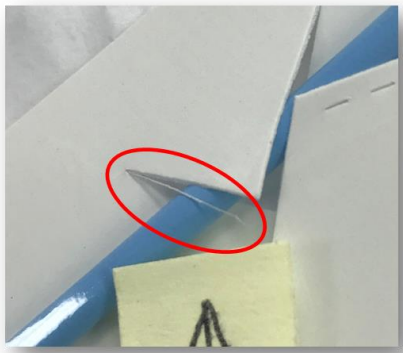
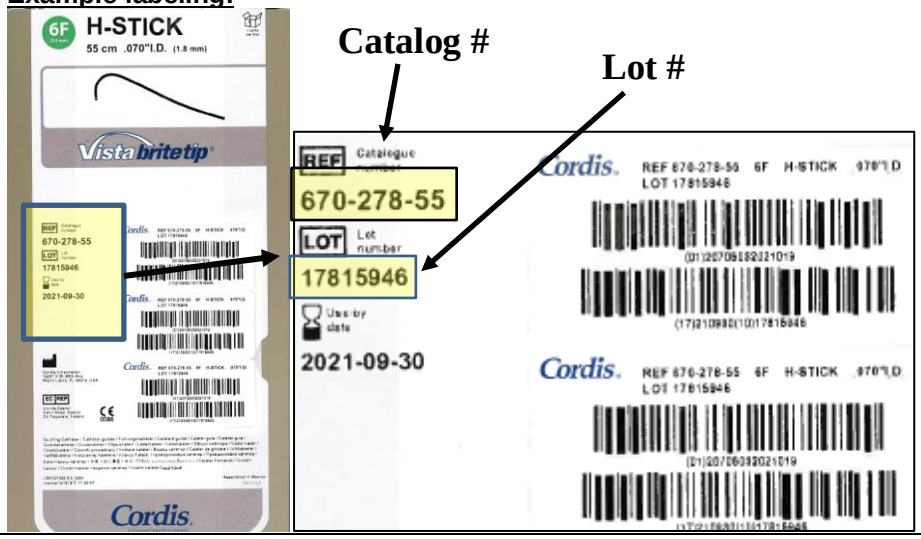
Urgent Field Safety Notice (Removal)

Cordis Vista Brite Tip® & ADROIT™ Guiding Catheters

February 07, 2019

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is recalling 173 lots of Cordis Vista Brite Tip® and ADROIT™ Guiding Catheter product.

Recall Overview:	Cordis has initiated a recall for 173 lots of Vista Brite Tip® and ADROIT™ Guiding Catheter due to frayed pieces of the mounting card being inside the primary packaging. See below image.  Frayed pieces of the mounting card were found in the sterile primary package. While the material may be identified when the product is opened and prepared for use, there is a potential for harm if the material is not discovered or if the device is not prepared properly. Prior to and during preparation of the device, if the frayed material is identified, the user would be prompted to exchange the device for another one, resulting in a pre-procedural or intra-procedural delay. However, if undiscovered, the frayed material could enter the patient's vasculature potentially resulting in ischemia, necrosis, or the need for additional intervention. The sterility of the product is not affected. Cordis has not received any reports of patient harm related to this issue. **Usage** The Vista Brite Tip® and ADROIT™ Guiding Catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.
Details on Affected Devices, to assist in identification of the product involved:	**Identification** See Table 1 below for catalog number and lot number list **Example labeling:** 

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased impacted Vista Brite Tip® and ADROIT™ Guiding Catheter lot numbers.

Actions requested on your part:	1) Read this Field Safety Notice (Removal) letter. 2) Immediately check your inventory to confirm whether or not you have any units from the affected lots in your possession. Identify and set aside any units from the affected lots in a manner that ensures the affected product will not be used. Check all storage and usage locations. 3) Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. 4) Return all affected product to the Cardinal Health distribution center. Please contact your local sales representative to facilitate return of the affected product, if necessary. Your sales representative will inform you of the product replacement or credit options. 5) Share this letter with others in your facility who need to be made aware of this recall and with any other facility that may have been sent the affected units of Vista Brite Tip® and ADROIT™ guiding catheter product from your facility. If any units of the affected lots are found to be at the other facility, please arrange the return of the units. 6) Maintain awareness of this notice until all affected product has been returned to Cordis and keep a copy of this notice with the affected product.

Description of the problem:	<u>What is the issue?</u> Cordis became aware of frayed pieces of the mounting card being inside the device primary packaging. <u>Why are we recalling this product?</u> Frayed pieces of the mounting card were found in the sterile primary package. While the material may be identified when the product is opened and prepared for use, there is a potential for harm if the material is not discovered or if the device is not prepared properly. Prior to and during preparation of the device, if the frayed material is identified, the user would be prompted to exchange the device for another one, resulting in a pre-procedural or intra-procedural delay. However, if undiscovered, the frayed material could enter the patient's vasculature potentially resulting in ischemia, necrosis, or the need for additional intervention. The sterility of the product is not affected. <u>What other actions is Cordis taking?</u> Cordis is investigating the root cause and will take appropriate corrective action. Cordis has not identified any other lots that may be affected.

Available Assistance:	If you have any questions regarding this recall, please contact your local sales representative or local sales office.

Additional Information:	**<u>Regulatory Notification</u>** The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.

We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cordis is committed to maintaining your confidence in the safety and quality of the products that Cordis supplies.

Respectfully yours,

Miguel Ávila
Vice President, Global Quality and Regulatory Affairs
Cordis Corporation

Table 1

Catalog #	Lot Number	Catalog Number	Lot Number
67019055	17744955 17750783 17757121	588840P	17756076 17816499
67021055	17735533 17735534 17744429 17744430 17750785 17757116	598943P	17746147 17807995 17811028 17814511 17818155
67021255	17748743 17750476 17755096 17757122	588843P	17777712 17816501
67021455	17753002	588845P	17729208
67027055	17779364	588841P	17753948
67027855	17815946	588857P	17756074 17816500
67028055	17805148 17815949	588858P	17756075
77821055	17746022 17762925	598945P	17755015
77821255	17733016 17747583 17749800 17752698 17767925 17769354 17771053 17772929	G780GOND	17724819 17742581 17756975 17771328 17794750 17814264 17816167
77822455	17722360 17735189	SM7673	17750494 17817649
77827055	17733019 17746026 17747584 17749793 17752703 17754875 17756762 17762928 17771058 17772931 17816029 17817637	588846P	17733005 17736643 17737608 17742559 17740605 17743099 17743101 17745965
77827855	17722359 17740611 17778655	77828055	17724480 17767923 17771049 17772926

67221255	17753959	6720540E	17800760

Table 1 (continued)

Catalog #	Lot Number	
55805400	17801566 17806219 17808004 17809486	
67005400	17802170	17811837
	17802171	17811839
	17803141	17813158
	17803142	17813159
	17803143	17815025
	17803536	17817001
	17803539	17817002
	17803540	17817004
	17804225	17817285
	17804226	17818563
	17804764	17818564
	17805447	17819221
	17805899	17819222
	17805901	17821534
	17806330	17800613
	17806331	17800614
	17806332	17800615
	17807603	17802172
	17807626	17803537
	17807628	17803538
	17807629	17804026
	17809536	17804222
	17809537	17804223
	17809538	17804224
	17809786	17804765
	17809791	17804766
	17809792	17805898
	17809793	17805900
	17810429	17805902
	17810430	17807627
	17810432	17811835
	17810433	17815021
	17811219	17815022
	17811220	17815023
	17811221	17815024
	17811834	17817003
	17811836	17819220
67205400	17806706 17807595 17811677 17812321 17814278 17814279 17814640 17814641 17814642 17814643 17815340 17806214	