# **Millipore**

Filtration, Separation & Preparation



# Mobius® Power MIX 2000 Single-Use Mixer

High performance mixing technology and ergonomic design features.

The Mobius® Power MIX 2000 combines high performance mixing technology with design features that make it 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. The system efficiently mixes the most challenging buffers, media and biopharmaceutical ingredients.

#### **Features and benefits:**

- Powerful magnetically coupled impeller designed to efficiently mix the most challenging buffer, media and biopharmaceutical ingredients
- Broad working volume, from 300 L to 2200 L, for processing flexibility
- Double doors that open to one half the mixer's diameter and easily accessible off-set drain for easy bag loading
- Optional integrated hoist for powder delivery
- Integrated load cells and temperature sensor
- Two in-process pH measurement options: Probe Port for easy insertion of a re-usable standard PG 13.5 threaded probe or pre-installed, pre-calibrated and pre-sterilized Hamilton OneFerm® Single-Use pH Sensor
- Closed, sterile, and zero deadleg sampling directly from the mixing bag
- Backed by industry-leading technical support and services





Figure 1.

Mobius® Power MIX 2000 bag secured to pins on top of carrier

Figure 2.

Mobius® Power MIX 2000 with doors open to one half the diameter of the carrier

## **Ergonomic Design Features**

Understanding that handling single-use assemblies for volumes greater than 1000 L can be difficult to maneuver, the Mobius® Power MIX 2000 has 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 off-set 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 2000 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.

Figure 3.
Needle-free sample ports
and Hamilton OneFerm pH
Sensor on Mobius® MIX
2000 bag



**Figure 4.**Hamilton OneFerm pH
Sensor



#### **In-Process Measurement Options**

Two options for in-process measurement of pH with mixing are available: the pH Probe Port, for use with re-usable probes, and the Hamilton OneFerm pH sensor, a classical electrochemical pH sensor designed for single-use applications. The pH Probe Port enables the easy insertion of your standard PG 13.5 threaded probe. The Hamilton OneFerm pH sensor is provided pre-installed, pre-calibrated and gamma-irradiated in the mixer bag for applications requiring sterility. Both the pH Probe Port and the Hamilton OneFerm pH sensor 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 2000 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 5.
Needle-free sample
ports with sample
bags and Hamilton
OneFerm pH Sensor

## **Certification Standards**

There is a demand for quality and regulatory compliance at every stage of process development. The standard Mobius® Power MIX 2000 L 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

## **PureFlex™ Films for Consistent Performance**

## **Reliable, Robust PureFlex™ Films**

The mixing containers are made of PureFlex $^{\text{TM}}$  or PureFlex $^{\text{TM}}$  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 polethylene (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 polyethlene (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.

# **Comprehensive Services**

Our qualification services enable you to decrease regulatory risks, save qualification time, and maximize your process efficiency. Our preventive maintenance services allow you to keep your equipment running, maximize production time, and save emergency repair costs.

Our services are provided by trained engineers, application scientists, and system designers who have unique internal knowledge of the equipment and years of experience.

For more information, please consult the Equipment Services brochure (PB1946EN00) or web page.



#### **Benefits**

By using our services, you can benefit from:

- · Unrivaled access to parts and testing
- Up-to-date training, service protocols and practices
- Thorough equipment understanding from a global install base
- Protocols and reports meeting industry and regulatory expectations

#### To place an order or to receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645 Germany: 069 86798021 Italy: 848 845 645 Spain: 901 516 645 Option

**Spain:** 901 516 645 Option 1 **Switzerland:** 0848 645 645 **United Kingdom:** 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

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