

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة

Safety Communication

To: Healthcare Providers	إلى: مقدمي الرعاية الصحية
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Title	Safety and Effectiveness of the Medtronic Evolut PRO Transcatheter Aortic Valve System	العنوان
Medical Device Description:	Evolut PRO Transcatheter Aortic Valve System	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Medtronic CoreValve,LLC	اسم المصنع
Authorized Representative	Medtronic Saudi Arabia LLC	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2020-0080	إذن التسويق
Potential /Associated risks	<p>Based on the SFDA's post-market clinical evaluation study conducted to evaluate the safety profile of the Evolut PRO Transcatheter Aortic Valve System, findings indicate an increased potential risk of new-onset or worsening conduction abnormalities following TAVR procedures. Observed adverse events and safety concerns include, but are not limited to:</p> <ul style="list-style-type: none"> • New-onset left bundle branch block (LBBB) • PR interval prolongation • High-grade atrioventricular (AV) block • Complete heart block • Increased requirement for permanent pacemaker implantation (PPI) • Arrhythmias (including atrial and ventricular arrhythmias) • Vascular complications related to access site or device delivery system <p>These complications may occur immediately post-procedure or may present in a delayed manner after hospital discharge. Delayed recognition of conduction abnormalities, arrhythmias, or vascular complications may lead to serious clinical consequences, including syncope, heart failure exacerbation, hemodynamic instability, bleeding, need for urgent intervention, or sudden cardiac events. Continuous and proactive clinical and rhythm surveillance is therefore considered essential to ensure timely detection and appropriate management.</p>	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي

<p>Recommendations</p>	<p>SFDA recommends healthcare providers to emphasize the need for continued active surveillance of conduction abnormalities, particularly the potential need for permanent pacemaker implantation following TAVR procedures. To enhance patient safety, healthcare providers are advised to implement the following practices:</p> <ol style="list-style-type: none"> 1. Perform a baseline ECG and rhythm assessment prior to TAVR to identify any pre-existing conduction disturbances that may elevate post-procedural risk. 2. Maintain continuous ECG monitoring (telemetry) for a minimum of 48–72 hours after the procedure, and extend monitoring for patients exhibiting new or progressive conduction delays. 3. Conduct daily ECG evaluations during hospitalization, and repeat immediately if the patient reports symptoms such as dizziness, presyncope, or syncope. 4. Arrange ambulatory rhythm monitoring (e.g., 14–30-day Holter) at discharge for patients with new-onset LBBB, PR interval prolongation, or other evolving conduction abnormalities. 5. Assess early for permanent pacemaker implantation in cases of persistent high-grade AV block, intermittent advanced block, or evidence of progressive conduction system deterioration. 6. Report all adverse events and device performance concerns through the SFDA National Center for Medical Devices Reporting (NCMDR) to support comprehensive national safety surveillance. 	<p>التوصيات</p>
<p>For Reporting</p>	<div style="display: flex; justify-content: space-around; align-items: center;"> <div data-bbox="358 1052 609 1161" style="border: 1px solid black; padding: 5px;">  </div> <div data-bbox="630 1062 1263 1161" style="border: 1px solid black; padding: 5px; display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <p>National Center for Medical Devices Reporting</p> </div> <div style="text-align: center;"> <p>المركز الوطني للإبلاغ الأجهزة والمستلزمات الطبية</p>  </div> </div> </div>	<p>للإبلاغ</p>