



**Miltenyi Biotec**

## A legacy of empowerment

Automate your cell separation with the  
CliniMACS® Plus Instrument

For more than two decades, scientists and clinicians have relied on the CliniMACS Plus Instrument for its ease of use and ability to automate clinical-scale immuno-magnetic cell separation. Easily enrich cells or deplete unwanted ones with the only closed and sterile system available for magnetic cell separation.

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



# Flexible cell therapy solutions

Whether it's enrichment of target cell populations or depletion of unwanted cells, the CliniMACS Plus Instrument delivers the flexibility you need for your cell therapy product development needs.

As one of the fastest-growing segments in life sciences, cell and gene therapies have led to life-altering discoveries and resulted in the development of treatments for a variety of diseases and conditions. The CliniMACS Plus Instrument's applications provide the ultimate flexibility for these critical processes.

A variety of strategies can be applied including:

- CD3/CD19 depletion
- CD4 and/or CD8 selection
- TCR $\alpha$ / $\beta$  depletion
- CD56 selection
- CD45RA depletion
- CD25 enrichment

The first step of any cell therapy manufacturing process involves isolating a target cell population (see fig. 4). The CliniMACS Plus Instrument plays an essential role in this initial phase since the device enables the isolation of high-quality cells for downstream manipulations.

Once the target cell population of interest has been obtained, the cells are ready for downstream manipulations. One can easily remove the collection bag from the CliniMACS Plus Instrument and transfer the cells to the next step in the cell manufacturing process. These steps are performed while maintaining the cells in a closed environment to ensure product sterility.

## Clinical expertise in cell therapy applications:

- 600 600+ supported INDs/IDEs in the USA
- 1000+ 1000+ clinical studies worldwide
- 30+ 30+ drug master files with the FDA
- 40 40 product dossiers in the EU

Please visit our website to learn more about how GMP-compliant cell isolation on the CliniMACS Plus Instrument allows for ultimate flexibility and unparalleled performance in providing the highest quality cells for downstream applications.

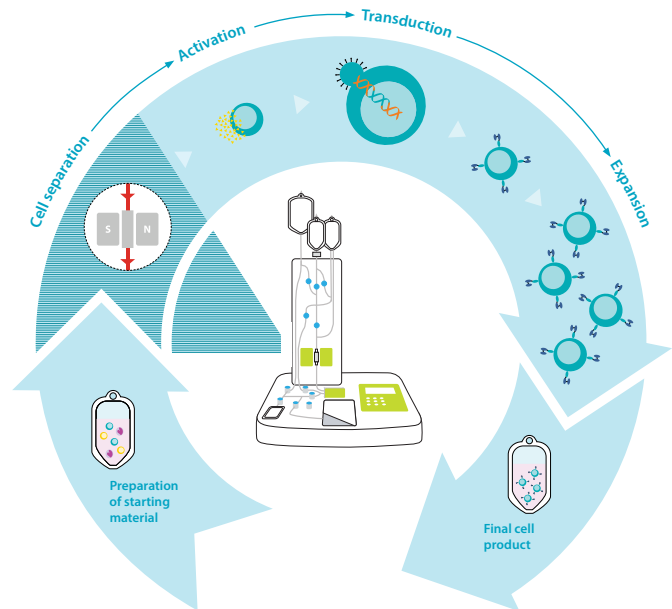


Figure 4: Cell manufacturing workflow

\*Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use.

## References

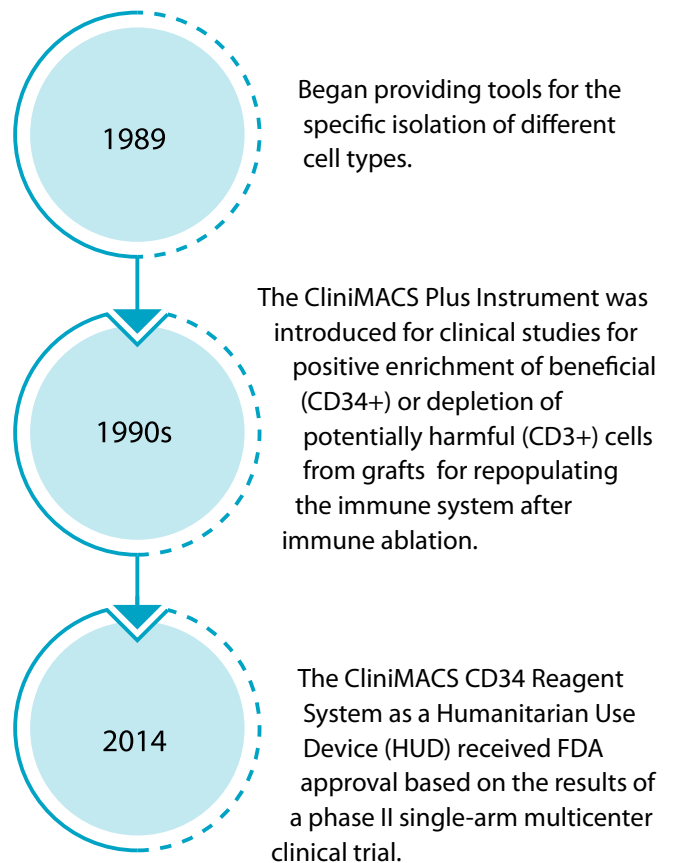
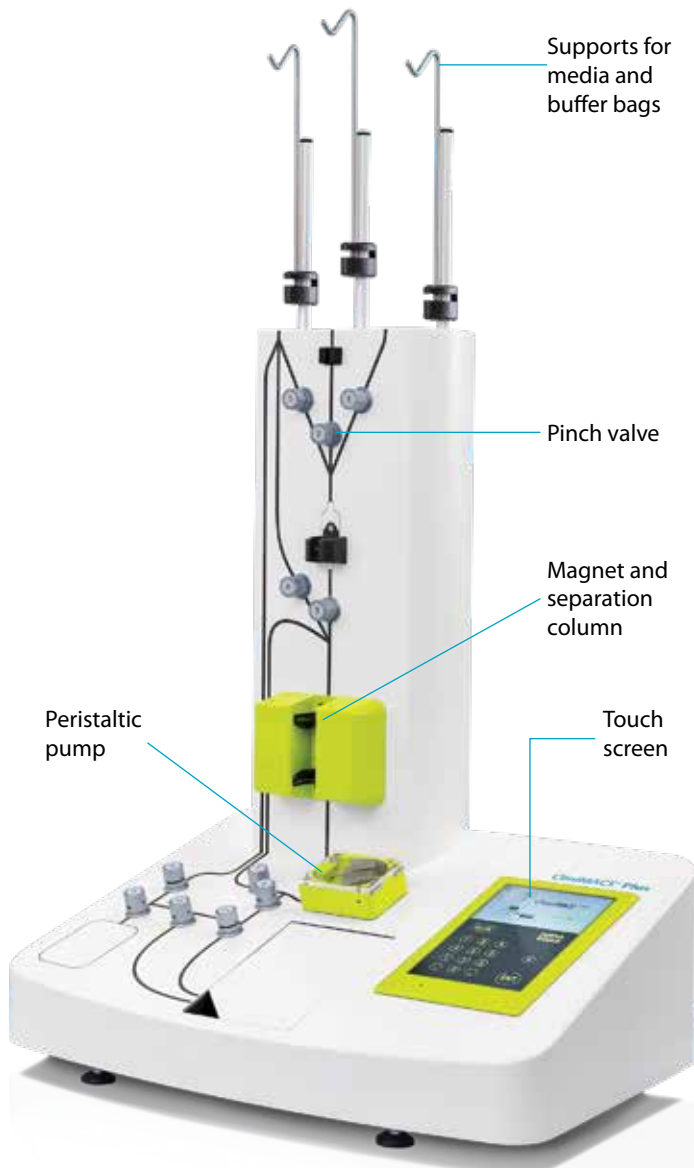
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2. Pasquini, *et al.* Comparative Outcomes of Donor Graft CD34 Selection and Immune Suppressive Therapy As Graft-Versus-Host Disease Prophylaxis for Patients With Acute Myeloid Leukemia in Complete Remission Undergoing HLA-Matched Sibling Allogeneic Hematopoietic Cell Transplantation. *J Clin Oncol* 2012 **30**:3194-3201.

# Cell separation experts for over 30 years

Physicians have counted on the CliniMACS Plus Instrument for automated magnetic cell separation in clinical trials since 1997\*.

Innovation has its rightful place in biotech but when it comes to the CliniMACS Plus Instrument, "legacy" is a more fitting description. This easy-to-use instrument has carved out its niche as the gold standard for automated magnetic cell separation.

Unlike inconsistent and costly manual cell enrichment, cell separation is simple with the CliniMACS Plus — a robust system that automates the enrichment of high-quality cells for downstream applications and efficiently enables the depletion of unwanted cells from cellular products.



Over the years, more than 65,000 patients have been treated with cellular products manufactured with the CliniMACS System, and new strategies addressing cellular therapy are continually being developed.

\*CE approval occurred in 1997 and the CliniMACS CD34 Reagent System gained HUD approval in 2014.

# Cell separation, simplified

The CliniMACS Plus Instrument's user-friendly applications are available for a variety of separations undergoing clinical testing.

The CliniMACS Plus Instrument may be used for the isolation of various types of cells such as hematopoietic stem cells, mesenchymal stem cells, monocytes, DCs, NK cells, B cells, and T cell subsets for investigational purposes. These applications are suitable for use in the fields of regenerative medicine, cell therapy, adoptive immunotherapy, and graft engineering.

Select from a range of application-specific tubing sets and reagents. CliniMACS consumables are provided with the documentation and support required for regulatory filings with governing bodies.

The CliniMACS Plus Instrument is:

- Versatile: A variety of cell separation strategies are available
- Compliant: Supports GMP manufacturing
- Easy to use: Automated cell separation ensures reproducibility
- Cost-efficient: Frees up technicians to focus on more complex tasks
- Manufactured in compliance with ISO 13485 and ISO 9001

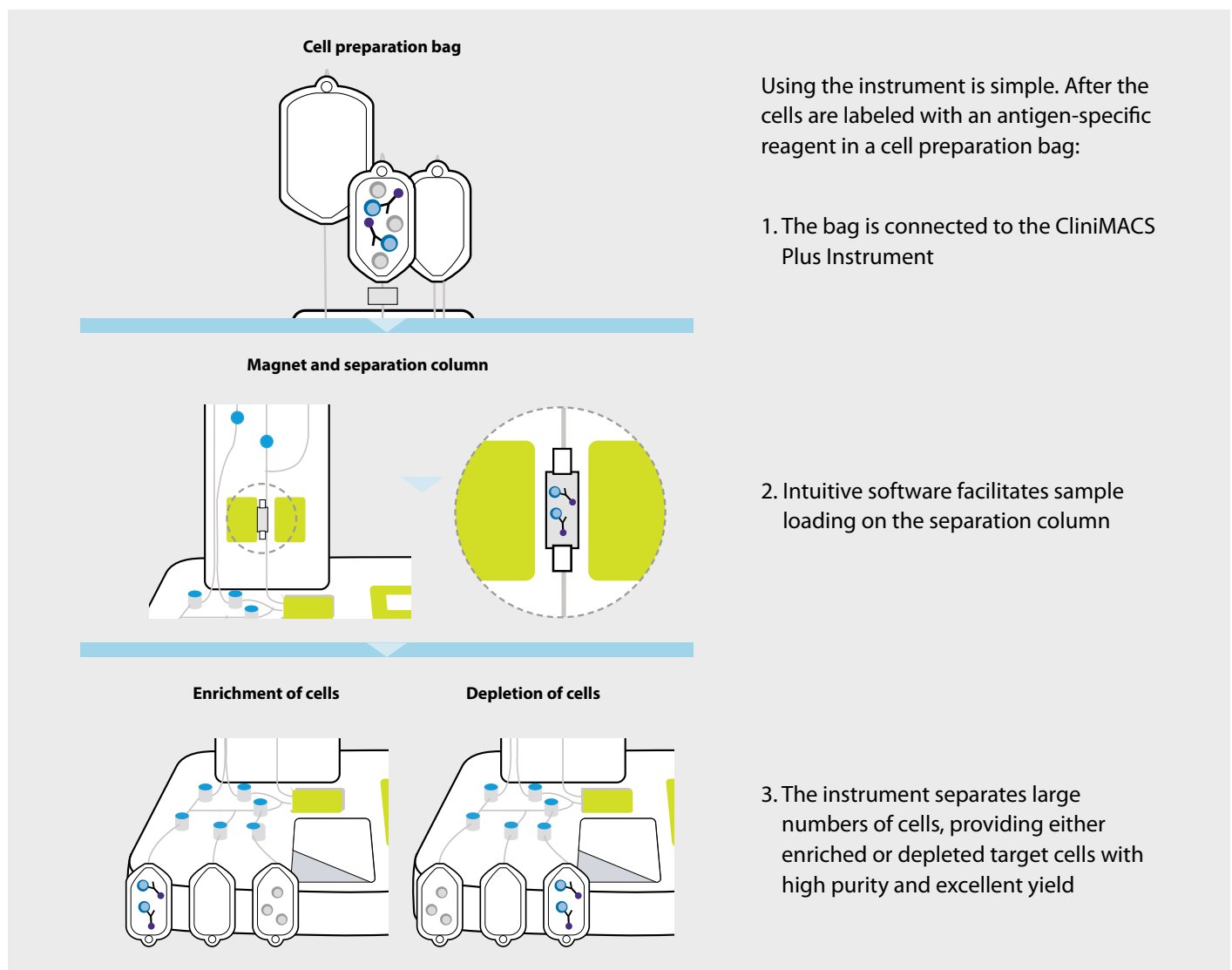


Figure 2: Workflow on the CliniMACS Plus Instrument

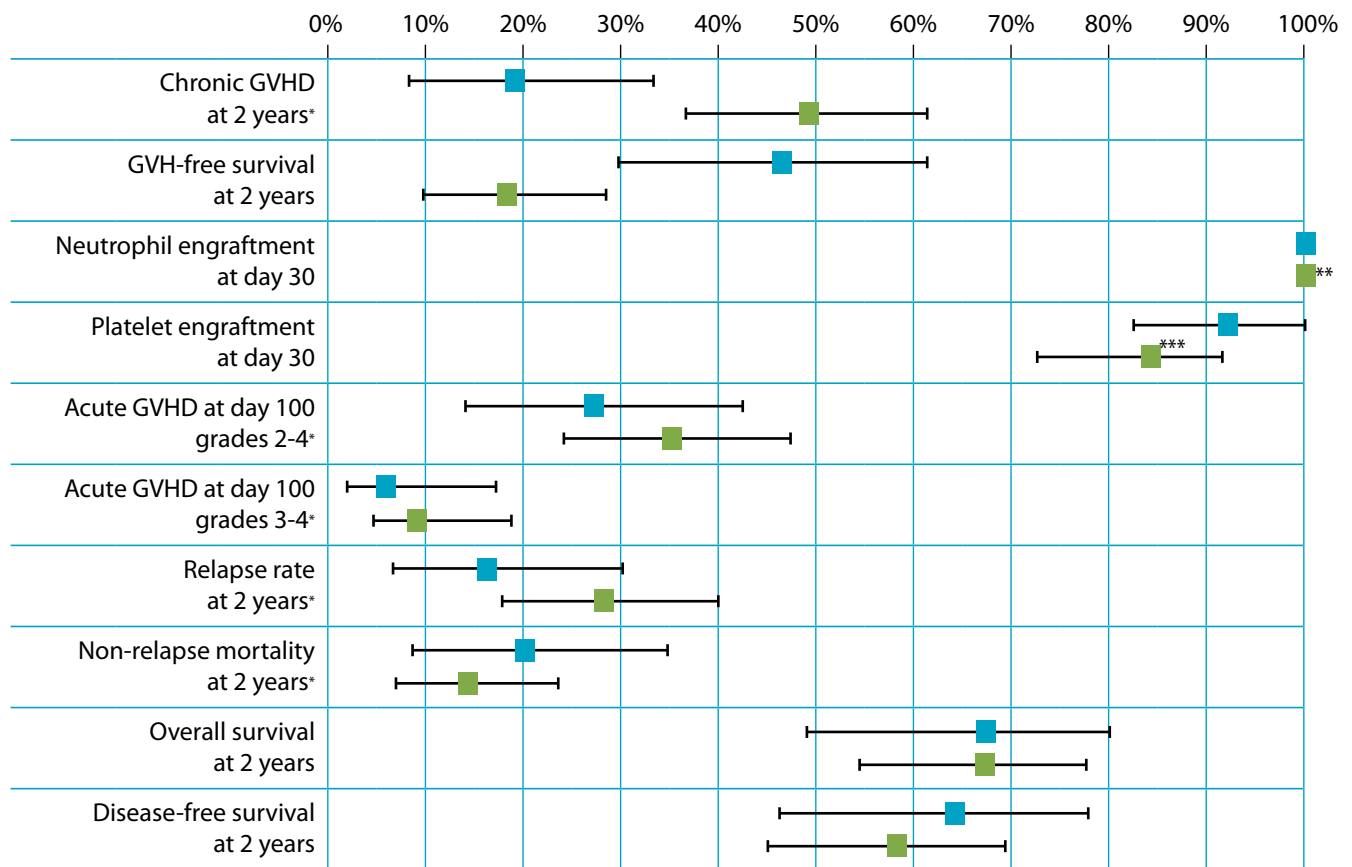
# FDA approved for HSCT

## Empower stem cell transplantation for your AML patients

While hematopoietic stem cell (HSC) transplantation is a well-founded therapeutic option for the treatment of a variety of hematologic malignancies and non-malignant diseases, it is also associated with severe side effects due to the potential immunogenicity of the graft. The automated CliniMACS Plus Instrument helps overcome some of these side effects by removing T cells, T cell subsets, B cells, and other unwanted cells from HSC grafts.

The CliniMACS Plus Instrument has provided consistent results for more than two decades. In the clinical study that led to the 2014 FDA approval of the CliniMACS CD34 Reagent System—which includes the CliniMACS Plus Instrument—it was shown that T cell depletion with the CliniMACS CD34 Reagent System resulted in a lower incidence of chronic graft-versus-host disease (GvHD) at two years (19%) and a high rate of GvHD-free survival at two years (46%).<sup>1</sup>

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.



■ Single-Arm CliniMACS CD34 Reagent System (n=37) ■ Historical controls using pharmacological immunosuppression (n=65)  
 — 95% CI \*Cumulative Incidence \*\*Neutrophil data missing for two patients \*\*\*Platelet data missing for one patient

Figure 3: Comparative analysis<sup>2</sup>



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