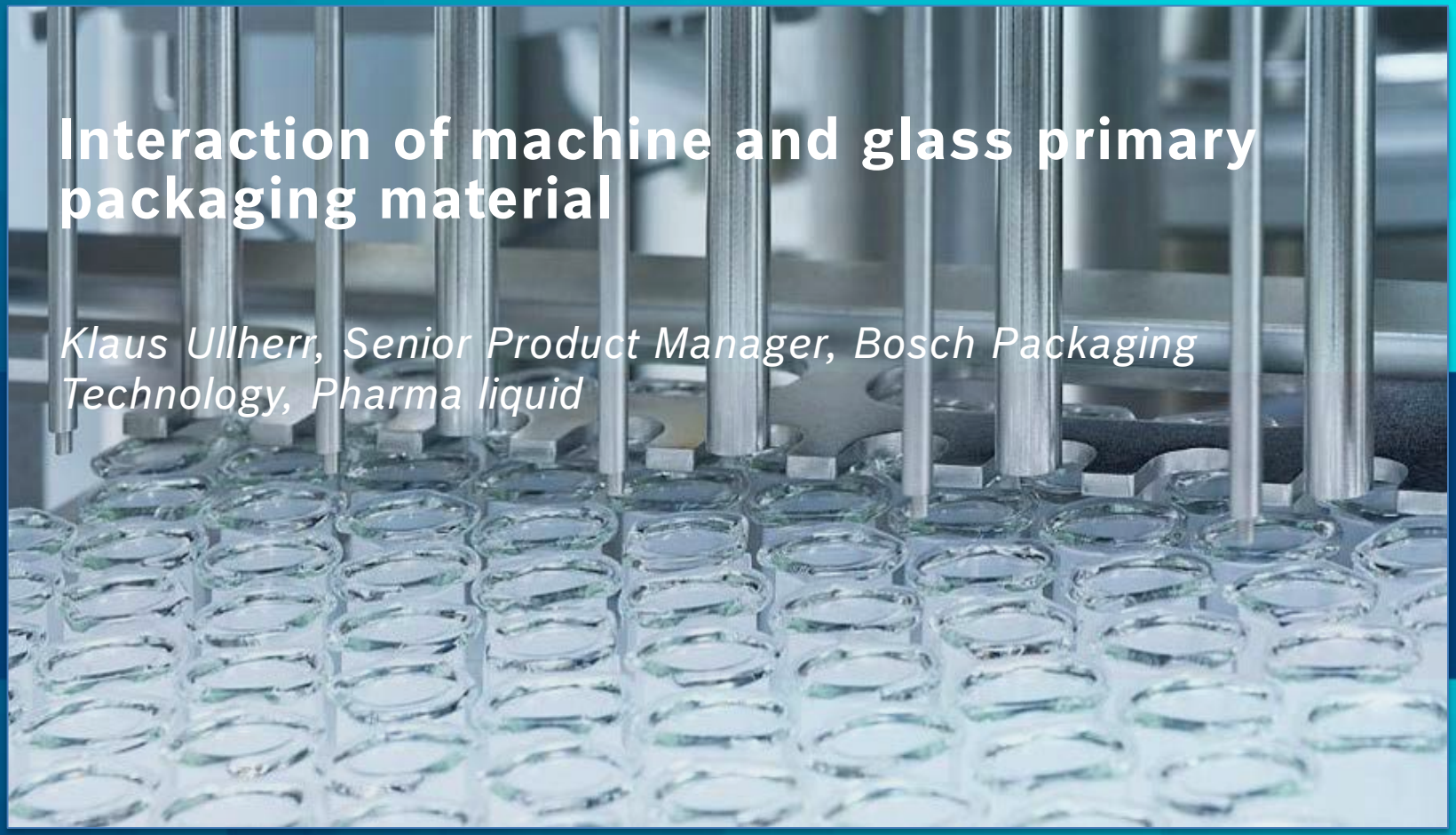
Mainz, 09./10. Oktober 2019



Interaction of machine and glass primary packaging material

Klaus Ullherr, Senior Product Manager, Bosch Packaging Technology, Pharma liquid

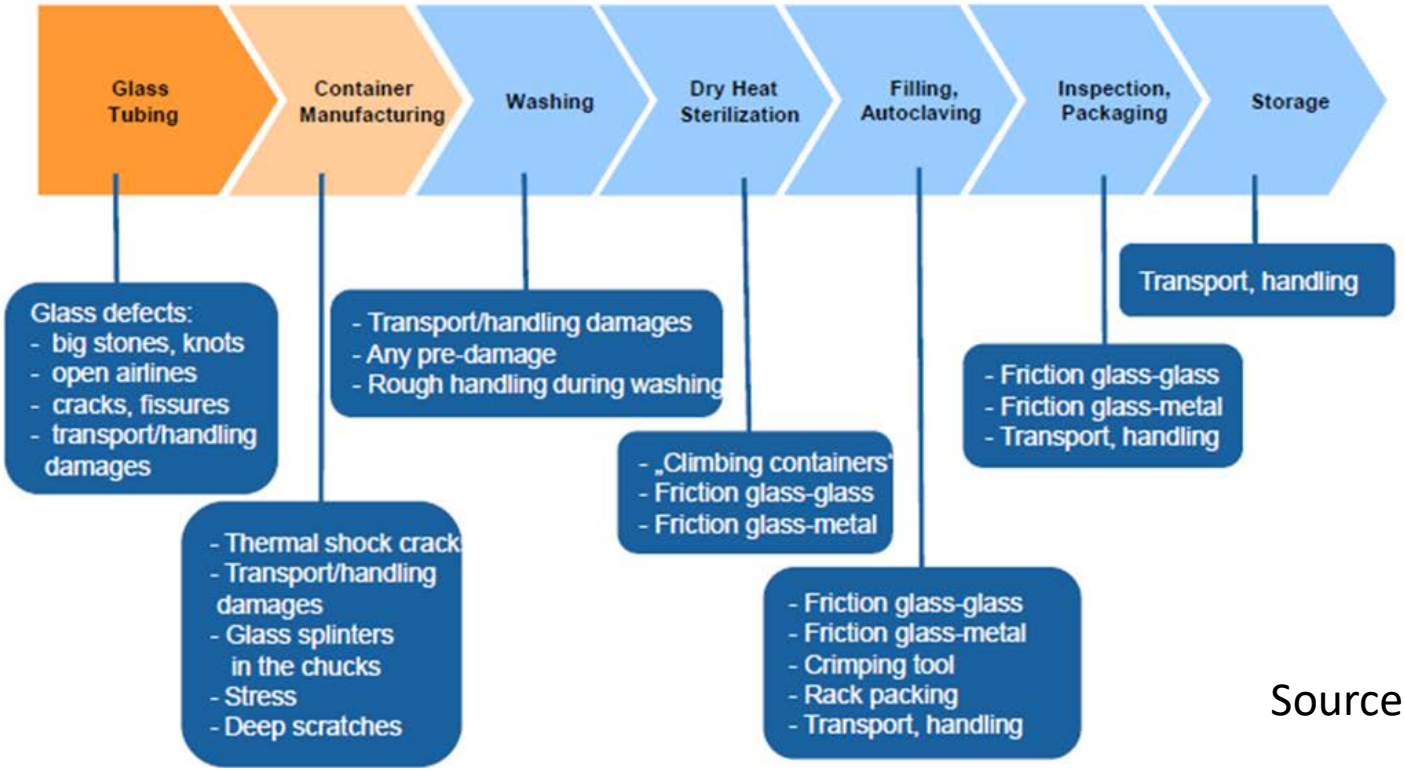
Machine impact on containers

Dr. Andreas Rothmund, Vetter
PDA IG Meeting April 2010,
Zero Glass Breakage – Dogma or Ambitious Goal

Machine impact on containers

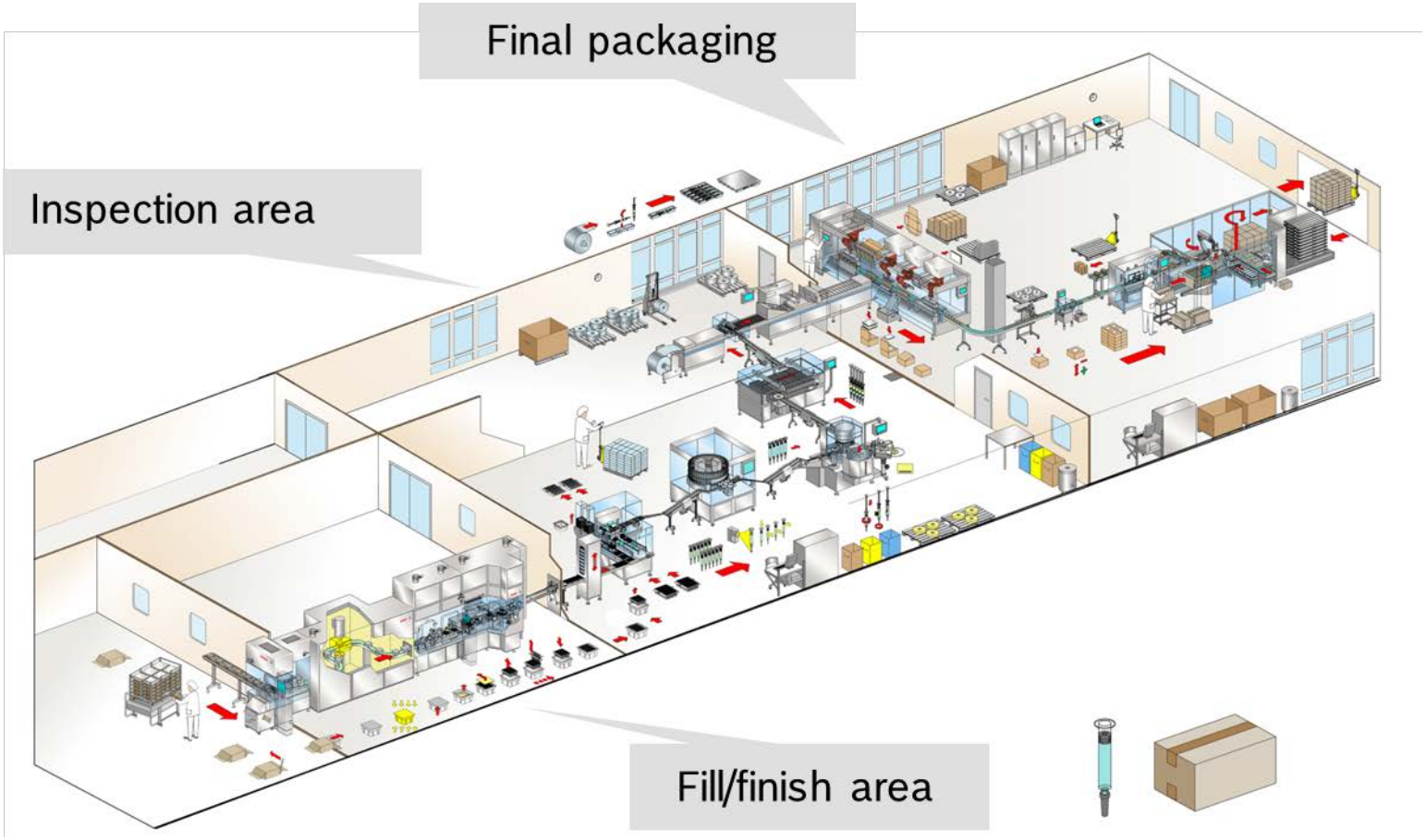
Breakage: Process Analysis

What can lead to breakage in the converting or filling process?



Source: Schott

The way of a syringe/cartridge



Bosch Packaging Technology | Business Unit Pharma | Klaus Ullherr (Product Manager)

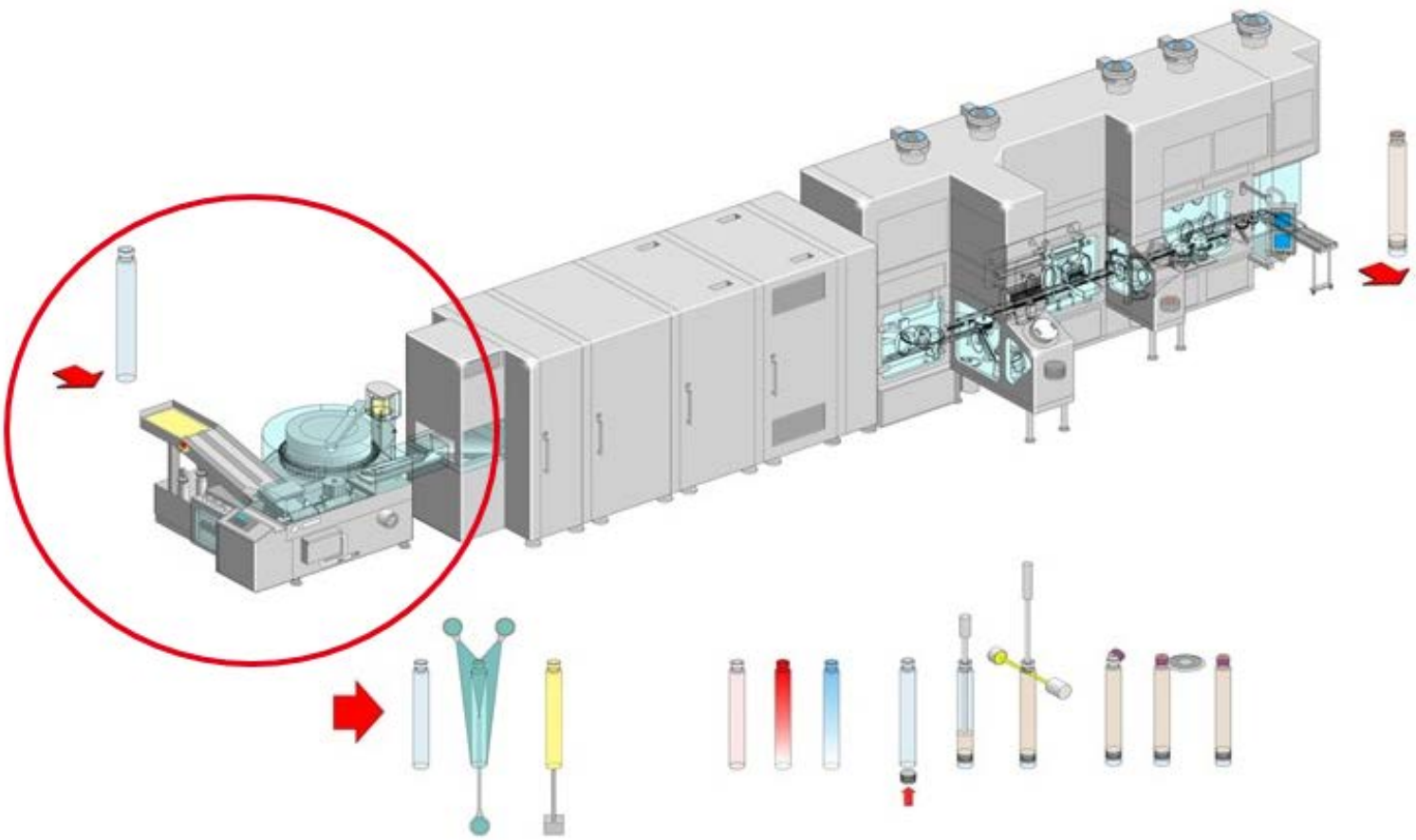
Machine impact on containers

Where is impact on the glass?

Cartridge processing

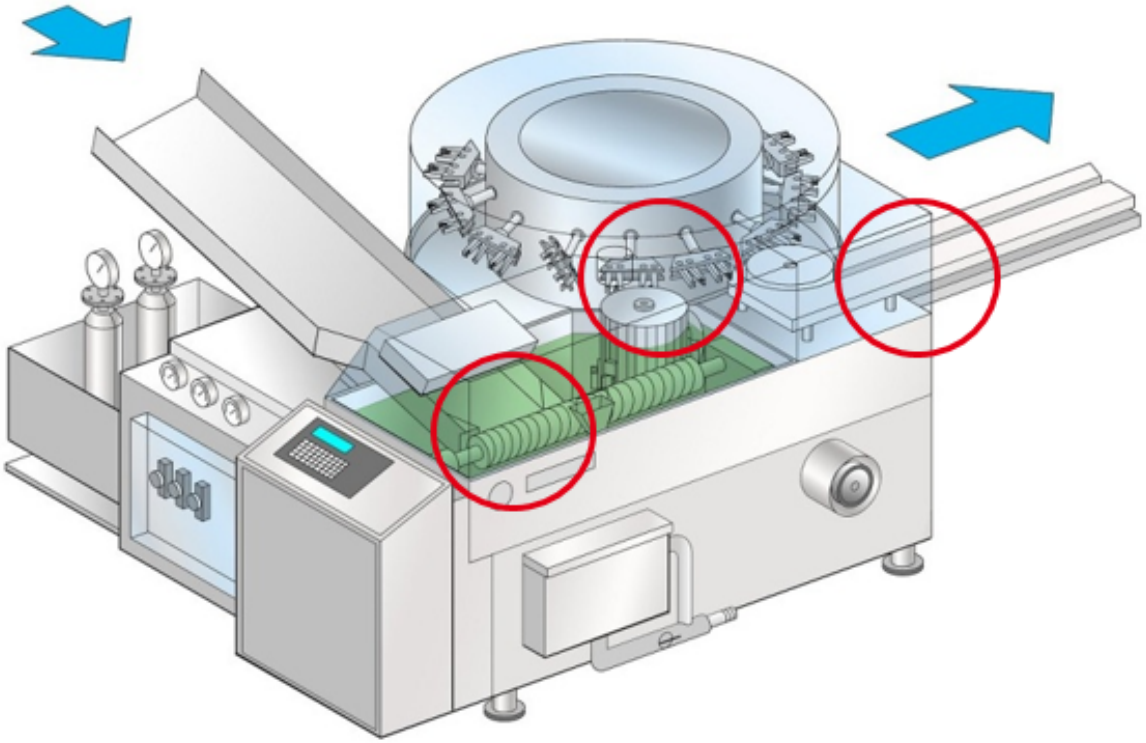
Machine impact on containers

Critical areas – Washing & Siliconizing



Machine impact on containers

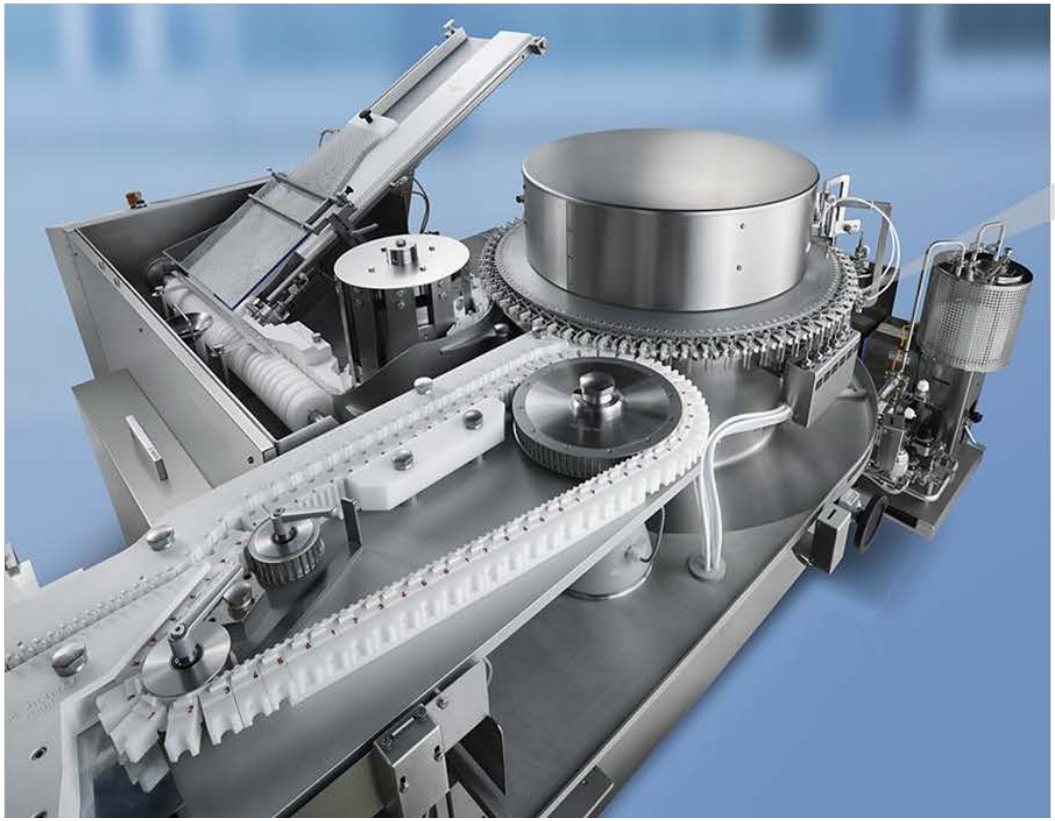
Critical areas – Washing & Siliconizing



- Bulk infeed and singularization
- Needles entering into Containers several times
- Glass to Glass Contact at handover to Sterilizing Tunnel

Machine impact on containers

Where is impact on the glass?



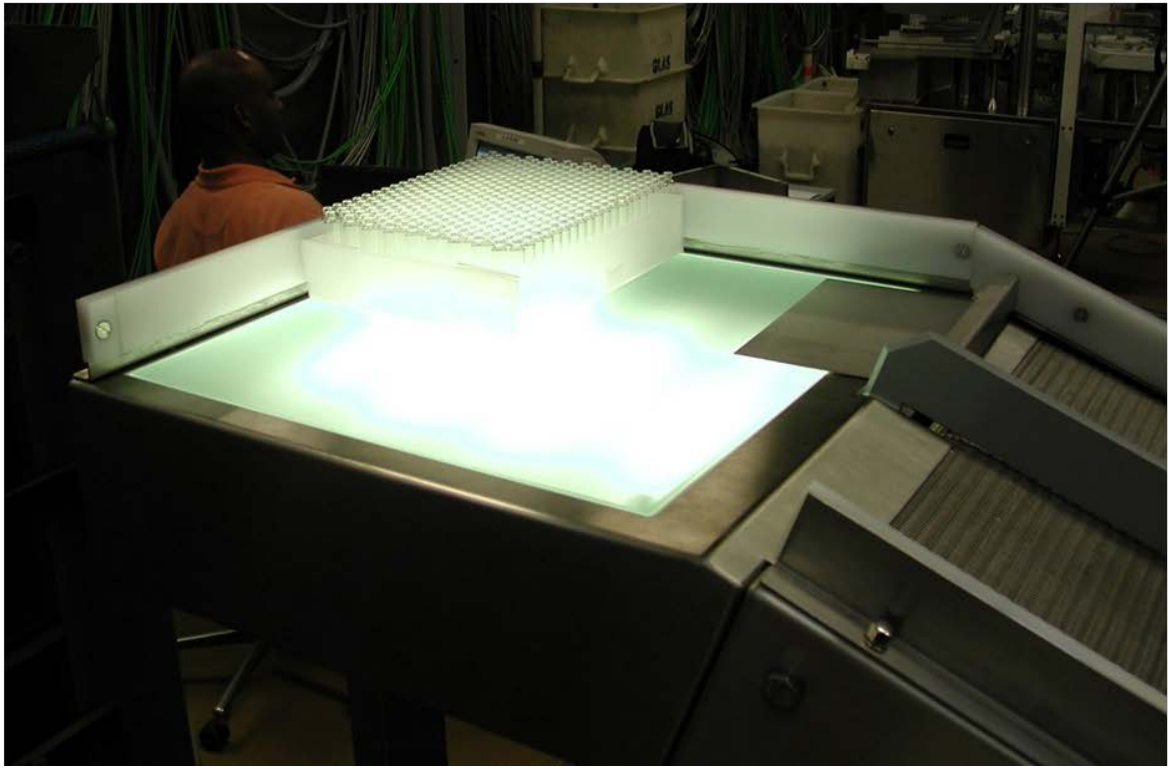
Needles for water and silicone are entering into the container

Cartridge processing, cleaning and transfer to sterilization

Machine impact on containers

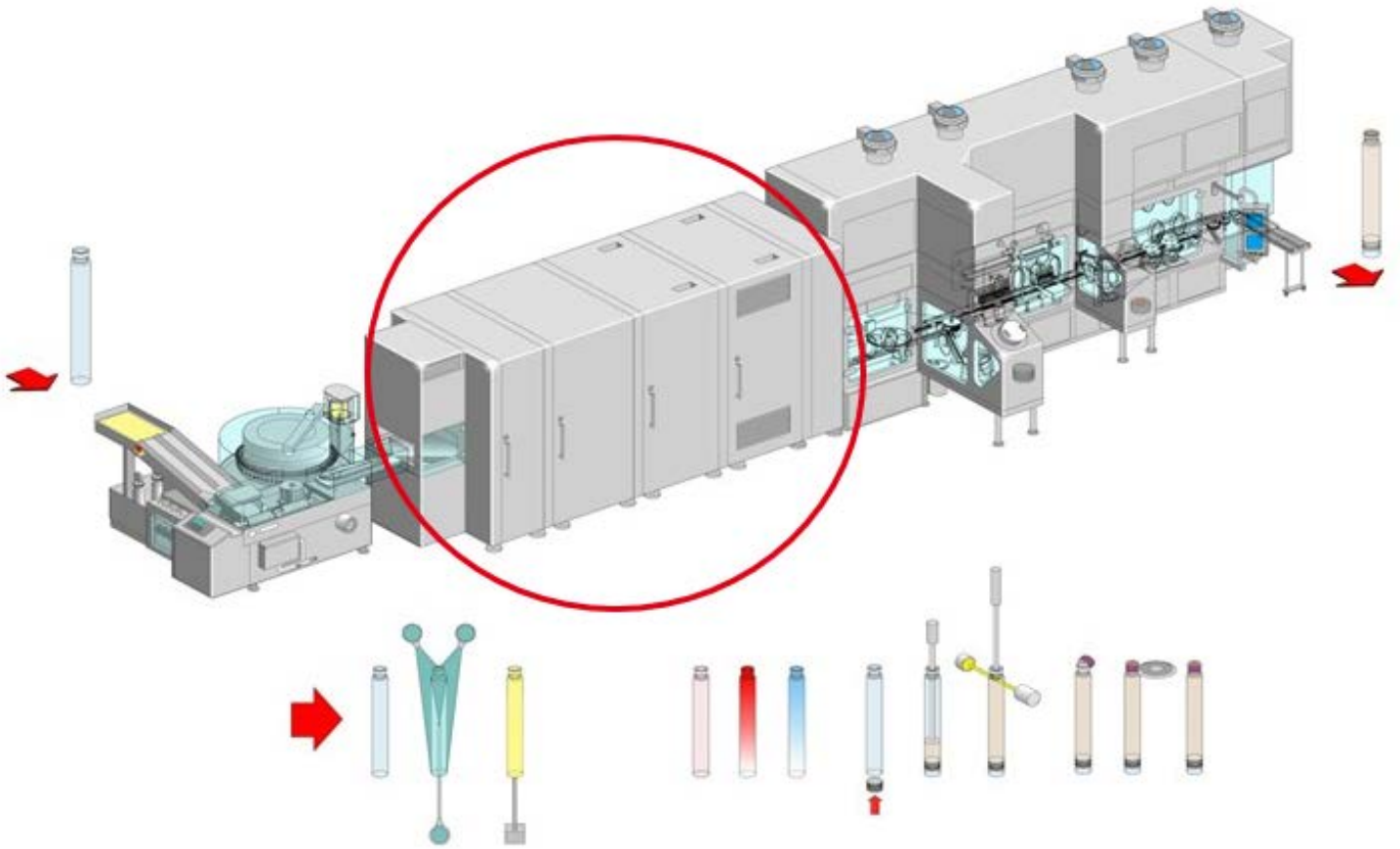
Solutions – Washing & Siliconizing

Special solution for detecting glass breakage



Machine impact on containers

Critical areas – Sterilization Tunnel



Machine impact on containers

Where is impact on the glass?

Cartridge processing,
Sterilizing tunnel.
Heating of glass containers
up to 300 degrees Celsius

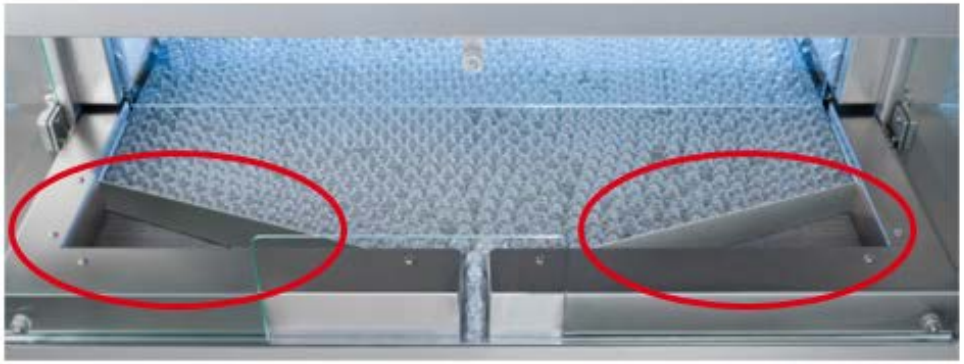
Critical areas – Sterilization Tunnel

- Direct **glass to glass contact** within the system
- **Pressure** on containers in tunnel infeed section
- Heating of glass containers up **to >300 degrees Celsius**
- ➔ Reduction/destruction of the **water skin** of the glass ➔ sticky containers, scratch sensitive containers

Sterilizing tunnel - Infeed / Discharge

- Accumulation control with bulk infeed, bulk transport and bulk discharge

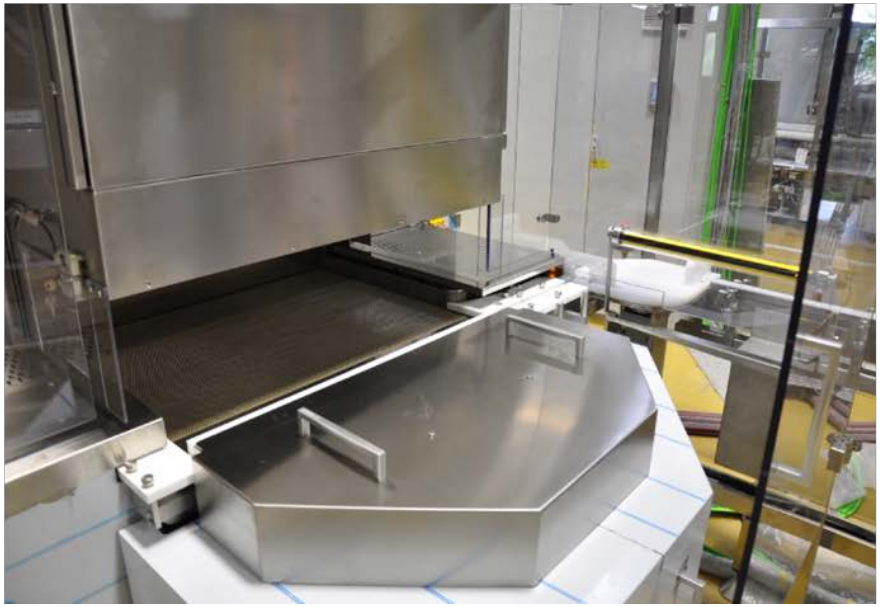
Solutions – Sterilization Tunnel

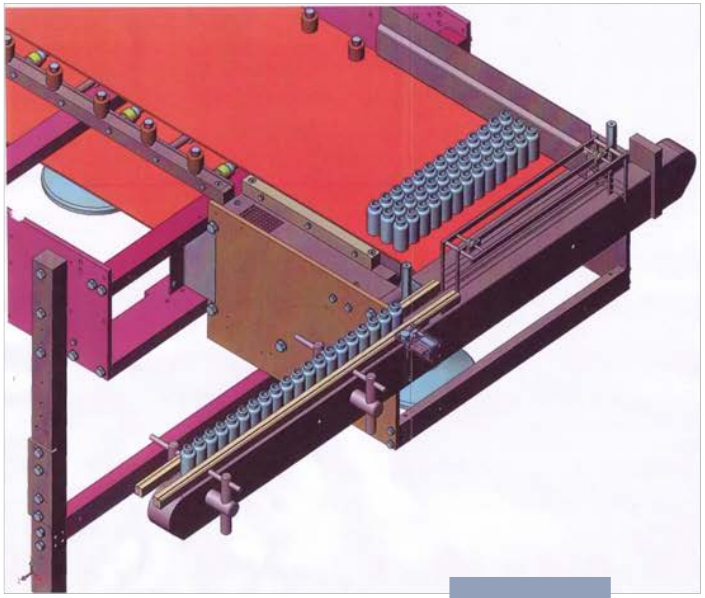


- **Accumulation control** at infeed section
- **Pre-Heating Zone** to reduce temperature influence
- **Row by row loading**: Loading onto the belt with minimal contact between the containers
- **Three Belt System**: Main belt and side belts movement is synchronized

Machine impact on containers

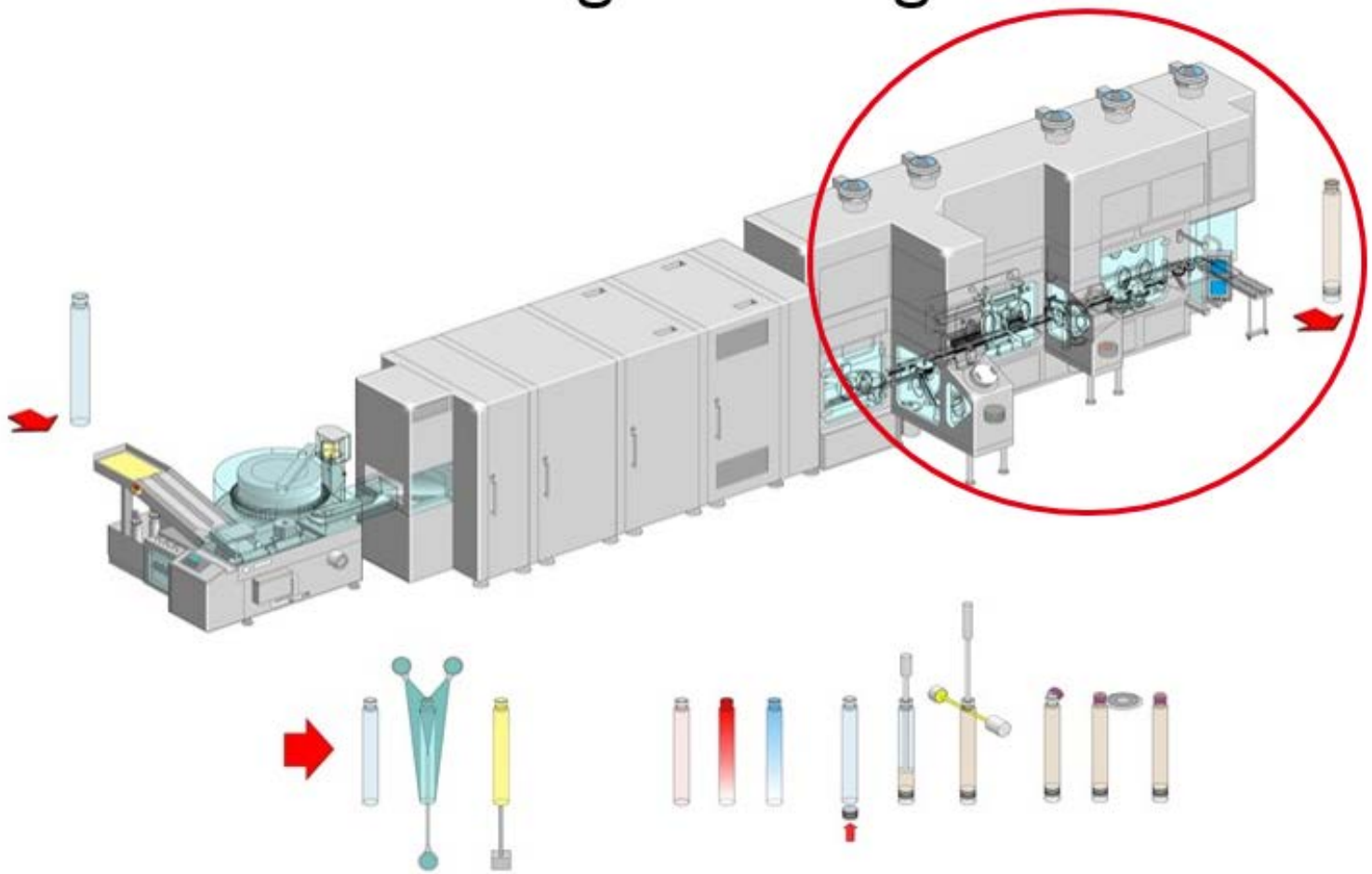
Row by row transfer





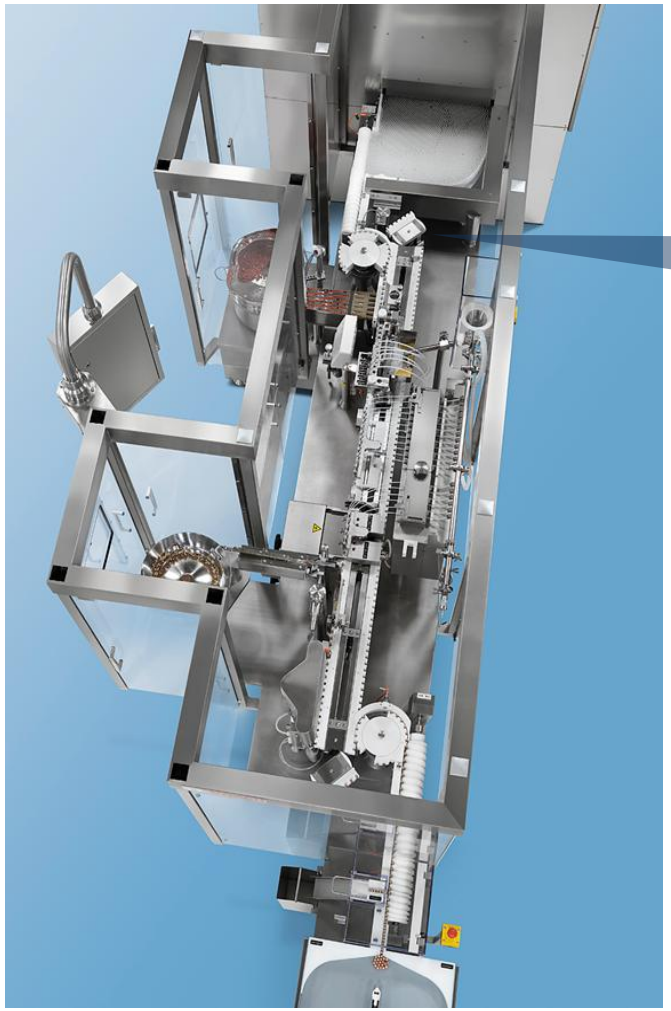
Machine impact on containers

Critical areas – Filling & Closing



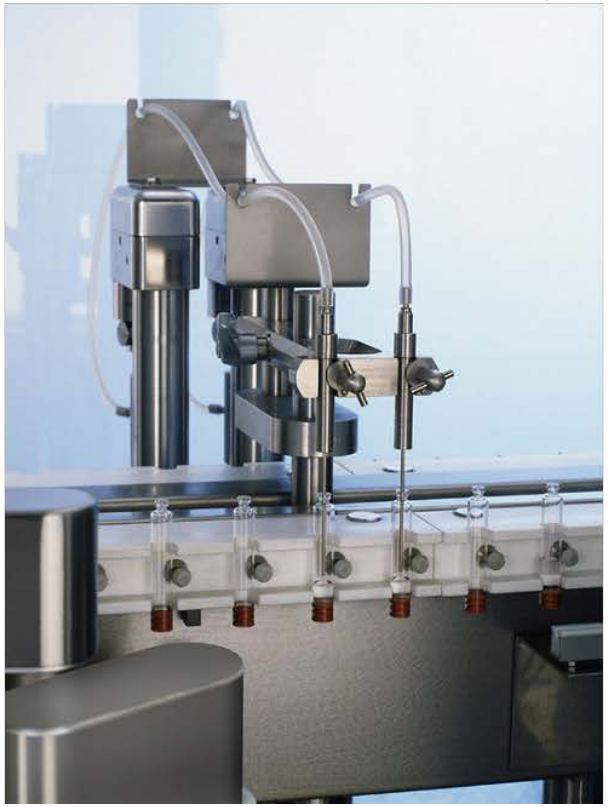
Machine impact on containers

Here: Cartridge processing



Critical point:
Separation of glass containers
after sterilization

Precision – Filling of cartridges



Cartridge for pen system
Hole for filling Ø (inner) = 3,15 ± 0,2mm

Filling needle Ø (outside) = 2 mm

Only 0,5 mm air gap!

Machine impact on containers

Solutions – Filling & Closing

Carrier System:

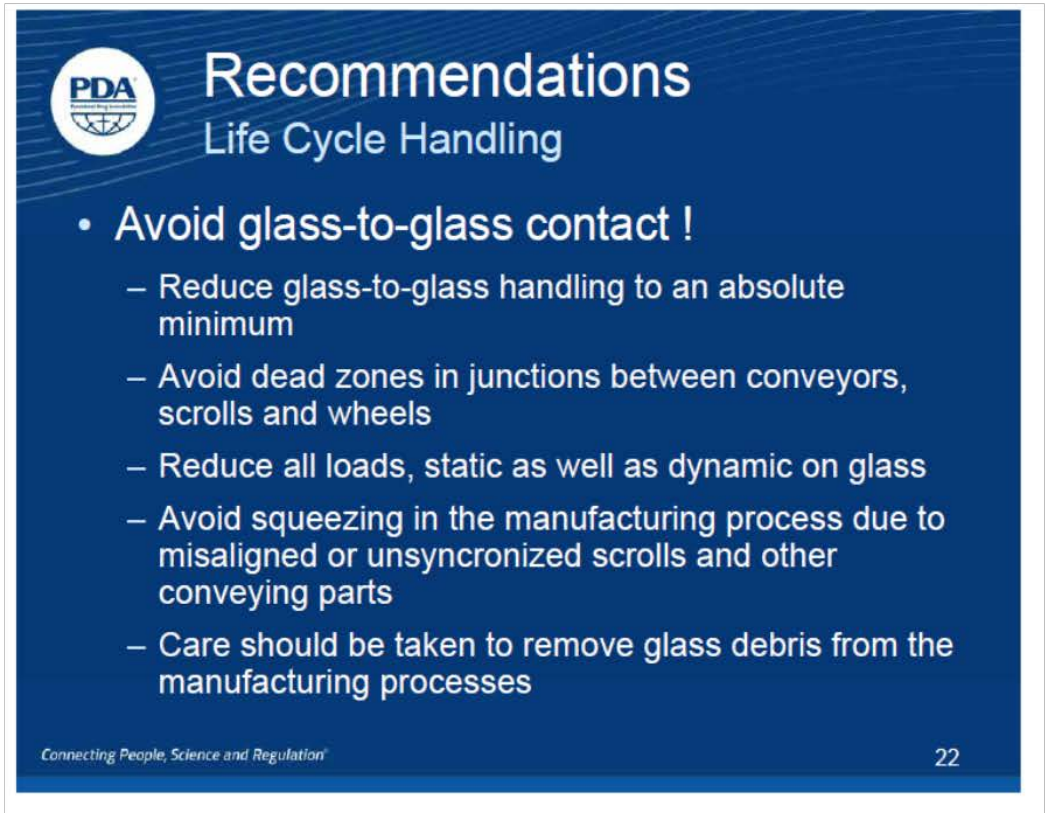
- **Precise** and **individual** transportation through the Filling and Closing Machine

Closing:

- **Adjustable** pressure and slight rolls
- Cartridge is **rotated from both ends**

Machine impact on containers

And how can the impact be reduced?



Mads Reedtz Espersen,
Novo Nordisk
PDA Parenteral Meeting,
October 2010,
Supply Chain Issues -
Glass breakage from
Purchase
to Dispatch

PDA – Training course glass

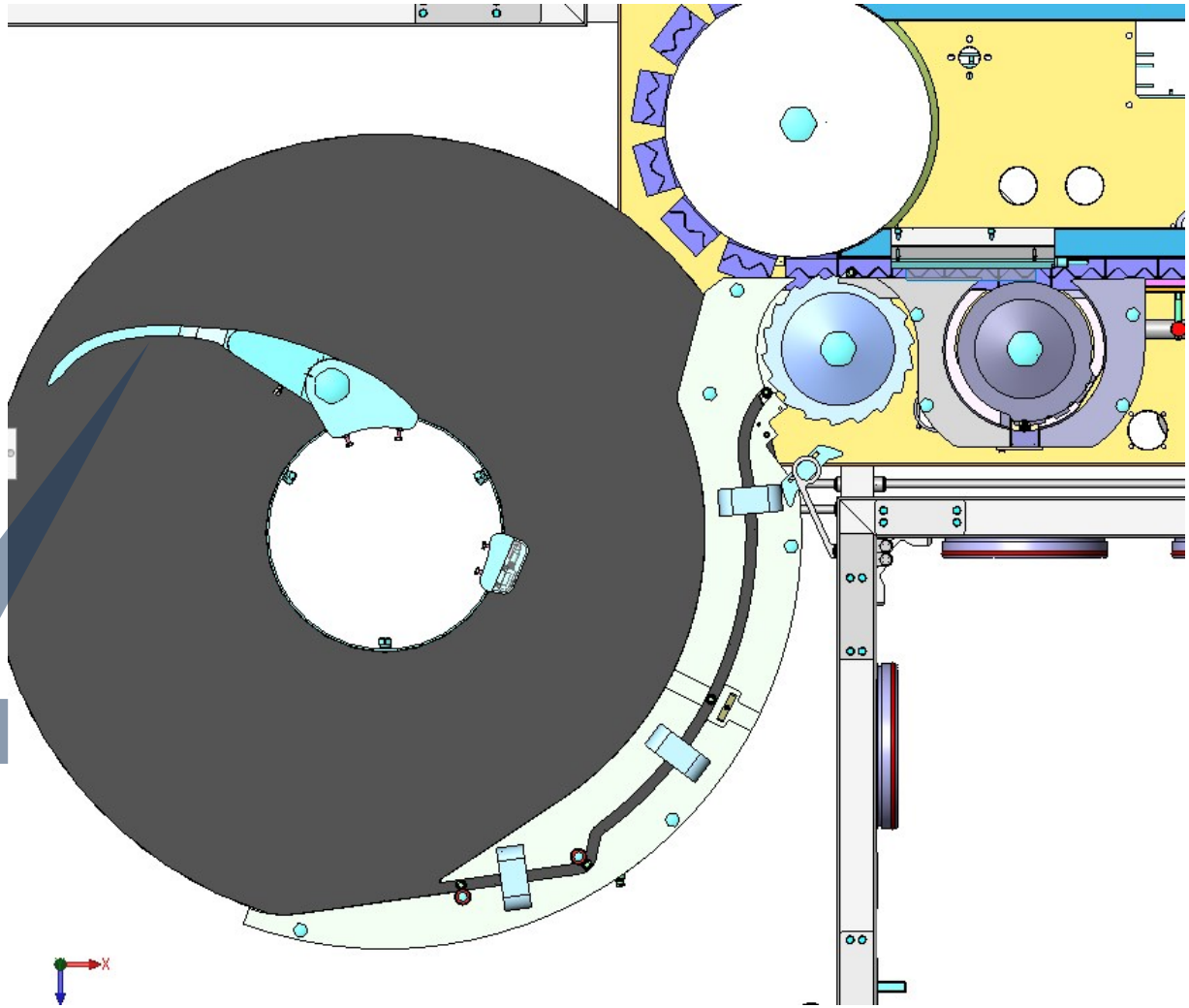
Example: Infeed turntable

Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Example: Infeed turntable

History

Focus: Infeed turntable



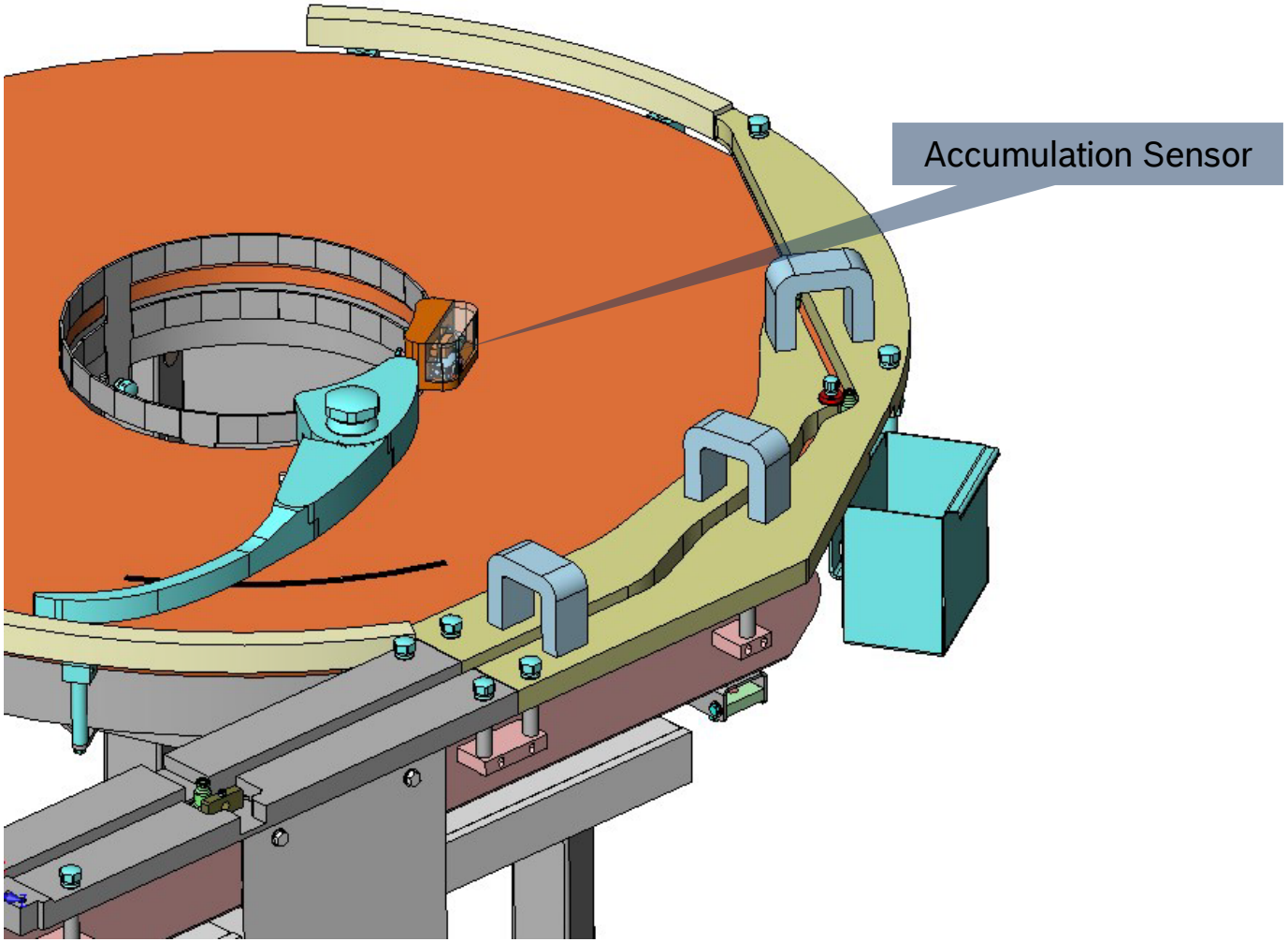
Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Focus: Infeed turntable

Not for distribution

Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Focus: Infeed turntable



Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Focus: Infeed turntable

Not for distribution

Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Focus: Guidance

Transfer

Transfer

Example: IPC

Not for distribution

Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Example: Infeed turntable

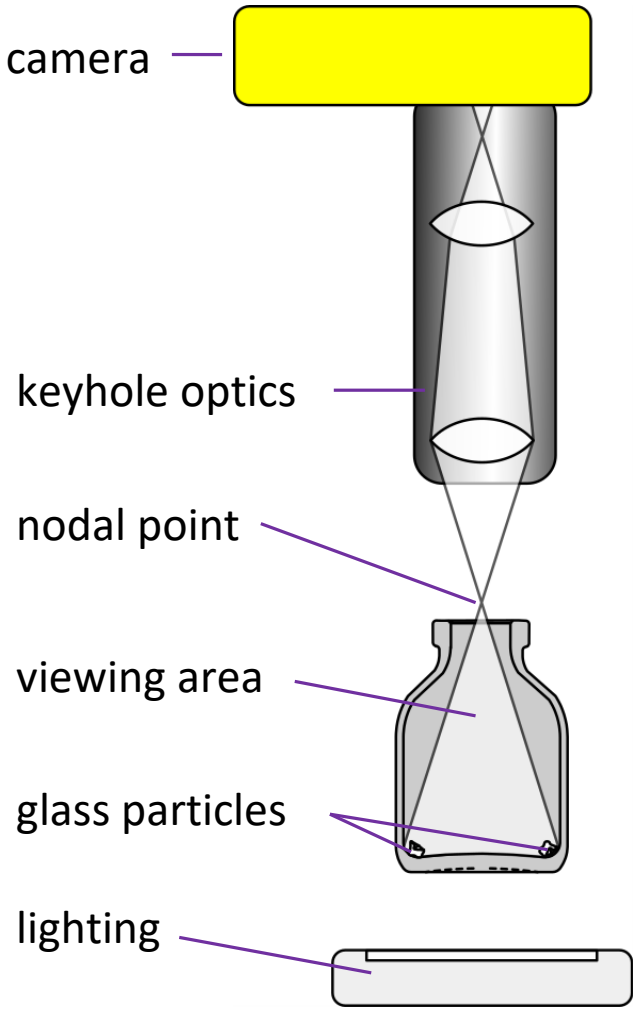
- Single lane infeed vials
- Double lane infeed vials
- Simulation vials
- Infeed washer
- Infeed ampoules

Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Example: Infeed turntable

Inspection of vial bottom FLC/MLF/RLA

Inspection principle: Keyhole optics



Technical Data:

The full bottom is observable

- Splinters, Particles
- Scratches and Defects

System covers wide range of formats

- Tubular glass vials 2R – 50R

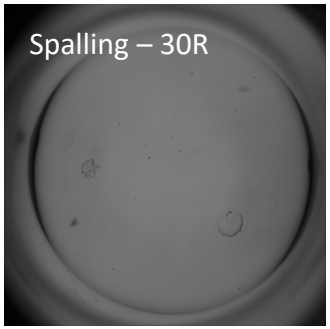
Field of view is maximized

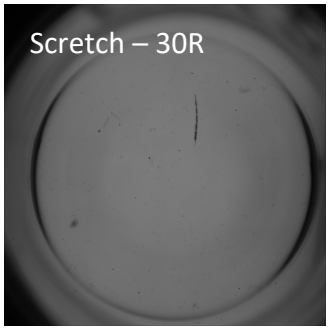
- Detectable defect size (5x5 pixel):
  - 2R – 10R: >175 µm
  - 15R – 20R: >250 µm
  - 25R – 50R: >300 µm

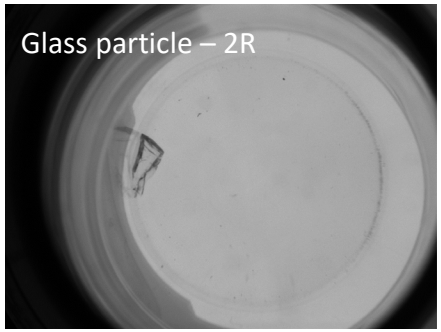
Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

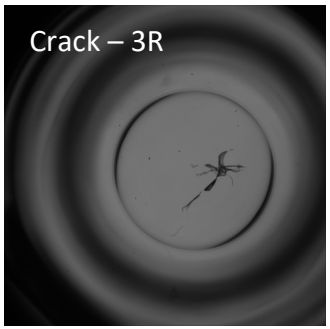
Example: Infeed turntable

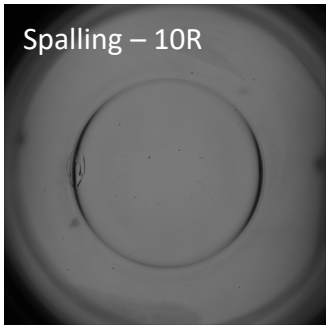
Error images from realized systems

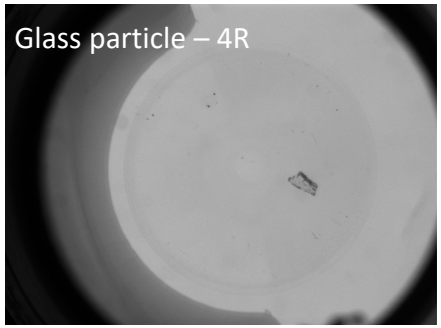




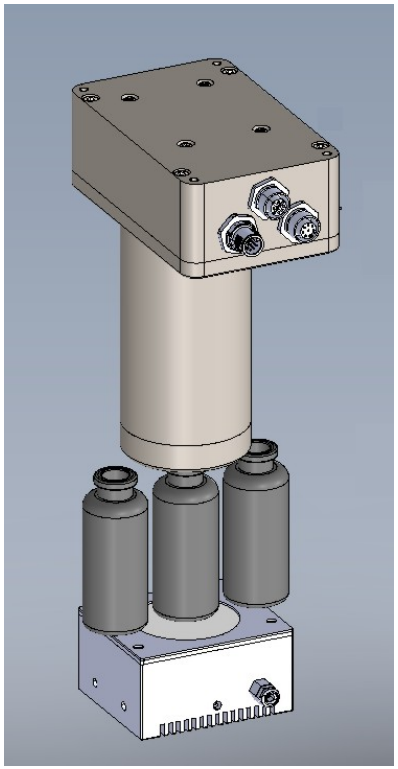








Setup



Klaus Ullherr | Product Manager | Bosch Packaging Technology | Pharma liquid

Machine impact on containers

And how can the impact be reduced?

Line without any
glass to glass contact

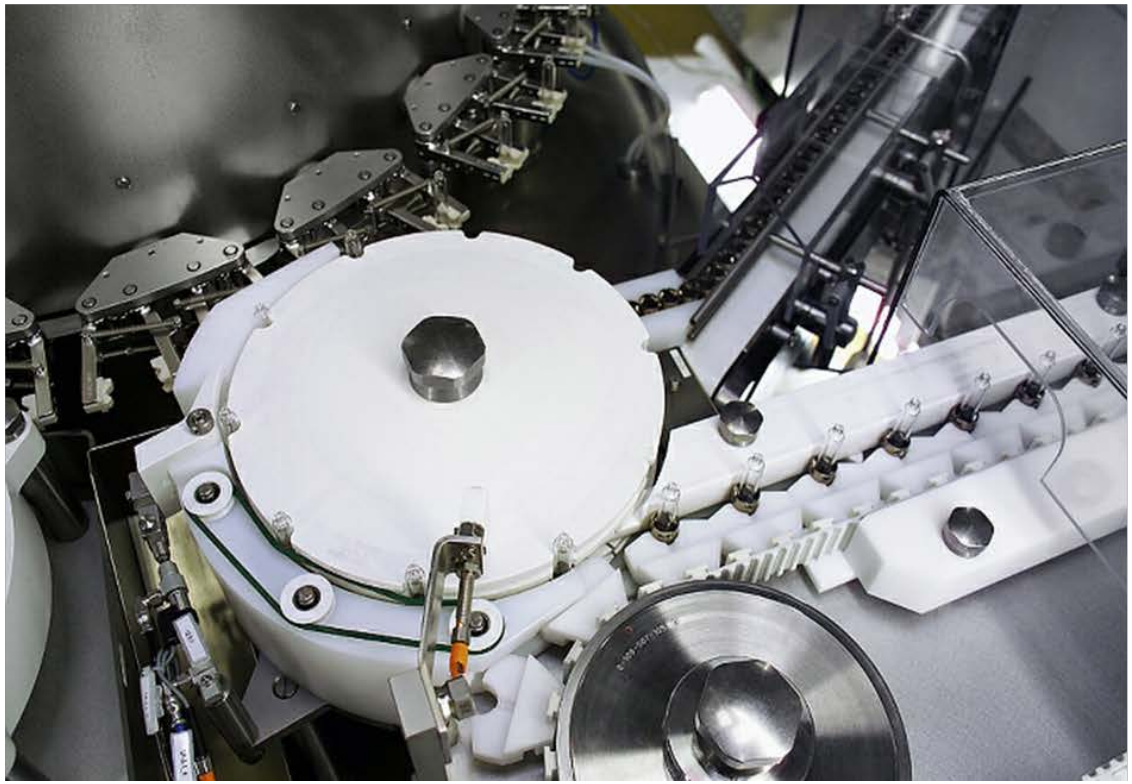
Machine impact on containers

Robotic feeding

Machine impact on containers

Stainless steel transport pucks

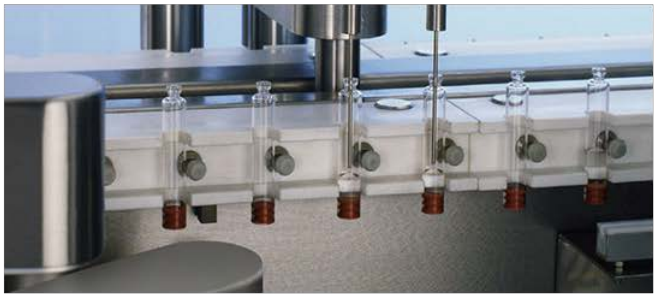
Washer outfeed/tunnel infeed - detail



Machine impact on containers

Infeed filling machine with transport pucks

Special transport carriers



Machine impact on containers

Infeed with robotic systems and transport tray

Machine impact on containers

Infeed with robotic systems and transport tray

Machine impact on containers

Infeed filling machine with transport pucks

Machine impact on containers

Infeed filling machine with transport pucks

Machine impact on containers

Nested syringes

Machine impact on containers

Nested syringes

Centering plate stainless steel

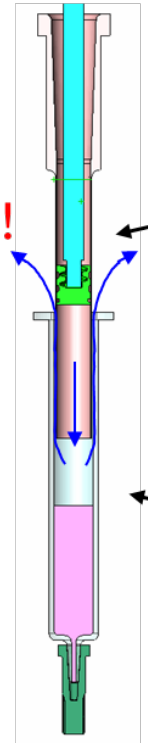
Nested syringes – alternative centering plate

Centering plate
plastic material

Bosch Packaging Technology | Business Unit Pharma | Klaus Ullherr (Product Manager)

Precision – Stoppering of syringes

Only 0,3 mm air gap!



Insertion tube Ø (outside) = 5,7 mm

Syringe 1ml long
Inner diameter 6,35 ± 0,1 mm
At the flange 6,05 mm

Machine impact on containers

Machine impact on containers

Special solution: Nested vials and cartridges

Photo: Schott, adaptiQ
Internet press news

Photo: Ompi, EZ fill

Machine impact on containers

Filling of nested vials

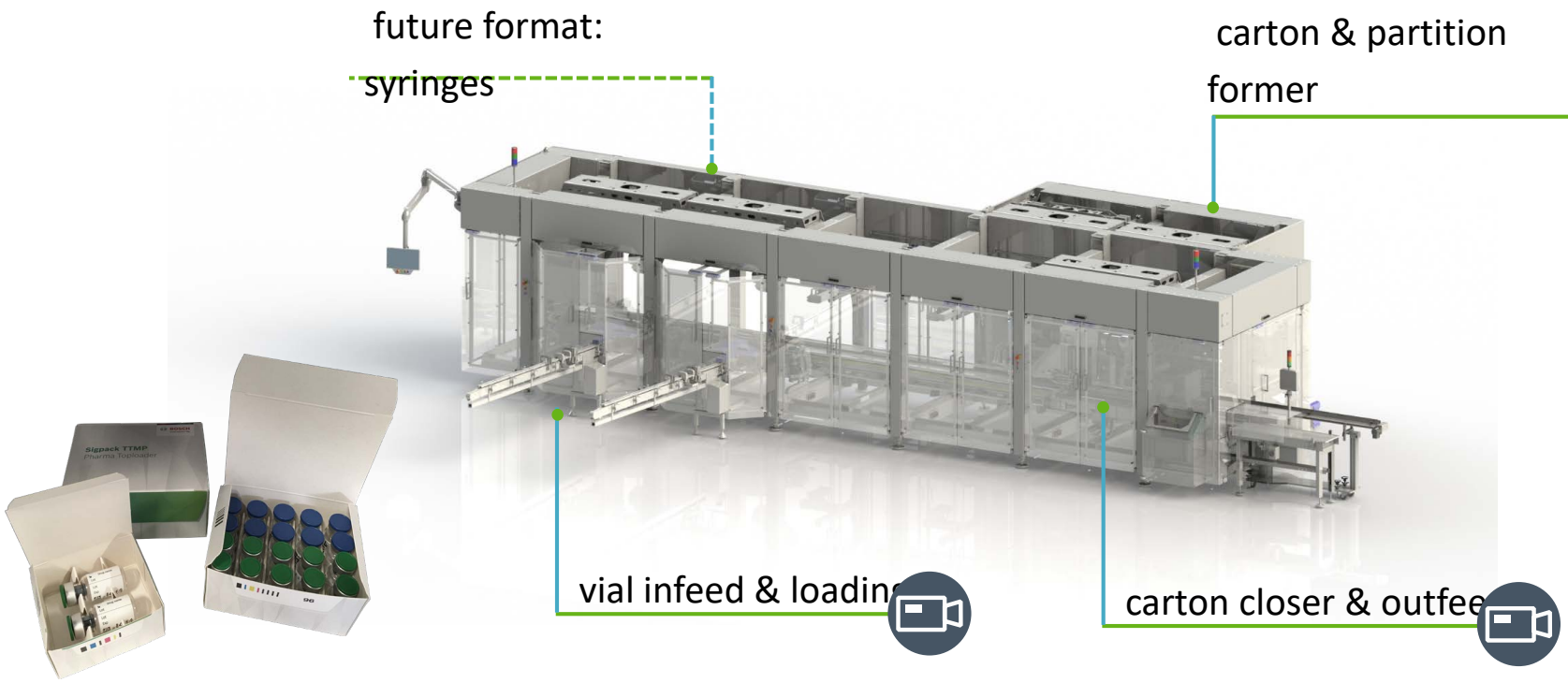
Downstream – example denesting

Inspektion

Inspection

Final packaging

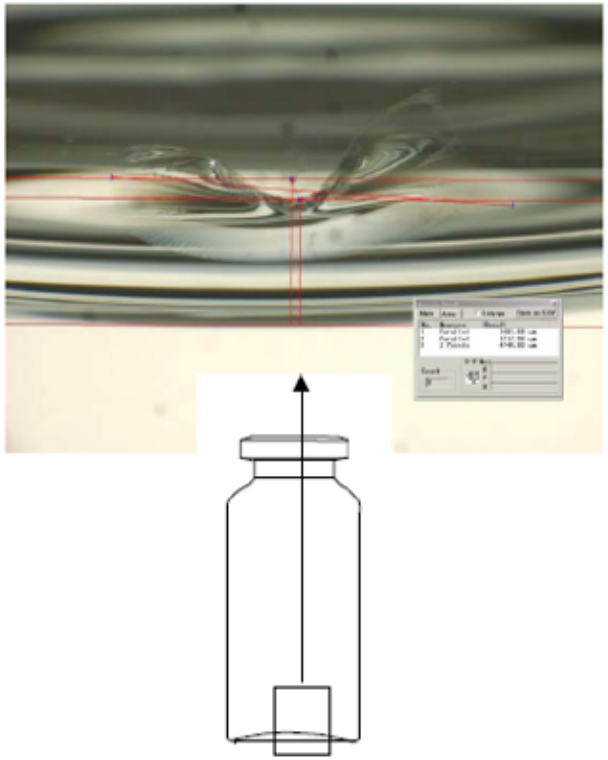
Top loader



Small batch filling

Robotic handling

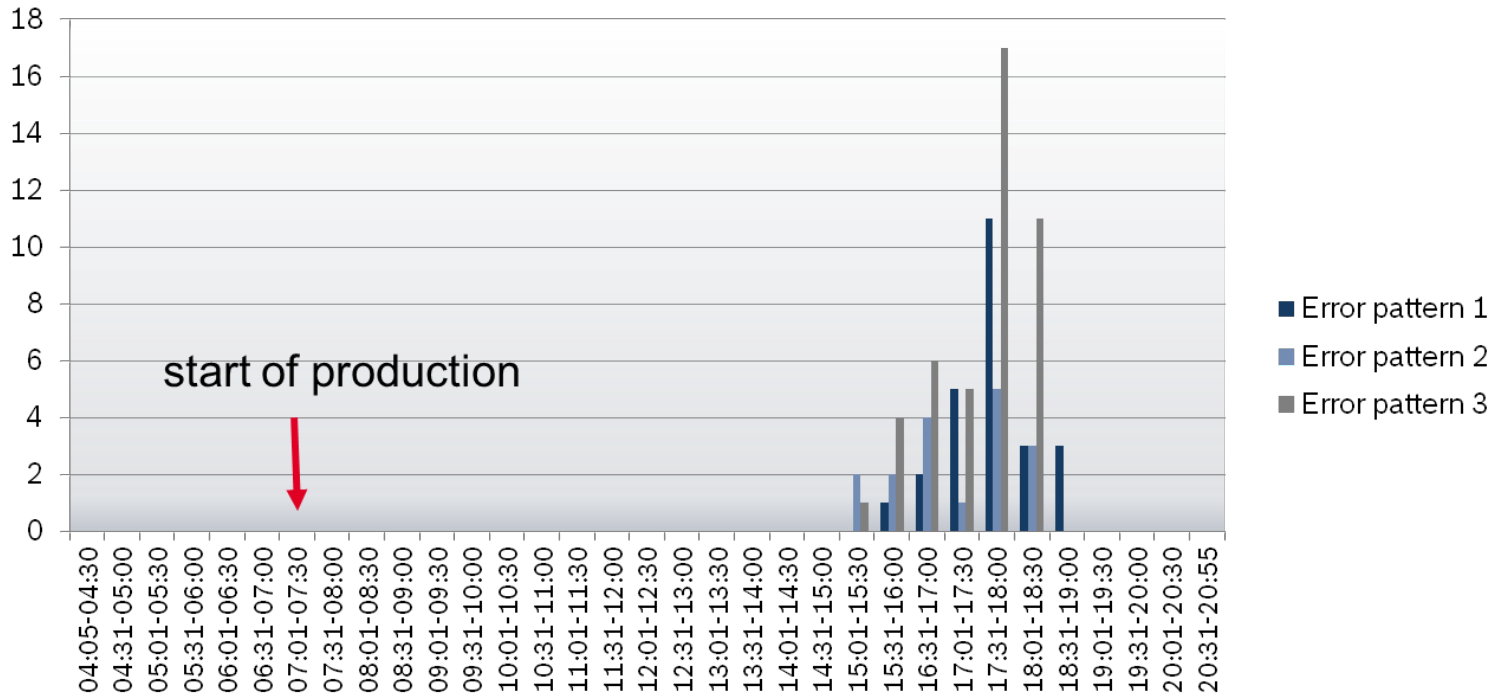
Case study – vials damaged in bottom area



Analysis by customer

- Analysis with microscope
- Determination of the height of impact
- (between 1,5 and 3,6 mm from bottom)
- Three kind of different damages

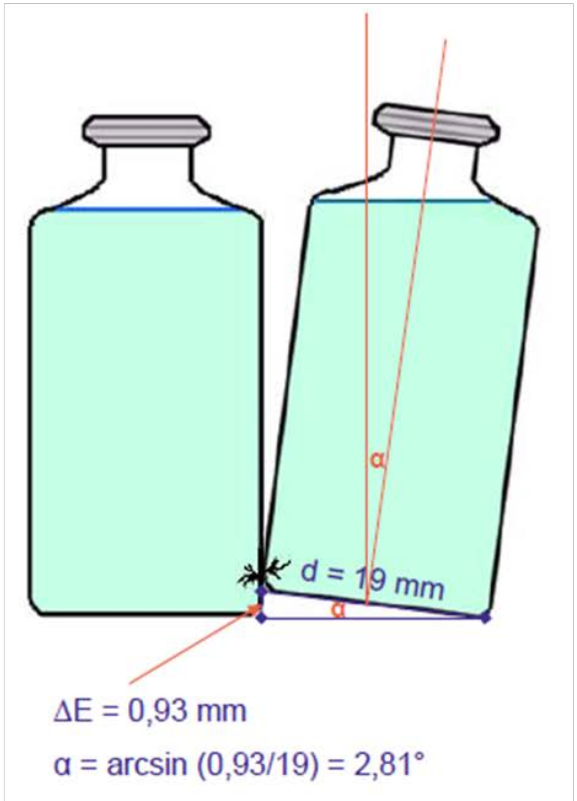
Number of damages over time



Analysis by glass manufacturer

- Vials with all three kind of damages
- Damages caused by glass to glass contact. No other materials found by analytical methods
- Probably all damages have the same origin

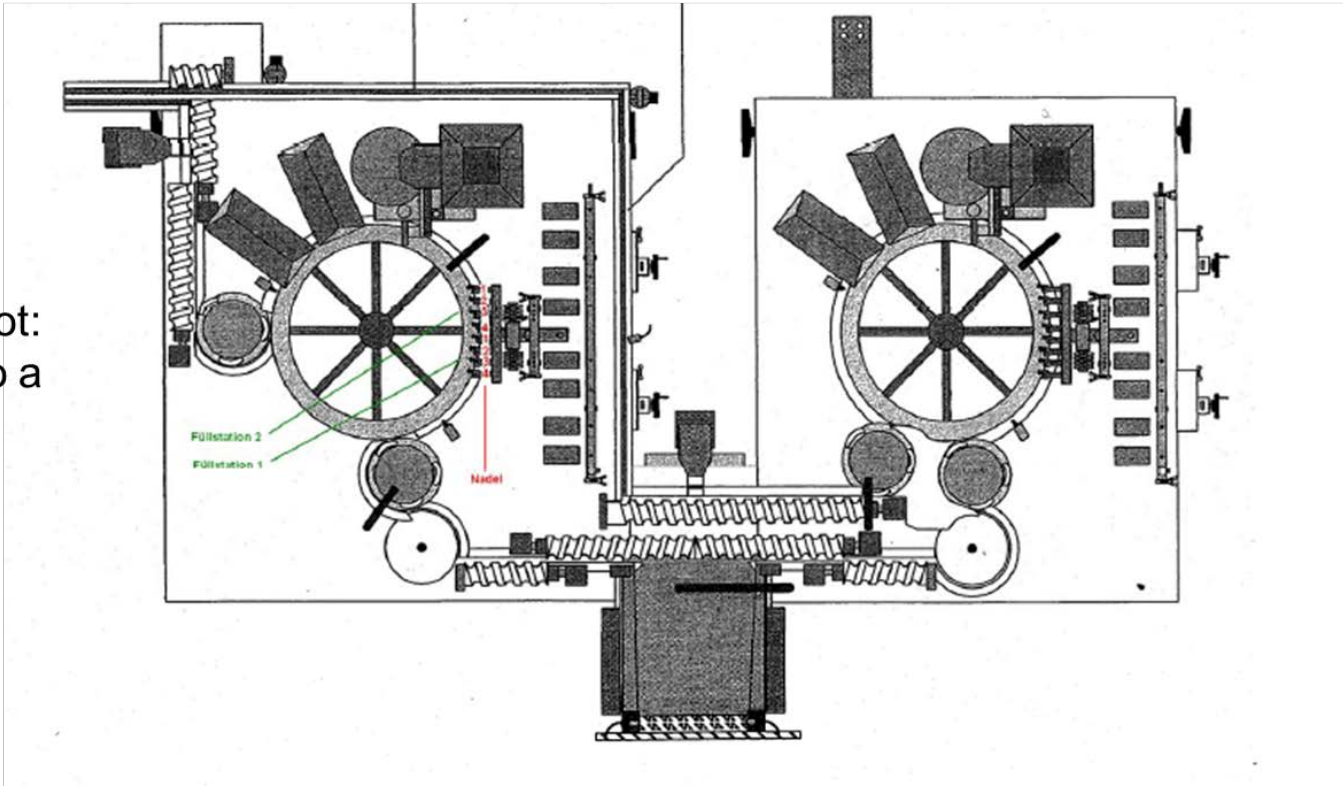
Crash constellation



Machine impact on containers

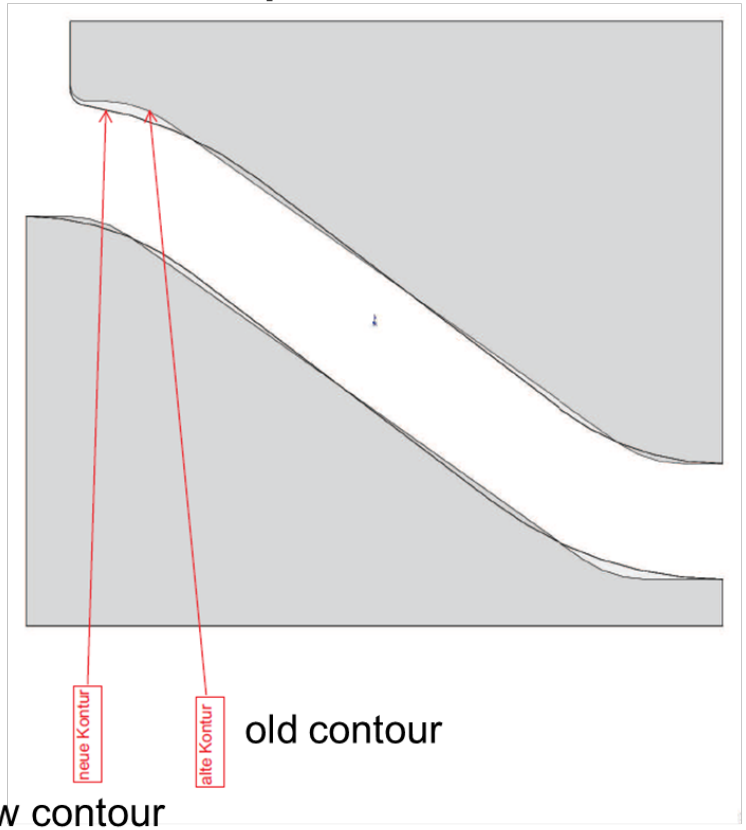
Machine layout

Critical spot:
Scroll onto a belt



Machine impact on containers

New sizepart at outfeed



Small change ➔ huge effect

Latest developments

Inline measuring of pressure, Smartskin

New glass vial

PDA Journal of Pharmaceutical Science and Technology

Particulate Generation Mechanisms during Bulk Filling and Mitigation via New Glass Vial

Christopher L. Timmons, Chi Yuen Liu and Stefan Merkle

PDA J Pharm Sci and Tech **2017**, *71* 379-392
Access the most recent version at doi:10.5731/pdajpst.2017.007724

Machine impact on containers

Summary

- Technical solutions/concepts are available
- But there are limitations (costs, space…)
- New, other disadvantages could be created
- Optimization vs. new concepts

Dr. Andreas Rothmund, Vetter
PDA IG Meeting April 2010,
Zero Glass Breakage – Dogma or Ambitious Goal

Questions?

BOSCH
Invented for life

Klaus.Ullherr@bosch.com