CliniMACS Prodigy® Tubing Set 621 CR/GMP

REF 200-073-619

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 Prodigy Tubing Set CR/GMP

Intended purpose

The tubing set is intended for *in vitro* processing and cultivation of human cells from heterogeneous cell populations in combination with the CliniMACS Prodigy System.

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 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 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 material 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

Use the product only in combination with the CliniMACS Prodigy equipped with a CliniMACS Formulation Unit.

The CliniMACS Prodigy TS 621 CR/GMP contains a large CentriCult™ Chamber requiring a specific drive shaft. Ensure the drive shaft is installed by Miltenyi Biotec Instrument Service before using the product. Any CliniMACS Prodigy with the SN 490 or lower needs the installation of the new drive shaft.

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 is observed during priming and separation.

Do not connect the product directly to the patient.

Do not store blood, blood fractions, or cell fractions in the product. For the storage of cell fractions in the Product Bags, it is the responsibility of the user to define and verify the appropriate storage conditions.

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.

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

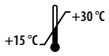
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210-004-080/02 | Issued: 2025-03 | Page 1/2

Storage



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

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 chosen application. For information on the capacity of the different applications, refer to the corresponding instructions provided by Miltenyi Biotec.

Instructions for use

The use and installation of the product to be used for a specific separation process are described in the corresponding instructions by Miltenyi Biotec for the respective application as applicable.

Refer to the corresponding instructions by Miltenyi Biotec of the corresponding application for the validated combinations of instrument, separation programs, reagents, tubing sets, and buffer.

The product is equipped with a mounting sheet and an additional information (“Installation aid”) is enclosed showing the fluid path of the tubing set.

Carefully remove residual air from the Product Bags, if applicable.

After filling, close the Product Bags by sealing. Test the seal integrity and remove the tubing distal to the seal.

Ensure, if sealing procedures are performed on ethyl vinyl acetate (EVA) material, to adjust dielectric or radio frequency (RF) sealing procedures accordingly, when using sealers other than MACS® TubeSealer.

Freezing: Ensure during this procedure that all surfaces of the Product Bags and the cassette are completely dry before freezing, because ice particles on the surface may damage the Product Bags. Place the Product Bags into the Overwraps and vacuum seal. Place the doubled bag into a protective metal cassette. Avoid bending, folding, or kinks of the Product Bags when closing the cassette. Seal off the tubing proximal to the Product Bags before freezing. Use of a controlled rate freezer is recommended.



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

Thawing: If the Product Bag is stored in the liquid phase of nitrogen, place the Product Bag into the vapor phase of nitrogen for a minimum of 4 hours before removal from the nitrogen tank and thawing. Remove the Product 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 Product Bag during storage may cause rapid expansion and subsequent bursting of the bag during rewarming.

Fluid transfer (out): Completely dry the Product Bag surface, remove the overwrap, twist off the top part of one of the spike ports and carefully access the Product Bag contents by puncturing the port seal with the spike of a sterile transfusion assembly.

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