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Technology

ROMMELAG

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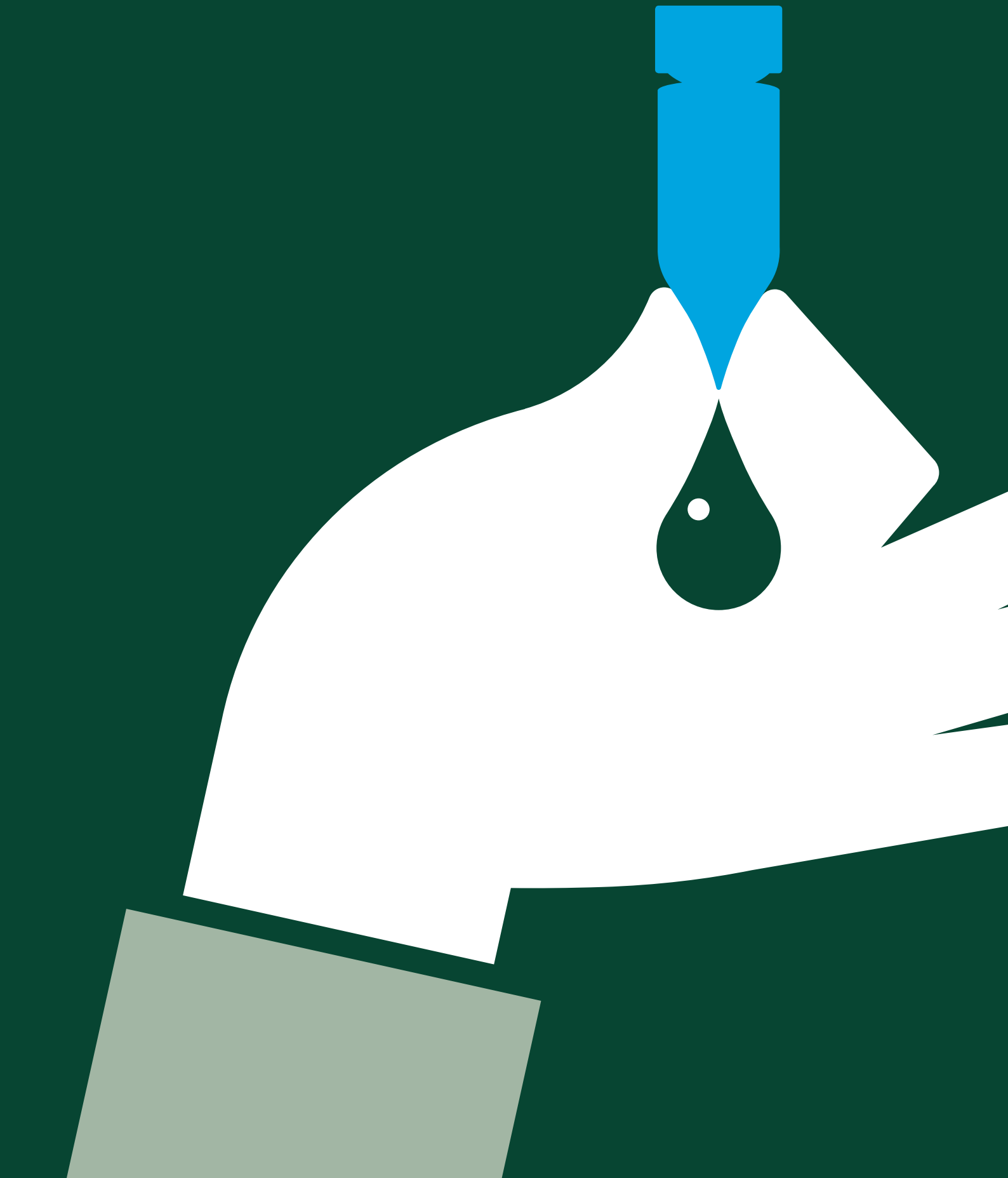
FILLING YOUR NEEDS

ROMMELAG ENGINEERING

BLOW-FILL-SEAL SOLUTIONS

bottelpack®



TO CUT A LONG PROCESS SHORT

IT'S BEEN OVER 50 YEARS SINCE WE FIRST CAME UP WITH THE 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 PRODUCTS.

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.

FROM A TO Z OR WHATEVER YOU LIKE

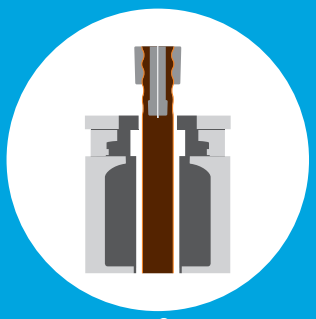
From your initial idea for a new product right through to launching it on the market, we'll be on hand to support you with our business expertise and in-depth technical knowledge. So whether it's planning your bottelpack system, connecting the interfaces properly, testing the equipment, or getting everything installed, our support ensures that everything runs smoothly and according to plan – just the way you want it. It also helps that we work in close partnership with our customers to develop individual packaging designs, test new materials and material compositions, and offer filling tests.

Even once your system is up and running, we'll still be happy to help at any time with compact employee training courses, professional system service, a first-class spare parts supply, and an open ear for our customers whenever they need to get in touch. You could call it a comprehensive service. We like to think of it as a trusting partnership.

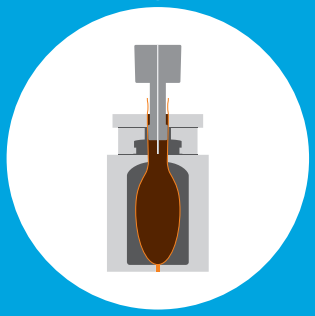
BLOW-FILL-SEAL OR COMPLEXITY

Every BFS process begins with the extrusion of a sterile polymer parison directly within the system. Once complete, the container can then be moulded, fi lled, 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.

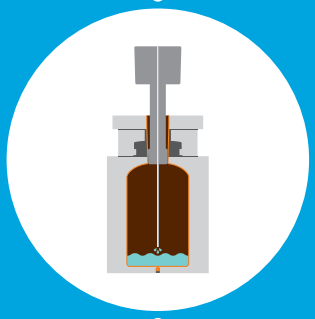
The experts at Rommelag ENGINEERING make sure that the end product from your bottelpack system is always exactly what you wanted and just what your customers need.



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



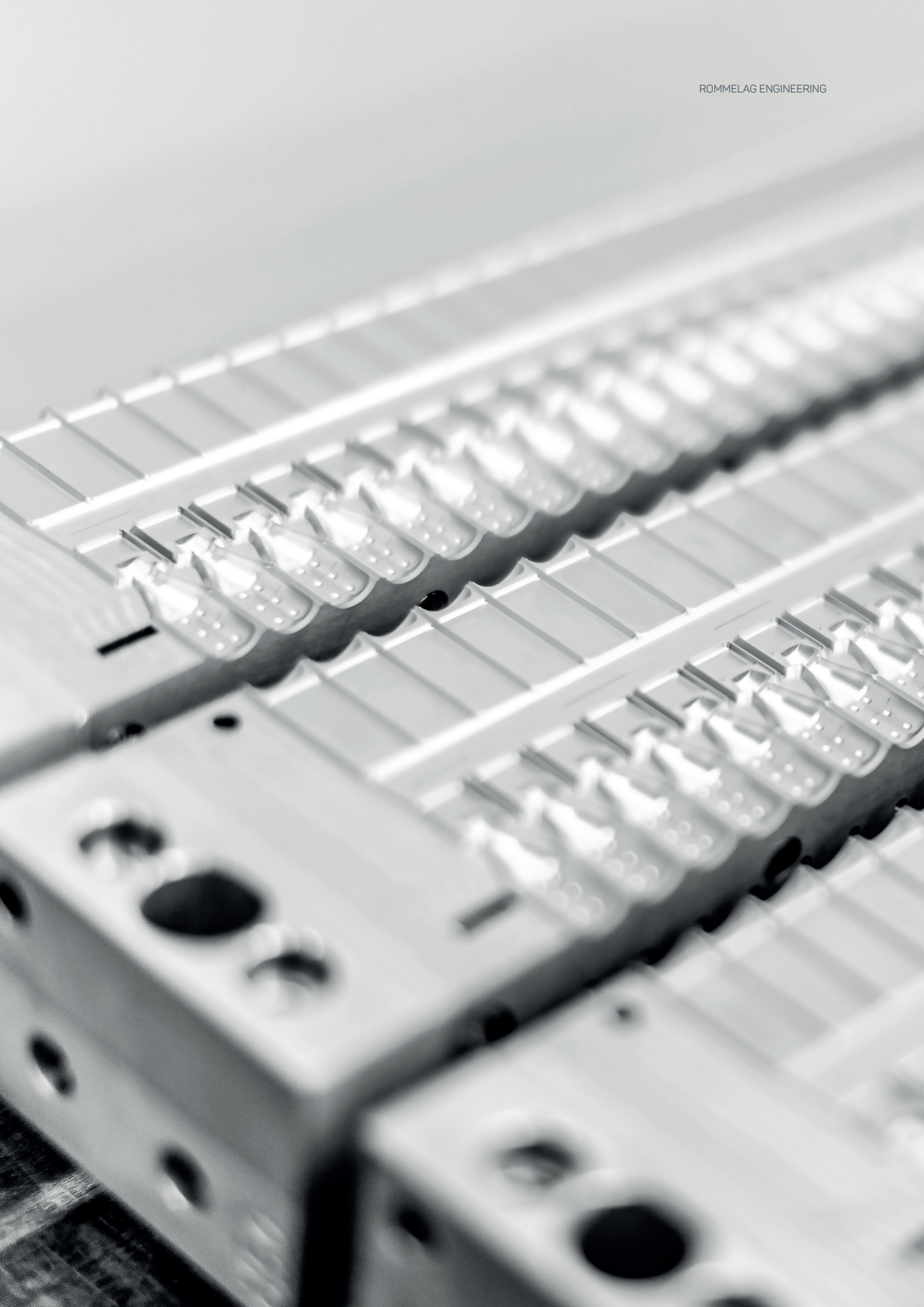
BLOWING – The mould closes and, in doing so, welds thebase. The mandrel is positioned on the neck of the container and blows sterile air into the parison to create the desired shape. Small containers are created using a vacuum.



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.



ONE SIZE FITS ALL OR THE PERFECT SOLUTION FOR EVERY SCENARIO

For anyone interested in reliable aseptic packaging solutions for bringing liquids and semisolids to market without having to invest in additional space, complex logistics, and added storage costs for empty containers, Rommelag's blow-fi ll-seal technology and bottelpack systems are the obvious choice.

The pharmaceutical industry is undeniably one of the main sectors to rely on the BFS process. And in addition to pharmaceuticals, the chemical industry is one of a number of other sectors in which liquid and semisolid materials are increasingly finding their way into BFS packaging. To name just a few examples: cleaning agents, maintenance products, and even functional food.

The processes of blowing, filling, and sealing the plastic containers all take place in a single operation. What's more, the entire BFS process takes place within the system under aseptic conditions, which means maximum protection for the filling without the need for any human intervention.

The various advantages of this contamination-free filling technique using breakproof plastic containers include application-specifi c packaging in virtually any conceivable design, low production costs, and high output rates – not to mention the minimal spatial requirements of the bottelpack systems.

Our bottelpack systems are individually configured for each task, making them the perfect choice for each area of application

- Canisters, bottles, parisons, ampoules, drop bottles, bellows containers, and portion packaging
- Polyethylene, polypropylene, or multilayer containers
- Output quantities of over 34,000 items/hour
- Filling levels from 0.1 ml up to 10,000 ml
- For pharmaceuticals, chemical products, functional food, and much more
- Ancillary cap welding machines and inspection systems also available

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 bottelpack 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 0.1 ml up to 10,000 ml, aseptically or conventionally – fully automatically and without human intervention in all cases.

NORMAL OR COOL-BFS

coolBFS

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 benefi t 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).*

ALL FOR ONE OR ONE FOR ALL

The pharmaceutical industry is still one of the main sectors to rely on BFS technology. The level of care required to handle pharmaceutical fluids is greater than in any other field: Products have to be stored a certain way, dosed with the utmost precision, bottled to suit the specific application, aseptically packaged, and transported safely. Fortunately, Rommelag's BFS technology is outstanding at dealing with each of requirements and more besides.

The blow-fill-seal process is an excellent choice in many fields when flexible, rapid, and cost-effective manufacturing solutions are required:

- Pharmaceutical industry (injection solutions, opthalmic products, etc.)
- Chemical industry (cleaning products, lubricating oils, antifreeze, etc.)
- Veterinary medicine (medication, etc.)
- Food industry (functional food, etc.)
- Automotive (oil, grease, lubricant, etc.)
- Agriculture industry (pheromones, etc.)
- Cosmetics industry (creams, gels, lotions, etc.)

PROFITING OR PROFILING

OUR EXPERIENCE HAS SHOWN THAT THE ASEPTIC FILLING TECHNIQUE USED IN THE BFS PROCESS IS A MORE FLEXIBLE AND COST-EFFECTIVE ALTERNATIVE TO CONVENTIONAL FILLING METHODS IN VIRTUALLY ALL CASES. BUT OF COURSE THAT'S WHAT WE'D TELL YOU, SO IT'S A GOOD THING WE'VE GOT SOME CONVINCING ARGUMENTS TO BACK IT UP.

Proven quality
Whether you're interested in bespoke containers, a bottelpack system itself, or the BFS process, at Rommelag we don't put our name to anything until it's been checked down to the last detail to ensure it's in perfect condition. To this end, we even have our own, purpose-built laboratory testing and production facilities.

Minimal spatial requirements
From bottles to ampoules: the chosen vessel is produced directly in the system, where it is then aseptically filled and reliably sealed before finally being dispensed as a completed container. As a result, there's no need to waste valuable space on stockpiling, cleaning, and disinfecting containers.

Perfect coordination
Our specialists design and set up every bottelpack system with maximum precision to ensure seamless production processes: from the ideal choice of components right through to the integration of the bottelpack system into your production line and beyond.

Exact dosing
Thanks to the exact individual dosing in each cavity, it is always possible to add just the right amount of fluid or semisolid to each container as specifi ed from the outset.

Maximum convenience
As every bottelpack system is unique, the software and user interfaces to go with it are also individually tailored to its scope of services.

Exceptional vertical integration
Virtually every component in our bottelpack systems is manufactured by us. And by that, we're talking about a whole lot of equipment. But we do this because it's the only way to be sure that you can always count on every one of our parts and components to function flawlessly. The extreme durability of our systems is the perfect testament to this philosophy on quality. We also offer professional maintenance and a prompt spare parts service to support you every step of the way. With Rommelag ENGINEERING, there's no more dealing with third parties: it's simply you and us, saving valuable time, money, and unnecessary stress.

Certified processes
Rommelag bottelpack systems are compliant with the strict requirements of the pharmaceutical industry, meaning our production processes are respected around the world.

THE INVENTOR OR THE IMPERSONATOR

Wherever you see the bottelpack label, you know you can count on uncompromising quality from the inventors of blow-fill-seal technology. Thanks to our German engineering and Swiss precision, we can always be sure that our systems will give you exactly what you're looking for – from the smallest 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
- Maximum filling accuracy
- A virtually unlimited range of container designs
- Individual adaptation to the specific application and administration type
- Modular design for easy installation in the gray and white system zone
- Significantly smaller spatial requirements than conventional filling systems
- Automatic cleaning and sterilization processes as required

FOR BOTTLES OR AMPOULES

bottelpack systems: an overview

	System	Number of moulds	Number of cavities	Container	Filling volume (ml)	Output (items/hour)
	bp**321**	1	3-12	Bottle	50-2,000	600-3,300
	bp**360**	2	6-24	Bottle	50-2,000	1,200-6,600
	bp**324**	1	4-16	Bottle	50-2,000	800-4,000
	bp**364**	4	4-16	Bottle	50-2,000	1,800-10,000
	bp**312M**	1	4-15	Ampoule	0.1-60	1,100-4,500
	bp**321M**	1	10-30	Ampoule	0.1-50	3,000-9,000
	bp**324M**	1	16-40	Ampoule	0.1-40	4,800-12,000
	bp**360**	2	20-60	Ampoule	0.1-50	6,000-18,000
	bp**434**	1	10-25	Ampoule	0.1-30	4,500-11,250
	bp**460-15**	15	10-25	Ampoule	0.1-30	10,000-30,000
	bp**460-20**	20	10-25	Ampoule	0.1-20	11,250-34,000
	bp**461**	14	8-25	Ampoule	3-60	8,000-25,000

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	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 x 5,800 x 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 x 7,600 x 3,500	
Rotating	3,700 x 2,300 x 3,600	7,000 x 6,000 x 4,000	4,000 x 600 x 2,200
Rotating	5,000 x 2,900 x 4,300	7,500 x 6,000 x 5,000	
Rotating	5,000 x 2,900 x 4,300	7,500 x 6,000 x 5,000	
Rotating	5,300 x 2,900 x 4,300	9,400 x 6,500 x 4,500	

NECESSARY OR INDISPENSABLE

Our extensive range of systems

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.

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.

AUTOMATED AND VISUAL

Cosmetic Inspection Machine (CIM)
Automated visual inspection technology reliably detects cosmetic defects on ampoule packaging to safely remove them from the blow-fill-seal production line.

These cosmetic defects include:

- filling variations
- black spots in the ampoule wall
- forming error or vacuum error
- punching error
- changes in colour of the filling and/or the plastic
- legibility of engravings or markings
- deformations of the flag and ampoule body

Your benefits with CIM

- Facilitate the qualification and validation process of your inspection equipment
- 100% inspection
- Non-destructive testing
- Modular design
- Can be equipped with multiple camera systems operating simultaneously
- Reliable detection of cosmetic defects in any type of container
- Automated rejection of defective containers
- Fast and complete access to measurement reports
- Minimal personnel operating costs

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

Leading Pharma Technology

GMP Compliant Systems

Experts in Aseptic Processing

Equipment Synergy

Your Number One Equipment Partner for Sterile Manufacturers in the UK & Ireland

Get in touch!

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