



Sartocon[®] Slice Self Contained Bag Loop Assembly

Bag loop assembly for SARTOFLOW[®] Alpha Plus SU,
Gamma irradiated

Product Profile

The gamma sterilized bag loop assembly consists of a Hydrosart[®] (Cellulose based) or Polyethersulfone membrane polymer integrated into a self contained filter unit, tubing, four pressure domes, retentate and permeate flow meters, two valve bodies for back pressure control in the retentate and permeate line, peristaltic pump tubing and a 10 L recirculation bag including a thermowell and a vent filter.



Description

Bag loop assemblies for the SARTOFLOW[®] Alpha plus SU are supplied sterile and ready to use. Due to the fully enclosed design the assembly is well suited for vaccine, recombinant protein and highly toxic ADC production. All product wetted parts of the system are supplied sterile and made from single-use components. The system is suitable for use in cGMP environments for process development, clinical trials and for small-scale production batches. The cassette is designed with the same hydrodynamic flow path as our larger production scale filter cassettes, enabling linear scale-up to larger filter areas. The single-use concept is an ideal choice for Contract Manufacturers, research and development applications and all companies with multiproduct through-put.

Features

- Totally enclosed process with integrated loop assembly
- Color coding
- Pre-flushed and sterile
- Single-use
- Low protein binding membrane
- No use of glues

Benefits

- Fully disposable results in operator safety due to no product contact
- Eliminating installation errors
- Ready to use
- No CIP with associated water flush and validation required
- No cleaning validation , CFW determination and storage preparation, leads to cost and time saving in set up and validation effort
- High product yield and high sustained flux
- Low extractables

Retention Rate

Hydrosart® and Polyethersulfone ultrafiltration Bag Loop Assemblies are available in the following nominal molecular weight cut-offs: 10 kD, 30 kD, 100 kD and 300 kD.

Available Sizes

Sartorius Stedim Biotech Sartocon® Slice Bag Loop Assemblies are available in 1, 2 or 3 stack format.

Required Filterholder

Sainless Steel hydraulic and manual holder available.

Filtration Area

Filter area from 0.1m² to 0.42 m²

Operating Parameters

Feed pressure, P_{in} 3 bar maximum

Operating temperature range: 2 – 40°C

pH stability: Polyethersulfone 1 – 10, Hydrosart® 2 – 10

Air diffusion rates: Hydrosart® ≤ 5 mL/min at P_{in} = 15 psi | 1 bar,

PESU UF and MF ≤ 15 mL/min at P_{in} = 15 psi | 1 bar

Preconditioning

This product was preflushed to a low level of contaminants and gamma irradiated with 25 kGray using a validated process in accordance with DIN/EN ISO 11137 regulations.

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.

Quality Control

Each Sartocon® Slice Bag Loop Assembly is individually assigned a serial number, integrity tested and certified. It 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 Technical Service or our Goettingen- based Applications Department in Germany.

Technical References

Validation Guide Publication No.: SPC5717

Directions for Use Publication No.: SPC6061



Materials of Construction

Slice Self Contained Device

Membrane	Hydrosart® or Polyethersulfone
Gaskets	Polypropylene or PVDF
Spacer	Polypropylene
Sealing compound	Silicone grey
Plates with connector	Stabilized Polypropylene

Bag Loop Assembly

Opta connector	Acrylate, PC, PP, PSU, TPV
Pressure interface	ABS, PEHD
Flowmeter	PVDF
Valve bodies	PEHD
10 l recirculation bag	STEDIM 40
Vent filter	Polyester, PP, PTFE
Tubing	Silicone PT, TPE C-Flex®*
Pump tubing	INOX, PP, TPE
Ports and connectors	PE, PP, Silicone PT, PC

Rejection Coefficient (Characterization of Membranes)

Hydrosart® Ultrafilter

Substance	Approx. Mol. Wt.	10 kD [%]	30 kD [%]	100 kD [%]
Cytochrome C	12,400	≥ 97.5	–	–
Albumin	67,000	–	≥ 97.5	≤ 60
γ-Globulin	169,000	–	–	≥ 96

Polyethersulfone (PESU) Ultrafilter

Substance	Approx. Mol. Wt.	10 kD [%]	30 kD [%]	100 kD [%]	300 kD [%]
Cytochrome C	12,400	> 95	60–90	–	–
Albumin	67,000	–	–	< 80	–
γ-Globulin	169,000	–	–	≥ 98	< 70
Dextran	2,000,000	–	–	–	> 95

– = not measured

Retention Coefficient (Static Conditions)

Marker	Retention
Mycoplasma	LRV > 7

Order Information

Available Types and Order Numbers with Hydrosart® or Polyethersulfone Membrane

Cut off	Membrane	Channel Configuration	0.14 m ²	0.28 m ²	0.42 m ²
10 kD	Polyethersulfone	ECO-Screen	SFA-SUM1463901	SFA-SUM1463921	SFA-SUM1463931
10 kD	Hydrosart®	ECO-Screen	SFA-SUM1443901	SFA-SUM1443921	SFA-SUM1443931
30 kD	Polyethersulfone	ECO-Screen	SFA-SUM1465901	SFA-SUM1465921	SFA-SUM1465931
30 kD	Hydrosart®	ECO-Screen	SFA-SUM1445901	SFA-SUM1445921	SFA-SUM1445931
100 kD	Polyethersulfone	ECO-Screen	SFA-SUM1466801	SFA-SUM1466821	SFA-SUM1466831
100 kD	Hydrosart®	ECO-Screen	SFA-SUM1446801	SFA-SUM1446821	SFA-SUM1446831
300 kD	Polyethersulfone	ECO-Screen	SFA-SUM1467901	SFA-SUM1467921	SFA-SUM1467931

Cut off	Membrane	Channel Configuration	0.1 m ²	0.2 m ²	0.3 m ²
10 kD	Polyethersulfone	E-Screen	SFA-SU-1463901	SFA-SU-1463921	SFA-SU-1463931
30 kD	Polyethersulfone	E-Screen	SFA-SU-1465901	SFA-SU-1465921	SFA-SU-1465931
0.1 µm	Polyethersulfone	W-Screen	SFA-SU-1545801	SFA-SU-1545821	SFA-SU-1545831

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* C-Flex® is a registered trademark of
Saint-Gobain Performance Plastics Corporation.