CliniMACS Prodigy® Tubing Sets CR/GMP

CliniMACS Prodigy TS 710 CR/GMP	REF 200-073-621
CliniMACS Prodigy TS 720 CR/GMP	REF 200-073-622
CliniMACS Prodigy TS 730 CR/GMP	REF 200-073-623

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 non-magnetic processing of cells from heterogeneous cell populations in combination with the CliniMACS Prodigy, and if applicable, other components of 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

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.

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.

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 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 depend on the separation program and the amount of cells to be separated and are described in the CliniMACS Prodigy User Manuals.

Refer to the corresonding 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 product.

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