DEVELOPMENTS IN STERILIZATION

Slide 1. Opening words

Slide 2. Overview: In this presentation I will summarize the latest developments in sterilization. This includes evolution in steam sterilizers, developments in low temperature sterilization methods, robots and RFID use in sterilization, new methods for routine control and validation of sterilization process, new packaging materials. I will also mention the current issues and new trends for endoscope reprocessing and sterilization logistics.

Slide 3. You may wonder why I am showing you these irrelevant photos. These photos are presenting the impacts of climate change. The effects may be different from region to region. We feel it with the heavy fog in China. In Africa it comes with intense storms, flooding and prolonged droughts threatening the food security. We have been already informed about the extinction risk of polar bears in the north pole but recently, it has been reported that Pizzly or grolar bear: grizzly-polar hybrid is a new result of climate change. In such an environment the only think we can do is to go for sustainable energy to be able to postpone the end of the earth. Maybe that is why, sustainable sterilization is the key point of the developments in sterilization.

Slide 4. Sustainable sterilization: One of the solutions recommended by US Dept of Energy is using retrofit kits in the steam sterilizers. Typical sterilizers continuously use between 1 gallon (3.78 L) and 5 gallons per minute to reduce the temperature of the hot condensate used in the sterilization process before it is sent down the drain. To eliminate the need for a continuous flow of water, a jacket and chamber condensate kit can be installed on the sterilizer. This retrofit kit captures the condensate during ready/standby mode and dissipates heat to the room before discharging the cooled condensate. It reduces the amount of water needed to cool the condensed steam during the ready/standby operation, significantly reducing in overall water use.
Slide 5. Green sterilizers (WaterEco®) With a full-recovery closed-loop system which is called retrofit system it is possible to minimize city water consumption. The full recovery system reduces waste water from the vacuum system by up to 99%. Based on today’s average utility costs, a single eco-friendly autoclave can save a facility, over 900,000 gallons of water per year. That’s the equivalent of $100,000 over a ten-year period.

Slide 6. Water saving sterilizers: Recently, the company Skytron got FDA approval for a steam sterilizer having the ability to reclaim water from steam condensation, steam creation and vacuum. The internal water reservoir maintains consistent water supply despite possible pressure fluctuations that can result in wet packs or cycle failures. Water temperature in the reservoir is maintained, thereby eliminating the need for additional cold water to meet drain temperature requirements.

Slide 7. Another important issue in sustainable sterilization is saving energy. Recently, Forbes McGain et al, from Australia, published a study entitled “Hospital steam sterilizer usage: could we switch off to save electricity and water?”. The objectives were to find: the time sterilizers spent active, idle and off; the variability in sterilizer use with the time of day and day of the week; and opportunities to switch off sterilizers instead of idling when no loads were waiting, and the resultant electricity and water savings. A strategy to switch off idle sterilizers would reduce electricity use by 66MWh and water use by 1004 kl per year, saving 26% electricity use and 13% of water use, resulting in a reduction in 79 tonnes of CO2 emissions per year.

Slide 8. Energy efficient designs: Company Celitron claims that an energy efficient design in the sterilizer including internal steam generator where the heaters are immersed in the water instead of external heaters like all the old sterilizers have, 20% of energy can be saved. Energy saving software integration can reduce the energy consumption up to 40%.
**Slide 9. Hybrid systems** Recently a Japanese company Sakura got an FDA approval for such an energy saving system. The hybrid system comprised of a “Steam Cell®” heat regenerative steam generator, reverse osmosis water generator and steam sterilizer – all unitized.

**Slide 10.** For me, the most striking invention is the use of nanoparticles to turn water into steam without boiling. I believe plasmonic heat with nanoparticles can be the future of steam sterilization.

**Slide 11. Plasmonic heat with nanoparticles** A new, extremely black material can turn water into steam using only sunlight. Made of gold nanoparticles tens of billionths of a meter wide affixed to a scaffold pocked with “nanopores,” the material is a deep black color because it reflects very little visible light. Thanks to its highly porous structure, the material floats on the surface of water, allowing it to soak up the sun’s rays. When light of a certain wavelength hits a gold nanoparticle inside one of the nanopores, it stirs up the electrons on the surface, sloshing them back in forth in an oscillation known as a plasmon. These plasmons produce localized, intense heating, which vaporizes the water nearby. Probably in near future we will have steam sterilizers using plasmonic heat with nanoparticles.

**Slide 12. Available low temperature sterilization methods**

Ethylene oxide, Formaldehyde, Hydrogen peroxide gas, Ozone, and Chlorine dioxide are the available and well known LTS methods. Sterilization with liquid sterilants was accepted as a sterilization method by CDC for years but after the severe infectious outbreaks due to poorly decontaminated laparoscopic instruments in US, CDC is also coming to the point that “Sterilization with liquid sterilants” is not acceptable for critical instruments.

**Slide 13. New methods for LTS**

3 new methods of LTS got FDA approval and came into the market recently. Sterizone is from Canada and Revox and Noxilizer are from US.
**Slide 14. Sterizone VP4** is a dual sterilant, low-temperature sterilization system that utilizes vaporized H2O2 and ozone. It has high compatibility with devices and greater flexibility of load configurations. Its unique *Dynamic Sterilant Delivery System™* automatically adjusts the quantity of injected sterilant based on the load composition, weight and temperature. It has 46 min cycle at room temperature.

**Slide 15. Revox VPA** is a gentle room temperature process without any harmful residuals as PAA chemistry breaks down to CO2, H2O, and O2. There is no need for lengthy preconditioning or post-processing aeration. Multiple chamber configuration options are possible for safe, efficient, on-site sterile processing. This method is claimed as the most gentle sterilization method available for fragile biological with onsite donor tissue sterile processing capabilities.

**Slide 16. Noxilizer** is a room temperature sterilization method using nitrogen dioxide. In comparison to ethylene oxide this method gives safer and shorter cycles. There is no need for preconditioning or aeration after sterilization as there is no harmful residuals.

**Slide 17. Robotics and artificial intelligence** have already been introduced to healthcare. There are programs to make diagnoses. Surgeons are already using robots in the operating theatre to assist with surgery. There are hospital beds available that are able to move autonomously to transport patients. Some hospitals are using robots to prepare medications and distribute drugs even to the patient. Many decisions on treatment can be made with the assistance of, or by, intelligent machines. Rehabilitation can be robotically assisted. It is even possible to read medical information, including medications from a chip under the skin.

**Slide 18. Robots in sterilization:** While robotics are more and more involved in patient care, of course it is inevitable to see them also in CSSDs. The first robots introduced to the CSSDs are transport robots to carry the items in the hospital.
Slide 19. French Centre Hospitalier Universitaire (CHU) de Nantes is using two robots, “Betty” and “Daisy”, to improve efficiency in delivering sterile endoscopes to the ICU. The pilot for this on-demand logistics solution was deemed “very satisfactory”, providing great flexibility to the ICU’s logistics.

Slide 20. The surgical operation and recovery setting is considered the fastest growing and most resource intensive section of the hospital accounting for approximately 30 – 50% of a hospital’s budget. Automating the device recognition, delivery, and accounting processes is expected to significantly reduce hospital costs.

Slide 21. Robots in sterilization: That is why, General Electric is working on an intelligent system managing the surgical instrument sterilization process in a hospital, ensuring safe delivery of care, enabling new levels of hospital efficiency, delivering with surgical accuracy all of the medical devices doctors need to perform life-saving procedures. This robot will be able to control even cleanliness and functionality of the instruments.

Slide 22. Expected benefits of this robot include increased patient safety, hospital quality and cost performance through reduction in surgical infections; increased efficiency in OR scheduling due to increased kit accuracy and reduction in instrument count time; freeing-up hospital personnel. So, staff could be retrained and re-deployed to perform more patient-focused jobs.

Slide 23. Recently I have read that factories in China are replacing humans with robots in a new automation-driven industrial revolution as they are cheaper, more precise and more reliable than the people. By the end of this year, China will overtake Japan to be the world’s biggest operator of industrial robots, according to the International Federation of Robotics. Probably that is why China’s biggest robot making company offered 5 billion USD to the German robot maker Kuka.

Slide 24. Data matrix coding and traceability: Another important development in sterilization is related to traceability of reprocessed items to the patient. Because it is well understood, that a good documentation system gives certainty to our department and safety to our patients. Data matrix coding on each instrument makes tray assembly much easier and faster for the staff and prevents loss of instruments.
Slide 25. In France, a robot is being used for autonomous tray assembly putting all the instruments in right tray thanks to the data matrix codes on the instruments and trays.

Slide 26. Today, even tracking of instruments with data matrix codes is becoming old-fashioned. Tighter safety regulations in Europe and United States have led hospitals to seek more automated solutions. More hospitals are turning to RFID to track surgical instruments and other medical equipment in order to manage inventory, reduce labor and improve patient safety by ensuring each instrument is accounted for and properly sterilized. Previous RF technology was not able to survive sterilization methods. Moreover it was difficult to read the RFID tags when they are in a box or a tray. The signals were interfering.

Slide 27. Super-Rugged RFID: The ultra high frequency (UHF) radio frequency TegoChip can easily stand up to gamma, eBeam, autoclave, and ethylene oxide sterilization without performance degradation. With UHF RF, it is possible to read all of the products in the tray.

Slide 28. By using such RFID system simultaneous reading of several instruments, counting control during and after surgery, readability of blood-smeared or packed instruments, and unique number for identification, continuous life cycle of each instrument, tracking of goods through automated reading will be possible.

Slide 29. RFID tracking is time saving application for hospital staff. Following an 18 months trial of UHF RF system in Rigshospitalet hospital in Denmark, the researchers reported that RFID system could save the hospital 31,000 hours a year in OR procedures alone as it could reduce the time spent for counting instruments before and after operation and also before sterilization process in CSSD.

Slide 30. Electronic indicator is a new product for routine steam sterilization traceability and cycle validation that is also using RFID technology. It allows complete scientific reading of all the critical parameters required to achieve sterility thanks to its special probe for data collection in most critical to sterilize areas of sterilization packs. It can be used as an individual electronic indicator or it can provide a complete traceability solution with a combined RFID reader for wireless reading and archiving of sterilization cycle parameters data. In that sense, it seems that electronic indicator will start a new era in routine control of sterilization process.
New biological indicators: As electronic control of sterilization is not well known yet, physical, biological, and chemical controls are still accepted as state of the art. For biological control there is a tendency in CSSDs to use rapid read out indicators which can give the result in few hours. As you all know, 3M is the market leader in rapid read out indicators for steam and ETO. But until today there was no rapid readout indicator for hydrogen peroxide gas plasma. Recently 3M got FDA approval for 3M Attest Rapid Readout BI 1295 & Autoreader 490H for routine monitoring of vaporized hydrogen peroxide sterilization processes in STERRAD® NX and 100NX systems. As biological control is important for each cycle of low temperature sterilization methods, this invention will fasten the product release after gas plasma sterilization.

Change in container design to prevent wet packs: Wet pack is a common and important but also a preventable problem of CSSDs. Besides the sterilizer itself, the cycle parameters and loading pattern, packaging material also plays an important role to prevent wet packs. That is why; packaging material producing companies are working more and more on new materials to prevent wet packs. As you all know, with the heavily loaded containers most of the time we see a couple of mililiters of water at the bottom of containers. To prevent this problem, OneTray company invented a container with a special geometry and design increasing air flow volumes which allows steam to quickly reach the lateral edges of the tray to eliminate “cold spots” and ensuring complete steam saturation of all surgical assets. It can move more steam volume at a higher efficiency than other technologies due to the 3 vent patented design. Its design forces residual moisture under the deck plate and out of direct contact with surgical assets.

However, there are controversies about container use. Shaffer et al conducted a study to evaluate the effectiveness of rigid containers versus wrapped instrument trays, to maintain a sterile internal environment poststerilization when challenged with aerosolized Micrococcus luteus under dynamic environmental conditions simulating air exchange events occurring during the sterilization, transportation, and storage of sterilized instrument trays in health care facilities. ....
They found that of 111 rigid containers tested, 97 (87%) demonstrated bacterial ingress into the container while of 161 wrapped trays, there was no bacterial ingress into the tray. Contamination rates of rigid containers found to be increased significantly with increasing duration of use. They concluded that sterilized wrapped trays demonstrated significantly greater protection than sterilized rigid containers against the ingress of airborne bacteria.

Slide 34. It was also proven by some researches from France, Germany and Switzerland that unchecked or unmaintained containers are a big problem causing bacterial ingress into the container.

Slide 35. New packaging materials: Dry, Drier, Driest: Sterilization wraps are also evolving in the same way. Clinipak produced a patented tray wrap to assist with achieving dry packs. It has an inner surface with a degree of absorbency, whilst the outer surface repels both water and alcohol. The absorbent surface allows the condensate formed within a typical steam sterilization process to be dispersed, assisting evaporation during the vacuum cycle. As a result, the incidence of wet packs is eliminated or drastically reduced, they claim.

Slide 36. Protective packaging: Protection of sterility of the packs during handling, transportation and storage is a very important issue, as in the new logistical approach CSSD is responsible from sterility of the instruments until the moment of use. There are two ways for protection. We can use an extra packaging to protect sterile packaging material or we can use baskets that look like baby carriers. TitePack is a revolutionary innovation developed for use in combination with all types of sterilization wraps to reinforce and give maximum protection to the barrier system. This kind of packaging maybe reminds you the shrinking protective packaging for glass bottles. TitePack is made-of temperature sensitive material that shrinks during the steam sterilization process, regardless to sterile pack material, wrapped trays or packs are held tightly and intact, all lost of integrity can be eliminated.

Slide 37. Dye migration test is important to check the integrity of sealing of paper pouches. In fact it is a dirty procedure as methylene blue is used as dye. If you are not careful enough even your working field can turn into blue. Company Arrowpack developed a patented Push Indicator Dye Test to perform easy, safe and quick ink test.
Slide 38. I have a few words also for the developments in sterilization logistics. In the new logistic approach, the most important objective is to ensure the sterility of medical devices until used. So, the responsibility of the CSSD has been extended to the operating rooms and to the patients. That is why stacking of nets over each other as in this photo, is not acceptable any longer. Manipulation of the nets must be prevented by using baskets for each single net. Baskets must be manipulated not the nets.

Slide 39. In the new logistic approach, stacking instrument nets in unsuitable condition in the OR is "out", "just in time" concept using case carts is "in" to facilitate the tasks of OR staff.

Slide 40. Preparing textile drapes and gowns in CSSD is "out", using "procedure packs" which are delivered sterile and including both the draping material and the single use medical devices in a pack per surgical procedure is "in".

Slide 41. Preparing gauzes at hospitals is "out", buying ready to use sterile gauzes is "in" to direct the staff for more patient related works.

Slide 42. "It is not the strongest or the most intelligent who will survive but those who can best manage change." said Prof. Leon Megginson. Indeed it is the most important capability in this era is to be able to manage change. If we want our CSSDs to be respected in the hospital we need to develop and change.

Slide 43. Before I finish my presentation, I would like to invite to two important events for the field of sterilization and disinfection. First one is the World Sterilization Congress organized by WFHSS and German Association which will be held between 4-7 October in Bonn, Germany.

Slide 44. And 10th International Sterilization Disinfection Congress organized by my association (DAS) which will be held between 29 November- 3 December in Antalya, Turkey. I hope to meet some of you in both congresses to discuss future of sterilization and to manage behavioral change in our departments.

THANK YOU!