



DATWYLER

DURA COAT COMBISEALS – DATWYLER'S NEXT GENERATION IN ALUMINIUM

In this article, Carina Van Eester, Global Platform Leader, Prefilled Syringes & Cartridges, Datwyler Sealing Solutions, covers the advantages presented by the company's new abrasion-resistant material, Dura Coat, used for combiseals on cartridges.

INTRODUCTION

When it comes to the future of pharmaceuticals and medical care, the WHO pursues a clear vision in its operations: "A world where every child, man and woman has access to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life." Therefore, the ambition is to improve and maintain access to high-quality pharmaceuticals and medical products in order to achieve the best possible treatment for everyone. Indeed, an increase in average age worldwide is driving

an increasing need for medical treatment.

In addition to providing access to appropriate medicines, the WHO considers innovation and development, as well as improving the use of medicines, to be among the steps that are essential to ensure patients receive essential, high-quality medicines. The global healthcare industry strives to meet these expectations by investing in the continuous research and improvement of their products and collaborating on an international level.

The UK, US, Germany, France and Japan are among the leading nations driving global health efforts. Also, in China, there is enormous political will to invest in health. Thus, the Chinese government passed the concept "Healthy China 2030". As part of this, a drive towards health equality, improvements in the health insurance system and stricter standards in the healthcare industry can be expected.

To handle these circumstances, aside from developing new products and meeting new and extended regulations, companies need to rely on appropriate sealing solutions to provide the utmost protection for their products. For example, a variety of pharmaceutical and biotechnological therapies, such as dental care and insulin management, are becoming ever more important, resulting in a steadily growing need for the cartridges used for these therapies.

Datwyler's Role in This Time of Change

A drug therapy continuously improved to increase its effectiveness fits perfectly



Carina Van Eester
Global Platform Leader,
Prefilled Syringes & Cartridges
T: +32 11 701 301
E: carina.vaneester@datwyler.com

**Datwyler Sealing Solutions
International AG**
Militärstrasse 7
6467 Schattdorf
Switzerland

www.sealing.datwyler.com



Figure 1: Datwyler offers best-in-class packaging solutions compatible with all types of glass cartridges.

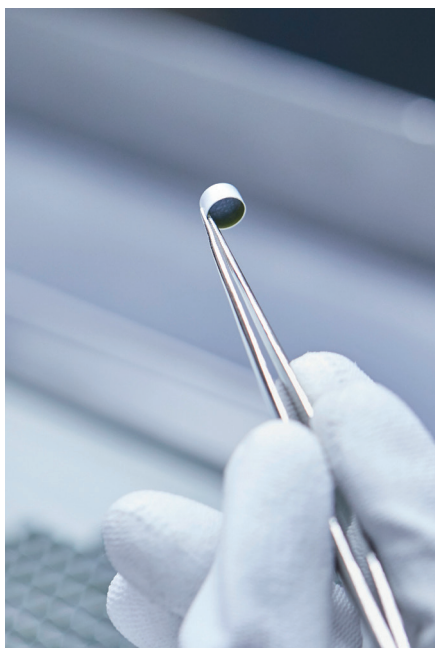


Figure 2: Datwyler aims to deliver the highest level of innovation, quality and safety in the industry.

with the ambitions of Datwyler Sealing Solutions. In a world where an abundance of innovation intersects with the opportunity to improve patients' lives across continents, there is an inevitable increase in complexity. Datwyler's healthcare offering rises to this challenge with the required market-specific product properties, highest quality and cleanliness (Figure 1). Datwyler combines long-standing experience and a history of innovation to better cater to its customers' needs and help them create a safer medical environment (Figure 2). In the company's portfolio of cartridges, two core components are included: a plunger and a combiseal.

IMPROVED COMBISEAL SOLUTIONS

Datwyler's plungers can perform a wide variety of functions to secure the integrity and efficacy of the drug. To ensure system

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integrity for cartridges, in addition to high-quality plungers, advanced combiseal solutions are needed.

It is important that combiseal components are multifunctional and offer multiple protection, a requirement which Datwyler's components meet. Even after multiple piercings, the combiseals maintain the integrity of the seal, while ensuring the lowest possible extractables and leachables profile for the application. For optimal usability and high resilience, the combiseals feature a dual-compound elastomeric liner inside the aluminium cap.

The components used in the combiseal must be produced with the utmost cleanliness. A zero-defect philosophy and sophisticated production technologies not only meet the qualitative and regulatory expectations of the pharmaceutical market, but also eliminate contamination risk for sensitive drugs. With highest chemical cleanliness, Datwyler develops some of the most complex and unique elastomeric compounds in the industry for medical use.

Different applications require tailored and specific solutions. Datwyler meets this challenge with components that offer a variety of possible combinations of type (monolayer or bilayer) and compound, including:

- **FM457:** A modern Type I bromobutyl formulation based on a unique polymer that offers a very high chemical purity. It is used as the contact side of the combiseal.
- **H1-7-207:** A synthetic polyisoprene which is used for the non-contact side of the combiseal in order to improve sealing properties during multi-piercing.

Different liner compositions are selectable depending on the number of piercings that will need to be made. Monolayer liner are used for single piercing applications, such as dental care treatments. Bilayer liners are used for multi-piercing applications, such as biologics, including insulin. Depending on the intended use, Datwyler offers its customers suitable products, and supports them in choosing the right components (Table 1). These combinations have been tested according to ISO11040-3 (seals for dental local anaesthetic cartridges) and ISO13926-3 (seals for pen injectors for medical use) to ensure that sealing, resealability and fragmentation are guaranteed for the number of piercings for which it is recommended.

THE NEXT GENERATION OF ALUMINIUM: DURA COAT

To guarantee the durability and reusability of combiseals, they have to be extremely robust and of the highest purity. Datwyler continually improves its products and processes and tackles

Monolayer Liner	Application	Liner Thickness
FM257 or FM457	<5 piercings	1,45 mm

Bilayer Liner (*contact compound)	Application	Liner Thickness
FM257* or FM457* + H1-7-207	>5 piercings <50 piercings	1,45 mm
FM257* or FM457 + H1-7-207	>50 piercings <100 piercings	1,95 mm

Table 1: Datwyler assists its customers in finding the most suitable combination of components to obtain a product tailored to their needs.

"When standard aluminium is used throughout various manufacturing processes naturally generate particles, which can contaminate combiseals."

this challenge with the next generation of aluminium: Dura Coat. A material newly developed by Datwyler, Dura Coat consists of an epoxy lacquer and polypropylene laminate which is applied to standard aluminium seals, meeting all the most stringent customer and regulatory requirements. Once these two layers are applied to a standard aluminium seal, the result is a durable and robust packaging solution (Figure 3).

This innovative product uses high-quality materials and therefore enables a clear reduction in particles during processing and handling. Furthermore, combiseals that use Dura Coat are more abrasion resistant than standard aluminium seals. Datwyler's testing showed that the product guarantees flawless processability in both production and usage. Utilising this proprietary material for combiseals helps to improve product robustness while also reducing the risk of drug product contamination. Dura Coat combines a high-quality alloy with a protective laminate, providing the customers with the cleanest product currently available on the market.

When standard aluminium is used throughout various manufacturing processes, such as deep drawing, assembly, washing, and crimping, naturally generate particles, which can contaminate combiseals. The cutting of standard aluminium, without strict specifications for earing, also results in aluminium particles. Epoxy based lacquers can also cause impurities, as they are not really robust with respect to flaking during production, transport and filling. When it concerns a silver cap, the transparent lacquer will also shed particulates, which are hardly visible. In case of other colours like blue, green or red, flakes can be created which finally end up on the liner and as such can contaminate the drug product.

Dura Coat reduces this particle generation up to 10 times more than

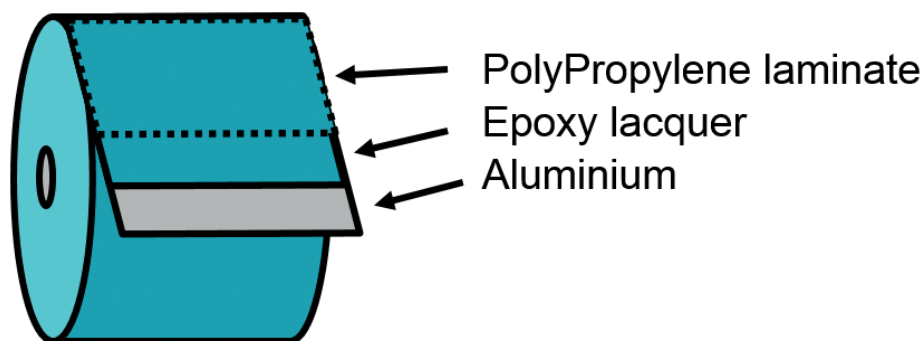


Figure 3: Once the epoxy lacquer and polypropylene laminate are applied to a standard aluminium seal, the end result is a durable and robust secondary packaging solution.

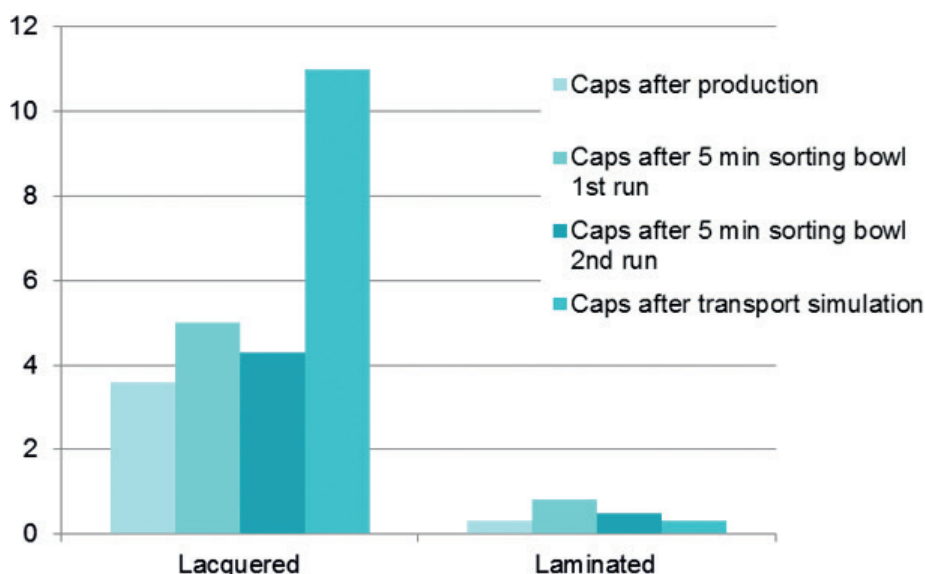


Figure 4: Dura Coat provides a protective barrier to external forces and thus significantly reduces the risk of abrasion during manufacturing and handling.

“The proprietary abrasion-resistant coating also provides a protective barrier to external forces, reducing the risk of abrasion during manufacturing and handling. In detail, Dura Coat combiseals contribute to the reduction of particles.”

lacquered alloy. The aluminium alloy used for the manufacturing of Dura Coat material conforms to ISO 8872, and the aluminium used is lacquered with epoxy

based lacquer. Datwyler purchases aluminium with strict specifications for earing in order to avoid the need to cut the aluminium after deep drawing.



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The protective laminate completely eliminates the issue. This allows an overall reduction in the number of particles produced during production due to the protective polypropylene liner.

Tested to Meet Highest Expectations

The proprietary abrasion-resistant coating also provides a protective barrier to external forces, reducing the risk of abrasion during manufacturing and handling (Figure 4). In detail, Dura Coat combiseals contribute to the reduction of particles. Abrasion can again result in flakes ending up in the drug product, which creates a high reject rate of the filled cartridges, but it can also result in visual defects, such as scratches, which, particularly for high-end products and certain markets, are not acceptable. For combiseals made of Dura Coat material, Datwyler offers a very low AQL (Acceptable Quality Limit) for this type of visual defect.

An extensive series of tests were undertaken to examine the robustness of the material and to assess the effectiveness and functionality of the laminated aluminium. For example, a Taber abrasion test, which measures how resistant an object is to wear over time, was performed in accordance with ASTM D1044-08. The results showed a significantly different wear resistance of the aluminium surface between non-coated (only epoxy lacquered) and Dura Coat-treated aluminium. While the Taber abraser wears completely through the lacquer layer on the non-coated samples during 500 cycles, the colour layer of the laminated material remains intact (Figure 5). This visual impression is also confirmed by the measured weight loss.

In order to provide every customer with unlimited functionality and flawless processability, according to their specific requirements, a combiseal can undergo various steps before treatment. There is a number of worst-case tests to make sure

Non-coated aluminum

Dura Coat treated aluminum

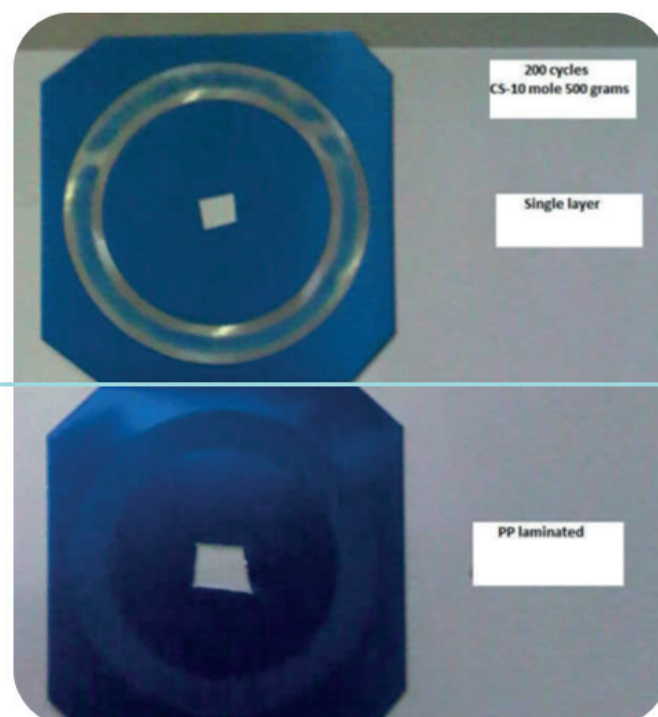


Figure 5: By applying a polypropylene liner to the aluminium prior to processing, Datwyler has found a way to create a cleaner and more effective aluminium seal.

that the material withstands different pre-conditioning processes like washing, sterilisation and drying before filling and post-sterilisation. This proof of quality ensures that the material is as durable as promised and that the customer receives a high-grade end product.

THE FUTURE OF CARTRIDGES HAS BEGUN

The Dura Coat material used for cartridge applications offers a very robust combiseal with a low particulate level, low level of visual defects, flawless processability and a seamless container closure. In combination with Datwyler's compounds, this product is the best solution to handle the growing demand for cartridges and to meet the expected increase in dental and insulin therapies. Datwyler is thus taking an important step towards the development programme set

out by the WHO, which aims to achieve universal access to safe and quality-assured health products and general healthcare by 2030.¹ This required change necessitates progress, including efficient and safe delivery systems and advanced drug packaging. With its components for cartridge applications, Datwyler Sealing Solutions keeps pace with these challenges.

ABOUT THE COMPANY

Datwyler Group is an international supplier of state-of-the-art industrial components with leading positions in global and regional market segments, a global manufacturing footprint on three continents, sales in over 100 countries and more than 7,000 employees. In its Sealing Solutions division, Datwyler provides customised sealing solutions to manufacturers and companies that operate in the healthcare and automotive industries, among others. The products and services of Datwyler are built on high-quality material, innovative technologies, outstanding engineering and process know-how.

REFERENCE

1. "Towards Access 2030: WHO Medicines and Health Products Programme Strategic Framework 2016-2030". WHO, 2017.

ABOUT THE AUTHOR

Carina Van Eester is Global Platform Leader, Prefilled Syringes & Cartridges at Datwyler Sealing Solutions. She has a Master's degree in Chemical Engineering and has been working in the pharma industry for 15 years as a packaging engineer. After several years of experience in Technical Key Account Management and Validation, Ms Van Eester's current position as Global Platform Leader for Prefilled Syringes and Cartridges includes managing strategic initiatives related to Datwyler's components for various applications.



IMPROVING PATIENTS' LIVES THROUGH OUR INNOVATIVE HEALTH CARE SOLUTIONS IS THE CORE OF OUR BUSINESS. **BECAUSE WE CARE.**

Datwyler Sealing Solutions is a leading industrial supplier and a key player in the health care world. Our state-of-the-art solutions for drug packaging and medical devices are built on over 100 years of experience.

We provide a unique range of products and services including the most advanced elastomer formulations, coatings, aluminum seals, and processing technologies.

Partnering up with the world's top pharmaceutical and medical companies, we stand by our mission to improve patients' lives.



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