California Medical Device Recall Information

Recall Name
Baylis Medical Recalls TorFlex Transseptal Guiding Sheath Kit Due to a Potential Defect

Recall Date	Product Description	Recalling Firm	Recall Reason
9/23/13	TorFlex Transseptal Guiding Sheath Kit	**Baylis Medical Company, Inc.** Montreal, Canada	*Potential for the sheath to remove particulate of less than 5 mm from the dilator. Particulate could potentially migrate into a patient's bloodstream.*

Recall Class	Product Identification	Distribution	Affected Dates
I		**CA**, nationwide	Manufactured between: **12/22/11 and 7/24/13**

Part	Lot Number	Expiry
TF8-32-63-90	TFFA070213	31-Dec-14
TF8-32-63-90	TFFA070912	30-Sep-13
TF8-32-81-135	TFFH070912	31-Aug-14
TF8-32-81-37	TFFD070912	31-Aug-14
TF8-32-81-45	TFFE070912	31-Aug-14
TF8-32-81-55	TFFF070912	31-Aug-14
TF8-32-81-90	TFFG070912	31-Jan-15
TF8-38-62-S	TFFA201212	31-Dec-14
TF85-32-63-37	TFFC070912	30-Sep-13
TF85-32-63-45	TFFA221211	31-Jul-14
TF85-32-63-45	TFFA250512	31-Jan-15
TF85-32-63-45	TFFC051212	31-Jan-15
TF85-32-63-45	TFFC230812	30-Sep-14
TF85-32-63-55	TFFA230113	29-Feb-16
TF85-32-63-55	TFFA290812	30-Sep-13
TF85-32-63-55	TFFB070612	31-Jan-15
TF85-32-63-90	TFFB230812	30-Sep-13
TF85-32-63-90	TFFC260413	31-May-16
TF85-32-63-90	TFFC280213	28-Feb-15
TF85-32-63-90	TFFF070213	31-Mar-15
TF85-32-81-135	TFFC280912	31-Oct-14
TF85-32-81-37	TFFA280912	31-Oct-14
TF85-32-81-90	TFFB280912	31-Oct-14

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm373911.htm