

Medicines & Healthcare products Regulatory Agency

What are FSNs and FSCAs?

A 'field safety notice' (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative.

FSNs tell you what you need to do to reduce the specified risks of using the medical device. They give you either new information or highlight/remind you about existing advice. The actions are referred to as 'field safety corrective actions' (FSCAs).

If you receive a field safety notice from a manufacturer, always act on it.

Do not wait for a communication from the MHRA.

It is important that your organisation takes the actions detailed in the FSN and that you tell the manufacturer that you have received the FSN.

Your organisation's reply is the evidence that the manufacturer, and the MHRA, needs to monitor the progress of the corrective actions to ensure patient safety.

Without your reply the manufacturer can't know if their important message has been received and the MHRA may need to issue a safety communication.