



Miltenyi Biotec

The CliniMACS Prodigy® Platform

The No. 1 platform for automated cell manufacturing



The CliniMACS Prodigy Platform

Empowering cell manufacturing into the future

Cell-based therapeutic products created in commercial-scale facilities and point-of-care cleanrooms are a new front against many diseases, from cancer to autoimmune and neurodegenerative disorders. Challenges in producing autologous and allogeneic therapies can be overcome by simplifying workflows through automation and integration. Such innovations in manufacturing shift handling from operator to machine and outcomes from uncertain to reliable.

Automating your cell and gene therapy (CGT) process is a must. Your choice of platform, however, is about longevity, flexibility, and expert support. Miltenyi Biotec and the CliniMACS Prodigy Platform redefined cell manufacturing over a decade ago. Today, we lead its evolution with integrated and streamlined solutions.

An all-in-one platform

Autologous and allogeneic cell therapy manufacturing with less hands-on time and no sample transfers (fig. 1).

An integrated and closed system

Single-use CliniMACS Prodigy Tubing Sets house all processing steps, boosting cell and staff safety.

Consistent and reliable results

Automation eliminates sources of variability to ensure process standardization.

Economic instrument placement

A compact footprint allows for flexible scale-out.

Configurable cell processing

Plug-and-play modules offer workflow versatility.

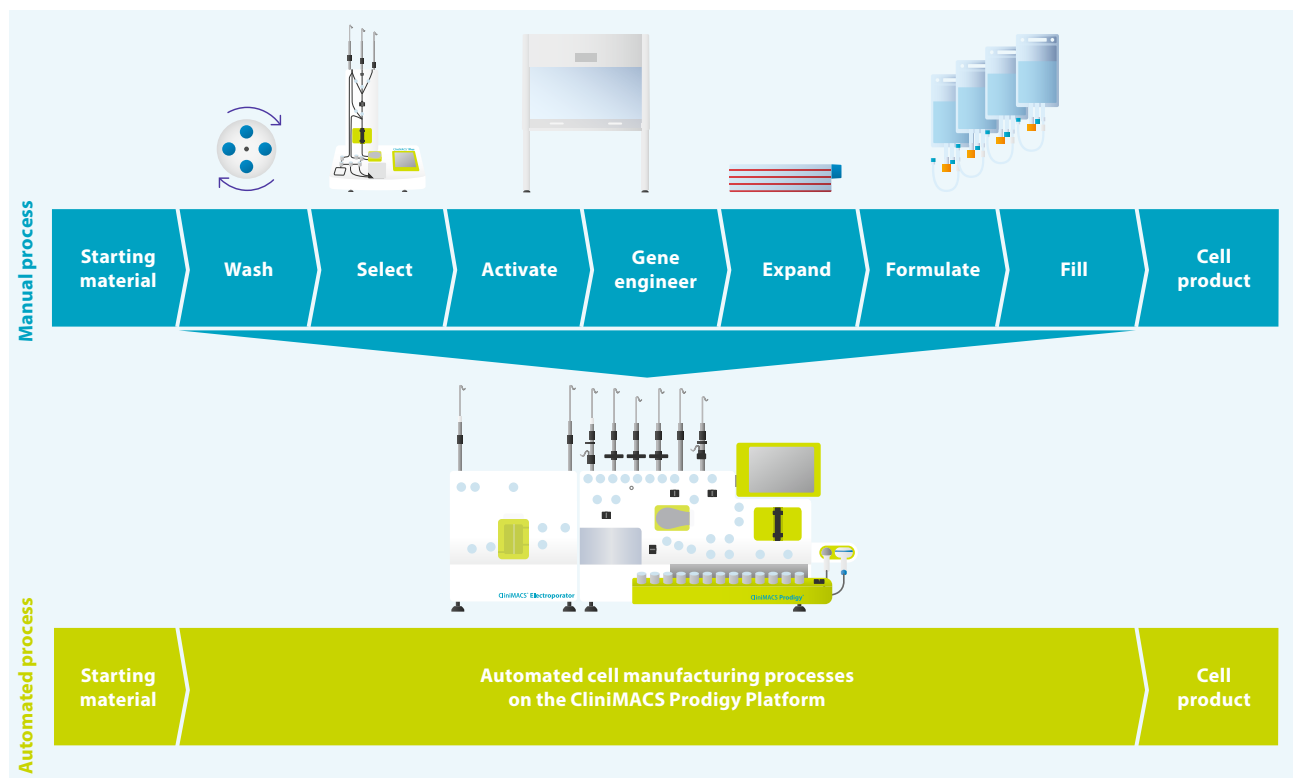


Figure 1: With the modular CliniMACS® Electroporator and CliniMACS Formulation Unit, the CliniMACS Prodigy Platform automates the entire cell manufacturing procedure and avoids error-prone manual steps and risky transfers between step-specific devices.

10+
years supporting
commercial
cell therapies

200+
active clinical trials
worldwide use the
CliniMACS Prodigy*

300+
customized applications
developed for
customers to date



Reliability



Simplicity



Flexibility



* Active clinical trials, hospital treatments, or commercial treatments using CliniMACS Prodigy for manufacturing of cell products.

Integrated cell manufacturing on the CliniMACS Prodigy Platform

Automated flow regulation

A peristaltic pump and pinch valves orchestrate the accurate and controlled flow of liquids through the tubing set.

Exact process control

Gas mixture and temperature modulation with a built-in alarm system ensures reliable operation.

Cell engineering options

Flexible cell engineering with inline viral transduction and/or non-viral transfection on the CliniMACS Electroporator.



Adaptable cell culture

Onboard cell culture up to 600 mL or the option to connect to external culture vessels.

Inline formulation

Automated formulation and filling for both fresh and frozen product strategies via the CliniMACS Formulation Unit.

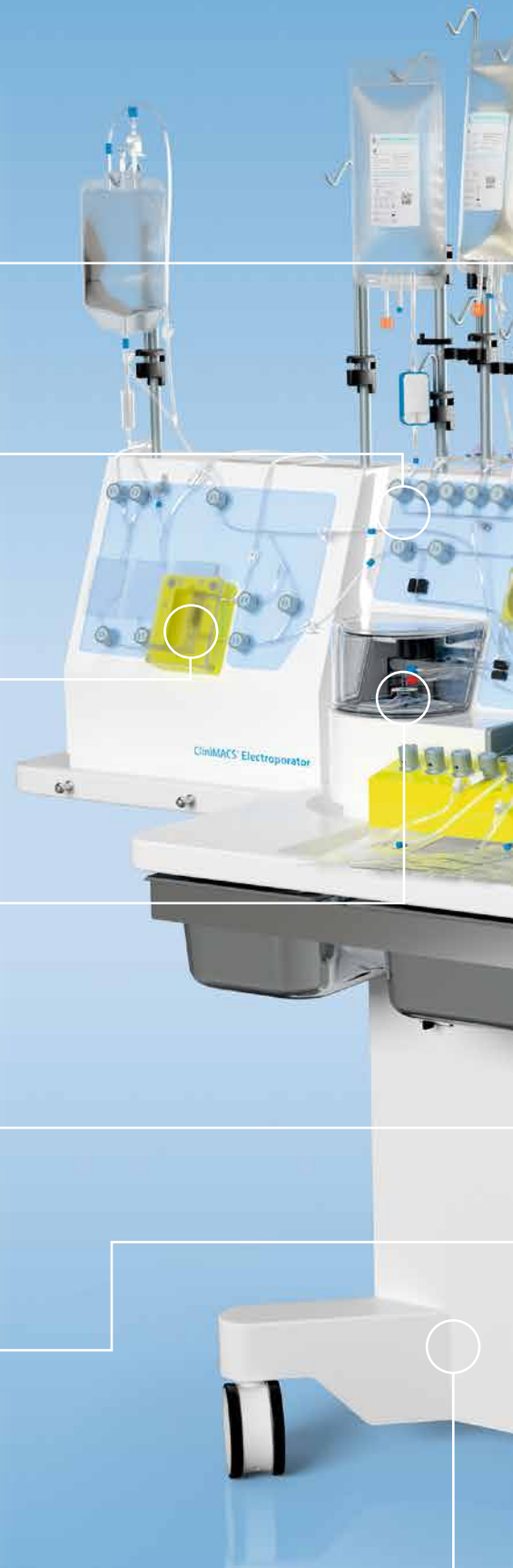


Built-in cell selection

Targeted depletion or selection of labeled cells takes place within an inline clinical-grade magnetic column.

Flexible stationing

Convenient and economic instrument placement with the sturdy mobility of the CliniMACS Workbench.





Central supply

Simplified power and gas connection, alarm relay, and data exchange without cable and supply line clutter.

Safe inputs and connections

Sterile connection of all reagents, buffers, media, and other materials via sterile spike ports or sterile welding.

Operator support

A user-friendly interface guides the operator through interactions and allows flexible programming of cell processing.

Scan. Seal. Go.

Easy documentation of CliniMACS Materials with on-hand barcode reader. Sterile adjustment of tubing with the MACS® Tube Sealer.

Compliance-ready

GMP and 21 CFR Part 11 supportive software with user management and audit trail features eases regulatory compliance and enables network functions.

Efficient use of space

Only 135.5 cm wide and 74 cm deep, the CliniMACS Prodigy Platform fits where you need it.

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Smart design. Seamless operation.
Discover the technology and applications
of the CliniMACS Prodigy Platform.

► miltenyibiotec.com/prodigy



A safe place for your cells

The single-use CliniMACS Prodigy Tubing Sets are conduits for the safe, sterile, and automated processing of cells. They afford a sealed and protective environment during GMP-compliant cell manufacture.

Each cell processing application comes with its own special requirements. We have developed a range of off-the-shelf tubing sets and pre-installed applications that cover these requirements. Simply let the CliniMACS Prodigy guide you through the tubing set installation and any steps needed to get started.

Parallel manufacturing with specific tubing sets

The pre-assembled tubing sets are equipped with process-specific components to support different cell processing protocols. All tubing sets contain a centrifugation chamber for cell fractionation, cell washing, and cell cultivation. Some tubing sets also contain a cell separation column and a heat exchange cartridge for temperature control. Sampling pouches allow for convenient quality control at various stages of your process. Starting material, reagents, and buffers can be easily connected to the tubing set by sterile welding and sterile connection ports. Thanks to the closed system setup, several CliniMACS Prodigy Instruments can be used in one clean room for parallel cell production.

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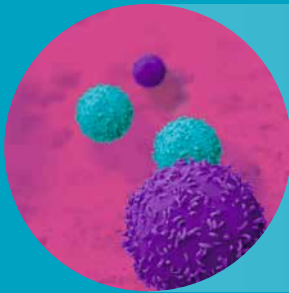
Learn about our
CliniMACS Prodigy Tubing Sets
and their components.

► miltenyibiotec.com/tubingsets

Match your cell type and application

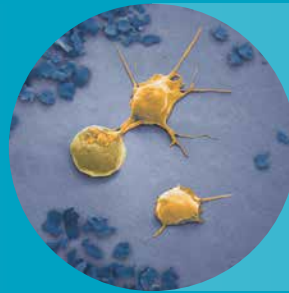
Our experts continually develop CliniMACS Prodigy applications to enable novel strategies and overcome challenges in CGT. Many of those applications are pre-installed on the CliniMACS Prodigy. With corresponding tubing sets and adjustable parameters,

they meet most manufacturing requirements. Our Customized Application Services team can help create a bespoke application with extensive documentation, on-site installation, and certified training.



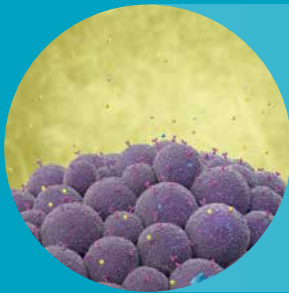
T cells

Efficient enrichment of tumor-infiltrating and regulatory T cells or novel engineering of CAR, TCR, and TCR γ / δ ⁺ T cells.



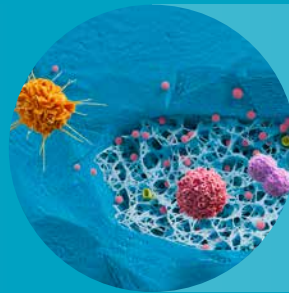
Natural killer cells

Enrich and engineer natural killer (NK) cells for the next advances in CGT.



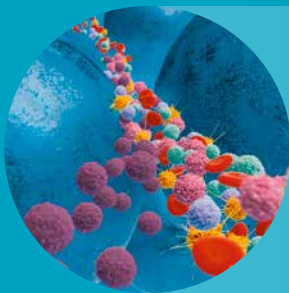
Regenerative medicine

Empower pluripotent (PSC) or mesenchymal stem cells (MSC) with efficient expansion or differentiation processes.



Hematopoietic stem cell engineering

Refine and improve hematopoietic stem cell (HSC) transplants via targeted cell enrichment and engineering.



Graft engineering

Design grafts through precise enrichment of stem cells or depletion of specific T cell populations.



Customized Application Services

Translate your manual protocol into a CliniMACS Prodigy application.



Your cells, your process.
Get an overview of our processes and customization services.

► miltenyibiotec.com/CGT

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Deploy harmonized IPC/RT analysis

CGT manufacturing goes hand-in-hand with standardized and scalable analytics. We offer solutions for flow cytometry-based analytics developed alongside the CliniMACS Prodigy Platform to enable seamless and robust in-process control and release testing (IPC/RT) adapted to every stage of the development journey.

Automated analytics

The manufacture of any CGT must be automated to ensure a standardized, cost- and time-efficient process. The MACSQuant® Analyzers and our extensive portfolio of high-specificity reagents are an all-in-one solution for deploying automated analytics. Start as early as possible with assay setup, data analysis, and process documentation powered by the unique Express Mode features.

Workflow integration

The MACSQuant Analyzer Platform, including software and consumables, integrates seamlessly into CliniMACS Prodigy workflows. Analytics co-developed with manufacturing processes are harmonized to provide all process-critical information for continuous and streamlined production on the CliniMACS Prodigy Platform. As a result, robust analytical testing, from starting material assessment to final product release, promotes efficiency and facilitates compliance.

Smart scale-out

The scale-out concept for the CliniMACS Prodigy flexibly accommodates commercial-scale production. The MACSQuant Analyzer matches that throughput growth. On the one hand, its Smart Gain Technology maintains analytical consistency and comparability across instruments and production sites. On the other hand, the instrument can be integrated into robotic systems.

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Find the perfect match.
Streamline cell manufacturing
with harmonized analytics.

► [miltenyibiotec.com/
perfect-match](https://miltenyibiotec.com/perfect-match)





MACS
Quant 16



MACS Quant 16

Our commitment beyond your instrument purchase



In-person and online training

Stay up-to-date and knowledgeable in your field and the use of your CliniMACS Prodigy with our dedicated training courses. We offer courses on the newest techniques, applications, or technologies designed for our academic, clinical, and industry customers. You can choose from live webinars and tutorials to hands-on training from experts at one of our Miltenyi Innovation and Training Centers (MITC) or at your site.

Technical support and instrument service

Your cell manufacturing tools should perform consistently and reliably. Our worldwide team of technical experts provides exceptional product and scientific support to maximize instrument uptime and help maintain regulatory compliance. Their work is also backed by tailored services contracts, covering preventive maintenance and software updates, qualification services, and 24/7 priority technical support.

Guidance in a changing regulatory landscape

The regulatory landscape of CGT is evolving at a rapid pace. Our highly experienced regulatory teams help you at every step from early development to market authorization. We provide documentation in support of your Investigational New Drug (IND) or Biological License Application (BLA) submission, or you can engage our specialized regulatory services to guide the process.



Join Miltenyi University and start learning with webinars and training sessions.

► miltenyibiotec.com/miltenyi-university

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A partner for the future of your cell therapy

Different cell therapy strategies require different manufacturing concepts. Production location, process throughput, and campaign logistics, from cell sourcing to product delivery, are complex factors that impact the planning and deployment of a CGT. As a partner, Miltenyi Biotec offers a helping hand to achieve any concept that facilitates the availability of novel therapies.

Decentralized or centralized?

Point-of-care manufacturing of cell-based therapies shortens turnaround times and simplifies logistics. A central production facility concentrates expertise and leverages economies of scale. Conceived as a self-contained, modular production unit, the CliniMACS Prodigy Platform accommodates both manufacturing forms and even flexibly adapts to changes in demand.

From clinical to commercial scale

The key to successfully scaling out cell manufacturing is to start early with automation. Selecting the right platform from the outset minimizes the risk and cost of changes during clinical development. Operating in concert with the MACSQuant Analyzer, the CliniMACS Prodigy Platform offers a fit-for-purpose solution from discovery to scalable production (fig. 2). We've perfected this setup for seamless expansion from clinical to commercial manufacturing and versatile deployment in decentralized and centralized scenarios in a single blueprint: the CliniMACS Cell Factory® concept.

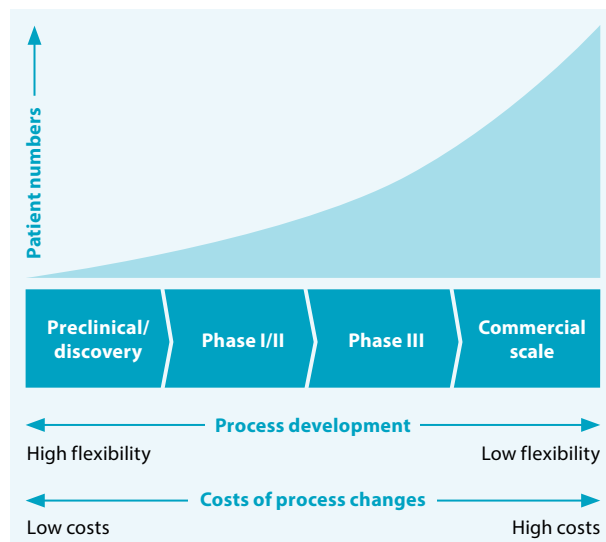


Figure 2: Automate your processes early to avoid high-risk, late-stage process modifications.

Full CDMO services

Miltenyi Bioindustry CDMO services build on years of experience in CGT development and manufacturing to accelerate your clinical development or partner in any manufacturing scenario. With deep process knowledge and cutting-edge technologies, our experts tackle development unknowns and process complexities to help advance your cell-based therapies unobstructed to market.



Accelerate your journey from idea to market with CDMO services from Miltenyi Bioindustry.

► [miltenyibioindustry.com](https://www.miltenyibioindustry.com)

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

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.

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