

# SEALING SOLUTIONS FOR **PREFILLED SYRINGES**



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Datwyler offers the highest-quality portfolio of prefilled syringe components.



Datwyler's prefilled syringe components are compatible with all standard prefilled syringes on the market.

Offering a range of sizes, Datwyler's prefilled syringe components are the ideal solution for a variety of therapeutic needs.

**Datwyler has the widest product portfolio and the most experience and knowledge in the industry for prefilled syringe applications:**

- Primary packaging for traditional pharmaceutical and biotech markets
- Compatible with a large variety of parenteral containers available in the market

Therefore, Datwyler is able to provide a complete solution that ensures drug and packaging stability and compatibility and results in container closure integrity.

## DATWYLER'S COMMITMENT TO QUALITY

The company'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. Datwyler can provide its customers with flexible supply chains to improve time-to-market and risk mitigation plans to ensure business continuity.





Datwyler's choice of plungers provides customers with a robust delivery system.





PLUNGERS FOR PREFILLED SYRINGES

Datwyler offers best-in-class packaging solutions for a variety of syringe types and drug classes, including anticoagulant, vaccine, ophthalmic, and biotech solutions. The goal is to provide customers with a robust delivery system compatible with all types of prefilled syringes and secondary delivery devices and to provide a state-of-the-art manufacturing experience.






Datwyler’s capabilities include the production of plungers for standard 0.5 ml to 10 ml prefilled syringes and the design and production of customized plungers with sizes from 0.5 ml to up to 50 ml. The range of plungers is also compatible with a number of secondary delivery devices on the market, including auto-injectors. All products meet the requirements specified in the ISO standard 11040-5.

Datwyler’s multiple years of experience as a manufacturer and sealing solutions supplier has enabled them to implement advanced manufacturing processes to help the company to meet its customers’ product requirements. With FirstLine, the company’s highest-quality manufacturing standard, Datwyler can also support customers with individualized packaging solutions or small batch packaging to meet their needs for drug development and clinical trials.

PLUNGERS

				
Dimension	0.5 ml	0.5 ml	1 ml long	1 ml long
Coated	–	Yes	–	Yes
Design	V9315	V9503	V9283	V9519
Compound	FM257 FM457	FM457	FM257 FM457	FM457

PLUNGERS

					
Dimension	1–3 ml	1–3 ml	1–3 ml	5 ml	10 ml
Coated	–	–	Yes	–	–
Design	V9258	V9531	V9517	V9319	V9344
Compound	FM257 FM457	FM257 FM457	FM457	FM257 FM457	FM257 FM457

## OFFERS A ROBUST PACKAGING SOLUTION

Datwyler's range of plungers offers a robust packaging solution for the prefilled syringe market. Using only the highest-quality materials and coating technologies, Datwyler's line of plungers is proven to be safe and effective during use. As experts in material science, Datwyler has developed the most innovative, clean elastomeric compounds used in plunger manufacturing. Developing proprietary compounds, such as FM257 and FM457, has allowed Datwyler to grow its product portfolio to meet a wide range of customer needs.

With its fluoropolymer spray coating technology, Datwyler contributes to a reduction in overall particles. The proprietary coating provides a protective barrier to external contaminants, prohibiting leachables from entering the product and ensuring a contact-safe surface that is compatible with the drug.

Datwyler's coated prefilled syringe plungers are part of the NeoFlex plunger platform, with sizes ranging from 0.5ml to 3ml. Compatible with all types of prefilled syringes, Datwyler's vast selection of plungers guarantees its customers the ideal type for their drug product needs. Datwyler's team of experts provides the support needed to ensure the appropriate product has been selected, issuing a variety of internal tests to confirm drug product compatibility and stability.

## Datwyler's quality promise to meet its customers' drug product needs is based on:

- A zero-defect philosophy
- A state-of-the-art manufacturing experience
- Best-in-class manufacturing standards: Advanced or FirstLine

### 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 has the research and development capabilities to partner with even the most specialized drug developers. As experts in material science, the company provides the support needed to ensure the appropriate product has been selected, issuing a variety of internal tests to confirm drug product and primary packaging stability.



Datwyler's rigid needle shield is a high-quality protective solution to ensure needle preservation and an easier and intuitive removal, reducing the risk of damaging the needle point.

**DATWYLER'S FM30  
RIGID NEEDLE SHIELDS**

Datwyler's premium needle shields compound, FM30, is the preferred solution for its prefilled syringe customers. Datwyler's FM30 rigid needle shields, available in **½ inch**, provide the necessary protection to both the needle during manufacturing and the end-user during handling. Compatible with EtO sterilization, Datwyler's rigid needle shields **is** a best-in-class offering for prefilled syringes.

**DATWYLER'S NEEDLE SHIELDS AND TIP CAPS  
FOR PREFILLED SYRINGES**

Using elastomeric compounds specifically designed for prefilled syringe solutions, Datwyler's syringe closures provide a sterile barrier for its customers' drug product while also protecting the needle from external forces. The line of needle shields and tip caps is designed to provide a safe and effective experience during manufacturing and handling of prefilled syringes.

**PROVIDING A SAFE AND EFFECTIVE SEALING SOLUTION**

Datwyler's range of needle shields and tip caps provides barrier properties to ensure maximum container closure integrity. Both the soft and rigid needle shields protect pre-attached needles from damage during manufacturing, filling, and distribution. Additionally, the rigid needle shields help reduce needle stick injuries during handling in the field. All products are compatible with all types of prefilled syringes.

**SOFT NEEDLE  
SHIELDS**

Dimension	½"	⅝"
Coating	–	–
Design	V6544	V6556
Compound	FM27 FM30	FM30



**RIGID NEEDLE  
SHIELDS**

Dimension	½"	⅝"
Coating	–	–
Design	V9812	V9813
Compound	FM27 FM30	FM30



**TIP CAPS**

	Ribbed	Mushroom
Coating	–	–
Design	V9406	V9257
Compound	FM27 FM30 FM257	FM27 FM30 FM257





## OPTIONS AND AVAILABILITIES

Due to the high production flexibility in its facilities, Datwyler is able to offer its components and applications in various options and availabilities:

- All plungers can be manufactured in line with Advanced or FirstLine production standard and are available in ready-for-sterilization (RFS) and ready-to-use (RTU) packaging, both in standard bags and Rapid Transfer Port bags
- All needle shields and tip caps are available in ready-for-sterilization (RFS) packaging
- The range of plungers is compatible with steam sterilization and gamma irradiation
- All needle shields and tip caps are compatible with ethylene oxide (EtO) sterilization

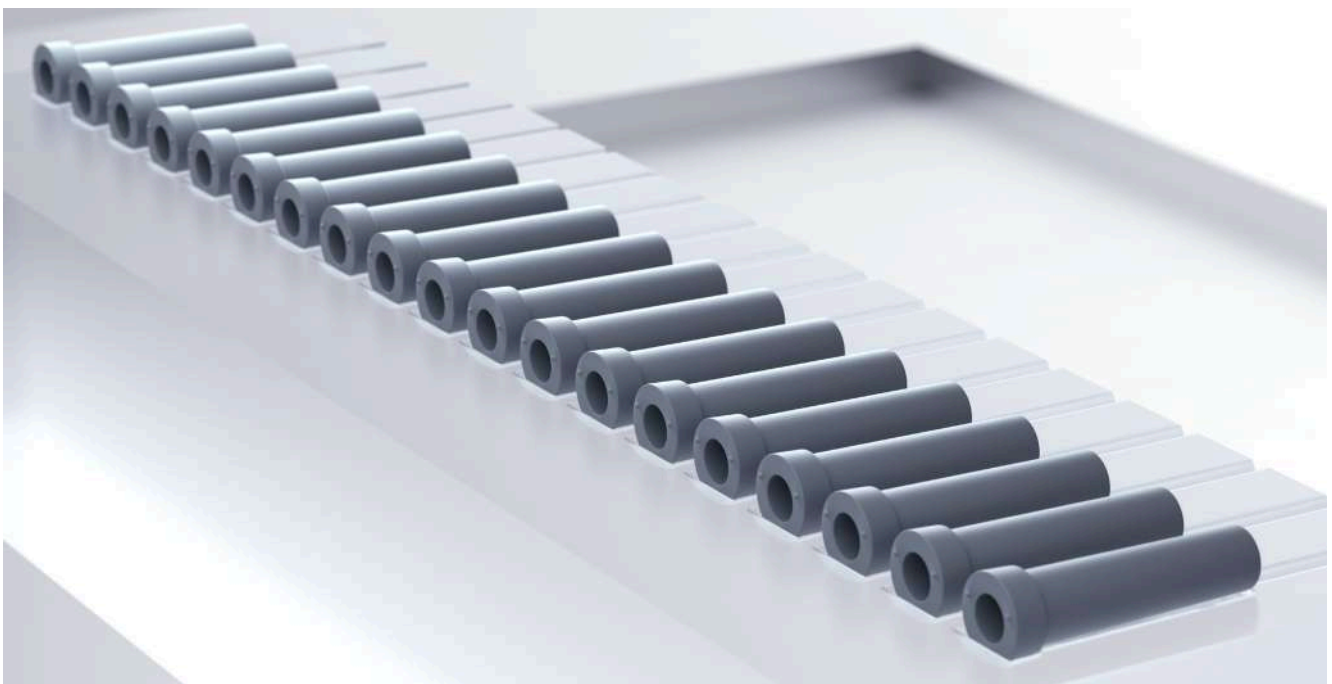
**For more information, see the brochure *Packaging and Sterilization*.**

## THE MOST INNOVATIVE SEALING SOLUTIONS ON THE MARKET

Datwyler's plungers, needle shields, and tip caps are used in prefilled syringe applications for the most common therapeutical purposes, including anticoagulants, vaccines, and biotech therapies. The applications represent highly effective solutions for these purposes and also offer market opportunities for new therapies.

Datwyler has the research and development capabilities to partner with even the most specialized drug developers and cultivate new and improved ways of integrating its products with emerging drug technologies. The company strives to offer the most innovative sealing solutions on the market.

Datwyler's range of needle shields and tip caps is designed to provide a safe and effective experience during filling and handling of the prefilled syringes.



**Datwyler's soft and rigid needle shields protect pre-attached needles from damage during manufacturing, filling, and distribution.**

**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 Cartridges  
FirstLine®  
Coated Sealing Solutions  
DuraCoat™ Combiseals  
Packaging & Sterilization  
Services  
StarterPack™



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