SARTORIUS

Product Datasheet

Ksep® Systems

Advanced, Scalable, Single-Use Automated Centrifugation Systems

Product Information

Sartorius Ksep® systems provide robust, single-use closed cell processing solution in the areas of cell therapy manufacturing, recombinant protein therapies, vaccine manufacturing, and blood processing. As per your process requirements, our fully-automated systems are optimized to recover solids (cells/microcarriers) or supernatant (media) in a continuous manner.

Ksep® systems solve the problems of traditional centrifugation and filtration-based technologies by handling low to very high densities efficiently while providing high recoveries and product quality.

Description

The patented Ksep® system technology is the only current technology that provides significant advantages for users that want to either harvest cells as product or discard cells as by-product during cell therapy or recombinant therapeutics manufacturing respectively.

Through the balance of centrifugal and fluid flow forces, the Ksep® retains particles such as cells or microcarriers, as a concentrated fluidized bed under a continuous flow of media or buffer. These are the only bowl centrifuges that do not stop rotating while discharging. The system can be operated under closed conditions and all consumables are delivered gamma irradiated.

Benefits

Smart Bioprocessing

- Integrates and automates processing steps, reducing both time and complexity
- Enhances recovery of solids and liquids
- Offers the capability to selectively remove small particulate impurities, such as plastic debris or cell waste
- Fully automated operation with the option for complete manual control
- No need for hardware changes for different applications
- Effectively handles cultures with low to high cell densities
- Features built-in scalability for seamless transition between development and manufacturing using the same technology

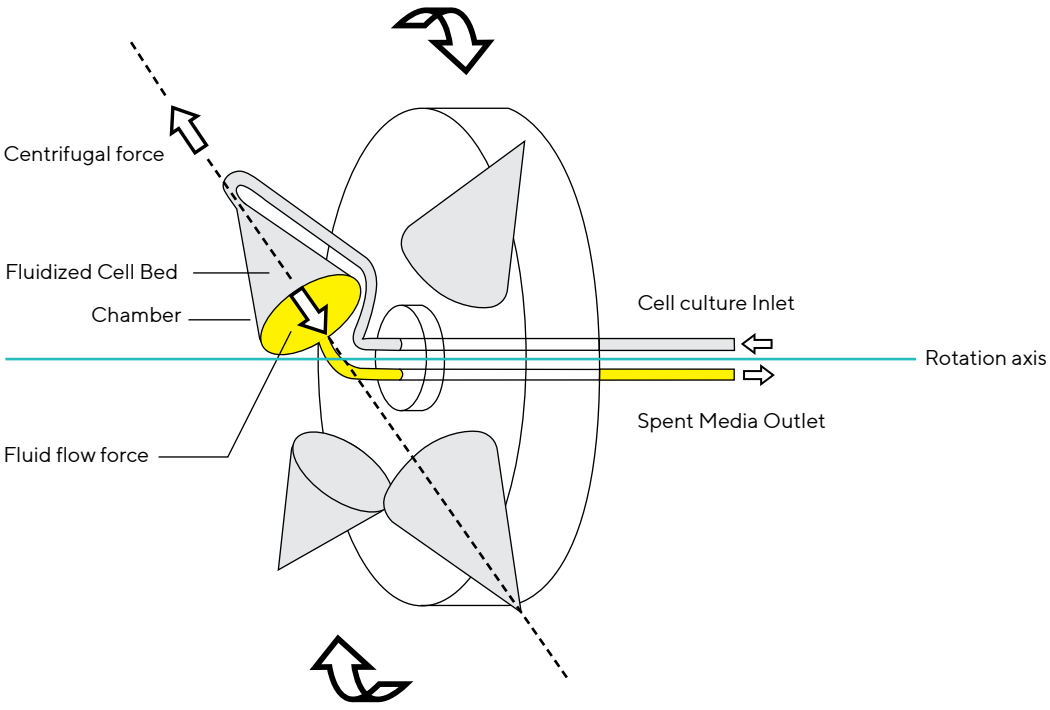
Advanced Cell Handling

- Imparts low shear on cells and keeps the cells intact
- Maintains a gentle environment to sustain cell viability
- Complete supernatant product recovery from slurry
- Reduces intracellular protein contamination for harvest applications by keeping the cells intact

Ensures cGMP Manufacturing

- Closed system with single-use class VI product contact surfaces
- Simple, robust, and scalable
- One software for all systems
- Clog-free and continuous operation
- Batch process records and audit trail for data traceability

Ksep® Centrifuge Functional Principle



Applications

- Cell Therapy
- Harvest | Clarification
- Vaccine Manufacturing
- Blood Processing

Concentrate-Wash-Harvest

Ksep® systems concentrate cells with high recovery while maintaining high viability. Additionally, Ksep® systems can remove cell debris, light particulate impurities, all while significantly reducing any aggregation of cells. Ksep® systems do not contain any rotary seals (providing completely closed system) or filters (for reduced issues from clogging). These features are critical for cell therapy manufacturing. Once captured and concentrated, the cells can efficiently be washed, manipulated, and harvested. Ksep® is a breakthrough for applications requiring maintenance of cellular integrity during processing. This automated sequence is currently being used for cell therapy manufacturing, perfusion, cell banking, and vaccine manufacturing processes. This is the only perfusion technology where the bleeding of cells does not cause loss of recovery.

Harvest Clarification

Ksep® systems are the first single-use centrifugation systems that are completely closed. These systems are fully-automated and designed to recover > 97% of product by efficient product displacement from slurry. This process is independent of cell density. In addition, low-shear process ensures reduced downstream contamination (due to cellular debris or proteolytic enzymes) and high product quality.

Technical Specifications

Attribute	Ksep® 50	Ksep® 400	Ksep® 6000S
Functional			
Counter flow centrifugal force [g]	2,000	1,000	2,000
Maximum peristaltic pump flow rate [L/hr]	48	114	720
Centrifuge chamber volume [mL]	50 (2 × 25)	400 (4 × 100)	6,000 (6 × 1,000)
Cell capacity per cycle*	Up to 10 Billion	Up to 80 Billion	Up to 1,200 Billion
Recommended input volume range [L]	0,1 – 20	10 – 200	100 – 2,000
Minimum output volume range [mL]	50	125	1,000
Process connection size	¼" × ⅛" C-Flex®	⅜" × ¼" C-Flex®	⅝" × ⅜" C-Flex®
Physical			
Dimensions (H × W × D, in cm)	176.3 × 72 × 81.8	140 × 107.5 × 72	179 × 225 × 106
Weight [kg]	246	350	2,141
Process Specifications**			
Cell recovery [%]	> 90	> 90	> 90
Cell viability [%]	< 5 change	< 5 change	< 5 change

* Dependent on cell density. ** Varies with process parameters and conditions.

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Utility Requirements			
Voltage	200 – 240 V 1Ph	208 – 240 V 1Ph	208 – 240 V 3Ph (US) | 400 V 3Ph (EU)
Current consumption, maximum	16 A	20 A	60 A
Process air	Not required	Not required	90 psi – ½" NPT
Connection	Country-specific plug	NEMA L6-20	Supplied by customer
Chilled Water	n/a	½" NPT (Optional)	¾" NPT

Ksep® 50

Ksep® 400

Ksep® 6000S

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