Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Updated guidance on the management of the recalled Endologix Nellix EndoVascular Aneurysm Sealing System

(DSI/2025/004)

Specialisms: *Radiology and imaging, Vascular and cardiac surgery*

DEVICE DETAILS

Endologix Nellix EndoVascular Aneurysm Sealing (EVAS) System

AFFECTED LOT SERIAL NUMBERS

All lot serial numbers

MANUFACTURED BY

Endologix LLC

Summary

Following a review, the MHRA provides an update to previous guidance on the management of patients treated with the recalled Endologix Nellix EndoVascular Aneurysm Sealing (EVAS) System to reflect updated recommendations. All implanted patients in the UK with this device should be identified and appropriate action taken.

Advice for Healthcare Professionals:

- previous MHRA advice regarding management of implanted patients with these devices has now been superseded (see 'Explanation of identified safety issue' section)
- healthcare professionals should identify, assess and treat patients with these devices in line with the updated recommendations from the European Society for Vascular Surgery (ESVS) Abdominal Aortic Aneurysm Clinical Practice Guidelines[1]
- refer to the ESVS guidelines for comprehensive steps for patient management, in summary you should:
    - identify all patients with an implanted Nellix device at your centre

- inform patients regarding the high mid- and long-term failure rates of EVAS and explain potential problems that may occur
- enrol patients in enhanced surveillance, for those deemed necessary
- for patients with a failing Nellix implant, early elective explantation is recommended as the preferred treatment in surgically fit patients

Advice for Healthcare Professionals to Provide to Patients:

- if you are implanted with one of these devices you will be contacted by your treatment centre. They will discuss the risks associated with your device and the options available to you depending on your circumstances
- if you experience any symptoms such as pain, numbness, or weakness in the legs back, chest or abdomen, dizziness, fainting, or rapid heartbeat, please seek urgent medical attention [2]

Advice for Distributors:

- n/a

Explanation of identified safety issue

The Nellix EVAS System was an implantable device used to treat abdominal aortic aneurysms (AAA). In 2019, Endologix, the manufacturer, voluntarily recalled the Nellix device due to high rates of graft failure caused by device migration, type 1 endoleak, and sac expansion. Endologix also ceased sales from this point. Consequently, the MHRA issued guidance in the UK via medical device alerts (MDA/2019/002; MDA/2019/021) outlining steps to identify and manage patients with failing Nellix implants, including recommendations for ongoing surveillance of implanted patients. The previous guidance on this issue is now superseded by this current Device Safety Information (DSI).

In February 2025, the MHRA received a request from a coroner following an inquest into a patient death which related to a Nellix device. The request highlighted concerns that some implanted patients may not have received initial notification of the alert and therefore were not receiving appropriate treatment or surveillance, and the need for a potential updated communication. Subsequently, the MHRA conducted a review on this issue.

The review concluded that there were some UK patients who still have the Nellix device implanted; this DSI presents an opportunity to address the coroner's concerns and to raise awareness of new recommendations. Accordingly, this DSI provides revised

guidance to align with the latest (2023) European Society for Vascular Surgery (ESVS) Abdominal Aortic Aneurysm Clinical Practice Guidelines.[1]

Details of failure rates are outlined in the ESVS Clinical Practice Guidelines[1] which references several additional or updated single UK centre studies which were published after the previous MHRA guidance. In summary, EVAS failure arises predominantly from caudal migration of the stent grafts and separation of the endobags leading to type 1a endoleak, sac pressurisation, and aneurysm expansion. These failures most commonly occur more than two years after the initial implantation. The ESVS Clinical Practice Guidelines highlights a systematic review and meta-analysis (range 24-72 months), the pooled incidence rates of type 1 endoleak, migration, and re-intervention was 25%, 22%, and 27%, respectively. [1,3]

The ESVS Clinical Practice Guidelines also emphasise the importance for healthcare professionals to clearly and transparently inform identified patients regarding the failure rates of the device.[1] It recommends a thorough face-to-face consultation to explain the need for enhanced surveillance and to discuss potential complications. For surgically fit patients, prompt surgical explantation is advised if device failure is identified by surveillance.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with their local medical device policies and procedures

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- The Vascular Society of Great Britain & Ireland (VSGBI)

- The British Society of Interventional Radiology (BSIR)
    - Professor Robert Morgan, BSIR President
- Major clinical sites which conducted Nellix implant procedures
- NHS England Patient Safety Team
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- Northern Ireland Adverse Incident Centre for Northern Ireland

References

1. Boyle JR, Tsilimparis N, Van Herzeele I, Wanhainen A; ESVS AAA Guidelines Writing Committee; ESVS Guidelines Steering Committee. Editor's Choice - Focused Update on Patients Treated with the Nellix EndoVascular Aneurysm Sealing (EVAS) System from the European Society for Vascular Surgery (ESVS) Abdominal Aortic Aneurysm Clinical Practice Guidelines. Eur J Vasc Endovasc Surg. 2023 Mar;65(3):320-322.
2. https://endologix.com/wp-content/uploads/2017/03/MM1344-Rev-01-Nellix-Patient-Guide-07-29-16.pdf (Accessed: 17 June 2025)
3. Kouvelos G, Nana P, Brodis A, et al. A Meta-Analysis of Mid-Term Outcomes of Endovascular Aneurysm Sealing. Journal of Endovascular Therapy. 2022;30(5):664-675.