CliniMACS® Tubing Sets CR/GMP

CliniMACS Tubing Set TS CR/GMP	REF 220-001-888 (165-01)
CliniMACS Tubing Set LS CR/GMP	REF 200-073-203 (168-01)
CliniMACS Depletion Tubing Set CR/GMP	REF 220-001-885 (266-01)

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® Tubing Set

Intended purpose

The tubing set is intended for *in vitro* pre-separation or processing of human cells from heterogeneous cell populations in combination with the CliniMACS Plus System only.

Limitations

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

Side effects

Side effects have not been reported.

Precautions

The instructions for use including those described in the corresponding CliniMACS Plus User Manuals must be followed.

Further processing and use in clinical applications must be in accordance with national legislation and regulations. In the U.S., the FDA investigational use regulations must be observed.

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.

For the manufacturing and use of target cells national legislations and regulations must be observed.

Any clinical application of the separated or otherwise processed cells is exclusively within the responsibility of the user.

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.

For additional safety, the integrity test must be performed as described in the CliniMACS Plus User Manuals. If the CliniMACS Plus Instrument is equipped with software version 2.2x, contact the Miltenyi Biotec Instrument Service for further Information.

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 if package is damaged. Before opening, inspect the packaging for damage, punctures, or tears. Use the product only if the package is undamaged and sealed.

Do not use if the product is damaged. Do not use if any leakages of the product are observed during priming or 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 cell separation.

Storage

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

Further information

STERILE EO The product is sterilized with ethylene oxide.

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

The depicted symbol indicates the single sterile barrier of the product with protective packaging outside.

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Performance

The performance of the product depends on the chosen CliniMACS Plus Separation. For information on the capacity of the different applications, refer to the CliniMACS Plus User Manuals.

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 Plus User Manuals.

The CliniMACS Depletion Tubing Set CR/GMP requires software version 2.4x or higher.

Refer to the CliniMACS Plus User Manuals for the validated combinations of instrument, separation programs, reagents, tubing sets, and buffer.

Regulatory and legal notes

Disclaimer & Quality Statement

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

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.