

## **Company Profile**



Advanced Microdevices (**mdi**) is a leader in innovative membrane technologies. Starting from a single person R&D operation in 1976, **mdi** has developed into a dedicated team of 1000 plus with more than 15000 products.

The company's core competence is its ability to develop new membrane technologies and innovate existing ones to deliver advantages to the customer for high end purification and separation applications in a wide range of industries such as pharmaceuticals, biopharmaceuticals, biotechnology, food and beverage, hospitals, and immunodiagnostics.

As membranes end up being incorporated into user friendly devices, plastic design and moulding and sealing technologies become an integral part of the chain to deliver value to the customer. Realizing this, **mdi** has grown into a vertically integrated company that helps deliver prototypes rapidly for quicker conversion to products for the market.

**mdi** products are used for critical applications in pharmaceutical and biopharmaceutical industries, such as sterilization of injectable drugs, sterility testing, sample preparation of drugs that are tested with highly sophisticated instrumentation, and development of new drug entities and formulations. **mdi** also offers world class membranes for making reliable immunoassays for testing of diseases at patient bedside.

**mdi** products meet or exceed industry standards and many of these are recognized as the best available in the world.

These products are manufactured by highly trained manpower in modern GMP facilities with large ISO class 7 production areas under ISO 9001 certified quality management system and are backed by state of the art QC testing, microbiology, reliability and validation laboratories.

A strong pipeline of new products is constantly being developed in its well equipped R&D labs.





World Class GMP Compliant
Multilocation Facilities (200,000 sq. ft.)

## Contents

		Pages
mdi Filters for Sample F	Preparation	2
	Disposable Membrane Syringe Filters	3
	Nylon 66 Membrane Disc Filters	5
	AseptiVac NS: Vacuum Filter Units for Glass Bottles	6
A	Nylon 66 Membrane Capsule Filters	7
	Capsule Filtration System	8
mdi Filters for Biologica	l Applications	9
	Polyethersulfone Membrane Syringe Filters	10
	50mm PES Filter Device with In-built Vent	11
	Vacufil: Vacuum Filtration Units	12
	AseptiVac KS: The Ultimate Vacuum Filter	13
	Polyethersulfone Membrane Capsule Filters	14
mdi Filters for Air / Gase	es	15
	Hydrophobic PTFE Membrane In-line Air/gas Filters	16
	Hydrophobic PTFE Membrane Capsule Filters	17
mdi Filters for Sterility T	Testing and Microbiology	18
	mdi Stericheck: Closed Sterility Test System	19
	- Steripump	
	- Stericheck: Sterility Test Devices	
	Edge Hydrophobic Membrane Disc Filters	22
S 2	E-Funnel	23
	M-Funnel	24
	Grid Marked Membrane Disc Filters	25
	Cellulose Nitrate Membrane Disc Filters	26
	Cendiose initiate menibidhe Disc Fillers	20
Chemical Compatibility		27
Ordering Information		28



#### **Filter Selection**

## Filters for Sample Preparation

Sample filtration is a very important part of any analytical procedure as it is required to safeguard highly sensitive analytical equipment from instrument downtime and also to ensure reliable results.

#### Accuracy and reliability

- 1. Eliminates background peaks
- 2. Assures correct and reproducible volumes are injected into the system
- $3. \quad Eliminates \ dissolved \ gases in the mobile \ phase \ which \ cause "noise" in the \ detector$

#### **Instrument downtime**

- 1. Prevents plugging of critical valves and small ID tubing
- 2. Extends the life of the analytical column

Product	Key Features	Туре	Dia / Size	Applications
Nylon 66 Membrane Disc Filters	- Wide chemical compatibility - Low extractables	HNN	13mm 25mm 47mm	Filtration of samples for HPLC (<10ml) Filtration of samples for HPLC (<100ml) Solvent filtration: HPLC mobile phase
Nylon 66 Membrane Syringe Filters	<ul><li>- Wide chemical compatibility</li><li>- Low extractables</li><li>- Low hold-up volume</li></ul>	SY4NN SY13NN SY25NN	4mm 13mm 25mm	For aqueous as well as organic samples
Nylon 66 Membrane Syringe Filters with pre-filter	- Highly retentive of colloidal particles	SY13GN SY25GN	13mm 25mm	For difficult to filter turbid samples
PTFE Membrane Syringe Filters	- Very wide chemical compatibility	SY4TF SY13TF SY25TF	4mm 13mm 25mm	For highly aggressive solvents
PTFE Membrane Syringe Filters with pre-filter	<ul><li>- Very wide chemical compatibility</li><li>- High throughputs</li></ul>	SY13TG SY25TG	13mm 25mm	For difficult to filter turbid samples
Hydrophilic PTFE Membrane Syringe Filters	- Very wide chemical compatibility	SY4TH SY13TH SY25TH	4mm 13mm 25mm	For aqueous as well as organic samples
Hydrophilic PVDF Membrane Syringe Filters	- Wide chemical compatibility	SY4VF SY13VF SY25VF	4mm 13mm 25mm	For sample filtration
Hydrophilic PVDF Membrane Syringe Filters with pre-filter	- Wide chemical compatibility - High throughputs	SY13VG SY25VG	13mm 25mm	For difficult to filter turbid samples
Hydrophilic Polypropylene Membrane Syringe Filters	- Wide chemical compatibility	SY4PP SY13PP SY25PP	4mm 13mm 25mm	For aqueous as well as organic samples
Hydrophilic Polypropylene Membrane Syringe Filters with pre-filter	- Wide chemical compatibility - High throughputs	SY13GP SY25GP	13mm 25mm	For difficult to filter samples
Regenerated Cellulose Membrane Syringe Filters	- Wide chemical compatibility	SY4RC SY13RC SY25RC	4mm 13mm 25mm	For sample filtration
Microglassfiber Syringe Filters	- Wide chemical compatibility	SY13GF SY25GF	13mm 25mm	For pre-filtration of difficult to filter samples
Automated Membrane Syringe Filters	- Specially designed for workstations for automated sample preparation	SZ25** ST25**	25mm	Automated sample filtration (<100ml)
Large Area Vacuum Filter Units for Glass Bottles	- Wide chemical compatibility - Low extractables	AseptiVac NS	100 cm <sup>2</sup> Filtration Area	Mobile phase filtration for aqueous as well as organic solvents
Nylon 66 membrane Capsule Filters	- Wide chemical compatibility - Low extractables	AseptiCap NL	1"	Particulate removal from solvents to be used in highly sensitive analytical instruments (500ml to 5 liter)
Capsule filtration system for solvents	- Wide chemical compatibility as no elastomers are used	CFS - S	5 liter capacity	Particulate removal from chemicals, solvents and drug solutions, as it does away with flexible tubing and peristaltic pumps in analytical and process development labs

<sup>\*\*</sup> Available with different membrane types

## Disposable Membrane Syringe Filters

#### **Unique Performance Advantages**

- ♦ Very low extractables: No spurious peaks
- Minimal adsorption: Low variation in area under the peak
- Very low hand pressure: Maximum throughput
- ♦ Wide Range for all types of samples

#### **Types Available**

**mdi** offers a wide range of syringe filters with different sizes, pore sizes and membrane filter media to suit the variety of analytical sample preparation needs:

- ♦ Nylon 66
- ◆ PTFE
- ♦ Hydrophilic PTFE
- Hydrophilic PVDF
- ♦ Hydrophilic Polypropylene
- ◆ Regenerated Cellulose
- Microglassfiber

#### **Syringe Filters for difficult to filter Turbid Samples**

Specially designed membrane syringe filters with multi layered pre-filtration for graded retention of colloidal particles associated with highly turbid solutions

- Very high retention efficiency for colloidal fines
- Minimal hand pressure
- High throughput even with highly turbid, difficult to filter solutions

#### **Syringe Filters for Automated Workstations**

**SZ25**\*\* and ST25\*\* are designed for use in workstations for automated sample preparation to ensure:

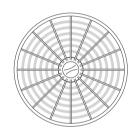
- Easy filter to filter release
- Consistently smooth movement
- Tight dimensional tolerances

SZ25\*\* for Zymark workstations and ST25\*\* for Sotax workstations are available with different membranes viz. Nylon, PVDF, PTFE and Polypropylene in different pore sizes. These are not available with pre-filters.

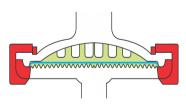
Zymark and Sotax are registered trade marks of the Sotax AG, Switzerland



#### 16 Channels for Maximum Flow Rate



### Designed for Maximum Throughput



#### **Specifications**

Diameter	4mm	13mm	25mm
EFA*	0.07cm <sup>2</sup>	0.8cm <sup>2</sup>	4.15cm <sup>2</sup>
Hold-Up Volume	<5µl	<20µl	<50µl

\* EFA: Effective Filtration Area

#### 0.45µm SYNN

Nylon 66 membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.45µm SYGN

Nylon 66 membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.45µm SYVF

PVDF membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.45µm SYVG

PVDF membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.45μm SYTF

PTFE membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.45µm SYTG

PTFE membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.45um SYPP

Polypropylene membrane syringe filter Ávailable in 4mm, 13mm, 25mm



#### 0.45µm SYGP

Hydrophilic Polypropylene membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.45μm SYTH

Hydrophilic PTFE membrane syringe filter Available in 4mm,13mm, 25mm



#### 0.45µm SYRC

Regenerated Cellulose syringe filter Available in 4mm,13mm, 25mm



#### 0.45μm SYGF

Microglassfiber syringe filter Available in 13mm, 25mm



#### 0.2μm SYNN

Nylon 66 membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.2μm SYGN

Nylon 66 membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.2μm SYVF

PVDF membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.2μm SYVG

PVDF membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.2μm SYTF

PTFE membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.2μm SYTG

PTFE membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.2um SYPP

Polypropylene membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.2μm SYGP

Hydrophilic Polypropylene membrane syringe filter with pre-filter Available in 13mm, 25mm



#### 0.2µm SYTH

Hydrophilic PTFE membrane syringe filter Available in 4mm, 13mm, 25mm



#### 0.2μm SYRC

Regenerated Cellulose syringe filter Available in 4mm, 13mm, 25mm



#### 1μm SYGF

Microglassfiber syringe filter Available in 13mm, 25mm

XX



Ту	pe
Type	Code
SYNN	SYNN
SYGN	SYGN
SYTF	SYTF
SYTG	SYTG
SYVF	SYVF
SYVG	SYVG
SYPP	SYPP
SYGP	SYGP
SYTH	SYTH
SYRC	SYRC
SYGF	SYGF

Si	ze	
Dia	Code	Р
4mm	01	
13mm	03	
25mm	06	

	126	10163
	Code	Pore Size
	01	0.2μm
L	02	0.45µm

	Inlet/Ou	ıtlet
•		Code
	Female Luer Lock	М
	Male Luer Slip	N

lillet/Ot	aciec
	Code
Female Luer Lock	М
Male Luer Slip	N

	Code
Non Sterile	1

Pack S	Size
Pack Size	Code
100	04

Example:	
----------	--

SYNN         06         01         MN         XX         1         04
---

SZ25\*\* and ST25\*\* syringe filters with the desired membrane type can be ordered by replacing \*\* with the membrane code. These are not available with pre-filters. **Example: For Nylon Membrane Syringe Filters for Zymark Workstations** 

SZNN	06	01	MN	хх	1	04
	••			2 2 2 2	_	• •

## Nylon 66 Membrane Disc Filters – Type HNN

HNN membrane disc filters are, hydrophilic, non-media migrating, biologically inert, plain white absolute filters useful for aqueous as well as organic solvent filtration.



#### **Special Features**

- Very low extractables
- ♦ Wide chemical compatibility
- ♦ HPLC certified: Assures that the filter will not add artifacts to the sample

#### **Specifications**

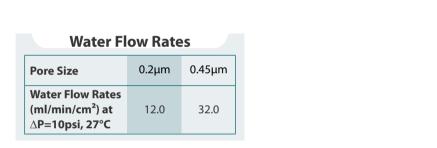
**Maximum Operating Temperature:** 80°C continuous

**Maximum Operating Pressure:** 5 Kg/cm<sup>2</sup>

**Extractables with Water:** Within limits specified in USP

Oxidizable Matter: Passes as per USP







Туре				
Type Code				
HNN HNNX				

Size			
Dia	Code		
13mm	03		
25mm	06		
47mm	09		

Pore Size				
Pore Size	Code			
0.2μm	01			
0.45µm	02			

хх	
----	--

Sterility		
Code		
Non Sterile	1	

Pack Size				
Pack Size Code				
100	04			

	_	
Evam	ml	^.
Exam	μ	e.

HNNX	09	01	XX	ХХ	1	04





## AseptiVac NS: Vacuum Filter Unit for **Glass Bottles**

AseptiVac NS are ready to use disposable vacuum filtration devices with a unique pleated cartridge filter built into a cap which fits into the neck of the receiver glass bottles with 45mm neck diameter.

The large area filter device with Nylon 66 membrane, allows high speed filtration and enhanced throughput with organic solvents and chemicals.

The conical shaped filter cartridge allows air bubbles to move away from the membrane, avoiding problems of membrane blockage.

#### **Features**

- Saves time with high speed filtration: 1000 ml in < 30 Sec (@500 mm Hg Vacuum)
- Unique built in large area pleated Nylon cartridge filter

#### **Specifications**

#### **Materials of Construction**

Filter Membrane :Nylon 66 Filter Housing :Polypropylene Funnel :Polypropylene

Filtration Area: 100 cm<sup>2</sup> Funnel Capacity: 450 ml Hold up Volume: <5ml Screw Cap Neck: 45 mm

Maximum Operating Temperature: 45°C

Microbial Retention: 0.2 µm: LRV>7 for B. diminuta

Extractables: AseptiVac NS vacuum filters exhibit very low extractables

XX

G

Туре		EFA*		Pore Size	
	Code		Code		Code
AseptiVac NS	ANSX	100 cm <sup>2</sup>	31	0.2μm	01
				0.45µm	02

Variant	
	Code
With Polypropylene Funnel	Р
With Hose Barb Adaptor	D
With Polypropylene Funnel and Hose Barb Adaptor	Υ

Variant		
	Code	
With Polypropylene Funnel	Р	
With Hose Barb Adaptor	D	
With Polypropylene Funnel and Hose Barb Adaptor	Y	

Sterili	ty		Pack S	Size
	Code	ĺ		Code
Non Sterile	1		12	08
EO Sterile	2			

\*EFA: Effective Filtration Area

**Example: ANSX** 31 01 Ρ XX G 1 08

## AseptiCap NL - Nylon 66 Membrane Capsule Filters

**mdi** 1" AseptiCap NL capsule filters employ Nylon-66 membranes for wide chemical compatibility. These large area filtration devices are ideal for large volume (5 - 20 liter) filtrations such as mobile phase filtration for preparative HPLC and for large laboratories with many HPLC systems.

#### **Features**

- ♦ Wide chemical compatibility
- ♦ Compact design
- ♦ Large filtration area
- Long service life
- ♦ 100% Integrity tested
- No elastomers or adhesives used in sealing
- Preflushed to minimize particulate release
- Non-toxic materials of construction
- Variety of end connections to suit different needs



Pore Size: 0.2 µm, 0.45 µm

**Length:** 40mm without end connections

Diameter: 42mm

Effective Filtration Area: 0.025m<sup>2</sup> (250cm<sup>2</sup>)

Hold-Up Volume: <5ml

Retention Efficiency: 0.2µm: LRV>7 for B. diminuta

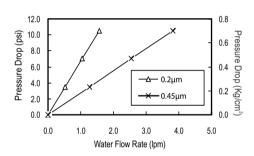
0.45µm: LRV>7 for S. marcescens

Maximum Differential Pressure: 4Kg/cm² @ 30°C
Maximum Operating Temperature: 80°C @ ≤2Kg/cm²

**Extractables with Water:** Passes as per USP **Oxidizable Matter:** Passes as per USP



#### **Water Flow Rates**



**Figure 1:** Water flow rates of 1" AseptiCap NL capsule filters.

Type Size		Туре		Pore S	ize	Inlet/Outle	t	Х	Bell		Sterili	ty	Pack S	Size	
Туре	Code	Size	EFA*	Code	Pore Size	Code	Connection	Code			Code		Code	Pack Size	Code
Asepticap NL	DNLX	1"	0.025m <sup>2</sup>	51	0.2µm	01	1/4" SHB	Α		Yes	В	Non Sterile	1	1	01
					0.45µm	02	1/4" MNPT	В		No	Х				
							½"Hose Barb	D							

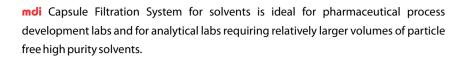
1½" Sanitary Flange
Quick Connector

\*EFA: Effective Filtration Area

DN	LX	51	01	ВА	Х	Х	1	01
----	----	----	----	----	---	---	---	----

## Capsule Filtration System for Solvents





#### **Features**

- ♦ Compact design
- ♦ Wide chemical compatibility
- Available in upto 20 liter capacity to filter volumes ranging from 500ml to 20 liters
- All components are of 316L stainless steel
- No polymeric tubing is used on the outlet
- Filters offered are Nylon 66 membrane capsule filters



- Very high flow rates (1-5 lpm) resulting in much reduced filtration time even with
   0.2µm capsule filters
- Very low hold-up volume helps minimize loss of expensive drug solutions
- Occupies very less laboratory space due to its compact design

#### **Components**

SS316L Pressure Vessel with vent
 valve and a special extended outlet
 connection to fit capsules with 1/4"
 MNPT Inlet

Available Sizes: 3, 5, 10 and 20 Liter

◆ mdi Nylon 66 membrane capsule filter - 05

Type : *AseptiCap NL*Pore Size : 0.2μm or 0.45μm

Size : 1"

End Connections : ¼"MNPT Inlet

1/4" Stepped hose barb outlet



Туре		
	Code	
Capsule Filtration System	CFSX	

Capacity						
	Code					
3 Liter	03					
5 Liter	05					
10 Liter	10					
20 Liter	20					

O-Rings/ Seals					
	Code				
Silicone	S				

Code
D
Н

Outle	Outlet					
	Code					
1/4" FNPT	0					

Press Pun	
	C
Yes	Г
No	Г

ressure Pump		Capsule Filte Type				
	Code		Cd			
es	Р	AseptiCap NL 0.2µm	DI			
lo	Х	υ.Ζμπ				

psule Fi Type	Iters	Pack	Size
	Code	Qty	Code
<i>ptiCap NL</i> µm	DN01	1	1
ptiCap NL			

CFSX	05	S	Н	0	Р	DN01	1
------	----	---	---	---	---	------	---

## Filters for Biological Applications

**mdi** Filters for Biologicals are specially designed filtration devices for filtration of culture media, culture soups, serum solutions, nutrients, growth regulators etc.

These filters are validated for absolute bacterial retention, hold-up volume, and protein recovery.

#### mdi Filters offer:

- Low protein binding
- ◆ Maximum product recovery
- ♦ High throughputs
- ◆ Absolute microbial retention



#### **Filter Selection**

Product	Key Features	Туре	Dia/ EFA*	Applications
		SY4PL-S	4mm	Sterilization of high value additives such as growth hormones, vitamins, and antibiotics (<1ml)
Presterilized Polyethersulfone Membrane Syringe Filters	- Low protein binding	SY13PL-S	13mm	Sterilization/clarification of protein solutions and culture media (<10ml)
riters		SY25PL-S	25mm	Sterilization/clarification of protein solutions, Culture media, and serum (<20ml)
Presterilized		SY13KG-S	13mm	Sterilization/clarification of difficult
Polyethersulfone Membrane Syringe	<ul><li>Low protein binding</li><li>High throughputs</li></ul>	SY25KG-S	25mm	to filter solutions such as pure serum and serum based culture media
Filters with Pre-filter		IKG-S	50mm	and serum based culture media
Presterilized Polyethersulfone Membrane Inline Filter with Built-in Vent	- Low protein binding - Zero hold up volume	IKT-S	50mm	Sterilization of high value fluids
Presterilized Polyethersulfone Membrane Bottle Top Vacuum Filter	- Low protein binding - High throughputs	Vacufil-S	75mm	Sterilization/clarification of protein solutions, culture media, and serum (≤1 liter)
Presterilized Large Area Vacuum Filters	- Low protein binding - Very high flow rates - Very high throughputs	AseptiVac KS	170 cm²	Sterilization of buffers, culture media, serum solutions and pure sera
Polyethersulfone Membrane Capsule Filters	- Low protein binding - High throughputs	AseptiCap KL/KS	1" (250 cm²)	Sterilization/clarification of protein solutions, culture media, and serum based culture media

<sup>\*</sup>EFA: Effective Filtration Area



## Pre-sterilized Polyethersulfone Membrane Syringe Filters

Microbially Validated as per ASTM F 838-05 Complies with USFDA 21 CFR 210.3(b)(6) Meets and Exceeds USFDA 21 CFR 177.1520



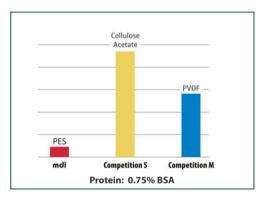


Figure 2: Protein loss with BSA

mdi pre-sterilized Polyethersulfone(PES) membrane syringe filters are available in pore sizes of 0.2µm and 0.45µm and several diameters to suit various applications for filtration in the laboratory.

#### Types Available

#### SY4PL-S, SY13PL-S, SY25PL-S

Low protein binding, high flow rate PES membrane syringe filters.

#### SY13KG-S, SY25KG-S

This special syringe filter houses a microglassfiber pre-filter along with the Polyethersulfone membrane filter and is ideal for filtering difficult to filter solutions.

#### **IKG-S**

This 50mm Polyethersulfone syringe filter with 1/4" stepped hose barb connections incorporates large filtration area and microglassfiber pre-filter for larger volume filtration. These filters can be used with 50ml syringe to filter volumes up to 500ml and also with a peristaltic pump for larger volumes.

#### **Specifications**

Pore Size		0.2μm,	0.45µm	
Diameter	4mm	13mm	25mm	50mm
EFA*	0.07cm <sup>2</sup>	0.8cm <sup>2</sup>	4.15cm <sup>2</sup>	20cm²
Hold-Up Volume	<5µl	<20µl	<50µl	<300µl
Retention Efficiency	•		3. diminuta S. marcesce	ens

<sup>\*</sup> EFA: Effective Filtration Area

#### For 4mm, 13mm, 25mm Filters

Ту	pe	Si	ze	Pore S	ize	Inlet/Out	let	X	X	Sterili	ty	Pack S	ize
Туре	Code	Dia	Code	Pore Size	Code		Code				Code	Pack Size	Code
SYPL	SYPL	4mm	01	0.2µm	01	Female	М			EO Sterile	2	100	04
*SYKG	SYKG	13mm	03	0.45µm	02	Luer Lock	171						
		25mm	06			Male	N		*SYk	(G is availa	able ir	13mm a	nd 25n

Example:	SYKG	06	01	MN	Х	Х	2	04

#### For 50mm Filters

Ту	pe	Si	ze	Pore S	ize	Inlet/Out	let	X	Bell		Sterilit	ty	Pack S	ize
Туре	Code	Dia	Code	Pore Size	Code		Code			Code		Code	Pack Size	Code
IKG	IKGX	50mm	10	0.2μm	01	1/4" Stepped	В		with Bell	В	EO Sterile	2	10*	02
				0.45µm	02	Hose Barb			without	Х			12	08

\*With Bell

**Example:** 

**IKGX** 01 X 10 BB X 2 08

### IKT: 50mm PES Filters with In-Built Vent

**mdi** disposable IKT filters are compact devices with a unique design, incorporating high flow rate, high throughput, low protein binding polyethersulfone membrane with a special inbuilt PTFE vent to ensure unique performance advantages in a multitude of applications in life sciences research, bio-pharmaceuticals, and healthcare. The IKT filters are validated and assured for quality to ensure superior performance.

#### **Special Features**

- ◆ Unique in-built PTFE vent
- Low protein binding
- Large effective filtration area
- ♦ High flow rates
- ♦ Heat sealed
- Light weight and self supporting
- 100% Integrity tested
- Total traceability: Unique marking on each filter

#### **Applications**

- Formulation development of high value drug molecules
- Sterile filtration of new protein molecules

#### **Specifications**

**Bubble Point (0.2 \mum):**  $\geq$ 18psi (1.26Kg/cm<sup>2</sup>) with 70% IPA **Sterilization:** 3 autoclave cycles at 125 °C for 30 minutes

**Air Flow Rate:** 16 lpm @  $\Delta P = 0.5 \text{ Kg/cm}^2$ 

**Water Flow Rate:** 140 ml/min @  $\Delta P = 0.35 \text{ Kg/cm}^2$  at 27 °C

Burst Pressure: 8 Kg/cm<sup>2</sup>

**Biosafety:** Passes the Biological Reactivity tests for Class VI plastics as per USP < 88>

**Extractables:** Within limits specified in USP **Oxidizable Matter:** Passes test as per USP





Microbially Validated as per ASTM F 838-05

Complies with USFDA 21 CFR 210.3(b)(6)

Meets and Exceeds USFDA 21 CFR 177.1520

#### Unique Performance Advantages

- Zero filtration losses during filtration of high value fluids as the unique air vent allows passage of even the last millilitre of fluid through the filter as well as downstream tubing
- Allows dosage of measured quantities into bio-reactors and culture vessels
- No wastage or contamination due to external vent
- No obstruction of fluid due to entrapped air in the upstream

Тур	pe		Size		Pore S	ize	Inlet/Out	tlet	x	Bell		Sterilit	у	Pack S	Size
Type	Code	Size	EFA*	Code	Pore Size	Code	Connection	Code			Code		Code	Pack Size	Code
IKT	IKTX	50mm	17cm²	10	0.2μm	01	1/4" SHB	В		Yes	В	Non Sterile	1	12	08
					0.45µm	02	1/8" MNPT	С		No	Х	EO Sterile	2		

\*EFA: Effective Liquid Filtration Area

Example: | IKTX | 10 | 01 | BB | X | B | 2 | 08





Microbially Validated as per ASTM F 838-05 Complies with USFDA

21 CFR 210.3(b)(6)



#### **Key features**

- Low protein binding
- Extra large filter area
- High flow rates
- > 100% Integrity tested
- No elastomers or adhesive used in sealing
- Non-toxic materials of construction

### Vacufil

**mdi** Pre-Sterilized Vacufil: Vacuum Filtration units come with an extra large 75mm diameter, low protein binding Polyethersulfone membrane for filtration of buffers, biologicals like sera and culture media, and other proteinaceous solutions. These have a hydrophobic filter in the vacuum arm to prevent passage of filtrate to the pump.

#### Types available

#### Vacufil: Complete Vacuum Filtration Unit with receiver bottle

#### **Available sizes**

- > 150 ml
- > 250 ml
- > 500 ml
- > 1000 ml

#### Vacufil: Bottle top vacuum filtration units

These filters screw perfectly on to vacuum safe bottles with 45mm neck size.

#### **Specifications**

#### **Pore Size**

0.2 μm, 0.45 μm

#### **Membrane Diameter**

75 mm

#### Connection

45mm (screw cap neck)

#### Hold-up Volume

<3ml

#### **Retention Efficiency**

0.2µm: LRV>7 for *Br. diminuta* (ATCC 19146) per cm<sup>2</sup> 0.45µm: LRV > 7 for *Sr. marcescens* (ATCC 14756) per cm<sup>2</sup>

#### Sterilization

Gamma sterilized

#### **Maximum Operating Temperature**

45°C

# ORDERING NFORMATION

Туре		Siz	ze	Pore	Size	Reciever E	Bottle	х	х	Sterility	•	Pack	Size
	Code		Code		Code		Code				Code		Code
Vacufil: Bottle top	VEDV	75 mm	11	0.2µm	01	No Bottle*	XX			Gamma Sterile	3	12	08
vacuum filtration units	VFPX			0.45 μm	02	150 ml	01						
Vacufil: Complete						250 ml	02						
vacuum filtration unit	VFPC					500 ml	05						
with reciever bottles						1000 ml	10						

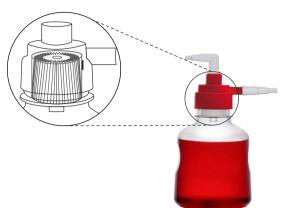
VFPC	11	02	02	Х	Х	3	08

<sup>\*</sup> No Receiver Bottle for Bottle Top Filters

AseptiVac are gamma sterile, ready to use disposable vacuum filtration devices with a unique pleated cartridge filter built into a cap which fits into the neck of the receiver bottle. This design reduces the height of the system making it more stable.

The large area filter device with high flow, low protein binding polyethersulfone membrane, allows high speed filtration and enhanced throughput with even difficult to filter solutions in biopharmaceuticals and life science research labs.

The conical shaped filter cartridge allows air bubbles to move away from the membrane, avoiding problems of membrane blockage. The hydrophobic vent in the filter body facilitates restart of filtration without air lock.





#### **Universal Device**

- Vented filter design with direct transfer adaptor allows suction of liquids from large reservoirs which are difficult to lift
- The filter design allows a funnel without filter to be fitted on the device for filtration of smaller volumes

#### **Applications**

 $\label{lem:asymptotic} \textit{AseptiVac} \ \ \text{vacuum filters find applications in cell expression labs and process } \ development \ labs \ in \ biopharmaceutical \ R\&D \ for sterile \ filtration \ of$ 

- Buffers
- Culture media
- ◆ Serum Solutions
- Pure Sera

### **Specifications**

#### **Materials of Construction**

Filter Membrane :Polyethersulfone
Filter Housing :Polypropylene
Funnel and Receiver :Polystyrene

Filtration Area: 170 cm<sup>2</sup> Hold up Volume: < 5 mL Screw Cap Neck: 45 mm

Max. Operating Temperature: 45 °C

Microbial Retention: 0.1μm - LRV > 7 for Acholeplasma laidlawii
0.2μm - LRV > 7 for Brevundimonas diminuta

**Bacterial Endotoxin**: Aqueous extracts exhibit < 0.25 EU/ml

**Biosafety**: Passes Bioreactivity test, In-vivo, as per USP <88> for Class VI plastics

Passes Biological Reactivity Tests, In Vitro, as per USP <87> for Cytotoxicity

#### **Options Available**



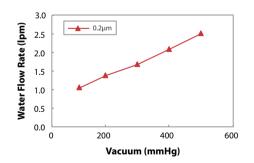




With Funnel

#### **Water Flow Rates**

• Saves time with high speed filtration: 1000 ml in < 30 Sec



Туре	•	EF	A	Pore S	Size	Variant		Receiv Bottle S	-
	Code		Code		Code		Code		Code
AseptiVac KS	AKX7	170 cm <sup>2</sup>	41	0.1µm	36	with Funnel	F	500 mL	05
				0.2 μm	01	with Hose Barb Adaptor	D	1000 mL	10
				0.45µm	02	with Funnel and Hose Barb Adaptor	Z		

х	Sterility	,	Pack	Size
		Code		Code
	Gamma Sterile	3	12	08

AKX7 41 02 F 10 X 3 08
------------------------





**Microbially Validated** as per ASTM F 838-05 Complies with USFDA 21 CFR 210.3(b)(6) **Meets and Exceeds USFDA 21 CFR 177.1520** 

#### **Water Flow Rates**

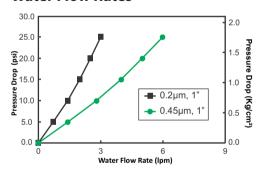


Figure 3: Water flow rates of AseptiCap KS capsule filters with 1/2" Hose Barb (DD) Connection

## AseptiCap KL/KS - Polyethersulfone Membrane Capsule Filters

mdi AseptiCap Polyethersulfone Capsule filters are self contained, ready to use, disposable filtration devices that contain a mini cartridge filter element sealed inside a polypropylene housing. The special design assures highest packing density of the membrane per unit volume resulting in a very compact capsule offering long service life.

#### **Types Available**

- ◆ AseptiCap KL: Single layered capsule filter for clear media, buffer filtration etc.
- AseptiCap KS: Serial filter, specially designed for filtration of difficult to filter solutions. These incorporate a large pore size upstream membrane layer to protect the downstream final filter.

#### **Special Features**

- Absolute retention
- Low protein binding
- Very low hold up volume
- High flow rates
- 100% Integrity tested

#### **Applications**

- Sterile filtration of high value fluids like vaccine concentrates, hormones and oncology drugs
- Scale up of new drug delivery systems
- Aseptic additions to fermentation processes

#### **Specifications**

Bubble Point: 0.2µm - ≥50psi (3.5Kg/cm²) with water Sterilization: 25 autoclave cycles of 30 minutes at 125 °C Maximum Differential Pressure: 60psi (4Kg/cm²) @ 25°C Maximum Operating Temperature: 80 °C @ < 30psi (2Kg/cm²)

Biosafety: Passes the Biological Reactivity tests for Class VI plastics as per USP < 88> Cytotoxicity: Passes Biological Reactivity Tests, invitro, USP <87> for cytotoxicity

Extractables with Water: Within limits specified in USP

Oxidizable Matter: Passes test as per USP

Туре		Size		Pore Size		Inlet/Outlet		Х	Bell		Sterility		Pack Size		
Туре	Code	Size	EFA*	Code	Pore Size	Code	Connection	Code			Code		Code	Pack Size	Code
AseptiCap KL	DKLX	1"	0.025m <sup>2</sup>	51	0.2μm	01	1/4" SHB	Α		Yes	В	Non Sterile	1	1	01
AseptiCap KS					0.45µm	02	1/4" MNPT	В		No	Х	EO Sterile	2		
(0.45µm	DKSX						½"Hose Barb	D							
Upstream)							1½" Sanitary Flange	Е							
AseptiCap KS							3//" Sanitary Flange	c							

34" Sanitary Flange

Quick Connector

\*EFA: Effective Filtration Area

**Example:** 

(0.8µm

Upstream)

	DKSX	51	01	AA	Х	Х	2	01
--	------	----	----	----	---	---	---	----

#### Filters for Air / Gases

**mdi** offers a range of air filtration devices incorporating hydrophobic PTFE membrane. These filters are validated for absolute bacterial retention and heat stability and are ideal for sterile filtration and venting of air/gases.

The hydrophobic nature of PTFE membrane allows efficient flow of air/gases even under conditions of entrained moisture which would otherwise tend to wet the filter element and restrict the airflow.

These filters are validated for microbial retention with liquid bacterial challenge test as per ASTM F838-05 to provide a high degree of sterility assurance for critical applications such as bioreactor/fermentor venting etc. even under high moisture conditions.

**mdi** PTFE membrane capsule filters are designed for long service life and are suitable for a variety of applications such as sterile venting of culture vessels, bioreactors, incubators and autoclaves, and sterilization of air/gases for fermentors and bioreactors. The table below highlights some of the applications and suitable products.

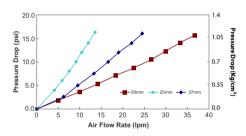


#### **Filter Selection**

Product	Key Features	Туре	Diameter / Size	Applications		
PTFE In-line Vent Filters	Hydrophobic	AseptiVent TF	25mm 37mm 50mm	filtration for small bioreactors and		
PTFE Membrane Capsule Filters	Hydrophobic	AseptiVent TF	1"	Air venting for autoclaves and sterile air filtration for bioreactors and fermentors Cleaning sterile surfaces		



#### **Air Flow Rates**



### AseptiVent TF- 25 mm, 37 mm, 50 mm

AseptiVent TF disposable In-line PTFE gas filters are convenient pre-fabricated devices used for sterilization of gases and as a bacterial air vent in various pharmaceutical and biopharmaceutical processes.

#### **Special Features**

- ♦ High flow rates
- ♦ High heat stability
- ♦ Heat Sealed
- ♦ Light weight and self supporting
- ◆ 100% Integrity tested
- ♦ Total traceability: Unique marking on each filter

#### **Types Available**

- ◆ AseptiVentTF 25mm
- ◆ AseptiVentTF37mm
- ♦ AseptiVentTF50mm

#### **Specifications**

Sterilization: 30 autoclave cycles of 30 minutes @ 125°C

Maximum Differential Pressure: 42 psi (3 Kg/cm²) @ 30°C

Maximum Operating Temperature: 60 °C

**Biosafety:** Passes the Biological Reactivity tests for Class VI plastics as per USP <88>

**Extractables with IPA:** Within limits specified in USP

Oxidizable Matter: Passes test as per USP

#### **Integrity Testing**

Pore Size	<b>Bubble Point (70% IPA wetted)</b>
0.2µm	<u>&gt;</u> 22 psi
0.45µm	≥10 psi

#### AseptiVent TF- 25 mm

Туре	•	Si	ze	Pore S	ize	Inlet/Outle	et	)
Type	Code	Dia	Code	Pore Size	Code		Code	
AseptiVent TF	ITFX	25 mm	06	0.2µm	01	Female Luer Lock	М	
				0.45µm	02	Male Luer Slip	N	

X	Sterilit	ty	Pack Size				
		Code	Pack Size	Code			
	Non Sterile	1	100	04			
	EO Sterile	2					

Example:

ITFX	06	01	MN	X	X	2	04
------	----	----	----	---	---	---	----

#### AseptiVent TF- 37 mm, 50 mm

Туре		Size		Pore S	ize	Inlet/Outlet		
Type	Code	Dia	Code	Pore Size	Code		Code	
AseptiVent TF	ITFX	37 mm*	08	0.2µm	01	1/4" SHB	В	
		50 mm	10	0.45µm	02	1/8" MNPT	С	
						3/4" Sanitary Flange	S	

(	X	Sterili	y		Pack Size			
			Code		Pack Size	Code		
		Non Sterile	1		10	02		
		EO Sterile	2	Ĭ				

	ITFX	08	01	ВВ	Х	Х	2	02
--	------	----	----	----	---	---	---	----

<sup>\*</sup> Note: AseptiVent TF- 37 mm is available with BB connection only

## AseptiVent TF - PTFE Membrane Capsule Filters

AseptiVent TF capsule filters employ hydrophobic PTFE membrane offering absolute retention and very wide chemical compatibility making these useful for sterile filtration of air/gases as well as aggressive solvents.

# STERILE

#### **Special Features**

- Hydrophobic
- ♦ Absolute retention
- ♦ Wide chemical compatibility
- 100% Integrity tested
- Total traceability: Unique marking on each filter

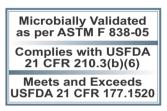


#### **Specifications**

**Sterilization:** 30 autoclave cycles of 30 minutes at 125 °C **Maximum Differential Pressure:** 4Kg/cm² (60psi) @ 30 °C **Maximum Operating Temperature:** 80 °C @ ≤2Kg/cm² (30psi)

**Biosafety:** Passes the Biological Reactivity tests for Class VI plastics as per USP < 88>

Oxidizable Matter: Passes test as per USP



#### **Integrity Testing**

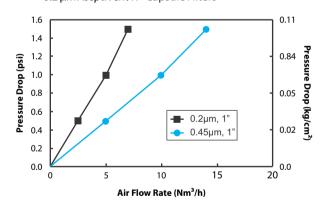
Pore Size	Bubble Point (70% IPA)				
0.2μm	≥ 22 psi (1.55kg/cm²)				
0.45µm	≥ 10 psi (0.7kg/cm²)				

#### **Air Flow Rates**

X

X

0.2 μm AseptiVent TF Capsule Filters



Туре		Size		Pore Size		Inlet/Outlet		
Туре	Code	Size	Code	Pore Size	Code	Connection	Code	
AseptiVent TF	DTLX	1"	51	0.2μm 01		1⁄4" SHB	Α	
				0.45µm	02	1/4" MNPT	В	
						½"Hose Barb	D	
						1½" Sanitary Flange	Е	
						¾" Sanitary Flange	S	
						Ouick Connector	ı	

Sterility		Pack S	Size
	Code	Pack Size	Code
Non Sterile	1	1	01
EO Sterile	2		

DTLX	51	01	AA	Х	Х	1	01

## Filters for Sterility Testing and Microbiology



**mdi** offers a wide range of membrane disc filters and membrane based filtration devices for microbiological analysis. These filters are validated for key performance parameters such as retention efficiency, microbial recovery, biological inertness, heat resistance, and water flow rates and undergo a strict quality control regimen which ensures consistency and reliability. All products are identified by fully traceable lot numbers.

#### **Applications**

**mdi** filters for microbiological analysis are specially designed for sterility testing, product microbiology and water microbiology in process industries such as pharmaceuticals and food & beverages, and in microbiology laboratories in water treatment plants.

#### **Filter Selection**

Product	Key features	Туре	Applications
Closed sterility test system	-Validated for sterility, microbial retention & microbial recovery	Stericheck	Sterility testing
Edge hydrophobic Cellulose Nitrate membrane filters	-Hydrophobic edge	EHCN	Sterility testing of antibiotics and drugs containing bacteriostats
Disposable device with Edge hydrophobic Cellulose Nitrate membrane filters	-Hydrophobic edge	E-Funnel	Product microbiology for antibiotics and drugs containing bacteriostats
Disposable device with Gridded Cellulose Nitrate membrane filters	-Non-inhibiting ink grids -Validated for microbial recovery	M-Funnel	Product and Water Microbiology
Gridded Cellulose Nitrate membrane filters	-Non-inhibiting ink grids -Validated for microbial recovery	GCN	Product and Water Microbiology
Gridded Cellulose Nitrate membrane filters in reel form	-Non-inhibiting ink grids -Validated for microbial recovery	RGCN	Product and Water Microbiology
Automatic Dispenser for dispensing pre-sterilized membrane disc filters in reel form	-Automatic single unit dispensing -Hands free operation -Compact and portable	Steridisc Dispenser	Sterility Testing and microbiology
Cellulose Nitrate membrane filters	-High throughputs	CN	Sterility testing Sterile filtration Bio-burden reduction

## Stericheck: Closed Sterility Test System

mdi Stericheck: Closed Sterility Test System offers the complete sterility testing solution from sampling, filtration, media exposure, to incubation in a closed loop, doing away with the possibility of any extraneous contamination and therefore false positives.

#### **Advantages**

- Fast
- Pre-sterilized and ready to use
- Minimizes false positives
- No false negatives

The Stericheck system incorporates disposable Stericheck devices and a specially designed easy to use peristaltic pump system for a septic transfer of fluids.

### mdi Steripump SP06: Automatic Pump System

mdi Steripump is an automatic peristaltic pump system which is an integral part of the Stericheck: Closed Sterility Test System and is specially designed to aseptically transfer sterile liquids from their respective containers to the Stericheck canisters through a sterile tubing.

Operations of the specially designed peristaltic pump are wirelessly controlled by a separate capacitive touch screen control panel through a specially designed software with convenient user friendly navigation and controls with the help of menu prompts.

It has a manual as well as automatic operating mode and offers large storage space for virtually unlimited user SOPs which are fed directly into the control panel.

It has a compact design for preventing undesirable air turbulence in laminar flow hoods and can also be installed into isolators. Steripump incorporates a variable speed super efficient drive motor, pump head, sample holder and the Stericheck Canister Holder cum Drain Tray. The pump head has been specially designed for easy threading of the canister tubing and comes with a safety feature which automatically stops the pump in case it is opened while running.

#### **Features**

- Polished 316LSS body
- Autoclavable SS 316L canister holder with Nylon drain tray
- Foot paddle for both hands free operation
- Touch screen control panel for easy navigation and control and a separate utility panel for creation and transfer to control panel of SOPs and generation of labels
- 21 CFR compliant software
- Auto backup of test reports and Audit Trail reports in a predefined repository on the lab server

#### **Web View**

Multiple users can access information on the number of recipes, active users, the number of manual and automatic tests on the Steripump SP06, through secured login credentials on their computers which are connected to the same network as Steripump. The control panel battery and memory status would also be displayed on the browser window.





**Wireless Pump Control** 

Туре	Model No.
<b>mdi</b> Steripump	Model - SP06

To ord	er p	lease	spe	ecify:
			7	

Type	Model No.	Qty

# STERILE





Non Coring Needle Design



Pre-installed Color Coded Clamps



Raised Transparent Vent



Special 'L' shaped Flow Directors



Tough Membrane



Archivable Chemical Indicator



Easy to Peel off, Impervious Blister Pack Cover



**Customized Needle Connections** 

## Stericheck- Sterility Test Devices

**mdi** Stericheck is a presterilized, nontoxic, non-pyrogenic, ready to use sterility testing device. The twin canisters along with the tubing is packed individually in a blister pack.

The Stericheck device is available with three different polymeric membranes

- ♦ Cellulose Nitrate
- ♦ PVDF
- ♦ Nylon

#### Validated for

- ♦ Sterility
- ♦ Microbial Recovery
- Microbial Retention
- ◆ Equal Sample Distribution

#### **Specifications**

Pore Size: 0.45µm

Water Flow Rates: > 0.3lpm @ 10psi at 25 °C

Sterilization: EO sterilized

Gamma sterilized

**Maximum Operating Temperature:** 35 °C continuous

Maximum Operating Pressure: 45psi

#### **Key Features**

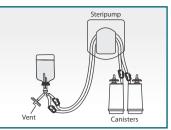
- Non coring needle design to prevent blockage by rubber particles from vial bungs
- Pre-installed color coded clamps for easy identification and clamping
- Raised transparent vent to prevent fluid logging and subsequent obstruction of air flow
- Special 'L' shaped flow directors to minimize frothing, specially with viscous fluids
- Tough membrane to withstand inadvertent back pressure
- Archivable chemical indicator in each Stericheck pack as evidence of EO gas/Gamma sterilization
- Easy to peel off, impervious blister pack cover for radiation sterilized Stericheck devices to prevent ingress of H<sub>2</sub>O<sub>2</sub> during isolator disinfection
- Customized needle connections for specific customer needs such as mini vials and cartridges in biopharmaceuticals

These devices are available with special needle connections for sterility testing of ampoules, vials, blood bags, dry injectables, pre-filled syringes, and I.V. Fluids with glass and plastic containers. Please refer ordering information table for ordering specific types.

#### Stericheck SVP1

Stericheck device for Small Volume Parenterals-Vials (Liquid).

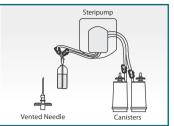
**Connection:** Dual vented needle with PVC tubing



#### Stericheck SVP2

Stericheck device for Ampoules and Collapsible bags.

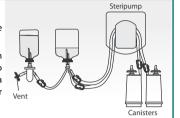
**Connection:** Single needle with PVC tubing and a separate air vented needle for venting media or rinse bottles during transfer steps.



#### Stericheck SVP3

Stericheck device for Small Volume Parenterals-Vials with soluble powder.

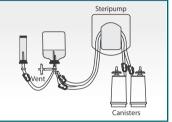
**Connection:** Single vented needle with single tubing to transfer sterile diluent to the vial for dissolving the powder and a double needle with double tubing for transferring the resulting solution.



#### Stericheck SVP4

Stericheck device for Small volume Parenterals - MIni vials and Cartridges.

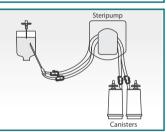
**Connection:** Single needle with single tubing to transfer sterile sample to a sterile pooling bottle, and a double vented needle with double tubing for transferring the pooled sample.



#### Stericheck PC

Stericheck device for Plastic containers.

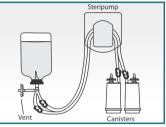
**Connection:** Single unvented, non-coring needle tip, PVC tubing and a separate air vented needle.



#### Stericheck LVP

Stericheck device for Large Volume Parenterals in glass bottles.

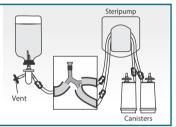
**Connection:** Single vented needle with PVCtubing.



#### Stericheck MPFS

Medical Devices with Male Luer Connection

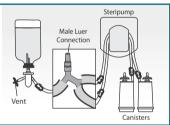
**Connection:** Specially designed adapter vented twin needle connection for rinse bottle and a female luer lock connection for sterility testing of medical devices with male luer lock.



#### Stericheck ML

Medical Devices with Female Luer Connection

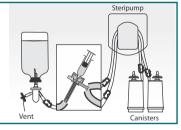
**Connection:** Specially designed adapter vented twin needle connection for rinse bottle and a male luer lock connection for sterility testing of medical devices with female luer lock.



#### Stericheck PFS

Stericheck device for pre-filled syringes

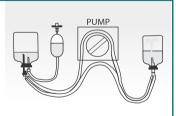
**Connection:** Specially designed adapter for sterility testing of the syringe's needle as well as its product. Testing of both inside and outside of the needle is ensured by the liquid flow pattern.



#### **SVP Dilutor**

SVP Dilutor for antibiotics and difficult to dissolve powders.

**Connection:** Single needle with expansion chamber and vent. Double needle with PVC tubing.



#### For Stericheck Canisters:

Туре				
_		Code		
Туре	PVDF	Cellulose Nitrate	Nylon 66*	
Stericheck SVP1	SV1V	SV1C	SV1N	
Stericheck SVP2	SV2V	SV2C	SV2N	
Stericheck SVP3	SV3V	SV3C	SV3N	
Stericheck SVP4	SV4V	SV4C	SV4N	
Stericheck LVP	SLVV	SLVC	SLVN	
Stericheck PC	SPCV	SPCC	SPCN	
Stericheck PFS	SPFV	SPFC	SPFN	
Stericheck MPFS	SMPV	SMPC	SMPN	
Stericheck ML	SMLV	SMLC	SMLN	

Size	
Dia	Code
47mm	09

Pore S	ize
Pore Size	Code
0.45µm	02

XX	X

Sterility	
	Code
EO Sterile	2
Gamma Sterile	3

Pack Size	
Pack Size	Code
10	02

#### \* Stericheck Devices with Nylon 66 membrane are available as EO sterilized only

#### **Example:**

SV1C	09	02	XX	ХХ	2	02

For SVP Dilutor pack of 20:

**EO Sterilized: SVPDXXXXXXXX209** 

Gamma Sterilized: SVPDXXXXXXXX309

## Edge Hydrophobic Membrane Disc Filters Type - EHCN







EHCN membranes are used for sterility testing of antibiotics and drugs containing bacteriostats. 6mm rim is hydrophobic and rest of the membrane is hydrophilic. The hydrophobic edge does not allow the drug to seep under the rim of the filter holder. This ensures complete removal of the drug during flushing so that growth of microorganisms which have been retained on the membrane is not inhibited due to the residual drug, improving the sensitivity and reliability of the test.

Cost reduction is possible by reducing or eliminating antibiotic breaking enzymes.

#### **Applications**

- Sterility testing of antibiotics and drugs containing bacteriostats
- Product Microbiology of antibiotics and drugs containing bacteriostats

#### Validated for

- Microbial recovery with antibiotic drug samples
- Microbial retention
- Sterility

#### **Specifications**

Pore Size: 0.45µm Diameter: 47mm

**Bubble Point:** >32psi (2.25Kg/cm<sup>2</sup>) with water **Retention Efficiency:** LRV > 7 for S. marcescens

#### **Water Flow Rates**

Туре	Water Flow Rates at $\Delta$ P = 10psi, 27 °C
EHCN	45ml /min/cm <sup>2</sup>

Ту	pe
Type	Code
EHCN	EHCN

Si	Size			
Dia	Code			
47mm	09			

Pore Size					
Pore Size	Code				
0.45µm	02				

XX	

XX

Sterilit	у
	Code
Non Sterile	1
EO Sterile	2

	Pack Size				
	Pack Size	Code			
	100	04			
1					

### E-Funnel

**mdi** E-Funnel is an easy to use pre-sterilized, individually packed, disposable filtration device specially designed to help facilitate and speed up microbial analysis of antibiotics and drugs containing bacteriostats in pharmaceutical API and formulation industries.

E-Funnel has a convenient design with a detachable 100 ml funnel and pluggable bottom for ease of sample collection and transfer to laboratory.

It houses a  $0.45\mu m$  Edge Hydrophobic Cellulose Nitrate membrane, to improve sensitivity and reliability by ensuring complete flushing of the drug sample, which is critical during bio-burden testing of antibiotics and drugs containing bacteriostats.

#### **Applications**

- Product bio-burden testing in pharmaceutical API manufacturing
- Raw material bio-burden testing in pharmaceutical formulation manufacturing

#### Validated for

- Microbial recovery with antibiotic drug samples
- Microbial retention
- Sterility

#### **Unique Performance Advantages**

- Ready to use
- No sterilization required
- No re-usable stainless steel or polysulfone funnels
- Minimum lab space
- Minimizes chances of extraneous contamination

#### **Specifications**

Pore Size: 0.45 μm Sterilization: EO Diameter: 47mm

**Water Flow Rates:** 200ml/min at 250mm Hg Vacuum **Retention Efficiency:** LRV > 7 for *S. marcescens* 





Тур	oe .	Si	ze	Pore Size		хх	хх	Sterility		Pack Size	
Туре	Code	Size	Code	Pore Size	Code				Code	Pack Size	Code
E-Funnel	FMEN	47mm	09	0.45μm	02			EO Sterile	2	24	12

<b>Example:</b>
-----------------

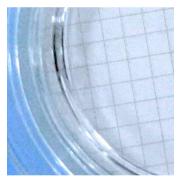
FMEN	09	02	XX	XX	2	12
------	----	----	----	----	---	----





#### **Key Features**

- Engraved volume markings for accurate measurement of sample volumes
- Validated ink grids for no inhibitory effect on microbial recovery and no inference with colony counting
- Universally adaptable design fits directly on most filter manifolds



Validated ink Grids

#### M-Funnel

**mdi** M-Funnel is an easy to use pre-sterilized, individually packed disposable filtration device, specially designed to help facilitate and speed up microbial analysis of water as well as product in pharmaceutical, beverages and food processing industries.

M-Funnel has a convenient design with a detachable funnel and pluggable bottom for ease of sample collection and transfer to laboratory. It houses a 0.45 $\mu$ m membrane, grid marked for ease of colony counting.

#### Membrane Type Available

- PVDF Membrane
- ◆ Cellulose Nitrate Membrane

#### **Available Sizes**

- ♦ 100ml
- ♦ 250ml

#### Validated for

- Microbial Recovery: ISO 7704
  - Water quality Evaluation of membrane filters used for micro biological analyses
- ♦ ASTM 4200-82
  - Evaluating inhibitory effects of ink grids on membrane filters
- ◆ Microbial Retention
- Sterility

#### **Specifications**

Pore Size: 0.45 μm Sterilization: EO Diameter: 47mm

**Water Flow Rates:** 200ml/min at 250mm Hg Vacuum **Retention Efficiency:** LRV > 7 for *S. marcescens* 

XX

# ORDERING IFORMATION

Туре		
Туре	Code	
M-Funnel with Cellulose Nitrate Membrane	FMCN	
M-Funnel with PVDF Membrane	FMVF	

Capacity		Sterility		Pack Size	
	Code		Code	Pack Size	Code
100ml	XX	EO Sterile	2	24(100ml)	12
250ml	01			12(250ml)	08

	FMCN	09	02	ХХ	ХХ	2	12
ı							

 $\label{thm:continuous} \mbox{Grid marked Cellulose Nitrate membranes are useful for water and product microbiology and the grid on the surface facilitates counting of colonies.}$ 

# STERILE

#### **Types Available**

GCN: Grid marked Cellulose Nitrate membrane
 RGCN: Pre sterilized GCN membrane in reel form

#### **Validated for**

- Inhibitory effect of ink grids on membrane filters as per ASTM D 4200 -82
- Microbial recovery
- Microbial retention
- Sterility



#### **Specifications**

Pore Size: 0.45µm Diameter: 47mm

**Bubble Point:**  $\ge$ 32psi (2.25Kg/cm<sup>2</sup>) with water **Retention Efficiency:** LRV > 7 for *S. marcescens* **Water Flow Rate:** 45ml/min/cm<sup>2</sup> at 10 psi, 27° C

Туре		
Type	Code	
GCN	GCNX	

Size			
Dia	Code		
47mm	09		
50mm	10		

Pore Size		
Pore Size	Code	
0.45µm	02	

ХХ
----

XX

Sterility		
	Code	
Non Sterile	1	
FO Sterile	2	

Pack Size			
Pack Size Code			
100	04		

**Example:** 

GCNX	09	02	XX	ХХ	2	04

Туре		
Code		
RGCN		

Size	
Dia	Code
47mm	09
50mm	10
	-

Pore Size	
Pore Size	Code
0.45µm	02

ХХ	хх

Sterilit	у
	Code
EO Sterile	2

Pack Size	
Pack Size	Code
150	15

RGCN   09   02   XX   XX   2   15
-----------------------------------

## Cellulose Nitrate Membrane Disc Filters - Type CN



CN membrane disc filters are hydrophilic, non-media migrating, biologically inert, plain white absolute membrane filters.

#### **Special Features**

- Absolute retention
- High flow rates



#### Validated for

- Microbial retention
- Microbial recovery
- Sterility

#### **Specifications**

**Pore Size:** 0.2μm, 0.45μm, 0.8μm

Diameter: 47mm

**Bubble Point:**  $0.2\mu m$ :  $\geq 50 psi (3.52 Kg/cm^2)$  with water

 $0.45\mu m: \ge 32psi(2.25Kg/cm^2)$  with water Retention Efficiency: 0.2µm: LRV > 7 for B. diminuta

0.45µm: LRV > 7 for S. marcescens

Sterilization: Autoclavable at 121°C for 30 minutes Maximum Operating Temperature: 80°C continuous

**Maximum Operating Pressure:** 5Kg/cm<sup>2</sup>

**Biosafety:** Passes the Biological Reactivity tests for Class VI plastics as per USP < 88>

Oxidizable Matter: Passes as per USP

#### **Water Flow Rates**

Pore	Water Flow Rates
Size	at $\Delta P = 10$ psi, 27 °C
0.2µm	20ml/min/cm <sup>2</sup>
0.45µm	45ml /min/cm²
0.8µm	200ml/min/cm <sup>2</sup>

#### Type Code CN CNXX

Size	
Dia	Code
47mm	09

Pore S	ize
Pore Size	Code
0.2μm	01
0.45µm	02
0.8µm	03

Sterilit	у
	Code
Non Sterile	1
EO Sterile	2

Sterilit	у		Pack S	Size
	Code		Pack Size	Code
Sterile	1		100	04
		1		

CNXX	09	02	ХХ	XX	1	04
CIVA	0,5	02		XX		04

## **Chemical Compatibility**

Table below shows the chemical compatibility of various laboratory filtration products with some commonly used solvents. All products were exposed to specified chemicals for 72 hours at 25°C. Chemical compatibility data on specific reagents is available on request.

Reagents	HNN	SYNN	SYGN	SYPL	SYKG	SYTF	SYTG	SYPP	SYGP	SYVF	SYVG	DKL/ DKS	DNL	DTL
Solvents														
Acetone	G	G	G	N	N	G	G	G	G	G	G	N	G	G
Acetonitrile	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Benzene	G	G	G	G	G	G	G	G	G	N	N	G	G	G
Benzyl Alcohol	G	G	G	N	N	G	G	G	G	G	G	N	G	G
Benzyl Alcohol 4%	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Diethyl Ether	G	G	G	G	G	G	G	G	G	N	N	G	G	G
Dimethylformamide	G	G	G	N	N	G	G	G	G	G	G	N	G	G
Ethyl Acetate	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Ethylene Glycol	G	G	G	G	G	G	G	G	G	N	N	G	G	G
Hexane	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Iso Propyl Alcohol	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Methanol	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Methylene Chloride	G	N	N	N	N	N	N	N	N	N	N	N	N	N
n-Butanol	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Peanut oil	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Tetrahydrafuran /Water (50:50)	G	G	G	N	N	G	G	G	G	G	G	N	G	G
Toluene	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Trichloroethylene	G	N	N	N	N	N	N	N	N	N	N	N	N	N
Acids														
Hydrochloric Acid 37%	N	N	N	G	G	G	G	G	G	G	G	G	N	G
Hydrofluoric Acid 10%	N	N	N	G	N	G	N	G	N	G	N	G	N	G
Nitric Acid 67%	N	N	N	N	N	G	G	G	G	G	G	N	N	G
Nitric Acid 7%	N	N	N	G	G	G	G	G	G	G	G	G	N	G
Sulphuric Acid 10%	N	N	N	G	G	G	G	G	G	G	G	G	N	G
Bases														
Ammonium Hydroxide 25%	G	G	G	G	G	G	G	G	G	G	G	G	G	G
Sodium Hydroxide 32%	G	G	G	G	G	G	G	G	G	N	N	G	G	G
Potassium Hydroxide 32%	N	N	N	G	G	G	G	G	G	N	N	G	N	G

G = Good, N = Not recommended

## **Ordering Information**

#### Shipment details for customers outside India

Through Federal Express, UPS, or DHL courier (specify complete street address).

By air freight for large quantities (specify airport of discharge).

Goods usually reach destination within 5-10 days from date of shipment.

Membrane products are light weight and air freight charges usually vary between 3% to 10% of the value.

 $Any \,duties/taxes\,in\,the\,country\,of\,destination\,are\,the\,responsibility\,of\,the\,consignee.$ 

#### Shipment details for customers inside India

The consignments can be sent through courier. Courier charges will be borne by the customer. Please specify the preferred courier and provide any form and instructions for octroi etc. that may be required for shipment.

#### How to order

Orders may be placed by phone/email/mail directly to Sales.

#### Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt - 133 006, INDIA Tel: +91-171-2699290, 2699471

Email: info@mdimembrane.com

## **mdi** Quality

#### **Quality Policy**

Quality is built into **mdi** products and services by not only adhering to well designed quality systems to consistently produce high quality, internationally acceptable products but also by striving to incorporate superior performance parameters into all our products and services and provide our customers with a unique performance advantage in their application. Our quality policy provides a glimpse of our commitment:

**mdi** strives to provide to its customers products and services of highest standards possible, consistently superior, and more satisfying than what is available anywhere else."

#### Stride Towards Excellence

At **mdi**, our mission is to constantly strive to achieve excellence in all our endeavors by establishing systems to create excellent products and services to fulfil the needs of our customers. To achieve this we

- Frequently compare our products with competing brands
- Simulate tests for functional use
- Develop easy-to-use innovative products

We are constantly working on improvements and welcome suggestions from our customers.

#### Guarantee

All mdi products are guaranteed and are backed by our

- Technical expertise and experience of over 35 years
- Validated mdi process'for consistency and repeatability
- Strict quality control and quality assurance regimen
- Certificate of Analysis accompanying all shipments

We have an unconditional replacement policy in case of any defects.









#### **Other Literature Available**

#### **INDIA Branch Offices**

#### AHMEDABAD

Mobile : +91-9328257987

#### **BANGALORE**

Mobile : +91-9972587761

#### CHENNAI

Mobile : +91-9972587761

#### **HYDERABAD**

Mobile : +91-9391935423

#### MUMBAI

Tel : +91-22-40214436

+91-22-40214435

Mobile : +91-9820026178

+91-9323801794

#### **USA Office**

Tel : +1-717-412-0943 : +1-717-695-9637 Fax

mdi Process Filtration Product Guide

mdi Biotech Product Guide

mdi Diagnostic Product Guide

### **Advanced Microdevices Pvt. Ltd.**

20-21, Industrial Area, Ambala Cantt -133006, INDIA

Tel: +91-171-2699290, 2699471 E-mail: info@mdimembrane.com Website: www.mdimembrane.com