

# The SPIRIT II Study - A Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Patients With *De Novo* Native Coronary Artery Lesions

## 3 Year Clinical Results

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On behalf of the SPIRIT II Investigators

# **SPIRIT II 3 Year Clinical Results**

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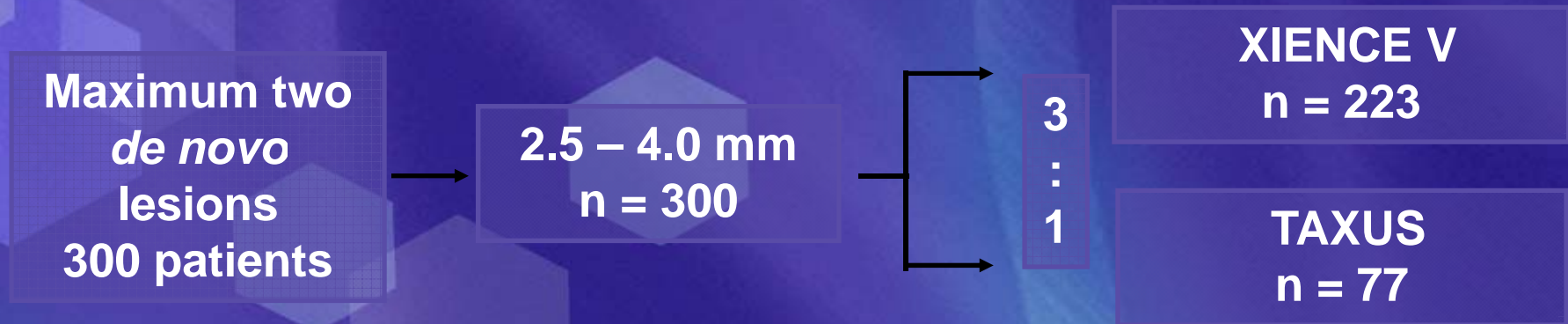
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# Study Design

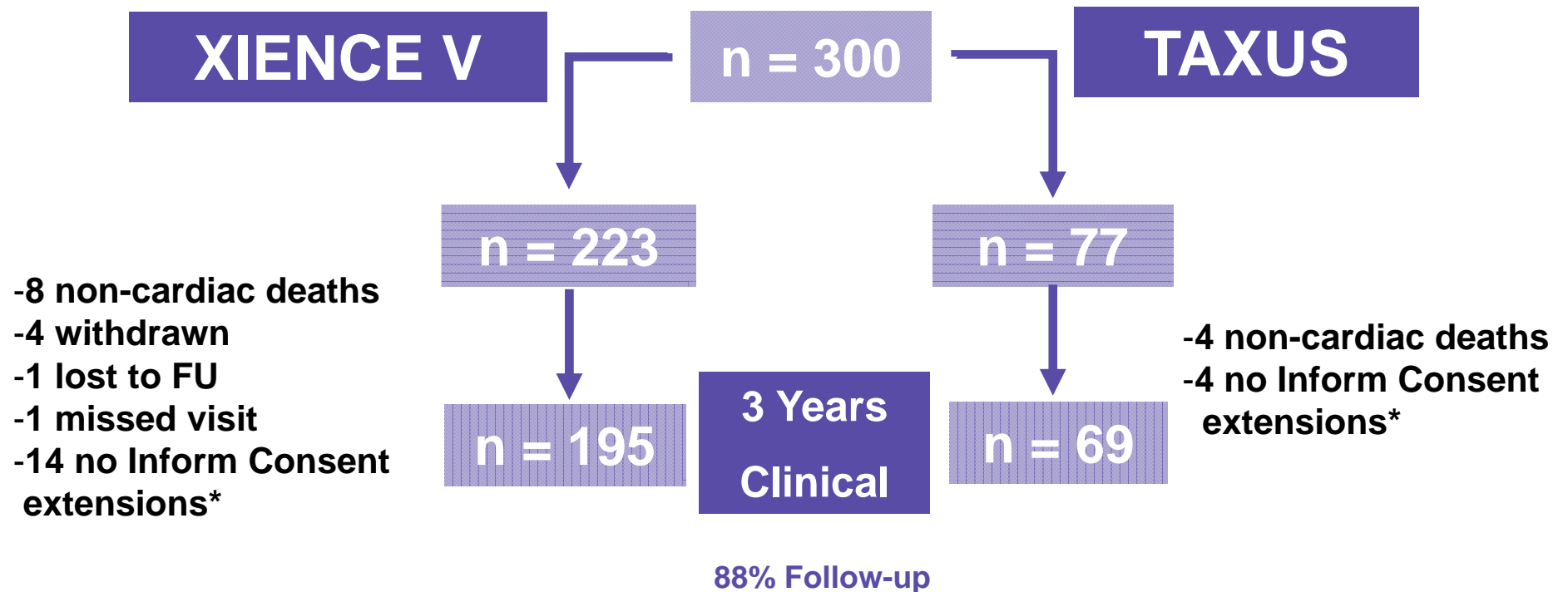


- Sponsor: Abbott Vascular
- PI: PW Serruys MD, PhD
- SC: E Garcia MD, J Ormiston MD, M Wiemer MD
- DSMB: J Tijssen PhD, T Lefèvre MD, P Urban MD
- CEC: C Hanet MD, D McClean MD, V Umans MD
- Angiographic and IVUS Corelab: Cardialysis (Rotterdam, NL)

- Prospective, randomized (3:1), single-blind, non-inferiority to TAXUS
- Primary endpoint: Angiographic in-stent late loss at 180 days (powered for sequential non-inferiority and superiority)
- Secondary endpoint: Angiographic in-segment late loss at 180 days (powered for non-inferiority)
- Clinical follow-up: 30, 180, 270 days, 1, 2, 3, 4 and 5 years. Angiographic and IVUS follow-up: baseline, 180 days & 2 years (only for 152 patients)

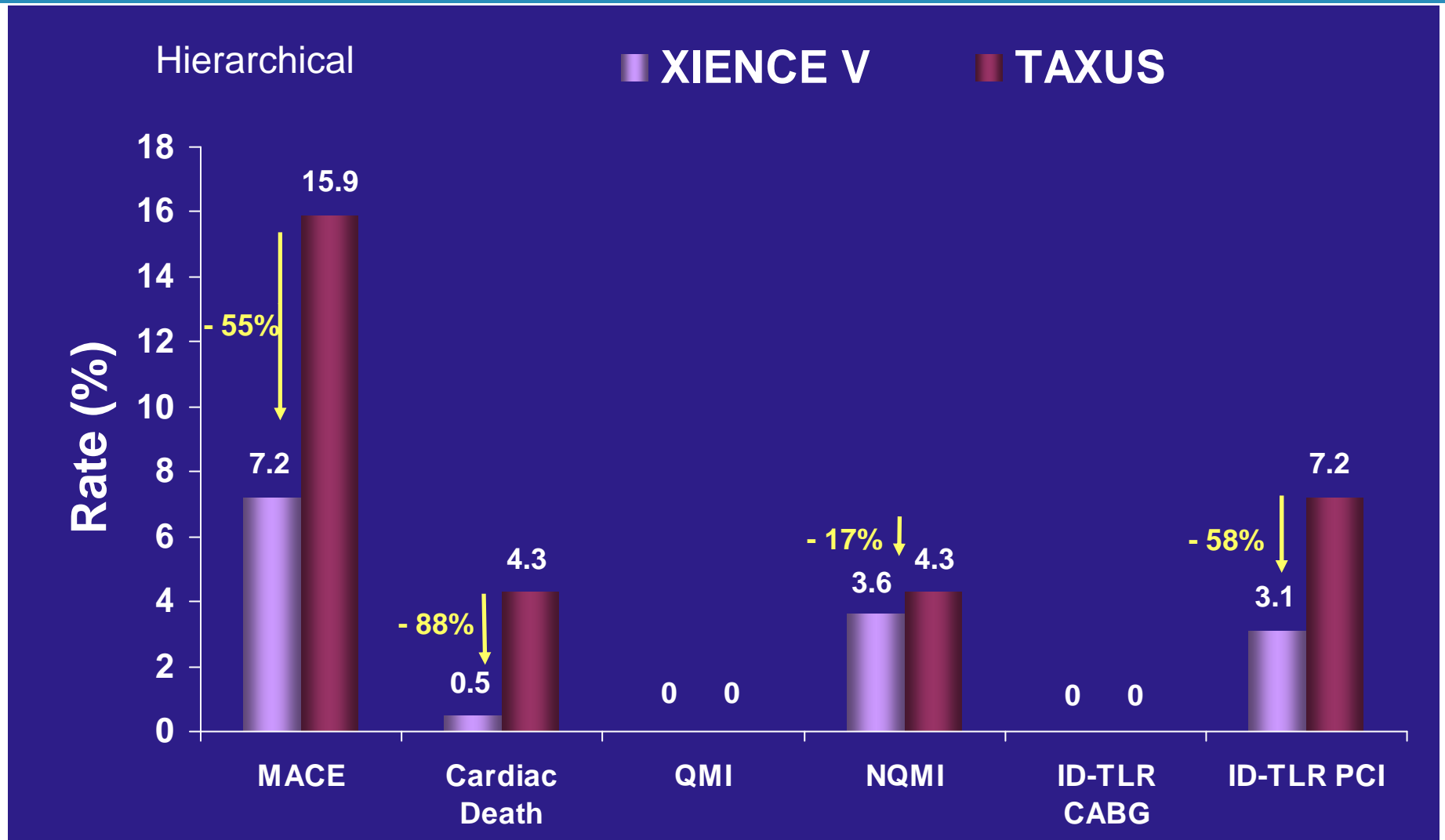
# Clinical Study Population

Spirit II



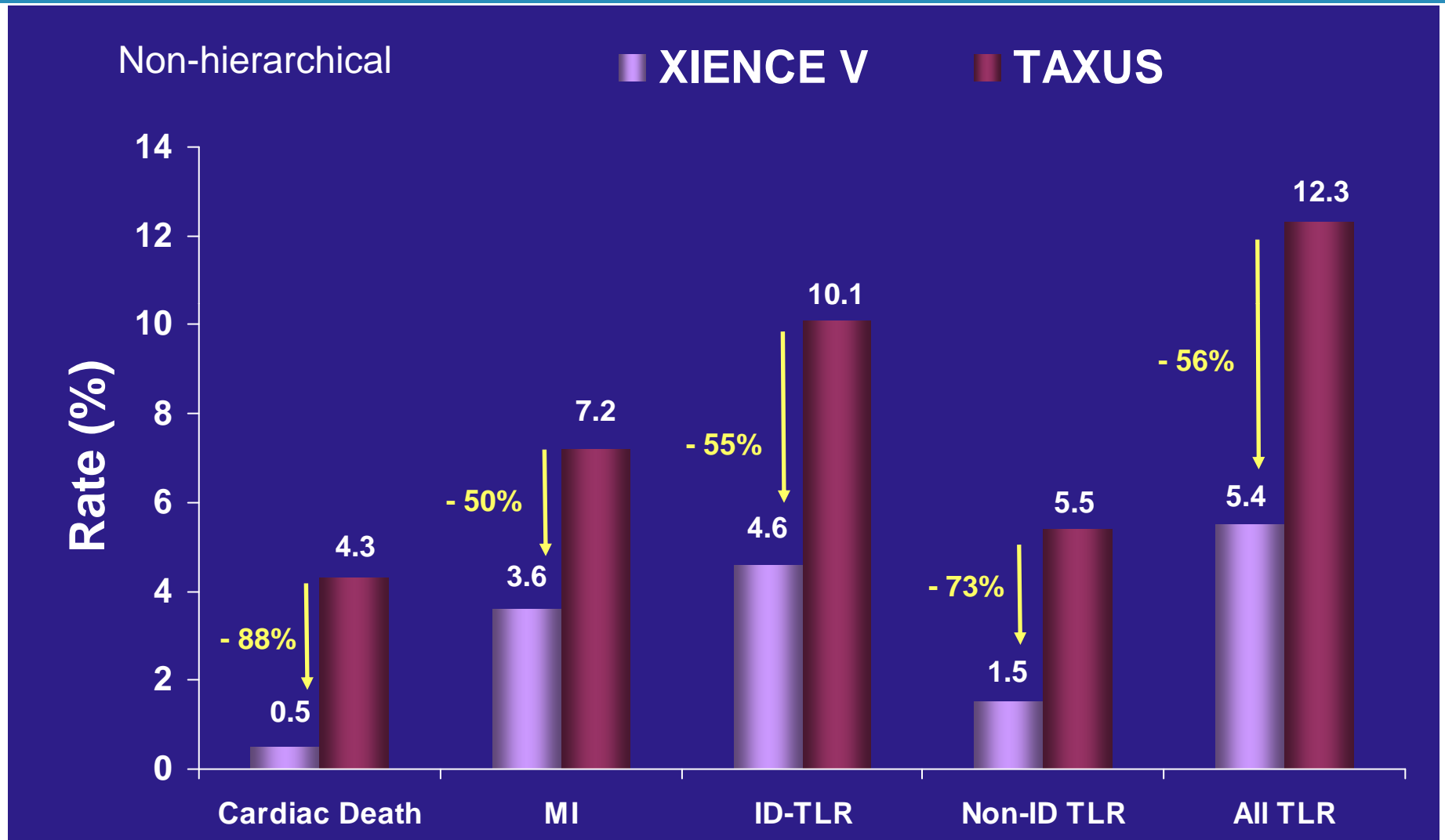
\* Original protocol planned 2-Year follow-up. Extension to 5-Year required new patient informed consent

# 3 Year Clinical Results

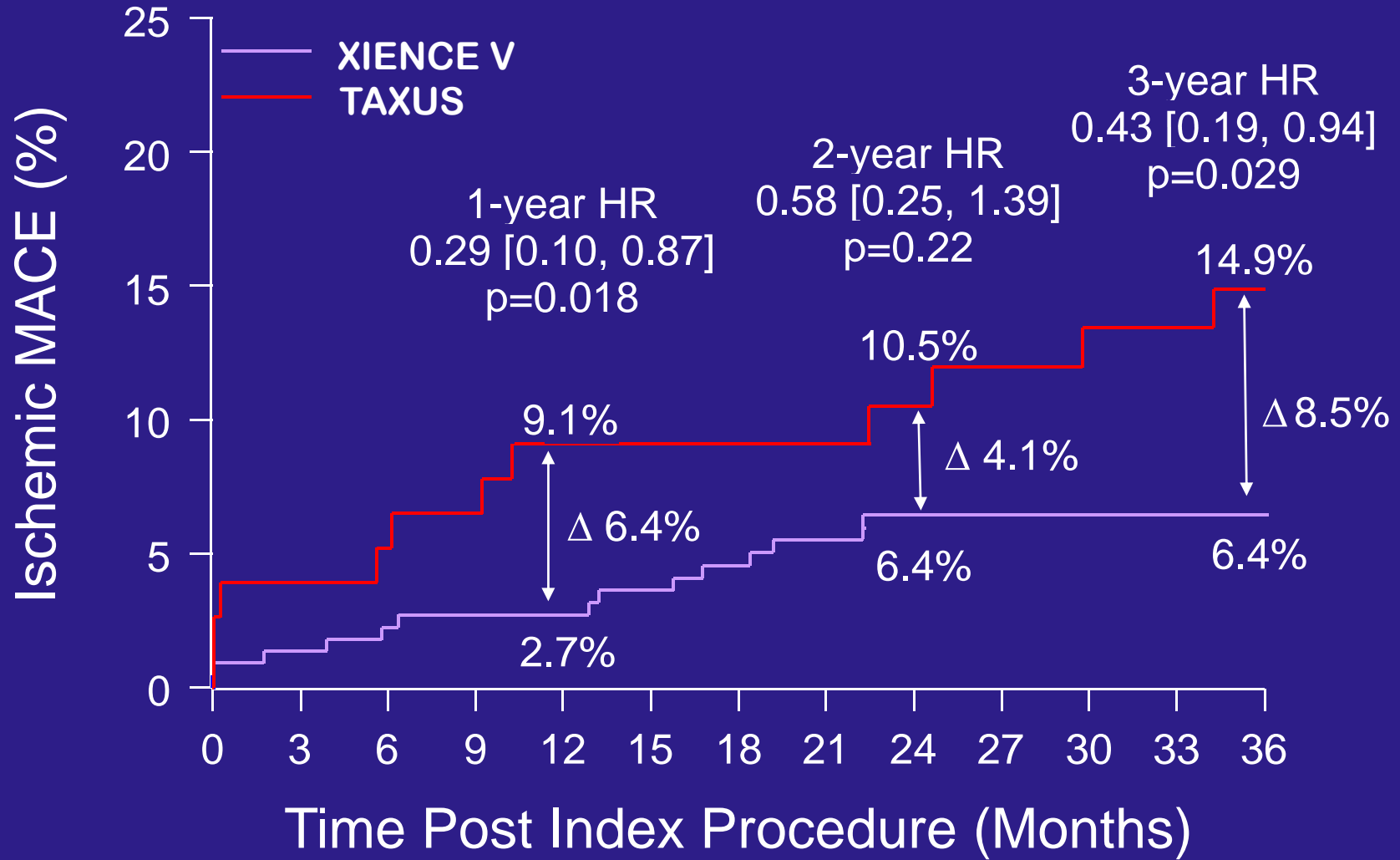


MACE: cardiac death, MI, ID-TLR by CABG or PCI

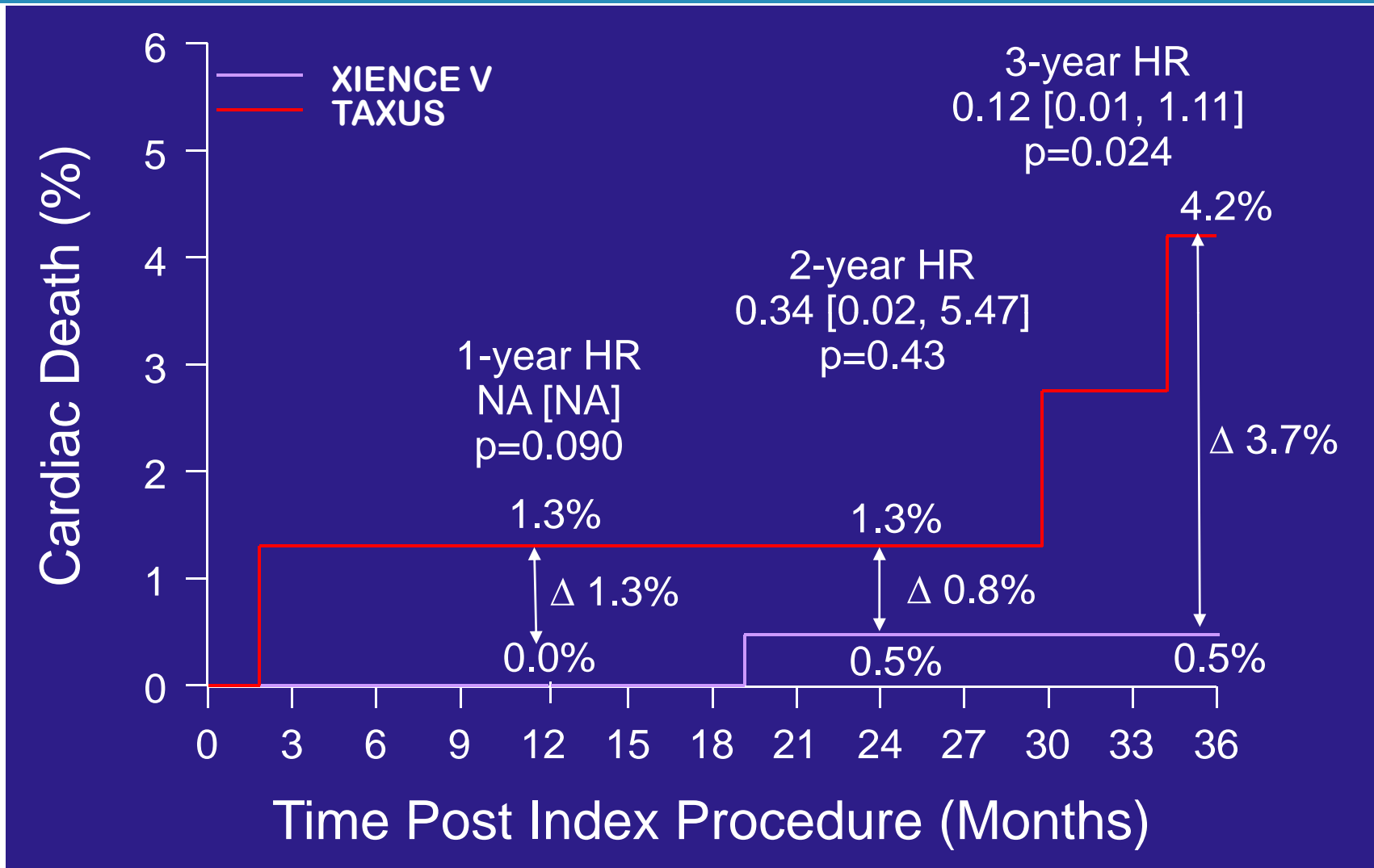
# 3 Year Clinical Results



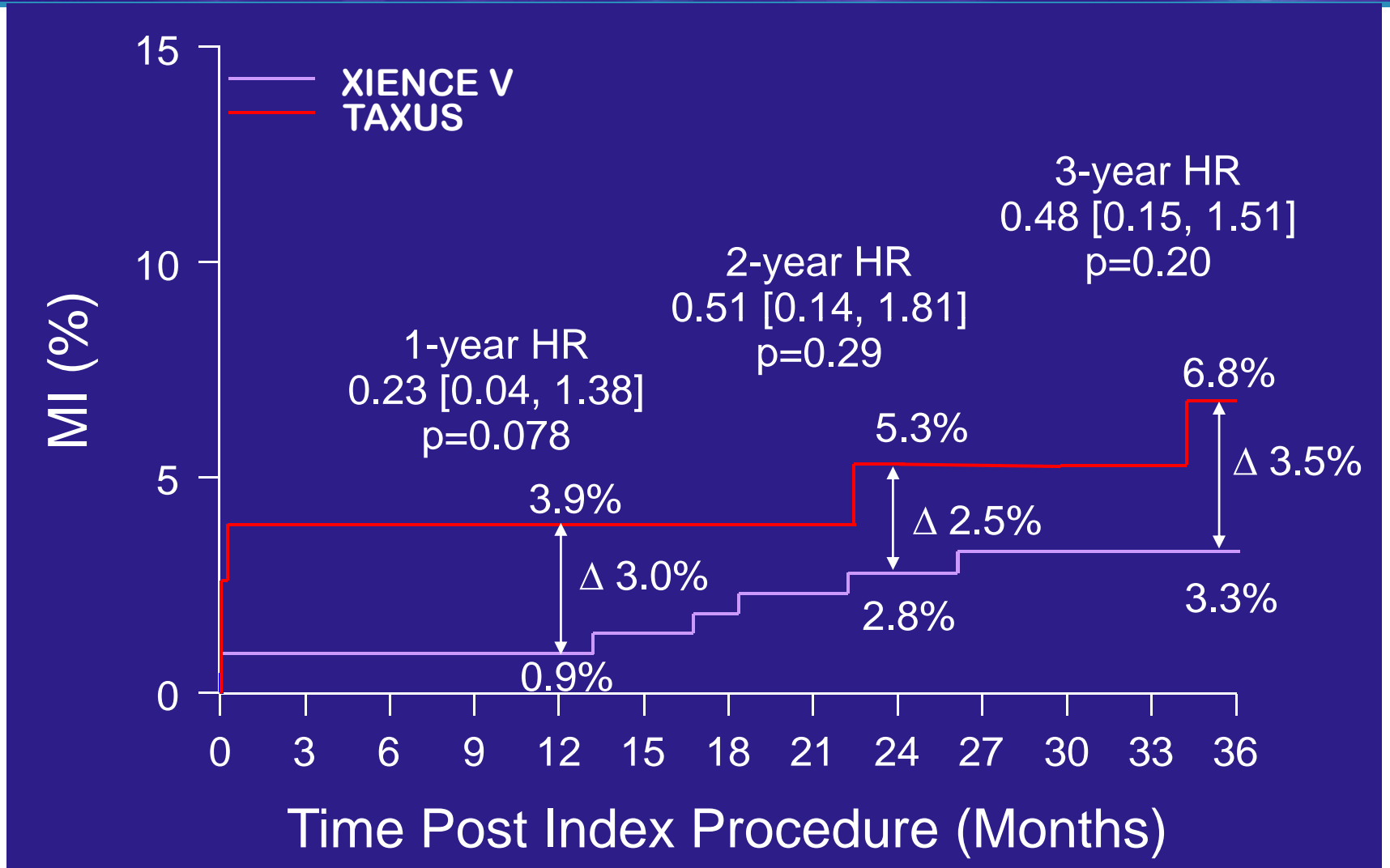
# Cumulative Incidence Rates of MACE



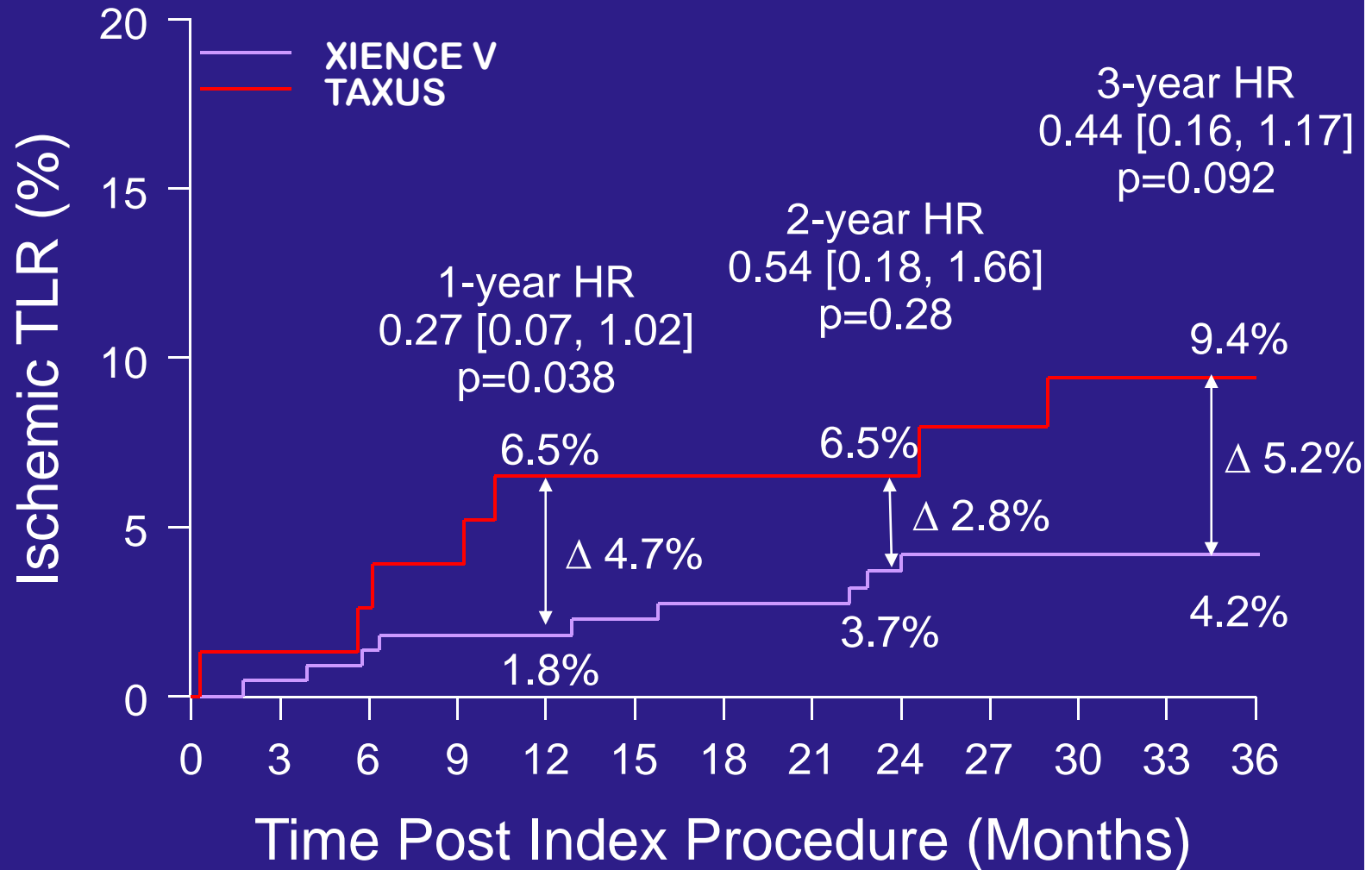
# Cumulative Incidence Rates of Cardiac Death



# Cumulative Incidence Rates of MI



# Cumulative Incidence Rates of ID-TLR



# 3 Year Clinical Results

	XIENCE V 203* patients n (%)	TAXUS 73* patients n (%)
Cardiac death %	<b>1 (0.5)</b>	<b>3 (4.1)</b>
Non-Cardiac death %	<b>8 (3.9)</b>	<b>4 (5.5)</b>
All death %	<b>9 (4.4)</b>	<b>7 (9.6)</b>

\*Denominator includes patients with 3 year follow-up or TVF event (any death, MI, TLR or TVR)

# ARC Stent Thrombosis

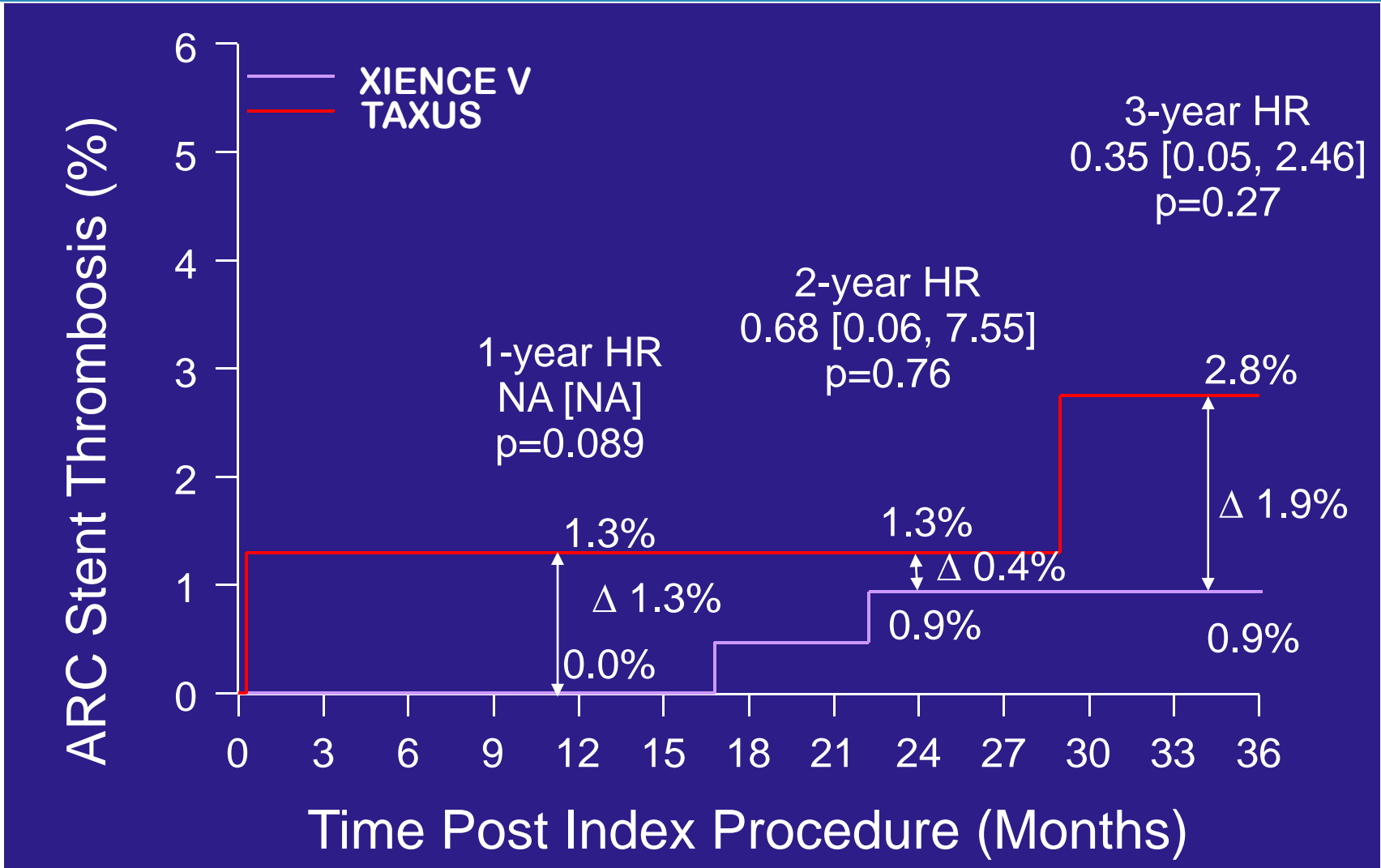
Definite and Probable	XIENCE V 223 patients n (%)	TAXUS 77 patients n (%)
Acute stent thrombosis (%) (<24h)	0.0	0.0
Sub-acute stent thrombosis (%) (24h – 30d)	0.0	1 (1.3)*
	220 patients	77 patients
Late stent thrombosis (%) (30d – 1Y)	0.0	1 (1.3)*
	193 patients	68 patients
Very late stent thrombosis (%) (>1Y)	2 (1.0)	1 (1.5)
<b>Total stent thrombosis (%)</b>	<b>2 (1.0)</b>	<b>2 (2.9)</b>

**One new stent thrombosis in the TAXUS arm between 2 years and 3 years, none in the XIENCE V arm**

p=NS

\* Same patient

# Cumulative Incidence Rates of ARC Stent Thromboses (Definite/Probable) Spirit II



# Summary

- **SPIRIT II 3 year data shows a consistent reduction in clinical events for XIENCE V vs TAXUS (MACE 6.4% vs 14.9%, p=0.029)**
- **Observed significant reduction in Cardiac Death in favour of XIENCE V (0.5% vs 4.2%, p=0.024)**
- **Observed lower MI (3.3% vs 6.8%) and ID-TLR rates (4.2% vs 9.4%) in the XIENCE V arm**
- **Low ARC stent thrombosis rate for XIENCE V compared to TAXUS at 3 years (0.9% vs 2.8%)**

From Kaplan Meier estimates and logrank test

# Conclusion

## At 3 Years Follow-up:

- **The continuing long-term safety and efficacy of XIENCE V is demonstrated**
- **XIENCE V continues to be clinically superior to TAXUS, with an 88% reduction in cardiac death and a 55% reduction in overall MACE**
- **With a 55% reduction in ID-TLR, XIENCE V continues to show lower clinical restenosis than TAXUS**

XIENCE V is a trademark of the Abbott Group of Companies.

TAXUS is a registered trademark of Boston Scientific