

# DuPont™ Kalrez®

## Life Sciences Product Selector Guide

Technical Information — October 2018

DuPont Kalrez® Perfluoroelastomer (FFKM) parts provide best in class chemical resistance, outstanding thermal & steam resistance and low contamination from extractables for demanding applications in pharmaceutical, life science and food handling where FDA compliance is required.

Kalrez® parts deliver longer seal life versus lower performing elastomers thereby improving productivity, efficiency and cleanliness. They also help to create a safer environment for medical packaging, disposable device handling and in the day to day running of pharmaceutical manufacturing facilities.

### Product Selector\*

The following guide provides a quick and easy tool for the selection of Kalrez® products for the Life Sciences Industry.

	Kalrez® 6230	Kalrez® 6221	Kalrez® LS205	Kalrez® LS390	Kalrez® LS222
<b>Available geometries</b>	O-rings & Specialty Shapes	O-rings	Specialty Shapes & O-rings	Hygienic couplings	High Volume Specialty Shapes
<b>Color</b>	Black	White	White	Grey	Black
<b>APPLICATIONS</b>					
<b>Rotating equipment (mixers, pumps, centrifuges, etc.)</b>	✓	✓	✓		
<b>Filtration and Drying</b>	✓	✓	✓		
<b>Piping</b>				✓	
<b>Flow regulation (valves)</b>				✓	✓
<b>WFI (water for injection)</b>	✓	✓			
<b>Medical packaging</b>					✓
<b>CERTIFICATIONS</b>					
<b>US FDA</b>	✓	✓	✓	✓	✓
<b>USP &lt;87&gt; &amp; &lt;88&gt; Class VI @ 121°C</b>	✓	✓	✓	✓	✓
<b>3-A</b>	✓	✓	✓		
<b>Japan Pharmacopeia</b>		✓	✓	✓	
<b>EC 1935/2004</b>	Please Contact DuPont for Additional Information				



\* Please consult a Kalrez® Application Engineer to assess perform fit for your specific application.

## Typical Physical Properties<sup>1</sup>

	<b>Kalrez® 6230</b>	<b>Kalrez® 6221</b>	<b>Kalrez® LS205</b>	<b>Kalrez® LS390</b>	<b>Kalrez® LS222</b>
<b>Maximum Application Temperature<sup>2</sup>, °C (°F)</b>	260 (500)	260 (500)	225 (437)	220 (428)	225 (437)
<b>Hardness<sup>3</sup>, Shore A</b>	75	70	75	88	75
<b>100% Modulus<sup>4</sup>, MPa, (psi)</b>	7.03 (1020)	7.24 (1050)	7.57 (1099)	11.16 (1618)	6.95 (1008)
<b>Tensile Strength @ Break<sup>4</sup>, MPa, (psi)</b>	16.54 (2400)	15.16 (2200)	21.11 (3062)	18.60 (2699)	17.39 (2522)
<b>Elongation @ Break<sup>4</sup>, %</b>	170	150	170	147	170
<b>Compression Set<sup>5</sup>, Pellet, 70 hrs. @ 204°C, %</b>	24	27	21	30 (-214 O-ring)	21

<sup>1</sup> Not to be used for specification purposes

<sup>2</sup> DuPont proprietary test method

<sup>3</sup> ASTM D2240 (pellet test specimens)

<sup>4</sup> ASTM D412 (dumbbell test specimens)

<sup>5</sup> ASTM D395B (pellet test specimens unless otherwise noted)

## Product Description

### Kalrez® 6230

DuPont™ Kalrez® 6230 perfluoroelastomer parts are compliant with the United States' Food and Drug Administration's regulations for repeated use in contact with food as described by 21 CFR177.2600 and Food Contact Notification 000101. Kalrez® parts made from compound 6230 have been tested in accordance with the United States Pharmacopoeia Class VI (USP Class VI) testing protocol and meet the test requirements of a USP Class VI polymer. This is a black product that offers excellent steam cycling resistance and reduces extractables from sealing materials to trace levels.

### Kalrez® 6221

DuPont™ Kalrez® 6221 perfluoroelastomer parts are compliant with the United States' Food and Drug Administration's regulations for repeated use in contact with food as described by 21 CFR177.2600 and Food Contact Notification 000101. Kalrez® parts made from compound 6221 have been tested in accordance with the United States Pharmacopoeia Class VI (USP Class VI) testing protocol and meet the test requirements of a USP Class VI polymer. This is a white product that offers excellent steam cycling resistance and reduces extractables from sealing materials to trace levels. It is only available in O-ring form; custom geometries are not available.

### Kalrez® LS205

DuPont™ Kalrez® LS205 perfluoroelastomer parts are a white product for use in food handling and pharmaceutical applications where FDA and/or USP <87> and <88> Class VI compliancy are required. Kalrez® LS205 parts provide superior chemical resistance and low extractables in demanding applications. This product is also well suited for custom parts and other non-O-ring applications. A maximum application temperature of 225°C (437°F) is suggested.

### Kalrez® LS390

DuPont™ Kalrez® LS390 perfluoroelastomer parts are a grey product for use as sanitary seals in food handling, beverage, and pharmaceutical applications where FDA, USP <87> and <88> Class VI compliance are required. In addition, Kalrez® LS390 parts also meets Japan Pharmacopoeia, edition 16\*. LS390 parts provide excellent chemical resistance to process chemicals, WFI (water for injection), as well as SIP and/or CIP processes, which helps increase MTBR (Mean Time Between Repair). LS390 sanitary seals have demonstrated low stiction properties and high hardness/modulus to make LS390 parts an excellent choice for sanitary seal applications. These properties also facilitate sanitary seal piping disassembly. Because of its unique grey color, LS390 parts are easy to identify for proper material selection and application. A maximum application temperature of 220°C (428°F) is suggested.



## Kalrez® LS222

DuPont™ Kalrez® LS222 perfluoroelastomer parts are black product that has been specifically developed for use in high volume medical packaging and disposable devices (e.g., micro-valves, needle covers, serum stoppers, plungers, infusion hangers, etc.). This exciting new development represents an expansion of the Kalrez product line to meet the demand from OEMs and Life Science Manufacturers who require large quantities of high quality parts. A wide range of dimensions and select custom shapes are offered.

## Application Success Stories

Listed below are several application success stories with Kalrez® Life Sciences Products. Additional application success stories are available upon request. Please contact a Kalrez® Application Engineer for more information.

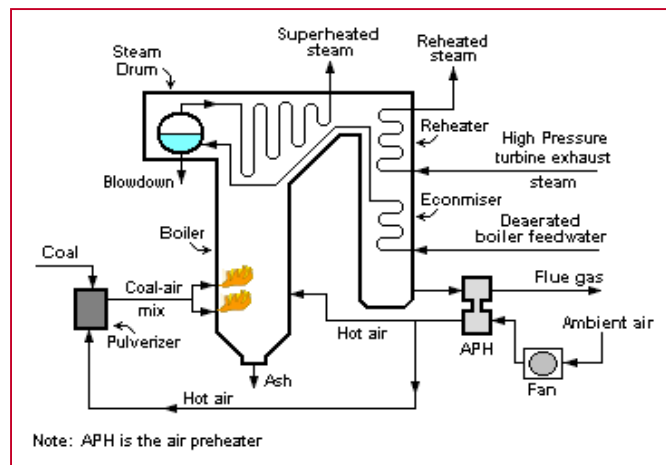
### Kalrez® 6230

**Application:** Steam Generator

**Equipment:** Device used to create steam by applying heat energy to water at low to medium pressure (0 to 20 bars) and at a working temperature between 130°C and 140°C

**Challenge:** Resistance to steam at high temperature as well as various cleaning procedures

**Solution:** In testing conducted by customers in the presence of saturated steam at 4 bars and 140°C, Kalrez® 6230 lasted 500,000 cycles; Competitive FFKM Materials and EPDM failed after 100,000 cycles.



## **Kalrez® LS390**

### **Customer: Major Japanese Pharmaceutical Manufacturer**

Customer is the one of the largest infusion drop product manufacturers in Japan. They were interested in Kalrez® LS390's improved chemical compatibility and low stiction properties. They agreed to run the initial evaluation in their pure steam line.

**Process:** Pure Steam (SIP) for Infusion Drop Production Process

**Temperature:** <140°C

**Pressure:** <0.4MPa

**Evaluation Period:** August 2014 through August 2015

**Incumbent Seal:** Silicone Rubber

**Performance Issues w/Incumbent Seal:** Poor steam resistance and high "stiction" (sticking) resulted in a more frequent maintenance cycle.

**Kalrez® LS390 Performance:** Kalrez®LS390 Sanitary Seals lasted for 1 year without any reported performance issues.



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