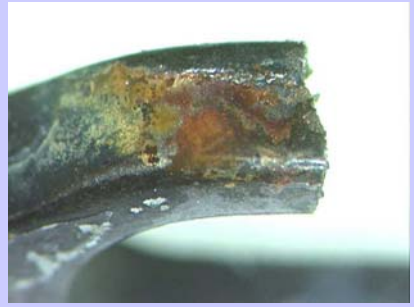
Reprocessing

Standpunt van de industrie

V.S.Z.: Studienamiddag: 28-04-2005

Inhoud



- Europese wetgeving
- Belgische wetgeving
- Europese toestand
- Huidige situatie
- Standpunt van de industrie
- Conclusie

UNAMEC

- Medische hulpmiddelen
- Secties en werkgroepen
- Contacten en samenwerking
  - RIZIV
  - DG III
  - Volksgezondheid en Sociale zaken
  - Economie
  - Financiën
  - ...
- Overlegplatform Medische Hulpmiddelen

Europese wetgeving (1)

- Richtlijn 93/42/EG
  - Medical devices should provide patients, users and third parties with a **high level of protection** and attain the performance levels attributed to them by the manufacturer
  - Any device must be **designed** and **manufactured** in such a way that, when used under the conditions and **for the purposes intended**, they will not compromise the clinical condition or safety of patients and health care workers

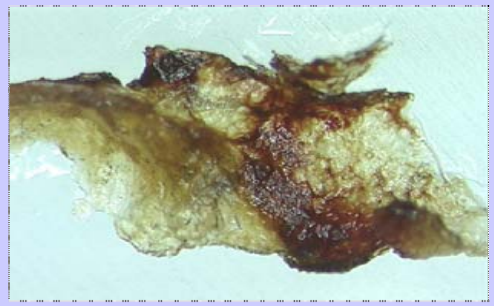
Europese wetgeving (2)

- Recycling of medical devices E. Liikanen (EU Commission 2001)
  - The intended use is defined by the manufacturer on the basis of design and technical constrains and includes the differentiation between single use and multiple use
  - Reuse of single use devices can change the structure of the device and impact its performance
- Reuse of medical instruments (E. Liikanen EU Commission 2003)
  - The Commission shares the point of view of virtually all Member States that re-use of single-use devices should not be promoted for reasons of Health Protection

Europese wetgeving (3)

- Report on the health implications of the MDD
  - Urges the Member States to take the necessary measures to ensure that single use devices are not reused, as the reuse of medical devices intended for single-use only poses a risk for patients and hospital staff

European Parlement: Rapporteur: Minerva M. Malliori



Belgische wetgeving (1)

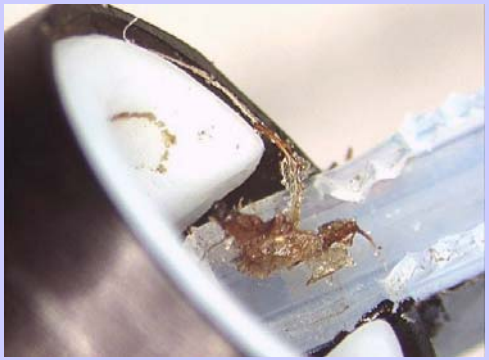
- Koninklijk Besluit van 18 maart 1999 betreffende <u>medische hulpmiddelen</u> (*omzetting van de Europese richtlijn 93/42 betreffende medische hulpmiddelen*).
  - Verstrekt de voorwaarden waaraan een medisch hulpmiddel moet voldoen vooraleer het voor het eerst op de markt wordt gebracht voor verdeling of ingebruikname.

Belgische wetgeving (2)

– Regelt eveneens:
  - het opnieuw gebruiken van het materiaal dat door de fabrikant als herbruikbaar wordt voorgesteld (zie bijlage I punt 13.6 h) van het KB)
  - het opnieuw steriliseren in geval van beschadiging van de verpakking waardoor steriliteit wordt gegarandeerd (zie bijlage I punt 13.6 g) van het KB)

Belgische wetgeving (3)

- Artikel 10, § 9: de inontvangstneming en de aflevering van steriele hulpmiddelen en (wel of niet steriele) inplanteerbare medische hulpmiddelen zijn voorbehouden aan de ziekenhuisapotheker en/of aan de officina-apotheker voor het publiek



Belgische wetgeving (4)

- Elk later gebruik van het hulpmiddel of eventueel gebruik voor een bestemming die niet strookt met de bestemming die door de fabrikant is bepaald, wordt niet gedekt door het K.B. van 18/03/1999. De fabrikant is alleen verantwoordelijk voor de kwaliteit en werking van het hulpmiddel bij een gebruik dat conform zijn bestemming is.

Belgische wetgeving (5)

- Wanneer een inrichting een hulpmiddel evenwel aanwendt voor een hergebruik dat door de fabrikant niet is bepaald, zijn alle betrokken personen, met name de apotheker die verantwoordelijk is voor de sterilisatie alsook de arts die de hulpmiddelen hergebruikt, verantwoordelijk voor de kwaliteit en de werking van het hulpmiddel.

Belgische wetgeving (6)

- Koninklijk Besluit van 4 maart 1991 houdende vaststelling van de normen waaraan een ziekenhuisapotheek moet voldoen om te worden erkend:
  - behandelt in afdeling 2 de specifieke taken van de ziekenhuisapotheker:

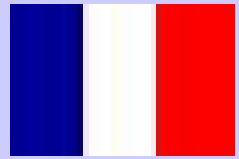
Belgische wetgeving (7)

- artikel 11: de ziekenhuisapotheker moet er meer bepaald op toezien dat het medisch-chirurgisch materiaal, de implantaten en de prothesen op nauwgezette wijze worden gebruikt.
- artikel 12: de ziekenhuisapotheker dient de dagelijkse activiteiten rond de centrale sterilisatie kwalitatief te waarborgen door:
  1° het verstrekken van advies omtrent de keuze van de apparatuur en van de sterilisatiemethodes;
  2° de validatie van de sterilisatieprocedures;
  3° het toezicht op de verschillende stappen voorafgaand aan de sterilisatie: reiniging, desinfectie, verpakking van het te steriliseren materiaal;
  4° het toezicht op de bewaringsmodaliteiten van steriel materiaal.

Belgische wetgeving (8)

– de uitbesteding van deze activiteiten is niet voorzien in de wetgeving

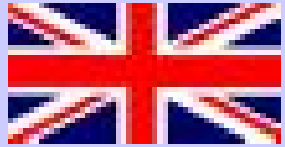
Europese toestand: France



- 1999, July 29, highest French court(1)
  - Reuse is a deception of the patient
- 2000, March 28, Court de Montpellier(1)
  - Reuse of CE marked SUD's is illegal
- 2001, June 22, Journal Officiel
  - Reuse is prohibited by law

(1) Resterilization of single use Medical Devices "Hygiene en milieu hospitalier" No 29 June/July 2000

Europese toestand: UK



- MDA Device Bulletin on Reuse(1)
  - "Single use devices should not be reused under any circumstances"
- Safety Notices(2)
  - Evidence that reuse affects safety, performance and effectiveness

- MDA DB 2000(4)
- Medical Devices one liners. Issue 19, October 2002

Europese toestand: UK

Reuse of a single use breathing tube:

According to the court the hospital ignored the guidance not to reuse single use devices, which contributed to the death of the 9 year old boy.

THE TIMES TUESDAY MAY 20 2003 2W

Hospital 'neglect' led to boy's death in routine surgery

By Adam Fresco

THE death of a nine-year-old boy during a minor operation on his finger was partly caused by "system neglect," an inquest jury decided yesterday.

Tony Clowes, from Dagenham, East London, died after a tube leading from the anaesthetic machine to his facemask became blocked as he was being prepared for surgery at the Broomfield Hospital, Chelmsford, Essex.

An inquest jury sitting at Chelmsford Coroner's Court returned a verdict of "accident contributed to by system neglect".

The foreman of the jury said: "Tony George Clowes died as a result of an accident and the cause of death was contributed to by system neglect, inadequate guidelines, failing to ensure the patency of all ancillary equipment, failure to disseminate important safety information to relevant personnel, and failure to follow guidelines concerning single-use medical devices."

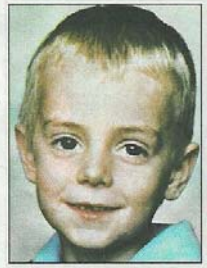
The verdict was the strongest one they could have returned in terms of condemning the hospital.

Tony's father, George, who took him to hospital in July 2001 after the boy trapped his finger in a bicycle chain, criticised hospital staff for not observing medical guidelines.

He said: "We are appalled and angry that his death was due to a failure on the part of senior members of staff and management of the hospital to observe clear guidelines and safety notices that were intended to protect patients.

"Those failures, which amounted to neglect, resulted in the death of our nine-year-old son Tony, whose life we entrusted into the hands of the professionals who failed in their duty towards him."

The inquest was told that doctors ignored safety guidelines and reused a tiny oxygen tube that should have been discarded after just one use. The cap from another piece of



Tony Clowes: trapped finger in bicycle chain

equipment had become lodged in the tube when they were both stored in a drawer.

The inquest was told that a safety notice from the Medical Devices Agency in 2000 said all single-use devices should not be reused under any circumstances. The jury was told that the MDA also said in 2001 that hospitals must check all components of breathing systems, as incorrect fitting could cause patients problems and there had been instances of blockages.

Mr Clowes, who works for a pharmaceutical company, said the family would also report the matter to the General Medical Council.

David Scott, a consultant anaesthetist and medico-legal expert who investigated the case, told the inquest that Tony would probably have been saved if doctors had disconnected the equipment and given him mouth-to-mouth resuscitation instead of concentrating on what they thought was a problem with the machinery.

Tony's death led to a major police operation, Operation Orcadian, during which detectives looked at 13 similar but non-fatal cases all over the country involving blocked oxygen tubes.

Three members of hospital staff were arrested over the incident and a file was submitted to the Crown Prosecution Service, but in July 2002 detectives said the boy's death was not the result of a criminal act. Speaking after the verdict, Detective Superintendent Win Bernard said that detectives would continue to work with the Health and Safety Executive while they considered what action to take.

Mr Bernard said: "No verdict today is consolation for Tony's family, who were devastated by the sudden and untimely loss of their son." He said shortly after Tony's death, a similar incident occurred at another Essex hospital when a man's life was saved because warnings had been given.

Andrew Pyke, the chief executive of Mid Essex Hospital Services NHS Trust, expressed the hospital's sadness to the Clowes family about what had happened. He said staff had been upset about the events and that changes had been put in place since the tragic event and the tube was now used only once then thrown away.

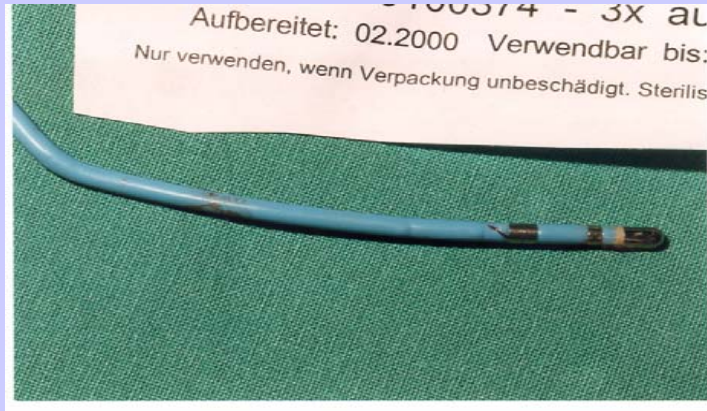
Europese toestand: Germany

- Reprocessing Regulation
  - Mandatory registration of reprocessors(1)
- Current status
  - Audits of reprocessors not mandatory(2)
  - Guideline on reprocessing
    - Focus on Hygiene Aspects
    - Status equal to harmonized Standard

(1) Medizinproduktegesetz §25
(2) Robert Koch-Institut: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten

Europese toestand: Germany

- Vigilance Reporting?
  - 1997 – 2001: BfArM received 4 reports on incidents where reuse of SUD‘s occurred
  - Effective Vigilance system to monitor reprocessing quality?
  - Who should report?
- Patient Awareness? (*)
  - 86% of the population is unaware of the reuse of single use devices
  - 74% expect to be informed prior treatment

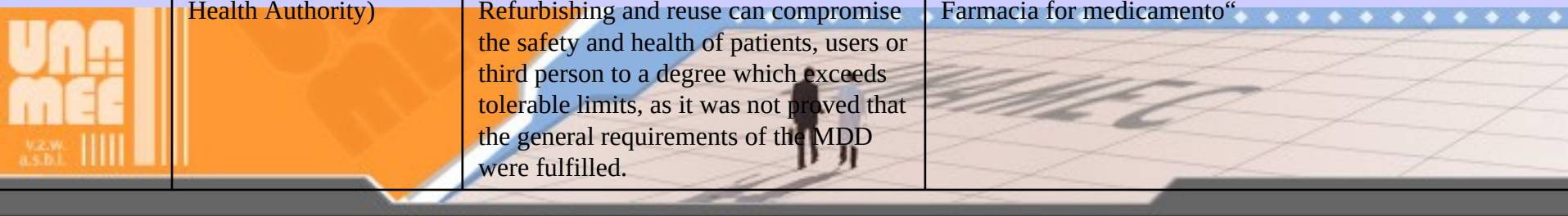


Reprocessed 3 times by 3’rd party
Reported to manufacturer

(*) GfK healthcare market research 2003, sponsored by BVMED

Country	Regulation	Comment	Reference
Belgium	No regulation		
Denmark	No regulation – no ban	Allowed under sole responsibility of users. No special surveillance, no reference in national law	answer „Sundhedsstyrelsen“ dated 24th August 1999
Germany	General regulation of reprocessing without differentiation of single use and multiple use devices. Regulation limited to registration of the reprocessing activity.	Since January 2002 the ordinance on operating medical devices requires a documented and validated process to ensure health and safety of patients, users and third parties. There is an assumption of adequate reprocessing if the RKI guideline on Reprocessing is followed. This guideline request certification per ISO 13485 standard for difficult to clean and not steam sterilisable devices. But since the RKI document is a guideline, it is not mandatory to follow the RKI guide or ISO 13485. The ordinance on operating medical devices “Betreiberverordung” bans any usage against the devices intended use. If single-use and multiple-use is part of the devices intended use, reuse is therefore illegal. Since the regulation does not clarify if reuse of single use devices is legal, there are different legal opinions if reuse is in compliance with German law or not.	MPG Änderungsgesetz Betreiberverordnung §2 (1) altered through MPG Änderungsgesetz RKI guideline „Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten“
Finland	No regulation – no ban	Allowed under sole responsibility of users according to the health authorities interpretation.	Answer „National Agency for Medicines“ dated 16th August 1999

France	Ban	The health authority requested not to reuse Single Use Products since 1984 . Confirmed through court decisions in 1999 and 2000. Refurbishing of Single Use Products is seen by court as a deception of the public, because a) patient is taking higher risk without any advantage and b) the product is invoiced as a new one. In June 2001 a law against reuse of single use devices was published	-December 1994, Ministry bans reuse -July 1999, highest French Court Cour de Cassation oReuse is a deception of public -March 2000, Court Decision, Montpellier oReuse ban for CE labelled Single Use Products -March 2001, CJD Circular oSingle Use Products and such with safety equipment are banned to be reused -June 2001, Journal Officiel oCJK Circular has law character oReuse of all Single Use Products is banned
Great Britain	Health Authority strongly advised against reuse of single use devices	The Health Authority MDA requests not to reuse of Single Use Products	-HSC 1999/178 vCJD minimizing the risk of transmission: o“devices, intended for single use have to be destroyed after use and are not allowed to be reused” -HSC 1999/179 decontamination of medical devices: o“Do not refurbish a medical device, intended for single use”
Italy	Ban (Interpretation)	Interpretation by the Health Authority	-MDA DB 200(4) MDA Device Bulletin on Reuse
Norway	Partly (not clear if implemented, no registration)	Defined as a product produced in the hospital which has to fulfil all requirements regarding safety (interpretation of authority)	Answer „Norwegian Board of Health” dated 09th June. 1999
Portugal	Ban (interpretation of Health Authority)	Position of Health Authority: Refurbishing and reuse can compromise the safety and health of patients, users or third person to a degree which exceeds tolerable limits, as it was not proved that the general requirements of the MDD were fulfilled.	Answer dated 25th June 1999 „Instituto Nacional da Farmacia for medicamento“



Sweden	Partly	Refurbished Single Use Products have to fulfil the MDD's essential requirements. No registration or post market surveillance requirements. Patient informed consent is required.	Medical Devices Act SFS1993:584
Switzerland	No regulation – no ban	Refurbishing is defined by the Authorities as manufacturing process, but there is no ban interpreted out of this	
Spain	Ban	Law requires to use medical devices according to the intended use of the manufacturer	Royal Decree 414/1996 §5 Answer of Authority "Ministerio de sanidad y consumo" dated 9th July 1999
U.S.A.	Regulation	Refurbishing of Single Use Products is manufacturing. Third party reprocessors and hospitals have to fulfil all requirements regarding Quality System Regulations, Product Registration, Labelling, reporting of incidents.	Enforcement Priorities for Single-Use Devices Reprocessed by third Parties and Hospitals FDA August14,2000

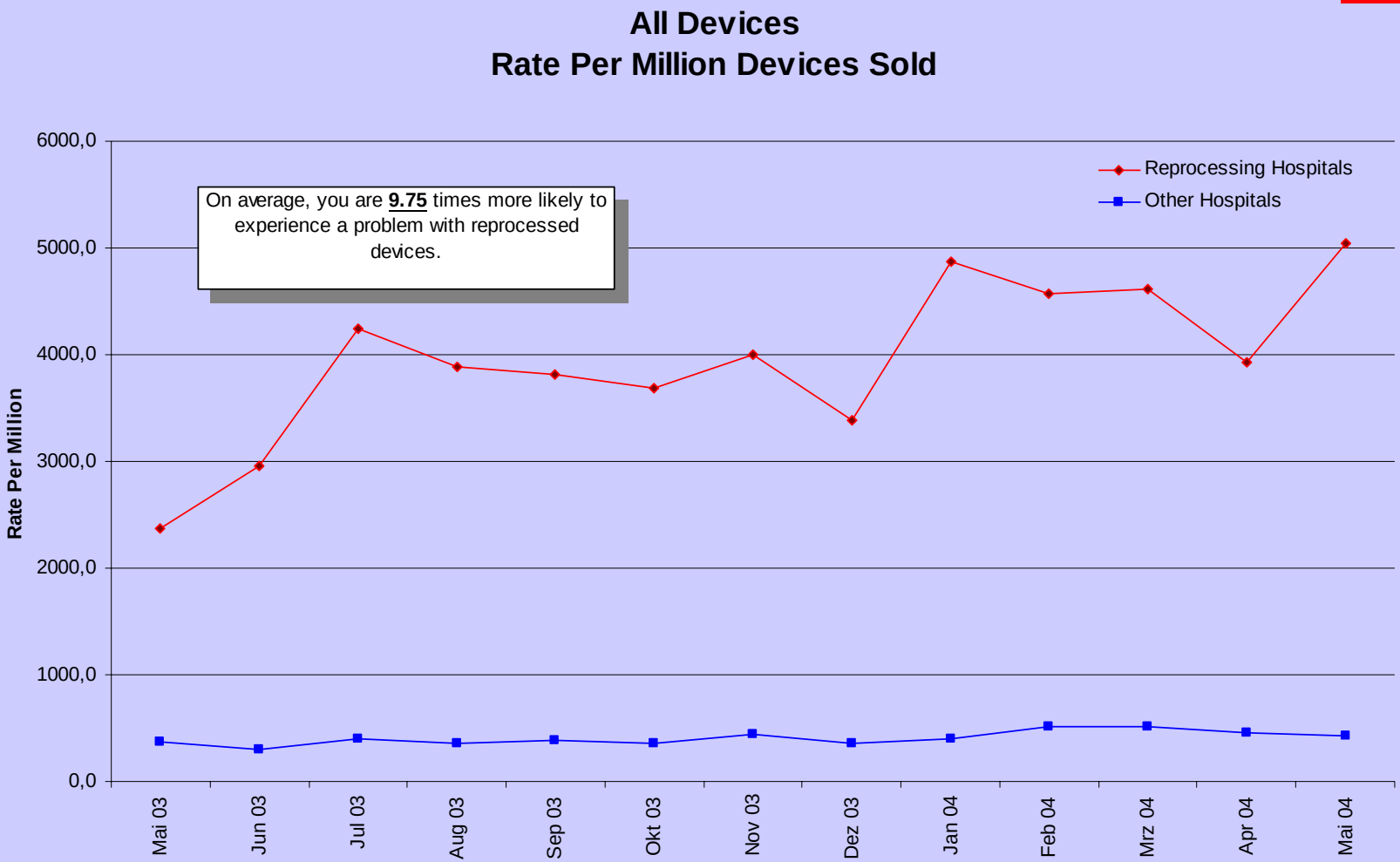
Huidige situatie: Vragen te stellen (1)

- Technical
  - Can a Single Use Device have the same characteristics after usage and refurbishing?
  - Refurbishers source of information for ongoing design changes?
- Economic
  - Is reuse economic when all aspects are reviewed?

Huidige situatie: Vragen te stellen (2)

- Legal Issues
  - Is reuse in compliance with existing regulations?
  - Are those regulations sufficient?
  - Users liability?
  - Reimbursement?
- Ethical
  - Is higher risk without direct patient benefit acceptable?

Huidige situatie: Complicaties VS

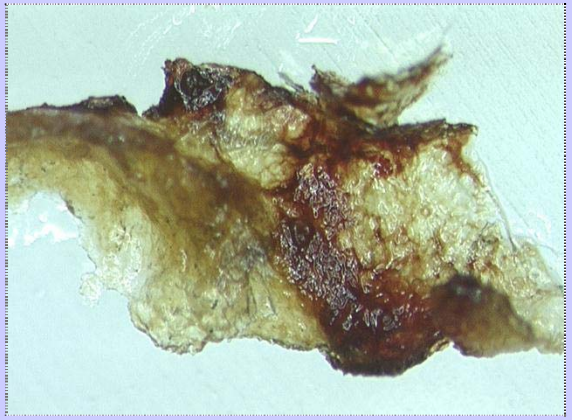


Huidige situatie: Design van MH (1)

- Designed and validated for single or multiple use
  - Materials are chosen to ensure maximum performance for the intended usage
    - Single use: maximum performance for one usage
    - Reusable: performance, reliability, cleanability = often a compromise
  - Biocompatibility for the intended environment
    - Single use: First sterilisation, conditions during surgery
    - Reusable: Cleaning, Disinfection, sterilisation, multiple usages
  - Risk-management
    - Single use: Avoid first failure
    - Multiple use: All risks inherent in multiple usage and reprocessing

Huidige situatie: Wetenschappelijk evidentie

Devices reprocessed by hospitals and 3'rd parties
Labelled as being sterile and ready to use(1)

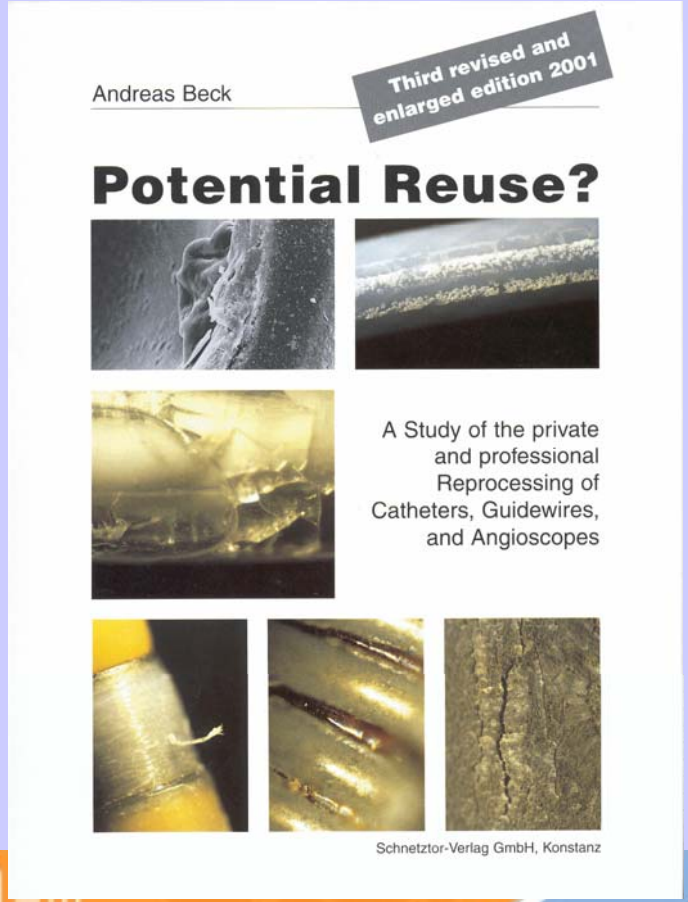


Reprocessed Clip Applier contaminated with blood and tissue from previous patient

- 55% of devices contaminated
- 38% of devices non-sterile
- 50% of devices out of specification

(1) Field Quality Engineering Report; Evaluation of Reprocessed Single Use Devices EES Inc. Oct. 1999

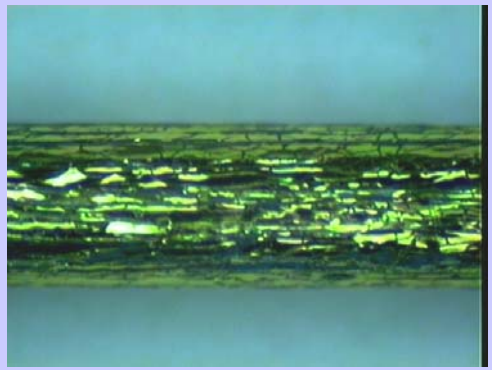
Huidige situatie: Wetenschappelijk onderzoek: A. Beck



- 3'rd party and in house reprocessing of SUD's
  - 49% surface changes
  - 45% contaminated
- Reprocessors QS
  - 23 severe damaged catheters sent to 3'rd party reprocessing; all 23 returned to the hospital as ready to use
- 8 years research on >2000 devices

Huidige situatie: Reprocessed catheters

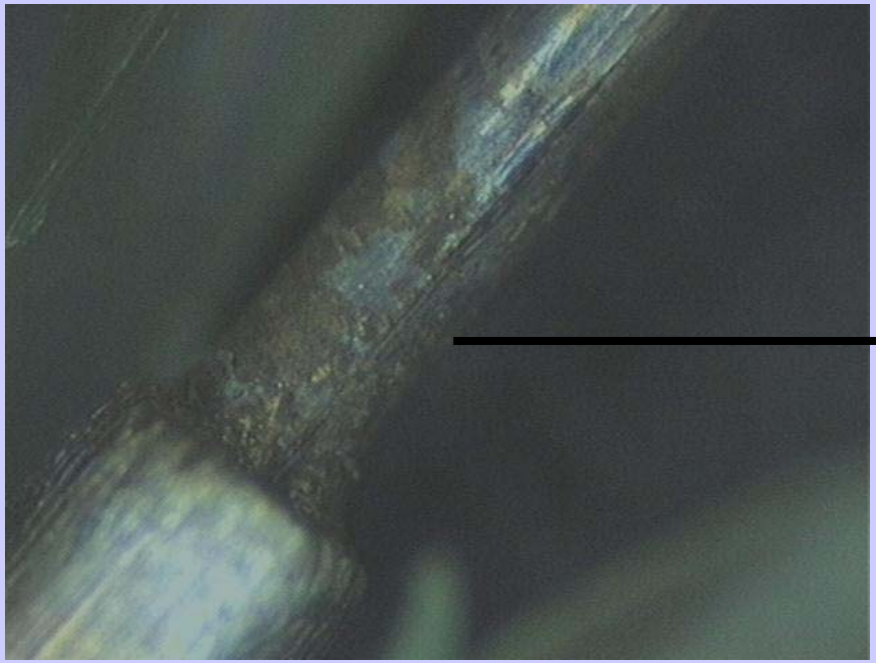
- Between 1998 and 2002 four studies have been carried out in Germany with similar results
- Reprocessed Catheters received from German hospitals (Study II, 1999)
  - 70% 3‘rd party reprocessors (certified QS)
  - 30% reprocessed by hospitals
  - Key Findings
    - 26% contamination (blood, proteins)
    - 50% contamination (contrast fluid)
    - 63% packaging failures
    - 100% without instructions for use

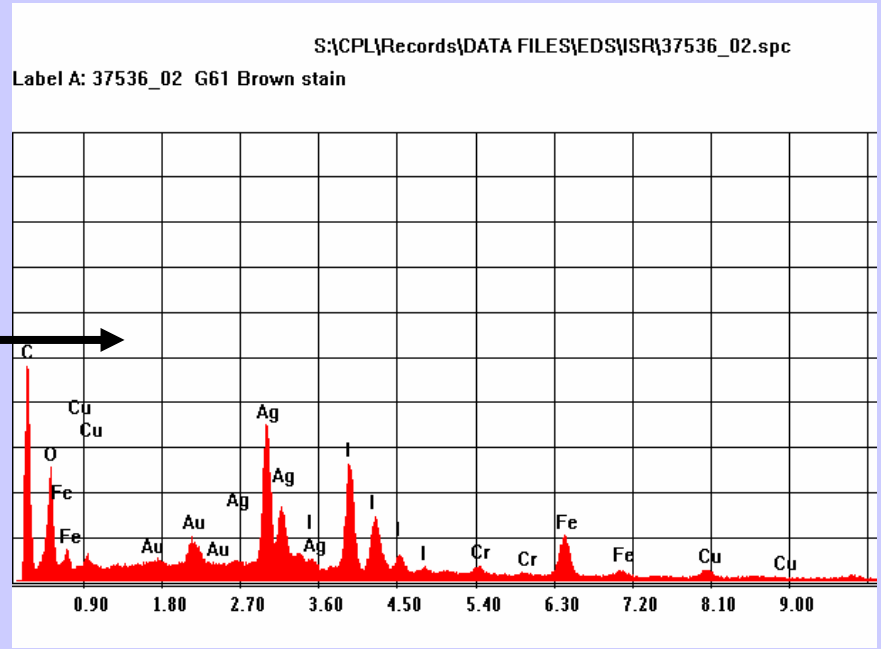


Balloon catheter:Flaking distal exit marker

Evaluation of refurbished single use devices, Quality Assurance Laboratory, October 27, 1999

Huidige situatie: PTCA balloon catheters





Brown contamination on balloon catheter wire

Identified via x-ray analysis as being corrosion product and Iodine

Evaluation of refurbished single use devices III, Chemical and Physical Quality Assurance Laboratory, 2002

Huidige situatie: Catheters Study IV

- Third party reprocessed diagnostic catheters n=15
  - 53% contaminated
  - 90% out of spec
  - 20% mislabelled
  - 73% without OEM lot number
  - 20% unreadable reprocessors lot number
  - 100% without IFU'S

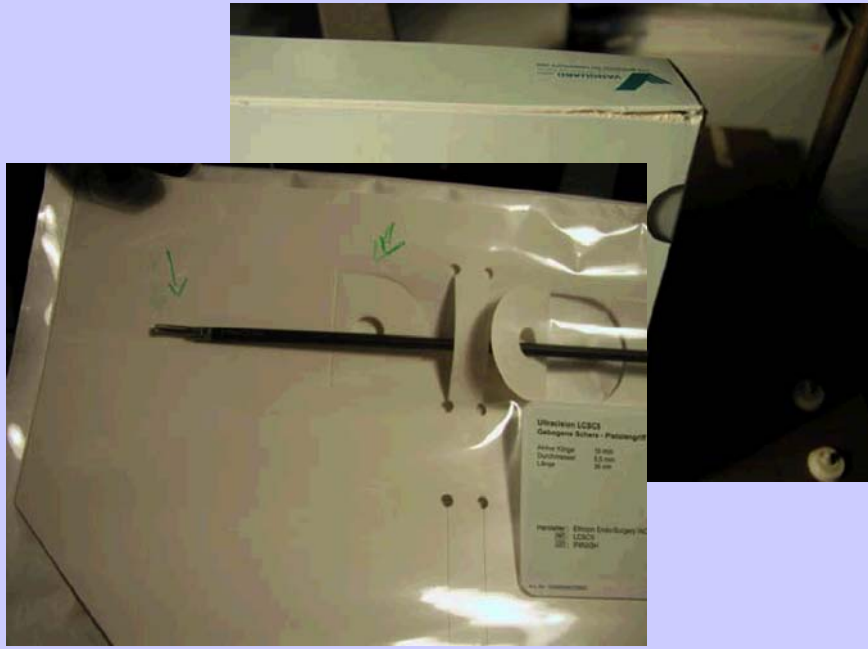
5 French catheter labelled 6F

Reprocessed Single Use Devices, Lab Report QA2001-154A

Huidige situatie: Hygienische aspecten

- Expert report by a leading EU Hygienist(*)
  - N= 19 devices reprocessed by a German 3‘rd party reprocessor
  - 17 Instruments with Packaging issues
  - **3 out of 19 devices non sterile !**

MDD, Annex I:Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method

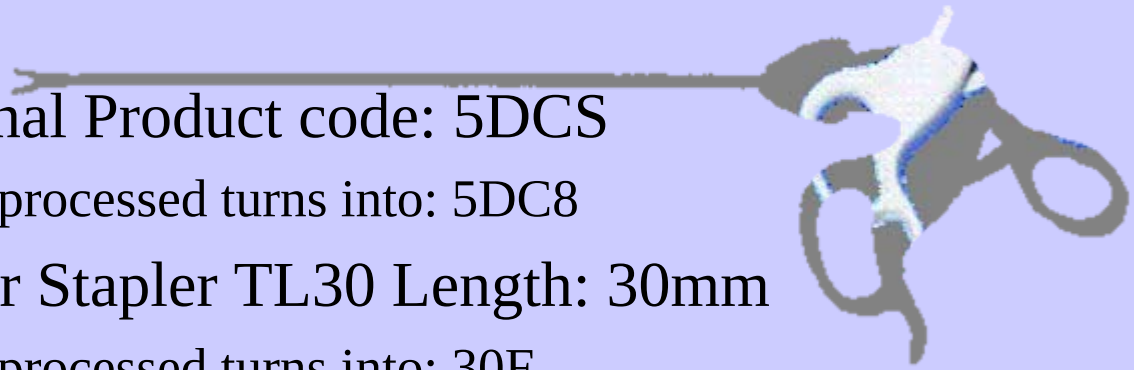


SN2609-16 HygCen

- Corrective Action?
  - Recall?
  - Customers informed?
  - Vigilance Report?

(*) „HygCen Experts Report dated 26. Mai 2003“

Huidige situatie: Labelling



- Original Product code: 5DCS
  - Reprocessed turns into: 5DC8
- Linear Stapler TL30 Length: 30mm
  - Reprocessed turns into: 30F
- Linear Cutter, Length: 55mm
  - Reprocessed turns into: Length 55X
- Number of previous usages missing (device withstands only a limited number of firings for a single procedure)

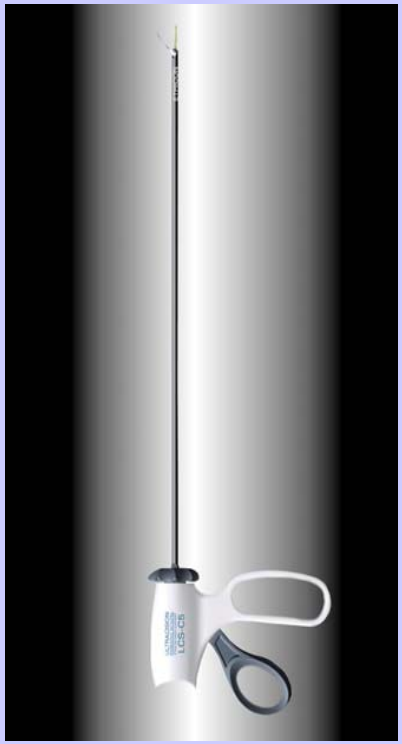
MDD, Annex I: 13.3 The label must bear the details strictly necessary for the user to identify the device and the contents of the packaging.

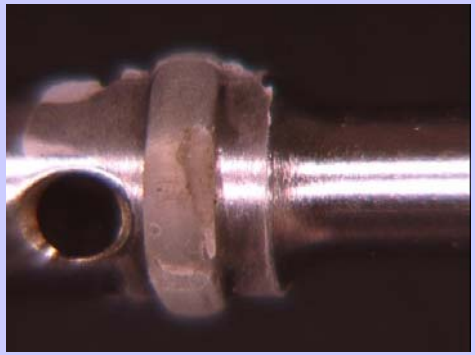
Experts Report on reprocessed products and CE marked original products (2003)

Huidige situatie: Basic Product Knowledge

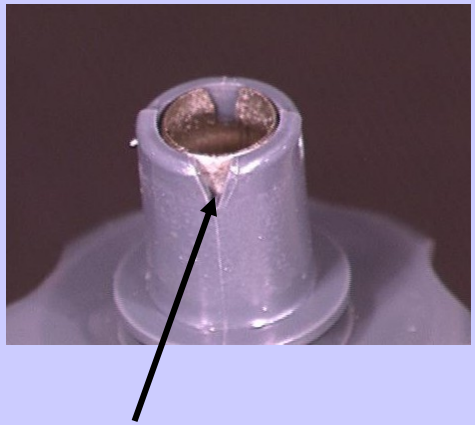
- New CE marked Linear Stapler
  - Pre-loaded with fully loaded cartridge
  - Integrated QS in Production
    - 100% check twice with automated systems
    - Empty cartridge = critical failure
- Reprocessed Device
  - Delivered by the 3‘rd party reprocessor pre-loaded with an empty cartridge
  - MDD, Annex 1: The devices must be designed and manufactured in such a way that, ... They will not compromise the clinical condition or the safety of patients ...

Huidige situatie: Repair or refurbished

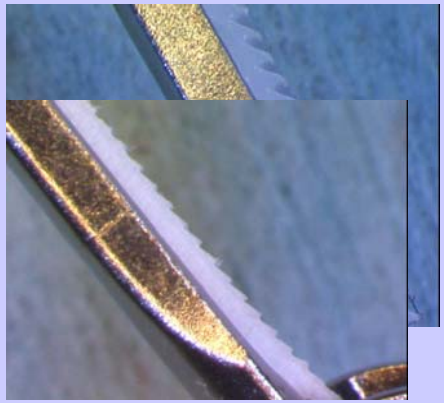




Damaged Bushing



Creative Assembly of rotation knob upside down



Replaced clamp pad

Product obviously has been broken apart, disassembled, cleaned, parts replaced and glued together.

Product specifications differ from those described in the manufacturers Design Specification, performance not the same any more. (Sect. 13 Annex I)

Standpunt van de industrie (1)

- Voorzichtigheid
- Respect van dezelde eisen dan de fabrikanten (conformiteit, risico beheer, …)
- Verantwoordelijkheid
- Informatie van patiënten: mogelijkheid om te kunnen kiezen
- ...

Standpunt van de industrie (2)

Summary – Call For Action

Scientific evidence documents need for action.

Equal application of regulations which have been proven to be adequate.

Regulate all reprocessing of medical devices intended for single use by medical practitioners, hospitals, reprocessors and original manufacturers,
in order to protect the health and safety of patients and health care workers.

Conclusie

Medical devices should provide patients, users and third parties with a **high level of protection** and attain the performance levels attributed to them by the manufacturer(1)

(1) Medical Devices Directive 93/42/EEC; Recital 5

Medical Technology

Saving Life...

Improving Quality of Life

Thank you !

Myriam Desmet
m.desmet@unamec.be