

DuPont™ Kalrez® Sanitary Seals

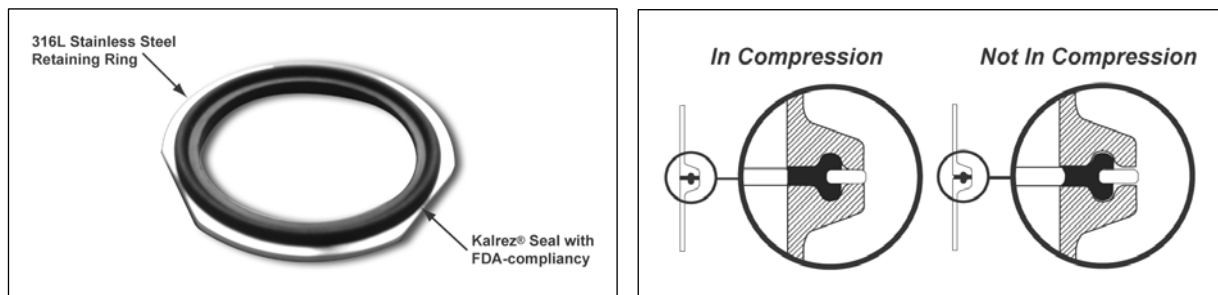
Stainless steel and DuPont™ Kalrez® perfluoroelastomer parts combined in a controlled-compression joint seal that provides premium performance.

Technical Information—Rev. 6, July 2010

Bioprocessing and pharmaceutical manufacturing processes must operate at the highest levels of cleanliness to assure product purity. Coupling joints in process lines can be a particularly troublesome source of contamination from various sources if the correct sealing material is not selected, as outlined in ASME's BPE Bioprocessing Equipment Standards. Substandard seal performance can also result in excessive process downtime and maintenance costs. Selecting the joint design and sealing material to provide the optimum balance of cleanliness and seal life is an ongoing challenge to the pharmaceutical process engineer.

DuPont answers that challenge with the DuPont™ Kalrez® Sanitary Seal design, a combination of two optimum performance engineering materials—stainless steel and Kalrez®. Developed using Finite Element Analysis to simulate the range of temperatures a seal can see, this seal is designed with a metal retainer that controls compression of the seal and minimizes its intrusion into the process stream. The result is a prefabricated seal that provides the cleanliness of PTFE and the elastic memory of an elastomer while meeting stringent ASME requirements for joints intended for clean-in-place (CIP) and steam-in-place (SIP) applications. The Kalrez® sealing element minimizes absorption, desorption and extractables to assure minimal contamination and a long sealing life.

Anatomy of the Kalrez® Sanitary Seal



Stainless Steel Retaining Ring

- Provides for controlled compression resulting in maximum seal life and reduced maintenance (eliminates the need to retorque)
- Rigid stainless steel ring helps maintain alignment during assembly
- Pry points to help with disassembly



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DuPont™ Kalrez® Seal

- Perfluoroelastomer part provides the ultimate sealing performance for maximum efficiency with FDA compliancy
- Extractable levels comparable to PTFE
- Resistant to high operating temperatures (up to 260 °C [500 °F])
- Compatible with most pharmaceutical process media, including CIP and SIP
- Concave inside diameter is designed to minimize elastomer intrusion during process operations

Avoid These Common Coupling Problems By Specifying Kalrez® Sanitary Seals

Intrusion from Overcompression

Too much sealing pressure can cause some elastomer seals to intrude into the process stream, resulting in product contamination. Overcompression can also result in seal splitting and loss of joint integrity.

Joint Leakage

Cold flow ("creep") of PTFE and some elastomers can cause loss of sealing pressure over time, requiring frequent inspections and retightening.

Seal Degradation

Incompatibility with fluids in the process line can cause some sealing materials to swell, crack and degrade, resulting in joint failure and process contamination. High process temperatures or repeated temperature cycling can also deteriorate seals made of many materials.

Sizes, Packaging and Availability

Kalrez® Sanitary Seals are available in compound 6230A (black), supplied in individual bags and bar coded for full traceability. Sizes for 1/2, 3/4, 1, 1-1/2, 2, 2-1/2, 3, and 4 inch tri-clamp fittings are available and other sizes may be available as special orders.

Visit us at kalrez.dupont.com or vespel.dupont.com

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Kalrez® perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made only from compounds 6221 and 6230 have been tested in accordance with USP protocols and meet the requirements of a USP Class VI polymer. USP testing was done to support use of Kalrez® parts in pharmaceutical processing and food processing applications. While USP Class VI compliance materials are not required for pharmaceutical and food processing applications, many pharmaceutical and food processing customers including customers seeking ISO 9000 certification, have requested compliance. Testing of any finished article that incorporates Kalrez® perfluoroelastomer parts is the responsibility of the manufacturer or seller of the finished article if certification that meets USP standards is required.

Caution: Do not use in medical applications involving permanent implantation in the human body. For other medical applications, discuss with your DuPont customer service representative and read Medical Caution Statement H-50103-3.

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