studies according to the pre-defined inclusion and exclusion criteria. The full-text publications will be retrieved by the author, and the full-text examination will be performed by two authors independently. The authors will provide a list of included and excluded studies. Discrepancies will be resolved by discussion or with the help of a third party. The Risk of bias (RoB) assessment of the included studies will be done according to the Cochrane Risk of bias tool on study and outcome level [1]. The 'Risk of bias' of each included trial will be assessed by two authors independently. Any disagreements will be resolved by consensus or by consulting a third party. The strength of evidence for all critical outcomes will be rated according to GRADE (Grading of Recommendations Assessment, Development and Evaluation) scheme, which takes into account issues related not only to internal validity (risk of bias, inconsistency, imprecision, publication bias) but also to external validity, such as directness of results [2]. The results of the rating will be presented in GRADE Summary of Findings (SoF) tables.

Table 2-3: Planned literature search strategy

Literature search strategy
For Effectiveness (EFF) and Safety (SAF) domains, we will perform a systematic literature search in the bibliographic databases PubMed, MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials and Cochrane Database for Systematic Reviews, according to the predefined search strategy.

Furthermore, a search in the clinical trials registries ClinicalTrials.gov, EU Clinical Trials Register and International ClinicalTrials Registry Platform (ICTRP) will be carried out for ongoing studies. In addition to the electronic search, a hand search (in reference lists of relevant studies), as well as an internet search, including HTA agencies websites, will be performed. Moreover, a search of regulatory documents will be carried out in US Food and Drugs Administration.

For the identification of studies, different search strategies adapted to each database were designed, combining with controlled terms (MeSH and EMTREE) and free text for indications (Aortic Aneurysm, Thoracic Aortic Aneurysm, Abdominal Aortic Rupture Aneurysm, Dissecting, Endoleak, Prosthesis Failure) and intervention (EndoAnchors, Endostaples, Heli-FX, Endosuturing, Enhanced fixation devices and Endovascular sutures aneurysm repair or ESAR).

Inclusion criteria: human subjects, without language restriction and according to PICO criteria.

Exclusion criteria: publication date before 2001.01.01 (date of first animal research publication about an Endoanchor system predecessor), and according to PICO criteria.

In order to avoid possible patient overlap in the studies, if the same institution has 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.

All titles and abstracts retrieved by electronic searching will be downloaded to a reference manager (EndNote X8), and duplicates will be removed.

Table 2-4: Plan for data extraction

Planned data extraction
Data to be extracted from the studies included: • Information about the study (authors, year of publication, setting/country, funding, study design, clinical trial identification number/ registry identifier and funding source). • Participant/patient characteristics (diagnosis, number of participants in the trial, age, clinical stage, any relevant risk category or risk factor). • Intervention and control characteristics (description of procedure, emergency/elective setting, comparator, name/type of the device, frequency of intervention per patient, length of follow up and loss to follow up). • Outcomes (see section 2.2.2). For missing data trial authors will be contacted by the author (via e-mail). If possible, dichotomous outcome results will be expressed as risk ratio (RR). Where continuous scales of measurement are used to assess the effects of treatment, the mean difference (MD) will be used; if different scales are used the standardised mean difference (SMD) will be used. Relevant subgroup analyses will be assessed especially for critical outcomes.

2.2.2 Project Scope

The EUnetHTA Guidelines, available at https://www.eunethta.eu/methodology-guidelines/ **need to be consulted** throughout the assessment process.

Table 2-5: Project Scope: PICO (please see HTA Core Model® for rapid REA)

Description	Project Scope
Population	***Clinical Scenario 1 or Primary intervention:*** ***Patients with abdominal or thoracic aortic aneurysm undergoing endovascular repair with a high risk of complications* (migration or endoleak type I).*** • **ICD10**: *I71.1 Thoracic aortic aneurysm, ruptured. I71.2 Thoracic aortic aneurysm, without mention of rupture. I71.3 Abdominal aortic aneurysm, ruptured. I71.4 Abdominal aortic aneurysm, without mention of rupture. I71.5 Thoracoabdominal aortic aneurysm, ruptured. I71.6 Thoracoabdominal aortic aneurysm, without mention of rupture. I71.8 Aortic aneurysm of unspecified site, ruptured. Incl.: Rupture of aorta NOS. I71.9 Aortic aneurysm of unspecified site, without mention of rupture. Incl.: Aortic Aneurysm, Dilatation or Hyaline Necrosis. S25.09 Other specified injury of thoracic aorta.S35.09 Other injury of abdominal aorta.* MeSH terms: Aortic Aneurysm, Thoracic C14.907.055.239.125, C14.907.109.139.125. Aortic Aneurysm, Abdominal C14.907.055.239.075, C14.907.109.139.075. Aortic Rupture C14.907.055.185.125, C14.907.055.239.175, C14.907.109.139.175, C26.761.125 **High-risk migration/endoleak (i.e. hostile neck in abdominal aortic aneurysm). "Hostile neck" is one with marked angulation, short length, complex shape, wide diameter or the presence of calcification or thrombus [3]* **Clinical Scenario 2 or Secondary intervention :** ***Patients with failure of previous endovascular repair of an aortic aneurysm (migration or endoleak type I) that need secondary aortic repair.*** • *ICD10: T82.8 Other specified complications of cardiac and vascular prosthetic devices, implants and grafts. (Embolism, Fibrosis, Hemorrhage, Pain, Stenosis. and Thrombosis). T82.9 Unspecified complication of cardiac and vascular prosthetic device, implant and graft* • *MeSH terms: Endoleak C14.907.055.501, C23.550.414.941.500, C23.550.767.850.500. Prosthesis Failure C23.550.767.865, E05.325.771.*
Intervention	Fixation with endoanchoring systems, like Heli-FX™ of Aortic aneurysm graft/stents in EVAR/TEVAR. Other Names: • EndoAnchors • Endosuturing • Endostaples • Heli-FX • Enhanced fixation devices • Endovascular sutured aneurysm repair (ESAR) Products/manufacturers: Aptus™ Heli-FX™ & Heli-FX™ Thoracic EndoAnchor™ Systems/Medtronic

Comparison	**Clinical Scenario 1 or primary intervention:** Primary endovascular aortic aneurysm repair with a high risk of complications** (migration or endoleak type I) without the use of endoanchoring systems (all EVAR/TEVAR stents/endografts) ***High-risk migration/endoleak (i.e. hostile neck in abdominal aortic aneurysm). "Hostile neck" is one with marked angulation, short length, complex shape, wide diameter or the presence of calcification or thrombus [3]* **Clinical Scenario 2 or Secondary intervention :** Secondary repair of EVAR/TEVAR complications (endoleak type I or endograft migration): embolisation, extensions of grafts-proximal /distal, balloon angioplasty, metallic stents) or open surgical repair. • MeSH terms: Endovascular Procedures E04.100.814.529, E04.502.382 Blood Vessel Prosthesis Implantation E04.100.814.868.500, E04.650.200. Rationale: The standard endovascular approach with endografts/stents in aortic aneurysm is without explicit use of external anchoring systems[4, 5] except for Endurant II/Endurant IIs Stent Graft System in short neck abdominal aortic aneurysm [6]. Almost all new generation aortic endografts/stents include active fixation mechanisms to avoid migration [7]. There is no standard treatment of endoleaks type I or migration of aortic endografts/stents [8].
Outcomes	**Effectiveness** • Rate of occurrence or recurrence of complications (freedom from graft migration or endoleak type I). (Critical) • Reintervention rate. (Critical) • Aneurysm rupture. (Critical) • Aneurysm-related mortality (30days-≥1y). (Critical) • All-cause mortality (early=30days/late≥1y). (Important) • Conversion to open surgical repair. (Important) • Technical and Procedural Success. (Important) • Health-related quality of life (HRQoL). (Important) • Rate of neck dilation or sac enlargement. Rate of sac regression. **Safety** All adverse events and serious adverse events (related or unrelated to the device or intervention): • Procedure-related mortality. (Critical) • Vessel damage (including dissection, perforation, and spasm). (Important) • EndoAnchor implant embolisation. (Important) • Endoleaks (Type II-V). (Important) • Stroke. (Important) • Vascular access complications (including infection, pain, hematoma, pseudoaneurysm and arteriovenous fistula). (Important) • Renal complications (renal artery occlusion/dissection or contrast-induced acute kidney injury). (Important) • Cardiac complications. (Important) • Respiratory failure. (Important) • Other ischemic complication. (Important) • Others: pneumonia, fever, Urologic & Gastrointestinal. (Important)

	Rationale: Included main outcomes already described in Instructions for Use and pivotal trial ANCHOR of Aptus™ Heli-FX™ and Heli-FX Thoracic EndoAnchor™ Systems by Medtronic, a preliminary search of literature and their objective selection [9-11].
Study design	Effectiveness: Randomized clinical trials (RCTs), prospective non-randomized controlled studies, other observational comparative studies Safety: Randomized clinical trials, prospective non-randomized controlled studies, other observational comparative and non-comparative studies, single arm studies with >10 patients.
Clinical Setting	**Tertiary referral hospital**

3 Communication and collaboration

Table 3-1: Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Scoping	Kick-Off meeting	[10/09/2018] [13/09/2018]	E-meeting/E-meeting/E-mail	Author(s), co-author(s), dedicated reviewers, and external experts.
	Internal Scoping Meeting: To internally discuss and reach consensus on the preliminary PICO	[29/10/2018]	*Face to face or e-meeting*	*Author(s), co-author(s), manufacturer(s), project manager*
		[DD/MM/YYYY]	*Additional e-meetings may be planned whenever needed*	*Author(s), Co-author(s), dedicated reviewer(s), project manager*
Feedback on draft submission file (optional)	*To point out the requirements for the final submission file by manufacturers*	*[DD/MM/YYYY]*	*E-mail*	*Author(s), project manager, manufacturers*
First draft of the rapid assessment	*To discuss comments of dedicated reviewers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers*
Second draft of the rapid assessment	*To discuss comments from ≥ 2 external clinical experts and manufacturers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers; external experts, manufacturers*

3.3 Dissemination plan

The final rapid assessment will be published on the EUnetHTA website: http://eunethta.eu/rapid-reas/ .

All stakeholders and contributors are informed about the publication of the final assessment by the project manager.

3.4 Collaboration with stakeholders

Collaboration with manufacturer(s)

There will be a review of the preliminary PICO and a fact check of the 2nd draft project plan and the 2nd draft assessment by the manufacturer(s).

Collaboration with other stakeholders

Patient involvement was planned and European patient organisations (European Heart Network and European Patient forum) as well as national patient organisations from Spain (Cardioalliance Spanish Patient´s Forum, Patient´s Alliance and Patient´s Platform) were contacted to provide input on the preliminary PICO and through the HTAi patient input form. We also invite individual patients through a local Hospital. However, it was not possible to identify and obtain participation.

Collaboration with EUnetHTA WPs

For the individual rapid assessment, some collaboration with other WPs is planned: WP7 [Implementation] will be informed of the project, in order to prepare activities to improve national uptake of the final assessment. Feedback on the WP4 REA process will be asked from the involved parties by WP6 [Quality Management], and this information will be processed by WP6 to improve the quality of the process and output.

3.5 Conflict of interest and confidentiality management

Conflicts of interest will be handled according to the EUnetHTA Conflict of Interest Policy. All individuals participating in this project will sign the standardised "Declaration of Interest and Confidentiality Undertaking" (DOICU) statement.

Author, co-author(s) and dedicated reviewers who declare a specific conflict of interest will be excluded from the whole work under this specific topic. However, they still may be included in other assessments.

For external experts, patients or other stakeholders involved, conflict of interest declarations are collected. External experts or patients who declare a specific conflict of interest will be excluded from parts of or the whole work under this specific topic. However, they still may be included in other assessments.

Manufacturer(s) will sign a Confidentiality Undertaking (CU) form regarding the specific project.

4 References

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5 Appendix A

5.1 Selected Assessment Elements

The table shows the assessment elements and the translated research questions that will be addressed in the assessment. They are based on the assessment elements contained in the 'Model for Rapid Relative Effectiveness Assessment'. Additionally, assessment elements from other HTA Core Model Applications (for medical and surgical interventions, for diagnostic technologies or for screening) have been screened and included/ merged with the existing questions if deemed relevant.

Table 5-1: Selected Assessment Elements

ID	Topic	Topic Issue	Relevance in this assessment [**Yes – critical**, **Yes** or **No**]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
Description and technical characteristics of technology					
B0001	Features of the technology and comparators	What are the technology and the comparator(s)?	**Yes – critical**	M	What is EndoAnchor fixation in EVAR/TEVAR procedures? What is EndoAnchor fixation in the management of endoleak I or stent/endograft migration in patients treated previously with EVAR/TEVAR? What are EVAR /TEVAR procedures without the use of EndoAnchor? What are embolisation, extensions of grafts-proximal/distal, balloon angioplasty, metallic stents or open surgical repair of endoleaks I or stent/endografts migration in patients treated previously with EVAR/TEVAR?
A0020	Regulatory Status	For which indications has the technology received marketing authorisation or CE marking? [This assessment element can be placed either in the TEC OR in the CUR domain]	**Yes – critical**	M	For which indications have Aptus™ Heli-FX™ & Heli-FX™ Thoracic EndoAnchor™ Systems from Medtronic received marketing authorisation or CE marking?
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?	**Yes**	M	What is the claimed benefit of EndoAnchor in high risk for endoleak type I or migration in relation to the comparator(s)? What is the claimed benefit of Endoanchors in the management of endoleak I or stent/endograft migration in patients treated previously with EVAR/TEVAR in relation to the comparator(s)?
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	**No**	NM	
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	**Yes**	M	Who administers EndoAnchors in EVAR/TEVAR procedures, embolisation, extensions of grafts-proximal/distal, balloon angioplasty, metallic stents or open surgical? In what context and level of care are EndoAnchors EVAR/TEVAR procedures, embolisation,

ID	Topic	Topic Issue	Relevance in this assessment [**Yes – critical**, **Yes** or **No**]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
					extensions of grafts-proximal/distal, balloon angioplasty, metallic stents or open surgical provided?
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	**No**	NM	
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	**Yes**	NM	What equipment and supplies are needed to use EndoAnchors EVAR/TEVAR procedures, embolisation, extensions of grafts-proximal/distal, balloon angioplasty, metallic stents or open surgical)?
A0021	Regulatory Status	What is the reimbursement status of the technology? [This assessment element can be placed either in the TEC OR in the CUR domain]	**Yes**	NM	What is the reimbursement status of Aptus™ Heli-FX™ & Heli-FX™ Thoracic EndoAnchor™ Systems from Medtronic?
Health problem and current use of technology					
A0002	Target Condition	What is the disease or health condition in the scope of this assessment?	**Yes – critical**	M	What is high risk for Endoleak type I or migration of stents/endografts in aortic aneurysm disease? What is Endoleak type I or migrations in patients previously treated with EVAR/TEVAR procedures?
A0003	Target Condition	What are the known risk factors for the disease or health condition?	**Yes**	NM	What are the known risk factors for high risk for Endoleak type I or migration of stents/endografts in aortic aneurysm disease? What are the known risk for Endoleaks type I or migration of stents//endografts after EVAR/TEVAR procedures?
A0004	Target Condition	What is the natural course of the disease or health condition?	**Yes**	M	What is the natural course of high risk for Endoleak type I or migration in aortic aneurysm disease? What is the natural course of Endoleaks type I or migration of stents//endografts after EVAR/TEVAR procedures?
A0005	Target Condition	What are the symptoms and the burden of disease or health condition for the patient?	**Yes**	M	What are the symptoms and the burden of high risk for Endoleak type I or migration in aortic aneurysm disease for the patient?
A0006	Target Condition	What are the consequences of the disease or health condition for the society?	**No**	NM	
A0024	Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	**Yes – critical**	M	How is high risk for Endoleak type I or migration of stents/endografts in aortic aneurysm disease currently diagnosed according to published guidelines and in practice? How is Endoleak type I or migration of stents/endografts currently diagnosed according to published guidelines and in practice?
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to	**Yes – critical**	M	How is high risk for Endoleak type I or migration of stents/endografts in aortic aneurysm disease currently managed according to published

ID	Topic	Topic Issue	Relevance in this assessment [**Yes – critical**, **Yes** or **No**]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		published guidelines and in practice?			guidelines and in practice? How is Endoleak type I or migration of stents/endografts currently managed according to published guidelines and in practice?
A0007	Target Population	What is the target population in this assessment?	**Yes – critical**	M	What is the target population in this assessment?
A0023	Target Population	How many people belong to the target population?	**Yes**	M	How many people belong to the target population?
A0011	Utilisation	How much are the technologies utilised?	**Yes**	M	How much are EndoAnchors utilised?
Clinical effectiveness					
D0001	Mortality	What is the expected beneficial effect of the intervention on mortality?	**Yes – critical**	M	What is the expected beneficial effect of EndoAnchors on mortality?
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	**Yes – critical**	M	How does EndoaAchors affect symptoms and findings (severity, frequency) of high risk for Endoleak type I or migration of stents/ endografts in aortic aneurysm disease? How does EndoAnchors affect symptoms and findings (severity, frequency) of Endoleak type I or migration of stents/endografts in post EVAR/TEVAR procedures?
D0006	Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	**Yes – critical**	M	How does EndoAnchors affect progression (or recurrence) of high risk for Endoleak type I or migration of stents/endografts in aortic aneurysm disease? How does EndoAnchors affect progression (or recurrence) of Endoleak type I or migration of stents/endografts in aortic aneurysm disease?
D0011	Function	What is the effect of the technology on patients' body functions?	**Yes**	M	What is the effect of EndoAnchors on patients' body functions?
D0016	Function	How does the use of technology affect activities of daily living?	**Yes**	NM	How does the use of EndoAnchors affect activities of daily living
D0012	Health-related quality of life	What is the effect of the technology on generic health-related quality of life?	**Yes**	M	What is the effect of EndoAnchors on generic health-related quality of life?
D0013	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	**Yes**	M	What is the effect of EndoAnchors on disease-specific quality of life?
D0017	Patient satisfaction	Were patients satisfied with the technology?	**Yes**	NM	Were patients satisfied with EndoAnchors?
Safety					
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	**Yes – critical**	M	How safe is EndoAnchors in relation to the comparator(s)?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the	**No**	NM	

ID	Topic	Topic Issue	Relevance in this assessment [**Yes – critical**, **Yes** or **No**]	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		technology?			
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	**Yes**	M	How does the frequency or severity of harms change over time or in different settings?
C0005	Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	**Yes**	M	What are the susceptible patient groups that are more likely to be harmed through the use of EndoAnchors?
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	**Yes**	NM	Is EndoAnchor use associated with user-dependent harms?
B0010	Safety risk management	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	**Yes**	M for medical devices	What kind of data/records and/or registry is needed to monitor the use of EndoAnchors and the comparator(s)?

5.2 Checklist for potential ethical, organisational, patient and social and legal aspects

1. Ethical	
1.1. Does the introduction of EndoAnchor and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new ethical issues?	Yes
The use of EndoAnchor would give rise to ethical issues related to equal access to the treatment. This intervention could not be available for every patient in need for it.	
1.2. Does comparing EndoAnchor to the defined, existing comparators point to any differences that may be ethically relevant?	No
2. Organisational	
2.1. Does the introduction of EndoAnchor and its potential use/non-use instead of the defined, existing comparator(s) require organisational changes?	No
2.2. Does comparing EndoAnchor to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	Yes
The use of EndoAnchor could need training processes, or a learning curve, especially in challenging cases.	
3. Social	
3.1. Does the introduction of EndoAnchor and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new social issues?	No
3.2. Does comparing EndoAnchor to the defined, existing	No

comparator(s) point to any differences that may be socially relevant?	
4. Legal	
4.1. Does the introduction of EndoAnchor and its potential use/non-use instead of the defined, existing comparator(s) give rise to any legal issues?	Yes
Legal requirements for providing patient with sufficient information about treatment (benefits and potential harms) must be met. Informed consent should be implemented in health care institutions especially if the use of Endoanchor is planned. Other potential legal aspects are associated with coverage and reimbursement decisions	
4.2. Does comparing EndoAnchor to the defined, existing comparator(s) point to any differences that may be legally relevant?	Yes
Endoanchor use can be recommended to selected patients with high risk of complications on EVAR/TEVAR procedures. The selection of these patients of high risk must be carefully evaluated. Endoleaks and other late complications of EVAR/TEVAR procedures are particularly prevalent in patients with hostile neck anatomy, validating the narrow anatomic spectrum indicated in EVAR device instructions for use. However, these stringent anatomic guidelines have led to widespread off-label use. EndoAnchor use could expand the indications of EVAR/TEVAR procedures.	