Membrane Technologies

AseptiCap NL/NS
Nylon-66 Membrane Capsule Filters

Data Sheet

mdi Nylon membrane capsule filters are ready to use, disposable, highly retentive filtration devices specially designed for sterilization of aqueous as well as organic solutions. Nylon-66 membrane, and polypropylene body used in these filters provide wide chemical compatibility. These capsule filters are heat resistant, biologically inert, autoclavable, and suitable for filtration and sterilization applications.

With the advantages of pre filtration layer built into the device for higher throughputs, linear scalability of filter area for smooth transitions from lab scale to pilot to process scale and widest range of end connections for quick and reliable connections to the existing fittings. **mdi** *AseptiCap NL/NS* filters are an ideal solution for pharmaceutical process filtration.

These filter devices are validated to meet compendia and regulatory requirements and are well characterized. They meet key process requirements such as high retention efficiency, extremely low extractables, high throughputs, wide chemical compatibility and other important characteristics.

AseptiCap NL/NS

Nylon-66 Membrane Devices

Datasheet

Asepticap NL/NS 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 NL/NS* are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Types Available

- AseptiCap NS: Double Layer (with Prefilter)
- AseptiCap NL: Single Layer (without Prefilter)

Applications

- Sterilizing filtration of stability batches in formulation development labs
- Sterilization of compatible solvents and chemicals

Key Features

- Absolute retention
- 100% integrity tested
- Very low hold up volume in filters
- High flow rates
- Serial construction with prefilter for higher throughput with fouling streams
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Widest range of end connections
- Products available for total scalability from a few ml to thousands of liters
- Total traceability through unique serial number for each filter
- Individual certificate of quality for each device
- Sterilizable by EO gas or autoclaving

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the 'Sterilizing Filter' 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.

Quality Assurance

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 F838-05 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 NL/NS* 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 NL/NS 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 NL/NS 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.

Endotoxin Testing

Aqeous extracts exhibit <0.25 EU/ml as established by Lumulus Amebocyte Lysate (LAL) test as per USP <85>.

Total Traceability

AseptiCap NL/NS 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.

Packaging Integrity

AseptiCap NL/NS filters are fitted with vent caps and are packed in pouch to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room process areas.

Other Regulatory Compliance

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

Easy Connect

Datasheet

Widest Range of End Connections

mdi *AseptiCap NL/NS* 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.

¾" Sanitary Flange

1½" Sanitary Flange

½" HB

1/2" Single Stepped HB

¼" SHB

Quick Connector

Some end connections available with AseptiCap.

Customized Connectivity

mdi *AseptiCap NL/NS* 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 NL/NS* 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 NL/NS* 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 5 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 NL/NS* filters there by reducing the additional validation cost and time.

AseptiCap NL/NS
25mm, 5cm^2

AseptiCap NL/NS
50mm, 20cm^2

AseptiCap NL/NS
1", 250cm^2/200cm^2

AseptiCap NL/NS
2", 900cm^2/700cm^2

AseptiCap NL/NS
5", 1800cm^2/1400cm^2

AseptiCap NL/NS
8", 2700cm^2/2100cm^2

Filter Devices	Hold up Volume
AseptiCap NL/NS 25 mm	< 50µl
AseptiCap NL/NS 50 mm	< 300µl
AseptiCap NL/NS 1"	< 5ml
AseptiCap NL/NS 2"	< 25ml
AseptiCap NL/NS 5"	< 45ml
AseptiCap NL/NS 8"	< 60ml
AseptiCap NL/NS 10"	–
AseptiCap NL/NS 20"	–
AseptiCap NS 30"	–

AseptiCap NS
10", 6000cm^2

Specifications

AseptiCap NL/NS

Datasheet

Construction			
Final Filter Pore Size		0.2 µm	0.45 µm
Pre-filter Membrane (in case of *AseptiCap NS*)		0.8 µm, 0.45µm	0.8 µm
Membrane		Nylon- 66	
Plastic Parts		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		25 mm	50 mm
EFA (Effective Filtration Area)		5cm^2	20cm^2
Dimension (End to End)	¼" SHB I/O	–	79 mm
	¾" Sanitary Flange Inlet I/O	–	51 mm
	Female Luer Lock Inlet/ Male Luer Slip Out let	23 mm	–
Operational Radius (with Vent/ Drain)		15 mm	28 mm
Operational			
Max. Operating Temperature		55 °C	60 °C
Max. Differential Pressure		5Kg/cm^2 (75 Psi) @ 25° C	3Kg/cm^2 (42 Psi) @ 30° C
Hold-up Volume(with air purge)		<50µL	<300µL
Burst Pressure		> 14 Kg/cm^2	> 8 Kg/cm^2
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 ANSI/AAMI/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 specified volume of purified water 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 NL/NS

Datasheet

Construction					
Final Filter Pore Size		0.2 µm		0.45 µm	
Pre-filter Membrane (in case of *AseptiCap NS*)		0.8 µm, 0.45µm		0.8 µm	
Membrane		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)	*AseptiCap NL*	250cm^2	900cm^2	1800cm^2	2700cm^2
	AseptiCap NS	200cm^2	700cm^2	1400cm^2	2100cm^2
Dimensions (End to End)	1½″ Sanitary Flange I/O	91 mm	110 mm	161 mm	211 mm
	½″ Hose Barb I/O	90 mm	112 mm	164 mm	215 mm
	1½″ Sanitary Flange Inlet ½″ Single Step Hose Barb Outlet	-	111 mm	162 mm	212 mm
	¾″ Sanitary Flange I/O	91 mm	103 mm	155 mm	205 mm
Operational Radius (with Vent/ Drain)		30 mm	65 mm	65 mm	65 mm
Vent and Drain		1/4" 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 ANSI/AAMI/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 specified volume of purified water 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 NL/NS

Datasheet

Construction					
Final Filter Pore Size		0.2 µm		0.45 µm	
Pre-filter Membrane (in case of *AseptiCap NS*)		0.8 µm, 0.45µm		0.8 µm	
Membrane		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
Dimensions (End to End) Inline Capsule Filters	½" Single Step Hose Barb I/O	217 mm	332 mm	607 mm	882 mm
	1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	203 mm	332 mm	607 mm	882 mm
	1½" Sanitary Flange I/O	207 mm	326 mm	601 mm	876 mm
Operational Radius (with Vent/Drain)		78 mm	78 mm	78 mm	78 mm
Vent and Drain		1/4" 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			

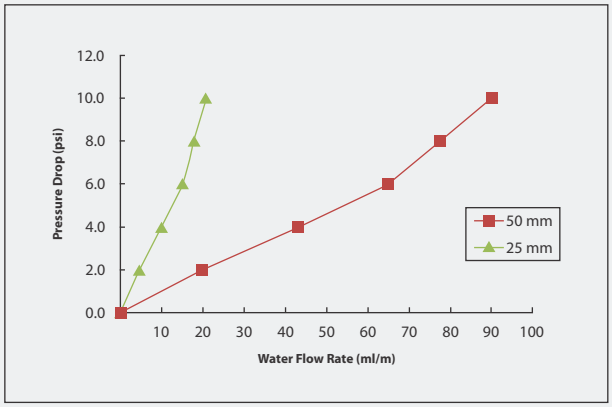
Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per 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 specified volume of purified water 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

Water Flow Rates

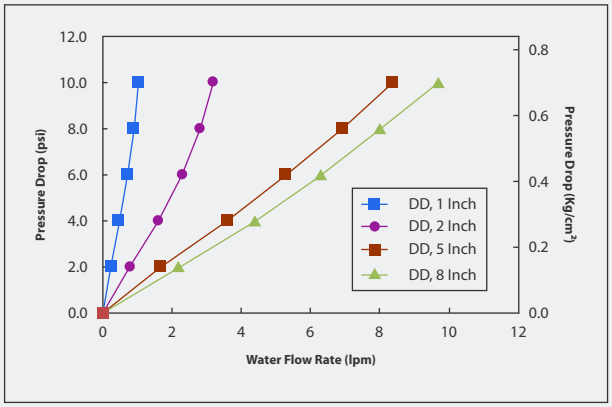
AseptiCap NS (with Prefilter)

Datasheet

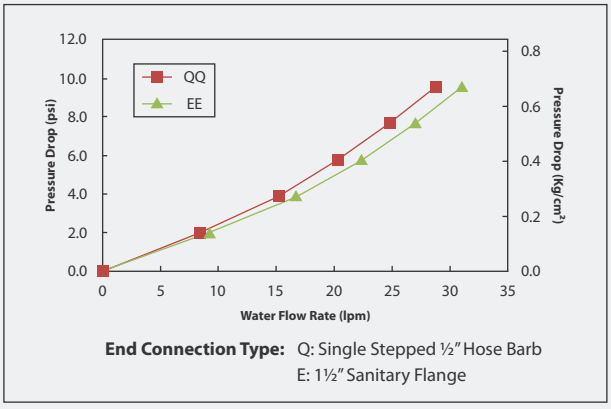
AseptiCap NL - 25 mm, 50 mm



AseptiCap NS, 1",2",5",8"



AseptiCap NS, 10"



End Connection Type: Q: Single Stepped ½" Hose Barb
E: 1½" Sanitary Flange

Ordering Information

AseptiCap NL/NS 25mm

Type	
	Code
AseptiCap NL (Single Layer)	INLX
*AseptiCap NS** (0.45µm upstream)	INSX
AseptiCap NS (0.8µm upstream)	INS5

Size	
Dia	**Code**
25 mm	06

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
Female Luer Lock	M
Male Luer Slip	N
⅛" Hose Barb	H
¼" Hose Barb	B

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
100	04

Example

INSX	06	01	MN	X	X	1	04

***0.45µm Upstream is only available in 0.2µm Pore Size**

AseptiCap NL/NS 50mm

Type	
	Code
AseptiCap NL (Single Layer)	INLX
*AseptiCap NS** (0.45µm upstream)	INSX
AseptiCap NS (0.8µm upstream)	INS5

Size	
Dia	**Code**
50 mm	10

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
¼" SHB	B
¾" Sanitary Flange	S

X

X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
	Code
10	02

Example

INSX	10	01	SS	X	X	1	02

***0.45µm Upstream is only available in 0.2µm Pore Size**

Note: Inlet/Outlet Connections and Pack Sizes available with different diameter filters as follows:

Connections Available		
Inlet/Outlet	**25mm**	**50mm**
1/4" - 3/4" Stepped Hose Barb	X	√
3/4" Sanitary Flange	X	√
Female Luer Lock	Inlet Only	X
Male Luer Slip	Outlet Only	X
1/8" Hose Barb	√	X
Male Luer Lock	Outlet Only	X
¼" Hose Barb	√	X

Pack Size Available		
Pack Size	**25mm**	**50mm**
12/Pack	X	√
100/Pack	√	X

Ordering Information

AseptiCap NL/NS 1", 2", 5", 8"

Type	
	Code
AseptiCap NL	DNLX
*AseptiCap NS** (0.45µm upstream)	DNSX
AseptiCap NS (0.8µm upstream)	DNS5

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

Pore Size	
	Code
0.2 µm	01
0.45 µm	02

Inlet/Outlet	
	Code
1/4" SHB	A
1/4" MNPT	B
1/2" MNPT	C
1/2" Hose Barb	D
1½" Sanitary Flange	E
¾" Sanitary Flange	S
Quick Connector	J
Single Step ½" H B	Q
Female Luer Lock	U
Male Luer Slip	W
3/16" Hose Barb	N
3/8" Hose Barb	I

X

Bell	
	Code
Yes**	B
No Bell	X

Sterility	
	Code
Non Sterile	1
EO Sterile	2

Pack Size	
Qty	**Code**
1	01

Example	**DNS5**	**53**	**01**	**QQ**	**X**	**X**	**1**	**01**

***0.45µm Upstream is only available in 0.2µm Pore Size**

****Bell is available with**
- ½"Hose Barb outlet connections in 1", 2", 5" and 8 inch capsule filters
- ¼" SHB outlet connection in 1" capsule filters only

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

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

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

Ordering Information

AseptiCap NS 5", 10", 20", 30"

Type	
	Code
*AseptiCap NS** (0.45µm upstream)	LNSX
AseptiCap NS (0.8µm upstream)	LNS5

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
Single Step ½" Hose Barb	Q
3/8" 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	**LNS5**	**56**	**01**	**EE**	**X**	**X**	**1**	**01**

*** 0.45µm Upstream is only available in 0.2µm Pore Size**

****T-line is not available in 5" Capsule filter**

****T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections only**

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

Inlet/Outlet	Inline				T-line			
	5"	10"	20"	30"	5"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	√	X	X	X	X
1½" Sanitary Flange	√	√	√	√	X	√	√	√
3/8" Hose Barb	√	√	√	√	X	X	X	X
1" Hose Barb	X	√	√	√	X	X	X	X

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