



FMS Pump™, FMS Pump Plus™

Warning: Do not use for intra-articular infusions.

User's Guide

DESCRIPTION

FMS Pump™ is a disposable infusion device that has an rate, continuous and pre-fixed flow rate. Its elastomeric silicone reservoir enables pumping without electrical power. **FMS Pump Plus™** is specially designed to deliver medications with continuous flow and bolus dose for patient controlled analgesia (PCA) infusion therapy. **FMS Pumps™** are designed for single-use in hospital, outpatient, and home care settings.

INDICATIONS

FMS Pumps™ are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue / body cavity) site. **FMS Pump Plus™** is also intended for patient controlled analgesia (PCA) infusion using the integrated bolus button. General infusion uses include pain management for preoperative, preoperative, postoperative surgery as well as chemotherapy and antibiotic therapy.

PRECAUTIONS

- Before use, the user must become thoroughly familiar with the information contained in the device operating instructions.
- Do not fill the reservoir with medications more than the maximum reservoir volume.
- Do not use the **FMS Pumps™** if the packaging has been previously opened or damaged.
- FMS Pumps™** are intended for single patient use only. Do not reuse. Do not resterilize.
- FMS Pumps™** must be stored at a temperature lower than 38°C (100°F) and protected from direct sunlight.
- Check the clarity of solution prior to administration. Do not use unless solution is clear.
- Confirm that the medications are prepared and administered in accordance with the drug manufacturer's recommendations and/or the order of a physician.

DIRECTION FOR USE

■ FILLING

Use aseptic technique when preparing **FMS Pumps™** for use.

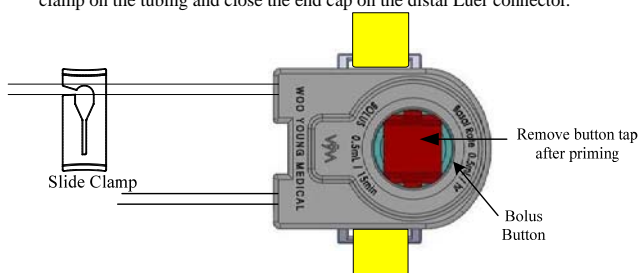
- Identify the nominal flow rate and reservoir capacity prior to opening the package. (See the "Specifications" section)
- Close the clamp on the tubing and remove Luer cap from the filling port.
- Fill a sterile syringe with the medications to be dispensed.
- Connect the filled syringe to the filling port and inject the medication into the medication reservoir slowly. (Repeat if necessary until desired volume of medication has been injected into the medication reservoir.)
- Do not fill beyond the maximum capacity.
- After the reservoir has been filled, disconnect the transfer syringe and close the Luer cap on the filling port.

■ PRIMING

- Open the clamp on the tubing and remove the female end cap on the distal Luer connector.
- The medication in the reservoir will flow toward the patient end of the set, expelling any air present in the system.
- Air will be also expelled through the air vent of the IV filter. The filter should be held upright as indicated by the arrow. Tapping the filter will accelerate air removal.
- After the air is removed and the medication flows out of the distal end, close the clamp on the tubing and close the end cap on the distal Luer connector.

In case of using FMS Pump Plus™

- Open the clamp on the tubing and remove the female end cap on the distal Luer connector.
- The medication in the reservoir will flow toward the patient end of the set, expelling any air present in the system including the PCA module.
- Air will be also expelled through the air vent of the IV filter. The filter should be held upright as indicated by the arrow. Tapping the filter will accelerate air removal.
- When air is not any more found in the tubing after the PCA module, remove the red tap on the bolus button.
- Caution:** If the red tap is not removed, bolus reservoir in the PCA module will not be filled with medication, and infusion can be made at a much higher flow rate.
- After the air is removed and the medication flows out of the distal end, close the clamp on the tubing and close the end cap on the distal Luer connector.



MIXING AND USE INFORMATION

- FMS Pumps™** are designed to flow at the nominal rate indicated on the device. This flow rate is fixed.
- Alteration of dosage may be achieved by adjustments in concentration of medication rather than flow rate.
- FMS Pumps™** are calibrated to deliver solution at the labeled nominal flow rate when the temperature of the infusate in the flow restrictor (distal end) is at **32°C± 2°C**.
- FMS Pumps™** are calibrated using **5% Dextrose in Water (D5W)** as the infusate. Flow rate increases as fluid viscosity decreases. (E.g., Using sterile water or 0.9% sodium chloride (N/S) as diluents will increase the flow rate by approximately 10%.)
- FMS Pumps™** are calibrated with **zero head height between reservoir and flow restrictor**. If reservoir is higher than restrictor, flow rate will become faster.

SPECIFICATIONS

Flow Rates (For FMS Pump Only)	Flow Rate Label Color	Flow Rate Label Color
0.5ml/hr	Red	4.0ml/hr Orange
1.0ml/hr	Blue	5.0ml/hr Green
1.5ml/hr	Sky Blue	8.0ml/hr Gray
2.0ml/hr	Yellow	10.0ml/hr Violet
System accuracy	Reservoir Volume	accuracy
	60ml/100ml	±10% of Nominal Flow Rate
	300ml/600ml	±15% of Nominal Flow Rate
Operating Pressure	6 to 9 psi	
Residual Volume	< 3ml (including Tubing + Reservoir + Filter)	
Filter	1.2µm or 5.0µm, Air-Eliminating, In-Line Filter	
Materials	DEHP-Free, Latex-Free	

CAUTIONS

- CAUTION:** Federal (USA) law restricts device to sale by or on the order of a physician.
- Delivery rate and total medication received by the patient may vary as much as +/- 15%, depending on the model selected. Take this variance into consideration when determining the delivery rate and duration, to reduce the possibility of an adverse event.
 - Intended for single patient use only. Do not re-use or re-sterilize.
 - Do not use the FMS pumps if the packaging is damaged or previously opened. The product is sterile only in unopened, undamaged packaging.
 - The clinician is responsible for educating the patient in proper use of the system.
 - The clinician is responsible for ensuring that the FMS pumps and medications are used according to the physician's infusion therapy prescription.
 - As with any infusion system, medications may interact with the FMS pumps materials. Consult the drug manufacturer's insert for precautions, guidelines, and instructions for preparing and using the medication.
 - Purge the air from the infusion line before connecting to the patient.
 - Do not fill the FMS pumps with more than the maximum reservoir volume. Overfilling will increase the flow rate.
 - Flow rate and reservoir volume are fixed. Choose the appropriate nominal flow rate and volume for the prescribed therapy.
 - Store at room temperature and protect from direct sunlight.
 - Use aseptic technique when preparing FMS pump for use.



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