

BIOTECH

Instructions For Use



USD 2932b

Mustang[®] Q - XT5, XT50, XT140, XT450, XT5000 Chromatography Capsules Assembly and Installation Procedures

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1 Types of Safety Symbols

All safety symbols: warning, prohibition, mandatory and GHS can /will be accompanied by additional text and signs to explain the reason for the warning, explain the nature of the prohibition, and explain the reason for the action required.

Table 1





ISO 7010 safety signs and symbols

Colour	Meaning / Purpose	Example	Description	Instruction and Information
Red	Prohibition / Danger		Red ring and diagonal bar with black symbol on white background	Specifies behaviour that is prohibited because it would result in an immediate or potential risk of personal injury or threat to health / life.
Yellow	Warning / Caution		Yellow triangle with black border and black symbol	Warns of hazards which could result in personal injury or threat to health.
Blue	Mandatory / Information		Blue circle with white symbol	Specifies an action required or informs of information to safeguard personal health and /or avoid risk of personal injury.
Red	GHS Hazards		Red diamond, white background with a black symbol	Classifies the hazards of chemical products and communicates health and safety information.

1.1 Safety Symbols Within This IFU

Table 2

Safety signs and symbols within this document

Symbol	Instruction and Information
	Prior to operating, the instructions must be read in entirety.
	Highlights important information.
	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.
	Identifies a situation that may cause system or filter damage and may pose a safety risk that can cause personal injury.

2 Introduction



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.



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.

Figure 1

Mustang (XT5, XT50, XT140, XT450, XT5000) capsules



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 and are identical in bed construction which offers seamless scalability from 5ml to 5000ml.

When using the Mustang XT capsules, it is strongly recommended that process feeds be filtered with a 0.2 μm filter. Please contact Pall for further information.

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.

3 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 - XT50,XT140, XT450 and 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

4 Specifications and Connections

4.1 Specifications

Table 3

Specifications.

	Q XT5	QXT50	Q XT140	QXT450	Q XT5000
Mustang Q XT capsule part No.	XT5MSTGQPM6	XT50mSTGQP05	XT140MSTGQP05	XT450MSTGP05	XT5000MSTGQP1
Functional group	Quaternary amine	Quaternary amine	Quaternary amine	Quaternary amine	Quaternary amine
Capacity BSA 80% Breakthrough (mg/mL)	85 ± 5	82 ± 15	69 ± 10	87 ± 3	75 ± 3
DNA binding capacity (80% breakthrough)	21 to 46 mg/mL	21 to 46 mg/mL	21 to 46 mg/mL	21 to 46 mg/mL	21 to 46 mg/mL
Membrane porosity	0.8 µm	0.8 µm	0.8 µm	0.8 µm	0.8 µm
Materials of Construction					
Membrane	PES ⁽¹⁾	PES ⁽¹⁾	PES ⁽¹⁾	PES ⁽¹⁾	PES ⁽¹⁾
Membrane support and drainage	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Housing	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Core/cage/endcaps	N.A.*	Polypropylene	Polypropylene	Polypropylene	Polypropylene
O-rings	Silicone	Silicone	Silicone	Silicone	Silicone
Valve	N.A.	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Volumes					
Total capsule liquid fill volume (B)	8 mL	98,3 mL	260 mL	760 mL	9.2 L
Membrane bed volume (A)	5 mL	50 mL	140 mL	450 mL	5 L
Fill volume/Membrane volume ratio (B/A)	1.60	1.97	1.86	1.71	1.84

Nominal Dimensions					
Length without protective inlet / outlet caps	39 mm (1.5 in.)	132mm (5.20 inches)	190 mm (7.48 in.)	339 mm (13.35in.)	605 mm (23.8 in.)
Diameter of capsule body (central section)	97 mm (3.8 in.)	107 mm (4.21 in.)	91 mm (3.6 in.)	107 mm (4.21 in.)	246 mm (9.7 in.)
Number of layers	16	16	16	16	16
Membrane bed height	2.20 mm	2.20 mm	2.20 mm	2.20 mm	2.20 mm
Nominal (frontal) effective chromatographic membrane area	22 cm ² (3.4 sq. in.)	236 cm ² (36.58 sq.in)	660 cm ² (0.71 sq. ft)	2121 cm ² (2.283 sq. Ft)	2.2 m ² (24 sq. ft)
Weight dry	182 g (6.6 oz.)	555 g (1.22lb.)	768 g (1.5 lb)	1436 g (3.16lb.)	10.3 kg (23 lb)
Weight in use (filled)	195 g (6.9 oz.)	653 g (1.44lb.)	1 kg (2 lb)	2207 g (4.86 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)	3 barg (43.5 psig)	3 barg (43.5 psig)
Maximum temperature	38 °C	38 °C	38 °C	38 °C	38 °C
Recommended flow rate	50 mL/min	500 mL/min	1.4 L/min	4.5 L/min	50 L/min
Sanitization	1 M NaOH	1 M NaOH	1 M NaOH	1 M NaOH	1 M NaOH

Connections					
Connections	Female M6 threads	12.7 mm (0.5 in.)	12.7 mm (0.5 in.)	12.7 mm (0.5 in.)	38 mm (1.5 in.)
		sanitary flange	sanitary flange	sanitary flange	sanitary flange
Tubing	1/8 in. OD x 1/16 in. ID	8 mm ID (0.31 in.)	8 mm ID (0.31 in.)	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) 6 mm (¼ in.)			N/A

(1) Modified hydrophilic polyether sulfone
*N.A. = Not applicable

4.2 Connections

Table 4
Connections.

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

5 Installation of Mustang Q XT Capsules



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.

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 before entering the capsule inlet. Continuous monitoring of the pressure drop across the Mustang Q chromatography membranes contained in the capsule is highly recommended.



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.

5.1 Installing Mustang Q XT5 Capsule

5.1.1 Chromatography Workstation Installation

When installing the Mustang Q XT5 Capsule on chromatography workstations where the 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 1/4-28 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 1/4-28 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.

For all other high-pressure chromatography systems, consult the appropriate manual. Other connection solutions tested in our laboratory are show in Table 5.

Table 5

Recommended connections and alternatives.

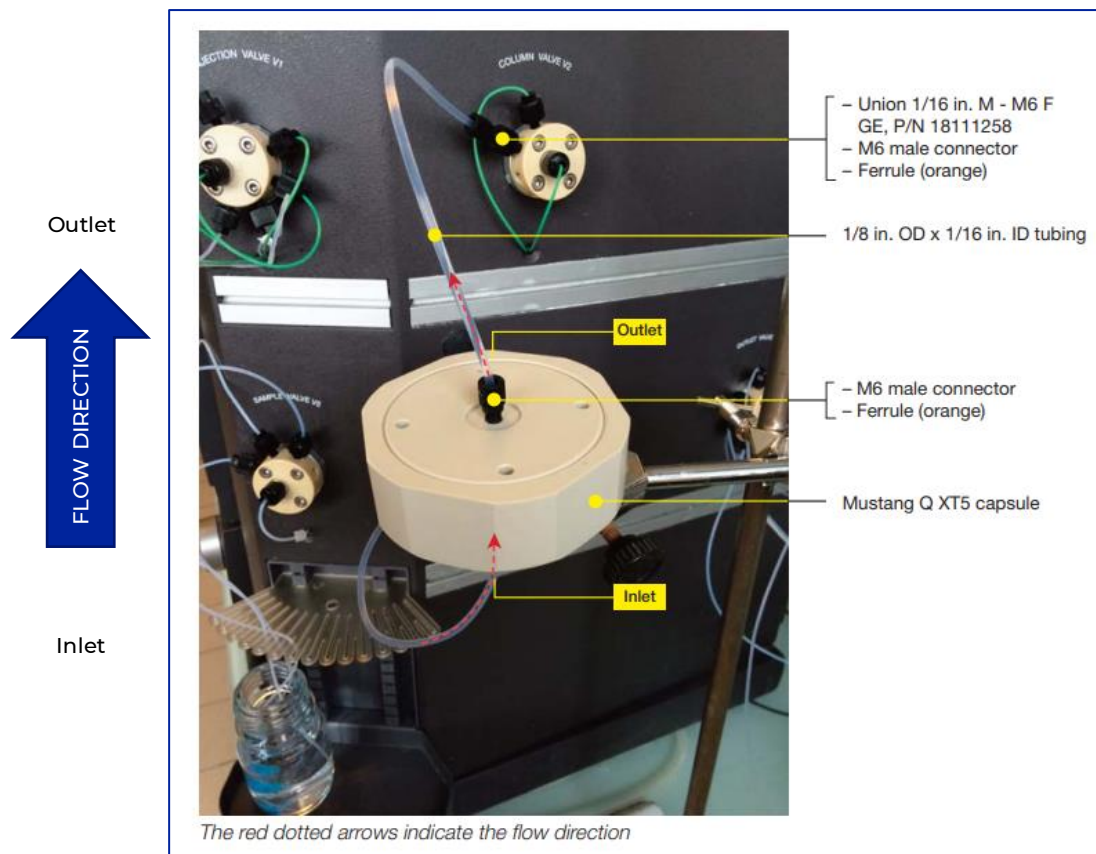
	Connectors or adaptors for AKTA column inlet and outlet valve (V2/V3)	Tubing	Connectors or adaptors for Mustang QXT5 inlet and outlet
	Union 1/16 in. M-M6 F GE, P/N 18-1112-58*		M6 male connector
	M6 male connector		
Recommended	Orange ferrule	1/8 in ODx1/16 in. ID, PTFE	Orange ferrule
			Union 1/16 in. F-M6 M, 1/16 in. male, GE, P/N 18-1112-57*
Alternative	Finger tight 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*	Finger tight connector 1/16 in. male, GE, P/N 18-1172-63*

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

** Polyether ether ketone

Figure 2

Connection of Mustang QXT5 capsule to a chromatography workstation.



5.2 Mustang Q XT50, XT140, QXT450 and Q XT5000 Capsules installation

5.2.1 Installation of a single capsule on a stand

1. Secure the Mustang Q XT (50 to 450) 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 XT(50-450) chromatography capsule. Do not allow flow in the direction opposite to that of the arrow on the capsule.
2. 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.

5.2.2 Connecting a single capsule

Connecting the Mustang Q XT (50-450) or Q XT5000 Chromatography Capsule In-Line.

1. Connect a 90° elbow with sanitary fittings – (12.7 mm [0.5 in.] for XT (50-450) 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.

5.2.3 Connection the Mustang Q XT5000 Chromatography Capsule in-line (two or three capsules in series)



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

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.

6 Operation

6.1 Air Displacement

6.1.1 General Recommendation



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.

For Q XT (50-450) capsule, use an adjustable wrench to open and close the vent valve. The Q XT (50-450) and Q XT5000 capsules must be vented when the flow is initially established. The vent valve should then be closed when all the air is displaced by liquid.

1. 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.

6.1.2 Specific Recommendation for Mustang Q XT5 Capsule

1. 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.
2. 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.

6.2 Pre-Conditioning

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 6).

Table 6

Pre-conditioning solutions for Mustang Q XT capsules.

Solutions required Q XT5 Q XT140 Q XT5000	QXT5	QXT50	QXT140	QXT450	QXT5000
1 M NaOH	5 MV	5 – 7 MV	5 – 7 MV	5 – 7 MV	5-6 MV
1 M NaCl in 25 mM phosphoric acid	5 MV	4 – 5 MV	4 – 5 MV	4 – 5 MV	4 – 5 MV
Flow rate	10 mL/min	100ml/min	280 mL/min	900 ml/min	10 L/min

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.

6.3 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 7. 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 7

Leak test data.

<u>Mustang capsule part No.</u>	<u>Recommended wetting rinse flow rate (mL/min)</u>	<u>0.9% saline wetting solution rinse volume (mL)</u>	<u>Leak test limit at 1.2 barg (17 psig) (mL/min)</u>
XT5MSTGQPM6	50	> 75	2
XT50MSTGQP05	500	> 750	3
XT140MSTGQP05	1400	> 2,100	5
XT450MSTGP05	4500	> 6750	11
XT5000MSTGQPI	50000	> 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 7 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.

6.4 Chromatography 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. Cleaning in Place (CIP) before first use see 6.4.4.1

6.4.1 Equilibration

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

1. Equilibrate the capsule with enough 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 8).

Table 8

Recommended working flow rates for Mustang QXT capsules.

Recommended Working Flow Rates				
Q XT5	Q XT50	Q XT140	Q XT450	Q XT5000
50 mL/min	500 mL/min	1.4 L/min	4,5 L/min	50 L/min

6.4.2 Load

1. Pump 0.2 µm-filtered feedstock onto the capsule at the same flow rate as mentioned in 6.4.1 to the desired endpoint.

6.4.3 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.

6.4.4 CIP and Storage

6.4.4.1 CIP

1. Pump 0.1 M NaOH through the device (Table 9).
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.

Table 9

Pump 1 M NaOH through the device according to the table below.

CIP				
Q XT5	Q XT50	Q XT140	Q XT450	Q XT5000
50 mL for Q XT5 capsule at 10 mL/min	500 mL for Q XT50 capsule at 100 mL/min	1.4 L for Q XT140 capsule at 280 mL/min	4500 mL for Q XT450 capsule at 900 mL/min	50 L for Q XT5000 capsule at 10 L/min

6.4.4.2 Storage

1. Pump 0.1 M NaOH in 1 M NaCl through the device (Table 10)
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 XT(50–450) 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.

Table 10

Pump 0.1 M NaOH in 1 M NaCl through the device according to the table below.

Storage				
Q XT5	Q XT50	Q XT140	Q XT450	Q XT5000
50 mL for Q XT5 capsule at 10 mL/min	500 mL for Q XT50 capsule at 100 mL/min	1.4 L for Q XT140 capsule at 280 mL/min	4500 mL for Q XT450 capsule at 900 mL/min	50 L for Q XT5000 capsule at 10 L/min

6.5 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.

1. Four (4) capsules: 2 in series x 2 in parallel
Or
2. Six (6) capsules: 3 in series x 2 in parallel

7 Maintenance

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

8 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.

9 Ordering Information

Table 11

Ordering information.

Part number	Description	Packaging
XT5000MSTGQP1	Mustang Q XT5000, Q chemistry with 5 L membrane volume for clinical manufacturing	1 /pkg
XT450MSTGQP05	Mustang Q XT450, Q chemistry with 450 mL membrane volume for clinical manufacturing	1 /pkg
XT140MSTGQP05	Mustang Q XT140, Q chemistry with 140 mL membrane volume for pilot scale process development	1 /pkg
XT50MSTGQP05	Mustang Q XT50, Q chemistry with 50 mL membrane volume for pilot scale process development	1 /pkg
XT5MSTGQPM6	Mustang Q XT5, Q chemistry with 5 mL membrane volume for scale-down process development; the capsule inlet and outlet have female M6 threads and include connectors and tubing	1 /pkg
MSTGXT25Q16	Mustang Q XT Acrodisc unit (0,86 mL)	4 /pkg

**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.*

Table 12

Stand and lifting stand ordering information.

Mustang Q XT5000 Stand and Lifting Handle Assembly

Part number	Description	packaging
XT5000B100	Stand base unit (lower section)	1 /pkg
XT5000T100	Top (upper) section	1 /pkg
XT5000H100	Lifting handle	1 /pkg



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