Miltenyi Biotec

CliniMACS® Accessories CR/GMP

Transfer Set Coupler/Coupler CR/GMP REF 220-001-899

Luer/Spike Interconnector CR/GMP REF 220-001-897

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 box contains:

Five Transfer Set Coupler/Couplers CR/GMP or
Five Luer/Spike Interconnectors CR/GMP

Intended purpose

The Transfer Set Coupler/Coupler CR/GMP is intended for interconnecting different containers or for connecting containers with the CliniMACS Tubing Sets or the CliniMACS Prodigy Tubing Sets to channel solutions or human cell suspensions to assist the enrichment or depletion of human cells with a CliniMACS System only, enabling further cultivation and/or genetic modification of the cells.

The Luer/Spike Interconnector CR/GMP is intended for interconnecting different containers or for connecting containers with the CliniMACS Tubing Sets or the CliniMACS Prodigy Tubing Sets to channel solutions or human cell suspensions or for sample collection to assist the enrichment or depletion of human cells with a CliniMACS 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.

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 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 components must be treated as infectious material. Regulations for the treatment of infectious materials 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 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 performance.

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

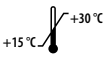
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Storage



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



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

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