

SEALING SOLUTIONS FOR **VIALS**



SEALING SOLUTIONS FOR VIALS

Datwyler's complete system solutions ensure drug and packaging stability, compatibility, and container closure integrity.



Datwyler's vial closures ensure drug and packaging stability.

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

Datwyler is the preferred solution partner to global pharmaceutical companies. Its unique range of products and services includes the most innovative elastomer formulations, coatings, aluminum seals, and processing technologies. Datwyler also offers one of the most extensive product portfolios for vial applications in the present pharmaceutical and biotech markets worldwide.

Datwyler's experience, knowledge, and engineering expertise translates into:

- Elastomeric closures and aluminum seals for traditional pharma and biotech solutions
- High compatibility with all types of small and large volume parenteral containers

As a result, Datwyler provides a complete solution which ensures drug and packaging stability and container closure integrity, maximizing the overall product compatibility.

DATWYLER'S COMMITMENT TO QUALITY

Datwyler products are manufactured in the most advanced production environment, including ISO-standard cleanrooms incorporating state-of-the-art automated production cells, fully automated camera inspection, and a unique washing process. Datwyler's worldwide operations stretch across three continents and include a total of seven production sites. Therefore, the company can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.



ELASTOMERIC CLOSURES – HIGHEST PURITY AND SAFETY

Datwyler offers best-in-class packaging solutions for the pharmaceutical and biotech markets. To ensure patient safety, the priority is to deliver safe and effective sealing solutions for drug packaging to its customers.

DATWYLER IS THE SOLUTION PARTNER TO ITS CUSTOMERS

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

Datwyler's experts for material science and processing technology develop some of the most complex and unique elastomeric compounds and coatings in the industry, always answering to the most stringent quality standards and regulatory requirements. Datwyler's industry know-how enables its customers to safely and securely package sensitive drugs without compromising their efficacy.

The company's most complex elastomer components are coated with a proprietary fluoropolymer spray coating, preventing any unwanted drug interactions. Datwyler's fluoropolymer spray coating provides barrier properties and eliminates the closure as a source of silicone oil-based subvisible particles. It is a proven fluoropolymer coating technology addressing the compatibility and performance challenges of the biologics industry and beyond. Datwyler's coated vial stoppers are part of the OmniFlex stopper platform, with a variety of dimensions and sizes. When combined with its FM457 compound, Datwyler's OmniFlex stoppers provide its customers with the highest-quality sealing technology for the pharmaceutical and biotech markets.

DATWYLER'S QUALITY PROMISE: SAFE AND EFFECTIVE DRUG PACKAGING

Datwyler'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 highly automated and geared towards optimal manufacturing processes.

SEVERAL OPTIONS AND AVAILABILITIES FOR EACH PRODUCT

- Production flexibility: products can be manufactured in line with Datwyler's Advanced or FirstLine production standard
- All products are available in ready-for-sterilization (RFS) and ready-to-use (RTU), both in standard bags and Rapid Transfer Port bags
- Steam sterilization and gamma irradiation are viable options

For more information, see the brochure **Packaging and Sterilization**.

ADVANCED AND FirstLine® PRODUCTION

Datwyler's Advanced manufacturing standard incorporates best-in-class production technologies matching the quality and regulatory expectations of the pharmaceutical markets. The company's most advanced manufacturing 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 has an experienced system approach considering all critical aspects for its customers to make the right decision when it comes to primary packaging.

SERUM*						
	Dimension	13 mm	13 mm	20 mm	20 mm	
	Type	–	–	–	–	
	Coated	–	Yes	–	Yes	
	Design	V9024	V9401	V9025	V9407	
Compound	FM140 FM257 FM457	FM457	FM140 FM257 FM457	FM457		
LYO						
	Dimension	13 mm	13 mm	13 mm	13 mm	
	Type	Igloo	Igloo	2-Leg	2-Leg	
	Coated	–	Yes	–	Yes	
	Design	V9250	V9402	HPP002	HPP079	
Compound	FM140 FM257 FM457 FM460	FM457	FM140 FM257 FM457 FM460	FM457		
LYO						
	Dimension	20 mm	20 mm	20 mm	20 mm	32 mm
	Type	Igloo	Igloo	2-Leg	2-Leg	4-Leg
	Coated	–	Yes	–	Yes	–
	Design	V9172	V9397	V9154	V9396	V9262
Compound	FM140 FM257 FM457 FM460	FM457	FM140 FM257 FM457 FM460	FM457	FM140 FM257 FM457 FM460	
INFUSION						
	Dimension	29 mm	32 mm	32 mm	32 mm	
	Type	–	DIN	ISO	ISO	
	Coated	–	–	–	Yes	
	Design	5294	V9003	V9240	V9240	
Compound	FM140 FM257 FM457	FM140 FM257 FM457	FM140 FM257 FM457	FM259		

*Serum stoppers: available in blowback and non-blowback designs; please contact Datwyler’s applications experts for further details.



Datwyler's packaging solutions guarantee the highest degree of quality and reliability.

ALUMINUM SEALS

With more than four decades of experience as a market leader in parenteral packaging, Datwyler understands the customers' need for product protection, manufacturing efficiency, and patient safety.

Produced, controlled, and tested under the industry's most stringent conditions, Datwyler's aluminum-plastic sealing solutions guarantee the highest degree of quality and reliability. Datwyler's seals are manufactured using best-in-class alloy and plastic polymers to provide the cleanest and safest solutions to its customers. The company's Center of Excellence in Germany ensures that its products meet all global standards and is continuously improving the manufacturing process to develop the most innovative sealing solutions.

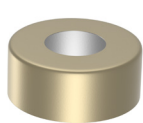
The goal is to improve customers' manufacturing efficiency and operational excellence, provide specialized solutions for the pharma and biotech markets, and develop customized options for market differentiation.

Datwyler's global team of cross-functional experts is aware of the challenges that customers are facing in their respective fields. Datwyler has an experienced system approach considering all critical aspects for its customers to make the right decision when it comes to parenteral packaging.

Datwyler's product portfolio offers a broad range of brands and solutions for the pharmaceutical and biotech markets, including the company's high-performance PrimeCaps.

STANDARD CAPS

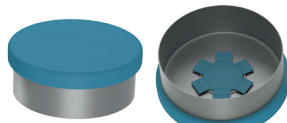
Datwyler offers a range of solutions to meet the specific needs of the global market:



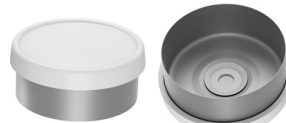
Aluminum Hole Cap



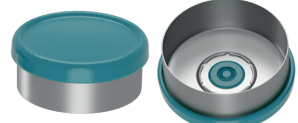
Pull Off Cap



Finger Design



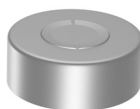
Scoreline Design



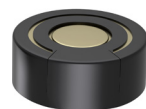
Bridge Design



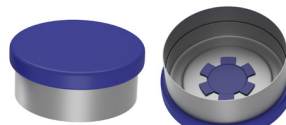
Scoreline Tear Off



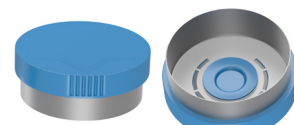
Center Tear Off



Double Tear Off



Universal Tear Off



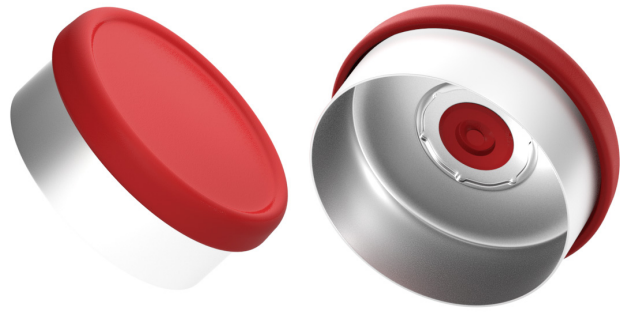
Flip Tear Off

PrimeCaps™

The company's solution dedicated to customers looking for flawless machineability on high speed filling lines.

PrimeCaps' advantages include:

- International operations to meet the customers' global supply needs
- Highest quality alloy
- Available in 13 and 20 mm in five standard aluminum colors
- Center-gated disc for enhanced machinability, available in 40 standard colors, matte and glossy
- Optimized design: straight skirt edge (Accurim)
- Available in standard and flush configurations
- Camera inspection
- Low bioburden and particulate levels
- CCI match with Datwyler's elastomer products
- Available in RFS/RTU/Rapid Transfer Port bags



PrimeCaps™ are Datwyler's high-performance solution for the specific needs of the pharma and biotech markets.

LARGE ADVANTAGES FOR SMALL COMPONENTS



1 Manufacturing efficiency and operational excellence

- Optimized design processes on all standard capping equipment
- Guarantee of proper inspection and sorting of the products
- Proven capping solutions meeting process and market needs



2 Dedicated technology for market-specific requirements

- High-quality manufacturing processes exceed industry and regulatory expectations
- Reduction of bioburden and particulate levels
- Fully-validated system approach to ensure container closure integrity



3 Customized options for market differentiation

- Range of standard dimensions available to meet customer needs
- Customized aluminum branding available to differentiate final packaging from competitors
- Design features to alert end users of drug specific requirements

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 Prefilled Syringes

Sealing Solutions for Cartridges
FirstLine®

Coated Sealing Solutions

DuraCoat™ Combiseals

Packaging & Sterilization

Services

StarterPack™



www.datwyler.com

December 2021

The information contained in this brochure is for general information purposes only. Datwyler assumes no responsibility for errors or omissions in the contents of the brochure. In no event shall Datwyler be liable for any special, direct, indirect, consequential, or incidental damages or any damages whatsoever, whether in an action of contract, negligence or other tort, arising out of or in connection with the use of the contents of the brochure. Datwyler reserves the right to make additions, deletions, or modification to the contents of the brochure at any time without prior notice. All IP and all trademarks mentioned herein are the property of their respective owners. Photos: Scanderbeg Sauer, Scott Witalis, Studio Frog

