

Ksep[®] Systems

Advanced, Scalable,
Single-Use Automated
Centrifugation Systems



Introduction

Sartorius Ksep[®] systems provide robust, single-use bioprocessing solutions in the areas of recombinant therapeutics, cell therapy, vaccine manufacturing, and blood processing. As per your process requirements, our fully-automated systems are optimized to recover supernatant or solids (cells | particles) in a continuous manner.

Ksep[®] systems solve the problems of traditional centrifugation and filtration-based technologies by handling very high cell densities 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 manufacturing.

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 sterile conditions and all consumables are delivered pre-sterilized.

Benefits

Smart Bioprocessing

- Integrates and/or reduces processing steps and time
- Improves recoveries of both solids and liquids
- Provides option to selectively remove small particulate impurities, e.g. plastic generated, cell debris
- Built-in scalability (4–6 fold) for development and manufacturing using the same system
- Automated with option to run in complete manual mode
- No hardware change for different applications
- Handles low to high cell density cultures (>150 million cells/mL) equally well

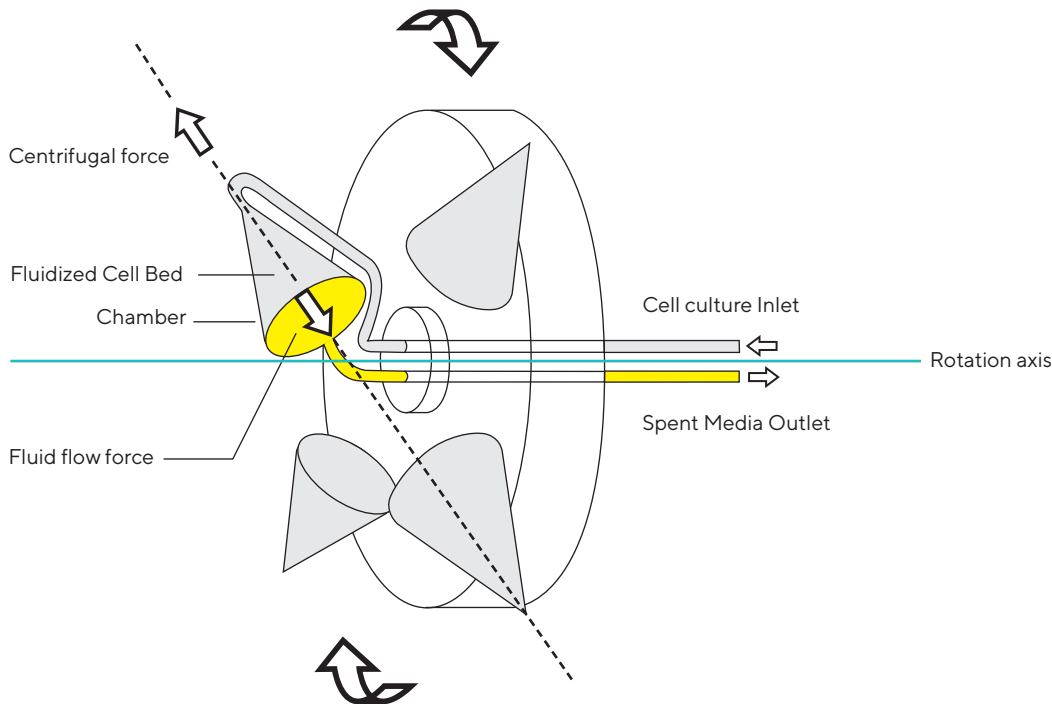
Advanced Cell Handling

- Imparts low shear on cells and keeps the cells intact
- Maintains a healthy environment to sustain cell viability
- Complete supernatant product recovery from slurry without dilution
- 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

Ksep[®] Centrifuge Function Principle



Applications

- Harvest | Clarification
- Cell Therapy
- 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.

Additional Applications

We are continually working with clients and have developed a wide range of additional applications including microcarrier separation and coating, blood separation, infection, and transfection.

Technical Specifications

Attribute	Ksep® 50	Ksep® 400	Ksep® 6000S
Functional			
Counter flow centrifugal force	2000 g	1000 g	2000 g
Maximum peristaltic pump flow rate	48 (L/hr)	114 (L/hr)	720 (L/hr)
Centrifuge chamber volume	50 mL (2 × 25 mL)	400 mL (4 × 100 mL)	6000 mL (6 × 1,000 mL)
Cell capacity per cycle*	Up to 10 Billion	Up to 80 Billion	Up to 1200 Billion
Recommended input volume range	0.1 L to 20 L	10 L to 200 L	100 L to 2000 L
Minimum output volume range	50 mL	125 mL	1000 mL
Process connection size	¼" × ⅙" C-Flex®	⅜" × ¼" C-Flex®	⅝" × ⅜" C-Flex®
Physical			
Dimensions (H × W × D)	176.3 × 72 × 81.8 cm	140 × 107.5 × 72 cm	179 × 225 × 106 cm
Weight	246 KG	350 KG	2141 KG
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.

Attribute	Ksep® 50	Ksep® 400	Ksep® 6000S
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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