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Thank You for Attending Our March Webinar

Eliminating Hygienic Process Leaks and the Potential Fines They Can Cause

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Eliminating hygienic process leaks, and potential sanctions.

- The real reason you have a bucket of hygienic clamps that don't work…
- How to keep seals from bulging into the process (while maintaining a tight connection)
- Preventing leachables and extractables from entering your process
- Lets talk about the Who, What, When, Where, Why and How.
- And the NOW.

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The WHO?

- Every Food and Pharma Manufacturing Facility on the Planet has these types of problems.
- These are not unique to your process or application.
- I have personally witnessed them in facilities around the globe and there are some commonalities, but it is typically not driven by the process condition.

The WHAT?

- Leaking Connections.
- Connections that cause system failures
- Connections that cause testing failures
- Connections that cause Environmental Hazards
- Connections that cause batch contaminations
- Connections that cause injury to personnel

What Makes Up a Sanitary Connection?

The WHEN?

- When Does a Union Leak?
- During Commissioning
- During Start Up
- During normal production processing
- During Filling
- During Testing
- A Union can leak at any time when processing

The WHERE?

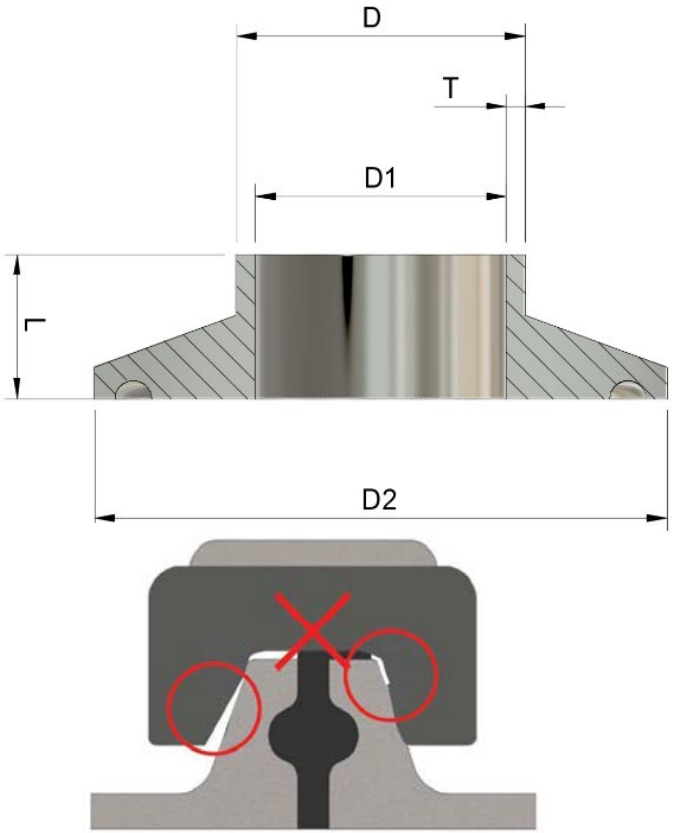
- Literally anywhere clamps can be found in your processing environment
  - R&D
  - Filling Areas
  - Laboratories
  - Production Suites
  - Testing Areas

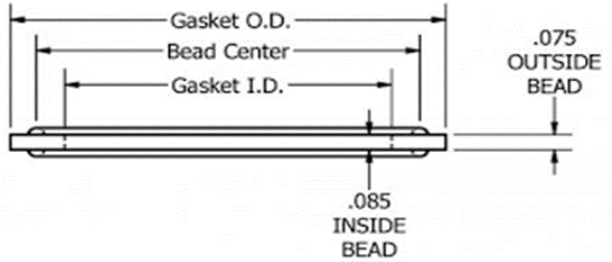
The WHY?

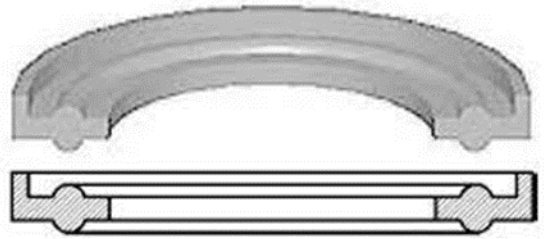
- This is where things start to get complicated and unique.
- The why can be caused by a number of Factors that we will discuss in short form.
- Why does a clamp leak? Or rather, Why does a Hygienic Union Leak?
  - Uneven Load
  - Poor Alignment
  - Ferrule Alignment and Geometry
  - Gasket Style
  - Most Likely, it is portions of ALL of the ABOVE

The WHY?

Tolerances or Tolerance Stacking has a heavy influence on why you have a leak.







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The WHY?

Tolerances or Tolerance Stacking has a heavy influence on why you have a leak.

- Tolerances for every component compound upon each other.
- Machining Tolerances and the effects of wearing tools. The frequency for validation of equipment and methods.
- Tooling Tolerances for molds, Dies wear with use. Some forms are more repeatable than others, but all wear over time.
- The elastomeric properties in gaskets change by formulation. Durometers change.
- Specific proprietary dimensions from manufacturer to manufacturer are different.
- The natural reaction is to then try to compensate for these differences by forcing a solution.
- Over Torquing a clamp to seal a leaky union is one of the most common attempts.

The WHY?

Tolerances or Tolerance Stacking has a heavy influence on why you have a leak.

- While ISO and BPE have tried to create some symmetry in the industry, these allowable tolerances can compound on each other.
- BPE only started doing this in the last 10 years or so. Do you have equipment that is more than 10 years old in your facilities? Prior to this ISO 2852 was the only standard that really addressed these components

How do we fix it?

- There are a variety of solutions. Picking the one that is right for your site or application is imperative to control the costs.
- Piping can be brought into better alignment.
- Elastomers can be changed to better suit your application.
- Tanks can be modified to be brought up to current standards.
- Many of these can be costly, and require a revalidation of the process, or recertification of the equipment you are using.
- If you have a leak, or problem union that requires repeated attention then it could be less costly to try a better-quality component before undertaking the above. A better designed clamp can solve more problems than you might think.

What do we do Now?

- The first step is to stop accepting what can be changed.
- Stop applying the same solution to every unique situation.
- Speak up and identify the situation causing your risk exposure.
- The products you manufacture are worth millions of dollars
- A single drip can cost you far more than the solution to your problems would.

Contamination from Leachables and Extractables

- Process Observation equipment, like fittings are not all created equal.
- Materials of construction differ depending on the manufacturer and are specialized for your unique needs.
- Glass is highly susceptible to degradation from your processing environment.
- Selecting the right glass for your application is as important as choosing the right elastomer. And just as easy.

Contamination from Leachables and Extractables

- Most everyone in the industry is familiar with U.S. Pharmacopeia's Class rating system for Elastomers.
  - For an elastomer to be classified as Class VI, it must be tested In Vetro or In Vivo.
  - This is USP88 Testing.
  - The results are not pass/fail. They merely outline that when tested, the results of cell death meet your outlined parameters as approved per dosage and life cycle requirements.
- Did you know that Glass has a similar but less well-known standard?
  - Glass has a USP Type system. If a glass is rated as USP Type 1, it is suitable for Parenteral Drug Manufacturing.
  - In order to receive this rating, it will be tested to ensure that its elemental properties cannot be leached from the component and into your process during its life expectancy.
  - The USP Type 1 Glass is classified as Borosilicate Glass.
  - Its recipe has been developed to resist degradation during Steam In Place and Clean In Place cycles commonly used int Pharma and Food Manufacturing procedures.

Contamination from Leachables and Extractables

- The largest concern for glass in processing is its failure.
- All of you are likely picturing a glass shattering when I say failure.
- Yes, a glass failure under pressure can be violent and catastrophic. It can severely injure an operator on the other side of it, and it can contaminate your process and the environment.
- But it is not the only way a glass can fail.
- Glass can be eroded by your process. Steam and Caustics will wear away at the inside surface of a window over time.
- Sometimes so cleanly that you will not see any defects while looking through it.
- Specifying glass by trade name or brand can't prevent such an occurrence.
- Trade names can be deceiving. Brands are bought and sold everyday in our society. New ownership can make formulation changes to a brand you trust and if it is what you have specified, you may be installing without knowing.
- Specifications should be written in a way that prevent the illusion of safety and performance.
- Documentation is imperative.

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Closing Summation

Costly Hygienic Leaks

- Leaking hygienic unions are a costly problem
- The root cause is very multifaceted
- The stacking of tolerances can create a lack of uniformity from one connection to the next
- Selecting engineered clamps with a built-in geometry that accounts for this tolerance spectrum can solve issues

Glass In Processing Environments

- Glass is a necessary component to processing environments
- We view through it to validate what instrumentation suggest is happening
- Not all Glass is created Equally
- You can write a non-restrictive specification for glass that still effectively controls your process environment
- Brands and Trade Names can be changed without notice
- USP Type 1 Glass should be the go-to classification for anything in contact with Injectables or Ingestibles

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