COATED SEALING SOLUTIONS
FOR SENSITIVE 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.

NEOFLEX™ PLUNGERS

<table>
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<tr>
<th>Dimension</th>
<th>0.5 ml</th>
<th>1 ml long</th>
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<tr>
<td>Application</td>
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<td>Cartridge</td>
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<tr>
<td>Design</td>
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<td>V9519</td>
<td>V9517</td>
<td>V9520</td>
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<tr>
<td>Compound</td>
<td>FM457</td>
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OMNIFLEX™ STOPPERS

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<tr>
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OMNIFLEX™ STOPPERS

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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.

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: ≈ 20 µm
6. Low coefficient of friction, no siliconization needed
Datwyler Sealing Solutions is a leading industrial supplier and a key player in the global healthcare industry with a strong sense of future trends and the ability to set new standards. Datwyler offers state-of-the-art solutions for parenteral packaging with more than 100 years of multi-industry experience.

Partnering with the world’s top pharmaceutical and medical companies, Datwyler stands by its mission to improve patients’ lives by constantly striving for zero defects in all its products. The company’s state-of-the-art cleanroom manufacturing technologies exceed the most stringent industry requirements.

As a solution partner, Datwyler assists its customers in mastering the challenges of global healthcare and helps them act on opportunities of new and personal therapies.

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

Healthcare
Full Visual Product Portfolio
For Vials
For Prefilled Syringes
For Cartridges
FirstLine™
DuraCoat™ Combiseals
Packaging & Sterilization Services
StarterPack™

www.sealing.datwyler.com