MHRA Device Safety Information

Reference **MDSI2201** Issues **17 Februry 2022**

Gemini Surgical UK: Stop using all lots and batches of vaginal speculums with smoke tube and gynaecological hysteroscopy sheaths

Summary

The MHRA has become aware that vaginal speculums with smoke tube and gynaecological hysteroscopy sheaths from Gemini Surgical UK are being sold with a falsely applied CE mark.

Action

Bring this notice to the attention of all appropriate managers, staff and contractors

1. Nominate a lead person to take responsibility for completing these actions.
   Note - we recommend including colleagues in purchasing, supplies, gynaecology, and the Incidents and alerts Safety Officer (ISO).
2. Identify if your organisation has purchased or received samples of these devices.
3. Stop using these devices and use a suitable alternative.
4. Remove and quarantine any affected devices from all locations in your organisation.
5. Complete and return this online form to MHRA.

Deadlines for action
Actions underway: 17 February 2022
Actions complete: 28 February 2022

Background

Vaginal speculums with smoke tube and gynaecological hysteroscopy sheaths from Gemini Surgical UK are being sold with a falsely applied CE mark. This means that these devices have been sold without evidence of safety and have been manufactured to unknown standards. They may also be labelled as Gemini Medical Innovations.

The affected devices are:

1. Insulated Medium Cusco Speculum with smoke tube REF GEM/6171
2. Gynaecological set hysteroscopic sheath REF SPHS1870

You can find pictures of the affected devices to help with identification here

All lots and batches are affected.

Due to the unknown potential risks to patient safety, MHRA wants to ensure that necessary steps are taken to safeguard public health by ceasing the use of these devices in the UK. It is important that you inform all relevant departments and ensure that the required actions are carried out.

Reporting Incidents

Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or Scotland's national incident reporting authority (Incident Reporting & Investigation Centre (IRIC).

Enquiries

(Incident Reporting & Investigation Centre (IRIC)

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.