

100pozdrav

# Nobori

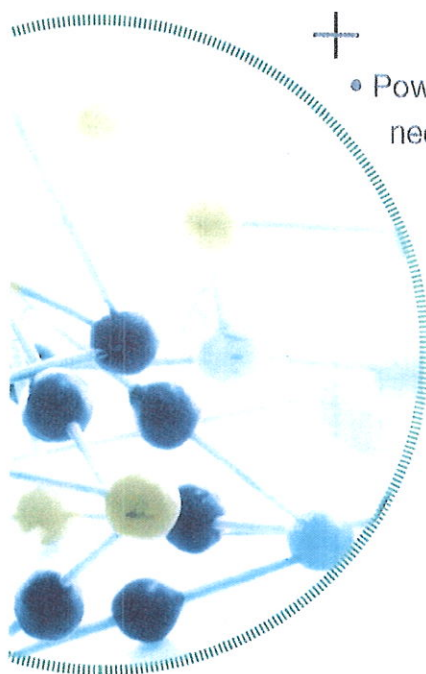
*Drug Eluting Stent with Biodegradable Polymer*

The biodegradable choice  
for patient safety

 **TERUMO®**

## Biolimus A9\*

a new limus drug designed for stent application provides efficacy

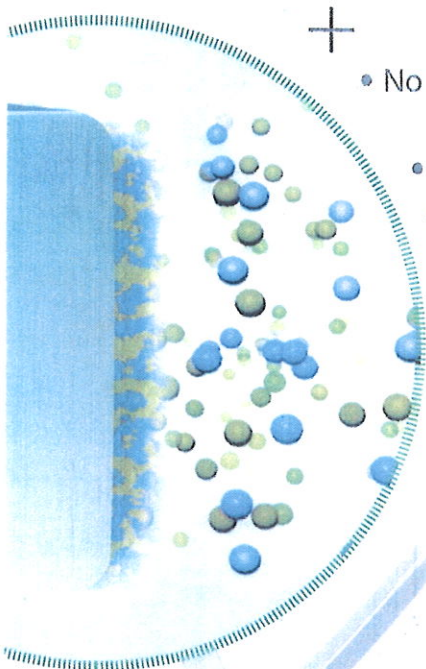


- Powerful anti-proliferative and anti-inflammatory properties to reduce neo-intimal proliferation
- Precise release kinetics with an initial burst and sustained elution through polymer degradation for long term efficacy
- Biolimus high lipophilicity facilitates diffusion into the vessel wall to provide an efficient local effect

In stent late loss  $0.11 \text{ mm} \pm 0.30 \text{ mm}^{(1)}$

## Biodegradable polymer PLA

on abluminal surface preserves endothelial function



- No drug on luminal surface enhances endothelialization
- Fully biodegradable PLA polymer eliminates chronic sensitivity and ensures complete drug release

Proven long-term safety

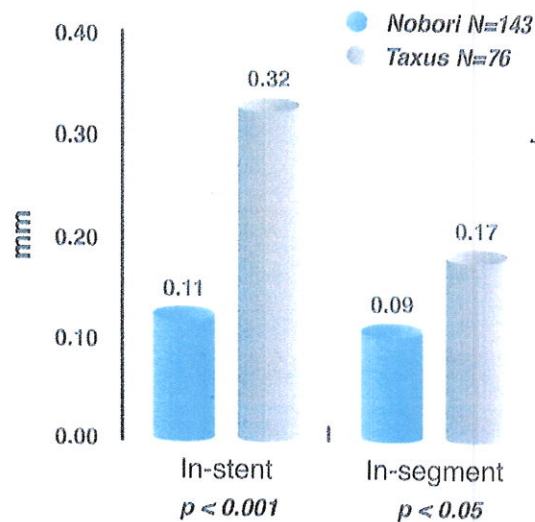
\* TM by Biosensors

1 NORORI 1 phase 2 (Chevalier B. *Circ Cardiovasc Interv* 2009;2:188-195)

# Clinical results

## NOBORI 1

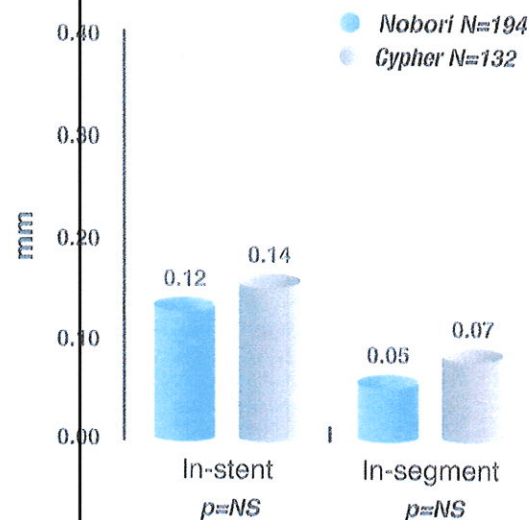
9 month angiographic follow-up



NOBORI 1 phase 2 (Chevalier B. Circ Cardiovasc Interv 2009;2:188-195)

## NOBORI JAPAN

8 month angiographic follow-up

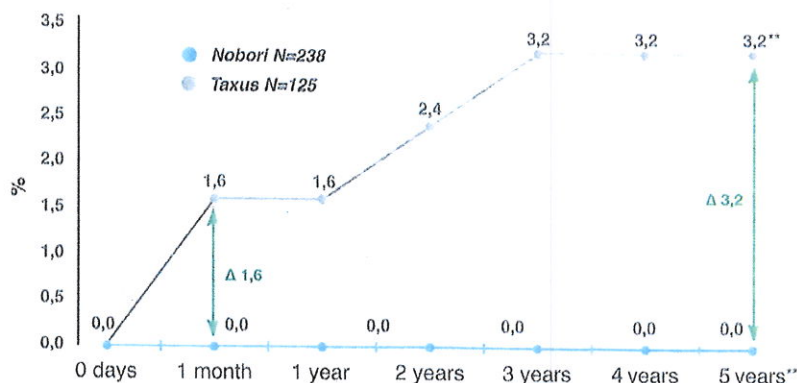


Kadota K. CCI 2011

Nobori® demonstrates higher efficacy compared to Taxus Drug Eluting Stent

## NOBORI 1

Stent Thrombosis at 5 years - both cohorts\*



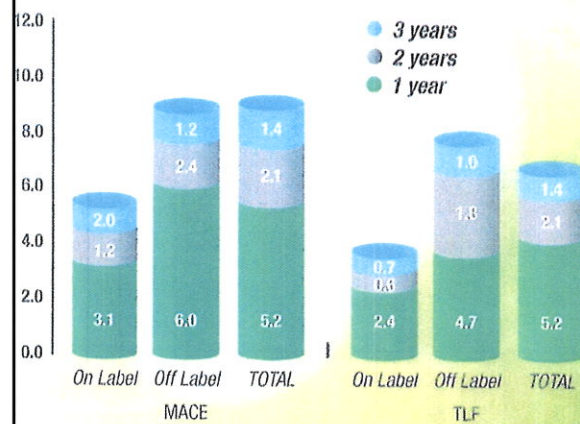
Stent thrombosis = Definite and Probable according to ARC definition

\* Pooled data from NOBORI 1, phase 1 and phase 2 Chevalier B. - EuroPCR 2010

\*\* Data on file Terumo Europe N.V.

## NOBORI 2 Study

Composite Endpoints at 3 years

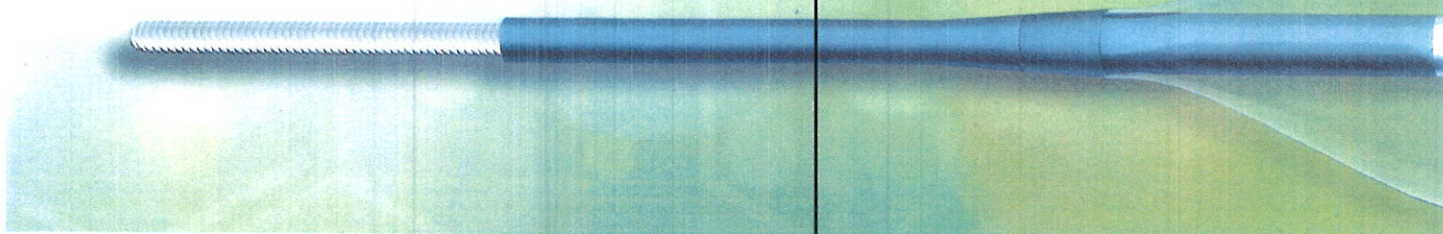


TLF = Cardiac death, MI (TV related), TLR

MACE = Cardiac death, any MI, TVR

Danzon GB, EuroPCR 2012

Nobori® has proven safe across the board for challenging lesions and high-risk patient subgroups



# Design supported by an extensive clinical program (>20.000 patients)

## Foundation

<b>NOBORI PK</b>	Single arm – FU 5 years	N=20
<b>NOBORI 1 Phase 1</b>	Randomized – Taxus – FU 5 years	N=120
<b>NOBORI 1 Phase 2</b>	Randomized – Taxus – FU 5 years	N=243
<b>NOBORI CORE</b>	Comparative Cypher – FU 5 years	N=107
<b>NOBORI Japan</b>	Randomized Cypher – FU 3 years	N=323

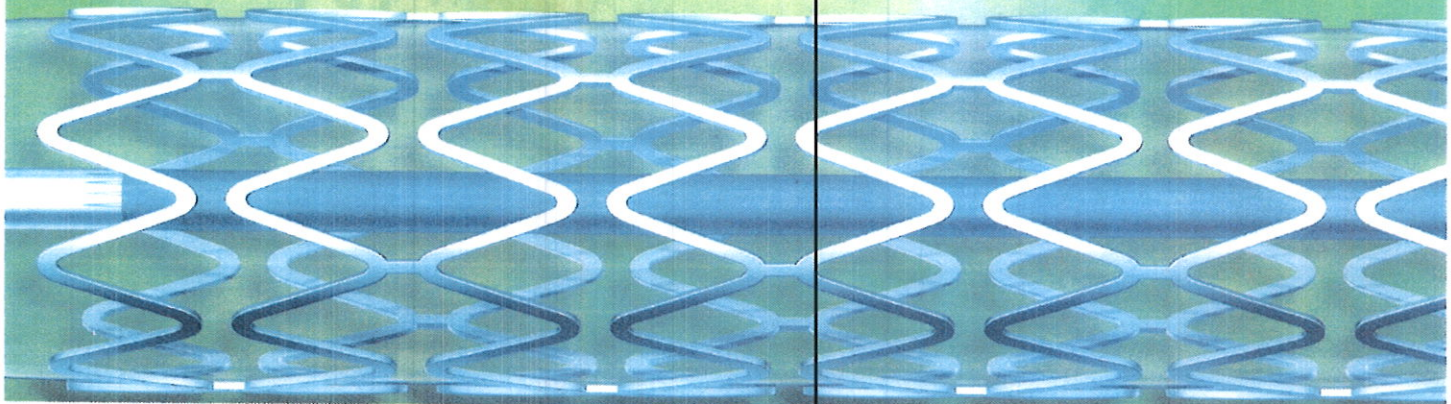
## Registries

<b>NOBORI 2</b>	Single Arm - FU 3 years	N=3067
<b>e-NOBORI</b>	Single Arm - Enrolling	N=8000
<b>IRIS - NOBORI</b>	Single Arm - Enrolling	N=1000

## Real Life Randomized

<b>COMPARE 2</b>	Nobori vs Xience V – PCR 2012	N=2700
<b>BASKET PROVE 2</b>	Nobori vs Xience vs BMS – Enrolling	N=2400
<b>SORT-OUT V</b>	Nobori vs Cypher – PCR 2012	N=2400
<b>ISAR Test 6</b>	Nobori vs Xience vs ISAR GE	N=2010
<b>SECURITY</b>	6 VS 12 months DAT	N=4000

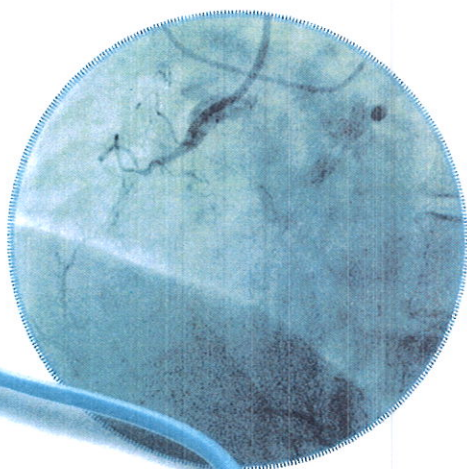
Taxus is a trademark of Boston Scientific Corporation.  
Xience is a trademark of Abbott Laboratories.  
Cypher is a trademark of J&J / Cordis Corporation.  
Biolimus A9 is a trademark of Biosensors.



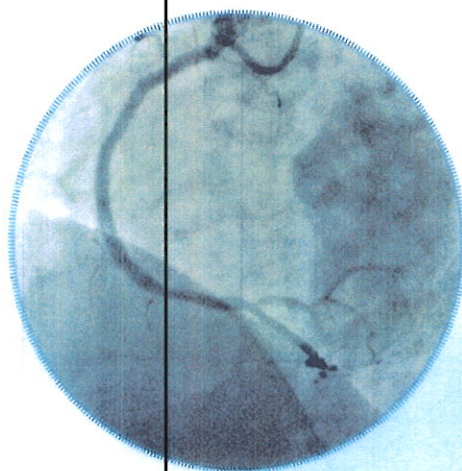
# Open cell design stent on a low compliant balloon for superior deliverability



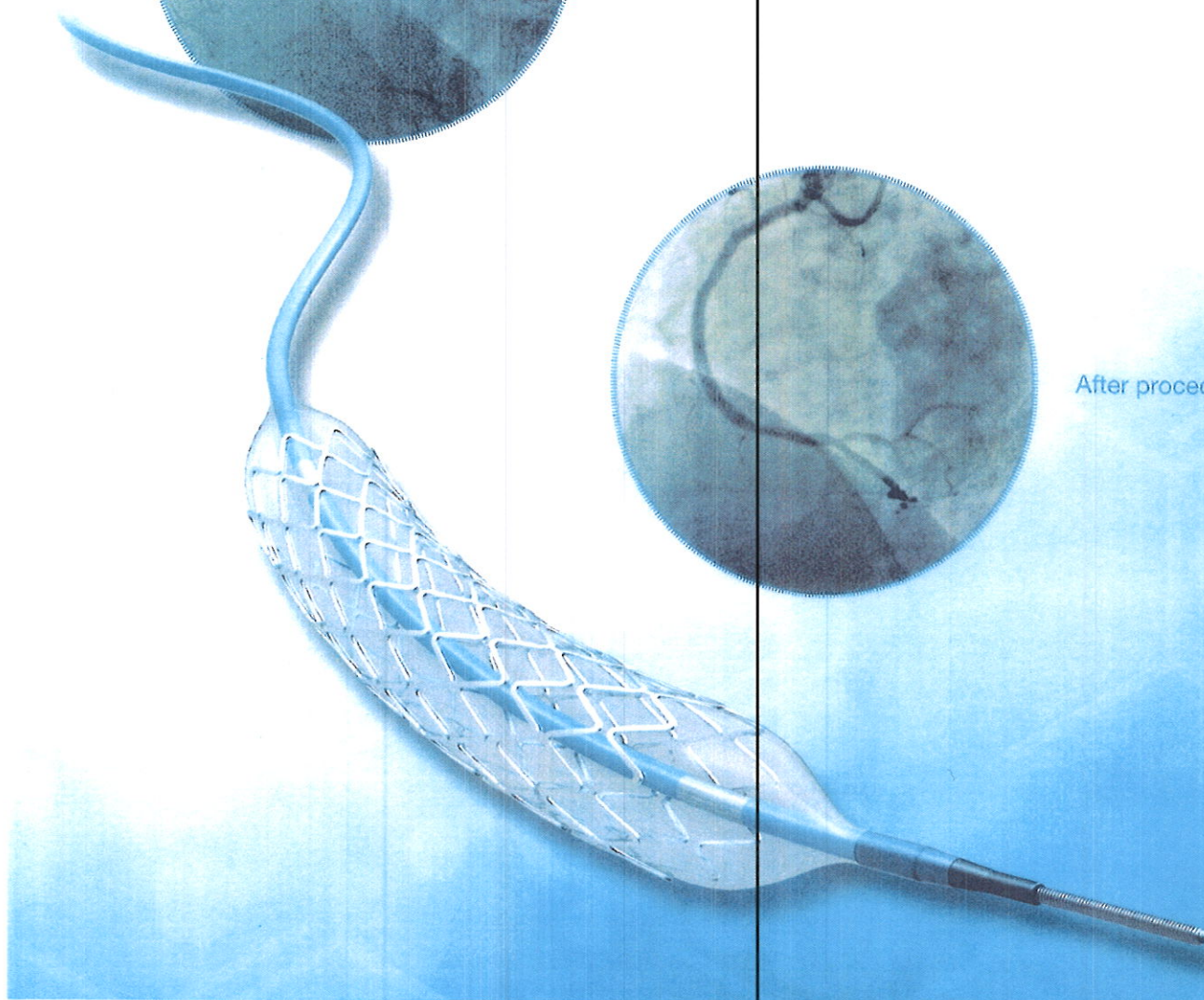
- Low compliant balloon ensures optimal stent expansion
- Open cell for convenient side branch access
- Innovative Ryujin™ shaft offers outstanding crossability



Before procedure



After procedure



# Specifications

## Balloon material:

Nylon (3 fold)

## Coating:

Hydrophilic - Distal shaft

Silicon - Proximal shaft

## Shaft:

Max. size - 2.5 F / 0.84 mm

Min. size - 2.0 F / 0.67 mm

## Diameter guidewire:

0.014" / 0.36 mm

## Nominal pressure:

8 ATM

## Profile:

0.042" / 1.05 mm - 2.25 mm

0.042" / 1.05 mm - 2.50 mm

0.043" / 1.09 mm - 2.75 mm

0.044" / 1.11 mm - 3.00 mm

0.045" / 1.13 mm - 3.50 mm

0.048" / 1.29 mm - 4.00 mm

## Entry profile:

0.017" / 0.43 mm

## RBP:

16 ATM - 2.25 to 3.0 mm

14 ATM - 3.5 to 4.0 mm

## Usable length:

145 cm

# Ordering information

Balloon diameter (mm)	Stent length / Product code				
	8 mm	14 mm	18 mm	24 mm	28 mm
2.25	DE-RA2208SM	DE-RA2214SM	DE-RA2218SM	DE-RA2224SM	DE-RA2228SM
2.50	DE-RA2508SM	DE-RA2514SM	DE-RA2518SM	DE-RA2524SM	DE-RA2528SM
2.75	DE-RA2708SM	DE-RA2714SM	DE-RA2718SM	DE-RA2724SM	DE-RA2728SM
3.00	DE-RA3008SM	DE-RA3014SM	DE-RA3018SM	DE-RA3024SM	DE-RA3028SM
3.50	DE-RA3508LM	DE-RA3514LM	DE-RA3518LM	DE-RA3524LM	DE-RA3528LM
4.00	DE-RA4008LM	DE-RA4014LM	DE-RA4018LM	DE-RA4024LM	DE-RA4028LM



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