Date: 25/08/2021 **To:** [redacted]
From: [redacted]

Subject: [redacted] with User report details MHRA Ref:

Attachments: <<>>

25/08/2021

MHRA Ref: [redacted]

We have received an adverse incident report from NHS - Queen Elizabeth Hospital, Birminham concerning the following device:

Device: Adhesive Control Devices
Item: Surgical tissue adhesive
Model: Histoacryl
Serial No:
Batch No: 219393n2

Reporting Organisation: [redacted]
Reporter's Name: [redacted]
Reporter's Email: [redacted]
Reporter's Local Reference:

Incident date:
Incident / Failure Description: [redacted] presented for [redacted]
Decision made for thoracic epidural insertion for perioperative analgesia under anaesthesia
Method of insertion:
Asleep, left lateral, skin clean with chlorhexidine spray and allowed to air dry, blue gauze used to further wipe the area in single motion from cranial to caudal motion, 16G tuohy needle used and catheter inserted, tuohy needle removed.
Slight ooze noted at catheter/needle insertion site, a drop of histoacryl applied - this resulted in exothermic reaction causing a diathermy like pop followed by a small plume of smoke and a skin burn.
Catheter patency was checked with flushing and aspirating and no leaks identified. Catheter dressed and utillised for perioperative analgesia

We do not have any further details for this report.

What you need to do now

The manufacturer has the responsibility for investigating incidents and for taking any corrective action where necessary.

You must include this report in your post-market surveillance programme and in any periodic summary reporting arrangements that you,ve already agreed with the MHRA. You can find more details on

this web page https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403818/Directives_Bulletin_no3.pdf

If you have already sent a vigilance report for this incident, email us as soon as possible on aic@mhra.gov.uk to tell us the MHRA reference number that we assigned to your report.

If you consider the report to meet the vigilance criteria
You must report post-market vigilance reports to the MHRA via the MORE https://aic.mhra.gov.uk/ system or by sending an XML output of the Manufacturer Incident Report (MIR) form https://ec.europa.eu/docsroom/documents/41681 to aicxml@mhra.gov.uk. You can find more details on this web pagehttps://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance

Quote this reference: [redacted] in 'Healthcare facility report number' Field 3.4c. This is the MHRA reference assigned to the user's report.

A separate MHRA reference number will be assigned following the submission of your report - and must be quoted in in any subsequent report in field 1.1c 'Reference number assigned by NCA for this incident'

You must use IMDRF (International Medical Device Regulators Forum) terminology in your vigilance report. This page http://www.imdrf.org/workitems/wi-aet.asp of the IMDRF website provides guidance and each IMDRF annex.

We need your final report within 30 days. If you don,t have all the information immediately available, you can send us a follow-up report but tell us when you expect to send us the final report.

Contact the reporter if you need more details of the incident and to obtain the device(s). The user may not be able to release the device if the police or coroner is involved until further advice has been obtained.
Please do not use or share the reporter,s details for any purpose beyond investigating the incident.

Once you,ve finished your investigation, you must share your investigation findings with the MHRA by submitting a final report, and with the reporter of the incident. Occasionally we may forward your device analysis results, remedial/corrective action and final comments to the reporter.

If your investigation leads to a field safety corrective action (FSCA), your FSCA report with FSN form must be sent separate to the final report. Log your FSCA on MORE or fill in this form http://ec.europa.eu/DocsRoom/documents/15506/attachments/4/translations and submit in XML format to aicxml@mhra.gov.uk. Provide extra information in the Description of the FSCA tab on MORE / in Section 7 of the form as detailed in Annex B below. Include this reference number: 2021/008/012/291/001 in 'Incidence reference number assigned by NCA' on MORE / in Section 1 of the FSCA form. A new reference number will be created for the FSCA.

If you do not consider the report to meet the vigilance criteria, we request that you confirm your rationale for this conclusion by answering the questions in Annex A. Please make sure you include this number: 2021/008/012/291/001 with your reply.

If this incident happened in: Scotland, Northern Ireland, Wales, the devolved administration of that country may contact you. We,ve contacted you because we,ve decided to open our own, parallel report. MHRA work with the UK devolved administrations, which operate their own reporting and investigation systems for medical device incidents. You should co-operate with us and the relevant devolved administration.

If the device is not CE-marked or UKCA-marked and has been granted an Exceptional Use Authorisation (EUA) by MHRA you must adhere to the report requirements as stated in your EUA authorisation letter and include this incident within the report submitted.

Following receipt of a final report, we will not +close, a record nor provide a +closure, confirmation as we continually monitor reports through signal detection. We will contact you if we require more information.

Yours sincerely
Adverse Incidents & Communications Team
MHRA, Devices

NOTE: From 1st August 2021 we will not log any vigilance reports that are not submitted via our Manufacturer,s On-line Reporting Environment (MORE) which you can access through our reporting page or by sending an XML output of the Manufacturer Incident Report (MIR) form to aicxml@mhra.gov.uk.
An email will be sent informing you that your report has not been logged and will contain guidance on how to correctly log your vigilance report. Please be aware that until your report is correctly logged you will not have met the legal obligations under vigilance.

Use this email address aic@mhra.gov.uk to contact us. We check it regularly.

You can access the Medical Device Safety Officer (MDSO) contact list via MORE in order to copy them in on communications regarding Field Safety Notices (FSNs). This can help you ensure appropriate targeting and prompt action of the FSN within the MDSO,s organisation.

ANNEX A: Rationale for not reporting under vigilance - MHRA Ref: [redacted]

Q1.1 It is possible that a malfunction or deterioration in the characteristics or performance of the device *may have caused or contributed** to the event? yes/no

Q1.2 If no, please confirm why:

Q2.1 Did the incident lead to, or under different circumstances could it have led to, a death or *serious deterioration in state of health*** ? yes/no

Q2.2 If no, please confirm why:

Vigilance Reporting Criteria and Notes) taken from MEDDEV 2.12-1 Rev 8

***Note1.** In case of doubt it should be assumed that the device *may have caused or contributed* to the incident and the manufacturer should err on the side of reporting.

****Note2.** A *serious deterioration in state of health* includes but is not limited to:

a) life-threatening illness,
b) permanent impairment of a body function or permanent damage to a body structure,
c) a condition necessitating medical or surgical intervention to prevent a) or b).
Examples: - clinically relevant increase in the duration of a surgical procedure,
- a condition that requires hospitalisation or significant prolongation of existing hospitalisation.

d) any indirect harm as a consequence of an incorrect diagnostic or IVD test result or as a consequence of the use of an IVF/ART device.
e) foetal distress, foetal death or any congenital abnormality or birth defects.

Note3. The manufacturer must decide whether the event is reportable and submit the report to the MHRA where appropriate, not later than:

2 calendar days after awareness for **serious public health threat,**

10 calendar days after awareness of a **death or serious injury**

30 calendar days after awareness of an event that could have caused death or serious injury

Note 4. If it is unlikely that sufficient information will become available to confirm whether an event is reportable within the timeframes listed above the manufacturer must submit a report.

Please copy this line into *mail:* ***Rationale for not reporting under vigilance - MHRA Ref:*** [redacted]
Copy the questions into the body of your email and provide your answers
Send your email to AIC@mhra.gov.uk

ANNEX B : Extra information we need in section 7 of your FSCA report

1. **Risk assessment for the FSCA including:**

   1.1. How many incidents have you received related to this FSCA?

   1.2. What is the hazard presented by using the device with this issue? Send us a copy of the Health Hazard Evaluation (HHE) or Clinical risk assessment report.

   1.3. If this is a batch issue, why it is restricted to these batches only?

   1.4. Do you know if this issue affects other devices? (eg own-brand labelled products).

   1.5. Provide update on root cause investigation / conclusions of tests and other investigations on suspect or other samples.

   1.6. Provide details of long-term corrective actions.

2. **Where the FSCA applies to the UK**:

   2.1. What is the FSN distribution list (named contacts and locations)? Include any additional people who will be sent the letter (e.g., chief executives, Medical Device Safety Officers (MDSOs), medical directors, community pharmacists etc). You can send us this as a separate document.

   2.2. How will you contact the end user if affected customers include distributors? Send us a copy of the list of distributors. Confirm who will be managing the FSCA and compiling reconciliation data for these end users.

   2.3. How many sites are affected in the UK? How many devices/tests did each site receive? You can send us this as a separate document.

   2.4. When was the affected product distributed/installed?

   2.5. How will you monitor the extent to which the FSN message has been received? (eg customer acknowledgement form / telephone follow-up). What are your key dates for actions?

   2.6. How many UK sites have confirmed receipt of your FSN?

2.7. How many UK sites have confirmed that they have successfully undertaken the action(s) specified in your FSN?

2.8. What is the expected date of completion of the field safety corrective action?

3. **Provide regular updates on points 2.6 and 2.7**