Evaluate Vantage

August 23, 2019

Edwards valve stumble hardly a total recall

Elizabeth Cairns

When is a recall not a recall? Almost always. The FDA has designated Edwards Lifesciences' recall of 1,585 delivery systems used with its Sapien 3 Ultra aortic valve class 1, meaning the faulty product could cause serious injuries or death. Despite the word "recall", however, the device has not been pulled from market; Edwards has simply notified doctors that 17 injuries and one death have been linked to the product, the balloon part of which can overinflate or burst during implantation. The company recommends that doctors simply deploy the device more slowly and carefully, and says it is working on a new version. The recall is not ideal since Sapien 3 Ultra was one of the valves the FDA approved last week for use in low-risk patients, a widely expected development following the smash hit in the Partner 3 trial in March. But recalls of medical devices are common and do not tend to lead to particularly dire consequences for manufacturers. Among the top five largest cardiology device companies, only Edwards and Medtronic have had recalls designated class 1 this year – six and seven, respectively – but no group has escaped the FDA's notice completely.

2019 class 1 device recalls – Edwards and Medtronic		
Date	**Company**	**Device**
Jan 31	Edwards Lifesciences	Swan Ganz thermodilution catheter
Feb 14	Medtronic	Relia dual chamber pacemaker
Feb 14	Medtronic	Versa dual chamber pacemaker
Feb 14	Medtronic	Sphera dual chamber pacemaker
Feb 14	Medtronic	Sensia dual chamber pacemaker
Feb 14	Medtronic	Vitatron dual chamber pacemaker
Feb 14	Medtronic	Attesta L DR MRI Surescan dual chamber rate responsive pacemaker
Feb 14	Medtronic	Adapta dual chamber pacemaker
Apr 25	Edwards Lifesciences	Fogarty dilation atrioseptostomy catheter
Apr 25	Edwards Lifesciences	Miller balloon atrioseptostomy catheter
May 21	Edwards Lifesciences	EV1000 clinical platform
Jun 11	Edwards Lifesciences	IntraClude intra-aortic occlusion device
Aug 21	Edwards Lifesciences	Sapien 3 Ultra delivery system
Source: FDA device recalls database.		

+81-(0)80-1164-4754