Southend University Hospital NHS
NHS Foundation Trust

Disinfection & sterilization of reusable medical devices for operating theatres

UK Practices

Where to start?

- Education for all personnel in both teams
- Quality of sterilized product
- Dropped RIMD’s
- Alice in Wonderland
- Responsibilities of both teams

Safety measures

- Trust
- Processing equipment – validation – independent monitoring
- Tracking & tracing – the process
- Tracking & tracing – the processor
- Product check list

Independent Auditors

- Medical Devices Directive
- Registered to the MHRA – place product on the market
- TQM (Total quality management)
- Internal Audit
- External Audit
- The ‘pain’ of the process

Quality systems

- Work procedures
- Work instructions
- Records, process, test, product and staff training
- Technical file
- Customer questionnaires
- Every aspect of the process

Any purchased product

- If reprocessing equipment must comply to ISO as appropriate
- Must have ppm by trained engineers
- Raw materials – must comply to standards
- The CE mark – a mark of quality – is it?
- Copies of suppliers quality registration documents – in technical file
- Copies of engineers training & calibration certificates

Routine practices - wash

- Received into department
- Prepared for automated cleaning as specified in manufacturers instructions
- Processed in validated washer disinfector
- Automatically discharged in IAP (Inspection & Packaging)
- Accepted into IAP

Routine practices IAP

- RIMD's checked for functionality – where possible
- Checked for cleanliness – if failure detected – return complete tray
- Placed in position as stated on theatre check list
- 2nd check for accuracy – check list signed
- Product sealed, labelled and sent for sterilization

Routine practices in sterilization

- Product allocated to a sterilizer that has passed daily checks and been subject to a validated ppm process
- Machine data inspected to ensure a successful cycle has been achieved
- Product allowed to cool naturally once process complete
- Product inspected for damage, dampness, torn packaging, that the indicator has changed appropriately, that it is correctly labelled etc.
- Product issued to user

Sterile Services & the OR - During transfer

- Product release
- Lifting & handling
- Secure transfer methods
- Time
- Product acceptance?

? Common issues

- Patient on table
- Wet packs
- Torn packs
- Missing RIMD’s
- Weights of trays

Patient on table

- User should ensure all required RIMD's available before the patient is on the table
- Wet pack – options
- Torn pack – options
- Missing RIMD – options
- Dropped RIMD - options

Content & weight of trays

- Is the kitchen sink required?
- 10kg
- Designer trays – uniform content – uniform procedures
- Information provided on the outside of the pack
- Check content before & after use
- Accountability – identification – both teams

Storage conditions

- Heat and humidity
- Numbers on the shelf
- Weight on the bottom tray?
- Squeeze in one more?
- Identification issues
- Amount of handling?

Tracking & Tracing

- Bar code on the tray
- Two bar codes if a container -
- Marking of every device?
- Scanning?
- Instrument migration
- It wasn’t there when we opened it

Device abuse….

- Opening that coffee tin
- Bristow's elevator or screwdriver?
- Mosquito artery forceps or needle holder?
- Returned to SSD – internal lift
- Orthopaedic trays on top of telescopes?
- Lost/missing instruments

Turn round times & ‘fast track’

- Shortage of specialized expensive equipment
- Four hours – on site - Five off??
- How many fast track requests from 17 theatres
- Which speciality is most important?
- Have you checked your store?

Communication – Friday 17th February

- To talk and to listen, to exchange information
- Water pump failed on our reverse osmosis plant
- Theatre informed – we can sterilize but not wash
- Person who was told calls back to order equipment
- Reminded that we cannot wash – “but I have a full board”

Friday 17th - continued

- Explained could be 3 hours, what are your immediate needs?
- The information cannot be given
- A range of products eventually requested – how much needed for the 17th?
- When evaluated – not much, just a ‘knee jerk’ response
- Communicate more – trust more…..

The numbers game

- Evaluate the number of trays required for the work being undertaken – together
- Plan operating lists to give enough time for reprocessing – together
- Review tray numbers and content – together
- Raise financial bids for more equipment – together
- Try to see life from the other end of the ‘telescope’

Finally

- SSD must focus on the equipment and the patient
- Users must focus on the patient and the equipment
- Together we can achieve it all –
- Any questions?