

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. 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 tells the manufacturer it's received the FSN.

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

Without your reply the manufacturer can't sign off its corrective actions and the MHRA may need to issue a Medical Device Alert.