Learning from Sterile Services

Regulations for medical device manufacture are strict, and our commitment to quality uncompromising. It's important to us that our teams are trained to the highest standards, aware of the medical device environment and its' unique requirements.

ISO 13485 remains the standard and benchmark by which we are measured and Surgical Holdings are proud to have been accredited for over 15 years. We continue to strive to be better and understand more about how our customers operate.

Sterile Services Technicians possess a wealth of expertise in understanding the quality, hygiene and overall condition of instruments. In January 2019 Surgical Holdings were pleased to take Shelley Kenney on-board to work within our order processing and repair functions. With her background in Sterile Services, Shelley immediately began to integrate and share ideas and best practice.

Here Shelley shares her experience about what goes on behind those sterile doors: -

Introduction: Shelley Kenney
I recently decided on a change of career. Having spent time working as a sterile services technician, I have insider knowledge to share!

A Sterile Services Department (SSD) or Central Decontamination Unit (CDU) are process driven environments with strict guidelines and rules to follow. These are governed by ISO 13485:2016- the Medical Devices Quality Management System.

Let me describe a day in the life of an SSD.

Procedure List
At the start of every day, SSD are provided with a list of procedures to be carried out in each theatre. With experience or the advice of a theatre assistant technicians determine what instrument sets are required for each procedure. Depending on the operation, this may be only one set or several. Consider how many of each set the hospital has vs. how many are required – perhaps some may need to be reprocessed urgently to ensure there are no cancellations.

Following the 1st Operation
Wearing single use gloves, collect the used instruments in a suitable transportation trolley with a lid (to reduce risk of contamination to clean areas of the hospital.) An SSD is usually split into three separate working areas; a wash room, sterile packing room and an autoclave room. The used/contaminated instruments must only come into contact with the wash area. Wearing personal protective equipment (PPE), non-slip shoes, theatre cap and visor reduce both the risk of contamination to the instruments and technician.

Sterile Services Floorplan

Preparing the Washer Disinfector

One by one, the technicians assess each instrument. If it is extremely dirty, instruments are pre-washed by hand, with water no hotter than 40° and dosed measurements of detergent. Each set needs to be checked against the instrument list, to ensure every component has been returned from theatre. Once done, the sets are loaded onto the washer carriage, and must be logged onto a washer cycle log sheet. This provides traceability and proves the set has been reprocessed. This log sheet must show the washer cycle number, the temperature at which the disinfection process took place and total cycle time. Washers print out the cycle information which must be transferred on to the log sheet, and also attached for more in-depth information. Disinfection in an automated washer must take place at 90° or more, with the appropriate detergent.

Example Washer Disinfector

Post Decontamination

The washers act as a gateway between the washroom and the sterile pack room and have doors on either side. Once the cycle has completed it will open on the packing room side and allow you to remove the carriage onto a trolley. The packing room is a sterile environment; so new PPE must be worn. The decontamination process makes the instruments safe for handling, although they are not yet sterile. For this reason you are not required to wear gloves, but hands must be thoroughly cleaned when entering and leaving the area. The air pressure and circulation is monitored and regulated to ensure a continuous flow of clean air. This too must be recorded each day and reported if there's a problem.

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Ensuring the set is fit for purpose
When checking a set, each instrument is laid out in-turn at a work bench and checked as it is removed it from it's tray. The compulsory checks include but are not limited to:

- Check the instrument is completely clean
- Ensure the instrument's coating is intact and there are no signs of rust or discolouration
- If the item has insulation, check for cracks or damage
- Check any box and/or screw joints for free movement
- Ensure any toothed instruments are meeting correctly
- Scissors must be loose enough to move freely when you hold them up and let go of one side, but not close completely

Recording and Traceability
One key rule in any SSD is **absolute traceability** for every instrument. Each set has a name, an individual ID number, and usually a barcode. When you scan it a worksheet is produced to tell you every item that should be included on the set. The instruments should never leave sets or be switched to another set. Once everything is up to standard, the technician can lay the set up, checking instruments in order (this is the order in which the surgeon would use the instruments during surgery.)

Wrapping the Set for Sterilisation
Each set is then wrapped in specially manufactured porous paper and drapes. Depending on local hospital guidelines, there will either be two or three layers. The inner layers will be green, and the outer usually blue. They are wrapped in a fashion that allows them to be opened in a sterile way in theatre. The paper/drape is fastened with special autoclave testing tape. This tape is designed to indicate whether a specific temperature has been reached during the sterilisation process. There will be a label attached to the outer layer of the set, showing it's ID.

Sterilisation Packing

The next step is the sterilisation process itself. Once again, every detail must be entered onto a log sheet to ensure traceability.

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Our thoughts

Insight into how our products are used day to day and understanding the processes behind SSD's can help us as a medical device manufacturer become more agile to the needs of our customers and tailor services. It can also show us where we can add value by making things simpler.

- The procedure lists can help us rationalise sets; including the more frequently used instruments and removing those that remain unused.
- The PPE process for inspecting the used instruments is enlightening. At Surgical Holdings we ensure instrument technicians have suitable PPE, although decontamination is less of an issue.
- Hearing that manual washing continues is positive. We understand that the machinery does not do all the work. Depending on the procedure and the instrument - some endure heavier soiling than others. At Surgical Holdings one thing we have noticed is bigger sets (up to 100 instruments) being squeezed into small baskets, not being given the best chance to be efficiently and effectively cleaned. Bigger baskets should always be used where possible to ensure sufficient space amongst instruments. Although this is of course not possible with containers.
- Post decontamination checks are essential; ensuring instruments are fit for purpose. Where possible they should be in-line with the manufacturers own checks and recommendations. Certain test materials are available for particular instruments, this allows the function to be tested as well as being checked visually. Some instruments contain working parts and should be lubricated using a CE-marked lubricant to avoid deterioration. There can be hidden dangers with insulated instruments (as with laparoscopic monopolar) where hidden insulation damage can cause injury to patients. We have also seen poor repairs being carried out, particularly on intricate scissors. Technicians should be aware of what is the expected condition of the device, to spot these issues. A poorly repaired plastics scissor could do considerable tissue damage to a patient.
- Traceability across sets is very important and as a manufacturer we provide LOT numbers, but barcodes are now going beyond this. The future will see us investigate RFID and other technology-led solutions. Traceability is particularly important for post-97 instrumentation, with some hospitals opting for colour coding to ensure these instruments stand out when being reprocessed to avoid mix-ups. As a manufacturer of orthopaedic implants, Surgical Holdings are fully aware of the importance of traceability and can apply this to individual components.
- As instrument manufacturers we don't wrap sets. But understanding the process helps us design and fill containers appropriately. It is important to ensure sensible weight distribution across sets, and where possible use protective instrument tips (silicone) that are steam permeable. The importance of drying is also key to good practice, ensuring cooling trays are not placed flat on cold stainless-steel tables and instruments with hollow components which may contain water are checked and dried thoroughly.

Ultimately we see that combining the expertise of the instrument technician with the skill of the decontamination team helps us all in ensuring that the patients receive devices that are fit for purpose and that healthcare facilities get the best possible service and value.