Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2026/00802**

20 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 22 July. You wrote:

> *Under the Freedom of Information Act 2000, I request the following information relating to Powered ECHELON PVS staplers at Blackpool Teaching Hospitals NHS Foundation Trust.*
>
> *1. Please provide details of all incidents recorded by the Trust involving Powered ECHELON PVS staplers during the last five years.*
> *2. Please provide details of all incidents recorded by the Trust involving Powered ECHELON PVS staplers between 15 December 2023 and 31 January 2024.*
> *3. Please provide any anonymised supporting information held in relation to these incidents, where this can be disclosed under the Freedom of Information Act 2000.*

MHRA Response

We confirm that we hold the information you have requested.

You asked for information regarding Powered ECHELON PVS staplers manufactured by Ethicon. We are unable to provide specific information relating to these products because this information is exempt under section 43 of the Freedom of Information Act 2000. This exemption applies where disclosure would, or would be likely to, prejudice the commercial interests of any person or organisation, including a third-party supplier, manufacturer, or the public authority itself. We are unable to provide information on the number of adverse incidents we have received regarding this specific device from Blackpool Teaching Hospitals NHS Foundation Trust due to commercial confidentiality reasons.

Disclosure could reasonably be expected to prejudice the commercial interests of the manufacturer and/or other relevant organisations by revealing information that is not otherwise publicly available and which could be used by competitors to gain a commercial advantage. We recognise the public interest in promoting transparency and accountability regarding medical devices and the activities of public authorities. However, we consider that there is a stronger public interest in protecting legitimate commercial interests where disclosure would be likely to cause commercial harm and could undermine the ability of organisations to participate openly and effectively in regulatory and commercial processes.

However, further to your request in point 1 we have conducted a search of our database for all adverse incident reports associated with the following Global Medical Device Nomenclature (GMDN) Collective Term (CT) codes which correspond to the description of Powered ECHELON PVS staplers:

- CT1539 – Staples
- CT1540 – Staplers

From the 10th of August 2021 until up to and including the 10th of August 2026, I can confirm that the MHRA has received 12 adverse incident reports involving devices associated with the above GMDN CT codes from the Blackpool Teaching Hospitals NHS Foundation Trust. Please note that this search was conducted across all relevant brands, models, and manufacturers associated with the GMDN CT codes listed above.

Further to your request in point 2, I can confirm that from the 15th of December 2023 until up to and including the 31st of January 2024, we received one adverse incident report involving devices associated with the above GMDN CT codes from the Blackpool Teaching Hospitals NHS Foundation Trust.

In response to point 3, please find below the International Medical Device Regulators Forum (IMDRF) codes reported in the cases from points 1 and 2. IMDRF codes provide a globally harmonized and hierarchical system for reporting medical device adverse incidents and cover device problems, clinical effects, and device components.

Annex A codes describe malfunctions, failures, or other problems associated with the device. Please find below table 1 which shows the Annex A codes reported and the corresponding number of cases reporting each code:

Table 1: Number of Cases by Annex A Code

Annex A Code	**Number of Cases**
A24 No Apparent Device Problem	3
A25 No Apparent Adverse Event	1
A050501 Failure to Fire	3
A050502 Misfire	2
A050704 Failure to Form Staple	1
A051104 Difficult to Open or Close	3
A150103 Premature Activation	1
A150208 Entrapment of Device	1

Annex E codes focus on health effects and describe clinical signs, symptoms, or conditions that occur as a consequence of device use or failure. Please find below table 2 which shows the Annex E codes reported and the corresponding number of cases reporting each code:

Table 2: Number of Cases by Annex E Code

Annex E Code	Number of Cases
E2014 Tissue Breakdown	2
E2403 No Clinical Signs, Symptoms or Conditions	6
E0506 Haemorrhage/ Blood Loss/ Bleeding	3
E0602 Cardiac Arrest	2
E0734 Pneumothorax	1

Annex F codes detail health effects, impacts, and consequences of a device-related adverse event. Please find below table 3 which shows the Annex F codes reported and the corresponding number of cases reporting each code:

Table 3: Number of Cases by Annex F Code

Annex F Code	Number of Cases
F02 Death	1
F08 Hospitalization or Prolonged Hospitalization	2
F11 Non-Serious Injury/ Illness/ Impairment	2
F1906 Modified Surgical Procedure	4
F2301 Additional Device Required	1
F2302 Blood Transfusion	1
F2306 Resuscitation	2
F24 Insufficient Health Impact Information	2
F26 No Health Consequences or Impact	6

When reviewing adverse incident data please note:

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues.

- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate

- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.

- The numbers may include reports where the incident has been taken from published literature.

- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.

- The inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. The data provided, therefore, is not a summary of known or proven adverse reactions to the device and must not be interpreted and used as such.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/