

Data Sheet

Mobius® Single-use Mixing Solution

Integrated powder delivery, mixing and filtration technology delivers economic and processing flexibility

The Mobius® single-use mixing solution delivers advanced technology for mixing pharmaceutical ingredients from intermediate to final drug products and for the preparation of process solutions, such as buffers and media.

This single-use integrated mixing solution offers economic and operational efficiency, saving valuable processing and validation time. The Mobius® mixing solution includes a powder delivery system, 100 L, 200 L, 500 L and 1000 L single-use mixers and the Mobius® FlexReady Solution for Buffer and Media Preparation.

You can also configure the appropriate filter, connector, and tubing for your specific application and environment, including sterile interfaces, from fermentation to final fill. Our proven, scalable, ready-to-use systems and processing technologies reduce the risk of contamination, improve economic and processing flexibility and deliver reproducible results.



Benefits

- Decreased risk of contamination
- Reduced downtime for cleaning validation
- Minimizes operator exposure to powders
- Validation, quality and regulatory compliance support
- Single-use technology for increased production capacity in multiproduct facilities
- Easy setup and use
- Convenient and easy to transport
- Closed, sterile sampling system enables representative samples



Figure 1.
The Mobius® powder delivery system

Powder Delivery

Mobius® Powder Delivery System

The Mobius® powder delivery system allows users to safely and easily dispense powder into Mobius® single-use mixers and compatible stainless steel vessels. The system includes a hoist, fill stand, support bracket and single-use powder container. The patented single-use asymmetric container minimizes clumping and blockage providing optimal flow into a mixer. A manually controlled butterfly valve allows users to control the speed and quantity of powder dispensed into the mixer improving mixing results. Ideally suited for the preparation of buffers, media, APIs, and other applications, the powder container is compatible with the majority of process vessels that feature a 4-inch port.

Powder Delivery System Benefits

- Unique asymmetric container facilitates better flow
- Range of sizes available, 5, 10, 15, 25 kg
- Large 4-inch port prevents arching
- Optional washdown handle
- Butterfly valve for short-term closure and metered powder addition

Sterile Storage

The powder container is ideally suited for storage of powders. A secure screw cap with internal O-ring provides a barrier against microbial ingress and a tamper proof seal assures users that the contents have not been tampered with between filling and mixing.

Remove Powder Safely and Effectively

The Mobius® powder containers are available with and without a washdown feature. The washdown feature safely and effectively washes residual powder from the container directly into the mixer. This feature also allows users to dispose of the container with confidence.

The fill stand holds the powder container securely enabling you to dispense powder into the container quickly, easily and safely. The height of the fill stand is adjustable and can be used with all four sizes of powder containers.

Safely Lift and Lower Powder Containers over Mixers and Vessels

The Mobius® hoist is designed for use with all Mobius® single-use carriers and vessels. The hoist is capable of lifting and lowering up to a 25 kg filled powder container directly over any mixer allowing users to quickly and safely connect the powder container to the mixing container and dispense the powder into the mixer.

A Mobius® support bracket, designed to support the 4-inch sanitary TC port on the Mobius® mixer container, is available for all mixer vessels. The bracket ensures that the mixer container is supported for easier connection to the powder delivery container.

Mixing

Mobius® Single-use Mixers

The Mobius® family of single-use mixers offers optimum mixing performance and process turnover. Each single-use mixing container includes a magnetically driven levitating impeller for improved mixing consistency and efficiency. Unlike traditional stainless steel mixers, single-use mixers reduce downtime due to CIP, SIP, cleaning validation, and process engineering. Mobius® single-use mixers also offer operational flexibility and can be up and running in less than five minutes. They are capable of mixing speeds up to 500* RPMs meeting the broadest range of mixing production requirements.

Mobius® Mixer Solution Benefits

- Proprietary magnetically-driven levitating impeller
- Fast, easy set up and use – instant-on electronics – no warm up needed
- Compact footprint and mobile carrier construction for enhanced flexibility
- Available in a range of sizes 100 L, 200 L, 500 L and 1000 L
- Safe, sterile sampling directly from the mixing container without dead legs

PureFlex™ Film for Consistent Performance

Reliable, Robust PureFlex™ Film

Both the powder delivery container and the mixing containers are made of PureFlex™ film. PureFlex™ film is a high purity, medical grade, coextruded film designed to provide strength, flexibility (with maximum resistance to flex-crack), excellent gas barrier performance and inert contact. The fluid contact material is made of ultra low density polyethylene (ULDPE). The gas barrier is made of polyethylene vinyl alcohol copolymers (EVOH). The outer layers are made of ethylene vinyl acetate (EVA) and ULDPE. PureFlex™ film contact layers comply with the Food and Drug Administration (FDA) regulation 21 CFR 177.1520.

Every single layer of PureFlex™ film passes both USP <87> and USP <88> tests under 100% extraction, i.e. worst-case conditions providing product protection in the event of a cross leach of the internal film layers to the contact layer.

Consistent Mixing

The offset, bottom-mounted levitating magnetic impeller provides consistent mixing performance.

- No paddle
- No stir bar
- No shaft
- No bearings
- No mechanical contact



Quicker Process Turnaround

The Mobius® mixing system is ideally suited for multiproduct facilities with high production requirements. Set up of this single-use mixer is easy and can be completed in approximately 5 minutes. Once setup is complete, an operator simply turns the mixer on and begins mixing. The Mobius® mixer does not require a warm up time, which significantly improves process turnaround and productivity.

Modular by design, the Mobius® MIX100 and MIX200 and the Mobius® MIX500 and MIX1000 allow you to freely interchange the electronic drive unit, motor, and handheld control for production flexibility and cost-savings. When mixing is complete and you need to process another batch elsewhere on the floor, simply disconnect the electronic drive unit, motor, and controller and take them to another Mobius® system carrier and begin mixing. It's that simple.

*Mixer size dependent

Safe, Sterile Sampling Directly from the Mobius® Mixing Containers

Every Mobius® Mix container includes optional 2 or 3 needle-free sampling valves (depending on the size of the container). The unique design of the sample device eliminates dead legs ensuring a representative sample while avoiding loss of valuable product. The closed concept allows users to obtain a sample directly from the mixing container without the risk of cross contamination. Once a sample is obtained, the sample container is separated from the mixing container using the NovaSeal™ crimping tool that crimps the collar on the sample tube resulting in two closed, sterile ends.

Ensuring optimum mixing performance and reliability

Ensuring optimum mixing performance is critical throughout your process development, scale up and production. Our team of experts is ready to provide you with a complete range of services to ensure your Mobius® disposable mixing system continues to deliver the level of mixing performance you depend on.

Choose from a suite of services including installation, commissioning validation, training and preventive maintenance that meet your specific processing requirements. All services are performed by Mobius® certified engineers.

Mobius® Disposable Mixing System Protocol and Service Agreements

Commissioning, Installation and Operational Qualification Protocol

Developed by our team of technical experts who understand cGMP regulations and validation requirements, this protocol contains procedures and acceptance criteria to ensure your Mobius® disposable mixing system is fully operational and easily validated on-site.

Commissioning, Installation and Operational Qualification Protocol Performance

This service includes one on-site visit by a trained field service engineer to perform the Commissioning, Installation and Operational Qualification Protocol. The protocol is executed in compliance with cGMP regulations. Our field service engineer will spend one working day at your site to execute the protocol. Note: Travel and accommodation expenses are included.

Figure 2.
The Mobius® family of single-use mixers

Filtration

Mobius® FlexReady Solution for Buffer and Media Preparation

The Mobius® powder transport and single-use mixers are designed to easily integrate into the Mobius® FlexReady Solution for Buffer and Media Preparation. This easy-to-use, single-use system is designed to fully support your buffer and media filtration needs.



The solution features single-use Flexware® assemblies, sterilizing-grade filters for buffer/media filtration, and process-ready hardware system for maximum scalability and optimal operational flexibility.

Choose from Millipore Express® PES or Durapore® filters, which are ideally suited for buffer preparation and cell culture media filtration.

- Designed for preparation of media or buffer in 100L, 200L, 500L, 1000L batch sizes for optimum scalability
- Easy integration with Mobius® single-use mixing systems, including the Mobius® MIX100, MIX200, MIX500 and MIX1000 mixers.
- Sterilizing-grade filters are pre-sized using our expertise and proprietary design tool, qualified for typical cell culture media and buffer applications
- Features Millipore Express® SHC, SHR and SHF and Durapore® filters
- High-pressure cut-off switch to ensure operator safety

Certification Levels

You demand quality, cost containment and regulatory compliance at every stage of process development. The Mobius® mixing and sampling assemblies are available in

either Gold or Bronze certification levels. The Flexware® assemblies used with the Mobius® FlexReady Solution for Buffer and Media Preparation are bronze certified.

Certification	Shelf Life Claim	Sterility Claim	LAL & Particulate	Leak Testing	Class VI USP (88)
Gold	2 years	Sterile, Quarterly Validation	Lot Release	100% of lot on full assembly and bag*	Post-gamma, component family
Bronze	None	Gamma-irradiated > 25 kGy, not validated sterile	No testing performed	No testing performed	Pre-gamma resin only

*Complete assembly testing is performed unless prohibited by the design.

Specifications

Powder Delivery

Mobius® Powder Containers

Materials of Construction

Butterfly valve, shaft, swing handle:	Glass-filled nylon
All other molded components:	High density polyethylene (HDPE)
Shaft O-ring, butterfly O-ring:	Silicone
Container and washdown bladder:	PureFlex™ film, LLDPE product contact layer
Washdown hose barb port cover:	PVC

Product contact:

Dust Cover, funnel, powder port housing, washdown handle:	High density polyethylene (HDPE)
Butterfly valve:	Glass-filled nylon
Shaft O-ring, butterfly O-ring:	Silicone
Container (bag):	PureFlex™ film

Gamma Irradiation 25–40 kGy

Volume (L) 5, 10, 15, 25 L

Maximum Weight (kg) 5, 10, 15, 25 kg

Powder Connection 4 in. sanitary TC

Wash Down Port ¼ in. hose barb

Container

Shelf life Container: 2 years

Leak Testing All containers are 100% integrity tested

Mobius® Powder Container Fill Stand

Materials of Construction

Fill stand, chain, clamp, and torque release mechanism:	316 Stainless steel
Hand tool:	Acetal
Base Width in. (cm)	19 (48)
Base Depth in. (cm)	13 (33)
Maximum Height without Funnel in. (cm)	32 (80)
Maximum Height with Funnel in. (cm)	23 (58)
Minimum Height without Funnel in. (cm)	24 (61)
Minimum Height with Funnel in. (cm)	15 (38)
Weight lb (kg)	17.25 (7.83)

Hoist

Materials of Construction

Frame and winch assembly:	304 stainless steel
Hook:	316 stainless steel
Cable:	302 stainless steel
Wheels with locking brakes:	304 stainless steel with polyolefin wheels, 2 in. front, 4 in. back
Pulleys:	Nylon
Sleeve bearings:	Ultra-high-molecular-weight polyethylene (UHMWPE)
Base width in. (cm)	28.5 (73)
Base depth in. (cm)	38.5 (98)
Total height in. (cm)	113 (287)
Weight lb (kg)	450 (205)

Mixing*

	MIX100	MIX200	MIX500	MIX1000
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Carrier

Materials of Construction

	Plastic/Steel	Plastic/Steel	Plastic/Steel	Steel
Tank	LLDPE/304 L SST	LLDPE/304 L SST	LLDPE/304 L SST	304 L SST
Stand	HDPE/304 L SST	HDPE/304 L SST	HDPE/304 L SST	304 L SST
Latch	18-8 stainless steel			
Casters	Polyurethane/304 L stainless steel			

Dimensions (LLDPE Carriers)

	MIX100	MIX200	MIX500	MIX1000
Height in. (cm)	48 (122)	49 (124.5)	64 (162.6)	—
Width in. (cm)	32 (81.3)	38.5 (97.8)	47 (119.4)	—
Depth in. (cm)	27 (68.6)	30.5 (77.5)	40 (101.6)	—
Weight empty lb. (kg)	74 (33.6)	86 (39)	200 (90.7)	—

Dimensions (Jacketed Carriers)

	MIX100	MIX200	MIX500	MIX1000
Height in. (cm)	45.6 (115.9)	45.7 (116)	61.1(155.2)	70 (178)
Width in. (cm)	34.4 (87.4)	38.3 (97.2)	48.3 (122.6)	66.5 (169)
Depth in. (cm)	27 (68.6)	29.3 (74.3)	40 (101.6)	49 (124)
Weight empty lb. (kg)	274 (124)	353 (160)	659 (299)	1425 (646)

Dimensions (Unjacketed Carriers)

	MIX100	MIX200	MIX500	MIX1000
Height in. (cm)	45.6 (115.9)	45.7 (116)	61.1 (155.2)	—
Width in. (cm)	32 (81.3)	36.5 (92.8)	47 (119.4)	—
Depth in. (cm)	27 (68.6)	29.3 (74.3)	40 (101.6)	—
Weight empty lb. (kg)	200 (91)	220 (100)	440 (200)	—

Control Box

Materials of Construction

Weight lb. (kg)	29.76 (13.5)	51 (23)
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Power Requirements

Electrical	115/230 VAC 50/60 Hz single phase	208 VAC 3 phase or 230 VAC single phase
Cable length in. (cm)	98.4 (250)	
Connector types	Separate for each country	
Ingress protection rating	IP65	

Regulatory Information

Regulatory Information	CE marked
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Hand Control

Weight oz. (kg)	8.81 (0.25)	8.81 (0.25)
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Motor

Type	Magnetic		
Weight lb (kg)	10.8 (4.9)	29 (13.1)	

Power Requirements

Electrical (max.)	300 W	1200 W	
Design speed	Up to 500 RPM	Up to 500 RPM	Up to 250 RPM Up to 250 RPM

Maximum operating speed has to be validated for each process individually, depending on volume, viscosity, etc.

Cable length in. (cm) 118.1 (300)

Ingress protection rating: IP67

Regulatory Information CE marked

* Mobius® single-use MIX100, 200 and 500 are also available with stainless steel (SST) carriers with and without external heat exchange jackets for accurate temperature control and clean room applications.

Specifications (continued)

Mixing*				
	MIX100	MIX200	MIX500	MIX1000
MIX Container Assembly				
Materials of Construction				
Mix container	PureFlex™ Film			
Adapters	SterilEnz™ LDPE	SterilEnz™ LDPE	Polypropylene	
Luer plugs	Kynar® Polyvinylidene Fluoride			
Connectivity	CPC® Polysulfone			
Tubing	Silicone			
Pinch clamp	PVDF			
Impeller	Sintered neodymium magnet NdFeB encased in polypropylene			
Bung port	Polyethylene			
TC gasket	Silicone			
TC clamp	Nylon			
TC end cap	Polypropylene			
Cup	SCLAIR 2909 HDPE			
Dimensions				
Height in. (cm)	26 (66)	33 (84)	42 (106)	46 (116)
Width in. (cm)	20 (50.8)	25 (63.5)	37 (94)	43.5 (110)
Depth in. (cm)	20 (50.8)	25 (63.5)	37 (94)	43.5 (110)
System Performance Properties				
Storage:	0-40 °C non-condensing environment			
Operating temperature (LLDPE carrier):	4-40 °C non-condensing environment	4-30 °C non-condensing environment		
Operating temperature (SST carriers):	4-60 °C non-condensing environment			

* Mobius® single-use MIX100, 200 and 500 are also available with stainless steel (SST) carriers with and without external heat exchange jackets for accurate temperature control and clean room applications.

Mixing*	
Integrated MIX Sampling Container	
Materials of Construction	
Sample bag fluid contact layer:	Polypropylene film
Tubing:	Medical-grade, platinum-cured silicone
Metallic pinch pipe:	Nickel plated brass
Port:	SCLAIR 2909 HDPE
O-rings:	Silicone
Dimensions	
Sampling bag dimensions (mm)	245 x 80
Volume (mL)	250
Environmental	
Maximum bag pressure conditions:	Withstand 4 psi at < 2°C and > 60°C
Operating temperature:	2 °C to 60 °C
Component material toxicity:	All components meet USP <88> Biological Reactivity Tests for Class VI plastics and USP <661> Physico-chemical tests for plastic components. Materials are derived from animal-free components
Endotoxin level:	<0.25 EU/mL
Particulates:	Sample collected meets the requirements of USP <788> Small Volume Parenterals

Ordering Information

Powder Delivery

Powder Container

Weight (kg)	Qty/Pk	With Washdown Port	Without Washdown Port
5	5	MIXPDR05W05	MIXPDR05N05
10	5	MIXPDR10W05	MIXPDR10N05
15	5	MIXPDR15W05	MIXPDR15N05
25	5	MIXPDR25W05	MIXPDR25N05

Hoist

	Qty/Pk	Catalogue Number
Hoist	1	MIXPDRHOIST
Fill stand	1	MIXPDRFILSTN

Support Brackets

MIX100	1	MIX0100BRKT4
MIX200	1	MIX0200BRKT4
MIX500	1	MIX0500BRKT4
MIX1000	1	MIX1000BRKT4

Mixing

	MIX100	MIX200	MIX500	MIX1000
Carrier with Electronics				
120V, 50/60 HZ	MIX0100L100*	MIX0200L100*	–	–
230V, 50/60 HZ	MIX0100L101*	MIX0200L101*	–	–
208V, 50/60 HZ	–	–	MIX0500L100*	MIXJS1000L100*
230V, 50/60 HZ	–	–	MIX0500L101*	MIXJS1000L101*
Carrier Only				
LLDPE Carriers	MIX0100L102	MIX0200L102	MIX0500L102	–
Jacketed	MIXJS0100L102	MIXJS0200L102	MIXJS0500L102	MIXJS1000L102
Unjacketed (ASME® coded)	MIXUJS100L102	MIXUJS200L102	MIXUJS500L102	–
Accessories				
Control box unit, 120V	MIX0200L103	MIX0200L103	–	–
Control box unit, 230V	MIX0200L104	MIX0200L104	MIX0500L104	MIX0500L104
Control box unit, 208V	–	–	MIX0500L103	MIX0500L103
Motor	MIX0200L107	MIX0200L107	MIX0500L107	MIX0500L107
Hand control and cable		MIX0200L106		
Electrical power cord (country specific)		MIX0200L108		
Stainless Steel Mixer Spare Parts				
Quick-connect coupling, male, 3/4 NPT	Qty/pk		Catalogue No.	
Quick-connect coupling, male, 3/4 NPT	1		MIXSST0109442	
Quick-connect coupling, female, 3/4 NPT	1		MIXSST0109441	

*Includes carrier, control box unit, motor, hand-held control and cable.

Mix Containers

	Qty/pk	100 L	200 L	500 L	1000 L
Bronze Certification					
2 in. Port without Needle-free Sample Containers	1	MIX0100LB01	MIX0200LB01	MIX0500LB01	–
	5	MIX0100LB05	MIX0200LB05	MIX0500LB05	–
With Needle-free Sample Containers					
4 in. TC Port with 2 Needle-free Sample Containers	1	MIX0100LSPB01	MIX0200LSPB01	MIX0500LSPB01	–
4 in. TC Port with 2 Needle-free Sample Containers	4	MIX0100LSPB04	MIX0200LSPB04	MIX0500LSPB04	–
4 in. TC Port with 3 Needle-free Sample Containers	3	–	–	–	MIX1000LSPB03
Single-use Liner Assemblies	5	MIX0100LLIN	MIX0200LLIN	MIX0500LLIN	–
Gold Certification					
Without Needle Free Sample Container	5	MIX0100LG05	MIX0200LG05	MIX0500LG05	–
4 in. TC Port with 3 Needle-free Sample Containers	3	–	–	–	MIX1000LSPG03
4 in. TC Port with 2 Needle-free Sample Containers	4	MIX0100LSG04	MIX0200LSG04	MIX0500LSG04	–

Services

	Qty/pk	Catalogue No.
Commissioning, Installation and Operational Qualification	1	DOCIQQMIX Protocol
Commissioning, Installation and Operational Qualification Protocol Performance	1	SVCBIOQMIXZ

Contact your local field sales representative for zone and service pricing.

Mobius® FlexReady Solution for Buffer and Media Preparation

Mobius® FlexReady Solution for Buffer and Media Preparation must be purchased separately. See datasheet DS1624EN00 for ordering information.

To Place an Order or Receive Technical Assistance

In the U.S. and Canada, call toll-free
1-800-645-5476

For other countries across Europe and the world,
please visit www.millipore.com/offices

For Technical Service, please visit
www.millipore.com/techservice



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