Greene Tweed

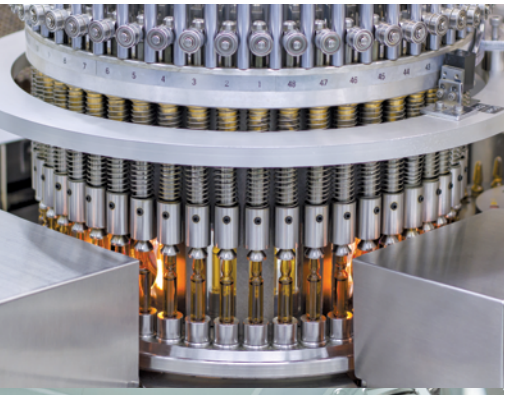
CHEMRAZ®

SEALS AND GASKETS

PHARMA | BIOTECH | FOOD | COSMETICS

Chemraz® perfluoroelastomer compounds are high-performance, low-extractable elastomeric materials with unparalleled thermal and chemical resistance. **Pharmaceutical, lab instrument, food, and cosmetic manufacturers rely on Chemraz® seals** for challenging processes and to reduce the risk of non-conformances, recalls, and irreparable brand damage from leaks and contamination.

The Chemraz® Advantage



Unparalleled Chemical Compatibility

All Chemraz® compounds are based on perfluorinated elastomers which provide chemical compatibility comparable to polytetrafluoroethylene (PTFE). Unlike PTFE, Chemraz® compounds also offer the long-term sealing force of a rubber. Seals and gaskets made from Chemraz® offer the best possible chemical compatibility of any elastomeric material.

Exceptional High-Temperature Range

FDA-compliant Chemraz® SD625 seals and gaskets are available for continuous service up to 260°C (500°F).

Steam Resistance

Chemraz® SD625 FDA-compliant seals and gaskets offer excellent performance in steam applications. In independent testing, exposure to 180°C (356°F) steam for 720 hours showed minimal changes to o-rings prepared from Chemraz® SD625.

Purity

Chemraz® SD517 FDA-compliant seals are prepared, cleaned, and packaged in an ISO 7 or better cleanroom, which offers extremely low particulates and extractables.

Cleanliness

Because of their chemical and thermal compatibility, Chemraz® seals and gaskets enable the cleanest environments possible. Chemraz® seals and gaskets maintain their performance after numerous cleanings with virtually any cleaning reagent or sterilant, including concentrated sodium hydroxide, steam, hydrogen peroxide, ethylene oxide, hypochlorite, and peracetic acid.

Chemraz® Grades for Life Sciences

GRADE	CHEMRAZ® 605	CHEMRAZ® SD517	CHEMRAZ® SD625
COLOR	Black	White	Black
HARDNESS, SHORE A	80	80	80
COMPRESSION SET (70 hours, 204°C/399°F) @ 25% Deflection, % of Original Deflection	25	25	25
TEMPERATURE RANGE	-20°C to 260°C (-4°F to 500°F)	-30°C to 220°C (-22°F to 428°F)	-20°C to 260°C (-4°F to 500°F)
COMPLIANCE	NA	• FDA Food Contact No. 247 • FDA 21 CFR 177.2400 (d) • 3-A, 18-03, C & D Rubber Class I • USP, <87> & <88> Class VI EU1935/2004	• FDA Food Contact No. 245 • FDA 21 CFR 177.2400 (d) • 3-A, 18-03, C & D Rubber Class I USP, <87> & <88> Class VI
APPLICATIONS	Analytical lab automation	• API synthesis • Bioprocessing • Food • Cosmetic	• API synthesis • Bioprocessing • Food • Cosmetic • High-temperature steam • Concentrated acids
SHAPES	Standard & custom o-rings, gaskets, diaphragms, sheets, custom shapes		

Color

While all Chemraz® compounds are high-performance materials, black Chemraz® SD625 compounds typically offer better performance in high-temperature steam and concentrated acid applications. This performance increase is due in part to the use of carbon black, one of the best elastomer reinforcers.

White Chemraz® compounds can offer aesthetic, usability, and purity advantages. White seals can easily be differentiated from standard black seals in procedures and processes using multiple seal types. Further, Chemraz® SD517 parts are prepared, cleaned, and packaged in an ISO 7 cleanroom or better, which reduces risk of particulates and extractables.

Regardless of color, both Chemraz® SD517 and SD625 have very low extractables in a variety of aggressive conditions, as required by compliance to FDA 21 CFR 177.2400 (d).

Chemraz® Applications

API Synthesis

Chemraz® seals and gaskets maintain sealing in nearly all chemicals used in active pharmaceutical ingredients (API) synthesis and cleaning methods. Their pliability makes them easier to use than stiff PTFE or PFA seals, ensuring long-term compliance.

Bioprocessing

Chemraz® seals and gaskets are stable to bioprocessing cleaning methods, and offer unparalleled lifetimes in steam-in-place and clean-in-place processes.

Food and Beverage

Chemraz® seals are used in food, beverage, and dairy industries because they maintain process cleanliness even after regular exposure to sterilizing steam and reagents.

Cosmetics

Chemraz® seals are compatible with all chemicals used in cosmetics. Equipment made with Chemraz® seals and gaskets can confidently be relied upon, even in processing difficult reagents such as concentrated essential oils and detergents.

Lab Instruments

Chemraz® seals and gaskets are compatible with nearly all chemicals used across all scientific disciplines. They can be relied upon for an outstanding leak-proof customer experience in high-performance liquid chromatology (HPLC), tissue processing, and automated synthesizers.

Chemraz® Success Stories

PFA-Coated Silicone Causing API Adulteration

The Problem: A major pharmaceutical manufacturer was using large PFA-coated silicone o-rings in access doors of API washing and drying equipment. PFA-silicone was used due to exposure to aggressive, volatile chemicals in API washing steps. However, upon opening and closing the access doors, the stiff PFA coating would crack open and flake, causing adulteration of the drug product.

The Chemraz® Solution: Greene Tweed designed a large (>1-foot diameter) Chemraz® o-ring to fit the access doors while providing the same chemical and thermal compatibility as the PFA coating. The custom-designed Chemraz® o-rings withstood repeated exposure to the chemical washes and door access without any physical damage or leaking after weeks of testing. The o-rings were successfully validated by the customer for future use in this and other applications.

Leaking PTFE Seals

The Problem: An analytical instrument OEM was using PTFE seals in mass spectroscopy (MS) equipment and customers were experiencing frequent leaks. PTFE seals have virtually no flexibility, and require near-perfect machining to properly seal. Even then, they can fail over time due to cold flow.

The Chemraz® Solution: Greene Tweed prepared a custom Chemraz® o-ring to replace the PTFE seal. The seal successfully resolved leaks and was adopted into the finished product.

Seals for Automated DNA Oligonucleotide Synthesizers

The Problem: The most common method for preparing synthetic DNA for bioprocessing and gene therapies is automated phosphoramidite chemistry. Automating DNA oligonucleotide synthetic chemistry requires a vast array of aggressive chemicals and solvents to be pumped through shared tubing and seals. A typical synthesizer uses trichloroacetic acid, pyridine and tetrazole bases, strong oxidants, and aggressive solvents such as tetrahydrofuran and tetrachloromethane. Typical seals made of NBR, silicone, EPDM, or FKM will swell and rapidly fail in at least one of these reagents.

The Chemraz® Solution: Our Chemraz® seals offer excellent compatibility in all reagents and solvents used in oligonucleotide phosphoramidite chemistry. Seals made from Chemraz® will retain their sealing force in phosphoramidite synthesis machines longer than NBR, silicone, EPDM, and FKM seals, enabling these machines to meet customer requirements for reliability.

The custom-designed Chemraz® o-rings withstood repeated exposure to the chemical washes and door access without any physical damage or leaking after weeks of testing.

Comprehensive Manufacturing Capabilities

Greene Tweed's manufacturing capabilities are flexible and far-reaching:

Standard Seals

A wide range of standard sealing types are available, including ASTM o-rings and sanitary gaskets.

Custom Seals

Custom Chemraz® seals solutions are available, including sheets, large-scale seals, and custom geometries. Assemblies using reinforced PTFE backup rings can be prepared to offer performance in high-pressure environments.

Large Seals

Chemraz® seals can be manufactured to larger diameters than standard seals. Our molding processes can produce seals meters in diameter.

Batch Validation

Greene Tweed validates all manufacturing processes for all Chemraz® parts.

Cleanroom Manufacturing

ISO 7 cleanrooms offer cleaning and packaging for high-purity compounds, including Chemraz® SD517.

Flexible MOQs

Greene Tweed can offer flexible minimum order quantities (MOQs) for seals, satisfying orders from the tens to hundreds of thousands.

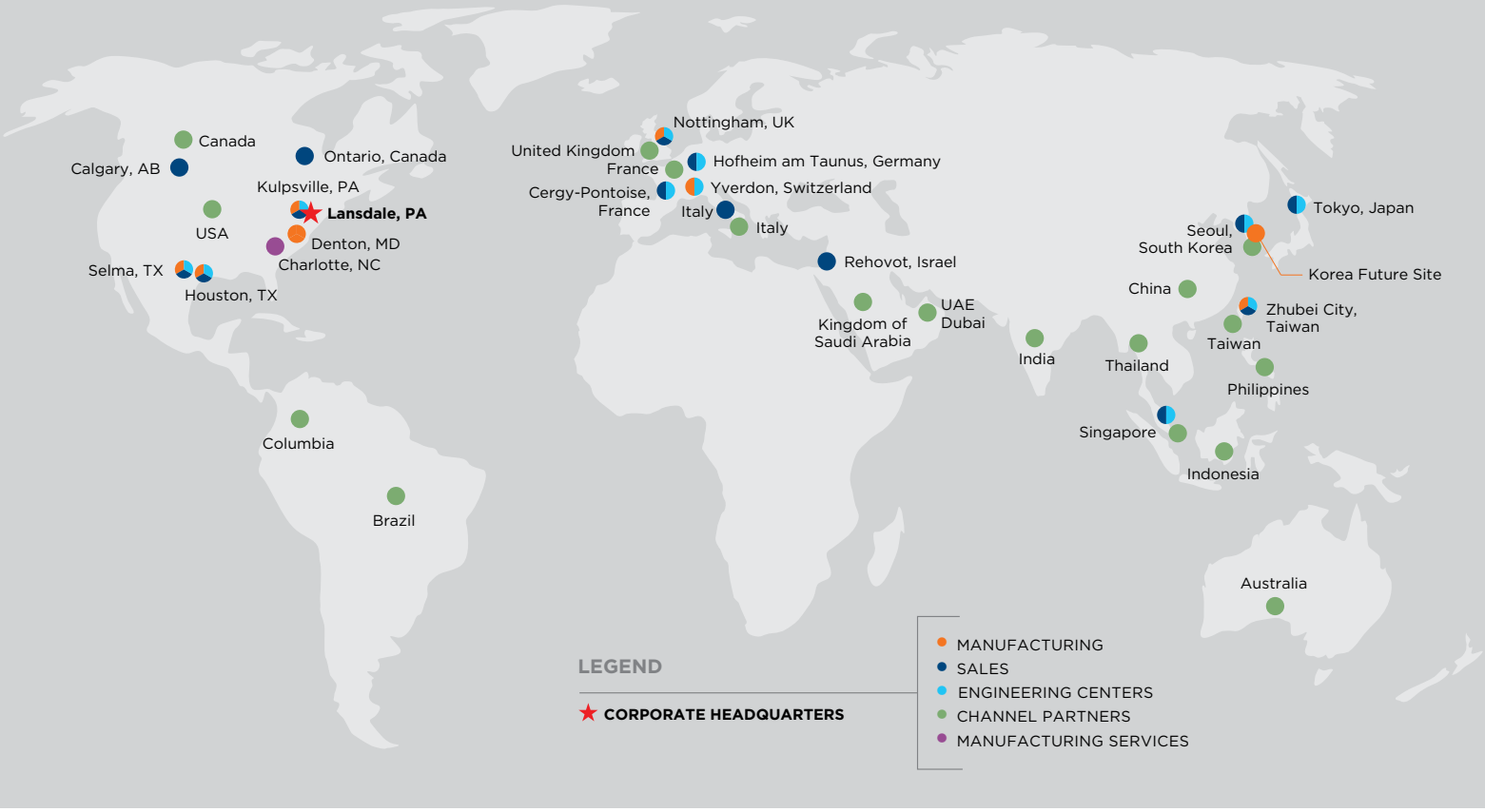
Custom Chemraz® seals solutions are available, including sheets, large-scale seals, and custom geometries.

Quality

All Greene Tweed manufacturing sites are ISO 9001:2015 certified, ensuring validated, robust, and traceable processes that drive customer satisfaction.

Greene Tweed regularly hosts customer audits for Quality Management System (QMS) and manufacturing audits at each of its manufacturing sites.

Whenever necessary, Greene Tweed can arrange change control agreements to satisfy specific regulatory needs.



With more than 1,900 employees across 11 countries, Greene Tweed can support your operations wherever you are located.

- **Global Presence** – Greene Tweed's worldwide sites are ISO 9001:2015 certified – Americas (Pennsylvania, Texas, Maryland); Asia (Korea, Singapore, Taiwan); and Europe (England, France, Germany)
- **Engineering Services** – Our team is ready to discuss and understand your application to ensure its success. Our engineering services cover design and process guidance, optimization, and troubleshooting. Whether simple or complex, your Chemraz® parts are engineered for reliability and high performance.
- **Performance Testing** – We can test the performance of your Chemraz® parts for your specific application, and will work with you to create documentation to support process validation.

Our **Chemical Compatibility Guide** shows Chemraz®'s compatibility in more than 2,000 different media, and addresses the ability of the seal material to resist a contacting fluid and help you select the right Chemraz® compound for your application needs.

Contact Greene Tweed today to discuss how we can offer the right Chemraz® solution to meet your application challenges.

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