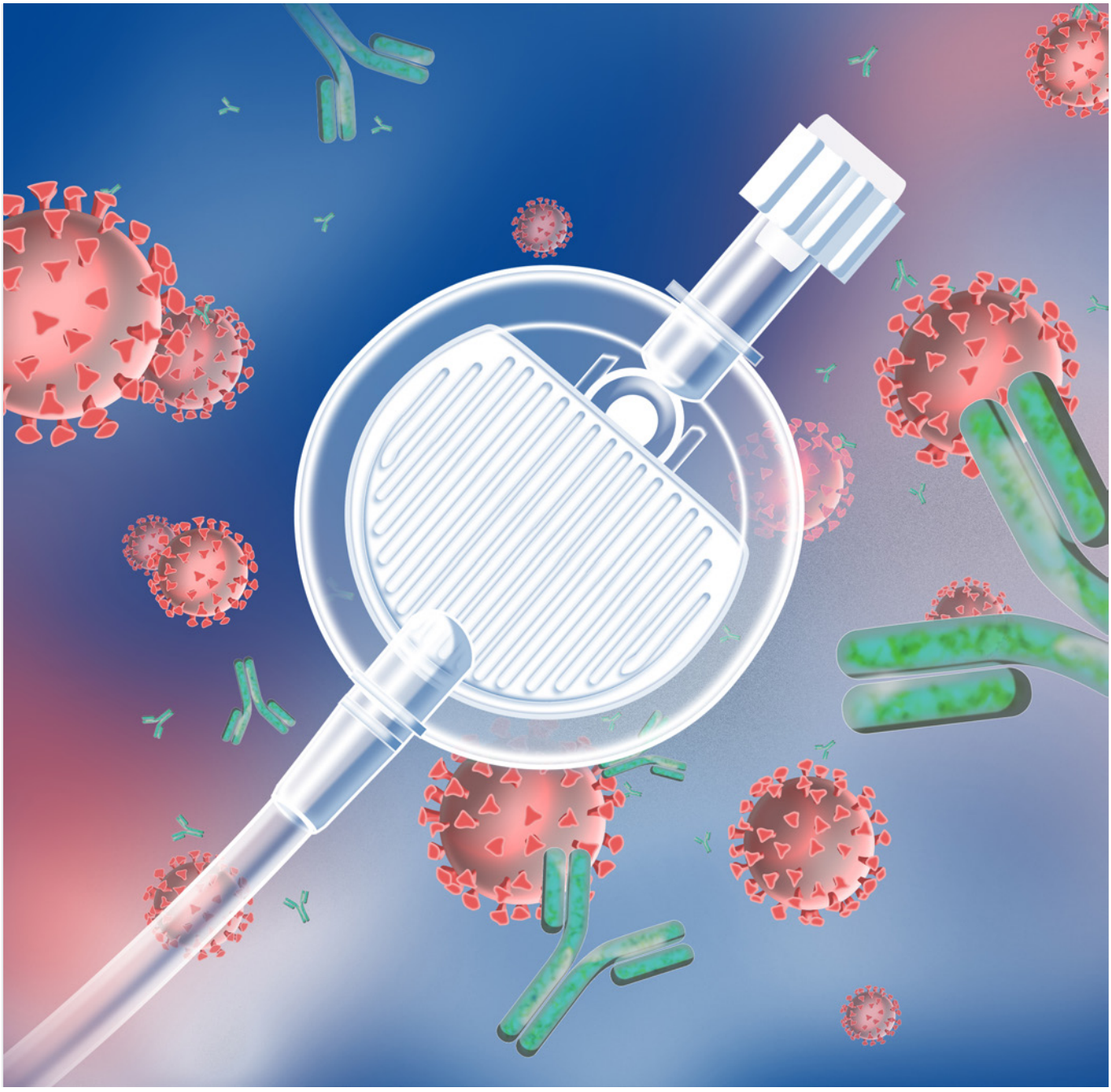
PALL Medical

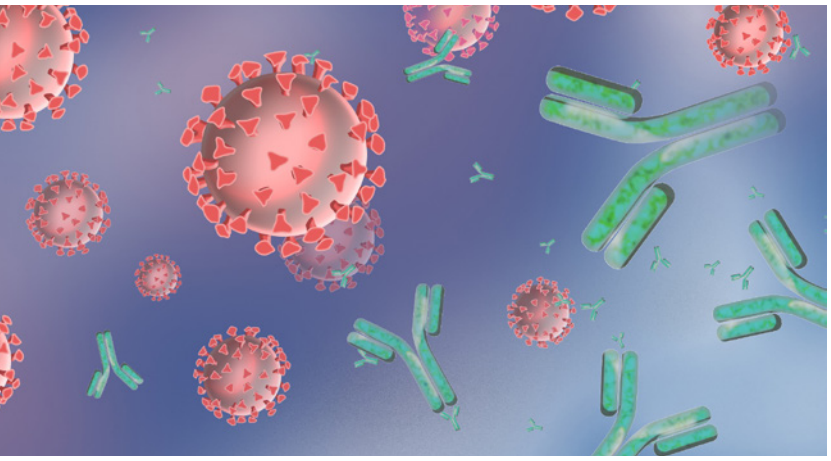
Supor™ AEF Filter 0.2 µm

Select the right filter for your monoclonal antibody therapy:

Pall 0.2 µm, low protein binding Supor™ polyethersulfone (PES) membrane filter



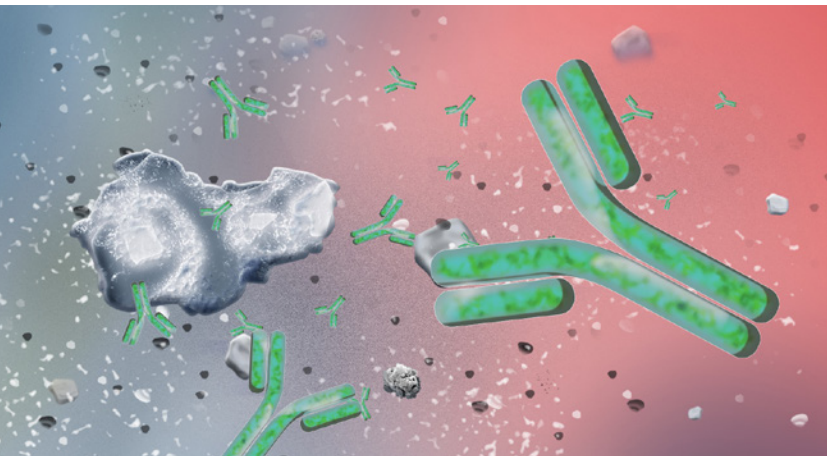
Protect What Matters - Every Day



Monoclonal Antibody Therapy

Monoclonal antibodies (names ending in '-mab') belong to the group of immunomodulators. At present, more than 100 monoclonal antibody drugs are approved in the US and the EU.[1]

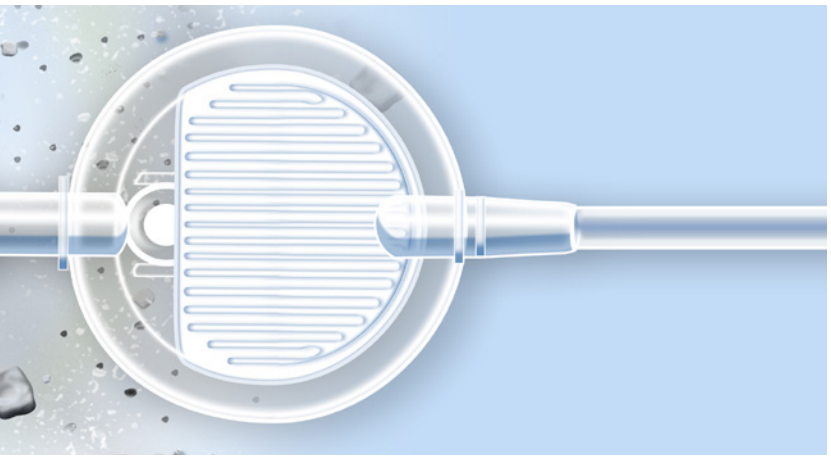
Many monoclonal antibodies (i.e. clones of a single parent cell) are currently under investigation for the treatment of Covid-19.[2]



Particles in antibody therapies: a potential issue

Particulate contamination arises from a variety of sources, intrinsically in infusate and equipment, and extrinsically due to manipulations. The large number of drugs administered simultaneously to patients in hospitals results in the formation of particles that may potentially be infused and in-line filters have been shown to be effective to remove particulate contamination during a pediatric multi-drug infusion protocol.[3]

Protein Aggregates: Protein drug products play an important role in the treatment of severe diseases. However, due to the instability of these complex molecules, protein aggregates can form which can compromise drug safety and efficacy including immunogenic reactions. It has been demonstrated that bedside filtration is a powerful tool to protect patients from protein aggregates.[4]



Intravenous (IV) in-line filters: a potential solution to retain particles

Many manufacturers of monoclonals have a requirement for IV filtration in their instructions for use, these include some of those being used for the treatment of Covid-19 patients.

Table 1: IV in-line Filter Statements regarding Preparation and Administration of monoclonal antibody therapies for the treatment of Covid-19 patients (current status as of January 2021)

Trade Name / Generic Name	Filter Statements	Link to statement
Bamlanivimab	Use of an in-line or add-on **0.20/0.22 micron polyethersulfone (PES) filter** is strongly recommended.	FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF BAMLANIVIMAB[5]
Casirivimab and Imdevimab	Administer as an IV infusion via pump or gravity over at least 60 minutes through an intravenous line containing a sterile, **in-line or add-on 0.2-micron polyethersulfone (PES) filter**.	FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB[6]

Supor™ AEF Filter 0.2 µm

One concern is that monoclonal antibodies could potentially bind to and be eliminated by the filters. The purpose of this study was to evaluate compatibility of Pall Supor AEF Intravenous filters, that contain a 0.2 µm low protein binding Supor membrane with monoclonal antibody drugs. Two typical monoclonal antibody drug administration scenarios were simulated by infusion of radiolabelled IgG in saline.

Method

- Administration regime A (high dose challenge) – infusion of 100 mg/hr IgG increasing by 100 mg/hr at 30 minute intervals to a maximum of 400 mg/hr. IgG concentration was 1.4 mg/mL with the total IgG challenge 747 mg.
- Administration regime B (low dosage challenge) – infusion of 30 mg IgG in 100 mL over a 1 hour period.

Result

Table 2: Absolute binding of IgG to Pall Supor AEF Intravenous Filters for Administration regimes A and B

	Regime A: IgG Bound	Regime B: IgG Bound
Filter	mg	mg
AEF1E	0.08	0.08

Conclusion

This study demonstrates that with a full clinical evaluation Pall Supor 0.2 µm AEF intravenous filters can potentially be used during infusion of monoclonal antibody-based drugs.

For more information download the full “Technical Report – Binding of Monoclonal Antibodies to Pall SuporAEF Intravenous Filters”[7] under https://www.pall.com/en/medical/infusion-therapy/monoclonal-antibodies.html

1. Antibody Society (2020). Antibody therapeutics approved or in regulatory review in the EU or US. Retrieved from https://www.antibodysociety.org/resources/approved-antibodies/
2. Jeff Craven (2020). COVID-19 therapeutics tracker. Retrieved from https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-therapeutics-tracker
3. Perez M, Decaudin B, Abou Chahla W, Nelken B, Storme L, Masse M, Barthelemy C, Lebuffe G, Odou P. Scientific Reports, 2018; May 16;8(1):7714.
4. Werner PW, Winter G. Journal of Pharmaceutical Sciences, 2018;107:2775-2788.
5. FDA (2020). Fact Sheet For Health Care Providers Emergency Use Authorization (Eua) Of Bamlanivimab. Retrieved from https://www.fda.gov/media/143603/download
6. FDA (2020). Fact Sheet For Health Care Providers Emergency Use Authorization (Eua) Of Casirivimab And Imdevimab. Retrieved from https://www.fda.gov/media/143892/download
7. Pall technical Report (2021). Technical Report – Binding of Monoclonal Antibodies to Pall SuporAEF Intravenous Filters, 210112.1IGL

The Pall Supor AEF Filter (AEF1E) is an air-eliminating filter with low protein binding 0.2 µm Supor membrane for up to 24 hours use, with any administration set, for the removal of inadvertent particulate debris, microbial contaminants and entrained air which may be found in solutions intended for intravenous use.

Contraindications

This device cannot be used to administer cellular blood products, suspensions, emulsions, including micro-emulsion vitamin preparations, or medications that are not fully dissolved in the fluid being administered.

The device should not be used to filter solutions that are known to be pyrogenic or contaminated with micro-organisms

AEF1E reorder code is FDA 510(k) cleared product and CE marked under the Medical Devices Directive (93/42/EEC).

PRECAUTIONS: FOLLOW INSTRUCTIONS FOR USE CAREFULLY

Specifications

Filtration Media:

- **Pore Size:** 0.2 µm hydrophilic (Supor) membrane
- **Surface Area:** Approx. 4.5 cm²

Air Elimination:

Two hydrophobic membrane vents

Tubing Extension:

- Microbore (0.9 mm ID/2 mm OD), 25 cm length downstream of the filter
- Non-phthalate (TOTM plasticised) polyvinyl chloride

Hold-up Volume:

Approx. 1.0 mL

Maximum Flow rate under gravity:

Approx. 9 mL/min with 0.9% (w/v) saline @ 1 m gravity feed.

Infusion Regime

The filters are compatible with all standard clinical infusion regimes including use with infusion pumps and syringe pumps.

Connections:

ISO female luer inlet and ISO male luer outlet

Sterility:

Sterile (Gamma irradiation) and non-pyrogenic fluid pathway

Shelf Life:

5 years

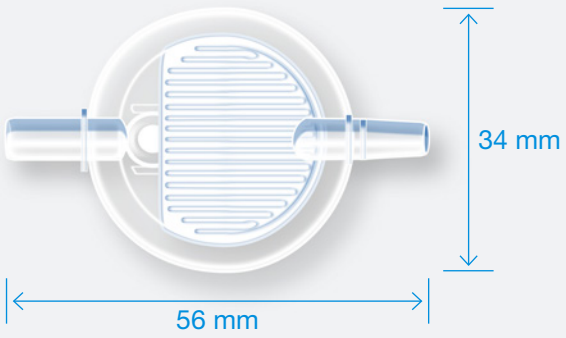
Biocompatibity:

All materials in the fluid pathway meet relevant sections of ISO 10993 series of standards.

Ordering information

Recorder Code	Product Description	Packaging	Quantity (units/case)
AEF1E	Supor AEF low protein binding intraveneous filter set for 24-hour use, inlet female luer connector, outlet microbore tubing, slide clamp, and male luer connector	Individually packaged	50

Supor AEF 0.2 µm Filter
shown at actual size
(AEF1E without the tubing extension)



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Protect What Matters - Every Day

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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