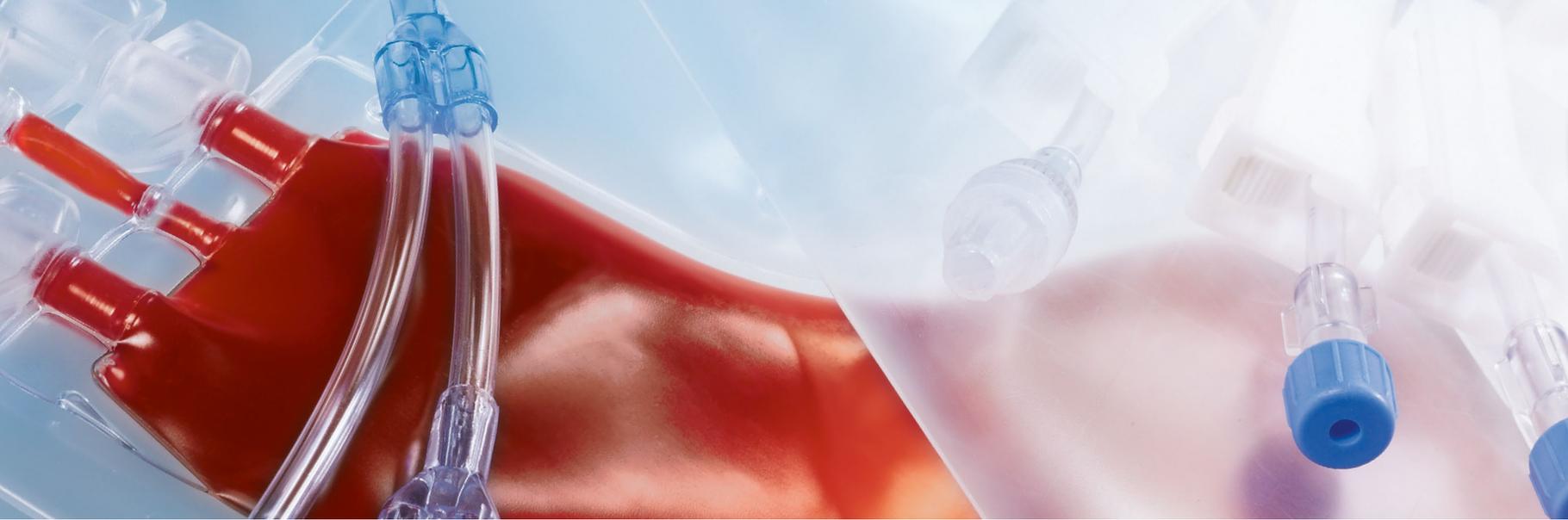




Miltenyi Biotec



CryoMACS® Products



CryoMACS Freezing Bags

The right step towards safe cryopreservation

Overwrap bag protects both sample and freezing bag during cryopreservation.

- Made of the same resistant tubular ethylene vinyl acetate (EVA) material as the freezing bag.
- Provided with each freezing bag.
- Space-saving shape enables compatibility with existing freezing cassettes.
- Ribbed structured material facilitates opening of overwrap bag and introduction of freezing bag.

Integrated filling assembly with injection port, two female Luer-Lock connectors, one male Luer-Lock connector, and roller clamps for high flexibility. The extra-long PVC tubing is compatible with sterile connecting devices.

Optimized Y-adaptor with combined Luer-Lock injection port.

Extra-long EVA tubing enables sampling for quality control by simple heat-sealing of sample-filled tubing sections.



Hanger holes for easy handling of the bag.

Advanced bag design enables full drainage of the bag.

Freezing bag made of a resistant tubular EVA film with fewer welds for more durability and less storage space.

Label pouch for written sample information and to ensure label integrity throughout the freeze-thaw cycle.

Two secure spike ports for removal of the thawed cell product.

- The single-component ports are secured with sealed, twist-off protective caps.
- Internal protection tubes inhibit perforation of the freezing bag during removal of the cell product.



CryoMACS Freezing Bags

Safety to rely on

Make assurance double sure

CryoMACS Freezing Bags consist of a freezing bag and a corresponding overwrap bag. Both bags are made of EVA. The overwrap bag provides extra security by protecting the freezing bag and the stored cellular product, while maintaining sterility and preventing contamination risks during storage.^{1,2}

Single sterile packaging for convenient handling

Each CryoMACS Freezing Bag and the corresponding overwrap bag is individually packed and sterilized by electron-beam irradiation.

The outer packaging can be disinfected for easy clean-room handling. This helps to maintain a sterile workflow from cell collection to storage and subsequent thawing.

Advanced bag design

The CryoMACS Freezing Bags are made of an EVA tubular film with few welds for high durability. The design is optimized for complete drainage of the bags. The extra-long EVA tubing of the integrated filling assembly allows the user to prepare small samples for quality controls: simple heat sealing can separate filled tube sections. The spike ports are secured with sealed twist-off protective caps to prevent cross-contamination. The spike ports' internal protection tube inhibits perforation of the freezing bag during removal of the thawed cell product.

References

1. Tedder, R *et al.* (1995) *Lancet* 346: 137–140.
2. Fountain, D *et al.* (1997) *Transfusion* 37: 585–591.

Designed for safer cryopreservation

- Unique bag concept with few welds making it highly durable
- Corresponding overwrap bag to protect freezing bag and stored product
- Optimized shape and spike ports for complete drainage of the freezing bag
- Single, sterile packaging helps to maintain aseptic workflow



Figure 1: CryoMACS Freezing Bag. More protection in the same storage space.



CryoMACS Freezing Bags

Developed by specialists,
used by experts

Robustness of the CryoMACS Freezing Bags for routine clinical use has been shown in a number of internal and external tests.

The integrity of CryoMACS Freezing Bags after filling and exposure to ten cycles of freezing and thawing has been demonstrated in a series of laboratory experiments (table 1).

Results of the freeze-thaw bag integrity test

Bag designation	Fill volume	Number of test failures	Failure at indicated cycle number
CryoMACS Freezing Bag 750	120 mL	2/90	9, 9
CryoMACS Freezing Bag 750	150 mL	0/10	-
Manufacturer A 750	150 mL	3/10	3, 4, 6
CryoMACS Freezing Bag 50	20 mL	0/100	-
Manufacturer A 50	20 mL	0/20	-

Table 1: Results of the freeze-thaw bag integrity test.

One hundred CryoMACS Freezing Bags 750 and ten 750 mL reference bags were filled and exposed to ten consecutive cycles of freezing and thawing. One hundred CryoMACS Freezing Bags 50 and twenty 50 mL reference bags were also tested. The results of all freezing tests are summarized here:

- 2 out of 100 (2%) of the 750 mL CryoMACS Freezing Bags developed leaks at very late stages
- 3 out of 10 (30%) of the reference bags failed the integrity test at early stages
- all 50 mL freezing bags passed the integrity test

CryoMACS Freezing Bags have been shown to be impermeable to microorganisms in accordance with the requirements of ISO 3826-1.*

The advanced bag design of the CryoMACS Freezing Bags (e.g. secured spike ports, appropriate overwrap bags) helps avoid viral contamination during use.*

Several external test series concluded that CryoMACS Freezing Bags are suitable for introduction into routine clinical use and clean-room processing.¹

A comparative study showed that CryoMACS Freezing Bags fulfill the requirements of a cryogenic freezing bag for the cryopreservation of human progenitor cells for transplantation.²

*Reprints of these technical reports of tests performed in-house are available on request.

References

1. Ings, S. J. *et al.* (2009) *Cytotherapy* 11: 10.
2. Sputtek, A. *et al.* (2011) *Cytotherapy* 13: 481–489.



CryoMACS Freezing Bags

Safety matters

The CryoMACS Freezing Bags are intended for a single cycle of freezing, storage (down to $-196\text{ }^{\circ}\text{C}$), and subsequent thawing (at $+37\text{ }^{\circ}\text{C}$) of hematopoietic progenitor cells.

Developed with the customer

CryoMACS Freezing Bags have been developed in cooperation with our clients and showed excellent standards for cryopreservation.

Proven quality

The freezing bags and their corresponding overwrap bags are made of EVA, a durable material that has been used for 30 years in liquid nitrogen cryopreservation procedures.

Different applications, different sizes

A useful range of CryoMACS Freezing Bags with nominal volumes ranging from 50 to 1000 mL (recommended fill volumes from 10 to 270 mL) is available and offers flexibility for various applications (table 2).

Product	Nominal volume	Recommended fill volume	Order no.
CryoMACS Freezing Bag 50	50 mL	10–20 mL	200-074-400
CryoMACS Freezing Bag 250	250 mL	30–70 mL	200-074-401
CryoMACS Freezing Bag 500	500 mL	55–100 mL	200-074-402
CryoMACS Freezing Bag 750	750 mL	80–190 mL	200-074-403
CryoMACS Freezing Bag 1000	1000 mL	125–270 mL	200-074-404

Table 2: The CryoMACS Freezing Bags are manufactured by Miltenyi Biotec and controlled under a quality system certified to ISO 13485. These products are available in Europe as CE-marked medical devices and are marketed in the USA under FDA 510(k) clearance. For availability in your country, please contact your local sales representative.



CryoMACS DMSO 10 (EP)

Tested and certified quality

CryoMACS DMSO 10 (EP) is a high-quality, pure, and 0.2 µm filtered dimethyl sulfoxide, supplied in glass vials.

DMSO is a well-established and commonly used cryoprotective agent. It protects cells during controlled freezing and storage at cryogenic temperatures.

CryoMACS DMSO is manufactured and tested under a certified ISO 13485 quality system and in compliance with relevant GMP guidelines.

Each batch of CryoMACS DMSO 10 (EP) is tested according to the European Pharmacopoeia (EP) and comes with a detailed batch-specific certificate.

CryoMACS DMSO 10 (EP) is for research use and *ex vivo* cell culture processing only, and is not intended for human *in vivo* applications.



Figure 2: CryoMACS DMSO 10 (EP).



Figure 3: CryoMACS DMSO 10 (EP).

Product	Components	Order no.
CryoMACS DMSO 10 (EP)	24x10 mL glass vials	170-076-303

Table 3: CryoMACS DMSO is for research use and *ex vivo* cell culture processing only, and is not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative. CryoMACS DMSO is manufactured and tested under a quality system certified to ISO 13485 and is in compliance with relevant GMP guidelines. It is designed following the recommendations of USP <1043> on ancillary materials.

► [miltenyibiotec.com/cryomacs](https://www.miltenyibiotec.com/cryomacs)



Miltenyi Biotec

Miltenyi Biotec B.V. & Co. KG

Friedrich-Ebert-Straße 68 | 51429 Bergisch Gladbach | Germany

Phone +49 2204 8306-0 | Fax +49 2204 85197

macsde@miltenyi.com | www.miltenyibiotec.com

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