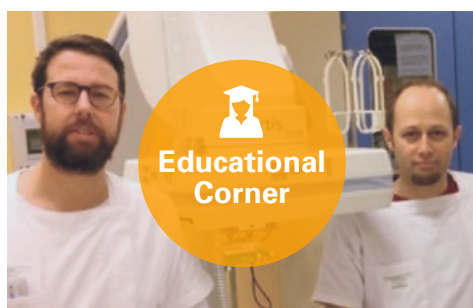


- The SYNERGY™ Stent Clinical Evidence for Optimal Healing and Safety: TCTMD Webcast
- Latest Data at TCT 2016 Confirms the Safety of the WATCHMAN™ Device in Real Life
- The LOTUS™ Valve: Simplifying Treatment Strategies and Optimising Outcomes in the Real World



- Live Case in Complex PCI (UZ Leuven, Belgium)
- Case Study: COMET™ Workhorse-like FFR Wire Assesses Complex Case with 90° Angle
- Case Study: ROTABLATOR™ Facilitating Stent Delivery



- The PLATINUM Diversity Study Presented at TCT 2016
- The SYNERGY™ Stent: Zero is on Safety Through Angioscopy



- Join the Complex PCI community
- Download New App: Stroke-Bleed Risk Calculator for AF Patients



## Congresses and Events



*Panelists (Left to Right): Dr. Colm Hanratty, Professor Takafumi Ueno, Dr. Dean Kereiakes, Dr. Ajay Kirtane*

### The SYNERGY™ Stent Clinical Evidence for Optimal Healing and Safety: TCTMD Webcast

SYNERGY™ is the only FDA-approved, Everolimus-Eluting Platinum Chromium Stent with a bioabsorbable PLGA polymer coating applied only on the abluminal (or vessel) side.

The SYNERGY™ Stent leverages the advantages of drug-eluting stent technology including reduced restenosis and inflammation.

However, because the polymer is bioabsorbable, it also provides freedom from long-term polymer exposure to promote optimal healing.

The SYNERGY™ Stent recently received FDA approval for use in patients with Diabetes Mellitus.

This video presents novel aspects of the SYNERGY™ Stent design, current clinical data supporting the safety and performance of the SYNERGY™ Stent, angiographic evidence of healing with the SYNERGY™ Stent, and real-world data.

### Latest Data at TCT 2016 Confirms the Safety of the WATCHMAN™ Device in Real Life

Different experiences from Europe and US confirm the safety of the WATCHMAN™ Device in real life, showing excellent real practice results. In addition the long-term results from the two Randomized Clinical Trials, **PROTECT AF** and **PREVAIL** show consistency in low rates of events.

#### NEW WATCHMAN™ results include:

**EWOLUTION** prospective registry analysis in patients  $\geq 85$  years showed that:

- LAAC with WATCHMAN™ in these patients is safe and effective even if this subgroup of patients is at high risk for embolic and hemorrhagic events, with:
  - High procedural success (98.8%)
  - 2.6% peri-procedural SAEs
  - 1.3% stroke rate after 3 months follow up
  - 5.2% bleeding rates after 3 months follow up

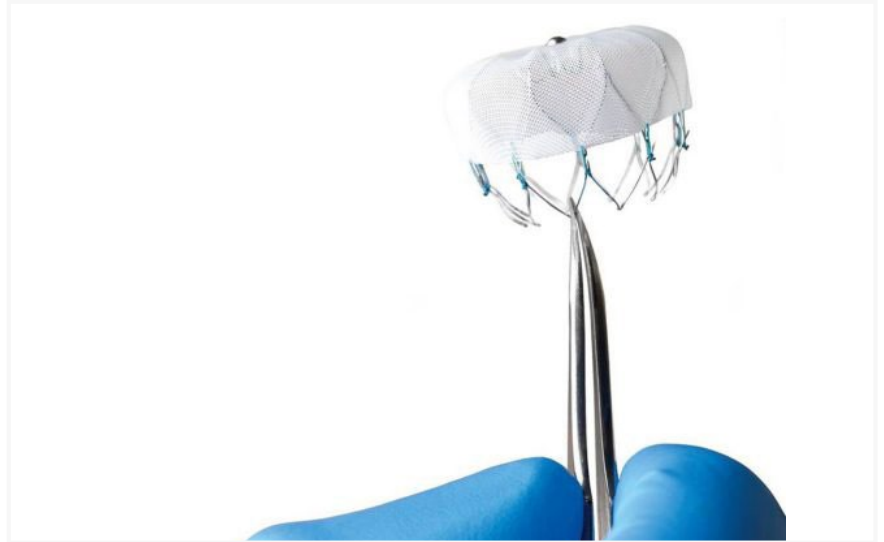


## Congresses and Events

- LAAC could be an alternative to oral anticoagulation for these patients

U.S. initial commercial performance of the WATCHMAN™ LAAC device in 3,822 patients since FDA approval in March 2015.

The experience counts the largest patient population reported to date and includes more patients than all of WATCHMAN™ patients enrolled in all of the clinical studies and the EWOLUTION registry combined.



The results confirmed the safety of the procedure with WATCHMAN™ Device in real life and complement the excellent EWOLUTION real practice results with:

- 95.6% implant success rate with ~70% new operators performing half the cases (this represents the highest implant success rate reported with WATCHMAN™ in the U.S.)
- Complication rates remained low and were comparable to previous WATCHMAN™ studies

The combined randomized clinical data from PROTECT-AF and PREVAIL, along with increased follow-up (5 years for PROTECT-AF and 3 years for PREVAIL), provided the most complete evaluation of the WATCHMAN™ efficacy. They are showing consistently low rates of ischemic stroke, comparable to those expected with anticoagulation in this high risk population, support an LAAC therapy strategy for stroke risk reduction in NVAf patients.

With more than 7,200 patients studied and more than 6,000 patient-years of follow-up WATCHMAN™ is the most studied LAAC device and the only LAAC device with long-term clinical data from randomized clinical trials and multi-center registries.

**With more than 7,200 patients studied and more than 6,000 patient-years of follow-up WATCHMAN™ is the most studied LAAC device and the only LAAC device with long-term clinical data from randomized clinical trials and multi-center registries.**

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## Congresses and Events



### Watch Prof. Foley, Prof. Sievert and Prof. Bergmann discuss the EWOLUTION Data and Implications for Clinical Practice

*"There are many patients who cannot take a full dose of NOACs. Today, we can apply the data that we have on WATCHMAN™ to all of these patients."*

*There has been a gap between the randomized trial and the recent development offered to patients who have an absolute or relative contraindication to OAC.*

*The EWOLUTION prospective registry is now closing this gap as we now have the majority of patients within the 1,000 studied that were deemed contraindicated for oral anticoagulants."*

Prof. Martin W. Bergmann

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### The LOTUS™ Valve: Simplifying Treatment Strategies and Optimising Outcomes in the Real World

Focusing on paravalvular leakage even in challenging anatomies, Prof. Lars Sondergaard, Dr. Ted Feldman and Dr. Matthias Götzberg discuss the technical features of the LOTUS™ Valve System and how they translate into promising clinical outcomes. This could be crucial to follow in the future with the expected expansion of indications.

The LOTUS™ Valve is still a relatively new device and while the community continues to gain experience, a growing number of clinical publications show a decrease in pacemaker rates. These reports include the results presented by Dr. Götzberg at EuroPCR where 8%\* of pacemaker rate was achieved on the last 50 patients.

Speakers: Prof. Lars Sondergaard,  
Dr. Ted Feldman and Dr. Matthias  
Götzberg

***"LOTUS™ is fully repositionable and fully retrievable which leads to a high degree of procedure success and also almost no mild paravalvular leak."***

Dr. Matthias Götzberg (Sweden)

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## Educational Corner

### Master the Complex: Live Case on Complex PCI (UZ Leuven, Belgium)



Interventional Cardiologists today are faced with an ever increasing set of complex patients to manage. Treating patients with more complex lesions and elderly patients where DAPT duration is important is requiring new technologies and technique to deal with this ever increasing complexity.

#### Educational objectives:

- Improve coronary angioplasty knowledge (techniques and approach strategies)
- Step-by-step treatment of complex left main trifurcation lesion (single vs double stent strategy/stent design and sizing in LMS PCI)
- Discuss the choice of a material for specific patients (short DAPT, early healing) and specific lesions (calcified, left main, bifurcation...) in your practice
- The role of intracoronary imaging modalities in guiding and optimising the PCI result
- Compare techniques and approach strategies of different experts



Friday July 8th,  
from 12:30 to 14:00 (Local time - Belgium, GMT+2)  
from 10.30 to 12.00 GMT  
**Coronary angioplasty : Master the Complex**  
Live session from Leuven, Belgium

**Operators and speakers**  
Pr. Christophe Dubois, Leuven, Belgium  
Dr. Nick Hiltrop, Leuven, Belgium  
Dr. Johan Bennett, Leuven, Belgium

**Program (GMT+2)**  
12:30 Introduction  
Clinical case presentation - strategy  
Live case starting  
Choice of material : Specifications & benefits  
Clinical results review about evolution of PCI  
in complex patients  
Live case conclusion  
Q&A session with experts  
14:30 Take home messages and conclusion



incathlab  
THE INTERACTIVE CARDIOVASCULAR CHANNEL  
presents  
a session broadcasted through support from  
**Boston  
Scientific**  
in collaboration with  
  
**KU LEUVEN**

Log in to the InCathlab channel to see the live case





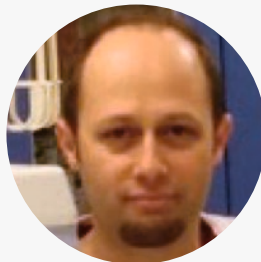
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## Educational Corner

### Case Study:

### COMET™ Workhorse-like FFR Wire Assesses Complex Case with 90° Angle

This case highlights the need for a FFR wire that can be used in highly tortuous anatomy. Prof. Gianluca Campo from the Sant' Anna University Hospital, Ferrara (Italy), uses the FFR where it may not have been possible before.



**Prof. Gianluca Campo & Dr. Matteo Tebaldi**  
Cardiovascular Institute, Azienda Ospedaliera  
Universitaria di Ferrara (Italy)



[Download Case Study »](#)

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### Case Study:

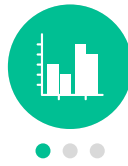
### ROTABLATOR™ Facilitating Stent Delivery

The ROTABLATOR™ System served as a facilitator of lesion compliance and ultimately, stent delivery and expansion. This case illustrates the ability of the ROTABLATOR™ System to modify calcified atherosclerotic plaque in order to facilitate optimal stent delivery and expansion.



[Download Case Study »](#)

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## Clinical Studies

### The PLATINUM Diversity Study presented at TCT 2016

As part of the commitment to support health equity for all patients, Boston Scientific Corporation sponsored the PLATINUM Diversity Study to evaluate the clinical outcomes of the Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in women and minorities. The clinical endpoints were presented at the Transcatheter Cardiovascular Therapeutics (TCT).

In this study, there were no significant outcome differences between white men and women or minorities for the composite primary endpoint of death, myocardial infarction (MI) or target vessel revascularization (TVR) at 12 months. The composite death/MI/TVR rate was 7.6% for white men compared to 8.6% for women ( $p=0.33$ ), and 9.6% for minorities ( $p=0.08$ ).

Additionally, secondary endpoint results were as follows (differences with  $p<0.05$  were statistically significant):

- All-cause death: 2.2% for white men compared to 3.4% for women ( $p=0.04$ ), and 3.7% for minorities ( $p=0.03$ )
- MI: 1.1% for white men compared to 1.9% for women ( $p=0.06$ ), and 3.1% for minorities ( $p=0.0002$ )
- TVR: 5.5% for white men compared to 4.6% for women ( $p=0.27$ ), and 5.4% for minorities ( $p=0.97$ )
- Definite or probable stent thrombosis: 0.7% for white men compared to 0.9% for women ( $p=0.55$ ), and 1.2% for minorities ( $p=0.22$ )



**PLATINUM**  
D I V E R S I T Y  

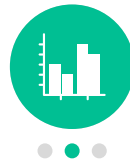
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**PROMUS PREMIER™**  
CORONARY STENT SYSTEM



See interview with Dr. C. Michael Gibson talks Dr. Wayne Batchelor about PLATINUM Diversity at TCTMD

*"Most clinical trials examine how any given treatment impacts patient outcomes; however, given that much of an individual's health is determined by non-clinical factors, we thought it important to design the PLATINUM Diversity Study in order to better understand the nature and magnitude of outcome disparities that exist for under-represented groups after contemporary coronary stent procedures,"* said Wayne Batchelor, M.D., co-principal investigator and chair of the Interventional Cardiology Council at Tallahassee Memorial Hospital, Tallahassee (Florida).



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## Clinical Studies

*“The initial evaluation of the primary endpoint is the first of many analyses that we believe will provide invaluable insights into the social, behavioral and economic determinants of health in women and minorities who undergo coronary stent procedures,”* said Roxana Mehran, M.D., co-principal investigator and director of the Office of Interventional Cardiovascular Research and Clinical Trials of Mount Sinai Heart and Professor of Cardiology and Population Health Science and Policy at Icahn School of Medicine at Mount Sinai in New York City.

Heart disease takes a greater toll on certain racial and ethnic groups yet historically, large-scale clinical trials in cardiology have had a disproportionately low inclusion of women and minorities. As a result, physicians have had little data on which to base their clinical decisions when treating these patients. The PLATINUM Diversity Study was initiated in October 2014 to provide important insights that can ultimately help physicians customize treatment plans for patient-specific demographics and socioeconomic status.

*“Our hope is that these ,real-world’ results from the PLATINUM Diversity Study will help clinicians, researchers and advocates understand the existing challenges so that we can work collaboratively to close the gender, race and ethnicity gap when treating cardiovascular disease.”* Says Paul Underwood, M.D.

***“The PLATINUM Diversity Study is tangible evidence of the commitment by Boston Scientific to raise awareness of the needs of underserved patient communities across the country, and is a critical first step in advancing care for all patients.”***

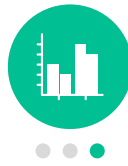
Paul Underwood, M.D. medical director of clinical interventional cardiology at Boston Scientific

### The PLATINUM Diversity study

This study is an observational, prospective, multicenter, open-label, single-arm, post-approval study that enrolled 1,501 patients at 52 sites in the U.S. from understudied populations, specifically women, African Americans, Latinos/Hispanics, American Indians or Alaska Natives. All patients in this single arm study received at least one Promus PREMIER™ Drug-Eluting Stent. Patient data from the PROMUS Element™ Plus Stent System post-approval study will be included in the full analysis to allow for comparisons to white men, increasing the total number of patients to 4,188.

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## Clinical Studies

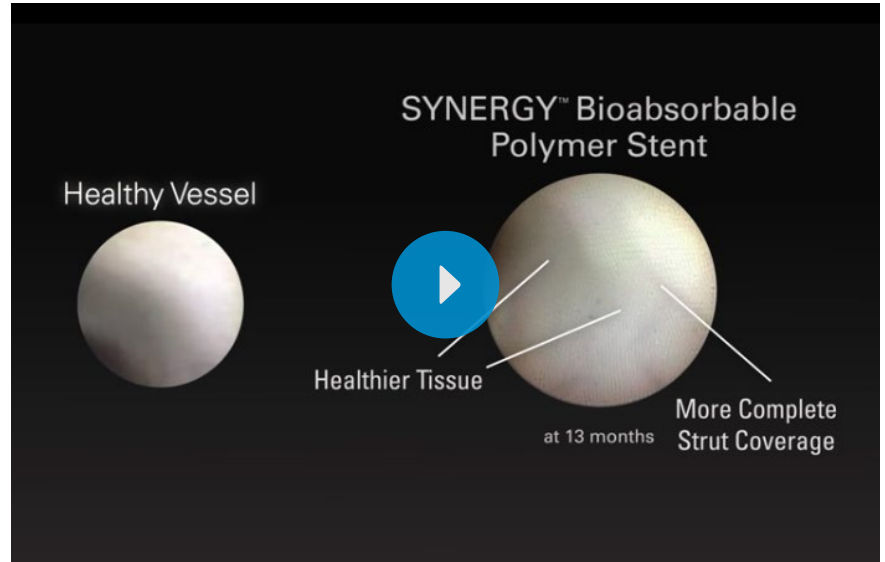
### The SYNERGY™ Stent: Zero is on Safety through Angioscopy

It's important to understand what type of healing and strut coverage is present with today's drug-eluting stents. Through angioscopy, we have a unique view into vessel healing with various generations of drug-eluting stents.

Compared to 1<sup>st</sup> and 2<sup>nd</sup> generation of stents, SYNERGY™ Stent has been proven to enhance healing and prevent vessels from long-term polymer exposure as evidence through Angioscopy.

Source:

Takafumi, Ueno, MD, Division of Cardiovascular Medicine,  
Kurume, University School of Medicine, Kurume (Japan)



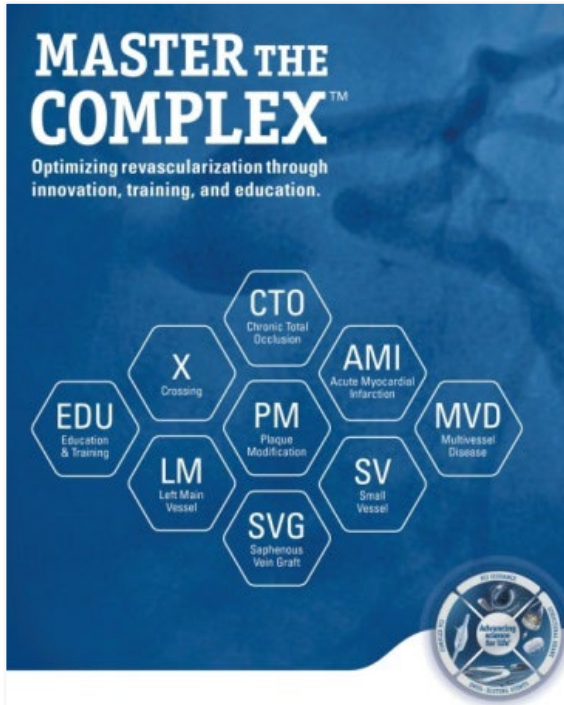
*Angioscopy: A look at Vessel Healing in Humans*

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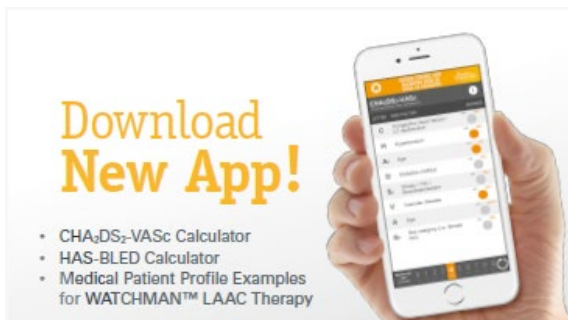
### Join the Complex PCI Community

Stay up to date with the latest advances for optimizing revascularization.

Join the Complex PCI Community and download the EuroIntervention Clinical Article: *"Rationale and design of the SYNTAX II trial evaluating the short to long-term outcomes of state-of-the-art percutaneous coronary revascularisation in patients with de novo three-vessel disease"* by Prof. Escaned et al.

Register Now »

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### NEW Stroke-Bleed Risks Calculator App

This App will help you easily balance the risk of stroke against the risk of bleeding prior to decide the best treatment option for your AF patients and consider the LAAC therapy.

download new App

Available on the  
App Store

ANDROID APP ON  
Google play

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**Boston  
Scientific**  
Advancing science for life™

\* Lund experience with the LOTUS™ Valve in an all-comers population, Matthias Götzberg, EuroPCR 2016

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