

Filtration and Mixing Solutions in Biopharma

FUNDAMIX®

Vibratory mixing systems

FUNDAMIX® SU

Single-Use mixing technology

FUNDABAC® SU

Single-Use filtration technology

STERIBAC®

Automated filtration and washing systems



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DrM

FUNDAMIX® - Vibratory Mixing Systems

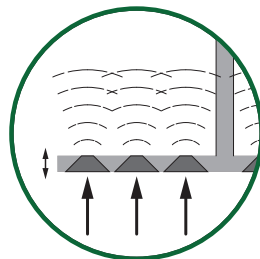
FUNDAMIX® - Mixing Systems

The FUNDAMIX®, also called Vibromixer, is a sophisticated mixing device that generates its mixing effect by vibrating a plate with conical bores. The oscillation of the plate causes the liquid to be pumped through the holes according to the Bernoulli effect. Its key advantages include low shear forces with a high mixing effect and high sterility due to the absence of rotating parts, resulting in low contamination risk. This mixing device is perfectly suitable for CIP and SIP and has very low energy consumption and maintenance costs.

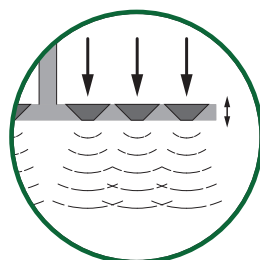
Over 1900 Systems are in operation for demanding applications such as insulin manufacturing, blood plasma fractionation, vaccine production and many more.



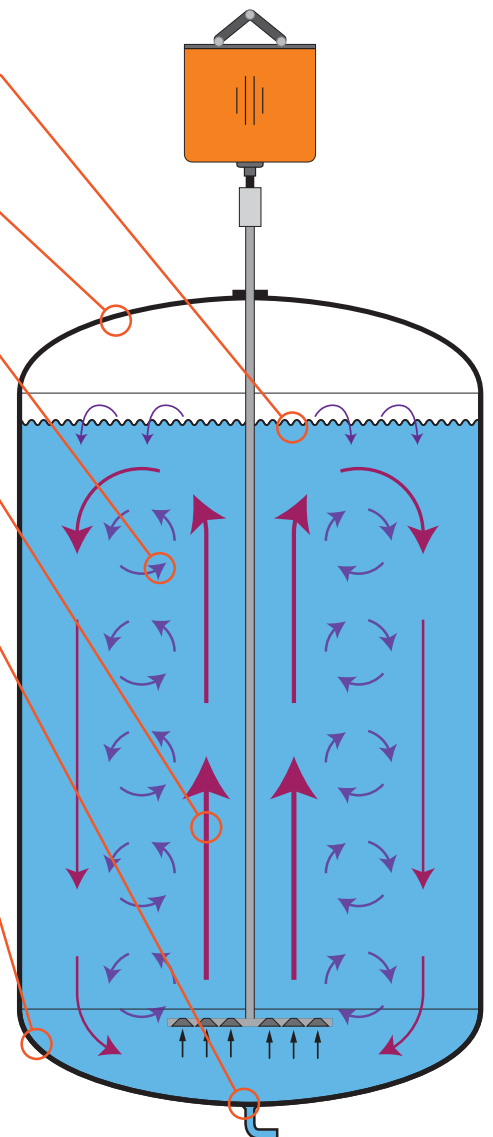
- No vortex formation
- Mixing volume: 0.1L in lab scale up to 40'000L in industrial scale
- Gentle mixing with low peak shear forces
- Axially agitated homogeneous mixing regime without the need for fluid breakers like baffles
- Reduced liquid heel volume due to low positioning of mixing plate
- No dead zones due to rounded container walls



type A: upwards flow



type B: downwards flow



Key Advantages:

- No rotating parts (low maintenance costs and less risk for contamination)
- No mechanical seal
- Effective & efficient mixing
- Low shear force
- Simple installation
- Long service life



FUNDAMIX® SU - Single-Use Mixing

FUNDAMIX® SU - Mixing Technology

Biopharmaceutical manufacturers are facing an ongoing change in terms of operational techniques and the selection of process equipment.

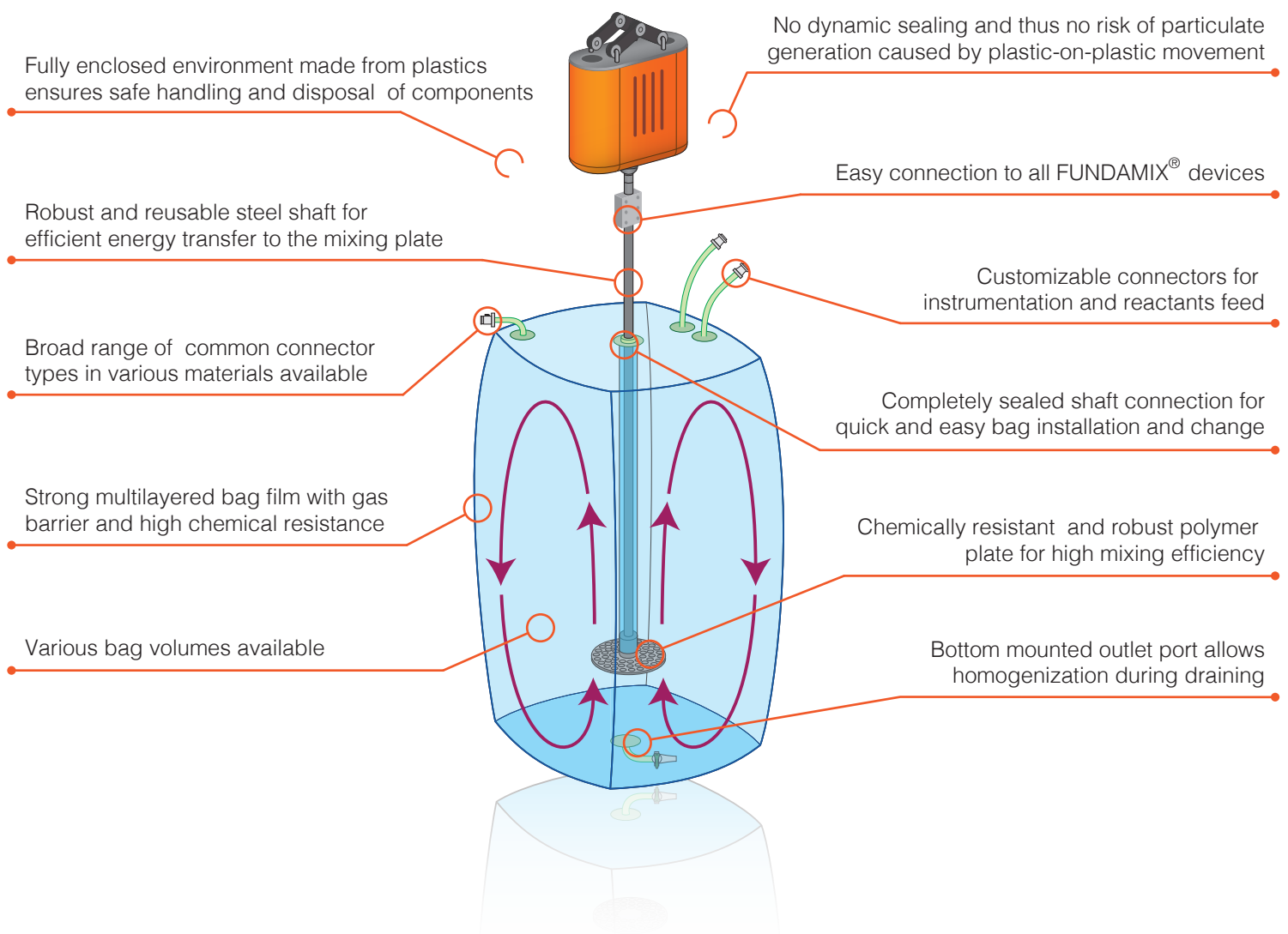
The current market demands and industry trends, i.e. industry 4.0, perfusion/continuous process, in-line measurement, real time control and single-use systems (SUS) offer best conditions to the biopharmaceutical manufacturers to decrease the COGS and increase speed, quality and flexibility throughout their entire production process.

To meet these demands, DrM has developed a new type of single-use mixing reactor, the FUNDAMIX® SU system, which combines the

proven FUNDAMIX® mixing technology (over 1900 stainless steel executions) with the advantages of a closed and disposable plastic enclosure. A broad range of different connections allows for a modular and very flexible approach in the design of the production chain. The bags are delivered sterilized and therefore cleaning/sterilization processes as CIP/SIP is no longer necessary.

Key advantages:

In addition to the main advantages of the FUNDAMIX® technology, the single-use bag system provides following benefits:



FUNDABAC® SU - Single-Use Filtration

FUNDABAC® SU - Filtration Technology

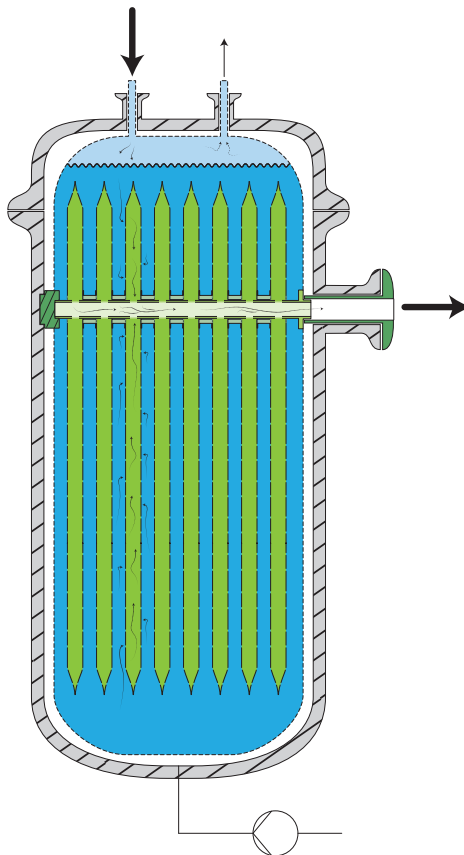
DrM's new single-use filter type, FUNDABAC® SU, consists of large surface area filter elements, packed into a fully contained plastic enclosure. It is a clever alternative for disposable filter cartridges for harvest and purification in biopharmaceutical processes.

The increased surface area boosts the filtration efficiency and results in a higher throughput. All exposed plastic surfaces are pre-sterilised and validated which makes CIP/SIP redundant. The filter bag is installed in a pressure vessel during filtration. This design opens up the possibility to compress the filter bag by applying an external pressure, resulting in very low liquid heel. The unique design allows a number of cycles, where the cake can be back-flushed and accumulated

on the bottom of the bag. Finally the compressed bag including the solid waste is in very compact form and can be removed and safely disposed of.

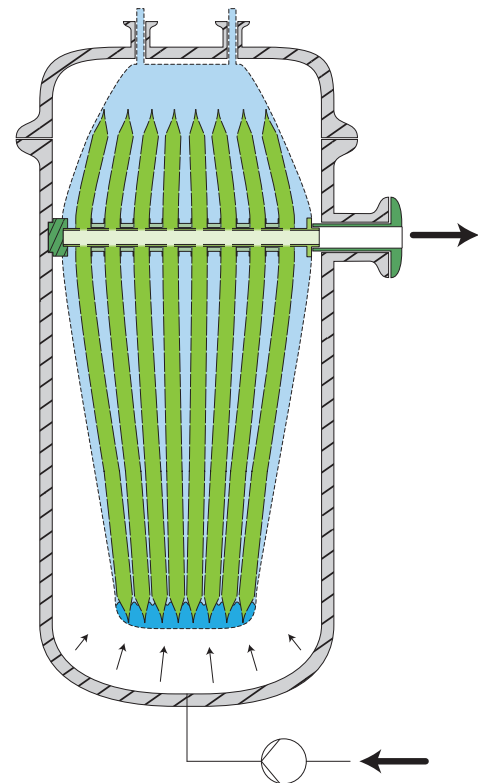
Key advantages:

- Decreased reactor downtime due to reduced cleaning and validation requirements
- Pre-sterilised and validated filter enclosure
- Reduced heel volume and compaction of solid waste due to the external pressure
- Fully enclosed containment made completely with plastics ensures safe handling and disposal of hazardous compounds
- Robustness
- Scalability



FILTRATION

During filtration the suspension enters the filter bag and is filtered through the filter membranes. The filtrate can then be extracted through manifold.



HEEL FILTRATION

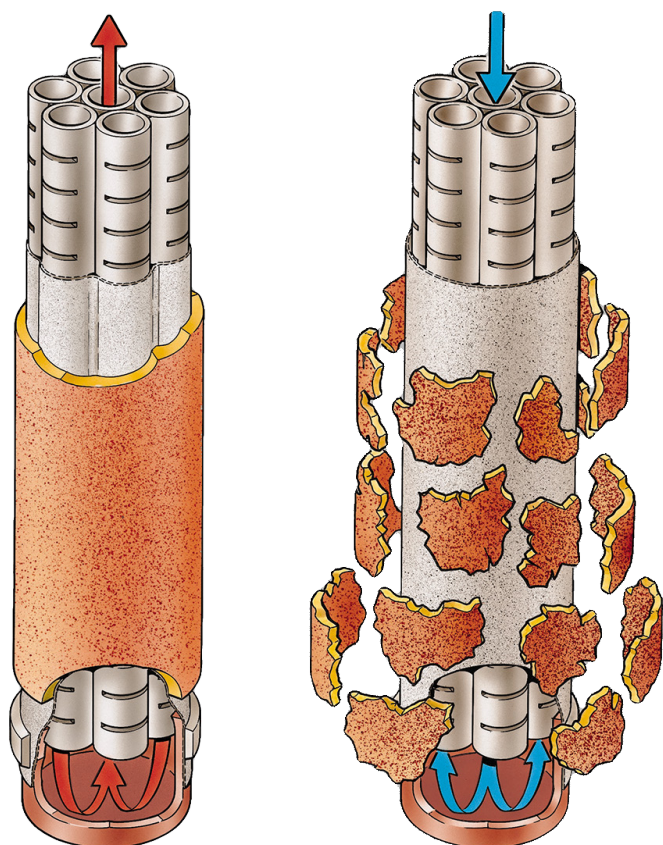
After the solid-liquid filtration is complete, air is pressed into the pressure vessel to squeeze the bag onto the filter elements. This reduces the liquid heel significantly.

STERIBAC® - Automated Systems

STERIBAC® - Filtration and Washing

The well-known technology of conventional DrM FUNDABAC® Filters is also the core of the STERIBAC® Filter; a permanent filtration system specifically designed for GMP applications. STERIBAC® Filters are closed, automatic systems with no rotating parts, suitable for CIP/SIP, with no residual product heel ensuring batch integrity.

The design of internals is a development of the FUNDABAC® and features: a polished surface down to $Ra=0.2\ \mu\text{m}$, a crevice-free candle shape, an extractable centre tube for quick disassembly and thorough cleaning and a bayonet coupling between the candle and register.



Formation and drying of the filter cake with DrM's automated FUNDABAC® candle filter system.



STERIBAC® automatic units in skid mounted execution. GSK Biologicals, Singapore.

Key advantages:

STERIBAC® Filters are the ideal solid-liquid separation equipment for API production processes, such as:

- Separation of biomass from fermentation slurries
- Separation of precipitates in downstream processes
- Separation of activated carbon or catalyst
- Separation and washing of crystals

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