

COATED SEALING SOLUTIONS FOR SENSITIVE DRUGS



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Datwyler's state-of-the-art fluoropolymer spray coating, meets the highest demands for quality and performance for highly sensitive, large molecule drugs.

Datwyler's fluoropolymer spray coating technology is their response to the healthcare market's ever-increasing demands for better packaging solutions. Datwyler's coated components provide exceptional container closure integrity, lowest interaction potential, uncompromised quality, and outstanding machineability to biotech, traditional pharma, and generic products.

QUALITY

Datwyler's coated components are exclusively manufactured in facilities incorporating Datwyler's FirstLine standard. FirstLine is the most advanced manufacturing concept in the industry exceeding the most stringent quality standards

of the European and US regulatory authorities.

The entire operation is based on validated ultra-modern cleanroom technology, automated production cells, state-of-the-art equipment, and a unique validated washing process.

ENHANCED DRUG SAFETY

Datwyler's coating technology is a proprietary fluoropolymer coating providing full coverage of the entire product and eliminating the need for siliconization. It forms a strong barrier between the elastomer component and the drug, thus providing a superior protection against extractables. The coating has a strong repellent effect against any aqueous solutions, further minimizing the possibility for potential interactions.



All coated products are manufactured in facilities across three continents that operate under Datwyler's FirstLine® standard.

CONTAINER CLOSURE INTEGRITY

The combination of specific designs, long-time proven elastomeric substrates FM257 and FM457, and a uniform total coating, assure an excellent and robust container closure system.

MACHINEABILITY

Datwyler's coated components can be operated on all filling lines in either bulk or nested form. It is suitable for both vacuum placements or insertion tubes.

COATED ELASTOMER PLATFORMS FOR VIALS, PREFILLED SYRINGES, AND CARTRIDGES

Datwyler's coated sealing solutions are available in two platforms: OmniFlex stoppers for vials and NeoFlex plungers for prefilled syringes and cartridges. Both the stoppers and plungers are coated using the exact same spray coating technology, with 100% coverage of the component. Both the OmniFlex stoppers and NeoFlex plungers are compatible with most standard vials, syringes, and cartridges in the market.

PERFORMANCE

Datwyler's coated plungers show excellent breakaway and gliding forces even after lengthy storage terms, thus offering patients more comfort and safety during administration.

DESIGN FLEXIBILITY

This spray coating process is complex but also flexible, providing the opportunity for custom-designed parts to be coated while still meeting the requirements of innovative delivery devices.

For more information on OmniFlex stoppers, refer to the Sealing Solutions for Vial Applications brochure. For more information on the NeoFlex plungers, refer to the Sealing Solutions for Prefilled Syringe Applications and Sealing Solutions for Cartridge Applications brochures.

NeoFlex™ PLUNGERS



Dimension	0.5 ml	1 ml long	1–3 ml	3 ml
Application	Prefilled Syringe	Prefilled Syringe	Prefilled Syringe	Cartridge
Design	V9503	V9519	V9517	V9520
Compound	FM457	FM457	FM457	FM457

OmniFlex® STOPPERS



Dimension	13 mm	13 mm	13 mm
Application	Serum Vial	Lyo Vial	Lyo Vial
Design	V9401	V9402	HPP079
Compound	FM457	FM457	FM457

OmniFlex® STOPPERS



Dimension	20 mm	20 mm	20 mm	32 mm
Application	Serum Vial	Lyo Vial	Lyo Vial	Infusion Vial
Design	V9407	V9397	V9396	V9240
Compound	FM457	FM457	FM457	FM259

FLUOROPOLYMER SPRAY COATING KEY FEATURES

1. Proprietary, inert fluoropolymer spray coating
2. Total coverage trim edge included for all designs
3. Covalent bond to rubber
4. Barrier properties
5. Thin and flexible: $\approx 20 \mu\text{m}$
6. Low coefficient of friction, no siliconization needed

Datwyler is a leading specialist for system-critical elastomer components and a key player in the global healthcare market. Our state-of-the-art solutions for drug packaging and medical devices, build on over 100 years of experience.

Within our healthcare offering, we provide a unique range of products and services, including the most advanced elastomer formulations, coatings, aluminum seals, and processing technologies. With our global production footprint, we make an important contribution to our customers' reliable supply chain.

Partnering with the world's top pharmaceutical and medical companies, we are a vital link and stand by our mission to improve patients' lives.

Find out more about Datwyler's pharmaceutical and biotech solutions in other brochures:

Sealing Solutions for Healthcare
Product Portfolio
Sealing Solutions for Vials
Sealing Solutions for Prefilled Syringes
Sealing Solutions for Cartridges
FirstLine®
DuraCoat™ Combiseals
Packaging & Sterilization
Services
StarterPack™



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