

## kSep<sup>®</sup> Technology

Advanced, scalable, single-use technology with diverse bioprocessing applications

Harvest Clarification – Cell Concentration – Cell Washing/Buffer Exchange – Cell Fractionation

kSep<sup>®</sup> technology solves the problems of traditional centrifugation and filtration-based cell retention technologies. The kSep<sup>®</sup> provides a healthy processing environment for gentle concentration, wash, and separation of cells.

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### DESCRIPTION

KBI's patented technology, kSep<sup>®</sup>, has multiple applications in cell therapy, vaccine, and recombinant protein manufacturing. Through the balance of centrifugal and fluid flow forces, the kSep<sup>®</sup> retains particles such as cells or microcarriers as a concentrated fluidized bed under a continuous flow of media or buffer. The kSep<sup>®</sup> concentrates cells with a high efficiency, maintains high viability, and provides constant access to nutrition. In addition, the kSep<sup>®</sup> removes cell debris, light particulate impurities, and does not promote aggregation of cells. Once captured and concentrated, the cells can efficiently be washed, manipulated, and harvested. This technology is a breakthrough for applications requiring maintenance of cellular integrity during processing.

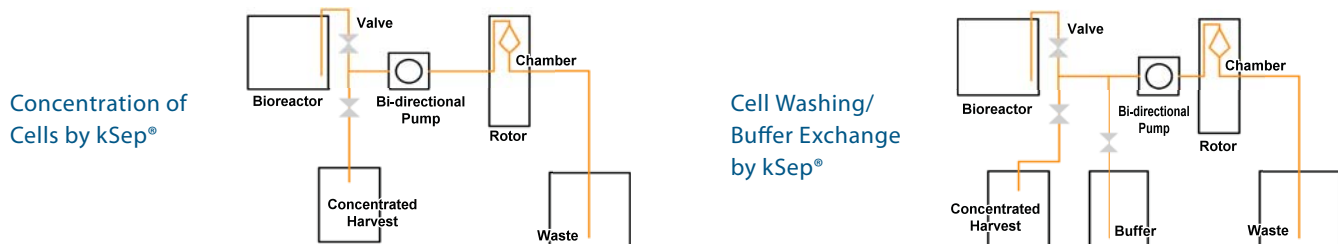


## APPLICATIONS

The kSep® technology has commercial applications in the manufacturing for allogeneic and autologous stem cell therapies. It also has applications in harvest/clarification and cell concentration (in perfusion bioreactor systems) for the production of therapeutic proteins. The technology imparts low shear on cells, maintains high cell viability, and minimizes feed stream contamination including cellular debris or destructive proteolytic enzymes. The kSep® is engineered for use in the cGMP manufacturing operations.

kSep® technology has successfully been applied for the:

- A. Concentration of cells during harvest
- B. Concentration of cells in perfusion bioreactor applications
- C. Washing of cells / Exchange of buffers
- D. Fractionation of differing cell types from a mixed population



KBI Biopharma is continually developing new applications and has successfully completed multiple evaluation programs funded by large pharma clients.

## ADVANTAGES

The system has many advantages over current processing technologies used in cell concentration, cell washing, and harvest clarification. As the kSep® is primarily designed to handle cells and maintain them in a healthy environment, it is ideally suited to processing applications where cell viability is critical.

Advantages of the kSep® include:

- A. Advanced cell handling
  - i. Imparts low shear on cells and keeps the cells intact; this results in reduced intracellular protein contamination for harvest applications
  - ii. Maintains healthy environment to sustain viability
- B. Bioprocessing
  - i. Integrates and/or reduces processing steps and time
  - ii. Improves recovery
  - iii. Efficient cell washing
  - iv. Provides option to selectively remove small particulate impurities (e.g., free plastic particulates, cell debris)
  - v. Potential to remove free virus
- C. cGMP manufacturing
  - i. Closed system with completely disposable fluid path
  - ii. Simple, robust and scalable
  - iii. Clog-free and continuous operation

## ABOUT US

In addition to developing and commercializing kSep® technology, KBI Biopharma provides a full range of services for companies developing protein therapeutic products. Our experienced team provides formulation and analytical development, process development and clinical manufacturing of biologic APIs using mammalian cell culture and microbial fermentation. We develop simple, scalable, and robust processes that result in quality products.

For more information about kSep® technology contact:

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