

| PROCESSING ENDOSCOPES INTO SURESTORE VACUUM PACKING VALIDATION AND STORAGE SYSTEM | | | |
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1.0 Purpose

"New systems are being developed to support prolonged storage of flexible channeled Endoscopes. These systems will allow the User to have an Endoscope at the point of use in areas where regular usage may not be a requirement (e.g. ICU, Out Patient Clinics). The majority of these systems operate on a partial vacuum packing method.

There are two types of vacuum systems that are currently available:

- 1. Vacuum systems which require that the external surfaces of the Endoscope are dry prior to storage. These vacuum systems provide a means of purging the internal channels of the Endoscope (this method used in CHI Crumlin).
- Vacuum systems which facilitate extended storage and require that the external surface and the
 internal channels of the Endoscope are fully dried prior to storage. This type of system requires
 the Endoscope to be dried in the CESC prior to vacuum storage (this method is not used in CHI
 Crumlin)".

The Surestore vacuum packing endoscope validation and storage system is used to store flexible endoscopes for up to 35 days (un-channelled endoscopes) and 100 days (channeled endoscopes) after decontamination in the Automated Washer Disinfector. Designated theatre staff are trained in the correct processing technique.

2.0 Responsibility

It is the responsibility of the CNM II, CNM I and the Endoscopy HCA trained in processing flexible endoscopes into the Surestore vacuum packing system to adhere to this procedure.

3.0 Guideline

All staff must adhere to this procedure to ensure that the endoscopes is retained and used in the optimum condition after decontamination.

4.0 Definitions

N-Sure: A peroxide based conditioning solution for maintaining the high level disinfection of endoscopes in the Surestore system. Product is non-hazardous under chemical (hazard information and packaging) regulation CHIP3 and EC Directive 67/548 (substances) and / or 1999/45 (preparations) including all amendments.

5.0 Procedure

The Surestore vacuum pack storage system prolongs the high level disinfection status period (HLDSP) of freshly processed endoscopes. A conditioning solution (N Sure) is used on the endoscopes internally and externally as applicable, dries and vacuum packs a decontaminated / disinfected endoscope.

The Surestore system provides a verifiable traceability printout of the process. The flexible endoscope is individually vacuum packed, immobilized, protected and stored in a rigid contoured box providing a

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transportable bio-static storage environment for up to 35 days(un-channeled endoscopes) and 100 days (channeled endoscopes).

Surestore initial startup procedure:

- 5.1 Decontaminate Surestore tubing and connectors in Wassenburg washer / disinfector as follows:
 - Connect tubing to any of the washer outlet ports;
 - Place connectors in baskets:
 - Code in "machine wash" cycle 8744 on normal program.
- 5.2 Damp dust, plug in and turn on Surestore processor;
- 5.3 When screen and coloured boxes appear, scan the "show figures" symbol on the white card attached to the machine with the bar coder provided. Figures will be indicated on the bottom left of the screen.
- 5.4 Using aseptic technique; set up a sterile trolley with sterile bowl, Surestore tubing and connectors (when decontaminated). Connect colour coded tubing to Surestore outlet ports on right side of the machine.
- 5.5 Press purple "prime" button then "continue prime".
- 5.6 When prime is completed; check the following figures air / water above 300, aspirate 1, 2 and aux water above 150.

6.0 Vacuum Packing Endoscope with Channels:

- 6.1 Requirements: Surestore moulded tray (without notches), large clear vaccum bag, white plaster sealer device, sterile items i.e. clean-a-scope tray liner, plain gauze squares, absorbent pad:
- 6.2 Alcowipe Surestore tray and place on Surestore trolley;
- 6.3 Decontaminate endoscope including any relevant connectors in Wassenburg washer / disinfector. Open door of clean side of washer when cycle is complete. Check endoscope traceability printout is correct;
- 6.4 Using aseptic technique, set up sterile trolley and take water sample/s from the endoscope pre vacuum packing as per SOP "Taking water samples from an Endoscope ...";
- 6.5 Select endoscope on Surestore screen as follows:
 - Press "select scope";
 - Tap rectangular box on bottom left of screen until cursor flashes;
 - Key in (on keyboard) scope barcode;
 - Double click scope barcode number in rectangular box (numbers go blue);
 - Select "done".
- 6.6 Open sterile requirements for vacuum packing (gauze, pad and liner);
- 6.7 **Don sterile gloves**; line Surestore tray with clear liner. Place endoscope in tray, connect Surestore tubing and biopsy cap (if required) to endoscope (see relevant diagram in Surestore folder):
- 6.8 Wrap distal end of endoscope in absorbent pad;
- 6.9 Using gauze to protect sterile gloves, select "start conditioning" on Surestore screen, discard the gauze into the bin:
- 6.10 Hold tip of endoscope with absorbent pad to absorbent pad to absorb excess N-Sure solution. Check that all connectors stay attached;
- 6.11 When conditioning is complete, check all figures on bottom left of screen i.e. air / water above 300, aspirate 1 or 2 and aux (if applicable) above 150;
- 6.12 Disconnect all connectors. Ensure endoscope and tray are completely dry. Wrap any sharp edges of endoscope in red tray liner or gauze;

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- 6.13 Place green sheet over molded tray;
- 6.14 Attach correct endoscope traceability printout from washer / disinfector to green sheet'
- 6.15 Place tray in large clear vacuum bag. Expel any excess air. Seal bag fully with white plastic sealer and run paper towel across the seal with your fingers and using the outside adhesive seal, attach to vacuum bag.
- 6.16 Connect vacuum tubing on Surestore machine to vacuum bag. Select "vacuum" cycle;
- 6.17 Ensure vacuum phase is completed and "ready to print" appears on the screen before removing tubing. Push black stopper fully into vacuum bag to ensure a tight seal. Vacuum figure on bottom left of screen should read above 12.
- 6.18 Print Surestore traceability label (ensure that printout has a valid expiry date and the correct endoscopy barcode) and attach this label to the vac pack.

With the 2nd label, which states the following text:

"Field Safety Notice: Flush all channels with sterile water x 20 seconds" onto vacuum package;

- 6.19 Put separate sticker on side of vacuum pack to indicate type, size, barcode and colour code (if applicable) of endoscope. Place vacuum endoscopes into relevant trolleys (Anaesthetics, Respiratory, ENT bronchoscopes or G.I. endoscopes)
- 6.20 Carry out terminal cleaning on Surestore machine.
- 6.21 Document details of the vac pack endoscope into vacuum packing record logbook.

7.0 Vacuum Packing Un-Channeled Endoscopes

- 7.1 Ensure that Surestore system is primed to follow steps 5.1 5.6;
- 7.2 Decontaminate endoscope in washer / disinfector, open door on clean side of washer when cycle is complete;
 - Alcowipe grey Surestore storage tray (with notches) and place on Surestore machine;
 - Follow 6.3 (above) to select required endoscope on the Surestore screen. Ensure that "non lumen" is indicated on the screen;
 - Open sterile gloves and place sterile clean-a-scope tray liner, sterile gauze blue steristrips and N-Sure rolls beside gloves:
 - Don sterile gloves, cover grey notched tray with sterile clear liner;
 - Dry and inspect endoscope and place in tray. Place N-Sure rolls into notches of tray, secure with steristrips. Leave red plastic cover in tray with endoscope;
 - Follow steps 6.12 to 6.15 (above);
 - Connect vacuum tubing on Surestore machine to vacuum bag;
 - Select "start conditioning" holding vacuum tubing horizontally while vacuum is in progress;
 - Select steps 6.17 to 6.21 (above). Do not need 2nd label here (one label only required as "Field Safety Notice not required as there are no channels).

8.0 To Change N-Sure Fluid

- Put on plastic apron and examination gloves;
- Slowly unscrew cap on N-Sure fluid until you hear "hiss" sound;
- Undo wires, push in silver button
- Remove into new bottle cap with tubing, screw tightly;
- Place back in and "click" close door;
- Run fluid prime, bottle works under pressure if not pressurized it will not work;
- Observe same figure as before Aux ↑ 150;
- If pressure not reached, check bottle again, tighten cap and run another fluid prime;
- Write date of opening on N-Sure bottle and document change details in Surestore record folder on Surestore trolley.

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9.0 To Change or Modify a Scope

- To select scope; type in number to find the inventory I.D;
- Select "done";
- Scan "enter new scope";
- Window opens;
- Find in inventory I.D that matches the relevant scope;
- Select "Yes" if auxiliary channel is present;
- Select "update inventory" then "done".

10.0 References

HSE Standards and Recommended Practices for Operational Management of Endoscope Decontamination Facilities June 2019 V.1 (QPSD-D-082-1)

Surestore System Manual 2013

N-Sure Material Safety Data Sheet 2013

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