New Self-expandable Stent Based Percutaneous Pulmonic Valve

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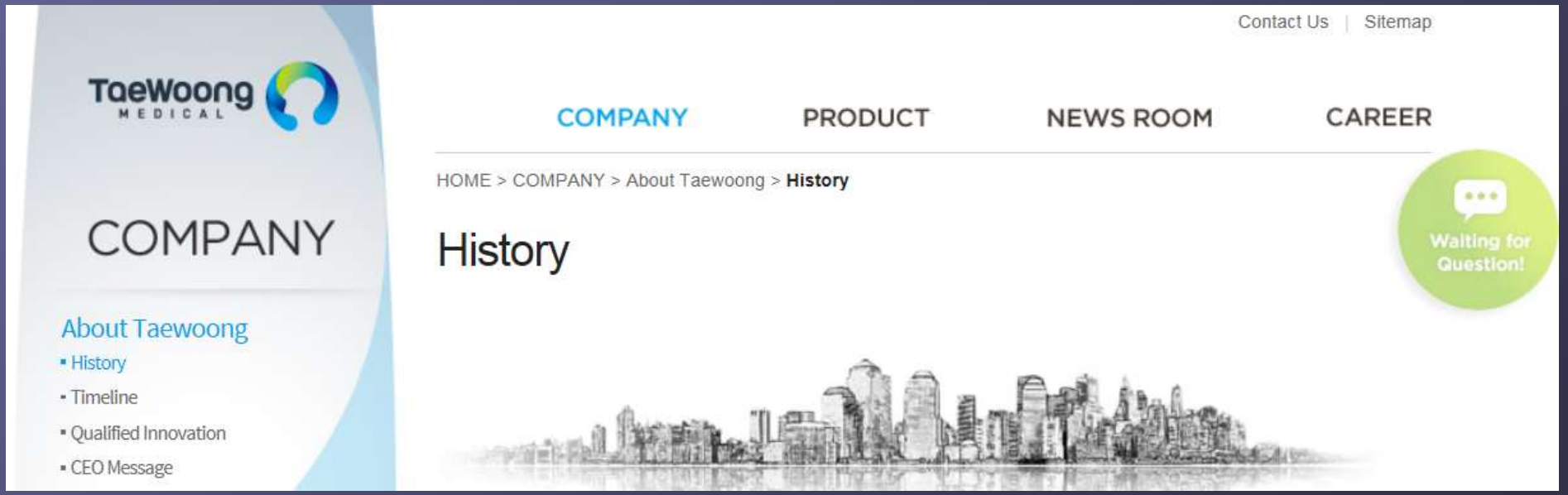
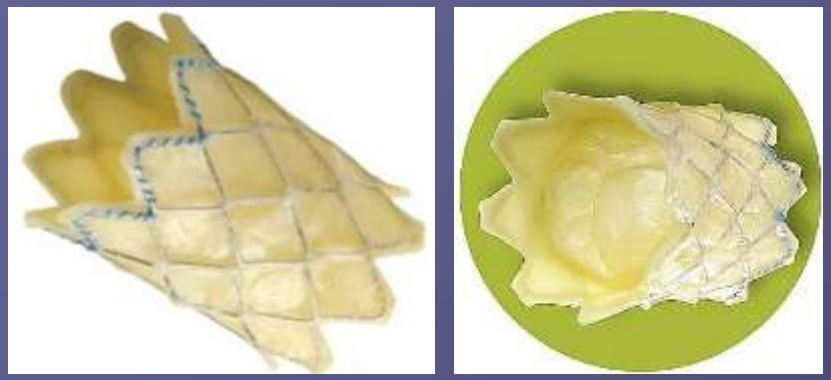
Disclosure

- Seoul National University Hospital Xeno-transplantation research center: financial support
- TaeWoong Medical Co., Ltd.: technical support



Status of valved-stent in pulmonic position in Korea

Melody valve



Edward- Sapien valve

- Not available in Korea
- Too expensive: ≈ 30,000 Dollars/valve
- Melody valve: recently approved by Korean FDA

New self-expandable valved stent

- **Stent** using **Nitinol-wire backbone**
  - **self-expandable**
- **Tissue valve** using **porcine pericardium**
  - **multiple steps for tissue preservation**

Tissue preservation for porcine pericardium

1. **Decellularization** with 0.25% SDS (sodium dodecyl sulfate)

2. 0.1 units/mL **alpha-galactosidase** treatment

   (for **reduction of immunogenicity**)

3. **Space filler** with PEG (polyethylene glycol)

4. 0.5 % **GA fixation** with solvent (75% ethanol + 5% octanol)

5. **Detoxification** with 0.1M glycine

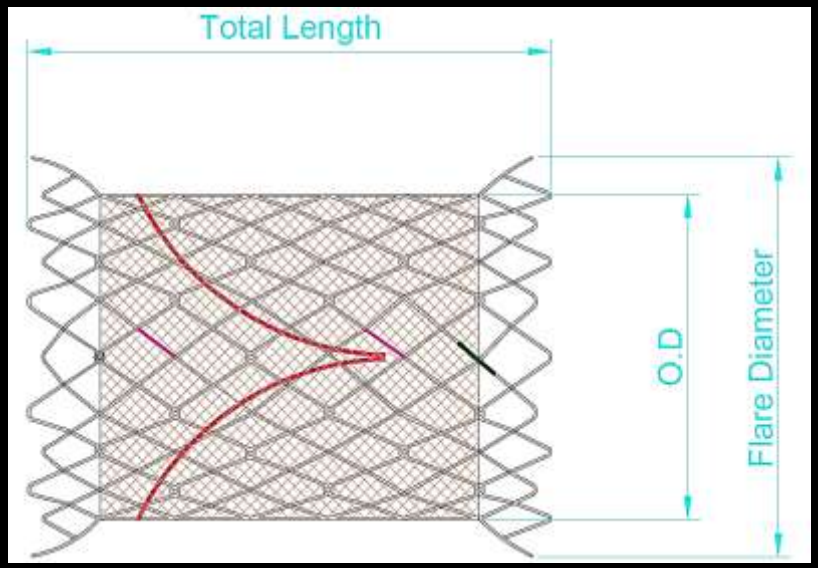
J Heart Valve Dis. 2012;21:387-97.
Eur J Cardiothorac Surg. 2012;41:383-90.
Int J Cardiol. 2014;173: 74–79.

Stent type modification
during pre-clinical study

Initial **Final**

Type	Can be folded in longitudinal axis	No folding in longitudinal axis
Wire thickness	0.008 inch (0.2mm)	0.011 inch (0.28mm)
Radial Force	0.17~0.20 kgf	0.45~0.63 kgf

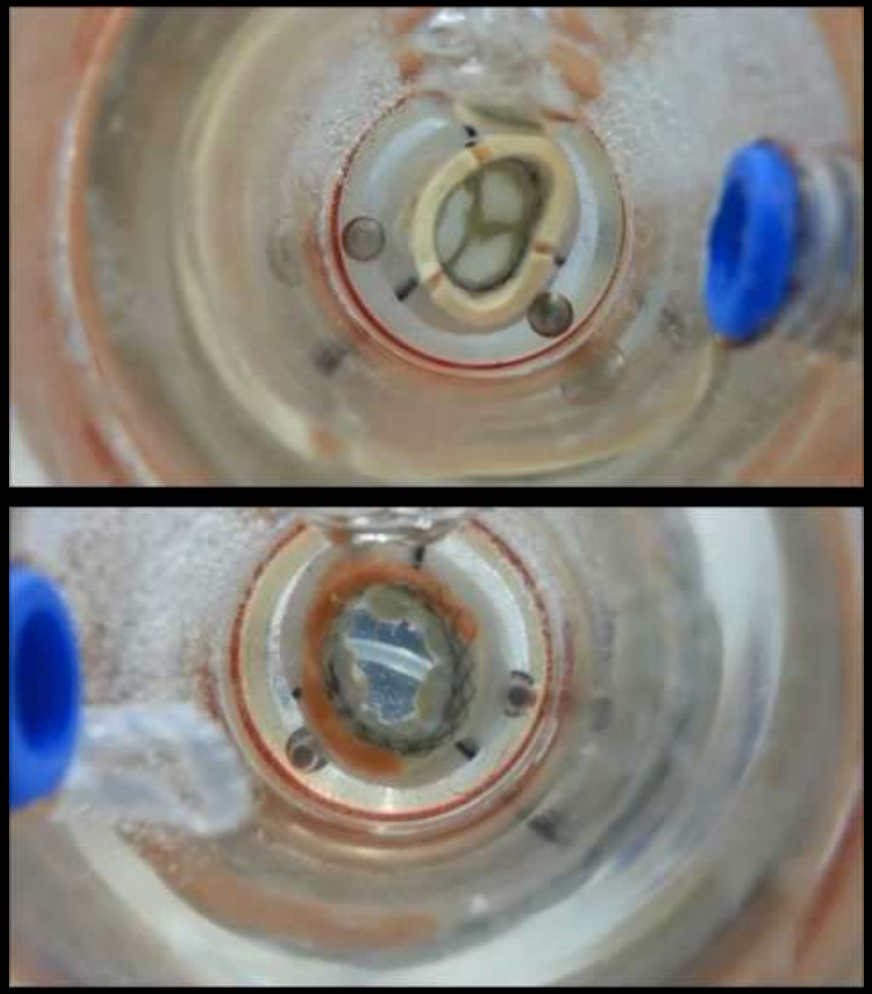
Pulmonary valved-stent shape



	Outer Diameter (mm)	Total Length (mm)	Flare Diameter (mm)	Expansion Force (gf)	Compression Force (gf)
TPV18	Ø18	28 ± 1.4	Ø22	628	1707
TPV20	Ø20		Ø24	630	1758
TPV22	Ø22	31 ± 1.55	Ø26	448	1468
TPV24	Ø24		Ø28	452	1540
TPV26	Ø26	33 ± 1.65	Ø30	473	1713
TPV28	Ø28		Ø32	453	1725

In Vitro valve motion test

In normal valve model

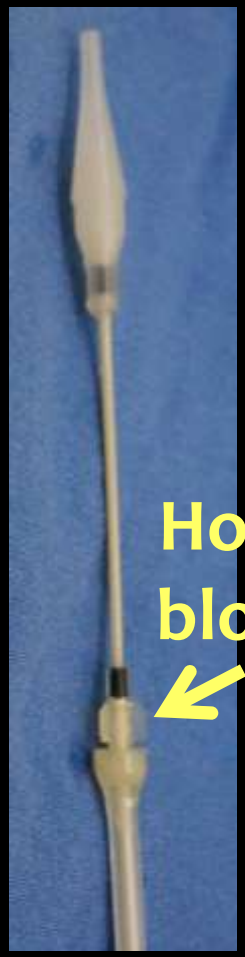


In diseased valve model

: 22 mm valve in 19 mm porcine Ao. valve

Trans-catheter delivery system

long delivery catheter



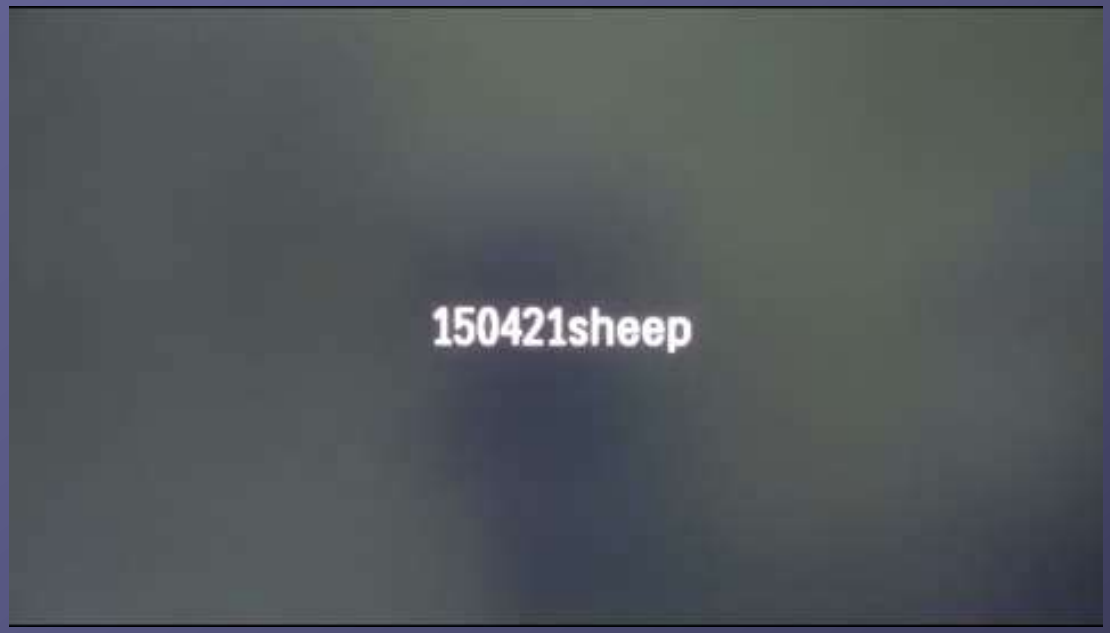
Head

Handle

12Fr. shaft

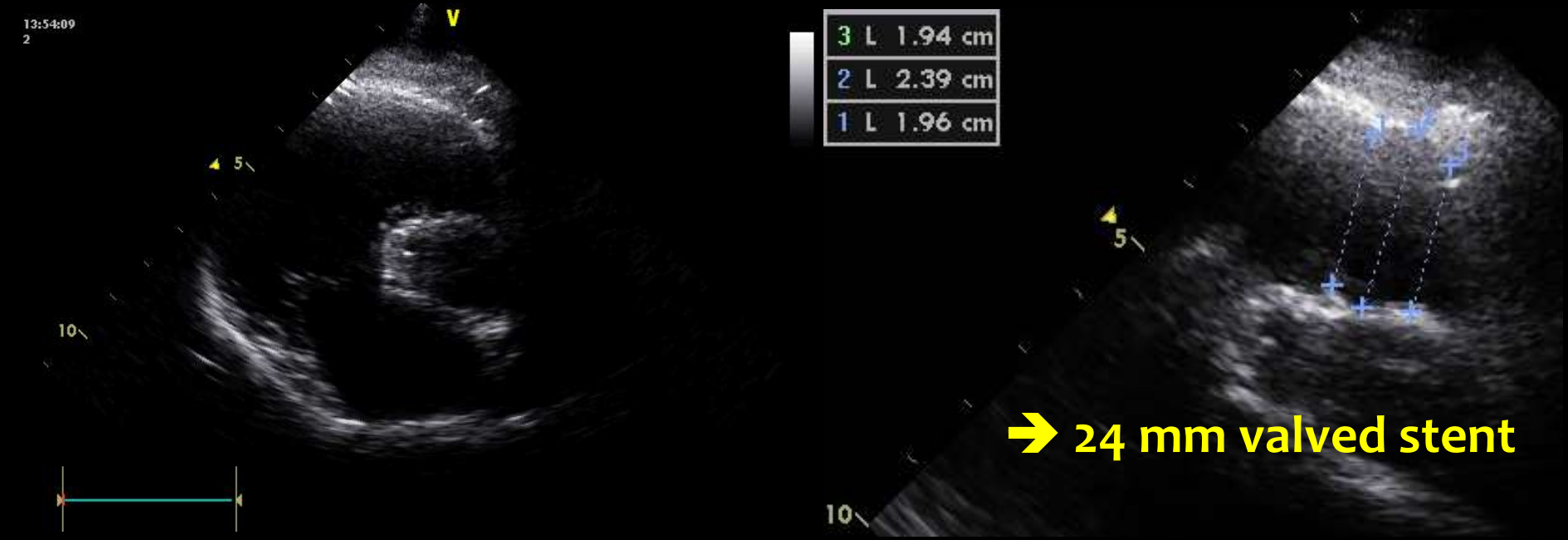
Animal case of percutaneous PVR

- 6 Month-old, 40 kg



Preparation

- Method
  - **Supine** position
  - Under **general anesthesia** and **mechanical ventilator**
  - **cut-down: cervical area**
    - **Internal Jugular vein**: 6 Fr. short sheath for RV angiography
    - **Carotid artery**: 4 Fr. short sheath for BP monitoring



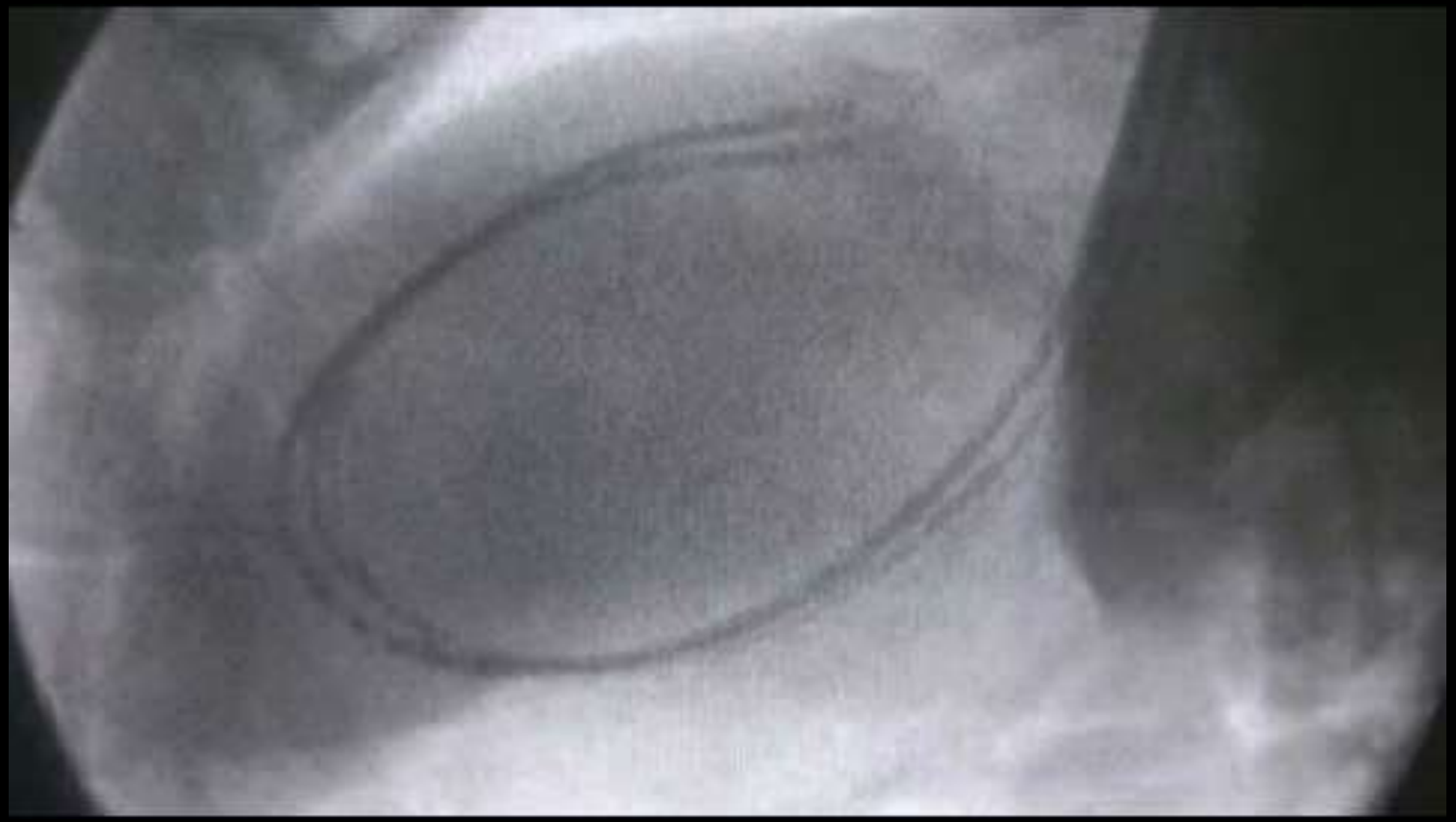
➔ **24 mm valved stent**

Femoral sheath insertion

USG-guided puncture

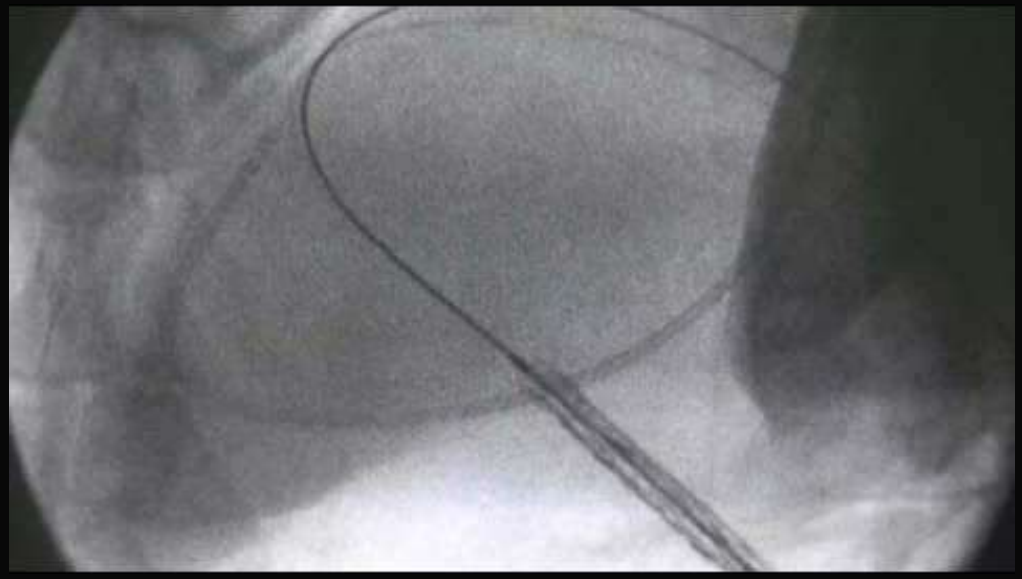
11 Fr. short sheath

RVOT angiogram

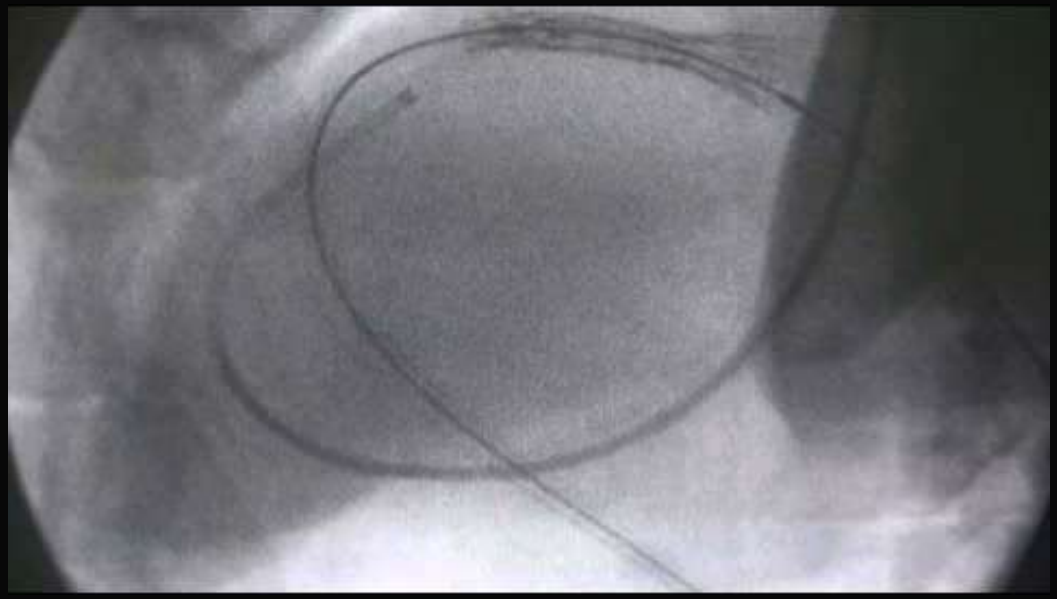


Stent loading

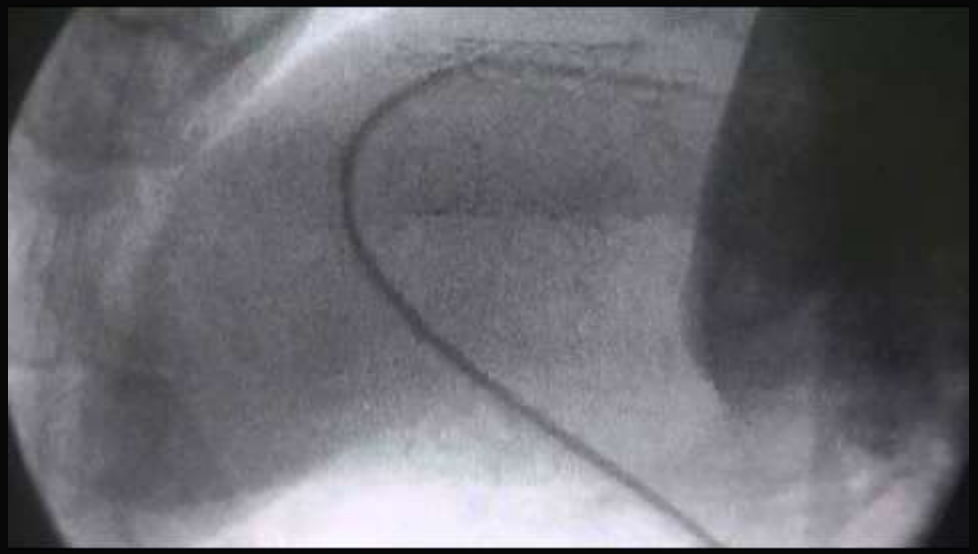
Delivery catheter insertion

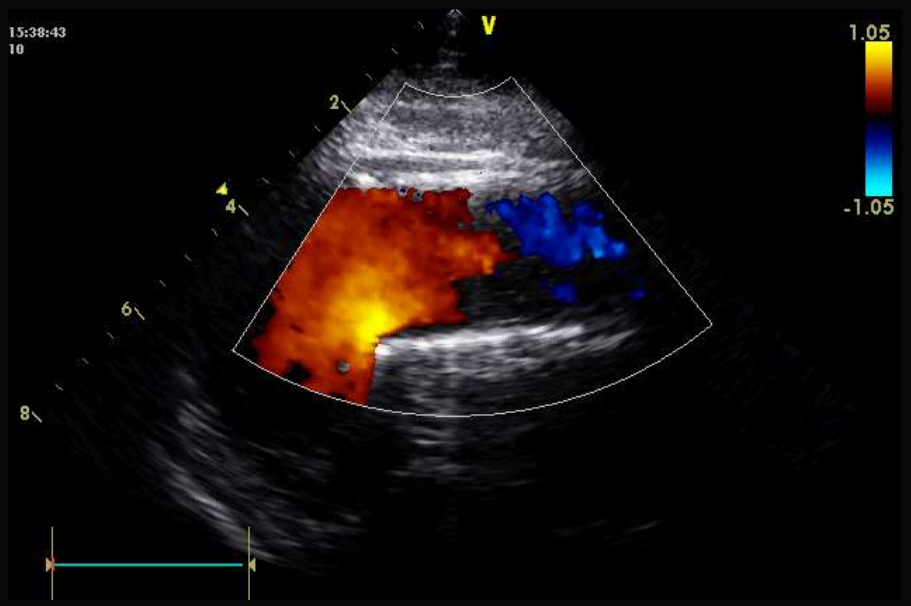


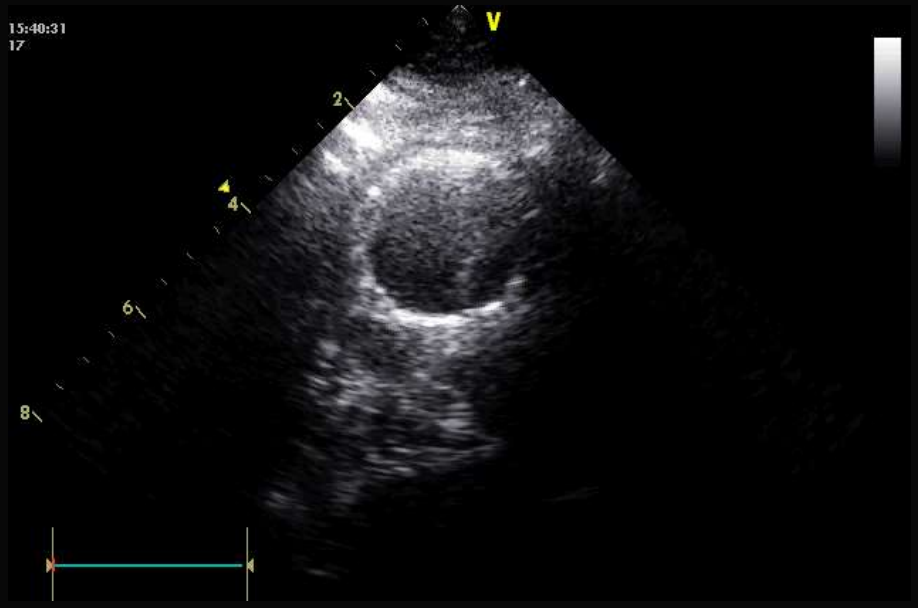
Valved-Stent deployment



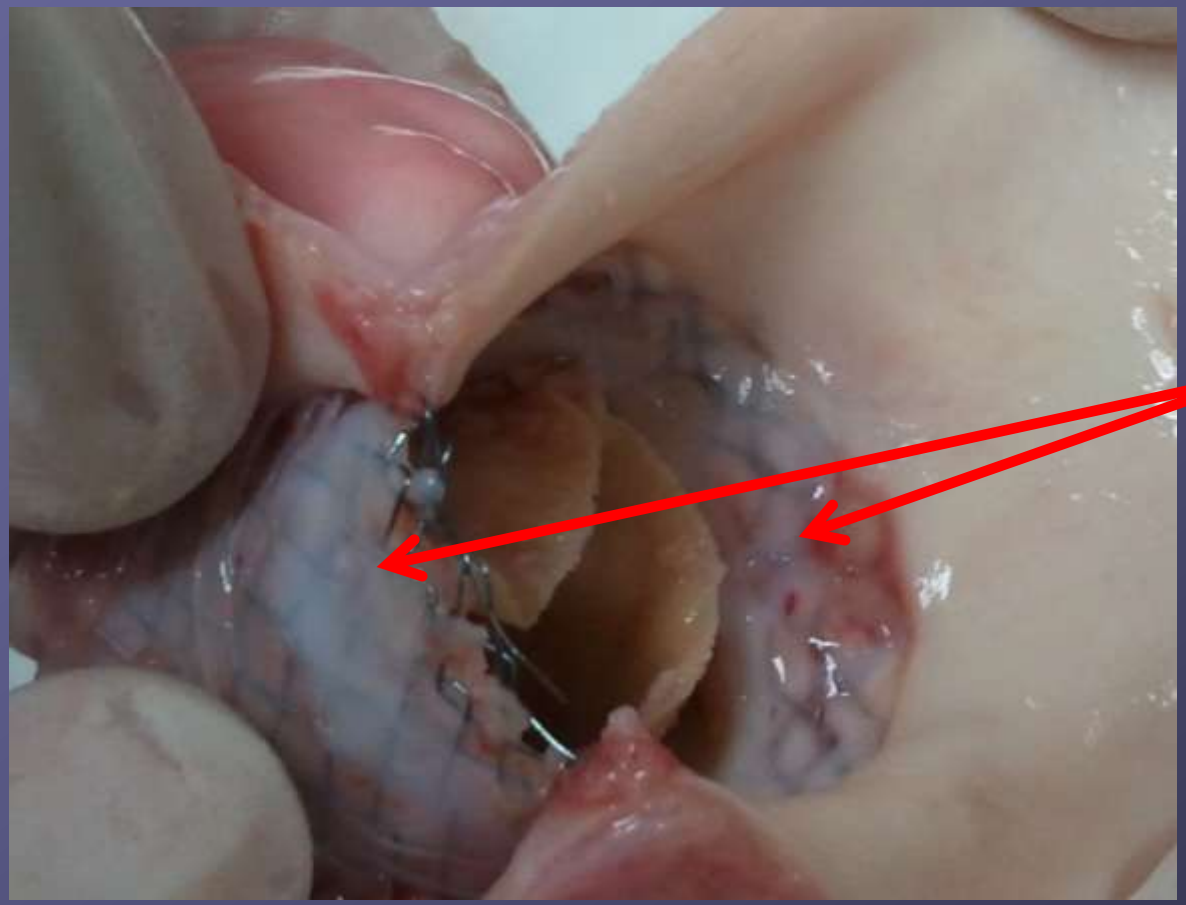
After deployment





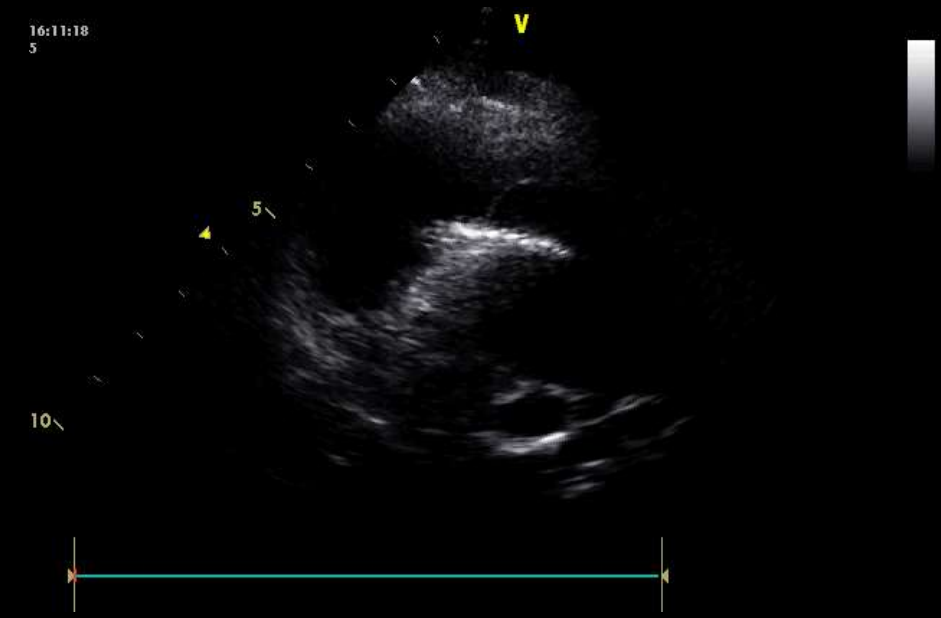


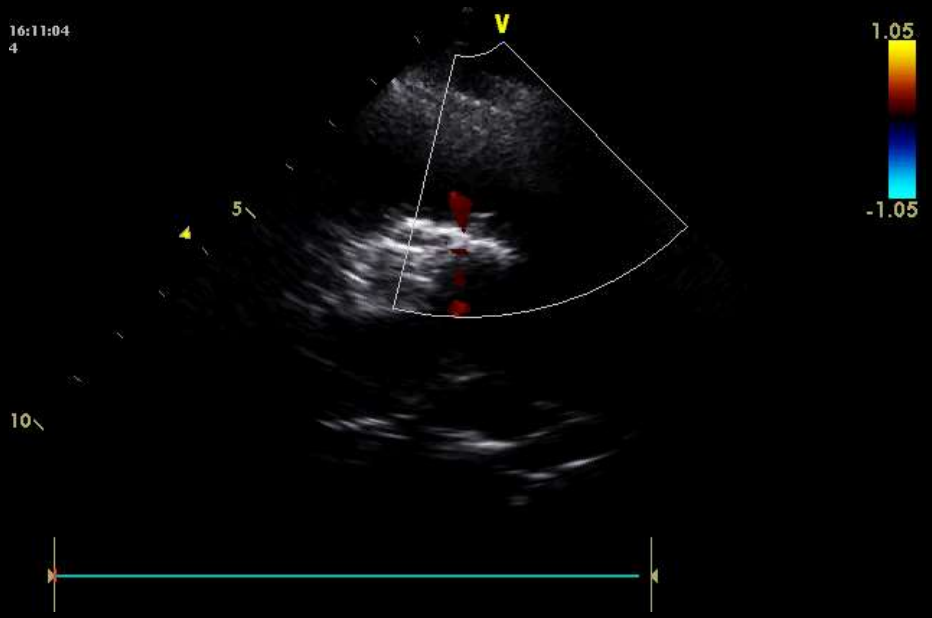
Endothelization

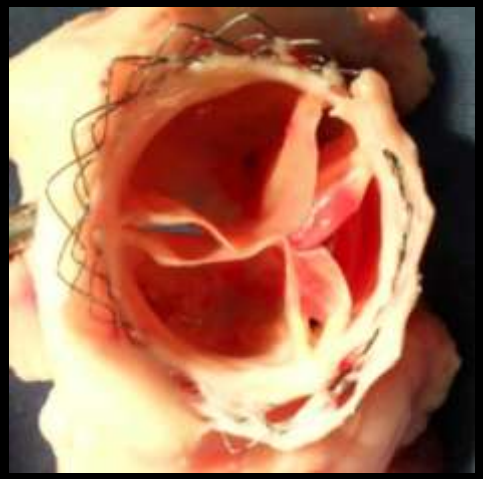


Full endothelization
after 3 months

6 Month F/U







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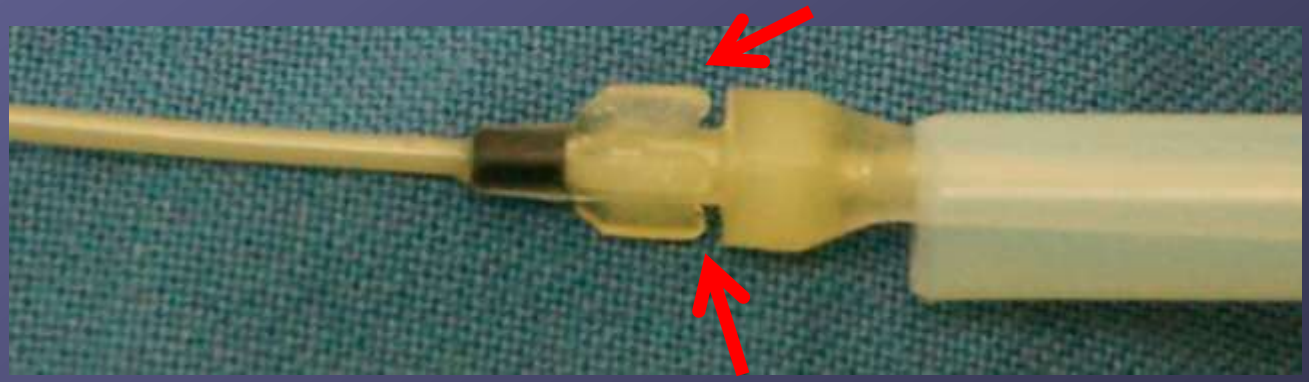
Merits of this valved-stent

- **Low profile catheter** compared with other valve
  - 18 Fr. delivery cable for 28 mm valve
- **Hook block** for controlled deployment



- Specific **tissue preparation** for longer durability

A feasibility study to evaluate the safety and short-term effectiveness of implantation of 'Transcatheter Pulmonary Valve (TPV)' for the treatment of Congenital heart disease with Pulmonary valve disease

- on **IRB** and **Korean FDA** approval process

- **A feasibility** study: **10** patients

: primary outcome

- Procedure success

- Procedural / Device related serious adverse events at 6month

- Hemodynamic functional improvement rate at 6month

A feasibility study

Study Procedure	Screening	Procedure	Follow-up				
			F/U (Short-term)				F/U (Long-term)
	Visit1	Visit2	Visit3	Visit4	Visit5	Visit 6	Visit 7~11
	Baseline	Day1	Discharge	1mon ±1week	3mon ±2week	6mon ±4week	Annually ±8week
	OPD/Adm.	Adm.	Adm.	OPD	OPD	OPD	OPD
Consent	√						
Demographic data	√						
Vital sign	√	√	√	√	√	√	√
physical exam.	√		√	√	√	√	√
History/Allergy	√						
Blood test	√	√	√	√	√	√	√
12-Lead ECG	√		√	√	√	√	√
Cardiac MRI	√					√	
X-ray	√	√	√	√	√	√	√
Echocardiography	√		√	√	√	√	√
Cardiac catheterization with Angiography		√				√	
TPV procedure		√					
Procedural success evaluation			√				
Clinical evaluation							
NYHA classification	√		√	√	√	√	√
Concomitant med.	√	√	√	√	√	√	√
Adverse event/SAE		√	√	√	√	√	√

Conclusions

- **Transcatheter** implantation of new **Nitinol-based self-expandable valved stent in pulmonic valve position** was feasible in a **preclinical animal study**
  - **Tissue valve durability** should be validated more
    : 6 months result was satisfactory
  - **Stable deployment** should be validated more
    : TEE, biplane fluoroscope and hook block could be helpful in the clinical study.
- **Now, a clinical trial for feasibility will start soon.**


Thank You for Attention !
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Characteristics of heart and vessel of sheep

- **Acute angle from RA to PA** : apex of heart points the land
- **Rather small RV** with relatively large pulmonic valve annulus

  ➔ difficult to stent introduction from RA to PA
- **Femoral vein is relatively small**