



Life Sciences

Instructions For Use

USD 2851

Mini Kleenpak™ Capsule Filterability Tool with Pegasus™ SV4 Virus Removal Filter Membrane

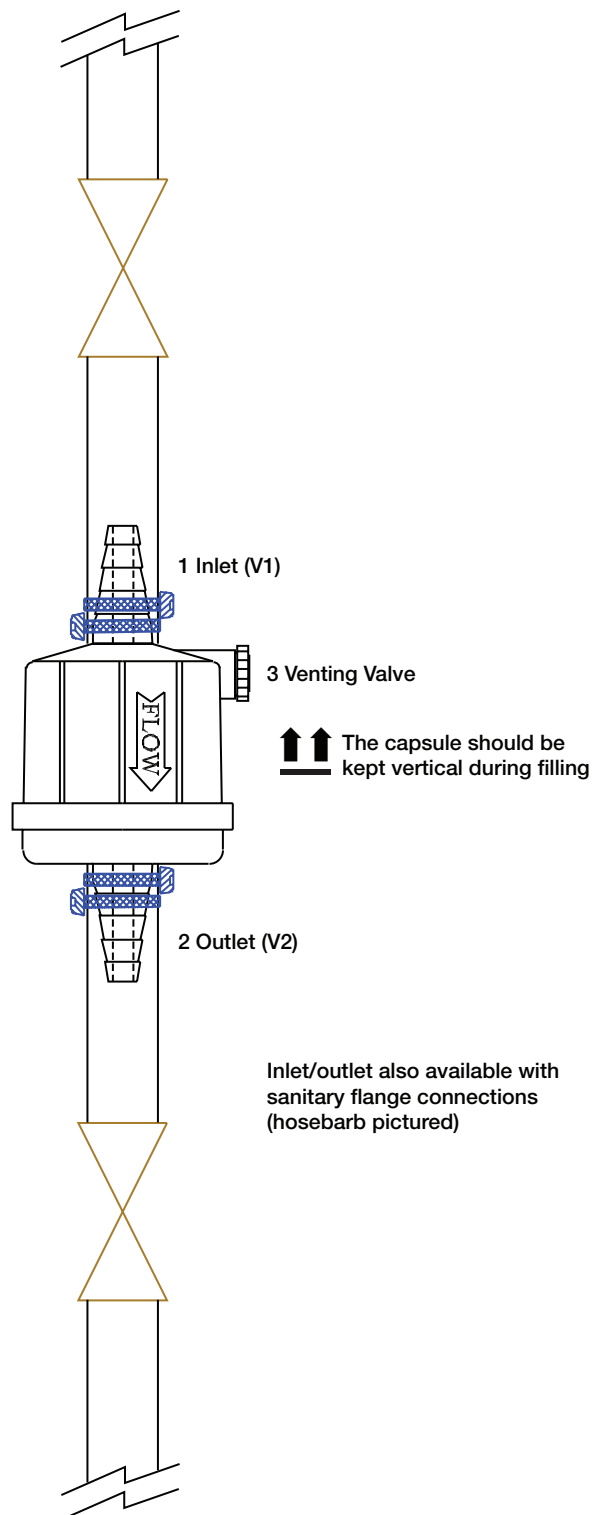


Mini Kleenpak Capsule Filterability Tools are for filter-sizing studies and evaluation during process development only. They are not qualified for bacteria or virus removal.

Pall Corporation provides filters for use during drug manufacture or for animal, human therapeutic or diagnostic needs. Please contact Pall for details of these filters where needed as Mini Kleenpak Capsule Filterability Tools are not intended for these purposes.

Figure 1

Mini Kleenpak Capsule Filterability Tool



Operating Parameters

Maximum Operating Pressure	4.1 barg (60 psig)
Recommended Operating Differential Pressure	2.1 – 3.1 barg (30 – 45 psid)
Operating Temperature Range	2 °C to 38 °C (36 °F to 100 °F)

Please refer to the product datasheet (Pall publication USD2852) or technical specifications for materials of construction and effective filtration area.

It is recommended that the Mini Kleenpak Capsule Filterability Tool is used under expected production conditions.

Pall's Scientific and Laboratory Services (SLS) Global Technical Support team can assist with filtration tests either at customer sites or in our own facilities.



Attention:

- Please observe the operating parameters and guidelines for use
- Use the Mini Kleenpak Capsule Filterability Tool exclusively for liquids
- Assess the compatibility of your fluid with the Mini Kleenpak Capsule Filterability Tool
- Keep the Mini Kleenpak Capsule Filterability Tool in an upright, vertical position during filling steps (see Figure 1).
- Make sure that no system pressure prevails during connection or disconnection of the Mini Kleenpak Capsule Filterability Tool

Operation and Guidelines for Use (Refer to Figure 1)

1. Prepare the Mini Kleenpak Capsule Filterability Tool, connecting to ancillary tubing
2. Connect upstream tubing to an appropriate pump or pressure source, depending on anticipated operating conditions at process scale
3. Close the valves V1 and V2 (see Figure 1)
4. Open the venting valve
5. Slowly open valve V1 and fill the Mini Kleenpak Capsule Filterability Tool with fluid until fluid escapes at the venting valve
 - First contact fluid should be 0.2 µm filtered DI water (or finer grade)
 - Fill rate should be ≤ 40 mL/min (≥ 1 minute capsule fill time for first fill)
 - If using a pump, stop the pump before closing the vent valve to avoid over-pressurization
6. Close the venting valve
7. Now open valve V2 and increase the pressure or adjust the flow rate to reach a differential pressure of 2.1 barg (30 psid)
8. Run initial water flush for 10 minutes
9. Measure the water flow rate
10. Stop the pump/depressurize the system
11. Drain excess liquid through the vent valve (invert the capsule)
12. An optional autoclave step may be implemented at this point
 - Refer to Pall document USTR805 for autoclave sterilization guidelines
 - Pegasus SV4 Mini Kleenpak Capsule Filterability Tools must be wetted with water prior to autoclaving
 - Pegasus SV4 Mini Kleenpak Capsule Filterability Tools must not be allowed to Dry Out after autoclaving
 - Repeat water wetting and flushing (steps 3-11) after autoclaving

13. Repeat the slow fill procedure above (steps 3-6) for subsequent fluids (buffer, product)
 14. Open valve V2, adjusting to the required flow rate or operating pressure as guided by small scale disc studies and/or production scale system specifications
 15. Process for the required throughput and time, recording the flow rate
 16. Safely stop the test (repeat steps 10-11)
 17. Following use, rinse if necessary and dispose of in accordance with local regulations
- Consult Pall for more detailed guidance on filter sizing under conditions of constant flow or constant pressure.



Important note:

All information contained is based on today's knowledge. It does not claim to be complete, therefore no liability can be accepted. All users are advised to test Pall products to ensure they meet their specific requirements and to exercise all necessary care when in use. The information in the instruction manuals issued by Pall should be strictly observed. Departure any specific instructions means Pall cannot accept any responsibility for damage which may result. Should you encounter specific problems, please contact our specialists. Pall reserves the right to make alterations without prior notice.



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