Patient Safety Alert

Veterans Health Administration Warning System
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Item: **Boston Scientific Stent System Recall**

General Information: Boston Scientific is voluntarily recalling specific lot numbers of four specific types of coronary stent systems: (identified here as "recalled stents" 1, 2, 3 and 4).

1) Taxus Express 2 Monorail (MR) Paclitaxel-Eluting
2) Taxus Express 2 Over-the-wire (OTW) Paclitaxel-Eluting
3) Express 2 Monorail (MR) bare-metal
4) Express 2 Over-the Wire (OTW) bare-metal.

Please NOTE: Patients who have successfully received (implanted) the stents are not affected by this recall.

Specific Incident: The FDA and the manufacturer received reports of at least one death and 18 injuries including 43 confirmed "no deflation" (failure of the balloon to deflate within one minute after deployment of the stent) complaints related to the Taxus Express 2 device system. The FDA and manufacturer also received reports of 2 deaths and 25 serious injuries including 52 confirmed "no deflation" complaints related to the Express 2 device system. The manufacturer has determined that due to the characteristics in the delivery catheters, there is the potential to impede balloon deflation during a coronary angioplasty procedure. The "no deflation" condition is caused by a narrowing of the inflation/deflation lumen, which restricts the flow of contrast media out of the balloon.

Actions:

1. Confirm that your facility received the manufacturer's recall letter dated 7/21/2004. (Letters were sent to Director of Cardiac Catheterization Labs and Risk Manager). If not contact Boston Scientific at (800) 832-7822.
2. By close of business July 30, 2004, ensure you have on site replacements from FDA approved stent suppliers, for existing, affected models ("recalled stents") of Boston Scientific stent systems. Do not sequester the "recalled stents" from use until you have replacements on hand.
3. Contact your local Boston Scientific sales representative to exchange the affected stents one for one with their replacements.

Source: Manufacturer and FDA

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