

Sartocon[®] Slice and Sartocube[®] Self-Contained Unit (SCU)

Product Summary

SCU's are 0.14 m² to 14 m² pre-sterilized disposable units suitable for use in cGMP environments. They are available in a variety of MWCOs and in Polyethersulfone (PES) and Hydrosart[®] membrane types.

PES membrane is a membrane polymer that is well established in the biotechnological and pharmaceutical industries. It is a stable polymer featuring a broad pH and temperature range. PES membranes are designed for use in the biotechnical and pharmaceutical industries.

The Hydrosart[®] high-performance membrane is a stabilized cellulose-based membrane optimized for biopharmaceutical process applications. It is stable across a broad pH range and extremely hydrophilic, making it non-protein binding and virtually non-fouling.

Unique Selling Points

- Pre-flushed, sterile, ready to use
- No CIP with associated water flush and validation required, which leads to cost and time savings in set up and validation efforts
- High product yield and high sustained flux due to low protein binding membrane
- No use of glues, and therefore low extractables



Relevant Applications

- Antibody-drug conjugates (ADC)
- Monoclonal antibodies (mAbs)
- Vaccines
- mRNA
- pDNA
- Recombinant proteins
- Biosimilars
- Viral vectors for gene therapy
- High viscosity injectables

Feature	Benefits
Available in seven different filtration areas	Flexibility and linear scale-up
High flow rates	Economical filtration runs
Presterilized and pre-flushed with WFI	Ready to use
Silicone sealing compound	No glue
AseptiQuik®* connectors	Quick connection to existing equipment

Relevant Process Steps

- Ultrafiltration

Technical Specifications

Attribute	Specification
Membrane	Hydrosart®, Polyethersulfone (PES)
Gaskets	Polypropylene
Spacer	Polypropylene
Sealing Compound	Silicone
Screen Type	ECO
Pore Size Retention Rate	10 kDa 30 kDa 100 kDa 300 kDa
Filtration Area	
Sartocube® SCU	1.4 m ² 3.5 m ² 7 m ² 14 m ²
Sartocon® Slice SCU	0.14 m ² 0.28 m ² 0.42 m ²
Available Filter Holder	Stainless steel holder is used for compression only.

Operation Parameters

Feed Pressure, P _{in}	SFM-AQ-144...	0.14 m ² 0.28 m ² 0.42 m ² 1.4 m ²	max. 4 bar 58.0 psi
	SFM-AQ-144...	3.5 m ² 7 m ² 14 m ²	max. 3 bar 43.5 psi
	SFM-AQ-146...	all sizes	max. 3 bar 43.5 psi
Operating Temperature	Max. 40 °C		
pH Stability	Hydrosart®	2–14	
	PES	1–14	
Air Diffusion Rates at P _{in} = 15 psi	Hydrosart® Sartocon® Slice Self Contained	0.1 to 0.42 m ²	≤ 5 mL/min
	PES Sartocon® Slice Self Contained	0.1 to 0.42 m ²	≤ 15 mL/min
	Hydrosart® and PES Sartocube® Self Contained	1.4 to 3.5 m ²	≤ 50 mL/min
		7 m ²	≤ 75 mL/min
	14 m ²	≤ 100 mL/min	

*AseptiQuik® is a brand of Colder Products Company

Preconditioning

Pre-flushed to a low level of contaminants and gamma irradiated with a minimum of 25 kGy.

Regulatory Compliance

All materials have passed the USP Biological Test. All materials are BSE and TSE free. The filtrate meets or exceeds the currently valid USP and EP for sterile water for injection, with respect to extractable substances, oxidizable substances, and bacteria endotoxins.

Retention Rates

Hydrosart®

Substance	Approx. Mol. Wt.	10 kDa (%)	30 kDa (%)	100 kDa (%)	300 kDa (%)
Vitamin B12	1,200	--	--	--	--
Inulin	5,000	--	--	--	--
Cytochrome C	12,400	≥ 97.5	--	--	--
Albumin	67,000	--	≥ 97.5	≥ 60	--
γ-Globulin	169,000	--	--	≥ 96	--
Blue Dextran	500,000	--	--	--	≥ 90

Polyethersulfone (PES)

Substance	Approx. Mol. Wt.	10 kDa (%)	30 kDa (%)	100 kDa (%)	300 kDa (%)
Vitamin B12	1,200	--	--	--	--
Cytochrome C	12,400	≥ 95	60 – 90	--	--
Albumin	67,000	--	--	< 80	--
γ-Globulin	169,000	--	--	≥ 98	< 70
Blue Dextran	2,000,000	--	--	--	> 95

-- = not measured

Average Dynamic Water Flux

Hydrosart® – Average Dynamic Water Flux*

NMWC (kD)	10	30	100	300
Permeate flow (L/h/m ²)	45	100	380	625

PES – Average Dynamic Water Flux*

NMWC (kD)	10	30	100	300
Permeate flow (L/h/m ²)	160	350	450	600

*Pfeed= 2 bar | 29 psi, Pret=0.5bar | 7 psi, Pfiltrate = open

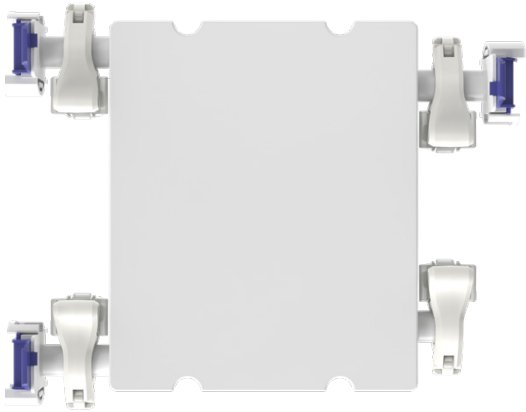
Quality Control

Each Sartocube® Self-Contained Unit is individually assigned a serial number, integrity tested, and certified. Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. For further assistance, please contact your local Sartorius Technical Service or our Goettingen-based Applications Department in Germany.

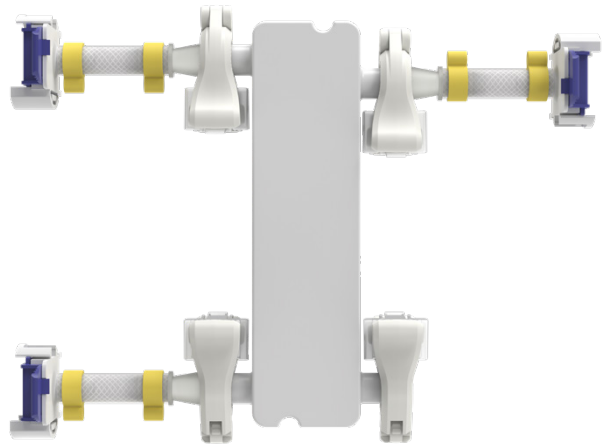
Technical References

Validation guide Publication No.: DIR: 2554012
Directions for use Publication No.: DIR: 2644901

Ordering Information



Sartocube® Self-Contained ECO



Sartocon® Slice Self-Contained ECO

Sartocon® Slice Self-Contained ECO | Sartocube® Self-Contained ECO for Sartoflow® Expert SU

Hydrosart® Membrane

		Sartocube® SCU				Sartocon® Slice SCU		
AseptiQuik® Connector		AQ L - 1" TC50 Feed, Retentate AQ G - ¾" TC25 Permeate		AQ G - ¾" TC25 Feed, Retentate, Permeate		AQ G - ¾" HB Feed, Retentate, Permeate		
Filtration Area		14 m ²	7 m ²	3.5 m ²	1.4 m ²	0.42 m ²	0.28 m ²	0.14 m ²
MWCO (kDa)	10 SFM-AQ-14439**	** = A4	** = 70	** = 35	** = 14	** = 31	** = 21	** = 01
	30 SFM-AQ-14459**							
	100 SFM-AQ-14468**							
	300 SFM-AQ-14479**							

PES Membrane

		Sartocube® SCU				Sartocon® Slice SCU		
AseptiQuik® Connector		1" TC50 Feed, Retentate ¾" TC25 Permeate				¾" HB Feed, Retentate ¾" HB Permeate		
Filtration Area		14 m ²	7 m ²	3.5 m ²	1.4 m ²	0.42 m ²	0.28 m ²	0.14 m ²
MWCO (kDa)	10 SFM-AQ-14639**	n.a.	n.a.	** = 35	** = 14	** = 31	** = 21	** = 01
	30 SFM-AQ-14659**							
	100 SFM-AQ-14668**							
	300 SFM-AQ-14679**							

Germany

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