



Flexel® Drum for LevMixer®



Description

The Flexel® Drum for LevMixer®¹ is a single-use mixing solution utilizing cylindrical tank geometries combined with the ATMI levitated impeller and Sartorius Stedim Biotech Flexel® 3D Bag technologies.

Components

1. LevMixer® Drum-PE are designed to fit perfectly with the Flexel® Drum Bags for LevMixer® and the integrated impeller. The tanks are positioned on a stainless steel LevMixer® Dolly to ensure a safe operation as well as easy access and drainage. The LevMixer® Dolly contains a railed port for coupling the LevMixer® Drive Unit with the Flexel® Drum Bag for LevMixer®. They are available in 50 L, 100 L, 200 L, 300 L, 370 L and 560 L volumes to be used with the 50 L to 560 L Flexel® Drum Bag for LevMixer®.

2. LevMixer® Drum-Stainless Steel are available in 50 L, 100 L, 200 L, 300 L and 370 L. The tanks are positioned on a stainless steel LevMixer® Dolly to ensure a safe operation as well as easy access and drainage. In the volumes of 560 L, 750 L and 1,000 L the tanks are mounted on legs that are equipped with cleanroom wheels for increased mobility. They incorporate an interface railed port for coupling the LevMixer® Drive Unit with the impeller inside the bag.

3. LevMixer® drive unit generates the levitation and rotation of the single-use magnetic impeller without surface contact. The Flexel® Drum® for LevMixer® can ideally be applied for ultra clean mixing, low shear mixing, liquid-liquid mixing, re-homogenization and re-suspension. The LevMixer® Drive Unit is mobile, cart-mounted and designed to interface with mixing tanks of different volumes. The LevMixer® Drive Unit is capable of local or remote operation and mixing recipes management via the touchscreen PLC.

4. Flexel® Drum Bags for LevMixer® contain a magnetic impeller assembly positioned for maximum flexibility and performance for all applications. They offer scalability, ease of use and robustness.

Clean and sterile mixing operation

A patented superconducting technology is utilized to levitate and drive the single-use impeller inside sterile single-use Flexel® Drum Bags for LevMixer®. When aligned with the specially designed LevMixer® impeller, the LevMixer® Drive Unit causes the impeller to levitate and lock in position. Thus it generates no friction or mechanical stress on the bag during mixing and avoids unwanted particle shedding that will influence the purity of the product.

Applications

The Flexel® Drum Bag for LevMixer® with a levitating impeller generates moderate mixing forces with an impeller speed up to 210 rpm. The Flexel® Drum Bag for LevMixer® can ideally be applied for ultra clean mixing, low shear mixing, liquid-liquid mixing, re-homogenization and re-suspension. Standard applications are:

- Cell harvest re-suspension,
- pH adjustment of intermediate bulk,
- Product collection from chromatography columns,
- Viral inactivation
- Formulation of adjuvant and final bulk.

Features & Benefits

Levitated mixing technology	Ultra clean and low shear mixing operation
Local or remote operation with the LevMixer® drive unit	Mixing process parameters monitoring and control
Real impeller speed reading	Process control and security
Mixing recipes management via touchscreen PLC	Process steps are executed exactly and in accordance with specified procedures
Various bag & tank sizes	High flexibility
Standard Flexel® Drum Bags for LevMixer® designs	Most designs are available from Stock
All connections are intensively qualified	Safe and robust
Multiple manufacturing sites	High security of supply
Full compliance with ISO 11137	Highest sterility assurance level

¹ LevMixer is a trademark or registered trademark of ATMI, inc in the United States, other countries or both and this product uses ATMI patented LevMixer® technology. Using ATMI patented mixing technology.

Flexibility

The LevMixer® Drive Unit operates independently of the cylindrical tank with the Flexel® Drum Bags for LevMixer® so that a single LevMixer® Drive Unit can serve multiple tanks of different sizes.

Flexel® Drum Bags for LevMixer® are available from stock. They can be readily customized to optimize the integration into specific processes. Expert design service is available on-site through Sartorius Stedim Biotech Application Specialists on a worldwide basis.

Validation

Flexel® Drum Bags for LevMixer® have been qualified applying the most stringent and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® Drum Bags for LevMixer® with data representing the widest range of process fluids in a variety of processing conditions. The validation of the Gamma Irradiation for all Sartorius Stedim Biotech single-use products is done in full compliance with ISO11137 to ensure a sterility assurance level of 10⁻⁶ over their shelf life.

Flexel® Drum Bags for LevMixer® are tested for compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulate
- ISO 11737: Bioburden
- ISO 11137: Sterilization of Medical Devices

Quality Assurance

Sartorius Stedim Biotech Quality Systems for Single-Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements

Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions based on collaborative supplier management and customer demand planning assures a state of the art and robust supply chain that can cope with strong market growth.

Specifications

1. LevMixer® Drive Unit

Footprint in mm (inches) W x L x H:	Collapsed configuration: 407 x 1118 x 915 mm (16 x 44 x 36 in.) Expanded configuration: 407 x 1311 x 915 mm (16 x 51.6 x 36 in.)
Weight:	123 lbs (56 kg)
Control box, cart & mixer enclosure material:	304L Stainless Steel
Control box, cart & mixer enclosure surface finish	At least 35 µin. Ra 0.89 µm Ra
Control box ingress rating:	IP 65
Enclosure ingress rating:	IP 23
Voltage:	100 – 230 VAC, 50 60Hz
Input Wattage:	Less than 350W
Amperage:	100V 3.0 A; 110V 2.5 A; 230V 1.5 A
Voltage fluctuation:	+/- 10%
Altitude rating:	1000 m (3280 ft)
Max humidity:	85%, avoid condensation
Ambient temperature:	4 – 40°C
Motor horsepower:	1/8 hp
Power cord length:	6 m (20 ft)
E-stop (present, yes no, location):	Yes, face of control box
Min and Max impeller speed:	20 to 210 RPM
Connections for remote output control:	TURCK RSFPV61, RSFPV579
Functions available from remote control panel:	Motor – start, stop Speed – adjustment, indication. Alarm – indication Mode of control (remote local) – indication
Signal type(s) for remote output control:	Impeller speed out 4 – 20 mA, motor control in 0 – 10VDC, discrete I O signals relay contact type
Mixer charge time:	35 minutes
Operator interface type:	Touchscreen PLC
Method for RPM measurement:	Direct measurement of impeller speed via non-contact magnetic sensor
Noise level at operator position:	67 dB
Mobility:	Mounted on stainless cart with four clean room wheels and push Handles 2 x swivel (front), 2 x stationary (rear)
Wheel material:	Polyurethane
Recipe storage:	Up to 10 recipes can be stored
Password protection:	Operator, Supervisor, Maintenance levels
CE Mark	Compliant
UL	Compliant

2. LevMixer® Drum-PE

Material:	HDPE
Volumes:	50 L – 560 L
Dimensions & weight:	Height Diameter
50 L:	22" (559 mm) 14.75" (374 mm) 8 lbs (3,6 kgs)
100 L:	35" (635 mm) 18.25" (463 mm) 9 lbs (4 kgs)
200 L:	37" (940 mm) 21.50" (546 mm) 22 lbs (10 kgs)
300 L:	46" (1,168 mm) 23.25" (590 mm) 35.5 lbs (16.1 kgs)
370 L:	41" (1,041 mm) 27.37" (695 mm) 38.5 lbs (17.5 kgs)
560 L:	53" (1,346 mm) 23.31" (744 mm) 53 lbs (24 kgs)

3. LevMixer® Drum-Stainless Steel

Material:	Stainless Steel # 316L	
Volumes:	50 L – 1,000 L	
Dimensions:	Height Diameter	
50 L:	22" (559 mm) 14.75" (374 mm) 35" (635 mm)	
100 L:	18.25" (463 mm) 200 L:	37" (940 mm) 21.50" (546 mm)
300 L:	46" (1,168 mm) 23.25" (590 mm)	
370 L:	41" (1,041 mm) 27.37" (695 mm)	
560 L:	53" (1,346 mm) 23.31" (744 mm)	
750 L:	48.5" (1,232 mm) 35.875" (911 mm)	
1,000 L:	48.5" (1,232 mm) 42.125" (1,070 mm)	

4. LevMixer® Dolly

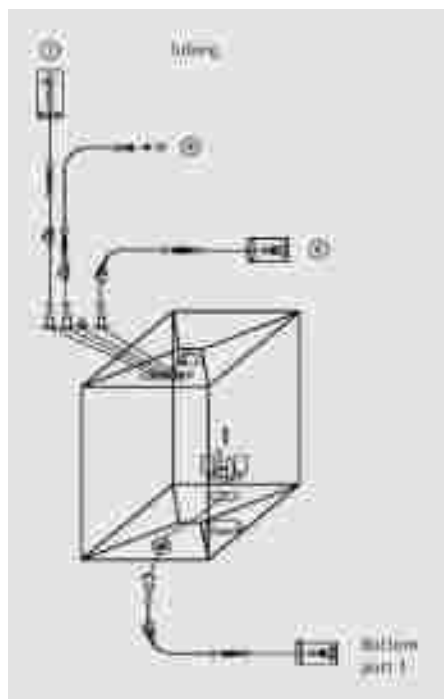
Material:	Stainless Steel # 316L
Finish:	Bead Blasting
Wheels:	Clean Room Wheels
Dimensions:	
LT-DBMC034	34" (860 mm) W × 40" (1010 mm) L × 36" (945 mm) H
LT-DBMC036	26" (660 mm) W × 44" (1117 mm) L × 34" (864 mm) H
Weight:	80 lb (36.5 kg)
Load capacity:	1,250 lb (570 kg)

5. Flexel® Drum Bags for LevMixer®

Bag Chamber:	Multiple Film Construction, including EVOH gas barrier layer, ULDPE Contact Layer
Impeller position:	Off-center
Impeller size:	50 – 100 liter – 4.95" (126 mm) 200 – 1,000 liter – 6.35" (161 mm)
Tubing material:	Silicone, TPE
Number of Ports:	3 top ports, 1 bottom port
Outlet Fittings:	MPC Quick Connect Coupling, Tri-clamp, Luer Lock female septum
Volumes:	50 L – 1000 L
Sterilization:	by Gamma Irradiation

Ordering information

1. Flexel® Drum Bags for LevMixer®



Line	Function	Tubing material	Tubing diameters and length	End Connector
Top port 1	Fill Addition	Silicone + TPE	1/2" x 3/4" x 1.5 m (60")	1/2" MPX male + sealing cap
Top port 2	Fill Addition	Silicone + TPE	1/2" x 3/4" x 1.5 m (60")	1-1/2" Tri-Clamp
Top port 3	Sampling Addition	Silicone + TPE	1/8" x 1/4" x 1.1 m (40")	LL female + needle free sampling port
Bottom port 1	Draining	Silicone + TPE	1/2" x 3/4" x 1.5 m (60")	1-1/2" Tri-Clamp

Part Number	Description	Qty/box
FXB111067	Flexel® 50 L – LevMixer® Drum Bag	4
FXB111101	Flexel® 100 L – LevMixer® Drum Bag	2
FXB111103	Flexel® 200 L – LevMixer® Drum Bag	2
FXB111104	Flexel® 300 L – LevMixer® Drum Bag	2
FXB111106	Flexel® 370 L – LevMixer® Drum Bag	2
FXB111108	Flexel® 560 L – LevMixer® Drum Bag	2
FXB111109	Flexel® 750 L – LevMixer® Drum Bag	2
FXB111110	Flexel® 1000 L – LevMixer® Drum Bag	2

2. LevMixer® Drive Unit and LevMixer® Dolly

LT-DBTL300 Superconducting drive machine on cart with universal latch for 8", 15" and 23" ports. Control panel (100–230 V) and lifting mechanism on handle and welded body. 304L Stainless Steel with 35 µm. Ra | 0.89 µm Ra surface finish. Includes tool box with accessories.

3. LevMixer® Drum-PE

Order-No	Volume	Drive Port off center	Side & Bottom drain
LT-DBMC032	30 liter	x	x
LT-DBMC057	50 liter	x	x
LT-DBMC106	100 liter	x	x
LT-DBMC208	200 liter	x	x
LT-DBMC303	300 liter	x	x
LT-DBMC370	370 liter	x	x
LT-DBMC560	560 liter	x	x

4. LevMixer® Drum–Stainless Steel

Order-No	Volume	Non jacketed-cylindrical	Jacketed	With insulation-cylindrical	Non-insulated cylindrical	Bottom & side drain port	With door	OD Finish: beadblast
LT-JTBB059	50 liter	x				x		x
LT-JTBB059A	50 liter	x		x		x		x
LT-JTBB059B	50 liter		x		x	x		x
LT-JTBB059C	50 liter		x	x		x		x
LT-JTBB110	100 liter	x				x		x
LT-JTBB111	100 liter	x		x		x		x
LT-JTBB112	100 liter		x		x	x		x
LT-JTBB113	100 liter		x	x		x		x
LT-JTBB216	200 liter	x				x		x
LT-JTBB217	200 liter	x		x		x		x
LT-JTBB218	200 liter		x		x	x		x
LT-JTBB219	200 liter		x	x		x		x
LT-JTBB308	300 liter	x				x	x	x
LT-JTBB309	300 liter	x		x		x	x	x
LT-JTBB310	300 liter		x		x	x	x	x
LT-JTBB311	300 liter		x	x		x	x	x
LT-JTBB370	370 liter	x				x	x	x
LT-JTBB371	370 liter	x		x		x	x	x
LT-JTBB372	370 liter		x		x	x	x	x
LT-JTBB373	370 liter		x	x		x	x	x
LT-JTBB560	560 liter	x				x	x	x
LT-JTBB561	560 liter	x		x		x	x	x
LT-JTBB562	560 liter		x		x	x	x	x
LT-JTBB563	560 liter		x	x		x	x	x
LT-JTBB752	750 liter	x				x	x	x
LT-JTBB753	750 liter	x		x		x	x	x
LT-JTBB754	750 liter		x		x	x	x	x
LT-JTBB755	750 liter		x	x		x	x	x
LT-JTTL027	1,000 liter	x				x	x	x
LT-JTTL028	1,000 liter	x		x		x	x	x
LT-JTTL029	1,000 liter		x		x	x	x	x
LT-JTTL030	1,000 liter		x	x		x	x	x

5. Accessories for LevMixer® Drive Unit

Part Number	Accessories
LT-SVSP402	Remote control cable – Analog I O Cable, 6 m (20 ft.)
LT-SVSP403	Remote control cable – Digital I O Cable, 6 m (20 ft.)

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