



Life Sciences

Instructions For Use

USD 2932a

Mustang[®] Q XT5, Q XT140, and Q XT5000 Chromatography Capsules

Assembly and Installation Procedures



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Safety Conventions in this Manual



Identifies important information about the current topic.



CAUTION! Identifies a situation that may cause system or filter damage and may pose a safety risk that can cause personal injury.



WARNING! Identifies a dangerous or potentially dangerous situation that may cause irreversible damage to equipment and poses a safety risk that can cause serious personal injury.

1. Introduction

Mustang Q XT capsules have been designed for optimum membrane chromatography performance, providing scalability from process development through to full scale manufacturing. Each capsule is constructed with the same anion exchange membrane bed height to maintain scalability for both dynamic binding capacity and pressure drop.

Mustang Q XT chromatography capsules are designed for use in the purification of biopharmaceuticals. Mustang Q XT5 capsule can also be used as a scaled-down partner.

When using the Mustang XT capsules, it is strongly recommended that process feeds be filtered with a 0.2 µm filter such as the Pall's Supor® EKV or Supor EX grade ECV sterilizing filters.

Optimized process conditions (pH, ionic strength, and volume for equilibration, wash and elution buffers) and the number of Mustang Q XT chromatography capsules required will depend on the manufacturing process.

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 Pall representative for assistance.



WARNING! All Mustang Q XT capsules should not be used with fluids incompatible with the materials of construction. Incompatible materials are those that chemically attack, soften, stress, crack or adversely affect the materials of construction in any way. No organic solvents should be used. Only 100% aqueous liquids should be used. It is the user's responsibility to check actual operating conditions to ensure that the capsule is compatible with the application and within local safety codes.



WARNING! European Directive 94/9/EC (ATEX). Equipment Intended for Use in Potentially Explosive Atmospheres. For information relating to this Directive, see page 12. For information relating to Zone 0/20 Applications, please contact Pall. More information can be obtained through Pall, your Pall representative or Pall website.

2. Receipt of Equipment

- Store Mustang Q XT capsules in clean, dry conditions, out of direct sunlight and whenever practical, store in the packaging provided. Ensure that the type of Mustang capsule selected is suitable for the intended application. In addition to the part number, there is a unique identification batch/serial number that identifies each capsule.
- Do not remove the protective packaging until installation. For Mustang Q XT140 and Q XT5000 capsules, do not remove the protective inlet/outlet end caps until the capsule has been properly secured in its stand. Removal of the caps before the capsule has been secured can result in damage to the sanitary flange.
- Mustang Q XT capsules should be inspected for signs of damage before use. If damage or any other irregularity is observed, the product should be replaced. If the white seal on the side is broken, the capsule should not be used.

3. Specifications and Connections

Table 1

Specifications

Mustang Q XT capsule part number	Q XT5 XT5MSTGQPM6	Q XT140 XT140MSTGQP05	Q XT5000 XT5000MSTGQP1
Functional group	Quaternary amine		
BSA binding capacity (80% breakthrough)	53 to 84 mg/mL		
DNA binding capacity (80% breakthrough)	21 to 46 mg/mL		
Membrane porosity	0.8 µm		
Materials of construction			
Membrane	PES ⁽¹⁾		
Membrane support and drainage	Polypropylene		
Housing	Polypropylene		
Core/cage/endcaps	N.A.*	N.A.	Polypropylene
O-rings	Silicone	Silicone	Silicone
Valve	N.A.	Polypropylene	Polypropylene
Volumes			
HUV ⁽²⁾ – Upstream	3.21 mL	105 mL	3.8 L
HUV – Downstream	3.21 mL	45 mL	1.6 L
Total HUV (excludes wetted membrane and pores)	6.42 mL	150 mL	5.4 L
Total capsule liquid fill volume (includes membrane, pores and total HUV)	8 mL	260 mL	9.2 L
Membrane bed volume	5 mL	140 mL	5 L
Membrane bed volume : total HUV ratio	1 : 1.3	1 : 1.1	1 : 1.1
Nominal dimensions			
Length without protective inlet/outlet caps	39 mm (1.5 in.)	190 mm (7.48 in.)	605 mm (23.8 in.)
Diameter of capsule body (central section)	97 mm (3.8 in.)	91 mm (3.6 in.)	246 mm (9.7 in.)
Number of layers	16	16	16
Membrane bed height	2.20 mm	2.20 mm	2.20 mm
Nominal (frontal) effective chromatographic membrane area	22 cm ² (3.4 sq. in.)	616 cm ² (0.66 sq. ft)	2.2 m ² (24 sq. ft)
Weight dry	182 g (6.6 oz.)	768 g (1.5 lb)	10.3 kg (23 lb)
Weight drained (wet membrane)	191 g (6.7 oz.)	917 g (2 lb)	14.2 kg (31 lb)
Weight in use (filled)	195 g (6.9 oz.)	1 kg (2 lb)	19.6 kg (43 lb)
Operating conditions			
Maximum operating pressure at 38 °C	5 barg (75 psig)	3 barg (43.5 psig)	3 barg (43.5 psig)
Maximum temperature	38 °C	38 °C	38 °C
Recommended flow rate	50 mL/min	1.4 L/min	50 L/min
Sanitization	1 M NaOH	1 M NaOH	1 M NaOH
Connections			
Connections	Female M6 threads	12.7 mm (0.5 in.) sanitary flange	38 mm (1.5 in.) sanitary flange
Tubing	1/8 in. OD x 1/16 in. ID	8 mm ID (0.31 in.)	30 mm ID (1.2 in.)
Vent/drain valve	N.A.	Hose barb (suitable for tubing with nominal bore of 6 mm [¼ in.])	

(1) Modified hydrophilic polyethersulfone

(2) Hold up volume

*N.A. = Not applicable

Table 2*Description of connector kits*

Part Number	Description	Color	Number of pieces in kit
FY01979	¼-28 Male Connector	Clear	2
FY01949	M6 Male Connector	Black	4
FY02076	M6 Plug	Black	2
FY01950	Ferrule (M6 Connector)	Orange	4
FY01980	Ferrule (¼-28 Connector)	Yellow	2
FY01981	Tubing 1/8 in. OD x 1/16 in. ID, PTFE*	Clear	2

* *Polytetrafluoroethylene*

4. Installation of Mustang Q XT Capsules



WARNING! It is the end user's responsibility to know the expected system pressures associated with the operation of any chromatography workstation. Because there is variability among commercially available systems with regard to pressure, two sets of installation instructions follow. It is highly recommended to install a pressure gauge upstream of the inlet side of the capsule so that the pressure can be continuously monitored at a point closest to the capsule. Failure to follow the appropriate procedure may result in damage to the capsule, loss of membrane integrity, and possible injury to the operator.



Important: Mustang Q XT capsules must always be oriented in the vertical position with the flow directional arrows pointed upwards. The process feed needs to be 0.2 µm filtered (for example with Pall's Supor EKV or Supor EX grade ECV sterilizing filters) before entering the capsule inlet. Continuous monitoring of the pressure drop across the Mustang Q chromatography membranes contained in the capsule is highly recommended.

4.1 Mustang Q XT5 Capsule

4.1.1 Installation on Chromatography Workstations Where Mustang Q XT5 Capsule Inlet Pressure is Less Than 5 barg (75 psig)

1. Orient the capsule so that the inlet port (as marked) is face down for operation in upward flow.
2. Connect an appropriate length of 1/8 in. OD x 1/16 in. ID tubing to the inlet and outlet ports of the Mustang Q XT5 membrane chromatography capsule using the M6 nuts and ferrules supplied in the connector kit.
3. Connect the tubing from the inlet port of the capsule to the port on the chromatography workstation that will supply fluid to the capsule. For low pressure systems, consult the appropriate manual.
4. Connect the tubing leading from the outlet port of the capsule to the port on the chromatography system that will receive fluid from the capsule. Use the ¼-28 nuts and ferrules supplied in the connector kit. Different systems will have different connection requirements. A set of M6 nuts and ferrules and a set of ¼-28 nuts and ferrules have been included to help the user connect via the most common means. Consult your systems operating manual for specific connection requirements.

4.1.2 Installation on ÄKTAexplorer System and Other Chromatography Workstations Where Mustang Q XT5 Capsule Inlet Pressure is Greater than 5 barg (75 psig)



WARNING! When operating a chromatography workstation such as the GE ÄKTAexplorer system, it is extremely important to follow the instructions in this section exactly as described. All steps must be followed to minimize the risk of capsule failure, equipment damage, and operator injury. **A key step to avoid these problems is shown in bold below and must be performed.**

As with any fittings involving ferrules, it is possible that the following procedure describing connections using the ferrules and fittings enclosed in the connector kit may result in the ferrules getting stuck in the capsule inlet or outlet threads. In order to avoid this, flangeless fittings can be used, as described in Alternative Connections in Table 3.

Steps for the installation:

- 1. Verify that any downstream flow restrictors have been removed from the system.**
2. Orient the capsule so that the inlet port remains face down for operation in upward flow.
3. Connect the appropriate length of 1/8 in. OD x 1/16 in. ID tubing to the inlet and outlet ports of the Mustang Q XT5 capsule using the M6 connectors and orange ferrules supplied in the connector kit.
4. Connect the tubing from the inlet port of the capsule to the port of the chromatography workstation that will supply fluid to the capsule. For ÄKTAexplorer system, use the M6 connectors and orange ferrules supplied in the connector kit and the union 1/16 in. M-M6F GE, P/N 18-1112-58 (not supplied).
5. Connect the tubing leading from the outlet port of the capsule to the port on the chromatography system that will receive fluid from the capsule. For the ÄKTAexplorer system, use the M6 connectors and orange ferrules supplied in the connector kit and the union 1/16 in. M-M6F, GE, P/N 18-1112-58 (not supplied). See Figure 1.

For all other high pressure chromatography systems, consult the appropriate manual. Other connection solutions tested in our laboratory are shown in Table 3.

Table 3
Recommended connections and alternatives

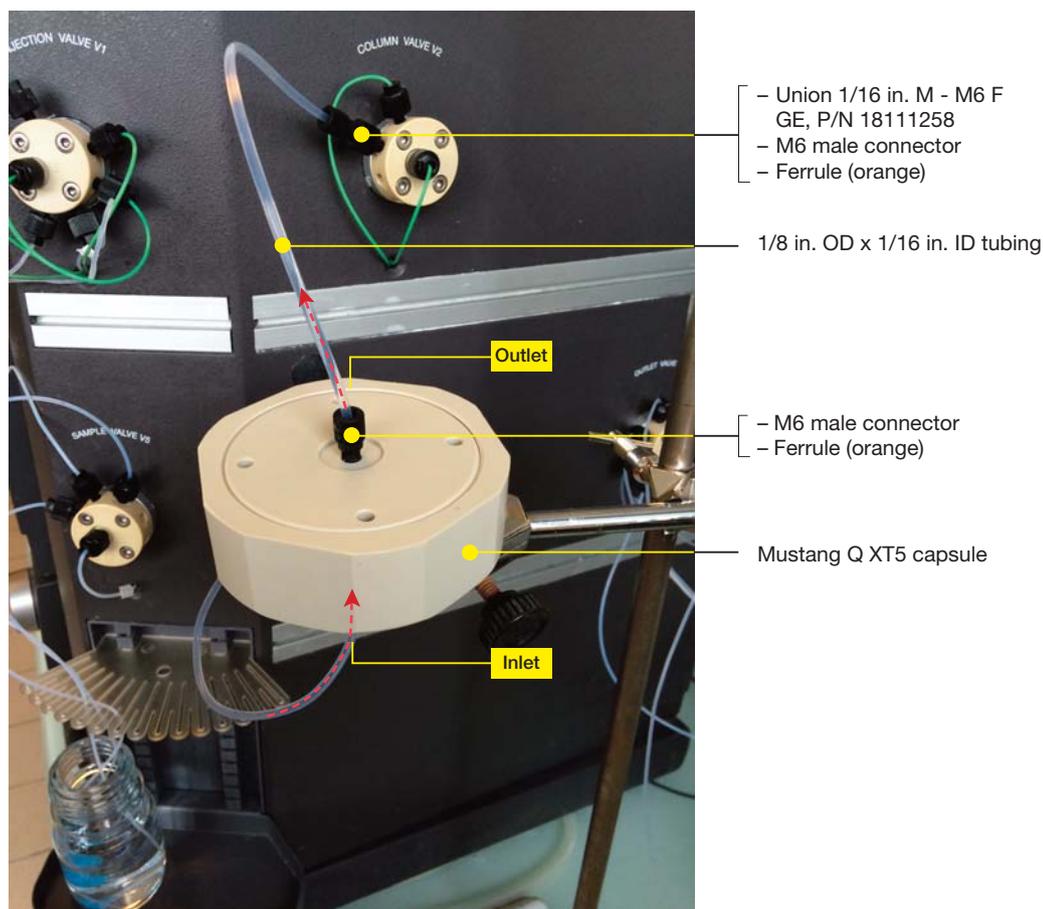
	Connectors or adaptors for ÄKTA column inlet and outlet valve (V2/V3)	Tubing	Connectors or adaptors for Mustang Q XT5 inlet and outlet
Recommended	Union 1/16 in. M-M6 F GE, P/N 18-1112-58*	1/8 in. OD x 1/16 in. ID, PTFE	M6 male connector
	M6 male connector		Orange ferrule
	Orange ferrule		
Alternative	Fingertight connector 1/16 in. male, GE, P/N 18-1172-63*	PEEK** 1/16 in. OD x 0.75 mm ID, GE, P/N 18-1112-53*	Union 1/16 in. F-M6 M, GE, P/N 18-1112-57*
			Fingertight connector 1/16 in. male, GE, P/N 18-1172-63*

* Not supplied, recommendation only, subject to availability from supplier

** Polyetheretherketone

Figure 1

Connection of Mustang Q XT5 capsule to ÄKTA[®] system



The red dotted arrows indicate the flow direction

4.2 Mustang Q XT140 and Q XT5000 Capsules

4.2.1 Installation on a Stand

- Secure the Mustang Q XT140 chromatography capsule to a stable ring stand using a clamp that is capable of tightly clamping the 9 cm (3.5 in.) to 10 cm (4 in.) diameter Mustang Q XT140 chromatography capsule. Do not allow flow in the direction opposite to that of the arrow on the capsule.
- The Mustang Q XT5000 capsule must be secure in its stand (refer to instructions for use Pall reference number USD 2369 for part number XT5000B100 stand base and part number XT5000T100 stand upper unit). Ensure that the directional arrows are pointing upwards (so the process flow will always be from the bottom inlet to the top outlet) and remove the protective end caps. Also remove the protective end caps from the two valves at the top and bottom of the capsule.

4.2.2 Connecting the Mustang Q XT140 or Q XT5000 Chromatography Capsule In-Line

1. Connect a 90° elbow with sanitary fittings – (12.7 mm [0.5 in.] for XT140 and 38 mm [1.5 in.] for XT 5000) – to the inlet and outlet openings of the capsule.
2. Connect a matching tee with sanitary fittings – (12.7 mm [0.5 in.] for XT140 and 38 mm [1.5 in.] for XT 5000) – to each of the 90° elbows that were attached to the inlet and outlet openings in Step 1.

3. Attach a pressure gauge (ranges: 0 – 4.14 barg / 60 psig or 0 – 6.9 barg / 100 psig) with sanitary fittings to each of the tees from Step 2.
4. Connect the process feed delivery tubing to the capsule inlet tee fitting.
5. Connect the capsule outlet tee to the downstream plumbing.
6. Attach a clear, flexible tube (ID 6 mm [0.25 in.]) to the air vent valve on the outlet side (top) of the capsule. Make sure the length of the tubing is long enough to empty into a container.

4.2.3 Connecting the Mustang Q XT5000 Chromatography Capsule In-Line (for a Two or Three Capsules in Series)

1. Connect a tee with sanitary fittings (38 mm [1.5 in.]) to the bottom of the capsule in the bottom (lowest) position. (The tee is upside down.)
2. Connect tees with sanitary fittings (38 mm [1.5 in.]) in between the bottom and middle (or top, if two capsules) and middle and top capsules. (The tees are sideways.)
3. Connect a tee with sanitary fittings (38 mm [1.5 in.]) to the top of the capsule in the highest position (the tee is upright).
4. Attach a suitable pressure gauge with sanitary fittings to each of the tees listed in Steps 1 to 3.
5. Connect the process feed delivery tubing to the capsule inlet (lowest) tee fitting.
6. Connect the capsule outlet (highest) tee to the downstream plumbing.
7. Attach a clear, flexible tube (ID 6 mm [0.25 in.]) to the air vent valve on the outlet side (top) of each capsule. Make sure the length of the tubing is long enough to empty into a container.

The use of plastic tees and clamps is recommended to prevent damage to the capsule sanitary flanges. Silicone gaskets are recommended.

5. Operation

5.1 Air Displacement

5.1.1 General Recommendation

The capsule must be operated in upward flow to make air displacement from the capsule as efficient as possible. The inlet side of the capsule must be oriented face down.



CAUTION! Air must be displaced from the capsule in order to establish uniform fluid flow through the membrane element. Failure to follow this procedure will result in increased pressure and decreased chromatographic performance. For this procedure, a pressure gauge is required immediately before the capsule inlet.



WARNING! For Q XT140 capsule, use an adjustable wrench to open and close the vent valve. The Q XT140 and Q XT5000 capsules must be vented when the flow is initially established. The vent valve should then be closed when all of the air is displaced by liquid.

5.1.2 Specific Recommendation for Mustang Q XT5 Capsule

Disconnect the outlet tubing from the chromatography system and divert to waste. This will eliminate chromatography system components downstream of the capsule as sources of backpressure and provide a completely accurate readout of pressure at the capsule inlet. Then pump equilibration buffer through in upward flow at 50 mL/min. Monitor the inlet pressure, and continue to pump buffer until the pressure has stabilized, usually around 0.55 – 0.69 barg (8 – 10 psig). Unstable or unusually high pressures may indicate that air is still entrapped within the capsule or between membrane layers. It may require pumping as much as 500 mL of buffer in order to achieve low-pressure stability.

5.2 Preconditioning

1. Pump approximately the recommended volume of 1 M NaOH through the capsule at the advised flow rate.
2. Followed by the recommended volume of 1 M NaCl in 25 mM phosphoric acid through the capsule at the same flow rate (see Table 4).

Table 4

Preconditioning solutions for Mustang Q XT capsules

Solutions required	Q XT5	Q XT140	Q XT5000
1 M NaOH	5 MV	5 – 7 MV	5 – 6 MV
1 M NaCl in 25 mM phosphoric acid	5 MV	4 – 5 MV	4 – 5 MV
Flow rate	10 mL/min	280 mL/min	10 L/min

MV = Membrane volume

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. Using 1 M NaCl buffered with an acidic solution such as 25 mM phosphoric acid minimizes the volumes to be used after the NaOH preconditioning steps.

5.3 Leak Test

Since the Mustang membrane is not a sterilizing grade membrane, this test is not considered as an integrity test as it is not correlated to bacterial retention. 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 prewetting saline solution (do not use water to avoid any swelling) rinse volumes are listed in Table 5. The capsules must be equilibrated with 0.9% saline solution at 1.2 barg (17 psig), until both the pH and conductivity of the outlet stream are the same as the original saline solution.

Table 5

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 psig) (mL/min)
XT5MSTGQPM6	50	> 75	2
XT140MSTGQP05	1,400	> 2,100	5
XT5000MSTGQP1	50,000	> 75,000	100

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 5 indicates the maximum acceptable air flow values at 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.

5.4 Chromatographic Operation

The following steps are provided as general guidelines for bind and elute chromatography. Specific procedures will need to be developed on a case-by-case basis. Optimal conditions of pH, ionic strength, and protein concentration for the purification of a specific biomolecule need to be developed by the end user. Contact your Pall representative for assistance.

5.4.1 Cleaning-In-Place (CIP) Before a First Use

See 5.4.6.

5.4.2 Equilibration

Equilibration buffer: Composition of buffer salts, concentration, pH, and volume need to be determined by the user for their particular application.

1. Equilibrate the capsule with a sufficient volume of an appropriate equilibration buffer, so that both the pH and conductivity of the outlet stream are the same as the original equilibration buffer.
2. Pump equilibration buffer (e.g., 25 mM Tris-HCl, pH 8.0) through the capsule until equilibration has been achieved using the working flow rate (Table 6).

Table 6

Recommended working flow rates for Mustang Q XT capsules

Q XT5	Q XT140	Q XT5000
50 mL/min	1.4 L/min	50 L/min

5.4.3 Load

Pump 0.2 µm-filtered feedstock onto the capsule at the same flow rate as mentioned in 5.4.2 to the desired endpoint.

5.4.4 Wash

1. Pump equilibration buffer through the capsule at the working flow rate.
2. Monitor UV absorbance (or other appropriate signal) to determine the volume required to return to baseline.

5.4.5 Elution

1. Elute the bound compounds at the same flow rate using either a series of salt steps or a linear salt gradient. Alternatively, elution can be achieved with pH steps or pH gradients, or pH used in combination with salt.
2. Monitor the UV absorbance (or other appropriate signal) to determine when bound components have desorbed from the membrane.
3. Fractionate the eluate according to your own procedures.

5.4.6 CIP and Storage

► CIP

1. Pump 50 mL of 1 M NaOH through Q XT5 capsule at 10 mL/min
or 1.4 L of 1 M NaOH through Q XT140 capsule at 280 mL/min
or 50 L of 1 M NaOH through Q XT5000 capsule at 10 L/min
2. Stop the pump and hold for 30 minutes. Proceed either to the equilibration step for the next run or proceed to the next step to condition the capsule for storage.

► Storage

1. Pump 50 mL of 0.1 M NaOH in 1 M NaCl through Q XT5 capsule at 10 mL/min
or 1.4 L of storage solution through Q XT140 capsule at 280 mL/min
or 50 L of storage solution through Q XT5000 capsule at 10 L/min
2. Stop the pump.

3. Disconnect the Q XT5 capsule, and cap the inlet and outlet ports. Store it in a cold room (4 – 8 °C). This will help retard bacterial growth and membrane dehydration. When taking a Q XT5 capsule out of storage and returning it to service, begin operation at the pre-conditioning step or start at the CIP step as in step 5.4.1.

Or drain the Q XT140 and Q XT5000 capsules completely of the storage solution and replace the protective end caps and dust covers on the inlet/outlet openings. Make certain that both drain/vent valves are closed. These capsules may be stored attached to their stand or in their original packaging at room temperature. If the original packaging is unavailable, place the capsule in a horizontal orientation in a designated storage area.

5.5 Use of Multiple Mustang Q XT5000 Capsules to Increase Dynamic Binding Capacities

To add additional binding capacity beyond what can be obtained with one capsule, capsules may be stacked up to three (3)-high in series to increase binding capacities. The accessory stand upper level support (part number XT5000T100) is designed to run this configuration conveniently.

Additional capacity beyond the three in series may then be added in parallel. Typical series/parallel configurations could be arranged as follow:

- Four (4) capsules: 2 in series x 2 in parallel, or
- Six (6) capsules: 3 in series x 2 in parallel.

Please consult your Pall representative for further assistance in setting up the multiple capsule configurations. For information on reuse of Mustang Q XT capsules please contact your Pall representative.

6. Maintenance

Clean the assembly and inspect for signs of damage or corrosion. There are no spare parts available for the assembly.

7. 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.

8. Ordering Information

Description	Part number
Mustang Q XT5 capsule ⁽¹⁾	XT5MSTGQPM6
Mustang Q XT140 capsule	XT140MSTGQP05
Mustang Q XT5000 capsule	XT5000MSTGQP1
Complementary products	
Mustang Q XT Acrodisc® unit (4 per pack)	MSTGXT25Q16
XT 5000 stand base unit (lower section)	XT5000B100
XT 5000 stand top (upper) portion	XT5000T100
XT 5000 stand lifting handle	XT5000H100

⁽¹⁾ The Q XT5 capsule inlet and outlet has female M6 threads and includes connectors and tubing. For details of available spare parts, please contact Pall or your local Pall representative.

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 representative.



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