Supor™ Prime

STERILIZING GRADE FILTERS

The filtration of complex biotech drug formulations, such as high-concentration mAbs and encapsulated products, comes with unique challenges. These can include premature blocking due to high particulate loads, high differential pressures due to high viscosities, and risk of bacterial penetration. These challenges result in a need for larger filters or additional filters, leading to increased hold-up volume and higher product loss.

Supor™ Prime sterilizing grade filters have been developed to meet these challenges. The high throughput of Supor Prime filters allows for reduced filtration area. By reducing the filter area, a smaller filter can be used resulting in increased product recovery per batch.

Supor Prime filters are best suited for sterile filtration in the most critical process steps: post ultrafiltration/diafiltration (UF/DF), bulk fill of drug substance, and final fill of drug product.

Benefits of Supor Prime filters

- Higher throughput and flow rate proven in feeds up to 220 g/L and 30 cP.
- Reduced filter sizing that can lead to increased product recovery.
- Low adsorption of active ingredients and excipients.
- Available in a range of scalable formats to grow with your process, from clinical development to licensed drug manufacture.
- Comprehensive regulatory dossier.

Fig 1. Supor Prime sterilizing grade filters, available in a range of filter cartridge and Kleenpak™ Spectrum capsule formats.

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Filter formats

Supor Prime filters are offered in a range of filter formats and sizes, designed to support all development stages from benchtop testing to clinical trials and full scale good manufacturing practices (GMP) manufacture:
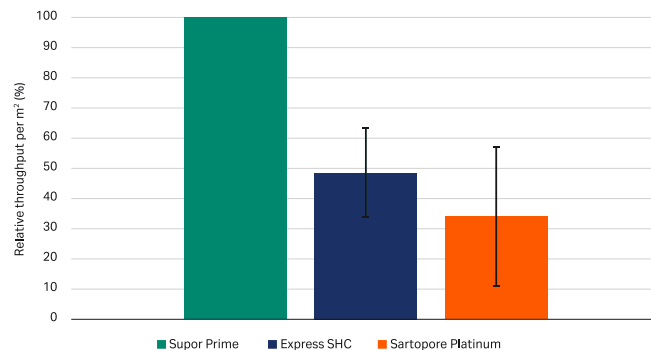
- Small Kleenpak Spectrum capsules and 47 mm discs to support filterability studies.
- Medium Kleenpak Spectrum capsules suitable for single-use applications. With a filter area of 240 cm² this format is typically used for volumes of > 1 L.
- Large Kleenpak Spectrum capsules suitable for single-use applications, available in four different areas ranging from 0.6 to 4 m² this format is typically used for volumes from 10 to > 100 L.
- Traditional cartridges ranging from 0.6 to 4 m² to support stainless steel applications.

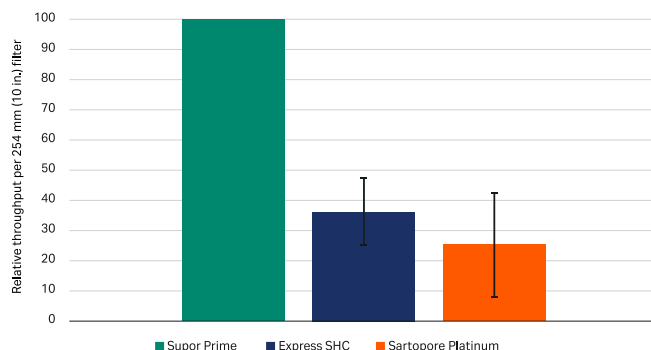## Benefits of Kleenpak Spectrum capsules

- High temperature and pressure rating to ensure robustness.
- Easy to use vent and drain valve.
- Scalable through all capsule sizes.

Achieve higher yield by ensuring less product lost to waste or as non-recoverable volume

Supor Prime filters deliver twice the volumetric throughput when compared to similar competitor filters. This provides operational benefits associated with smaller filters such as increased yield and reduced water consumption, alongside the environmental benefits of reduced shipping and disposal weights.

Fig 2. Average relative throughput performance per m² of membrane compared to Supor Prime membrane. Error bars represent one standard deviation of the mean. The difference in the mean is highly significant (p<0.01) for both Express SHC (n=17) and Sartopore Platinum (n=17) using a two-tailed paired Student's t-test. Results for individual feeds will vary.

Fig 3. Average relative throughput per 254 mm (10 in.) filter when compared to Supor Prime filter. Each data point is scaled using published filtration areas. Error bars represent one standard deviation of the mean. The difference in the mean is highly significant (p<0.01) for both Express SHC (n=17) and Sartopore Platinum (n=17) using a two-tailed paired Student's t-test. Results for individual feeds will vary.

Product specifications

Supor Prime sterilizing grade filters	Kleenpak Spectrum filter capsules			Filter cartridges
	Small capsule (filterability tool)	Medium capsule	Large capsule	Cartridge
Product code prefix	DC3	MC200	FC	AB
Nominal effective filter area (EFA)	3.0 cm²	240 cm²	FC5 – 0.61 m² FC6 – 1.34 m² FC7 – 2.68 m² FC8 – 4.02 m²	AB05 – 0.61 m² AB1 – 1.34 m² AB2 – 2.68 m² AB3 – 4.02 m²
Removal rating	0.2 µm sterilizing-grade	0.2 µm sterilizing-grade	0.2 µm sterilizing-grade	0.2 µm sterilizing-grade
Filter element size	N/A	N/A	FC5 – 127 mm (5 in.) FC6 – 254 mm (10 in.) FC7 – 508 mm (20 in.) FC8 – 762 mm (30 in.)	AB05 – 127 mm (5 in.) AB1 – 254 mm (10 in.) AB2 – 508 mm (20 in.) AB3 – 762 mm (30 in.)

Materials of construction	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule	Filter cartridges
Filter membrane	Polyethersulfone (PES)	PES	PES	PES
Support and drainage	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Filter hardware	Polypropylene Polypropylene with TiO$_2$ whitener [1] Polypropylene/polyethelene copolymer (luer cap)	Polypropylene Polypropylene with TiO$_2$ whitener [1] Polypropylene/polyethylene copolymer with titanium dioxide (TiO$_2$) whitener [1]	Polypropylene Polypropylene with TiO$_2$ whitener [1] Polypropylene/polyethylene copolymer with titanium dioxide (TiO$_2$) whitener [1]	Polypropylene Polypropylene with TiO$_2$ whitener [1]
O-rings	Silicone elastomer	Silicone elastomer	Silicone elastomer	Silicone elastomer
Sealing technology	Thermal bonding	Thermal bonding	Thermal bonding	Thermal bonding

Non-product contact materials

Capsule valve actuator	N/A	Polybutylene terephthalate (PBT)	PBT	N/A

[1] TiO$_2$ is an insoluble inorganic mineral filler that does not contribute to organic extractables.

Operating conditions [2]	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule	Filter cartridges
Maximum differential pressure (forward direction)	1 bar (14.5 psi) at 20°C [3]	4.1 bar (60 psi) at 40°C [4]	5.0 bar (73 psi) at 40°C	5.0 bar (73 psi) at 40°C 3.0 bar (44 psi) at 80°C
Maximum operating pressure (capsule)	6.5 barg (94 psig) at 60°C [3]	6.5 barg (94 psig) at 60°C [4]	6.5 barg (94 psig) at 60°C [4]	N/A

[2] In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction
[3] Based on 12 h maximum continuous service
[4] Based on 24 h maximum continuous service

Sterilization compatibility	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule	Filter cartridges
Autoclave	1 × 30 minutes at 135°C	3 × 30 minutes at 135°C	2 × 60 minutes at 135°C	2 × 60 minutes at 135°C
In-situ steam	Not supported [5]	Not supported [5]	Not supported [5]	Dry: 2 × 60 minutes at 135°C Wet: 10 × 30 minutes at 135°C
Maximum differential pressure in the forward direction during steaming	Not supported [5]	Not supported [5]	Not supported [5]	300 mbar
Gamma-irradiation	Up to 50 kGy [6]	Up to 50 kGy [6]	Up to 50 kGy [6]	Not supported

[5] Capsules **must not** be sterilized *in-situ* by passing steam under pressure.
[6] Pre-irradiated Kleenpak Spectrum capsules must not be re-sterilized.

Extractables [7]	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule	Filter cartridges
Typical non-volatile residue (NVR) extractables in water [8]	N/A	< 3 mg	FC5 < 32 mg FC6 < 65 mg FC7 < 130 mg FC8 < 185 mg	AB05 < 32 mg AB1 < 65 mg AB2 < 130 mg AB3 < 185 mg
Compound specific extractables	Qualitative assessment available per BioPhorum Operations Group standard [9]			

[7] Tested on filters without pre-flushing, post-irradiation or post autoclave.
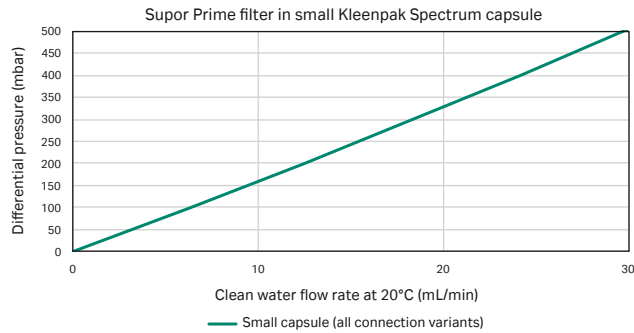[8] Measured following a 24 h extraction in water at 20°C.
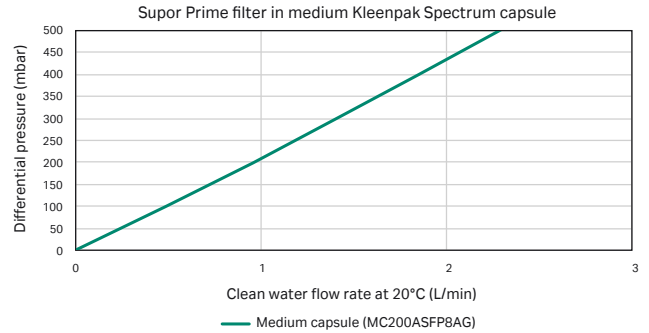[9] Full report available on request.

Integrity test values (test gas air; water wet)	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule	Filter cartridges
Forward flow test pressure	N/A	3.6 bar (52 psi)	3.6 bar (52 psi)	3.6 bar (52 psi)
Maximum forward flow value	N/A	0.9 mL/min	FC5 – 22 mL/min FC6 – 44 mL/min FC7 – 88 mL/min FC8 – 132 mL/min	AB05 – 22 mL/min AB1 – 44 mL/min [10] AB2 – 88 mL/min [10] AB3 – 132 mL/min [10]
Minimum bubble point pressure value	N/A	4.15 bar (60 psi)	4.15 bar (60 psi)	4.15 bar (60 psi)

[10] Contact us for multi-element integrity test values or other fluid values and recommended test procedures including flushing guidelines.
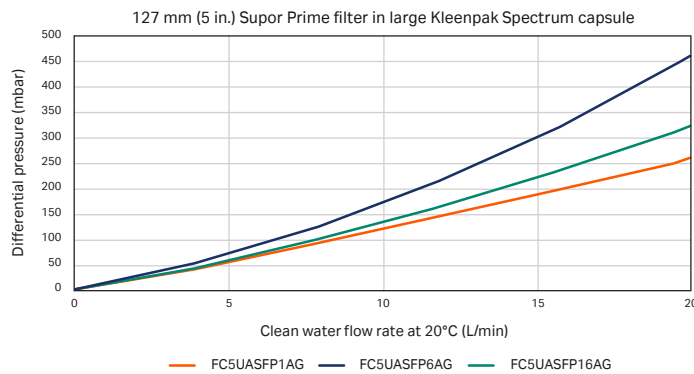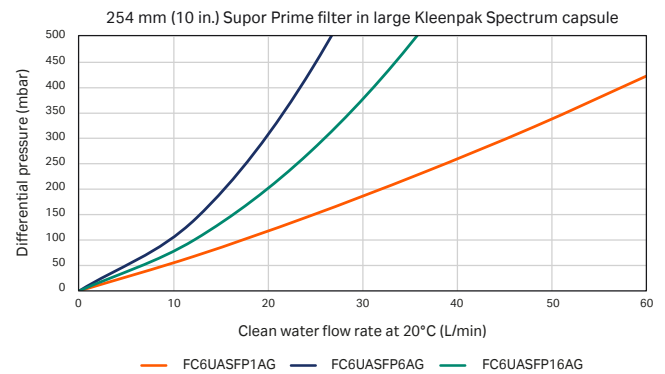
Typical water flow rates

Fig 4. Typical clean water flow vs differential pressure for Supor Prime filter in small Kleenpak Spectrum capsule (all connection variants).
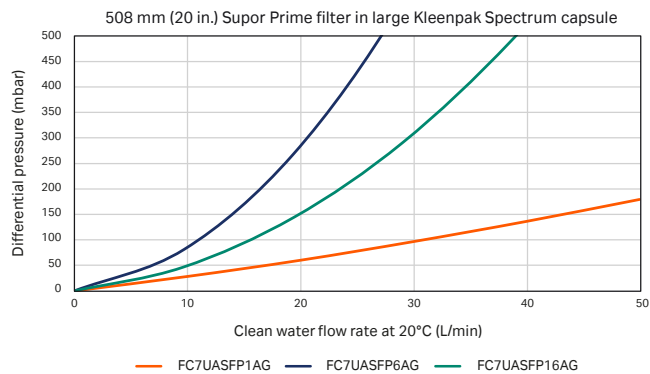

Fig 5. Typical clean water flow vs differential pressure for Supor Prime filter in medium Kleenpak Spectrum capsule.
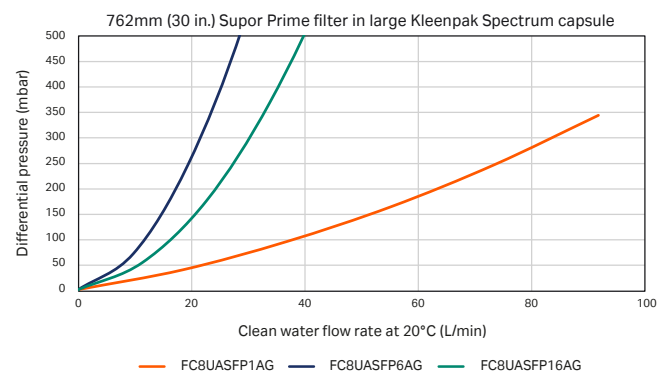

Fig 6. Typical clean water flow for 127 mm (5 in.) Supor Prime filter in large Kleenpak Spectrum capsule.

Fig 7. Typical clean water flow for 254 mm (10 in.) Supor Prime filter in large Kleenpak Spectrum capsule.
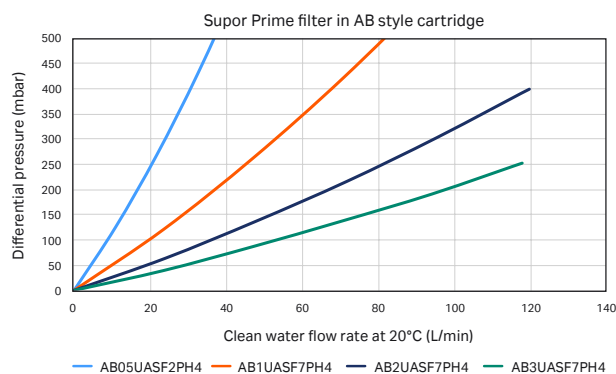

Fig 8. Typical clean water flow for 508 mm (20 in.) Supor Prime filter in large Kleenpak Spectrum capsule.

Fig 9. Typical clean water flow for 762 mm (30 in.) Supor Prime filter in large Kleenpak Spectrum capsule.

Fig 10. Typical clean water flow for Supor Prime filter in AB style cartridge.

Capsule connections	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule
Vent	Female luer connection with protective cap	Stäubli connector with integral valve	Stäubli connector with integral valve
Drain	N/A	N/A	Stäubli connector with integral valve
Inlet option	¼ in. hose barb or ½ in. sanitary flange [11]	¼ in. hose barb or ½ in. sanitary flange [11]	½ in. hose barb or 1½ in. sanitary flange [11]
Outlet options	¼ in. hose barb	¼ in. hose barb or ½ in. sanitary flange [11]	½ in. hose barb or 1½ in. sanitary flange [11]

[11] To American Society of Mechanical Engineers bioprocessing equipment (ASME BPE) 2014, table DT-7-1, type A.

Cartridge configuration	Code 2	Code 7
Open end	Double 226 O-rings with bayonet lock	Double 226 O-rings with bayonet lock
Closed end	Flat end cap	Locating fin

Capsule connections	Kleenpak Spectrum small capsule (filterability tool)	Kleenpak Spectrum medium capsule	Kleenpak Spectrum large capsule
Laser marking of product	Alphanumeric part, lot and serial number 2D barcode (GS1 data matrix) including part, lot and serial number		
Primary packaging and outer box	Label includes product family name, part number, lot number, quantity, manufacturing date and 2D barcode (GS1 data matrix) including part number and lot number		

Ordering information

Disc membrane

Description	EFA	Product code
47 mm disc for filterability trials (box of 25 discs)	Holder dependent	FTKASF

Small capsule

Autoclavable/gamma irradiation compatible

Description	EFA	Product code
Supor Prime filter in small Kleenpak Spectrum capsule ¼ in. hose barb inlet and outlet – pack of 3 (filterability tool)	3.0 cm²	DC3ASFP2LGFT
Supor Prime filter in small Kleenpak Spectrum capsule ½ in. sanitary flange inlet and ¼ in. hose barb outlet – pack of 3 (filterability tool)	3.0 cm²	DC3ASFP82LGFT

Pre-sterilized by gamma irradiation

Description	EFA	Product code
Supor Prime filter in small Kleenpak Spectrum capsule ¼ in. hose barb inlet and outlet – pack of 3 (filterability tool)	3.0 cm²	DC3ASFP2LSFT
Supor Prime filter in small Kleenpak Spectrum capsule ½ in. sanitary flange inlet and ¼ in. hose barb outlet – pack of 3 (filterability tool)	3.0 cm²	DC3ASFP82LSFT

Medium capsule

Autoclavable/gamma irradiation compatible

Description	EFA	Product code
Supor Prime filter in medium Kleenpak Spectrum capsule ¼ in. hose barb inlet and outlet – pack of 3	240 cm²	MC200ASFP2AG
Supor Prime filter in medium Kleenpak Spectrum capsule ½ in. sanitary flange inlet and outlet – pack of 3	240 cm²	MC200ASFP8AG
Supor Prime filter in medium Kleenpak Spectrum capsule ½ in. sanitary flange inlet and ¼ in. hose barb outlet – pack of 3	240 cm²	MC200ASFP82AG

Pre-sterilized by gamma irradiation

Description	EFA	Product code
Supor Prime filter in medium Kleenpak Spectrum capsule ¼ in. hose barb inlet and outlet – pack of 3	240 cm²	MC200ASFP2AS
Supor Prime filter in medium Kleenpak Spectrum capsule ½ in. sanitary flange inlet and outlet – pack of 3	240 cm²	MC200ASFP8AS
Supor Prime filter in medium Kleenpak Spectrum capsule ½ in. sanitary flange inlet and ¼ in. hose barb outlet – pack of 3	240 cm²	MC200ASFP82AS

Large capsule

Autoclavable/gamma irradiation compatible

Description	Nominal filter length	EFA	Product code
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	127 mm (5 in.)	0.61 m²	FC5UASFP1AG
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	127 mm (5 in.)	0.61 m²	FC5UASFP6AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	127 mm (5 in.)	0.61 m²	FC5UASFP16AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	254 mm (10 in.)	1.34 m²	FC6UASFP1AG
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	254 mm (10 in.)	1.34 m²	FC6UASFP6AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	254 mm (10 in.)	1.34 m²	FC6UASFP16AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	508 mm (20 in.)	2.68 m²	FC7UASFP1AG
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	508 mm (20 in.)	2.68 m²	FC7UASFP6AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	508 mm (20 in.)	2.68 m²	FC7UASFP16AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	762 mm (30 in.)	4.02 m²	FC8UASFP1AG
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	762 mm (30 in.)	4.02 m²	FC8UASFP6AG
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	762 mm (30 in.)	4.02 m²	FC8UASFP16AG

Pre-sterilized by gamma irradiation

Description	Nominal filter length	EFA	Product code
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	127 mm (5 in.)	0.61 m²	FC5UASFP1AS
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	127 mm (5 in.)	0.61 m²	FC5UASFP6AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	127 mm (5 in.)	0.61 m²	FC5UASFP16AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	254 mm (10 in.)	1.34 m²	FC6UASFP1AS
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	254 mm (10 in.)	1.34 m²	FC6UASFP6AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	254 mm (10 in.)	1.34 m²	FC6UASFP16AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	508 mm (20 in.)	2.68 m²	FC7UASFP1AS
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	508 mm (20 in.)	2.68 m²	FC7UASFP6AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	508 mm (20 in.)	2.68 m²	FC7UASFP16AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and outlet	762 mm (30 in.)	4.02 m²	FC8UASFP1AS
Supor Prime filter in large Kleenpak Spectrum capsule ½ in. hose barb inlet and outlet	762 mm (30 in.)	4.02 m²	FC8UASFP6AS
Supor Prime filter in large Kleenpak Spectrum capsule 1½ in. sanitary flange inlet and ½ in. hose barb outlet	762 mm (30 in.)	4.02 m²	FC8UASFP16AS

Filter cartridges

Description	Nominal filter length	EFA	Product code
Supor Prime filter cartridge Double O-ring (silicone elastomer), bayonet lock and flat end (code 2)	127 mm (5 in.)	0.61 m²	AB05UASF2PH4
Supor Prime filter cartridge Double O-ring (silicone elastomer), bayonet lock and fin (code 7)	254 mm (10 in.)	1.34 m²	AB1UASF7PH4
Supor Prime filter cartridge Double O-ring (silicone elastomer), bayonet lock and fin (code 7)	508 mm (20 in.)	2.68 m²	AB2UASF7PH4
Supor Prime filter cartridge Double O-ring (silicone elastomer), bayonet lock and fin (code 7)	762 mm (30 in.)	4.02 m²	AB3UASF7PH4

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