

G[®]REX[®] 500M

Gas Permeable
Cell Culture Product

REF
Catalog Number

G285500 / G285500-RU

INSTRUCTIONS FOR USE (IFU)

PRODUCT DESCRIPTION

The G-Rex[®]500M are single-use, open products 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.

Use	REF	STERILITY
GMP	G285500	Sterile Fluid Path, Sterilized Using Irradiation (SAL=10 ⁻⁶)
RUO	G285500-RU	Gamma Irradiated, Sterility Assurance Level (SAL) has not been validated

INDICATIONS FOR USE

The G-Rex500M cell culture systems are 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 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 use if the product is damaged.
4. Do not use the product if there is an apparent breach to sterility.
5. Unauthorized modification and improper use may result in the inability to culture cells or maintain a sterile environment.

PRECAUTIONS

1. Do NOT contact bottom surface of product with a pipette or similar instrument. Damage to the gas permeable membrane may occur causing leakage.
DO NOT USE the product if any of the following are observed:
2. Damage to the product or packaging that may have occurred during shipping or storage
3. The product was frozen with fluid inside, the product is not designed for freezing fluid.
4. The product Use By Date (YYYY-MM-DD) has been exceeded.
5. The product has been grossly overfilled.
6. Do NOT re-sterilize or reuse the product. All G-Rex products are single-use only.

PREPARATION

- Remove G-Rex from the packaging.
- Preheat Media to 37°C.

ADDING MEDIA AND CELLS

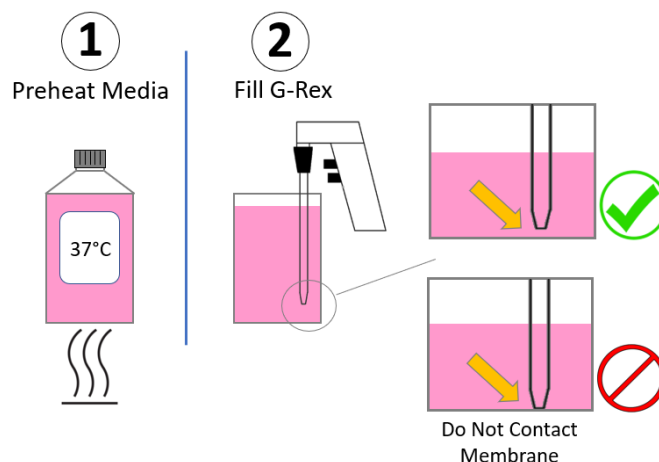
Fill G-Rex with preheated media to working volume listed in table below.

Add desired cells and reagents.

Use care when working with a pipette or similar instruments near the bottom of the G-Rex. The gas permeable membrane can be damaged resulting in product leak.

Product Capacities:

Working Volume	Maximum Capacity
5 Liters	5.5 Liters



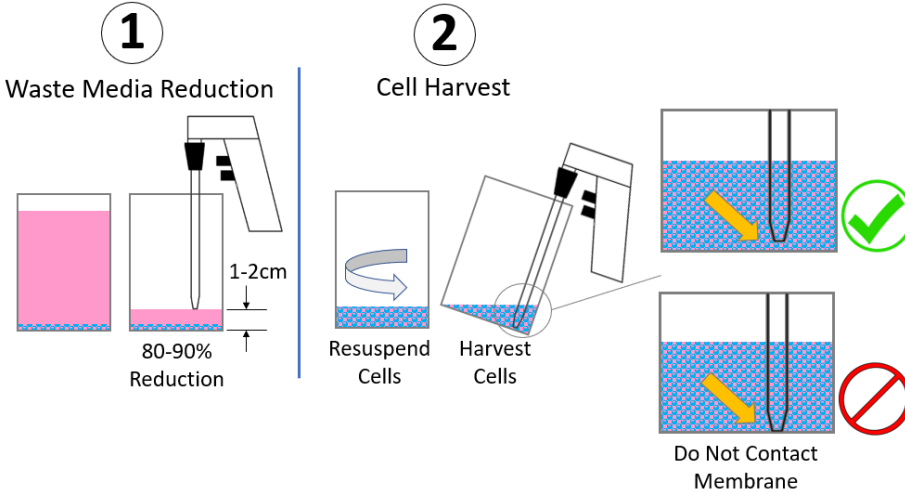
HARVESTING

Remove 80-90% of the Waste Media. Keep pipette 1-2cm from bottom of G-Rex to avoid removing cells.

Replace the G-Rex cap and resuspend cells in remaining media by agitating and swirling device.

Remove cap, then tilt G-Rex and remove cells using a pipette.

Use care when working with a pipette or similar instruments near the bottom of the G-Rex. The gas permeable membrane can be damaged resulting in product leak.



MANUFACTURED BY

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