

# Patient Safety Alert

Veterans Health Administration Warning System  
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- Item:** J&J/Cordis Cypher™ Sirolimus-Eluting Coronary Stent
- General Information:** FDA issued a Public Health Web Notification <http://www.fda.gov/cdrh/safety/cypher.html> informing Physicians of sub-acute thromboses (SAT) and hypersensitivity reactions with the use of the Cordis Cypher™ drug eluting Coronary Stent.
- Specific Incident:** FDA issued a Public Health Web Notification to inform healthcare professionals of sub-acute thromboses (SAT) and hypersensitivity reactions with use of the Cordis Cypher™ Coronary Stent. As of October 20, 2003, FDA has received more than 290 reports involving sub-acute thrombosis (SAT) associated with the Cypher™ stent. More than 60 reports of SATs were associated with patient death and the remaining reports were associated with patient injury requiring medical or surgical intervention. FDA also received more than 50 reports, including some deaths that Cordis considers possible hypersensitivity reactions. The symptoms reported include: pain, rash, respiratory alterations, hives, itching, fever, and blood pressure changes.
- Actions:**
- 1. Interventional Cardiologist:** In addition to following the manufacturer's recommendation (see attached letter from Cordis dated July 7, 2003), coordinate with the post-stent care physicians to ensure that the required antiplatelet therapy regimen is continued post-stenting.
  - 2. Post-stent Care Physicians:** As recommended by Cordis [http://www.fda.gov/bbs/topics/news/cordis\\_ltr.pdf](http://www.fda.gov/bbs/topics/news/cordis_ltr.pdf) and referred to by the FDA "Administration of continued antiplatelet therapy for three (3) months post-stenting is considered critical."
  3. Report all adverse events to Cordis at 1 (800) 327-7714 and FDA via MedWatch.
- Additional Information:** This Alert is **NOT** intended to discourage the use of the Cypher™ stents in the VA.
- Source:** FDA
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Or Cordis at 1 (800) 327-7714