Safety Communication رسالة سلامة

Risk of Transcatheter Aortic Valves leaflet damage when performing a post-implant balloon dilatation

Device/ Product Description:	CoreValve™ Evolut™ R/PRO Transcatheter Aortic Valve
Affected product:	**Bioprosthesis Model Numbers** CoreValve™ EVOLUT™R: EVOLUTR-23, EVOLUTR-26, EVOLUTR-29, EVOLUTR-34 EVOLUT™PRO: EVOLUTPRO-23, EVOLUTPRO-26, EVOLUTPRO-29
Manufacturer:	Medtronic
Problem:	The manufacturer has received reports of the devices leaflet damage occurring following PID. These complaints of damage to the bioprosthetic leaflets resulted in moderate or severe aortic insufficiency which were detected acutely or during follow up. These reported events required re-intervention (77%), conversion to surgery (19%), re-intervention followed by surgery (2%), or were treated conservatively (2%). No other serious adverse event outcomes associated with these events have been reported.
Recommendation /Actions:	1- Review this notice and ensure that all affected personnel within your organization are aware of the contents. 2- Review the updated instructions provided in Appendix A. 3- Contact the Authorized Representative for required assistance. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

Devices/Products photo:		
Authorized Representative Details	AR name:	Medtronic Saudi Arabia
	Assigned Contact Person:	Nahar Alsurayi
	Mobile/Phone:	0555066900
	Email:	nahar.s.alsurayi@medtronic.com