Vascutek FSN Ref: SP22-003
Date: 11 November 2022
For the Attention of: All those implanting or managing affected patients, Distributors, Authorised Representative
EU manufacturer SRN: GB-MF-000003643
Applicable implant date period: 2012- to date

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Urgent Field Safety Notice
Device: Anaconda (Custom made)
UDI: not applicable

Dear Vascutek Customer,

This Field Safety Notice contains important information regarding the Anaconda (Custom made) vascular implant device you may have received in the past.

1. Information on affected devices

The intended purpose of the Anaconda Stent-Graft System (Custom made) is exclusion of abdominal aortic aneurysm from blood circulation, in order to reduce the risk of further enlargement and rupture.

2. Description of device problem

Vascutek has identified proximal ring stent fractures in certain Anaconda (Custom made) devices.

To date, there have been 29 reported fractures, representing 0.52% of the 5,500 worldwide main body Custom Anaconda device (Bifurcate, Cuff and AUI) known implantations.

The prevalence is, however, significantly higher for certain device configurations, suggesting that some patients are at higher risk of experiencing ring stent fracture than others:

	# fractures in 29 reported cases	Occurrence rate within configuration	Occurrence rate of total Anaconda Custom made devices
By Number of Fenestrations			
devices with three fenestrations or fewer	25	0.94%	0.45%
devices with four fenestrations	4	0.15%	0.07%
By Proximal Ring Configuration			
devices with fenestration between the proximal rings	8	2.93%	0.14%
fully augmented configuration	7	0.75%	0.13%
standard proximal ring configuration	10	0.27%	0.18%
partially augmented configuration	4	0.64%	0.07%

Further details of device and patient factors (including device placement and disease progression) identified as contributing to the risk of stent ring fracture are given in section 7 below.

3. Potential Clinical Consequence of Proximal Ring Stent Fracture

Potential risks/ hazards associated with ring fracture include aneurysm growth, occlusion of vessels within the treatment area, pulsatility, migration, vessel puncture caused by migration or protrusion, endoleaks and compromised device integrity.

However, a study of a similar devices, Liang et all (2021)[1] concluded that although ring stent fractures were found, within the 5 year follow up there was no clinical sequalae, migration, endoleaks development, sac enlargement or rupture or aneurysm related reintervention were attributed to these fractures.

Although ring fractures have been reported for Anaconda (Custom made) implants since 2015, to date the only cases of loss of proximal seal have also been associated with disease progression at the proximal landing zone. There is currently limited implant experience of device performance and safety beyond 4 to 5 years following a ring stent fracture, therefore enhanced patient surveillance is recommended as a precautionary measure (see section 5 below.)

4. Detectability of a Ring Stent Fracture

To date ring stent fractures have been observed between 2-62 months from the implantation date, most commonly within 12-36 months.

A detailed retrospective review of all Anaconda (Custom made) implants by 2 high volume centres found that nearly 6% of implants had experienced ring stent fracture. These were early adopting centres with a high number of implants with factors contributing to the risk of fracture (fenestration between proximal rings, fully augmented configurations) as detailed in Section 7, and hence the true prevalence of fractures in the wider patient population remains unknown[1].

Therefore, the following required actions and advice intend to improve detectability, allowing proactive patient management, dependent upon device and patient characteristics.

5. Patient management guidance

Vascutek recommends physicians proactively contact patients implanted with the Anaconda (Custom made) devices and perform follow up imaging every six (6) months, or as frequently as deemed appropriate in the physician's medical judgment. The imaging is for the evaluation of any progressive changes in the integrity of the proximal ring stents.

Perform follow up imaging

- with particular attention to ring integrity and assessment for any of the contributing factors identified in Section 7 below
- to reduce risks to patients by exposure to x-Ray, an interim review using plain film imaging should be considered between routine follow-up CT imaging to monitor the integrity of the proximal rings for device designs that have been identified to have a higher risk of proximal ring stent fracture (see section 2)

In addition, for patients found or known to have a fracture:

- during increased patient follow up imaging, pay particular attention to potential adverse events that might be the result of the loss of ring integrity
- In cases where wire strands escaped from the bundle to/into close proximity to the liver and IVC, or in cases where strands of wire are in the vertebral disc space; if there is no sign of clinical impact, continue monitoring. If there are signs of clinical impact, course of action shall be determined that might include explanation or relining the graft with another device.

[1] - Liang et al [(2021) Abdominal aortic and iliac artery aneurysms, Five-year results of the INSPIRATION study for the INCRAFT low-profile endovascular aortic stent graft system, Journal of Vascular Surgery Volume 73, Issue 3, March 2021, Pages 867-873, prospective study] documented that even at a follow up a ring stent fracture may be missed. The study they carried out for a similar device observed unanticipated ring stent fractures in 20 (n=190) patients during a 5 year follow up of the Incraft low profile endovascular aortic stent graft system. Fractures were not initially recognised and were only identified after a second detailed review of the entire imaging data set by a second core laboratory.

6. New patients who have not received implant to date

Anatomical considerations should be made to determine the suitability of any identified proximal landing zone to eliminate the risk of a potential proximal ring stent fracture. A suitable proximal landing zone should:

- Be free of significant calcification and thrombus
- Have sufficient clearance between the proximal rings and visceral/renal arteries
- Have sufficient clearance between the proximal rings and adjacent vertebral body (≥3mm)
- Have sufficient clearance to the diseased region of aorta, ensuring both proximal sealing rings and fixation hooks engage in healthy vessel

7. Investigation of factors contributing to the risk of proximal stent fracture

The internal investigation conducted following the receipt of retrospective field information found, that devices with the combination of certain device features and disease progression, as outlined below, could result in unusual loading on the proximal rings stents which may lead to ring fractures:

- disease progression around the level of the proximal landing zone of the device
- devices implanted in unsuitable landing zone
- interaction of the proximal sealing rings with branch vessel ostia
- interaction of the proximal sealing rings with the spine
- interaction of the proximal sealing rings with branch stents
- interaction of the fixation hooks with branch stents
- interaction of the fixation hooks with the spine

Data analysis demonstrated that devices with the following characteristics have a higher risk of proximal stent fracture when combined with at least one contributing factor:

- Devices with fenestration between the proximal rings
- Devices with 2/3 fenestrations with a landing zone in close proximity to visceral/renal arteries (augmented proximal ring configuration)

Devices with the following characteristics were shown to have a lower risk of proximal stent fracture:

- Devices landing higher in the aorta above the celiac artery with a joining ring between the proximal sealing rings and the Celiac fenestration
- Devices landing proximally within a thoracic stent graft device (TEVAR)

The investigation showed a decreasing trend in demand in both the fenestration between proximal rings and fully augmented configurations and an increasing trend for devices sealing higher in the aorta above the Celiac Artery.

8. Observations of ring stent fractures in the non custom-made Anaconda devices

All available clinical data from manufacturer sponsored studies and published literature relating to the standard CE-marked Anaconda Stent-Graft System was reviewed, with follow-up data up to 6 years, and no instances of stent fractures were identified.

9. Steps already in place/planned to modify device design/processing

The case planning work instructions were revised to reflect and reduce the likelihood of occurrence of ring fractures and risks associated with these occurrences by eliminating one of the contributing factors listed above.

The implemented Corrective actions include:

- Updated planning guidelines to increase minimum required distance between vessels when landing Anaconda device between vessels
- Updated planning guidelines to include potential ring/spine interaction assessment
- Updated design guidelines to increase minimum distance between most proximal fenestration and proximal rings
- Removed ‘Fenestrated Valley’ configuration from available design options (this was the most common proximal ring configuration to experience fracture)

We are also looking to introduce an improved form of Nitinol in the manufacturer of future proximal ring stents.

Transmission of this Field Safety Notice

Please share this information with anyone in your organisation who needs to be aware or to whom may have received the affected devices.

This action by Vascutek Ltd is being taken with the knowledge of the National Competent Authority – Medicines and Healthcare Products Regulatory Agency (MHRA).

Contact

Patient safety is paramount to Vascutek and your detailed review of the information in this document is appreciated. If you have any questions regarding this FSN, please contact taracustoms@terumoaortic.com. Alternatively, please feel free to contact your local Sales Representative or Vascutek Ltd Clinical Service personnel.

For and on behalf of Vascutek Ltd

[redacted]
Regulatory Affairs Manager