

BIOPHARMA

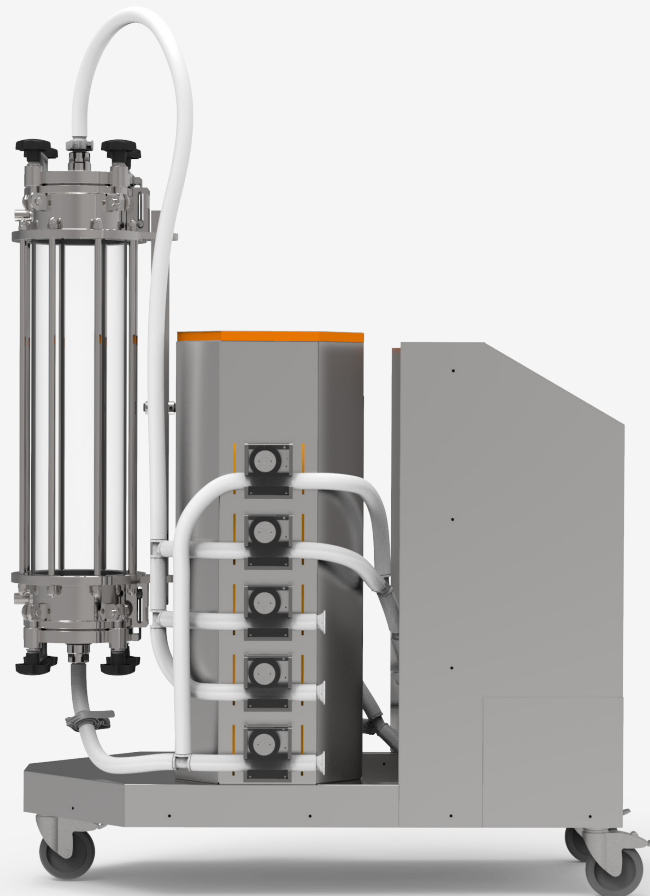
Filtration and mixing solutions



FUNDALOOP[®]©

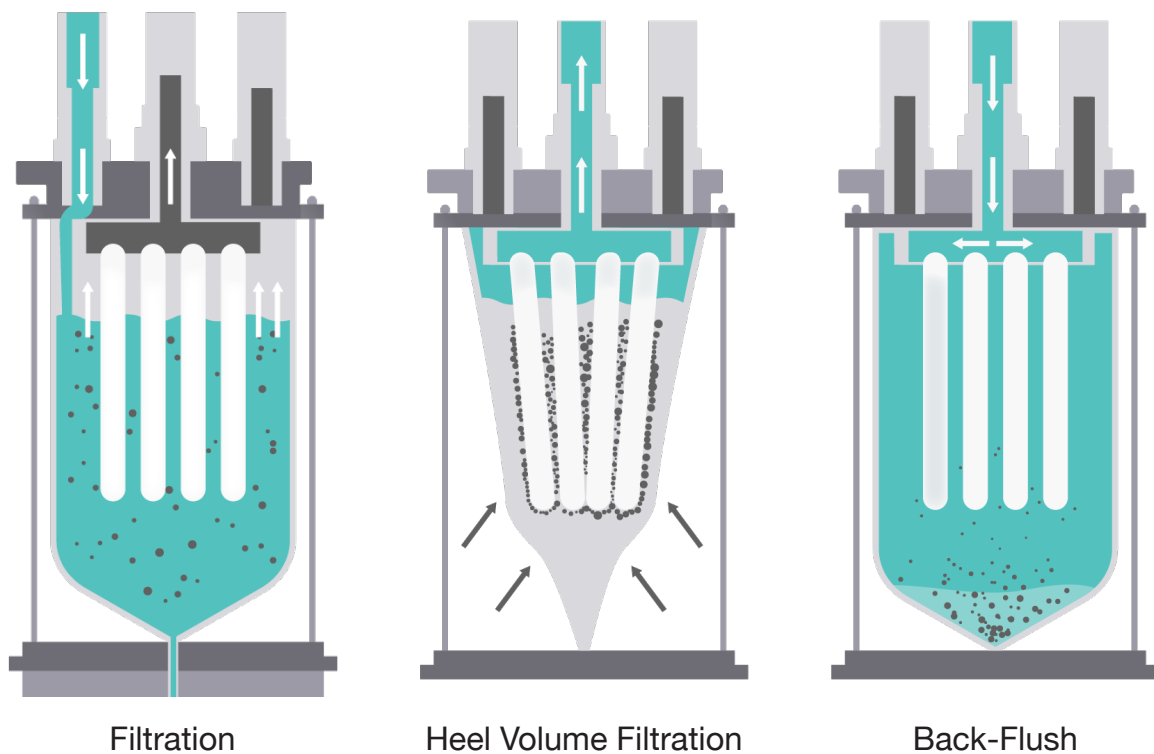
Single-use filtration system

Our new single-use filter type, FUNDALOOP[®], consists of large surface area filter elements, each of which is surrounded by a filtration cloth and packed into a fully contained plastic enclosure. It is a clever alternative to 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 allows the ability to compress the filter bag by applying an external pressure, pushing all of the remaining suspension forward and reducing the heel volume as much as possible.

The filter can be run a multi-cycle operation, where the cake can be back-flushed and discharged of the bag. The back flush step restores the filter cloths to their full capacity, and the filter bag is ready to be filled and filtered for another cycle. This single-use but multi-cycle design sets the FUNDALOOP[®] apart from every other filtration solution.



The unique FUNDALOOP® design allows for performing single-cycle and multi-cycle filtrations, where the cake can be back-flushed and accumulated on the bottom of the bag. Finally the compressed bag containing the solid waste is removed and safely disposed of in a very compacted form.

Key advantages

- 2-3 times faster flow rates than depth filters
- Decreased downtime due to reduced cleaning and validation requirements
- Pre-sterilised and validated filter enclosure
- Capable of combining both primary and secondary filtration in one step
- No turbidity breakthrough
- One 30L filter bag can process up to 2000L of material
- Lowers amount of plastic waste necessary to process a single batch
- No preflushing with water necessary
- Reduced heel volume and compaction of solid waste due to external pressure
- Closed system can be used over multiple cycles without compromising sterility

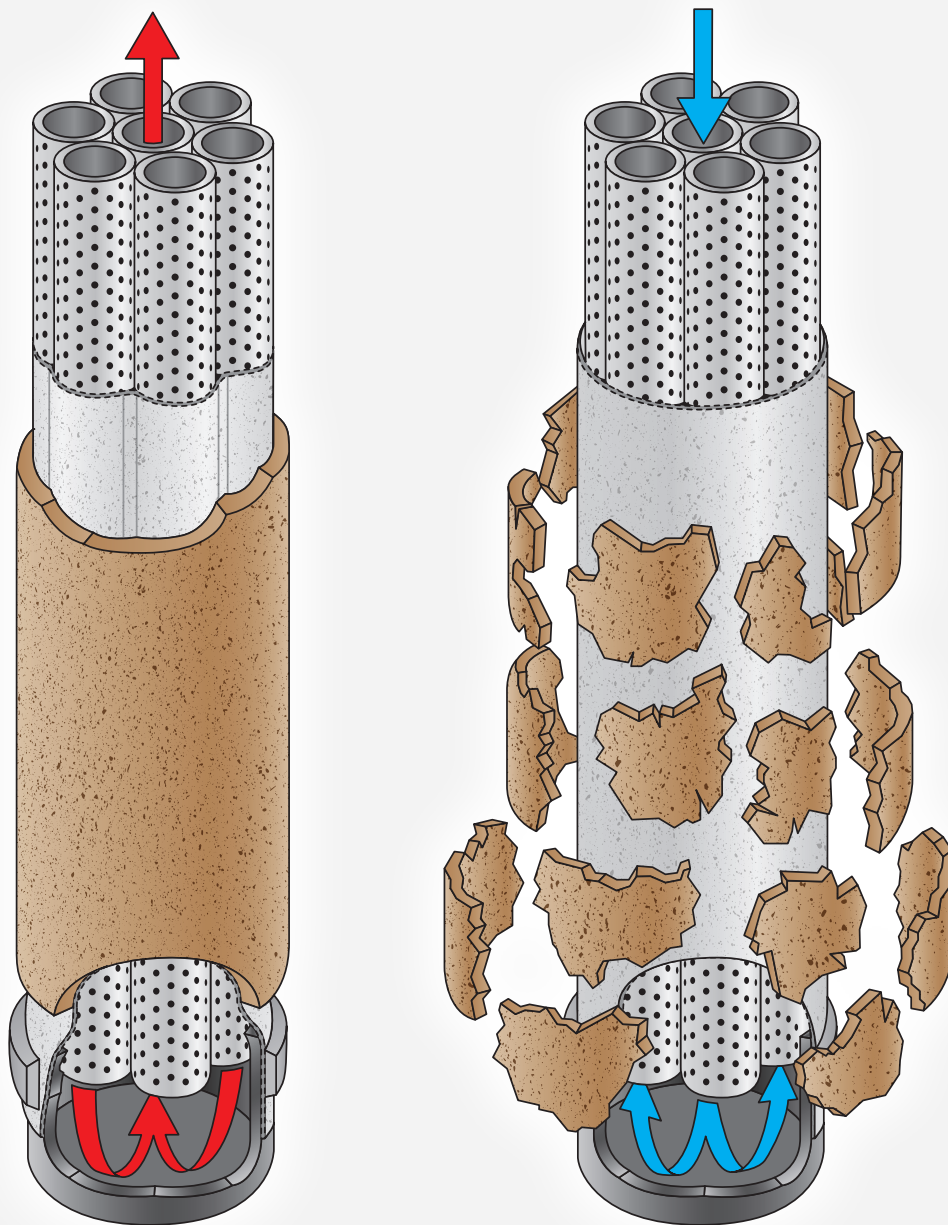
STERIBAC[®]

Hygienized filtration system

The well known technology of conventional DrM FUNDABAC[®] Filters is also the core of the STERIBAC[®] Filter; a permanent filtration system specifically designed for cGMP 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 $Ra=0.2 \mu m$, 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 the automated STERIBAC® candle filter system.

Key advantages

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

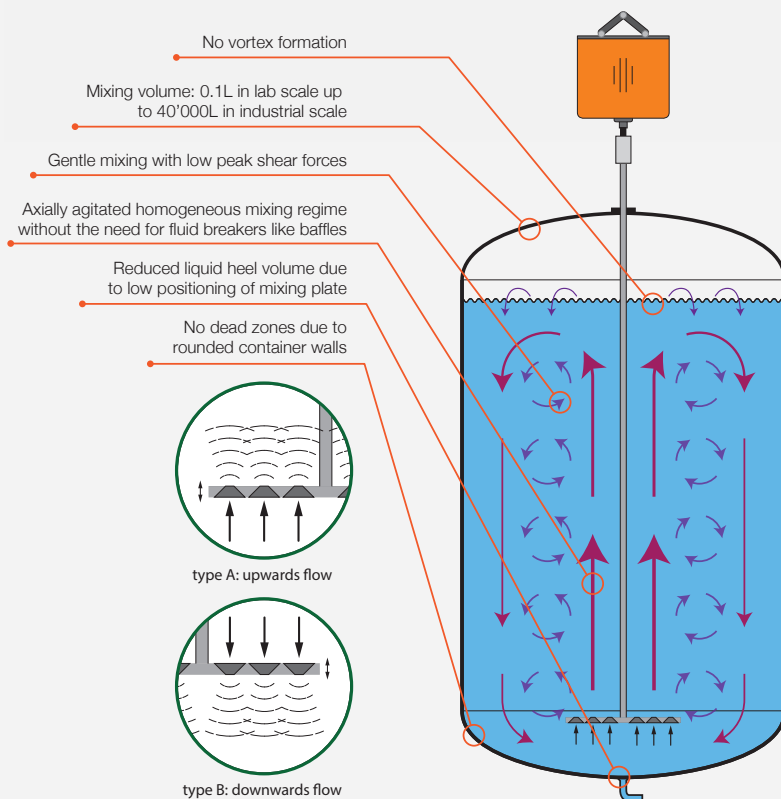
- Separation of biomass from fermentation slurries
- Separation of precipitates in downstream processes
- Separation of activated carbon or catalyst
- Separation and washing of crystals

FUNDAMIX[®]

Vibratory mixing system

The FUNDAMIX[®] 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 manufacture, blood plasma fractionation, vaccine production and many more.



Key advantages

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

FUNDAMIX[®] SU

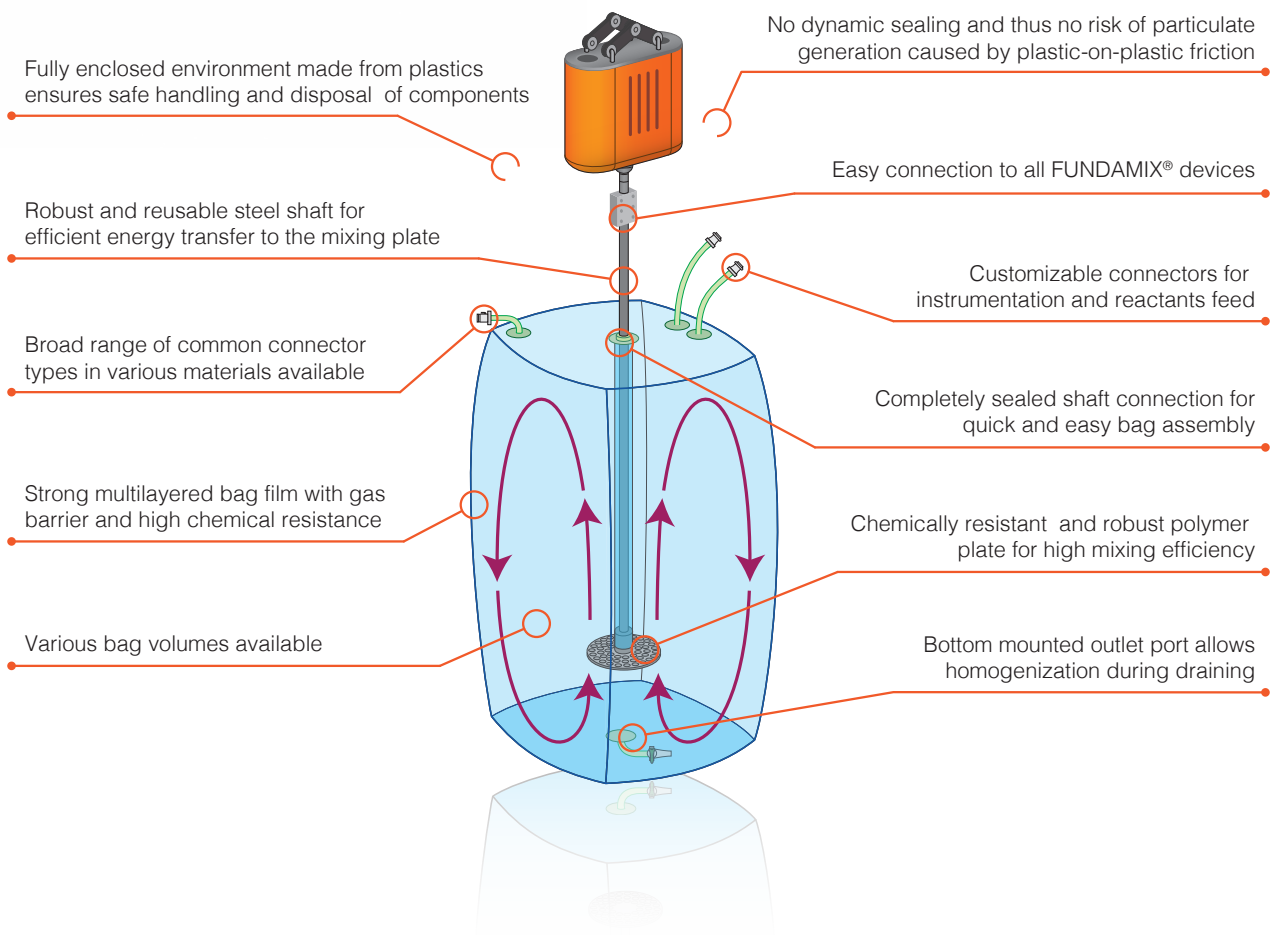
Single-use vibratory mixing system

DrM has developed a new type of single-use mixing device, 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 wide 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

The FUNDAMIX[®] SU mixing technology provides the following benefits, in addition to the main advantages of the conventional FUNDAMIX[®] technology:





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