Whatman Polycap AS

Aqueous Solution Filter Capsule Instructions for Use

Introduction

Important

Read these instructions carefully before using the products.

Intended use

The products are intended for research use only, and shall not be used in any clinical or *in vitro* procedures for diagnostic purposes.

Description

The Polycap AS family of disposable filtration capsules combines "state of the art" materials and design engineering to give you the finest in safety and efficient filtration.

Disposable filtration devices provide great labor efficiency while ensuring superior filtration when compared to hand assembled reusable filter housings.

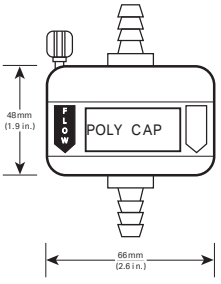
The Whatman™ Nuclepore™ modern filtration Device Manufacturing and Quality Assurance facilities ensure the highest of integrity and cleanliness. Our testing levels of raw materials, production systems and our final Quality Control Department ensure that this product will perform as intended.

This bulletin provides general information on the products listed above. The specifications in the Technical Data section are intended to provide the basis for establishing functional use, as well as set ting the quality assurance test performance levels.

Polycap AS Features

- **Final Filter is Nylon** This microporous membrane is inherently hydrophilic, has low extractables, is biosafe and has excellent flow rates.
- **Prefilter** The glass microfiber depth media is an unsurpassed prefilter. Prefilters are included in all Polycap AS to provide long life.
- **Support Systems** Polypropylene (drain screen, core, end caps, back pressure support). This rugged material was chosen for its outstanding record of biocompatibility and stability.
- **Sealing** All bonds are fused—no extraneous materials are used, no glues, adhesives, metals or epoxies are used in Polycap AS.
- **Ultra Clean** No surfactants or mold release agents used in these devices.
- **Bio safe** materials USP Class VI.
- **Connections:** Hose barbs. Tri-clamp™ flange, 3/8" FNPT. See Product Guide.
- **Integrity Testable:** BP, Pressure Decay.
- **Compact** Incredibly efficient design provides high effective filtration area in small size.
- **Rugged construction**
- **Product Identification and Lot No.** stamped into each housing.
- **Protected Outlet:** A protective sheath makes outlet side of the Polycap a sterile chamber and provides protection against touch contamination.
- **Vented:** Manual vent on inlet side with luer lock can function to: bleed air from upstream, serve as injection or sample port.
- **Manufactured in Clean Room GMP** controlled production facilities by registered medical device manufacture.

Polycap 36 AS



Effective Filtration Area:

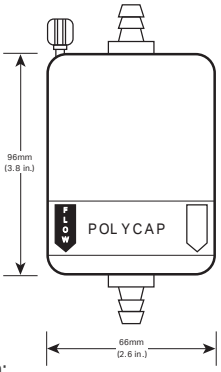
400 cm^2

Housing Volume:

70 mL, an air purge will minimize non-recoverable solution.

Packaged Five(5)/pk.

Polycap 75 AS



Effective Filtration Area:

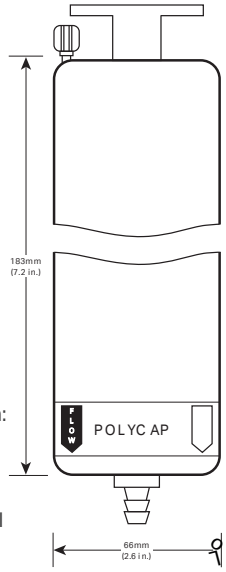
820 cm^2

Housing Volume:

125 mL, an air purge will minimize non-recoverable solution.

Packaged Five(5)/pk.

Polycap 150 AS



Effective Filtration Area:

1650 cm^2

Housing Volume:

250 mL, an air purge will minimize non-recoverable solution.

Packaged Five(5)/pk.

Typical Applications for Whatman's Polycap AS Aqueous Solution Filter Capsule

- Tissue Culture Media
- Reagent Preparation
- Salt Solutions
- Cleaning/Rinsing Solutions
- Admixtures
- Enzymes
- Biologicals
- Immunologicals
- Virus Suspensions
- Buffers/Nutrients
- Pharmaceutical Preparations
- Respiratory Therapy Solutions
- Extemporaneous Solutions
- Opthalmic Solutions
- Irrigation Solutions

OPERATING INSTRUCTIONS

SAFETY:

Considering the special factors of your application, see Table 1 to determine the correctness of use. Key safety concern is to not exceed the pressure, temperature, or chemical compatibility recommendations.

MEMBRANE CONSIDERATIONS:

The membrane used in Polycap AS is nylon — This naturally hydrophilic membrane is recommended for most aqueous solutions. It provides high flow rates and throughput. However, it is not suitable for aggressive chemicals (Arbor tech recommends its Polycap TF).

The special nylon membrane in Polycap AS is hydrophilic. A hydrophilic membrane passes gas easily until it is wet. Once it has been "wetted" is will not pass gas easily. The pressure required to pass gas through a wetted membrane is dependent on the membrane's pore size. This pressure is called the "bubble point" and is used to test for membrane integrity. Air entrained on the upstream side of a wetted hydrophilic membrane blocks the flow path and reduces or stops flow. (See Air Lock in Filter Installation paragraph.)

EFFICIENCY:

To maximize filtration throughput, use the largest pore size filter that will provide the required cleanliness. If the material to be filtered is heavily contaminated, consider prefilters. To extend filter life use low flow or pressure.

STERILIZATION:

Some of these filter devices are radiation sterilized. They may be autoclaved once (autoclave max. 131°C 15 minutes). However, an integrity test should be performed following autoclaving.

FILTRATION INSTALLATIONS:

Small volumes may be filtered using a syringe; larger volumes may be filtered by connecting a hose to the outlet of a pressure vessel, or "in line" using gravity, vacuum, or peristaltic pump for the pressure required to filter. Air Locks seriously hamper flow rates. To eliminate during the initiation of flow, use low pressures (<5 psi/0.3 bar), bleed off air with vent, and then increase pressure and flow. The air in the system and filter device must be flushed prior to the membrane being wetted. (Use the manual vent to exhaust entrained air.)

Because of the design and testing of Polycap AS it is not normally required to test these products prior to use. It may be required because of a protocol, special application, use of special solutions, or if the units are autoclaved.

INTEGRITY TESTING: BUBBLE POINT (BP) TEST:

Flush the filter device with an appropriate aqueous solution. After the membrane is completely wetted, apply air under controlled pressure until air breaks through the membrane and bubbles from the outlet connector. The pressure at which air passes through the "wetted" membrane is the "bubble point". Refer to Table 1 for pore size and BP values. The test is conducted with outlet connector pointed downward.

PRESSURE DECAY:

And other similar tests may be used to test integrity. Follow test equipment instructions.

SPECIAL NOTES:

1. The four layers of filter material in the Polycap AS can inhibit the membrane from being completely "wetted", causing a false low value in the bubble point test. Following steps 2 & 3 should aid in this situation.
2. When flushing capsules prior to BP test, use low pressures (<5 psi/ 0.3 bar), bleed off air with vent, and then increase pressure and flow.
3. IF a lower than normal BP is obtained, integrity of the capsule should be verified by wetting out the capsule with alcohol, flushing again with two liters of water, and repeating the BP procedure. Alternately the bubble point test can be run in isopropyl alcohol.
4. Integrity test enhancement method. Another method for improving the filter wetting process is to fill the filter with 79° C (175° F) pure water, holding for five minutes, then flushing with cold water for 2-3 minutes. The filter should be at ambient temperature before performing the integrity test.
5. WET filters will autoclave more reliably.
6. Filtering at low pressures maximizes throughput.

Table 1. TECHNICAL DATA: Polycap AS FOR AQUEOUS SOLUTIONS

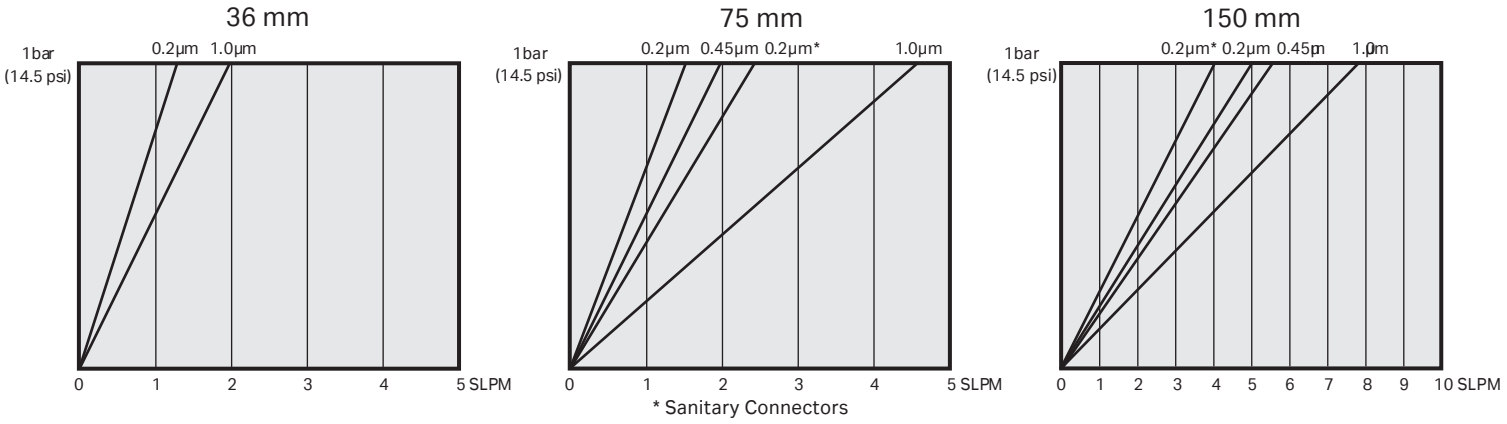
Product Guide		Polycap AS (non-sterile)	
Fitration Ratings	**Inlet and Outlet Fittings**		
Pore Size	**Capsule Size**	**1/4" – 3/8" (6-9mm) Stepped Hose Barb**	**3/8" FNPT**
0.2µm	Polycap 36 AS		2606T
	Polycap 75 AS		2706T
	Polycap 150 AS		2706T
0.45µm	Polycap 36 AS	2607NS	

These filters have been sterilized by gamma radiation. They may be autoclaved once (at 131°C for 15 minutes). However, an integrity test should be performed following autoclaving. All lots of sterile capsules are non-pyrogenic per LAL testing with Endotoxin levels 0.5 EU/ML.

Technical Specifications

Housing:	Polypropylene
Vent:	On Inlet
Prefilter:	Glass microfiber double laminated with polyolefin monofiliment nonwoven
Final Filter:	Nylon membrane
Support System:	Polypropylene
Sealing:	Heat fused
Maximum Pressure:	60 psi (4.1 bar)
Water Bubble Point:	0.2µm – 42 psi (2.9 bar) 0.45µm – 30 psi (2.1 bar) 1.0µm – 8 psi (0.5 bar)
Alcohol Bubble Point:	0.2µm – 16 psi (1.1 bar) 0.45µm – 10 psi (0.69 bar) 1.0µm –2.9 psi (0.20 bar)
Biosafety:	Materials pass USP Class VI

Table 2. Polycap AS Flow Rates in Water



Chemical resistance summary[1]

Polycap AS is designed principally for Aqueous Solutions

Classes of Substances 20°C (68°F)	Polypropylene/NYLON Guide[1] for use
Acids, dilute	Usable
Acids, concentrated	Not usable
Alcohols (selected)	Usable
Aldehydes	Not usable
Bases	Usable
Esters	Short term use
Hydrocarbons, aromatic	Not usable
Hydrocarbons, halogenated (selected)	Short term use
Ketones	Not usable

[1] Published as a general guide only. Due to time, temperature, and stress variations the user must evaluate the specific product and application to determine the appropriateness of use.

Whatman manufactures Polycap TF which is designed from materials resistant to a broad spectrum of aggressive chemicals.

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