

High performance 40 μm solutions for arterial line blood filters SEFAR **MEDIFAB**® 07-40/40 and 07-40/35

Introduction

During open-heart surgery, a complex system of medical devices temporarily replaces heart and lung functions. Vital components of this extracorporeal circulation, ECC (also called cardiopulmonary bypass, CPB, or heart lung machine) include very precise filter devices integrated into the venous/cardio-reservoirs, oxygenators, blood bags and arterial line blood filters.



Sefar's precision woven mono-filament fabrics are the industry standards in these cardiopulmonary devices and help guarantee patient safety.

High flow rates, precise mesh openings and proven biocompatibility of Sefar filters contribute to the excellent reliability and performance of the ECC.

SEFAR MEDIFAB® 07-40/40 High Performance

Arterial line blood filters are employed as the final security filters before the purified, oxygenated and thermostatted blood is perfused into the patient. The arterial filter safely blocks both air bubbles and particulate emboli.

SEFAR MEDIFAB® 07-40/40 High Performance offers unrivalled technical and commercial benefits for arterial filters:

- Lowest pressure drop
- Minimal priming volume
- Reduced foreign surface
- Cost advantage

SEFAR MEDIFAB® High Performance Solutions for Arterial Line Blood Filters

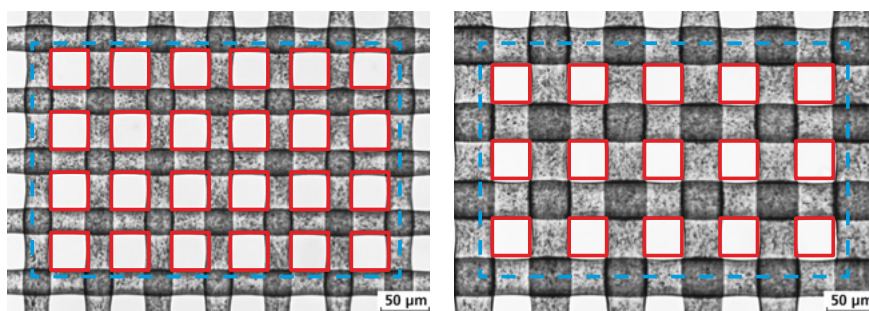
Recently, Sefar set a new standard in arterial filtration by introducing SEFAR MEDIFAB® 07-40/35.

With 35 % open filter area the fabric reduces the pressure drop of the arterial line blood filter by more than 25 %.

Now, the new SEFAR MEDIFAB® 07-40/40 High Performance fabric achieves an unrivalled high open area of 40 % with unaffected mesh opening of 40 µm.

Using this new fabric the performance of an arterial filter can be increased by 60 % without changing the design of the device.

+60% Open Area



60 % open area increase of SEFAR MEDIFAB® 07-40/40 High Performance (left) in comparison to 07-40/25.

The table below provides an overview on the most important properties of the SEFAR MEDIFAB® range for arterial filtration. The last two columns indicate the possibilities for arterial filtration devices.

Comparison of SEFAR MEDIFAB® 07-40/40 High Performance and 07-40/35 with 07-40/25.

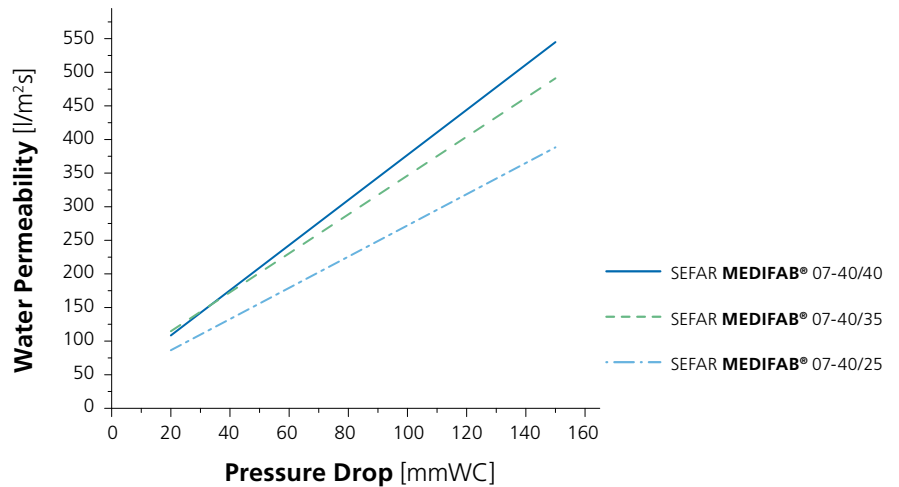
Parameter	Mesh Opening [µm]	Yarn Diameter [µm]	Open Area [%]	Open Area Gain [%]	Filter Size Reduction [%]
SEFAR MEDIFAB® 07-40/25	40	34	25	0	0
SEFAR MEDIFAB® 07-40/35	40	27	35	40	29
SEFAR MEDIFAB® 07-40/40 High Performance	40	24	40	60	37

Performance – Pressure Drop

The performance of a heart lung machine is defined, among others, by the performance of various filters integrated into the circuit.

The figure shows a comparison of the liquid permeability of SEFAR MEDIFAB® 07-40/40 High Performance, 07-40/35 and 07-40/25.

The corresponding reduction in pressure drop is computed as 29 % and 37 % for 07-40/35 and 07-40/40 High Performance, respectively.

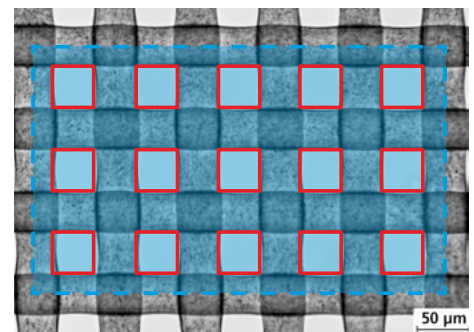
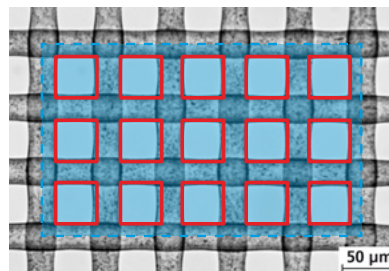


Comparison of the water permeability of different SEFAR MEDIFAB® 40 µm fabrics

Priming Volume – Extracorporeal Blood Volume

Adverse effects during ECC are reduced by having a smaller priming volume. Using SEFAR MEDIFAB® 07-40/35 a theoretical reduction of 29 % is possible. The very high open area of SEFAR MEDIFAB® 07-40/40 High Performance fabric provides the opportunity to reduce the total filter surface by as much as 37 %. As it is only the total filter surface area that is reduced, leaving the open area of the filter unchanged, flow and pressure drop are not affected.

-37% Filter Size



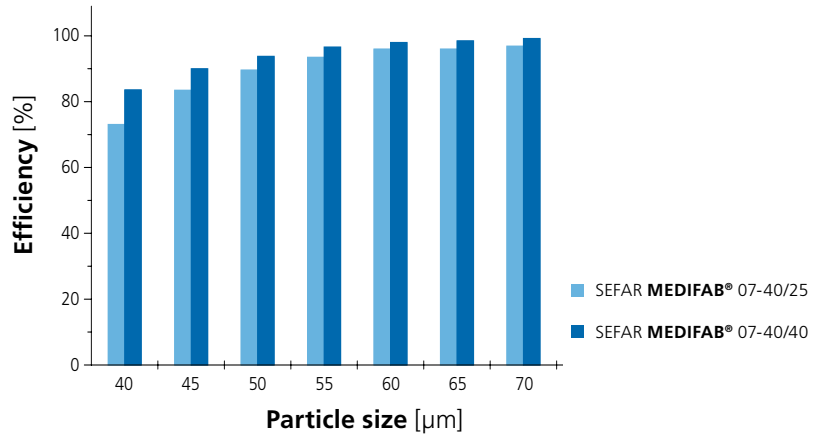
37 % reduction in filter surface with the identical open filter areas of SEFAR MEDIFAB® 07-40/40 High Performance (left) in comparison to SEFAR MEDIFAB® 07-40/25.

The filter fabric of the arterial filter is usually pleated so that a high filter surface occupies a smaller volume. Sefar recently developed new pleating methods to enhance this effect. This allows the free space between filter surfaces to be maintained whilst significantly reducing the volume occupied by the filter element.

The combination of the new capabilities results in a very important reduction in priming volume as well as in extracorporeal blood volume.

Filtration Efficiency – De-bubbling

Patient's security and the requirement set out in ISO 15675 demands a filtration efficiency of more than 80 % of micro aggregates that exceed 40 µm. Sefar's arterial filter fabrics fulfill this requirement irrespective of the open area. The figure on the right-hand side shows the filtration efficiency in the range of 40 µm and above. The removal of air bubbles during priming and operation is unaffected by the open area.



Filtration efficiency of SEFAR MEDIFAB® 07-40/25 and SEFAR MEDIFAB® 07-40/40 according to ISO 15675.

Foreign Surface

By use of SEFAR MEDIFAB® 07-40/35 or SEFAR MEDIFAB® 07-40/40 High Performance the total foreign surface is reduced by over 27 % and 35 %, respectively.

Semi Finished Elements

Sefar has the resources to incorporate the filter element into customer specific plastics and molds. The resulting semi finished element is easily handled and reduces supply chain costs tremendously.

Surface Modifications

Sefar is set up to apply a wide variety of surface modifications to the fabric. Coatings might include functionalities such as:

- Hemo- / bio- compatibility
- Low bio- adsorption
- High wettability
- Low wet friction
- Anti- thrombogenic
- Drug-containing/drug-eluting
- Biomimetic surface
- pH- regulation
- Immuno- suppressant

Solutions can be tailored according to customer needs.

General Information on SEFAR MEDIFAB®

- All polyester (PET) and polyamide (PA) materials are FDA compliant according to 21CFR177
- SEFAR MEDIFAB® fabrics are bio-compatible according to USP Class VI
- SEFAR MEDIFAB® fabrics comply with ISO 10993
- SEFAR MEDIFAB® fabrics are:
 - Non-pyrogenic
 - Non-hemolytic
 - Non-cytotoxic
- SEFAR MEDIFAB® fabrics show low extractables
- Fabrication is in a class 7 clean room
- Quality systems ISO 9001:2008, ISO 13458, ISO 14001 and ISO 16949

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