

SEALING SOLUTIONS FOR **CARTRIDGES**



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Datwyler offers a comprehensive product portfolio and the most experience and knowledge in the cartridge applications industry.



Datwyler's components are compatible with a large variety of glass cartridges.

Datwyler delivers the highest level of innovation, quality, and safety in the industry.

Datwyler is the preferred solution partner to global pharmaceutical companies. The unique range of services and products includes the most innovative elastomer formulations, coatings, aluminum seals, and processing technologies.

In addition, Datwyler offers a comprehensive product portfolio and the most experience and knowledge in the cartridge applications industry, including solutions for dental treatments, insulin management, and other pharmaceutical and biotech therapies. To facilitate drug administration, Datwyler's priority is to provide its customers with a reliable and robust drug delivery solution compatible with all types of parenteral containers and devices.

DATWYLER'S COMMITMENT TO QUALITY

Datwyler's production standards are among the most advanced in the industry, assuring commitment to the highest level of quality. All Datwyler products are manufactured in the most advanced manufacturing environment, including ISO-standard cleanrooms incorporating state-of-the-art automated production cells, camera inspection capabilities, and a unique washing process.

Datwyler's worldwide operations stretch across three continents and include a total of seven production sites. Therefore, Datwyler can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.





Datwyler’s plungers offer an optimized extractables and leachables profile to secure the integrity and safety of the customer’s drug.



PLUNGERS FOR CARTRIDGES






Datwyler offers best-in-class packaging solutions compatible with all types of glass cartridges and secondary delivery devices in different nominal capacities and dimensions from 1 to 3 ml.

GUARANTEEING MULTIPLE PROTECTIONS FOR CUSTOMERS’ CARTRIDGE DELIVERY SYSTEMS

Datwyler’s plungers, a key component of cartridge delivery systems, can perform a wide variety of functions. They are made of specialized butyl-based formulations with all of the physical, chemical, and mechanical properties essential for the safe and easy administration of the drug product. A long-term contact between the drug and the rubber components places high demands on the compatibility profile of the seal. Therefore, Datwyler’s plungers are designed to offer an optimized extractables and leachables profile which prevents chemical reactions with the drug and secures the drug’s integrity and efficacy. Even after several years of storage, Plunger Barrel Seal Integrity (PBSI) is guaranteed.

When the plunger and combiseal components are integrated into the full delivery device, system functionality is imperative to ensure the treatment is delivered properly. Rigorous testing and extensive experience confirm that Datwyler’s plungers and combiseals are an effective packaging solution for cartridges.

PLUNGERS

					<div>NeoFlex™ </div>
Dimension ø	6.85 mm	8.65 mm	9.65–9.7 mm	9.65–9.7 mm	9.65–9.7 mm
Coated	–	–	–	–	Yes
Design	V4528	V9321	V9336	V9478	V9520
Compound	FM257 FM457	FM257 FM457	FM257 FM457	FM257 FM457	FM457 FM457

ø = nominal inner diameter of glass cylinder as for ISO13926-1

DATWYLER'S QUALITY PROMISE: SAFE AND EFFECTIVE DRUG PACKAGING



1 Highest chemical cleanliness to eliminate risks

Datwyler develops some of the most complex and unique elastomeric compounds and coatings in the industry, answering to the most stringent quality standards and regulatory requirements. As a result, Datwyler's innovative compounds provide some of the highest levels of chemical cleanliness and lowest extractable levels, eliminating any risk of drug contamination.

2 NeoFlex™ coated plungers for highly sensitive drugs

For sensitive drug packaging, Datwyler offers a range of NeoFlex plungers, utilizing Datwyler's proprietary fluoropolymer spray coating technology. Datwyler's spray coating technology is the first coating to both provide barrier properties and eliminate the closure as a source of silicone oil-based subvisible particles.

For more information about NeoFlex™ plungers, refer to the NeoFlex™ brochure.

3 Close collaboration as solution partner

Datwyler's team of experts supports customers in finding the right packaging solution for their product. Together, Datwyler co-engineers the functionality and design of its customers' products by utilizing industry expertise and engineering know-how.



Datwyler's production facilities operate under a zero-defect philosophy.

DATWYLER'S UNIQUE COMPONENTS MEET THE HIGHEST PRODUCTION STANDARDS

Datwyler offers state-of-the-art manufacturing processes and sets new industry standards. Through innovative process technologies and efficient production processes, Datwyler runs high-volume production lines with consistently high quality. The company's state-of-the-art facilities operate under a zero-defect philosophy and meet the most stringent industry requirements for the production of high-performance elastomer components. All facilities are fully automated and geared towards optimal manufacturing processes.

COMBISEALS FOR CARTRIDGES

Datwyler offers the most advanced combiseal components to meet the multiple challenges of cartridge closures. Thanks to its industry expertise and engineering know-how, Datwyler provides its customers with the best possible solution for their application.

In combination with plungers, Datwyler's rubber-lined aluminum combiseals ensure the system integrity of the cartridge.

GUARANTEEING SUPERIOR PROTECTION FOR CARTRIDGE DELIVERY SYSTEMS

Datwyler components are multi-functional – even after multiple piercings with pen needles, its combiseals maintain the integrity of the seal, while ensuring the lowest possible extractables and leachables profile for the application. For superior usability and a high resilience, Datwyler's combiseals feature a dual compound elastomeric liner inside the aluminum cap.

ADVANCED AND FirstLine® PRODUCTION

Datwyler's Advanced manufacturing standard incorporates best-in-class production technologies matching the quality and regulatory expectations of the pharma markets. The innovative standard, FirstLine, is specially designed to manufacture pharmaceutical rubber components for high-end pharma and biotech markets in a fully integrated cleanroom environment conforming to the highest industry standards. The process flow, gowning protocols, personnel and material flow, as well as state-of-the-art automation processes, all result in the lowest endotoxin, bioburden, particulate, and defect levels available in the industry.

Datwyler offers the most advanced combiseal solutions to meet the multiple challenges of cartridge closures. In combination with plungers, Datwyler's rubber-lined aluminum combiseals ensure the system integrity of the cartridge.

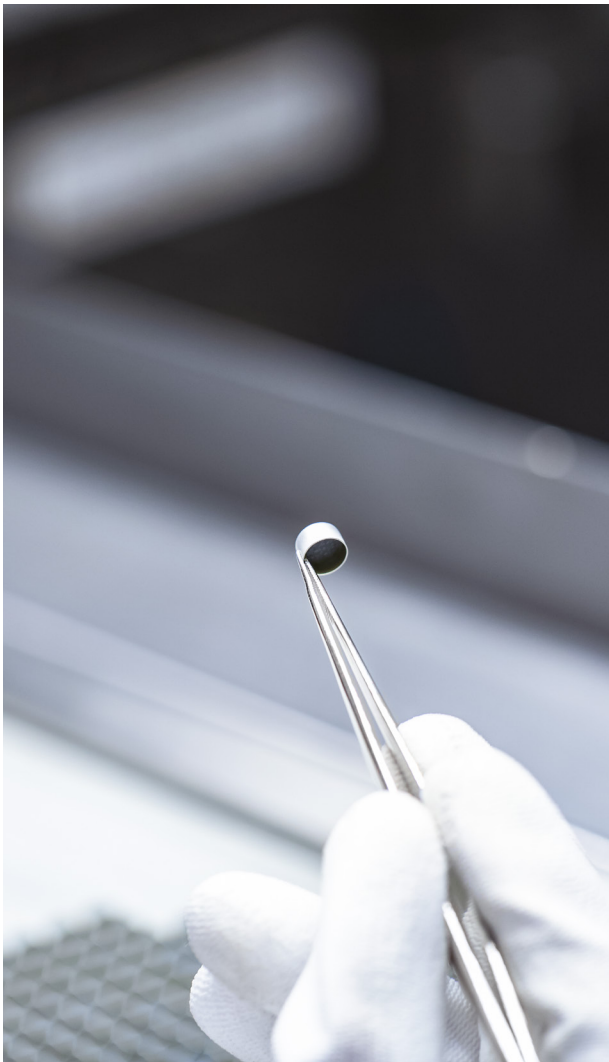


Datwyler's combiseals are available with mono and dual compound elastomeric liner inside the aluminum cap to meet different market needs.


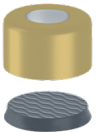

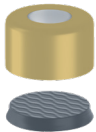

DuraCoat™ COMBISEALS

Datwyler is constantly striving for improvements of its products and processes. The company has developed the next generation in aluminum lamination. This proprietary material, applied to standard aluminum seals, is designed to meet the most stringent requirements for customers and authorities.

- **Highest quality materials:**
Datwyler’s laminated aluminum combines a high-quality alloy with a protective laminate, giving Datwyler’s customers a higher-quality end product
- **A clear reduction in particles:**
An overall reduction in particles generated during manufacturing due to the protective lamination
- **Less abrasion than standard aluminum seals:**
Laminated aluminum provides a protective barrier to external forces, reducing the risk of abrasion during manufacturing and handling
- **Flawless processability:**
A laminated aluminum seal has been proven to run effectively on standard manufacturing lines
- **Robust testing:**
A full suite of tests has been completed to ensure effectiveness and functionality of the laminated aluminum



Datwyler’s next generation aluminum lamination, is designed to meet the most stringent requirements for customers and authorities.

	DuraCoat™				
					
COMBISEALS					
Dimension	From 1 ml to 3 ml	From 1 ml to 3 ml	From 1 ml to 3 ml	From 1 ml to 3 ml	From 1 ml to 3 ml
Type	Bi-layer	Mono-layer	Bi-layer	Mono-layer	Bi-layer
Design	ACS0001	ACS0002	ACS0003	ACS0004	ACS0006
Compound	FM257 + H1-7-207 FM457 + H1-7-207	FM257 FM457	FM257 + H1-7-207 FM457 + H1-7-207	FM257 FM457	H5-23-5 + H1-7-207 FM457 + H1-7-207 FM257 + H1-7-207

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:

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



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