Mitral valve regurgitation is a heart condition that affects an estimated 4 million people in the United States. A type of mitral valve disease, mitral regurgitation can be classified as either primary or secondary regurgitation: primary is commonly referred to as degenerative where abnormalities exist in the mitral valve itself. Secondary regurgitation, also referred to as functional mitral regurgitation, occurs when abnormalities of the left ventricle prevent the mitral valve from functioning properly.

Causes and Consequences
Normal blood flow of the heart will come into the left atrium, pass down through the mitral valve and into the left ventricle for circulation to the rest of the body — however, when mitral regurgitation occurs, blood flows backward through the mitral valve and into the atrium each time the left ventricle contracts. The leakage that occurs increases blood volume and pressure in the left atrium, which can increase pressure in the pulmonary veins. If regurgitation is severe, the high volume of pressure may result in congestion (or fluid build-up) in the lungs. If left untreated, mitral regurgitation can also lead to declining heart function and heart failure.

Risk Factors
The risk of developing mitral regurgitation increases with age because the valve is prone to wear and tear over time. Prior heart attacks and heart disease can lead to mitral valve regurgitation. Additionally, the mitral valve leaflets can become damaged or stretched out where they don’t close properly, which allows blood to flow backward.

Signs and Symptoms
Mitral valve regurgitation often occurs with no early warning signs, and symptoms may develop gradually. Once they do, symptoms vary, but may include:

- Shortness of breath or dyspnea — especially with increased activity or when you lie down
- Heart murmur — blood flowing abnormally through the heart
- Fatigue — especially during times of increased activity
- Heart palpitations — sensations of a rapid, fluttering heartbeat
- Swollen feet or ankles
Treatment Options

Some patients may be treated with medication and lifestyle changes, while others will undergo mitral valve repair or replacement. Because open-heart surgery is an invasive procedure, approximately 50 percent of patients are considered at high risk of death for surgery.\textsuperscript{1,2,5} Due to the complexity of the mitral valve anatomic structure, limited minimally invasive treatments are currently available to patients.

Therefore, a new catheter-based alternative to open-heart surgery — called transcatheter mitral valve replacement (TMVR) — is currently being studied by Medtronic, following receipt of an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA). The APOLOLO Trial will evaluate whether TMVR is a safe and effective option for treatment of these patients. In this investigational procedure, a valve made from bovine tissue is compressed inside a hollow tube and inserted between the ribs. It is then expanded within the diseased mitral valve to help restore normal blood flow through the heart and to the rest of the body.

\textsuperscript{1} U.S. Census Bureau. Statistical Abstract of the U.S.: 2006, Table 12.