Parametric control of cleaning processes in the age of vCJD

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Präzise Reinigungsprozesse

Conclusion (Instruments Processing and Prions: An Update)

In our studies we could show, that a combination of alcaline cleaning followed either by disinfection or sterilization delivers high log reductions.

The comparison of different alcaline detergents showed, that the ph-value of the detergent is not the only parameter, which influence the efficacy. Temperature as well as the formulation of the detergent are important factors, too.

Therefore each procedure has to be tested and validated.

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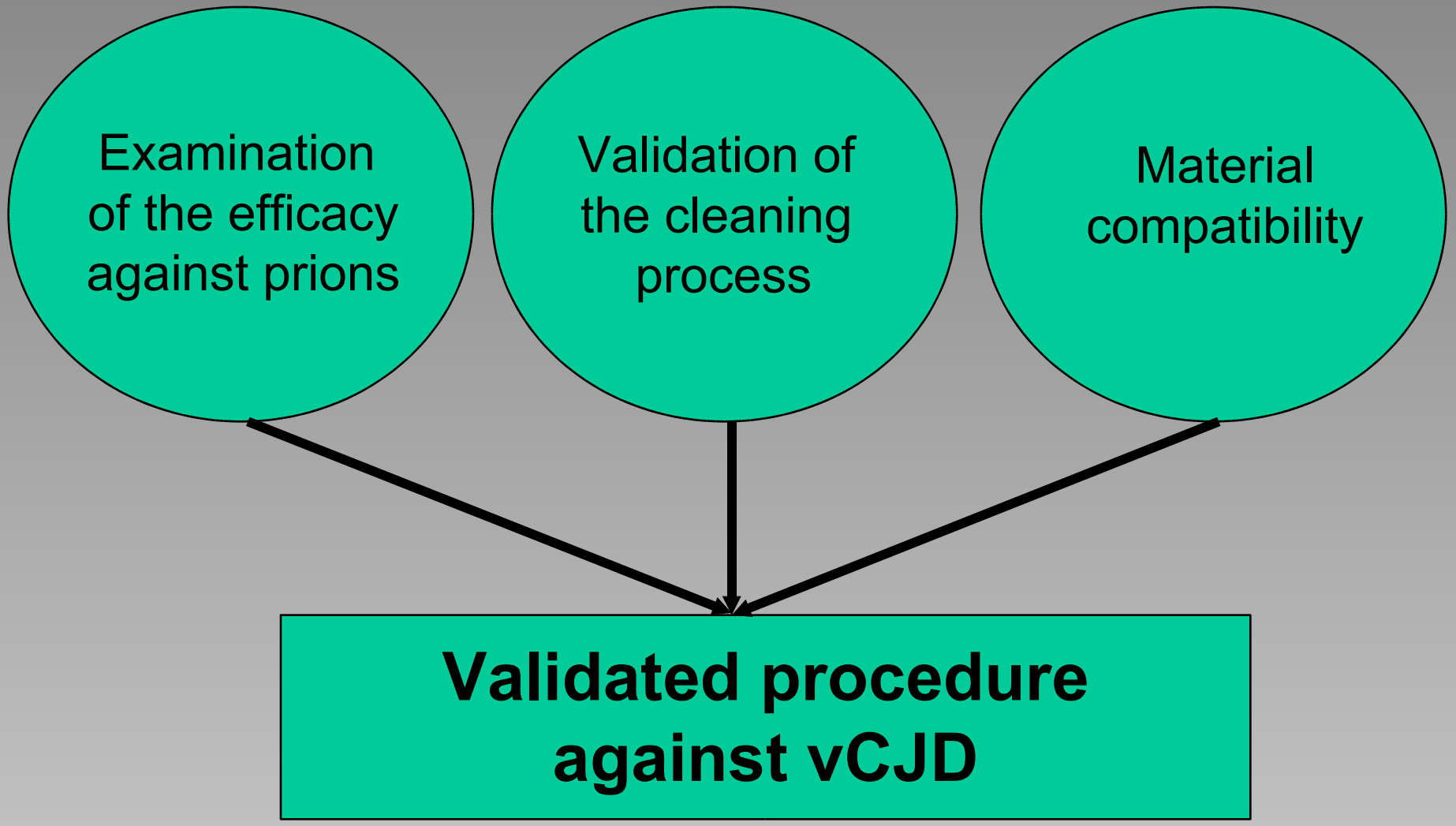
Relevance of the tests



New Standards

EN/ISO 15883 1-4

Requirements for the performance of the washer/disinfector and test procedures

EN/ISO 17664

Information to be provided by the manufacturer of a medical device to the user

Requirements of EN/ISO 17664

- Preparation at the point of use
- Transport
- Cleaning
- Disinfection
- Functionality testing
- Packaging
- Sterilisation
- Release and Documentation
- Storage

EN/ISO 17664

3.5 Cleaning

A validated method of cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued.

Where appropriate, at least the following information shall be included:

.accessories required for cleaning process;

.identification and concentration of chemicals required for cleaning;

.identification of water quality,

.limits and monitoring of chemical residues

.limits on temperature, concentration of solution(s), exposure time,

.process temperature(s);

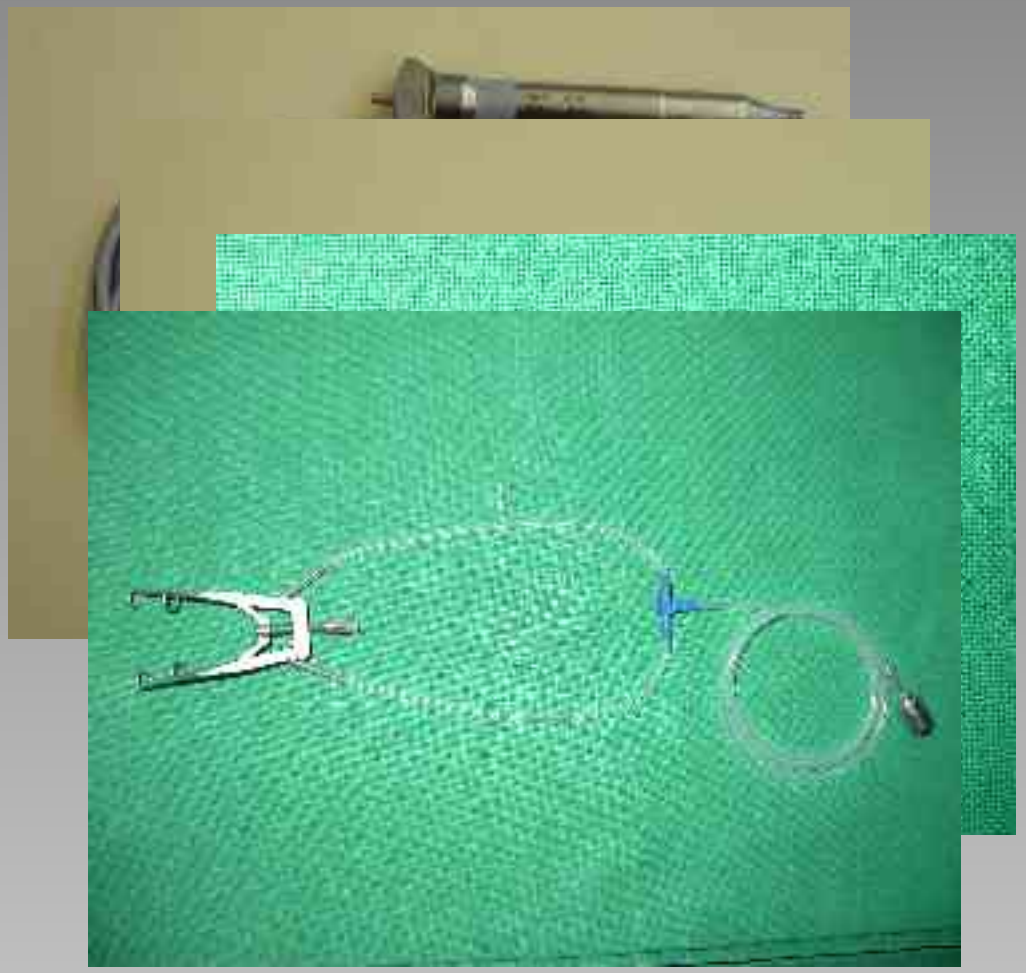
.techniques to be used including rinsing;

Categories of instruments and specific requirements for use:

- Instruments, to be used outside the body. → Clean / Disinfected
- Instruments, to be used inside the body without penetration of the mucosa or skin. → High Level Disinfected
- Instruments, penetrating the skin or mucosa. → Sterile

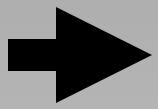
Typical Content of a Katharakt Set

- Phacohandpiece
- Bimanual Handpiece
- Sauter canulla
- Cirkel
- Scissor
- Pinzette
- Lidopener



Validiation of each single Instrument

- Validation of the cleaning behavior with the Radionuklidmethod
- Validiation of the disinfection with microorganism and parametric release with data loggers
- Cytotox evaluation
- Examination for remaining alkalinity by XPS
- Validation of the sterilisation behavior



Evaluation of all parameters and the minimum requirements

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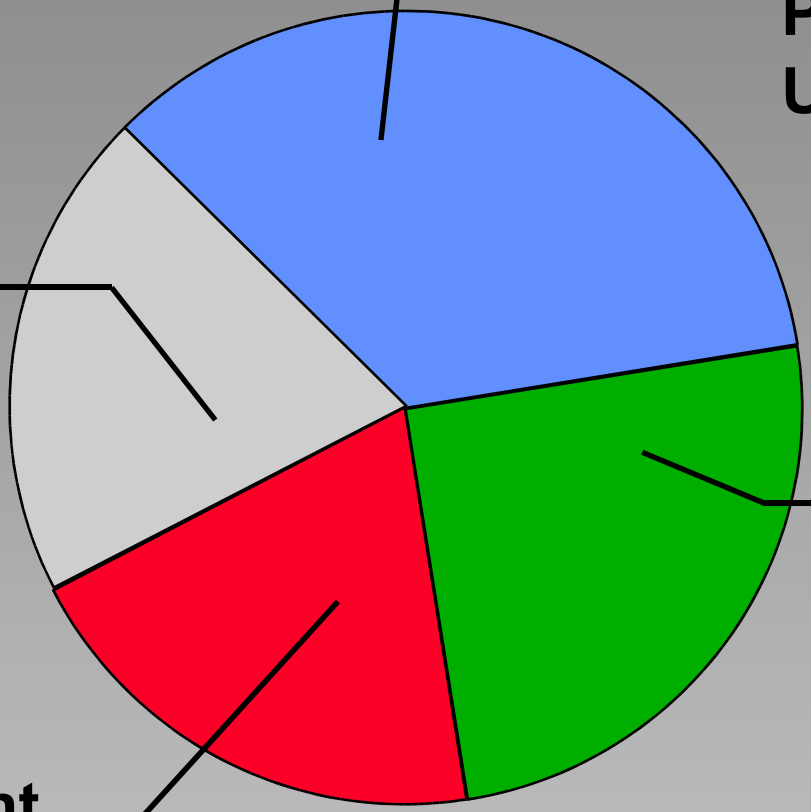
Parameters of the Cleaning Cycle



Mechanics: Amount of Water
Pressure
Ultrasound

Interacting
Time

Temperature

Chemical Agent
Water Quality

Radionuclide Method

A non destructive test procedure for the validation of the cleaning process of surgical devices with lumens and hidden surfaces;

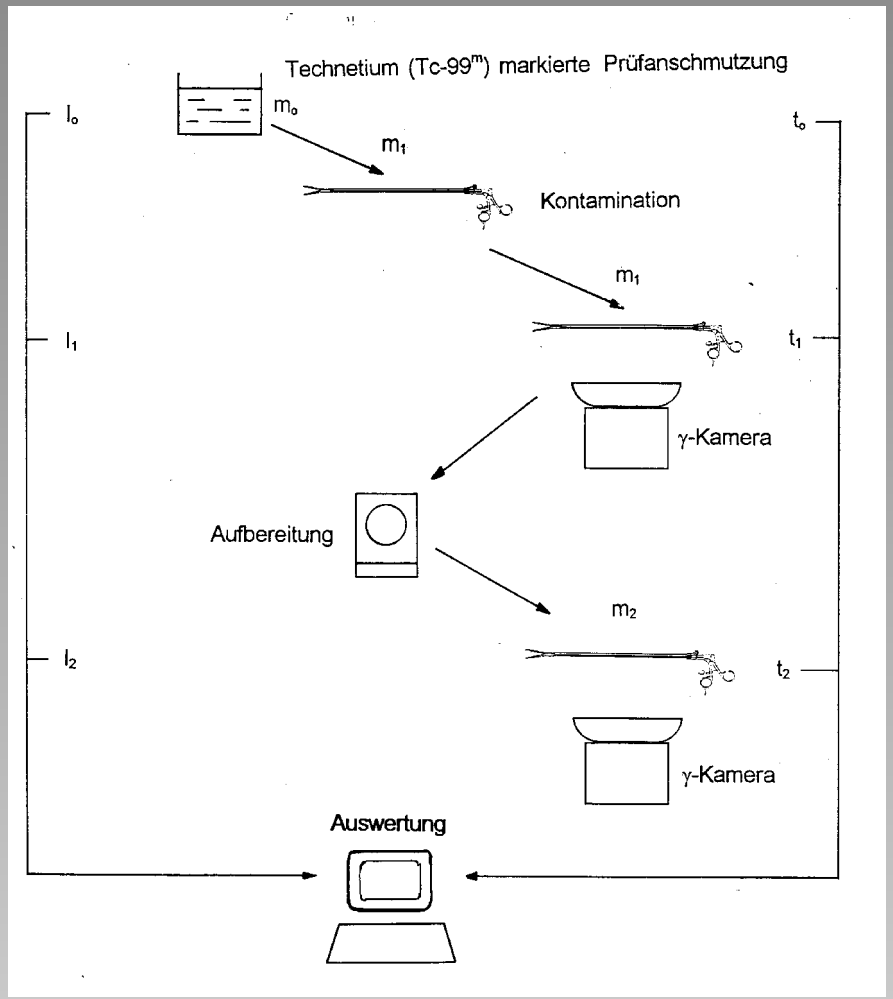
e.g.

- forceps and scissors for open surgery
- devices for minimally invasive surgery
- devices for flexible endoscopy

Radionuclide Method

- Standardized in vitro contamination
- Quantification of remaining dirt
- Detection of problematic spots in instruments without destruction
- Validation method for cleaning processes
- Applied for ASTM – Standard
- Mentioned in AAMI TIR 30

Radionuclide Method

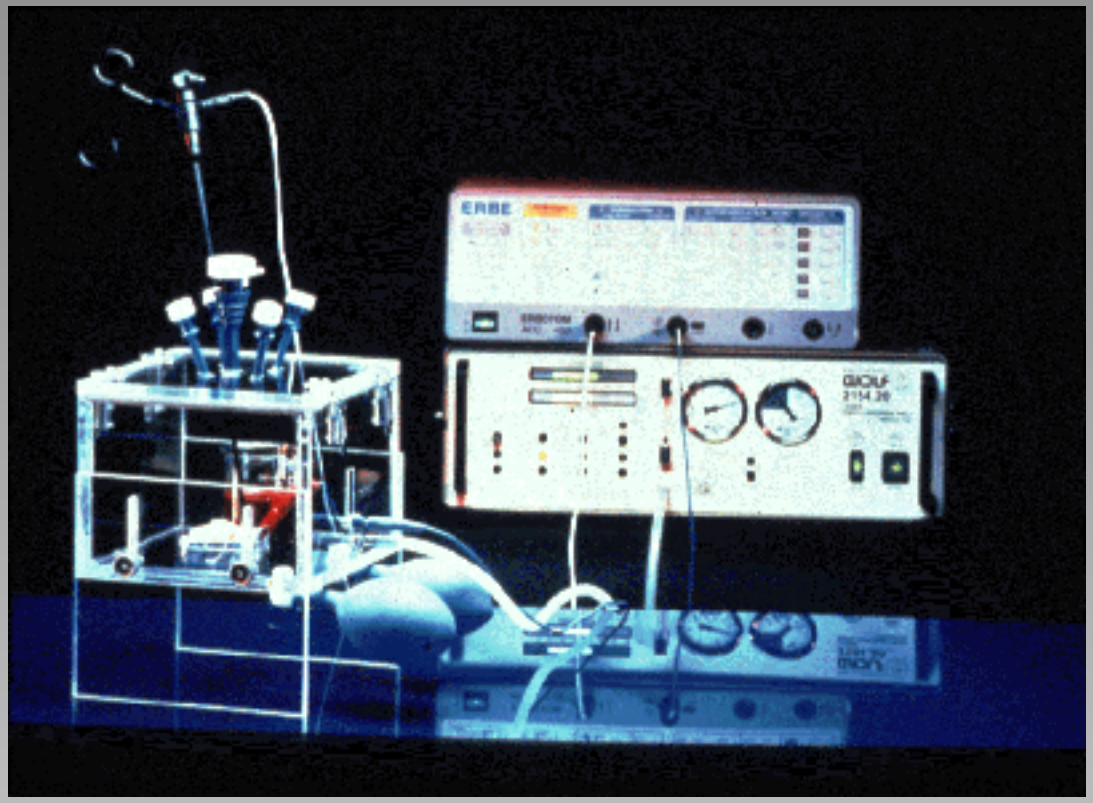


- Radioactive labelling of the blood with Tc 99m
- Contamination of the devices
- Measuring of the devices with the gammacamera
- Reprocessing of the devices
- Measuring of the devices after reprocessing
- Analysation

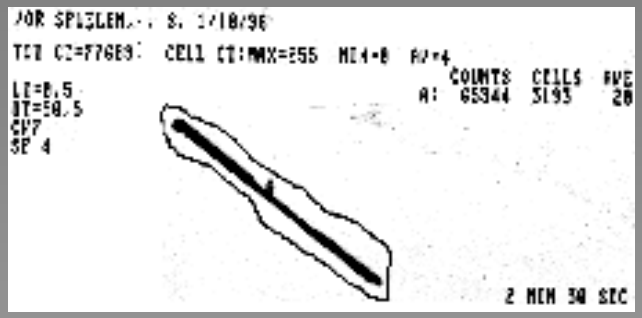
Radionuclide Method

- **In vitro contamination of devices:**

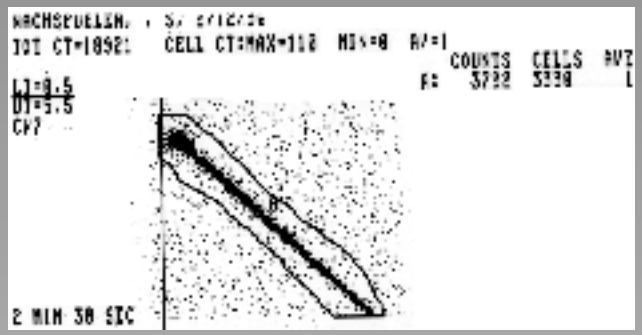
The devices are introduced into the simulation model, the tip of the device is submerged into radioactively labelled blood. The model is insufflated with 15 mm Hg. During the contamination time (10 min) the jaws of the device will be moved.



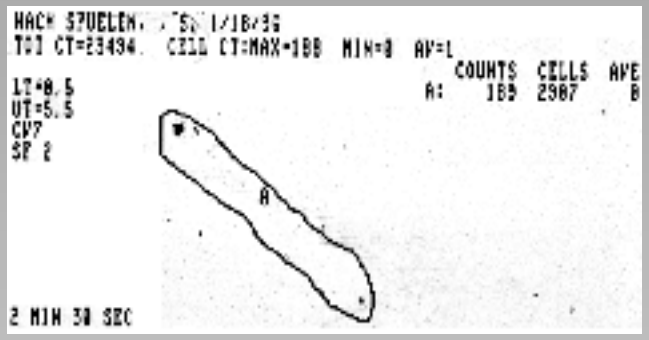
Insufflation pressure, capillary forces and pump effects lead to inside contamination of the device.



Picture 1 shows an MIS device before cleaning

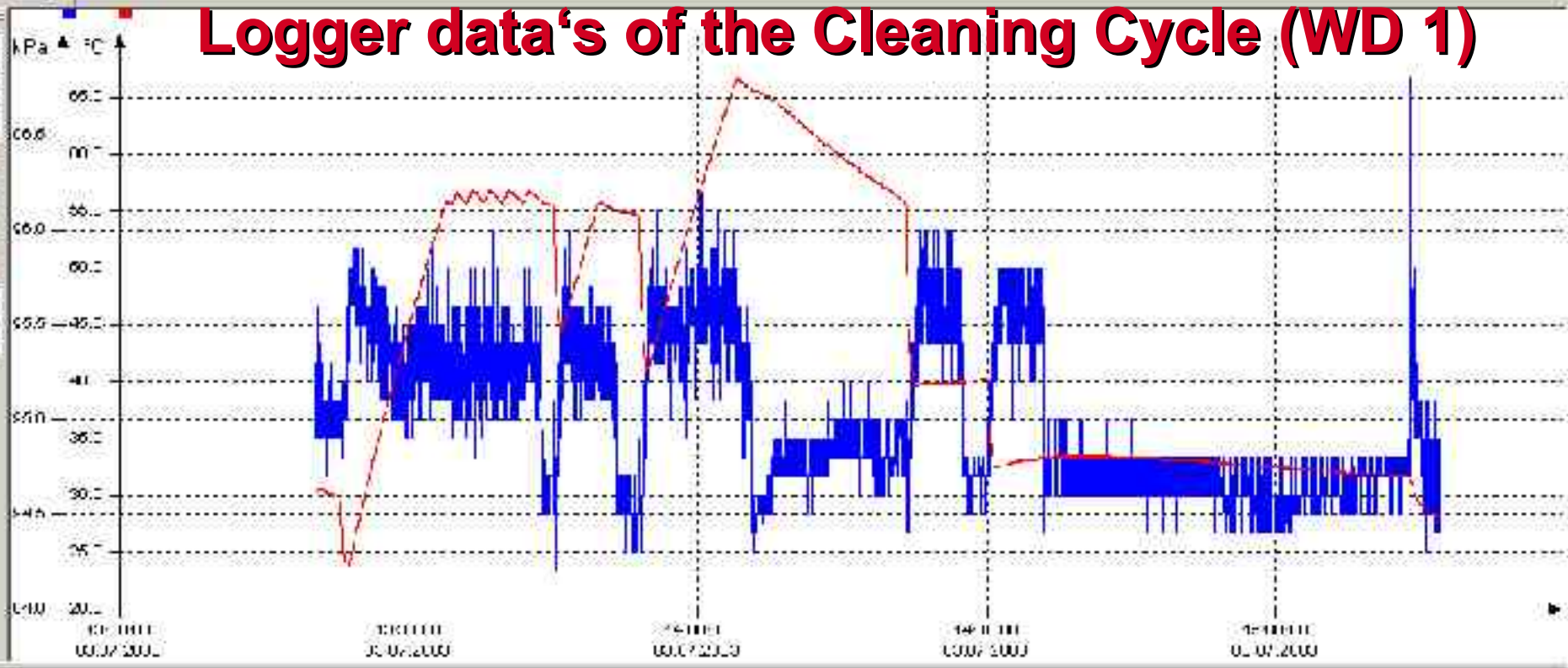


Picture 2 shows the same device after cleaning. The inner lumen could not be cleaned due to an unsufficient design of the device



Picture 3 shows the same device after redesign. Two spots in the area of the joints and the region of the rinsing port show remaining contamination. But the level of remaining contamination is beneath the acceptance criteria

Logger data‘s of the Cleaning Cycle (WD 1)



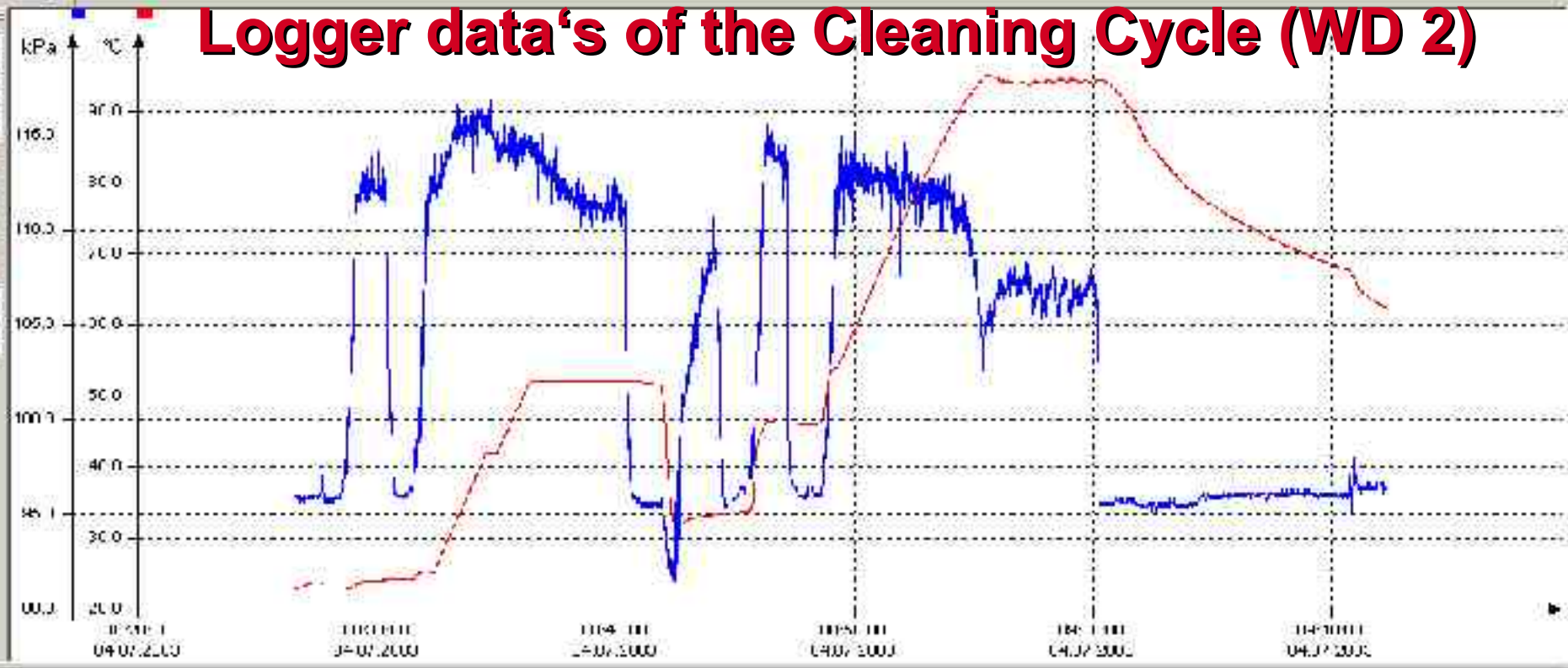
Automated Cleaning Process with manual Precleaning (WD 2)

Manual precleaning:
The instruments were given in an water bath with deconex 23 Neutrazym 0,5% (Borer; Zuchwil) for 15 minutes at 40°C
After the water bath the instruments were rinsed for 10 seconds with a water jet pistol with tap water

Automatic cleaning:
cleaning in a washer disinfector G 7735 CD (Miele) using an ophthalmologic rack with the program Vario TD (without disinfection step)

Vario TD program (without disinfection):
4 min pre-washing with cold water
6 min washing with deconex 28 Alka One 0,5% (Borer Zuchwil) at 70°C
3 min neutralising with warm water (>40°C)
2 min intermediate rinsing with warm water (>40°C)

Logger data‘s of the Cleaning Cycle (WD 2)

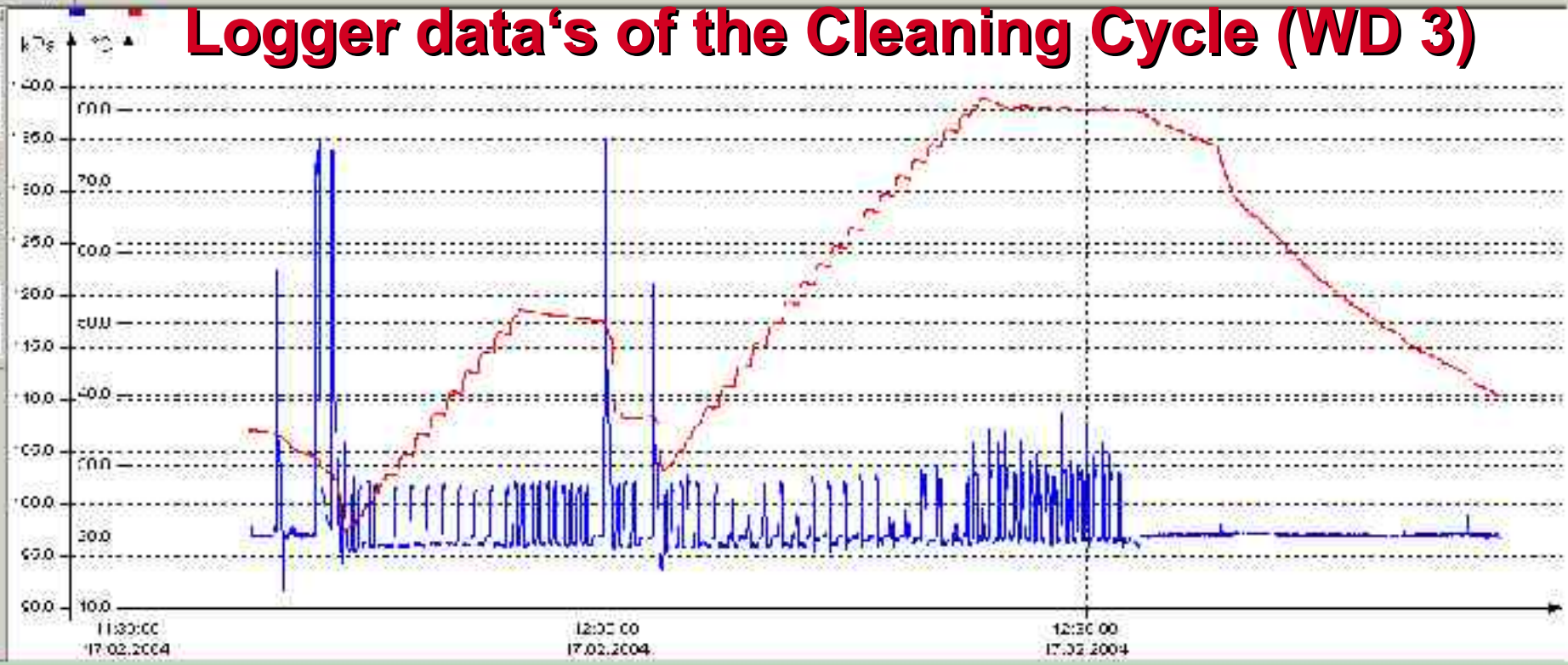


Positioning of the Instruments

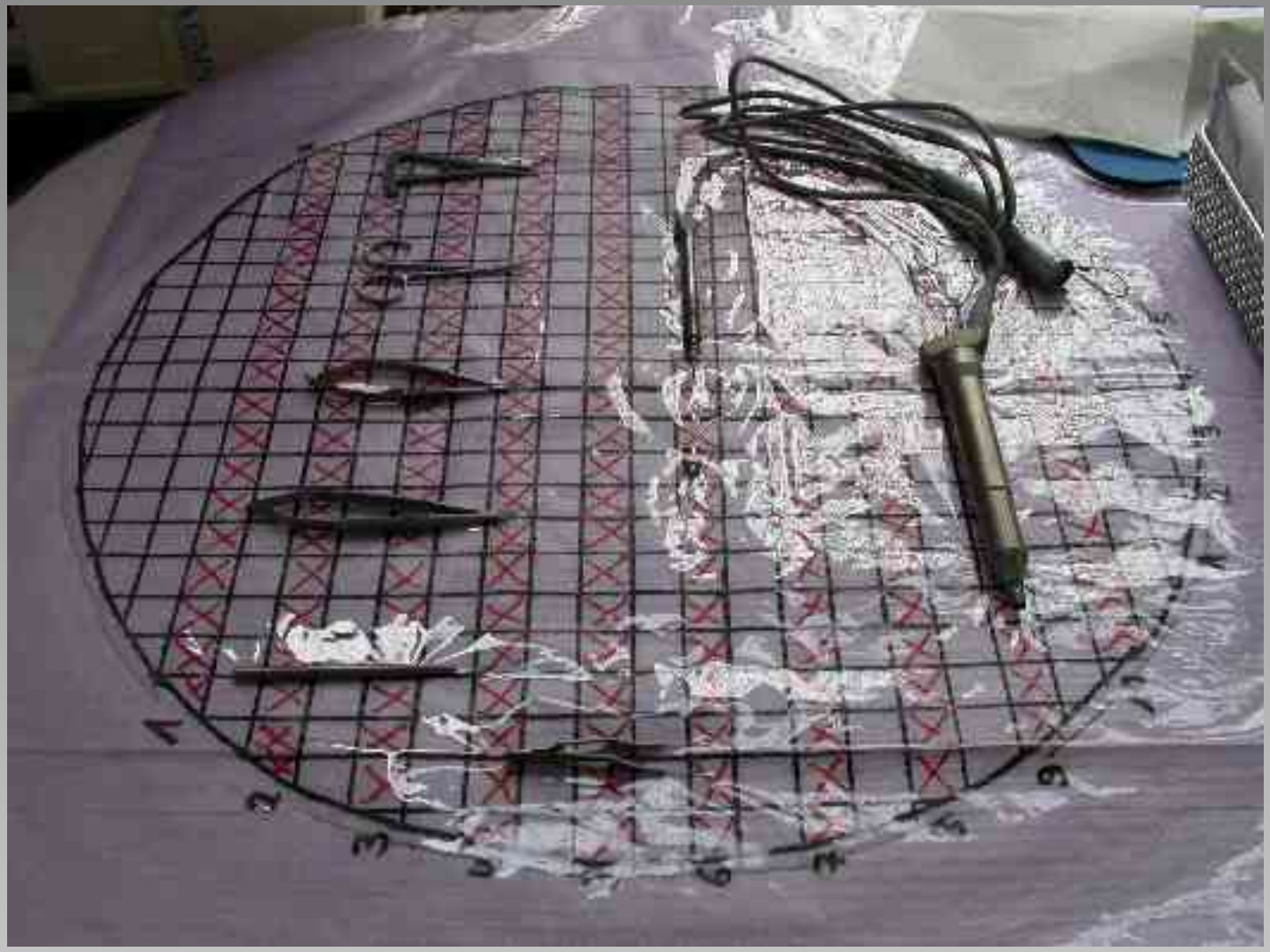
Positioning of the Instruments on the Tray

Positioning of the Instruments on the Tray in the Machine (WD 3)

Logger data‘s of the Cleaning Cycle (WD 3)



Instruments on the Gamma camera:



Results of Cytotox Evaluation and XPS- Measurement

No Cytotoxity detectable

Results of the XPS-Evaluation

Konzentrationen [at%*] / Probe	Fe	Cr	O	C	N	P	Si	Na	Ca	Ti	Al
56199-ALC-01-01 Einspülkanal, distal, IS	2	<1 (0,6)	26	58	2	<1 (0,6)	11	<0,1	<1 (0,3)	<0,1	
56199-ALC-01-02 Einspülkanal, proximal, IS	2	1	26	58	3	<1 (0,6)	8	<0,1	<1 (0,6)	<0,1	

Im Einspülkanal wird die typische Zusammensetzung einer gereinigten Edelstahl-oberfläche gemessen. Identifiziert werden die Elemente des Werkstoffes Eisen, Chrom und Sauerstoff. Weiterhin werden als Elemente der Kontamination auf der Werkstoffoberfläche Kohlenstoff, Silizium und Stickstoff nachgewiesen. Zusätzlich werden im Bereich der Nachweisgrenze von XPS sehr geringe Konzentrationen von Phosphor und Kalzium festgestellt

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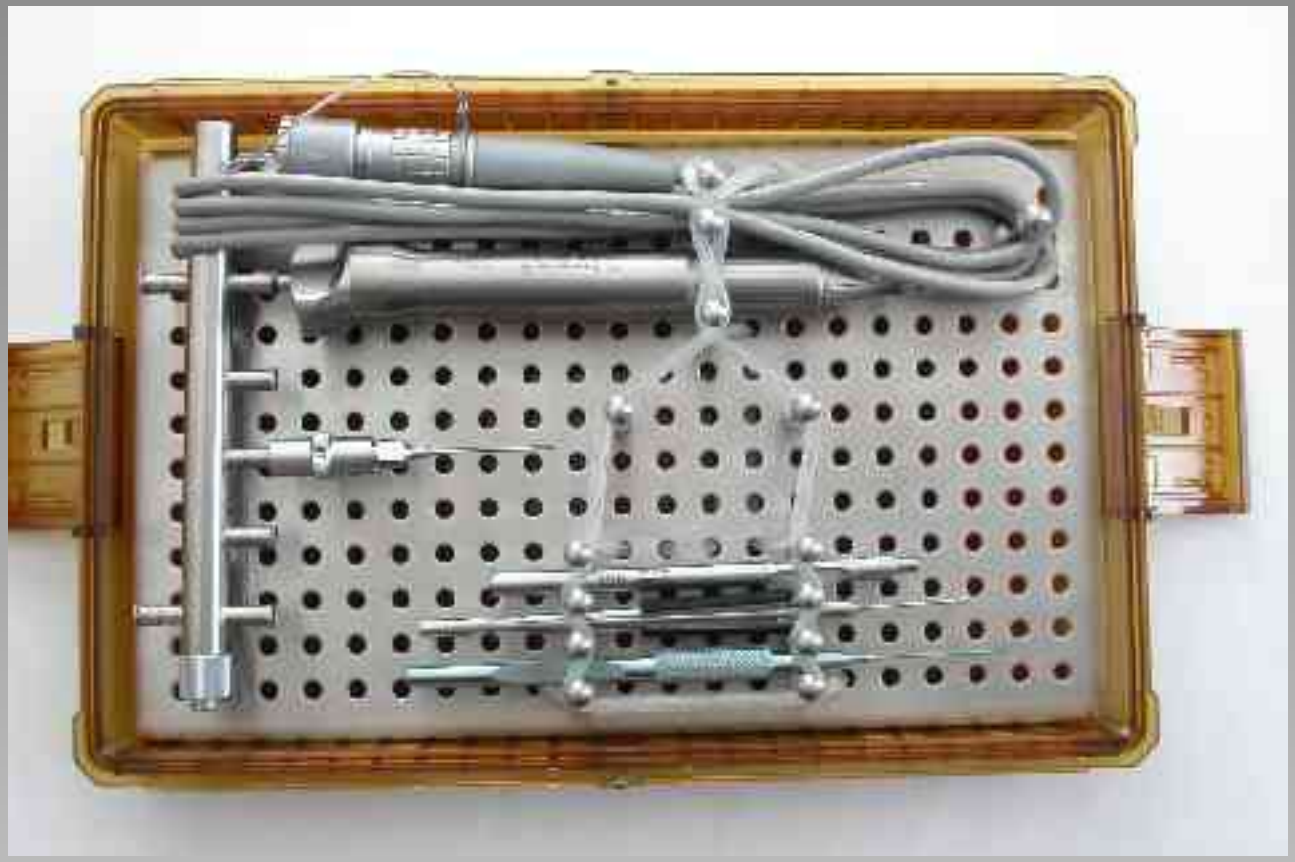
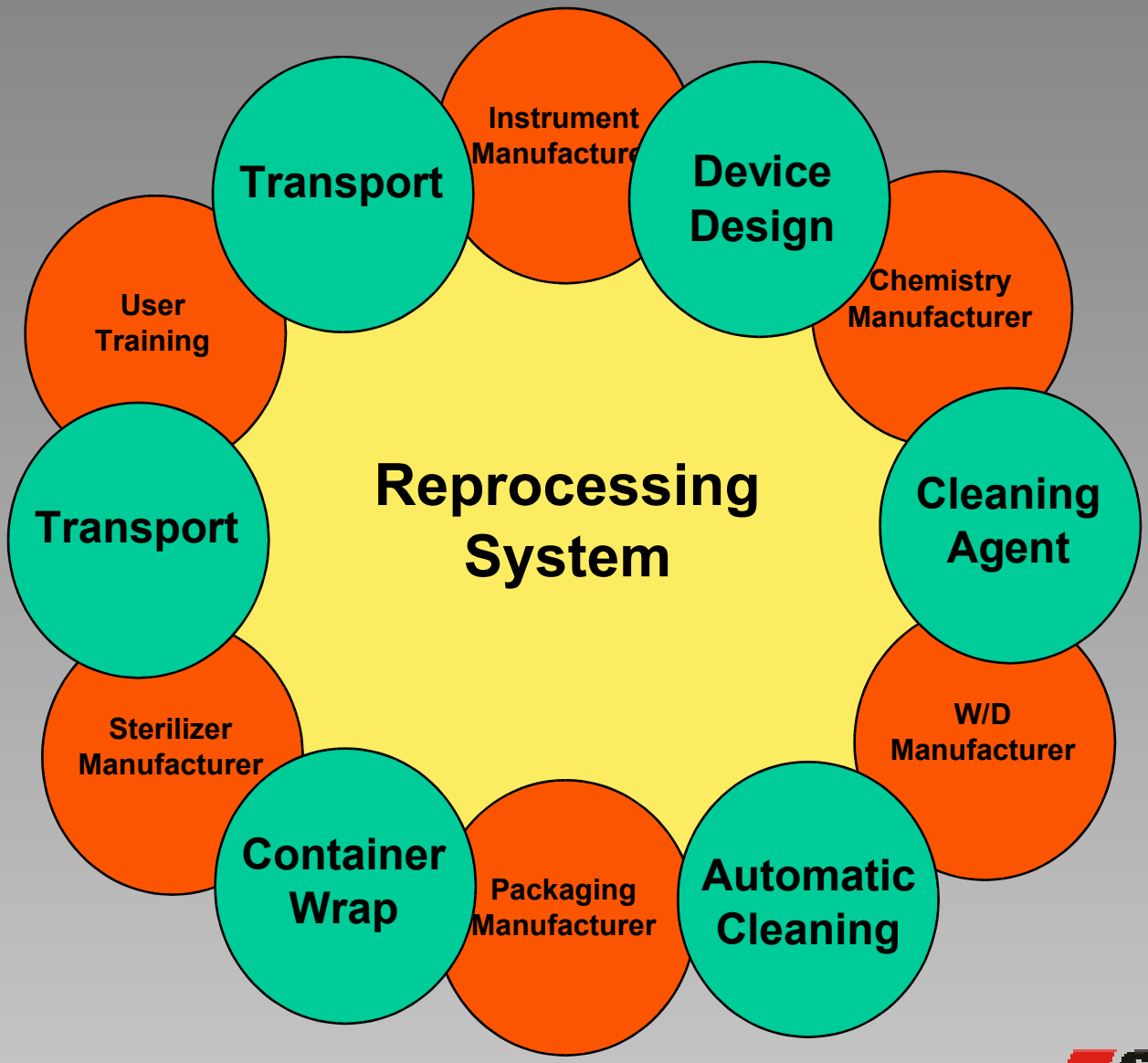
Tray in Sterilisation Container:




Reprocessing System
Instrument Manufacturer
Device Design
Chemistry Manufacturer
Cleaning Agent
W/D Manufacturer
Automatic Cleaning
Packaging Manufacturer
Container Wrap
Sterilizer Manufacturer
Transport
User Training
Transport

Conclusion

The cleaning agent has to show his efficacy against prions in separate tests.

The Validation of the processing cycle of critical instruments has to Include

- **Design verification of the instruments with respect of their capability for cleaning, disinfection and sterilization**
- **Definition of the position in the WD**
- **Examination of the instruments for residues**

For lumen instruments the applied water pressure has an high influence to the process quality

The processing system should be designed userfriendly to avoid mistakes and get a high acceptance

The safety during transportation of the instruments has to be taken into account

The traceability of the instruments is easier to perform for a defined instrument set, than for single instruments

Allready validated Instruments

Phaco Handpieces:

- AMO
- Alcon
- Bausch & Lomb
- Wefis / Ruck
- Dorc

Other ophthalmic Instruments

- AMO
- Alcon
- Bausch & Lomb
- Geuder
- Oertli
- Synergetics
- Dorc

Easy-Clean-System for MIS-Instruments

More details in
the poster exhibition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Friday: Comparative assessment of various automated processes