

Tofflon



**Single-use Liquid Preparation
and Storage System Solutions**

EXPERTISE IN BIO-PHARMACEUTICAL

MANUAL CONTENTS

Company Introduction	1
Liquid Mixing Solution	2
SUM All-in-one Liquid Mixing System	3
SUM Split Mixing System	4
SUM Desktop Mixing System	5
SUM Magnetic Levitation Distribution System	6
SUM Mechanical Stirring System	7
SUM Swing Mixing System	8
Liquid Storage and Transport Solutions	9
Stainless Steel Transfer Car	10
Collapsible Box	10
Plastic Drum	10
Single-use Sterile Bag	11
Biopharmaceutical Membrane	12
Single-use Mixing Bag	14
Single-use 2D Storage Bag	15
Single-use 3D Storage Bag	16
Single-use Sterile Sampling Bag	17
Single-use Lining Bag	18

Tofflon Life Science Co.,Ltd



Founded in 1993, Tofflon Science and Technology Group Co., Ltd. (SZ:300171) is a comprehensive pharmaceutical equipment and service provider that provides the global pharmaceutical enterprises with overall solutions for pharmaceutical technology, core equipment and system engineering, whose products are applied in injectates, solid preparations, chemical APIs, bioengineering, traditional Chinese medicine, medicine, food and other fields. Tofflon's Life Sciences Co.,Ltd. focuses on the research and development of front-end technologies in the biopharmaceutical and medical industries, and provides the one-stop services integrating equipment system, devices and consumables (including bio-reagents, resin, filters, disposable bags and holder):

- In the field of cell therapy, we provide the overall solutions for the preparation and production of immune cell pipeline, stem cell pipeline, tumor cell vaccines, etc.
- In the field of gene therapy, we provide the overall solutions for the research & development and industrialization of nucleic acid drugs (mRNA/DNA) and viral vector drugs.
- In the field of biological sample bank, we perform the research and development of automatic sample storage management system to provide the overall solutions for cell seed and tissue sample.
- In the field of consumables, we have formed a complete consumable scheme in disposable bags (culture bags/mixing bags/storage bags), bio-reagents (culture media/cryoprotectants/Ficoll/growth factors), resin (GFC,AC,AEX,CEX,HIC,MMC), filtration (microfiltration/deep filtration/TFF/cassette), and hard packaging materials.
- In the field of disinfection, we are committed to clean room disinfection, surface and external disinfection, infection control, terminal disinfection and multi-drug resistant microorganism disinfection, providing an overall solution for environmental disinfection.

Relying on Tofflon Group's mature design, manufacturing, engineering construction and after-sales service capabilities all around the world, Tofflon Life Sciences Division can serve the biopharmaceutical industry more quickly and professionally.

Liquid Mining Solution

Tofflon

SUM All-in-one Liquid Mixing System

Tofflon's single-use mixing systems are designed for easy and efficient mixing of buffers, media, intermediates and products, and other process fluids. The single-use system eliminates the time-consuming and expensive hassle of cleaning-in-place (CIP), steam-in-place (SIP) procedures and cleaning verification. The result is efficient processing and fast batch-to-batch changeover.

Product Feature

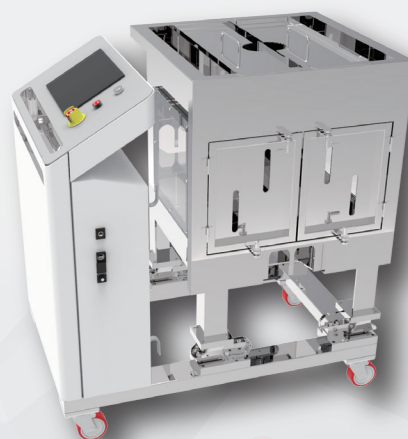
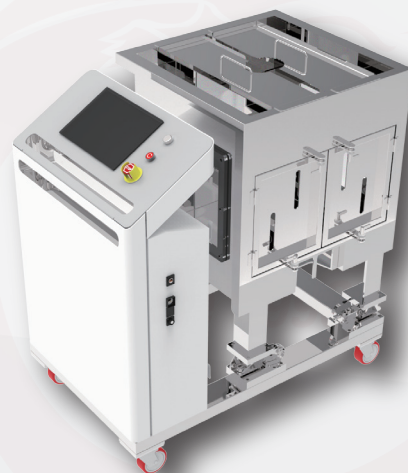
- ✓ Use with single-use mixing bags for mixing volumes from 50L-3000L.
- ✓ Requirements for formulation from R&D to production.
- ✓ Requirements for the formulation of fluids needed for R&D to production.
- ✓ From eliminating costly cleaning and cleaning validation procedures.
- ✓ The combination allows for on-line weighing, pH, conductivity and temperature control.
- ✓ Function inverter or servo drive provides strong power for magnetic mixing.
- ✓ User-centred design maximizes security and ease of use. Accepts user customization (hardware and software).

Functional Parameter

- ✓ Modular system with optional matching of required functions.
- ✓ Touch screen operator interface, ergonomic and compliant with regulations such as data integrity.
- ✓ Single-use mixing bag for use, pre-sterilised and wash-free.
- ✓ Magnetic inductively coupled drive mixing paddle, cable closed alignment, prevent signal interference, easy to clean.
- ✓ IP55 protection for the whole machine, key components up to IP69 can be connected to the central control, to achieve the whole centralised control of the whole.

Application Fields

- | | |
|----------------------|-------------------------------------|
| ✓ Buffer preparation | ✓ Semi-finished product preparation |
| ✓ Virus inactivation | ✓ Mixing of intermediate products |
| ✓ Medium preparation | ✓ Mixing of vaccine adjuvants |

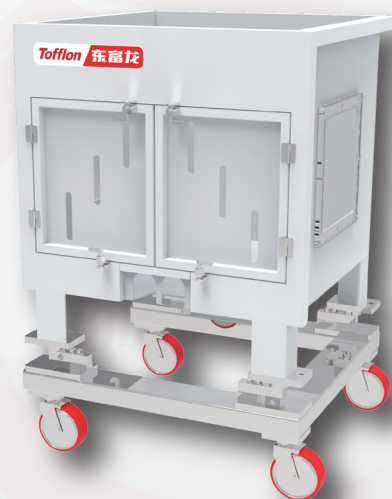


SUM Split Mixing System

Tofflon's single-use mixing systems are designed for easy and efficient mixing of buffers, media, intermediates and products, and other process fluids. The single-use system eliminates the time-consuming and expensive hassle of cleaning-in-place (CIP), steam-in-place (SIP) procedures and cleaning verification. The result is efficient processing and fast batch-to-batch changeover.

Product Feature

- ✓ The single-use mixing system consists of two parts: a 304 stainless steel stand and an automatic control system.
- ✓ With rapid mixing solid-liquid or liquid-liquid function, used for culture medium, buffer, high concentration of acid and alkali, high chlorine solution preparation and so on.
- ✓ Operable sight window for easy installation of mixing bag and placing of mixing bag pipeline according to the need for temperature control, optional with jacket and without jacket.
- ✓ Temperature control: movable TCU temperature control trolley can be compatible with different specifications of tanks.
- ✓ Split form of the bottom magnetic stirring, low requirements for the height of the room.
- ✓ Automatic control system optional weighing, temperature control, pressure, pH, conductivity detection and other networks: 21CFR PART11 and data integrity requirements.
- ✓ Support SCADA system, reserved Ethernet network interface, convenient to dock with other systems.



Magnetic Trolley

- ✓ First Generation Trolley : Stirrer drive, digital meter and control switch, simple and practical functions, SS304 frame, easy to clean.
- ✓ Second-generation trolley: self-control upgrades, can be integrated with a variety of functional modules, including audit trails, etc., and can interact with information technology systems.



SUM Desktop Mixing System

It is a safe, reliable, stable and efficient single-use mixing system. With the acrylic support vessel, it can meet the needs of liquid-liquid mixing, solid-liquid mixing and so on. It is more responsive to customer needs for small volume mixing, and is more sophisticated and integrated than larger volume mixing equipment.

Product Feature

- ✓ Adopting new type magnetic levitation motor to drive the stirring paddle inside the disposable magnetic stirring bag for stirring, with low power consumption, safety, long service life, small volume and accurate rotation speed.
- ✓ Magnetic levitation stirring process, no friction, will not produce temperature changes, particles, so as to ensure product quality.
- ✓ No mechanical seal, no mixing shaft through the tank, no lubricating oil, in the mixing at the same time will not produce particles, thus reducing the risk of pollution.
- ✓ PLC control is stable, easy and simple to operate, one person can build the whole mixing system in 5 minutes.
- ✓ Modular design, according to different needs to develop different solutions, such as conductivity, PH, temperature monitoring, weighing, printing and other functions.
- ✓ Meet the demand of small volume liquid dispensing, beautiful and neat appearance, easy to install, easy to clean the equipment, convenient to use and operate.
- ✓ Customizable to meet GMP requirements for data integrity of the three levels of authority, audit trail, electronic signature and other functions.



SUM Magnetic Levitation Distribution System

- ✓ Rapid mixing of solids and liquids for medium preparation, buffer preparation, masterbatch dilution, working solution preparation, end-of-preparation and storage of intermediate/finished products.
- ✓ Operable side door and viewing window for easy installation of mixing bag and placing of mixing bag tube.
- ✓ Ergonomic design of the operating platform, 12-inch human-machine interface.
- ✓ One-piece bottom suspension mixing, bearing less design, contactless mixing, reduce the risk of particle dislodgement.
- ✓ Square stirring design, increase the spoke direction disturbance, improve the mixing effect.
- ✓ Outstanding mixing ability, streamlined paddle design, reduce shear force.
- ✓ Side doors and view windows are available for large volumes.
- ✓ Functions: optional weighing, temperature control, pressure, ventilation, pH, conductivity detection, etc.
- ✓ Automatic control: Siemens PLC control system, in line with FDA 21CFR PART11 and data integrity requirements, support for SCADA system, reserved Ethernet network interface, can communicate with the central control system.



Product Feature

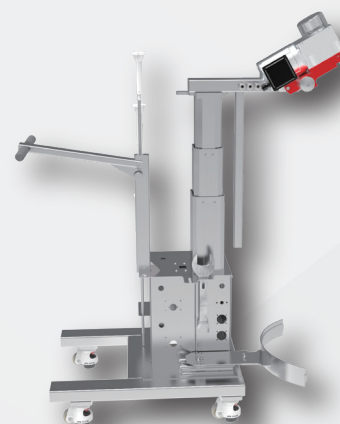
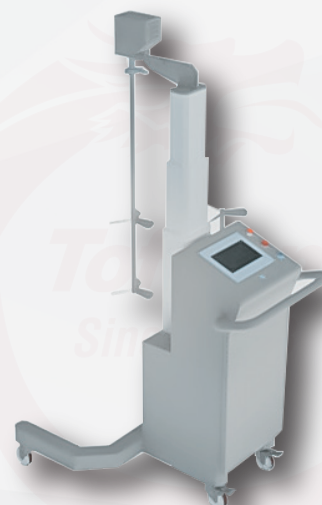
- ✓ Bearingless design to reduce the risk of contamination.
- ✓ Contactless mixing, no risk of particle shedding.
- ✓ No gap between the mixing impeller and the shell, reducing the risk of bacteria being wrapped in.
- ✓ High speed design, up to 1000rpm, specially designed for Mixer.
- ✓ The mixing paddle impeller is made of polypropylene (PP), which can be sterilised by gamma irradiation; it is biocompatible with
- ✓ FDA, USP-VI, and is not of animal origin.
- ✓ Small size for easy bag mounting and transit.

SUM Mechanical Stirring System

Upper Mechanical Mixing Trolley: Adopting top mechanical mixing technology, it is suitable for uniform mixing and stirring of liquid-liquid and solid-liquid, and can be matched with aseptic bag and open bag. The lifting mechanism and different specification of mixing shaft length can be used to meet the mixing process of different volume.

Product Feature

- ✓ A single mixing equipment can meet the demand of 50-500L liquid dispensing.
- ✓ With rapid mixing of solid-liquid or liquid-liquid function, for the preparation of culture medium, buffer preparation, as well as mother liquor dilution, working solution preparation, etc.
- ✓ With plastic drum, only for open mouth mixing.
- ✓ Stirring components are made of 316L material to meet GMP requirements; stirring paddles can be customised according to customer's requirements.
- ✓ Adjustable motor angle, applicable to the needs of liquid dispensing in multiple working conditions.
- ✓ Human-computer interaction interface, a key to open the mixing, flexible adjustment of the mixing speed.
- ✓ One key to adjust the height of the lift, adapting to the needs of multiple working conditions.
- ✓ Self-control: PLC + embedded tablet control system, can collect data such as mixing, time and so on.
- ✓ Reserve Ethernet port for communication with SCADA system and data acquisition.



SUM Swing Mixing System

The Tofflon SUM Swing Mixing System, with its non-invasive wave shaking mixing, provides a gentle, low shear mixing environment. Matching disposable aseptic bag for use, no need to clean and sterilise, according to the preset parameter values of the swing angle and speed, online weighing monitoring and alarm functions such as full-automatic program operation, to provide aseptic closed system for the swinging of the homogenising, to avoid direct contact between the material and the operator, to ensure that the whole process of the operation of the safety of the liquid-liquid homogenising to ensure the safety of the liquid-liquid homogenising, high efficiency, and asepticity.

Product Feature

- ✓ With single-use mixing bag working volume: 200ml-100L.
- ✓ Simultaneously supports mixing of two bags up to 100L.
- ✓ Swing angle 2-12 ° , swing speed up to 42 rpm, transmission mechanism using high-precision robot joints.
- ✓ Sensor precision C3, effectively guarantee the accuracy of weighing.
- ✓ Provides lower shear and gentler mixing than paddle mixing.
- ✓ Customisable trays, different sizes of trays according to customer needs, working volume compatibility by customising bags with smaller widths.

Application Fields

- ✓ Virus culture mixing, semi-finished product mixing to ensure mixing safety and sterility.
- ✓ Intermediate products are mixed and processed for good results and easy validation.
- ✓ Liquid-liquid mixing requirements up to 100L.



**Liquid Storage and
Transfer Solution**

Tofflon

Stainless Steel Transfer Car

Made of SS304 stainless steel, with flexible mobile casters at the bottom, front opening design for easy bag installation and removal, and smooth surface for easy cleaning. Applications include storage and transfer of culture media and buffers, sample storage, and product transfer.

Product specifications:

50L/100L/200L/500L/1000L/1500L/2000L/2500L/3000L



Collapsible Box

Made of polypropylene (PP) material, sturdy and durable, removable design to meet the stacked placement of storage, improve space utilisation, matching stainless steel transit base to use.

Used for the collection and storage of large volume liquid, product storage and transfer.

Product specification :250L/500L/1000L



Plastic Drum

Made of polyethylene (PE), resistant to common alcohol disinfectant wipe, flared design, convenient lining bag flap fixed, clean and uniform material, smooth inner wall, no damage to the soft body of the bag (can not be autoclaved), supporting the use of stainless steel transfer base. Used for large volume liquid storage and transfer.

Product specification: 50L/100L/200L/300L/500L

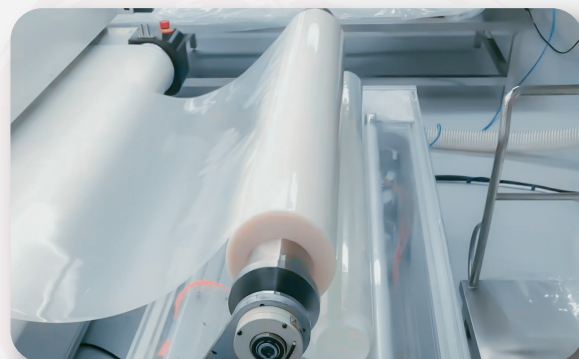


**Single-use
Sterile Bag**

Tofflon

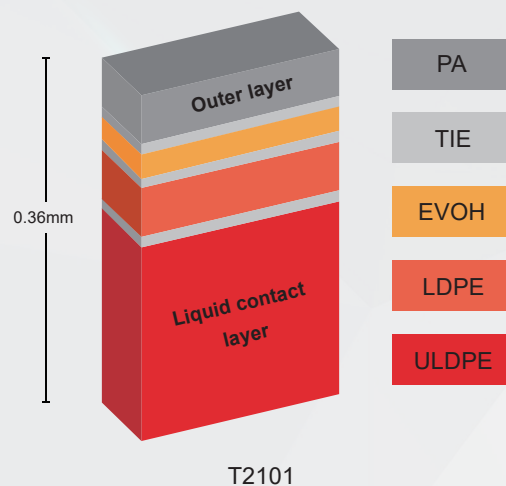
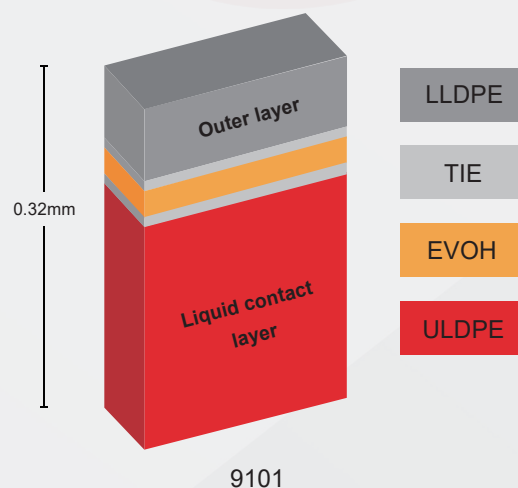
Biopharmaceutical Membrane

The main raw material of disposable aseptic bag is multilayer biopharmaceutical membrane. The thickness of the film material is 0.3-0.4mm, and the inner surface fluid contact layer is made of ultra-low density polyethylene (ULDPE), which has excellent chemical compatibility and biological safety, low dissolved precipitates, and no animal derived components (ADCF). The intermediate layer is made of ethylene - vinyl alcohol copolymer (EVOH), which can effectively block oxygen, carbon dioxide and water vapor. The outermost non-contact layer is made of linear low density polyethylene (LLDPE) or polyamide (PA), which provides high mechanical strength while also imbuing the material with biological inertness against fluid contact.



Physical characteristics		
Name	Test value (before radiation after radiation)	Reference standard
Fog degree	7/7°C	ASTM D-1003
Transparency ratio	97/97°C	ASTM D-1003
Transmittance	93/93°C	ASTM D-1003
Tensile strength	14/13MPa	ASTM D-882
Tensile ratio at break	280/300%	ASTM D-882
Elastic coefficient	370/350%	ASTM D-882
Low temperature tolerance	-45/-45°C	ISO8570
Density	0.9g	ASTM D-792
Water vapor penetration	0.35/0.32(g/M.day) (23°C,100%RH)	ASTM D-1249
Oxygen transmission rate	< 0.05L < (cm/M.day.bar) (23°C,0%RH)	ASTM D-3985
Carbon dioxide transmittance	< 0.21 < 0.2 (cm/M.day.bar) (23°C,0%RH)	ASTM D-2476

Pharmacopoeia compliance with biocompatibility evaluation items		
Evaluation item	Reference standard	
Hemolysis	ISO 10993-4	
Cytotoxicity	ISO 10993-5	
Implantation	ISO 10993-6	
Irritation and Sensitization tests	ISO 10993-10	
Acute Systemic Toxicity tests	ISO 10993-11	
Acute Systemic Toxicity tests	USP<85>	
Biological reactivity testing,in vivi,class VI	USP<88>	
Plastic Containers European Pharmacopoeia tests,CH.3.1.5	USP<661>	



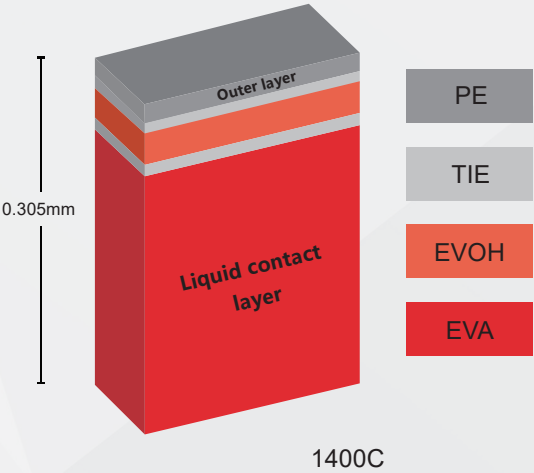
Shanghai Tofflon Medical Packaging Materials Co., Ltd. produces single-use sterile bags made of multi-layer laminated biofilm BF-1400C. Layered bio-film BF-1400C, the thickness of the film material is 0.305mm±10%.

The film thickness is 0.305mm±10%, which has the advantages of low solubility and no animal-derived components.

Our products are double-layered and individually packaged. BF-1400C is a three-layer biopharmaceutical membrane designed specifically for bioprocess applications. The solution contact layer of the film is made of EVA material, which has good chemical stability. The middle layer is made of kneading-resistant barrier resin (EVOH), which has excellent barrier properties for many gases such as oxygen and carbon dioxide. The middle layer is made of kneading-resistant barrier resin (EVOH), which has excellent barrier properties for many gases such as oxygen and carbon dioxide. The outer layer is made of LDPE with good transparency and mechanical properties.



Physical characteristics		
Physical property	Value	Standard
Haze	89%	ASTM D-1003
Clarification	31%	ASTM D-1003
Transmittance	88%	ASTM D-1003
Tensile Strength	17MPa	ASTM D-882
Elongation at break	800%	ASTM D-882
Modulus of elasticity	94MPa	ASTM D-882
Low Temperature Rupture Temperature	Below -40°C	ASTM D-1890
Density	0.96g/cm³	ASTM D-792
Water vapour transmission rate	1.58g/(m² .day) (23°C, 100%RH)	ASTM D-1249
Oxygen transmission rate	3.40cm³/(m² .day) (23°C, 0%RH)	ASTM D-3985
Carbon dioxide transmittance	8.25cm³/(m² .day) (23°C, 0%RH)	ASTM D-2476



Single-use Mixing Bag

Product Description: Disposable mixing bags can be widely used in the mixing step in the upstream and downstream processes of biopharmaceuticals, such as the preparation of buffers and culture media and other solutions, to meet the needs of a variety of process specifications. The bags can be used in a wide range of biopharmaceutical upstream and downstream processes. Customized connections of suitable filters, connectors and pipework can be supplied and the overall assembly improves the flexibility and efficiency of the treatment operation, thus increasing productivity.

Product Specifications : 50L / 100L / 200L / 500L / 1000L / 2000L (Customised)



Product Feature

- ✓ Adequate stocking: Raw materials, membranes and modules are adequately stocked to ensure the stability of the supply chain.
- ✓ Wide range of applications: It can meet various solid-liquid and liquid-liquid mixing requirements in the downstream process of biopharmaceuticals.
- ✓ Integrity testing: 100 per cent integrity testing, higher quality requirements to reduce the risk of use.
- ✓ Membrane properties: The membrane has good physical strength, chemical compatibility and biocompatibility.
- ✓ High-efficiency mixing: bottom welding stirring device, a variety of speed options, to achieve rapid mixing.

Application Fields

- | | |
|--------------------------------------|--|
| ✓ Configuration of buffers and media | ✓ Virus inactivation |
| ✓ PH adjustment | ✓ UF/DF formulations |
| ✓ Resuscitation | ✓ Product mixing |
| ✓ Chromatographic bath | ✓ Inventory storage and trans-shipment |



Single-use 2D Storage Bag

Product Description: Single-use 2D storage bags are designed for use in a wide range of small-scale applications in the cell therapy, antibody drug seed expansion and vaccine development and clinical manufacturing phases. They are used for sterilisation, filtration and storage of buffers and media, stock solution harvesting, product consolidation, sample collection, batch intermediate preservation, and transport of final products, ensuring a sterile environment and reducing the risk of contamination.

Product specification: 0.5L/1L/2L/3L/5L/10L/20L/50L (Customised)



Product Feature

- ✓ The bag is made of multilayer polymer biopharmaceutical film with good biocompatibility.
- ✓ 100% integrity tested and gamma irradiated to ensure sterility.
- ✓ Product features can be customised according to customer requirements.
- ✓ Accommodate the storage and transfer of all types of solutions in bioprocesses.
- ✓ One-piece design with small liquid residue.
- ✓ Customisable service.

Application Fields

- ✓ Storage of small-scale media, buffers and other sterile solutions
- ✓ Storage of intermediates, semi-finished products
- ✓ Liquid harvest
- ✓ Product storage
- ✓ Functions of buffer bags



Single-use 3D Storage Bag

Product Description: Disposable 3D liquid storage bags are designed for the storage and transfer of liquids in biopharmaceutical processes. They are used for sterilization, filtration and storage of buffers and media, stock solution harvesting, product consolidation, sample collection, batch intermediate preservation, and end-product shipment to ensure an aseptic environment and reduce the risk of contamination.

Product specification: 50L/100L/200L/500L/1000L/2000L/3000L (Customized)



Product Feature

- ✓ Membranes have good physical strength, chemical compatibility and biocompatibility.
- ✓ Highly transparent film for supportive process judgement.
- ✓ Meets the storage and transfer needs of all types of solutions in the biopharmaceutical process.
- ✓ Flexibility to customize sizes and pipework for a wide range of processes.

Application Fields

- ✓ Storage and transfer of buffers and media
- ✓ Cell culture harvest clarification
- ✓ Purification component collection
- ✓ Adequate liquid-liquid mixing process
- ✓ Liquid storage and transfer



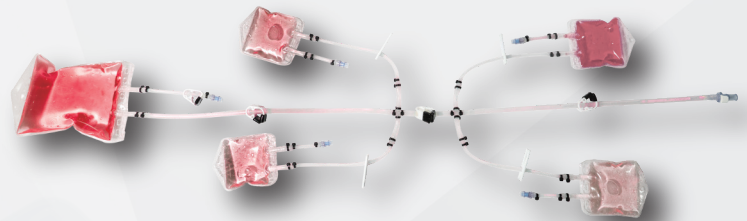
Single-use Sterile Sampling Bag

Product Description: Single-use aseptic sampling bag and sampling system are designed for sampling in cell culture, media preparation and other processes. The systematic design of the sampling bag and sampling system ensures the sterility and low residue of the pipeline connection and sampling. This makes the sampling process safer and reduces material loss and repeatability.

Product Specification: 50mL-3L (Customised)

Product Feature

- ✓ Multi-channel delivery and sampling possible.
- ✓ Ensure sterility throughout the sampling process.
- ✓ Customisable size interface.



Single-use Sterile Sampling System

- ✓ Suitable for Tofflon equipment, suitable for ASME BPE standard clamping. Suitable for stainless steel tank mounting type, pipe mounting type, suitable for different sampling volumes.
- ✓ Adaptable to single-use bags and tubes for sampling.



Single-use Lining Bag

Product Description: Single-use Lining bags can be used as liners for plastic or stainless steel cartridges. They are designed to be used as one-off containers for the preparation of nutrient or buffer fluids, etc. This reduces cleaning of the containers and improves turnaround time.

Product specification: 50L/100L/200L/300L/500L (Customized)



Product Feature

- ✓ Higher economy compared to closed bag types.
- ✓ Open-mouth design facilitates quick input of large quantities of material.
- ✓ Any combination of pipework can be used to reach through the mouth of the bag to extract the material.
- ✓ Customized version with bottom outlet tube (recommended for taller bags).
- ✓ Pockets can be tied to mitigate cross-impact or risk to the environment.

Application Fields

- ✓ Medium preparation.
- ✓ Buffer preparation.
- ✓ Short-term storage and transit of cell harvesting fluids.
- ✓ Short-term storage of purification intermediates.
- ✓ Waste liquids from the purification process.





Tofflon Tofflon Science and Technology Group Co.,Ltd.

Address: No.1509,Duhui Road,Shanghai,China 201108

Tel: +86 21 6490 1123 / 6490 6201

Fax: +86 21 6490 5148 / 6490 6202

E-mail: lifescience.info@tofflon.com

www.tofflon.com

