Anastomotic devices for coronary bypass: lethal complications have been previously reported!*1

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Received 5 August 2003; accepted 20 October 2003

Keywords: Anastomosis; Anastomotic device; Complication; Coronary surgery; Coronary bypass; Quality control

I read with interest the referenced article [1]. The authors state a paucity of reported serious complications of the first generation ‘Symmetry Bypass System’ device (pp. 925–6).

I note that, according to the Manufacturer and User Facility Device Experience Database (MAUDE) of the Food and Drugs Administration (FDA) in the USA [http://www.fda.gov/cdrh/maude.html, see on-line search], there had been, up to the date of the final submission of this paper, 61 separate incident reports (some of which fatal).

Would the authors feel the need to modify their aforementioned statement?

References


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