

## Resolute Integrity

Zotarolimus-Eluting Coronary Stent System

### Performance in Diabetics

RESOLUTE Pooled Analysis

Independent, Italian All-Comers Registry from the RISICO Study Group



# Resolute Integrity DES: Performance in Diabetics Summary

- Strong performance in diabetics in the RESOLUTE clinical program
  - No significant difference in TLF rates in diabetics vs. nondiabetics
  - Low 3.3% TLR rate at 12 months
  - Low 0.3% ARC definite/probable stent thrombosis rate at 12 months
- Strong performance in real-world diabetics in independent, investigator-initiated study
  - Nonsignificantly different rates in diabetics vs. nondiabetics at 15 months
  - Low rates observed across all endpoints at 15 months
    - TLF for diabetics vs. nondiabetics (3.7% vs. 5.0%, p = 0.97)
    - 3.5% TLR rate in real-world diabetics

Resolute Integrity DES: The Simple Choice in Diabetics



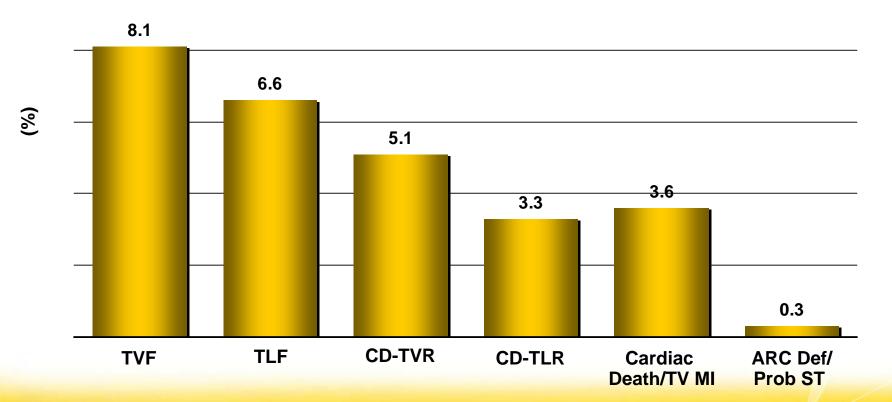
## **RESOLUTE** Pooled Analysis

Enrollment of Resolute DES diabetic patients by clinical trial

	Diabetic Patients*
RESOLUTE	24
RESOLUTE All Comers	85
RESOLUTE International	242
RESOLUTE US	482
RESOLUTE Japan	45
Pooled RESOLUTE Dataset	878

## Powerful Performance in Diabetics Across All Clinical Endpoints

RESOLUTE Pooled Analysis, 12-Month Data n = 867





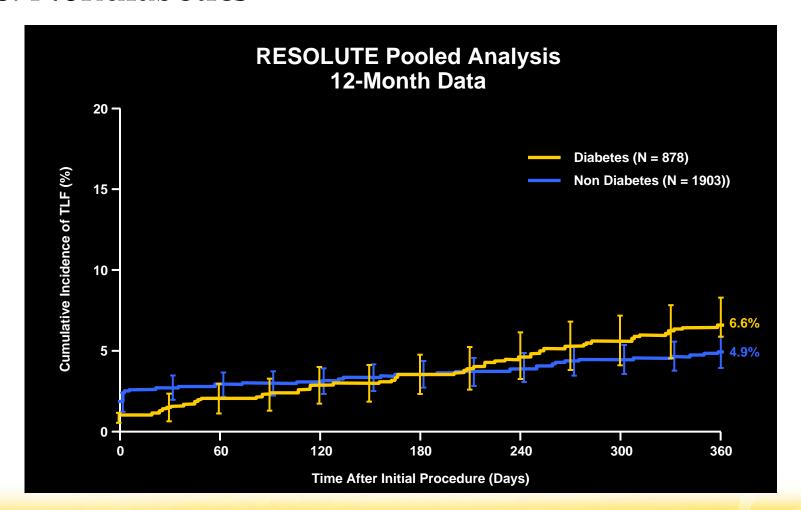
## Higher Comorbidities in Diabetic Arm

Diabetic vs. nondiabetic group in RESOLUTE pooled analysis

Baseline Characteristics	Diabetic Patients (N = 878)	Nondiabetic Patients (N = 1903)	<i>p</i> -Value
Age (yr)	65.2±10.2	63.5±10.8	<0.001
Men (%)	66.4	74.4	<0.001
History of smoking (%)	58.1	59.3	0.562
History of hypertension (%)	87.6	73.1	<0.001
Prior PCI (%)	34.6	29.5	0.007
Prior MI (%)	24.9	25.5	0.724
Prior CABG (%)	10.5	7.4	0.006
Lesion Characteristics			
B2/C lesions (%)	65.9	65.3	0.776
RVD (mm)	2.66±0.48	2.73±0.49	<0.001
Lesion length (mm)	13.52±5.72	13.63±5.86	0.627



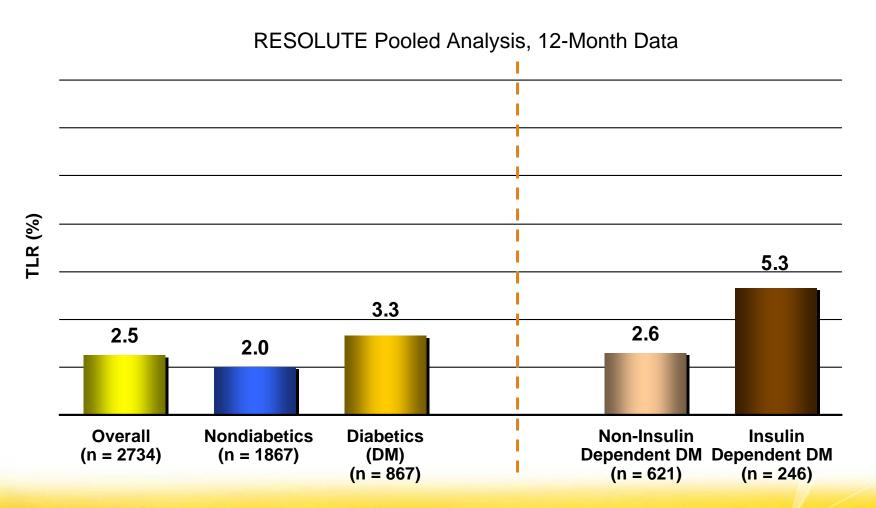
# No Significant Difference in TLF Rates in Diabetics vs. Nondiabetics





### Low TLR Rate in Diabetics

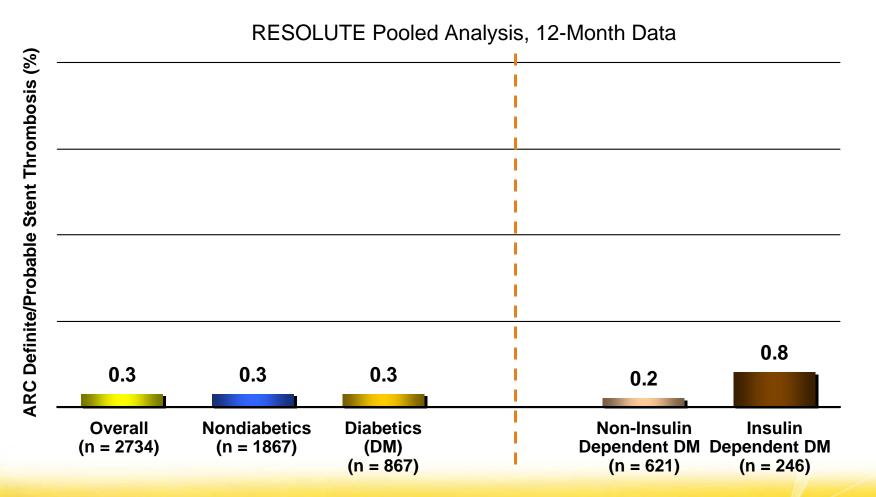
Excellent efficacy results in challenging diabetic patient group





## Similar ST Rates in Diabetic vs. Nondiabetic Groups

Less than 1% ST rate even in the high-risk IDDM group





## Resolute Integrity

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Independent, Multicentre Italian Evaluation A Ielasi, PCR 2011



### Diabetic vs. Nondiabetic Patients

Patient and lesion baseline characteristics

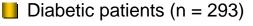
	Diabetic Patients (N = 271)	Nondiabetic Patients (N = 584)	<i>p</i> -Value
Age (yr)	67.2±9.4	64.6±10.8	p < 0.0001
Hypertension (%)	87.1	72.8	p < 0.0001
IDDM (%)	16.4	-	-
ACS (%)	46.6	46.1	0.89
Multi-Vessel Disease (%)	23	22.3	0.80
CTO (%)	8.2	8.2	0.97
B2/C (%)	66.9	72.2	0.78
Bifurcations (%)	26.1	33.3	0.01
Left main (%)	3.4	3.8	0.69
SVG	1.7	2.3	0.50
Lesion Characteristics			
Mean stent diameter (mm)	2.9±0.5	3.0±0.4	0.002
Total stent length (mm)	28.7±17.7	26.2±14.7	0.037



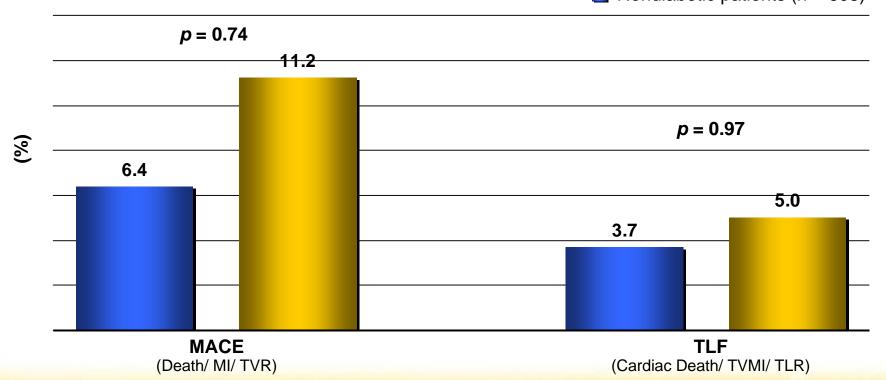
## Strong Performance in Diabetic, All-Comer Patients

No significant difference in diabetic vs. non diabetic group

Independent, Italian All Comer Registry from the RISICO Study Group Dr. A lelasi et al, 15-month data



Nondiabetic patients (n = 603)



Resolute Integrity



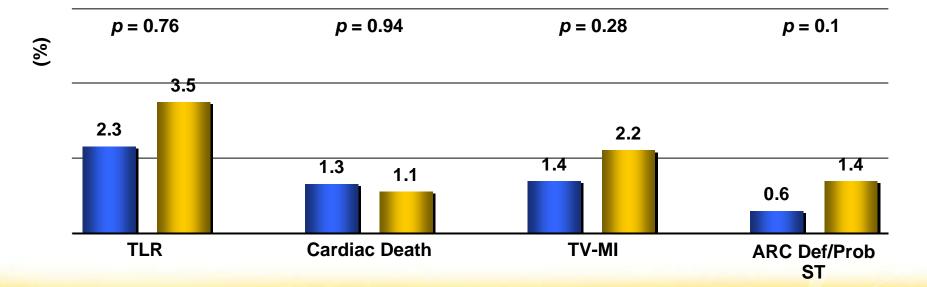
## Low Rates Across All Efficacy and Safety Outcomes

No significant difference in diabetic vs. non diabetic group

Independent, Italian All Comer Registry from the RISICO Study Group Dr. A lelasi et al, 15-month data

Diabetic patients (n = 293)

Nondiabetic patients (n = 603)





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Resolute Integrity DES: The Simple Choice in Diabetics



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Resolute Integrity DES now has expanded indications for diabetes mellitus, multivessel disease, long lesions and small vessels.