

June 14, 2011

Encik Zamane Bin Abdul Rahman
Medical Device Bureau
Ministry of Health Malaysia
Level 5, no 26 Boulevard Plot 3C4
Persiaran Perdana, Precint 3
62675 Putrajaya, Malaysia

URGENT FIELD SAFETY NOTICE
Notice of Potential Stent Expansion Uniformity Out of Specification Condition

Cordis CYPHER SELECT®+Sirolimus-eluting Coronary Stent
Catalog numbers CRB28XXX and CRB33XXX (see listing at end of letter)

Dear Sirs:

This letter is to inform you that there is a possibility of having units within distributed lots of CYPHER SELECT®+Sirolimus-eluting Coronary Stent (Catalog number CRB33XXXX) that may not meet the Cordis internal design specification for Stent expansion uniformity (SEU). As a proactive preventive measure actions are also extended to Catalog number CRB28XXX.

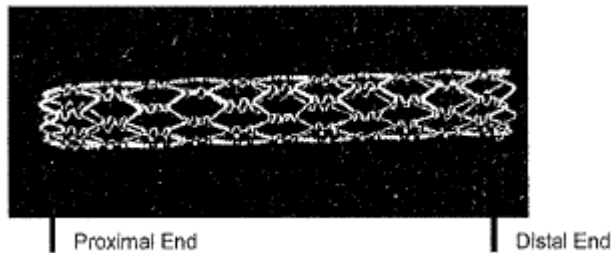
THIS IS NOT A RECALL (REMOVAL). The aim of the field safety notice is to raise awareness of the potential issue and to provide guidance should the issue occur.

Summary

Stent Expansion Uniformity refers to the percentage difference between the largest and smallest outer diameter measurement on a single stent deployed in an unconstrained manner to its rated burst pressure in engineering laboratory testing.

The SEU acceptance criterion for CYPHER® product is <10%.

An example of a stent that does not meet SEU internal design criterion is shown below. This condition is related to alignment between the balloon, marker band and stent. For the affected devices, the proximal end of the stent may be positioned over the tapered section of the balloon. Note that the proximal end of the stent is not as dilated as the central region and distal end. Therefore, the difference between the stent diameter at the proximal end and the rest of the stent is $\geq 10\%$ in this example.



During the internal non-production testing, Cordis determined that some did not meet the SET criterion at the proximal end of the stent. SEU is an internal design criterion aimed at providing consistency in the uniformity of the deployed stent. Lots currently distributed meet all of their Quality Control release requirements, which include measurement of stent expanded diameter in the central region of the stent. However, these release requirements have not included testing for SEU in the past. Testing for SEU has recently been added as a lot release requirement, as further confirmation of the corrective actions already incorporated.

Cordis has performed a root cause investigation and has taken corrective actions. The investigation determined the cause for the Stent Expansion Uniformity (SEU) over 10% is due to the positioning of the stent outside of the balloon working length during manufacturing. Cordis has implemented a corrective action of adjusting the position of the stent on the balloon during assembly.

The SEU condition may not be readily apparent to the user since, in clinical practice, non-uniformity of the deployed stent can occur due to the nature of the lesion. Non-uniformity of stent expansion greater than 10% is a common finding prior to high pressure post-dilatation with a non-compliant balloon. This condition is not expected to affect the functional performance of the device. To date, no adverse events related to this issue have been reported to Cordis and there have been no complaint trends over the last three years with respect to Stent Expansion Uniformity.

Patient harm is unlikely when using stents with this particular SEU condition, when the condition is recognized and treated appropriately. In the event a stent with the SEU condition is used in a patient, additional balloon dilatation (as directed in the CYPHER® instructions for use) is appropriate. Consistent with the IFU, it is common medical practice in interventional cardiology to assess the adequacy of stent deployment and in the majority of cases, to perform a second inflation with a non-compliant balloon at high pressure before this final assessment is completed. Given this standard practice of post-dilatation, it is unlikely the SEU condition would persist. Based on our investigation and data on experience in the field, the SEU condition has not been associated with a risk to patient safety.

In keeping with our commitment to provide quality products, Cordis had voluntarily decided to notify customers that this condition may exist in some distributed product.

Actions

The scope of this notice applies to the following CYPHER SELECT®+ Sirolimus-eluting Coronary Stent Catalog numbers that were built prior to implementation of corrective action.

- All CRB33XXX lots with Jul 2011 and prior Expiration Date
- All CRB28XXX lots with Nov 2011 and prior Expiration Date

Based on analysis these catalog numbers were determined to be only catalogs that may have the possibility of an SEU condition. We have identified multiple affected lots imported into Malaysia as per attachment 1.

Communication of this Field Action

All our customers will be notified about this Field Safety Notice. The product codes and lot numbers are printed on container boxes.

If you require additional information regarding this matter, please contact the Johnson & Johnson Regulatory Affairs Manager on +603 7962682.

Kind Regards



Ong Yean Ting
Johnson & Johnson Sdn Bhd, Medical Division
Regulatory Affairs Manager

Attachment 1: Listing of impacted CYPHER SELECT® + Sirolimus-eluting Coronary Stent Product Codes

Stent Length (mm)	Stent Diameter (mm)				
	2.25	2.5	2.75	3.00	3.50
28	CRB28225	CRB28250	CRB28275	CRB28300	CRB28350
33	CRB33225	CRB33250	CRB33275	CRB33300	CRB33350