

How to build a TAVI Team

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Disclosure

***Consultant and involved in the
Training / Proctoring program for
Edwards Lifesciences***

Edwards Sapien
balloon expandable

CoreValve
self expandable

**CE mark
2007**



- > 40 000 treated Pts worldwide
- Improved and satisfactory immediate and mid-term results in high risk patients



**Growing interest
in the medical community**

Near all operators are willing to learn and apply this technique

This raises several questions:

- **Who should do these procedures ?**
- **Which centers should be open ?**
- **How to get prepared and organized?**
- **How to get trained?**

Multiple new issues for the physicians

- **Caring with unusually sick patients and choosing the best therapeutic option**
- **Creating a cohesive multi-disciplinary team**
- **Returning to basics (crossing aortic valve)**
- **Learning new interventional and surgical procedures (new devices, large introducers, new technical modalities)**
- **Facing new specific complications**

European Statement - 2008



European Heart Journal (2008) 29, 1463–1470
doi:10.1093/eurheartj/ehn183

SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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European Heart Journal (2008) 29, 1463-1470

Should be concerned high volume and experienced centers for both AVR and interventional cardiology

With expertise in structural heart disease intervention and high-risk valvular surgery

- AVR > 200 per year
- PCI > 600 per year

Each step is crucial to achieve a safe procedure

Staff and Team preparation

Equipement, imaging modalities

Patient Screening

Pre-implantation valvotomy

Large sheath insertion

Valve positioning and delivery

Devices retrieval



High quality imaging matters

- Ideally: Hybrid room for all procedures
- If hybrid room not available:
 - *Cath-Lab adapted to meet surgical sterility*
 - *Operating room with validated mobile C-arm for the transapical approach*

GENERAL ELECTRIC: OEC 9800 & 9900

ZIEHM: Vision R & FD

PHILIPS: BV Pulsera

SIEMENS: Artis U

Patient selection

***Aortic valve assessment
anatomy, calcium distribution
valve sizing***

***Selection of access
Vascular imaging***

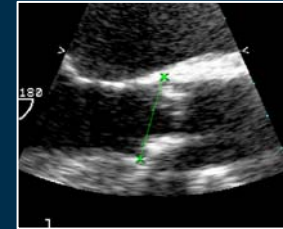
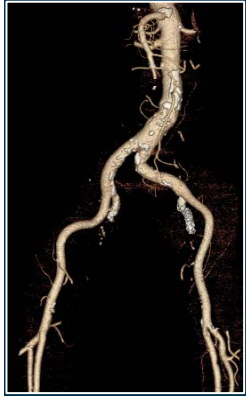
**Multiple
Disciplinary
Approach**

***Technique of BAV
and RVP***

***THV positioning
and delivery***

***Prevention and treatment
of complications***

Close cooperation of team specialists in valve disease



Radiologist

Echocardiographer

**Successful
THV Program**

Anesthesiologist

Nurses
Technicians



Cardiac surgeon

Cardiologist

Each procedural step matters

Arterial access



FEMORAL

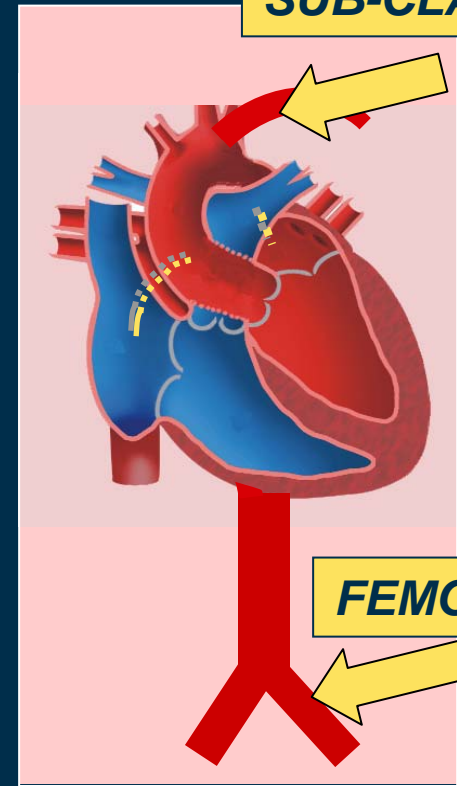
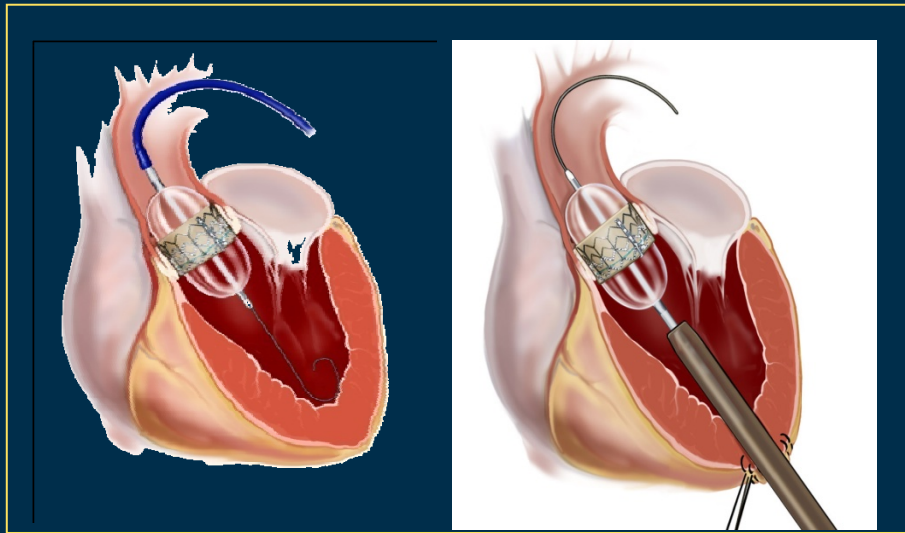
**Percutaneous?
Arterial cut-down?
Lateral sternotomy**

**General or local
Anesthesia?**

APICAL



SUB-CLAVIAN

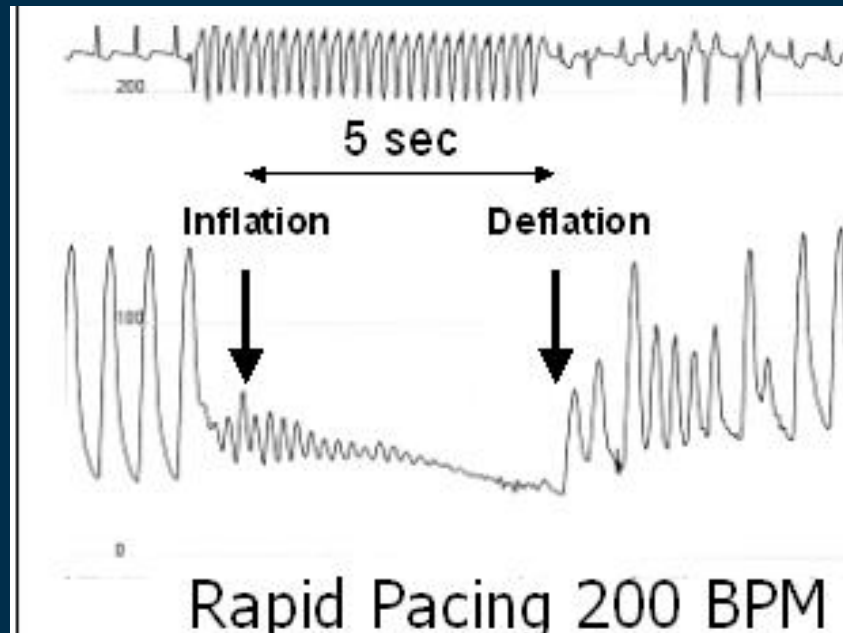
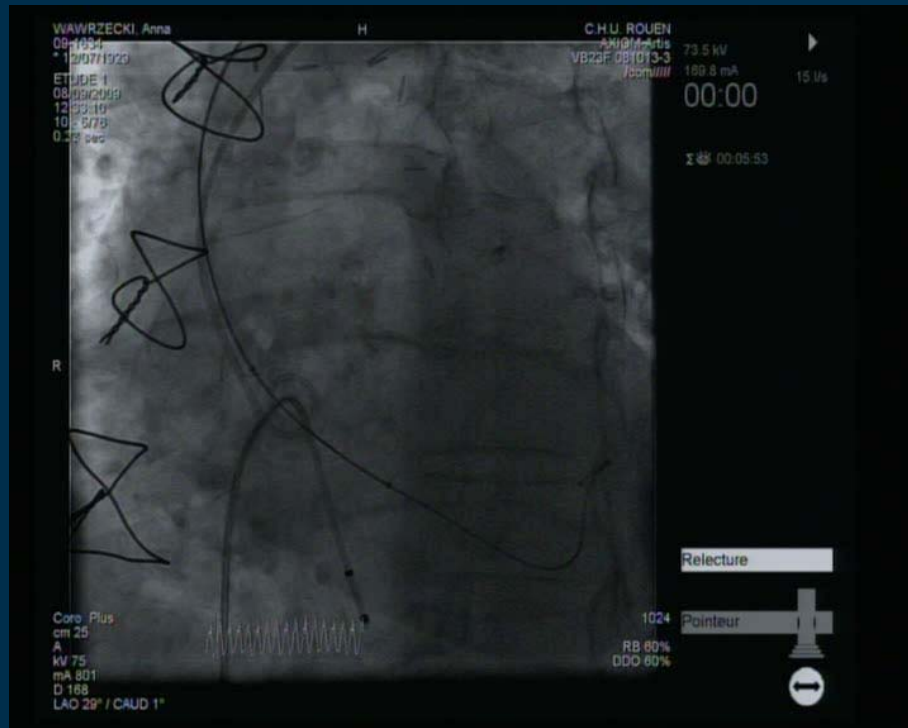


FEMORAL

Each procedural step matters

Ballon pre-dilatation

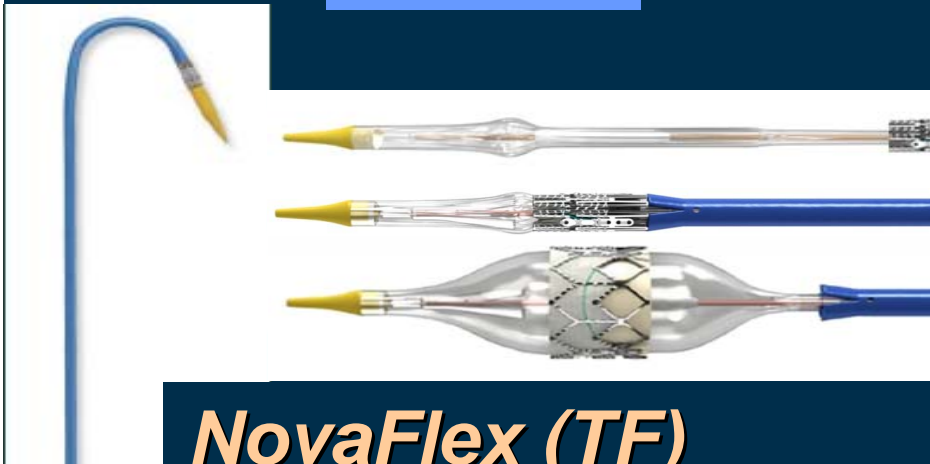
- Crossing the valve; wire selection and preshaping
- Balloon selection, preparation and positioning
- Rapid ventricular pacing
- Simultaneous aortogram (validation of THV size)



Each procedural step matters

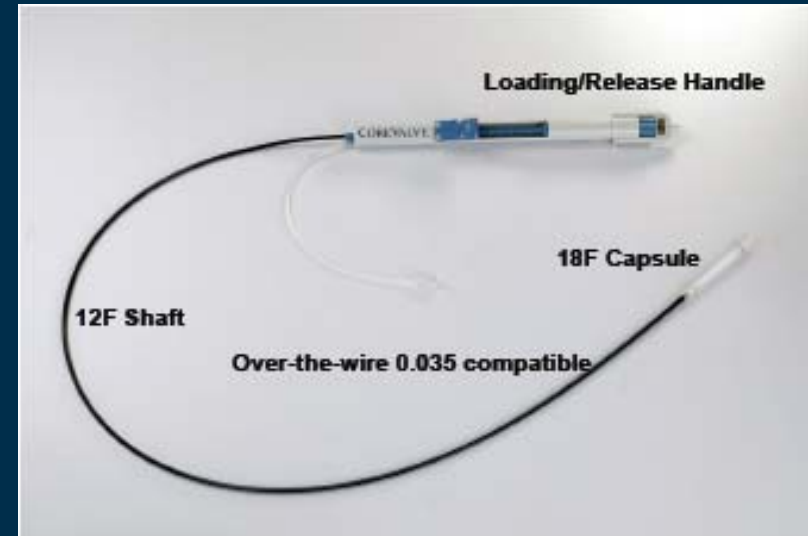
Preparation and use of introducers and delivery systems

EDWARDS



NovaFlex (TF)

COREVALVE



*CoreValve
delivery system*



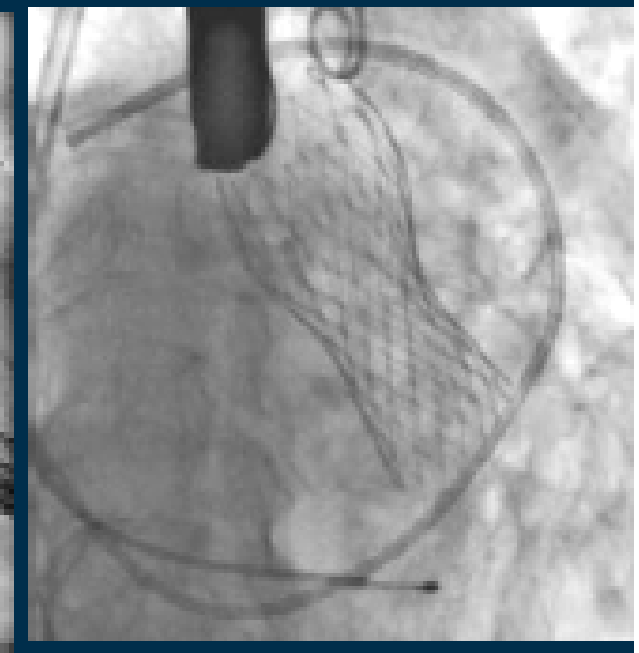
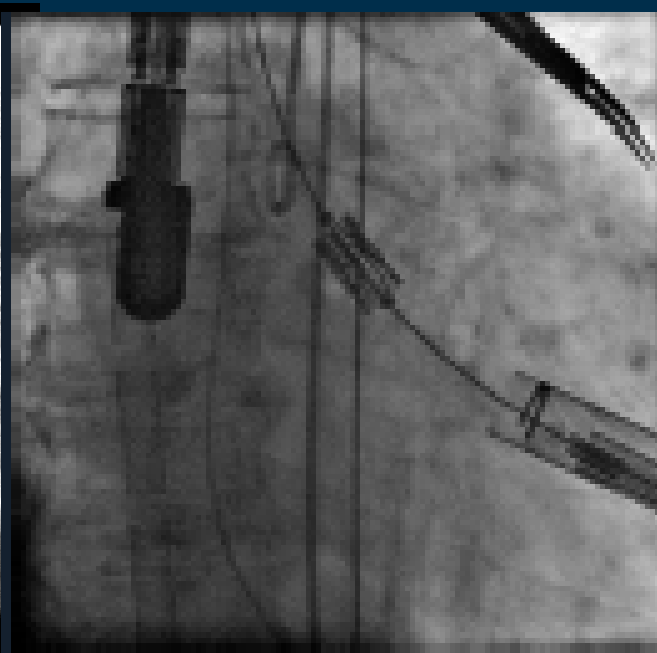
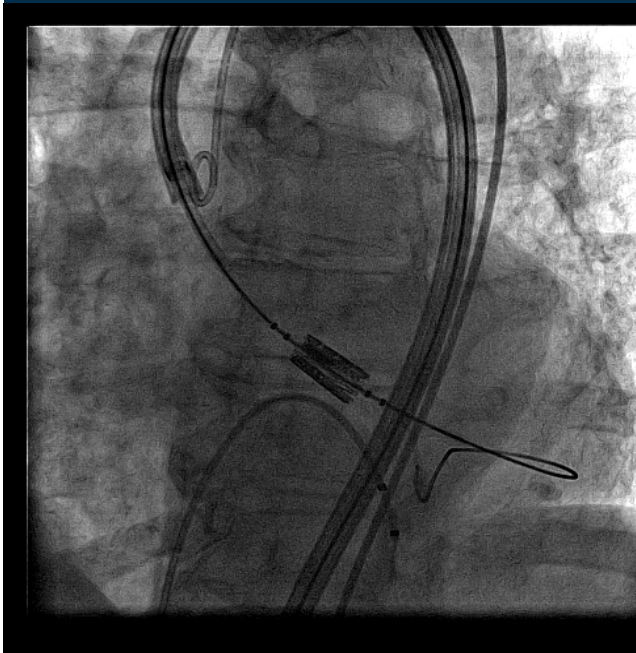
Ascendra (TA)

Each procedural step matters
THV positioning and delivery

EACH DETAIL MATTERS !

EDWARDS

COREVALVE



Transfemoral

Transapical

Transfemoral

Prevention and treatment of complications

Be prepared to manage the complications

VASCULAR complications:

- Aorta balloon occlusion
- Covered /non covered stents
- Surgical repair

TAMPONADE:

Pericardial drainage

CORO. Occlusion

Stenting

Cardiac assistance

OTHER SEVERE COMPLICATIONS

POSSIBILITY OF CONVERSION TO SURGERY

Organize POST-implantation phase

- **In-hospital management**
- **Compliance to Registries**
(ideally with a research nurse)
- **Organize the follow-up**

Training is the KEY !

- **Acquiring basic, then advanced device specific skills**
- **Acquiring knowledge of valve disease (clinical, catheterization techniques, imaging)**
- **Working in a sterile environment**
- **Understanding the equipment**
- **Anticipating and treating complications**

Training sessions organized by both companies

EDWARDS

- **Rouen-France**
(1 or 2 per month)
- **Leipzig-Germany**
(1 or 2 per month)
- **Nyon-Switzerland**
- **Vancouver- Canada**
- **New-York- USA**

COREVALVE

- **Switzerland**
(2 per month)
- **On-site**

- **Simulators**
- **Didactic**
- **Cases review**
- **Hands on**
- **Live cases**



Learning Curve

Several levels of learning

- The learning curve is permanent from one case to the other
- It has to re-start after each technological advancement

The impact of the learning curve on the safety of TAVI has been fully demonstrated

On site-proctoring

- Organized by both companies
- Clinical assistance for the first cases
- After re-assessment of each patient's screening
- Ideally ≥ 2 cases/day (pre-selected cases)
- Same 2 operators (main + assistant)
- Proctored cases:
 - *4 to 6 for Edwards*
 - *15 for Corevalve*
- Certification

Optimal training of the team

Valve crimping

*Specific training of nurses
by the compagny's clinical specialists*

Assistance for the first 10 cases

Start of certified centers

- **Start with optimal cases (*ex:good femoral access, no EF depression*)**
- **Short delay after on site proctoring**
- **Same two trained operator**

The TAVI Team Summary

- *Importance of physician and staff training
validating training and proctoring programs*
- *Dedicated cath-labs and / or hybrid OR
with optimal imaging capabilities*
- *Interventional vs surgical operators
no competition, no fight, optimal partnership*
- *Team work for screening and procedures*

Conclusions

- Even though results are good in experienced teams, there is a learning curve and training/proctoring is crucial
- TAVI should be used in selected centers with experience of valvular disease
- Training and personal preparation of the operators and their team, patient's selection and cooperative work are crucial for the success and the future of the procedure