

# POREX® STERILIZING & BIOBURDEN REDUCTION FILTERS

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Since 1961, Porex has been a global leader in porous plastic solutions. Our technological proficiency, commitment to stringent regulatory and quality standards, and dedication to customer service have enabled us to serve many diverse and demanding markets. From advanced filtration media to cutting-edge fluid management, our engineering expertise and extensive global manufacturing network empower our partners to explore new realms of innovation and efficiency. At our core, we strive in everything we do to make the world safer, healthier, and more productive.

Porex BioSolutions is extending this legacy in support of our bioprocessing customers, enabling them to bring life-saving therapies to market quickly and safely.

#### **Our promise:**

- **Validated performance** – Our filters undergo rigorous testing and validation to ensure performance and reliability.
- **Precision manufacturing** – Manufactured in a clean room facility, our filters adhere to ISO9001 and GMP standards. Each filter is integrity tested and comes with a Certificate of Quality.
- **Exceptional service** - We are committed to providing superior service. Through continuous diligence, we maintain short lead times and responsive support to meet your needs efficiently.

## **Porex BioSolutions**

Porex BioSolutions sterilizing grade and bioburden reduction filters are engineered to surpass the highest filtration and microorganism control standards for sterile fluids.

The sterilizing grade filters are validated for bacterial retention of *Brevundimonas diminuta* (ATCC 19146) at test loading of  $10^7$  CFU/cm<sup>2</sup> (Colony Forming Units). Bioburden reduction filters are tested for retention of *Serratia marcescens* (ATCC 14756) removal at test loading of  $10^7$  CFU/cm<sup>2</sup> (Colony Forming Units) with Log Reduction Values of more than 5 (LRV>5).

Filters are produced utilizing a unique multi-pleated configuration integrating asymmetric and hydrophilic polyethersulfone (PES) membrane, single or dual layers format with inert pleat support materials. This multi-pleated approach increases filters' life, strength, durability, and allows multiple steam sterilization cycles without sacrificing product integrity. Remaining components are constructed entirely from 100% polypropylene and assembled by solvent-free thermal bonding. These filters comply with FDA CFR Title 21 and USP Biological Reactivity for Class VI Plastics. Ultrapure components with low protein binding make them ideally suited for microbial control in critical bioprocessing applications.

Our capsule design features an inlet and outlet vent, ensuring confident start-up and secure efficient processing. All Porex BioSolutions capsules are available sterile and non-sterile, and with multiple inlet and outlet fitting configurations.

## Formats

Porex BioSolutions filters are available in a variety of formats and sizes, facilitating the seamless scalability from small volume filtrations to full-scale processes.

- **Cartridges and capsules** are available with asymmetric PES membrane, in sterilizing and bio-bioburden reduction grades.
- **Cartridges:** Available non-sterile in two sizes with effective filtration area (EFA) of 0.28 and 0.63 m<sup>2</sup>. Connection formats are available in flat, fin, 222 and 226 end caps.
- **Capsules:** Available sterile and non-sterile, offered with EFA ranging from 0.095 to 0.63 m<sup>2</sup>. Connection formats are available in multiple sanitary flange fittings (1" and 1.5" for capsules; ¾" and 1" for mini capsules) and multiple hose barb sizes (1/4" and 1/2" for capsules; ¼", 3/8" and ½" for mini capsules).
- **Absolute pore rating:** Available in 0.2/0.2µm and 0.45/0.2µm dual-layer sterilizing grades, as well as 0.2µm, 0.45µm and 0.8µm single-layer bioburden reduction grades as standard configurations. Other sizes/configurations are available upon request.

## Features

- High-capacity, high-flux hydrophilic PES membranes.
- 100% integrity tested, with guaranteed reliability, consistency, and repeatable filtration performance
- Validated for bacteria retention greater than 7 LRV for sterilizing grade filters.
- Expanded surface area and capacity, enhancing process efficiency and economy, resulting in a longer service life, reduced change-outs, and decreased operating costs.
- Superior throughput in challenging, high fouling streams, including those containing media and proteins.
- 100% thermally bonded materials, incorporating ultrapure polypropylene supporting materials to minimize leachables, eliminate fiber migration and shedding.
- Broad chemical compatibility across a wide pH range (1-14), making it compatible with caustic solutions.
- Materials comply with safety and biocompatibility requirements including CFR Title 21 (include BSE/

## Applications

- Buffers
- Cell culture media, supplements, additives and feeds
- CIP and WFI water
- Harvest clarification and intermediate process steps of Biotherapeutics including mAbs, recombinant proteins, vaccines, viral vectors, etc
- Plasma and serum
- Chromatography protection - packed resin & membrane
- Small volume parenteral (SVP)
- Large volume parenteral (LVP)

## Quality

Every Porex BioSolutions filter is:

- 100% integrity tested
- Identified by lot for traceability
- Meets USP<88> Biological Reactivity test in vivo, for class VI plastics
- Meets the criteria for extractables per USP Physiochemical Tests for Plastics, and USP Oxidizable Substances.
- Non-cytotoxic per MEM elution ISO® 10993-5
- Meets the criteria for a non-fiber releasing filter per 21 CFR 210.3 (b)(6)
- Pass USP <85> Bacteria Endotoxins (< 0.25 EU/mL)

TSE and fiber shedding), ROHS, REACH, in vitro cytotoxicity (ISO® 10993-5), USP Class VI and low extractables standards.

- Sterilization options are available. Capsules can be provided pre-sterilized by Gamma irradiation. Non-sterile capsules and cartridges can be sterilized by steam or autoclave.
- Validation Guide is available upon request, providing comprehensive information on the product's performance and capabilities.

# SRC Product Family for Sterile Filtration

SRC 0.2-0.2							
		SRC Mini 1SFT Capsule	SRC Mini 2SFT Capsule	SRC 5" Capsule	SRC 10" Capsule	SRC 5" Cartridge	SRC 10" Cartridge
General	Grade	Sterilizing					
	Absolute Pore Rating	0.2 µm					
	Maximum Length	6.0" (152mm) w/ hosebard inlet/outlet 5.0" (127mm) w/ sanitary flange inlet/outlet	7.7" (196mm) w/ hosebard inlet/outlet 6.6" (168mm) w/ sanitary flange inlet/outlet	5" (12.7cm)	10" (25.4cm)	5" (12.7cm)	10" (25.4cm)
	Body Diameter	The widest point on the body not including the vent/drain is 86.4 mm diameter		8.89 cm	8.89 cm	6.87 cm	6.87 cm
	Filtration Area	948 cm <sup>2</sup>	1,728 cm <sup>2</sup>	0.28 m <sup>2</sup>	0.60 m <sup>2</sup>	0.28 m <sup>2</sup>	0.60 m <sup>2</sup>
	Filter Membrane	Dual layer PES					
	Pleat Support Material	Polypropylene					
	End Caps/Cage/Core	Polypropylene					
	Reinforcing Ring						316 Stainless Steel
	Seals	Silicone, Buna N, Viton, EPDM					
Functional	Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology					
	Water Flow Rate	typical ≈0.5 LPM at 50 mbar with sanitary flange fittings	typical ≈1.0 LPM at 50 mbar with sanitary flange fittings	typical ≈4.5 LPM at 100 mbar with sanitary flange fittings	typical ≈9.5 LPM at 100 mbar with sanitary flange fittings	typical ≈4.5 LPM at 100 mbar	typical ≈9.5 LPM at 100 mbar
	Max. Operating Temp.	82°C continuous duty					
	Max. Operating Pressure	70 psi @ 21.1°C					
	Max. Differential Pressure (Forward)			75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C
	Max. Differential Pressure (Reverse)			50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C
	Bubble Point (water)	≥ 49 psi					
	Air Diffusion	max 2.8 mL/min @ 40 psig	max 5 mL/min @ 40 psig	max 7.15 mL/min @ 40 psig	max 16 mL/min @ 40 psig	max 7.15 mL/min @ 40 psig	max 16 mL/min @ 40 psig
Chemical	Non Volatile Residue	Pass with USP limit of <15mg					
	Heavy Metals	Pass with USP limit of <1ppm					
	Residue on Ignition	Pass with USP limit of <5mg					
	Buffering Capacity	Pass with USP limit of <10ml					
	USP Oxidizable Substances	Pass					
Biological	USP Cytotoxicity	Non-toxic per MEM elution ISO® 10993-5					
	Biological Reactivity - In Vivo	Meet the criteria of the USP <88> Reactivity Test for Class VI plastics					
	Bacteria Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test					
	Indirect Food Additive	Cartridge/capsule materials meet CFR 21 for food and beverage contact					
Regulatory	Animal Origin Free	Yes					
	TSE/BSE Statement	Yes					
	REACH	Yes					
Sterilization Validation	In-Line Steam	Not Compatible				20 times x 60 min, 125°C @ <3psid	
	Autoclave	3 times x 60min				20 times x 60 min, 125°C @ <3psid	
	Gamma	Compatible				Compatible, recommend max 27.5kGy	

# SCW Product Family for Sterile Filtration

SCW 0.45-0.2							
		SCW Mini 1SFT Capsule	SCW Mini 2SFT Capsule	SCW 5" Capsule	SCW 10" Capsule	SCW 5" Cartridge	SCW 10" Cartridge
General	Grade	Sterilizing					
	Absolute Pore Rating	0.2 µm					
	Maximum Length	152 mm with hosebard inlet/outlet 127 mm with sanitary flange inlet/outlet	196 mm with hosebard inlet/outlet 168 mm with sanitary flange inlet/outlet	12.7 cm	25.4 cm	12.7 cm	25.4 cm
	Body Diameter	The widest point on the body not including the vent/drain is 86.4 mm diameter		8.89 cm	8.89 cm	6.87 cm	6.87 cm
	Filtration Area	948 cm <sup>2</sup>	1,728 cm <sup>2</sup>	0.28 m <sup>2</sup>	0.60 m <sup>2</sup>	0.28 m <sup>2</sup>	0.60 m <sup>2</sup>
	Filter Membrane	Dual layer PES					
	Pleat Support Material	Polypropylene					
	End Caps/Cage/Core	Polypropylene					
	Reinforcing Ring						316 Stainless Steel
	Seals	Silicone, Buna N, Viton, EPDM					
Functional	Bacterial Retention	Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology					
	Water Flow Rate	est. 0.8 LPM @ 50 mbar with sanitary flange fittings	est. 1.5 LPM @ 50 mbar with sanitary flange fittings	est. 5.4 LPM @ 100 mbar with sanitary flange fittings	est 12 LPM @ 100 mbar with sanitary flange fittings	>5.4 LPM @ 100 mbar	>12 LPM @ 100 mbar
	Max. Operating Temp.	82°C continuous duty					
	Max. Operating Pressure	70 psi @ 21.1°C					
	Max. Differential Pressure (Forward)			75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C
	Max. Differential Pressure (Reverse)			50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C
	Bubble Point (water)	≥ 49 psi					
	Air Diffusion	max 4 mL/min @ 40psig	max 7 mL/min @ 40psig	max 11.6 mL/min @ 40 psig	max 26 mL/min @ 40 psig	max 11.6 mL/min @ 40 psig	max 26 mL/min @ 40 psig
Chemical	Non Volatile Residue	Pass with USP limit of <15mg					
	Heavy Metals	Pass with USP limit of <1ppm					
	Residue on Ignition	Pass with USP limit of <5mg					
	Buffering Capacity	Pass with USP limit of <10ml					
	USP Oxidizable Substances	Pass					
Biological	USP Cytotoxicity	Non-toxic per MEM elution ISO® 10993-5					
	Biological Reactivity - In Vivo	Meet the criteria of the USP <88> Reactivity Test for Class VI plastics					
	Bacteria Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test					
	Indirect Food Additive	Cartridge/capsule materials meet CFR 21 for food and beverage contact					
Regulatory	Animal Origin Free	Yes					
	TSE/BSE Statement	Yes					
	REACH	Yes					
Sterilization Validation	In-Line Steam	Not Compatible				20 times x 60 min, 125°C @ <3psid	
	Autoclave	3 times x 60min				20 times x 60 min, 125°C @ <3psid	
	Gamma	Compatible				Compatible, recommend max 27.5kGy	

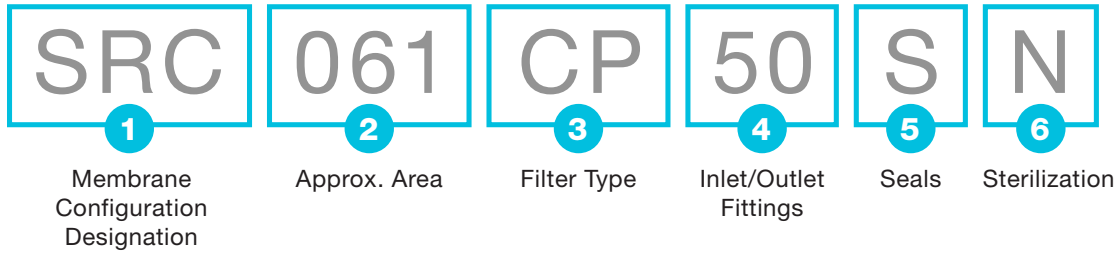
# BHS Product Family for Bioburden Reduction

BHS 0.2							
		BHS Mini 1SFT Capsule	BHS Mini 2SFT Capsule	BHS 5" Capsule	BHS 10" Capsule	BHS 5" Cartridge	BHS 10" Cartridge
General	Grade	Bioburden Reduction					
	Absolute Pore Rating	0.2 µm					
	Maximum Length	152 mm with hosebard inlet/outlet 127 mm with sanitary flange inlet/outlet	196 mm with hosebard inlet/outlet 168 mm with sanitary flange inlet/outlet	12.7 cm	25.4 cm	12.7 cm	25.4 cm
	Body Diameter	The widest point on the body not including the vent/drain is 86.4 mm diameter		8.89 cm	8.89 cm	6.87 cm	6.87 cm
	Filtration Area	1,189 cm <sup>2</sup>	2,155 cm <sup>2</sup>	0.28 m <sup>2</sup>	0.63 m <sup>2</sup>	0.28 m <sup>2</sup>	0.63 m <sup>2</sup>
	Filter Membrane	Single Layer PES					
	Pleat Support Material	Polypropylene					
	End Caps/Cage/Core	Polypropylene					
	Reinforcing Ring						316 Stainless Steel
	Seals	Silicone, Buna N, Viton, EPDM					
Functional	Bacterial Retention	LRV>5 Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Brevundimonas diminuta</i> ATCC® 19146 per ASTM® F838 methodology					
	Water Flow Rate	typical ≈1 LPM at 50 mbar with sanitary flange fittings	typical ≈ 2 LPM at 50 mbar with sanitary flange fittings	typical ≈8.5 LPM at 100 mbar with sanitary flange fittings	typical ≈ 18.9 LPM at 100 mbar with sanitary flange fittings	typical ≈ 8.5 LPM at 100 mbar	>18.9 LPM at 100 mbar
	Max. Operating Temp.	82°C continuous duty					
	Max. Operating Pressure	70 psi @ 21.1°C					
	Max. Differential Pressure (Forward)			75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C
	Max. Differential Pressure (Reverse)			50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C
	Bubble Point (water)	≥ 49 psi					
	Air Diffusion	max 18 mL/min @ 40 psig	max 33 mL/min @ 40 psig	max 45 mL/min @ 40 psig	max 100 mL/min @ 40 psig	max 45 mL/min @ 40 psig	max 100 mL/min @ 40 psig
	Chemical	Non Volatile Residue	Pass with USP limit of <15mg				
Heavy Metals		Pass with USP limit of <1ppm					
Residue on Ignition		Pass with USP limit of <5mg					
Buffering Capacity		Pass with USP limit of <10ml					
USP Oxidizable Substances		Pass					
Biological	USP Cytotoxicity	Non-toxic per MEM elution ISO® 10993-5					
	Biological Reactivity - In Vivo	Meet the criteria of the USP <88> Reactivity Test for Class VI plastics					
	Bacteria Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test					
	Indirect Food Additive	Cartridge/capsule materials meet CFR 21 for food and beverage contact					
Regulatory	Animal Origin Free	Yes					
	TSE/BSE Statement	Yes					
	REACH	Yes					
Sterilization Validation	In-Line Steam	Not Compatible				20 times x 60 min, 125°C @ <3psid	
	Autoclave	3 times x 60min				20 times x 60 min, 125°C @ <3psid	
	Gamma	Compatible				Compatible, recommend max 27.5kGy	

# BTG Product Family for Bioburden Reduction

BTG 0.45							
		BTG Mini 1SFT Capsule	BTG Mini 2SFT Capsule	BTG 5" Capsule	BTG 10" Capsule	BTG 5" Cartridge	BTG 10" Cartridge
General	Grade	Bioburden Reduction					
	Absolute Pore Rating	0.45 µm					
	Maximum Length	152 mm with hosebard inlet/outlet 127 mm with sanitary flange inlet/outlet	196 mm with hosebard inlet/outlet 168 mm with sanitary flange inlet/outlet	12.7 cm	25.4 cm	12.7 cm	25.4 cm
	Body Diameter	The widest point on the body not including the vent/drain is 86.4 mm diameter		8.89 cm	8.89 cm	6.87 cm	6.87 cm
	Filtration Area	1,189 cm <sup>2</sup>	2,155 cm <sup>2</sup>	0.28 m <sup>2</sup>	0.63 m <sup>2</sup>	0.28 m <sup>2</sup>	0.63 m <sup>2</sup>
	Filter Membrane	Single layer PES					
	Pleat Support Material	Polypropylene					
	End Caps/Cage/Core	Polypropylene					
	Reinforcing Ring						316 Stainless Steel
	Seals	Silicone, Buna N, Viton, EPDM					
Functional	Bacterial Retention	LRV>5 Quantitative retention of 10 <sup>7</sup> CFU/cm <sup>2</sup> <i>Serratia marcescens</i> ATCC® 14756 per ASTM® F838 methodology					
	Water Flow Rate	typical ≈1.7 LPM at 50 mbar with sanitary flange fittings	typical ≈3.5 LPM at 50 mbar with sanitary flange fittings	typical ≈15 LPM at 100 mbar with sanitary flange fittings	>33.4 LPM @ 100 mbar with sanitary flange fittings	typical ≈15 LPM at 100 mbar	>33.4 LPM at 100 mbar
	Max. Operating Temp.	82°C continuous duty					
	Max. Operating Pressure	70 psi @ 21.1°C					
	Max. Differential Pressure (Forward)			75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C	75 psid (5.1 bar) @ 24°C 40 psid (2.8 bar) @ 82°C
	Max. Differential Pressure (Reverse)			50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C	50 psid (3.4 bar) @ 24°C
	Bubble Point (water)	≥ 38 psi					
	Air Diffusion	max 18 mL/min @ 30 psig	max 33 mL/min @ 30 psig	max 45 mL/min @ 30 psig	max 100 mL/min @ 30 psig	max 45 mL/min @ 30 psig	max 100 mL/min @ 30 psig
	Chemical	Non Volatile Residue	Pass with USP limit of <15mg				
Heavy Metals		Pass with USP limit of <1ppm					
Residue on Ignition		Pass with USP limit of <5mg					
Buffering Capacity		Pass with USP limit of <10ml					
USP Oxidizable Substances		Pass					
Biological	USP Cytotoxicity	Non-toxic per MEM elution ISO® 10993-5					
	Biological Reactivity - In Vivo	Meet the criteria of the USP <88> Reactivity Test for Class VI plastics					
	Bacteria Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test					
	Indirect Food Additive	Cartridge/capsule materials meet CFR 21 for food and beverage contact					
Regulatory	Animal Origin Free	Yes					
	TSE/BSE Statement	Yes					
	REACH	Yes					
Sterilization Validation	In-Line Steam	Not Compatible				20 times x 60 min, 125°C @ <3psid	
	Autoclave	3 times x 60min				20 times x 60 min, 125°C @ <3psid	
	Gamma	Compatible				Compatible, recommend max 27.5kGy	

# Nomenclature



## Membrane Configuration Designation

### 1 SRC - 0.2/0.2 Hydrophilic PES

- SCW - 0.45/0.2 Hydrophilic PES
- BHS - 0.2 Hydrophilic PES
- BTG - 0.45 Hydrophilic PES
- BRH - 0.8 Hydrophilic PES

## Approx. Area (m<sup>2</sup>)

- 009
- 017
- 030
- 032
- 2 061**
- 063

## Filter Type

- CR - Cartridge

### 3 CP - Capsule

## Inlet/Outlet Fittings

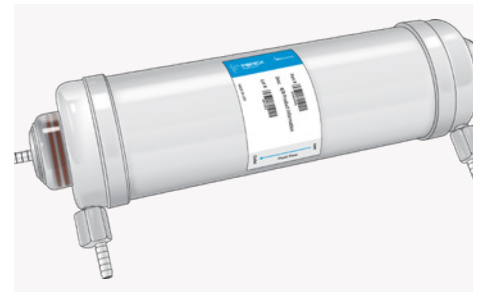
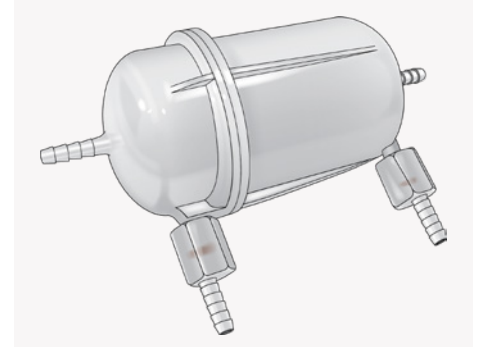
- 10 - Flat/222
- 11 - Flat/226
- 12 - Fin/222
- 13 - Fin/226
- 4 50 - 0.25" HB**
- 51 - 0.375" HB
- 52 - 0.5" HB
- 53 - Stepped HB
- 80 - 0.75" Sanitary
- 81 - 1"/1.5" Sanitary

## Seals

- 5 S - Silicone**
- B - Buna N
- V - Viton
- E - EPDM

## Sterilization

- 6 N - Non Sterile**
- G - Gamma



For technical information including performance guide, instructions for use, and certificate of quality, please visit our website.

## CONTACT US

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