Clean care is safer care

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Our problem

- Dutch law places responsibility for sterility of medical devices with hospital directors ➔ this responsibility is delegated to 'DSMH' ➔
- DSMH is responsible for quality of decontamination processes

but

- DSMH controls from a distance…

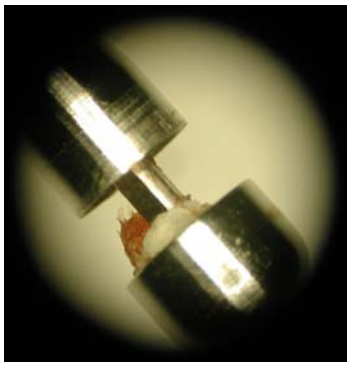
The real problem

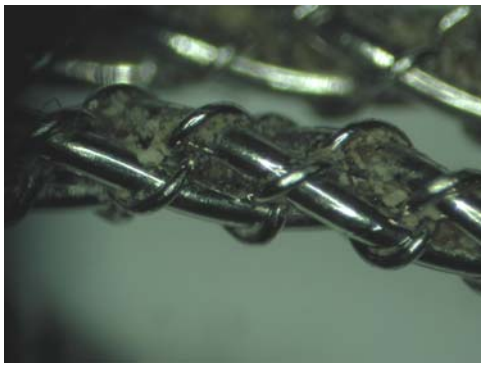
- Patient safety is compromised if decontamination is not performed properly!
  - Sterility
  - Functionality
  - Safety
    - Patient
    - User

Clean care is safer care

Soil spoils

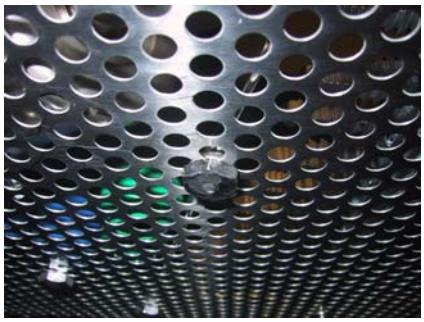
Decontamination problems





Soiled before and after cleaning

Packaging problems



damaged paper caused by nuts sticking out

Wet loads

Heavy metal & silicone inserts causing wet load

Not submersible

Internal defibrillator paddles

Responsibility for decontamination quality

Can only be accepted by DSMH when

- processes are validated
- staff is qualified

Therefore:

- no deviant processes allowed

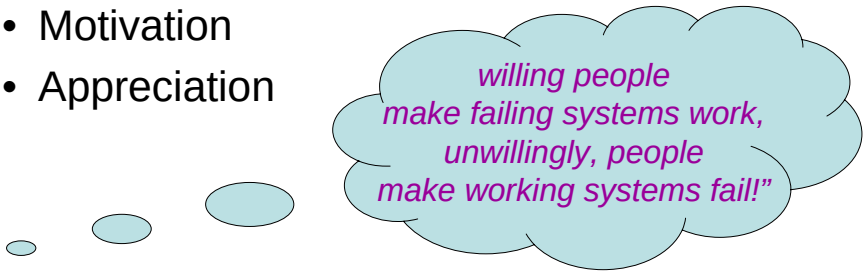
Validated processes means

- Equipment validation
  - Sterilizers
  - Washer/disinfectors
  - Heat sealers
- Fixed load configuration
- Fixed programmes
  - Fixed time/temperature combinations (F_0, A_0)
  - Sterilization: Pre-vacuum cycles

Qualified staff

- Education
  - School
  - Vocational training
  - Life-long learning
- Motivation
- Appreciation

- Sterilization technician
- Team leader
- Manager
- DSMH



Guidelines

- MDD 93/42/EEC revision ➔ MDD 07/47/EC
- UK: CJD committee:
  "Improve design for better cleanability"
- EN-ISO 17664:2004
- US: AAMI: TIR 30:2003
  - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- NL:
  - NEN standards
  - RIVM reports

Problems in reprocessing

- Meetings of experts and managers of the CSD from all university hospitals resulted in:
  - recognizing problems in reprocessing
  - development of the “grey list”: a list with problem causing instruments
    - question: which criteria do we use for placing instruments on the list?

Assessment criteria for new reusable medical devices (RMD)

DSMH Vereniging van Deskundigen Steriele Medische Hulpmiddelen

BEOORDELINGSCRITERIA
NIEUWE RECIRCULERENDE MEDISCHE HULPMIDDELEN (RMH)

	Voldoet?	Norm	Aandachtspunten
ALGEMEEN			
CE markering aanwezig?	Ja/Nee	(BMH)	- Geen CE: is er sprake van naar maat gemaakt RMH of een RMH ten behoeve van h onderzoek?
Heeft de fabrikant informatie bijgeleverd met voorschriften voor reiniging, desinfectie en sterilisatie?			
Is deze informatie voldoende?			einigings- en/of desinfectiemiddel? oncentraties? ingsmethodiek (geautomatiseerd of atig) aal één gevalideerde methode sterilisatieprocessen kunnen worden ast? (Stoom, WPGP, ETO, LTSF) sterilisatietijd/-temperatuur conform ederland gebruikte processen? (zoals 3 min 134 °C of 15 min 121 °C?)
Geeft de fabrikant toestemming tot hergebruik?			ak kan/mag het hergebruikt worden? van toepassing: is voorgeschreven ik onderhoud of ijking in de schreven frequentie uitvoerbaar?
Verpakkingvoorschriften bijgeleverd?			
NET/MAND/CONTAINER:			
Is het net van roestvast staal?			unststofcassette
Vormt het net/ de mand/ de container geen belemmering voor een adequate reiniging/desinfectie, drogine en sterilisatie?	Ja/Nee	(B9210)	- Voldoende open structuur

- 2006: developed by AZO
- April 2007: accepted by the VDSMH

Assessment criteria for new reusable medical devices (RMD)

- General:
  - CE marking
  - information manual

- Instrument design:
  - lumen
  - visual inspection
  - submergible

Assessment criteria for new reusable medical devices (RMD)

- Tray / container
  - mesh tray
  - size
  - weight
  - arrangement

- Properties:
  - reprocessable in Dutch CSD's?

Next step

- Today:
  - Assessment criteria in your conference bag
  - On the website VDSMH www.cscnl.net/divers/vdsmh
- Nearby future:
  - Dutch Technical Specification (NTA)?
  - Translation in English?

Other developments

- Loaner instruments:
  - a field standard and a list of requirements
  - december-07: a meeting with all parties concerned
  - NTA (Dutch Technical Specification)?
- Re-sterilization of disposable medical devices
  - NEN 301.08104: NPR (Dutch Technical Report)?

Conclusion

- Criteria are available for:
  - loaning
  - buying and
  - re-sterilization of single-use MD
- These criteria will help to make the right decisions for safer care to patients and for protecting employees

or

One small step…

for man(ufacturer),
one giant leap for mankind
(patient safety)

Neil Armstrong,
the Moon,
July 21, 1969, 109:24:20.