



CORNING

Valor® Glass Product Information
21st Century Drugs Require a 21st Century Glass

The Future of Glass Packaging is Here

Corning Valor® Glass enhances the storage and delivery of drugs, provides more reliable access to medicines essential to public health, and improves manufacturing efficiency.



Why Corning Pharmaceutical Technologies?

Corning's fundamental strengths and manufacturing platforms are uniquely suited to solving glass quality issues that have plagued the pharmaceutical industry for decades.

We leveraged our core technologies to develop Corning Valor Glass— a purpose-built pharmaceutical glass specifically designed to address the challenges of today's manufacturing operations.

A Food and Drug Administration (FDA) approval means pharmaceutical manufacturers now have a choice in parenteral packaging. This approval makes Valor Glass the first and only fundamentally new glass composition to be approved by the FDA since the advent of conventional borosilicate glass more than 100 years ago.

Valor Glass Product Benefits

- Eliminates delamination
- Reduces glass particulate generation
- Resists damage and breakage
- Prevents* cracks
- Enables higher throughput through smoother filling line operations
- Decreases total cost of ownership

*In laboratory testing, Valor Glass vials provided at least 30x protection against cracks than conventional borosilicate glass vials

Important Considerations

- Performs as a drop-in solution
- Displays compatibility with modern manufacturing equipment and processes including depyrogenation, lyophilization, and terminal sterilization
- Compatible with automated visual inspection systems (AVI)
- Compatible with standard labeling technology
- Available in ISO and custom formats upon request

Quality by Design

Improved Chemical Durability

Manufacturers invest heavily in quality protection. Valor Glass complies with the highest international quality standards. Valor technology offers equivalent or better overall performance for extractables, leachables, and improved hydrolytic resistance compared to conventional vials.

- Offers a chemically homogeneous drug-contacting surface
- Meets USP and Ph. Eur. Type I hydrolytic performance criteria
- Demonstrates lower extractable concentrations against a wide range of pHs

Eliminates Delamination

Delamination can result in costly issues and potential FDA recalls. Corning identified the root cause of delamination. During the process of converting conventional borosilicate glass, evaporation and condensation of boron rich vapor creates a heterogenous drug-contacting surface that can increase the likelihood of delamination.

Innovation from the Inside Out



Tube Forming

Raw materials are batched, melted, and formed into tubes. Advanced process controls help ensure consistent high quality.



Converting

Tubing is reformed into containers; annealing removes residual stress. Consistent geometry and flaw management enables product performance.



Ion Exchange

Containers are chemically strengthened through ion exchange. This improves load bearing strength and helps to prevent cracks.



Coating

Low coefficient of friction (COF) coating is applied to the exterior of the containers improving damage resistance and machinability and reducing particulate generation.



Inspection

Containers are 100% inspected to meet dimension and cosmetic quality compliance.

Valor® Glass' uniform surface chemistry does not form boron-rich heterogeneities during converting. The removal of boron from Valor Glass eliminates the potential for delamination to occur.

The composition and uniform surface chemistry and chemically durable drug contact surface makes this new technology ideally suited for sterile, injectable medicines.

Glass Components		Aluminosilicate Bulk Glass (Weight %)
Glass Formers	SiO ₂	73.8
	Al ₂ O ₃	10.4
	B ₂ O ₃	<0.01
Fluxes	Na ₂ O	11.7
	K ₂ O	
Property Modifiers	MgO	3.5
	CaO	
Finishing Agents	SnO ₂	0.5
	As ₂ O ₅	<0.01
	Cl	<0.01

Chemical Resistance		
Hydrolytic Resistance	ISO 719	Meets HGB 1 Criteria
Hydrolytic Resistance	Ph. Eur. 3.2.1/USP <660>	Meets Type I Hydrolytic Criteria
Soluble Alkali Test	JP 7.01	Meets Criteria
Acid Resistance Class	DIN 12116	Class S1
Alkali Resistance Class	ISO 695	Class A2

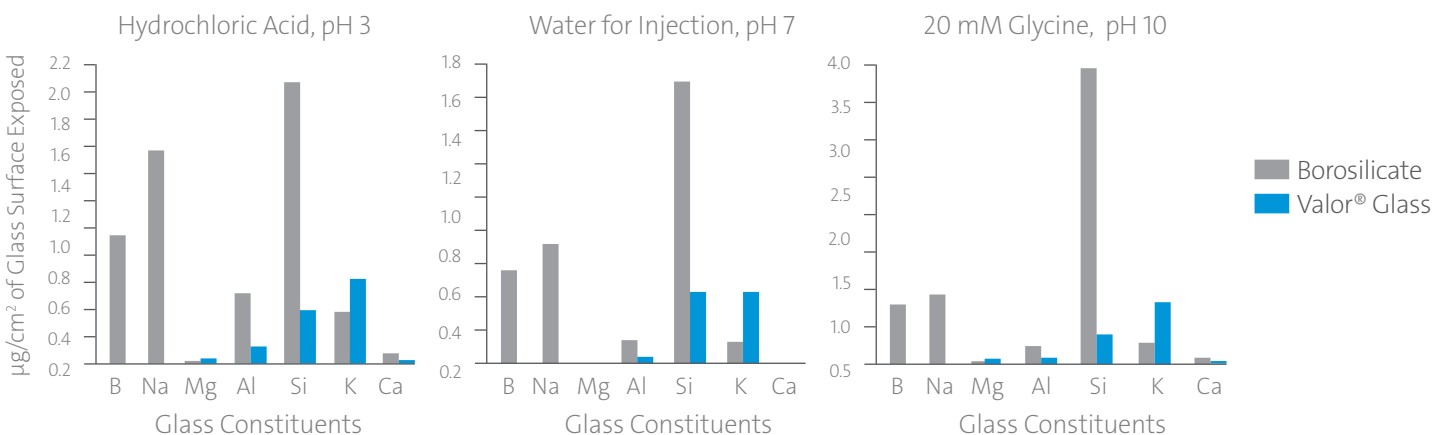
■ Intentionally added
□ <0.01%

Extractable Concentrations by ICP-MS

Valor Glass exhibits equivalent or better extractable concentrations against a wide range of pHs compared to conventional borosilicate glass.

3 mL containers used during extractable testing underwent a two-minute hot water rinse followed by depyrogenation at 320°C for 60 minutes prior to test execution. The containers were then filled with appropriate solutions to a fill volume of 3.5 mL, stoppered and autoclaved for 1 hour at 121°C, then stored at 50°C for 30 days.

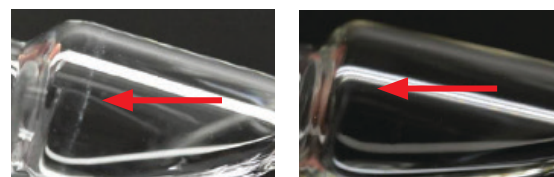
Test conditions above are approximately equivalent to 639 days at room temperature (25°C) or 121 days at accelerated (40°C)



*ICH Q3D Class 1 (Cd, Pb, As, Hg), Class 2A (Co, V, Ni), Class 2B (Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt), Class 3 (Li, Sb, Ba, Mo, Cu, Cr) elements are not added to the glass composition and were below analytical evaluation thresholds.

Resists Damage

The low COF exterior coating reduces glass particulate generation and enhances machinability. Valor Glass containers have demonstrated up to a 96% reduction in peak particle counts on commercial filling lines, substantially reducing risk of glass particulate contamination. The coating also protects the glass from scratches that lead to cosmetic rejects and strength limiting defects.



Visible scratches are less evident after pharmaceutical processing with Valor Glass vials (right) compared to conventional borosilicate containers (left)

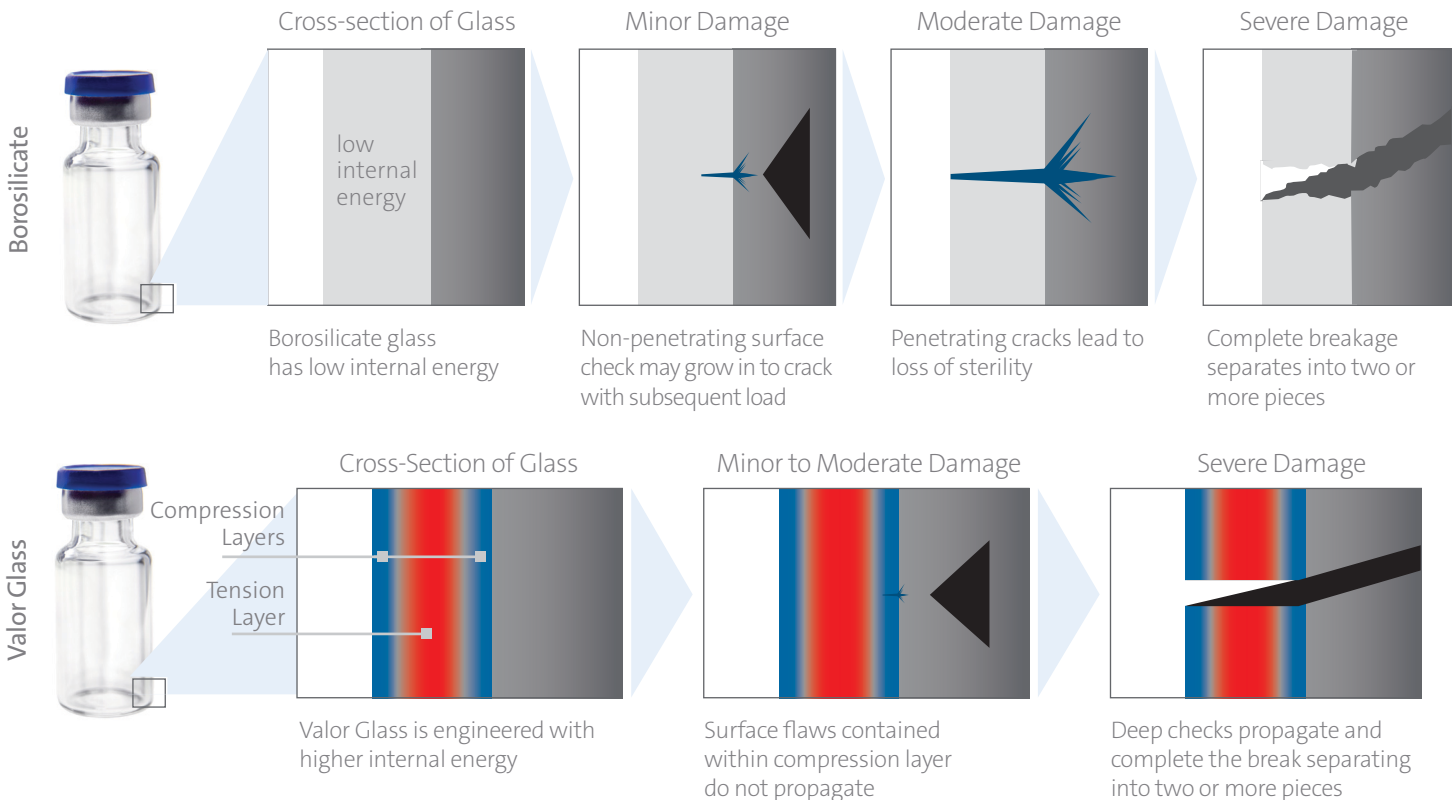
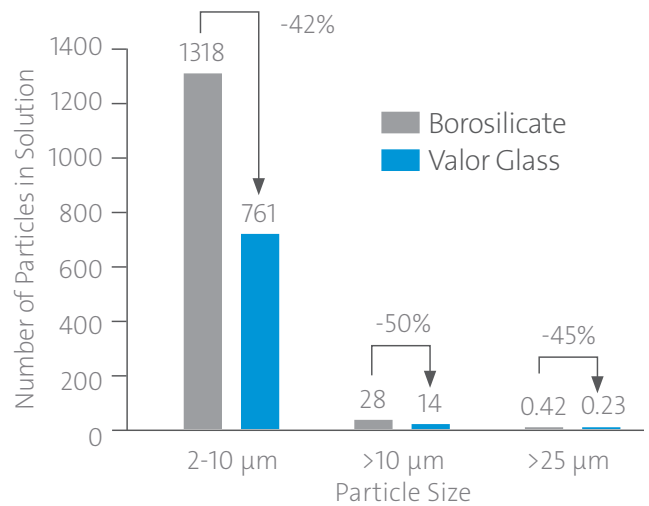
Particles in Solution

In solution particles measured by USP <788> light obscuration method; samples collected during an engineering trial.

Prevents* Cracks

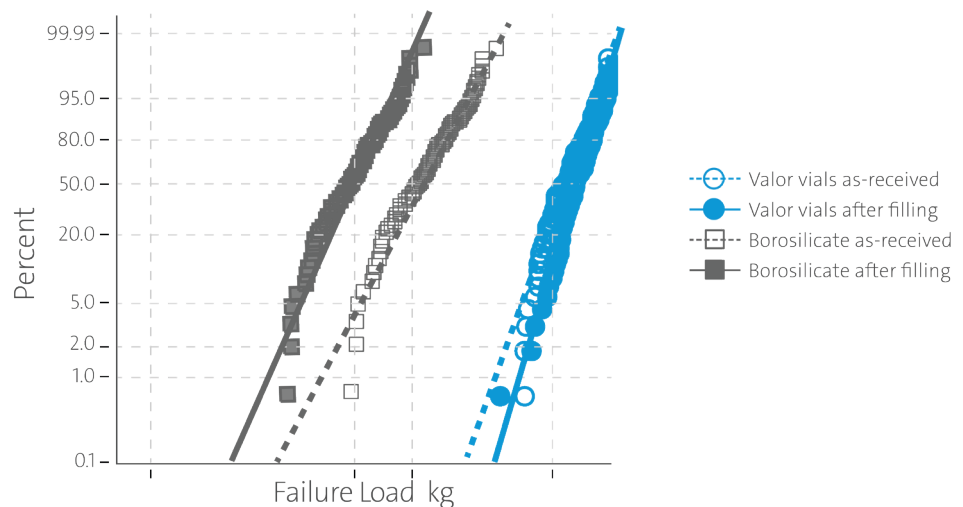
Valor® Glass is engineered with higher internal energy than conventional borosilicate packaging. Damage introduced on filling lines or during shipping can create sub-visible flaws and cracks that can potentially compromise drug product sterility that may result in serious contamination. Valor Glass is uniquely designed to prevent cracks and improve the quality of pharmaceutical packaging bringing a higher level of protection to parenteral drugs and reduces the likelihood of global drug product recalls, supply interruptions, and drug shortages.

*In laboratory testing, Valor Glass vials provided at least 30x protection against cracks than conventional borosilicate glass vials.



Resists Breakage

Valor packaging is inherently strong and better able to withstand extreme events during pharmaceutical processing and field applications. These robust containers reduce downtime due to glass-related interventions and provide enhanced protection for medicines in the hands of end users. Valor Glass demonstrates strength up to 10 times stronger than conventional borosilicate vials.

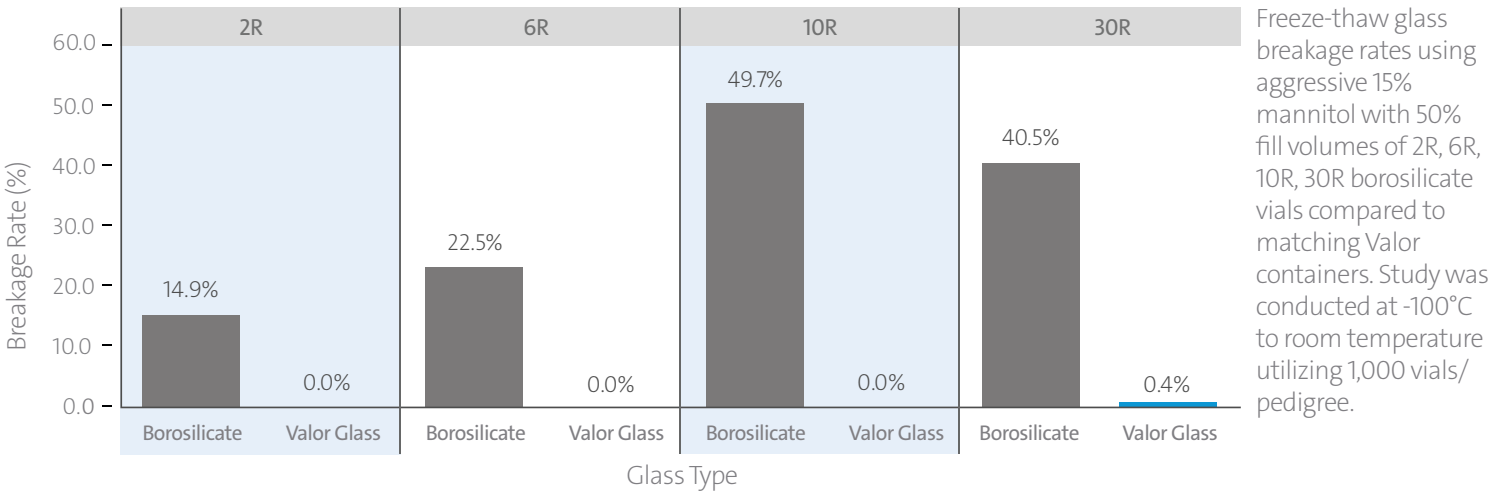


A Robust Container for Challenging Applications

Compared to conventional vials, Valor vials significantly reduce damage and breakage during low temperature processes such as lyophilization. The chemical strengthening process for Valor vials imparts compressive stress on the glass surface that typically exceeds

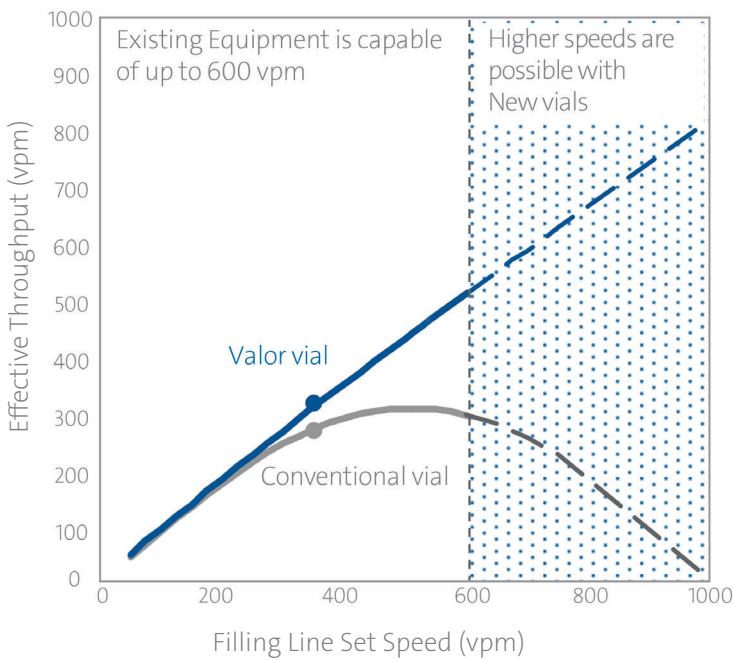
the tensile stresses generated in freeze-thaw processes dramatically reducing the potential for breakage. The advanced parenteral glass packaging technology and low COF exterior surface of Valor® Glass enables the potential for reduced start-to-finish times and improves yields. This may reduce total cost of quality as well as overall manufacturing cost.

Lab Freeze-thaw Glass Breakage Rate



Increased Throughput Potential Can Lower Unit Fill Cost

Valor Glass' high dimensional consistency, low COF exterior coating, and chemical strengthening enables smoother filling operations on old and new filling lines by reducing glass-related interventions, enabling lines to run at much higher speeds with improved yields. This immediate increase in efficiency helps maximize the utilization of capital-intensive manufacturing equipment.



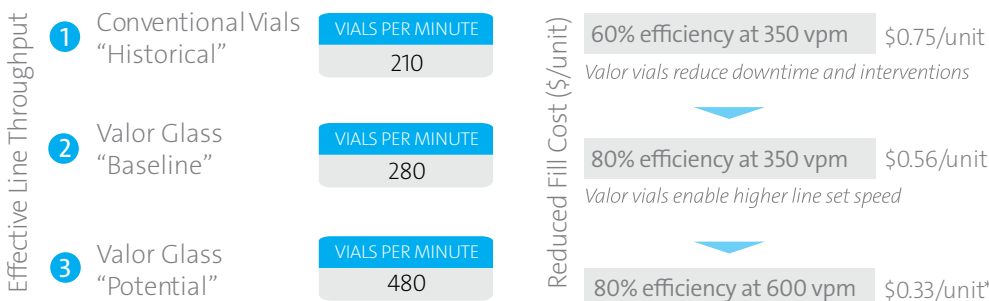
- Reduction or elimination of filling line lubrication
- Less micro-stops and line interventions
- Less rejects

Valor Vials Increase Filling Throughput

Vial friction is a bottleneck when running conventional vials. The high dimensional consistency and low COF exterior coating of Valor vials improve bulk filling line efficiency and throughput.

Valor vials can maintain high efficiency (>80%) at higher filling line set speeds.

Valor Vials Can Lower Manufacturing Filling Cost



*Equivalent to \$0.42/unit of value.



Dimensional Quality and Specifications

SKU	2R	6R	10R	20R	25R	30R
Outer Diameter (mm)	16	22	24	30	30	30
Wall Thickness (mm)	1	1	1	1.2	1.2	1.2
Overall Height (mm)	35	40	45	55	65	75
Blowback Type	EU	EU	EU	EU	EU	EU
Inner Diameter (mm)	7	12.6	12.6	12.6	12.6	12.6
Finish (mm)	13	20	20	20	20	20
Flange Height (mm)	3.6	3.6	3.6	3.6	3.6	3.6
Brimful Capacity (mL)	4	10	13.5	26	32.5	37.5
Weight (g)	4.7	8.5	10	16.5	19.2	22.6

*Custom formats available upon request.



Best in Glass Quality

Fully Controlled and Automated Production Process

Innovative process control monitors the entire state-of-the-art production flow for Valor® Glass through built-in feedback loops and dedicated in-line and in-process inspections.

- Rigorous process control to ensure compliance with specified vial dimensions, cosmetic quality, and functionality
- Valor vials are manufactured according to ISO 9001 and ISO 15378
- Optimized production process leveraging Six Sigma principles

Visual Quality Inspection

Dimensions

All customer defined critical to quality dimensions are measured on 100% of Valor vials through industry-leading automated inspection equipment with advanced algorithms determining accept/reject criteria.

Cosmetics

Valor vials receive 100% automated cosmetic inspection and rejection for converting and coating defects resulting in significantly lower defect rates than sampling-based acceptable quality limits.

Finishing and Packaging

- Fully automated packaging station
- Labeling for traceability

Sustainability: On the Side of Right

Corning continues to evolve its sustainability programs and policies to demonstrate commitment to positive environmental, social, and governance-related business practices. We are committed to making the world a better place, not only with our innovations, but also with our actions.

We see a future state of pharmaceutical manufacturing that is locally sourced and fully supportive of products that improve patient safety, lower cost, minimize regulatory hurdles and help increase global capacity and access to life saving drugs. By doing so, we're helping to create a sustainable future for the company, the communities where we operate, and the planet we all share.

Uncommon Commitment to Customer Success

Corning supports a consultative approach to customer engagement. From marketed drugs to pipeline planning, a dedicated team of commercial, technical, quality, and regulatory experts are committed to helping you identify opportunities, navigate challenges, and achieve your goals. Services and partnership opportunities include:

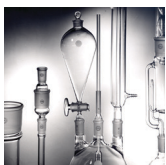
- Regulatory path support
- Technical support and collaboration
- Continued technical research and development

About Corning

For nearly 170 years, Corning has combined its unparalleled expertise in glass science, ceramics science, and optical physics with deep manufacturing and engineering capabilities to develop life-changing innovations and products.

Over 100 Years of Innovative solutions for Life Sciences and Pharmaceutical applications

Corning's inspiration for innovation comes from collaborating with customers to solve tough technology challenges. The end result is category defining best in class products that transform entire industries and enhance people's lives.



1915

PYREX® Heat-Resistant Lab Glassware



1935

Charles Lindbergh develops PYREX® perfusion pump



1939

PYREX® vessels used in Penicillin production



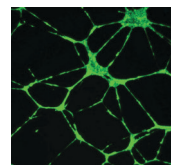
1950s

PYREX® labware used in production of Salk's polio vaccine



1970s

Corning Roller Bottles enable large-scale, single-use vaccine production



1989

Corning® Matrigel® Matrix, patented by NIH, leads to widespread use of 3D cell culture



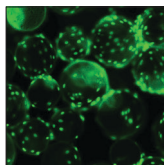
1997

Launched Gentest™ Supersomes™



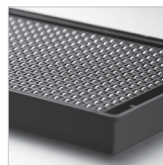
2007

Corning launches multi-layer HYPER technology for increased surface area



2012

Corning® Microcarrier Beads



2014

Corning® Spheroid Microplates for Cell-Based Assays



2016

5L Erlenmeyer Flasks



2017

Corning Valor® Glass

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