

MicroCap[™] Depth Filter Capsules

Uniquely Flexible to Meet Your Processing Needs



Efficient, Cost-Effective Batch Processing

A Capsule Suite Customized to Fit Your Processing Needs

Eliminate Batch Pooling

Tired of expensive and inefficient pooling of multiple batches to sustain processing?

MicroCap Capsules offer the most flexible solution and the most consistent results for all of your batch processing needs.

MicroCap single-use capsules are a uniquely flexible line of disposable depth filter products designed to optimize scale-up and scale-down studies.

The MicroCap Capsule Suite with six different capsule sizes can meet your process volume requirements without requiring the pooling of multiple batches.

Lab-scale through clinical scale process volumes can be easily managed within the framework of cost-effective, efficient processing. Scale-up and scale-down studies can be efficiently managed through capsules sized and aligned to standard process volumes.

Advantages

- ➤ Uniquely flexible options in capsule size, effective filter area and connection styles to suit your needs
- ➤ Linear Scalability assurance of application and throughput from lab to production scale
- ➤ Low hold-up volume reduced post-use rinsing volumes for product recovery
- ➤ Completely disposable no cleaning or cleaning validation

Processes

- ➤ Mammalian cell cultures
- ➤ Bacteria, yeast, and insect cell lysates
- **➤** Vaccines
- ➤ Blood plasma proteins and serum
- ➤ Media



Applications

- ➤ Primary separations/prefiltration
- ➤ Secondary clarification
- ➤ Cell culture harvest
- ➤ Cell culture clarification
- ➤ DNA reduction
- ➤ Endotoxin reduction
- ➤ Host Cell Protein (HCP) reduction
- ➤ Protein aggregate removal
- **➤** Decolorization

Advanced Performance

An extensive range of enhanced depth filter medias has been developed by ErtelAlsop to meet the stringent requirements of the Biopharmaceutical industry and its unique filtration needs. Supported by comprehensive validation, ErtelAlsop's range of depth filter media enables reliable and efficient performance.

Reliability

All MicroCap depth filter capsules provide performance consistency and lot-to-lot traceability in easy-to-use formats. All MicroCap capsules are batch tested in order to meet all quality requirements and meet all applicable USP requirements including Class VI Biological Testing for Plastics.

Scalability

The versatility of MicroCap capsules enhances filtration efficiencies of laboratory, pilot and small-scale processes. The range of capsules and respective filter area enable both linear scalability in performance and as well as through the range of capsule sizes.

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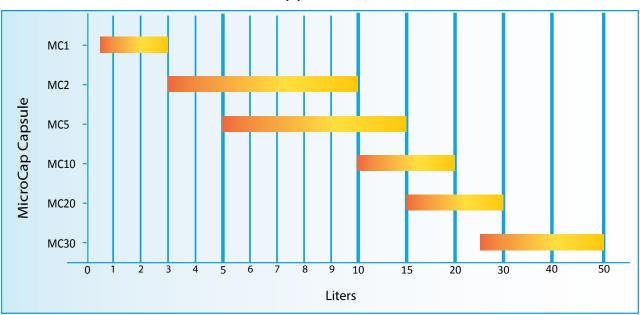


Filter Area

| MicroCap Capsule | Single Layer (cm²)* | Double Layer (cm ²)** | | |
|------------------|---------------------|-----------------------------------|--|--|
| MC1 | 22,5 | 22,5 | | |
| MC2 | 170 | 80 | | |
| MC5 | 330 | 170 | | |
| MC10 | 960 | 500 | | |
| MC20 | 1920 | 1000 | | |
| MC30 | 2880 | 1500 | | |

^{*} Single-layer media such as MicroMedia®, XL Series™, and MicroClear™

Approximate Batch Size



Efficient, Cost-Effective Processing

Available in a variety of sizes and configurations, MicroCap Capsules enable single-batch processing without costly pooling of multiple batches. This variety in capsule sizes and configurations also provides adequate filter area to complete entire processing runs in an efficient and cost effective manner.

Consistent Processing

MicroCap Capsules offer processing consistency through manufacturing controls of the depth filter media, creating the lot-to-lot consistency of the filter media required for performance reliability. These manufacturing controls, coupled with capsule design that utilizes the same internal structure and flow path, enables consistent processing from run to run and from capsule to capsule.

Predictable Processing

Consistent product design, internal structure and flow path coupled with reliable filter media performance enable predictive scalability throughout the range in capsule sizes.



^{**} Double-layer media such as DXL Series



Capsules for Process Development and Lab Scale Processing

MicroCap capsules are available in 6 different sizes (1 in., 2.5 in., 5 in., 10 in., 20 in. and 30 in. in height) ranging in effective filter area from 23 cm² to 2880 cm² with single-layer media (23 cm² to 1500 cm² with double-layer media). This enables processing without the necessity of pooling multiple batches of material to efficiently utilize the appropriate single-use capsule.

The MC1capsule* is designed to suit your testing needs as a screening tool for depth filter media selection. The MC1 provides optimal throughput and predictive, scalable results from small batch sizes ranging from approximately 0.5 liters to 3 liters.

Positioned for use during laboratory development and optimization of scale-up and scale-down studies, MC1 capsules, with 23 cm² of effective filter area (EFA), are effective tools for quickly determining the correct depth filter media to suit your processing needs. With the same filter media, flow paths and design as the larger capsules in this series, the MC1 capsule allows for simplified process development studies.

The MC2 and MC5 capsules are intended for use in processes batch sizes typical of early stage laboratory to process development ranging from approximately 3 to 15 liters. Available with a large variety of depth filter media options and optional inlet/outlet configurations, MicroCap capsules provide simple, reliable capsule performance suited to your process needs.

*The MC1 is also available in the MicroCap Laboratory Cabinet. Please reference: Technical Bulletin Cab-13.

MC1 MC2 MC5





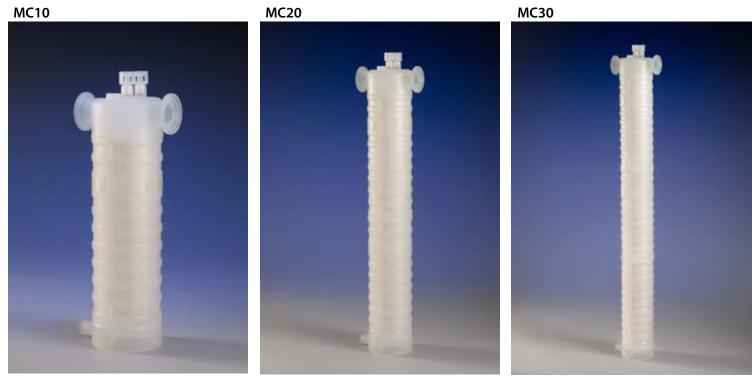




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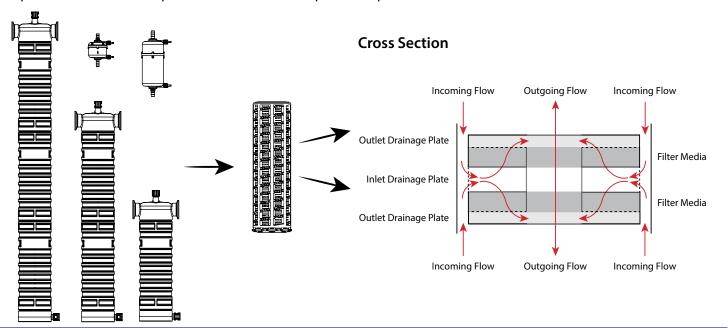
Capsules for Lab and Production Scale Processing

Intended for larger volume processing (10 to 50 or more liters), the MC10, MC20, and MC30 MicroCap capsules share the same internal structure, flow path, and robust design as the smaller capsules in the MicroCap line. These T-style capsules are easily manifolded to seamlessly integrate additional filter area or establish a fully encapsulated filter train. With effective filter areas of 960 cm², 1920 cm² and 2880 cm² in single-layer format (500 cm², 1000 cm² and 1500 cm² in double-layer format) the MC10, MC20 and MC30 MicroCap capsules are ideally sized for larger process development though production scale needs.



Common Flow Path for Predictable Scaleup

MicroCap Capsules use the same internal cartridge design for processing consistency. Their consistent structure and flow path provide enhanced and predictable linear scale-up for all capsule sizes.



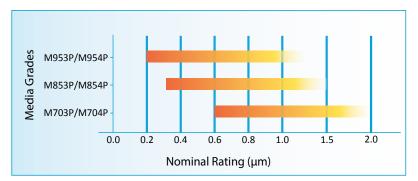
MicroMedia Filter Sheets

Pharmaceutical grade MicroMedia Filter Sheets contain a high performance filter media consisting of a balance of cellulose fibers, diatomaceous earth (DE) filter aid, and a wet strength resin. MicroMedia Filter Sheets provide consistent performance across a variety of applications.

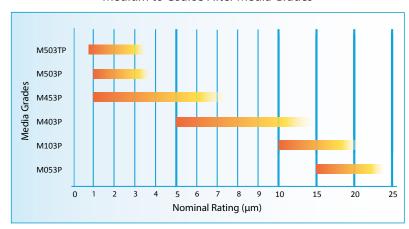
XL Series

ErtelAlsop's MicroMedia XL Series depth filter media incorporates a high performance grade of diatomaceous earth (DE) for greatly enhanced filter performance. In addition, its high purity, low extractables and rigorous quality control make it the leading product for depth filtration in critical applications such as pharmaceuticals and biologics. The reduced levels of metals/contaminants result in increased permeability compared to conventional DE contribute to its purity and usability as a filter for products that must meet the highest standards.

Fine to Medium Filter Media Grades



Medium to Coarse Filter Media Grades



MicroMedia Grades

| Media Series | Media Grades | Nominal Rating (µm) | Format | Filter Properties/Material |
|--------------|--------------|---------------------|--------------|---------------------------------------|
| MicroMedia | M954P | 0.25 – 1.0 | | |
| | M854P | 0.3 – 1.25 | | Cellulose with filter aid |
| | M704P | 0.45 – 1.5 | | |
| XL Series | M953P | 0.25 – 1.0 | | |
| | M853P | 0.3 – 1.25 | | |
| | M703P | 0.45 – 1.5 | Cinalo Lavor | |
| | M503TP | 0.8 – 2.75 | Single Layer | |
| | M503P | 1.0 – 3.0 | | Cellulose with high purity filter aid |
| | M453P | 2.5 – 6.0 | | |
| | M403P | 5.0 – 12.0 | | |
| | M103P | 10.0 – 17.0 | | |
| | M053P | 15.0 – 20.0 | | |



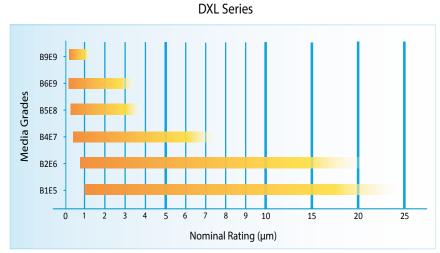
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DXL Series

Consisting of two distinct layers, the double-layer configuration of DXL Series depth filter media maximizes contaminant loading within the body of the filter structure for prolonged filter life. DXL Series depth filter media efficiently manage process streams containing high solids that are often associated with low viability cell cultures. Combining any two layers of ErtelAlsop's XL Series media allows the design of a filter solution to address the unique characteristics of a process stream and to improve process optimization.



Consisting of immobilized activated carbon and cellulose fibers, ErtelAlsop's MicroClear depth filter media provides superior adsorption characteristics over traditional stirred tank or packed bed carbon applications. Designed for use in a single-pass process, the large surface area of carbon to the process stream enables highly efficient color or odor removal. Unlike other depth filter media, designed for mechanical particle removal, MicroClear depth filter media are designed for adsorption of colors, odors or other soluble contaminants.



Carbon per Unit Area

| Effective Filter Area | Amount of Carbon (grams) |
|-----------------------|--------------------------|
| 23 cm ² | 2 |
| 170 cm ² | 15 |
| 330 cm ² | 29 |
| 960 cm ² | 83 |
| 1920 cm ² | 166 |
| 2880 cm² | 249 |

MicroClear Media Grades

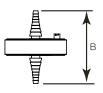
| Media Grades | Activation Method | Typical Application | | |
|--------------|----------------------|--|--|--|
| MC55P | Steam Activated | General Applications | | |
| MC55CP | Chemically Activated | Decolorization in Pharmaceutical Applications | | |
| MC55GP | Steam Activated | Fine Chemical and Pharmaceutical intermediates | | |

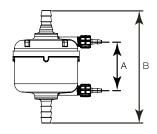
MicroMedia Grades

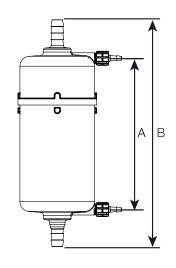
| Media Series | Media Grades | Nominal Rating (µm) | Format | Filter Properties/Material |
|-----------------------|----------------------|---------------------|--------------|---------------------------------------|
| DXL Series* | B9E9 | 0.25 – 1.0 | | |
| | B6E9 | 0.25 – 2.75 | | |
| | B5E8 | 0.3 – 3.0 | Double Layer | |
| | B4E7 | 0.45 – 6.0 | | Cellulose with high purity filter aid |
| | B2E6 | 0.8 – 17.0 | | |
| | B1E5 | 1.0 – 20.0 | | |
| MicroClear | MC55 | Steam Activated | | |
| | MC55CP | Chemical Activated | Single Layer | Cellulose with activated carbon |
| | MC55GP | Steam Activated | | |
| * Other media combina | tions available upon | request | | |











C

| MicroCap Capsule Dimensions (mm) | | | | | | | | |
|----------------------------------|-------------|----|----|-----|-----|-----|--|--|
| Inlet/Outlet Fittings | MC1 MC2 MC5 | | | | | | | |
| | Α | В | Α | В | Α | В | | |
| Hose Barb | - | 79 | 80 | 148 | 137 | 205 | | |
| Sanitary Clamp | - | - | 80 | 126 | 137 | 183 | | |

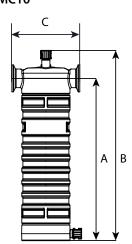


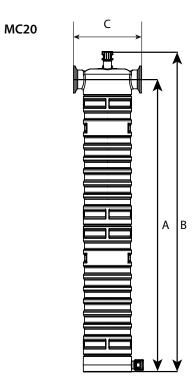
MC5

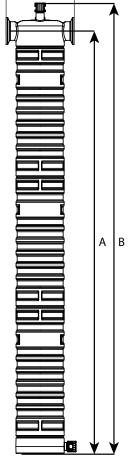




MC10







| Micro | c Car | тм |
|-------|---------------|----|
| | gle-Use Capsu | - |

| MicroCap Capsule Dimensions (mm) | | | | | | | | |
|--|--|--|--|--|--|---|--|--|
| Inlet/Outlet Fittings MC10 MC20 MC30 | | | | | | | | |
| A B C A B C A B C | | | | | | С | | |
| Sanitary Clamp 304 356 127 547 599 127 790 842 127 | | | | | | | | |

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Technical Specifications

| Materials of Construction | |
|-------------------------------|--|
| Capsule Shell and internals | Polypropylene |
| Capsule Filter Media | Cellulose fibers Diatomaceous earth Powdered activated carbon* Resin |
| O-rings | Silicone |
| | |
| Maximum Operating Pressure | |
| MicroCap MC1 | 2.5 barg (36 psig) @ 22 °C |
| All Other MicroCap Capsules | 5.5 barg (80 psig) @ 22 °C |
| | |
| Maximum Differential Pressure | |
| MicroCap MC1 | 2 bard (30 psid) |
| All Other MicroCap Capsules | 2.4 bard (35 psid) |
| | |
| Sterilization - Autoclave | |
| MicroCap MC1 | 1 cycle @ 121 ℃ for 30 minutes |
| All Other MicroCap Capsules | 2 cycles @ 125 ℃ for 60 minutes |

^{*} Carbon with MicroClear Capsules Only

Hold-up Volume MicroCap **Total Void Holdup Volume Capsules** Volume (mL)* (mL)** MC1 MC2 176 68 MC5 299 142 MC10 1080 392 MC20 2160 784 **MC30** 3240 1176

MicroCap Laboratory Cabinet



The MicroCap Laboratory
Cabinet has been created to
simplify filtration and separation
studies for research and
development and process
development laboratories.

Choose from three cabinet options, each containing MicroCap MC1 capsules with 23 cm² (3.48 in.²) of effective filtration area. The MicroCap Laboratory Cabinet can serve your clarification, cell harvest, or color removal needs.

For more, please reference: **Technical Bulletin Cab-13**.

^{*} **Total Void Volume** = Total upstream and downstream void volume with internal cartridge installed

^{**} **Holdup Volume** = Liquid remaining in depth filter media post blow down.

Ordering Information

 $\textbf{Example: M053PCAP05MTB} \ is \ a \ MC5 \ capsule \ with \ M053P \ media, 1/2 \ in. \ sanitary \ clamp \ inlet/outlet, \ and \ vent \ valves.$

| M053P | CAP | 05 | MT | | В | |
|------------------------|------|------|------------------|--|------|---------------------------------|
| Media Grade | Туре | Size | Inlet/ Outlet | Description | Vent | Description |
| See Media Grades Table | CAP | 01 | Н | Stepped Hose Barb | 0 | Luer Lock |
| | | 02 | 3H | ³/₃ in. Hose Barb | В | Vent Valve |
| | | 05 | MT | ¹ / ₂ in. Sanitary Clamp | D | vent valve |
| | | 10 | | | | |
| | | 20 | TC | 11/2 in. Sanitary Clamp | С | Inlet/Outlet ¼ in. Bleed Valve |
| | | 30 | | | | 74 III. Bicca valve |

Media Grades

| Media Series | Media Grades | Nominal Rating (μm) | Format | Filter Properties/Material | | | |
|---|--------------|---------------------|--------------|---------------------------------------|--|--|--|
| MicroMedia | M954P | 0.25 – 1.0 | | | | | |
| | M854P | 0.3 – 1.25 | | Cellulose with filter aid | | | |
| | M704P | 0.45 – 1.5 | | | | | |
| XL | M953P | 0.25- 1.0 | | | | | |
| | M853P | 0.3 – 1.25 | | | | | |
| | M703P | 0.45 – 1.5 | Single Layer | | | | |
| | M503TP | 0.8 – 2.75 | Single Layer | | | | |
| | M503P | 1.0 – 3.0 | | Cellulose with high purity filter aid | | | |
| | M453P | 2.5-6.0 | | | | | |
| | M403P | 5.0 – 12.0 | | | | | |
| | M103P | 10.0 – 17.0 | | | | | |
| | M053P | 15.0 – 20.0 | | | | | |
| DXL* | B9E9 | 0.25 – 1.0 | | | | | |
| | B6E9 | 0.25 – 2.75 | | | | | |
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| | B2E6 | 0.8 – 17.0 | | | | | |
| | B1E5 | 1.0 – 20.0 | | | | | |
| MicroClear | MC55 | Steam Activated | | | | | |
| | MC55CP | Chemical Activated | Single Layer | Cellulose with activated carbon | | | |
| | MC55GP | Steam Activated | | | | | |
| * Other media combinations available upon request | | | | | | | |

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www.ErtelAlsop.com to verify that this information remains valid.

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