Membrane Technologies

AseptiCap® NSZ
Positively Charged Nylon-66 Membrane Capsule Filters

Data Sheet

mdi *AseptiCap NSZ* positively charged Nylon-66 membrane capsule filters are absolute retention filtration devices for sterilization of liquids. The positive charge of the membrane offers enhanced capability to retain negatively charged contaminants such as endotoxins and debris even smaller than the membrane pore size rating. These filters are biologically inert, autoclavable, heat resistant, exhibiting wide chemical compatibility, and are suitable for a large number of filtration and sterilization applications including ophthalmic and injectable solutions.

Applications

- Filtration of pharmaceutical solutions
- Sterilizing filtration of wide variety of compatible organic solvents
- Sterilization of laboratory disinfectants
- Filtration of buffers and other non-aqueous solutions

Key Features

- Positively charged to retain contaminants smaller than pore size rating
- High flow rates and throughputs
- Minimal extractables
- High heat resistance
- Wide chemical compatibility
- Absolute reliability
- Biologically inert
- Hydrophilic

Quality Assurance

Datasheet

AseptiCap® NSZ capsule filters use **mdi** Nylon membrane in Polypropylene housing. No adhesives or glue are used in the manufacturing process and all bonding is done by heat welding.

The products are deeply validated for use in pharmaceutical applications. *AseptiCap® NSZ* are manufactured in class 10,000 clean rooms and ISO 9001:2015 certified facilities.

mdi's quality management system emphasizes on quality by design rather by 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.

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.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with Brevundimonas diminuta ATCC 19146 as per ASTM F838 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiCap® NSZ* is tested for integrity to comply with validated acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Pressure, Temperature Endurance

AseptiCap® NSZ filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Extractables

Extractables/leachables from sterilizing filters may impact the impurity profile of the desired product.

AseptiCap® NSZ filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

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

Total Traceability

AseptiCap® NSZ filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Other Regulatory Compliance

- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for Indirect Food Additives
- Materials of construction tested for toxicity as per Biological Reactivity Tests, invivo, USP <88> for class VI Plastics

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filters with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Easy Connect

Datasheet

Widest Range of End Connections

mdi *AseptiCap® NSZ* filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including EO sterilization and autoclaving.

½" HB

½" Single Stepped Hose Barb

1/4" MNPT

¼" SHB

Quick Connector

Male Luer Slip

3/8" Hose Barb

Female Luer Lock

1½" Sanitary Flange

¾" Sanitary Flange

½" MNPT

1" Hose Barb

Some end connections available with AseptiCap®.

Customized Connectivity

mdi *AseptiCap® NSZ* filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs in pharmaceutical process assemblies where, for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.

1½" Sanitary Flange to ½"Barb Hose

1½" Sanitary Flange to ¾" Sanitary Flange

***AseptiCap® NSZ* with HighSecurity ½" hose barb connection**

Linear Upscaling from R&D to Production Process

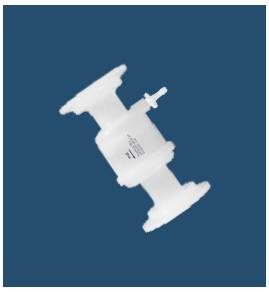
Datasheet

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from R&D to pilot scale to full scale production processes.

mdi offers a wide range of *AseptiCap® NSZ* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process is identical for all filter devices starting from 200 cm^2 to 18000cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiCap® NSZ* filters there by reducing the additional validation cost and time.



AseptiCap® NSZ
1", 200 cm^2

AseptiCap® NSZ
2", 700 cm^2

AseptiCap® NSZ
5", 1400 cm^2

AseptiCap® NSZ
8", 2100 cm^2

AseptiCap® NSZ
5" Large, 3000 cm^2

AseptiCap® NSZ
10", 6000 cm^2

AseptiCap® NSZ
20", 12000 cm^2

AseptiCap® NSZ
30", 18000 cm^2

Filter Devices	Hold up Volume
AseptiCap® NSZ 1"	< 5ml
AseptiCap® NSZ 2"	< 25ml
AseptiCap® NSZ 5"	< 45ml
AseptiCap® NSZ 8"	< 60ml
AseptiCap® NSZ 5" Large	< 80ml
AseptiCap® NSZ 10"	< 150ml
AseptiCap® NSZ 20"	< 250ml
AseptiCap® NSZ 30"	< 350ml

***EFA: Effective Filtration Area**

Specifications

AseptiCap® NSZ

Datasheet

Construction					
Final Filter Pore Size		0.2 µm		0.45 µm	
Membrane		Positively Charged Nylon- 66			
Support Layer		Polyester			
Body and Core		Polypropylene			
Integrity Testing / Retention					
Bubble Point (with 50% IPA Wetted)		> 17psi (1.19Kg/cm^2)		> 11psi (0.77Kg/cm^2)	
Microbial RetentioMicrobial Bacterial Retention (LRV >7 for)		*Brevundimonas diminuta* (ATCC 19146) per cm^2		*Serratia marcescens* (ATCC 14756) per cm^2	
Size					
Size		1″	2″	5″	8″
Effective Filtration Area (Nominal)		200 cm^2	700 cm^2	1400 cm^2	2100 cm^2
Operational Radius (with Vent/ Drain)		30 mm	65 mm	65 mm	65 mm
Vent and Drain		¼" Hose Barb with Silicone "O" rings			
Operational					
Max. Operating Temperature		80 °C @ < 30 psi (2 Kg/cm^2)			
Max. Differential Pressure		< 60 psi (4 Kg/cm^2) @ 30 °C			
Sterilization	By Gas	Sterilizable by Ethylene Oxide			
	By Autoclave	Autoclavable at 125°C for 30 minutes. Can not be in-line steam sterilized			
Shelf Life		3 years after EO sterilization			

Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Extractables with WFI	Passes NVR test as per USP <661>
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a 3 liter of WFI flush
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices.
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

AseptiCap® NSZ

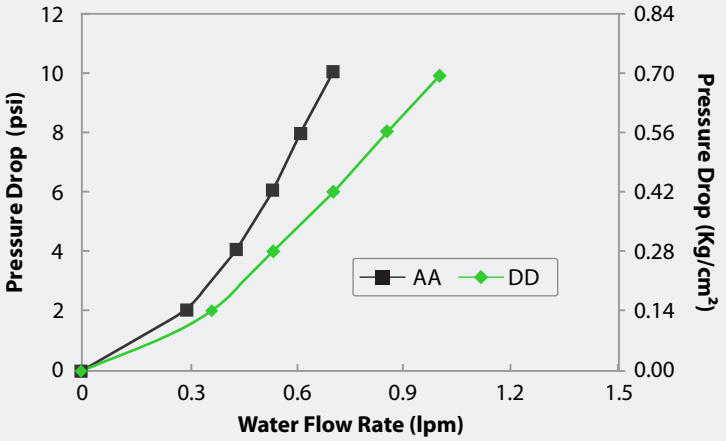
Datasheet

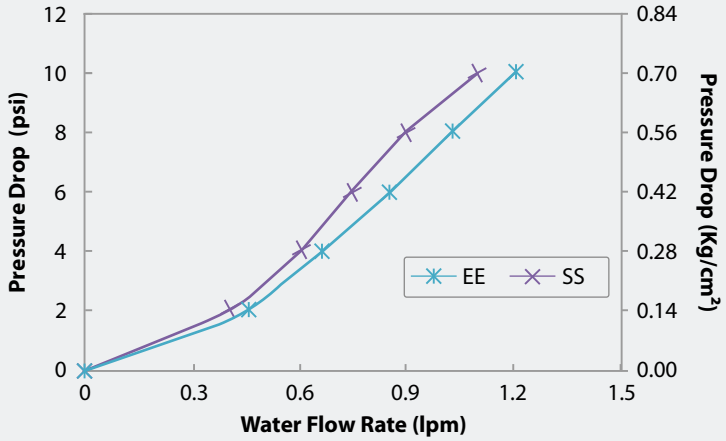
Construction					
Final Filter Pore Size		0.2 µm		0.45 µm	
Membrane		Positively Charged Nylon- 66			
Support Layer		Polyester			
Body and Core		Polypropylene			
Integrity Testing / Retention					
Air Diffusion Flow per 10″ Capsule Filter (water wetted)		< 30ml/min @ 37 psi (2.60 Kg/cm^2)		<30ml/min @ 22 psi (1.54 Kg/cm^2)	
Microbial Bacterial Retention (LRV >7 for)		*Brevundimonas diminuta* (ATCC 19146) per cm^2		*Serratia marcescens* (ATCC 14756) per cm^2	
Size					
Size		5″	10″	20″	30″
Effective Filtration Area (Nominal)		3000 cm^2	6000 cm^2	12000 cm^2	18000 cm^2
Operational Radius (with Vent/Drain)		78 mm	78 mm	78 mm	78 mm
Vent and Drain		¼" Hose Barb with Silicone "O" rings			
Operational					
Max. Operating Temperature		80 °C @ < 2 Kg/cm^2 (30 psi)			
Max. Differential Pressure		< 4 Kg/cm^2 (60 psi) @ 30 °C			
Sterilization	By Gas	Sterilizable by Ethylene Oxide			
	By Autoclave	Autoclavable at 125 °C for 30 minutes. Can not be in-line steam sterilized			
Shelf Life		3 years after EO sterilization			
Assurance					
Toxicity		Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics			
Bioburden		Bioburden level is < 1000 cfu/filter device as per ISO 11737-1:2018			
Bacterial Endotoxin		Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>			
Non Fiber Releasing		Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release			
Extractables with WFI		Passes NVR test as per USP <661>			
Particle Shedding		The filtrate complies with USP <788> test for particulate matter in injections			
TOC/Conductivity at 25 °C		Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a 3 liter of WFI flush			
Indirect Food Additive		All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520			
Good Manufacturing Practice		These products are manufactured in a facility which adheres to Good Manufacturing Practices.			
Oxidizable Substances		Passes test as per USP <1231>			
Quality Management System		ISO-9001 Certified			
USFDA		DMF No. 015554			

Typical Water Flow Rates

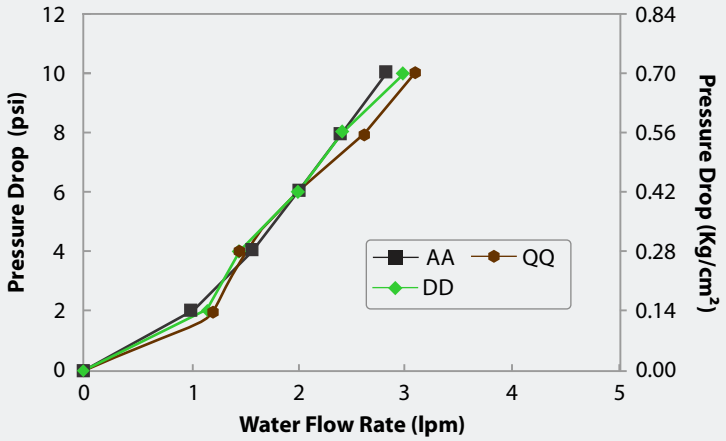
Datasheet

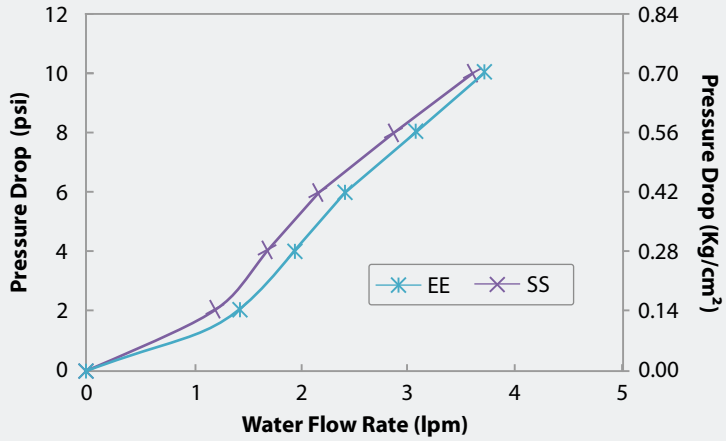
0.2µm *AseptiCap® NSZ*, 1″ Capsule Filters



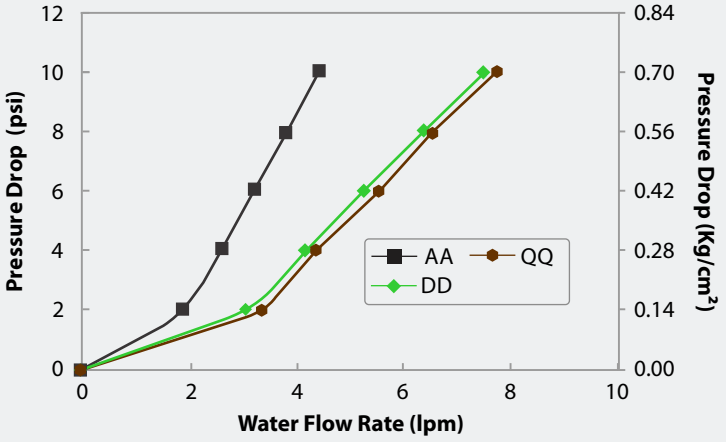


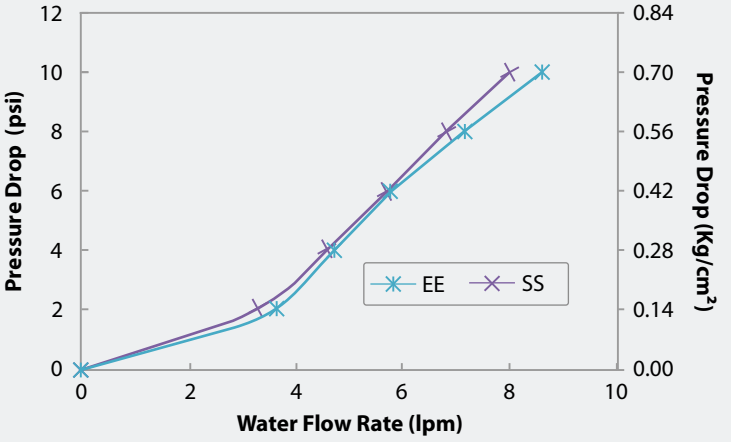
0.2µm *AseptiCap® NSZ*, 2″ Capsule Filters





0.2µm *AseptiCap® NSZ*, 5″ Capsule Filters





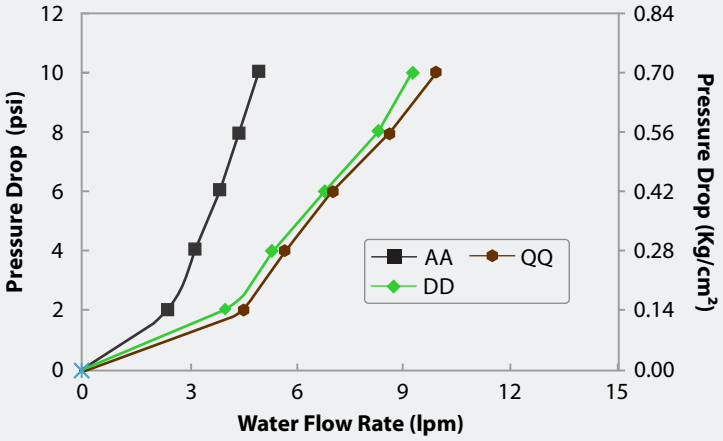
End Connection Type:

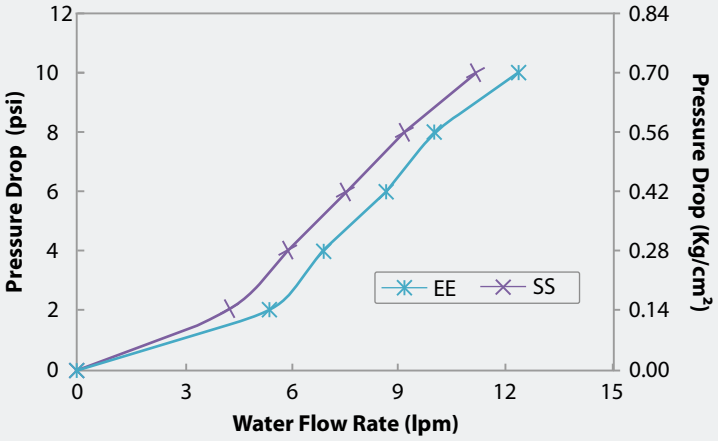
A: ¼″ Stepped Hose Barb Q: ½″ Single Step Hose Barb E: 1½″ Sanitary Flange D: ½″ Hose Barb S: ¾″ Sanitary Flange

Typical Water Flow Rates

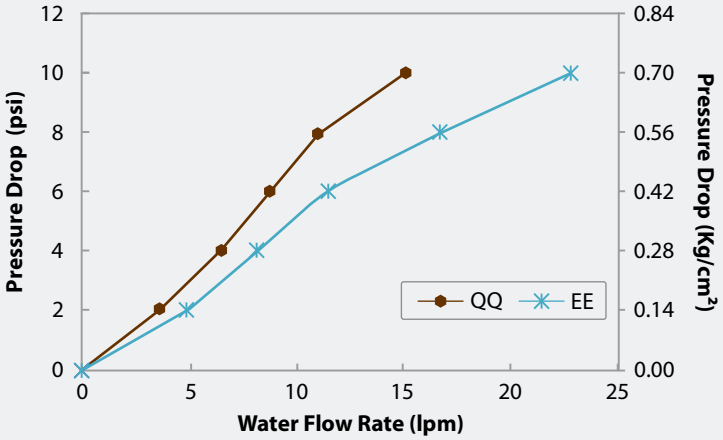
Datasheet

0.2µm *AseptiCap® NSZ*, 8" Capsule Filters

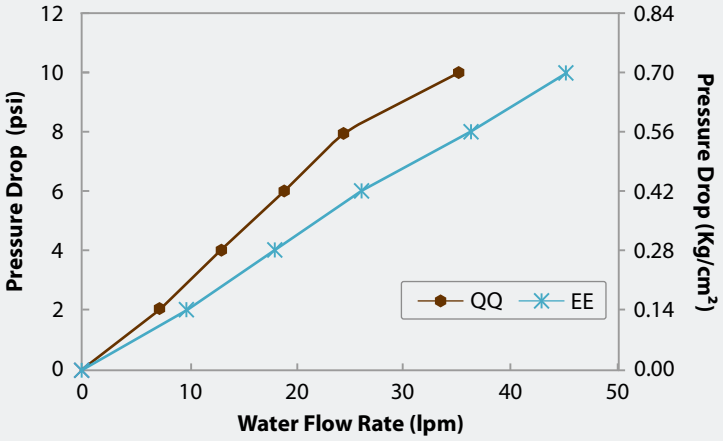




0.2µm *AseptiCap® NSZ*, 5" Large Capsule Filters



0.2µm *AseptiCap® NSZ*, 10" Large Capsule Filters



End Connection Type:

A: ¼" Stepped Hose Barb Q: ½" Single Step Hose Barb E: 1½" Sanitary Flange D: ½" Hose Barb S: ¾" Sanitary Flange

Ordering Information

AseptiCap® NSZ 1", 2", 5", 8"

Type	
	Code
AseptiCap® NSZ (0.45µm Upstream)	DNZX
AseptiCap® NSZ (0.8µm Upstream)	DNZ5

Size	
Size	Code
1"	51
2"	52
5"	53
8"	57

Pore Size	
	Code
0.2µm	01
0.45µm*	02

Inlet/Outlet	
	Code
¼" SHB	A
¼" MNPT	B
½" MNPT	C
½" Hose Barb	D
1½" Sanitary Flange	E
¾" Sanitary Flange	S
Quick Connector	J
Single Step ½" HB	Q
Female Luer Lock	U
Male Luer Slip	W
3⁄16" Hose Barb	N
3⁄8" Hose Barb	I
¼" Single Step Hose Barb	R

X

Bell	
	Code
Yes*	B
No Bell	X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
Qty	Code
1	01

Example	DNZX	53	01	QQ	X	X	1	01

* 0.45 µm pore size is available only with 0.8µm upstream

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
¼" Stepped Hose Barb	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
½"Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
½" MNPT	X	√	√	√
¼" MNPT (18TPI)	√	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
3/16" Hose Barb	√	√	Outlet Only	X
3/8" Hose Barb	√	√	√	√
¼" Single Step Hose Barb	√	√	√	√

Dimensions (in mm)	Small Capsule Filters			
End Connections	**1"**	**2"**	**5"**	**8"**
¼" SHB I/O	94	122	172	223
¾" Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½" Sanitary Flange I/O	92	112	164	216
½" Hose Barb I/O	90	112	162	214
½" Single Step Hose Barb I/O	-	115	165	218
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	165	216
3/8" Hose Barb I/O	-	115	167	217
¼" Single Step Hose Barb I/O	90	106	160	212
Operational Radius	40	65	65	65

**Bell at Outlet Available with (Size/Outlet)
1" / ¼" SHB
1", 2", 5", 8"/ ½" HB

Ordering Information

Datasheet

AseptiCap® NSZ 5", 10", 20", 30"

Type	
	Code
AseptiCap® NSZ (0.45µm Upstream)	LNZX
AseptiCap® NSZ (0.8µm Upstream)	LNZ5

Size	
Size	**Code**
5"	53
10"	54
20"	55
30"	56

Pore Size	
	Code
0.2 µm	01
0.45 µm*	02

Inlet/Outlet	
	Code
1½" Sanitary Flange	E
¾" Sanitary Flange	S
Single Step ½" Hose Barb	Q
⅜" Hose Barb	I
1" Hose Barb	Z

X

Inline/T-line	
	Code
Inline	X
T-line	T

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
Qty	**Code**
1	01

Example

LNZX	56	01	EE	X	X	1	01

* 0.45 µm pore size is available only with 0.8µm upstream

Note: Inlet/Outlet Connections available with different Sizes/Length as follows:

Inlet/Outlet	Inline				T-Line		
	5"	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	√	X	X	X
1½" Sanitary Flange	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	X	X	X	X	X
⅜" Hose Barb	√	√	√	√	X	X	X
1" Hose Barb	X	√	√	√	X	X	X

Dimensions (in mm)	Inline Capsule Filters				T-line Capsule Filters		
End Connections	**5"**	**10"**	**20"**	**30"**	**10"**	**20"**	**30"**
1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¾" Sanitary Flange I/O	214	335	x	x	x	x	x
½" Single Step Hose Barb I/O	218	336	630	890	x	x	x
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x
⅜" Hose Barb I/O	211	332	634	878	x	x	x
1" Hose Barb I/O	x	405	635	895	x	x	x
Operational Radius	80	80	80	80	80	80	80

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