



RECOMMENDATIONS FOR PATIENTS WITH MEDTRONIC COREVALVE™ OR EVOLUT™ R TRANSCATHETER AORTIC VALVES REQUIRING IMPLANT OF IMPELLA 2.5® AND IMPELLA CP®

RECOMMENDATIONS

There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a Medtronic CoreValve™ Evolut™ R transcatheter aortic valves resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system.

The outflow struts of the CoreValve or Evolut R nitinol frame can enter the outlet opening of Impella and damage the impeller. This interaction while running the pump can result in fracture of the impeller material. **See figure 1 to the right.** Although no events have been identified, systemic embolization of the fractured impeller material is a possibility.

Clinicians are cautioned to position the Impella system carefully in patients with the Medtronic CoreValve or Evolut R transcatheter aortic valves prostheses and to be aware of this potential interaction. In this situation, clinicians should **avoid repositioning while the device is running and should turn the device to P0 during repositioning or any movement that could bring the outlet windows into proximity to the valve stent structures.**

WHAT'S NEW?

Important Considerations for Impella Use in Patients with Medtronic CoreValve or Evolut R Transcatheter Aortic Valve Prostheses

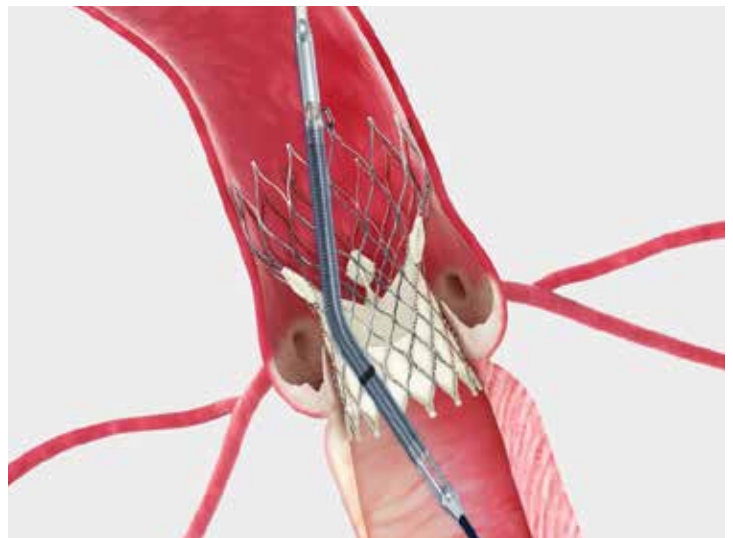


Figure 1: Illustration of a Medtronic CoreValve Transcatheter Aortic Valve and Interaction of Impella® Motor Housing