

# Single-Use Filtration and Mixing

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Solutions for cell harvesting and bioreactor agitation



# Single-Use Filtration

## FUNDALOOP®

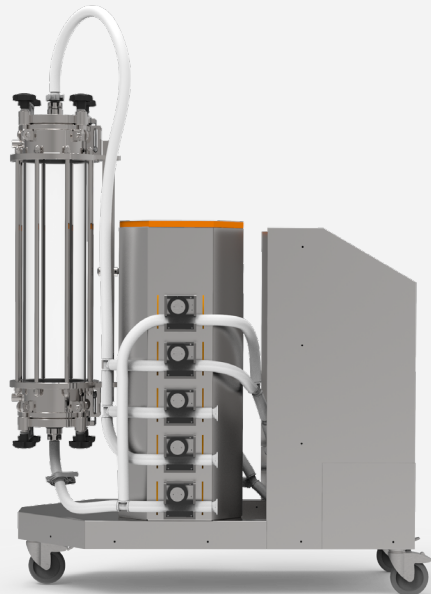
DrM's new single-use filter FUNDALOOP® consist of large surface filter elements, packed into a fully contained plastic enclosure. It is a clever alternative to disposable filter cartridges for cell harvesting and purification in biopharmaceutical processes.

Additionally, the design is ideally suited for handling toxic or otherwise hazardous substances in a fully enclosed environment. The filtered solids can be sent for disposal inside the closed plastic bag and do not need to be handled further.

The increased surface area boosts the filtration efficiency and results in high throughput. For pharma/biotech applications, plastic components in contact with the process medium can be pre-sterilised, making 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 at the end of the filtration cycle, thus also allowing filtration of the liquid heel.

Both single-cycle and multi-cycle filtrations can be performed due to the unique filter design. The cake can either be back-flushed and accumulated on the bottom of the bag, allowing for a safe disposal of the solid waste once the required filtration cycles are performed. Alternatively, the cake can be discharged out of the filter bag after each cycle.

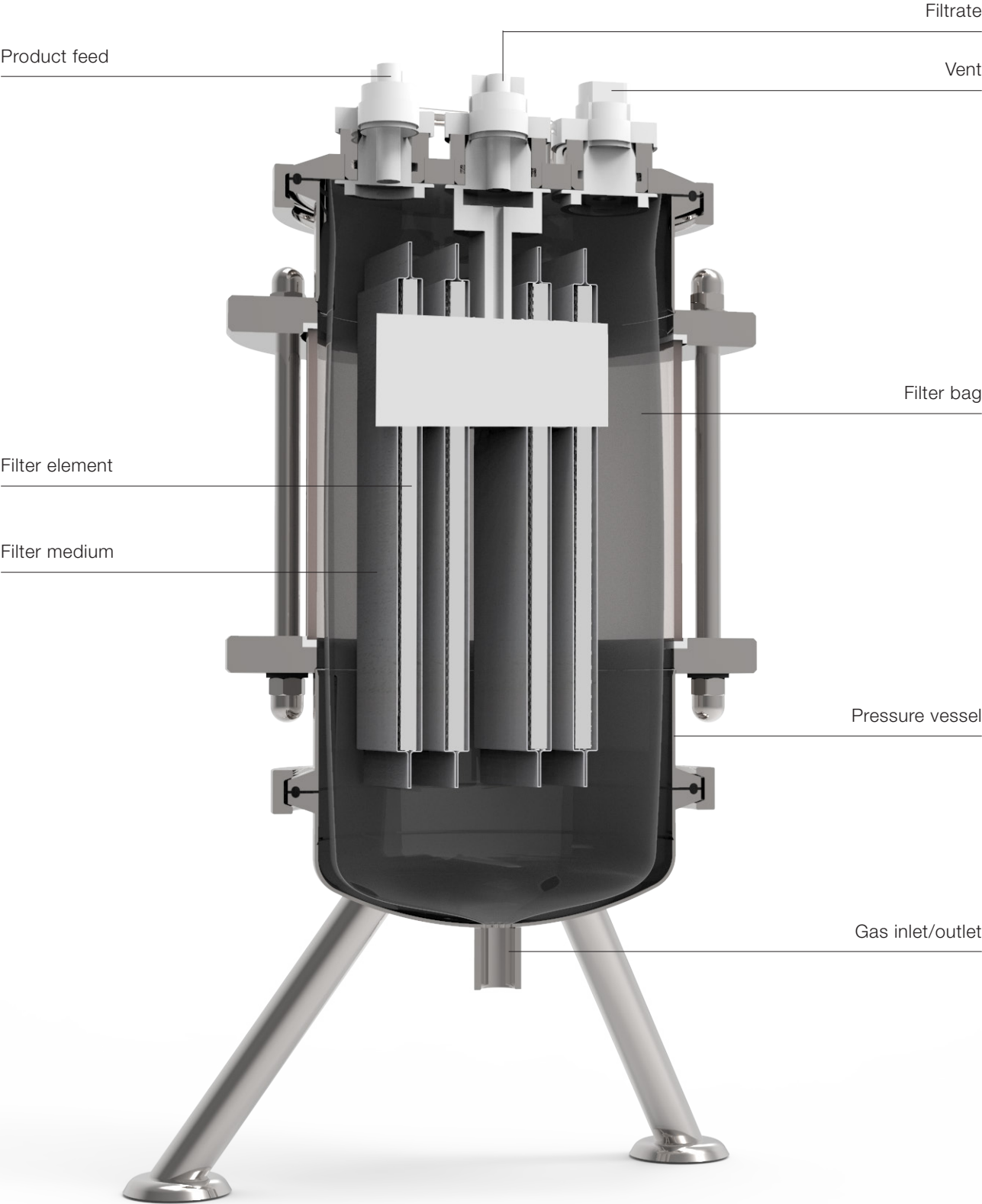


## Key advantages

- High throughput
- Increased yield in cell recovery and enzyme recovery operations
- Shorter reactor downtime due to reduced cleaning and validation requirements
- Pre-sterilised and validated filter enclosure available for pharma/biotech applications
- Reduced heel volume and compaction of solid waste thanks to the external pressure
- Fully enclosed containment made completely with plastics ensuring safe handling and disposal of hazardous components
- Multilayered plastic bag providing superior robustness

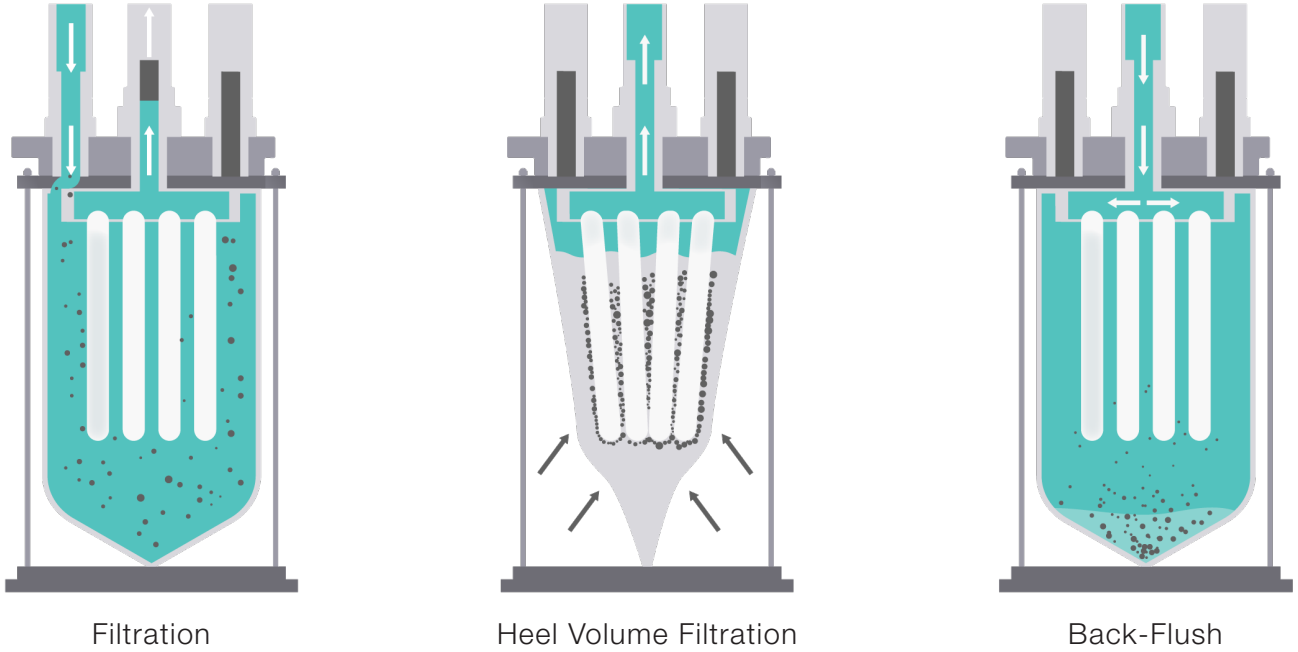
# FUNDALOOP®

## A closer look at the main components



# FUNDALOOP®

## Multicycle filtration operating principles

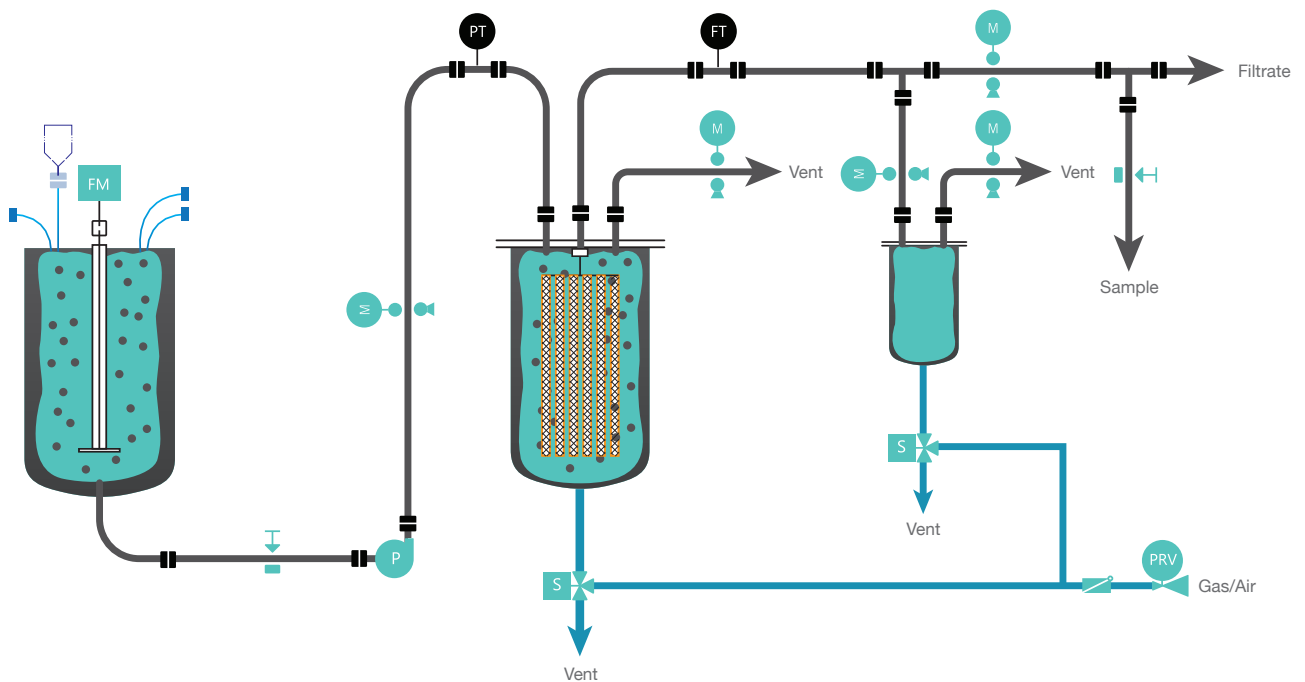


The unique FUNDALOOP® design allows for performing single-cycle and multi-cycle filtrations, where the cake can be back-flushed and accumulated on the bottom of the bag. Finally the compressed bag containing the solid waste is removed and safely disposed of in a very compacted form.

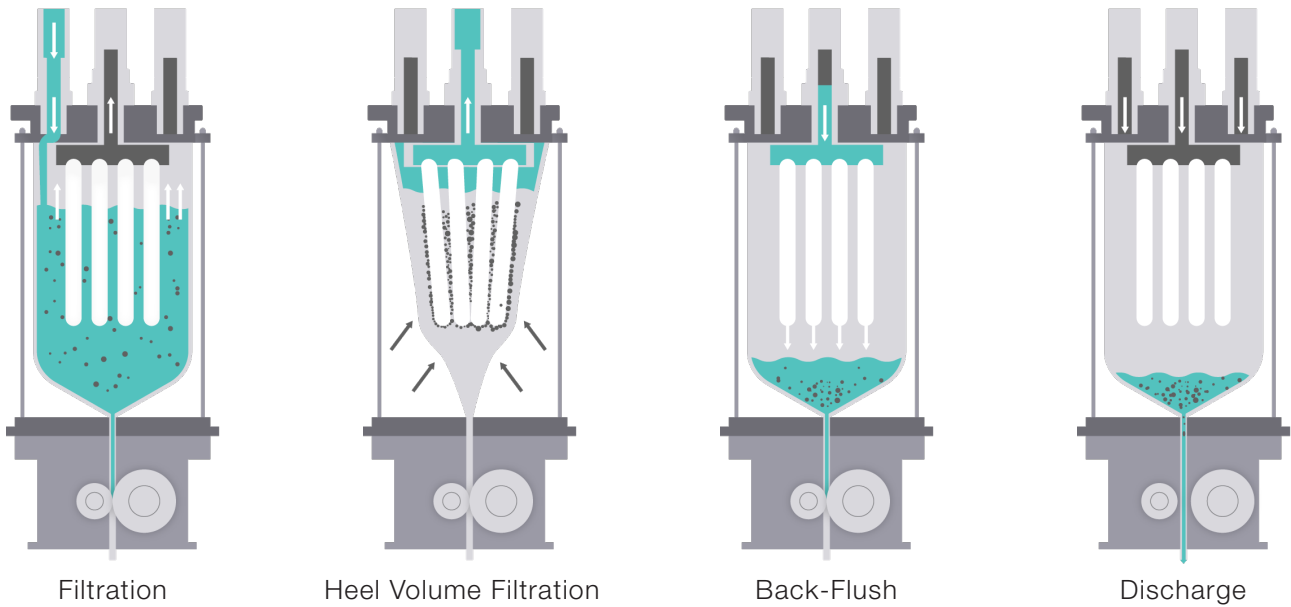
FUNDAMIX® SU

FUNDALOOP®

BACK-FLUSH TANK



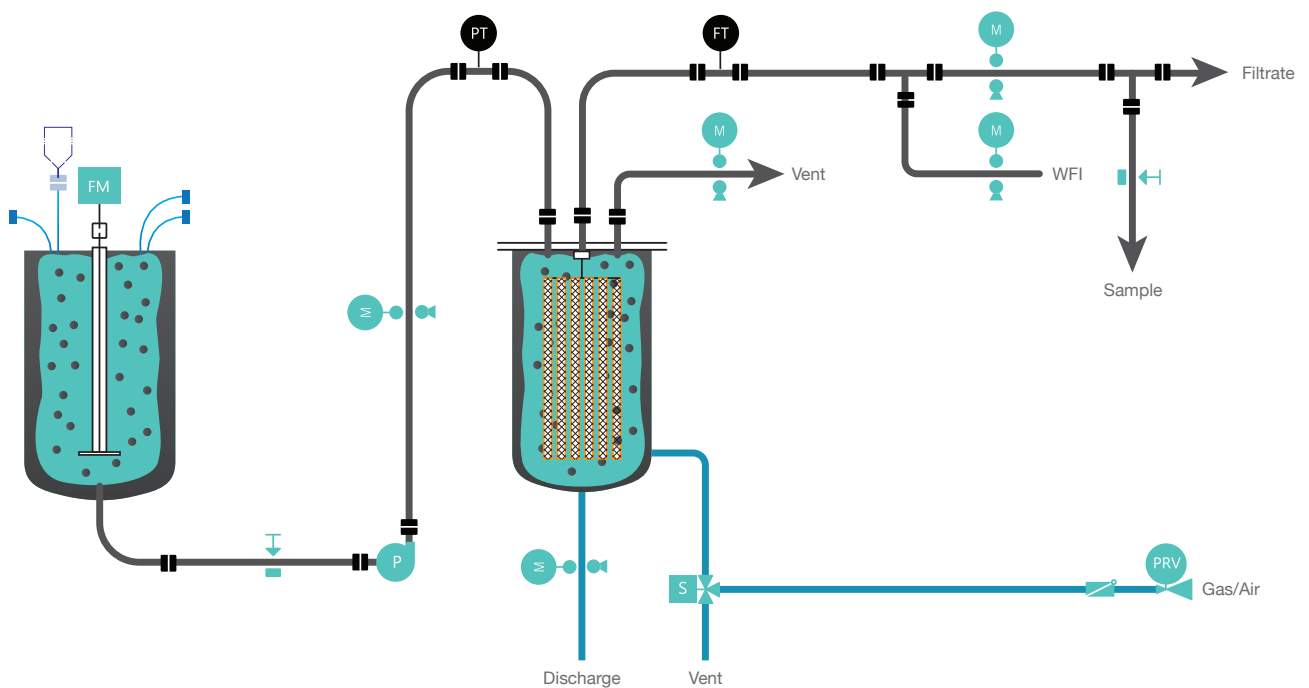
# High capacity filtration operating principles



This unique FUNDALOOP® design incorporates a discharge opening to allow almost unlimited filtration cycles. This significantly increases the capacity at minimum footprint and reduces operating cost.

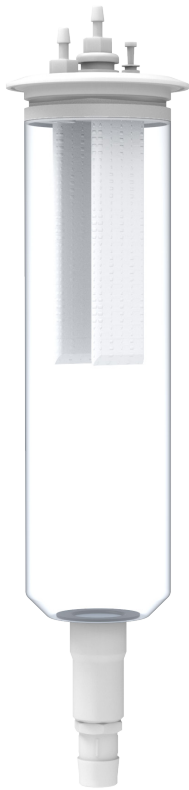
FUNDAMIX® SU

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# FUNDALOOP®

## CHO cell harvest test results

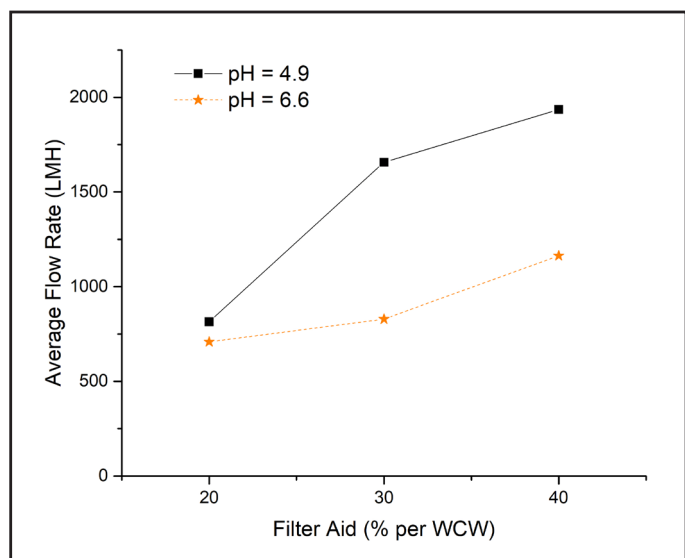


### FUNDALOOP® bag

A FUNDALOOP® 200 filter with two elements was used to filter out Chinese Hamster Ovary (CHO) cells. The cell suspension was mixed with Cellpure C300 filter aid to enhance the filtration rate and quality. A highly permeable filter cake was formed during the filtration, which was subsequently back-flushed to regenerate the filter media. Once back-flushed, the cake was discharged through the bottom connector to regenerate the encapsulating plastic bag for the next cycle.

### Flow rate

- Cake filtration allows for high average flow rates to be achieved
- The flow rate increases with increasing amount of filter aid
- A pH reduction agglomerates impurities such as cell debris, DNA, and host cell proteins, thereby increasing the flow rate



Average flow rates over 5 minutes of filtration at a pressure of 1.5 bar. The tested culture had 22 million cells per ml. The filter aid is given relative to the wet cell weight (WCW).

## Multi-cycle

- After each cycle, the filter media is back-flushed, which removes the cake and regenerates the filter
- Due to the regeneration, a high average flow rate can be maintained over many cycles
- Other benefits of the cyclic operation are:
  - Smaller filter required
  - Lower footprint
  - Lower investment/operating cost
  - Less leachables/extractables
  - Suitable for large batches and high cell densities

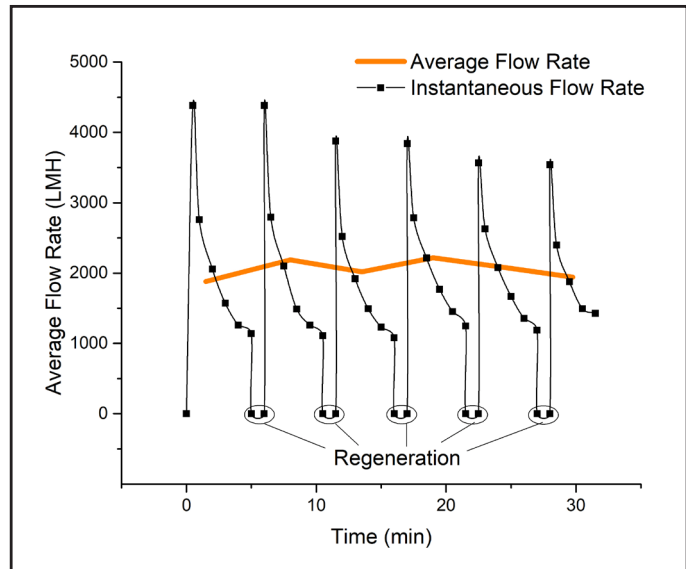


Figure 2: Instantaneous and average flow rates at a reduced pH, performed at a pressure of 1.5 bar and 40% filter aid per WCW. The tested culture had 22 million cells per ml.

## Turbidity

- Regardless of the amount of filter aid and pH, turbidities below 15 FNU are achieved
- The turbidity is reduced by 98 – 99%
- The high filtrate quality extends the lifetime of downstream filters

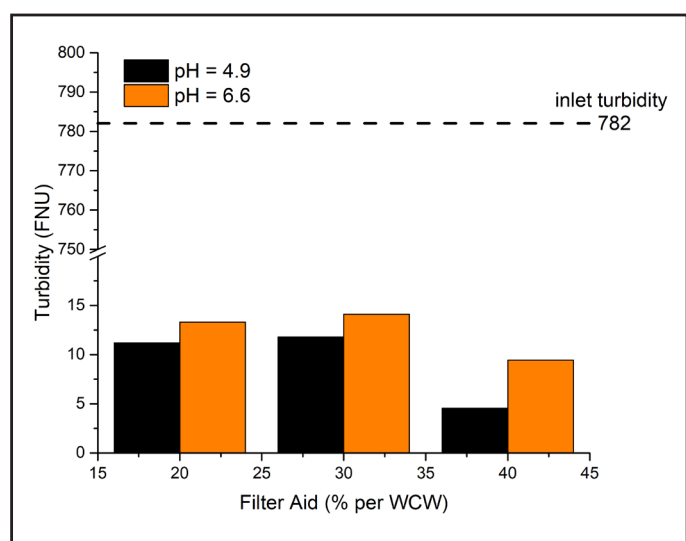


Figure 3: Turbidity measurements at the crude pH and a reduced pH for 20 – 40% filter aid per WCW. The tested culture had 11 million cells per ml. The dashed line shows the inlet turbidity.

# Single-Use Mixing Technology

## FUNDAMIX® SU – Mixing technology

DrM has developed a new type of single-use mixing device, the FUNDAMIX® SU system, which combines the proven FUNDAMIX® high performance mixing technology 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. For biotech applications the bags for our single-use mixer are delivered pre-sterilized and therefore cleaning/sterilization processes as CIP/SIP are no longer necessary.

The FUNDAMIX® SU offers many distinctive features of the standard FUNDAMIX® technology, such as low shear force but powerful mixing action, making it perfectly suited for homogenisation, powder suspension, pH adjustment, media preparation, fermentation and many other typical biotech process operations.

Lab scale tests can be meant to investigate a few basic parameters (homogenization efficiency, possibility to achieve a shear-free mixing, capability of suspending settling or floating solids, etc.) or can simulate a whole process (crystallization, fermentation, heat transfer, pH control). DrM can provide laboratory sets and accessories for special applications or complete customized systems based on the exact client's requirements.

### Key advantages

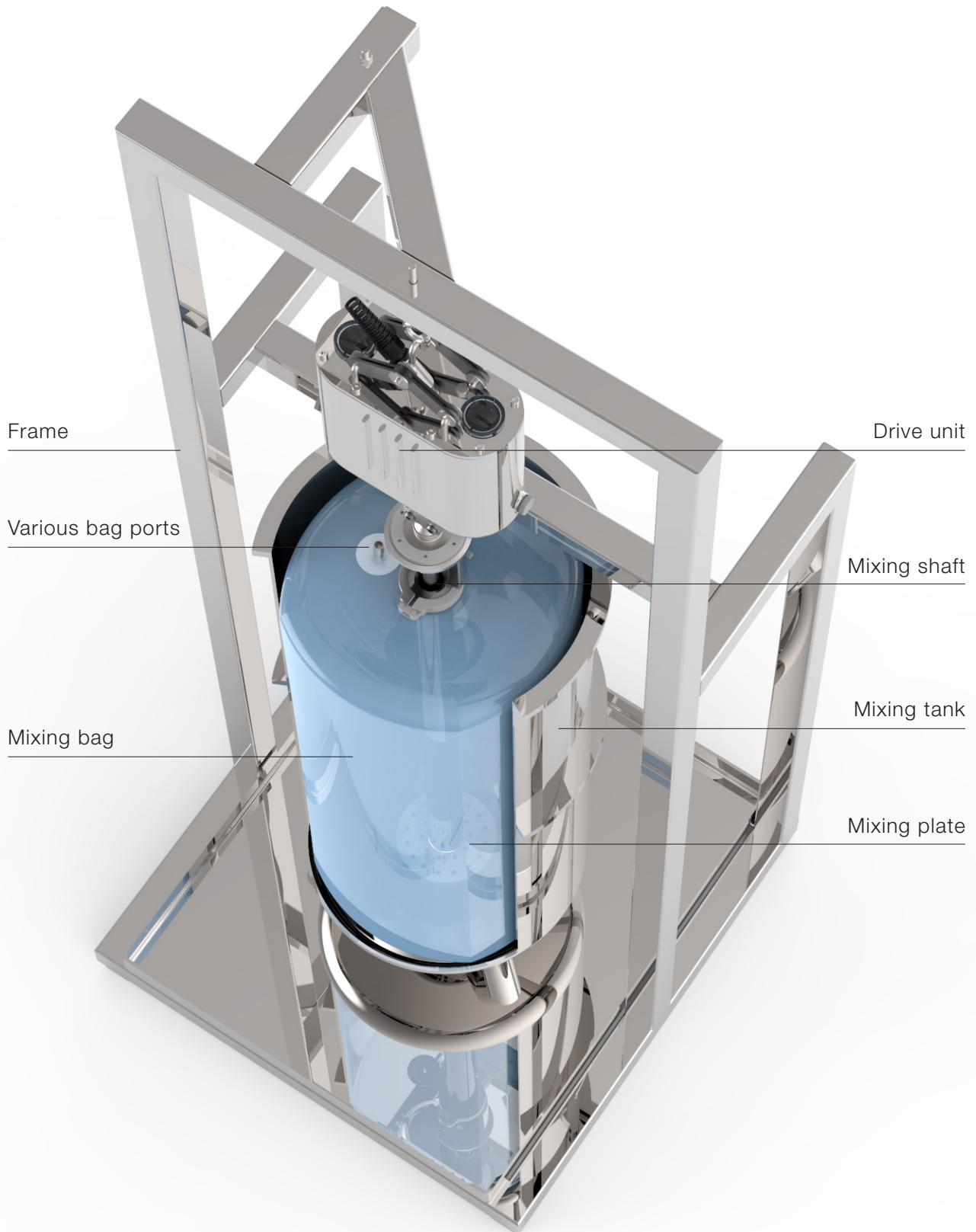
- Fully enclosed environment made from plastics ensures safe handling and disposal of components
- Robust and reusable steel shaft for efficient energy transfer to the mixing plate
- Strong multilayered bag film with gas barrier and high chemical resistance
- Various bag volumes available
- No dynamic sealing and thus no risk of particulate generation caused by plastic-on-plastic friction
- Easy connection to all FUNDAMIX® drive devices
- Completely sealed shaft connection for quick and easy bag assembly
- Chemically resistant and robust polymer plate for high mixing efficiency
- Bottom mounted outlet port allowing homogenization during draining





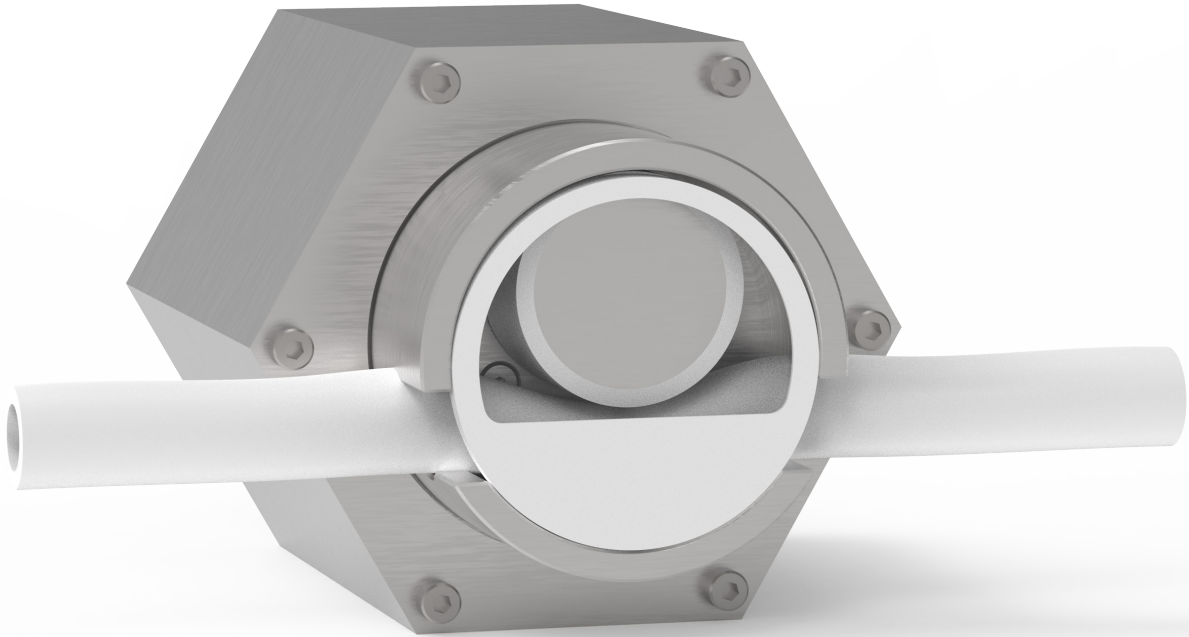
# FUNDAMIX<sup>®</sup> SU

A closer look at the main components



# Single-use Pinch Valve

full on/off flow control

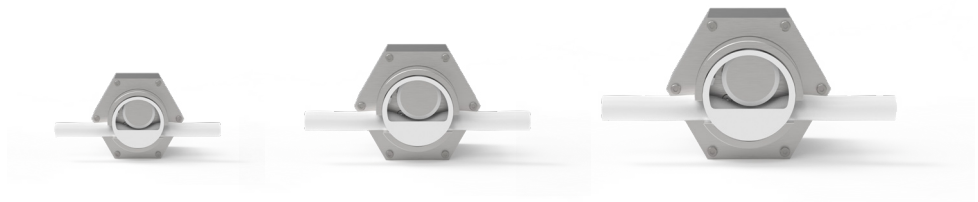


Pinch valves are often used in single-use applications for on/off flow control. As the valve does not get in contact with the process media it does not require replacement of any parts. Only the flexible tubing is being changed as a single use item. For non-pressure designs simple solenoid-driven pinch valves can be used, but when pressure needs to be applied, such as in filtration equipment the significantly tougher tubings together with the internal pressure pose a significant burden to the pinch valve and standard solenoids normally cannot do the job.

A newly developed design allows for on/off control of pressurized single-use tubings in a compact package. The electrically driven actuator is a microprocessor-controlled geared motor which opens and closes when an ON or OFF signal is received. The tubing firmly sits in a well-defined bed which guarantees uninterrupted operation for many cycles. The valve can either be supplied as stand-alone type or it can be easily installed within a cabinet with only the actuated part being visible.

The combination of this component with our single use filtration system is a perfect fit.

SU VALVE	Micro	Mini	Uni
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Type	Pinch, non-invasive	Pinch, non-invasive	Pinch, non-invasive
Actuation	Remote from PLC, local with switch and via App (iPhone)		
Actuation Time (open and close)	3 sec	3 sec	3 sec
Weight	0.2 kg	1.1 kg	2.6 kg
Dimensions (L x Ø)	97mm x 50mm	140mm x 73mm	195mm x 120mm
Max. op. Pressure (barg)	5 - 20 (*1)	5 - 20 (*1)	5 - 20 (*1)
Max. op. Temperature	60 °C	60 °C	60 °C
Hose size	OD 3 - 9 mm OD 1/8" - 3/8"	OD 9 - 20 mm OD 3/8" - 3/4"	OD 20 - 35 mm OD 3/4" - 1 3/8"
Material	316L / HDPE / POM	316L / HDPE / PA	316L / HDPE / PA
Protection Rating	IP65	IP65	IP65
Power consumption	Idle position: 0.1W In operation (3s): 5W	Idle position: 0.1W In operation (3s): 10W	Idle position: 0.1W In operation (3s): 20W
Power Supply	12 - 24 Vdc (*2)	24 Vdc	24 Vdc
Material	316L / HDPE / POM	316L / HDPE / PA	316L / HDPE / PA
Max. op. Pressure (barg)	5 - 20 (*1)	5 - 20 (*1)	5 - 20 (*1)
Max. op. Temperature	60 °C	60 °C	60 °C
Protection rating	IP65	IP65	IP65
Signal Input (Analog Mode)	4...20mA (24Vdc)	4...20mA (24Vdc)	4...20mA (24Vdc)
Signal Input (ON/OFF Mode)	NC: ON (24Vdc) / OFF (0Vdc) NO: ON (0Vdc) / OFF (24Vdc)		
Non Conformity Alarm	Normal: 0Vdc / Non Conformity: 24Vdc		
Electrical connections	Power 24Vdc, Ground, Signal Input 24Vdc, Non Conformity Output 24Vdc		
Chemical resistance	Suited for IPA Cleaning (Cleanroom airlocks)		
Notes	*1: Max. operating pressure depends on tube size. *2: Nominal voltage 12V. Valve can operate at 24V by adjusting power settings in the App. Opening and closing times depend on power setting and tube diameter.		



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