Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Suzhou Surgicare disposable Hysteroscopy Sheath– Recall due to withdrawn CE certificate.

DSI/2025/001

Specialisms: *Obstetrics and Gynaecology*

DEVICE DETAILS

Disposable Hysteroscopy Sheath

AFFECTED LOT SERIAL NUMBERS

All

MANUFACTURED BY

Suzhou Surgicare Medical Technology Ltd

Summary

The MHRA has become aware of Hysteroscopy Sheaths supplied in the UK market with a withdrawn CE certificate. Healthcare professionals and providers should immediately stop use, quarantine, and stop supply of any identified product(s).

Advice for Healthcare Professionals and Providers:

- Review your inventory and determine if you have any affected devices.
- Immediately stop use, quarantine and stop supply of any identified product(s)
- Return unused stock to the distributor HJ Medical (GyneVision)
- Providers should ensure all relevant members of staff receive this safety information and that they understand the problem and actions to be taken.
- Report any suspected or actual adverse incidents involving these devices. There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
  - in England and Wales to the Yellow Card scheme or via the Yellow Card app

Advice for Healthcare Professionals and Providers *continued*:

- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Advice for Healthcare Professionals to Provide to Patients:

There is no advice for healthcare professionals to provide to patients regarding this DSI

Advice for Distributors:

There is no advice for distributors regarding this DSI

Explanation of identified safety issue

The MHRA has become aware of Hysteroscopy Sheaths supplied in the UK market with a withdrawn CE certificate. These products are manufactured by Suzhou Surgicare Medical Technology Ltd and distributed by HJ Medical (GyneVision). The CE certificate was withdrawn by the manufacturer's Conformity Assessment Body due to concerns relating to the manufacturer's surveillance activities.

The Surgicare Disposable Hysteroscopy Sheath is intended to be used as a single-use operative sheath for use with the Flex-Eye HD hysteroscope, forming an integrated system designed to enable rapid diagnostic-to-therapeutic conversions during hysteroscopic procedures.

The MHRA has safety concerns relating to these products such as; the risk of infection and inappropriate sterilisation procedures.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

Stakeholder engagement:

- Incident Reporting & Investigation Centre (IRIC) for Scotland
- NHS Wales
- Northern Ireland Adverse Incident Centre for Northern Ireland
- NHS England Patient Safety Team
- NHS Supply Chain

An advance copy for review was sent to all the devolved administrations for stakeholder engagement.