

## Depth Filtration

### BECODISC® BP Range

#### Stacked Disc Cartridges for the Pharmaceutical Industry

**BECODISC BP stacked disc cartridges meet the high demands of the pharmaceutical industry. Exceptionally pure raw materials and a special production method produce BECODISC BP stacked disc cartridges with low endotoxin content. The special characteristic of this range is high endotoxin retention during the filtration of many pharmaceutical products.**

The specific advantages of BECODISC BP stacked disc cartridges:

- High endotoxin retention as well as a maximum germ retention rate.
- The innovative production process guarantees an endotoxin content of less than < 0.125 EU/ml.
- Maximum raw material purity for minimum migration of soluble ions.
- The ideal combination of various filtration mechanisms (surface, adsorption, depth filtration) and adsorptive properties ensures maximum reliability.
- Comprehensive quality assurance for all raw and auxiliary materials and intensive in-process controls ensure consistent quality of the finished products.
- Prior to delivery, the pyrogen content of < 0.125 EU/ml of all BECODISC BP stacked disc cartridges is tested with the help of an LAL test. A certificate is available on request.
- A Validation Guide is available upon request.

#### Microbial Reduction and Removal

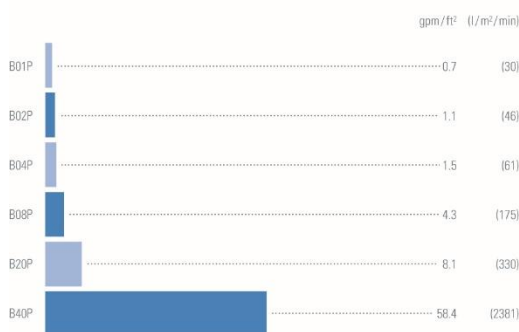
##### BECODISC B01P, B02P, B04P

BECODISC stacked disc cartridges boast high microbial retention rates achieved through the tight-pored structure and an electrokinetic potential with an adsorptive effect.

These stacked disc cartridges are characterized by high endotoxin retention rates. Due to their great retention capacity for colloidal components, these filter sheets are particularly suitable as prefilters for subsequent membrane filtration.



Water throughput BECODISC BP range



Conditions: Δp = 14.5 psi (100 kPa, 1 bar), Medium: Water at 68 °F (20 °C)

#### Fine Filtration

##### BECODISC B08P

BECODISC stacked disc cartridges for achieving a high degree of clarification. These stacked disc cartridges reliably retain ultra-fine particles and provide bioburden reduction.

In practice, these depth filter sheets serve as ideal prefilters for protection of membrane filters, reverse osmosis systems, and to protect chromatography columns.

#### Clarifying Filtration and Coarse Filtration

##### BECODISC B20P, B40P

BECODISC stacked disc cartridges with a large-volume pore structure. These stacked disc cartridges have a high dirt holding capacity for particles and are very suitable for clarifying filtration applications.



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## Physical Data

This information is intended as a guideline for the selection of BECODISC stacked disc cartridges. The water throughput is a laboratory value characterizing the different BECO depth filter sheets. It is not the recommended flow rate.

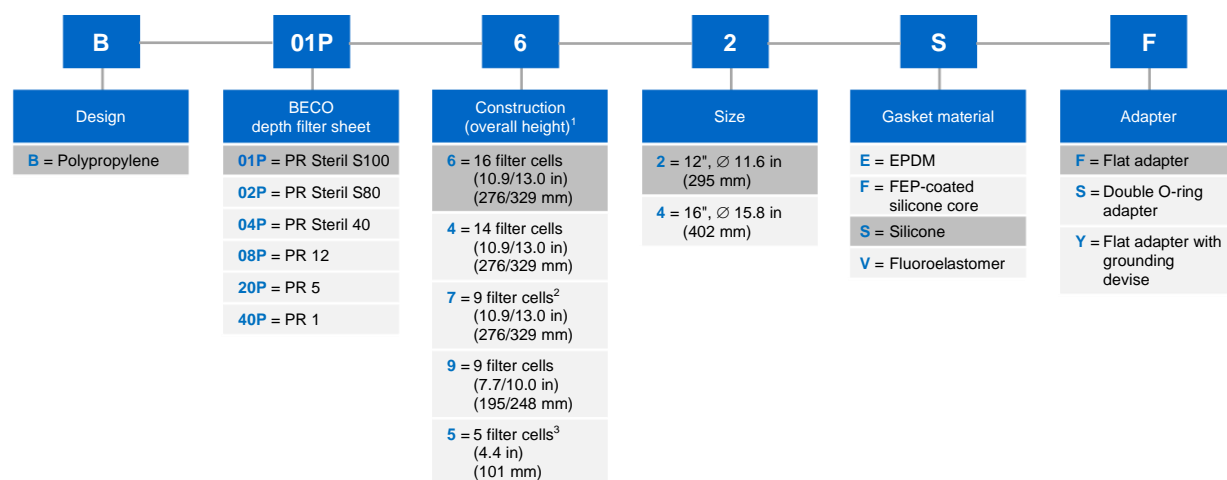
Type*	Utilized BECO® depth filter sheet	Nominal retention rate µm	Thickness		Ash content %	Bursting strength wet		Water throughput at		Endotoxin content*** EU/ml
			in	(mm)		psi	(kPa**)	Δ p = 14.5 psi gpm/ft <sup>2</sup>	(Δ p = 100 kPa** l/m <sup>2</sup> /min)	
B01P	PR Steril S100	0.1	0.15	(3.9)	58	> 7.3	(50)	0.7	(30)	< 0.125
B02P	PR Steril S80	0.2	0.15	(3.9)	50	> 11.6	(80)	1.1	(46)	< 0.125
B04P	PR Steril 40	0.4	0.15	(3.9)	49	> 7.3	(50)	1.5	(61)	< 0.125
B08P	PR 12	0.8	0.15	(3.9)	50	> 18.9	(130)	4.3	(175)	< 0.125
B20P	PR 5	2.0	0.15	(3.9)	50	> 8.7	(60)	8.1	(330)	< 0.125
B40P	PR 1	4.0	0.17	(4.3)	48	> 6.5	(45)	58.4	(2381)	< 0.125

\* B = Polypropylene version (e.g. B01P)

\*\* 100 kPa = 1 bar

\*\*\* Endotoxin content analysis after rinsing with 1.23 gal/ft<sup>2</sup> (50 l/m<sup>2</sup>) of WFI (Water for Injection)

## Ordering Information



<sup>1</sup> Flat adapter/Double O-ring adapter | <sup>2</sup> With cell spacer rail |

<sup>3</sup> Cannot be combined with double O-ring adapter

### Example: B01P62SF

Polypropylene stacked disc cartridge with BECO PR Steril S100 depth filter sheets, nominal retention rate of 0.1 µm, 16 filter cells, 10.9 in (276 mm) high, 12", with silicone gaskets and flat adapter.

	BECODISC 12", Ø 11.6 in (295 mm)					BECODISC 16", Ø 15.8 in (402 mm)				
Number of cells	16	14	9 <sup>1</sup>	9	5	16	14	9 <sup>1</sup>	9	5
Filter surface area [ft <sup>2</sup> (m <sup>2</sup> )]	20.5 (1.9)	17.8 (1.65)	11.8 (1.1)	11.8 (1.1)	6.4 (0.59)	39.8 (3.7)	34.4 (3.2)	22.6 (2.1)	22.6 (2.1)	12.4 (1.15)
Pre-coat volume [gal (l)] <sup>2</sup>	-	0.9 (3.6)	2.1 (8.0)	-	-	-	1.8 (7.0)	4.1 (15.4)	-	-
Overall height flat adapter [in (mm)]	10.9 (276)	10.9 (276)	10.9 (276)	7.7 (195)	4.4 (101)	10.9 (276)	10.9 (276)	10.9 (276)	7.7 (195)	4.4 (101)
Overall height double O-ring adapter [in (mm)]	13.0 (329)	13.0 (329)	13.0 (329)	10.0 (248)	-	13.0 (329)	13.0 (329)	13.0 (329)	10.0 (248)	-
Cell spacer rail	-	-	✓	-	-	-	-	✓	-	-

<sup>1</sup> Special stacked disc cartridge configuration with cell spacer rails providing increased mechanical stability for holding filter cake | <sup>2</sup> Calculated values (BECO depth filter sheets with 0.16 in/4.0 mm thickness)

## Compliance Notice

BECO depth filter sheets fulfill the requirements of Regulation (EC) 1935/2004 as well as the FDA Guideline 21 CFR § 177.2260 test criteria. The polypropylene components comply with Regulation (EU) 10/2011. The polypropylene meets FDA requirements, 21 CFR § 177.1520. The sealing materials (silicone, EPDM) meet FDA requirements, 21 CFR § 177.2600. The depth filter sheet and the polypropylene components of the BECODISC BP stacked disc cartridges meet the requirements of the USP Plastic Class VI – 70 °C test. For further details on individual components and materials see the declaration of conformity.

## Pyrogens/Endotoxins

Pyrogens are biological or chemical substances that can induce a rise in body temperature. One common example is endotoxins. These are cell wall components known as lipopolysaccharides that are embedded in the outer membrane of gram-negative bacteria.

Quantitative evidence of endotoxins can be determined using the LAL test (**L**imulus **A**mebocyte **L**ysate). This method is an efficient and economical alternative to the rabbit fever test. An independent institute examines the depth filter sheets.

The endotoxin content of the specimens examined is specified in EU/ml (**E**ndotoxin **U**nits).

The measurement is carried out after rinsing with 1.23 gal/ft<sup>2</sup> (50 l/m<sup>2</sup>) of WFI water.

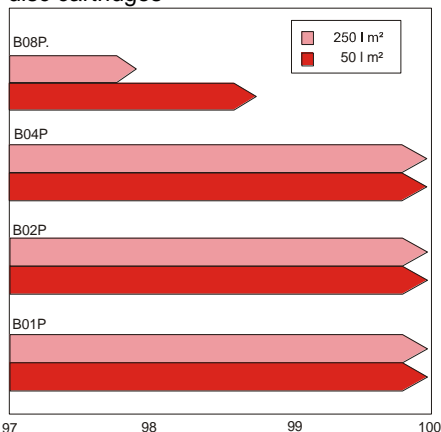
## Endotoxin Retention Rate

To measure endotoxin retention, a 40% glucose solution containing a defined amount of lipopolysaccharide (LPS) in pyrogen-free water is passed through a depth filter sheet. A defined sample of the filtrate is then measured by means of the LAL test.

Filtration flow rate:	12.3 gal/ft <sup>2</sup> /h (500 l/m <sup>2</sup> /h)
Sampling after:	1.23 gal/ft <sup>2</sup> and 6.14 gal/ft <sup>2</sup> (50 l/m <sup>2</sup> and 250 l/m <sup>2</sup> )
Amount of endotoxin added:	2.2 mg LPS <i>E. Coli</i> 055:B5, this equals 4.4 µg LPS/ml or 4.4 x 10 <sup>4</sup> EU/ml

The endotoxin retention rate is indicated in the following graphic.

Endotoxin retention rate of BECODISC BP stacked disc cartridges



Application	Germ-reducing filtration	Fine filtration	Clarifying filtration
	PR Steril S 100, PR Steril S 80, PR Steril 40	PR 12	PR 5, PR 1
Dialysis concentrate			x
Human albumin		x	
Photoresist		x	
I-globulin		x	x
Coagulation factors		x	x
Plasma expander solutions	x	x	
Enzyme production		x	x
Hormones	x	x	x
Amino acids	x	x	x
Infusion solutions	x	x	x
Vaccine production	x	x	x
Serums from rabbits, sheep, horses, cattle, calves	x	x	x

## Components

The depth filter sheets for the BECODISC BP stacked disc cartridges are manufactured from particularly pure materials, i.e., finely fibrillated cellulose fibers from deciduous and coniferous trees, cationic charge carriers, and high-quality, particularly pure diatomaceous earth.

## Recommendations for Avoiding Damage

BECODISC stacked disc cartridges can be used only in the specified flow direction. This applies to product filtering as well as sanitizing with hot water, and sterilizing with the stacked disc cartridges with saturated steam. In order to avoid damage to the filter cells, the system should be protected with a suitable non-return valve. Refer to the insert included with each BECODISC stacked disc cartridge carton for detailed application information.

Depending on the filtered liquids, the operating temperature should not exceed 176 °F (80 °C). Please contact Eaton regarding filtration applications at higher temperatures.

## Intermediate Plates

If more than two BECODISC stacked disc cartridges (12" or 16") with double O-ring adapters are stacked in the housing, install a central spindle for safety reasons. In the event, more than one 16" BECODISC stacked disc cartridge (flat adapter/double O-ring adapter) is used in the housing, Eaton recommends the installation of stainless steel intermediate plates between the BECODISC stacked disc cartridges. When silicone/FEP coated gaskets are used the stainless steel plates are mandatory.

## Sanitizing and Sterilizing (Optional)

### Sterilizing with Hot Water

The hot water temperature should be 185 °F (85 °C). A differential pressure of 21.8 psi (150 kPa, 1.5 bar) must not be exceeded when sterilizing with hot water.

Sterilization time: At least 30 minutes once a temperature of 185 °F (85 °C) is reached at all filter openings. In the interest of energy conservation, the water may be circulated provided the specified temperatures are maintained.

### Sterilizing with Steam

The wetted BECODISC stacked disc cartridges can be sterilized with saturated steam up to a maximum temperature of **250 °F (121 °C)** as follows:

- Steam quality: The steam must be free of foreign particles and impurities.
- Temperature: Max. **250 °F (121 °C)** (saturated steam)
- Duration: Approx. 20 minutes after steam exits from all filter valves.
- Rinsing: After sterilizing with 1.23 gal/ft<sup>2</sup> (50 l/m<sup>2</sup>) at 1.25 times the flow rate.

### Filter Preparation and Filtration

Unless already completed after sterilization, Eaton recommends pre-rinsing the closed filter with 1.23 gal/ft<sup>2</sup> (50 l/m<sup>2</sup>) of water at 1.25 times the flow rate prior to the first filtration. Depending on the application, this usually equals a rinsing time of 10 – 20 minutes. Test the entire filter for leakage at maximum operating pressure.

High-proof alcohol solutions and products that do not allow pre-rinsing with water should be circulated for 10 to 20 minutes. Dispose of the rinsing solution after rinsing.

### Differential Pressure

Terminate the filtration process once the maximum permitted differential pressure of 43.5 psi (300 kPa, 3 bar) is reached. A higher differential pressure could damage the depth filter sheet material. For safety reasons, a differential pressure of 21.8 psi (150 kPa, 1.5 bar) should not be exceeded in applications for separating microorganisms.

### Safety

When used and handled correctly, there are no known unfavorable effects associated with this product.

Further safety information can be found in the relevant Material Safety Data Sheet, which can be downloaded from our website.

## Waste Disposal

Due to their composition, BECODISC stacked disc cartridges can be disposed of as harmless waste. Comply with relevant current regulations, depending on the filtered product.

## Storage

BECDISC stacked disc cartridges must be stored in a dry, odor-free, and well ventilated place.

Do not expose the BECODISC stacked disc cartridges to direct sunlight.

BECDISC stacked disc cartridges are intended for immediate use and should be used within 36 months after production date.

## Quality Assurance According to DIN EN ISO 9001

The Quality Management System of Eaton Technologies GmbH has been certified according to DIN EN ISO 9001.

This certification verifies that a fully functioning comprehensive Quality Assurance System covering product development, contract controls, choice of suppliers, receiving inspections, production, final inspection, inventory management, and shipment has been implemented.

Extensive quality assurance measures incorporate adherence to technical function criteria and chemical purity and quality recognized as safe under the German legislation governing the production of foods and beverages.

All information is given to the best of our knowledge. However, the validity of the information cannot be guaranteed for every application, working practice and operating condition. Misuse of the product will result in all warranties being voided.

Subject to change in the interest of technical progress.

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