



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00931**

21 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 21 August. You wrote:

Thank you for your response dated 20 August 2026 in relation to FOI2026/00802.

I would like to request the following further information regarding the adverse incident reports involving GMDN CT1539 – Staples and/or CT1540 – Staplers from Blackpool Teaching Hospitals NHS Foundation Trust.

- 1. In relation to the 12 adverse incident reports identified, please provide the month and year of each.*
- 2. If the month and year cannot be provided, please provide a breakdown by year.*
- 3. Please provide the same search and coding breakdown for incidents that took place between 1 January 2020 and 20 December 2023 involving GMDN CT1539 – Staples and/or CT1540 – Staplers from Blackpool Teaching Hospitals NHS Foundation Trust. Please provide the relevant IMDRF Annex codes, where available.*
- 4. In relation to the one adverse incident report identified between 15 December 2023 and 31 January 2024, please provide the incident date associated with that report.*
- 5. Please provide all Annex code / codes that were applied to that incident.*
- 6. Please confirm whether any Annex F code applied to that incident is associated with death, including Annex F code F02 Death.*

MHRA Response

In relation to the 12 adverse incident reports identified in our previous response, you have requested the month and year of each report. We are unable to provide the month of each report as this information is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient identification as outlined in our Privacy Policy [Privacy Policy | Making medicines and medical devices safer \(mhra.gov.uk\)](#). The policy states that we may receive requests for Yellow Card report data under the Freedom of Information Act and while we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded. In response to point 2, please find below Table 1 summarising the number of the 12 identified adverse incident reports by year.

Table 1: Number of Cases by Year of Submission

Month and Year	Number of Reports
2023	1
2024	4
2025	5
2026	1

Further to point 3, please find below the IMDRF Annex codes associated with incidents that took place between the 1st of January 2020 and the 20th of December 2023 involving GMDN CT1539 – Staples and/or CT1540 – Staplers from Blackpool Teaching Hospitals NHS Foundation Trust:

Table 2: Number of Cases by Annex A Code

Annex A Code	Number of Cases
A051104 Difficult to Open or Close	1
A050702 Failure to Cut	1
A050704 Failure to Form Staple	1
A0503 Ejection Problem	1

Table 3: Number of Cases by Annex E Code

Annex E Code	Number of Cases
E2403 No Clinical Signs, Symptoms or Conditions	1
E10 Gastrointestinal System	1
E0602 Cardiac Arrest	2
E0734 Pneumothorax	1

Table 4: Number of Cases by Annex F Code

Annex F Code	Number of Cases
F1906 Modified Surgical Procedure	1
F1908 Prolonged Surgery	1
F26 No Health Consequences or Impact	1

Further to your requests in point 4 to 6, we are unable to provide the specific incident details associated with this report. Unfortunately, we are unable to disclose this data as it is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act as detailed above.

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

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>