“Lean Production” meets “Hygienics”
- Are we safe or efficient or can we be both?

Dr. Gerhard Kirmse
Director Technical Competence Center

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Aesculap Technical Competence Center

Dr. Gerhard Kirmse

- Biomedical Engineering
- Doctorate on Instrument Cleaning
- Lean Professional
- Bachelor of Business Administration
- Various Committes and Workgroups

Daily Questions:

- Is our process safe (enough)?
- What can be do to reduce risks?
- How can we make best use of limited ressources?

Research, Consulting and Training on Reprocessing, worldwide

⇒ Be Efficient
⇒ Be Safe
At the same time
How?

What is „Lean“ ?

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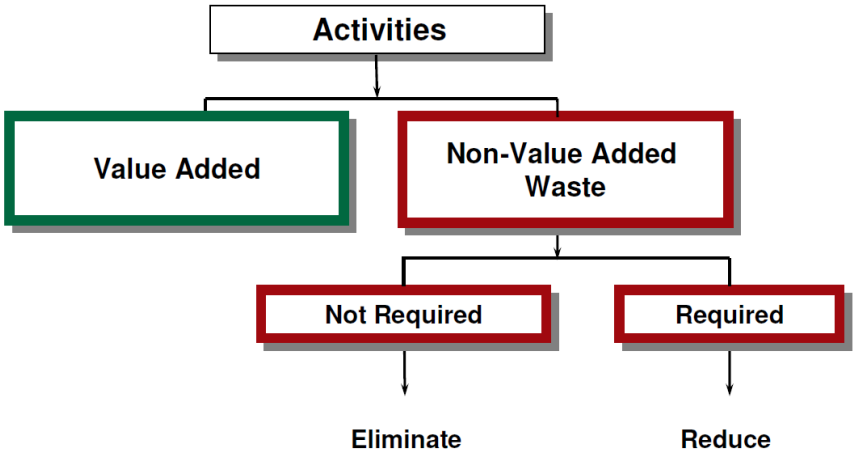
Management system

- Origin in Japan

- Meanwhile adopted worldwide



History of the Production

Skill

Combination of man and machine

- Made to order
- Quality depending on level of skill
- High costs and prices
- Long delivery times
- Low volumes

"Ford" mass production

Specialized equipment and division of labor

- Low customer orientation
- Good quality
- Drastic reduction in cost
- Reduced delivery times
- High volumes

Lean manufacturing

The Toyota production system

- Optimization of all resources, low costs
- Focus on the elimination of waste to ensure complete customer satisfaction
- Great flexibility
- Low volumes per type, yet large total volume

What is waste? What is value?
…..in a hospital environment

TPS – The evolution

- Extensive analysis of waste

Over-production

Sets, which the OR does not need

Idle times

Morning shift with no available sets

Transport

Unneeded items In sets / in case carts

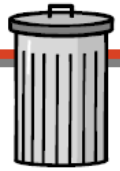
Current capacity = Work + Waste

TPS – The evolution

- Extensive analysis of waste

Over processing
During the manufacturing process

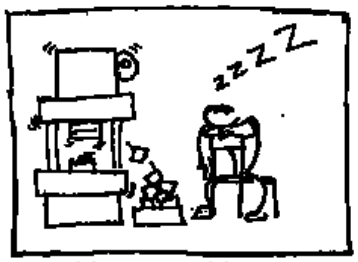
Scrap / rework



Inventory
In the warehouse

Excessive movement


looking for tools


watching a machine run


waiting for material


rework


carrying heavy loads


counting parts


defects

Value

- Available on time (unplanned)
- Safety (Function, Cleanliness, Sterility)
- Proof of proper process
- Efficiency (Turn around, Cost)

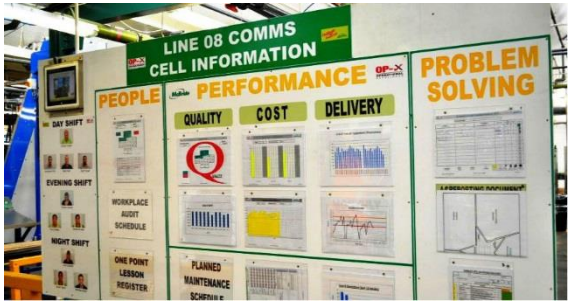
Value stream

- How does each step contribute to value (goals)?
  - Activities, Cost

Example: Airline

- Booking
- To the airport
- Waiting
- Check-In
- Luggage drop-off
- Waiting
- Safety Check
- Waiting for Gate
- Waiting at Gate
- Boarding / Seating
- Wait for Loading
- Taxying
- Flying

Tools



Visualization
- Boards, Lights (Andon)

Simplification
- Poka Yoka (Support Tools)
- Autonmoation (Machine Intelligence, Jidoka)

Production Organization
- Cellular Production
- Flow Production
- Balancing (Heijunka)
- KanBan Logistics
- Process Flow (Nagara)
- Pull principle
- Error elimination
- SMED (Single Minute Exchange of Dice)
- Six Sigma (to be explained)
- 5S

Reduction of
- Muda (waste)
- Mura (unbalanced work)
- Muri (Stress)

Not
- Work faster

From: Introduction into Lean, PennState Univeristy

How safe is enough?
Do – Check – Double Check – Triple Check …..

Risk Management as a tool

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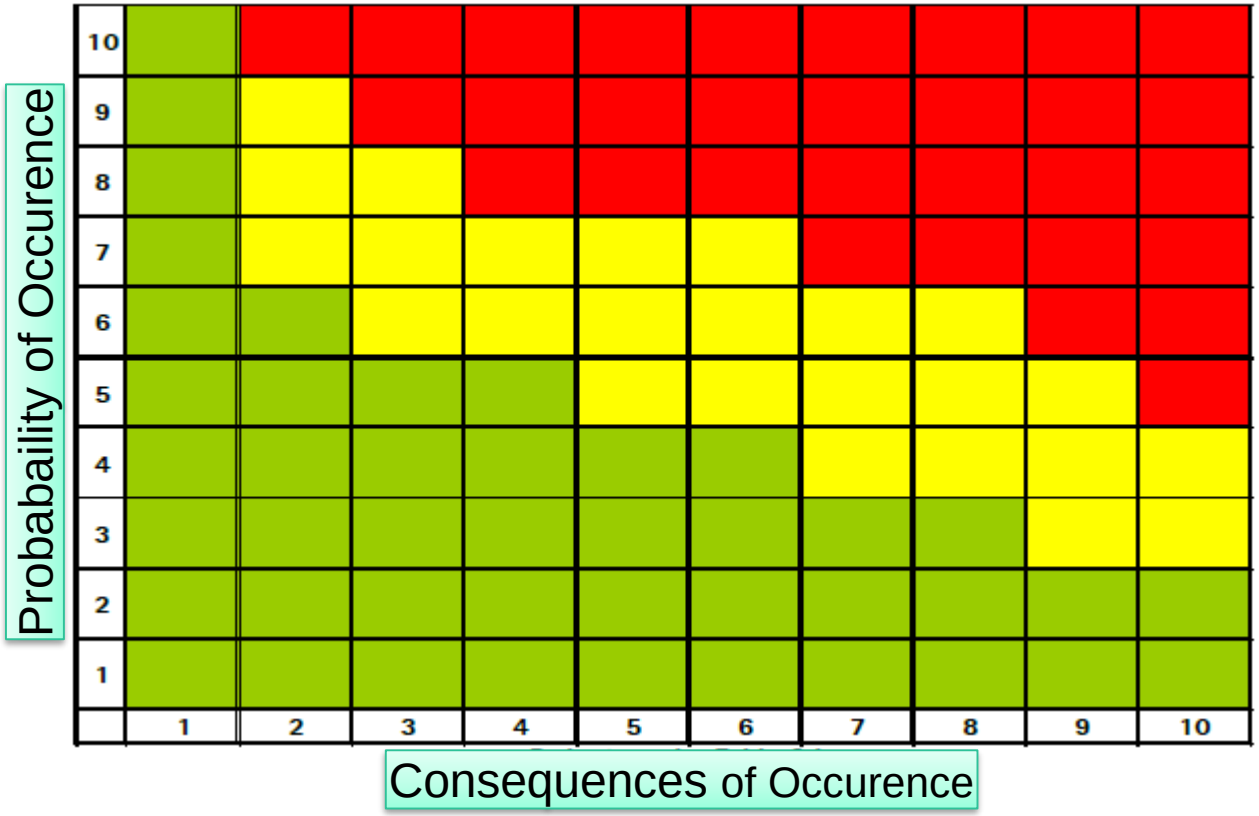
Risk Evaluation ISO 14971- 2 Level



yellow=
reduce risk
„as low as
reasonably possible“
ALARP

Severity: depending on patient condition
Work on „Occurrence“ (Equipment, Education) and „Detection“

Risk Management VDI 5700

Probability

frequent					
probale					
occasional					
rare					
unlikely					
	very low	low	severe	critical	catastrophy

Consequence

Probability		**Consequence**	
frequent	> 1: 1.000	catastrophy	death
probale	1:1.000 - 1:10.000	critical	irreversible injury
occasional	1: 10.000 - 1: 100.000	severe	injury requiring medical attention
rare	1: 100.000 - 1: 1.000.000	low	injury not requiring medical attention
unlikely	< 1: 1.000.000	very low	temorary discomfort

Probability: Consequences in xx Use Situations (P1* P2) (Patients)

- P1: probability **occurrence of a risk situation** (e.g. use of a corroded instrument)
- P2: probability of a **consequence in a risk situation** (e.g. wound healing disorder)

(may be difficult to estimate)

Risk of Traffic Accidents?

- How often do you forget to look over your should 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

What to do?
- Avoid
- Technical Support
- Teach, Train and Supervise

Risk Management Process according to VDI 5700 => Guidance

Potential Risk Areas

- Function
- Hygienics
- Biocompatibility
- Employee Protection

Potential Risk Sources

- Change of properties
  - mechanical
  - chemical
  - …
- Poor repair
- Wear
- Accessories
- Identification
- Poor reprocessing
  - Cleaning
  - …
- Recontamination
- Biocompatibility
- Toxicity
- Organizational issues

Where are we?
- What can we do?

1. Logistics
2. Sterilization
3. Sterility
4. Cleaning

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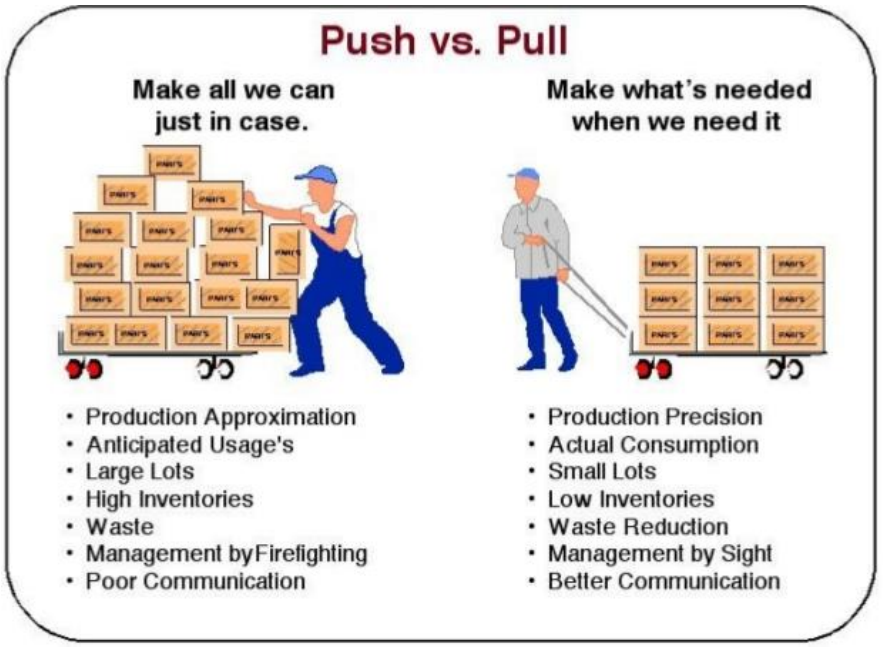
Does this look familiar?

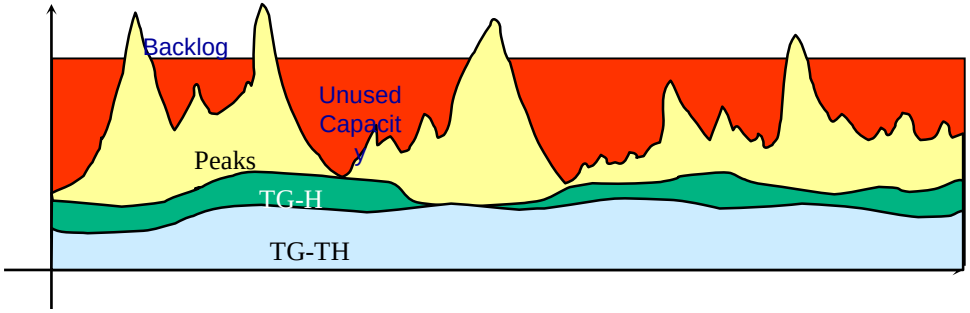


- All sets have to be packed and sterilized until next day
- What does OR need?

What would be “lean” here?

- “Produce” what is needed
  - Interaction with OR Planning System
  - “Priority”-System

⇒ Even out workload



- Case Carts (Quick room turn around)
  - Safety Stock

- Only have really needed instruments in a set
  - No defective instruments
  - No missing instruments
    - Back Up Stock

- KanBan Systems
  - Not ParLevel

Proper Set Structures help

Average

- approx. 30% of instruments in sets are unused
- No consistant basic + supplementary set structure

Analyze needs and workflow!

Setcode	Setbezeichnung	Anzahl Sets	Anzahl Produktionen	Anzahl produzierter Siebe an einem Tag														
				1x	2x	3x	4x	5x	6x	7x	8x	9x	10x	11x	12x	13x	14x	15x
SBK-O-AVC-001	AVC Laparotomie	10	1163	34	47	43	47	43	36	16	9	9	0	2	0	0	0	0
SBK-O-AVC-055	LSK II	8	1228	42	30	25	34	36	40	34	15	13	2					
SBK-O-AVC-059	Kleines Sieb	8	730	64	51	48	31	22	6	11	8	1	0	0	0	0	0	0
SBK-O-AVC-011	LSK Adipositas	3	131	63	21	8	2											

Setcode gehe zu Set-Details	Setbezeichnung	Anzahl Setcodes	Anzahl Sets	Anzahl Produktionen	Anzahl Artikel	Produzierte Artikel dieses Set	Produzierte Artikel in %	Produzierte Artikel Nr.	Produzierte Artikel kummuliert	Produzierte Artikel in %
	Gesamt:	**30**	**175**						**1.386.304**	
SBK-O-UCH-050	UCH Grundsieb	13	1.837	97	178.189	8,8 %	1	178.189	8,8 %	
SBK-O-AVC-001	AVC Laparotomie	10	1.163	132	153.516	7,5 %	2	331.705	16,3 %	
SBK-O-AVC-057	LSK 1	8	1.215	85	103.275	5,1 %	3	434.980	21,4 %	
SBK-O-AVC-055	LSK II	8	1.228	59	72.452	3,6 %	4	507.432	24,9 %	
SBK-O-AVC-059	Kleines Sieb	8	730	94	68.620	3,4 %	5	576.052	28,3 %	
SBK-O-GCH-001	GCH Gefäß-Grundsieb	8	545	121	65.945	3,2 %	6	641.997	31,5 %	
SBK-O-GYN-022	Sectio	9	738	79	58.302	2,9 %	7	700.299	34,4 %	
SBK-O-UCH-052	UCH Hand-Fuß	4	664	81	53.784	2,6 %	8	754.083	37,1 %	
SBK-O-AVC-060	Endo-Appendix	3	343	128	43.904	2,2 %	9	797.987	39,2 %	
SBK-O-NEU-001	Bandscheibe	6	588	71	41.748	2,1 %	10	839.735	41,3 %	
SBK-O-HNO-023	HNO Septum-Endo	5	347	104	36.088	1,8 %	11	875.823	43,0 %	
SBK-O-GYN-002	Abreslo HSK	9	620	57	35.340	1,7 %	12	911.163	44,8 %	
SBK-O-GYN-013	LSK I	5	512	66	33.792	1,7 %	13	944.955	46,4 %	

- Workload analysis!
- Software or color coding system

Sterilization

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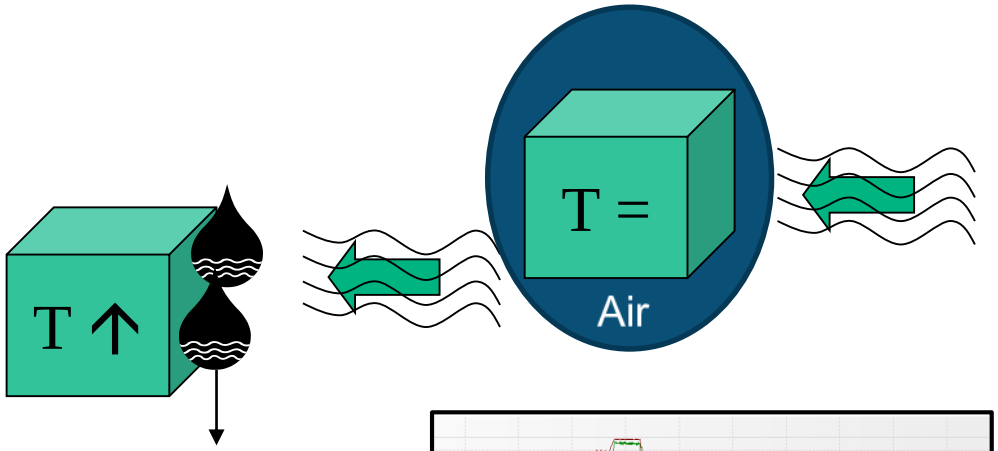
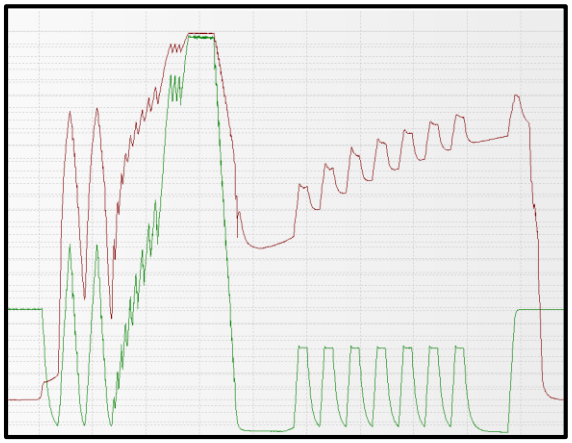
Sterilization effect

1. Air removal
   - Pre heating

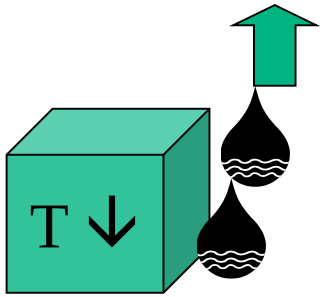


2. Bring surface of product to a temperature of 134°C to 137 °C



3. Drying

4. Keep Sterile



Required
- Contact with steam
- Temperature
- Time

Standards

- **EN285**: Large steam sterilizers
  - Equipment, steam supply, testing process

- **ISO17665**: Steam sterilization of health care products
  - Validation and routine control, definitions
  - **EN554** replaced

- **ISO 11607**: Packaging material, requirements and test methods
  - **EN868**: Requirements and test methods for various sterile barrier materials

- **ISO11138**: Biological indicators, performance, qualification etc.
  - **EN866**: Use of biological indicators

- **ISO 11140**: Chemical Indicators, classes
  - **EN 867**: Use of non-biological Indicators in Sterilizers
    - Process Indicators, BD tests, Steam Penetration Test

What do we do (worldwide)?

	AAMI	KRINKO
Process Indicator (outside)	**yes**	**Yes** (EN556)
Chemical Indicator per Set	**yes**	**No** (ISO17665)
Chemical Indicator per Load	**Yes**	**No** (ISO17665)
PCD (chemical) per load	**Recommended**	**No** (ISO 11140-4)
Biological Indicator	**Daily, each implant load**	**No** (ISO 11138)
Bowie-Dick-Test	**Daily**	**Daily** (ISO 11140-3)
Vacuum/ Leakage-Test	**Daily**	According to **IFU** (ISO 17665-2)
Non condensable Gas Test	**„regular“**	**Annually** (ISO 17665-1)
Parametric Release	**Check all data**	**Yes**
Double Sensor Systems	**no**	**Yes** (EN285)
Verification	**yes**	-
Validation	**-**	**Annual Validation** (ISO 17665)

What are the issues we see?

- Wet sets
  - Heavy sets, overloaded chambers
  - Mixed loads

=> Validation

large plastic, hollow

- Equipment failures
  - Damaged gaskets, valves
  - Vacuum, Steam supply

⇒ Equipment sensors
⇒ Helix test
⇒ BD-test

- Stains and Rust
  - Steam Quality

=> Validation

porous

What don´t we see?

- Chemical Indicator failures
- Biological Indicator failures

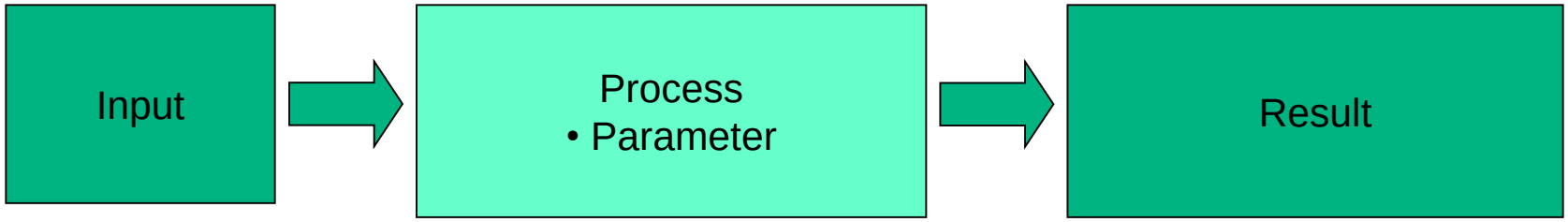
(Test system reliability)

Cost / Benefit comparison

Assumption: Sterilizer with 10 STE used for 8 loads per day,
Daily cost, material and work time, based on €20/h

Test	Cost	Daily Cost	Information
Validation	€3000/year	€12	Sterilizer Performance Allowable Loads
Parametric Release	48min /day	€16	Sterilization, Drying, Documentaion
BD Test	€2-8/piece 10min	€6-12	Steam penetration porous
Helix Test Per load	€0,50/piece	€4	Steam penetration lumen
Class 1 per set	€0,10/piece	€8	Process ves/no
Class 6 per set	€0,60/piece	€48	Sterilization per set
BI per day	€6 /piece 10min	€9,30	„Sterilization performance“
BI per Impl Load	4x/day	€46,50	„Sterilization performance“

Risk Management : Validation



A validation proofs that:

- a process
- which is completely described by parameters
- with fixed input
- will always give the same results

- Worst case input
- Stable parameters
- Proof of stable results

Validations are used if a process result is important but can not be measured continuously with reasonable effort.

Keeping it sterile?

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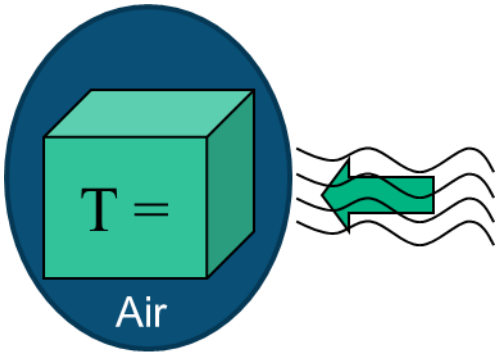
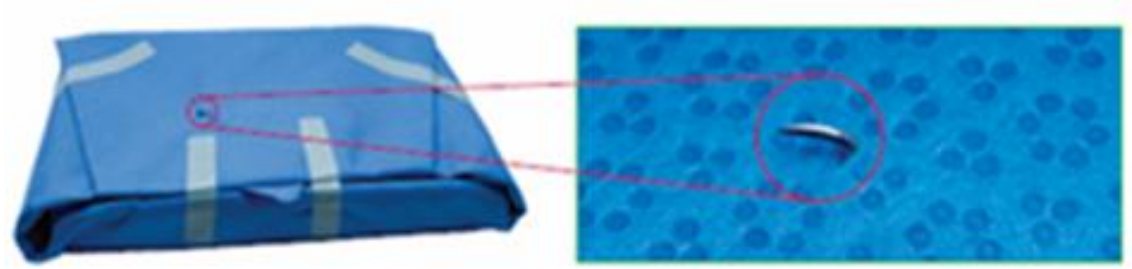
Potential failures sterility

1. Sterilization Condition not reached
   Time – Temperature - Contact



2. Sterile Goods not dry

3. Sterile Barrier Compromised



Potential risks

- Improper packing => no full sterile barrier function
- Damaged container => no full sterile barrier function
- Mechanical perforation of sterile barrier
- Moisture from outside, sterile barrier penetration
- Residual condensate in sterile packaging

=> risk of recontamination

Risks, which really occur – Review of literature

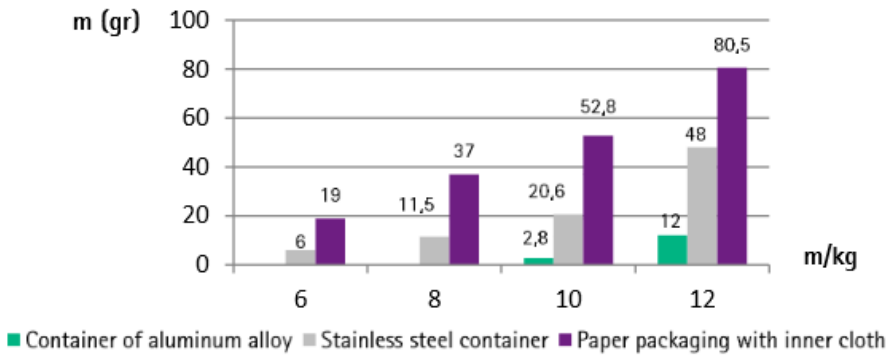
- Softpacks compromised by moisture or damaged
  - T.I. Overthrow, Zentralsterilisation 4:2009 (lower retention with moisture)
  - D. Goulet, Zentralsterilisation 5:2009 (risk of moist sterile barriers)
  - S. Dancer, Zentralsterilisation 2:2013 (deaths due to sterile barrier failure by moisture)

- Damages by handling / improper storage of soft packs (Consulting)
  - T. Fengler: Forum 4:2012
  - Waked WR, Simpson AK, Miller CP, Magit DP, Grauer JN. Sterilization wrap inspections do not adequately evaluate instrument sterility. Clin Orthop Relat Res. 2007 Sep;462:207-11.

- Risk of damaged containers : Proper function if visual inspection is performed
  - U. Junghannß et al. Zentralsterilisation 3:1999 (proper sterile barrier function even with damaged containers)

- Moisture in sets (Improper loading, overloads, mix, set content, cycle design
  - D. Goulet, Zentralsterilisation 5:2009 (risk of moist sterile barriers)
  - K. Engels: Zentralsterilisation 02: 2012

Residual condensate over instrument load weight for various types of packaging:



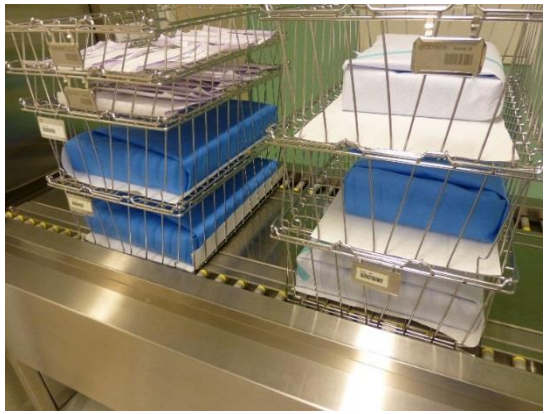
What can be do?

Drying

- Qualify load configurations
- Avoid drip water / collection
- Set weights according to content
- Customized drying cycle

Soft wrap

- Basket systems
- Weight according to IFU
- (Inspection in OR)



Container systems

- Inspection in CSSD
- Use according to IFU

Cleaning

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How do we make sure instruments gets clean?

Routine Checks

- Spray arms
- Visual

Daily Indicator Test

- (Model)
- Performance Change

What is clean enough?

- Risk Based Approach: no harm below this limit
- Feasibility Based Approach: achievable with reasonable effort

- No unclean instruments?
- Clean lumens?
- No pressure loss
- ..

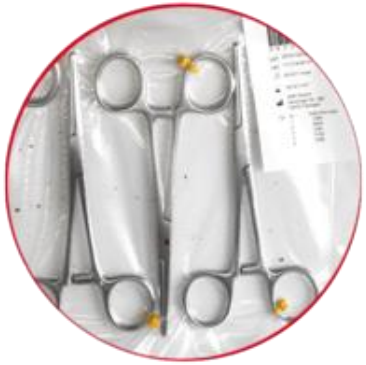
Validation ISO15883

“Worst Case Conditions”

- 5 Test Instruments
- 5 OR Instruments

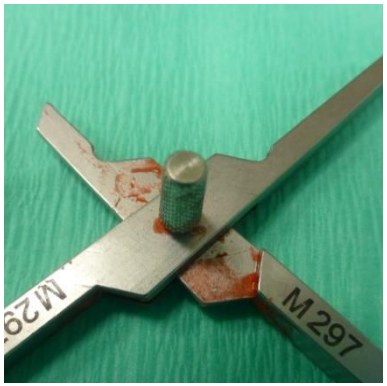
Effort

- minimum 3 cycles,
  - Reference body (Crile),
  - Hospital instruments
  - Protein Test
- Dosage, water
- Pressure, temperature
- Conductivity final rinse
- approx. €1500-2500 / machine
- yearly or upon process changes

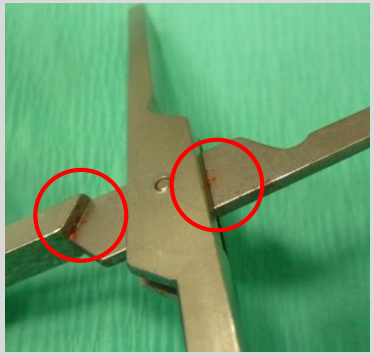


Inspection is no proper control….

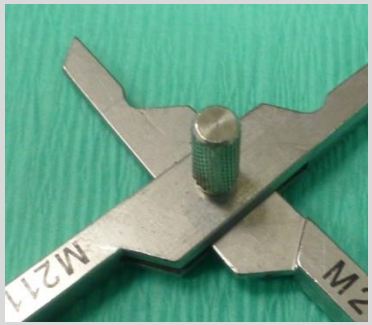
Visible contamination
is the tip of the iceberg !!!



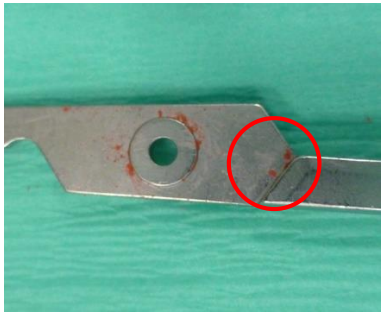
Cleaning



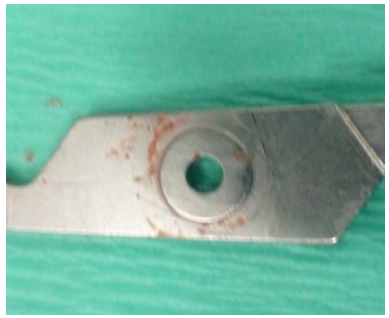
Residue !
=> post cleaning



Visually o.k.
=> sterilization



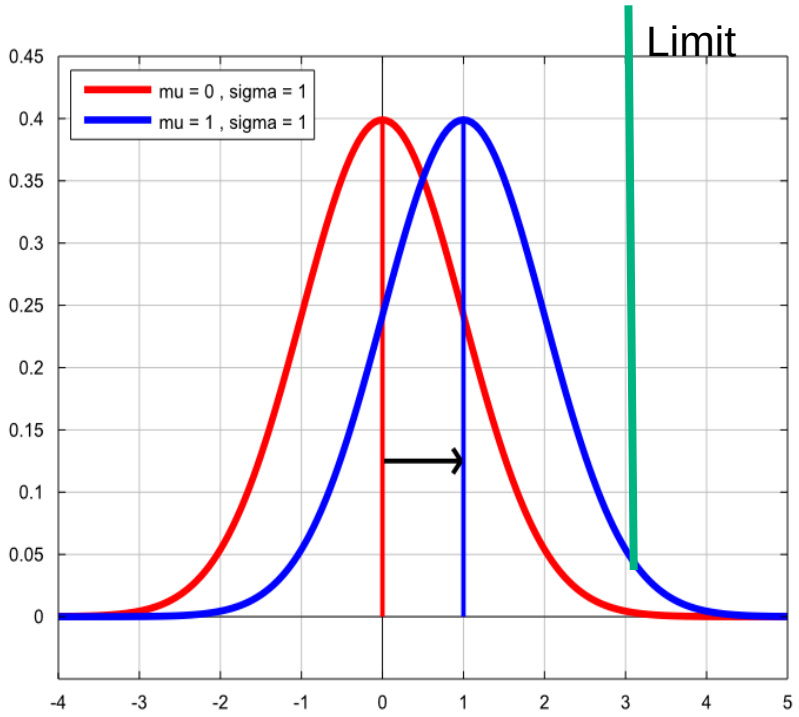
Inside



Inside

We have to get better in cleaning (and monitoring)!

Back to Six Sigma



Typical standard deviations
σ=20-30µg protein / instrument

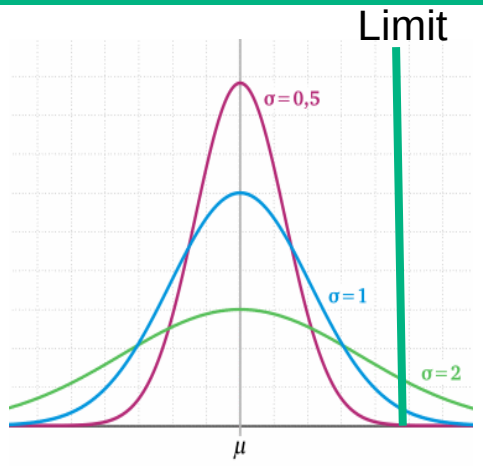
Distance limit / avarage
1 σ: 15.5% over limit
2 σ : 2,2%
3 σ : 0,13%

Improvement by
- Bringing average down
- Decreasing standard deviation

6σ-Processes: less then 1:1.000.000 out of specifictation:

With a limit of 100µg

- Σ =20µg => All Tests have to be 0µg
- Σ =10µg => All Tests have to below 40µg



Risks in daily process – Errors in process - Efforts versus risk

Detected by machine (ISO 15883)

- Temperature error
- Dosage error

Loss of pressure

- Foaming (machine)
- Couplings (carts) => pressure test

Damaged / clogged spray arms
=> Rotation (machine), inspection

Mix up of detergents => SOP´s, colors

Change of water quality => Visual, regular tests

Standardized Tests for Cleaning Power

- How clean in ideal original status?
- How clean now ?

Position

Risks in daily processes – Manual errors

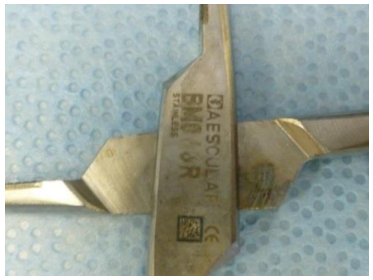
Detection in packing

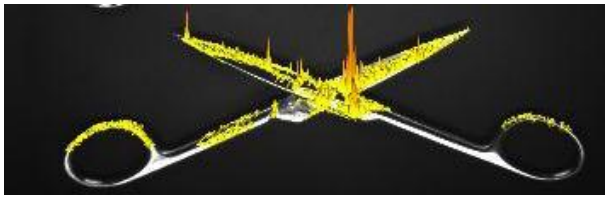
Loading errors

- Overloaded trays
- Shadows by large items
- Unsuitable trays
- Not connected
- …

Lack of Pre-cleaning

- Forgotten
- Lack of capacity
- Improper execution
- …





(picture: D. Perrett)

Detection

- Visual Inspection (Load, Instruments)
- Manual Protein Test (Swab) (10-15µg)

- Pro Reveal

Conclusion

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Summary

Standards and practices differ severaly from country to country (“Do bacteria know country borders? => wfhss 2017)

Traditional standards due not necessarily reflect modern considerations regarding risk management, evidence and efficiency

“Lean” and “Risk Management” are valuable tools to design processes but there is no routine yet

YES, we can be
“lean” and “safe”,
but we have to challenge
traditional approaches

My opinion:
Focus on the biggest Issues !

Start thinking outside the Box

Looking to another Area

frequent					
probale					
occasional					
rare					
unlikely					
	very low	low	severe	critical	catastrophy

One nurse at night takes care of 40 Patients

- What is the chance of delayed attention to a patient because he/she is already busy?
  - 1:200 (would mean once a month) (1 week stay)
- What is the chance of a negative consequence in such a case?
- How severe is the consequence?
  - discomfort: 1:1
  - injury w/o medical: 1:5
  - severe: 1:25
  - death or irreversible: 1:1000

catastrophy	death
critical	irreversible injury
severe	injury requiring medical attention
low	injury not requiring medical attention
very low	temorary discomfort

Thank you for your attention !

Should we hire more nurses?

Or

Spend more money for our CSSD ?

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SHARING EXPERTISE