



# Mobius® Power MIX Single-use Mixing Systems

High Performance Mixing Technology and Ergonomic Design Features



The Mobius® Power MIX single-use mixing systems combine high performance mixing technology with design features that make them easy-to-use. The impeller design and motor are based on our magnetically coupled NovAseptic® mixing technology, a proven mixing technology in stainless steel tanks. These systems efficiently mix the most challenging buffers, media and biopharmaceutical ingredients.

## Features and Benefits

- Range of sizes available from 100 L to 3000 L
- Powerful magnetically coupled impeller designed to efficiently mix the most challenging buffer, media and biopharmaceutical ingredients
- Broad working volumes that range from 10% of the nominal volume to 10% above (size dependent) for processing flexibility
- Stainless steel units have doors that open to one half the mixer's diameter for easy bag loading
- The 1000, 2000, 2500 and 3000 L sizes have an easily accessible off-set drain for easy bag loading
- 100, 200 and 500 L models are available in plastic or jacketed stainless steel
- Optional integrated hoist for powder delivery available on the Mobius® Power MIX 2000 model
- Integrated load cells and temperature sensor
- In-process pH and conductivity measurement option
- Closed, sterile, and zero deadleg sampling directly from the mixing bag
- Backed by industry-leading technical support and services

## Ergonomic Design Features

All the models of the Mobius® Power MIX systems are designed with operator ease and safety in mind. Handling single-use assemblies for volumes greater than 1000 L can be difficult to maneuver, so the Mobius® Power MIX 1000, 2000, 2500 and 3000 have additional features for end-user ease-of-use. One operator is able to safely load the bag. The doors open to one half the carrier's diameter, and the impeller and drain are positioned for easy bag loading. The bag can easily be secured to pins positioned around the top of the carrier to further help with bag loading.

## Proven NovAseptic® Technology for Mixing of Challenging Buffer and Media Powders

The design of the Mobius® Power MIX mixing systems is based on proven NovAseptic® mixing technology, traditionally used with stainless steel. The off-set bottom-mounted impeller contained in the mixer bag is magnetically coupled to the motor assembly, which has been redesigned for single-use. The magnetic coupling does not use a bearing surface.

The design properties of the impeller, such as the surface area, diameter, wing angle and number and type of magnets, were matched to the NovAseptic® impeller to achieve similar mixing performance.

## Ready To Connect Control Box

The Mobius® Power MIX can be monitored and controlled locally or remotely. Plug the ready to connect control box to the network and use Ethernet IP communication protocol to monitor speed, weight, temperature, pH and conductivity remotely. The ready to connect control box is a separate box on a four wheels chassis that can be easily moved around the Mobius® Power MIX carrier. Optimize your layout and get a better access to control your Mobius® mixing system by freely positioning the control box around it. The 21 CFR Part 11 compliant data recorder option displays data trends in real time and ensures process data integrity when recording.



**Figure 2.** Ready to connect control box



**Figure 1.** Mobius® Power MIX 2000 has double doors that open to one half the diameter of the carrier; the Mobius® Power MIX 100, 200, and 500 have a single door that opens to one half the diameter of the carrier.

## In-Process Measurement Options

The Probe Ports enable easy insertion of your standard PG13.5 threaded probes for in-process pH and conductivity measurement. They may be attached to the Mobius® single-use mixer bag at the position of the needle-free sample port.

## Safe, Sterile Sampling Directly from the Mixing Containers

The standard Mobius® Power MIX single-use bag contains two needle-free sampling valves. 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 bag without the risk of cross contamination. Once a sample is obtained, the sample bag is separated from the mixing bag using the NovaSeal™ crimping tool that crimps the collar on the sample tube, resulting in two closed, sterile ends.



**Figure 3.** Needle-free sample ports with sample bags

## PureFlex™ Films for Consistent Performance

### Reliable, Robust PureFlex™ Films

The mixing containers are made of PureFlex™ or PureFlex™ Plus single-use process container films.

The PureFlex™ family of single-use process container films are high purity, medical grade and coextruded to provide strength, flexibility (with maximum resistance to flex-crack), excellent gas barrier performance, and inert contact. The fluid contact layer of both types of PureFlex™ films is made of ultra-low density polyethylene (ULDPE). For both films, the gas barrier is made of polyethylene vinyl alcohol polymers (EVOH). The outer layers are made of ethylene vinyl acetate (EVA) and ULDPE. PureFlex™ Plus film is constructed with a tough, linear low density polyethylene (LLDPE) outer layer, designed specifically for the demanding applications often encountered in large volume operations (>500 L).

The contact layers of PureFlex™ films comply with the Food and Drug Administration (FDA) regulation 21 CFR 177.1520. Every layer of the PureFlex™ films passes 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.

## Certification Standards

There is a demand for quality and regulatory compliance at every stage of process development. The standard Mobius® Power MIX mixing bags are available in either Gold or Bronze certification levels.

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 container*	Post-gamma, component family
Bronze	None	Gamma-irradiated > 25 kGy, not validated sterile	No testing performed	No testing performed	Pre-gamma resin only

## Services

### Installation Qualification/Operational Qualification (IQ/OQ)

Our IQ/OQ service ensures your system is fully documented, operational, compliant with pharmaceutical regulatory requirements, and ready for your Performance Qualification.

IQ/OQ includes static and dynamic tests:

- Completion of as-built system documentation
- Visual inspection
- Mechanical tests
- Electrical tests
- Instrumentation verification (depending on system option)
- Functional tests

### Preventive Maintenance (PM)

With our PM service, your equipment will be verified using established protocols to ensure documented compliance with quality requirements. Maintenance kit parts will be replaced (parts to be purchased separately). Maintenance recommendations and a full report of the services performed will also be provided to ensure that the validated state of the equipment is maintained.

### Corrective Maintenance

In the unlikely case your system does experience a problem, our engineers will provide on-site technical support to get you back up and running as quickly as possible.

### Spare Parts

Utilizing our service offerings also provides direct access to the spare parts needed to maintain and repair your system. Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original.

### 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: [EMDMillipore.com/offices](https://EMDMillipore.com/offices)

For Technical Service, please visit: [EMDMillipore.com/techservice](https://EMDMillipore.com/techservice)

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Figure 4. Mobius® Power Mix 500

