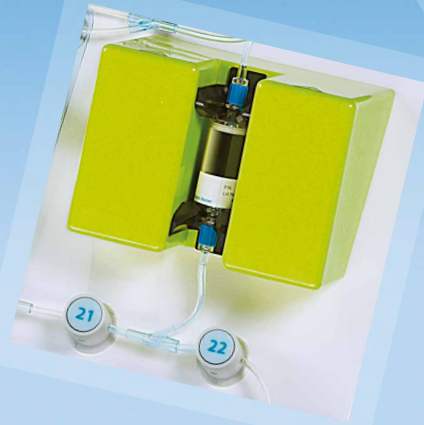




Miltenyi Biotec

CliniMACS Prodigy® Platform

Mastering the complexity of cell processing



The art of cellular product manufacturing

Dedicated, just like you

We are an inquisitive species. Our quest for knowledge leads us in many directions and the path can be surprisingly difficult. The CliniMACS Prodigy® is designed to smooth the journey; an instrument of excellence that enables you to pursue your goals.

Whether for cell manufacturing in a commercial or academic setting, the CliniMACS Prodigy Platform is the way forward.

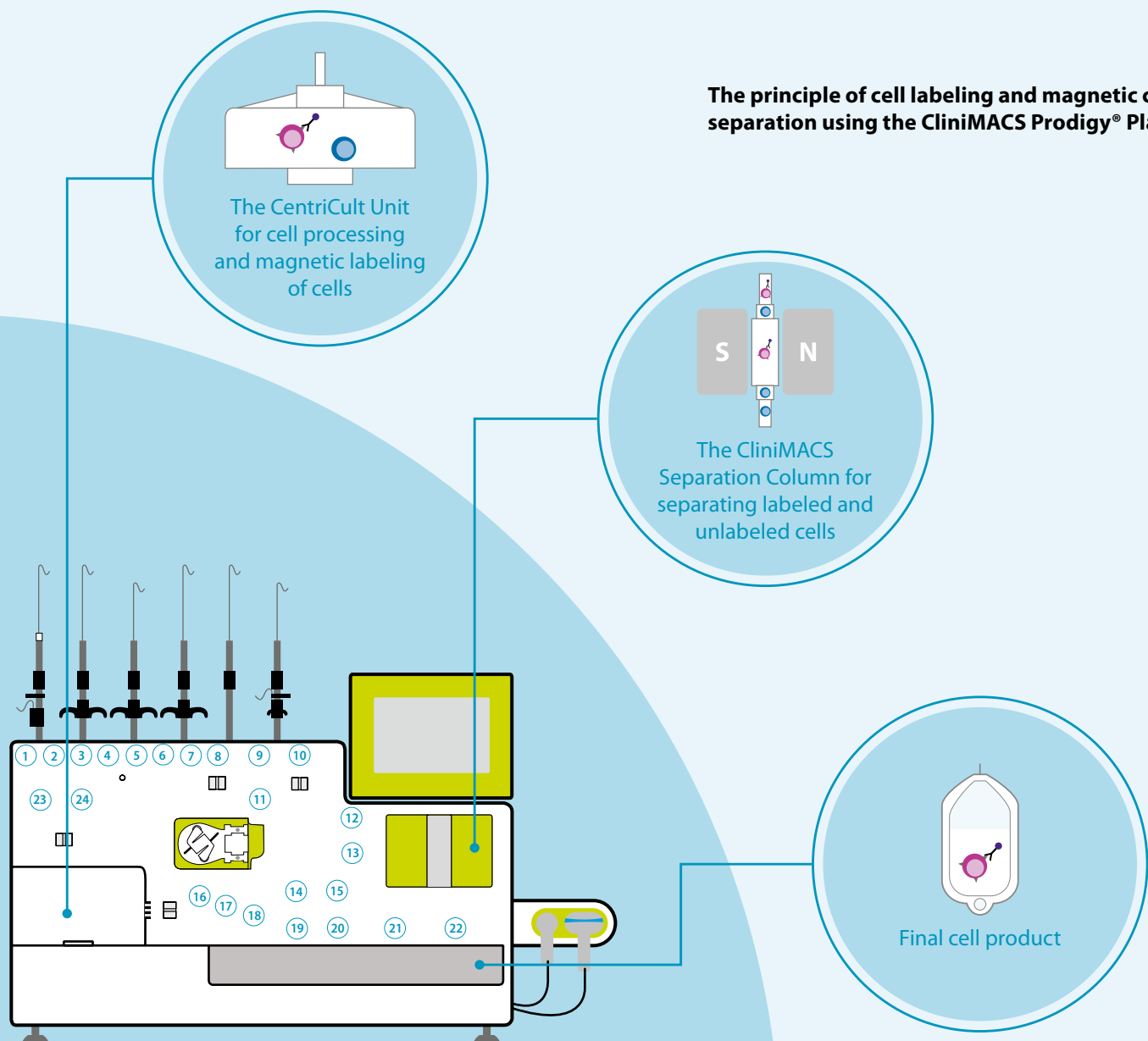




Like you, the
CliniMACS Prodigy® Platform
is committed to success.



Meeting your needs in cell product manufacturing





Moving cell manufacturing to the next level

Since its introduction in 1997, the CliniMACS® Cell Separation System has become a proven technology for the development and establishment of cell-based therapies.

Now, the new CliniMACS Prodigy® Platform provides advanced integrated solutions for streamlining cell-processing workflows: from cell separation, through cell culture, to formulation of the final product. With this flexible technology platform, **fully automated cell processing for innovative and complex cell manufacturing protocols becomes a reality.**

- **Standardization for easy access to complex procedures**
- **Reproducibility ensuring GMP-compliant cell products**
- **Cost-effectiveness through automated procedures and reduced cleanroom requirements**
- **Customization through modularity and flexible programming**



Standardization for easy access to complex procedures



Figure 1: CentriCult Unit with inserted CentriCult Chamber.

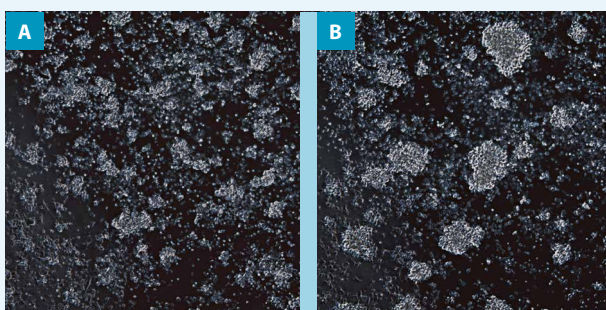


Figure 2: Activated T cells cultured in CentriCult Chamber at day 1 (A) and day 3 showing typical clustering of T cells (B). Magnification 400-fold.

The CliniMACS Prodigy® Platform is designed to automate and standardize complete cellular product manufacturing processes. It combines CliniMACS® Separation Technology with a wide range of sensor-controlled, cell processing capabilities.

- Innovative disposable CentriCult™ Chamber enabling standardized cell processing and cultivation
- Automated cell labeling with CliniMACS Reagents
- Cell enrichment and depletion capabilities, alone or combined
- Cell cultivation and cell expansion
- Final product formulation in pre-defined medium and volume



Reproducibility ensuring GMP-compliant cell products

To ensure reproducible manufacturing of high quality cell products, process development for the CliniMACS Prodigy® Platform is committed to the highest level of standardization. Thus, the need for skilled handling of several different appliances has been eliminated. This reduces operator-to-operator variability and handling errors.

- Fully-automated, sensor-controlled processes
- Integrated centrifugation with camera-controlled layer detection for cell washing, buffer exchange, and cell concentration
- Delivery of CliniMACS® Reagents, as well as MACS® GMP Reagents and Media, via sterile filters
- Integrated sampling pouches for QC samples

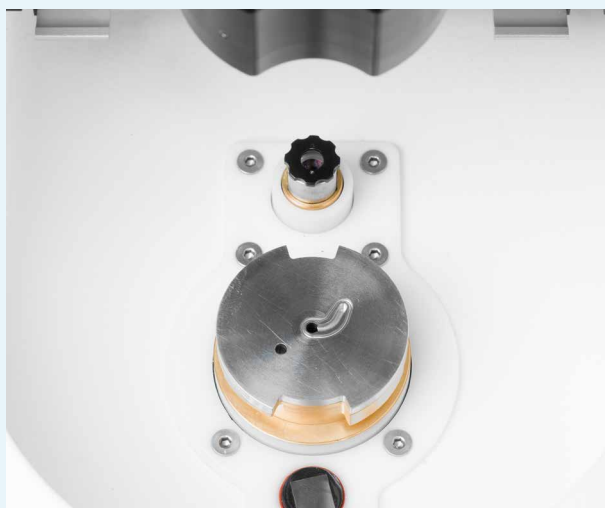


Figure 3: CentriCult™ Unit equipped with infrared sensor, chamber drive socket, microscope camera and Layer Detection Camera (from bottom to top).



Figure 4: Sterile connections to ensure GMP-compliant cell product manufacturing.



Cost-effectiveness through automated procedures and reduced cleanroom requirements



Figure 5: CliniMACS Prodigy Tubing Sets: dedicated to safety and simplicity in the laboratory.

The high level of automation provided by the CliniMACS Prodigy® Platform leads to substantially reduced hands-on time. This enables the individual operator to perform several procedures in parallel on multiple devices. Fewer manual processing steps and reduced cleanroom requirements are the key to cost-effective cell product manufacturing.

- Sterile connection procedures
- Dedicated, disposable tubing sets
- Closed system for product and operator safety
- Reduced cleanroom requirements



Customization through modularity and flexible programming

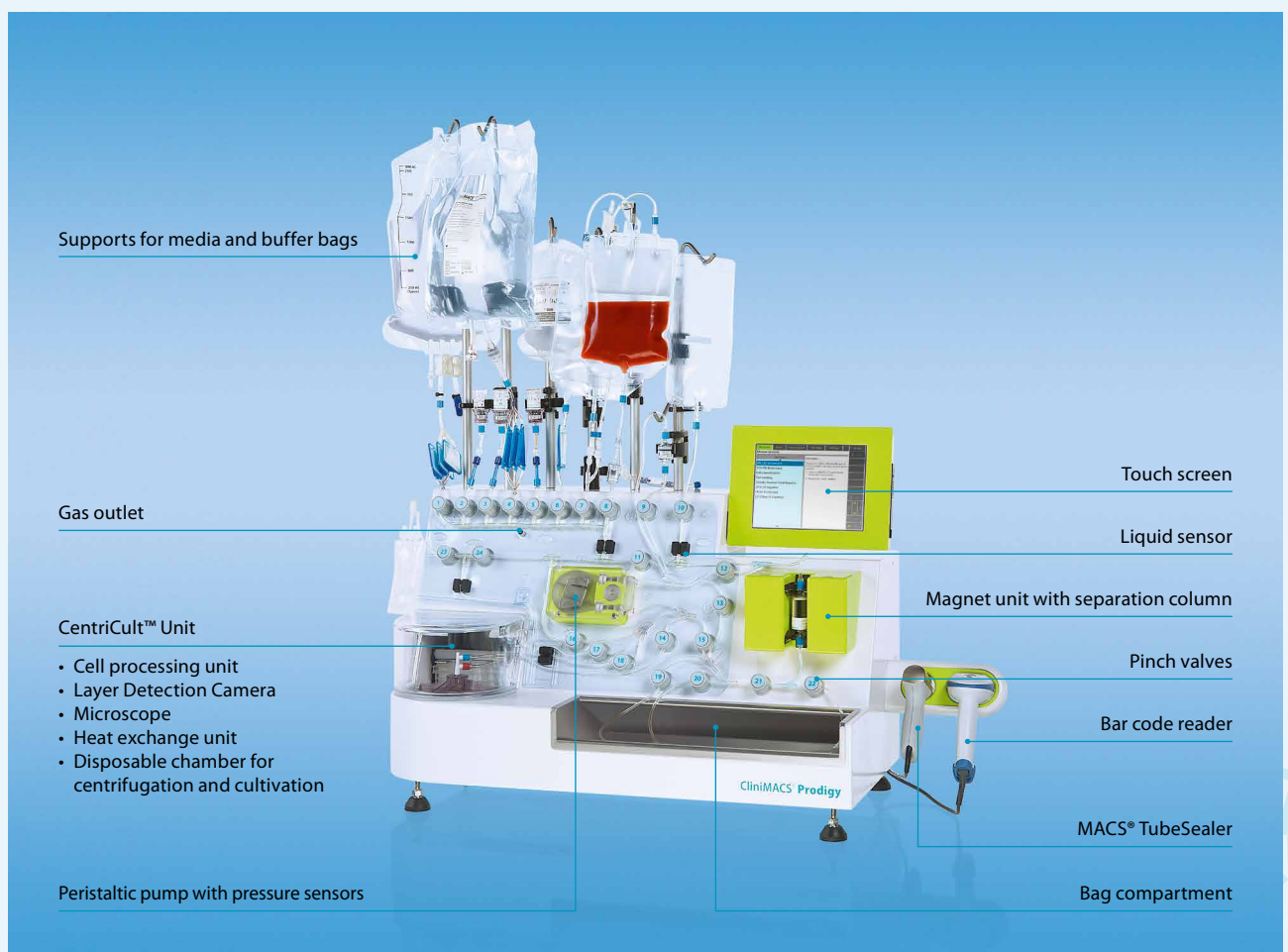
In addition to fully validated cell manufacturing procedures, the CliniMACS Prodigy® Platform also enables the translation of individual projects into GMP-compliant processes. The spectrum of use can even be extended by attaching cell-processing tools, such as MACS® GMP Cell Culture Bags or other scale-up technologies.

- Flexible Programming Suite (FPS) for customization of cell processing
- Tailor-made tubing sets for a variety of applications
- Partnering projects for individual solutions



Figure 6: Touch screen for operational control of the device. The integrated FPS allows flexible programming of processing modules.

The compact solution for manufacturing a large variety of cell products





Technical specifications

Model	CliniMACS Prodigy® Instrument (# 200-075-301)
Dimensions	73.5 cm × 40 cm × 48 cm (w × d × h). With bag hangers, the height increases by 42–60 cm.
Weight	approx. 70 kg
Input voltage	100–240 V~
Power consumption	810 W
Frequency	50/60 Hz
Pump speed	2–400 mL/min
Atmosphere control	Gas mix unit for CO ₂ , compressed air, and N ₂ ; min. pressure: 1.0 bar, max. pressure: 2.5 bar
Temperature control	+4 °C to +38 °C
Centrifugation	Max. 2,500 rpm (400×g)
Microscope camera	Max. magnification: 400-fold
Monitor	10.1" TFT touchscreen
MACS TubeSealer	For sealing CliniMACS Prodigy Tubing Sets PVC tubes
Types of starting material	Leukapheresis, bone marrow, cryopreserved PSCs
Available cell processing steps	Cell washing, density gradient centrifugation, cell activation, fluorescent antibody labeling of cells, cell depletion and / or enrichment via magnetic cell separation, viral transduction, cell expansion, expansion and differentiation of adherent cells, cell culture and medium exchange, formulation of final cell product
Tubing Sets and accessories	Dedicated CliniMACS Prodigy Tubing Sets and Accessories available
IPC/QC	Integrated IPC/QC sampling pouches allow sterile sample removal
Manufacture and availability	Manufactured in Germany and shipped worldwide

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. MACS® GMP Products are for research use and *ex vivo* cell culture processing only, and are not intended for human *in vivo* applications. For regulatory status in the USA, please contact your local representative. MACS GMP Products are manufactured and tested under a quality system certified to ISO 13485 and are in compliance with relevant GMP guidelines. They are designed following the recommendations of USP <1043> on ancillary materials. The CliniMACS® System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485.

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.

CryoMACS® Freezing Bags are manufactured by Miltenyi Biotec B.V. & Co. KG and controlled under an ISO 13485–certified quality system. These products are available in Europe as CE-marked medical devices and are marketed in the USA under FDA 510(k) clearance.

The complete workflow for clinical research



**Leukapheresis, blood,
bone marrow, tissue**

gentleMACS™
Dissociators (RUO)



Cell separation

CliniMACS Prodigy®
Instrument

CliniMACS® Reagents

CliniMACS Prodigy
Tubing Sets

CliniMACS
PBS/EDTA Buffer



**Cell expansion or
differentiation**

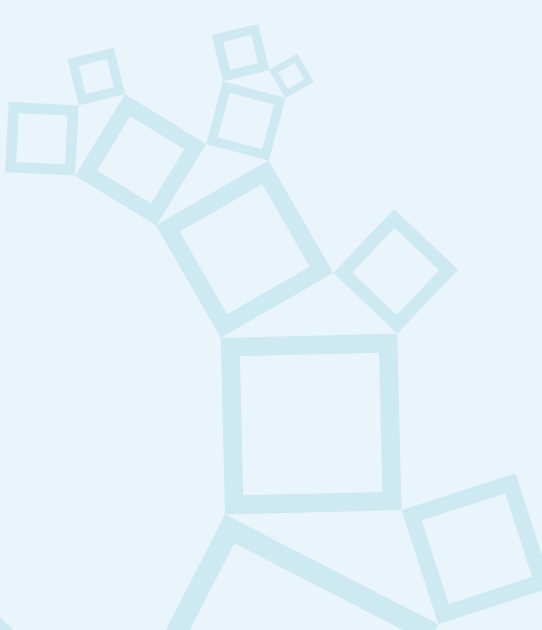
MACS® GMP
Antibodies

MACS GMP Antigens

MACS GMP Media

MACS GMP Cytokines

MACS GMP
Cell Culture Bags





Analysis tools

MACSQuant®
Instruments (RUO)

MACS Antibodies
(RUO)

Cryopreservation

CryoMACS®
Freezing Bags

CryoMACS DMSO
(EP, USP)

Ready to use
cellular product



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