Medicines & Healthcare products Regulatory Agency

MHRA

Medical Devices Safety Bulletin

Regular safety information for healthcare professionals

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Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) has responsibility for the safety of medicines and medical devices on the UK market.

This is a pilot for a regular bulletin from MHRA to inform health and care professionals in the UK of new or ongoing safety issues with medical devices. We are no longer issuing medical device alerts (MDA).

To help ensure the safety of patients, we recommend you read this bulletin and act on any aspects that affect your practice or the care you provide. You should also share the content of these safety messages with colleagues who you think need to know this information.

Some topics covered in this bulletin will also be disseminated through other mechanisms such as manufacturers field safety notices (FSN).

We are collecting feedback and data on this new bulletin and will use it to evaluate and develop this communication tool.

MHRA also issues safety communications for medicines, including Drug Safety Update. Sign up to receive MHRA email alerts here.

In this issue

National Patient Safety Alerts

MHRA is now accredited to issue National Patient Safety Alerts (NatPSA), which will replace MDAs for the most serious patient safety issues.

You will no longer receive MDAs from us, and this bulletin will inform you about medical device concerns that do not meet NaPSAC criteria. Look out for the National Patient Safety Alert logo to identify these alerts.

We need your feedback

Take this short online survey to tell us your thoughts on this new safety communication from MHRA

Medical devices safety information

HeartStart MRx monitor / defibrillator

The Philips HeartStart MRx monitor / defibrillator therapy selector switch may fail, resulting in abnormal device behaviours including:

- the device may not perform the selected function
- the therapy knob may not change to the energy setting selected
- the device may deliver a shock with an energy level different from the setting selected by the user.

If one of these behaviours occurs in clinical use, there may be a delay of therapy or a failure to deliver the intended therapy.

Advice for healthcare professionals
Read the manufacturer's field safety notice (FSN) – it gives advice on how to prevent this from happening.

Dermal fillers

All models of dermal filler Top-Q® (hyaluronic acid filler manufactured by Qufu Hi-Tech Trading Co Ltd) are being sold with a falsely applied CE Mark.
These devices have been manufactured to unknown standards and their safety as medical devices cannot be verified.
Treatment with Top-Q® may lead to unexpected effects or complications in injected patients.

Advice for healthcare professionals
Do not use any Top-Q® dermal fillers and quarantine them immediately.

Do not buy Top-Q® dermal fillers.

Report suspected or actual adverse events involving these devices.

Contact MHRA Devices Compliance team (Devices.Compliance@mhra.gov.uk) about concerns regarding any devices you have or intend to purchase.

Field safety notices

A field safety notice (FSN) is an important communication about the safety of a medical device that a manufacturer, or their representative, sends to customers. For more information, see our flyer.

MHRA publishes these for information only. If you have affected devices, the manufacturer or distributor should send the FSN directly to your organisation.

If you are a Medical Devices Safety Officer (MDSO) you can ask manufacturers to add you to their FSN distribution lists.

Targeted letters

A targeted letter (TL) is a safety communication about a medical device, which we send only to the healthcare organisations that have the device. We will also send TLs to professional bodies and other organisations to send it on to the relevant target audience.

You can access recent TLs here.

Reporting safety issues

The Yellow Card scheme is vital in helping the Medicines and Healthcare products Regulatory Agency (MHRA) monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users. See guidance.

Report a suspected problem or incident involving:

- side effect to a medicine, vaccine, herbal or homeopathic remedy
- a medical device including diagnostic tests, software and apps
- defective medicine (not of an acceptable quality)
- falsified or fake medicine or medical device
- side effect or safety concern with an e-cigarette

Report through the Yellow Card website or download the Yellow Card app (from iTunes for iOS devices or PlayStore for Android devices).

You can also report side effects for medicines through some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

There are different ways for healthcare professionals to report a problem with a medical device if you're in Scotland or Northern Ireland.

You can use our new dedicated COVID-19 reporting website to report any suspected side effects from medicines, future vaccines or medical devices relating to COVID-19 treatment.