# SARTURIUS

# Sartocon<sup>®</sup> Single-Use Cassettes

Protein Purification,
Concentration and
Diafiltration Cell Removal



### Description

### The Polyethersulfone Membrane

The polyethersulfone membrane (PESU) is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. The PESU membrane is a stable polymer that features a broad pH and temperature range. Its wide temperature range makes it possible to sterilize some of the membrane by either steam or autoclaving. Because of these features, the PESU membrane is ideally suited for biotechnological applications.

Polyethersulfone membranes are designed for single-use applications use in the biotechnological and pharmaceutical industries.

They can be used for the following applications:

- laG
- Blood factors
- Enzymes
- Peptides

### Product Information

The polyethersulfone membrane in Sartocon® Single-Use Cassettes has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by always out-of-the-box performance. Some PESU ultrafiltration | microfiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
New filter-cassette in each production run	Reproducability  Consistent process economics "Ready to use   easy to use conditions"  High target protein rejection "Consistent yield"  Sustained performance (lot-to-lot)  Batch-to-batch consistency "Always out-of-the-box performance"
Single use	Eliminate cleaning Validation reduced down time
Alcohol   Glycerol storage	Consistently low TOC limits
Consistent performance	Minimal processing time
Self-sealing cassette	No gaskets required
Silicone sealing internal   external	No glue No polyurethane extractables
Opimized cassette construction	Lower pressure drop across the cassette

## Specifications

Materials of Construction				
Membrane	Polyethersulfone			
Gaskets	PVDF			
Spacer	Polypropylene			
Sealing compound	Silicone			

### Pore Size | Retention Rate

PESU ultrafiltration and microfiltration cassettes are available in a choice of the following ultrafilters with nominal molecular weight cut-offs: 1 kD, 5 kD, 8 kD, 10 kD, 30 kD, 50 kD, 100 kD, 300 kD and microfilters with a pore size of 0.1  $\mu$ m.

### Available Sizes

Sartorius Sartocon® Single-Use Crossflow Cassettes are available in standard cassette format size for pilot | production scale.

### Available Filter Holder

Sartorius Sartocon® Single-Use Crossflow Cassettes are designed for Sartorius filter holders like Sartocon®, Sartocon® 2 Plus, and different Sartoflow® holders.

### Filtration Area

Filter area

Sartocon® Cassette

0.7 m<sup>2</sup> UF 0.6 m<sup>2</sup> MF

# Operating Parameter

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at P <sub>in</sub> = 15 psi   1 bar	Ultrafilters: 1 kD-300 kD: 50 ml 50 ml air/min for 0.7 m² filter area   Microfilters: 15 ml air/min for 0.6 m² filter area

### Sterilization

Only 30 kD | 100 kD | 300 kD and 0.1 µm, 121°C, 30 min, steaming; 121°C, 110 min, autoclaving

### Regulatory Compliance

All materials have passed the current USP Biological Test. The filtrate meets or exeeds USP and EP requirements for Sterile Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals.

### Quality Control

Each filter cassette is individually assigned a serial number, integrity tested and certified.

It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available on request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius field engineer or our Goettingen-based Applications Department in Germany.

### **Technical References**

Validation Guide

Publication No.: SPC5701-e

Directions for Use

Publication No.: SPC6001-a

### Order Information

Available types and order numbers

Cut-off	Pore size	Sartocon® Single-Use Cassettes filter area 0.7 m²	Sartocon® Single-Use Cassettes filter area 0.6 m²
5 kD		3021462907ESUD	
8 kD		3021463407ESUD	
10 kD		3021463907ESUD	
30 kD		3021465907ESUD	
50 kD		3021465007ESUD	
100 kD		3021466807ESUD	
300 kD		3021467907ESUD	
	0.1 μm		3021545806WSUD

# Retention Rates Polyethersulfone Ultrafilter

Substance	Approx. Mol. wt	1 kD	5 kD	8 kD	10 kD	30 kD	50 kD	100 kD	300 kD
Vitamin B12	1.200	>70	>50	<45	-	-	_	-	_
Inulin	5.000	>85	>70	-	-	-	-	-	-
Cytochrome C	12.400	-	>99	>99	>95	>60	-	-	-
Myoglobin	17.000	-	-	-	>99	>98	>95	<80	-
Albumin	67.000	-	-	-	>95	-	-	-	-
γ-Globulin	169.000	-	-	-	-	-	>99	>98	<70
Dextran	2,000.000	-	-	-	-	-	-	-	>95

# Retention Coefficient Polyethersulfone Microfilter

Marker	Retention (static conditions)
Mycoplasma	LRV > 7
Brevundimonas diminuta	LRV>7

# Typical Water Flux Release Data

Cut-off	Pore size	Sartocon® Single-Use Cassettes [I/h]	
1 kD		9	
5 kD		21	
8 kD		125	
10 kD		160	
30 kD		280	
50 kD		460	
100 kD		530	
300 kD		630	
	0.1 μm	850	

<sup>\* (</sup>Feed pressure,  $P_{in}$  = 22 psi | 1.5 bar; Retentate pressure,  $P_{out}$  = closed valve;  $P_{filtrate}$  = open valve)

### Germany

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