"Sterilization" goes beyond the shores of the continents and, also globally, it has become a dedicated scientific discipline that found, as such, its place and recognition.

“The” challenge we are facing today is to ensure that the "state of art" is further integrated in the daily practice of the sterilization departments. In this way the differences, which still exist, can be gradually eliminated and thus the objective of WFHSS to bring about the worldwide harmonization of sterilization departments and of decontamination practices will be a step closer. This is a must because while language, cultural traditions and customs define the structure and authenticity of a community and provide a frame of reference in a growing multicultural society, this is not acceptable for sterilization. In this case especially there needs to be searched for a universal, common identity because it is important for the patient and for the department.

This is the lesson history has taught us because centralization and standardization in sterilization on the level of the hospital have led to an improved quality and have reduced the costs. If we can do the same at a higher echelon and achieve harmonization between departments, this can certainly lead to a uniform, rational, scientific, economic, ecologic and thus better and more efficient national and international practice.

A pre-condition is that all actors put their own ‘right’ aside and release themselves from the emotional component which is still often attached to sterilization. These stand the further professionalization of our discipline and a practice based on science in the way. For this reason the “state of art” will have to be clearly
defined, because this is not the case today. To give one example: there is a fundamental difference in approach to “sterilization” and, thus, to its derived product “patient safety” between the USA and Europe. Where the North-Americans emphasize the final control of the production with chemical and biological indicators, the Europeans more move in the direction of mastering of the component processes, the validation of these processes and the support of production through quality systems. We should find a worldwide consensus about the “state of art”. I hope that, in the interest of sterilization, an answer can be given to this challenge. Then we can, all together, take the same road towards the future.

The pressing necessity to describe the “state of art” is also evident from the topic of my talk namely “Controversies on Fast Cycle Sterilization Protocols”. This topic perfectly illustrates the lack of agreement and unity on a number of crucial sterilization issues. Indeed fast cycle sterilization –what’s in a name- is controversial for a number of reasons. In my presentation I'll take a closer look at it and will explain my position on it.

Slide Overview

Overview of my presentation:

. What is fast cycle sterilization?

. Controversies regarding:
  - Cleaning
  - Sterilizing
- Wrapping
- Storage and transportation
- Personnel

. Why fast cycles?
- Fallen instruments
- Lack of time and shortage of instruments

4. Conclusions

Slide Fast cycle definition

1. What is fast cycle sterilization?

A popular term for fast cycle sterilization is “flash” sterilization. It means open sterilization of non-wrapped, non-porous devices using a short program. The goal is to put an instrument or a set of instruments at the disposal of the surgeon as quickly as possible.

Slide Perkins

Perkins refers in “Principles and Methods of sterilization in Health Sciences” (1969) to emergency sterilization. He describes it as follows: “In the emergency sterilization of instruments, no compromise with safety can be tolerated. The method selected must be adequate for the destruction of resistant spores and it should be rapid so as not to greatly inconvenience the surgeon.

Slide SOP

He also already provides the SOP:

When reading this text it has to be kept in mind that it was written 48 years ago. In between times have changed!
Perkins refers to a high speed pressure instrument sterilizer but in a substantial number of cases a gravity steam sterilizer and/or a gravity program is used. This, often small, sterilizer, is located in the operating theatre.

Slide AAMI IUS

In the USA, where “flash” sterilization still is very popular, a significant development has taken place. The ANSI/AAMI (American National Standards Institute/Association for the Advancement of Medical Instrumentation) still refers in the ST 79-2010 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” to “flash” sterilization but in a joint announcement of the AAMI and amongst others IAHCSMM the name was changed because it did not accurately reflect current use and processes.

The following explanation is given: “Today, however, "flash" sterilization is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use. Current guidelines may require longer exposure times and/or the use of single wrappers or containers designed to allow for aseptic transfer of an item to the point of use. The term "immediate-use steam sterilization" more accurately reflects the current use of these processes. The same critical reprocessing steps (such as cleaning, decontaminating, and transporting sterilized items) must be followed regardless of the specific sterilization cycle employed; a safe process does not include short-cuts or workarounds”.

All this sounds more scientific but does it also mean that the procedures and processes are better and safer? Not in my opinion! On the contrary! The introduction of the term “immediate-use
sterilization” implies the official approval and consequently even the further entrenchment of a method, whose use can only be justified in emergencies.

Slide Fast sterilization

To complete matters I also have to mention that apart from “flash” sterilization a number of manufacturers talk about "fast cycles". They refer to programs which are either carried out:

- In small B sterilizers which are conform to the requirements that big pre-vacuum sterilizers have to meet. (I come back to this point later on). The length of the program will be about 45 minutes.
- Or in big sterilizers while applying special techniques such as the use of deep vacuum pumps with high performance without the use of cooling water. This leads to a 25% reduction in cycle time in comparison to regular steam sterilizers.

The time gained in both types of fast cycles in comparison to normal pre-vacuum sterilizers is not of such an order that it is possible to consider these fast cycles as a real breakthrough.

Slide Controversies

2. Controversies

“Flash” and/or immediate-use sterilization” remains, in spite of the change of name controversial and open for discussion. Moreover, the clarification of the AAMI/IAHCSMM abounds with contradictions.

Let's start in logical order, at least from the perspective of sterilization, with the cleaning process

Slide Cleaning
- **Cleaning**

Currently cleaning is seen as the key element for a reliable sterilization. Cleaning is the delicate interplay of temperature, time, mechanical action and detergence. Preferably a mechanical treatment in washer-disinfectors that are conforming to the EN/ISO 15883 is carried out as they allow for the standardized and thus reproducible treatment of the instruments. Moreover, thermal disinfection with an Ao value of 3000 (5 min at 90°C) allows it to substantially reduce the bioburden and makes it possible for the members of staff to safely handle the medical devices.

The SAL 10-6 specified in EN 556 can be achieved only if a contaminated device is properly cleaned and disinfected before sterilization. This excludes the cleaning of the device under running water since this method would not result in adequate microbial reduction. Heat-sensitive solid medical devices that might lend themselves to open sterilization using a quick program should undergo automated cleaning and thermal disinfection before sterilization, since this represents the safest method of microbial reduction. This cleaning and disinfection process in itself takes about 45 min in turbo machines and around 60 minutes in standard machines. The time advantage of “flash” is thus already compensated by the correct cleaning and disinfection of a medical device.

**Slide AAMI controversies**

The AAMI declaration confirms that “The same critical reprocessing steps must be followed regardless of the specific sterilization cycle employed”. If it concerns “flash” then this is because of the length of time, needed for cleaning, already a first and important contradiction! The meeting of these criteria in the case of ‘immediate –use sterilization’, if we make the distinction, renders this way of
sterilizing in principle superfluous. The time gain through a shortened sterilization cycle only compared to normal treatment will be minimal.

Slide Sterilization cycles

- Sterilization

The “flash” sterilization cycles that are currently available for use are the gravity displacement cycle, the pre-vacuum cycle and the single wrap cycle.

Slide Gravity displacement

. Gravity displacement cycle:

Gravity-displacement autoclaves are not for sterile articles! This is the simplest type of steam sterilizer. The standard method for air removal is based on steam being lighter than air; when steam is introduced in the autoclave chamber it forms a stratified layer across the top internal volume. With increased volumes of steam introduced, the steam will press the air towards the bottom. In the bottom a valve opens and lets the air out when steam is forced into the chamber – downward displacement. The valve only closes when pure steam is passing through it and makes the evacuation of steam/air mixtures possible. Then pressure is increased until the sterilization temperature is reached. The way in which the air is evacuated – the air will be pushed out by the generated steam - will in porous loads (textiles) and in materials with a narrow lumen result in insufficient air evacuation. Because the air is pushed out by the steam, in a number of cases this air will be forced into instead of out of the load. This results in air bubbles and in an unreliable sterilization result.
Slide drawbacks

Other important drawbacks are: As the steam is introduced into the chamber, the air pushed downwards by the steam wave front can diffuse into the steam. Even if microscopic, the remaining air-pockets will prevent the steam from getting into contact with the items to be sterilized. And no contact means no condensation, no energy-release and consequently no sterilization in these areas. Introducing steam with great speed into the chamber has another disadvantage. High-velocity steam carries with it microscopically small water particles. This results in moist steam, which is not capable of releasing as much energy as saturated steam.

An additional problem with high-velocity steam is that the introduction causes turbulence in the autoclave chamber, thereby increasing the mixing of air with the steam.

Slide Graphic

A gravity cycle looks as follows:

Slide Prevacuum cycle

In a pre-vacuum cycle, air is mechanically sucked out from the sterilizer during the conditioning phase (usually 4 steam injections) and steam is actively sucked out during the exhaust phase.
The parameters for the single wrap cycle are preset by the sterilizer manufacturer. This cycle is designed for flash sterilization of all-metal, non-porous items only, arranged on a perforated tray. No sterilization of items with lumens or complex medical devices should be carried out because air removal and steam contact within them may not be achieved in this cycle that has fewer pre-vacuum pulses than a regular pre-vacuum cycle.

The grave danger is that, in practice, without experienced personnel and without expert supervision instruments will be processed for which neither the sterilizer nor the program is suited.

In all these types of “flash” sterilization the evacuation of air can be a problem because this depends in the first instance on the depth and the number of vacuum pulses. At the WFHSS congress of Crete (Greece) Peter Hooper (UK) stated that a program with one long deep pre-vacuum had a worse result than a program with a fractionated pre-vacuum. The helix study group of the Dutch Sterilization society writes that in order to achieve optimal air evacuation minimally 2 but preferably 3 sub atmospheric pulses up to plus minus 5 kpa are necessary.

The dilution factor is calculated as follows:
According to EN 285 the volume of non condensable gases (such as air) can be maximally 3,5% or 3,5 ml gas per 100 ml condensate or 3,5 ml/169,4 l at 100°C or 3,5 ml/60,3 l steam at 134°C.

Slide Saw tooth profile

Super atmospheric air evacuation with saw tooth profile was widely used in the Netherlands some time ago but it is not an optimal way of evacuating air.

S Dry heat

Extending the sterilization time to compensate for inadequate air removal is not a solution because in places where there is air the steam sterilizer will behave like a hot air sterilizer. Because microorganisms die off less quickly in dry heat than in humid heat at the same temperature the temperature in a hot air sterilizer has to be higher than in a steam sterilizer. Dry heat sterilization is not very effective at temperatures below 160°C! At 160°C you need 2h for sterilization, at 121°C 6h, at 140°C 4h. (180°C 30 min).

The conditioning phase is in actual fact the most important one in the sterilization process and the design of the sterilization program will determine the end result. In the EN/ISO 13060 for small sterilizers this is linked to the type of sterilizer:

Slide programs

B cycle for sterilizing all objects (solid instruments, porous objects and A and B hollow objects, both wrapped and not wrapped);

N cycle for sterilizing only not wrapped solid instruments;

S cycle for sterilizing not wrapped solid instruments plus one other of the types indicated for cycle B (to be specified by the maker).
When purchasing a small sterilizer pay due attention to the type to make sure that your instruments are compatible with the sterilizer and the program.

And also pay attention to the way in which the water, which is used for the generation of steam, is piped and stored. Because this can prevent problems. A microbiological check of the water that is used for steam generation in our small cassette sterilizer showed that it was massively contaminated. Neither disinfecting the storage tank nor its replacement with a new one provided a solution. The contamination remained. I wasn't comfortable with it as I try to avoid microbes in the storage tank in an attempt to keep the bioburden as low as possible in order to be in a position to guarantee the sterility of the end product.

Slide Contradiction

The second contradiction is that “flash” – “immediate-use” sterilization make use of programs in which air evacuation can be a problem.

Slide Wrapping

- Wrapping

Recontamination of the medical devices should be ruled out after processing until the time of use. Wrapped articles remain sterile after sterilization until the time of use provided that they are properly stored, transported and removed under aseptic conditions. Just for this reason a sterilized but unwrapped device cannot be considered as sterile! Because the wrapping is an essential part of the process.
An essential pre-condition is that the wrapping material has to be intact as is already written on a number of wrappings. But safeguarding the integrity of wrapping is not evident.

“Flash” sterilization excludes in principle the use of wrapping.

But, at the other hand be also careful: The wrapping inhibits contact with the steam and makes the transfer of energy a lot more difficult. We have also established this in our hospital. In the pharmacy injectable preparations are made which are not available commercially. After preparation the ampoules or vials are sterilized in a paper bag with steam at 121°C and with a gravity program.

The bag was used to keep the batches together and to avoid them getting mixed up with other formulas. At validation it transpired that the temperature in the ampoules (in the bag) at the beginning of the sterilization phase only reached about 80°C instead of the required 121°C. So please beware of gravity programs in combination with wrapping!

Carpel EF et all compared in their article: “Full-cycle steam sterilization in ophthalmic surgery- the effect of wrapping instruments” (Am J Ophthalmol. 2012 Mar) the number of postoperative infections on the basis of wrapped and non wrapped sterilization. They came to the conclusion that there was no statistical difference between both methods. They say that: “This provides strong evidence that if the eye surgical facilities carefully clean surgical instruments and follow manufacturer guidelines, they can, with confidence, use either of these 2 methods of sterilization”. But,
and this is my remark, out of 19 000 interventions they counted 8 more infections in the non wrapped group. So, again, I would apply the precautionary care principle here and I prefer to wrap medical devices all the more so because full cycles are used here. There is no good reason not to wrap the instruments.

Slide Third contradiction

The third contradiction is that the wrapping keeps the device sterile until it is used. With “flash” sterilization no such guarantee can be given!

Slide Storage and transport

- Storage and transport

But there is more: after sterilization the medical devices should cool down to room temperature in a conditioned environment. Because cooling leads to the reduction in volume of the still warm air and thus for the sucking in effect of fresh (cold) air with the risk of recontamination of the devices by microbe carrying particles in the air. A cooling down process which happens too quickly, e.g. by contact with a cold surface, furthermore can lead to condensation which increases the risk of recontamination.

Slide Dunkelberg

The wrapping normally functions as a filtering system which should prevent this recontamination. Dunkelberg and de Bruyn already pointed in their articles at the importance of the type and the quality of the wrapping. The risk of recontamination of unwrapped instruments will be a lot higher than for wrapped instruments and can be directly correlated to the length of the exposure.

Slide Dalstrom
This point is also made by Dalstrom et al in the article: “Time-dependent contamination of opened sterile operating-room trays “J Bone Joint Surg Am” 2008 May;90(5):1022-5.

The purpose of the study was to determine the time until first contamination and the rate of time-dependent contamination of sterile trays that had been opened in a controlled operating-room environment.

CONCLUSIONS: Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays. Coverage of surgical trays with a sterile towel significantly reduced the contamination risk.

We can extrapolate this to “flash” sterilized items: the longer they are uncovered, the bigger the risk.

The flash sterilized item must be transferred immediately, using an aseptic technique, from the sterilizer to the actual point of use, usually the sterile field in an ongoing sterile procedure. But manipulation after sterilization and the transport of “flash” sterilized instruments will substantially increase the risk of recontamination.

But the recommendation to “Use items processed in a Flash Cycle immediately” should not be taken too literally! Don't forget that the instrument can still be warm, sometimes too warm. It can lead to burns in patients. Burns result from heat applied for a specific time and above a certain critical temperature. Above this temperature (± 42°C) after some time damage will occur.

Slide 4 Anomaly

A fourth anomaly is that the risk of recontamination during cooling and by manipulation and transport of the “flash” sterilized instrument is substantially increased.
Slide Personnel

- Training of personnel

I don't think that this needs extensive discussion. Well trained and motivated personnel are the quality guarantee a sterilization department should be able to offer to its customers. “Flash” and “immediate-use” sterilization are carried out in the operating theatre by untrained, uninterested and unmotivated members of staff who do not have the adequate machines at their disposal. It is, in a manner of speaking, a situation in which the clock is turned back more than 60 years. Theoretically all operating theatre personnel should have received adequate training as the AAMI guidelines prescribe. However theory and reality do not always make good bedfellows. Moreover, the decentralized treatment of surgical instruments is in direct conflict with the principle of the centralization and standardization of the treatment of instruments which has been proven to lead to better quality, more efficiency and an important reduction in costs.

My own experience with flash sterilization is a case in point.

The pre-history: in tempore non suspecto in orthopedics about 10 to 12 arthroscopies were planned in one morning. The length of the intervention: 20 min. The surgeons only had 3 sets of instruments at their disposal. Way too few. The solution: in an annex of the operating theatre the instruments were immersed in glutaraldehyde. Obviously not for the required 6 h but for only 10 min.

Slide Glutaraldehyde 1

This is clearly a breach of good practice: apart from the risk of infection due to insufficient decontamination there also was the risk
of a sterile chemical infection by glutaraldehyde remnants (when the rinsing with sterile water is not done adequately).

As a more acceptable alternative we decided to purchase a small “flash” sterilizer which was installed in the operating theatre. The instruments were compatible with the process, a huge step forward especially for the patients. But control and documentation remained problematic: the orthopedic personnel did not keep a record of what had been sterilized, did not add the chemical indicators, the cycles were not kept on paper, water was not replenished on time etc. In short: an untenable situation. After applying pressure (for a long time) sufficient sets were bought which in fact made the sterilizer superfluous. But the sterilizer remained in the operating theatre to be used for fallen instruments. Until the head nurse of the CSSD came across gross misuse. By different medical disciplines instruments and sets were sterilized without taking into account the limitations of the sterilizer and of the program. The medical director was informed and he agreed – in view of the risk to patients – to remove the sterilizer straight away from the operating theatre. The orthopedic surgeons were not pleased and predicted problems with fallen instruments for which the CSSD would be held responsible. Despite the protests the decision was carried out. Fortunately we have never had problems. Not a single fallen instrument was brought to the CSSD for urgent sterilization since the removal of the sterilizer.

Slide Instruments

Slide Treatment of instruments

Slide 5 anomaly

The fifth anomaly is that it is a requirement that the members of staff know what their duties are. But this cannot be expected of the
personnel in the operating theatre which carries out “flash” sterilization or “immediate-use” sterilization!

Slide Why

- Why flash cycles?

. The first argument for the use of “flash” always is a fallen instrument. But I've learnt from experience that there is no need for such a procedure.

And what if the fallen instrument is not compatible with the available program? What then?

A traceability system could be very useful in finding an identical instrument in another set of other disciplines.

. A shortage of instruments is the second argument. This can be solved by simply buying more sets (the additional cost is negligible most of the time) or by planning the interventions better. It can never be an excuse for a lower quality of the reprocessed instruments.

The daily, personal contact between the head nurse of the CSSD with his colleagues of the operating theatre and the surgeons can result in a shaking up of attitudes by creating more understanding and a better insight into sterilization procedures. Surgeons are most of the time not aware of the requirements regarding reprocessing and of the risks linked to the suboptimal sterilization of instruments to the patients. When they understand they become cooperative in looking for good solutions.
A not too big steam sterilizer in the CSSD can be very useful for sets which have to be urgently sterilized.

Slide Conclusions

- Conclusion

“Flash” and ‘immediate use sterilization’ are not conform to the “state of art” in sterilization.

The following contradictions are insoluble:

- between cleaning and rinsing in running water,
- between a regular pre-vacuum and a flash program,
- between wrapped and unwrapped sterilizing,
- between trained and untrained members of staff.

Slide Academic discussion

But to me the discussion itself is an academic one. A hospital does not need flash sterilization whatever people may say. Therefore, organization of “flash” by stipulating the conditions it should meet, means institutionalizing a way of working which does not meet the present standards of care expected of a hospital and of its sterilization department. And this is indeed the main contradiction.

The responsibility of the CSSD is based on means, man and knowledge. We are doing an injustice to ourselves but mainly to the patient when we hand back our responsibility to the end user. It is the duty of the CSSD to safeguard the right of every patient to be treated with a medical device of good quality at all times.

Thank you for your attention and lots of success in sterilization and in your life!
Slide Thank you

Wim Renders,

Brugge, 28/06/2017


http://csao.net/files/pdfs/Flash%20Sterilization.pdf