



Biotech

Instructions For Use

USD 2933c

Mustang[®] Q, S and E Single-Use Capsules

Assembly and Installation Procedures

For Part Numbers:

- CLM05MSTG*P1, CL3MSTG*P1
- NP6MSTG*P1, NP7MSTG*P1, NP8MSTG*P1

* = Q, S or E depending on product chemistry

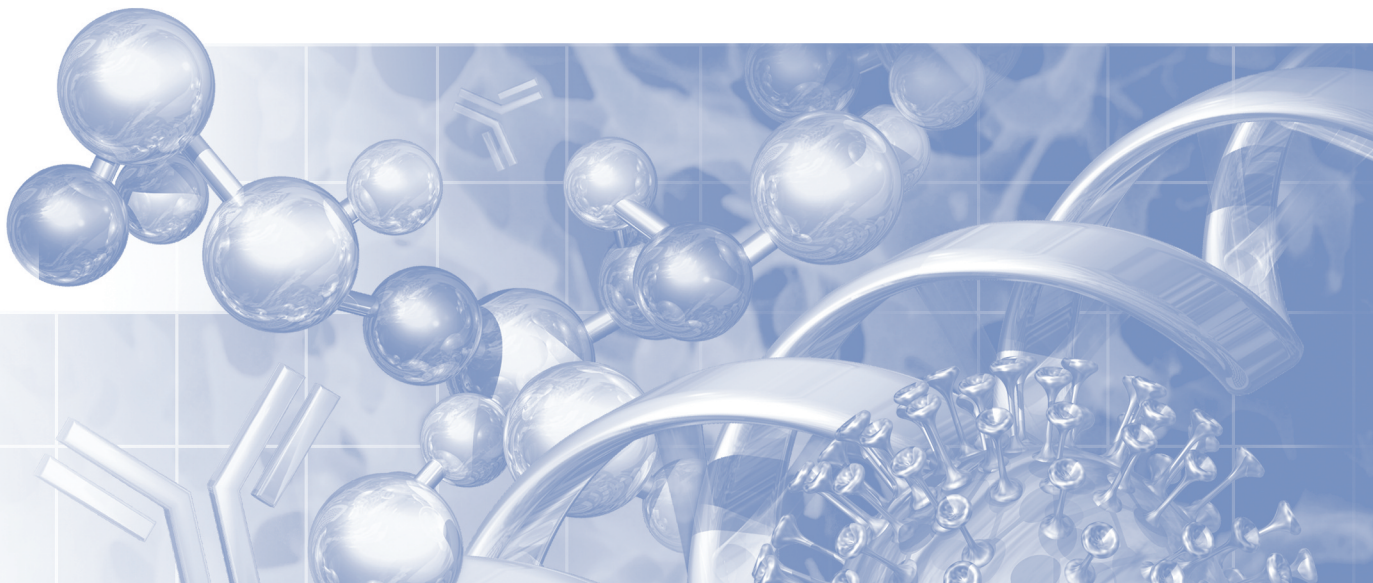


Table of Contents

1. Introduction.....	3
2. Receipt of Equipment	3
3. Specifications	3
4. Installation	4
5. Operation	5
5.1 Preconditioning and Equilibration Step.....	5
5.2 Leak Test.....	6
5.3 Sterilization	6
5.4 Capsule Replacement	6
6. Scientific and Laboratory Services	7
7. Ordering Information	7
Technical Addendum for ATEX 94/9/EC Pall Encapsulated Filter Assemblies	8

1. Introduction

Mustang capsules are single-use membrane chromatography devices designed for use in the purification of biopharmaceuticals and are particularly well suited for flow through contaminant removal applications and virus capture. Mustang capsules are for use with aqueous liquids only. It is strongly recommended that these products be used in downstream processing where the process stream has been filtered with a 0.2 µm filter such as the Pall's Supor® EKV or Supor EX grade ECV (both sterilizing grade capsules) or Supor EAV (bioburden and particulate grade) filters. The user determines the number and size of the Mustang units needed. As with all adsorptive separation technologies, ionic strength, pH and other components of samples or buffers may exert an effect on Mustang product performance.

Please read the following information carefully. It is important to follow these instructions to ensure optimal product performance. If appropriate, these instructions may serve as a template for your standard operating procedures. If some of the procedures are not suitable for your process, please consult your local Pall Biotech representative for assistance.

2. Receipt of Equipment

- Store Mustang capsules in clean, dry conditions, out of direct sunlight, at room temperature (about 22 °C) in the original package before installation.
- DO NOT remove the protective packaging until installation.
- Ensure that the type of Mustang capsule selected is suitable for the intended application. Verify the part number of the Mustang capsule you have received. The part number is on the capsule with a unique batch/serial number to identify each capsule.



WARNING! Mustang capsules should be inspected for correct part number and signs of damage before use. Any irregularity should be reported to Pall Biotech or your local authorized Pall distributor for replacement.

3. Specifications

Table 1

Specifications of Mustang Q, S and E capsules

Part Number	CLM05MSTG*P1 CL03MSTG*P1	NPxMSTG*P1 (x = 6, 7 or 8)
	* = Chemistry : Q (quaternary amine), S (sulfonic acid), or E (highly cross-linked quaternized amine)	
Number of layers	Q and S: 16 layers E: 3 layers	
Pore size membrane	Q: 0.8 µm S: 0.65 µm E: 0.2 µm	
Materials of Construction		
Membrane	PES ⁽¹⁾	
Membrane support and drainage layer assembly	Polypropylene	
Endcaps/adaptors	Polypropylene	
Core/cage	Polypropylene	
O-rings	Silicone elastomer	
Housing	Polyetherimide	Polypropylene

Table 1
Specifications of Mustang Q, S and E capsules (continued)

Part Number	CLM05MSTG*P1 CL03MSTG*P1	NPxMSTG*P1 (x = 6, 7 or 8)
* = Chemistry : Q (quaternary amine), S (sulfonic acid), or E (highly cross-linked quaternized amine)		
Nominal Dimensions		
Maximum diameter, including valves	123 mm (4.8 in.)	154 mm (6.1 in.)
Length with Tri-Clamp♦ connections	CLM05: 84 mm (3.3 in.) CL3: 157 mm (6.2 in.)	NP6: 335 mm (13.2 in.) NP7: 581 mm (22.9 in.) NP8: 831 mm (32.7 in.)
Membrane bed volume	CLM05: 10 mL CL3: 60 mL for Q&S 40 mL for E	NP6: 260 mL for Q&S 160 mL for E NP7: 520 mL for Q&S 320 mL for E NP8: 780 mL for Q&S 480 mL for E
Area	CLM05: 44 cm ² CL3: 264 cm ²	NP6: 1,144 cm ² NP7: 2,288 cm ² NP8: 3,432 cm ²
Operating Characteristics ⁽²⁾		
Maximum operating and differential pressure at 38 °C	4.1 barg (59.5 psig)	
Maximum sanitization conditions	1 M NaOH for 30 minutes for one cycle only	
Autoclave conditions	121 °C for 30 minutes, one cycle only	
Connections	Inlet/outlet: 1 in. – 1.5 in. Tri-Clover♦ compatible Vent valve: Stäubli♦ connection to suit an RBE 03.1906 female Stäubli socket Drain valve: Hosebarb connection to suit flexible pipe with internal diameter (ID) between 5 and 7 mm	

⁽¹⁾ Modified hydrophilic polyethersulfone ⁽²⁾ See warning



WARNING! Mustang capsules should not be used with fluids which are incompatible and may damage the materials of construction. It is the users' responsibility to ensure their actual operating conditions are compatible with their applications and in compliance within local safety codes.

4. Installation

Before installation, it is essential to verify the Mustang capsule's part number to ensure that the appropriate product has been selected. Please follow the instructions listed below.

Mustang capsules must be installed with the process flow as indicated by the flow direction arrow on the capsule with appropriate connections.

1. The capsule should be positioned in a vertical position allowing effective venting and draining of the capsule. Ensure that the directional arrows are pointing upwards (so the process will always be from the bottom inlet to the top outlet). Venting and draining will be carried out before use and may be needed during the process.
2. Where a positive pressure exists downstream of the capsule, a sensitive check valve may be needed to prevent back pressure damage.

3. When a pulsating flow is present, the capsule should be protected by a surge protector on the upstream side.
4. If a downstream valve is closed too quickly, the pressure pulse may damage the Mustang capsule and affect chromatographic performance.
5. Sample loading should only be introduced to the Tri-Clamp connection marked as the inlet. Sample introduction through either vent valves on the side of the capsule, or the Tri-Clamp connection marked as the outlet should be avoided during installation and use.
6. Over-tightening of the inlet and outlet Tri-Clover clamps on Mustang capsules may result in fracture of the inlet and outlet Tri-Clover connectors. It is recommended that the clamps be fully tightened by hand and then loosened by one-quarter turn. It is also recommended that users verify that this clamp provides a leak proof seal.

5. Operation

The capsule must be vented when the flow is initially established. The vent valve should then be closed when all the air is displaced by liquid.

i **NOTE:** Capsules and feed lines should be drained of buffer before loading the feedstream containing solution to maximize the capacity.

5.1 Preconditioning and Equilibration Step

The recommended capsule preconditioning protocols include flow rates, solutions and the minimum volumes as listed in Table 2.

Table 2
Preconditioning protocols

Part Number	Membrane Volume (mL)	Flow Rate (mL/min)	1 M NaOH Volume (mL)	1 M NaCl Volume (mL)	Buffer Volume (indicative) (mL)
Mustang Q and S Capsules					
CLM05MSTG*P1	10	100	> 100	> 100	> 300
CL3MSTG*P1	60	600	> 600	> 600	> 1,800
NP6MSTG*P1	260	2,600	> 2,600	> 2,600	> 7,800
NP7MSTG*P1	520	5,200	> 5,200	> 5,200	> 15,600
NP8MSTG*P1	780	7,800	> 7,800	> 7,800	> 23,400
Mustang E Capsules					
CLM05MSTGEP1	10	100	> 100	> 100	> 300
CL3MSTGEP1	40	400	> 400	> 400	> 1,200
NP6MSTGEP1	160	1,600	> 1,600	> 1,600	> 4,800
NP7MSTGEP1	320	3,200	> 3,200	> 3,200	> 9,600
NP8MSTGEP1	480	4,800	> 4,800	> 4,800	> 14,400

* = Q or S depending on product chemistry

After preconditioning, the unit must be equilibrated with a sufficient volume of an appropriate buffer, so that both the pH and conductivity of the outlet stream are the same as the original buffer.

i **TIP:** In order to minimize the volumes to be used after the NaOH preconditioning step, it is advised to use 1 M NaCl buffered with an acidic solution, like 25 mM phosphoric acid.

5.2 Leak Test

This leak test refers to an installation test to ensure there is no leak in the capsule and no oversized flow channels.

The recommended capsule flow rates and pre-wetting saline solution (do not use water to avoid any swelling) rinse volumes are listed in Table 3. The capsules must be equilibrated with 0.9% saline solution at 1.2 barg (17.4 psig) until both the pH and conductivity of the outlet stream are the same as the original saline solution.

Table 3

Leak test data

Mustang Capsule Part Number	Recommended Wetting Rinse Flow Rate (mL/min)	0.9% Saline Wetting Solution Rinse Volume (mL)	Leak Test Limit at 1.2 barg (17.4 psig) (mL/min)
CLM05MSTG*QP1	100	> 300	2
CM3MSTG*P1	600	> 1,800	5
NP6MSTG*P1	3,000	> 9,000	10
NP7MSTG*P1	6,000	> 18,000	20
NP8MSTG*P1	9,000	> 27,000	30

* = Q, S or E depending on product chemistry

When performing the leak test, the Mustang capsule is drained. Then, with the vent valve closed, slowly begin pressurizing the drained Mustang capsule with air to a constant 1.2 barg (17 psig). Let the system stabilize for 5 minutes, then record the air flow through the wetted membrane. Table 3 indicates the maximum acceptable air flow values at 1.2 barg (17 psig) (leak test limit).

The gas flow through the wetted membrane is usually measured on the downstream side, but gas flow measurement can also be performed in opposite direction if needed. The leak test can be performed using a sensitive measurement instrument such as the Palltronic® Flowstar filter integrity test device.

5.3 Sterilization

The single-use Mustang capsules can be sterilized by autoclaving.



WARNING! Do not autoclave the Mustang capsule in the bag. Mustang capsules are supplied non-sterile.

The Mustang capsules should only be autoclaved as follows (one cycle only):

- At 121 °C for 30 minutes dry (we recommend to set the autoclave at 123–125 °C to ensure that 121 °C is reached)
- DO NOT steam in place
- For specific autoclave limitations, please contact your Pall representative

Pall recommends to pre-wet the Mustang Q membrane with saline solution before autoclaving to stabilize the Q chemistry.

5.4 Capsule Replacement

Mustang capsules are single-use units and should be replaced after every use.

6. Scientific and Laboratory Services

Pall operates a technical service team to assist in the application of all filter and separation products. This service is available to you and we welcome your questions. Your requests allow us an opportunity to help. Pall has a full network of technical representatives available throughout the world.

7. Ordering Information

Type of Mustang Capsule	Bed Volume	Pack Quantity	Part Number
Mustang Q capsule	10 mL	1	CLM05MSTGQP1
	60 mL	1	CL3MSTGQP1
	260 mL	1	NP6MSTGQP1
	520 mL	1	NP7MSTGQP1
	780 mL	1	NP8MSTGQP1
Mustang S capsule	10 mL	1	CLM05MSTGSP1
	60 mL	1	CL3MSTGSP1
	260 mL	1	NP6MSTGSP1
	520 mL	1	NP7MSTGSP1
	780 mL	1	NP8MSTGSP1
Mustang E capsule	10 mL	1	CLM05MSTGEP1
	40 mL	1	CL3MSTGEP1
	160 mL	1	NP6MSTGEP1
	320 mL	1	NP7MSTGEP1
	480 mL	1	NP8MSTGEP1

Technical Addendum for ATEX 94/9/EC Pall Encapsulated Filter Assemblies

Installation and maintenance should be undertaken by a competent person. National and local codes of practice, environmental regulations and Health and Safety directives must be adhered to and take precedence over any stated or implied practices within this document.

For fluids having low conductivity, there exist the possibility of the generation of static electricity during use with polymeric components. This could potentially lead to a static electricity discharge resulting in the ignition of a potentially explosive atmosphere where such an atmosphere is present. **These Pall products are not suitable for use with such low conductivity fluids in an environment that includes flammable liquids or a potentially explosive atmosphere.**

Where flammable or reactive fluids are being processed through a Pall capsule assembly, the user should ensure that spillages during filling, venting, depressurizing, draining and capsule change operations are minimized, contained or directed to a safe area. In particular, the user should ensure that flammable fluids are not exposed to surfaces at a temperature that may ignite the fluid, and that reactive fluids cannot contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable.

Pall capsule assemblies do not generate heat, but during the processing of high temperature fluids, including steam sterilization operations and process upset conditions, it will take on the temperature of the fluid being processed. The user should ensure that this temperature is acceptable for the area in which the filter is to be operated, or that suitable protective measures are employed. When processing flammable fluids, the user should ensure that any air is fully purged from within the assembly during filling and subsequent operation to prevent the formation of a potentially flammable or explosive vapor/air mixture inside the equipment. This can be achieved through careful venting of the assembly or system as detailed in the user instructions.

To prevent damage or degradation which may result in leakage of fluids from this equipment it is imperative that the end user check the suitability of all materials of construction (including seals on the connections where appropriate) with the process fluid and conditions. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that seals (where appropriate) are renewed after every capsule change.

Leakage of flammable or reactive fluids from this assembly, arising through incorrect installation or damage to the equipment (including any seals), may generate a source of ignition if flammable fluids are exposed to a heated surface, or if reactive fluids contact incompatible materials that may lead to reactions generating heat, flame or that are otherwise undesirable. The user should ensure that the assembly is regularly inspected for damage and leaks, which should be promptly corrected, and that any seals are renewed after every filter change.

The user should ensure that these products are protected from foreseeable mechanical damage that might cause such leakage, including impact and abrasion.

Should you have any questions, please contact your Pall Biotech representative.



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