Hygienic Design Principles

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Professor and Extension Specialist

What is Hygienic Design of Food Processing Equipment?

- **Design, construction, and installation, that allows "timely and effective cleaning of equipment"**
- Sometimes referred to as "sanitary design"
- Set of principles which help improve:
  - Food safety and quality
  - Operational efficiency

- Some equipment requires a management plan

Simple Example

Which is more Hygienic?

Impact of Hygienic Design

- REDUCE RISK of hazards - physical, microbiological, and allergen
- IMPROVE PRODUCT QUALITY and extend shelf-life
- REDUCE CLEANING TIME and improve cleaning effectiveness
- May also reduce: environmental monitoring costs, product loss, potential for product recall, maintenance time, etc.
- ROI can be as low as 3-5 years

Food Contact vs Non-Food Contact Surfaces

- **Is hygienic design different for different surfaces?**

- All surfaces need to be accessible, cleanable & inspectable
- Environmental testing or “swabthons” have exploded
- More focus seems to be on non-food contact surfaces (open)
  - Zone 1 - Direct food contact surface, e.g. conveyor belt or tabletop
  - Zone 2 - Not direct food contact but in close proximity, e.g. machine framework
  - Zone 3 – Non-food contact surfaces, e.g. walls, floors, drains

GFSI Benchmarking Requirements – Version 2020

SQF

BRC

GFSI Requirements …

- Multidisciplinary team
- Evaluate hygienic design and risk assessment for equipment and facility
- Training for team members on hygienic design
- Periodic review of hygienic status of equipment

Where can I learn about hygienic design ?

- Various commercial entities
- 3A SSI – Has annual educational meeting and website with hygienic design E-learning modules – www.3-a.org
- Various Universities
- European Hygienic Engineering and Design Group – www.EHEDG.org
  - University of Tennessee – only EHEDG authorized testing lab in US
  - Mark Morgan – EHEDG authorized trainer

10 basic Principles of Hygienic Design

1. Made of Compatible Materials
2. Accessible for Inspection, Maintenance, Cleaning and Sanitation
3. No Product or Liquid Collection
4. Hollow Areas Avoided or Hermetically Sealed
5. No Niches
6. Sanitary Operational Performance
7. Hygienic Design of Maintenance Enclosures
8. Hygienic Compatibility with Other Plan Systems
9. Cleanable to a Microbiological Level
10. Validated Cleaning and Sanitizing Protocol

From meatinstitute.org

Hygienic Design may look different

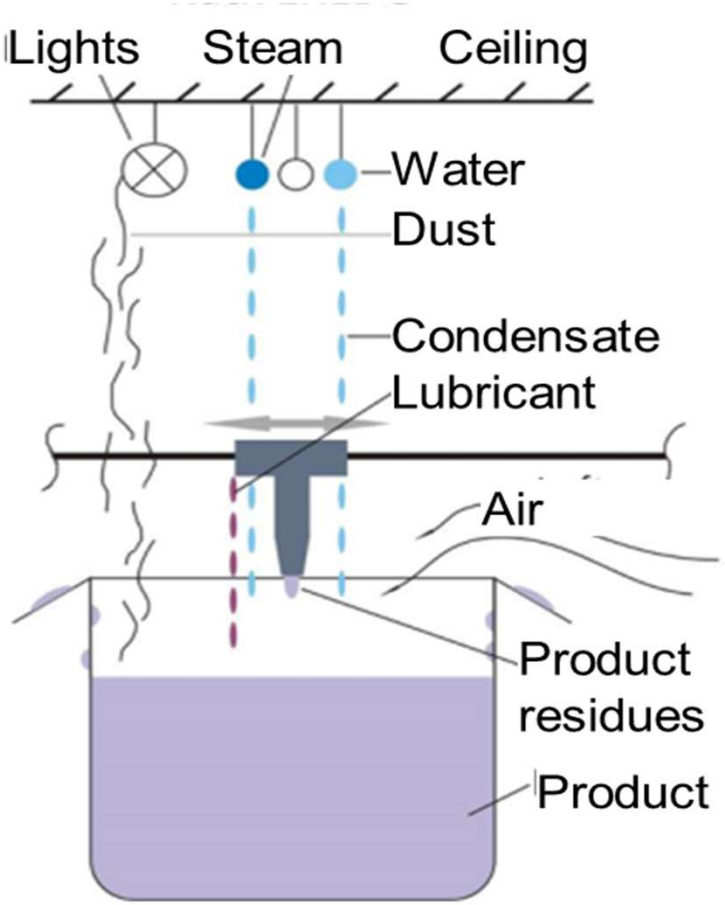
Factors that impact hygienic Design

- Product Contact Surfaces vs Non-product contact surfaces
- Open vs Closed Equipment
- Clean-in-Place vs Clean-Out-of-Place
- Wet vs Dry cleaned equipment

What is a Product Contact Surface?

- Any surface in direct contact with product
- All surfaces from which liquids, or soil can drip, drain, or be drawn into the product or onto other surfaces in contact with product

Look out for overhead utilities/equipment which may drip onto open product or surfaces



Source: Fraunhofer AVV

Open vs Closed Equipment

- Open Equipment
  - open vessels, conveyors, mixers, sorters, scales, etc.
  - product is exposed to the plant environment
- Closed Equipment – tanks, pumps, process piping
  - product is fully contained within the system and not exposed to the environment

Cleaned-in-Place (CIP) vs Cleaned-out- of-Place (COP)

- CIP – removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions & water rinses onto and over the surfaces to be cleaned.
  - Not disassembled for cleaning
- COP – removal of soil when the equipment is partially or totally disassembled. Soil removal is affected by circulating chemical solutions and water rinses in a wash tank. Includes manual cleaning with brushes, scrapers, and pressure hoses.
  - Some disassembly for cleaning

CIP vs COP designs

- CIP equipment
  - MUST not have metal-metal crevices where liquid and soil can harbor
  - Shadow zones MUST be eliminated so all areas can be cleaned/inspected
- COP equipment
  - Less strict design criteria
  - Equipment should be “easy” to disassemble for cleaning (i.e. wingnuts, minimal number of fasteners, etc.)

Dry Cleaning

- Keeping it dry reduces risk of bacterial growth
- Vacuums, brushes, alcohol, CO_2 (dry ice)

COURTESY OF VIKAN.

Wet Cleaning

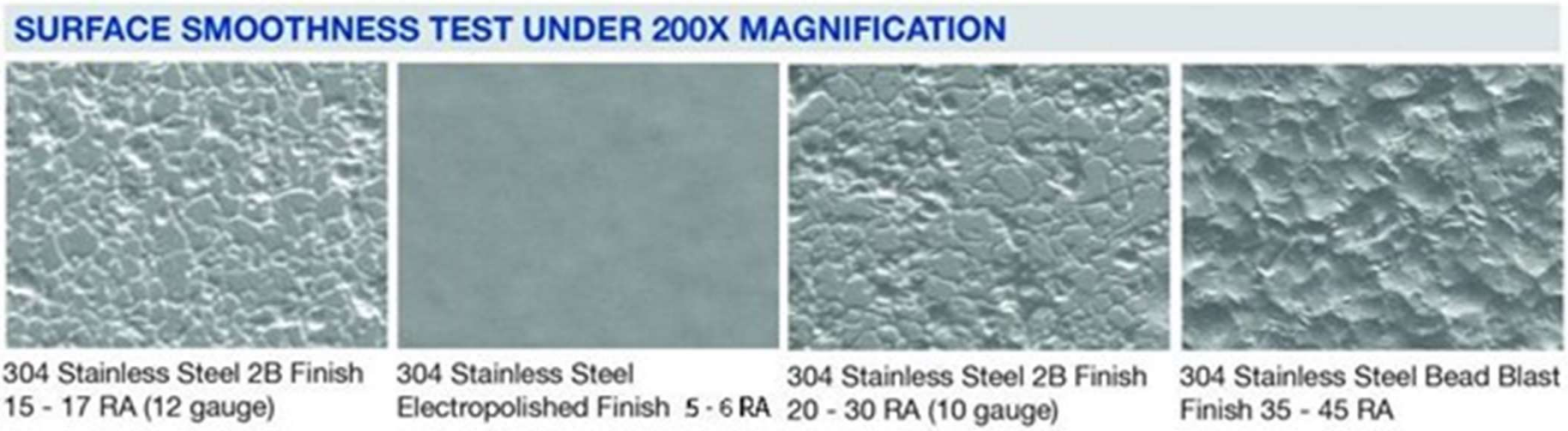
- Moisture must not be trapped in equipment
- Drainability is important
- Materials must be compatible with cleaning agents

Main concepts of hygienic design

1. **Compatible materials**
2. Smooth construction without “niches”
3. All hollow areas sealed
4. Drainable
5. Accessible for cleaning, maintenance, and inspection

Stainless Steels used in Food Industry

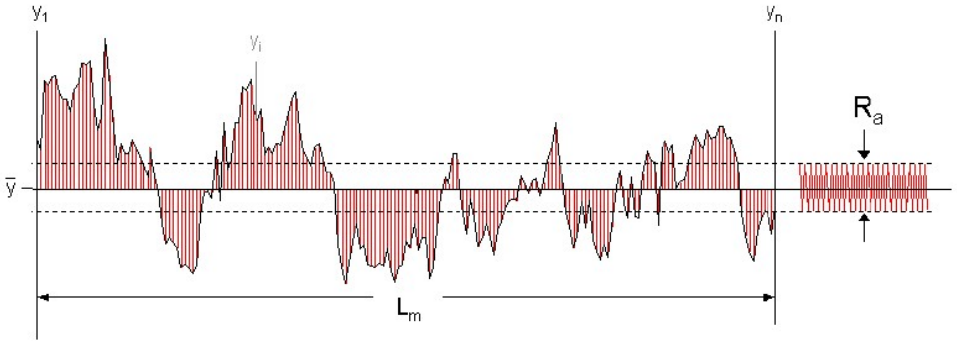
- Typically, 304 or 316 stainless steels
- Corrosion Resistant - due to chromium
- Surface should be smooth, scratch free, Ra < 32 µ inch (0.8 µm)

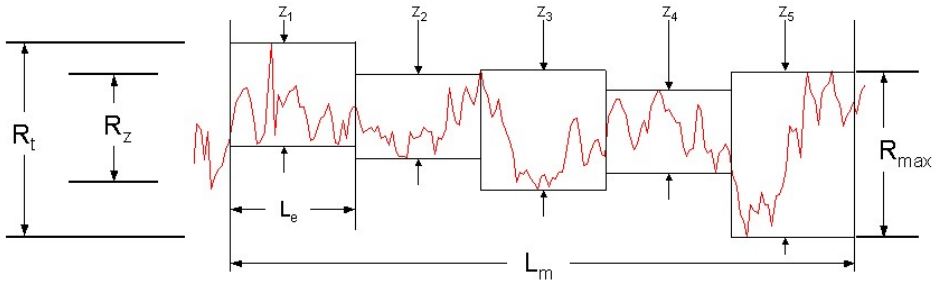


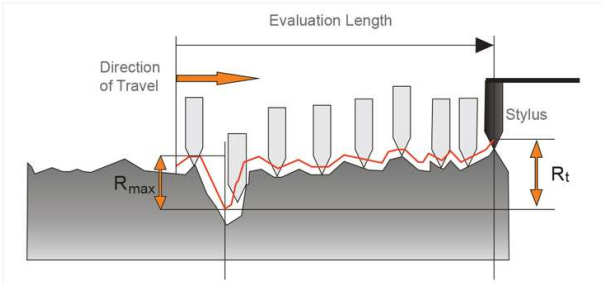
J. Jacobson, et. al. with Apache Stainless Equipment Corp. Beaver Dam, WI apachestainless.com.

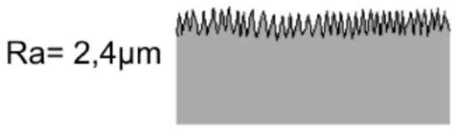
Surface characterization – Ra values

- Arithmetic average of roughness – Ra value

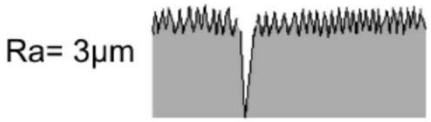




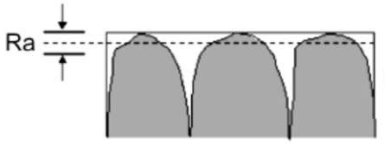




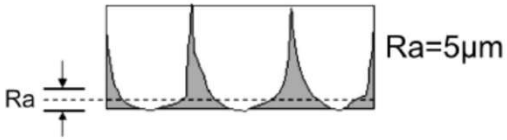
94 microinch



118 microinch



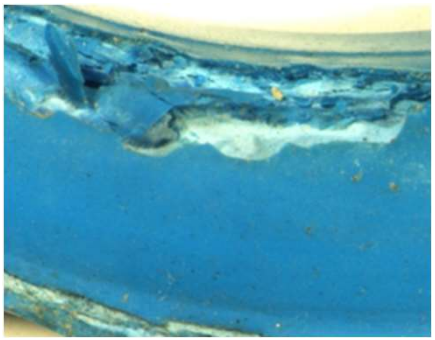
197 microinch

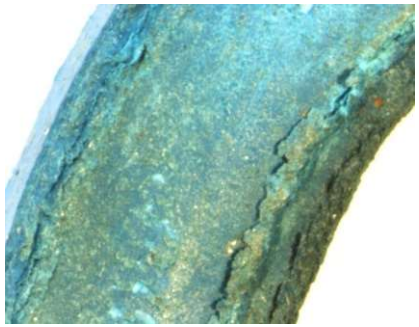


Source: Alfredo Calvimontes, Topographic characterization of polymer materials at different length scales and the mechanistic understanding of wetting phenomena, PhD Thesis, TU Dresden

Compatible Materials - Elastomers

- Highly elastic – for seals, gaskets, hoses
- Swelling and shrinkage can be a problem
  - may absorb fluids and swell
  - may shrink and leach out
  - Expand/contract with temperature
  - Quality is important
- Heat and stress or chemical damage





From EHEDG Guidelines

Quality of Replacement Parts: O-rings

- Sometimes “third party” vendors are used to cut costs
- Elastomer seals are not all the same quality
- Spending extra in capital costs to get a hygienically designed pump but using poor o-rings defeats the purpose.

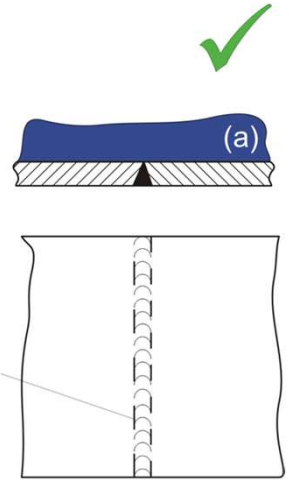
  - E.g. Mold parting lines, surface quality, dimensional tolerances may all be different.

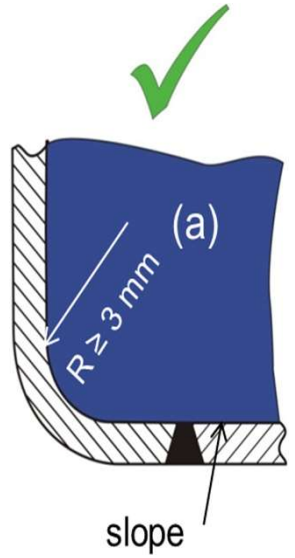


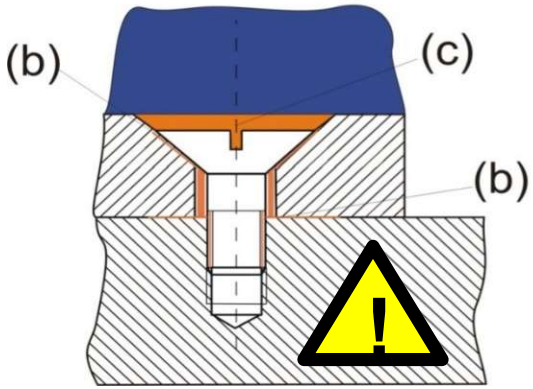


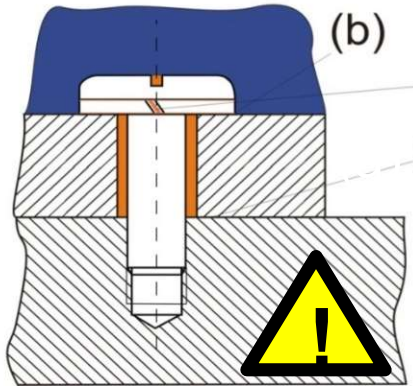
Smooth surfaces – no niches

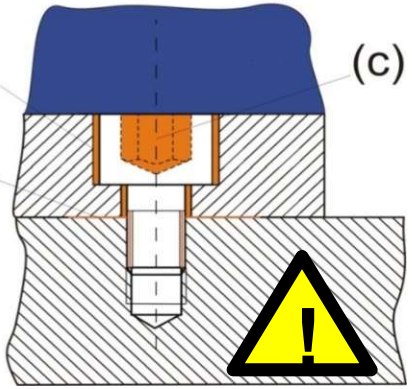
- Ideally prefer all-welded surfaces
- ≥ 3 mm radius in corners
- Fasteners sometimes needed







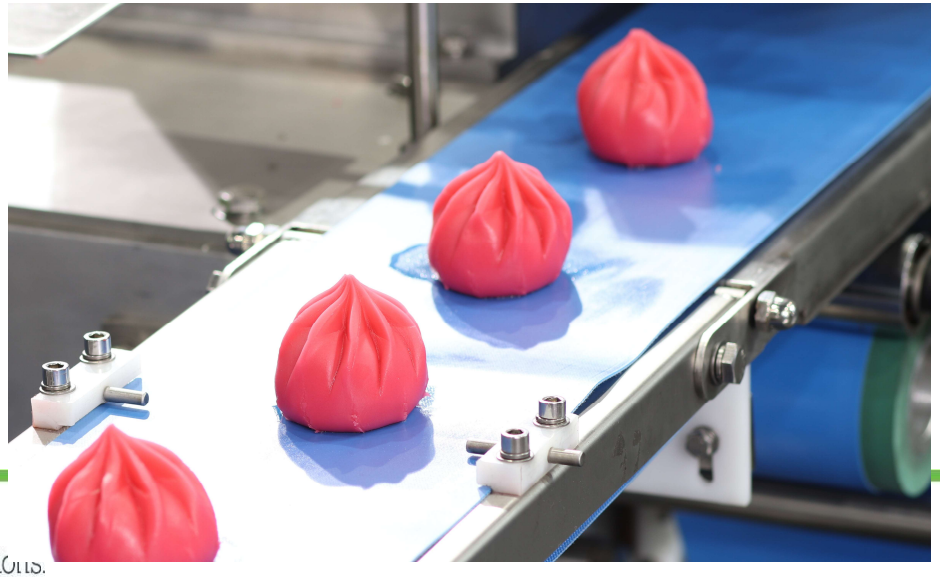




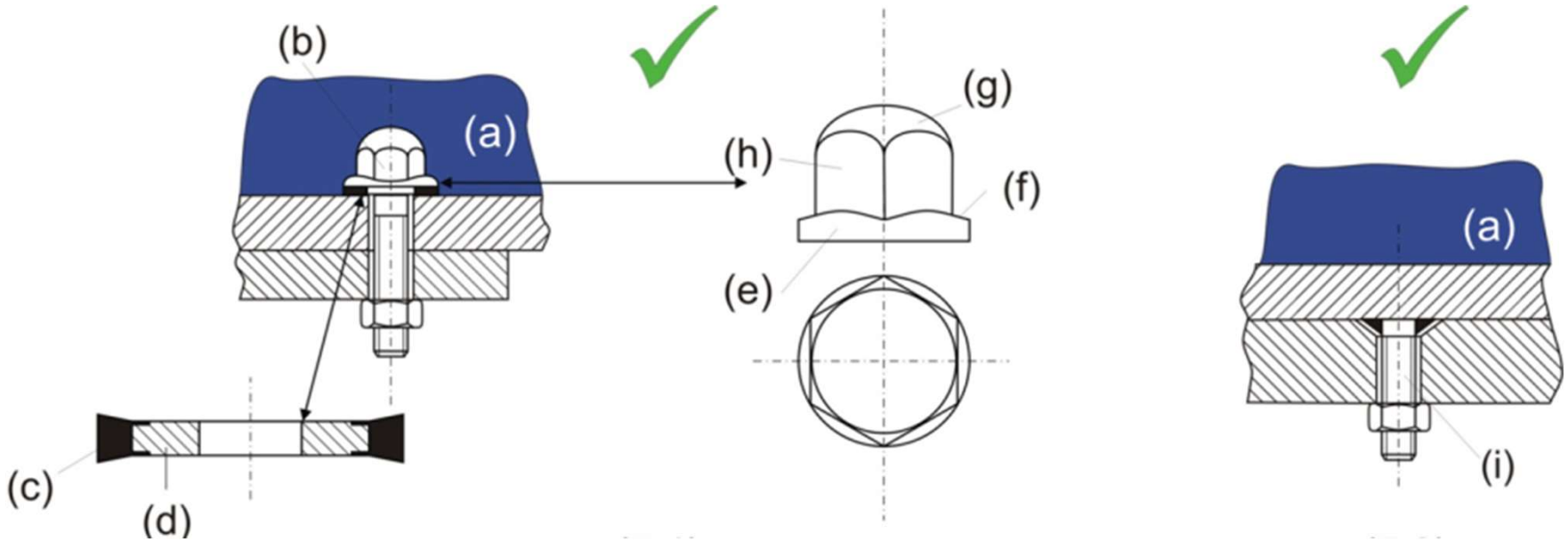
(a) product area, b) metal-to-metal contact, c) dead area,crevice

From EHEDG Guidelines

Eliminate Fasteners in Product area



Preferred Hygienic Fasteners with special gasket

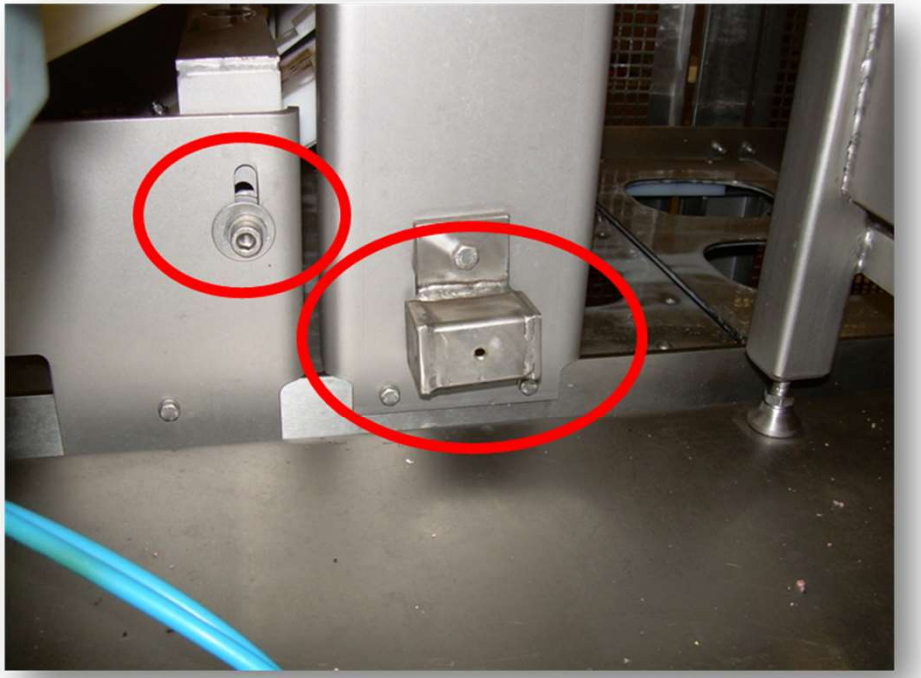


(a) product area, (b) domed head, (c) elastomer, (d) metal, (e) circular collar (f) sloped, (g) domed, (h) hexagon, (i) stud

From: EHEDG Guidelines

From: Kipp.com

Hollow frameworks are potential issues

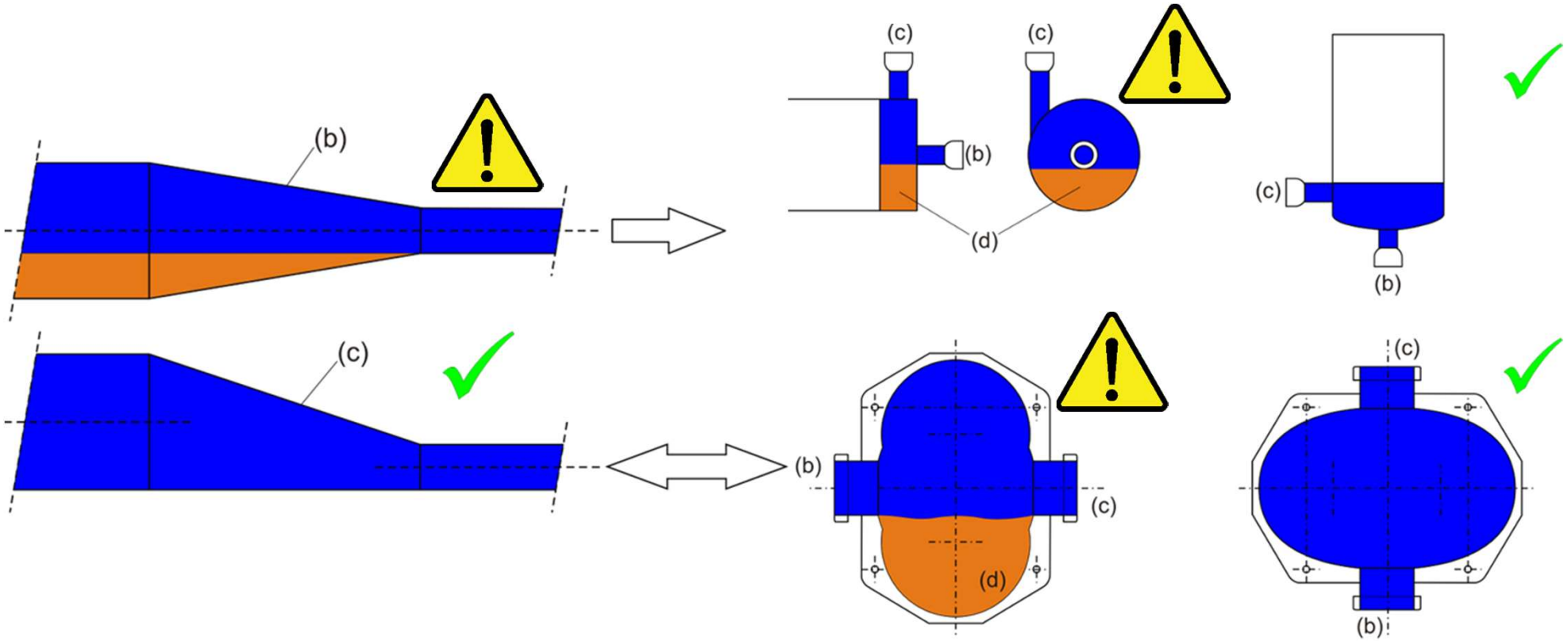


Smooth construction without "niches"

Eliminate metal-metal joints

From: nhkmachineryparts.com

Drainability of closed equipment

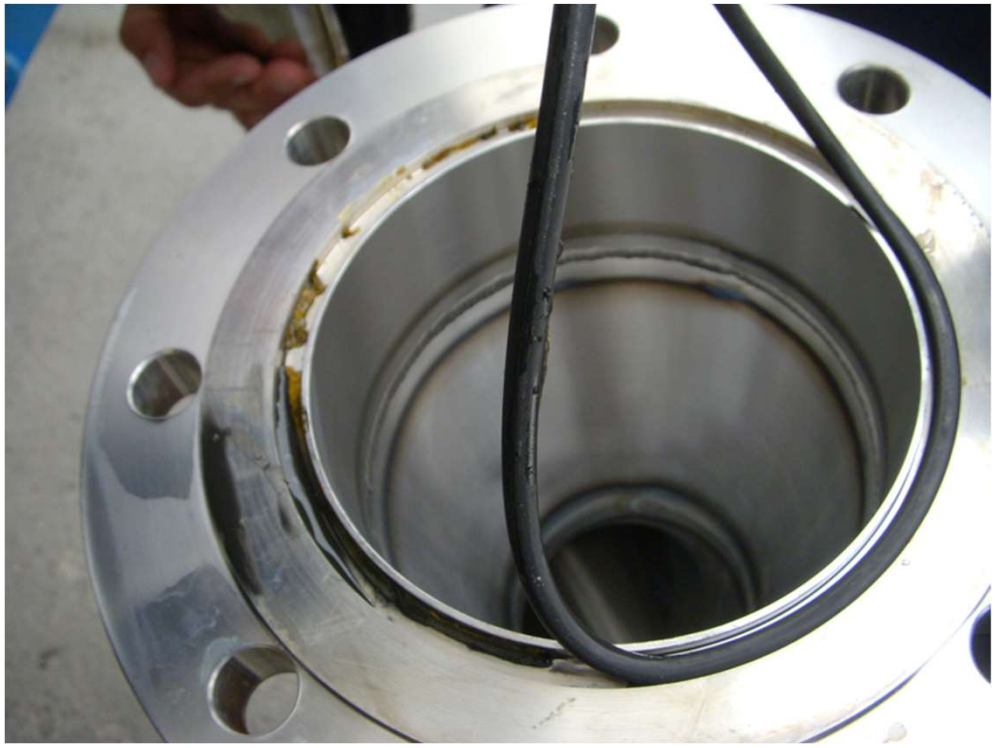


(a) product area, (b) concentric reducer,
(c) eccentric reducer, long version,

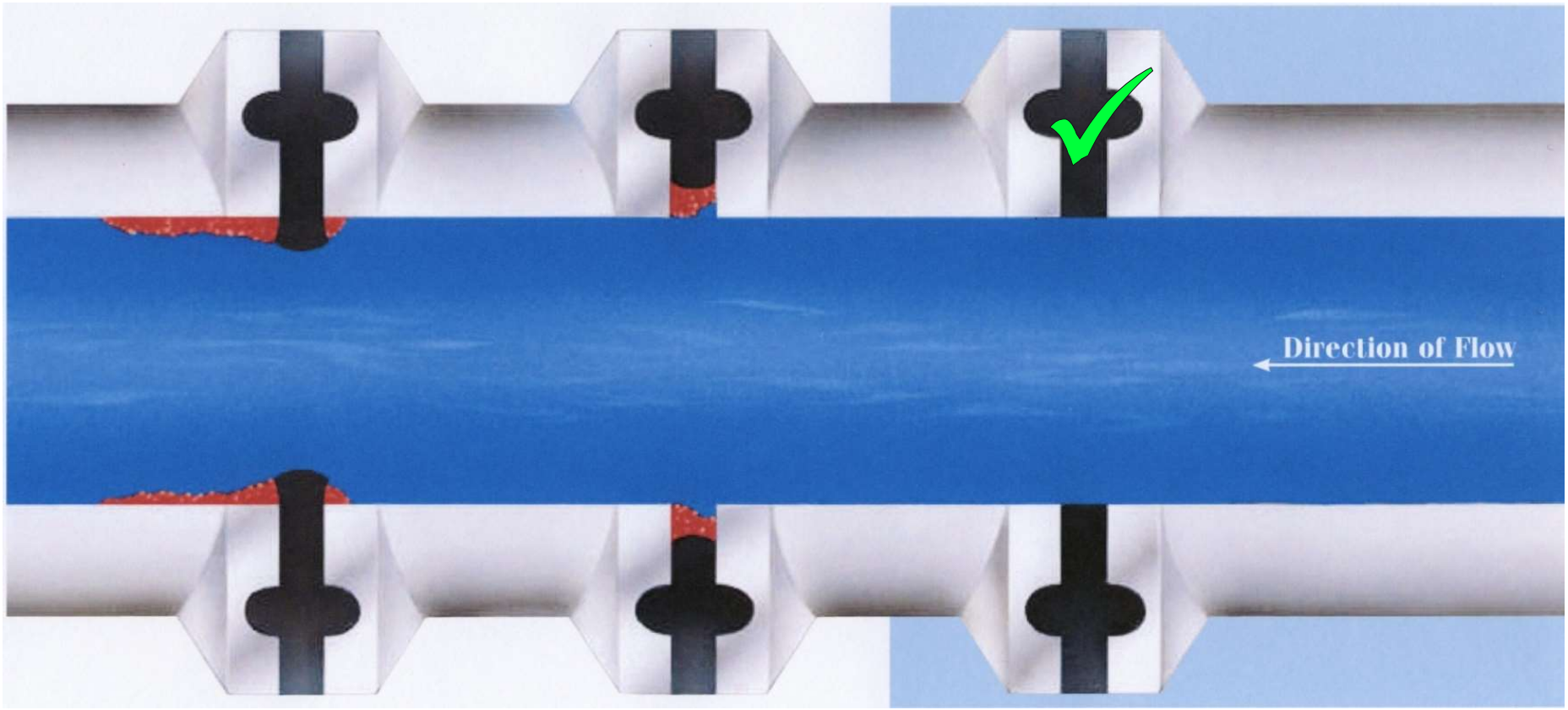
(a) product area, (b) inlet, (c) outlet,
(d) undrainable volume

Closed Equipment – static seal issues

- Static Seals – Round o-ring in a square groove
- Seals are usually the least hygienic part of the design!



Clamp Fittings – aka Tri-clamp style



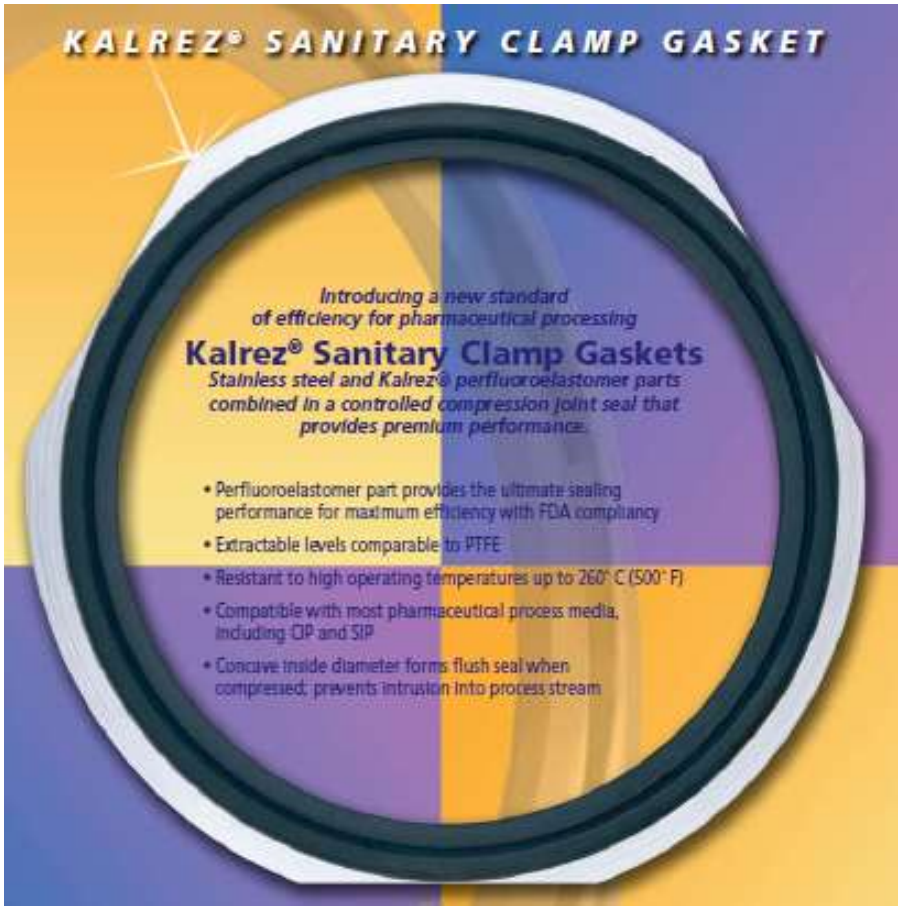
Controlled compression of the gasket is required to prevent cleaning and draining problems.

Damaged Clamp Gasket

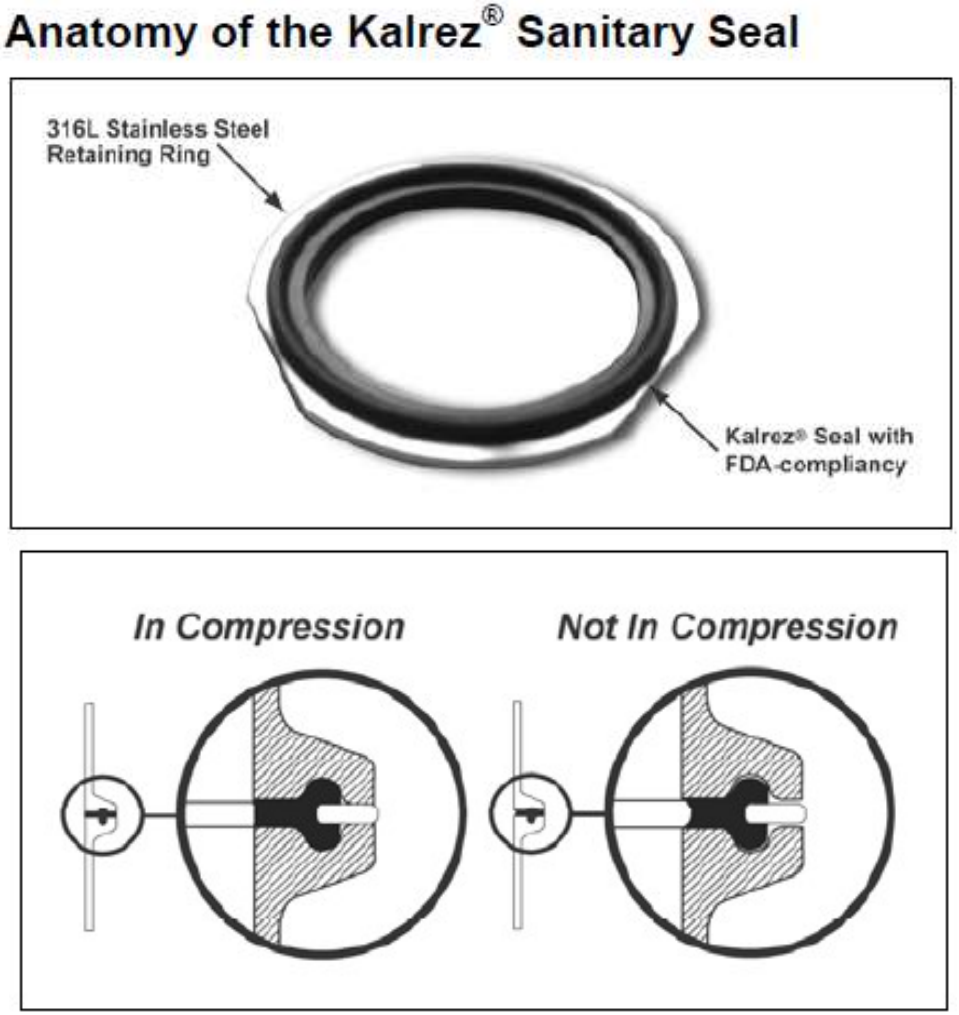
Courtesy of A. Timperley

Improvement to Clamp Fittings

- Replace gaskets (at a cost)



From: www.newmangasket.com



From: DuPont

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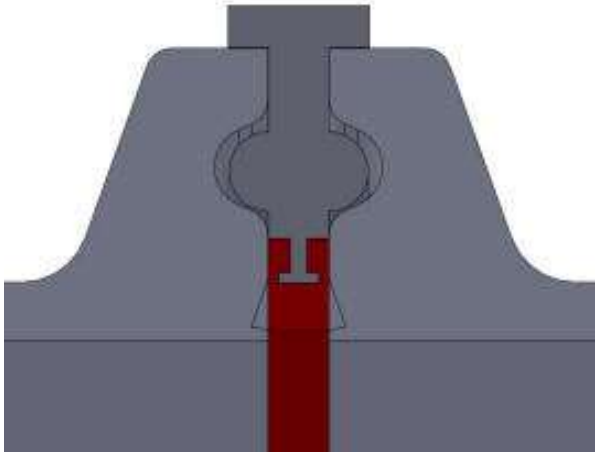
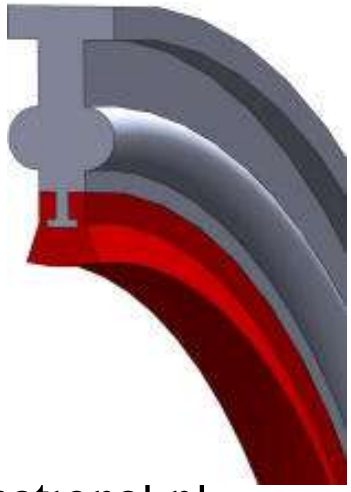
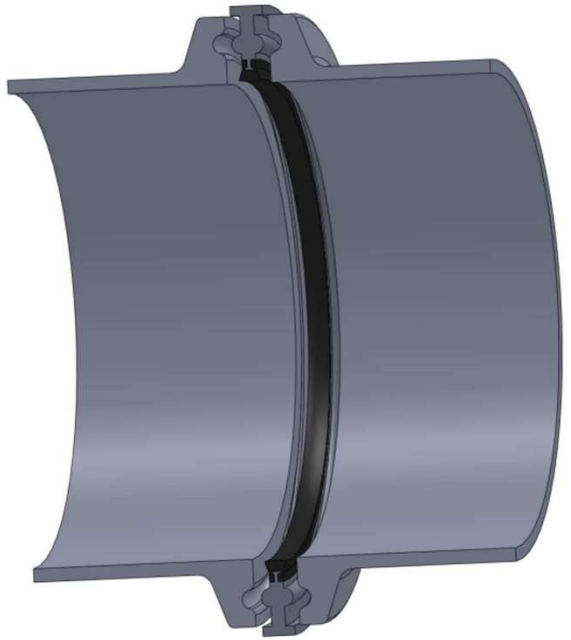
EHEDG approved gasket for Clamp Fittings

- Combifit international bv - Netherlands







From: www.combifitinternational.nl

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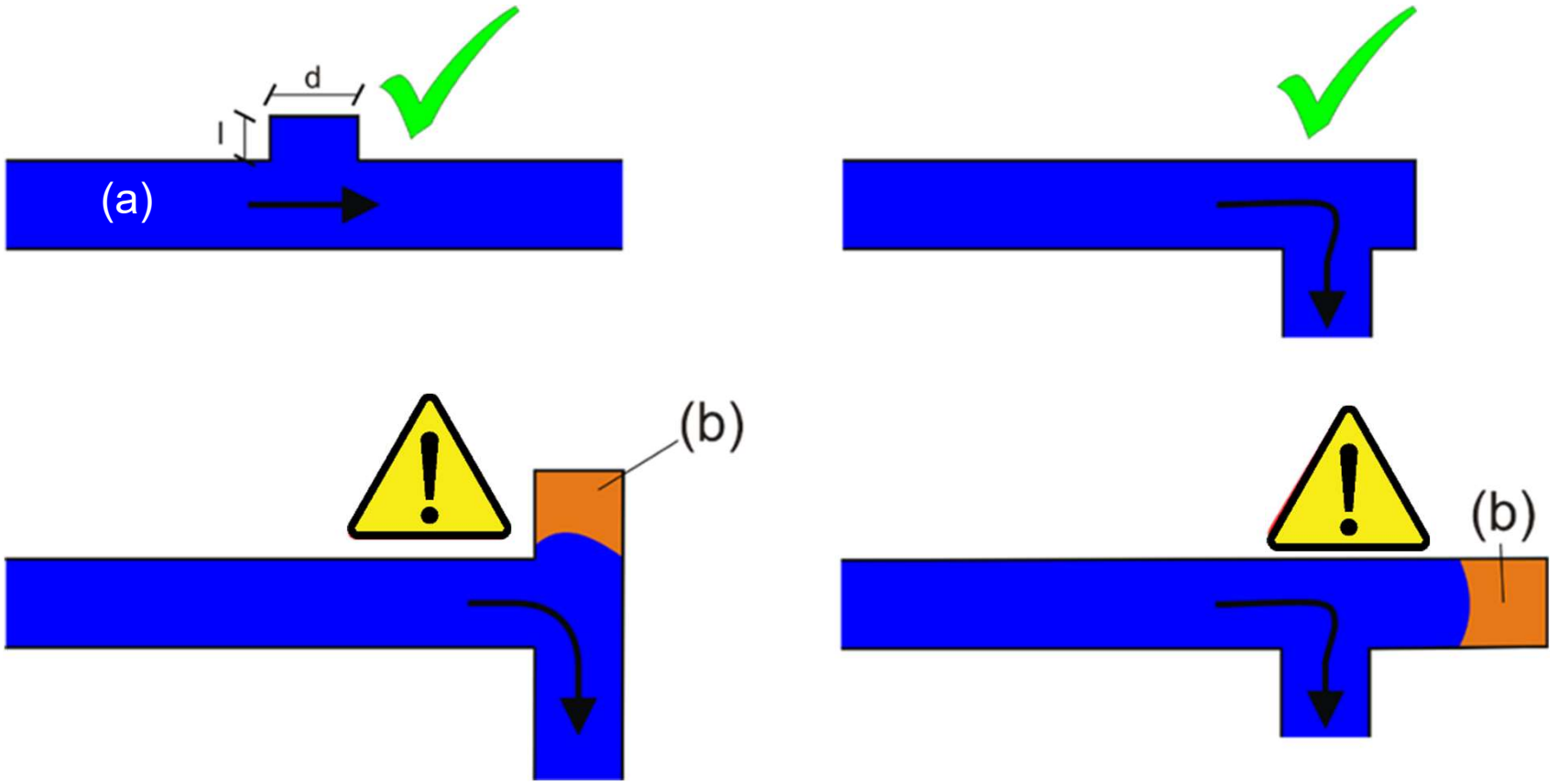
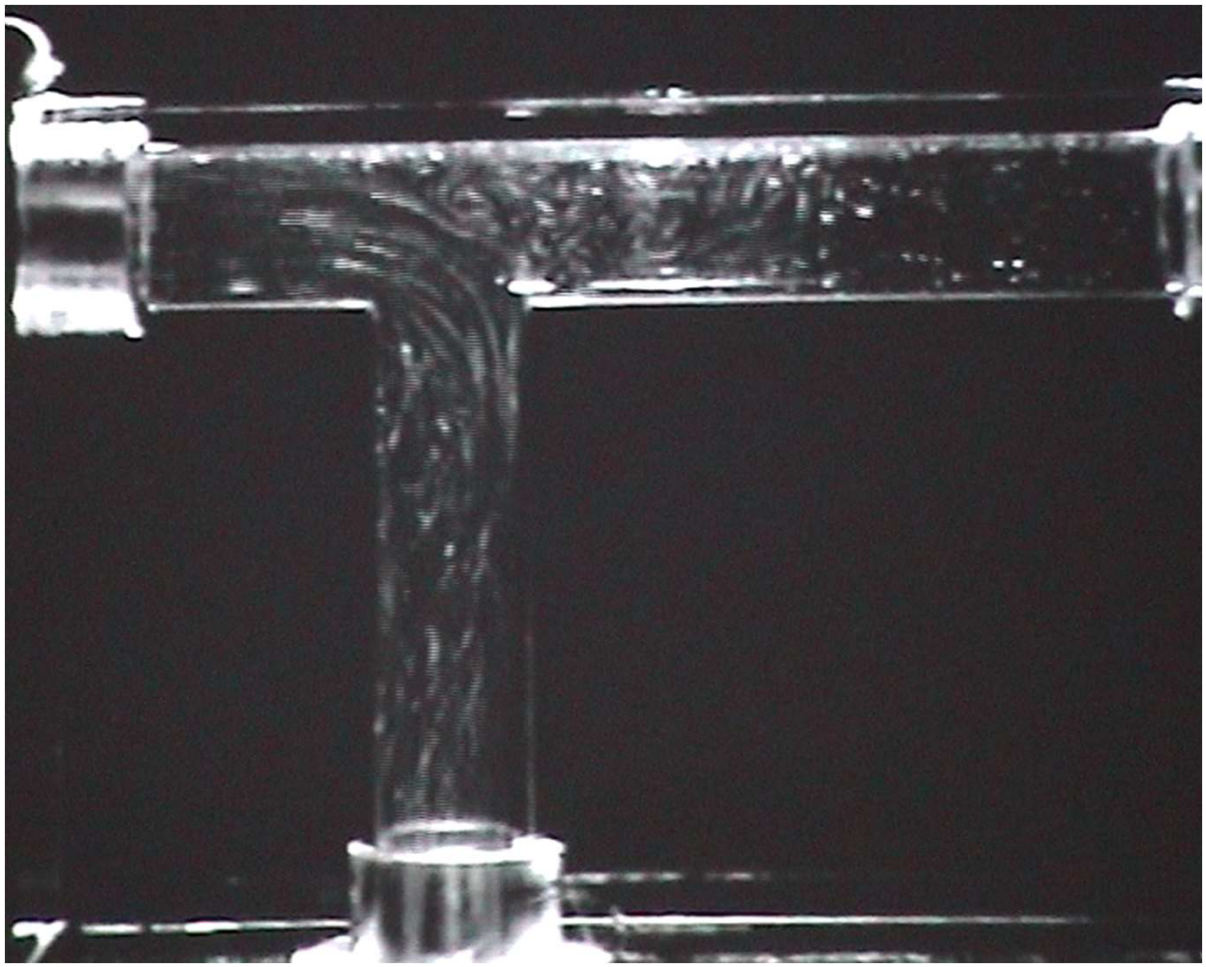
Avoid Dead Ends/Dead Legs

For Tee pieces – l/d <1



(a) product area, (b) dead leg with residual soil

Dead Ends – why they don't clean



Cleaning of Tee pieces

Flow velocity =1.5 m/s or ~ 5 ft/sec

L/D=1.0

L/D=1.5

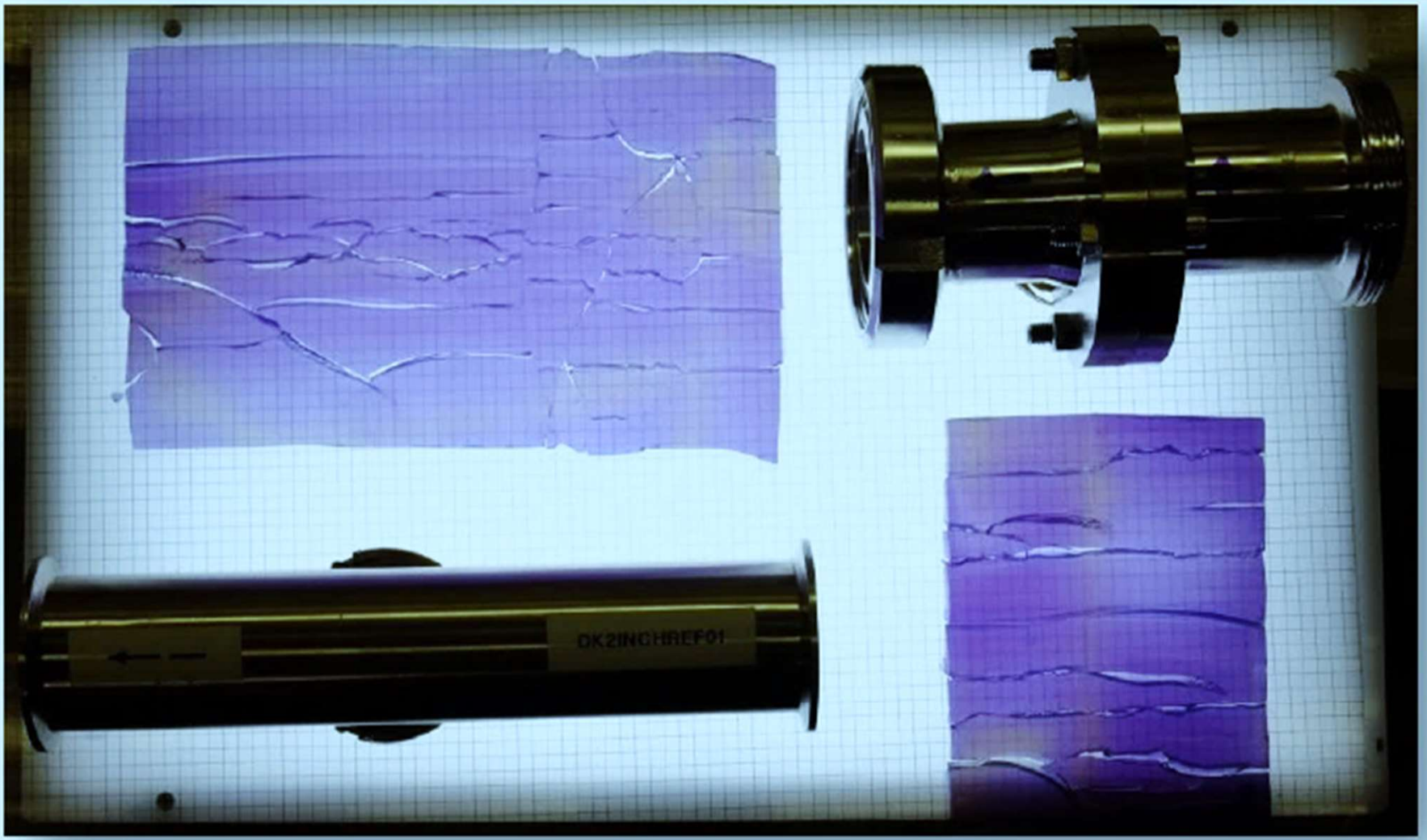
EHEDG Cleanability Test for Closed Equipment

Test procedure Steps …

Incubate overnight and remove

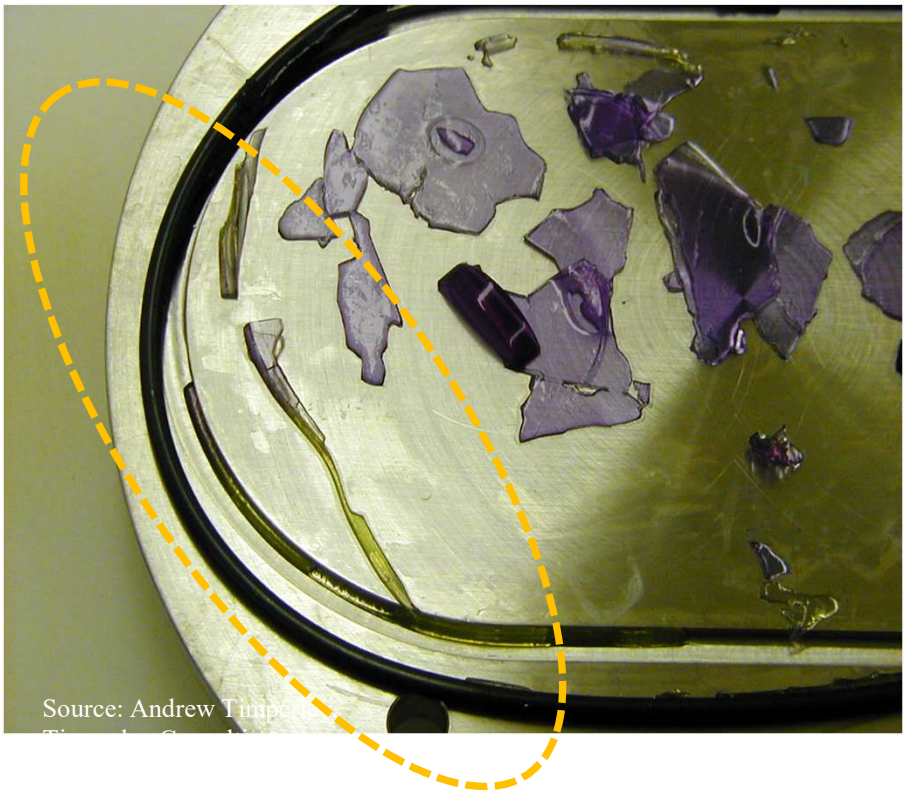
EHEDG cleanability test for closed equipment

Results of Testing…

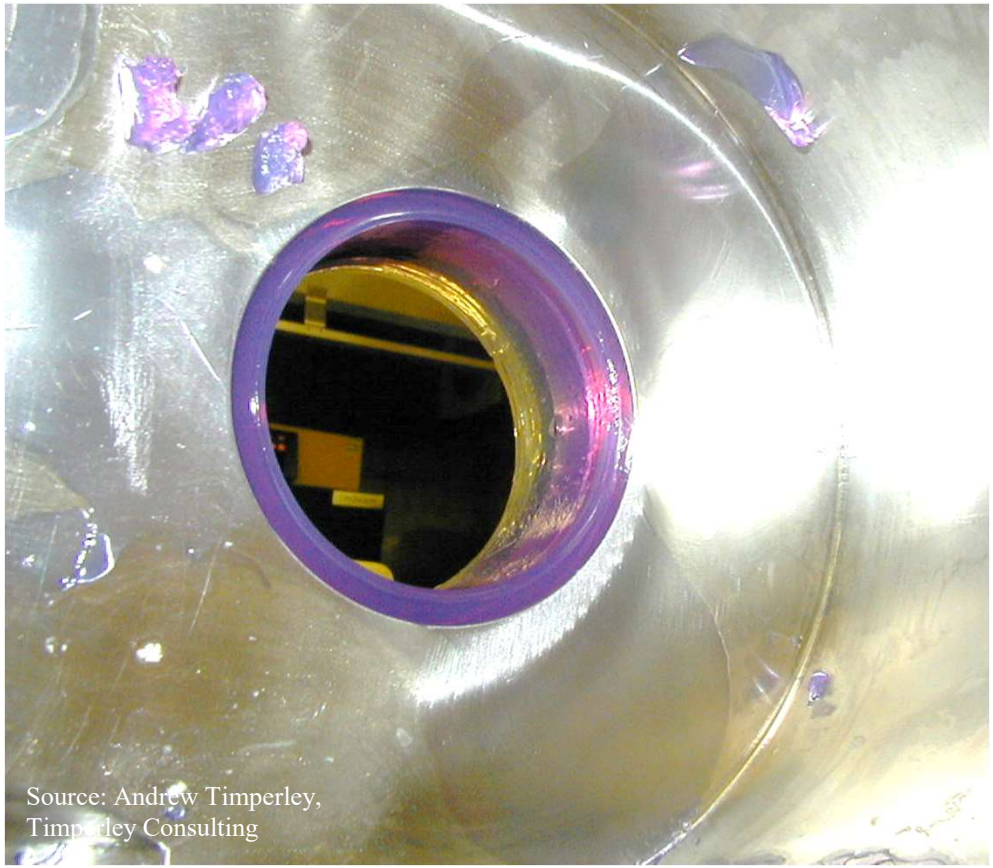


EHEDG cleanability test for closed equipment

Yellow areas in agar within a test item



O-ring groove



Mechanical seal of pump

Contact Information

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