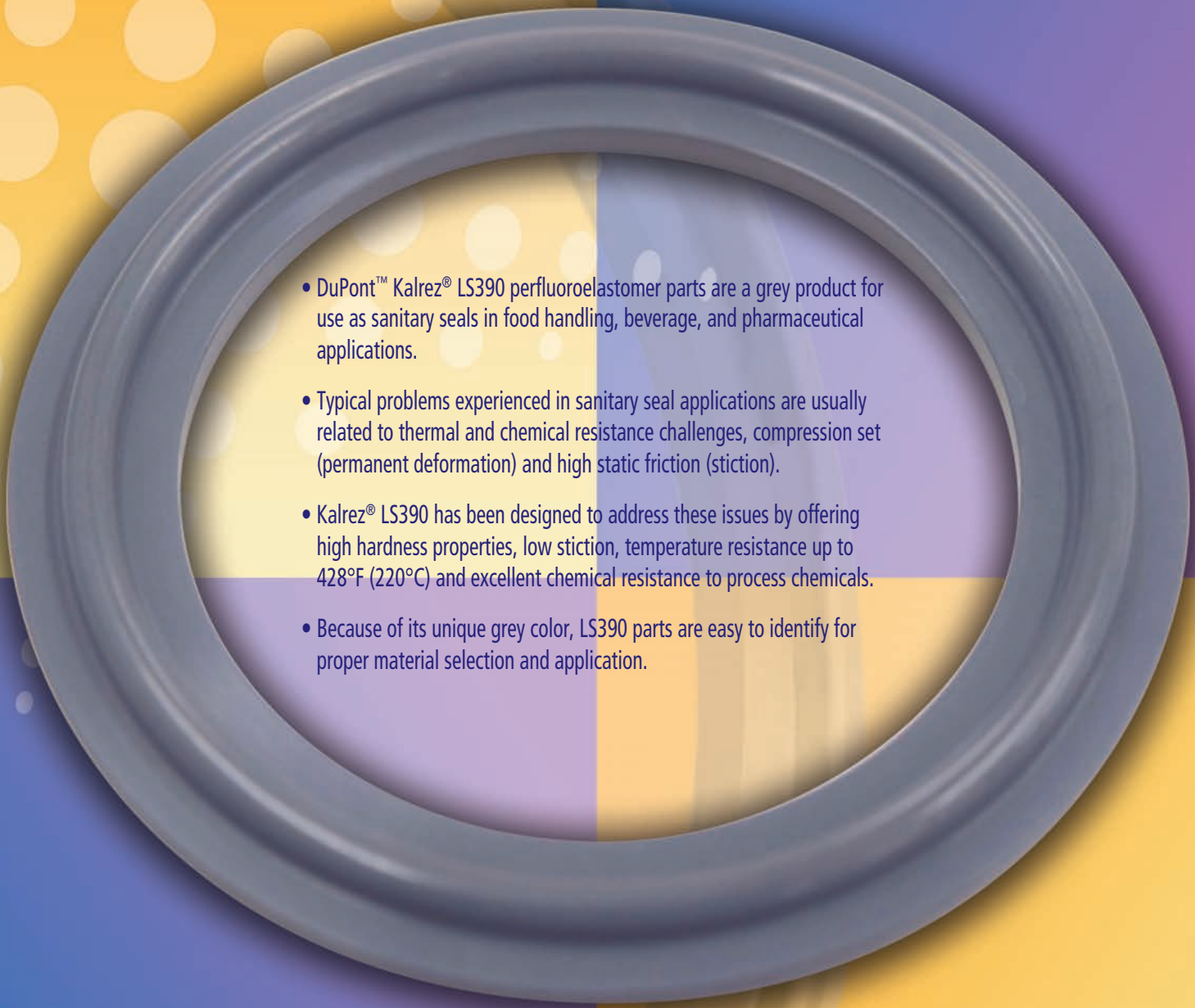
Introducing a new standard of efficiency for pharmaceutical processing

KALREZ® LS390 SANITARY CLAMP GASKET

Kalrez® LS390 perfluoroelastomer parts provides premium performance.



- DuPont™ Kalrez® LS390 perfluoroelastomer parts are a grey product for use as sanitary seals in food handling, beverage, and pharmaceutical applications.
- Typical problems experienced in sanitary seal applications are usually related to thermal and chemical resistance challenges, compression set (permanent deformation) and high static friction (stiction).
- Kalrez® LS390 has been designed to address these issues by offering high hardness properties, low stiction, temperature resistance up to 428°F (220°C) and excellent chemical resistance to process chemicals.
- Because of its unique grey color, LS390 parts are easy to identify for proper material selection and application.

ISO 9001 CERTIFICATION ESTD.

NEWMAN™
SANITARY GASKET COMPANY

AUTHORIZED DISTRIBUTOR
Kalrez®
perfluoroelastomer parts
DuPont Performance Elastomers

PRODUCTS OF INTEGRITY...FROM PEOPLE OF INTEGRITY

Kalrez® LS390

perfluoroelastomer parts - a product of DuPont™ Performance Elastomers

Sanitary seals used to manufacture food, beverages and bio-pharmaceuticals are required to maintain the highest levels of product purity. At the same time, they are also expected to minimize process downtime and maintenance costs. Selecting the proper seal to optimize both is a constant challenge to the high-purity process engineer.

DuPont Performance Elastomers is answering that challenge with the development of the new Kalrez® LS390 Sanitary Gasket. A prefabricated seal that provides the cleanliness and chemical resistance of PTFE with the elastic memory of an elastomer, it was designed to meet the stringent requirements of ASME BPE for clamp connections used in biopharmaceutical applications. Kalrez® LS390 material minimizes what can be absorbed by or extracted from the gasket. At the same time it offers one of the widest ranges of chemical and thermal resistance. This translates into a pure process and a long seal life!

Kalrez® LS390 Material Properties[1]

Color	Grey
Shore A[3] Durometer, points	88
Tensil Strength[4], psi (MPa)	2697 (18.60)
Ultimate Elongation[4] %	147
100% Modulus, psi (MPa)	1618 (11.16)
Compression Set[5] %, 70 hrs. at 392°F (200°C)	30
Max Operating Temperature[2] °F (°C)	428 (220)

Typical problems experienced in sanitary seal applications are usually related to thermal and chemical resistance challenges, compression set (permanent deformation) and high static friction (stiction). These factors can cause intrusion in the production line or dead space, which increases the risk of contamination or leakage unless seals are continually tightened. Kalrez® LS390 has been designed to address these issues by offering high hardness properties, low stiction, temperature resistance up to 220°C (428°F) and excellent chemical resistance (Tables 1 and 2) to process chemicals, WFI (water for injection), as well as SIP and/or CIP processes. These properties, enable increased MTBR (Mean Time Between Repair). Because of its unique grey color, LS390 parts are easy to identify for proper material selection and application.

Table 1: Chemical Immersion Data[6] – % Volume Swell (168 hrs. exposure)

Chemical/Product	Temp.°C	Kalrez® LS390	General EPDM
CIP AC-101™ [7] (5% diluted NaOH)	95	4	22
CIP HOROLITH V [7] (5% diluted HNO3)	95	17	46
CIP Oxonia Active [7] (5,000 ppm Peracetic acid)	95	5	43

Table 2: Chemical Immersion Data[6] – % Volume Swell (502 hrs. exposure)

Chemical/Product	Temp.°C	Kalrez® LS390
CIP-100 [8]	70	1
CIP-200 [8]	70	1
Bleach	70	1
Distilled water (SIP)	130	6

[6] ASTM D471 (size AS568-214 O-rings) [7] ECOLAB [8] Steris Life Sciences

Sizes, Packaging and Availability and Compliance

Kalrez® LS390 Sanitary Clamp gaskets are supplied in individual bags, bar coded for full traceability. Kalrez® LS390 parts comply with the requirements of the U.S. FDA regulation 21 CFR 177.2600, the extractive limitations of 21 CFR 177.2400, as well as USP <87> and USP <88> Class VI requirements for biocompatibility. Kalrez® LS390 parts also meet Japan Pharmacopeia, edition 16.

Kalrez® LS390 Clamp Gasket Sizes (ISO and ASME BPE Standard Inch Ferrules)

Size	LS390 Part #	Size	LS390 Part #
ISO 8A	40RXKLISO8A	3"	40RXKL0300
ISO 10A	40RXKLISO10A	3½"	40RXKL0350
ISO 15A	40RXKLISO15A	4"	40RXKL0400
½"	In Design	4½"	40RXKL0450
¾"	In Design	5"	40RXKL0500
1"	40RXKL0100	5½"	40RXKL0550
1.5"	40RXKL0150	6"	40RXKL0600
2"	40RXKL0200	6½"	40RXKL0650
2½"	40RXKL0250		

[1] Not to be used for specification purposes
[2] DuPont proprietary test method
[3] ASTM D2240 (plied sheet test specimen)
[4] ASTM D1414
[5] ASTM D395B (AS568-214 O-ring)

[i] ASME BPE – Bioprocessing Equipment Standard – www.asme.org
[ii] For additional information on FDA compliance, please refer to Food Contact Notification (FCN) number 1116. USP <87> and <88> class VI compliance was tested at 121°C. Japan Pharmacopeia, edition 16 requirements for section 7.03 – Rubber Closure for Aqueous Infusions.

NEWMAN™ SANITARY GASKET COMPANY

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AUTHORIZED DISTRIBUTOR Kalrez® perfluoroelastomer parts DuPont Performance Elastomers

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