

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, May 16, 2016 11:39 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Product Recall - Baxter Healthcare Corp

Baxter Healthcare Corporation is issuing a product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. This issue was identified as a result of an increase in complaints for COSEAL. The affected lots were distributed between 11/10/2015 and 04/07/2016.

Product Code	Product Description	Lot Numbers	Expiration Date	UDI
934070	COSEAL Surgical Sealant Kit, 2mL	HA160136	01/31/2017	5413765404610
934071	COSEAL Surgical Sealant Kit, 4mL	HA160151	01/31/2017	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151205	11/30/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151036	10/31/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151026	09/30/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA151035	10/31/2016	5413765404627
934071	COSEAL Surgical Sealant Kit, 4mL	HA160229	02/28/2017	5413765404627
934072	COSEAL Surgical Sealant Kit, 8mL	HA151038	10/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA151220	12/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA151037	10/31/2016	5413765404634

934072	COSEAL Surgical Sealant Kit, 8mL	HA151028	09/30/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA160114	12/31/2016	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA160115	01/31/2017	5413765404634
934072	COSEAL Surgical Sealant Kit, 8mL	HA160222	02/28/2017	5413765404634

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