



AseptiBag Gold

2D Single Use Systems for Storage and Transfer

Biopharmaceutical process involves a very wide range of process fluids such as media, growth regulators, harvests, post centrifuge supernatants, buffers, process intermediates, drug substance and formulations.

A critical requirement is storage and transfer of these fluids during and between process step(s) as well as between different process areas. Process owners using conventional reusable storage and transfer systems involving glass bottles, large carboys or stainless steel vessels face multiple challenges in terms of extraneous contamination due to multiple open system handling, cleaning validation and documentation, limited availability of storage space (specially at low temperatures up to - 20 ° C) due to large footprint and issues of safe transportation.

Single Use Systems

Single use disposable pre-sterilized storage and transfer systems help overcome all the above functional challenges and help achieve greater regulatory compliance. These systems however, need to address user concerns with respect to integrity and strength, sterility, endotoxins, biosafety, extractables, particle/fiber release that may impact the identity, strength, quality and purity of the process fluids.

MDI ***AseptiBag*** Gold systems provide validated and reliable single use disposable solutions for biopharmaceutical process requirements such as storage and transfer of sterile media, process intermediates, sterile buffers with wide ranging pH, sterile drug substances and formulations. These are well characterized for various physical, chemical and microbiological properties to alleviate all the above mentioned concerns.

AseptiFlex-D

The Heart of AseptiBag Gold Systems

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The MDI **AseptiFlex-D** Film type FBG-1 is a highly inert, multilayered polyethylene film specially designed for bioprocess applications.

The film is physically tough and inert to chemicals and solvents used in the biopharmaceutical industry and the various layers of the film provide an excellent barrier to Oxygen, CO₂ and moisture.

The contact layer is 130 µm ultra low density Polyethylene layer without any additives.

The AseptiFlex-D film is produced in classified areas through validated processes to ensure consistently high quality meeting various regulatory as well as functional requirements.

Deeply characterized and validated

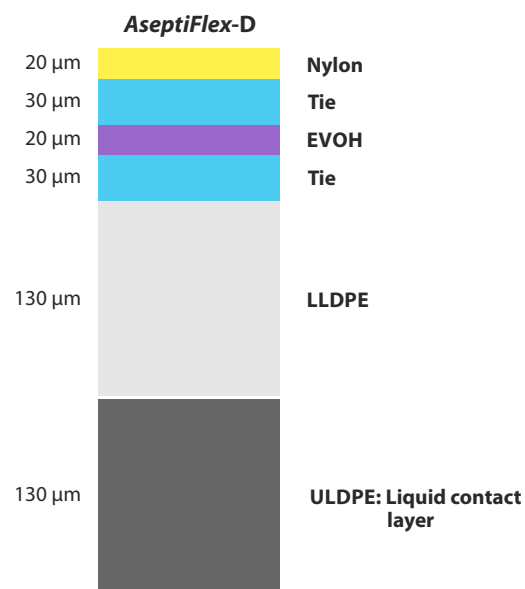
AseptiFlex-D has been extensively characterized after gamma irradiation at 50 kGy to deliver high performance:

High strength and flexibility: for safety and integrity during handling, storage and transport

| Test | | Reference Standard | Average Values |
|------------------------------|----|--------------------|---------------------------|
| Tear strength | TD | ASTM D1938 | 25.556 N |
| | MD | | 17.873 N |
| Puncture Resistance | | EN14477 | 10.9578 N |
| Tensile Strength (MD) | | ASTM D-882 | 27.0298 N/mm ² |
| Flex Durability Test (Gelbo) | | ASTM F-392 | Passes |

Protection of stored liquids from oxidation, change in pH and change in concentration of critical components: with high barrier properties for Oxygen (O₂), Carbon dioxide (CO₂) and water vapour (WV)

| Test | Reference Standard | Average Values |
|-----------------------------------|--------------------|------------------------------|
| O ₂ Transmission Rate | ASTM D3985-05 | 0.168 cc/m ² /day |
| CO ₂ Transmission Rate | ASTM F 2476 | <1.0 cc/m ² /day |
| WV Transmission Rate | ASTM F1249-13 | 0.879 g/m ² /day |



Biocompatibility for media storage and cell growth:

AseptiFlex film is made of plastics of Non Animal Origin and is validated for Biological Reactivity tests as per USP

| Test | Reference Standard | Result |
|-------------------------|---|--------|
| Intracutaneous Toxicity | Biological Reactivity Tests, <i>In Vivo</i> , as per USP <88> | Passes |
| Acute Systemic Toxicity | | Passes |
| Muscle Implantation | | Passes |
| Cytotoxicity | Biological Reactivity Tests, <i>In Vitro</i> , USP <87> | Passes |

No impact on purity of process fluids: Very low extractable profile

| Test | Reference Standard | Result |
|----------------------|--------------------|--------|
| Non Volatile Residue | as per USP <661> | Passes |
| Heavy Metals | as per USP <661> | Passes |
| Buffering Capacity | as per USP <661> | Passes |
| Effect on WFI | as per USP <1231> | Passes |

AseptiBag Gold

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Unique Features and Applications

AseptiBag Gold is made from AseptiFlex-D film offering multiple advantages such as:

- Very low extractable profile for low 'Product' risk
- Long term storage of media and cell growth
- Stability at very low temperatures of up to -20°C
- Higher strength and flexibility

Unique Features

- 100% integrity tested with pressure leak test
- High barrier properties for protection of product molecule, product pool and media components
- Robust and flexible with high burst strength
- Easy inlet and outlet quick connections
- User friendly easy to hold/hang design
- Custom designed to suit user specific process applications

Applications

MDI AseptiBag Gold systems are used for critical biopharmaceutical process steps such as:

- Long term aseptic storage of sterile media, buffers and drug substances at low temperatures
- Transfer of sterile media to bioreactors
- Transfer of process intermediates between process areas
- Aseptic transfer of drug substance to formulation facilities



**Easy Inlet/outlet
Quick Connections**



Easy to Hold/Hang



Validated Pinch Clamps



Leak Proof Ties

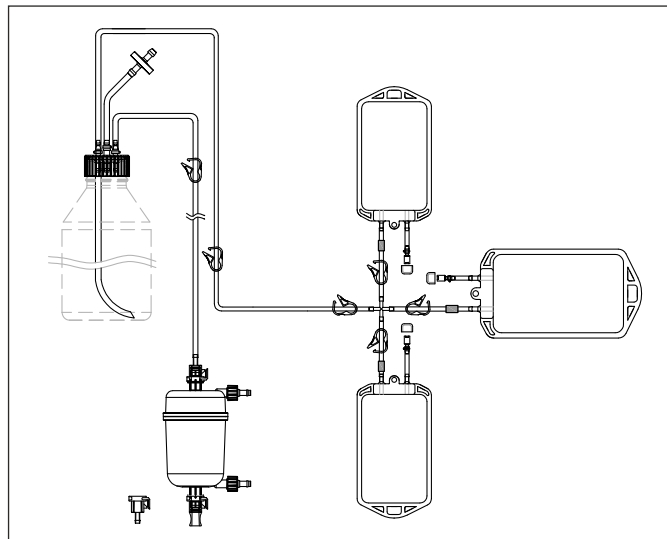


Customized Single Use Systems

MDI works closely with the process owners in biopharmaceutical manufacturing to understand their application requirements in order to establish the technical feasibility of a single use system (SUS) in terms of size, pressure, temperature, complexity of the system as well as compatibility, and to design customized systems by integrating *AseptiBag Gold* with a wide range of pre-qualified components such as membrane capsule filters, connectors, tubing and fittings.

All the system components are deeply characterized and validated for microbial retention, bio-burden, bacterial endotoxins, biosafety and extractables etc to minimize 'product risk' and maximize regulatory compliance.

These customized systems are realized from user approved drawings with detailed definitions of materials of constructions, pore size and dimensions.



Components

Sterilizing grade membrane capsule filters

MDI capsule filters with PES and hydrophilic PVDF membranes are available in different pore sizes, sizes and end connections for sterile filtration of cell culture media, buffers, drug substance and drug formulations. To know more, visit the link:

<http://www.mdimembrane.com/microfiltration/product-by-type/capsule-filter>

Tubing

MDI offers multiple tubing options of thermoplastic elastomers (TPE) as well as platinum cured silicone. These are available in a wide range of internal and outer diameters to meet the process requirements with respect to fitment into peristaltic pump and to different size hose connections.

TPE tubing offers chemical compatibility with a wide range of organic solvents and buffers. These are heat weldable to allow leak free sterile connections for sampling and storage applications.

Platinum cured silicone tubing offers enhanced flexibility for easy integration into single use systems and for use in peristaltic pumps.

Fittings

A wide range of MDI gamma stable fittings such as cross connections, T connections, Y connections and reducers are available to support various plumbing requirements within these customized single use systems.

Quality Assurance

MDI quality management system emphasizes on quality by design rather than by end product testing only. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

MDI *AseptiBag* Gold single use storage and transfer systems are produced by trained personnel in validated ISO class 7 facilities under ISO 9001 quality management systems using validated production processes.

Each lot has well compiled batch manufacturing records that ensure complete traceability of raw materials, machines, in process controls, personnel and quality control test data.

These are tested and validated as per international standards and guidelines such as CFR, ASTM, ISO and USP and supported by well designed, state of art physical, chemical and microbiology laboratories.

100% Integrity Tested

Each *AseptiBag* Gold is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

AseptiBag Gold systems are validated to endure operating pressure and wide temperature conditions which may be encountered during use.

These bags are also validated for burst pressure with liquid to ensure user as well as product safety in case of inadvertent pressure build-up.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/bag.

Biosafety

Passes Biological Reactivity test, In-Vivo, as per USP <88> for Class VI plastics

Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP <87>

Endotoxin Testing

Aqueous extracts exhibit < 0.125 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test

Extractables

Extractables/leachables from sterile containers, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

AseptiBag Gold systems are validated to exhibit very low extractables under harsh extraction conditions.

Package Integrity

AseptiBag Gold systems are double packed in polybags to ensure package integrity during transit as well as to prevent contamination while transferring to clean room assembly or process areas.

Certificate of Quality

Each lot is accompanied with a Certificate of Quality and the lot number is mentioned on the packaging of each *AseptiBag* Gold storage and transfer system to ensure traceability at the user's end.

AseptiBag Gold

Specifications

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Materials of Construction

| | |
|-------------------------|------------------------------|
| Bag Film | AseptiFlex-D film type FBG-1 |
| Connection ports | Polycarbonate |
| Clamps | Polyester |
| Tubing | Platinum cured silicone |

Operating Temperature

-80°C to 45°C

Freeze - Thaw Conditions

Minimum Temperature : -80°C

Maximum No. of Freeze - Thaw Cycles : 05

Storage Temperature

-20°C to 45°C

Sterilization

Gamma Sterilizable upto 50 kGy

Sterility

The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6}

Bacterial Endotoxin

Aqueous extracts exhibit < 0.125 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Biosafety

Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>.

Passes the Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

Fiber Release

Passes microscopic test for fibers

Particle Release

Complies with USP <788> test for particulate matter in injections

Extractables with WFI

Does not affect the quality of Water for Injection (passes tests as per USP <661>)

Available Sizes

3 mL, 10 mL, 50 mL, 100 mL, 250 mL, 500 mL, 1 L, 2 L, 3L, 5 L, 10L, 20 L and 50 L

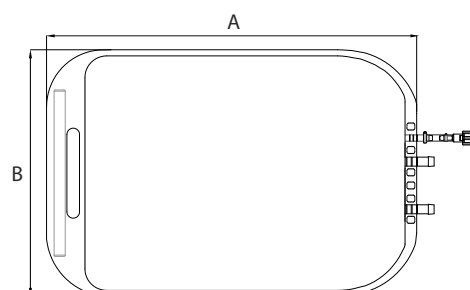
Fill Volume*

MDI AseptiBag Gold are designed for an overfill volume of $\geq 10\%$ over the specified bag size (volumes).

*Overfilling may result in leakages under freezing conditions.

Dimensions

| Bag Size | A | B |
|----------|--------|--------|
| 3 mL | 75 mm | 55 mm |
| 10 mL | 90 mm | 60 mm |
| 50 mL | 157 mm | 87 mm |
| 100 mL | 179 mm | 92 mm |
| 250 mL | 189 mm | 134 mm |
| 500 mL | 226 mm | 155 mm |
| 1 Litre | 275 mm | 200 mm |
| 2 Litre | 350 mm | 200 mm |
| 3 Litre | 378 mm | 247 mm |
| 5 Litre | 410 mm | 319 mm |
| 10 Litre | 620 mm | 322 mm |
| 20 Litre | 520 mm | 580 mm |
| 50 Litre | 860 mm | 582 mm |



End Connections

| Size | 3 mL | 10 mL to 250 mL | 500 mL to 50 L |
|---------------|------------------|------------------|----------------------|
| Inlet | Female Luer Lock | Female Luer Lock | Male Quick Connector |
| Outlet | - | Male Luer Lock | Male Quick Connector |

Sampling Port

Needleless

Tube Length

| Tube | Length | | |
|----------|--------|-----------------|----------------|
| | 3 mL | 10 mL to 250 mL | 500 mL to 50 L |
| Inlet | 2 Inch | 4 Inch | 6 Inch |
| Outlet | - | 4 Inch | 6 Inch |
| Sampling | - | - | 6 Inch |

Customization

The 500 mL to 50 litre storage bags can be customized to suit user requirements. Female quick connector can be provided for inlet port/outlet port and rubber septum for sampling port.

Larger sizes in 2D AseptiBag Gold are available as per user requirements.

AseptiBag Gold

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Chemical Compatibility

Different samples of MDI AseptiBag Gold were filled with specific chemicals/reagents for a specified time period @ 40°C. Post exposure the bags were visually inspected and tested for any leakages, film weight and thickness. These tests were conducted on 250 mL bags.

Acceptance Criteria

- ◆ Visual: Color changes, stress marks and clarity
- ◆ Change in weight: $\pm 7\%$
- ◆ Change in thickness: $\pm 10\%$
- ◆ Leakage: No Leakage @ 5 psi

| Chemical/ Reagents | Exposure | Compatibility |
|--------------------------|----------|---------------|
| 95% Ethanol | 7 Days | ■ |
| 0.5% Chloroform (in IPA) | 1 Month | ■ |
| 100% Ethyl Acetate | 7 Days | ■ |
| 100% Glycerol | 7 Days | ■ |
| 30% Isopropanol | 7 Days | ■ |
| 50% Acetic acid | 7 Days | ■ |
| 1% Citric Acid | 7 Days | ■ |
| 10% HCl | 7 Days | ■ |
| 40% Nitric Acid | 7 Days | ■ |
| 25% Phosphoric Acid | 1 Month | ■ |
| 100% Ethylene Dichloride | 7 Days | ● |

| Chemical/ Reagents | Exposure | Compatibility |
|--------------------------|----------|---------------|
| 30% Sulfuric Acid | 7 Days | ■ |
| Buffer pH 4 | 7 Days | ■ |
| Buffer pH 10 | 7 Days | ■ |
| 1M Ammonium Chloride | 7 Days | ■ |
| 2M Sodium Acetate | 1 Month | ■ |
| 0.3M Sodium Acetate | 1 Month | ■ |
| 4M Sodium Chloride | 7 Days | ■ |
| 30% Hydrogen Peroxide | 7 Days | ■ |
| 4-6% Sodium Hypochlorite | 7 Days | ■ |
| 100% Methanol | 7 Days | ■ |
| 100% Chloroform | 7 Days | ● |

- Resistant
- Not Resistant
- Limited Resistance

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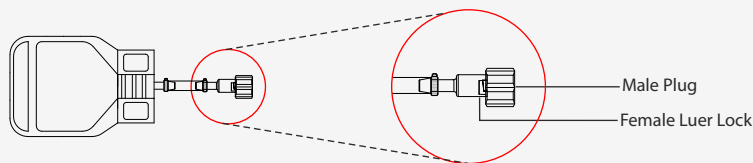
Ordering Information

For 3 mL Storage Bags

| Type | Bag Size | | Inlet Port | | X | XXX | Tube | | X | Sterility | | Pack Size | |
|----------------|----------|------|------------|------------------|------|-----|-------------------------|------|---|---------------|------|-----------|------|
| | Code | | Code | | Code | | | Code | | | Code | | Code |
| AseptiBag Gold | ABDX | 3 ml | U | Female Luer Lock | M | | Platinum Cured Silicone | X | | Gamma Sterile | 3 | 10 | 02 |

Example

| | | | | | | | | | | | | | |
|------|--|---|--|---|--|---|-----|--|---|--|---|--|----|
| ABDX | | U | | M | | X | XXX | | X | | 3 | | 02 |
|------|--|---|--|---|--|---|-----|--|---|--|---|--|----|

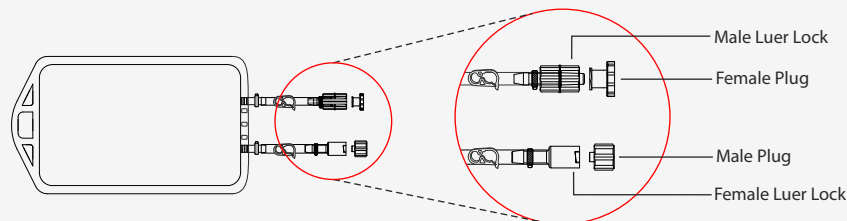


For 10 mL to 250 mL Storage Bags

| Type | Bag Size | | Inlet Port | | Outlet Port | | XXX | Tube | | X | Sterility | | Pack Size | |
|----------------|----------|--------|------------|------------------|-------------|----------------|-----|-------------------------|------|---|---------------|------|-----------|------|
| | Code | | Code | | Code | Code | | | Code | | | Code | | Code |
| AseptiBag Gold | ABDX | 10 ml | T | Female Luer Lock | M | Male Luer Lock | L | Platinum Cured Silicone | X | | Gamma Sterile | 3 | 10 | 02 |
| | | 50 ml | S | | | | | | | | | | | |
| | | 100 ml | A | | | | | | | | | | | |
| | | 250 ml | B | | | | | | | | | | | |

Example

| | | | | | | | | | | | | | | | |
|------|--|---|--|---|--|---|-----|--|---|--|---|--|---|--|----|
| ABDX | | B | | M | | L | XXX | | X | | X | | 3 | | 02 |
|------|--|---|--|---|--|---|-----|--|---|--|---|--|---|--|----|



For 500 mL to 50 L Storage Bags

| Type | Bag Size | | Inlet Port | | Outlet Port | | Sampling Port | | XX | Tube | | X | Sterility | | Pack Size | |
|----------------|----------|--------|------------|----------------------|-------------|----------------------|---------------|------------|----|-------------------------|------|---|---------------|------|-----------|------|
| | Code | | Code | | Code | Code | | Code | | | Code | | | Code | | Code |
| AseptiBag Gold | ABDX | 500 mL | V | Male Quick Connector | J | Male Quick Connector | J | Needleless | N | Platinum Cured Silicone | X | | Gamma Sterile | 3 | 10 | 02 |
| | | 1 L | C | | | | | | | | | | | | | |
| | | 2 L | D | Female Luer Lock* | M | Male Luer Lock* | L | | | | | | | | | |
| | | 3 L | W | | | | | | | | | | | | | |
| | | 5 L | E | | | | | | | | | | | | | |
| | | 10 L | F | | | | | | | | | | | | | |
| | | 20 L | G | | | | | | | | | | | | | |
| | | 50 L | H | | | | | | | | | | | | | |

*Female Luer Lock and Male Luer Lock is available only for 500mL, 1L and 2L bag sizes

Example

| | | | | | | | | | | | | | | | | | |
|------|--|---|--|---|--|---|--|---|----|--|---|--|---|--|---|--|----|
| ABDX | | C | | J | | J | | N | XX | | X | | X | | 3 | | 02 |
|------|--|---|--|---|--|---|--|---|----|--|---|--|---|--|---|--|----|

