



SureStore™ Storage and Endoscope Transport System

The company Cantel and the Danish supplier BRAUN Scandinavia A/S have asked National Center for Infection Control (CEI) for an evaluation of the product SureStore™ Storage and Endoscope Transport System.

SureStore is a storage and transport system for storage of various endoscopes up to 100 days.

Method and procedure

The reprocessed endoscope is placed in a clean and disinfected storage tray on top of a transparent basic plastic liner (CLEANASCOPE™ liner). Taken directly from an endoscope washer-disinfector, it is recommended that the endoscope's surfaces are wiped with a sterile wipe to remove any residual water. Tubes from SureStore, which may be specific depending on the type of endoscope, is connected to all the channels of the endoscope. By the use of a computer control panel, HEPA filtered air is blown through the endoscope channels to remove any residual rinse water. Secondly, a liquid (N-Sure solution) containing the active substance hydrogen peroxide at a concentration of 1.5% is passed through the channels of the endoscope. Afterwards, HEPA-filtered air is blown through the channels to remove residual fluid, which is collected from the distal end of the channels using an absorbent pad. The absorbent pad is removed and the tray is covered with a tight-fitting green plastic film, which together with the basic plastic liner forms an inner package. Next, the inner package is placed in an outer laminated pouch (SureStore pouch), which is sealed and connected to the suction connector on the SureStore unit, to create a partial vacuum within the outer package. The vacuum packaging leaves air with hydrogen peroxide vapor and residuals in the inner package to create a bacteriostatic environment, which prevents the growth of microorganisms on the surface and in the channels of the endoscope.

The computer system has a logging and documentation function, which is preprogrammed for each relevant type of endoscope. Additionally, a label with relevant information (including expiry date) is printed at the end of the cycle and should be applied to the outer package of the endoscope. Several packaged trays with endoscopes can then be stored in a transportable cabinet (Cantel TranScope and StoraScope).

Cantel claims that the endoscopes can be stored for up to 100 days based on the independent microbiological testing undertaken by Biotech Germande in France.

As the flushing with hydrogen peroxide will leave vapor and liquid droplets with hydrogen peroxide in the endoscope during storage, it is recommended, that all of the endoscope channels should be flushed with sterile water for at least 20 seconds before using the endoscope.

Cantel and the UK Notified Body (Lloyd's Register Quality Assurance Limited) has classified SureStore as a Class I medical device according to the Medical Devices Directive, so the documentation to obtain a CE marking of the product is not assessed by a notified body.

The English National Health Service (NHS) has approved SureStore since 2015 and Cantel advice that an excess of 300,000 cycles are being performed annually with the system within Europe.

Documentation

Documentation has been submitted in the form of various test reports conducted by a modification of the French standard NFS 98-030:2012 and one test report conducted by a modification of the European standard EN 16442:2015, which is designed to test controlled environment storage cabinet for processed thermolabile endoscopes. The tests are carried out in a modified form as both test standards are designed for testing of conventional storage cabinets for endoscopes. The tests have used contamination with different test organisms (*S. aureus*, *Ps. Aeruginosa*, *E. coli*, *C. Albicans*, *M. terrae* and *B. subtilis*). Various types of endoscopes (enteroscopes, duodenoscopes, gastroscopes and colonoscopes (all with channels) and bronchoscopes (without channels) from Olympus, Fujinon and Pentax) have been tested at different storage times (1, 3, 7, 16, 24, 35 and 100 days). Not all of the tests have been performed on all types of endoscopes and storage times. According to the test results, the use of SureStore reduced the amount of microorganisms in pre-contaminated channels of the endoscopes and no growth of microorganisms was found on the

outer surfaces of the endoscopes while contaminated control endoscopes not stored in the SureStore had growth of microorganisms in the channels.

Cantel claim that the chemistry involved is material compatible with all the tested types of endoscopes and the British firms Olympus KeyMed Group Companies Limited and KARL STORZ Endoscopy (UK) Ltd. state that they are not aware of any compatibility issues. Additionally, they declares no objections on the use of SureStore to store their endoscopes, but they will not accept any liability from damage to the endoscopes, which subsequently leads to injury of either the user or patient.

In an Urgent Field Safety Notice from July 16th, 2018 Cantel declared that there has been reported cases of patients with mucosal bleaching after the use of endoscopes stored in SureStore. Accordingly, Cantel recommended that all endoscopes, which have been stored in SureStore should have all channels flushed with sterile water for a minimum of 20 seconds before use on patients.

Only one peer-review study regarding the use of SureStore has been published¹. The study is a small clinical trial testing gastroscopes, colonoscopes, duodenoscopes and echoendoscopes stored in SureStore for up to 15 days. A total of 100 samples were taken by flushing the channels of the endoscopes with a neutral solution containing Tween 80 and sodium thiosulfate. The samples were taken after different storage times and tested for growth of indicator microorganisms. 92 samples contained <5 CFU per endoscope, 6 samples had 5-25 CFU per endoscope and 2 samples had >25 CFU per endoscope. There was no correlation between the number of positive findings and the length of storage time.

Conclusion

The method and procedure for storage and transport used by SureStore is relatively new and therefore until now unknown to CEI.

There are currently no standards for testing this method and procedure, and CEI does not have proper knowledge of the test standards used particularly when used in a modified form.

According to the literature, there is only limited clinical testing of the use of SureStore.

Therefore, CEI cannot at this point of time recommend SureStore to be used for the storage of endoscopes on a routine basis.

However, CEI finds SureStore interesting, and CEI does see that there is several potential benefits by using the system.

Therefore, CEI encourages Cantel and BRAUN Scandinavia A/S to enter into cooperation with local endoscopy departments, clinical microbiological departments, infection control units, and manufacturers of endoscopes to investigate both material compatibility with different types of endoscope and potential storage times in controlled clinical studies, where possible side effects in patients are monitored.

Reference:

1. Minebois C, Saviuc P, Shum J, Tuvignon P, Pelloux I, Brenier-Pinchart MP, Landelle C, Mallaret MR. Evaluation of a new packaging process for non-autoclavable endoscopes: results for the first 100 microbiological samples. *J Hosp Infect.* 2017 Dec;97(4):333-337. doi: 10.1016/j.jhin.2017.06.032. Epub 2017 Jul 4.