

# Operational Application of Instruments and Infection Prevention – the Surgeon's View

Th. Fengler, E. Kraas



Design of Surgical Instruments:  
Thursday, 22.11. 2007 at 9.40-10.15  
Radboud University Nijmegen, Medical Centre  
The Netherlands

Cleanical Investigation & Application  
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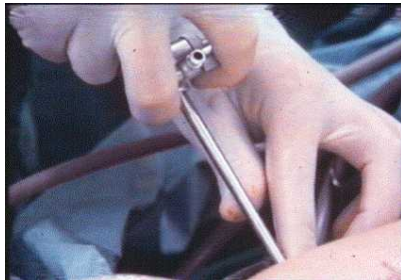


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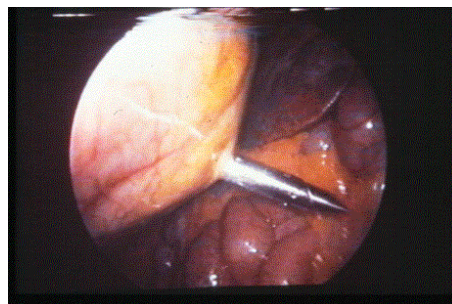
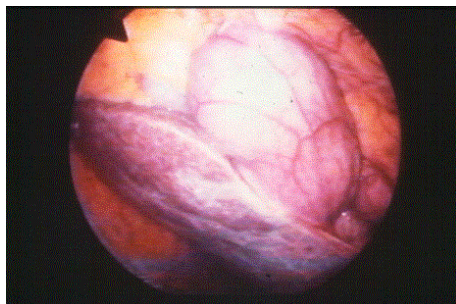


- 1993** Foundation of the „Chirurgie-Instrumenten-AG (CIA“) in the hospital Moabit Berlin
- Secretary Dr. med. Dipl.-Ing. **Thomas W. Fengler**, Member of the following Scientific Organisations:  
German Society of Surgery, German Society of Abdominal Surgery, the European Association of  
Endoscopic Surgery (E.A.E.S.), German Society of Sterile Processing (DGSV) e.V.
- Technical Consultant **Helmut Pahlke**, Member of the DGSV e.V.
- 1994** Quality of instruments for laparoscopy – Retro- and prospective Clinical studies on medical devices for  
abdominal surgery in the hospital Moabit Berlin
- 1998** Projects with different manufacturers (BODE, KARL STORZ Endoscopes, Miele PROFESSIONAL,  
ebro Electronic, Olympus, Stryker) on residual contamination and process control during the steps of  
processing, and optimisation of medical devices
- 1999** Organisation of the worldwide first multicentric study on remaining contamination after automated cleaning  
and before thermal disinfection for different instrument design in 6 CSSD of German hospitals
- 1st International FORUM Medical Devices & Processes in the Congress Center, MEDICA Düsseldorf.
- 2000** Foundation of the SMP GmbH in Tübingen – Validating, testing, investigating  
CEO **Klaus Roth**
- 2001** New Company ZEHNACKER CLEANICAL® GmbH for processing services
- 2002** 3rd International FORUM comes to Berlin
- 2005** International Business Support – “FORUM on Tour” Armenia, China, Georgia, Ireland, Mexico, Norway, Russia
- 2007** New Companies CMP GmbH (Validation) and CLEANICAL® GmbH (Coaching Hospitals and manufacturers)

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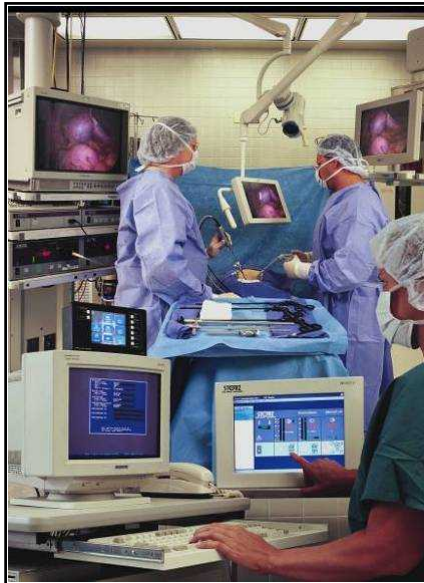


**Intelligent medical devices  
lead to new approaches in  
surgery ....  
.....and dentistry as well.**



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Complex interacting devices need skilled staff and „training on the job“ - not only for the surgeon .....



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There has been a tremendous Development since the 80's in Surgery.

- What happens to the instruments?
- What happens to process control?

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Quirófano 4

No ingresar a la sala  
Preservar los alrededores  
y material quirúrgico  
a través de la ventanilla

Operational Application



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Infection Prevention ?

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What about  
dentistry?

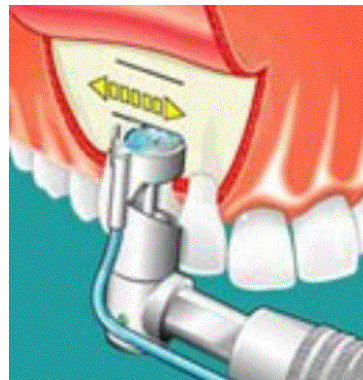
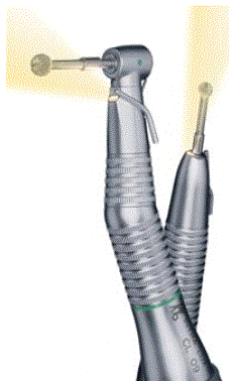
We see the dentist  
perhaps more often  
than any other  
doctor.  
Implantology urges  
the need for  
process control in  
this field of surgical  
treatments as well

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German Hygiene Recommendations distinguish for tissue between  
*Non critical, semi-critical, critical* (Spaulding) and for the design aspect in  
*A, B, C* with respect to the easiness of access to all surfaces and the  
resistance to heating up the medical device

Recommendation of the Robert-Koch-Institut (RKI) 2001



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## TC 102 WG8/TC 198 WG 13 (ISO/DTS 15883-5)

„C“ like „complexe“ or like „certified“?!  
„What do we mean by clean?“



Example of a dental turbine with air pressure

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### Considering operational application....

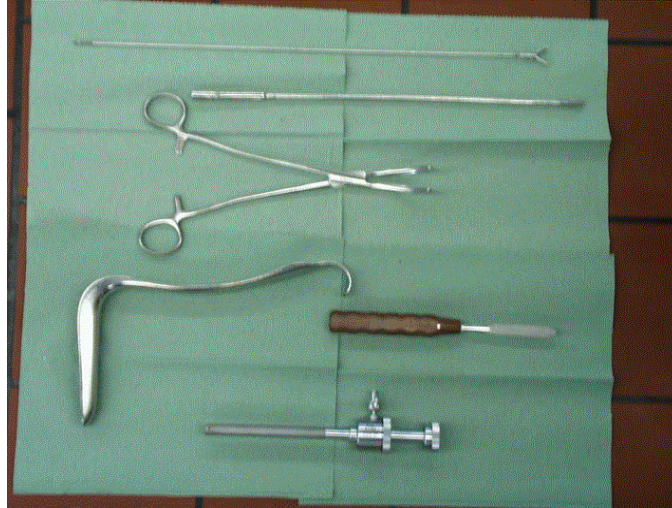
- Medical devices become **finer** and more complexe in design which makes them prone to damage (Ophthalmology, ENT, microsurgery, neurosurgery, traumatology, robotic surgery)
- Processing has to be executed following the „**state of the art**“ requiring skills and knowledge of the regulatory affairs.
- **Process control** is verification and validation of available parameters on a „reasonable value“
- **Documentation** results and reassures the process
- **Cleaning** is still a complexe parameter and automated cleaning is recommended but not in every case (possible)
- **Good processing preserves the investment** for them medical devices

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## German Multicenter Study Residual Contamination after automated Cleaning

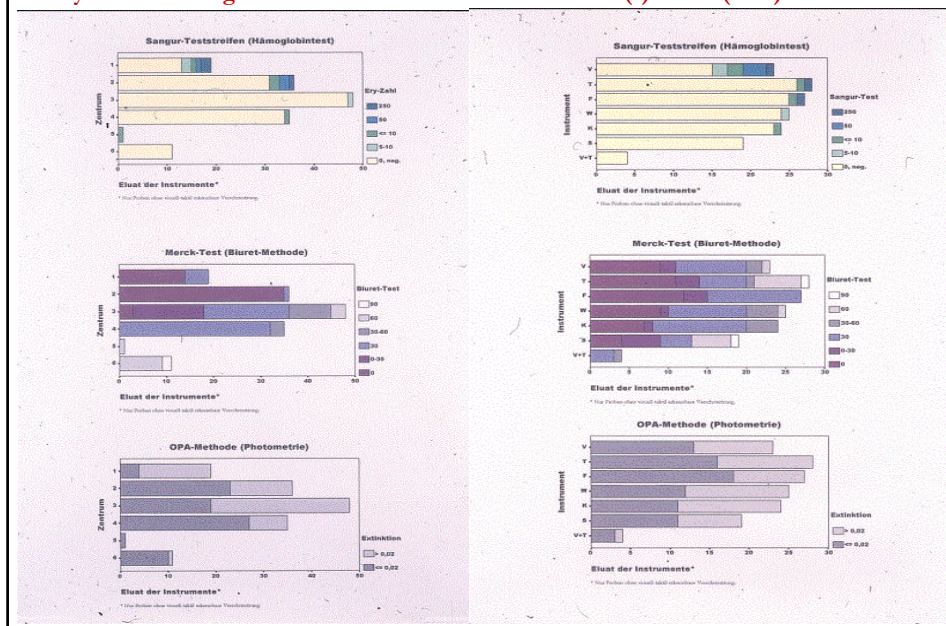


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Fengler ThW, Pahlke H, Michels et al.:

Are Processed Surgical Instruments Protein-free? Results of the Clinical Multicenter Study on Remaining Contamination. Zentralsterilisation 9 (1): 20-32 (2001)



## A broad Field of Applications ...

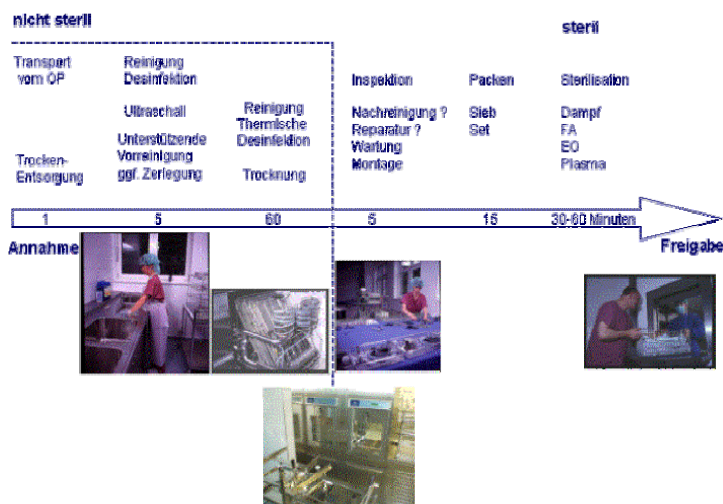


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## Reprocessing needs time

### Aufbereitung von Medizinprodukten

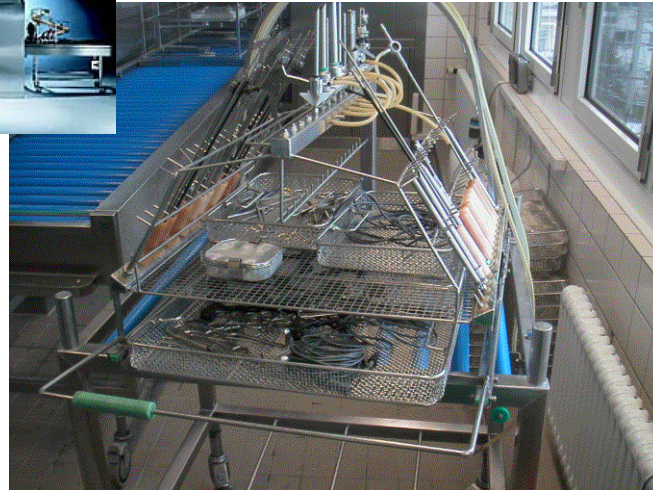


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In Surgery, there is no time left,  
but Processing has its Steps



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Everybody knows what to do?  
Clear description of the „operations“?



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## Any manual Precleaning?



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## How ?



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Take care of Your work and of Yourself !



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Under pressure ... it does not work!



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## Adequate Devices at the State of the Art ?



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## Small Parts Showing up



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No messing around ...



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Typical Faults with  
Ultrasound



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## Fine instruments need fine Treatment

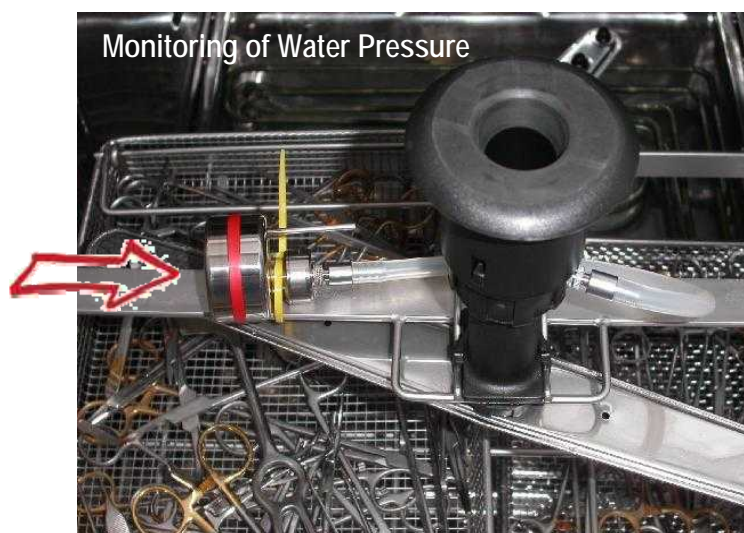


Complemento apto para posicionar, enjuagar de todos lados con suficiente presión

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## Validated Processing needs Verification



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## Are You correctly connected ?



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## Heavy Load



CEN ISO 15 883 Part 1-5.

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## Basket Call



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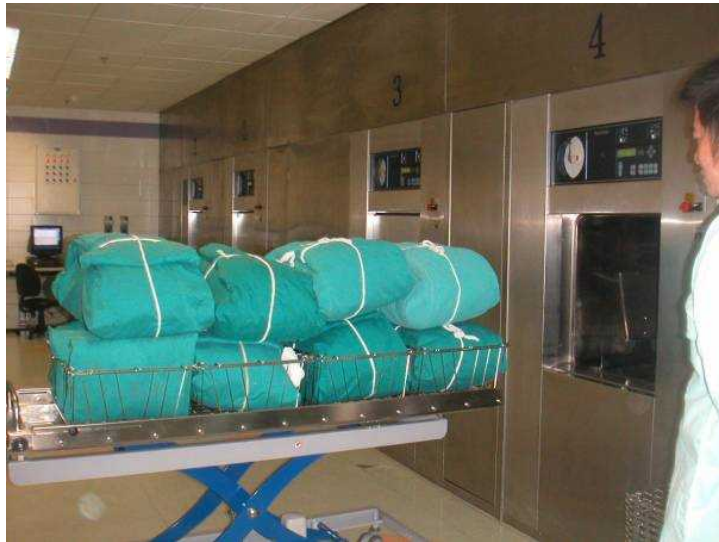
## Foggy



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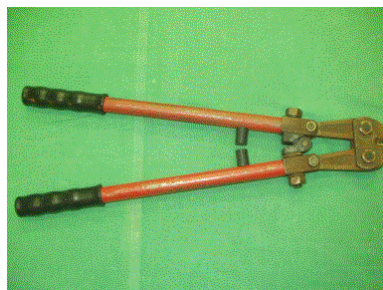
## Textiles are the Contrary of Instruments



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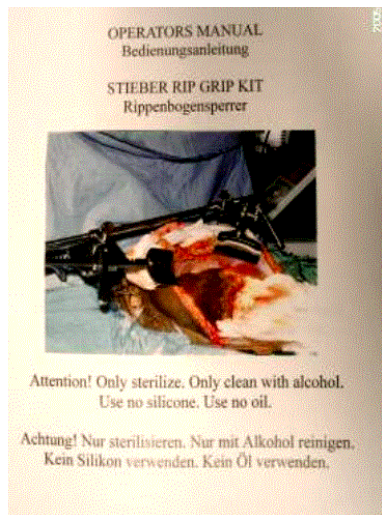
Intended Use ?



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## EN ISO 17664:

The manufacturer provides the user of the re-processable medical device with information on its intended use (function, handling) including an information for manual and (preferably) automated reprocessing.

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## Complete Manual



....understood ?

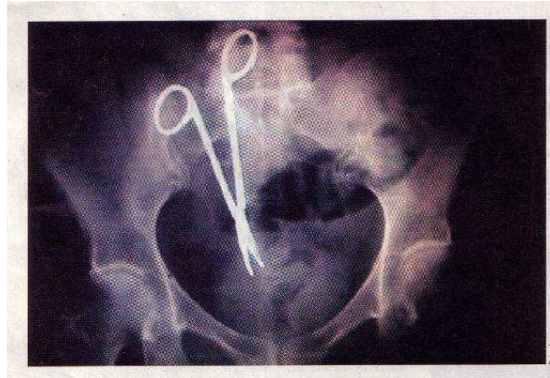
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**Messing around?**

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**Right Instrument - wrong Place**

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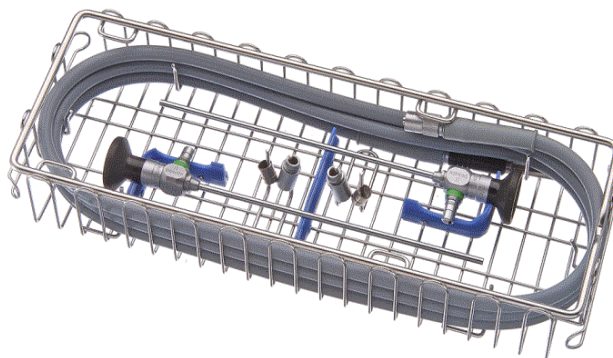
I have a dream:  
„One touch“ from Operating Theatre to  
Central Sterile Supply Department ...



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„One touch“ :  
Transport ... Cleaning ... Packaging ... Sterilisation

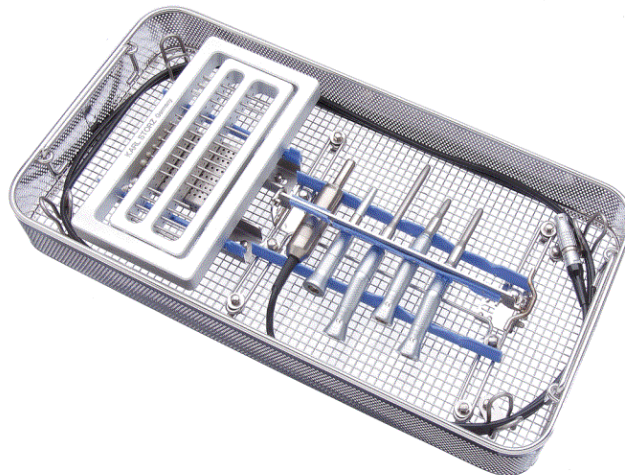


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## Transport in Baskets without Complications



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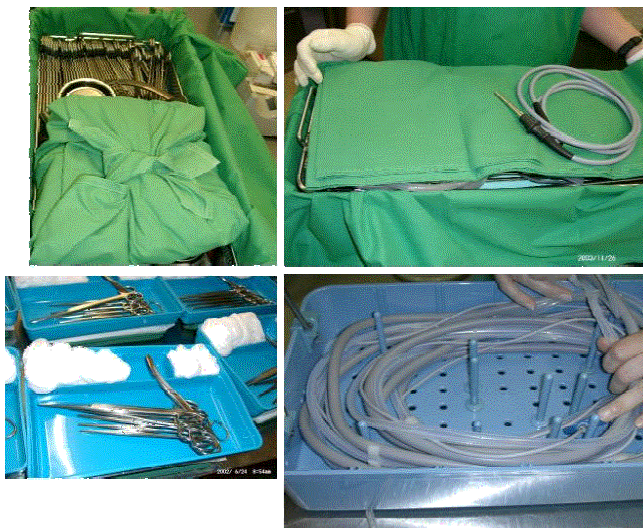
## Plastic Baskets are prone to Wetness



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## The Art of Packaging



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## Trauma is a Trauma



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## In those plastic Containers You can see typical Condensation



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## Baskets and wrapping Paper is the State of the Art



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## Alternatives to Steam Sterilisation

Peróxido de hidrógeno-  
 Esterilización a baja temperatura



Formaldehido



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## Documentation is always possible



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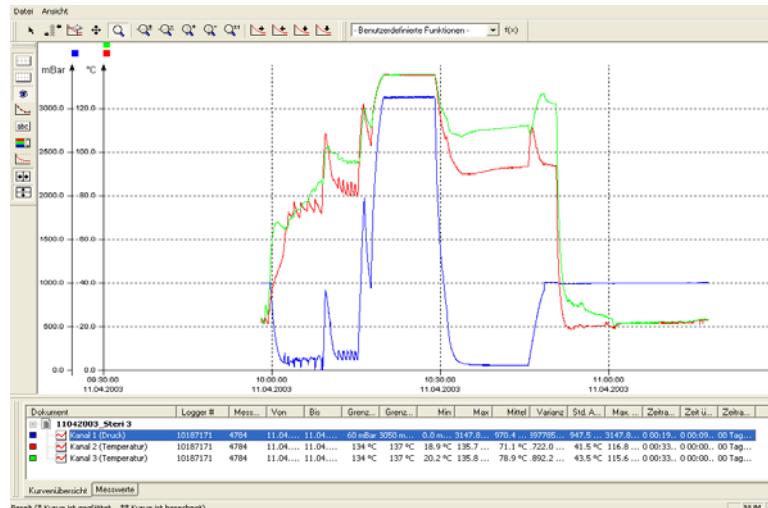
## The Description of the Working Place has to be in Place



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## Data Logger – to replace chemical and biological Indicators



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## What do we care? We are Surgeons, we want:



- Form follows function – Function enables therapy!
- Surgeons want to take the instrument in their hand feeling familiar with it.
- They need to have confidence in **function**.
- Confidence means for **hygiene** reproducible quality of processing for sterile use.

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## Quality in Surgery

How to measure **quality** generally and with special regard to instruments? It depends strongly on the **surgeon's skills**.

Wound infection, pain scale, scarring, general recovery time are quite **soft parameters** in relation to the instruments used.

Obviously the mortality rate is a highly relevant indicator of the success of a (surgical) therapy. According to internationally published data the mortality lies between 0,04% und 0,09% for laparoscopic cholecystectomy (*Hölbling et al. 1995, Ludwig et al. 2001, Shea et al. 1996*).

Laparoscopic cholecystectomy is a safe, effective, and cost-efficient alternative to open cholecystectomy.

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## Single-use vs. Multiple-use Instruments

In a **survey of 10 studies** we could resume:

- Reusable medical devices (instruments) are far superior to single-use instruments from an economic point of view (7-27 times less expensive).
- Considering the economic arguments single-use devices are only recommended in case of better performance in specific surgical tasks. Some instruments are available exclusively in a single-use variety.

Note: For medical devices manufacturing, transportation and ecological considerations (waste, water, detergents) are still a debatable field of calculation.

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## What the Surgeon needs ...

As far as reliability of the instrument is concerned, no significant differences between single-use and multiple-use instruments could be observed.

Repair data and quality of specific complex instruments are difficult to examine.

Occurrences of malfunction of reprocessed instruments was mentioned once.

(Paolucci V, Schaeff B, Gutt CN, Encke A. Department of General Surgery, Johann-Wolfgang-Goethe University, Frankfurt am Main. *Disposable versus reusable instruments in laparoscopic cholecystectomy. A prospective, randomised study.*

*Endosc Surg Allied Technol.* 1995 Apr-Jun;3(2-3):147-50.)

**Note: We have studied the performance of laparoscopic instruments in the Surgical Work Group Berlin (1998):**

*Fengler TW, Pahlke H, Kraas E.*

*Sterile and economic instrumentation in laparoscopic surgery. Experiences with 6000 surgical laparoscopies, 1990-1996. Surg Endosc* 1998;12:1275-9

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## What the Patient needs ...

As far as safety of the patient is concerned, no significant differences between single-use and multiple-use instruments could be detected in this analysis.

**Note:**

Patient safety mainly depends still on the skills of the surgeon and the organisation of the whole surgical procedure. The choice of medical devices, processing modalities, equipment and staff is just a part of it.

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## Re-use of Single-use Medical Devices

Re-using single-use medical devices results in a transfer of **liability** from the manufacturer to the processor (external or CSSD, one day surgery) for all relevant features e.g. function, material alterations, hygienic deficits.

The practice of re-use for economic reason is commonly performed, but cannot be generally recommended.

The manufacturer's reasons for declaring an instrument „single-use only“ must be known if re-processing is considered e.g. thermolability.

Disposable laparoscopic instruments may be safely re-used under carefully monitored conditions and with strict guidelines.

*(Descoteaux JG, Poulin EC, Lortie M, Murray G, Gingras S. Department of Surgery, Hopital du Saint-Sacrement, Universite Laval, Quebec, Que. Reuse of disposable laparoscopic instruments: a study of related surgical complications. Can J Surg. 1995 Dec;38(6):477)*

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## Criteria for Staplers

**Stapler** in their different forms (hernia stapler, Endo-GIA, EEA) must be safely applying clips. It is useful to have magazines for recharging (separate sterile package).

Re-processing with the different steps of transportation and cleaning is critical for the safe function of the stapler.

These single-use devices offer a high safety, are saving time especially for anastomosis and broaden the possibilities for the operation.

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## Criteria for Dissectors

Even blunt **dissection** causes bleeding. To stop bloodloss and to keep a clear view on the field of operation multiple techniques are used.

Most time consuming is sewing with the needle.

A safe and time-saving alternative for the closure of vessels is dissection with the support of heat (electrocoagulation) or ultrasound (cavitation).

Cleaning of these instruments is very difficult and remnants lead to a reduced function and hygiene seems to be a problem.

A separately packed inlet in case of a dismantable instrument might bring the solution – no single-use, no reprocessing of the whole instrument.



## Criteria for Scissors

**Scissors** must be sharp for dissection. For mechanical reasons, but also with the use of monopolar current laparoscopic scissors become easily blunt.

The advantage of single-use scissors is a guaranteed sharpness (If not so You can return it to the manufacturer).

An alternative is an extra packed inlet for reusable instrument shaft and grip.



## Criteria for Trocars

There seem to be few arguments to choose single-way **trocars**.

The silicon closure valve of certain trocars that are claimed to be „disposable“ offer features for intraabdominal sewing and external application of the knot thus avoiding gas leakage.

There are no „safety shield“ trocars that used to be frequently one way medical devices. Most severe accidents of aorta perforation happened, because surgeons were not aware of the fact that during penetration there still is a certain moment when the obturator can penetrate deeply.

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## Criteria for Accessories like ...

The function (sharpness, cleanliness) of the **Veress-needle** could be a reason to offer it as a disposable.

**Balloons** for preperitoneal hernia repair, **mesh**, **liposuction cannulas** the **endobag** are certainly disposables.

Note: It is advised to compare different alternatives (vary or even change the technique of operation).

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## Resumée

- The surgeon has high confidence in his co-workers and in the medical devices.
- The surgeon is aware that remanents on external and internal surfaces of instruments might reduce the function and can cause hygienical problems harm to the patient.
- Sterilisation means cleaning in the first place. Reusable instruments are without any doubt the most economical choice.
- Where cleaning is not possible or where the complexity of the function is obvious, single-use instruments are preferable.
- Adequate documentation is an obligation.

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Friday, 29th of February 2008



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