



Medicines & Healthcare products
Regulatory Agency



Simon Jones
Assistant Coroner
Coroner's Court,
2 Faraday Court,
Faraday Drive,
Fulwood,
Preston,
Lancashire,
PR2 9NB

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

11 April 2018

Dear Mr Jones

REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

Thank you for contacting me and drawing our attention to the circumstances of the death of Margaret Elizabeth Clark in your Regulation 28 report to prevent future deaths.

You wished to bring this matter to our attention in order that a review into the safety and reliability of Ecolab sheaths be undertaken with the hope that fatal consequences may be avoided as the MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.

The MHRA requested and received from the manufacturer details of complaints recorded for this device. Ecolab sheaths were first placed on the market in 2010. Since then there have been over 425,000 devices sold throughout the EU. Ecolab reported that they had received only 8 complaints; none of which were serious. The MHRA are aware that not all incidents are reported.

The MHRA performed a review of the adverse incident database, looking for incidents relating to Ecolab sheaths and found only two reports that relate to TOE probe covers splitting, this includes the report from Blackpool Victoria Hospital.

The MHRA requested details of the ultrasound systems used in the reported incidents, but the Trust have not provided this information.

The MHRA are unable to compare "softness" of sheaths on the market and therefore cannot recommend that Ecolab sheaths are replaced in all hospitals and Trusts by the Probetecion sheaths.

The safety of TOE probe covers will continue to be monitored and appropriate regulatory action to protect public health will be taken as and when necessary.

I hope that you find this response satisfactory. Thank you for bringing your concerns to my attention.

Yours sincerely

A handwritten signature in black ink, consisting of several loops and a long horizontal tail.


Director of Devices

Telephone: 020 3080 7900

E-mail: 