How will TAVI technologies evolve over the next 5-10 years?

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Potential conflicts of interest

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

Receipt of grants / research support: Bard, Claret Medical, Edwards Lifesciences, Medtronic, St. Jude Medical

Receipt of honoraria or consultation fees: Boston Scientific and Symetis, Medtronic

Stock shareholder: Claret Medical, TMI
TAVI in perspective – Early pioneers

- Hening Rud Andersen-
  1989: *First porcine implant*

- Philipp Bonhoeffer-
  2000: *First human implant (RV to PA conduit)*

Courtesy of Dr. M. Leon, TVT 2017
TAVI and SAVI in the STS Registry

* SAVR= isolated surgical aortic valve replacement; ACSD=Adult Cardiac Surgery Database

Source: STS/ACC TVT Registry Database as of Oct 18, 2016; STS ACSD 2015 Annual Report
Growth of TAVR Procedures from 2010-2018

CAG: EU 14%
US 27%

~90K procedures by 2018

Number of Procedures (x 1000)

2010: 0.7
2011: 2
2012: 5
2013: 11
2014: 16
2015: 20
2016: 27
2017: 32
2018: 37
Estimated TAVI Growth

In the next 10 years, TAVR growth will increase X4!

SOURCE: Credit Suisse TAVI Comment – January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

Courtesy of Dr. M. Leon, TVT 2017
STS database 2002-2010 (141,905 pts)

- High risk (STS > 8%): 6.2%
- Intermediate risk (STS 4-8%): 13.9%
- Low risk (STS <4%): 79.9%

Since 2007, in the U.S., >15,000 patients have been enrolled in FDA studies (including 8 RCTs) with multiple generations of two TAVR systems!

Courtesy of Dr. M. Leon, TVT 2017
TAVI Innovations

Next Generation Abbott TAVI Technology*

- **ATRAUMATIC PROXIMAL STENT CELLS**
- **EXPANDED TREATMENT RANGE**
  - Expanded annular and aortic treatment ranges
- **NEW INNER CUFF MATERIAL**
  - Maintain delivery system profile
- **DESIGNED FOR IMPROVED STABILITY**
- **NEW OUTER SKIRT**
  - Improve PVL rates
- **EXTENDED CUFF**
  - Improved sealing

*In development, not approved for sale in any geography*
Next Generation Abbott TAVI Delivery System

EASE OF USE
- Handle improvements
- Retainer release improvements

REDUCED INSERTION PROFILE
- Sheathless approach with integrated sheath
- Compatible with expandable sheaths
- Hydrophilic coating

IMPROVED PLACEMENT ACCURACY
- Stability layer
- Improved flexibility and trackability
- Passive alignment

*In development, not approved for sale in any geography.

SJM-PTC-0977-0097a | Item approved for Global use.
The Next Generation LOTUS Edge™ Valve System

**Design Goals**

- **Maintain benefits of first generation Lotus**
  - Adaptive seal to minimize PVL
  - Complete repositionability
  - Early valve function

- **Improve delivery**
  - Lower profile system
  - More flexible catheter

- **Optimize deployment**
  - Depth Guard™ limits depth of implant
  - One-view locking with additional RO Markers

LOTUS Edge is not available for sale in the US
Depth Guard Deployment Technology
Limit depth of implant with LOTUS Edge

Optimizing Valve Deployment:

• Anchors early during deployment

• Minimizes depth of valve frame reducing LVOT interaction

• More predictable placement

LOTUS Edge is not available for sale in the US
CAUTION: Lotus is an investigational device and restricted under federal law to investigational use only. Not available for sale.
The Edwards SAPIEN 3 Ultra System

- On-balloon design removes the need for valve alignment
- Redesigned distal end
- Next-generation seamless expandable sheath
- 14F for all valve sizes
Edwards CENTERA Transcatheter Heart Valve System

- Short valve height
- Bovine pericardium
- Novel contoured frame geometry

23 mm
26 mm
29 mm
18 mm
21 mm
23 mm
Edwards CENTERA Transcatheter Heart Valve System

- **Pre-attached valve** for rapid device preparation
- **14F sheath** for all valve sizes
- **Fully motorized delivery system** for stable valve deployment
- **Repositionable and recapturable** if needed

Valve Deployment

Valve Loading and Recapturing
**E VOLUT PRO**
ADVANCED SEALING WITH PROVEN PLATFORM PERFORMANCE

Supra-Annular Valve
Porcine Pericardial Tissue
Cell Size Enables Coronary Access

Self-Expanding Frame
Pericardial Skirt

Sealing can occur at multiple levels; including above and below calcification with a self-expanding frame

Evolut™ R  Evolut™ PRO

Pericardial Wrap Increases Surface Contact with Native Anatomy

Skirt Height 13 mm

Added Tissue Volume between the TAV & native anatomy to reduce gaps
TAVI PIPELINE
CADENCE OF CONTINUOUS, MEANINGFUL INNOVATION

- **Evolut™ PRO**
  - Advanced Sealing

- **EnVeo™ PRO**
  - Seamless Tracking

- **34 PRO**
  - PRO Performance: Large Valve

- **Next Gen Evolut™**
  - Superior Ease of Use
  - Positioning Accuracy
  - Low Profile

- **Horizon**
  - Transformative Aortic Platform

FDA & CE-Mark Approved

IN DEVELOPMENT

IN DEVELOPMENT

IN DEVELOPMENT

IN DEVELOPMENT

Investigational devices and not approved for sale
Summary and Conclusion

- Explosive growth in TAVI worldwide
- Evolving recommended use guidelines
- The Heart Team is now the preferred model for managing complex CV diseases
- Carry-over effects in the development of a new subspecialty – Structural Heart Disease
- Acceptance of a multi-modality imaging for diagnosis, therapy guidance, and FU
- Exploration of new clinical indications
- Improved disease awareness and access to TAVI (esp. underserved populations)
- Accelerated innovation of TAVI platforms (e.g. tissue engineered heart valves)
- Re-defining AS disease state and „trigger points“ for therapy (beyond Braunwald-Ross)
- Realization of new clinical indications
Thank you!