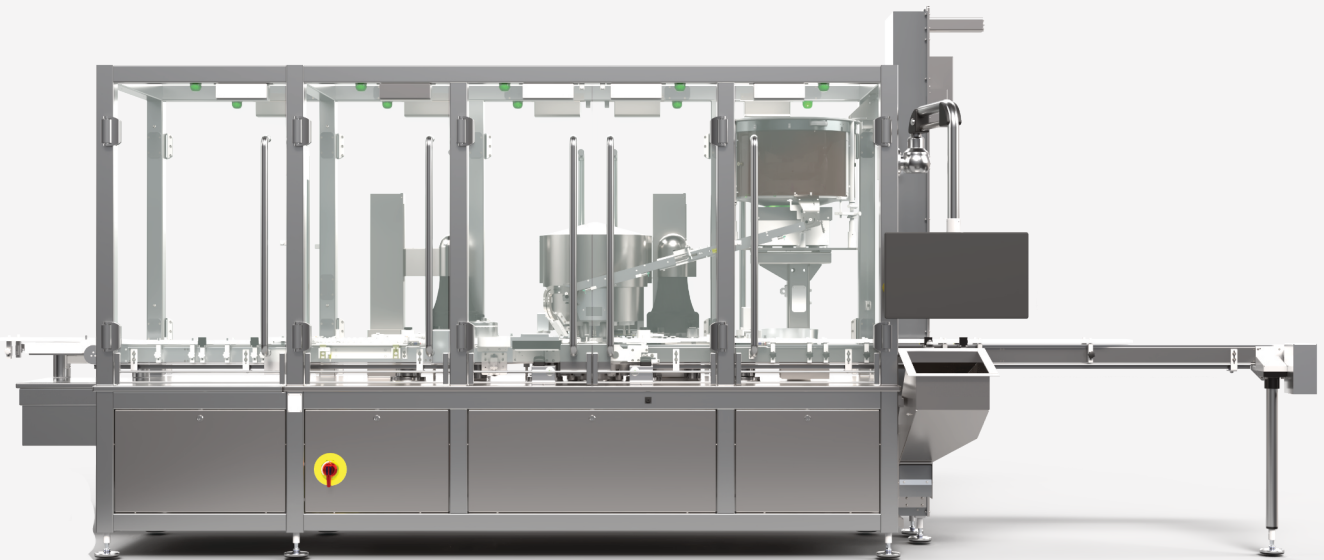




Genesis Packaging Technologies

RW Westcapper®

High Speed, Large Volume, Vial Sealing



The RW Westcapper® is a fully automated, constant motion, rotary crimper. Ideal for large production runs of time sensitive products such as lyophilized vaccines, the Genesis RW Westcapper® is capable of sealing parenteral vials at up to 750 vials per minute.

Design Highlights

Genesis stands at the forefront of parenteral vial sealing, offering advanced solutions that ensure container closure integrity for critical injectable pharmaceuticals. With over 75 years of expertise, Genesis has developed the RW Westcapper® – a high-speed, fully automated, continuous motion crimper designed to meet the rigorous demands of modern pharmaceutical manufacturing.

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.

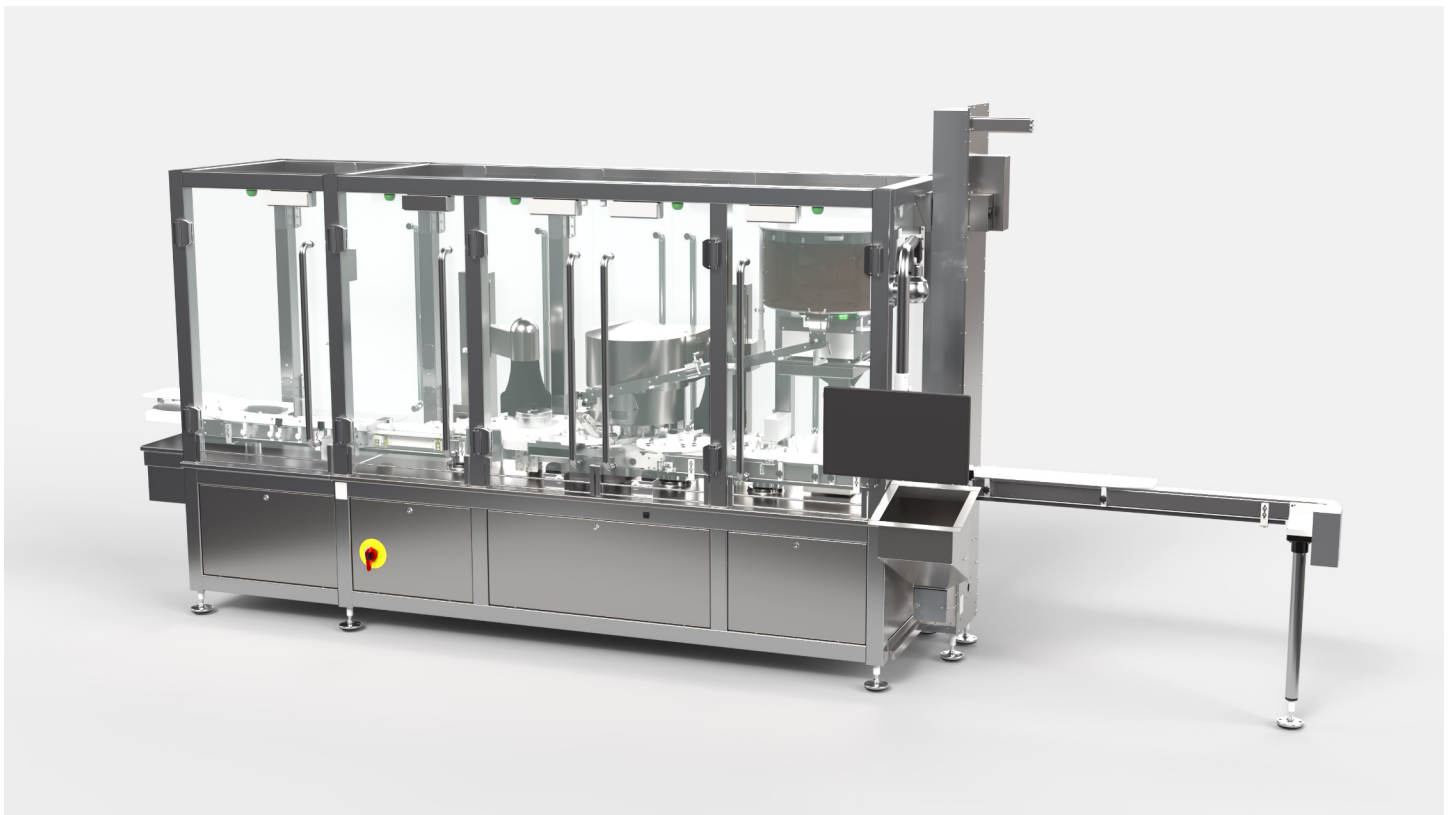
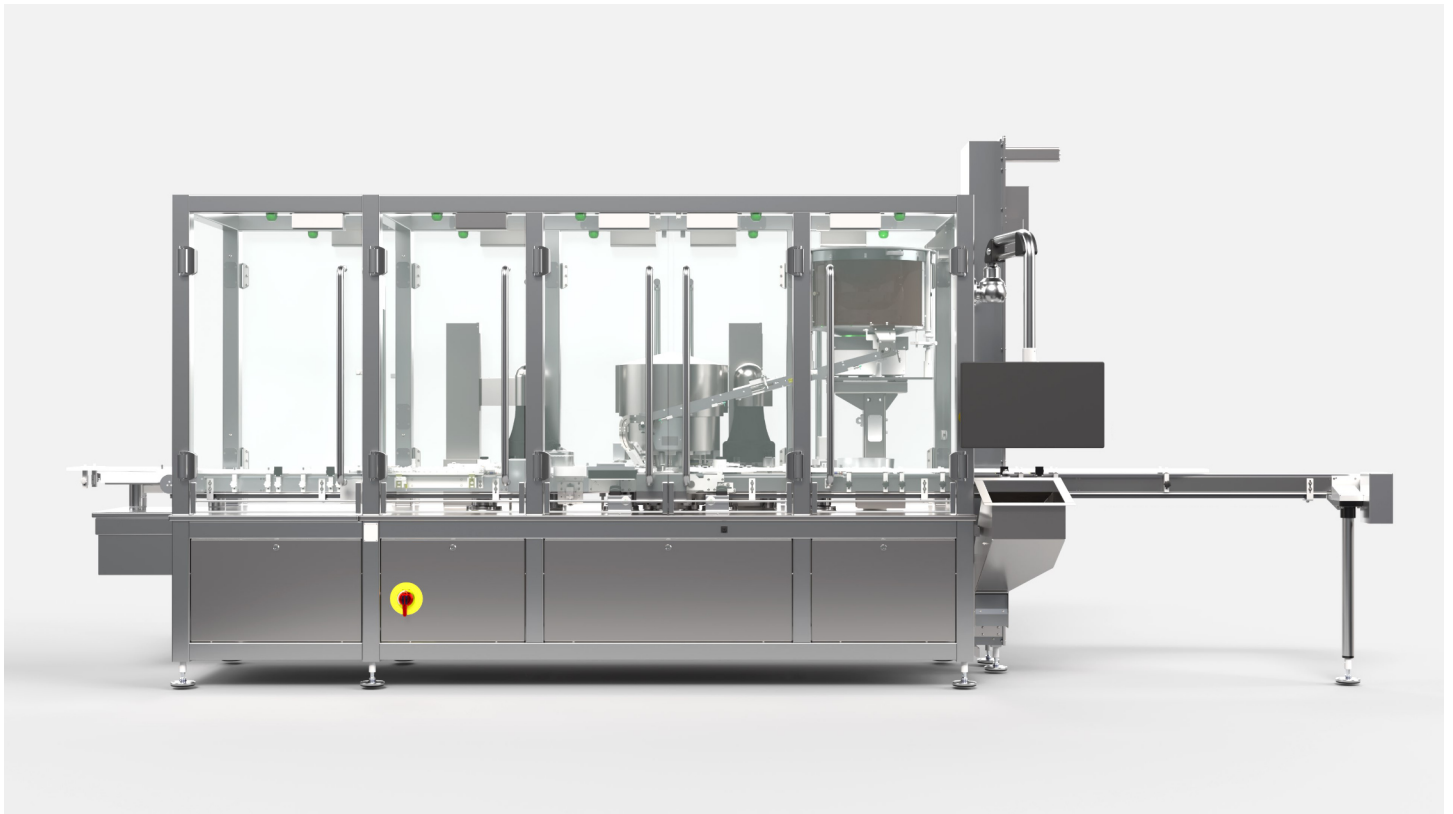
Ensuring Container Closure Integrity in Parenteral Packaging

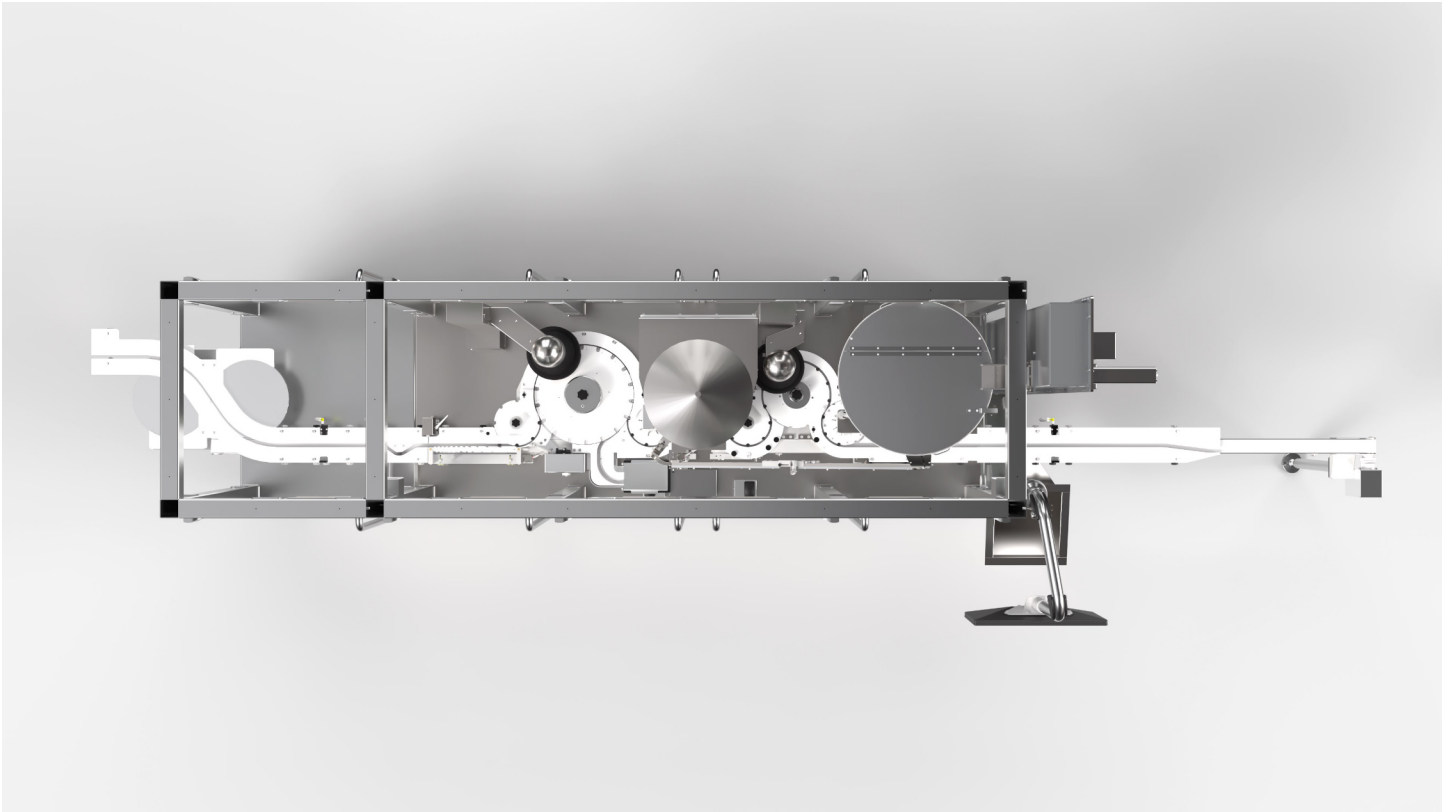
In parenteral drug delivery, the integrity of the container closure system is paramount. A stoppered vial achieves true integrity only when the elastomeric stopper is compressed adequately against the vial's sealing surface and secured with a crimped aluminum ferrule. This compression ensures a hermetic seal, preventing microbial ingress and maintaining the sterility and stability of the drug product.

The RW Westcapper® addresses this critical aspect by precisely controlling the force applied during the crimping process. By regulating the compression of the elastomeric closure, the system minimizes variability, resulting in consistent and reliable seals across production batches.

RW Westcapper®: Advanced Design for High-Volume Production

- **Optimized Cap Feeding:** The vibratory cap bowl is strategically positioned on the discharge side, significantly reducing the risk of particulate contamination during sealing.
- **Compact Footprint:** Relocating the hopper system away from the head height adjustment mechanism has lowered the machine's overall height, facilitating integration into various production settings.
- **Flexible Configuration:** The system accommodates vial flow from left to right as standard, with right-to-left flow available as an option. Conveyor heights range from 35¼" to 38", and the standard conveyor length is 98", with customizable lengths upon request.
- **Safety Compliance:** An OSHA-compliant safety shield encloses the capping area, with interlocks that halt operation immediately upon shield opening, ensuring operator safety.





Seal Integrity

RW Westcapper® with Advisum-AI Powered by Boon Logic's AVIS

The RW Westcapper® is available with Advisum AI, an integrated AI-based vision inspection system that monitors upstream and downstream operations of the sealing process—identifying missing or improperly inserted stoppers before the crimping operation, and detecting improperly sealed vials and cosmetic defects after crimping. This proactive monitoring helps ensure only properly stoppered and sealed vials progress further, reducing potential risks of leakage, contamination, or non-compliance.

At the core of this capability is Advisum AI, powered by Boon Logic's AVIS anomaly-detection platform, which leverages unsupervised machine learning to model “normal” compliant units and flag deviations as defects.

Key performance attributes include:

- Recipe/training time measured in minutes (e.g., training on ~500 compliant units) rather than the weeks/months typical of traditional supervised vision systems.
- Reduced false rejects (e.g., feasibility studies showing detection accuracies of ~90% with false eject rates of ~6% on challenging products).
- Flexibility to retrofit existing capping machines, integrate into existing visual inspection cabins, or deploy as standalone inspection stations—preserving legacy investments while upgrading inspection capability.

Typical defect types the system is designed to detect include: missing or raised stoppers, mis-aligned or cocked caps, cracked or chipped vial necks, deformed cap skirts, wrong cap color, particulate contamination under the cap, and cosmetic anomalies.

Because this inspection is applied both upstream and downstream of the sealing operation, it helps reinforce the entire container closure integrity (CCI) journey—boosting confidence in the sealed vial, reducing rework and scrap, and supporting regulatory expectations for 100% inspection (where required) or robust risk-based inspection strategies.

Beyond defect detection, the RW Westcapper® with Advisum AI provides real-time process intelligence that enables operators and quality teams to identify emerging trends before they become batch-impacting events. By continuously learning normal production behavior and surfacing subtle shifts in stopper placement, crimp force outcomes, and cosmetic consistency, the system supports proactive maintenance, faster root-cause analysis, and continuous process optimization—aligning with modern pharma manufacturing goals around quality by design (QbD) and digital transformation initiatives.

Compliance

Comprehensive Services to Support Quality and Compliance

Stopper Compression Analysis: Genesis provides a detailed service to determine the optimal stopper compression percentage to achieve the desired leak-rate cut-off, correlating this value to Residual Seal Force (RSF) and verifying via standard leak-testing methods. This ensures that the sealing process is tuned for efficacy and repeatability.

Machine Training Programs: Recognizing that machine performance, change parts, package components, and setup procedures are all inter-related, Genesis offers detailed training and hands-on studies to optimize the interrelationship among these variables — thereby supporting consistent, high-quality oversealing performance.

Service & Training Packages: Annual service visits, preferred scheduling, and technical support packages are offered to maintain peak machine performance, preserve uptime, and ensure ongoing compliance with evolving standards.

By combining cutting-edge hardware (like the Westcapper®), advanced inspection (Advisum AI/AVIS), and robust service/training offerings, Genesis Packaging Technologies provides a holistic solution — one that not only equips manufacturers with best-in-class technology, but also actively supports them in maintaining high-performance operations and regulatory alignment.

In addition, Genesis supports customers with data-driven documentation and validation assistance aligned with regulated pharmaceutical environments. Service engagements can include support for IQ/OQ/PQ activities, development of defensible process windows, and generation of objective evidence linking machine settings, stopper compression, and sealing outcomes to container closure integrity (CCI) performance. This structured, science-based approach helps manufacturers streamline validation efforts, respond confidently to audits, and maintain long-term control over critical sealing parameters throughout the product lifecycle.

Summary

In short, Genesis's commitment is two-fold:

Provide the mechanical sealing excellence via the Westcapper® platform.

Augment that with AI-driven inspection, training, and service capabilities so that manufacturers can safeguard product integrity, reduce downstream defects, and demonstrate compliance.

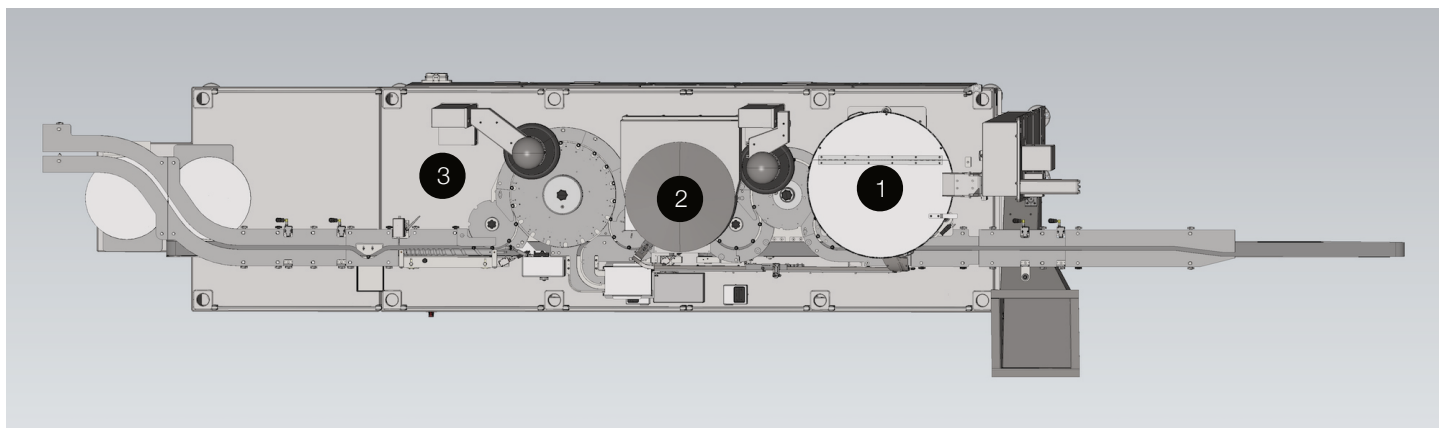
Together, these offerings form a comprehensive packaging quality ecosystem — from optimal compression, through sealing, through AI-based inspection and ongoing support.

Compliance

Annex 1 & Container Closure Integrity

EU GMP Annex 1 emphasizes two critical areas:

1. A robust Contamination Control Strategy (CCS), focusing on minimizing particulate and microbial ingress.
2. Container Closure Integrity (CCI): ensuring seals prevent leaks and contamination throughout a vial's shelf life.



SECTION	REQUIREMENT	WESTCAPPER COMPLIANCE
§119	Particulate control via separate station + air extraction.	1: FIFO hopper separated from crimp head; air-extraction system installed.
§120	Grade A air protection during capping.	2: Grade A air supplied over stoppers, seals, and hopper as needed.
§121	Automated rejection of improper stoppers.	3: Sensors detect and reject missing or raised stoppers pre-crimping.
8.21–8.28*	CCI validation, process monitoring.	Controlled crimp force; RSF analysis; vision-based inspection supports compliance.

RW Product Matrix

	18 Spindles	12 Spindles	6 Spindles
Max Speed (vpm)	750	600	300
Sealing Technology	Sealing Rail	Sealing Rail	Sealing Rail
Hopper System	Gravity Fed Vibratory	Gravity Fed Vibratory	Gravity Fed Vibratory
Seal Size	13-32mm	13-32mm	13-32mm
Seal Style	All Standard Serum	All Standard Serum	All Standard Serum
Vial Diameter	12.7-38.1 mm	12.7-57.15 mm	12.7-82.55 mm
Vial Height	28.575-158.75 mm	28.575-158.75 mm	55.549-180.84 mm
Construction	Stainless Steel	Stainless Steel	Stainless Steel
Control System	PLC Touchscreen Interface	PLC Touchscreen Interface	PLC Touchscreen Interface
Vial Infeed Sensor	✓	✓	✓
Jam Control Sensor	✓	✓	✓

Change Parts Cabinets

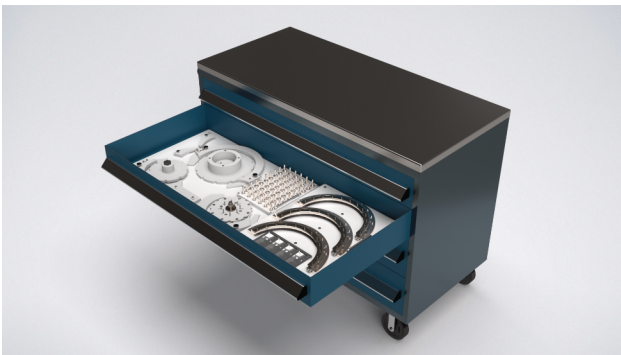
Heavy Duty Rolling Cabinets to Organize & Store All Your Change Parts

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.

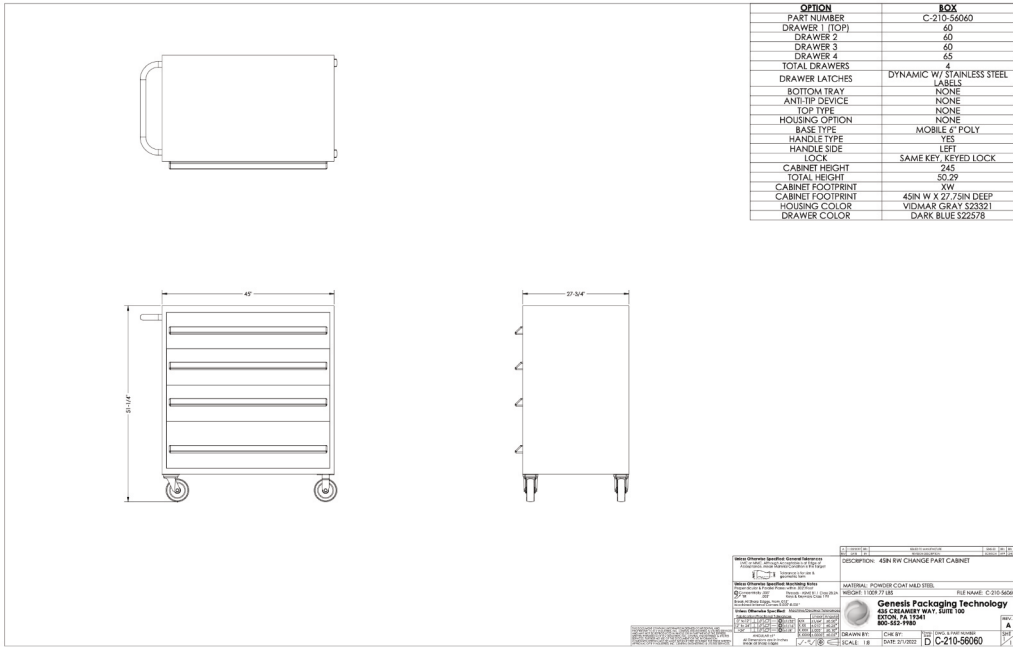
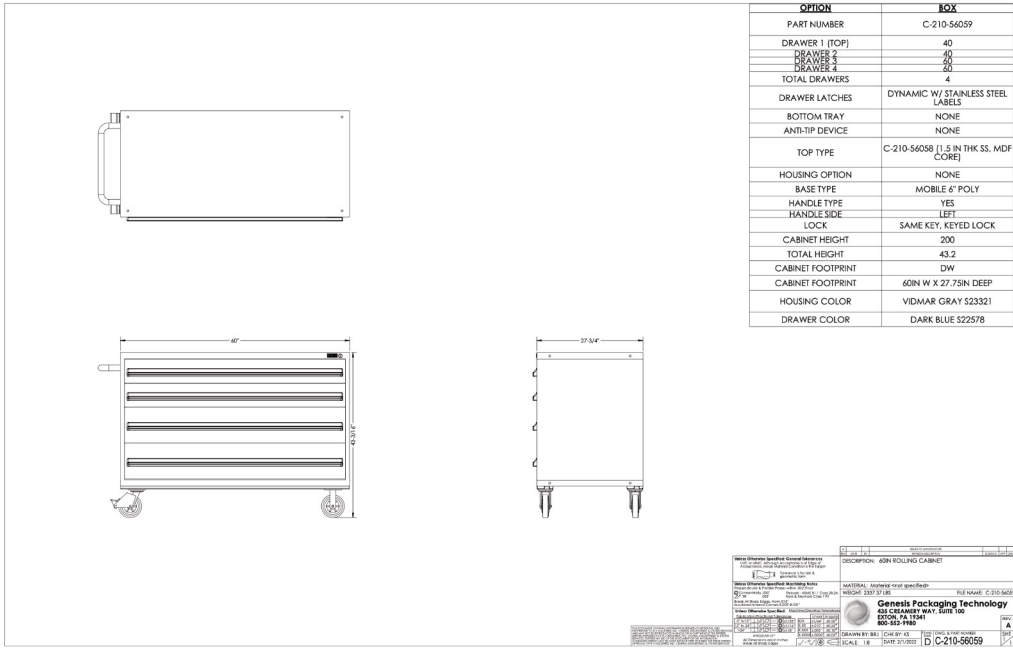
Custom rolling cabinets that are tailored to your Genesis capper to securely house it's change parts. Each cabinet is made from high grade steel and utilizes ball bearing drawer slides that allow you full, uninhibited access to the entire drawer. The chassis rolls on 6 inch Polyurethane wheels. Each 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.



Change Parts Cabinets



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 scientists & engineers 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)

Training

In order to benefit from the full range of your Genesis crimper capabilities, a sound understanding of the interrelationship between package components, machine change parts and setup procedures is required. The Genesis Machine Training Program offers a detailed study of these significant process categories which, when applied, will insure consistent high quality oversealing, seal integrity, and machine performance.

Building Expertise in Precision Vial Sealing Operations

Genesis Packaging Technologies offers a comprehensive Crimping Machine Training Program designed to help pharmaceutical manufacturers fully understand and optimize overseal performance. The program focuses on the critical relationships between machine mechanics, package components, and change parts that directly impact container closure integrity. Through detailed instruction on setup procedures, adjustments, and component interaction, participants gain the technical foundation needed to achieve consistent, high-quality sealing results.

Hands-On Knowledge That Improves Quality and Efficiency

Training covers the key variables that influence crimp quality, including vial and cap change part selection, mechanical alignment, and fine-tuning adjustments that ensure repeatable performance. By learning how each element affects seal formation, operators and maintenance personnel can quickly identify issues, minimize downtime, and maintain peak machine efficiency. This practical, application-driven approach helps reduce variability while improving throughput and production confidence.

Empowering Teams for Long-Term Operational Excellence

Designed for operators, maintenance staff, engineers, and quality professionals, Genesis' training strengthens in-house expertise and promotes best practices aligned with pharmaceutical manufacturing standards. Emphasizing proper setup techniques, OEM components, and preventative understanding, the program supports long-term equipment reliability and robust package integrity. The result is a more knowledgeable workforce, improved seal consistency, and greater assurance in every vial produced.

Service

Optimize. Maintain. Upgrade. – Unmatched Service for Your Vial Sealing Equipment

Machine Service & Maintenance

To ensure your vial crimping systems remain reliable, accurate, and performing at peak capability, Genesis offers comprehensive machine service and upgrade options for all equipment manufactured by Genesis and the former Machinery Systems Division of The West Company.

Key Service Offerings Include:

- **Annual Maintenance & Machine Evaluation** – Tailored visits to keep machines operating smoothly and prevent unscheduled downtime.
- **Oil-Free Conversion** – Replace traditional lubrication with FDA-compliant self-lubricating components, eliminating the risk of oil exposure near vial product surfaces.
- **Mechanical Upgrades & Component Rebuilds** – Including partial rebuilds, main drive shaft kits, conveyor support assembly rebuilds, and clutch and gearbox service kits to extend machine longevity.
- **Precision Enhancements** – Upgrades such as vial rest lock nuts, missing stopper/raised stopper detectors, missing cap counters, and updated control relay systems that improve reliability and production quality.
- **Safety & Efficiency Add-Ons** – Modern safety interlocks and process control upgrades that bring older machines up to current operational and compliance standards.

Each service engagement is performed by trained Genesis technicians, with a focus on minimizing disruption to your production environment while enhancing machine performance, uptime, and product quality.

Why Service Matters

Maintenance and upgrades from Genesis aren't "routine"; they are targeted performance improvements designed to:

- Protect seal integrity and sterilization confidence.
- Reduce costly downtime and unscheduled replacements.
- Extend the life and capability of installed vial sealing systems.

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, USP 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

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.

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