

Process Applications

Single-Use bags can be used for handling products in a closed system throughout the entire bioprocess sequence. Specific applications are discussed below:



Chromatography eluate collection by Flexboy® bag. Waste collection using a Flexel® Tankliner

1 Product Hold

Collection, pooling and storage of fluids produced by bioprocess unit operations.

2 Process Sampling

Collection, transport, and temporary storage of samples collected as part of the production monitoring process.

Product Hold

Process solutions containing products can be held in Sartorius Stedim Biotech bags on a temporary basis prior to processing by the next unit operation. Product solutions may also be held as an intermediate stock at ambient temperature, as a cooled liquid, or frozen. Intermediate stocks are often held in order to allow optimisation of the flow of material through different sections of a process.



Chromatography fraction collection using Flexboy®bags and Manifold system.

Single-use bags are supplied ready sterilized, and pyrogen free and so are highly suitable for the storage of intermediate products. In addition, Celsius-Pak enables the fully controlled freezing and thawing of therapeutic protein in bags.

This approach can also be used in applications such as chromatographic fraction collection, where the collected fluid varies with time. In this case individual fractions may be collected in separate bags and sampled to determine which fractions to pool prior to further processing. Reactions can be performed in Flexel® 3D Bags using aseptic mixing by recirculation.



Flexel®3D Aseptic Mixing by Recirculation

The Flexel® 3D range may be used to hold large volumes of product, with custom bags of up to 2500L available. For smaller volumes the Flexboy® range can be used to hold volumes up to 50L. The adoption of a manifold system also allows the sequential filling of multiple bags from a single common connection.



Cell Culture Using Flexel® 3D System

A common use for single-use disposable bags is feed and harvest of product from a perfusion bioreactor where the continuous flow of harvested material is collected in bags. The flow of material is switched between bags as each is filled to capacity. Whilst each bag is filled another can be aseptically spliced into the harvest system using a tube fuser. The addition of the Palletank® shipping kit also allows Flexel® 3D Bags to be used for the shipping of stable intermediate between sites if required.

Process Sampling

High levels of process sampling are a feature of biopharmaceutical manufacturing operations. This is especially true during the performance of process development and validation activities. In-process sampling is used to monitor the process state using off-line laboratory analysis. The sampling results provide evidence of satisfactory process operation, can be used to detect irregularities, and to meet requirements for process documentation and validation.

Process Sampling using Flexboy® Bags



During the course of an operation, such as fermentation, it may be necessary to sample the bioreactor at regular intervals. When sampling from the process special care must be taken so as to avoid contamination of both the process itself and the sample being collected. Sartorius Stedim Biotech sampling manifolds and Flexboy® Bags allow the collection of a series of process samples from a common connection. Manifold assemblies can be assembled under sterile conditions and then connected to the process equipment through the use of an aseptic connector or a tube fuser. The manifold can then be used to draw off samples as required without further need for new connections. As samples are collected they may be isolated and disconnected using the Sebra Omni™ Sealer.

Q.C. Sample Bags on Flexel® 3D System



Flushing of the sampling manifold between sampling events can be accommodated by the provision of a separate, defined, waste pathway. This waste pathway can be fitted with a larger bag suitable for holding the total waste generated over the lifetime of the manifold.

Sampling manifolds can be assembled in response to demand, or purchased pre-assembled as sterile modules. Sampling manifold modules typically consist of between 2-4 Flexboy® Bags and associated tubing and clamps. If required modules can be linked by use of the aseptic connectors to create any desired configuration.