CliniMACS® Electroporation Buffer

REF 170-076-625

The CliniMACS Electroporation Buffer is for *ex vivo* cell processing only and is not intended for human *in vivo* applications.

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Contents	One bag contains 500 mL CliniMACS Electroporation Buffer.
Intended purpose	The CliniMACS Electroporation Buffer is an ancillary material intended to be used as a electroporation buffer that allows short term storage of cells or nucleic acids (RNA, DNA) and facilitates electroporation of eukaryotic cells. The CliniMACS Electroporation buffer is intended to be used to prepare cells *ex vivo* prior to the electroporation and to supply the nucleic acids. The CliniMACS Electroporation Buffer is intended for *ex vivo* use only and not for direct infusion into patients. It is intended to be used by trained operators. The CliniMACS Electroporation Buffer does not address the suitability of the cells for the final therapeutic goal or directly address the therapeutic benefit of the target cells.
Limitation	Miltenyi Biotec as the manufacturer of the CliniMACS System does not provide any recommendations regarding the use of the manufactured cells for therapeutic purposes and does not make any claim regarding a clinical benefit.
Disclaimer	The CliniMACS Electroporation Buffer is for *ex vivo* cell processing only and is not intended for human *in vivo* applications. For regulatory status in the USA, contact the local representative. The CliniMACS Electroporation Buffer is intended to be used by trained operators only.
Quality statement	The CliniMACS Electroporation Buffer is manufactured and tested under a quality management system (ISO 13485) and is in compliance with relevant GMP guidelines. It is designed following the recommendations of USP <1043> on ancillary materials. The declaration of animal- or human-derived materials is given on the Certificate of Origin.
Precautions	For the manufacturing and use of genetically modified target cells in humans the national legislation and regulations must be followed. Thus, any clinical application of the genetically modified target cells is exclusively within the responsibility of the user of a CliniMACS System. In particular, genetic modification of cells, handling and any clinical application of genetically modified target cells must be performed in compliance with legislation regarding genetic engineering work, biological safety containment levels, and environmental risk assessment. All materials which have come into contact with blood and blood products must be treated as infectious material. Regulations for the treatment of infectious materials must be observed. The corresponding CliniMACS Prodigy® User Manuals must be followed. The processing of cells using the product must be performed by trained operators only. Aseptic working procedures must be applied for the unpacking, assembly, and use of the product. Ensure application of RNAse- and DNAse-free components to the system.
Warnings	Do not use after the use-by date indicated on the product label. Do not use if package is damaged. Before opening, inspect the packaging for damages, punctures, or tears. Use the product only if package is undamaged and sealed. Do not use if precipitation is observed in the product. Do not use if any leakage of the product is observed during priming, separation, and/or electroporation. Do not connect the product directly to the patient. Not for parenteral use. Not for infusion. Do not re-use, the product is only for one process.
Storage	The CliniMACS Electroporation Buffer must be stored at room temperature. Do not freeze.
Further information	The CliniMACS Electroporation Buffer is 0.1 µm filtered.
Performance	The performance of product depends on the chosen process. For information on the capacity of the different applications, refer to the corresponding CliniMACS Prodigy User Manual. The performance of the system relies on usage of components free of RNAse and DNAse. This product is tested to be free of RNAse and DNAse after 1 hour at +37 °C.
Instructions for use	The use and installation of the product is described in the CliniMACS Prodigy User Manual for the respective application. Refer to the corresponding CliniMACS Prodigy User Manual for the validated combinations of CliniMACS Reagents, application processes, tubing sets, and buffers/media. This document and corresponding information can be found under **www.miltenyibiotec.com/170-076-625**.

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