Processing of Medical Devices: Risk Management and Plausibility Control

Interlockmed
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Dr. med. Dipl.-Ing Thomas W. Fengler
Chirurgie Instrumenten Arbeitsgruppe Berlin

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Berlin at night…

…nice events

Other events…

…may become incidents!

The evidence* of a final event:

risk

* *evidence* - the available body of facts or information indicating whether a belief or proposition is true or valid

https://en.oxforddictionaries.com/definition/evidence

A risk is the possibility of harmful *events.*

A risk is the possibility of harmful *events…* possibly arising from the intended use of a medical device (MD)

Today, a given clinical environment (medically, technically) faces changes as the events of lethal outcomes (duodenoscopy, USA) led to a worldwide discussion about which are the crucial elements of processing of flexible scopes.

- Do we have “critical” procedures in duodenoscopy, bronchoscopy, and/or in the urogenital indications?
- Is “high-level” disinfection enough?
- How can we avoid biofilms which are often detected if work channels are stripped and extracted from the scope?
- How can we measure contamination? By dilution with sterile water or microbial investigation of the brushes?
- Is brushing and flushing efficient enough for cleaning?

The main aim of hygiene is prevention of such *events*.

Surgical (endoscopical) intervention is event-related.
An „event“ for…

- the patient: expectation of minimal invasiveness
- the medical device: frequence of use, misuse, life span
- the variety of accessories: disposable or reusable (valves, brushes, pouch or container)
- its processing processes: countable (t, T) or “narrative” (SOP) parameters
- the staff: personal protective equipment (PPE), skills
- the infected patient: “evidence”

The operator has the responsibility for results

Operator responsibility pertains to all services of a hospital or other health care facility, which includes the processing of medical devices (MD), usually carried out in a Sterile Processing Department (SPD) or Central Sterile Supply Department (CSSD) or Reprocessing Unit for Medical Devices (RUMED).

There is an obligation to actively request/seek out information in order to keep up with current developments.

The delegation of responsibilities (e.g. to service providers) does not affect the responsibility for the results. The onus of control is on the operator, within his stipulated mandate to provide care.

The manufacturer provides the necessary information for use (IFU) and after sales services supporting the customer.

Risk management
is a part of quality management

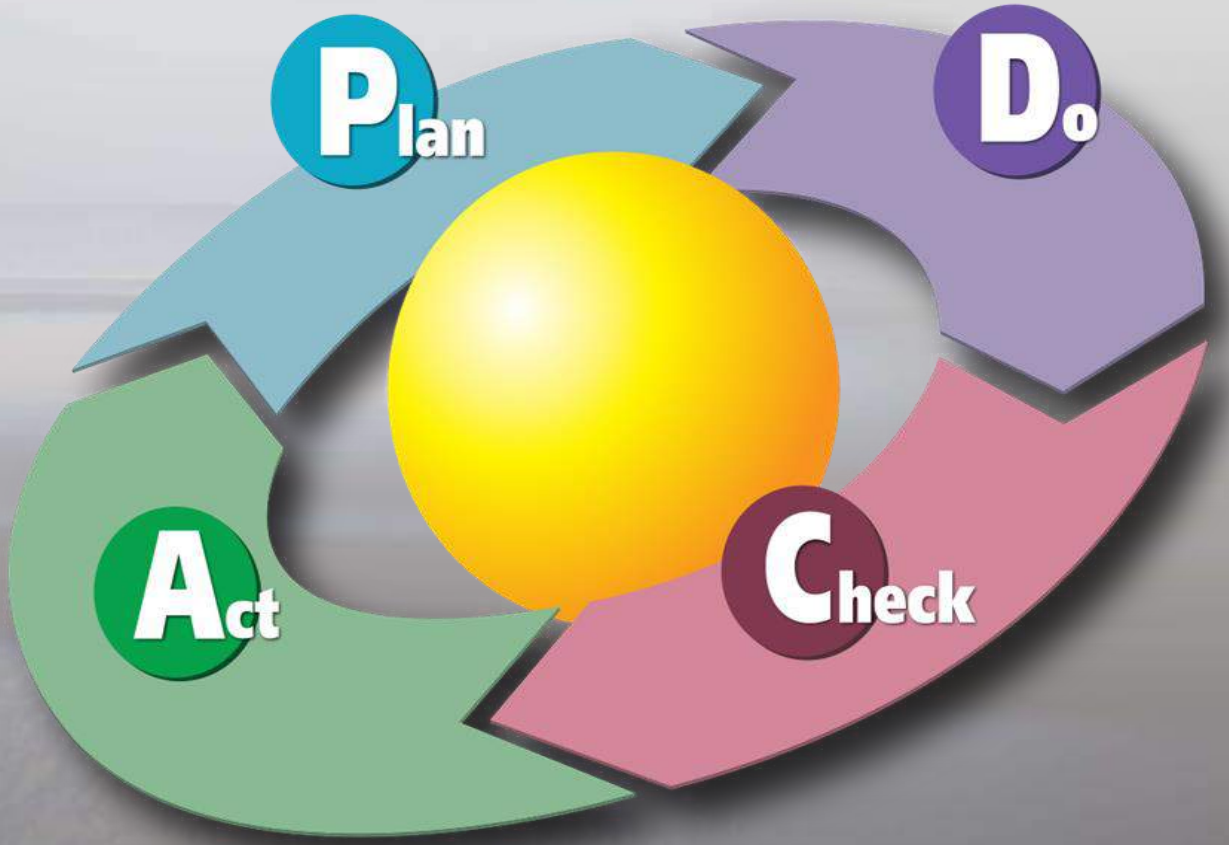
1. Why risk management?

Responsibility
Because an operation is very dangerous for a patient (in this situation he is not a client anymore).

2. Why plausibility control?

Evidence
Because work must be carried out focused, efficiently and purposefully after all (“just do it, or get it done…).

The PDCA-Cycle (Deming)



A risk exists everywhere in life, limiting it is an essential part of reasoned conduit and interaction between humans; to reduce it is a part of the quality management of an organisation, e.g. a hospital.

Problems → Tasks → Solutions

Sufficient and appropriate medical devices (MD)

Facilities (quality, quantity of equipment)

Training (on the job, hands on, education)

Processing steps (to be described)

Acceptance criteria (parameters or SOP)

Certified process quality (verification & validation)

Processing following norms and guidelines (state of art)

What is a risk?

Risk is the possible negative outcome of taking action or inaction, combined with damages, disadvantages or loss. Also defined as the intentional interaction with uncertainty.

Risk = probability x expected loss

Examples:

- “Fear the risk” or take it into account
- “A big risk” might be the lack of sterility in MD.
- The patient and health facility are “taking a risk”.
- The operator shall “not take any risks”.
- The insurance company “carries the risk”?
- “Taking into account” and “thinking through the risks” shows responsibility.

Risk management

Risk management is executed in such a way that possible risks are

- identified
- weighed
- eliminated
- or at least minimized

with regard to the patient, the clinical user or a third person.

The way to go about it is to identify and describe occurring problems (e.g. cleanability), transform them into tasks (e.g. assure safety of verified processing steps) and to find solutions (e.g. standard operating procedures - SOP) that can be (and has to be) controlled during the work process.

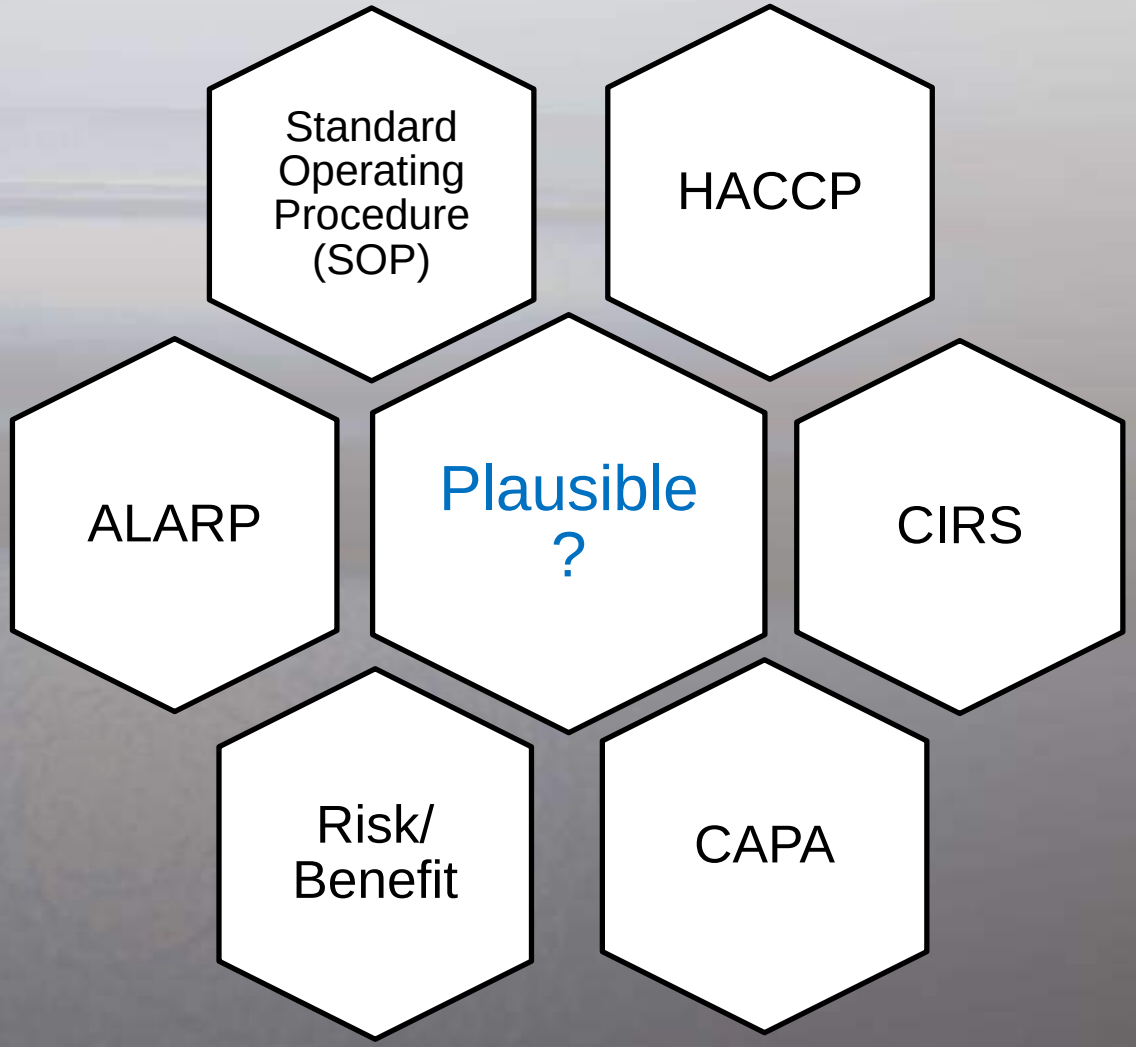
Risk management

We need parameters for standardization of the production of processed items.

Our means of control are few:

1. Control of standard operating procedures (SOP)
2. Visual-tactile inspection
3. Monitoring physical parameters (time, pressure, temperature, concentration, conductivity) with data loggers or colorimetry (Bowie Dick, ink indicators)
4. Routine testing (verified and validated test system)
5. Organized documentation (in written)

Principles of risk management



Principles of risk management

Corrective and Preventive Actions (CAPA)

Quality management concept for systematic investigation of discrepancies (e.g. failure/deviations) in order to avoid repeated occurrence (“corrective action”) or to prevent the occurrence in advance (“preventive action”).

To ensure that the measures are effective, a systematic study of outages or deviations is essential.

A system could be for example ISO 13485 or ISO 14971 or the ISO 9000 series.

Principles of risk management

Hazard Analysis and Critical Control Points (HACCP)

A critical control point is a point, step or procedure in the whole processing process, at which controls are possible in order to prevent risks arising from the medical device, so as to eliminate or reduce them to an acceptable level.

Through a hazard analysis, potential hazards (= risks) can be identified and plans for countermeasures be drafted. The control points need to be specified and action limits at each point are to be determined.

The critical intervention limit is the maximum or minimum value, that physical, chemical or biological hazards must be checked for, in order to avert or eliminate a threat, or reduce it to an acceptable level.

Principles of risk management

As Low As Reasonably Practicable (ALARP)

In essence, making sure a risk has been reduced. ALARP is about weighing the risk against the sacrifice (cost, effort) needed to further reduce it. The decision is weighted in favour of health and safety because the presumption is that the duty-holder should implement the risk reduction measure. To avoid having to make this sacrifice, the duty-holder must be able to show that it would be grossly disproportionate to the benefits of risk reduction that would be achieved. Thus, the process is not one of balancing the costs and benefits of measures but, rather, of adopting measures except where they are ruled out because they involve grossly disproportionate sacrifices.

Principles of risk management

Risk Benefit Analysis – weighing the goods

In some cases the only way to mitigate a risk may be to do without a specific instrument. We need it, but we cannot clean it properly. The decision to use this instrument requires the residual risks to be balanced against the anticipated benefits of the procedure.

Sometimes these judgments can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient. It is up to the user to judge if infection is possible.

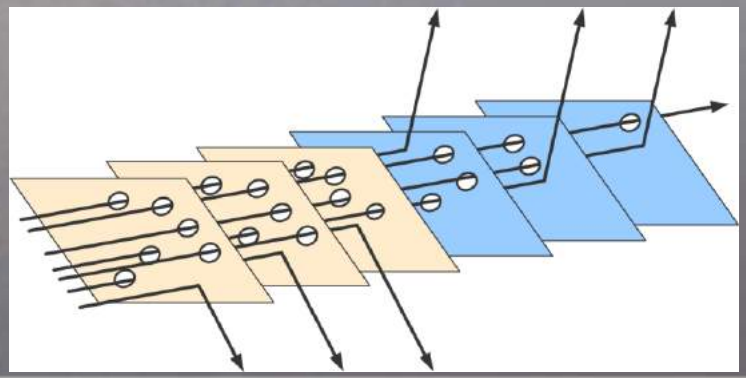
With the help of the IFU and on the basis of the existing medical device he might come to the conclusion that it is better not to use it. Or he makes sure, perhaps even by tests of his own and interpretation of the results, that the risks are bearable, because a method for cleaning is described.

Principles of risk management

Critical Incident Reporting System (CIRS)

Risk documentation can be done by CIRS, a reporting system for anonymous reporting of critical incidents and near-misses as an essential part of quality management.

The goal is risk reduction by closing holes in the multi-layered defenses against risks, which are often due to active and latent failures (Swiss cheese model). This is not possible without risk monitoring and testing.



Principles of risk management

Establish responsibility

Plausibility Control

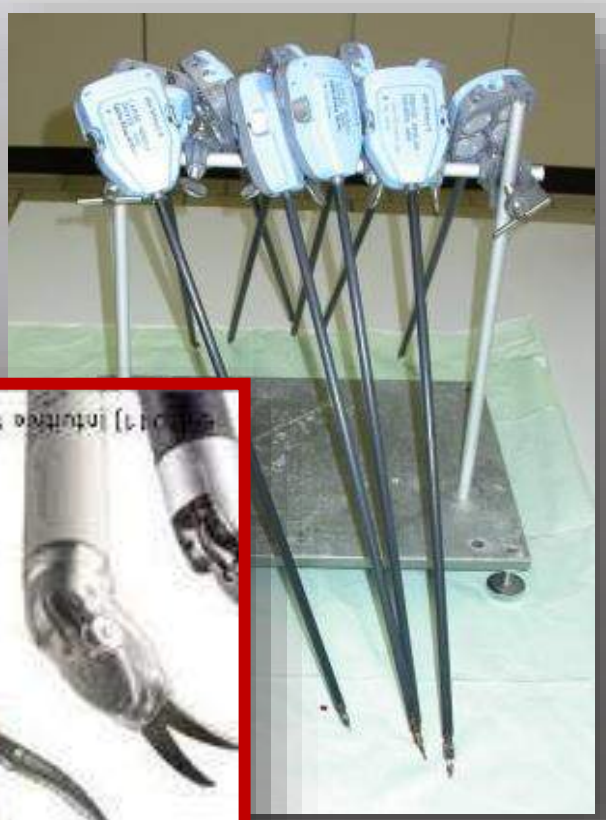
Risk analysis must face plausibility checks in the first place, before planning an (evidence-based) study. The plausibility check is a rough estimate verification of a result, whether something is plausible (acceptable, reasonable) at all.

Do the figures make sense? Thus a possible obvious mistake can be detected early on. And sometimes, this is really all it takes! Plausibility checks can be carried out with only minimal effort on the basis of already existing knowledge.

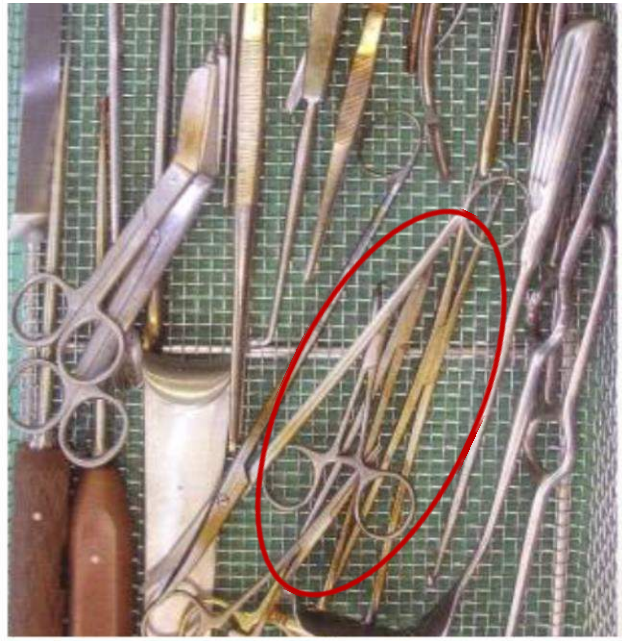
"The absence of evidence is not the evidence of absence"

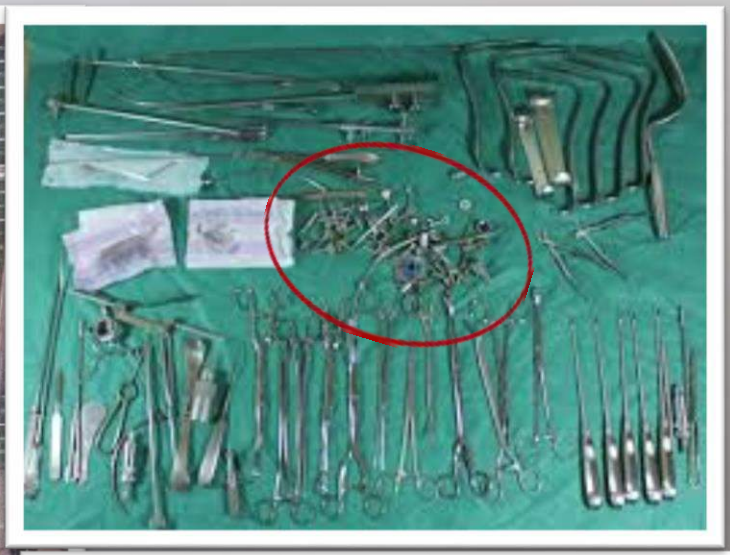
Plausible:

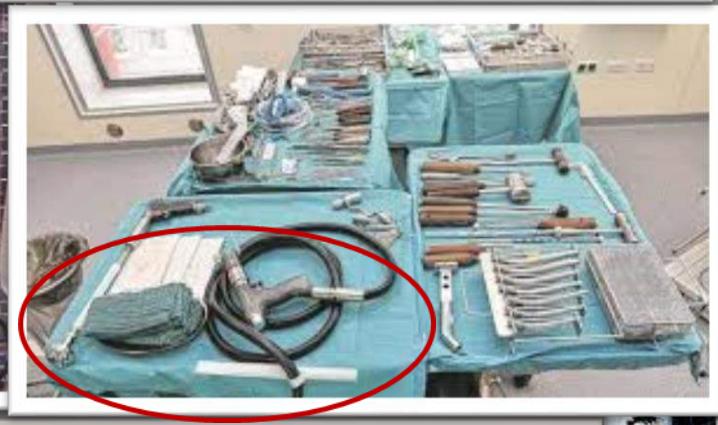
complex manipulators of robotic surgery are complex in processing



Plausible: Similar MD pose similar risks
→ creating MD families







Risk assessment: requirements for grouping into those families to anticipate processing issues of specific MD:

- Which instruments are potentially “problematic”?
- In which way (function, cleanability, sterilization)?
- Which MD requires a manual pre-treatment?
- Which MD must be validated (following a specific protocol)?
- How can they be validated (design of the protocol)?
- Which parameters are known for the different processing steps including mechanically supported “automated” washing and disinfection processes as well as manual aspects?
- Or is it narrative requiring a standard operating procedure?
- Specific protocols shall only include relevant and structured information for documentation.

Endoscope families

Risk assessment
Manufacturers of endoscopes and endoscope WD

Group 1

- with air/water channel
- with an instrument and suction channel
- with/without an additional instrument channel
- with an additional rinsing channel

Gastroscopes, colonoscopes

Group 2

- With air/water channels
- With an instrument and suction channel
- With(out) and additional instrument channel
- With(out) Albarrán channel
- With up to 2 steering channels for balloon catheter

Gastrointestinal tract

Group 3

- With up to 2 channels, but without channel system in supply tube
- Without channels in the entire endoscope

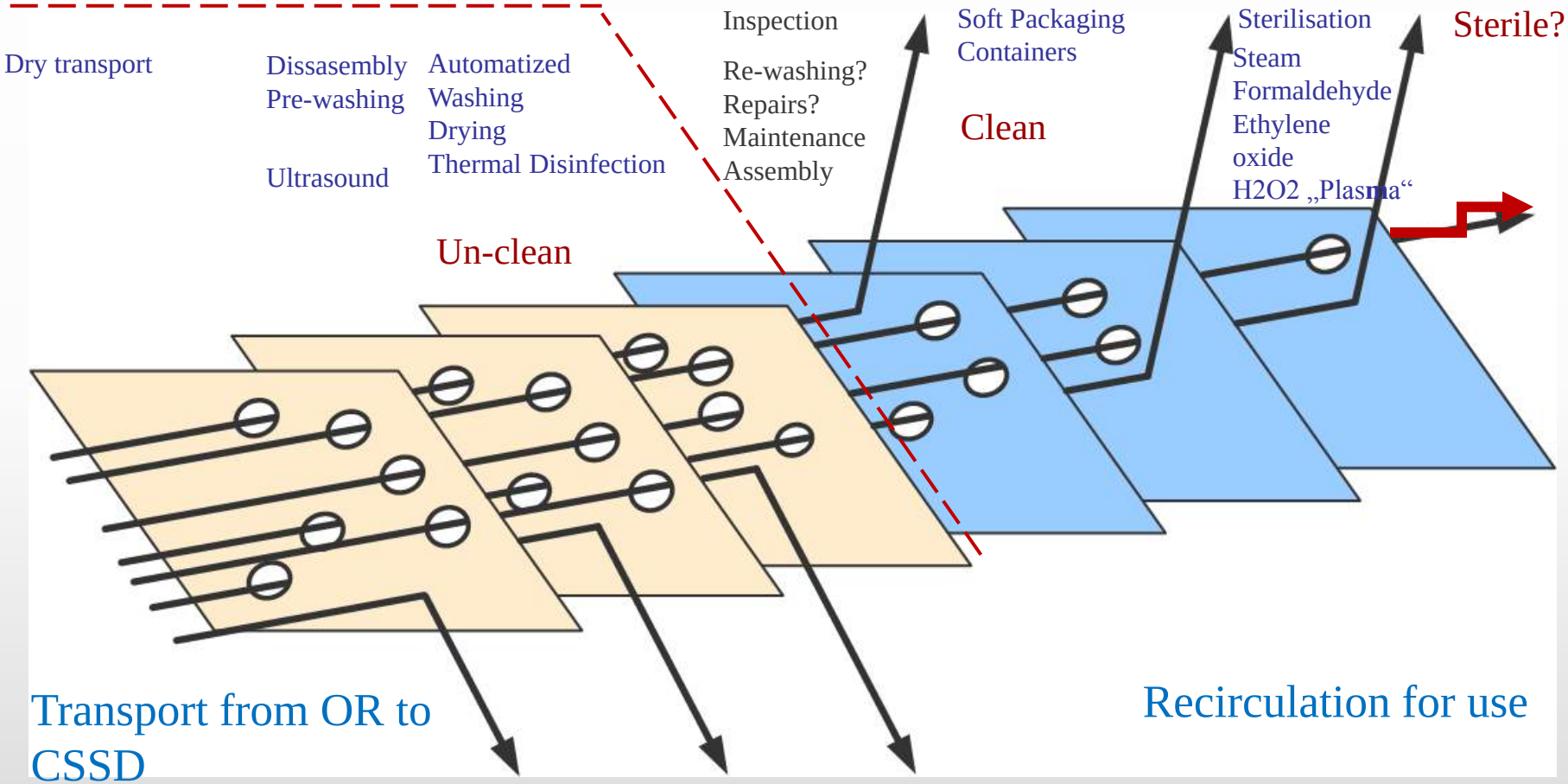
Bronchoscopy, Otorhinolaryngology, urology

When risks lead to damage, it is an event (or evidence)

A measure to lower the existing risk:

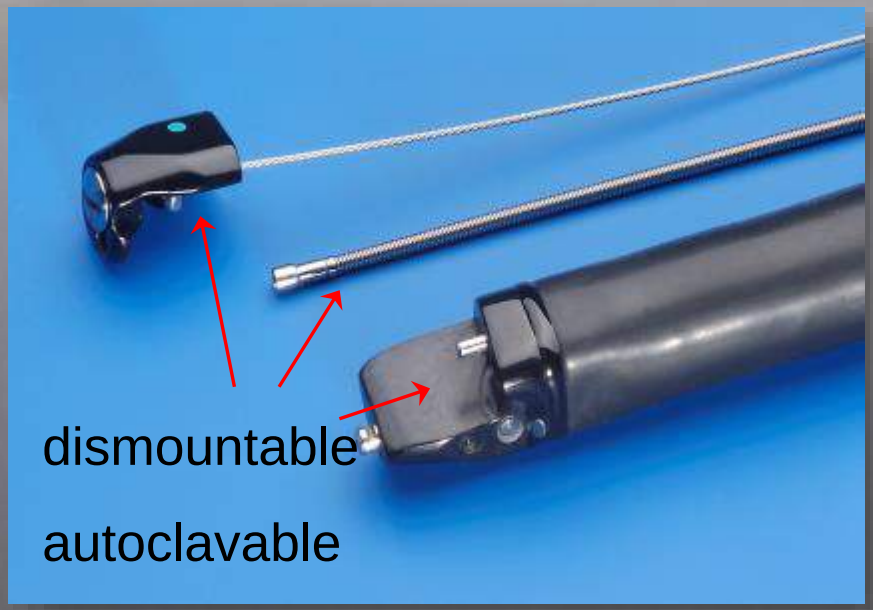
leak test following the information for use (IFU) of the manufacturer

Step by step: Hazard analysis and critical control points



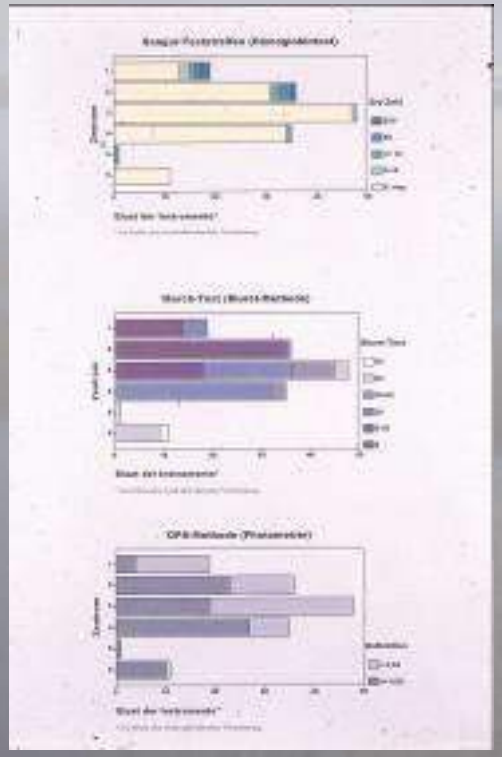
Risk reduction options:

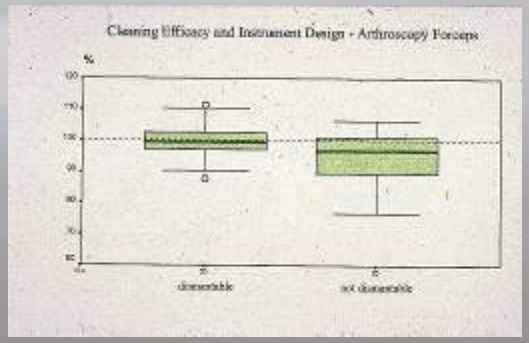
Innovative product solutions for processability of Albarrán mechanism.



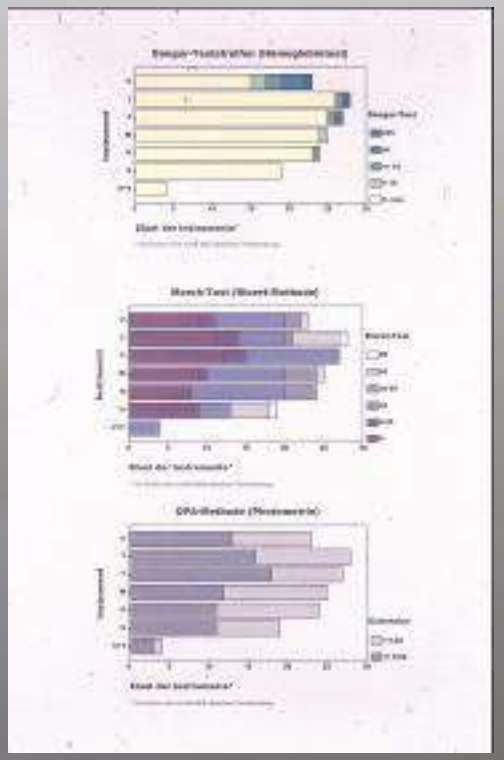
Investigating the risks:

Construction of instruments for correct function (and adequate use)





Arthroscopic forceps
dismantable (yes/no)



Related to processing unit in the hospitals

Related to MD

Evaluation of risks:

Is there any evidence of contamination?

The proof of protein traces in our clinical multicenter study 1999-2001* showed that 1-2 out of 3 MD showed protein traces in the solution.

Study profile:
Analysis (3 different methods) from the rinsing solution (SDS) after eye examination for particles (and subsequent exclusion from further examination)
6 CSSD (SPD, RUMED) in Germany
6 different instrument design
6 samples each
3 different methods choosen: OPA, modified Biuret, Pseudoperoxydase reaction for hemoglobin

*Fengler Th, Pahlke H, Michels W et al.:
Are processed surgical instruments free of protein? Results of a multicenter study on remnants.
Central Service 9 (1): 27-32 (2001)

How clean are sterile instruments? Symposium of the World Federation for Central Service in Hospitals, Orlando, FL, May 16–20, 1999.

FENGLER TW, BISSON S, PAHLKE H, FRISTER H, and MICHELS W. Multicenter study on clean instruments. Abstract. Poster presented at the 7th World Congress of Endoscopic Surgery, Singapore, June 1–4, 2000a.

FENGLER TW, PAHLKE H, BISSON S, and KRAAS E. The clinical suitability of laparoscopic instrumentation. A prospective clinical study of function and hygiene. *Surg Endosc*, 2000b, vol. 14, pp. 388–394.

FENGLER TW, PAHLKE H, BISSON S, MICHELS W, and KRAAS E. Regaining soils from instrument surfaces: SDS-OPA method with native blood as contaminant. Abstract. Poster presented at the 7th World Congress of Endoscopic Surgery, Singapore, June 1–4, 2000c.

FENGLER TW, PAHLKE H, BISSON S, MICHELS W, and KRAAS E. How clean are sterile instruments? Parameters - Testing - Clinical data. Proceedings of the EUROMAT, International Congress on Advanced Materials and Processes. Munich, September 27–30, 1999. In: *Materials for Medical Engineering*, vol. 2, Stallforth, 2000d.

FENGLER TW, PAHLKE H, BISSON S, and MICHELS W. Are processed surgical instruments free of protein? *Central Service*, 2001, vol. 9, pp. 27–32.

FRIEDEN J. Human error needs consideration <http://www.reutershealth.com>, February 20, 2001.

FRISTER H and MICHELS W. Comparative assessment decontamination processes. *Hygiene Medizin*, 1994, vol.

GLASER ZR. Some unanticipated changes in implant bi implant. *Pharmacopeial Forum*, 1993, vol. 19, no. 2, pp.

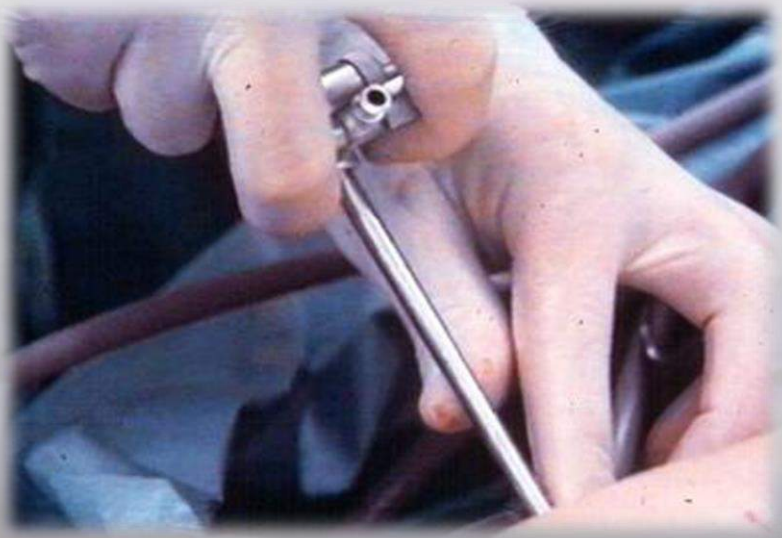
GLASER ZR and SCHULTZ JK. Maintaining surgical in no. 5, pp. 12–27.

GREEN M, MERRITT K, BROWN SA, and VITCHINS V devices. *Trans Soc Biomaterials*, 2001, vol. XXIV, p. 528.

GRIFFITH CJ, COOPER RA, GILMORE J, DAVIES C, and LEWIS M. An evaluation of hospital cleaning regimes and standards. *J Hosp Infect*, 2000, vol. 45, pp. 19–28.

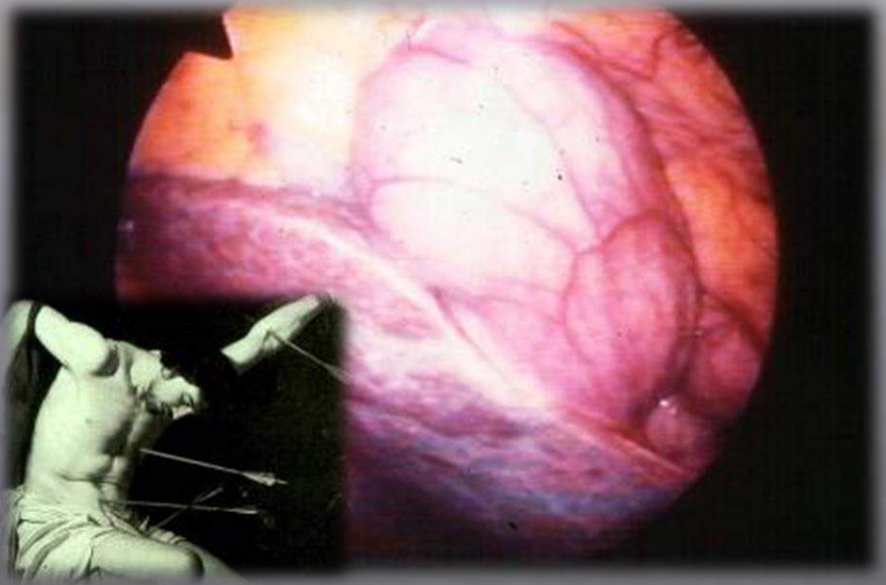
HEEG P. Effectiveness study of a low temperature liquid sterilization process using peracetic acid. *Zentr Steril*, 1999, vol. 7, pp. 18–29.

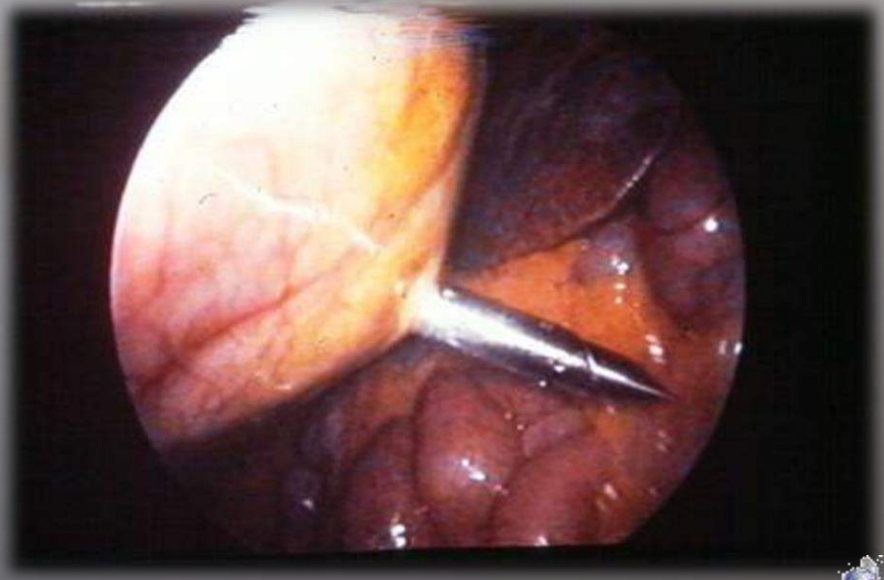
… meanwhile we know that cleanability and design of the medical device are connected. It is established knowledge for officials and in regulatory affairs (e.g. TIR 30, USA).



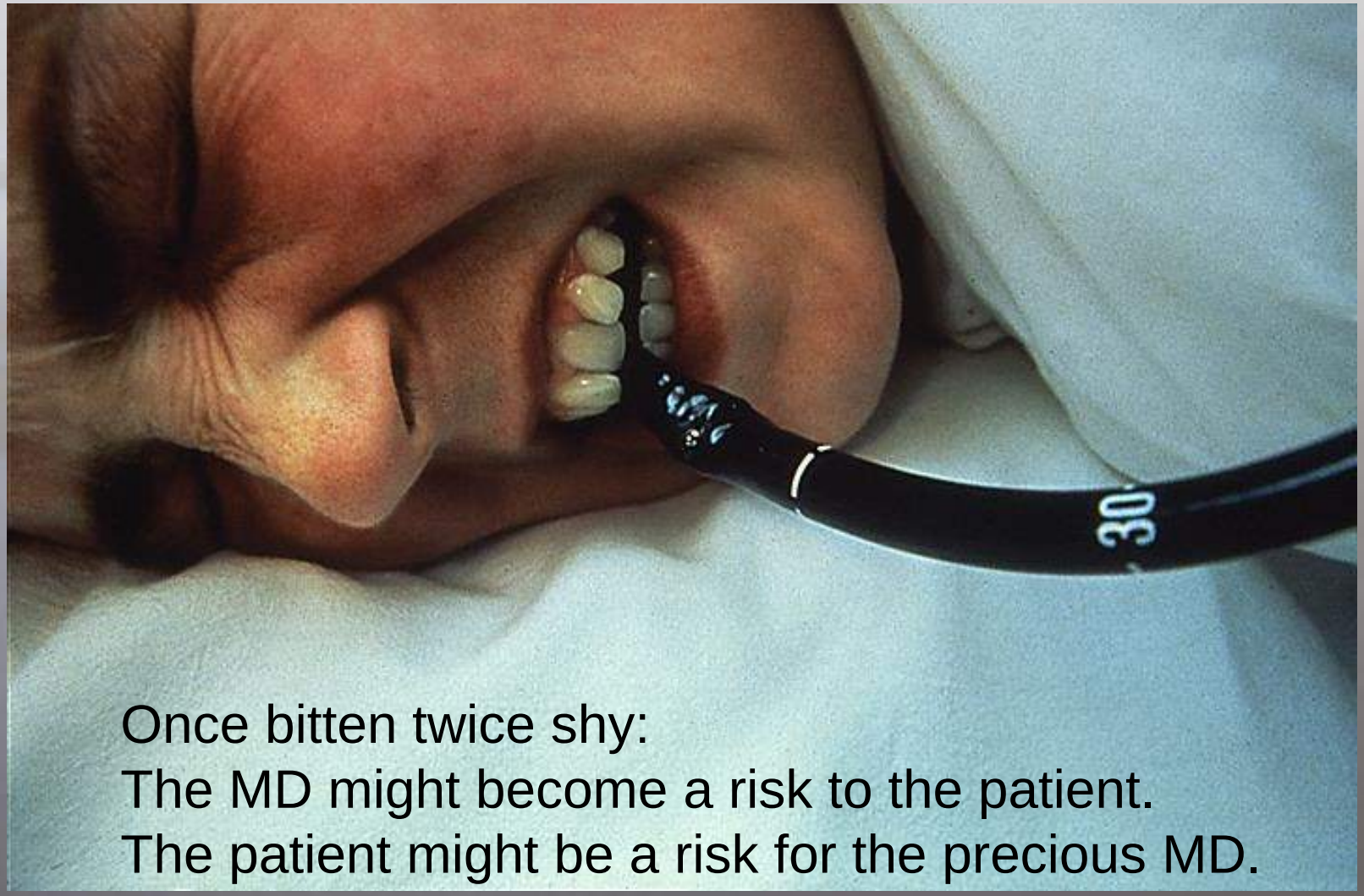
New risks

Innovative MD might enable new surgical therapies.
At the same time they might innoculate microorganisms precisely in the midth of the human body (e.g. laparoscopy)





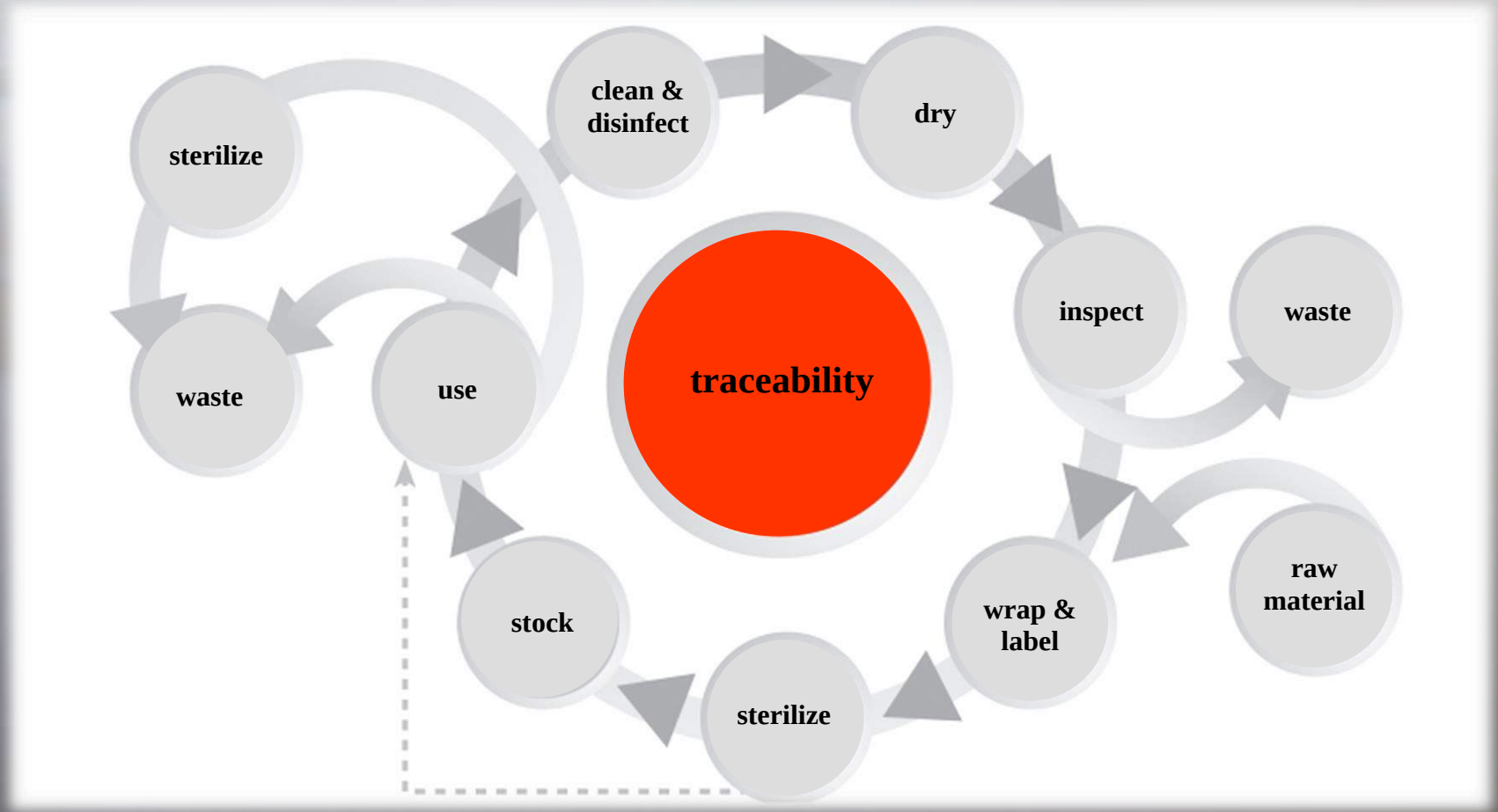
Tasteful impression



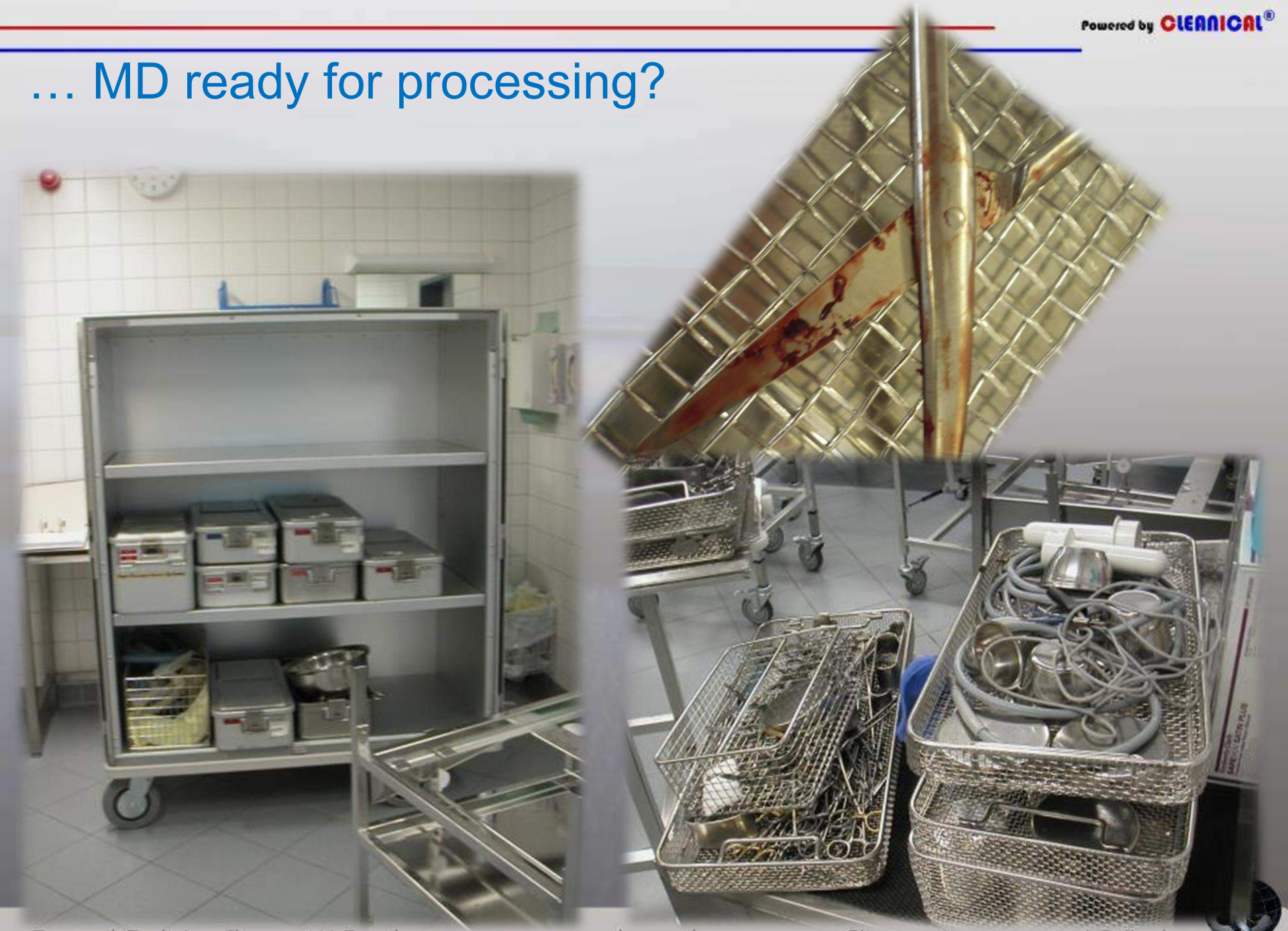
Once bitten twice shy:
The MD might become a risk to the patient.
The patient might be a risk for the precious MD.

A process oriented quality concept

What does (re-)processing of medical devices imply?



… MD ready for processing?



Central Sterile Service Department (CSSD)

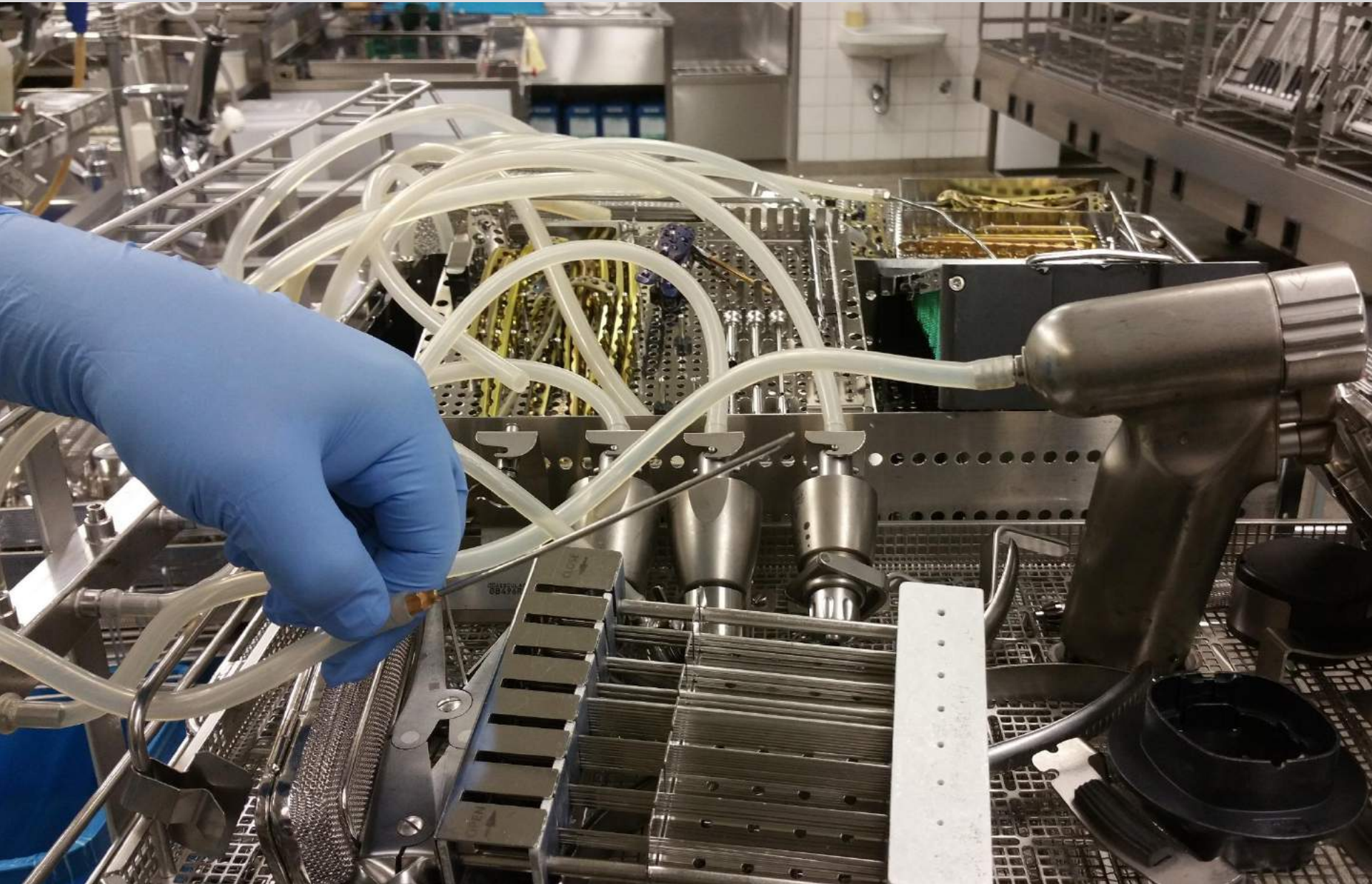
Analysing risks

All medical products shall be treated as described in Standard Operating Procedures (SOP) to avoid evidence of failure.

Transport Disassembling Pre-treatment Washing	Visual & tactile inspection Physical parameters (T, p, t, concentration)
Disinfection Drying Maintenance, Care Control	Control: ➢ Progress (Data logger) ➢ End result (colorimetry)
Packaging Sterilisation	Documentation SOP

SOP – standard operating procedure

Procedures must be adapted to the task



All methods start manually, and there is no “automated” processing:

The use of automated endoscopy cleaners (AER) is strongly recommended by experts, but the achievable result might be deceptive.

- adaptation of channels might fail
- flow control might be illusory
- contaminated washing chamber
- pump pressure too low
- defective device
- endoscope not validated for the AER

Risky manual activities:

Processing is „brainy & brawny“ including a lot of manual work!

Risky manual activities:

sometimes „brawny“ (heavy load) but always „brainy“ (know how)

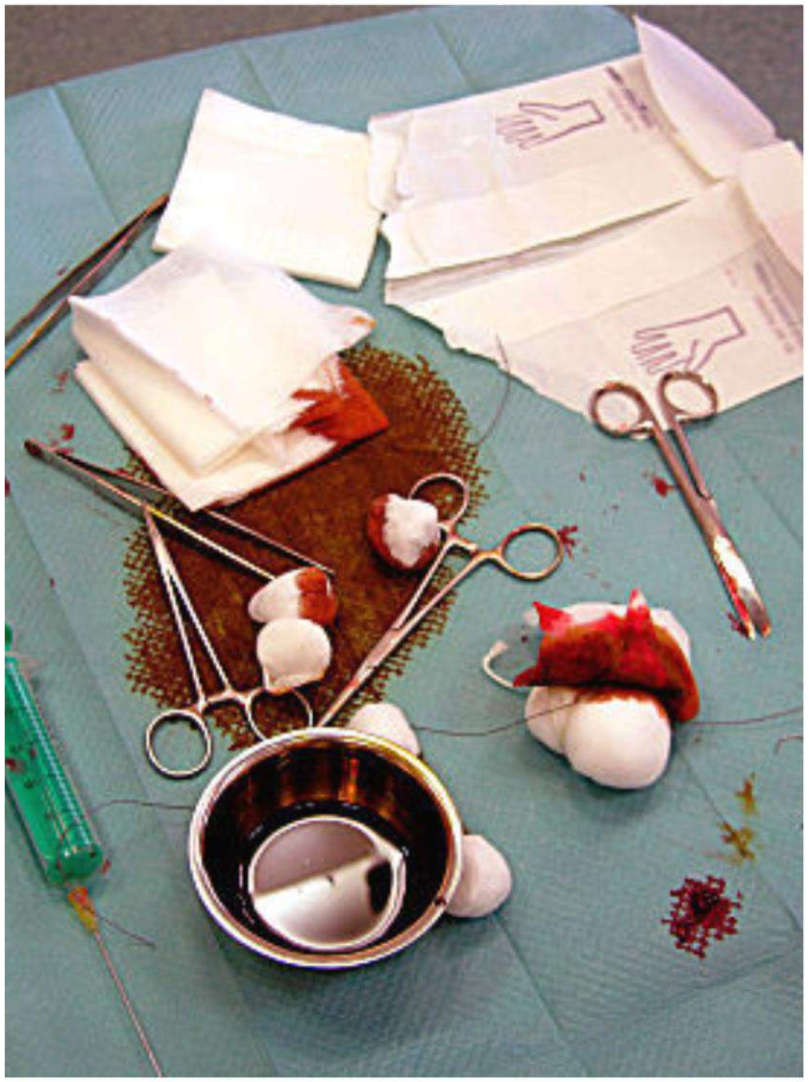
Possible risk: Microorganisms might be pathogenic

Pathogens are substances or organisms that might cause harmful processes in other organisms.

Those are assigned in medicine the property of pathogenicity.

Pathogens can be bacteria, fungi, parasites, viruses or prions.

Not all microorganisms cause diseases but many can potentially do so.



Risk awareness: Protect yourself!

Hygiene is “the science of prevention of diseases and the preservation, promotion and strengthening of health.“

It is related to microbiology, infectiology and environment protection.

And circumstances…

(Pre-) Cleaning

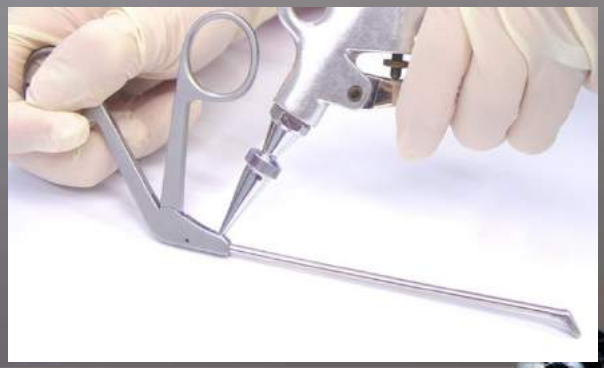
Manual

soaking

brushing

flushing

ultrasonic (pre)cleaning



Both cleaning and biocidal action are disinfection

Cleaning, rinsing, biocidal action (“disinfection”) and final rinsing with sterile desalinated water have to be executed separately!

MD often have a complex design e.g. flexible scopes

Most critical although semi-critical?

Intended use of a medical device (e.g. flexible scope)

Today, a given clinical environment (medically, technically) faces changes as the events of lethal outcomes in the US led to a worldwide discussion which are the crucial elements of processing of flexible scopes.

- Do we have “critical” procedures in duodenoscopy, bronchoscopy, and/or in the urogenital indications?
- Is high-level disinfection enough?
- How can we avoid biofilms which finally are detected if work channels are stripped and extracted from the scope?
- How can we measure contamination? By dilution with sterile water or microbial investigation of the brushes?
- Is brushing and flushing efficient?

The main aim of hygiene is prevention.

Flexible endoscopy is event-related: An event for….

> the patient:

expectation of minimal invasiveness

> the flexible scope:

frequence of use, misuse, life span

> its accessories:

disposable or reusable (valves, brushes, pouch or container)

> its processing processes:

countable (t, T) or “narrative” (SOP) parameters

> the staff:

personal protective equipment (PPE)

skills

> the infected patient

“evidence”

Cleaning AER

„Automated“ Endoscope Reprocessor require correct adaptation and sufficient pump pressure

Information for use (IFU)

Internet information available

Accessories
(e.g. brushes)
Materials, agents and biocompatibility

Processing Information for Flexible Scope

Flexible Endoscope (Fiberscope / Video-Endoscope)

- Preparation

Leakage test, brushing channels, wipe surfaces

- Cleaning

Manually or automated

max. temperature 65°C !!

recommended chemicals

- Disinfection

Manual or automated chemical disinfection process

- Maintenance

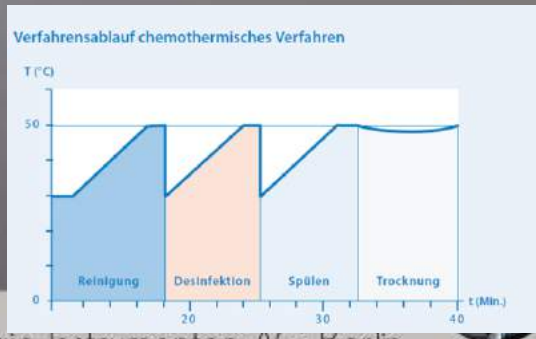
Clean optical surfaces with 70% alcohol (Ethanol/Isopropyl)

Leakage test

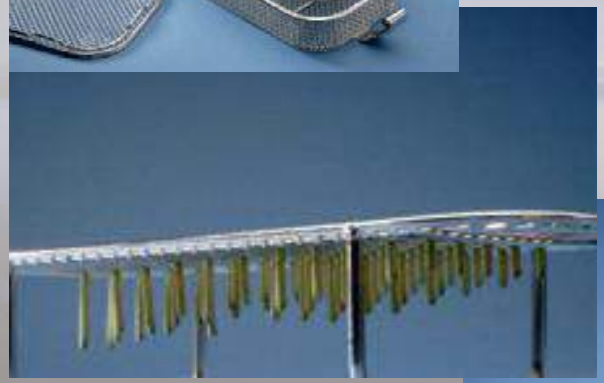
- Sterilization

Low temperature processes: (IFU)

H2O2 (STERRAD / STERIS V-PRO), ETO, FA



Transport solutions to lower risks



Ultrasound is very powerful for mobilizing remnants

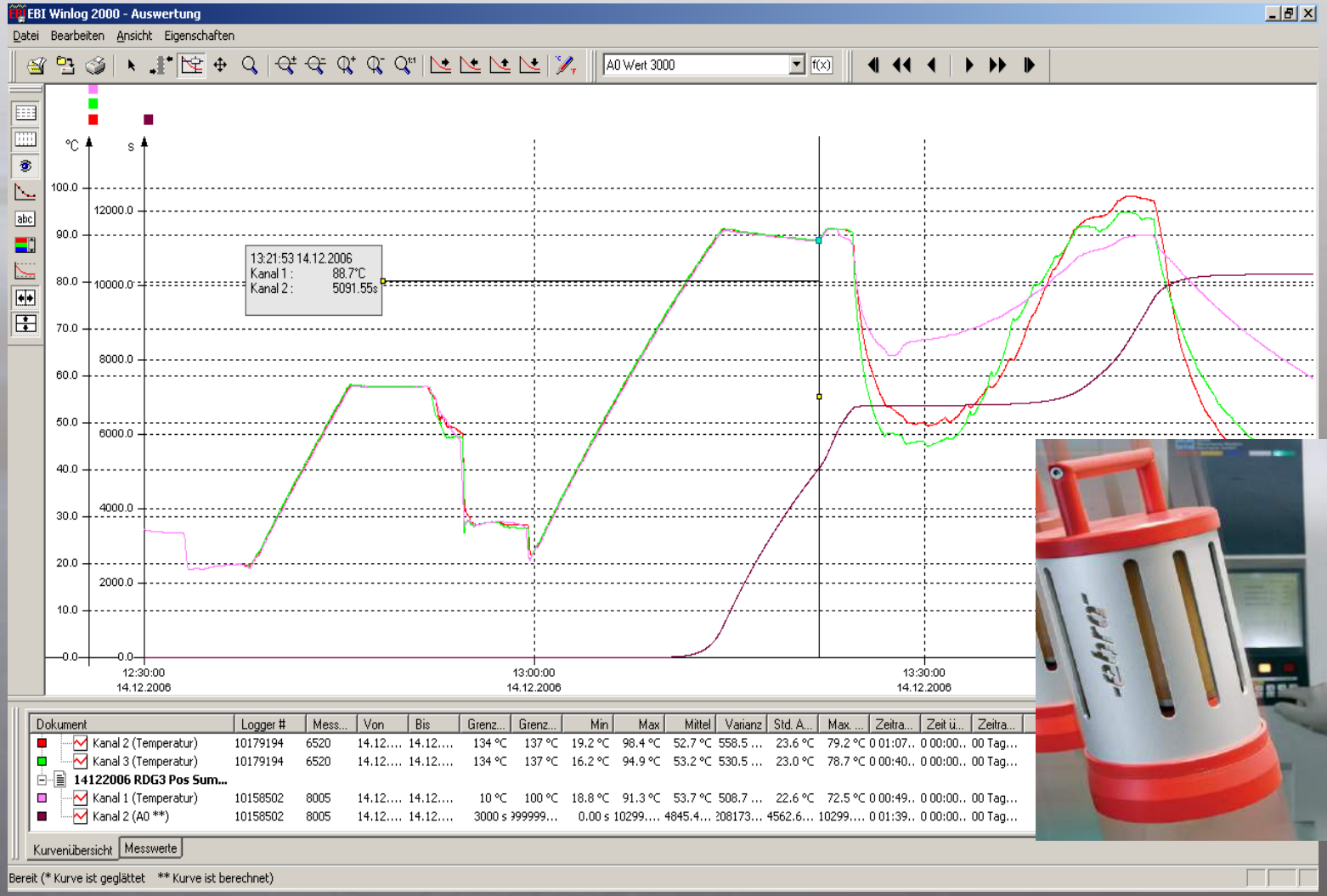
Before

After

Riesgo de infección:

Humedad restante (condensado) proporciona
a los microorganismos la posibilidad de „nadar“

Protocol of a Datalogger for process control…



Validación de procesos es la verificación de propriedades especificadas especificado antes del proceso

National laws (e.g. HTM 2030)

Operator´s regulations

International guidelines & Recommendations

WHO 2016

http://apps.who.int/iris/bitstream/10665/250232/1/9789241549851-eng.pdf

KRINKO 2012

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Hygiene_Requirements_Medical_Devices_2012.pdf?__blob=publicationFile

Standards:

ISO 15883 series on cleaning

EN 16442 Storage cabinets

ISO 17664 (new DIS for voting)

EN 60601 series (electrical safety and cleaning)

Prior arts (state of science & technologies)

- Medical devices have a specific intended use on patients.
- Risks of clinical interventions have to be minimized for the patient.
- Proper handling and correct use are described in the information for use (IFU). The user has standard operating procedures (SOP).
- Medical devices are a precious and expensive investment.
- Correct processing is crucial to enable correct and hygienic function for a longer work life of the flexible endoscope.
- The processing of medical devices is regarded as “fully controllable” and has to be organized faithful. But in fact, insufficient processing cannot be detected easily on flexible scopes.
- Medical devices possibly do not work properly if not clean. Cleaning means disinfection, but disinfectants do not clean!
- “Event-related” handling means therefore a risk assessment.

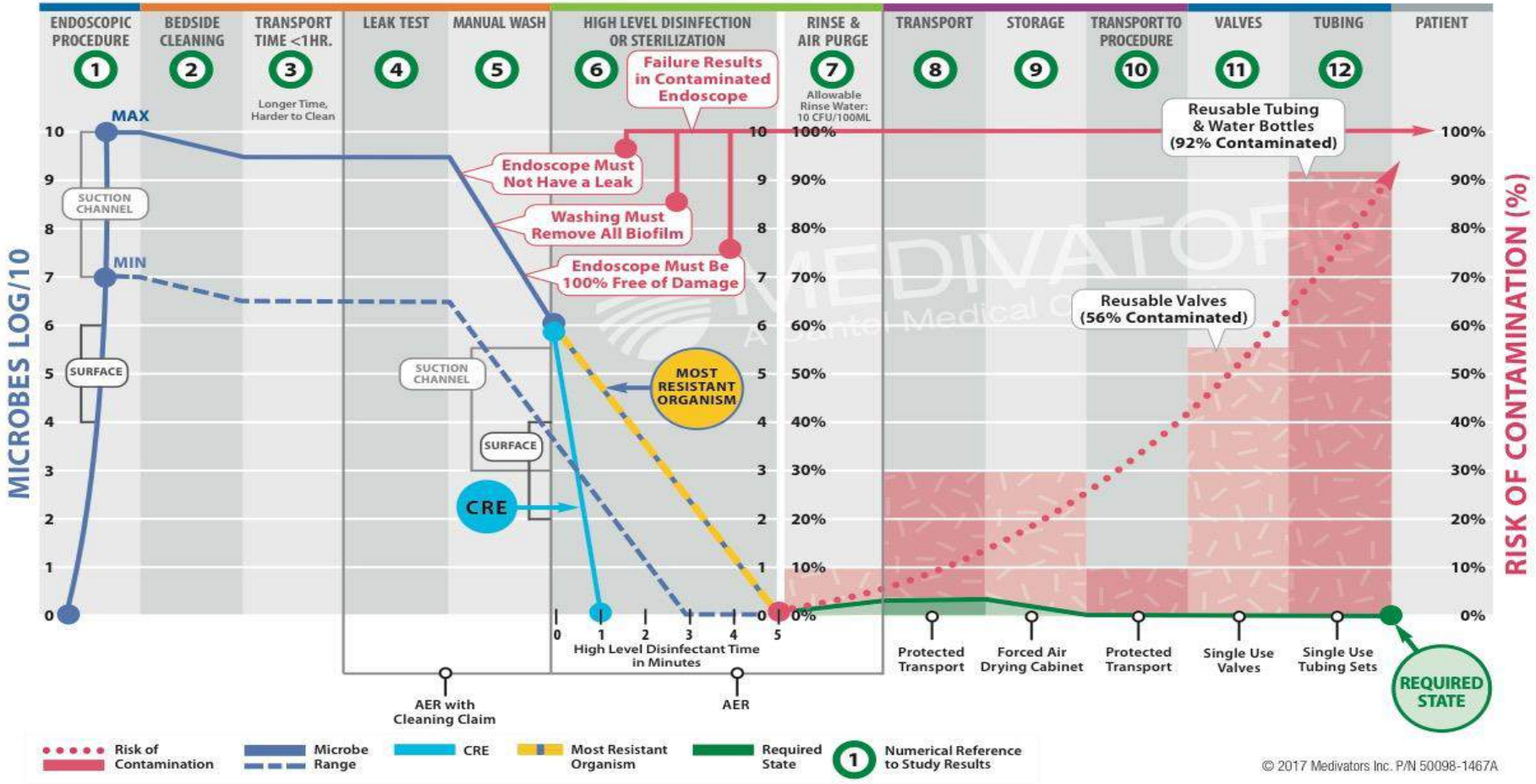
Hygiene requirements

Requirements to be observed:

- General hygiene requirements
- Requirements for premises, areas, rooms, spaces
- Requirements for machinery & devices
- Requirements for procedures & processes
- Personnel training “on the job” (professional qualification)
- Personnel requirements (personal protective equipment – PPE)
- Requirements for operating material/resources
- Requirements for safety of patient, staff and third parties
- Environmental requirements, logistics and waste management

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Hygiene_Requirements_Medical_Devices_2012.pdf?__blob=publicationFile

COMPLETE CIRCLE OF REPROCESSING



Processing: Considerations

- One-way flow

Dirty

Clean

Dirty

Clean

BIOHAZARD

OSHA
Regulatory
Requirement

Summary:

Risk management - which processes which means?

Problems with processing?

Let´s create tasks!

Looking for solutions… not admiring the problem.

1. Identification of the risk(s)
2. Evaluation of the identified risks
3. Management of risks
4. Supervision of risks
5. Lowering risks
6. Documentation of risks

Hygiene is in your hands!

Prevent events.

Surgical Instruments Work Group Berlin
Chirurgie-Instrumenten-AG Berlin
AUGUSTA Hospital[1] – Training center

[1]Hospitals used to have graveyards nearby

International FORUM Medical Devices & Processes: 20 years in 2018