





## ALpHA® G Capsules

ALpHA<sup>®</sup> G is a unique absolute rated depth type filter media which has been optimized for compatibility with a gamma irradiation cycle commonly used to sterilize single-use systems. It features a tapered pore structure that provides high flow rates and throughput and delivers extraordinary dirt holding capacity. ALpHA<sup>®</sup> G media is available in absolute retention ratings from 0.6 to 20 µm.

The ALpHA® G filter is available in a wide range of capsule configurations to provide seamless scalability from laboratory work to process development through production. All ALpHA® G capsule filters utilize pleated media construction, providing surface areas as small as 0.02 m<sup>2</sup> (CM capsule configuration) up to 2.5 m<sup>2</sup> (UltraCap® H.D. 50" capsule configuration). Larger scale applications, especially those requiring multistage filtration, can be accommodated with the UltraSnap™ filter assembly. This assembly configures multiple ALpHA® G capsules into a rigid pre-assembled filtration solution.

The ALpHA® G capsule filter offers a truly plug and play clarification step for biopharmaceutical processes. The ALpHA® G depth filtration step can be integrated into a BioFlex® single-use tubing assembly and delivered sterile, ready for use, with exceedingly low and well characterized extractables and endotoxin levels. Typical use does not require a time consuming rinse step as often necessary with other clarification processes. The exceptionally low hold up volume of ALpHA® G capsule filters provides excellent product recovery without the use of elaborate post-use rinse and blow down steps.

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## Features and Benefits

- Gamma irradiatable ALpHA® G capsule filters are compatible with gamma irradiation and can be ordered sterile for immediate use.
- Scalable Quickly and easily scale-up from capsules with filter surface areas of 0.02 m<sup>2</sup> to capsules with filter surface areas of 2.5 m<sup>2</sup>.
- Ready to use convenience ALpHA<sup>®</sup> G capsule filters typically do not require pre-rinse steps before use or post-use rinse and blow down steps for product recovery.
- UltraSnap<sup>™</sup> compatible ALpHA<sup>®</sup> G UltraCap<sup>®</sup> H.D. filters can be secured in an UltraSnap<sup>™</sup> assembly for applications requiring multistage filtration solution and/or larger surface areas than can be accommodated by a single filter. The complete UltraSnap<sup>™</sup> assembly can be delivered as a single presterilized unit for true plug and play functionality at any scale.
- · Remarkably low, well characterized extractables

MEISSNER CH2H03-115 ALanta

### Materials of Construction

Filter Media:	Polyester
Upstream Support:	Polypropylene
Downstream Support:	Polypropylene
Core/Outer Guard:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene
Sealing Method:	Thermal Bonding

All materials of construction listed above are FDA approved for food contact use per 21 CFR 177.

ALpHA<sup>®</sup> G capsules are manufactured in conformance to cGMP. ALpHA<sup>®</sup> G capsules meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of ALpHA<sup>®</sup> G capsules are less than 0.5 EU/mL, as determined using the Limulus amebocyte lysate (LAL) test. No binders, adhesives or surfactants are used in the construction of ALpHA<sup>®</sup> G capsules. ALpHA<sup>®</sup> G capsules are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

## **Filtration Ratings**

Absolute Pore Sizes (µm): 0.6, 1.2, 2.4, 5, 7,10, 20

### **Capsule Dimensions (nominal)**

Model	Diameter	<b>Total Dimension</b>
CM2/GM2	1.25" (3,2 cm)	5.50" (14,0 cm)
CK2/GK2	1.25" (3,2 cm)	6.25" (15,9 cm)
CS2/GS2	2.75" (7,0 cm)	4.50" (11,4 cm)
CL2/GL2	2.75" (7,0 cm)	6.90" (17,5 cm)

UltraCap <sup>®</sup> H.D.	Dimensions (ne	ominal)	Capsule Lengt
Model	Diameter	Total Dimension	(on Order Matrix)
T-Style	3.5" (8,9 cm)	11.7" (29,7cm)	10" (25 cm)
CR2/GR2		21.1" (53,6 cm)	20" (50 cm)
		30.6" (77,7 cm)	30" (75 cm)
		40.0" (101,6 cm)	40" (100 cm)
		49.5" (125,7 cm)	50" (125 cm)
Inline	3.5" (8,9 cm)	17.3" (43,9 cm)	10" (25 cm)
CR2/GR2		26.8" (68,1 cm)	20" (50 cm)
		36.2" (91,9 cm)	30" (75 cm)
		45.7" (116,1 cm)	40" (100 cm)
		55.2" (140,2 cm)	50" (125 cm)



Data shown is for "CS2" style capsule with %" hosebarb connections. Consult factory for complete flow rate information.

## **Configuration Options**

ALpHA<sup>®</sup> G capsule filters can be ordered as discrete CM2/CK2, CS2/CL2, or UltraCap<sup>®</sup> H.D. capsule filters or incorporated into our BioFlex<sup>®</sup> filter/tubing assemblies and our UltraSnap<sup>™</sup> filter assemblies. UltraSnap<sup>™</sup> filter assemblies offer pre and final capsule filters bundled together in a presterilized filtration solution that features one inlet and one outlet connection for plug and play use.

## Sterilization

ALpHA<sup>®</sup> G products are often delivered presterilized via gamma irradiation. However, they can be ordered non-sterile, and subsequently sterilized via autoclave by an end-user.

Autoclave CM2/CK2 and CS2/CL2 capsules at a minimum of 121 °C for 60 minutes or 125°C for 45 minutes. UltraCap® H.D. capsules should be autoclaved at a minimum of 121 °C for 60 minutes. Additionally, the T-style UltraCap® H.D. configuration should be placed in the autoclave with the inlet/outlet in the down position. All capsules can be repeatedly autoclaved without loss of integrity. Support heavy attached fittings (e.g. sanitary clamps) while autoclaving.

Autoclaving gamma irradiated capsules is not recommended. Capsules must not be *in situ* steam sterilized (SIP) as exposure to direct steam at 121 °C, 15 psig (1 bar), will exceed material design limits and can result in a rupture of the plastic housing.

## **Operating Characteristics**

CM2/GM2, CK2/GK2, CS2/GS2, CL2/GL2 Model Maximum Pressure and Temperature for Liquids: 75 psig @ 32 °F to 100 °F (5,2 bar @ 0 °C to 38 °C) 35 psig @ 160 °F (2,4 bar @ 71 °C)

Maximum Pressure and Temperature for Gases: 50 psig @ 32 °F to 100 °F (3,4 bar @ 0 °C to 38 °C) 35 psig @ 160 °F (2,4 bar @ 71 °C)

## Operating Characteristics

UltraCap<sup>®</sup> H.D. CG2/GR2 Model

Maximum Pressure & Temperature for Liquids: 90 psig @ 32°F to 100°F (6,2 bar @ 0°C to 38°C) 55 psig @ 140°F (3,8 bar @ 60°C)

Maximum Pressure & Temperature for Gases: 60 psig @ 32°F to 100°F (4,1 bar @ 0°C to 38°C) 35 psig @ 140°F (2,4 bar @ 60°C)

# Typical Water Flow Rates per 10" Cartridge



## ALpHA<sup>®</sup> G Capsules

# **Ordering** Information

CM2 / CK2 Capsule Options			Retention Rating (µm)
	CM2	MG	0.6
<b>CM2</b> =	Standard (non-sterile)	)	0.6
	0.2 ft² (0,02 m²)		1.2
<b>GM2</b> =	Gamma irradiated 0.2 ft <sup>2</sup> (0,02 m <sup>2</sup> )		2.4
СК2 =	Standard (non-sterile)	)	5
	0.4 ft <sup>2</sup> (0,04 m <sup>2</sup> )		7
<b>GK2</b> =	Gamma irradiated 0.4 ft <sup>2</sup> (0.04 m <sup>2</sup> )		10
	0.4 11 (0,04 111)		20

CS2 / CL2 Capsule Options		Retention Rating (µm)
CS2	MG	1.2
CS2 = Standard (non		0.6
1.0 ft² <i>(</i> 0,09 m	/	1.2
<b>GS2</b> = Gamma irradia 1.0 ft <sup>2</sup> (0,09 m		2.4
CL2 = Standard (non	-sterile)	5
2.0 ft² (0,19 m	2) '	7
GL2 = Gamma irradia 2.0 ft <sup>2</sup> (0,19 m		10
2.0 11- (0, 19 11	/	20

## Inlet / Outlet Connections

11
<b>11</b> = 1/4" (6 mm) hose barb
<b>22</b> = 3/8" (10 mm) hose barb
<b>44</b> = 1/4" (6 mm) MNPT
71 = 3/4" (19 mm) TC in; 1/4" (6 mm) hose barb out
72 = 3/4" (19 mm) TC in; 3/8" (10 mm) hose barb out
77 = 3/4" (19 mm) sanitary (TC) flange

## Inlet / Outlet Connections

0C
00 = 1" (25 mm) sanitary (TC) flange
02=~1" (25 mm) TC in; 3/8" (10 mm) hose barb out
09 = 1" (25 mm) TC in; 1/2" (13 mm) hose barb out
<b>99</b> = 1/2" (13 mm) hose barb
<b>22</b> = 3/8" (10 mm) hose barb
2B = 3/8" (10 mm) hose barb w/ filling-bell
<b>44</b> = 1/4" (6 mm) MNPT
55 = 3/8" (10 mm) FNPT
66 = 3/8" (10 mm) MNPT
77 = 3/4" (19 mm) sanitary (TC) flange

88 = 3/4" (19 mm) hose barb

## Vent / Drain Ports

- 0 = No vent / drain ports
- 1 = One, luer port with cap, inlet side
- 2 = Standard; two, luer ports with caps
- 4 = Two, sanitary valve with hose barbs
- 5 = One, sanitary valve with hose barb, inlet side
- One, sanitary valve with hose barb, 6 = outlet side

## Vent / Drain Ports

- 0 = No vent / drain ports
- 1 = One, luer port with cap, outlet side
- 2 = Standard; two, luer ports with caps
- 4 = Two, sanitary valve with hose barbs
- 5 = One, sanitary valve with hose barb, outlet side

## UltraCap<sup>®</sup> H.D. **Capsule Options**

# CR2 = Standard (non-sterile)

# GR2 = Gamma irradiated

# MG

Rating (µm)	Length	Body Style
0.6	2	Т
0.6	<b>1</b> = 10"	T = T-style
1.2	• • • • •	N. Inline
2.4	<b>2</b> = 20"	N = Inline
5	<b>3</b> = 30"	
7		
10	<b>4</b> = 40"	
20	<b>5</b> = 50"	

Capsule

Retention

## **Capsule Options**



## Inlet / Outlet Connections

00 =	1" sanitary flange
77 =	3/4" sanitary flange
02 =	1" sanitary flange inlet; 3/8" hose barb outlet
<b>0C</b> =	1" sanitary flange inlet; 1/2" hose barb outlet
09 =	1" sanitary flange inlet; 9/16" hose barb outlet
08 =	1" sanitary flange inlet; 3/4" hose barb outlet
0D =	1" sanitary flange inlet; 1" hose barb outlet
<b>22</b> =	3/8" hose barb
CC =	1/2" hose barb
<b>99</b> =	9/16" hose barb
<b>88</b> =	3/4" hose barb
– חח	1" hose barb

- DD = 1" hose barb
- AA = 1/2" Flaretek®
- BB = 3/4" Flaretek®

## Vent / Drain Ports

## T-Style 0 = No vent; no drain 1 = No vent; 1/4" sanitary drain plug 2 = Sanitary vent; 1/4" sanitary drain plug **3** = Sanitary vent; 3/4" sanitary flange gauge port; 1/4" sanitary drain plug

- 4 = Sanitary vent; no drain
- 5 = Sanitary vent; 3/4" sanitary flange gauge port; no drain
- 6 = No vent or drain; 3/4" sanitary flange gauge port
- A = No vent; sanitary drain valve
- **B** = Sanitary vent; sanitary drain valve
- **C** = Sanitary vent; sanitary drain; 3/4" sanitary flange gauge port

### Inline

- 0 = No vent; no drain
- 2 = Two sanitary vent/drain valves
- 4 = One sanitary vent/drain valve, outlet side

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