

The smaller the Instrument, the bigger the Task!

Our own Processing Experiences

Dr. med. Dipl.-Ing. Thomas W. Fengler



Medical Devices & Related Processes

Clinical
Investigation &
Application



Chirurgie-
Instrumenten-AG Berlin

Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

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Clinical
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Product & Process

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History

1993

Foundation of the „Chirurgie-Instrumenten-AG (CIA) am Krankenhaus Moabit Berlin“

1994

Quality of Laparoscopic Instruments – retrospective and prospective clinical investigations on medical devices in abdominal surgery at the city hospital Moabit

1998

Projects with different manufacturers (BODE, KARL STORZ Endoskope, Miele PROFESSIONAL, Olympus, Stryker) in surgery and endoscopy on remanent contamination and process control and device improvement

1999

Organisation of the worldwide first clinical multicenter study on remanent contamination after automated cleaning, before thermal disinfection for different instrument design in 6 German CSSD

1. International FORUM Medical Devices & Processes, Congress Centre, MEDICA Düsseldorf.

2001

New company for CSSD Services - ZEHNACKER CLEANICAL® GmbH

2002

3. International FORUM Medical Devices & Processes moves to Berlin

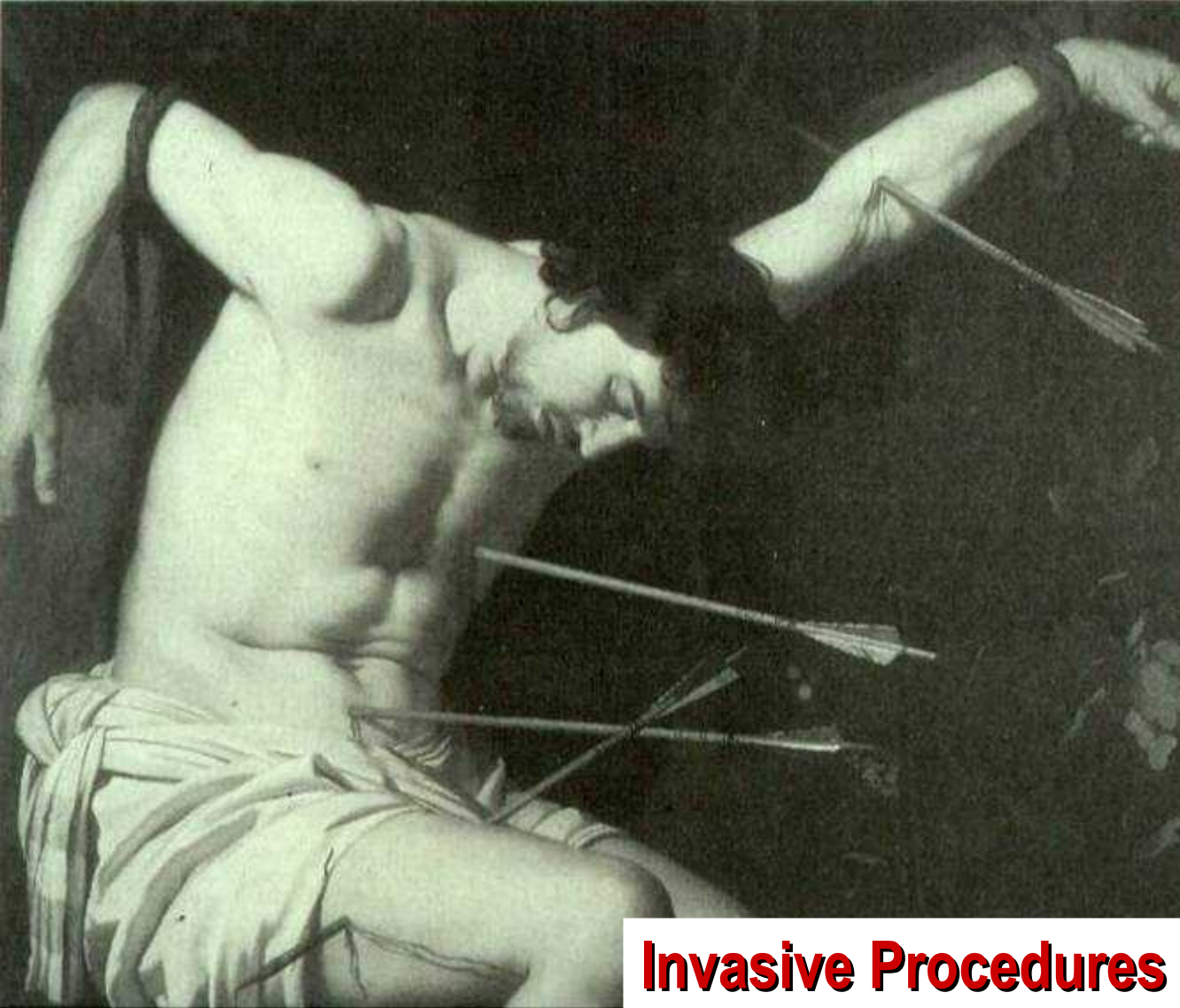
2005

Business Support International:

FORUM-Tour Armenien, China, Georgien, Irland, Mexico, Norwegen, Russland

2006

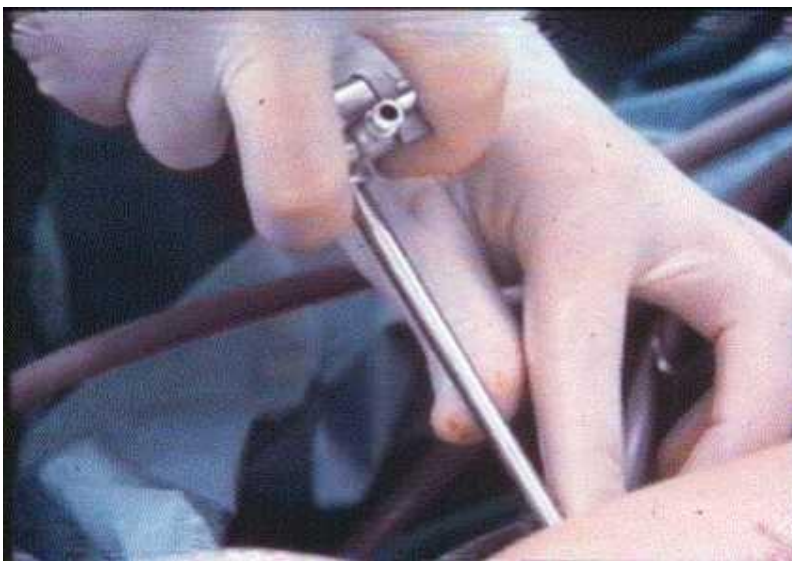
New Companies – CMP GmbH (Validation) and CLEANICAL® GmbH (Coaching)



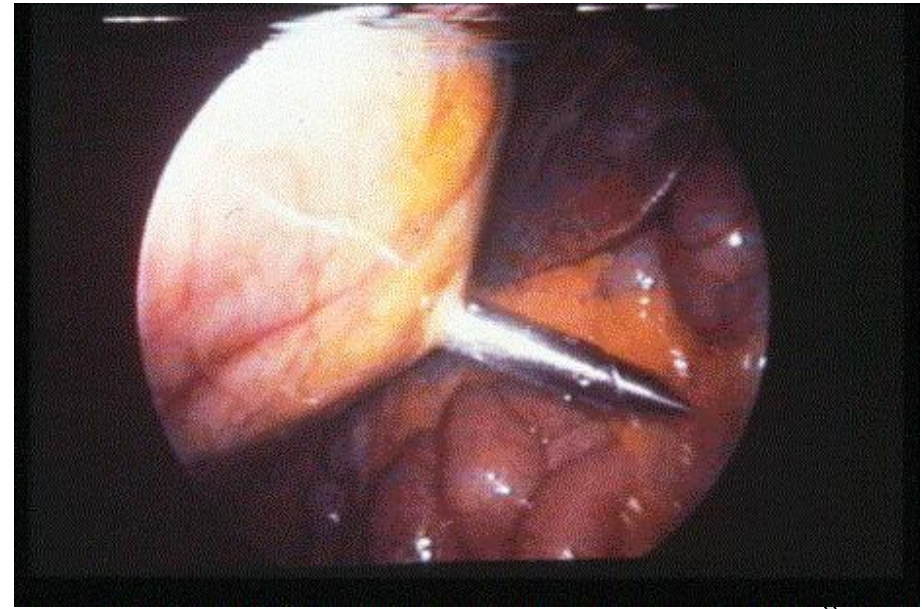
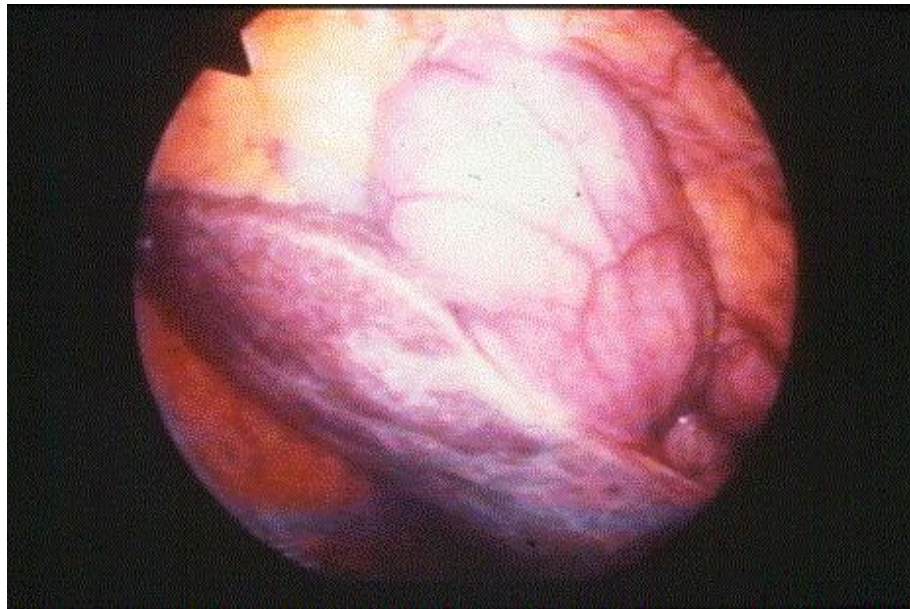
Invasive Procedures have to be justified.

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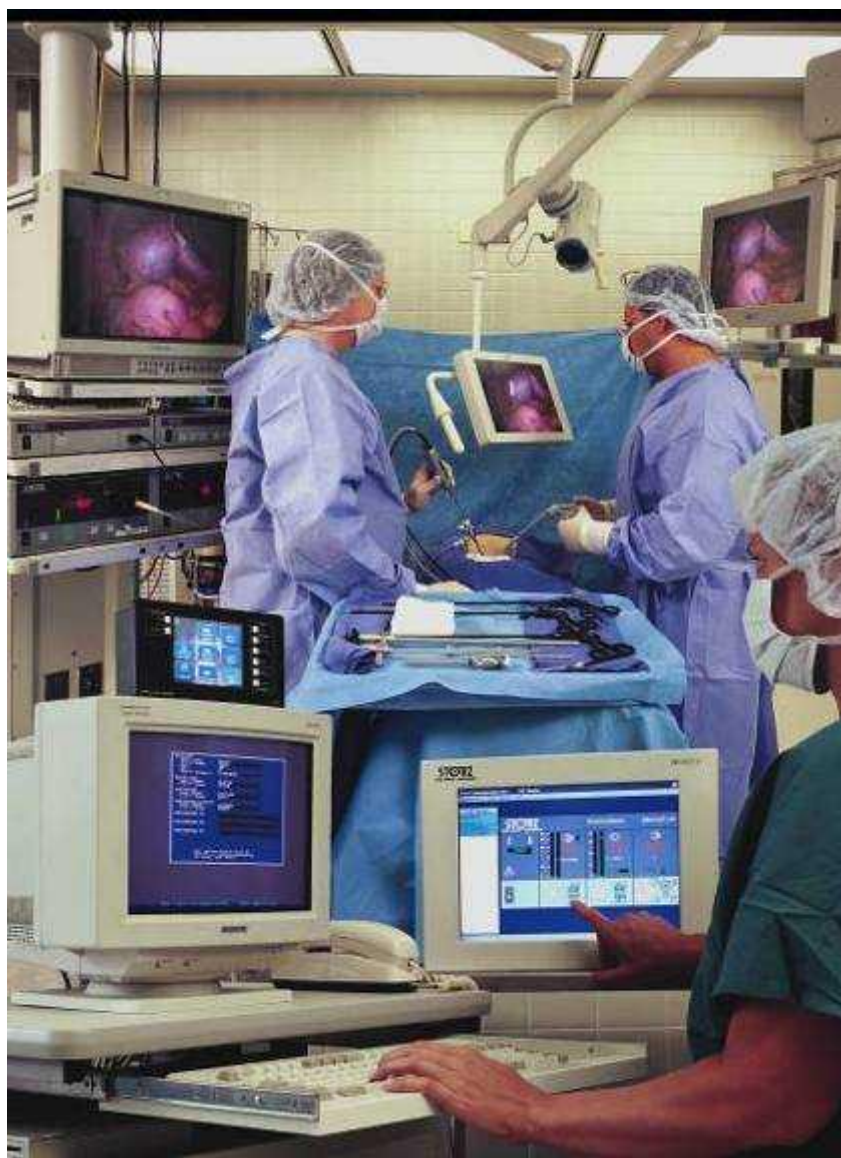
Intelligent Medical Devices enable New Therapeutic Approaches in Medicine & Dentistry



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A complex environment requires understanding and training on the job – not only for the surgical staff



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***„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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Product & Process

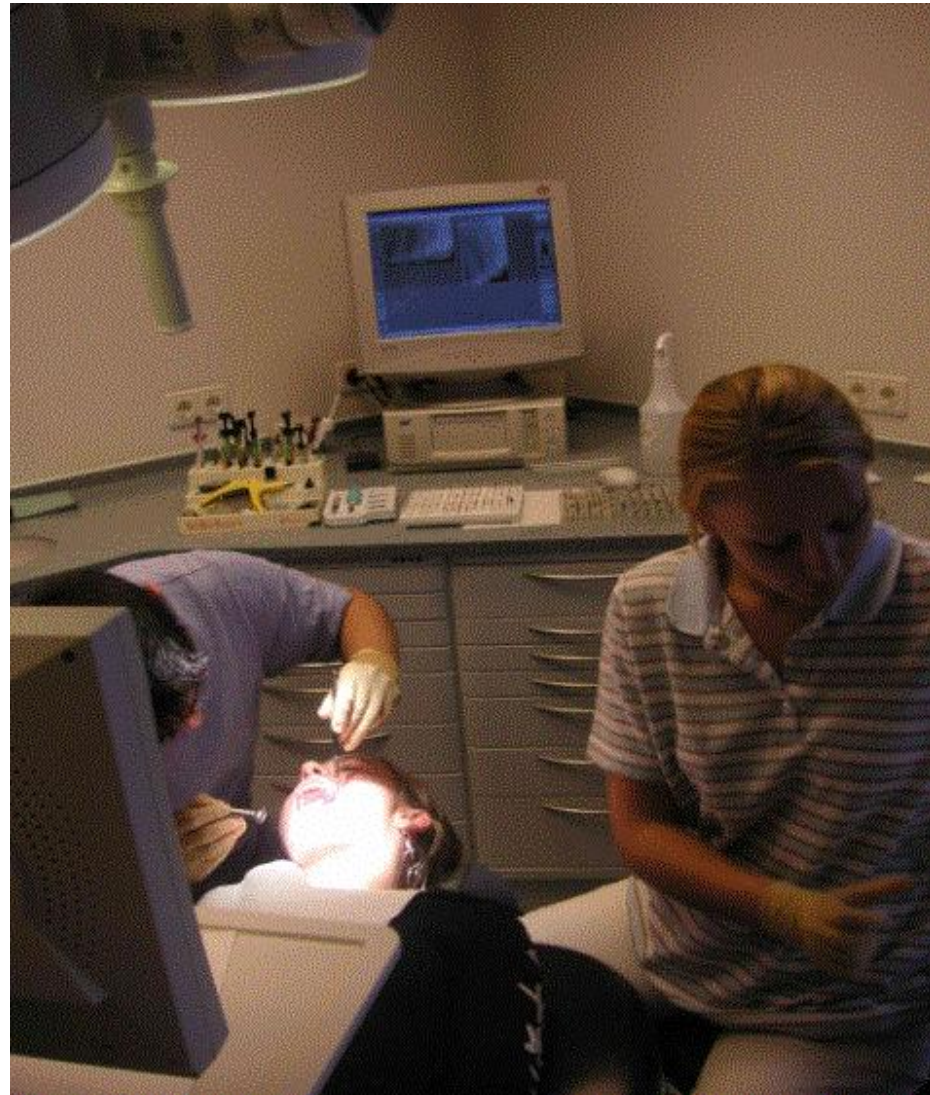
Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

We see the Dentist more often than any other Doctor.



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Product & Process

Ultrasound & Validation

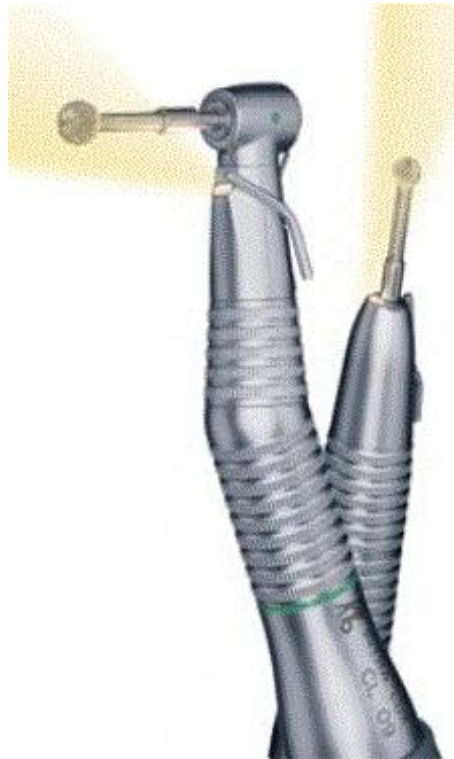
Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Product & Process

German RKI-Recommendation remains debatable:
Classification „Critical“: Penetration in sterile tissue
„C“ for complexe design with inner surfaces, rotation etc.



Disinfection is not enough !



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

UV light and shadows



Products & Processes: Potential for Improvement

Cleanliness....

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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusibility

Product & Process

Talking about Sterile Processing means to consider Practices and existing Regulations.

Medical Devices become more complexe

(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.

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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

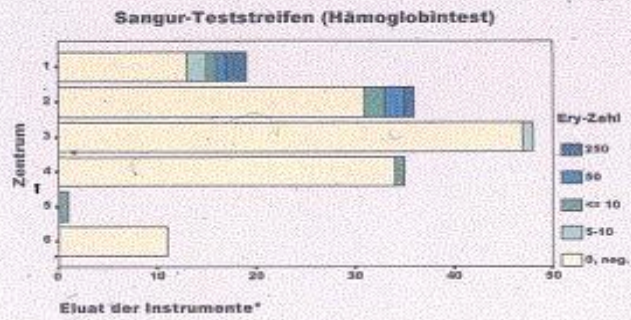
Design & Ergonomy

Hygiene & Reusability

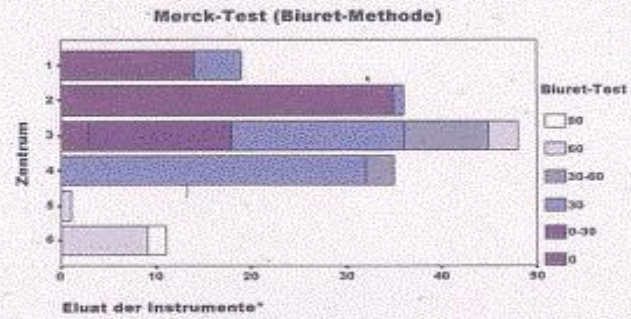
German Multicenter Study on Remaining Contamination



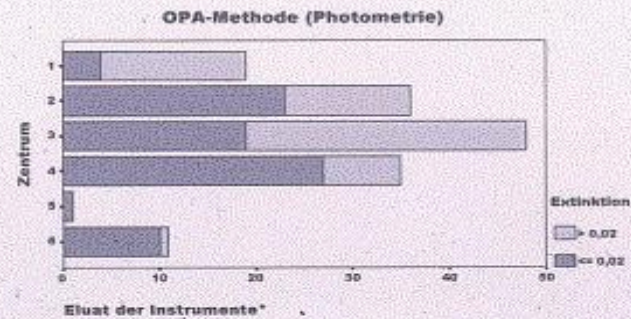
Fengler ThW, Pahlke H, Michels et al.: Are Processed Surgical Instruments Protein-free? Results of the Clinical Multicenter Study on Remaining Contamination. Zentralsterilisation 9 (1): 20-32 (2001)



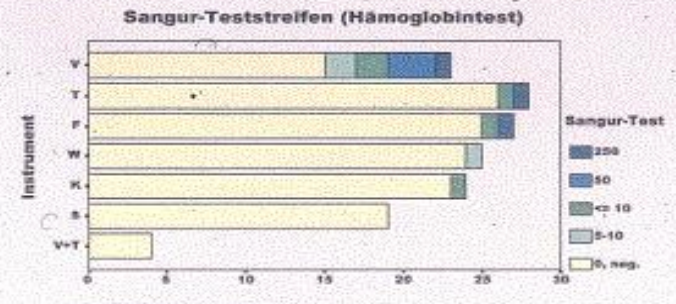
* Nur Proben, die nach H&G mikroskopische Verschmutzung



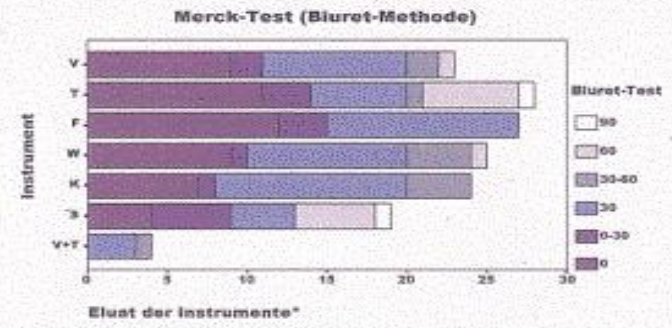
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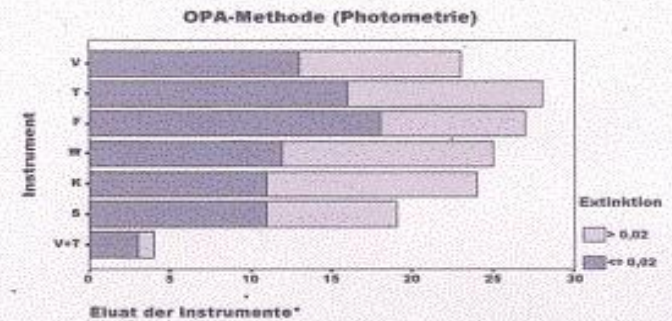
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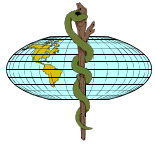


* Nur Proben, die nach H&G mikroskopische Verschmutzung



* Nur Proben, die nach H&G mikroskopische Verschmutzung

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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Function & Intended (Re-)Use





Products & Process

Aufbereitung von Medizinprodukten

nicht steril

steril

Transport
vom OP

Reinigung
Desinfektion

Inspektion

Packen

Sterilisation

Ultraschall

Reinigung
Thermische
Desinfektion

Nachreinigung ?
Reparatur ?
Wartung
Montage

Sieb
Set

Dampf
FA
EO
Plasma

Trocken-
Entsorgung

Unterstützende
Vorreinigung
ggf. Zerlegung

Trocknung

1

5

60

5

15

30-60 Minuten

Annahme

Freigabe



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Function
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Hygiene & Reusability

Microbes cannot read – a magic barrier



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Product & Process

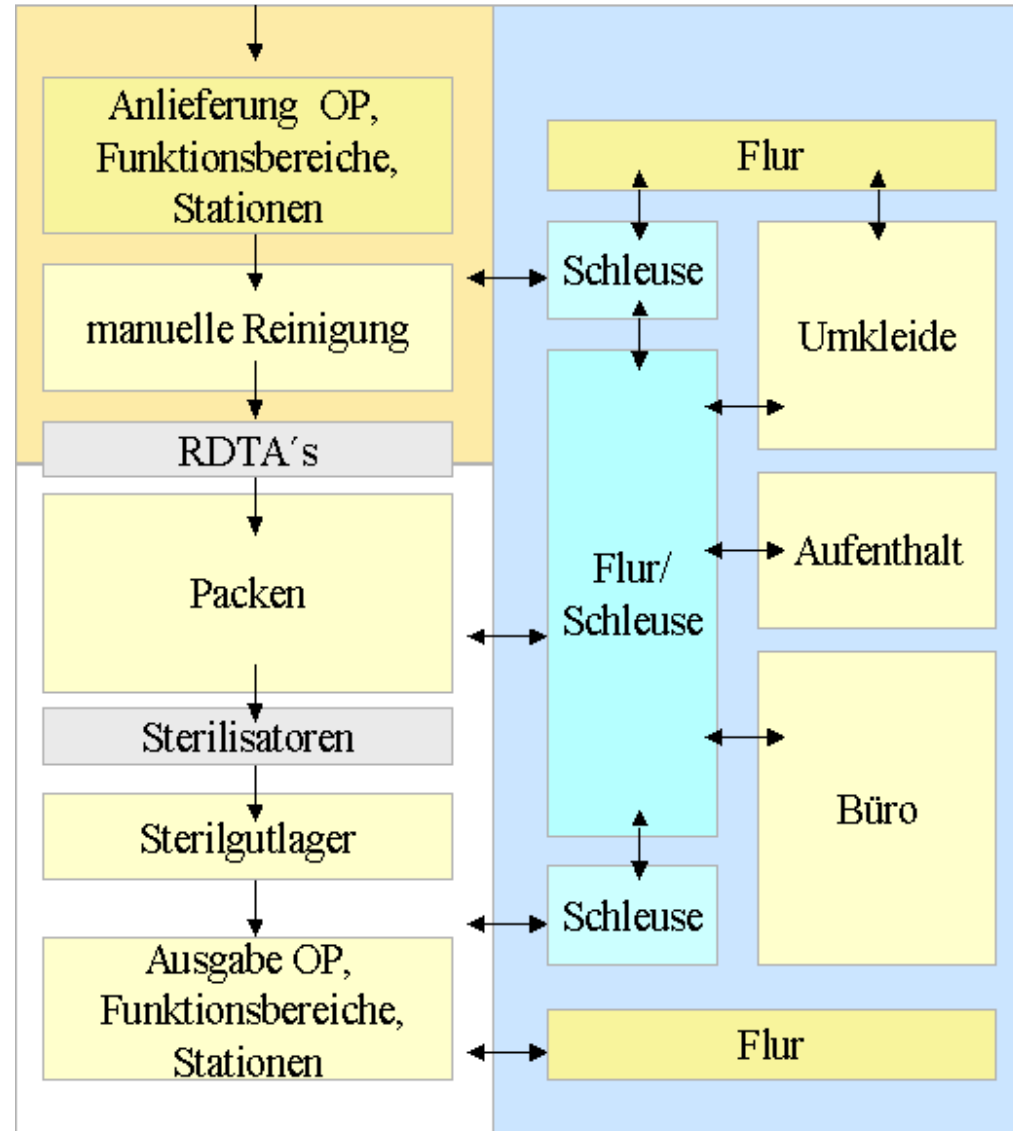
Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Organisation & Facility



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Ultrasound & Validation

Function
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Preselection – no crossways



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Ultrasound & Validation

Function
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Design & Ergonomy

Hygiene & Reusability

Product & Process

**Manual cleaning is limited to daily conditions:
Poor reproducibility, temperature $< 40^{\circ}\text{C}$**



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Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

CSSD – unclean side....



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Product & Process

„Proper“ documentation of device parameters?



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Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Product & Process

Means and devices - which process parameters?



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Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Well educated Staff?



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Function
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Design & Ergonomy

Hygiene & Reusability

Correct connection for rinsing?



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Unconnected tubes lower rinsing pressure



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Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Manual (Pre-)Cleaning?



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Function
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Hygiene & Reusability

It is time-consuming and ...



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... might even lead to Damage!



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Hygiene & Reusability

Contact with blood is contact to infection



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Product & Process

Ultrasound & Validation

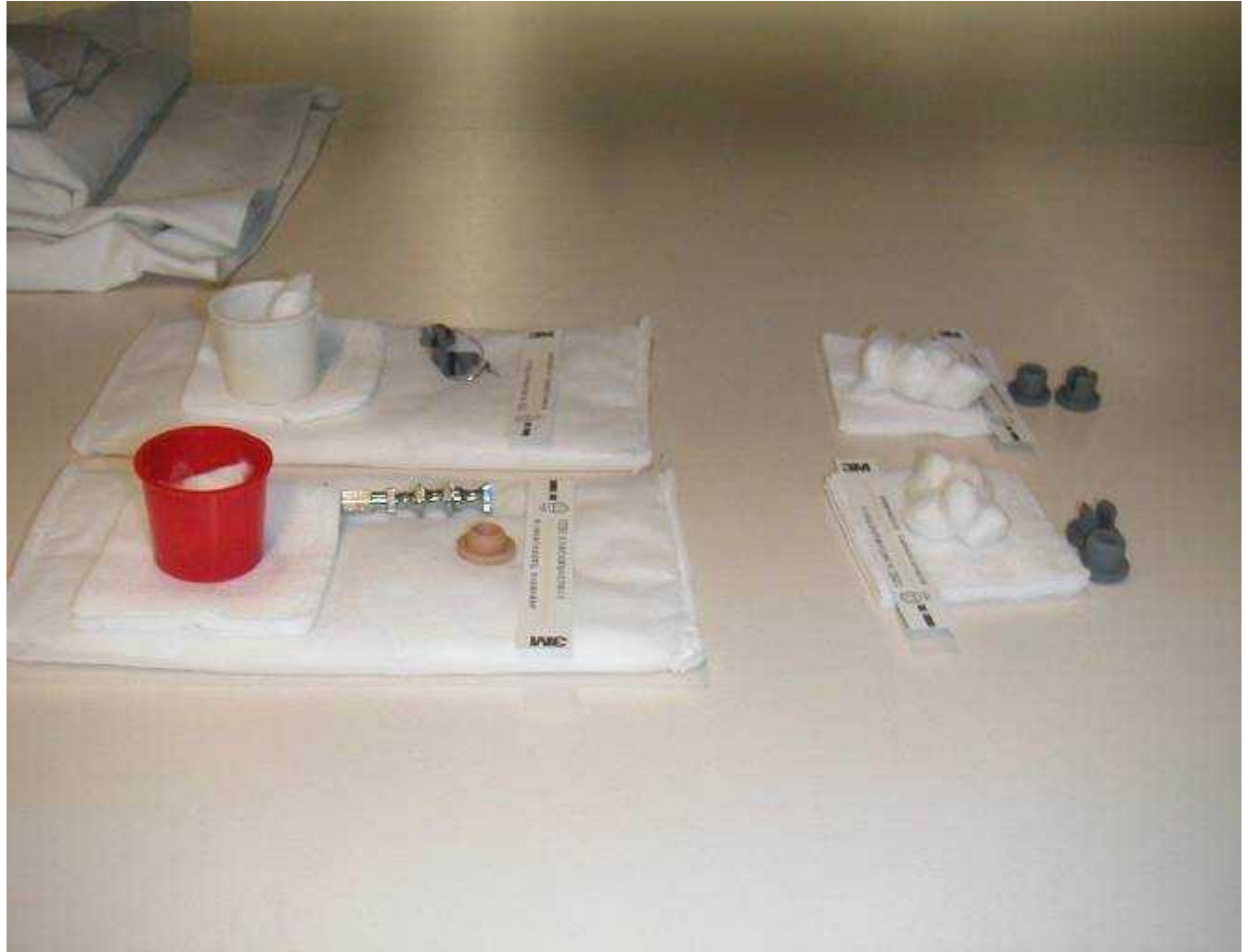
Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Product & Processes

Small parts and manual cleaning remain tricky



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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Baskets for small parts





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).



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Ultrasound & Validation

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Design & Ergonomy

Hygiene & Reusability

Product & Process

This is no thermal disinfection!



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Ultrasound: cleaning or bathing?



It takes Time, it needs Space and it is noisy.

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Product & Process

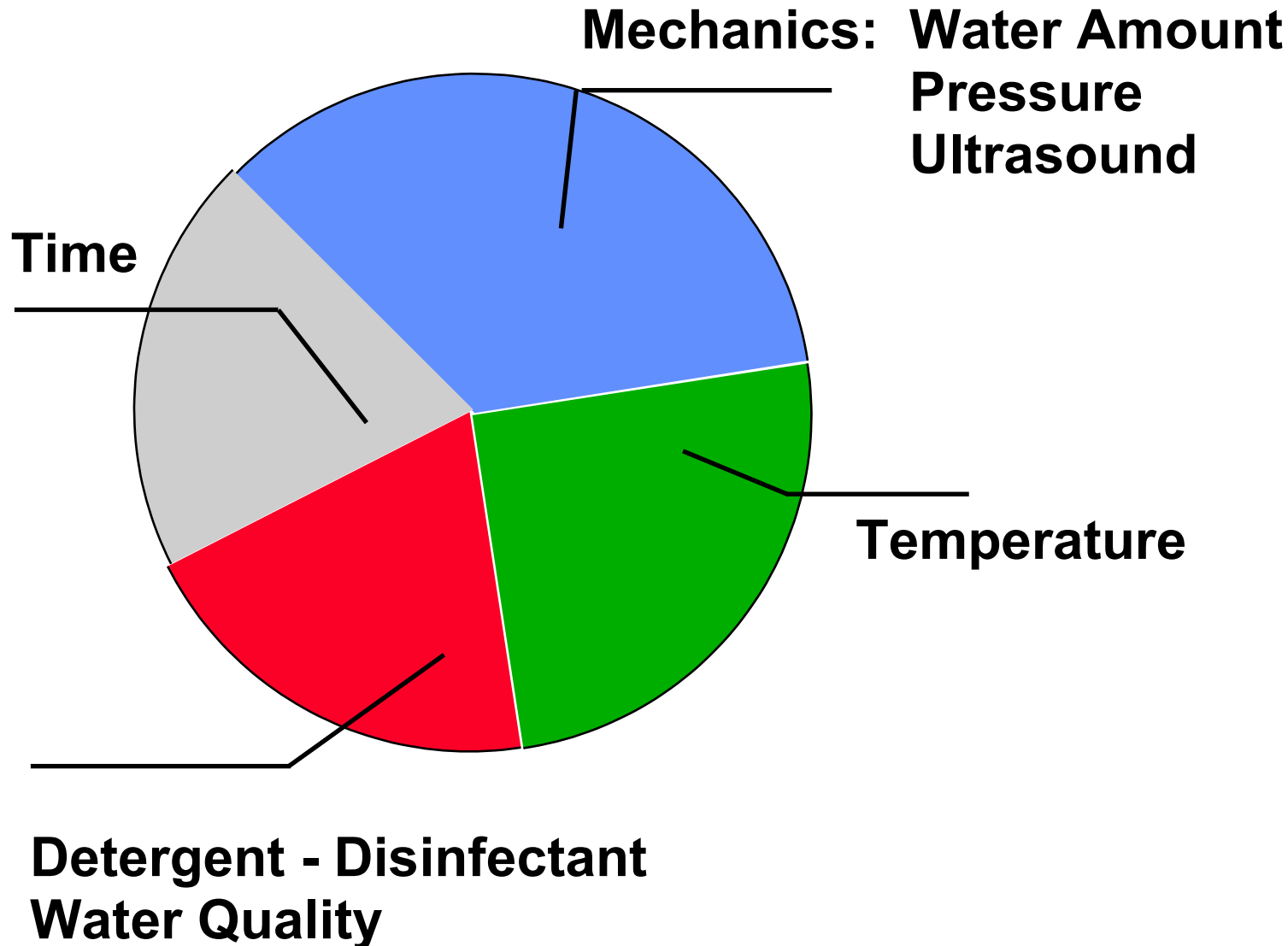
Ultrasound & Validation

Function
Intended (Re-)Use

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Hygiene & Reusability

Cleaning Parameters (Sinner) generally



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusibility

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**

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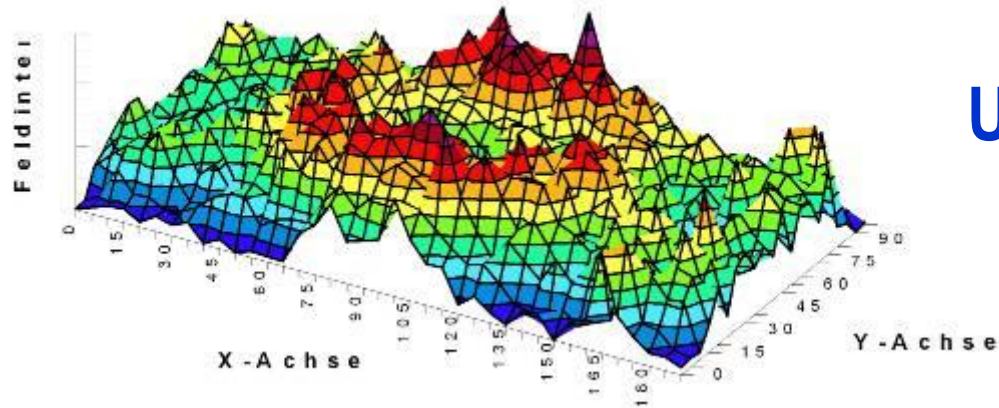
Ultrasound & Validation

Function
Intended (Re-)Use

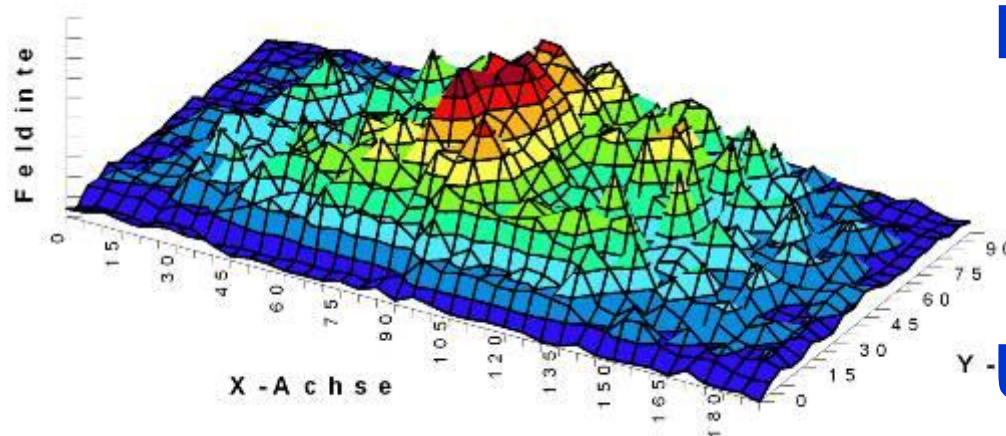
Design & Ergonomy

Hygiene & Reusability

Possible Energy Distribution



US 1



Different
Levels/Volumes

US 2

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Product & Process

Ultrasound & Validation

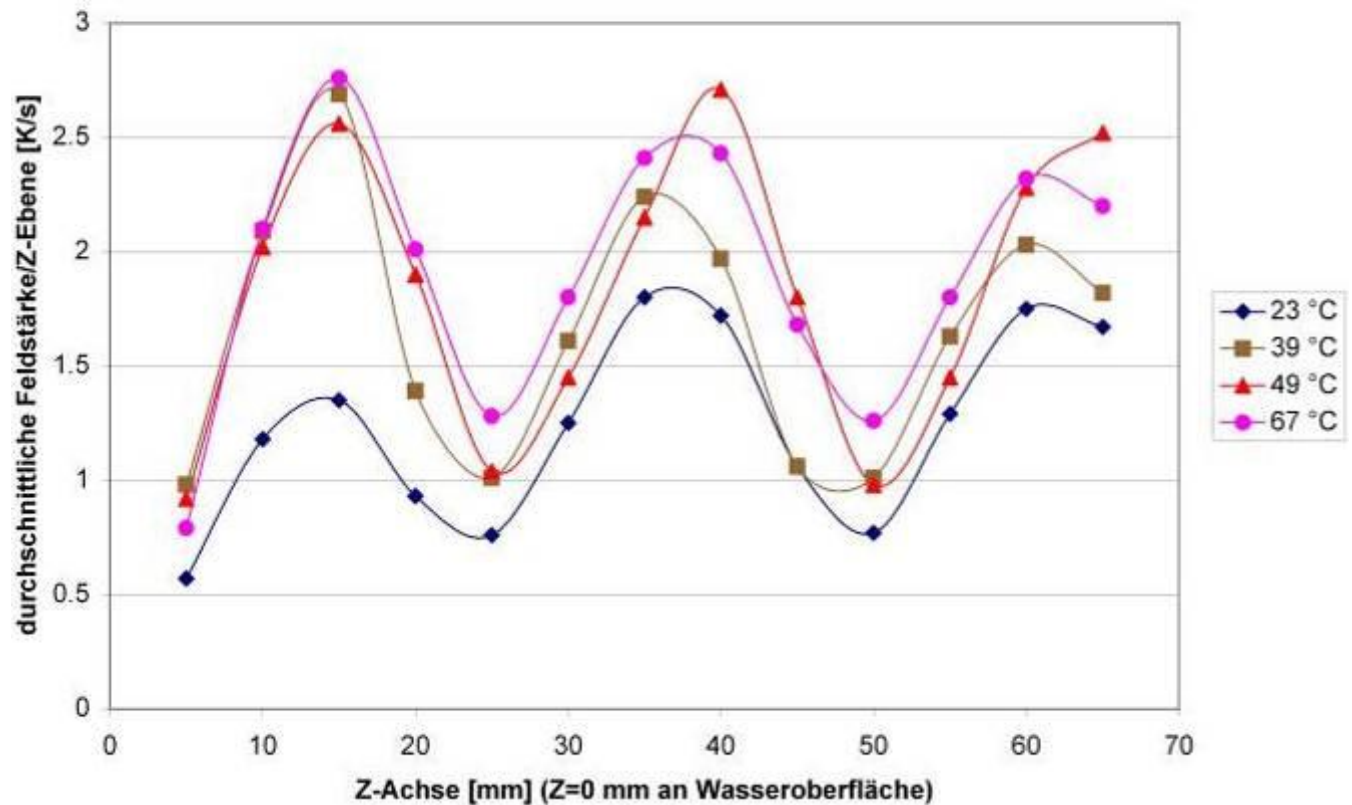
Function
Intended (Re-)Use

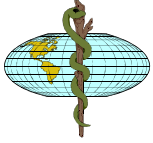
Design & Ergonomy

Hygiene & Reusability

Temperature Influence

Dependency of Field/Z-Level of Solution-Temperature





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?

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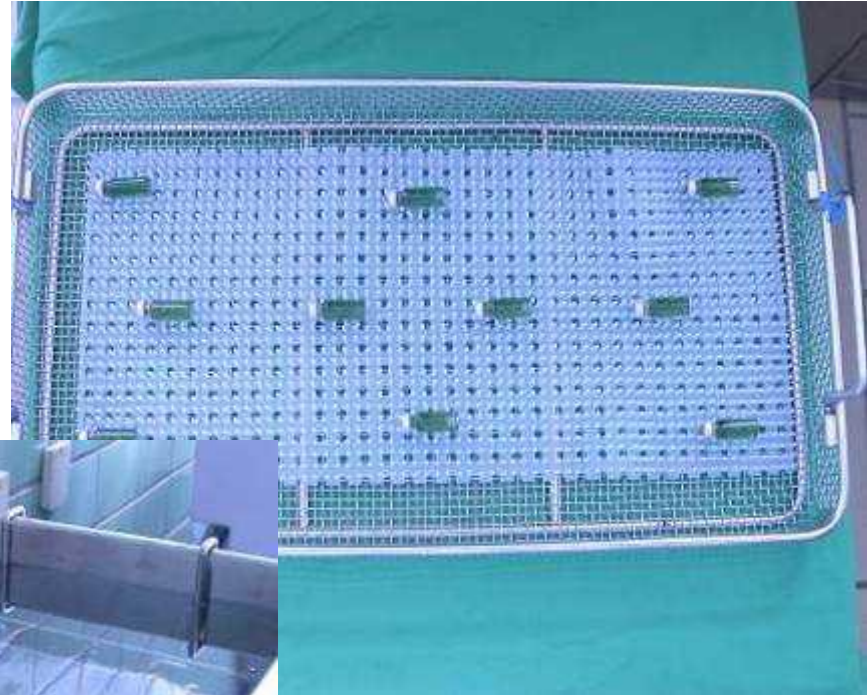
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Function
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Hygiene & Reusability

For Example: Influence of Silicon Mat



No Cavitation

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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Heavy Loads absorbing Energy

Too much is not enough





Parameters of Ultrasound (to conclude)

**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.**

**These results were confirmed by similar
investigations of L. Jatzwauk (Dresden,
Germany).**

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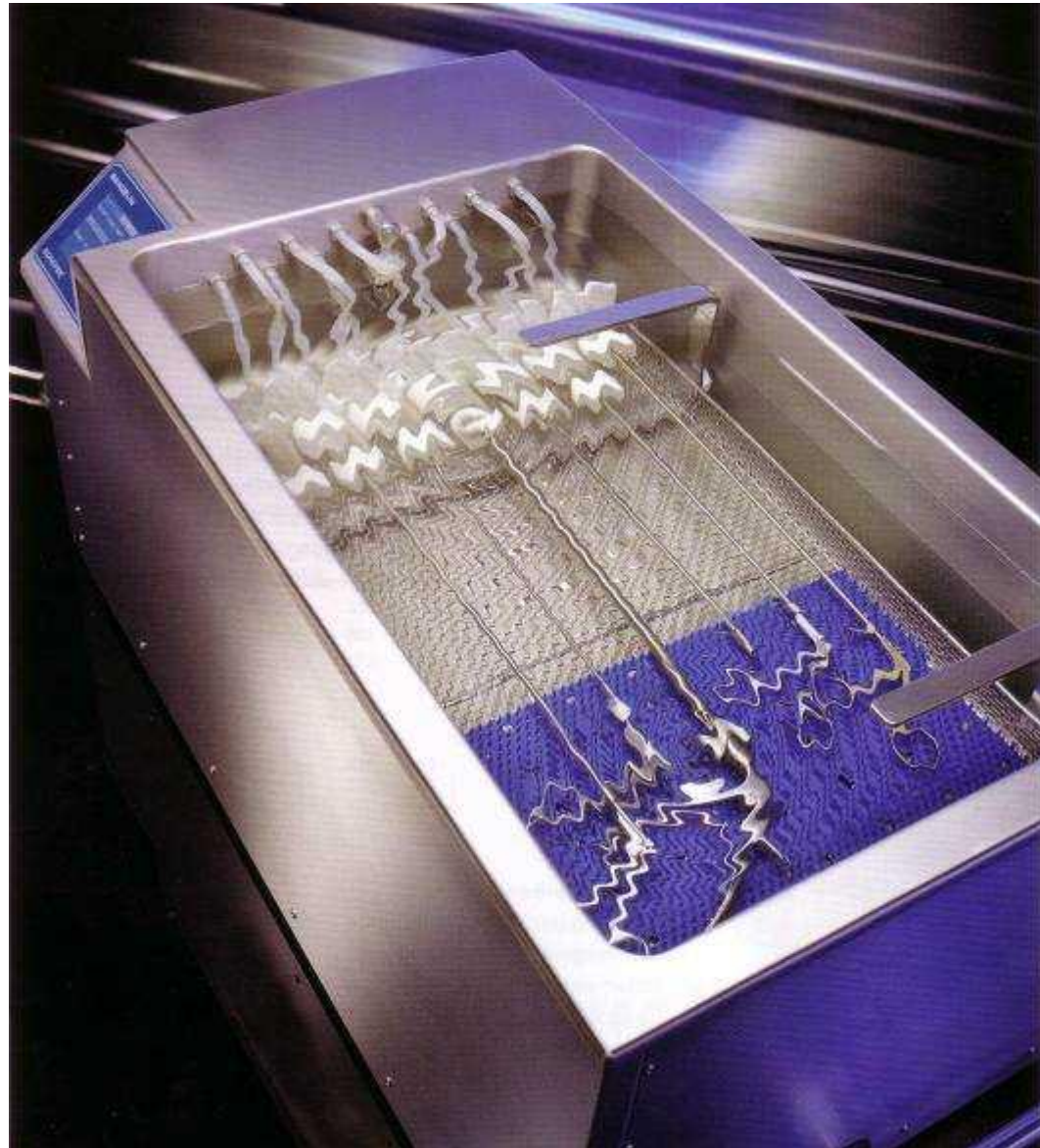
Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Ultrasound and Rinsing



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Ultrasound & Validation

Function
Intended (Re-)Use

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Hygiene & Reusability

What about Washer Disinfector?



**Washer Disinfector can possibly rinse even
Inner Lumina with a defined Pressure ...**

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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Automated Processing



**... if Positioning in specifically constructed Trays
is correct and the Pressure adequate high.**

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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Validation of the Cleaning Step ...

**Monitoring of
water pressure**



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Function
Intended (Re-)Use

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Hygiene & Reusability

.... beware of the Load!



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Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Cleaning must be(come) reproducible



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Intended (Re-)Use

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Hygiene & Reusability

Baskets allow Cleaning of Small Parts



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Hygiene & Reusability

Correct Cleaning dries the Load ...



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Function
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... the Precondition for Sterility



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Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Efficient Loads?



**Kidney dishes
are possibly
disposables.**

**Save the load for
instruments.**



Differing Loads

**Different parameters for cleaning efficiency:
Textiles have soft surfaces and big volumes.
Instruments are small and have hard and complexe**





**These are no
medical devices.
There „intended
use“ is somehow
different.**



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Product & Process

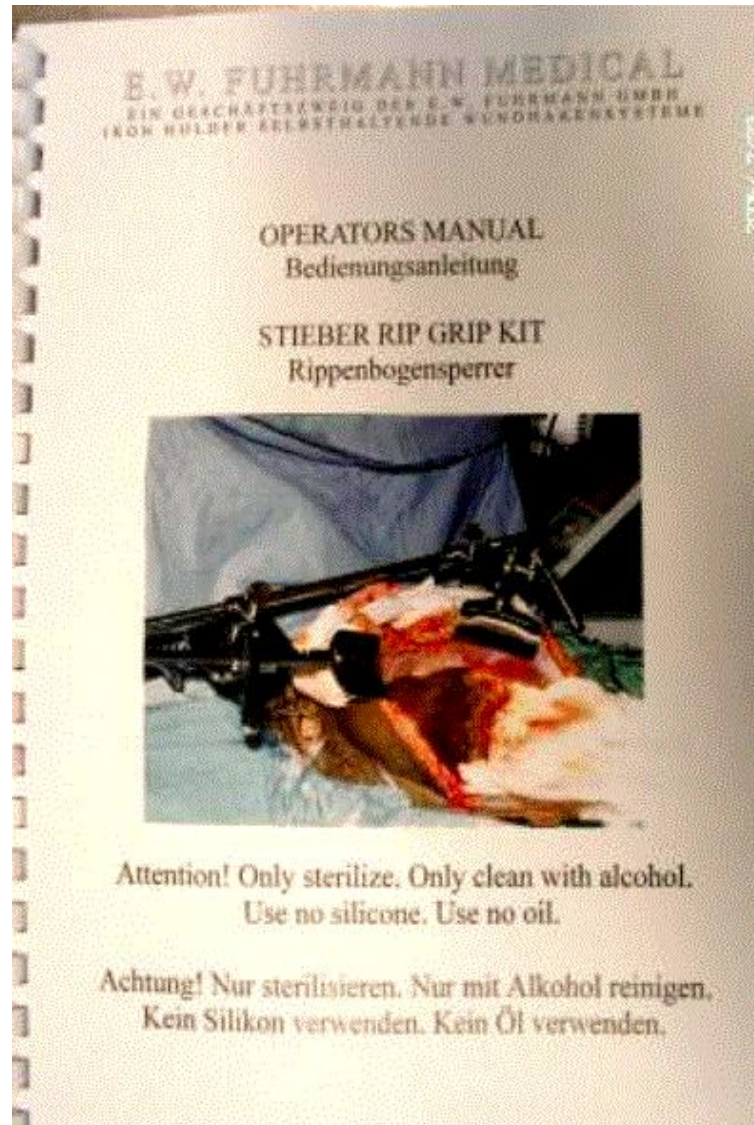
Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Incomplete Manual



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.**

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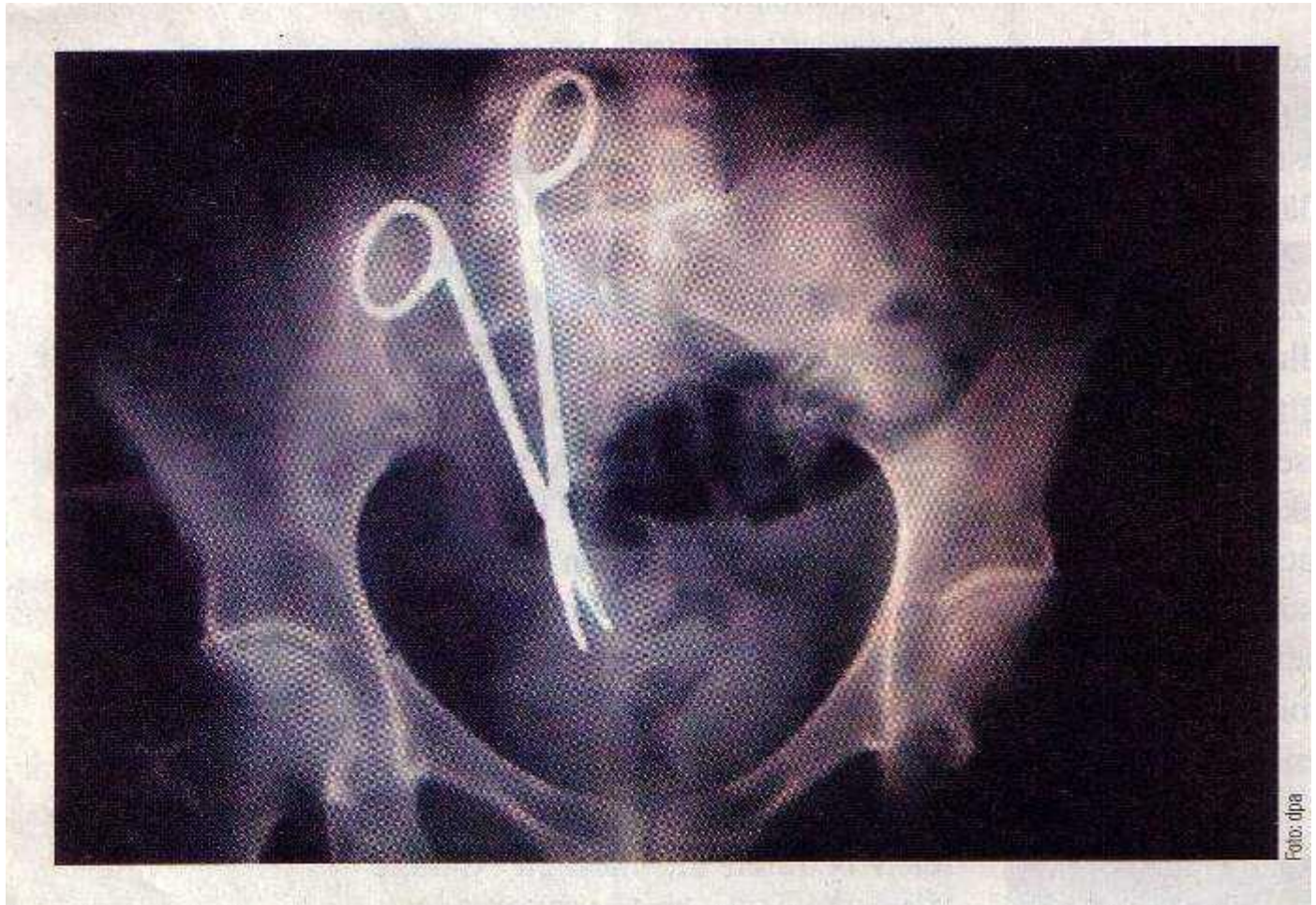
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Function
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Hygiene & Reusability

The right instrument in the wrong place



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Hygiene & Reusability

Adequate Transport Containment.....



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

..... ready for Automated Cleaning



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Function
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Design & Ergonomy

Hygiene & Reusability

Transport and Cleaning Tray



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Inadequate Container





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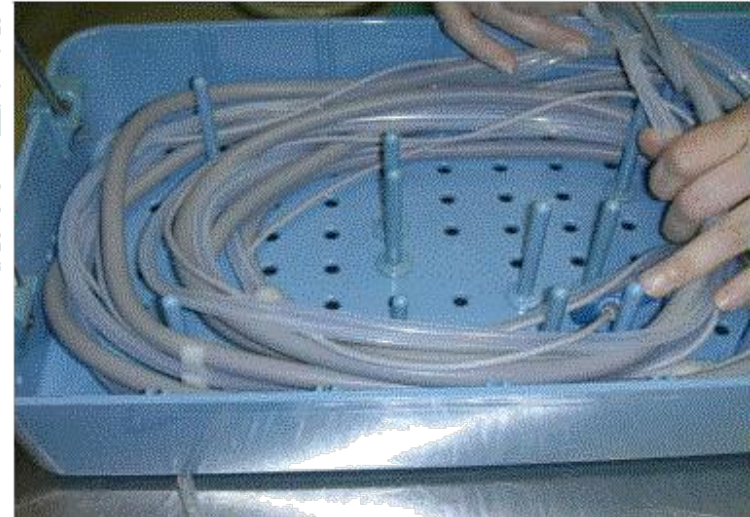
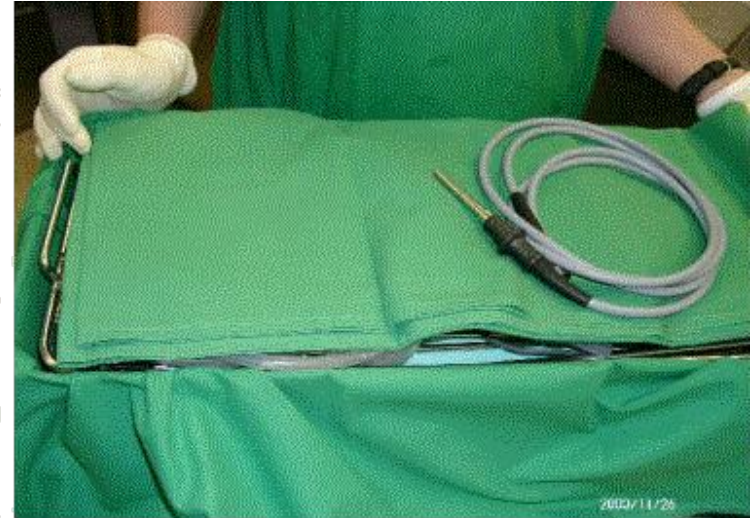
Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

The Art of Packaging



Failures...



Wet means not sterile!

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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Trays for trauma ... are sometimes a trauma!



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Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Modern Set-Pack with Baskets



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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Packaging



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Product & Process

Ultrasound & Validation

**Function
Intended (Re-)Use**

Design & Ergonomy

Hygiene & Reusability

Sealing



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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Correct Sterilisation - what's inside?



Sterile Units:

6 StE

98,5 kg



4 or 5 StE

Mixed Fill?

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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

Design & Ergonomy

Hygiene & Reusability

Documentation is knowledge

Appropriate means?

Just do it!



Clinical Investigation & Application



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Product & Process

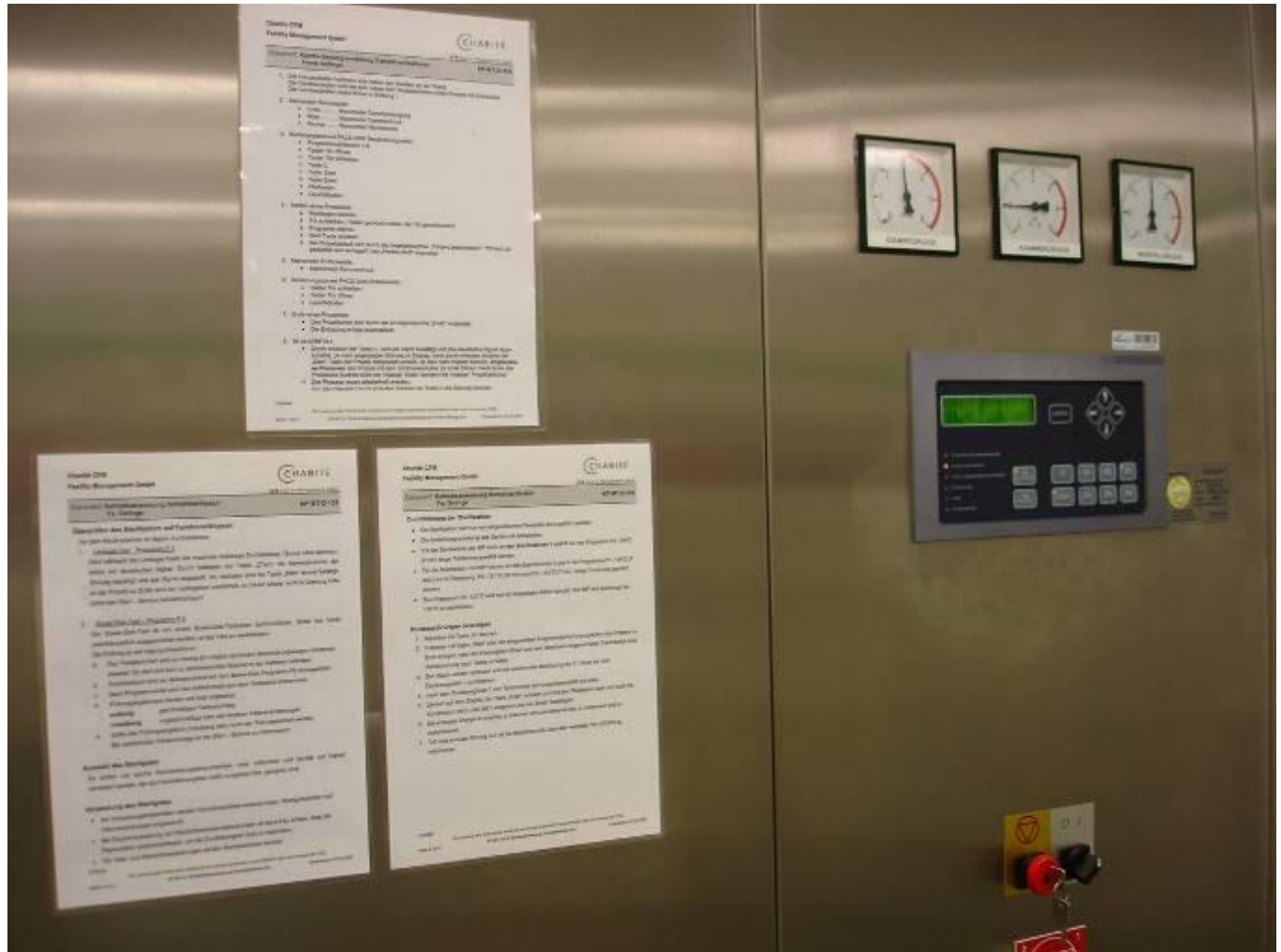
Ultrasound & Validation

Function Intended (Re-)Use

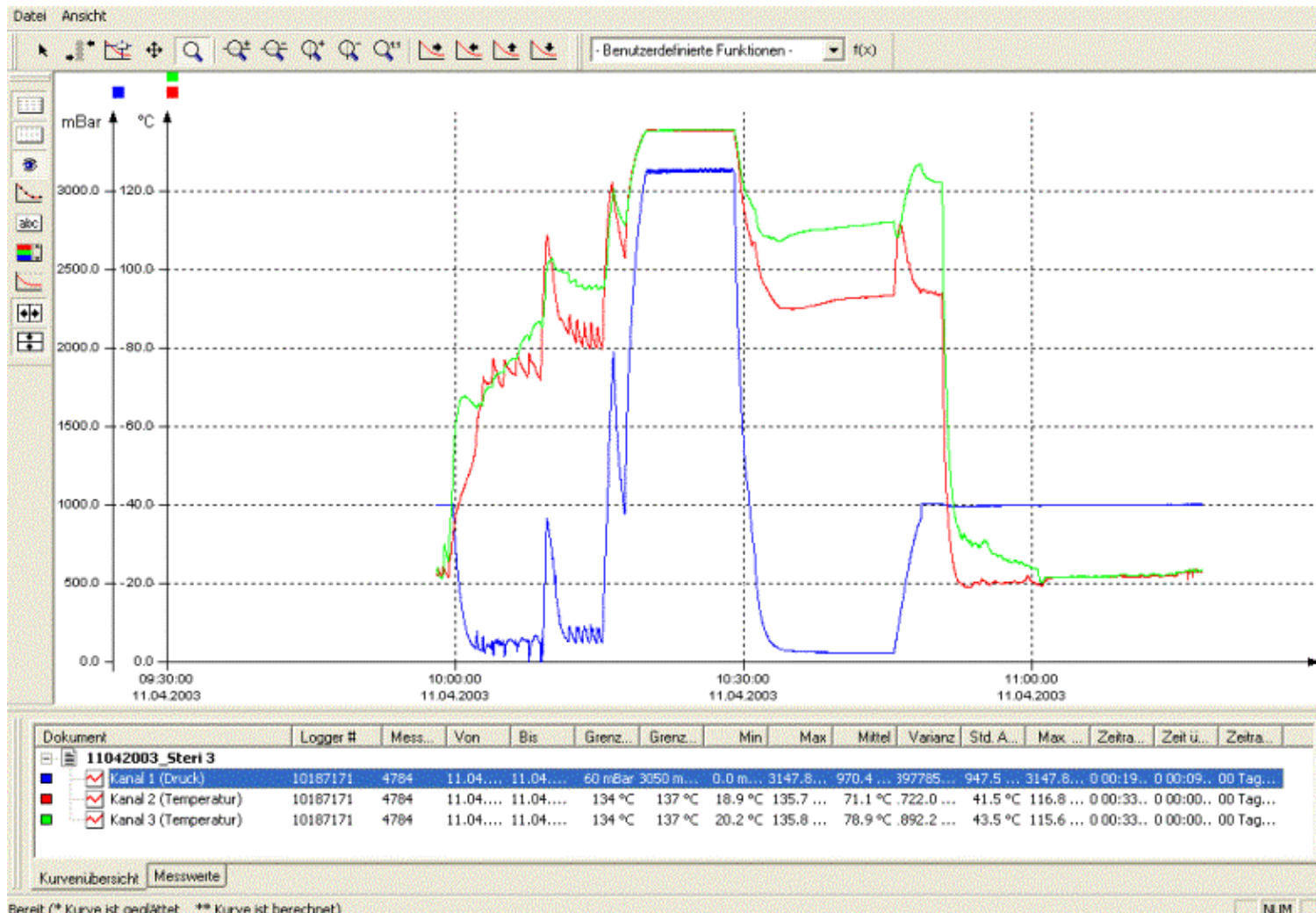
Design & Ergonomy

Hygiene & Reusability

Working place description in place



Process Control (not only) for Sterilisation



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Product & Process

Ultrasound & Validation

Function
Intended (Re-)Use

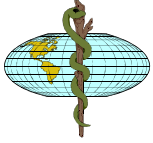
Design & Ergonomy

Hygiene & Reusability

Alternatives to steam



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Regulatory Affairs

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

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Product & Process

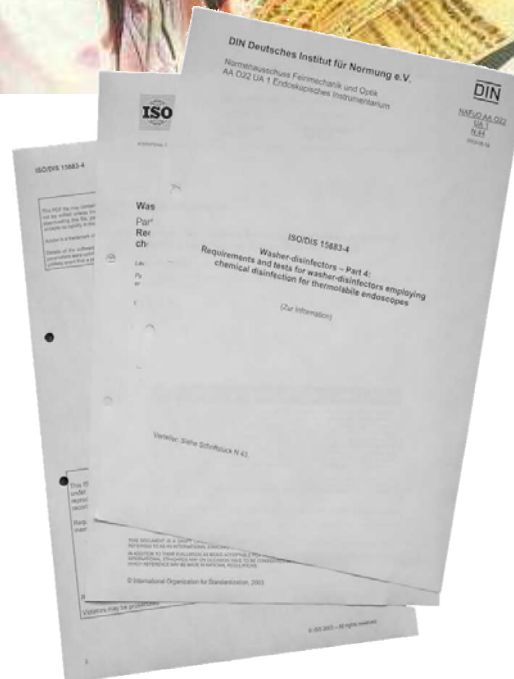
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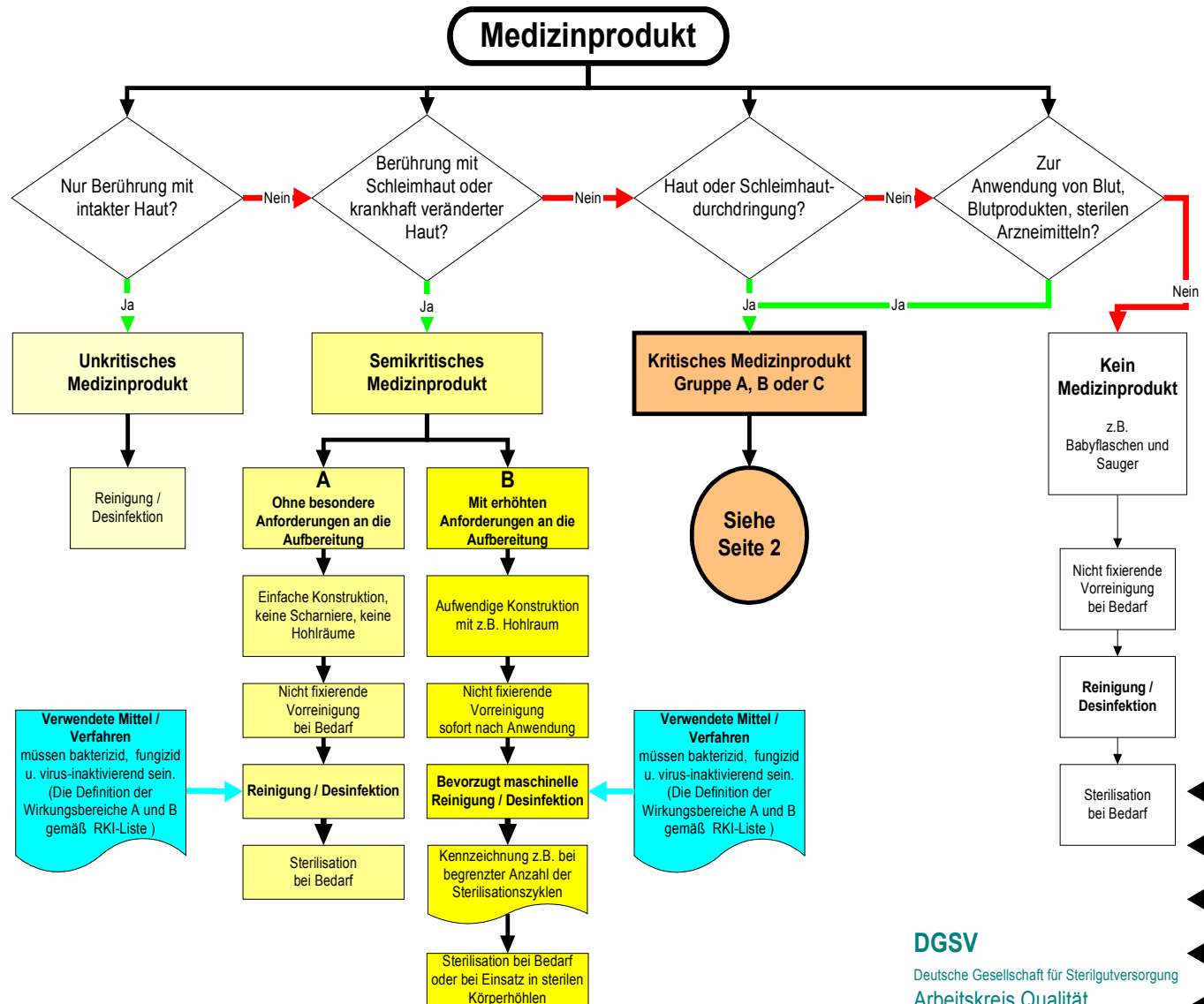
Hygiene & Reusability

Regulatory Affairs - debatable



„DIN, DIN-EN (CEN), DIN-ISO und Richtlinien oberster Bundesbehörden (BGA/RKI) gelten als antizipierte Sachverständigengutachten zum aktuellen Stand von Wissenschaft und Technik. Der Bundesgerichtshof hat in ständiger Rechtsprechung ein Abweichen von DIN-Normen, sowie von Richtlinien oberster Bundesbehörden als haftungsbegründend im Schadensfall bewertet, wenn der Verantwortliche nicht nachzuweisen vermag, dass der Schaden auch bei Beachtung dieser Vorschrift eingetreten wäre.“

*Bundesgerichtshof – Entscheidungen in Zivilsachen
103, 338, 341*



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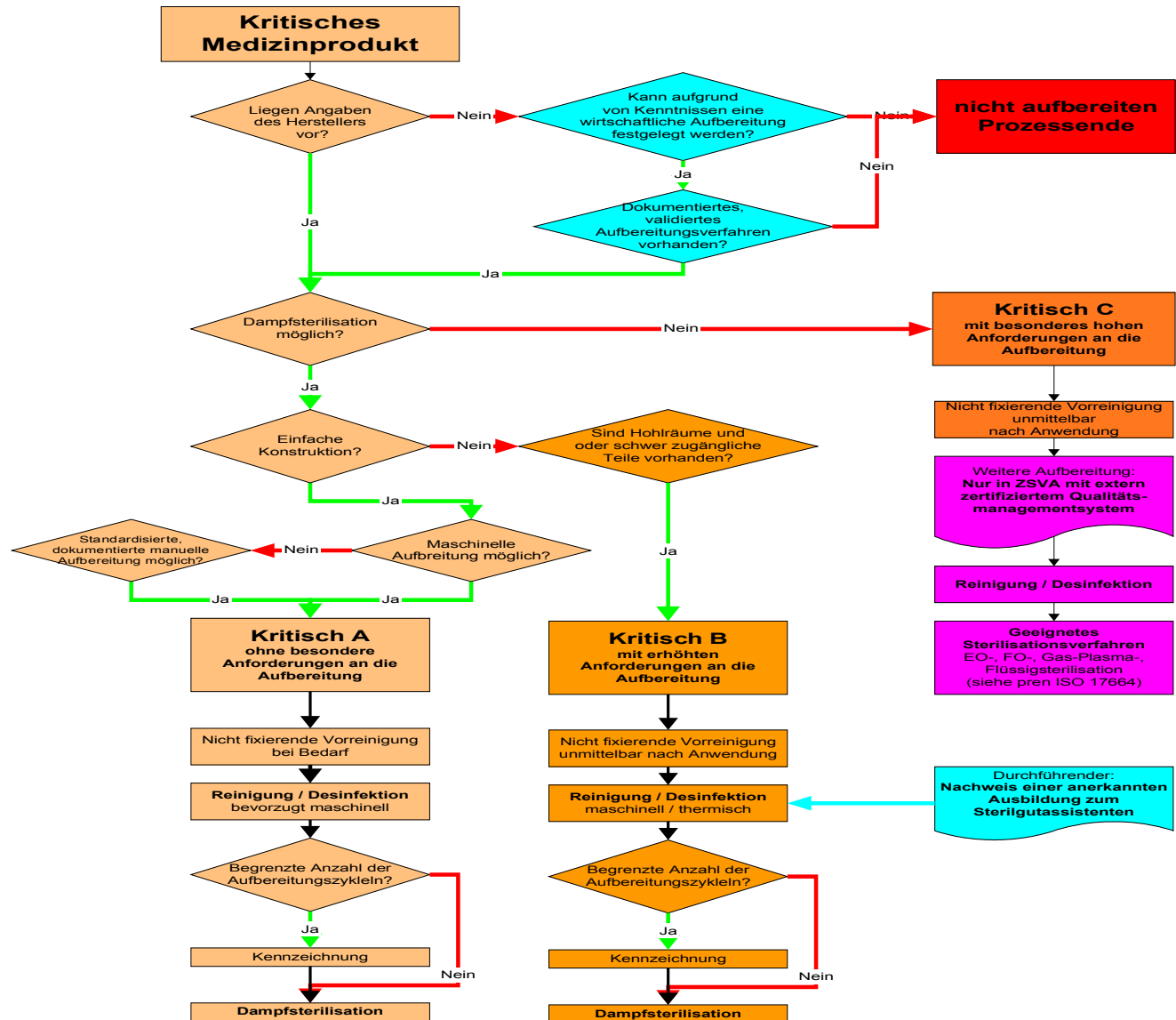
Product & Process

Ultrasound & Validation

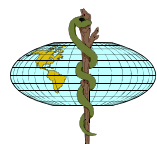
Function Intended (Re-)Use

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China – Provisions for Medical Device Classification

Criteria for Medical Devices Classification									
Contacting or Inserted Device A									
Form of Operation	Temporary use-1			Short-term use-2			Long-term use-3		
	Skin/ Cavity and Tract	Trauma/ Tissue	Blood Circulation/ Central Circulation	Skin Cavity and Tract	Trauma/ Tissue	Blood Circulation/ Central Circulation	Skin Cavity and Tract	Trauma/ Tissue	Blood Circulation/ Central Circulation
Passive Device A									
1 Device for transportation and storage of pharmaceutical liquid	2	2	3	2	2	3	2	3	3
2 Device for alteration of blood and body fluids	–	–	3	–	–	3	–	–	3
3 Device for medical dressing	1	2	2	1	2	2	–	–	–
4 Surgical instruments (inserted)	1	2	3	2	2	3	2	3	3
5 Reusable surgical instruments	1	1	2	–	–	–	–	–	–
6 Disposable aseptic surgical Device	1	2	3	2	3	3	2	3	3
7 Implantables	–	–	–	–	–	–	3	3	3
8 Device for contraception and birth control	2	2	3	2	3	3	3	3	3
9 Device for sterilization and cleaning	2	2	2	2	2	2	2	2	2
10 Other contacting passive device	1	2	3	2	2	3	2	3	3
Form of Operation	Minor Injuries-1			Injuries-2			Serious Injuries-3		
Active Device B									
1 Device for treatment through energy	2			2			3		
2 Device for diagnostic monitoring	2			2			3		
3 Device for body fluid transportation	2			3			3		
4 Device for ionized radiation	2			3			3		
5 Other general active device	2			2			–		
Non-contacting Device B									
Form of Operation	Basically or No Impact			Indirect Impact			Substantial Impact		
Passive Device A									
1 Device for patient care	1			2			–		
2 In vitro diagnostic reagent	1			2			3		
3 Other supplementary device	1			2			–		
Form of Operation	Basically or no Impact			Indirect Impact			Substantial Impact		
1 Device for laboratory use	1			2			–		
2 Device for sterilization	1			2			–		
3 Other supplementary device	1			2			–		

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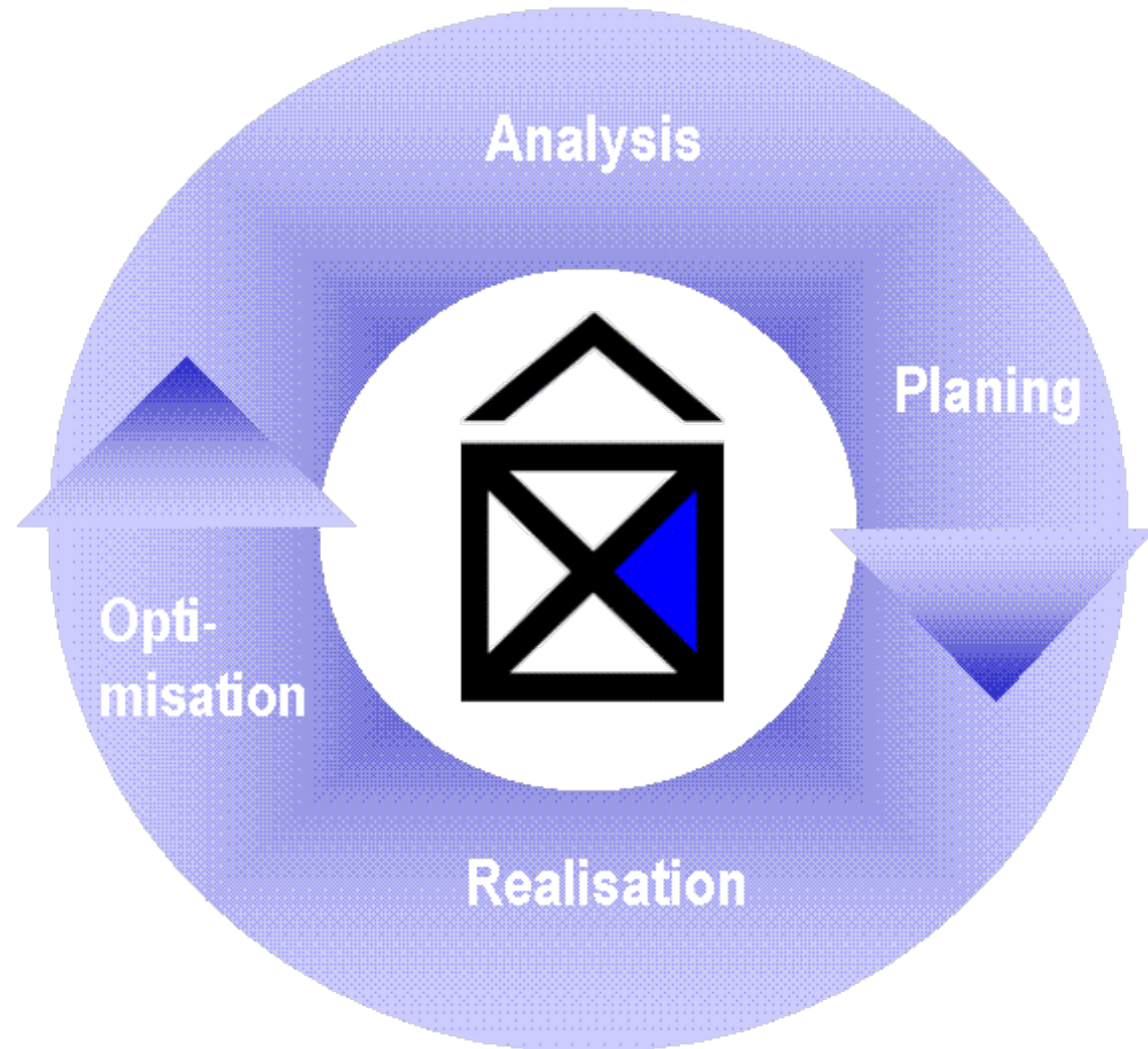
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Quality Cycle





Hygiene & Reusibility

**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**



Hygiene & Reusability

... but how „common“ is the interest?

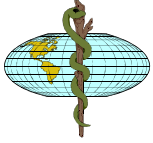
First: What kind of Operation is performed?

Liability and Weighting of the Interests:

Indication for Surgical Intervention can be

- **Vital (Accident)**
- **Elective (Gall Bladder)**
- **Optional (Liposuction)**

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Hygiene & Reusibility

... 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



.....?! 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, Documentatio



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„Process Control“ next ...

Vorankündigung
9. Internationales
FORUM 2008
Medizinprodukte & Prozesse
29. Februar 2008 Berlin



„Prozesskontrolle“

Chirurgie-Instrumenten Arbeitsgruppe (CLEANICAL®) Berlin

Teilnahmegebühr inklusive Referateband deutsch-englisch
90,00 €
Frühbucher bis 21.12.2007
70,00 €