IABP, cannulae, and IVUS recalls now Class I: FDA

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Silver Spring, MD – Recent recalls of intra-aortic balloon pumps (IABPs), coronary ostia cannulae, and intravascular ultrasound (IVUS) catheters have been deemed by the **FDA** to be among the most urgent.

The agency has categorized the recalls of Maquet Datascope intra-aortic balloon pumps, Terumo coronary ostia cannulae, and Boston Scientific iCross and Atlantis SR Pro 2 coronary imaging catheters as class I, indicating that the FDA believes the problem with the device has a reasonable probability of causing serious adverse health consequences or death.

For the past four months, Maquet Datascope has been notifying customers that a misshapen retaining ring in the fan in the device's power supply may cause the fan to stop in a small number of units. This could cause the power supply to overheat and shut down the pump without warning, potentially leading to ischemia, thrombus formation, organ injury, or other serious events. The company says it has provided replacements to about 55% of the 840 US customers and 453 international customers affected by this field correction [1].

On May 16, Terumo began recalling 25-cm coronary ostia cannulae when it discovered that foreign fragments of adhesive and plastic in the cannula tip could embolize and cause arterial injury, hemorrhaging, or other serious events. The firm is removing the product line from the market and will discontinue further supply of that model. The recall affects 6220 devices [2].

As reported by heartwire, on May 27, Boston Scientific alerted customers that the tips of its iCross and Atlantis A Pro2, 40-Mhz IVUS coronary imaging catheters may break inside a patient and embolize in about 0.027% of cases. The company now estimates that a total of 110 020 devices are affected by this recall. The company is asking customers to stop using the devices and send any inventory back to Boston Scientific [3].

Sources

1. Food and Drug Administration. Medical device recalls. Maquet Datascope Corp intra-aortic balloon pumps. June 14, 2011. Available here.
2. Food and Drug Administration. Medical device recalls. Terumo coronary ostia cannula 10, 12, 14 Fr. June 14, 2011. Available here.
3. Food and Drug Administration. Medical device recalls. Boston Scientific iCross and Atlantis SR Pro 2 coronary imaging catheters. June 14, 2011. Available here.

Related links

- Boston Scientific iCross IVUS catheter recalled
  [*Interventional/Surgery > Interventional/Surgery*; May 30, 2011]
- MitraClip recalled due to problems with delivery system
  [*Interventional/Surgery > Interventional/Surgery*; May 09, 2011]
- Certain Lifeline and ReviveR AEDs recalled
  [*Arrhythmia/EP > Arrhythmia/EP*; May 04, 2011]
- UPDATE: More warfarin lots recalled
  [*heartwire > News*; Feb 22, 2011]