Miltenyi Biotec

MACS® GMP Cell Expansion Bag

Cell Expansion Bag REF 170-076-403

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1. Description

Components 1 unit contains 5 Cell Expansion Bags with a flexible volume of 15, 50, and 100 mL (27, 59, and 116 cm^2, respectively) (please see table below).

For labeling purpose, sample identification tags and connection strips are provided.

Size	Product	Volume/Area	Minimal fill volume
1 unit	5× Cell Expansion Bag	27 / 59 / 116 cm^2	8 / 16 / 20 mL

Sterility Sterile and non-pyrogenic.

Transport Room temperature

Storage Store at room temperature.

Shelf life Do not use after use-by date as given on the package.

Disclaimer

MACS GMP Products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative.

Quality statement

MACS GMP Products are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

2. Applications

- The transparent MACS GMP Cell Expansion Bags are intended for the *in vitro* cultivation and expansion of cells from heterogenous hematologic cell populations, for example, for the expansion of antigen-specific T cells. The Cell Expansion Bag consists of three sealed compartments, which permits flexible culture volumes of 15 mL, 50 mL, and 100 mL in one bag (fig. 1). As culture volume increases, seals can easily be opened to provide larger culture volume of up to 100 mL. The transparent cell culture bag allows for the cell culture process to be monitored by microscopy.

3. Warnings and precautions

- The instructions for use must be followed.
- When using this product, the national legislation and regulations must be followed. Any application of *ex vivo* processed target cells is exclusively within the responsibility of the user.
- For single use only. Do not reuse.
- Use undamaged and sealed product only.
- Do not use after the use-by date indicated on the product label.
- Cell Expansion Bags should not be centrifuged.
- Do not use for cryopreservation.
- Writing on or labeling the Cell Expansion Bag surface is not recommended.
- Surface disinfection: The bags are compatible with aldehyde and peroxide-based disinfection reagents. However, alcohol and quaternary ammonium complexes may compromise the integrity.
- Organic solvents, e.g., dimethyl sulfoxide (DMSO), may cause damage to Cell Expansion Bags.

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4. Instructions for use

- Use aseptic techniques.
- Be sure to carefully remove air from the bag when filling the first compartment.
- Careful disinfection of the septum before and after usage is recommended.
- The transfer or removal of fluids can be performed by using the female luer lock connection at the end of the tubing (fig. 1) or by using the tubing for sterile docking (tubing PVC. inner/outer diameter 2.5/4.1 mm).
- Observe the instructions for use supplied by the manufacturer of the tube welding device.
- The septum can be used to apply or remove fluids using a syringe and needle (e.g. cytokines or sample for analysis).
- To open a consecutive compartment, transfer additional medium as necessary and apply gentle pressure on the fluid in the direction of the seal until it is fully opended.

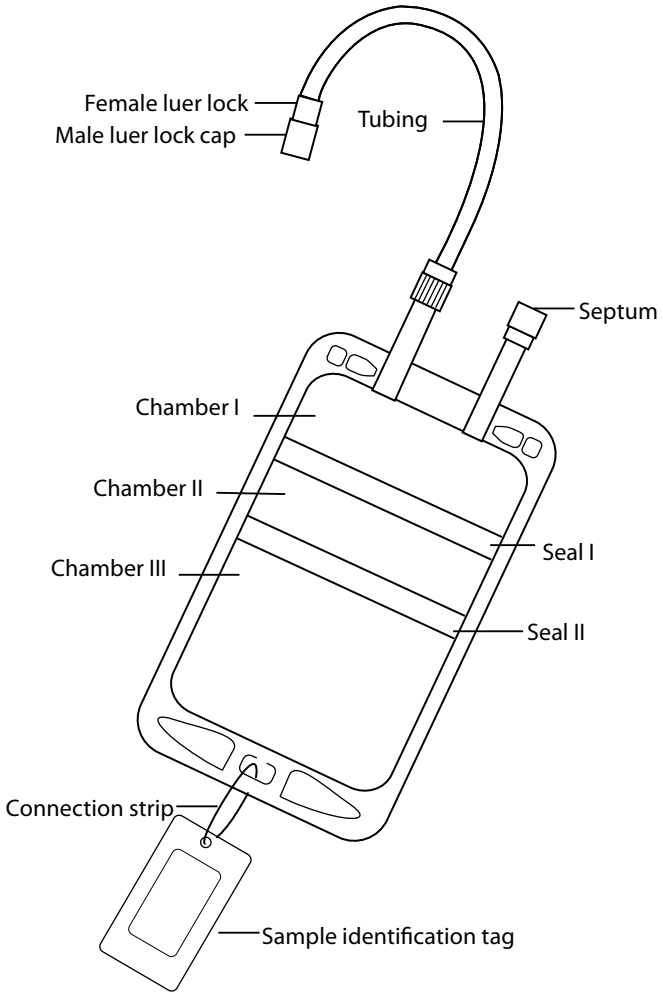


Figure 1: Cell Expansion Bag.

5. Glossary of symbols

	Manufacturer	STERILE R	Sterilized using irradiation
REF	Order number		Do not re-use
P/N	Part number		Phone
LOT	Batch code		Fax
	Consult instruction for use		E-mail
	Use-by date		Website
	Do not use if package is damaged.		

This data sheet and corresponding information can be found under **www.miltenyibiotec.com/170-076-403**.

Warranty

The products sold hereunder are warranted only to be free from defects in workmanship and material at the time of delivery to the customer. Miltenyi Biotec B.V. & Co. KG makes no warranty or representation, either expressed or implied, with respect to the fitness of a product for a particular purpose. There are no warranties, expressed or implied, which extend beyond the technical specifications of the products. Miltenyi Biotec B.V. & Co. KG's liability is limited to either replacement of the products or refund of the purchase price. Miltenyi Biotec B.V. & Co. KG is not liable for any property damage, personal injury or economic loss caused by the product.

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