

# Dedicated Bifurcation Stents for True Coronary Bifurcation Lesions

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# Disclosure Statement of Financial Interest

## TCTAP2014: Seoul, Korea; April 22-25, 2014

### Martin B. Leon, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

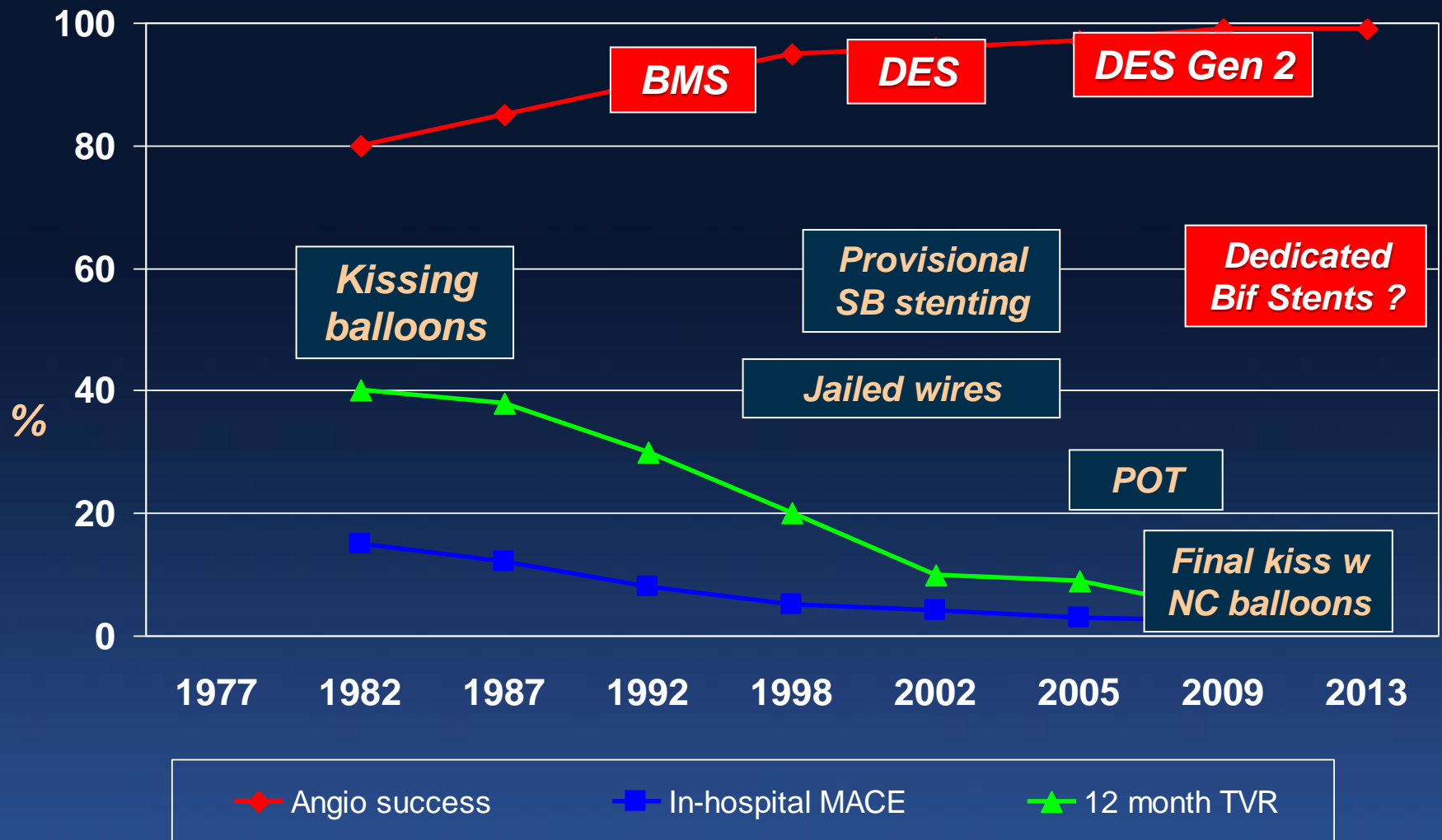
#### Affiliation / Financial Relationship

- Grant / Research Support
- Consulting Fees / Honoraria
- Shareholder / Equity

#### Company

- Abbott, Boston Scientific, Edwards Lifescience, Medtronic
- Angioscore, Meril Lifescience, Micell,
- Apica, Angiometrix, Backbeat, Caliber, Cappella, Claret, Coherex, Elixir, GDS, Medinol, Mitralign, Valve Medical

# Evolution of Bifurcation Therapy



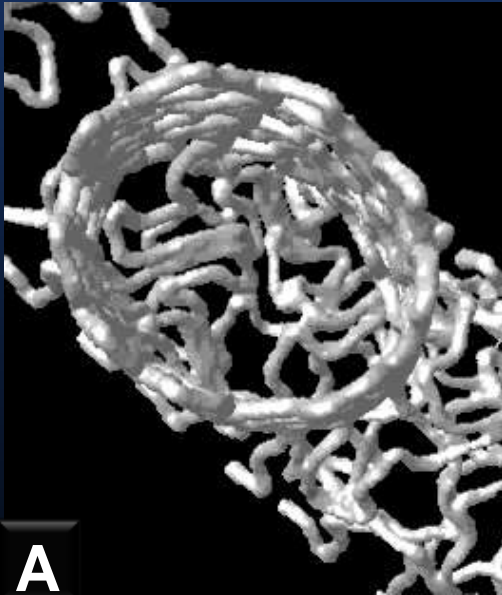
# The Case “FOR” Dedicated LM Bifurcation Stents

## ***1. The data supporting provisional bifurcation stenting as a primary strategy are flawed!***

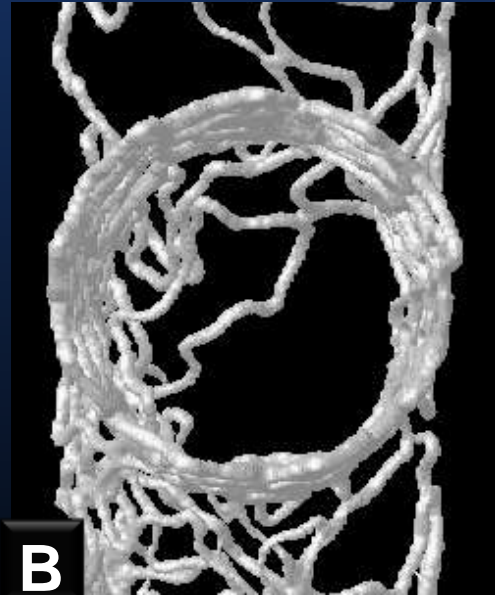
- Enrollment bias in the RCTs - patients enrolled in the RCTs had to be “appropriate” candidates for either 1- or 2-stent strategies, selectively excluding patients where 2 stents were preferred or necessary
- Technical rigor required for optimal 2-stent strategies was never emphasized or required until recently (e.g. final 2-step kissing with NC balloons, POT, etc.)

# “Ormography”- Importance of “2-step” kissing

No Kiss



One-step Kiss



Two-step Kiss

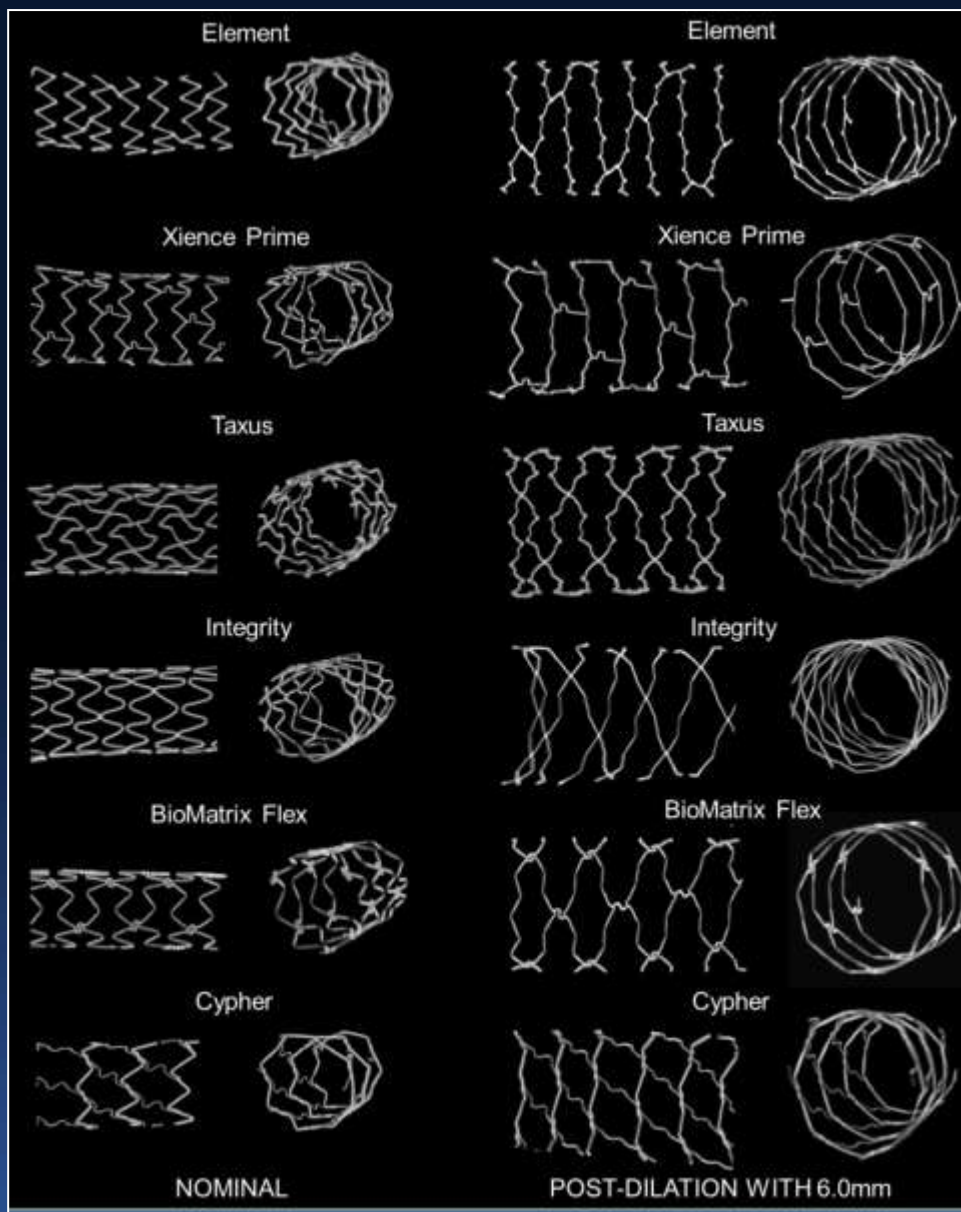


Slide courtesy of John Ormiston

# The Case “FOR” Dedicated Bifurcation Stents

**2. In situations where a 2-stent strategy is “preferred” for bifurcations (? 10-30% of cases) - diffuse side branch disease or complex lesion morphology with large myocardial territory “at risk” - the current 2-stent techniques and devices are problematic!**

- “Dysfunctional creativity” = (1) markedly variable application of 2-stent strategies to conform to anatomic heterogeneity and (2) non-uniform and difficult technical execution for operators
- Current coronary stent designs are ill suited for 2-stent bifurcation strategies



**Stent deformation with over-expansion is a common problem in treating bifurcation lesions affecting both the side branch origin and the proximal main vessel. *Markedly exaggerated in LM lesions!***

# The Case “FOR” Dedicated Bifurcation Stents

**3. *Dedicated bifurcation stents offer the promise of: (1) optimal anatomic integration of the stent with the side branch and main vessel; (2) side branch “protection” to reduce safety concerns in high-risk anatomy; (3) consistent operator technique; (4) improved late outcomes, esp. recurrence at the side branch ostium!***

- BUT... these dedicated bifurcation stents must:
  - (1) be generally applicable to most bifurcation lesions and user-friendly to most operators;
  - (2) incremental benefit must be demonstrated in rigorous clinical trials



# Dedicated Bifurcation Stents

## Device Landscape















# Dedicated Bifurcation Stents

## *General Categories*

- Complete bifurcation “Y” stents
- Sidebranch access MB stents
- Sidebranch only stents
- Specialty designs (e.g. carina or for LM disease)

# Classification of Bifurcation Stent Strategies

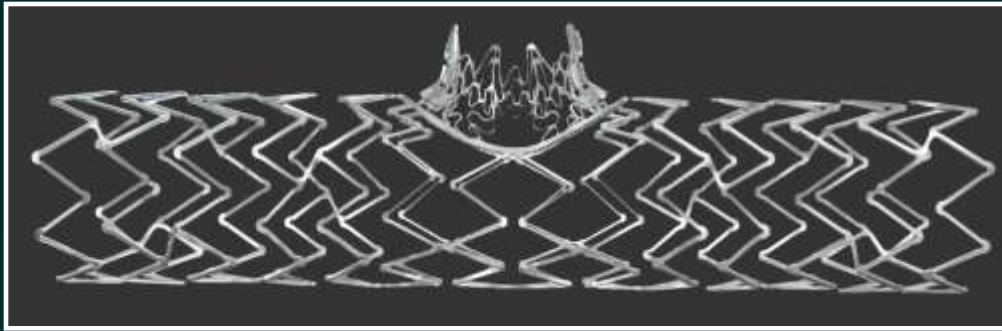
## *Application to Dedicated Bifurcation Stents*

| Intention             | <b>M</b>  | <b>A</b>  | <b>D</b>  | <b>S</b>  |
|-----------------------|---|---|---|---|
| Final                 | Main prox. first  | Main Across side first  | Distal first  | Side branch first   |
| 1 <sup>st</sup> stent | <br>PM stenting  | <br>MB stenting across SB    |  <br>DM stenting    Provisional SKS | <br>SB ostial stenting   |
| After balloon         | <b>Axxess</b>   | <b>Abbott SB<br/>BIOSS<br/>BSC Petal<br/>Minvasys NilePax<br/>StentYs<br/>TriReme<br/>Twin-Rail<br/>Y-med</b> | <b>MDT<br/>"Y" stent</b>  | <b>ABS<br/>Cappella<br/>Tryton</b>  |
| 2 stents              |  <br>Skirt + DM    Skirt + SB |   |  <br>V stenting    SKS              |   <br>Syst. T Stenting    Minicrush    Crush |
| 3 stents              | <br>Extended V   |   | <br>Trousers legs and seat   |   |



# BSC TAXUS Petal

## *Design Characteristics*



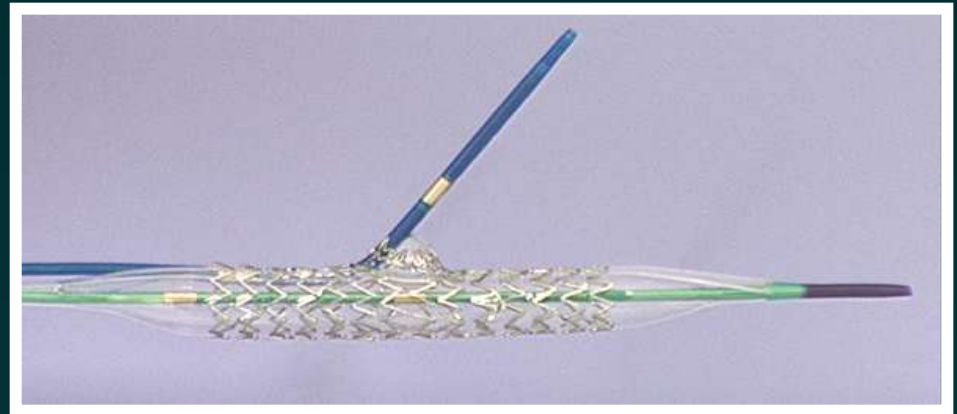
*Element stent geometry*

### *Stent Advantages*

- Special stent feature to cover ostium of sidebranch (~2mm)
- Reduces sidebranch “gap” and need for 2nd stent
- Placing 2nd stent, when necessary, is technically simplified

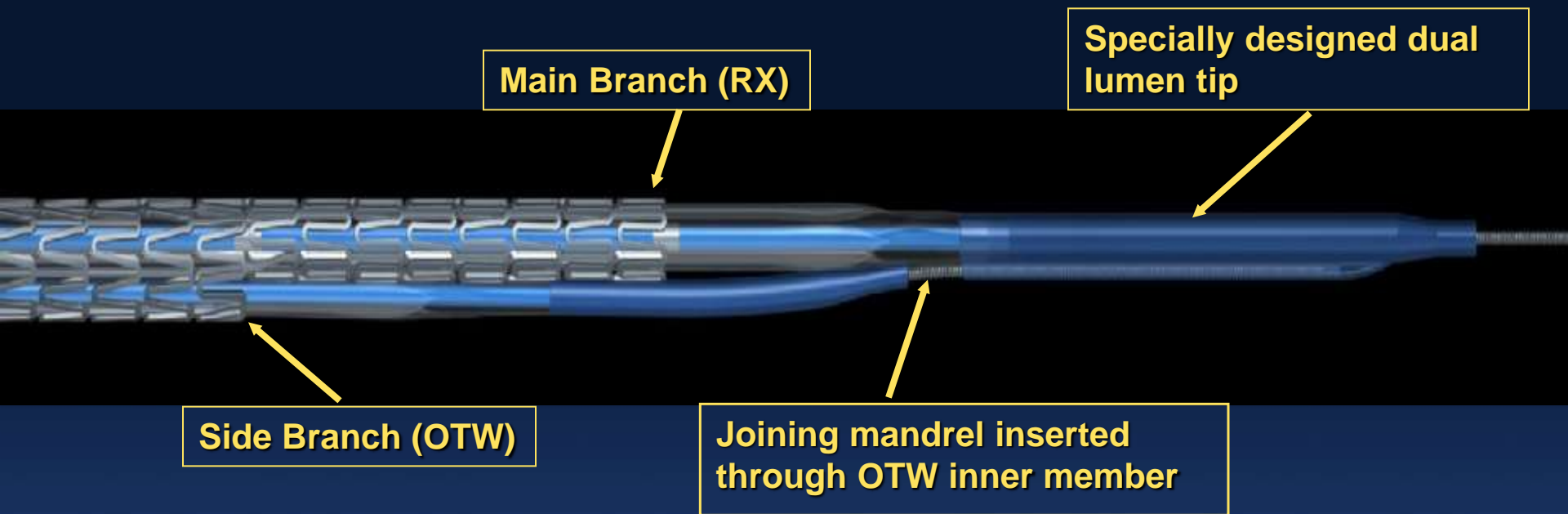
### *Delivery System Advantages*

- Side Branch wire lumen aids in alignment at ostium
- Side branch “pre-wired”, no need to re-access through stent
- Final Petal size determined by post dilatation balloon



# Abbott Bifurcation DES

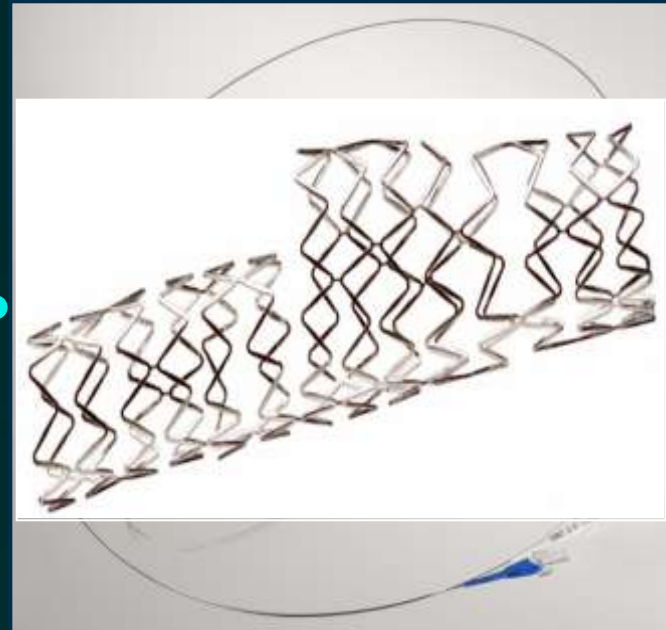
## *Design Characteristics*



- *Single-Tip Delivery* to avoid wire wrap
- *Two Wires* maintain access across both branches
- *Kissing Balloon Deployment* to minimize plaque shift
- *Provisional T-Stent* approach maintains options for additional treatment

# Minvasys Nile Pax (+ DCB) *Design Summary*

**One System  
Two independent catheters**



**Side branch  
balloon**

**Main branch  
Balloon + stent + tip**



# StentYs Bifurcation Stent

## Design Characteristics

Self-expanding  
nitinol

Anatomical reconstruction of  
the bifurcation shape

Positioning  
tolerance  
(disconnectable  
struts on full length)

Excellent ostium  
coverage with SB  
stent

Excellent SB  
access

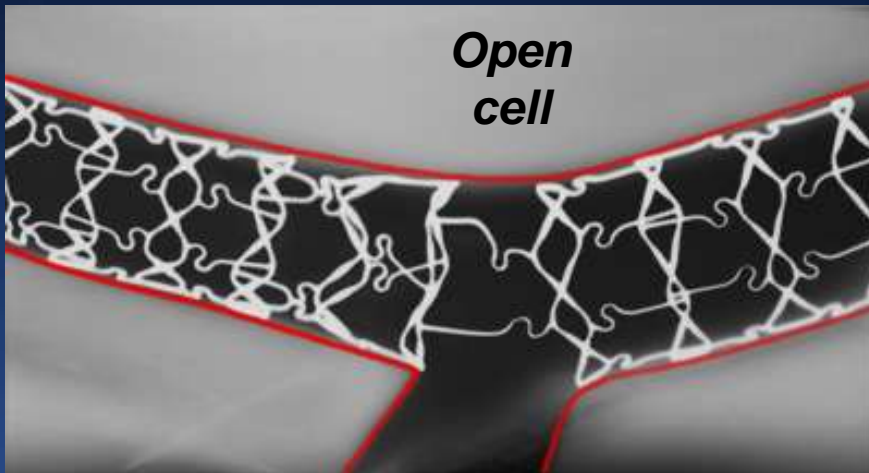
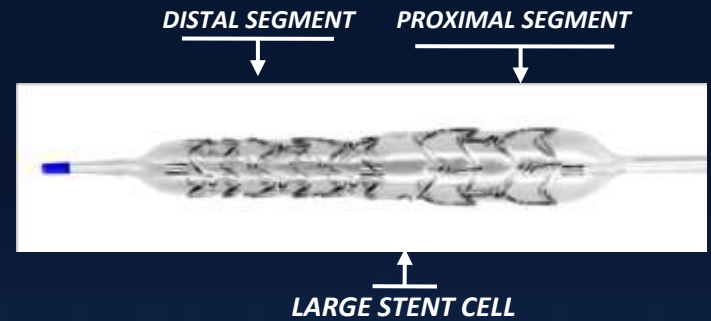
Distal MB  
stented

Single wire 5F delivery system



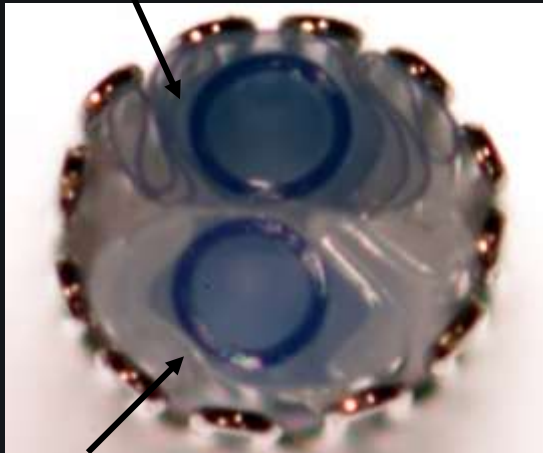
# BIOSS

## Bifurcation Optimized Stent Systems



# Medtronic Bifurcation Stent *Dual Balloon Configuration*

*Side branch  
balloon*



*Main branch  
balloon*



***Mounted on Dual monorail delivery system,  
single inflation lumen***

# Cappella Sideguard *Sidebranch Stent*

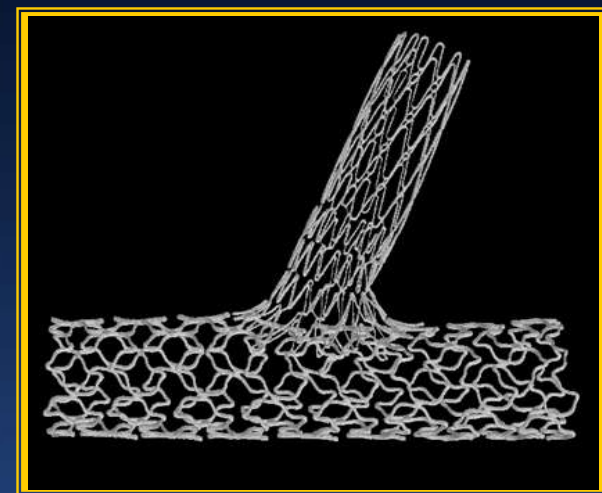
*Self-Expanding, Balloon-Actuated,  
Anatomically-Shaped Coronary Side Branch Stent*



Balloon-Actuated  
Catheter System (3.1 Fr)

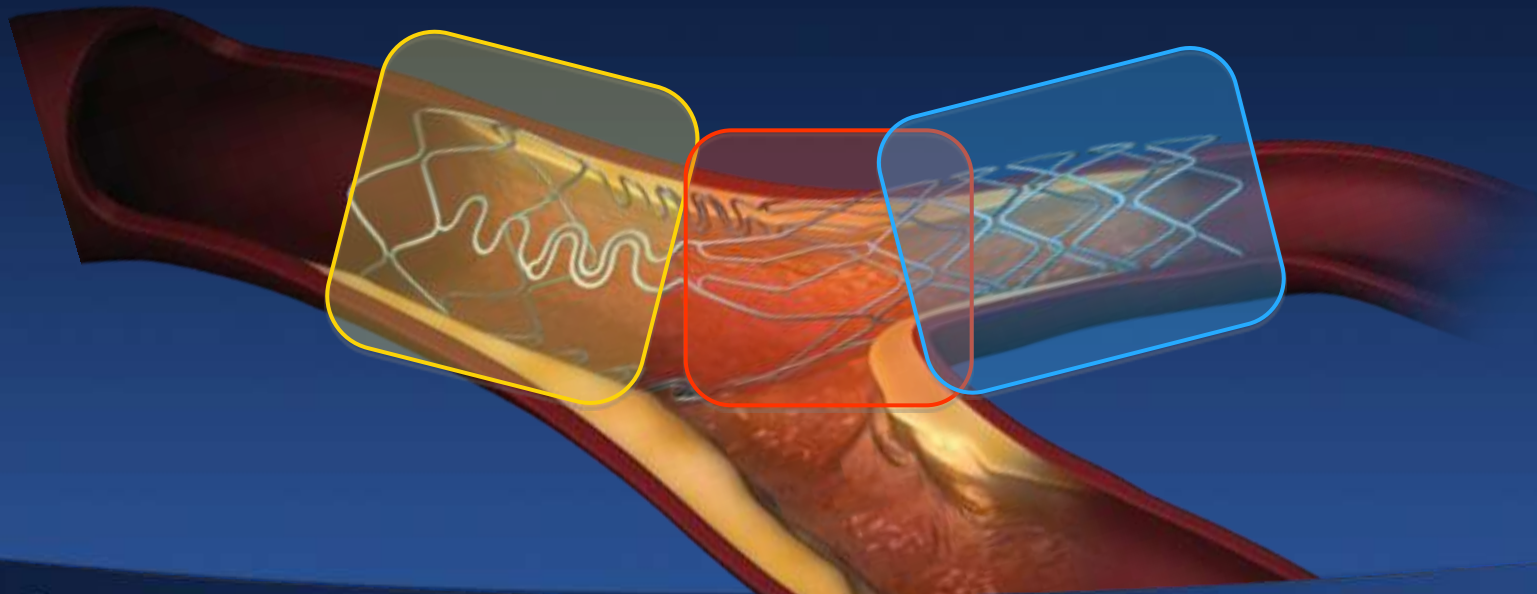
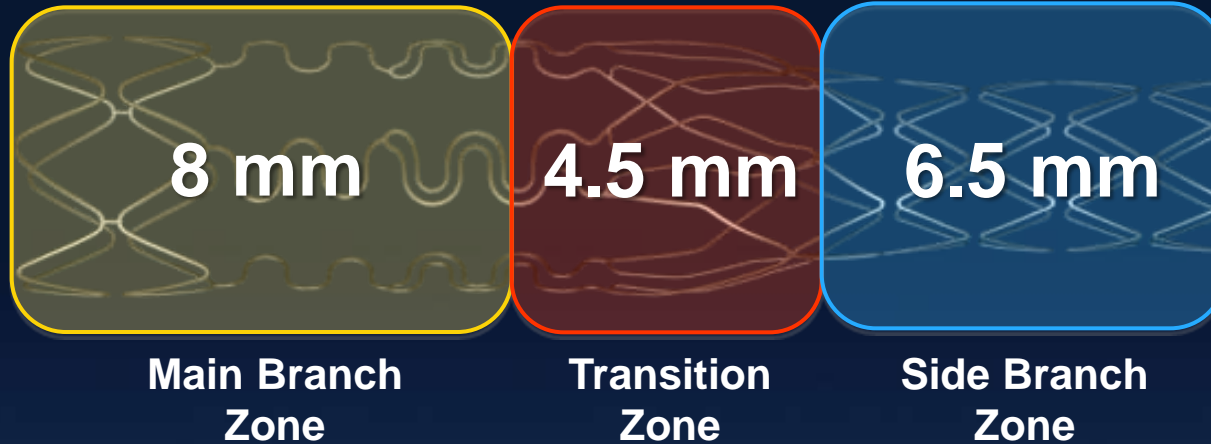


Self-Expanding  
Nitinol SB Stent



Anatomically-Shaped  
Design

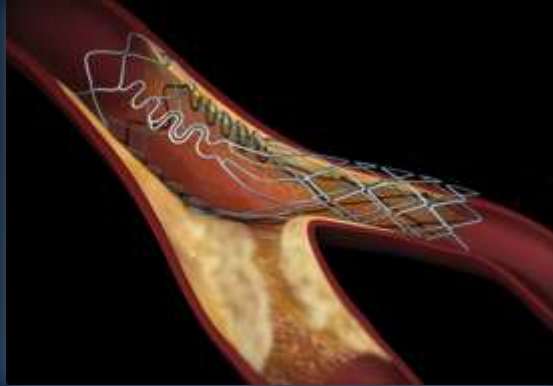
# Tryton Side Branch Stent



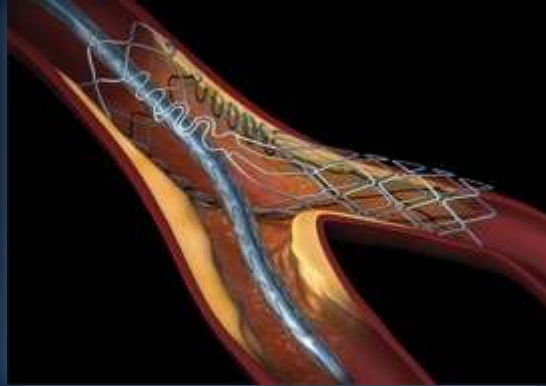
# Tryton Bifurcation Study

## Main Study Results

# Tryton Deployment Sequence



Tryton positioned and deployed after pre-dilatation (secures and protects side branch)



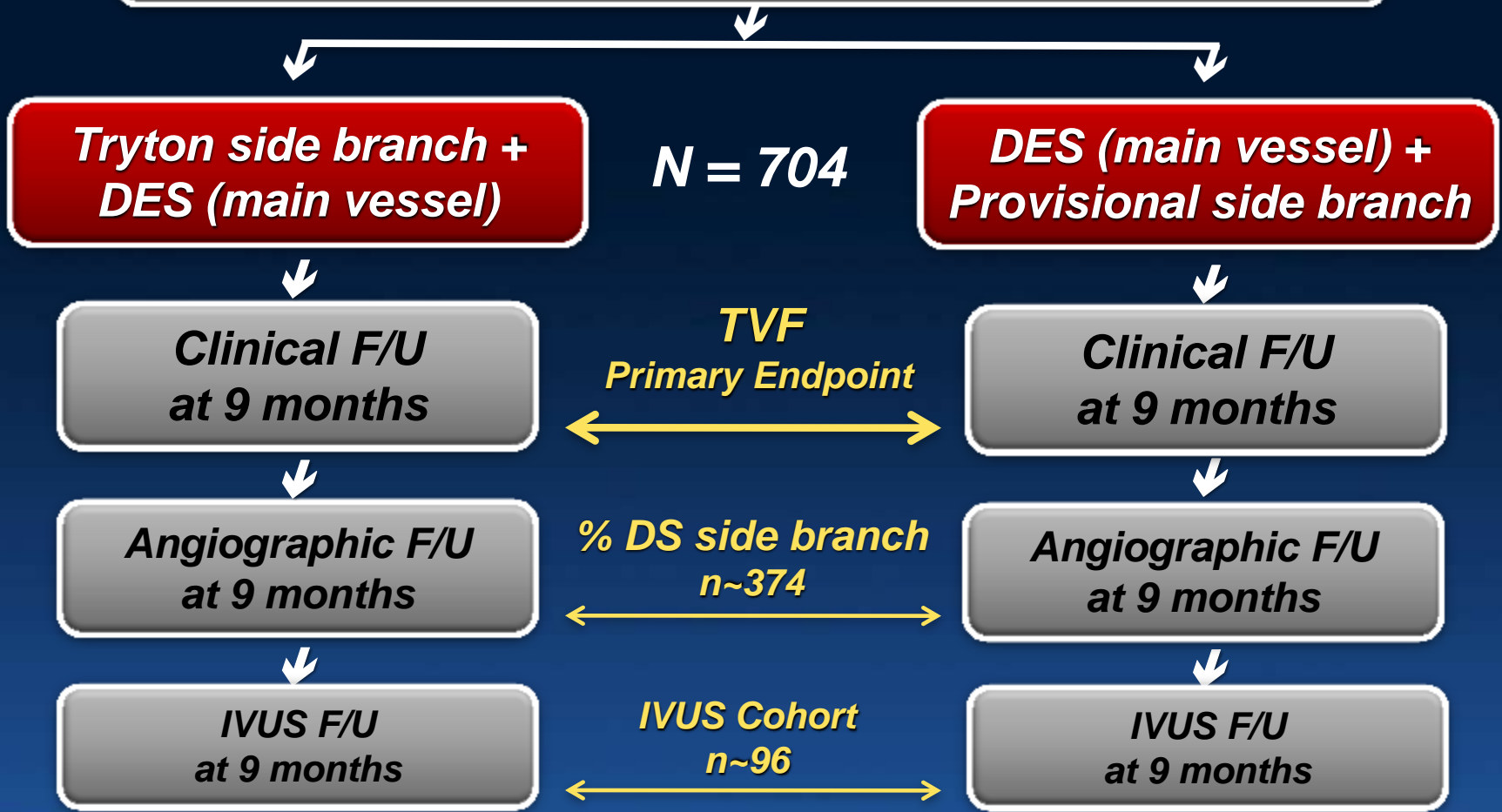
Main vessel treated with approved DES through main vessel portion of Tryton



Kissing balloon post-dilatation to insure complete lesion & ostium coverage

# Tryton Study Design

Baseline Angiography – Eligible for Randomization



# Inclusion Criteria

- **Single de novo “true” bifurcation lesion** in a native coronary artery involving both the main vessel and the side branch (Medina classification 1.1.1, 1.0.1, or 0.1.1 by visual assessment)
- **Symptoms or objective evidence of ischemia**
- **Vessel diameter:** main vessel  $\geq 2.5$  mm and  $\leq 4.0$  mm; side branch  $\geq 2.5$  mm and  $\leq 3.5$  mm
- **Lesion length:** main vessel  $\leq 28$  mm; side branch  $\leq 5$  mm
- Limited treatment of **multi-vessel disease and staging**, per protocol (after successful treatment of  $\leq 2$  non-complex, non-target lesions)



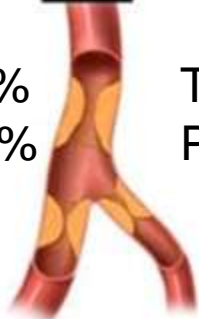
# Primary and Secondary Endpoints

- **Study design:** Intention-to-treat (ITT) is primary analysis cohort, 1:1 randomization
- **Primary Endpoint:** Target vessel failure @ 9 months follow-up (all patients): non-inferiority
  - cardiac death
  - target vessel MI (peri-procedural > 3X CK-MB)
  - target vessel revascularization (ischemia-driven, main vessel or side branch)
- **Secondary Endpoint:** % diameter stenosis (in-segment) of side branch at 9 months follow-up (angiographic cohort only): superiority

# Medina Classification (Site Reported)

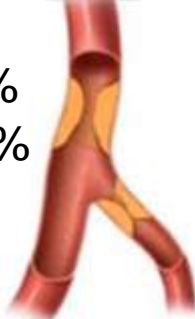
1,1,1

T: 73.2%  
P: 68.7%



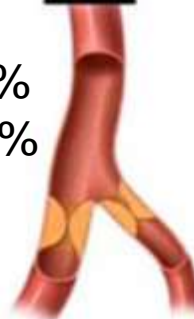
1,0,1

T: 11.5%  
P: 12.4%



0,1,1

T: 14.6%  
P: 18.7%



“True”  
Bifurcation

T: 99.3%  
P: 99.8%

1,0,0

T: 0.3%  
P: 0%



1,1,0

T: 0%  
P: 0%



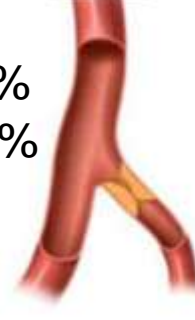
0,1,0

T: 0%  
P: 0%



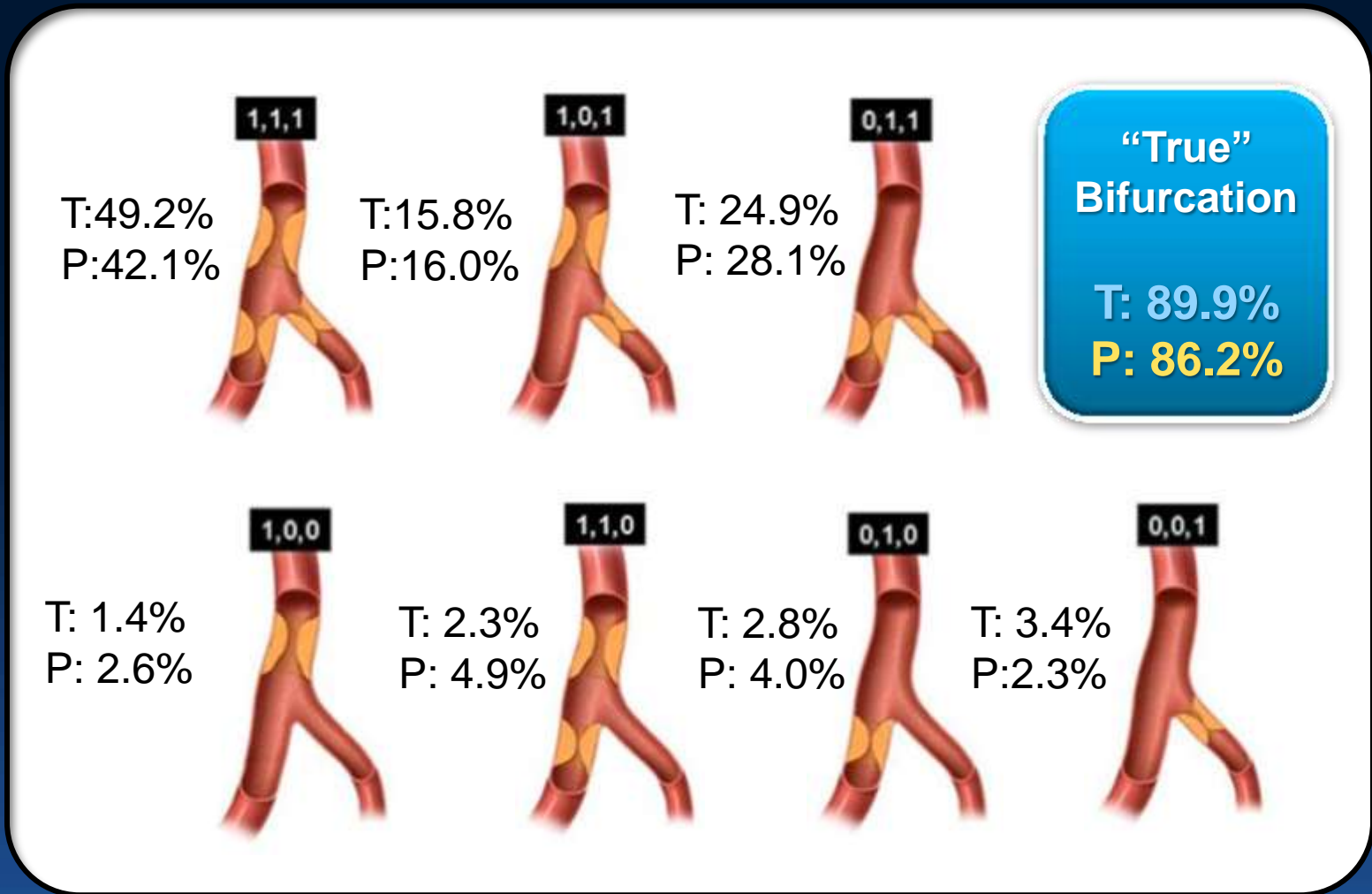
0,0,1

T: 0.3%  
P: 0.3%



P = Provisional    T = Tryton

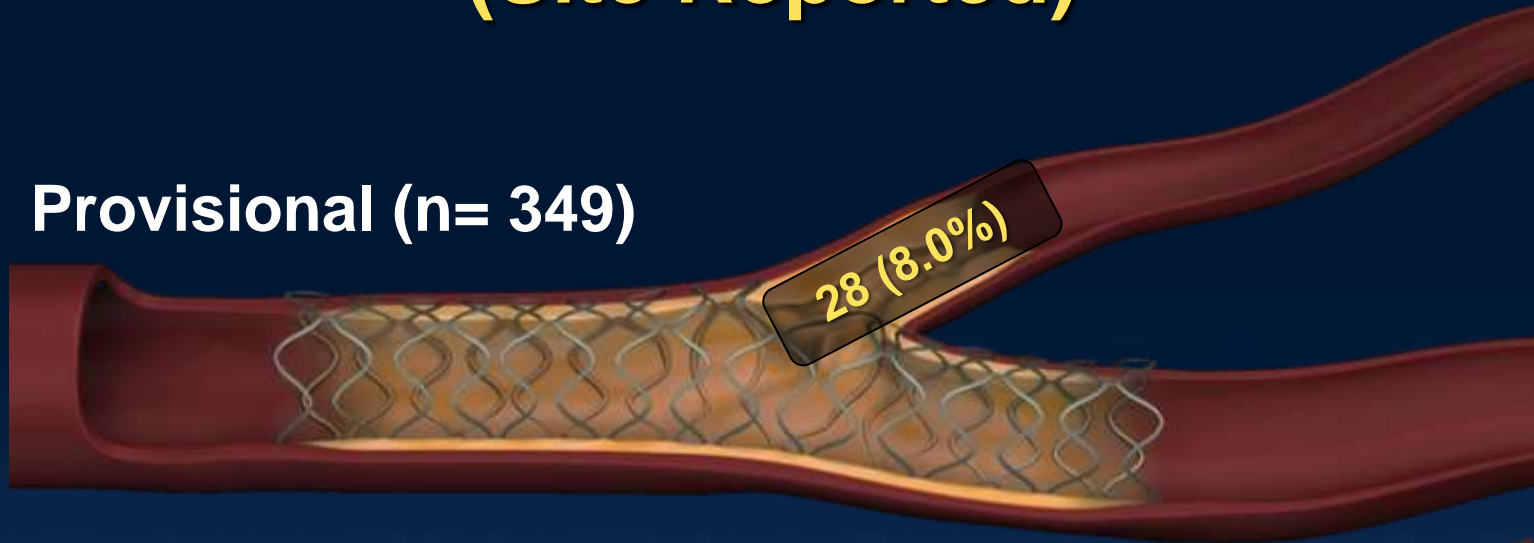
# Medina Classification (Core Lab)



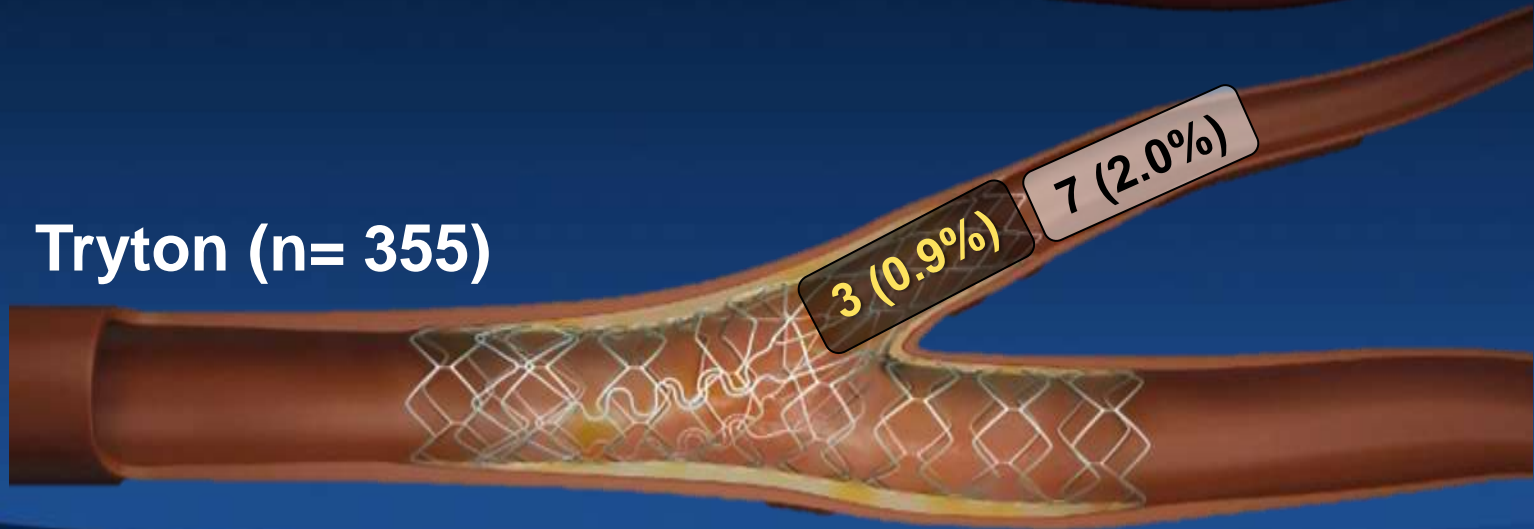
P = Provisional    T = Tryton

# Additional Side Branch Stents (Site Reported)

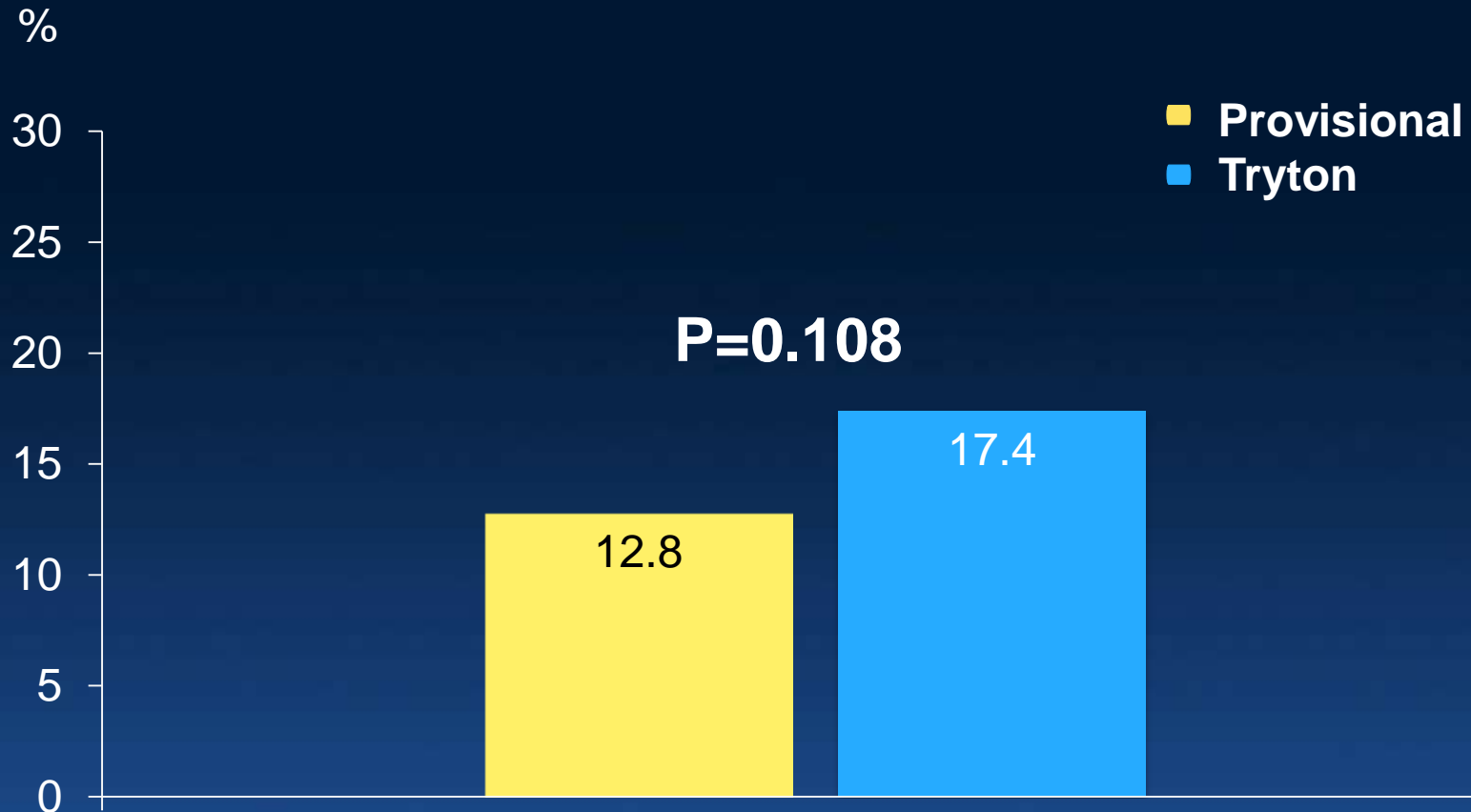
Provisional (n= 349)



Tryton (n= 355)

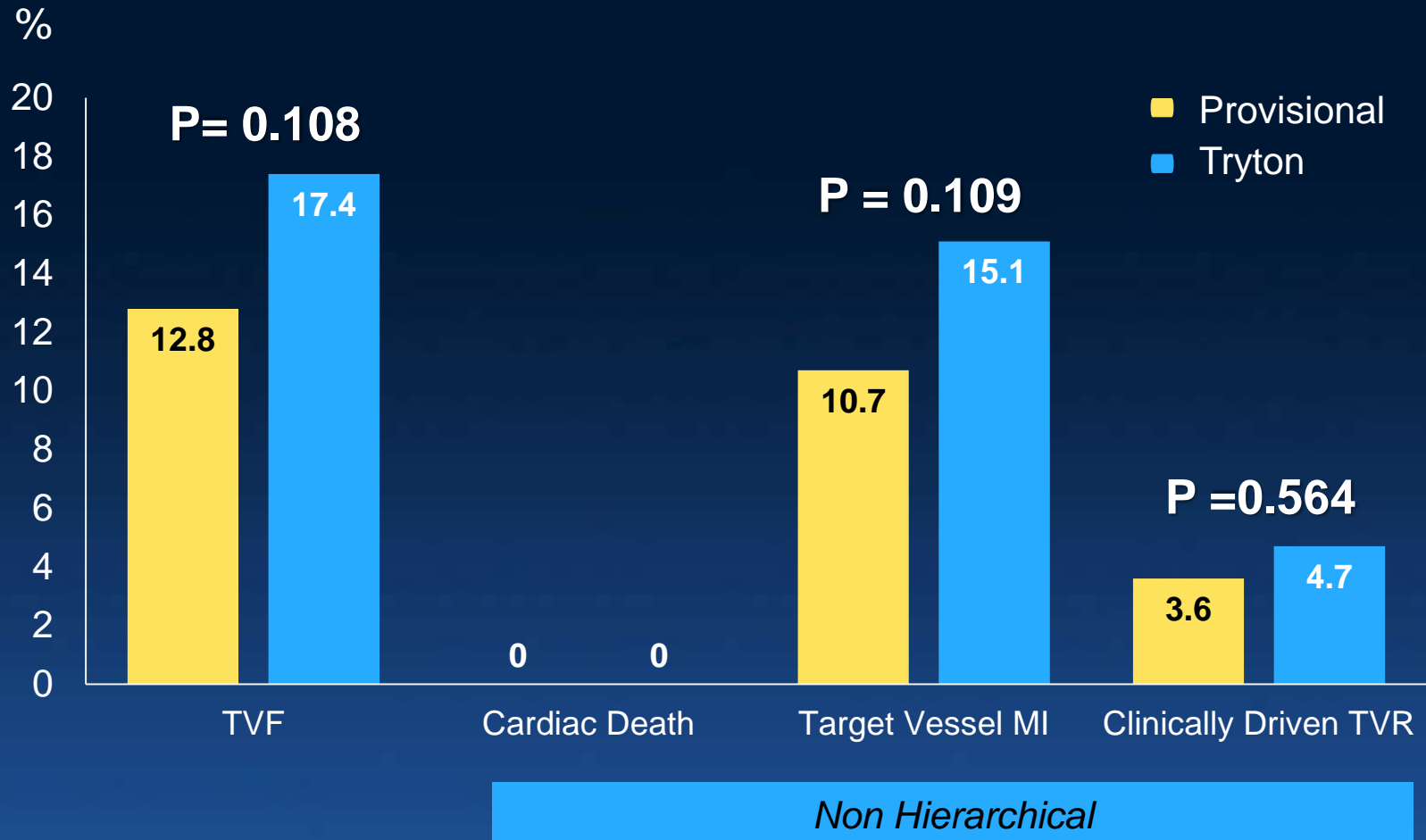


# Target Vessel Failure (TVF)\* Primary Endpoint



\* TVF = Cardiac death, TV-MI and TVR

# Target Vessel Failure (TVF) Primary Endpoint



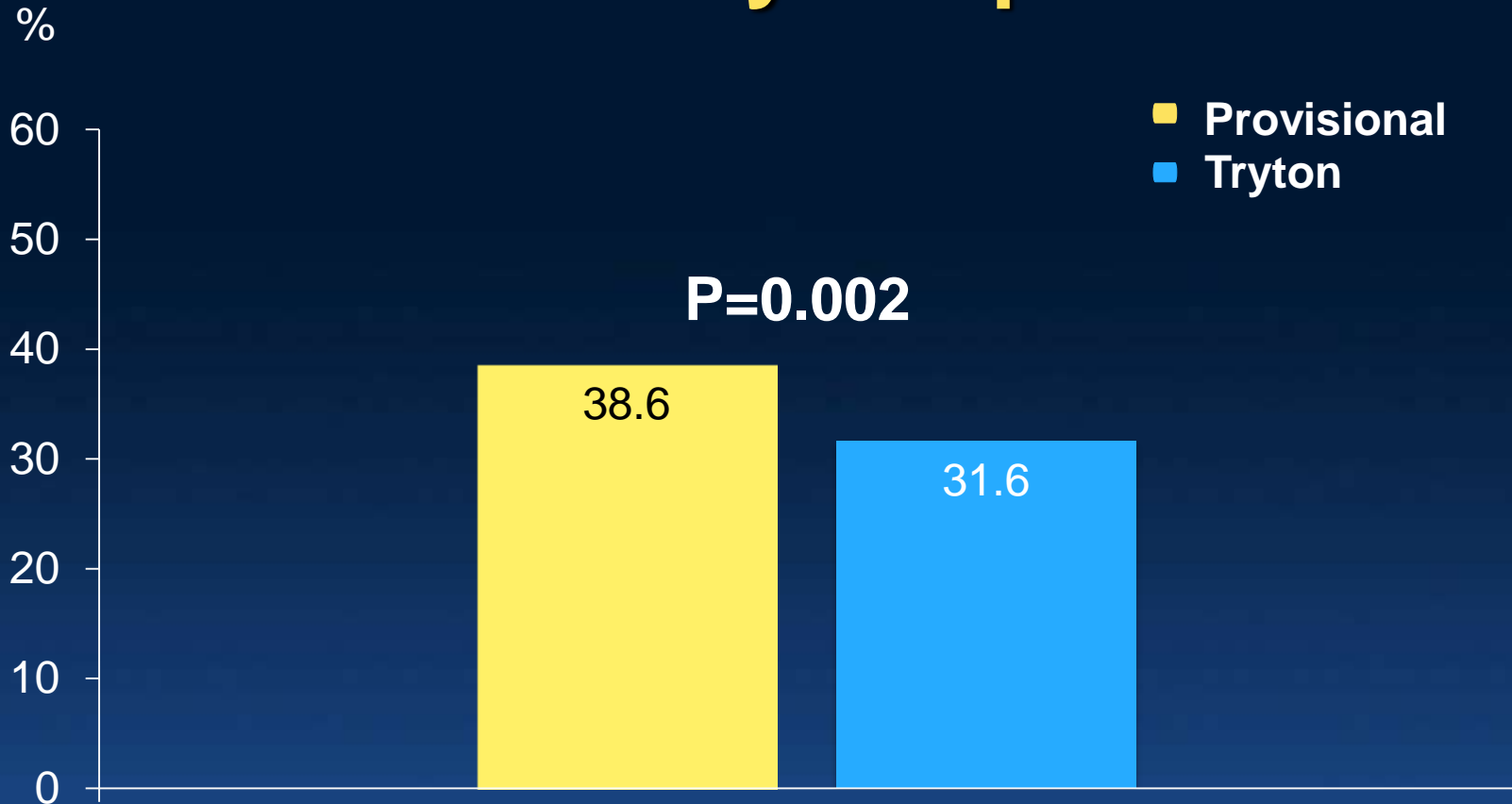
# Stent Thrombosis (ARC)

## 9-month Follow-up

| Event - % (n)             | Provisional<br>(N=349) | Tryton<br>(N=355) | P-Value |
|---------------------------|------------------------|-------------------|---------|
| <i>All – to 270 days</i>  |                        |                   |         |
| definite                  | 0.3 (1)                | 0.6 (2)           | 1.00    |
| probable                  | 0                      | 0                 | na      |
| def + prob                | 0.3 (1)                | 0.6 (2)           | 1.00    |
| <i>Early (0-30 days)</i>  |                        |                   |         |
| definite                  | 0.3 (1)                | 0.6 (2)           | 1.00    |
| probable                  | 0                      | 0                 | na      |
| def + prob                | 0.3 (1)                | 0.6 (2)           | 1.00    |
| <i>Late (30-270 days)</i> |                        |                   |         |
| definite                  | 0                      | 0                 | na      |
| probable                  | 0                      | 0                 | na      |
| def + prob                | 0                      | 0                 | na      |

**Overall = 0.4%**

# Side Branch % DS (In-segment) Secondary Endpoint



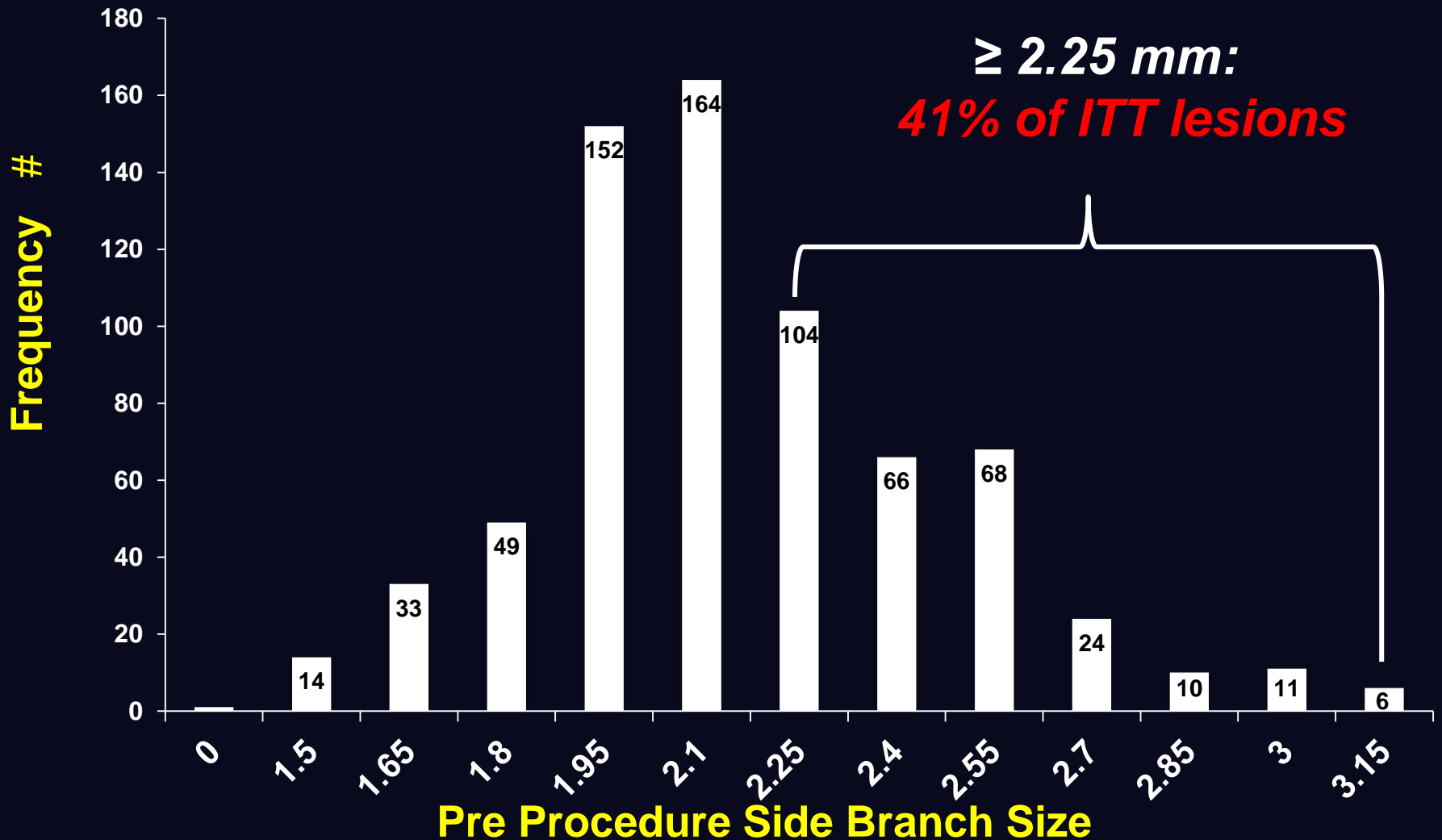
**Secondary Superiority Endpoint Met**



# Tryton Bifurcation Study

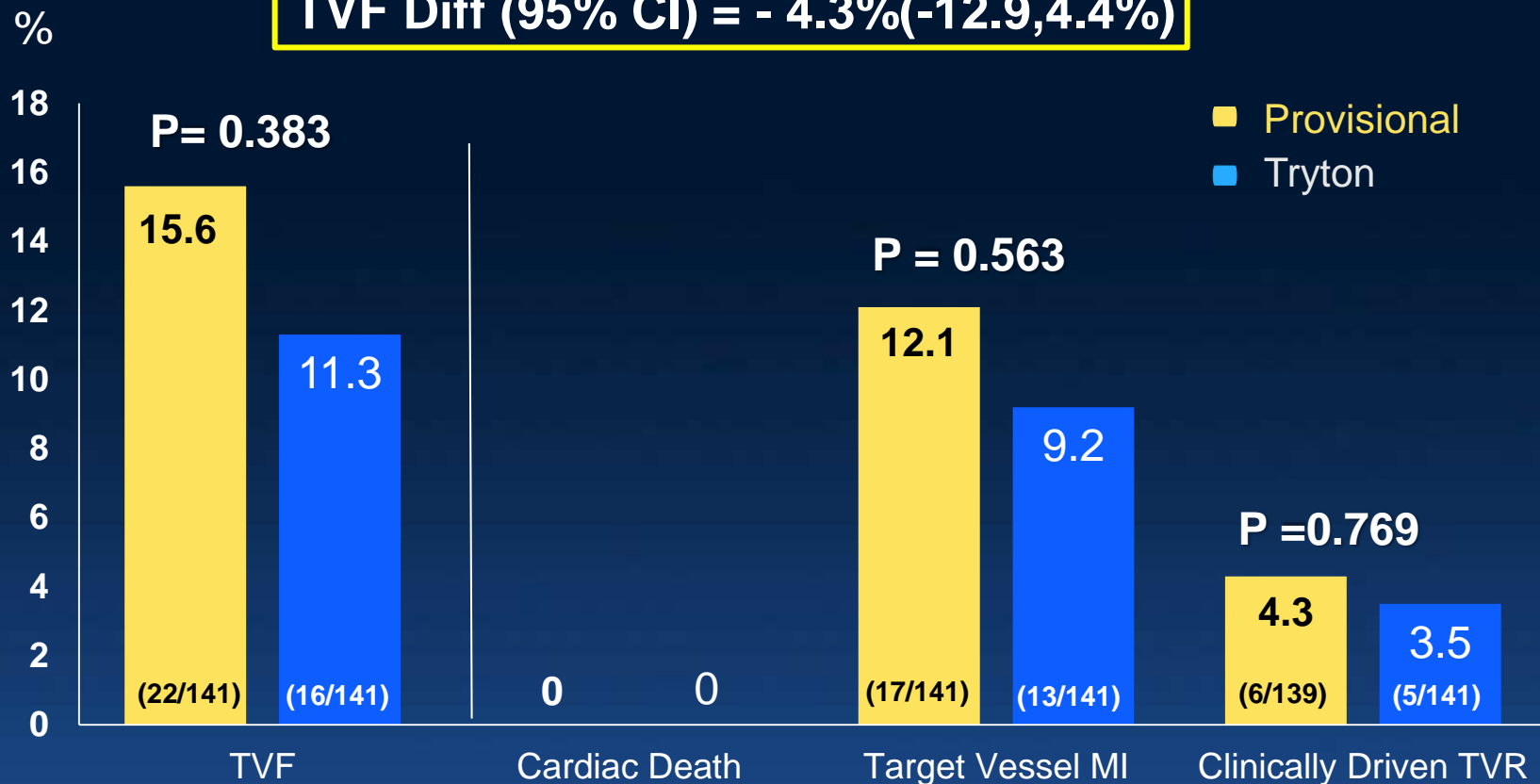
**Side Branch  
> 2.25 mm**

# Side Branch RVD (Core Lab)



# Target Vessel Failure (TVF) Side Branch $\geq 2.25$ mm

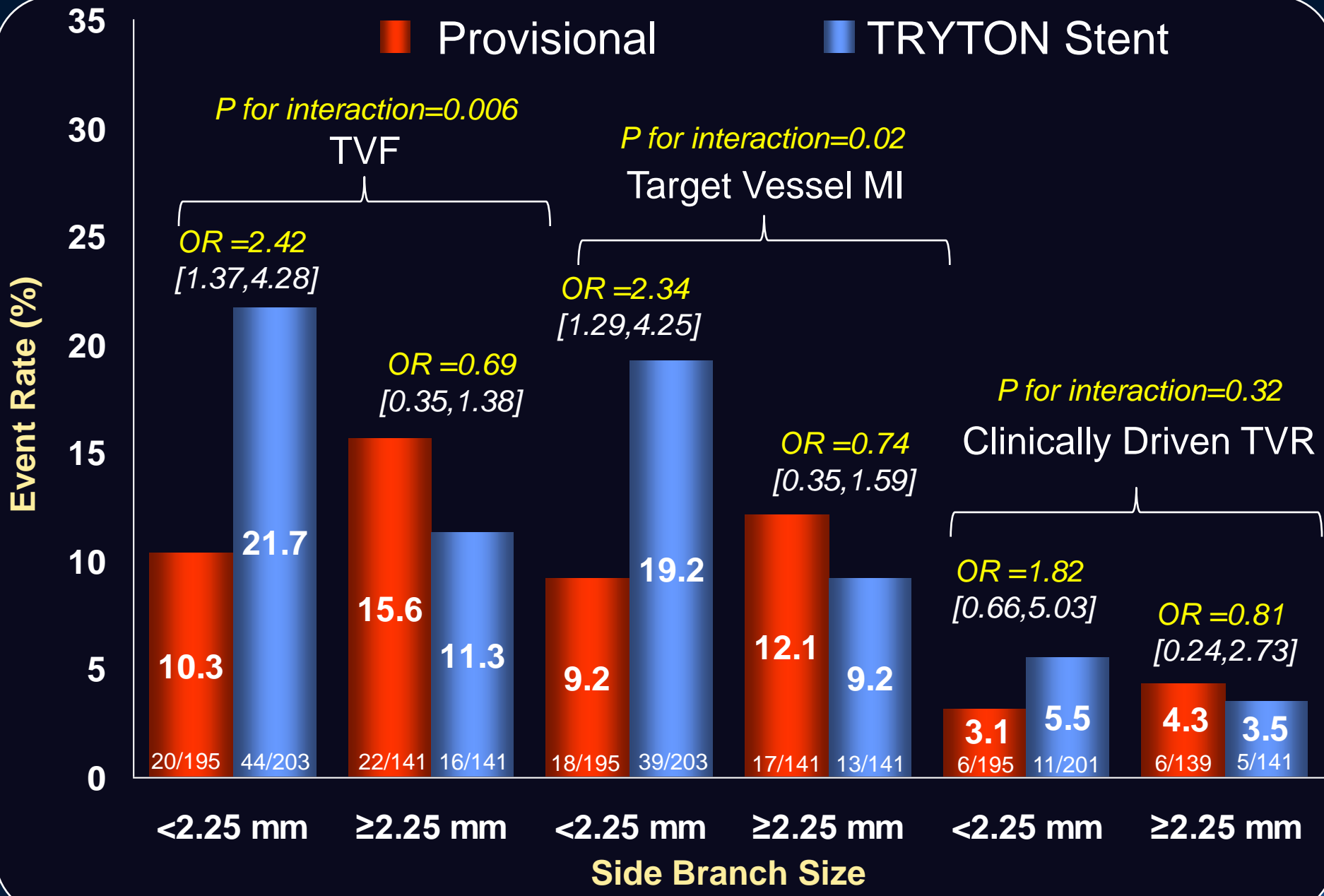
TVF Diff (95% CI) = - 4.3%(-12.9,4.4%)



*Non Hierarchical*

Provisional N=143 Tryton N=146

$\Delta$  (Total Study Cohort) = 5.5%



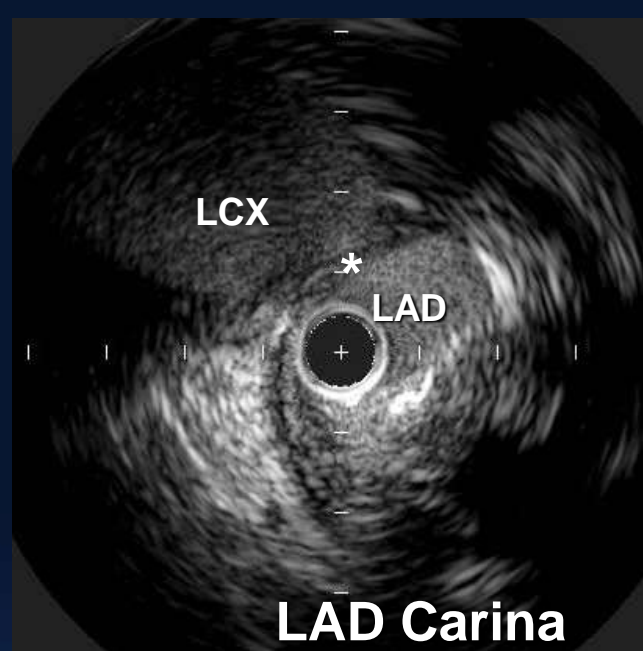
# Dedicated Bifurcation Stents

## Left Main Bifurcation Issues

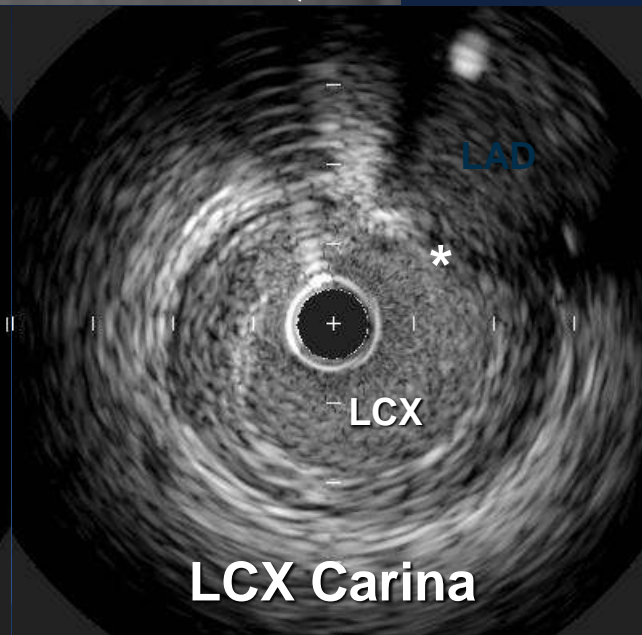
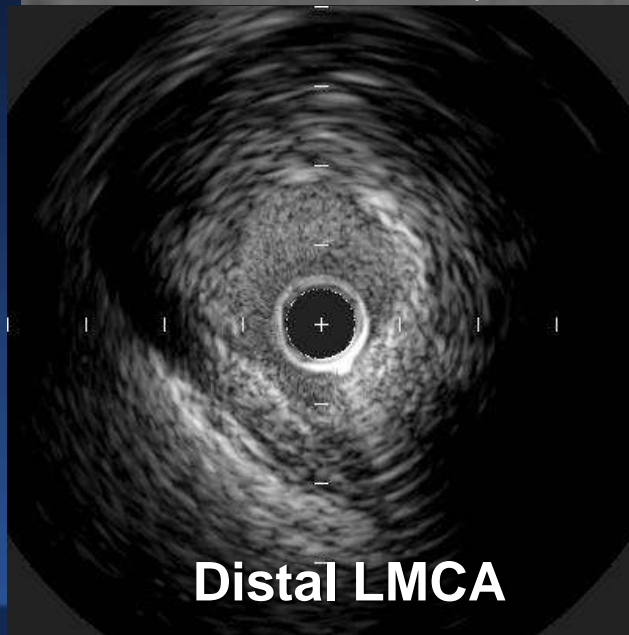
# LM Bifurcation PCI

## *Caveats and Perspectives*

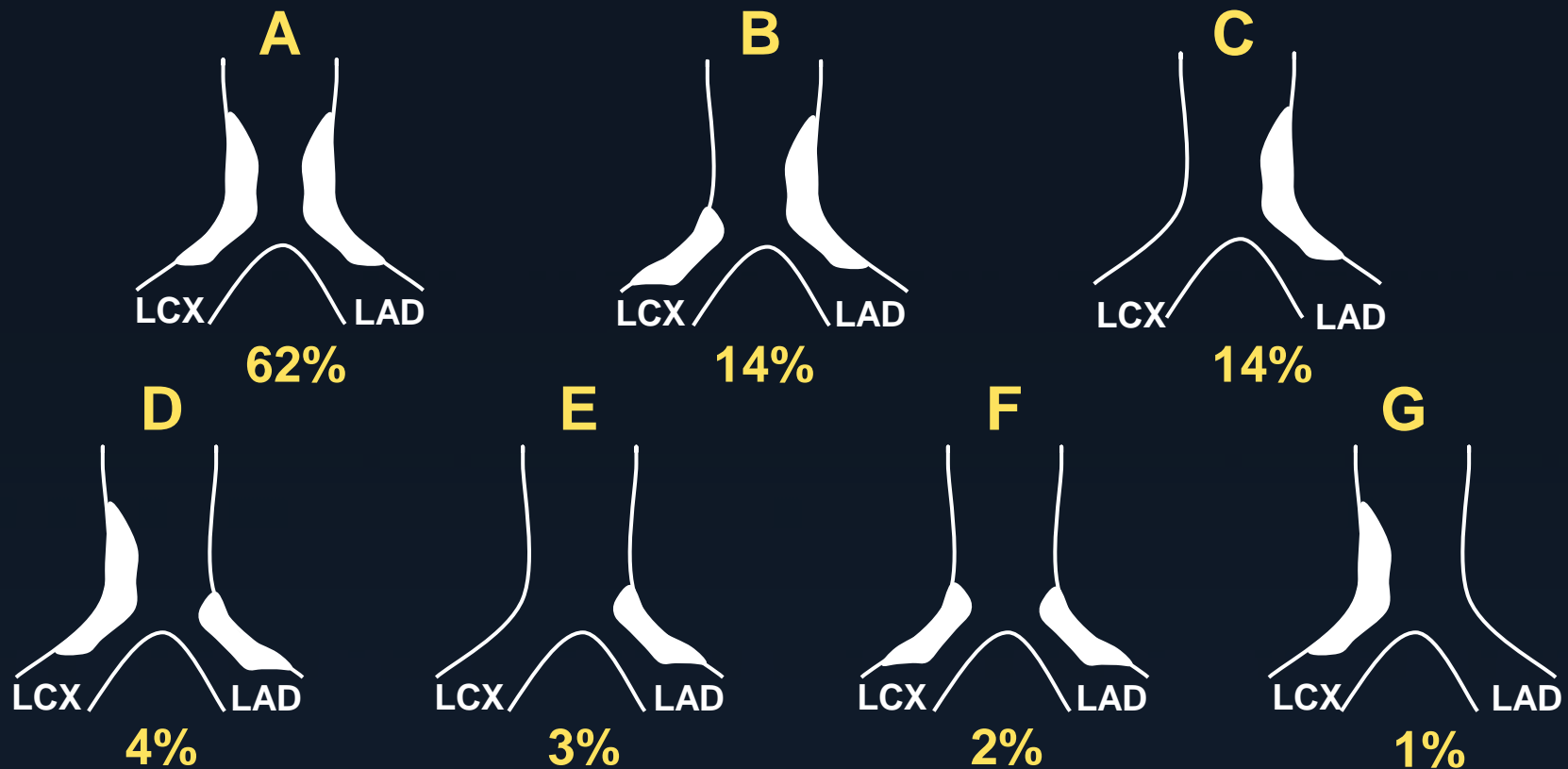
- Large territory of myocardium at risk – premium on optimal procedural technique and long-term outcomes (must = CABG)
- Disease usually extends into major branches (LAD and LCx)



## IVUS Findings in Left Main Lesions (140 pts)



# IVUS Findings in Left Main Lesions



- 140 pts; 93% with IVUS LM lesions
- Usually diffuse; no flow divider disease
- Eccentric lesions w neg remodeling

- LM → LAD 90%, LM → LCX 66%,  
→ LAD + LCX 62%, only LAD 9%,  
and only LCX 17%



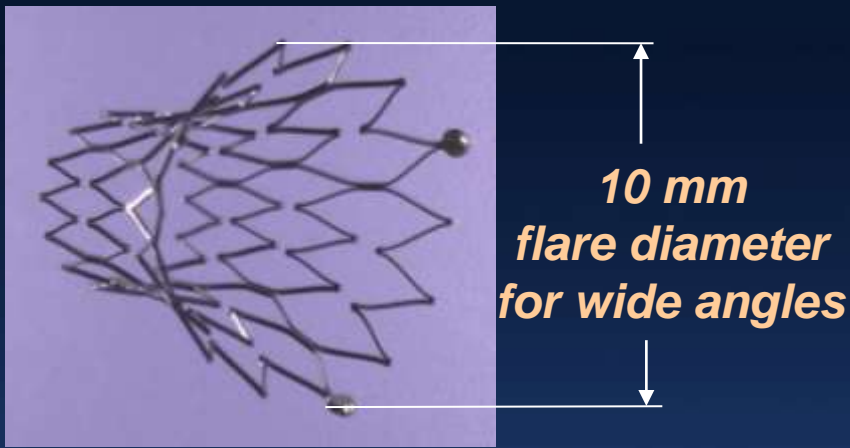
# LM Bifurcation PCI

## *Caveats and Perspectives*

- Large territory of myocardium at risk – premium on optimal procedural technique and long-term outcomes (must = CABG)
- Disease usually extends into major branches (LAD and LCx)
- Frequent use of IVUS and FFR to guide and assess therapy
- Greater need for dedicated bifurcation stents (esp. DES) to reduce restenosis (esp. in LCx side branch)

# New AXXESS 4.0 X 9 mm

*The Axxess 4.0x9mm has been designed to suit larger vessel diameters (up to 4.75) and wider distinct bifurcation angles (flare-end diameters of 8,10 and 12 mm).*



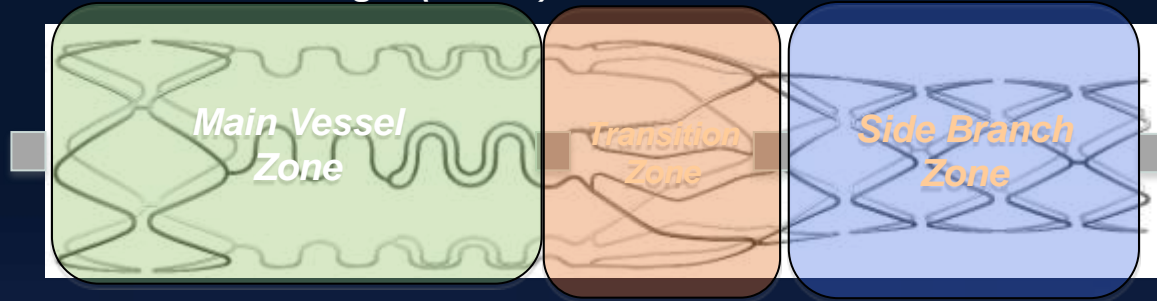
**Main modifications compared to the AXXENT stent:**

- Shorter length to fit larger vessel diameters
- Shorter strut length
- Redesigned link pattern to optimize strut apposition

|                      |                            |
|----------------------|----------------------------|
| <b>Material:</b>     | <b>Nitinol</b>             |
| <b>Vessel Range:</b> | <b>3.75-4.25 mm</b>        |
| <b>Length:</b>       | <b>9 mm</b>                |
| <b>Drug:</b>         | <b>Biolimus A9</b>         |
| <b>Polymer:</b>      | <b>PLA (Biodegradable)</b> |

# TRYTON SHORT

**STANDARD Length (18mm)\***



**NEW SHORT Length (15mm)**



## ***New Design Features***

- ***Stent Design: 3 mm shorter main vessel zone***
- ***Markers Position Optimized for Large Vessels***
- ***Improved delivery system***

\* Large vessels sizes

# The Tryton LM Registry stent

- Retrospective registry of patients with LM bifurcation disease treated with Tryton
- Inclusion period of 12 months
- Results of the first 100 patients

## Baseline and Procedural Outcomes

- Previous CABG: 15%
- Syntax score  $20 \pm 8$
- Medina 1,1,1: 63%
- Tryton implanted in 100%
- Final kissing balloon

CLINICAL RESEARCH

**Acute procedural and six-month clinical outcome in patients treated with a dedicated bifurcation stent for left main stem disease: the TRYTON LM multicentre registry**

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**KEYWORDS**

- 3-D quantitative coronary angiography
- dedicated bifurcation stents
- left main stem bifurcations
- procedural success
- six-month MACE

**Abstract**

**Aims:** Tryton side branch (SB) reverse culotte stenting has been employed for the treatment of left main (LM) stem bifurcations in patients at high risk for bypass surgery. The aim of this study was to assess acute angiographic results and six-month clinical outcome after implantation of the Tryton stent in the LM.

**Methods and results:** We studied 52 consecutive patients with LM disease treated in nine European centres. Angiographic and clinical data analysis was performed centrally. Fifty-one of 52 patients (age 68±11 yr, 73% male, 42% unstable angina, SYNTAX score 20±8) were successfully treated with the Tryton stent. Median class was 1,1,1 in 33 (63%), 1,0,1 in 7 (13%), 1,1,0 in 3 (6%), 0,1,1 in 5 (9%) and 0,0,1 in 1 (2%). The Tryton stent on a stepped balloon (diameter 3.5–2.5 mm) was used in 41/51 (80%) of cases. The mean main vessel stent diameter was 3.4±0.4 mm with an everolimus-eluting stent employed in 30/51 (59%) of cases. Final kissing balloon dilatation was performed in 48/51 (94%). Acute gain was 1.52±0.56 mm in the LM and 0.92±0.47 mm in the SB. The angiographic success rate was 100%, the procedural success rate reached 94%. Periprocedural MI occurred in three patients. At six-month follow-up, the TLR rate was 12%, MI 10% and cardiac death 2%. The hierarchical MACE rate at six months was 22%. No cases of definite stent thrombosis occurred.

**Conclusions:** The use of the Tryton stent for treatment of LM bifurcation disease in combination with a conventional drug-eluting stent is feasible and achieves an optimal angiographic result. Safety of the procedure and six-month outcome are acceptable in this high-risk lesion PCI. Further safety and efficacy studies with long-term outcome assessment of this strategy are warranted.

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- 100% procedural success
- 94% procedural success
- 0% periprocedural MI
- 12% six-month follow-up

# TRYTON Clinical Evidence in LM

- **Prospective Multi-Center Study: eTryton Left Main**



**Tryton Medical Receives CE-mark for the Left Main Indication**  
***Tryton Medical first & only coronary bifurcation stent indicated for Left Main***

Durham, N.C. – February 13, 2014 – Tryton Medical, Inc., the leading developer of stents designed to treat bifurcation lesions, announced that it has received CE Mark for the treatment of Left Main Coronary artery disease. With this approval, Tryton Medical becomes the first company to earn a CE Mark for this indication.

- **Angio/IVUS: Baseline & Follow-up**
- **Multi center Study**



# Dedicated Bifurcation Stents

**Final  
Thoughts**

# Dedicated Bifurcation Stents

## *Final Thoughts*

- For “routine” bifurcation PCI lesions, a provisional one-stent strategy remains the preferred approach.
- For complex or high-risk bifurcations (? 10-30% of cases; esp. in LM disease), a two-stent approach may offer some advantages.
- Current two-stent techniques may be suboptimal in some patients and dedicated bifurcation stents can be a worthwhile alternative (esp. in lesions with large side branches).

# Dedicated Bifurcation Stents

## *Final Thoughts*

- In the future, expect a more customized strategy to complex true bifurcation lesions, with several new DES-based dedicated bifurcation stents as an important component!*