

CliniMACS Prodigy® EP-2/CliniMACS Prodigy EP-4

CliniMACS Prodigy EP-2 REF 200-073-624

CliniMACS Prodigy EP-4 REF 200-073-625

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.



Miltenyi Biotec B.V. & Co. KG

Friedrich-Ebert-Straße 68

51429 Bergisch Gladbach

Germany

☎ +49 2204 8306-3803




For U.S. distributed by:

Miltenyi Biotec Inc.

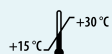
2303 Lindbergh Street

Auburn, CA 95602

USA

Contents	
QTY	One CliniMACS Prodigy EP-2 or one CliniMACS Prodigy EP-4
Intended purpose	The CliniMACS Prodigy EP-2 and the CliniMACS Prodigy EP-4 are intended for <i>in vitro</i> electroporation of human cells in combination with the CliniMACS Prodigy System only.
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	The CliniMACS Prodigy EP-2 and EP-4 are for research use and <i>ex vivo</i> cell culture processing only, and are not intended for human <i>in vivo</i> applications. For regulatory Status in the U.S., contact your local representative. In the U.S. for use in patients the products can only be used under IND/IDE or FDA approval.
Quality Statement	The CliniMACS Prodigy EP-2 and EP-4 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	<p>The corresponding instructions by Miltenyi Biotec must be followed.</p> <p>Aseptic working procedures must be applied for the unpacking, assembly, and use of the tubing set.</p> <p>After installation of the product check all luer connections for tightness. If necessary retighten the luer connections.</p> <p>Before human applications, the suitability of target cells must be demonstrated regarding indication, quality and quantity.</p> <p>The manufacturing and use of genetically modified target cells for clinical applications must be in accordance with national legislations or with FDA investigational use regulations. Any clinical application of the genetically modified target cells is exclusively within the responsibility of the user of a CliniMACS Prodigy 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 environment risk assessment.</p> <p>The separation or other processing of cells using the product must be performed by trained operators only.</p> <p>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.</p>
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, separation, and/or electroporation.
	Do not connect product set directly to the patient.
	Do not store blood, blood fractions, and/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 to inefficient performance.

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.



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 by Miltenyi Biotec.

Instructions for use



The use and installation of the product, to be used for a specific separation and/or electroporation process, is described in the corresponding instructions by Miltenyi Biotec for the respective application.

Refer to the corresponding instructions by Miltenyi Biotec for the validated combinations of CliniMACS Reagents, separation programs, tubing sets, and buffers/media.

The product is equipped with additional information ("Installation Aid") showing the fluid path of the product installed to the electroporator.