State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cordis Recalls Flex Biliary Stent due to Potential for Distal Tip to Dislodge

Recall Date	Product Description	Recalling Firm	Recall Reason
11/24/2021	**SMART FLEX 6x120 BIL, 120cm** The S.M.A.R.T.© Flex Biliary Stent System is indicated for use in the palliation of malignant strictures in the biliary tree.	**Cordis Corporation,** Miami Lakes, Florida	There is a potential for distal tip dislodgement or separation.
11/24/2021	**SMART FLEX 6x150 BIL, 120cm**	**Cordis Corporation,** Miami Lakes, Florida	Distal tip separation.
11/24/2021	**SMART FLEX 8x60 BIL, 80cm**	**Cordis Corporation,** Miami Lakes, Florida	Distal tip separation.

Recall Class	Product Identification	Distribution	Affected Dates
II	**SMART FLEX 6x120 BIL, 120cm** Product Code: SF06120MB Lot No. 266401	1 Devices in California	October 2021 and prior
II	**SMART FLEX 6x150 BIL, 120cm** Product Code: SF06150MB Lot No. 266417	1 Devices in California	October 2021 and prior
II	**SMART FLEX 8x60 BIL, 80cm** Product Code: SF08060SB Lot No. 266523	4 Devices in California	October 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov