

URGENT FIELD SAFETY NOTICE

May 11, 2009

Re: Cypher Select™ + Hub Crack Complaints

Dear Valued Customer,

Over the last few months, we have had an increase in the number of complaints relating to the occurrence of cracks in the balloon inflation port hub of Cypher Select™ + Sirolimus–Eluting Coronary Stents currently in the field. The purpose of this letter is to inform you of these events, as well as what Cordis has learned from its investigation of these complaints, describe the nature of the hub crack issue, and provide you with specific direction on how to identify a hub crack prior to use. We will also describe the actions we are taking to correct the situation and prevent future occurrences. Our Notified Body and affected Competent Authorities have been informed of this matter by Cordis Europa N.V. Regulatory authorities in the Asia Pacific region including the Malaysian Medical Device Bureau are also being informed of this issue as required by local regulations.

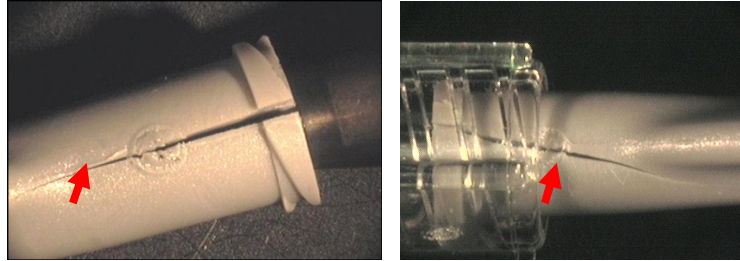
Cordis recently determined that these hub cracks are associated with certain environmental conditions that were present during the hub molding process for a limited period of time during 2008. The current complaint rate for specific lots of Cypher Select™ + associated with hubs manufactured during this period is 0.161%. The vast majority occurred before any appreciable inflation of the balloon. Approximately half of the complaints have involved hub cracks that were detected either prior to introduction of the device into the patient, or after introduction into the patient but before inflation was attempted. In most of the remaining cases, inflation was attempted but, due to the loss of pressure from the hub crack, there was no appreciable effect on balloon inflation or stent expansion. In these cases, the unit was not used, and the patient was treated with another device. In five reported cases, the hub cracks were detected during inflation. One of these required post-dilation of an underexpanded stent, three were able to be deployed, and in the last one, the stent delivery system was able to be exchanged for another device. In all five cases, the procedure was completed successfully. All cases involving hub cracks were completed successfully with no complications reported.

If a catheter were to exhibit a hub crack or leak during balloon inflation, there is the possibility that an underexpanded stent may be deployed which would require post dilation, or that the stent may dislodge from the stent delivery system. To date, no stent dislodgement, patient injury, or clinical adverse event has been reported.

Based on this information from our evaluation of these complaints, and of the general conditions for preparation and use of this product, as outlined in the Instructions for Use, we believe that patient harm as a result of these hub cracks is unlikely. To reduce the risk of a hub crack leading to any difficulties with balloon inflation or stent expansion during a patient procedure, it is important to follow the inspection and preparation steps in the Instructions for Use and as outlined below.

Steps You Should Take

Carefully inspect and prepare the delivery system, as per the Instructions for Use. Pay special attention to any indication of a hub crack or leak that may result from the stress on the hub that occurs (1) during the steps of connecting the hub to the stopcock (after the stopcock has been attached to the inflation device), and (2) when applying negative pressure to purge the balloon of air after the stent is positioned across the lesion. If cracks are noticed during this inspection, the device should be removed and returned to Cordis for analysis following established complaint handling processes. Below is a photograph showing the area where a potential crack may occur:



Steps Cordis has Taken to Address This Issue

As noted above, our investigation identified certain environmental conditions which can occur during the hub molding process and can affect the brittleness of the hub. Every device is tested for leaks and cracks during our manufacturing process. However, the brittleness does not always result in a crack at that time, but can subsequently manifest as a crack during use in your hospital. As a result, the manufacturing process has been changed to implement controls and continuous monitoring for these environmental conditions.

Although these hub cracks occur at a low incidence, we do realize these cause concern and inconvenience to you. In keeping with our commitment to provide you with quality products, Cordis is taking further actions in addition to the improved manufacturing controls noted above. We are suspending further distribution of Cypher Select™ + lots containing hubs from the suspect period. Only product with new hub inventory will be distributed. The list of affected lots of product currently in the field is attached to this letter. While this may result in a short-term, temporary backorder for certain sizes, we should be in a position to provide full service to our customers and patients within a few weeks. With these actions, we estimate that the rate of complaints will be significantly reduced in the near term.

With this information, we hope we have addressed any concerns you may have with respect to Cypher Select™ + hub cracks. We are committed to maintaining your confidence in the quality of our products and appreciate your understanding in this matter. The Cypher brand of drug eluting stents continues to have a wealth of evidence to support its safety and efficacy, with over 6 years of successful clinical experience. We value your satisfaction as a customer, and more importantly, we value patient safety. Please contact your sales representative if you would like any further clarification.

Sincerely,



Jacqueline Maestri
Vice President, Quality Assurance

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Cordis Cypher Select™ + Sirolimus-eluting Coronary Stent – Affected Product

30 Catalog numbers (343 lots listed below only)

CRB08225	CRB08250	CRB08275	CRB08300	CRB08350	CRB13225	CRB13250	CRB13275	CRB13300	CRB13350
CRB18225	CRB18250	CRB18275	CRB18300	CRB18350	CRB23225	CRB23250	CRB23275	CRB23300	CRB23350
CRB28225	CRB28250	CRB28275	CRB28300	CRB28350	CRB33225	CRB33250	CRB33275	CRB33300	CRB33350

343 affected lots, listed by ascending Lot #; Other lot#s in the range are not affected.

Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cont'd	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd
13465269	14009696	14020184	14028253	14037803	14044896	14053856	14065137	14077621
13466025	14009697	14020189	14028501	14037804	14044897	14053857	14065139	14077624
13466677	14010461	14021116	14028796	14038521	14044898	14053858	14065288	14078117
13466684	14010462	14021117	14028797	14038975	14044915	14053860	14066097	14078122
13466688	14010463	14021118	14028798	14038976	14045691	14053864	14066098	14079031
13467520	14010464	14021119	14028799	14038978	14045692	14053869	14066392	14079032
13468169	14010465	14021135	14029485	14038979	14045693	14054521	14066393	14079852
13468656	14011277	14021794	14029488	14038980	14045694	14054709	14066394	14079853
13469565	14011998	14021795	14029489	14038981	14045695	14055318	14066398	14080488
14000263	14012790	14021796	14029490	14038982	14045696	14055319	14066399	14080489
14001128	14013490	14022415	14030203	14039985	14046339	14055320	14067101	14081488
14001208	14013494	14022416	14030210	14040507	14046342	14055321	14067105	14081492
14001735	14013495	14022451	14030211	14040658	14046375	14055694	14067106	14081555
14001736	14014243	14022452	14031361	14040659	14046986	14055696	14067107	14083505
14001737	14014244	14022453	14032495	14040661	14046989	14056102	14067873	14083527
14001739	14014245	14022454	14032496	14040662	14047006	14056105	14067875	14084173
14002376	14014247	14022455	14033111	14041540	14047007	14057003	14068957	14084174
14002377	14014947	14022456	14033114	14041977	14047520	14057004	14068959	14085008
14002379	14014948	14023111	14033116	14042061	14047620	14057234	14068962	14086100
14003204	14014950	14023112	14033119	14042062	14049173	14057520	14068966	14087478
14003206	14014951	14023113	14033121	14042063	14049174	14057522	14070339	14089989
14003207	14015103	14023942	14033123	14042064	14049557	14057527	14070831	14091340
14004108	14015734	14024715	14033125	14042066	14049558	14058646	14070832	14091346
14004109	14015735	14024716	14034157	14042067	14049561	14058647	14070833	
14004157	14016393	14024717	14034162	14042082	14049563	14058648	14072210	
14004809	14016395	14025288	14034164	14042834	14049565	14059281	14072426	
14006022	14016398	14025357	14034165	14042835	14050422	14059282	14072427	
14006024	14017113	14025358	14034498	14042836	14050423	14059284	14073395	
14006026	14017114	14025359	14034590	14042837	14050424	14059311	14073396	
14006788	14017757	14025360	14035293	14042838	14051457	14059553	14073397	
14006791	14017759	14025361	14036104	14042839	14051458	14060476	14073398	
14007721	14017760	14025363	14036106	14043649	14051460	14060845	14074037	
14007722	14018618	14025366	14036109	14043652	14051461	14061197	14074038	
14007775	14018619	14026195	14036987	14043655	14051462	14061684	14074039	
14008239	14018620	14026196	14037077	14043660	14051463	14061687	14074040	
14008240	14018621	14026197	14037078	14044256	14052606	14061690	14074862	
14008398	14018622	14027549	14037590	14044257	14052609	14061699	14075250	
14008400	14018624	14027553	14037593	14044258	14052612	14062725	14075251	
14009692	14019401	14027556	14037796	14044259	14052613	14063524	14076469	
14009693	14020183	14027558	14037798	14044894	14052615	14065134	14076475	