Urgent Customer Communication

Notice of potential leakage during procedure preparation due to cracked luer hub

Cordis® S.M.A.R.T.® Flex Vascular Stent System
85 lots across 48 catalog numbers- See listing in Table 1

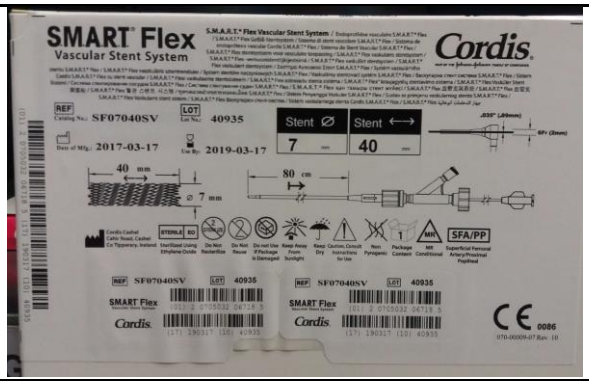
November 15, 2017

Dear Valued Customer,

The purpose of this communication is to inform you of a potential leakage scenario with the S.M.A.R.T.® Flex Vascular Stent System. The leak may occur due to potentially cracked hubs in some units from within the 85 lots listed in Table 1.

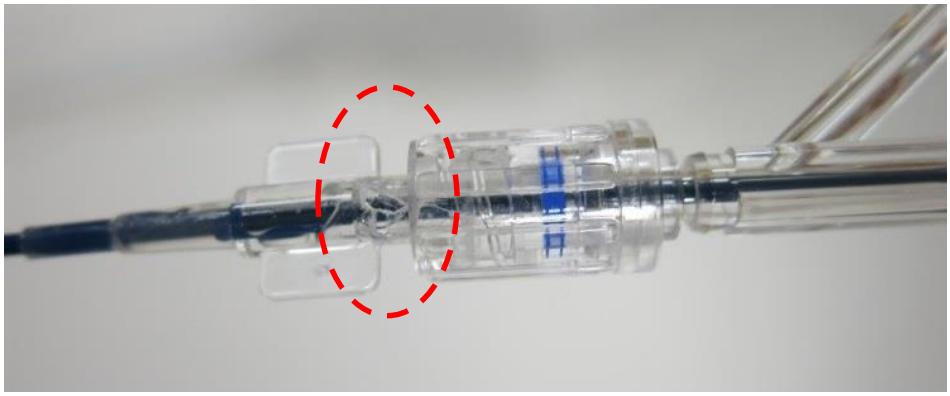
Correction Overview:	Based on one complaint and the subsequent investigation, Cordis has determined that 85 distributed lots of S.M.A.R.T.® Flex Vascular Stent System have a potential for cracked luer hubs, due to a manufacturing error. The luer hub is used to inject contrast/saline during procedure preparation, prior to insertion of the stent system into the patient. A cracked hub could result in leakage of saline, or in the worst case, inability to flush the outer sheath of the catheter. The potential medical consequence would be a delay in device preparation, resulting in the need to prepare a replacement device for use. Cordis does not anticipate any other patient impact. Cordis would therefore like to emphasize the following steps already contained within the Instructions For Use: *Use a 1-3 cc syringe to flush the outer sheath (1) with sterile heparinized saline through the female luer (4) on the handle. Flush until only a few drops of saline exit the distal end of the outer sheath. Complete system flushing may require 2-3 flushings with a 1cc syringe.* *Warning: If the outer sheath (1) cannot be flushed do not use the device.* There is no safety concern for patients that are treated successfully using product from these lots. This is a customer communication only. This is not a removal.

Details on Affected Devices, to assist in identification of the product involved:	**<u>Product involved</u>** • 85 lot numbers of 48 catalog numbers. Reference Table 1. The lot number range is from 40932 through 41637, but not all lots in the range are affected. • The newest lot involved has a Use By Date of 2019-04-26. • Although it is possible that some additional uninspected units in the supply chain will be distributed, most additional units from the affected lots distributed in the future will have been inspected and confirmed to be free of visible cracks at the luer hub. **<u>Identification</u>** The following photos are provided to help you identify the S.M.A.R.T.® Flex Vascular Stent System. Affected lots are identified by the Lot number on the carton and pouch.



Usage (to assist in identification of where devices are kept in facility)
The S.M.A.R.T. ® Flex Stent iliac indication is intended for use in the common and external iliac arteries to improve luminal diameters in patients with symptomatic vascular stenotic and/or occlusive diseases.
The S.M.A.R.T. ® Flex Stent superficial femoral artery and proximal popliteal indication is intended as a treatment for atherosclerotic superficial femoral artery lesions and proximal popliteal lesions.

Actions requested on your part:	1) **Read** the "Description of the problem" section carefully to fully understand the issue involved. 2) **Check** your inventory to determine if you have any remaining affected product in your possession. Check all storage and usage locations. The purpose is to identify the product, not to remove the product. 3) **Keep** a copy of this notice with any affected product. Due to low severity of the condition, a formal acknowledgement is not requested. 4) **Share** this letter with anyone who needs to be informed in your facility, or in any facility where potentially affected devices may have been transferred. 5) **During procedure preparation, check** for cracks/leaks. If the user detects a crack prior to flushing, or a leak during flushing, select a replacement device. (See inspection section below.) Report the incident through the standard complaint process. 6) **Maintain awareness** of this notice until all affected product has been consumed.
Description of the problem:	**What is the summary of the issue?** Due to a manufacturing error, some luer hubs in the affected lots may have cracks. Most of the cracks observed in the investigation were minimal, resulting in slight leakage of saline, but the degree of cracking varies. **What are the health consequences if product with a cracked hub is used?** Pre-procedural delay: Devices are prepared for use in advance of the start of the procedure. At that time, in accordance with the IFU, the user prepping the devices should readily identify a leakage scenario, resulting in a pre-procedural delay and no consequence to the patient. Catheterization Lab personnel are highly trained in identifying and mitigating hazards associated with these medical devices. Exchange and preparation of a replacement unit is conducted efficiently; therefore, there should be minimal intra-procedural delay. There is no safety concern for patients that are treated successfully using product from these lots.

Inspection details:	As stated in the Instructions for use, users are warned that the device should not be used if the outer sheath cannot be flushed. Inspect for leakage during preparation of the device. Leakage may be more likely in the affected product due to cracks in the luer. At time of actual flushing, if there is no leakage observed, the product may be safely used. For reference, cracks, when present, are visible in the region indicated in the photo below.  A noted above, it is possible that some additional uninspected units in the supply chain will be distributed. However, most additional units from the affected lots distributed will have been inspected and confirmed to be free of visible cracks at the luer hub.
Why you are being contacted:	You are receiving this letter because our records indicate that you have received one or more of the affected lots.

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

Additional Information:	**<u>What other action is Cordis taking?</u>** Cordis has performed a root cause investigation and taken immediate corrective action. There are no other lots involved in that other lots were either already inspected for the condition after manufacture or not manufactured in the time frame of the manufacturing error. Cordis is voluntarily taking this action. **<u>Regulatory Notification</u>** This communication is not considered a Field Safety Corrective Action as defined in the EU Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12-1 rev 8). Therefore, notification to EU regulatory bodies does not apply.

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 we supply.

Respectfully yours,

[redacted]

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

Table 1- **Cordis® S.M.A.R.T.® Flex Vascular Stent System Impacted Lots**

GTIN	Catalog	Lot Number					
20705032066980	SF05060MV	41064	41191	41327			
20705032066720	SF05060SV	41065					
20705032067123	SF05080MV	41303	41328				
20705032066881	SF05080SV	41059					
20705032066614	SF05100MV	41109					
20705032066751	SF05100SV	41192					
20705032066362	SF05120SV	41460					
20705032066492	SF05150MV	41066	41067	41330			
20705032066386	SF05150SV	40940	41331				
20705032066430	SF06030MV	41110	41462				
20705032066676	SF06040MV	41332	41463	41464	41465		
20705032066997	SF06060MV	41304	41333				
20705032067031	SF06060SV	40932	41060				
20705032066898	SF06080MV	41007	41014	41061	41111	41112	41335
20705032066737	SF06080SV	41012	41113				
20705032066621	SF06100MV	40941	41193	41337			
20705032066560	SF06120MV	41194	41339				
20705032066775	SF06120SV	41190	41468				
20705032066577	SF06150MV	40938	41340	41341			
20705032066485	SF06150SV	41342					
20705032066683	SF07040MV	41343					
20705032067185	SF07040SV	40935	41306				
20705032067000	SF07060MV	41469					
20705032066973	SF07060SV	41015					
20705032066904	SF07080MV	41116	41346				
20705032067116	SF07080SV	41307	41308				
20705032066638	SF07100MV	41008	41347				
20705032066478	SF07100SV	41300					
20705032066911	SF07120MV	41473	41474				
20705032066782	SF07120SV	41013					
20705032066508	SF07150MV	41475					
20705032066935	SF07150SV	41005					
20705032066843	SF07200MV	41016	41195				
20705032066584	SF08040MV	41068	41071	41591			
20705032066669	SF08040SV	40936	41348				
20705032067086	SF08060MV	41476					
20705032066454	SF08080MV	41350					
20705032066744	SF08080SV	41312	41351	41637			
20705032066416	SF08200MV	41118					
20705032065549	SF09020MV	40933					
20705032066850	SF09030MV	41017	41062				
20705032066706	SF09060MV	41019					
20705032066966	SF09060SV	41009	41196				
20705032067109	SF09080MV	41006					
20705032066461	SF09100SV	41011					
20705032066119	SF10020SV	41183					
20705032067055	SF10030MV	41120					
20705032067154	SF10100MV	41070					