

Sartocube[®] Self-Contained Unit (SCU)

Product Summary

SCU's are 1.4 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

Disposable and presterilized tangential flow filtration cassettes suitable for use in cGMP manufacturing environments.

Feature	Benefits
Available in three 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	1.4, 7, 14 m ²
Available Filter Holder	Stainless steel holder

Operation Parameters

Feed Pressure, P _{in}	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	1.4 m ² filtration area : ≤50 mL/min. 7 m ² filtration area: ≤75 mL/min. 14 m ² filtration area: ≤100 mL/min.

*AseptiQuik® is a brand of Colder Products Company

Preconditioning

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

Technical References

Validation guide Publication No.: 2554012-000-00
Directions for use Publication No.: 2644901-000-01

Retention Rates

Substance	Approx. Mol. Wt.	1 kDa (%)	5 kDa (%)	8 kDa (%)	10 kDa (%)	PES _{max} kDa (%)	30 kDa (%)	50 kDa (%)	100 kDa (%)	300 kDa (%)
Vitamin B12	1,200	>70	50 – 80	-	-	-	-	-	-	-
Cytochrome C	12,400	-	-	99	>95	-	60 – 90	-	-	-
Albumin	67,000	-	-	-	-	> 99.9	-	>95	<80	-
γ-Globulin	169,000	-	-	-	-	-	-	>99	≥98	<70
Dextran	2,000,000	-	-	-	-	-	-	-	-	>95

Protein Markers (PES Ultrafilter) (MWCO); - = not measured

Quality Control

Each Sartocube® Self-Contained Unit 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.

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

Ordering Information

TFF Cassettes – Sartocube® Self-Contained ECO

Hydrosart®

MWCO (kDa)	Filtration Area (m ²)	Order Code
10	1.4	SFM-AQ-1443914
10	7	SFM-AQ-1443970
10	14	SFM-AQ-14439A4
30	1.4	SFM-AQ-1445914
30	7	SFM-AQ-1445970
30	14	SFM-AQ-14459A4
100	1.4	SFM-AQ-1446814
100	7	SFM-AQ-1446870
100	14	SFM-AQ-14468A4
300	1.4	SFM-AQ-1447914
300	7	SFM-AQ-1447970
300	14	SFM-AQ-14479A4

PES

MWCO (kDa)	Filtration Area (m ²)	Order Code
10	1.4	SFM-AQ-1463914
30	1.4	SFM-AQ-1465914
100	1.4	SFM-AQ-1466814
300	1.4	SFM-AQ-1467914

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