

Customized Application Service

Your partner in mastering automated cell manufacturing

- Taking advantage of tailor-made solutions on the CliniMACS Prodigy®
- Conversion from manual processes into an automated closed system
- Move your cell process towards preclinical and clinical studies
- Comprehensive workflow, design control documentation provided

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The Customized Application Service

The diversity in cell manufacturing is continuously growing. On one side these processes are often complex and include manual or semi-automated steps across several devices. On the other side standardization and reproducibility are crucial to enable GMP compliant cell manufacturing.

The CliniMACS Prodigy® is a single benchtop instrument offering a variety of pre-installed, automated, and GMP supporting cell manufacturing procedures, like e.g., antigen specific T cell enrichment, the generation of CART cells or the differentiation of monocyte-derived dendritic cells. In cases, where these processes may not match the user requirements, Miltenyi Biotec offers the translation of individual cell product manufacturing processes into tailormade and automated GMP supporting procedures on the CliniMACS Prodigy®. Hence, our team of specialists configures and aligns predefined software modules following customer specifications. With this Customized Application (CAP) Service, you benefit from fully automated cell processing in a closed system with single-use disposables that may results in reduced cleanroom requirements, effective labor allocation and thus improved cost-time-effectiveness, and lift your cell manufacturing to the next level for clinical research.

Start to improve your cell process workflow today and contact your local Miltenyi Biotec representative or our global Customized Application Service:

E-mail: Application_Development@miltenyi.com

The CAP Service workflow



^{*} Major steps in the workflow are documented following design control standards



Figure 1: CliniMACS Prodigy® cell manufacturing.



Figure 2: CliniMACS 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

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