

SONY

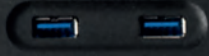


CGX10 Cell Isolation System



Sony Biotechnology Inc.

POWER



STOP



CGX10 CELL ISOLATION SYSTEM

Cell Isolation You Can Count On

The CGX10 Cell Isolation System

is the only fully closed, cell isolation system for GMP-compliant cell production and cell sorting applications. The innovative system design provides superior cell isolation along with ease of operation, with unparalleled flexibility that enables a smooth transition from process development to cell production.

Progress in the area of cell and gene therapies has accelerated significantly in recent times. Flow cytometry based cell sorting has been used to sort cells by desired phenotype based on the presence of one or more biomarkers. Sorted cells have been expanded *ex vivo* and reinfused into patients as cell-based therapies. The ability to use multiple biomarkers is important. It enables identification and isolation of specific immune cells possessing the desired phenotype. Multi-marker based cell isolation not only delivers a higher purity of isolated cells, but also enables selection to eliminate non-target cells, or therapeutically ineffective cells, for example, over-differentiated T cells.

However, the use of traditional flow cytometers has been limited to research laboratories and preclinical and early phase studies. The complex design of conventional flow cytometers and their usability issues make them poorly suited to a cell production environment that is GMP compliant. Certain conventional flow cytometers have also been known to shear or cause electrically-induced stress or damage to sorted cells.

The CGX10 Cell Isolation System has been developed with the goal of enabling multi-marker selection to isolate target cells while ensuring high cell viability. The system delivers a user experience that is suited to the GMP compliant cell production environment, and transcends the complexity and subjectivity of conventional sorter platforms.



The CGX10 is designed to fit your GMP environment with its compact design, intuitive touch screen user interface, ease of operation and sterile single-use consumables which ensure operation as a fully-closed system.



Next Generation Cell Therapy Enablement



Closed System

The CGX10 Cell Isolation System is the only fully closed, cell isolation system that addresses GMP-compliant cell production and cell isolation needs. The innovative system design provides superior cell isolation along with ease of operation and unparalleled flexibility, which enables a smooth transition from process development to cell production.



GMP-Ready

The tubing kits are sterilized using the Ethylene Oxide Gas (EOG) sterilization process to fit into a controlled environment. The sterilization and closed mode operation of the tubing kit protect cells from the external environment and lower the risk of contamination. All consumables which may come in contact with cells are manufactured and tested in ISO 13485 standard compliant facilities. Moreover, certification is available for each lot of consumables to support work in a compliant facility.



Simple Operation

On screen prompts guide users on how to isolate cells of interest. The software automates appropriate instrument setup without requiring beads, reducing the risk of contamination. A dedicated operator mode is available for routine operation in a GMP environment backed by 21 CFR Part 11 compliance tools. Touch screen operation eliminates the need for keyboard and mouse, reducing space required.



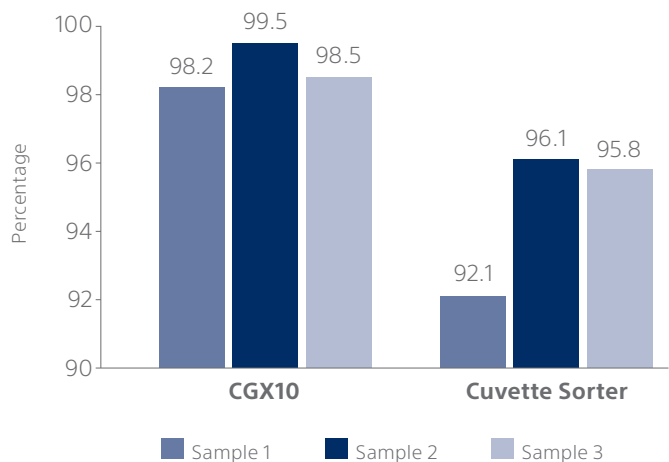
High Cell Viability

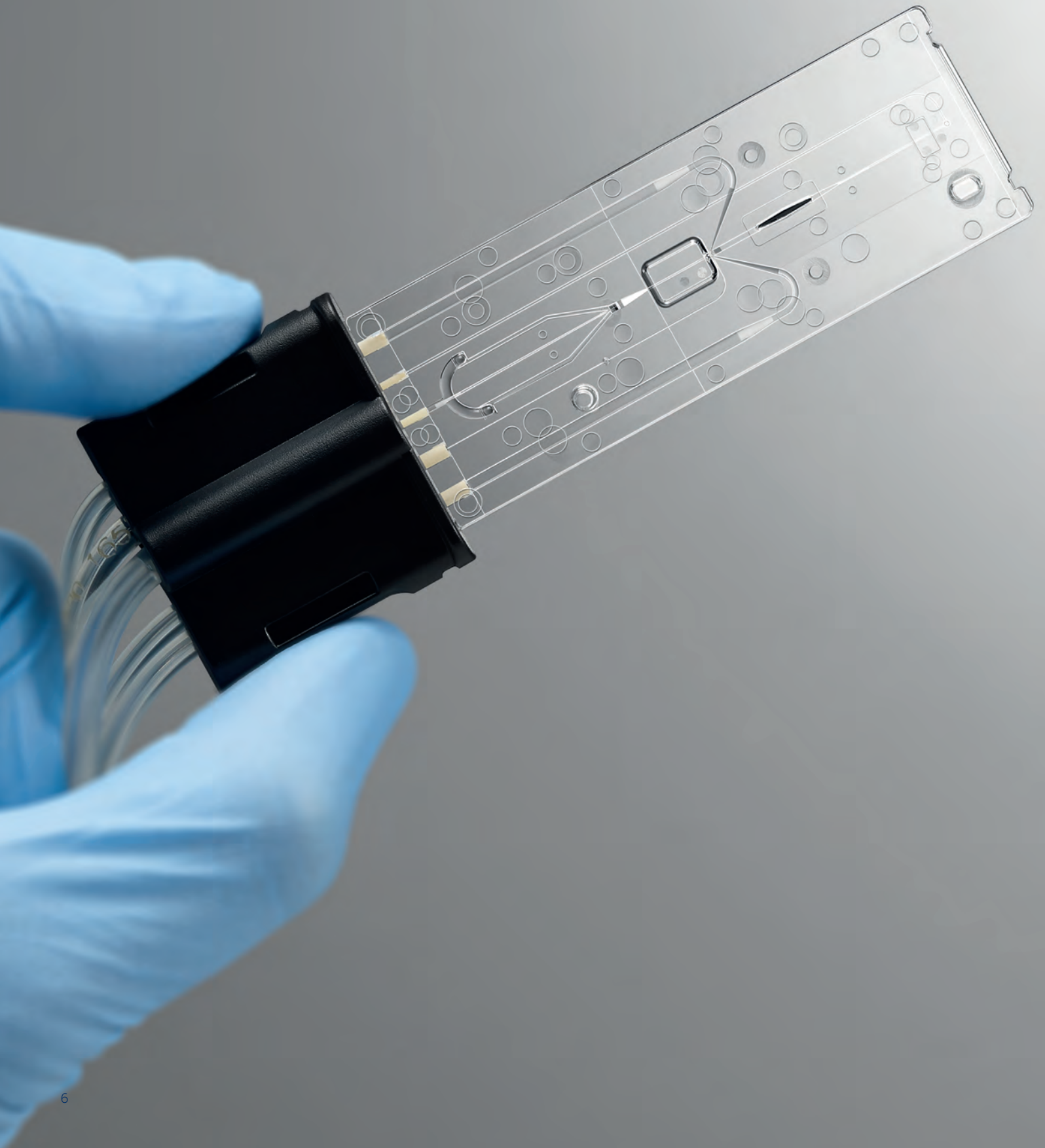
Sony's novel microfluidics based cell isolation technology isolates cells, minimizing stress to the cells, due to absence of mechanical valves and droplet based methods. This technology maintains cell viability and helps maintain function. Additionally, independent temperature control of the sample and sort output reservoirs (from 4°C to 34°C) provides the environment needed for your cells. (Fig 1).

Figure 1: Comparison of cell viability obtained when using a conventional cuvette based sorter and CGX10 Cell Isolation System

Three samples were used to sort target cells using the two types of systems. The viability of sorted cells was calculated and compared side by side. Data indicates that cells isolated using the CGX10 consistently showed higher viability than those sorted using the conventional cuvette based sorter in all three cases.

Data generated in collaboration with Mie University.



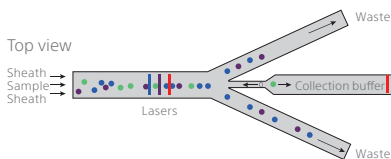


Innovative Microfluidics Based Cell Isolation Technology

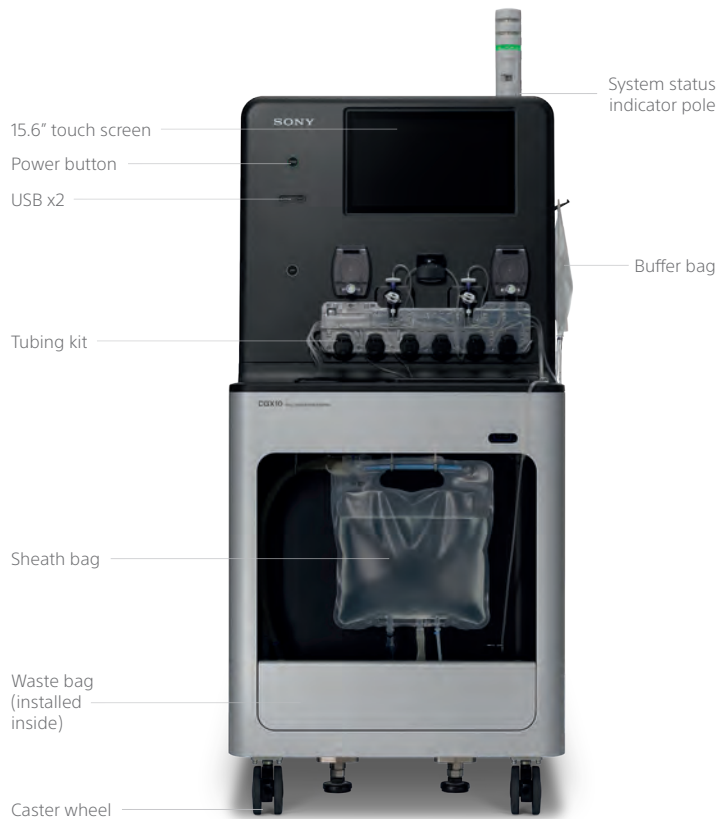
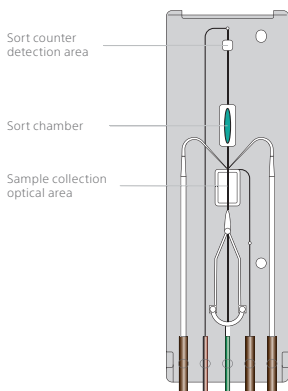
The CGX10's novel microfluidics cell isolation technology is high speed, gentle, and robust for cell manufacturing applications. The hydrodynamic sorting mechanism handles cells gently within the microfluidics without any mechanical manipulation. The independent temperature control function (4°C–34°C) helps keep cells viable. Well controlled cell positioning in a line with laminar flow provides precise detection and higher purity cells.

The separated sample collection line and waste lines reduce clogging. Additionally, the automatic clog detection and recovery function allow walkaway operation. The system is equipped with four lasers (405 nm, 488 nm, 561 nm, 638 nm) and ten detection channels (two scatter and eight fluorescence) to provide flexible fluorochrome selection for various cell types (e.g., naive T cells, Tscm, Tcm, Treg, iPSC). The mixed sorting ratio control feature expands capabilities for cell selection.

Hydrodynamic Sorting



Microfluidic Chamber



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The CGX10 Cell Isolation System and related products are intended for use by trained laboratory technicians in research, process development or manufacturing environments all related to ATMP/regenerative medicine, including cell and gene therapy. The CGX10 instrument and related products are for *ex vivo* cell separation processing only, and are not intended for therapeutic, diagnostic, or human *in vivo* applications. Any clinical application of the cells is exclusively within the responsibility of the user of the CGX10 instrument and related products. For the manufacturing and use of cells in humans, regulations must be followed. The CGX10 Cell Isolation System and related products are not sold as medical devices.