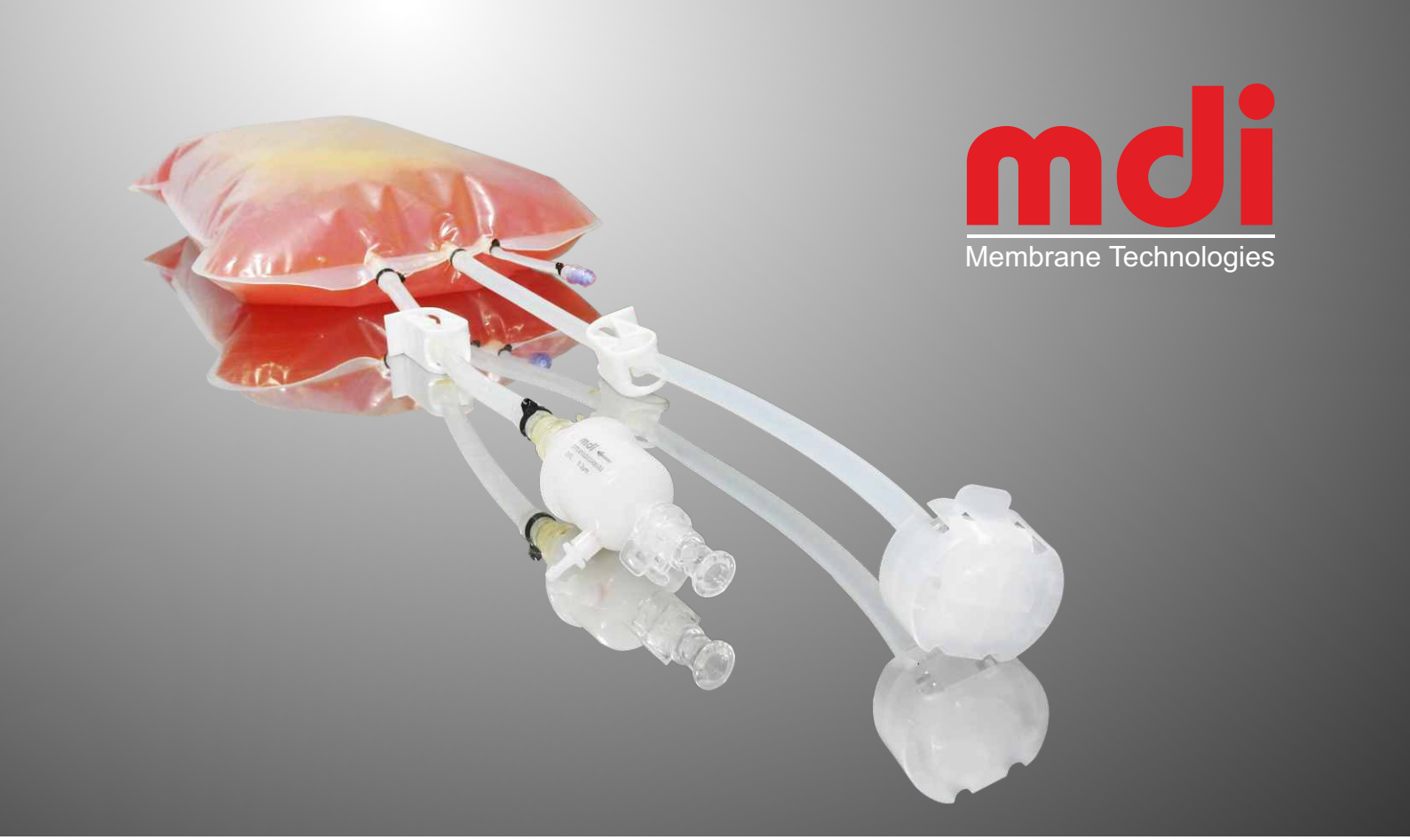

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Single Use Systems

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.

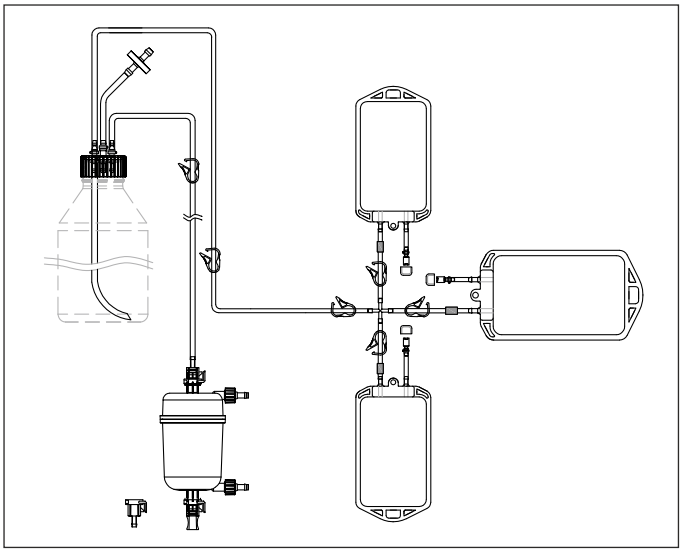
SUS have not only facilitated continuous processing but also enabled research scientists as well as process owners to work with different molecules such as antibodies, proteins, vaccines etc in the same facility. All this has resulted in faster lab to market movement of the new bio pharmaceutical drugs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

User Specified SUS Design Specifications

User process flow requirements such as working environment, volume range, temperature conditions, fluid pressure, size and number of connections, transfer lengths, sampling needs etc. are established

↓

Technical feasibility

Based on the above information and available components a technical feasibility of the Single Use System is done and an initial drawing of same is submitted for user approval

↓

Design approval

- User approval of SUS drawing
- Changes to finalize drawing, if required

↓

Finalized Single Use System

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.

200,000 Sq. ft. GMP Facilities

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

Physical Testing Laboratory

Analytical Laboratory

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, 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>

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

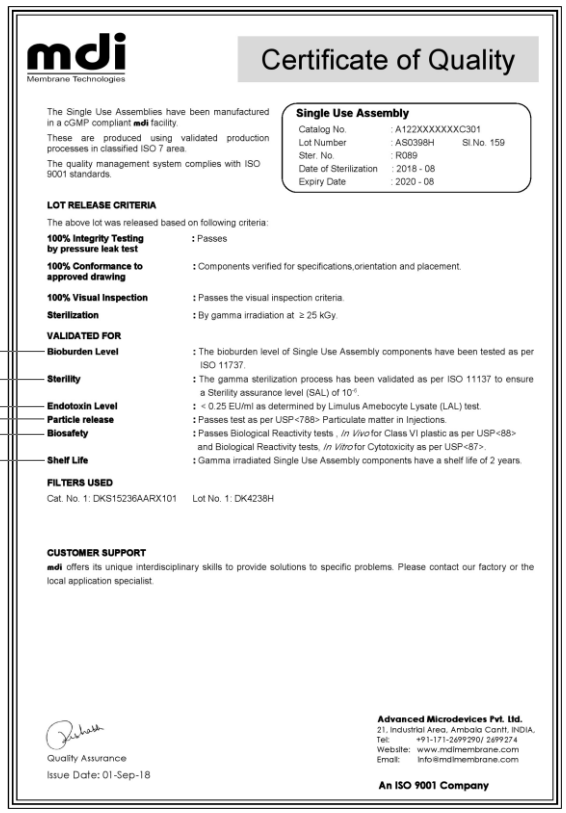
Certificate of Quality

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



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Certificate of Quality

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. : A122XXXXXXXC301
Lot Number : AS0398H Sl.No. 159
Ster. No. : R089
Date of Sterilization : 2018 - 08
Expiry Date : 2020 - 08

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.

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 , *In Vivo* for Class VI plastic as per USP<88> and Biological Reactivity tests, *In Vitro* 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: DKS15236AARX101 Lot No. 1: DK4238H

CUSTOMER SUPPORT
mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

Quality Assurance
Issue Date: 01-Sep-18

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21, Industrial Area, Ambala Cantt, 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

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.

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.

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.

Tubing Connections

A wide range of 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.

Other Components

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

Single Use Systems

Storage and Transfer Bags

AseptiBag Gold: 2D Storage and Transfer Bags

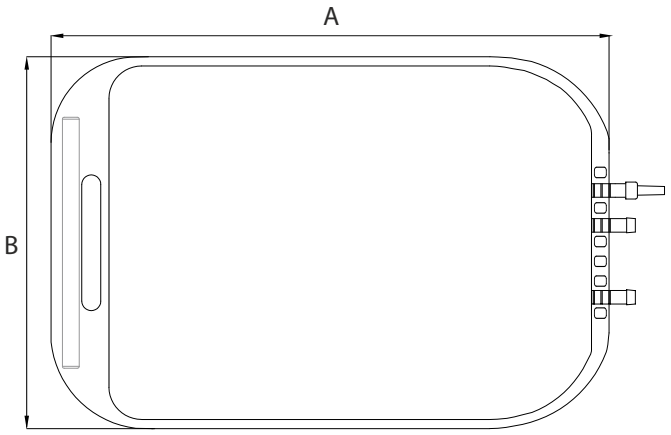
MDI *AseptiBag* Gold systems provide validated and reliable single use disposable solutions for biopharmaceutical process requirements such as storage and transfer of sterile media, process intermediates, sterile buffers with wide ranging pH, sterile drug substances and formulations. These are well characterized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

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	375 mm	319 mm
10 Litre	590 mm	322 mm
20 Litre	490 mm	580 mm
50 Litre	775 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

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

Needleless

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

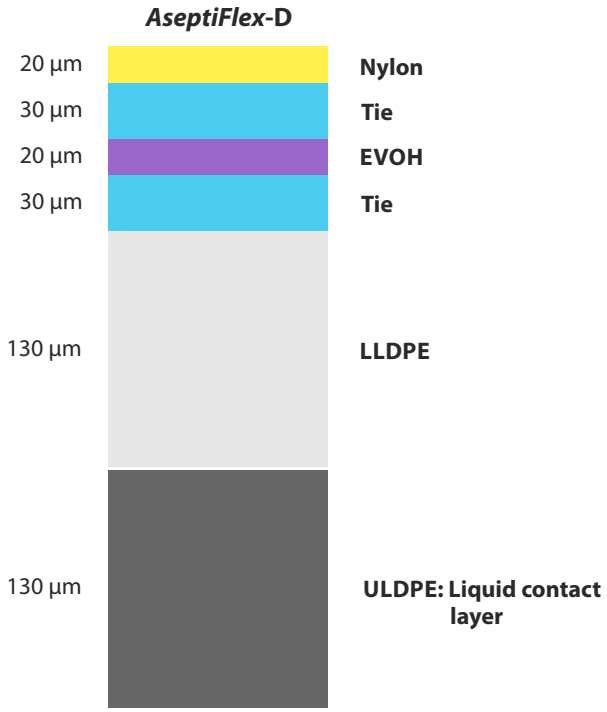
Multilayered Film for Storage and Transfer Bags

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, CO_2 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/m²/day
Carbon dioxide Transmission Rate		ASTMF2476	<1.0 cc/m²/day
Water Vapour Transmission Rate		ASTMF1249-13	0.879 g/m²/day
Tear strength	TD	ASTMD1938	25.556 N
	MD		17.873 N
Puncture Resistance		EN14477	10.9578 N
Tensile Stregth (MD)		ASTMD-882	27.0298 N/mm²
Flex Durability Test (Gelbo)		ASTM F-392	Passes

Other Properties

Test		Reference Standard	Result
Biosafety	Intracutaneous Toxicity	Biological Reactivity Tests, *In Vivo*, as per USP <88>	Passes
	Acute Systemic Toxicity		Passes
	Muscle Implantation		Passes
	Cytoxicity	Biological Reactivity Tests, *In Vitro*, 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

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 cm^2 capsule filters with very low hold up volumes to 18000 cm^2 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.

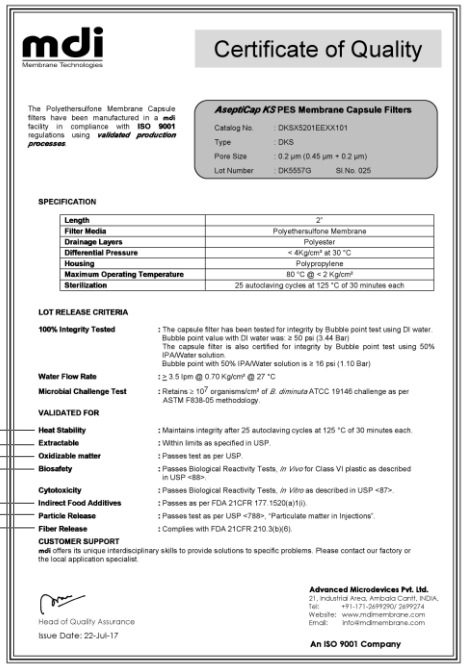
Certificate of Quality

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



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Certificate of Quality

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. : DKSX5201EEXX101
Type : DKS
Pore Size : 0.2 µm (0.45 µm + 0.2 µm)
Lot Number : DK5557G Sl.No. 025

SPECIFICATION

Length	2"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm²
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 @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 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.
Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
Cytotoxicity : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.
Indirect Food Additives : Passes as per FDA 21CFR 177.1520(a)1(i).
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

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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(i)

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

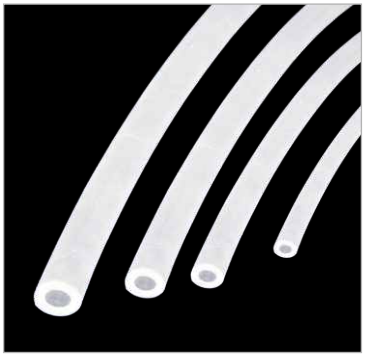
Tubing and Connections

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.

Thermoplastic Elastomer (TPE)

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.



Sizes
ID x OD -1/8″ x 1/4″
ID x OD -1/4″ x 7/16″
ID x OD - 3/8″ x 5/8″
ID x OD -1/2″ x 3/4″
ID x OD - 2.8 mm x 5.3 mm

Platinum Cured Silicone

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

Sizes
ID x OD -1/8″ x 1/4″
ID x OD - 3/16″ x 5/16″
ID x OD - 1/4″ x 7/16″
ID x OD -1/4″ x 3/8″
ID x OD - 5/16″ x 1/2″
ID x OD - 3/8″ x 5/8″
ID x OD -1/2″ x 3/4″
ID x OD -3/4″ x 1″

Tubing Connections

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.

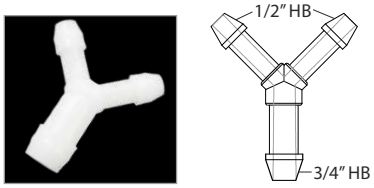
Cross Connection

Size
1/8" HB (5mm nipple)

T Connection

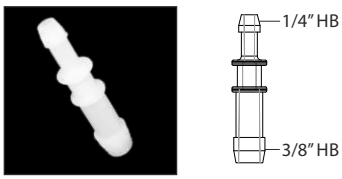
Sizes
3 X 1/8" HB
3 X 3/8" HB
2 x 3/8″ and 1 x 1/8" HB

Y Connection

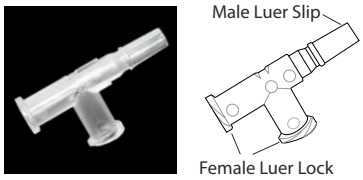


Sizes
1/8" HB (5mm nipple Y)
1/4" HB
3/32" HB
2 x 3/32" and 1 x 1/8" HB
2 x 1/2" x 1 x 3/4" HB

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
3/8" HB to Female Luer lock
1/8" HB to Female Luer lock
Male luer slip nipple with 1/8" HB



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

Single Use Systems

Connectors

AseptiLink SV: Steamable Valve Connector

AseptiLink SV: Steamable Valve Connector

MDI offers reliable and easy to use *AseptiLink SV* steamable valved 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" sanitary flange connection and 3/8" hose barb at other end to connect with the tubing.

Available End Connections
3/8" Hose Barb

Quick Connectors

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

Male Quick Connect with 3/8" Hose Barb

Female Quick Connect with 3/8" Hose Barb

1/4" Coupling Insert (Male Connector)

1/4" Coupling Body (Female Connector)

Male Plug

Female Plug

1/2" Hose Barb Male Connector

1/2" Hose Barb Female Connector

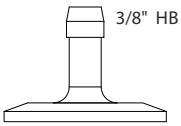
Male Plug for 1/2" Hose Barb Female Connector

Female Plug for 1/2" Hose Barb Female Connector

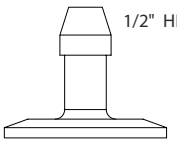
Single Use Systems

Other Components

1.5"Triclover with HB Connection

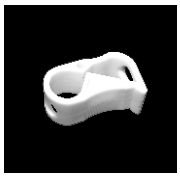


Sizes
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb
3/4" Hose Barb



Clamps

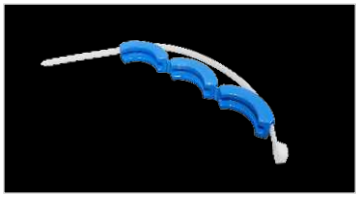
Tubing Clamps



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

*Tube clamp for TPE tubes (Bioflex)

Sanitary Flange Clamp



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

Sizes
*Bioflex Clamp for 3/4"Triclover (Mini)

* Outsourced Components

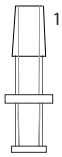
Valves

*Reflux Check Valve female to male luer

*Check Valve female to male luer with silicone disc

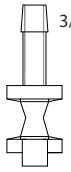
Plugs

Press in Plugs



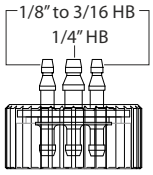
Sizes
1/8" Hose Barb
1/4" Hose Barb
3/8" Hose Barb
1/2" Hose Barb

Baxa Spike



with 3/8" Hose Barb

Bottle Covers



Sizes
2 x 1/8" to 3/16 HB and 1 x 1/4" HB for 45mm Bottle Cover
2 x 1/8" to 3/16" HB for 33mm Bottle Cover
1 x 1/8" to 3/16" HB and 1 x 1/4" HB for 38mm Bottle Cover

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