CliniMACS® Formulation Set CR/GMP

REF 200-073-626

Miltenyi Biotec

CAUTION:

The product as part of the MACS GMP family is for *ex vivo* cell processing only and it is Limited by Federal (or United States) Law to Investigational Use or under an FDA Approval. The product is not intended for human *in vivo* applications.

Contents

QTY One CliniMACS Formulation Set CR/GMP

Intended purpose

The CliniMACS Formulation Set is intended to enable the *in vitro* formulation, sampling and further storage of cell populations within the CliniMACS Prodigy Cell and Gene Manufacturing System for clinical applications.

Side effects

Side-effects have not been reported.

Limitation

Miltenyi Biotec as the manufacturer of the CliniMACS System does not give any recommendations regarding the use of the separated cells.

Disclaimer

CR/GMP products are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.

Quality Statement

CR/GMP products are designed, manufactured and tested under an ISO 13485 quality management system and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

Precautions

The corresponding instructions provided by Miltenyi Biotec must be followed.

Aseptic working procedures must be applied for the unpacking, assembly, and use of the product.

After installation of the product, check all luer connections for tightness. If necessary, retighten the luer connections.

Before human applications, the suitability of stored target cells must be demonstrated regarding indication, quality and quantity.

Further processing and use for clinical applications must be in accordance with national legislations or with FDA investigational use regulations. Any clinical application of the separated or otherwise processed cells is exclusively within the responsibility of the user of a CliniMACS Prodigy System.

The processing of cells using this product must be performed by trained operators only.

All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious materials must be observed.

Any use of disinfectants on the product is exclusively within the responsibility of the user and risks must be assessed within the user's own risk management.

Warnings

Do not use after the use-by date printed on the product label.

Do not use the product if package is damaged. Before opening, inspect the packaging for damage, punctures, or tears. Use the product only if package is undamaged and sealed.

Do not use if the product is damaged. Do not use if any leakage of the product or its connection is observed during processing.

Do not connect the product directly to the patient.

Do not re-use. The re-use of the product or its parts leads to the endangerment of the patient due to biological contamination and inefficient performance.

Use only the provided labeling pouch for identification of contents.

Use only permanent sealing for tubing closure.

Administer DMSO only at a concentration up to 22.5% (w/w) to the bag. DMSO can cause degradation of plastic materials.

Storage

+15 °C +30 °C The product must be stored at room temperature (+15 °C to +30 °C [+59 °F to +86 °F]).

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Further information

STERILE R The product has been sterilized using irradiation.

Single sterile barrier system inside protective packaging.

The product contains a non-pyrogenic, sterile fluid path.

Performance

The performance of the product depends on the application and chosen user-specific filling process. For information on the capacity of the different applications, refer to the instructions provided by Miltenyi Biotec.

The CliniMACS Formulation Set contains 4×500 mL bags, 1×250 mL bag, 4×50 mL bags as primary containment as well as two overwraps for 50 mL bags and four overwraps for 500 mL bags as secondary containment.

Recommended fill volume:

• For fresh products up to 50 mL per 50 mL bag, up to 250 mL product for 250 mL bag and 500 mL for 500 mL bag.

• For frozen product 10-30 mL per 50 mL bag, 30-70 mL for 250 mL bag and 55-100 mL for 500 mL bag.

The optimal fill volume and storage conditions must be validated by the user. For cryopreservation, the fill volume recommendations are based on freezing in a horizontal position with the use of a protective metal cassette with an internal thickness of 4 mm.

Handling instructions

1. Unpacking

Open packaging of CliniMACS Formulation Set.

2. Connection of CliniMACS Formulation Set to a CliniMACS Prodigy Tubing Set

The CliniMACS Formulation Set has to be connected to a CliniMACS Prodigy Tubing Set via Luer Lock connection or sterile connection using a sterile tube welder. Consult the instructions for use supplied by the manufacturer of the sterile welding device.

Note: The CliniMACS Formulation Set needs to be connected to a CliniMACS Prodigy Tubing Set before installation on the devices (CliniMACS Prodigy and CliniMACS Formulation Unit) and start of the process. The tube including a filter (pore size 64 µm) on the right side of the CliniMACS Formulation Set is used for connection to a CliniMACS Prodigy Tubing Set (see Figure 1, connection tube). The use of the filter is optional.

Note: The CliniMACS Prodigy Tubing Set can be connected below or above the 64 µm filter of the connection tube of the CliniMACS Formulation Set (see Figure 1, connection sites).

By using the connection site below the 64 µm filter, the filter is removed from the resulting fluid path. When connecting above the 64 µm filter, the filter is included in the resulting fluid path. The connection site on the CliniMACS Prodigy Tubing Set depends on the type of set used for the respective process. Please refer to the instructions for the process provided by Miltenyi Biotec.

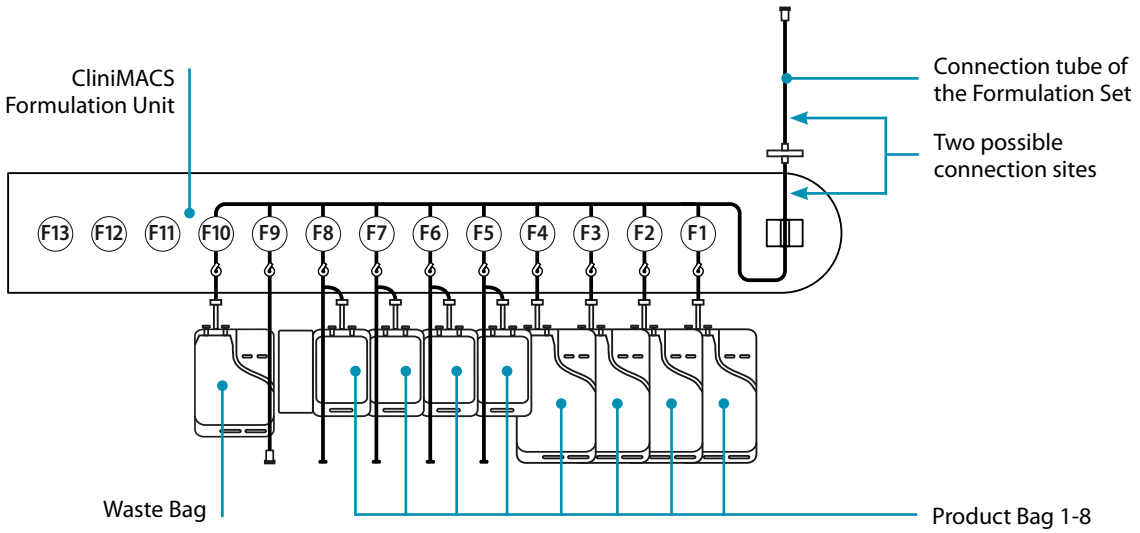


Figure 1: CliniMACS Formulation Set (installed on CliniMACS Formulation Unit)

3. Installation

The CliniMACS Formulation Set needs to be installed on the CliniMACS Formulation Unit. Follow the instructions provided by Miltenyi Biotec for installation, check of the CliniMACS Formulation Set and further handling.

Note: After installation on the CliniMACS Formulation Unit, all clamps of the CliniMACS Formulation Set have to be open before starting the formulation process.

If no CliniMACS Formulation Unit is used, place the connected CliniMACS Formulation Set in front of the CliniMACS Prodigy and follow the instructions provided by Miltenyi Biotec for further handling.

The bags below valves F1 to F8 are used as product bags, quality control (QC) bags, or retain bags respectively. The usage depends on the respective process.

Bags with the following nominal fill volumes are available: 4×500 mL and 4×50 mL. The 50 mL bags are additionally equipped with a tubing and a luer connector to facilitate the removal of samples using a syringe. The tubing below valve F9 is suitable for connection of cryopreservation solution. The 250 mL bag below valve F10 is used for the collection of waste fluids during the formulation process

4. Final handling

After the formulation process is finished, follow the instructions provided by Miltenyi Biotec for final handling of the CliniMACS Formulation Set.

5. Labeling

Place an identification tag into the label pocket of the bag and spot seal intermittently along the edge. Do not seal the pocket completely.

6. Fluid transfer (out)

Follow aseptic working procedures. Completely dry the bag surface, twist off the top part of one of the spike ports and carefully access the bag contents by puncturing the port seal with the spike of a sterile transfusion assembly.

The customer has to decide, what storage condition is to be applied. In case of frozen storage down to -196 °C (-321 °F), please follow the subsequent instructions for proper handling.

7. Freezing

Carefully remove any residual air from the bags after filling and close the bag by sealing the tubing. Test the seal integrity and remove the bag distal to the seal. Ensure during this procedure that all surfaces of the bags and the cassette are completely dry before freezing because ice particles on the surface may damage the bags. Place the bag into an overwrap bag and vacuum seal. Place the doubled bag into a protective metal cassette. Avoid bending, folding, or kinking of the bag when closing the cassette. Use of a controlled rate freezer is recommended.

8. Storage

Storage should be performed in the vapor phase of liquid nitrogen. Temperature fluctuations during storage should be avoided.

9. Thawing

If the bag is stored in the liquid phase of nitrogen, place the bag into the vapor phase of nitrogen for a minimum of 4 hours before removal from the nitrogen tank and thawing. Remove the bag with its overwrap from the cassette and inspect for leaks or ruptures before thawing in a water bath at +37 °C (+99 °F). Entry of air or nitrogen into the bag during storage may cause rapid expansion and subsequent bursting of the bag during rewarming.

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