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 stable option for clinical as well as commercial manufacturing. To reduce time to market multiple facilities 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 filtrations 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. Their design has been optimized to allow them to handle higher operating pressures e.g. during virus filtration. Metal rings (Oetiker® clamps) have replaced cable ties to strengthen connections. Manufacturers can choose between different types of tube lengths and connection needed for flexible process implementation.

Multiple test were performed during product validation and respectively a few examples are shown:

3. MaxiCaps® MR Virosart®

Larger virus filtration areas are needed when it comes to larger bioreactor volumes (up to 20k L) or when the minimums 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.

4. Summary

These new developments enable a fully sterile single-use operation for the virus filtration step. Quick and easy to handle up to 24 m² pre-sterilized within one step for manufacturing scale with the option of sterile pre-use IT for highest process safety.