Elaborating of a Reprocessing Instruction
According to ISO 17664

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

<table>
<thead>
<tr>
<th>Year</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
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<td>1661</td>
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<td>1765</td>
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<td>Estimated for England and Wales</td>
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<td>9900</td>
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<td>10500</td>
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</table>

** 57/340 Datensätze

* mit freundl. Genehmigung G.Shapp MP
Requirements of EN/ISO 17664

- Preparation at the point of use
- Transport
- Cleaning
- Disinfection
- Functionality testing
- Packaging
- Sterilisation
- Storage
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:

- identification and concentration of chemicals required for cleaning;
- identification of water quality,
- accessories required for cleaning process;
- techniques to be used including rinsing;
- process temperature(s);
- limits on temperature, concentration of solution(s), exposure time,
- limits and monitoring of chemical residues
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.
Exampel 1: Automated alcaline process with manuell pre-cleaning

Stufe 1
- Maschinell im RDG

Stufe 2
- Manuelle Vorreinigung + Maschinell im RDG

Stufe 3
- Manuelle Vorreinigung + zusätzliche Behandlung mit Ultraschall + Maschinell im RDG

Ja
- Bestätigen
Nein
- Nicht validiert

ok

Ja
- Bestätigen
Nein
- Nicht validiert

ok

Ja
- Bestätigen
Nein
- Nicht validiert

ok

Ja
- Bestätigen
Nein
- Nicht validiert

ok

Ja
- Bestätigen
Nein
- Nicht validiert
Alkaline process: Step 1

Automated cleaning in the WD
The cleaning is 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
The cleaning is performed only in a washer disinfector G 7735 CD (Miele) (Program abortion before disinfection step).
The instruments are placed on the specific tray and the cleaning and disinfection program Vario TD gets started:

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

**Automated cleaning in the w/d**
The cleaning is performed only in a washer disinfector G 7735 CD (Miele) Directly after contamination without manually precleaning (Program abortion before disinfection step).
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- emptying
- 2 min intermediate rinsing with warm water (>40°C)
- emptying
Stabile Water Pressure

Graph showing water pressure changes over time, with data points at various temperatures and pressures.
Specification of the groups

Group 1: Critical A Instruments, like hooks; don’t need validation

Group 2: Critical B Instruments
Scissors, Clamps

Group 3: Shift shaft instruments
need validation, as the result of the cleaning can not be inspected

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: Complex Devices
have 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
Classification in Groups

Group 1: Critical A Instruments, like hooks, don't need validation

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**

scissors and clamps are already covered by the requirements for the WD

Sub-classification:

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

B: Box lock approx. 12 x 20 mm

C: Box lock approx. 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.
Group 2 (Instruments with hidden surfaces): Crile Clamp,

<table>
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<th>Pixel</th>
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<th>Imp/Sec</th>
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<td>Crile clamp 3</td>
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Group 2 (Instruments with hidden surfaces): Side cutter

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<td>65</td>
<td>3</td>
<td>4</td>
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</table>
Group 3: Shift shaft instruments

Tischler-Morgan (Not dismountable)

Step 1:
- Yes 1
- Yes 2
- Yes 3
- No

Step 2:
- Yes 1
- Yes 2
- Yes 3
- No

Step 3:
- Yes 1
- Yes 2
- Yes 3
- No

Validation not successful
Group 3 (Shift shaft instruments): Rongeur, Arthroskopiezangen etc.

1. Messung nach Kontamination
2. Messung nach Vorreinigung + 10 min 40° C Einweichen
3. Messung nach Reinigung

<table>
<thead>
<tr>
<th>Nr.87/26</th>
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<tr>
<td>Zr</td>
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Group 3: Shift shaft instruments

Keerizon Rongeur (Dismountable)

Step 1

Yes 1: Yes 2: Yes 3: No

Step 2: Yes 1: Yes 2: Yes 3: No

Step 3: Yes 1: Yes 2: Yes 3: No

Validation not successful
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.
View to a bright future