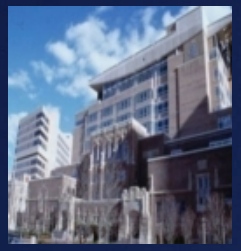
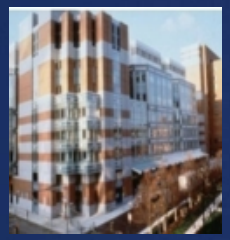
The Bard TRUE Balloon: Design Features and Clinical Applications

Jeffrey J. Popma, MD

Professor of Medicine
Harvard Medical School
Director, Interventional Cardiology
Beth Israel Deaconess Medical Center
Boston, MA



Beth Israel Deaconess Medical Center



Conflict of Interest Statement

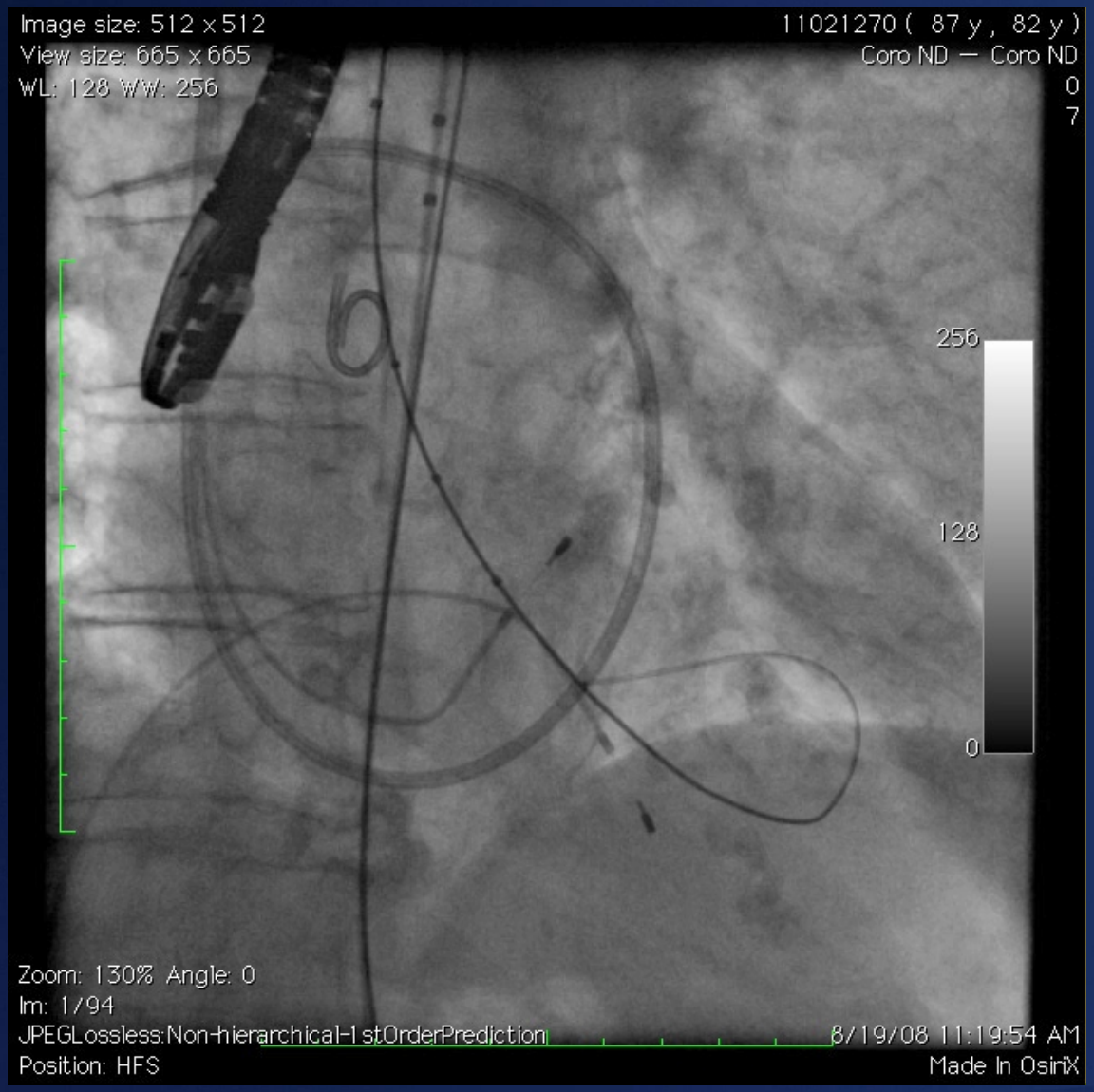
Over the past year, I have received the following:

Institutional Grants: Medtronic, Boston Scientific, Abbott Vascular, Direct Flow, Cook

Medical Advisory Board: Boston Scientific, Abbott Vascular, GE Healthcare, Covidien

Non Vested Equity: Intelemage, Healthworks, Direct Flow Medical

Lessions from TAVR about BAV



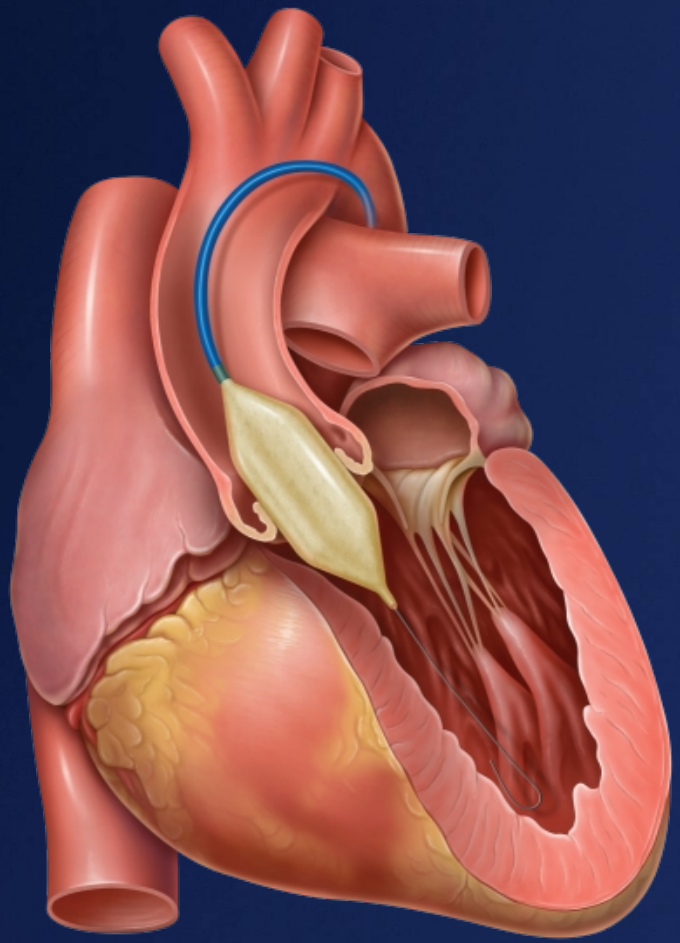
Prolonged Pacing

Balloon Movement

Risk of Rupture

High PPM Rates

Unmeet for Balloon Valvuloplasty Balloon



Short Length
Rapid Inflation
No Growth
No Rupture

Balloon Aortic Valvuloplasty

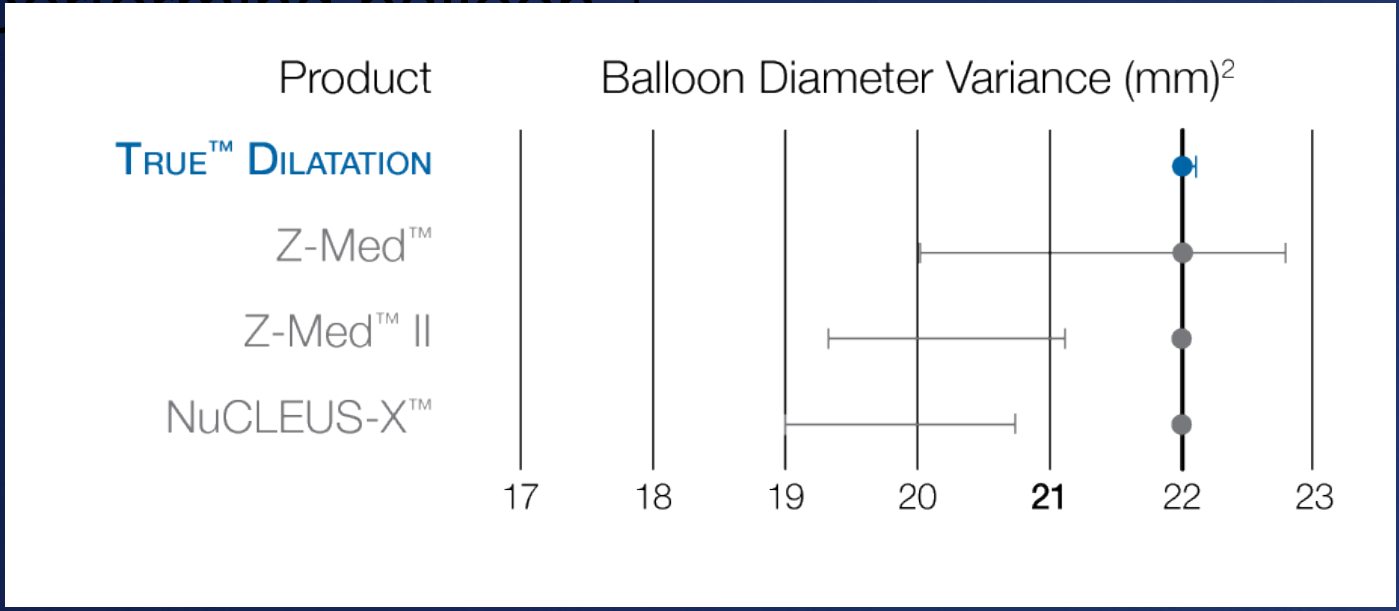
Loma Vista Balloon (Kevlar constructed

- 2-3 times faster inflation and deflation
- 1.5% oversizing
- Rupture resistant

				
Catalog No.	02045-11	02245-12	02445-12	02645-13
Balloon Description	20mm x 4.5cm	22mm x 4.5cm	24mm x 4.5cm	26mm x 4.5cm
Diameter (mm)	20	22	24	26
Length (cm)	4.5	4.5	4.5	4.5
Operating Inflation Pressure (atm/bar)	3	3	3	3
Maximum Inflation Pressure (atm/bar)	6	6	6	6
Inflation Volume (cc)	23	27	32	36

Precision Diameters

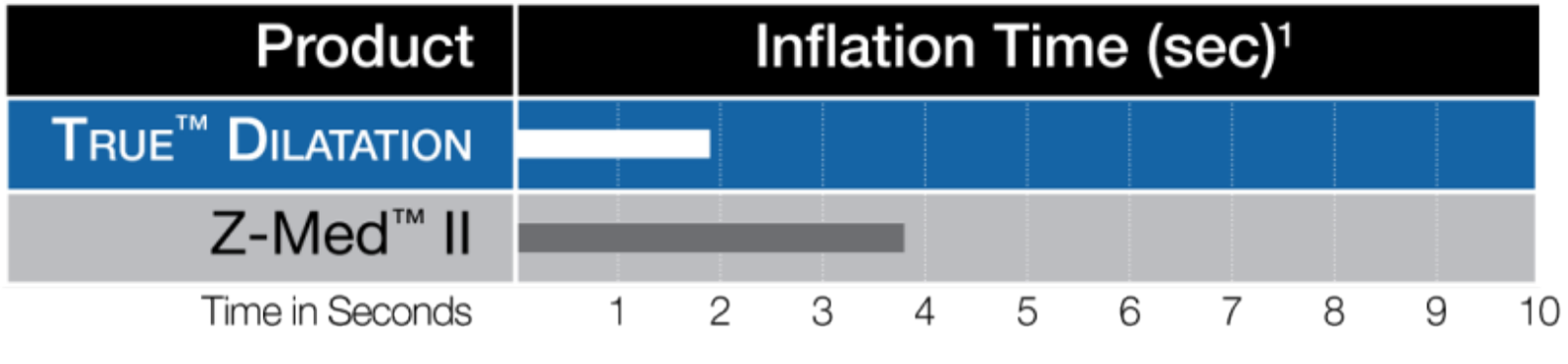
The proprietary fiber technology in the **TRUE™** balloon is designed to deliver accurate balloon sizing. Bench testing and competitive IFUs indicate that **TRUE™** is over 7 times more accurate than the next best performing balloon.[1]



1. Data for competitive balloons obtained from manufacturer IFUs. Data for TRUE™ based on bench data, on file at Bard Peripheral Vascular, Inc., Tempe, Arizona. Percentage stretch calculated using 22mm balloons. Bars indicate range of balloon diameter from 1 ATM to RBP.

True Balloon Speed of Inflation

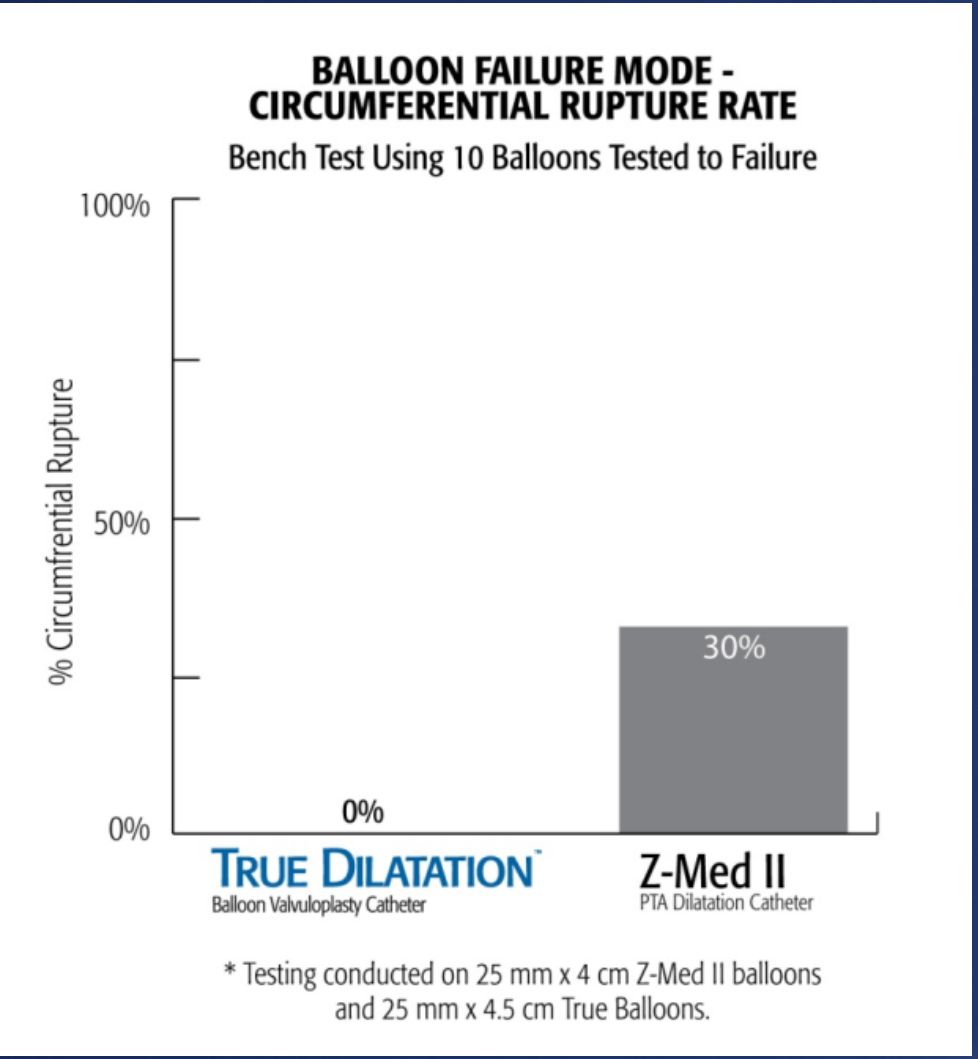
Designed to minimize rapid pacing times, the **TRUE™** balloon inflates and deflates significantly faster than the leading competitive balloon.[1]



1. N=10. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results. Compared a TRUE™ 20mm x 4.5 cm balloon to Z-Med II, 20mm x 4 cm balloon.

True Balloon: Rupture Resistance

Bard's proprietary fiber technology is designed for rupture resistance to minimize catastrophic bursts versus PET* competitive balloons.



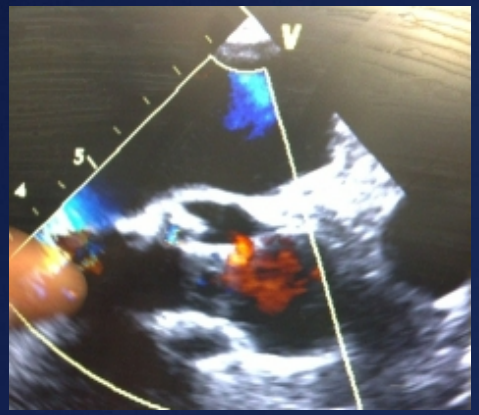
*Data on file: Bench testing using the same test methods using Z-Med II balloons. Bench data may not be representative of clinical outcomes.

Post Evolut-R: Evaluate Hemodynamics

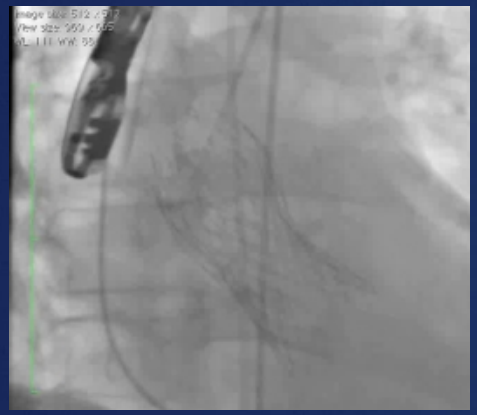
Assess valve function using echocardiography, angiography, and hemodynamics

- If all findings indicate the absence of significant paravalvular regurgitation and complete expansion of valve, the procedure can be completed
- If there are findings suggestive of PVL, wait 10 minutes to reassess and address the cause of the PVL

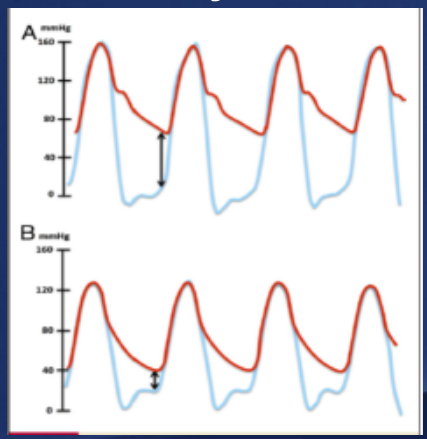
Echocardiography



Angiography

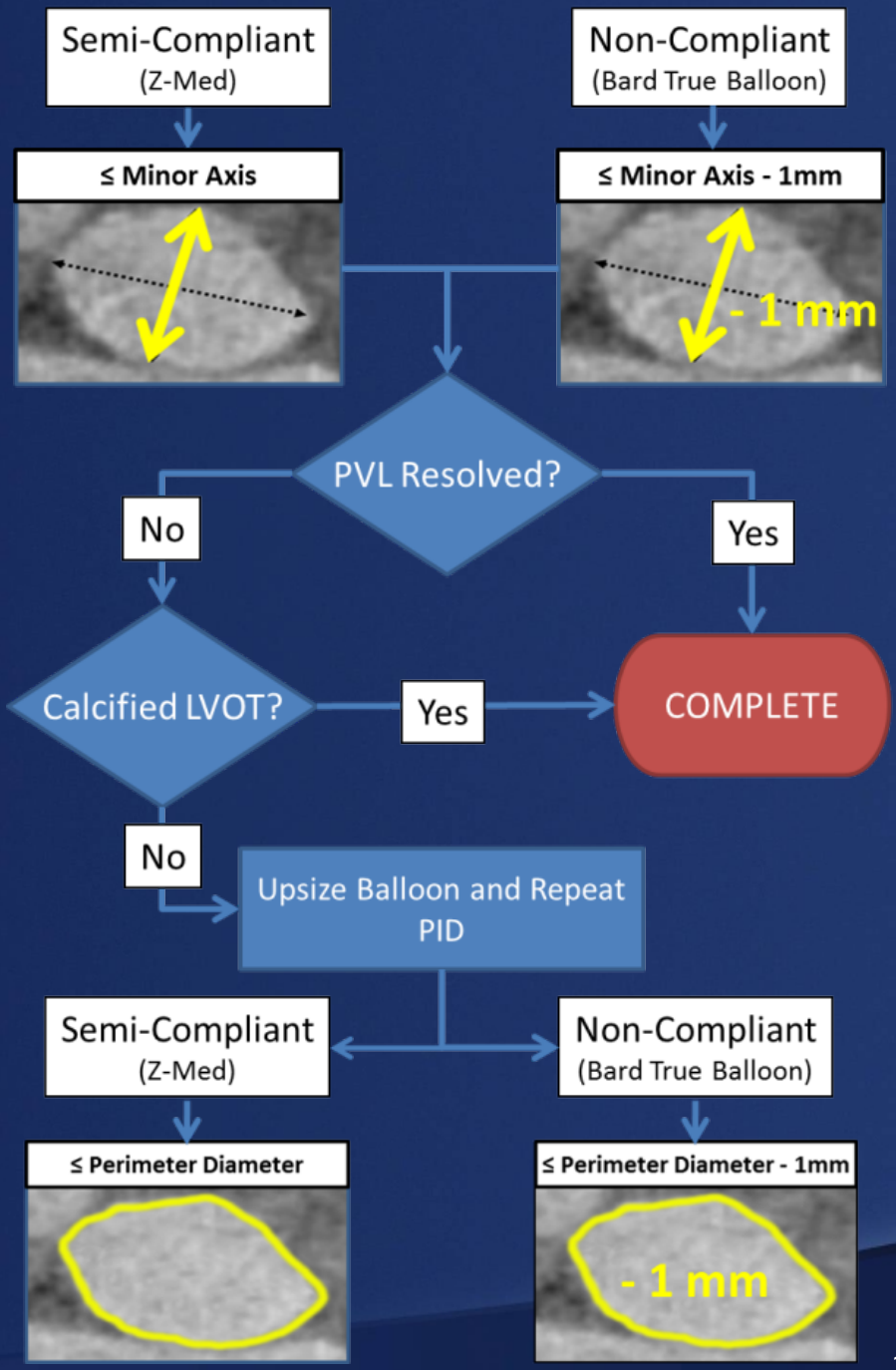


Hemodynamics



Post Implant BAV

- Consider balloon type and the presence of calcification in the LVOT when selecting balloon size
  - For non-compliant balloons (True Balloon) undersize balloon by 1 mm to the minor axis bottom bulb of the valve to perform the BAV



Case Presentation

56 yo woman

- 2008 aortic dissection
- Coronary compromise
- Debranching graft placement to transverse arch
- Bentall ascending root replacement with 21 mm Sorin Mitroflow
- Complicated coronary reimplantation procedure due to coronary dissection

DATE OF SERVICE: 10/16/2008

PREOPERATIVE DIAGNOSIS:
Acute ascending type A aortic dissection.

POSTOPERATIVE DIAGNOSIS:
Acute ascending type A aortic dissection.

OPERATION:
A Bentall procedure plus a replacement of the aortic arch with reimplantation of left carotid and right innominate arteries.

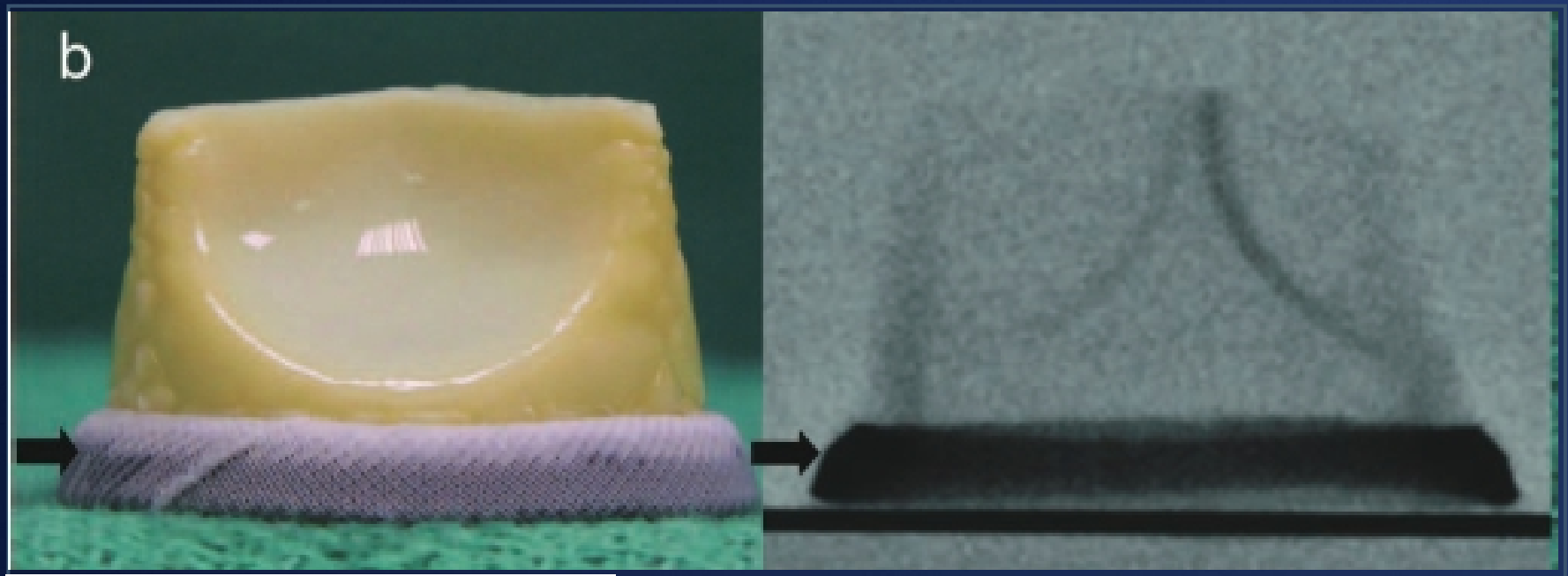
SURGEON:
[redacted]

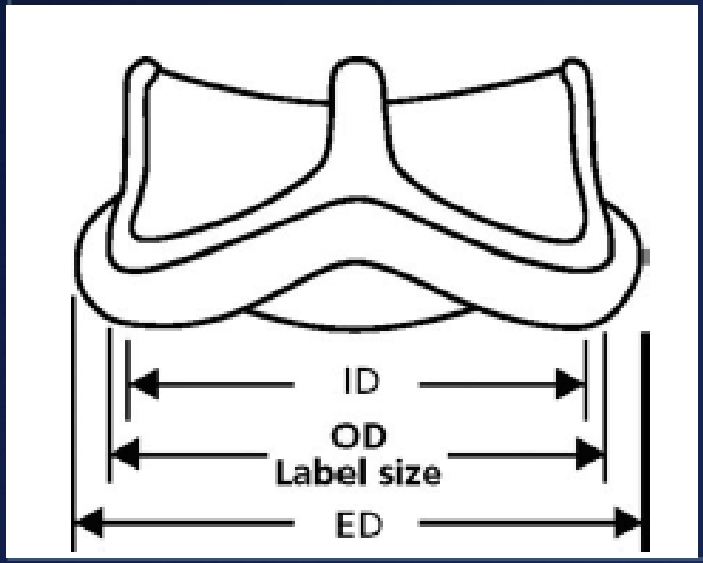
ASSISTANT:
[redacted]

ANESTHESIOLOGIST:
[redacted]

ANESTHESIA:
General.

FINDINGS:
The patient is a 51 hypertensive woman who came, transferred from another hospital, after a diagnosis of acute aortic dissection. The patient was taken down to the operating room maintaining with stable vital signs. There was severe sternal osteoporosis. The pleural cavities were not entered. There was truncal obesity. The left femoral artery was isolated and eventually cannulate and it was somewhat on the big size of 10 with calcific changes. There was no evidence of hemopericardium. There was left ventricular hypertrophy. There was evidence of calcifications affecting the coronary artery on the surface of the heart. There was right side dilatation and four chamber dilatation of the heart, as well. The heart was suffering from acute aortic insufficiency although the cardiac output was maintained. There was edema affecting all the tissues of the mediastinum. The aortic root was under tension and somewhat dilated. Some bluish discoloration and (_____) was seen in tissues between aorta and pulmonary artery. The tear in the aortic root started at the level of the left main coronary artery and proceeded circumferentially around to the right coronary ostium going over the left and right coronary cusp. The right coronary ostium was partially involved with the tear and the left main was seen to have somewhat of a funnel shape aneurysmatic shape. There was a clear flap which involved the entire aortic root. The re-entry point was at the top of the aortic arch. This caused a spiral dissection affecting both the innominate and the left carotid. The innominate was unglued for a length of about 2 cm and ripped. The left carotid was unglued for about 3 to 4 cm and the proximal vessel taking off from the aortic arch was essentially denuded of intima. There was a false lumen which involved the descending thoracic aorta for a length of about 10 to 12 cm. The takeoff of the left subclavian was preserved yet the aorta was somewhat shredded in the vicinity





21 mm Mitroflow

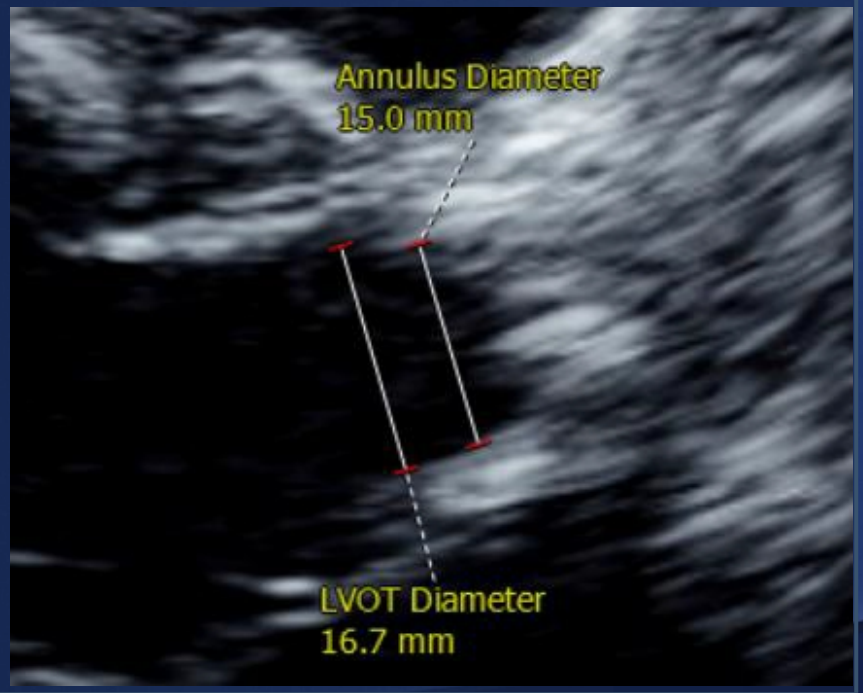
Stent ID = 17.3 mm
True ID = 17.0 mm
Height = 13.0 mm

Case Presentation: Clinical History/Echo

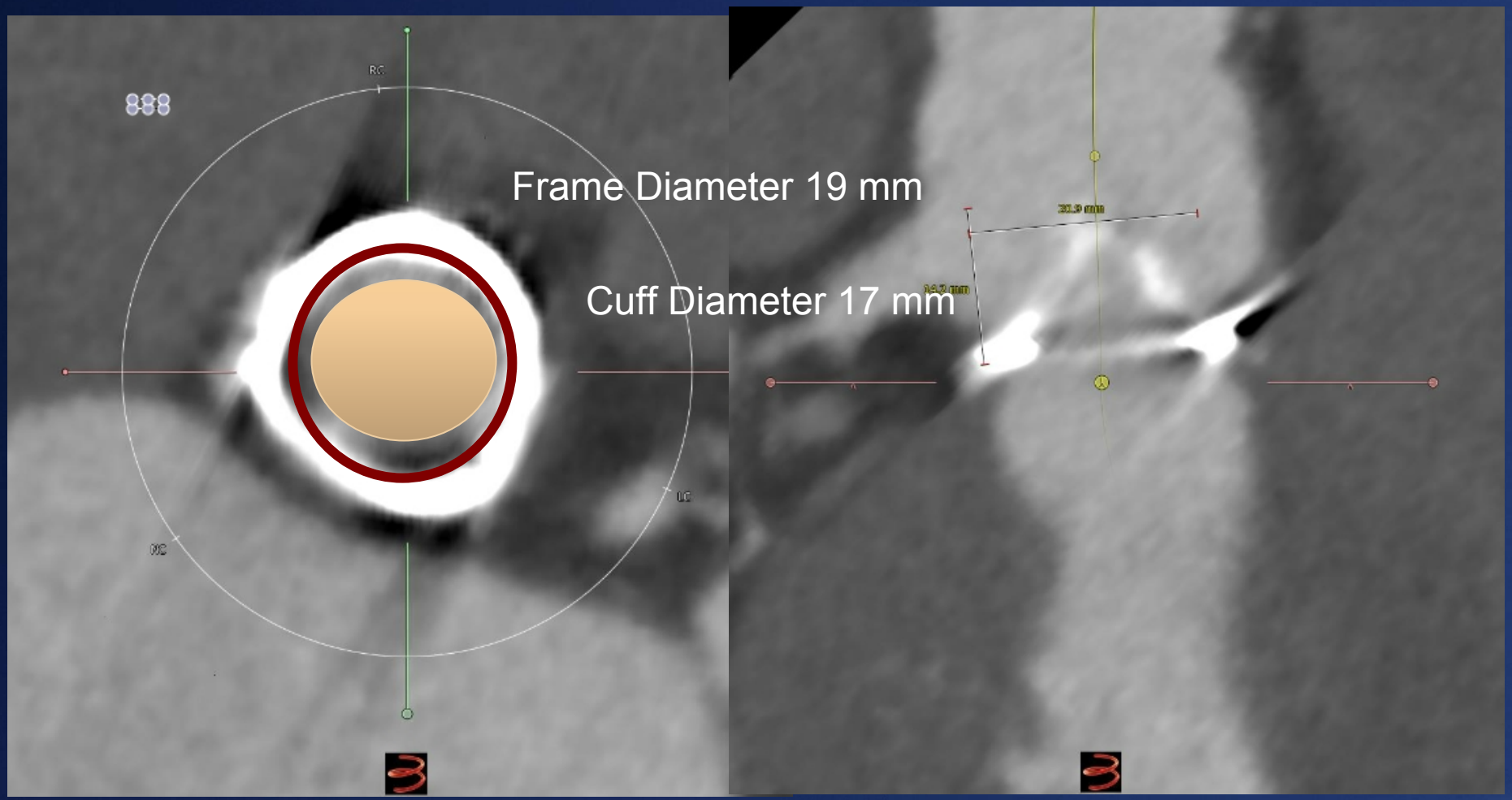
- Represented with recurrent congestive heart failure
- Class III-IV symptoms, recurrent hospitalization
- s/p frontal lobe stroke due to cerebral aneurysm
- Non operative candidate by multiple cardiac surgeons

TTE

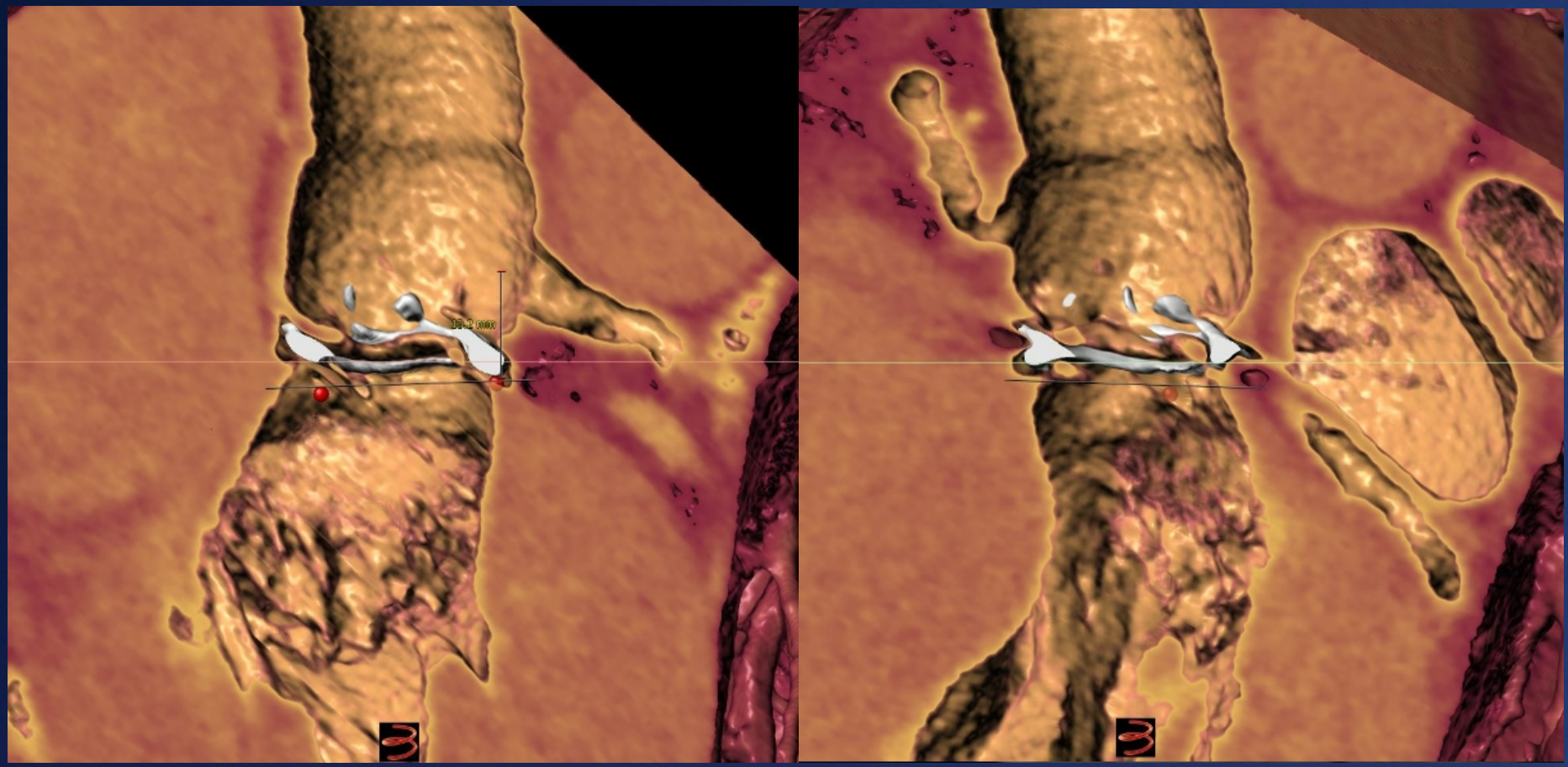
- Mean Gradient 85 mmHg
- Peak Velocity 5.7 m/sec
- AVA 0.60 cm
- LVEF 60%



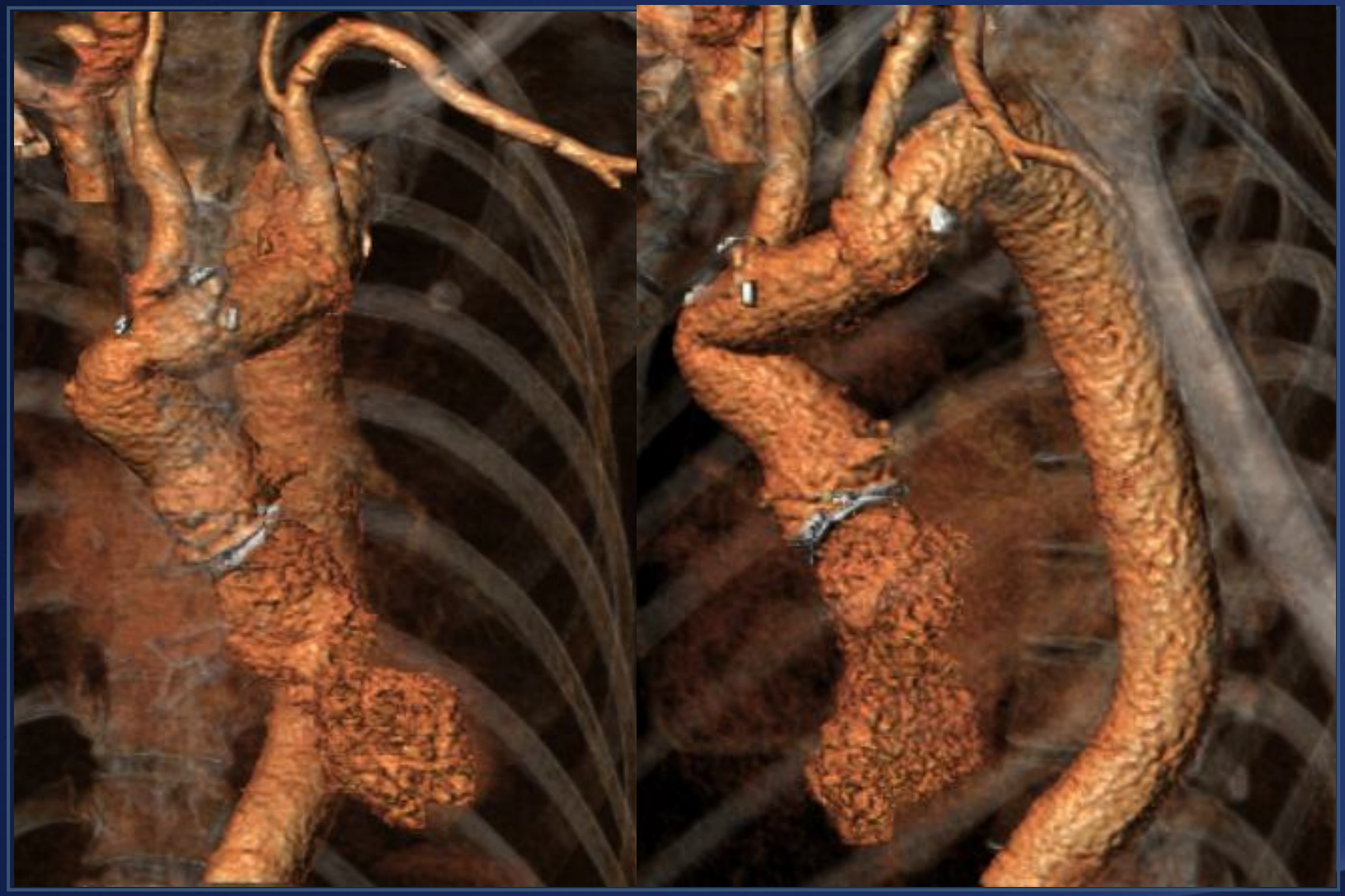
Case Presentation: CT Annular Sizing



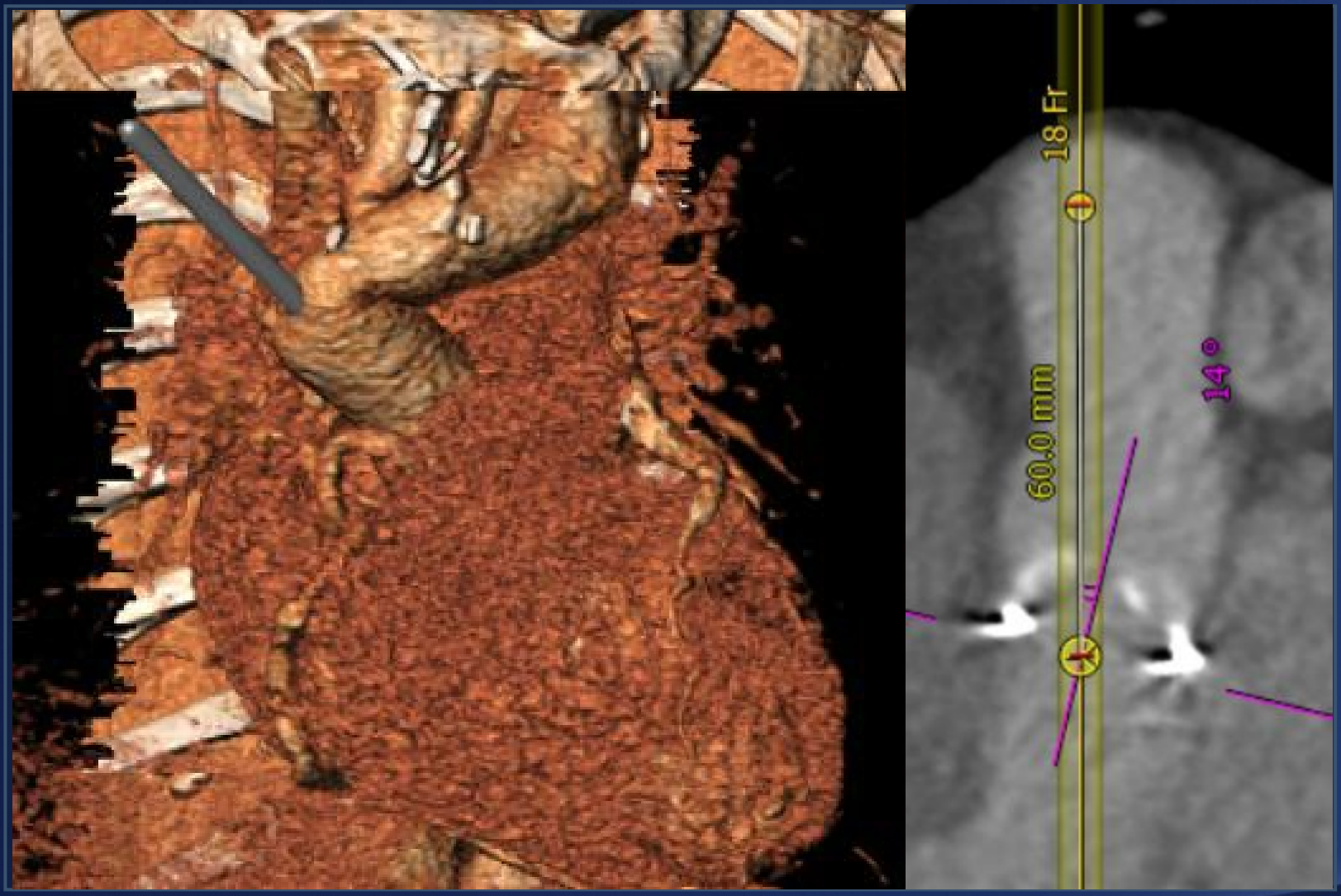
Case Presentation: CT Case Planning



Case Presentation: CT Case Planning

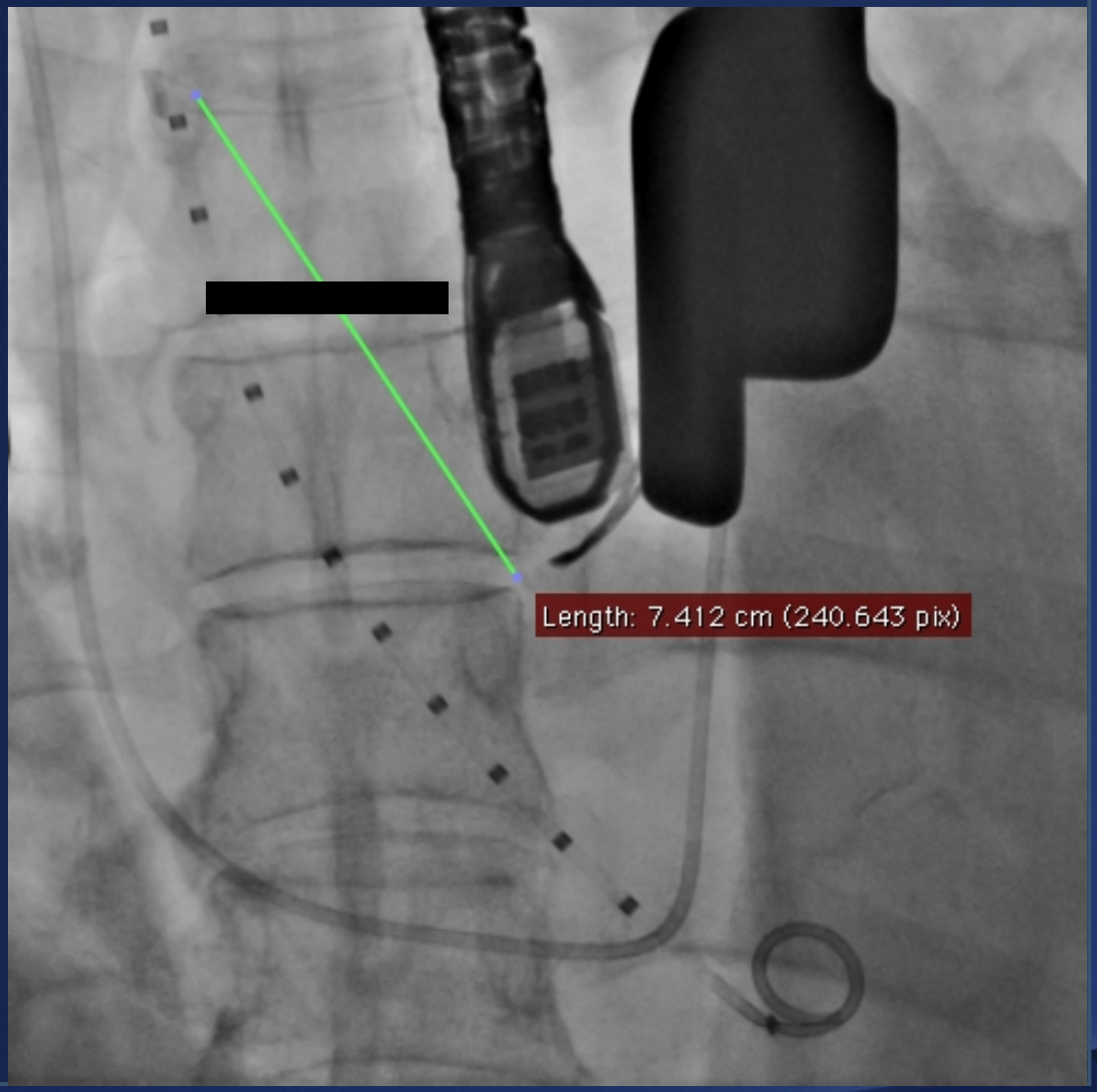


Case Presentation: CT Case Planning



Case Presentation: Procedure

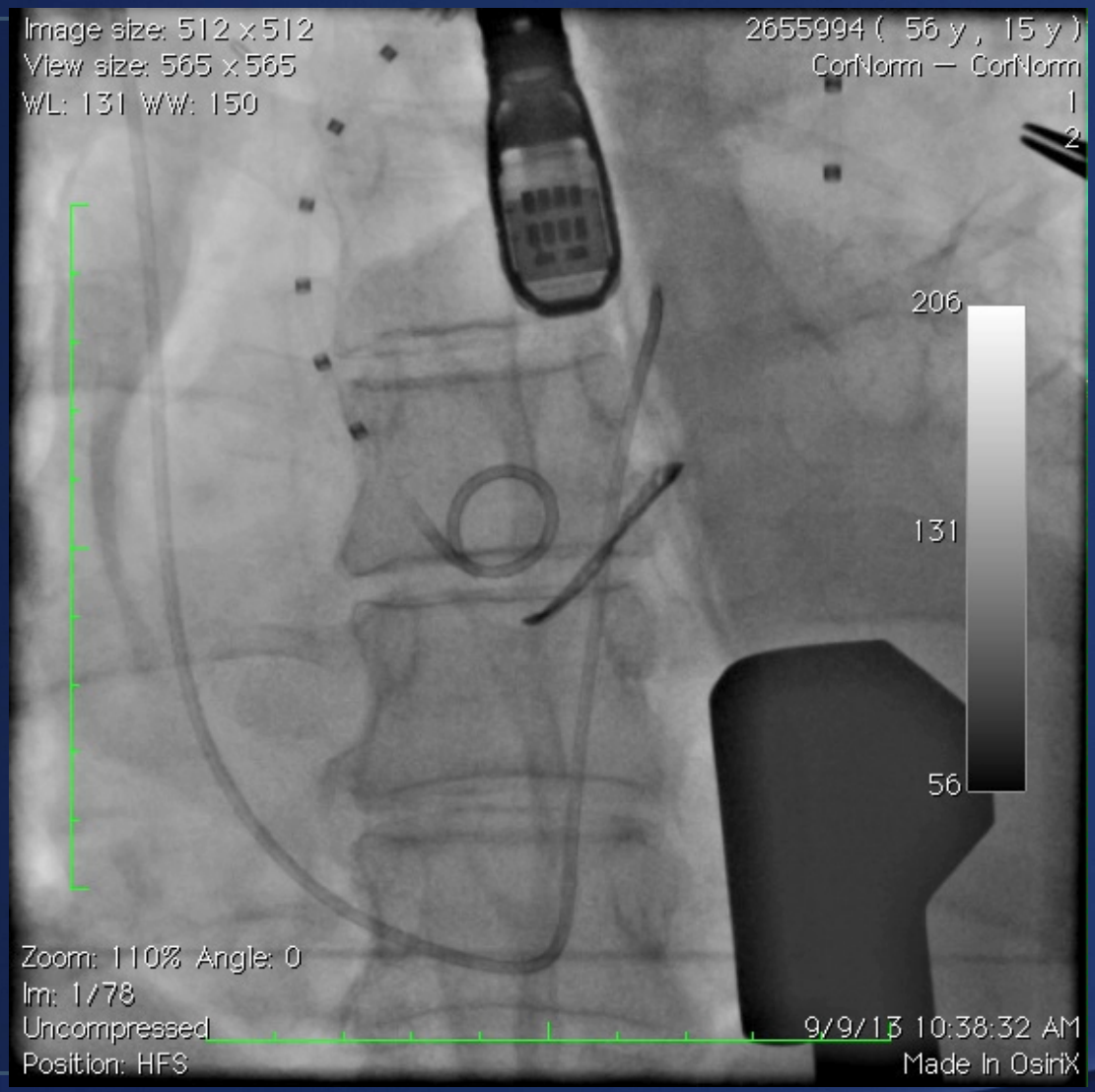
- Median sternotomy
- Clip at planned Graft purse string
- Calibrated pigtail
- Measurement 7.4 mm from insertion to valve ring



Case Presentation: Procedure

Optimal Angle to visual tangential view of annular ring

Aortography shows moderate aortic regurg and LVEDP 42 mm Hg



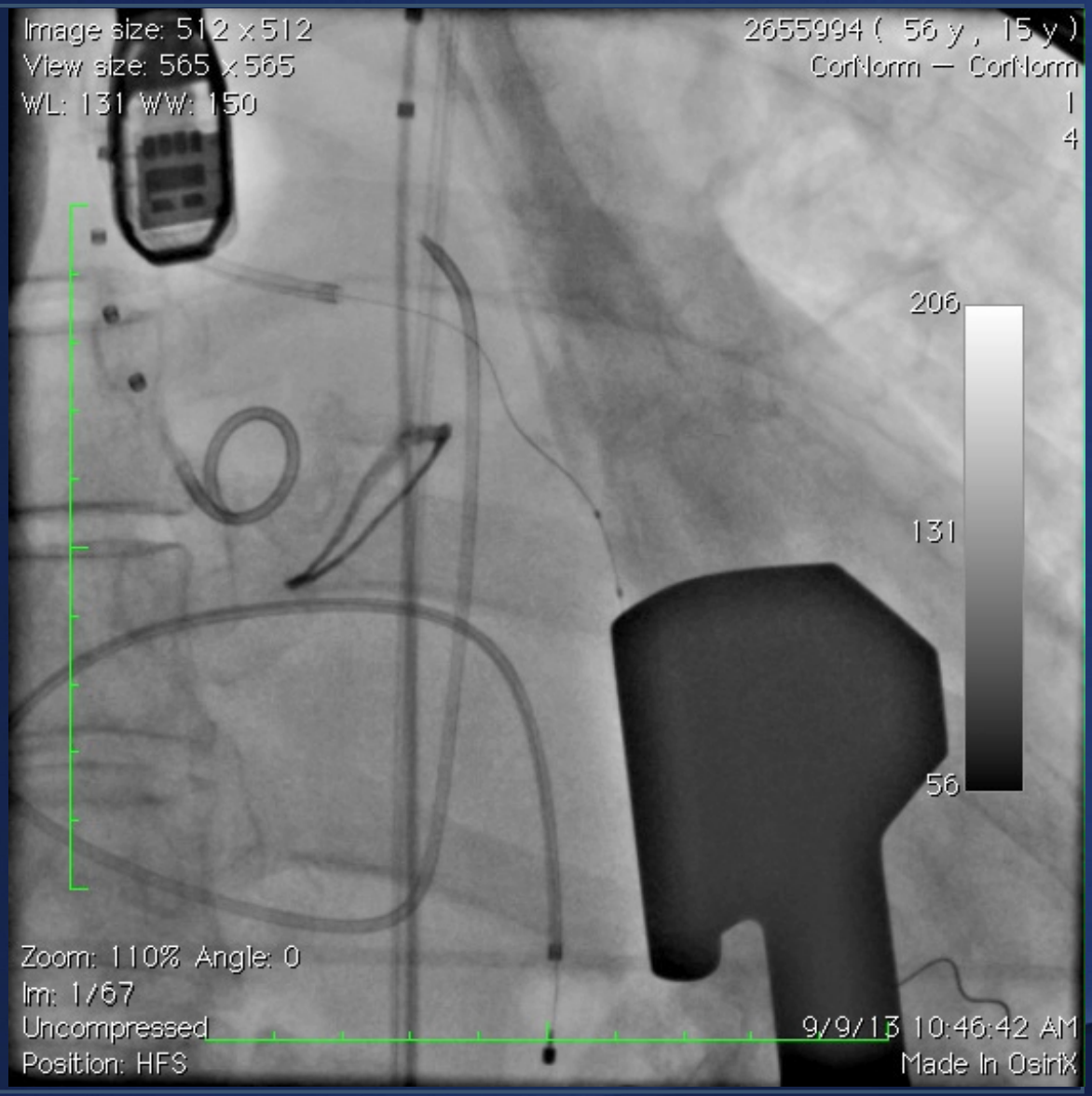
Case Presentation: Coronary Protection

6 Fr XB 3.5 Guide

0.014 wire

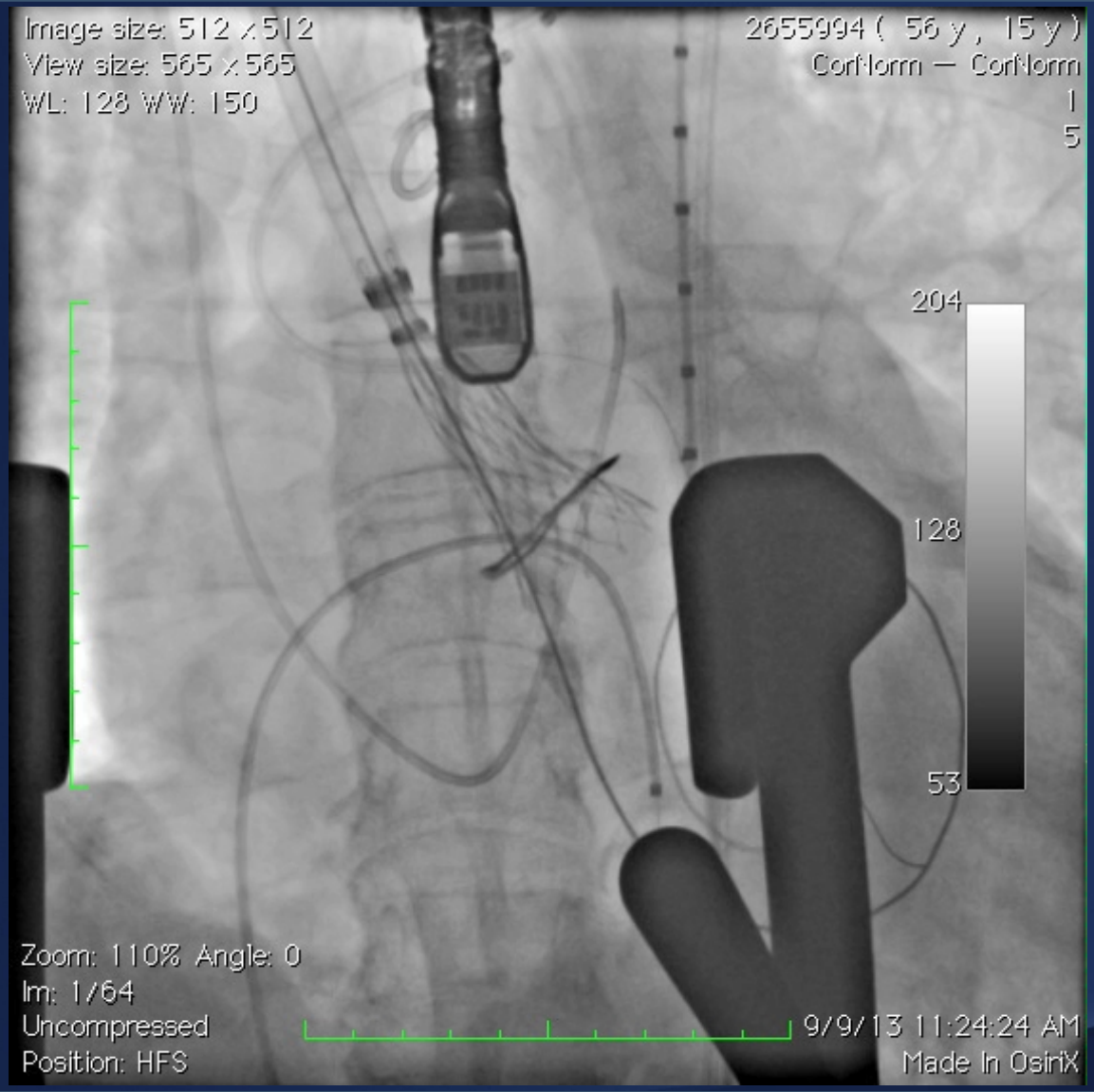
3.0 mm balloon

Guide catheter withdrawn into central aorta



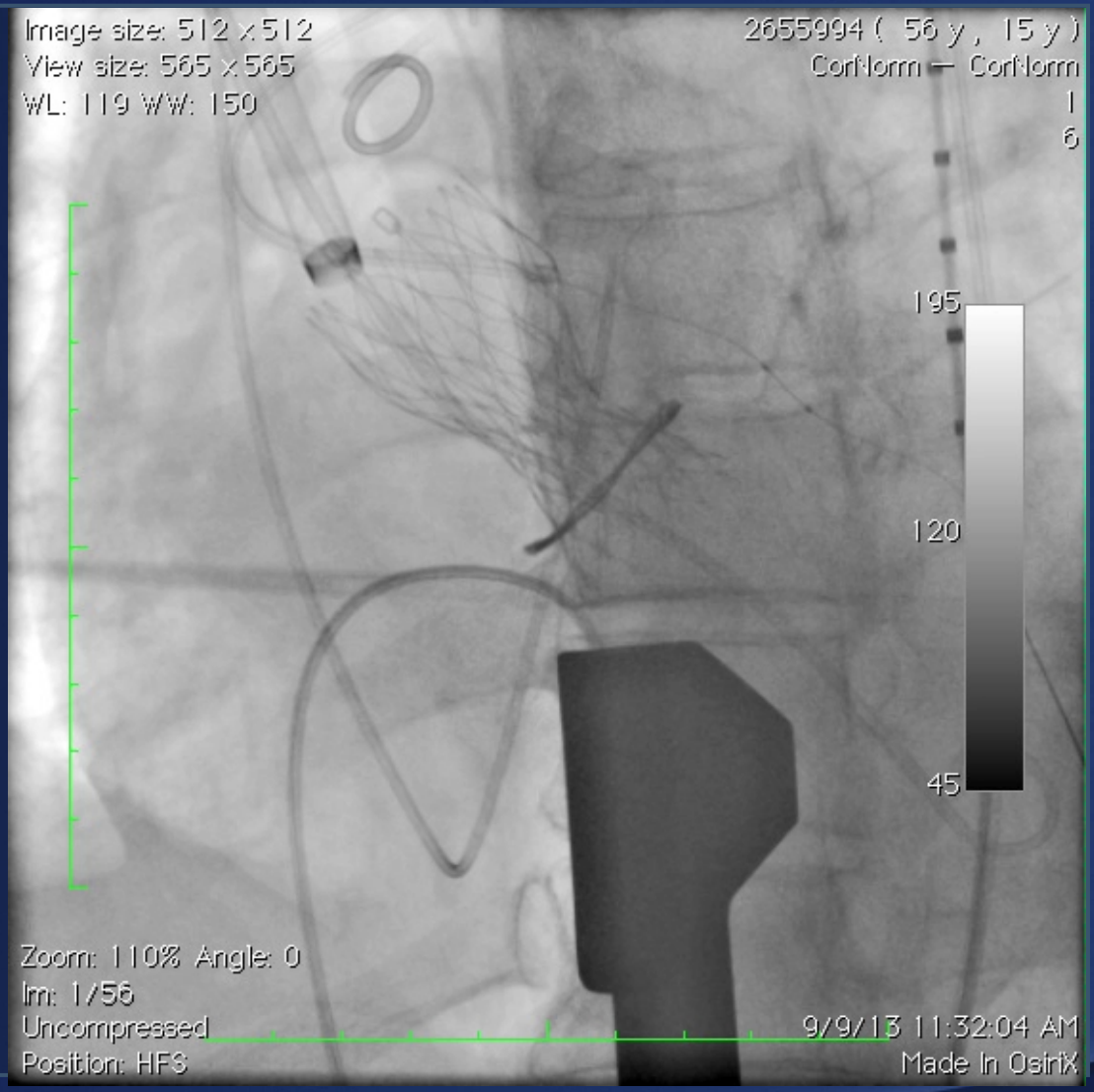
Case Presentation: Procedure

- 23 mm Evolute
- Deployment to two-thirds 4-6 mm below ring
- Pressure returns
- Check coronary patency

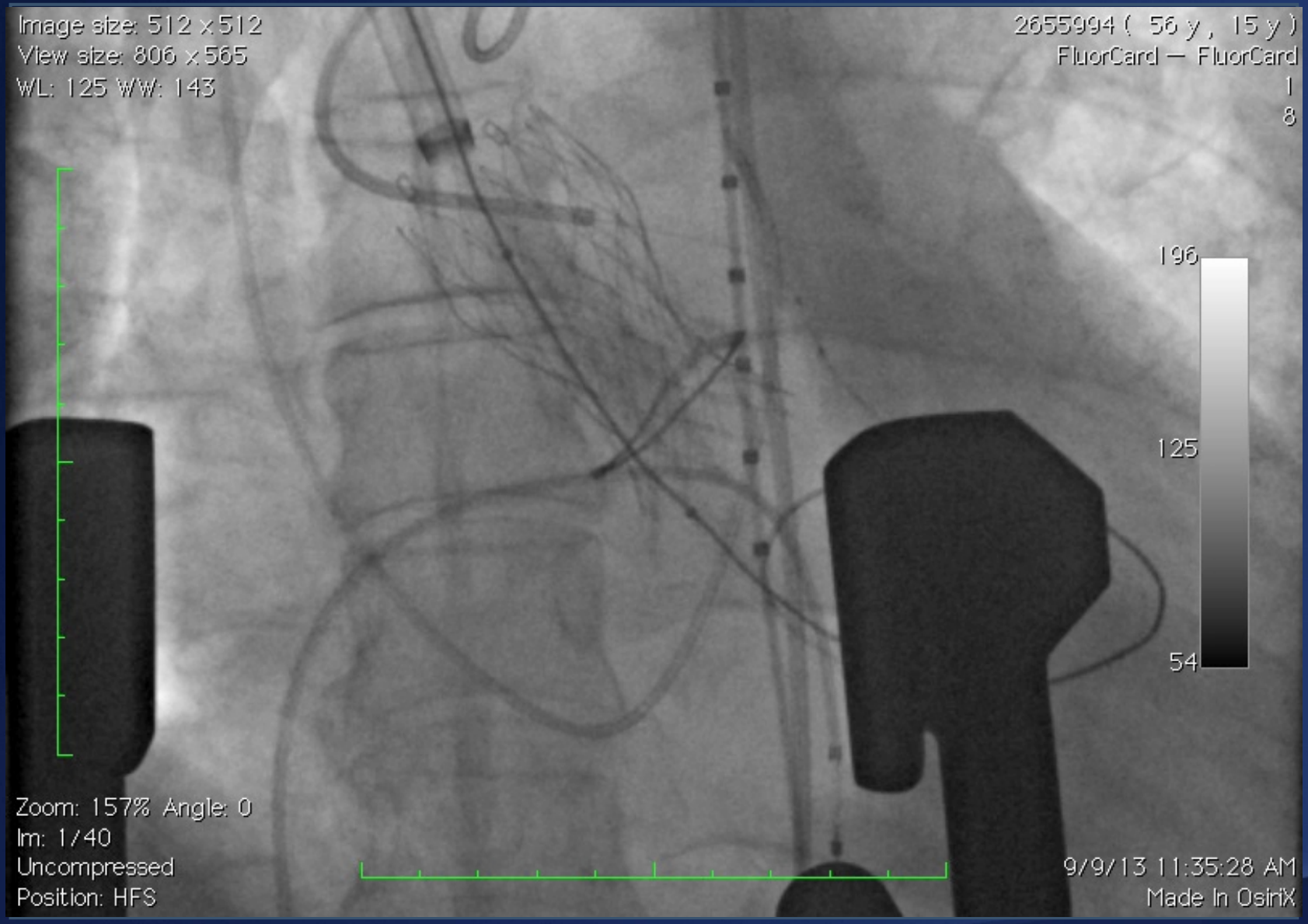


Case Presentation: Procedure

- Deployment
- Incomplete expansion
- Residual gradient 28 mmHg
- Coronaries patent



Post Dilatation Using 20 mm True

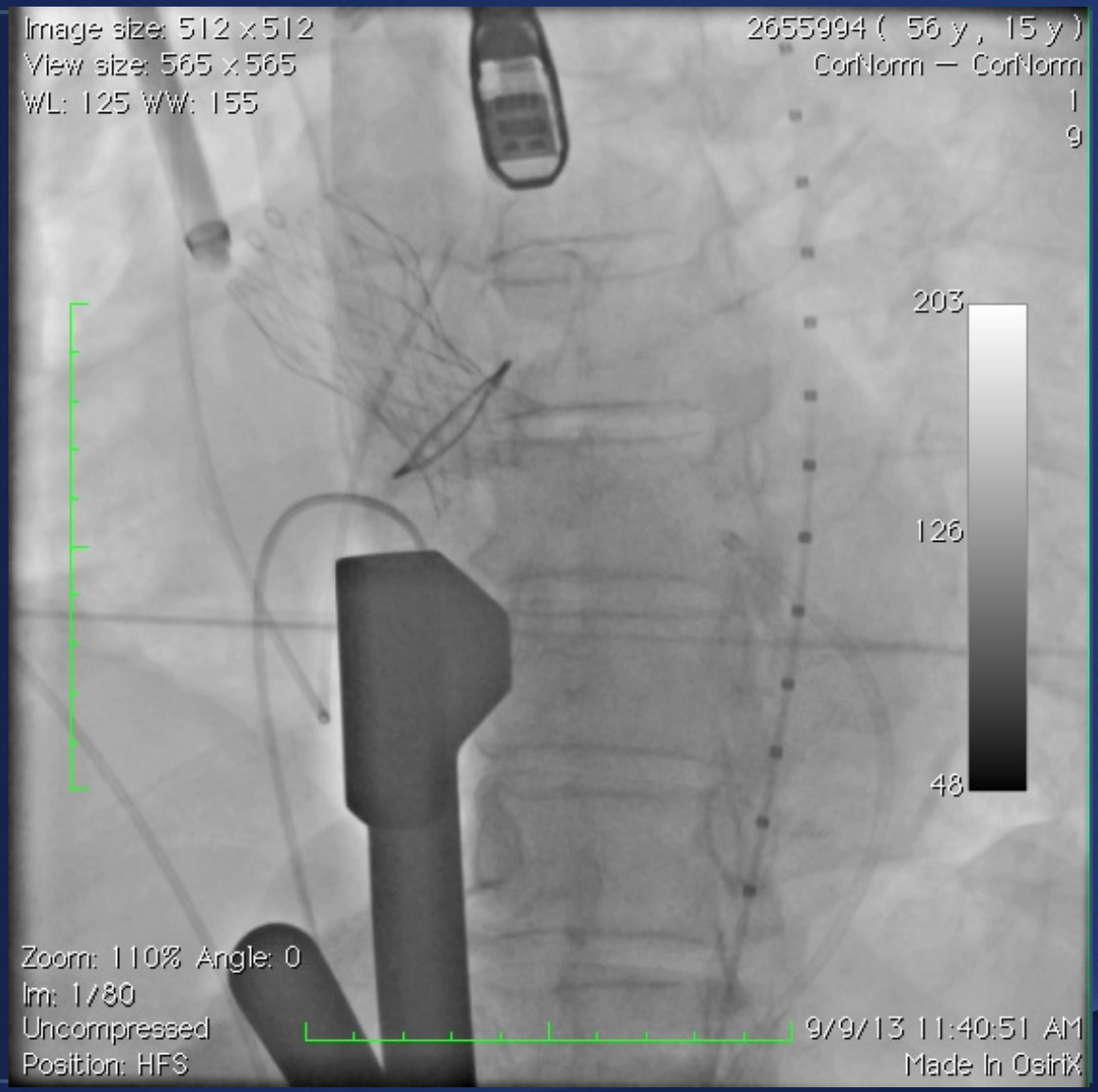


Case Presentation

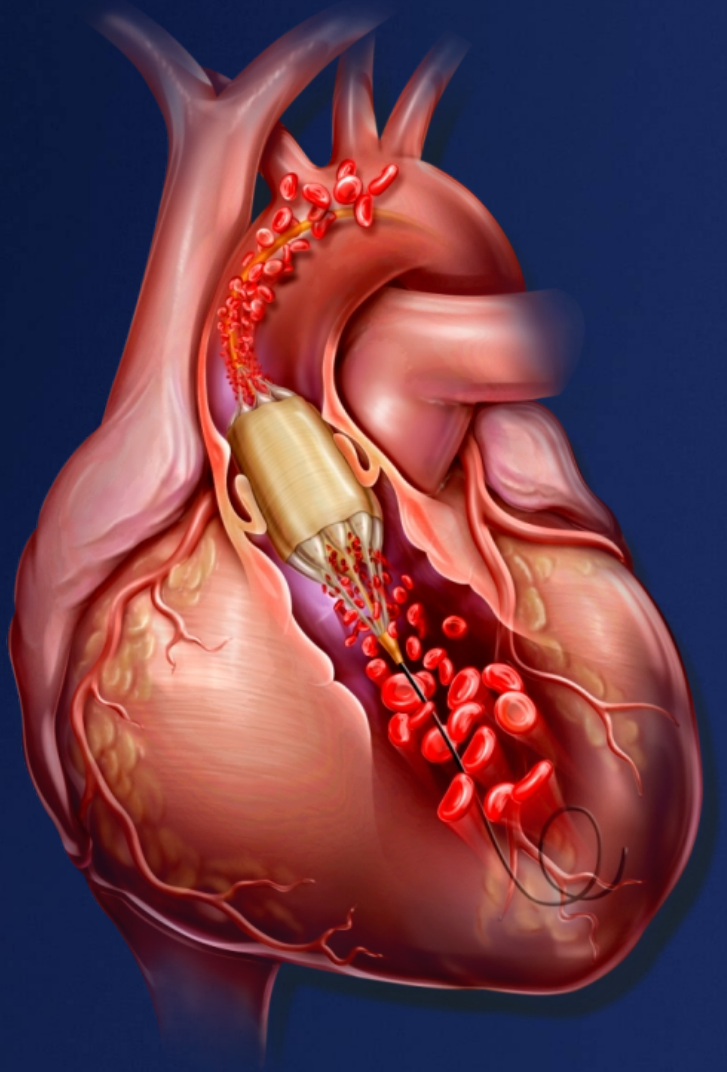
Complete Expansion

Residual gradient 20 mmHg

Coronaries patent



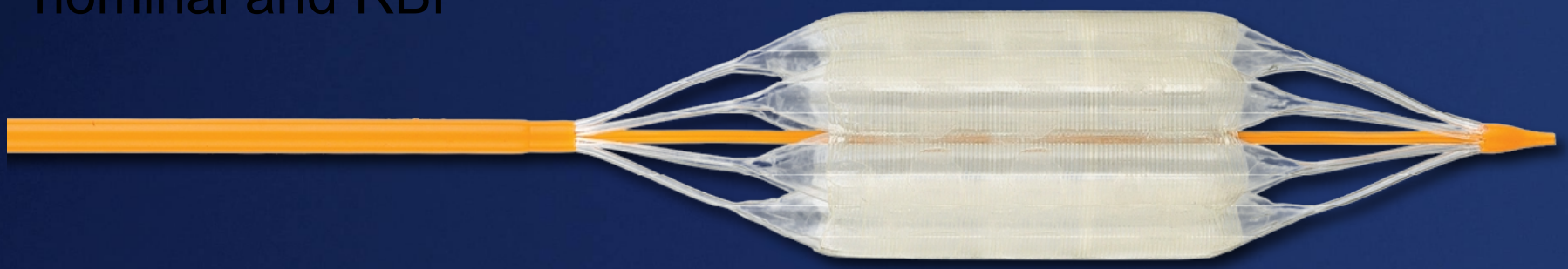
TRUE Flow Valvuloplasty Perfusion Catheter



What is needed in a next generation balloon valvuloplasty balloon is forward ventricular flow during inflation

TRUE FLOW Dilatation
Valvuloplasty Perfusion Catheter

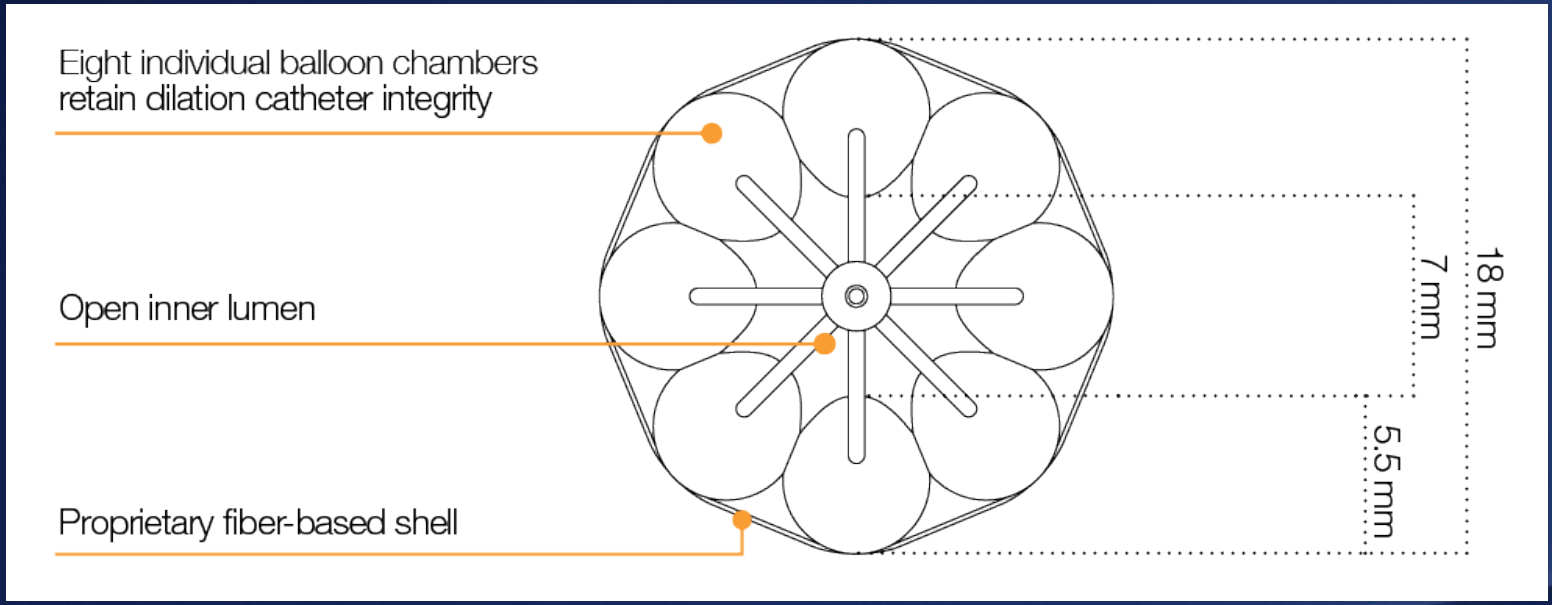
The **TRUE FLOW** Valvuloplasty Perfusion Catheter has an open inner lumen and designed to allow continuous cardiac blood flow, independent of the heart's rhythmic state[1]. The proprietary fiber technology in the outer shell of the **TRUE FLOW** balloon is designed to deliver accurate balloon sizing, with demonstrated growth rates of less than 1.0% between nominal and RBP



1. US and EU markets, as of Feb 2016
2. Data for competitive balloon obtained from manufacturer IFUs. Data for TRUE® FLOW based on bench data, on file at Bard Peripheral Vascular, Inc., Tempe, Arizona. Percentage stretch calculated using 20mm balloons.

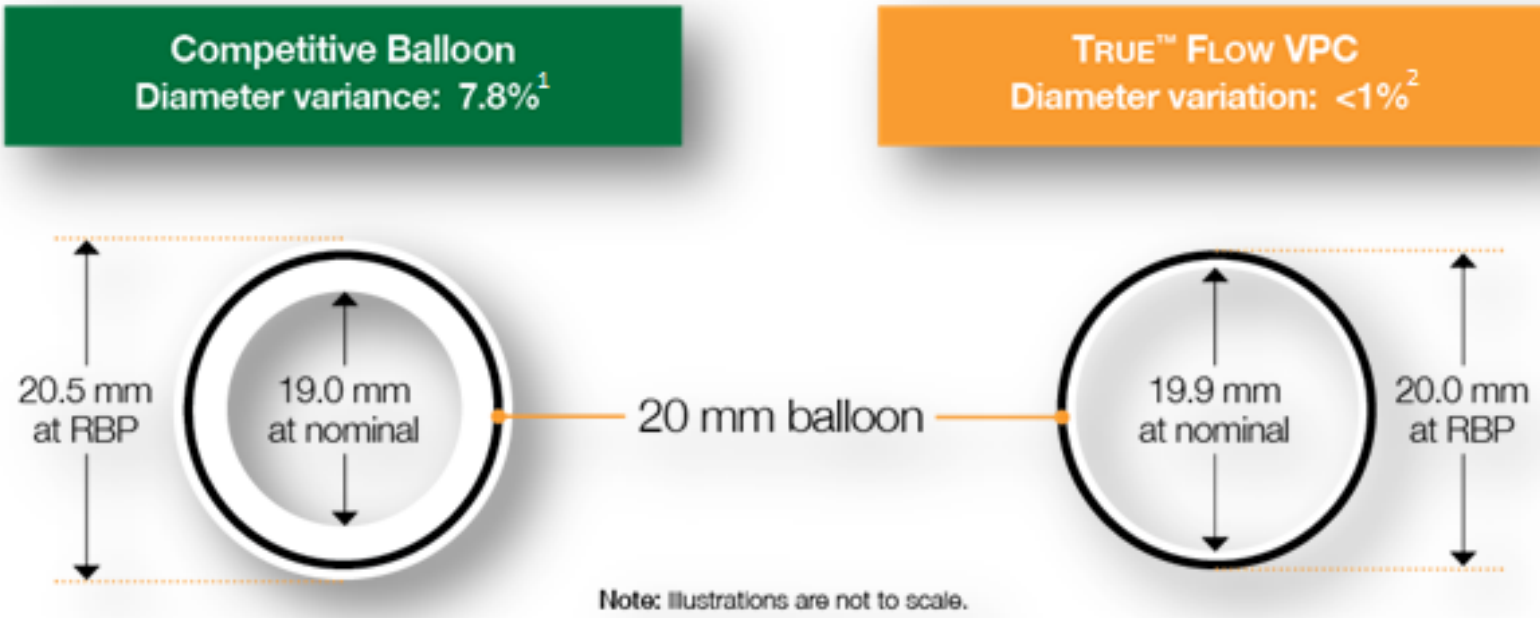
Designed to Allow Continuous Blood Flow

The **TRUE FLOW** balloon contains an open inner lumen and is designed to allow blood to flow through while inflated, independent of the heart's rhythmic state. Eight individual balloon chambers retain dilation catheter integrity, and are wrapped in a rupture resistant fiber-based shell.



Dimensions for an 18 mm balloon. More sizes are available.

The Science
Precision



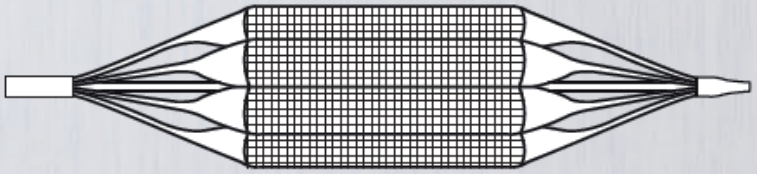
1. Z-Med™ II 20 mm balloon. Variance calculated using nominal and RBP measurements listed in manufacturer IFU.
2. Based on simulated bench testing for 20 mm True™ Flow balloon, N =30. May not be indicative of actual clinical performance. Data on file at Bard Peripheral Vascular, Inc., Tempe, Arizona. Different tests may yield different results.

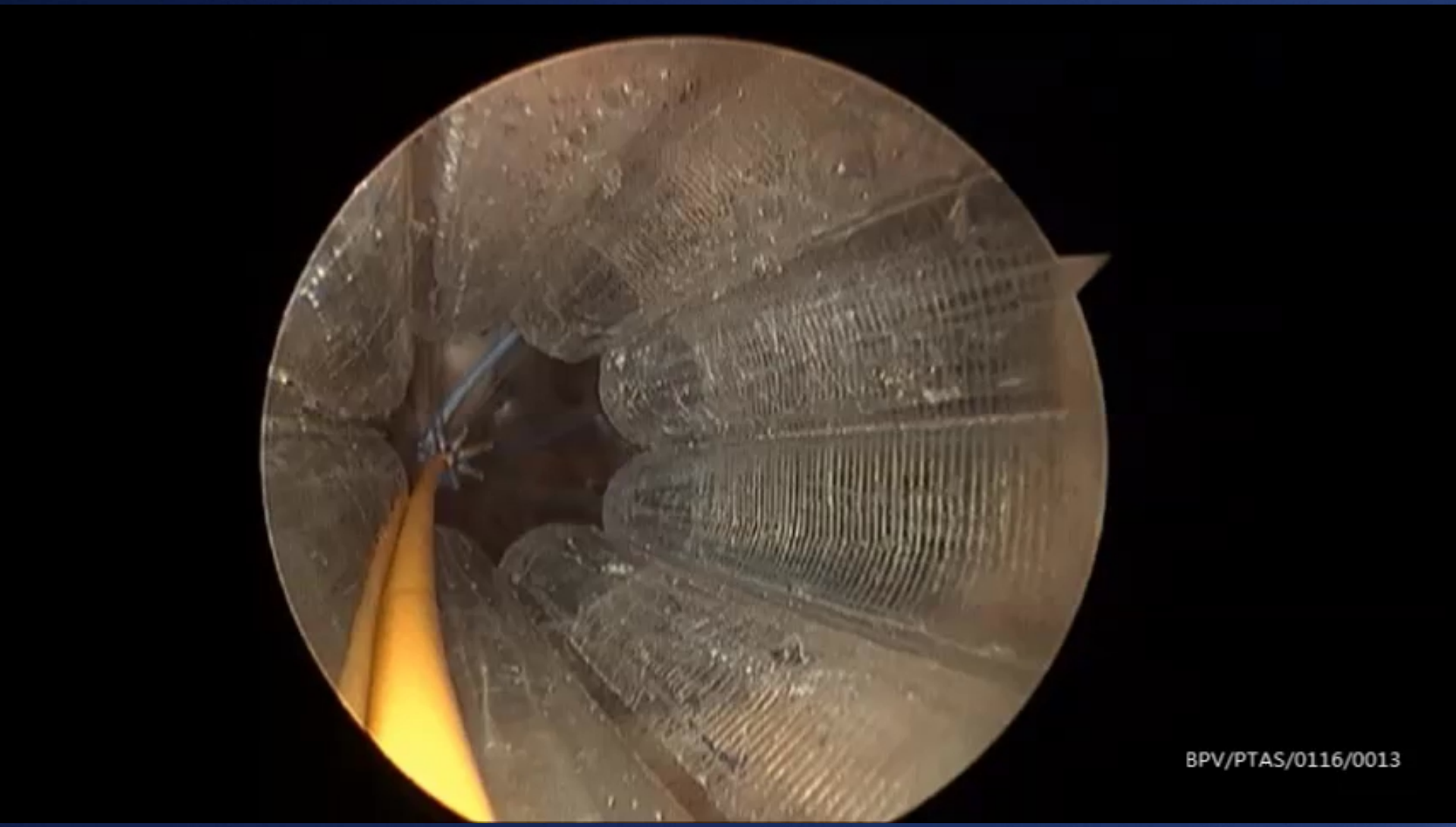
TrueFlow Fiber Technology

The **TRUE FLOW** Valvuloplasty Perfusion Catheter utilizes the same proprietary fiber technology as the TRUE Dilatation Balloon Valvuloplasty Catheter. The fiber-based shell of the **TRUE FLOW** balloon is designed to be rupture resistant and inflate to precise diameters.

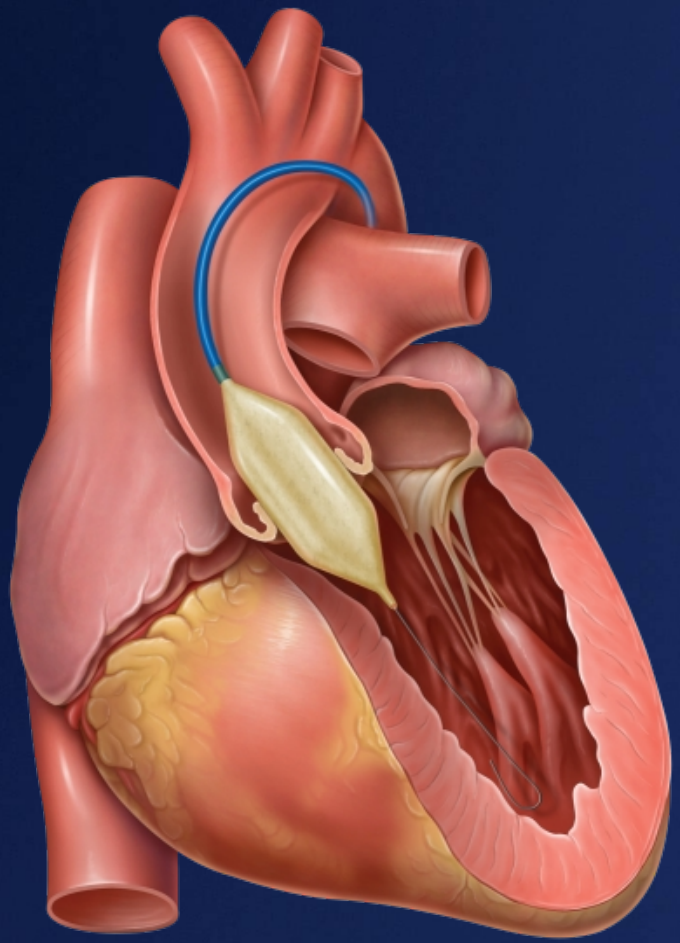
Competitive Balloon
Exterior material: Polyethylene (PET)

TRUE™ FLOW VPC
Exterior material: Fiber-based shell




BPV/PTAS/0116/0013

Why True and TrueFlow?



Short Length
Rapid Inflation
No Growth
No Rupture

? No need for pacing