

**Validation of Cleaning Processes  
for  
tubular instruments  
following  
EN/ISO 17664**

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# Categories of instruments and specific requirements for use:

Instruments, to be used outside the body.



**Cleaned /  
Disinfected**

Instruments, to be used inside the body without penetration of the mucosa or skin.



**High Level  
Disinfected**

Instruments, penetrating the skin or mucosa.



**Sterilized**

# Requirements of EN/ISO 17664

- **Preparation at the point of use**
- **Transport**
- **Cleaning**
- **Disinfection**
- **Functionality testing**
- **Packaging**
- **Sterilisation**
- **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;

# New Standard EN/ISO 17664

A.2.1 Table: Examples of suitable reprocessing procedures

			Medical device								
Process			A	B	C	D	G	H	I	J	
			Reusable surgical instruments	Endoscopes (thermostable)	Endoscopes (thermolabile)	Instruments for use with endoscopes	reusable containers	Elastic products 1)	HF-cable and handpieces	Powertools	
Preparation at the point of use	Deposition	Wet	+	+	+	+	-	+	+	+	
		Dry	+	+	+	+	+	+	+	+	
Decontamination	Preparation	Selection according to the Cleaning and Disinfection Procedures									
	Cleaning	Manual <sup>3)</sup>	+	+	+	+	+	+	+	+	+
		Machine <sup>3)</sup>	+	+	+	+	+	+	+	+	+
		ultrasonic	+	-	-	+	N.A.	-	+	-	-
		alkaline	+	+	+	+	. <sup>2)</sup>	+	+	-	-
		acidic	-	-	-	-	. <sup>2)</sup>	+	+	-	-
		neutral	+	+	+	+	+	+	+	+	+
	Rinsing <sup>3)</sup>										
	Disinfection	chemical	+	+	+	+	+	+	+	+	+
		thermal	+	+	-	+	+	+	+	+	+
Drying	T <sub>max</sub>										
Maintenance											
Sterilization		Moist heat	+	+	-	+	+	+	+	+	
		Formaldehyde	+	+	+	+	-	+	+	-	
		Ethylene oxide	+	+	+	+	-	+	+	-	
		Dry heat max. 180 °C	+								
		Liquid Sterilant	+	+	+	+	+	+	+	+	+
		Gas Plasma	+	+	+	+	+	+	+	+	+

<sup>1)</sup> Rubber or latex (also combined), silicon elastomer, plastics, closed hollow bodies, thermolabile

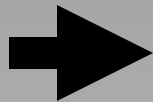
<sup>2)</sup> Applies only for aluminium alloys

<sup>3)</sup> For final rinsing deionized water is recommended

Key: + may be suitable  
- not suitable

# Validation of each Instrument Design

- Validation of the cleaning behavior with the Radionuclide method
- Validation of the disinfection step with microorganism or parametric release with data loggers
- Examination for remaining cleaning detergent
- Validation of the sterilisation behavior



**Evaluation of all parameters to define the minimum requirements**

<b>Products:</b>	Horizon & Hemolok Endoscopic Take-Apart Applier / Remover	
<b>ADVICE:</b>	<p>Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.</p> <p>In case of damage the device should be reprocessed before sending back to the manufacturer for repair.</p>	
<b>Reprocessing Instructions</b>		
<b>Preparation at the Point of Use:</b>	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.	
<b>Transportation:</b>	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.	
<b>Preparation for Decontamination:</b>	The devices must be reprocessed in a disassembled state.	
<b>Pre-Cleaning:</b>	<p><b>Warning: Do not allow the instruments to rest on the bottom of an ultrasonic cleaner unit during cleaning, as damage or incomplete cleaning could result.</b></p> <p>10 minutes at 40°C in an ultrasonic bath with 0,5% detergent.</p> <p>Brushing the instrument under running tap water until all visible residues are removed</p> <p>Flushing the inner lumens of all parts with a water jet pistol (pressure min. 3 bar) with cold tap water for at least 10 seconds.</p>	
<b>Cleaning:</b>	<p>Manual Cleaning Process:</p> <ol style="list-style-type: none"> <li>1. Rinsing under running tap water (&lt;40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove visible soil;</li> <li>2. Submerge instruments in an detergent (if ultrasonic bath is used, ultrasonic process of 3 minutes and ultrasonic frequency of 35 kHz have been shown to be effective). Follow the instructions of the manufacturer of the detergent;</li> <li>3. Rinse the instrument under running tap water to remove the detergent.</li> </ol>	<p>Automated Cleaning:</p> <p>Connect the instrument to a rack for MIS-instruments and start the program</p> <ul style="list-style-type: none"> <li>• 4 min pre-washing with cold water (&lt;40°C);</li> <li>• 6 min washing with 0,5% detergent at 55°C;</li> <li>• 3 min neutralising with warm water (&gt;40°C);</li> <li>• 2 min intermediate rinsing with warm water (&gt;40°C).</li> </ul> <p>Special instructions of the manufacturer of the automated washing machine have to be followed.</p>

<b>Disinfection:</b>	Manual Disinfection: 1. Submerge instruments in an disinfection detergent according to the instructions of the manufacturer of the detergent; 2. Rinse the instrument with sterile water to remove the detergent.	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A <sub>0</sub> -Value (see EN 15883)
<b>Drying:</b>	Manual Drying: Dry the instrument with a lint free towel. The instrument may never be heated up >140°C. To avoid water residues we recommend using sterile compressed air to insufflate cavities.	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
<b>Functional Testing, Maintenance:</b>	Functional testing, if available according to instructions of use and visual inspection for cleanliness. If necessary perform reprocessing process again until instrument is visibly clean.	
<b>Packaging:</b>	Appropriate packaging for sterilization.	
<b>Sterilization:</b>	Sterilization of instruments by applying a fractionated pre-vacuum process (according DIN EN 554 / ISO 11134) under consideration of the respective country requirements.  <b>Parameters for the pre-vacuum cycle:</b> 3 prevacuum phases with at least 60 milli bar Heat up to a minimum sterilization temperature of 132°-134°C Minimum Holding time: 3,5 min Drying time: minimum 10 min <b>Flash sterilization is not allowed on lumen instruments!</b>	
<b>Storage:</b>	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.	
<b>Reprocessing validation study information</b>	The following testing test devices, materials & machines have been used in this validation study;  Detergent: deconnex 28 Alka One, (Borer, Zuchwil, Switzerland) deconnex 23 Neutrazym, (Borer, Zuchwil, Switzerland) Washer / Disinfector: Miele 7735 CD Instrument Rack: Miele E450-1  Details: See report SMP 05506011407-1	

# Radionuclide Method

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

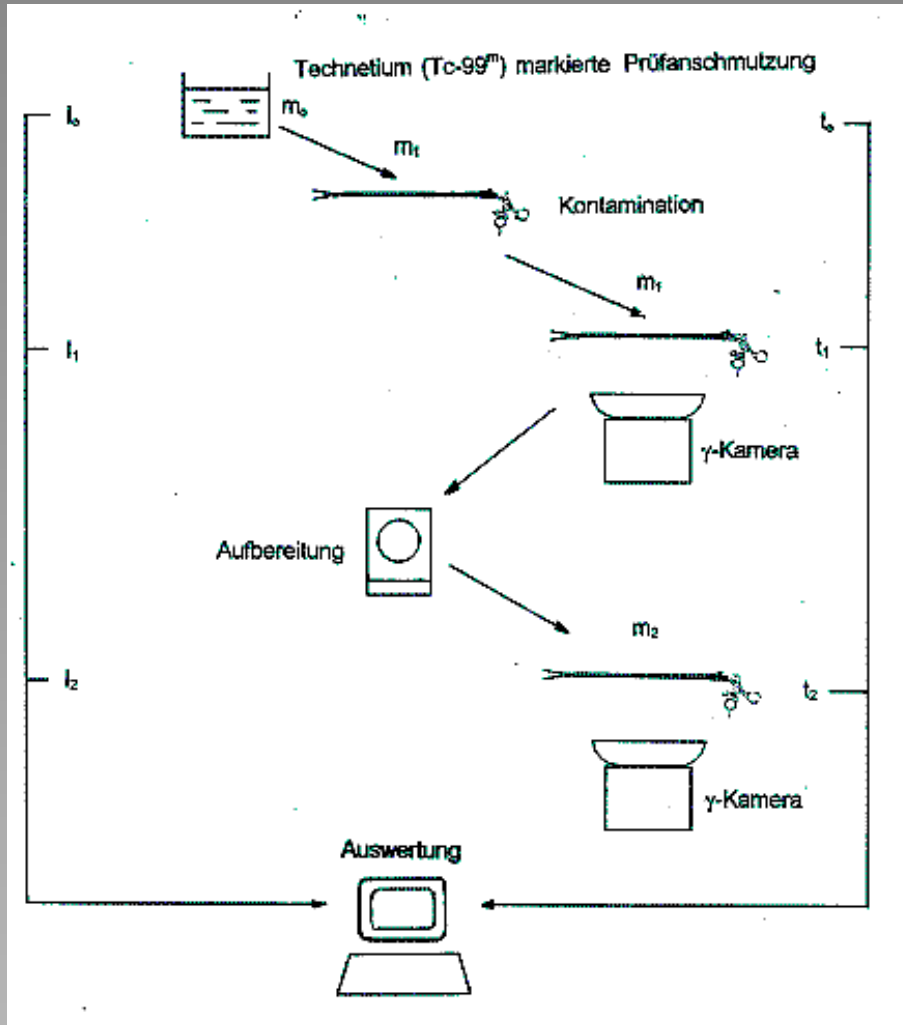
**e.g.**

- **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



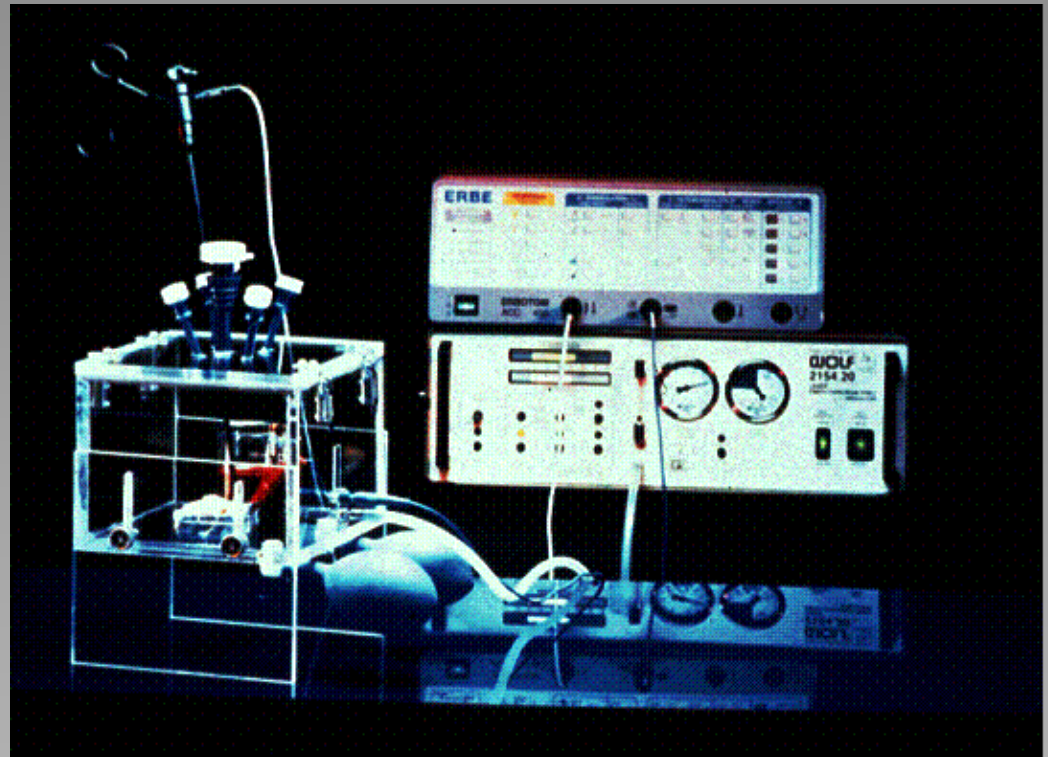
- Radioactive labelling of the blood with Tc 99m
- Contamination of the devices
- Measuring of the devices with the gammacamera
- Reprocessing of the devices
- Measuring of the devices after reprocessing
- Analysation

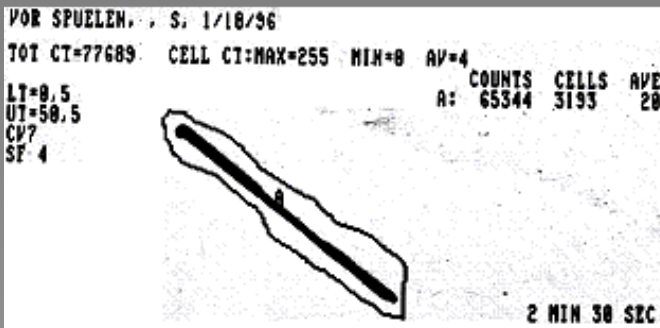
# Radionuclide Method

- **In vitro contamination of devices:**

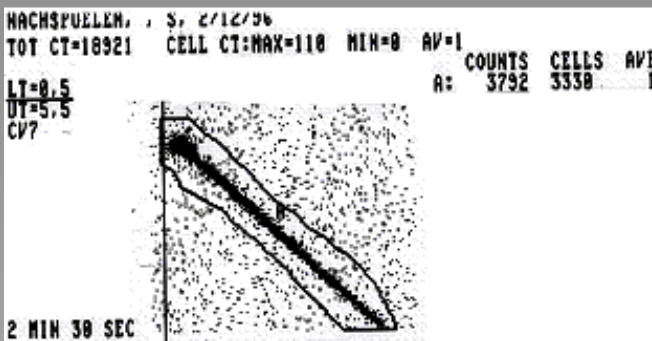
The devices are introduced into the simulation model, the tip of the device is submerged into radioactively labelled blood. The model is insufflated with 15 mm Hg. During the contamination time (10 min) the jaws of the device will be moved.

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

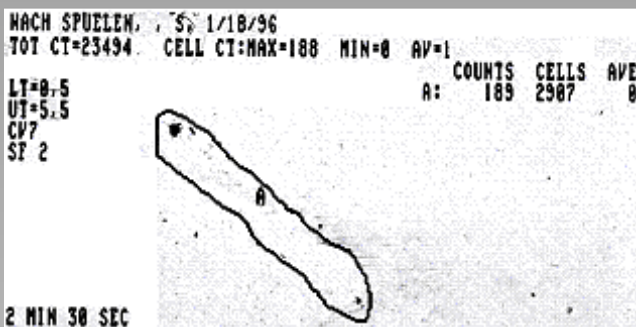




Picture 1 shows an MIS device before cleaning

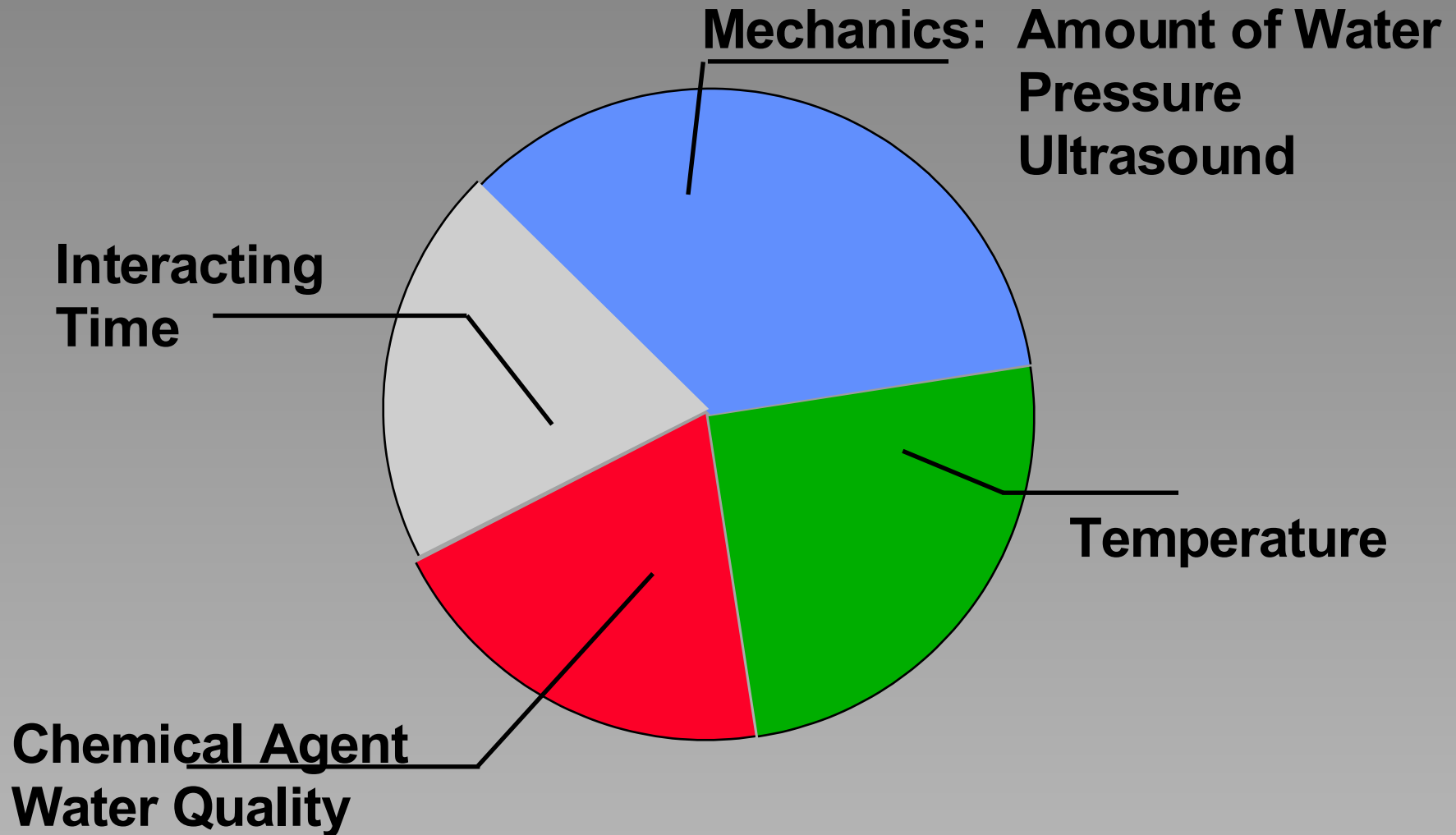


Picture 2 shows the same device after cleaning. The inner lumen could not be cleaned due to an insufficient design of the device



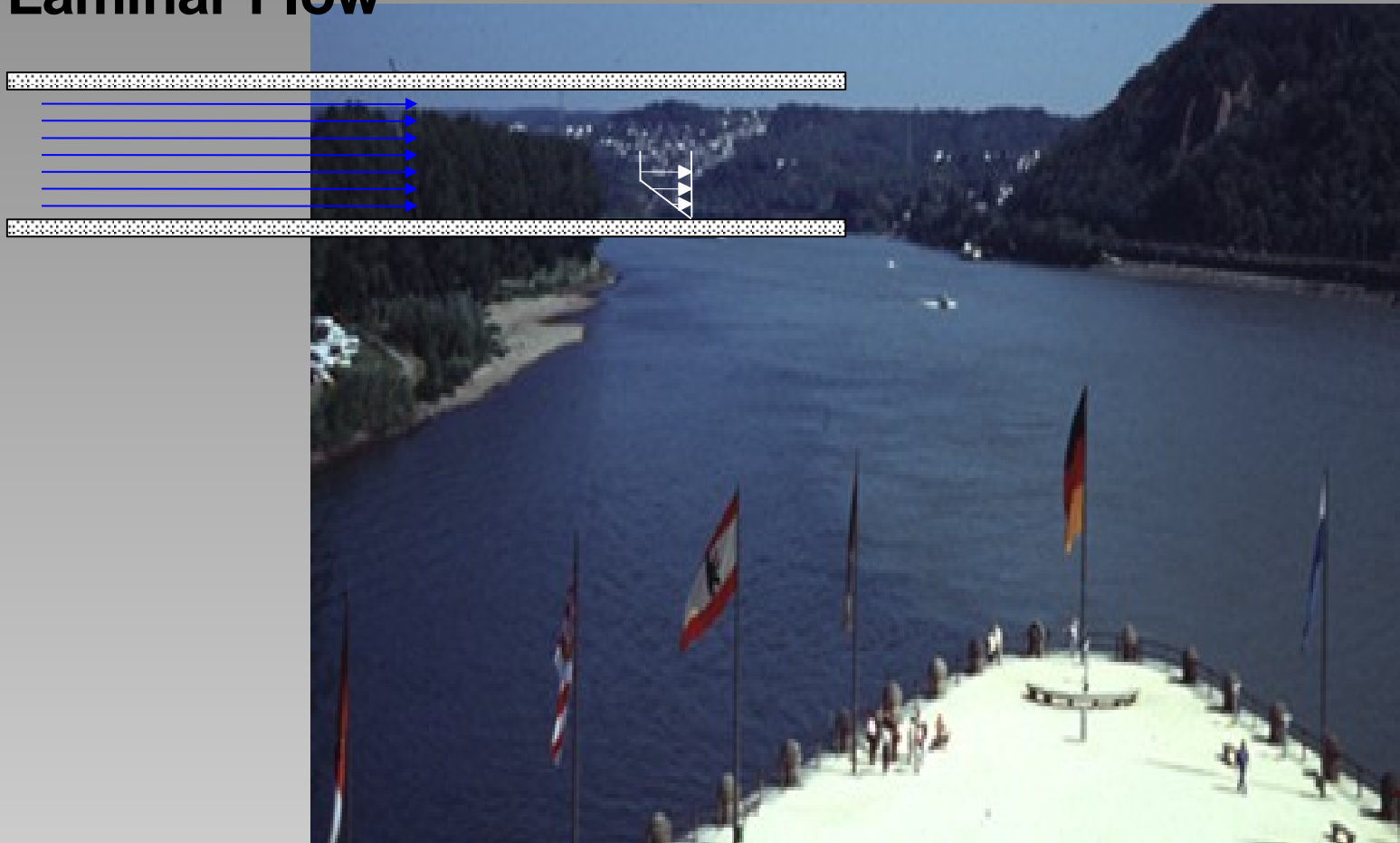
Picture 3 shows the same device after redesign. Two spots in the area of the joints and the region of the rinsing port show remaining contamination. But the level of remaining contamination is beneath the acceptance criteria

# Parameters of the Cleaning Cycle



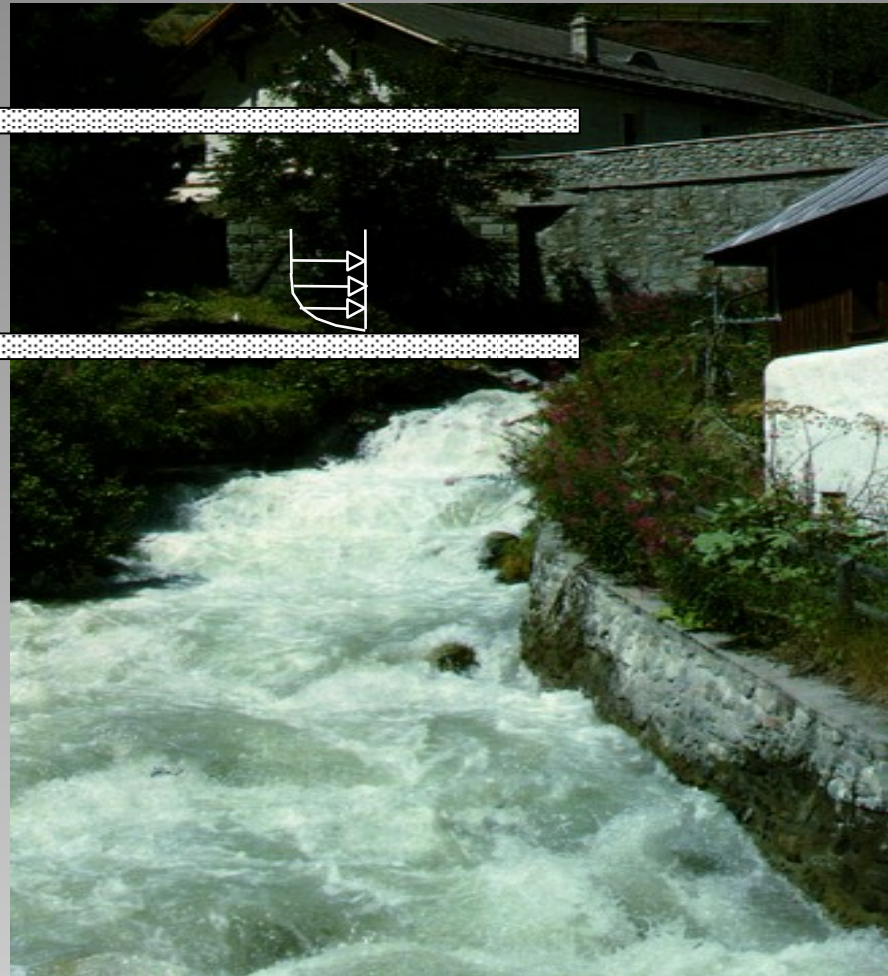
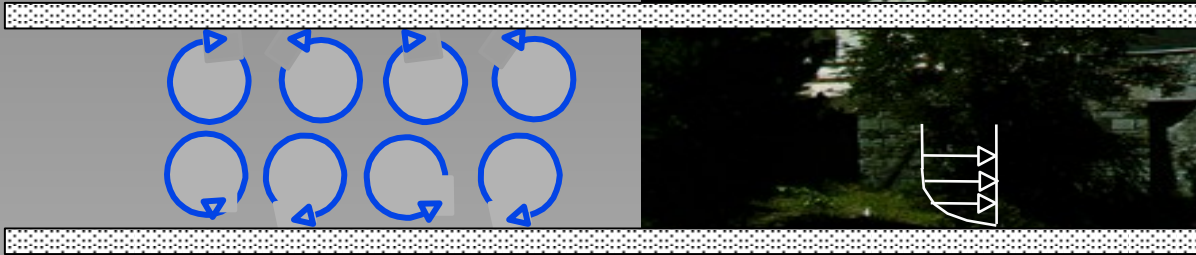
# Influence of Velocity of Flow

## Laminar Flow



# Influence of Velocity of Flow

## Turbulent Flow



Re	Reynolds number
$\rho$	Density
v	Velocity
l	Length
$\mu$	Viscosity
$\nu$	kin. Viscosity

$$Re = \frac{l \cdot \rho \cdot v}{\mu}$$

# Categories of instrument design

- Single use devices
- Non dismantable and not rinsable devices
- Non dismantable but rinsable devices
- Dismantable devices
- Can not be reprocessed, as no information is available
- Can not be reprocessed, as the lumen can not be rinsed
- Can be reprocessed; needs high water pressure
- Easy to be reprocessed in a washer disinfector

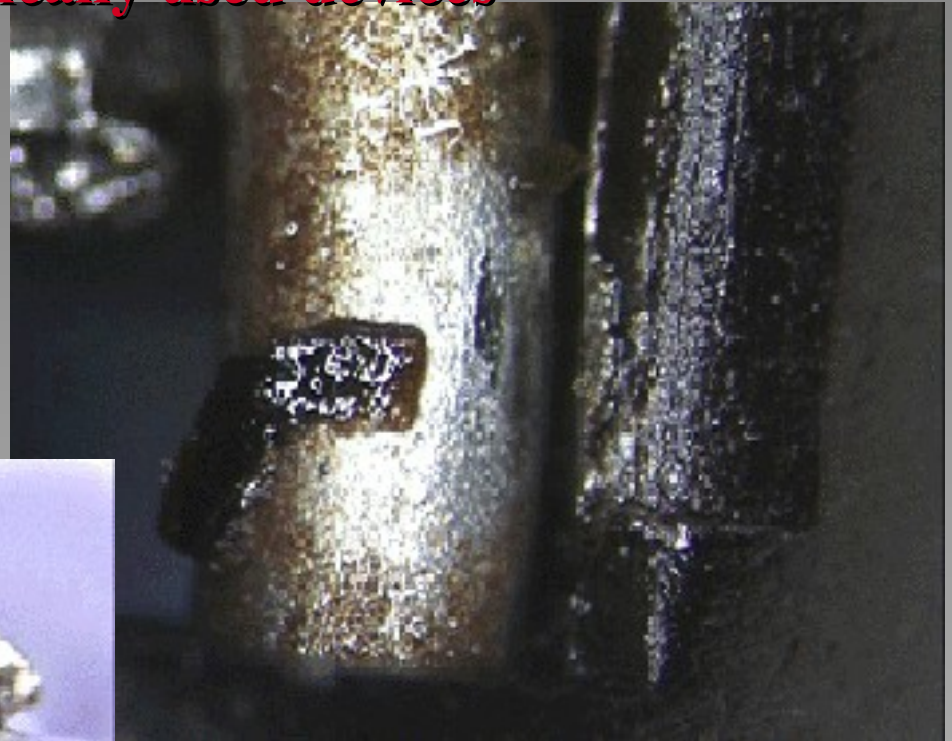
# LCS C5; reprocessed by a third party reprocessor



# Reprocessing of Single Use MIS - Devices

## Results of clinically used devices

Remaining blood  
in the region of the hinge



# Reprocessing of Single Use MIS - Devices

## Results of clinically used devices

**Package damaged: 11 %**

**Incomplete device: 33 %**

**Microbiological tests  
Failure: 40 %**

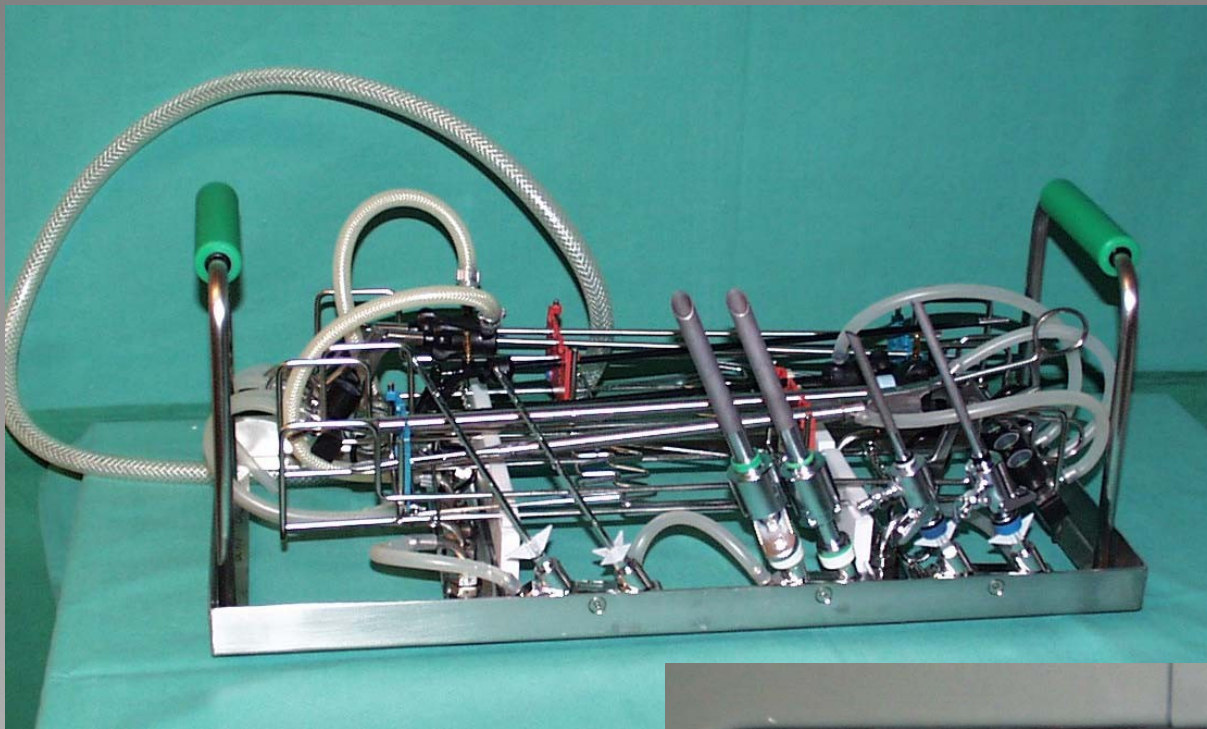
**Functionality tests  
Failure: 54 %**

**How can we assure, that we meet  
all requirements of the validated  
cycle ?**

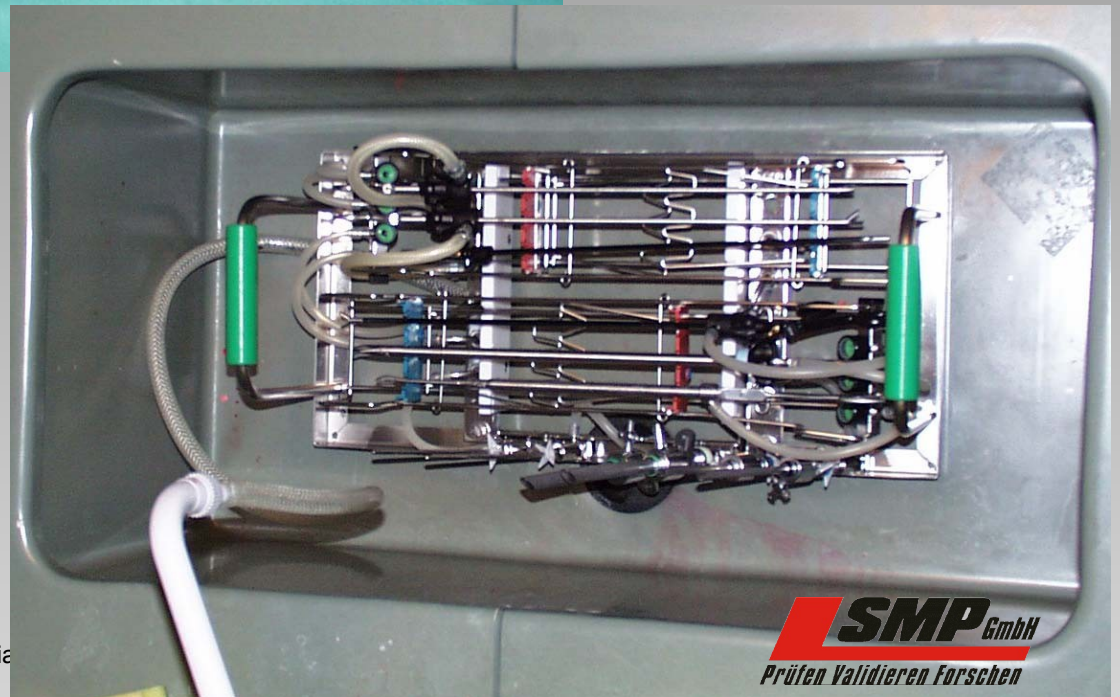
**How can we apply enough water pressure  
over a sufficient time?**

**automated cleaning?**

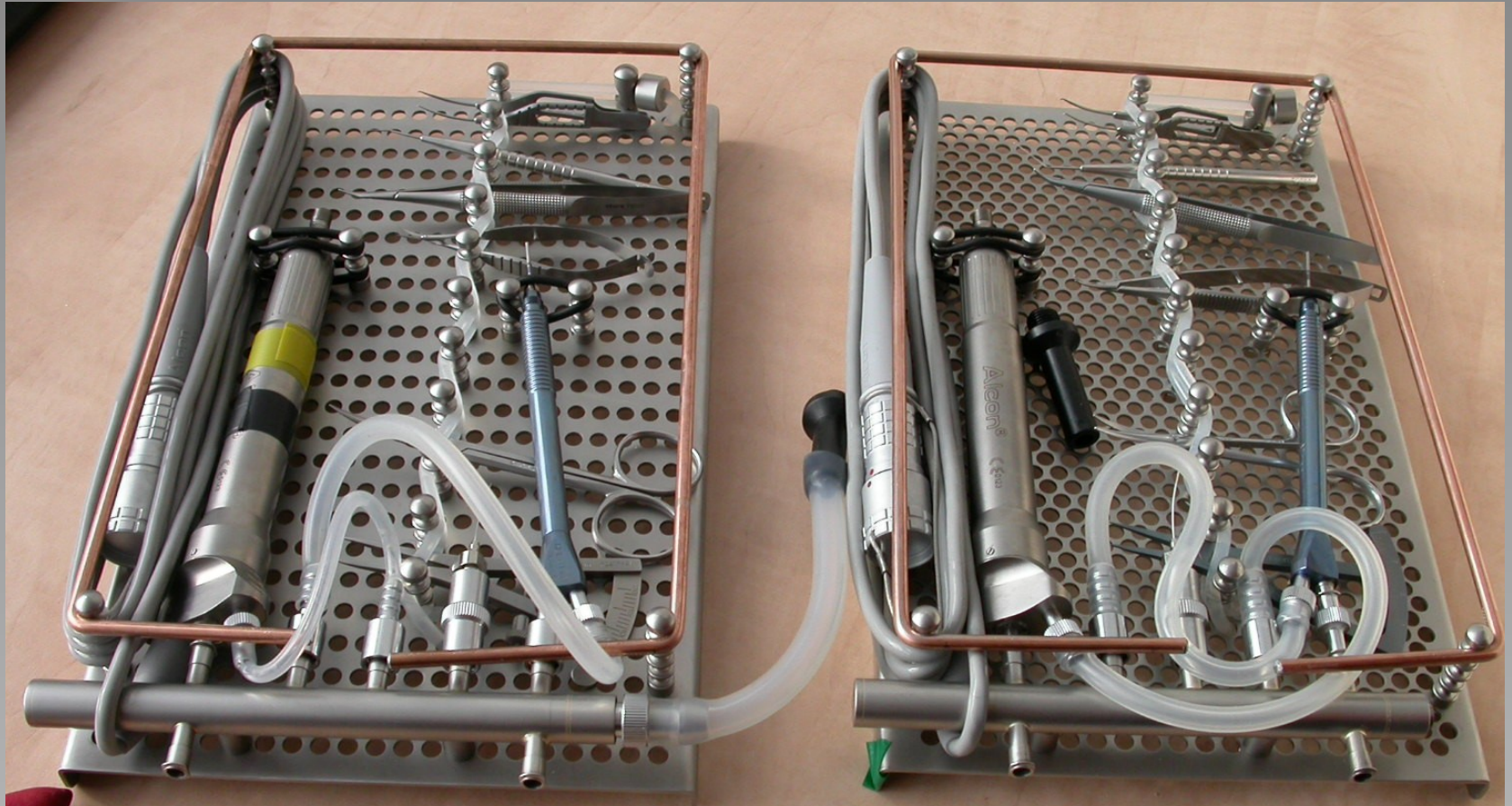
**manual cleaning?**



# Instrument Tray



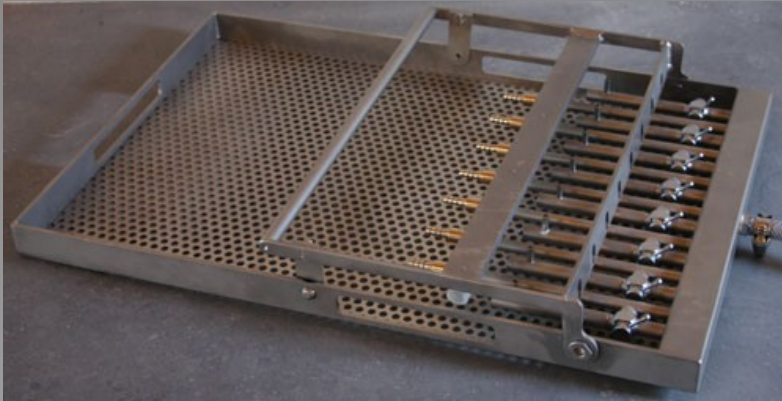
# Positioning of the Instruments on the Tray



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



# Easy-Clean-System for MIS-Instruments



## Cannulated Instrument Cleaner

Reliable cannulated instrument cleaning with process monitoring facility

Compatible with:

- General Instruments and devices
- Laparoscopic Instruments
- Complex Instruments
- Cannulated/Lumened Instruments

- Sonic Irrigation
- Cannulated Pulse Flushing System
- Load performance optimisation
- prENISO15883/HTM2030 compliant
- E-Zee Load Tray System compatibility
- Process Interlock
- 12 cannulated instruments connections



# Conclusion

**Tubular instruments need specific care for reprocessing**

**The cycle has to be validated by the manufacturer, as the lumen can not be visually inspected**

**High water pressure (3 bar or more) is needed to guarantee good cleaning results**

**Meanwhile specific trays and washer disinfectors are on the market, which provide good cleaning results of tubular instruments**

**Single use devices and not rinsable devices can not be reprocessed, as the lumen can not be cleaned.**

**Thank you for your attention**

**Further informations**  
**[www.smpgmbh.com](http://www.smpgmbh.com)**