

# G<sup>®</sup>REX<sup>®</sup> 100M-CS

Gas Permeable Cell Culture Product

**REF**  
Catalog Number

**J81100-CS**

## INSTRUCTIONS FOR USE (IFU)

### PRODUCT DESCRIPTION

The G-Rex<sup>®</sup>100M-CS is a single-use, closed system product designed for the expansion and recovery of mammalian cells.

Cells reside undisturbed on the gas permeable membrane and divide until they reach a maximum density or harvest timepoint.

The final cell population is typically harvested via the GatheRex<sup>™</sup> Cell Harvest Pump, followed by further processing prior to the final application.

Use	REF	STERILITY
GMP	J81100-CS	Sterile Fluid Path, Sterilized Using Irradiation (SAL=10 <sup>-6</sup> )

### INDICATIONS FOR USE

The G-Rex100M-CS cell culture system is intended for expansion and recovery of non-attachment dependent mammalian cells.

Wilson Wolf Manufacturing, LLC makes no claims regarding the performance of this product for clinical treatment or therapeutic applications. It is the responsibility of the end user to assess its suitability for specific applications.

### CONTRAINDICATIONS

1. Not to be used with peristaltic pumps or other liquid pumping systems not designed to recover and concentrate final cell populations.
2. Not suitable for use in conditions outside of those typically intended for the maintenance and expansion of mammalian cell lines.

### WARNINGS

1. This IFU is not a comprehensive reference for the application of use in cell culture protocols.
2. Users should be familiar with appropriate application and aseptic techniques involved with the use of this product and the G-Rex cell culture platform technology.
3. Do not exceed a fill rate of 300ml per minute.
4. Closed System functionality cannot be assured if cap is removed.
5. Do not use if the product is damaged.
6. Do not use the product if there is an apparent breach to sterility.
7. Unauthorized modification and improper use may result in the inability to culture cells or maintain a sterile environment.

### PRECAUTIONS

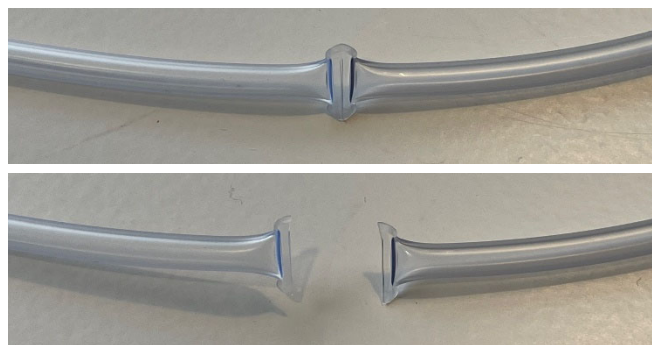
DO NOT USE the product if any of the following are observed:

1. Damage to the product or packaging that may have occurred during shipping or storage
2. Loose or misshaped luer fittings on the product.
3. Open-ended or unattached tubing are present on the exterior of the product.
4. The product was frozen with fluid inside, the product is not designed for freezing fluid.
5. The product Use By Date (YYYY-MM-DD) has been exceeded.
6. The product has been grossly overfilled.
7. Do NOT re-sterilize or reuse the product. All G-Rex products are single-use only.

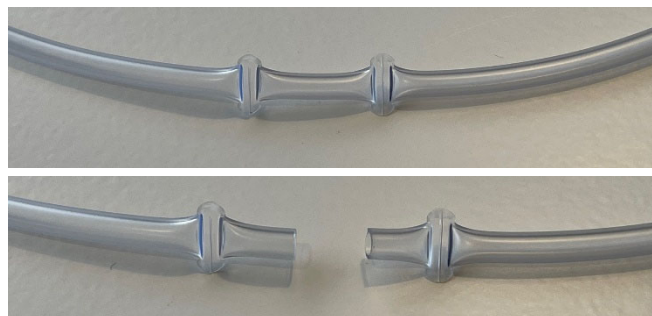
### PREPARATION

- Remove G-Rex from the packaging.
- Verify the internal harvest line (the tube that contacts the bottom membrane) is positioned against the side wall of the vessel where the wall meets the bottom surface. You may need to tilt the G-Rex at an angle and tap the vessel to move this tube into place.
- Check and hand tighten each luer fitting on the product. Do not overtighten.
- **IMPORTANT** – This product is shipped with a “Looped” Harvest Line 2 that is connected to the Sample Line. Prior to product use, the user must create separate weldable tubing lines (Sample & Harvest) by performing one or more sterile tubing seals near the center of the clear Harvest/Sample Line. Sterile tubing seals and line separation examples are shown below.

Single Sterile Seal (separated by hand)



Dual Sterile Seals (separated by cutting between seals)



- The vent filter should always remain open (unclamped) during fill, throughout the culture period and at time of harvest.
- Preheat Media to 37°C.

Notes:

- A. The vent filter line should only be clamped as a precaution during transit when the product is filled with media or when resuspending the cells (i.e., mixing the fluid). This ensures the vent filter does not become wet and will function properly in its dual-purpose role:
  - a. Allows air to be displaced when filling the product with fluid and acts to equalize headspace pressure and gas composition during the culture period
  - b. Serves as a sterile air filter if pressurizing the product during cell harvest.

Contact Wilson Wolf Technical Support for further assistance (contact info located at end of this document).

**ADDING MEDIA AND CELLS**

Media and cells can be added through any of the following 3 ports:

- 1. Sample Port via sample line
- 2. Media Reduction Ports
  - a. Reduction line 1
  - b. Reduction line 2
- 3. Cell Harvest Ports
  - a. Harvest line 1
  - b. Harvest line 2

Notes:

- A. Pay close attention to any clamps that need to be open to allow proper fluid flow.
- B. Do not exceed a fill rate of 300ml per minute, as this will result in fluid leakage due to over pressurization of the vessel. If uncertain, contact Technical Support for step by step guidance.
- C. Ensure each port is adequately flushed with media or sterile air following fluid addition so cells or growth factors are not retained in the fluid lines.
- D. To maintain product integrity, it is best practice to add and remove media/cells using thermal welds with the weld-compatible PVC tubing sets that consist of the media reduction port, line 1 (red-stripe) and the cell harvest port, line 2 (clear). Each line is 30 inches long and terminates in a luer fitting with a cap or plug.
- E. Product Capacities:

Working Volume	Maximum Capacity
1,000 ml (1 liter)	1,100 ml (1.1 liter)

**SAMPLING AND ALTERNATE MEDIA FILL METHODS**

**SAMPLE LINE (one line)**

- 1. The Sample Line consists of weldable PVC tubing. This line can be used to introduce reagents or remove samples during the culture period in a sterile manor.
  - o The sample line corresponds to the silicone tube on the inside of the product which terminates about 50% of the way into the vessel
  - o **IMPORTANT** – This product is shipped with “Looped” Harvest Line that is connected to the Sample Line. Prior to product use, create separate weldable tubing lines (Sample & Harvest) by performing one or more sterile tubing seals near the center of the clear Harvest/Sample Line.

**MEDIA REDUCTION PORT (two lines)**

- 1. Reduction line 1 is red-striped PVC tubing, terminating in a female luer lock and luer plug. This tubing is thermal weld compatible for functionally closed connections to a transfer bag. This tubing is contiguous with the tube on the inside of the product that terminates about 1cm above the bottom membrane.
  - o The female luer lock fitting can be used to dock a media/cell bag or syringe. This operation should be performed in a biosafety cabinet. Replace luer plug.
- 2. Reduction Line 2 has a quick connect fitting ending on the larger diameter silicone tube.
  - o This line corresponds to the tube on the inside of the product which terminates about 1cm above the membrane (same as reduction line 1).
  - o Use of this line to add media is an alternative to welding the media source to the reduction line 1 and should be performed in a biosafety cabinet. To do this, remove the end plug and aseptically connect a media bag to the quick connect fitting. Lift the bag above the G-Rex and allow media to gravity drain into the product. Replace the end plug.

**CELL HARVEST PORT (two lines)**

- 1. Harvest line 1 is the short silicone tube that comes off a T-fitting and terminates in a female luer lock.
  - o This line corresponds to the silicone tube on the inside of the product that is angled into the side wall and touches the bottom membrane.
  - o Similar to media reduction Line 2, harvest line 1 can be used as an alternate method for filling the product with media prior to inoculation.
  - o Attachment to this line should be performed in a biosafety cabinet. To do this, aseptically remove the end plug, dock a media bag onto the female luer fitting and gravity drain fluid into the product. Replace the end plug fitting.
- 2. Harvest line 2 is a clear PVC tubing line that terminates with tubing seal that is created by the user after removing device from packaging (see PREPARATION section). This tubing is thermal weld compatible which is necessary to maintain a functionally closed connection to a media transfer bag.
  - o This line corresponds to the silicone tube on the inside of the product that is angled toward the side wall and touches the bottom membrane (same as harvest line 1).
  - o As described for media reduction line 1, this line can be used to fill the product prior to inoculation. If a sterile weld is not performed, the male luer lock fitting can be attached to a media bag and used to fill the product. This operation should be performed in a biosafety cabinet, followed by replacement of the end cap fitting.

## HARVESTING

Cell harvest should be performed in conjunction with the GatheRex Liquid Handling, Cell Harvest Pump.

Below is a brief guide. Reference the GatheRex User Manual for additional information:

1. Dock a waste media collection bag (or other receptible) onto reduction line 1 or reduction line 2. Use reduction line 1 (red-stripe PVC tubing) in conjunction with thermal weld equipment for functionally closed processing.
2. Dock a cell collection bag (or other receptible) onto harvest line 1 or harvest line 2. Use harvest line 2 (clear PVC tubing) in conjunction with thermal weld equipment for functionally closed processing.
3. Lay reduction line 1 and harvest line 2 in the corresponding conduit pathway of GatheRex Pump. Ensure the tubing is properly seated in the housing and close the clamps.
4. Connect the gas line from the GatheRex to the vent filter. Ensure the clamps for the selected fluid pathways are open to the media and cell collection bags and turn on the GatheRex pump.
5. Press the red arrow for media removal, allowing the device to pressurize and move fluid out of the vessel down to the 1cm height of the internal media reduction line.
6. With 90% of the full working volume (waste media) removed, swirl the remaining ~100 mls to resuspend the cells residing on the gas permeable membrane. Tilt the device so the fluid collects/pools where the internal harvest line touches the base/side of the vessel. Press the blue arrow for cell harvest, allowing the device to pressurize and move the cell population and all remaining fluid into the cell harvest bag.
7. Clamp reduction line 1 and harvest line 2 in order to seal the waste media and cell collection bags. Press release clamps button on GatheRex Pump and remove the tubing.
8. Seal the collection bags with sterile tube welder. Discard G-Rex vessel and waste media.

## MANUFACTURED BY

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## TECHNICAL SUPPORT / ORDERING

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G-Rex® is a registered trademark of Wilson Wolf Manufacturing, LLC

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**FIGURE 1:** Reduction, Harvest, Sample Line and All Three Internal Lines

