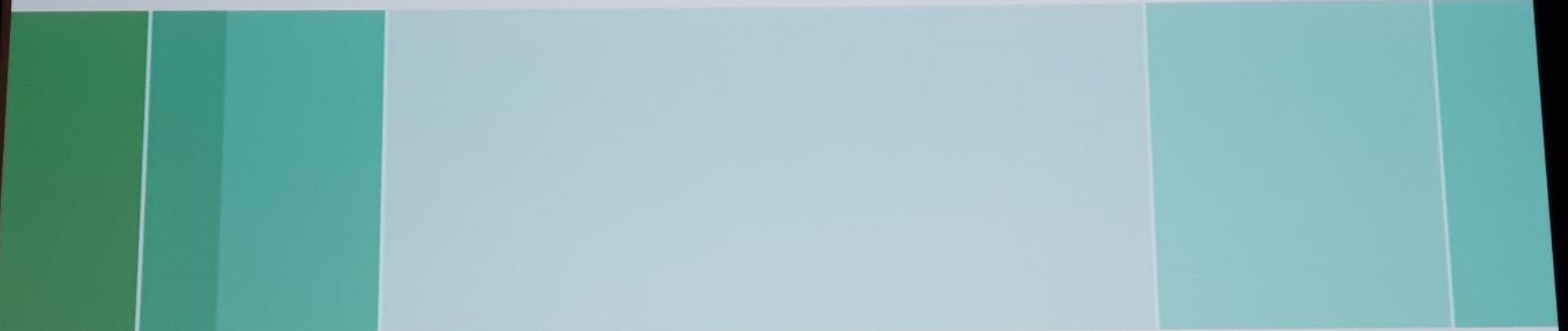




Welcome

to the 20<sup>th</sup> World Sterilization Congress





## Discoloration and Surface Changes

Dr. Ing. Gerhard Kirmse, Dr. Lena Höcker, M.Sc. Philipp Steinmetz, Silke Winandi

Aesculap AG  
Technical Competence Center

**B | BRAUN**  
SHARING EXPERTISE

## Isn't all said about this?

- Why do we still have these issues?
- Do we really understand it?

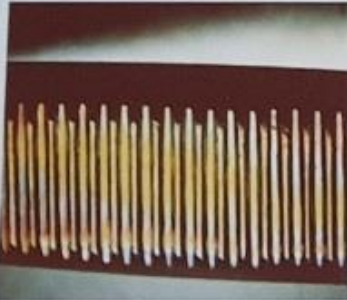




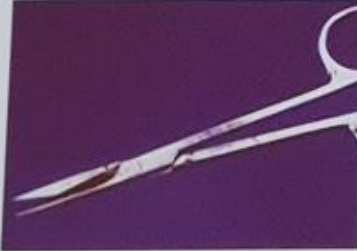
# Surface Changes Classification



• Water Spots



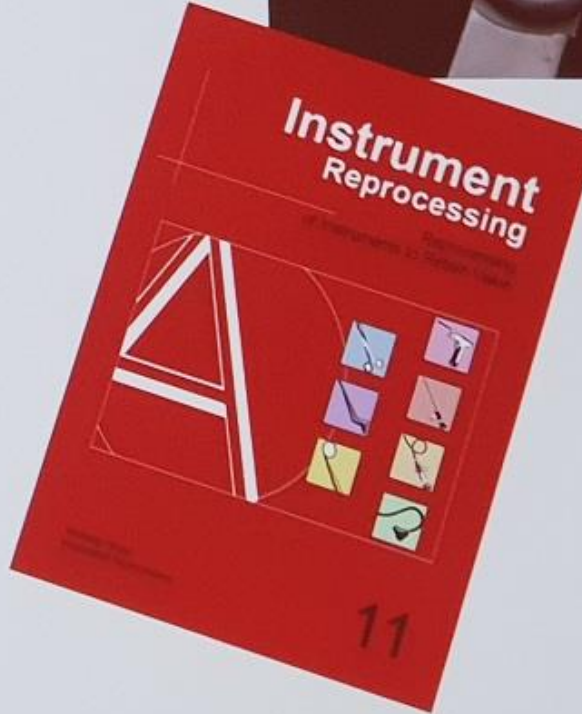
• Discoloration



• Corrosions



• Residue



## Types of Corrosion / Causes



**Pinhole corrosion**  
- Chloride ions



**Stress crack corrosion**  
- Chloride ions  
- Overstraining  
- Material stress



**Friction corrosion**  
- Insufficient lubrication



**Crevice corrosion**  
- Chemical residues  
- Insufficient drying

12.7 Metal Corrosion - Pitting

Type of surface change

Origin and causes

Pitting-like corrosion holes in stainless steel. Frequently microscopic and surrounded by sparkling, reddish-brown or multi-colored corrosion spots, often associated with circular corrosion deposits around the corrosion hole. This is to be confused with nodular corrosion deposits around the corrosion inclusions that may occur in low-quality stainless steels or with contact corrosion symptoms when only stainless steel instruments are used.

- In stainless steel, caused by exposure to halide ions (bromides, iodides and chlorides), but especially chlorides, that locally break through the passive layer of instrument steel, thus causing pitting.
- Caused on organic residues, e.g. blood, pus, secretions.
- Frequent pitting is due to the use of ligands with a high chloride content, in more specifically due to the use of ligands with a high chloride content, instrument surfaces, e.g. if the concentration of chlorides in the final rinse water is too high or if residues of physiological salt solutions remain on the instruments.
- Sharp new instruments are particularly susceptible to attack by marks containing chlorides due to their still thin passive layer. Instruments that

## Types of Corrosion / Causes



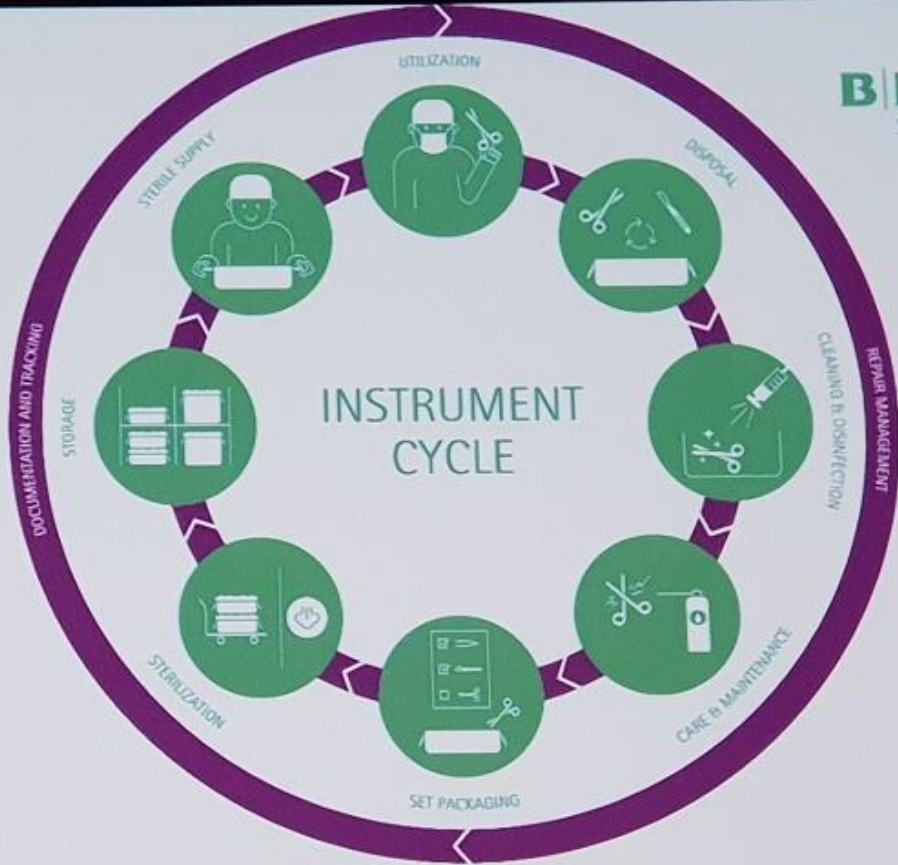
**Surface corrosion**  
- Chemical Influence  
- Material



**Contact corrosion**  
- Moist transportation  
- Drying Issues



**Foreign rust / Rust film / Secondary corrosion**  
- Reprocessing together with corroded steel  
- Contaminated water  
- „Black steam“



Root causes may be everywhere in the process

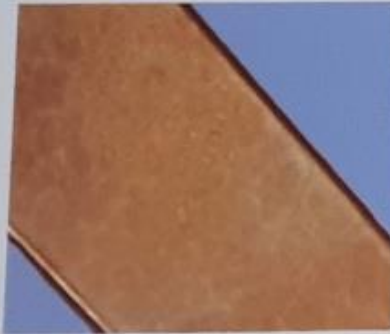


## Discoloration



### Lime Scale

- Hardness of water
- Steam quality
- Can be removed by demineralized water or acids



### Silicate

- Variety of appearance
- Water quality, Steam quality
- “Silicate breakthrough”
- (Cleaner carry over)




### Black Discoloration

- Only specific steel compositions
- Caused by acids / neutralizer
- Overdosage / Carry over
- No chemical removal possible



We know fairly well  
how it happens !

Individual Root  
Cause  
Analysis and  
Optimization



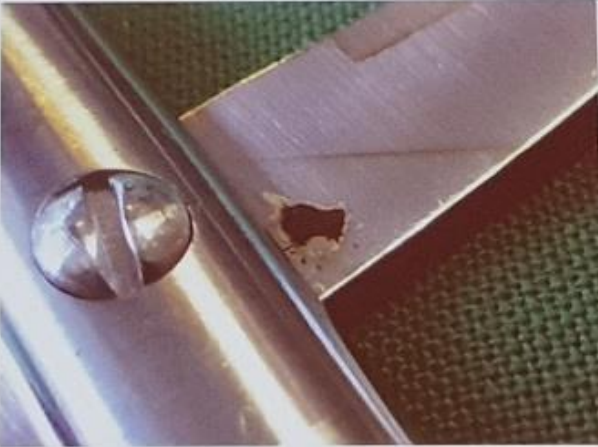
Why is it a problem ?



# Hard to see a Difference between Corrosion versus Patient Residue



- Possible Solutions**
- Protein Test (not very sensitive)
  - Second Cleaning
  - .....

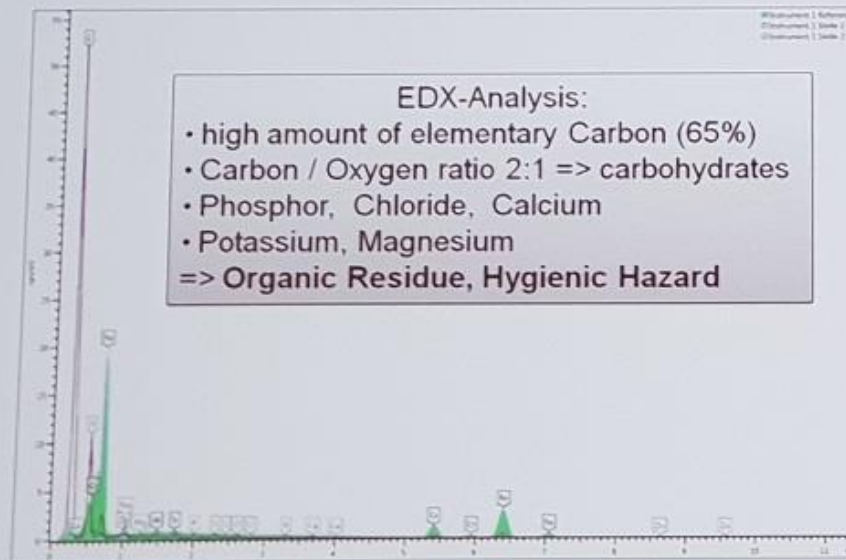


## Laboratory Analysis of Surface Changes

- REM-Picture: Structure / Dimension
- EDX Analysis



Instruments picked from working Sets  
primary Assessment: Corrosion

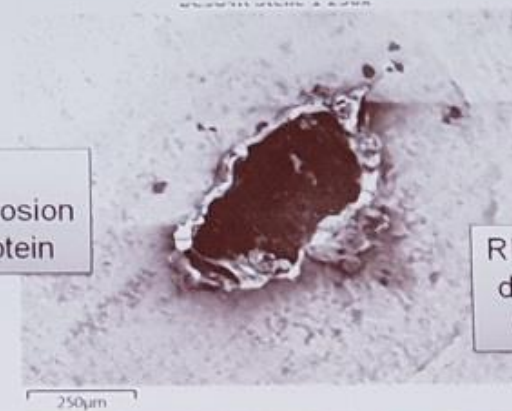


REM Picture => Structure, Volume  
here: about 90µg of Protein





Example:  
Old Pitting Corrosion  
here 63µg Protein



REM-Picture:  
deep Pitting  
Corrosion



Example:  
12% Carbon  
no link between carbon  
and visual appearance



REM-Picture:  
Residue on  
Surface

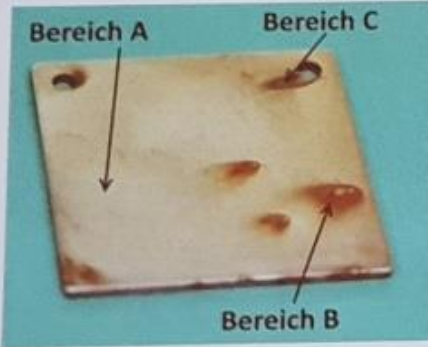
**Results:**

- In 24 of 34 analyzed instruments, the elementary carbon content of residue was more than 10%
- Co-Elements like Nitrogen, Sulfur, Potassium frequently point **towards organic / patient residue**

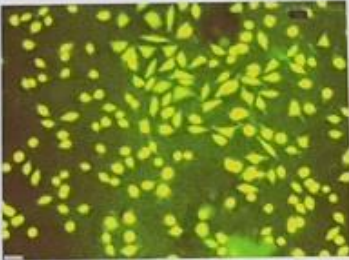


# Further Studies Results

„Laboratory –  
created  
Pitting Corrosion“



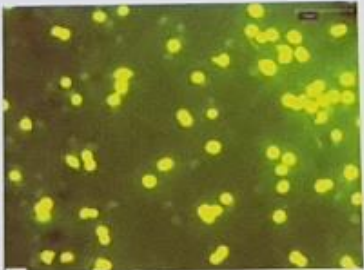
Partially Zytoxicity



Viastarfung von L929-Zellen nach 24-stundiger Inkubation auf Bereich B der Probe Z0501-08-17 (200x Vergroerung; mit dem Blaufilter)



No Zytotoxicity

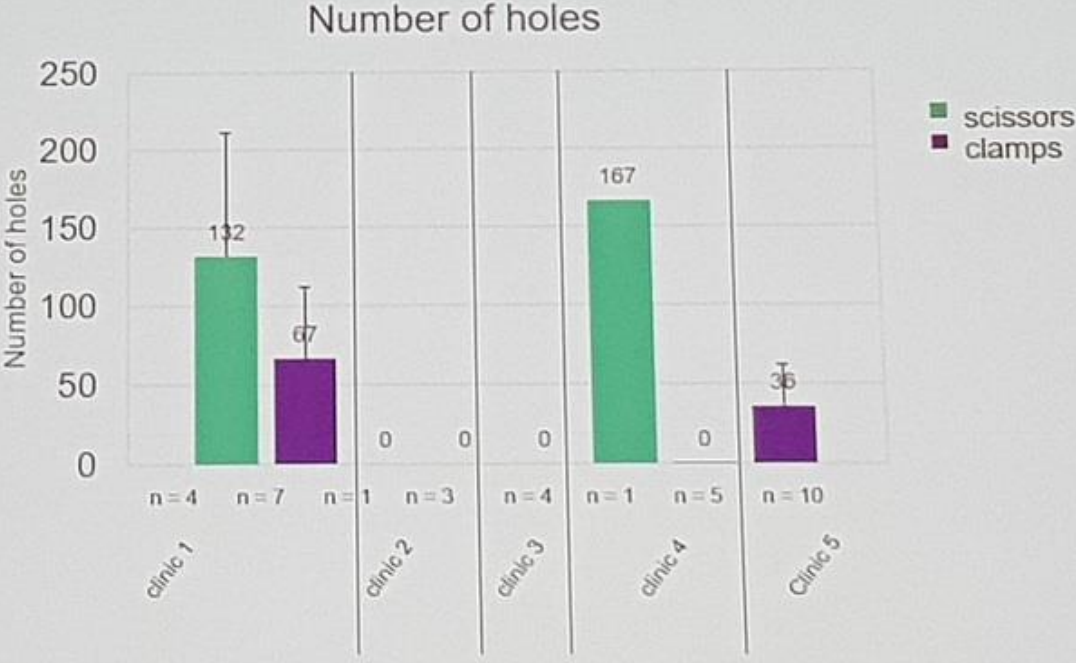
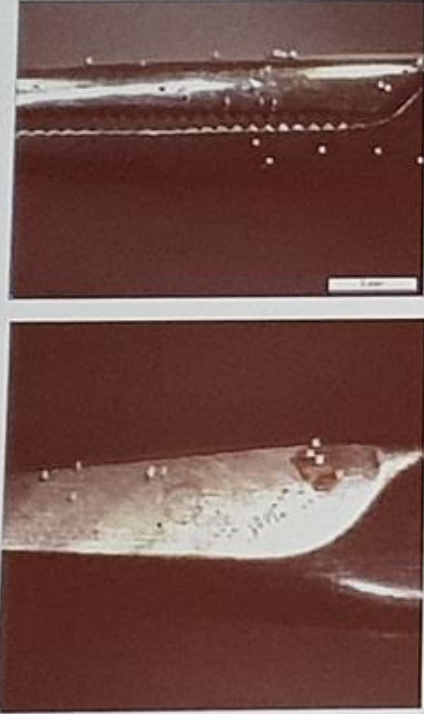


Viastarfung von L929-Zellen nach 24-stundiger Inkubation auf Bereich C der Probe Z0501-08-17 (100x Vergroerung; mit dem Blaufilter)

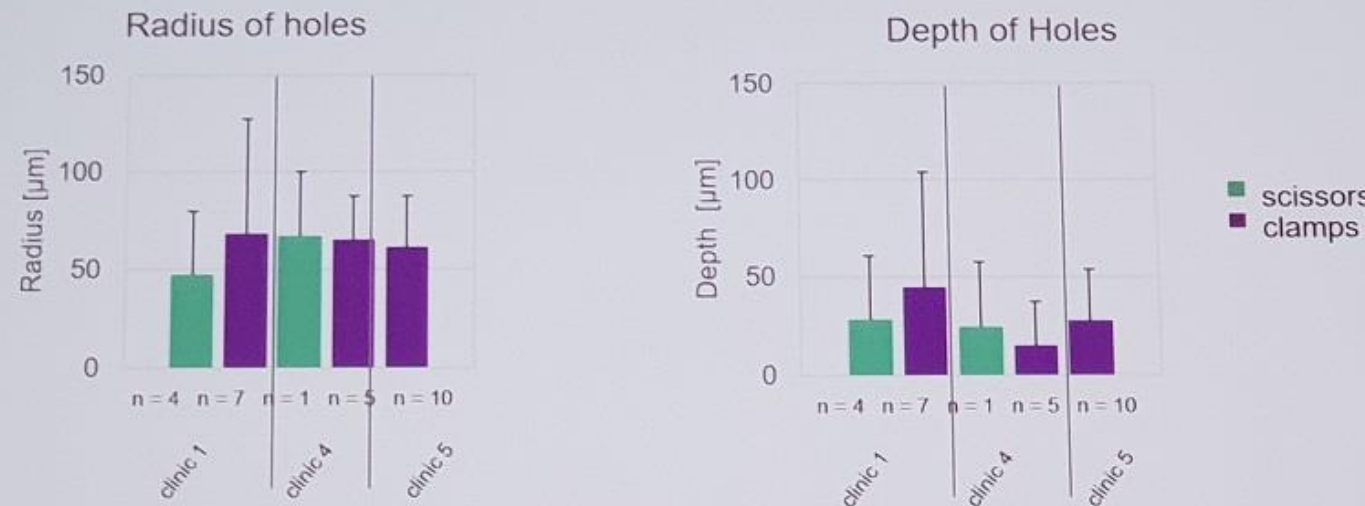


Zytotoxicity

# Microscopic Evaluations of Hospital Instruments (Laser Microscopy)



# Results



- Ongoing
- No reasonable results yet about quantities of residue in holes



So what does this mean ?

How many patient incidents do we have with rusty instruments?

It is a Risk !

EXAMPLE:



- How often do you forget to look over your shoulder before changing lanes ?  
=> Risk
- How often does a traffic accident happen?
  - Fortunately avoided.....
  - Which other circumstance contributed?
- How severe is it?
  - Deaths or Body Damage



**Ratio between Risks and Incidents Is not exactly known**

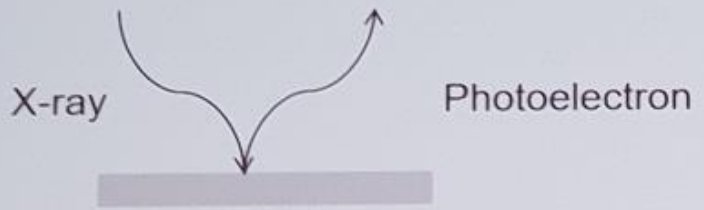
**But:**

- Hints are available
- Incidents with unknown root causes
- Avoidable

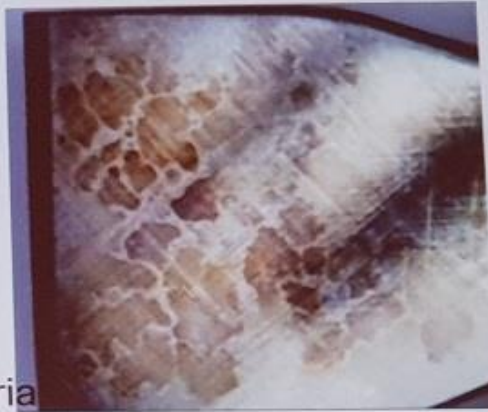
### Silicate Layers

Research by Dr. Tschoerner / Dr. Weigert

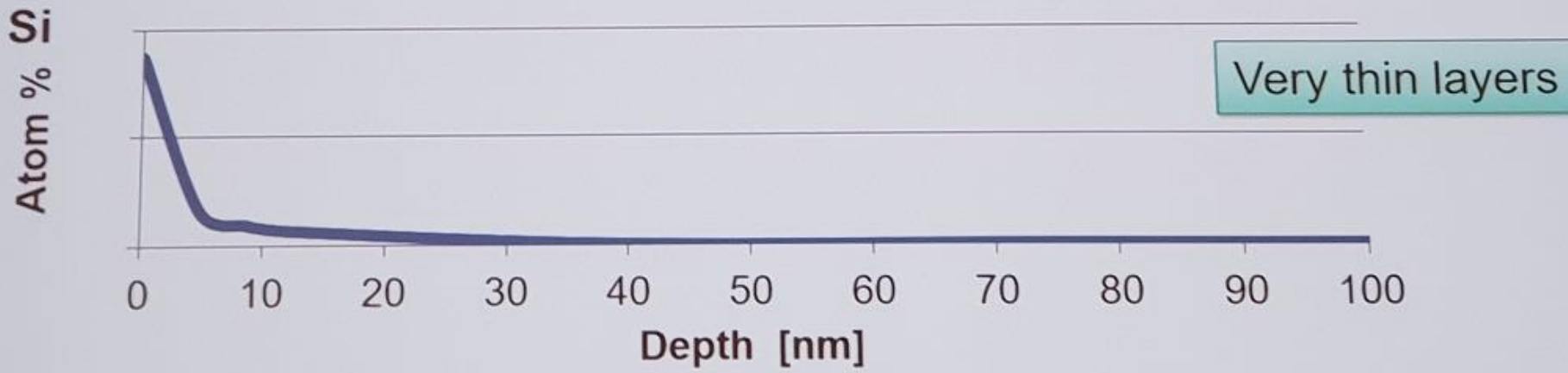
- ESCA / XPS – Photoelectronenspektroskopie



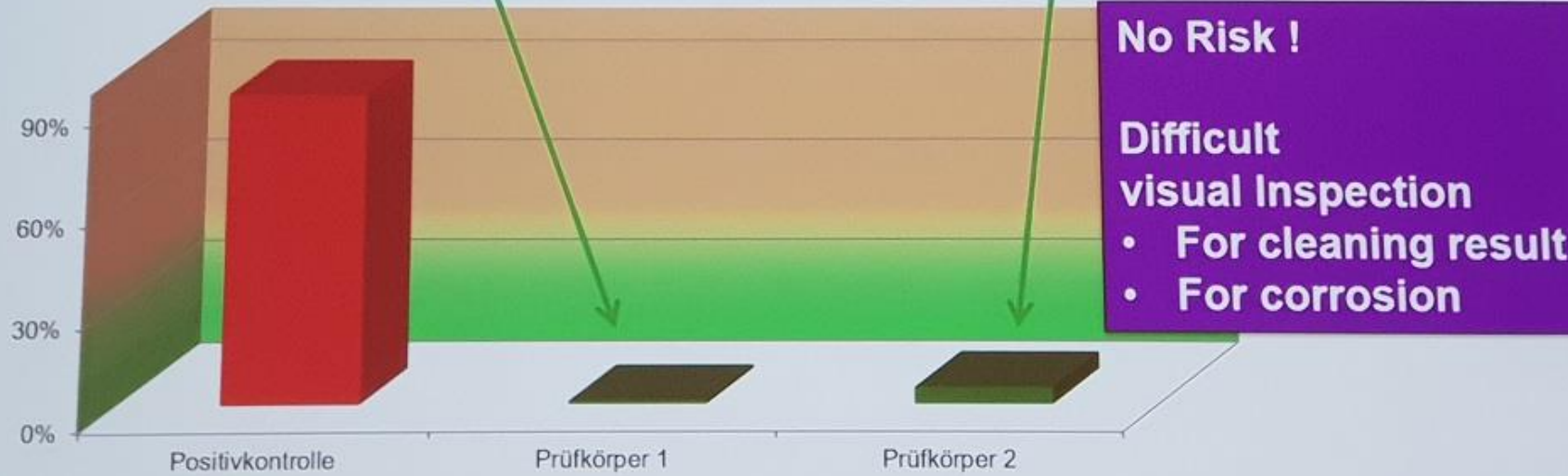
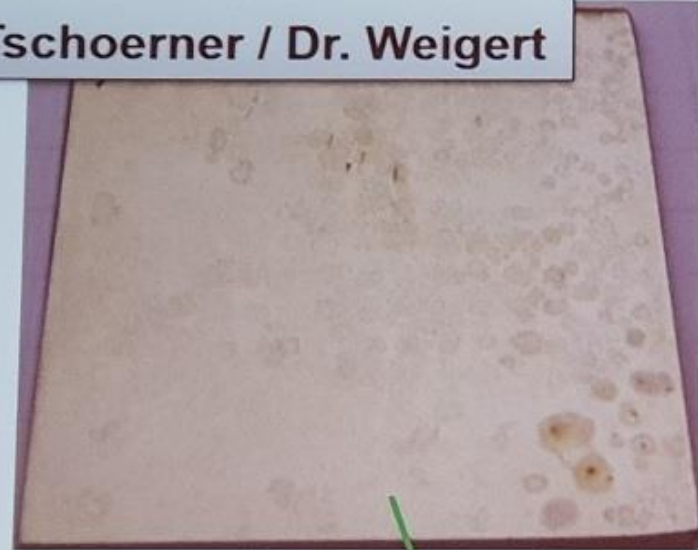
Depends on Material



- Layer Thickness 1 – 10 nm
- Si  $E_b$  102,8 eV  $\rightarrow$  chemical Condition  $SiO_2$



**Toxicity of Silicate**  
**Study by Dr. Tschoerner / Dr. Weigert**





## Bone, blood, bugs found on instruments at Denver hospital after surgical breach, report says

Written by Alyssa Rege | June 14, 2018 | Print | Email

in Share

Tweet

51

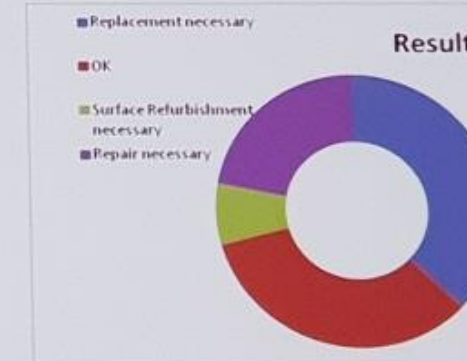
The Colorado Department of Public Health and Environment completed its investigation into Denver-based Porter Adventist Hospital April 17. In its report, the CDPHE found the hospital failed to adequately sterilize surgical instruments, some of which were found to have chunks of bone, blood, dead bugs, hair and cement, among other contaminants, according to *ABC 7 Denver*.

The department initiated an investigation into the hospital Feb. 22 after becoming aware of the infection control lapse one day prior.

On April 4, the hospital notified approximately 5,800 orthopedic and spine surgery patients who received care at the hospital between July 21, 2016, and Feb. 20, 2018, that they may be at risk for surgical site infections or exposure to hepatitis B, hepatitis C or HIV due to inadequate sterilization practices. The hospital suspended surgeries scheduled to take place April 5 and April 6 after DOH officials began their investigation. Porter Adventist resumed surgeries "on a limited schedule" April 12.

Hospital officials determined April 14 the infection control lapse resulted from a human error.

The DOH investigation found 76 instances of contaminated surgical instruments and trays being used at the hospital between Jan. 1, 2017, and April 2, 2018. The probe also found that because the instruments were not properly sterilized, surgeries at the hospital were delayed or in some cases interrupted, according to *ABC 7 Denver*.



- How could this happen?
- Who is responsible?

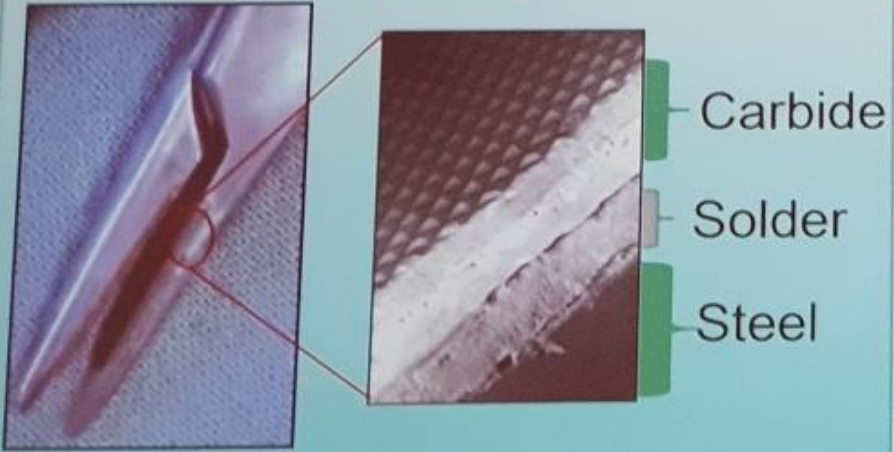
=> Expensive Replacement / Refurbishment

# Corrosion Resistance of Instruments is limited !

### Limiting Factors

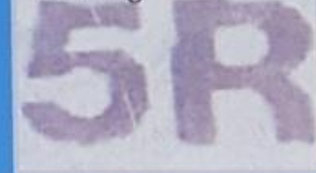
- Steel Quality
- Hardness
- Stress
- Surface roughness
- Marking
- Contruaction (solder, weld)

### Solder and Welding



### Marking

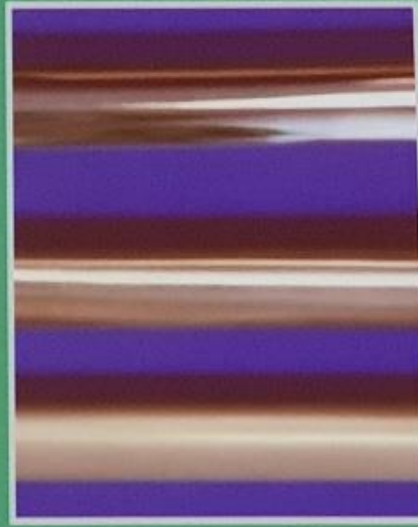
Etching



Laser



### Surface



glossy

brushed  
fine blasted

blasted

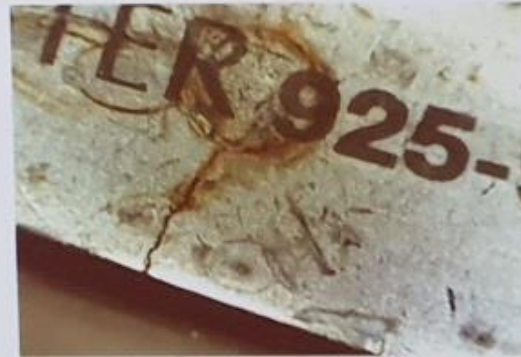




# The To Do List (most urgent, based on experience)

1. Proper Water and Steam Quality
  - Silicate and Corrosion
2. Point of Use cleaning, Quick transportation
3. Proper Cleaning
4. Targeted Oiling
5. Thorough Inspection

**=> Act early**





# 1 WATER QUALITY

## Boiling Test DIN EN ISO 13402 - Test Method for Corrosion resistance



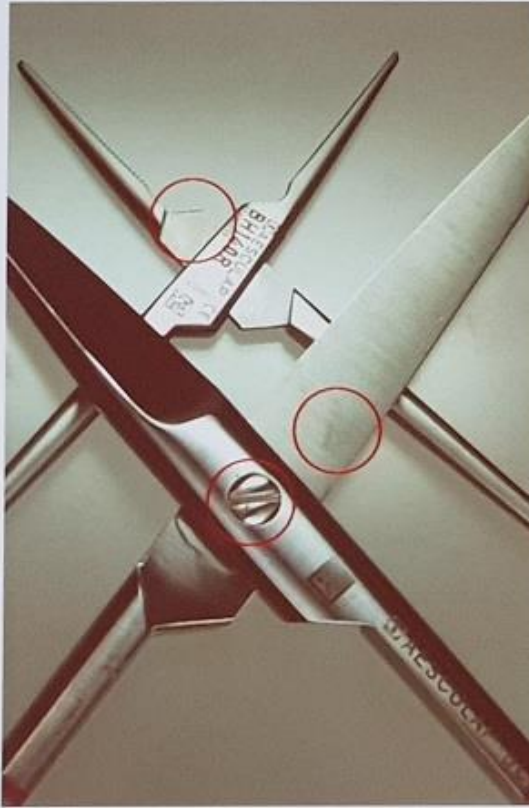
### Execution

- Clean
- Boil 30 min in Demineralized Water (EN 285)
- Cool 60 min in Water
- Dry 120 min (Air)
- Inspection

# Results



by Standard  
max. 2mg/l Chloride



4mg/l Chloride  
(1ml phys. NaCl /l)



20mg/l Chloride



at room temperature



20mg/l Chlorid, 1h



100mg/l Chlorid, 1h



100mg/l Chlorid  
Boiling Test



NaCl 0,9%, 1h

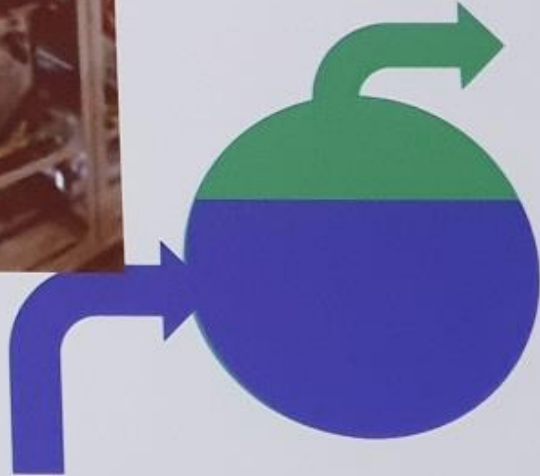


# Proper Water and Steam Quality

- EN285 is the best water standard in regards of material protection
  - Production method does not matter (Osmosis, Ion Exchange, Combination)
  - Monitoring and testing crucial
- Minimum the Thermal Disinfection has to be demineralized water
  - Other steps depend on water quality
- Sterilization steam has to be made from demineralized water
  - Clean Steam: EN285
  - Maintenance and testing crucial
  - “Black Steam” ; difficult to achieve stable quality

Contamination in the supply water to an assigned steam generator

Substance/property	Feed water
Evaporation residue	≤ 10 mg/l
Silicates (SiO <sub>2</sub> )	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metal residues, except for iron, cadmium, lead	≤ 0.1 mg/l
Chlorides (Cl <sup>-</sup> )	≤ 0.5 mg/l
Phosphates (P <sub>2</sub> O <sub>5</sub> )	≤ 0.5 mg/l
Conductivity (at 20 °C)*	≤ 5µS/cm
pH value (degree of acidity)	5 to 7.5
Appearance	colorless, clear, no deposits
Hardness (Σ of alkaline earth metal ions)	≤ 0.02 mmol/l



# POINT OF USE CLEANING AND QUICK TRANSPORTATION

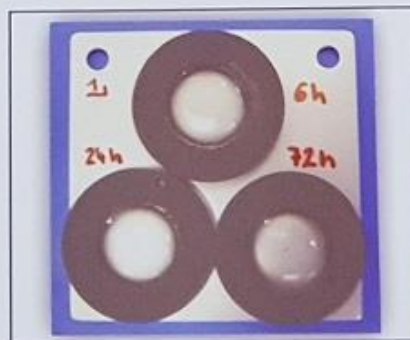
- Body Fluids are highly corrosive !
- Dried body fluids are difficult to clean !

## In OR

- Wipe instruments with water
- Flush lumens
- Prepare for cleaning

## Transport quickly

- Red Brochure: max. 6h
  - Depends on contamination
    - Sprays or moist Transportation supports cleaning
      - May contribute to corrosion

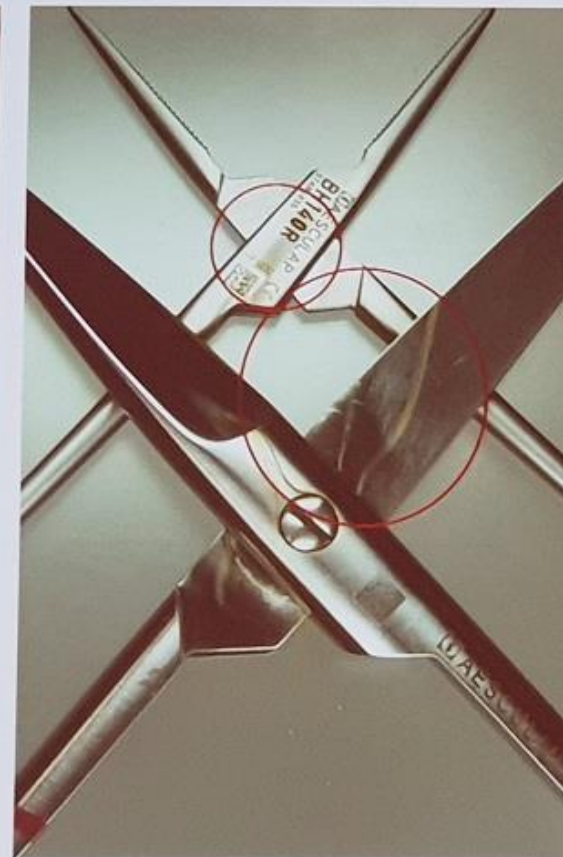




# Sodium Chloride



NaCl 0,9%, 1h



NaCl 0,9%, 2h

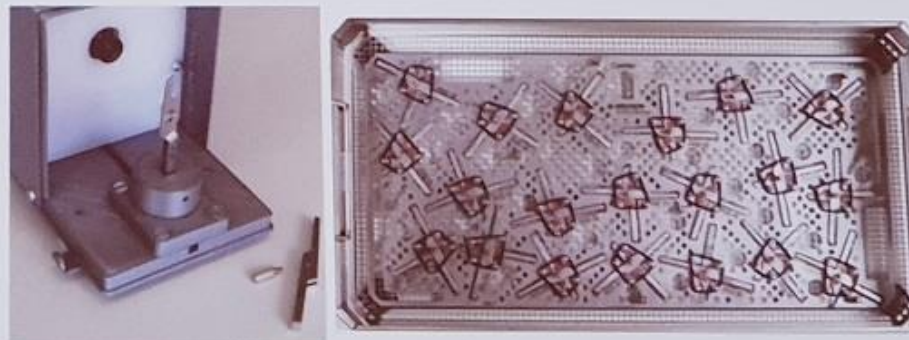


NaCl 0,9%, 6h

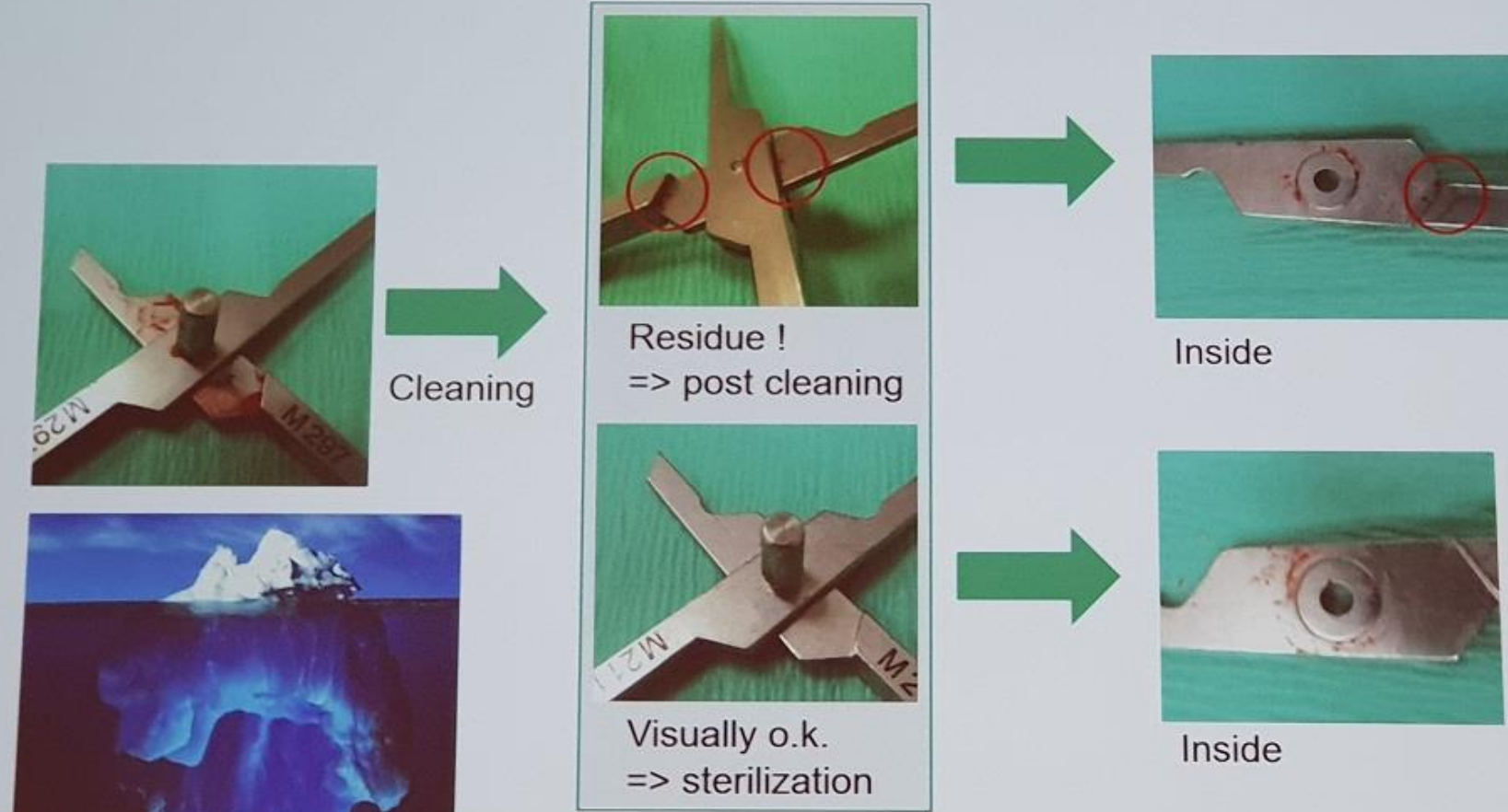


# EFFICIENT CLEANING

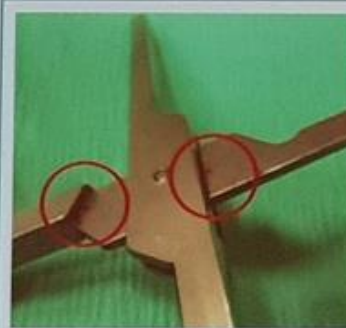
- Educated personnel
- Manual / Ultrasound Pre-cleaning for critical instrument
  - Immersion does not help much
  - Brushing takes time
- Efficient machine cleaning
  - Proper Loading Racks (MIS)
  - Loading (open...)
  - Minimum 10min cleaning time
  - Alkaline Cleaners more efficient than Neutral (material compatibility)
  - Neutralizers help
  - Maintenance
  - Testing



# Inspection does not replace proper cleaning processes



Visible contamination is the tip of the Iceberg !!!  
=> Validation and Testing is Crucial !





# TARGETED OILING

“Instrument Milk” does not help

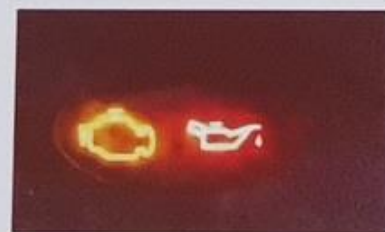
Usage in final rinse

- Dosage 1-2ml/l water (example 60ml /40l)
  - consisting of 30% Paraffin Oil
  - Maximum 10% stick on instruments
- ⇒ 1,8ml of oil

Distributed over ca 400 Instruments

- joint area is about 5% of an instruments surface

- ⇒ 0,23µl oil per joint
- ⇒ required: 5-10µl



Usage in bath: risk of recontamination  
About 80-90% of oil gets removed in cleaning



Surface must not feel oily

**Targeted Oiling**

- Paraffin oil / white oil
- pharmaceutical guideline (patient contact)
- steam-penetrable / sterilizable / biocompatible





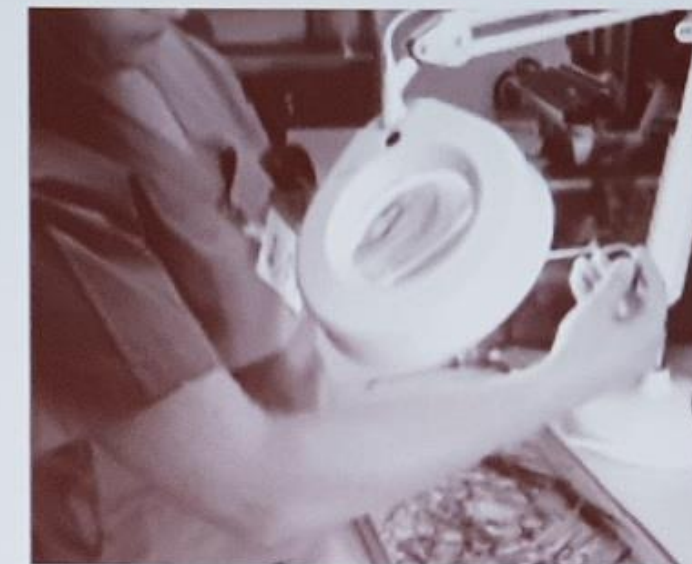
# INSPECTION

## Mystery of Selective Blindness

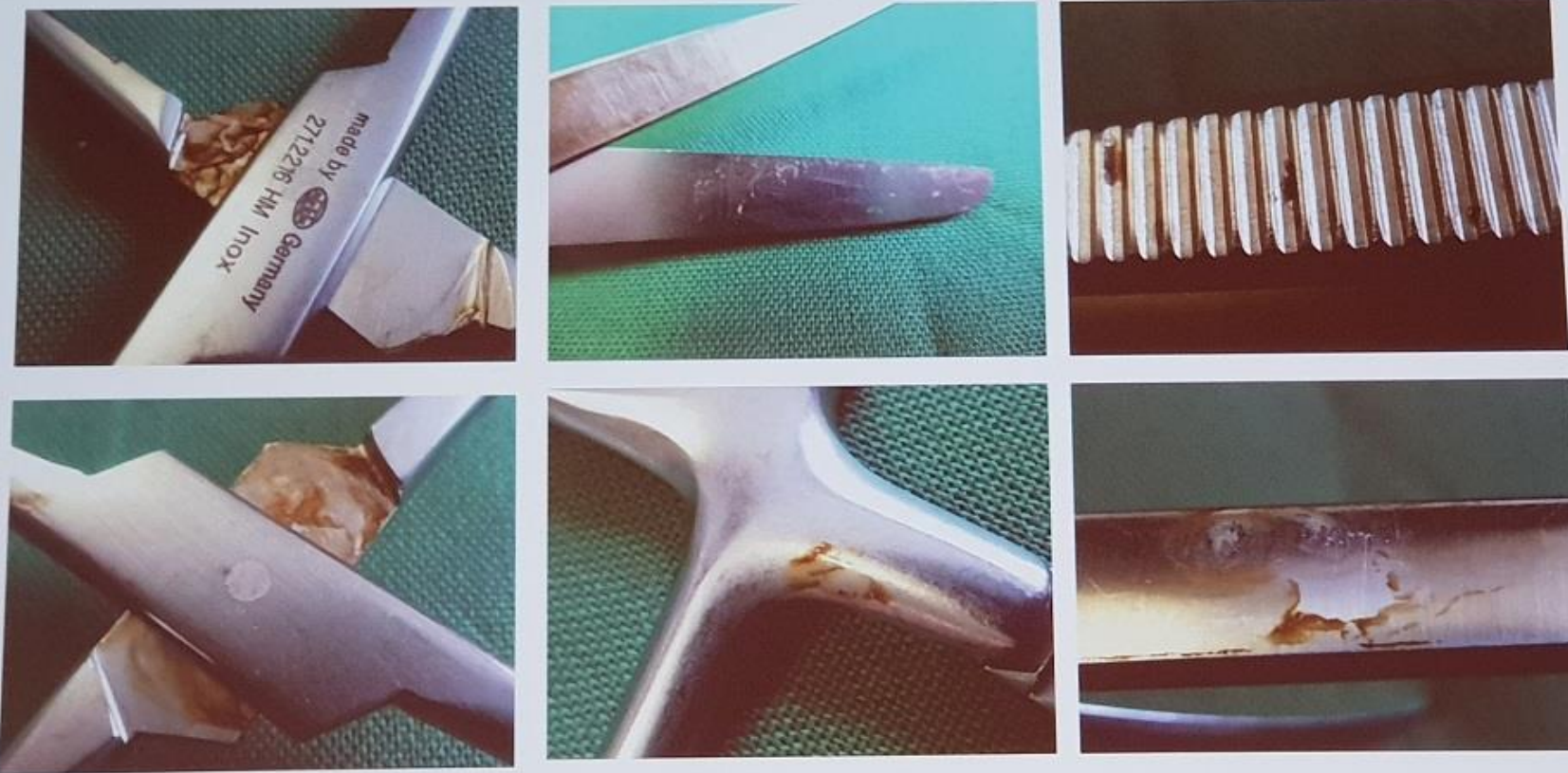


Statement from German Hospital on TV

- impossible to detect in routine inspection
- special light and microscope necessary



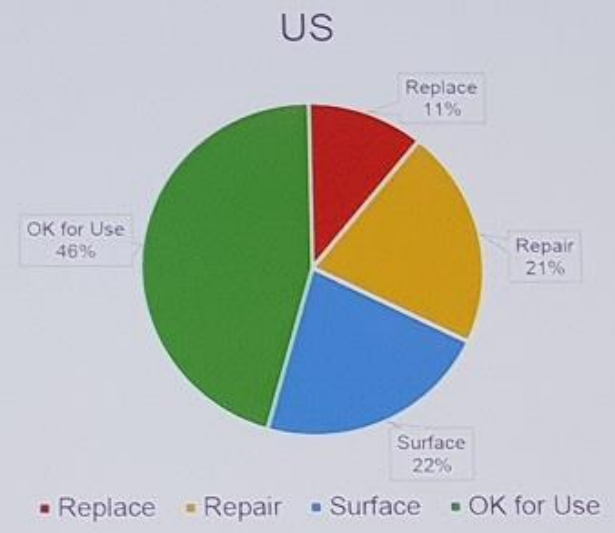
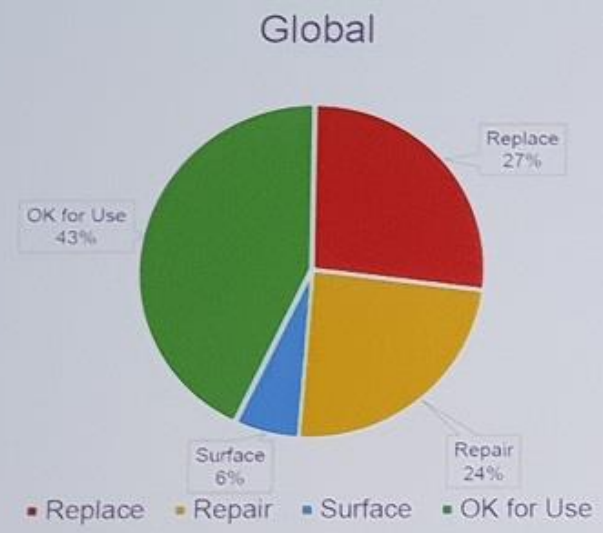
### Claimed as „Ready to Use“



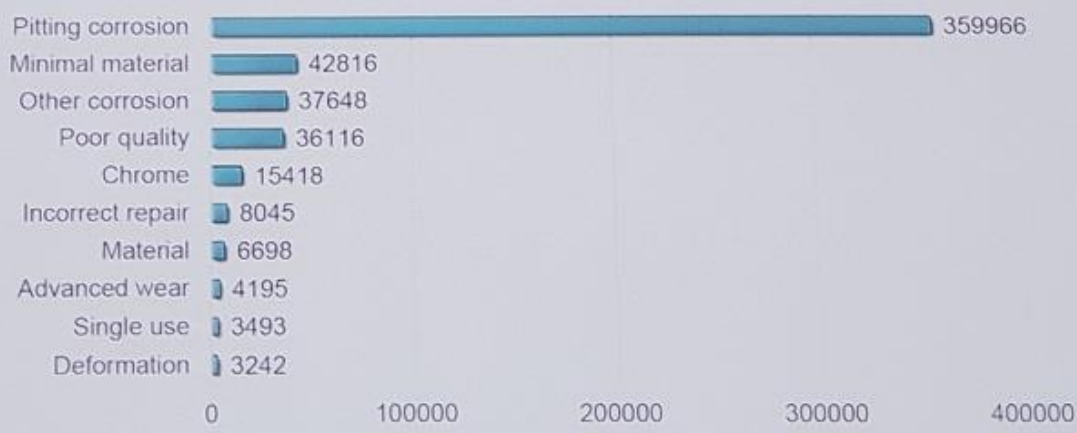
- No clear standard set
- People not trained / no time
- Discouraged !!!



# Condition of Instruments



- Only 40%-50% fit for use
- Pitting is number the one reason for replacement



# Motivation and Monitoring



„keep sets clean“ !

**tackle root causes!**  
 => **Reduce**

sporadic Issue  
 => clean / repair

systematic / persistent issues  
 => process optimization

## Killer phrases

- We urgently need this set !
- We have no time !
- Half of our instruments look like this !
- The instruments are old !
- .....

## Inspektionsliste

Datum/ von \_\_\_\_\_

Set	Artikle Nr	Beschreibung	Herstell/ Rep Datum	Problem	Maßnahme

**Indicator**



# What to do?

- Packing Area (Hygienics ?)**
- Cloth with instrument oil
  - Alcohol / Acetone / Tape EX / Ether
  - Aluminum-Oxide -Rubber
  - (Steamer)
  - (Hydrogenperoxide)

- Decontamination Area**
- Refer Instrument to Set
  - Brush / Ultrasound
    - Hydrogenperoxide (+ alkaline cleaner)
    - Concentrated Enzymatic Cleaner
    - Liquid abrasive (Chirol)
    - (Rotating Brushes)
  - Surgistain or similar (Phosphoric Acid)



# Basic Cleaning / Refresh .... in WD

- Collect ! (=> Set ?)
- Different Philosophies

- Pre Clean
- Mild alkaline cleaning  
Max Konz, 70°C, 15min
- Intermediate Rinse
- Neutralizer Citic Acid  
10ml/l, 70°C, 10min
- Rinse
- Rinse (withTherm Desinf)
- Dry

- Pre Clean
- Alkaline Cleaner  
mid Konz, 80°C, 10min
- Intermediate Rinse
- Neutralizer Citic Acid  
10ml/l, 80°C, 10min
- Rinse
- Rinse (withTherm Desinf)
- Dry

- Pre Clean
- Alkaline Cleaner  
mid Konz, 70°C, 5min
- Intermediate Rinse
- Phosphoric / Nitic Acid  
20ml/l, 90°C, 10min
- Rinse
- Rinse (withTherm Desinf)
- Dry

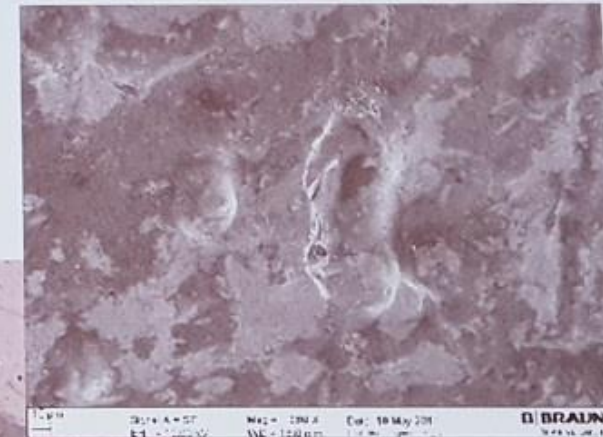
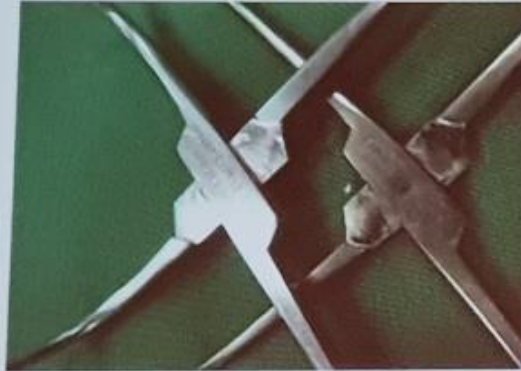
- Neutralizer Citic Acid  
30ml/l, 85°C, 30min
- Rinse
- Rinse
- (Dry)

- Phosphoric Acid  
40ml/l, 60°C, 20min
- Rinse
- Rinse
- (Dry)

Material Compatibility - Who decides?



# Results



- Corrosion holes/ Scratches remain
- Limited access to crevices and cavities



# Backup Instruments



**Backup Stock**

- Which items? How many?
- Controlled Inventory or KanBan

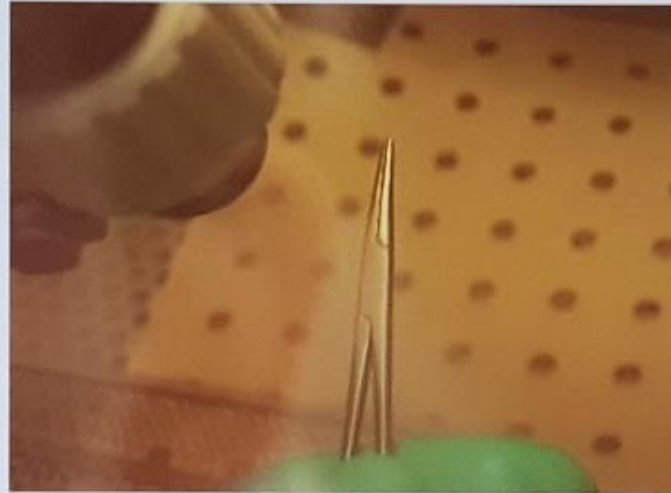


Missing Parts?

- Essential parts?
- Not case by case



## Qualified Repair



### Surface

- assembled/ disassembled
- with/ without new marking

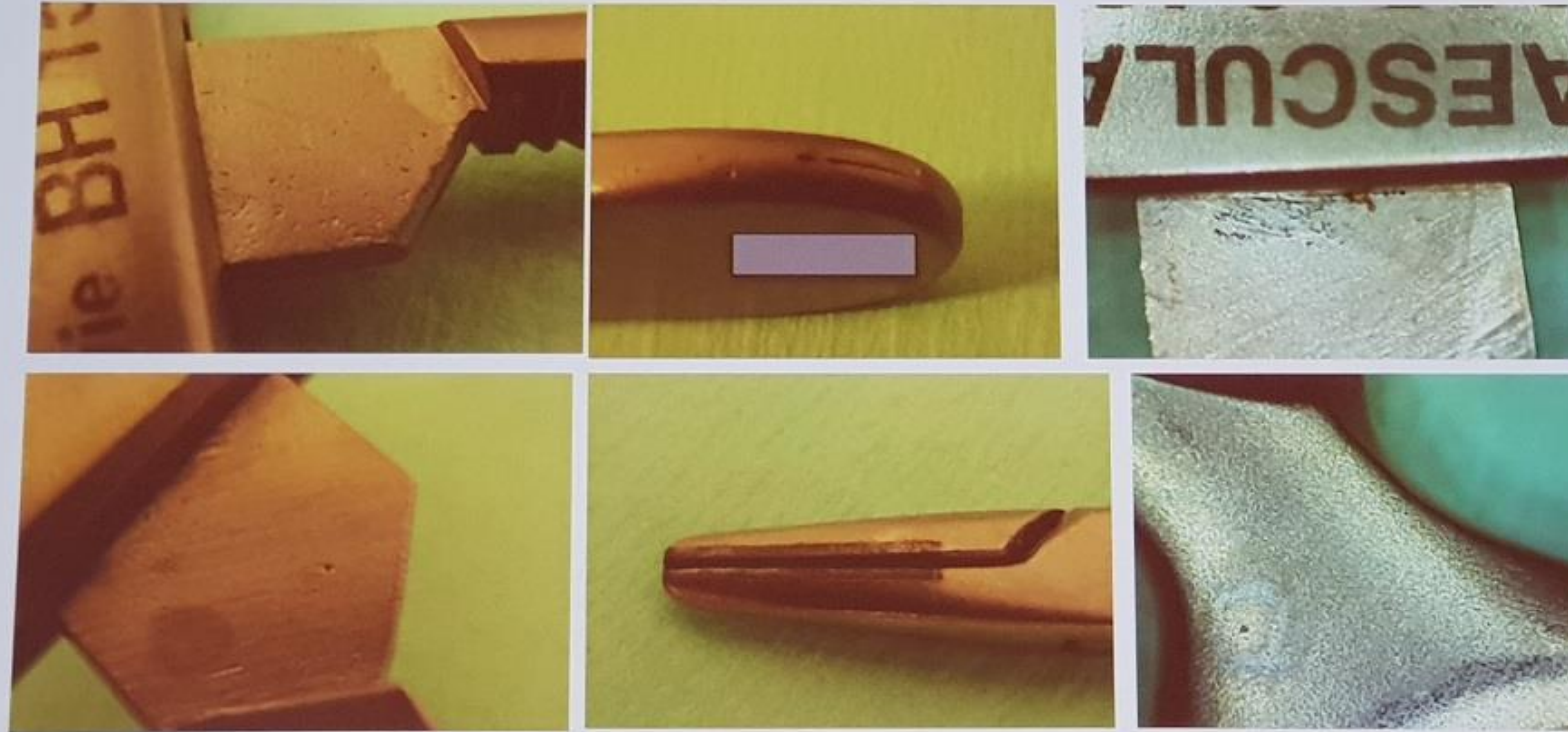
Grind down to undamaged material



### Logistics: Repair versus Exchange

- Exchange-Instruments shipped over night
  - Price depending on condition of instrument
- => For essential Instruments

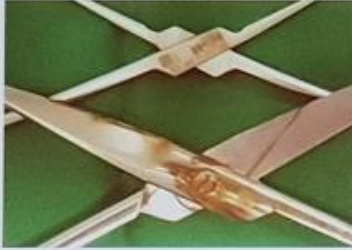
# „Low level“-Repair – Surface Repair of corrosion



- Surface repair does not work on deep corrosion
- Surface / solder / etc remain damaged
  - Corrosions re-occur quickly (here: 2 months)



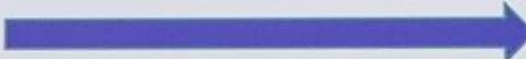
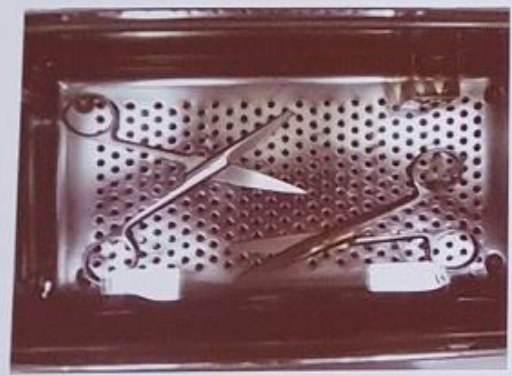
# Corrosion Transfer => Boiling Test



Contact



Tray



# Corrosion Transfer

Corrosion in one area



Will travel over time



Quantity

Distance



# Check new Processes and after Changes ...

We found

- shreds and corrosion in pipes..
- wrong connection of pipes
- faults in programs (no rinse)
- wrong dosage
- mix up of canisters
- leakages of valves/ chemistry
- poor vacuum in sterilizer
- lack of capacity
- interfaces / waiting times



**Better: Have planning supported !**

# Summary

1. Proper Water and Steam Quality
  - Silicate and Corrosion
2. Point of Use cleaning, Quick transportation
3. Proper Cleaning
4. Targeted Oiling
5. Thorough Inspection

**=> Act early**

**Looking back is a reward  
for many efforts.....**





Thank You!

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Director Technical Competence Center  
phone: +49 7461 95 2880  
[gerhard.kirmse@aesculap.de](mailto:gerhard.kirmse@aesculap.de)



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SHARING EXPERTISE