



Miltenyi Biotec

# CliniMACS® Tubing Sets

CliniMACS Tubing Set

REF 170-076-650 (165-01)

CliniMACS Tubing Set LS

REF 170-076-651 (168-01)

CliniMACS Depletion Tubing Set

REF 170-076-652 (266-01)

## CAUTION:

The CliniMACS Tubing Sets are for *ex vivo* cell processing only, and are not intended for human *in vivo* applications.

## Contents

**QTY** One CliniMACS Tubing Set or one CliniMACS Tubing Set LS or one CliniMACS Depletion 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.

## Limitation

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


## Disclaimer

The CliniMACS Tubing sets are for *ex vivo* cell processing only and are not intended for human *in vivo* applications. For regulatory status in the USA, contact your local representative.

## Quality Statement

The CliniMACS Tubing Sets are manufactured and tested under a quality management system (ISO 13485) and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials.

## Precautions

 The corresponding CliniMACS Plus user manual must be observed.

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

After installation of the tubing set check all luer connections for tightness. If necessary retighten the luer connections.

For the manufacturing and use of target cells in humans the national legislation and regulations must be observed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS System.

The processing of cells using the tubing set must be performed by trained operators only.

All materials that have been in contact with blood or blood components must be treated and disposed as biohazardous materials. Therefore, standard hospital or institutional requirements and national legislations must be observed.

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

## 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 package is undamaged and sealed.

Do not use if the tubing set is damaged. Do not use, if any leakage of the product is observed during priming and separation.

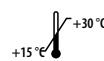
Do not connect the tubing set directly to the patient.

Do not store blood, blood fractions, or cell fractions in the tubing set.



Do not re-use. The re-use of the tubing sets or parts of them leads to the endangerment of the patient due to biological contamination or to inefficient cell separation.

## Storage



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

## Further information



The tubing set is sterilized with ethylene oxide.



The tubing set contains a non-pyrogenic, sterile fluid path.



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## Performance

The performance of the tubing set depends on the chosen CliniMACS Plus Separation. For information on the capacity of the different applications, refer to the CliniMACS Plus user manual.

## Instructions for use



The use and installation of the tubing set depend on the separation program and the amount of cells to be separated and are described in the CliniMACS Plus user manual.

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

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