

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, June 01, 2017 8:51 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Medtronic

Medtronic is voluntarily recalling specific production lots of its Covidien Monoject™ 0.9% sodium chloride flush syringes and hemodialysis catheter procedure kits containing the dual pouches of these syringes. This voluntary recall is being conducted due to the potential for the sterility of the outer barrel of the syringe to be compromised. The flush solution contained in the syringe remains sterile. The use of products with this condition may result in a potentially increased risk for infection. **No patient injuries have been reported related to sterile packaging seal issues.** The complaint rate for these reports is 0.002%.

The recalled Monoject™ 0.9% sodium chloride flush syringes may compromise the integrity of a sterile field during IV therapy. Patients having received IV therapy with the recalled Monoject™ 0.9% sodium chloride flush syringes should be closely monitored for adverse effects. Signs and symptoms of bacteremia and/or sepsis can include, but are not limited to headaches, fever, chills, nausea, vomiting and diarrhea. Patients complaining of these symptoms should seek medical attention.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

Item Code	Product Description	Lot Number
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15091
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15081
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15080
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15079
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15078
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15071
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15070
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15069
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15064
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15063
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15059
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15058
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15057
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15056
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15049
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15048
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15047
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15046
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15042
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15041
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15037
8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15036

8881570129	Monoject™ 0.9% Saline Flush Prefill Double Pouch	P15035
8888135137	Mahurkar™ Acute Dual Lumen Catheter Tray, High Flow Straight Extensions with IC* Safety Components, 13.5 FR x 13.5 cm	1508200108
8888135139	Mahurkar™ Acute Dual Lumen Catheter Tray, High Flow Pre-Curved with IC* Safety Components, 13.5 FR x 13.5 cm	1506500122
8888211424	Mahurkar™ Elite Acute Dual Lumen Catheter Tray, High Flow Straight Extensions with IC* Safety Components, 13.5 Fr x 24 cm	1506200114
8888211424	Mahurkar™ Elite Acute Dual Lumen Catheter Tray, High Flow Straight Extensions with IC* Safety Components, 13.5 Fr x 24 cm	1506900083