Latest clinical update on Watchman LAAC and why and when I use Watchman in my clinical practice.

Dr. Gary Shing-him CHEUNG

張誠謙

MBBS(HK), FHKCP (HK), FHKAM (HK)
Associate Consultant & Honorary Clinical Assistant Professor
Head of Structural Heart Intervention
Division of Cardiology, Department of Medicine & Therapeutics,
Prince of Wales Hospital, The Chinese University of Hong Kong

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Speaker's name : Gary Shing-Him CHEUNG

☑ I have the following potential conflicts of interest to report:

I am a physician proctor for Watchman (Boston Scientific) and Amulet (Abbott) LAAO devices.

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- I was frequently asked by a question.

“ What is your favourite LAAO device? How to choose the LAAO device for the patient? ”

Their concerns over Watchman LAAO device:

1. Post LAAO anticoagulation regime: The patient must take warfarin?
2. LAAO morphology: chicken-wing, short and shallow.

Post LAAO anticoagulation regime

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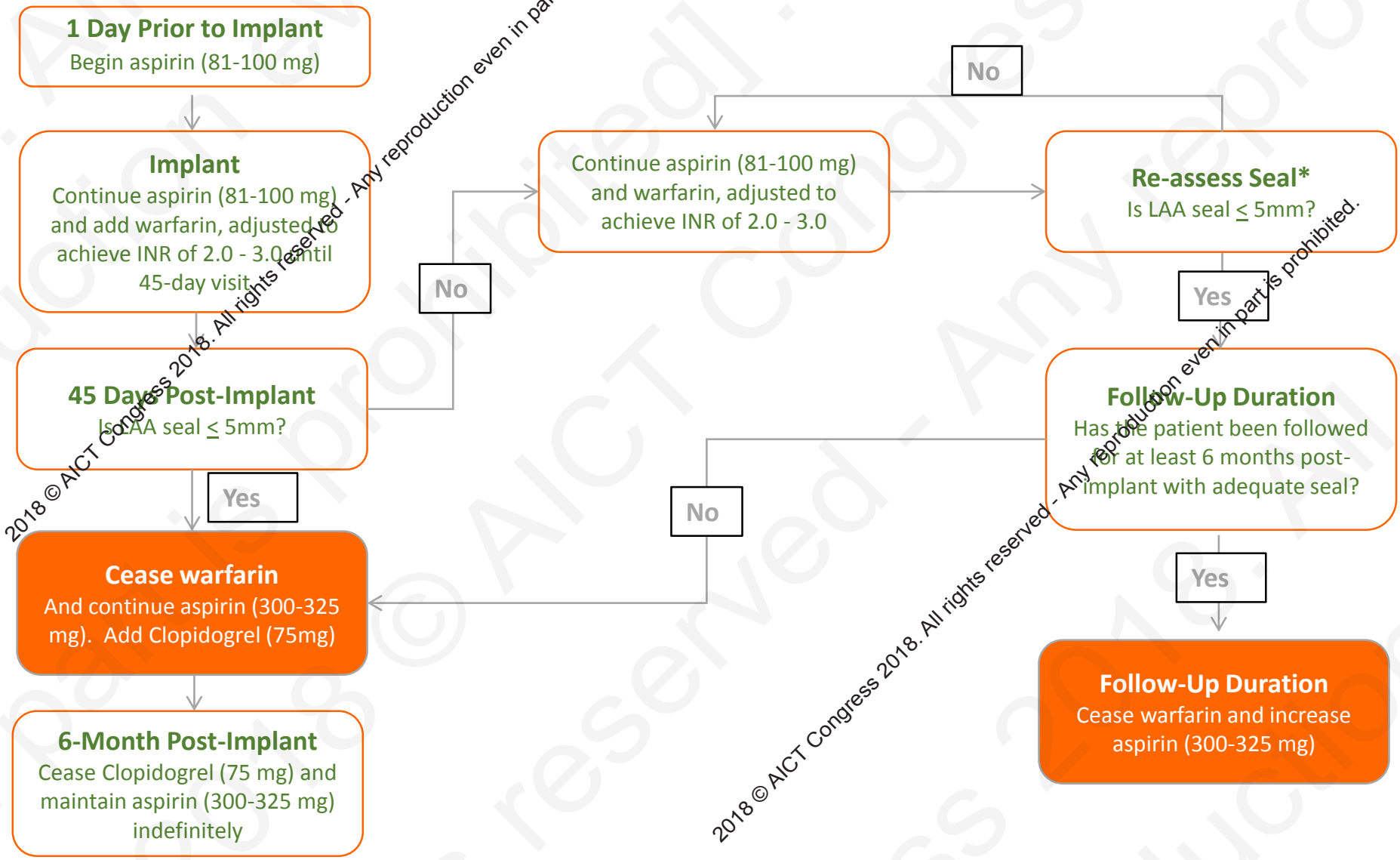
WATCHMAN Implant Procedure

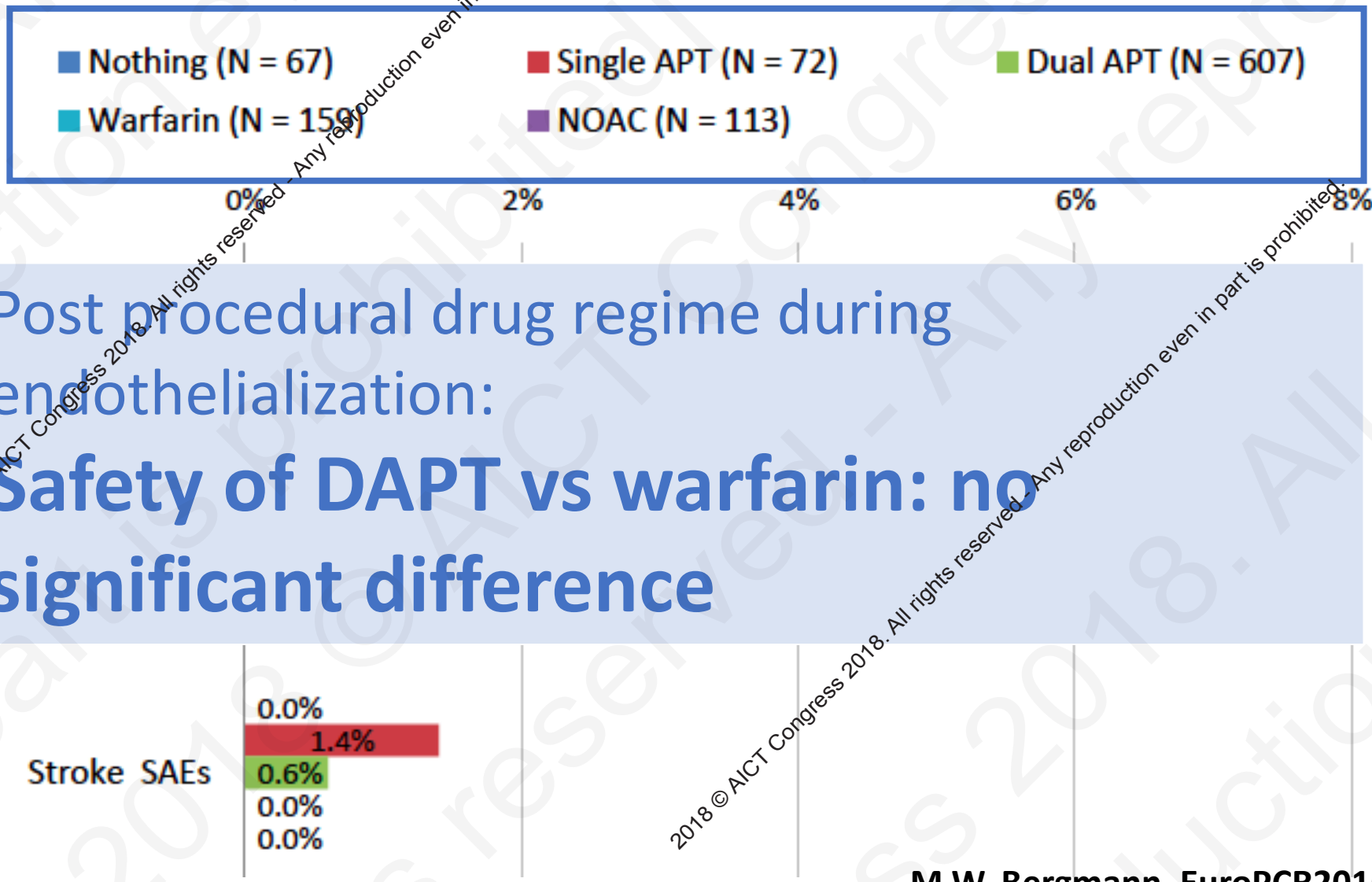


Registry on WATCHMAN Outcomes in Real-Life Utilization: EVOLUTION

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Study Objective:	Collect real-world WATCHMAN LAAO experience outside of selected populations in prior RCT
Study Design:	Prospective, single-arm, multi-center registry of the Watchman LAA Closure Technology
Primary Endpoint:	Primary analysis includes procedural success and safety, incidence of stroke, bleeding, and death after 2 yr of FU Investigator and Medical Safety Group for adjudication
Patient Population:	>1000 patients
Number of Sites:	47 throughout Europe, Russia and Middle East
Enrollment:	Started October 2013 - Completed May 2015
Follow-up:	Standard practice at participating centers • Normally 1-3 months post-procedure • Annually thereafter for a total of 2 years

Impact of post-procedural anticoagulation – 3-months data



Post procedural drug regime during endothelialization:

Safety of DAPT vs warfarin: no significant difference

M.W. Bergmann, EuroPCR2016

ASAP-TOO (NCT02928497): Overview

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Study Objective	Evaluate LAA Closure with WATCHMAN in NVAF patients deemed not suitable for oral anti-coagulation therapy
Study Design	Prospective, multi-center Randomized 2:1 (Watchman vs Control)
Primary Endpoint	<u>Effectiveness Endpoint</u> Time to first occurrence of ischemic stroke or systemic embolism <u>Safety Endpoint</u> 7-day rate of all-cause death, ischemic stroke, systemic embolism, or device- or procedure- related events requiring open cardiac surgery or major endovascular intervention
Patient Population	888
Number of Sites	100 global sites
Follow-up*	• 3 month with TEE • 6,18 month phone visit • 12 month with TEE • Bi-annually for years 2-5

ASAP-TOO
Device Group Medication Therapy

WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Visit Interval	Aspirin	Clopidogrel*
Discharge through 3-month visit	Yes, suggested dose: 75-100mg	Yes Suggested dose: 75mg
3-month visit through 12-month visit	Yes, suggested dose: 75-100mg	No, unless other indication
Following the 12-month visit	No, unless other indication	No, unless other indication

***Clopidogrel may be substituted with ticagrelor or prasugrel if the subject requires the medication for other indications (e.g. acute coronary syndromes treated with drug eluting stents) or if the subject has a known resistance to clopidogrel.**

****Patients are allowed to be on dual antiplatelet therapy (outside of the protocol required 3- months period) if indicated due to a condition other than WATCHMAN implantation.**

Watchman LAAO in Chicken-wing LAA Morphology

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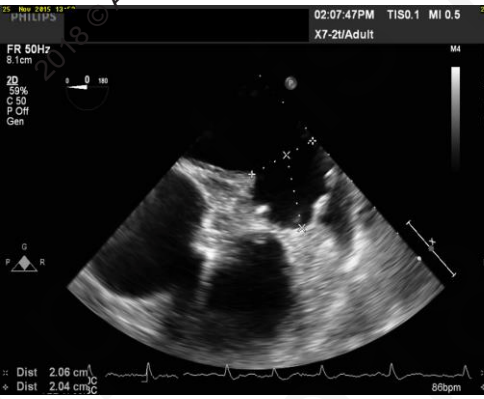
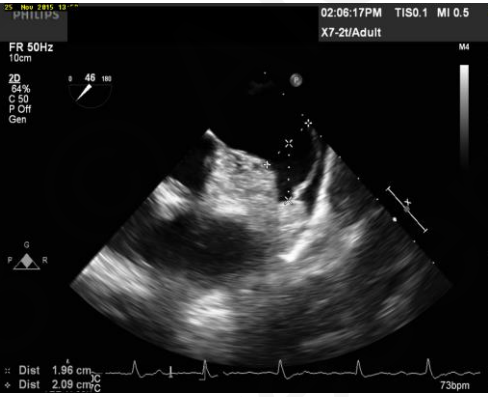
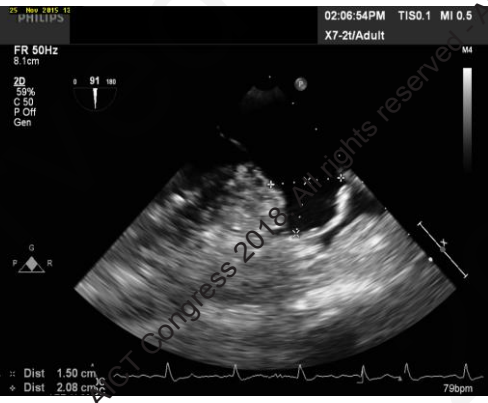
Pre LAAO TEE measurement

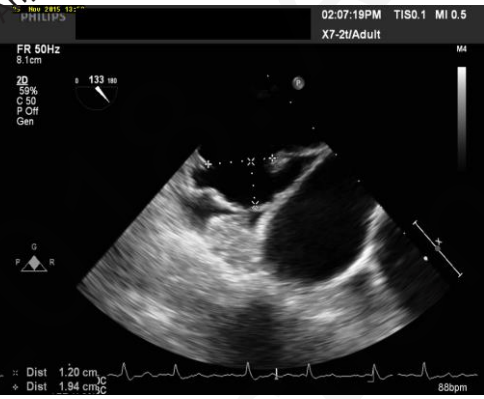



0’ 45’ 90’ 135’









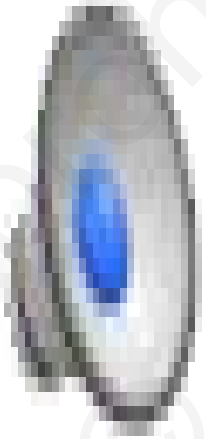
Width 20 Depth 21

Width 21 Depth 20

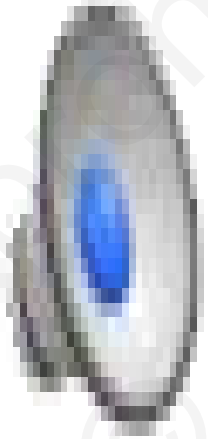
Width 21 Depth 15

Width 19 Depth 12

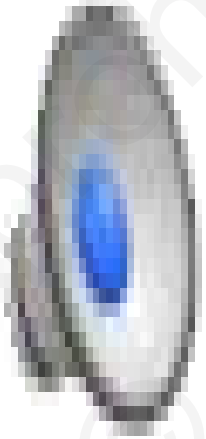
Baseline LAAgram



Deployment by 24mm Watchman device by one attempt



Tug test then release



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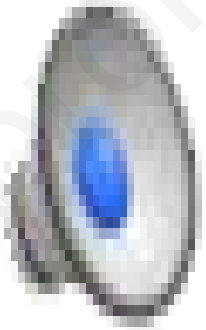
Post LAAO TEE



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WATCHMAN FLX™ Design

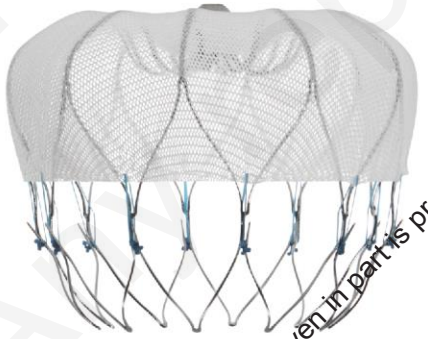
Boston Scientific

WATCHMAN FLX™

- **Wider Treatment Range**
  LAA ostium diameters:
  14mm – 31.5mm

  Min LAA depth:
  ½ device width
- **LAA Conformance**
  18 struts for enhanced LAA apposition and sealing
- **Shallow Access**
  Closed distal end for shallow access deployment
- **Full Recapture**
  New anchor design allows full recapture and redeployment

WATCHMAN™



- **Specifications**
  LAA ostium diameters:
  16.8mm – 30.4mm

  Min LAA depth:
  1:1 LAA diameter

  10 struts

DESIGN GOALS

FLEXIBILITY: Treat more patient anatomies
CONTROL: Improved maneuverability
SEAL and **HEAL:** Confident closure

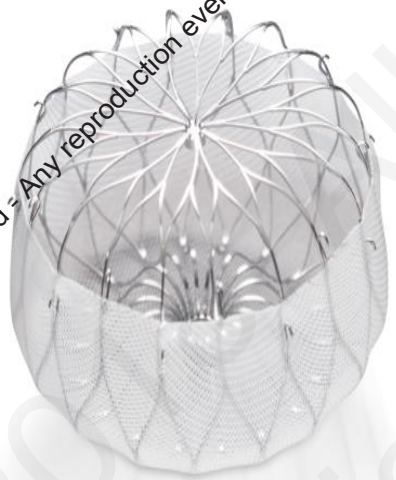
Caution: The WATCHMAN FLX™ Left Atrial Appendage Closure Device is an investigational device and is not available for sale in the U.S. or Europe.

PINNACLE FLX IDE Study

US-only IDE

- Single arm non-randomized study design
  - DOAC only options for post-implant drug regimen
  - Non-inferiority to performance goal based on WATCHMAN 2.5
- Up to 490 enrollments (includes 90 roll-ins)
- Up to 45 US sites
- Primary Safety Endpoint
  - The occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device- or procedure- related events requiring open cardiac surgery or major endovascular intervention such as pseudoaneurysm repair, AV fistula repair, or other major endovascular repair.
- Primary Effectiveness Endpoint
  - The rate of effective LAA closure defined as any peri-device flow ≤ 5mm demonstrated by TEE at 12 months (US)
- Secondary Endpoints
  - The occurrence of ischemic stroke or systemic embolism at 24 months from the time of enrollment
- Follow-up at 45 days, 6, 12, 18 and 24 months

PINNACLE FLX
CLINICAL TRIAL



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Conclusion

- Post LAAO anticoagulation regime by DAPT apparently as effective and safe as standard post Watchman regime; undergoing RCT will definitely answer this issue.
- LAAO by Watchman device is also feasible in difficult LAA anatomy, like chicken-wing morphology.
- Newer generation of Watchman: Watchman Flx 2.5 will be available soon

2018
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9th Asia Pacific Congenital and Structural Heart Intervention Symposium

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Thanks your attention!

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