Vascutek FSN Ref:	FSN2026-001 Thoraflex Hybrid IFU update
Date:	Xx Feb 2026
For the Attention of:	Health care providers, hospital risk teams, all Thoraflex Hybrid devices users
EU manufacturer SRN:	GB-MF-000003643
Basic UDI DI:	Thoraflex Hybrid: 5037881 THBFK

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Field Safety Notice
INFORMATION REGARDING INTRALUMINAL THROMBOSIS AND FROZEN ELEPHANT TRUNK REPAIR
Device: Thoraflex Hybrid

Dear Vascutek device user,

Further to feedback, received at Vascutek regarding experience with the Thoraflex Hybrid devices, we are proactively communicating to advise of updates to the Instructions for Use (IFU) to enhance the information for the users. Vascutek is updating the IFU to include the following wording:

Section 4 'Warnings and Precautions –Section 4.5 Treatment and Follow-up'
Patients that present with potential risk factors for postoperative complications of FET such as intraluminal thrombosis formation should be considered for potential additional early imaging surveillance and treatment as discussed in Section 14.7.

Section 14.7 Additional Surveillance and Treatment
Additional surveillance should be considered for patients presenting with suspected risk factors for intraluminal thrombosis formation following FET; the possible early onset nature of this event should be accounted for when prescribing individualized follow-up in line with the relevant clinical practice guidelines. In cases where intraluminal thrombosis is detected, current clinical practice guideline recommendations should be considered in the formation of individualized treatment plans.

1. Information on the affected devices

1.1. Intended purpose
The Thoraflex Hybrid device is intended for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection.

1.2. Device description
Thoraflex Hybrid is designed for the open surgical repair of aneurysms and/or dissections in the aortic arch and descending aorta with or without involvement of the ascending aorta. Thoraflex Hybrid is designed to perform the Frozen Elephant Trunk (FET) procedure in which a diseased aortic arch/ascending aorta is replaced by a surgical graft and a stented graft is placed in the descending thoracic aorta (DTA).

1.3. Target patient group
The intended patient group for Thoraflex Hybrid devices are patients with a damaged or diseased aortic arch and descending aorta in cases such as aneurysm and dissection, with or without involvement of the ascending aorta.

2. Description of device problem
FET treatment involves a complex surgical procedure that requires lifelong, regular follow-up to ensure the ongoing safety and effectiveness of the repair. As with most complex surgeries and concomitant patient co-morbidities, there are potential risks that must be considered and weighed as part of the patient selection and treatment process. One potential adverse event for FET repair is intraluminal thrombosis (ILT) and is the focus of this communication and an outcome of close collaboration with the FDA. ILT is characterized by the presence of thrombus within the stent graft typically identified through imaging during the early postoperative period. While in some cases ILT can be resolved through therapeutic anticoagulation, ILT is associated with a risk of embolization which may result in thromboembolic events.

2.1. Affected devices
- All models of Thoraflex Hybrid devices

3. Risk assessment
Literature aiming to identify risk factors for the development of ILT following FET was reviewed inclusive of:
- De Silva et al, Thrombotic complications after aortic arch replacement with frozen elephant trunk stent-graft: A 10-year United Kingdom institutional experience. JTCVS Open, August 2025

- Misfeld et al, Early intraluminal frozen elephant trunk stent graft thrombosis after aortic arch surgery. Ann Thorac Surg 2023; 116:450-8
- Ibrahim et al, In-hospital thromboembolic complications after frozen elephant trunk aortic arch repair. Journal of Thoracic and Cardiovascular Surgery, Volume 167, Number 4, April 2024
- Martens et al, Features and risk factors of early intraluminal thrombus formation within the frozen elephant trunk stent graft. Journal of Thoracic and Cardiovascular Surgery, 2023
- Walter et al, Postoperative in-stent thrombus formation following frozen elephant trunk total arch repair. Frontiers in Cardiovascular Medicine, Volume 9, June 2022
- Benk et al, Comparative study of Male and Female patients undergoing frozen elephant trunk total arch replacement. J Clin Med, 2023, 12,6327

In summary, these studies (inclusive of Thoraflex Hybrid and competitor devices) included cohorts ranging from 125 to 362 patients, with the ILT occurrence rate ranging from 5 – 17%. Several of these publications examined pre-operative patient characteristics, device selection and procedural outcomes to identify any differences between patients developing ILT and those that did not.

Factors examined included:

- Degenerative aneurysms
- Female sex
- Stent graft sizing
- Low cardiac output
- Distal Endoleak
- Distal endoleak
- Central positioning of the stent in the native aorta
- Autoimmune disorders
- High volumetric size of the descending aorta
- Major bleeding with conservative management

There was heterogeneity throughout the factors of interest reported across the publications as well as conflicting levels of statistical significance, limiting the ability to form a definitive list of potential risk factors for ILT formation.

4. Occurrence rate

In the limited instances where Thoraflex Hybrid thrombosis complaints have been reported (~0.2% rate), in-depth internal investigations using the available imaging, patient pathology and condition, etc., have been conducted and although direct causality could not be demonstrated, 3 common factors were observed: severe aortic angulation, poor distal seal and/or excessive oversizing.

5. Corrective actions

Vascutek is updating the IFU to include the following wording:

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6. User actions

Vascutek does not require specific corrective actions from the users, patients, healthcare facilities or risk managers, since all affected devices are fit for use. However, users shall read the IFU carefully, acknowledge and return the completed Appendix 1 to confirm receipt of this notice. Although the risk factors are addressed in the current IFU warnings and sizing/ technique guidelines, it was considered prudent to emphasise that patients presenting with potential risk factors for post-operative complications such as ILT be considered for possible additional early imaging surveillance.

7. Potential clinical consequence

The Thoraflex Hybrid device has been evaluated in a variety of clinical settings (THOR, EXTEND) and data continue to be gathered. In addition to the follow-up on the patient cohort from the pivotal IDE study upon which PMA approval was based, there is an on-going all-comers global Post-Approval Study, EXTEND-001 (NCT05639400) and

an all-comers global Post-Market Clinical Follow-up study (THOR-0001, NCT03414866). Together, both studies include over 400 patients.

The relevant observations related to ILT in each study are presented below for the IDE study, THOR and EXTEND. It is worth noting ILT is not consistently reported as an adverse event, and there is considerable variability in how it is captured/defined. This likely is a contributing factor in the data and rates being reported and/or observed.

IDE	One case of vascular stent thrombosis was reported in the IDE study leading to an incidence of 1.5% (1/65). This was a CEC-adjudicated event.
EXTEND*	An interim analysis identified one case of ILT from Core Lab observations and an additional five cases of ILT (not Core Lab observed) from AE narratives among 268 patients resulting in a total incidence of 2.2% (6/268).
THOR*	There were 11 cases of ILT identified from AE narratives (not CEC adjudicated) among 157 patients (study initiated 2017) resulting in an incidence of 7.0% (11/157)[1].

* ILT events were extracted from AE narratives but were not CEC-adjudicated.

ILT is not consistently reported as an adverse event, and there is considerable variability in how it is captured/defined:

- Some cases document ILT without clinical sequelae.
- Others identify ILT retrospectively after a thromboembolic event, which tends to underrepresent its true incidence and only a fraction of patients with ILT go on to experience thromboembolic events.

The lower incidence of ILT in the IDE study compared to recent post-market reports likely reflects increased awareness of this complication. Publications describing ILT only emerged between 2022–2025, whereas the IDE study concluded in 2021. As awareness grows, ILT will increasingly be detected through imaging before clinical complications occur. While this may appear as a rise in complication rates, it actually represents improved reporting accuracy and will represent a greater alignment with the presence of ILT rather than ILT-related clinical events

8. Transmission of this Field Safety Notice

Awareness of this Field Safety Notice is important and shall be distributed to operating surgeons, clinicians and users.

Please share this information with anyone in your organisation who needs to be aware or is a user of the affected devices. **Complete and return Appendix 1 to:**

TA UK FSN2026-001 Thoraflex Hybrid IFU update <fsn2026-001 Thoraflex Hybrid IFU@terumoaortic.com>

Contact

Patient safety is paramount to Vascutek Ltd and your detailed review of the information in this document is appreciated. If you have any questions regarding this FSN, the associated device or the IFU, please contact:

TA UK FSN2026-001 Thoraflex Hybrid IFU update <fsn2026-001 Thoraflex Hybrid IFU@terumoaortic.com>

Alternatively, please feel free to contact your local sales representative.

For and on behalf of Vascutek Ltd

Signed by:
Signer Name: Dina Justice
Signing Reason: I approve this document
Signing Time: 16Mar2026 | 08:05:35 PDT
B4B18B390CF84ED5915E3DB60CE14A17

Dina Justice
Vice President, Regulatory Affairs

[1] Note there is likely some duplication of patients between the literature (Martens et al., 2023, Benk et al., 2023, Walter et al., 2022, Ibrahim et al., 2022b) and the manufacturer sponsored study THOR, due to the same study sites being involved in both.

APPENDIX 1 – RETURN CONFIRMATION

Vascutek Ltd reference: FSN2026-001 Thoraflex Hybrid IFU update

Return the completed form immediately to:

TA UK FSN2026-001 Thoraflex Hybrid IFU update <fsn2026-001 Thoraflex Hybrid IFU@terumoaortic.com>

By signing below:

- I acknowledge receipt of this Field Safety Notice and confirm that I understand the contents
- I have communicated the Field Safety Notice to the users in my territory
- The notification communication with the affected users is attached to this document.

THIS SECTION TO BE COMPLETED BY THE DISTRIBUTOR/ LOCAL REPRESENTATIVE
Distributor print name
Territory responsible for
Person responding (print name)
Email address (person responding)
Title
Signature
Date of signature

NAME OF USER NOTIFIED

Hospital/ Health care facility name, address and contact print name	**Signature date (dd-mmm-yyyy) of hospital/healthcare facility contact/ acknowledgement**

Add lines as required