



Leaflet Modification with the ShortCut™ Device

This guide is to help you understand more about leaflet modification with ShortCut™, which is performed prior to your valve-in-valve TAVR procedure. This information is not intended to replace the medical advice of your doctor. All medical treatment decisions should be made in consultation with and under the direction of your doctor. After reviewing this information, be sure to discuss any questions you have with your doctor.

ShortCut™ is a medical device cleared by the U.S. Food and Drug Administration for splitting bioprosthetic valve leaflets for patients at risk for coronary obstruction. **Indications for Use:** ShortCut is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction. The ShortCut is designated as a prescription (Rx) device. **Contraindications:** Patients will not be eligible for the procedure if any of the following conditions apply: Known hypersensitivity or contraindication to all intra-procedural anticoagulation and antiplatelet medication, or any product material. Known allergy to contrast media that cannot be adequately controlled with premedication. Active endocarditis on the aortic valve. Thrombosis on the aortic valve. **Warnings:** ShortCut is intended for use in patients undergoing a valve-in-valve procedure. It should not be used unless the patient is undergoing a concomitant TAVR procedure. ShortCut has not been investigated in a patient population that is not at risk of coronary ostia obstruction. ShortCut has not been investigated for splitting native aortic valve leaflets.



ShortCut™ Clinical Study

A global clinical study evaluating the safety and efficacy of the ShortCut in patients with failed bioprosthetic valves at risk of coronary obstruction¹.

100% Splitting success
per patient

100% Procedural
survival

98.3% Freedom
from stroke

¹) Dvir, D. et al. ShortCut Pivotal Study. EHJ 2024

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*A guide for patients
and their families*

What is Valve-in-Valve?

Over time, your bioprosthetic heart valve may deteriorate and lose functionality requiring a replacement procedure. A valve-in-valve (ViV) procedure utilizing transcatheter aortic valve replacement (TAVR) is a minimally invasive solution for patients who previously underwent open-heart surgery or TAVR. During the ViV procedure, a new transcatheter heart valve is placed inside the failed valve, pushing the old valve leaflets aside.¹

What is the risk of coronary obstruction with ViV?

Coronary obstruction is a partial or complete blockage of a coronary artery - the blood vessel that supplies oxygen and nutrients to the heart. Coronary obstruction can cause major complications if not addressed prior to undergoing ViV TAVR, and is associated with a mortality rate of up to 50%.² Leaflet modification may address the risk of developing a coronary obstruction prior to TAVR.



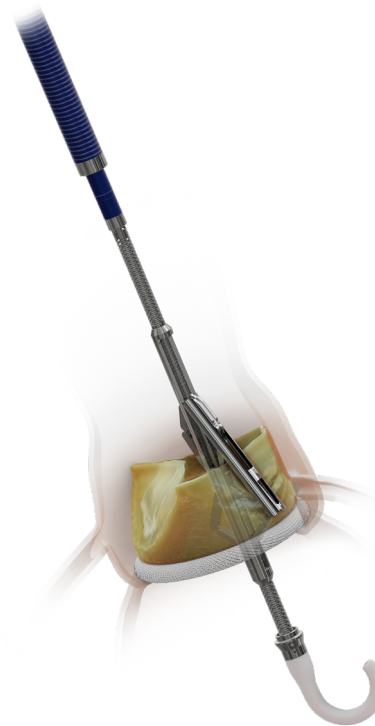
Illustration showing obstructed coronaries post ViV TAVR procedure.

1. <https://www.umcv.org/conditions-treatments/valve-in-valve-tavr>
2. <https://www.jacc.org/doi/10.1016/j.jcin.2023.06.029>



ShortCut™ Device

ShortCut™ is a leaflet modification device that mechanically splits pre-existing valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction and enabling a safer valve-in-valve procedure. The device includes a Splitting Element, which is placed at the designated location to carry out the leaflet splitting.

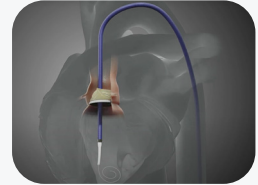


The ShortCut™ Procedure

The ShortCut procedure is performed immediately before the TAVR procedure.

Step 1

The ShortCut device is inserted through a small incision that is made in a large artery in your groin, thereby giving it access to the aortic valve.



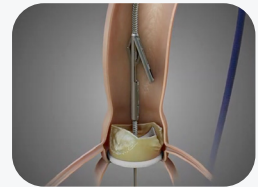
Step 2

Once the ShortCut device reaches the aortic valve, the device is deployed sequentially on each leaflet that needs to be split. The leaflet is then split by gently retracting the device.



Step 3

After the leaflet(s) are split, your physician will remove the ShortCut device and proceed to perform the TAVR procedure.



Step 4

Various tests will then be performed after the procedure to ensure healthy blood flow to your coronary arteries.

