



# Datwyler Sealing Solutions


The correct selection of rubber closures for parenteral applications.

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## **Presentation content:**

- General introduction
  - Our foundations in Healthcare
  - Our complete offering for Parenteral Packaging
- 

# General introduction

# Who we are

Datwyler Sealing Solutions is a **Swiss-based, leading supplier** and a key player in the global healthcare industry. We offer state-of-the-art solutions for **drug packaging and medical devices**. Our **unique range of services and products** includes the most advanced elastomer formulations, coatings, aluminum seals, and processing technologies.



# Our Values



# Multi-industry experience



## HEALTHCARE

### Applications:

- Parenteral drug packaging solutions
- Elastomeric closures and aluminum seals
- Medical devices



## AUTOMOTIVE

### Applications:

- Brake systems
- Fuel and tank systems
- Exhaust gas treatment
- Powertrain, suspension
- Thermoplasts and LSR
- E-Mobility, electrification



## GENERAL INDUSTRY

### Applications:

- Consumer Goods
- Civil Engineering
- Oil & Gas
- Power tools, valves & fittings
- Machines for process industries
- Water and waste water
- Hydraulic and pneumatic

# Healthcare facts and figures

**2000**

talents globally

7000 of parent company

**600**

customers in  
65 countries

**50**

years of experience

100 years of parent company

**16**

billion components  
every year

**7**

facilities on three  
continents

**400**

million CHF revenue

1,4 billion CHF of parent company

# Our key agenda in Healthcare



## PATIENT SAFETY

We prioritize patient safety, constantly striving for **zero defects**.



## GLOBAL LEADERSHIP

We assist our customers in mastering the challenges of **global healthcare**.



## FUTURE HEALTH

We help our customers act on opportunities of new therapies and **personal therapies**.





# Our foundations in Healthcare

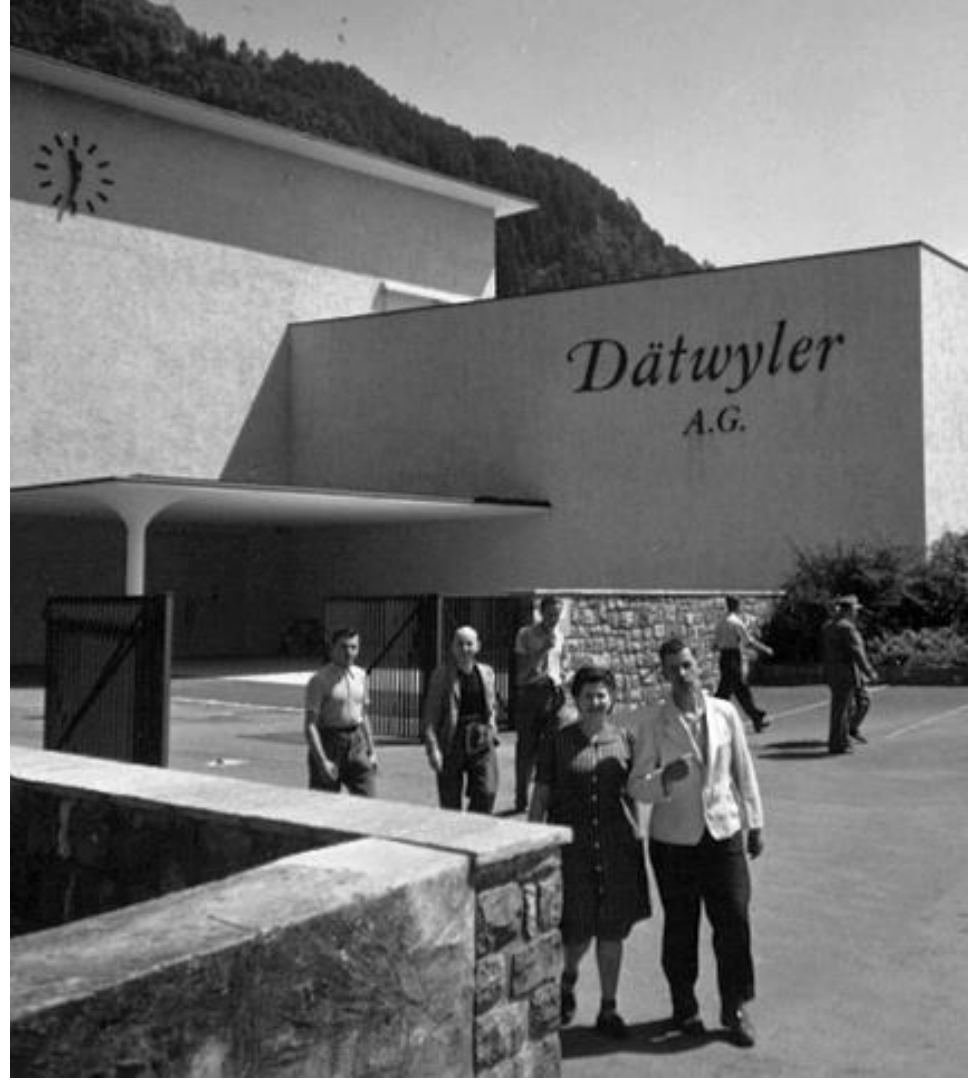
# Our foundations in Healthcare

- Leadership in sealing solutions for Healthcare
- Customer centric approach
- Global production footprint
- Zero defect philosophy
- Quality by design
- Material and engineering expertise

# Leadership in sealing solutions for Healthcare

With **50 years of experience** in the pharmaceutical and medical industry\*, our **product knowledge** and **service expertise** helps to make Datwyler a **market leader for sealing solutions**.

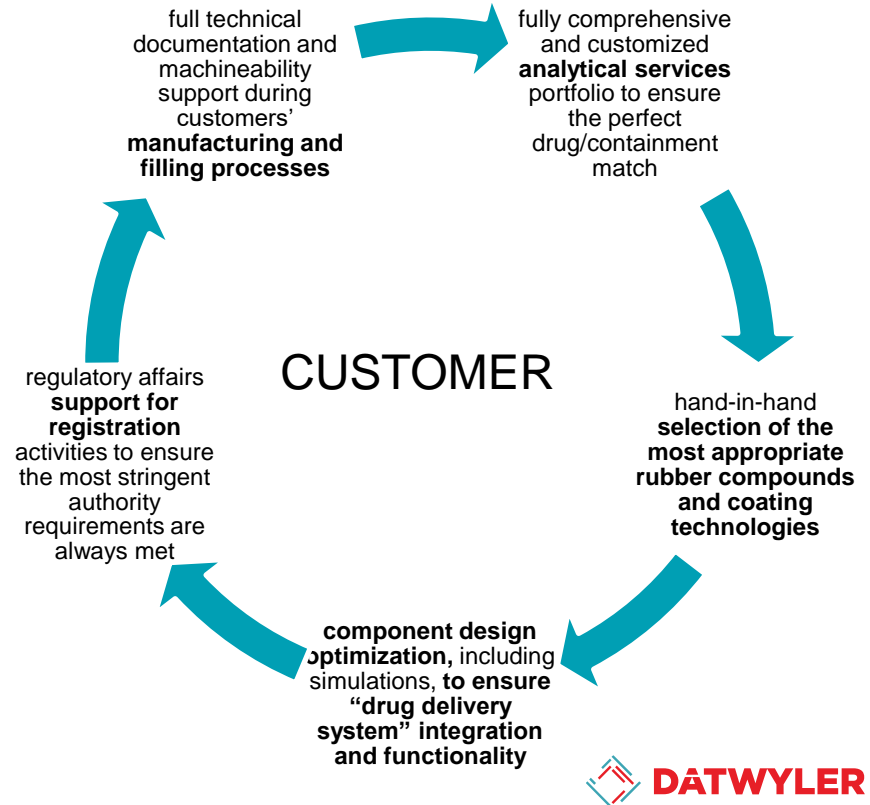
Our efforts to constantly improve allows us to continually expand our **innovative portfolio of products and services** and keep our customers at the **forefront of technological advancement** in our industry.



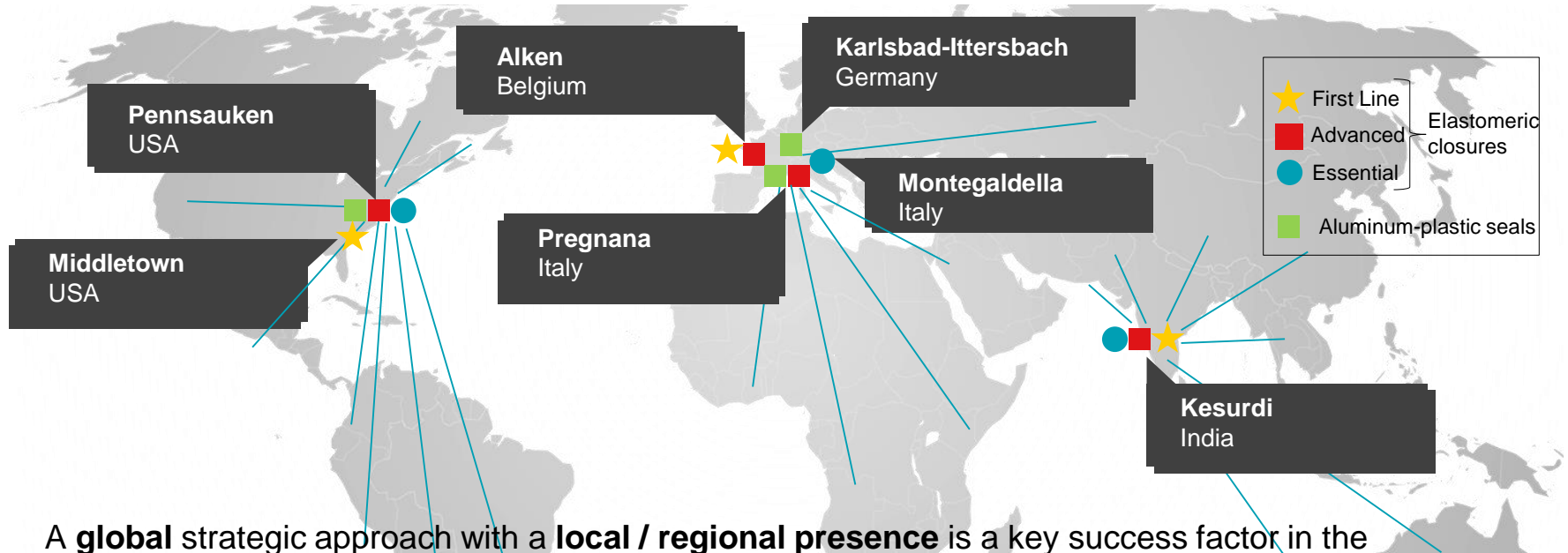
# Customer centric approach

Our **global multidisciplinary team of experts** can offer **unique support to the Customer**: from drug development, through production challenges, to commercial launch and ramp-up.

At Datwyler, we have an experienced **holistic approach** considering all critical aspects for our customers.



# Global production footprint



A **global** strategic approach with a **local / regional presence** is a key success factor in the **pharmaceutical** market. **Datwyler's manufacturing set-up** guarantees identical quality standards on a global level. We meet our customers' needs for **flexible supply chains** and **risk mitigation plans** in order to ensure business continuity.

# Best-in-class production technologies

## ADVANCED

the **proven and reliable solution** matching the quality and regulatory expectations for **pharmaceutical** applications

Controlled particulate cleanliness

Bioburden:  $\leq 2$  or  $\leq 5$  CFU/product

Endotoxins:  $\leq 1$  or  $\leq 2.5$  EU/product

Washing log 3 reduction in endotoxins

Siliconization target levels

## FIRST LINE

the **highest level** of innovation, quality and safety in the elastomeric pharma industry, designed for **high end pharmaceutical and biotech** applications

State-of-the-art **100% camera inspection\***

**Best-in-class** particulate cleanliness

Bioburden:  $\leq 0.05$  CFU/cm<sup>2</sup>  
(4 times lower than Advanced for 20mm Serum Stopper)

Endotoxins:  $\leq 0.02$  EU/cm<sup>2</sup>  
(5 times lower than Advanced for 20mm Serum Stopper)

Washing **log 5 to 6** reduction in endotoxins\*\*

Siliconization **specification** levels\*\*\*

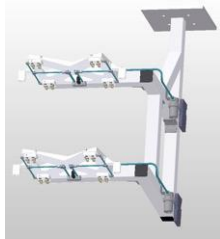
# The Manufacturing process of Rubber closures

# ELASTOMERIC MANUFACTURING PROCESS

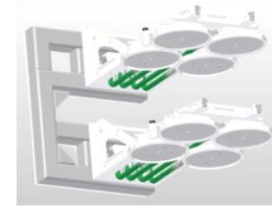
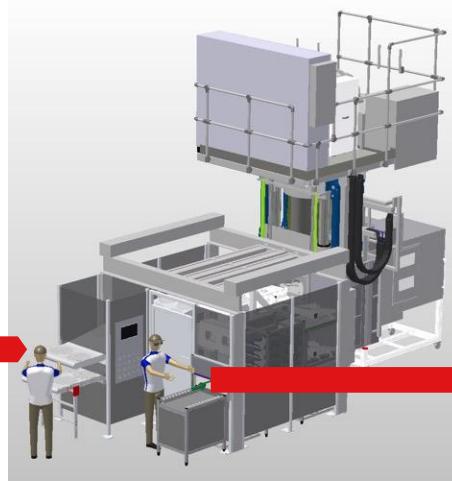




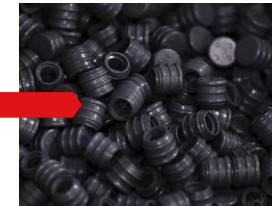
# STATE OF THE ART AUTOMATION



Loading manipulator



Unloading manipulator



<p><b>PROCESS CHANGE</b></p>	<p>Reduced operator handling</p>	<p>Automated spraying of mold release</p>	<p>Automated demolding</p>
<p><b>ZERO DEFECT IMPACT</b></p>	<p>Reduced risk for foreign material / biological contamination</p>	<p>Reduced risk for non-fills, embedded defects</p>	<p>Reduced risk for tearing / rubber particle generation</p>

# STATE OF THE ART AUTOMATION



# STATE OF THE ART CAMERA INSPECTION

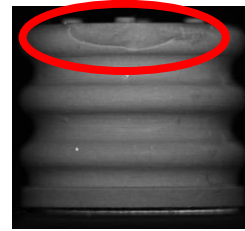
## REJECTED DEFECTS:

### Capabilities: What can we see and remove?

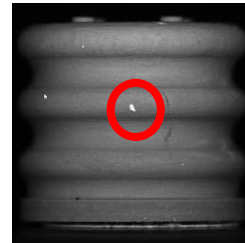
- Particulates (fiber, hair, dust, etc.)
- Discoloration -- Embedded metal
- Dimensional errors
- Incomplete features
- Damages or defects

### What are the limits?

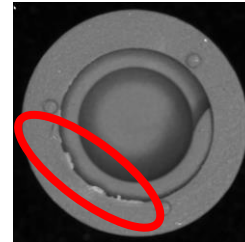
- System will capture and remove particulates of area size  $<0.03\text{mm}^2$  or  $\sim 175 \times 175$  microns in area (threshold)
- Minimum 10% contrast ratio difference in gray values (product color is important)



Deformed product



Foreign Matter



Damaged Coating

# STATE OF THE ART CAMERA INSPECTION<sub>c</sub>



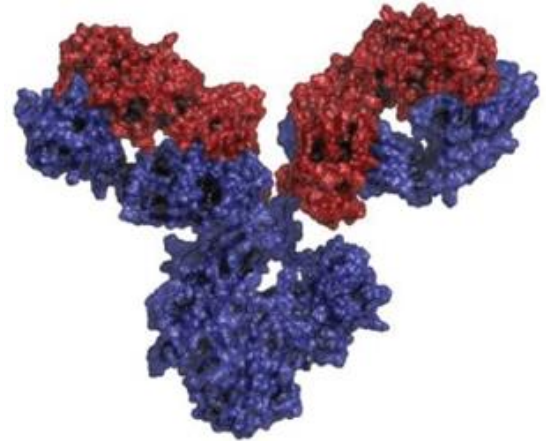
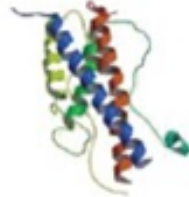


# Our complete offering for Parenteral Packaging

# Our complete offering

We have a complete offering of **products, technologies and services** to support our Customers' needs for **parenteral packaging**:

- dealing with **small molecule drugs** in the traditional pharmaceutical market;
- developing innovative biotech solutions **for large molecule and highly sensitive drugs**

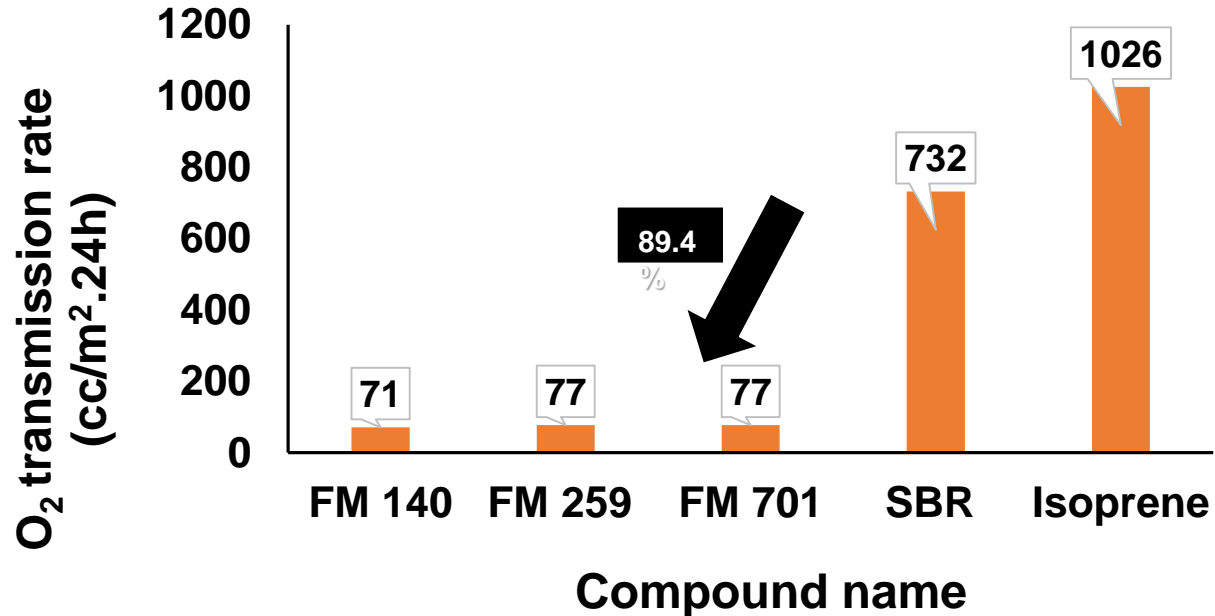


Small molecule  
Low sensitivity

Large molecule  
High sensitivity

# Oxygen transmission rate in standard rubber compounds

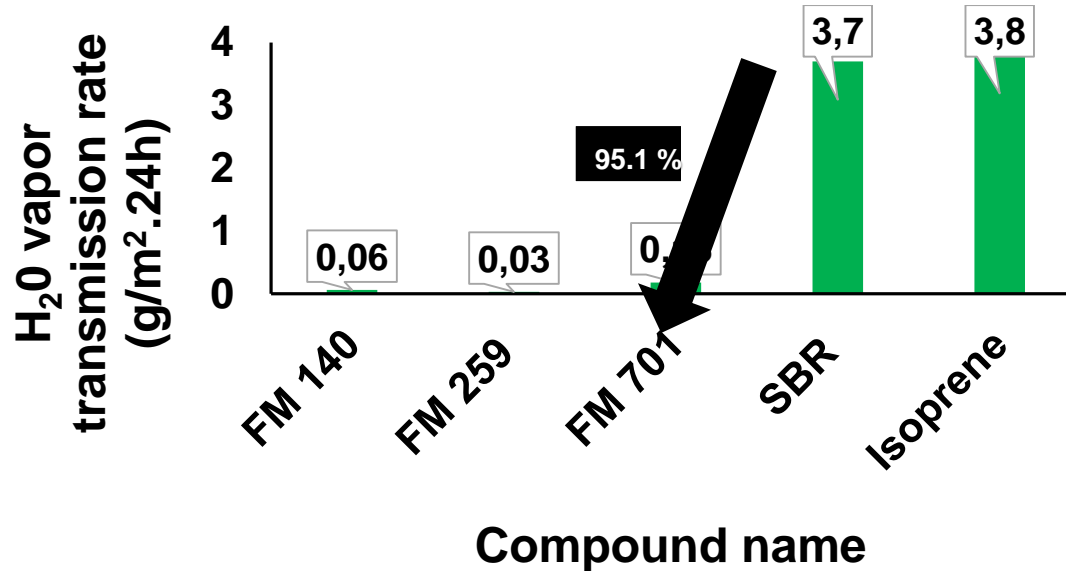
(Mocon, 38°C, 90%RH, 100% O<sub>2</sub>, 1.22 mm thickness (typical value))



- Data is shown for typical SBR (styrene-butadiene) and isoprene compounds.
- FM 259 is a Omni Flex coated compound

# Water vapor transmission rate in standard rubber compounds

(Mocon, 38°C, 100%RH, 1.22 mm thickness, (typical value))



- Data is shown for typical SBR (styrene-butadiene) and isoprene compounds.
- FM 259 is a Omniflex coated compound



# STANDARD FORMULATION PORTFOLIO

	FM257	FM140	FM457	FM460	FM480	FM30	FM701
Elastomer Base	BIIR	CIIR	BIMS	BIIR	BIIR / SBR	SBR	CIIR
Recommended Applications	Wide-range applications	Wide-range applications	WFI & Sensitive Drugs	Lyo	Pre-filled	Needle shields / tip caps	Wide-range multi dose vials
Exceptional Performance Attribute	Fewest Ingredients, Ultra-low Gas Permeability	Exceptional Resealing	Lowest Extractables	Ultra-low Moisture	Irradiation Set	Highest EtO permeability	Multipiercing
Vials / PFS	Both	Vials	Both	Vials	PFS	PFS	Vials
Hardness (Shore A)	52	46	47	46	53	51	41
Available Omniflex-Coated	✓		✓				
Available Combi-Seal	✓ (*)		✓ (*)		✓		✓

# Complete products portfolio applications

We have a **complete products portfolio for Parenteral Packaging.**

We can offer a **large variety of standard and customized solutions** to meet the needs of our Customers dealing with different type of primary containers:

- **Stoppers and aluminium seals for Vial applications**
- **Plungers and Combiseals for Cartridge applications**
- **Plungers, Tip Caps and Needle Shields for Prefilled syringe applications**



# Sealing solutions for Vials

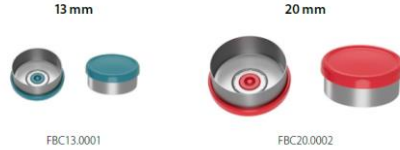


	SERUM		LYO			
			IGLOO		2-LEG	
13 mm						
Coating	-	Omni Flex	-	Omni Flex	-	Omni Flex
Design	V9024	V9401	V9250	V9402	HPP002	HPP079
Compound	FM140 FM257 FM457	FM457	FM140 FM257 FM457 FM460	FM457	FM140 FM257 FM457 FM460	FM457
	SERUM		LYO			
			IGLOO		2-LEG	
20 mm						
Coating	-	Omni Flex	-	Omni Flex	-	Omni Flex
Design	V9025	V9407	V9172	V9397	V9154	V9396
Compound	FM140 FM257 FM457	FM457	FM140 FM257 FM457 FM460	FM457	FM140 FM257 FM457 FM460	FM457
	INFUSION	DIN		ISO		LYO
						4-LEG
29 mm						
Coating	-			Omni Flex		-
Design	5294	V9003	V9240	V9240	V9262	
Compound	FM140 FM257 FM457	FM140 FM257 FM457	FM140 FM257 FM457	FM259 O+	FM140 FM257 FM457 FM460	

# Sealing solutions for Vials

## PRIME CAPS

Also available in flush design



STANDARD CAPS	13 mm	20 mm	32 mm	SPECIAL CUSTOMIZATIONS
ALUMINIUM HOLE CAP	 AHC13.0005	 AHC20.0004	 AHC32.0009	 Dedicated aluminum color
CENTER TEAR OFF	 CTO13.0006	 CTO20.0010	 CTO32.0009	 Inkjet printing
SCORELINE TEAR OFF		 STO20.0004	 STO32.0006	 Wallpapered aluminum
DOUBLE TEAR OFF		 DTO20.0001	 DTO32.0002	 Engraving
FLIP CAP	 FC13.0009	 FC20.0016	 FC32.0011	
SCORELINE FLIP CAP	 SFC13.0008	 SFC20.0020	 SFC32.0001	
UNIVERSAL TEAR OFF		 Flip-Tear UTO20.0017	 UTO32.0016	
		 Tear-Off UTO20.0022		
PULL OFF CAP			 POC32.0003	

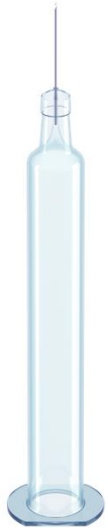
# Sealing solutions for Cartridges



	From 1–3 ml							
	COMBISEALS		DURA COAT					
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 FM257 + H1-7-207 FM457 + H1-7-207			
	PLUNGERS		ø 6.85 mm		ø 8.65 mm		ø 9.65–9.7 mm	
Coating	–	–	–	–	–	–	–	
Design	V4528	V9321	V9336	V9336	V9478	V9478	V9478	
Compound	FM257 FM457	FM257 FM457	FM257 FM457	FM257 FM457	FM257 FM457	FM257 FM457	FM257 FM457	

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

# Sealing solutions for Prefilled Syringes



## SOFT NEEDLE SHIELD

1/2"



## RIGID NEEDLE SHIELD

1/2"



## TIP CAPS

RIBBED

MUSHROOM



Coating	-	-	-	-
Design	V6544	V9812	V9406	V9257
Compound	FM27 FM30	FM27 FM30	FM27 FM30 FM257	FM27 FM30 FM257

## PLUNGERS

0.5 ML

1 ML LONG

1-3 ML

5 ML

10 ML



Coating	-	Omni Flex	-	Omni Flex	-	Omni Flex	-	-
Design	V9315	V9503	V9283	V9403	V9258	V9416	V9319	V9344
Compound	FM257 FM457	FM257	FM257 FM457	FM257	FM257 FM457	FM257	FM257 FM457	FM257 FM457

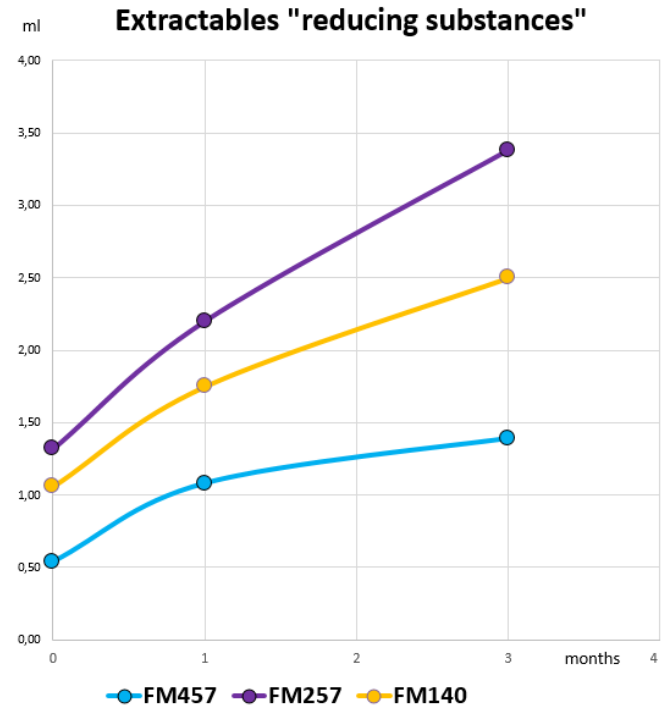
# Focus on: FM457

Based on a unique polymer, **FM457 is a modern bromobutyl formulation, specifically** developed for stopper and plunger applications:

Thanks to its **excellent characteristics**, such as:

- very high chemical purity and ultra-low extractable compound
- high resistance to Gamma irradiation\*
- superior functional characteristics\*\*

**FM457** represents the **best-in-class solution** for customers looking for the highest levels of rubber compound purity and compatibility, **matching the needs of sensitive drugs.**



# Focus on: Prime Cap

Our solution dedicated to customers looking for flawless machineability on high-speed filling lines.

## Prime's advantages include:

- **Worldwide operation** and supply
- **Highest quality alloy**
- Available in 13 and 20 mm in **5 standard aluminum colors**
- **Center-gated plastic disc** for enhanced machinability, available in **40 standard colors, matte and glossy**
- **Optimized design**: straight skirt edge (Accurim)
- Available in **standard and flush disc configurations**
- **100 % camera inspection**
- **Low bioburden and particulate** levels
- **CCI match with Datwyler's elastomer** products
- Available in **RFS / RTU / RTP**
- **Additional services**: customized colors, wallpapered aluminum, embossing and engraving, inkjet printing, serialization support





# Unique material treatment technologies

## Omni Flex

- Omni Flex is a proprietary, **inert fluoropolymer spray coating for rubber components.**
- Available **for a variety of Vial stoppers and PFS/Cartridge plungers as part of our First Line** manufacturing concept.
- Developed to meet the highest demand for quality, compatibility and performance of **sensitive, large molecule drugs.**

## Dura Coat

- Dura Coat is patented **abrasion-resistant technology** that is **applied to aluminum.**
- Available for Cartridge **Combiseals.**
- Designed for markets looking for **more robust and cleaner sealing material reducing the risk of contamination** during filling operations.

# Omni Flex coating

Omni Flex is the **state-of-the-art coating solution** to meet the highest demands for quality and performance of **highly sensitive, large molecule drugs**.



## Omni Flex key features:

- **proprietary, inert fluoropolymer spray coating**
- **total coverage** trim edge included (for all designs), no concerns about the ‘ring of uncertainty’
- **covalently bound** to rubber
- **barrier properties**
- **thin and flexible:**  $\approx 20\mu\text{m}$
- **low coefficient of friction**, no silicone needed for machineability and plunger functionality

# Omni Flex coating

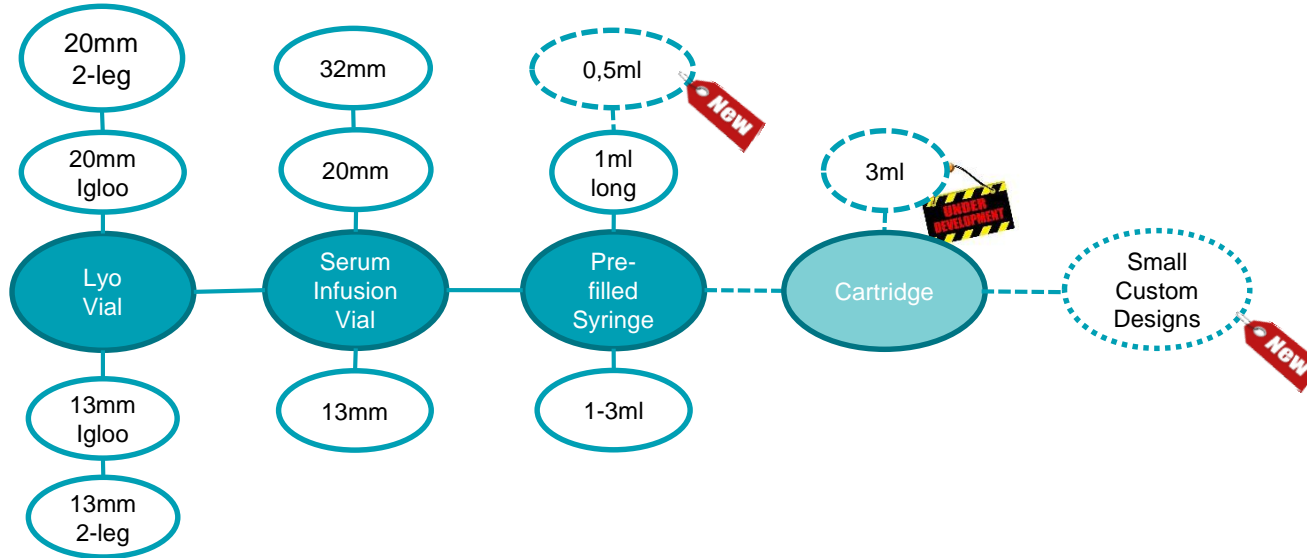
## Why Omni Flex for our Customers:

- **Highest quality standards:** Omni Flex is part of our First Line concept with highest quality levels.
- **Best-in-class sub-visible particle levels:** Elimination of silicone removes one of the largest sources of sub-visible particles.
- **Superior chemical compatibility:** Omni Flex is the preferred option for proteins prone to oxidation in the presence of metal ions, oil based formulations, and other compatibility challenges.
- **Most consistent delivery forces:** Absence of silicone oil enables an optimized design ensuring the most consistent delivery forces.
- **Excellent design flexibility:** Spray coating process lends itself to coating custom-designed parts to meet the needs of innovative delivery devices.



# Omni Flex coating (3/3)

Omni Flex platform can help solve the issue of **drug primary containment integration** for sensitive drugs and the need to revalidate when **shifting from one container to another**.



## Benefits for our customers:

- reduced risk of failures during primary containment validation
- reduced time to market
- improved lifecycle management of the drug on multiple containers

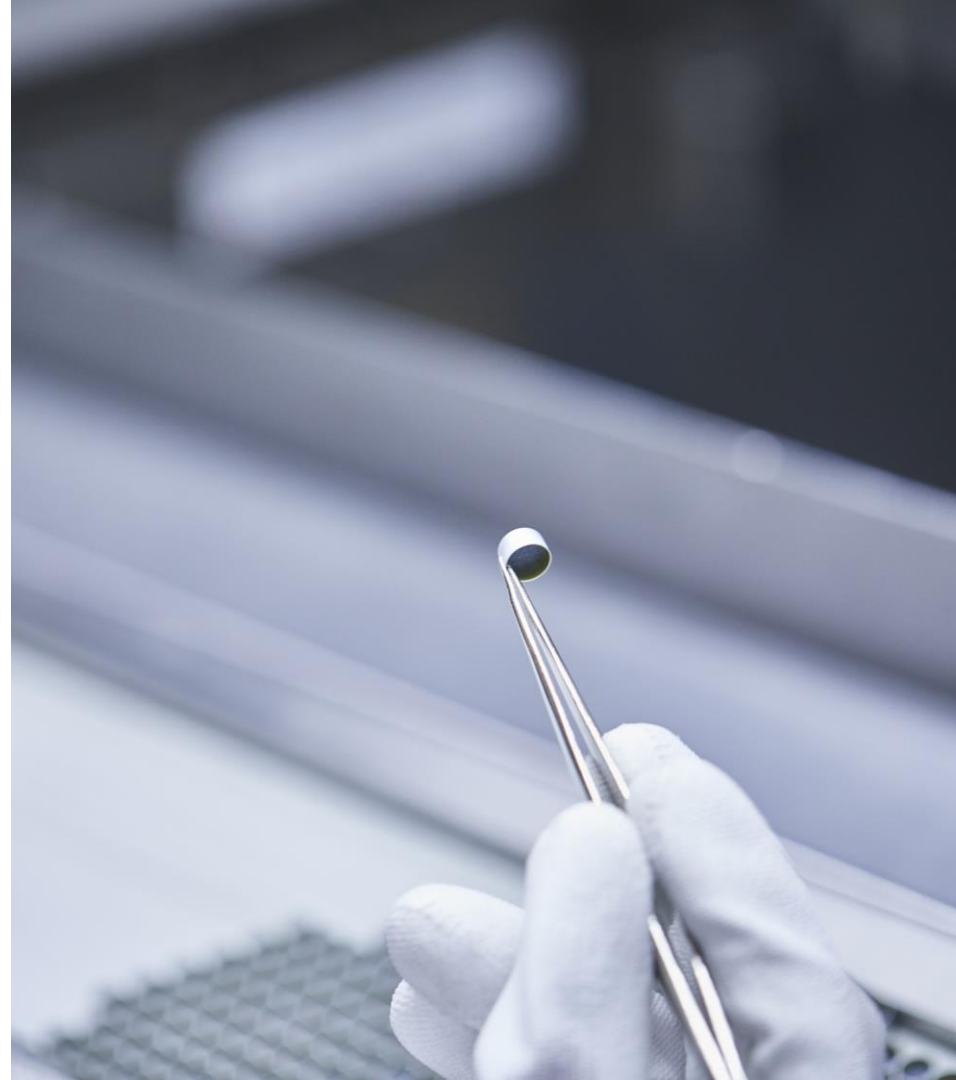
# Dura Coat

Dura Coat is a patented **lamination technology** that is applied to aluminum (today only Combiseals) to ensure a more robust and sterile product.

Dura Coat helps to reduce overall particles generated during the manufacturing process, allowing for a **cleaner product from assembly to end-use.**

Dura Coat **key features:**

- **Clear reduction of particles** during processing and handling
- **Less abrasion** seen on seal compared to standard aluminum
- **No delamination**
- **No adhesion issues**
- **Processes like standard aluminum** during manufacturing
- **Robust testing and analysis** confirms Dura Coat is a **best-in-class, effective sealing solution**



# Final packaging solutions:

## Ready-for-Sterilization (RFS)

## Ready-to-Use (RTU)

### RFS: optimizing process efficiency and cost management

All RFS components guarantee a **very high standard of particulate and biological cleanliness**.

By taking responsibility for the washing and siliconization process, Datwyler's RFS components **give customers the freedom to focus on their core manufacturing and filling processes**.

### RTU: greater process efficiency and reduced total cost

A **wide variety of sterile products ready for immediate use**, straight from the warehouse.

RTU components not only **simplify stock management** and **operational planning**: the increased efficiency, flexibility and security of supply chain will also result in **faster lead times** and a **reduction of risk and labor costs**.



# Final packaging solutions:

## Rapid Transfer Port (RTP)

A **reliable and secured product transfer solution**, in combination with RFS and RTU, meeting the evolving requirements of pharmaceutical filling operations and authority regulations.

### Customer benefits:

- **meet stringent regulatory and quality requirements**, minimizing human intervention in the pharma process and reducing the risk of contamination
- **gain operational efficiency**, facilitating routine operation.



# Service Offering

In order to provide our customers with a single source solution for their packaging needs, **Datwyler offers a suite of services designed to:**

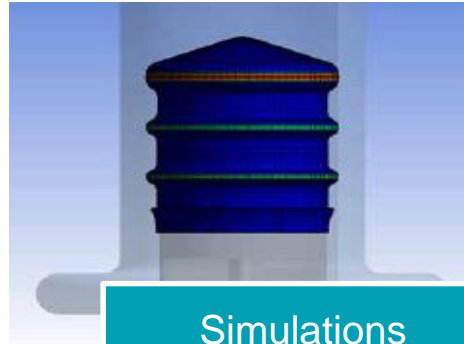
- **Promote product safety and efficacy**
- **Build stronger relationships with our customers**
- **Ensure a path towards future growth as a worldwide supplier**



Lab Testing



Custom Product Designs



Simulations



Business Continuity Plans



# Nelson Labs (Toxikon) - Datwyler Partnership

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*bringing analytical and rubber  
compounding experts together enabling  
the best services*

- A premium service to the pharmaceutical packaging industry enabling a fast and safe regulatory approval.
- Common R&D programs show the ambition to continue offering the best-in-class knowledge and expertise in pharmaceutical elastomer formulations.
- Enjoy a discount for all your analytical study work.

**Thank you**

