# Design of Surgical Instruments – Patient Safety First

## 1st meeting of the Dutch Association of Experts for Sterile Medical Devices Nijmegen, 22 November 2007

*Dr. Gudrun Westermann, Wiesbaden*

Around 100 delegates had assembled in the Medical Centre of Radboud University in Nijmegen to spend the day discussing various aspects of the manufacture and decontamination of surgical instruments.

### Trying to meet different requirements

In the first lecture, Dr. Th. Fengler, Berlin, described the requirements addressed to instruments and infection prevention from the surgeon's perspective. While instrument functionality was the most important requirement as far as the surgeon was concerned, the issue of decontamination had also to be addressed as otherwise it would not be possible to make available the instruments needed. Medical device decontamination was a task that was not given much public recognition, but this was desirable so as to attract the necessary investments and qualified personnel. Dr. Fengler pointed out that decontamination steps took time and had to be carried out in the strict order prescribed.

Decontamination had to be performed in line with the state of the art; here one had to bear in mind that standards often lagged behind the state of the art.

Dr. Fengler described problem areas in the field of decontamination, e.g. minimally invasive surgery and dentistry. When dental hand pieces were used to treat a patient, liquid was often aspirated into their channels. Hence, reprocessing such hand pieces, classified as Critical B devices, posed a residual risk. He rounded off his talk by outlining a number of mistakes picked up during process control, e.g. silicone mats in the ultrasonic basin impeding ultrasonic cleaning, incorrect connection of tubular fittings giving rise to inadequate water pressure or overloading of trays, which also hampered proper cleaning. Packing mistakes were also common.

Frank Raymaekers, manager of the procurement department at Erasmus University Hospital in Rotterdam, reported on instrument procurement. Here various demands had to be reconciled with each other, ranging from legal provisions through amenability of the respective device to decontamination to the demands made by the surgeon, whose main aim was to the minimise the pain caused to the patient, while expediting patient recovery. All these requirements had to be incorporated into a professional procurement process. But whose requirements should take precedence? Citing by way of example a retractor which was amenable only to manual cleaning, Raymaekers described the decision-making process. For more information on procurement please visit www.medicaldevice.nl.

### The development process – decontamination at a glance

Ingrid Griffioen described the instrument development process from the perspective of an instrument designer. The aim here was to optimise the design and counter the production of any unsuitable products. The designer concentrated on functionality, costs and time needed to develop the product. During the development process the costs rose sharply as from a certain point in time. Hence it was important to incorporate any proposed improvements at an early stage. This could be accomplished through repeated testing of prototypes and regular meetings with experts working as a flexible team, so as to have continuous feedback from such experts.

F.-W. Oertmann described the development of MIS instruments from their infancy up to the present day. Whereas during the 1960s development and risk analysis were mainly orchestrated by the surgeons themselves, today these tasks were carried out by experts so as to meet the more stringent requirements in terms of the device's amenability to cleaning and to other decontamination steps. Being able to dismantle devices was of paramount importance so as to assure proper cleaning and sterilisation.

During the 1990s trends were driven in particular by two events: the coming


Thomas W. Fengler


Frank Raymaekers


Ingrid Griffioen


Diana Bijl


Klaus Roth


F.-W. Oertmann

into force of the German Medical Devices Act (MPG) and the emergence of variant Creutzfeldt-Jakob disease (vCJD). In its recommendation published in 2002, the CJD Task Force at the Robert Koch Institute (RKI) had advocated that alkaline cleaning be carried out for 18 min at temperatures above 55 °C before sterilisation at 134 °C. Since this had resulted in the destruction of many MIS instruments, manufacturers had to meet new requirements: instead of aluminium, titanium was now used and certain polymers could no longer be used. This in turn led to a shorter service life for the instruments.

Oertmann pointed out that these provisions were valid only for the European market. He finished off by demonstrating various single-use and reusable instruments. Special attention had to be paid to validated decontamination processes in the case of instruments that could not be dismantled. Of paramount importance in any case was conversancy with the reprocessing parameters before purchasing an instrument; relevant information on this topic could be consulted in some cases on the manufacturer's websites.

Tessa ten Cate demonstrated various surface coatings that could help to control the degree of contamination. It was possible to prevent adhesion of microorganisms through an astute choice of materials. Mrs ten Cate reported on studies that compared a hydrophilic brush coating, which was much better than traditional epoxy resin or silicone coatings at preventing bacterial and cellular adhesion. Any biofilm deposits on such surfaces could also be removed much more easily.

The coating of surfaces with nanoparticles was done for the same reason, providing for structured control.

The release of antibiotics represented a further use. Retarded-release systems could assure efficacy over a longer period of time.

### Decontamination – who is responsible?

Philip de Vries, co-organiser of the event, described competences in the Netherlands: the experts for sterile medical devices were responsible for the decontamination quality. It was not always easy to verify this, especially since the competent

persons were not employed in the Central Sterile Supply Departments (CSSDs).

Using photos, he showed a number of problem areas, e.g. instruments that were still dirty after cleaning as well as moist loads.

Mr. De Vries stressed that no deviations from the validated process were permitted. Ensuring this called for specially qualified staff and continuing professional development.

Diana Bijl, likewise co-organiser of the symposium, continued with a talk about inclusion of instruments that regularly caused problems on a "Grey List". A checklist was drawn up because of regular occurrence of such problems and this could be consulted when purchasing new instruments; this was available at www.cscnl.net/divers.

Evoking Neil Armstrong's words when he landed on the moon, Bijl described the requisite decontamination instructions in her own words as "one small step for the manufacturer; one giant leap for patient safety".

L. Meinders from the Dutch Health Supervisory Authorities elaborated on the duties of manufacturers and users. Medical devices had to meet the requirements and manufacturers were obliged to monitor the safety of their products. The user was responsible for safe use of the device.

To highlight this interplay, Mr Meinders reported on an investigation carried out by his authorities into adverse events associated with laparoscopic surgery. This had revealed that maintenance of such instruments and supervision of decontamination activities could be further improved. What was important was a functional quality assurance system as well as appropriate risk management and continuing professional development of staff. The user was responsible for reporting adverse events to the competent authorities, since otherwise they could not become involved.

Frederike Tesser, legal adviser to Nijmegen University Hospitals, described the responsibilities borne by those using medical devices. Apart from the physician using the instrument, this also included the hospital and the manufacturer. Whereas the physician had a duty of care to use instruments only if they met the requirements, the hospital could also be held responsible for the quality of decontamination. Hence documentation of sterilisation processes in general and of process data for each batch was essential, as was regular verification of the functionality of the medical devices used.


Winfried Michels


Philip de Vries*


Tessa ten Cate


L.W. Meinders*


Frederike Tesser*


Adrie de Bruijn*

In the last analysis, the manufacturer had to assume product liability for his instruments and had also the legal obligation to investigate the causes of problems relating to his product. In the event of serious adverse events, users could also report these directly to the competent statutory health authority.

### Validation of cleaning processes

In the afternoon Klaus Roth, Tübingen, reported on his experiences gleaned from validation of cleaning processes. The aim here was to be able to use the same decontamination cycle for all types of instruments. Using a flow chart, Roth demonstrated how the instruments could be divided into 7 groups based on their design, ranging from very basic to highly complex and flexible instruments.

A validated decontamination guide was produced for each instrument at the end of this process. Roth recommended analysing a decontamination process for an instrument before purchasing it and obtaining pertinent information from the manufacturers. In the event of repairs or of having to purchase replacement instruments it should be clarified whether in the meantime new or possibly an easier to clean version of the device was available.

Dr. W. Michels traced the history of washer-disinfectors from the beginning up to the present. Cleaning technology, to cite Michels, had hardly changed over the past 30 years. Nor were there any new trends in the commercially available detergents. Dr. Michels pointed out that in one study some detergents had not proved to be any better than pure water. Conversely, much innovation was seen as far as loading trolleys were concerned, as demonstrated by Michels using a trolley for anaesthesia accessories by way of example. The question was what the future would hold in this field. Michels named a few innovative technologies such as plasma or $CO_2$ cleaning, which would have to be addressed in the future.

### ISO 17664 – decontamination instructions still far from perfect

In the last lecture of the day Adrie de Bruijn from the Dutch Institute for Public Health RIVM dealt with the topic of decontamination instructions and the requirements enshrined in ISO 17664. Manufacturers were obliged to provide clear decontamination instructions. In a study, published in *Central Service* in 2006, it was revealed that these instructions often left much to be desired. Often, manual decontamination methods were described, the customarily used sterilisation processes were not recommended, reference was made to foreign guidelines that were not valid in the Netherlands or only the most inadequate information was provided. There were also often many mistakes in the translations.

De Bruijn stressed that the decontamination instructions should definitely be consulted before purchasing a medical device. The published checklist could prove beneficial here.

And that brought to a close a symposium that covered all relevant topics ranging from development through technical details to legal competences, while highlighting one detail: good cooperation between the user, CSSD and manufacturer is the chief determinant of patient safety. ✦

* Photo: C. van de Venne, Radboud University Nijmegen Medical Centre