Clarity

clear solutions

Biopharmaceutical and Pharmaceutical Filtration

The STRAINRITE Companies | World Class Filtration

Dedicated to Science and Service

The STRAINRITE Companies | World Class Filtration

Strainrite Headquarters
Auburn, Maine, 2016

Since 1978, The Strainrite Companies have designed and manufactured leading-edge filtration products for a variety of industries worldwide.

The heritage of The Strainrite Companies is closely tied to the initial development of filter bag technology. Our founder, John H. Lapoint Jr., was an integral part of the team that conceived, perfected, and offered the original filter bag.

Our Clarity™ pleated depth and membrane cartridge product lines offer a clear advantage over the competition. Building on our proven product development capabilities and over 30 years of experience manufacturing filtration products for a variety of global industries, our Clarity™ products offer our clients pleated filter cartridges that exceed expectations for quality, efficiency and total value.

Our MADD-MAXX™ filters are engineered for critical high purity applications, optimizing thoughput while maintaining an absolute rated performance that is consistent and reliable. These filters feature a media structure with high surface area and increased void volume, as well as optimized pore size geometry.

Strainrite manufactures both standard and customized filter vessels, made in our own ISO9001:2015 certified facilities, including vessels stamped to ASME code. Our vessels are hydrostatically tested in accordance with industry accepted standards.

We also offer special quality assurance tests which include X-ray, Magnetic Particle, Liquid Penetrant, Ultrasonic and Brinell hardness testing. Our consultative approach focuses on custom solutions to filtration problems. We commit the time and resources to tailor our products to our clients' unique requirements.

All Clarity™ and Madd MAXX™ cartridges are manufactured in our facility by GMP-trained personnel. Our Quality Management System is certified to ISO 9001:2008.

Our state-of-the-art equipment and highly skilled technicians are able to maintain the highest levels of product reliability and repeatability, from receipt of raw materials to shipment of finished filters.

Our test regimen and manufacturing controls include:

- Raw material performance verification
- Bubble point and air diffusion testing
- Bacteria challenge verifications of performance
- Extractable verification and determination
- Ultra-pure water rinsing with resistivity verification of effectiveness

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Pleated Depth & Membrane Cartridges

Service Is Our Sole Focus

Let's face it, there have been reports of some filters taking as long as 6 months to a year to ship – **Strainrite can deliver faster than many of our competitors.** When competitors say "no" to a customized filter, Strainrite seizes the opportunity. **We can supply on time, by manufacturing in the USA in a timely manner.** Further our network of Master Distributors are equipped with testing capabilities and keep safety stock in a nearby warehouse.

We believe in developing and maintaining long-term, strategic relationships with clients in order to deliver **innovative real time solutions** to specific customer and market requirements.

Our new product innovations are derived from a collaborative philosophy where new products are developed through customer-supplier communication and cooperation. Additionally, within our organization, a cross-functional approach to product development is utilized to ensure that the product realization cycle is fast, complete, and efficient. Due to this unique cross-functional approach and our customer-focused company culture to support this philosophy; we are able to consistently meet and exceed our customers' expectations.

Science Is Our Specialty

Strainrite's experienced personnel possess product knowledge as well as biopharma and regulatory training to assist with a wide range of challenges. Our pharmaceutical grade filters are **specialized, validated, designed-for-purpose, QC tested, and clean room manufactured to ISO9001 and cGMP standards.**

We can help you to optimize a process to filter a batch effectively at the lowest cost per liter. Our consultative approach focuses on custom solutions to filtration problems. We commit the time and resources to tailor our products to our clients' unique requirements.

As we encounter new and evolving applications, we respond with innovative, application-specific solutions. By working with us and our network of specialized distributors, our clients realize:

- Innovative solutions
- Operational cost savings
- Improved process efficiency
- Enhanced finished product quality
- Reduced waste costs

Satisfaction Is Our Standard

We can help you satisfy regulatory requirements with filters **certified to USP standards, validated to perform, factory tested, and testable** by the filter user in production.

We can satisfy diverse filter needs, from liquid pre- and final-filters to filtration of sterile gases — with a wide array of filter materials to choose from.

Extensive research and development, coupled with stringent quality control standards, provides our clients with consistent, reliable filtration products.

Our field sales professionals and distributors, in conjunction with our technical support engineers, will work with you to assess what Strainrite product, service, or combination will best suit your requirements. Call our network of distributors, sales professionals or our home office, and we will provide you with information detailing how a relationship with Strainrite will benefit your firm.

		Pur-MAXX SG Sterilizing Grade 0.2µm PES Membrane Filter	Endo-MAXX CN Charged Nylon 0.2µm Membrane Filter	Vent MAXX Hydrophobic PTFE Membrane Filter	MAXX-Cap Ultrapure Polypropylene Filter Capsules	AND MORE More Fine Clarity Filter Options to Choose From
UTILITIES	DI Water Microbial Filtration					Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	DI Water Trap Filtration					Poly-MAXX Select / Pur-PLEAT Select Gradient Density Polypropylene Depth
	DI Water Pre-Filtration					Poly-MAXX G / Pur-PLEAT G Nominally Rated Polypropylene Depth
	DI Water Endotoxin Control					Pur-MAXX CN / Mem-Pleat CN Charged Nylon 6,6 Membrane
	POU (Point Of Use)					
	DI Water Storage Tank Venting					
	Sterile Compressed Air					
API ACTIVE PHARMACEUTICAL INREDIENTS	Sterile Filtration Of Final Liquid Product					
	Filtration Of Solvents					Pur-MAXX T / Mem-Pleat T PTFE Membrane
	Carbon Fine Removal					Poly-MAXX / Pur-PLEAT Absolute Rated Polypropylene Depth
	Filtration Of Toxic Compounds					
	Compressed Air					
	Nitrogen Blanket					
	Sterile Gases					
	Sterile Holding Tank Venting					
	Replacement Of Filter Presses					Madd MAXX MF Absolute Rated Polypropylene Hybrid Elements

TARGET MARKETS
Clarity Solutions

		Pur-MAXX SG Sterilizing Grade 0.2µm PES Membrane Filter	Endo-MAXX CN Charged Nylon 0.2µm Membrane Filter	Vent MAXX Hydrophobic PTFE Membrane Filter	MAXX-Cap Ultrapure Polypropylene Filter Capsules	AND MORE More Fine Clarity Filter Options to Choose From
LARGE VOLUME PARENTERALS	Bioburden Reduction Prior To Filling & Terminal Sterilization					Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Sterilizing Filtration: Aseptic Filling					
	Pre-Filtration					Poly-MAXX / Pur-PLEAT Absolute Rated Polypropylene Depth
	Endotoxin Reduction					
	Sterile Holding Tank Venting					
SMALL VOLUME PARENTERALS	Sterilizing Filtration: Aseptic Filling					
	Pre-Filtration					Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Endotoxin Reduction					
	Single-Use System Component					
	Sterile Holding Tank Venting					

TARGET MARKETS

Clarity Solutions

		Pur-MAXX SG Sterilizing Grade 0.2µm PES Membrane Filter	Endo-MAXX CN Charged Nylon 0.2µm Membrane Filter	Vent MAXX Hydrophobic PTFE Membrane Filter	MAXX-Cap Ultrapure Polypropylene Filter Capsules	AND MORE More Fine Clarity Filter Options to Choose From
NUTRACEUTICAL / COSMECEUTICAL	Biomass Extraction					Customized Biomass Pillow Bags
	Botanical Debris Conainment					Monofilament Mesh Micron-Rated Mesh Filter Bags
	Wax Removal From Botanicals					WRPF / WRB Wax Removal Bags
BIOLOGICALS - UPSTREAM PROCESSING	Sterile Filtration Of Final Liquid Product	■			■	
	Carbon Fine Removal				■	Poly-MAXX / Pur-PLEAT Absolute Rated Polypropylene Depth
	Culture Media, Sterilizing Filtration	■			■	
	Culture Media, Mycoplasma Reduction				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Endotoxin Reduction		■		■	
	Buffers				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	PH Adjust				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Makeup Water				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Compressed Air Inlet			■	■	
	Exhaust Air			■	■	
	Sterile Gases			■	■	
	Sterile Holding Tank Venting			■	■	
	Single-Use System Component				■	

TARGET MARKETS

Clarity Solutions

		Pur-MAXX SG Sterilizing Grade 0.2µm PES Membrane Filter	Endo-MAXX CN Charged Nylon 0.2µm Membrane Filter	Vent MAXX Hydrophobic PTFE Membrane Filter	MAXX-Cap Ultrapure Polypropylene Filter Capsules	AND MORE More Fine Clarity Filter Options to Choose From
BIOLOGICALS - DOWNSTREAM PROCESSING	Cell Removal				■	Poly-MAXX Select / Pur-PLEAT Select Gradient Density Polypropylene Depth
	Cell Debris Removal				■	Fiber-MAXX / Glass-PLEAT Absolute-Rated Microglass Depth
	Bioburden Reduction				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Pre-Filtration: Protection Of Membrane Systems				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Protection Of Columns: Buffer Filtration				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Nanometer Rated Filters As Pre-Filtration For Virus Filters				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Sterilizing Filtration: Aseptic Filling	■			■	
	Sterile Venting			■	■	
	Single-Use System Component				■	
EN-VITRO DIAGNOSTICS	Sera & Reagents: Sterilizing Filtration	■			■	
	Sera & Reagents: Microbial Control				■	Pur-MAXX E / Mem-Pleat E Polyethersulfone Membrane
	Sera: Prefiltration				■	Fiber-MAXX / Glass-PLEAT Absolute-Rated Microglass Depth
	Endotoxin Reduction		■		■	
	Compressed Air			■	■	
	Sterile Gases			■	■	
	Sterile Holding Tank Venting			■	■	
	Single-Use System Component				■	

VALIDATED 0.2 µm ABSOLUTE RATED MEMBRANE CONFIGURATION

- DOCUMENTED BACTERIAL RETENTION TESTING
- CORRELATION OF CHALLENGES TO NON-DESTRUCTIVE INTEGRITY TESTS
- LAL TESTING
- DOCUMENTED CYTOTOXICITY TESTING
- STEAM STERILIZATION DURABILITY TESTING
- USP CLASS VI BIOLOGICAL REACTIVITY IN VIVO, TESTING
- USP PHYSICOCHEMICAL TESTING
- VALIDATION GUIDE AVAILABLE ON REQUEST

CERTIFIED QUALITY

- MANUFACTURE AND TESTING IN THIRD PARTY VALIDATED CLEAN ROOMS IN ACCORDANCE WITH OUR ISO 9001-2000 CERTIFIED QUALITY MANAGEMENT SYSTEM
- COMPLIANCE WITH THE REQUIREMENTS FOR CLASS VI 121°C PLASTICS BASED ON THE CURRENT USP BIOLOGICAL REACTIVITY TESTS, IN VIVO.
- 100% INTEGRITY TESTED
- USP BACTERIAL ENDOTOXINS LAL SAMPLES TESTED
- MULTIPLE STEAM (STERILIZATION CYCLES — AUDIT TESTING
- USP OXIDIZABLE SUBSTANCES — AUDIT TESTING
- USP PHYSICOCHEMICAL TESTS FOR PLASTICS — SAMPLES TESTED
- INTEGRITY TESTED
- WATER FLOW — AUDIT TESTED
- BACTERIAL RETENTION — AUDIT TESTED

RUGGED & DURABLE CONSTRUCTION

- TESTED AND VALIDATED TO RETAIN INTEGRITY AFTER MULTIPLE STEAM CYCLES
- 316 SS REINFORCED END TREATMENTS
- 100% THERMALLY-BONDED CONSTRUCTION
- ABSOLUTE-RATED DUAL LAYER MEMBRANE PROVIDES RELIABLE, CONSISTENT AND REPEATABLE FILTRATE QUALITY
- PES MEMBRANE OFFERS BROAD CHEMICAL COMPATIBILITY

POSITIVE ZETA POTENTIAL

- REMOVES CHARGED PARTICLES SMALLER THAN THE ABSOLUTE RETENTION RATING OF THE FILTER
- HAS BEEN APPLIED FOR REDUCING ENDOTOXIN IN WATER AND AQUEOUS FLUIDS

VALIDATED PERFORMANCE

- 3RD PARTY LABORATORY TESTED
- LAL TESTED
- DOCUMENTED CYTOTOXICITY TESTING
- VALIDATION GUIDE AVAILABLE UPON REQUEST

CERTIFIED QUALITY

- INTEGRITY-TESTED AT FACTORY
- MANUFACTURED AND TESTED IN THIRD PARTY VALIDATED CLEAN ROOMS
- FABRICATED IN ACCORDANCE WITH OUR ISO 9001-2000 CERTIFIED QUALITY MANAGEMENT SYSTEM
- TESTED AND COMPLY WITH THE REQUIREMENTS FOR CLASS VI 121°C PLASTICS BASED ON THE CURRENT USP BIOLOGICAL REACTIVITY TESTS, IN VIVO
- TESTED ON SAMPLE BASIS AND DETERMINED TO CONTAIN LESS THAN 0.0050 EU/ML USING THE LIMULUS AMEBOCYTE LYSATE (LAL) TEST
- AUDIT TESTED TO VERIFY INTEGRITY AFTER EXPOSURE TO TWENTY (20) ONE-HOUR STEAM CYCLES AT 135°C (275°F).
- SAMPLES TESTED TO USP PHYSICOCHEMICAL TESTS FOR PLASTICS

RUGGED & DURABLE CONSTRUCTION

- TESTED TO DEMONSTRATE RETENTION OF INTEGRITY AFTER MULTIPLE STEAM CYCLES
- 316 SS REINFORCED END TREATMENTS
- 100% THERMALLY-BONDED CONSTRUCTION
- NYLON 6,6 MEMBRANE CAST ON POLYESTER SUPPORT FOR STRENGTH
- DOUBLE-LAYER MEMBRANE FOR RELIABILITY

SELLING FEATURES

Vent-MAXX Double Layer PTFE
for Sterilization in Air & Vent Gas Applications

VALIDATED PERFORMANCE

- VALIDATION GUIDE FOR VENT-MAXX CARTRIDGES – AVAILABLE ON REQUEST
- BACTERIAL CHALLENGE TESTING — LIQUID "WORST CASE" CHALLENGE
- CORRELATION OF BACTERIAL CHALLENGE TO INTEGRITY TEST
- CYTOXICITY TESTING
- BIOLOGICAL REACTIVITY USP CLASS VI TESTING
- USP PHYSICOCHEMICAL TESTS FOR PLASTICS TESTING
- LIMULUS AMEBOCYTE LYSATE (LAL) TESTING

CERTIFIED QUALITY

- INTEGRITY-TESTED AT FACTORY
- MANUFACTURED AND TESTED IN THIRD PARTY VALIDATED CLEAN ROOMS
- FABRICATED IN ACCORDANCE WITH OUR ISO 9001-2000 CERTIFIED QUALITY MANAGEMENT SYSTEM
- TESTED AND COMPLIED WITH THE REQUIREMENTS FOR CLASS VI 121°C PLASTICS BASED ON THE CURRENT USP BIOLOGICAL REACTIVITY TESTS, IN VIVO
- TESTED ON SAMPLE BASIS USING THE LIMULUS AMEBOCYTE LYSATE (LAL) TEST
- AUDIT TESTED TO VERIFY INTEGRITY AFTER EXPOSURE TO TWENTY-FIVE (25) ONE-HOUR STEAM CYCLES AT 135°C (275°F)
- SAMPLES TESTED TO USP OXIDIZABLE SUBSTANCES
- SAMPLES TESTED TO USP PHYSICOCHEMICAL TESTS FOR PLASTICS
- AIR FLOW — PRESSURE-DROP AUDIT TESTED
- BACTERIAL RETENTION AUDIT TESTED

RUGGED & DURABLE CONSTRUCTION

- TESTED TO DEMONSTRATE RETENTION OF INTEGRITY AFTER MULTIPLE STEAM CYCLES
- 316 SS REINFORCED END TREATMENTS
- 100% THERMALLY-BONDED CONSTRUCTION
- DOUBLE-LAYER HYDROPHOBIC PTFE MEMBRANE FOR RELIABILITY

SELLING FEATURES

Strainrite MAXX-Cap
single-use / multi-use ultrapure polypropylene capsules

DISPOSABLE CAPULE FORMAT

- GREAT FOR SINGLE USE SYSTEMS
- ELIMINATES CIP (CLEAN IN PLACE) EXPENSE
- LESSENS OPERATOR EXPOSURE TO CONTAINED COMPOUNDS
- AVOIDS/REDUCES CAPITAL (STAINLESS STEEL) INVESTMENT
- WIDE RANGE OF SIZES, FILTER TYPES, AND END FITTINGS ARE AVAILABLE

VALIDATED PERFORMANCE

FILTERS ARE AVAILABLE FOR INSTALLATION IN THE MAXX-CAP CAPSULE THAT ARE SUPPORTED BY A FULL VALIDATION GUIDE. EXAMPLES OF VALIDATED PERFORMANCE:

- BACTERIAL RETENTION
- CORRELATION OF INTEGRITY TEST VALUES
- STEAMABILITY/AUTOCLAVABILITY
- LAL TESTING
- USP CLASS VI TESTING
- MUCH MORE — REQUEST A VALIDATION GUIDE FOR THE FILTER CARTRIDGE OF INTEREST

CERTIFIED QUALITY

SPECIFIC CERTIFICATION DEPENDS ON THE SELECTED CAPSULE AND FILTER. EXAMPLES OF POSSIBLE CERTIFICATIONS ARE:

- INTEGRITY-TESTED AT FACTORY
- MANUFACTURED AND TESTED IN THIRD PARTY VALIDATED CLEAN ROOMS
- FABRICATED IN ACCORDANCE WITH OUR ISO 9001-2000 CERTIFIED QUALITY MANAGEMENT SYSTEM
- TESTED AND COMPLY WITH THE REQUIREMENTS FOR CLASS VI 121°C PLASTICS BASED ON THE CURRENT USP BIOLOGICAL REACTIVITY TESTS, IN VIVO
- TESTED ON SAMPLE BASIS USING THE LIMULUS AMEBOCYTE LYSATE (LAL) TEST
- AUDIT TESTED TO VERIFY INTEGRITY AFTER EXPOSURE TO TWENTY-FIVE (25) ONE-HOUR STEAM CYCLES AT 135°C (275°F).
- SAMPLES TESTED TO USP OXIDIZABLE SUBSTANCES
- SAMPLES TESTED TO USP PHYSICOCHEMICAL TESTS FOR PLASTICS
- FLOW — PRESSURED DROP AUDIT TESTED
- BACTERIAL RETENTION AUDIT TESTED

RUGGED & DURABLE CONSTRUCTION

- VARIETY OF END-FITTINGS AVAILABLE
- 100% THERMALLY-BONDED CONSTRUCTION
- RUGGED POLYPROPYLENE OUTER SHELL, BROADLY CHEMICAL COMPATIBLE
- RATED TO 70 PSIG
- AUTOCLAVABLE

STRAINRITE PUR-MAXX SG 0.2 STERILIZING GRADE 0.2µm PES MEMBRANE FILTERS

Application: Sterilizing Filtration of a Pharmaceutical.
Strainrite Product: Strainrite Pur-MAXX SG 0.2 sterilizing grade 0.2µm PES membrane filters / Strainrite pharmaceutical grade Pur-MAXX polypropylene microfiber pre-filters.
Process: Filtration occurs downstream of a batching tank and is aseptically filled into final containers.
Challenge: The company needed to evaluate a pre-filter to final filter combination that would economically filter the entire batch in the required time frame. The customer was uncertain about filter selection and sizing. In addition, some competitors had reported prolonged lead times.
Strainrite Solution: Strainrite Pur-MAXX SG 0.2 sterilizing grade 0.2µm PES membrane filters and pharmaceutical grade Pur-MAXX polypropylene microfiber pre-filter cartridges are used to economically sterile-filter the product immediately prior to filling the final container.
Details: During the customer's process development stage, Strainrite and their distribution partner provided laboratory services to determine an economical filtration scheme, demonstrated feasibility bench scale, and provided scale-up assistance. The filter train was demonstrated pilot scale using Strainrite's Maxx-CAP filter capsules and was scaled up to cartridge filters in stainless steel filter housings. Strainrite provided a documentation package including a "Validation Guide" and quality audit questionnaire response.
Payoff: The customer was able to launch the product on-time, and reliably and consistently produces product. The customer appreciates the quality documentation that Strainrite supplies in support of the filters. Additionally, the customer reportedly obtains filters with "months" shorter lead time than a competitor, avoiding lost revenue. The customer had an unplanned surge in demand and Strainrite was able to supply in time.

VENT MAXX FILTER WITH HYDROPHOBIC PTFE MEMBRANE

Application: Sterile compressed air and exhaust air in a fermentation process.
Strainrite Product: Strainrite Vent Maxx 0.2 µm PTFE membrane filter.
Process: The biotechnology firm uses sterile-filtered compressed air for fermentation. The customer employs steam-in-place (SIP).
Challenge: This customer required a filter that is fully validated to retain B. diminuta in a liquid challenge, and that is manufactured for use in conformance with pharmaceutical GMP.
Strainrite Solution: Strainrite provided a Vent Maxx filter with 0.2 µm PTFE membrane which is validated to retain challenge micro-organisms even under worst-case liquid challenge conditions, is supported by a Validation Guide, and is manufactured for customers subject to GMP.
Challenge: The previous filter supplier had a product that was validated to retain organisms under aerosol conditions only, but was not validated to be retentive under worst case "liquid challenge" conditions. The customer uses SIP and has potential for water condensate buildup, and the customer did experience occasional batch contaminations. The customer also experienced late deliveries and consequent delayed production.
Details: The firm decided to change to the Strainrite Vent-MAXX filter and purchased sanitary filter housings which enabled condensate drainage.
Payoff: Air-attributed contaminations were eliminated with use of the liquid-challenge validated Vent-MAXX filters and condensate drainage improvements of their new sanitary housings. In addition, the local Strainrite distributor keeps inventory which eliminated stock-outs.

ENDO-MAXX CN 0.2MM CHARGED NYLON MEMBRANE

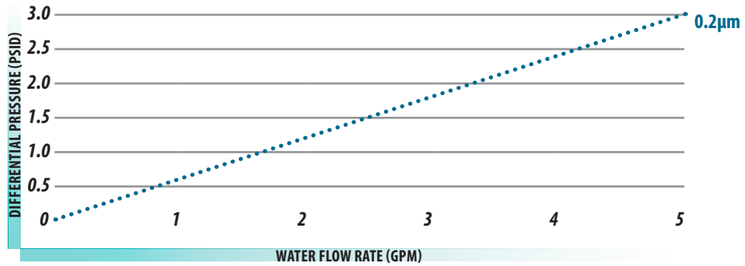
Application: Endotoxin reduction for an aqueous pharmaceutical solution with a stringent LAL specification.
Strainrite Product: Strainrite Endo-Maxx CN 0.2 µm charged nylon membrane filter.
Process: The customer's water system contains filters in a recirculating loop.
Challenge: The customer had used a competing filter but had periodic LAL test failures and complained of high price and long deliveries. LAL failures are not acceptable because of the potential for patients to have a pyrogenic response.
Strainrite Solution: The customer now successfully uses the Strainrite Endo-MAXX CN 0.2µm charged nylon membrane which quantitatively removes micro-organisms and also possesses a positive zeta potential in water to adsorb negatively charge endotoxins. The product is supported by Certificate of Quality and by Strainrite's validation documentation booklet Validation Guide Endotoxin Reduction ENDO-MAXX.
Details: Strainrite worked closely with the customer to help them with strategies to determine change-out frequency in order to prolong filter use and achieve maximum economics while also achieving quality water meeting demanding specifications.
Benefits: Using Srainrite Endo-MAXX CN helps the customer meet LAL test specifications for their water and ultimately produce a quality final product. Because of this favorable experience, and faced with long lead times and rising prices from other filter companies, they are now reviewing the feasibility of re-validating certain products to Strainrite filters.

STRAINRITE MAXX-CAP FILTER CAPSULE

Application: Filling of Active Pharmaceutical Ingredients (APIs) into bulk containers.
Strainrite Product: Strainrite MAXX-Cap filter capsule with pharmaceutical grade Pur-MAXX E 0.2µm PES membrane / Strainrite Poly-MAXX absolute rated polypropylene microfiber pre-filters.
Process: Filter train consists of pre-filters to an autoclaved 0.2 micron filter in a MAXX-Cap filter capsule configuration, for microbial control upstream of packaging.
Challenge: Incumbent stainless steel assemblies into which cartridge filters were placed were difficult to clean between batches and then autoclave. Handling the used cartridge filters exposed operators to toxic compounds. The incumbent filter was subject to long lead times.
Strainrite Solution: Strainrite MAXX-Cap filter capsule with pharmaceutical grade Pur-MAXX E 0.2µm PES membrane. Also Poly-MAXX absolute rated polypropylene microfiber cartridges as pre-filters.
Details: Customer uses Strainrite Poly-MAXX pharmaceutical grade polypropylene pre-filters upstream of Pur-MAXX E 0.2 µm PES membrane filters in a disposable MAXX-Cap configuration with sanitary flange* inlet and outlet. The customer purchases the capsules as non-sterile product and autoclaves in-house.
Benefits: The customer saves CIP labor, reduces operator exposure to toxic compounds, and shrinks costs by using a Strainrite MAXX-Cap disposable capsule instead of a replacement element in a stainless steel housing. In addition, the customer finds autoclaving the capsules to be easier and faster than autoclaving stainless steel assemblies. The product consistently meets quality levels and the customer appreciates that the Poly-MAXX pre-filter and Pur-MAXX 0.2 µm PES final filter are provided with the required quality documentation that they need for their batch records. The Strainrite filters have much shorter lead times as compared to another filter supplier. The local distributor was attentive to the customer's requests for assistance with testing and samples, and even keeps stock for the customer.

** Tri-Clover or equivalent. Tri-Clover is s trademark of Alfa Laval.*

PUR-MAXX SG



Strainrite's Sterilizing Grade Pleated Polyethersulfone Membrane Cartridges are engineered to meet the highest standards of microorganism control for sterile fluids. These filter elements are validated for complete removal of Brevundimonas diminuta (ATCC 19146) at test concentrations of 10^7 CFU/cm^2 (Colony Forming Units).

This product is ideally suited for applications where microorganism contamination causes product defects or extra processing time due to increase fluid instability. These cartridges are produced utilizing a unique multi-pleated configuration integrating highly asymmetric and hydrophillic polyethersulfone membrane with exceptional pleat support materials. This novel multi-pleated approach increases cartridge life, strength and durability, and allows our filter cartridges to withstand multiple sterilization cycles without sacrificing product integrity.

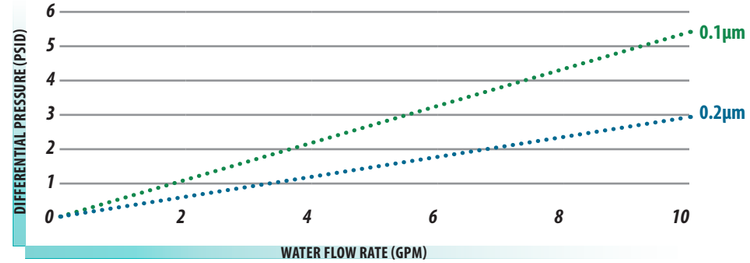
These cartridges comply with FDA CFR Title 21 and USP Biological Reactivity for Class VI Plastics. By combining these ultra pure components with the low protein binding features of highly asymmetric hydrophillic polyethersulfone membrane makes them perfect for applications in the biopharmaceutical and bottled water industries.

ENDO-MAXX CN

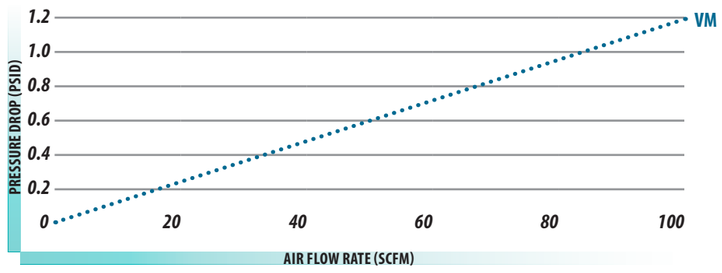
Strainrite's Endo-Maxx CN was developed for the filtration of fluids that require a high degree of particle and bacterial retention while achieving a two and a half log reduction of endotoxin.

Hydrophilic charged nylon membrane provides excellent flow rates, broad chemical compatibility, low extractability, high mechanical strength, and temperature resistance in a variety of industries for the biopharmaceutical and dialysis processes.

The Endo-Maxx CN meets USP Biological Reactivity Test, in vivo for class VI-121°C plastics. Sterilizable using industry recognized and accepted methods.



VENT-MAXX



Strainrite's Vent-Maxx gas sterilizing filters set a new standard for PTFE membrane elements. These filters utilize a technologically advanced membrane in our unique pleat construction to deliver unrivalled efficiency, superior strength, and high flow rates.

Vent-Maxx double layer PTFE membrane filters are designed to remove microorganisms and particulate in your most demanding air and gas applications. These liquid validated sterilizing grade filters are designed to meet the highest levels of security required in the pharmaceutical, food and beverage, and biopharmaceutical industries.

Vent-Maxx filters conform to USP Class VI – 121oC and 21 CFR Part 177. Strainrite delivers clear solutions to your air and gas filtration applications.

PUR-MAXX SG

ABSOLUTE RATED RETENTION			
0.2			
MAXIMUM DIFFERENTIAL PRESSURE			
Forward: 75 psid (5.1 bar) @ 75°F (24°C) 40 psid (2.8 bar) @ 180°F (82°C)		**Reverse:** 50 psid (3.4 bar) @ 75°F (24°C)	
MAXIMUM OPERATING TEMPERATURE			
180°F (82°C) Continuous Duty Polypropylene			
TOXICITY			
Cartridge materials meet USP Class VI and CFR 21 for food and beverage contact			
STERILIZATION			
Cartridge can be sterilized via steam or Autoclave: 20 times at 275°F (135°C) Cartridge may be sanitized in place with common sanitizing agents, contact factory for chemical compatibility			
PACKAGING ECONOMY			
Bulk packaging in case quantities to reduce material disposal: 5 inch - 48 per carton | 10 inch - 24 per carton | 20 inch - 12 per carton | 30 inch - 12 per carton | 40 inch - 9 per carton			
FILTER MEDIA	**END CAPS/ CAGE/CORE**	**PLEAT SUPPORT MATERIAL**	**REINFORCING RING**
Polyethersulfone	Polypropylene	Polypropylene	316 Stainless Steel

ENDO-MAXX CN

ABSOLUTE RATED RETENTION			
0.1, 0.2			
MAXIMUM DIFFERENTIAL PRESSURE			
Forward: 75 psid (5.1 bar) @ 75°F (24°C) 40 psid (2.8 bar) @ 180°F (82°C)		**Reverse:** 50 psid (3.4 bar) @ 75°F (24°C)	
MAXIMUM OPERATING TEMPERATURE			
180°F (82°C) Continuous Duty			
TOXICITY			
Cartridge materials meet USP Class VI and CFR 21 for food and beverage contact			
STERILIZATION			
Cartridge can be sterilized via steam or Autoclave: 20 times at 275°F (135°C) Cartridge may be sanitized in place with common sanitizing agents, contact factory for chemical compatibility			
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Bulk packaging in case quantities to reduce material disposal: 5 inch - 48 per carton | 10 inch - 24 per carton | 20 inch - 12 per carton | 30 inch - 12 per carton | 40 inch - 9 per carton			

VENT-MAXX

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MAXIMUM OPERATING TEMPERATURE			
180°F (82°C) Continuous Duty			
TOXICITY			
Cartridge materials meet USP Class VI and CFR 21 for food and beverage contact			
STERILIZATION			
Vent-Maxx cartridges have been validated for bacterial removal in air at an aerosol bacterial challenge level of Brevundimonas diminuta at 10^7 per cm^2 per ASTM (F 838-05) Liquid challenge validated as sterilizing grade filter at a challenge level of Brevundimonas diminuta at 10^7 per cm^2 per ASTM (F 838-05) Water Intrusion Test (WIT) value of > 60 psi with a WIT not to exceed 75 psi			

SEALS		CONSTRUCTION METHOD	
Buna N | Fluorocarbon | EPDM | Silicone		Thermal Bond	
OUTSIDE DIAMETER		**APPROXIMATE SURFACE AREA**	
MPESG: 2.55" (6.48cm) | PRMXESG: 2.7" (6.87cm)		6.5 square feet per 10" equivalent	
180°F (82°C) Continuous Duty Polypropylene			
LENGTHS			
5 inch (12.7 cm) | 10 inch (25.4 cm) | 20 inch (50.8 cm) | 30 inch (76.2 cm) | 40 inch (102 cm)			
INTEGRITY TEST VALUES			
PORE SIZE	**BUBBLE POINT**	**TEST PRESSURE**	**AIR DIFFUSION**
0.2-SG	50 psig	40 psig	≤16mL/min
USP PHYSIOCHEMICAL TESTS FOR PLASTICS			
Ultrapure water extracts from multiple lots of cartridges were tested and shown to have values that comply with USP limits			
TEST	**RESULTS**	**USP LIMIT**	
Non volatile residue Heavy Metals Residue on Ignition Buffering Capacity	<2mg <1ppm <2mg <1mL	<15mg <1ppm <5mg <10ml	

FILTER MEDIA	END CAPS	PLEAT SUPPORT MATERIAL	CAGE/CORE
Charged Nylon 6,6 cast on Polyester	Polypropylene	Polypropylene Polyester	Polypropylene
SEALS			
Buna N | Fluorocarbon | EPDM | Silicone | FEP Encapsulated Fluorocarbon | FEP Encapsulated Silicone | PTFE Foam | PTFE Hard			
CONSTRUCTION METHOD			
Thermal Bond			
OUTSIDE DIAMETER		**APPROXIMATE SURFACE AREA**	
2.7" (6.87cm)		6.8 square feet per 10" equivalent	
LENGTHS			
5 inch (12.7 cm) | 10 inch (25.4 cm) | 20 inch (50.8 cm) | 30 inch (76.2 cm) | 40 inch (102 cm)			
ENDOTOXIN REDUCTION			
The Endo-MAXX CN cartridge media has been third party verified to deliver a >2 log reduction of bacterial endotoxin using the gel-clot characterization method			

PACKAGING ECONOMY			
Bulk packaging in case quantities to reduce material disposal: 5 inch - 48 per carton | 10 inch - 24 per carton | 20 inch - 12 per carton | 30 inch - 12 per carton			
FILTER MEDIA	**END CAPS/ CAGE/CORE**	**PLEAT SUPPORT MATERIAL**	**END CAP INSERT**
Double Layer PTFE	Polypropylene	Polypropylene	316 Stainless Steel
SEALS		**CONSTRUCTION METHOD**	
Fluorocarbon | Silicone		Thermal Bond	
OUTSIDE DIAMETER		**APPROXIMATE SURFACE AREA**	
2.7" (6.87cm)		7.5 square feet per 10" equivalent	
LENGTHS			
5 inch (12.7 cm) | 10 inch (25.4 cm) | 20 inch (50.8 cm) | 30 inch (76.2 cm)			
INTEGRITY TEST VALUES			
All cartridges are integrity tested prior to shipment using pressure decay test method. Values below are for cartridges wetted with 100% IPA.			

The Strainrite MAXX-Cap capsule is made of ultrapure polypropylene using FDA compliant materials. The MAXX-Cap was designed for single-use and multi-use applications. Strainrite's depth filters and our complete line of membranes can be installed in our proprietary capsule design.

D1/01 - Sanitary

D2/02- 1/2" Female NPT

D3/03 - 1/4" Hose Barb

D4/04 - 1/2" Hose Barb

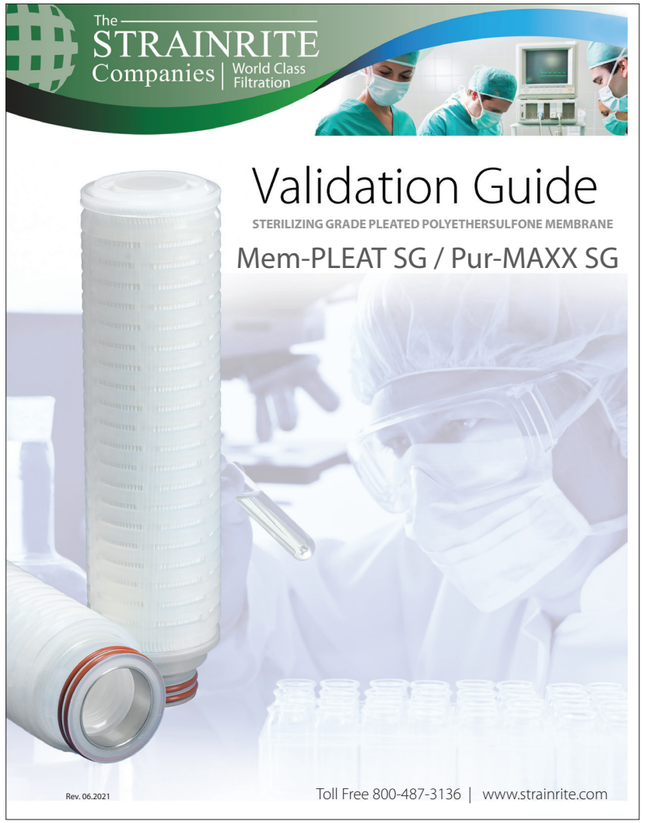
D5/05 - Graduated Hose Barb

Our proprietary design utilizes an inlet and outlet vent for confident start up and safe efficient processing. Strainrite offers a wide array of materials from the innovative SG to our charged modified CN as well as absolute and nominal media like polypropylene and microglass. Strainrite capsules will also accept our sterile air and vent product line, the Vent Maxx and Vent Rite.

MAXX-Cap is available in sizes from 5" to 40". Strainrite offers the advantages of a capsule with low internal void space, that reduces valuable product loss by reducing your process costs. All Strainrite capsules are adaptable for use with sanitary fittings that can be autoclaved. Strainrite MAXX-Cap capsules may be integrated into existing capsule applications.

Made of 100% polypropylene, Strainrite's capsule design incorporates thermal bonding. Thermal bonding provides an integral fit that requires no glues, binders, surfactants or adhesives. This design ensures low extractable filtrate when incorporated with our low extractable 100% clean room manufactured cartridges.

MAXIMUM PRESSURE		MAXIMUM OPERATING TEMPERATURE	
70 psi @ 70°F (21.1°C)		180°F (82°C) Continuous Duty	
TOXICITY		**STERILIZATION**	
Cartridge materials meet USP Class VI and CFR 21 for food and beverage contact		Autoclave: May be autoclaved 3 times for 60 minutes. Not in line steam sterilizable.	
PACKAGING ECONOMY			
Bulk packaging in case quantities to reduce material disposal: 5 inch - Individually Boxed - 6 case / 9 case quantity 10 inch - Individually Boxed - 6 case / 12 case quantity 20 inch - Individually Boxed - 6 case quantity 30 inch - Individually Boxed - 6 case quantity 40 inch - Individually Boxed			
MEMBRANE MEDIA	**PLEATED DEPTH MEDIA**	**PLEAT SUPPORT MATERIAL**	**CAPSULE HARDWARE**
Polyethersulfone Polysulfone Nylon	Borosilicate Microglass Polypropylene Microfiber	Polypropylene Polyester	Polypropylene
END CAPS	**CAGE/CORE**	**CARTRIDGE SEALS**	**CAPSULE VENT SEALS**
Polypropylene	Polypropylene	Buna N | Fluorocarbon | EPDM | Silicone	Buna N | Fluorocarbon | EPDM | Silicone
OUTSIDE DIAMETER	**NOMINAL LENGTHS**	**CONSTRUCTION METHOD**	
3.5" (8.89cm)	5 inch (12.7 cm) | 10 inch (25.4 cm) | 20 inch (50.8 cm) | 30 inch (76.2 cm) | 40 inch (102 cm)	Thermal Bond	

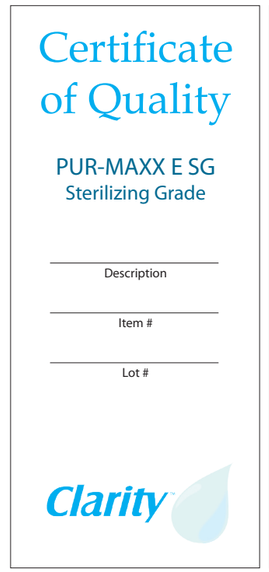


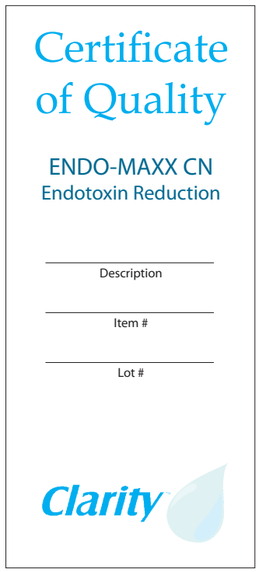
Each Strainrite Validation Guide provides important information about a specific Strainrite filter range to filter users in regulated industries such as biopharmaceuticals, and even provides copies of actual 3rd party test reports. The information can relate to performance (for example, bacterial retention), validation of QC test parameters (such as correlation of non-destructive filter integrity test to bacterial retention), aspects of cleanliness (such as in the case LAL testing, or extractables reports), durability (such as in the case of verification of integrity after steaming), and safety (such as with Cytoxicity and USP Class VI testing).

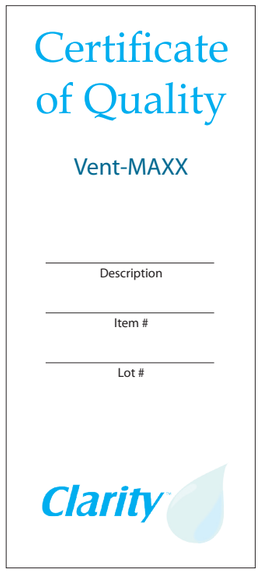
Filter users keep these Validation Guide documents on file in order to help them demonstrate compliance to cGMP or other regulatory requirements. These documents also provide assurance that Strainrite filters are a qualified, top-quality, consistently-produced product that will protect processes, products, assets and people.

Lastly, the Validation Guide is a differentiator between these Strainrite Pharmaceutical Grade filters and a vast and sometimes confusing array of competitive filters that are not always supported by such rigorous testing and controls.

In addition to Validation Guides, Certificates of Quality are also available. All cartridges are shipped with a Certificate of Quality which provides information on efficiency and performance for each item and lot number.







SANITARY HOUSING

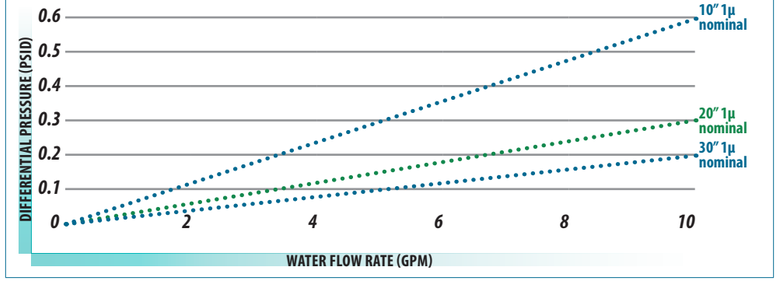
Clarity Solutions

Strainrite sanitary housings for biopharmaceuticals and food and beverage industries are differentiated from industrial housings in that they are designed to streamline features such as corners and threads where contamination can hide from cleaning procedures, are engineered to accept application-appropriate filters, are polished (including electropolishing) to achieve stringent surface roughness average (Ra) specifications, facilitate the customer's performance of a filter integrity test, and allow steam sterilization of the filter assembly.

Strainrite's range of sanitary housings includes single-element housings and multi-element housings with removable tubesheets, and accommodates a variety of filter sizes. In addition, Strainrite keeps many of these housings in stock to enable immediate supply, and supports these housings with drawings and maintenance of spare parts.

SRCT SINGLE CARTRIDGE	
Maximum Operating Pressure: 150 psi (67°F)	
Electropolished finish ensures optimal cleanability in critical areas	
Stainless steel legs	
Sterilization using in-line steam, autoclave or hot water	
Fitted for code 7 filter cartridge	
SRCT MULTI-CARTRIDGE	
Maximum Differential Pressure: 25 PSID	Maximum Flow Rate: 25 GPM water
Filter Cartridge Life: 0-25 PSID	Flow Range: 1-20 GPM
Electropolished finish ensures optimal cleanability in critical areas	
Stainless steel legs	
Sterilization using in-line steam, autoclave or hot water	
Fitted for code 7 and code 6 filter cartridges	
SRVT SINGLE & MULTI-CARTRIDGE	
Maximum Operating Pressure: 100 psi (200°F)	
316 Stainless steel	
Removable cartridge plates for cleaning	
Bleeder valve vents and drains	
Silicone Gaskets	
Holds 226/Fin (C7) Cartridges	

PERFORMANCE CHARACTERISTICS - SINGLE CARTRIDGE



SRCT single cartridge

Strainrite's SRCT and SRVT Sanitary Cartridge Vessels offer the aesthetics and operational durability of stainless steel at affordable prices. The SRCT's innovative design ensures optimal cleanability in critical areas and can accomodate either 10", 20" or 30" cartridges in a single cartridge housing and 20", 30" or 40" filter cartridges in a multi-cartridge vessel.

SRCT filters are designed specifically for liquid filtration in the food and beverage industry, offering microbiological safety, corrosion resistance and durability.

SRVT filters offer the same innovative design with a 100 PSI maximum operating pressure at 200°F.

SRVT multi cartridge

END CAP CONFIGURATIONS

Clarity Solutions

Code 1 (C1)
Double Open Ends

Code 5 (C5)
Recessed Cup/222

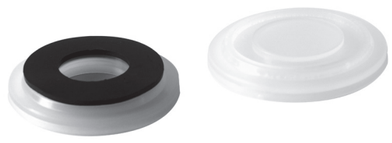
Code 2 (C2)
213/Recessed Cup

Code 6 (C6)
Flat/226

Code 3 (C3)
Flat/222

Code 7 (C7)
Fin/226

Code 4 (C4)
Single Open End/Flat Closed End



Code 8 (C8)
Fin/222

CROSS REFERENCE CHART

Clarity Solutions

This Cross Reference Chart is for general guidance only.
The appropriate Strainrite filter to recommend will depend on the specific application.

Top reasons to make a change to Strainrite:

Validated performance – We have thoroughly tested and documented our filters' performance. Request our validation guides to support your validation program.

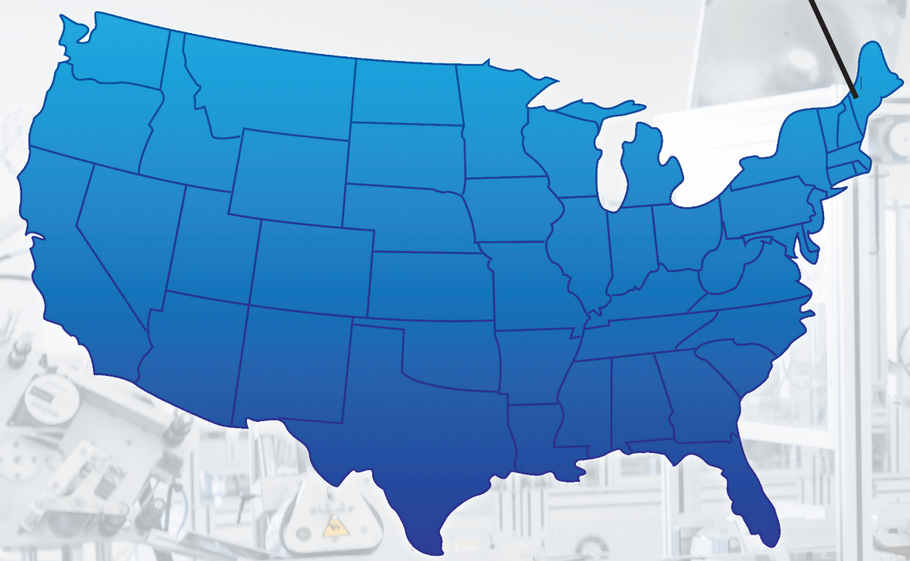
Stringent manufacturing – Pharmaceutical grade products are clean-room manufactured to ISO9001 and cGMP standards, are 100% integrity tested when appropriate, and are supplied with Certificates of Quality for customer batch records. Send us your questions about how we manufacture and test pharmaceutical grade filters.

Superior service – We are continually investing to keep lead times short and competitive. In addition, our network of master distributors are committed to keeping safety stock for critical customer processes. Request a quote and lead time on filters for your process.

Competitor Filter	Strainrite Filter
Pall Supor® EKV Filter **Millipore Express® SHF (Sterile High Flux) Filter**	**Mem-PLEAT SG & Pur-MAXX SG Sterilizing Grade Pleated Polyethersulfone Membrane**
Pall Posidyne® Filter	**Endo-MAXX CN Charged Nylon for Endotoxin Reduction**
Pall Emflon® PFR PTFE membrane filter **Millipore 0.2 µm Aervent® PTFE membrane filter**	**Vent-MAXX Double Layer PTFE for Sterilization in Air & Vent Gas Applications**
Pall Kleenpak™ capsule filters **Millipore Opticap® capsule filters**	**MAXX-Cap Single Use/Multi-Use Ultrapure Polypropylene Capsules**

The STRAINRITE Companies | World Class Filtration

Corporate Headquarters



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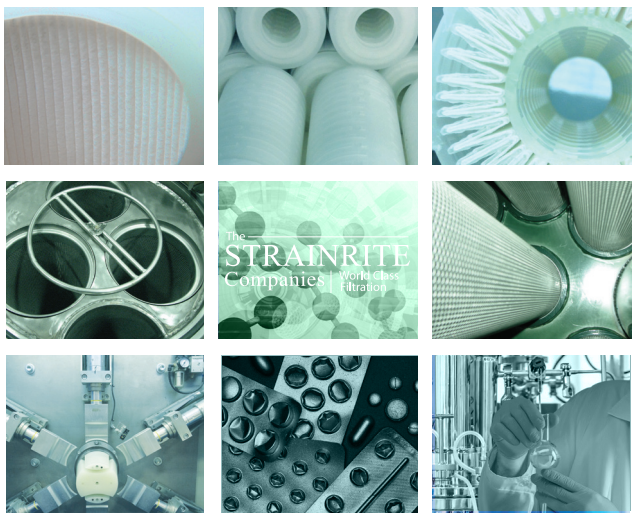
Filtration Products Since 1978



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