

# **G-Rex**<sup>®</sup> Bioreactors

Creating hope for cancer patients, one bioreactor at a time.



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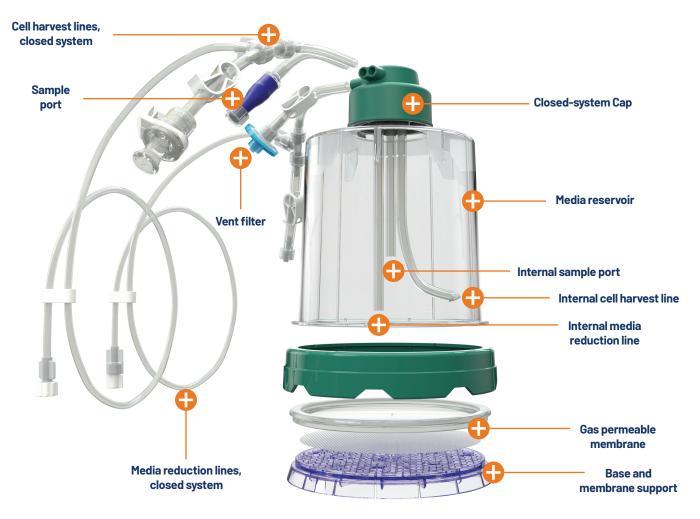
# Scale Intelligently and Successfully

G-Rex® is the only cell culture bioreactor equipped to meet current and future patient demand for immune cell therapies. Designed for cost-effective and practical cell expansion, G-Rex reproducibly generates a healthy, high-quality cell product while enabling parallel patient processing in an economical footprint. Using G-Rex, the cell therapy industry will be able to scale production to meet the growing demand for cell-based therapeutics, from preclinical through commercial manufacturing.

G-Rex<sup>®</sup> bioreactors result in predictable and scalable immune cell expansion. Its intuitive design eliminates unnecessary cell culture complexities to create a reproducible and streamlined system for expansion of autologous and allogeneic T cell or NK cell therapies. Combining single-step media addition along with a unique gas permeable membrane, G-Rex eliminates forced media replenishment and oxygen circulation. This allows cells to expand undisturbed, increasing expansion reproducibility and eliminating cell phenotype variability.

## G-Rex<sup>®</sup> Bioreactor M-Series Design

Closed-system bioreactor for cell production.



# Advantages of G-Rex® Bioreactors

#### **Scale Up with Predictability**

Protocols established in research translate directly to commercial production without altering cell phenotypes or critical quality attributes.

#### **Scale Down for Rapid Process Development**

By using the same protocol to grow either 10 million or 10 billion cells, small-scale G-Rex bioreactors quicken the pace of model development, process iterations, and primary and secondary reagent qualification.

#### **Scale Out Practically**

A single G-Rex generates enough cells for a clinical dose in an autologous therapy and offers massive space and operational savings for allogeneic cell manufacturing workflows.

#### **Streamline Unit Operations in One Device**

Cell activation, transduction, and expansion can all be performed in G-Rex, while achieving high cell product viability and recovery.

#### **Repeatable Cell Quality**

Cells expand undisturbed in G-Rex bioreactors, allowing them to naturally reach maximum cell densities without intervention. The result is reproducible expansion of healthy memory and naïve immune cells.

#### **Reduce Manufacturing Costs**

By design, G-Rex bioreactors minimize the overall footprint of cell manufacturing and significantly reduce initial capital investment to create a costeffective, long-term manufacturing strategy.

#### **Optimize Downstream Processing**

Using GatheRex, cells are harvested in small volumes without centrifugation. This simplifies downstream processing and minimizes cell loss.

#### **Stable and Secure Supply Chain**

Maintain a high level of quality, compliance, and supply, minimizing unexpected product availability gaps that can result in expensive manufacturing delays.

> "One of the advantages of the G-Rex is that it can be easily scaled up, allowing us to be able to create models much faster."

**Juan Vera** 

Chief Product Development Officer Marker Therapeutics



**Research and Pre-clinical** 

Clinical

# G-Rex<sup>®</sup> Mechanism of Action

The G-Rex mechanism of action undermines the complexities of modern bioreactors. G-Rex M-Series bioreactors are designed to hold the optimal media volume per square centimeter of gas permeable membrane. This environment allows cells to grow completely undisturbed with no user interventions or mechanical motion, proving automated bioreactors introduce unnecessary complexities that increase process variability and prohibit scalable manufacturing.



### 1. Gas Permeable Membrane

G-Rex features a gas permeable membrane that provides efficient, passive diffusion of oxygen and carbon dioxide in culture. This creates an ideal static culture environment by eliminating the need for complex pumping mechanisms or measuring instruments.

#### 2. Boundary Layer of Diffusion

Within the 300 µm boundary layer of diffusion, cells reside completely undisturbed with unlimited access to oxygen. This static environment promotes cell-to-cell communication and maximizes expansion.

#### 3. Nutrients on Demand

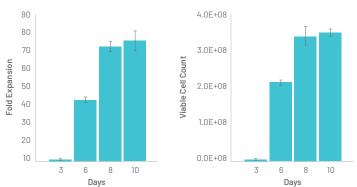
G-Rex bioreactors are filled with an optimized volume of media at the start of the culture. Cells residing in the boundary layer access unlimited nutrients from the media on-demand, while waste biproducts diffuse and dilute into the media.

#### 4. Convection Forces Create a Static Bioreactor

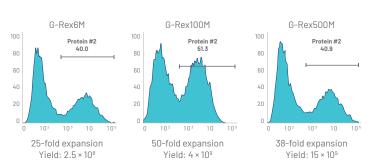
Convection delivers media nutrients and growth factors to the boundary layer on-demand. Cells grow statically within the boundary layer without stirring and rocking mechanisms that often contribute to product variability.

## Application Data

#### **T** Cells

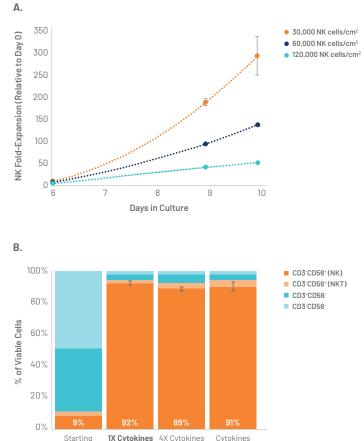


**Robust T Cell Expansion in G-Rex6M.** Purified CD3<sup>+</sup> human T cells were seeded (0.5 × 10<sup>6</sup> cells/well) into G-Rex6M and cultured using ExCellerate<sup>™</sup> T Cell Expansion Medium with GMP IL-7, GMP IL-15, and Cloudz<sup>™</sup> T Cell Activation Kit. Fold expansion (left) and cell yield (right) were measured at Day 3, 6, 8, and 10.



Scalable Gene-edited T Cell Expansion in G-Rex Bioreactors. Increasing numbers of T cells (1 × 10<sup>7</sup>, 8 × 10<sup>7</sup>, and 40 × 10<sup>7</sup>) were electroporated to introduce CAR-T constructs using TcBuster<sup>™</sup> the non-viral gene editing technology, TcBuster. Electroporated cells were seeded into small-, mid-, and large-scale G-Rex bioreactors, respectively, for expansion. TcBuster successfully transposed cells with >30% efficiency and resulted in 25-, 50-, and 38-fold expansion in the G-Rex.

#### Natural Killer (NK) Cells



Determining Human NK Cell Seeding Density and Feeding Schedule.

Day 0

Every 3 days

Populations

Dav 0

A) Human NK cells were seeded in G-Rex6M well plates at specific cell densities (NK cells/cm<sup>2</sup>). 3 × 10<sup>4</sup> cells/cm<sup>2</sup> yielded the best fold expansion (~300-fold) following 10 days in culture. B) NK cells (3 × 10<sup>4</sup> cells/cm<sup>2</sup>) were cultured in G-Rex6M well plates following varying feeding schedules. A single starting dose of 1X cytokines at Day 0 yielded similar NK cell phenotypes and viability compared to a 4X cytokines at Day 0 or a 1X cytokine refresh every 3 days. Single 1X cytokine administration reduces process interventions while maintaining consistent cell phenotypes. For all experiments, NK cells were expanded using Cloudz<sup>™</sup> NK Cell Expansion Kit and media supplemented with IL-2, IL-12, IL-18, and IL-21.

#### **CAR-modified T Cells**

# Portfolio

The G-Rex® bioreactor portfolio is structured to provide a transparent and practical path to commercialization. Featuring open and closed-system bioreactors, each available at clinical (sterile) or research quality, enables you to generate a cell product at the scale, cost, and quality required for each stage in your path to the clinic. This unique flexibility results in cost-savings during process development, earlier transitions to full-scale testing, and accurate cost forecasting for scale-up and scale-out. For pricing, contact a ScaleReady technical account manager today at info@scaleready.com

## G-Rex<sup>®</sup> M-Series Bioreactors – Closed System

Solidify closed-system process and incorporate volume reduction and cell harvest with GatheRex.



**G-Rex10M-CS** P/N: 80110-CS (Clinical) P/N: 80110S-CS (Research) Membrane size: 10 cm<sup>2</sup> Media volume: 100 mL



**G-Rex100M-CS** P/N: 81100-CS (Clinical) P/N: RU81100-CS (Research) Membrane size: 100 cm<sup>2</sup> Media volume: 1000 mL

### GatheRex<sup>°</sup> Liquid Handling System

GatheRex is a specialized pump for closed-system volume reduction and cell harvesting from G-Rex bioreactors. It enables collection of a concentrated cell product without centrifugation and significantly reduces the amount of time that cells are left without oxygen during downstream processing, preserving the viability and function of your cell therapy product.

P/N: 80000E and 80000Z



**G-Rex50M-CS** P/N: 80550-CS (Clinical) P/N: RU80550-CS (Research) Membrane size: 50 cm<sup>2</sup> Media volume: 500 mL



**G-Rex500M-CS** P/N: G285500-CS (Clinical) P/N: RU05500-CS (Research) Membrane size: 500 cm<sup>2</sup> Media volume: 5000 mL



#### **G-Rex**<sup>®</sup> **M-Series Bioreactors – Open System**

Confirm linear scale-up protocols in open system process-size units.



G-Rex5M

P/N: 80055 (Clinical)

P/N: 80055 (Research)

Membrane size: 5 cm<sup>2</sup>

Media volume: 50 mL





G-Rex10M P/N: 80110 (Clinical) P/N: 80110S (Research) Membrane size: 10 cm<sup>2</sup> Media volume: 100 mL

G-Rex100M P/N: 81100 (Clinical) Membrane size: 100 cm<sup>2</sup> Media volume: 1000 mL



G-Rex500M P/N: G285500 (Clinical) P/N: RU81100 (Research) P/N: G285500-RU (Research) Membrane size: 500 cm<sup>2</sup> Media volume: 5000 mL

#### Well Plates

Define your rapid cell expansion protocols at small scale knowing that the protocol will linearly scale. Research use only.



**G-Rex24 Well Plate** P/N: 80192M Membrane size:  $2 \text{ cm}^2$ Media volume: 8 mL



**G-Rex6 Well Plate** P/N: 80240M Membrane size: 10 cm<sup>2</sup> Media volume: 40 mL



**G-Rex6M Well Plate** P/N: 80660M Membrane size: 10 cm<sup>2</sup> Media volume: 100 mL

# Testimonials

"When we were looking at many of our CQAs [critical quality attributes] and process performance metrics, there really wasn't a way to make the more complex systems work while maintaining product quality. For us, we had to make a decision early on to go with one platform over another and making sure we made the right decision was critical. We ran many head-to-head experiments and ultimately the simplicity, ability to scale the process, and flexibility to work around complex unit operations made it a pretty clear decision to go with G-Rex."

James Bolling Team Lead, Cell Therapy Process Development Precision Biosciences

"The streamlined procedure reduces the hands-on time of transduction to minutes rather than hours and eliminates all cell transfer and wash steps. Further, the increased output per starting material reduces cost of materials compared with the standard method. Cells can be expanded in the G-Rex with limited operator intervention without specialized equipment."

**Bellicum Pharmaceuticals** 

"Collaborations in the industry, like the idea of ScaleReady and its devices, the [G-Rex] bioreactor from Wilson Wolf, the raw materials and the ease of preparing the raw materials and consumables. So consortiums, like ScaleReady, that's going to help empower and enable more closed-system processing."

Michael Paglia Chief Operating Officer Elevate Bio, Basecamp

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