

New Devices For Complex Coronary Interventions

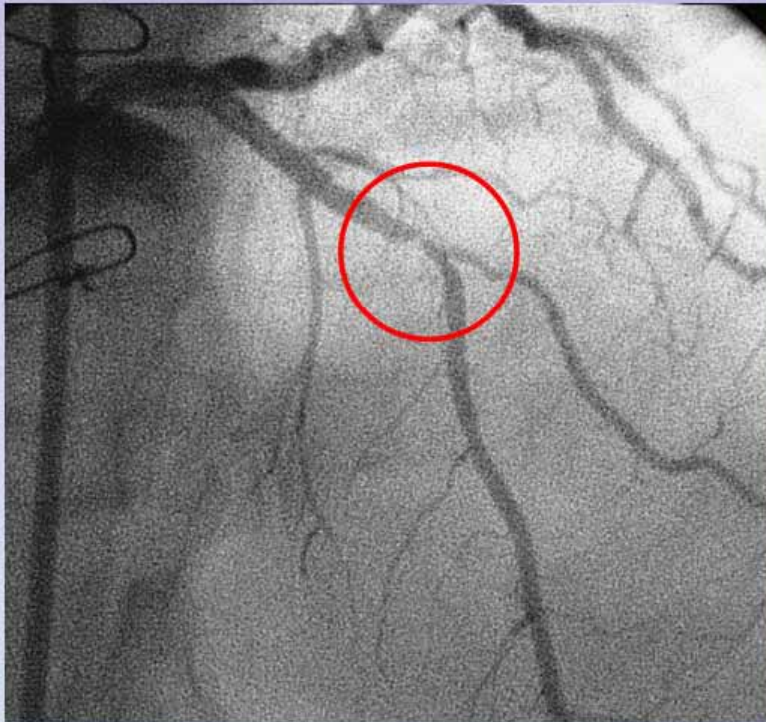
TCT Asia Seoul, 2006

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**sideKick™ Stent Delivery
System
for the Treatment of
Coronary Bifurcation and
Ostial Lesions**

Clinical Issues

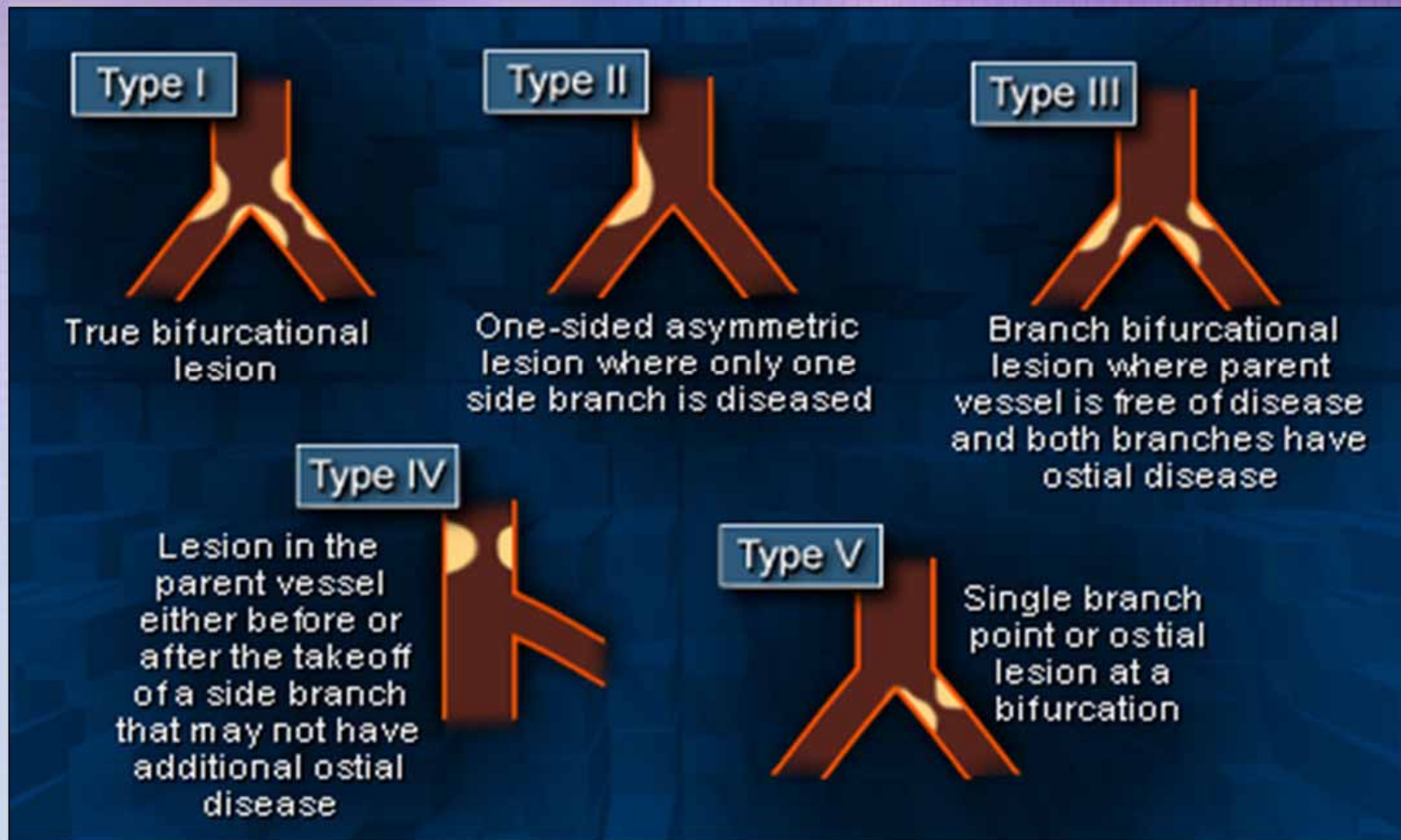
Side branch involvement in at least 30% of all PCI cases



- **True bifurcation**
- **Side branch protection during main branch stenting**
- **Accurate & precise ostial stent placement**

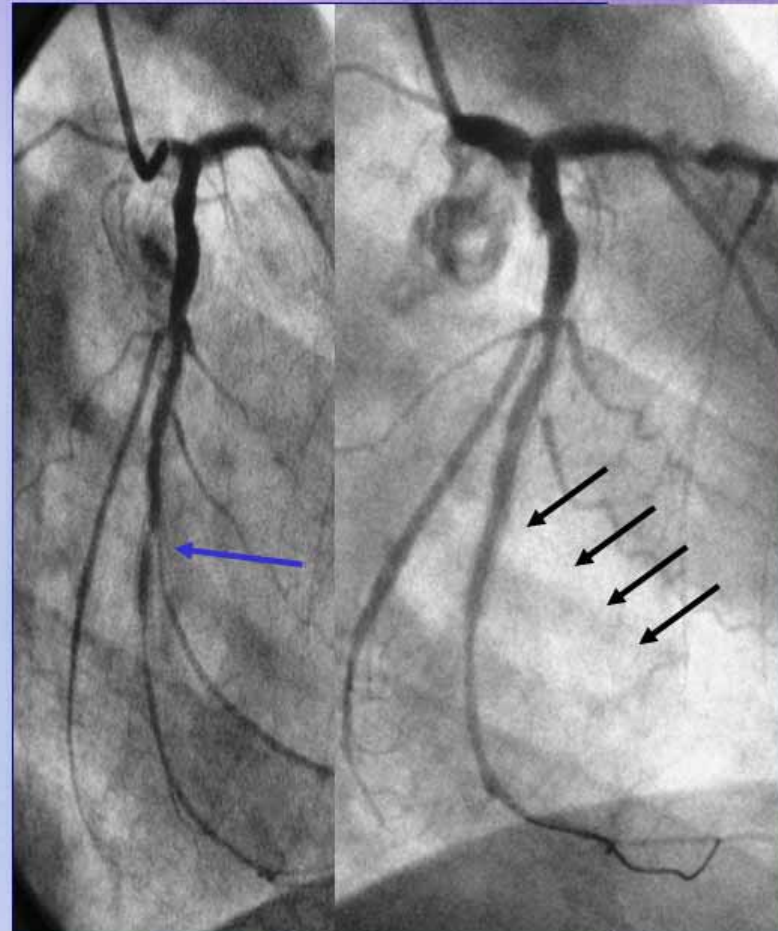
Clinical Issues:

Main vessel lesion with side branch involvement



Current Challenges

- **Inconsistent plaque distribution, unpredictable side branch angulation**
- Short-term complications
 - Side branch occlusion
 - Early and late stent thrombosis
- Long-term complications
 - Higher Restenosis rate



Bifurcation Treatment

Alternatives

- **Specialized techniques w/ standard devices**
 - *Kissing stents: Y, T, V*
 - *Culotte stenting*
 - *Crush*
- **Dedicated, specialized systems**
 - *Frontier™ stent (Guidant)*
 - *Avion™ Bifurcation RX2 (Invatec)*
 - *AXXESS™ stent (Devax)*
 - *PETAL™ stent (AST)*
 - *Nile™ SDS (Minvasys)*
- ***Suboptimal deliverability, incorrect side branch orientation and suboptimal scaffolding***

Side Branch Protection Systems



Innovative, Differentiated, Proprietary

Side Branch Protection System (Mid Exit Port)



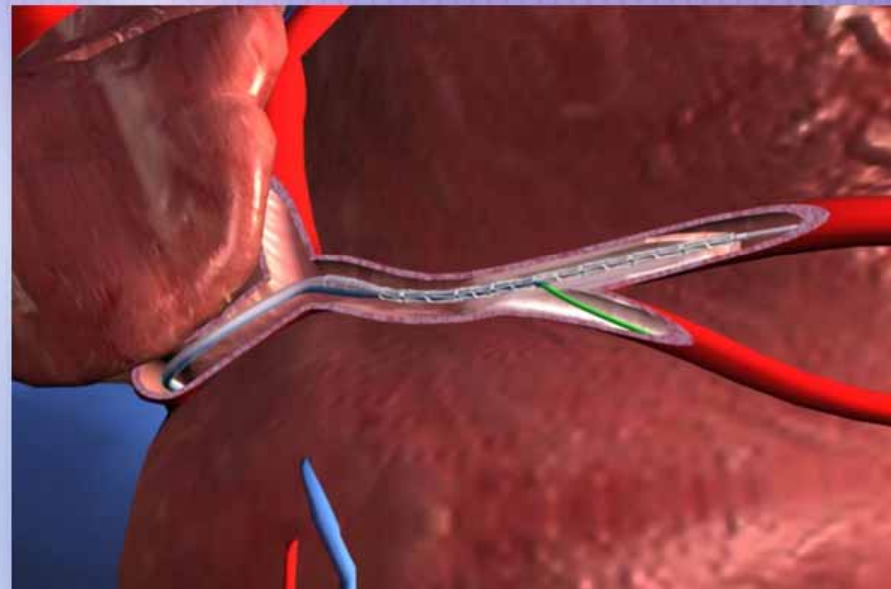
Side Branch Protection System Design

Innovative

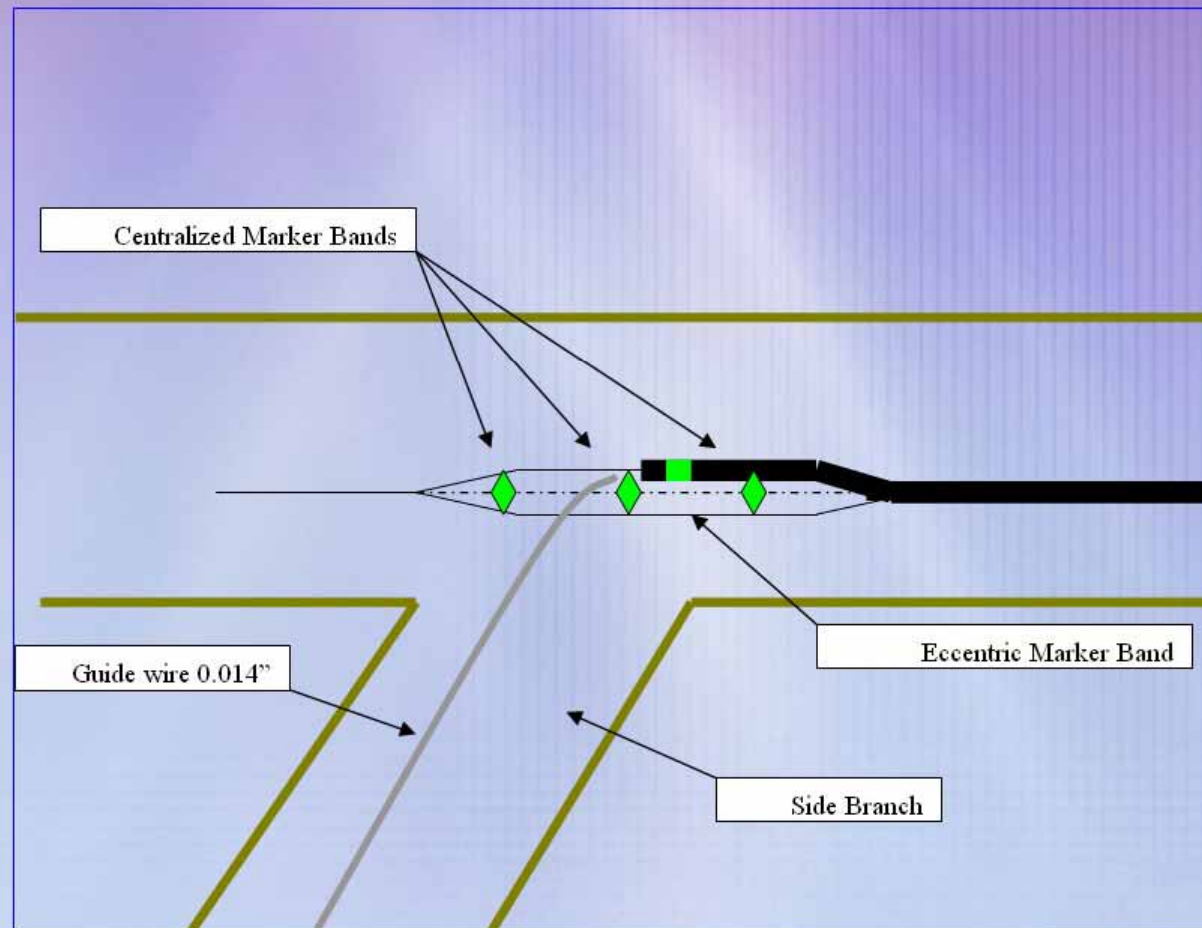
Significant advance in side branch protection

Differentiated

- *Ultra low profile*
- *Operator friendly*
- *Torquable system*

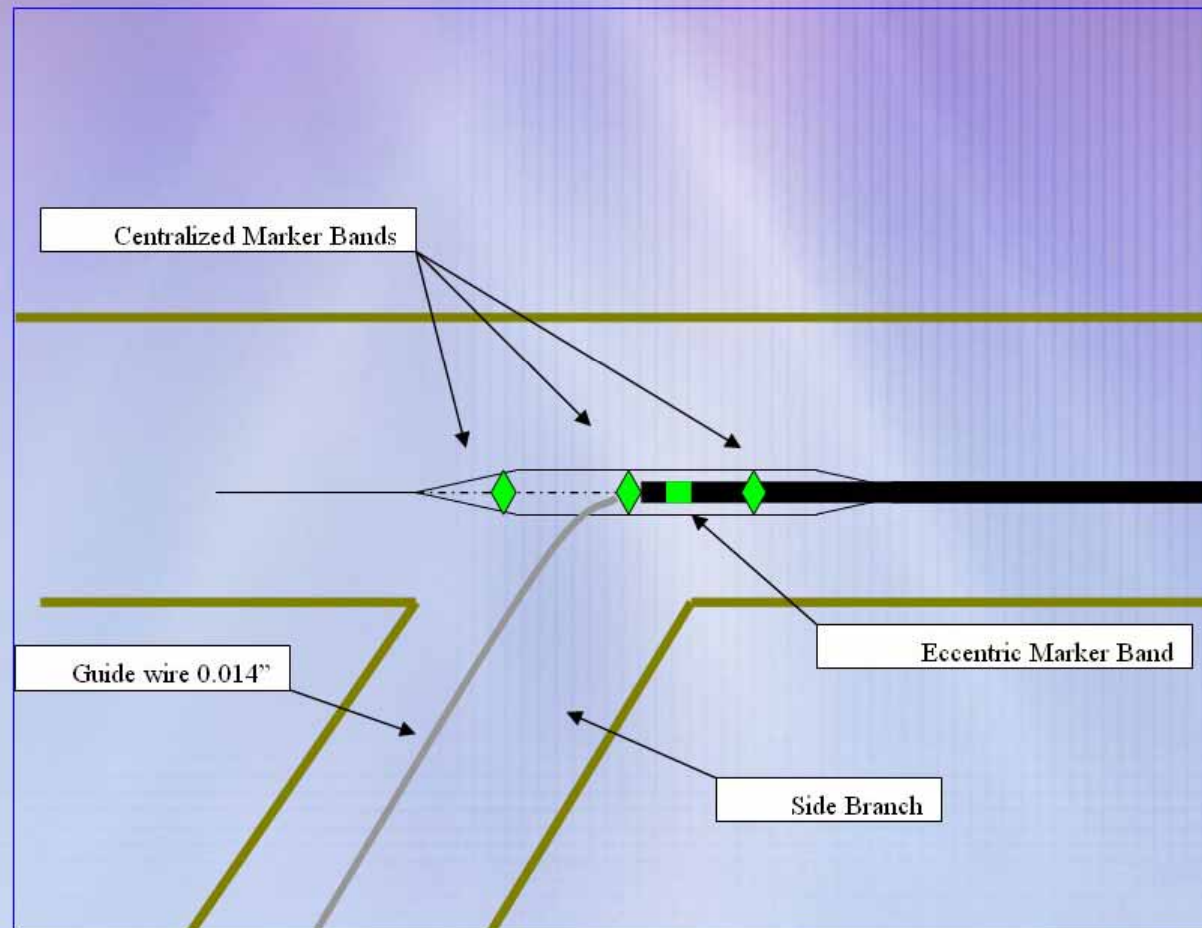


Marker Bands Configuration



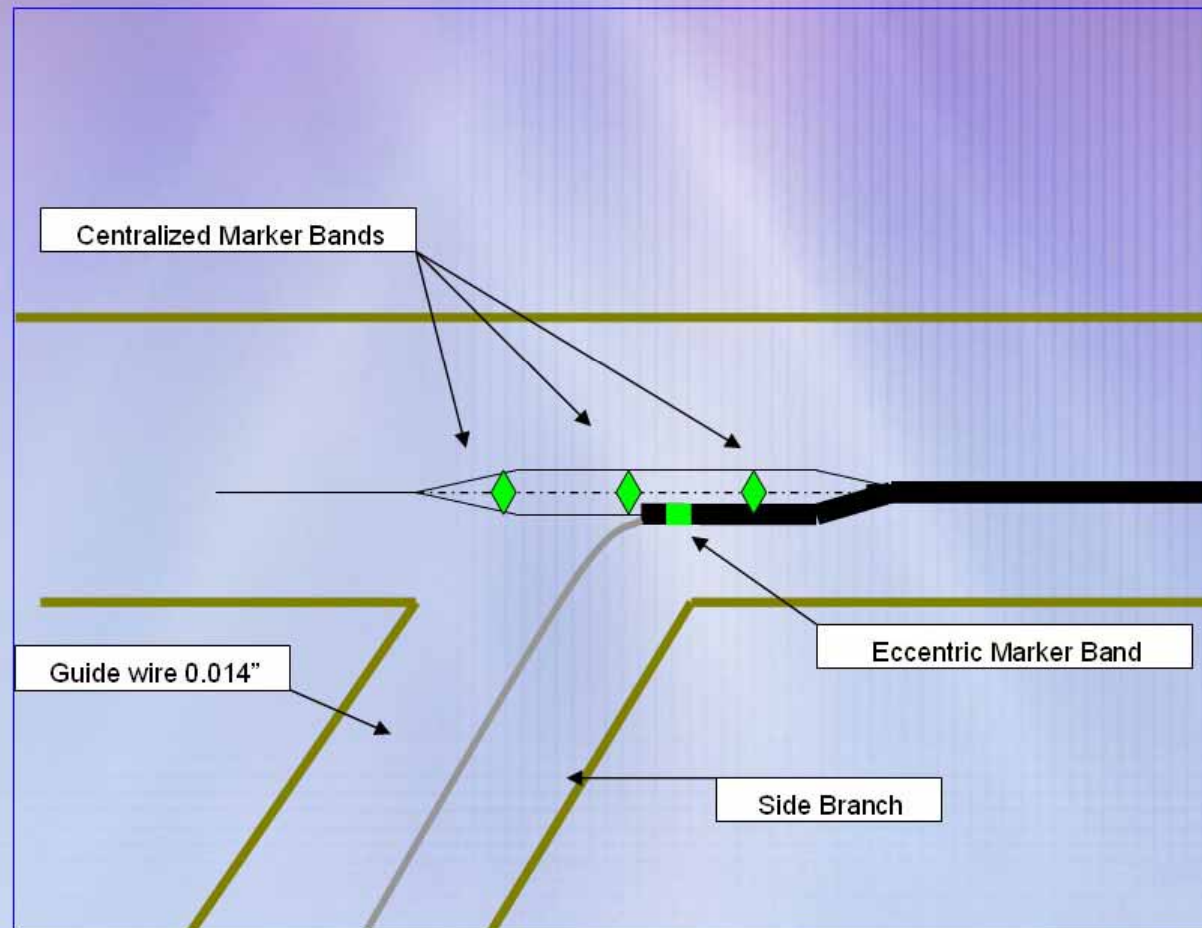
Marker Bands Configuration

Rotate for accurate positioning



Marker Bands Configuration

Rotate for accurate positioning



Stent cell / Sidehole Orientation: Improper Alignment



sideKick™

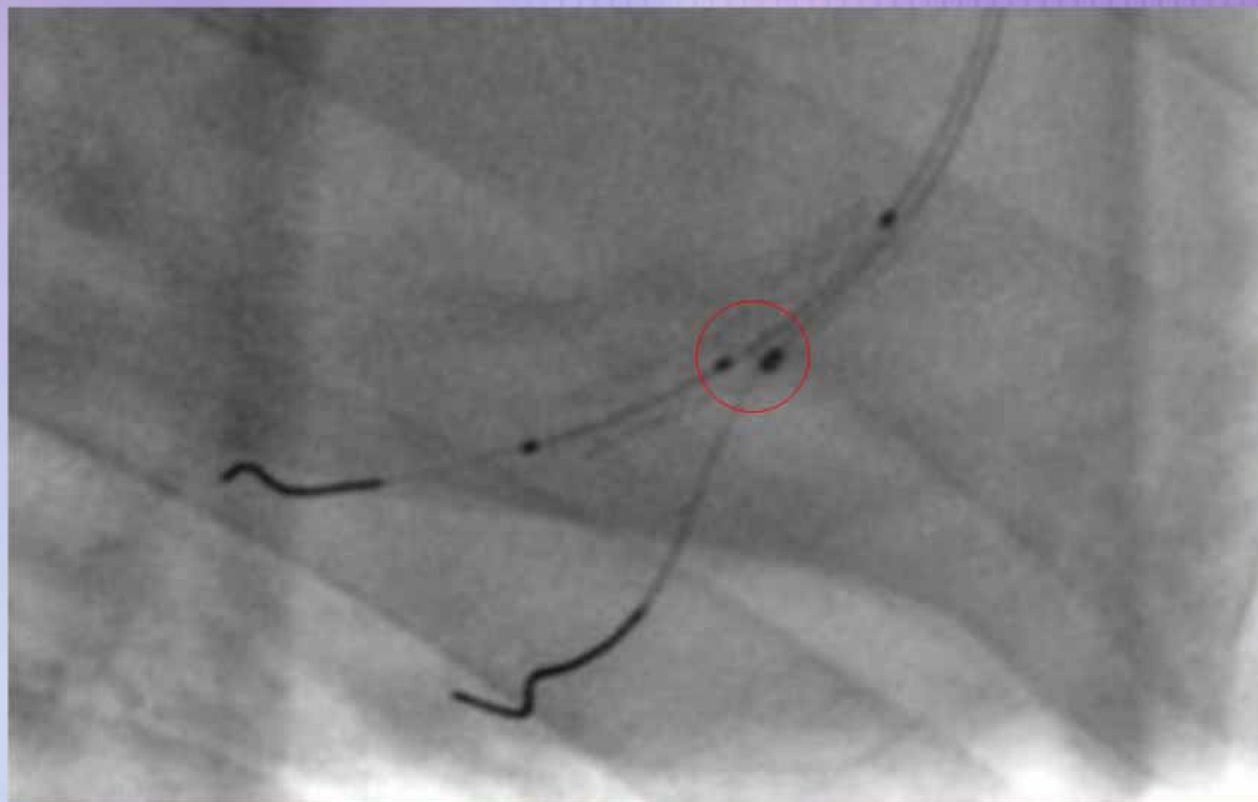
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Stent cell / Sidehole Orientation: Proper Alignment



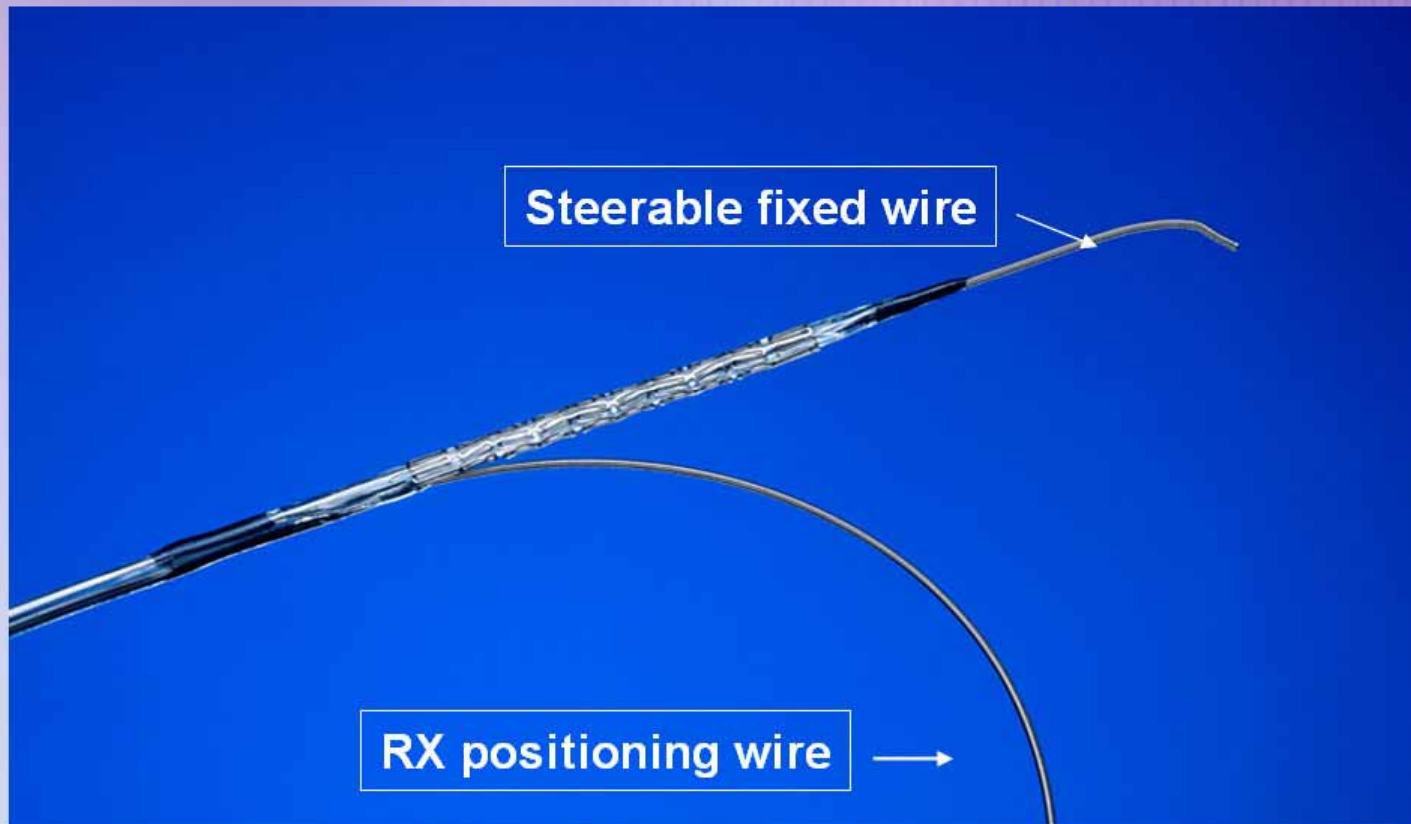
Stent cell / Sidehole Orientation: Inflation and markers aligned to ostium



Post Stent Deployment



Side Branch Protection System (Proximal Exit Port)



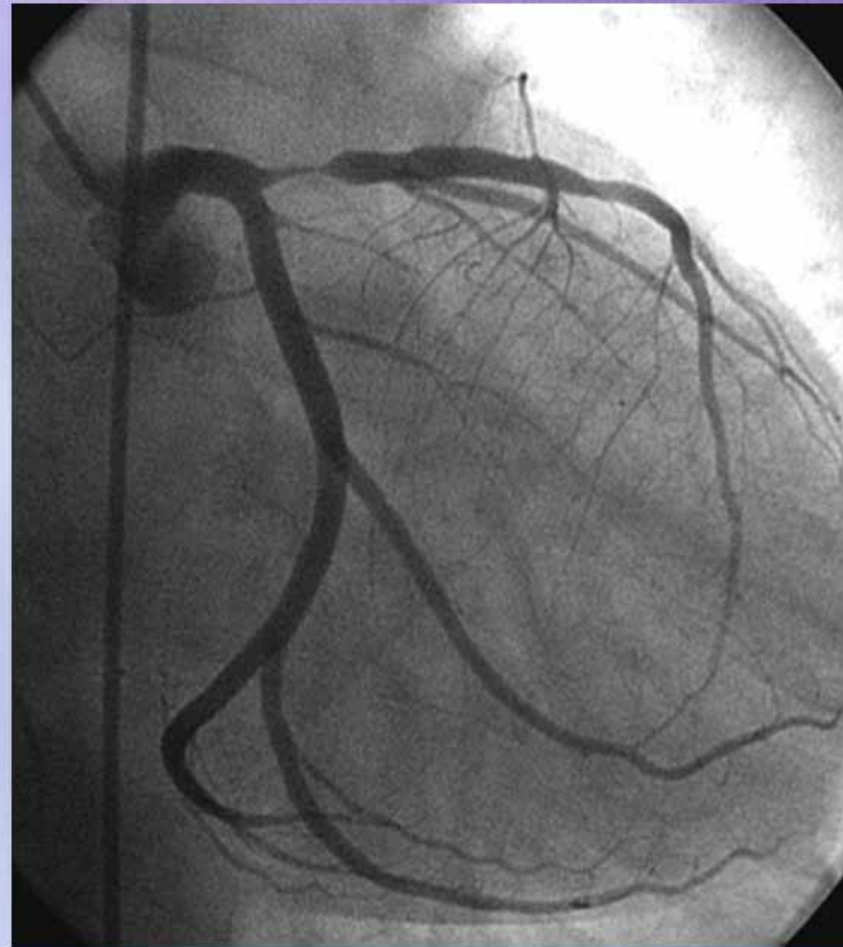
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Ostial Positioning System Design

- Provides main vessel and ostial coverage
- Ultra low crossing profile



First-In-Man Clinical Study

- **Initiated: October 2005**
- **Study Objectives:**
 - to evaluate safety and effectiveness
 - Enrollment of up to 20 patients
- **Participating sites:**
 - Bogenhausen Hospital, Munich (Prof. T. Ischinger)
 - Heart Center, Siegburg (Prof. E. Grube)

Summary

Interim Conclusion

The sideKick features a steerable, low profile system which enables the operator to accurately position stents at ostial lesions, bifurcation lesions, while preserving access to side branches

Future Direction

sideKick dilatation catheter development for pre-dilatation treatment of coronary and peripheral disease, and CTO.