

Application Note: CGX10 Cell Isolation System
 Designed for a GMP-Compliant Environment

CGX10 Cell Isolation System Designed for a GMP-Compliant Environment

Materials and Methods

The CGX10 Cell Isolation System and accessory products are intended for fully-closed, cell isolation and cell separation through flow-cytometry-based sorting. The CGX10 software enables 21 CFR Part 11 compliance for electronic records and signatures. The CGX10 instrument is manufactured and tested in an ISO 9001 compliant facility.

The accessory products which may come in contact with biological material include the Sterile Tubing Kit (Standard Operation), Sterile Tubing Kit (Process Development), Sterile Sheath Bag, and Sterile Buffer Bag. These accessory products are designed to be single use and sterile, and are made using biocompatible materials. They are manufactured and tested in ISO 13485 compliant facilities.

The CGX10 is designed for use in GMP-compliant manufacturing Advanced Therapy Medicinal Products (ATMP) regenerative medicine applications, including cell and gene therapy. Related accessory products are supplied with harmonized documentation such as Certificates of Analysis, Certificates of Origin, Product Information Files, and access to authorization letters for the Device Master Files (MAF).

Note: The CGX10 Cell Isolation System and related accessory products are not sold as medical devices.

Key features of the CGX10 Cell Isolation System and Accessory Products

- Closed microfluidics-based cell isolation system
- Sterile (compliant with relevant ISO standards) and single use accessory products
 - Accessory products which may come in contact with biological material produced in ISO 13485 compliant facilities
- Biocompatibility evaluation completed for the Sterile Tubing Kit (Standard Operation) and Sterile Tubing Kit (Process Development) per ISO 10993 compliance
- Enables compliance for electronic records and signatures per the 21 CFR part 11 guidance
- Installation Qualification/Operation Qualification (IQ/OQ package)
- Comprehensive service contract includes preventive maintenance

GMP Support Documentation (Accessory Products)

The CGX10 Cell Isolation System is designed for use in GMP manufacturing, and accessory products are supplied with harmonized documentation to enable smooth transition from process development to clinical and commercial manufacturing.

Table 1

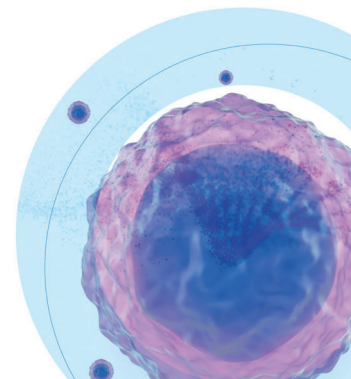
List of regulatory and quality support files offered with the CGX10 Cell isolation system and accessory products.

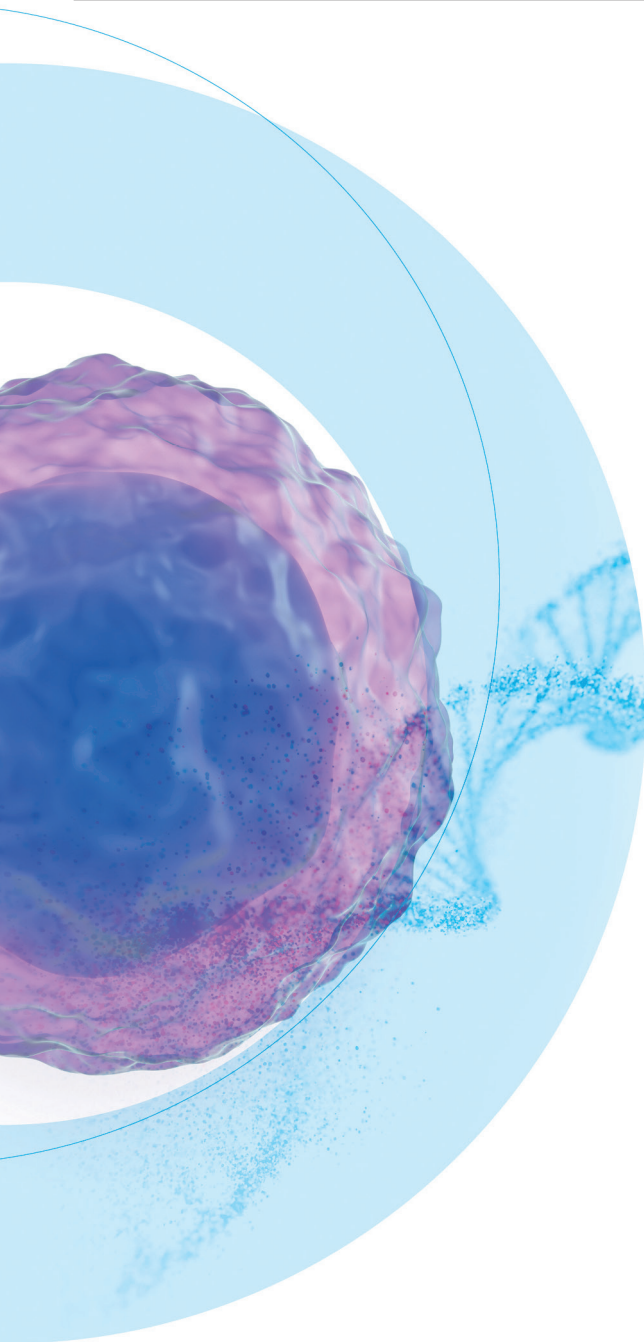
	Sterile Tubing Kit (Standard Operation)* Sterile Tubing Kit (Process Development)*	QC Beads Kit (Sterile)	CGX10 Cell Isolation System
Certificate of Analysis (CoA) sterility information included	Yes**	Yes***	NA
Certificate of Origin (CoO: TSE/BSE free)	Yes	Yes	NA
SDS	Yes	Yes	NA
Certificate of Conformity	NA	NA	Yes
Device Master File (MAF) (US)	Yes	Yes	Yes
Product Information File (EU and Japan)	Yes	Yes	Yes

* Sterile Tubing Kit-Extender and Sterile Sample Preparation Bag are included and have appropriate documentation.

** Sterility Assurance Level (SAL) is 10⁻⁶.

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Customer support

Sony provides the highest quality of customer service, scientific support, and field service resources to ensure the best customer experience.

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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, the regulations must be followed. The CGX10 Cell Isolation System and related products are not sold as medical devices.