

POREX® MEDICAL

# POREX® MEDICAL MATERIALS & FILTERS

The World's Leader in Porous  
Polymer Technology



## MEDICAL DEVICE EXPERIENCE

- Infection Control
- Injection Therapy
- Dialysis
- Topical & Drug Therapy
- Medical & Pharmaceutical Packaging
- Orthopedics
- Urology & Ostomy Care

The changing global healthcare environment requires differentiated, reliable and reproducible medical materials to help provide precision, accuracy and consistency in current and next generation medical and surgical devices. POREX® is the world leader in porous polymer technology in components for the healthcare industry including sintered particles featuring POREX® Virtek™ Medical PTFE, bonded fiber and open-cell foam. Today, we are the leading producer and supplier of these products to the industry. Our long history of innovation in porous plastics design, materials selection, and proprietary manufacturing processes provides cost-savings, enhanced performance, and convenience for a wide range of medical device applications. Our applications provide innovative solutions in filtering, venting, wicking, diffusing, absorbing and applying challenges for our customers.

When performance counts, turn to POREX® to partner in your next medical innovation and see for yourself how POREX® Medical Materials and Filters can advance product outcomes and turn your next innovation into reality.



### Infection Control

POREX® offers a broad array of materials for use in infection control products to help advance patient and staff safety, address antimicrobial resistance, emerging pathogens and infectious diseases and optimize health-care practice environments.

### Fluid Management Materials

POREX® fluid canister, negative wound pressure and suction filters help improve infection control outcomes by preventing unwanted fluid transmission through use of specialized, porous polymer valves that close off liquid and air flow when fluids reach a critical level.

Available in an extensive array of materials and geometric shapes. Design options include an integrated splash guard to prevent premature shut-off due to splash issues, the patented color change<sup>1</sup> valve, manufactured with intrinsic color change indicator which activates upon liquid exposure and the enhanced infection control design with activated carbon that allows for odor control and prevention of unwanted fluid spillage.

POREX® Fluid Management products have been tested for Bacterial Filtration Efficiency using test methods that conform to ASTM F2101, modified. Airflow measured at a vacuum of 0.28 inches Hg, using a Gast 2567-V1008 vacuum source, Dwyer RMC-104 SSV-CPF flow meter and Dwyer DPGA-00 pressure gage.

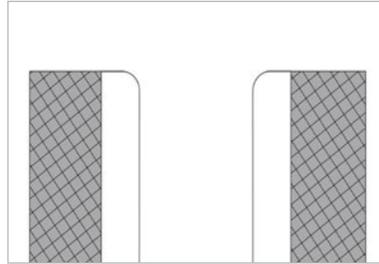
Table 1. BFE results (modified ASTM F2101)

Product	Description	BFE	Airflow SCFH
PPV1	Standard BFE	99.98%	29.2
PPV2	High BFE	99.996%	27.6
PPV3	Super BFE	99.999994%	15.0

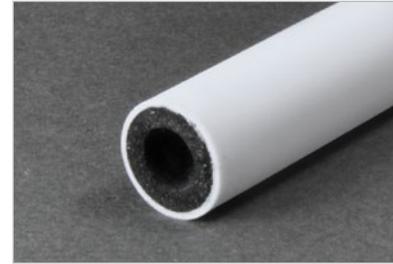
### Color Change Indicator



### Integrated Splash Guards



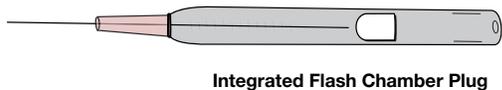
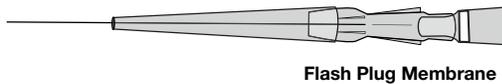
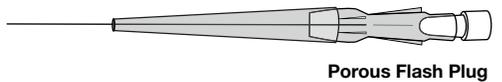
### Enhanced Infection Control



## Injection Therapy

IV catheter and arterial syringe devices serve a number of important patient functions including fluid introduction, medication administration and blood sample retrieval.

Preventing accidental needlestick injuries, blood borne pathogen exposure and healthcare acquired infections, continues to be major concerns for healthcare workers and practitioners. Injection therapy flash plug products pioneered by POREX®, eliminate blood bypass from the flashback chamber and help reduce accidental blood exposure.



### IV Safety Catheter Plugs

POREX® IV Safety Catheter plugs, available in a porous flash plug, integrated flash chamber plug and flash plug membrane, allow air or gases to freely pass through the porous media but when wet, block liquids by forming an immediate viscous solution, thus shutting off the air flow. Patented color change technology also available for material incorporation.

### Arterial Syringe Vents

Samples of blood gas analysis collected under arterial pressures require high air flow and prevention of contamination from blood and blood-borne pathogens. POREX® arterial syringe vents allow for maximized air flow at arterial pressures and elimination of blood by pass through use of specially designed porous vents that help prevent aqueous liquid contamination.

**Table 2. POREX® Virtek™ IV Catheter Media**

Material	Thickness, mm Nominal	Airflow, l/hr/cm <sup>2</sup> Typical at 70 mbar	BFE <sup>2</sup> % Nominal	WEP, mbar Typical
MD10	0.13	125 (min 70)	>99.9	270 (min 175)
MD10L	0.30	85 (min 48)	>99.9	270 (min 175)
MD15	0.18	70 (min 45)	>99.99	380 (min 265)
MD20	0.25	34 (min 16)	>99.9999	520 (min 350)
MD25	0.19	5 (min 2)	>99.9999	1000 (min 750)



## Dialysis

POREX® Dialysis filters provide containment of dialysis system media, such as those utilizing bicarbonate concentrates in disposable and dry formulations.

Dialysis fluid is prepared according to individual patient needs and POREX® filters, both inlet and outlet, help regulate concentrate bag fluid flow and back pressure, allow for balanced filtration efficiency and provide optimized chemical and physical resistance. Filters can be customized to accommodate specific device design and function requirements.



## Topical and Drug Delivery

POREX® fluid, adhesive and drug delivery materials are designed for pliability and to transfer liquid and medications quickly and accurately. An extensive line of porous materials in press-fit assemblies are available including porous composites and functionalized and bio-activated products.

### Topical Therapies

POREX® fluid media, designed to function as an applicator tip, maximizes fluid delivery, minimizes applicator tip fluid retention and filters out unwanted particles or device fragments in pre-operative skin preparation, ocular and other topical therapies including over-the-counter and prescription medicines.

### Drug Delivery Media

POREX® media help facilitate dose controlled, continuous medication systems and pump spray bottle designs where it is critical to maintain low air resistance for adequate diffusion of medical or therapeutic agents. Materials with structural integrity and functional additives are available to provide enhanced airflow, balanced diffusion and filtration and sterility maintenance.

## Medical & Pharmaceutical Packaging

Medical packaging plays an important role in preventing healthcare associated infection (HAI). The sterile barrier system, a mainstay in operating rooms and healthcare facilities, is an intrinsic element in the prevention of HAI's and surgical site infections. With prevention and reduction of HAI a major healthcare initiative, practitioners want to be assured about the protection afforded by medical device packaging after sterilization. POREX® Virtek™ Medical PTFE medical and pharmaceutical packaging materials, designed for optimal functionality and reliability, are available in various pore size, volume and structure configurations.



Table 3. POREX® Virtek™ PTFE P3 Medical Technology™ Materials

Material	Thickness, mm Nominal	Airflow, l/hr/cm <sup>2</sup> Typical at 70 mbar	BFE <sup>2</sup> % Nominal	WEP, mbar Typical
PMP31	0.14	125 (min 70)	>99.9	270 (min 175)
PMP32	0.26	65 (min 35)	>99.999	380 (min 250)
PMP33	0.18	70 (min 45)	>99.99	380 (min 265)

### POREX® Virtek™ Medical P3 Technology™

To assist device manufacturers with the prevention of HAI, POREX® developed Virtek™ Medical P3 Technology™, a specialty porous POREX® Virtek™ Medical PTFE membrane technology that harmonizes high air flow and sterile barrier capabilities to improve ETO

sterilization efficiency. Helping to maintain medical device sterility after sterilization, POREX®'s Virtek™ Medical P3 Technology™, with USP Class VI compatibility, incorporates a major advancement in material uniformity over flashspun high density polyethylene and complies with various ASTM F2638 packaging requirements.

## Sterilization Containers — POREX® Virtek™ Medical PTFE Reusable Filters

Reusable container systems used for the packaging, transportation and storage of surgical and dental instruments prior to, during and after steam sterilization have traditionally contained disposable, single use paper or textile filters. POREX® Virtek™ Medical PTFE Reusable Filters are made from medical grade PTFE, is the robust and reusable medical media with dual capabilities: a vent that allows pressure equalization during the sterilization process and a filter bacteria barrier for subsequent storage conditions. Available in two configurations, in compliance with USP class VI requirements,

**Table 4. POREX® Virtek™ Medical PTFE Sterilization Media**

Material	Thickness, mm Nominal	Airflow, l/hr/cm <sup>2</sup> Typical at 70 mbar	BFE <sup>2</sup> % Nominal	WEP, mbar Typical
MA10	0.65	35 (min 25)	>99.9999	300 (min 200)
MA15	1.00	30 (min 14)	>99.9999	350 (min 200)

free of animal-derived additives and with batch ID and date code printing for usage monitoring. These reusable filters, comprised of polytetrafluoroethylene (PTFE) engineered & designed to withstand repeated sterilization cycles as well as deliver substantial performance, convenience, and cost savings over traditional single-use paper and textile filter materials.



**Table 5. Staphylococcus aureus (gram pos)**

Product	Initial CFU	24 hrs CFU	% Reduction	Log Reductions
Negative Control	3.3 x 10 <sup>6</sup>	3.7 x 10 <sup>6</sup>	-13	-0.05
Standard Product (without CHX)	3.3 x 10 <sup>6</sup>	3.4 x 10 <sup>6</sup>	-2	-0.01
Barrier Technology (with CHX)	3.3 x 10 <sup>6</sup>	<200	>99.994	>4.22

**Table 6. Escherichia coli (gram neg)**

Product	Initial CFU	24 hrs CFU	% Reduction	Log Reductions
Negative Control	2.4 x 10 <sup>6</sup>	2.9 x 10 <sup>7</sup>	-1212	-1.12
Standard Product (without CHX)	2.4 x 10 <sup>6</sup>	2.8 x 10 <sup>7</sup>	-1075	-1.07
Barrier Technology (with CHX)	2.4 x 10 <sup>6</sup>	<200	>99.9915	>4.07

**Table 7. Escherichia coli**

Sample Time	Volume (L)	E. Coli Challenge Counts (CFU/ml)	E. Coli Effluent Counts (CFU/ml)	% Reduction
30 Sec	0.5	690,000	0	100
1 Min 30 Sec	1.5	690,000	0	100
3 Min 30 Sec	3.5	690,000	0	100
5 Min 30 Sec	5.3	690,000	0	100

## Antiseptic Materials

A major challenge to patient and practitioner safety is the increased prevalence of hospital acquired infections and the resulting need for improved antimicrobial technologies. POREX® Barrier Technology™ available in standard bacterial filtration, microbicidal and silver antimicrobial medias is an integrated porous media that helps inhibit microbial growth on product surfaces and kills microbes on contact in liquid and gas streams.

Effective against a wide range of microbes, including gram positive and gram negative bacteria, virus, fungi, algae and spores, POREX® Barrier Technology™ can be applied in medical devices to help reduce infection caused by airborne and blood/fluid contact exposures.

Independent, third party laboratory testing using Japanese Industrial Standard JIS Z2801:2000 /JIS Z2801 to quantify antimicrobial activity levels. Results shown on the left.



### Bone/Tissue Protective Packaging

How well a medical device performs, can depend on how well it vents. POREX® Virtek™ Medical PTFE lyophilization vents are hydrophobic, with high airflow and high Bacterial Filtration Efficiency (BFE). Used as cap liners for bone graft and other tissue containers, POREX® Virtek™ Medical PTFE lyophilization vents provide a sterile barrier with high efficiency venting and help maintain the sterile integrity of bone/tissue grafts.

## Orthopedics

### Adhesive Fume Media

Potentially harmful fumes can result from the bone cement mixing process used in various orthopedic and surgical procedures. POREX® adhesive fume media maximizes the airflow rate from the bone cement mixing chamber and adsorbs and traps monomer fumes to maximize removal of offensive gases prior to discharge in the operating room.

## Urology & Ostomy Care

### Urinary Drainage Bag POREX® Virtek™ Medical PTFE Vents

Urine collection products are gravity dependent with the majority of inpatient products hanging down the side of a hospital bed.

POREX® Virtek™ Medical PTFE Vents are hydrophobic urine collection vents are manufactured utilizing precisely sized geometries and porosities to facilitate press fit assembly solutions, to equalize pressure differences between the drainage bag's interior and exterior regions and to expedite urine disposal during draining procedures.



### Ostomy System POREX® Virtek™ Medical PTFE Vents

POREX® Virtek™ PTFE Vents are hydrophobic and engineered, designed and optimized to allow gases to escape from the ostomy pouch while also preventing water from penetrating the filter during bathing or swimming activities. The continuous venting ostomy material helps stoma product manufacturers design patient friendly ostomy products with improved lifestyle outcomes.



1. Patent #8187534
2. Photo courtesy EuroTec BV- Roosendaal, Netherlands.

**All's well that vents well**

**Porex Corporation** has launched a new porous material portfolio of medical-grade PTFE, with high bacterial filtration efficiency over a wide range of airflows. Medical-grade porous PTFE can be used as specialty vents in medical devices for infection control and fluid management.

**P**orous polymer compositions that are formed by creating polymer particles with a controlled macroporous structure, are used to create porous PTFE membranes. These porous PTFE membranes are used in medical devices for infection control and fluid management. The porous PTFE membranes are formed by creating polymer particles that are formed by creating polymer particles with a controlled macroporous structure, are used to create porous PTFE membranes. These porous PTFE membranes are used in medical devices for infection control and fluid management.

Material	Flow Rate (L/min)	Bacterial Filtration Efficiency (%)	Pressure Drop (mmHg)	Material Thickness (mm)	Material Diameter (mm)
PTFE 100	1.0	99.999	0.1	0.5	100
PTFE 200	2.0	99.999	0.1	0.5	200
PTFE 300	3.0	99.999	0.1	0.5	300
PTFE 400	4.0	99.999	0.1	0.5	400
PTFE 500	5.0	99.999	0.1	0.5	500
PTFE 600	6.0	99.999	0.1	0.5	600
PTFE 700	7.0	99.999	0.1	0.5	700
PTFE 800	8.0	99.999	0.1	0.5	800
PTFE 900	9.0	99.999	0.1	0.5	900
PTFE 1000	10.0	99.999	0.1	0.5	1000

Material specifications may be subject to change.



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