Size based membrane filtration provides critical virus removal assurance in most established and new biopharmaceutical molecule production processes. Even for highly purified process intermediates, the presence of protein aggregates, denatured proteins and other impurities limit hydraulic performance of virus filters, increasing the required filter area and costs.

Pretreatment of feed streams can remove plugging species, resulting in more favorable economics and robust processing. Our Viresolve® Pro Shield or Shield H are effective at removing these species from many monoclonal antibody (mAb) processes. They provide an adsorptive removal that improves the capacity of the Device by an average of two-fold while allowing the Device to deliver high parvovirus removal and flux. Results of the Viresolve® Pro Device capacity improvement are shown in Figure 1.

We were issued two patents that cover the use of adsorptive depth filters and charged or surface modified microfiltration (MF) membranes to remove aggregates from protein solutions in order to enhance performance of virus filters.

Figure 1. The Viresolve® Pro Shield or Shield H improves the Viresolve® Pro Device performance across a broad range of pH and/or conductivity.
Expansion of Viresolve® Pro Solution

Viresolve® Pro Shield + Viresolve® Pro Device =

Viresolve® Pro Shield or Shield H may be optimal

Figure 2. The contour plot shows the optimal performance for Shield or Shield H depending on the pH and conductivity of the mAb.

Viresolve® Pro Shield
- Membrane based
- Cation exchange adsorptive chemistry
- Caustic stable
- Low extractables

Viresolve® Pro Shield H
- Membrane based
- Mixed mode adsorptive chemistry
- Caustic stable
- Low extractables

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US Patent 7,118,675 B2 covers the use of adsorptive depth filters or charged or surface-modified microfiltration membranes in front of a viral filter to enhance the virus filter performance by removing aggregates from protein solutions.

US Patent 7,465,397 B2 involves the process of removing aggregates and viruses using a depth filter upstream of a viral filter in either a constant pressure or pump system. Adsorptive depth filters and modified microfiltration filters that allow for increased capacity and robustness of our virus filters are part of the Viresolve® offering. As part of our continued goal to provide our customers with the right tools and technologies to perform effective and robust virus filtration, we provide customers with a free license to use the process.