Innovations in Interventional Cardiology: Next Generation DES, Percutaneous Aortic Valve Replacement and Left Atrial Appendage Closure

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Boston Scientific Corporation
April 26, 2011

Disclosures

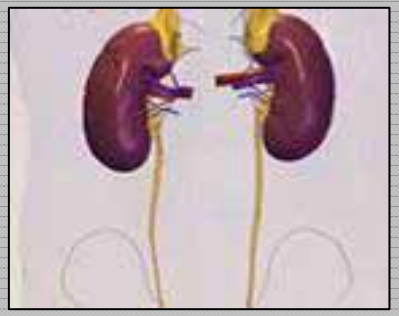
Employee

- Boston Scientific Corporation

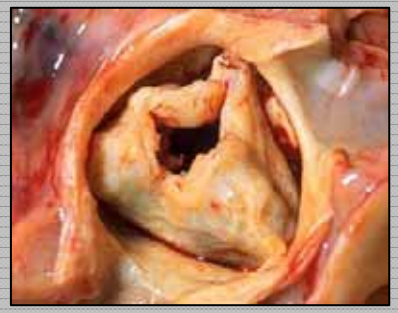
Stockholder

- Boston Scientific Corporation

New Device Technologies

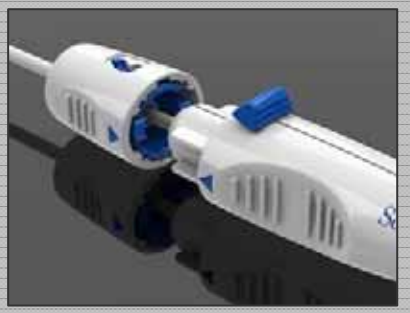


Hypertension - Renal

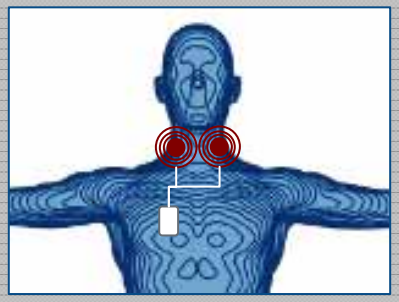


Aortic Valve

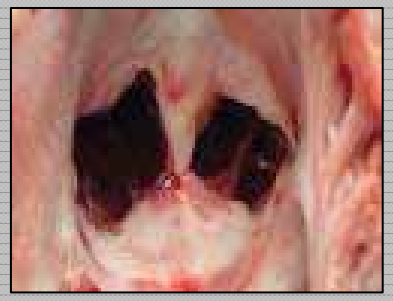
Atrial Fibrillation



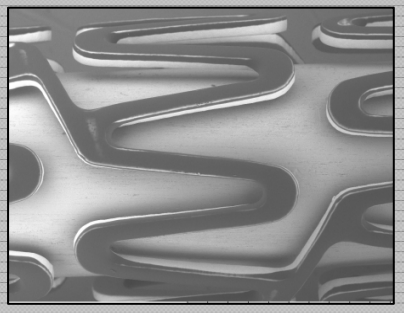
Vascular Closure



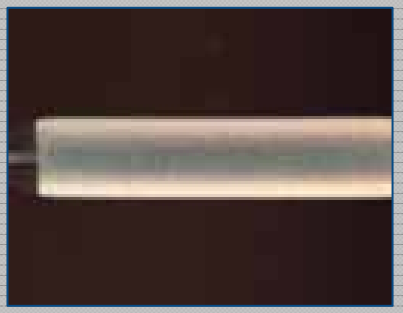
Hypertension - Carotid



Mitral Valve



Next Generation DES



Drug Eluting Balloon

Minimally invasive devices are now being used to treat many cardiovascular conditions previously treated surgically or with chronic pharmacologic therapy

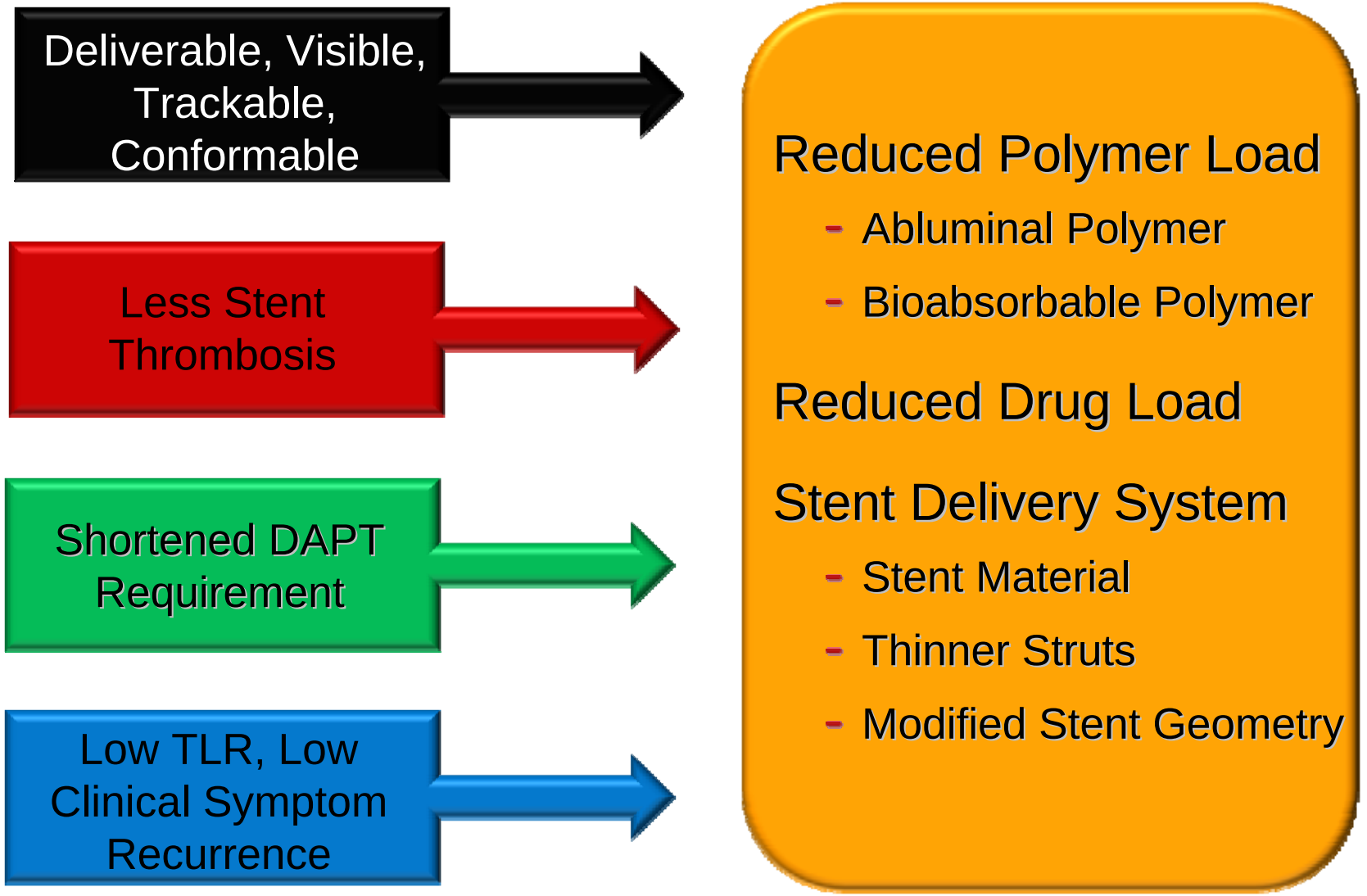
Agenda

SYNERGY Bioresorbable Polymer Platinum Chromium Stent

LOTUS Transcatheter Aortic Valve

WATCHMAN Left Atrial Appendage Closure Device

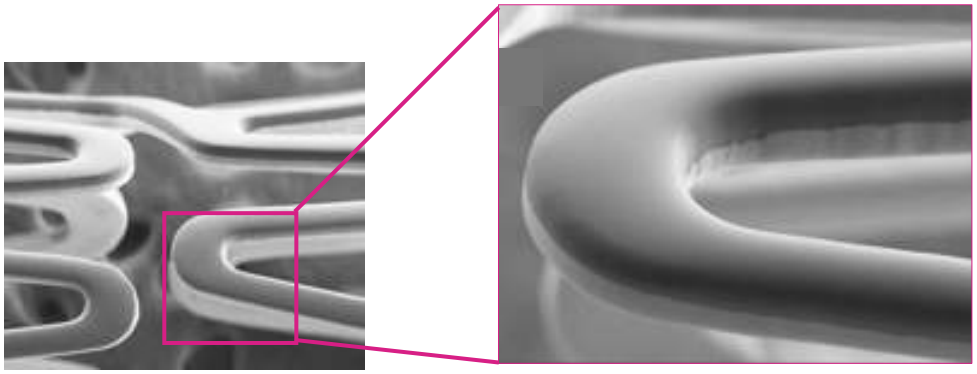
Next Generation DES Attributes



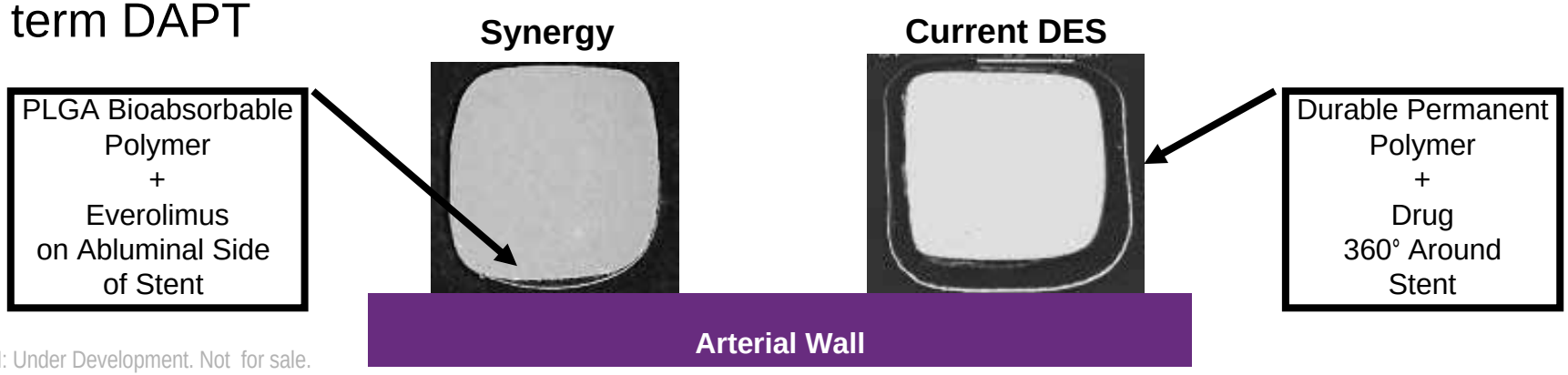
SYNERGY Stent Overview

SYNERGY

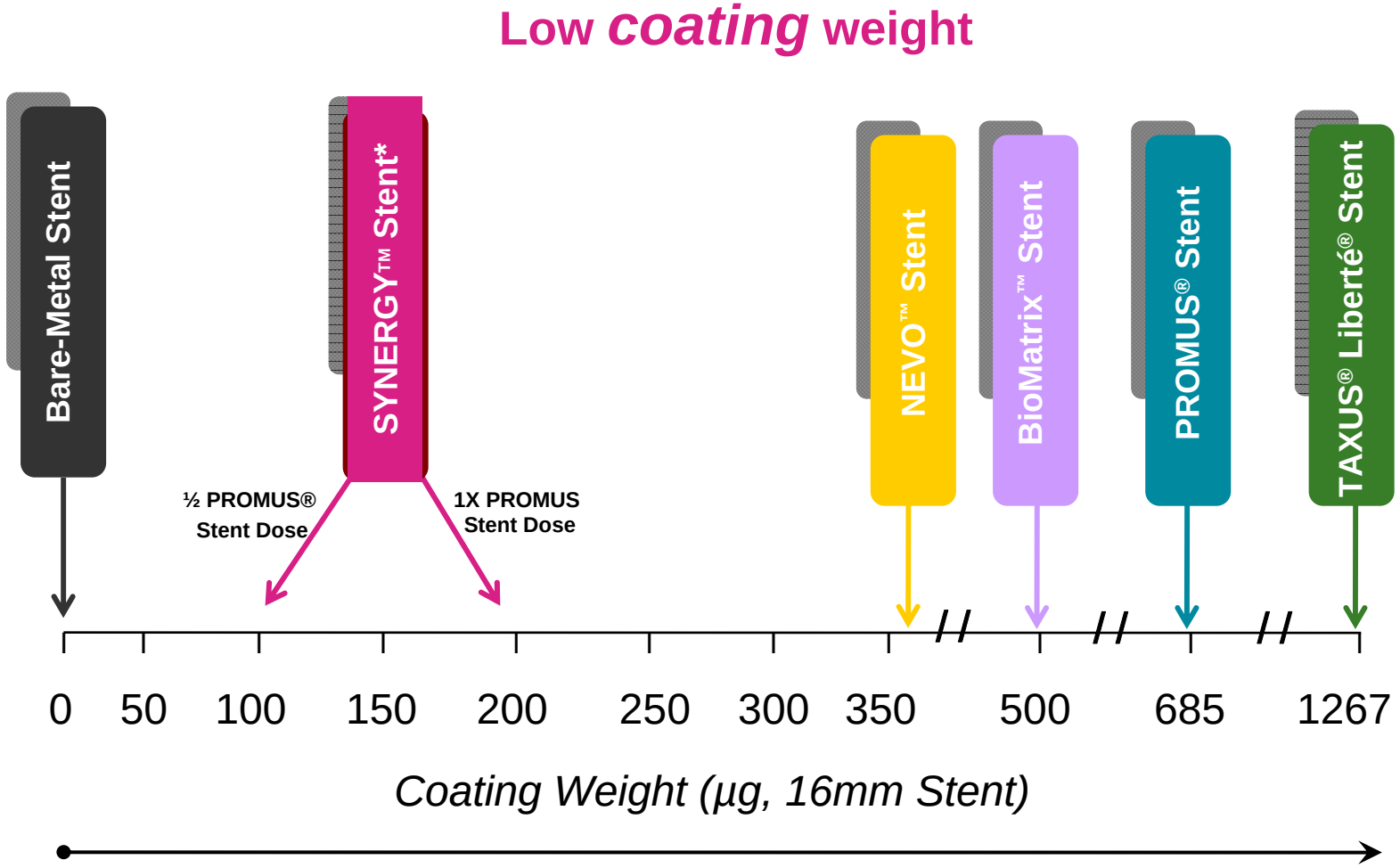
Bioabsorbable Polymer
PtCr Drug-Eluting Stent



- SYNERGY design goal: *Polymer and drug (Everolimus) gone within 6 months while achieving the same clinical efficacy as PROMUS Element*
- Ultra-thin layer of bioabsorbable polymer (PLGA) and drug are applied only to the abluminal surface of a very thin strut (0.0029”) PtCr Stent
- Lowest coat weight of any DES currently on the market
- Design may reduce the risk of ST and minimize the requirement for long-term DAPT



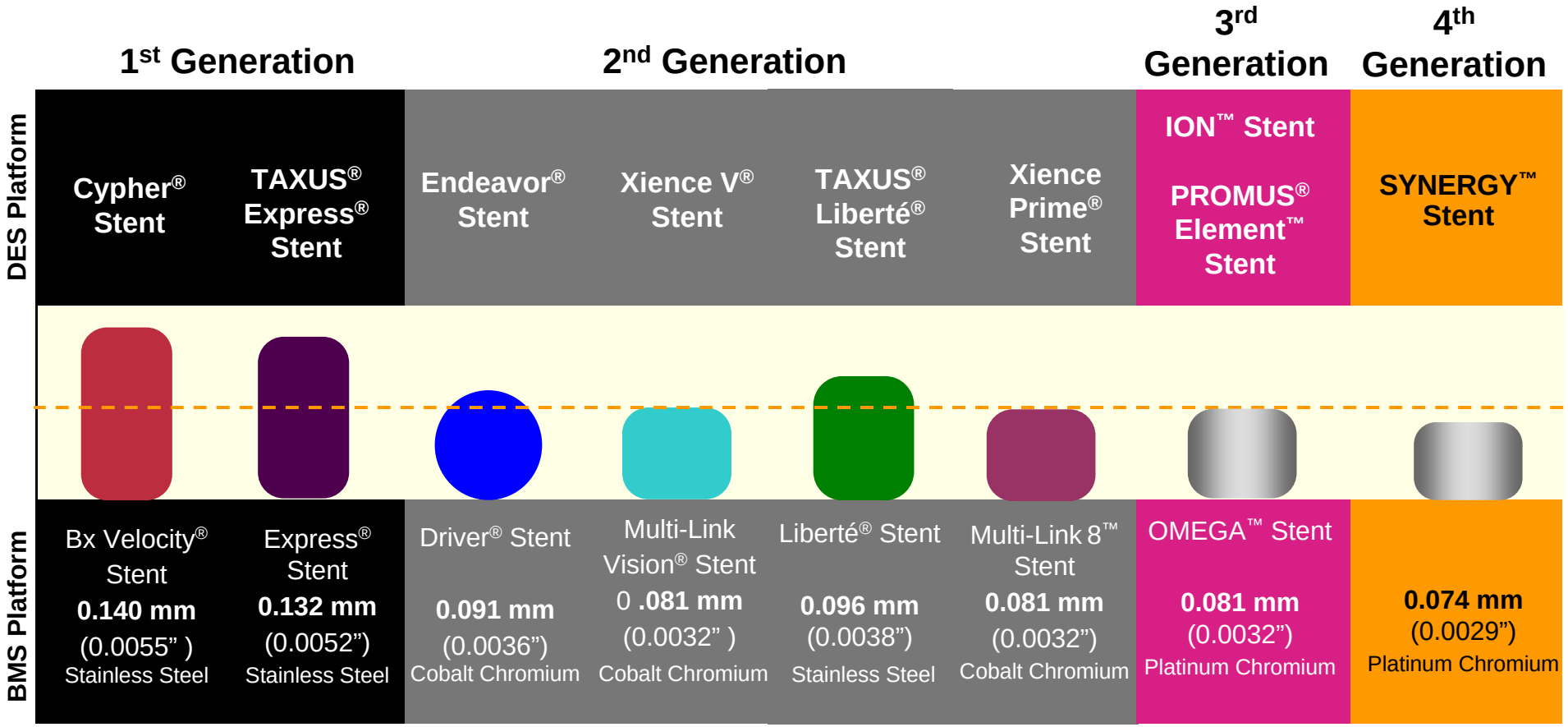
Relative Drug Coating Weights Across Various DES Platforms



Initial coat weight is minimized and the polymer resorbs over a period of 4-6 months

*CAUTION: Under Development. Not for sale. Data on file Boston Scientific. PROMUS stent is a private-labeled XIENCE V® Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. PROMUS is a trademark of Boston Scientific Corporation or its affiliates. XIENCE V is a trademark of Abbott Laboratories group of companies.

Relative Strut Thickness with Synergy



Data suggests that thinner strut stents have less inflammation and lower rates of restenosis

EVOLVE Clinical Trial

Study Objective:	To assess the safety and efficacy of the SYNERGY™ Everolimus-Eluting Coronary Stent System compared to the PROMUS® Element™ Stent	
Patient Population:	Symptomatic CAD and 1 or 2 de novo lesions up to 28 mm in length in a native coronary artery 2.25 mm to 3.5 mm in diameter	
Study Design:	Prospective, randomized, single blind, non-inferiority trial	
Primary Safety Endpoint:	TLF (TV-CD, TV-MI, TLR) at 30 days	
Primary Angiographic Endpoint:	In-stent late loss at 6 months	
Number of Patients:	SYNERGY Stent SYNERGY Stent (half dose) PROMUS Element Stent	n = 97 n = 97 n = 97
Number of Sites:	29 (EU, Australia, New Zealand)	
Enrollment:	July 2010 – Jan 2011	

Anticipate presentation of results at TCT 2011

Presented by Ian Meredith, MBBS, PhD, TCT 2010.

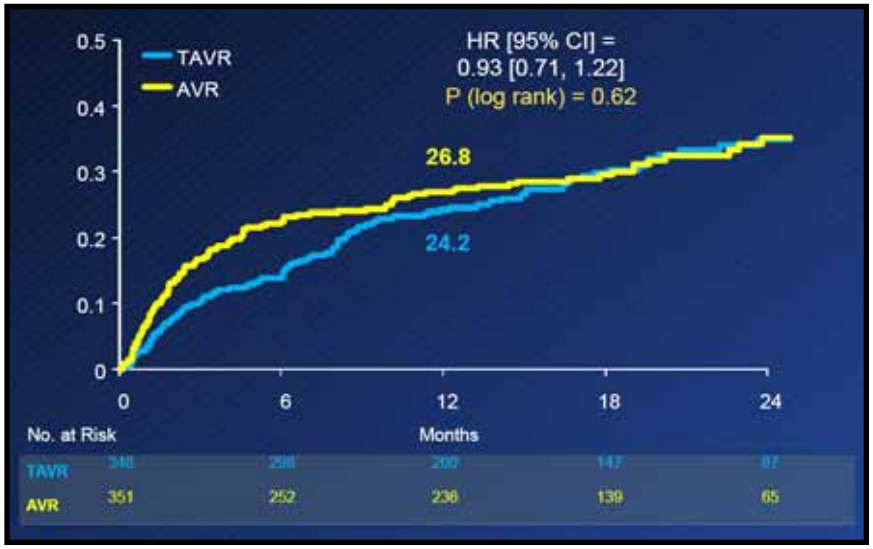
Agenda

SYNERGY Bioresorbable Polymer Platinum Chromium Stent

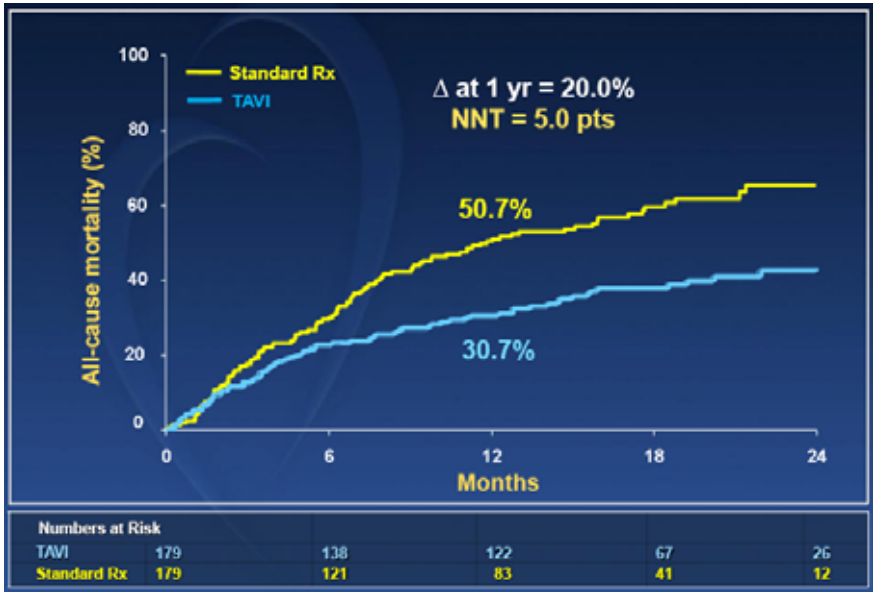
LOTUS Transcatheter Aortic Valve

WATCHMAN Left Atrial Appendage Closure Device

PARTNER Trial
Primary Endpoint Cohorts A and B

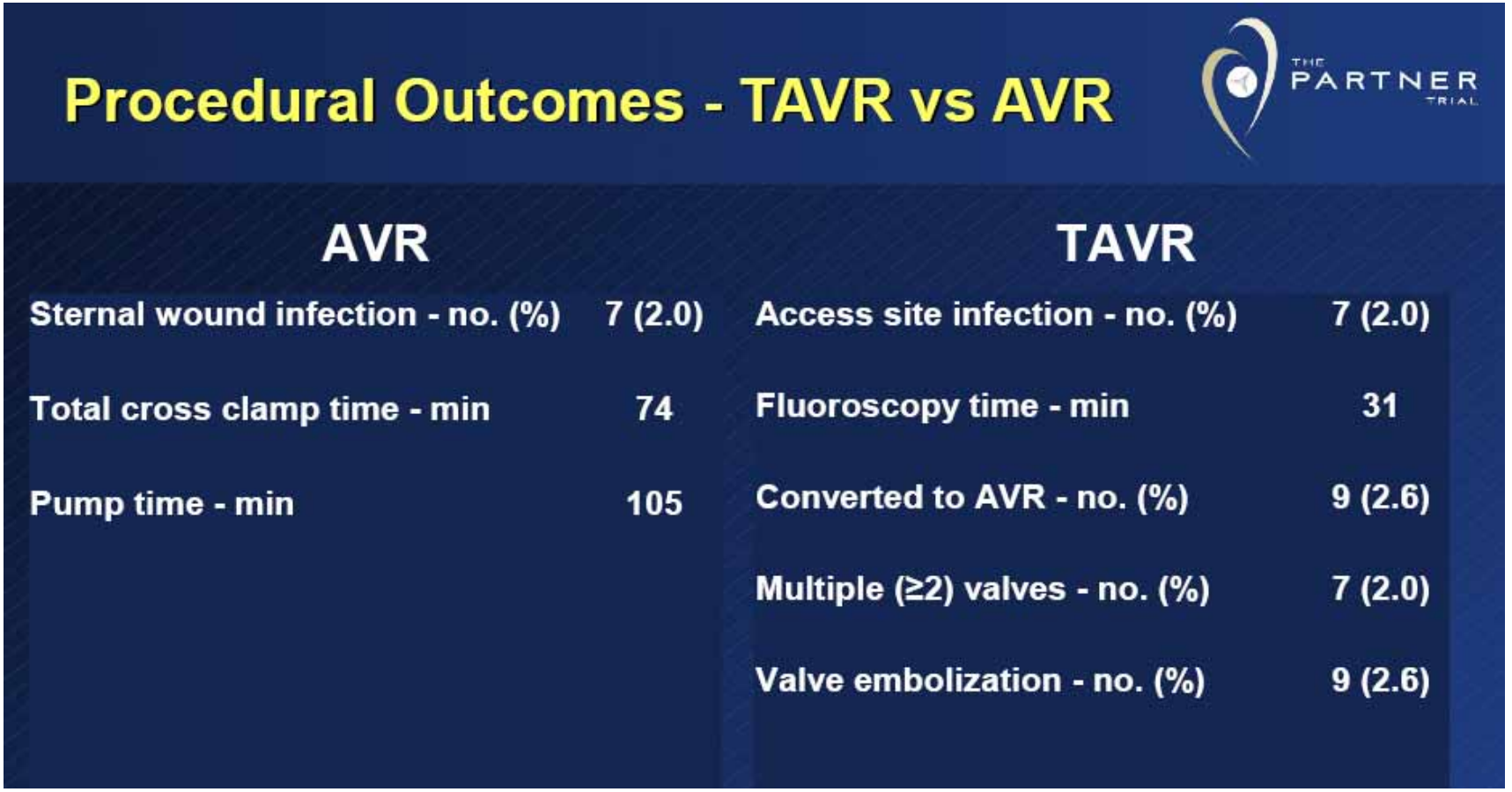


- Cohort A – High Risk Patients
- Presented by Craig Smith, ACC 2011
- 1:1 TAVR vs surgical AVR
- Showed TAVR non-inferior to surgical AVR for primary endpoint of all-cause mortality at 1 year



- Cohort B – Inoperable Patients
- Presented by Marty Leon, TCT 2010
- 1:1 TAVI vs standard therapy
- Showed TAVI to be superior to standard therapy with regards to primary endpoint of all-cause mortality at 1 year

PARTNER Trial
Cohort A (High Risk Patients)



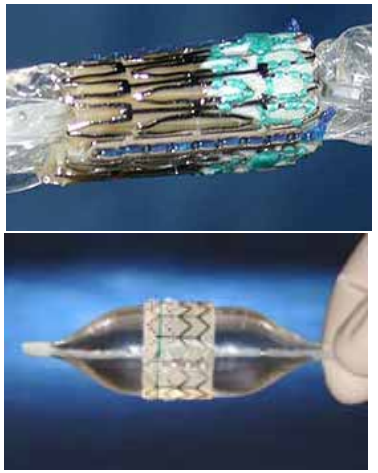
Rates of stroke and vascular complications higher with TAVR

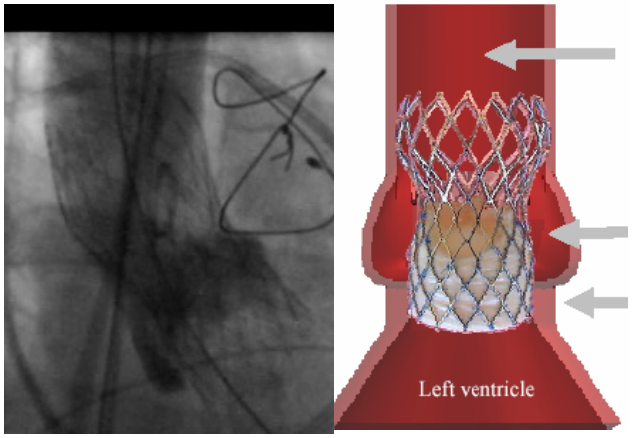
Technically challenging procedure with relatively high rates of valve embolization (2.6%) and placement of multiple valves (2.0%)

Limitations of Current Devices

Provide patients with another option for AS treatment

- Difficult to position precisely
  - Too deep in the ventricle
    - Impingement of mitral valve
    - Damage to the conducting system
  - Too high in the aorta
    - Coronary occlusion
- Limited or no ability to reposition
- Cannot be recaptured and redeployed
- Perivalvular regurgitation is common





Background and Company Status

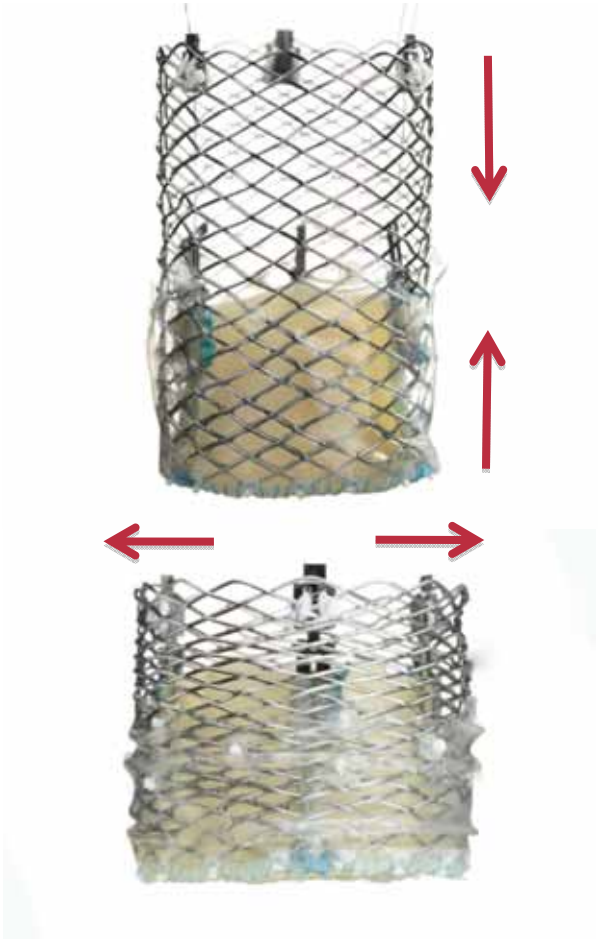
- Since 2007, Boston Scientific Corp. has been a strategic investor in Sadra Medical, Inc.
- Nov 19, 2010 - Boston Scientific entered into a definitive merger agreement with Sadra Medical
- Jan 4, 2011 – Boston Scientific completed acquisition of Sadra Medical.

Lotus Valve Components

Lotus™ Valve Concept

Braided nitinol stent structure

- Radial expansion as it shortens
  - Enables a more flexible delivery system
  - Enables device repositioning or retrieval
  - Provides significant radial strength



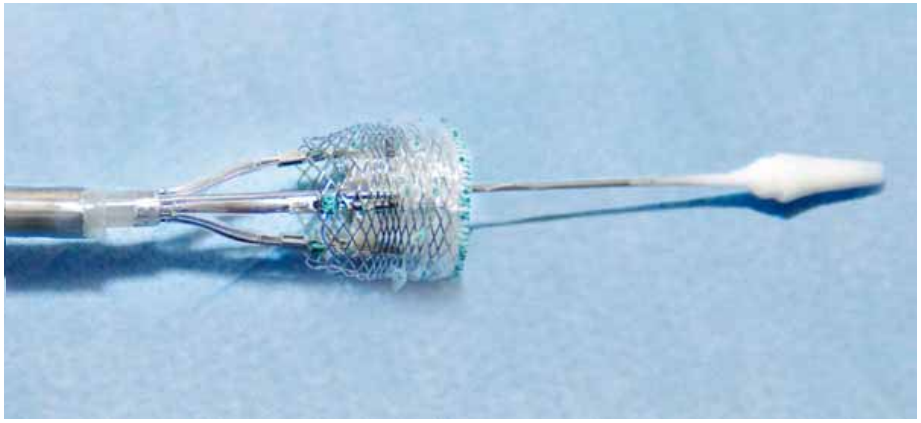
Advantages of the Lotus Valve System

Ease of Use

- System is pre-packaged on delivery system
- Two handle controls
  - 1 - deploy / retrieve and 2 - rele

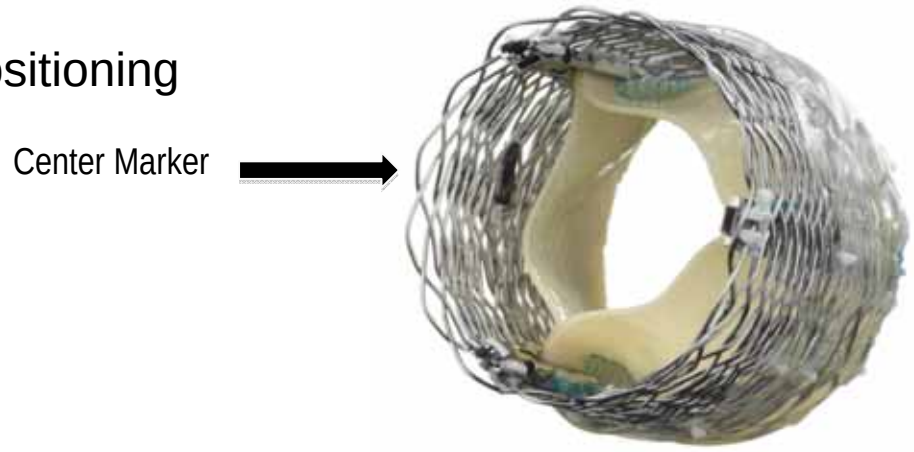
Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
  - Predictable, reversible deployment
  - Recapturable and retrievable at any point prior to release
  - Fully repositionable, both toward the ventricle or back into the aorta as needed



Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
  - Center marker facilitates alignment with native valve
  - Valve leaflet function begins early during deployment
    - Hemodynamic stability
    - Enhances precision positioning



Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
- Minimal perivalvular leakage
  - Adaptive™ Seal fills gaps between native valve and implant

Adaptive Seal

Advantages of the Lotus Valve System

- Ease of Use
- Controlled Positioning
- Accurate Placement
- Minimal perivalvular leakage
- Percutaneous delivery
  - Proprietary Lotus Introducer Sheath provides access to ≥ 6.0mm femoral vessels - equivalent to Cook 18F introducer

LOTUS Valve Clinical Program

- FIM (n=10) and Feasibility (n=12) studies already conducted using earlier iterations of the Sadra device
- CE Mark study
- US pivotal trial

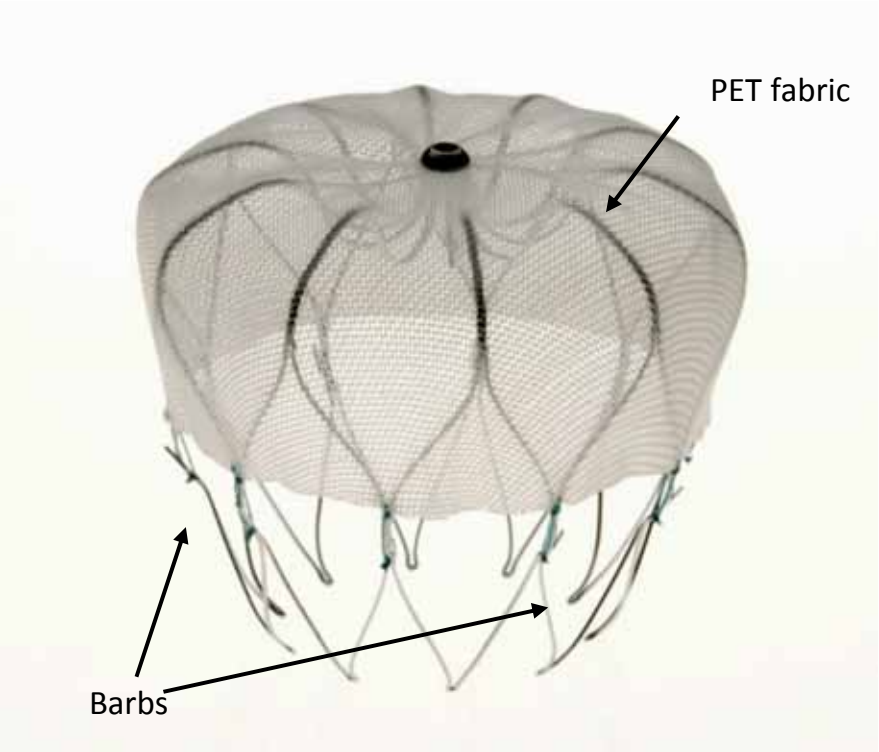
Agenda

SYNERGY Bioresorbable Polymer Platinum Chromium Stent

LOTUS Transcatheter Aortic Valve

WATCHMAN Left Atrial Appendage Closure Device

WATCHMAN® LAA Closure System Implanted Device



Frame: Nitinol structure

- Available sizes:
  - **21, 24, 27, 30, 33 mm (diameter)**
  - 10 Fixation barbs around device perimeter engage LAA tissue
  - Contour shape accommodates most LAA anatomy

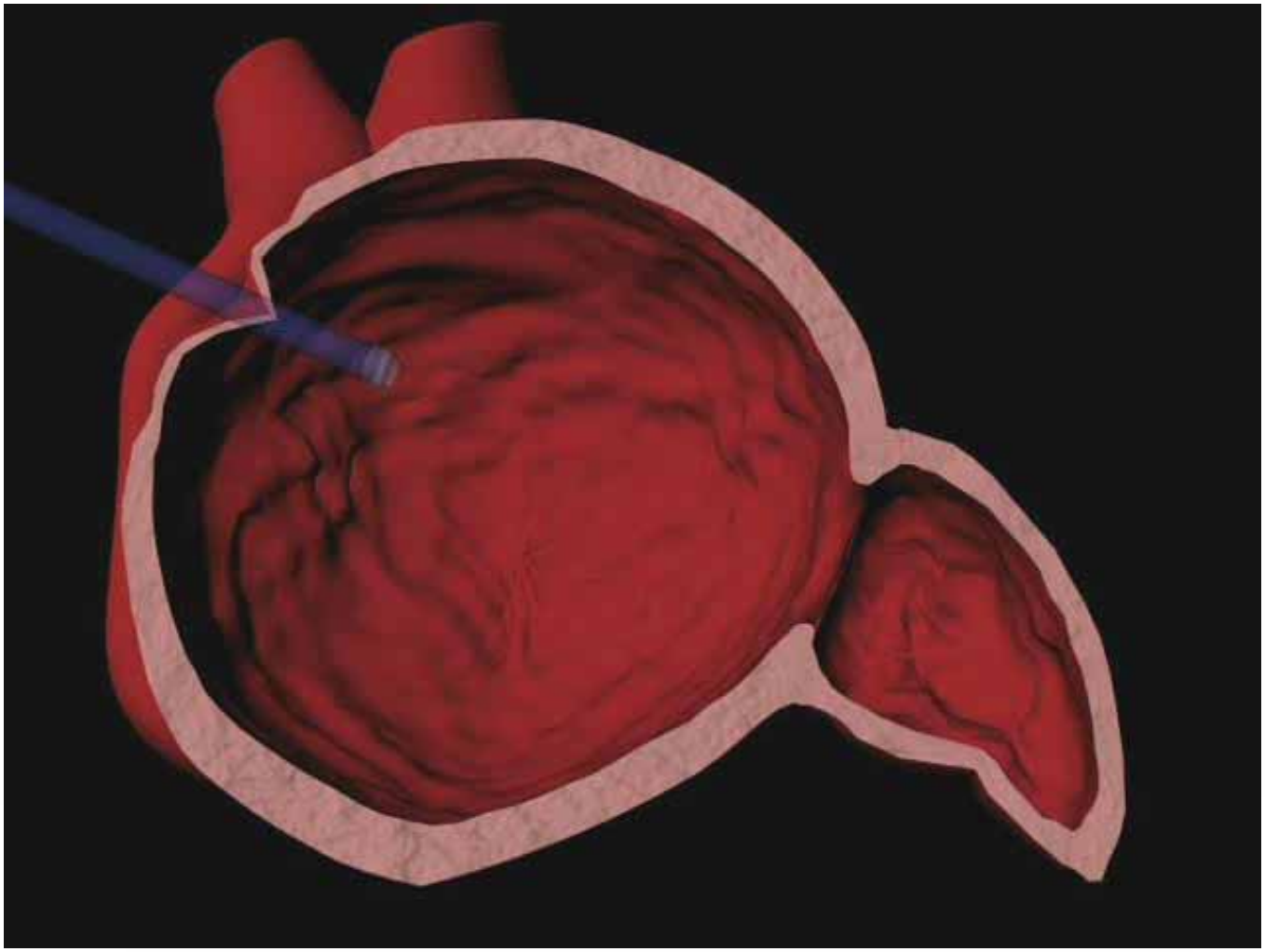
Fabric Cap: (PET) Fabric Polyethyl terephthalate

- Prevents harmful emboli from exiting during the healing process
- 160 micron filter

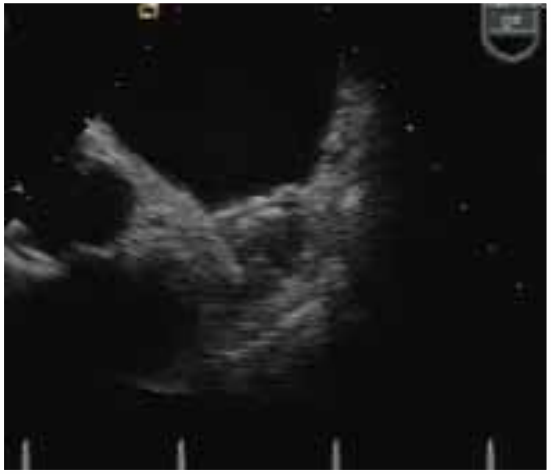
Watchman device is deployed in the left atrial appendage, endothelializes over time and excludes the LAA from the circulation

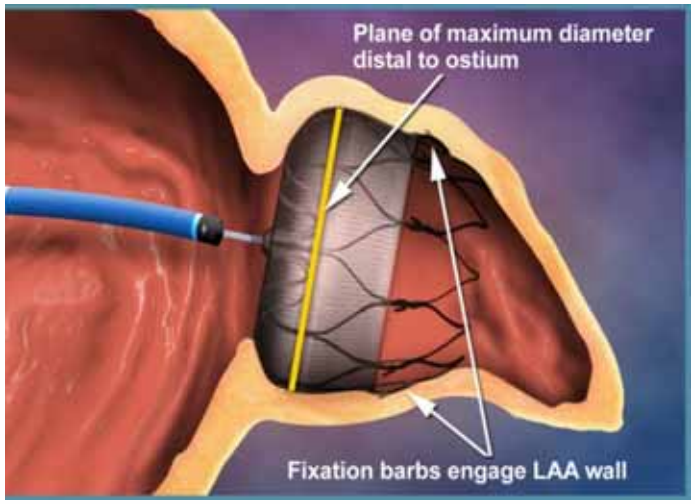
Hypothesis is that LAA closure with Watchman will reduce the incidence of thromboembolism in patients with AF

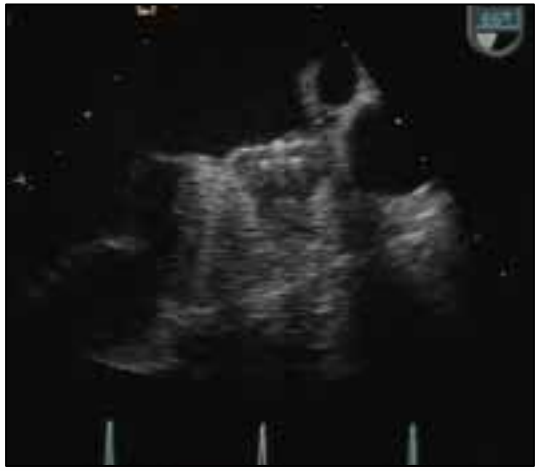
Watchman Deployment

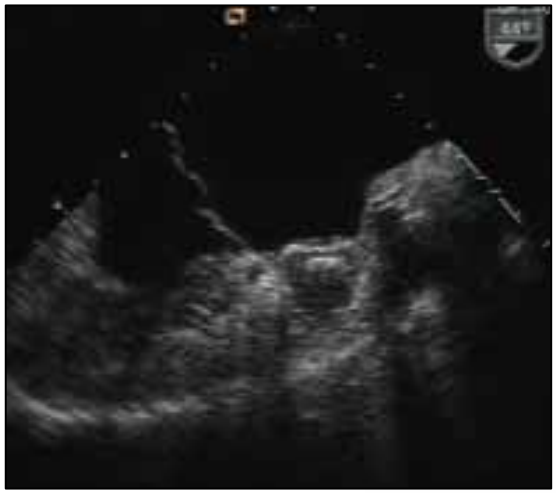


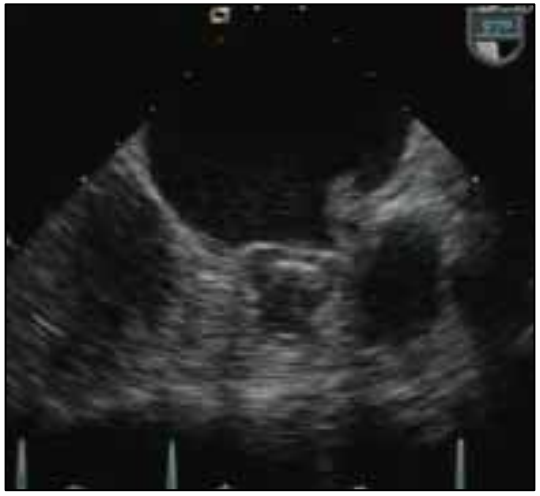
WATCHMAN Positioning

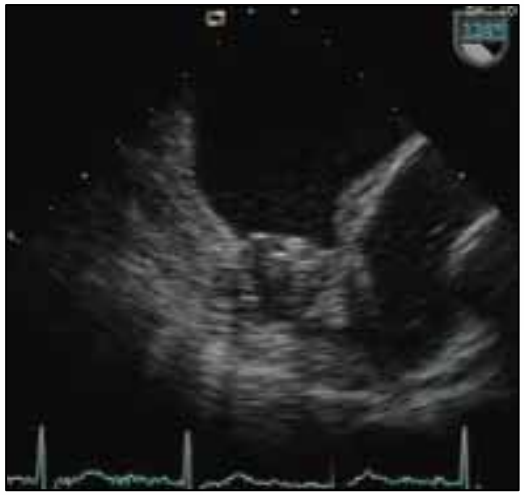












Clinical Studies

STUDY	PATIENTS	SITES	COMMENTS
Pilot	66	8	• 318 patient years of follow-up • 30 patients with 5+ years of follow-up
PROTECT AF	800	59	• 1,500 patient years of follow-up • 27 months average follow-up per patient
Continued Access Registry (CAP)	567	26	• Significantly improved safety results
ASAP	106	4	• Treat patients contra-indicated for warfarin
EVOLVE	50	3	• Evaluate next generation WATCHMAN®
PREVAIL	31	≤50	• Same endpoints as PROTECT AF • Revised inclusion/exclusion criteria • Initiate enrollment October 2010

Total 1,620

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PROTECT AF Clinical Trial

- Prospective, randomized study of WATCHMAN® LAA Device vs. long-term warfarin therapy in patients with non-valvular AF and CHADS2 score ≥1
- 2:1 allocation ratio device to control
- 800 patients enrolled from February 2005 to June 2008
  - 93 roll-in; 707 randomized
- 59 enrolling centers (U.S. & Europe)
- Follow-up requirements
  - TEE follow-up at 45 days, 6 months and 1 year
  - Clinical follow-up biannually up to 5 years
  - INR monitoring every 2 weeks for 6 months and monthly thereafter

Holmes D R et. Al, Lancet 2009;374:534-42

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Intent-to-Treat: Primary Efficacy Results

Primary efficacy endpoint:
- **stroke (ischemic or hemorrhagic)**
- **cardiovascular or unexplained death**
- **systemic embolism**

Cohort	WATCHMAN®		Control		Relative Risk (95% CI)		Posterior Probabilities	
	Rate (95% CI)		Rate (95% CI)				Non-inferiority	Superiority
600 pt-yrs	4.4	(2.6, 6.7)	5.8	(3.0, 9.1)	0.76	(0.39, 1.67)	0.992	0.734
900 pt-yrs	3.4	(2.1, 5.2)	5.0	(2.8, 7.6)	0.68	(0.37, 1.41)	0.998	0.837
1065 pt-yrs*	**3.0**	**(1.9, 4.5)**	**4.9**	**(2.8, 7.1)**	**0.62**	**(0.35, 1.25)**	**>0.999**	**0.900**
1350 pt-yrs	2.9	(2.0, 4.3)	4.2	(2.5, 6.0)	0.69	(0.42, 1.37)	>0.999	0.830
1500 pt-yrs	3.0	(2.1,4.3						0.846

Results are consistent over time, demonstrating approximately a 30% reduction in primary efficacy, stroke and mortality risk

Presented by Holmes, MD, TCT 2010

*Published Results: Holmes D R et. Al, Lancet 2009;374:534-42

Intent-to-Treat: All Cause Mortality

Cohort	WATCHMAN®		Control		Relative Risk (95% CI)		Posterior Probabilities*	
	Rate (95% CI)		Rate (95% CI)				Non-Inferiority	Superiority
600 pt-yrs	3.4	(1.8, 5.4)	4.9	(2.3, 7.8)	0.69	(0.33, 1.66)	0.991	0.779
900 pt-yrs	2.9	(1.7, 4.4)	4.7	(2.5, 7.1)	0.61	(0.32, 1.32)	0.999	0.889
1065 pt-yrs*	**3.0**	**(1.9, 4.5)**	**4.8**	**(2.8, 7.1)**	**0.62**	**(0.34, 1.24)**	**>0.999**	**0.907**
1350 pt-yrs	3.1	(2.1, 4.4)	4.4	(2.6, 6.1)	0.70	(0.43, 1.36)	>0.999	0.823
1500 pt-yrs	3.2	(2.3, 4.5)	4.5	(2.8, 6.2)	0.71	(0.46, 1.28)	>0.999	0.852

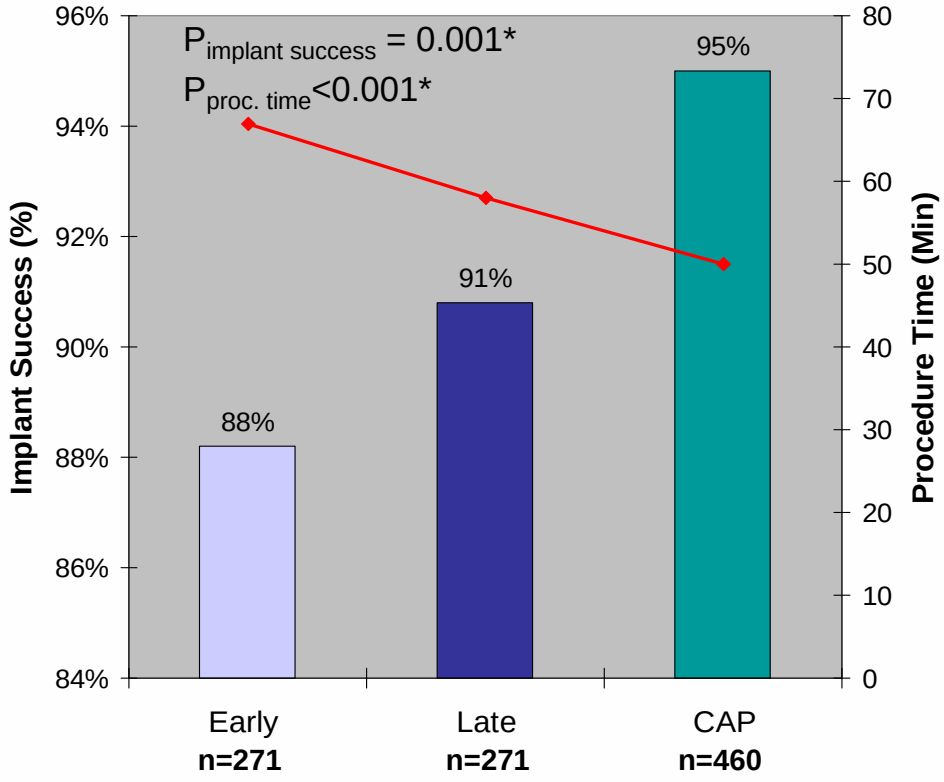
*No adjustment made for multiple comparisons

29% lower relative risk in WATCHMAN® Group

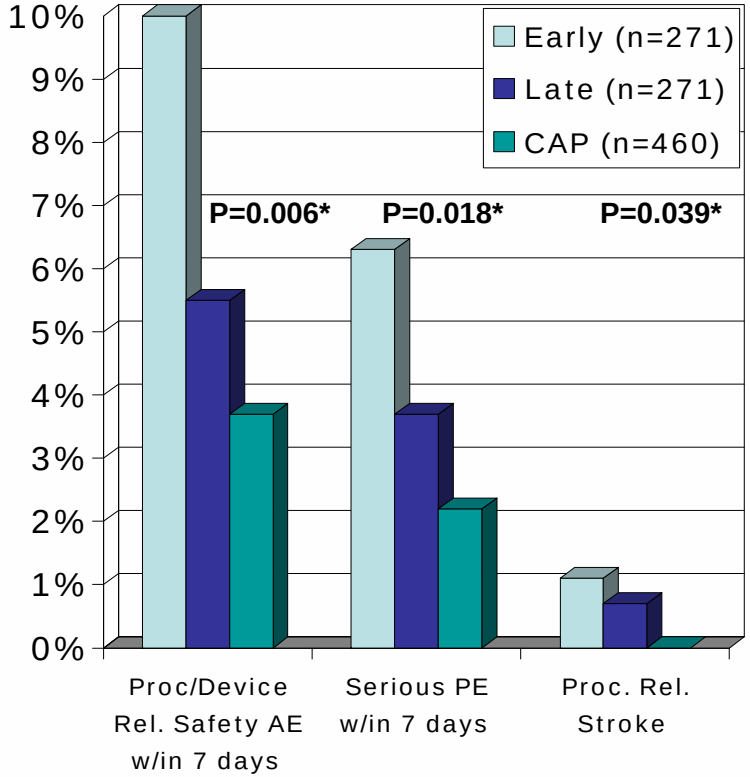
Presented by Holmes, MD, TCT 2010
*Published Results: Holmes D R et. Al, Lancet 2009;374:534-42

CAP Results versus Early and Late PROTECT AF: Progression of Procedural Success and Safety

Procedure Metrics



Procedure Outcomes



*From tests for differences across three groups: early PROTECT AF (1st 50%), late PROTECT AF (2nd 50%), and CAP)

Reddy VY et al, Circulation AHA 2011

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PREVAIL Study Overview

Study Objective: To provide additional information on the safety and efficacy of WATCHMAN LAA Closure Technology

Study Design: Prospective, randomized (2:1) study of WATCHMAN versus long-term warfarin therapy

Scope and Duration:

- Currently Enrolling
- Up to 475 patients (75 roll-in, 400 randomized) at up 50 U.S Centers
  - 25% randomized patients must be enrolled by new operators

Key entry criteria

- Calculated $CHADS_2$ score of 2 or greater. Patients with a CHADS score of 1 may be included if any of the following apply:
  - Female age 75 or older
  - Baseline LVEF ≥ 30 and < 35%
  - Aged 65-74 and has diabetes or coronary artery disease
  - Aged 65 or greater and has congestive heart failure

Conclusions

Thromboembolism in AF is a major cause of morbidity and mortality

- Although Oral Anticoagulation is Effective, many patients will not tolerate it due to the risk of major bleeding

WATCHMAN LAA Closure Device occludes the Left Atrial Appendage preventing embolism of LAA thrombi

- In Protect-AF (800 patients, 1500 patient-years of follow-up), the device was non-inferior to oral anticoagulation in patients at high-risk of thromboembolism with a trend toward improved outcomes

The PREVAIL, ASAP and EVOLVE trials will provide further information on the safety and effectiveness of the device, the indicated population and next generation technology