



# Albumin Ultrafiltration Cassettes "PESUmax"

Albumin concentration

Crossflow Filtration



## Specifications

### Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

### Pore Size | Retention Rate

PESUmax ultrafiltration cassette is available in a retention rate of >99.99% for Albumin.

### Available Sizes

Sartorius Stedim Biotech Crossflow Cassettes are available in **Standard Cassette** size and Sartocube® size for pilot- and production scale, and in **Sartocon® Slice** as well as Sartocon® Slice 200 format for reduced volume handling.

### Available Filterholder

Sartorius Stedim Biotech Crossflow Cassettes are designed for Sartorius Stedim Biotech filter holders like Sartocon® Slice, Sartocon® 2 Plus, SARTOFLOW® 10 and 20 holders.

### Operating Parameters

Feed pressure, P <sub>in</sub>	58 psi   4 bar maximum
Operating temperature	50°C maximum
Air diffusion rates at P <sub>in</sub> = 14.5 psi   1 bar	≤ 2 ml air/min for 0.02 m <sup>2</sup> ≤ 5 ml air/min for 0.1 m <sup>2</sup> ≤ 20 ml air/min for 0.7 m <sup>2</sup> ≤ 20 ml air/min for 3.5 m <sup>2</sup>
Cleaning	NaOH, 1M, 40°C, 60 min
Disinfection	NaOH, 1 M, max. 50°C, 30 min
Storage	NaOH, 0.1 M

## Description

### The PESUmax Membrane

The PESUmax membrane is made out of polyethersulfone (PESU). This membrane polymer is well established in the biotechnological and pharmaceutical industries.

The PESUmax cassette, is designed for use in the blood market specially for ALBUMIN rejectable applications. The PESUmax membrane is a stable polymer that features a broad pH and temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for blood market applications.

## Product Profile

The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated re-use. PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet hole	Lower pressure drop

### Sterilization

Sterilization NaOH, 1 M, max. 50°C, 30 min

### The Sartorius Stedim Biotech Design "Stress Test" as an Indication of Cassette Cleaning Cycles

#### Purpose

The goal of this test is to establish that Sartorius Stedim Biotech Cassette is resistant to NaOH exposure as is recommended in this Guide for cleaning and storage.

#### Test Procedure

PESUmax Sartococon<sup>®</sup> cassette (Mat. No. 302146AL07K--SW) are tested under stress test conditions according to demonstrate compatibility with caustic. The test conditions are: feed pressure in 4 bar; retentate pressure 0 bar and permeate open; pH is 14 with 1 N NaOH at above 50°C for minimum 200 hours.

#### Results

All released and published Sartococon<sup>®</sup> cassettes are validated according to this procedure. All cassettes passed the integrity test after minimum 50 hours.

#### Regulatory Compliance

All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, Ammonia, Chloride, Sulfate, Calcium and Bacteria Endotoxins.

#### 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 upon 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 Stedim Biotech field engineer or our Goettingen- based Applications Department in Germany.

#### Technical References:

Validation Guide Publication No.: SPC5701-e

Directions for Use (Sartocube<sup>®</sup> | Sartococon<sup>®</sup> | Sartococon<sup>®</sup> Slice | Sartococon<sup>®</sup> Slice 200 Cassettes) Publication No.: SPC6051-a

### Average Dynamic Water Flux

#### Permeate

	per Slice 200 cassette 0.02 m <sup>2</sup>	per Sartococon <sup>®</sup> Slice cassette 0.1 m <sup>2</sup>	per Sartococon <sup>®</sup> cassette 0.7 m <sup>2</sup>	per Sartocube cassette 3.5 m <sup>2</sup>
approx.	10 l/h	50 l/h	250 l/h	1250 l/h

(P<sub>feed</sub> = 29 psi | 2.0 bar, P<sub>retentate</sub> = 7 psi | 0.5 bar)

### Retention Coefficient PESUmax

Marker	Retention
Albumin	>99.9%

### Ordering Information

Available types and Order Numbers

Cutoff	Sartococon <sup>®</sup> Slice 200 0.02m <sup>2</sup> filter area	Sartococon <sup>®</sup> Slice Cassettes 0.1 m <sup>2</sup> filter area	Sartococon <sup>®</sup> Cassettes 0.7 m <sup>2</sup> filter area	Sartocube Cassette 3.5 m <sup>2</sup> filter area
Albumin	308146AL02K--SW	305146AL01K--SW	302146AL07K--SW	302146AL35K--BSW

Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen, Germany

Phone +49.551.308.0  
Fax +49.551.308.3289  
www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178  
UK +44.1372.737159  
France +33.442.845600  
Italy +39.055.63.40.41  
Spain +34.90.2110935  
Russian Federation +7.812.327.5.327  
Japan +81.3.5639.9981

Specifications subject to change without notice. Printed and copyrighted by Sartorius Stedim Biotech GmbH. | W  
Publication No.: SPC2046-e13044  
Order No.: 85030-522-86  
Ver. 04 | 2013