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Second Meeting of the (EBC) European Bifurcation Club

Friday 29 - Saturday 30
September 2006

GRAND HOTEL
Palazzo Carpegna





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The sideKick SDS for the treatment of Bifurcation Lesions

Rome, Italy September 2006

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Provisional T-stenting and kissing balloon in the treatment of coronary bifurcation lesions: results of the French multicenter "TULIPE" study.

Catheter Cardiovasc Interv. 2006 Jun 8;:

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Brunel P, Lefevre T, Darremont O, Louvard Y.

Unite de Soins et de Cardiologie Interventionnelle, Nouvelles Cliniques Nantaises, Nantes, France. brunel-philippe@wanadoo.fr

BACKGROUND: In previous prospective studies, a strategy of (a) stenting of the main branch, (b) provisional T-stenting of the side branch, and (c) final kissing balloon inflation, was associated with high success and low target lesion revascularization (TLR) rates on the long-term. **OBJECTIVES:** To examine the performance of this strategy in a multicenter study. **METHODS:** Consecutive patients were treated at 14 French medical centers for de novo coronary bifurcation lesions with the same technique used. Immediate results and clinically-driven TLR at 7 months were examined. **RESULTS:** The mean reference diameters of the main and side branches were 3.2 +/- 0.6 mm and 2.4 +/- 0.5 mm, respectively. The side branch was stented in 34% of patients. A <30% residual stenosis in the main branch was achieved in 99%, <50% in the side branch in 90%, and both in 89% of procedures. The in-hospital major adverse cardiovascular event were a Q-wave and 5 non-Qwaves MI (0.54% and 2.7%). At 7 months of follow-up, 3 patients (1.76%) had died, 1 suffered a non-Q-wave MI (0.59%), and 28 (15.88%) underwent TLR. By multivariate analysis, a lower left ventricular ejection fraction (OR: 0.934), moderate calcifications (OR: 7.86), and non-use of the "tailed" wire technique (OR: 4.26) were associated with reinterventions during follow-up.

CONCLUSIONS: A strategy of provisional T-stenting with a tubular stent and final kissing balloon angioplasty for the treatment of coronary bifurcation lesions was safe and associated with a low TLR rate at 7 months. This strategy should be applicable to the new era of drug eluting stents.



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Bifurcation Intervention: Keep it Simple - James B. Hermiller, MD

J Invasive Cardiol. 2006 Feb;18(2):43-4

“.... Various techniques have been devised to enhance the outcomes of the side branch. Bifurcation stenting techniques include the provisional T, the planned T, the V, the simultaneous kiss (SKS), the culotte, and most recently, the crush. Data from bare metal stent studies suggest no benefit of two stents versus one stent, and to the contrary, a consistent theme has been that one stent is superior. These analyses have been limited by a lack of prospective randomization, **however, and do not exclude the possibility that those lesions receiving two stents are at inherently higher risk for restenosis. In one randomized study of systematic side branch stenting versus single main branch stenting, the single-stent group had lower overall restenosis rates (18.7% versus 28%) and fewer stent thromboses (6.6% in the two-stent group).**³ Pan and colleagues reported similar findings in the other randomized study of single versus two stents in bifurcations....



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Unmet Needs

- **Low profile, sleek device**
- **Easy to use (single wire, single operator)**
- **Torquable**
 - **For optimal stent positioning**
- **Accurate device orientation for optimal stent deployment**
- **Means to assess position and orientation**
- **Side branch access post-stent deployment**
- **Versatile platform for various bifurcation anatomies**

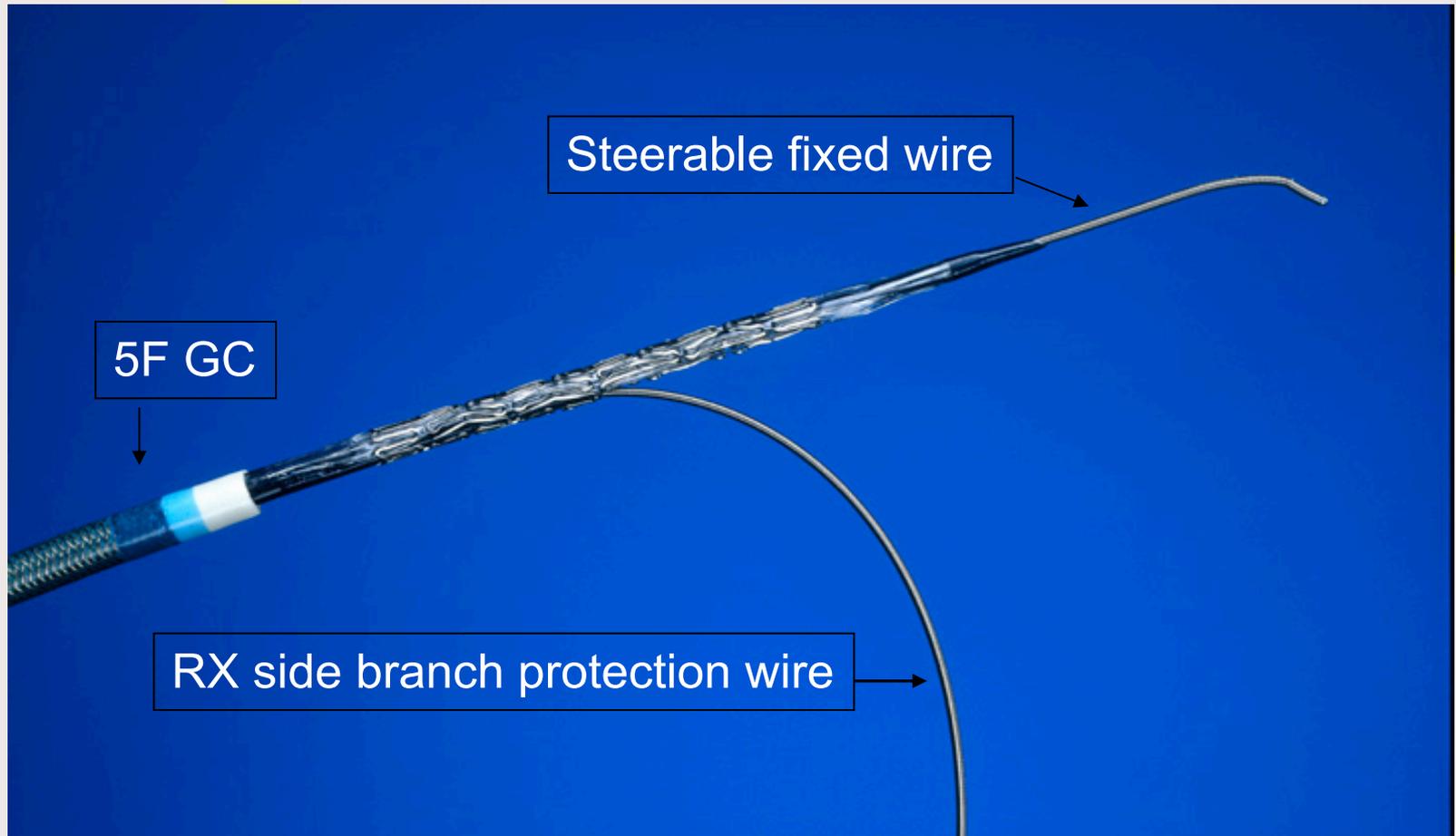


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sideKick™

Stent Delivery System Mid Exit Port Model



sideKick™

Stent Delivery System

Proximal Exit Port Model

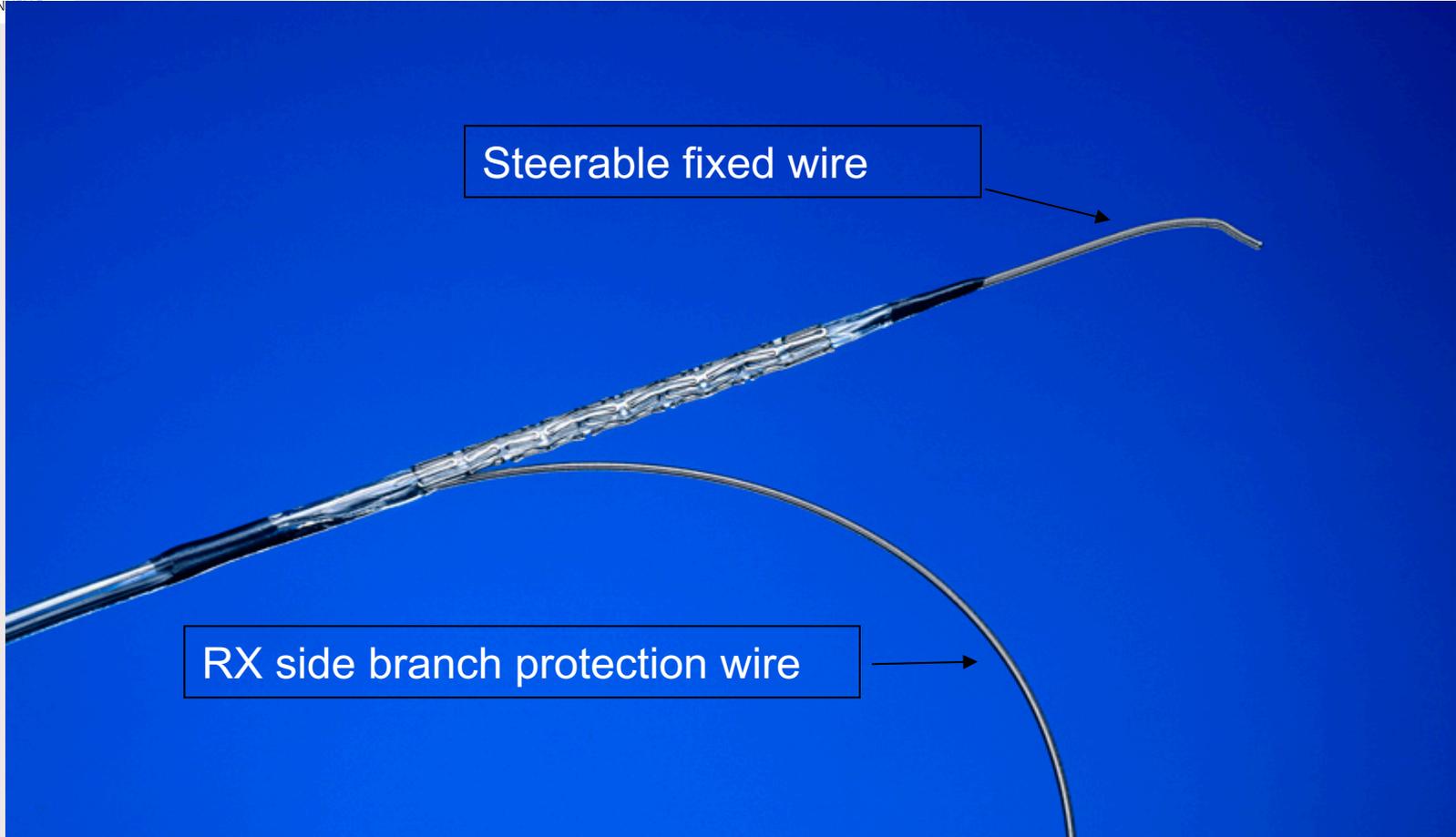


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Steerable fixed wire

RX side branch protection wire



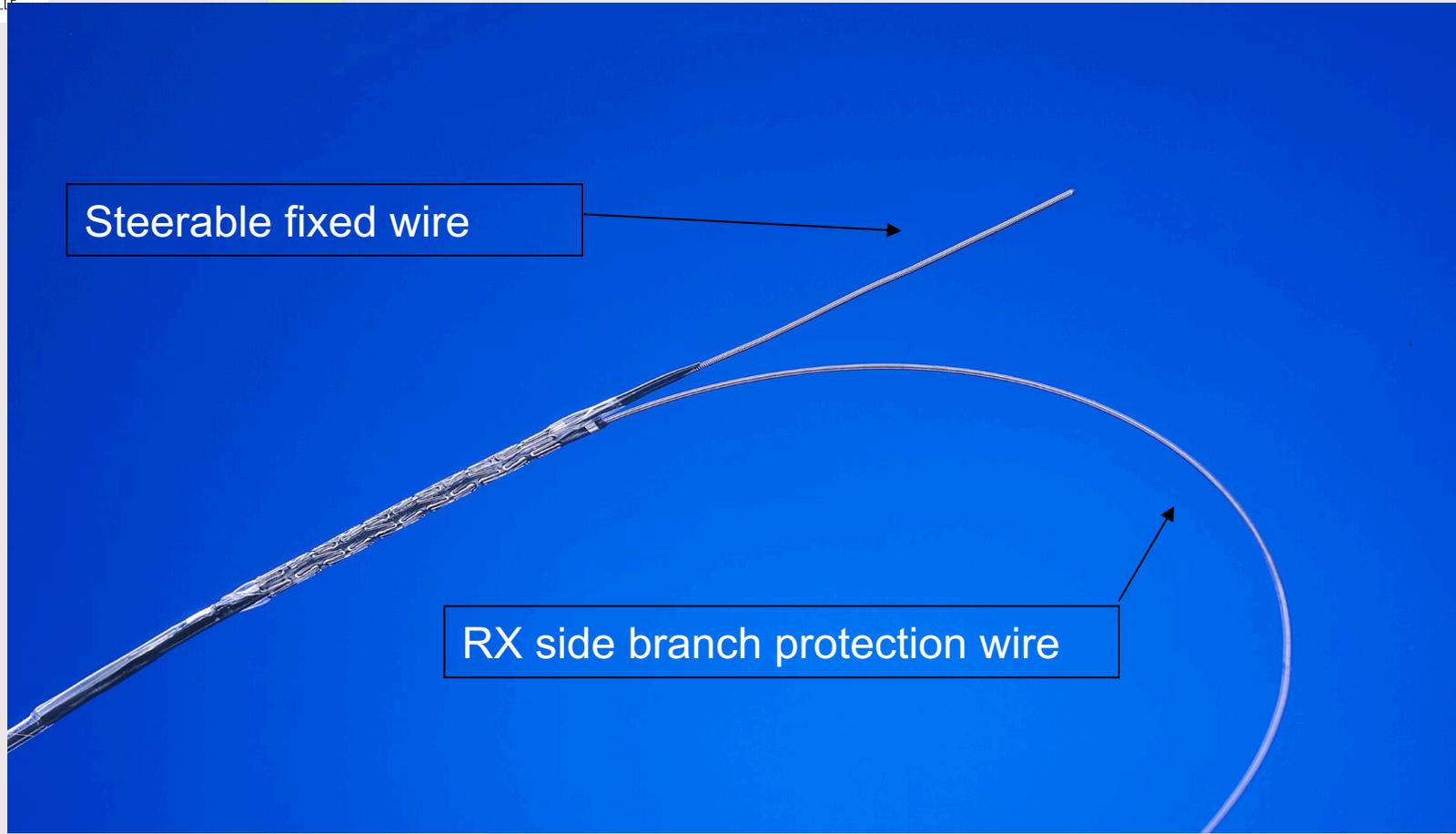


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Stent Delivery System Distal Exit Port Model





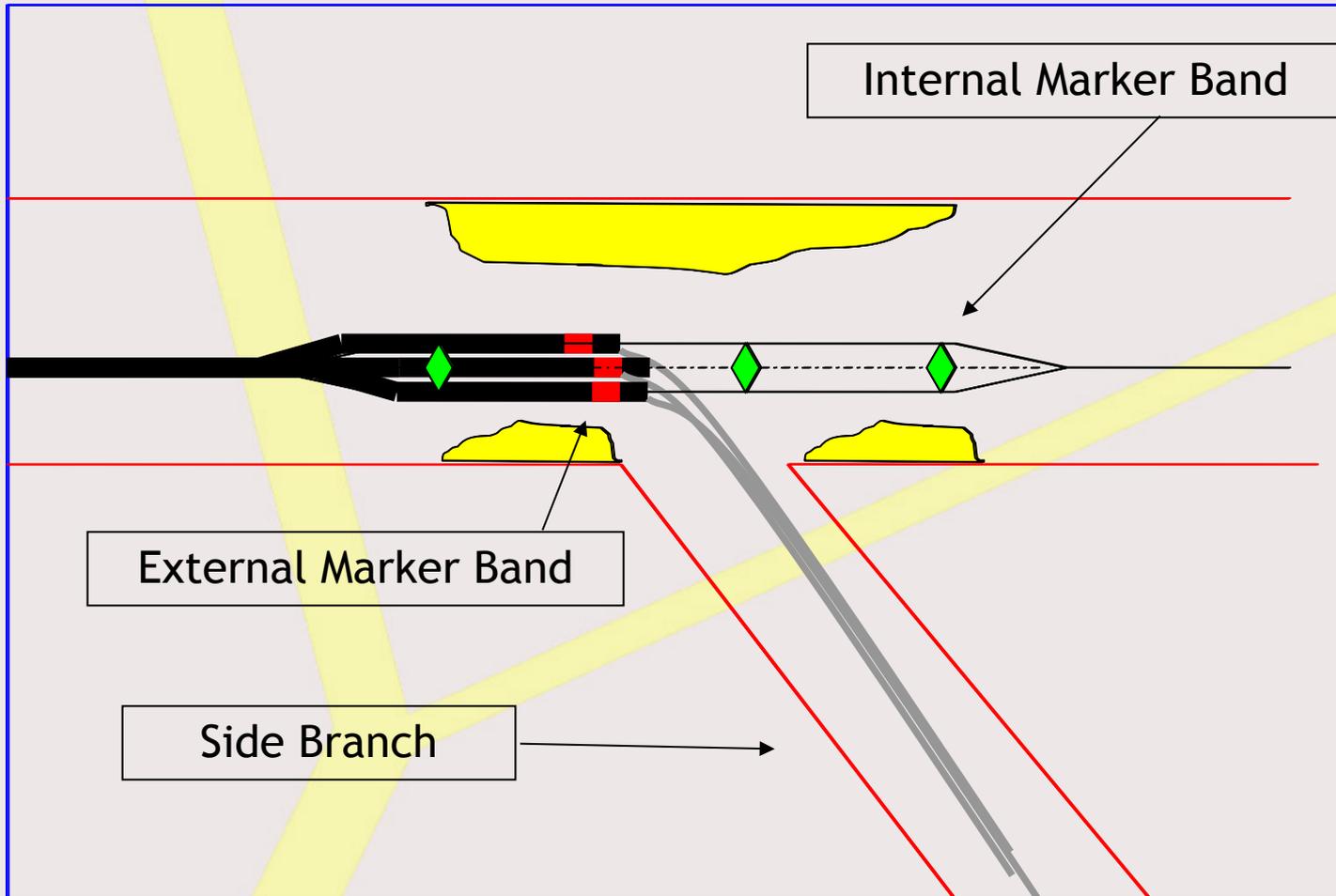
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Unique Marker Configuration

Rotation mechanism for Accurate placement





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sideKick™

First-In-Man Clinical Study

Initiated: October 2005

- ***Study Objectives: To evaluate safety and effectiveness of the sideKick mid, proximal and distal models***
- ***Study Design: Any patient with lesion involving side branch***
- ***17 patients, 20 Lesions***
- ***Participating sites:***
 - ***Bogenhausen Hospital, Munich (Prof. T. Ischinger)***
 - ***Heart Center, Siegburg (Prof. E. Grube)***

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side**Kick**TM

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- ***Stent used - Open Cell BMS***
- ***All 3 sideKickTM models***
 - ***Proximal, Mid, Distal***
- ***1° endpoint: Technical success & 30-day MACE***



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Lesions (n=20)

	<u>Location</u>	<u>Bifurcation Class</u>	
LAD	6 (30%)	2	5 (25%)
CX	3 (15%)	3	5 (25%)
RCA	11 (55%)	4	2 (10%)
		4A	2 (10%)
		4B	6 (30%)



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Results



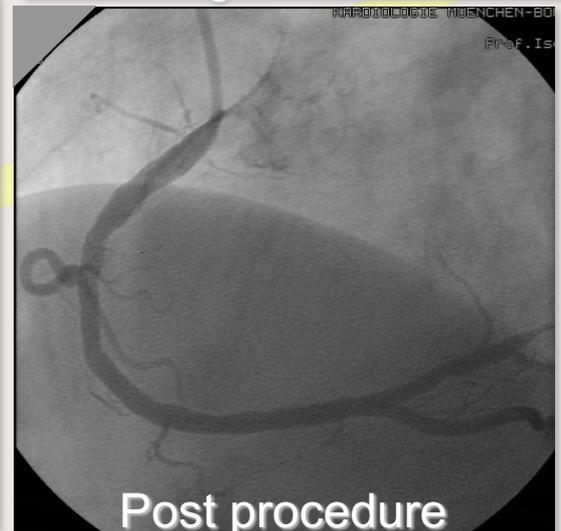
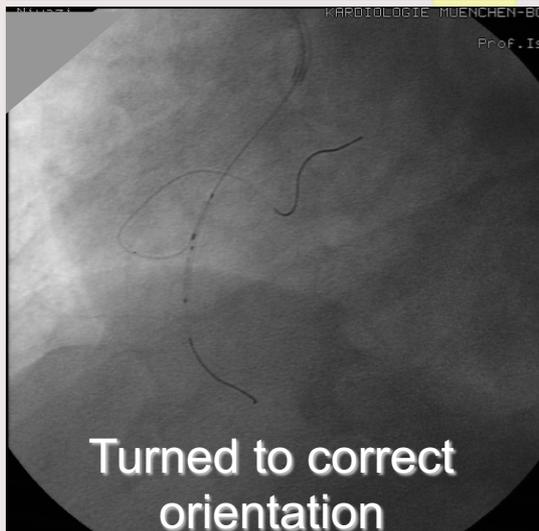
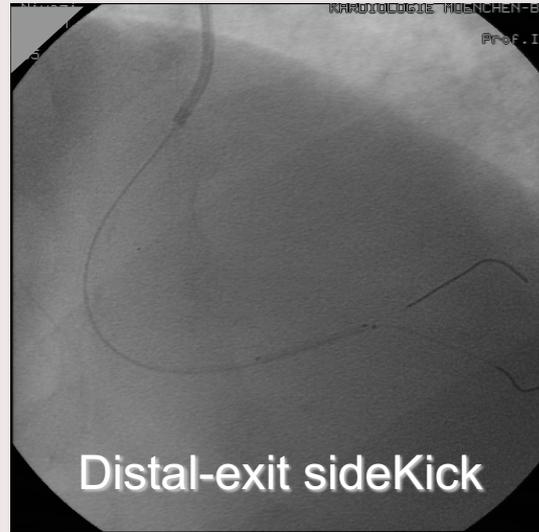
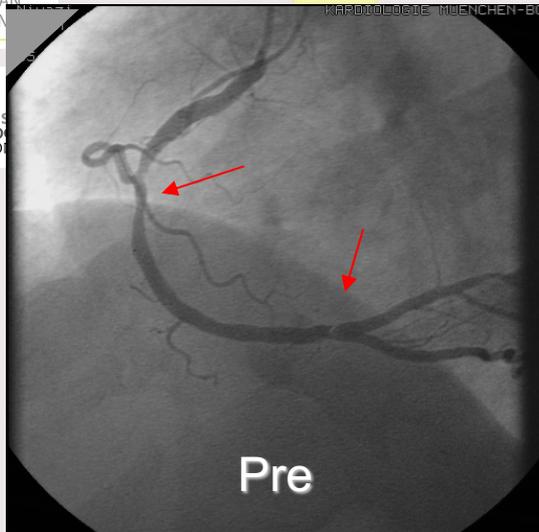
Device Success	16 (80%)	Post-dil	6 (30%)
Procedure Success	20 (100%)	Additional Stent	8 (40%)
Final MLD, mm	2.91 ± 0.46	Side Branch PTCA	4 (20%)
Final %DS	9.1 ± 11.9		



Case # 1-8: 68 YOM: Proximal RCA Type II bifurcation; Distal RCA Type III bifurcation

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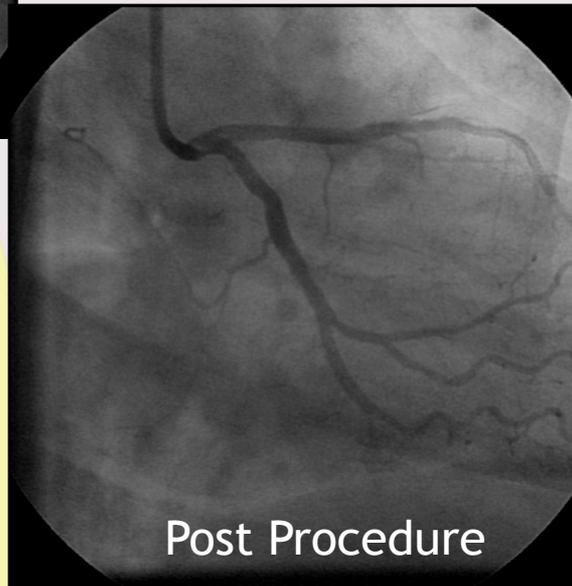
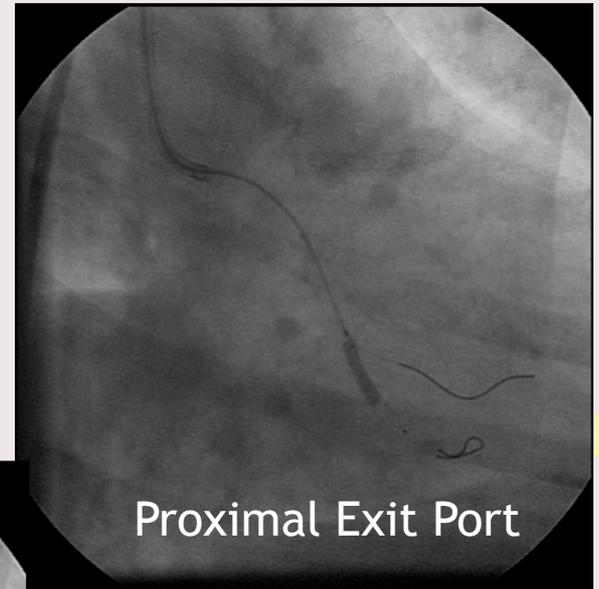
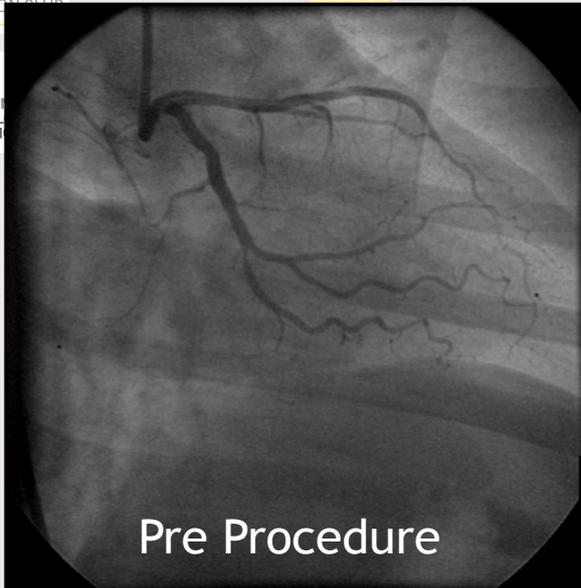
Courtesy of Prof. Thomas Ischinger
Investigational use only



Case # 2 - 2: 68 YOM: Mid CRx Type 4B bifurcation;

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Courtesy of Prof. Eberhard Grube
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Summary

In this First-in-Man feasibility and safety study, the sideKick™ Stent Delivery System design appears to provide a safe, effective and user-friendly stent delivery technique in bifurcation lesions.



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Next Steps

- CE Mark of the delivery system is expected by 2nd quarter 2007
- The company evaluate different DES to integrate with the delivery system
- Randomized studies are planned to be performed late 2007.