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

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.

Seal integrity is achieved by adequately compressing the elastomeric closure against the sealing surface of the vial and maintaining that compression with a crimped aluminum ferrule. The amount of elastomeric compression is determined by the force applied during the crimping process. The Westcapper® controls the force being applied to the elastomeric closure during this process which in turn, reduces variability of stopper compression, producing more consistent seals.

A number of design improvements have been made to the RW Westcapper® . Of these the most significant is the placing of the vibratory cap bowl to the discharge side of the capper. This greatly reduces the chances of particulate contamination in vials as they are sealed. The overall height of the capper has also been reduced due to the head height adjustment no longer raising and lowering the hopper system as it has been moved off to the side.

The Westcapper® has also been updated 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.

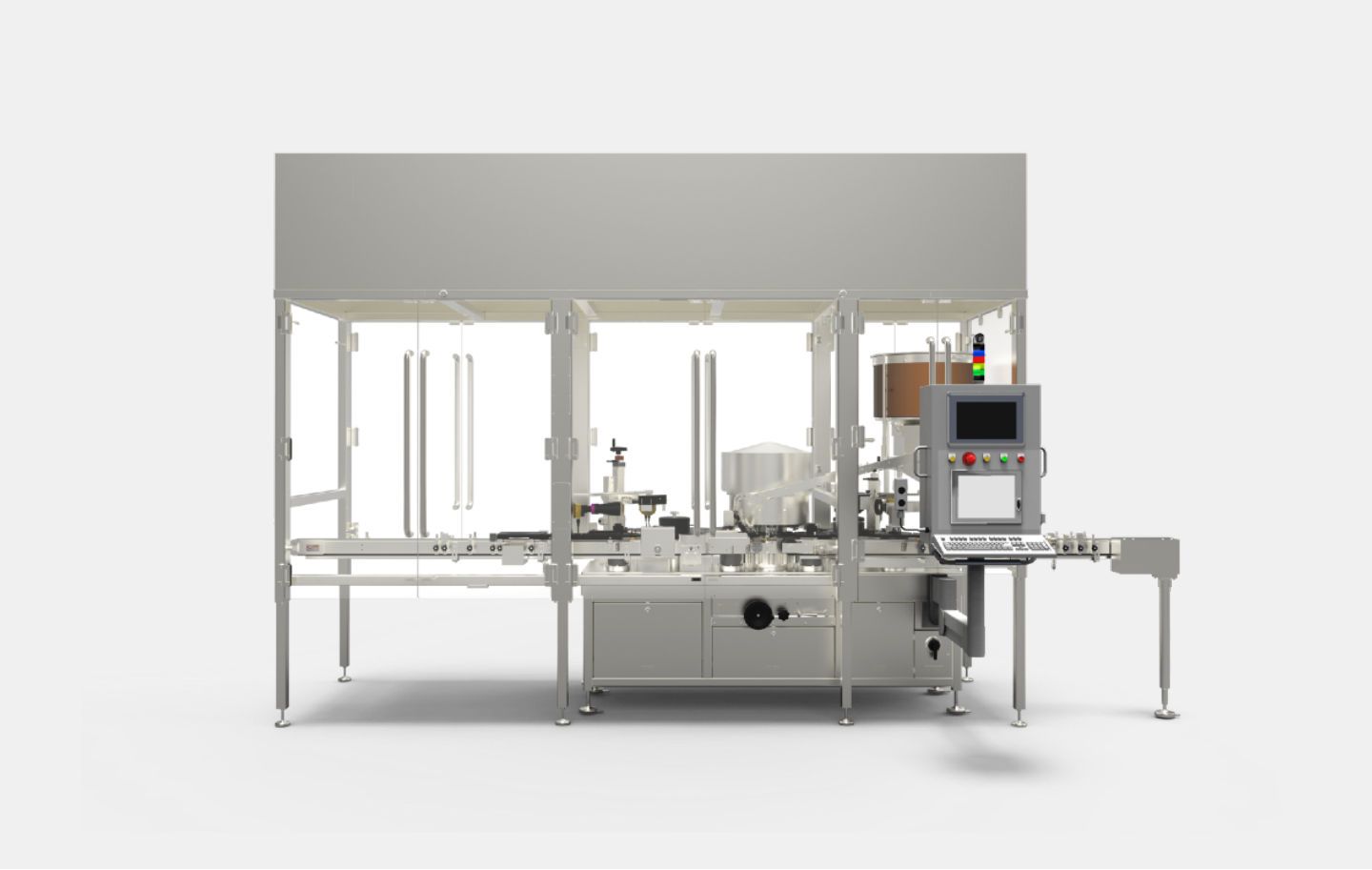
Compact Size

Features & Specifications

The RW Westcapper® is also available in a smaller footprint design making it ideal for applications where space is at a premium.

Maximum operation speed is up to 750 vpm, depending on cap size and spindle count.

A standard capper includes rolling casters. Stationary stainless steel legs are also available. Standard vial flow is from left to right. Vial flow from right to left is an available option. Conveyor height can range from 35-1/4″ to 38″. Standard conveyor length is 98″ with other conveyor lengths available as options.



The Standard RW

Features & Specifications

Maximum operation speed is 750 vpm, depending on cap size.

A standard capper includes rolling casters. Stationary stainless steel legs are also available. Standard vial flow is from left to right. Vial flow from right to left is an available option. Conveyor height can range from 35-1/4″ to 38″. Standard conveyor length is 98″ with other conveyor lengths available as options.

The entire capping area of the machine is enclosed with an OSHA compliant safety shield. The capper will immediately shut down when the shield is opened.

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

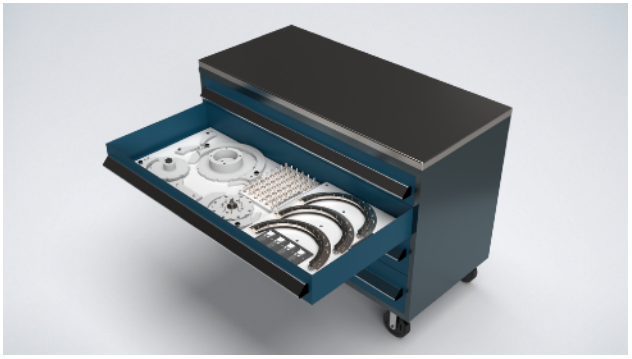
Heavy Duty Rolling Cabinets to Organize & Store All Your Change Parts

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.

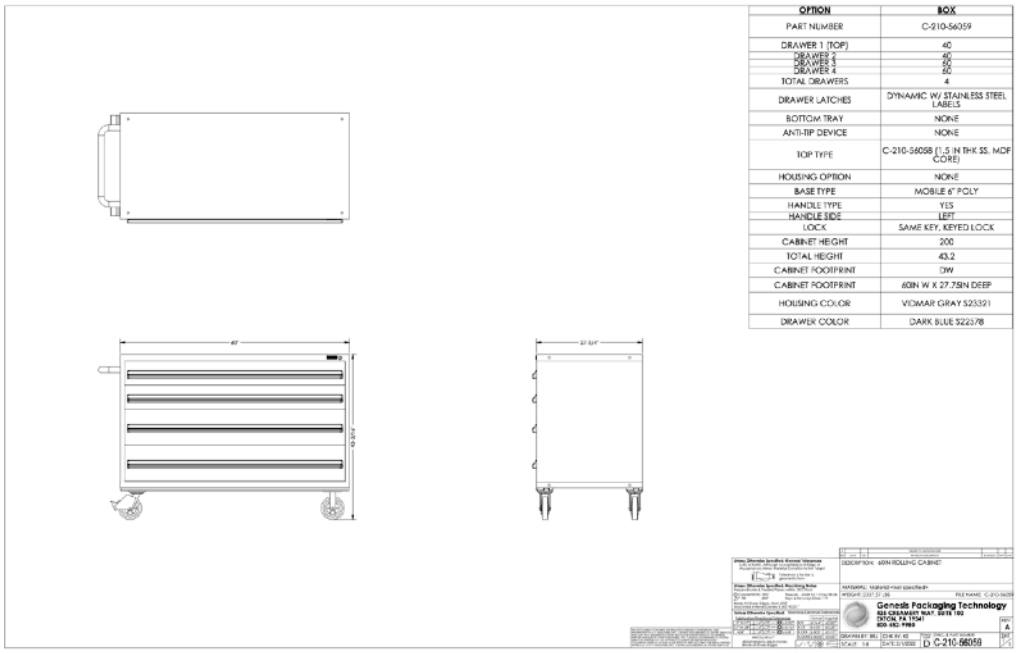
Custom rolling cabinets that are tailored to your Genesis capper to securely house it's change parts. Each cabinet is made from high grade steel and utilizes ball bearing drawer slides that allow you full, uninhibited access to the entire drawer. The chassis rolls on 6 inch Polyurethane wheels. Each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

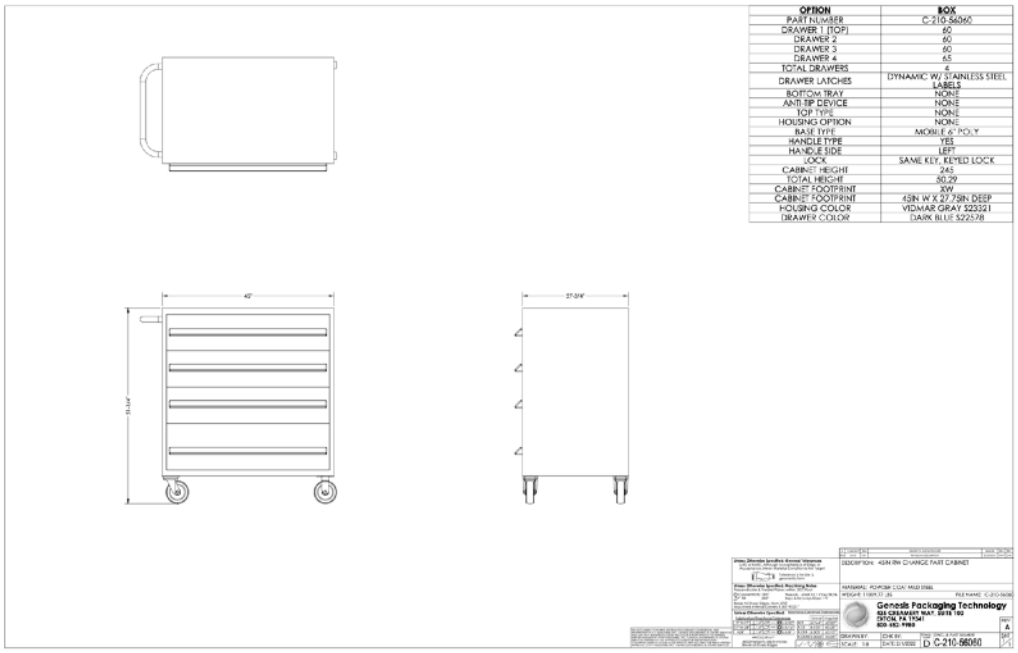
Available in 45 inch and 60 inch width sizes.



Change Parts Cabinets



OPTION	BOX
PART NUMBER	C-210-56059
DRAWER 1 (TOP)	40
DRAWER 2	40
DRAWER 3	50
DRAWER 4	50
TOTAL DRAWERS	4
DRAWER LATCHES	DYNAMIC W/ STAINLESS STEEL LABELS
BOTTOM TRAY	NONE
ANTI-TIP DEVICE	NONE
TOP TYPE	C-210-56058 (1.5 IN THK SS. MDF CORE)
HOUSING OPTION	NONE
BASE TYPE	MOBILE 6" POLY
HANDLE TYPE	YES
HANDLE SIDE	LEFT
LOCK	SAME KEY, KEYED LOCK
CABINET HEIGHT	200
TOTAL HEIGHT	43.2
CABINET FOOTPRINT	DW
CABINET FOOTPRINT	60IN W X 27.75IN DEEP
HOUSING COLOR	VIDMAR GRAY S23321
DRAWER COLOR	DARK BLUE S22578



OPTION	BOX
PART NUMBER	C-210-56060
DRAWER 1 (TOP)	60
DRAWER 2	60
DRAWER 3	60
DRAWER 4	65
TOTAL DRAWERS	4
DRAWER LATCHES	DYNAMIC W/ STAINLESS STEEL LABELS
BOTTOM TRAY	NONE
ANTI-TIP DEVICE	NONE
TOP TYPE	NONE
HOUSING OPTION	NONE
BASE TYPE	MOBILE 6" POLY
HANDLE TYPE	YES
HANDLE SIDE	LEFT
LOCK	SAME KEY, KEYED LOCK
CABINET HEIGHT	245
TOTAL HEIGHT	50.29
CABINET FOOTPRINT	XW
CABINET FOOTPRINT	45IN W X 27.75IN DEEP
HOUSING COLOR	VIDMAR GRAY S23321
DRAWER COLOR	DARK BLUE S22578

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

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.
- ✓ 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.
- ✓ 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.
- ✓ 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.
- ✓ 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.

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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

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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