Hygienic Design of Seals

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• Basic requirements for static seals (Elastomeric Seals)

- $\,\circ\,$ Things to be considered in groove design for seals
- Finite Element Analysis (FEA) as a design tool
- Dynamic seals

Imagine.....



Processing and filling equipment without seals?





Seals are indispensable in equipment for food processing and filling!

But if they are not properly <u>designed</u>, <u>manufactured</u> and <u>maintained</u>, they can pose a hygienic hazard!

This presentation is intended to create awareness regarding the most important requirements of sanitary seal design principles



Basic Requirements - Hygienic design of seals

All of those requirements should be fulfilled !





Requirement 1: Material

- \circ Comply with relevant state regulations like 21 CFR 177.xxxx
- Nonabsorbant, nontoxic
- No alteration of organoleptic properties of the food
- Corrosion resistant in the environment of intended use
- Thermally stable within the specified temperature range
- Non-porous





Requirement 2: controlled compression

- Define and limit compression by proper housing design
 Seal and housing are a unit that have to fit together
- ISO 14159 gives 15% compression as a guideline for a 70
 Sh A O-Ring to achieve bacteria tightness. With 20%
 compression or p = 2 N/mm² there are more reserves.





Requirement 3: surface quality of housing

General requirement: Ra 32 μin / Ra 0,8 μm or No 4 finish / 150 grit





A good surface quality is important for the metal parts in the seal contact area. Scratches can cause a hygienic hazard.



Requirement 3: surface quality of seals

Ra value is difficult to measure with rubber parts. Important criteria: closed mold skin (gentle deflashing method), no flow marks, high quality trimming of the flash (parting line).







Requirement 4: calculated groove fill

Because the O-Ring in this flange coupling had no room for thermal expansion in it's groove, it extruded through the opening on the product side into the internal cavity at only 248 °F/120°C



To be considered: volume of groove and seal, thermal expansion and volume swell caused by fluids



Requirement 5: alignment



Misalignment can also lead to reduced drainability





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Requirement 6: avoid gaps and crevices





Requirement 7: seal has to be flush with product side

Bad Example !

If the seal is not flush with the other product-facing areas, it's difficult or even impossible for CIP fluids to remove residues.





O Basic requirements for static seals (Elastomeric Seals)

 $\,\circ\,$ Things to be considered in groove design for seals

- Finite Element Analysis (FEA) as a design tool
- **O** Dynamic seals



Things to be considered in groove design for seals

Gasket retaining grooves have to be easily cleanable for maintenance purposes. This requires minimum radii. 3-A Sanitary Standards proposes e.g. for O-Ring grooves:

OR Cross Section, Nominal AS 568	OR Cross Section, Actual AS 568	OR Cross Section, Actual ISO 3601-1	Minimum Groove Radius
1/16 in.	0.070 in.	1,80 mm	0.016 in. (0.41 mm)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.79 mm)
1/8 in.	0.139 in.	3.55 mm	0.031 in. (0.79 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.58 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.39 mm)



Things to be considered in groove design for seals

- 1. Surface quality
- 2. Minimum groove radii
- 3. Radio of depth to width no deeper than width





• Basic requirements for static seals (Elastomeric Seals)

 $\,\circ\,$ Things to be considered in groove design for seals

• Finite Element Analysis (FEA) as a design tool

○ **Dynamic seals**





Finite Element Analysis (FEA) or Finite Element Method (FEM) is a numerical technique to predict behavior of mechanical components under e.g. load or temperature.

With material data obtained on test specimen, a two- or three dimensional network of the component is created in the software and then pressure, load or temperature behaviour is simulated.





Both designs fulfil hygienic design requirements and 3-A 63





Clamp fitting ISO 2852

DIN 11864



Behaviour of EPDM seal when heated up to 150°C / 302 °F







Behaviour of EPDM seal when heated up to 150°C / 302 °F







Behaviour of Perfluoro FFKM seal when heated up to 302 °F





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• Dynamic seals

Linear Seal – non sterile equipment

Requirements of hygienic equipment are different to requirements of hygienic AND sterile equipment.



Linear Seal – with sterile barrier

Requirements of hygienic equipment are different to requirements of aseptic / sterile equipment.





Linear Seal – hermetic solution

Utilize a Bellow or Diaphragm made of rubber, thermoplastics or metal – make the wall flexible instead of using a sliding seal.





Rotary Seal

For sanitary design, use flush to productside design, for aseptic requirements, use double seal arrangement.





To Take Home

- The basic requirements for hygienic seals are a few and they appear to be simple
- $\,\circ\,$ But do not overlook only one of the important facts
- Be careful when making changes in the system, e.g. utilizing seals from a different manufacturer.
- Specify the most important things. (material type, cleaning procedures, temperatures, 3-A Std. 18-03)
- Have equipment tested for cleanability or bacterial tightness by e.g. applying EHEDG test No. 2 or 7
- Seals are ageing and wearing preventive maintenance is essential!

Hygienic Design of Seals

Disclaimer:

The illustrations and information given in this presentation are intended to give general guidelines only.

They are not meant as advice for a given application and cannot replace a recommendation from your seal supplier based on detailed information about the specific application and operating conditions.

Testing of new solutions and designs is always recommended. Preventive maintenance is also key to sanitary operation.



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Thank you for your attention!

Any questions are welcome.