WILSONWOLF

G|REX

TECHNICAL DATA SHEET

Product: **G-Rex®5 & 10-Series Gas Permeable Cell Culture Products**

REF (Catalog Numbers):

Usage	G-Rex®5M	G-Rex®10	G-Rex®10M	G-Rex®10M-CS
GMP Sterile Fluid Path	**80055**	**80040S**	**80110**	**80110-CS**
RUO Gamma Irradiated	**RU80055**	*Not Available*	**80110S**	**80110S-CS**

1) Description

The G-Rex®5 & G-Rex®10 series products are single-use cell culture bioreactors designed for the expansion and recovery of mammalian cells.

G-Rex®5M

G-Rex®10

G-Rex®10M

G-Rex®10M-CS

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2) Key Characteristics & Dimensions

Specification	G-Rex5M	G-Rex10	G-Rex10M	G-Rex10M-CS
Functional Use	Open System			Closed System
Cell Growth Area (membrane)	5 cm^2	10 cm^2		
Nominal Working Volume	50 mL	40 mL	100 mL	
Maximum Fluid Volume	55 mL	45 mL	110 mL	110 mL
Approximate Dry Weight	0.31 lbs. (141 grams)	0.11 lbs. (49 grams)	0.19 lbs. (86 grams)	0.35 lbs. (160 grams)
Estimated Filled Weight @ Nominal Working Volume	0.42 lbs. (191 grams)	0.20 lbs. (89 grams)	0.41 lbs. (186 grams)	0.57 lbs. (260 grams)
Maximum Product Height	5.56 inch (14.1 cm)	2.56 inch (6.5 cm)	5.56 inch (14.1 cm)	6.25 inch (15.9 cm)
Maximum Product Diameter	2.19 inch (5.6 cm)	2.40 inch (6.1 cm)	2.19 inch (5.6 cm)	3.45 inch (8.8 cm)
Sample Tubing Line Connection	N/A (open system)	N/A (open system)	N/A (open system)	▪ MicroClave® Connector ▪ Total Sample Line Residual Volume (~1.5 mL)
Reduction Tubing Line Connection Options	N/A (open system)	N/A (open system)	N/A (open system)	▪ Female MPC ▪ Female Luer Lock ▪ Weldable PVC Tubing (0.114" ID / 0.160" OD) ▪ Weldable Tubing Length (30"/ 76.2 cm)

Harvest Tubing Line Connection Options	N/A (open system)	N/A (open system)	N/A (open system)	▪ Male Luer Lock ▪ Weldable PVC Tubing (0.114" ID / 0.160" OD) ▪ Weldable Tubing Length (30"/ 76.2 cm)

3) Packaging

Feature	G-Rex5M	G-Rex10	G-Rex10M	G-Rex10M-CS
Packaging Materials	PETG Tray & Retainer, Tyvek® Lid	PETG Tray & Retainer, Tyvek® Lid	PETG Tray & Retainer, Tyvek® Lid	PETG Tray & Retainer, Tyvek® Lid
Devices per Package	1			
Minimum Shipping Quantity	3-pack (Case)	12-pack (Case)	3-pack (Case)	3-pack (Case)
Case Dimensions (Length x Width x Height)	L 14.0 in (35.6 cm) W 9.63 in (24.4 cm) H 4.0 in (10.2 cm)	L 14.63 in (37.2 cm) W 10.13 in (25.7 cm) H 3.0 in (7.6 cm)	L 14.0 in (35.6 cm) W 9.63 in (24.4 cm) H 4.0 in (10.2 cm)	L 14.0 in (35.6 cm) W 9.63 in (24.4 cm) H 4.0 in (10.2 cm)
Case Weight	1.91 lbs. (0.87 kg)	2.22 lbs. (1.01 kg)	1.53 lbs. (0.69 kg)	2.06 lbs. (0.93 kg)
Shelf Life	3-years			
Recommended Storage Conditions	Ambient (64 - 82°F (18 to 28°C), No Humidity Controls)			

4) Packaging Images

Individual Packaging

G-Rex5M

G-Rex10

G-Rex10M

G-Rex10M-CS

Multi-pack Cases

G-Rex5M (3-pack)

G-Rex10 (12-pack)

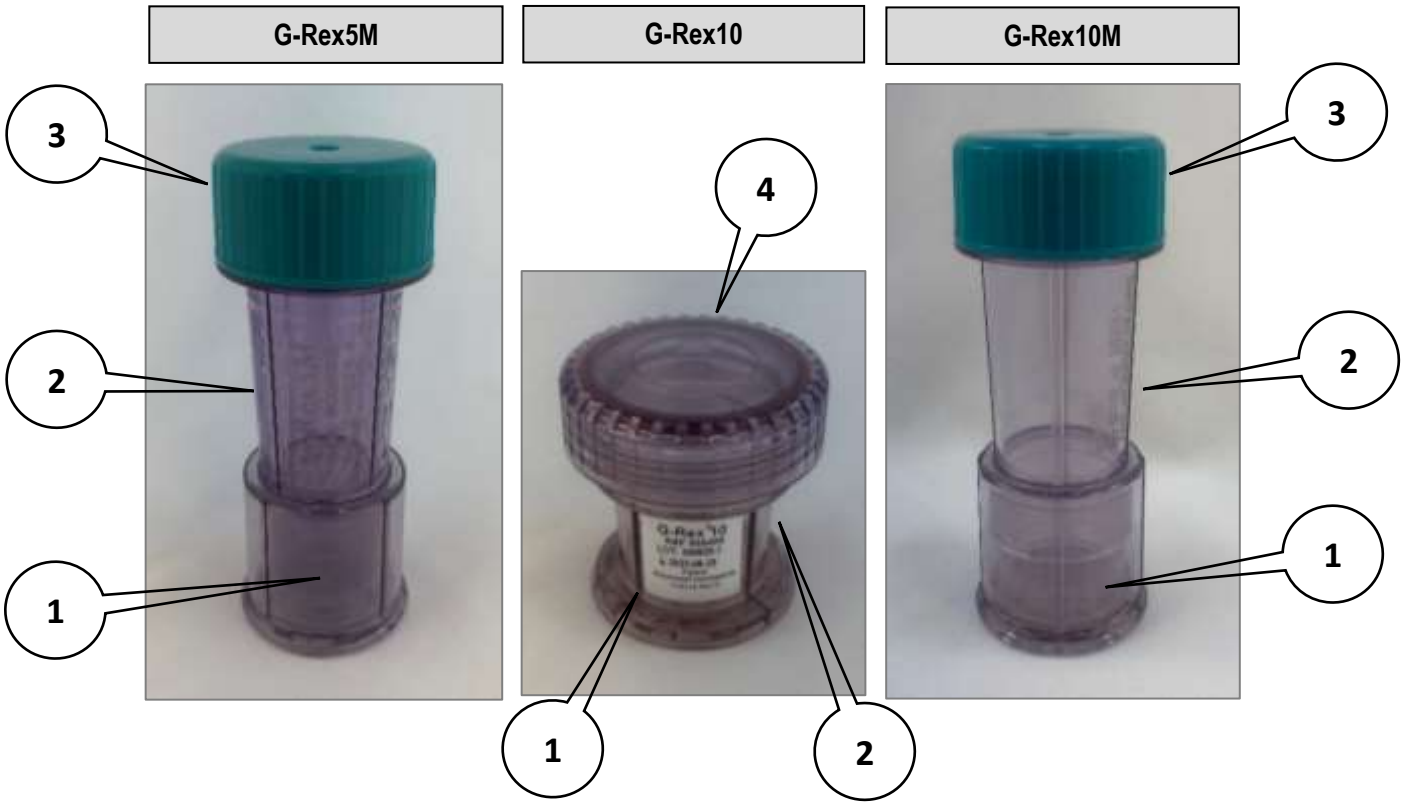
G-Rex10M (3-pack)

G-Rex10M-CS (3-pack)

5) Other Product Information

Feature	Value
Certificate of Compliance (CoC)	Provided with Every Shipment
Viral Penetration Tested (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 www.wilsonwolf.com

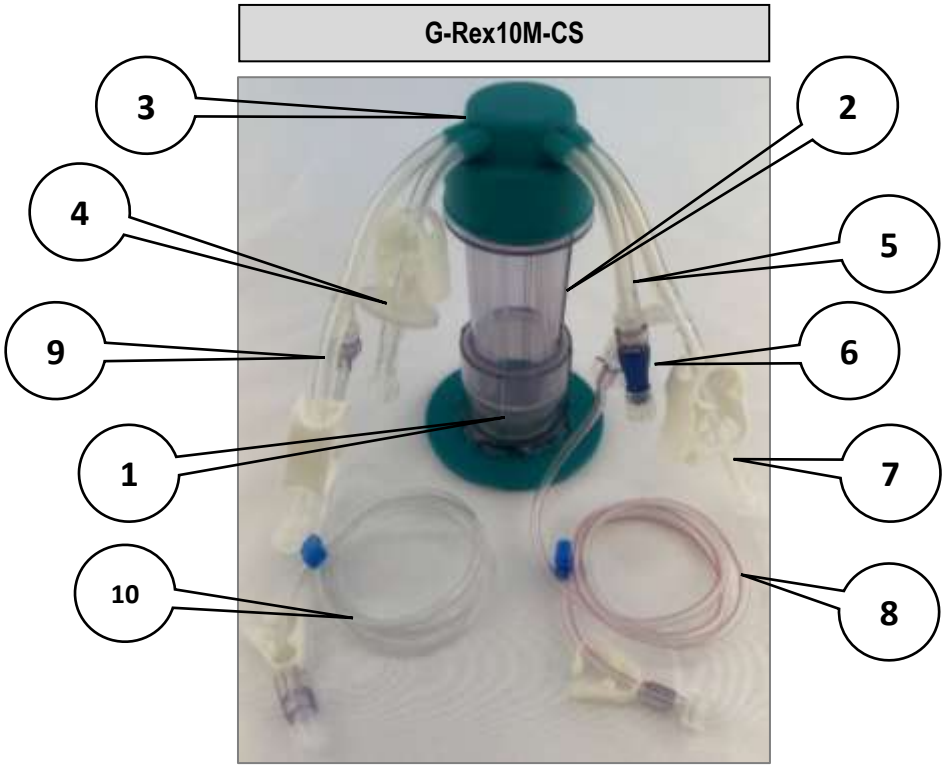
6) Product Materials



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, Filter Membrane: Hydrophobic ePTFE (0.2 µm)	USP Class VI, ISO 10993
4	Cap (non-vented)	Polycarbonate	USP Class VI, ISO 10993

TECHNICAL DATA SHEET



Fluid Pathway Components (numbered)

#	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 Versapor® Vent Filter (non-fluid pathway)	0.2 µm, Acrylic Copolymer Membrane, Hydrophobic, Versapor® Membrane (Pall® Product No. 6004700)	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 USP Class VI, ISO 10993
7	Reduction Line Tubing	Silicone 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
-	Various Luer Fittings	Polycarbonate	USP Class VI, ISO 10993
-	Various Luer Caps	Polypropylene	USP Class VI, ISO 10993

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 Classification Name: System, Suspension, Cell Culture Product Code: KJF Regulation Number and Description: 21 CFR 864.2240 Cell and Tissue Culture Supplies and Equipment Regulation Medical Specialty: Hematology Premarket Submission Type: 510(k) Exempt
Patents	www.wilsonwolf.com/patents

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.