

## Pharmaceuticals and Biologicals



**High-Value Filtration Systems**

# Pharmaceuticals and Biologicals

Assurance of your product quality and purity must be consistent for every batch produced. Through our filtration platform we are able to ensure cost effective solutions to support your critical processes and so enable you to bring your product to market. Our platforms integrate proven services and technologies for the development and manufacture of pharmaceutical and biopharmaceutical products.

Masterfilter offers a wide range of reliable and high-quality filtration solutions including cartridges, capsules and discs, single-use, integrity test equipment, virus filtration and filter housings. In close cooperation with our customers, we continuously strive to offer solutions to achieve the highest possible productivity and effectiveness in the pharmaceutical and biopharmaceutical industry.

<b>Cartridges</b>  PP, GF, NYLON, PTFE, PES, PVDF	<b>Capsules and Discs</b>  PP, GF, NYLON, PTFE, PES, PVDF	<b>Single-Use Equipment</b>  CUSTOMISED SOLUTIONS
<b>Virus Filtration</b>  PES, CELLULOSE	<b>Filter Housings</b>  STAINLESS STEEL AISI 316L	<b>Services</b>  VALIDATION SERVICE

## Focused Applications

- Water (Well, Tap and PW & Cold WFI)
- Compressed Air and Gas
- Venting
- API Clarification and Removal
- Sterile API
- Ophthalmic Solutions
- LVP Solutions
- Dialysis Solutions
- SVP Aseptic Production
- Buffer Solutions and Growth Media
- Blood Derivatives
- Biotechnology

# Cartridges

Masterfilter supplies reliable and high-quality filter cartridges for the microfiltration of liquids and gases. Various materials such as PP, GF, NYLON, PTFE, PES and PVDF as filter media with micron ratings from 0.1 to 70 µm and many end cap configurations are available.

## Particle Removal Cartridges

PP - Polypropylene				F - Glass Fiber	
<b>APK</b> Absolut pleated  Micron ratings: 0.2 to 20 µm Liquids	<b>APKM</b> Multi-layer  Micron ratings: 0.2 to 70 µm Liquids	<b>HPK</b> Nominal pleated  Micron ratings: 0.2 to 50 µm Liquids	<b>MBK-A</b> Melt blown absolute  Micron ratings: 0.3 to 50 µm Liquids	<b>LGFK</b> Very low level of extractables  Micron ratings: 0.1 to 5 µm Liquids	<b>DPESGF</b> PES membrane with GF layer  Micron ratings: 0.2 to 0.8 µm Liquids

## Sterilising Membrane Cartridges

NYLON		PES - Polyether Sulphone			
<b>NYPC</b> Positive charged  Micron ratings: 0.2 to 1.2 µm Liquids	<b>NYTC</b> Non charged  Micron ratings: 0.2 to 1 µm Liquids	<b>DPES</b> Double-layer  Micron ratings: 0.1 to 0.65 µm Liquids	<b>PESA</b> Asymmetric  Micron ratings: 0.2 to 1.2 µm Liquids	<b>PESE</b> Bioburden Control  Micron ratings: 0.2 to 1.2 µm Liquids	<b>PESS</b> Symmetric  Micron ratings: 0.1 to 1.2 µm Liquids

PVDF - Polyvinylidene Fluoride		PTFE - Polytetrafluoroethylene			
<b>PVDN</b> Hydrophilic  Micron ratings: 0.1 to 1 µm Liquids	<b>PVDD</b> Hydrophilic  Micron ratings: 0.1 to 1 µm Liquids	<b>PFA</b> Highly resistant  Micron ratings: 0.2 to 10 µm Liquids   Gases	<b>SLF-T</b> Hydrophobic  Micron ratings: 0.2 µm Gases	<b>SLF-HT</b> High temperature  Micron ratings: 0.2 µm Gases	<b>SLF-L</b> Solvent filtration  Micron ratings: 0.2 to 10 µm Liquids

## Capsules and Discs

Masterfilter supplies reliable and high-quality filter capsules and discs for the microfiltration of liquids and gases. Various filter media such as PP, GF, NYLON, PTFE, PES and PVDF with micron ratings from 0.1 to 70 µm and various configurations are available up to 30-inch length. Single-use filtration systems save cleaning time and validation costs.

### Liquid and Gas Filtration Capsules



The **MasterCap MC-Capsule** are used for removal of micro-organisms and fine particles from liquids and gases. Made of polypropylene shell and high-performance filtration media such as PP, PES, PTFE, PVDF, NYLON and Glass Fiber (GF) with a pore size of from 0.1 to 10 µm. They are the ideal filters to satisfy the highest standards in a broad range of applications.

#### Features:

- Available from 500 cm<sup>2</sup> to 30" lengths
- T-style and inline versions available
- High throughput and 100 % integrity tested
- Sterilisable in autoclave multiple cycles

### In-Line Steam Sterilisable Capsules



The **MasterSip MS-Capsules** are designed for use in sterile air and gas filtration in biopharmaceutical and other applications. Composed of a hydrophobic 0.2 µm PTFE membrane and a polyetherimide housing, these capsule filters provide an alternative to a stainless-steel housing/filter combination and thus reduces operating costs and maintenance time.

#### Features:

- In situ integrity testable by WIT
- Low investment cost compared to a standard cartridge and stainless-steel housing system
- Repeated SIP cycles for a long service life
- Able to operate at high gas pressure up to 6.9 bar

### Liquid and Gas Filtration Discs



The **Masterfilter DF Disc Filters** offer many different options for membrane filtration in various applications. Robust polypropylene hardware and high-performance hydrophobic 0.2 µm PVDF and PTFE membrane suit to satisfy the highest standards in a broad range of applications.

#### Features:

- Removal of particles and microorganisms for liquids and gases
- Minimal hold-up volume
- Autoclavable

# Single-Use Equipment and Virus Filtration

## Single-Use Equipment

Whether you are looking for an economical standard single-use system or require a custom-designed and built single-use system, Masterfilter can offer proven solutions at every scale. You can fully benefit of our experience and advantages of our single-use solutions to accelerate your time to market, improve your manufacturing flexibility and reduce your costs.

Our single-use portfolio includes storage bags, assemblies, mixers and systems for large volume transport and storage. A range of sterile connectors ensure closed connection and disconnection and our sterile sampling systems provide a reliable option for process monitoring.



2D/3D Bags



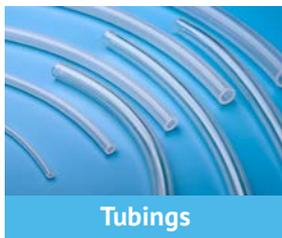
3D Mixing Bags



Aseptic Sampling Bags



Containers



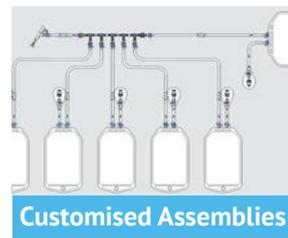
Tubings



Accessories



Foldable Totes



Customised Assemblies

## Virus Filtration

Virus removal filtration is regarded as a very effective and robust step for virus retention and has been widely applied in biologics manufacturing due to advantages such as simple and gentle operation, clear mechanism and ease of validation. Virus removal filters with a cut-off pore size of 20 nm are the most widely used solution as it provides high retention assurance toward minute viruses.



The **Viruclear® PVF virus removal capsule filter** adopts a PES membrane with a continuous gradient structure. It provides sufficient space for retention of the foulant which are basically protein aggregates. The pore size on the downstream side of the membrane is uniformly distributed around 20 nm that endows the membrane with robust virus retention even under the condition of process interruption or depressurisation. This virus filters are available with filtration areas from 0.017 to 1.5 m<sup>2</sup>.



The **Viruclear® VF virus removal membrane cassette** adopts a hydrophilic modified PES membrane. The upgradation gives improved mass capacity and adaptability across a broad range of typical protein feed streams, thus brings increased process economics. The VF also enables robust linear scale-up and easy process optimisation. This virus filters are available with filtration areas from 0.018 to 1.5 m<sup>2</sup>.

## Filter Housings



Masterfilter offers reliable and high quality 316L stainless steel filter housings for the microfiltration of liquids and gases. The housings are available in lengths from 2.5 to 30 inches in single or multiple stacks and different configurations. Our engineering team can design customer specific housing with optional mountings, high temperature and pressure designs.

### Liquid Filter Housings



The **Masterfilter Liquid Filter Housings** are manufactured for filtration of liquids. They are available in 2.5, 5, 10, 20 and 30-inch lengths. The housings are marked with a unique serial number for traceability. These filter housings are available with a range of pharmaceutical compliant vents and inlet/outlet connections and different configurations.

#### Features:

- T-style, Inline and Self-drainable design
- Manufactured in accordance with European regulations
- Fully sanitary design

### Gas Filter Housings



The **Masterfilter Gas Filter Housings** are manufactured for filtration of gases. They are available in 2.5, 5, 10, 20 and 30-inch lengths. The housings are marked with a unique serial number for traceability. These filter housings are available with a range of pharmaceutical compliant vents and inlet/outlet connections and different configurations.

#### Features:

- T-style and Inline design
- Manufactured in accordance with European regulations
- Fully sanitary design

### Vent Filter Housings



The **Masterfilter Vent Filter Housings** are manufactured for filtration of gases. They are available up to 30-inch lengths. The housings are marked with a unique serial number for traceability. The Vent filter housings are available with a range of pharmaceutical compliant connections and different configurations.

#### Features:

- Inline design
- Manufactured in accordance with European regulations
- Fully sanitary design

## Technical Support

Getting pharmaceutical drugs to the market demands high investments for the manufacturers and so a wide product range and high value technical support facilitates manufacturing timescale.

With the availability of generic and proprietary filter medias for use in drug manufacturing, selecting the correct filter media is critical to ensure full compliance and optimization of the filtration process.

## Technical Services

Our technical services provide testing of fluids and an evaluation of current procedures. Filter analysis includes microscopy and other resources to measure particle counts, turbidity, pH, etc.

- Filterability test (FI/SDI)
- Filtration system configuration
- Troubleshooting / Fault analysis
- Contaminant identification (FTIR, SEM, LM)
- Integrity test on and off site
- Flow decay curves
- Sterilisation method and effect on filter integrity
- Process optimization
- Filtration system assessment

## Validation Support

Masterfilter can offer our customers full support on Validation of Sterile Filters for their process. Whether it is on existing filters or for the introduction of alternative filters, as part of the control change process.

With global changes and uncertainties on supply chains it is important that fast and robust validation support is available to minimize risks to production in critical processes, to speed production process changes or, simply, reduce manufacturing costs. The services we can offer include:

- Viability
- Microbial challenge also with specific micro-organism
- Compatibility
- Adsorption
- Extractables and Leachables
- Integrity test value with product
- Toxicity assessment



Integrity Test Equipment

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