Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/021 Issued: 1 May 2019 at 14:30 Valid until: 29/01/2020

Updated: Nellix Endovascular Aneurysm Sealing (EVAS) System - Device recall and enhanced patient surveillance

Summary

Endologix has stopped selling the Nellix EVAS device and is recalling unused stock. MHRA recommends enhanced patient surveillance due to a high risk of graft failure beyond two years after implantation.

Update includes further advice on how to detect features of Nellix endograft failures. This advice has been produced by MHRA's Nellix independent Expert Advisory Group.

Note: This Medical Device Alert (MDA) updates guidance previously given in MDA/2019/002 issued 25 January 2019.

Action

1. Immediately stop further implants of the device.
2. Identify if your centre has any device inventory that should be returned to Endologix following the instructions in the Field Safety Notice (dated 04 January 2019).
3. Identify all patients implanted with a Nellix device under surveillance at your centre.
4. Notify your nearest UK expert centre (identified in the protocol at appendix 1) with the number of patients you currently have remaining under surveillance and discuss in advance the support this centre can provide if a patient requires re-intervention.
5. Continue to undertake lifelong follow-up of all patients according to normal clinical practice. Enhanced surveillance involving CT imaging should be repeated at least annually, unless the patient is considered unfit for secondary intervention. Arrange for early CT surveillance for all patients who have not received CT imaging within the last 12 months.
6. The most recent scans should be compared to immediate post-operative images to identify signs of device failure. This includes significant device migration, Type I endoleak and/or aneurysm sac expansion. MHRA's independent Expert Advisory Group has produced extra information on how to detect features of device failure. For more information please follow this link.
7. Discuss with the nearest UK expert centre all patients being considered for secondary intervention.
    a. Patients that are suitable for surgical explant may be treated either locally or referred on to a larger volume centre if appropriate.
    b. All patients in whom a Nellix-in-Nellix intervention is proposed as the optimum treatment should be treated at one of the named UK expert centres, according to the conditions set out in the protocol at appendix 1.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Action by
Interventional radiologists and Vascular Surgeons

Deadlines for actions
Actions underway: 08 May 2019
Actions complete: 22 May 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Problem / background

Affected hospitals should already have received the Field Safety Notice from Endologix, explaining that the company has stopped distributing the device and is withdrawing any unused devices from hospital inventory via a field safety corrective action (FSCA).

The CE-mark (EU market authorisation) for this device is currently suspended by the Notified Body. This MDA provides advice on steps that can be taken in the UK to identify and treat a patient with a failing Nellix implant, together with further background information.

Reason for the FSCA
MHRA has considered recent evidence on the Nellix EVAS system, both published and awaiting publication, (some of which is referenced below) together with reported adverse incident data. We have identified concerns over the safety and performance of the device two years after implantation. Specifically, we have noted a high rate of graft failure due to device migration, Type 1 endoleak, or sac expansion.

A number of changes have been made to the device design, indications for use and recommended implantation technique which were the subject of previous FSNs. MHRA considers these now require robust clinical investigation to determine their effectiveness. Endologix has undertaken this voluntary FSCA to address concerns over the continued commercial use of the device.

This MDA has been prepared in consultation with the MHRA's independent expert clinical advisors and has been shared with Endologix.

References:

1. Editor's Choice – Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System – a Single Centre Experience. Seamus C. Harrison, Andrew J. Winterbottom, Patrick A. Coughlin, Paul D. Hayes, Jonathan R. Boyle
   Cambridge University Hospital Trust. Eur J Vasc Endovasc Surg (2018) 56, 342-348
2. Stent Frame Movement Following Endovascular Aneurysm Sealing in the Abdominal Aorta
   Asma Yafawi, MPhil, Richard G. McWilliams, FRCR, EBIR, Robert K. Fisher, MD, FRCS
   Institute of Translation Medicine, University of Liverpool, UK J Endovasc Ther 2018 Nov 28 - https://doi.org/10.1177/1526602818814548
3. Anatomical Predictors of Endoleaks or Migration After Endovascular Aneurysm Sealing
   Kim van Noort MSc, Johannes T. Boersen PhD, Aleksandra C. Zoethout MD, et al **on** behalf of the DEVASS (Dutch Endovascular Aneurysm Sealing Study) Group J Endovasc Ther 2018 Oct 25 - https://doi.org/10.1177/1526602818808296

Manufacturer contacts

Endologix International Holdings B.V.
Burgemeester Burgerslaan 40
5245 NH, Rosmalen, Netherlands
Tel: +31 88 116 91 01
Email: customerservice@endologix.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Medical directors
- Radiologists
- Radiology departments
- Radiology directors
- Renal medicine departments
- Renal medicine, directors of
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/021 or 2017/003/003/203/001**.

Technical aspects

Sophie Clewlow, Alexander McLaren and Hazel Randall, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

Appendix 1

Protocol for UK case referral for the exceptional use of a Nellix to treat a failing existing implant

This protocol has been prepared by MHRA based on advice from external clinical experts.
Endologix has stopped distribution of the device, and market approval* is currently suspended. It is, however, acknowledged that there may be a certain narrow range of circumstances where supply of the device would be in the patient's best interests**.
The purpose of this document is to describe those circumstances and to define arrangements for supply of the device in the UK to meet this requirement.

A. Conditions to be met

1. The patient characteristics:
    a. Already has a Nellix implant;
    b. Is identified as at significant risk of aneurysm rupture (see assessment of implanted patients) and has not suffered actual rupture;
    c. Is not suitable for surgical explant of the in situ Nellix;
    d. Further intervention with another Nellix device is identified as the best treatment option for the patient compared to any other viable alternatives***;
    e. Will be treated as an inpatient at one of the hospitals listed below.
2. The hospital performing the procedure is one of the MHRA recognised centres with adequate expertise in the UK. These centres will have:
    a. Completed at least 100 cases;
    b. Significant intervention with Nellix patients within the last 2 years;
    c. Undertaken a number of Nellix-in-Nellix interventions;
    d. An active governance programme such as demonstrated by publication of results;

    See section C for a list of recognised centres.
3. The operator implanting Nellix:
    a. Is a consultant at one of the recognised expert centres;
    b. Is on the list of named individuals at that hospital that has suitable expertise.

B. The process to be followed

1. The patient is identified as meeting the criteria above:
    a. This is done by the implanting operator and;
    b. Agreed by a suitable local senior governance group under the auspices of the Medical Director of the hospital.
2. For any potential patient not in one of the recognised expert centres:
    a. Qualification to the above criteria should be discussed with the named individuals at the nearest of those hospitals;
    b. The recognised expert centre will confirm whether they are able to accept the patient for secondary intervention with a Nellix device.

3. The patient must be informed of the reasons for the device suspension and give consent after receiving the consent information agreed by MHRA and the implant centres.
4. Endologix Medical Affairs will be advised of the potential candidate for a Nellix Secondary Intervention. Feedback will be given to the clinician and MHRA regarding clinical suitability, logistics for product supply and case support.
5. The consultant undertaking the procedure shall inform MHRA before the procedure of the patient's details and planned procedure.
6. Once agreement has been given to the consultant by MHRA, arrangement can be made to admit the patient for the procedure.
7. Once authorisation has been given by MHRA to Endologix, the Company will supply necessary devices to the hospital if at all logistically possible within 48 hours.
    a. A representative of Endologix should bring the device to the hospital and support the procedure. The need for further support, including possible proctorship, will depend on the individual case requirements.
    b. The Endologix representative will remove any unused devices after the procedure.
8. The patient and procedure details shall be recorded:
    a. in the patient's records and any local hospital audit system
    b. by Endologix in a complete list of cases
    c. in the database created by MHRA for this purpose.

C. List of MHRA recognised expert centres

1. Royal Liverpool University Hospital
2. Cambridge University Hospitals, NHS Trust
3. St George's University Hospital, NHS Trust

Note:
See MHRA's guidance on exceptional use of non-CE marked medical devices:
https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices

* EU market approval for a medical device requires a valid CE-mark to be in place.

** Medical devices which do not have a valid CE-mark may be supplied in the interests of public health, subject to certain conditions, authorised under regulation 12(5) of the Medical Devices Regulations 2002.

***A Nellix device is being used to significantly reduce the mortality or morbidity of the treatment, compared to use of alternative CE marked devices.