



Robotic and laparoscopic medical device reprocessing:

PITFALLS AND OPPORTUNITIES FOR IMPROVED SAFETY

THIS IS THE THIRD OF FIVE WEBINARS DEDICATED TO MEDICAL DEVICE REPROCESSING PRESENTED BY ASP MEDICAL EDUCATION.

MINIMALLY INVASIVE SURGERY WHICH INCLUDES BOTH LAPAROSCOPIC AND ROBOTIC SURGERY HAS BROUGHT NEW CHALLENGES WITH REGARDS THE REPROCESSING OF MEDICAL DEVICES. MOST OF THESE INSTRUMENTS ARE NOT DESIGNED TO BE DISASSEMBLED FOR CLEANING, DISINFECTION, AND STERILISATION.

SPEAKER:

Moya Alexander
Decontamination Lead

IMPERIAL COLLEGE HEALTHCARE NHS TRUST
LONDON, UNITED KINGDOM



Laparoscopic & Robotic surgery

Robotics are the new trend because the technology and advanced precision allow to do some procedures with more accuracy (on delicate tasks) and others that were unsuitable for laparoscopy methods. Besides reduce invasiveness and length of stay, those instruments are not prepared to be disassembled for proper cleaning and sterilisation. The typical specialities where nowadays is use are common: Cardiac, Colorectal, Gynaecology, Orthopaedics, Toracic, Urology and Ophthalmology.

However, this surgery procedures length are higher and the hospital need, not only to have a good turnaround for this expensive MD (750-5000€), as well to achieve the return on investment (~2 Million).

Reprocessing challenges of robotic instruments

Challenges to remove bioburden, char (tissue carbonization) and biofilms from these tight, complex segments of a robotic MD instrument, can block cleaning agents and sterilant from reaching these difficult and intricate areas and impede their action: besides this also can lead to biofilms formation that are very difficult to remove and can contribute to SSIs.

At Theater (OR)

To ensure proper cleaning of robotic MD, its key to follow every step of the IFU, starting with point-of-use treatment (disassembly, channel perfusion and treatment to maintain moisture). Robotic MD remain secured to the robot arms which make it challenging compared to laparoscopy MD, beside they require additional steps adding the challenge to remember which steps for each MD and that can lead to bioburden dry on the surface and become most hard to remove.



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Robotics are fairly new technology and are still finding their way into the market and still have limitations.

At Decontamination (SPD or CSSD)

Robotic MD cleaning involves multiple steps (disassembling, perfusion, manual/ultrasonics cleaning, etc.), equipment (light magnification at the sinks, washer machines dedicated cycle, racks & adaptors) and consumables/biocides. Its key to follow MD manufacture IFU (Ex: da Vinci Endowrist instruments require >15 steps) and this complexity is reflected on the time (> 3h/set following IFU). Staff can be tempted to skip reprocessing steps to meet OR turnaround needs. This attempt to shorten the reprocessing steps can potentially lead to residual soils and biofilm remain on the surface.

Nowadays we've washing machines with dedicated cycles and racks/adaptors to guarantee robotic instruments optimal cleaning, however they may not fully replace required pre-washing manual and/or ultrasonic cleaning processes.

Finally, to ensure proper sterilization, we need to guarantee that we have the right sterilization methods for the different laparoscopic and robotic instruments and more important that those MD have been tested and validated by the MDM for those sterilization methods.

MD Usages

Another challenge is the MD reuse limitations. Over reuse (due to bad traceability) may lead to instrument failure or biofilm formation jeopardizing the patient safety. Under usage (open sets for only few MD use), will increase costs for the institutions.

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Addressing the challenges and pitfalls

Theater (OR) staff play a big role on the reprocessing process, since their contribution are key for achieve proper MD cleaning in subsequent actions. Theater (OR) staff that handle with robotic MD, should be trained on all required steps and competencies to ensure consistence and the efficiency of the process.

Its key also to have the right facilities, equipment's and and consumables to reprocess the MD, both on OT & CSSD, according to MDM IFU's:

- Compatible cleaning;
- Compatible biocides;
- Compatible sterilization methods, however studies show LTS, such as HPGP, preserve more the MD;
- Staff education (Theatre & Decontamination);

In a nutshell, we must follow the IFU, have the right equipment's, consumables and accessories for the proper MD reprocessing. Besides we need to train both OT & CSSD staff on each one important steps on the reprocessing process, perform annual recertification and daily cleaning tests to evaluate cleaning efficacy.



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Meeting the IFUs decreases the challenges of reprocessing and meets the latest guidelines.

Futures perspectives for improve safety

Robotic MD come to stay and they will increase exponentially in the near future. We need to address this challenge by implementing quality management processes, that should include:

- Staff education and continuous training/recertifications - its key for both, the ones that need to reprocess the MD (CSSD) as well the users (OT);
- Partnerships between MDM & Washers & sterilizer manufactures - in order to improve MD design and disassemble to allow proper cleaning and action respectively;
- MDM IFU steps follow up/crosscheck – Check list for OT and CSSD staff as well the methods, consumables and accessories used (manual cleaning vs tunnel washer, steam vs Low temp, biocides, accessories, etc.);
- MDM must develop MD resistance - made of more durable material so they can withstand ultrasonic machines, tunnel washers and other sterilisers;
- Automatization of all the steps from the reprocessing process to take away the potential errors from manual reprocessing;
- Instruments Management (instrument Tracking Systems) to avoid the over usage of the MD and also the under usage improving the patient safety and reducing costs.



“As robotics surgery grows the competition between companies increases and this makes the MDs more effective for use.

Take Home Messages

1. THERE ARE CHALLENGES WITH MINIMAL INVASIVE SURGERIES AND ROBOTIC INSTRUMENTS AND THEY ARE EXTREMELY EXPENSIVE
2. TO IMPROVE THE CLEANING THEREFORE PREVENTING BIOBURDEN AND BIOFILMS BUILD-UP AND PREVENT HCAI's AND SSI's
3. FOLLOW THE MANUFACTURER'S INSTRUCTIONS AND MAKE SURE THAT FUTURE DEVELOPMENTS ARE IN LINE WITH BEST PRACTICE
4. TRAINING, EDUCATION AND COMPETENCIES ARE KEY TO MAKE THIS WORK



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ASP Advanced Sterilization Products

ASP International GmbH, Zug Branch
Bahnhofstrasse 2, Zug 6300, Switzerland
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