

ACEs™ | Automated Cell Expansion System

A next-generation solution that simplifies and streamlines the expansion of cell therapy products.



ACEs™ |

Automated Cell Expansion System

ACE is an innovative, all-in-one platform that automates and streamlines immune cell expansion.

Powered by Medigen's patented **TrackClamp** technology, ACE replaces traditional wave-based systems that rely on rocking motion with a **static culture environment**—minimizing mechanical stress on cells while enabling automated, dynamic medium input for feeding, without active waste removal. This ensures a stable nutrient supply without disrupting the delicate cell microenvironment.

With its **compact and integrated design**, ACE combines cell expansion, monitoring, media storage, and manual processes into a single, seamless system. It is easy to operate, compatible with standard consumables, and engineered for both large-scale production and personalized therapies.



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Core Technology - TrackClamp

ACE integrates innovative technology, **TrackClamp**, which utilizes a rolling clamp mechanism to control parameters of the culture bag—ensuring optimal conditions for cell expansion. **TrackClamp** enables a static, planar culture environment, minimizing turbulence and shear stress commonly associated with wave-based bioreactors. **TrackClamp** is designed as a modular unit specifically for the cell expansion stage within the ACE system.

Key advantages of TrackClamp :

- Space-saving design: TrackClamp operates with a flat-surface rolling mechanism, significantly reducing space requirements.
- High compatibility: compatible with standard, commercially available lab consumables and easily integrated into existing workflows.
- High performance: supports expansion of diverse suspension cells. 30–50 ml of blood can yield over 10^9 immune cells.
- Built for system integration: compact, modular design allows flexible integration with other production units such as isolators, or incubators, enabling streamlined and customized manufacturing workflows.



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All-in-one System for Cell Expansion

ACE is designed as an **all-in-one system** that integrate four key stages of cell manufacturing—cell expansion, monitoring, media storage, and traditionally manual procedures—into a single compact system.

Key Advantages:

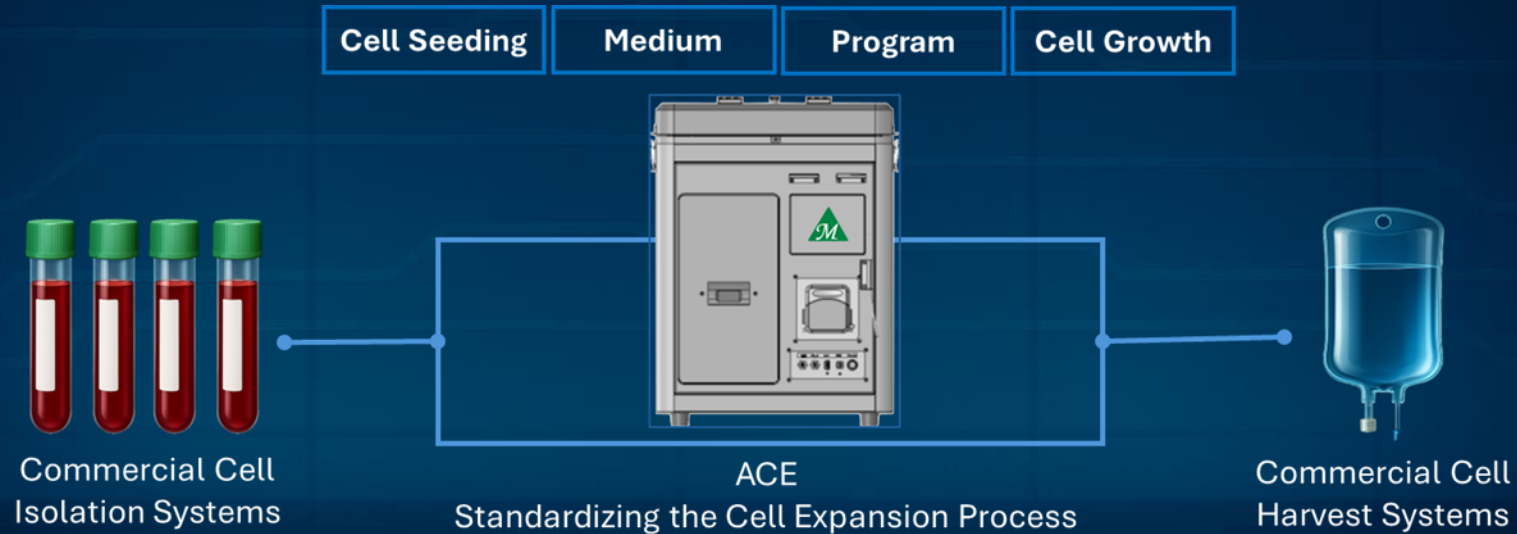
- Contamination prevention: automated and closed system design, combined with sealed, contamination-free consumables.
- Precise environmental control: built-in control of temperature and CO₂.
- Reduced manual handling: automated media addition and circulation.
- High compatibility: supports standard lab consumables and devices for seamless integration.

Key Capability:

- Supports culture volumes from 500 ml to 1,500 ml, enabling single-batch yields of up to 10⁹ cells.
- Proven to support the expansion of diverse immune cells, including CIK, NK, and γδT (GDT) cells.



ACEs™ | ALL-IN-ONE SYSTEM



ACEs[™] | Built for Scalable Suspension Cell Production

ACE is purpose-built to support the **cell expansion section** of the suspension cell manufacturing workflow, which typically includes three major stages: cell isolation, cell expansion, and cell harvest. ACE handles the cell expansion stage with precision, integrating four critical steps into a single device: **1). cell seeding; 2). culture medium control; 3). programmed process setup; and 4). cell growth and monitoring.** Engineered for high compatibility, ACE can be seamlessly integrated with a wide range of commercial cell isolation and harvest systems. As a closed-expansion device, ACE utilizes single-use cell culture bags and tubing, minimizing contamination risks while reducing labor, time, and operational costs. Moreover, by standardizing the expansion process, ACE enables consistent, stable, and efficient cell production, making it an ideal solution for modern cell therapy manufacturing.

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Build Your Own Clinics for Personalized Medicine

ACE system features a compact, closed, all-in-one design that is both **space-efficient and easy to operate**. It is ideal for laboratories, hospitals, and clinical settings, supporting the simultaneous production of diverse cell therapy products in line with the growing demand for **personalized medicine**.

At its core, the patented **TrackClamp** module replaces traditional wave-based expansion methods. Its flat, rectangular design offers superior space efficiency and high integration flexibility, allowing seamless connection with existing laboratory equipment and workflows.

With its static and highly controllable culture environment, ACE enables flexible process customization—ideal for clinics developing personalized cell therapy protocols.



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Expanding Diverse Immune Cells for Cell Therapy

ACE has demonstrated its capability and efficiency in producing high-quality immune cells across various cell types.

Item	CIK	$\gamma\delta$ T (GDT)	NK
Formulation	Published Formulation	Medigen's Formulation	Medigen's Formulation*
Process duration	14 days	14 days	14 days
Key Phenotype	CD3 ⁺ T CD3 ⁺ CD56 ⁺ NKT	CD3 ⁺ TCR $\gamma\delta$	CD3 ⁻ CD56 ⁺
Cell number**	$\geq 1 \times 10^9$	$\geq 1 \times 10^9$	$\geq 1 \times 10^9$
Viability	$\geq 80\%$	$\geq 80\%$	$\geq 80\%$
Purity	CD3 ⁺ T $\geq 80\%$ NKT $\geq 15\%$	$\gamma\delta$ T $\geq 70\%$	NK $\geq 70\%$

*Medigen's Formulation is developed in-house using commercially available components. Medigen's Formulation, designed for the production of natural killer cells (Magicell®-NK), has been approved by the Taiwan FDA for use in both autologous and allogeneic settings in Phase I/II clinical trials.

**Cell count is assessed on Day 14 of the expansion process.

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Patent Portfolio and Certificates

Patent Portfolio:

Medigen's ACE system and its proprietary TrackClamp technology are protected by a broad global patent portfolio, with coverage across United States, Canada, Europe, China, Japan, Korea, and Southeast Asia.

ISO 13485:2016 Certification:

With ISO 13485:2016 certification in place, ACE is fully positioned for technology transfer, contract manufacturing, and licensing partnerships, ensuring regulatory readiness and quality compliance.



ACEs™ | Specification



Control System

Culture volume: 10~1500 ml
Culture temperature: 37 ± 1 °C
CO₂: 5 ± 0.5 %
Reefer system: 4~10°C

Dimensions

455 x 620 x 560 mm (W x L x H)

Weight

approx. 41 kg

Input Voltage

110V

Frequency

60Hz

System Language

Chinese, English

I/O

USB 2.0 Type B (Connect PC)
USB 2.0 Type A (Environment Log file storage)

Human Machine Interface (HMI)

4.3 " touchscreen



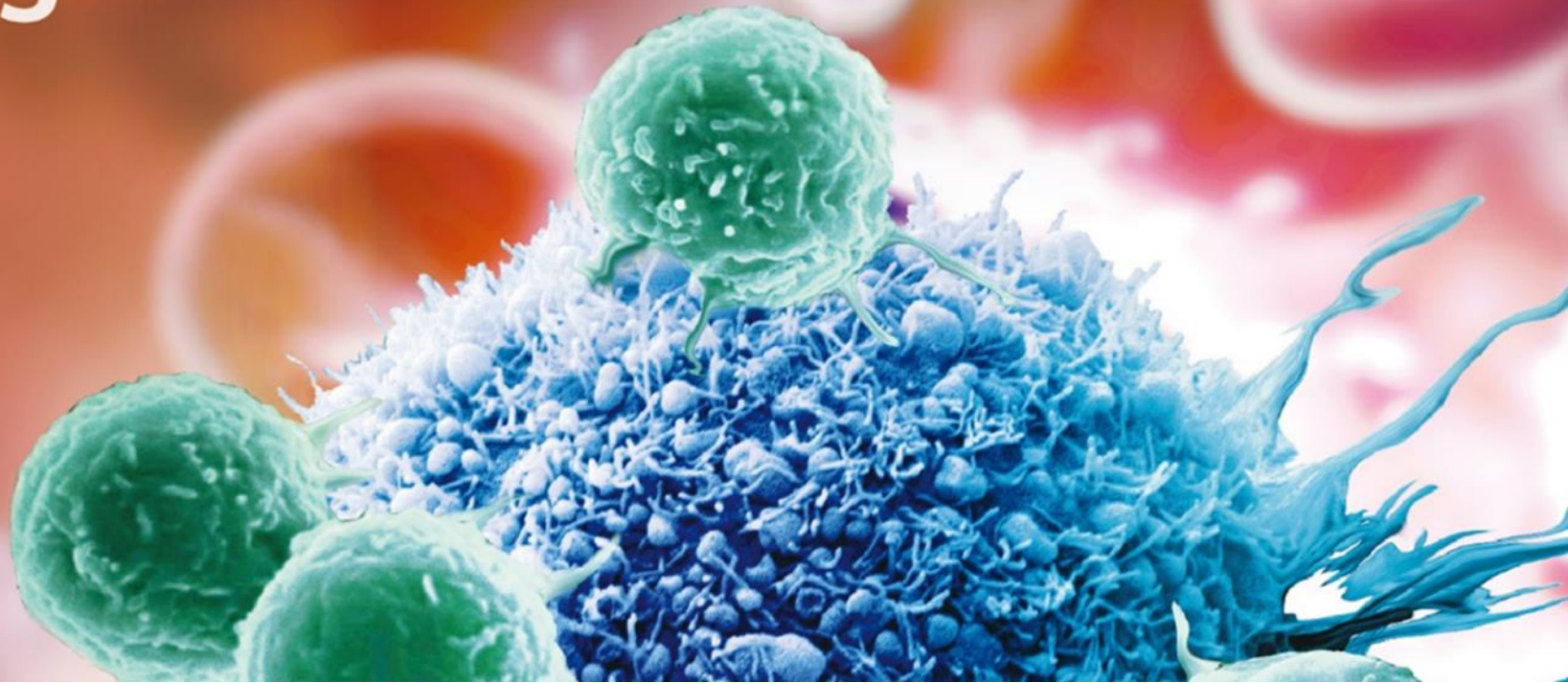
Consumable supplies

Culture bag
Connecting tube

* Single Use



Innovations for a Better Life



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