

## TECHNICAL DATA SHEET

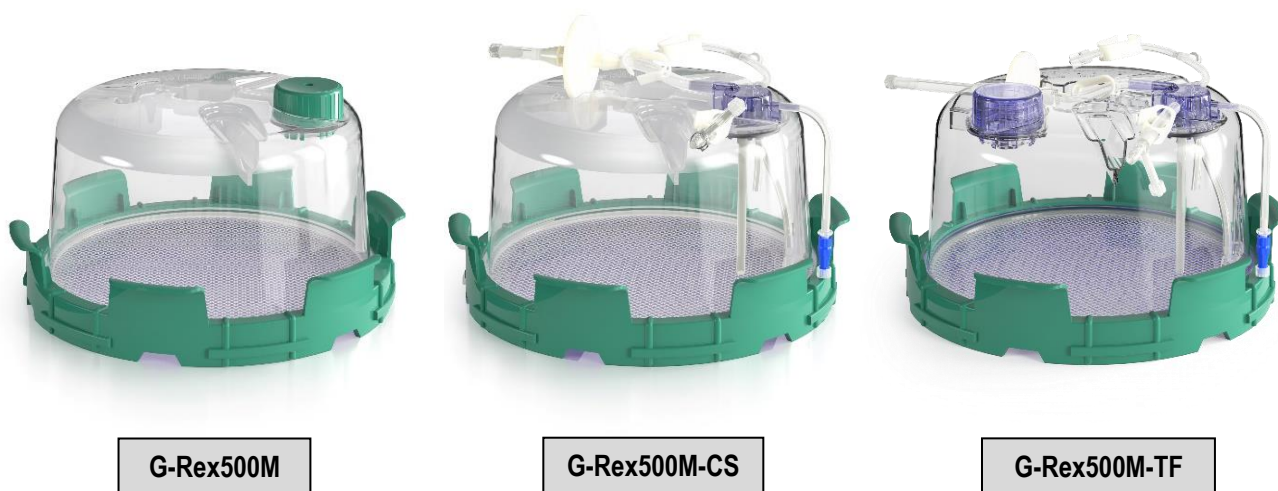
**Product:** G-Rex<sup>®</sup>500-Series Gas Permeable Cell Culture Products

**REF (Catalog Numbers):**

| Usage                            | G-Rex <sup>®</sup> 500M | G-Rex <sup>®</sup> 500M-CS | G-Rex <sup>®</sup> 500M-TF |
|----------------------------------|-------------------------|----------------------------|----------------------------|
| <b>GMP</b><br>Sterile Fluid Path | <b>G285500</b>          | <b>G285500-CS</b>          | <b>G285500-TF</b>          |
| <b>RUO</b><br>Gamma Irradiated   | <b>G285500-RU</b>       | <b>RU05500-CS</b>          | <b>RU85500-TF</b>          |

### 1) Description

The G-Rex<sup>®</sup>500 series products are single-use cell culture bioreactors designed for the expansion and recovery of mammalian cells.



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### 2) Key Characteristics & Dimensions

| Specification                                       | G-Rex500M                   | G-Rex500M-CS                                                                                                                                                                                                                                                                    | G-Rex500M-TF                |
|-----------------------------------------------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| Functional Use                                      | Open System                 | Closed System                                                                                                                                                                                                                                                                   |                             |
| Cell Growth Area (membrane)                         | 500 cm <sup>2</sup>         |                                                                                                                                                                                                                                                                                 |                             |
| Nominal Working Volume                              | 5,000 mL                    |                                                                                                                                                                                                                                                                                 |                             |
| Maximum Fluid Volume                                | 5,500 mL                    |                                                                                                                                                                                                                                                                                 |                             |
| Approximate Dry Weight                              | 2.50 lbs.<br>(1,135 grams)  | 2.75 lbs.<br>(1,249 grams)                                                                                                                                                                                                                                                      | 2.82 lbs.<br>(1,278 grams)  |
| Estimated Filled Weight<br>@ Nominal Working Volume | 13.53 lbs.<br>(6,135 grams) | 13.78 lbs.<br>(6,249 grams)                                                                                                                                                                                                                                                     | 13.84 lbs.<br>(6,278 grams) |
| Maximum Product Height                              | 7.13 inch<br>(18.1 cm)      | 7.88 inch<br>(20.0 cm)                                                                                                                                                                                                                                                          | 7.88 inch<br>(20.0 cm)      |
| Maximum Product Diameter                            | 12.27 inch<br>(31.2 cm)     |                                                                                                                                                                                                                                                                                 |                             |
| Sample Tubing Line<br>Connection                    | N/A<br>(open system)        | <ul style="list-style-type: none"> <li>▪ MicroClave® Connector</li> <li>▪ Total Sample Line Residual Volume (~1.5 mL)</li> </ul>                                                                                                                                                |                             |
| Reduction Tubing Line<br>Connection Options         | N/A<br>(open system)        | <ul style="list-style-type: none"> <li>▪ Female MPC</li> <li>▪ Female Luer Lock</li> <li>▪ Weldable PVC Tubing (0.114" ID / 0.160" OD)</li> <li>▪ Weldable C-Flex Tubing (0.250" ID / 0.375" OD)</li> <li>▪ Weldable Tubing Length of PVC and C-Flex (30" / 76.2 cm)</li> </ul> |                             |
| Harvest Tubing Line<br>Connection Options           | N/A<br>(open system)        | <ul style="list-style-type: none"> <li>▪ Male Luer Lock</li> <li>▪ Weldable PVC Tubing (0.114" ID / 0.160" OD)</li> <li>▪ Weldable Tubing Length (30" / 76.2 cm)</li> </ul>                                                                                                     |                             |

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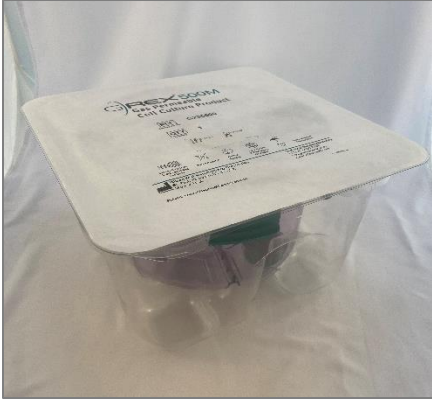
### 3) Packaging

| Feature                                      | G-Rex500M                                                            | G-Rex500M-CS                        | G-Rex500M-TF                        |
|----------------------------------------------|----------------------------------------------------------------------|-------------------------------------|-------------------------------------|
| Packaging Materials                          | PETG Tray & Retainer,<br>Tyvek® Lid                                  | PETG Tray & Retainer,<br>Tyvek® Lid | PETG Tray & Retainer,<br>Tyvek® Lid |
| Devices per Package                          | 1                                                                    |                                     |                                     |
| Minimum Shipping Quantity                    | 2-pack (Case)                                                        |                                     |                                     |
| Case Dimensions<br>(Length x Width x Height) | L 18.38 in (46.7 cm)<br>W 15.38 in (39.1 cm)<br>H 15.63 in (39.7 cm) |                                     |                                     |
| Case Weight                                  | 10.91 lbs.<br>(4.95 kg)                                              | 11.21 lbs.<br>(5.09 kg)             | 11.59 lbs.<br>(5.26 kg)             |
| Shelf Life                                   | 3-years                                                              |                                     |                                     |
| Recommended<br>Storage Conditions            | Ambient<br>(64 - 82°F (18 to 28°C), No Humidity Controls)            |                                     |                                     |

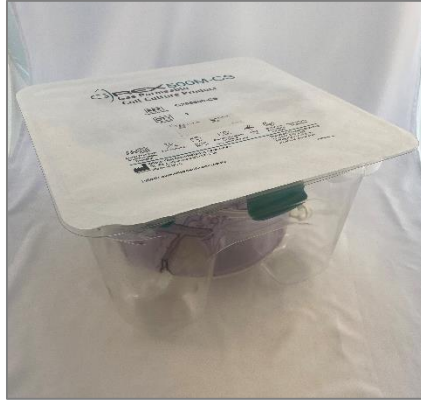
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### 4) Packaging Images

#### Individual Packaging



**G-Rex500M**



**G-Rex500M-CS**



**G-Rex500M-TF**

#### 2-Pack Cases



**G-Rex500M**



**G-Rex500M-CS**



**G-Rex500M-TF**

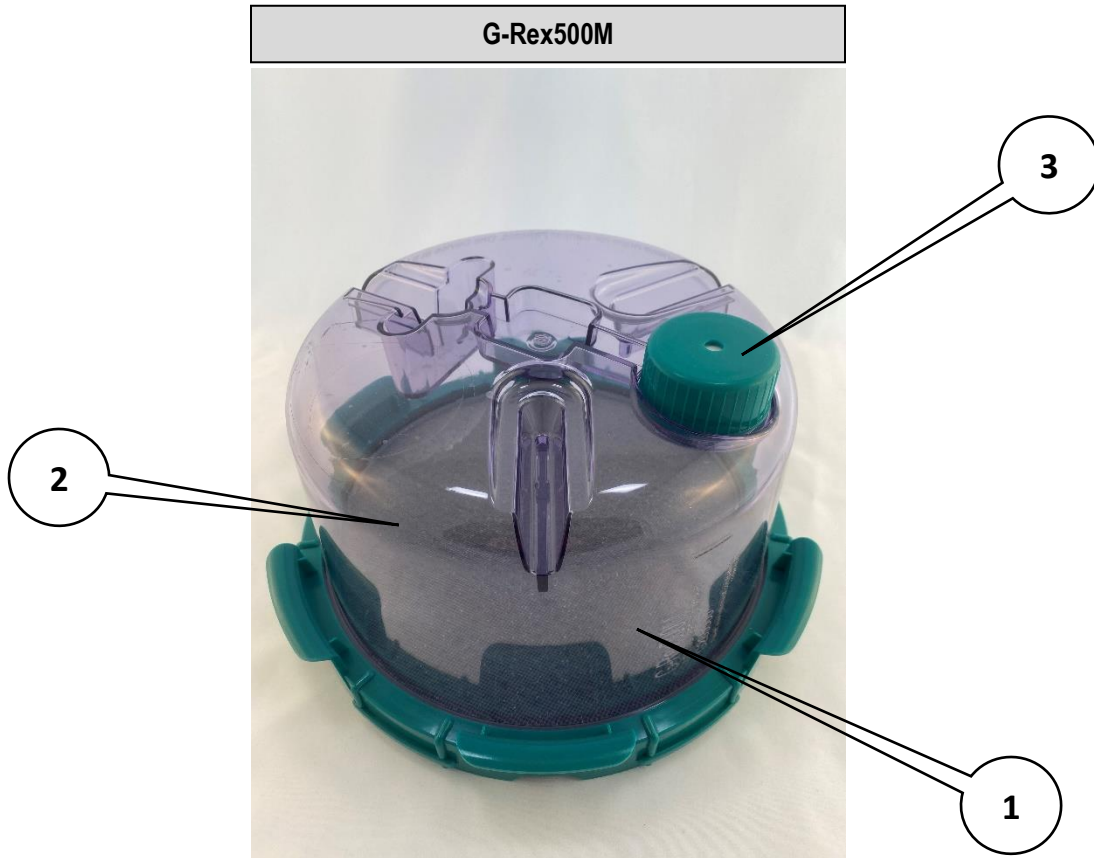
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### 5) Other Product Information

| Feature                                              | Value                                                                                                                                                               |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Certificate of Compliance (CoC)                      | Provided with Every Shipment                                                                                                                                        |
| Viral Penetration Tested<br>(Membrane Material only) | ASTM F1671                                                                                                                                                          |
| No Chemical Additives Statement                      | G-Rex Products Do Not Use Latex, BPA, Phthalates, Nitrosamines, Residual Solvents or Mold Release Agents in their Component Manufacturing or Final Device Assembly. |
| Electronic Instructions for Use (eIFU)               | Visit <a href="http://www.wilsonwolf.com">www.wilsonwolf.com</a>                                                                                                    |

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### 6) Product Materials

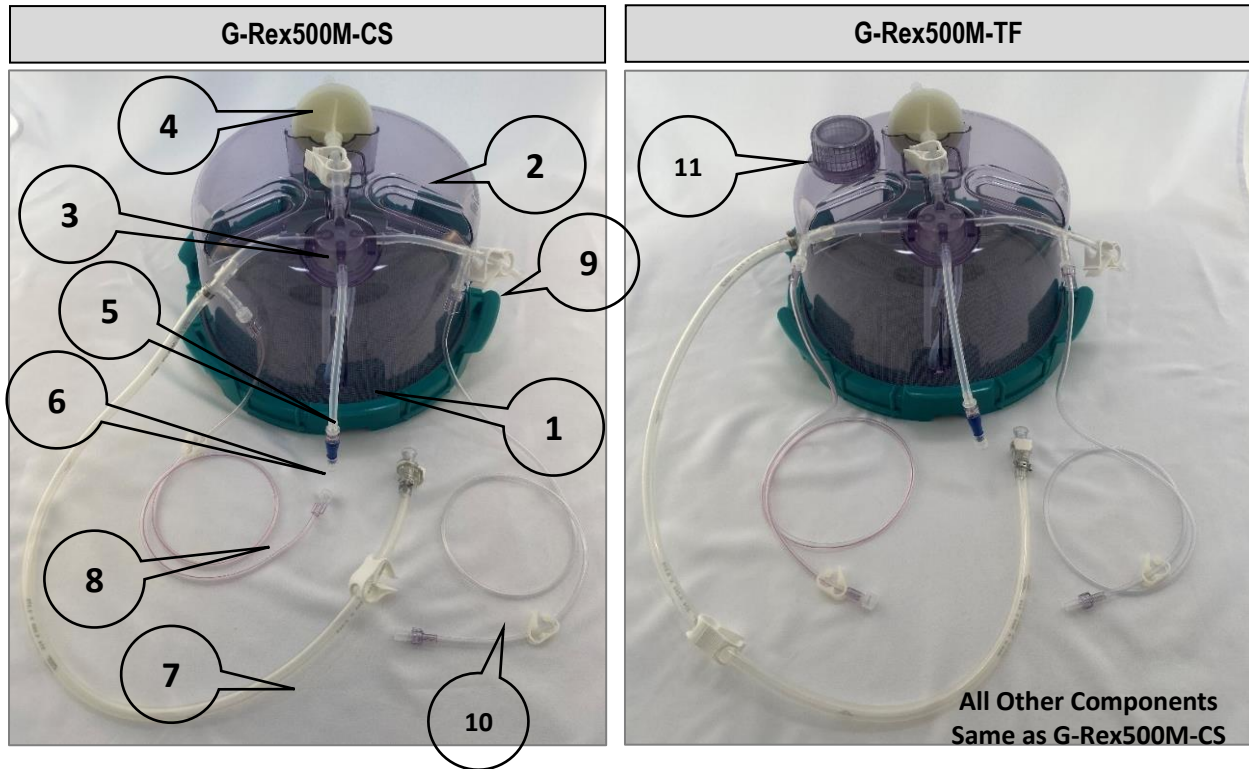


**Fluid Pathway Components (numbered)**

| # | Component Name         | Material                                                                | Material Grade          |
|---|------------------------|-------------------------------------------------------------------------|-------------------------|
| 1 | Gas Permeable Membrane | Silicone Elastomer                                                      | USP Class VI, ISO 10993 |
| 2 | Shell (Vessel)         | Polycarbonate                                                           | USP Class VI, ISO 10993 |
| 3 | Cap with Vent Filter   | Cap: Polypropylene,<br>Filter Membrane: Hydrophobic ePTFE (0.2 $\mu$ m) | USP Class VI, ISO 10993 |



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| #  | Component                                        | Material                                                                                                                                                   | Material Grade                                |
|----|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 1  | Gas Permeable Membrane                           | Silicone Elastomer                                                                                                                                         | USP Class VI, ISO 10993                       |
| 2  | Shell (Vessel)                                   | Polycarbonate                                                                                                                                              | USP Class VI, ISO 10993                       |
| 3  | Multi-Port Cap                                   | Polypropylene                                                                                                                                              | USP Class VI, ISO 10993                       |
| 4  | Pall® Emflon® II Vent Filter (non-fluid pathway) | 0.2 µm, 50mm Diameter, Hydrophobic Polyvinylidene fluoride (PVDF), Emflon® II membrane in mini Kleenpack™ filter capsule (Pall® Product No. KM5V002P2G100) | USP Biological Reactivity Tests, In Vivo <88> |
| 5  | Sample Line Tubing                               | Silicone Elastomer                                                                                                                                         | USP Class VI, ISO 10993                       |
| 6  | MicroClave® Connector                            | Body: Polybutylene Terephthalate (PBT), Seal: Silicone, Spike: Polycarbonate, Lubricant: Silicone.                                                         | FDA Class 2 Device<br>USP Class VI, ISO 10993 |
| 7  | Reduction Line Tubing                            | C-Flex®, Thermoplastic Elastomer                                                                                                                           | USP Class VI, ISO 10993                       |
| 8  | Weldable Reduction Line                          | Polyvinyl chloride (PVC), non-toxic, non-phthalate                                                                                                         | USP Class VI, ISO 10993                       |
| 9  | Harvest Line Tubing                              | Silicone Elastomer                                                                                                                                         | USP Class VI, ISO 10993                       |
| 10 | Weldable Harvest Line                            | Polyvinyl chloride (PVC), non-toxic, non-phthalate                                                                                                         | USP Class VI, ISO 10993                       |

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|    |                       |               |                         |
|----|-----------------------|---------------|-------------------------|
| 11 | Cap (non-vented)      | Polycarbonate | USP Class VI, ISO 10993 |
| -  | Various Luer Fittings | Polycarbonate | USP Class VI, ISO 10993 |
| -  | Various Luer Caps     | Polypropylene | USP Class VI, ISO 10993 |

### Fluid Pathway Components (numbered)

#### 7) Regulatory / Compliance

|                               |                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Company Certifications        | ISO 13485                                                                                                                                                                                                                                                                                                                                                                         |
| OUS Product Classification    | GMP raw material for the manufacturing of cellular products, also known as an ancillary material per ISO/TS 20399-3:2018(en) Biotechnology - Ancillary Materials Present During The Production Of Cellular Therapeutic Products - Part 3: Best Practice Guidance For Ancillary Material Users, and USP <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products. |
| FDA Est. Reg. # and Est. Type | 3004982543, Medical Device Manufacturer                                                                                                                                                                                                                                                                                                                                           |
| FDA Product Classification    | Device Class: I<br>Classification Name: System, Suspension, Cell Culture<br>Product Code: KJF<br>Regulation Number and Description: 21 CFR 864.2240 Cell and Tissue Culture Supplies and Equipment<br>Regulation Medical Specialty: Hematology<br>Premarket Submission Type: 510(k) Exempt                                                                                        |
| Patents                       | <a href="http://www.wilsonwolf.com/patents">www.wilsonwolf.com/patents</a>                                                                                                                                                                                                                                                                                                        |

#### 8) Legal Disclaimer

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.