

# **The Abbott Vascular Bifurcation Program: Transitioning Pathfinder to the Xience S.B.A. Platform**

**David G. Rizik, M.D., F.A.C.C., F.S.C.A.I.  
Director of Interventional Cardiology  
Scottsdale Heart Group at Scottsdale Healthcare Hospitals**

# Disclosure

- **Cordis Scientific Advisory Panel**
- **Abbott Medical Advisory Board**
- **Boston Scientific: Research Support**
- **TherOx Scientific Panel**
- **InfraRed X Advisory Panel**
- **TriReme Medical Scientific Advisory Board**

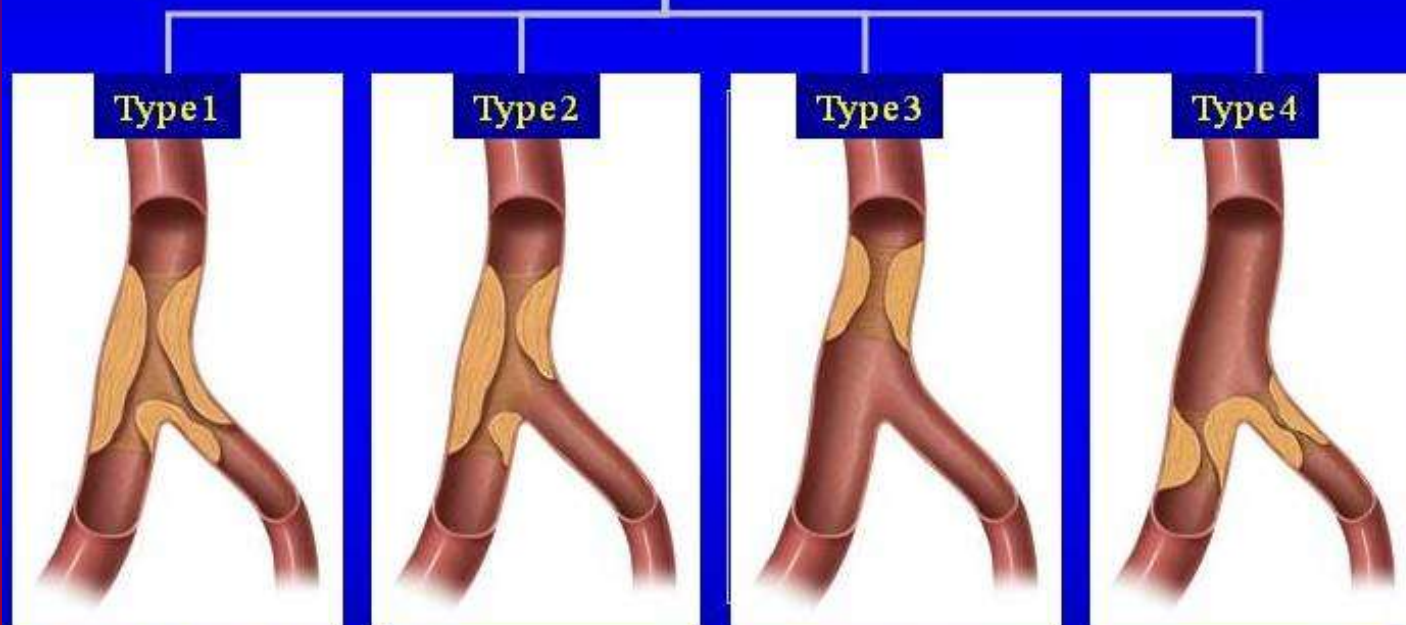


# Overcoming Obstacles

## Heterogeneity of Bifurcations



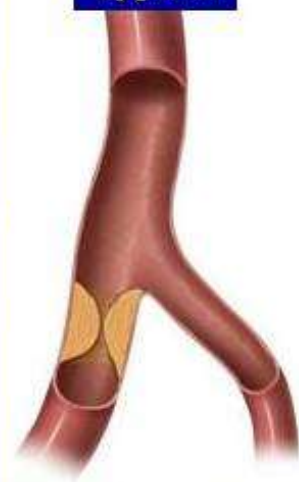
### Plaque Distribution



True bifurcation

Pseudo-bifurcational lesions:  
*PCI treatment of main vessel lesion can  
cause plaque shift into side branch*

Type 4a



Type 4b



# **Dedicated Bifurcation Stents**

- 1. StentYs**
- 2. Devax AXXESS Plus**
- 3. Minvasys Nile**
- 4. Invatec Twin Rail**
- 5. Y Med Sidekick**
- 6. Taxus Petal**
- 7. Medtronic Y stent**
- 8. TriReme Medical Anatres Stent**
- 9. Tryton**
- 10. Capella**
- 11. Xience S.B.A.**
- 12. Advanced Bifurcation Systems M&D System**



# Dedicated Devices

- Main Branch Only: **Devax Axxess, Stentys**
- Side Branch Only: **Tryton, Capella Sideguard**
- MB + SB: **Petal (Boston Sci), Medtronic Y Stent, Advanced Bifurcation Systems M&D**
- MB Stent with SB Access Port: **Y-Med sideKick, TriReme Medical Antatres System, Xience S.B.A.**





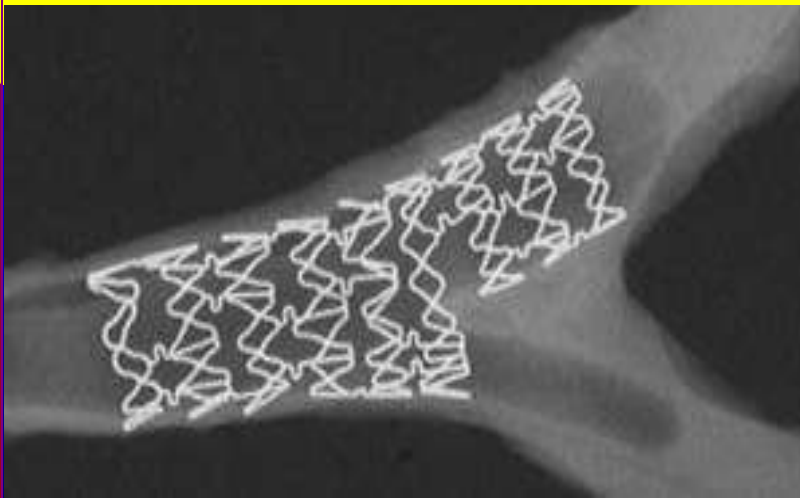
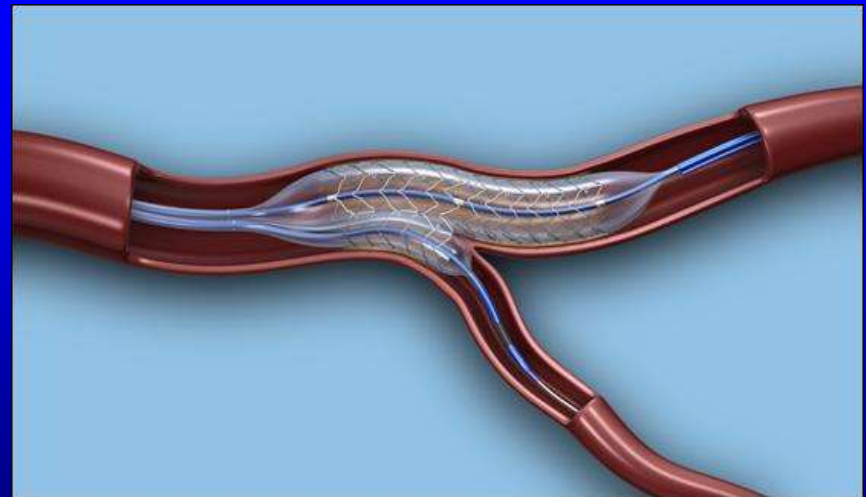
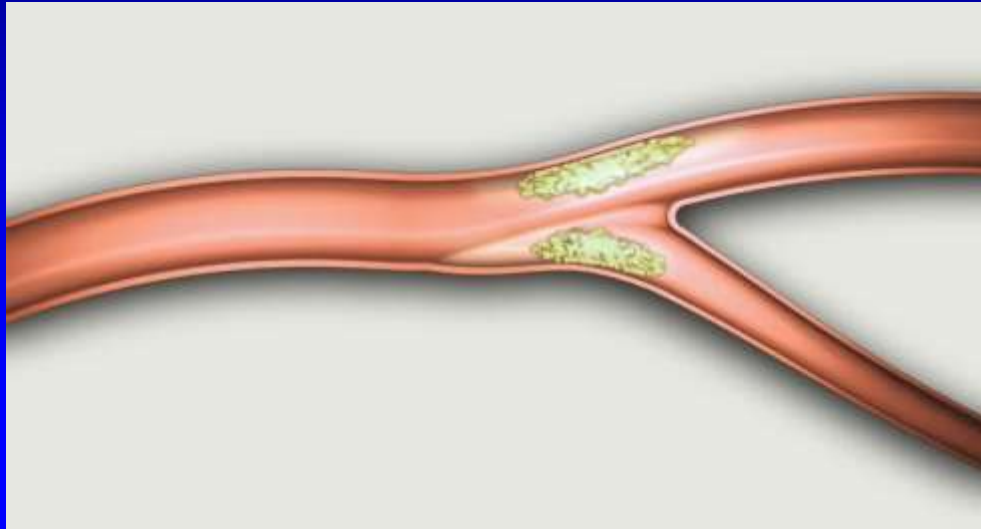
**\*\* The device formerly known as **Frontier & Pathfinder****

**\*\* Design & profile issues and therefore the practical conversion of the Frontier Catheter to Abbott's **Xience V** platform**

**\*\* Identical to **Xience V** in terms of metal, strut thickness, polymer, drug, elution kinetic**

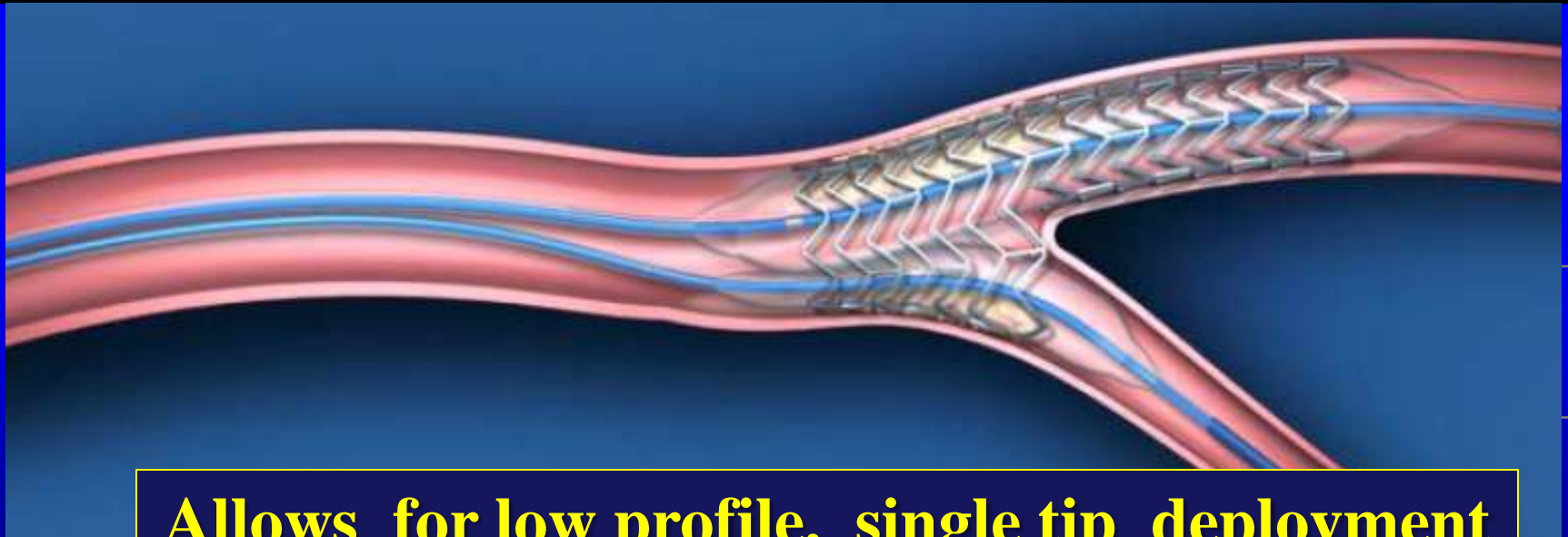
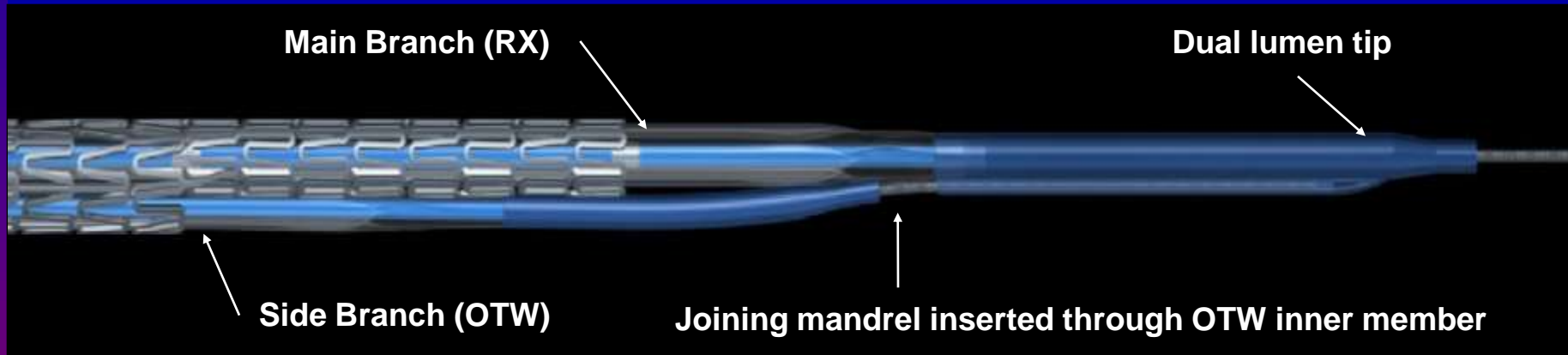
# Xience SBA Program

## Legacy of the Guidant Initiative

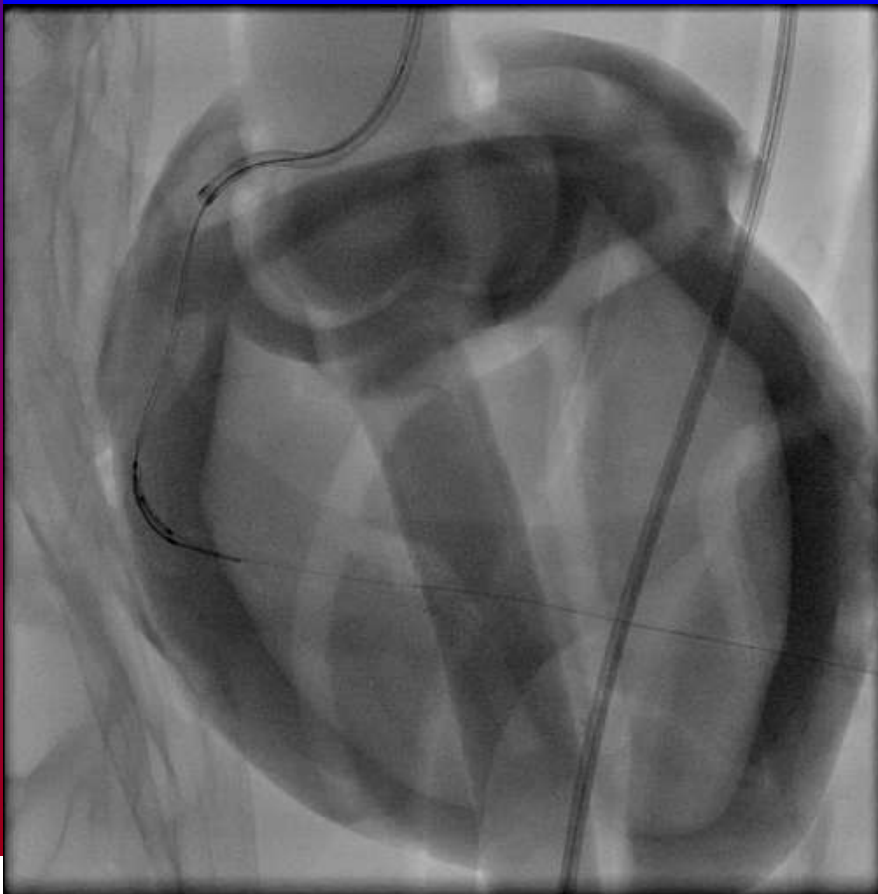
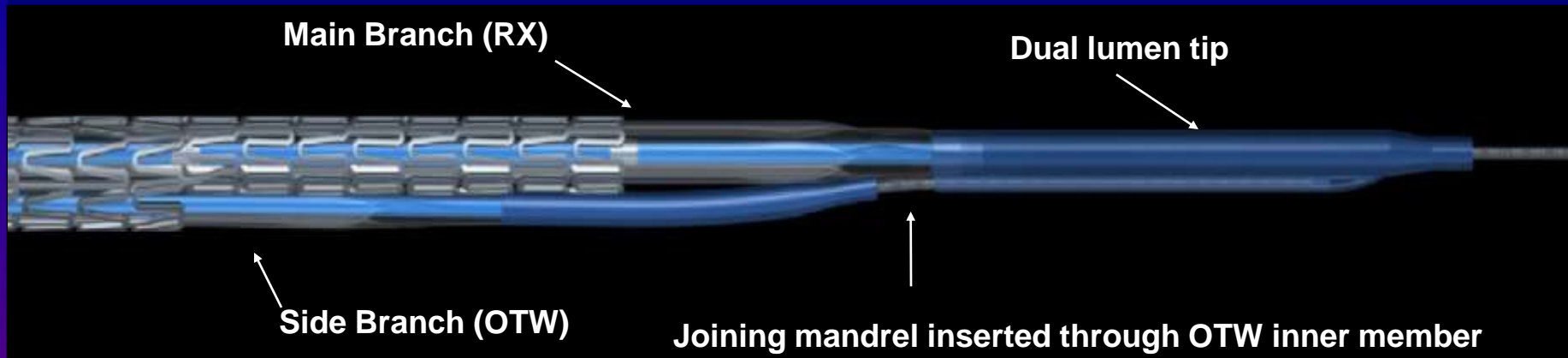


# Xience SBA Program

Based Upon MULTI-LINK® FRONTIER™ Concept

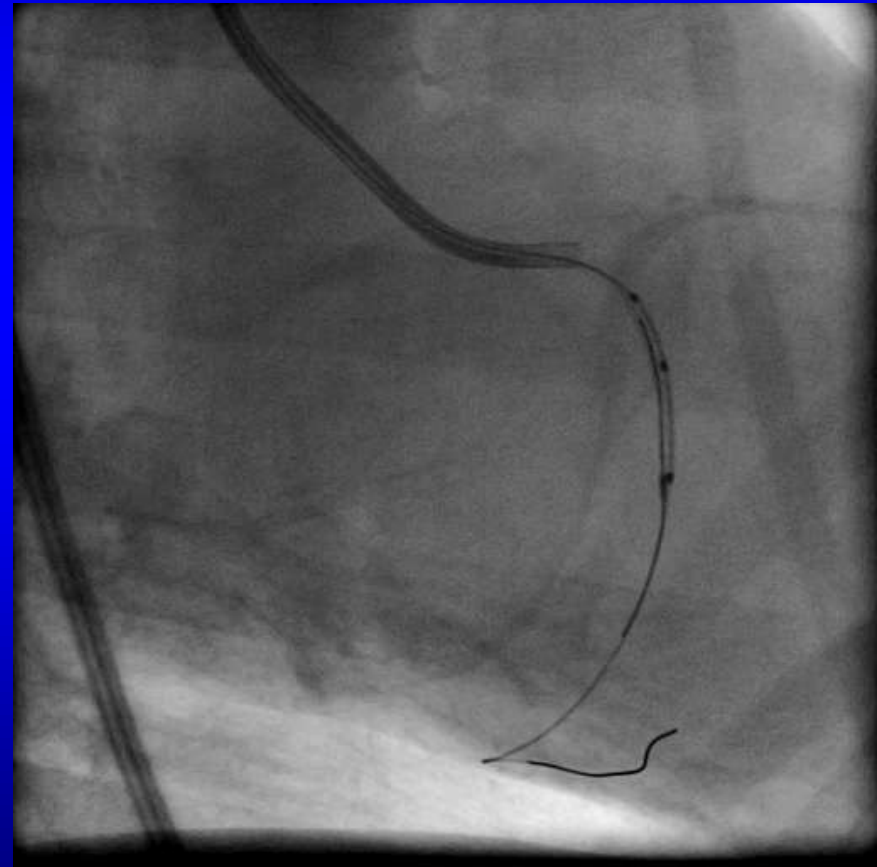
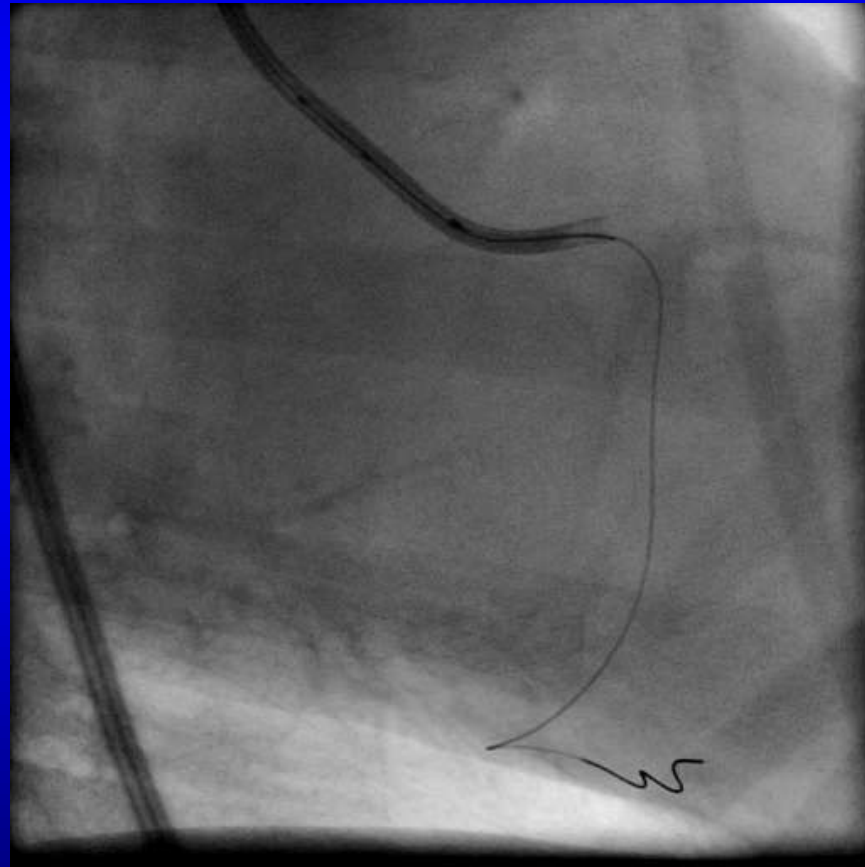


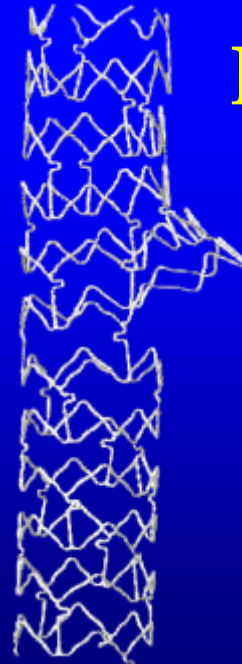
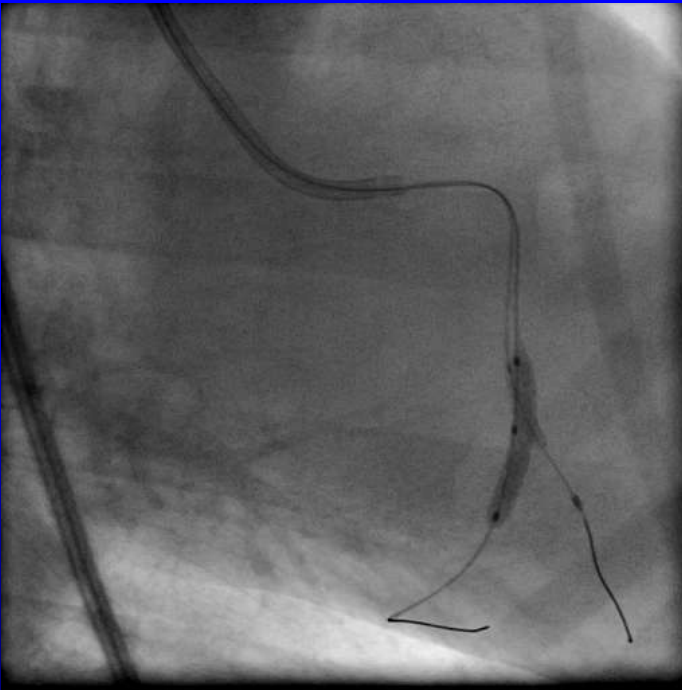
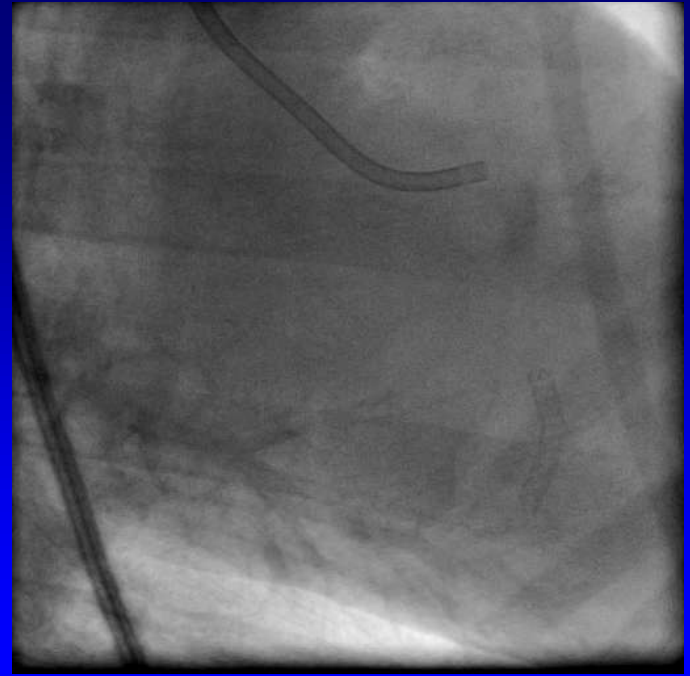
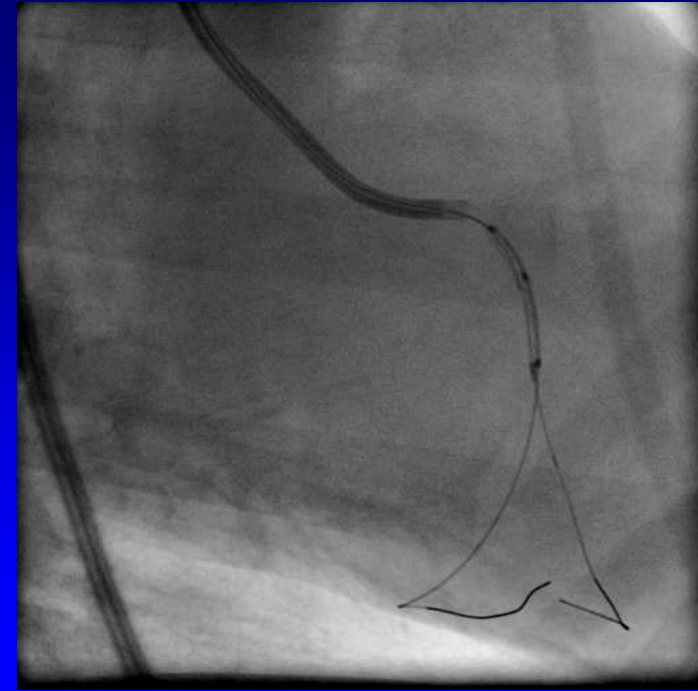
**Allows for low profile, single tip deployment**





# Pre-Clinical Experience in Ovine & Perfused Synthetic Heart Models

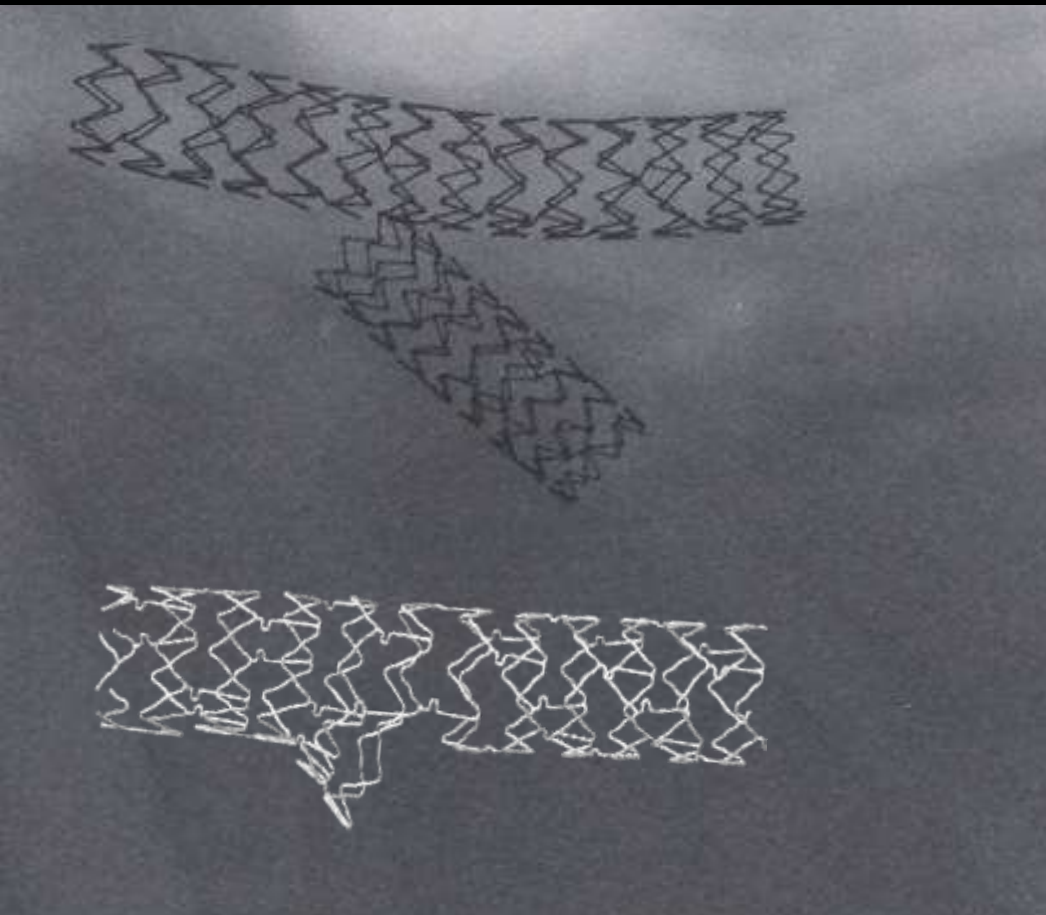




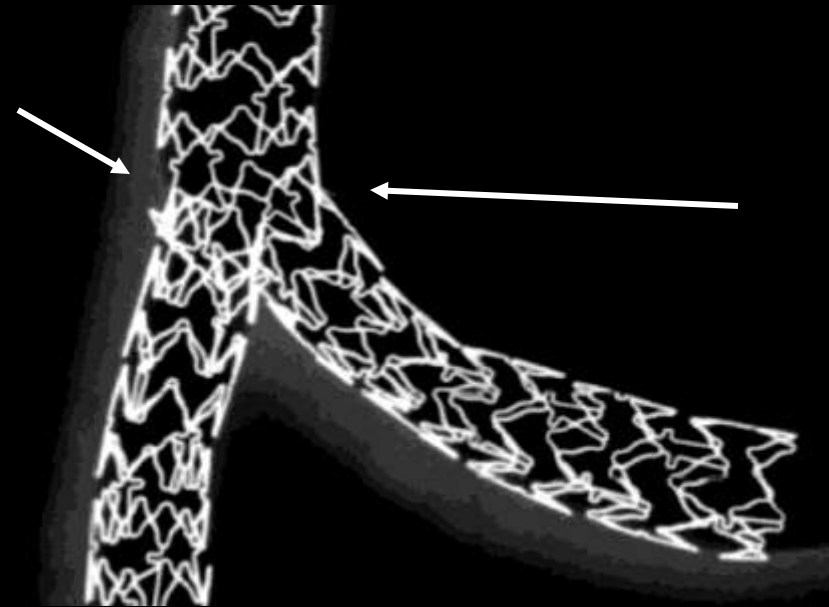
**Portal opening  
into S.B.**



stenting) as well as dedicated angle overlap into the main ending into the side branch

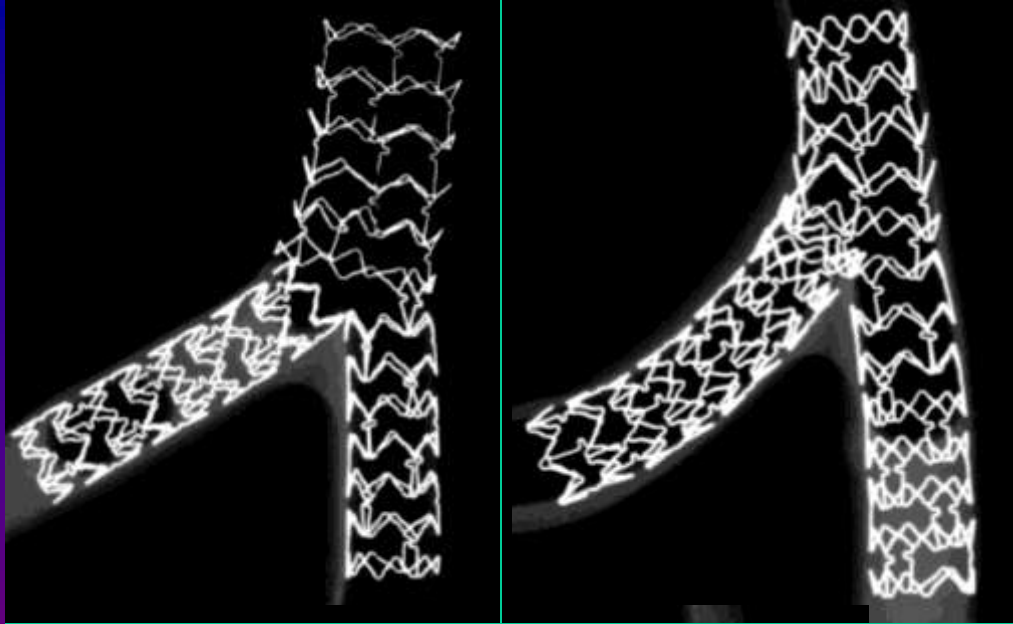


**Provisional T Stenting with overlap into the main branch**

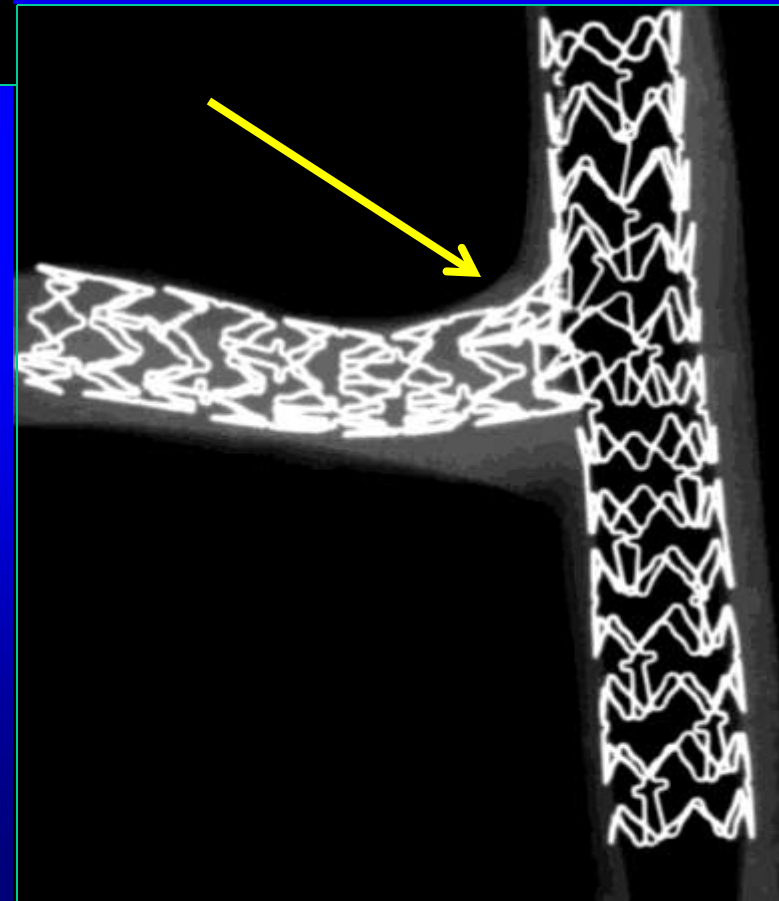
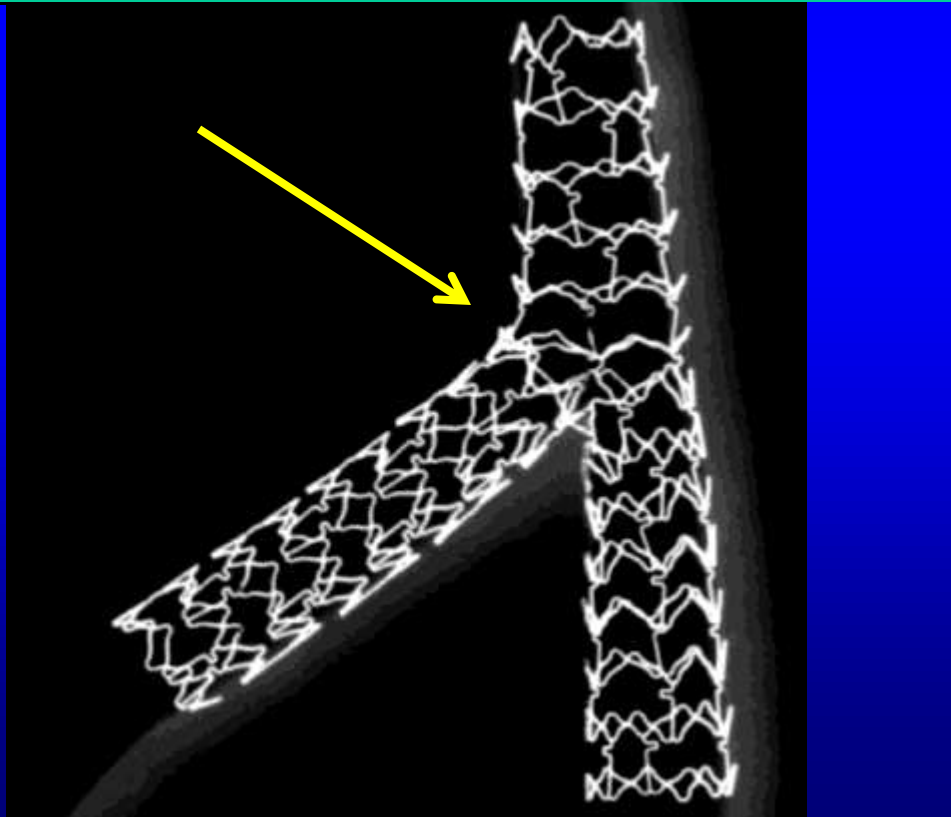


**There is overlap of the side branch stent into the main branch, occupying over 50% of the main branch lumen. This is the nidus for restenosis and stent thrombosis**





**Xience S.B.A.: good ostial  
SB coverage without ostial  
gap and without main  
branch overlap**





# Bench & Ovine Deployment Studies

Abbott Xience SBA system compared to Provisional T-stenting in PVA perfused synthetic heart models

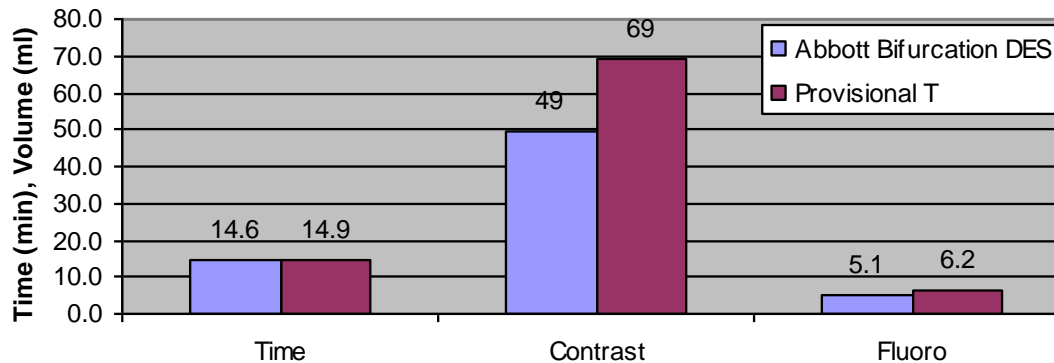
In this bench top model the Xience SBA system reduced **contrast** usage by approximately **30%**

**Fluoro** time was **17%** less with SBA use

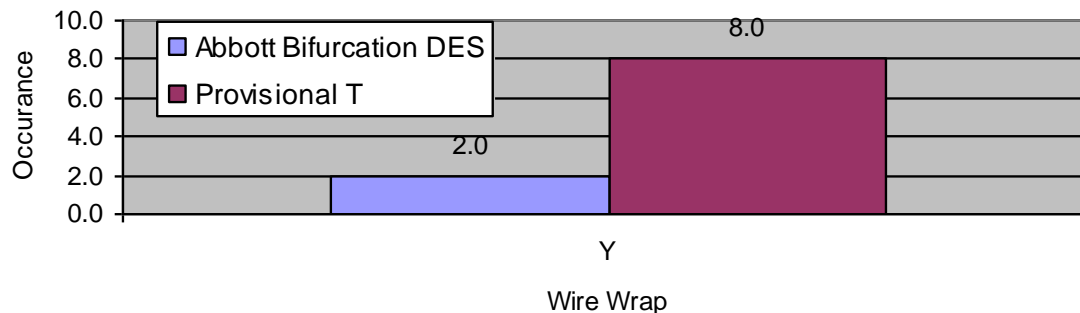
The SBA system reduced **wire wrap** by **75%**

January 2010; JOIC

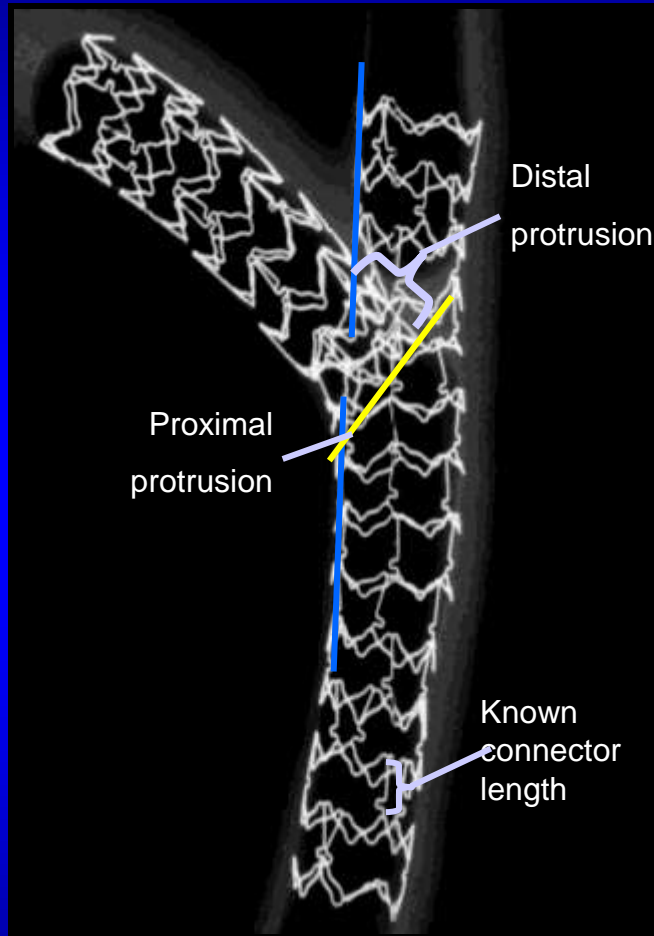
Total Procedure



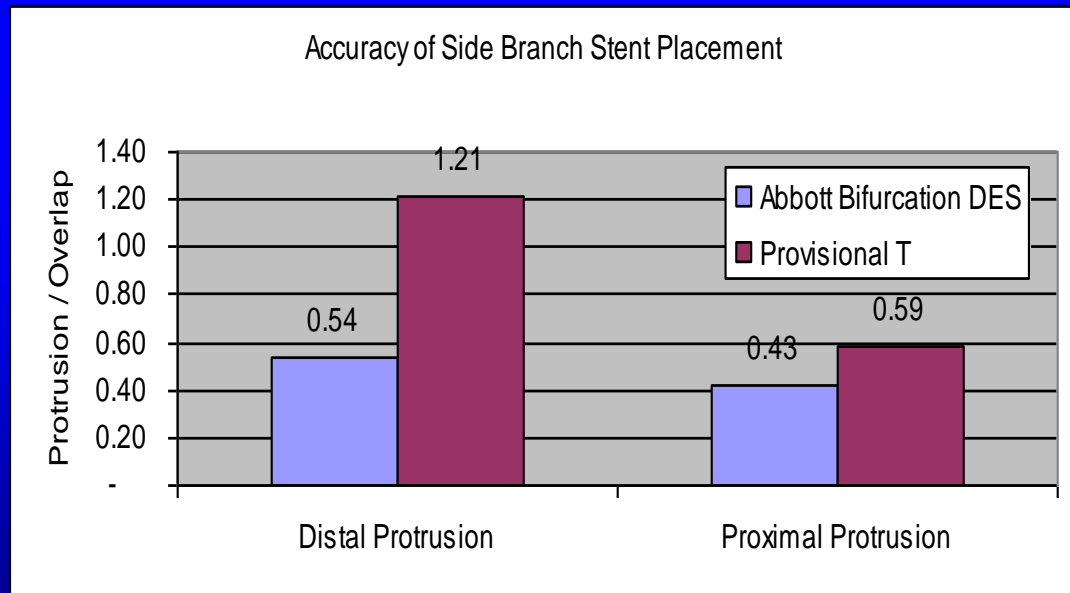
Wire Wrap throughout entire procedure



# Bench Deployment Study Results



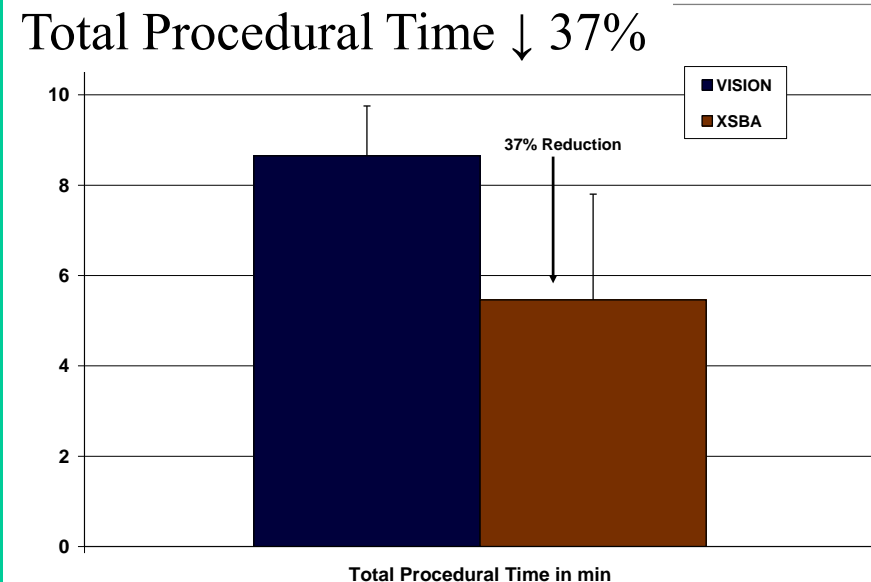
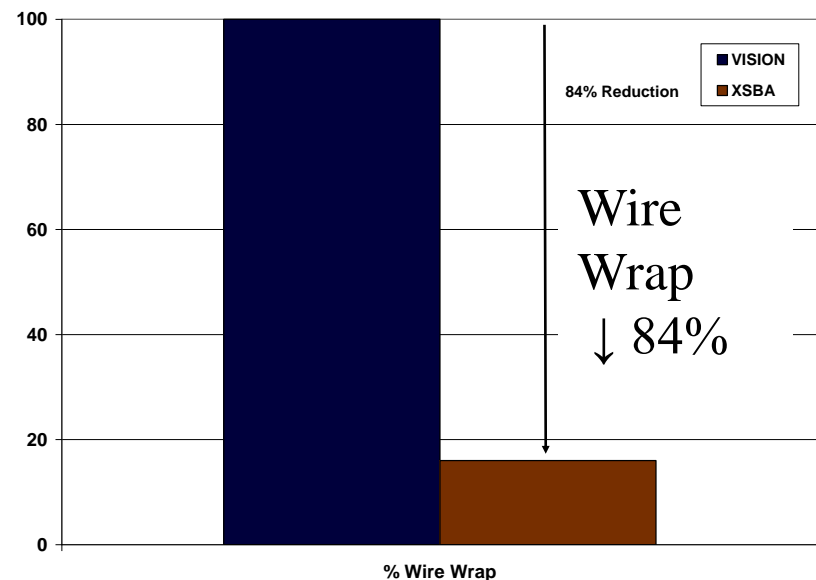
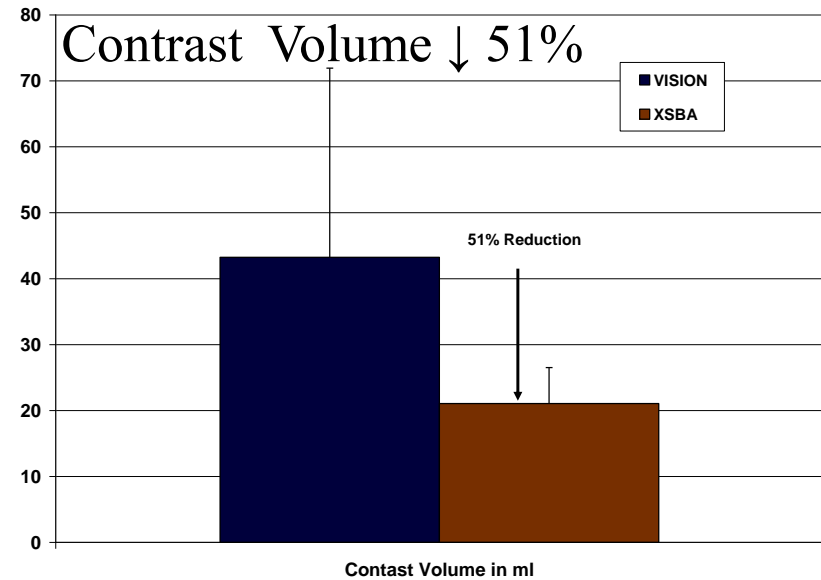
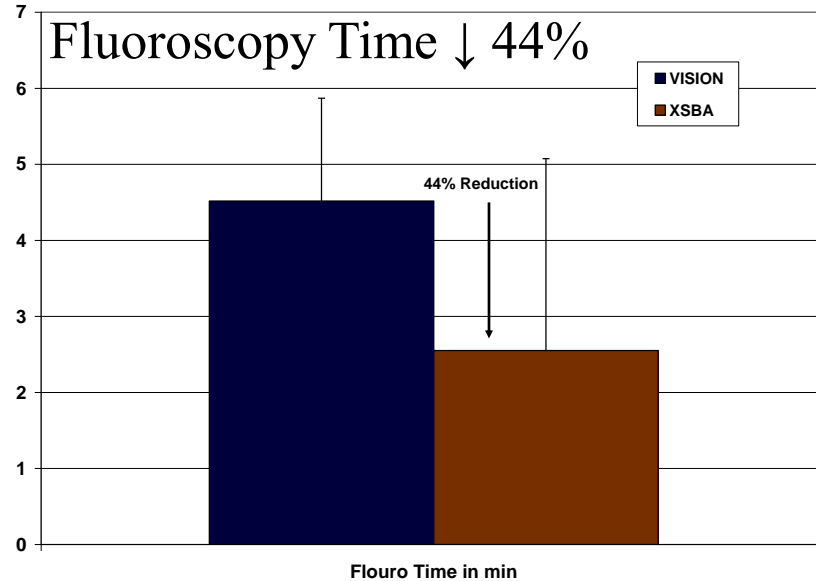
Compared with Provisional T-stenting, the Xience SBA system was associated with **less distal protrusion** into the main branch when side branch stenting was performed (**1.21 mm versus 0.54mm**)



\*\*\* Measurements utilizing known dimensions of the stent struts and connector length

Jan. 2010; JOIC

# Ovine Beating Heart Study: XSBA vs. Provisional T-Stenting

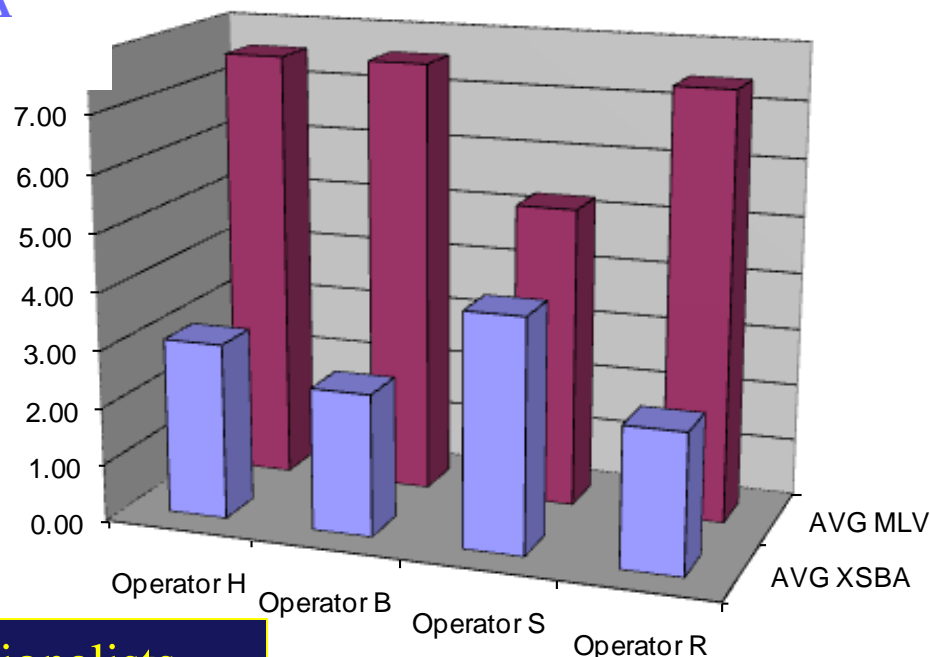


# Ease of Use Multiple Operator Study

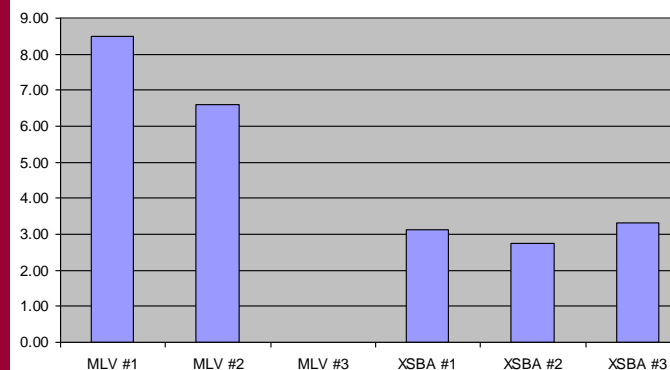
## Xience SBA vs. Workhorse Stent

**Workhorse**  
**X-SBA**

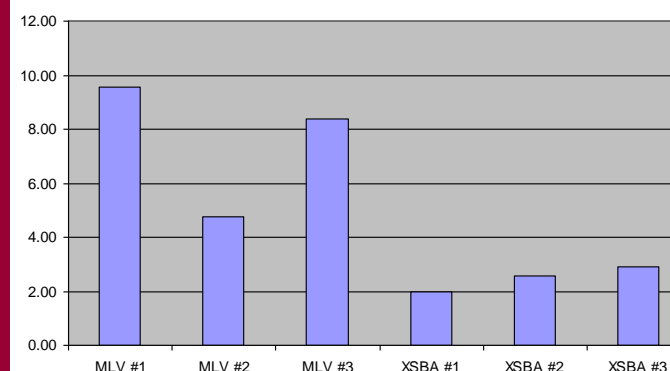
Average Elapsed Times to SB Access



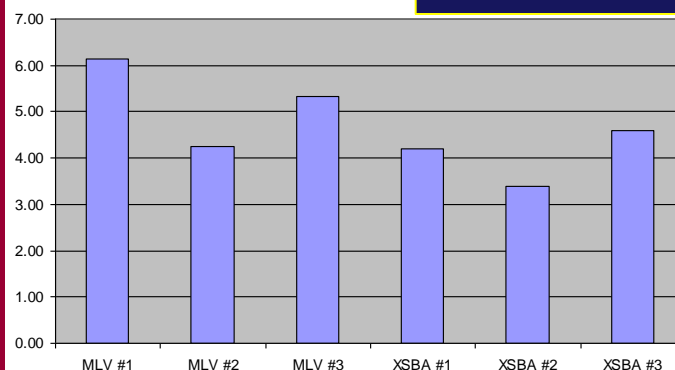
Operator H SB-Access Times



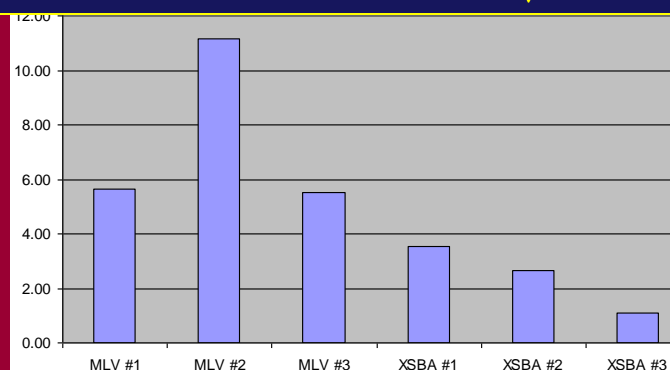
Operator B SB-Access Times



Operator S SB-Access



**Time to access of the side branch: ↓ 54%**



Interventionalists who recently completed interventional training with no previous exposure to Xience SBA

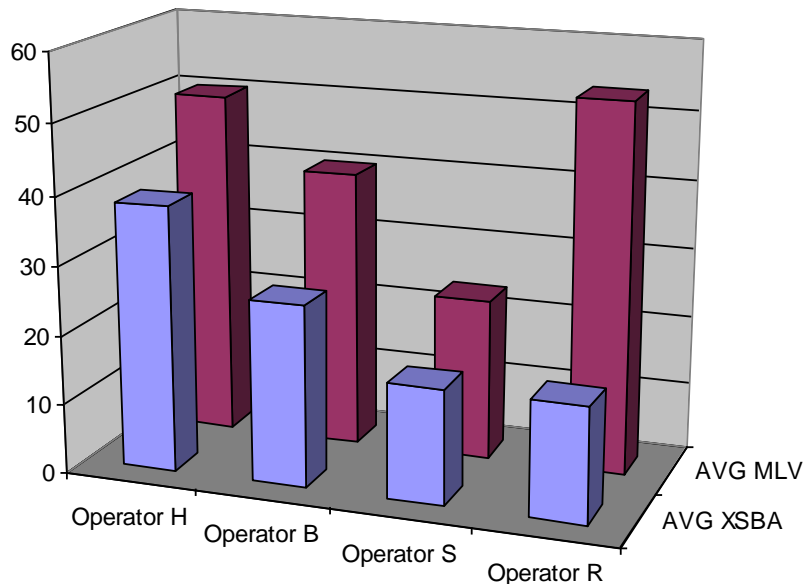




# Procedural Data

## Fluoroscopy Time & Contrast Media Usage Xience SBA versus Workhorse Stent

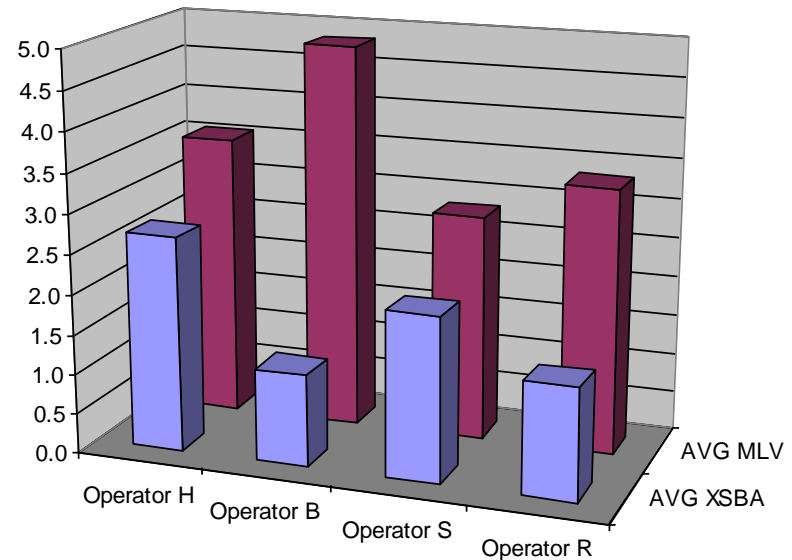
Average Contrast Usage (ml)



**Contrast Usage: ↓ 39%**

**Fluoroscopy Time: ↓ 46%**

Average Fluoro Time (Radiation)



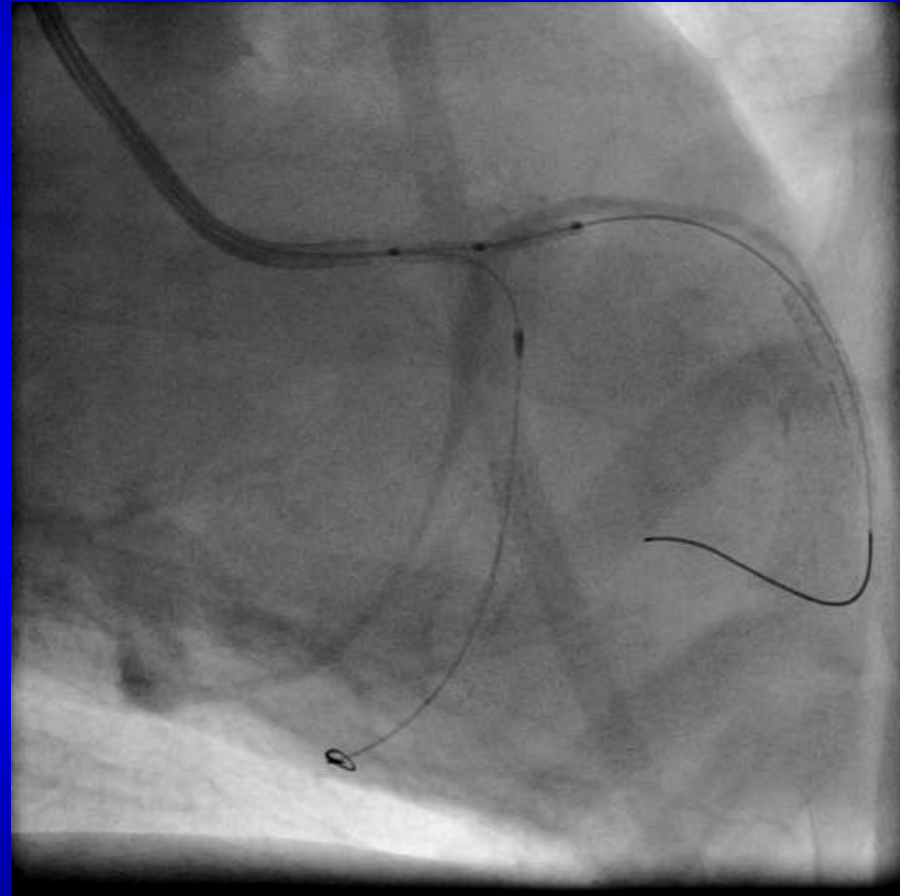
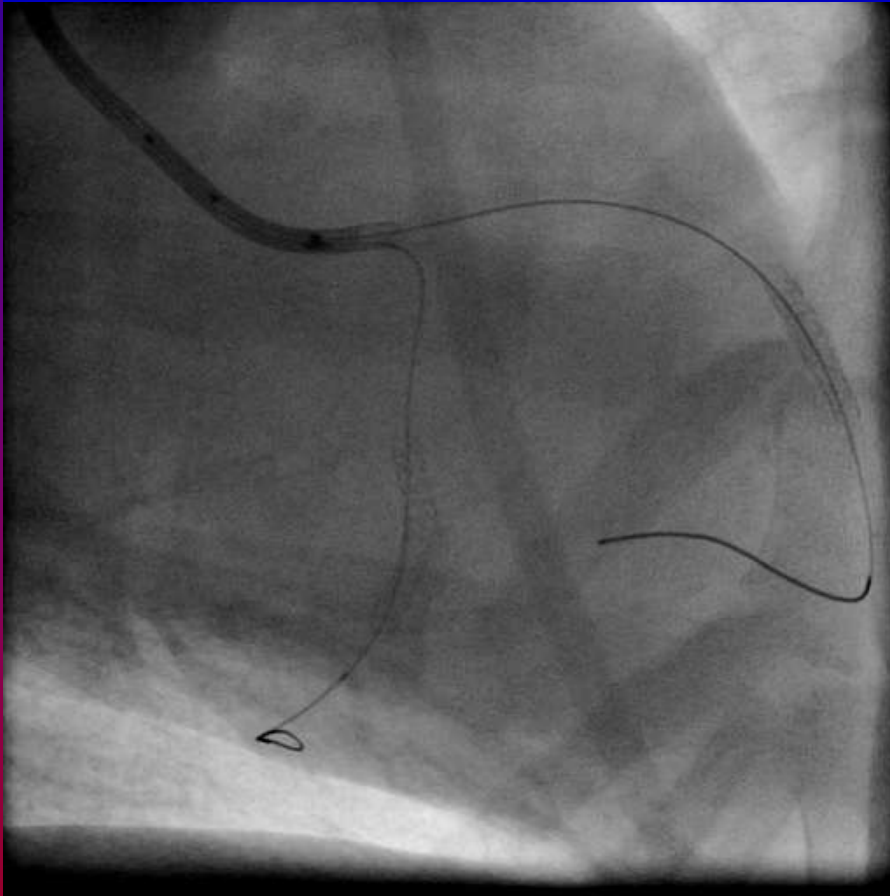
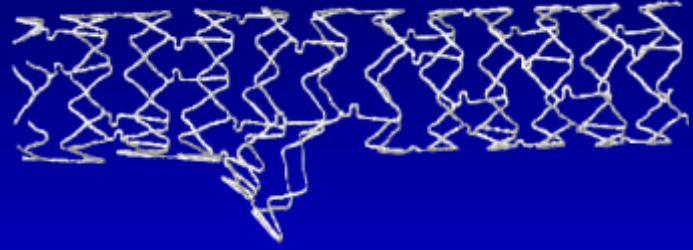
# Xience SBA Left Main Feasibility

- The feasibility of left main deployment of the Xience SBA stent was explored in an ovine beating heart model.
- In each of 8 healthy sheep, the Xience SBA stent (3.0 x 18 mm) was deployed in the left main vessel with **either the LAD or LCX designated as the MB, and the opposing vessel designated as the SB**. Following deployment, a Multi-link Vision stent (either 2.5 x 18 mm or 3.0 x 18 mm) was placed in the designated SB.
- The total **procedure time** for completion of the two-stent procedure **was 22.4 +/- 12.6 minutes** (i.e. Xience SBA+ Multi-Link Vision in the SB).
- **Contrast usage and total fluoroscopy time averaged 55 mL and 11.6 +/- 7.1 minutes**, respectively. Guide wire entanglement (wire wrap) did not occur in any of the procedures (0%).



# Left Main Ovine Study

Testing the Concept of LM Deployment



## Left Main Deployments in Beating Heart Ovine Models

**L.A.D.**

**Left Main**

**L.A.D.**

**Full metal jacket**

**Left Circumflex**

**L.A.D.  
as M.B.**

**L.C.X.**

**L.A.D.**

**L.C.X. as M.B.**



# Summary of Dedicated Bifurcation Devices

---

- There is no single, clear-cut regulatory pathway which ensures device approval.
- SB devices (Capella, Tryton) require different randomized trial design and comparator arms than other devices (Xience SBA, Boston Scientific Petal etc...)
- Where there is MB disease present, emphasis must remain on achieving durable main branch patency.
- Greatest emphasis: SIMPLICITY, SIMPLICITY, SIMPLICITY!!!!!!
- Devices need to be developed which can be applied broadly: i.e. to a heterogeneous pool of bifurcations including (and especially) LM disease.



# Summary of Dedicated Bifurcation Devices

---

- Until recently, the psychology of treating bifurcation lesions has been focused on the provisional SB methodology as a “preferred” treatment strategy.
- However, with newer data now being published which confirms the merit of an upfront 2-stent strategy, it seems reasonable that those devices providing the greatest versatility are likely to enjoy the greatest adoption (i.e. a dedicated devices would be applicable to 1-stent and 2-stent strategies, Provisional SB stenting, and even a simple SB preservation technique).



# 1 Year Outcomes DK Crush Versus Provisional Stenting

↓TLR and ↓TVR favoring DK Crush

↓ in MB and SB angiographic restenosis favoring DK Crush

Trend toward reduced MACE

**Table 1. One-Year Outcomes**

	<b>Double Kissing Crush</b>	<b>Provisional Stenting</b>	<b>P Value</b>
<b>MACE</b>	10.3%	17.3%	0.070
<b>Cardiac Death</b>	1.1%	1.1%	1.000
<b>MI</b>	3.2%	2.2%	0.751
<b>TVR</b>	6.5%	14.6%	0.017
<b>TLR</b>	4.3%	13.0%	0.005
<b>Definite Stent Thrombosis</b>	2.2%	0.5%	0.372



# Summary of Dedicated Bifurcation Devices

---

- Until recently, the psychology of treating bifurcation lesions has been focused on the provisional SB methodology as a preferred treatment strategy.
- However, with newer data now being published which confirms the merit of an upfront 2-stent strategy, it seems reasonable that those devices providing the **greatest versatility** are likely to enjoy the greatest adoption (i.e. a dedicated devices would be applicable to 1-stent and 2-stent strategies, Provisional SB stenting, and even a simple SB preservation technique).

