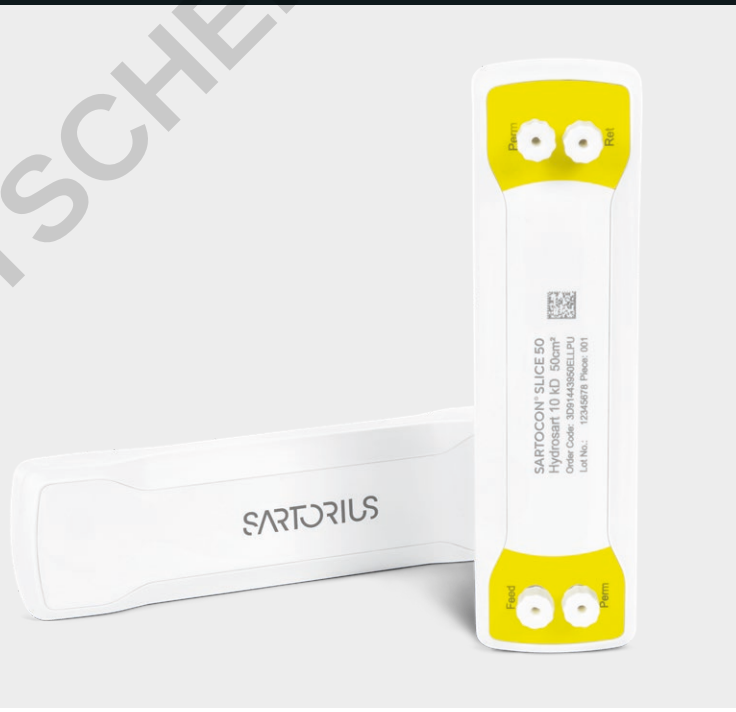
SARTORIUS

Product Datasheet

Sartocon® Slice 50

Small Scale Process Development Disposable Ultrafilters for Biopharmaceutical Applications



DOMINIQUE DUTSCHER SAS

Product Information

Sartocon® Slice 50 is available with both Hydrosart® and Polyethersulfone membranes. It can easily be used with the Sartoflow® Smart system.

Sartocon® Slice 50

The Sartocon® Slice 50 is a ready to use 50 cm^2 fully disposable crossflow module that is ideally suited for membrane screening and process development, available in a wide variety of MWCO's and polymers. The Sartocon® Slice 50 can easily be used with the Sartoflow® Smart system as well as many other laboratory scale crossflow systems.

Flow Channel Geometry

Sartocon® Slice 50 is available in two flow channel geometry versions. E-Screen filters are dominantly used for protein concentrations up to above 20% as well as viscosity conditions greater than 3 cp. ECO-Screen devices mainly used for water based protein solutions of below 20% protein concentration as well as lower than 3 cp viscosity.

Hydrosart® Membrane

Hydrosart® high performance membrane is a stabilized cellulose based membrane that has been optimized for biopharmaceutical process applications. Hydrosart® is stable across a broad pH range, is extremely hydrophilic, making it non-protein binding, and virtually non-fouling. Membrane depyrogenation can be accomplished by using NaOH even at elevated temperatures. These features make Hydrosart® an ideal membrane for biological applications.

Feature	Benefits
Available in all membrane materials and cut offs	Flexibility in membrane screening
Self contained unit	Ready to use, no compression holder needed
Low adsorption	Minimal product loss
Low protein-binding	High flux and product yield
DataMatrix code	Fast access to order code and shelf life data.
Luerlock Female ports	Quick connection to existing equipment ready to use on Sartoflow® Smart system
Low hold up volume	High concentration factor

Polyethersulfone Membrane

Polyethersulfone (PESU) membrane is an established membrane polymer that is well suited to many biopharmaceutical process applications. PESU membrane is a stable polymer that can operate in a broad pH and temperature range, and withstand aggressive cleaning cycles.

Technical Data

Specifications Materials of Construction

Membrane	Hydrosart® | Polyethersulfone
Sealing and Gaskets	Silicone, Epoxide, Polypropylene
Spacer	Polypropylene, PVDF
Encapsulation	Reinforced ABS
Connector	ABS

Available Filterholder

No special filter holder is reqired to operate a Sartocon® Slice 50. For ease of handling in vertical orientation a matching holder (order number 3ZG—0108) can be used.

Rejection Coefficient (Characterization of Membrane)

Retention Rates Hydrosart®

Substance	Approx. Mol. Wt.	2 kD [%]	5 kD [%]	10 kD [%]	30 kD [%]	100 kD [%]	300 kD [%]
Vitamin B12	1,200	≥ 88	–	–	–	–	–
Inulin	5,000	–	≥ 96	–	–	–	–
Cytochrome C	12,400	–	–	≥ 97,5	–	–	–
Albumin	67,000	–	–	–	≥ 97,5	≥ 60	–
γ-Globulin	169,000	–	–	–	–	≥ 96	–
Blue Dextran	500,000	–	–	–	–	–	< 90

Retention Rates Polyethersulfone (PESU)

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 – 80	–	–	–	–	–	–
Cytochrome C	12,400	–	–	≥ 99	> 95	60 – 90	–	–	–
Albumin	67,000	–	–	–	–	–	> 95	< 80	–
γ-Globulin	169,000	–	–	–	–	–	> 99	≥ 98	< 70
Dextran	2,000,000	–	–	–	–	–	–	–	> 95

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Operating Parameters	
Feed pressure P_{in}	3.5 bar maximum
Operating temperature range	2 – 40°C,

Air diffusion rates	≤ 3.0 mL/min at 2.5 bar
pH stability	Hydrosart 2 – 14 | PESU 1 – 14
Hold up volume	1 – 2 ml
Recommended cross flow rate E Screen	50 – 120 mL/min
Recommended cross flow rate ECO Screen	20 – 60 mL/min
Cleaning	NaOH, 1 M, 40°C
Disinfection	NaOH, 1 M, 40°C, 30 min
Storage	NaOH, 0.1 M

Quality Control

Each Sartocon® Slice 50 is individually assigned a serial number, integrity tested and certified. It complies with cGMP requirements 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. For further assistance, please contact your local Sartorius Stedim Biotech Application Department.

Sterilization

No thermal sterilization possible.

Regulatory Compliance

All product contact materials have passed the current USP Biological Test and Cytotoxicity 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

Directions for Use	1000062289
Validation Guide	SPC6067

Ordering Information

Sartocon® Slice 50 available as "E"-Screen and "ECO"-Screen Filter

Membrane Polymer"	Cut-Off	Material Number "E"-Screen Filter	Material Number "ECO"-Screen Filter
Hydrosart®	2 kD	3D91441950ELLPU	
Hydrosart®	5 kD	3D91442950ELLPU	
Hydrosart®	10 kD	3D91443950ELLPU	3D91443950MLLPU
Hydrosart®	30 kD	3D91445950ELLPU	3D91445950MLLPU
Hydrosart®	100 kD	3D91446850ELLPU	3D91446850MLLPU
Hydrosart®	300 kD	3D91447950ELLPU	3D91447950MLLPU
PESU	1 kD	3D91460950ELLPU	
PESU	5 kD	3D91462950ELLPU	
PESU	8 kD	3D91463450ELLPU	
PESU	10 kD	3D91463950ELLPU	3D91463950MLLPU
PESU	30 kD	3D91465950ELLPU	3D91465950MLLPU
PESU	50 kD	3D91465050ELLPU	
PESU	100 kD	3D91466850ELLPU	3D91466850MLLPU
PESU	300 kD	3D91467950ELLPU	3D91467950MLLPU

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Available Crossflow System

The Sartoflow® Smart is a modular and flexible small scale benchtop crossflow system optimized for ultrafiltration and diafiltration applications used in many downstream processes, such as purification of vaccines, monoclonal antibodies and recombinant proteins. The system is suitable for use in laboratory environments for process development and clinical trials as well as for cGMP environments.



Sartoflow® Smart including options

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Specifications subject to change without notice.
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