Rubber Fab
a Garlock Hygienic Technologies company

Leading Innovator of Sanitary Gaskets, Hoses, Hose Assemblies and Pump Parts

It’s all about hygiene – hygienic seals for highest process reliability

26.06.2020 – Webinar 04

by Sascha Butter, Christoph Neuffer, Dominik Wiese

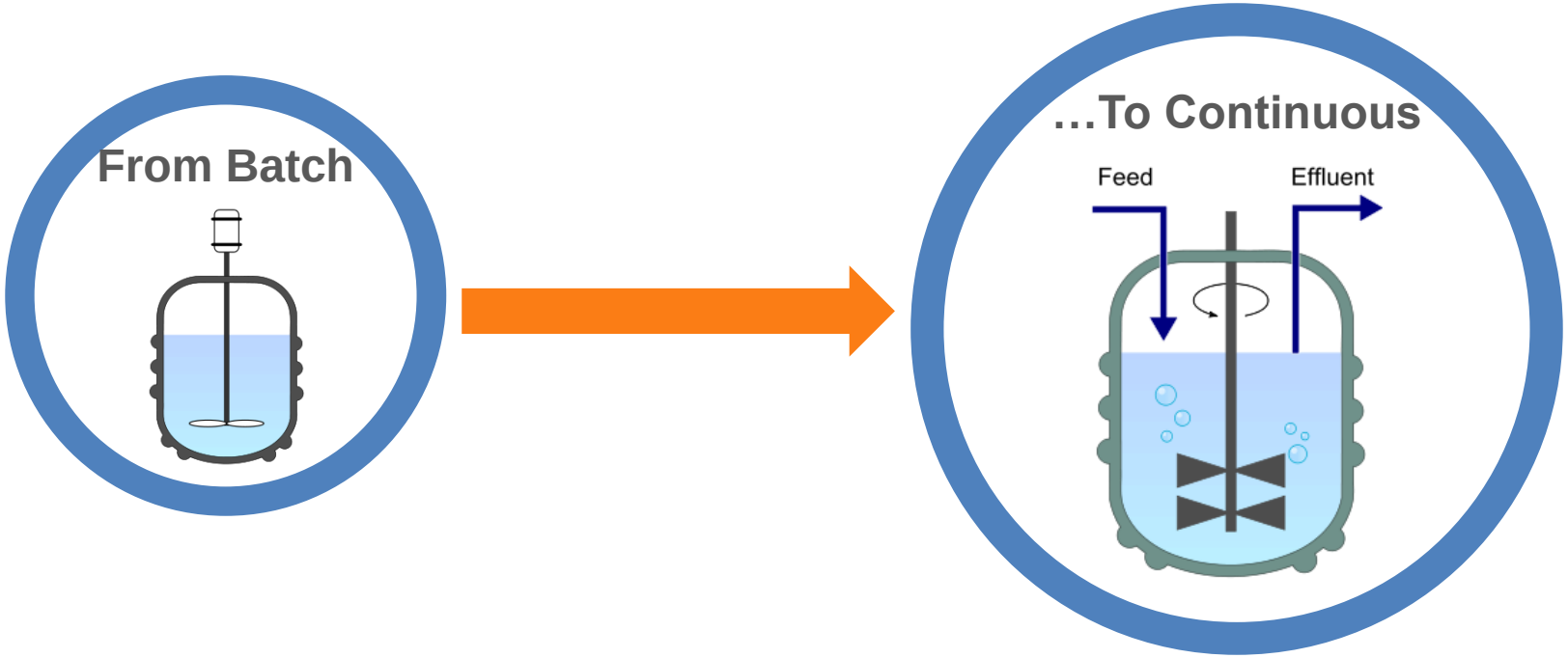
Faster Production

Process Engineer

“The demands of faster production speeds and shorter batch runs are putting increased pressure on process manufacturing requirements, while assuring product safety through the use of automated cleaning processes”

Pharmaceutical Manufacturing

Process engineers are now responsible for always faster batch-changeovers as well as assuring safety and operateability for continuous manufacturing.



Industry trends

“Continuous manufacturing represents the future of advanced pharmaceutical manufacturing and will produce significant improvements in efficiency, safety, cost and speed to market”

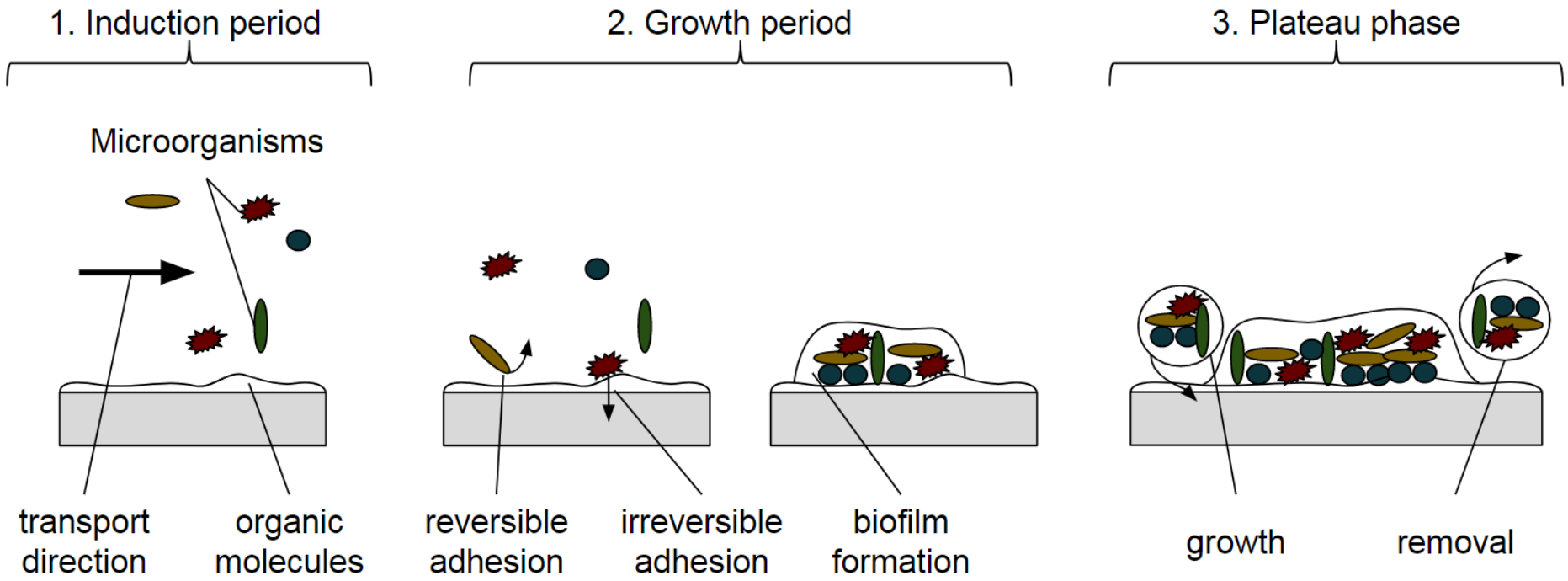
Prof. Dr. Fernando J. Muzzio, PhD,
Director of the National Science Foundation/Engineering Research Center

BCC Research’s new report on Continuous Manufacturing for Pharmaceuticals (PHM214A)

One common misconception

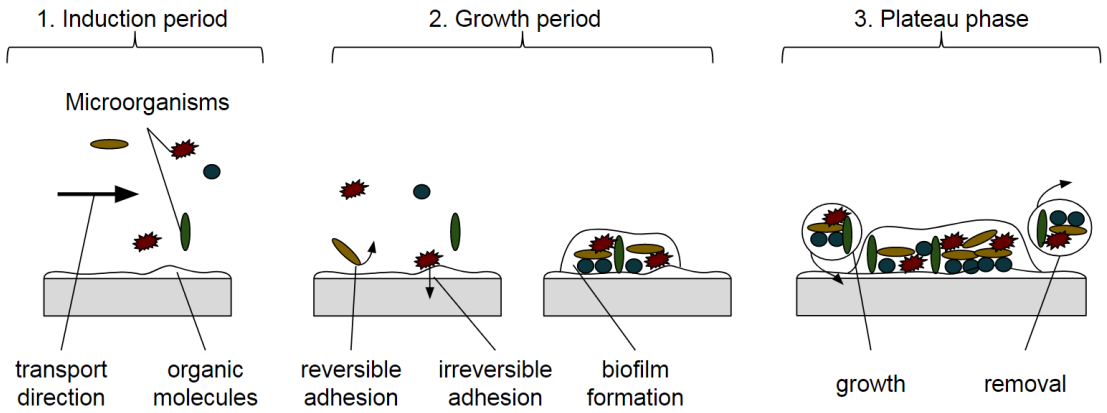
One common misconception is that automated cleaning systems always assure safe operation when in fact even the best cleaning processes only result in inactivating bacteria not eliminating it.

Why microorganisms remain?



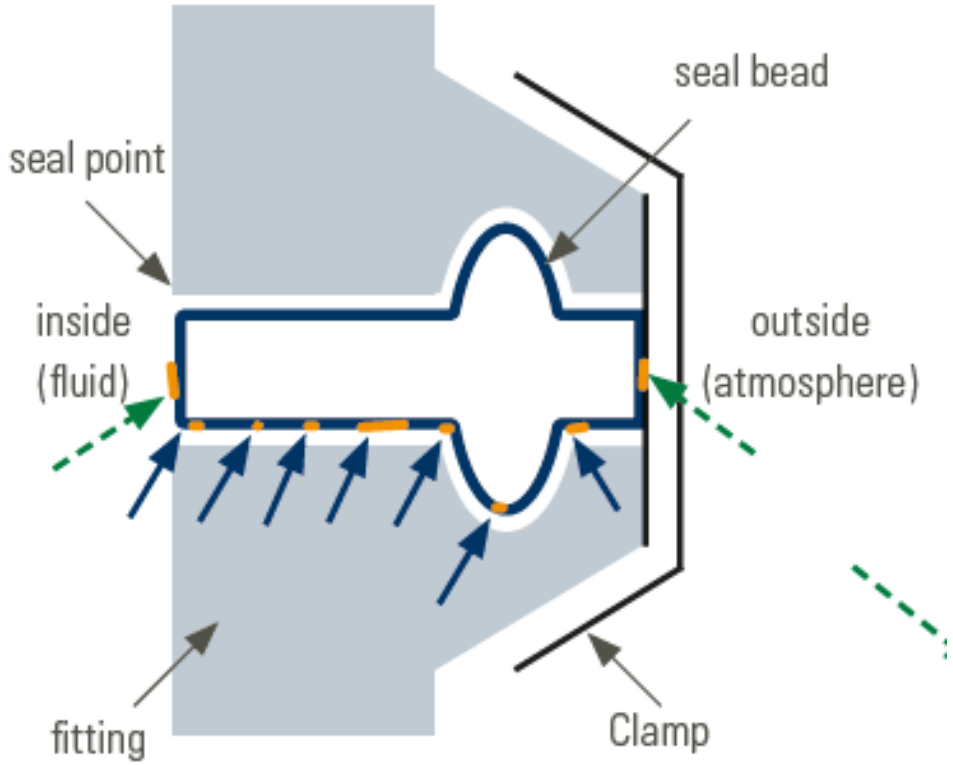
Biofilms

- Interference with product quality
- Reduced heat transfer
- Increased filtration and friction resistance
- Material destruction (biocorrosion)



The detection of biofilms is not always guaranteed

Why cleanability is compromised?



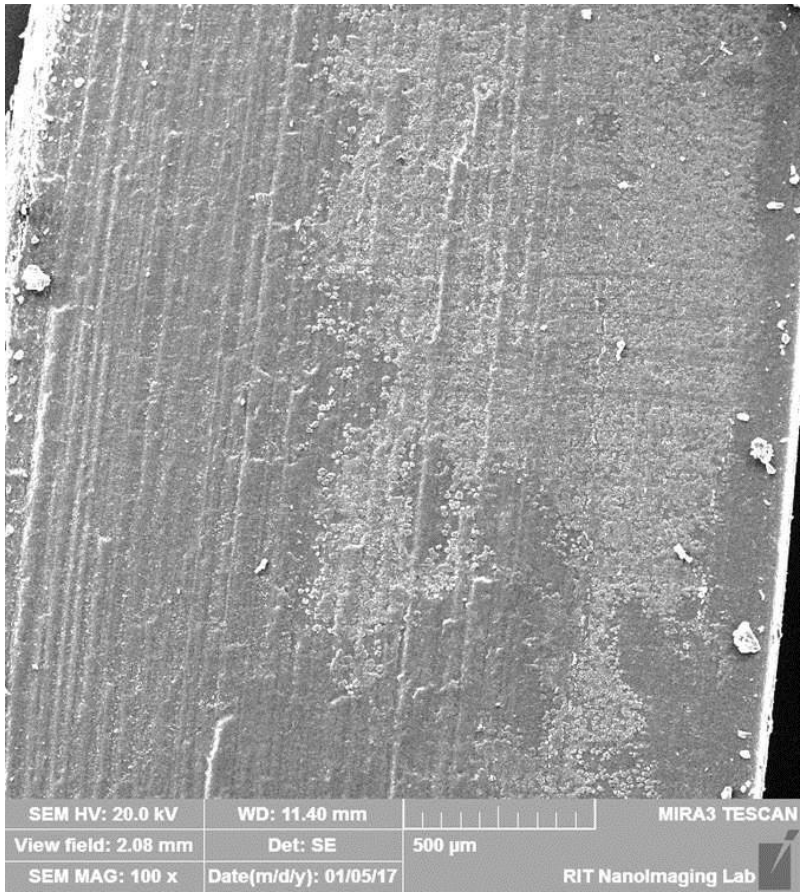
- Maintaining the **ideal sealing point** is critical to prevent leakage and entrapment
- Heat and chemicals over time cause swelling of the gasket (expand/contract)
- Compression of gasket is critical to seal

Uneven loading of the gasket

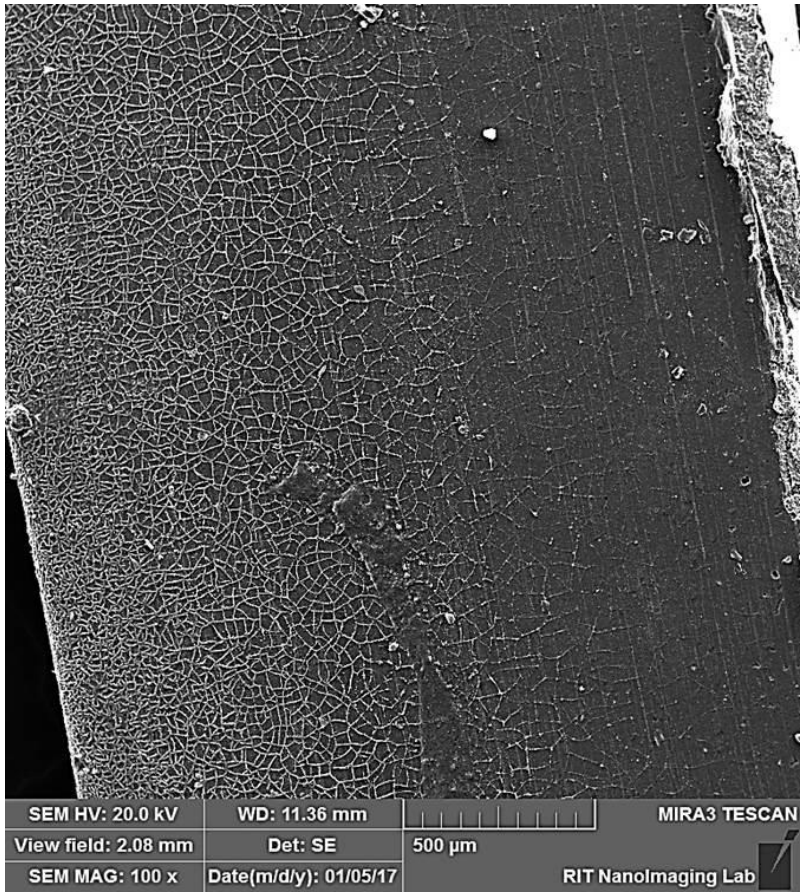
» OD 119 mm “Tri-Clamp” hygienic connection torqued to 8 Nm

Rough surface of gaskets

EPDM

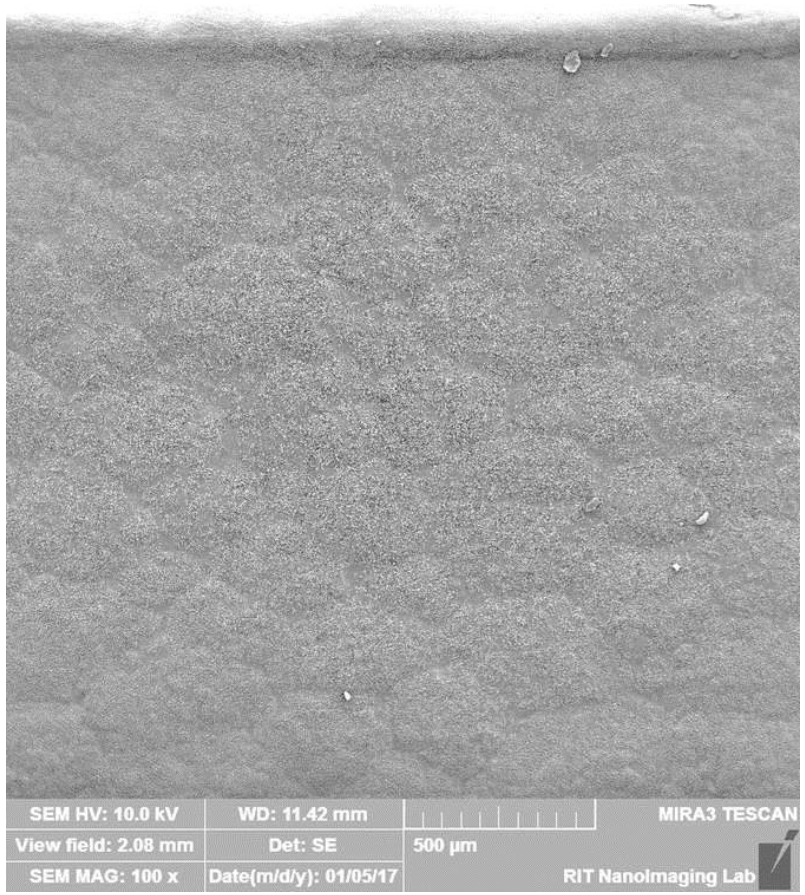


FKM

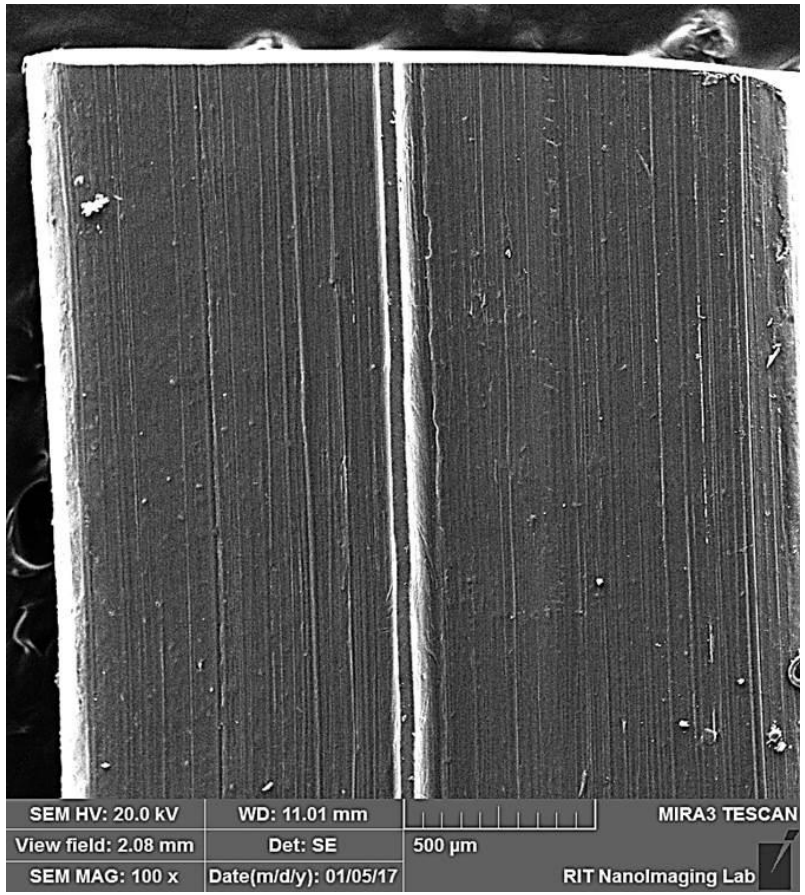


Rough surface of gaskets

Virginal PTFE

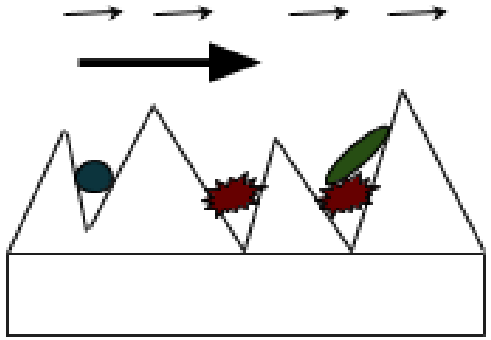


Silicone



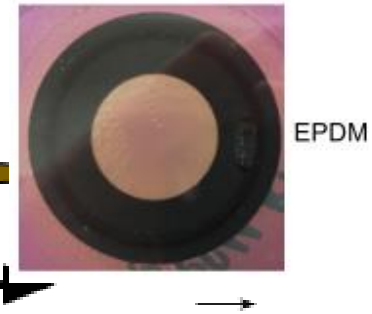
Rough surface of gaskets

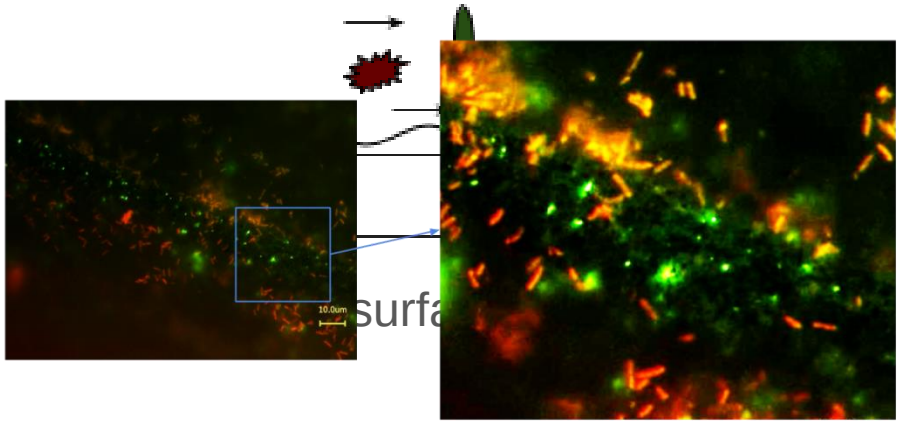
» A rough surface with a relatively high free surface energy causes an entrapment risk



Rough surface of gasket

Vs.





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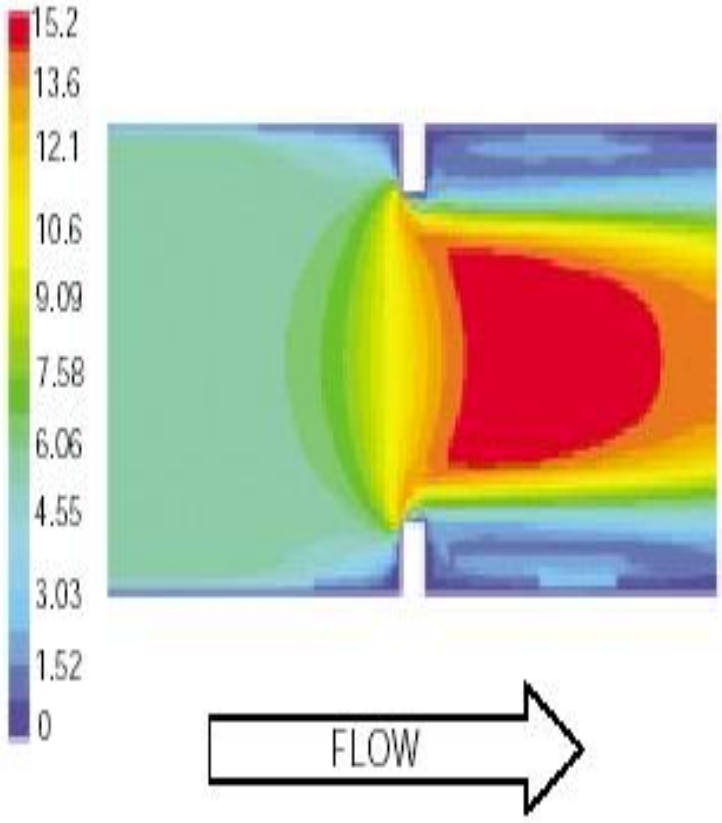
Gasket Intrusion

- Difficulty in cleaning, very costly
- Cross contamination, very costly
- Product Hold-Up, very costly
- Creates Dams- turbulences
- Restriction in flow
- Higher velocity created
- Longer cleaning cycles



Common gasket shown!

System contamination, what‘s next?

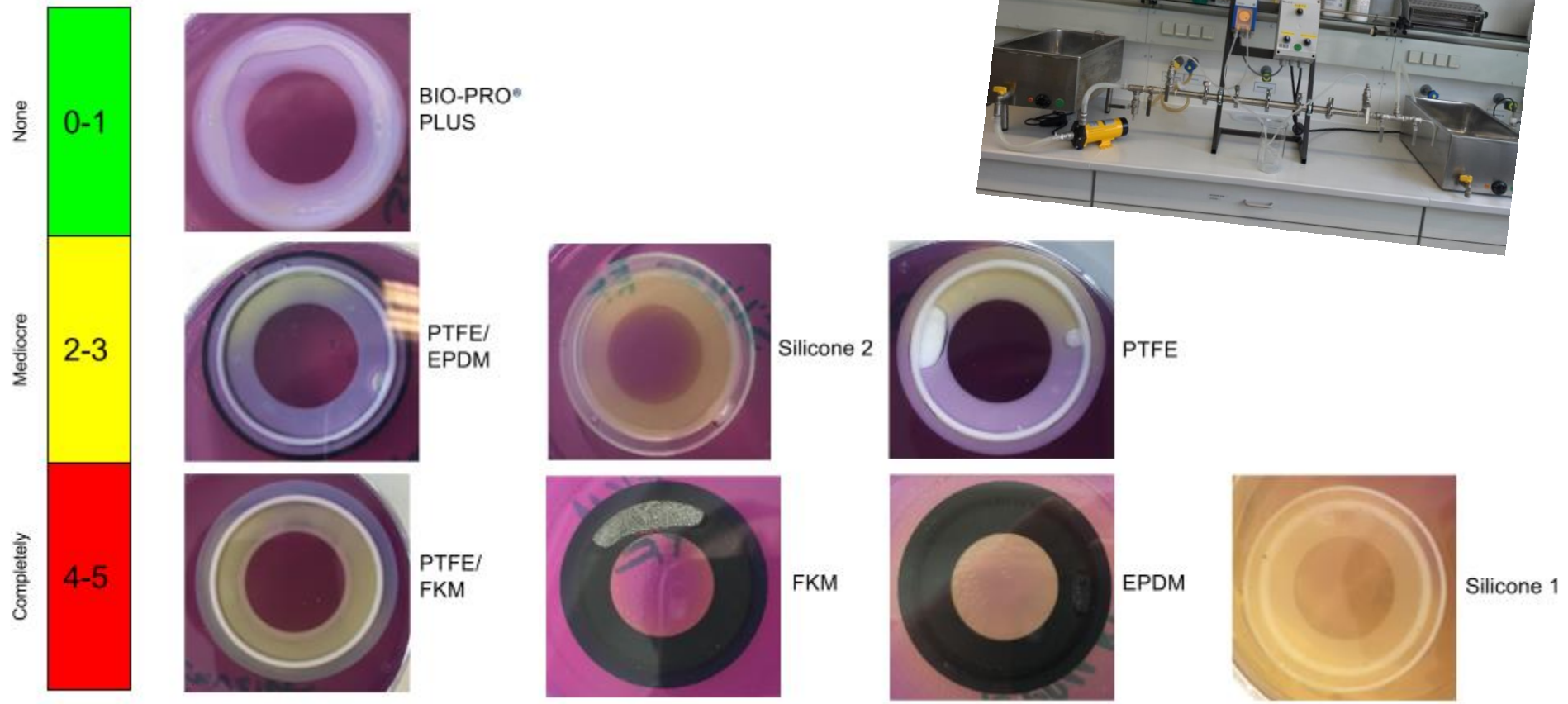
- Find bad batch/ pressure loss/ leackage -> 1-2 days
- Replacing gaskets/ components/ media etc. -> 1-3 days
- Retorque all gaskets -> 4-6 hours
- Additional cleaning cycles -> 1-4 hours
- Lab testing -> 0,5 hours
- Pressure testing -> 0,5 hours
- Destroy contaminated batch
- Paperwork
- …..

There is a Better Way

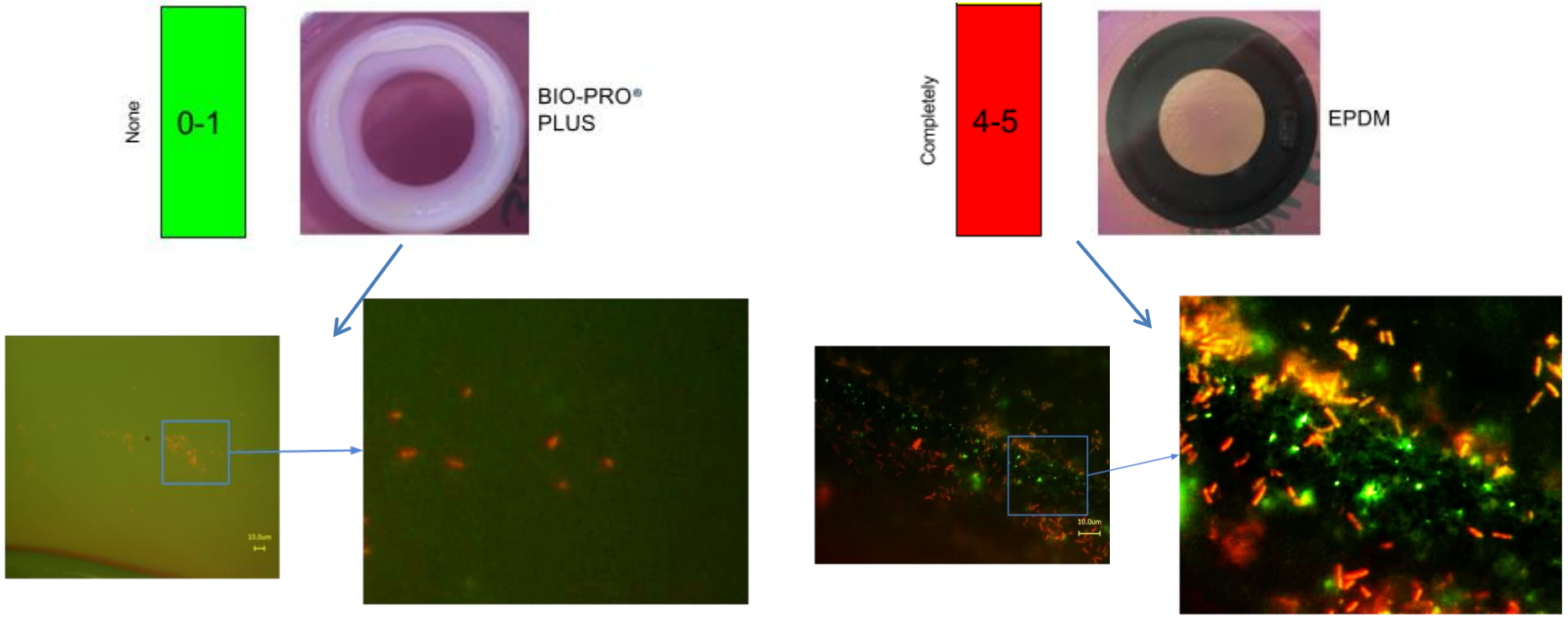
- What if you could eliminate most contamination issues by using a gasket that offers the same or better cleanability than the pipe itself. Not only that, but also with eliminating the need to retorque your connections?

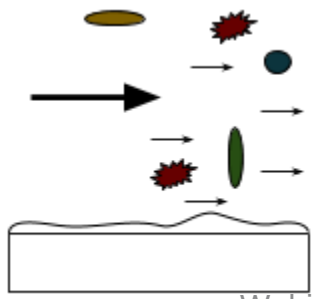
- This would not only reduce contamination related costs like downtime and product loss but also increase production time and overall product quality.

Cleanability

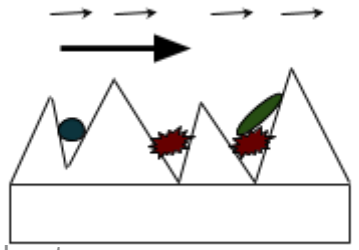


Cleanability



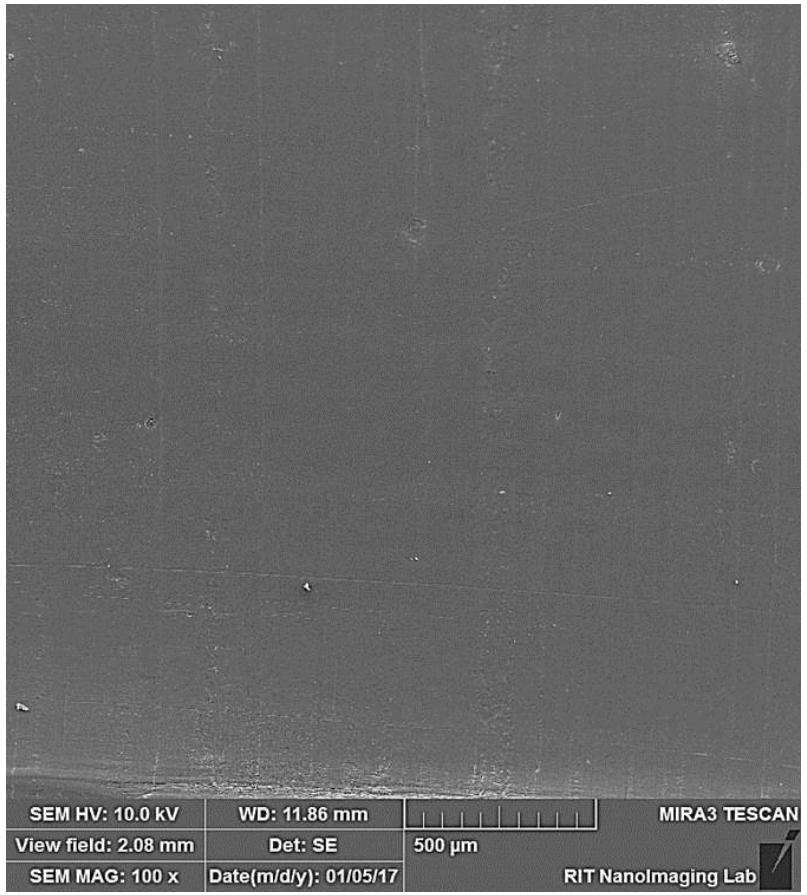


Surface as smooth as stainless steel!

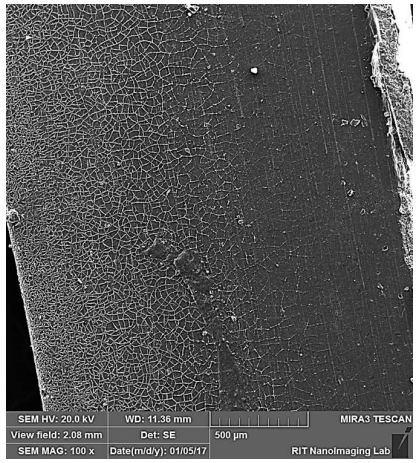


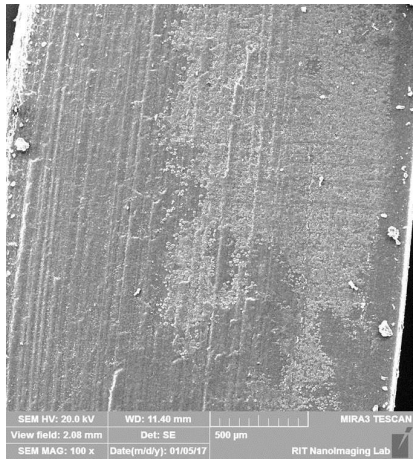
Surface quality

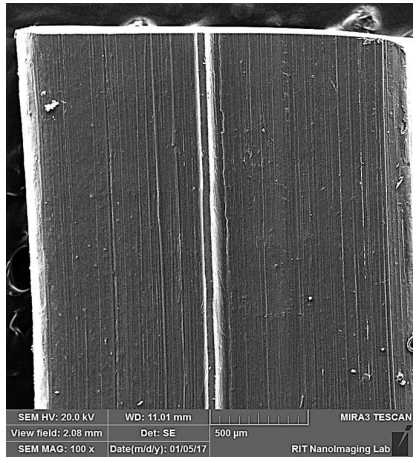
GYLON BIO-PRO® PLUS

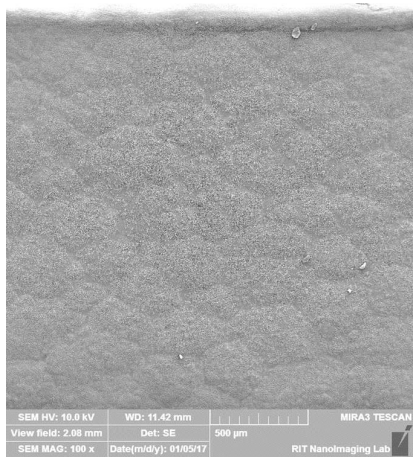


Other



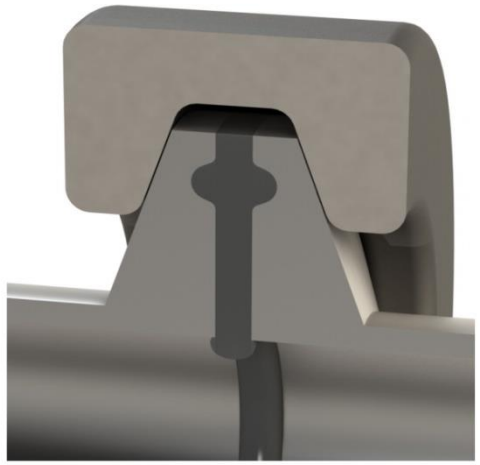






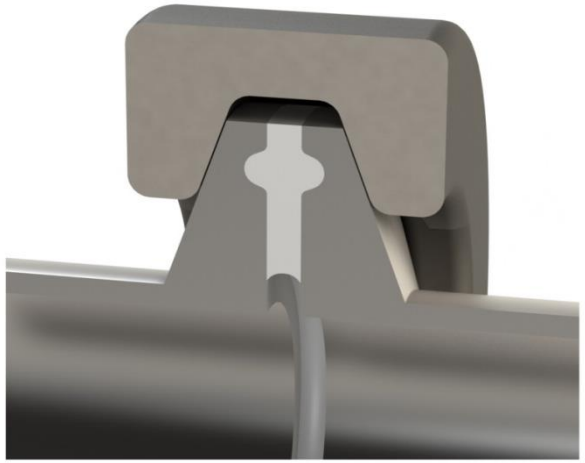
Dimensional stability

Elastomeric Gasket



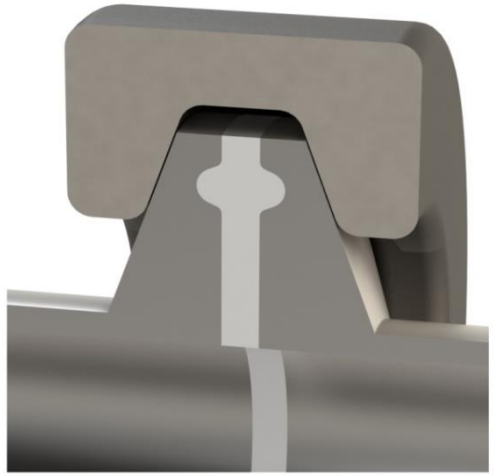
- ID intrusion
- Product accumulation
- Bacterial build-up

Traditional PTFE



- Re-torquing necessary
- ID-Recession
- Product accumulation
- Bacterial build-up

GYLON BIO-LINE®



- Smooth bore
- Easy cleaning
- Dimensional stability

→ Hygienic connection

GYLON BIO-PRO® PLUS

Characteristics:

- Compliant to 3-A Sanitary, FDA, USP Class VI, etc.
- Sealing integrity - proprietary GYLON® resists creep and cold flow
- Eliminates gasket recession or intrusion into the process flow
- Complies with ASME-BPE for dimensional stability, initial fit up and SIP
- Ease of removal with zero gasket residue
- Exceptional chemical and thermal cycling capabilities
- Non-additive and non-absorptive
- Universal with unlimited shelf life-simplifies inventory and gasket selection
- Ideal for SIP (steam in place) & CIP (clean in place) processes
- Fully traceable with quality documents and certifications

GYLON® Style 3522

GYLON BIO-PRO®

Characteristics:

- Compliant to FDA, USP Class VI, EU10/2011, etc.
- Sealing integrity - proprietary GYLON® resists creep and cold flow
- Eliminates gasket recession or intrusion into the process flow
- Complies with ASME-BPE
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GYLON® Style 3504

GYLON BIO-LINE®

GYLON BIO-PRO® PLUS

GYLON® Style 3522

GYLON BIO-PRO®

GYLON® Style 3504

Feedback and outlook

- Feedback in Microsoft Teams chat area – Microsoft Forms survey
- Feel free to address additional feedback by mail
  - Dominik Wiese – Area Sales Manager – dwiese@rubberfab.com
  - Sascha Butter – Product Manager – sbutter@rubberfab.com
  - Christoph Neuffer – Application Engineer – cneuffer@rubberfab.com
- Training handout
- Webinars
  - Webinar 04: It's all about hygiene – hygienic seals for highest process (GYLON® BIO-LINE)
  - Webinar 05: Mastering challenges of hygienic assemblies (Gasket Installation)
  - Webinar 06: To be announced (New product launch)