

BLOW-FILL-SEAL SOLUTIONS





TO CUT A LONG PROCESS SHORT

PERFECT ALTERNATIVE TO CONVENTIONAL LIQUID FILLING
PROCESSES FOR OUR CUSTOMERS – PARTICULARLY THOSE IN
THE PHARMACEUTICAL SECTOR. OUR AIM? TO MAKE SURE THAT
EVERY LAST PRECIOUS DROP IS PACKAGED MORE RELIABLY,
MORE FLEXIBLY, AND IN A MORE USER-FRIENDLY WAY. IT IS
BASED ON THIS PRINCIPLE THAT BLOW-FILL-SEAL TECHNOLOGY
CAME TO LIFE: THE WORLD'S FIRST ASEPTIC FILLING PROCESS
OF ITS KIND FOR LIQUIDS, SEMISOLIDS, AND EVEN SOME HIGHLY
SENSITIVE PRODLICTS

Customers from all over the world now place their trust in the German engineering and Swiss precision that make each and every aseptic bottelpack system so special. With more than 50 billion packaging units per year, our invention is instrumental in protecting something of real value: ideas that help people, down to the very last drop. We are Rommelag – the inventors of BFS technology.

BLOW-FILL-SEAL OR COMPLEXITY

Every BFS process begins with the extrusion of a sterile polymer parison directly within the system. Once complete, the container can then be moulded, filled, sealed, and immediately demoulded – all in a single process, in a self-contained system, and without the need for any external intervention. This eliminates the need for expensive logistics, not to mention time-consuming cleaning and sterilization processes for prefabricated containers. All of the filling processes – including the dosing system – are designed with CIP/SIP in mind. What this means is that all of the product-handling lines are cleaned, sterilized with pressurized steam, and dried with sterile-filtered air by automatic programs. This makes bottelpack technology the most reliable aseptic filling method.

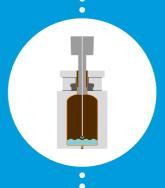
The experts at Rommelag ENGINEERING make sure that the end product from your bottelpack system is always exactly what you wanted and just what your customers need.



EXTRUDING – The polymer parison is extruded from granulate and positioned inside the open mould.



BLOWING – The mould closes and, in doing so, welds the base. The mandrel is positioned on the neck of the container and blows sterile air into the parison to create the desired shape. Small containers are created using a vacuum.



FILLING – The exact amount of filling as measured by the dosing system is fed into the container via the mandrel.



SEALING – Once the mandrel is removed, the head mould comes together to form the desired closure type.



DEMOULDING – Opening the mould releases the container from the system and the next cycle begins.





BOTTLES OR AMPOULES

Whether a bottle or an ampoule is to be filled, how it is filled, and what additional functions the container needs are usually based on the intended use. Rommelag's bottlepack systems can manufacture canisters, bottles, parisons, ampoules, drop bottles, bellows containers, and portion packaging in a variety of forms and plastic blends, with filling volumes ranging from 0.04 to 10,000 ml, aseptically or conventionally – fully automatically and without human intervention in all cases.



NORMAL OR COOL BFS

cool BFS

Our standard procedure is to fill products at room temperature. Particularly in the pharmaceutical industry, however, there is an increasing requirement to handle fillings that are highly sensitive to temperature. This is exactly why Rommelag has developed the cool-BFS process, incorporating special measures that keep the filling at the correct temperature before the filling process begins, and ensuring that the freshly demoulded plastic bodies cool down quickly. As a result, the processing speed remains high and the filling can benefit from maximum protection at all times. BFS at its best.



A SINGLE LAYER OR MULTIPLE LAYERS

In most cases, one layer of polyethylene or polypropylene is more than enough to package the filling reliably and appropriately for its designated use. But sometimes, one layer just won't cut it. This is often the case when the packaging solution has additional roles to fill, such as increasing steam or gas barriers in particular. In this and many other cases, multilayer plastic packaging can be made using special bottelpack CoEx systems. In more straightforward terms, this type of packaging has several layers with the perfect properties to offer maximum protection for the filling. So no matter what you need for your fillings, Rommelag systems always have it covered.



SEALING OR DOSING

Eye drops, inhalers, products for rectal or vaginal application, ointments, creams, or gels: to accommodate all of the different products and applications on the market, all BFS containers are produced ready to use and in line with requirements. What's more, they can be tailored to become functional parts in medical devices.



SINGLE DOSE OR MULTIDOSE

No matter whether your product is intended for single or multiple use, our systems are the ideal choice for moulding virtually every type of container complete with the precise level of filling and the appropriate seals to go with them.



LUER OR COMPLICATED

When syringes are used, the bottelpack ampoule design guarantees straightforward and reliable Luer fit or Luer lock connections. The liquid can be drawn up into the syringe simply, safely, and without the need for an additional needle. With the vented Luer connection, the pressure is equalized automatically, which is a pretty neat solution and just one of countless ways in which BFS technology offers genuine ingenuity.

TWIST OR PUNCTURE OR TWIST AND PUNCTURE

When it comes to deciding on the right closure for you, it essentially comes down to how the product will be used and whether it's for single or repeated use. But the one thing they all have in common is the fact that every container is hermetically sealed to create a fully functional closure for a clean, convenient, and practical result.



The **twist-off cap** is a closure design that has proven its worth millions of times and is used in a large number of applications.



The KME closure is complemented by a screw cap with a mandrel. Screwing the mandrel in creates an opening through which the product can be dripped or squeezed out



The **KMT** closure consists of two parts and allows the user to accurately dispense drops of the product.



With the **eurohead closure**, the hermetically sealed container is combined with the eurohead cap. It was specifically designed to meet the requirements of infusion bottles (IV bottles).





THE INVENTOR OR THE IMPERSONATOR

Wherever you see the bottelpack label, you know can always be sure that our systems will give you you can count on uncompromising quality from the exactly what you're looking for – from the smallest inventors of blow-fill-seal technology. Thanks to our German engineering and Swiss precision, we

ampoule to the largest container. That's a promise.

The advantages of BFS technology

- ◆ Break-proof plastic containers
- ◆ The ideal choice for aseptic filling of liquids, suspensions, emulsions and gels
- ▼ Maximum safety thanks to ISO class 5 conditions at the filling point
- ◆ The inventor of and global market leader in BFS technology
- ◆ Recognized advanced aseptic system by regulators
- ◀ Fully automated manufacturing, filling and sealing processes in a single operation
- ▼ Exceptional process and product reliability
- ◆ A virtually unlimited range of container designs
- ◄ Individual adaptation to the specific application and administration type
- ◀ Modular design for easy instalation in the gray and white system zone
- ◆ Significantly smaller spatial requirements than conventional filling systems
- ◆ Automatic cleaning and sterilization processes as required
- ◄ And much more

FOR BOTTLES OR AMPOULES

bottelpack systems: an overview

	System	Number of moulds	Number of cavities	Container	Filling volume (ml)	Output (items/hour)
THE STATE OF THE S	bр 321	1	3-12	Bottle	50-2,000	600-3,300
The same	bp 360	2	6-24	Bottle	50-2,000	1,200-6,600
	bр 324	1	4-16	Bottle	50-2,000	800-4,000
	bp 362	2	8-32	Bottle	50-2,000	1,600-8,000
	bp 364	4	4-16	Bottle	50-2,000	1,800-10,000
	bр 312М	1	4–15	Ampoule	0,1–60	1,100-4,500
	bр 321М	1	10-30	Ampoule	0,1–50	3,000-9,000
	bр 324М	1	16-40	Ampoule	0,1-40	4,800-12,000
	bр 360М	2	20-60	Ampoule	0,1–50	6,000-18,000
	bр 430	1	5-15	Ampoule	0,1–60	2,250-6,750
<u> </u>	bр 434	1	10-25	Ampoule	0,1–30	4,500-11,250
	bр 460-15	15	10-25	Ampoule	0,1–30	10,000-30,000
	bр 460-20	20	10-25	Ampoule	0,1–20	11,250-34,000
	bр 461	14	8-25	Ampoule	3-60	8,000-25,000
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Technical modifications reserved

Category	System installation dimension (L × W × H in mm)	Recommended room size (L × W × H in mm)	Sep. control cabinet (L × W × H in mm)
Cyclic	6,600 x 2,600 x 3,900	9,000 x 6,000 x 4,500	
Cyclic	6,100 x 4,500 x 3,900	10,000 x 7,600 x 4,500	
Cyclic	7,400 x 6,500 x 3,800	11,500 x 9,500 x 4,500	4,000 x 600 x 2,200
Cyclic	11,000 x 7,100 x 3,900	11,000 x 14,000 x 4,500	5,000 x 600 x 2,200
Cyclic	13,000 x 6,600 x 4,500	16,000 x 10,000 x 6,000	5,000 x 600 x 2,200
Cyclic	3,000 x 1,700 x 2,800	6,000 × 5,800 × 3,500	600 x 2,500 x 2,100
Cyclic	6,600 x 2,600 x 3,200	9,000 x 6,000 x 3,500	
Cyclic	6,600 x 7,400 x 3,900	9,600 x 11,000 x 4,500	4,000 x 1,200 x 2,200
Cyclic	6,100 x 5,000 x 3,200	9,500 × 7,600 × 3,500	
Rotating	3,700 × 2,300 × 3,600	7,000 × 6,000 × 4,000	4,000 × 600 × 2,200
Rotating	3,700 x 2,300 x 3,600	7,000 × 6,000 × 4,000	4,000 × 600 × 2,200
Rotating	5,000 x 2,900 x 4,300	7,500 × 6,000 × 5,000	
Rotating	5,000 x 2,900 x 4,300	7,500 × 6,000 × 5,000	
Rotating	5,300 × 2,900 × 4,300	9,400 x 6,500 x 4,500	

NECESSARY OR INDISPENSABLE

Our extensive range of systems





ROMMELAG ENGINEERING 20

CAP ON OR CAP OFF

Cap welding machine (SM)

The specially designed cap welding machine allows plastic caps (ports) to be welded onto moulded BFS containers. To cover the widest possible range of applications, Rommelag ENGINEERING offers these machines as semi-automatic and fully automatic solutions. Both of these systems come complete

with automatic unloading machines and conveyors. Customers looking to integrate a bottelpack and cap welding machines can expect a turnkey solution that has passed comprehensive in-line testing. The challenges to integrate multiple systems are now well and truly in the past.

MANUAL OR AUTOMATIC

Vial inspection system (VIM)

With a qualified and validated VIM ampoule inspection system, you decide how the BFS ampoule blocks should be inspected. Fully automatic or manual feeding – both are equally possible. The sophisticated inspection system logs the cavity and mould numbers, and measures the opening and separation forces, ampoule net and filled

weights, and ampoule wall thickness. VIM can be seamlessly integrated into the production process and checks the quality of your containers. All the in-process measurement protocols are available electronically plotted for trending. Set point deviations can be identified instantly. An optional filling volume feedback system is also available.

HAZARD A GUESS OR USE THE LATEST TECHNOLOGY

Automatic particle inspection machine (PIM)

To ensure your products reach your customers in perfect condition, automated particle inspection machines can be installed downstream of the bottelpack systems. The PIM checks containers with various shapes and sizes as individual or blocks of containers. Only premium-quality products make it through to your customers.

Your benefits with PIM

- Qualified and validated particle inspection machines
- ▼ 100 percent control
- ✓ Non-destructive testing
- One or more camera systems working in parallel
- Detection of particles of various materials and cosmetic defects in any container shapes
- ◄ Innovative vibration system to detect particles without rotating containers

- ▼ Reliable detection of particles floating or suspended in the filling
- ▼ Detection of particles stuck to or trapped in the container walls
- Automatic rejection of containers with imperfections
- ▼ Rapid availability of all measurement reports in full
- ▼ Minimal personnel costs
- ◄ And much more

HIGH-VOLTAGE OR AT EASE

High-voltage leak detector (HVLD)

There are some things that simply go hand in hand. The HVLD offers a non-destructive and fully automated container closure integrity (CCI) test. As long as the product has some conductivity the system can perform high speed testing on a

multitude of shapes and designs. The HVLD is an inline system that can be supplied turnkey with a bottelpack system. Faulty containers are rejected immediately after inspection and records are maintained by the system.

THE END? OR JUST THE BEGINNING?

WELL THAT'S ENTIRELY UP TO YOU. THIS BROCHURE
IS DESIGNED TO GIVE YOU A TASTE OF WHAT ROMMELAG
ENGINEERING AND BFS TECHNOLOGY CAN DO FOR YOU,
AS WELL AS AN INSIGHT INTO THE KEY BENEFITS AND
POSSIBILITIES OF PACKAGING MANUFACTURED USING THE
BLOW-FILL-SEAL PROCESS. AS FAR AS BROCHURES GO,
THIS IS AS MUCH AS WE CAN EXPECT TO ACHIEVE

We are firm believers that nothing beats personal contact. After all, each of our systems is as individual as your requirements. This is why we think it's best to speak to our customers directly, and we look forward to learning more about you and your needs. Contact us via www.rommelag.com and we'll be glad to pay you a visit.

We're always by your side

With its four specialist divisions of ENGINEERING, CMO, FLEX, and SERVICE, the Rommelag brand represents a strong network of local, independent companies across Germany and Switzerland that each share the same end goal: reaffirming to you on each and every project that choosing Rommelag was the best decision you ever made.

www.rommelag.com





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