TECHNICAL PAPER

Sealing, SIP and CIP — what do I need to know?

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The performance and reliability of a sealing system is a critical concern for engineers and operators working in any process industry, but in food and pharmaceutical production where human safety is directly affected, it is especially important that the correct sealing materials and profiles are specified.

A key factor in an elastomer's suitability for use in life science applications is its resilience to SIP and CIP processes – but what do these processes involve, and how do different sealing material options fare against these thermal and chemical challenges?

What is 'SIP'?

The term SIP stands for 'sterilize-in-place', or sometimes 'steam-in-place', and refers to a technique which enables the deep cleaning of a complete process system without the need for major disassembly. The disconnection and reassembly of pipes and gaskets in a process system can take a long time, and any time spent preparing the process line for thorough cleaning is time which is not spent making a saleable product. The adoption of in-situ sterilizing methods, like SIP or CIP (clean-in-place), therefore has real economic value to a life science business.

The SIP sanitization routine typically follows every production batch, and involves not only the removal of processing soils but micro-organisms such as bacteria and spores. Every section of the process line can then be prepared for the next batch without fear of cross-contamination between process media, ingredients or other sources of impurity which may have developed within the system.

SIP uses the thermal energy of high temperature condensed steam (also known as dry steam), applied for a given amount of time, in order to reach the Sterility Assurance Level (SAL) necessary to kill micro-organisms. The sterilization phase typically reaches temperatures between 121°C and 135°C for at least half an hour, with exposure time dependent on the complexity and design of the process system at hand. This high temperature phase is then followed by a cool down phase. A key benefit of condensed steam use is that it has been slightly superheated, enough to avoid any problems which may arise through condensation issues within the process equipment.

What is 'CIP'?

As opposed to SIP, CIP (or 'clean-in-place') involves the introduction of cleaning chemicals and disinfecting media into the process line equipment, in order to prevent the formation of biofilms on equipment surfaces. These chemicals are typically highly aggressive, in order to be effective to the very demanding standards required from food and pharmaceutical safety standards. CIP is typically used in conjunction with SIP in order to remove calcification, which may occur in process lines but can be resistant to SIP techniques.

Key groups of CIP chemicals include:

- Alkaline CIP – cleaning media based on sodium hydroxide (NaOH) or potassium hydroxide (KOH)
- Acidic CIP – cleaning media based on mineral organic acids, such as nitric acid (HNO_3) or phosphoric acid (H_2PO_4)
- Acidic CIP – corrosive anti-microbial mixtures, such as sulfuric acid (H_2SO_4) with peracetic acid (PAA, CH_3CO_3H)
- Additives – often used to increase the cleaning effect of the media with active oxygen, such as hydrogen peroxide (H_2O_2)

The CIP process typically involves a caustic wash, followed by an acidic wash, and finally a sanitizer. Chemically intensive CIP techniques may not always be used in conjunction with SIP techniques –which are regularly employed to leave the process line contaminant-free after a process batch – and may only be as frequent as a monthly basis. However, if a sealing material has been specified for the application which is not able to perform under both SIP and CIP conditions, the seal is at a high risk of degradation and could impact the safety of the end product. How can this risk be counteracted?

The main challenges for sealing

Elastomer seals are a critical element within the process line. They prevent external environmental contamination of the product, as well as internal contamination between ingredients. However, without due consideration of the conditions faced by elastomer seals in a process system, and the specified material's ability to perform under these conditions, the risk of contamination through seal degradation is increased.

An operator can help to ensure their elastomeric sealing solution is not compromised by SIP and CIP cleaning methods, by considering four key factors.

Temperature

The sustained temperature of the condensed steam used in SIP can reach up to 135°C, which is beyond the sealing capability of some elastomer material types.

Chemical concentration

The aggressiveness of the chemicals used in CIP processes, and particularly in the acidic washes, can prove incredibly corrosive to elastomers – and depending on the material type, can cause seal failure almost immediately.

Exposure time

SIP and CIP processes can take approximately thirty minutes for a standard sterilization, and potentially longer depending on the nature and complexity of the job.

Seal profile and design

Elastomer seals can be molded in a wide range of profiles, from simple O-rings through to custom -designed hygienic gaskets. Where will the seals face the most exposure, and which seals could risk failure first?

The consequences of incorrect specification of seal material and seal type in a life science application can be financial, in terms of lost product batches as well as a reputational cost with recalls on potentially contaminated product. Moreover, poor seal specification can also lead to compliance issues with strict regulatory bodies for food and pharmaceutical production.

The Food & Drug Administration (FDA) is one of the main guardians of safety for life science industries. The FDA is the US Federal Agency responsible for ensuring the safety of foods, medicines, cosmetics and a range of other products set for consumption. Their Code of Federal Regulations Title 21.177.2600 features a list of rubber materials approved for contact with food and pharmaceuticals during manufacture. It is important to note that while a material may well be FDA-compliant for contact with foodstuffs or pharmaceuticals, and have the appropriate documentation to certify that, this does not necessarily mean that the material grade has been deemed safe for use under *all* conditions. Dry foods, aqueous foods and fatty foods all place different demands on their sealing systems, making the choice of FDA-compliant material not always so black and white. A specialist sealing engineer can help to minimize operational risk on this front.

Another important regulatory body is the United States Pharmacopeia (USP). With the goal of ensuring the quality of medicines and related healthcare technologies, the USP like the FDA has also codified a series of compliance standards for elastomers, plastics and polymeric materials. Compliance with USP Class VI is an important facet of seal material suitability in life science applications.

Figure 1 - A sample arrangement of O-rings molded from elastomer materials compliant with FDA CFR 21.177.2600.

Material Type	Chemical Compatibility						
	Acids	Alkalis	Fats and Oils	Alcohol	Solvents	Amines	Steam
FFKM	1	1	1	1	1	1	1
FKM	1	4	1	1	4	4	1*
EPDM	2	1	4	1	2	2	1
HNBR	3	2	1	2	3	3	3
Nitrile (NBR)	4	2	1	2	3	4	4
Silicone (VMQ)	4	2	2	1	4	2	3
PTFE	1	1	1	1	1	1	1
PEEK	2	1	1	1	1	1	1

KEY: 1 = Excellent, 2 = Good, 3 = Doubtful, 4= Do not use

* Specialist steam-resistant grades required, consult sealing specialist

Figure 2 - Overview of material sealing performance across a range of different media types.

The elastomer sealing material candidates

As highlighted, SIP and CIP processes are aggressive environments capable of causing major damage to elastomeric seals. The selection of elastomer sealing material for a CIP and SIP process is dependent on the combination of chemicals used, and whether the seal is used in applications with load and pressures. The chosen material will have to be capable of withstanding high temperatures and steam. With these factors in mind, which materials are most frequently specified for applications where SIP and CIP are used?

FFKM

Perfluoroelastomers, such as the Perlast® family of materials, have been designed to deliver best in class sealing performance under very high temperatures (in excess of 300°C in certain formulations), combined with the almost total chemical resistance of PTFE (see *Figure 2*). FFKM is the most expensive elastomer material commonly used in life science applications.

FKM

Fluoroelastomers were developed in the late 1940s as a more chemically resistant alternative for nitrile materials, and today offer excellent all-round sealing capability for a wide range of applications and industries. They have the thermal and chemical resistance required to provide many years of reliable service when used correctly within life science applications.

EPDM

Ethylene propylene diene monomer rubber, or EPDM, is a synthetic rubber which when specified correctly can seal effectively with good temperature range resistance. This has resulted in the popularity of EPDM for cost effective steam and hot water sealing, across gaskets and O-rings. However, when compared with FKM and FFKM, EPDM materials are much closer to their upper bound service temperatures (150°C) at the temperatures involved in SIP. As the potential for seal failure is greater, alternative materials may be more suitable.

Other elastomeric materials (HNBR, NBR, VMQ etc) do not have the same combination of high temperature resistance and excellent chemical resistance qualities, and as such should not be considered for life science applications where SIP or CIP conditions may be present.

		Material type (PPE grade), and measured change in							
		EPDM (E70Q)		Silicone (S71U)		FKM (V70SW)		FFKM (G74S)	
Fluid	Conditions	Hardness (Shore A)	Volume (%)	Hardness (Shore A)	Volume (%)	Hardness (Shore A)	Volume (%)	Hardness (Shore A)	Volume (%)
Butter Oil	22h @ 70°C	-11	14.1	0	0.1	0	0.0	0	0.1
Distilled Water	22h @ 70°C	-2	1.2	-3	2.5	-3	0.5	-1	0.7
Nitric Acid 0.5%	22h @ 82°C	-1	3.8	-1	1.0	-3	2.3	-2	1.7
Orthophosphoric Acid 1.0%	22h @ 82°C	-2	1.1	0	0.8	-1	0.7	1	0.7
Sodium Hydroxide 1.0%	22h @ 82°C	-4	1.5	-2	0.9	-3	0.6	1	0.6
Sodium Hypochlorite 1.0%	22h @ 82°C	-4	2.1	2	0.0	-1	0.5	-1	0.8

Figure 3 - Comparative analysis of EPDM, Silicone, FKM and FFKM sealing performance in various fluids, measured by hardness and volume change.

Which material is best for SIP or CIP?

The short answer, it depends. Between food and pharmaceutical process environments, the variables of media, temperature and mechanical strain can differ so significantly that a sealing material which is totally unsuitable in one application may be perfect for another.

FKM is a good general purpose candidate for sealing in SIP or CIP conditions. It is a robust material with excellent chemical resistance and a good temperature range, and combined with good mechanical properties and compression set performance, it is understandably the incumbent sealing material choice for many life science applications. *Figure 3* illustrates the step change in chemical resistance from EPDM and Silicon to FKM. However, among all material candidates, and bearing in mind the consequences for seal failure in food and pharmaceutical production especially, FFKM is the safest bet.

FFKM demonstrates a virtually universal resistance to all chemicals, and along with its exceptional sealing performance across a broad temperature range, FFKM material grades give operators the closest thing to total peace of mind when sealing in life science applications. The key disadvantage for FFKM is a higher cost compared to FKM and EPDM. However, with a subsequent lower total cost of ownership, and significantly shorter time periods between maintenance and repair windows, operators can expect to recoup any initial outlay on FFKM material specification with cost savings in the medium term.

Conclusion

The high temperatures and aggressive chemicals involved in Steam In Place (SIP) and Clean In Place (CIP) processes place restrictions on the kinds of material which can be specified in sealing solutions for these life science applications. Perfluoroelastomers (FFKMs) deliver best in class sealing performance with a wider temperature range and more extensive chemical resistance than fluoroelastomers (FKMs). Where budget permits, FFKMs represent the optimal choice of sealing material in life science applications where SIP and CIP processes will be used.

A specialist sealing engineer can evaluate the demands of your application and specify a material type and grade which will perform reliably to a very high standard.

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