

UniFuge® Cell Processing Platform

Gentle, Tunable & Scalable Cell Separation
Tubular Bowl Technology for Cell Therapy



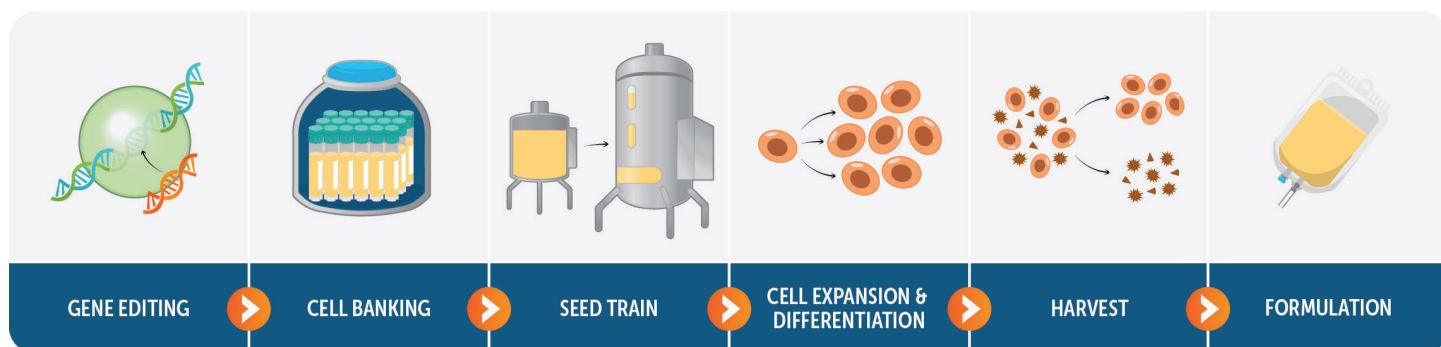
CARR Biosystems UniFuge Systems

The UniFuge cell processing platform provides a versatile single-use cell processing solution for cell therapy manufacturing applications benefiting from gently separating and manipulating whole cells.

The platform's core tubular bowl technology is optimal to achieve high cell viability and recovery, efficient concentration and washing, and fast processing times. UniFuge addresses the challenges of conventional centrifugation by continuously separating cells in a low shear, scalable, and automated system.

Cell Separation Applications

The UniFuge family is a versatile cell processing platform that can be utilized in multiple separation processes throughout cell development and commercial manufacturing.



Gene Editing

Cells are concentrated and media is exchanged with buffers in preparation for gene editing.

Cell Banking

Harvest and concentrate cells from bioreactor then exchange media with buffers in preparation for cryopreservation.

Seed Train

Separate and concentrate cells to prepare for re-seeding n-X bioreactor.

Expansion & Differentiation

Exchange media by concentrating cells; optional washing removes residual media or additives before returning to bioreactor for further cell culture expansion.

Harvest

Gently separate and concentrate cells; optional washing removes residual media or additives.

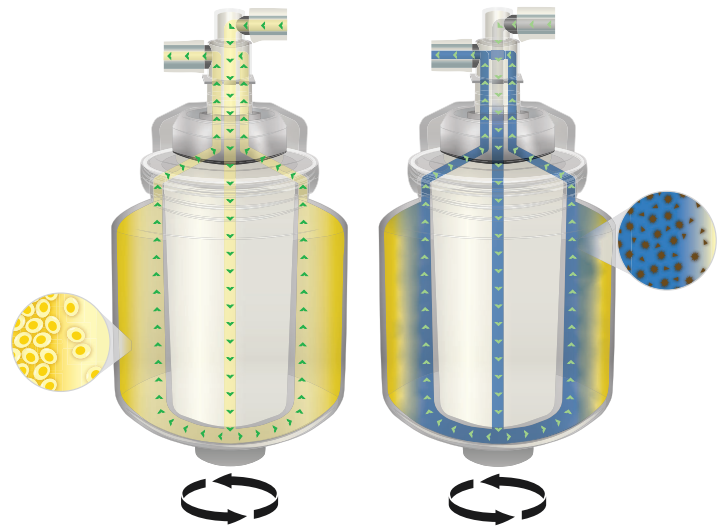
Formulation

Concentrate cells from bioreactor then exchange media with buffers in preparation for cryopreservation.

UniFuge® Tubular Bowl Technology

Tubular bowl technology provides significant advantages for developers who want to maintain cell health and viability throughout cell separation while minimizing the time between critical cell processing steps. Through the balance of centrifugal forces and fluid flow rates, cells are gently concentrated in the tubular bowl while the supernatant – cell free media or buffer – flows into a collection chamber.

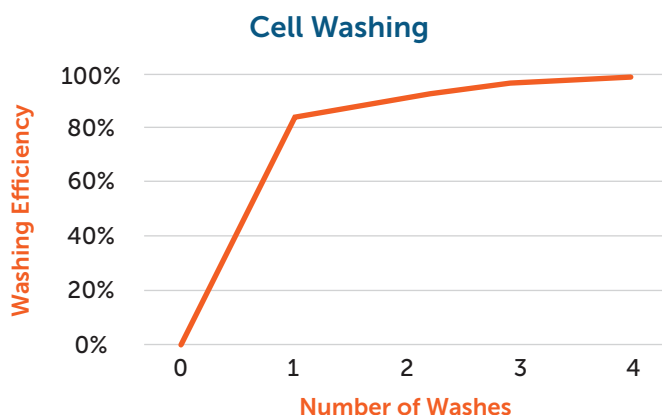
The concentrated cells can then be washed or exchanged with another medium or buffer within the same closed chamber. Once processing is complete, the cell concentrate is automatically collected. This functionality of tubular bowl technology enables tunable, high separation efficiency while minimizing product loss during start-up and/or discharge steps. These fully automated, single-use systems enable developers to achieve desired separation process goals across multiple separation applications.



The UniFuge® family is available in four sizes that enable linear scaling, providing seamless transition from benchtop process development to commercial manufacturing.

Cell Viability & Recovery

Cell Type	Cell Recovery	Cell Viability
iPSC	>98%	>98%
TIL	>98%	>97%
Stem	>98%	>98%
NK	>98%	>98%
MAPC	>95%	>99%



Benefits

High Cell Viability

- Low shear separation maintains cell health
- Cell wash/buffer exchange – remove spent media or reagents

High Cell Recovery

- Cell line specific – optimize recovery with tunable separation parameters, flow rate and g-force
- No cell loss as centrifuge accelerates to full speed
- Tunable cell concentration

Fast Processing




- Maintain cell health by minimizing time between steps or dwell time outside bioreactor
- Match processing volume and concentration targets with UniFuge working volumes

Scalable, Versatile Manufacturing Strategy – 250mL to >2000L

- Scale seamlessly from development through manufacturing
- Automated
- GMP-compliant Audit Trail for 21 CFR Part 11 Compliance
- Single-use, set up under 15 min

Technical Specifications

The UniFuge family is a versatile cell processing platform that can be utilized from process development through commercial manufacturing, enabling reliable process outcomes and manufacturing efficiency.

						
Machine	UFMini		UFPilot		U2k	
Attribute Module	UFMicro	UFMini	UFPilot Standard	UFPilot Shallow Pool	Continuous	Intermittent
Functional						
Recommended Bioreactor Volume	500mL - 10L	5 - 25L	25 - 500L		500 - 2000L+	
Bowl Volume	70mL	270mL	1.8L	0.9L	9L	9L
Flow Rate	50 - 1000mL/min		1 - 4L/min		3 - 20 L/min	
G-force	100 - 4000 x g		100 - 4000 x g		100 - 3000 x g	
Physical						
Footprint (Approx.)	69 x 56 x 38 cm w/d/h (27" x 22" x 15")		61 x 99 x 117 cm w/d/h (24" x 39" x 46")		80 x 206 x 200 cm w/d/h (31" x 81" x 78")	
Weight	~40 kg (90lbs)		~291 kg (640lbs)		~1050 kg (2,300lbs)	

Enabling GMP compliance

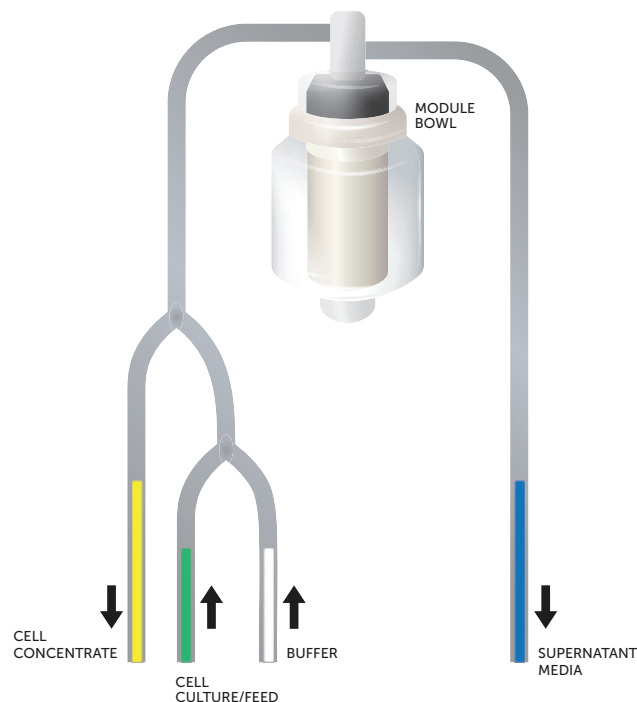
UniFuge products are designed to enable clinical and commercial biomanufacturing and are backed by testing and regulatory support.

Instrument

- Audit Trail Data for 21 CFR Part 11 Compliance
- SCADA Capabilities
- cGMP, SAT and IQ/OQ documents

Single-Use Modules

- Manufactured in ISO 13485 facility with Class 7 Cleanroom
- Biocompatibility: USP <87>, USP <88> Class VI (or ISO 10993)
- Physicochemical: USP <661> for plastic materials
- Animal Derived Component Free or treated to render BSE/TSE inactive
- Endotoxins: < 0.25 EU/mL
- Gamma irradiated



Ordering Information

UniFuge Equipment

Product	Description	Compatible Modules	Modules Product #
UniFuge UFMini	UFMini System	UFMicro module	C68390012
		UFMini module	C68390001
UniFuge UFPilot	UFPilot System	UFPilot Standard module	C61390184
		UFPilot Shallow Pool module	C61390214
UniFuge U2k	U2k System	U2k Intermittent module	C63390266
		U2k Continuous module	C63390267

Additional Resources

Learn about our solutions to help achieve cell therapy goals from research to commercialization at carrbiosystems.com/market/cell-therapies

See how UniFuge can be used in multiple cell therapy, gene therapy, recombinant proteins, vaccines and cellular agriculture at carrbiosystems.com/resources/publications

For more information, or to request a quote, go to carrbiosystems.com or contact us at: Connect@CarrBiosystems.com

Contact Us

For customer service, contact:

CustomerService@CarrBiosystems.com

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Markets We Serve

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Enabling cell separation processes across applications.
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