



# Sartocon<sup>®</sup> Self Contained Filter Loop Assembly

Filter loop assembly for FlexAct<sup>®</sup> UD,  
Gamma irradiated

## Product Information

The gamma sterilized loop assembly consists of a Hydrosart<sup>®</sup> (Cellulose based) or Polyethersulfone membrane polymer integrated into a self contained filter unit, two pressure domes, a TMP control pinch valve, a disposable pump head and tubing with Opta<sup>®</sup> connectors. Feed and permeate lines are color coded.



## Description

Filter Loop assemblies for the FlexAct<sup>®</sup> UD system 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 Sartocon<sup>®</sup> Slice Self Contained device, enabling linear scale-up from smaller 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
- Thin channel design

## Benefits

- Fully disposable loop assembly 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
- High mass transfer at low feed flow rates

**Retention Rate**

Hydrosart® and Polyethersulfone ultrafiltration Filter 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 Sartococon® Loop Assemblies are available in 2 or 5 stack format.

**Required Filterholder**

Sainless Steel hydraulic holder available.

**Filtration Area**

Filter area 1.4 m<sup>2</sup> and 3.5 m<sup>2</sup>

**Operating Parameters**

Feed pressure, P<sub>in</sub> 3 bar maximum

Operating temperature range: 2 – 40°C

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

Air diffusion rate: ≤ 50 mL/min at P<sub>in</sub> = 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**

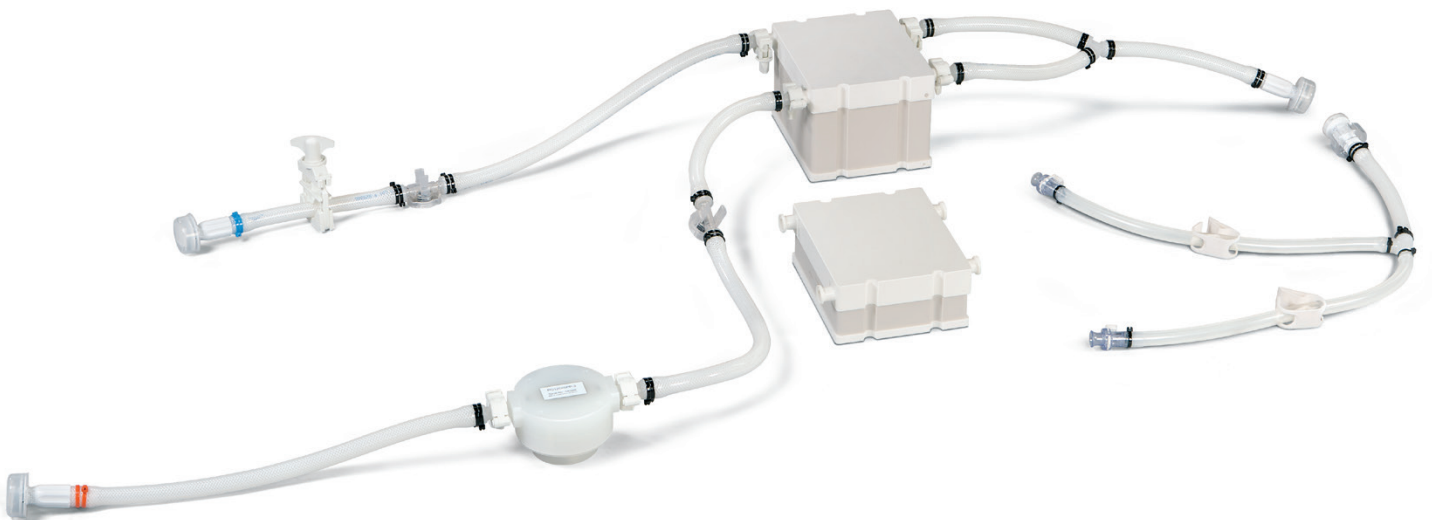
Each Sartococon® Filter Loop Assembly is individually assigned a serial number, integrity tested and certified. It is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available upon request.

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

### Sartocon® Self Contained Device

Membrane Polymer	Hydrosart® or Polyethersulfone
Gaskets	Polypropylene
Spacer	Polypropylene
Sealing compound	Silicone grey
Plates with connector	stabilized Polypropylene

### Filter Loop Assembly

Opta connector	Acrylate, PC, PP, PSU, TPV
Pressure interface	ABS
Pumphead	PP, EPDM
Tubing	Silicone PT, TPE C-Flex®*
Ports and connectors	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

## Order Information

### Available Types and Order Numbers with Hydrosart® Membrane

Cut off	1.4 m <sup>2</sup>	3.5 m <sup>2</sup>
10 kD	4XC31	4XC27
30 kD	4XC32	4XC28
100 kD	4XC29	4XC33

### Available Types and Order Numbers with Polyethersulfone Membrane

Cut off	1.4 m <sup>2</sup>	3.5 m <sup>2</sup>
10 kD	4XC40	4XC41
30 kD	4XC34	4XC37
100 kD	4XC35	4XC38
300 kD	4XC36	4XC39

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

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