



Sealing Solutions
for Vials

Sealing Solutions for Vials

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



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

Datwyler is the preferred partner to global pharmaceutical companies. With a complete offering of products, technologies, and services, Datwyler meets the customers' needs for parenteral packaging.

Rubber Stoppers and Aluminum Caps for Vials

Produced, controlled, and tested under the industry's most stringent conditions, Datwyler's rubber stoppers and aluminum caps solutions guarantee the highest degree of quality and reliability for a wide range of pharmaceutical and biotech applications.

Datwyler's experience and engineering expertise translates into a complete solution suitable for all types of vial containers. It ensures sterility and stability of drugs while maximizing operational performance.

Global Production Footprint

Datwyler's worldwide operations stretch across three continents and include a total of eight production sites and guarantees consistent quality standards on a global level. Therefore, the company can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.



Datwyler has an experienced system approach considering all critical aspects of its customers to make the right decision when it comes to primary packaging.

Rubber Stoppers

Broad Range of Clean Compounds

Datwyler's experts for material science and processing technology develop some of the most complex and unique elastomeric compounds 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. For sensitive drugs with compatibility challenges, such as biologics, the use of coated stoppers contributes to better performance. Our complementary coating solutions allow to answer any customer challenge.

Datwyler's Commitment to Quality

Datwyler's 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. Rubber stoppers can be manufactured in line with Datwyler's Advanced or FirstLine production standard. Datwyler's Advanced manufacturing standard incorporates best-in-class production technologies matching the quality and regulatory expectations of the pharmaceutical markets.

For more information, see the brochure Packaging and Sterilization.



Our FirstLine standard provide the highest level of innovation, quality and safety in the elastomeric pharma industry.

FirstLine manufacturing concept incorporates state-of-the-art automation and 100% camera inspection, resulting in exceptional quality that exceeds industry standards with best-in-class particle level specifications. It also results in significantly lower bioburden and endotoxin levels compared to a standard quality level.

Stoppers Designed to Answer Parenteral Drugs Challenges

Our extensive industry experience and engineering expertise have enabled us to develop best-in-class rubber stoppers that meet both functionality and design requirements. These products ensure operational efficiency and provide a reliable seal on containers, preserving their closure integrity.

Several Options and Availabilities for each Product

All products are available Ready-For-Sterilization (RFS) and Ready-To-Use (RTU), both in standard bags and Rapid Transfer Port bags. Both Steam and Gamma sterilization technologies are available for RTU configurations.

OmniFlex®

Backed by over 25 years of proven performance, OmniFlex® is Datwyler's unique solution to meet the highest demands for quality and performance for highly sensitive, large molecule drugs in vials. The combination of our low extractable Bromobutyl rubber FM457 and a fluoropolymer coating forms a barrier to obtain the lowest level of extractables and leachables.

Datwyler's proprietary spray coating technology allows for total coverage of the stopper, eliminating the use for surface silicone, resulting in better chemical compatibility and greater cleanliness due to a vast reduction of subvisible particles. Furthermore, the characteristics of fully coated stoppers and optimized stopper designs prevent them from sticking to the shelf, making them the optimal solution for lyophilization processes.

Manufactured in our FirstLine® facilities and 100% camera inspected these components ensure the lowest level of visual defects, bioburden, endotoxin and particulate contamination. With OmniFlex® you opt for peace of mind during your drug development phase with optimal time-to-market and rest assured of your brand reputation through enhanced patient safety.

For more information, see the OmniFlex® Leaflet.



STOPPERS

SERUM
13 mm

non-blowback

OmniFlex®

blowback

OmniFlex®

Coated

Design

Compound

LYO
13 mm

igloo

OmniFlex®

2-leg

OmniFlex®

Coated

Design

Compound

SERUM
20 mm

non-blowback

OmniFlex®

blowback

OmniFlex®

Coated

Design

Compound

LYO
20 mm

igloo

OmniFlex®

2-leg

OmniFlex®

Coated

Design

Compound

INFUSION
32 mm

DIN

ISO

OmniFlex®

Coated

Design

Compound



Aluminum Caps

Manufacturing Efficiency and Operational Excellence

Datwyler is committed to providing our customers with the highest quality caps possible. Our cutting-edge manufacturing facilities are equipped with the latest automation technology and staffed by a team of experienced professionals. This enables us to manufacture aluminum caps that meet the most stringent industry standards. Furthermore, our state-of-the-art equipment, with its high level of automation, significantly reduces bioburden and particulate levels throughout the entire manufacturing process.

Tightened Control for Most Stringent Requirements

Datwyler guarantees that every product leaving our facility adheres to, or even exceeds, your specifications. We have implemented a fully automated camera inspection system that meticulously sorts assembled products, ensuring high-performing caps.

Every batch is subjected to a comprehensive inspection, including visual (detecting defects), dimensional (verifying exact height), and functional (ensuring appropriate opening force) checks.

Wide Range of Cap Designs

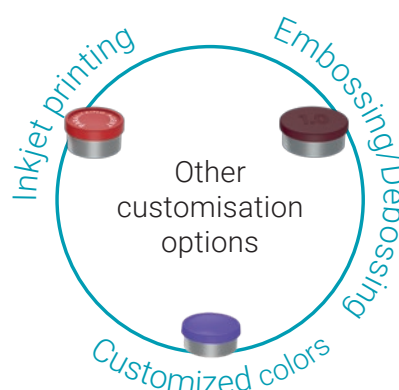
To meet the specific needs of the market, Datwyler offers one of the most extensive product portfolios of caps for vial applications. It includes a variety of flip caps, designed to enhance safety by protecting the piercing area against microbiological and particulate contamination and increasing tamper evidence. We also provide a comprehensive range of all-aluminum cap design to address specific needs and support primary care for human or animal health.

Several Options and Availabilities for Each Products

All products are available Ready-For-Sterilization (RFS) and Ready-To-Use (RTU), both in standard bags and Rapid Trasfer Port bags. Gamma sterilized by a validated gamma irradiation process. Guaranteed sterile with a Sterility Assurance Level (SAL) of 10⁻⁶.

Customized Options

Datwyler offer large possibility to customize your caps for better market differentiation, mix-up prevention and anti-counterfeit:



PrimeCap™

Datwyler's PrimeCaps™ are the industry's leading solution for parenteral packaging, using best-in-class alloy and plastic polymers. Accurim technology & state-of-the-art operational standards results in flawless machineability on high-speed filling lines and proper container closure integrity with minimized reject levels and superior end-user experience.

Availability across different manufacturing sites and standardized dimensions allow for a local supply and supports interchangeability.

CAPS

13 mm

PrimeCaps™



FBC13.0001

20 mm

PrimeCaps™



FBC20.0001



BIO-BASED
POLYPROPYLENE FLIP CAP

STANDARD FLIP-OFF CAP



SFC13.0016



SFC20.0020



SFC32.0001
Compatible with
V9003 stopper



SFC32.0002
Compatible with
V9240 stopper

TOTAL TEAR OFF CAP



UTO20.0017
Flip Tear



UTO20.0022



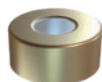
UTO32.0015

ALUMINUM HOLE CAP

13 mm

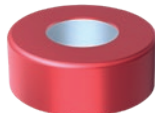


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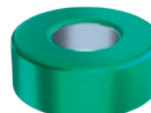


AHC13.0016
US Market

20 mm

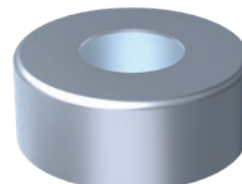


AHC20.0004



AHC20.0001
US Market

32 mm



AHC32.0009

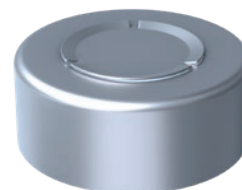
CENTER TEAR OFF CAP



CTO13.0006



CTO20.0010

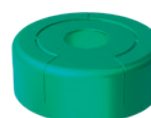


CTO32.0009

TOTAL TEAR OFF CAP



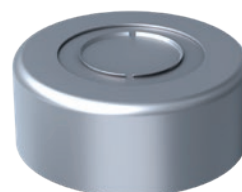
STO20.0004



STO20.0035
US Market



DTO20.0001



DTO32.0002

CUSTOMIZED OPTIONS

WIDE VARIETY OF ALUMINUM AND PLASTIC COLORS - INKJET PRINTING - EMBOSSING/DEBOSSING

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.



healthcare.datwyler.com