



Miltenyi Biotec

CytoGenics  
life science innovation



# The CliniMACS Prodigy®

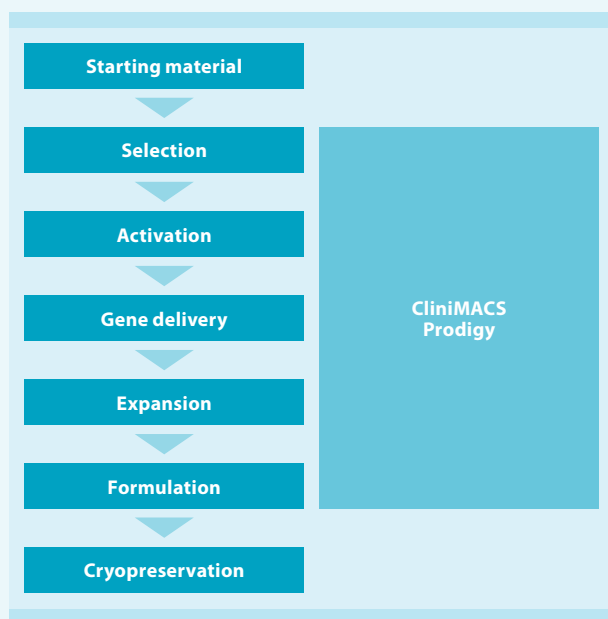
## Mastering the complexity of cell processing

- A single closed system from starting material to final cellular product
- Full automation of complex procedures, including manufacturing of gene-engineered T cells
- Integrated electroporation system for non-viral gene delivery
- Multiple sampling pouches for convenient IPC/QC

► [miltenyibiotec.com](http://miltenyibiotec.com)

The promise of cell and gene therapy is great, but not without its challenges. Complex processes, such as CAR T cell manufacturing, often require multiple steps that are performed across several devices. With the introduction of hands-on manipulations like cell transfer between vessels, the risk of contamination, human error, and cell loss increases.

The CliniMACS Prodigy® automates cell processing from starting material to final cellular product in a single benchtop instrument. All major cell manufacturing steps are automated and standardized for increased reproducibility in a closed system to enable the production of GMP-compliant cell products.



**Figure 1:** The CliniMACS Prodigy TCT Process for the manufacturing of gene-engineered T cells integrates and automates critical steps of the procedure.



**Figure 2:** Critical steps in the cell manufacturing process, including electroporation, are performed in the closed system of the CliniMACS Prodigy.

A variety of cell manufacturing procedures are made possible by the CliniMACS Prodigy, including:

- **Automated generation of CAR T cells**
  - Verified workflow with MACS® GMP Products
  - Enrichment step for the generation of CD4<sup>+</sup>/CD8<sup>+</sup> or CD62L<sup>+</sup> cells
  - Easy sample collection for IPC/QC
- **Ex vivo GMP-compliant antigen loading of DCs**
- **Automated manufacturing of antigen-specific T cells**
- **Custom processes**
  - Density gradient centrifugation
  - Volume reduction
  - Buffer exchange
  - Selection and cultivation of hematopoietic stem cells and induced pluripotent stem cells

The CliniMACS Prodigy also enables the translation of individual cell product manufacturing procedures into automated GMP-compliant processes through Miltenyi Biotec's customized programming service.

**Ask your local Miltenyi Biotec representative for more information or visit [miltenyibiotec.com/prodigy](http://miltenyibiotec.com/prodigy)**



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In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. The CliniMACS Reagents and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients. The CliniMACS Reagents in combination with the CliniMACS System are intended to separate human cells. Miltenyi Biotec as the manufacturer of the CliniMACS System does not give any recommendations regarding the use of separated cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of target cells in humans the national legislation and regulations – e.g. for the EU the Directive 2004/23/EC ("human tissues and cells"), or the Directive 2002/98/EC ("human blood and blood components") – must be followed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS System.

In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Sets TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. Other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or FDA approval. CliniMACS GMP MicroBeads are for research use and *ex vivo* cell processing only. CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use. CliniMACS, CliniMACS Prodigy, MACS, and the Miltenyi Biotec logo are registered trademarks or trademarks of Miltenyi Biotec and/or its affiliates in various countries worldwide. Copyright © 2021 Miltenyi Biotec and/or its affiliates. All rights reserved.