

Simplifying Large Scale Single-Use Filtration While Decreasing Risk With a Novel Modular Approach

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Introduction

Filtration plays a critical role in assuring the safety and quality of biopharmaceutical products. Stainless steel multi-round housings are commonly used in conventional large-scale filtration processes, while filter assemblies with multiple components and connections provide a single-use alternative (Figure 1). Single-use systems offer flexibility and speed in the production of pharmaceuticals and vaccines. Large-scale production increases material consumption (due to the increased number of components involved), process complexity and associated risks. To meet these challenges, Sartorius developed a modular platform-based approach called Maxicaps® MR that offers a simplified, standardized design with integrated functionality for large-scale filtration applications in protein- and virus-based therapy production processes.



Figure 1: Filter Assembly

Leakage Risk Mitigation by Design

Figure 2a shows the number of process connections that must be performed by the operator (via sterile connectors, welding, and hygienic clamps) across different filter configurations for filter assemblies compared to the Maxicaps® MR. Each connection, if not performed properly, creates a risk of leakage. Cable tie connections pose an additional leakage risk if not done correctly during production or if the tubing is bent near the connection (Figure 2b).

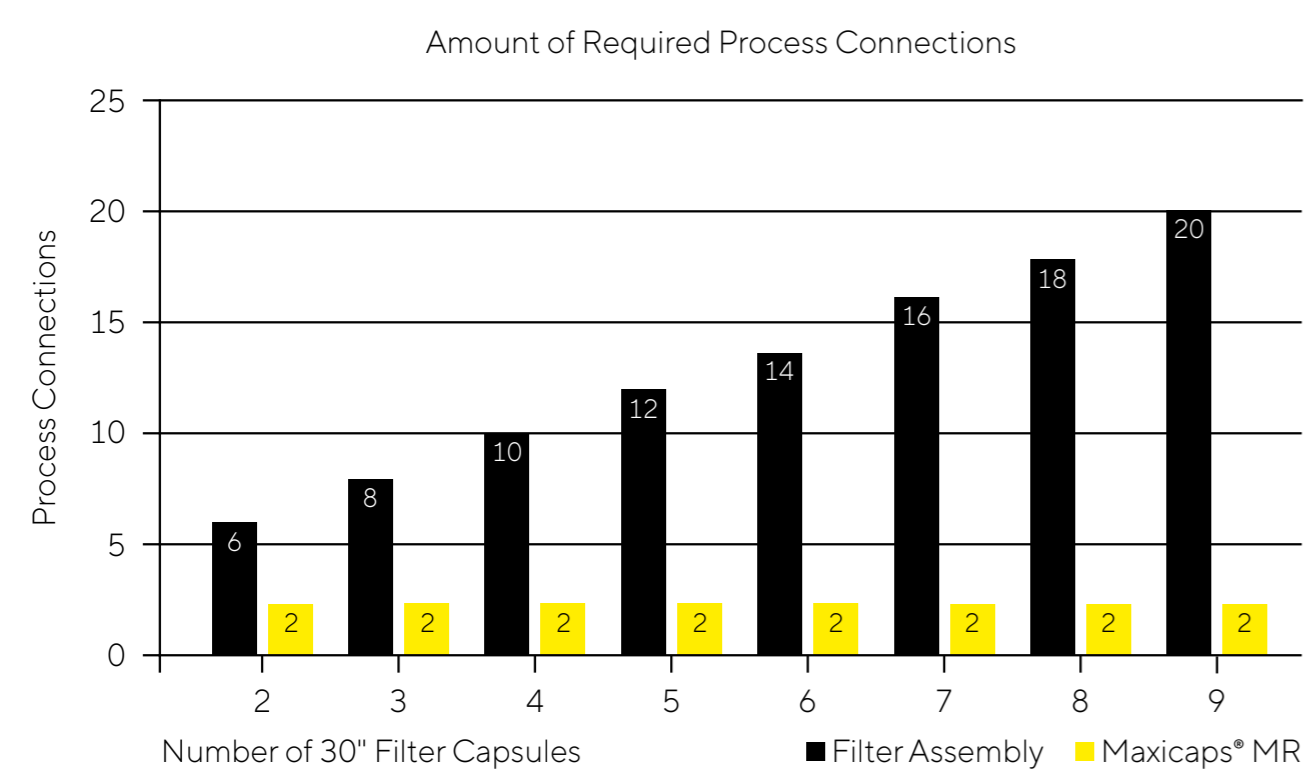


Figure 2a: Comparison of Process Connections

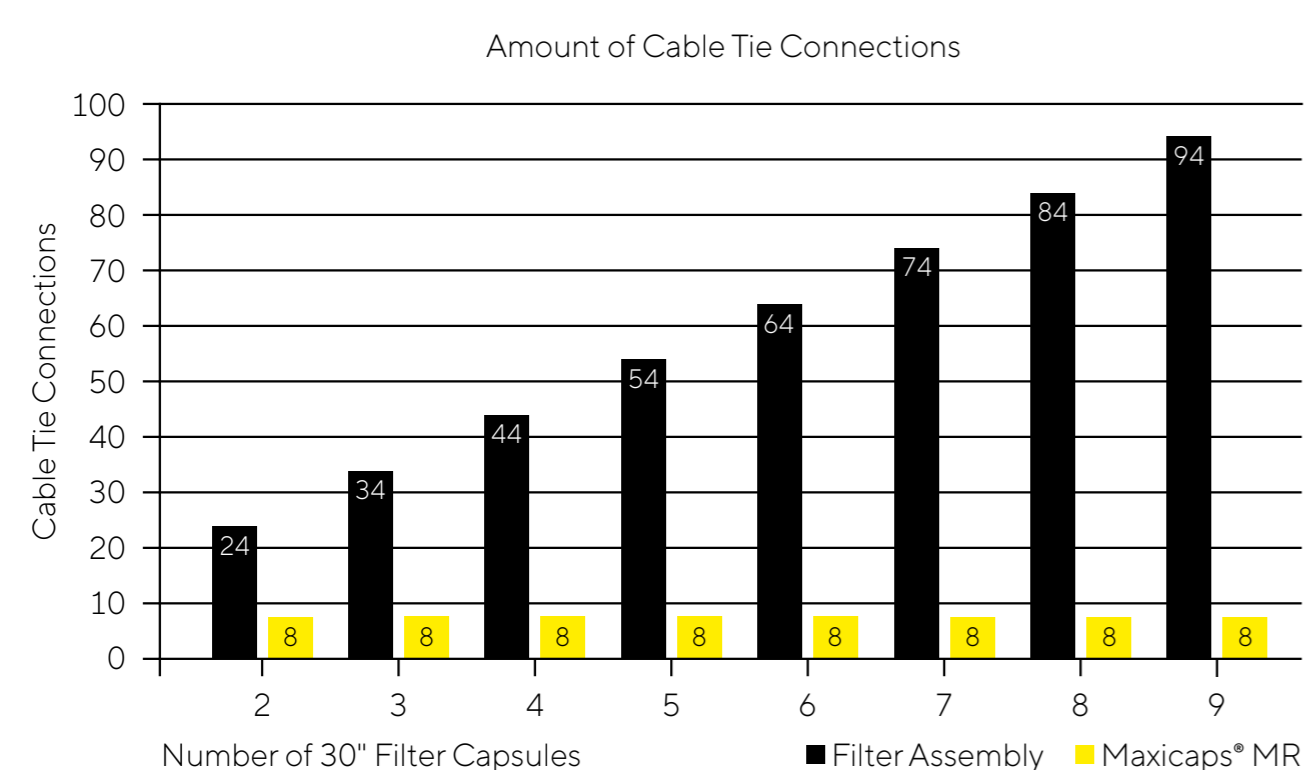


Figure 2b: Comparison of Cable Tie Connections

Figure 3 shows the large-scale filtration device Maxicaps® MR, the first available product based on this unique platform.



Figure 3: Maxicaps® MR

Novel Integrated Connections and Valve Technology

A key aspect of this modular design is finding the right level of granularity. A common approach is to focus on the part of the product which can not be divided into further components based on its function. In this specific case, this part is the filter element. Around the filter element, further components were designed according to essential functionalities: connectivity of various elements, fluid distribution and control, shown in Figure 4.

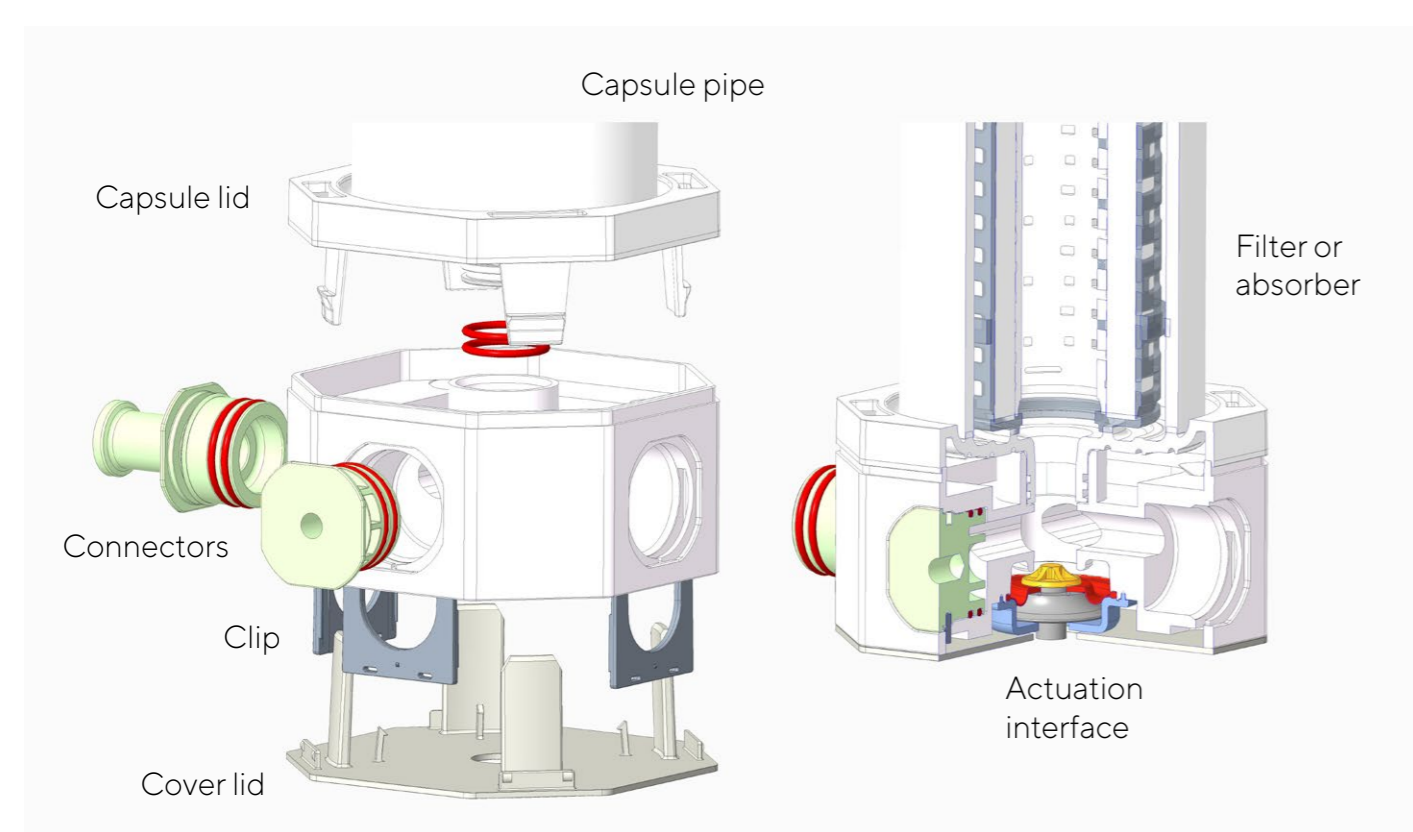


Figure 4: Modular Design Concept With Integrated Connection and Technology

Reduced Material Usage

The new modular design concept offers another significant advantage compared to filter assemblies: a much lower material usage, shown in Figure 5. The lower material usage of the Maxicaps® MR is mainly due to reduced packaging as well as connection and tubing material.

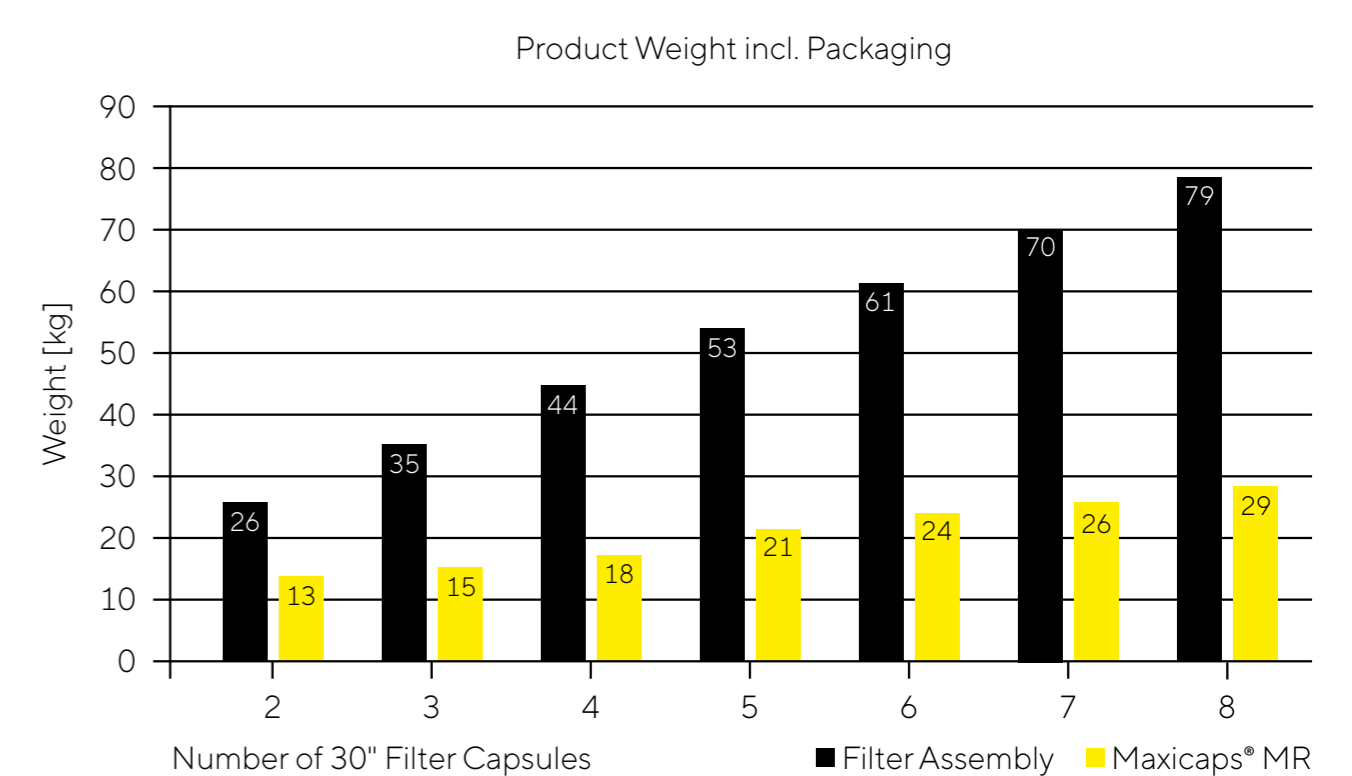


Figure 5: Comparison of Material Usage

Conclusion

This data demonstrates that the Maxicaps® MR, with its novel integrated connection and valve connection technology, minimizes the risk of leaks and significantly reduces overall material usage.

Maxicaps® MR key features:

- Effective filter area from 2.4 to 27 m²
- Minimal operator intervention required
- Only two process connections
- Low-waste product and packaging design

Outlook

This newly developed, unique modular design concept has advantages in biopharmaceutical production beyond large-scale filtration. This concept allows process intensification by combining multiple unit operations into a single unit, reducing space, energy consumption, and waste generation (Figure 6).



Figure 6: Single Unit With Multiple Integrated Unit Operations