# SYFPAC®

Blow Fill Seal

Innovative Solutions for Aseptic Packaging

BREVETTI ANGELA®

Advanced manufacturing technologies

# 40 YEARS OF BLOW FILL SEAL EXPERTISE

Since 1977, **BREVETTI ANGELA** has been focusing on the challenging needs of pharmaceutical companies and healthcare providers. A sector in which the request for a high quality, aseptic primary packaging has to meet the demand of a global market which is always more competitive, in terms of cost-efficiency and long shelf-life.

With 40 years of experience and a deep knowledge of the pharmaceutical market, **BREVETTI ANGELA** provides custom-tailored solutions to meet most of primary packaging requirements.

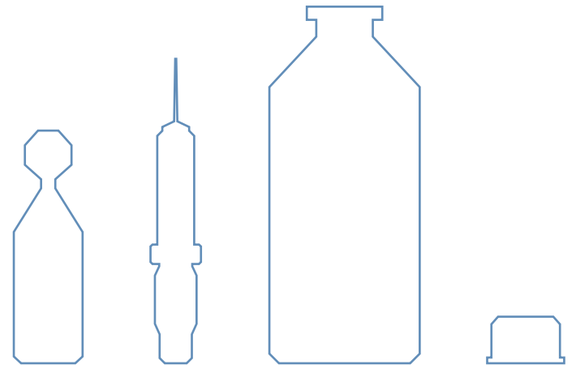
BREVETTI ANGELA®
*Advanced manufacturing technologies*

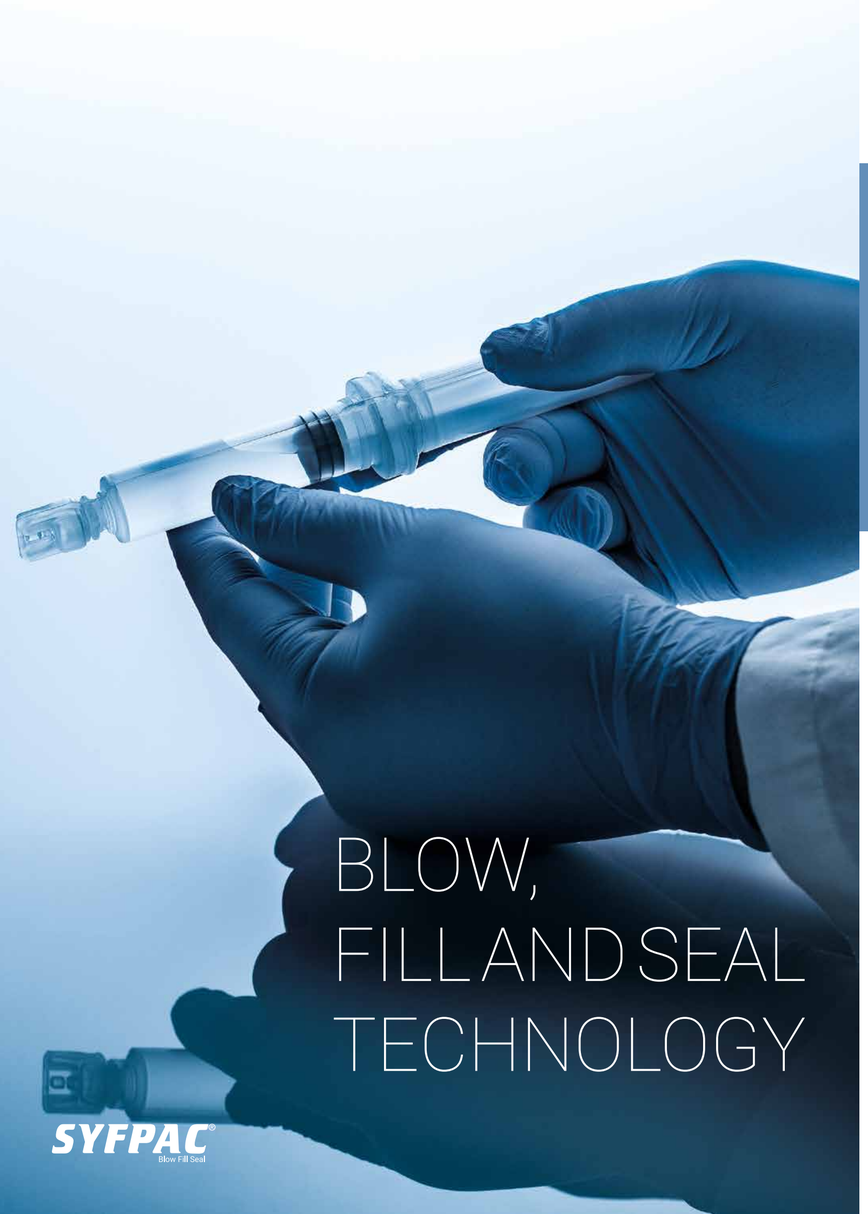
IF YOU ARE LOOKING FOR A PRIMARY PACKAGING TECHNOLOGY THAT IS

CONTAMINATION FREE
PARTICULATE FREE
COST EFFECTIVE TO MANUFACTURE,
TRANSPORT AND STORE
SUITABLE FOR MASS PRODUCTION

# SYFPAC® SYSTEM IS THE SOLUTION FOR YOU!

**SYFPAC®** is Brevetti Angela's latest generation of Blow Fill Seal equipment: a complete range of machines, engineered to achieve the highest quality by design and a cutting-edge technology for the aseptic packaging of sterile pharmaceutical fluids.





# BLOW, FILL AND SEAL TECHNOLOGY

SYFPAC®
Blow Fill Seal

## BLOW FILL SEAL: THE PRINCIPLE

The Blow Fill Seal technique (BFS) has been developed so that the formation, filling and sealing of the container can take place in a single machine within a controlled environment, ensuring that the packaging of the pharmaceutical liquid is aseptic.

## THE BLOW FILL SEAL PROCESS OFFERS MANY ADVANTAGES

### REDUCES

Manufacturing footprint
Probability of viable and non-viable contamination
Cleanroom area and personnel requirements
Cost of logistics

### INCREASES

Process automation
Protection from contamination
Cost efficiency
Shelf-life without preservatives

### ALLOWS

Versatile production
Flexible and customizable shapes



## THE PROCESS

### EXTRUSION

Extrusion of plastic granules in the form of a hot hollow pipe of molten plastic called "parison".

### BLOW

While the mould closes over the parison, the container gets formed and acquires the desired shape due to pressure difference between inner and outer side of the parison, which can be created either by blowing sterile filtered compressed gas (air, nitrogen* or any other inert gas) or by applying the vacuum on the mould cavities.

### FILL

The filling nozzles enter from the top of the container and inject the product in the formed containers. During this step, the filling nozzles and the opening of the containers are protected by a shower of sterile filtered air to avoid contamination. The performance of sterile air can be continuously monitored by a particle counter*.

### SEAL

After filling, the top of the parison (which is still hot) gets pressed between the mould to seal the container. The result is hermetically sealed containers every 10 to 15 seconds.

### DEFLASH

The last step is removing the flash (excess polymer or scrap), trimming and delivering the containers outside the machine.

*Items on request.

# BFS TECHNOLOGY

## THE PROCESS OF CHOICE FOR ASEPTIC PACKAGING

BFS technology is nowadays the preferred primary packaging solution not only by pharmaceutical companies and healthcare providers, but wherever there is the need to package products at minimal cost ensuring contamination free packing.

In fact, modified filling systems can be developed also for the packaging of:

### COSMETIC PRODUCTS
Pastes, creams, gels etc

### FOOD & BEVERAGE LIQUIDS
Fresh juices, milk, non-aerated drinks

### THIXOTROPIC SUBSTANCES
Plasma and serum separation gel

### QUICK-SETTING OR DRYING SUBSTANCES
Crazy glue

SYFPAC® offers the highest protection against contamination at the lowest cost.



# SYFPAC® SYSTEM

**SYFPAC®** stands for: **SY**stem for **F**illing **P**arenterals **A**septically into **C**ontainers of plastic materials.

It works on the principle of BFS and has been conceived to allow creative applications and versatile engineering design.

# SYFPAC® IS DESIGNED AND BUILT FOR:

## HIGH PERFORMANCES

It is designed to perform reliably and precisely for over 3 shifts a day, 365 days a year.

## SIMPLIFIED PACKAGING PROCESS

The whole packaging process is carried out by just one machine and in few seconds, with very limited or no human intervention.

## LOW MAINTENANCE

Its smart and robust construction prevents frequent and expensive maintenance.

## GREAT FLEXIBILITY

Factory-made moulds allow a great flexibility in the choice of shape, size and to emboss relevant information such as Company logo, expiry date, batch number etc.



# VERSATILITY

## SAME MOULD, SAME MACHINE, WIDE CHOICE OF POLYMERS

The unique design of SYFPAC® allows the use of different types of polymer (PP, PE, HDPE) **without changing the mould** nor requiring complicated operations.

PP PE HDPE

## PARISON THICKNESS CONTROL

Thanks to its special engineering, SYFPAC® can control the wall-thickness of the parison and allows to manufacture containers from very rigid to lightweight, self-collapsible to the extent of imitating flexible bags.

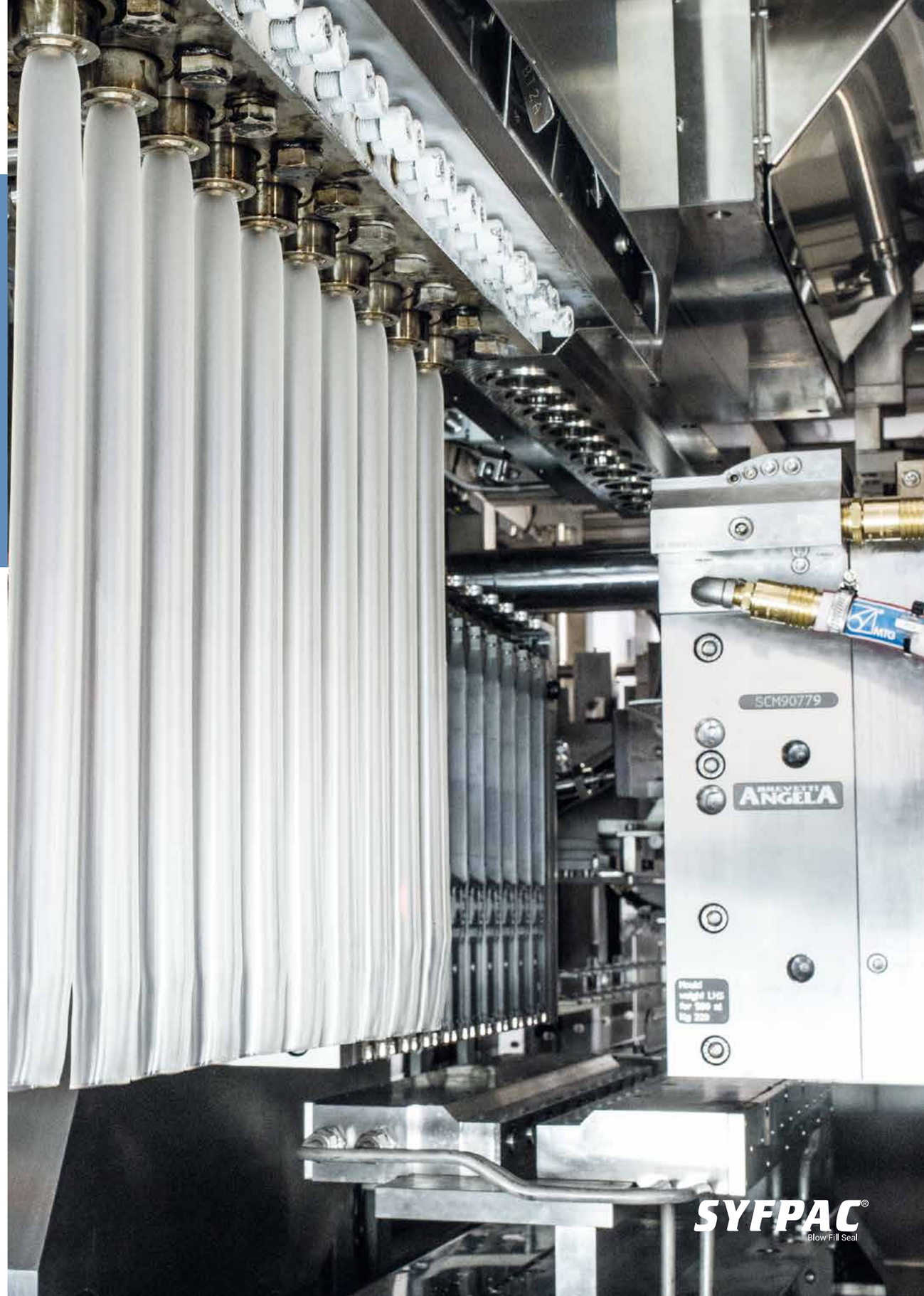
## CUSTOM-TAILORED HEAD SHAPE

Re-closable twist-off heads, luer-lock, calibrated drop caps: it is possible to adjust the head shape to the product application.

## FROM STANDARD TO FULL-OPTIONAL

The standard SYFPAC® design can be customized with a wide choice of optional items and functions, to achieve the desired product.



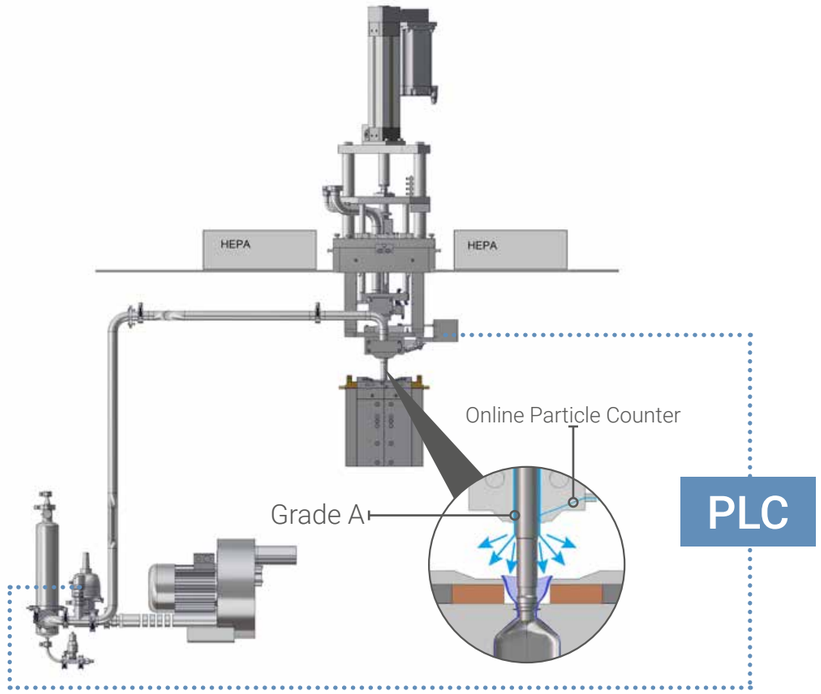



# COMPLIANCE

SYFPAC® aseptic technology is used in many countries, in compliance to different GMPs, and the drugs packed with this system have been tested and approved by Pharmacopeias worldwide. SYFPAC® is in fact wisely built in our factory plant in Italy, in compliance with UNI/EN/International Safety Standards, EU GMP and EHEDG guidelines, CE Directives and FDA regulations (CFR 21 part 11) to meet International Standards.

## GRADE A RESULT IN A GRADE C ENVIRONMENT

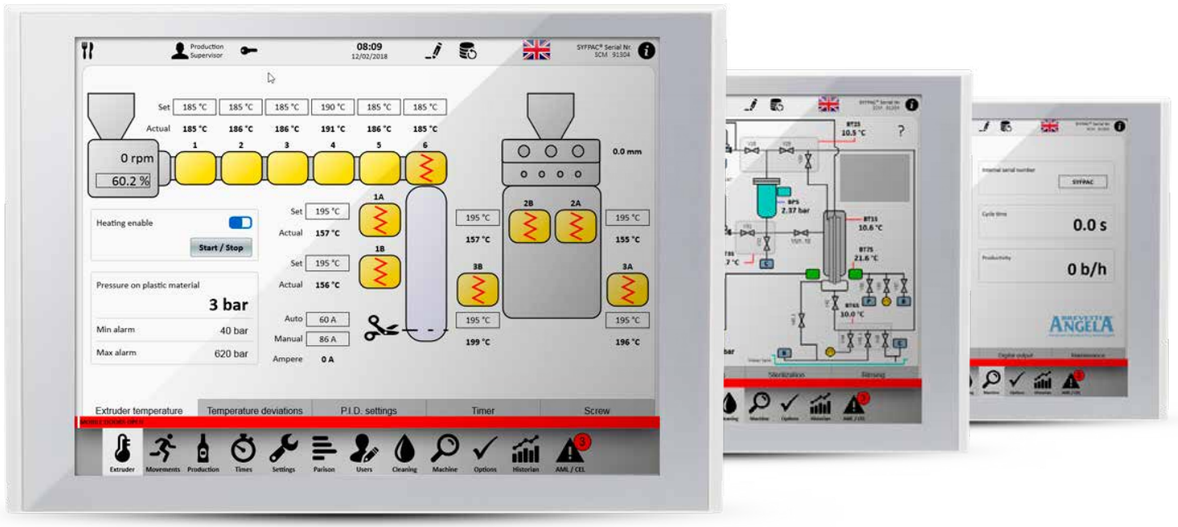
SYFPAC® system can operate inside a grade C clean room environment, as the aseptic condition of the process is guaranteed by the grade A sterile air shower during the filling and sealing steps. To ensure a contamination free product, it handles the process media through pre-sterilized pipes, valves and absolute filters.




SYFPAC®
Blow Fill Seal

## SCADA, HMI AND CONTROL SYSTEM

The system is designed to capture, record and monitor all changes made to the machine operation parameters. If requested, such recording and storage could be CFR 21 part 11 compliant. The system also stores all alarm conditions generated during all phases of machine operation; it automatically performs CIP & SIP, drying, filter integrity tests; it provides information regarding preventive maintenance activities and keeps their record.




# SOLUTIONS FOR YOUR ASEPTIC PACKAGING

# SYFPAC® SVP

| | |
|---|---|
| **Fill Volume** | 0.20 ml up to 50 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 16.000 units per hour** |
| **Clean room size** | 5,2 x 6,4 x 3,1 m |


**SYFPAC® SVP** is conceived for the aseptic primary packaging of **Small Volume Parenterals** in the shape of vials and ampoules.

Moulds with 10 to 50 cavities, machined with special inserts to emboss a graduated scale or variable information are available.

It's designed for volumes from 0.2 ml to 50 ml and, thanks to the advantages offered by plastic moulding, it allows to obtain containers of great variety of shapes and forms, to suit various applications.

A special optional unit **MASEP** (Machine For Automatic Separation) has been developed for the trimming and separation of the blocks of containers in single vials. This unit is controlled by the SCADA system of the SVP.

*Modified systems can be developed to handle liquids at higher temperature.
**Depending on the viscosity of the solution and the bottle design.

# SYFPAC® SVP TWIN

| | |
|---|---|
| **Fill Volume** | 0.20 ml up to 20 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 27.000 units per hour** |
| **Clean room size** | 5,2 x 6,4 x 3,1 m |


This is the latest generation of SYFPAC® developed by Brevetti Angela. Key feature of the **SYFPAC® SVP TWIN** is the double-decker mould.

- With same floor space and same clean room requirements, SYFPAC® SVP TWIN optimizes the production rate up to 27.000 units per hour.
- It increases the efficiency by 60%.
- With almost the same utility consumption, it allows to speed-up the production and, therefore, also the cost-efficiency of each batch produced.

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# SYFPAC® SECUREJECT®

| | |
|---|---|
| **Fill Volume** | 0.5 ml to 20 ml |
| **Temperature of the liquid** | 5°C to 30°C* |
| **Production rate** | Up to 8.400 units per hour** |
| **Clean room size** | 6.25 x 9.25 x 3.4 m |

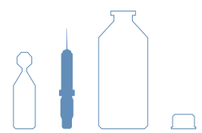

**SYFPAC® SECUREJECT®** is specifically designed for the manufacturing of **aseptic pre-filled syringes (PFS) and injection devices** using BFS technology.

There is an upward trend in the use of pre-filled syringes by healthcare professionals, who recognize that they are distinctly advantageous because:

- PFS prevent overfill and, consequently, dosage error;
- They are easy to use, both for patients and for healthcare professionals;
- They reduce the risks of contamination, reuse and cross infection.

SYFPAC® SECUREJECT® can significantly reduce the cost of pre-filled syringe manufacturing, the number of production steps as well as the cost of secondary packaging.

PRE-FILLED SYRINGES



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# SYFPAC® LVP

| | |
|---|---|
| **Fill Volume** | 50 ml up to 2500 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 2.700 units per hour** |
| **Clean room size** | 5,4 x 6,4 x 3,2 m |


Especially in the field of **Large Volume Parenterals (LVP)**, plastic containers made on BFS machines are rapidly replacing conventional glass bottles, thanks to their high quality packaging at a very reasonable cost. Moreover, BFS is proven to be one of the cleanest technologies for the packaging of intravenous fluids.

**SYFPAC® LVP** offers several advantages that make it a preferred process:

- Bottles can be made from PP, PE or HDPE: this wide choice of materials, available worldwide, enables to pack different formulations.
- Thanks to its special engineering, SYFPAC® LVP can manufacture self-collapsible bottles similar to flexible bags. Such bottles present all the advantages of bags, but at a lower cost.
- Collapsible bottles do not need an air vent during administration: this prevents contamination while dispensing intravenous fluids, thus is preferred by medical staff.
- Brevetti Angela's patented **ECO-head design** allows a further cost reduction, since it eliminates the need for the additional EURO-cap and its related cost.
- BFS bottles have an optimal resistance to terminal sterilization as well as an excellent stability of product and shelf-life.

*Modified systems can be developed to handle liquids at higher temperature.
**Depending on the viscosity of the solution and the bottle design.

LARGE VOLUME PARENTERALS

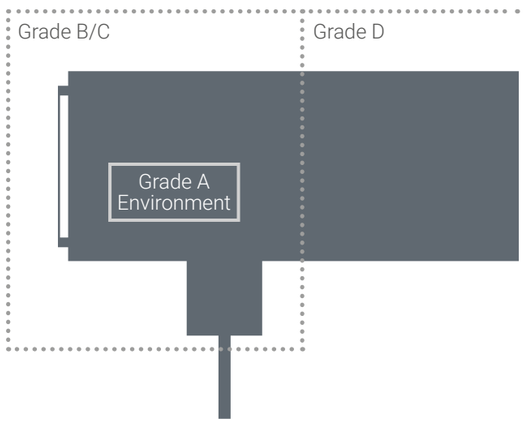
# SYFPAC® ULTRACLEAN

| | |
|---|---|
| **Fill Volume** | 0.20 ml up to 50 ml / 50 ml up to 2500 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 27.000 / 2.700 units per hour** |
| **Clean room size** | 5,4 x 6,4 x 3,2 m |

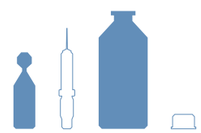

To further reduce the chances of contamination from viable and non-viable particles, Brevetti Angela developed **SYFPAC® ULTRACLEAN**, which guarantees protection against any contamination, comparable to the modern isolator technology.

SYFPAC® ULTRACLEAN has been designed so that:

- Only essential parts or assemblies remain inside the clean room: the rest of the parts are taken out in an adjacent area.
- Human intervention is reduced almost to nil: most work of setting can be performed from outside the clean room by using the 2nd control panel. The presence of an operator is required only during start-up and maintenance.
- Self-contained HEPA filter modules are installed in the area below the extruding head, so that the transfer of the open vials from the extruding to the filling position can take place under the protection of HEPA filtered air. Containers are thus protected against contamination even during the fraction of second of transit time.
- The operator's exposure can be minimized while producing highly potent and active drugs.




HIGH-POTENCY FORMULATIONS



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# MECAS

| | |
|---|---|
| **Production rate** | Up to 2.500 units per hour |
| **Space required T2** | 3,8 x 3,4 x 2,7 m |
| **Space required 9Z** | 5,4 x 3,4 x 2,7 m |

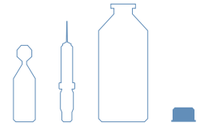

**MECAS** is the fully-automatic cap assembling and sealing system that completes the SYFPAC® LVP line wherever EURO-type caps are required.

MECAS is composed of two units, connected between them by a conveyor belt:

1. The first unit, named **T2**, assembles the EURO-caps onto the container head, right after placing a drop of water for injection between the cap and the bottle head. This operation facilitates an effective sterilization of the space between cap and bottle head during terminal sterilization.
2. The second and final processing station is named **9Z** and has the function to seal the cap to the bottle by injection moulding. This unit is equipped by individual hot-runner injection units, to have a complete control over each station.

MECAS system is runner-less, so there is no waste of plastic during production. Thanks to its accurate sealing, leaks between cap and bottle collar are prevented.

EUROHEAD CAP




# SOLUTIONS FOR OTHER APPLICATIONS

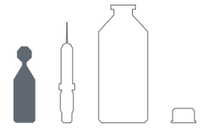
# CYNOPAC

| | |
|---|---|
| **Fill Volume** | 0.20 ml up to 5 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 18.000 units per hour** |
| **Clean room size** | 11 x 6 x 3,4 m |

Besides the pharmaceutical field, Brevetti Angela has developed advanced technology solutions also for other applications.
One of them is the packaging of cyanoacrylate adhesive which, especially at high speed, is quite a challenging task: its polymerization occurs very quickly, under adverse conditions or in contact with undesired materials, so these events must be avoided to keep the adhesive in a liquid form.

Thanks to the completely automatic **CYNOPAC** system it is possible to manufacture containers starting from the polymer granules, print the product name and other information, fill and seal them all within one continuous automatic line with reliability of over 99,5 % and a speed up to 18.000 units per hour.

CYANOACRYLATE ADHESIVE



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**Depending on the viscosity of the solution and the bottle design.

# LIQUIDPAC

| | |
|---|---|
| **Fill Volume** | 0.5 ml up to 1000 ml |
| **Temperature of the liquid** | 4°C to 30°C* |
| **Production rate** | Up to 16.000 units per hour** |
| **Clean room size** | 5,4 x 6,4 x 3,2 m |


**LIQUIDPAC** is a system analogous to SYFPAC®; the only difference is that LIQUIDPAC has been studied to address the packaging needs of the Food and Beverage industry. This equipment allows to design very creative and ergonomic bottles.
In fact, Brevetti Angela has realized some patented packaging projects, such as a strap-off-seal milk bottle with re-closable cap and a fruit juice bottle with inbuilt straw.

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FOOD AND BEVERAGE

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