CliniMACS Prodigy® Tubing Sets CR/GMP

CliniMACS Prodigy TS 310 CR/GMP	REF 200-073-610
CliniMACS Prodigy TS 500 CR/GMP	REF 200-073-609
CliniMACS Prodigy TS 510 CR/GMP	REF 200-073-611

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* pre-separation or other processing of human cells from heterogeneous cell populations in combination with the CliniMACS Prodigy System only, enabling further cultivation and/or genetic modification of the cells.

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 users 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. For storage of cell fractions in the Target Cell Bag of the CliniMACS Prodigy TS 500 CR/GMP, 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.

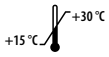
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Storage



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

Further information



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 CliniMACS Prodigy TS 310 CR/GMP and TS 500 CR/GMP are each equipped with a mounting sheet, which delineates the fluid path of their corresponding product by dotted lines which are engraved into the sheet. These lines assist the correct installation and positioning of the tubing into the corresponding valves. The CliniMACS Prodigy TS 510 CR/GMP is equipped with a mounting sheet, which does not contain such dotted lines. Additional information ("Installation aid") is added to the packaging of the CliniMACS Prodigy TS 310 CR/GMP and TS 510 CR/GMP showing the fluid path of the product.

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