WOLF-PAK®

MEDI-FLO®
ELASTOMERIC PUMP

Clinical Guide

What to Expect, Preparation, Treatment and Troubleshooting

Delivering Efficiency to Healthcare®

Distributed by: Wolf Medical Supply, An NDC Company
13951 NW 8th Street / Sunrise, FL 33325 / www.medi-flo.com / 800.335.9653

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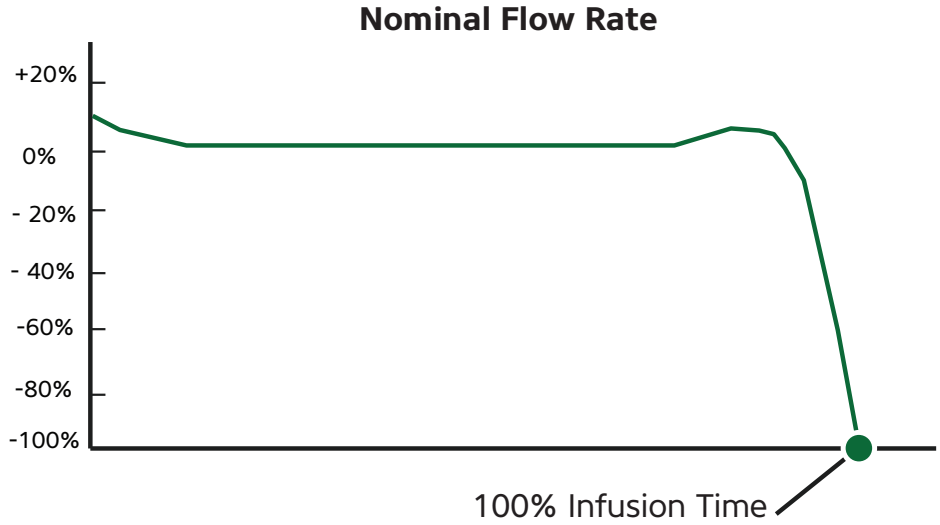
Why Wolf-Pak MEDI-FLO® Elastomeric Pumps?

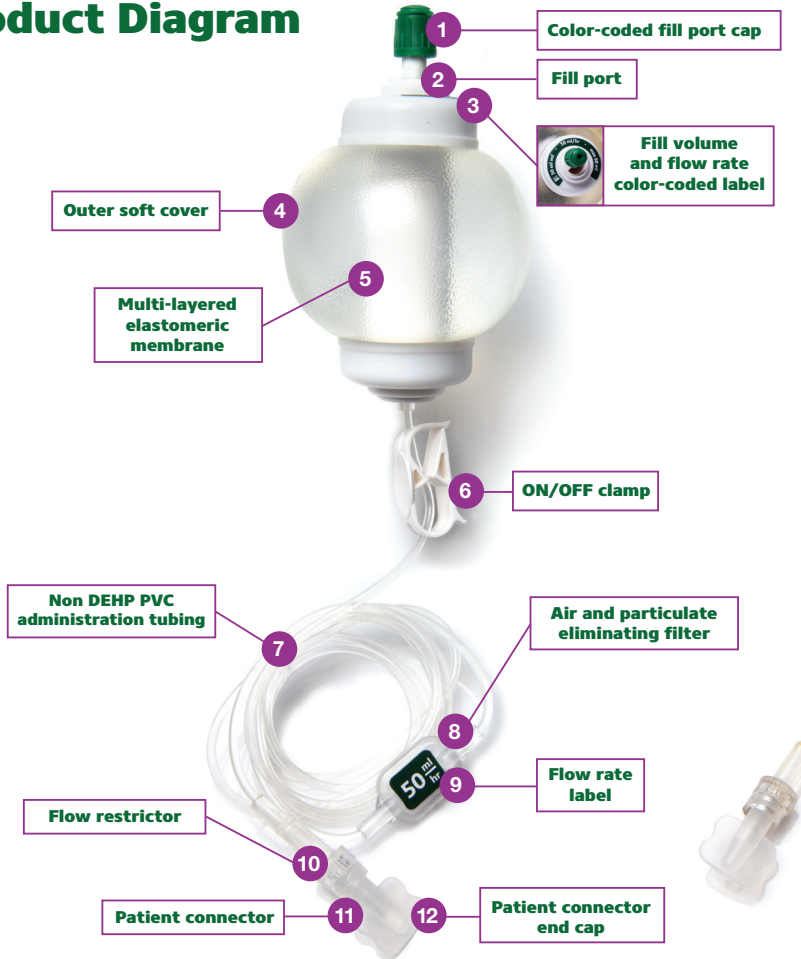
MEDI-FLO® Elastomeric Pumps are proven to be safe and effective and are a convenient alternative to electronic infusion pumps. Ideally suited for home infusion, long-term care and outpatient chemotherapy treatments. MEDI-FLO® pumps give the patient mobility and freedom to maintain an active lifestyle.

How Does It Work?

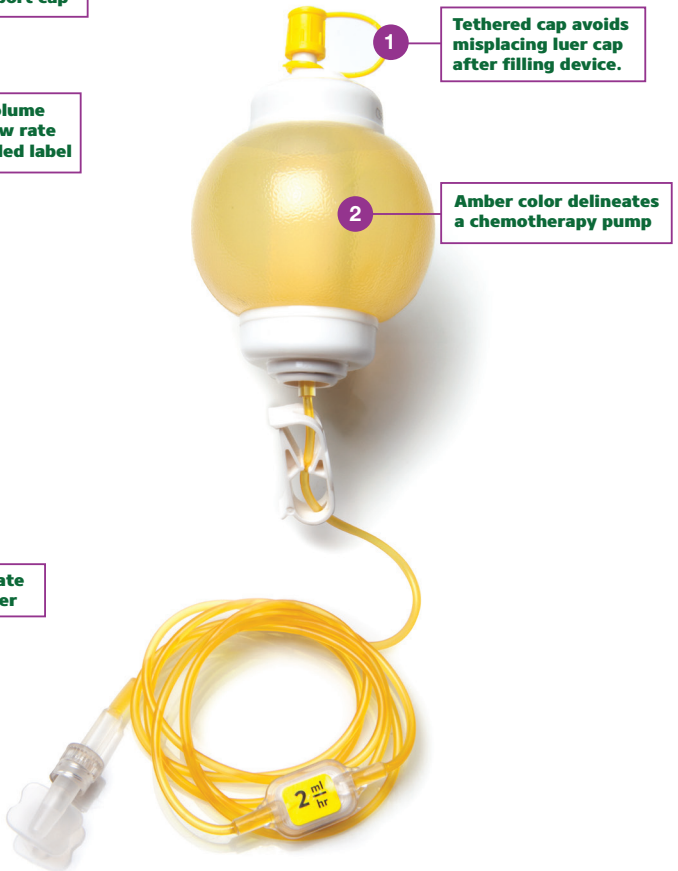
The MEDI-FLO® Elastomeric Pump delivers medication using a specially designed multi-layered balloon-like reservoir. It exerts mechanical pressure thereby administering the pump contents through an orifice tube at a predetermined flow rate. The rate is controlled by a flow restrictor at the end of the tubing and by flow restrictive tubing (MEDI-FLO® Chemotherapy Pumps only). When used according to manufacturer's recommendations and instructions for use, flow accuracy is within +/- 15% of the nominal (label) flow rate (at 99% confidence level) when filled at nominal volume.



Product Diagram



Short/Long Duration Pump



Chemotherapy Pump

Choosing the Right MEDI-FLO® Elastomeric Pump for Your Patient

The MEDI-FLO® Elastomeric Pump is easy to fill and color-coded for quick and accurate device identification. A wide variety of sizes and flow rates are available along with an extensive library of drug stability data. The range of SKUs available offers dosing flexibility to administer various infusion therapies. Please refer to the Fill Volume and Delivery Time Tables on pages 4-7, as well as the Drug Stability Guide to help determine which product is best suited for the needed therapy.

Drug Stability

Drug Stability data is available on a wide range of medications. The Drug Stability Guidelines for the administration of medications using the MEDI-FLO® Elastomeric Pump were developed as a result of testing performed by independent laboratories, review of various medical publications and manufacturers' product information, and available elastomeric infusion pump drug stability data. The stability data relates to chemical stability of the drugs tested, not to sterility.

The pharmacist dispensing the drug is responsible for ensuring proper preparation using validated aseptic techniques to prevent microbiological contamination. For practice and quality standards, refer to USP 797 Pharmaceutical Compounding – Sterile Preparations and USP 800 Hazardous Drugs - Handling in a Healthcare Setting.

Contact your sales representative at 1-800-335-9653, or refer to our website, www.medi-flo.com, for the most up to date drug stability information.

Fill Volumes and Delivery Times

Refer to the tables on the following pages to determine the appropriate pump model based on the fill volume and desired delivery time. Residual volume information is also included.

The MEDI-FLO® nominal flow rates are based on sodium choloride (0.9%, 31° C/88° F) as reference. Use of 5% dextrose will result in 10% slower flow rate or correspondingly 10% longer delivery time.

PLEASE NOTE:

1. Delivery times for partial or overfill volumes are approximate values.
2. Filling the pump more than the nominal fill volume results in a faster flow rate.
3. Filling the pump less than nominal fill volume results in a slower flow rate.
4. Do not fill the pump less than the minimal or more than the maximum fill volume specified on the chart.
5. It is recommended that the MEDI-FLO® pump be filled with diluent before adding the drug/medication.

MEDI-FLO® Short Duration Filling Guide

Item Code	MDE050500	MDE100500	MDE101000	MDE102000	MDE200100	MDE200200	MDE250050	MDE250100
Nominal Fill Volume	50 mL	100 mL	100 mL	100 mL	200 mL	200 mL	250 mL	250 mL
Nominal Flow Rate	50 mL/H	50 mL/H	100 mL/H	200 mL/H	100 mL/H	200 mL/H	50 mL/H	100 mL/H
Min Fill Volume	50 mL	75 mL	50 mL	50 mL	150 mL	150 mL	150 mL	200 mL
Max Fill Volume	60 mL	110 mL	120 mL	100 mL	300 mL	300 mL	275 mL	300 mL
Residual Volume	2 mL	2 mL	2 mL	2 mL	2 mL	2 mL	3 mL	3 mL

Approximate Delivery Time (Hours:Min)								
0:15				50 mL				
0:30			50 mL	100 mL				
0:45			75 mL			150 mL		
1:00	50 mL		100 mL			200 mL		
1:15	60 mL		120 mL			250 mL		
1:25								
1:30		75 mL			160 mL	300 mL		
1:45					180 mL			
1:55								
2:00		100 mL			200 mL			200 mL
2:15		110 mL			220 mL			220 mL
2:30					240 mL			250 mL
2:45								275 mL
3:00							150 mL	300 mL
3:30								
4:00								
4:30								
5:00							250 mL	
5:30							275 mL	

Item Code	MDE250125	MDE251750	MDE252500	MDE250500	MDE271750	MDE401000	MDE402000	MDE502500
Nominal Fill Volume	250 mL	250 mL	250 mL	250 mL	270 mL	400 mL	400 mL	500 mL
Nominal Flow Rate	125 mL/H	175 mL/H	250 mL/H	500 mL/H	175 mL/H	100 mL/H	200 mL/H	250 mL/H
Min Fill Volume	150 mL	140 mL	150 mL	250 mL	250 mL	275 mL	200 mL	360 mL
Max Fill Volume	300 mL	300 mL	300 mL	300 mL	340 mL	550 mL	500 mL	550 mL
Residual Volume	3 mL	3 mL	3 mL	3 mL	3 mL	5 mL	5 mL	5 mL

Approximate Delivery Time (Hours:Min)								
0:15								
0:30			150 mL	250 mL				
0:45		140 mL	200 mL	300 mL				
1:00		175 mL	250 mL				200 mL	
1:15	150 mL	220 mL	300 mL				250 mL	360 mL
1:25					250 mL			
1:30	180 mL	250 mL			270 mL		300 mL	400 mL
1:45	220 mL	300 mL			300 mL		350 mL	475 mL
1:55					320 mL			
2:00	250 mL				340 mL		400 mL	500 mL
2:15	280 mL						450 mL	550 mL
2:30	300 mL						500 mL	
2:45						275 mL		
3:00						300 mL		
3:30						360 mL		
4:00						400 mL		
4:30						450 mL		
5:00						500 mL		
5:30						550 mL		

MEDI-FLO® Long Duration Filling Guide

	LONG DURATION				
Item Code	**MDL100002**	**MDL270002**	**MDL270005**	**MDL270010**	**MDL500020**
Nominal Fill Volume	100 mL	270 mL	270 mL	270 mL	500 mL
Nominal Flow Rate	2 mL/H	2 mL/H	5 mL/H	10 mL/H	20 mL/H
Min Fill Volume	75 mL	150 mL	250 mL	230 mL	360 mL
Max Fill Volume	110 mL	300 mL	360 mL	360 mL	500 mL
Residual Volume	2 mL	3 mL	3 mL	3 mL	5 mL

Approximate Delivery Time						
Hours:Min	**Day(s)**					
18:00						380 mL
20:00					230 mL	440 mL
25:00	**1**				250 mL	500 mL
27:00	**1**				270 mL	
30:00	**1**				300 mL	
36:00	**1.5**	72 mL			330 mL	
40:00	**1.5**	80 mL				
46:00	**1.5**	96 mL		240 mL		
50:00	**2**	100 mL		250 mL		
54:00	**2**	108 mL		270 mL		
62:00						
72:00	**3**			330 mL		
75:00	**3**					
80:00	**3**		200 mL			
100:00	**4**		220 mL			
125:00	**5**		250 mL			
135:00	**6**		270 mL			
144:00	**6**		300 mL			

MEDI-FLO® Chemotherapy Filling Guide

	CHEMOTHERAPY				
Item Code	**MDC100002**	**MDC270010**	**MDC270020**	**MDC270050**	**MDC300060**
Nominal Fill Volume	100 mL	270 mL	270 mL	270 mL	300 mL
Nominal Flow Rate	2 mL/H	10 mL/H	2 mL/H	5 mL/H	6 mL/H
Min Fill Volume	75 mL	230 ml	150 mL	250 mL	250 mL
Max Fill Volume	110 mL	360 mL	300 mL	360 mL	360 mL
Residual Volume	2 mL	3 mL	3 mL	3 mL	3 mL

Approximate Delivery Time						
Hours:Min	**Day(s)**					
18:00						
20:00			230 mL			
25:00	**1**		250 mL			
27:00	**1**		270 mL			
30:00	**1**		300 mL			
36:00	**1.5**	72 mL	330 mL			
40:00	**1.5**	80 mL				250 mL
46:00	**1.5**	96 mL			240 mL	280 mL
50:00	**2**	100 mL			250 mL	300 mL
54:00	**2**	108 mL			270 mL	320 mL
62:00						360 mL
72:00	**3**				330 mL	
75:00	**3**					
80:00	**3**			200 mL		
100:00	**4**			220 mL		
125:00	**5**			250 mL		
135:00	**6**			270 mL		
144:00	**6**			300 mL		

Preparing the MEDI-FLO® Elastomeric Pump

Instructions for Filling

Use Aseptic Technique

1. Unscrew the fill port cap.
2. MEDI-FLO® Elastomeric Pump can be filled with a syringe or automated fluid dispensing device. Remove trapped air from the filling device and attach it securely to the fill port.
3. Close the ON-OFF clamp and fill the MEDI-FLO® Elastomeric Pump with no more than the maximum recommended volume. When using a syringe to fill, push the plunger to dispense the fluid. Do not push the barrel onto the fill port as the syringe tip or fill port may break. Repeat as necessary.
4. Remove filling device from the fill port. Screw on the fill port cap.
5. Label with appropriate pharmaceutical and patient information.

PLEASE NOTE:

Actual infusion time may vary due to the following:

- Filling the device less than the nominal volume generally results in slower flow rate.
- Filling the device more than the nominal volume generally results in faster flow rate.

Priming the Administration Tubing

Use Aseptic Technique

1. Open the ON-OFF clamp.
2. Loosen the patient end cap. Medication will start to flow and fill the tubing. When all air is expelled, tighten the patient end cap.
3. Close the ON-OFF clamp.

Priming Technique for Drugs

For Drugs Prone to Precipitation

1. Fill MEDI-FLO® Elastomeric Pump with 10 mL of diluent first.
2. Using the above priming method, prime the tubing.
3. Fill the remaining volume with diluent and medication. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication.

Storage

The MEDI-FLO® Elastomeric pump should be stored under general warehouse conditions at 68° F to 77° F (20° C to 25° C) and be protected from light sources and heat, prior to filling with medication. Refer to drug manufacturer's requirements for storage after filling the pump with medication.

Prior to starting infusion, the pump should be allowed to reach room temperature.

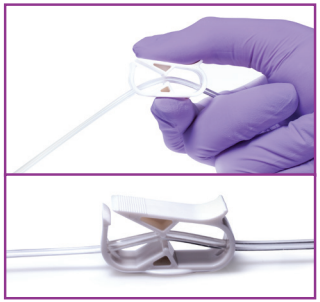
The table below provides guidelines for the estimated amount of time it will take for the pump to reach room temperature after refrigeration based on the nominal fill volume. Please note the MEDI-FLO® pump should not be stored in a freezer.

Nominal Fill Volume	Refrigerated Temperature	Estimated Time to Reach Room Temp
50 mL – 100 mL	35.6° to 46.4° F (+2° to +8° C)	6 hours from refrigerator
50 mL – 100 mL	-0.4° F (-18° C)	12 hours from refrigerator
100 mL+	35.6° to 46.4° F (+2° to +8° C)	12 hours from refrigerator
100 mL+	-0.4° F (-18° C)	18 hours from refrigerator

Guidelines for Infusion

Starting Infusion

Use Aseptic Technique



Open position, infusion has started.

1. Allow the MEDI-FLO® Elastomeric Pump to warm to room temperature before use, especially when infusate has been refrigerated.
2. Infusion should preferably be started 1 – 8 hours after filling.
3. Verify that the ON/OFF clamp is closed.
4. Clean patient access point site as directed by facility protocol. Attach the patient connector to the injection site.
5. Flow restrictor should be taped to patient's skin to maintain the appropriate temperature for accurate medication delivery.
6. Begin infusion by opening the ON/OFF clamp, fluid will begin to flow immediately.
7. Ensure the ON/OFF clamp remains in the ON/OPEN position and the tubing remains free of kinks.
8. If kinks are observed in the tubing they can be released by rolling the tubing between fingers to restore shape of tubing and facilitate fluid flow.

During Infusion

Patient Guides for the MEDI-FLO® Elastomeric pump are available and should be provided to the patient prior to infusion. Healthcare provider is responsible for educating the patient on proper use.

Depending on the pump size, a change in the look and size of the pump may appear fairly quickly. It may take longer to see this change if the length of the infusion is more than 24 hours.

Full Pump
The inside of the pump will be filled with medication and will be round and firm. The outer cover will be smooth and stretched over the ball.

During Infusion
During the infusion, the inside reservoir will shrink in size and the outer cover will begin to form wrinkles.

Empty Pump
At the end of the infusion, the inner ball will become a tall cylinder and the outer cover will collapse.

During Infusion *(continued)*

The filled pump should not be squeezed or played with. Applied pressure may result in rupture or breakage and will result in increased flow rate.

During use, the pump may be placed in a carrying case, patient's pocket or on a table/bed next to the patient. Carrying cases are available for purchase from Wolf Medical Supply.

Ensure the section of tubing from the filter to the patient connector is kept underneath clothing and in contact with the patient's body.

Depending on the therapy, the patient may be using the pump while sleeping. If so:

- The pump should be placed on a bedside table or on top of the bed covers. If placed underneath the bed covers the pump may become too warm, and flow rate may increase.
- Do not place the pump on the floor or hang the pump on a bed post.

It is not recommended that the patient use the pump while bathing or swimming. Patient may shower with proper direction from facility or healthcare provider, if pump and access site are protected from water.

End of Infusion

Infusion is complete when the elastomeric membrane is no longer expanded. Close the clamp and disconnect from access site. Flush access site and dispose of pump and supplies as directed by facility protocol.

Closed position, pump is not infusing.

Cautions

The MEDI-FLO® Elastomeric Pump is designed for optimal performance, effectiveness and safety as a single use device and not for reuse. Performance, effectiveness and safety may be compromised if the device is reused.

The MEDI-FLO® is sterile and nonpyrogenic. The pump should not be used if sterile pouch has been opened, damaged, or if either protector cap is not in place.

Do not exceed the maximum labeled fill volume of the pump as this may affect the indicated flow rate accuracy.

Prevent the filter from getting wet. Do not get alcohol or detergents on the filter as this may cause a leak.

The MEDI-FLO® Elastomeric pump is not intended for use for the infusion of insulin, blood or blood products, TPN, lipids or fat emulsions.

Troubleshooting

If pump does not seem to be working properly, please make sure:

1. The pump is at room temperature. If higher than room temperature, infusate will flow faster than the labeled rate.
2. The ON/OFF clamp is in the open position and moves freely on the tubing.
3. All clamps on the catheter are open and filter is not covered.
4. There are no kinks in the pump tubing.
5. Verify that the fill volume is within the guidelines provided for the device that is being used. Underfilling the pump will cause it to flow slower than the labeled rate. Overfilling the pump will cause it to flow faster than the labeled flow rate.

If you have checked all of the above and your pump still does not seem to be working, please contact Wolf Medical Supply at 1-800-335-9653 for further instructions.

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