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Cantel UK Urgent Field Safety Notice

Commercial name of the affected product:

SureStore system

FSCA Identifier:

Ref. 18-01-053

Type of action:

Identification and reporting of a low clinical risk identified during patient diagnostic procedure.

Date: 16th July 2018

Attention: Endoscopists, Decontamination Leads, Endoscopy Unit Managers, Endoscopy Nurses, Endoscopy Assistants, Private Hospital Decontamination Centres.

Details on affected devices:

All endoscopes processed through SureStore Endoscope Conditioning System with the exception of non-lumen models.

Description of the problem:

It has been identified that a very small number of patients undergoing an endoscopy procedure have exhibited signs of mucosal 'blanching' when the water channel of the endoscope was activated to expel fluid onto the scope lens and to remove debris from the scope view.

There are no reports of long-term tissue damage or adverse impact on patient health and welfare other than requiring the procedure to be repeated at a later date.

The root cause is believed to be the endoscope retaining a small amount of hydrogen peroxide solution (N-Sure) used to condition and maintain the high-level state of disinfection following preparation prior to use on a patient.

In order to condition the scope prior to packing and to maintain the high-level state of disinfection within the package, the SureStore system injects N-Sure (1.5% aqueous hydrogen peroxide solution) through each channel of the flexible endoscope. The channels are then purged with HEPA filtered air to remove any excess fluid. In excess of 300000 cycles have been completed for all procedures using the SureStore system since launch in 2013.

Advice on action to be taken by the user:

Cantel (UK) Ltd has updated their IFUs for SureStore with the following text which can be found on page 9, a copy of which is attached to this FSN.

AFTER UNPACKING AN ENDOSCOPE WHICH HAS BEEN CONDITIONED USING THE SURESTORE SYSTEM, FLUSH ALL ENDOSCOPE CHANNELS FOR A MINIMUM OF 20 SECONDS PRIOR TO USE ON A PATIENT. USERS SHOULD REFER TO THE INSTRUMENT MANUFACTURER'S INSTRUCTIONS FOR USE FOR GUIDANCE IN THE PREPARATION OF THE ENDOSCOPE.

Users are advised to replace their current version of their IFUs with the updated version (50098-1027-EN REV B (IFU-061 REV 7), which will also be automatically sent as a separate attachment once the check below has been signed. Additional copies can be obtained either from the Cantel Customer Box location, Cantel Customer Services or your local Clinical Advisor.

Transmission of the field safety notice:

This notice needs to be passed to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

Contact reference person:

Name: Richard Manford

Organisation: Cantel UK Ltd.
Campfield Road
Shoeburyness
Essex, SS3 9BX

E Mail: UK-Quality@cantelmedical.co.uk

FIELD CORRECTION EFFECTIVENESS CHECK

This form is to confirm receipt of the attached Cantel (UK) Ltd urgent field safety notice dated 16th July 2018 regarding the SureStore system.

To confirm receipt of this FSN please reply either by email to the address above confirming you have received and understood the FSN request, or print this sheet and return it to the postal address given above.

When replying by email, please also include your name, unit and hospital details in your response.

A copy of the updated IFUs (50098-1027-EN REV B (IFU-061 REV 7) is also attached to this FSN.

I have read and understood the urgent field safety notice provided in this communication. I have/will pass this information to all personnel in the organization who need to be aware.

Signed: Date:

Name of person completing this form: _____

Position: _____

Department: _____

Organisation: _____

Address: _____

Contact e mail: _____