1. Introduction
Current bio-manufacturing processes have reached a high degree of standardization and companies are working on the basis of proven technology platforms. Single-use technology has become a viable option for clinical as well as commercial manufacturing. To reduce time to market multiple process lines with fully single-use technologies are used which provides highest flexibility to bring the products fast into the market. Investment costs are much lower and in addition also safety aspects are considered in a much better way. These are just some advantages of fully single-use processes. This poster will focus on concepts for creating single-use virus filtration steps in different manufacturing ways.

2. Virus Filter Transfer Sets
Virus Filter Transfer Sets are pre-assembled, pre-sterilized and fully pre-qualified ready to use virus filters that allow an easy integration into a single-use set up. They have been optimized to allow them to handle higher operating pressures of 2.0 up to 3.0 bar typically needed for the virus filtration steps. Therefore pressure stable reinforced tubing have been implemented into the filter assembly. Water flow rates were measured at 2.0 bar | 30 psi. Mechanical stability test. A peristaltic pump was used for 2 hours to operate the filter assembly at the diffusion limit is 60 mL/min at 4.5 bar. The filter assembly was first undergoing a mechanical stability test. A peristaltic pump was used for 2 hours to operate the filter assembly at an operating pressure of 3.0 bar. The tubing were checked for leaks at the IT test. The appearance of the tubing is 60 at an inlet pressure of 6.5 bar.

3. MaxiCaps® MR Virosart®
Larger virus filtration areas are needed when it comes to larger bioreactor volumes (up to 20k L) or when the molecules are rather challenging to filter. Therefore a pre-filter (Virosart Max®) and the virus filter (Virosart® HF) have been implemented into the MaxiCaps® MR with different areas being available. One central venting lines allows easy handling. The device comes pre-connected and ready to use with max. 4 connections at inlet and outlet have to be made on site. Multiple test were performed during product validation and respectively a few examples are shown: Adsorptive Pre-filter (Virosart® Max) Virus Filter (Virosart® HF)

4. Summary
These new developments enable a fully sterile single-use operation for the virus filtration step. Quick and easy to handle up to x4m² pre-sterilized within one step for manufacturing scale with the option of sterile pre-use IT for highest process safety.