Allegro™ Ready

FILTER SETS

Collected data highlights that each delay in biotech projects generates revenue losses. With a significantly reduced lead time, our Allegro™ Ready range of single-use systems have been developed to accelerate implementation and reduce costly delays within your process. As standard designs, they are manufactured using preferred components from our advanced central management system (ACMS) data management system, enabling us to select from a vast pool of qualified and stocked components. In addition to the increased speed from the time of order to delivery, our Allegro Ready systems are accompanied by a quality risk management data package that covers the life cycle of the system. Access to our regulatory support documentation also comes as standard, providing full qualification documentation to meet your project milestones and satisfy regulatory requirements.

The Allegro Ready filter sets are available with different sterilizing-grade filter media and filter sizes and a choice of different connection types and tube materials.

Allegro Ready filter sets can be used in wide range of applications, including monoclonal antibodies (mAbs), vaccines, for plasma, cell and gene therapies, at any process step for liquid buffer/media, semi-product filtration or final product filtration.

All standard filter sets are supplied gamma irradiated and supported with a comprehensive documentation package.

Two sterilizing-grade filter medias are available in standard filter sets – Supor™ EKV filters and Fluorodyne™ II DFL filters for different applications.

Supor EKV filters include a 0.2 micron-rated validated sterilizing-grade filter membrane. The incorporated polyethersulfone (PES) membrane demonstrates high compatibility over the whole pH range plus low protein binding to optimize transmission of the active ingredients (see data file Supor EKV filters).



Fig 1. Example of Allegro Ready filter set.

Fluorodyne II DFL filters also feature a 0.2 micron-rated validated sterilizing-grade filter membrane. The incorporated polyvinylidene fluoride (PVDF) membrane ensures low extractables and adsorption. They are recommended for sterilizing filtration of pharmaceutical fluids including solutions with active ingredients, biologicals, biotech proteins, ophthalmics and other dilute preservative solutions (see data file Fluorodyne II filters).

The Kleenpak™ capsules are rugged and compact filter capsules available with a broad range of filter media and different sized formats designed for a variety of small to large scale pharmaceutical manufacturing applications with volumes of 2 to 1000 L.

The Kleenpak Presto sterile connectors are integrated into standard filters sets. The Kleenpak Presto sterile connector is quality assured and inspected at point of manufacture to allow device traceability, as each device has its own serial number. The manufacturing process of Kleenpak Presto sterile connectors uses an automatic vision system that limits defects in the membrane and membrane welding (see data sheet Kleenpak Presto sterile connectors).



Quality standards

The Allegro Ready single-use filter sets are manufactured under a quality management system certified to ISO 9001 quality management systems. All Cytiva single-use systems are produced according to the quality by design approach, including considering components, validation, junction validation and application validation. All joints are 100% tested. The single-use systems are manufactured in a controlled environment (ISO 7 in operations).

- Manufactured for use in conformance with current good manufacturing practices (cGMP).
- Filters included into the design are integrity tested.
- ISO 9000 certified quality system.
- Meets United States Pharmacopeia (USP) <88> biological reactivity test, in vivo, for class VI – 121°C plastics.
- Test correlated to microbial retention.
- Meets USP <85> bacterial endotoxins test.
- Meets USP <788> particulate matter in injections.
- The assembled systems undergo stringent qualification and validation as part of the manufacturing process.
 Additionally, all assembled systems are inspected for quality.



Fig 2. Example of Allegro Ready filter set in use.

Ordering information

A summary of available Allegro Ready filter sets configurations and detailed design information are shown in Table 1 and Table 2. Design configurations according to the figures below.

To order standard Allegro systems, please contact us and quote the desired product code listed in the tables, or visit cytiva.com.

Each unit placed is double bagged and heat sealed. Supplied in box quantities, gamma irradiated.

In order to reduce our carbon footprint, we strive to provide single-use systems manufactured regionally. However, to increase security of supply you may receive product from multiple global sites.

To order standard Allegro systems, please contact us and quote the desired product code listed in the tables above or go to cytiva.com

Table 1. Allegro Ready filter sets with Supor EKV filter capsules.

Product	Inlet	Filter type	Outlet	Pressure rating	MOQ (1)	Configuration	Product code
Standard filter set	0.1 m of platinum cured silicone tubing with tri clamp connection 1½ in.	KM5EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 3	7090-1621G
Standard filter set	0.1 m of thermoplastic elastomer tubing with tri clamp connection 1½ in.	KM5EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 3	7090-1598F
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	KM5EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 4	7090-1622Z
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	KM5EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 4	7090-1599P
Standard filter set	0.1 m of platinum cured silicone tubing with tri clamp connection 1½ in.	KA02EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 5	7090-1621H
Standard filter set	0.1 m of thermoplastic elastomer tubing with tri clamp connection 1½ in.	KA02EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 5	7090-1598G

Product	Inlet	Filter type	Outlet	Pressure rating	MOQ (1)	Configuration	Product code
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	KA02EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 6	7090-1623B
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	KA02EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 6	7090-1599Q
Standard filter set	Tri clamp connection 1½ in.	KA1EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1619T
Standard filter set	Tri clamp connection 1½ in.	KA1EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1388B
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA1EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1620T
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA1EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1438A
Standard filter set	Tri clamp connection 1½ in.	KA2EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1619U
Standard filter set	Tri clamp connection 1½ in.	KA2EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1388C
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA2EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1620U
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA2EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1438B
Standard filter set	Tri clamp connection 1½ in.	KA3EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1619V
Standard filter set	Tri clamp connection 1½ in.	KA3EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1388D
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA3EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1620V
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA3EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1438D
Standard filter set	Tri clamp connection 1½ in.	NP5LEKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 9	7090-1621J
Standard filter set	Tri clamp connection 1½ in.	NP5LEKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 9	7090-1598H

Product	Inlet	Filter type	Outlet	Pressure rating	MOQ (1)	Configuration	Product code
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	NP5LEKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 10	7090-1623C
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	NP5LEKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 10	7090-1599R
Standard filter set	Tri clamp connection 1½ in.	NP6EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 11	7090-1619S
Standard filter set	Tri clamp connection 1½ in.	NP6EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 11	7090-1387Z
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	NP6EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 12	7090-1620S
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	NP6EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 12	7090-1437Z
Standard filter set	Tri clamp connection 1½ in.	NT7EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 13	7090-1618T
Standard filter set	Tri clamp connection 1½ in.	NT7EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 13	7090-1387Y
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	NT7EKV	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 14	7090-1620M
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	NT7EKV	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 14	7090-1437U

⁽¹⁾ MOQ – minimum order quantity

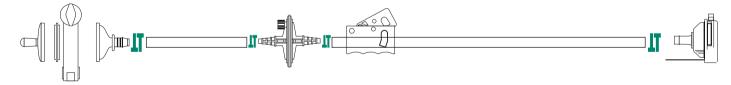


Fig 3. Kleenpak KM5 filter capsules.

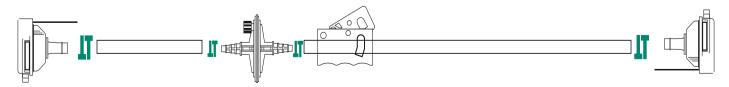


Fig 4. Kleenpak KM5 filter capsules.

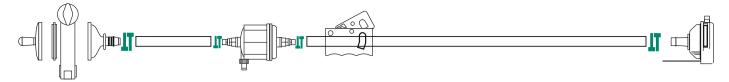


Fig 5. Kleenpak KA02 filter capsules.

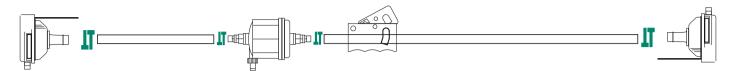


Fig 6. Kleenpak KA02 filter capsules.



Fig 7. Kleenpak KA, KA2 and KA3 filter capsules.

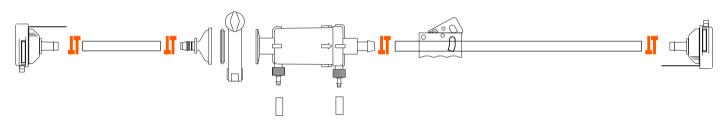


Fig 8. Kleenpak KA1, KA2 and KA3 filter capsules.

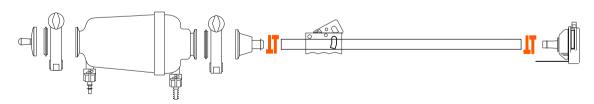


Fig 9. Kleenpak Nova NP5 filter capsules.



Fig 10. Kleenpak Nova NP5 filter capsules.

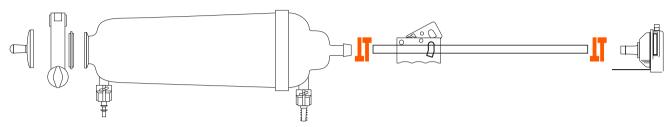


Fig 11. Kleenpak Nova NP6 filter capsules.

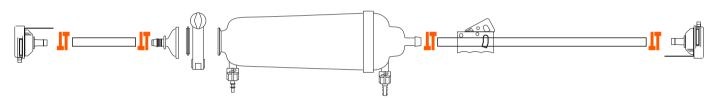


Fig 12. Kleenpak Nova NP6 filter capsules.

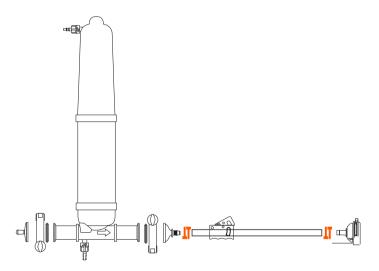


Fig 13. Kleenpak Nova NT7 filter capsules.

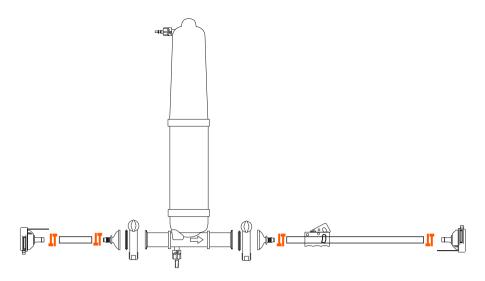


Fig 14. Kleenpak Nova NT7 filter capsules.

Table 2. Allegro Ready filter sets with Fluorodyne II filter capsules.

Product	Inlet	Filter type	Outlet	Pressure rating	MOQ (1)	Configuration	Product code
Standard filter set	0.1 m of platinum cured silicone tubing with tri clamp connection 1½ in.	KA02DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 5	7090-1621A
Standard filter set	0.1 m of thermoplastic elastomer tubing with tri clamp connection 1½ in.	KA02DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 5	7090-1597X
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	KA02DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 6	7090-1622U
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	KA02DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector % in.	0.4 bar	12	Figure 6	7090-1598U
Standard filter set	Tri clamp connection 1½ in.	KA1DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1621B
Standard filter set	Tri clamp connection 1½ in.	KA1DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1597Y
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA1DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1622V
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA1DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1599J

Product	Inlet	Filter type	Outlet	Pressure rating	MOQ (1)	Configuration	Product code
Standard filter set	Tri clamp connection 1½ in.	KA2DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1621C
Standard filter set	Tri clamp connection 1½ in.	KA2DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1598B
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA2DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1622W
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA2DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1599K
Standard filter set	Tri clamp connection 1½ in.	KA3DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1621D
Standard filter set	Tri clamp connection 1½ in	KA3DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 7	7090-1598C
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	KA3DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1622X
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	KA3DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 8	7090-1599M
Standard filter set	Tri clamp connection 1½ in.	NP5LDFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 9	7090-1662D
Standard filter set	Tri clamp connection 1½ in	NP5LDFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 9	7090-1662B
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	NP5LDFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 10	7090-1618K
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	NP5LDFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	12	Figure 10	7090-1437X
Standard filter set	Tri clamp connection 1½ in.	NP6DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 11	7090-1621E
Standard filter set	Tri clamp connection 1½ in	NP6DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 11	7090-1598D
Standard filter set	0.1 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	NP6DFL	0.5 m of platinum cured silicone tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 12	7090-1622Y
Standard filter set	0.1 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	NP6DFL	0.5 m of thermoplastic elastomer tubing with Kleenpak Presto sterile connector ½ in.	0.4 bar	6	Figure 12	7090-1599N

 $^{^{\}mbox{\scriptsize (1)}}$ MOQ – minimum order quantity

Documentation

The documentation supplied with these systems is as follows:

- · System certificate
- Irradiation certificate

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