

Reuse of Single Use Devices

Global Harmonization Task Force

8th Conference

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Peter Schröer
EUCOMED / Ethicon Endo-Surgery

EU Regulations

- Medical Device Directives e.g. 93/42/EEC
 - Regulates first placing on the market
 - Covers fully refurbished products
 - In-house manufactured products not covered
- Work Equipment Directive 89/655/EEC
 - Work equipment provided for use after December 31st of 1992 has to comply with the provisions of any relevant Community directive.

EU Member States

- Total ban and classifying reuse as deception of patients (France)
- Advise not to reuse, encourage use of SUD's for certain procedures to limit transmission of prions (UK)
- Essential requirements to be met and patient informed consent (Sweden)
- General requirements on reprocessing (Germany)

EU Member States

- No country has enforced regulation to allow safe reuse
- Loopholes in the law or non-enforcement allow uncontrolled reuse
 - Define single use as not being part of the intended use
 - Bypassing regulations by not placing devices newly on the market (in-house manufacturing or contract refurbishing)
- Tendency to act against reuse caused by high number of HAI and risk of CJD transmission

Extent of Reuse

- Mainly in hospitals estimated to be 10% in UK, 30% in Denmark, 100% in Norway
- Scandinavian Study showed decrease of 33% caused by awareness campaign 1996 - 1998
- Refurbishing by 3rd parties in Germany only
 - Local reprocessing companies without any QA and validation, over-regional refurbishers with group validation and certified ISO 9001 system
 - Some refurbishers select products and reject defective non-cleanable others leave it to the user

Design, Validation & QS

- SUD's are validated and designed for one use
 - Materials are chosen to ensure maximum performance for the intended single use
 - Biocompatibility is ensured for materials exposed to the intended environment
 - Many devices are subjected to miniaturisation to further reduce unnecessary trauma of the patient and enhance functionality to improve procedures
 - OEM's validation and performance testing is limited to initial failure

Areas of Concern

- Manufacturers and 3rd party studies revealed the following major issues
 - Validation of design, materials, cleanability
 - Validation of process
 - Quality systems to identify external - internal damages, material deterioration, OEM's material and design changes
 - Traceability, Labelling, Packaging
 - Post Market Surveillance

Questions


- Can a SUD have the same characteristics after usage and refurbishing?
 - Are they as clean as new?
 - Are the materials unchanged?
 - Do they perform the same way?
- For many devices the answer is: NO
- But what is the clinical relevance?
- If the parameters are not the same, shall we treat the refurbisher as manufacturers?

Design Validation

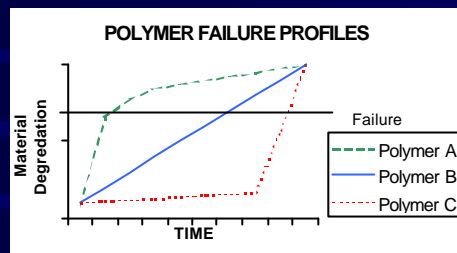
- Materials
 - Validate device exhaustion or wear out
 - Characterise failure points
 - Identify time to failure
 - Evaluate biocompatibility
- Variables
 - Number of previous usage's
 - Stress during previous usage
 - Deterioration during cleaning, disinfecting, sterilisation, reprocessing

Validation of Materials

- Stainless steel martensitic 400'er series
 - Designed for max hardness of blades
 - Especially susceptible to corrosion
- Example: jaws for SUD`s
 - Modification of the heat treatment process made device more robust for the first use but caused cracking when reprocessed due to *stress corrosion cracking and hydrogen embrittlement*

 Refurbishers have to understand materials and manufacturing process

Plastics



David L. West et al. "Scientific & Regulatory Consideration for the Review and Approval of Reprocessed Single Use Devices Pre - market Submissions"

Mechanical degradation

- Material fatigue
- Wear
- Tensile strength
- Crazing

- Plastics are often susceptible to polymer crazing (alignment of polymer molecules) identified by the distinct white line which signals a change in polymeric properties and is the section most likely to fail (e.g. catheters)



Identify point of critical failure: model-by-model evaluation

Case Study EP Catheters

- Why is a detailed understanding of design parameters necessary?
 - Some EP catheters electrodes are crimped over the polymer
 - The polymer may expand or shrink under reprocessing conditions
 - This can cause the electrode to separate from the polymer

Case Study EP Catheters

Reprocessed Catheters: Physical defects



Loss of seal integrity: The electrodes separated on 2 out of 67

- ➔ Potential contamination in the lumen
- ➔ Electrodes may move during treatment

EP Catheter Incident

Product: EP catheter with tip electrode and several ring electrodes used for diagnostic and ablation

Reprocessed 3 times by 3rd party reprocessing firm in Germany

Electrodes separated - moved distally - heart valve trapped between both Electrodes. Catheter had to be pulled back by using extensive force which damaged the heart valve.

Liability currently discussed: Manufacturer - User - Refurbisher?



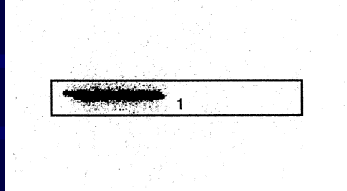
EP Catheter

- Reprocessor did not validate shrinkage of material
 - Reprocessor did not test seal integrity
 - Reprocessor did not validate model specific
- ➔ Detailed knowledge of material, design and function is necessary
- ➔ Validation of the refurbishing process is not sufficient

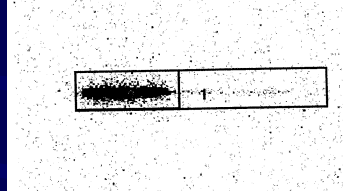
Validation: Cleaning

- Devices which have not been validated to be cleanable are reprocessed
 - Challenges
 - In-homogeneity of incoming material caused by previous use such as caking material on the device, cracks which may harbour pathogens
 - Long and hollow lumen, irregular surfaces, low clearance joints, no flushing channel
- ➔ Document that all debris, endotoxin and chemical residues are removed by the cleaning process

Case Study: Laparoscopic Instruments



X-ray picture of contaminated instrument prior cleaning



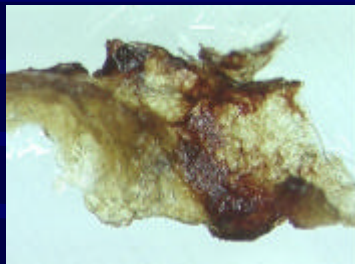
X-ray picture of instrument after cleaning

Radionucleide Method by University Tuebingen



Contamination spread over the length of the device without significant decrease

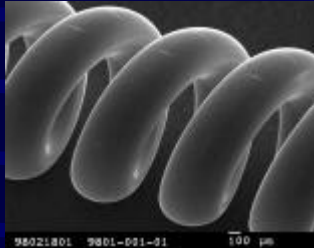
Contamination



Contamination / performance issues: endoscopic clip applicator

- First firing: mass of blood and proteinaceous material ejected (left picture)
- Misfiring due to build up of debris in the clip feed track (left picture)

Single Use Biopsy Forceps



Wire of new biopsy forceps



Reprocessed biopsy forceps

Current validation techniques are often not sufficient
Analysed by refurbisher: sterile
Analysed by University Tuebingen: 9 out of 10 non-sterile
Difference: device has been cut into fragments of 25 cm prior analysis

Biocompatibility

- Ensure biocompatibility has not been altered
 - Define impact of use, cleaning sterilisation and bioburden
 - Material changes such as less flexible, change in colour indicate changes of materials which require new validation
- If equivalence to OEM product is not ensured
 - ➔ ISO 10993 series (biological evaluation of medical devices) to document biocompatibility

Quality Systems

- OEM Quality systems
 - Homogeneous batches, known quality of raw materials
 - Destructive and non-destructive testing for incoming components and finished goods per sampling plan
 - Automated, model specific test equipment to ensure high detection rate
 - Quality designed into device
- Refurbishers Quality systems
 - Inhomogeneous product
 - Each new device is a new batch
 - Attempt to test product quality and reliability into a device often fails

Quality Systems

Hidden Contamination is usually not at all detected.
Even obvious contamination is not found or classified as being not relevant




Reddish Brown Contamination on EP catheters

Sterile Dirt?

Is this of clinical relevance?

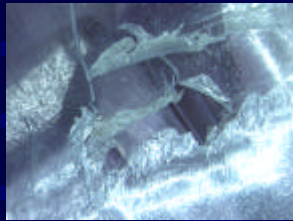
EP Catheters

- Comparison of new and reprocessed catheter tips
 - Implantation into the jugular veins of dogs
standard in vivo thrombogenicity tests
 - Results of NAMSAs analysis
 - New catheter, 4 hours: minimal thrombosis
 - Refurbished catheter, 2 hours: slight to moderate thrombosis
- Reprocessed devices which are not
 adequately cleaned pose a measurable higher risk to patients

Shelf Life

- Original shelf life
 - Not solely a function of sterility
 - It is also a function of material degradation
- Accelerated ageing caused by cleaning, sterilisation and prior usage has to be addressed
- Legal requirement in Germany to respect original exp. date

Package Integrity



Tear through two layers of packaging



Package Torn at Trocar Cannula Edge



Solid devices require packaging designed and validated specifically for each model in order to protect sterility and functionality

Labelling / Traceability

- Add instructions for use, include new device characteristics and limitations
- Clearly identify the refurbisher
- OEM and refurbishers lot number
- Document number of usage's and device history

Complaints & Vigilance

- Often processed by OEM's due to absence of clear identification of the refurbisher
 - Today's complaint, MDV and MDR numbers partially include reprocessed devices
- Today's recalls do not cover refurbished SUD'S due to
 - Lack of traceability
 - Refurbishers do not operate MDR /MDV systems
 - No clear identification of OEM's model / batch #
- Evidenced during various recalls in Germany

Summary

The ease with which non-sterile or poor functioning instruments are detected after reprocessing by hospitals or 3rd party reprocessors documents the dimension of the potential risk. Neither in-house nor 3rd party reprocessing provides users with instruments which meet essential requirements intended to protect patients and users, such as those provided in the new approach directives.

Conclusion

Reuse of SUD's should be accepted only if the practice is proven to be safe.

This may be achieved by applying existing regulations.

If those are sufficient is questionable since new challenges arise.

UK: Daily Mail August 21, 2000



