Configuration of Surgical Instruments:

Influence and Validation of the Cleaning Process 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>
</tr>
</thead>
<tbody>
<tr>
<td>Data of 57  hospitals**</td>
<td>1252</td>
<td>1661</td>
<td>1926</td>
<td>1765</td>
</tr>
<tr>
<td>Estimated for England and Wales</td>
<td>7500</td>
<td>9900</td>
<td>11500</td>
<td>10500</td>
</tr>
</tbody>
</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:

- 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;
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 fulfilled by special manual pre-cleaning or special equipment 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.
**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:

<table>
<thead>
<tr>
<th>Step</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 min pre-washing with cold water</td>
</tr>
<tr>
<td>emptying</td>
</tr>
<tr>
<td>3 min pre-washing with cold water</td>
</tr>
<tr>
<td>emptying</td>
</tr>
<tr>
<td>5 min washing with 0.5 % alkaline cleaner by 55°C (Dr. Weigert, Neodisher FA)</td>
</tr>
<tr>
<td>emptying</td>
</tr>
<tr>
<td>3 min neutralizing with warm water (&gt;40°C)</td>
</tr>
<tr>
<td>emptying</td>
</tr>
<tr>
<td>2 min intermediate rinsing with warm water (&gt;40°C)</td>
</tr>
<tr>
<td>emptying</td>
</tr>
</tbody>
</table>
### 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 time 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:

- 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 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). 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
Example 1: Automated alcaline process with manuell pre-cleaning

Step 1: Automated cleaning in a W/D

Confirm

Step 2: Manual pre-cleaning
Followed by automated cleaning

Confirm

Step 3: Manual pre-cleaning plus ultrasonic cleaning
Followed by automated cleaning

Confirm

Not validated
Which Test Method should be selected?

Swab Test on the instruments?

Cleaning indicators?
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.
Classification of the instruments the groups

Group 1: Critical A Instruments, like hooks

Group 2: Critical B Instruments, 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: Complex 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
Classification in Groups

Group 1: Critical 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: Forceps and Scissors

Sub-classification:

A: Crile-Clamp 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
Group 3 (Shift shaft instruments):
Rongeur, Arthroskopiezwangen etc.

Subclassification:
- Category A up to 3 mm diameter
- Category B 3 to 5 mm
- Category C bigger than 5 mm
Comparison of Group 2 Instruments

Crile Clamp, Side cutter
Comparison of Group 2 Instruments

Crile Clamp,

<table>
<thead>
<tr>
<th>Nr.87/26</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crile clamp 1</td>
<td>98</td>
<td>4</td>
<td>4</td>
<td>122</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Crile clamp 2</td>
<td>66</td>
<td>3</td>
<td>3</td>
<td>97</td>
<td>3</td>
<td>3</td>
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<td>Crile clamp 3</td>
<td>121</td>
<td>2</td>
<td>2</td>
<td>145</td>
<td>3</td>
<td>3</td>
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</tbody>
</table>
Group 2 (Instruments with hidden surfaces): Side cutter

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wire cutter 1</td>
<td>69</td>
<td>10</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Wire cutter 2</td>
<td>79</td>
<td>9</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wire cutter 3</td>
<td>59</td>
<td>9</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Results:**

1. Measurement after contamination + 10 min 40°C immersion
2. Measurement after cleaning + ultrasonic 10 min 40°C
Group 3: Shift shaft instruments

Tischler-Morgan (Not dismountable)

Yes 1 → Yes 2 → Yes 3 → Validation not successful

No

Yes 1 → Yes 2 → Yes 3

No

Yes 1 → Yes 2

No

Yes 1
Group 3 (Shift shaft instruments): Rongeur, Arthroskopiezangen etc.

<table>
<thead>
<tr>
<th>Nr. 87/26</th>
<th>Zr</th>
<th>Zr</th>
<th>Zr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rongeur 1</td>
<td>85</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>Rongeur 2</td>
<td>121</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Rongeur 3</td>
<td>88</td>
<td>17</td>
<td>17</td>
</tr>
</tbody>
</table>

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

ROI-Auswertung

Ergebnisse der ROI-Auswertung

<table>
<thead>
<tr>
<th>ROI-Name</th>
<th>Impulse</th>
<th>Pixel</th>
<th>Imp/Pixel</th>
<th>Imp/Sec</th>
<th>Imp/Pixel/Sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthrot S</td>
<td>12430</td>
<td>457</td>
<td>3.24</td>
<td>89.54</td>
<td>0.3593</td>
</tr>
<tr>
<td>Arthrot R</td>
<td>487</td>
<td>457</td>
<td>3.88</td>
<td>111.35</td>
<td>0.3639</td>
</tr>
<tr>
<td>Arthrot G</td>
<td>12377</td>
<td>473</td>
<td>2.77</td>
<td>89.48</td>
<td>0.3489</td>
</tr>
</tbody>
</table>

ROI-Auswertung
Group 3: Shift shaft instruments

Bronchoscopy Forceps (Dismountable)

Yes 1 → Yes 2 → Yes 3
Step 1

Yes 1 → No → Step 2
Yes 1 → Yes 2 → Yes 3

Yes 1 → No → Step 3
Yes 1 → Yes 2 → Yes 3

No → Validation not successful
Group 3: Shift shaft instruments
Group 3: Shift shaft instruments
### Group 2: Alkaline

<table>
<thead>
<tr>
<th>Effort for cleaning</th>
<th>2 A Titan</th>
<th>2 A Ceramic</th>
<th>2 B</th>
<th>2 C</th>
<th>2 D</th>
<th>2 E</th>
<th>2 F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Instruments sorted by category

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

### Group 2: Enzymatic automated and manual if necessary

<table>
<thead>
<tr>
<th>Effort for cleaning</th>
<th>2 A Titan</th>
<th>2 A Ceramic</th>
<th>2 B</th>
<th>2 C</th>
<th>2 D</th>
<th>2 E</th>
<th>2 F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Step 2</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Instruments sorted by category

Tab. 59: Zusammengefasste Ergebnisse Gruppe 2 „Enzymatisch maschinell und ggf. manuelle Vorreinigung“
Instruments for Minimally invasive surgery
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.
<table>
<thead>
<tr>
<th>Products:</th>
<th>Endoscopic Take-Apart Instrument / Company:…….</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADVICE:</td>
<td>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.</td>
</tr>
<tr>
<td>Reprocessing Instructions</td>
<td></td>
</tr>
<tr>
<td>Preparation at the Point of Use:</td>
<td>Remove gross soiling by submerge the instrument into cold water (&lt;40°C) immediately after use. Don't use a fixating detergent or hot water (&gt;40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.</td>
</tr>
<tr>
<td>Transportation:</td>
<td>Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.</td>
</tr>
<tr>
<td>Preparation for Decontamination:</td>
<td>The devices must be reprocessed in a disassembled state.</td>
</tr>
<tr>
<td>Pre-Cleaning:</td>
<td>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.</td>
</tr>
<tr>
<td>Cleaning:</td>
<td>Manual Cleaning Process: 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; 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.</td>
</tr>
<tr>
<td>Automated Cleaning:</td>
<td>Connect the instrument to a rack for MIS-instruments and start the program  • 4 min pre-washing with cold water (&lt;40°C); • 6 min washing with 0.5% detergent at 55°C; • 3 min neutralising with warm water (&gt;40°C); • 2 min intermediate rinsing with warm water (&gt;40°C). Special instructions of the manufacturer of the automated washing machine have to be followed.</td>
</tr>
</tbody>
</table>
| **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 A₀-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°C-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)  
deconnex 23 Neutrazym, (Borer, Zuchwil, Switzerland)  
Washer / Disinfector: Miele 7735 CD  
Instrument Rack: Miele E450-1  
Details: See report SMP 05506011407-1 |  |
Soluções H. Stratall para limpeza e esterilização de ciclo rápido

Otimização e economia para o seu centro cirúrgico

Limpeza:

DETERGENTE ENZIMATICO HS-ZYME
3 enzimas, não espumante, maior aproveitamento da solução

SONIC IRRIGATOR
Lavadora Ultra-sônica, com sistema de bombeamento para limpeza de materiais de difícil acesso

ENDO PURGE
Equipamento para limpeza de endoscópios flexíveis. Eficácia na limpeza e secagem do interior dos lómenes
MANUTENÇÃO E CUIDADOS COM O INSTRUMENTAL CIRÚRGICO ENDOSCÓPICO
Guia de Recomendações
Complex Surgical Devices for Robotic Surgery
Automated Cleaning Process ?
Parameters of the Cleaning Cycle

- Mechanics: Amount of Water, Pressure, Ultrasound
- Interacting
- Time
- Temperature
- Chemical Agent
- Water Quality
Influence of Velocity of Flow

Laminar Flow
Influence of Velocity of Flow

Turbulent Flow

\[ \text{Re} = \frac{\rho \cdot v \cdot l}{\mu} \]

\( \text{Re} \) 
Reynolds number
\( \rho \) 
Density
\( v \) 
Velocity
\( l \) 
Length
\( \mu \) 
Viscosity
\( \mu_{\text{kin.}} \) 
kine Viscosity
Medisafe SI PCF

- Pre-Wash – internal & external @ 2 bar
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external @ 2 bar
- Pre-Rinse – internal & external @ 2 bar
- Final Rinse
- Empty – each cycle
Cycle in the Medisafe PCF
Test procedure: OPA-Testing according to ISO 15883
Improved Cycle of the Medisafe PCF with High Pressure Ultrasonic Irrigation

- Pre-Wash – internal & external @ 3 bar
- Detergent Dispense
- De-gas
- 15 minute Ultrasonic Main Wash – internal/external @ 3 bar
- Pre-Rinse – internal & external @ 3 bar
- Final Rinse
- Empty – each cycle
More Test with the PCF

Investigation of MIS Instruments to avoid manual pre-cleaning:

Finished:

Conmed
Boss
Stryker

In preparation:

Storz
Wolf
New Washer / Disinfector: Niagara by Medisafe
New Washer / Disinfector: Niagara by Medisafe
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 incorporating ultrasonic irrigation are on the market, which provide good cleaning results of tubular instruments

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.
Thank you for your attention

Further informations

www.smpgmbh.com