

Classification of Instruments

Elaborating of a Reprocessing Instruction According to ISO 17664

Klaus Roth



**Operation, which have been cancelled due to not sufficient
reprocessed instruments**

Year	2002	2003	2004	2005
Data of 57 hospitals**	1252	1661	1926	1765
Estimated for England and Wales	7500	9900	11500	10500

** 57/340 Datensätze

* mit freundl. Genehmigung G.Shapp MP



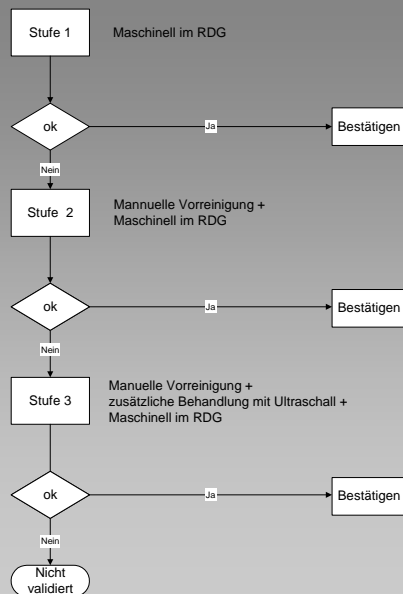
It is the aim of the research project to use the same reprocessing cycle for all kind of instruments.

Enhanced requirements for the cleaning process has to be fulfil by special manual pre-cleaning or special equipement for the pre-cleaning or the w/d.

To many different reprocessing cycles may lead to difficulties in the daily routine and following the specifications.



Exempel 1: Automated alkaline process with manuell pre-cleaning



Alkaline process: Step 1

Automated cleaning in the w/d

The cleaning are performed only in a washer disinfector G 7735 CD (Miele) Directly after contamination without manually precleaning (Program abortion before disinfection step). After dismantling the instruments are placed on the specific tray and the cleaning and disinfection program Vario TD is started:

- 1 min pre-washing with cold water
- emptying
- 3 min pre-washing with cold water
- emptying
- 5 min washing with 0,5 % alkaline cleaner by 55°C (Dr. Weigert, Neodisher FA)
- emptying
- 3 min neutralizing with warm water (>40°C)
- emptying
- 2 min intermediate rinsing with warm water (>40°C)
- emptying



Alkaline process: Step 2

Manually pre-cleaning

- The instruments are immersed into cold tap water for 5 minutes.
- The instruments are brushed under cold tap water until all visible residues are removed.
- The instruments are dismantled and brushed again until all visible residues are removed.
- Inner lumens, threads and holes are flushed each with a water jet pistol for 5 seconds and brushed again.

Automated cleaning in the w/d

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Alkaline process: Step 3

Manually pre-cleaning

- The instruments are immersed into cold tap water for 5 minutes.
- The instruments are brushed under cold tap water until all visible residues are removed.
- The instruments are dismantled and brushed again until all visible residues are removed.
- Inner lumens, threads and holes are flushed each with a water jet pistol for 5 seconds and brushed again.

Additional pre-cleaning with ultrasonic:

- The instruments are immersed into an ultrasonic bath with alkaline detergent (Dr. Weigert neodisher FA 0,5%) and treated with ultrasonic for 15 minutes at 40°C

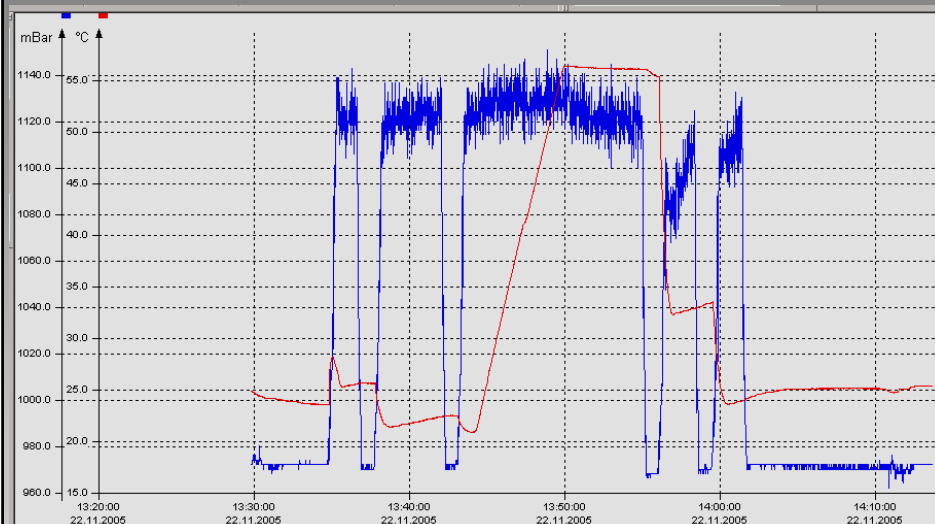
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Stabile Water Pressure



Automated Cleaning Process ?



SMP
Profilen Management System

Specification of the groups

- Group 1:** **Critical A Instruments,**
like hooks; don't need validation
- Group 2:** **Critical B Instrumentse**
Scissors, Clamps
- Group 3:** **Shift shaft instruments**
Rongeur etc.
- Group 4:** **Shaft instruments for MIS**
need validation, as the result of the cleaning can not be inspected
- Group 5:** **Micro surgical Instruments**
need validation, as the result of the cleaning can not be inspected
- Group 6:** **Complexe Devices**
has to be tested, as no analogical conclusions can be made
- Group 7:** **Flexible Instruments**
need validation, as the result of the cleaning can not be inspected

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Profilen Management System

Classification in Groups

Group 1: Critical A Instruments,

Requirements:

No drill hole with a relation smaller than 1 to 1

No dead end holes

No hinges and joints



Classification in Groups

Group 2: Critical B Instruments

Sub-classification:

A: Crile-Klemmen and similar hinge size, Box lock circa 7 x 14 mm

B: Box lock circa 12 x 20 mm

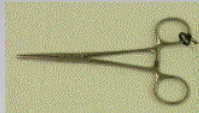
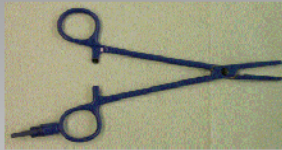
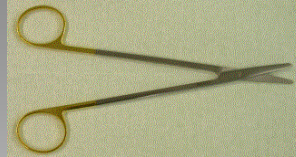
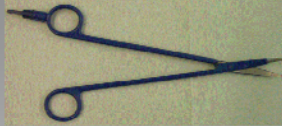
C: Box lock circa 16 x 25 mm

D: Instruments with pivot joint



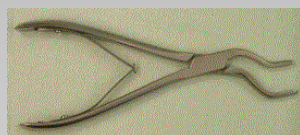
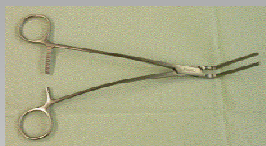
**Group 2 (Instruments with hidden surfaces):
Crile Clamp, etc.**

Category A



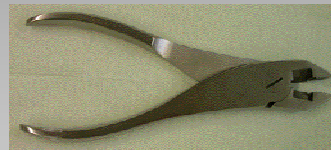
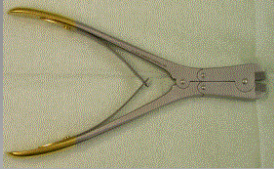
**Group 2 (Instruments with hidden surfaces):
Side cutter etc.**

Category B



Group 2 (Instruments with hidden surfaces):
Side cutter etc.

Category C



Group 3 (Shift shaft instruments):
Rongeur, Arthroskopiezangen etc.

Category A up to 3 mm diameter

Category B 3 to 5 mm

Category C bigger than 5 mm

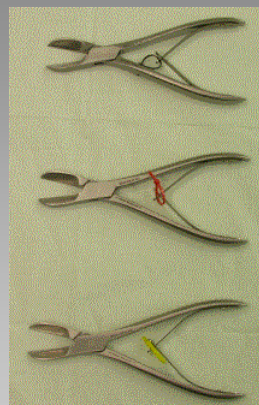
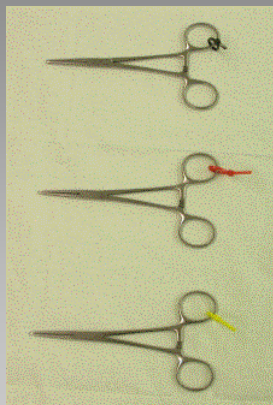


Definitions for the minimum requirements for the Instrument design

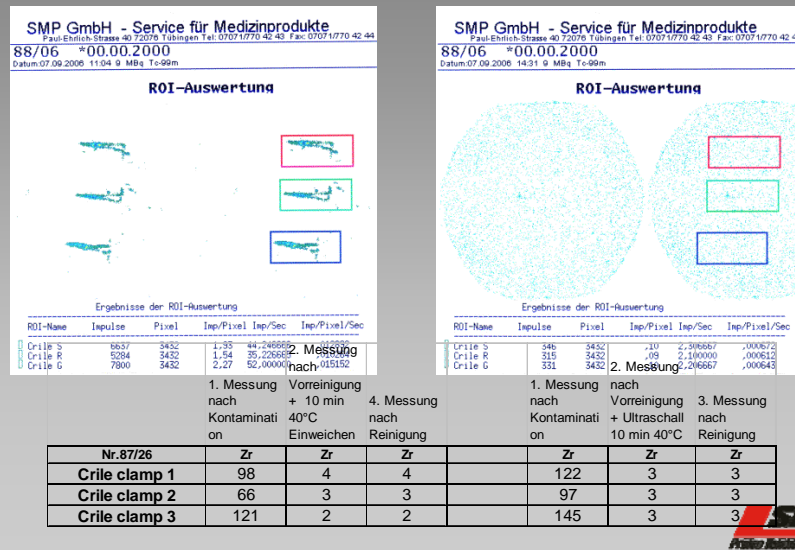
- Gap length and depth
- Dismantling of Instruments
- Rinsing of Lumen
- Definition of Diameters



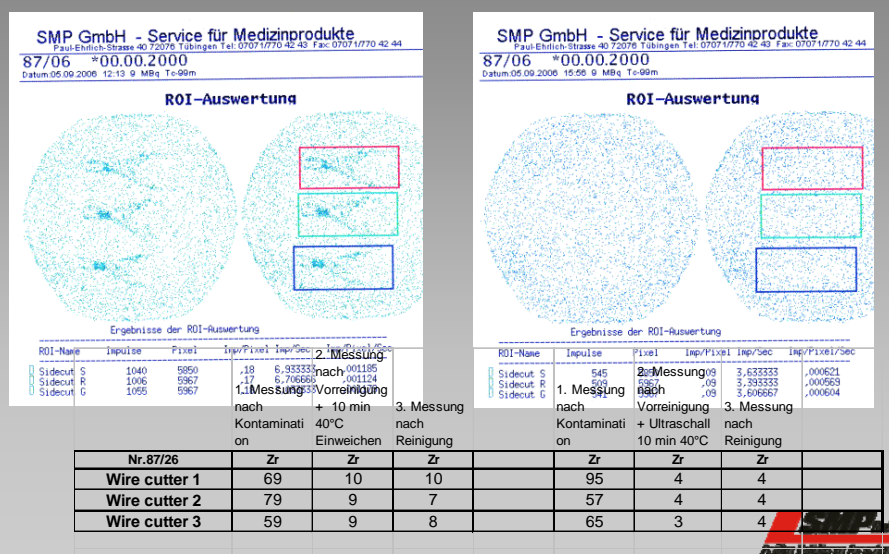
Group 2 (Instruments with hidden surfaces):
Crile Clamp, Side cutter etc.



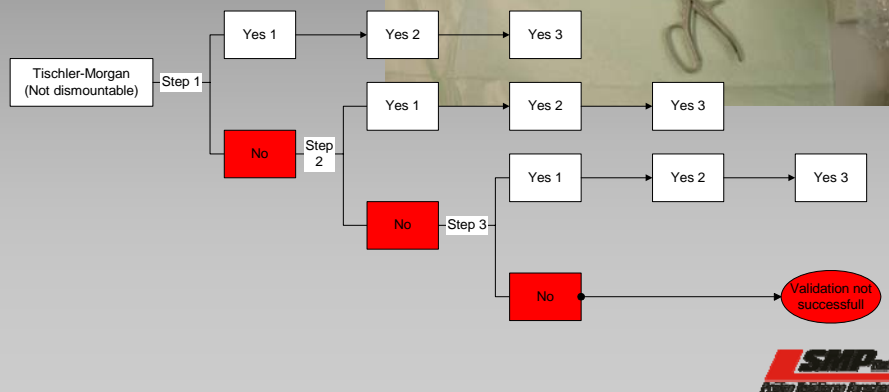
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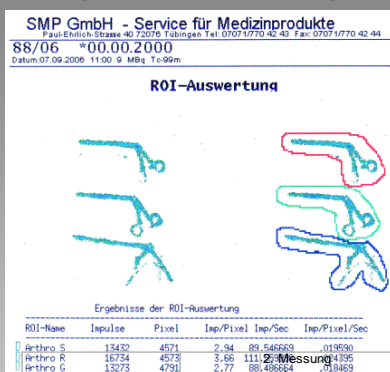
Group 2 (Instruments with hidden surfaces):
Side cutter



Group 3: Shift shaft instruments

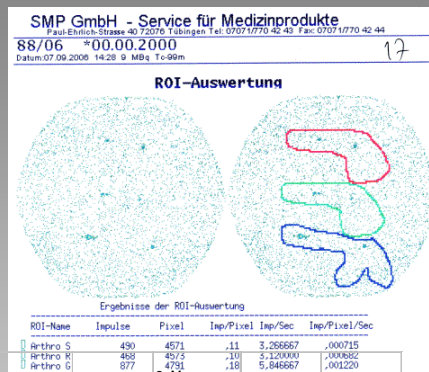


Group 3 (Shift shaft instruments): Rongeur, Arthroskopiezangen etc.

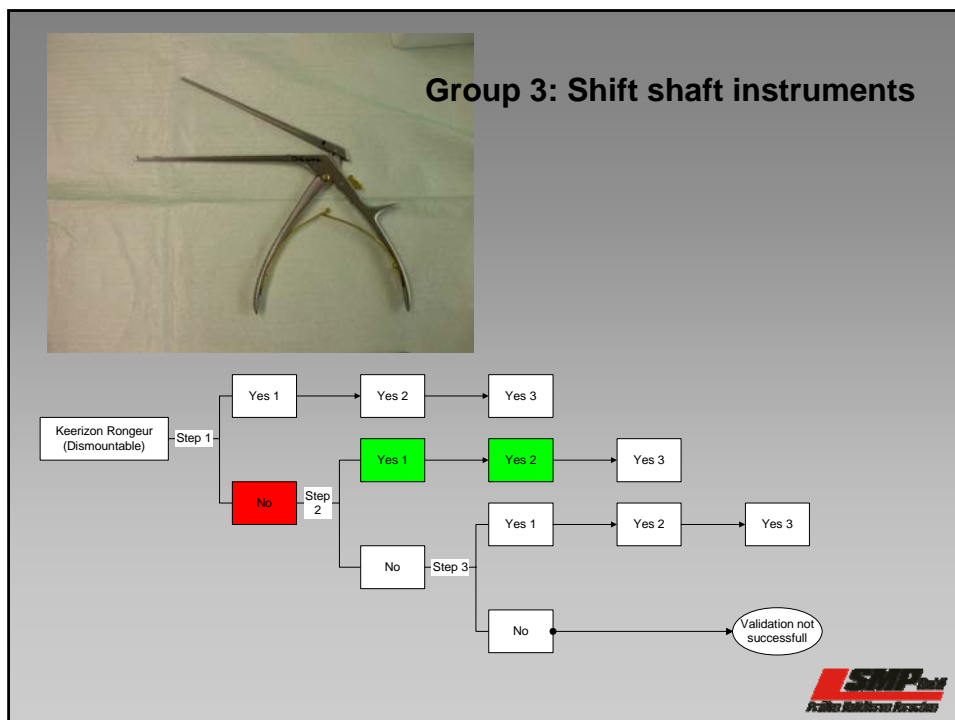


1. Messung Vorreinigung
nach + 10 min
Kontaminati- 40°C
on Einweichen
4. Messung nach
Reinigung

Nr.87/26	Zr	Zr	Zr		Zr	Zr	Zr
Rongeur 1	85	14	16		249	13	7
Rongeur 2	121	11	10		311	12	7
Rongeur 3	88	17	17		245	30	17

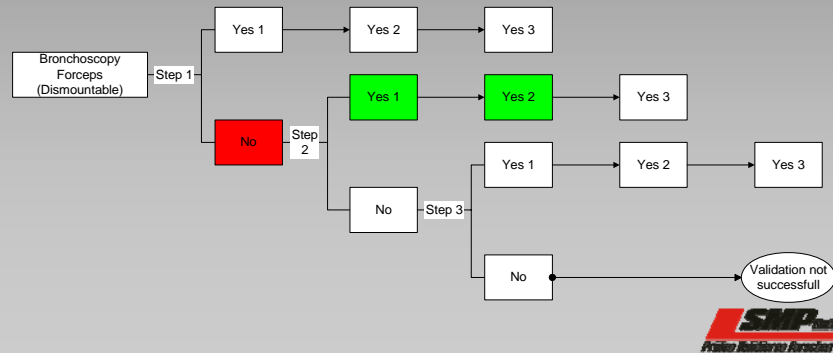


1. Messung nach
Vorreinigung + 10 min
Kontaminati- 40°C
on Einweichen
3. Messung nach
Reinigung





Group 3: Shift shaft instruments




Group 2: Alkaline							
Effort for cleaning	Step 3						
	Step 2						
	Step 1						
Instruments sorted by category							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E

Tab. 58: Zusammengefasste Ergebnisse Gruppe 2 „Alkalisch maschinell und ggf. manuellen Vorreinigung“

Group 2: Enzymatic automated and manual if necessary							
Effort for cleaning	Step 3						
	Step 2						
	Step 1						
Instruments sorted by category							
		2 A Titan	2 A Ceramic	2 B	2 C	2 D	2 E

Tab. 59: Zusammengefasste Ergebnisse Gruppe 2 „Enzymatisch maschinell und ggf. manuelle Vorreinigung“

Products:	Endoscopic Take-Apart Instrument / Company:.....	
ADVICE:	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. In case of damage the device should be reprocessed before sending back to the manufacturer for repair.	
Reprocessing Instructions		
Preparation at the Point of Use:	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.	
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.	
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state.	
Pre-Cleaning:	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. 10 minutes at 40°C in an ultrasonic bath with 0,5% detergent. Brushing the instrument under running tap water until all visible residues are removed 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.	
Cleaning:	Manual Cleaning Process: 1. Rinsing under running tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove visible soil; 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; 3. Rinse the instrument under running tap water to remove the detergent.	Automated Cleaning: Connect the instrument to a rack for MIS-instruments and start the program <ul style="list-style-type: none">• 4 min pre-washing with cold water (<40°C);• 6 min washing with 0,5% detergent at 55°C;• 3 min neutralising with warm water (>40°C);• 2 min intermediate rinsing with warm water (>40°C). Special instructions of the manufacturer of the automated washing machine have to be followed.

**ESAP**
Endoscopic Society of America
Practitioner Education Association



Disinfection:	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 ₀ -Value (see EN 15883)
Drying:	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.
Functional Testing, Maintenance:	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.	
Packaging:	Appropriate packaging for sterilization.	
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum process (according DIN EN 554 / ISO 11134) under consideration of the respective country requirements. Parameters for the pre-vacuum cycle: 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 Flash sterilization is not allowed on lumen instruments!	
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.	
Reprocessing validation study information	The following testing test devices, materials & machines have been used in this validation study; Detergent: deconnex 28 Alka One, (Borer, Zuchwil, Switzerland) Washer / Disinfector: deconnex 23 Neutrazym, (Borer, Zuchwil, Switzerland) Instrument Rack: Miele 7735 CD Miele E450-1 Details: See report SMP 05506011407-1	



Complex Surgical Devices for Robotic Surgery



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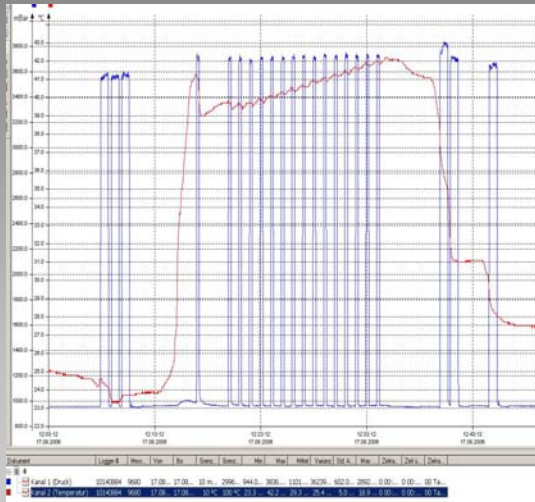
Medisafe SI PCF



- Pre-Wash –internal & external @ 30psi
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external 30psi
- Pre-Rinse – internal & external @ 30psi
- Final Rinse
- Empty – each cycle

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Profilen. Modifizieren. Perfizieren.

Test procedure: OPA-Testing according to ISO 15883 Improved Cycle of the Medisafe PCF with High Pressure Ultrasonic Irrigation



- Pre-Wash –internal & external @ 40psi
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external 40psi
- Pre-Rinse – internal & external @ 40psi
- Final Rinse
- Empty – each cycle



Conclusion

- It is important to analyze the reprocessing behavior before purchasing new instruments
- Check what kind of information are available from the manufacturer
- If instruments are substituted due to repair, make sure that the same instrument is not available in an easy to clean version.





More information:

www.smpgmbh.com

