Genesis Packaging Technologies

Integra

Laboratory Vial Crimper

The Integra Laboratory Crimper is a small vial crimper that is ideal for development, pre-clinical, clinical, pilot and compounding pharmacy operations. Available in four configurations the Integra can meet your small batch size needs assuring the best possible seal integrity.

Design Highlights

The Integra uses a proven three spinning roller sealing head design to crimp seals on your vial. A servo driven actuator will bring the sealing head to the vial and utilize a load cell to accurately provide proper sealing pressure. This functionality provides a quality seal despite variations in vial height.

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 Integra controls the force being applied to the elastomeric closure during this process which in turn, reduces variability of stopper compression, producing more consistent seals.

The process starts by placing the vial in the holder and closing the safety guard. Pressing the cycle start button engages the actuator to bring the sealing head assembly in contact with the cap until the proper sealing force is achieved. The spinning rollers will engage the skirt of the cap and the rotating sealing head performs the crimping action. The sealing head assembly then disengages the vial and raises to the home position. The Operator Interface will notify the operator that it is safe to open the guard and remove the vial.

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.

Design Highlights

Available in Four Different Configurations

Single Vial Unit

The Base Model - One vial package loaded at a time by the operator

Compact Starwheel Unit

A 10 pocket constant indexing starwheel unit designed specifically for tight spaces.

Standard Starwheel Unit

A larger 18 pocket constant indexing starwheel unit for faster throughput.

Dual Turntable Unit

A dual turntable unit allowing for up to 200 vials to be processed at a time.

All Integra modals have been certified for use with Vaporized Hydrogen Peroxide making them ideal for small batch use within an isolator.

Single Vial Unit

Features & Specifications

The base modal Integra is available as a single vial unit in which the operator places a single assembled vial package onto the Integra one at a time for crimping

Features include an all stainless steel construction with plastic feet and acrylic safety enclosure. The Operator Interface is a 10.1 inch touchscreen panel.

All manuals for the Integra Laboratory Crimper are provided digitally as a PDF file.

Vial Finish Diameter	Vial Diameter	Vial Height	Power	Size	Weight
8mm to 20mm	Up to 50mm	Up to 101mm	110V AC	20" W x 19" D x 25" H	160 lbs

Semi Automated COMPACT Integra with Starwheel

Features & Specifications

The Integra is also available with an automated indexing 10 pocket starwheel in a compact size making it ideal for use in smaller spaces such as in an isolator. An operator would hand place and remove assembled vials as the starwheel automatically advances. The compact Integra can seal 10 vials per minute. An optional foot pedal is available for on/off operation.

Features include an all stainless steel construction with plastic feet and acrylic safety enclosure. The Operator Interface is a 10.1 inch touchscreen panel.

All manuals for the Integra Laboratory Crimper are provided digitally as a PDF file.

Vial Finish Diameter	Vial Diameter	Vial Height	Power	Size	Weight
8mm to 20mm	Up to 50mm	Up to 101mm	110V AC	22.75" W x 25" D x 28" H	185 lbs

Semi Automated Integra with Starwheel

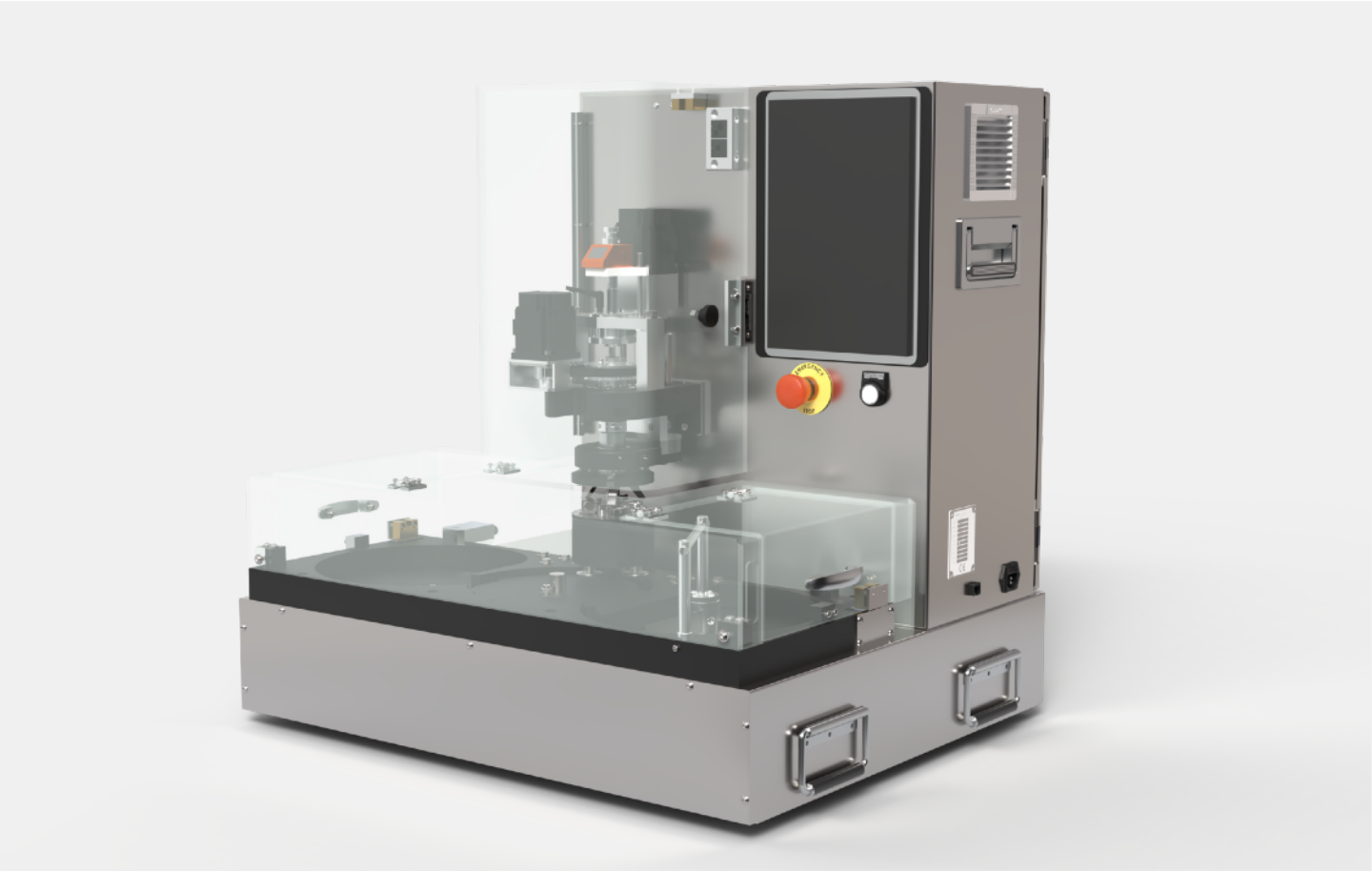
Features & Specifications

The Integra is also available with a 12 pocket starwheel which is able to automatically feed assembled vials at approximately 14 vpm. An operator would hand place and remove the vials as the starwheel automatically advances.

Features include an all stainless steel construction with plastic feet and acrylic safety enclosure. The Operator Interface is a 10.1 inch touchscreen panel.

All manuals for the Integra Laboratory Crimper are provided digitally as a PDF file.

Vial Finish Diameter	Vial Diameter	Vial Height	Power	Size	Weight
8mm to 20mm	Up to 50mm	Up to 101mm	110V AC	27″ W x 30" D x 30″ H	225 lbs



Semi Automated Integra with Turntables

Features & Specifications

The Integra is also available with two turntables which are able to automatically feed and then hold up to 200 assembled vials at a time depending on the vial size. The capper seals at approximately 14 vpm.

Features include an all stainless steel construction with plastic feet and acrylic safety enclosure. The Operator Interface is a 10.1 inch touchscreen panel.

All manuals for the Integra Laboratory Crimper are provided digitally as a PDF file.

Vial Finish Diameter	Vial Diameter	Vial Height	Power	Size	Weight
8mm to 20mm	Up to 50mm	Up to 101mm	110V AC	30″ W x 25" D x 30″ H	225 lbs

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 Vera 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 anyadditional 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.

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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