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Important Information Regarding Evolut Low-Risk Trial Long-Term Reintervention Observations

Product Name	Bioprosthesis Models			
CoreValve™	EVOLUTR-23-US	EVOLUTR-26-US	EVOLUTR-29-US	EVOLUTR-34-US
EVOLUT™ R	EVOLUTR-23-C	EVOLUTR-26-C	EVOLUTR-29-C	EVOLUTR-34-C
CoreValve™	EVOLUTPRO-23-US	EVOLUTPRO-26-US	EVOLUTPRO-29-US	
EVOLUT™ PRO	TAV-MDT2-23-C	TAV-MDT2-26-C	TAV-MDT2-29-C	

February 2026

Dear Health Care Provider:

This notification provides an update on the long-term reintervention rates for the Medtronic Evolut R and Evolut PRO valves based on complete 6-year and partial 7-year follow-up data from the Medtronic Evolut Low-Risk Trial, and supports existing patient management recommendations, including following the current guidance on balloon post-dilation in the Instructions for Use (IFU).

For background, the Evolut Low-Risk Trial was a multi-center, international, prospective, randomized, pre-market study, which evaluated the safety and effectiveness of Medtronic transcatheter aortic valve replacement (TAVR) systems in patients with severe aortic stenosis (AS) at low risk for surgical aortic valve replacement (SAVR). Three valve models were used in the trial, namely, CoreValve, Evolut R, and Evolut PRO. A total of 1,478 subjects were enrolled in the trial (737 subjects randomized to TAVR and 741 to SAVR) from March 2016 to May 2019. The majority (73%) of patients randomized to TAVR received an Evolut R valve. As a condition of approval for the low risk indication in the U.S., patients enrolled in the trial were required to be followed for 10 years post procedure.

Evolut Low-Risk Trial Data Update

The complete 6-year and partial (76.1% for TAVR and 70.3% SAVR) 7-year follow-up data are now available for the Evolut Low-Risk Trial (please see webpage link or QR code in the Reference section for the full published results). The results showed no statistically significant difference in all-cause mortality or disabling stroke rate (the original trial primary endpoint), all-cause mortality, or

cardiovascular mortality between the TAVR arm and the SAVR arm. The results demonstrated a statistically significant difference in reintervention rates between treatment groups through the partial 7-year follow-up. The cumulative incidence reintervention rates were 5.5% for TAVR and 3.3% for SAVR at 6 years and 9.8% for TAVR and 6.0% for SAVR at 7 years. Reintervention after TAVR was not associated with increased mortality, as demonstrated by comparison of mortality in patients who underwent reintervention and those who did not.

Contributing Factors Analysis

In consultation with the U.S. FDA, Medtronic conducted an in-depth investigation into the reintervention events observed in the Evolut Low-Risk Trial. The investigation found the following:

1. Reintervention due to recurrent AS occurred at similar rates between the TAVR group and the SAVR group at 6 (1.8% vs. 1.4%) and 7 (3.6% vs. 3.5%) years, whereas the reintervention rate due to aortic regurgitation (AR) was higher in the TAVR group (3.1% vs. 1.0% at 6 years and 5.6% vs. 1.6% at 7 years).
2. Evolut R had higher AR-related reintervention than SAVR through 7 years: 3.7% vs. 1.0% at 6 years and 6.7% vs. 1.6% at 7 years), and the highest rate of AR-related reinterventions occurred with Evolut R 34mm with balloon post-dilation that was outside of current labeling recommendations (16.7% at 6 years and 19.1% at 7 years). Note that: (1) the Evolut R 34mm valve was at that time a newly introduced valve size and did not have an outer wrap for paravalvular leak [PVL] reduction; and (2) approximately 1/3 of TAVR implants in the Low-Risk trial were Evolut R 34mm.
3. At 6 and 7 years, the differences in reintervention rate between the Evolut PRO valve and SAVR did not reach statistical significance (5.2% vs. 3.3% and 9.8% vs. 6.0%, respectively).

During Evolut Low-Risk Trial, investigators often managed PVL by performing balloon post-dilation, which was done in 30.4% of patients. However, no guidance on performing balloon post-dilation was provided by Medtronic at that time. In 2020, Medtronic noted that performing balloon post-dilation outside of current guidelines, especially on the Evolut R 34mm valve, increased the risk of reintervention due to leaflet damage caused by overexpansion of the valve waist region. As a result, Medtronic issued a field safety communication in October 2020 and provided guidance on optimal balloon post-dilation, including balloon size, type, and pressure recommendations (please refer to the webpage link or QR code in Reference section for additional information).

Since the field safety communication, Medtronic has seen a 64% decrease in complaints for aortic insufficiency associated with bioprosthetic leaflet damage in the Evolut family valves. Advances in Evolut technology implemented in newer valve models, such as the addition of the outer wrap, have

also reduced the need for balloon post-dilation to address PVL. For example, the balloon post-dilation rate was 14.1% in the Global Optimize PRO study (NCT04091048) and 10.6% in the Optimize PRO Evolut FX Addendum.

Additional Clinical Evidence

The Nordic Aortic Valve Intervention (NOTION) trial randomized low risk patients to TAVR with the CoreValve self-expanding bioprosthesis or SAVR. At 10 years, NOTION showed a cumulative reintervention incidence of 4.3% for TAVR and 2.2% for SAVR, a non-statistically significant difference¹.

The STS/ACC TVT Registry (Transcatheter Valve Therapy Registry) is a collaborative national database in the U.S., established by the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC). It systematically tracks patient safety and real-world outcomes for transcatheter valve procedures, including TAVR. By linking TVT Registry data with Centers for Medicare & Medicaid Services (CMS) claims data, Medtronic tracks long-term reintervention rates of TAVR devices. While data are limited by currently available follow-up time since commercial product launches, the KM reintervention rates in the real-world setting are 3.1% for Evolut R at 6 years and 2.0% for Evolut PRO at 5 years in the low-risk population.

Patient Management Recommendations

- Physicians treating patients with a transcatheter bioprosthetic heart valve should adhere to guideline-directed follow-up, including routine surveillance with annual echocardiograms.
- When implanting the Evolut valves, it is very important to follow implantation best practices and current IFU on balloon post-dilation.

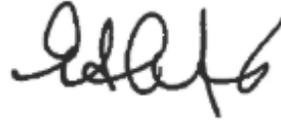
Medtronic records indicate that your facility has received one or more Evolut valves. As a result, Medtronic requests that you share this information with other physicians in your facility who implant the Evolut valves or who manage patients who have received an Evolut valve.

Medtronic continues to monitor device performance to ensure the safety of our products and to provide you with prompt, relevant data and guidance that can improve patient care. If you have any questions regarding this communication, please contact your Medtronic Field Representative.

Sincerely,



Dr. Kendra Grubb
Vice President, Chief Medical Officer
Structural Heart



Eliezer De Jesus Hernandez
Vice President, Quality
Structural Heart & Aortic

References:

¹Thyregod, H. G. H., Ihlemann, N., Jørgensen, T. H., et al. (2024). Transcatheter or surgical aortic valve implantation: 10 year outcomes of the NOTION trial. *European Heart Journal*, 45(13), 1116-1127.
<https://doi.org/10.1093/eurheartj/ehae043>

Refer to Medtronic Low Risk Reintervention Webpage below for additional information:

Webpage Link	QR Code
Medtronic.com/TAVRdatainsights	