Medical Device (Re-)Processing: Our own Cleaning Experience and its Parameters – The Value of Ultrasound

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Products & Processes

Cleanical Investigation & Application
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Invasive Procedures have to be justified.
Intelligent Medical Devices enable New Therapeutic Approaches in Medicine & Dentistry

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We see the Dentist more often than any other Doctor.
„What You see is what You get“: Surgery has developed since then. What about Instruments, Devices ... ... and last not least Sterile Processing?

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Cleanliness....

Products & Processes: Potential for Improvement
Talking about Sterile Processing means to consider Practices and existing Regulations. Medical Devices become more complex (Ophthalmology, ENT, MIS, Robotic Surgery). Reusibility depends on knowledge of Processes and Parameters. Monitoring of Parameters is only partially available. Cleanability is a complexe Parameter itself. Good Cleaning Results enable safer Handling (Function, Hygiene) and Preservation of Value.
German RKI-Recommendation
Classification Critical C: Penetration in sterile Tissue.
Complexe Design with inner Surfaces shows this Drilling Device penetrating the serosa.
Disinfection is not enough!
German Multicenter Study on Remaining Contamination
Function & Intended (Re-)Use
### Aufbereitung von Medizinprodukten

<table>
<thead>
<tr>
<th>nicht steril</th>
<th>steril</th>
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<tbody>
<tr>
<td>Transport vom OP</td>
<td>Inspektion</td>
</tr>
<tr>
<td>Reinigung Desinfektion</td>
<td>Packen</td>
</tr>
<tr>
<td>Ultraschall</td>
<td>Sieb</td>
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<tr>
<td>Unterstützung Vorreinigung</td>
<td>Nachreinigung ?</td>
</tr>
<tr>
<td>ggf. Zerlegung</td>
<td>Reparatur ?</td>
</tr>
<tr>
<td>Trocknung</td>
<td>Wartung</td>
</tr>
<tr>
<td>Trocken-Entsorgung</td>
<td>Montage</td>
</tr>
<tr>
<td></td>
<td>Sterilisation</td>
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<tr>
<th>1</th>
<th>5</th>
<th>60</th>
<th>5</th>
<th>15</th>
<th>30-60 Minuten</th>
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</thead>
</table>

**Annahme**

[Images of people performing medical procedures]

[Images of medical equipment]

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Unclean....
Well educated Staff?
Manual (Pre-)Cleaning ...
... is Time-Consuming and ...
... might even lead to Damage!
Contact with Blood is Contact to Infection
What about the Value of Ultrasound?

An Ultrasound Bath is moving the water on located Spots. It is not affecting the inner Lumen of Medical Devices (unless by rinsing it e.g. Medisafe).
Ultrasound: Cleaning or bathing?

It takes Time, it needs Space and it is noisy.
SMP GmbH (Tuebingen, Germany) could show localized Cavitation in Bath, on Surfaces depending on distinct Parameters.
Parameters of Cleaning (Sinner) generally

- Mechanics: Water Amount, Pressure, Ultrasound
- Time
- Temperature
- Detergent - Disinfectant
- Water Quality
Sonoluminiscence

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Product & Process

Function Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusibility

Ultrasound & Validation

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Energy Distribution of Ultrasound

Bright Areas are Spots with high Energy (maximal Cavitation)
Main Parameters of the Ultrasound Effect

- Cleaning Agent (Detergent – Disinfectant)
- Volume of Solution (Level in Relation to Transducers)
- Number and Location of Transducers
- Tray Material, Construction & Position
- Temperature of Solution
- Particle Content
Possible Energy Distribution

US 1
Different Levels/Volumes

US 2
Einfluß verschiedener Reinigungsmittel auf die Feldverteilung im Elma T460H

<table>
<thead>
<tr>
<th>Z-Achse [mm]*</th>
<th>bidest. Wasser</th>
<th>bidest. Wasser+5% elma clean 10</th>
<th>bidest. Wasser+5% elma clean 40</th>
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<td>Meßdatum : 4.8.97</td>
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<tr>
<td>50</td>
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*Z=0 mm an Wasseroberfläche
<table>
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<th>Z-Achse [mm]</th>
<th>ohne Instrumenten-Träger</th>
<th>mit Instrumenten-Träger</th>
<th>mit Kunststoffwanne</th>
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<td><img src="image14" alt="Graph" /></td>
<td><img src="image15" alt="Graph" /></td>
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Temperature Influence

Dependancy of Field/Z-Level of Solution-Temperature

![Graph showing the temperature influence on field strength/level of solution temperature. The graph plots the average field strength per Z-plane against the Z-axis (mm) for different temperatures: 23 °C, 39 °C, 49 °C, and 67 °C. The x-axis represents the Z-axis in millimeters, with Z=0 mm at the water surface, and the y-axis represents the average field strength per Z-plane in [K/s].](image)
What to be verified with Ultrasound

- Quantity and Quality of Load
- Kind of Tray used
- Positioning of the Tray
- Cleaning Agent (Chemistry)
- Interval of Renewal of Cleaning Agent
- Level/Quantity of Solution
- Actual Temperature
- Movable Transducers?
For Example: Influence of Silicon Mat

No Cavitation
Heavy Loads absorbing Energy

Too much is not enough
Parameters of Ultrasound (to conclude)

These Results were confirmed by similar Investigations of L. Jatzwauk (Dresden, Germany).

Ultrasound Cleaning is difficult to standardize. Contact Time to Instruments can be enlarged. Specific Instruments can be severely damaged.

Ultrasound remains an additional Tool for Pre-Cleaning of selected Instruments.
What about Washer Disinfector?

Washer Disinfector can possibly rinse even Inner Lumina with a defined Pressure ...
... if Positioning in specifically constructed Trays is correct and the Pressure adequate high.
Validation of the Cleaning Step …

Monitoring of water pressure
.... beware of the Load!

Approval of CEN ISO 15 883 Part 1-3 has just been decided ...
Cleaning must be(come) reproducible
Baskets allow Cleaning of Small Parts
Correct Cleaning dries the Load ...
... the Precondition for Sterility
Efficient Loads?

Kidney pans are possibly disposables.

Save the load for instruments.
These are no medical devices. There „intended use“ is somehow different.
CEN ISO 17664: The manufacturer must provide the clinical user with valid informations about the medical device, its function, maintenance and reusability which includes validated methods for cleaning, disinfection and sterilisation.
Keep Your Working Place in Order ....
You will have more Space needing less Instruments!

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Having the right Instruments in Place is better than having them in Store.
Adequate Transport Containment.....
...... ready for Automated Cleaning
Transport and Cleaning Tray
Inadequate Container
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The Art of Packaging

Failures...
Modern Set-Pack with Baskets
Packaging
Sealing
Correct Sterilisation - what's inside?

- **Sterile Units:**
  - 6 StE
  - 98,5 kg
- **Mixed Fill?**
  - 4 or 5 StE

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Hygiene & Reusibility
Product & Process
Function Intended (Re-)Use
Design & Ergonomy
Ultrasound & Validation
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Process Control for (not only) Sterilisation

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Every Medical Device has an „Intended Use“ – described in the Manual of the Manufacturer (EN ISO 17 664)

Disposable or Reuse:
A Decision of the Manufacturer
But a Decision with Consequences:
• Costs (Products and Process)
• Function (Design, Ergonomy, Performance)
• Hygiene (Reusibility – Cleanability)

Success of the Operation is the common Interest of Patient and Hospital / Doctor
... but how „common“ is the interest?
First: What kind of Operation is performed?

Liability and Weighting of the Interests:
Indication for Surgical Intervention can be

- Vital (Accident)
- Elective (Gall Bladder)
- Optional (Liposuction)
... last not least:
The Medical Device is Part of the Action.

Availability of all „Means“
Skills at the State of the Art
Adequate Devices and Accessories
Time and Organisation
Money and Investment
Documentation of Process & its Parameters
A Compexe Hierarchy

- European and German Laws
- Health and Safety for Staff
- Ecology
- Guidelines for Training on the Job
- Guidelines and Recommendations of Notified Bodies and Scientific Associations (RKI, DGKH, DGHM, DGSV)
- National and International Normation
We must investigate a Solution adapted to existing Problem: Medical Device for “Intended (Re)Use”

- Type Testing
- Validated Products and Processes

„Form follows Function“

Hygiene, Costs, Usefulness
Respect for Regulatory Affairs
Verification, Validation, Documentation

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INTERNATIONAL FORUM 2007

Prevention & Medical Devices

Friday, 23th of February 2007

Berlin - Germany
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