Identification and prevention of surface alterations on surgical Instruments caused by waterborne minerals

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Objective

Water Constituents and Influences on processing of Medical Devices

Water Qualities for processing of Medical Devices

Characterization of surface alterations caused by Waterborne Minerals

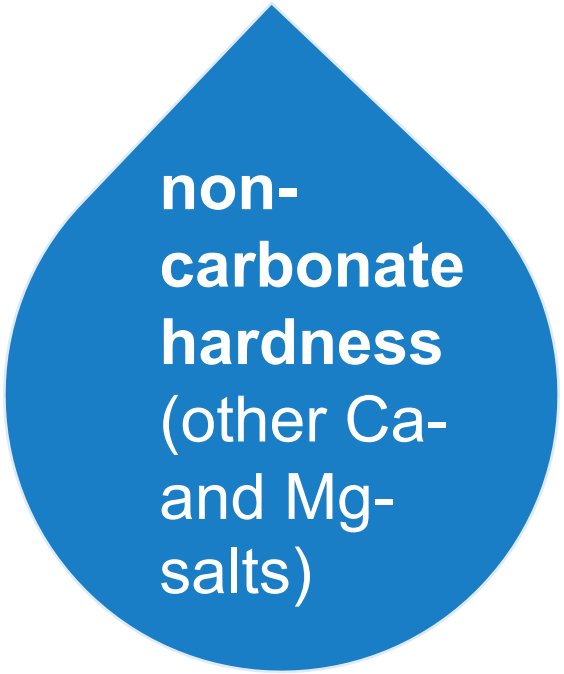
Working with the invisible chemical...

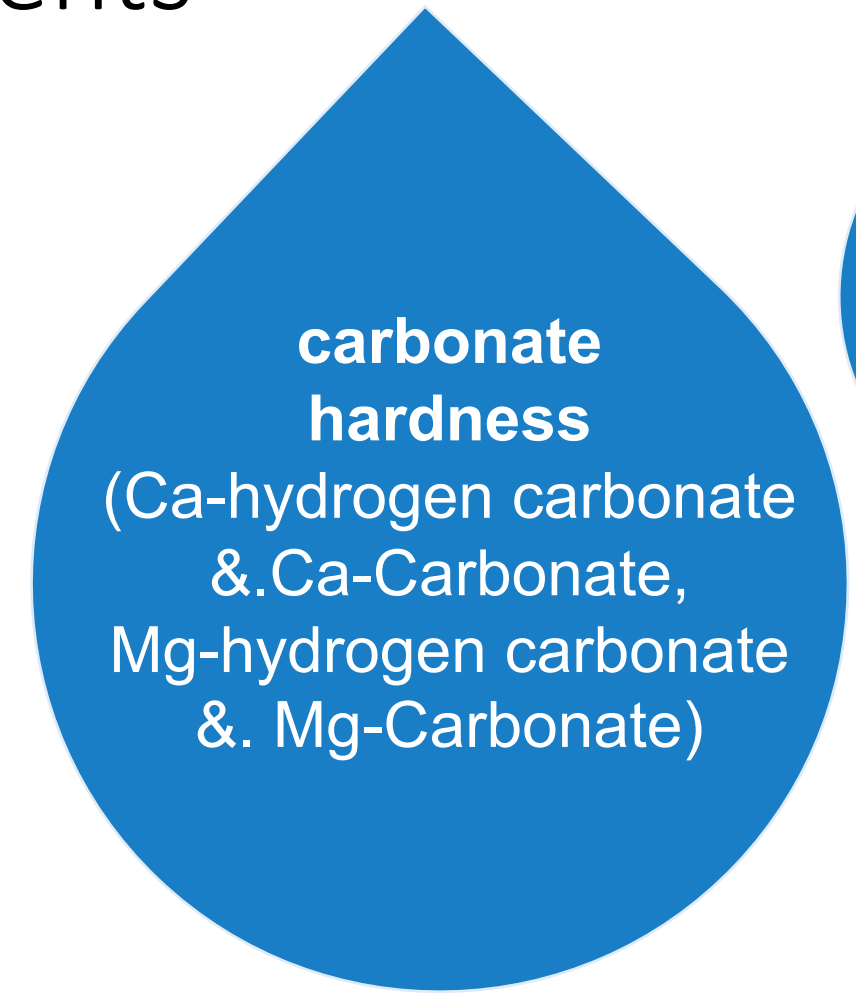
Water qualities & ingredients

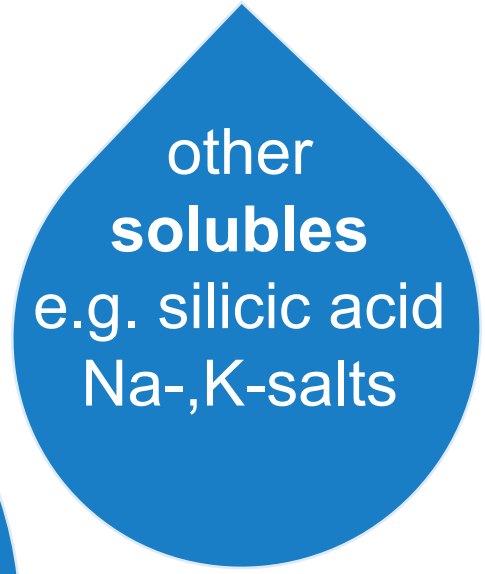
When heating water

non-carbonate hardness remains in solution,

but **carbonate hardness** leads to stubborn **lime deposits**.



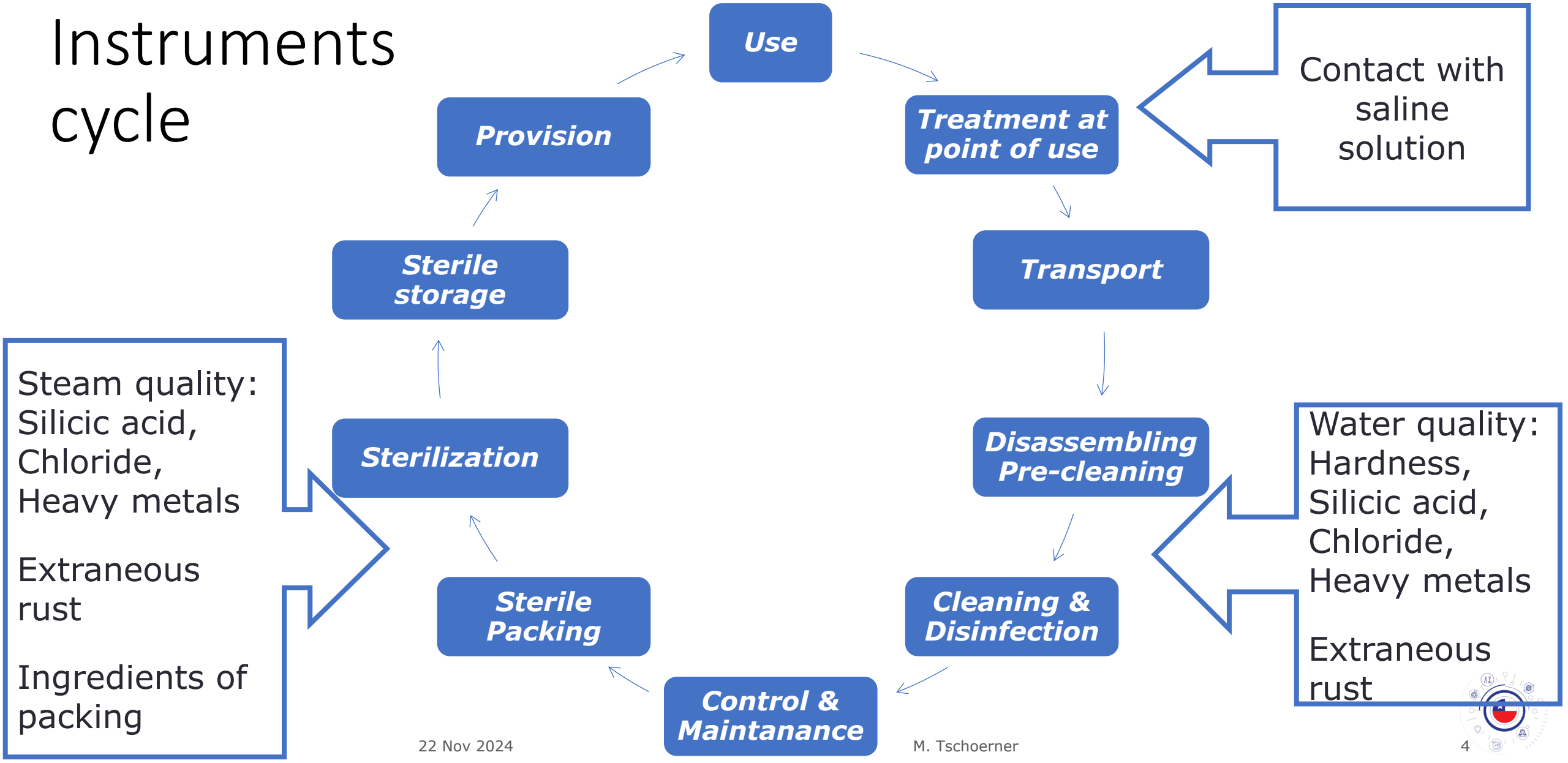




Total hardness = non-carbonate hardness + carbonate hardness

200 mg $CaCO_3$/l = 50 mg/l + 150 mg/l ppm = mg/L

Instruments cycle

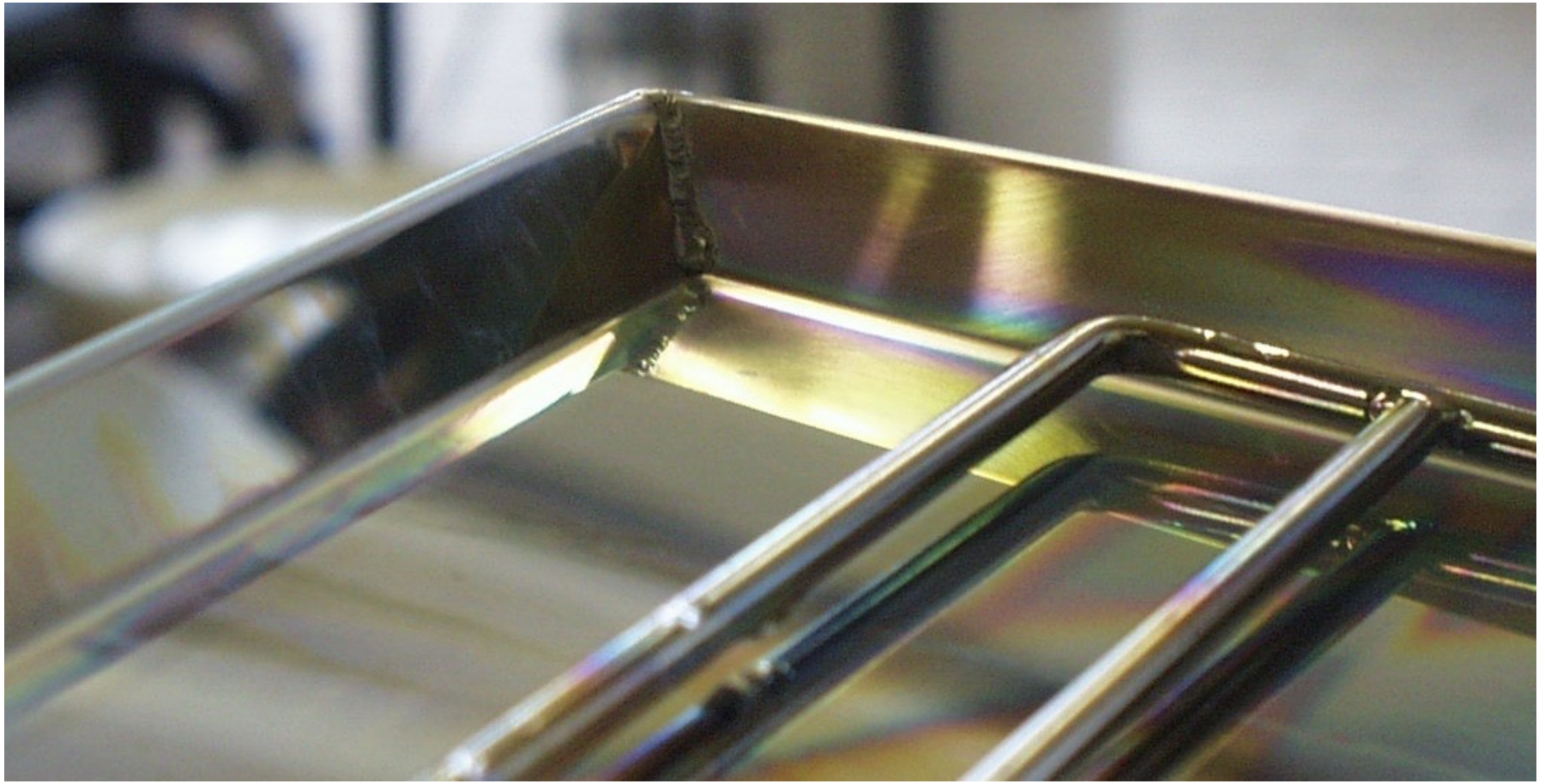


Constituents in water, which may cause problems in washer disinfectors

Evaporation residues

high amount of minerals in the water for cleaning and rinsing

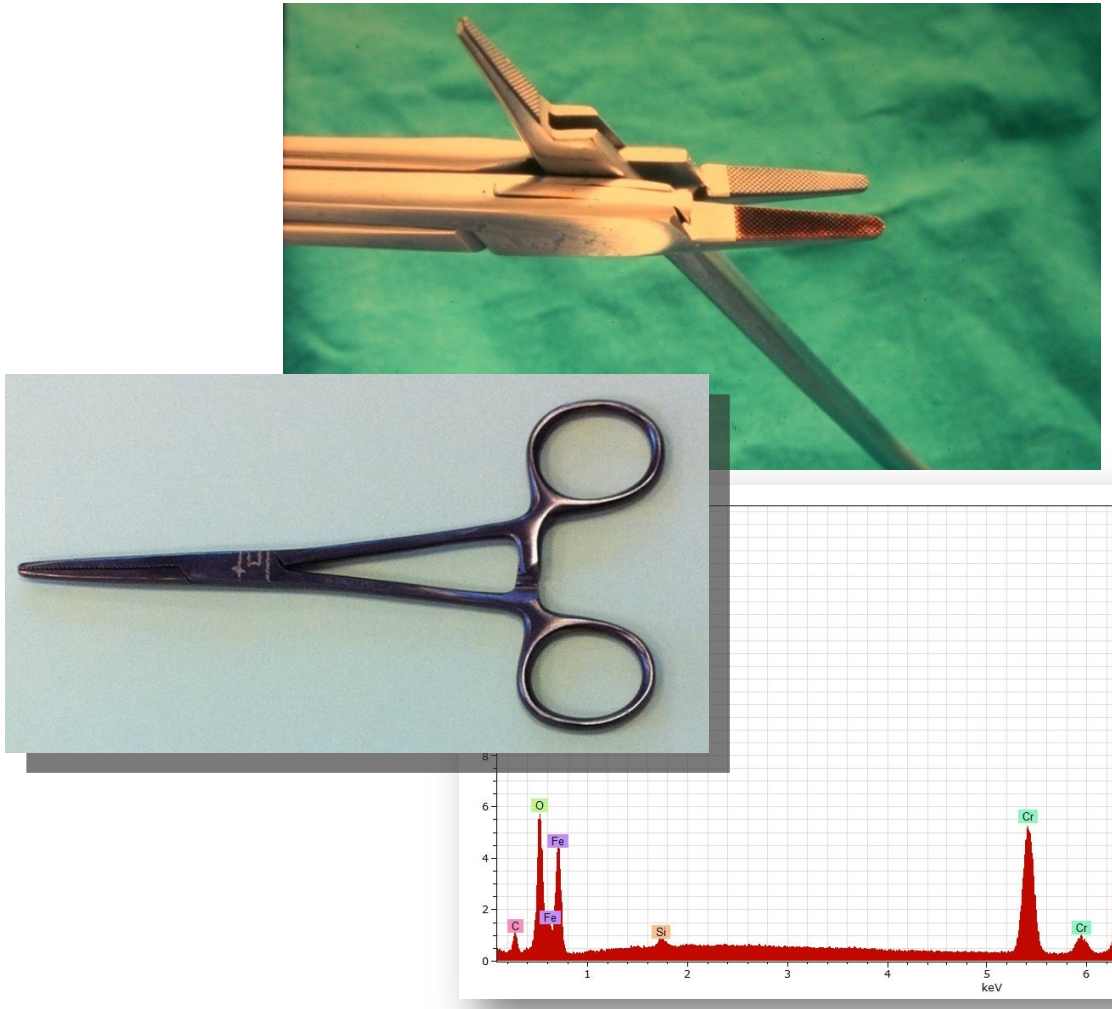
Constituents in water, which may cause problems in washer disinfectors



Very thin layer of limestone

Constituents in water, which may cause problems in washer disinfectors

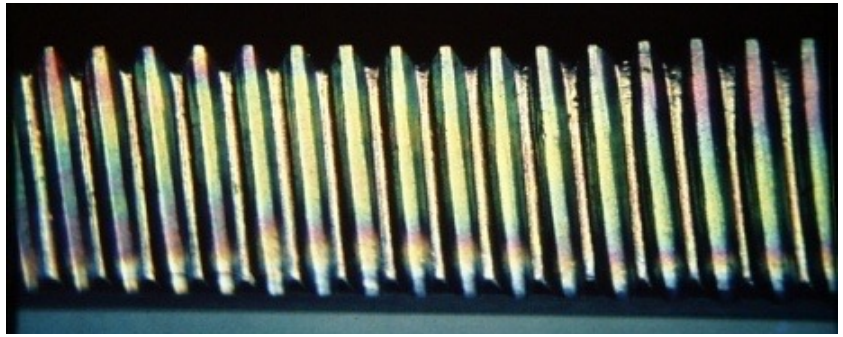
Heavy and non-ferrous metals
(Iron, Manganese, Copper):
Dark discolorations and deposits,
inactivation of water softener



Constituents in tap water, which may cause problems in washer disinfectors

Silicic acid/ silicates

Stubborn yellowish-brown or bluish-violet glaze-like deposits



Constituents in tap water, which may cause problems in washer disinfectors

Chloride
Chloride induced pitting corrosion

Rust particle
Rust transfer

Water for the processing of medical devices

American National Standard

ANSI/AAMI ST108:2023
Water for the processing of medical devices

Washer Disinfector

- Tap water (utility water)
- Softened water (utility water)
- Deionised water (critical water)

Working group for instrument reprocessing (AKI), "Red brochure" on www.a-k-i.org

ANSI/AAMI ST108:2023 Water for the processing of medical devices

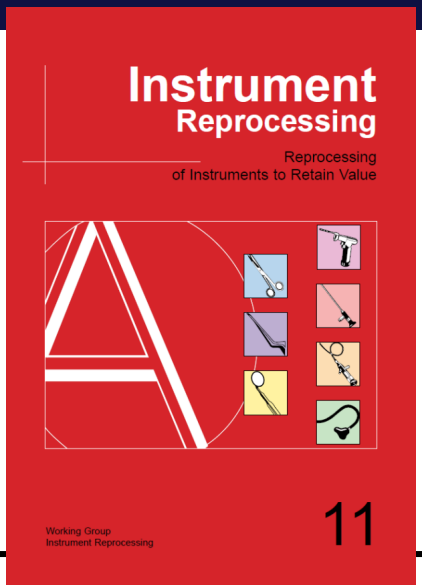
Steam Sterilizer

- Deionised water

ANSI/AAMI ST108:2023 Water for the processing of medical devices

EN 285:2015 (A1:2021) Sterilization – Steam sterilizers – Large sterilizers

Working group for instrument reprocessing (AKI), "Red brochure" on www.a-k-i.org



Recommended Water Qualities

Flushing / Washing / Rinsing:

Softened Water (Utility Water)

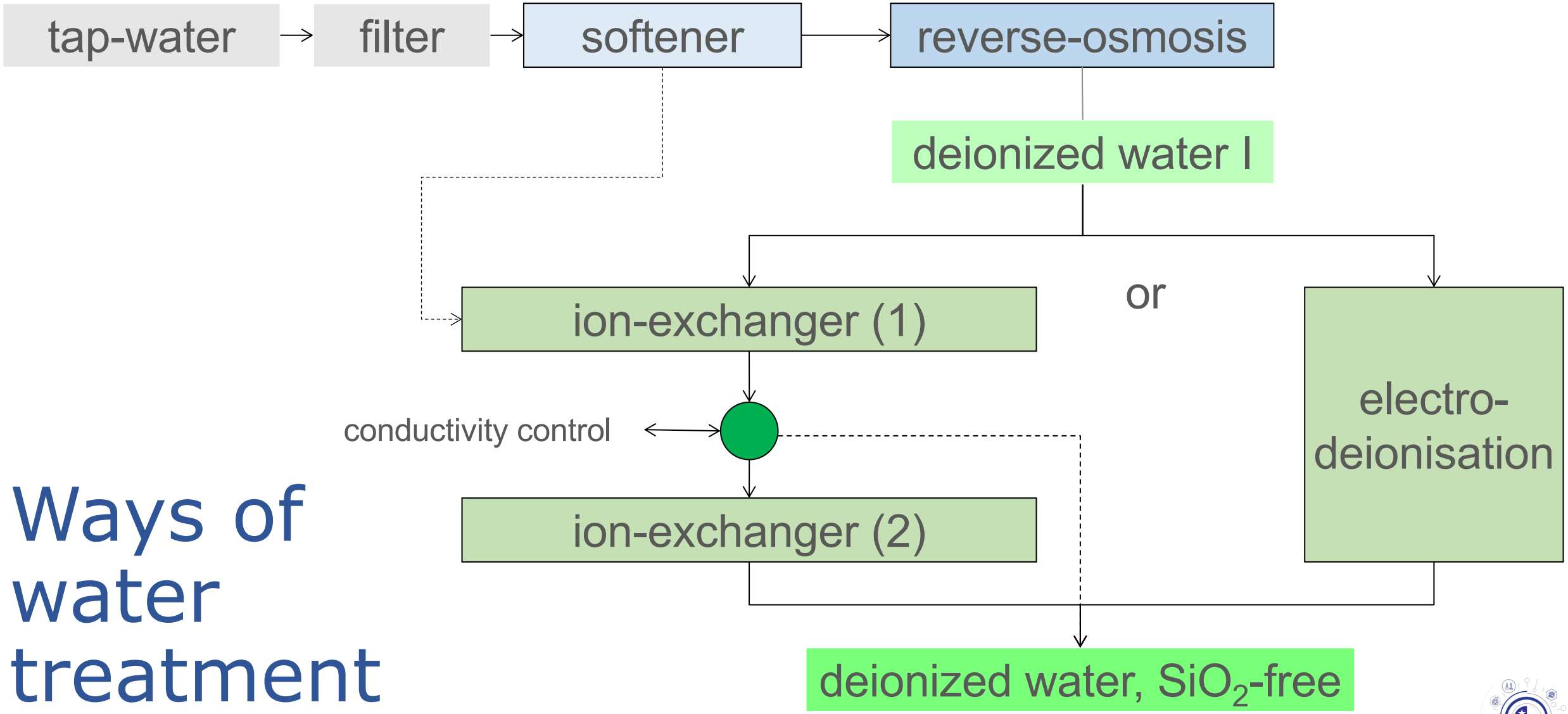
	AKI	AAMI ST108
Appearance	Colourless, clear	Colorless, clear, without sediment
Total hardness	53 mg $CaCO_3$/l (3 °d)	< 150 mg $CaCO_3$/l
pH-value	5 – 8	6.5 – 9.5
Evaporation residue	≤ 500 mg/l	
Chlorides	≤ 100 mg/l	< 250 mg/l

Recommended Water Qualities

Final Rinse & Sterilization Deionized water (Critical water)

	AKI Final Rinse	EN 285 / AKI feed water	AAMI ST108
Appearance	Colourless, clear, without sediments		
Electrical conductivity	≤ 15 µS/cm	≤ 5 µS/cm	< 10 µS/cm
pH-value	5 – 7.5	5 – 7.5	5 – 7.5
Evaporation residue	≤ 10 mg/l	≤ 10 mg/l	
Chlorides	≤ 0.5 mg/l	≤ 0.5 mg/l	< 0.1 mg/l
Silicates (SiO_2)	≤ 1 mg/l	≤ 1 mg/l	≤ 1 mg/l
Phosphate (P_20_5)	≤ 0.5 mg/l	≤ 0.5 mg/l	≤ 1 mg/l
Water hardness	≤ 2 mg $CaCO_3$/l	≤ 2 mg $CaCO_3$/l	≤ 1 mg $CaCO_3$/l

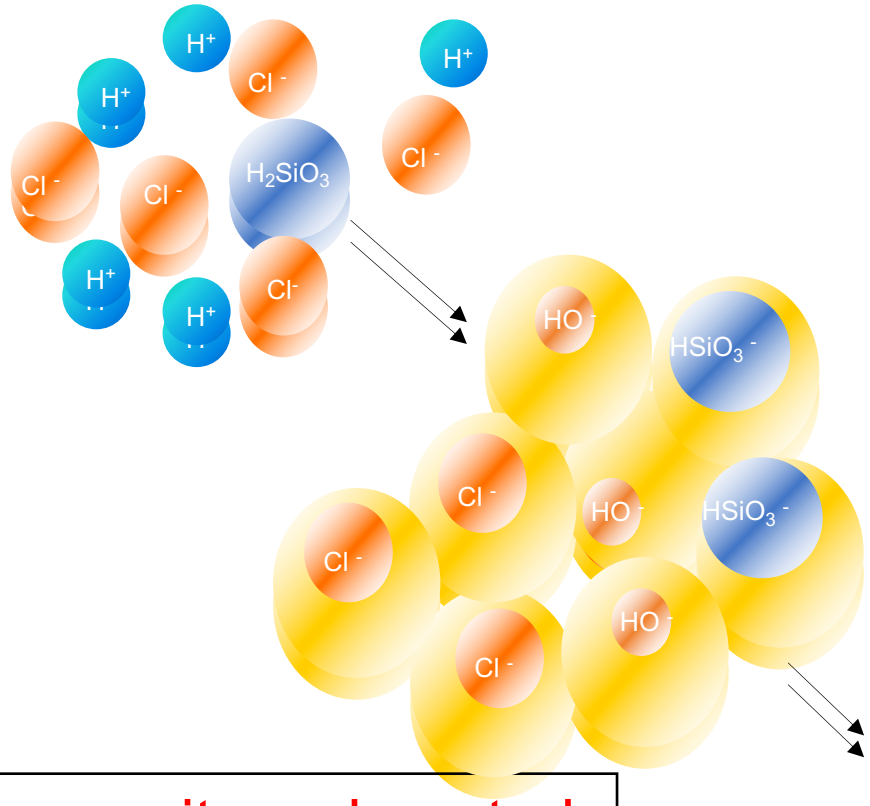
Ways of water treatment

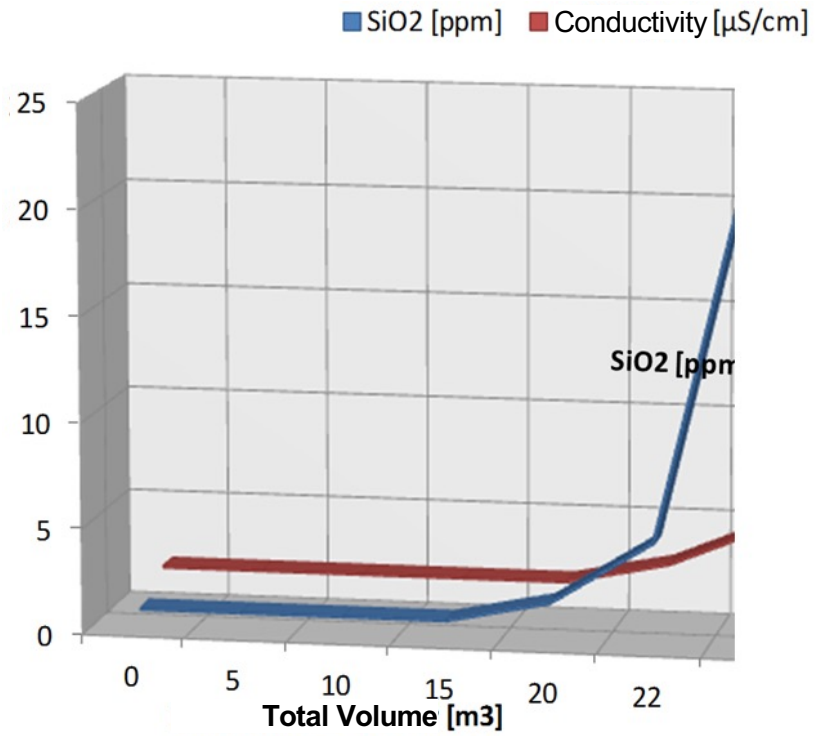


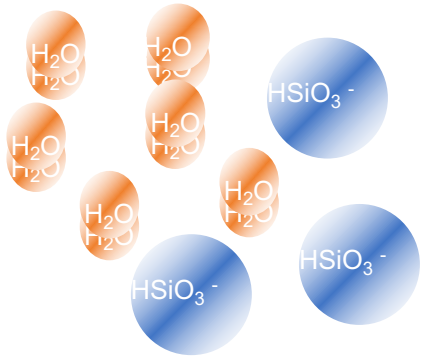
Water Treatment - Changing Water Quality

	Units	Tap water	Softened water	Deionised water	
				Reverse-Osmosis	Ion-Exchanger
Evaporation residue	ppm	500	530	30	5
Electrical Conductivity	µS/cm	650	700	30	3
Total hardness	mg $CaCO_3$/l	250	< 1.8	8.9	< 1
Sodium salts	ppm	20	160	2	< 1
Chlorides	ppm	40	40	3	< 1
Silicates or Silicic acid	ppm SiO_2	12	12	2.1	< 0.1
pH value		6.7	ΔT 7.5 → 9.5	6.0	5.5

Silicic acid slippage







Ion exchanger – capacity exhausted
Silicic acid slippage

Ion exchanger – full capacity

Wasseranalyse Nr. ☐	WD14-1309	WD14-1310	WD14-1311		
Herkunft	AWT-Nr:14782				
Probennahmedatum	15.10.2014	15.10.2014	16.10.2014		
Probenbezeichnung	Probe 1: VE-Wasser vor Regeneration	Probe 2: VE-Wasser nach Regeneration	Probe 3: VE-Wasser ein Tag nach Regeneration	Empfehlung **EN 285:2009-08** (Tabelle B.1) Speisewasser	Empfehlung **EN 285:2009-08** (Tabelle B.2) Kondensat
Parameter					
Aussehen	farblos, klar, ohne Ablagerungen	farblos, klar, ohne Ablagerungen	farblos, klar, ohne Ablagerungen	farblos, klar, ohne Ablagerungen	farblos, klar, ohne Ablagerungen
pH Wert (1)	5,4	5,3	5,6	5 - 7,5	5 - 7
pH / Messtemperatur (9) °C	23,1	23,1	23,2	-	-
Leitfähigkeit (25°C) (2) µS/cm	< 3	< 3	< 3	≤ 5	≤ 3
Abdampfrückstand (3) mg/l	112	< 10	< 10	≤ 10	-
Gesamthärte (8) °d	< 0,1	< 0,1	< 0,1	≤ 0,1	≤ 0,1
mmol/l	< 0,0173	< 0,0173	< 0,0173	≤ 0,02	≤ 0,02
Eisen (Fe) (7) mg/l	< 0,1	< 0,1	< 0,1	≤ 0,2	≤ 0,1
Kupfer (Cu) (4) mg/l	< 0,05	< 0,05	< 0,05	-	-
Zink (Zn) (4) mg/l	< 0,05	< 0,05	< 0,05	-	-
Cadmium (Cd) (4) mg/l	< 0,005	< 0,005	< 0,005	≤ 0,005	≤ 0,005
Blei (Pb) (4) mg/l	< 0,05	< 0,05	< 0,05	≤ 0,05	≤ 0,05
Schwermetalle (außer Fe,Cd,Pb) mg/l	< 0,1	< 0,1	< 0,1	≤ 0,1	≤ 0,1
Chlorid (5) mg/l	< 0,1	0,1	< 0,1	≤ 2	≤ 0,1
Phosphate (P_2O_5) (5) mg/l	< 0,1	< 0,1	< 0,1	≤ 0,5	≤ 0,1
Silikat/Kieselsäure SiO_2 (6) mg/l	57,7	< 0,1	< 0,1	≤ 1	≤ 0,1

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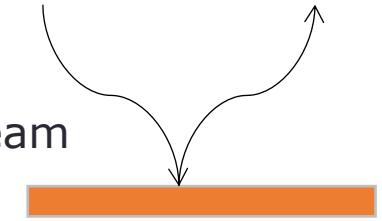
Surface alterations on surgical instruments after reprocessing

Visual appearance

- gold-brown to blue-violet, iridescent, uniformly discoloration of smooth high-gloss stainless steel surfaces
- discoloration like condensation droplet stains on all surface structures

Characterization of surface alterations

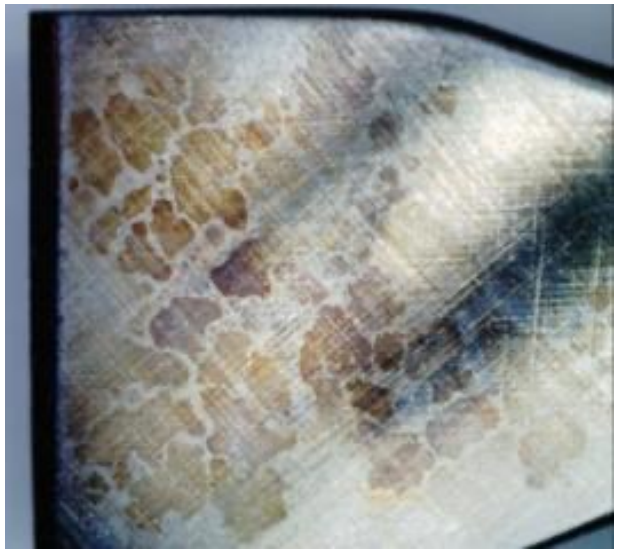
SEM-EDX, Scanning Electron Microscopy with Energy Dispersive X-ray Spectroscopy

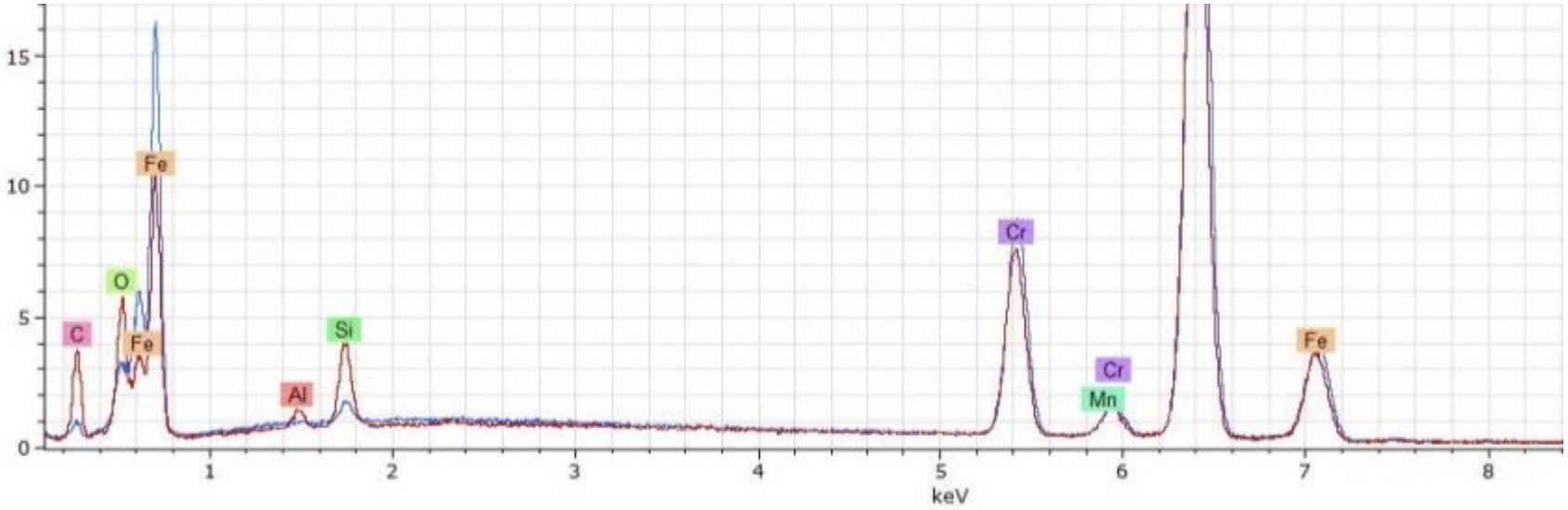


Electron beam

X-ray – element specific

Information depth 1 – 3 µm





Tschoerner, M., ZAHN PRAX 16, 5, 274-277 (2013)

Characterization of surface alterations

ESCA / XPS – Electron scattering for Chemical Analysis / X-ray Photoelectron Spectroscopy

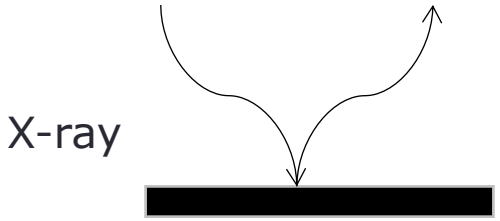
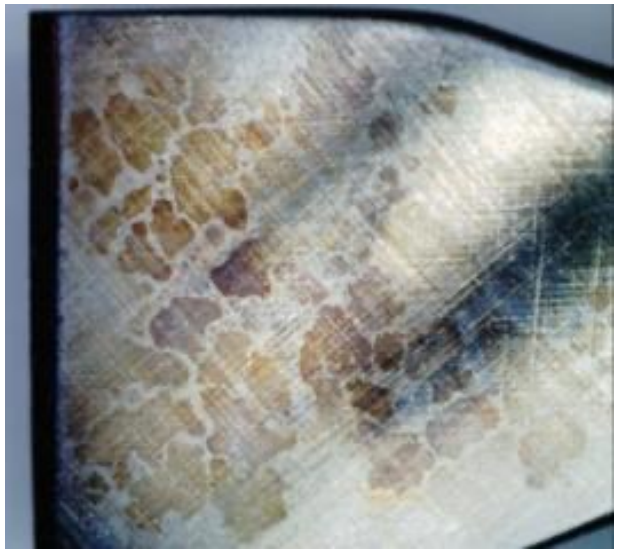
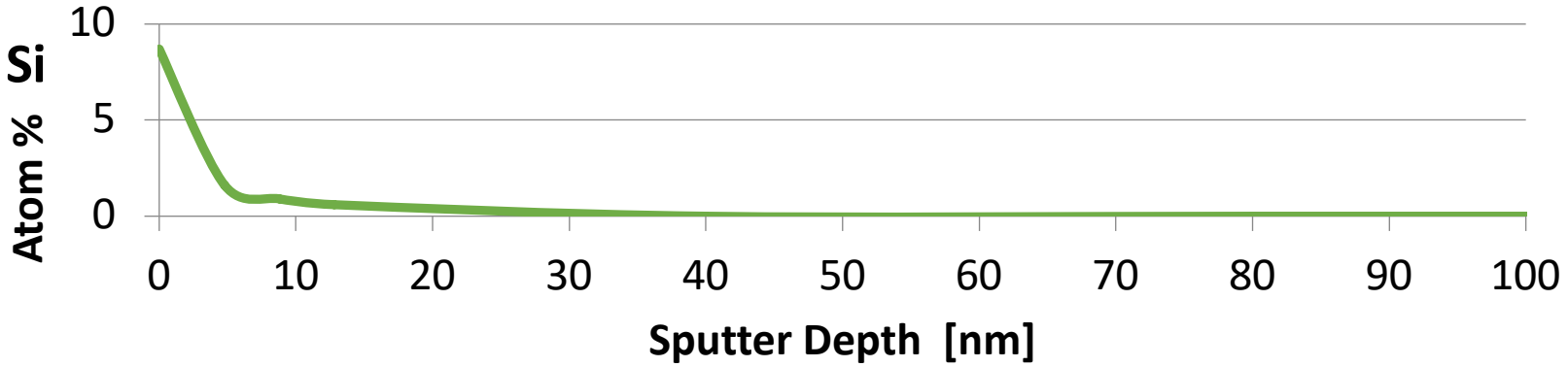


Photo elektrons $E_{kin} = h\nu - E_B - \Phi$
element specific



- Information depth 1 – 10 nm
- Si E_b 102,8 eV → chemical shift specific for bonding state: SiO_2
- Depth profiling by sputtering with Ar → layer thickness approx. 10 nm

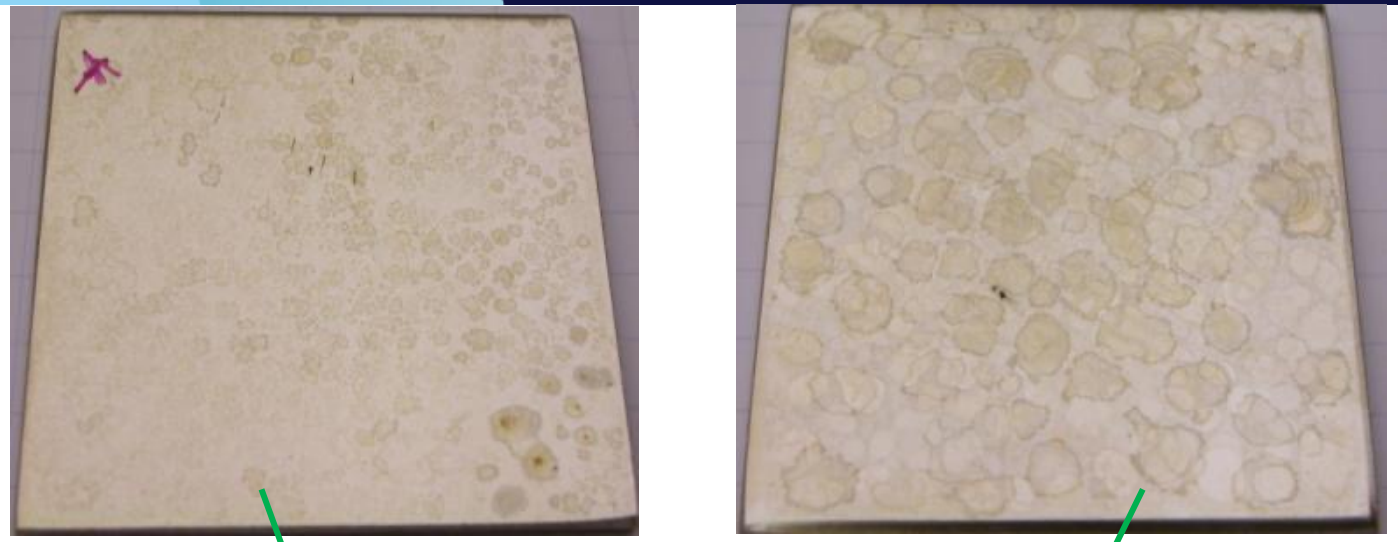


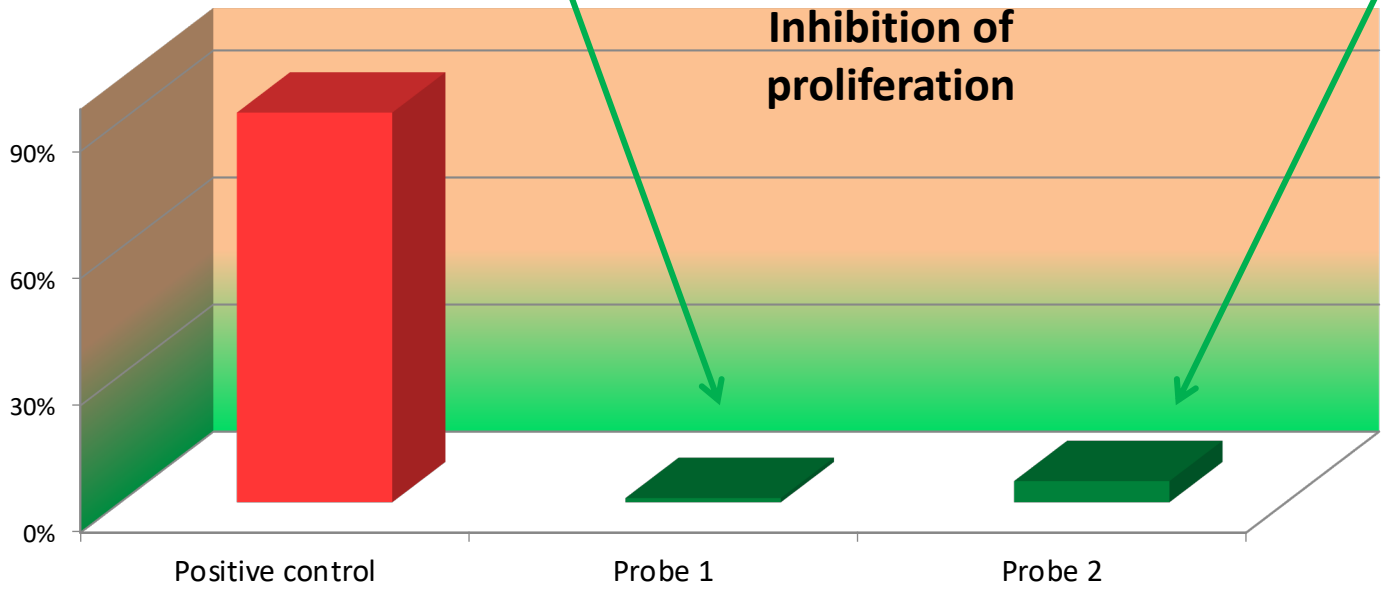
Tschoerner, M., ZAHN PRAX 16, 5, 274-277 (2013)

Cytotoxicity

Strong spots due to silicate deposits during sterilization in the autoclave.

ISO 10993-5,
ISO 10993-12





Characterization of surface alterations on surgical instruments caused by silicates and titanium oxides

Wolfgang Fuchs[1], Elisabeth Schneider – 1 – AKI - Working Group Instrument Reprocessing; Aesculap AG, Tuttlingen
Dr. Matthias Tschoerner[1] – 1 – AKI - Working Group Instrument Reprocessing; Chemische Fabrik Dr. Weigert GmbH und Co. KG, Hamburg

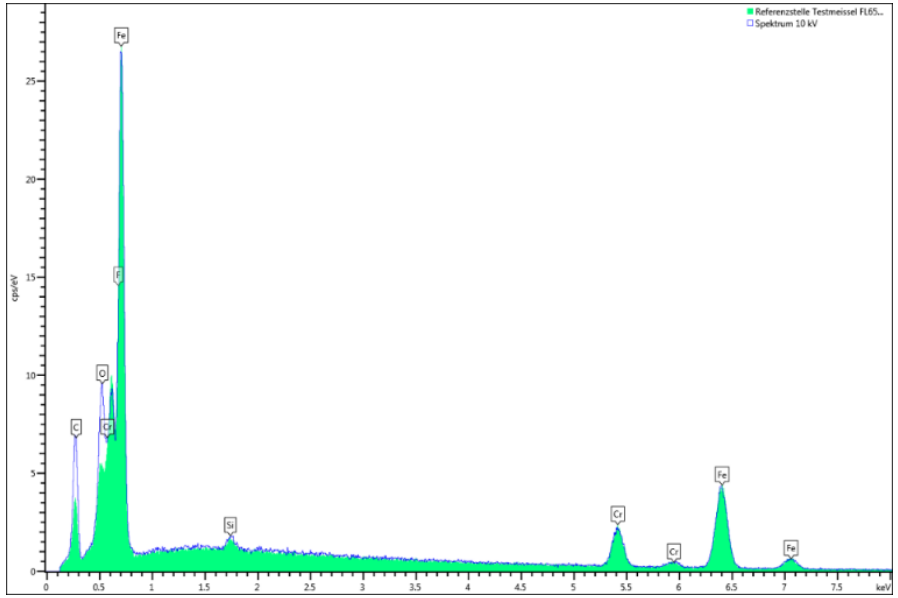
EDX and XPS-Analysis:

Probes from clinics

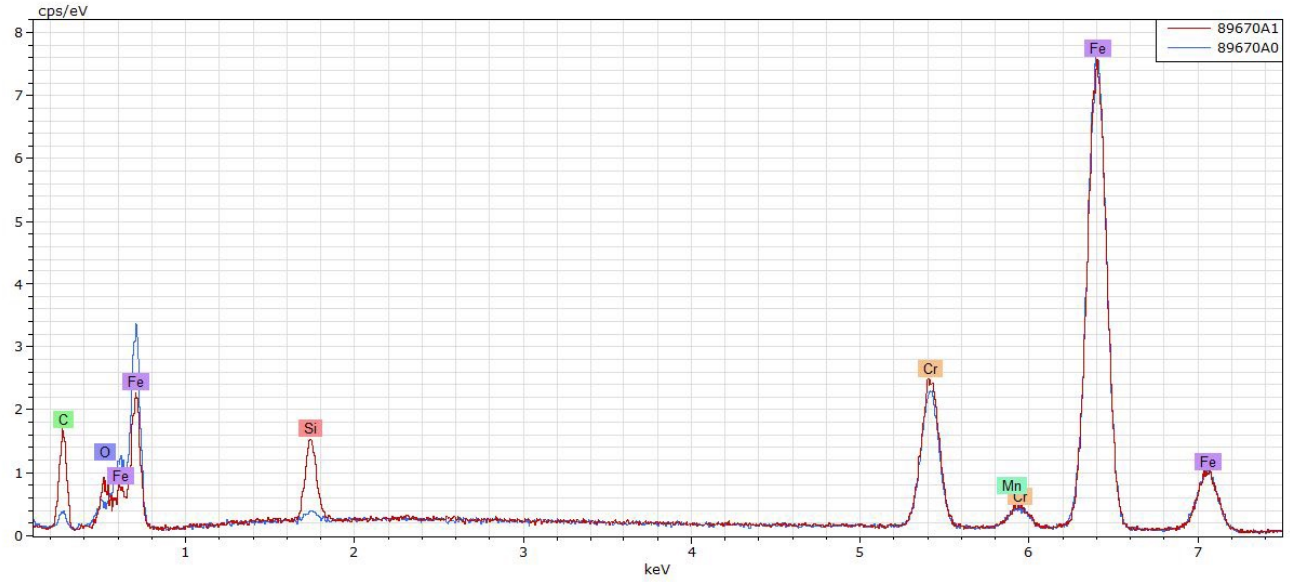
Osteotom
Wound hook golden
Wound hook green
Wound hook blue
Wound hook grey

Osteotom, EDX

Element analysis	C	O	Si	Cr	Fe
Instrument material	8,23	2,91	0,41	13,7	73,2
Discolored Surface	4,49	0,86	0,37	14,4	79,9



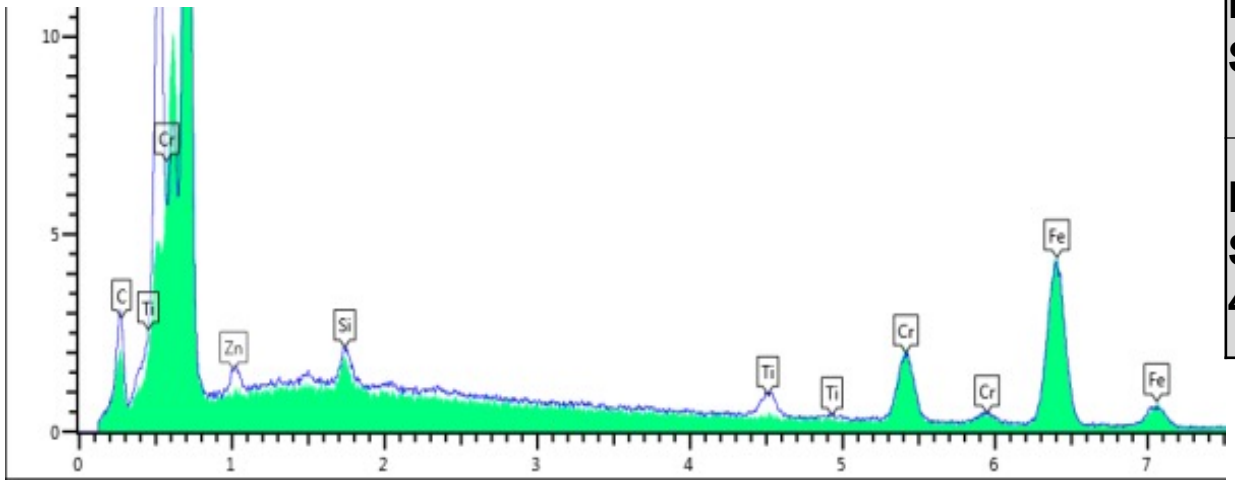
EDX-Analyse Fa. Aesculap - Probe TM



EDX-Analyse Dr. Weigert – Probe: 89670A

Wound hook blue, EDX and XPS

Element analysis	C	O	Si	Ti	Cr	Fe
Instrument material	2,02		0,58	0,37	13,7	83,3
Discolored Surface	0,9	1,59	0,22	1,24	8,35	86,9



EDX-Analyse Fa. Aesculap - Probe WH Blau

Element analysis	C	O	Si	Ti	Cr	Fe
Discolored Surface	76	17,3	0,6	1,5	0,3	0,7
Discolored Surface, 4 min sputtered	17	46,9	-	13,8	1,9	18,8

XPS-Analyse Dr. Weigert – Probe: 89668A

discoloration like condensation droplets on all surface structures

Silica deposits (ca. 10 nm)

silicic acid deposits caused by contaminated sterilization steam

gold-brown to blue-violet, iridescent, uniformly discoloration of smooth high-gloss stainless steel surfaces

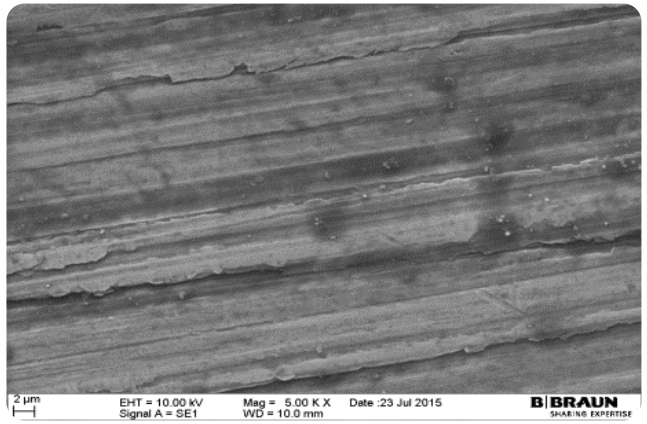
Titanium oxide layers (ca. 10 nm)

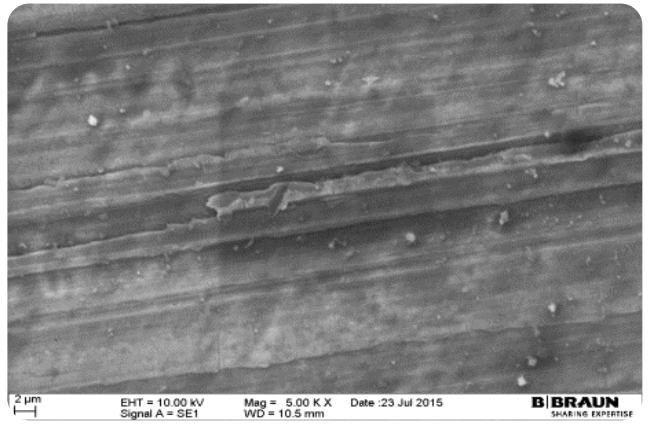
caused by traces of titanium minerals in silicate-containing cleaners

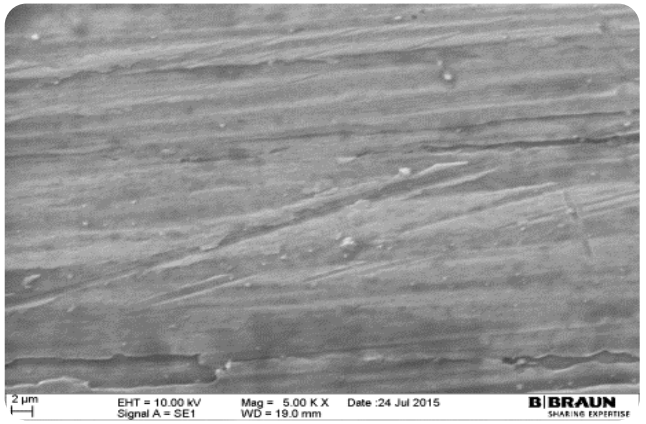
Mechanical Stressing on Instruments with Titanium Oxide Layers and Silica Deposits

Bending test in the area of elastic and plastic deformation with SEM imaging before and after the test (SEM, resolution < 2 µm)

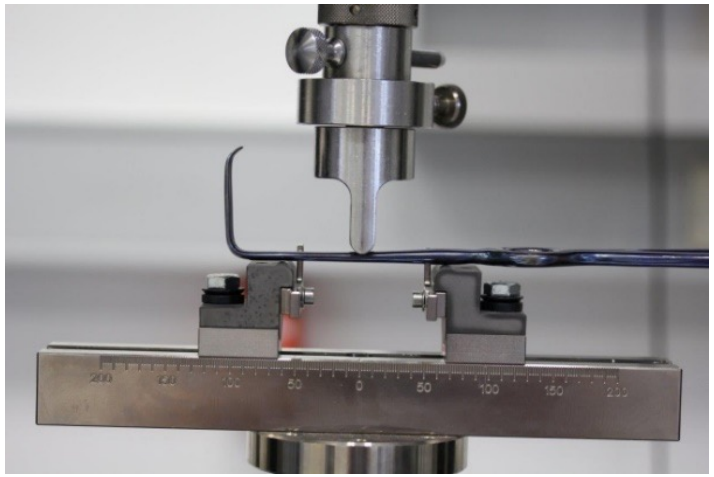
Start	Bending 2 mm **Elastic deformation**	Bending 4 mm **Plastic deformation**
Picture A (start condition)	**Picture B1** (elastic deformation)	**Picture B2** (plastic deformation)



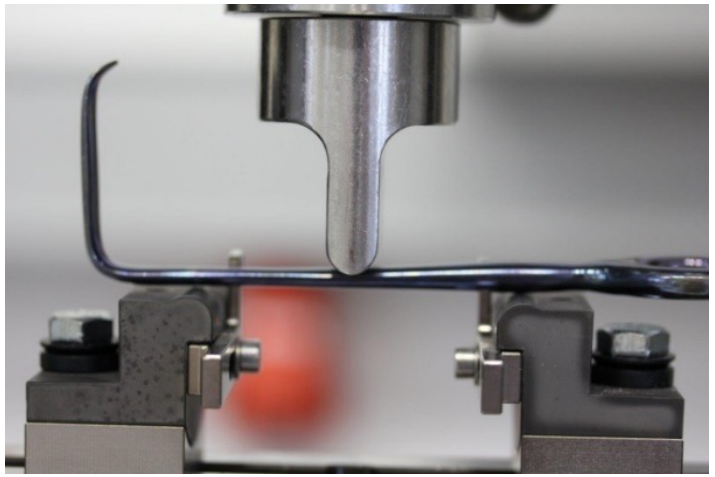


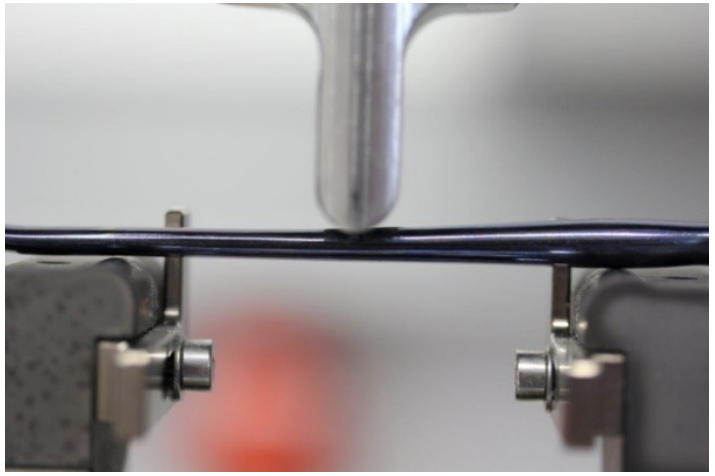


Bending Test



Methode of beding test



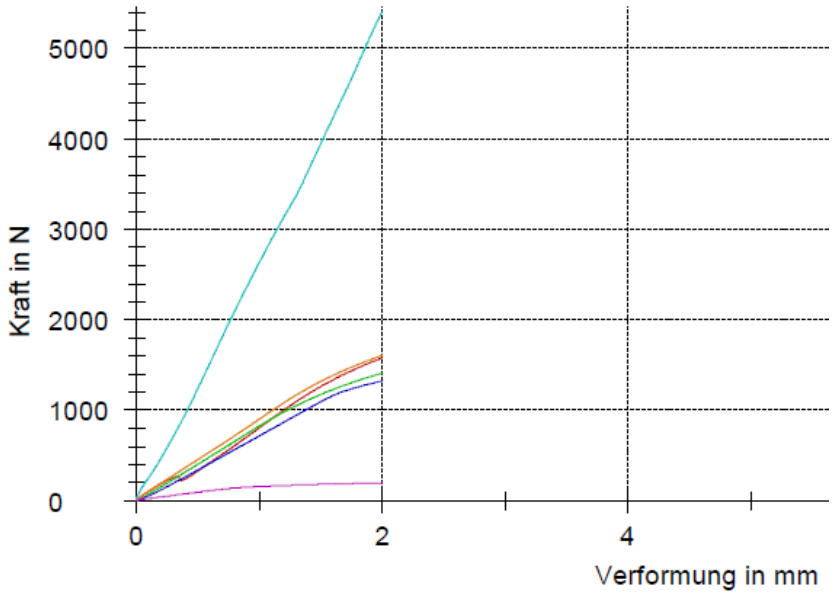


Parameter:

Deformation:	2 mm (elastic) 4 mm (plastic)
Initial force:	5 N
Test speed :	5 mm/min

Bending Test

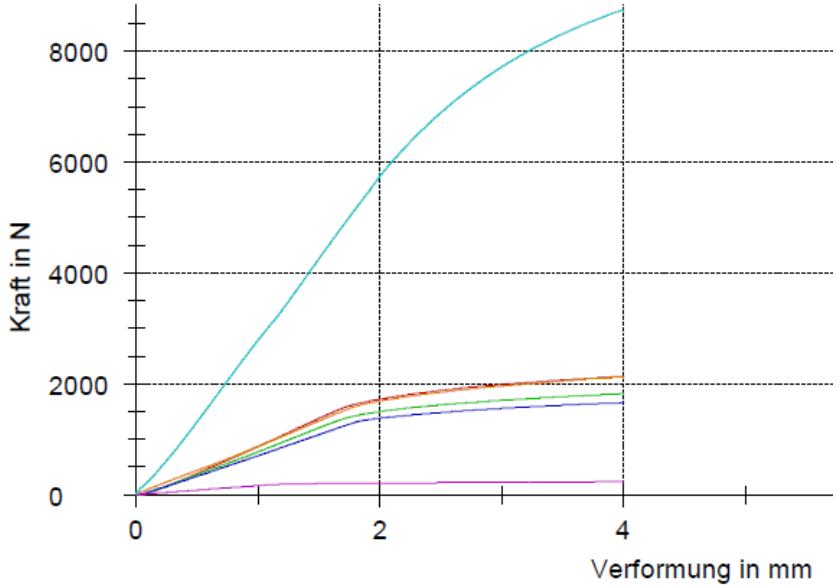
Elastic Deformation 2 mm



Results:

Legende	Nr	Bezeichnung der Unterserie	Probenbezeichnung	F_{max} N	dL bei F_{max} mm
	1.1	Verformung 2,0 mm	Gold	1580	2,0
	1.2		Grau	1410	2,0
	1.3		Grün	1320	2,0
	1.4		Blau	1600	2,0
	1.5		Schwarz Martin	195	2,0
	1.6		FL653R	5400	2,0

Plastic Deformation 4 mm

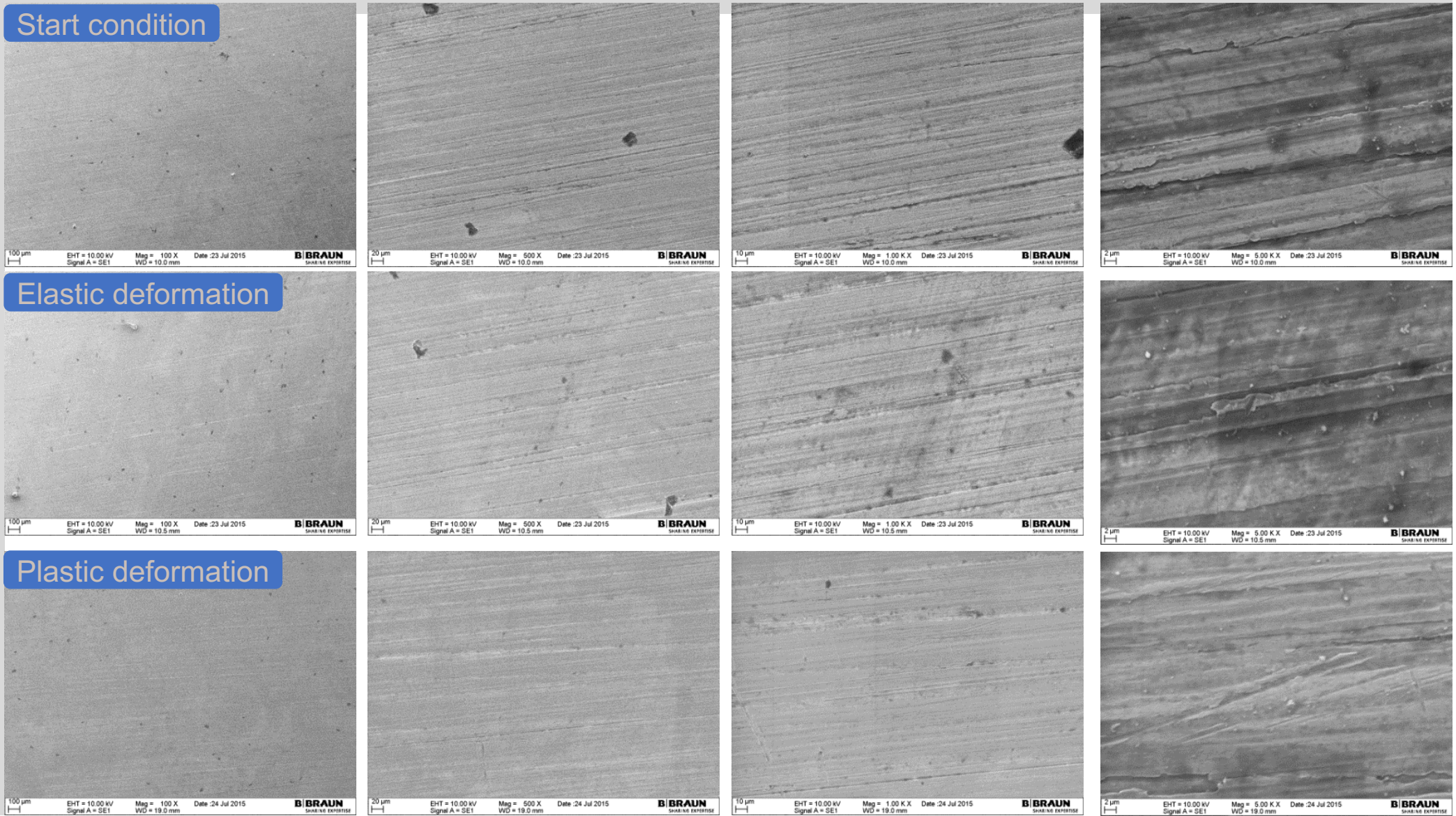


Results:

Legende	Nr	Bezeichnung der Unterserie	Probenbezeichnung	F_{max} N	dL bei F_{max} mm
	2.1	Verformung 4,0 mm	Gold	2140	4,0
	2.2		Grau	1820	4,0
	2.4		Grün	1660	4,0
	2.3		Blau	2120	4,0
	2.5		Schwarz Martin	235	4,0
	2.6		FL653R	8750	4,0

Osteotom

	100	500	1000	5000
A	Start condition			
B1	Elastic deformation			
B2	Plastic deformation			



Conclusion

- The discolorations are caused by a few nm thin titanium oxide layers and silicate layers.
- After mechanical stressing, no changes in the surface structure was observed for all characterized linings. No disruption or detachment was observed with SEM.
- Due to mechanical stress, no particles of SEM detectable size were separated from the test instruments.
- The investigated deposits show no cytotoxic properties.

Questions?

Thanks!