



# Advantages of the Evolut™ FX system implant procedure

## Key steps and rationale

The information in this document is intended for educational purposes based on an identified need, is not meant as a substitute for the Instructions for Use or product training and is not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. The physician is solely responsible for all decisions and medical judgments relating to the treatment of their patients. Please see the complete Instructions for Use for products discussed or demonstrated, including all product indications, contraindications, precautions, warnings, and adverse events. Practice, ease of use, and outcomes may vary based on clinical practice and judgment.

**Medtronic**

## Benefits of implant procedure

### PPI rates – technique matters

Beyond PPI rates – ease of use and predictability

### Implant procedure overview

Determine correct view

Cusp overlap view

DCS insertion

Proper starting location

NCC depth assessment

LCC depth assessment

## Benefits of the Evolut™ FX system implant procedure

# PPI rates – technique matters

The Optimize PRO second interim analysis,<sup>1</sup> as well as the sub analysis by Gada et al,<sup>2</sup> demonstrate that proper implant technique is a significant factor in achieving lower rates of permanent pacemaker implantation (PPI).

**Optimize PRO  
Second Interim Analysis**  
Shows excellent clinical outcomes<sup>1</sup>

**Gada sub-analysis:**  
Predictability drives precision<sup>2</sup>

<sup>1</sup> Grubb K, Gada H, Mittal S, et al. Clinical Impact of Standardized TAVR Technique and Care Pathway: Insights from the Optimize PRO Study. *JACC Cardiovasc Interv.* March 13, 2023;16(5):558-570.

<sup>2</sup> Gada, et al. Adherence to Key Cusp Overlap Steps Reduced Pacemaker Implantation in the Optimize PRO Study. Presented at TCT 2022.

## Benefits of implant procedure

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**Beyond PPI rates – ease of use and predictability**

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## Benefits of the Evolut™ FX system implant procedure

# Beyond PPI rates – ease of use and predictability



**1** The Evolut implant procedure is predictable, reliable, and reproducible.

Less guesswork and subjectivity = better ease of use



**2** Standardized, familiar working view in majority of cases with patient-specific COV.

No extra camera manipulation necessary



**3** Approach target depth from above, every time.

- Valve advanced to target depth from above with only forward pressure needed.
- Reduced catheter and wire manipulation to arrive at ideal implant depth.



**4** Reliable commissure alignment to promote lifetime management of patient.

### Key principles

#### Benefits of implant procedure

PPI rates –  
technique matters

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#### Implant procedure overview

Determine  
correct view

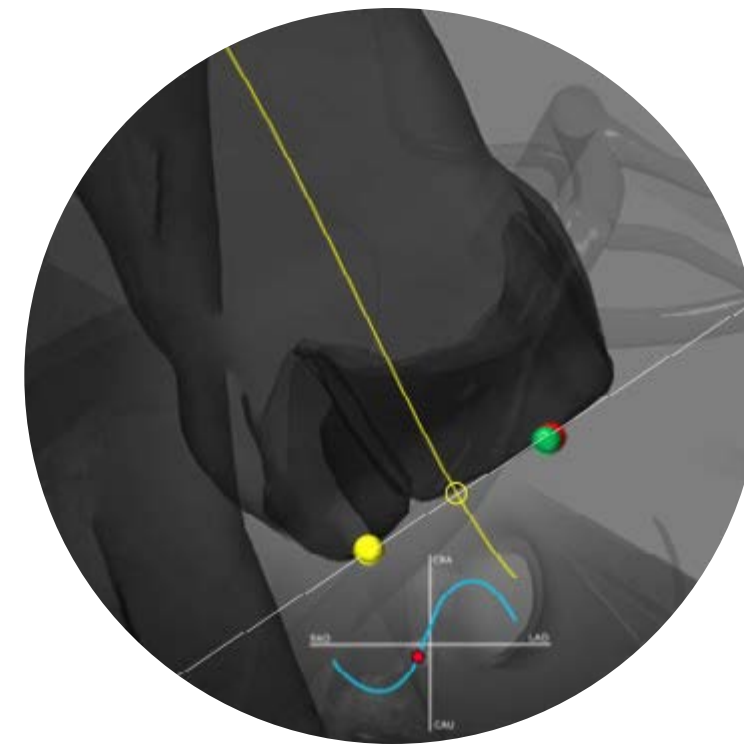
Cusp overlap view

DCS insertion

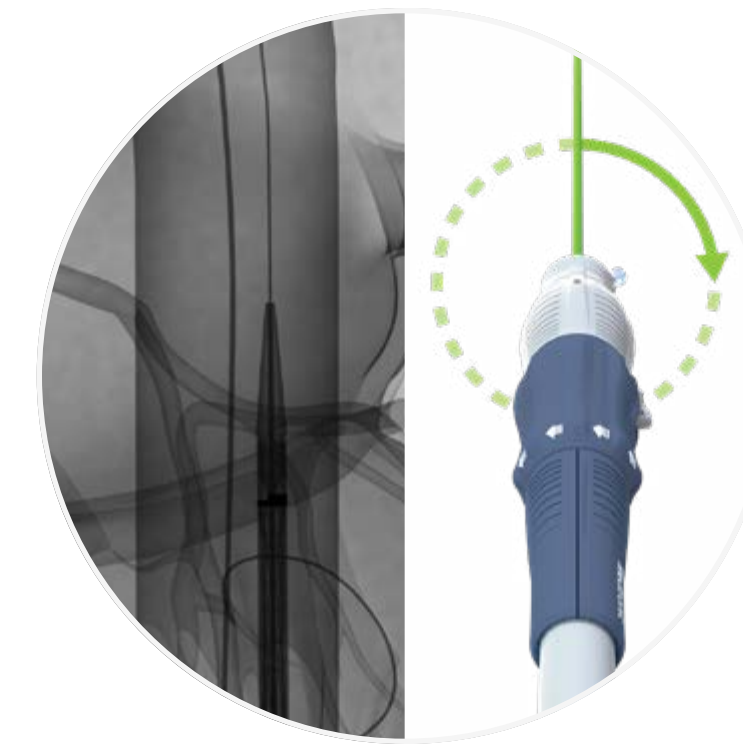
Proper starting  
location

NCC depth  
assessment

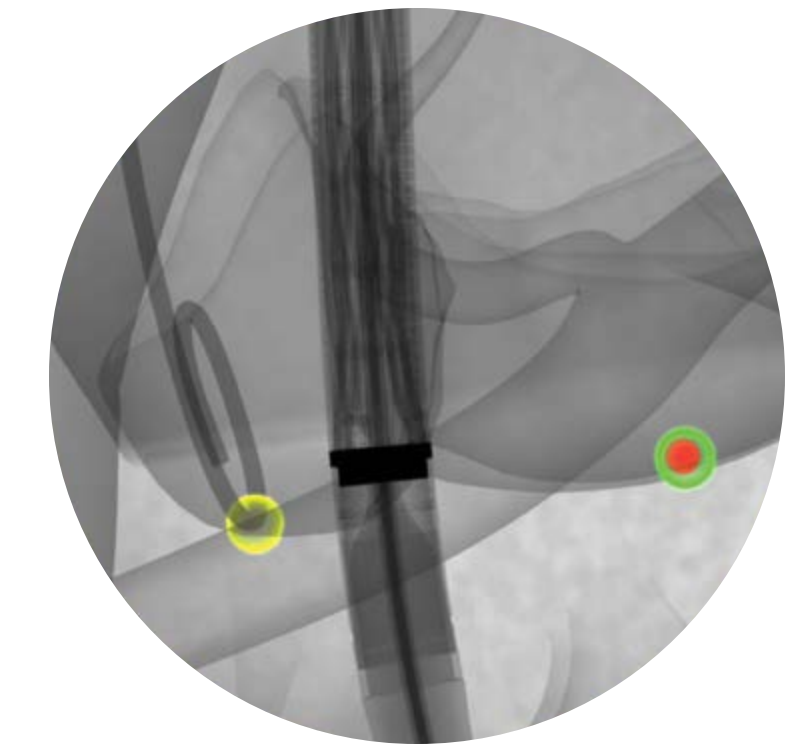
LCC depth  
assessment



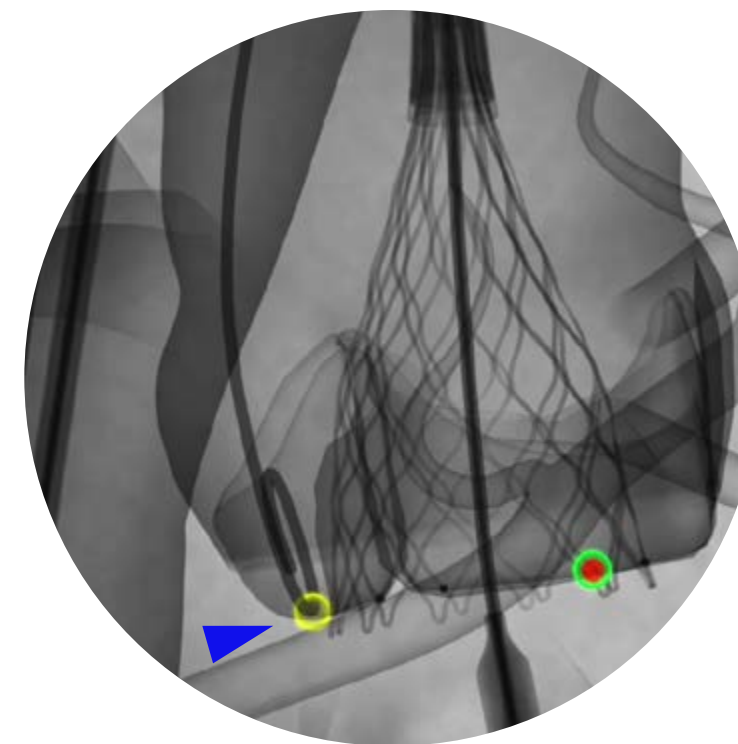
**Determine the correct view**



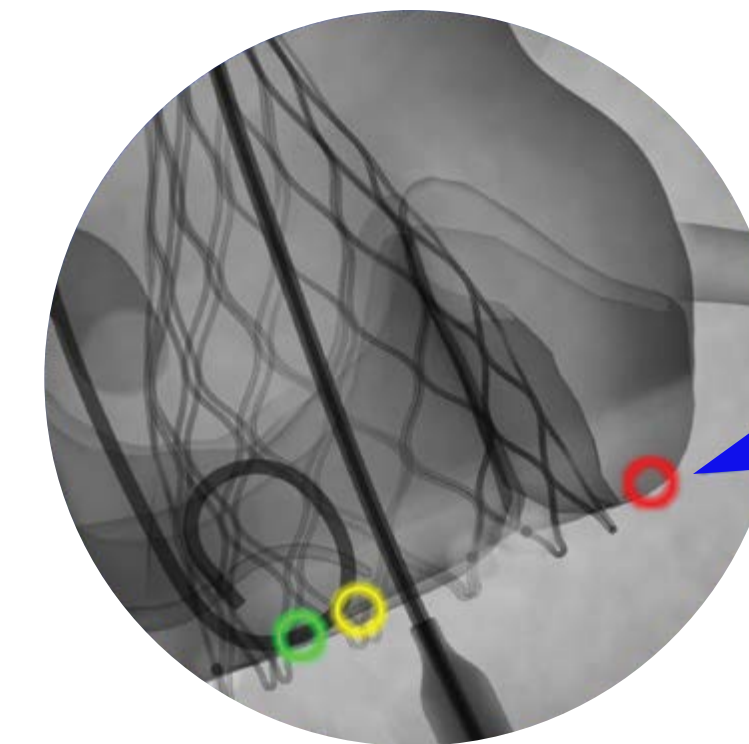
**DCS insertion and commissure alignment**



**Proper starting location**



**NCC depth assessment**



**LCC depth assessment and final release**

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## Implant procedure overview

### Determine correct view

Cusp overlap view

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Proper starting location

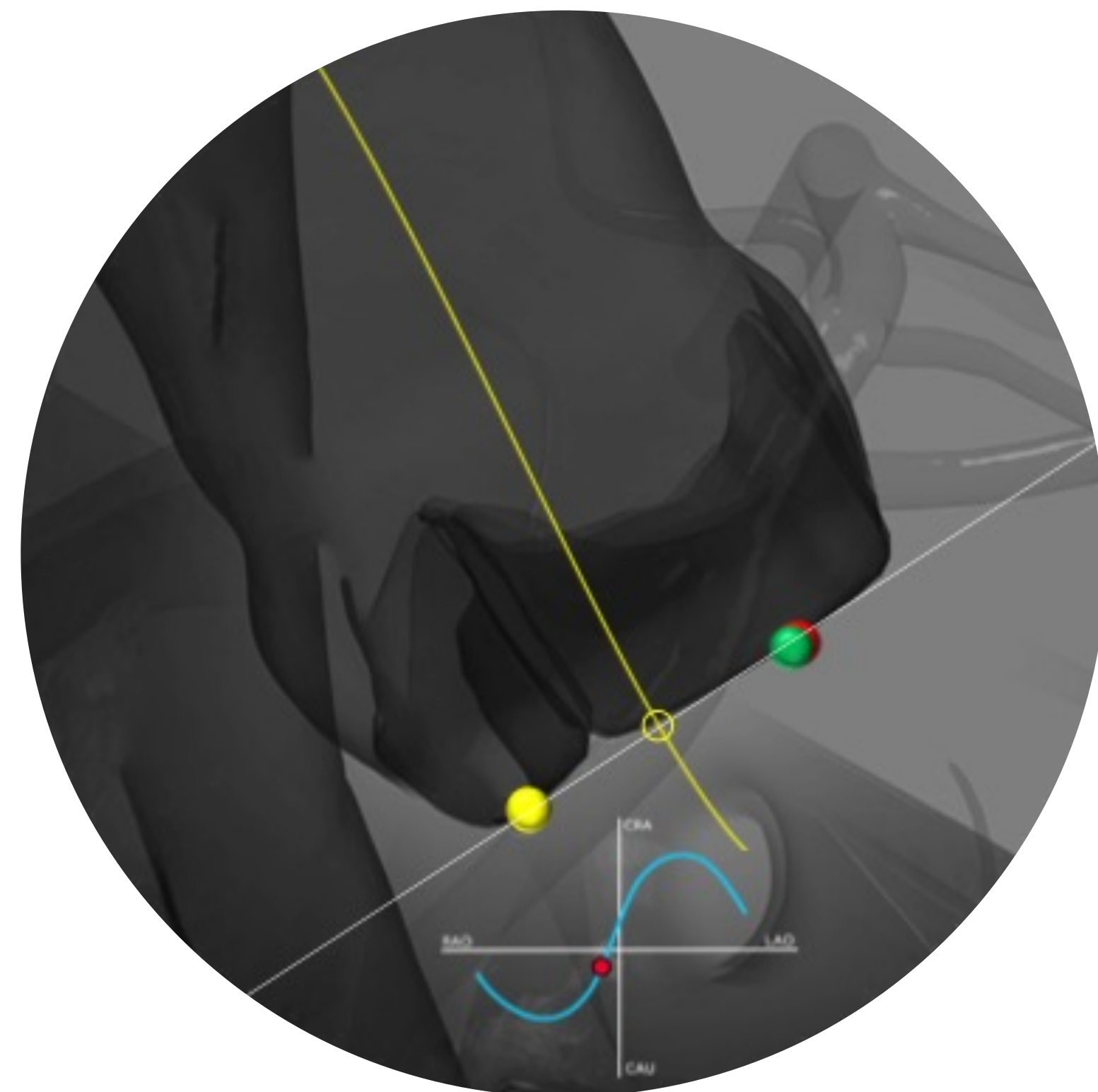
NCC depth assessment

LCC depth assessment

## Evolut™ FX system implant procedure overview

# Determine the correct view

Determine cusp overlap imaging projection through precise CT planning.



## Why is this important?

- Using the cusp overlap view (COV) shows you where you are in relation to both the annular plane and the conduction system.
- The COV provides a standardized, familiar working view that is directly derived from patient anatomy.
  - Maintains basal plane alignment of the coronary cusps
  - Elongates the view of the LVOT
  - Reduces or removes parallax in the marker band
  - Provides an accurate view of the root regardless of angulation



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Determine  
correct view

### Cusp overlap view

DCS insertion

Proper starting  
location

NCC depth  
assessment

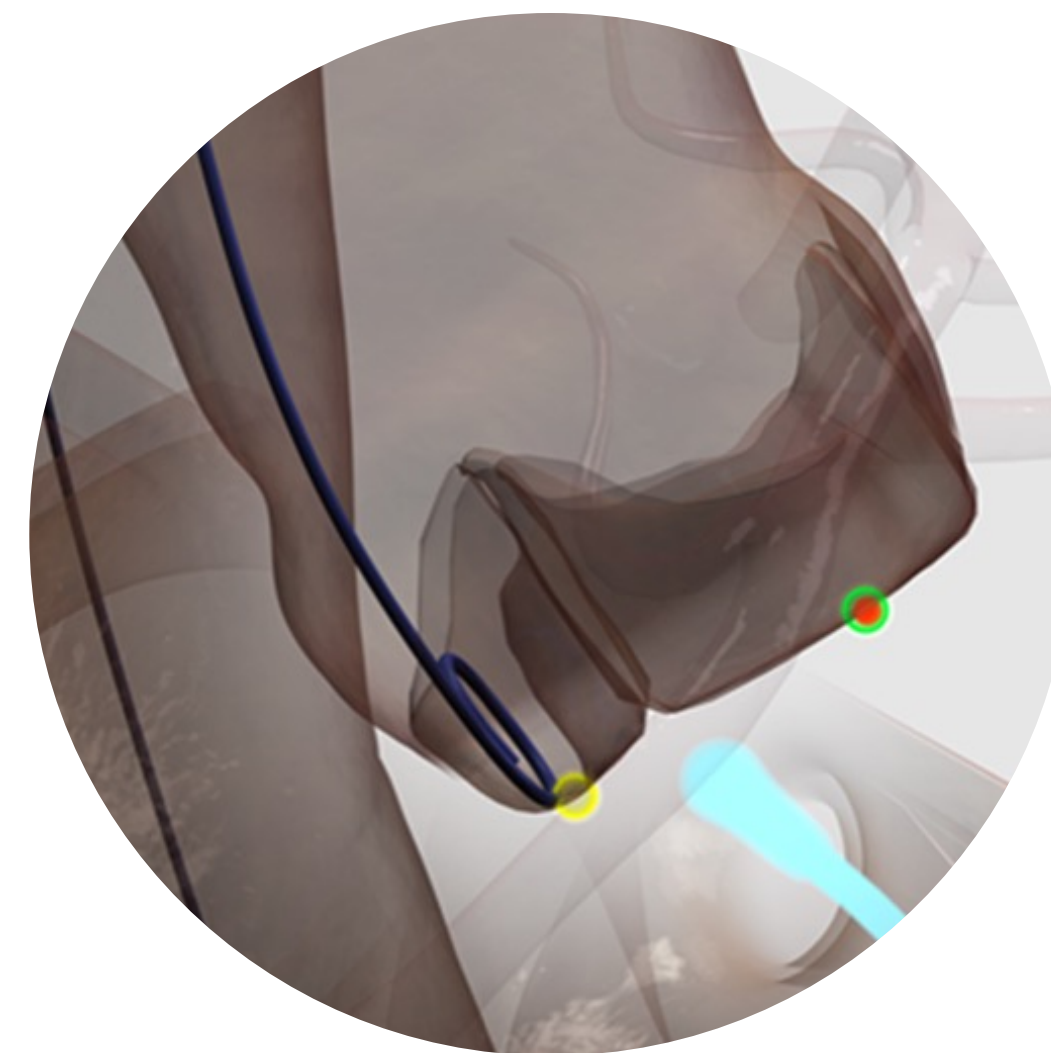
LCC depth  
assessment

## Evolut™ FX system implant procedure overview

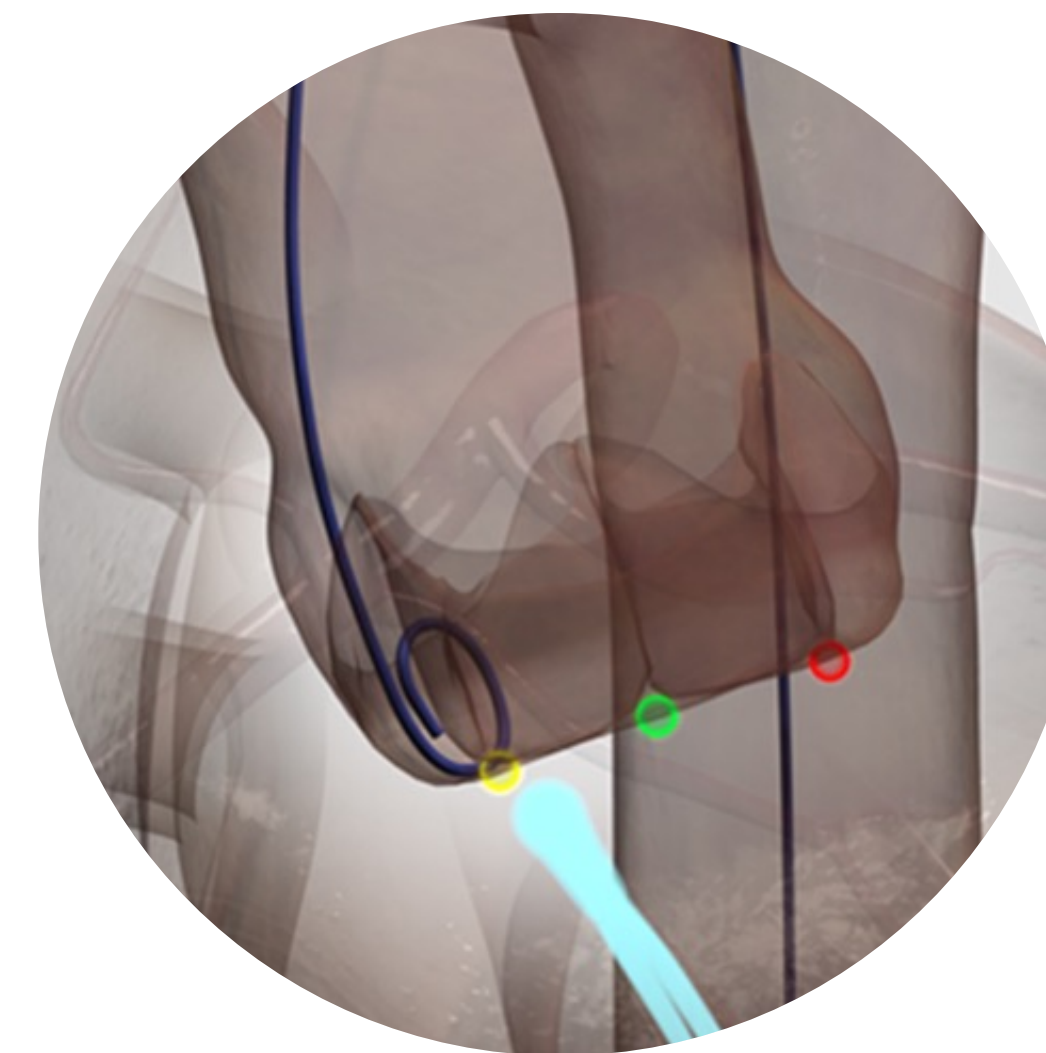
# Cusp overlap view

## Centralized conduction system – cusp overlap view vs. other views

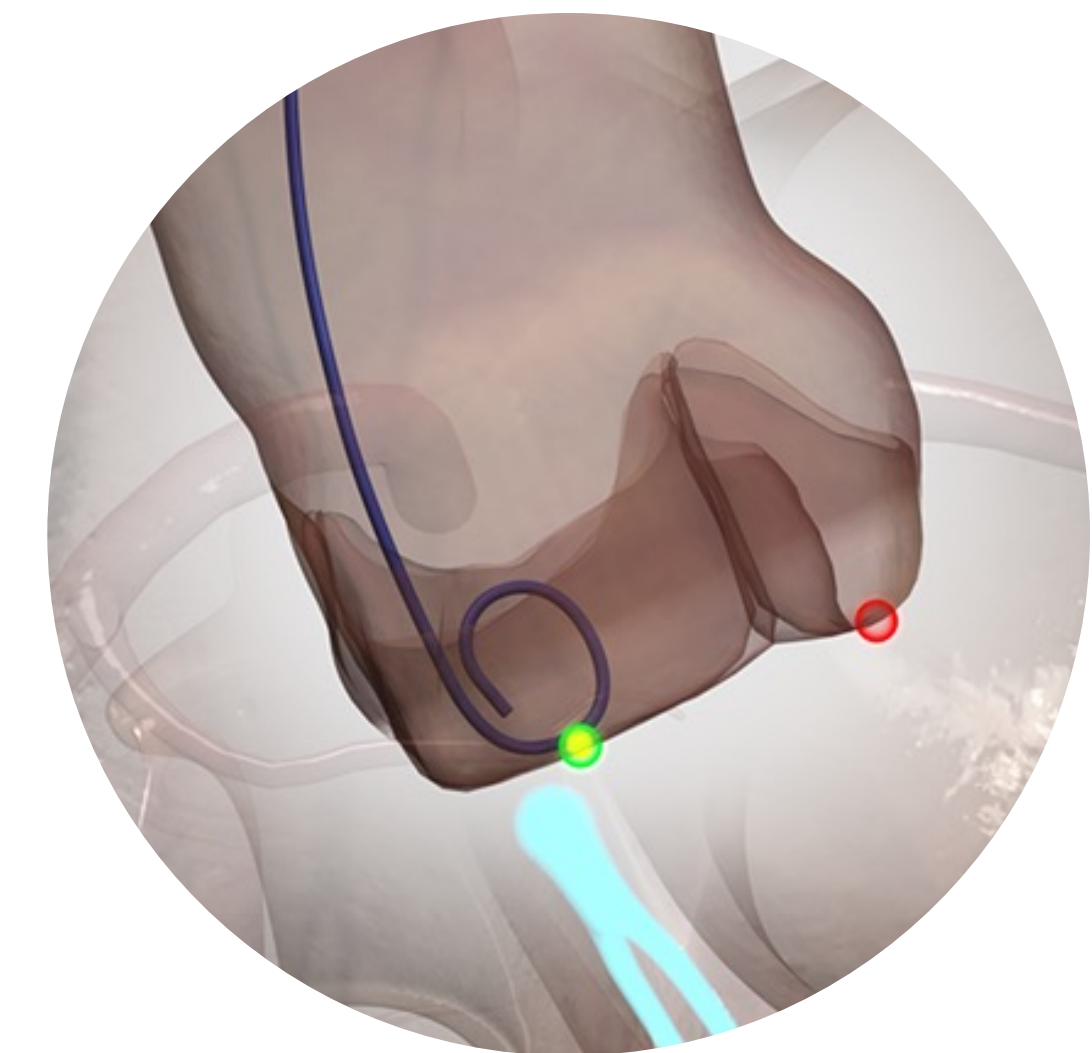
Cusp overlap view



3 cusp coplanar view



LAO view



Cusp overlap view shows you where you are and helps you arrive at a precise implant.



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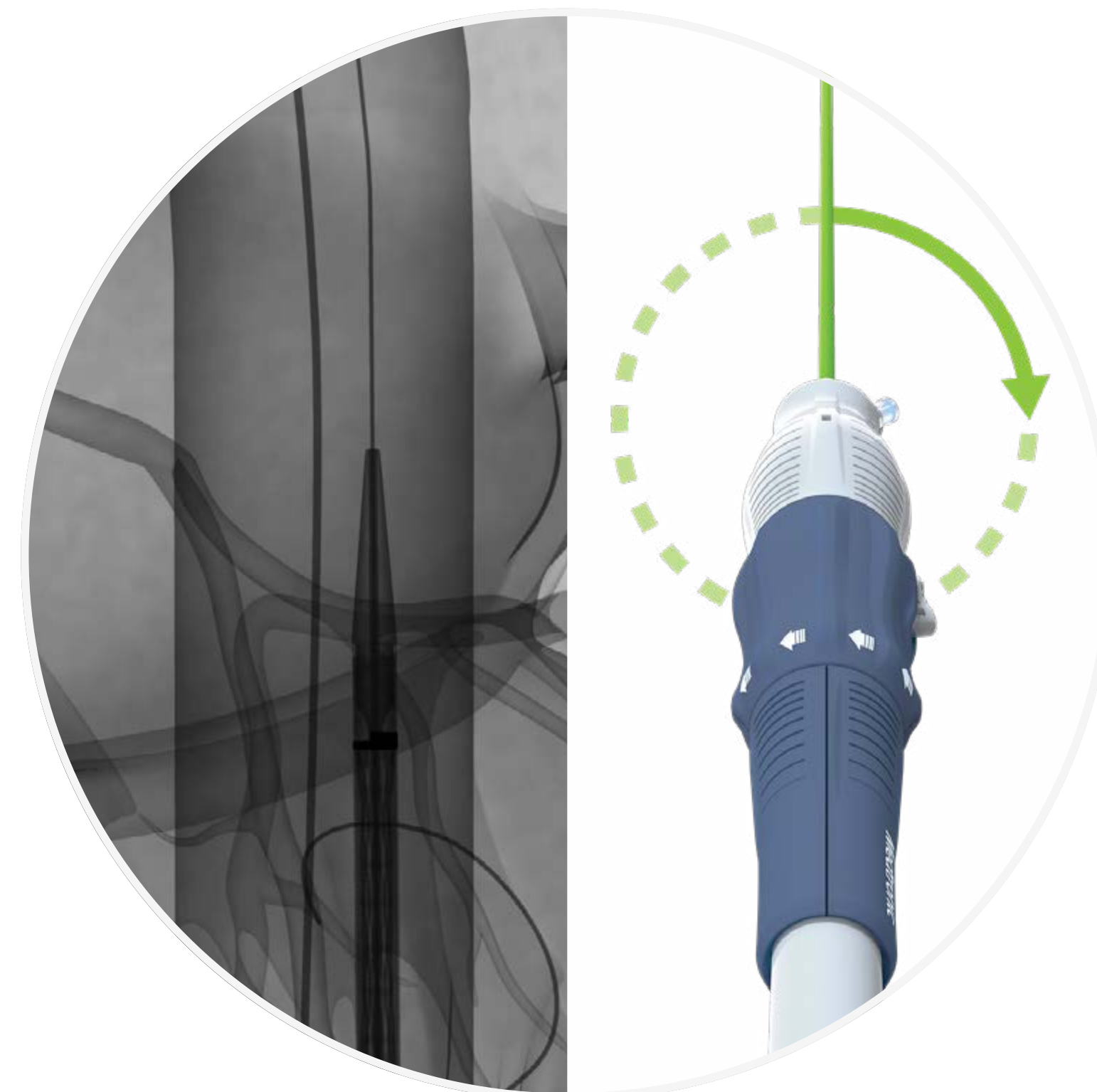
LCC depth  
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## Evolut™ FX system implant procedure overview

# DCS insertion and commissure alignment prep



- Insert delivery system with flush port at 3 o'clock.
- Verify flush port position remains at 3 o'clock and hat marker approximately facing greater curvature before crossing arch (adjust up to ¼ turn in descending aorta, if necessary).
- Advance system to ascending aorta.



### Why is this important?

- Promotes proper alignment of catheter, which:
  - Promotes commissure alignment
  - Promotes smoother crossing of the arch with better trackability

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## Proper starting location

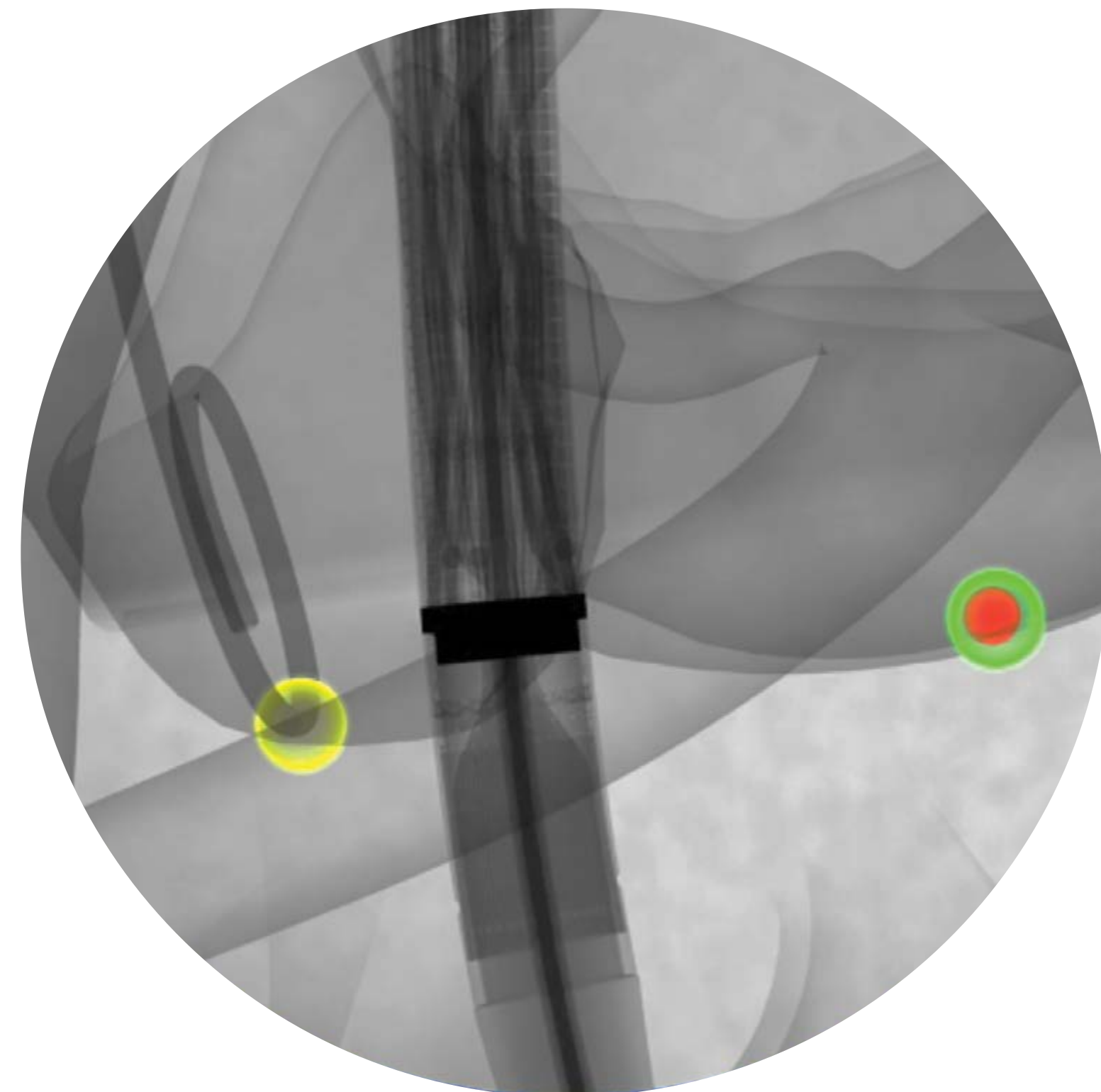
NCC depth  
assessment

LCC depth  
assessment

## Evolut™ FX system implant procedure overview

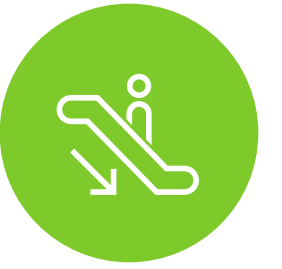
# Proper starting location

- Change to cusp overlap view and advance valve to deployment position with marker band near bottom of pigtail.
- **Approach (and do not exceed) target depth (3 mm) from above.**
- Consider recapturing and restarting if depth is ever  $< 1$  mm or  $> 5$  mm.



## Why is this important?

- Beginning deployment at the appropriate depth allows approach to the target depth (3 mm) from above.
  - Starting deployment here requires only steady forward pressure to continue advancing the valve, promoting a more coaxial valve deployment and reducing excess catheter manipulation.
- Avoiding unwanted interaction with the conduction system reduces the likelihood of PPI.





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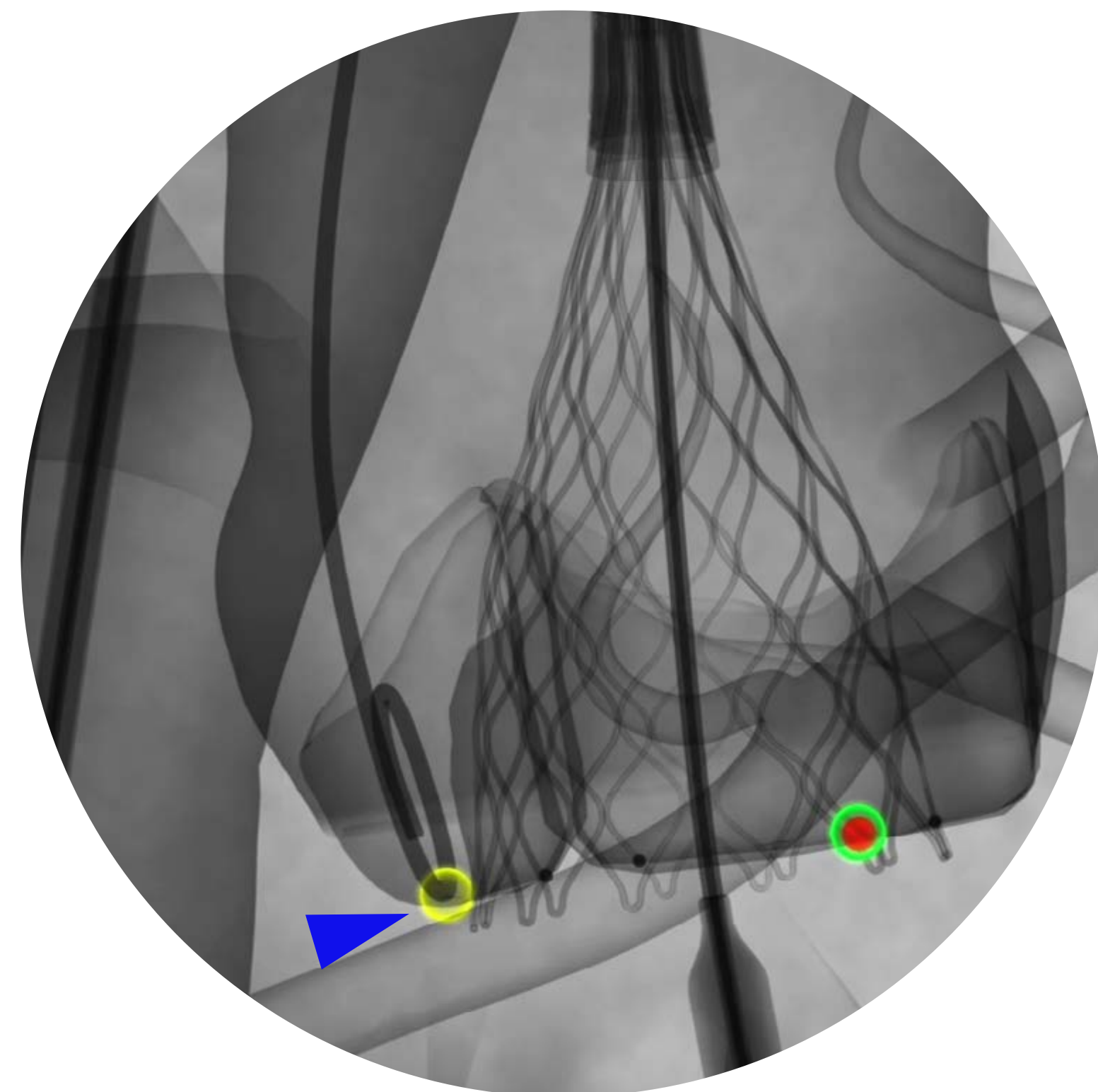
## NCC depth assessment

LCC depth  
assessment

## Evolut™ FX system implant procedure overview

# NCC depth assessment

Assess depth accurately under the NCC in cusp overlap view just before point of no recapture.



## Why is this important?

- Focusing only on the pigtail catheter and the valve frame immediately adjacent allows more accurate assessment of depth under NCC.



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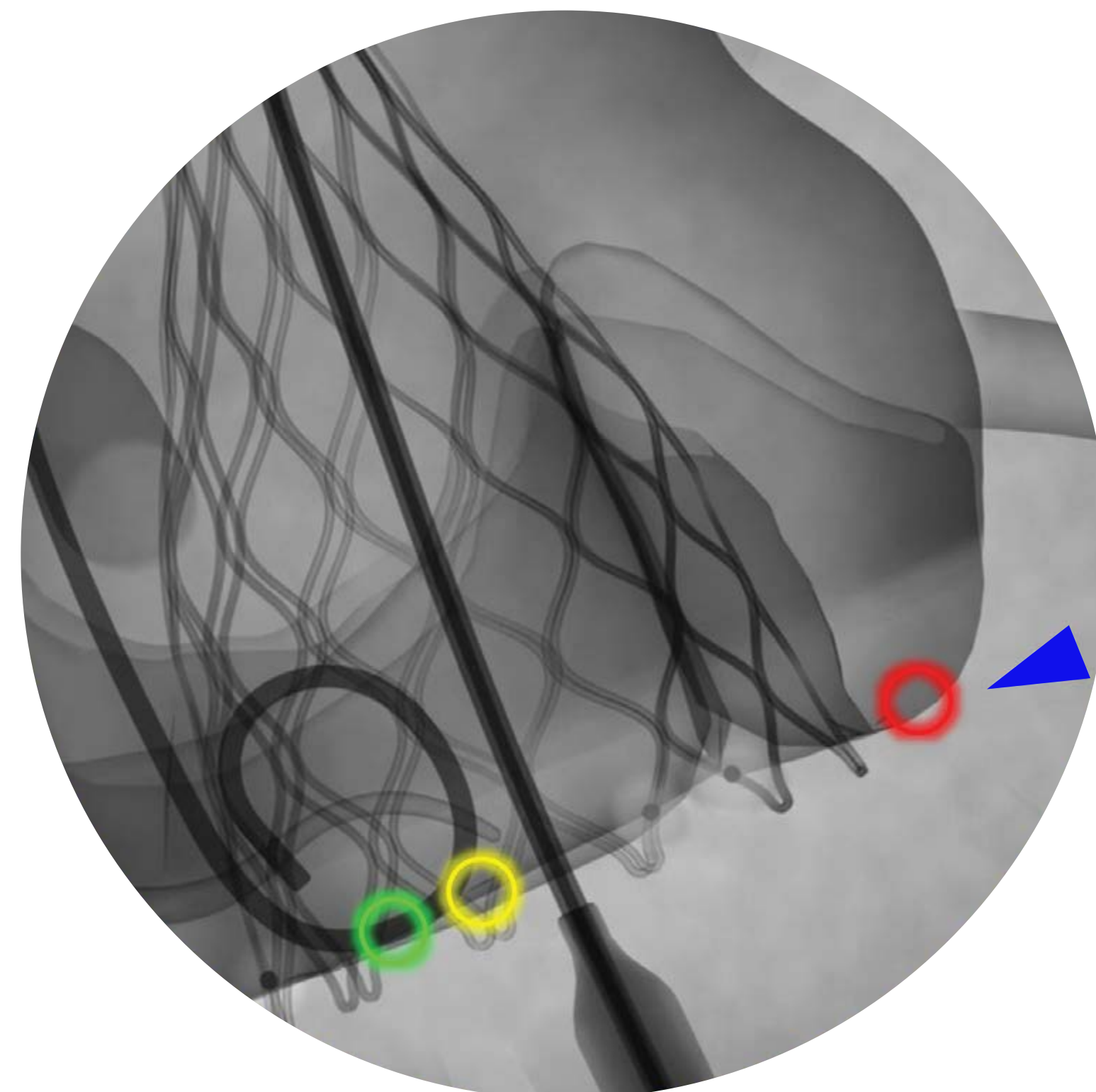
NCC depth  
assessment

**LCC depth  
assessment**

## Evolut™ FX system implant procedure overview

# LCC depth assessment and final release

- Confirm depth under the LCC using an LAO view and perform slow, controlled release of valve with slight forward pressure, if position is acceptable.
- Remove system carefully to avoid unwanted DCS/valve interaction.



## Why is this important?

- Due to the FX platform's uniform deployment depth between the NCC and LCC, this step verifies that the depth under the LCC is also acceptable, as the cusp overlap view is only intended to provide accurate assessment of depth under the NCC.
- A slow release and slight forward pressure both help avoid unwanted movement of the valve.
- Removing the system carefully with guidewire manipulation as needed can help reduce any unwanted interaction between the DCS and the implanted valve.



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LCC depth  
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This material does not replace or supersede the instructions for use. It should not be considered the exclusive source of information, and should be used in conjunction with the Evolut™ FX manual manual. CE0344

See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+, and Evolut™ FX device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System, and the commercial name of the Evolut™ FX device is Medtronic Evolut™ FX System.

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Important: Always refer to the Instructions For Use (IFU) packaged with the product/e-IFU for complete instructions, indications, contraindications, warnings, and precautions.

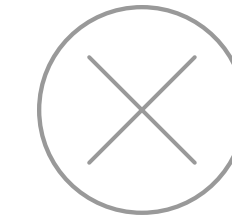
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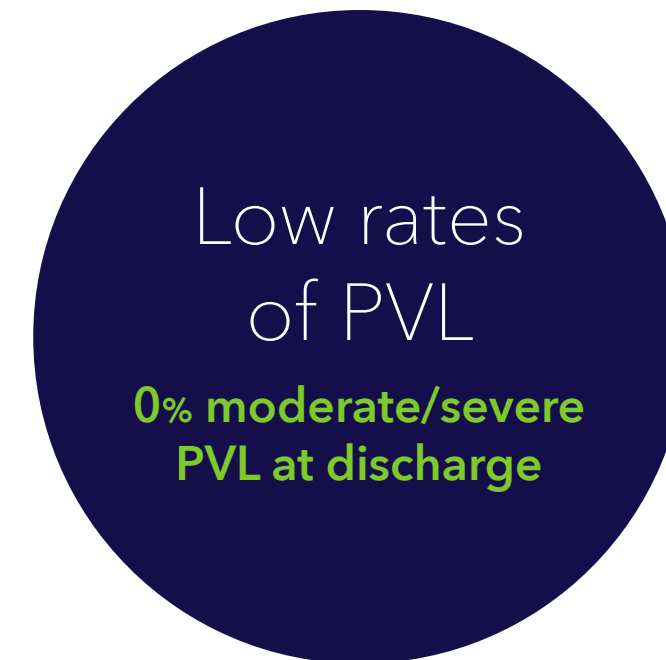
Optimize PRO second interim analysis shows excellent clinical outcomes<sup>1</sup>



Why does it all matter?

# Single-digit PPI rate and no moderate+ PVL

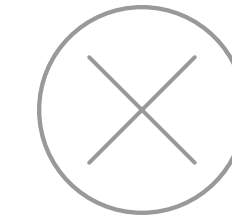
The cusp overlap technique with an optimized care pathway continues to show excellent clinical outcomes.<sup>†</sup>



<sup>†</sup>This is an interim analysis of 504 patients (104 roll-in and 400 main cohort). The data presented here include only the main cohort patients. At the conclusion of the study more than 650 patients will have been evaluated. Devices used are 91.3% Evolut PRO+ and 8.3% Evolut PRO systems.

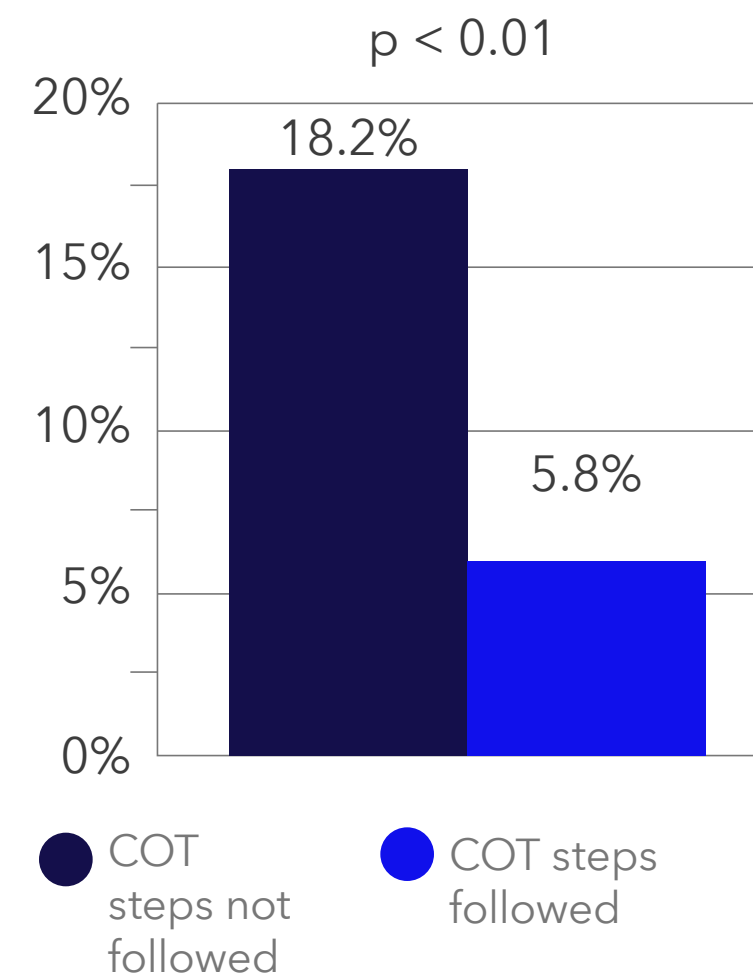
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Gada sub-analysis: Predictability drives precision<sup>1</sup>



# Predictability drives precision

5.8% permanent pacemaker implant rate when essential cusp overlap steps are followed.



Utilization of the four essential cusp overlap technique steps lowers pacemaker implantation rates.<sup>1</sup>

- 1 CTA reconstructed angiography overlay of COV.
- 2 Fluoro image of Lunderquist®\* wire positioned in the left ventricle.
- 3 Fluoro image demonstrating 3 mm depth in COV prior to/after full annular contact below the non-coronary cusp.
- 4 Final aortography performed in COV.

<sup>1</sup> Gada et al. Adherence to Key Cusp Overlap Steps Reduced Pacemaker Implantation in the Optimize PRO Study. Presented at TCT 2022.