



# High Bleeding Risk and DAPT Duration – Bifurcation PCI A Case Presentation

*A Case Based Approach to Complex PCI  
Satellite Symposium TCTAP – 18 March 2022*

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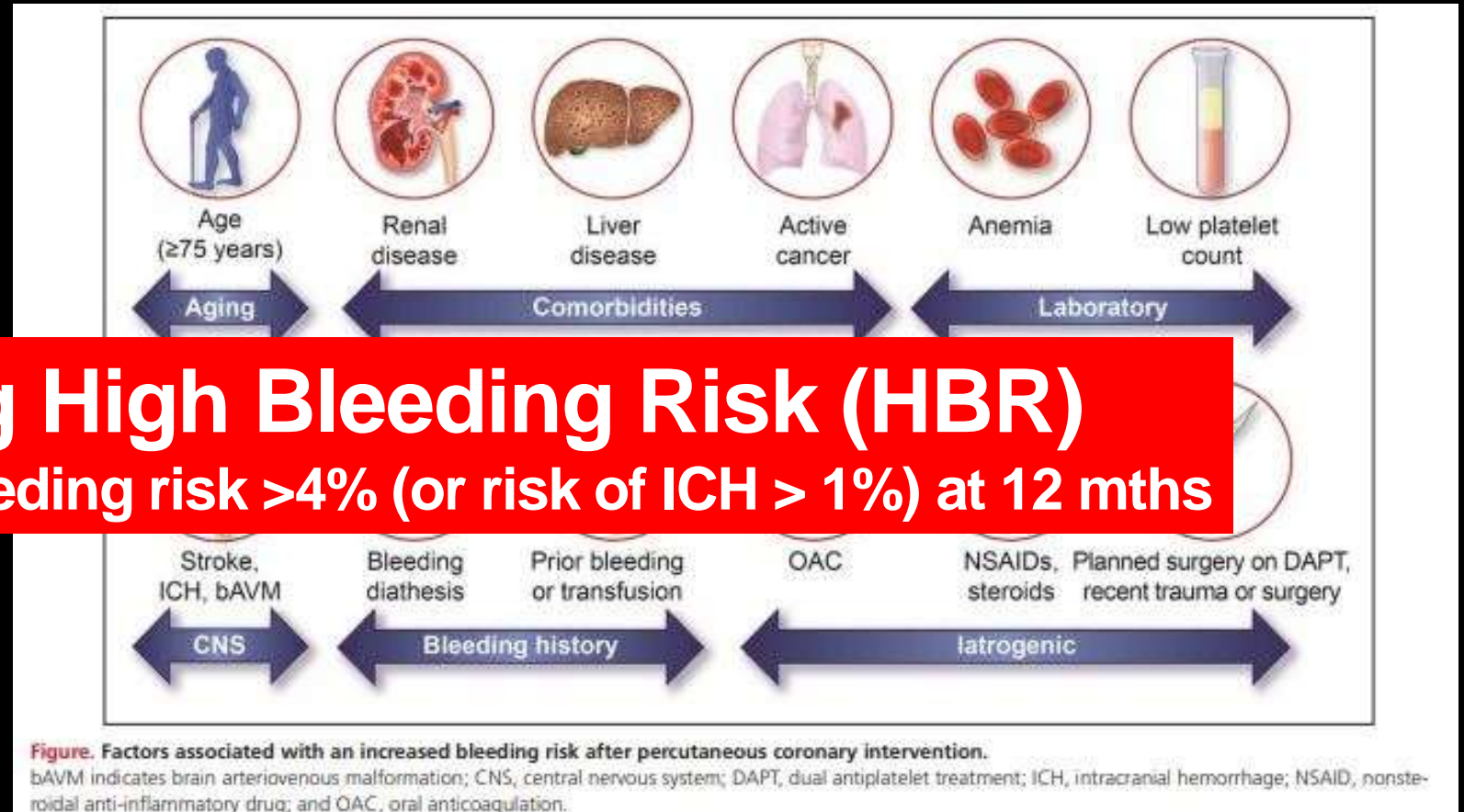
# Factors Associated with Increased Bleeding Risk After PCI

Circulation

WHITE PAPER

## Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention

A Consensus Document From the Academic Research Consortium for High Bleeding Risk

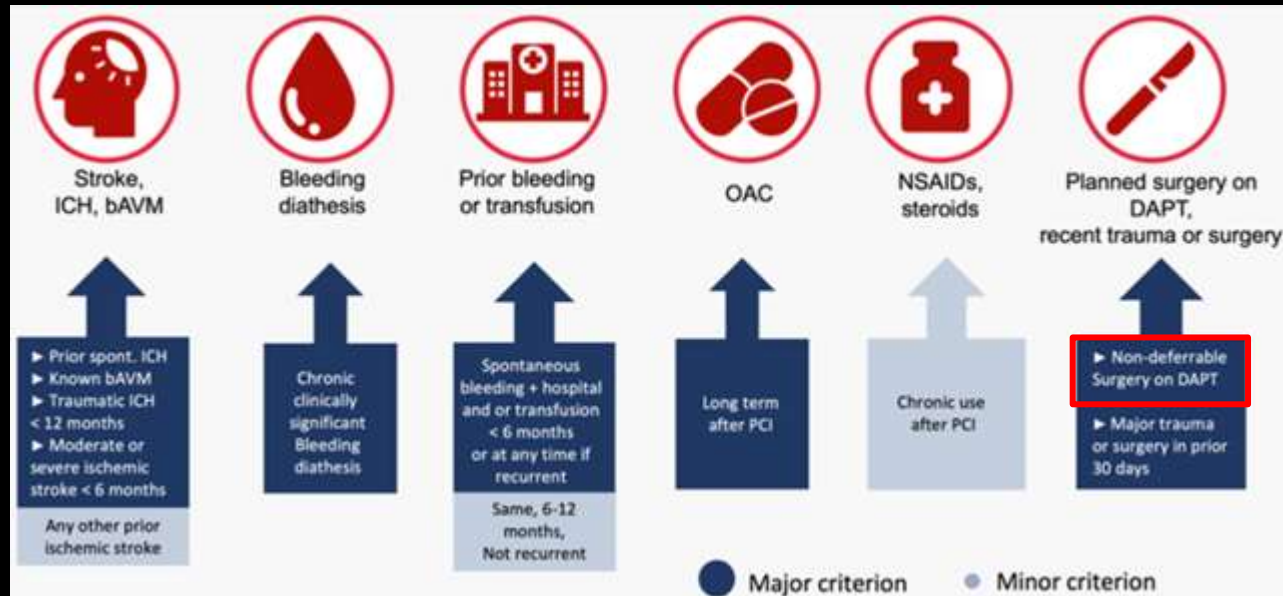
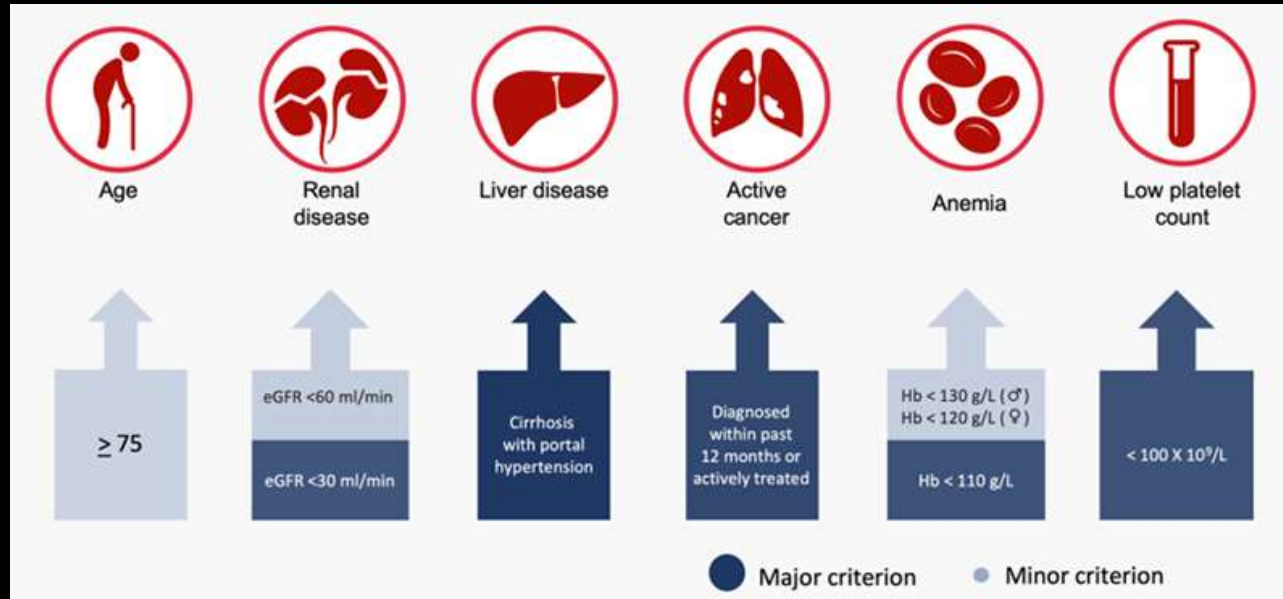


**Defining High Bleeding Risk (HBR)**  
BARC 3 or 5 bleeding risk  $>4\%$  (or risk of ICH  $> 1\%$ ) at 12 mths



# High Bleeding Risk (HBR) Criteria

≥ 1 major  
≥ 2 minor



## Circulation

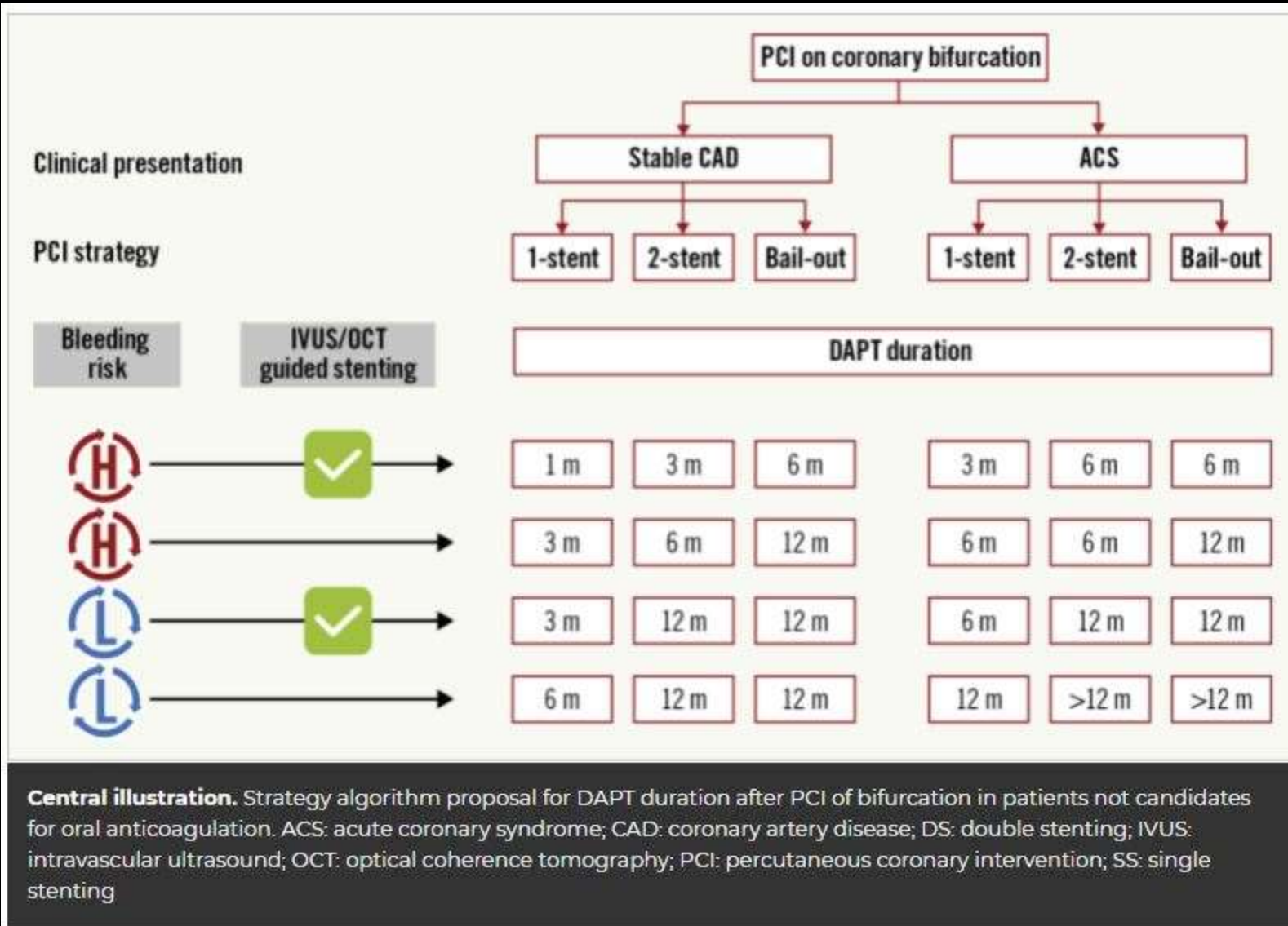
### WHITE PAPER

#### Defining High Bleeding Risk in Patients Undergoing Percutaneous Coronary Intervention

A Consensus Document From the Academic Research Consortium for High Bleeding Risk



# DAPT Duration after Bifurcation PCI



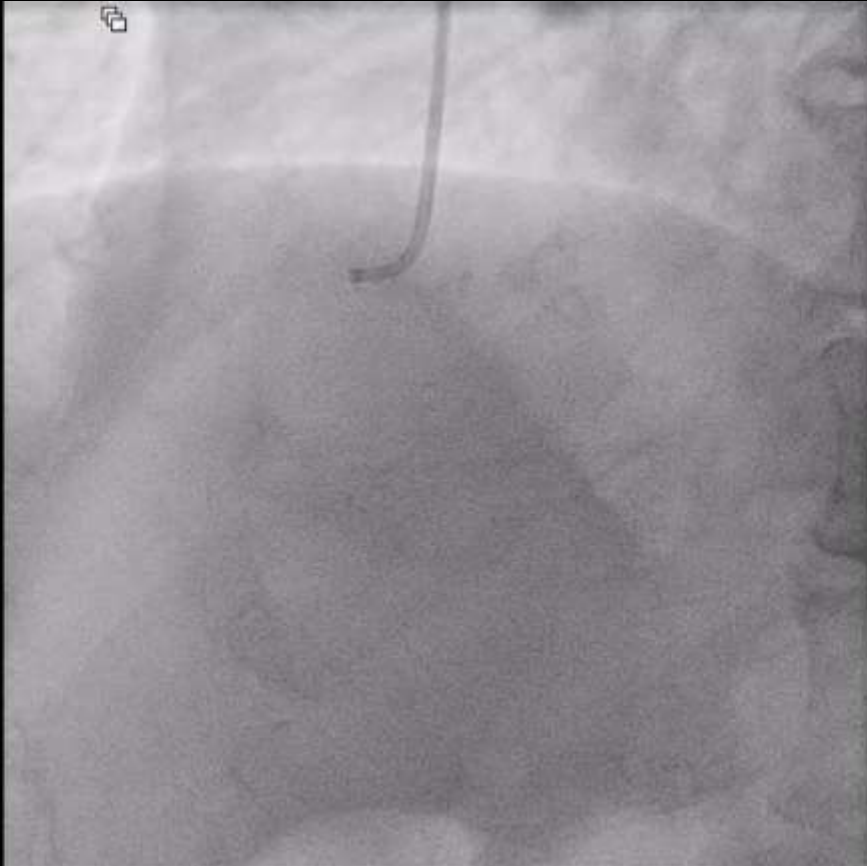
# Case Presentation

**71 year old male -**

- ♥ **Presentation**      Recurrent angina < 2 weeks, GTN responsive, ECG SR NAD
- ♥ **Pathology**        Cr 87 mmol/L, eGFR 76 mL/min/1.73m<sup>2</sup>, Hb 160, Plat 142, TnT - negative
- ♥ **Background**        No IHD, hyperlipidaemia, R renal mass – nephrectomy scheduled
- ♥ **Medications**        Nil regular medications, NKDA
- ♥ **Investigations**     *TTE* –normal ventricular size and function, nil valvular abnormalities  
*EST* – 5.5 min, typical chest pain after 3 min, anterolateral hypokinesia  
at peak exercise (HR 135 bpm)

***Invasive coronary angiography (after DAPT)***



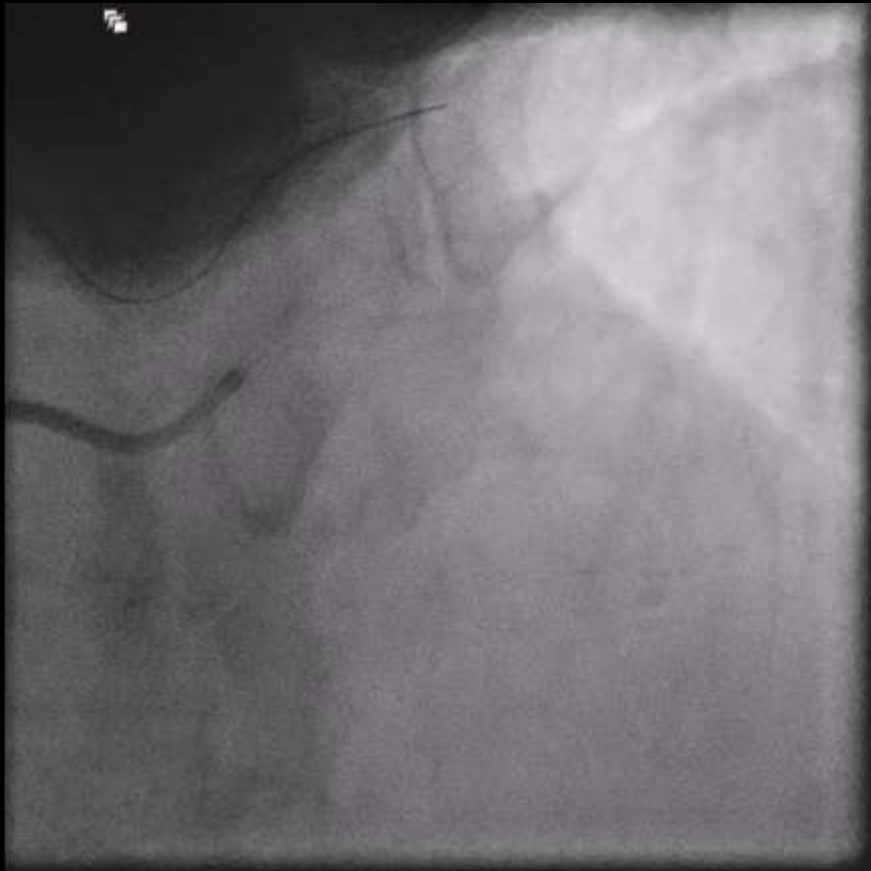


DummyInstName!  
**Prima...**  
09:38:10 AM



LAO: 35.8°  
CRA: 0.1°  
Tilt: 0.0°

DummyPerfPhys!



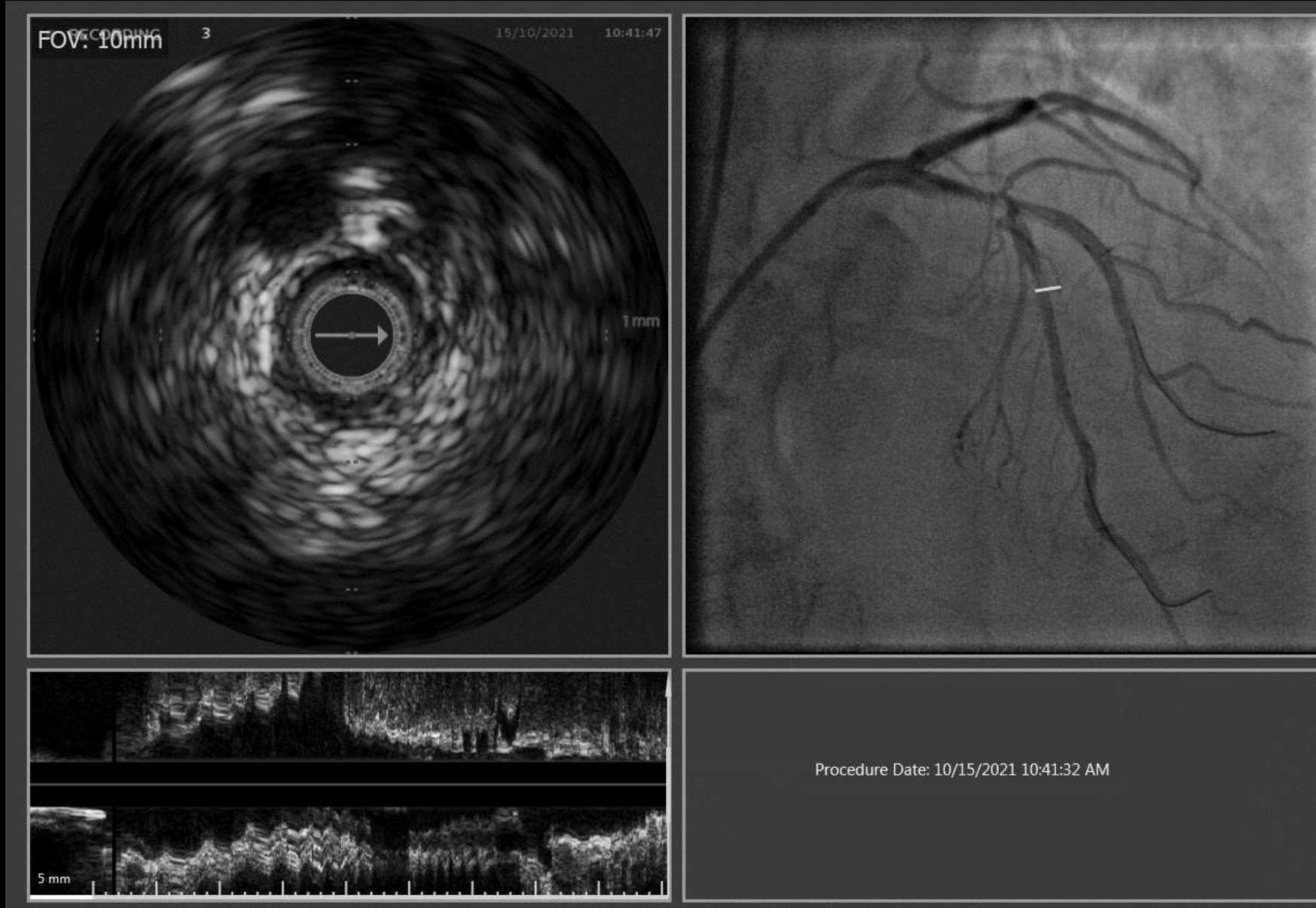
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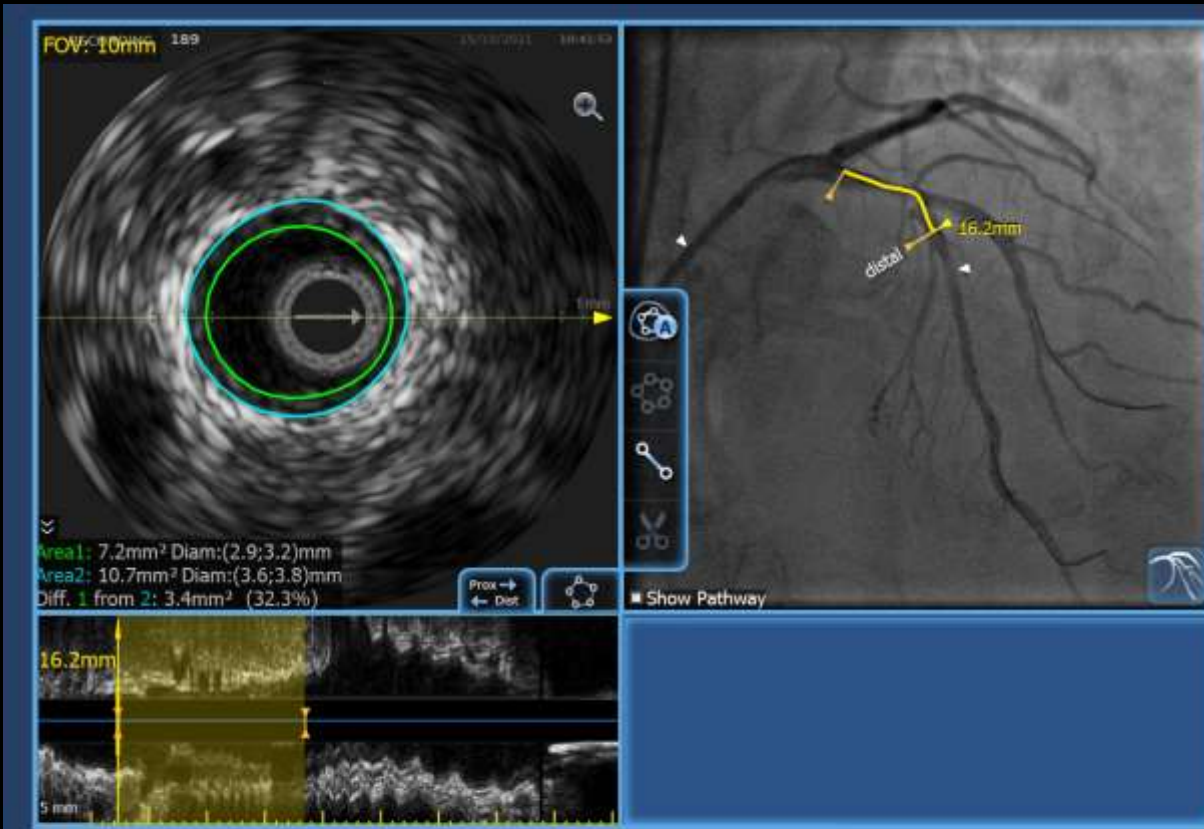
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CRA: 34.8°  
Tilt: 0.0°

# IVUS Guided (Co-registration) Bifurcation PCI



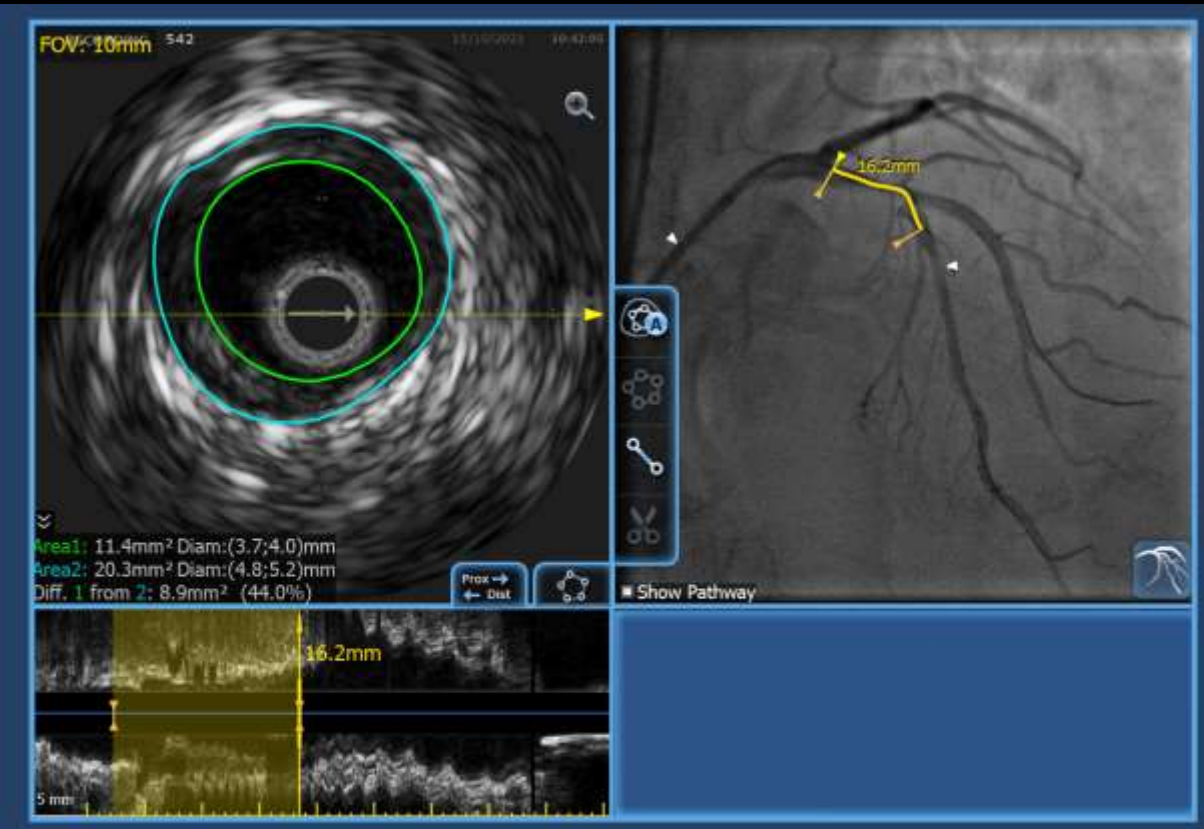


# IVUS Guided (Co-registration) Bifurcation PCI



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Philips SyncVision



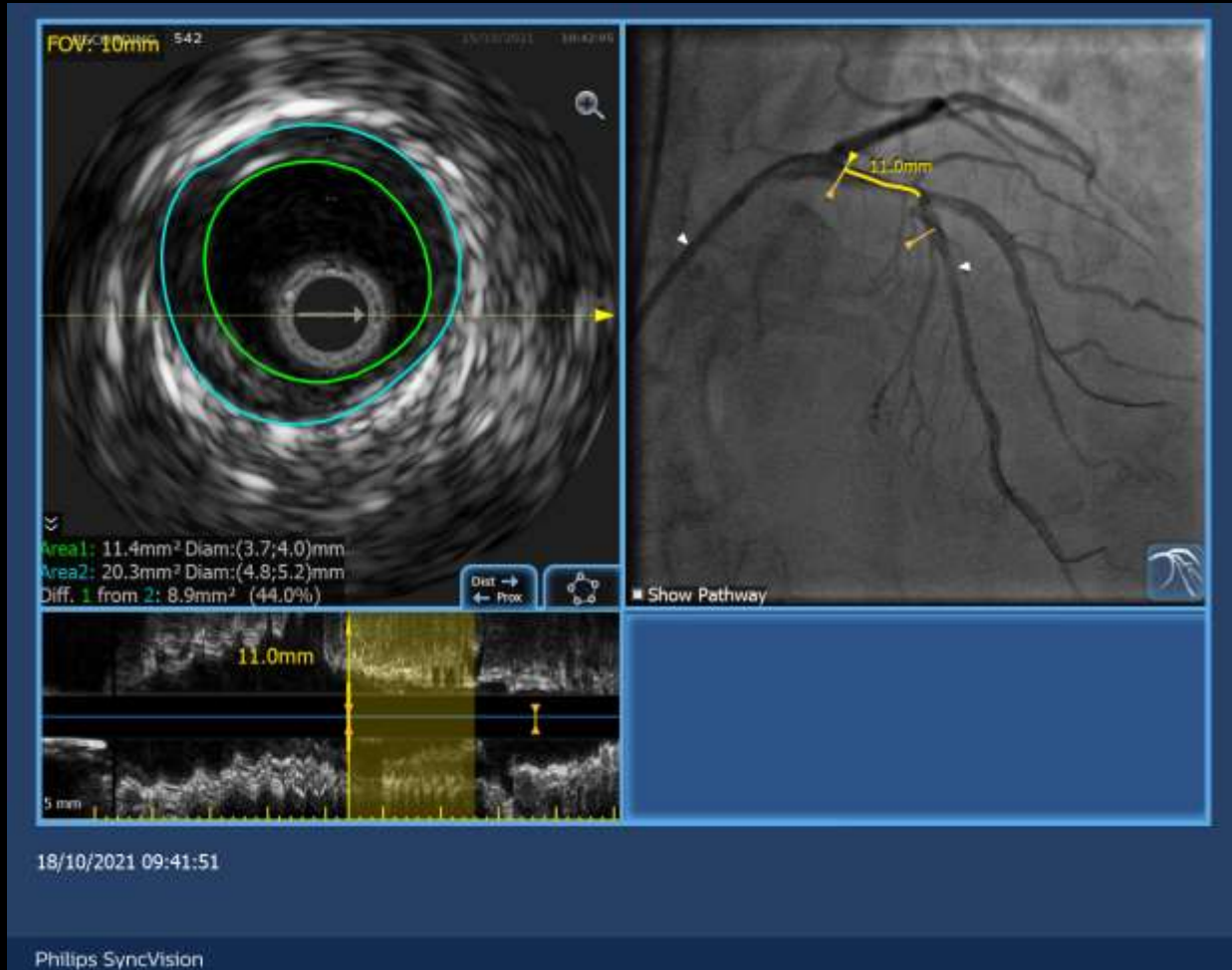
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Philips SyncVision

**Distal reference - 3.7 mm**

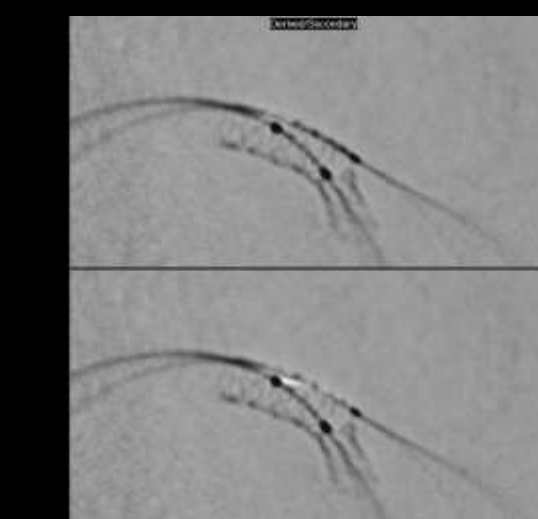
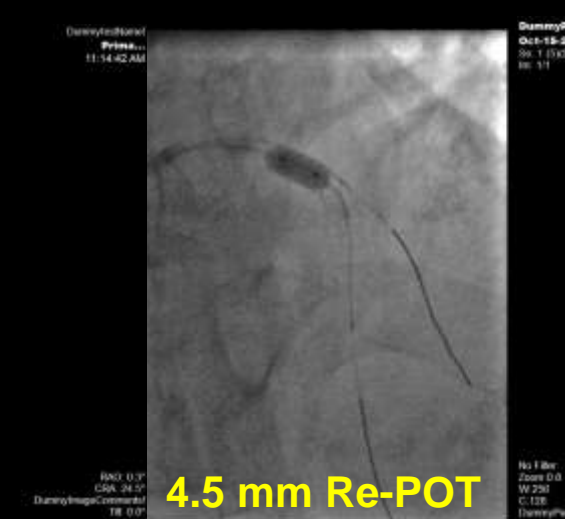
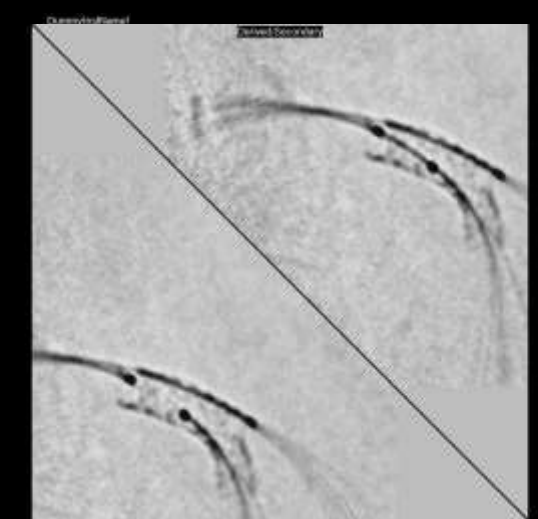
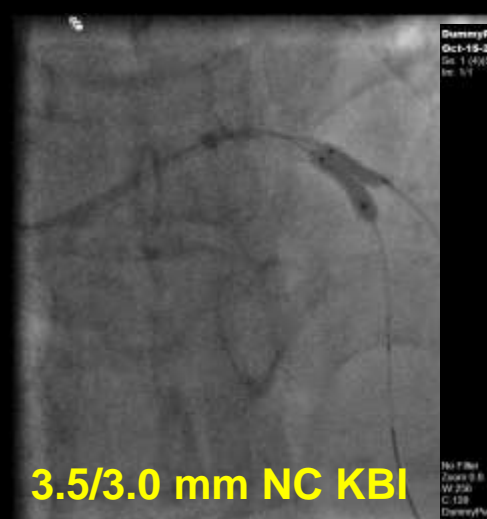
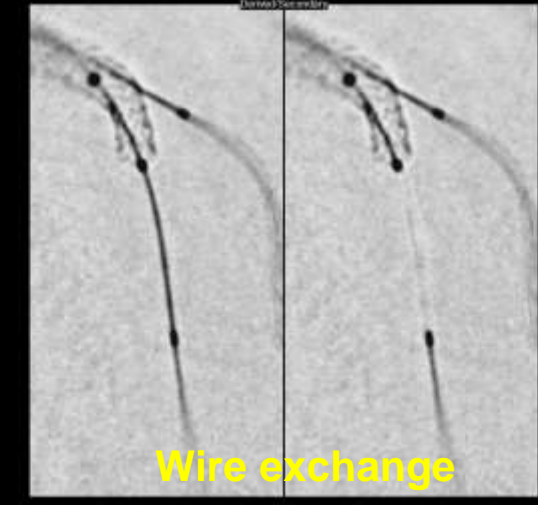
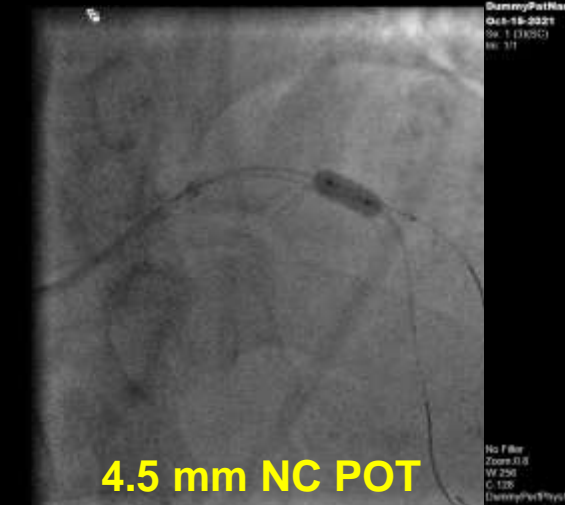
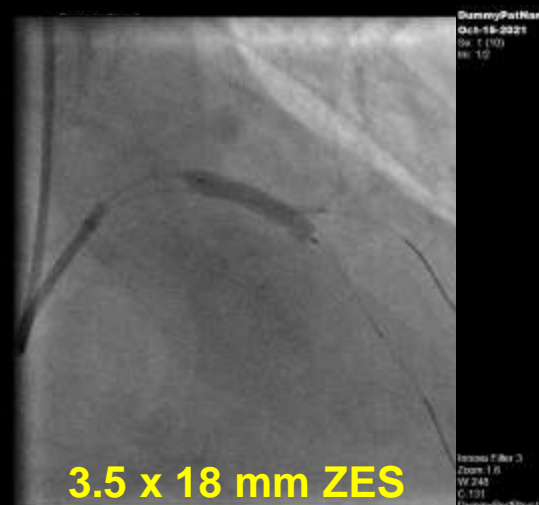
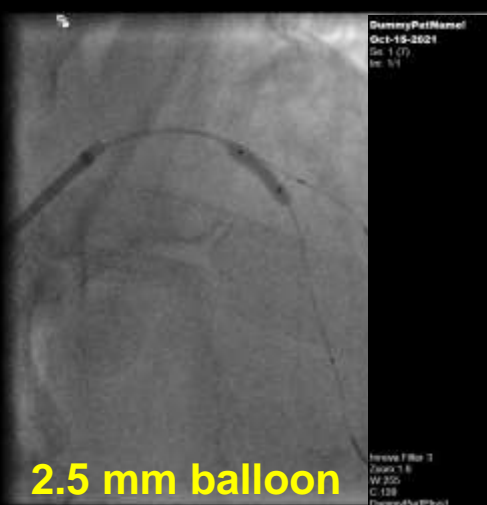
**Proximal reference – 4.9 mm**





## PCI Planning – IVUS Guided

- **Lesion length 16 mm**
- **Distal ref 3.7 mm**
- **Proximal ref 4.9 mm**
- **3.5 x 18 mm ZES**
- **Provisional Strategy (1,0,0)**
- **POT 4.5 mm – 10mm NC**
- **(DOT 3.5 mm)**



# Stent Selection – Expansion Capacity

## INDUSTRY DEFINED STENT EXPANSION LIMITS



DRUG ELUTING STENTS					
Company	Stent	Nominal Stent Diameter (mm)	Stent Lengths (mm)	Max Exp Limit (mm) <u>ON LABEL</u>	Max Exp Limit (mm) <u>OFF LABEL</u>
Medtronic	Resolute Onyx	2.25 – 5.0	8, 12, 15, 18, 22, 26, 30, 34, 38	2.25 to 2.5 = <u>3.25</u> 2.75 to 3.0 = <u>3.75</u> 3.5 to 4.0 = <u>4.75</u> 4.5 to 5.0 = <u>5.75</u>	2.5 → <u>3.3</u> 3.0 → <u>4.3</u> 4.0 → <u>5.5</u> 5.0 → <u>5.9</u>
Abbott	Xience Sierra	2.0 – 4.0	8, 12, 15, 18, 23, 28, 33, 38	2.0 to 3.25 = <u>3.75</u> 3.5 to 4.0 = <u>5.5</u>	<b>X</b>
Abbott	Xience Expedition	2.5 – 3.5	48	2.5 = <u>3.25</u> 3.0 = <u>3.75</u> 3.5 = <u>4.5</u>	<b>X</b>
Biotronik	Orsiro	2.25 – 4.0	9, 15, 18, 22, 30	2.25 to 3.0 = <u>3.5</u> 3.5 to 4.0 = <u>4.5</u>	3.0 → <u>4.0</u> 4.0 → <u>5.2</u>
Boston Scientific	Synergy	2.25 – 4.0	8, 12, 16, 20, 24, 28, 32, 38	2.25 to 2.75 = <u>3.5</u> 3.0 to 3.5 = <u>4.25</u> 4.0 = <u>5.75</u>	2.75 → <u>3.6</u> 3.5 → <u>4.2</u> 4.0 → <u>5.7</u>
Terumo	Ultimaster	2.25 – 4.0	9, 12, 15, 18, 24, 28, 33, 38	2.25 to 3.0 = <u>4.3</u> 3.5 to 4.0 = <u>5.8</u>	<b>X</b>
BARE METAL STENTS					
Biotronik	Pro-Kinetic Energy	2.25 – 4.5	13, 15, 18, 20, 33	2.25 to 3.0 = <u>3.5</u> 3.5 to 4.0 = <u>4.65</u>	<b>X</b>



DummyPatName!

Oct-15-2021

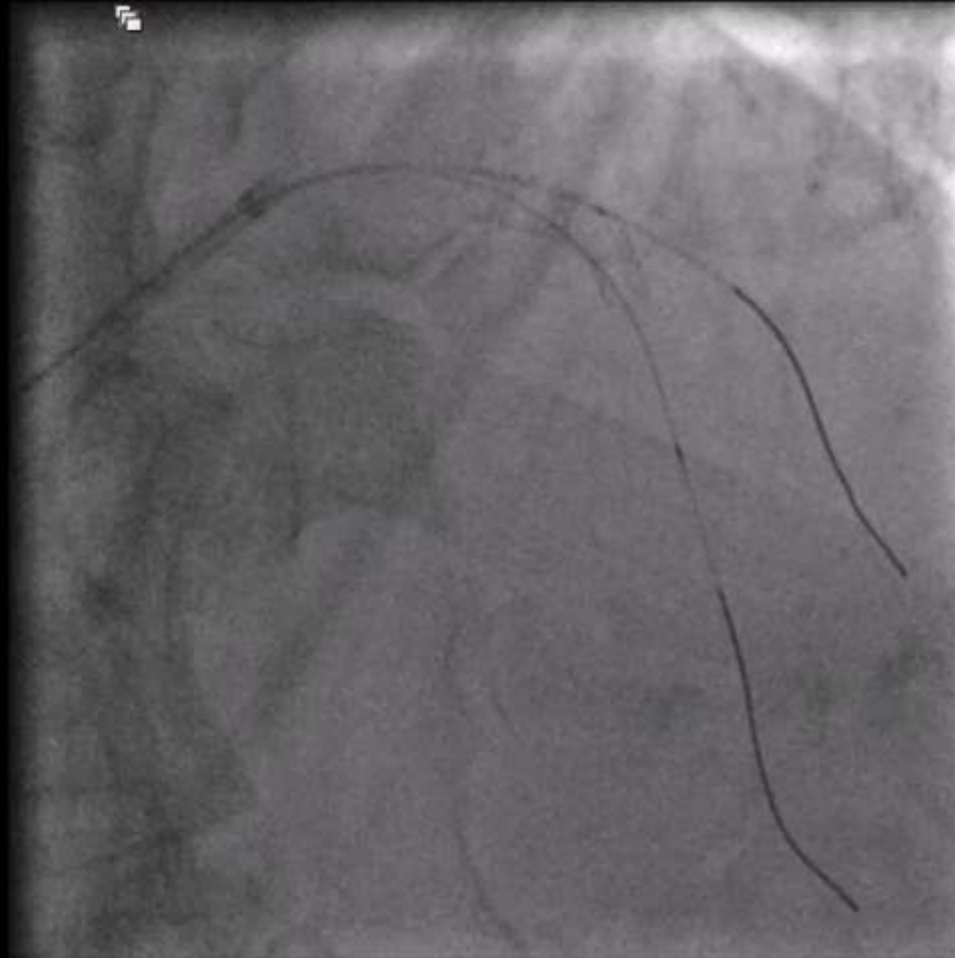
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DummyInstName!

Prima...

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Innova Filter 3

Zoom: 1.6

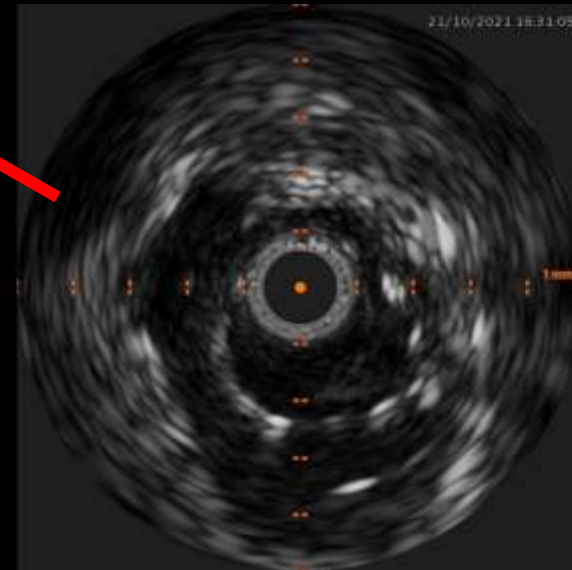
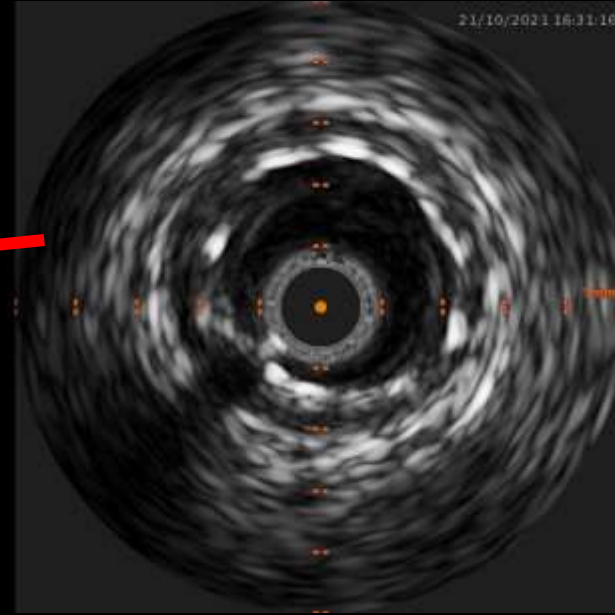
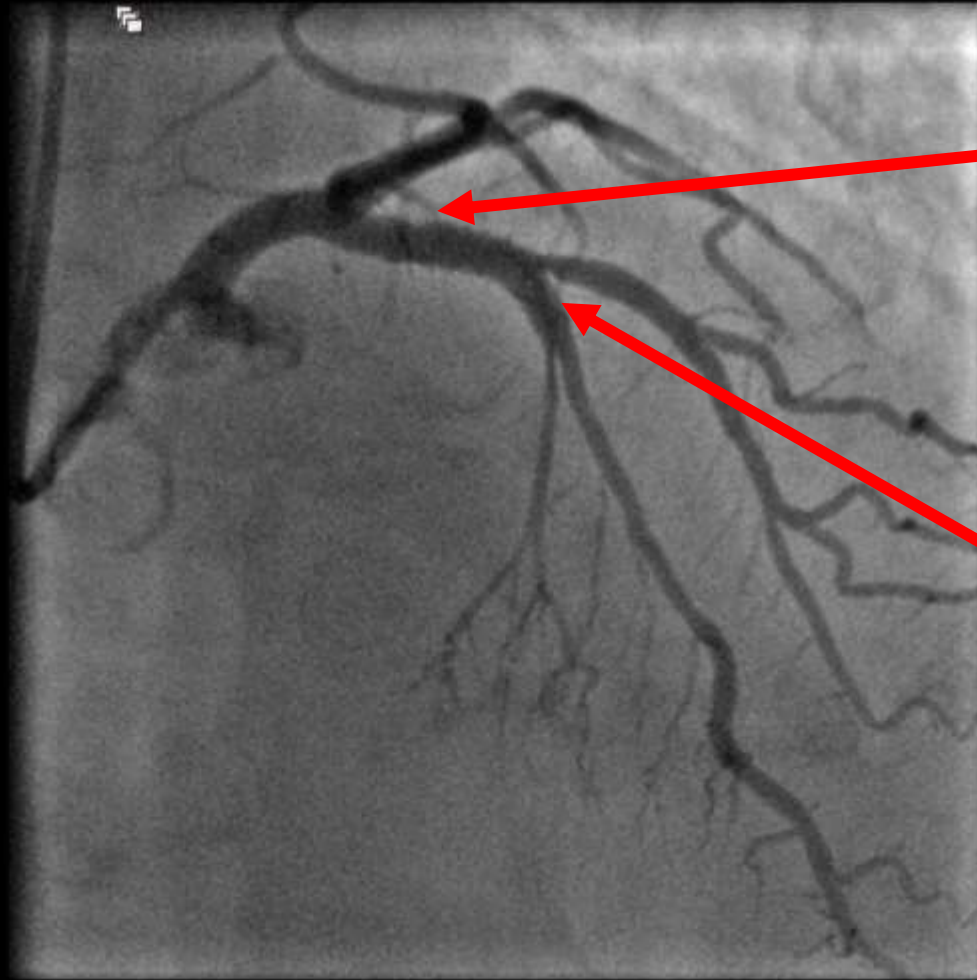
W: 255

C: 128

DummyPerfPhys!





RAO: 8.8°  
CRA: 24.6°  
mAs: 185.0  
Tilt: 0.0°



# IVUS Guided Bifurcation PCI

## PCI Planning – IVUS Guided Optimized

- *Lesion length 16 mm*
- *Distal ref 3.7 mm*
- *Proximal ref 4.9 mm*
- *3.5 x 18 mm ZES*
- *Provisional Strategy (1,0,0)  *KBI 4.0/3.0 mm NC balloons**
- *POT 4.5 mm – 10mm NC  *POT 5.0 mm NC balloon**



DummyPatName!  
 Oct-15-2021  
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 Im: 1/104



DummyInstName!  
 Prima...  
 11:30:24 AM



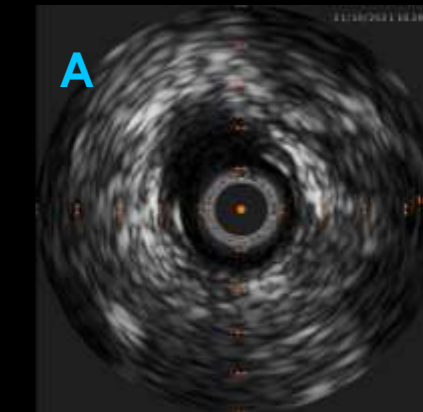
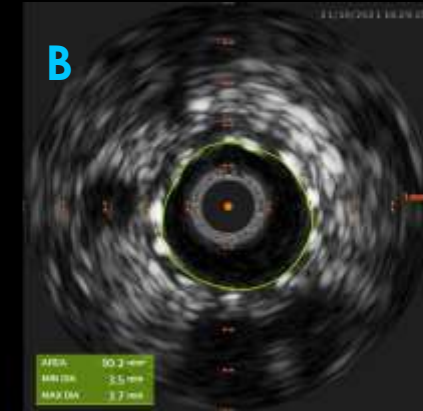
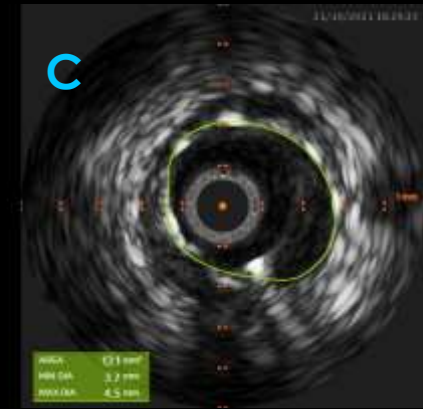
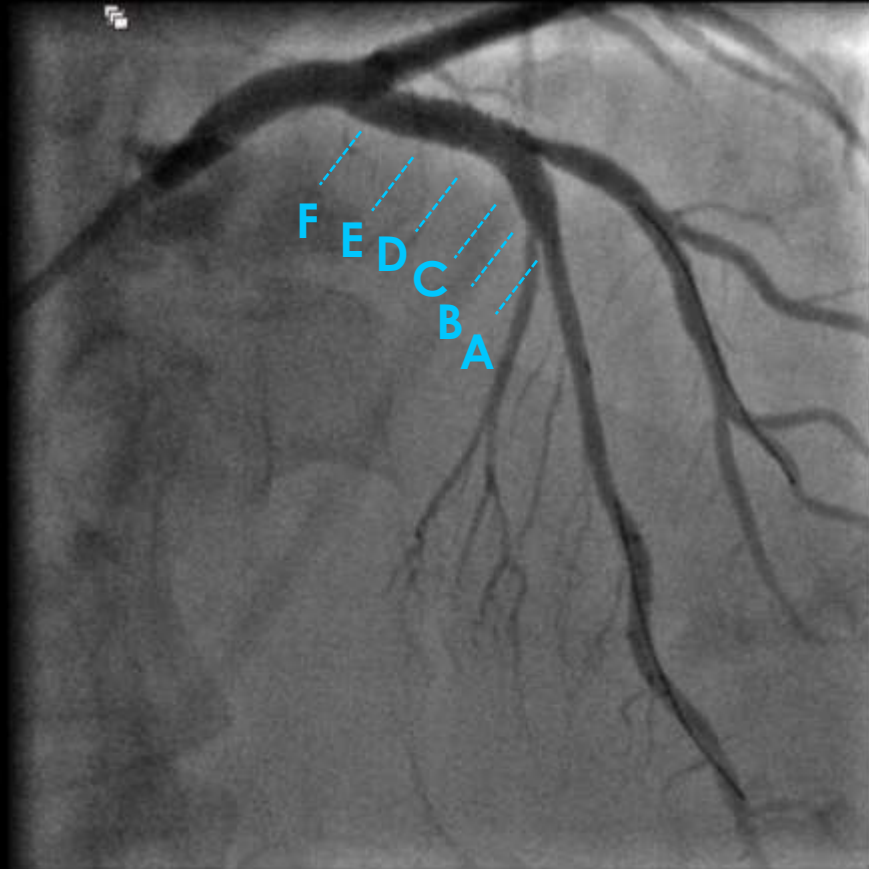
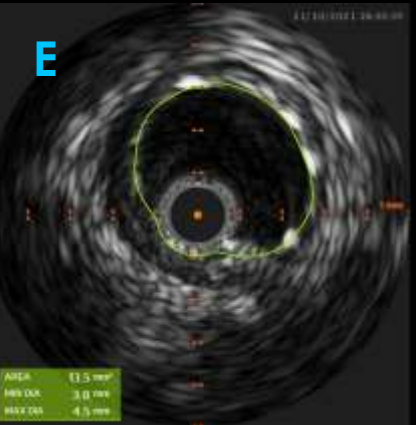
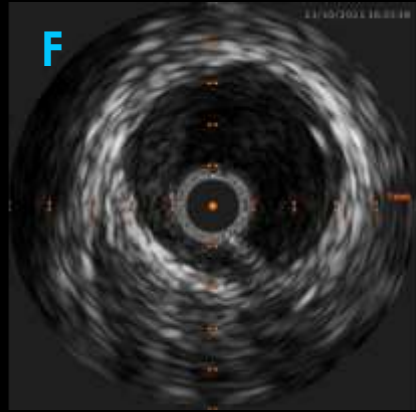
Innova Filter 3  
 Zoom: 1.6  
 W:242  
 C:132  
 DummyPerfPhys!

0 FPS  
 RAO: 22.0°  
 CRA: 31.5°  
 mAs: 323.0  
 Tilt: 0.0°

**Final Result**







**Final Result**



Australian Government  
Department of Health  
Therapeutic Goods Administration



## Australian Register of Therapeutic Goods Certificate

Issued to

**Medtronic Australasia Pty Ltd**

for approval to supply

### Medtronic Australasia Pty Ltd - Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System - Drug-eluting coronary artery stent, non-biodegradable-polymer-coated

<b>ARTG Identifier</b>	263413
<b>ARTG Start Date</b>	17/11/2015
<b>Product Category</b>	Medical Device Included Class III
<b>GMDN</b>	56284
<b>GMDN Term</b>	Drug-eluting coronary artery stent, non-biodegradable-polymer-coated
<b>Intended Purpose</b>	<p>The Resolute Onyx Stent System is intended for use in patients eligible for percutaneous transluminal coronary angioplasty (PTCA) with a reference vessel diameter of 2.0 mm to 5.0 mm. The Resolute Onyx Stent is indicated for the treatment of the following patient and lesion subsets:</p> <ul style="list-style-type: none"> <li>- One month of dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients, including patients who are unable to tolerate long term DAPT</li> <li>- Diabetes Mellitus</li> <li>- Multivessel Disease</li> <li>- Acute Coronary Syndrome (ACS)</li> <li>- Acute Myocardial Infarction (AMI)</li> <li>- Unstable Angina (UA)</li> <li>- Bifurcation Lesions</li> <li>- In-Stent Restenosis (ISR)</li> <li>- Chronic Total Occlusions (CTO)</li> <li>- Total Occlusions (TO)</li> <li>- Left Main (LM)</li> <li>- Small Vessel (SV)</li> </ul> <p>The Resolute Onyx Stent is intended to improve coronary luminal diameters of either single or multiple vessels as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.</p>

Manufacturer Details	Address	Certificate number(s)
Medtronic Inc	710 Medtronic Parkway Minneapolis , MN , 55 432 United States Of America	DV-20060914-MC-025191-11

#### ARTG Standard Conditions

The above Medical Device Included Class III has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

#### Products Covered by This Entry



# Onyx ONE: The only DES vs. DES trial in HBR patients with 1-month DAPT



**Primary endpoint:** Composite of cardiac death, MI, and ST at 1 year

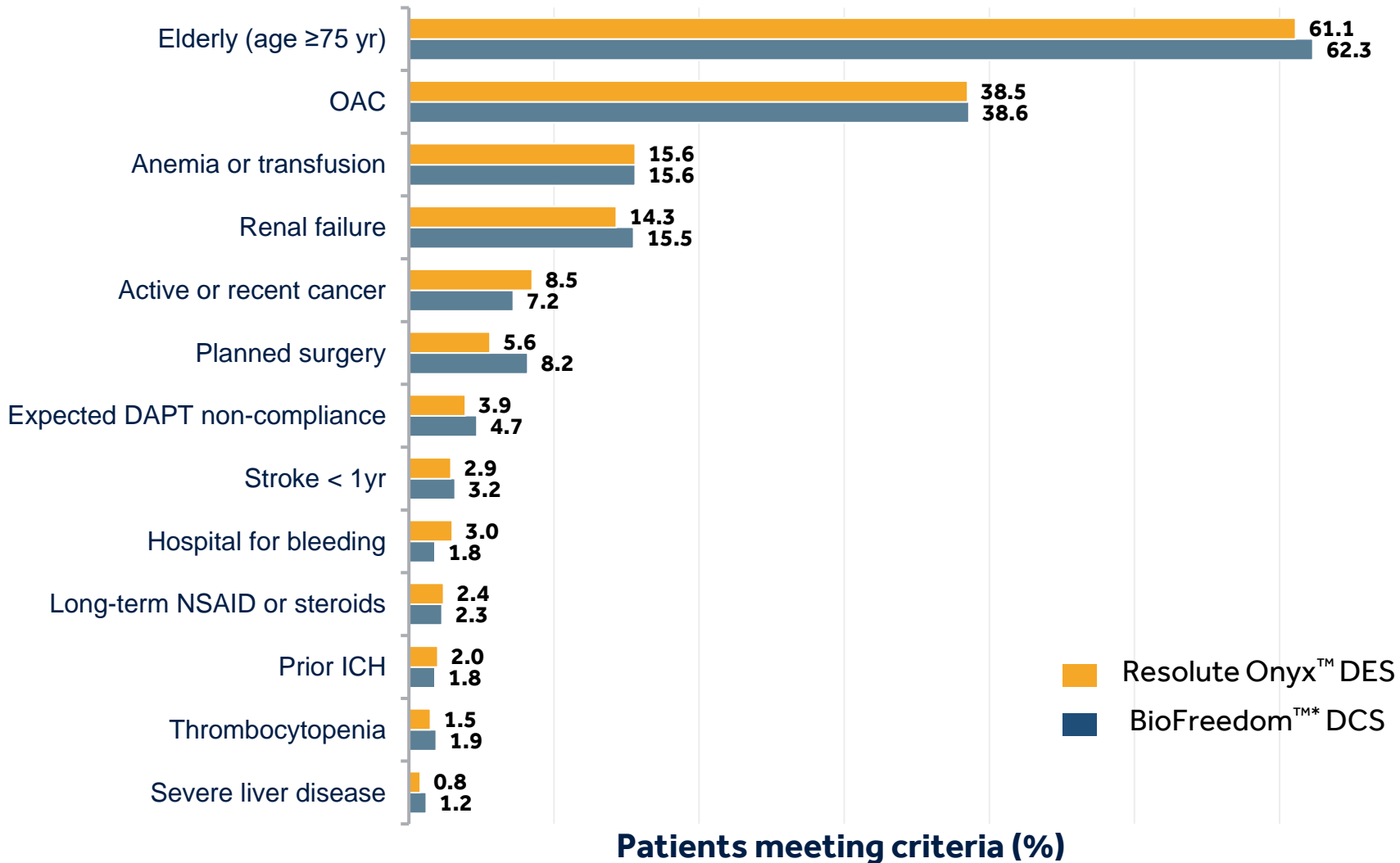
**Powered secondary endpoint:** TLF: CD, TVMI or cdTLR at 1 year

**Antiplatelet therapy:** After one month, subjects will continue on aspirin (75–100 mg daily) or P2Y<sub>12</sub> inhibitor, recommended per guidelines

<sup>†</sup>CAD patients (ACS + stable angina) undergoing PCI who are at increased risk of bleeding or in whom DAPT > 1 month is undesirable, see inclusion criteria for HBR definition.  
Source: Windecker S, et al. *N Engl J Med*. 2020;382:1208-1218.



# HBR Inclusion Criteria



**1.6**  
Average  
Criteria per  
Patient

**46%**  
of patients met 2 or  
more criteria for  
high bleeding risk

Source: Windecker S, et al. *N Engl J Med*. 2020;382:1208-1218.

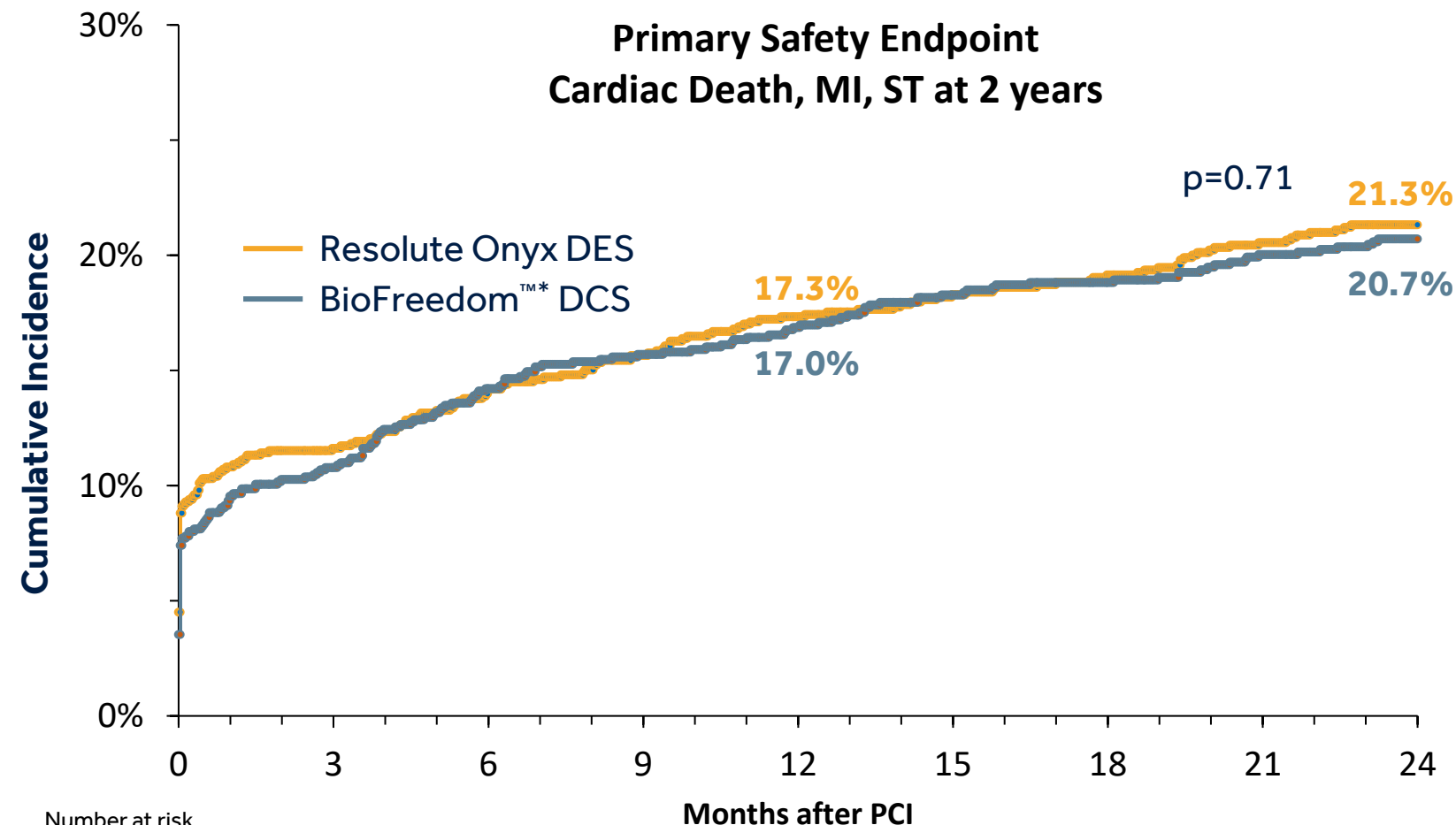




# Resolute onyx™ DES in complex HBR patients with 1-mo DAPT at 2 years



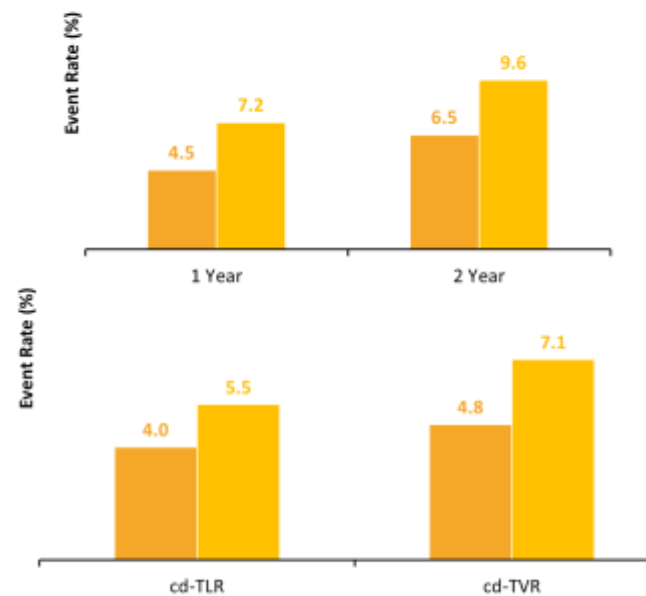
## Primary Safety Endpoint Cardiac Death, MI, ST at 2 years



Number at risk		Months after PCI							
	0	3	6	9	12	15	18	21	24
DES	1003		866		807		762		730
DCS	993		861		793		752		727

2yr Results**	Resolute Onyx DES (N = 1003)	BioFreedom DCS (N = 993)	Non-inferiority P-value
CD/MI/ST	21.3%	20.7%	0.71
CD	7.7%	6.0%	0.14
MI	15.2%	17.0%	0.35
ST <sup>†</sup>	1.7%	2.5%	0.19

### Significantly lower spontaneous MI with Resolute Onyx™ DES



<sup>†</sup>Def/prob ST. \*\*Based on Kaplan-Meier estimates.

Source: Windecker S, et al. Final Two-Year Results from the Randomized Onyx ONE Trial in High Bleeding Risk Patients Treated with 1-month DAPT. Presented at ACC 2021.

