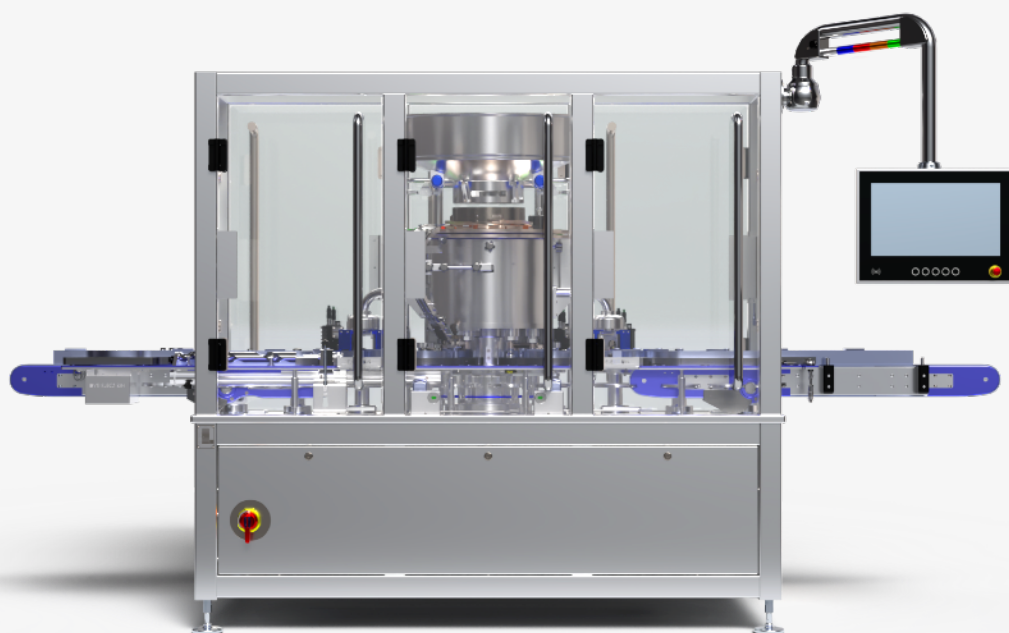




Genesis Packaging Technologies

# Aptus

Modular Vial Crimping System



The **Aptus** is a fully automated, servo driven, constant motion, rotary crimper. Ideal for mid to large production runs of time sensitive products such as lyophilized vaccines, the Genesis Aptus is capable of sealing both large and small parenteral vials at up to 300 vials per minute.

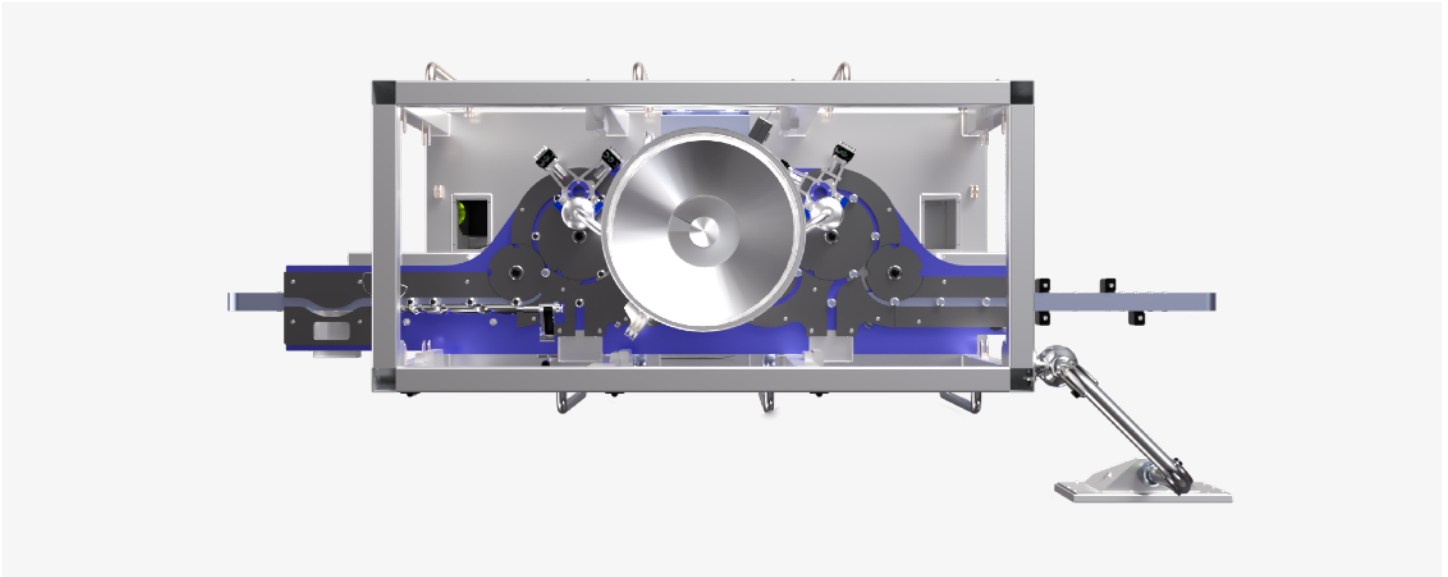
# Design Highlights

A stoppered vial is a prevalent parenteral drug container closure system. The system however, should not be considered integral until the rubber stopper is crimped firmly in place with sufficient compression against the vial, assuring all potential leakage is cut off at the seal interface. It is well understood that seal quality is critically important to maintaining sterility and stability of the drug product.

The Aptus was designed to satisfy the mid to large production crimping process. The system offers state-of-the-art controls and capping parameter settings. It is FULLY modular allowing small to large scale options to be easily implemented for all customer requirements. All functions are completed while the vial is under complete control in the stars and turrets of the Aptus. The "system" functionally consists of two additional stars immediately following the standard capper discharge star, and a platform on which marking and reading equipment can be mounted on the capper. The first additional star is used to position the vial for marking and reading, the second serves as an eject star for non-conforming vials. The capper utilizes modern servo controls for critical motions including the rotary motion of all stages and the vertical motion of the capping head assembly. The overall height of the capper has been kept to a minimum allowing it to fit in tighter spaces. The cap hopper can be offset to the discharge side of the capping head to minimize particulate and further reduce the height of the unit. The Aptus has also been designed to help you meet the European Annex 1 regulations of the Manufacture of Sterile Medicinal Products.



Genesis brings to the table much more than the time-honored Westcapper® sealing technology. We bring a complete understanding of the parenteral package itself. Our technical experts maintain long-standing relationships with parenteral package component manufacturers. We know the vial package. Our expertise in the science of sealing is deep-rooted and so is our commitment to seal integrity.



# Features & Options

## Flexibility

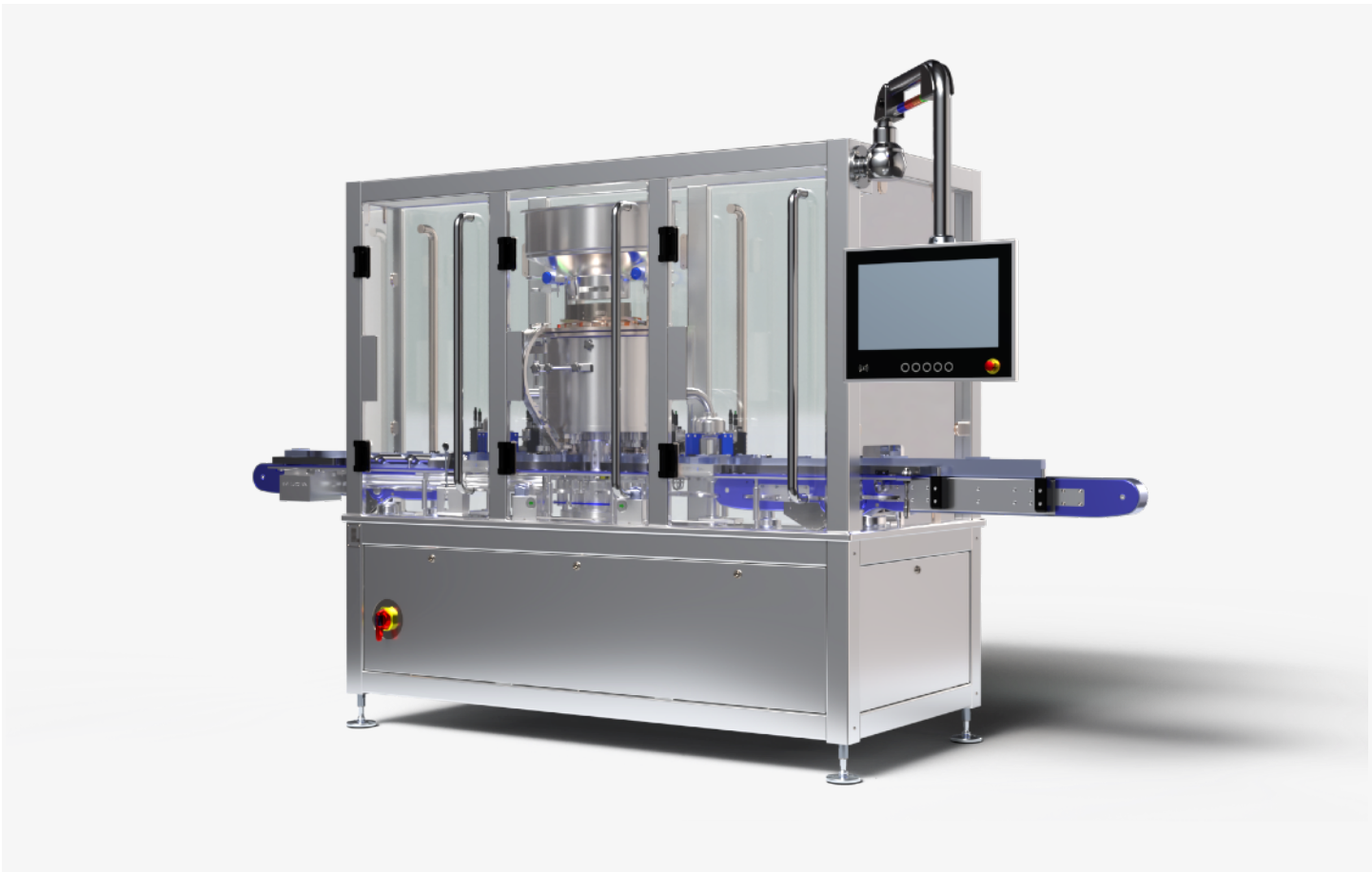
Genesis recognizes that each customer may have different requirements for both upstream and down stream system integration. While we offer standard capper features and options, the design concept provides a flexible platform, with the vial under complete control, on which a wide variety of customer preferences can be accommodated.

## Raised | Missing Stopper Detection

The Aptus platform can be fitted with a vision based raised/missing stopper detection system. As the vials enter the capper they pass in front of the system which determines whether or not a stopper is missing or raised based on the criteria that has been set in the PLC/PC based controls. All vials failing this criteria are rejected and ejected out of the system by a starwheel before entering the sealing stage of the capping process. The system is based on a Dual Camera system with Color Smart cameras. The redundant cameras offer extended coverage of the vial inspection. Color cameras allow for very detailed inspection of stoppers and ensure the proper components are being used. We can add an optional AI system to enable learned good products for endless analysis.

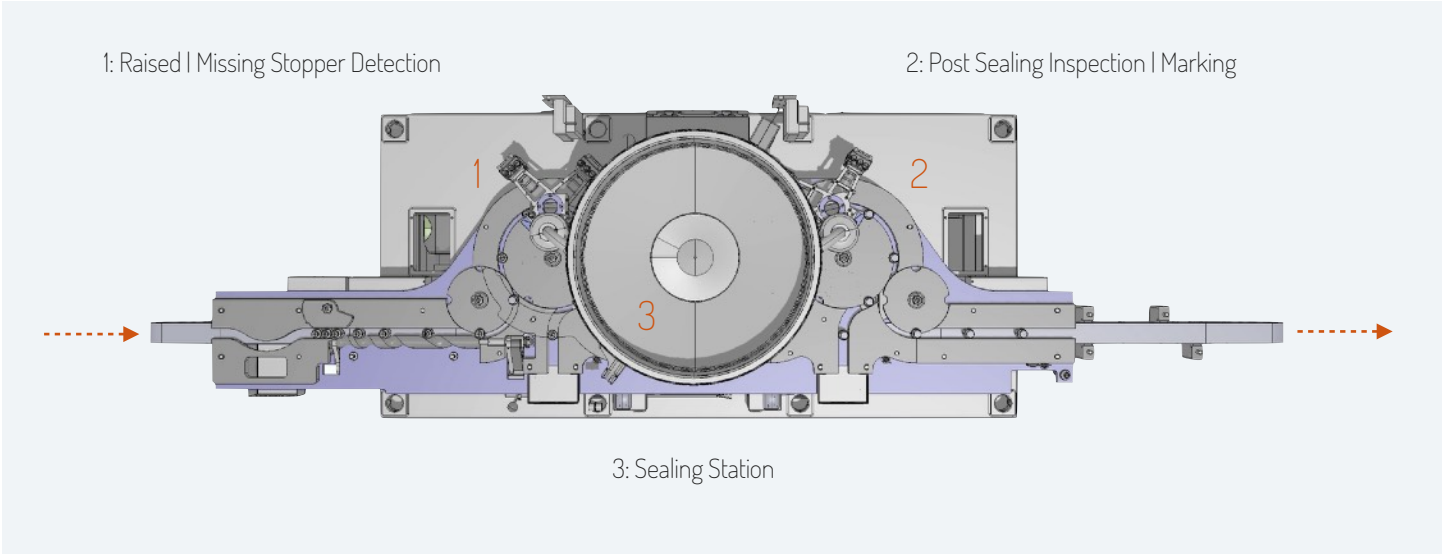
## Vial Marking and Verifications

The Aptus can be equipped with a post capping marking system with an immediate OCR vision system confirming that the mark has been properly applied (is able to be read). In the event of a non-conforming mark, the vial will be ejected from the production line for further action. With the optional vision system located prior to the labeler, the system ensures full compliance with current regulations. Options are available for ink jet and laser marking. When the Applied Force Monitor option is elected, the system can identify the cause for rejection for each vial and maintain batch records (in addition to all the normal Applied Force Monitor functions).



Post Sealing Inspection

The Aptus can be fitted with a post sealing inspection station to visually inspect vials as they exit the sealing station on the capper. As the vials leave the capper sealing station they pass in front of the system which determines whether or not a vial has been mis-crimped or is missing a seal entirely based on the criteria that has been set in the PLC/PC based controls. All vials failing this criteria are rejected and ejected out of the system by a starwheel before continuing down the line away from the capping machine. The system utilizes two vision cameras to increase the coverage of the inspection. Color cameras are utilized to allow for inspection on cap and button colors to ensure the proper components are being used. We can add an optional AI system to enable learned good products for endless analysis.





## Reporting

Data Storage/Reports (21CFR11 Capable)



## Networking

User/Active Directory & Network Integration

# Specifications

Max Speed (vpm)	120 - 300 Vials per Minute
Sealing Technology	Sealing Rail
Hopper System	Gravity Fed Vibratory
Seal Size	13-32 mm
Seal Style	All Standard Serum
Vial Diameter	12.7-82.55 mm
Vial Height	28.702-158.75 mm
Construction	Stainless Steel
Control System	PLC with PC Touchscreen Interface
Vial Infeed Sensor	✓
Jam Control Sensor	✓

# Change Parts Cabinets

Heavy Duty Rolling Cabinets to Organize & Store All Your Change Parts

Custom rolling cabinets that are tailored for your Genesis capper to securely house its change parts. Each cabinet is made from high grade steel and utilizes ball bearing drawer slides that allow you full, uninhibited access to the entire drawer. The chassis rolls on 6 inch Polyurethane wheels. Each cabinet is secured with a key that can be configured to unlock a single cabinet or an entire set of cabinets depending on your needs. The cabinet meets and exceeds the 5S standard by ensuring your change parts to stay safe, protected from damage, dust, debris, and always kept organized on kaizen boards for quicker change overs.

Drawers include custom labels that are visible from across the room, which can indicate the contents of the drawers or what size vial the enclosed set uses. Our 60 inch cabinet supports the option for a 304 Stainless Steel top work surface.

Available in 45 inch and 60 inch width sizes.



# Stopper Compression Analysis

## The Stopper Compression Analysis Service Provides Critical Information Necessary to Insure Robust Seal Integrity and Repeatable Capper Setup

A stoppered vial is a universal parenteral drug container closure system. The system however, should not be considered integral until the rubber stopper is crimped firmly in place with sufficient compression against the vial finish assuring all potential leakage is cut off at the seal interface. Analysis of this seal integrity should be a critical aspect of the packaging development, evaluation and qualification.

A parenteral vial container closure system is made integral by compressing the flange of a rubber stopper against the sealing surface of a vial (finish crown) and securing it in place with a crimped aluminum ferrule or seal. The elastomeric properties of the rubber maintain a force that effectively seals the vial. Our experienced technicians analyze your specific container closure system and determine the optimal compression percentage to achieve leak rate cut off. This value is then correlated to Residual Seal Force (RSF) and verified by a standard leak testing method.

The RSF value is the measured stress the compressed rubber closure flange continues to exert on the vial-sealing surface after application (crimping) of an aluminum ferrule. By correlating RSF values for each set of vials to the compression calculation for those vials, RSF can then be used as an indirect test method to estimate closely the elastomeric closure compression.

RSF values may be used in effectively setting up vial cappers and for monitoring the crimping process. With an

understanding of compression and leak rate cut-off RSF can be further used as a predictor of leakage risk.

Genesis provides a complete report which includes all the test procedures used and data collected. This information can then be used to develop your vial sealing SOP's.

### **The report includes:**

1. Stopper Flange Compression Analysis
2. Levels of Compression Graphics
3. Compression and Residual Seal Force Data
4. Residual Seal Force Measurements
5. Helium Leak Testing
6. Discussion and Recommendations
7. Stopper Compression Measurement Procedure
8. Residual Seal Force Measurement Procedure
9. Package Component Specifications



# Vial Optimization

The onsite vial optimization procedure carried out by Genesis is a means by which capping machine parameters are obtained through a careful process of studying component structure, variation and stopper compression analysis.

## Optimizing for Container Closure Integrity

Machine settings are considered optimal when optimum stopper compression has been achieved. Genesis bases its optimal compression standards on research and experience. Where feasible, a quality, aesthetic package appearance is also obtained.

It is extremely important to understand, and it should be noted, that the optimized machine settings are directly related to the components being processed during the optimization procedure. If any one component i.e. overseal, stopper or vial, is changed, the machine parameters are no longer applicable and new studies need to be carried out.

The following tasks are carried out during the optimization procedure:

1. Precise package measurements.
2. Stopper compression analysis based on package measurements.
3. Vials processed below optimal compression (spring related).
4. Vials processed above optimal compression (spring related).
5. Vials processed at optimal compression (spring related).
6. Residual Seal Force studies of vials processed at all levels of compression.
7. If requested by the customer, leak testing of randomly selected vials from each compression group can be provided.
8. Sealing Rail Setup (performed only at optimal compression and head height settings)
9. Head Height Setup (performed only at optimal compression and rail settings)

# Service Packages

## Small Machine Packages

Service and training packages for the Integra Laboratory Crimper and the Residual Seal Force Tester. Discounts are available for purchase of multi-year or combination (service & training) packages.

### Select Service Annual Billing

- ✓ Includes one visit annually plus all travel and living expenses.
- ✓ Preferred scheduling.
- ✓ Up to 4 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

### Premium Service Annual Billing

- ✓ Includes two visits annually plus all travel and living expenses.
- ✓ Priority scheduling.
- ✓ Up to 8 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

### Select Training Annual Billing

- ✓ Includes one on-site training session annually for up to 4 operators plus all travel and living expenses.
- ✓ Preferred scheduling.
- ✓ Up to 4 hours of telephone or virtual training support with any additional hours billed in ¼ hour minimum increments.

### Premium Training Annual Billing

- ✓ Includes two visits annually plus all travel and living expenses.
- ✓ Priority scheduling.
- ✓ Up to 8 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

# Service Packages

## Large Machine Packages

Service and training packages for the RW, PW and Aptus line of Westcappers. Discounts are available for purchase of multi-year or combination (service & training) packages.

### Select Service Annual Billing

- ✓ Includes 1 two day visit annually plus all travel and living expenses.
- ✓ 5% discount on any parts purchased during the contract term.
- ✓ Preferred scheduling.
- ✓ Up to 8 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

### Premium Service Annual Billing

- ✓ Includes 2 two day visits annually plus all travel and living expenses.
- ✓ 10% discount on any parts purchased during the contract term.
- ✓ Priority scheduling.
- ✓ Up to 16 hours of telephone or virtual tech support annually with any additional hours billed in ¼ hour minimum increments.

### Select Training Annual Billing

- ✓ Includes 2 one day on-site training sessions annually for up to 4 operators plus all travel and living expenses.
- ✓ 5% discount if purchased with accompanying Select or Premium Service Contract.
- ✓ Preferred scheduling.
- ✓ Up to 8 hours of telephone or virtual training support with any additional hours billed in ¼ hour minimum increments.

### Premium Training Annual Billing

- ✓ Includes 2 two day on-site training sessions annually plus all travel and living expenses.
- ✓ 10% discount if purchased with accompanying Select or Premium Service Contract.
- ✓ Priority scheduling.
- ✓ Up to 16 hours of telephone or virtual training support with any additional hours billed in ¼ hour minimum increments.

# How Can We Help?

Genesis provides technical consultation and training in all areas of parenteral packaging including: the selection and utilization of container/closure components, materials of construction, packaging development, risk assessments, supplier qualification, container/closure integrity, regulatory compliance and investigations.

Genesis brings to the table much more than the time-honored Westcapper® sealing technology. We bring a complete understanding of the parenteral package itself. Our technical experts maintain long-standing relationships with parenteral package component manufacturers. We know the vial package. Our expertise in the science of sealing is deep-rooted and so is our commitment to seal integrity.

Parenteral pharmaceutical packaging is the core of our work. It's scope includes the traditional vials with elastomeric stoppers, cartridges and pre-filled syringe systems, and in developing novel and innovative components, and drug delivery systems, including combination products. We have extensive experience with the customary materials of glass, rubber and metals, but also with the advanced plastics and laminate materials being promoted today.

We are knowledgeable of the regulatory requirements and guidances concerning the packaging of pharmaceuticals and container closure systems and have experience with US and worldwide authorities. Our consultants are professionals serving on various technical committees and interest groups of organizations such as PDA, ISPE, ISO and ASTM. They are

teachers, sharing their knowledge at seminars and training sessions around the world.

## **Some of the things we do:**

1. Container/Closure System Development
2. Product/Process Improvements
3. Container/Closure system Evaluation and Qualification
4. Supplier Management
5. Training and Education
6. Vial Optimization



[www.gen-techno.com](http://www.gen-techno.com)

## Genesis Packaging Technologies is a Worldwide Leader in the Science and Technology of Parenteral Vial Sealing and Residual Seal Force Testing

We provide advanced vial sealing equipment for the packaging of critical injectable pharmaceutical products. Genesis designs, develops and builds vial cappers with innovative technologies that meet the technical challenges of parenteral pharmaceutical packaging, assuring seal integrity in compliance with advancing regulatory requirements for aseptic processing and container closure integrity. Offering our customers the tools and knowledge to consistently achieve container closure integrity remains our priority.

Purchasing equipment from Genesis provides customers support from a company with over 75 years of experience dealing specifically with vial handling equipment and technologies. Service is available on all equipment manufactured by Genesis and the former Machinery Systems Division of The West Company.

For the better part of a century Genesis Packaging Technologies has been at the forefront of sealing technology. Providing the pharmaceutical industry with parenteral vial sealing solutions is what we do.

## Genesis Packaging Technologies

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