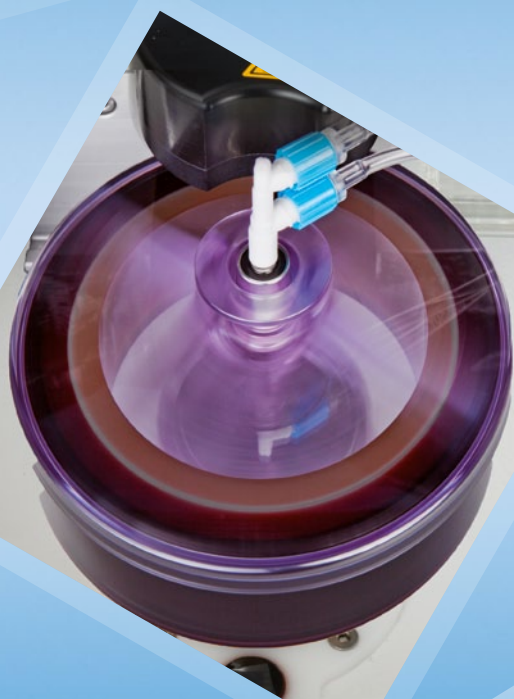


CliniMACS Prodigy® System

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 System is the way forward.

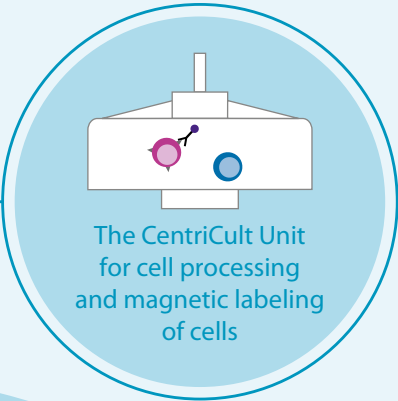


Like you, the
CliniMACS Prodigy® System
is committed to success.

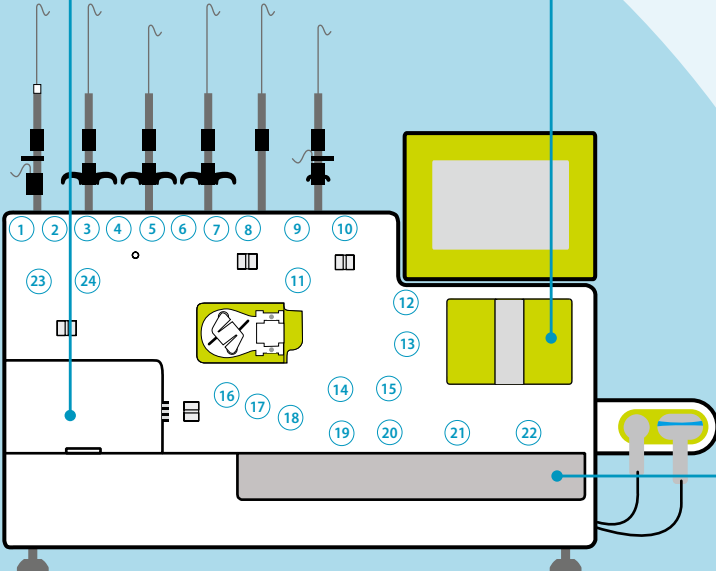
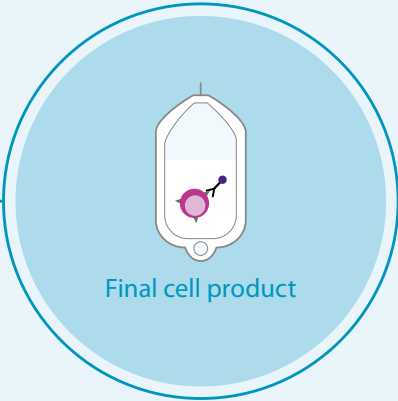
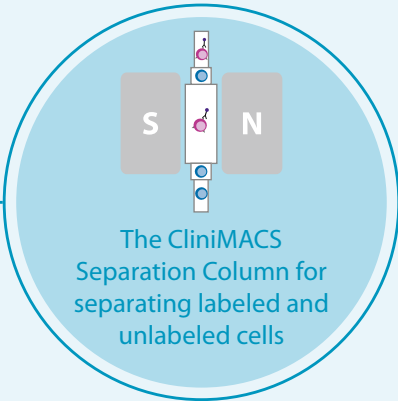




Meeting your needs in cell product manufacturing



The principle of cell labeling and magnetic cell separation using the CliniMACS Prodigy® System





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® System 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.

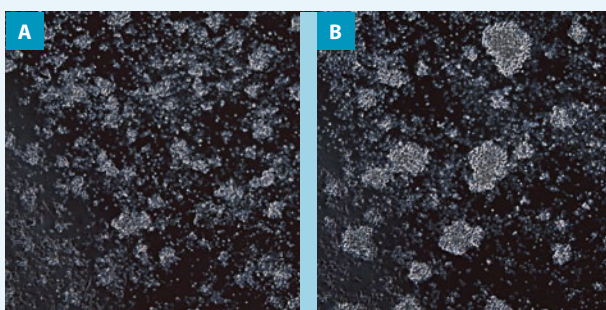


Figure 2: Activated T cells cultured in CentriCult Chamber at day 1 (A) and day 3 showing typical clustering of T cells (B). Magnification 400-fold.

The CliniMACS Prodigy® System 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® System 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

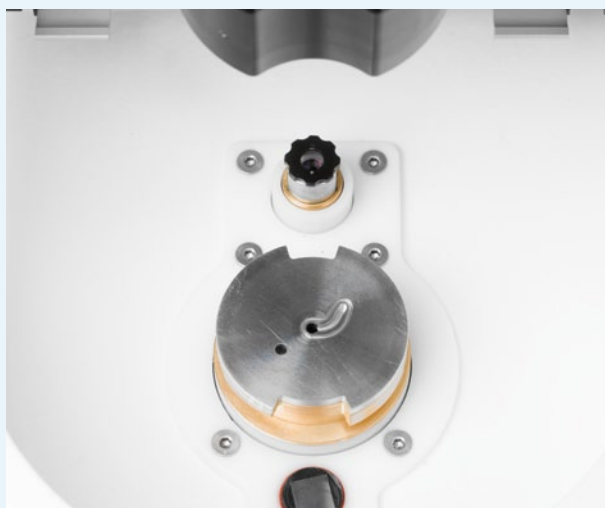


Figure 3: CentriCult™ Unit equipped with infrared sensor, chamber drive socket, microscope camera and Layer Detection Camera (from bottom to top).



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® System 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® System 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.

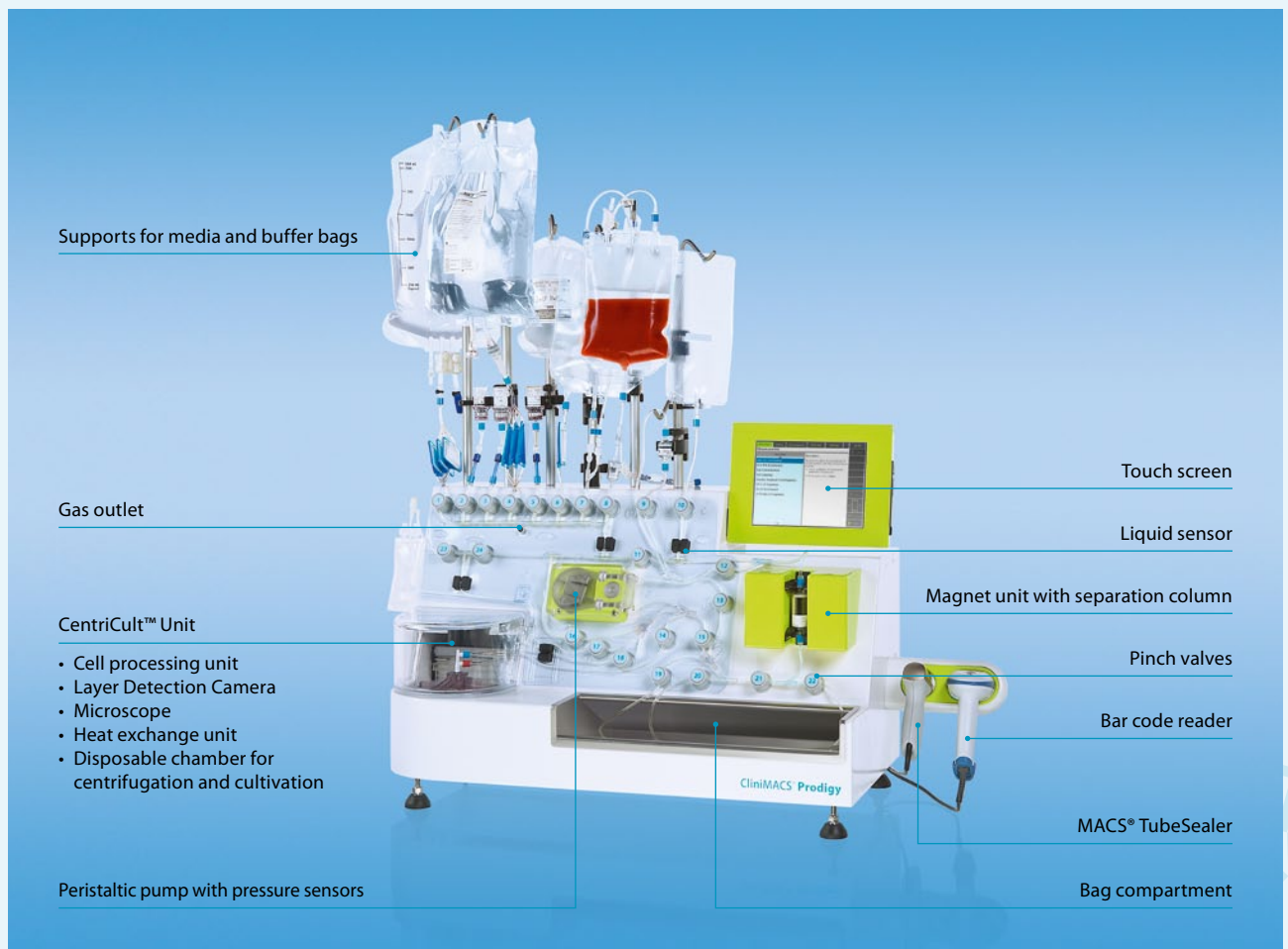
- Flexible Programming Suite (FPS) for customization of cell processing
- Tailor-made tubing sets for a variety of applications
- Partnering projects for individual solutions



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	Width: 73.5 cm (plus approx. 20 cm for holder of bar code reader and MACS® TubeSealer) Depth: 40 cm housing Height: 48 cm housing (plus max. 60 cm for bag hangers)
Weight	approx. 70 kg (excluding weight of attached fluids and accessories)
Input voltage	100–240 VAC (Single phase alternating current)
Power consumption	810 VA
Frequency	50/60 Hz
Pump speed	2–600 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	8.4" TFT touchscreen
MACS TubeSealer	For sealing PVC and EVA tubes of CliniMACS Prodigy Tubing Sets

The CliniMACS® System components including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer are manufactured and controlled under an ISO 13485 certified quality system. In the EU, the CliniMACS System components are available as CE-marked medical devices. In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Set TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved; all other products of the CliniMACS product line are available for use only under an approved Investigational New Drug (IND) application or Investigational Device Exemption (IDE). In the US, the components of the CliniMACS Prodigy System are for research use only and not for human therapeutic or diagnostic use. CliniMACS MicroBeads are for research use only and not for human 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. CryoMACS Freezing Bags are manufactured by Miltenyi Biotec GmbH and controlled under an ISO13485 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. Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research only and not for therapeutic or diagnostic use. For an updated regulatory status in your country, please contact your local Miltenyi Biotec representative.

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**

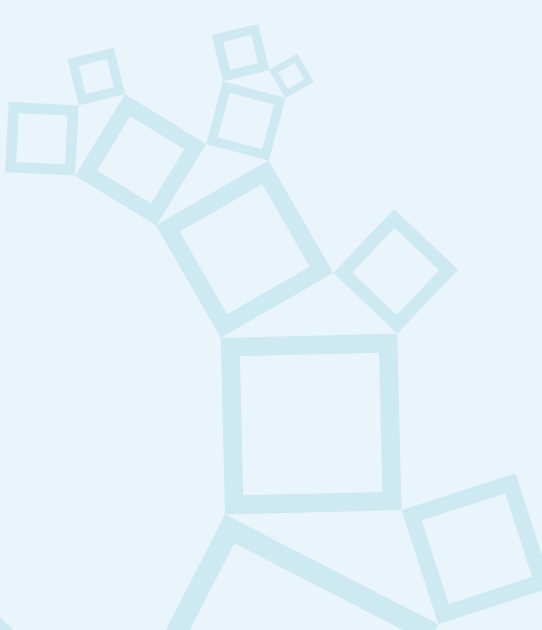
MACS® GMP
Antibodies

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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