Tofflon Life Science



# Single-use Assemblies Brochure


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# Company Profile

Shanghai Tofflon Medical Packaging Material Co., Ltd. is a leading one-stop solution provider of bioprocess components. We are engaged in R&D, production and sales of single-use assemblies. Adhering to the mission of quality and integrity, Tofflon is committed to following the development of the biopharmaceutical industry, making every effort to satisfy all kinds of process needs of our customers, providing the world's leading new type of single-use process consumables, as well as innovating and continuously improving.

The company has passed the three systems certification, the whole production process meets the GMP requirements, the products have DMF registration, and has 2 production sites, the production capacity can be up to 800,000 sets/year. Our products applications cover the fields of biomolecule drugs, vaccines, cellular and gene therapy drugs, etc. We can provide total solutions of single-use process technology for each process step, including: cell culture solutions, final filling solutions, mixing and storage solutions and fluid management solutions.

# Biopharmaceutical Membrane



IX9101 membrane for Single-use Cell Culture Bag, Single-use Bioreactor Bag and Single-use Filling Systems is a five-layer co-extruded membrane with a total thickness of up to 0.32mm, featuring good flexibility and transparency, excellent biocompatibility and chemical compatibility.

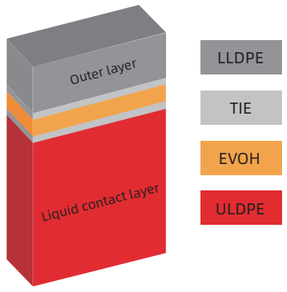
T2101 membrane for Single-use Mixing Bags,Single-use 2D Storage Bag and Single-use 3D Storage Bag is a seven-layer co-extruded membrane with a total thickness of up to 0.36mm. It has excellent mechanical strength and toughness, which improves the strength of the membrane material, and is characterized by resistance to abrasion, puncture and folding.

1958 membrane for Single-use 2D Storage Bag and Single-use 3D Storage Bag is a seven-layer co-extruded membrane with a total thickness of up to 0.33mm, which has excellent mechanical and processing properties, along with characteristics such as high sealing performance, strong barrier properties, and resistance to crumpling.

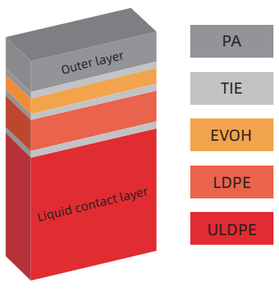
1250 membrane for Single-use 2D Storage Bag, Single-use 3D Storage Bag and Single-use Bioreactor Bag is a ten-layer co-extruded membrane with a total thickness of up to 0.318 mm. It features low extractables, high barrier properties, high mechanical strength, and fluid-resistant inertness.

## Product Features

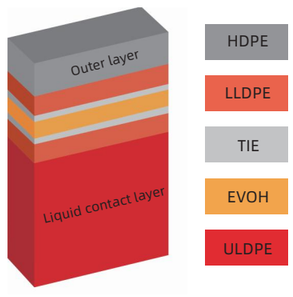
- LLDPE has high transparency and excellent flexibility to increase membrane processing performance.
- EVOH has high barrier properties and provides better water and air resistance.
- PA increases the physical properties of the membrane.
- ULDPE is highly inert, low precipitation dissolution and suitable for direct contact with biological fluids and pharmaceuticals.
- HDPE features high rigidity and strength, making it suitable for use as the outer layer to provide protection and support.
- TPE has high mechanical strength while also exhibiting high inertness.
- PE has high inertness, good flexibility, and low-temperature resistance.



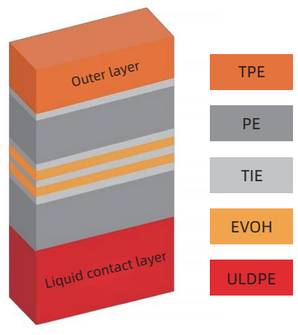

Membrane IX9101




Membrane T2101




Membrane 1958




Membrane 1250



## Physical Test

| Part | Post-irradiation test values | Reference standard |
|---|---|---|
| Tensile Strength | 13MPa | ASTM D-882 |
| Tensile Strength at Break | 300% | ASTM D-882 |
| Coefficient of Elasticity | 350% | ASTM D-882 |
| Transparency | 97% | ASTM D-1003 |
| Water Vapor Infiltration | 0.35/0.32(g/M.day)(23℃,100%RH) | ASTM D-1249 |
| Oxygen Permeability | < 0.05L < (cm/M.day.bar)(23℃,0%RH) | ASTM D-3985 |
| Carbon Dioxide Transmission | < 0.21 < 0.2(cm/M.day.bar)(23℃,0%RH) | ASTM D-2476 |

## Chemical Test

| Part | Reference standard |
|---|---|
| Extractable | BPOG |
| Heavy Metal (chemistry) | USP<661> |
| Non-volatile Residues | USP<661> |
| Chemical Compatibility | Customizable |

## Biocompatibility

| Part | Reference standard |
|---|---|
| Hemolysis Test | ISO 10993-4 |
| Cytotoxicity | ISO 10993-5 |
| Implantation Test | ISO 10993-6 |
| Sensitization Test | ISO 10993-10 |
| Acute Systemic Toxicity Test | ISO 10993-11 |
| Cellular Endotoxin | USP<85> |
| in Vivo Biological Reaction | USP<88> |

# Cell Culture Solutions

We provide Single-use Cell Culture Bag, Single-use Bioreactor Bag and Single-use Fermentation Bag for upstream cell culture processes.

- Single-use Cell Culture Bag
- Single-use Bioreactor Bag
- Single-use Fermentation Bag



## Single-use Cell Culture Bag

The Single-use Cell Culture Bag is designed for cell therapy, antibody drug seed expansion and vaccine production applications. The Single-use Cell Culture Bag provides rapid cell expansion through the use of CES, SUR and other equipment, and provides excellent mixing and aeration to ensure a sterile environment and reduce the risk of contamination.

### Product Features

- Made of multilayer polymer biopharmaceutical membrane with good biocompatibility;
- 100% integrity tested and gamma irradiated to ensure sterility;
- The bags can be customized to integrate sensors such as pH, DO, etc. for complex process control;
- Supports the selection of perfusion membranes and sheet carriers, and the perfusion function helps to realize high-density cell culture faster.
- Product features can be customized according to customer needs.



Single-use Cell Culture Bag



Single-use Perfusion Bag

### Product Applications

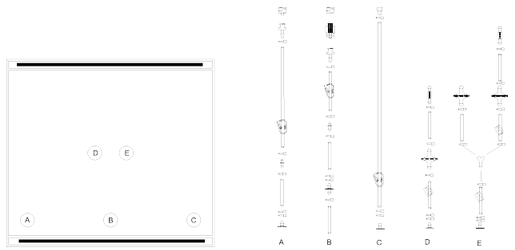
- Immune cell therapy (CAR-T, primary T lymphocytes, etc.)
- Stem cell preparation (cord blood stem cells, embryonic stem cells, etc.)
- Antibody drug preparation (PD-1, PDL-1, etc.)
- Recombinant protein product preparation (recombinant coagulation factors, EPO, TPO, etc.)
- Viral vector preparation (adenovirus, lysovirus, etc.)
- Vaccine preparation (adenovirus-vectored neoguana vaccine, mRNA neoguana vaccine, etc.)
- Laboratory process development and mapping

### Product Information

| Model Number | XPD-T series standard configuration | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Part Number | XPD-T-1LA1 | XPD-T-2LA1 | XPD-T-5LA1 | XPD-T-10LA1 | XPD-T-20LA1 | XPD-T-50LA1 | XPD-T-100LA1 | XPD-T-200LA1 |
| Specification | 1L | 2L | 5L | 10L | 20L | 50L | 100L | 200L |
| Minimum working Volume (L) | 0.1L | 0.2L | 0.5L | 1L | 1L | 5L | 10L | 20L |
| Maximum working Volume (L) | 0.5L | 1L | 2.5L | 5L | 10L | 30L | 50L | 100L |
| Operating Temperature | 0-40°C | | | | | | | |
| Product Customization | * pH, DO fiber optic electrode line, 1.2μm/3μm/7-12μm perfusion membrane optional, sheet carrier optional, overall customizable. Maximum and minimum volume is the working volume of the standard bag. | | | | | | | |

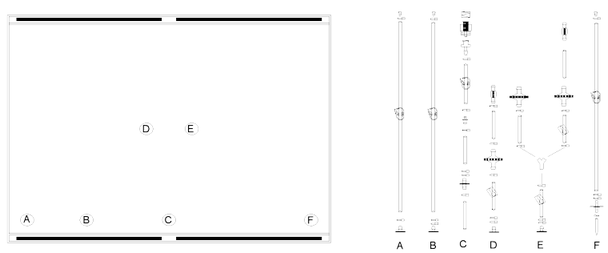
| Part Number | | XPD-T-1LA1、XPD-T-2LA1、XPD-T-5LA1<br>XPD-T-10LA1、XPD-T-20LA1、XPD-T-50LA1 |
|---|---|---|
| Specification | | 1L、2L、5L、10L、20L、50L |
| Configuration | A | Feed line: 6.4*9.6mm Silicone Tube 7cm, Reducer Connector, 3.2*6.4mm TPE Tube 150cm, Luer connector |
| | B | Sampling line: (Outside) : 6.4*9.6mm Silicone Tube 7cm, 3.2*6.4mm TPE Tube 7cm, Luer connector, needleless sampler (Inside): 6.4*9.6mm Silicone Tube 7cm |
| | C | Harvesting line: 9.6*16mm Silicone Tube 7cm, 3.2*6.4mm TPE Tube 150cm, Luer connector |
| | D | Exhaust Line: 8*12.7mm Silicone Tube 5cm, Slide Clamp, 0.2μm filter, check valve |
| | E | Inlet/Pressure Monitoring Line: 8*12.7mm Silicone Tube 5cm, Slide Clamp, Y-connector, 0.2μm filter, check valve |

## Schematic Diagram




| Part Number | | XPD-T-100LA1 |
|---|---|---|
| Specification | | 100L |
| Configuration | A | Feed line: 3.2*6.4mm TPE tube 150cm, plugs |
| | B | Wave filling line: 6.4*11.1mm TPE Tube 110cm, plugs |
| | C | Sampling line: (Outside): 6.4*9.6mm Silicone Tube 6cm, 3.2*6.4mm TPE Tube 7cm, luer connector, needleless sampler (Inside): 6.4*9.6mm Silicone Tube 6cm |
| | D | Exhaust Line: 8*12.7mm Silicone Tube 5cm, Slide Clamp, 0.2um filter, check valve |
| | E | Inlet/Pressure line: 8*12.7mm Silicone Tube 5cm, Slide Clamp, Y-connector, 0.2um filter, check valve |
| | F | Harvest line: (Outside) : 9.6*16mm TPE Tube 150cm, plugged (Inside): 6.4*9.6mm Silicone tube 7cm (tail tip cut) |

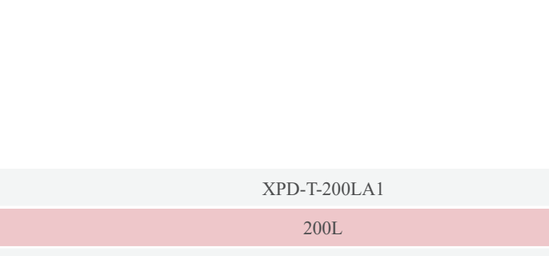
## Schematic Diagram






| Part Number | | XPD-T-200LA1 |
|---|---|---|
| Specification | | 200L |
| Configuration | A | Feed line: 6.4*11.1mm TPE Tube*110cm plug |
| | B | Feed line: 3.2*6.4mm TPE Tube 200cm, plugs |
| | C | Sampling line: (Outside): 6.4*9.6mm Silicone Tube 7cm, 3.2*6.4mm TPE Tube 20cm, luer connector, needleless sampler; (Inside): 6.4*9.6mm Silicone Tube 10cm |
| | D | Harvest line: (Outside): 9.6*16mm TPE Tube 20cm, plug (Inside): 6.4*9.6mm 10cm Silicone Tube (tail tip cut) |
| | E | Exhaust Line: 8*12.7mm Silicone Tube 8cm, Slide Clamp, 0.2um filter, check valve |
| | F | Inlet/Pressure measurement line: 8*12.7mm Silicone Tube 8cm, Slide Clamp, Y-connector, 0.2um filter, check valve |
| | G | Temperature monitoring:(Outside): 6.4*9.6mm silicone tube 4cm, 9.6*16mm silicone tube 6cm (Inside): 4.8*8.0mm Silicone Tube 20cm, plugs |
| | H | Exhaust piping: 8*12.7mm Silicone Tube 8cm, shut-off clamp, 0.2um filter, check valve |

## Schematic Diagram




## Cell Expansion System






# Single-use Bioreactor Bag

The Single-use Bioreactor Bag is designed for upstream applications in cell therapy, antibody drug seed expansion and vaccine production. Originally developed for immersion mixing applications, the mixing system provides excellent stability as well as good mixing and aeration.

## Product Features

- Portability: single-use technology eliminates the need for cleaning, thus avoiding the risk of cross-contamination;
- Stability: made of multilayered transparent membrane that provides mechanical strength against tearing, as well as biological resistance to fluid contact;
- Customizability: Single-use Bioreactor Bag can be customized with connectors, tubes, and special attachments;
- Stirring device, aeration sump unit: powerful mixing capabilities,excellent oxygen mass transfer capacity;
- Configurations: a variety of connectors, sensors or filters for different functions to support the upstream and downstream requirements of buffers, media, products and intermediates as well as other process fluids;
- 100% integrity testing prior to delivery.



Single-use Bioreactor Bag



Single-use Bioreactor

## Product Applications

- Cell culture
- Process development, process scale-up
- Cell Culture Media Preparation

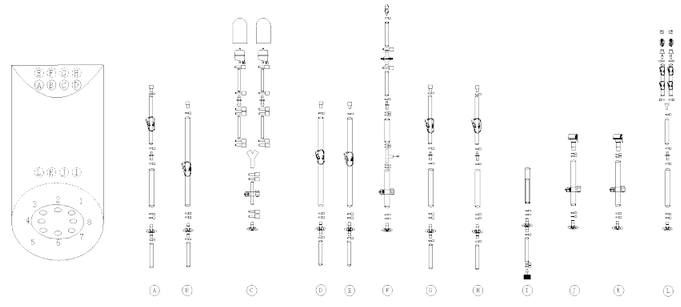
## Product Information

| Model Number | SUB-A series standard configuration | | | | |
|---|---|---|---|---|---|
| Part Number | SUB-A-50LA1 | SUB-A-200LA1 | SUB-A-500LA1 | SUB-A-1000LA1 | SUB-A-2000LA1 |
| Specification | 50 | 200 | 500 | 1000 | 2000 |
| Minimum Working Volume (L) | 10 | 40 | 100 | 200 | 400 |
| Maximum Working Volume (L) | 50 | 200 | 500 | 1000 | 2000 |
| Stirring Speed | 0-360 | 0-360 | 0-250 | 0-140 | 0-115 |
| pH Sensor | 1 | 2 | 2 | 2 | 2 |
| DO Sensor | 1 | 2 | 2 | 2 | 2 |
| Stirring type | Bottom magnetic stirring | | | | |
| Ventilation | Bottom large bubble + small bubble ventilation/surface layer ventilation | | | | |
| Operating Temperature | 37℃ | | | | |
| Temperature Port | Support | | | | |
| Bag Pressure Port | Support | | | | |
| Sampling System | Luer connector Aseptic Sampling | | | | |



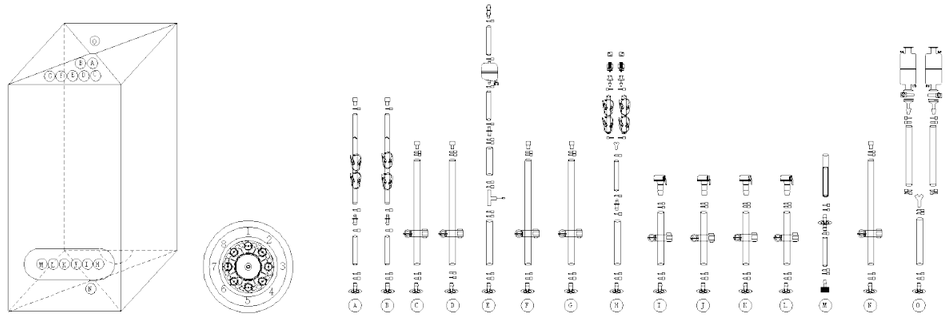
| Part Number | | SUB-A-50LA1 |
|---|---|---|
| Specification | | 50L |
| Configuration | A | Feed line:(Outside): 6.4*11.1mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*120cm,<br>plug (Inside): 6.4*9.6mm Silicone Tube*2.6cm |
| | B | Liquid inlet line: (Outside): 6.4*11.1mm TPE Tube*120cm,<br>plug (Inside): 6.4*9.6mm Silicone Tube*2.6cm |
| | C | Exhaust Line: 12.7*19.1mm TPE Tube*10cm<br>(Left) 12.7*19.1mm TPE Tube*10cm,6.4*11.1mm TPE Tube*8cm,0.2μm 2in Air Filter<br>(Right)12.7*19.1mm TPE Tube*10cm,6.4*11.1mm TPE Tube*8cm,0.2μm 2in Air Filter |
| | D/E | Liquid inlet line: (Outside): 6.4*11.1mm TPE tube*120cm,<br>plug (Inside): 6.4*9.6mm Silicone Tube*2.6cm |
| | F | Pressure monitoring/surface vent line: 12.7*19.1mm TPE Tube*30cm, pressure sensor,<br>12.7*19.1mm TPE Tube*15cm, 6.4*11.1mm TPE Tube*8cm, 0.2μm air filter,<br>6.4*11.1mm TPE Tube*8cm, 1/4NPT turn 1/4 Pagoda, 1/4 Air Connector |
| | G/H | Feed line: (Outside): 6.4*11.1mm TPE tube*8cm, 3.2*6.4mm TPE Tube*120cm,<br>plug (Inside): 6.4*9.6mm Silicone Tube*2.6cm |
| | I | Temperature monitoring line: (Outside): 6.4*9.6mm Silicone Tube*4cm, 9.6*16mm Silicone<br>Tube*6cm (Inside): 4.8*8.0mm Silicone Tube*5cm, fiber optic connector |
| | J/K | pH/DO line: 16mmID*12.7mmID Reducer Silicone Tubing, sterile connector |
| | L | Sampling line: 6.4*11.1mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*8cm<br>(Left)3.2*6.4mm TPE Tube*32cm, 32mm female luer connector,needleless sampler,cap guard<br>(Right)3.2*6.4mm TPE Tube*32mm, 3.2mm fe,ale luer connector,needleless sampler,cap guard |

## Schematic Diagram



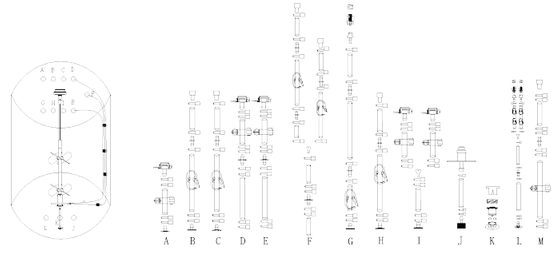
| Model Number | | SUB-A series standard configuration |
|---|---|---|
| Part Number | | SUB-A-200LA1、SUB-A-500LA1、SUB-A-1000LA1、SUB-A-2000LA1 |
| Specification | | 200L、500L、1000L、2000L |
| Configuration | A | Feed line: 6.4*9.6mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*305cm, plugs |
| | B | Feed line: 6.4*9.6mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*305cm, plugs |
| | C | Liquid inlet line: 12.7*19.1mm TPE tube*300cm, Plugs |
| | D | Liquid inlet line: 12.7*19.1mm TPE tube*300cm, Plugs |
| | E | Pressure monitoring/Surface Vent Line: 12.7*19.1mm TPE Tube*60cm, Pressure Sensor, 12.7*19.1mm TPE Tube*16cm, 6.4*11.1mm TPE Tube*8cm, 0.2μm 2in Gas Filter, 6.4*11.1mm TPE Tube*8cm, 1/4NPT turn 1/4 Pagoda, 1/4 Air Connector |
| | F | Liquid inlet line: 12.7*19.1mm TPE tube*300cm, Plugs |
| | G | Liquid inlet line: 12.7*19.1mm TPE tube*300cm, Plugs |
| | H | Sampling line: 6.4*9.6mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*5cm (left) 3.2*6.4mm TPE Tube*30cm, 3.2mm female luer connector, needleless sampler, needleless cap (right) 3.2*6.4mm TPE Tube*30cm, 3.2mm female luer connector, needleless sampler, needleless cap |
| | I | pH/DO line: 16ID*12.7ID Reducer silicone tube*8cm, sterile connector |
| | J | pH/DO line: 16ID*12.7ID Reducer silicone tube*8cm, sterile connector |
| | K | pH/DO line: 16ID*12.7ID Reducer silicone tube*8cm, sterile connector |
| | L | pH/DO line: 16ID*12.7ID Reducer Silicone Tube*8cm, sterile connector |
| | M | Temperature monitoring line: (Outside): 6.4*9.6mm Silicone Tube*4cm, 9.6*16mm Silicone Tube*6cm (Inside): 4.8*8.0mm Silicone Tube*16.5cm, fiber optic connector |
| | N | Harvesting Line: 12.7*19.1mm TPE Tube*150cm, plugs |
| | O | Exhaust line: 12.7*19.1mm TPE Tube*10cm (Left) 12.7*19.1mm TPE Tube*16cm, 0.2μm 5in gas filter (Right) 12.7*19.1mm TPE Tube*16cm, 0.2μm 5in gas filter |

## Schematic Diagram



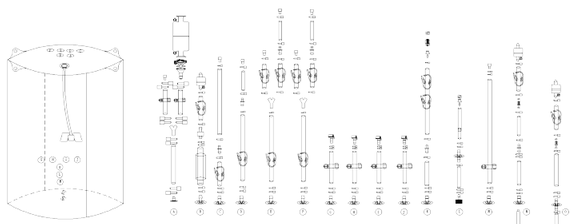
| Model Number | | SUB-E series standard configuration | | | | |
|---|---|---|---|---|---|---|
| Part Number | | SUB-E-50LA1 | SUB-E-200LA1 | SUB-E-500LA1 | SUB-E-1000LA1 | SUB-E-2000LA1 |
| Specification | | 50 | 200 | 500 | 1000 | 2000 |
| Minimum Working Olume (L) | | 12.5 | 50 | 150 | 250 | 500 |
| Maximum Working Volume (L) | | 50 | 200 | 500 | 1000 | 2000 |
| Stirring Speed | | 240 | 150 | 110 | 90 | 70 |
| pH Sensor | | 1 | 2 | 2 | 2 | 2 |
| DO Sensor | | 1 | 2 | 2 | 2 | 2 |
| Stirring type | | Double paddle magnetic stirring | | | | |
| Ventilation | | Bottom large bubble + small bubble ventilation/surface layer ventilation | | | | |
| Operating Temperature | | 37°C | | | | |
| Temperature Port | | Support | | | | |
| Bag Pressure Port | | Support | | | | |
| Sampling System | | Luer connector Aseptic Sampling | | | | |
| Configuration | A | Surface ventilation line: 12.7*19.1mm Silicone Tube*15cm, CPC sterile connector | | | | |
| | B | Liquid inlet line: 9.6*16mm Silicone Tube*250cm, 9.6*16mm TPE tube*50cm, Plug | | | | |
| | C | Liquid inlet line: 9.6*16mm Silicone Tube*250cm, 9.6*16mm TPE tube*50cm, Plugs | | | | |
| | D | Large bubble inlet piping: (Outside): 12.7*19.1mm Silicone Tube*15cm, CPC sterile connector (Inside): 12.7*19.1mm TPE Tube*120cm | | | | |
| | E | Small bubble inlet line: (Outside): 12.7*19.1mm Silicone Tube*15cm, CPC sterile connector (Inside): 12.7*19.1mm TPE Tube*120cm | | | | |
| | F | Feed line: (Outside): 9.6*16mm Silicone Tube*15cm (Left) 9.6*16mm Silicone Tube*10cm, 6.4*9.6mm Silicone Tube*250cm, 6.4*9.6mm TPE Tube*50cm, Plug (right) 9.6*16mm Silicone Tube*250cm, 9.6*16mm TPE Tube*50cm, Plug (Inside): 9.6*16mm TPE Tube*100cm | | | | |
| | G | Liquid inlet line: 6.4*9.6mm Silicone Tube*15cm, 3.2*6.4mm Silicone Tube*250cm, 3.2*6.4mm TPE Tube*50cm, 3.2mm Female Luer Connector + Needle-Free Sampler + Cap for Sampler | | | | |
| | H | Defoaming Line: 6.4*9.6mm Silicone Tube*250cm, 6.4*9.6mm TPE Tube*50cm, plugs | | | | |
| | I | Outlet line: 12.7*19.1mm Silicone Tube*10cm (Left) 12.7*19.1mm Silicone Tube*20cm, CPC sterile connector (Right) 12.7*19.1mm Silicone Tube*20cm, CPC sterile connector | | | | |
| | J | Temperature monitoring line: temperature electrode weldment, 4.8*8.cm Silicone Tube*5cm, fiber optic connector | | | | |
| | K | pH/DO lines: pH/DO patch connector, pH fiber optic sensors, DO fiber optic sensors | | | | |
| | L | Sampling line: 6.4*11.1mm TPE Tube*8cm, 3.2*6.4mm TPE Tube*8cm (Left) 3.2*6.4mm TPE Tube*50cm, 3.2mm Female Luer Fitting, Needleless Sampler, Needleless Cap (Right) 3.2*6.4mm TPE Tube*50cm, 3.2mm Female Luer Connector + Needle Free Sampler + Cap for Sampler | | | | |
| | M | Harvesting line: passive seat, 12.7*19.1mm silicone tube*250cm, 12.7*19.1mm TPE tube*50cm, plugs | | | | |

## Schematic Diagram



| Model Number | SUB-B series standard configuration | | | | | |
|---|---|---|---|---|---|---|
| Part Number | SUB-B-50LA1 | SUB-B-100LA1 | SUB-B-250LA1 | SUB-B-500LA1 | SUB-B-1000LA1 | SUB-B-2000LA1 |
| Specification | 50L | 100L | 250L | 500L | 1000L | 2000L |
| Minimum Working Olume (L) | 25L | 50L | 125L | 250L | 500L | 1000L |
| Rated Working Volume (L) | 50L | 100L | 250L | 500L | 1000L | 2000L |
| Stirring Speed | 30-200rpm | 30-200rpm | 30-137rpm | 30-137rpm | 20-90rpm | 20-75rpm |
| pH sensor | 2 | 2 | 2 | 2 | 2 | 3 |
| DO Sensor | 2 | 2 | 2 | 2 | 2 | 3 |
| Stirring type | Top mechanical stirring | | | | | |
| Ventilation | Bottom large bubble + small bubble ventilation/surface layer ventilation | | | | | |
| Operating Temperature | 37℃ | | | | | |
| Temperature Port | Support | | | | | |
| Bag Pressure Port | Support | | | | | |
| Sampling System | Luer connector Aseptic Sampling | | | | | |
| Configuration | A | Exhaust line: 12.7*19.1mm TPE Tube*20cm, (Left) 12.7*19.1mm TPE Tube*25cm, plug (Right) 12.7*19.1mm TPE Tube*25cm, 0.2μm gas filter | | | | |
| | B | Surface ventilation line:25*35mm Silicone Tube*8cm, 6.4*11.1mm TPE Tube*15cm, 6.4*11.1mm TPE Tube*15 cm, 0.2μm gas filter | | | | |
| | C | Inlet line: 6.4*11.1mm TPE Tube*15cm, 3.2*6.4mm TPE Tube*150cm, plugs | | | | |
| | D | Inlet line: 6.4*11.1mm TPE Tube*150cm, 3.2*6.4mm TPE tube*60cm, plugs | | | | |
| | E | Rehydration line: 9.6*16mm TPE Tube*150cm (left) 9.6*15.9mm TPE Tube*50cm, plug (Right) 9.6*15.9mm TPE Tube*50cm, 6.4*9.6mm TPE Tube*50cm, plugs | | | | |
| | F | Feed line: 9.6*16mm TPE Tube*150cm (Left) 9.6*15.9mm TPE Tube*50cm,plugs (Right) 9.6*15.9mm TPE Tube*50cm, 6.4*9.6mm TPE Tube*50cm, plugs | | | | |
| | G | pH/DO line: 16mmID*12.7mmID Reducer Silicone Tube, sterile connector | | | | |
| | H | pH/DO line: 16mmID*12.7mmID Reducer Silicone Tube, sterile connector | | | | |
| | I | pH/DO line: 16mmID*12.7mmID Reducer Silicone Tube, sterile connector | | | | |
| | J | pH/DO line: 16mmID*12.7mmID Reducer Silicone Tube, sterile connector | | | | |
| | K | Sampling line: 6.4*9.6mm TPE tube*5cm, 3.2*6.4mm TPE Tube*60cm, 3.2mm Female Luer Connector + Needleless Sampler + Cap for Sampler | | | | |
| | L | Temperature monitoring line: (Outside): 6.4*9.6mm Silicone Tube*4cm, 9.6*15.9mm Silicone Tube*4cm, 6.4mm female luer connector, male luer cap; (Inside): 4.8*8.cm Silicone Tube*16cm, fiber optic connector | | | | |
| | M | Harvesting Line:12.7*19.1mm TPE Tube*150cm, plugs | | | | |
| | N | Bottom small bubble line: (Inside): 10μm Ventilation rod Stick (Outside): 16*22.2mm Silicone Tube*6cm, Reducer connector,6.4*9.6mm TPE Tube*16cm, Check Valve, 6.4*9.6mm TPE Tube*120cm,0.2μm 2in Gas Filter | | | | |
| | O | Bottom large bubble piping: (Inside): 6.4*9.6mm TPE Tube*5cm (Outside): 6.4*9.6mm TPE Tube*30cm, Check valve, 6.4*9.6mm TPE Tube*120cm, 0.2μm 2in gas filter | | | | |

## Schematic Diagram





# Single-use Fermentation Bag

The Single-use Fermentation Bag is designed for the upstream cultivation of microorganisms such as E. coli, Pseudomonas, and yeasts, and maintains its integrity under high speed, turbulent mixing conditions, while its six straight-blade disc turbine design, high VVM (Ventilation speed ratio) airflow, and baffle design allow it to meet the demands of high-density microbial fermentation.

## Product Features

- Portability of use: single-use technology eliminates the need for cleaning, thus avoiding the risk of cross-contamination;
- Stability: made of a multilayer transparent membrane that provides high mechanical strength against tearing, as well as biological resistance to fluid contact;
- Stirring device, aeration sump unit: powerful mixing capacity, excellent oxygen mass transfer, provides up to 2 vvm of aeration and venting, single venting air KLa The KLa of single through-air is up to 100h-1, which is the only single-use fermenter in the domestic market that can reach the simulation of the traditional equipment;
- Configuration: BPC integrated foam detection electrode, safer to use; redundant design, supporting tail gas filter for one use, safer.

## Product Applications

- High-density microbial fermentation

## Product Pictures

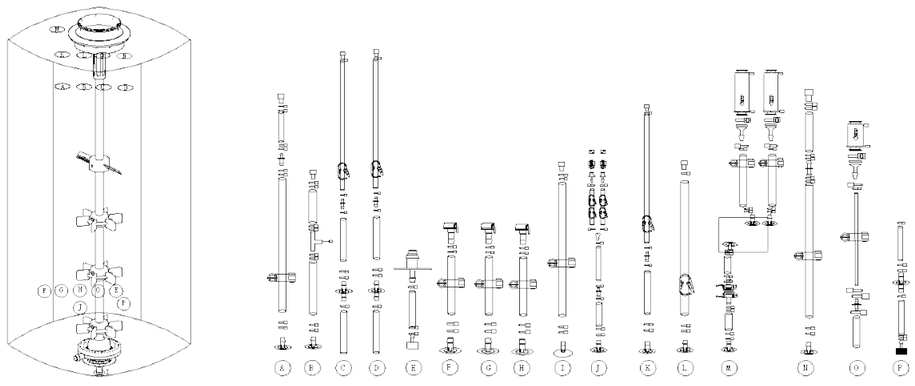
| Product Name | Single-use Fermentation Bag | Single-use Fermenter |
|---|---|---|
| Product Pictures |  |  |

## Product Information

| Model Number | SUF-T series standard configuration | |
|---|---|---|
| Part Number | SUF-T-50LA1 | SUF-T-200LA1 |
| Specification | 50L | 200L |
| Minimum Working Olume (L) | 10L | 40L |
| Rated Working Volume (L) | 50L | 200L |
| Stirring Speed | 0-550 | 0-450 |
| pH Sensor | 1 | 2 |
| DO Sensor | 1 | 2 |
| Stirring type | Magnetic Stirring | |
| Ventilation | Bottom Aeration Disk Aeration | |
| Operating Temperature | 0-40℃ | |

| Part Number | | SUF-T-50LA1、SUF-T-200LA1 |
|---|---|---|
| Product Specification | | 50L、200L |
| Configuration | A | Liquid inlet line: (Outside): 12.7*19.1mm Silicone Tube*1500mm, 12.7*19.1mm TPE Tube*500mm, Plugs |
| | B | Pressure monitoring Line: 12.7*19.1mm TPE Tube*80mm, Pressure Sensor, 12.7*19.1mm TPE Tube*80mm, Plugs |
| | C/D | Feed line: (Outside): 6.4*11.1mm TPE Tube*80mm, 3.2*6.4mm TPE Tube*1200mm, plugs (Inside): 6.4*11.1mm TPE Tube*25mm |
| | E | Temperature monitoring line: temperature electrode weldment, 4.8*8.0mm Silicone Tube*100mm, fiber optic connector |
| | F/G/H | pH/DO line: 16ID*12.7ID Reducer Silicone Tube, sterile connector |
| | I | Harvesting Line: passive seat barb mouth, 12.7*19.1mm TPE Tube*2000mm, plugs |
| | J | Sampling line: 6.4*11.1mm Silicone Tube*80mm, 3.2*6.4mm TPE Tube*80mm (Left) 3.2*6.4mm TPE Tube*320mm, 3.2mm female luer connector, Needleless Sampler, Needleless Cap (Right) 3.2*6.4mm TPE Tube*320mm, 3.2mm female luer connector. Needleless Sampler, Cap for Sampler |
| | K | Feed line: (Outside): 6.4*11.1mm TPE Tube*80mm, 3.2*6.4mm TPE Tube*1200mm, plugs |
| | L | Feed line: (Outside): 6.4*11.1mm TPE Tube*1200mm, plugs |
| | M | Exhaust Line: 19.1*25.4mm Silicone Tube*350mm, Sterile connector, sterile connector, 19.1*25.4mm Silicone Tube*300mm Condensate Pouch (Front) 19.1*25.4mm Silicone Tube*280mm, 2μm 10in Gas Filter (Behind) 19.1*25.4mm Silicone Tube*280mm, 2μm 10in Gas Filter |
| | O | Gas Inlet line: (Outside): 12.7*19.1mm Silicone Tube*2000mm, 2μm 5in gas filter, 6.4*11.1mm Silicone Tube*200mm, Pagoda connector, air hose connector; (Inside) 12.7*19.1mm silicone tube*150mm |
| | P | Gas Inlet line: (Outside): 12.7*19.1mm Silicone Tube*110mm (Inside): 12.7*19.1mm Silicone Tube*155mm, stainless steel plugs |

## Schematic Diagram



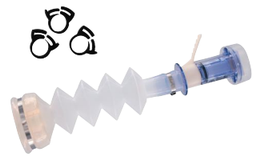


# Single-use Electrode Corrugated Tube Assembly

The Single-Use Electrode Corrugated Tube Assembly is designed for aseptic monitoring of pH, DO in biopharmaceuticals. It consists of corrugated silicone tubing, sterile quick couplings and PG13.5 threaded connector. It needs to be autoclaved in a sterilizing kettle at 121℃ for thirty minutes to one hour before it is put into use. Its black hand clamp cannot be autoclaved. The working of the sensor is guaranteed to isolate the sensor from external contamination such as stray bacteria by means of aseptic connectors.

## Product Features

- High temperature resistance: can be sterilized together with the sensor at high temperature;
- Asepticity: aseptic connector docking, blocking external bacteria and other contaminants;
- Chemical inertness: the main body of the material meets USP Class VI, does not react with the material;
- Electrical insulation: silicone bellows has a high resistivity, to avoid interference in the monitoring process;
- Convenient to use: corrugated line expansion and contraction of free, flexible and convenient.



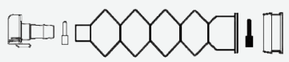
## Product Applications

- Commonly used for isolation and fixation of pH and DO electrodes in cell culture and single-use mixing system.

## Product Parameters

| Part Number | BWG-01 | BWG-F-01 | BWG-B-01 |
|---|---|---|---|
| Connector Type | KPC Aseptic connector | CPC sterile connector | CPC sterile connector |
| Sterilization Method | Not before leaving the factory, high-temperature moist heat sterilization when in use | | |
| Product Body | Silicone | | |
| Storage Temperature | 0-40°C | | |
| Storage Humidity | 35%-75% | | |
| Validity Period | 2 years | | |

## Product Assembly

| Product Name | CPC sterile connector + bllows + PG13.5 threaded connector + plug | KPC sterile connector + bellows + PG13.5 threaded connector |
|---|---|---|
| Product Pictures |  |  |

# Final Filling Solutions

Final filling systems are pre-sterilized, sterile, single-use consumables that are flexible, safe, shorten cycle times and reduce initial investment costs.

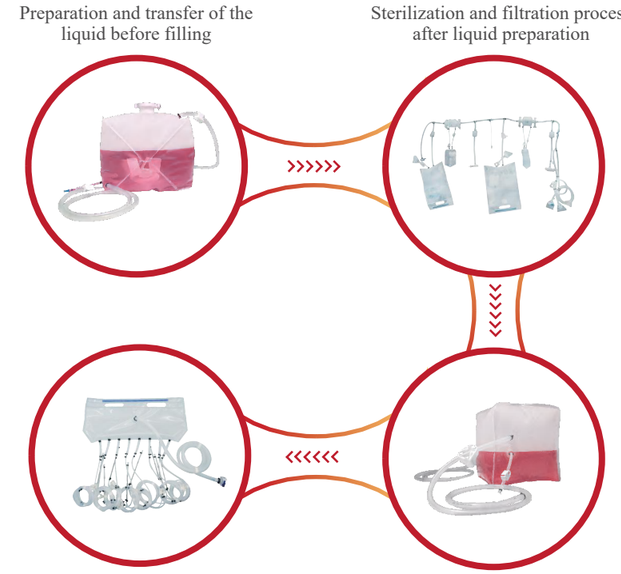
- Single-use Redundant PUPSIT Filtration
- Single-use Filling System
- Single-use beta Bag



## Final Filling Systems

Contains assemblies such as single-use mixing bag, single-use redundant PUPSIT filtration (with filter), single-use storage bag (buffer bag), single-use filling bag, filling lines and single-use filling needles.

### Process

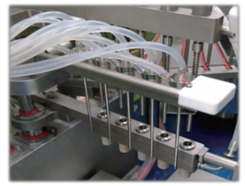



### Product Features

- Provide single-use filling total solution, provide flexible solutions for customer needs;
- Modular aseptic consumables, easy to install and operate, saving time and cleaning and verification costs;
- The use of single-use membrane materials with excellent performance and high transparency;
- Inverted trapezoidal design of the bag body to reduce the residue;
- With many years of experience in the development of solutions for the filling machine and the isolator, the consumables and the filler with high suitability, has a reliable Filling accuracy.

### Product Applications

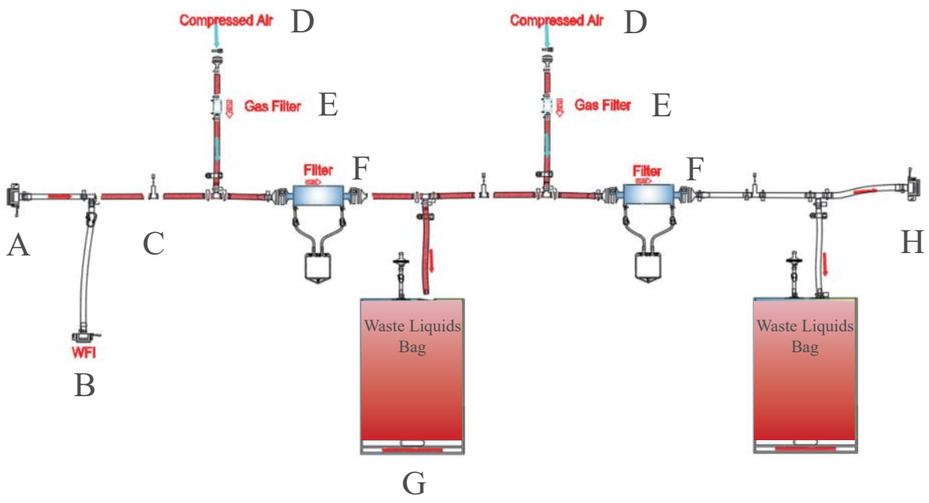
Semi-finished product preparation, sterilization filtration, and aseptic filling of vaccines, monoclonal antibodies, ADCs,double antibodies,recombinant proteins,etc.



# Single-use Redundant PUPSIT Filtration

The single-use redundant PUPSIT filtration, based on a sterilization and filtration process comfiguration, is a robust, sterile, ready-to-use design that allows flexibility in all process steps. The line can be designed according to the customer's process, with appropriate line length, material, line docking method, filter size, etc. The design supports pre-use integrity testing of sterilization filters.The filter can be selected from 0.22μm, 0.45μm single and double layer filter membranes,with sizes ranging from 1-20 inches.

## PUPSIT design




## Piping Description

- A: Liquid inlet
- B: WFI
- C: Pressure sensors
- D: Compressed air inlet
- E: Gas filter
- F: Liquid filter
- G: Waste liquid bag
- H: Liquid outlet

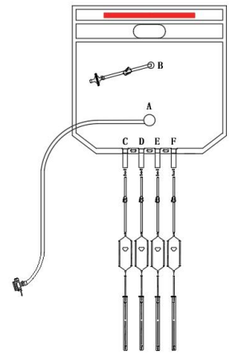


# Single-use Filling System

The Single-use Filling System is a pre-sterilized sterile filling consumable consisting of a sterile single-use connector, single-use filling bag, filling lines and single-use filling needles.

## Product Features

- Provide full specification stainless steel filling needle, single-use PEEK filling needle, can also be customized filling needle size, flexible to adapt to different brands of filling machines and the use of liquid medicine working conditions;
- Designed to minimize the use of adapters in the filling line, the design reduces the number of reducers between the bag and the pump tube, and between the pump tube and the needle, resulting in less residue and improved filling accuracy;
- Single-use ready-to-use RTP valve ports are available to enable rapid transfer of parts inside and outside the isolator;
- Well-designed dispensing piping to ensure filling accuracy;
- Class C+A environment for production and assembly, higher cleanliness;
- Bag volume can be customized (2L-10L).




## Piping Description

- A: Liquid inlet
- B: Air filter
- C-F: Filling line

## Product Pictures

| Product Name | Single-use Filling System | MiniKUFill Automatic Filling System |
|---|---|---|
| Product Pictures |  |  |

# Single-use Filling Needles

The Stainless steel filling needle consists of a 316L material lumen and a barbed interface that can be connected to a silicone tube.The length of the lumen is 100mm.
The stainless steel nitrogen-filled filling needle is assembled from a stainless steel inner needle equipped with a sealing ring and a nitrogen-filled needle.

## Product Features

- It can be used directly as a single-use or can be repeatedly cleaned and sterilized;
- The inner surface of the syringe is smooth and clean, without seams, and the finish is ≤ Ra0.4;
- Meets the requirements of insoluble particles and endotoxin tests without the need for pre-rinsing and drying;
- It can be sterilized by gamma irradiation, high temperature steam sterilization, and can be used at any time after sterilization;
- Straight filling needles allow high-speed filling control from bottom to top;
- The diameter of the tube lumen does not form liquid droplets, precise volume filling.

## Product Information

| Name | Stainless steel filling needles | Stainless steel nitrogen filling needle |
|---|---|---|
| Material | 316L | 316L+ Silicone Seal |
| Filling Needle Inner Diameter(mm) | 0.5、1.1、2.0、2.5、3.0、4.6、5.1 | 0.5、1.1、2.0、2.5、3.0、3.5、4 |
| Quantity/box | 12/ box | 10/ box |
| Product Pictures |  |  |

The Single-use plastic filling needle, consisting of a polyether ether ketone (PEEK) lumen and a polypropylene Luer connection with an interanl thread Luer connector, with and a filling needle lumen length of 75 mm.

## Product Features

- Meets the requirements of insoluble particles and endotoxin tests without the need for pre-rinsing and drying;
- The product contact parts are made of PEEK/PP, which is especially suitable for stainless steel sensitive biological agents;
- The smooth inner lumen diameter does not form liquid droplets and ensures precise volume filling;
- Female Luer connectors with O-ring seals allow for easy connection to the filling line or system O-ring seals prevent slipping of the filling head unit.

## Product Information

| Name | Single-use Plastic Filling Needle | |
|---|---|---|
| Filling needle inner diameter(mm) | 0.8、1.6、3.2 | 3.2、4、5、6 |
| Interface Type | Maurer | Barbed mouth |
| Product contact part material | Polypropylene Luer, PEEK Tubing | PEEK Tube |
| Non-contact material | Silicone O-Ring, Polycarbonate Boot | Silicone O-Ring, Polycarbonate Boot, Polypropylene Luer |
| Quantity/box | 12/box | |
| Product Pictures |  | |



# Single-use beta Bag

Tofflon has many years of experience in developing solutions for filling machines and isolators in aseptic pharmaceutical manufacturing. When bringing, removing or transferring materials from one container area to another, Tofflon offers solutions for safe, fast and contamination-free transfer of assemblies that can maintain high production speeds.

## Product Features

- Maintenance-free for efficient, flexible and scalable production processes;
- The use of pre-filled, single-use beta Bags ensures that complete sterility is maintained and reduces process time by eliminating the need for maintenance, cleaning, washing and pre-decontamination;
- Bi-directional protection is available; RTU (ready-to-use) or RTS (ready-to-sterilize) products ensure safe, sealed transfers;
- 100% of production is inspected, including leakage tests, visual inspections and mechanical connection tests.

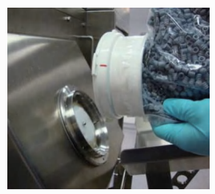
## Product Applications

- Tyvek™ material is commonly used for the aseptic transfer of assemblies such as rubber stoppers, aluminum caps, and plastic bottles.
- PE is commonly used for cross-class transfer of filling lines in Class A environments.

## Product Information

| Part number | BTD-T-10LP1 | BTD-T-30LP1 | BTD-T-10LP2 | BTD-T-30LP2 | BTD-T-30LC1 | BTD-T-30LC2 |
|---|---|---|---|---|---|---|
| Capacity | 10L | 30L | 10L | 30L | 30L | 30L |
| Membrane Material | Tyvek™ | | | | PE/EVOH/PE | |
| Valve Size(mm) | 190 | | 105 | | 190 | 105 |
| Customizable | *Bag volume support customization (10L-150L) | | | | | |

## Product Pictures

| Product Name | Single-use beta Bag | | Supporting equipment |
|---|---|---|---|
| Product Pictures |  |  |  |

# Mixing and Storage Solutions

We offer complete solutions for mixing, storage and aseptic transport in bioprocesses, covering the full range of sizes from 5ml-3000L, as well as customized solutions.

- Single-use Mixing Bag
- Single-use 2D Storage Bag
- Single-use 3D Storage Bag
- Single-use Open Lining Bag
- Single-use Feed Bag



## Single-use Mixing Bag

The Single-use Mixing Bag can be widely used for mixing steps in upstream and downstream processes of biopharmaceuticals, such as preparation of buffer and medium solutions, mixing of intermediates, preparation and transfer of semi-finished products. It meets the needs of full volume process specifications. Customized connections of suitable filters, connectors and line can be provided, and the overall assembly improves the flexibility and efficiency of processing operations, thus increasing productivity.

### Product Features

- Wide range of applications: It can meet all kinds of solid-liquid and liquid-liquid mixing in the upstream and downstream processes of biopharmaceuticals;
- Integrity testing: 100% integrity testing, higher quality requirements for reduced risk of use;
- Membrane: Good physical strength, chemical compatibility and biocompatibility;
- High-efficiency mixing: Welded stirring device at the bottom, multiple speed options for fast mixing;
- Adequate supply: Raw materials, membranes and modules are adequately stocked to ensure supply chain stability;
- Various stirring forms: magnetic coupling stirring, magnetic levitation stirring, mechanical stirring, etc.

### Product Applications

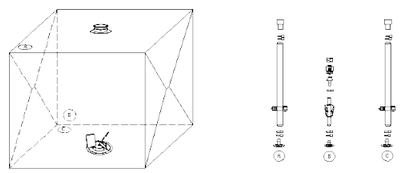
- Buffer and media preparation
- Purification intermediate mixing treatment
- Virus inactivation system
- Product Mixing
- Semi-finished preparations
- Liquid storage and transfer

### Product Pictures

| Product Name | Single-use Mixing Bag | Multiple paddle types |
|---|---|---|
| Product Pictures |  |  |
| Product Name | Single-use Mixing System | |
| Product Pictures |  | |

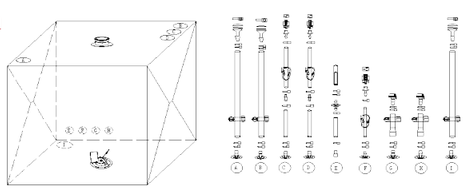
| Model Number | | SUM-A series standard configuration | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Part Number | | SUM-A-50LH1 | SUM-A-100LH1 | SUM-A-200LH1 | SUM-A-500LH1 | SUM-A-1000LH1 | SUM-A-2000LH1 | SUM-A-2500LH1 |
| Specification | | 50L | 100L | 200L | 500L | 1000L | 2000L | 2500L |
| Minimum Working Volume (L) | | 17L | 28L | 44L | 76L | 119L | 230L | 280L |
| Maximum Working Volume (L) | | 50L | 100L | 200L | 500L | 1000L | 2000L | 2500L |
| Number of Mixing Paddles | | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| Feed Port (customizable) | | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches |
| Stirring type | | 3-Blade Inclined Blade Mixing Paddle | | | | | | |
| Recommended Speed | | 10-200rpm | | | | | | |
| Operating Temperature | | 0-40°C | | | | | | |
| Configuration | A | Inlet: 1/2"*3/4" Silicone Tube 150cm, TC50 flange assembly | | | | | | |
| | B | Sampling Port: 1/4"*3/8" Silicone Tube 15cm, Needleless Sampling Kit | | | | | | |
| | C | Outlet: 1/2"*3/4" Silicone Tube 150cm, TC50 flange assembly | | | | | | |

## Schematic Diagram



| Model Number | | SUM-A series standard configuration | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Part Number | | SUM-A-50LH2 | SUM-A-100LH2 | SUM-A-200LH2 | SUM-A-500LH2 | SUM-A-1000LH2 | SUM-A-2000LH2 | SUM-A-2500LH2 |
| Specification | | 50L | 100L | 200L | 500L | 1000L | 2000L | 2500L |
| Minimum working volume (L) | | 17L | 28L | 44L | 76L | 119L | 230L | 280L |
| Maximum working volume (L) | | 50L | 100L | 200L | 500L | 1000L | 2000L | 2500L |
| Number of mixing paddles | | 1 | 1 | 1 | 1 | 1 | 2 | 2 |
| Feed Port (customizable) | | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches | 3 inches |
| pH Port | | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Conductivity Port | | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Stirring type | | 3-Blade Inclined Blade Mixing Paddle | | | | | | |
| Recommended Speed | | 10-200rpm | | | | | | |
| Operating Temperature | | 0-40°C | | | | | | |
| Configuration | A/B | Inlet: 1/2"*3/4" TPE pipe 120cm, TC50 flange assembly | | | | | | |
| | C/D | Rehydration port: 1/4"*3/8" silicone tube 10cm, 1/8"*1/4 "mm TPE tube 90cm, needleless sampling kit | | | | | | |
| | E | Temperature: outside the bag: 1/4"*3/8" silicone tube 4cm, inside the bag: 3/16*5/16mm silicone tube 16.5cm, hose plugs | | | | | | |
| | F | Sampling port: 1/4"*3/8" TPE tube 16cm, needleless sampling kit | | | | | | |
| | G/H | pH/conductivity: ID5/8mm*ID1/2 "mm Reduced diameter silicone tubing 8cm, PALL sterile connectors | | | | | | |
| | I | Liquid outlet: 1/2"*3/4" TPE pipe 120cm, TC50 flange assembly | | | | | | |

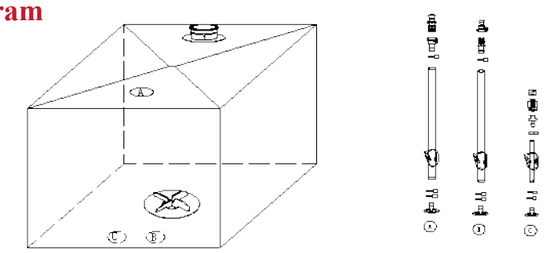
## Schematic Diagram





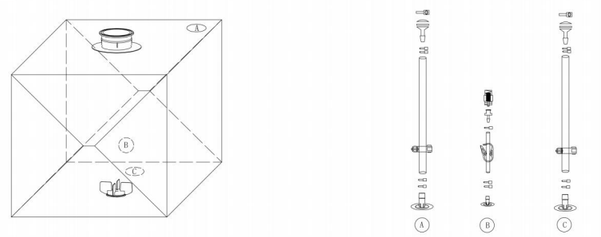
| Model Number | | SUM-T series standard configuration | | | | |
|---|---|---|---|---|---|---|
| Part Number | | SUM-T-5LH1 | SUM-T-10LH1 | SUM-T-15LH1 | SUM-T-20LH1 | SUM-T-30LH1 |
| Specification | | 5L | 10L | 15L | 20L | 30L |
| Minimum Working Volume (L) | | 0.8L | 1.2L | 1.5L | 2L | 2L |
| Maximum Working Volume (L) | | 5L | 10L | 15L | 20L | 30L |
| Number of Mixing Paddles | | 1 | 1 | 1 | 1 | 1 |
| Feed Port (customizable) | | 2 inches | 2 inches | 2 inches | 2 inches | 2 inches |
| Stirring type | | 4-blade inclined blade mixing paddle | | | | |
| Recommended Speed | | 200-1000rpm | | | | |
| Operating Temperature | | 0-40°C | | | | |
| Configuration | A | Inlet: 3/8"*5/8" Silicone Tube 50cm, CPC connector | | | | |
| | B | Liquid outlet: 1/2"*3/4" silicone Tube 50cm, CPC connector | | | | |
| | C | Sampling port: 1/4"*3/8" silicone Tube 15cm, needleless sampling kit | | | | |

## Schematic Diagram



| Model Number | | SUM-E series standard configuration | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Part Number | | SUM-E-50LH1 | SUM-E-100LH1 | SUM-E-200LH1 | SUM-E-400LH1 | SUM-E-650LH1 | SUM-E-1000LH1 | SUM-E-1500LH1 | SUM-E-2000LH1 |
| Specification | | 50L | 100L | 200L | 400L | 650L | 1000L | 1500L | 2000L |
| Minimum Working Volume (L) | | 13L | 19L | 29L | 47L | 64L | 83L | 150L | 200L |
| Maximum Working Volume (L) | | 50L | 100L | 200L | 400L | 650L | 1000L | 1500L | 2000L |
| Number of Mixing Paddles | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Feed Port (customizable) | | 2 inches | 2 inches | 2 inches | 2 inches | 2 inches | 2 inches | 2 inches | 2 inches |
| Stirring type | | 4-blade inclined blade mixing paddle | | | | | | | |
| Recommended Speed | | 10-300rpm | | | | | | | |
| Operating Temperature | | 0-40°C | | | | | | | |
| Configuration | A | Inlet:PD8 bag snap, 12.7*19.1mm thermoplastic tube*1500mm, 25.4mm large pipe clamp, 12.7mm TC50 flange joint, gasket, cover, clamp | | | | | | | |
| | B | Liquid outlet:PD4 bag snap, 6.4*9.6mm thermoplastic tube*150mm, 9.6mm Robert clamp, 6.4mm mother type Ruhr connector, needleless sampler (cap) | | | | | | | |
| | C | Sampling port:PD8 bag snap, 12.7*19.1mm thermoplastic tube*1500mm, 25.4mm large pipe clamp, 12.7mm TC50 flange joint, gasket, cover, clamp | | | | | | | |

## Schematic Diagram



# Single-use 2D Storage Bag

The Single-use 2D Storage Bag is 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. It is used for sterilizing filtration and storage of buffers and media, stock solution harvesting, product consolidation, sample collection, batch intermediate preservation, and end-product transport, ensuring a sterile environment and reducing the risk of contamination.

## Product Features

- The bags are made of multilayer co-extruded membrane with good biocompatibility;
- Gamma-irradiated to ensure sterility;
- Product features can be customized according to customer needs;
- Meet the storage and transfer of all types of solutions in bioprocesses;
- One-piece design with small liquid residue.

## Product Applications

- Storage of small-scale culture media, buffers
- Storage of intermediates, semi-finished products
- Liquid Harvest
- Product Storage
- Buffer bags for pharmaceutical solutions

## Product Pictures

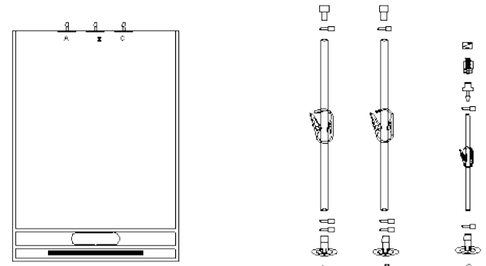
| Product Name | Single-use 2D Storage Bag | 2D Bag Tray and Auxiliary Platform |
|---|---|---|
| Product Pictures |  |  |



## Product Information

| | | |
|---|---|---|
| Model Number | | 2DB-T series standard configuration |
| Part Number | | 2DB-T-1LH1、2DB-T-2LH1、2DB-T-5LH1、2DB-T-10LH1、2DB-T-20LH1、2DB-T-50LH1 |
| Specification | | 1L、2L、5L、10L、20L、50L |
| Configuration | A | Liquid inlet: 3/8"*5/8" Silicone Tube 50cm, hose plug |
| | B | Liquid outlet: 3/8"*5/8" Silicone hose 50cm, hose plug |
| | C | Sampling port: 1/4"*3/8" Silicone Tube 20cm, needleless sampling kit |

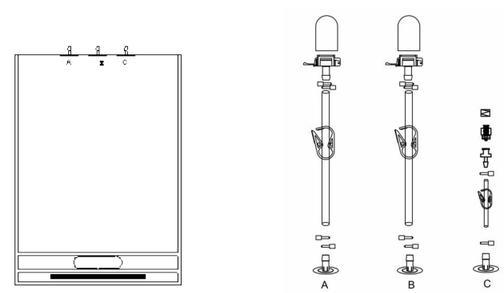
## Schematic Diagram




## Product Information

| | | |
|---|---|---|
| Model Number | | 2DB-E series standard configuration |
| Part Number | | 2DB-E-1LH1、2DB-E-2LH1、2DB-E-5LH1、2DB-E-10LH1、2DB-E-20LH1、2DB-E-50LH1 |
| Specification | | 1L、2L、5L、10L、20L、50L |
| Configuration | A | Liquid inlet: PD6, 9.6*16mm Silicone tube*500mm, 12.7mm Robert clamp, CPC Aseptic Connector, Ziplock Bag |
| | B | Liquid outlet: PD6, 9.6*16mm Silicone tube*500mm, 12.7mm Robert clamp, CPC Aseptic Connector, Ziplock Bag |
| | C | Sampling port: PD2, 3.2*6.4mm Silicone tube *200mm, 9.6mm Robert clamp, 3.2mm female Luer connector, needleless sampler (cap) |
| Customizable | | Configuration can be customized. |

## Schematic Diagram



# Single-use 3D Storage Bag

The Single-use 3D Storage Bag is designed for liquid storage and transfer in biopharmaceutical processes. It is used for sterilizing filtration and storage of buffers and culture media, stock solution harvesting, product consolidation, sample collection, batch intermediate preservation, and end-product transportation, ensuring a sterile environment and reducing the risk of contamination.

## Product Features

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

## Product Applications

- Storage and transfer of buffers and culture media
- Cell harvesting fluid transport
- Storage and transfer of stock solutions

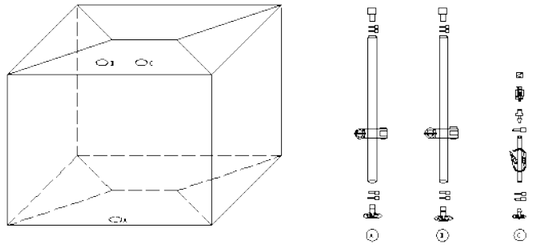
## Product Pictures

| Product Name | Single-use 3D Storage Bag | Single-use Storage System |
|---|---|---|
| Product Pictures |  |  |

## Product Information

| | | |
|---|---|---|
| Model Number | | 3DB-T series standard configuration |
| Part Number | | 3DB-T-50LH1、3DB-T-100LH1、3DB-T-200LH1、3DB-T-300LH1、3DB-T-500LH1、3DB-T-1000LH1、3DB-T-2000LH1 |
| Specification | | 50L、100L、200L、300L、500L、1000L、2000L |
| Configuration | A | Liquid outlet: 1/2"*3/4" Silicone hose 150cm, hose plug |
| | B | Liquid inlet: 1/2"*3/4" Silicone Tube 150cm, hose plug |
| | C | Sampling port: 1/4"*3/8" Silicone Tube 15cm, needleless sampling kit |
| Customizable | | Size adapted to Tofflon stainless steel liquid storage BIN, overall volume and configuration can be customized. |

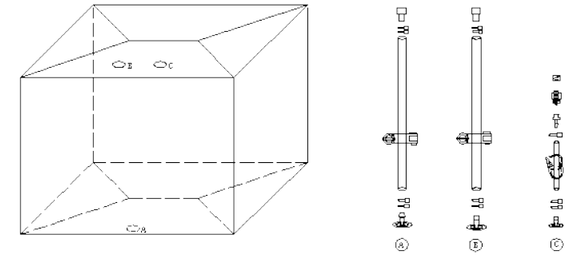
## Schematic Diagram





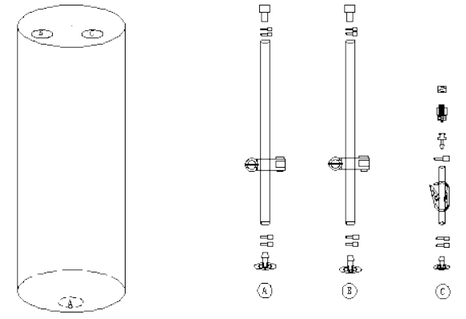
| | | |
|---|---|---|
| Model Number | | 3DB-T series standard configuration |
| Part Number | | 3DB-T-250LH2、3DB-T-500LH2、3DB-T-1000LH2 |
| Specification | | 250L、500L、1000L |
| Configuration | A | Liquid outlet: 1/2"*3/4" Silicone hose 150cm, hose plug |
| | B | Liquid inlet: 1/2"*3/4" Silicone Tube 150cm, hose plug |
| | C | Sampling port: 1/4"*3/8" Silicone Tube 15cm, needleless sampling kit |
| Customizable | | Size adapted to Tofflon plastic folding box BIN, overall volume and configuration can be customized. |

## Schematic Diagram



| | | |
|---|---|---|
| Model Number | | 3DB-T series standard configuration |
| Part Number | | 3DB-T-50LH3、3DB-T-100LH3、3DB-T-200LH3、3DB-T-300LH3、3DB-T-500LH3 |
| Specification | | 50L、100L、200L、300L、500L |
| Configuration | A | Liquid outlet: 1/2"*3/4" Silicone hose 150cm, hose plug |
| | B | Liquid inlet: 1/2"*3/4" Silicone Tube 150cm, hose plug |
| | C | Sampling port: 1/4"*3/8" Silicone Tube 15cm, needleless sampling kit |
| Customizable | | Size adapted to BIN of Tofflon plastic drums, overall volume and configuration can be customized. |

## Schematic Diagram



# Single-use Open Lining Bag

The Single-use Open Lining Bag is suitable for lining plastic or stainless steel buckets, designed for single use tanks such as culture media or buffer solutions, reducing container cleaning time and costs, and better accelerating turnover.

## Product Features

- Higher economy compared to closed bag type;
- Open-mouth design facilitates quick input of large quantities of material;
- Any combination of lines can be used to reach through the mouth of the bag to extract material;
- Models with a bottom outlet tube are available;
- The bag opening can be tied to mitigate cross-impact or risk to the environment;
- Multiple sizes are available and volumes can be customized from 50-568L.

## Product Applications

- Media preparation
- Buffer Preparation
- Storage and transit in harvested cells
- Short-term storage of purification intermediates
- Waste liquid collection during purification

## Product Pictures

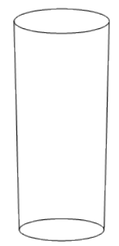
| Product Name | Single-use Open Lining Bag | Single-use Storage System |
|---|---|---|
| Product Pictures |  |  |



## Product Information

| | |
|---|---|
| Model Number | CKD-T series standard configuration |
| Part Number | CKD-T-50LH1、CKD-T-100LH1、CKD-T-200LH1、CKD-T-300LH1、CKD-T-500LH1 |
| Specification | 50L、100L、200L、300L、500L |
| Partial Tear | IX9101 |
| Sterilization Method | gamma irradiation |
| Customizable | Overall volume can be customized |

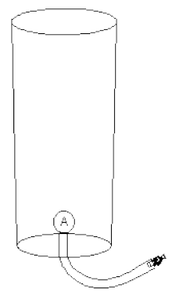
## Schematic Diagram



## Product Information

| | |
|---|---|
| Model Number | CKD-T series standard configuration |
| Part Number | CKD-T-50LH2、CKD-T-100LH2、CKD-T-200LH2、CKD-T-300LH2、CKD-T-500LH2 |
| Specification | 50L、100L、200L、300L、500L |
| Partial Tear | IX9101 |
| Sterilization Method | gamma irradiation |
| Conduit Layout | 1/2"*3/4" Silicone Tube 1200mm, CPC Quick Coupler |
| Customizable | Overall volume can be customized |

## Schematic Diagram



# Single-use Feed Bag

The Single-use Feed Bag is a single-use consumable designed for upstream media and downstream buffer configuration feeding. It is mainly used in single-use mixing bag, which can effectively avoid material spilling and dust splashing.

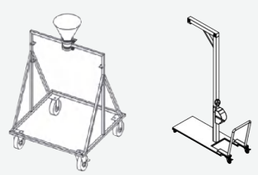
## Product Features

- Simple and easy to use: no need to wash and sterilize, reducing the risk of material contamination;
- Wide applicability: multiple specifications are available for customized volume;
- Safe and secure: the mouth part closely fits the feeding port of the liquid dispensing bag, effectively avoiding residue and dust;
- There are a variety of sizes to choose from for the feeding port;
- We can provide feeding bracket to fit different specification equipments.

## Product Applications

- Buffer Preparation
- Media preparation
- Bulk powder feeding

## Product Pictures

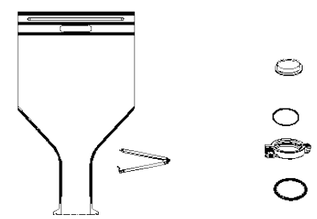
| Product Name | Single-use Feed Bag | Feeding bracket |
|---|---|---|
| Product Pictures |  |  |



## Product Information

| | |
|---|---|
| Model Number | TLD-T Series Single-use Feed Bag Standard Configuration |
| Part Number | TLD-T-3LH1、TLD-T-5LH1、TLD-T-10LH1、TLD-T-15LH1、TLD-T-25LH1、TLD-T-30LH1、TLD-T-40LH1、TLD-T-50LH1 |
| Specification | 3L、5L、10L、15L、25L、30L、40L、50L |
| Partial Tear | T2101 |
| Sterilization Method | gamma irradiation |
| Feeder Assembly | 4 inches |
| Customizable | Feed ports 2", 3", 4", 6", 8" inches Tri-clamp available, overall volume can be customized |

## Schematic Diagram



# Fluid Management

Provides Single-use consumables for fluid management in biopharmaceutical processes.

- Single-use Sterile Sampling Bag
- Single-use Freeze-Thaw Bag
- Single-use Lyophilization Tray
- Single-use Freeze Storage Bag



## Single-use Sterile Sampling Bag

The Single-use Sterile Sampling Bags and Sampling Systems are designed for sampling in cell culture, media preparation and other processes. The systematic design of the bag and sampling system ensures the sterility and low residue of the line connections and sampling. This makes the sampling process safer and reduces material loss and repeatability.

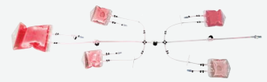
### Product Features

- Multi-channel delivery and sampling possible
- Ensure sterility throughout the sampling process
- Volume, interface can be customized
- Y-type sampling needle form available

### Product Applications

- Transfer of the sample from the reactor through the fluidic channel to the sampling bag

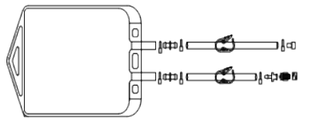
### Product Pictures

| Product Name | Single-use Sterile Sampling Bag | Single-use Sampling System | Sampling Support |
|---|---|---|---|
| Product Pictures |  |  |  |

### Product Information

| | | |
|---|---|---|
| Model Number | | SSB-T series standard configuration |
| Part Number | | SSB-T-50MLA1、SSB-T-100MLA1、SSB-T-250MLA1、SSB-T-500MLA1、SSB-T-1LA1、SSB-T-2LA1、SSB-T-3LA1 |
| Specification | | 50mL、100mL、250mL、500mL、1L、2L、3L |
| Configuration | A | 1/4"*3/8" TPE Tube*20cm, Hose Plugs |
| | B | 1/4"*3/8" Silicone Tube*8cm, Needleless Sampling Assembly |
| Customizable | | Overall volume 5mL-3L, configurations can be customized. |

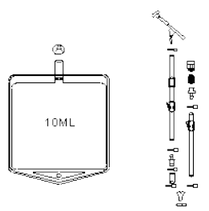
### Schematic Diagram



| | | |
|---|---|---|
| Model Number | | SSB-C series standard configuration |
| Part Number | | SSB-C-10MLA1 |
| Specification | | 10mL |
| Configuration | A | 6.8*8.8mm PE Tube*3.5cm, Y-connector (Left: 6.4*9.6mm Silicone Tube*8cm, C4-2 reducer, 3.2*6.4mm Silicone Tube*25cm, 6.4mm metal disconnecting ring, Y-type sampling needle) Right: 6.4*9.6mm Silicone Tube*25cm, luer connector, cap) |
| Y Sampling Needle Diameter | | 1mm |

| | | |
|---|---|---|
| Model Number | | SSB-C series standard configuration |
| Part Number | | SSB-C-50MLA1、SSB-C-100MLA1、SSB-C-250MLA1、SSB-C-500MLA1、SSB-C-1000MLA1 |
| Specification | | 50mL、100mL、250mL、500mL、1000mL |
| Configuration | A | 6.8*8.8mm PE Tube*3.5cm, reducer, 3.2*6.4mm Silicone Tube*25cm, 6.4mm metal disconnecting ring, Y-type sampling needle |
| | B | 6.8*8.8mm PE Tube*3.5cm, reducer, 3.2*6.4mm Silicone Tube*25cm, luer fitting, cap |
| Y Sampling Needle Diameter | | 1mm |

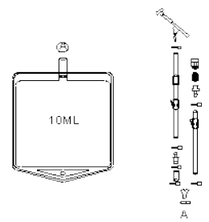
## Schematic Diagram




| | | |
|---|---|---|
| Model Number | | SSB-C series standard configuration |
| Part Number | | SSB-C-10MLA2 |
| Specification | | 10mL |
| Configuration | A | 6.8*8.8mm PE Tube*3.5cm, Y-connector (Left: 6.4*9.6mm Silicone Tube*8cm, C4-2 reducer, 3.2*6.4mm Silicone Tube*25cm, 6.4mm metal disconnecting ring, Y-type sampling needle) Right: 6.4*9.6mm Silicone Tube*25cm, luer connector, cap) |
| Y Sampling Needle Diameter | | 2mm |

| | | |
|---|---|---|
| Model Number | | SSB-C Series Primary Sterile Sampling Bag Standard Configuration |
| Part Number | | SSB-C-50MLA2、SSB-C-100MLA2、SSB-C-250MLA2、SSB-C-500MLA2、SSB-C-1000MLA2 |
| Specification | | 50mL、100mL、250mL、500mL、1000mL |
| Configuration | A | 6.8*8.8mm PE tube*3.5cm, reducer, 3.2*6.4mm Silicone Tube*25cm, 6.4mm metal disconnecting ring, Y-type sampling needle |
| | B | 6.8*8.8mm PE Tube*3.5cm, reducer, 3.2*6.4mm Silicone Tube*25cm, luer fitting, cap |
| Y Sampling Needle Diameter | | 2mm |

## Schematic Diagram






# Single-use Freeze-Thaw Bag

The Single-use Freeze-Thaw Bag is mainly used in stability of stock solution experiments, preclinical research, clinical research, large-scale production of stock solution storage, repeated freezing and thawing experiments, freeze-preserved stock solution intermediates, which can ensure the consistency and reproducibility of the freeze-thawing process in the production of biopharmaceuticals and research and development. It is widely used in the freeze-thawing of antibody drugs, vaccines, blood products, cytokines, insulin, growth hormone, probiotics and other products. This product can be customized to enable insertion of thermocouple sleeves for monitoring, making Temperature Port more convenient.

## Product Features

- Resistant to -80°C to 40°C
- Sterile
- Repeatable freeze-thaw
- Low dissolution precipitation
- Solid structure, not easily damaged in use

## Product Applications

- Original solution
- Vaccinations
- Process intermediate
- Clinical products, etc.

## Product Pictures

| | |
|---|---|
| Product Name | Single-use Freeze-Thaw Bag |
| Product Pictures |  |

## Product Information

| | | |
|---|---|---|
| Model Number | | DR-T series standard configuration |
| Part Number | | DR-T-5LA1、DR-T-10LA1、DR-T-20LA1 |
| Specification | | 5L、10L、20L |
| Configuration | A | Feed line: 3.2*6.4mm Silicone Tube*50cm, Luer cap |
| | B | Temperature monitoring line: (Outside): 9.6*16mm TPE Tube*50cm, plugs; (Inside): 9.5*12.7mm EVA Tube*16cm (bottom heat sealing) |
| | C | Feed line: 9.6*16mm TPE Tube*50cm, plugs |
| | D | Harvesting Line: 9.6*16mm TPE Tube*50cm, plugs |
| Customizable | | Size reference bracket |

# Single-use Freeze Storage Bag

The Single-use Freeze Storage Bag is an indispensable product in the production of cell therapy drugs. Since the frozen products such as stem cells and CAR-T cells are high value end products, we pay more attention to the quality and stability of the products. Tofflon has launched a cGMP-compliant single-use cryopreservation bag, the body of which is made of pure ethyl acetate (EVA) membrane, which is able to withstand the low temperature of -196℃ to ensure a worry-free liquid nitrogen cryopreservation. The complete testing program ensures good cell status and viability. The combination of automated freezing equipment makes cell freezing more intelligent and convenient.

## Product Features

- High-frequency welding is strong and reliable, ensuring the integrity of the bag;
- One-piece welded bag making with low risk of leakage;
- The inlet tube is on one side for easy venting;
- Low solvent precipitation, pure and reliable;
- The line supports customization and is easy to use.

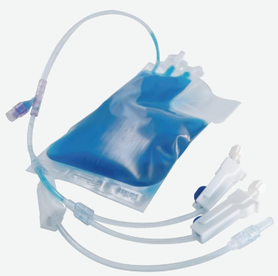
## Product Applications

- Freezing and resuscitation of cells such as CAR-T, NK, etc., umbilical cord blood, stem cells, etc. in cell therapy

## Product Specification

- 50mL, 250mL, 500mL, 750mL (customized)

## Product Pictures

| Product Name | Single-use Freeze Storage Bag |
| --- | --- |
| Product Pictures |  |



# Single-use Lyophilization Tray

The Single-use Lyophilization Tray is a new type of single-use lyophilization tray developed based on traditional lyophilizer usage scenarios and lyophilization process needs. It can be used in the same way as traditional trays and is compatible with most freeze-drying processes, which can greatly save cleaning time and validation costs. The unique material of light and thin, strong air permeability makes good contact between the sample and the plate layer, uniform heat transfer, effectively optimizing the lyophilization process and improving the working efficiency. The lyophilization tray is designed as a disposable container, utilizing the e-PTFE membrane principle. It has a good guarantee of sterility and at the same time can effectively prevent the products from flying and improve the product yield, which is widely used for high-end freeze-drying products.

## Product Features

- Saving the time of cleaning the tray, saving the cost of verification and labor, thus improving the work efficiency, no metal particles are generated during the sampling, and it is easy to dispose of the drug after the sampling is completed;
- The lyophilization tray is made of thin and light material with strong air permeability, and adopts flexible bottom membrane, which makes the heat transfer from the tray frame uniform and effectively optimizes the lyophilization effect, and the heat transfer is even to ensure the consistency of the products;
- The product is close to the plate layer to effectively overcome the splash phenomenon during the freeze-drying process and reduce waste;
- Aseptic closed system for easy liquid storage and reduced storage space;
- The material has good stability;
- No dust exclusion;

## Product Applications

- Development of freeze-drying process for biologics peptides, oligonucleotides, proteins, drug intermediates, polysaccharides, strains and other APIs
- Clinical staging
- Large-scale production

## Product Specification

| | |
| --- | --- |
| Model Number | LDT-1.8LS1 |
| Specification | 1.8L |

## Product Pictures

| Product Name | Single-use Lyophilization Tray |
| --- | --- |
| Product Pictures |  |

# Tofflon Validation Center

## Product Solution Integrity Testing

Product Solution Integrity Testing In actual manufacturing environments, since most process fluids/drugs contain components that can alter the surface interaction between the filter and the wetting solution or bind directly to the membrane, failure to effectively clean these components may alter integrity test results, utilizing the correlation between the product integrity data and the standard liquid integrity data, using the actual filtered product as the The correlation between product integrity data and standard liquid integrity data is utilized to perform post-use filter integrity testing using the actual filter product as the wetted media.




## Chemical compatibility testing

The chemical compatibility test is used to evaluate the chemical effect of the media to be filtered on the filter under specific process conditions.

### Product assemblies



Membrane
Appearance, tensile strength, flux, thickness, electron microscopy



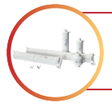
filtration
Integrity, flux, appearance



Seals
Appearance, wire diameter, weight



Support Component
Appearance, weight



Subassemblies
Appearance, weight

| Test Item | Test Parts | | | | | |
|---|---|---|---|---|---|---|
| | Appearance | Weight | Biometrics | Tensile Strength | Fluxes | Completeness |
| Diaphragm | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Filter | ✓ | | | | ✓ | ✓ |
| Support assemblie | ✓ | | | | | |
| Seals | ✓ | ✓ | ✓ | | | |
| Ultrafiltration Nanofiltration | ✓ | | | | ✓ | ✓ |

## Extractables, leachables testing

Extractables are compounds that can be extracted from packaging or production assemblie materials (plastics, elastomers, and their coated membrane) using solvents of different physicochemical properties (solvents of different polarities or solutions similar to the product's liquid solution) under demanding experimental conditions (e.g., solvents, temperatures, time). Leachables means compounds that migrate into the drug product from production assemblies, packaging components or drug delivery appliances under Specification production processes, storage and use conditions.



### Basic Testing Process

- Simulated leaching/simulated migration based on different component samples
- Potential leachables inferred from simulated leaching assay results
- Risk substances based on leachate measurements
- Safety assessment based on risk substance content

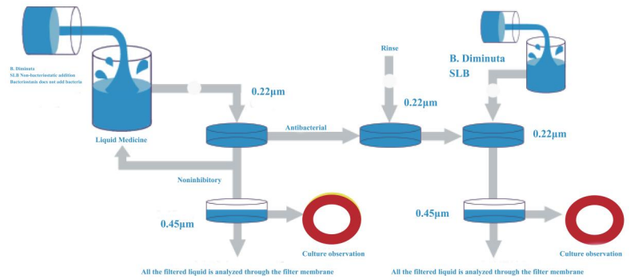
## Bacterial retention validation

### Sterilization filters

Refers to filters that retain 1.0 x 107 cfu of defective Aeromonas sp. (ATCC 19146) per square centimeter of effective filtration area at a specific flow rate or pressure. -ASTMF838-20

### Bacterial retention process validation

The retention capacity of a decontamination grade filter with a specific process fluid under specific filtration conditions is tested for bacterial retention at a laboratory scale with equivalently reduced process conditions.




### Bacterial retention validation process

The purpose of the bacterial retention test study is to simulate the worst conditions in an actual production filtration process by filtering a product solution or product replacement solution containing a certain amount of challenging microorganisms to confirm the microbial retention capacity of the decontamination filter. Tofflon Validation Center will scientifically and reasonably evaluate your products and process conditions, and provide you with proven and reasonable test methods and complete test analysis reports.

## Testing Services

S V C

SVC=Shiofron Verification Center Code

M L

Laboratory Classification
ML = Microbiology Laboratory
VL = Virus Laboratory
EL = Chemistry Laboratory
IL = Performance Laboratory

0 0 1

Test Part Type
002= Bacterial retention validation
004 = Virus removal test
005 = Extractables testing and safety assessment
006 = Leachate testing and safety assessment
007 = Chemical compatibility test
008 = Product integrity testing
009 = number of uses/lifetime validation