

ShortCut™ Leaflet Modification Device - Press Kit

This press kit is a resource to help your institution discuss your work with performing leaflet modification with the ShortCut device in patient with aortic stenosis and at risk of coronary obstruction, requiring a valve-in-valve TAVR procedure. The kit includes various documents to support you communicate with different media channels. You may repurpose the materials for your institution's needs.

I. Press Release Template:

This is a sample press release that can be customized to announce your institution's first use of the ShortCut leaflet modification device.

Audience: Reporters

II. Social Media Posts:

This document includes templates for LinkedIn, X and Facebook posts that can be used on your hospital's social media channels to announce the use of the ShortCut leaflet modification device at your institution.

Audience: Patients, Caregivers

III. Product Backgrounder:

This document provides background information on the ShortCut leaflet modification device. The content includes highlights of the ShortCut device and clinical results.

Audience: Reporters

IV. Talking Points:

This document includes key messages about valve-in-valve procedures and the risk of coronary obstruction, highlights of the ShortCut device and clinical results.

Audience: Spokespeople

You can also download additional resources, such as the device image or animation, [here](#). If you have any questions, please contact: info@pi-cardia.net.

I. Press Release Template

HEADLINE 1: [INSERT FACILITY NAME] Is First in [INSERT CITY/REGION] To Perform a leaflet modification procedure with ShortCut

HEADLINE 2: [INSERT FACILITY NAME] Now Offers the ShortCut Device – A Leaflet Modification Solution Designed to Reduce the Risk of Coronary Obstruction during TAVR

[INSERT CITY], [INSERT STATE], [INSERT MONTH, DAY, YEAR] – [INSERT TIMING], [INSERT PHYSICIAN NAME] completed a procedure using ShortCut™, the world's first FDA cleared device that is dedicated to leaflet modification, enabling a safer valve-in-valve (ViV) Transcatheter Aortic Valve Replacement (TAVR) procedure in patients at risk of coronary obstruction. This is the first time this device was used in [INSERT STATE, CITY OR REGION].

TAVR has become the preferred treatment for aortic stenosis, recently surpassing surgery even in patients younger than 65.¹ As bioprosthetic valves degenerate over time, these patients will at some point likely need a valve-in-valve procedure to be performed, and a significant portion of them who are at risk for coronary obstruction will require leaflet splitting with ShortCut™. Recently published models predict that by 2035, more than 40,000 valve-in-valve procedures will be performed annually in the U.S., representing more than 15% of all TAVR procedures.² Future planned indication expansion into native and bicuspid valves may mean that around 30% of future TAVR cases will require leaflet modification with ShortCut™ in order to be performed safely and obtain optimal results for patients.

ShortCut is ground-breaking device that is specifically designed to mechanically split preexisting valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction or impaired coronary access and enabling a safer ViV TAVR procedure. For more information, visit <https://www.pi-cardia.net/>

[INSERT CLINIC BOILERPLATE DESCRIPTION HERE]

CONTACT:

[HOSPITAL PR CONTACT NAME]
[TITLE],
[HOSPITAL NAME]
[PHONE NUMBER]
[EMAIL ADDRESS]

References

1. O'Riordan, Michael. TCTMD, June 2024
2. Généreux, Philippe., et al. Structural Heart Journal, July 2024

II. Social Media Posts

Below is suggested text for LinkedIn, X and Facebook posts that you can use to announce the first ShortCut procedure performed at your institute and generate interest in your use of the ShortCut™ device.

Keep in mind:

- For added engagement with your followers:
 - Include a photo of the physician who performed the first procedure or a photo of the patient with any of the messages. [Make sure to obtain appropriate permissions to publish the images.]
 - Consider using an image of the device in relevant posts.
 - Tag @Pi-Cardia and include the #ShortCut hashtag in the post
- You can create a shortened web link – also known as a bit.ly – by copying and pasting the web address of your desired page destination into <https://bitly.com>. It will produce a shorter web link that can be tracked.

Sample Posts

LinkedIn:

- We are proud to have performed the first #ShortCut procedure in [INSERT STATE/REGION]. This groundbreaking device mechanically splits preexisting valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction, enabling a safer ViV TAVR procedure. Read our announcement [link to hospital announcement] and see how it works here: <https://www.pi-cardia.net/>
- We are excited to offer a groundbreaking technology to help patients with aortic stenosis undergoing valve-in-valve procedure reduce the risk of coronary obstruction during TAVR. The #ShortCut device mechanically splits preexisting valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction, enabling a safer ViV TAVR procedure. Read our announcement [link to hospital announcement] and see how it works here: <https://www.pi-cardia.net/>

X (Twitter):

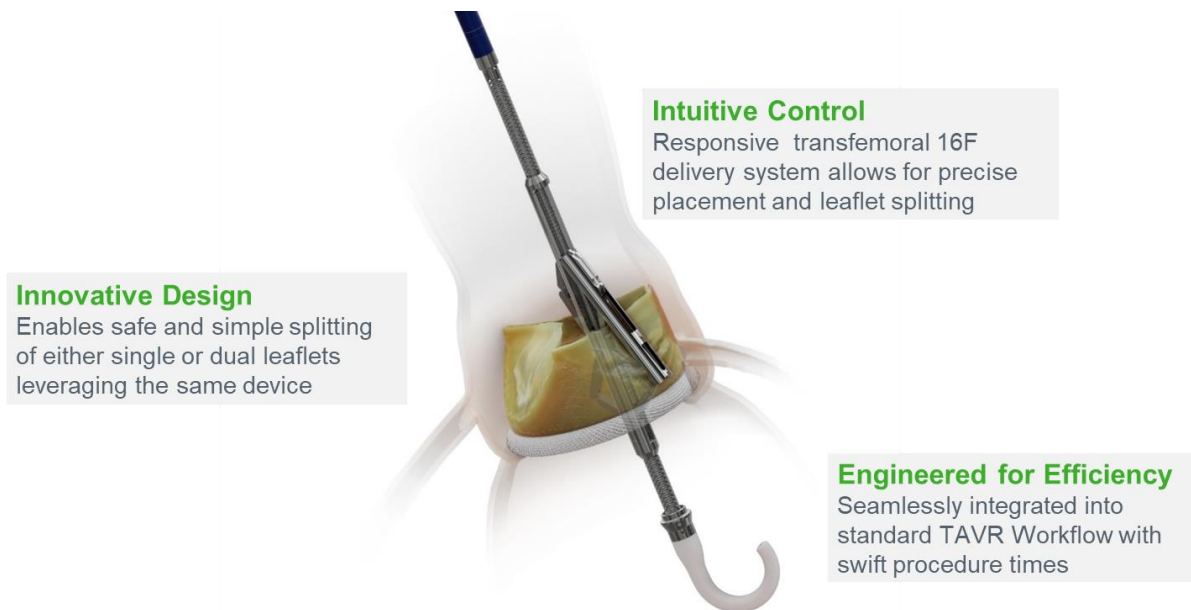
- We are proud to have performed the first #ShortCut procedure in [INSERT STATE/REGION], which mechanically splits preexisting valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction, enabling a safer ViV TAVR procedure. Read our announcement [link to hospital announcement] and see how it works here: <https://www.pi-cardia.net/>
- Excited to offer the new #ShortCut leaflet modification device that aims to reduce the risk of coronary obstruction, enabling a safer ViV TAVR procedure. [link to YouTube animation video or hospital release]

Facebook:

- We are proud to have performed the first #ShortCut procedure in [INSERT STATE/REGION]. This groundbreaking device mechanically splits preexisting valve leaflets prior to TAVR, aiming to reduce the risk of coronary obstruction, enabling a safer ViV TAVR procedure. Read our announcement [link to hospital announcement] and see how it works here: <https://www.pi-cardia.net/>

III. Product Backgrounder

ShortCut™ Leaflet Modification Device



1. The ShortCut leaflet modification device

- ShortCut is the first FDA-cleared device specifically designed to mechanically split pre-existing valve leaflets before TAVR, aiming to reduce the risk of coronary obstruction and enabling a safer ViV procedure.
- ShortCut is a safe, simple, and effective approach for treating both single and dual leaflets. The operators have full control throughout the procedure and is able to precisely place the device at the target location.
- The procedure is short and easy to teach, making it highly adoptable and integrates seamlessly into the standard TAVR workflow.

2. ShortCut Pivotal Study Key Take-Aways

- The ShortCut Pivotal Study included 60 patients treated with failed bioprosthetic valves (SAVR & TAVR) at risk for coronary obstruction (single split 63% and dual split 37%).
- Leaflet splitting with ShortCut met the primary safety endpoints, with 0% procedural mortality and 1 (1.7%) stroke.
- Primary efficacy endpoint of successful leaflet splitting was achieved in 100% of patients.
- Leaflet split was achieved efficiently with a single attempt in all cases, despite being performed by first time users.

3. Potential of leaflet modification

- Leaflet modification may also play an important role in TAVR-in-native, especially for young patients in whom it is critical to prepare the valve to ensure future coronary access, as well as in patients with bicuspid valves where tricuspidization techniques may improve the transcatheter valve opening and function, and mitral to prevent the risk of LVOT obstruction.

IV. Talking Points

The following are the **primary points** that should be communicated in interviews around the ShortCut device:

- 1. The main challenge during valve-in-valve (ViV) procedures is that the leaflets of the pre-existing degenerated valve may be pushed sideways, compromising normal flow in the sinuses and may hinder coronary access. This can turn into a life-threatening complication of coronary obstruction, which is associated with a mortality rate up to 50%.¹**
- 1. Total annual ViV is projected to reach more than 40,000 US procedures in 2035, representing more than 15% of all TAVR procedures.²**
4. Currently TAVR-in-SAVR dominates the ViV market, but with the increase in TAVR usage, we will see a wave of TAVR-in-TAVR usage start to hit. The annual TAVR-in-TAVR is expected to match TAVR-in-SAVR by 2028 and will dominate the ViV market thereafter.
5. Future planned indication expansion into native and bicuspid valves may mean that around 30% of future TAVR cases will require leaflet modification.
6. Leaflet modification will be important for the lifetime management of patients requiring multiple valve interventions.
- 2. ShortCut is the first FDA-cleared device specifically designed to mechanically split pre-existing valve leaflets prior to the TAVR procedure, reducing the risk of coronary obstruction and enabling a safer ViV procedure.³**
3. ShortCut is a safe, simple, and effective approach for treating both single and dual leaflets. The operators have full control throughout the procedure and is able to precisely place the device at the target location.
 - The procedure is short and easy to teach, making it highly adoptable and integrates seamlessly into the standard TAVR workflow.
- 4. Key findings of the ShortCut Pivotal Study include:⁴**
 - The ShortCut Pivotal Study included 60 patients treated with failed bioprosthetic valves (SAVR & TAVR) at risk for coronary obstruction (single split 63% and dual split 37%).
 - Leaflet splitting with ShortCut met the primary safety endpoints, with 0% procedural mortality and 1 (1.7%) stroke.
 - The primary efficacy endpoint of successful leaflet splitting was achieved in 100% of patients.
 - Leaflet split was achieved efficiently with a single attempt in all cases, despite being performed by first time users.
- 5. Leaflet modification may also play an important role in TAVR-in-native, especially for young patients in whom it is critical to prepare the valve to ensure future coronary access, as well as in patients with bicuspid valves where tricuspidization techniques may improve the transcatheter valve opening and function, and mitral to prevent the risk of LVOT obstruction.**

References

1. Ribeiro HB, Rodes-Cabau J, Blanke P, et al. Incidence, predictors, and clinical outcomes of coronary obstruction following transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry. *Eur Heart J* 2018;39:687–695. [PubMed: 29020413]
2. Génèreux P, Leon MB, Dar RD, et al. Predicting treatment of bioprosthetic aortic valve failure in the United States: a proposed model. *Struct Heart*. Published online July 9, 2024. doi: 10.1016/j.shj.2024.100339
3. Pi-Cardia receives FDA market clearance for ShortCut™. Published September 30, 2024. <https://www.businesswire.com/news/home/20240928442730/en/Pi-Cardia-Receives-FDA-Market-Clearance-for-ShortCut%E2%84%A2>
4. Dvir D, Tchetché D, Leon MB, et al. Leaflet modification before transcatheter aortic valve implantation in patients at risk for coronary obstruction: the ShortCut study. *Euro Heart J*. 2024;45:3031-3041. doi: 10.1093/eurheartj/ehae303