FDA Public Health Web Notification*: Final Update of Information for Physicians on Sub-acute Thromboses (SAT) and Hypersensitivity Reactions with Use of the Cordis CYPHER™ Sirolimus-eluting Coronary Stent

Issued 10/18/2004

On October 29 and November 25, 2003, we issued Web Notifications alerting physicians that patients with the CYPHER Stent might experience a higher incidence of sub-acute thromboses (SATs) and hypersensitivity reactions than those with bare metal stents. This was based on reports we received through the Medical Device Reporting (MDR) system. We now have additional information from a 30-day follow up of 2,063 patients enrolled in the post-approval registry established by Cordis Corporation as a condition of approval to market the CYPHER™ Stent.

Information from this registry, along with FDA review of comparable bare-metal stent data, leads us to conclude that the Cypher stent, when implanted in accordance with the approved indications for use, is not associated with an excess of SATs compared to bare-metal stents. SAT remains a relatively rare event that occurs within the first 30 days following the stenting procedure. Based on our review of data from the registry as well as the MDR system, it appears that the reported rate of SATs is not greater now than it was during the premarket clinical trials, and is within the expected rate for any stent.

We are also continuing to monitor reports of hypersensitivity reactions. In most cases reported to FDA, hypersensitivity seen with implantation of the CYPHER Stent was minor (e.g., skin rashes and itching that cleared up within a few days of onset). There were, however, rare severe reactions, including anaphylaxis. Although some of the reactions we have observed so far remain unexplained, most of the reactions seem to be related to peri-procedural concomitant medications. Similar reactions to medications used in association with stenting have been well documented. Many of the reactions reported in association with the CYPHER stent resolved spontaneously with discontinuation of the peri-procedural medication(s).

The CYPHER™ Stent remains a safe and effective product when used according to the labeling, particularly with regard to patient selection and appropriate peri-procedural medications.

FDA Contacts

Laura Alonge
Office of Surveillance and Biometrics (HFZ-510)
1350 Piccard Drive, Rockville, Maryland, 20850
Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov.

Additionally, a voice mail message may be left at 301-594-0650 and your call will be returned as soon as possible.

---

* CDRH Web Notifications are intended to augment the existing Safety Notification program by providing a mechanism to quickly disseminate device–related safety information that may be beneficial to healthcare providers. Unlike other forms of Notifications, such as Safety Alerts or Public Health Advisories, Web Notifications usually do not make specific recommendations and are typically used in situations where the available information and our understanding of an issue are still evolving.

Updated October 18, 2004
