

Single Use Systems

The biopharmaceutical industry is increasingly moving towards use of single use disposable systems for development as well as manufacture of a wide range of vaccines, therapeutic proteins and Mab's.

Biopharmaceutical processes involve multiple steps with a multitude of process intermediates with different process conditions and objectives at each step. Single Use Systems (SUS) offer multiple advantages of reduced capital expenditure, reduced change over time and increased process flexibility while doing away with expensive and time consuming CIP/ SIP procedures and validation requirements associated with reusable stainless steel systems.

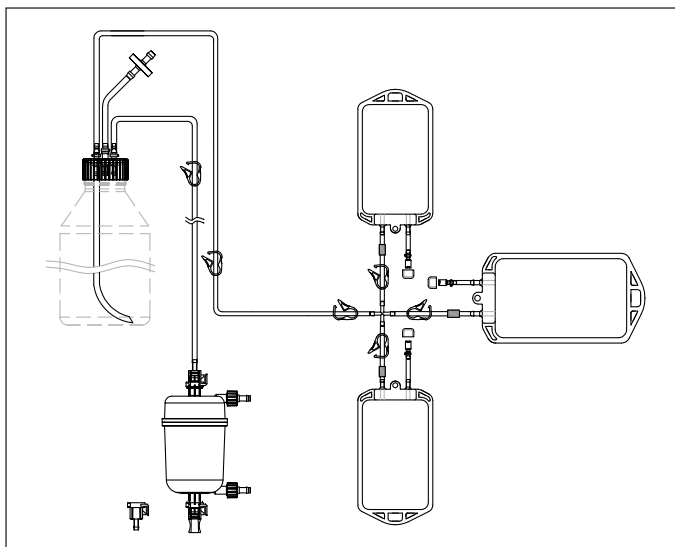
SUS have not only facilitated continuous processing but also enabled research scientists as well as process owners to work with different molecules such as antibodies, proteins, vaccines etc in the same facility. All this has resulted in faster lab to market movement of the new bio pharmaceutical drugs contributing to overall growth of the industry.

However, SUS involve a wide variety of polymeric components such as membrane filtration devices; bags; connectors; tubing; and fittings; and range from simple transfer systems to complex disposable filling lines. This along with the criticality of the applications that they serve raises multiple concerns at the user's end ranging from regulatory such as microbial retention; sterility; bacterial endotoxins; and biosafety as well as functional such as flow rates; burst strength; temperature; and pressure resistance.

One key concern area is extractables/leachables as it has impact on the impurity profile of the drug substance. Since SUS include a wide range of polymeric components, the incidence of different compounds and their degradants leaching into the drug product is very high. The user needs to quantify these and their subsequent impact on drug purity. Detailed information on extractables from the SUS supplier is thus an important requirement as a precursor to leachable studies.

Single Use Systems

mdi offers a wide range of gamma irradiated SUS for various critical applications in biopharmaceuticals and pharmaceuticals. These range from simple storage and transfer systems for media, buffers and drug substances; and sampling manifolds for bioreactors and process intermediate reservoirs; to more complex disposable filling lines complete with separate tubing connections for integrity testing and drain bags for collection of wetting fluids. **mdi** Single Use Systems are custom designed, in close interaction with the user, to maximize regulatory compliance and process efficiency. All the key components used in these SUS are produced in house which are deeply characterized and validated for integrity, microbial retention/ingress, sterility, bacterial endotoxins, biosafety and extractables.

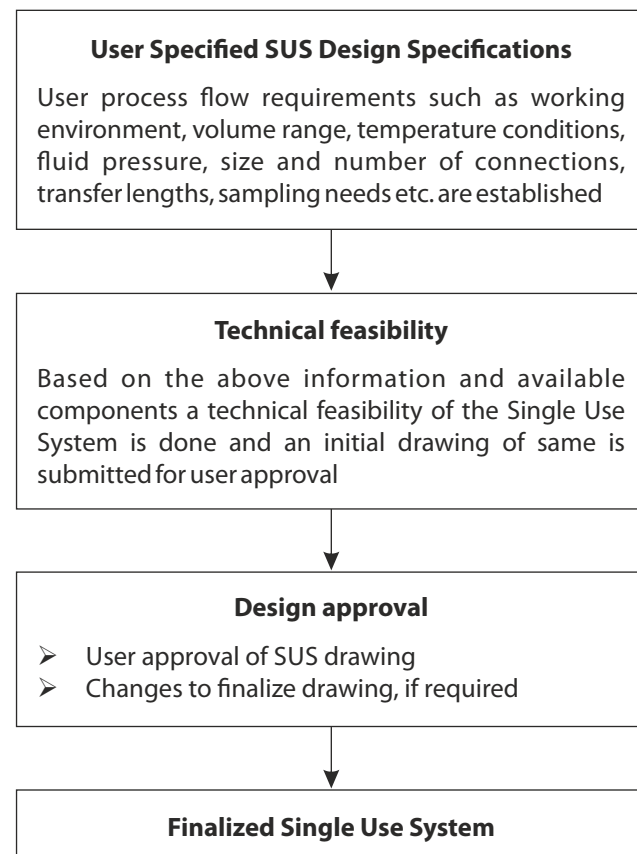


Typical Single Use System

Product Realization

mdi works closely with the process owners to understand their application requirements in terms of working environment, volume range, temperature conditions, fluid pressure, size and number of connections, transfer lengths, sampling needs, chemical compatibility etc. Subsequently technical feasibility of the system is established based on available single use components and to propose an initial SUS drawing. Product prototyping and final approval lead to customized product realization.

Product Realization Flow Chart



Single Use Systems

Quality Assurance

Quality Management System

mdi Single Use Systems are well designed products with in-built quality assurance. ISO-9001 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality assemblies.



36 Acre Campus

Validation

Validation at **mdi** is an integral part of product and process development. As per Bio-Process Systems Alliance (BPSA) guidelines and standards committee document and component quality test matrices for SUS, a wide range of physical, chemical, biological, and functional tests are to be conducted to qualify and validate various product specifications and ensure compliance.

Since SUS are used for aseptic transfer, storage and transport of fluids in biopharmaceutical processes, their validation has been carried out to provide detailed evidence of compliance with regulatory as well critical process requirements with regard to sterility, microbial recovery, endotoxins, biosafety, extractables, product integrity, packaging and transportation. These validations have been designed based on various regulatory and industry standards and guidelines such as USP, ISO, ASTM and CFR.

Manufacturing Facilities



ISO Class 7 Manufacturing Areas

mdi quality management system emphasizes on quality by design along with end product testing. 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 Single Use Systems are produced by trained personnel in validated ISO class 7 facilities using validated production processes.

Employee hygiene, gowning and continuous monitoring of clean room environment are an essential part of these 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 the art physical, chemical and microbiology laboratories.

Single Use Systems

Quality Assurance

World Class Testing Facilities



100% Integrity Tested

Each Single Use System is tested for integrity to comply with validated acceptable integrity test specifications.

Pressure, Temperature Endurance

SUS are validated to endure operating pressure and wide temperature conditions that may be encountered during use.

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

Extractables

mdi has strong analytical abilities with in-house state of the art analytical instrumentation such as HS-GCMS, GCMS, QTOF-LCMS, TOC Analyzer along with well qualified and trained manpower to deeply characterize different SUS components for volatile, semi-volatile and non-volatile extractables with multiple extraction media under different conditions of time and temperature.

Sterilization

mdi SUS are sterilized by gamma irradiation to provide a sterility assurance level of 10^{-6} . The sterilization process has been validated as per ISO 11137-2 which includes dose verification, dose mapping and quarterly dose audits.

The sterilization dose of 25 kGy has been substantiated through careful definition of the test samples, bio-burden testing of multiple lots of the selected test samples, calculation of verification dose and sterility testing.

Endotoxin Testing

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP $<85>$

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 $<87>$



Microbiology



Physical Testing Laboratory

Single Use Systems

Quality Assurance

Packaging and Traceability

mdi SUS are double packed in polyethylene bags to ensure package integrity during transit as well as to prevent contamination while transferring to clean room assembly or process areas.

Traceability

The lot number is mentioned on each pack of **mdi** Single Use System. The lot number is a seven digit alphanumeric number. In addition, each system is identified by a unique three digit numeric serial number mentioned on the pack to ensure complete traceability.

Examples of lot numbers with serial numbers are given below:

Lot No. AS0398H
Sl. No. 159

AS - Single Use System
039 - Batch Number
8 - Last Digit of Year of Manufacture
H - Month of Manufacture*
159 - Serial Number

* A is for January, B is for February and so on.



Gamma Sterile Double Polyethylene Packing


Certificate of Quality

Each lot is accompanied with a Certificate of Quality and the lot number is mentioned on the packaging of each Single Use System to ensure traceability at the user's end.

Endotoxin level: < 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test

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

Bioburden Level: The bioburden level of Single Use Assembly components have been tested as per ISO 11737

Certificate of Quality	
mdi Membrane Technologies	
The Single Use Assemblies have been manufactured in a cGMP compliant mdi facility. These are produced using validated production processes in classified ISO 7 area. The quality management system complies with ISO 9001 standards.	
Single Use Assembly	
Catalog No.	:XXXXXXXXXXXXX0301
Lot Number	:ASXXXXX
Ser. No.	:RXXXX Rev. No. XX
Date of Sterilization	:XXXX - XX
Expiry Date	:XXXX - XX
LOT RELEASE CRITERIA	
The above lot was released based on following criteria:	
100% Integrity Testing by pressure leak test	: Passes
100% Conformance to approved drawing	: Components verified for specifications, orientation and placement.
100% Visual Inspection	: Passes the visual inspection criteria.
Sterilization	: By gamma irradiation at 25 kGy to 40 kGy
VALIDATED FOR	
Bioburden Level	: The bioburden level of Single Use Assembly components have been tested as per ISO 11737.
Sterility	: The gamma sterilization process has been validated as per ISO 11137 to ensure a Sterility assurance level (SAL) of 10^{-6} .
Endotoxin Level	: < 0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.
Particle release	: Passes test as per USP<788> Particulate matter in Injections.
Biosafety	: Passes Biological Reactivity tests, <i>In Vivo</i> for Class VI plastic as per USP<88> and Biological Reactivity tests, <i>In Vitro</i> for Cytotoxicity as per USP<87>.
Shelf Life	: Gamma irradiated Single Use Assembly components have a shelf life of 2 years.
FILTERS USED	
Cat. No. 1:XXXXXXXXXXXXXXX Cat. No. 2:XXXXXXXXXXXXXXX Cat. No. 3:XXXXXXXXXXXXXXX	
CUSTOMER SUPPORT	
mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.	
 Head of Quality Assurance Issue Date: XX-XXX-22	
Advanced Microdevices Pvt. Ltd. Jawahar Road, Village: Tepda, Ambala, INDIA. Tel: +91-171-2699290/2699274 Website: www.mdimembrane.com Email: info@mdimembrane.com An ISO 9001 Company	

Shelf life: Gamma irradiated Single Use Assembly components have a shelf life of 2 years

Biosafety: Passes Biological Reactivity tests, *In Vivo* for Class VI plastic as per USP<88> and Biological Reactivity tests, *In Vitro* for Cytotoxicity as per USP<87>.

Particle Release: Passes test as per USP<788> Particulate matter in Injections.

Single Use Systems

Components & Hardware

mdi SUS are deeply characterized and validated with detailed documentation for microbial retention, bioburden, bacterial endotoxins, biosafety and extractables etc.

Most of these components such as sterilizing filters, bags, sterile connectors, quick connectors, fittings and tubing are produced in house through validated processes under stringent quality management systems. However, to facilitate extensive customization **mdi** outsources and incorporates user specified components as well.

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.

AseptiFlex™-D Film type FBG-1

The **mdi** AseptiFlex™-D Film type FBG-1 is a highly inert, multilayered polyethylene film specially designed for bioprocess applications. The film is used to produce storage bags, sampling bags, wave bioreactors, scaled and tapered bags.

AseptiBag 2D and 3D Storage Bags

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.

AseptiBag™ ULO+ Bags for Light Sensitive Media

mdi AseptiBag™ ULO+ systems are specially designed to provide validated and reliable storage and transfer solutions for light sensitive media as well as drugs for biopharmaceutical processes.

AseptiBag™ LT Bags for Low Temperature Storage

mdi AseptiBag™ LT systems are made from low extractable ULDP film, and provide robustness to ensure integrity at sub zero temperatures during freezing, storage, transportation, and thawing.

AseptiLiners

mdi AseptiLiners™ are specially designed for biopharmaceutical processes involving storage, preparation and transfer of process intermediates such as post centrifuge slurries, pellets, buffers, media and process intermediates.

AseptiMix™ MI Mixer Systems

mdi AseptiMix™ MI 3D mixer bags provide validated and reliable mixing solutions for biopharmaceutical process requirements such as mixing of media, process intermediates, sterile buffers with wide ranging pH, and formulations. These mixer bags replace the need of mixing in open tank liner systems.

Mixer Bottle and Carboy Assemblies

mdi AseptiMix™ are gamma sterilized vented bottle and carboy mixer assemblies, suitable for mixing, safe transfer and storage of biopharmaceutical products and reagents. The assembly does not require any additional hardware and can directly be placed on a magnetic mixer for mixing with a stir bar or impeller placed inside.

Wave Bioreactors

mdi AseptiWave™ single use bioreactors are designed for efficient culture of different type of cells including Mammalian cells, Plant cells, Insect cells, Microbial cells, Stem cells etc.

ASESS® Sampling Systems

mdi ASESS® are gamma irradiated single use disposable systems for aseptic fluid sampling at various stages in pharmaceutical and biopharmaceutical processing. These systems minimize chances of false positives and reduce cleaning requirements over traditional sampling systems.

ASESS sampling systems are also available as pre-loaded disposable sampling port cartridge with adapter. This system does away with tedious, time consuming assembly of ASESS® sampling system ports in the cartridge and subsequently in the multiport adapters. This provides an easy, faster, ready to use sampling system which fits directly on to the vessel port.

Single Use Systems

Components & Hardware

Acufil™ Disposable Single Use Filling Lines

mdi *Acufil™* disposable single-use filling lines offer customized solutions for final fill of drug products, overcoming flexibility and productivity constraints associated with traditional fill and finish systems.

Acufil™ Filling Needles

mdi *Acufil™* single use filling needles for aseptic filling of liquids are designed for accurate volume filling of both mobile and viscous drug products without drip formation.

Scaled Bags

mdi *AseptiBag™ AV 2D* scaled bags are designed to use in **mdi** single use systems for accurate volume storage and transfer. The printed scale provided on the bag allows the exact volume to be collected or transferred within or between critical process steps.

Tapered Bags

mdi *AseptiBag™ HV* are specially designed for minimizing losses of high value drug substances and drug products in transfer and filling applications due to negligible hold up volumes.

Connectors

AseptiLink™ SV Steam To Connector

mdi offers reliable and easy to use *AseptiLink™ SV* steam to connector which lets you integrate steamable hard-piped process equipment with disposable sterile fluid paths

AseptiLink™ ST Steam Through Connector

mdi *AseptiLink™ ST* steam through connectors are designed to provide safer, secure and validated connection for transfer of sterile fluids. This connector enables integration of steamable hard piped processing systems to gamma sterilized disposable flow paths in single use assemblies.

QuiKconnect™ Quick Connectors

mdi *QuiKconnect™* Polycarbonate Quick Connectors are designed to provide extra reliability and easy connectivity in critical aseptic process steps in the manufacture of pharmaceuticals and biopharmaceuticals.

AseptiLink™ SC/SL Genderless Sterile Connectors

mdi *AseptiLink™ SC/SL* genderless sterile connectors are designed to provide a fast and convenient aseptic connection between two processing streams, such as a container to a sampling line, media bags to a bioreactor or a filtration assembly to a filling line, without the need of a biocontainment hood.

AseptiDlink™ Disconnectors

mdi *AseptiDlink™* sterile disconnectors are designed to provide a fast and smooth, leak free aseptic disconnection of single use systems. This allows the user to maintain sterility during disconnection while doing away with pinch clamps and tube welders.

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.

AseptiFit Fittings

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

Other Components

A wide variety of other essential components such as tubing clamps, sanitary flange clamps, plugs, valves and bottle covers are also available.

Hardware

mdi offers a variety of hardware for Single Use Assemblies line BioKart stainless steel trolley for 2D bags, *BioSafe™* stainless steel totes for 3D bags, Liner drum with trolleys, Mixer Totes for Mixer bags.

Single Use Systems

Sterilizing Grade Membrane Capsule Filters

mdi offers hydrophilic PES membrane capsule filters specially designed for simple, quick and efficient filtration of fluids and gases used in lab, pilot and small scale applications, with superior flow and particle removal efficiency at 0.1, 0.2 & 0.45µm. These DI water rinsed filters are the solution to a wide variety of applications in the beverage, pharmaceutical and biopharmaceutical industries. PES membrane is compatible with EO, Gamma irradiation and autoclave methods of sterilization.

mdi provides hydrophobic membrane capsule filters that provides high flow rates, sterility assurance and high throughputs. They are used for sterile filtration of liquids in small and large volume systems, containers and gas venting applications. This membrane (PVDF) reliably eliminates contaminants and microorganisms in sterilizing applications, even at high pH.

mdi also offers *AseptiPrime*® KS capsule filters specially designed for very high throughputs. These capsule filters provide high retention efficiency, high protein recoveries, extremely low extractables, wide chemical compatibility and sterilization applications in biopharma process development, pilot scale and production batch sizes.



Scale

Bioprocess engineers are looking for optimum filter sizes to minimize filtration costs and reduce product loss. **mdi** offers a complete range of sizes to choose from small 5 cm² capsule filters with very low hold up volumes to 18000 cm² filters for large scale production.

To know more, visit the link:

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

Easy Connectivity

mdi offers a wide range of high quality, reliable, flexible, functionally convenient standard and customized inlet/outlet connections.

Quality Assurance

mdi capsule filters are produced in ISO class 7 clean rooms with validated processes under stringent quality management system which ensure total traceability and consistent quality.


Certificate of Quality

Each capsule filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end. It certifies the product compliance to various regulatory as well as user requirements.

Oxidizable Matter: Passes test as per USP <1231>

Extractable: Within limits as specified in USP <661>

Heat Stability: Maintains integrity after 25 autoclaving cycles at 125 °C of 30 minutes each

Certificate of Quality	
mdi Membrane Technologies	
The Polyethersulfone Membrane Capsule filters have been manufactured in a mdi facility in compliance with ISO 9001 regulations using validated production processes	
AseptiCap KS PES Membrane Capsule Filters	
Catalog No.	DKS5201EEX101
Type	DKS
Pore Size	0.2 µm (0.45 µm ± 0.2 µm)
Lot Number	DK5557G St. No. 925
SPECIFICATION	
Length	2"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4kg/cm ² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ ± 2 Kg/cm ²
Sterilization	25 autoclaving cycles at 125 °C of 30 minutes each
LOT RELEASE CRITERIA	
100% Integrity Tested	: The capsule filter has been tested for integrity by Bubble point test using DI water. Bubble point value with DI water was ≥ 50 psi (3.44 Bar). The capsule filter is also certified for integrity by Bubble point test using 50% IPA/Water solution. Bubble point with 50% IPA/Water solution is ≥ 16 psi (1.10 Bar)
Water Flow Rate	: ≥ 3.5 lpm @ 0.10 Kg/cm ² @ 27 °C
Microbial Challenge Test	: Retains > 10 ⁷ organisms/cm ² of <i>S. almonata</i> ATCC: 10146 challenge as per ASTM F838-05 methodology
VALIDATED FOR	
Heat Stability	: Maintains integrity after 25 autoclaving cycles at 125 °C of 30 minutes each
Extractable	: Within limits as specified in USP
Oxidizable matter	: Passes test as per USP
Bioactivity	: Passes Biological Reactivity Tests, <i>In Vivo</i> for Class VI plastic as described in USP <88>
Cytotoxicity	: Passes Biological Reactivity Tests, <i>In Vitro</i> as described in USP <87>
Indirect Food Additives	: Passes as per FDA 21CFR 177.1520(a)(1)
Particle Release	: Passes test as per USP <788> "Particulate matter in Injections"
Fiber Release	: Complies with FDA 21CFR 210.3(b)(6)
CUSTOMER SUPPORT	
mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.	
 Head of Quality Assurance Issue Date: 22-Jul-17	
Advanced Microdevices Pvt. Ltd. D, Industrial Area, Ambala Cantt., INDIA, Tel: +91 171-2619290/2619274 Website: www.mdimembrane.com Email: info@mdimembrane.com	
An ISO 9001 Company	

Fiber Release: Complies with FDA 21CFR 210.3(b)(6)

Particle Release: Passes test as per USP <788> Particulate matter in Injections

Indirect Food Additives: Passes as per FDA 21CFR 177.1520(a)(1)

Biosafety: Passes Biological Reactivity tests, *In Vivo* for Class VI plastic as per USP <88> and *In Vitro* for Cytotoxicity as per USP <87>

Single Use Systems

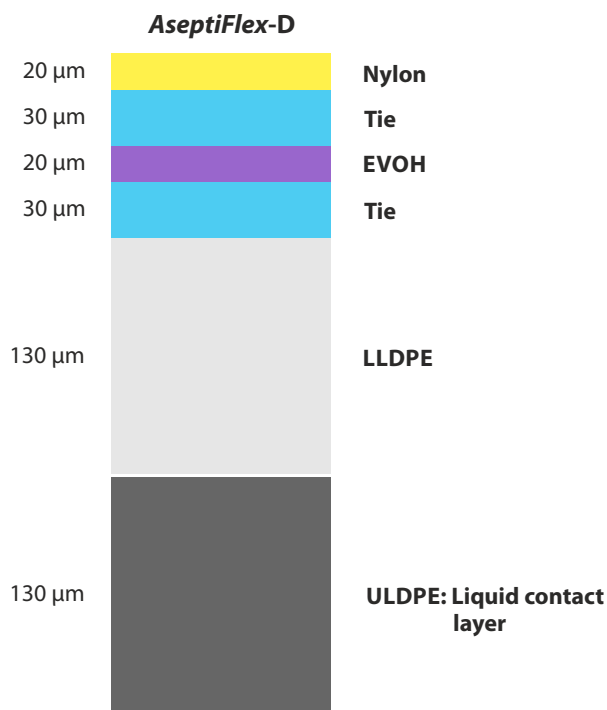
Multilayered Film for Storage and Transfer Bags

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.



Physical Properties

Test	Reference Standard	Average Values
Oxygen Transmission Rate	ASTMD3985-05	0.168 cc/m ² /day
Carbon dioxide Transmission Rate	ASTMF2476	<1.0 cc/m ² /day
Water Vapour Transmission Rate	ASTMF1249-13	0.879 g/m ² /day
Tear strength	ASTMD1938	TD 25.556 N
		MD 17.873 N
Puncture Resistance	EN14477	10.9578 N
Tensile Strength (MD)	ASTMD-882	27.0298 N/mm ²
Flex Durability Test (Gelbo)	ASTM F-392	Passes

Other Properties

Test	Reference Standard	Result	
Biosafety	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> for cytotoxicity	Passes
Extractables	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
Fiber/Particle Release	Fiber Release	USFDA 21 CFR Part 210.3(b)(6)	Passes
	Particle release	USP <788> test for particulate matter in injections	Passes

FBG-1 film is a Class VI plastic of Non Animal Origin

Single Use Systems

Storage and Transfer Bags

AseptiBag Gold Storage and Transfer Bags

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 regulatory, functional and biosafety concerns discussed above.

AseptiBag Gold 2D Bags

Available Sizes

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

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

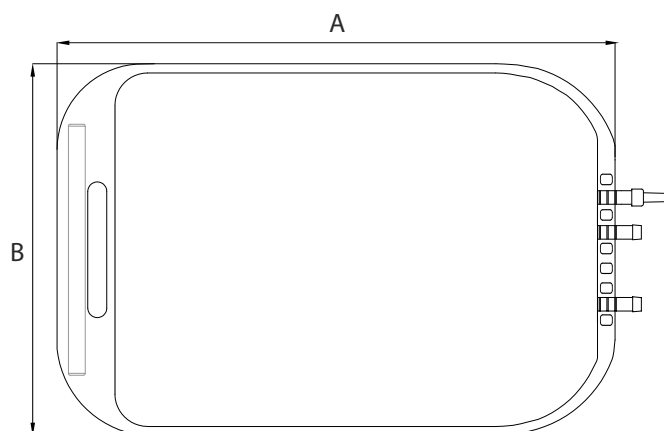
End Connections

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

Note: 500mL, 1L and 2L bag sizes are also available with Female Luer Lock at inlet and Male Luer Lock at outlet.

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



Sampling Ports

Needless

Customization

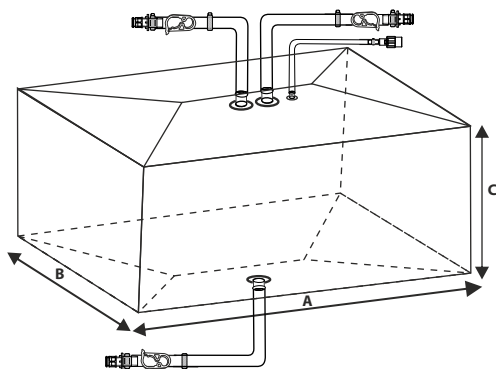
The 500 mL to 50 litre storage bags can be customized to suit user requirements. Female quick connector can be provided for inlet port/outlet port and rubber septum for sampling port.

Single Use Systems

Storage and Transfer Bags

AseptiBag™ Gold 3D Bags

For Rectangular Totes



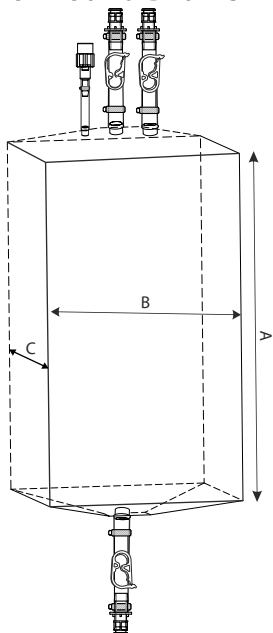
Available Sizes

50L, 100L, 200L, 500L, 1000L and 2500L

Dimensions

Bag Size	A	B	C
100 Litre	730 mm	530 mm	310 mm
200 Litre	730 mm	530 mm	610 mm
500 Litre	1100 mm	720 mm	730 mm
1000 Litre	1100 mm	890 mm	1180mm
2500 Litre	2085 mm	1145 mm	1095 mm

For Round Drums



Dimensions

Bag Size	200 Litre
A	900 mm
B	510 mm
C	470 mm

Customization

mdi works closely with the process owners to understand their application requirements. This storage bag can be customized to suit user requirements regarding tubing sizes, sizes, type of inlet ports, sampling ports, and position and type of drain ports. A technical feasibility of the required design is established based on available components and an initial drawing is proposed. Products prototyping and final approval leads to customized bag realization.

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



Easy Inlet/outlet Quick Connections



Validated Pinch Clamps



Leak Proof Ties

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

Single Use Systems

2D Bags for Light Sensitive Fluids

AseptiBag™ ULO⁺ Bags

Many biopharmaceutical drug substance/products, process intermediates and also chemically defined media (for mammalian cell culture) are light sensitive.

Exposure of light sensitive drugs to UV or visible light, may result in degradation of drug molecules that may impact patient safety. In case of light sensitive media, degradation of vital ingredients such as vitamins can reduce process efficiencies in mammalian cell expression systems.*

mdi AseptiBag™ ULO⁺ systems are specially designed to provide validated and reliable storage and transfer solutions for light sensitive media as well as drugs for biopharmaceutical processes.

[*Media photo-degradation in pharmaceutical biotechnology – impact of ambient light on media quality, cell physiology, and IgG production in CHO cultures](#)

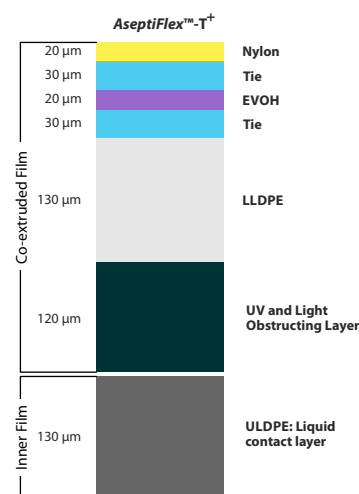


Unique Feature

AseptiBag™ ULO⁺ are designed to protect light sensitive fluids with a unique layer for minimizing UV and light transmission. These bags have been tested for transmittance of UV (200nm - 400 nm) as well as visible light (400nm-780nm) using a spectrophotometer with a wavelength accuracy of ± 0.1nm.

The following table show the comparison between transmittance of UV and visible light with standard AseptiBag™ and AseptiBag™ ULO⁺.

Bag Type		AseptiBag™	AseptiBag™ ULO ⁺
		Transmittance (%)	
UV Light	<250nm	> 4 %	< 0.08 %
	250 nm - 400 nm	> 46 %	
Visible Light	(400 nm - 780 nm)	> 70 %	< 0.008%



mdi AseptiFlex™-T⁺ Film is a highly inert film specially designed for bioprocess applications involving light sensitive drugs and chemically defined proprietary media.

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 UV and light obstructing layer, co-extruded with the outer barrier layer minimizes transmission of light within the wavelength range of 200 nm to 780 nm.

The contact layer is 130 µm ultra low density Polyethylene (ULDPE) layer without any additives and ensures very low extractables.

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

Single Use Systems

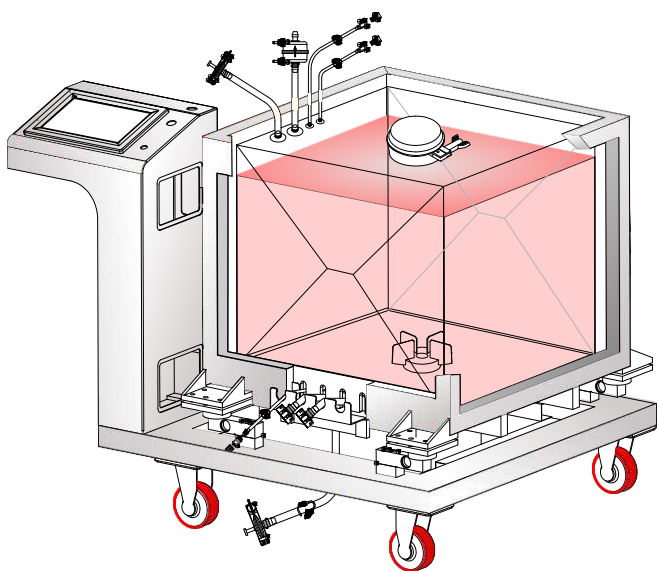
Mixer Systems

AseptiMix™ MI Mixer Bags

mdi AseptiMix™ MI 3D mixer bags provide validated and reliable mixing solutions for biopharmaceutical process requirements such as mixing of media, process intermediates, sterile buffers with wide ranging pH, and formulations. These are well characterized for various physical, chemical and microbiological properties to alleviate all the above mentioned concerns. These mixer bags replace the need of mixing in open tank liner systems.

mdi AseptiMix™ MI single use mixer bags are designed for uniform and fast mixing of cell culture media, process fluids, buffers, reagents and formulations. The impeller is located inside the AseptiMix™ MI mixer bags which is rotated with the help of magnetic drive. The AseptiMix™ MI mixer bag is also available with 4" and 8" sanitary flange powder port for powder-to-liquid mixing.

The **mdi** AseptiMix™ MI mixer bags are available for volumes upto 1000 liters.



Available Sizes

50L, 100L, 200 L, 650L and 1000 L

AseptiMix™ MI is made from AseptiFlex-D film offering multiple advantages such as:

- Uniform and fast mixing
- Customized to user requirements
- Very low extractable profile for low 'Product' risk

Unique Features

- Custom designed to suit user specific process applications
- Multiple Impeller options for uniform and easy mixing
- Available with 4" and 8" sanitary flange powder ports for powder-to-liquid mixing
- Easy inlet and outlet quick connections
- 100% integrity tested with pressure leak test

Applications

mdi AseptiMix™ MI mixer bags are used for critical biopharmaceutical process steps involving:

- Mixing and transfer of
 - Cell culture media
 - Buffers
 - Formulations
 - Process intermediates

Single Use Systems

Mixer Bottle and Carboy Assemblies

AseptiMix™ Mixer Bottle and Carboy Assemblies

mdj AseptiMix™ are gamma sterilized vented bottle and carboy mixer assemblies, suitable for mixing, safe transfer and storage of biopharmaceutical products and reagents. The assembly does not require any additional hardware and can directly be placed on a magnetic mixer for mixing with a stir bar or impeller placed inside.

The stir bar/impeller inside the mixer assembly has wide chemical compatibility and it ensures the proper mixing of solution without any particle shedding.

These assemblies are fitted with a self supporting light weight, sterilizing grade 0.2µm PVDF vent filter to prevent ingress of microorganisms during filling and removal of high value products.



AseptiMix™ VC vented carboy mixer assemblies



AseptiMix™ VB vented bottle mixer assemblies

Bottle Body	LDPE
	PETG
Cap	Polypropylene
Inlet Tube	Platinum Cured Silicone
Dip Tube	Platinum Cured Silicone
Vent Filter Membrane	0.2 µm Hydrophobic PVDF
Vent Filter Body	Polypropylene
Impeller	Polypropylene
Stir Bar	PVDF

Carboy Body	LDPE
	Polypropylene
	HDPE (white color)
	HDPE (amber color)
Cap	Polypropylene
Inlet Tube	Platinum Cured Silicone
Dip Tube	Platinum Cured Silicone
Vent Filter Membrane	0.2 µm Hydrophobic PVDF
Vent Filter Body	Polypropylene
Impeller	Polypropylene
Stir Bar	PVDF

Single Use Systems

AseptiWave Bioreactors

AseptiWave™ Bioreactors

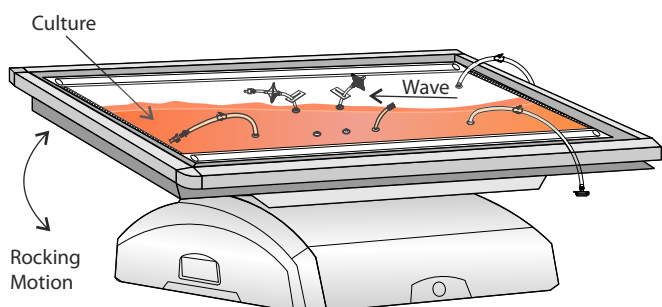
mdj AseptiWave™ single use bioreactors are designed for efficient culture of different type of cells including Mammalian cells, Plant cells, Insect cells, Microbial cells, Stem cells etc.

These are available gamma sterilized, in multiple sizes ranging from 2 liters for clone selection and media optimization labs, up to 50 liters, for process development as well as GMP production of biopharmaceuticals.



Mechanism

AseptiWave™ Bioreactors require a rocking platform to induce rocking motion for optimal mixing and gas transfer required for efficient cell growth.



Applications

- Cell Culture
- Expansion of anchorage dependent cells such as epidermal and connective tissue cells
- Small scale expansion of stem cells
- Inoculum propagation
- Development and manufacture of:
 - Therapeutic protein
 - Monoclonal Antibodies (mAbs)
- Expansion of CART cells for cell therapy

Types Available

AseptiWave™ bioreactors are available with and without pH and DO sensors.

AseptiWave™ OS bioreactors integrate pre-calibrated optochemical pH and DO sensors, for monitoring pH and dissolved oxygen in the culture, allowing efficient cell cultivation. The calibration data for the optical sensors is provided along with the bioreactors.

Type	pH and DO Optical Sensor
AseptiWave™	No
AseptiWave™ OS	Yes

Sizes Available

Size	Minimum Working Volume (L)	Maximum Working Volume (L)	Surface Area (cm ²)
2L	0.2	1	1452
10L	0.5	5	3430
20L	1.0	10	6272
50L	5.0	25	9344

Single Use Systems

Acufil® Filling Lines

Acufil™ disposable single-use filling lines

mdi Acufil™ disposable single-use filling lines offer customized solutions for final fill of drug products, overcoming flexibility and productivity constraints associated with traditional fill and finish systems.

These ready to use, gamma sterilized filling assemblies are designed to not only ensure regulatory compliance but also enhance product and operator safety.

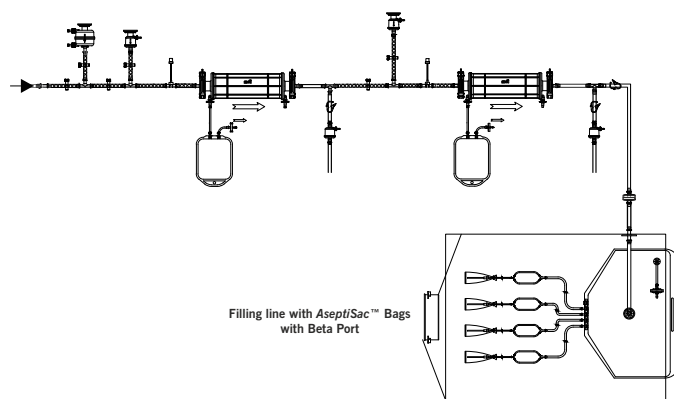


mdi Acufil™ disposable single-use final fill assemblies ensure:

- Accurate Filling
- Minimal loss of high value drug products
- Quick turnaround time
- Increased flexibility and productivity
- Product and operator safety
- Reduced risk of cross contamination
- No cleaning validation

mdi Acufil™ single use filling lines are customized to suit new as well as existing fill and finish systems. These are designed to comply with regulatory requirements such as “Final sterile filtration should be carried out as close as possible to the filling point” and “The integrity of the sterilized filter should be verified before use and should be confirmed immediately after use by an appropriate method such as a bubble point, diffusive flow or pressure hold test” (European Union Current Good Manufacturing Practices).

However, combining both these within an Isolator/RABS* system becomes quite challenging.



Disposable Filling Lines for Isolator/RABS

These ready to use gamma sterilized filling lines are also available housed within a specially designed *AseptiSac* bag with Beta Port for transfer into and out of an Isolator or RABS.

These assemblies are pre-validated, pre-assembled, pre-sterilized systems with bags, tubings, connectors, filters and filling needles, placed inside a beta port bag for easy and secure insertion and removal around the aseptic filling system.

The beta port bags come with a special port which connects the sterilizing filters with the filling lines, making it convenient for the user to conduct PUPSIT (Pre-use/Post Sterilization Integrity Testing).

Customization

mdi works closely with the process owners to understand their functional as well as regulatory requirements. A technical feasibility of the required design is established based on available components and an initial drawing is proposed. Product prototyping and final approval leads to user specific filling line realization.

Customization may include but is not limited to:

- Bag size and ports
- Filter MOC, size and pore size
- Tubing length, lumen and thickness
- Different filling needle lumen for different fill volumes
- Filling needle hub connections with hose barb or female luer lock

*Restricted Access Barrier System

Single Use Systems

Acufil™: Single use filling needles

mdj Acufil™ single use filling needles for aseptic filling of liquids are designed for accurate volume filling of both mobile and viscous drug products without drip formation. These offer ready to use filling solutions both as part of complete gamma sterilized single use filling lines and as a gamma sterile individually packed components to be used in existing filling lines.

mdj Acufil™ single use filling needles offer flexibility as these come in different sizes i.e 1.6 mm, 3 mm, 4 mm, 5 mm and 5.4 mm with female luer connection or hose barb connections.

Materials of Construction

Hub : Polypropylene

Needle : SS 316

Special Features

- No drip formation
- Accurate volume filling
- Available in two different internal diameters to facilitate different fill volumes
- Female luer connection and hose barb connection facilitates easy integration in filling line or systems

Water Flow Rate

1.6mm Needle: >350ml/min @ 2.5psi

3.0mm Needle: >500ml/min @ 2.5psi

Applications

Small volume parenterals filling in pharmaceutical and biopharmaceutical manufacturing

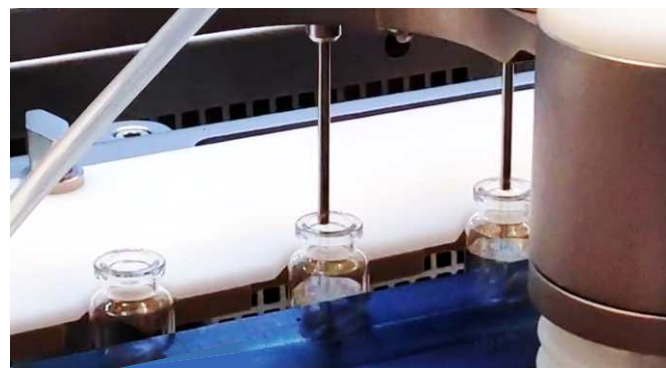
Specifications

Bacterial Endotoxin

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

Particle Release

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



Extractables

Comply with USP <661> Plastic Packaging Systems and Their Materials of Construction; Physicochemical Tests for Nonvolatile Residue

Bioburden Levels

Bioburden level is < 1000 cfu/device as per ISO 11737-1 : 2018

Single Use Systems

Acufil™: Single use filling needles

Sizes, Connections and Hub Style

Needle ID	Connection	Length	Part No.	Hub Style
0.9 mm	3/32" HB	90 mm	NLXA07IACXXX	13mm HUB
		32 mm	NLXA12IAKXXX	4.8mm HUB
	1/8" HB	138 mm	NLXA06IHDXXX	8mm HUB with T Holder
1.3 mm	3/32" HB	120 mm	NLXA11PAIXXX	7.8mm HUB
1.6 mm	1/8" HB	100 mm	NLXA01AAAXXX	8mm HUB
		138 mm	NLXA06AHXXXX	8mm HUB with T Holder
		140 mm	NLXA02AHAXXX	8mm HUB
	3/32" HB	90 mm	NLXA07AACXXX	13mm HUB
		100 mm	NLXA01AHAXXX	8mm HUB
		127 mm	NLXA09AAJXXX	11.5mm Jacketed hub with O-ring Gas Connection
		138 mm	NLXA06AAEXXX	8mm HUB with T Holder
		140 mm	NLXA02AHAXXX	8mm HUB
		Female Luer Lock	121 mm	NLXA04AMBXXX
	2.0 mm	1/8" HB	138 mm	NLXA06NHEXXX
1/8" HB		178 mm	NLXA10NHXXXX	10mm HUB with Steps
2.5 mm	3/16" HB	148 mm	NLXA08SNEXXX	8mm HUB with T Holder
3.0 mm	1/8" HB	100 mm	NLXA01BHAXXX	8mm HUB
	1/8" HB	140 mm	NLXA02BHAXXX	8mm HUB
	3/16" HB	148 mm	NLXA08BNEXXX	8mm HUB with T Holder
4.0 mm	3/16" HB	127 mm	NLXA09ONGXXX	11.5mm Jacketed Hub with 3/16" HB
	3/16" HB	148 mm	NLXA08ONEXXX	8mm HUB with T Holder
5.0 mm	1/4" HB	100 mm	NLXA01CBAXXX	8mm HUB
	3/16" HB	90 mm	NLXA07CNCXXX	13mm HUB
	1/4" HB	118 mm	NLXA13CBAXXX	8mm HUB
	1/4" HB	165 mm	NLXA16CBNXXX	4mm HUB
5.4 mm	1/4" HB	148 mm	NLXA08MBEXXX	8mm HUB with T Holder

Single Use Systems

Scaled Bags

AseptiBag™ AV Scaled Bags

mdj AseptiBag™ AV 2D scaled bags are designed to use in **mdj** single use systems for accurate volume storage and transfer. The printed scale provided on the bag allows the exact volume to be collected or transferred within or between critical process steps.

The design is such that the printing is on the seal area, which ensures that the ink does not diffuse through the bag film into the stored fluid.

Applications

mdj AseptiBag™ AV Scaled Bags are used for critical applications such as:

- Drug Formulation: Accurate volume storage and transfer of drug substance for drug formulation
- PUPSIT with the drug product: Ensures exact flush volume with high value drug products, thereby minimizing losses

Sizes Available

mdj AseptiBag™ AV 2D Scaled Bags are available up to 6 Liter

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



Specifications

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>)

Single Use Systems

Tapered Bags

AseptiBag™ HV Tapered Bags

Biopharmaceutical drug substances and drug products are high value fluids and process owners are looking to minimize losses during transfer and filling processes.

mdi AseptiBag™ HV are specially designed for minimizing losses of high value drug substances and drug products in transfer and filling applications due to negligible hold up volumes.

A comparative against standard flat bottom bags used in disposable filling lines shows a significant advantage in terms of reducing product losses.

Bag Type	Hold up Volumes
Standard Flat Bottom Bags	32 mL
AseptiBag HV Tapered Bags	1 mL

Identification and Traceability

The Part Number for these bags incorporates the drawing number in which this bag shall be used.

For example:

B2BA **A9893** EXR

A9893 represents the drawing number.

Bag Film

AseptiFlex™ D film

Storage Temperature

-20°C to 45°C

Sterilization

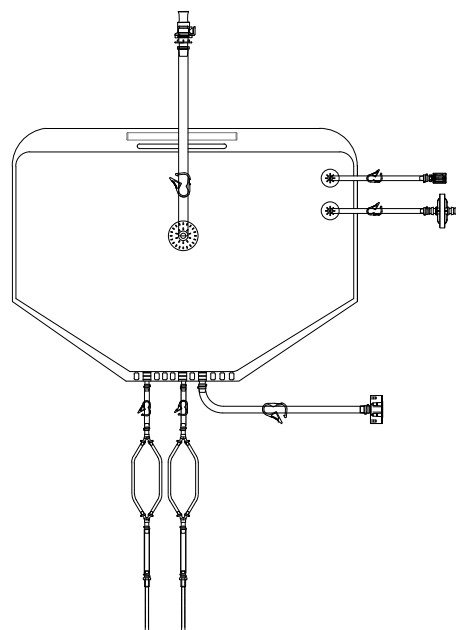
Gamma Sterilizable upto 50 kGy

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 < 0.25 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

Effect on WFI

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

Extractable Studies

The Extractable study was performed as per **Biophorum Best Practices Guide for Extractable Testing of Polymeric Single-Use Components used in Biopharmaceutical Manufacturing.**

Single Use Systems

Low Temperature Bags

AseptiBag™ LT Low Temperature Bags

mdj AseptiBag™ LT single use storage and transfer systems are designed for cold chain applications in biopharmaceuticals. These systems are designed for low temperature storage of up to -80 °C, as well as multiple freeze thaw applications involving high value drug substances and process intermediates.

mdj AseptiBag™ LT systems are made from low extractable ULDPE film, and provide robustness to ensure integrity at sub zero temperatures during freezing, storage, transportation, and thawing.

AseptiBag™ LT offers multiple advantages such as:

- Compatible with long term storage at low temperatures of up to -80 °C
- Ability to withstand multiple freeze thaw cycles
- Very low extractable profile
- High strength and flexibility
- High transparency

Applications

mdj AseptiBag™ LT systems are used for long term low temperature storage of:

- Process intermediates
- Drug substances
- Vaccine active raw materials (arm)
- Monoclonal Antibodies (mAbs)
- Recombinant proteins

Specifications

Film: Ultra-Low Density Polyethylene (ULDPE)

Operating Temperature: -80°C to 45°C

Storage temperature: up to -80°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 < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Fiber Release: Passes microscopic test for fibers



Biosafety: Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88> and Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

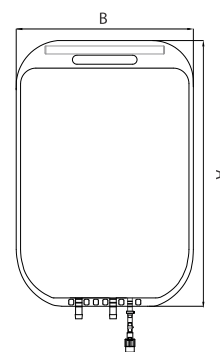
Particle Release: Complies with USP <788> test for particulate matter in injections

Extractable Studies

The Extractable study was performed as per **Biophorum Best Practices Guide for Extractable Testing of Polymeric Single-Use Components used in Biopharmaceutical Manufacturing.**

Available Sizes and Dimensions

Bag Size	A	B
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



Product Availability

mdj AseptiBag™ LT low temperature bags are only available as part of **mdj** single use systems.

Customization

mdj AseptiBag™ LT systems can be customized to suit user requirements in terms of tubing, fittings, end connections and connectors.

Single Use Systems

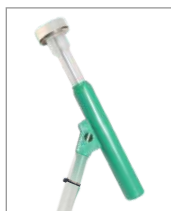
ASESS® Sampling Systems

ASESS® Sampling System

mdi ASESS® are gamma irradiated single use disposable systems for aseptic fluid sampling at various stages in pharmaceutical and biopharmaceutical processing. These systems minimize chances of false positives and reduce cleaning requirements over traditional sampling systems.



Needle Options



1mm Needle for standard fluids



2mm Needle for viscous fluids

Applications

Aseptic sampling of:

- Sterile bulk and sterile transfers
- Vaccine formulations at different maturation steps
- Fermentation cycles
- Cell culture from bioreactors

Pre-loaded ASESS® Aseptic Sampling System

mdi pre-loaded disposable sampling port cartridge does away with tedious, time consuming assembly of ASESS® sampling system ports in the cartridge and subsequently in the multiport adapters. This provides an easy, faster, ready to use sampling system which fits directly on to the vessel port.



Special Features

- Closed system for maximum operator safety and zero contamination
- Easier, faster and completely disposable, ready-to-use solution for sampling application
- No tedious time consuming assemblies of sampling system ports in cartridges and multi-port adaptors

Customization

ASESS® Aseptic Sampling Systems can be customized to suit user requirements regarding tubing sizes, sizes, sampling ports, **sampling containers** and vessel port. A technical feasibility of the required design is established based on available components and an initial drawing is proposed. Products prototyping and final approval leads to customized system realization.

Sampling Containers Options



Bags



Bottles



Centrifuge Tubes



Precision Syringes up to 25mL

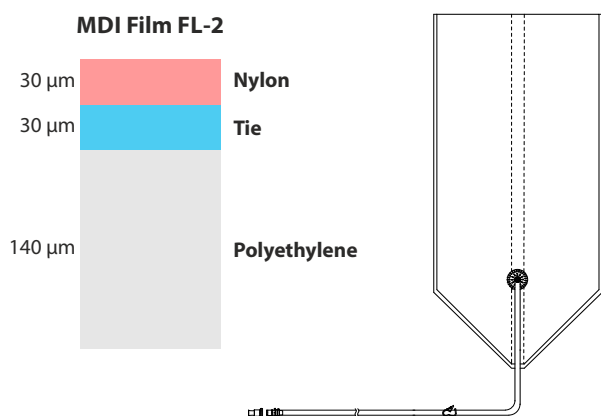
Single Use Systems

AseptiLiner™

AseptiLiner™ 3D Liners with drain port

mdi AseptiLiner™ 3D liners with drain port are specially designed for biopharmaceutical processes involving preparation and transfer of buffers, media and process intermediates.

These liners are made from robust multilayered film FL-2 with a polyethylene contact layer.



Physical Properties of Film

MOC

Film : Multilayered film type FL-2
 Tube : Platinum Cured Silicone

Film Thickness: 200µm

Tensile Strength : >25 N/mm² when tested as per ASTM D-882

Elongation @ Break: >400% when tested as per ASTM D-882

Gelbo Flex Test: No pinholes after Flex durability test as per ASTM F 392

Tube Length: 18 inch

Drain Port: 1/2" HB male quick connector with female plug

Sterilization: Gamma Irradiated @25 kGy

AseptiLiner™ 3D Liners without drain port

mdi AseptiLiner™ 3D liners are specially designed for biopharmaceutical processes involving storage and transfer of process intermediates such as post centrifuge slurries and pellets. The easy to seal design using wire ties ensures leak proof storage and transfer.



Materials of Construction

Film FL-1 : Ultra Low Density Polyethylene (ULDPE)

Physical Properties of Film

Tensile Strength: >20 N/mm² when tested as per ASTM D-882

Elongation @ Break: >280% when tested as per ASTM D-882

Sterilization: Gamma Irradiated @25 kGy

Drum Dimensions

AseptiLiner™ Volume	Drum Size	
	Diameter	Depth
50 Litre	43 cm	46.5 cm
100 Litre	51 cm	63.5 cm
200 Litre	59 cm	91 cm
500 Litre	79 cm	126 cm

Applications

- Preparation of media and buffers before filtration
- Pooling process intermediate solutions
- Waste collection from downstream purification processes

Single Use Systems

Connectors

Quick Connectors

mdi QuiKonnnect™ Polycarbonate Quick Connectors are designed to provide extra reliability and easy connectivity in critical aseptic process steps in the manufacture of pharmaceuticals and biopharmaceuticals.

The special extra large side wings in the female connector help prevent accidental release of connection.

These connectors significantly improve the service ability of fluid systems by saving time, reducing the spills/leakage and increasing safety, while minimizing the risk of cross contamination likely to happen with reusable components.

mdi QuiKonnnect™ Quick Connectors are made up of materials which fulfill critical requirements such as free flow passage, wide chemical compatibility, and minimal leachables.



AseptiLink™ SC/SL: Genderless Sterile Connector

Single Use Systems (SUS) are increasingly being used in the biopharmaceutical manufacturing process. Aseptically connecting single use components to form a usable assembly or to connect a SUS to another single use or a reusable system, for example a sterile media bag to a bioreactor, is a critical requirement.

mdi AseptiLink™ SC/SL, genderless connectors are designed to provide a fast and convenient aseptic connection between two processing streams, such as a container to a sampling line, media bags to a bioreactor or a filtration assembly to a filling line, without the need of a biocontainment hood. In other words, it provides a validated robust connecting mechanism within sterile as well as non sterile environments, while eliminating the need for sophisticated and complicated hardware.

Sizes Available

AseptiLink™ SC

- 1/4" Hose Barb

- 3/8" Hose Barb

- 1/2" Hose Barb

AseptiLink™ SL

- 3/4" Hose Barb



Gamma Sterilizable Sterile Connectors



Autoclavable Sterile Connectors

Application

Gamma Sterilizable Connectors:

Aseptically connects two gamma sterile single use systems

Autoclavable Connectors:

The autoclavable *AseptiLink™ SC* can be connected to SS hardware and sterilized by autoclaving. The complete assembly can then be connected aseptically to gamma sterile single use systems.

Example: Reusable bioreactors to gamma sterile media bag assemblies

Single Use Systems

Connectors & Disconnectors

AseptiLink™ SV Steam To Connector

mdi offers reliable and easy to use *AseptiLink™ SV* steam to connector which lets you integrate steamable hard-piped process equipment with disposable sterile fluid paths. It is gamma compatible and autoclavable making it ideal for integration into sterilized assemblies through 1.5" or 25 mm sanitary flange connection and 3/8" hose barb at other end to connect with the tubing.



50mm Sanitary Flange with
3/8" Hose Barb



25mm Sanitary Flange with
3/8" Hose Barb

AseptiLink™ ST Steam Through Connector

mdi *AseptiLink™ ST* steam through connectors are designed to provide safer, secure and validated connection for transfer of sterile fluids. This connector enables integration of steamable hard piped processing systems to gamma sterilized disposable flow paths in single use assemblies.

mdi *AseptiLink™ ST*, as part of the gamma irradiated single use disposable assembly is connected to stainless steel vessels/piping through its sanitary flange inlet connection. This connection is steam sterilized, along with SS component of the process flow, effecting a sterile connection between the two.



AseptiLink™ ST with 25 mm
Sanitary Flange Inlet
3/8" Hose Barb Steam and Fluid
Outlet



AseptiLink™ ST with 50 mm Sanitary
Flange Inlet
1/2" Hose Barb Steam and Fluid
Outlet

AseptiDlink™ : Sterile Disconnecter

Single Use Systems (SUS) are increasingly being used in biopharmaceutical, and cell and gene therapy manufacturing processes. Aseptically disconnecting single use components such as bags from a single use assembly being used is a critical process requirement.

mdi *AseptiDlink™* sterile disconnectors are designed to provide a fast and smooth, leak free aseptic disconnection of single use systems. This allows the user to maintain sterility during disconnection while doing away with pinch clamps and tube welders.

Sizes Available

- 1/4" Hose Barb - 3/8" Hose Barb - 1/2" Hose Barb



Gamma Sterilizable
Disconnectors



Autoclavable
Disconnectors

Applications

Sterile disconnection from processing equipment and components such as:

- Single use bioreactors
- Filter capsules
- Single use bags
- Sampling systems
- Transfer lines

Single Use Systems

Tubing

mdi has developed Platinum Cured Silicone (PCS) tubing and Thermoplastic Elastomer (TPE) tubing. These tubing are manufactured in ISO clean rooms that offers less contamination and enhanced smooth fluid flow operation.

mdi offers different kind of tubing for various applications:

- PCS tubing:

- AseptiFlo™ for fluid transfer
- PresFlo™ High pressure tubing for fluid transfer applications
- AcuFlo™ for accurate pumping applications
- PumpFlo™ for pumping applications

- TPETubing:

- AseptiFlex™ for fluid transfer

AseptiFlo™ PCS Tubing

mdi AseptiFlo™ Platinum Cured Silicone (PCS) tubing offers a reliable solution for fluid transfer and management in biopharmaceutical processes.

Applications

- Single use assemblies for fluid transfer
- Tube and bag manifolds for aseptic sampling

Specifications

Hardness	55 Shore A
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Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure
1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi
1/16" (1.6 mm)	1/8" (3.1 mm)	0.75 mm	22 psi	65 psi
1.6 mm	3.4 mm	0.90 mm	22 psi	65 psi
1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi
1/8" (3.1 mm)	1/4" (6.3 mm)	1.59 mm	28 psi	85 psi
1/8" (3.1 mm)	5/16" (7.9 mm)	2.38 mm	31 psi	94 psi
3/16" (4.8 mm)	5/16" (7.9 mm)	1.55 mm	19 psi	57 psi
3/16" (4.8 mm)	3/8" (9.5 mm)	2.35 mm	26 psi	78 psi
1/4" (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi
1/4" (6.3 mm)	7/16" (11.1 mm)	2.38 mm	18 psi	55 psi
1/4" (6.3 mm)	1/2" (12.7 mm)	3.20 mm	27 psi	80 psi
5/16" (7.9 mm)	7/16" (11.1 mm)	3.18 mm	17 psi	50 psi
5/16" (7.9 mm)	1/2" (12.7 mm)	2.40 mm	23 psi	70 psi
3/8" (9.5 mm)	9/16" (14.3 mm)	2.40 mm	18 psi	54 psi
3/8" (9.5 mm)	5/8" (15.8 mm)	3.18 mm	17 psi	50 psi
1/2" (12.7 mm)	3/4" (19.0 mm)	3.18 mm	17 psi	50 psi
5/8" (15.9 mm)	7/8" (22.2mm)	3.16 mm	17 psi	50 psi
1" (25.4 mm)	1.33" (34.0mm)	4.30 mm	13 psi	40 psi
3 mm	5.30 mm	1.15 mm	18 psi	55 psi



PresFlo™ High Pressure PCS Tubing

mdi PresFlo™ Platinum Cured Silicone (PCS) tubing offers a reliable solution for high pressure fluid transfer and management in biopharmaceutical processes.

Applications

Processes requiring high pressure fluid transfer such as Pre-use Post Sterilization Integrity Testing (PUPSIT) tubing/ single use assemblies which should withstand air/gas pressure up to 5 bar.

Specifications

Hardness	77 Shore A
-----------------	------------

Inner Diameter (ID)	Outer Diameter (OD)	Wall Thickness	Working Pressure	Burst Pressure
1/4" (6.3 mm)	3/8" (9.5 mm)	1.60 mm	33 psi	100 psi
3/8" (9.5 mm)	5/8" (15.9 mm)	3.20 mm	50 psi	150 psi
1/2" (12.7 mm)	3/4" (19.0 mm)	3.15 mm	33 psi	100 psi
3/4" (19.0 mm)	1" (25.4 mm)	3.20 mm	32 psi	95 psi
1" (25.4 mm)	1 1/8" (34.9 mm)	4.75 mm	32 psi	95 psi

Customized tubing for Extreme Pressure Applications

Inner Diameter (ID)	Outer Diameter (OD)	Wall Thickness	Working Pressure	Burst Pressure
1/4" (6.3 mm)	9/16" (14.4 mm)	4.05 mm	73 psi	220 psi
9.0 mm	20.0 mm	5.50 mm	77 psi	230 psi

These tubing are specially designed for extreme pressures applications such as PUPSIT assemblies. Contact us for your customized tubing requirement.

Single Use Systems

Tubing

AcuFlo™ Accurate Pump PCS Tubing

AcuFlo™ accurate pump PCS Tubing is specially designed for biopharmaceutical applications where accurate dispensing and consistent flow rates are required.

AcuFlo™ tubing has well finished and extremely smooth fluid contact surface that helps in consistent flow rates without any particle generation.

Application

Single use disposable filling lines for pumping and accurate fluid transfer from surge bags to filling needles

Physical Properties

Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure
0.8 mm	4.0 mm	1.60 mm	13 psi	40 psi
1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi
1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi
1/8" (3.1 mm)	1/4" (6.3 mm)	1.59 mm	28 psi	85 psi
1/4" (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi

Key Features

1. Accurate Dispensing

AcuFlo™ accurate pump PCS tubing comply with USP <1151> PHARMACEUTICAL DOSAGE FORMS.

Fill Volume	Recommended Excess Volume	Percentage	Volume Variability
5 mL	0.30 mL	6 %	0.20 %
10 mL	0.50 mL	5 %	1.76 %
20 mL	0.60 mL	3 %	0.40 %
30 mL	0.80 mL	2.6 %	0.21 %
50 mL	–	2 %	0.97 %
80 mL	–	2 %	0.70 %
100 mL	–	2 %	0.30 %
200 mL	–	2 %	0.72 %

2. No Drip Formation

AcuFlo™ accurate pump PCS Tubing do not show any drip formation at different fill volumes with a pause time of 30 seconds with water.

3. No Spallation : No Particle Generation

AcuFlo™ accurate pump PCS Tubing comply with USP <788> for Particulate Matter in Injections and USP <790> for Visible Particulate in Injections over 4 hours of pumping.

4. Consistent Flow Rates

AcuFlo™ accurate pump PCS Tubing offers consistent flow rates.

PumpFlo™ Pump PCS Tubing

PumpFlo™ Pump PCS Tubing are designed to withstand rigours of prolonged usage in peristaltic pump. These tubing are validated to ensure no spallation and consistent flow rates.

Application

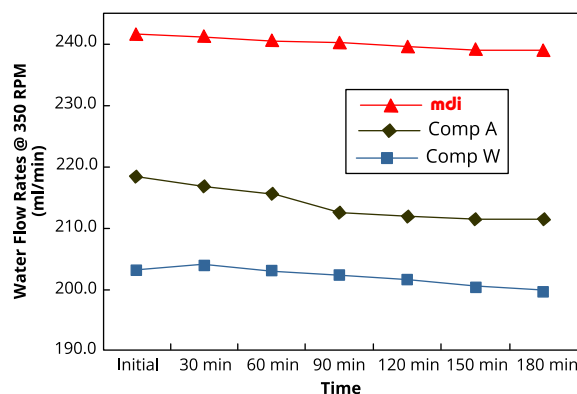
Use in peristaltic pumps for fluid transfer

Key Features

No Spallation : No Particle Generation

PumpFlo™ pump PCS Tubing comply with USP <788> for Particulate Matter in Injections and USP <790> for Visible Particulate in Injections over 4 hours of pumping.

Consistent Flow Rates



Physical Properties

Inner Diameter	Outer Diameter	Wall Thickness	Working Pressure	Burst Pressure
1.2 mm	4.4 mm	1.60 mm	13 psi	40 psi
1/16" (1.6 mm)	3/16" (4.8 mm)	1.59 mm	33 psi	100 psi
1/8" (3.1 mm)	1/4" (6.3 mm)	1.59 mm	28 psi	85 psi
1/4" (6.3 mm)	3/8" (9.5 mm)	1.58 mm	16 psi	48 psi
3/8" (9.5 mm)	5/8" (15.8 mm)	3.18 mm	17 psi	50 psi
1/2" (12.7 mm)	3/4" (19.0 mm)	3.18 mm	17 psi	50 psi
1" (25.4 mm)	1.33" (34.0 mm)	4.30 mm	42 psi	125 psi

Single Use Systems

Tubing and Connections

TPE Tubing

mdi AseptiFlex™ thermoplastic elastomer (TPE) tubing offers a reliable solution for process requiring fluid transfer and management.

AseptiFlex™ TPE tubing are manufactured in certified clean rooms and have been validated to meet standard regulatory and functional requirements for critical applications ranging from aseptic sampling to sterile filling of drug products.

Applications

- Tube welding for sterile fluid pathway connections
- Tube sealing for sterile fluid pathway disconnections
- Single use bag and tubing assemblies

Key Features

- Heat weldable
- Heat sealable
- Uniform, smooth inner bore for efficient fluid flow

Physical Properties

Hardness		60 Shore A		
Inner Diameter	Outer Diameter	Working Pressure	Burst Pressure	Wall Thickness
1/8" (3.2 mm)	1/4" (6.3 mm)	30 psi	90 psi	1.5 mm
1/4" (6.3 mm)	7/16" (11.1 mm)	27 psi	80 psi	2.4 mm
1/4" (6.3 mm)	3/8" (9.5 mm)	20 psi	60 psi	1.6 mm
1/4" (6.3 mm)	1/2" (12.7 mm)	40 psi	120 psi	3.2 mm
5/16" (7.9 mm)	1/2" (12.7 mm)	23 psi	70 psi	2.4 mm
3/8" (9.5 mm)	1/2" (12.7 mm)	17 psi	50 psi	1.6 mm
3/8" (9.5 mm)	5/8" (15.9 mm)	23 psi	70 psi	3.2 mm
1/2" (12.7 mm)	3/4" (19.0 mm)	20 psi	60 psi	3.2 mm
3/4" (19.0 mm)	1" (25.4 mm)	15 psi	45 psi	3.2 mm



Weld Strength

mdi AseptiFlex™ thermoplastic elastomer tubing offers high weld strength and welds well with other TPE tubing such as C-Flex® and AdvantaFlex® with commercially available equipment under industry standard welding cycles.

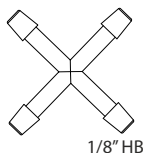
Tubing	Burst Strength		
	1/8" (3.2 mm) ID - 1/4" (6.3 mm) OD	1/4" (6.3 mm) ID - 7/16" (11.1 mm) OD	3/8" (9.5 mm) ID - 5/8" (15.9 mm) OD
mdi to mdi	101 psi	80 psi	75 psi
mdi to AdvantaFlex	75 psi	65 psi	75 psi
mdi to C-Flex	77 psi	65 psi	52 psi
AdvantaFlex to AdvantaFlex	103 psi	55 psi	77 psi
C-Flex to C-Flex	75 psi	60 psi	52 psi
AdvantaFlex to C-Flex	78 psi	65 psi	52 psi

Single Use Systems

Fittings

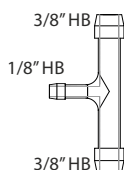
A wide range of **mdi AseptiFit™** gamma stable fittings such as cross connections, T connections, Y connections and reducers are available to support various plumbing requirements within these customized single use systems.

Cross Connection



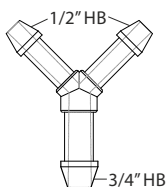
Size
1/8" HB (5mm nipple)
4 x 1/4" HB
4 x 3/8" HB
4 x 1/2" HB

T Connection



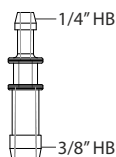
Sizes
3 X 1/8" HB
3 X 3/8" HB
2 x 3/8" and 1 x 1/8" HB
2 X 3/8" HB and 1 x 1/4" HB
2 X 1/2" HB and 1 x 1/4" HB
2 X 1/2" HB and 1 x 1/8" HB
2 X 1/2" HB and 1 x 3/8" HB
3 X 1/2" HB

Y Connection

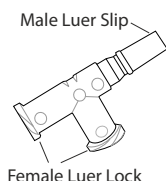


Sizes
1/8" HB (5mm nipple Y)
1/4" HB
3/32" HB
2 x 3/32" and 1 x 1/8" HB
2 x 1/2" x 1 x 3/4" HB

Reducers

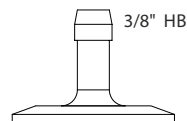


Sizes
1/4" to 1/8" HB
3/8" to 1/4" HB
1/2" to 1/4" HB
1/2" to 3/8" HB
3/4" to 1/2" HB
1" to 1/2" HB
1/4" to 3/32" HB
1/8" to 3/32" HB
3/16" to 1/8" HB

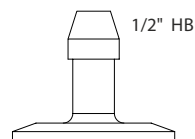


*Tee with female luer lock on two sides and male luer slip on one side

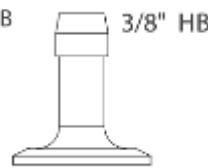
1/2" Sanitary Flange with Hose Barb Connection



Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb
1" Hose Barb



3/4" Sanitary Flange with Hose Barb Connection



Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb

Single Use Systems

Other Components

Clamps

Pinch Clamps

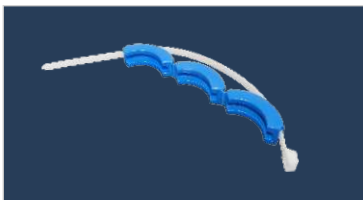


Sizes
Tube clamp small for 1/8" ID tubes
Tube clamp medium for 1/4" ID tubes
Tube clamp medium for 1/2" ID tubes

Sanitary Flange Clamp



Sizes
Clamp for 25 mm Sanitary Flange
Clamp for 50 mm Sanitary Flange
Clamp for 3" Sanitary Flange
Clamp for 4" Sanitary Flange
Clamp for 5" Sanitary Flange



Sizes
*Sanisure Clamp for 1.5" Triclover
*Sanisure Clamp for 3/4" Triclover

Valves



*Reflux Check Valve female to male luer

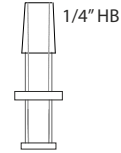


*Check Valve female to male luer with silicone disc

* Outsourced Components

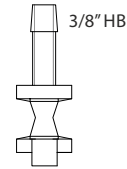
Plugs

Press in Plugs



Sizes
1/8" Hose Barb
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb

Baxa Spike



Sizes
3/8" Hose Barb

Single Use Systems

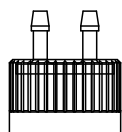
Other Components

Bottle Covers

mdi provides different types of cap adapters for gamma sterilized bottle and carboy assemblies for various applications. **mdi** provides different size and type of cap adapters with different types of bottles and carboys.

PETG Bottles Cap Adapters

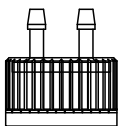
- 60ml PETG Bottle with 22mm Closure



Port	Size
A	1/8" HB

***Component Part No. APXA15LLXXX**

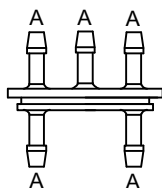
- 60ml PETG Bottle (tamper proof) 22mm closure



Port	Size
A	1/8" HB

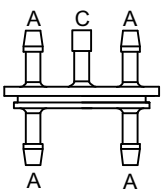
***Component Part No. APSA15LLXXX**

- 125ml, 250 ml, 500 ml, 1L PETG Bottle with 38mm Closure



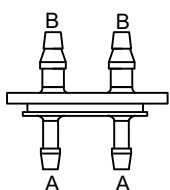
Port	Size
A	1/8" HB

***Component Part No. APGA02ALAXXX**



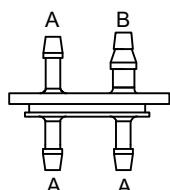
Port	Size
A	1/8" HB
C	1/8" HB Closed Port

***Component Part No. APGA02APAXXX**



Port	Size
B	1/4" HB
A	1/8" HB

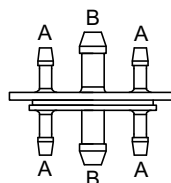
***Component Part No. APGA02CCXXXX**



Port	Size
A	1/8" HB
B	1/4" HB

***Component Part No. APGA02ACXXXX**

- 2L PETG Bottle with 53mm Closure

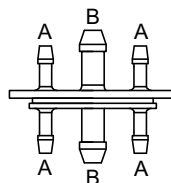


Port	Size
A	1/8" HB
B	1/4" HB

***Component Part No. APGA05ADAXXX**

LDPE Bottles Cap Adapters

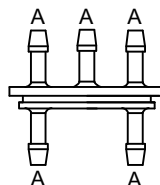
- 500ml LDPE Bottle with 53mm Closure



Port	Size
A	1/8" HB
B	1/4" HB

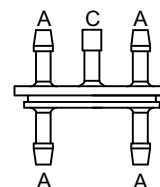
***Component Part No. APGA05ADAXXX**

- 1L and 2L LDPE Bottle with 38mm Closure



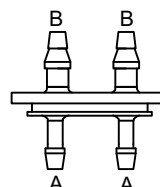
Port	Size
A	1/8" HB

***Component Part No. APGA02ALAXXX**



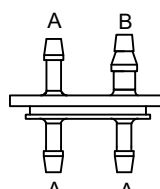
Port	Size
A	1/8" HB
C	Closed Port

***Component Part No. APGA02APAXXX**



Port	Size
B	1/4" HB
A	1/8" HB

***Component Part No. APGA02CCXXXX**



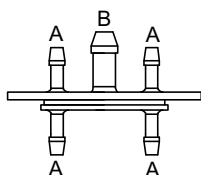
Port	Size
A	1/8" HB
B	1/4" HB

***Component Part No. APGA02ACXXXX**

Single Use Systems

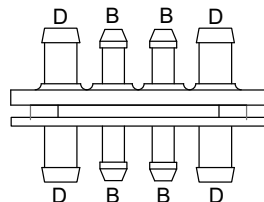
Other Components

- 1L LDPE Bottle (Wide Mouth) with 63mm Closure



Port	Size
A	1/8" HB
B	1/4" HB Open Port

Component Part No. APGA06ABAXXX

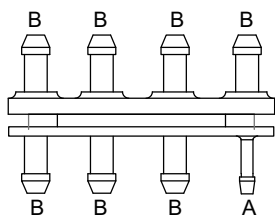


Port	Size
D	3/8" HB
B	1/4" HB

***Component Part No. APGA08GDDGXX**

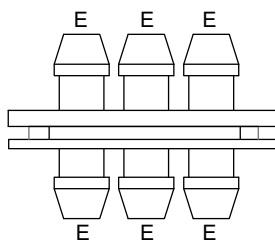
Carboys

- 10L and 20L LDPE Carboy, 50L Amber Carboy with 83mm Closure



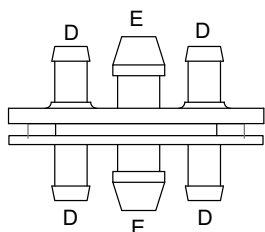
Port	Size
B	1/4" HB
A	1/8" HB

***Component Part No. APGA08DDDCXX**



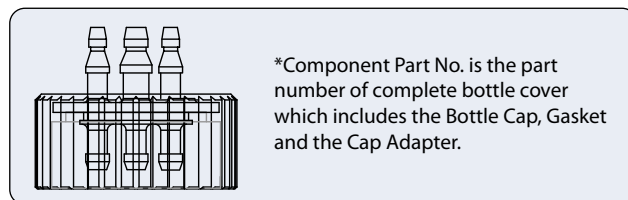
Port	Size
E	1/2" HB

***Component Part No. APGA08OOOXXX**



Port	Size
D	3/8" HB
E	1/2" HB

***Component Part No. APGA08GOGXXX**



*Component Part No. is the part number of complete bottle cover which includes the Bottle Cap, Gasket and the Cap Adapter.

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