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## White Paper

# Sanitary Fittings Best Practices

## The Importance of Clean and Safe Process Clamp Connections

In the pharmaceutical and biotech world, the routine activity of disassembling, cleaning and reconfiguring clamp connections is essential in maintaining sterile process control. An improper connection can harbor bacteria. What's more, it may cause a leak. If a process fluid can get out, then there's a chance that contaminants can get in and an entire batch could potentially be scrapped. Even a single drip of a process material can be extremely costly.

Most important, however, is the safety of those working with clamp connections. Pressure, temperature, and caustic process materials are all potential workplace hazards. Improper handling practices can be costly and unsafe. When it comes to process equipment, maintenance and training are critical to ensuring reliability and safety.

### Clamp Connection Design



Figure 1. Clamp connections are designed to seal two ferrules together quickly, securely and without creating sites where contamination can collect.

There are many clamp and fastener options available to meet a wide array of applications. Sizes typically range from ½" to 12" for tubing and 4" to 12" for pipe. However, all sanitary clamp connections consist of the same components: two ferrules, a gasket, and a clamp.

1. **Ferrules:** Provide a mating surface for the connection. The beveled surface on the outside diameter of the ferrule mates with the inside diameter of the clamp. Additionally, a groove on the face of the ferrule provides a seat for the gasket. (BPE, or Bio Processing Equipment, standards were created to allow ferrules from any compliant manufacturer to be connected to ferrules from any other manufacturer.) Ferrules are typically constructed of 304 or 316 stainless steel. Both of these materials are easy to clean, with 316 offering superior corrosion resistance to solutions of sulfuric acid, chlorides, bromides, iodides, and fatty acids at high temperatures.

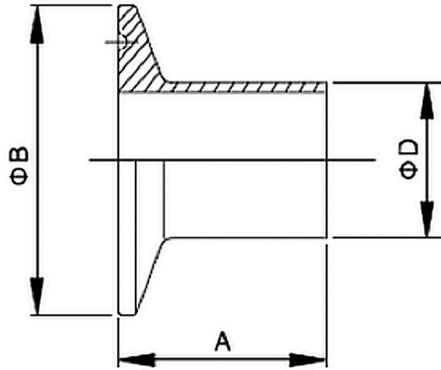
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Size	A (mm)	B (mm)	D (mm)
½"	44.5	25.4	12.7
¾"	44.5	25.4	19.1
1"	44.5	50.5	25.4
1½"	44.5	50.5	38.1
2"	57.2	64.0	50.8
2½"	57.2	77.5	63.5
3"	57.2	91.0	76.2
4"	57.2	119.0	101.6

Figure 2. Standard ASME BPE Ferrules. Note that the O.D. of the flange, "B", is the same for ½" and ¾" fittings, as well as for 1" and 1½" fittings. Therefore, it is imperative to take care to measure the O.D. of the tubing, not the flange, when sizing fittings.

2. **Gasket:** The gasket provides a leak-proof seal between the two ferrules when clamped. Commonly used gasket materials are Buna-N, EPDM, fluoroelastomer, silicone, and Teflon® (PTFE). Gasket material should be selected to be compatible with the material being transferred, as well as the operating pressure and temperature of the system.

Characteristic	Buna-N	EPDM	Fluoro-elastomer	Silicone	PTFE
Temperature Range (F)	-65° to 200°	-60° to 300°	-20° to 350°	-40° to 450°	-40° to 200°
Acid Resistance	Good	Good to Excellent	Good to Excellent	Poor to Good	Good to Excellent
Alkali Resistance	Fair to Good	Good to Excellent	Good to Excellent	Poor to Good	Good to Excellent
Resistance to Fats/Oils	Good to Excellent	Poor	Good to Excellent	Poor to Good	Excellent
Abrasion Resistance	Excellent	Good	Good to Excellent	Poor	Fair
Compression Set Resistance	Good	Fair	Good to Excellent	Good to Excellent	Cold Flows

Figure 3. Proper gasket selection is essential in maintaining a safe, clean, and leak-free connection. Temperature rating and resistance to degradation are key factors when determining the ideal gasket material.

3. **Clamp:** Provides the mechanical force to compress the gasket between the two ferrules. Different clamp types include single pin, double pin, high pressure, ASME, safety, and lockout. In instances where ferrules from different manufacturers need to be mated, L.J. Star's Advanced Coupling clamp has been designed to provide an efficient, leak-proof seal. While mating ferrules from different manufacturers can often be problematic, the "Omega" profile design of this particular clamp pushes the ferrules into proper alignment with high clamping efficiency, greatly reducing the possibility of a failed connection. Both wing nut and hex nut fasteners are available for securing all types of these clamps. Clamps are typically constructed of 304 or 316 stainless steel.



## White Paper

### A Note on Surface Finish

As with sanitary tubing, sanitary fittings are supplied with a polished surface finish, which reduces friction and eliminates surface imperfections that can harbor contaminants. The correct surface finish for a fitting is determined by the application; the standard finish for food and dairy applications is 32Ra, while pharmaceutical and biopharmaceutical applications use the ASME BPE standard, which ranges from SF0 to SF6.

Standard Grit (reference only)	Ra $\mu$ in	Ra $\mu$ m	RMS $\mu$ in	RMS $\mu$ m
150	27 - 32	0.68 - 0.80	30 - 35	0.76 - 0.89
180	16 - 23	0.46 - 0.58	20 - 25	0.51 - 0.64
240	14 - 18	0.34 - 0.46	15 - 20	0.38 - 0.51
320	8 - 10	0.21 - 0.25	9 - 11	0.23 - 0.28

Surface Designation	Finish (Ra)	
SF0	No Finish Requirement	
SF1	20 Ra	Mechanically Polished
SF2	25 Ra	
SF3	30 Ra	
SF4	15 Ra	
SF5	20 Ra	Electropolished
SF6	25 Ra	

**Grit:** Measures the number of scratches per linear inch of abrasive pad. Higher numbers indicate a smoother surface.

**RMS:** Defined as Root Mean Square roughness, this method measures a sample for peaks and valleys. Lower numbers indicate a smoother finish.

**Ra:** Known as the arithmetic mean, this measurement represents the average of all peaks and valleys. Lower numbers indicate a smoother finish.

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### Steps for Correctly Installing a Clamp Connection

#### Inspection

Before the clamp connection is installed, a close inspection of the ferrules, gasket, and clamp must be performed.

##### 1. Ferrule Inspection

- a. Check the alignment of the ferrules. The alignment of the ferrules is critical. The clamp cannot be used to pull pipes and components into alignment.
- b. Check the gap between the ferrule faces. Ideally, to minimize pipe stress, the gap between the ferrules should be the same width as the gasket.
- c. Check the surface of the ferrules for imperfections. Defects such as a gouge or scratch can create a leak pathway; even a tiny scratch can be an area where bacteria can grow.
- d. Examine the ferrules for residue. Residue from a previous gasket should be carefully removed to provide a smooth, flat surface. If there is residue on the mating face of the ferrule, the gasket will not seat properly.

##### 2. Gasket Inspection

- a. Prior to installation, visually inspect the gasket for discoloration, cracks, and imperfections such as gouges, tears, or product buildup on the surface of the gasket.
- b. The gasket also needs to be checked for pliability, as they can become brittle with use and age. An elastomeric gasket should not crack when it is flexed or bent
- c. Confirm that the size of the gasket is correct. Along with using an imperfect or expired gasket, the use of an incorrectly sized gasket will allow for voids and intrusions where material can collect and bacteria can grow.

3. **Clamp Inspection:** Check the clamp for common defects, such as deformations and bent components, loose hinges, damaged threads, and any indentations caused by uneven compression.

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### Installation

After the clamp components pass inspection, a clamp connection can be installed.

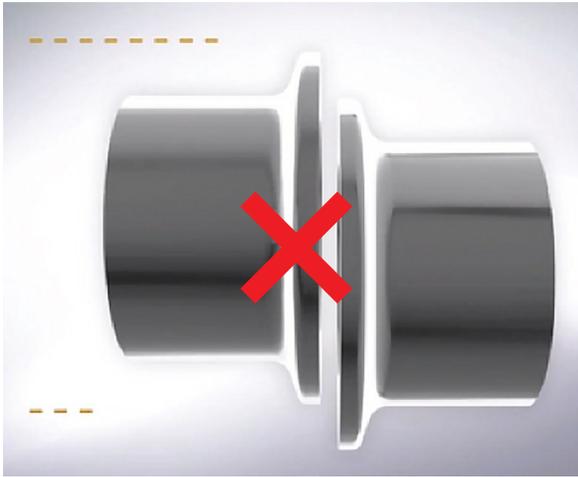


Figure 4. Ferrules must be completely aligned and the clamp cannot be used to pull pipes and components into alignment.



Figure 5. Here are improperly aligned ferrules. One side of the gasket is overcompressed and the other side has a dangerous gap.

Step 1: Position the gasket between the ferrule flanges.

Step 2: Align the bead of the gasket with the grooves of both ferrule flange faces.

Step 3: Mate the faces together and then apply the clamp.

Make sure both flanges are within the clamp groove. When the clamp is tightened, it squeezes on the flanges, pushing the ferrules toward each other. This creates a proper seal. The clamp connection should perfectly align the two ferrules, providing uniform crush to the gasket.

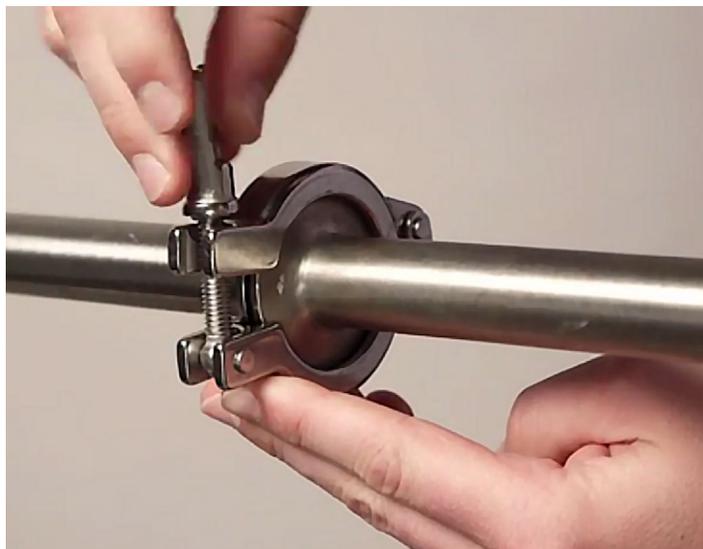


Figure 6. Tighten the clamp around the ferrules and gasket, making sure proper alignment is maintained.

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In a proper installation, the gasket is slightly compressed and the bead is centered in the ferrule groove. The gasket's inside diameter should be aligned with the pipe's inside diameter so there is no intrusion or void (the ASME-BPE standard for gasket intrusion is  $\pm 0.025''$ ). The alignment here is critical; it must be precise and even on all sides. Any irregularities will result in inconsistent or incomplete compression. Sometimes the ferrules are not perfectly aligned. If they meet at an angle, then one side of the gasket will be overcompressed and the other side will have gaps that can trap bacteria or process material.

Being off by even the slightest angle can be problematic. The maximum allowable misalignment is only 2 to 3 degrees. When a clamp is tightened as specified, the ferrules draw together very slightly. For instance, on a BPE ferrule, a secure seal compresses the gasket only  $0.3\text{mm}/0.012''$ .

### Undertightening vs. Overtightening Process Clamp Connections

Finish installation by tightening the clamp. Undertightening the clamp will leave gaps between the ferrule and the gasket. Even if the connection doesn't drip, the gaps may trap material where clean-in-place processes cannot reach. That's where bacteria could collect.

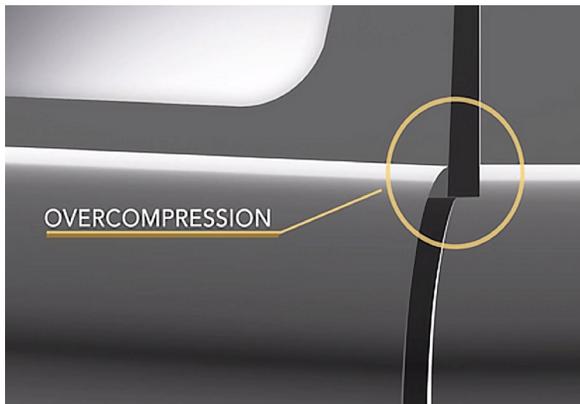


Figure 7. Overcompression of the gasket will lead to intrusion of the gasket into flow of the material being transferred.

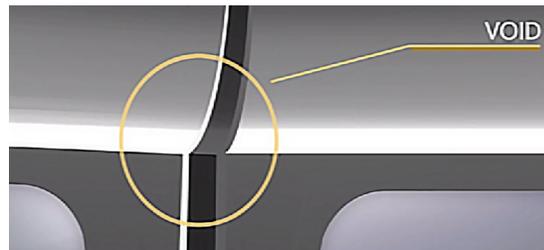


Figure 8. Misaligned ferrules or improperly mated ferrules will result in leakage or voids.

On the other hand, overtightening the clamp will overcompress the gasket and cause it to protrude into the pipeline. Any such intrusion will create a foothold for buildup and bacteria. In order to get the proper degree of tightness, either hand-tighten or use an approved torque tool. Always tighten to the appropriate torque specification.

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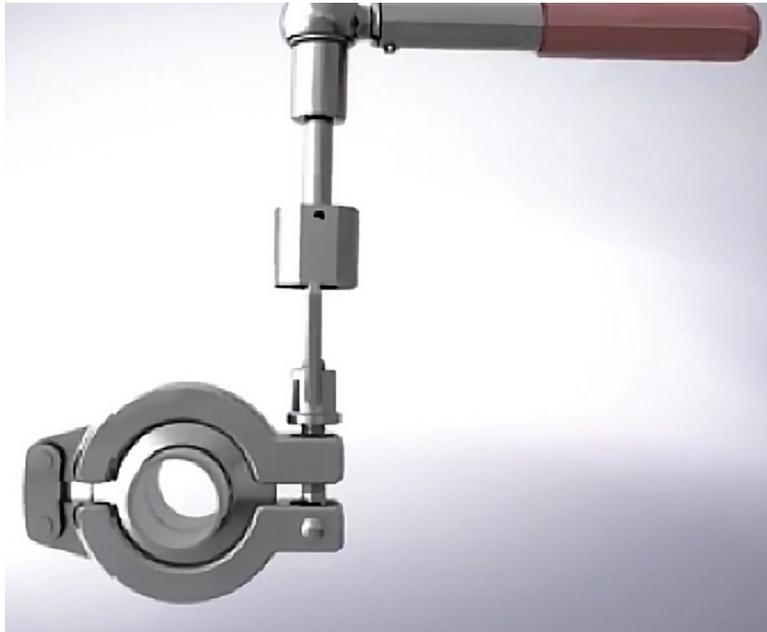


Figure 9. Use of an approved torque tool will prevent overtightening the clamp.

The clamp jaws should never touch after tightening. If the jaws touch, there may not be enough compression on the gasket to create a proper seal. This could be caused by a deformed or damaged clamp, overtightening, or using the wrong size clamp for the ferrule assembly.

### Process Clamp Connection Maintenance

Inspect clamps regularly to ensure that they remain at their installed torque setting. In particular, it is very important to monitor high-pressure steam lines for changes in torque. Due to thermal cycling, the compression on the gasket will vary. Also, gaskets can lose elasticity or they can cold flow with age.

These factors can degrade the quality of the connection and cause leaks. This can be avoided by performing maintenance on an adequate schedule, replacing gaskets as necessary and checking for clamps loosened by vibration. With an eye to installing, inspecting, and maintaining clamp connections properly, process clamp connections can be effectively and safely utilized in process equipment operations.

### Training

While they are relatively simple in their design, sanitary clamps must be used correctly to ensure a safe, leak-free connection. This should be accomplished by providing training for any individual who is responsible for working with sanitary clamps. A well-designed training program should cover clamp inspection, installation, and maintenance, as well as any topics that pertain to specific operational conditions, such as the material being transferred and the operating parameters of the system.