See Related Information[22]

## Class 2 Device Recall Cordis S.M.A.R.T. Flex Vascular Stent System

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|---|---|
| **Date Initiated by Firm** | February 16, 2017 |
| **Create Date** | April 15, 2017 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-1826-2017 |
| **Recall Event ID** | 76800[23] |
| **Product Classification** | Stent, coronary[24] - **Product Code** MAF[25] |
| **Product** | Cordis S.M.A.R.T. Flex Vascular Stent System |
| **Code Information** | 1.) Catalog Numbers SF05200MV, Size 5 x 200mm, Catheter length 120 cm GTIN -Carton Level 20705032066829 Lot #'s: 34551, 34552, 34585, 34586, 34587, 35009, 35199, 35228, 35706, 35741, 35859, 35860, 36160, 36275, 36380, 36666, 36792, 36859, 36902, 36903, 37007, 37091, 37155, 37349, 37350, 37350, 37961, 37962, 38059, 38315, 38515, 38529, 38529, 38628, 38629, 39001, 39002, 39195, 39398, 39427, 39644, 39862, and 39974, 2.) Catalog Numbers SF05200SV, Size 5 x 200mm, Catheter length 80 cm GTIN -Carton Level 20705032066409 Lots #'s: 35707, 35742, 35965, 36161, 36667, 36793, 37351, 37963, 39158, 39351, 39352, 39554, 39641, and 39863, 3.) Catalog Numbers SF06200MV, Size 6 x 200mm, Catheter length 120 cm GTIN -Carton Level 20705032066836 Lots #'s: 34469, 34470, 34588, 34589, 34823, 3487534993, 35006, 35068, 35069, 35229, 35287, 35352, 35469, 35470, 35715, 35755, 35823, 35868, 35945, 35971, 36032, 36033, 36163, 36279, 36322, 36388, 36537, 36678, 36742, 36804, 36865, 37019, 37106, 37168, 37250, 37352, 37707, 37975, 38063, 38282, 38319, 38429, 38513, 38569, 38747, 38850, 38921, 39007, 39162, 39200, 39267, 39358, 39405, 39949, and 39955 and , 4.) Catalog Numbers SF06200SV Size 5 x 200mm, Catheter length 80 cm GTIN -Carton Level 20705032067024 Lots #'s 35077, 35165, 35361, 35500, 35568, 35597, 35716, 35756, 35824, 35946, 35972, 36034, 36164, 36538, 36679, 36680, 36805, 37107, 37169, 37541, 37579, 37708, 38064, 38167, 38168, 38320, 38321, 38530, 38748, 39201, 39439, 39440, 39645, 39646, 39959, and 39971<br><br>ALL UNEXPIRED LOTS NUMBERS. |
| **Recalling Firm/ Manufacturer** | Cordis Corporation<br>14201 NW 60th Ave<br>Miami Lakes FL 33014-2802 |
| **For Additional Information Contact** | 786-313-2000 |
| **Manufacturer Reason for Recall** | Deployment Difficulty. |
| **FDA Determined Cause [2]** | Other |
| **Action** | Email to the Cardinal Health and J&J country entities sent February 16, 2017. Each country will perform the recall locally. (This is an OUS only Removal.) |
| **Quantity in Commerce** | 2,700 |