

A Step by Step Guide to MHRA Reporting

Please MHRA report all equipment defects. Examples include failed deployment of stents and balloons, coating coming away from guide wires and cannulas with defecting valves.

- 1) Go to <https://yellowcard.mhra.gov.uk/> you can contact IT to add a link on your Trust's intranet
- 2) Select devices:

Welcome to the reporting site for the Yellow Card Scheme

Report a suspected problem or incident:

Side effect to a medicine, vaccine, herbal or homeopathic remedy	Side effects
Medical device adverse incident	Devices
Defective medicine (not of an acceptable quality)	Defective
Counterfeit or fake medicine or medical device	Fake
Side effect or safety concern for an e-cigarette	e-cigarette

- 3) Fill in your details

About the reporter & the device **Device & Incident details** **Submit Form**

Reporter's name: *

Position/Occupation

Reporting Organisation: *

Address (including postcode): *

Telephone number:

E-mail address:

This address will be used to send you a copy of your report. This will be in a printer friendly format.

4) Select the type of device and the continue

- Type of device *
- ☐ General Report Form / All other devices
 - ☐ Artificial Limbs / External limb prostheses
 - ☐ Cochlear implants
 - ☐ Orthotic devices
 - ☐ Implantable pacemakers/defibrillators
 - ☐ In Vitro Diagnostic Medical Devices
 - ☐ Wheeled Mobility and Associated Equipment
 - ☐ Breast implants

Continue

5) Fill in the device details. Always keep the defective device as this will need returning to the manufacture for investigating:

[About the reporter & the device](#) [Device & Incident details](#) [Submit Form](#)

Type of device *

Model

Manufacturer name *

Manufacturer phone number

Catalogue number

Serial number

Lot or batch number

Date of manufacture

Day -- ▼ Month --- ▼ Year ---- ▼

Expiry date

Day -- ▼ Month --- ▼ Year ---- ▼

Quantity defective
(Enter number not text)

Current location of device

- 6) Additional Details: A bit like a regular incident/Datix form complete date of incident, whether manufacture is aware, is the product CE marked, injury to patient or outcome of incident

Has the manufacturer / supplier been contacted?

☐ Yes
☐ No

Is the device CE Marked?

☐ Yes
☐ No
☐ Don't Know

Date of Incident

Day --▼ Month ---▼ Year ----▼

Type of Injury - ?

☐ Death
☐ Serious
☐ Minor
☐ None

Details of Incident / nature of device defect:


Details of Injury (to patient, carer or healthcare professional):

Action taken (includes any action by patient, carer or healthcare professional, or by the manufacturer or supplier):


Attach File ? Attach file

- 7) Attach any pictures or defect, product details (batch number and expiry in case a whole batch has to be recalled) or another other information that you think is relevant and click submit (for example: picture of the unemployed stent/balloon, wire coating becoming detached).

Note: Please keep in mind that even faults and defects in cannulas should be MHRA reported with the batch number and relevant details, otherwise batches cannot be re called for checking if there is a manufacturing defect/issue rather than a one off incident.

Attach File 

File Name & Comment	Date	Actions
Transfer of devices to MHRA Do not send medical devices to MHRA unless you have been specifically requested to do so.		



This process takes around 15 minutes and the more we report the better our records are and the better our evidence becomes on product safety. MHRA reporting can be completed by anyone at all levels and should be encouraged throughout departments. Treat MHRA reporting exactly the same as if you would record adverse drug reactions through the yellow card scheme, it is just as important.