

PRODUCT DESCRIPTION

The G-Rex®100M-CS Gen 2.0 is a single-use, closed system cell culture product designed for efficient, large-scale expansion of mammalian cells. The integrated tubing system enables closed addition of cells and media, sampling, media removal and volume reduction (concentration), and recovery of concentrated cell suspensions.

INTENDED USE

The G-Rex100M-CS Gen 2.0 cell culture product is intended for closed-system cell culture workflows. The end user is responsible for determining suitability for each cell type, process, and application.

PRODUCT INFORMATION

USE	REF	STERILITY
GMP	G281100-CS	Sterile fluid path; sterilized by irradiation; SAL 10 ⁻⁶
RUO	RUG281100-CS	Gamma irradiated; SAL not validated



IMPORTANT Wilson Wolf makes no claims regarding the performance of this product for clinical treatment or therapeutic applications. The end user is responsible for assessing suitability for specific applications.

WARNINGS AND PRECAUTIONS - Read all warnings before use

- For single use only. Do not reuse, re-sterilize, or freeze.
- Do not use the product if the packaging, tubing, seals, connectors, or product body is damaged or compromised.
- Do not expose the gas-permeable membrane to excessive alcohol or disinfectant vapors. Allow cleaned surfaces to dry before placing G-Rex on cleaned surfaces.
- Do not exceed 300 mL/min during filling or extraction.
- Use aseptic technique and closed-system connections, sealing, and liquid-handling methods where appropriate.
- Do not use after the Use By Date.

Preparation and System Overview

PREPARATION

- Pre-warm media to 37 °C.
- Inspect the packaging for damage or compromise. Do not use if damaged or compromised.
- Peel back the perimeter seal of Tyvek and remove the product from the plastic tray. Inspect tubing, tubing seals, and connections before use. Do not use if damaged or compromised.
- Keep the vent filter open during filling, culture, and harvest. Clamp only temporarily during movement or mixing to prevent filter wetting.

PRODUCT CAPACITY

WORKING VOLUME	MAXIMUM CAPACITY
1,000 mL (1 liter)	1,100 mL(1.1 liter)

GENERAL INSTRUCTIONS AND METHODS OF USE

- Use closed-system connections, such as sterile tube welding, whenever possible. Mix cells and media thoroughly before transferring to promote even distribution across the gas-permeable membrane.
- Please contact technical support at info@wilsonwolf.com for standard closed system GMP cell manufacturing consultation and support.

General Processing Notes

- Ensure required fluid path clamps are open prior to fluid transfer.
- Do not exceed a fill or extraction rate of 300 mL/min. Gravity flow is recommended.
- Flush tubing, if appropriate, to minimize retention of cells or process reagents.
- Use the Media Reduction Line (red striped) and Cell Harvest Line (clear) with compatible sterile welding methods to maintain a closed fluid path.
- Cells should reach surface densities of 35-45 x 10⁶ cells/cm² without intervention for media feeding or cytokine supplementation.

TUBING LINES AND PORTS (See APPENDIX 1)

TUBING LINE	DESCRIPTION AND PRIMARY USE
Sample Line	Thermal weld compatible, clear PVC tubing ending in an access port suitable for syringe or male luer docking for small-volume sampling or reagent addition. Internally, the sample line terminates at approximately mid-height within the vessel enabling sampling from the mid-volume region.
Media Reduction Line	Thermal weld compatible, red-striped PVC tubing used for media addition or volume reduction. Internally, the Reduction line is fixed to the inner side wall of the G-Rex to maintain a consistent height of the Reduction line tubing above the membrane.

TUBING LINE	DESCRIPTION AND PRIMARY USE
Harvest Line	Thermal weld compatible, clear PVC tubing used to recover concentrated cell suspension. The harvest line is fixed to the inner side wall of the G-Rex100M-CS shell to fix internal harvest tubing directly on the membrane.
Vent Filter	Supports gas exchange and pressure equalization; connects to GatheRex if used during harvest.

RECOMMENDED EQUIPMENT MATERIALS AND REAGENTS

SUPPLIER	DESCRIPTION	CATALOG #
Wilson Wolf	GatheRex Liquid Handling, Cell Harvest Pump	80000E
Wilson Wolf	G-Rex 250mL Processing Bag	WW-FP250ML
Wilson Wolf	G-Rex 1L Processing Bag	WW-SV1L444
Bio-Techne	GMP Human T Cell Media	CCM038-GMP-1B
Bio-Techne	ProPak™ GMP Recombinant IL-7	PPK-007-GMP-010
Bio-Techne	ProPak™ GMP Recombinant IL-15	PPK-015-GMP-010
Bio-Techne	GMP Human AB Serum	HABS001-GMP-50B

* **Complete media** refers to GMP Human T Cell Media supplemented with cytokines and serum

T CELL ACTIVATION, TRANSDUCTION, AND EXPANSION

DAY	EXAMPLE APPLICATION PROCEDURE
0	Prepare PBMC or selected T cells in complete media * at $0.5\text{--}2.0 \times 10^6$ cells/mL, typically in approximately 100 mL total volume. Add activation reagent per manufacturer recommendation. Gently mix to create a homogeneous cell and reagent suspension, transfer to G-Rex through the reduction line, gently mix and incubate.
1	If applicable, add viral vector and optional transduction enhancer at the desired MOI using closed-system methods. After adding viral vector and optional transduction enhancer, gently mix to create a homogeneous cell and reagent suspension, then incubate overnight.
2–3	Gently mix to create a homogeneous cell suspension. Gravity-drain complete media into the G-Rex to the working volume, not to exceed 1,100 mL total volume. Gently mix during transfer, then return to the incubator.
7–10	Harvest cells according to the instructions in Appendix 2 if using a GatheRex Liquid Handling, Cell Harvest Pump.

HARVESTING

If using a GatheRex Liquid Handling, Cell Harvest Pump a ~90% volume reduction and cell concentration followed by concentrated cell harvest can be performed in approximately 5 minutes.

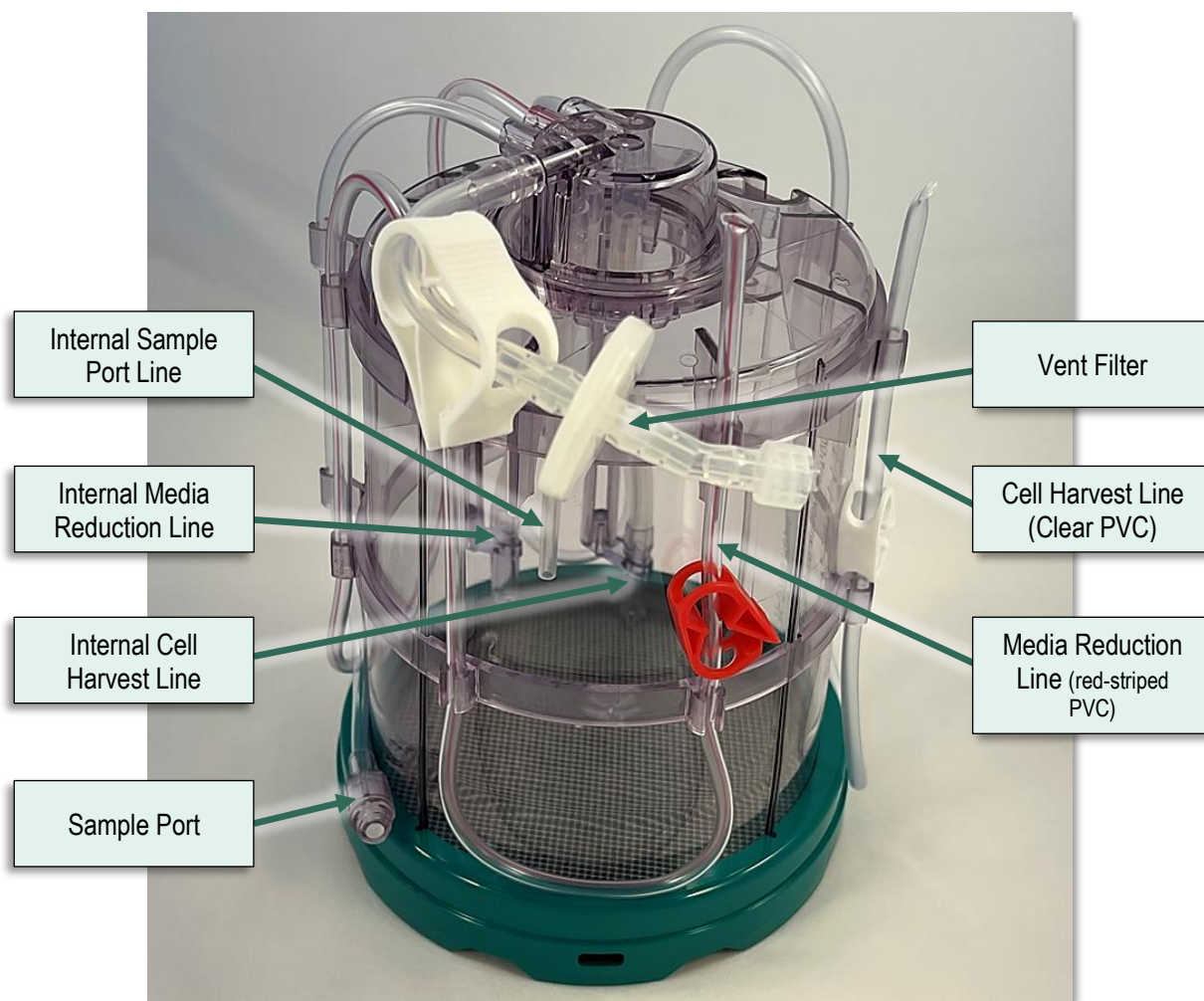
SUPPLIER	DESCRIPTION	CATALOG #
Wilson Wolf	GatheRex Liquid Handling, Cell Harvest Pump	80000E

Refer to Appendix 2, Closed System Harvest Instructions, for the recommended closed-system procedure for volume reduction and concentrated cell harvest from the G-Rex100M-CS Gen 2.0. Refer to the GatheRex User Manual for additional operating information.

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APPENDIX 1 - G-Rex100M-CS Gen 2.0
. Tubing Line Identification



G-Rex100M-CS Gen 2.0

DEVICE REFERENCE

APPENDIX 2 – GatheRex Closed System Harvest Instructions

STEP 1

Carefully remove the G-Rex100M-CS Gen 2.0 from the incubator taking care not to disturb the cell layer.

Sterile weld a 1 L waste media collection bag onto the Reduction Line. Position the weld approximately 20 cm from where the tubing connects to the G-Rex and 20 cm from the tubing connection on the 1 L bag.



STEP 2

Sterile weld a cell harvest bag onto the Harvest Line. Position the weld approximately 30 cm from where the tubing connects to the G-Rex and 20 cm from the tubing connection on the harvest bag.



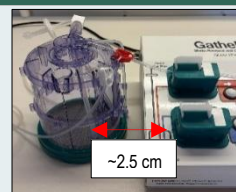
STEP 3

Turn on the GatheRex pump and wait for the green Power light to turn on.



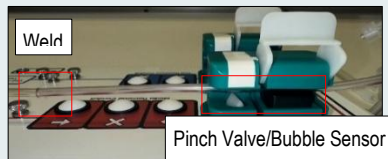
STEP 4

Position the GatheRex in the center of the workstation, G-Rex on the left approximately 2.5 cm away from the GatheRex, and the processing bags on the right. Thread the welded Reduction Line tubing through the pinch valve housing of the Media Removal Conduit.



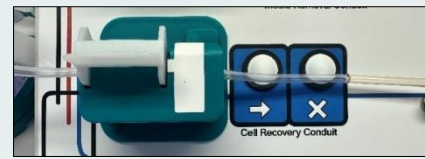
STEP 5

Verify the tubing weld is outside of the pinch valve housing and the tubing is oriented above the bubble sensor and the pinch valve.



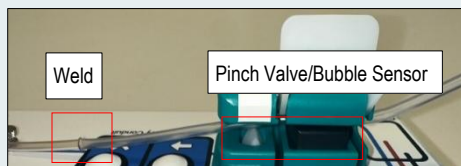
STEP 6

Thread the welded Harvest Line tubing through the pinch valve housing of the Cell Recovery Conduit.



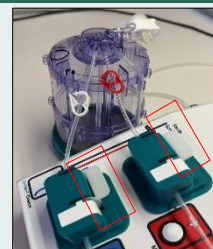
STEP 7

Verify the tubing weld is outside of the pinch valve housing and the tubing is oriented above the bubble sensor and the pinch valve.



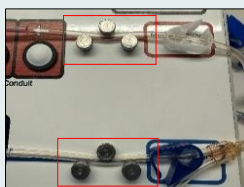
STEP 8

Close the Pinch Valve Doors.



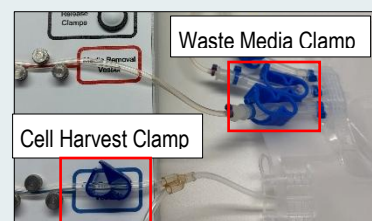
STEP 9

Route the tubing lines through the cleats on GatheRex.



STEP 10

Connect the gas line from the GatheRex to the vent filter on the G-Rex100M-CS Gen 2.0. Ensure the clamps for the selected fluid pathways are **OPEN** to the waste media collection and cell harvest bags.



STEP 11

Press the red arrow toward the waste media collection bag to begin volume reduction. Media will transfer from the G-Rex into the waste media collection bag while the cell layer remains undisturbed.



STEP 12

When the liquid level reaches the opening of the internal Reduction Line, the bubble sensor will detect an air bubble in the Media Removal Conduit and automatically stop fluid flow.

STEP 13

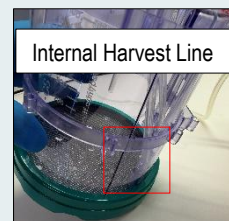
Approximately 90% of the full working volume will have been removed (waste media) leaving approximately 100 mL of media and highly concentrated cells in G-Rex. Rock and swirl the remaining ~100 mL to resuspend the cells residing on the gas permeable membrane.

STEP 14

Tilt the device so the concentrated cell suspension collects/pools where the internal harvest line touches the base/side of the vessel.



Internal Harvest Line (lowest line)



Internal Harvest Line

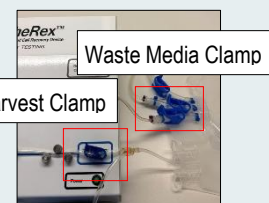
STEP 15

With the concentrated cell suspension pooled at the harvest line, press the blue arrow to begin cell harvest. The concentrated cell suspension and remaining fluid will transfer from the G-Rex into the cell harvest bag.



STEP 16

Ensure the clamps for the selected fluid pathways are closed to the waste media collection and cell harvest bags before proceeding to the next step.



STEP 17

Heat seal the waste collection and cell harvest bag with tubing sealer. Proceed with downstream processing.