

-FAQ

- Why is there a need for the hospitals to have a full **traceability and documentation system** for their surgical instruments ?

Since 10 years international and local laws have been changed. Whereas in previous years patients who had undergoing surgical operations and had post-operative infections due to their operation had to bring the prove that the hospital made a mistake. Due to bureaucratic reasons most of the patients were not able to do so or had no access to the documentation of the hospital.

Some 10 years ago this has changed.

Nowadays when a post-operative infection occurs at a patient the hospital has to bring prove that only properly sterilised instruments have been used during the operation as well that every pre-caution has been taken to avoid any infections.

This is the very reason for Hospitals to maintain a documentation and traceability system in place for all the processes involved in re-processing instruments as they don't know when these cases occur as they might occur at any moment in time.

- What is the **traceability** of surgical instruments and why is it needed?

Traceability of surgical instruments is about knowing which instrument tray has been used on a particular patient and how and by which steriliser this instrument tray has been sterilised before being used at the OR.

Traceability of surgical instruments is needed when there are only a few specific sets of instruments available and there is a need to trace them in order to have full insight in when this tray will be available again for the next operation.

Another reason can be that the hospital wants to have a record on how many times a specific set of instruments has been sterilised and used in order to have a track on durability.

- Why is **documentation** needed?

Documentation is a system of record keeping of the functioning of the steriliser, when instrument trays have been sterilised (at what date, which kind of process, with which batch) , how sterilised instrument trays have been stored, what the expiry date of the sterilised instrument is, on what patient the specific instrument tray has been used.

In other words to have a complete track of the re-processed instrument trays in between operations.

- What is ISO 9001-2000 standard requiring?

Standard working procedures, checks, training and re-call procedures are covered by the ISO 9001-2000 standard.

- What is DIN-ISO 15883 standard requiring?

This standard is covering the cleaning and disinfection of the surgical instruments. Requiring the hospital to have a full documentation and traceability of packing, loading, sterilisation and storage of surgical instruments.

- What are EN 285 and EN 554 Norms are requiring?

In accordance with the EN 285 and EN554 the documentation starts already at the design table of the manufacturer of the steam steriliser. After type testing the initial design, each and every steriliser produced should be undergoing a works test to prove conformity to the approved design criteria. After installation at the site the steriliser is calibrated and an initial validation should take place as a proof to the hospital that equipment is conform EN 285 / EN 554.

At handing-over the steriliser the hospital will be handed-over not only the equipment but also the responsibility for maintaining the equipment and to keep record on its status.

- What are the other European Standards applicable?

MDD: Medical Device Directive
EN 866 Biological indicators
EN 867 Chemical indicators
EN 868 Packaging

- What is a Bowie-Dick test?

Bowie-Dick is steam penetration test which detects air leaks and inadequate air removal for pre-vacuum steam sterilizers. Bowie-Dick test is performed with an empty cycle at 134°C and 3.5 minutes. The chemical indicator used for B&D test meets EN 867-4 Class B and ISO 11140 Class 2.

- What is a lot (batch) control test?

The lot control is used for the control of one complete sterilization cycle. The test holder simulates the most difficult goods to sterilize. The correct color change of the indicator proves that all goods out of this lot have been penetrated by steam / formaldehyde / ethylene oxide and therefore sterilization was effective. The chemical indicator used lot control test meets EN 867-4 Class B and ISO 11140 Class 2.

- What is the difference between lot control, bowie-dick and steam penetration test?

The lot control is used during the normal cycles during the day. It is checking the performance of the steam sterilizer and is critical in terms of detection failures like vacuum, non-condensable gases etc.

The B&D test set (Helix) is the standard B&D test which is used for big hospital steam sterilizers.

The Steam penetration test is only suitable for smaller bench top steam sterilizers (class B steam sterilizers)

The lot control is having a class D or class 5 indicator, the b&d test set AND the Steam penetration test are having a class B or class 2 indicator but the helix devices are different.

- How can CSSD know the equipment is working properly?

Next to a yearly calibration and validation (after preventive maintenance has taken place) the CSSD should perform the following checks:

- Weekly Air tightness test, to ensure steriliser chamber and piping, valves etc. are airtight
- Daily Bowie & Dick Steam penetration test at the beginning of each working day
- Each cycle Lot control test as well as print-out of recorded parameters

The above-mentioned tests and their results should be documented in the CSSD log-book. The chemical indicators of the Bowie & Dick test and lot control as well as the print-out of the parameters should be filed and kept for 10 years. In some countries even up to 30 years.

- What is the use of Famos *double marking labels* and a label gun?

A label gun dispenses a double marking label with printing of lot number, steriliser number, packing date as well as expiry date (necessary according MDD).

The double labels are available in different colours which can be used for indicating different months of productions. As one f.i. use blue labels in January and yellow in February one can easily recognise the sets in sterile storage which has an earlier expiry date (i.e. blue ones). The labels are double because easy removal of the label is practical when one like to use these for documentation purposes in the patient file. The labels of each used set are then put into this patient file whereby a track is realised which set has been used and when it has been sterilised.

- What is a **process indicator**?

The process indicators on the outside of the pack are class A chemical indicators. These are only showing that the pack was sterilised but doesn't say anything whether sterilisation parameters were OK during the sterilisation process.

Process indicators are applied before sterilisation as the chemical indicator should change colour during sterilisation.

- Is use of a process indicator necessary?

In each pack a process indicator should be clearly visible attached in order to prevent a mix up between sterile and unsterile goods. Process indicators are available on steam tapes, labels for the label gun as well as larger labels which can be printed by means of a computer with printer.

- Why should chemical integrators be used at the same time with process indicators?

The process indicators don't test the parameters of correct sterilisation. That is a reason for many hospitals to use an in-pack class D chemical indicator (or integrator) which react only when specific steam sterilisation conditions like time, temperature etc. have been met.

Also, when the pack is opened at the operation room, the packaging materials with the process indicator are folded over the mayo table in order to create a sterile field. The process indicator is now no longer visible for the OR personnel. Whereas integrators are put on top of the instruments before packaging is closed. When the pack is opened at the OR this integrators can be taken out and used for final check and documentation purposes.

- Is the chemical indicator able to show why sterilisation could not be achieved (low temperature, short duration, ...)

The chemical indicator as such cannot find out what the problem is it can only show a malfunctioning of the steam sterilizer.

- What is the use of Famos **patient documentation labels**?

The Class D chemical integrators are also available as a patient documentation label. The label is giving next to the indicator the possibility to write details on it and to use it for better documentation and traceability possibilities.

- How is tracing a surgical instrument from operated patient back to CSSD is possible?

Where a double label with process indicator, integrator or patient documentation label is used, the files at the OR are filled with those indicators and coupled to the patients name / record number. As those labels etc. are mentioning lot numbers, sterilisation date etc. a full traceability is possible based upon the OR or patient file back to the date and steriliser when the instrument trays have been sterilised.

- Are **biological indicators** different for steam and ethylene oxide sterilisations?

Biological indicators are designed differently for steam and EO sterilisation processes. The contents of self contained biological indicators and the temperatures they are reacting are different from each other.

- What is the content of Famos self contained biological indicator for steam sterilisation?

Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores soaked on a strip of a paper. It also has a growth indicator media of purple colour contained in the glass ampoule.

- How is Famos biological indicator for steam sterilisation performing?

Famos biological indicators for the monitoring of vacuum assisted steam sterilization processes at 121°C-134°C and for steam sterilisation cycle at 121°C-123°C in a gravity displacement air.

- What is the content of Famos self contained biological indicator for EO sterilisation?

Each tube contains a population of spores of *Bacillus atrophaeus* ATCC 9372 soaked in a strip of paper. It also has a growth indicator media of blue colour contained in the glass ampoule.

- How is Famos biological indicator for EO sterilisation performing?

Famos self contained biological indicator EO is specifically designed for the monitoring of ethylene oxide sterilisation processes?

- Does the lot control indicator represent every single instrument in the sterilizer?

The lot control is measuring the presence of non-condensable gases during a normal sterilisation process. It has been designed to represent hollow instruments and is in accordance with EN867 part 5 in which diameter and length of the tube is precisely described. If new instruments are bought by the Hospital one should ask the manufacturer of the instrument whether the instrument can be successfully sterilised by a normal steam sterilisation process on 134 degrees Celsius and 3,5 minutes. The instrument manufacturer should comply to the sterilisation process which has been standardized as such. In case they do comply with this the lot control can be used as a worst case model for hollow instruments.

- Is there a failure rate for the lot control set?

Before a newly produced batch of the lot control indicators is released these are tested to be in accordance with the specifications. As the production process is a continuous one batch process without any change of printing parameters the testing will give evidence that the whole batch comply with the engineering specification of the lot control indicators. The test before releasing the new batch for sales and distribution is bringing the evidence so there cannot be any failure rate for the lot control test.

- What are the benefits / disadvantages of laminated indicators?

Famos is producing both, laminated and unlaminated indicators for the Bowie & Dick test as well as the Lot control test. The reason is that in some countries the laminated indicators are presented in the past to be a better indicator. Famos is convinced that the laminated indicators don't have any advantages as the reason given by other manufacturers for the lamination is that the indicator ink doesn't come into contact with the instruments. As both Bowie & Dick test and Lot Control test use a Helix type of Process Challenging Device (PCD) the indicators cannot come into direct contact with the instruments as they are capsuled by the PCD. Next to that the Famos indicators should be folded in such a way that the absorbing filtration paper will cover all the indicator fields. Another reason given by the other manufacturers is that the indicator ink cannot stain or 'leak' due to condensate. It is just this reason that Famos is promoting the unlaminated indicators as they are affected by too much condensate. Whereas the laminated indicators are less sensitive to the presence of too much condensate, the unlaminated indicators of Famos does detect the too much of condensate in an early stage.

- What is the difference between steam integrators and three phased integrators?

The differences are as follows. The normal steam integrator is a class 5 integrator for normal steam processes. The three phase integrator is class 6 and has three different inks to react to different holding times. (Holding time is the time that the sterilizer is at 134 degrees Celsius) The three phased integrator is our so called PRION cycle integrator class 5. Prion cycles are used in Europe for sterilizing instruments which has been used on patient which are suspected to have HIV or JCD diseases. As prions are hard to sterilize one uses holding times up to 18 minutes in stead of the normal 3,5 minutes.

- How does the *instrument protector* work? What is the use of this product?

The instrument protector is used for sharp objects like scalpels etc. The sharp point of the scalpel is placed in side the pocket and to hold it into this position the rest of the instrument is put in between the gaps. The purpose is to keep the sharp point away from the normal packaging material. So the instrument is placed in the instrument holder and then this combinaitno is placed and sealed in a normal pouch.

- Which printers are usable with Famos *printable labels*?

All printers can be suitable for printing our labels. But the old type of needle printers are less suitable as the colour of printing is slightly grey instead of black. Ink jet printers are hardly used as the ink cannot withstand steam conditions. So the most common used printer is the thermal transfer printer which is working with an ink ribbon.

- Is it safe for the heat sealer to be switched on the whole day / all the time?

Yes. Our heat sealers are designed in such a way that they can work continuously during a normal working day. So normally our customers are switching on the heat sealer in the morning and switch it off at the end of the day.

- Can the Helix device be used for more than 200 tests ?

The complete test set was tested by us for 300 tests and therefore we can guarantee it for 200 tests only. As manufacturer we are responsible for testing and guaranteeing the air tightness of the tube and indicator holder (Helix). Maybe it seems to be the case that Helix will last longer than 200 tests only but as said before we have to guarantee this and the only way we can do that is by supplying complete sets. Next to that, the price difference including or excluding the Helix is not significant.